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# A foreword from the Editor-in-Chief

Charles F. Bellows

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Prof. Bellows received his MD from the Medical College of Pennsylvania and received his general surgery training at Tulane University. He joined Department of Surgery at University of Florida as an Assistant Professor of Surgery, then he was promoted to Associate Professor at Baylor University and then to Professor of Surgery and Vice Chair of Research at Tulane University. For 8 years, Prof. Bellows was the chief of General Surgery at both Tulane University and the University of New Mexico. His clinical interests have mainly focused on minimally invasive gastrointestinal surgery as well as bariatric and hernia surgery. His research interests have mainly focused on cell-based therapies to treat various diseases. He successfully mentored and has been PI of several projects (including an NIH funded mentored award), collaborated with other researchers. He has authored over 100 scientific articles and 2 books. He has been serving as the Editor-in-Chief and the editorial boards of 10 leading national and international journals. Currently, he is involved in the clinical teaching supported by evidence-based surgery and scholarly activity for the students of the University of Colorado.

Greetings from the desk of your editor and welcome to the inaugural issue of *Mini-invasive Surgery*.

I feel both privileged and excited to be the Editor-in-Chief of this prestigious international peer-reviewed journal. *Mini-invasive Surgery* focuses on translational, clinical and outcomes research in all fields of surgery. We aim to publish articles that promote the greater exchange and dissemination of ideas, findings, novel techniques, and the utilization of new instruments and materials among experts in this discipline of minimally invasive surgery around the world. Our journal also aims to document specific clinical findings that may indicate new or alternative understanding of existing surgical techniques. The journal provides a global platform that deals with all extensive works and researches related

to all areas of minimally invasive surgery, endoscopy, treatment, and diagnosis. The journal welcomes submissions that possess significance and scientific excellence within the following topics: endoscopy and other minimally invasive procedures, including general surgery, urology, bariatric surgery, colorectal surgery, trauma surgery, breast surgery, transplant surgery, orthopedics, gynecology, vascular surgery, cardiothoracic surgery, neurosurgery, cosmetic surgery, and otolaryngology.

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Review Articles, Case Reports, Brief Communications, Editorial, and Letters to Editor. Moreover, images and videos about novel minimally invasive technologies are also welcomed. Our journal will allow rapid publication of manuscripts after rigorous peer review. Currently, the journal does not charge for submission, processing, or publication of manuscripts; color reproduction of photographs is also free. We look forward to helping advance the field of mini-invasive surgery by providing a premier medium for publication.

In this issue, readers will find a diverse group of manuscripts. The features of the articles in this volume touch upon developments in the spectrum of activities related to the field of minimally invasive surgery as applied to areas of clinical research, surgical techniques, reviews and editorials relevant for improved clinical practice.

I hope the readers are making frequent use of this valuable resource and are finding it helpful in their clinical practice. We hope that this journal serves to stimulate a robust scientific understanding of minimally invasive surgery with the long-term aim of improving the health of the public. I would like to thank and

extend my gratitude to my co-editors, editorial board members, and reviewers, as well as the contributing authors for creating this first issue.

The Editorial Board and myself will continue to provide our readers with meaningful articles on the spectrum of minimally invasive surgery that are well written and up-to-date.

### **Authors' contributions**

C.F. Bellows contributed solely to this paper.

### **Financial support and sponsorship**

None.

### **Conflicts of interest**

There are no conflicts of interest.

### **Patient consent**

Not applicable.

### **Ethics approval**

Not applicable.

# Improved percutaneous endoscopic translaminar approach for lumbar foraminal stenosis at L5/S1

Hisashi Koga<sup>1,2</sup>

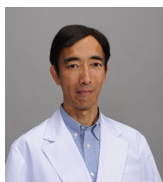
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The operative approach for lumbar foraminal stenosis (LFS) is one of the most challenging for spinal surgeons.<sup>[1-3]</sup> Excessive removal of the dorsal area of the foramen in a posterior approach can easily lead to iatrogenic spondylolysis, subsequently increasing lumbar instability and spondylolisthesis. A posterolateral approach is one solution to this problem. However, LFS in the L5/S1 region is difficult to treat using a posterolateral approach, because of an anatomic peculiarity: the lateral aspect of the foramen is surrounded by the L5 transverse process, sacral ala, and hypertrophic facet joint. LFS usually develops after the age of 50 and is one of the most common degenerative spinal diseases in the elderly. As a result of this the vertebral height generally decreases, depending on the degree of disc degeneration. Compared with the younger patients without disc degeneration, the surgical

access becomes more difficult.

Recent advances in the percutaneous endoscopic lumbar discectomy (PELD) technique have made access to the lateral aspect of the lumbar foramen possible without excessive removal of surrounding structures.<sup>[4]</sup> Despite this advance using a fully endoscopic system, access to the L5/S1 region remains difficult. At L5/S1, the surgeon cannot adequately tilt the endoscope to access the medial portion of the foramen due to the obstacle created by the ipsilateral iliac crest. To access the medial part of the L5 foramen, we improved the PELD approach, which had been developed for lumbar disc herniation (LDH) with migration into the hidden zone.<sup>[5]</sup>

This improvement uses a primarily posterior approach

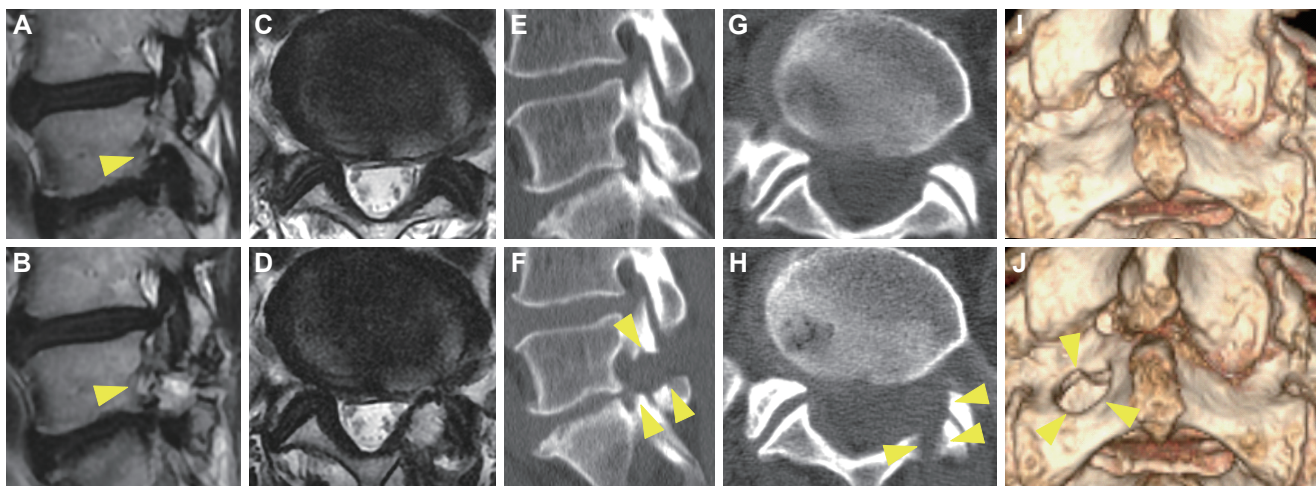


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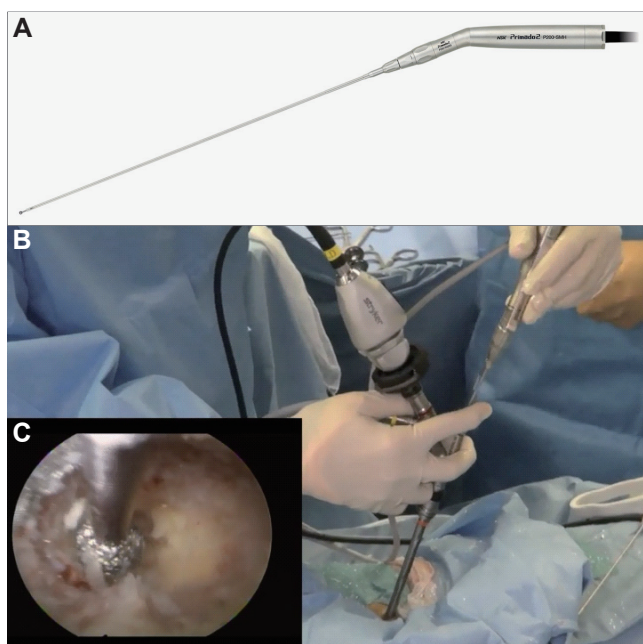
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**Figure 1:** Representative case of improved PETA. A 70-year-old male complained of left leg pain that worsened with walking. Neurological examination revealed no muscle weakness and a negative SLR sign. Sagittal lumbar MRI revealed left foraminal stenosis at the L5/S1 intervertebral disc level, with marked compression of the left L5 nerve root (A, arrow head). We performed PETA, and his symptom improved (NRS 8 → 0, JOA 15 → 22) 2 weeks after PETA. Postoperative MRI revealed decompression of the foramen (B, arrow head). Comparison of preoperative (C, E, G, I) and postoperative (D, F, H, J) CT findings demonstrated the extent of bone removal (arrow heads). (A, B, E, F) sagittal view, (C, D, G, H) axial view, (I, J) 3-dimensional reconstruction. PETA: percutaneous endoscopic translaminar approach; SLR: straight leg rising; NRS: Numeric Rating Scale; JOA: Japanese Orthopedic Association; MRI: magnetic resonance imaging; CT: computed tomography



**Figure 2:** (A) Photograph of the electrical high-speed drill used for percutaneous endoscopic translaminar approach (NSK-Nakanishi Japan, Tokyo, Japan), and (B) intraoperative manipulation of the drill. The surgeon must hold both the endoscope and the drill. It will be necessary to develop a device to hold the endoscope to simplify this procedure. The surgeon can confirm the extent of bone removal in the endoscopic visual field (C)

through an 8-mm skin incision placed just above the corresponding pars interarticularis. The endoscope sheath is placed on the surface, and the dorsal area of the foramen is removed with a high-speed drill.

The entrance keyhole is small enough to prevent

iatrogenic spondylolysis; however, the area of bone removal is enlarged in the deep part of the hole [Figure 1]. Therefore, the dorsal part of the foramen is adequately removed. Bone removal and widening toward the bottom requires special skill with the 25 degree angled endoscope. Therefore, not only preservation of the pars interarticularis but also removal of the medial part of the foramen is accomplished using this percutaneous endoscopic translaminar approach (PETA) [Figure 1].

Previously, the combination of decompression of the foramen and a fusion procedure was performed in patients with significant LFS at L5/S1.<sup>[6]</sup> However, improvements in the decompression technique reported by several investigators make it possible to avoid fusion.

Among these improvements, intra-extra canal and contralateral interlaminar approaches show promise for the prevention of iatrogenic spondylolysis.<sup>[7,8]</sup> Although their common basis is in the operative direction of dorsomedial to ventrolateral decompression, these approaches are still invasive, and involve muscle retraction and extensive bone and ligament removal. The combination of a fully endoscopic system and development of a high-speed drill for use through a long and narrow endoscopic lumen has created options for minimally invasive spinal surgery for LFS at L5/S1 [Figure 2]. The improved PETA results in almost no damage to muscle and minimal removal of the surface of the vertebral arch.

PETA was first proposed by Dezawa *et al.*<sup>[5]</sup> for the

treatment of LDH with migration into the hidden zone. The authors used PETA in 9 cases of hidden-zone LDH, and successful removal of LDH was confirmed using postoperative magnetic resonance imaging in all cases. They created a 4-mm bone hole using a high-speed drill with a diameter of 3.2 mm, as a larger bone hole is required for the treatment of LFS at L5/S1. We therefore made an approximately 10 mm diameter entry hole at the pars interarticularis using a high-speed drill with a diameter of 3.5 mm. Dezawa *et al.*<sup>[5]</sup> pointed out that the disadvantages of PETA are its technically demanding nature and the hand-eye coordination learning curve, and recommended that PETA should only be attempted after developing significant skill in standard endoscopic techniques. Du *et al.*<sup>[9]</sup> also used PETA in 7 highly down-migrated LDH cases and obtained good outcomes. Compared with the treatment of LDH, the treatment of LFS is more difficult, because LFS occurs in older patients with combined facet joint osteoarthritis and disc degeneration. Further refinement of the technique will make this improved PETA available to spine surgeons who treat such patients.

In general the duration of the operation for PETA exceeds 1 h (longer than that for PELD), we therefore perform PETA under general anesthesia. To avoid possible nerve damage, measurement of transcranial motor evoked potentials (Tc-MEPs) is performed. Tc-MEPs are recorded in tibialis anterior, extensor hallucis longus, and gastrocnemius muscles in the lower extremities as described in our previous report.<sup>[10]</sup> The start point to perform drilling is the most important matter for PETA to minimize the bone removal. To determine appropriate position of drilling, anteroposterior (AP) and lateral views of a fluoroscope are used just after patient's positioning on an operative bed (skin incision is placed at medial border of L5 pedicle on AP view and at caudal margin of the pedicle on lateral view). During the operation, we leave the fluoroscope across the center of the operative table in order to ensure appropriate drilling. The thickened superior articular process is carefully removed using the electrical high-speed drill. After removal of these hypertrophic tissues, we confirm good exposure and decompression of the corresponding nerve root by tilting and rotating the 25-degree angled endoscope. As a lens of camera is attached to the tip of the endoscope and enables to observe closely a wide range of the operative field. The extent of decompression is also confirmed with fluoroscopy using a dissector (width 3.0 mm). At the final stage of bone removal, we can easily confirm the tip of the dissector penetrating vertebral foramen. If a surgical navigation system for PETA will be developed, it can lead to considerably higher precision of bone removal.

With the aging of population and advances in

diagnostic methods, the need for surgical treatment of LFS has increased.<sup>[6]</sup> On the other hand, patient demand for minimally invasive surgery is also rapidly increasing. The development of new equipment for fully endoscopic spinal surgery will be key to the introduction of this procedure. I expect that equipment manufacturers will partake in the development of this new surgical approach.

### Financial support and sponsorship

None.

### Conflicts of interest

There are no conflicts of interest.

### Patient consent

All involved patients gave their consent forms.

### Ethics approval

Not applicable.

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# Preoperative workup, patient selection, surgical technique and follow-up for a successful laparoscopic Nissen fundoplication

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## ABSTRACT

Experienced surgeons have reported excellent results for laparoscopic Nissen fundoplication to treat gastroesophageal reflux disease (GERD). Others, however, associate this operation with unacceptable rates of morbidity, mortality and inferior outcomes. Results are certainly linked to an appropriate patient selection, work up, technical details and follow-up. This review focuses on the proper preoperative workup, patient selection, surgical technique, and follow-up for a successful laparoscopic Nissen fundoplication. Certainty of the diagnosis of GERD and the esophageal physiology is essential. An extensive dissection of the esophagus and crus in the abdomen and mediastinum, an adequate hiatoplasty, and a short-floppy fundoplication are important technical points. New onset or persistent symptoms after the operation must be carefully studied. Excellent outcomes may be reproducible if a proper preoperative workup, patient selection, surgical technique and follow-up are rigorously observed.

## INTRODUCTION

Some experienced surgeons have reported good and excellent results in more than 90% of patients submitted to laparoscopic Nissen fundoplication for gastroesophageal reflux disease (GERD).<sup>[1-4]</sup> Others, however, associate this operation to unacceptable rates of morbidity, mortality and inferior outcomes.<sup>[5]</sup> Results are certainly linked to an appropriate patient selection, work up,<sup>[6]</sup> technical details<sup>[7]</sup> and follow-up.<sup>[8]</sup>

This paper focuses on the proper preoperative workup, patient selection, surgical technique and follow-up for a successful laparoscopic Nissen fundoplication.

## WORKUP

An extensive esophageal work up with endoscopy, barium esophagography, manometry and pH monitoring is mandatory before an antireflux operation.<sup>[9,10]</sup>

First of all, outcomes will be excellent if GERD is actually present. Thus, the certainty of the correct diagnosis is required. Although the diagnosis may be easy to perform in patients with typical symptoms and evident alterations in endoscopy as well as pH monitoring, this task may be more difficult in those with extra esophageal symptoms and normal tests. This is true due to the fact that these tests have a significant



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rate of false-negativity.

Many studies have shown that even typical symptoms such as heartburn and regurgitation have low accuracy leading to an incorrect diagnosis of GERD in 30-50% of patients.<sup>[11,12]</sup> Likewise, the presence of reflux or hiatal hernia on esophagogram does not correlate well with reflux on pH monitoring, or esophagitis on endoscopy.<sup>[10]</sup>

Extra esophageal symptoms may bring additional difficulty for the diagnosis. Other tests, such as laryngoscopy may be added to the armamentarium; however, a low positive predictive value for the diagnosis of GERD is anticipated.<sup>[13]</sup> Other diseases may coexist with GERD, and symptoms may have other causes or may be multifactorial with GERD as only an adjuvant. The response to specific GERD treatment as a trial, and the association of the symptom with reflux episodes at the time of pH monitoring may help to determine the cause of the symptom.

Ambulatory 24-h pH monitoring should be routinely performed in the preoperative workup of patients suspect of having GERD.<sup>[10]</sup> Either alone or in combination with multichannel intraluminal impedance (MII-pH) pH monitoring. This testing provides the best objective information on esophageal acid exposure, allowing diagnosing and quantifying GERD, and temporal correlation between symptoms and episodes of reflux.<sup>[14]</sup>

Lastly, an adequate preoperative workup should bring several pieces of information in order to allow a clinical judgement for a better diagnosis since diagnostic tests individually (laryngoscopy, endoscopy, and even pH- or pH-impedance monitoring) may not be sufficient to make the definitive diagnosis of GERD.<sup>[15]</sup>

## PATIENT SELECTION

Following the example of any other elective surgical procedure, patients planned to undergo an antireflux operation should be carefully clinically evaluated. Patients under high anesthetic risk or those with uncontrolled co-morbidities should not be offered this kind of therapy.

Some predictors of worse outcomes after a fundoplication have been identified [Table 1]. Some are inherent to the patient, others to the disease, and some to technical difficulty during the operation.<sup>[16-19]</sup> With the exception of obesity, these predictors cannot be changed in the majority of patients.

The certainty of the GERD diagnosis and attribution of

the symptoms to the disease increase the likelihood of excellent outcomes. Thus, a pathologic pH monitoring increases the chance of success by 5 times compared to a normal test,<sup>[20]</sup> and clinical response to acid suppression therapy has been associated with a 3 times better response to surgical treatment.<sup>[20]</sup> Esophageal symptoms are more prone to be caused by GERD, and also have a better prognosis compared to extra-esophageal symptoms.<sup>[18,20]</sup>

“Illness behavior” may influence<sup>[19-21]</sup> expectations, satisfaction and tolerance to post-operative side effects.

This fact may explain worse outcomes in females, patients with psychiatric disorders, and individuals of lower socioeconomic status.

Although not unanimously, some series show poorer outcomes for obese patients<sup>[18,22]</sup> that undergo a fundoplication likely due to a more demanding operation with longer operative times<sup>[23]</sup> and more complications.<sup>[24]</sup>

One must consider the operation contraindicated in the presence of various predictors for unsuccessful outcomes, while older age and esophageal dysmotility (excluding achalasia) do not influence outcomes.<sup>[25,26]</sup>

## TECHNIQUE

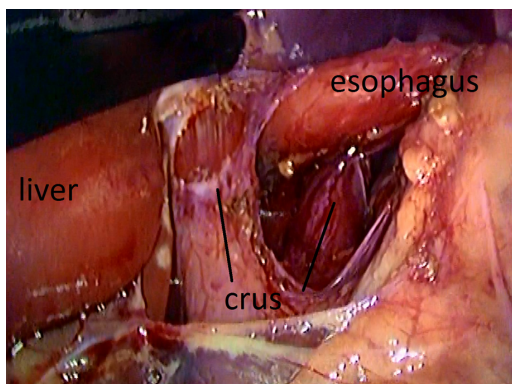
Some technical points must be followed to ensure an adequate fundoplication.

An extensive esophageal dissection in the abdominal and lower thoracic segments to achieve a 2-4 cm segment of abdominal esophagus is helpful to prevent hernia recurrence. The presence of a long abdominal esophagus is *per se* an efficient antireflux mechanism [Figure 1],<sup>[27]</sup> and careful attention should be taken to avoid damage to the vagal branches that are close to this portion of the esophagus.<sup>[16,28]</sup>

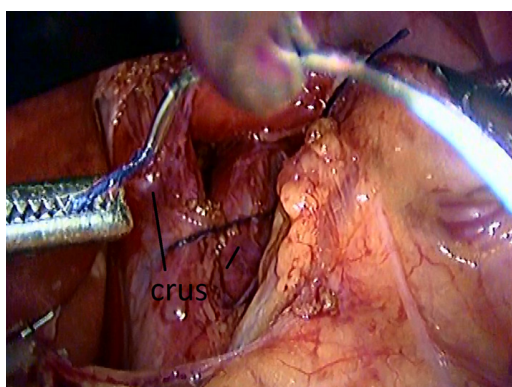
Hiatal closure is an important part of this operation since the integrity of this muscle barrier exerts synergistic

**Table 1: Predictors for bad outcomes after laparoscopic Nissen fundoplication**

Patient	Disease	More difficult operation
Female gender	Extra-esophageal symptoms	Obesity
Psychiatric disorders	Lack of response to acid suppression therapy	Reoperation
Low socioeconomic status	Absence of hiatal hernia	



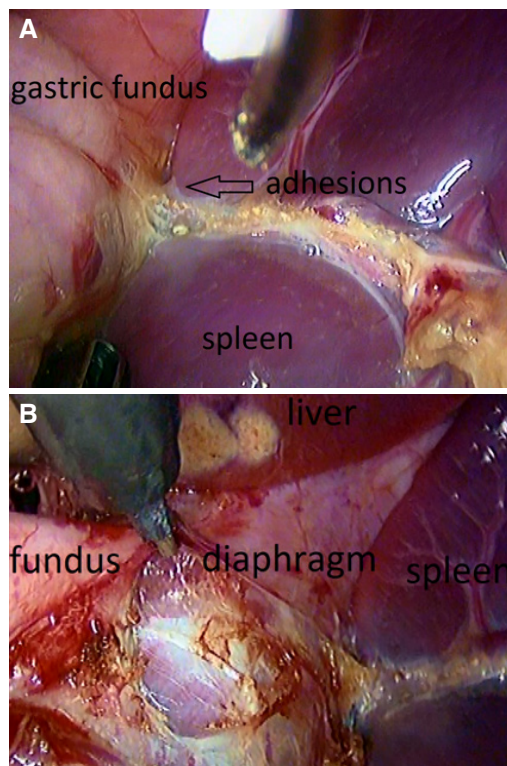
**Figure 1:** Extensive dissection of the esophagus including the lower mediastinum ensures a long segment of the abdominal esophagus (ideal > 2.5 cm)



**Figure 2:** Hiatal closure must be performed with interrupted non-absorbable X-shaped stitches (e.g. 2-0 or 0, polypropylene, mersilene). Stitches must be well anchored in the crus

effect with the lower esophageal sphincter at the esophagogastric junction,<sup>[29]</sup> and prevents herniation of the wrap to the chest [Figure 2]. This type of herniation of the stomach (wrap) through the diaphragmatic hiatus is one of the main causes of failure after antireflux surgery. Some propose the use of prosthetic material (mesh) to reinforce the closure of the esophageal hiatus. The use of mesh for this purpose is still the subject of much discussion.<sup>[30]</sup> While many believe that the use of this material can reduce the failure rates of the hiatal closing,<sup>[31]</sup> others oppose this practice due to the risks of erosion of abdominal viscera (especially esophageal and gastric). The indication for the hiatal mesh repair should be selective taking into account the tension during crural closure and weakness of hiatal tissue.<sup>[29,32]</sup>

The fundoplication should be floppy, short, tension-free, and constructed with the fundus of the stomach around the esophagus. An extensive dissection of the posterior attachments of the gastric fundus and an ample retroesophageal window are essential to make a tension-free fundoplication. Short gastric vessels division may also help attain a floppy fundoplication,



**Figure 3:** (A) A complete dissection of the gastric fundus ensures a tension-free fundoplication (arrow); (B) adhesiolysis of attachments of the gastric fundus to the spleen, diaphragm and retroperitoneum must be done even after division of the short gastric vessels

since it promotes the decrease of gastric fundus tension [Figure 3].<sup>[33]</sup>

An intraluminal bougie is advocated by some to calibrate the fundoplication,<sup>[34]</sup> although other different series do not show advantages.<sup>[35]</sup> Another key step in this operation is the choice of the right place to create and position the wrap. Thus, gastro esophageal junction should be well identified, with the removal of the fat pad that is frequently located there. This is done to make sure that the gastric fundus is brought around the esophagus not the stomach. Also, the gastric fundus, not the gastric body should be used to create the fundoplication [Figure 4].

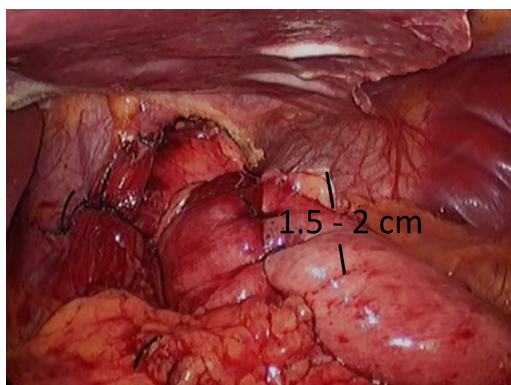
## FOLLOW-UP

A good follow-up is important to achieve a satisfactory postoperative result. Patients who undergo this operation should be alerted about the common occurrence of transitory dysphagia in the first three months due to edema and esophageal ileus.<sup>[36]</sup> Also, the improvement of extra esophageal symptoms may not be immediate and new symptoms, such as gas symptoms, may occur after surgery. These facts, however, do not decrease significantly quality of life and patient satisfaction with treatment.<sup>[5]</sup>

**Table 2: Current results for laparoscopic Nissen fundoplication in adults in series over 100 patients in the last 5 years**

Author	n	Follow-up	Outcomes	Morbidity	Mortality
Andolfi <i>et al.</i> <sup>[6]</sup>	176	17 months	88% symptom relieve	Conversion rate 0.6% Abdominal wall complications 1.7%	0
van Rijn <i>et al.</i> <sup>[46]</sup>	125	14-25 years	62% satisfaction	NS	NS
SarÅ <i>et al.</i> <sup>[47]</sup>	162	18 months	75% symptom relieve 9% postoperative medication usage	NS	NS
Warren <i>et al.</i> <sup>[48]</sup>	185	Minimum 12 months	89% satisfaction 12% postoperative medication usage	2 cases of abscess linked to mesh hiatoplasty 1 case of precocious revision due to obstruction	0
Koetje <i>et al.</i> <sup>[49]</sup>	329	24 months	Significant improvements in symptom score and QOL measurements	Reoperation 7%	NS
Teixeira <i>et al.</i> <sup>[50]</sup>	399	14 months	98% symptom relieve	NS	NS
Rossetti <i>et al.</i> <sup>[51]</sup>	301	56 months	Significant improvement in QOL	NS	NS
Simorov <i>et al.</i> <sup>[52]</sup>	297	70 months	70% improvement in GERD symptoms	Reoperation 0.9% 5 bleeding 4 pneumothoraces requiring decompression 10 wound infections 3 prolonged ileus 8 urinary retention	NS
Kellokumpu <i>et al.</i> <sup>[53]</sup>	249	10 years	98% symptom relieve 83% satisfaction	Morbidity 7.6%	0
Qin <i>et al.</i> <sup>[54]</sup>	215	5.6 years	100% symptom relieve	NS	0
Schietroma <i>et al.</i> <sup>[55]</sup>	178	Minimum 11 years	94% symptom relieve	Conversion rate 6%	0
Beenen <i>et al.</i> <sup>[56]</sup>	222	11 years	87% satisfaction	NS	NS
Ross <i>et al.</i> <sup>[57]</sup>	510	Minimum 10 years	89% symptom relieve	NS	NS

NS: not stated; QOL: quality of life; GERD: gastroesophageal reflux disease



**Figure 4:** Fundoplication must be short-floppy and using gastric fundus only

## CONCLUSION

New antireflux therapies are currently available. Novel acid suppressant drugs and other classes of medication are available or under development.<sup>[37]</sup> However, up to now these medications have not shown clear advantages over current medication. Surgical therapy is aimed at the pathophysiology of the disease<sup>[38]</sup> and can be more effective than current medical therapy.<sup>[39]</sup> Surgical procedures other than a fundoplication; however, never gained acceptance for uncomplicated GERD cases. This is with the exception of bariatric procedures that control GERD and may be a good alternative to a fundoplication in obese individuals.<sup>[40]</sup> Surgical technique has not changed expressively in the last several years; however, a

Nissen fundoplication may now be accomplished by endoscope.<sup>[41]</sup> The technique is restricted to selected cases, lacks hiatal closure and results are inferior to a laparoscopic Nissen. Single port laparoscopy another option for performing a fundoplication;<sup>[42]</sup> yet most believe it brings solely cosmetic improvement with a higher risk for complications.<sup>[43]</sup> The aid of a robot in the operating room<sup>[44]</sup> does not bring any advantage to the procedure and may add cost and time to the procedure. More recently, the fundoplication has been replaced by a magnetic chain of beads placed laparoscopically around the distal esophagus.<sup>[45]</sup> Although good results are shown, the drawback of foreign material in the hiatus precludes dissemination of the technology.

Laparoscopic Nissen fundoplication continues to be safe and provides excellent outcomes [Table 2], not only in experienced hands, but also these results may be reproducible in community hospitals as well,<sup>[58,59]</sup> if a proper preoperative workup, patient selection, surgical technique and follow-up are observed [Figure 5].

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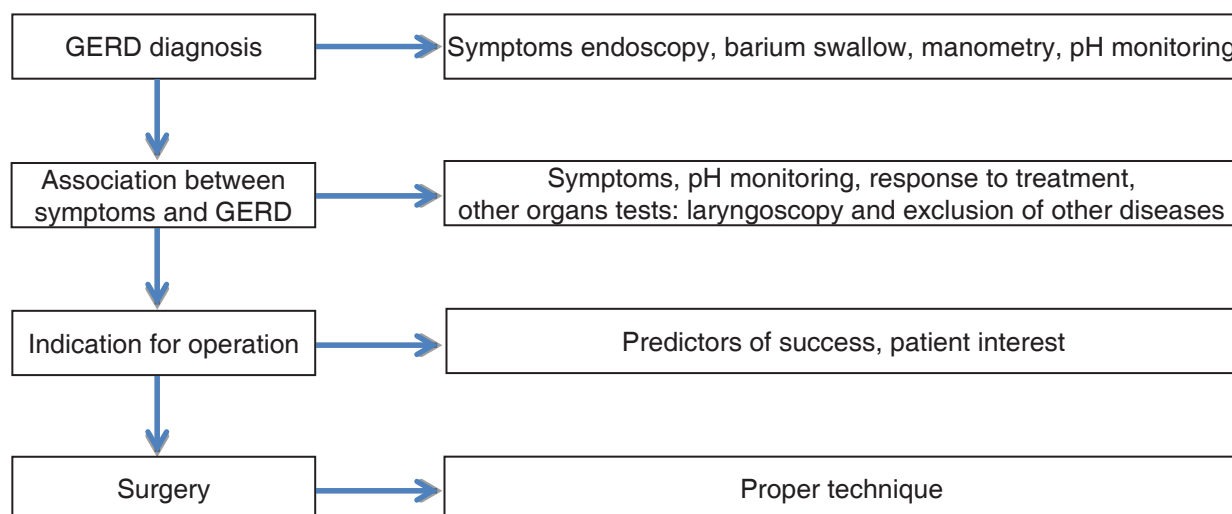
Nil.

## Conflicts of interest

There are no conflicts of interest.

## Patient consent

There is no patient involved.



**Figure 5:** Road to a successful laparoscopic Nissen fundoplication. GERD: gastroesophageal reflux disease

## Ethics approval

This review article is waived for ethical approval.

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# Pulmonary wedge resection for clinical stage I non-small cell lung cancer: a review of a mini-invasive treatment

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## ABSTRACT

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Non-small cell lung cancer, wedge resection, sublobar resection, stage I, stereotactic body radiation therapy

Non-small cell lung cancer (NSCLC) is one of the leading causes of cancer-related deaths in the world. Therefore, there is a need to intensify treatments of these tumors. Because stage I NSCLC is a nonmetastatic disease, local therapies are indicated, among which surgery is the most commonly deployed strategy. Pulmonary wedge/sublobar resection is therefore discussed in comparison to stereotactic body radiation therapy for stage I lung cancer. Review of retrospective and prospective clinical trials reveal similar outcomes for both strategies, while a multicenter randomized prospective study comparing the efficacy of both therapies is on-going. Because the results of pulmonary wedge/sublobar resection may depend on tumor size, tumor-distance from surgical margin, tumor size-to-margin distance ratio, and margin cytology, prospective studies to evaluate the clinical implications of these factors, so as to inform patient prognostication, are recommended.

## INTRODUCTION

The need for less invasive treatment strategies has been increasing, partly due to the increase in the ageing population.<sup>[1]</sup> Because stage I lung cancer is a localized disease without evidence of metastases<sup>[2]</sup> and is associated with low morbidity and mortality, minimally invasive (mini-invasive) local therapies are central to managing the high-risk or medically unfit patient such as the elderly. The various types of mini-invasive

local therapies for stage I lung cancer are defined by the amount of lung tissue targeted or resected. These include segmentectomy and wedge resection (wedge/sublobar resection), radiation, radiofrequency ablation,<sup>[3,4]</sup> and cryoablation therapies.<sup>[5]</sup> Currently, the most commonly used strategies are wedge/sublobar resection and radiation therapy, including stereotactic body radiation therapy (SBRT). We therefore review pulmonary wedge/sublobar resection in comparison to SBRT for stage I lung cancer.



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### Quick Response Code:



In order to retrieve articles, the author (N. S.) searched “PubMed” using key words relevant to the context of this review. Specifically, in addition to “lung cancer” and “stage I”, either “wedge” or “SBRT” was chosen as key words. Incorporating the terms “wedge” and “SBRT”, found a total of 169 and 250 articles, respectively. The author read the abstracts to select appropriate articles, which were then read in full. Article references were checked for useful studies that were not detected via “PubMed” searches.

Limited pulmonary resection varies such that making a distinction between segmentectomy and wedge resection can sometimes be difficult. Some segmentectomies fall under wedge resection; however, others with large amounts of resected pulmonary parenchyma are similar to lobectomy. Therefore, in this review, sublobar and wedge resections are discussed together. All contributors read the draft manuscript for comments, and when necessary, issues presented in the text were rewritten after discussion.

## RETROSPECTIVE STUDIES

### Pulmonary wedge resection for solid lesions

Stage I lung cancer comprises tumors that are not larger than 5 cm in diameter. It is usually technically difficult to achieve complete tumor removal by wedge resection for stage I tumors that are 5 cm in size (T2AN0M0; stage IB). It has therefore been speculated that such cases were excluded from retrospective analyses of pulmonary wedge resections for solid lesions. In addition, although the main subtypes of non-small cell lung cancer (NSCLC), adenocarcinoma, squamous cell carcinoma, and large-cell neuroendocrine carcinoma are associated with different prognosis, there are a few studies of pulmonary wedge resections for these tumors.

Among patients with early stage NSCLC, the rates of operative morbidity and mortality were reported to be lowest in those who underwent wedge resection, followed by segmentectomy, and then lobectomy. This was the conclusion of a study that aimed at investigating the grade of invasiveness of pulmonary wedge resection, segmentectomy, and lobectomy using registry data. Linden *et al.*<sup>[6]</sup> therefore state that the Society of Thoracic Surgery database was reviewed for stage I and II NSCLC patients undergoing wedge resection and anatomic resection to analyze postoperative morbidity and mortality. Propensity scores were estimated using a logistic model adjusted for a variety of risk factors. Between 2009 and 2011, 3,733 wedge resection and 3,733 anatomic resection patients were matched. The operative mortality was

1.21% for wedge resection versus 1.93% for anatomic resection ( $P = 0.0118$ ). Major morbidity occurred in 4.53% of wedge resection patients versus 8.97% of anatomic resection patients ( $P < 0.0001$ ).<sup>[6]</sup> They concluded that wedge resection has a 37% lower mortality and 50% lower major morbidity rate than anatomic resection and these perioperative benefits must be carefully weighed against the increase in loco-regional recurrence and possible decrease in long-term survival associated with the use of wedge resection for primary lung cancers.<sup>[6]</sup>

Reports before 2000 that studied stage I NSCLC patients who received wedge/sublobar pulmonary resection provide a calculated 5-year overall survival rate (5-YSR) of 60-70%, and a local recurrence rate of approximately 25%.<sup>[7-9]</sup> Errette *et al.*<sup>[8]</sup> reported in 1985 that the 5-YSR of wedge resection and lobectomy cases were 69% and 75%, respectively, which was not statistically significant. In the 1997 study of the efficacy of thoracoscopic surgery for stage I NSCLC, Landreneau *et al.*<sup>[9]</sup> reported a 5-YSR of 58%, 65%, and 70% for patients who received open wedge resection, video-assisted wedge resection, and lobectomy, respectively. Although the calculated survival rate was not statistically significant between the open and video-assisted wedge resection groups, there was a difference in the 5-YSR between the wedge resection and lobectomy groups due to a significantly greater non-cancer-related deaths that occurred within 5 years among the wedge resection group (38% vs. 18%,  $P = 0.014$ ).

The results of retrospective institutional studies of pulmonary wedge resections for stage I NSCLC published in the 2000s are summarized in Table 1. The mortality rate was very low; however, the long-time survival rate was inferior to reports before 2000, which were investigations based on non-biased patient populations,<sup>[10-13]</sup> while the rate of local recurrence did not change.<sup>[13,14]</sup> In addition, the 5-YSR was not different between the wedge/sublobar resection and lobectomy groups.<sup>[10,12,15]</sup> There have also been detailed analyses based on parameters speculated to be indicators of prognosis. Kraev *et al.*<sup>[12]</sup> reported on the long-time survival of patients who underwent pulmonary wedge resection and lobectomy. Of 215 lobectomy and 74 wedge resection patients matched for age, tumor size, and other comorbidities, there was a non-significant overall trend towards better survival times (mean survival time, 5.8 vs. 4.1 years, respectively;  $P = 0.112$ ). However, this trend gained significance in analysis of smaller cancers, where patients who underwent lobectomy had better survival times than those who underwent wedge resection for tumors less than 3 cm

**Table 1: Retrospective institutional study of pulmonary wedge resection for clinical stage I NSCLC from 2000 to 2010**

Author	Year	n	Age, years	T1a < 2 cm, n (%)	GGO dominant	OP	Margin positive	Mortality, n (%)	Local relapse, n (%)	5-YSR (%)	[3-YSR (%)]	RR
Griffin <i>et al.</i> <sup>[10]</sup>	2006	31	Mean 69	NA	NA	Wedge	NA	NA	NA	(35)	NA (35)	0.8
Yendamuri <i>et al.</i> <sup>[11]</sup>	2007	68	NA	NA	NA	Wedge	NA	0 (0)	NA	(58)	NA (52)	0.08
Kraev <i>et al.</i> <sup>[12]</sup>	2007	74	NA	31 (42)	NA	Wedge	NA	NA	NA	(37)	NA (35)	0.1
						T > 3 cm				(35)	NA (60)	0.9
						T < 3 cm				(35)	NA (60)	0.01
El-Sherif <i>et al.</i> <sup>[14]</sup>	2007	81	Mean 70	NA	NA	Sublobar (wedge 55; 68%)	NA	0 (0)	6 (7)	NA (RFS)	NA (NA)	NA
		40				MD > 1		0 (0)	3 (8)	(35) [80]	NA (NA)	0.2
		41				MD < 1		0 (0)	6 (15)	(58) [78]	NA (NA)	(0.7)
Grills <i>et al.</i> <sup>[13]</sup>	2010	69	0 (0%)	NA	NA	Wedge	NA	0 (0)	20 (29)	(52) [79]	NA (NA)	0.01
Wisnivesky <i>et al.</i> <sup>[15]</sup>	2010	196	> 75 (62%)	196 (100)	NA	Sublobar	NA	NA	NA	1.1	NA (Ref)	NS (Cox)

NSCLC: non-small cell lung cancer; GGO: ground glass opacity; OP: operation; YSR: year survival rate; RR: relative risk; NA: not assessed or not available; MD: margin distance; RFS: relapse free survival rate; NS: not significant; Seg: segmentectomy; Lob: lobectomy; Ref: reference

in size ( $P = 0.029$ ). They concluded that tumor size appears to be an important factor to be considered in preoperative planning.<sup>[12]</sup> Based on these findings, the authors recommended randomized trials to confirm the superiority of lobectomy over wedge resection for stage IA lung cancers.<sup>[12]</sup> The implications of tumor distance from surgical margin (margin-distance) in mini-invasive surgery have also been addressed. El-Sherif *et al.*<sup>[14]</sup> demonstrated that margin-distance had a significant impact on local recurrences. In their report, 14.6% (6/41) of the patients with margin-distances of less than 1 cm developed local recurrences compared to 7.5% (3/40) of patients with margin-distances equal to or greater than 1 cm ( $P = 0.04$ ). Segmentectomy was the choice of surgery for 17% (7/41) and 47.5% (19/40) of the patients with margin-distances of less than 1 cm and equal to or greater than 1 cm, respectively. The authors concluded that margin-distance was an important consideration after sublobar resection of NSCLC, because wedge resection was frequently associated with margins less than 1 cm and a high-risk for loco-regional recurrence.<sup>[14]</sup> Although the clinical implications of tumor size and margin-distance were evaluated, margin cytology and ground glass opacity (GGO) did not receive much attention in the 2000s.

Investigations published in the 2010s are summarized in Table 2. The mortality rate was also very low during this period, with a 5-YSR of 55-65% (median, 61%) for all ages<sup>[16-20]</sup> and 41% for aged patients.<sup>[21]</sup> The 5-YSR seems to have improved in the 2010s, and this may be because the detection rate of small stage I tumors had increased for every decade as shown in the report from the Japanese Joint Committee of Lung Cancer Registry.<sup>[22]</sup>

The status of surgical margin of wedge resected clinical

stage I NSCLC and patient outcomes has often been a consideration in the 2010s. This critical observation may have led to the designation of “occult margin malignancy” (malignant positive cytological surgical margin without histological positive result), which was introduced by Sawabata *et al.*<sup>[23]</sup> This “occult margin malignancy” occurs not only in wedge resections, but also in segmentectomies and lobectomies.<sup>[24]</sup> Furthermore, it had been revealed that insufficient margin-distance correlated with positive margin cytology results.<sup>[25]</sup> Therefore, in order to achieve clean surgical margins (negative for malignancy) recent wedge resection may be carried out with sufficient margin-distance. Sawabata *et al.*<sup>[17]</sup> reported that both M/T and margin cytology findings were indicators of cancer recurrence and survival. In their series, all seven cases of surgical margin recurrences were associated with positive margin cytology results. Additionally, the 5-year survival rate was 54.2% ( $n = 24$ ) for M/T less than 1, and 84.6% for M/T more than 1 ( $n = 13$ ,  $P = 0.05$ ), while it was 38.5% for positive margins ( $n = 13$ ) and 79.2% for negative margins ( $n = 24$ ,  $P = 0.001$ ). The authors therefore concluded that a pulmonary wedge resection for peripheral NSCLC should result in a negative malignant margin, which might be achieved with an M/T of more than 1. However, Maurizi *et al.*<sup>[26]</sup> reported that among 243 consecutive patients with a functional contraindication to major lung resection, and who therefore underwent wedge resection with systematic lymph node (LN) dissection for clinical stage I NSCLC, loco-regional (lung parenchyma, hilum, mediastinum) recurrence rate was 26.4% ( $n = 48$ ), distant recurrence rate was 11% ( $n = 20$ ), 5-YSR was 70.4%, and 5-year disease-free survival (DFS) rate was 51.7%. When the first 3 groups were compared, there was no statistically significant difference in loco-regional recurrence ( $P = 0.9$ ), distant

**Table 2: Retrospective institutional study of pulmonary wedge resection for clinical stage I NSCLC after 2011**

Author	Year	n	Age, years	T1a < 2 cm, n (%)	GGO dominant, n (%)	OP	Margin positive, n (%)	Mortality, n (%)	Local relapse, n (%)	5-YSR (%) {4-YSR (%)}, RR			
										Sublober/wedge	Seg	Lob	P
Nakamura <i>et al.</i> <sup>[16]</sup>	2011	84	NA	NA	28 (33)	Wedge	NA	0 (0)	NA	(55)	(82)	(87)	NA
Sawabata <i>et al.</i> <sup>[17]</sup>	2012	37		25 (67)	NA	Wedge	13 (35)	0 (0)	9 (23)	(64)	NA	NA	0.01
		24				MNMC	0 (0)		0 (0)	(79)	NA	NA	
		13				MPMC	13 (100)		8 (62)	(39)	NA	NA	
		13				MD/TS > 1	0 (0)		0 (0)	(85)	NA	NA	
		24				MD/TS < 1	12 (50)		8 (33)	(54)	NA	NA	
Matsuo <i>et al.</i> <sup>[18]</sup>	2014	65	Median 65	NA	NA	Sublober	NA	0 (0)		(61)	NA	NA	NA
Mediratta <i>et al.</i> <sup>[19]</sup>	2014	540	Median 72	NA	NA	Wedge	NA	NA	NA	(65)	NA	NA	NA
Mohiuddin <i>et al.</i> <sup>[27]</sup>	2014	479	> 80 (10%)	118 (25)	NA	Wedge	NA	1 (0)	NA	(RFS)			0.03
		169				MD < 0.5 cm				{63}			
		123				0.5 cm < MD < 1.0 cm				{70}			
		NA				1.0 cm < MD < 1.5 cm				{80}			
		NA				1.5 cm < MD				{82}			
Ambrogi <i>et al.</i> <sup>[20]</sup>	2015	59	Median 70	NA	NA	Wedge	NA	0 (0)	NA	(55)	NA	NA	NA
Maurizi <i>et al.</i> <sup>[26]</sup>	2015	182	Mean 70	138 (76)	NA	Wedge	NA	2 (1)	48 (26)	NA	NA	NA	NS
		30		24		MD < 1 cm				(47)	NA	NA	
		80		63		1 cm < MD < 2 cm				(54)	NA	NA	
		72		51		2 cm < MD				(58)	NA	NA	
Fiorelli <i>et al.</i> <sup>[21]</sup>	2016	90	> 75 (100%)	40 (44)	1 (2)	Sublober	NA	0 (0)	12 (13)	(41)	NA	(61)	0.1
Altorki <i>et al.</i> <sup>[28]</sup>	2016	160	Median 74	136 (85)	22 (14)	Wedge	2 (1)	0 (0)	15 (9)	Ref	1.1		0.7 (Cox)
		58				MD/TS > 1	NA						
		84				MD/TS < 1	NA						
Stiles <i>et al.</i> <sup>[36]</sup>	2016	166	Median 72	159 (95)	27 (16)	Wedge	NA	0 (0)	16 (10)	NA	NA	NA	0.04
		138	Median 72	111 (80)	20 (14)	LN	NA	0 (0)	8 (7)	(83)	NA	NA	
		58	Median 72	48 (83)	7 (12)	NLN	NA	0 (0)	8 (7)	(56)	NA	NA	
Moon <i>et al.</i> <sup>[41]</sup>	2017	91		67 (74)	52 (57)	Sublober (wedge 63; 69%)	NA	0 (0)	NA	(RFS)			< 0.001
		14	Mean 66	13	14	MD < 0.5 cm	NA		0 (0)	(100)			
		38	Mean 61	35	38	MD > 0.5 cm	NA		0 (0)	(100)			
		11	Mean 71	6		MD < 0.5 cm	NA			(24)			
		28	Mean 69	23		MD > 0.5 cm	NA			(80)			

NSCLC: non-small cell lung cancer; OP: operation; GGO: ground glass opacity; YSR: year survival rate; RR: relative risk; NA: not assessed or not available; RFS: relapse free survival rate; MNMC: malignant negative margin cytology; MPNC: malignant positive margin cytology; MD: margin distance; TS: tumor size; Ref: reference; NS: not significant; Seg: segmentectomy; Lob: lobectomy

recurrence ( $P = 0.3$ ), and overall survival ( $P = 0.07$ ) rates. It was therefore concluded that wedge resection is a viable option for the surgical treatment of stage I NSCLC when lobectomy is contraindicated, while the distance between the tumor and the parenchymal suture margin does not influence recurrence or the survival rate when an R0 resection is achieved.<sup>[26]</sup> In contrast, Mohiuddin *et al.*<sup>[27]</sup> after reviewing 497 non-biased adult patients who had undergone wedge resections for small (less than 2 cm) NSCLC reported that the overall unadjusted 1 and 2 year local recurrence rates were 5.7% and 11.0%, respectively. However, from the adjusted analyses, an increased margin-distance was significantly associated with a lower risk of local recurrence ( $P = 0.033$ ), and patients with a 10 mm margin-distances had a 45% lower local recurrence risk than those with a 5 mm distance [hazard ratio (HR) 0.55, 95% confidence interval (CI): 0.35-0.86], while beyond 15 mm, no evidence of additional benefit was achieved. It was therefore

concluded that in wedge resection for small NSCLC, increasing the margin distance 15 mm significantly decreased the local recurrence risk, with no evidence of additional benefit beyond 15 mm.<sup>[27]</sup> However, both Maurizi *et al.*<sup>[26]</sup> and Mohiuddin *et al.*<sup>[27]</sup> did not consider surgical margin cytology in their studies.

In view of the clinical implications of surgical margin cytology and distance, Altorki *et al.*<sup>[28]</sup> compared the outcomes of pulmonary wedge resection to segmentectomy for peripheral small sized lung cancers by examining both parameters. With a median follow-up of 34 months, there was no difference between patients who underwent wedge resection and anatomical segmentectomy in regards to local recurrence (9% vs. 11%;  $P = 0.68$ ) and 5-year DFS (51% vs. 53%;  $P = 0.7$ ). On the other hand, Smith *et al.*<sup>[29]</sup> reported inferior survival outcome for wedge resection to segmentectomy using registry data. Analyses with adjustment for propensity scores of 3,525 patients

**Table 3: Retrospective study of pulmonary wedge resection for clinical stage I NSCLC using registry data**

Author	Year	n	Age, years	T1a < 2 cm, n (%)	GGO dominant, n (%)	OP	Margin positive	Mortality	Local relapse	5-YSR (%) {4-YSR (%)}, RR			
										Sublobar/wedge	Seg	Lob	P
Mery <i>et al.</i> <sup>[35]</sup>	2005	1,403	NA	NA	NA	Wedge	NA	NA	NA	NA	NA	NA	
		NA	< 60							(50)	NA	(67)	0.03
		NA	60-75							(40)	NA	(54)	0.0009
		NA	> 75							(32)	NA	(39)	0.5
Kates <i>et al.</i> <sup>[30]</sup>	2011	688	> 70 (43%)	688 (100) (< 1 cm)	NA	Sublobar	NA	NA	NA	1.1	NA	Ref	NS (Cox)
Witson <i>et al.</i> <sup>[32]</sup>	2012	768	> 80 (12%)	407 (53)	NA	Wedge	NA	NA	NA	(47)	(69)	(68)	< 0.001
Yendamuri <i>et al.</i> <sup>[31]</sup>	2013	361 (1998-2004)	NA	361 (100)	61 (17)	Wedge	NA	NA	NA	{50}	{60}	{75}	< 0.05 (wedge vs. Lob)
		737 (2005-2008)	NA	737 (100)	115 (16)	Wedge	NA	NA	NA	{64}	{73}	{80}	NS
Smith <i>et al.</i> <sup>[29]</sup>	2013	1,568	Mean 70	Mean size 1.82 cm	187 (12) (pure)	Wedge	NA	NA	NA	Ref	0.8	NA	< 0.05 (Cox)
Warwick <i>et al.</i> <sup>[33]</sup>	2013	210	Median 72	NA	NA	Wedge	NA	NA	NA	(45)	NA	(68)	0.003
Khullar <i>et al.</i> <sup>[34]</sup>	2015	7,297	Mean 68.9	NA	NA	Wedge	292 (4%)	11 (2%)	NA	(54)	(58)	(71)	< 0.001 (wedge vs. Lob)

NSCLC: non-small cell lung cancer; OP: operation; GGO: ground glass opacity; YSR: year survival rate; RR: relative risk; NA: not assessed or not available; RFS: relapse free survival rate; Ref: reference; NS: not significant; Seg: segmentectomy; Lob: lobectomy

from the Surveillance, Epidemiology and End Results (SEER) registry revealed that, segmentectomy was associated with significant improvement in overall survival (HR 0.80, 95% CI: 0.69-0.93) and lung cancer-specific survival (HR 0.72, 95% CI: 0.59-0.88) compared to wedge resection. Thus, it was concluded that these results suggest that segmentectomy should be the preferred technique for limited resection of patients with stage IA NSCLC.<sup>[29]</sup> However, margin status of wedge resection was not registered in the SEER registry.

In addition, it is reported that survival outcome of pulmonary wedge resection is similar to lobectomy for patients with tumors of less than 2.0 cm.<sup>[30,31]</sup> The registry data shows that demonstrate inferior<sup>[29,32-34]</sup> or non-inferior<sup>[30,31]</sup> survival outcomes of pulmonary wedge resection to lobectomy [Table 3]. Furthermore, there is a report showing that the outcome of surgery was age-dependent.<sup>[35]</sup>

Lymph node (LN) dissection is also worthy of consideration because this is a standard procedure performed during lobectomy. However, because of potential side effects, caution should be exercised in choosing to perform this procedure. Stiles *et al.*<sup>[36]</sup> evaluated all patients undergoing wedge resection for peripheral clinical stage IA NSCLC, and grouped them into those with and without LN dissection. Of 196 patients undergoing wedge resection, of whom 138 (70%) had LNs (median = 4 nodes) resected and the remainder did not, there were no significant differences in the clinical or pathologic characteristics between the two groups. Additionally, no difference in terms of

operating room time, estimated blood loss, chest tube duration or length of hospital stay was uncovered. However, the LN dissected group had higher probability of freedom from loco-regional recurrence compared to the no lymph node (NLN) group (5-year: 92% vs. 74%,  $P = 0.025$ ) and higher probability of freedom from local recurrence ( $P = 0.024$ ) in propensity matched groups. The conclusion therefore was that LN removal appears to decrease loco-regional recurrence and may be associated with a survival benefit.<sup>[36]</sup>

### Intentional pulmonary sublobar resection for solid lesions

As a standard practice, lung cancer patients with limited pulmonary function undergo limited resections, such as wedge resection or segmentectomy, which are referred to as “compromised resections”. However, some surgeons prefer ‘intentional’ sublobar resections in patients with normal lung functions.

In 1997, Kodama *et al.*<sup>[37]</sup> conducted a 10-year study of 63 patients who received limited resections (46 segmentectomies and 17 wedge resections) and 77 patients who underwent the standard operation (lobectomy plus complete mediastinal LN dissection) as curative-intent treatments for T1N0M0 NSCLC. The 5-year survival rate was 93% in the intentional/limited resection group, and this was not different from that of the 77 patients who underwent the standard operation. The frequency of local/regional recurrence in the intentional resection group was 8.7% (4/46), with mediastinal involvement in 3 patients. It was thus concluded that sublobar resection should be considered

an acceptable alternative treatment for selected patients with T1N0M0 disease. Koike *et al.*<sup>[38]</sup> studied 74 patients who received intentional limited resections for T1N0M0 (< 2 cm) disease, and uncovered that the calculated 3-year and 5-year survival rates were 94.0% and 89.1%, respectively, which did not significantly differ from those of a lobectomy group. They therefore concluded that in patients with peripheral T1N0M0 NSCLC whose maximum tumor diameter was 2 cm or less, the outcome of limited pulmonary resection is comparable with that of pulmonary lobectomy. Okada *et al.*<sup>[39]</sup> also examined 260 sublobar resections, including 30 wedge resections, in comparison to 260 lobectomies, and found that DFS and overall survivals were similar in both groups. The 5-year DFS and overall survival were 85.9% and 89.6%, respectively for the sublobar resection group, and 83.4% and 89.1%, respectively for the lobar resection group. The conclusion was that sublobar resection should be considered as an alternative for stage IA NSCLC 2 cm or less, even in low-risk patients.<sup>[39]</sup> These results could lay the foundation for starting new randomized controlled trials, which could revolutionize lung cancer surgery in this era of early detection. In this context, a phase III randomized trial of lobectomy versus limited resection (segmentectomy) for small (2 cm or less) peripheral NSCLC (JCOG0802/WJOG4607L) has been conducted in Japan.

### Pulmonary wedge resection for GGO predominant lesions

In the 2010s, there was an increase in the number of articles that examined GGO lesions in regard to surgery. Asamura *et al.*<sup>[40]</sup> conducted a prospective multi-institutional study whereby image diagnosis was used to define early (noninvasive) adenocarcinomas of the lung (Japan Clinical Oncology Group 0201). This study demonstrated that a consolidation/tumor ratio on thin-section computed tomography (CT) scans of 0.25 or less for cT1a (less than or equal to 2.0 cm) lesions was a better radiologic criterion for early pathology than a ratio of 0.50 or less for T1a-b (less than or equal to 3.0 cm) tumors. This criterion was used for prognostic evaluation of 545 patients with adenocarcinoma who underwent lobectomy and lymph node dissection. Using a consolidation/tumor ratio of 0.25 or less, the overall survival and 5-year relapse-free survival of the patients were 90.6% and 84.7%, respectively. With a ratio 0.5 or less for T1a-b lesions, the 5-year overall survival for radiologic noninvasive (121 patients, 22.2%) and invasive (424 patients, 77.8%) adenocarcinomas was 96.7% and 88.9%, respectively, and this difference was statistically significant ( $P < 0.001$ , log-rank test). However, when a consolidation/tumor ratio of 0.25 or less for clinical T1a was used, the 5-year overall survival rates of radiologic

noninvasive (35 patients, 12.1%) and invasive (254 patients, 87.9%) adenocarcinomas were 97.1% and 92.4%, respectively, and the difference was not statistically significant. It is currently widely accepted that the radiologic criteria of a consolidation/tumor ratio of 0.25 or less in clinical T1a and 0.50 in clinical T1a-b are both able to define a homogeneous group of patients with an excellent prognosis before surgery.

Margin-distance is an indicator of recurrence among patients with solid but not GGO predominant lesions. In the study by Moon *et al.*,<sup>[41]</sup> there was no recurrence in GGO-predominant tumors after sublobar resection, and this was not influenced by margin-distance. However, for solid-predominant tumors, the 5-year recurrence-free survival after sublobar resection according to margin-distances of less than 5 mm and more than 5 mm were 24.2% and 79.6 %, respectively ( $P = 0.001$ ). The conclusion therefore was as follows that the distance between the tumor and resection margin does not affect the recurrence after R0 sublobar resection in patients with clinical N0 GGO-predominant lung cancer less than 3 cm but margin distance is a significant risk factor for recurrence after sublobar resection in patients with clinical N0 solid-predominant lung cancer.<sup>[41]</sup>

### Stereotactic body radiation therapy

Because conventional 2-dimensional radiation therapy of lung cancer has resulted in inadequate rates of local control and adverse effects, it is being replaced by SBRT, which is mainly administered for stage I lung cancer with acceptable morbidity and local control rates.<sup>[42,43]</sup> Among inoperable patients, the mortality and severe morbidity from SBRT were few, and the 5-year survival rate was less than 20% (17-19%).<sup>[44-46]</sup> Additionally, in non-biased patients with stage IA NSCLC, mortality and severe morbidity seldom occurred, but controllable radiation pneumonitis developed in up to 20% of the patients, and the median 5-year survival rate was 39% (ranged, 30-73%).<sup>[47-50]</sup> It has also been reported that the outcome of surgery is superior to SBRT.<sup>[51-53]</sup>

### Comparison of pulmonary wedge resection and radiation therapy

Clinical observational studies that compared the outcomes of pulmonary wedge resection to SBRT suggest SBRT is inferior<sup>[11,13,18]</sup> but comparable to wedge/sublobar pulmonary resection among operable<sup>[53]</sup> and elderly<sup>[54]</sup> patients.

## PROSPECTIVE CLINICAL STUDIES

### Pulmonary wedge resection

The Lung Cancer Study Group (LCSG) conducted the

first multicenter prospective study in 1995 that compared wedge/sublobar pulmonary resection to lobectomy.<sup>[55]</sup> In this study, the rate of local recurrence was 17% in patients who received wedge/sublobar resections (40 wedge resections) in contrast to 6% for the lobectomy group ( $P = 0.008$ ). The 3- and 5-year survival rates of the wedge/sublobar resection group were 79% and 48%, respectively. Although the survival rate was not statistically significant between the groups ( $P = 0.1$ ), wedge/sublobar resection has not been accepted as a standard therapy for clinical stage I NSCLC.

A number of clinical trials have now been conducted to evaluate the usefulness of various surgical strategies for treating early stage lung cancer. Recently, a phase III randomized trial (JCOG0802/WJOG4607L) was conducted in Japan to evaluate the non-inferiority of overall survival of limited resection (segmentectomy) over lobectomy in patients with small peripheral NSCLC (2 cm or less, the proportion of maximum diameter of the tumor itself to consolidation  $> 0.5$ ).<sup>[56]</sup> In addition, a non-randomized confirmatory study (JCOG0804/WJOG4507L) has been conducted to evaluate the efficacy and safety of limited resection (wedge resection in general) in patients with small (2 cm or less) peripheral radiological noninvasive lung cancer, diagnosed by preoperative thin-section CT scan images.<sup>[57]</sup> Another confirmatory trial (JCOG1211) has been conducted to confirm the efficacy of limited resection (lung segmentectomy) in patients with GGO-predominant lung cancers of less than or equal to 3 cm in diameter based on thin-section CT scans.<sup>[58]</sup> In South America, a randomized phase III trial has also been conducted to compare the efficacy of different types of surgeries used to treat patients with stage I NSCLC.<sup>[59]</sup> Wedge resection or segmentectomy may be less invasive surgeries with fewer side effects and improve recovery than lobectomy for NSCLC, but it is not yet known whether wedge resection or segmentectomy are more effective than lobectomy in treating stage IA NSCLC. However, there have been only three completed multicenter prospective studies of pulmonary wedge resections, including the LCSG study.<sup>[55,60,61]</sup>

The American College of Surgeons Oncology Group (ACOSOG) completed a multicenter prospective study named Z4032.<sup>[60]</sup> The ACOSOG Z4032 was a randomized phase III trial comparing sublobar resection to sublobar resection plus brachytherapy (wire of I-125 implantation at the site of surgical margin) in patients with stage I NSCLC who were considered high-risk for lobectomy. The study was closed to accrual in January 2010 after a planned enrollment of 222 evaluable patients. Although the study failed to reveal the efficacy of I-125 brachytherapy, its results are important

reference data of pulmonary wedge/sublobar resection of NSCLC. The ASOCOG Z4032 results revealed a local control rate of 71% and a 3-year survival rate of 76% in the wedge/sublobar resection group. Although the local control rate was not different regardless of brachytherapy administration, it was higher among cases with cytological malignant positive surgical margins that receive I-125 brachytherapy. Thus I-125 brachytherapy was proven to be effective.

The Kanetsu Lung-cancer Study Group (KLSG) conducted a one arm multicenter prospective study (KLSG0801) to investigate the feasibility of wedge/sublobar pulmonary resection among patients with limited cardio-pulmonary preservation in Japan.<sup>[61]</sup> This study uncovered grade 3 morbidity in only 2 cases (7%), a calculated 3-year surgical margin control rate of 97%, a calculated 3-year local recurrence control rate of 76%, and a calculated 3-year overall survival rate of 79%, supporting the feasibility of wedge/sublobar pulmonary resection for NSCLC. In the KLSG0801 study, surgical margin cytology was carried out in 21 (67%) and margin-distance was measured in all (100%) cases. The calculated 3-year overall survival rate was 88% for negative margin cytology in contrast to 20% for those with positive margins. This finding suggests the importance of determining surgical margin cytology during pulmonary wedge resection of NSCLC. Furthermore, 80% of cases that revealed malignant positive margin cytology possessed M/T ratio of greater than 1, which further emphasizes the importance of performing pulmonary wedge resection with sufficient parenchymal surgical margin-distance. The results of a prospective study of wedge/sublobar resection for clinical stage I NSCLC are summarized in Table 4.

### Stereotactic body radiation therapy

A prospective multicenter study of SBRT demonstrated a 3-year recurrence-free survival rate of 48-80%, 3-year overall survival rate of 56-90%, and tumor control rate of 86-98% with acceptable rates of adverse effects [Table 5].<sup>[62-64]</sup> In addition, a recent prospective phase III study with SBRT and lobectomy arms suggests SBRT could be an option for treating operable stage I NSCLC; however, a limitation of this study was the small sample size.<sup>[64]</sup>

Besides, there are technical limitations associated with SBRT such as “no-fly-zone” and irradiation of hilar tumors, and complications such as pulmonary fibrosis and hemoptysis, which should be considered when comparing surgery to SBRT. In addition, patients with unknown histologic diagnosis received SBRT in most of the studies.

**Table 4: Prospective studies of pulmonary wedge/sublobar resection for clinical stage I NSCLC (%)**

Study	Year	n	Operation		Margin exploration			3-year recurrence free rate						3-year overall survival rate		
			Seg	Wed	MD	All	MC(+)	Margin recurrence free			Recurrence free			All	MC(+)	MC(-)
								All	MC(+)	MC(-)	All	MC(+)	MC(-)			
LCSG <sup>[55]</sup>	1995	122	82	40	NA	NA	NA	NA	NA	NA	78	NA	NA	79	NA	NA
ASCOG Z4032 <sup>[60]</sup>	2014	222	47	155	100	NA	7	NA	NA	NA	71	< 60	NA	76	< 70	NA
KLSG 0801 <sup>[61]</sup>	2016	32	1	31	100	67	16	97	80	100	76	NA	NA	79	20	88

NSCLC: non-small cell lung cancer; NA: not assessed or not available; MD: margin distance; MC: margin cytology; (+): malignant positive; (-): malignant negative; Seg: segmentectomy; Wed: wedge

**Table 5: Prospective studies of stereotactic body radiation therapy for clinical stage I NSCLC**

Study	Year	Design	Operability	n	Age (median, years)	Tumor size (median, cm)	3-year recurrence free rate (%)	3-year overall survival rate (%)	Tumor control rate (%)	Mortality (%)
RTOG0236 <sup>[62]</sup>	2010	Phase II	In-operable	55	72	T1, 2	48	56	98	0
JCOG0403 <sup>[63]</sup>	2015	Phase II	Operable	65	79	2.1	69	76	86	0
			In-operable	104	78	2.1	50	60	88	0
STARS, ROSEL <sup>[64]</sup>	2015	Randomized	Operable	58						
			SBRT	31	67	NA	86	95	96	0
			Surgery	27	66	NA	80	79	100	0

NSCLC: non-small cell lung cancer; SBRT: stereotactic body radiation therapy; NA: not assessed or not available

## Comparison of pulmonary wedge resection and stereotactic body radiation therapy

Investigators from both ACOSOG and the Radiation Therapy Oncology Group (RTOG) embarked on a randomized phase III study of SBRT vs. pulmonary wedge resection for high-risk operable NSCLC patients (ACOSOGZ4099/RTOG1021) that opened for accrual in 2012.<sup>[65]</sup> The ACOSOG Z4099 is a randomized phase III study that will compare sublobar resection (SR) and SBRT for high-risk operable NSCLC patients. Eligible patients will have clinical stage I disease with tumors of 3 cm or less in the maximum diameter. Invasive lymph node staging will not be mandatory for all patients. However, patients with clinically suspicious lymph nodes (defined as > 1 cm on the short axis by CT scan and/or positive by positron emission tomography) will require biopsy to confirm N0 status before registration. Biopsy methods can include mediastinoscopy, anterior mediastinotomy, endoscopic ultrasonography, endobronchial ultrasonography, CT-guided techniques, and video-assisted thoracic surgical biopsy. It is possible that in the surgical arm of the study, the diseases of some patients will be upstaged. However, the primary analysis will be an "intent-to-treat" analysis, and all patients registered and randomized will be included in that analysis. Tumors will have to be in locations that will permit sublobar resection, and also not within 2 cm of the proximal bronchial tree in all directions. Tumors in close proximity to the bronchial tree have previously been demonstrated to have a high incidence of grade 4 and 5 toxicity with

standard-dose SBRT.<sup>[66]</sup> Additionally, tissue diagnosis confirming NSCLC will be required for all patients before registration. Eligible patients will be defined as high-risk using the ACOSOG Z4032 criteria.<sup>[60]</sup> The ACOSOG Z4032 was a randomized study undertaken to compare wedge/sublobar resection alone to wedge/sublobar resection plus brachytherapy for stage I lung cancer. Although closed to accrual, the primary endpoint data was not yet available at the time ACOSOG Z4099 opened. Brachytherapy is not a requirement in the surgical arm of ACOSOG Z4099, and the decision to use brachytherapy will be determined by institutional preference. The primary endpoint for the study will be 3-year overall survival. The secondary endpoint will include comparisons of loco-regional recurrence (using a uniform definition), DFS, grade 3 or higher adverse effects during a 1-year period, the effect of therapy on pulmonary function, and adverse effects and pulmonary function test results in patients with high or low Charlson comorbidity index scores. In addition, some correlative studies will be undertaken to consider patients' quality of life, as well as molecular studies using tissue and blood samples. The target accrual for ACOSOG Z4099 is 420 patients. Unfortunately this study seems to have been closed due to very slow patient accrual.

## COMMENTS

The outcome data of clinical studies of pulmonary wedge/sublobar resection and/or SBRT were not different, and both had acceptable morbidity and

mortality rates. However, technical limitations and complications associated with SBRT, including “no-fly-zone”, irradiation of hilar tumors, pulmonary fibrosis, and hemoptysis should be considered when comparing surgery to SBRT. Moreover, in many studies, patients with unknown histologic diagnosis received SBRT. However, in order to perform SBRT, the lesion should be diagnosed cytologically and/or pathologically. Because diagnosing a cancer lesion involves some interventions, it is necessary to consider the merits and demerits of each diagnostic procedure.

There are three main methods used to diagnose lung cancer are transbronchial biopsy with flexible fiberoptic bronchoscopy (FFB), CT-guided fine needle aspiration biopsy (FNAC), and surgical resection.<sup>[67]</sup> Each method is important but has some drawbacks. FNAC has potential to disseminate cancer cells through the needle tract.<sup>[68]</sup> In a clinical settings, it has been reported that the relapse rate due to pleural recurrences is higher in FNAC than other diagnostic methods.<sup>[69,70]</sup> There are also reports that reveal a prognostic disadvantage of biopsy using FFB.<sup>[71,72]</sup> Pulmonary wedge resection is also a useful diagnostic technique for pulmonary nodules suspicious of malignancy, in addition to complete lesion resection with sufficient margin. As such, wedge/sublobar resection may be more suitable than SBRT in operable patients with no pathological diagnosis, and a select group of patients even if the cytological and/or pathological diagnosis is attained. In addition, if surgeons decide to carry out sampling of suspicious lymph nodes as in ACOSOG Z4032, knowledge of lymph node metastasis can inform adjuvant therapy.<sup>[60]</sup>

Even if the results of ACOSOGZ4099/RTOG1201 is affirmative for SBRT, it would be important for selecting a subgroup of patients for wedge/sublobar resection based on tumor size, location, margin-distance, M/T ratio, and margin cytology. In addition, it has been reported that pure GGO and mixed GGO lesions are different from pure solid lesions in regards to surgical and radiation therapies.<sup>[40,73,74]</sup> Therefore the proportion of GGO in a tumor is a very important parameter for choosing a treatment method. The International Lung-Clinical-Study Organization/Kanetsu Lung Cancer Study Group therefore embarked on a multicenter prospective study of wedge pulmonary resection for clinical stage I NSCLC (ILO1502/KLSG1602, UMIN000024303) that opened in October 2016, with mandatory assessment of GGO, resection type, tumor location, tumor size, margin-distance, M/T ratio, and margin cytology with the primary end-point of local control.<sup>[75]</sup>

In conclusion: (1) patient survival after wedge/

sublobar resection of stage I NSCLC is improving, and is not significantly different globally for peripheral small-sized tumors; (2) there are phase III studies comparing lobectomy and segmentectomy but not wedge resection; (3) survival probability of wedge resection seems to be similar to that of SBRT, but SBRT has limitations such as “no-fly-zone”, irradiation of hilar tumors and associated complications such as pulmonary fibrosis and hemoptysis; and (4) a suitable subgroup of patients for wedge/sublobar resection may be found based on tumor size, location, margin-distance, M/T ratio, and margin cytology.

## Authors' contributions

Organizing this review and writing: N. Sawabata  
Making a discussion and comments on the context of this review: A. Kawase, N. Takahashi, T. Kawaguchi, N. Matsutani

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There are no conflicts of interest.

## Patient consent

Not applicable.

## Ethics approval

Not applicable.

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# Evaluation of laparoscopic rectosigmoidopexy for the treatment of complete rectal prolapse in children

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## ABSTRACT

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### Key words:

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3-point fixation

**Aim:** Rectal prolapse in children is a common condition in infancy and early childhood that usually responds to conservative measures. Surgery is reserved only for resistant cases that fail to respond to conservative measures. This study was designed to evaluate the efficacy of 3-point fixation concept (retrorectal dissection, rectopexy to presacral fascia of the sacral promontory and sigmoidopexy onto the anterior abdominal wall) in treatment of complete rectal prolapse in children using laparoscopy. **Methods:** This prospective study was conducted on 12 children with persistent complete rectal prolapse who failed to respond to adequate conservative measures from July 2015 to July 2016. The technical details of the procedure are described. Patients were followed up for at least 6 months and were assessed clinically and radiologically for continence and constipation using the appropriate scoring systems. **Results:** Twelve patients were included, 8 females and 4 males, laparoscopic rectopexy and sigmoidopexy were done for all cases. The mean duration for surgery was 58.42 min. No intraoperative complications recorded. One case (8.3%) had partial thickness recurrence and 1 case had skin stitch sinus. No postoperative constipation nor incontinence was observed. **Conclusion:** The laparoscopic rectopexy and sigmoidopexy is an effective approach for the treatment of refractory complete rectal prolapse in children. The 3-point fixation proved efficient in controlling rectal prolapse in children with minimal complications.



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## INTRODUCTION

Complete rectal prolapse is defined as the protrusion of all layers of the rectal wall through the anal canal. If prolapse of the rectal wall occurred but does not protrude through the anus it is called “rectal intussusception” or “occult rectal prolapse”. Complete rectal prolapse should be distinguished from mucosal prolapse, in which mucosal prolapse the only protrusion is the anal mucosa. In children it usually presents as a self-limiting disorder. The peak incidence is between 1 and 3 years of age and it has equal gender distribution.<sup>[1-3]</sup>

Prolapse can be either partial or complete. The majority of cases have no obvious cause, though in western countries it is usually related to excessive straining, constipation, cystic fibrosis or functional defecation disorder, however, gastroenteritis and parasitic infestation associated with rectal prolapse are commonly seen in third-world countries.<sup>[4-6]</sup>

Conservative measures are considered the first line of treatment in all cases of rectal prolapse in children. It proved to be effective in controlling prolapse in most of primary cases.<sup>[7]</sup> This includes reduction of the prolapse to decrease edema, bleeding and mucosal ulceration. Supporting the perineum during defecation, defecation in recumbent position, and taping the buttocks to prevent the prolapse from recurring spontaneously, may be helpful as well as proper toilet training. Medical and dietary treatment for the predisposing factors with stool softeners, laxatives, adequate fluid intake and high fiber diet for treatment of constipation and avoidance of straining is important. Further, treatment for parasitic infestations and investigation and treatment for malabsorption and cystic fibrosis are among conservative measures.

Surgical treatment should be reserved for cases resistant to adequate conservative measures. Surgical treatment includes a wide range of abdominal or perineal surgical operations. With such a wide variety of treatment options and variable success rates, the optimal treatment for this condition in children is widely controversial.<sup>[3,4,7,8]</sup>

The aim of surgical management of full-thickness prolapse is to eliminate the external prolapse of the rectum, improve bowel function, and reduce the incidence of recurrence.<sup>[9,10]</sup> Presacral rectopexy has become one of the successful approaches to the treatment of rectal prolapse. This technique has many modifications in addition to the use of different types of mesh. However, all involved mobilization and upward fixation of the rectum to the presacral fascia and was

done by open or laparoscopic approach. Laparoscopy is gaining wide acceptance in the management of rectal prolapse in children.<sup>[6,7,11,12]</sup>

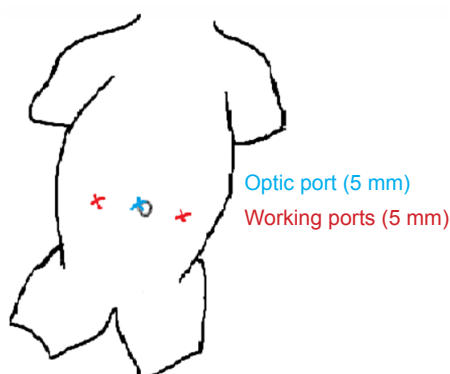
The laparoscopic approach facilitates many minimally invasive techniques that proved to be effective and simple with many advantages including better cosmesis, rapid return of intestinal motility, short hospital stay, low morbidity and low recurrence rate. We propose our concept of laparoscopic rectopexy and sigmoidopexy by 3-point fixation is a new concept for management of complete persistent rectal prolapse.

## METHODS

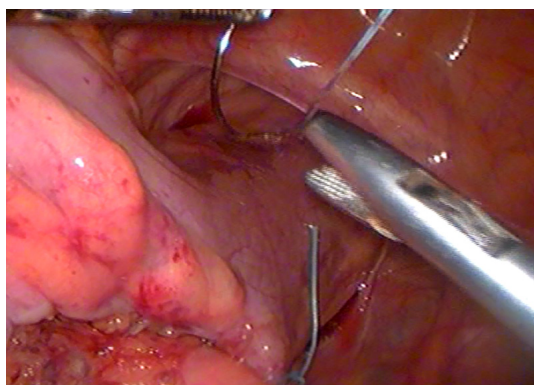
From July 2015 to July 2016, a total of 65 children with complete rectal prolapse presented to Pediatric Surgery Department in El Shatby University Hospital were enlisted and evaluated. Detailed history from all patients including: age, gender, weight, history of the presenting symptoms, duration of the prolapse. Associated symptoms e.g. bleeding, constipation, incontinence, straining and ulcers, associated comorbidities as ectopia vesicae, nutritional history and history of previous operations for treatment of rectal prolapse such as injection sclerotherapy and the Thiersch operation. They were subjected to clinical examination in the form of general examination, inspection of perineum for externally visible prolapse, and rectal examination to detect ulcers and polyps, degree of prolapse and prolapse length. Routine laboratory investigations and stool analysis for parasitic infestation was performed.

Conservative measures were attempted in all cases in the form of proper toilet training, reduction of the prolapsed bowel, adhesive strapping of the buttocks, avoidance of squatting position on defecation, adequate fluid intake, high fiber diet, stool softeners and laxatives for 3 months. Twelve of 65 cases were filtered. The inclusion criteria included cases with complete persistent rectal prolapse more than 3 months with optimum conservative measures, recurrent or persistent prolapse after previous trials of injection sclerotherapy or other previous surgery for rectal prolapse correction. The exclusion criteria were grade I prolapse, complete rectal prolapse grade II responding to conservative measures and patients with spinal or sacral anomalies.

Cystic fibrosis testing was deemed unnecessary due to the extremely low incidence in our population. All children with persistent rectal prolapse after successful treatment of secondary causes, as well as those who had recurrence after previous surgery, underwent Laparoscopic rectopexy and sigmoidopexy. Patients



**Figure 1:** Trocars placement sites

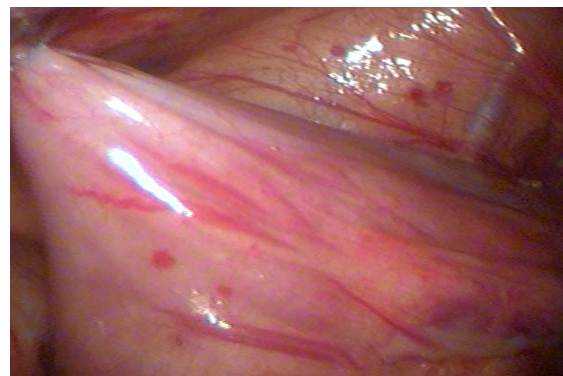


**Figure 2:** Retrorectal dissection with fixation of the rectum to the periosteum of the sacral promontory

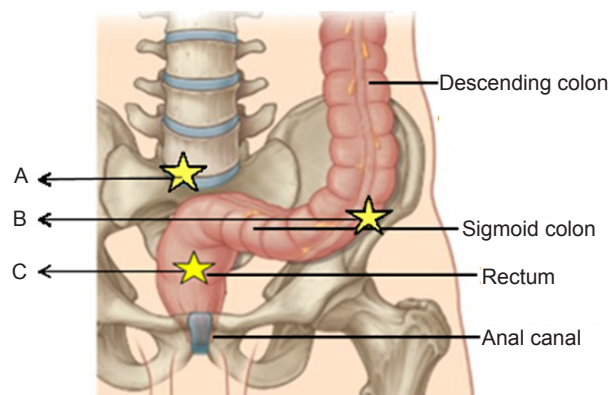
were only allowed clear fluids for 24 h before surgery and had laxative suppositories the night before surgery.

### Operative details

Each patient was informed about the operation, the possible complications and also the possibility of conversion to open surgery was explained to each patient. A written consent was taken from each patient before the operation. The procedure was performed with the patient under general anesthesia and in supine position. After insertion of a suitable Foley's catheter to empty the bladder and monitor the urine output, three 5 mm ports were used [Figure 1] for mobilization, retrorectal dissection and bowel fixation: an umbilical port for the scope and two lateral working ports in the midclavicular line at the level of the umbilicus. The table was tilted head down to evacuate the pelvis and allow better exposure of the rectum. After reduction of the prolapsed bowel, the peritoneum was incised on the right side of the rectum starting from the peritoneal reflection to the sacral promontory [Figure 2]. The right ureter was identified prior to the peritoneal incision to avoid its injury. The retrorectal space was dissected to the level of the pelvic floor without division of the lateral ligaments [Figure 3]. One to two seromuscular 2/0 Ethibond® sutures were used to suspend the rectum to



**Figure 3:** Fixation of the sigmoid colon to the anterior abdominal wall two inches above and medial to the left anterior superior iliac spine



**Figure 4:** Points of fixation of the rectum and sigmoid colon. A: Rectal fixation to sacral promontory; B: sigmoid fixation to anterior abdominal wall; C: fibrosis developed by retrorectal dissection

the presacral fascia of the sacral promontory. Another suture was used percutaneously to fix the seromuscular wall of the sigmoid colon to the anterior abdominal wall 2 inches above and medial to the left anterior superior iliac spine suture with the knot buried under the skin [Figure 4]. The operative time, mean hospital stay, operative and postoperative complications and any recurrence were recorded. After discharge a Barium enema was done for all cases 1 month postoperatively to detect any bowel dilatation and delayed bowel evacuation. Patients were followed up in the outpatient clinic at 1, 3 and 6 months after the procedure and then at yearly intervals.

### Statistical analysis

Data were collected using Microsoft Office Excel 2010 (Microsoft Corp.), imported into SPSS modeler and analyzed using IBM® SPSS Statistics 19.0 (IBM Corp.).

### RESULTS

The total number of cases of rectal prolapse presented to the Outpatient Clinic of the Pediatric Surgery Department in El Shatby University Hospital from July 2015 to July

**Table 1: Demographic data of the cases (n = 12)**

Age group	Male, n (%)	Female, n (%)	Total, n (%)
< 3 years	0 (0)	6 (75)	6 (50)
3-6 years	2 (50)	2 (25)	4 (33.3)
6-9 years	2 (50)	0 (0)	2 (16.7)
Total	4 (33.3)	8 (66.7)	12 (100)
Mean $\pm$ SD	6.83 $\pm$ 2.93	1.98 $\pm$ 1.29	

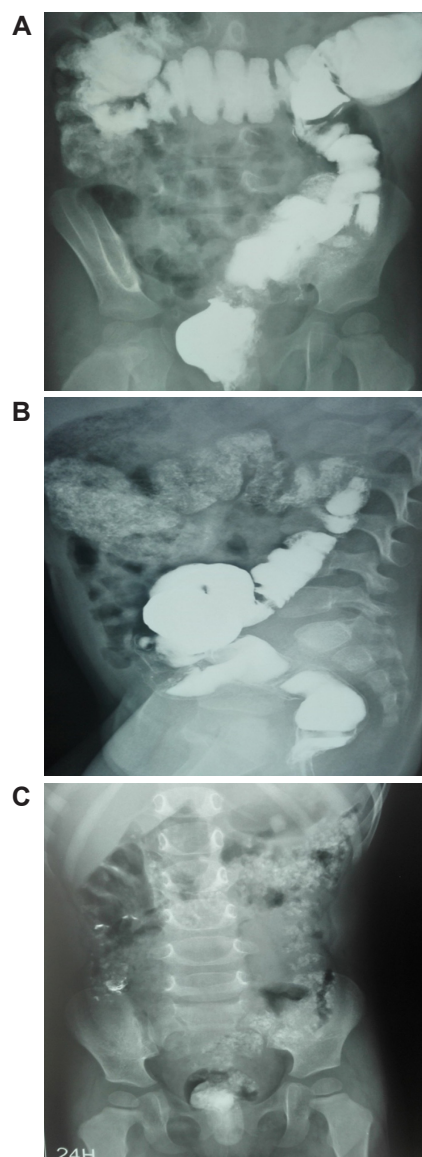
2016 was 65 cases: 15 cases (23.1%) who failed to respond to conservative measures were admitted to Alexandria Pediatric Surgery Department. Two of the 15 were at the age of 2 months and 1 case had huge splenomegaly due to Gaucher disease and they were unfit for laparoscopic management, so were excluded from the study. The remaining 12 cases underwent laparoscopic rectopexy and sigmoidopexy [Table 1].

The mean age of presentation of our cases was  $3.32 \pm 2.70$  years, 8 (66.7%) females and 4 (33.3%) males with a female to male ratio of 2:1. The median duration of symptoms was 5.5 months.

All 12 cases (100%) were complaining of frequent “bowel prolapse” of variable length ranged between 4 and 15 cm with a mean of  $7.0 \pm 3.02$  cm, most frequently falling in the range of 5-7 cm, 8 of them (66.7%) presented by persistent continuous prolapse that descends immediately after reduction and 4 cases (33.3%) presented by prolapse that occurs on straining and after every defecation with mandatory manual reduction from the start of their complaint. Bleeding per rectum was a complaint in 4 cases (33.3%) only with prolapse. Constipation was present in 3 cases (25%). The mean Wexner/Agachan score<sup>[13]</sup> was  $17.3 \pm 1.52$  (range 16-19). Persistent straining was present in 6 cases (50%) with or without constipation and 2 of which were known ectopia vesicae patients and 1 case was complaining of urinary bladder stones. Solitary rectal ulcer was present in 1 case (8.3%). Two cases had ectopia vesicae (16.7%). Fecal incontinence was not encountered in any case. Four cases (33.3%) had previous Thiersch procedure that failed 2 weeks to 1 month postoperatively and 1 case had undergone a repeat Thiersch. The mean operative time was  $58.42 \pm 22.75$  min.

There were no reported intraoperative complications. All cases were completed laparoscopically without conversion to open surgery. All patients achieved full recovery, oral feeding started as soon as return of bowel motion with mean hospital stay of  $2.50 \pm 0.52$  days.

The mean follow-up duration was  $9.17 \pm 3.86$  months. Postoperative complications were skin stitch sinus in 1 case (8.3%) at the site of sigmoidopexy which was treated by removing the stitch. Recurrence was reported



**Figure 5:** (A) Barium enema postoperative (postero-anterior view); (B) barium enema postoperative (lateral view); (C) barium enema postoperative delayed film (postero-anterior view)

in 1 case (8.3%). The recurrence occurred 1 week after the repair as a partial mucosal prolapse and was managed conservatively. Bleeding resolved completely (100%) after correction of prolapse. Constipation neither recurred in the complaining cases nor complicated new ones during the follow-up period. The mean Wexner/Agachan score<sup>[13]</sup> was  $6.83 \pm 1.64$ . Incontinence didn't complicate any of our cases during the follow-up. The mean Kelly's score<sup>[14]</sup> was  $5.58 \pm 0.51$  (range 5-6). Barium enema was done for all cases in our study 1 month after surgery and showed no colonic dilatation and no residual barium in their bowel [Figure 5].

## DISCUSSION

Rectal prolapse is a common condition in children and

**Table 2: Comparison of results of different techniques for treatment rectal prolapse in children**

Studies	No. of cases	Technique	Success rate (%)
Wyatt <sup>[21]</sup>	21	Posterior sagittal (mesh fixation)	95.2
Ashcraft <i>et al.</i> <sup>[18]</sup>	46	Posterior sagittal (levator repair + suspension)	89
Petren <sup>[22]</sup>	26	Ekehorn (transanal suture rectosacropexy)	100
Nazem <i>et al.</i> <sup>[3]</sup>	41	Perineal mesh rectopexy with sterile talc	98.4
Sander <i>et al.</i> <sup>[10]</sup>	56	Ekehorn (transanal suture rectosacropexy)	100
Ismail <i>et al.</i> <sup>[19]</sup>	40	LSRP with sigmoid fixation	100
Shalaby <i>et al.</i> <sup>[7]</sup>	52	Laparoscopic mesh rectopexy	100
Koivusalo <i>et al.</i> <sup>[17]</sup>	16	LSRP = 6 cases; PSRP = 10 cases	100; 75
Laituri <i>et al.</i> <sup>[23]</sup>	10	PSRP	70
Puri <sup>[15]</sup>	19	LSRP	95
Montes-Tapia <i>et al.</i> <sup>[24]</sup>	2	LSRP with sigmoid fixation	100
Awad <i>et al.</i> <sup>[6]</sup>	20	LSRP	90
Potter <i>et al.</i> <sup>[12]</sup>	19	LSRP	95
Gomes-Ferreira <i>et al.</i> <sup>[11]</sup>	8	Laparoscopic modified Orr-Loygue	100
Our study	12	LSRP with sigmoid fixation	91.7

LSRP: laparoscopic suture rectopexy; PSRP: posterior sagittal rectopexy

is usually self-limiting as it mostly occurs as a primary condition without any predisposing factors. Surgery is reserved for a very limited number of cases with persistent prolapse not responding to conservative measures. These cases can develop ulceration and bleeding with frequent admissions to the hospital due to irreducible prolapse and/or poor compliance of patients or their parents with conservative treatment.

Laparoscopic approach for rectal prolapse facilitates many simple and effective minimally invasive techniques that carry low morbidities and low recurrence rate together with short hospital stay and better cosmesis. Of the various laparoscopic techniques, we chose the 3-point fixation of the rectosigmoid colon. Fibrosis developed by retrorectal dissection, rectopexy to the periosteum of the sacral promontory and sigmoidopexy onto the abdominal wall.

Our study was conducted on 12 cases, 8 females and 4 males with a male to female ratio of 1:2. Randall *et al.*<sup>[2]</sup> in their study reported that there was no sex difference (6 females and 5 males), however, Awad *et al.*<sup>[6]</sup> Shalaby *et al.*<sup>[7]</sup> Potter *et al.*<sup>[12]</sup> and Puri<sup>[15]</sup> in their studies reported that male patients outnumbered female ones. The age incidence in our series ranged from 6 months to 9 years with a peak of 1-3 years [Table 2].

Conservative measures are the key for treatment of rectal prolapse and it should be tried in all cases. In the present study, the success rate of conservative measures was 76.9%. Generally, surgical intervention is only recommended after failure of conservative measures. However, this period varies depending on the severity of prolapse (frequent manual reductions, non-compliant patient/parents, length of prolapse, ulceration, and impending gangrene).

Chronic constipation is by far the most common prolapse association as noticed by many authors.<sup>[2,16,17]</sup> However, persistent straining was found to be the second most common presentation in the present study which may or may not be accompanied by constipation. Straining was found in 6 of our cases (50%); 2 cases with ectopia vesicae, 1 case with multiple urinary bladder stones and the last 3 cases was associated with constipation. Chronic constipation together with hard stool causing more straining, which in turn causes increase in the intra-abdominal pressure. The increased intra-abdominal pressure acts upon the less developed protecting mechanisms causing the rectum to prolapse.

All of our 12 patients were essentially presenting with a full-thickness rectal prolapse either primary or secondary so all of them underwent laparoscopic rectopexy and sigmoidopexy. The concept behind is to create 3-point fixation, 2-point fixation to the rectum by suture and fibrosis developed after dissection and the 3rd fixation point is at the sigmoid colon thus preserving and restoring of the normal rectosigmoid angle preventing the occurrence of intussusception at a higher points, proposed as a cause of failure as reported in other studies<sup>[18]</sup> while adding additional fixation to the bowel. Sigmoid fixation also resolved the problem of rectosigmoid redundancy, a major cause of recto anal intussusception.

The mean operative time in our series was 58.42 ± 22.75 min, similar to the mean time in Ismail *et al.*<sup>[19]</sup> (60 min), but less than the mean time in other studies using laparoscopy.<sup>[6,11,12,15]</sup>

The overall recurrence was 1 case out of 12 cases (8.3%). It was mucosal prolapse which improved over 6 weeks by conservative measures in the form of

sitz bath, oral laxatives and anti-inflammatory drugs. These data are similar to the results of other surgical procedures including Ekehorn rectosacropexy, modified Orr-Loygue mesh rectopexy, posterior repair and suspension, sclerotherapy and transabdominal rectopexy with omental flap and laparoscopic mesh rectopexy. They have reported excellent results with little morbidity.<sup>[7,10,11,18,20]</sup>

Koivusalo *et al.*<sup>[17]</sup> had no recurrence in his cases who underwent laparoscopic suture rectopexy (LSRP). Also Puri<sup>[15]</sup> reported 1 case recurrence out of 19 cases during the follow-up for his cases. Rintala and Pakarinen<sup>[1]</sup> preferred laparoscopic rectal fixation to the anterior sacrum without using mesh, and they claimed that this approach was successful in many patients. In Ismail *et al.*,<sup>[19]</sup> LSRP was done in 8 of 40 cases with excellent success rate and low morbidities and no recurrence. The recurrence rate in Awad *et al.*<sup>[6]</sup> using suture rectopexy was 1 case in 20 patients (5%). Randall *et al.*<sup>[2]</sup> reported failure in all of his cases treated by laparoscopic suture rectopexy. The cause of failure in his series may be attributed to the fact that it was conducted on a different cohort of patients who were older (median age at operation was 14 years). Potter *et al.*<sup>[12]</sup> reported also 1 case (5%) full thickness recurrence and mucosal prolapse in 2 cases (11%).

Correction of the prolapse also helped in controlling the associated symptoms: bleeding completely disappeared, improvement of constipation was noticed during the outpatient visits and the postoperative Barium enema showed no bowel dilation, no bowel kink and no residual dye indicating no delayed bowel emptying.

As regards incontinence, it did not complicate any of our cases preoperatively and was not encountered in our cases postoperatively. The mean Kelly's score<sup>[14]</sup> among our cases was 5.58 indicating good continence. On the other hand, constipation, which was a major contributing factor in our cases, improved postoperatively in cases presented with constipation and it did not complicate any of our cases postoperatively. The mean Wexner/Agachan score<sup>[13]</sup> preoperatively was 17.3 (range 16-19) which improved postoperatively to a mean of 6.83 (range 5-10). Koivusalo *et al.*<sup>[17]</sup> reported 2 patients with postoperative constipation. Puri<sup>[15]</sup> reported 1 case with postoperative constipation. Ismail *et al.*<sup>[19]</sup> reported 1 case of postoperative constipation that was managed conservatively.

Laparoscopic suture suspension of the rectum to the sacrum results in fibrosis due to retro-rectal dissection together with sigmoid fixation to add more support preventing recurrence without exerting undue tension

on the bowel that may cause alteration of bowel motility and possible postoperative constipation. Laparoscopic rectopexy and sigmoidopexy is favorable to mesh fixation as it is a easier technique, has shorter operative time, more cost-effective and without complications of the mesh (e.g. pelvic abscess and rectal kink over the edge of the mesh causing constipation). In addition, laparoscopic rectopexy and sigmoidopexy showed almost equal recurrence rate.<sup>[2,6,7,11,12,16]</sup>

If compared to suture rectopexy alone, laparoscopic rectopexy and sigmoidopexy has lower recurrence rate, almost equal operative time, nearly similar morbidities with less post-operative constipation.<sup>[6,12,17]</sup>

In conclusion, we believe that our technique of laparoscopic rectosigmoidopexy is an effective and efficient technique for treating children with persistent full-thickness rectal prolapse having a low recurrence rate and minor complications. The anatomical restoration of the normal rectosigmoid angle is credited to our 3-point fixation concept. We propose the new concept of 3-point fixation in the surgical treatment of persistent complete rectal prolapse as a favorable alternative to other more complex open or laparoscopic techniques with inevitably lower efficacy, higher morbidity and lower recurrence rates.

### Authors' contributions

Study conception and design, performing the surgical technique: S. Shehata

Critical revision and assistance in operations: M. Abouheba

Acquisition of data, drafting of manuscript: A. Mokhtar

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### Conflicts of interest

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### Patient consent

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### Ethics approval

The protocol of work was approved by the ethical committee of our hospital.

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# Hybrid mesh for sports hernia repair

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## ABSTRACT

**Aim:** Mesh is commonly utilized in the laparoscopic repair of sports hernias. A hybrid mesh was recently released containing a single light weight layer of macroporous, polypropylene mesh between layers of biologic mesh. Having an extensive experience with laparoscopic and sports hernia repairs, a small sample of hybrid mesh was trialed. **Methods:** From April 2015 to August 2016, 16 male patients with sports hernias were consented for hybrid mesh repair. A prospective data base was developed and patients were followed at 1 week, 4 weeks and 4 months after surgery. **Results:** Ages ranged from 18 years to 43 years (average 22.9 years). Operative times ranged from 25 min to 75 min (average 42.5 min). All were athletes playing basketball, soccer, baseball, football and track. There were no operative problems. Two patients developed post-operative seromas requiring radiologic drainage. All patients completed a post-operative therapy program and all have returned to their sport without problems. **Conclusion:** There is not one type of mesh repair that has been proven to be the most effective treatment for sports hernias. Continued follow up as well as a more structured study will be necessary to prove if hybrid mesh has long term effectiveness for the laparoscopic treatment of sports hernias. The initial study has promising findings.

## INTRODUCTION

Sports hernia or Gilmore's groin was described in 1966 by Cabot and popularized in the 1980s by Gilmore.<sup>[1]</sup> Gilmore noted a dilated internal ring in soccer players who did not clinically have an inguinal hernia. Other pathologic findings were noted in these athletes

including torn conjoint tendons, torn external oblique aponeurosis and chronic osteitis pubis that did not improve with conservative treatment. It was not until 1992 that the term "sports hernia"<sup>[2]</sup> or "sportsman hernia" was introduced to define a tear in the posterior inguinal floor or transversalis fascia. Most physicians describe a lack of physical findings in the athlete's



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groin and were not able to demonstrate a definite inguinal hernia on exam. Surgery to repair these hernias has been popularized in the United States by Dr. William C. Meyers.

Many approaches to the treatment of this condition have been described in the literature and not one approach has been studied to be superior to any other. The laparoscopic approach to repair inguinal hernias has been demonstrated to be safe and effective. Using mesh or a synthetic prosthesis is commonplace. Despite the availability of different types of mesh, no one mesh has yet to be proven applicable to all patients or hernia repairs. Biologic mesh is designed to leave behind a minimal amount of foreign material and reduce the inflammatory response associated with polypropylene mesh. This has theoretical advantages for the athlete. Biologic mesh has been shown to be a safe and effective alternative to polypropylene mesh.<sup>[3]</sup> However, studies on incisional hernias using biologic mesh have found late recurrences and this fact has led to incorporating an ultra-lightweight polypropylene mesh into the biologic mesh matrix.<sup>[4]</sup> Selecting the most appropriate mesh to repair and reinforce a hernia while minimizing the failure rate but optimizing the return of the athlete to their sport is mandatory. In 2014, a hybrid mesh was released having a 6 layers of porcine small intestine sub mucosa covering a lightweight, macroporous, polypropylene mesh (Zenapro, COOK Surgical). This mesh was the basis of this study.

## METHODS

Patients were seen and examined because of a suspected sports hernia. All patients had an magnetic resonance imaging (MRI) showing signs of a rectus abdominis injury or chronic osteitis pubis that persisted after a trial of conservative therapy including rest, non-steroidal anti-inflammatory medication (NSAIDs) and physical therapy. Proper informed consent was obtained on all patients. Surgery was performed on an outpatient basis. Patients were seen 7 days to 10 days after surgery and started on a rigid physical therapy program over 4 weeks. They were seen again at 4 weeks post-op before being released to full contact. The athletes were seen for a final visit at 4 months after surgery.

A modified, double incision, total extra-peritoneal (TEP) hernia repair was performed. Patients were placed supine on the operating room table under a general endotracheal anesthesia. Five mL of 0.5% bupivacaine at each of the 2 skin incisions. Ten mL of bupivacaine was injected into the pre-peritoneal space at the completion of the procedure. A balloon

cannula was used at the umbilicus to create a space for surgery down to the pubis in the pre-peritoneum. Stay sutures of 0 Vicril were placed in the fascia to hold a 12 mm Hasson cannula in place for the 0 degree laparoscope. Insufflation of carbon dioxide gas at a 12 mmHg pressure was used for the surgery. A single, 5 mm cannula was placed in the midline, 6 cm below the umbilicus. A flat dissector was used at the 5 mm portal to dissect out the cord structures away from the pubis exposing the epigastric vessels, iliopubic tract and both inguinal areas looking for pathology. Once the dissection was complete, a 10 cm × 15 cm hybrid mesh was opened on the operative field and moistened in 20 mL of bupivacaine prior to rolling it up and introducing it into the pre-peritoneal space. The flat dissector was used to position the mesh over the cord structures to the lateral edge of the balloon dissection and past the midline under the pubis. Four absorbable tacks were used to hold the mesh in place - superior medial, superior lateral, midline pubis and inferior into the lacunar ligament near the femoral canal. Five mL of fibrin sealant was then sprayed on both sides of the mesh. The remaining bupivacaine was injected into the pre-peritoneal space before removing all of the CO<sub>2</sub> gas. The umbilical fascia was closed with a 0 Vicril suture and both skin incisions were closed with a subcuticular, 4-0 monocril suture followed by skin glue.

## RESULTS

From April 2015 to August 2016, 16 male athletes with a diagnosis of a sports hernia were consented for hybrid mesh repair. Their ages ranged from 18 years to 43 years with an average age of 22.9 years. Operative times ranged from 25 min to 75 min with an average of 42.5 min. The athletes played sports including: soccer (5), basketball (3), track (3), football (2), baseball (1), weight lifting (1) and ultimate frisbee (1). There were no operative complications. Two patients (soccer) developed seromas overlying the urinary bladder causing intense pressure. Interventional radiology was consulted for drainage of these sterile fluid collections 2 weeks after surgery. All patients completed a post-operative therapy program and all have returned to their sport without problems.

## DISCUSSION

Sports hernia involves a set of injuries in the abdominal wall and pelvis causing a weakness of the posterior inguinal wall. It is a chronic, activity related groin pain that is worsened by turning or twisting movements. Athletes can usually play through the pain but by the day following the activity, there is pain in the groin on the affected side. Rest is beneficial but resumption

of the activity causes the pain to recur. Athletes will commonly describe that pain occurs while running and then attempting to move quickly in an opposite direction. They may find it difficult to go from a stationary position and initiate a running motion.

The physical exam is frequently not helpful in the work up of groin pain, but certain subtle findings on the exam of an injured athlete are important. Adductor tightness and pain at the inferior pubic insertion is not uncommon when the adductor longus tendon is involved in the injury. Rectus abdominis injury can elicit tenderness on the anterior pubic bone but generalized osteitis pubis will also cause tenderness to palpation in that area. With the athlete standing, palpation of the posterior pubic area and posterior inguinal floor can find cause pain or alternatively, a laxity of the posterior inguinal floor is appreciated. I will have the athlete lay supine on my exam table while placing my index finger into the external ring while having the athlete do a bilateral straight leg raise while their arms are lifted to the ceiling. I find that the same laxity or pain in the inguinal floor is a reproducible physical finding on patients with a "sports hernia".

An ultrasound can demonstrate a classic inguinal hernia and is an adequate study to go forward with surgical treatment. An MRI is commonly obtained to look at the pelvis and hip for musculo-skeletal injuries that might benefit from orthopedic consultation.

Sports hernia can be managed either non-operatively or operatively. Non-operative management consists of a combination of rest, NSAIDs, corticosteroid injections or platelet derived plasma injections, all followed by physical therapy. Athletes can return to sports in 3-4 weeks if they are pain free. However, if after 6-12 weeks they are not pain-free, repeat MRI and operative intervention should be considered.

The operative management of sports hernias involve the re-inforcement of the posterior abdominal wall using suture as described by Meyers *et al.*<sup>[5]</sup> or Minnich *et al.*,<sup>[6]</sup> which consists of modifications of the classic Bassini hernia repair. Alternatively, a laparoscopic repair as described by Paajanen *et al.*<sup>[7]</sup> or Edelman and Selesnick<sup>[8]</sup> involves mesh placed behind the inguinal floor in the pre-peritoneal space. Mesh is commonly used in the laparoscopic repair of inguinal hernias and sports hernias.<sup>[9]</sup> Fixing the mesh with absorbable tacks or fibrin sealant is encouraged. Presently, polypropylene is the most commonly used prosthetic. In 2006, the laparoscopic treatment of sports hernia using porcine submucosa, biologic mesh

was published demonstrating excellent results.<sup>[8]</sup> The ideal material, mesh or suture, for hernia repair should be inexpensive to produce, easy to use, promote host tissue ingrowth, result in a healed repair with equal strength to normal tissue over extended periods of time, provide resistance to infection, elicit little or no inflammatory response and inhibit adhesion or fistula formation. Surgisis was initially used as a graft material for arteries, veins, ligaments, dura, urinary bladders and wound coverage. It has also been shown to be effective in the repair of abdominal wall hernias. Biologic mesh, like porcine submucosa, acts as a scaffold for host tissue collagen to re-populate the injured area with excellent revascularization.<sup>[10]</sup> However, over time, there has been a question of the long term durability and strength with biologic mesh.<sup>[4]</sup> Hybrid mesh was released in 2014 to meet the unmet need of a predecessor mesh for optimizing hernia repair. By adding a very lightweight polypropylene mesh to a few layers of a biologic collagen matrix, it is hoped that a beneficial host response will result in an optimal repair.<sup>[11]</sup> This initial study on a select group of patients suggests the benefits are excellent and supports continued investigation into the use of hybrid mesh for abdominal wall repair and re-inforcement.

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Nil.

### Conflicts of interest

There are no conflicts of interest.

### Patient consent

All involved patients gave their consent forms.

### Ethics approval

IRB/Ethics review was not needed by my institution to review this data.

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# Robot-assisted simple prostatectomy with temporary internal iliac arteries clamping: our preliminary results

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## ABSTRACT

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**Aim:** This study proposed the robot-assisted laparoscopic simple prostatectomy (RASP) as safe and reliable surgical option for the treatment of men with prostate size > 80 mL. It was aimed to evaluate preoperative and postoperative results in RASP using a surgical variation to the standard technique: the temporary bilateral internal iliac arteries clamping. **Methods:** This study analyzed 18 patients underwent RASP with temporary clamping of bilateral internal iliac arteries. Procedures were performed by two surgeons in two different hospitals using the same surgical technique. Preoperative and postoperative data were collected and statistically analyzed. **Results:** The temporary clamping duration was less than 12 min during each adenoma's enucleation. Despite the vascular control, the median operating time was similar to RASP performed without iliac clamping. The results showed minimal blood loss, a median catheter duration of 5 days, a median duration of postoperative continuous catheter irrigation of 41 h, and short hospitalization (3.2 days). A significant correlation was observed between the estimated blood loss and the duration of irrigation. **Conclusion:** RASP performed with bilateral vascular control, combined with the known benefits of minimally invasive surgery resulted in bleeding reduction. The minimal blood loss further reduces catheter duration, decreases continuous catheter irrigation and patient's hospitalization duration.



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## INTRODUCTION

Currently, minimally invasive surgery is the most common surgical approach for symptomatic benign prostatic hyperplasia (BPH). According to the EAU (European Association of Urology) guidelines, transurethral resection of the prostate represents the treatment of choice for men with prostate size < 80 mL.<sup>[1]</sup> Some patients can be affected by complex conditions such as large adenoma (> 80 mL) associated with moderate-to-severe lower urinary tract symptoms (LUTSs) and/or concomitant bladder diverticulum. In these cases, the endoscopic approach should be replaced by more invasive procedures. Open surgeries such as Trans-Vesical or Retropubic Adenomectomies are indicated in case of large adenoma and/or complex BPH but these techniques often show massive intraoperative blood loss and have the risk of blunt dissection particularly in the area around the apex and the urinary sphincter.<sup>[2-5]</sup> For this reason, new techniques have been developed to combine the benefits of open simple prostatectomy with potential advantages of minimally invasive technique such as laparoscopic and robotic approaches. Robot-assisted laparoscopic simple prostatectomy (RASP) represents a new treatment alternative, in expert hands, for these complex cases. This new alternative combines the advantages of laparoscopic surgery and three-dimensional vision, and increased digital degrees of freedom, resulting in surgical precision and improved results.<sup>[6,7]</sup> The aim of the present study was to demonstrate the possibility of obtaining better intraoperative and postoperative results with RASP in terms of estimated blood loss, postoperative care and hospitalization using a surgical variation to the standard technique: the temporary bilateral internal iliac arteries clamping.

## METHODS

### Patients and methods

We retrospectively reviewed 18 cases of RASPs performed by two surgeons from March 2010 to May 2012 at two different hospitals. Each procedure was performed according to Sotelo's technique<sup>[7]</sup> with the addition of the temporary clamping of internal iliac arteries. All patients were affected by severe symptomatic benign prostatic hyperplasia. Preoperative assessment included physical examination, International Prostate Symptom Score (IPSS) evaluation, serum creatinine, prostate specific antigen (PSA), uroflowmetry (except for the patients with an indwelling catheter) and volumetric suprapubic ultrasonography (US). The median preoperative IPSS was 25.2 (range 16-38). Fourteen patients (77.7%)

presented PSA value < 3.5 ng/mL; four patients (22.2%) presented higher PSA value and underwent previous trans-rectal ultrasound guided biopsy that confirmed the diagnosis of benign prostatic hyperplasia. Uroflowmetry revealed in all patients a peak flow < 10 mL/s and an average flow < 5 mL/s. The median prostatic adenoma weight estimated preoperatively by US was 95 g (range 80-195). Based on these characteristics, our patients were classified as affected by complex prostatic hyperplasia and were scheduled to robot-assisted laparoscopic simple prostatectomy. We collected data about postoperative International IPSS evaluation, the duration of surgery, the estimated blood loss, postoperative care and hospitalization. Then, we statistically analyzed our results in a linear regression using the Fisher's test.

### Surgical technique

All patients were placed in supine position and the table in deep Trendelenburg fashion. The surgeries were performed with a transperitoneal approach under general anesthesia in each case. Positioning included adequate padding of the pressure points on shoulder, back, legs and arms. The first trocar (camera port) was placed paraumbilical with the open (Hassan) technique. After the pneumoperitoneum was obtained, we performed a peritoneoscopy and placed the other robotic trocars under direct visualization. The abdomen was insufflated with a medium pressure of 12 mmHg carbon dioxide gas. The ports were placed according to Sotelo *et al.*<sup>[7]</sup> [Figure 1]: two robotic ports (8 mm) placed 9 cm from the camera port on an imaginary line joining the anterior superior iliac spine to the umbilicus; the third robotic port (8 mm) was placed in the left iliac fossa. Two additional ports were placed for the assistant instruments: one of 5 mm between the camera port and the first robotic arm on the upper right side and one of 12 mm in the right iliac fossa. We used both 0° and 30° optics, monopolar and bipolar robotic instruments. The 4-arm da Vinci® Surgical System was docked and the intervention started with the development of the Retzius space and the isolation of the internal iliac arteries bilaterally using two vessel loops. Then, we cleared the anterior surface of the prostate capsule. In Figure 2 are showed the iliac arteries occluded with two Bulldog clamps. After clamping the arteries, a horizontal cystotomy, through the bladder mucosa, was made one centimeter cranial to the bladder neck. We dissected the adenoma along the subcapsular plane taking care of the prostatic capsule. We used two 2-0 vicryl stitches on the adenoma surface for traction. Extra care was taken at the apex of the prostate to avoid injury to the external sphincter. Accurate hemostasis was achieved before removing the prostatic adenoma en bloc in an Endo-

Catch bag. The Bulldog clamps on the internal iliac arteries were removed; 2-0 monocryl running sutures were used for cystotomy closure in two layers. The prostatic fossa was then “trigonized” according to the technique described by Sotelo<sup>[7]</sup> suturing the posterior edge of the bladder neck to the posterior edge of the urethra. An 18 French three-way Dufour catheter was placed and the balloon inflated to 30 mL. Finally, we tested the bladder suture for leaks. We placed one drainage in the pelvis behind the bladder. The robotic arms were removed under vision and the abdominal wall was closed.

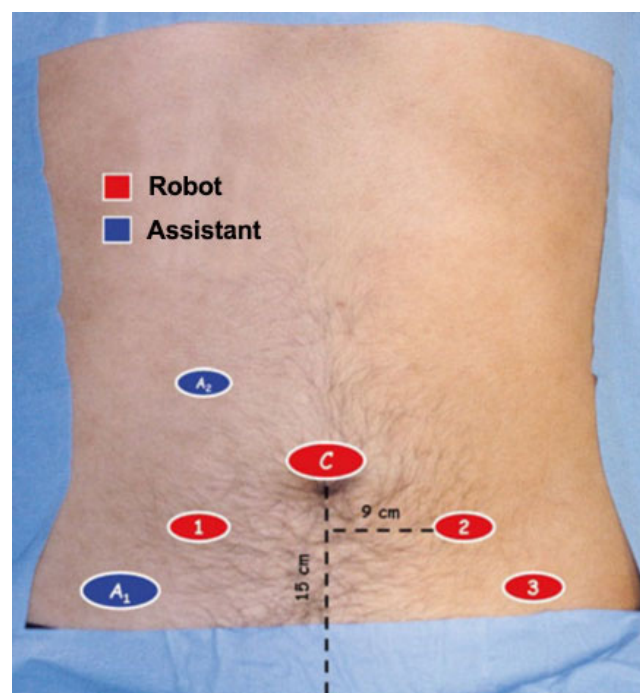
## RESULTS

The demographics preoperative clinical data are showed in the Table 1. Patients' median age was 74 (range 65-88). The median postoperative IPSS at three months after surgery was 8 (range 3-13). The median operative duration was 205 min (range 120-300) and the median estimated blood loss (EBL) was about 200 mL (range 100-350) irrespective of prostate weight. The median temporary clamping of internal iliac arteries duration average 12 min (range 11-14) during each adenoma's enucleation that were performed in about 10 min. The median prostate weight on the pathological examination was 100 g (range 80-195). Pathology revealed a benign glandular-stromal hyperplasia in all patients. The abdominal drain was removed on postoperative day 2. Continuous postoperative catheter irrigation was maintained for a median time of 41.5 h (range 18-55) in all patients. The median hospital stay was 3.2 days (range 2-6). The median catheter duration was 5.6 days (range 5-7). No patient required blood transfusion. Statistical analysis was performed between the estimated blood loss and the duration of continuous catheter irrigation. The logistic linear regression showed a significant statistical relation between these parameters ( $P = 0.0395$ ) [Figure 3]. Furthermore, patients did not present with symptoms of pelvic ischemia at the follow-up four months after surgery.

## DISCUSSION

Although the definition of “large prostate” is still unclear, the surgical treatment of BPH is strictly dependent on prostate volume. For medium-size glands, transurethral resection of the prostate (TURP) is considered the gold standard.<sup>[4]</sup> In fact, the EAU guidelines suggest TURP for men with prostate sizes < 80 mL and moderate-to-severe lower urinary tract symptoms (LUTSs).<sup>[8]</sup> Properly, a “large prostate” can be assumed as a gland > 80 mL. In these cases, the surgical treatment is still controversial. Even though the lasers are becoming

more popular especially for the treatment of medium-small prostate adenomas, open simple prostatectomy (OP) performed with either the Millin (retropubic) or the Freyer (open transvesical) technique is still an effective and reliable procedure<sup>[9]</sup> for prostates > 80 mL. Holmium laser enucleation of prostate (HoLEP) is seen as close rival of TURP.<sup>[10,11]</sup> This procedure is showing good results in terms of blood loss, transfusion rates, and a hospital stay at the expense of longer operative time and postoperative dysuria. Despite its invasive nature, simple prostatectomies represent the 14-32% of all invasive procedures performed for BPH in Europe.<sup>[12]</sup> Open procedure is often preferred in men who have a concomitant bladder condition, e.g. symptomatic bladder diverticulum, bladder calculus or inguinal hernia. Yet the disadvantages of open simple prostatectomy compared with transurethral resection are those of every open procedure such as the incision, the higher estimate blood loss and the necessity of

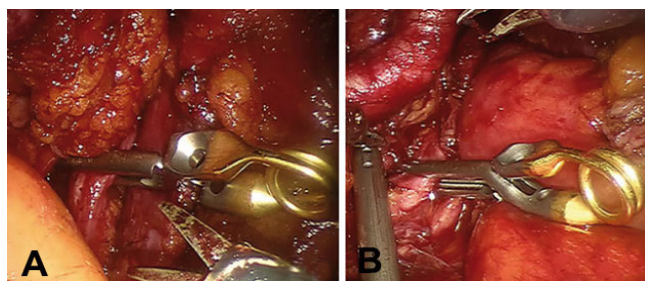


**Figure 1:** Port placement for simple prostatectomy. C: 12 mm robotic camera port; 1,2,3: 8 mm robotic working ports; A<sub>1</sub>: 12 mm assistant port; A<sub>2</sub>: 5 mm assistant port

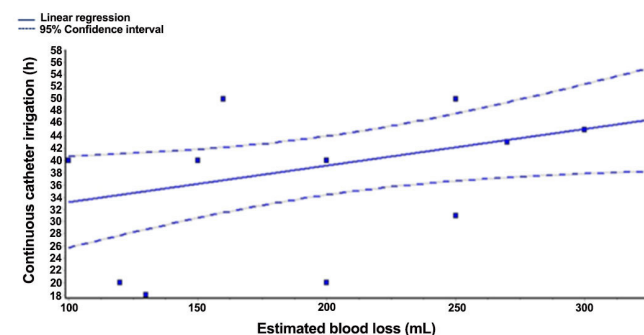
**Table 1: Epidemiology and clinical data**

Characteristics	Median	Range
Age (years)	74.3	65-88
Operative duration (min)	205	120-300
Ematic blood loss (mL)	200	100-350
Catheterization (days)	5.6	5-7
Drainage (days)	2	2
Hospitalization (days)	3.2	2-6
Prostate weight (g)	100	80-195
Preoperative IPSS	25.2	16-38
Postoperative IPSS	8	3-13
Continuous catheter irrigation (h)	41.5	18-55

IPSS: International Prostatic Symptoms Score



**Figure 2:** Occlusion of bilateral internal iliac arteries. A: on the right side; B: on the left side



**Figure 3:** Logistic linear regression (X intercept: estimated blood loss; Y intercept: hours of continuous catheter irrigation)

transfusions, the prolonged hospital stay with a longer convalescence period. Transfusion rate of 0% to 57% has been reported due to excessive bleeding.<sup>[9]</sup> In 20th century, minimally invasive surgeries have been developed to limit the blood loss, to provide a shorter hospitalization and urethral catheterization, and to allow minimal postoperative pain and complications. So, the minimally invasive approach for BPH is replacing open surgery. Both laparoscopic and robotic techniques have those benefits. The first laparoscopic simple prostatectomy (LSP) was first described by Mariano *et al.*<sup>[13]</sup> in 2002. This procedure combined the benefits of open simple prostatectomy (OSP) with the potential advantages of a minimally invasive approach. Subsequently, several papers in the literature started to compare the open surgery and laparoscopic approach. Porpiglia and colleagues showed that the only benefit of laparoscopic simple prostatectomy was a less intraoperative blood loss. The other parameters such as: operation duration, postoperative pain, catheterization duration and hospitalization were almost the same between the laparoscopy group and the open procedures.<sup>[14]</sup> Also McCullough and associates compared the same two groups. In their study, the operation duration was significantly longer in laparoscopy group but catheterization and hospitalization were significantly shorter. There was no difference between bleeding and irrigation periods.<sup>[15]</sup> Case series in the literature are few but the reported results showed that laparoscopic adenomectomy is a reasonable alternative to the open prostatectomy.<sup>[16]</sup>

With continued expansions in the field of robotic surgery, urologists are now available to combine the advantages of laparoscopic procedures such as shorter hospitalization, less total amount of blood loss, more efficient intracorporeal suturing and cosmetic results and those of robotic surgery: 6 degrees of freedom, dexterity enhancement, 3-D vision, and tremor filtering. The feasibility of robotic-assisted adenomectomy was confirmed by Sotelo *et al.*<sup>[7]</sup> in 2008. Their data showed that the patients who underwent robotic-assisted prostatectomy had significant improvements in urinary flow, postvoid residual measurements, IPSS scores and cosmetic results than those who had undergone open surgery. The operative times, the hospitalization, the low dose of analgesics required and the minimal blood loss calculated, were similar to those seen in laparoscopic series.<sup>[7,15,17-19]</sup> Matei *et al.*<sup>[20]</sup> have recently reported the series of 35 patients underwent RASP. Although Matei and colleagues presented the largest series of RASP, we reported our series of 18 patients treated with RASP and early vascular control: the temporarily bilateral internal iliac arteries clamping. The early vascular control makes the procedure a safer alternative for treating BPH.<sup>[21]</sup> Our results showed a median estimated blood loss (EBL) of 200 mL that is less than the median value of the other series (> 300 mL).<sup>[20]</sup> No transfusions have been necessary. Despite the vascular control, our median operating time is superimposable to the RASP performed without clamping the iliac arteries. Furthermore, we reported a median catheter duration of 5.6 days (range 5-7 days) that is lower than Matei *et al.*<sup>[20]</sup> Our results showed also a significant statistical relation between the EBL and the duration of continuous catheter irrigation ( $P = 0.0395$ ) with median hospitalization of 3.2 days (range 2-6 days). The early vascular control reduces the intraoperative blood loss and possibly the necessity of transfusion. Consequently, also the catheter duration and the hospitalization can be shorter and costs decrease. Our results agree with those of more recent larger series.<sup>[22-23]</sup> The most important possible side effect of clamping the internal iliac arteries is the pelvic ischemia. It can manifest in different ways and often the symptoms are transient and resolve with time. It is very important to take care not to prolong the arteries clamping for a long time. In these cases, patients can present serious complications such as colorectal ischemia, gluteal necrosis and neurological deficit or buttock claudication and sexual dysfunction.<sup>[21]</sup> The intensity of possibly complication depends on the status of collateral circulation around the internal iliac artery and/or the presence of stenosis of the origin of the remaining internal iliac arter.<sup>[24]</sup> In our series, the internal iliac arteries clamping was performed for less than 12 min in each surgery and we did not have

cases of pelvic ischemia manifestation. Nevertheless, robotic-assisted laparoscopic simple prostatectomy is considered a new surgical approach and prospective future comparative studies are needed to determine the efficacy of this procedure. Our paper showed the preliminary results of robotic assisted laparoscopic simple prostatectomy with temporary internal iliac arteries clamping and we believe that this approach could be a safe surgical option for the treatment of large prostatic adenomas (> 80 mL) reducing the estimated blood loss and decreasing needed postoperative care.

In conclusion, the surgical treatment of large prostatic adenomas remains a controversial issue. The minimally invasive approach for BPH is replacing open surgery. Both laparoscopic and robotic techniques have benefits. We propose robotic assisted laparoscopic simple prostatectomy with early vascular control as technique able to associate the benefits of minimally invasive surgery with those of minimal estimated blood loss. We believe that this approach could be a safe surgical option for the treatment of large prostatic adenomas (> 80 mL) especially for surgeons at the beginning of their learning curve.

### Authors' contributions

Original idea and data collection: C. Falavolti

Data and statistical analysis: T. Petitti

Drafting of the text: M. Buscarini

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None.

### Conflicts of interest

There are no conflicts of interest.

### Patient consent

The informed consent was obtained from all patients.

### Ethics approval

This article is waived for ethical approval in authors' affiliations.

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# Preface of the special issue on "Percutaneous endoscopic system for spinal diseases"

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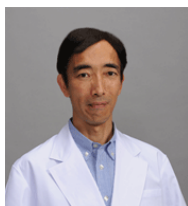
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Dr. Hisashi Koga is the Deputy Director and the Head of Education and Training Center, Iwai Orthopaedic Medical Hospital, Japan. He obtained his MD in the University of the Ryukyus Faculty of Medicine (Okinawa, Japan) and PhD in the Graduate Medical School of Kumamoto University (Kumamoto, Japan). His research interest focuses on endoscopic spinal surgery and minimally invasive spinal surgery. He has authored 8 articles on his research field in recent 3 years. He also obtained research grant from Humboldt foundation.

It is our great privilege to present the special issue of *Mini-invasive Surgery*, an open-access journal devoted to exploring many contemporary issues affecting minimally invasive surgery. The first special issue of *Mini-invasive Surgery* is intended to introduce the latest advancement of percutaneous endoscopic lumbar discectomy (PELD), which is a single portal full-endoscopic system originally developed for the treatment of lumbar disc herniation (LDH). As PELD has been rapidly growing in East Asia (China, Korea, and Japan), we invited submissions from these countries. The majority of the articles are from Japan. However, articles presented in this issue cover all recent advancements in the field of PELD.

PELD technique has been developed along with the

advancement of operative instruments. In particular, the development of a high-speed drill used in narrow and long endoscopic lumen has expanded not only target spinal diseases, but also the operative spinal area. Currently, we are already able to successfully treat cervical radiculopathy (Ohmori *et al.*), lumbar spinal canal stenosis (Ohara *et al.*), LDH with narrow interlaminar space (Koga *et al.*), and cervical spinal canal stenosis (Nishimura) with PELD. However, this technique does have some limitations, which must be recognized and we must utilize the supportive materials such as free-running electromyogram monitoring (Kitahama *et al.*) to secure safety of the technique.

The technique of PELD requires some specific technical and anatomical considerations that will be



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addressed in this special issue of *Mini-invasive Surgery*. For example, the initial stage of PELD is a completely blind maneuver. Therefore, anatomical knowledge is imperative (Sakane) along with accurate preoperative measurement using radiological data (Kitahama *et al.*). In addition, the appropriate preoperative diagnosis remains extremely important. Accordingly, we asked Dr. Kim to submit review article regarding differential diagnosis of LDH. From each of these articles, we hope that readers with varying levels of experience with PELD can utilize this issue, from the beginner to the expert who can imagine new operative approaches.

We also have emphasized that the technical difficulties associated with this procedure and a lack of a steep learning curve. Therefore, strict training programs under the guidance of expert surgeons is essential for the expansion of PELD. We propose that the establishment of a training system is the most important factor for safely disseminating PELD. From this viewpoint, we would like to introduce the well-established training system from Japan for orthopedic surgeons (Dezawa), for neurosurgeons (Mizuno) and from China (Yang). These systems are anticipated to be disseminated to other countries to assist spinal surgeons with mastering PELD.

We would like to acknowledge various people who have contributed to the completion of this issue, with special mention to our co-Guest Editors: Dr. Kyongsong Kim

(Department of Neurosurgery, Chiba Hokusō Hospital, Nippon Medical School) and Dr. Manabu Sasaki (Department of Neurosurgery and Spine Surgery, Iseikai Hospital, Osaka, Japan) and Assistant Editor: Ms. Anne Niu. Without their tireless efforts in editing and personal sacrifice, this special issue would not have been published. We would also like to acknowledge our publisher, OAE publishing Inc., for their support of this international special issue. Finally we also express our appreciation and thanks to the Japanese Spine Surgical Societies (Orthopaedic and Neurosurgical) and the special communities of these societies (Japan PED study group, Less-Invasive and Endoscope Spinal Neurosurgery) who deeply recognize the importance of minimally invasive spinal surgery.

### Authors' contributions

H. Koga contributed solely to this preface.

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There are no conflicts of interest.

### Patient consent

Not applicable.

### Ethics approval

Not applicable.

# Common diseases mimicking lumbar disc herniation and their treatment

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## ABSTRACT

Lumbar disc herniation (LDH) is a common disease characterized by leg pain, numbness, and low back pain, which are also encountered in peripheral nerve and paralumbar spine disease. This study describes other diseases with symptoms similar to LDH. Patients with paralumbar spine diseases such as superior cluneal nerve entrapment neuropathy (NEN), gluteus medius muscle pain, piriformis syndrome, and sacroiliac joint pain experience lowback, buttock, and leg pain. Peripheral nerve diseases of the leg including lateral femoral cutaneous NEN, common and superficial peroneal NEN, and tarsal tunnel syndrome also cause leg symptoms. These diseases can produce intermittent claudication, thought to be specific to lumbar spine disease, and can be misdiagnosed as LDH. They are rather common and can be treated less invasively. As a misdiagnosis may result in failed back-surgery syndrome, it is important to differentiate between LDH and the diseases described here.

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treatment,  
paralumbar spine disease

## INTRODUCTION

Lumbar disc herniation (LDH) is common; its symptoms of leg pain, numbness, and lowback pain (LBP), are also reported by patients with peripheral nerve and paralumbar spine diseases. Since they can cause intermittent claudication, thought to be specific to lumbar spine disease, differential diagnosis can be difficult. As misdiagnosis can result in failed back surgery syndrome (FBSS), spinal surgeons must be able to differentiate them from LDH.

## PARA-LUMBAR SPINE DISEASES

### Superior cluneal nerve entrapment neuropathy

#### Definition and symptoms

The superior cluneal nerve (SCN) is a sensory nerve that originates from the lower thoracic and lumbar posterior nerve. It is comprised of 4 to 6 nerves, runs around the paraspinal muscle, penetrates the thoracolumbar fascia near the iliac crest, and ends at the buttock [Figure 1]. The clinical features and etiology

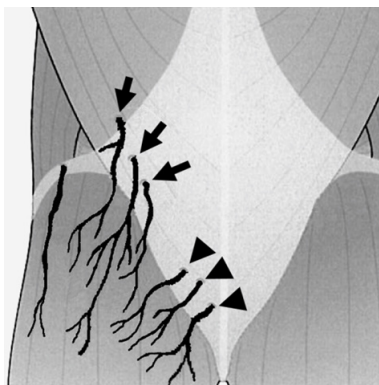


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**Figure 1:** The superior cluneal nerve (arrows) consists of 4-6 nerves; it runs around the paraspinal muscle and penetrates the thoraco-lumbar fascia near the iliac crest before it arrives at the buttock. The middle cluneal nerve is identified by arrowheads

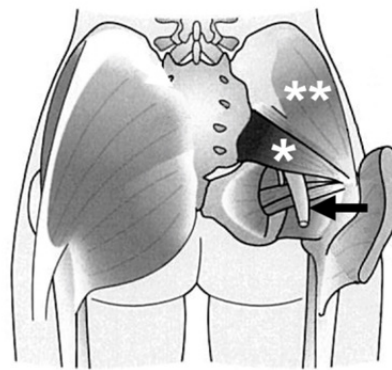
of SCN-entrapment neuropathy (EN) remain poorly understood. LBP occurs when the SCN is entrapped where it penetrates the thoraco-lumbar fascia. LBP attributable to SCN-EN involves the iliac crest and buttocks and can be misdiagnosed as a lumbar disorder. The reported incidence of SCN-EN ranges 1.6-14%.<sup>[1,2]</sup>

The most common symptom of SCN-EN is LBP around the iliac crest. It is exacerbated by lumbar movements involving flexion, extension, bending, rotation, standing, and walking. It can produce intermittent claudication, with 50% of patients reporting leg symptoms.<sup>[1,3]</sup> As these symptoms are similar to those of lumbar disease, their differentiation is important for treatment planning.

The pathogenesis of SCN-EN remains unknown. It is seen in patients with vertebral compression fractures, LDH, lumbar spinal canal stenosis, FBSS, and Parkinson's disease.<sup>[1,3-6]</sup> As it is also encountered in the elderly, soldiers, and athletes, age-related spondylotic changes, sports-related activities, high body training, and trunk rotation may be related to the manifestation of SCN-EN.<sup>[1,5-8]</sup>

### Diagnosis and treatment

The SCN is thin and difficult to identify through the skin surface. As SCN-EN cannot be identified with radiological and electrophysiological studies, its diagnosis is based on clinical symptoms.<sup>[2,9]</sup> When we suspect SCN-EN because patients report LBP involving the iliac crest and buttocks, we identify the trigger point that elicits radiating pain over the posterior iliac crest located approximately 7 cm from the midline where the SCN penetrates the thoraco-lumbar fascia to confirm entrapment. The trigger point has been localized in earlier reports and is not affected by patient age, height, gender, or race. When SCN block successfully decreases pain, we make a diagnosis of SCN-EN.



**Figure 2:** The location of the gluteus medius muscle (GMeM) (\*\*) and piriformis muscle (\*). The GMeM (\*\*) is located in the buttock over the gluteus minimus and partially under the gluteus maximus muscle; it is covered by a tight gluteal aponeurosis. The piriformis muscle (\*) connects the sacrum and greater trochanter. Loading of this muscle results in buttock pain and affects the adjacent sciatic nerve (arrow)

SCN-EN can be treated by less invasive procedures such as local SCN block and SCN neurolysis under local anesthesia. We usually perform peripheral nerve surgery under local anesthesia without nerve block using no special techniques because we want to observe symptom changes and monitor the affected nerve during surgery. Approximately 28-100% of patients with SCN-EN respond to SCN-EN blocking.<sup>[1,2,7]</sup> In some instances, SCN block is useful for treating refractory severe LBP. If only transient pain amelioration is achieved, SCN blockage can be repeated. When SCN-EN cannot be controlled by observation therapy including SCN blocks, it can be treated by less invasive SCN neurolysis under local anesthesia.<sup>[9-11]</sup>

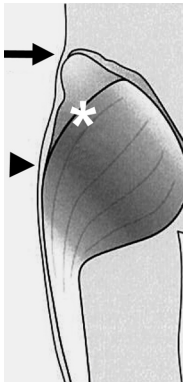
## Gluteus medius muscle pain

### Definition and symptoms

The gluteus medius muscle (GMeM) is located in the buttock over the gluteus minimus and partially under the gluteus maximus muscle; it is covered by a tight gluteal aponeurosis [Figure 2]. The GMeM supports the pelvis and femur when standing on one leg, walking, and running. GMeM pain results in buttock pain.<sup>[6,12]</sup> It is elicited by walking, prolonged sitting, standing, and standing on one leg. Lateral and posterior femoral pain is reported by 80% of patients.<sup>[12]</sup> The symptoms are similar to those of lumbar disease, and differentiation of GMeM from LBP is important for treatment planning. Given its size, the GMeM generates an exceptionally large force, and this background may be related to GMeM pain severity.<sup>[13]</sup> The GMeM plays a significant role in chronic LBP.<sup>[14-16]</sup>

### Diagnosis and treatment

GMeM pain cannot be identified radiologically, so its diagnosis relies on clinical symptoms.<sup>[6,12]</sup> In our



**Figure 3:** The trigger point (\*) for gluteus medius muscle pain is located at the edge of the gluteus maximus muscle at the midpoint between the iliac crest (arrow head) and greater trochanter (arrow)

practice, we consider GMeM involvement in buttock pain when it is located around this muscle. The trigger point is located on the GMeM at the edge of the gluteus maximus muscle equidistant from the iliac crest and greater trochanter [Figure 3]. Some patients report pain radiation to the lateral-posterior thigh. When transient pain amelioration is obtained by local GMeM block, we diagnose GMeM pain.

When GMeM pain cannot be controlled by medication and physiotherapy, GMeM block may be useful. Some patients experience gait disturbance due to transient leg paralysis after blockage. Non-responders to conservative therapy may require less invasive GMeM decompression surgery under local anesthesia.<sup>[6,12]</sup> This treatment can benefit even very old patients with intractable buttock and leg pain due to the GMeM. Peripheral block and less invasive surgery under local anesthesia are other treatment options.<sup>[6]</sup>

## Piriformis syndrome

### Definition and symptoms

The piriformis muscle connects the sacrum and greater trochanter. When it is overburdened, buttock pain also involving the adjacent sciatic nerve with nerve pain down to the lower thigh may be experienced. The pain is similar to that elicited by S1 radiculopathy and may be attributable to anatomic anomalies of the piriformis and sciatic nerve. It is more common in women than men.<sup>[17,18]</sup>

There are no specific symptoms. Patients report lower buttock pain and S1-like sciatic pain that rarely involves the ankle. The symptoms are exacerbated by prolonged sitting, stairclimbing, and walking.<sup>[19,20]</sup> Some patients experience decreased pain with walking. The etiology of piriformis syndrome involves exercise load, trauma, and tumor; lumbar spine disease may be an idiopathic cause.

The accurate diagnosis of piriformis syndrome avoids FBSS and insufficient decompression after surgery.

Among patients with LBP, 5-17% manifest piriformis syndrome.<sup>[17,19,21-23]</sup> Some patients develop piriformis syndrome after percutaneous endoscopic lumbar discectomy (PELD). Kim and Kim<sup>[22]</sup> reported that the incidence of piriformis syndrome was 13.7%. Within 3 months of PELD, 40.4% of operated patients presented with piriformis syndrome; its incidence was highest in the first postoperative month. Their observations suggest that heightened anxiety in patients undergoing PELD under local anesthesia may increase the incidence of piriformis syndrome elicited by walking. They suggested that general anesthesia may reduce the incidence of piriformis syndrome after PELD, although local anesthesia is preferable because it allows for intraoperative monitoring. Anxiolytic administration makes intraoperative patient cooperation difficult, particularly in older patients, and their use may have adverse effects. A proper preoperative period stretching of the piriformis muscle may be useful in locally anesthetized patients.

### Diagnosis and treatment

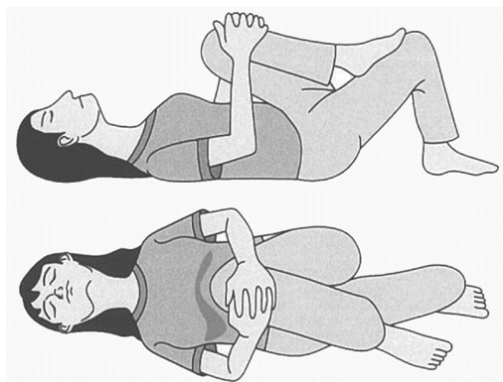
Piriformis syndrome cannot be identified by radiological and electrophysiological studies; its diagnosis is based on clinical symptoms and palpation.<sup>[18-22]</sup> During palpation, the swollen, stiff piriformis muscle is identified as a sausage-shaped mass over the piriformis muscle. There is tenderness, and some patients report radiating pain along the sciatic nerve. Symptom alleviation obtained by piriformis muscle block is diagnostic.<sup>[18,20-22]</sup>

Piriformis muscle stretching is useful in addition to medication and rehabilitation [Figure 4]. Some patients experience pain alleviation upon piriformis muscle stretching, but this exercise must be continued for more than 2 weeks. When these methods fail, piriformis muscle block may be useful. Piriformis muscle block may elicit transient leg paralysis 30-60 min after injection when the anesthetic reaches the sciatic nerve. Non-responders may require piriformis muscle dissection.

## Sacroiliac joint pain

### Definition and symptoms

The sacroiliac joint (SIJ) connects the spine and pelvis; it is comprised of articular and posterior ligamentous compartments. It is reinforced with hard ligaments and moves only slightly. SIJ pain can be elicited by everyday activities and involves both articular and posterior ligament regions. It is felt not only in the lower back and buttocks but also in the groin and lower extremities, it can be difficult to discern from pain secondary to other disorders. The major pathological factor in SIJ pain is joint dysfunction.<sup>[24]</sup> Repetitive movements and/or accidental minor subluxation of the SIJ may damage



**Figure 4:** Piriformis muscle stretching

SIJ-related structures such as the joint capsule and the posterior ligament.

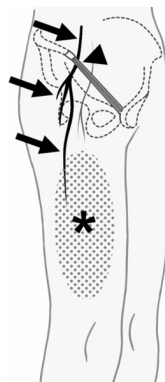
SIJ pain is commonly perceived in the gluteal region; it can be referred to the lower limbs and groin region, and is similar to symptoms due to lumbar diseases.<sup>[24-26]</sup> The pain area tends to be located around or within 2 cm of the posterosuperior iliac spine (PSIS). SIJ pain should be considered in patients reporting lowerback and buttock pain.<sup>[24,27]</sup> Approximately 50% of patients with SIJ pain experience groin pain,<sup>[24,28,29]</sup> which is exacerbated by sitting on a backless chair.<sup>[24]</sup>

While SIJ pain may occur alone, 39% of patients also manifested LDH and LSS.<sup>[30]</sup> It has been reported after lumbar fusion and lumbar decompression surgery.<sup>[31-33]</sup> In patients with lumbogluteal and/or lower extremity pain and a high SIJ-related score,<sup>[24]</sup> SIJ pain should be considered even in the absence of lumbar disease or prior lumbar surgery.

#### Diagnosis and treatment

As it is difficult to identify SIJ pain radiologically, its diagnosis is based on clinical symptoms and the effect of SIJ block. Kurosawa *et al.*<sup>[24]</sup> proposed a score for diagnosing SIJ pain to distinguish it from pain elicited by other lumbar diseases [Table 1]. Their scoring system includes six items and is useful for both diagnosing and understanding SIJ pain. Patients often point to an area within 2 cm around the PSIS as the most painful area when instructed to identify the affected area with one finger (one-finger test). The SIJ shear test is the most useful provocation test. With the patient in the prone position, the examiner places a palm over the patient's posterior iliac wing and thrusts the palm inferiorly to produce a shearing force across the SIJ.

Besides medication and rehabilitation, conservative approaches include a pelvic belt and SIJ block. Blocking the posterior ligament and periarticular region of the SIJ under fluoroscopic guidance yielded more effective



**Figure 5:** The course and entrapment point (arrowhead) of the lateral femoral cutaneous nerve (arrow). This sensory nerve branches off the L2 and L3 nerve roots, merges, passes through the inguinal ligament inside the superior iliac spine, and then distributes subcutaneously through the femoral fascia (\*). From Clinical diagnosis for low back pain by palpation (2015), Isu T & Kim K, CHUGAIIGAKU. CO., LTD

pain relief than intra-articular SIJ injection.<sup>[24,27,28,34]</sup> Injecting a local anesthetic into the posterior ligament can also relieve SIJ pain. While intra-articular SIJ injection is not recommended as a definitive diagnostic tool for pelvic girdle pain, it can be combined with the injection of a local anesthetic into the extra-articular SIJ ligaments to alleviate pain.<sup>[34,35]</sup> SIJ denervation or fixation is a treatment option in non-responders.

## PERIPHERAL NERVE DISEASES

### Lateral femoral cutaneous nerve EN

#### Definition and symptoms

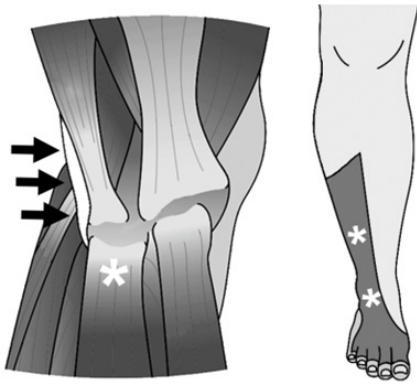
The lateral femoral cutaneous nerve (LFCN) is a sensory nerve that branches off the L2 and L3 nerve roots, merges, passes through the inguinal ligament inside the superior iliac spine, and is then distributed subcutaneously through the femoral fascia [Figure 5]. The incidence of LFCN-EN is 33-43 individuals per 100,000; the site where the nerve penetrates the inguinal ligament is often involved.<sup>[36,37]</sup>

Obesity, pregnancy, compression by tight undergarments and corsets, lower abdominal surgery, autogenous iliac bone, and nerve compression due to posterior spinal surgery in the prone position have been reported to be implicated; 77% of LFCN-EN is idiopathic.<sup>[36-38]</sup> Diabetes and alcoholism are metabolic risk factors for LFCN-EN, which can be unilateral or bilateral.<sup>[38-40]</sup> The symptoms are pain, abnormal perception, numbness, and a burning sensation in the

**Table 1: Sacroiliac joint pain scoring**<sup>[24]</sup>

Item	Score	Odds ratio
1. One-finger test	3	25.9
2. Groin pain	2	14.5
3. Pain while sitting on a chair	1	1.4
4. Sacroiliac joint shear test	1	1.8
5. PSIS tenderness	1	2.2
6. STL tenderness	1	2.2
Total score	9	

PSIS: posterosuperior iliac spine; STL: sacrotuberous ligament. Scores above 4 are considered high SIJ pain scores



**Figure 6:** The common peroneal nerve (arrow) runs around the fibular head, then between the soleus and the peroneus longus muscle (PLM) (\*), and then into the PLM. Patients experience pain and paresthesia of the affected area, the lateral aspect of the lower calf, and the dorsum of the foot (\*\*)

anterior lateral region of the thigh; they are elicited by hip joint movement and alleviated by squatting. Some patients complain of intermittent claudication.<sup>[38,41,42]</sup>

### Diagnosis and treatment

The symptoms above and Tinel-like signs at the nerve penetration site inside the superior iliac spine are diagnostically relevant. In some patients without clear Tinel-like symptoms, the disappearance of symptoms after nerve block is useful for a diagnosis. Electrophysiological studies can also be helpful. Patients with symptoms clearly attributable to LFCN-EN may report perception anomalies on the outside of the thigh when the nerve is compressed in the pelvis or in the presence of a retroperitoneal tumor. Consequently, pelvic lesions must be ruled out when blocking fails to be effective.

Conservative therapy and nerve block are effective in 90% of patients.<sup>[42-44]</sup> Tagliafico *et al.*<sup>[42]</sup> reported that 80% of patients improved after a single block; others required 2 blocks to decrease symptoms. The nerve block is applied at the site with Tinel-like symptoms, 2 cm inside and 2 cm below the anterior superior iliac spine. As the anesthetic infiltrates the femoral nerve running on the inside, approximately 5% of patients experience transient femoral nerve paralysis.<sup>[43,45]</sup> Non-responders to conservative therapy may require neurolysis or neurectomy under local anesthesia.<sup>[38,46,47]</sup>

## Common peroneal nerve EN

### Definition and symptoms

Common peroneal nerve (CPN)-EN is the most common peripheral entrapment neuropathy eliciting leg symptoms. The CPN runs around the fibular head and then between the soleus and peroneus longus muscle (PLM) to the inner PLM [Figure 6]; it can become entrapped in this area. As the nerve runs a shallow

course on the bone, external compression neuropathy is not infrequent. However, EN has been reported in patients whose daily activities failed to account for its elicitation.<sup>[48-50]</sup>

The symptoms are pain and paresthesia of the affected area on the lateral aspect of the lower calf and the dorsum of the foot. Drop foot is a severe symptom, although some patients report only pain and paresthesia without severe paresis.<sup>[48-52]</sup> Walking and prolonged standing may lead to symptom exacerbation and intermittent claudication.

### Diagnosis and treatment

CPN-EN cannot be diagnosed radiologically. While nerve conduction studies may be useful, the anomaly may not be detectable in patients with dynamic neuropathy-like intermittent claudication.<sup>[48-51,53]</sup> In these situations, it can be difficult to distinguish CPN-EN from lumbar spine disease because the symptomatic area is similar to L5 radiculopathy with intermittent claudication.<sup>[48-50]</sup> CPN-EN diagnosis is based on clinical symptoms. Although the Tinel-like sign is useful diagnostic information, it may be absent.<sup>[51]</sup>

Repetitive plantar flexion of the ankle joint is a useful provocation test because the CPN is entrapped by the PLM and soleus muscle;<sup>[48,49]</sup> these muscles are most heavily loaded during maximum plantar flexion. CPN-EN results in intermittent claudication. At a cutoff of 110 s, sensitivity and specificity were 94.1%, suggesting that the repetitive plantar flexion test is diagnostically useful.<sup>[48]</sup>

When conservative treatment fails, surgical neurolysis around the fibular head under local anesthesia is a useful treatment. It is important to intraoperatively confirm sufficient decompression by ankle movement because dynamic neuropathy is an important factor in CPN-EN etiology.

## Superficial peroneal nerve EN

### Definition and symptoms

CPN-EN is more common than superficial peroneal nerve (SPN)-EN. The SPN bifurcates from the CPN around the fibular head and runs along the peroneal tunnel between the peroneus longus/brevis muscles and the extensor digitorum longus muscle. The SPN can be entrapped in this area.

Patients with SPN entrapment report pain and paresthesia in the affected area, the lateral aspect of the lower calf, and the dorsum of the foot. Styf and Morberg found SPN entrapment in 17 of 480 (3.5%) patients with chronic leg pain.<sup>[54]</sup> According to



**Figure 7:** Tarsal tunnel syndrome is an entrapment neuropathy of the posterior tibial nerve (arrow) in the tarsal tunnel (\*). Only the sole of the foot has symptoms (\*\*); there is no heel pain

others,<sup>[55-57]</sup> SPN-EN was attributable to entrapment due to muscle herniation, trauma, compression by a mass lesion, (e.g. varicose veins or lipoma), or an idiopathic origin.

#### Diagnosis and treatment

SPN-EN diagnosis is based on its symptomatology because it is difficult to diagnose on radiological and nerve conduction studies.<sup>[54-57]</sup> Its symptoms tend to be exacerbated by walking and exercise, and SPN-EN must be differentiated from other lumbar diseases. The Tinel-like sign is diagnostically useful.<sup>[54-57]</sup> Tinel-like signs are occasionally observed at multiple compressed points along the SPN.<sup>[54]</sup> SPN block with lidocaine may provide transient pain relief. SPN-EN can co-exist with CPN-EN; Franco *et al.*<sup>[56]</sup> reported that 78% of patients who underwent SPN-EN surgery had undergone CPN decompression surgery. In patients with muscle herniation, static palpitation and radiological studies may not identify the lesion, and the loaded posture may be necessary for a correct diagnosis.

The decision to intervene surgically depends on SPN-EN etiology. Neurolysis may be effective in patients with idiopathic origins. The area requiring decompression is not necessarily limited to the part with the Tinel sign. Some patients may require decompression involving the area from the PLM to the SPN exit point along the SPN.

### Tarsal tunnel syndrome: posterior tibial nerve EN

#### Definition and symptoms

The tarsal tunnel is a fibro-osseous tunnel under the flexor retinaculum below the medial malleolus. The posterior tibial nerve bifurcates to the medial and lateral plantar nerve and passes inside the tarsal tunnel together with the posterior tibial artery and vein. Tarsal tunnel syndrome (TTS) is an entrapment neuropathy of the posterior tibial nerve within the tarsal tunnel [Figure 7].

The etiology of TTS has been ascribed to tumors; changes in anatomical structures due to trauma; and idiopathic factors such as tortuous vessels, hypertrophy of the flexor retinaculum, and fibrosis with a variety of origins. Compression of tortuous arteries and veins can elicit TTS, although a tortuous vein may be a normal variation. TTS was idiopathic in 18-69% of patients.<sup>[58-60]</sup>

The symptoms are sensory disturbance in the sole of the affected foot, paresthesia, a foreign-body sensation like walking on gravel, cold sensation, and burning or tingling. They are exacerbated by prolonged standing or walking; they do not involve the heel of the affected foot (heel sparing) because the branch to the heel bifurcates proximal to the tarsal tunnel. Heel sparing is therefore useful for the diagnosis of TTS.<sup>[58,59,61-63]</sup>

#### Diagnosis and treatment

An accurate diagnosis is difficult, and TSS is regularly underdiagnosed based on clinical symptoms affecting the plantar aspect of the foot.<sup>[61-64]</sup> Although sonography, computed tomography, and magnetic resonance imaging studies are diagnostically useful in patients with space-occupying lesions, the identification of idiopathic TTS remains difficult. False-positive and false-negative findings make diagnosis of TTS based on electrophysiological means alone difficult.<sup>[61,65-67]</sup> A positive Tinel-like sign and radiating pain on the entrapment point of the tibial nerve in the tarsal tunnel are diagnostically useful. A positive Tinel sign is the best indicator of a favorable outcome after decompression surgery.<sup>[58,59,62,64]</sup>

TTS symptoms may be misdiagnosed as part of the symptomatology of spinal disease and as sequelae after spinal surgery. TTS was found in 4.8% of patients with lumbosacral radiculopathy and tends to complicate lumbar spine disease. FBSS should be considered in the absence of clear evidence of TTS.<sup>[68,69]</sup> TTS must be ruled out or addressed when patients treated by spinal surgery continue to experience anterior sole numbness and/or pain.

When TTS fails to respond to observation therapy, we perform neurolysis under local anesthesia.<sup>[62,63]</sup> We make a 3-4-cm bow-like incision 1.5 cm below the medial malleolus over the point of the Tinel-like sign without using a tourniquet. In some cases, besides cutting the flexor retinaculum and opening the tarsal tunnel, sufficient decompression from the neurovascular band and transposition may be necessary. Although the outcome of surgery for idiopathic TTS tends to be good, some patients experience only partial or no improvement.<sup>[60,61,64,67]</sup> Significant pain alleviation after tarsal tunnel decompression surgery has been

reported by 44-90% of patients. An incorrect diagnosis, incomplete surgical decompression, adhesive neuritis, neural trauma or damage, systemic disease, double crush syndrome, and prolonged symptoms are factors that must be considered in patients with failed TTS surgery.<sup>[60,62,64,67]</sup>

## CONCLUSION

We described typical peripheral nerve and paralumbar spine diseases with symptoms similar to those of LDH. These diseases are common, and unless they are diagnosed and treated correctly, patients may progress to FBSS. In some instances, these diseases respond well to less invasive treatment methods, and some patients experience dramatic improvement. The surgical procedures described herein are less invasive and do not require sophisticated techniques.

It is important to recognize that the diseases we discussed may be associated with LDH. Therefore, a better understanding of specific diseases other than LDH and their treatment is necessary. Symptoms in patients with LDH may be attributable to such diseases, and they may accompany symptoms elicited by LDH. The careful analysis of factors that contribute to the patients' symptoms is important for making a correct diagnosis and may broaden the range of beneficial treatments and improve their quality of life.

## Authors' contributions

Concept and design: K. Kim, T. Isu

Manuscript preparation: K. Kim

Manuscript editing: K. Kim, T. Isu

Literature search: D. Morimoto, N. Iwamoto, R. Kokubo, J. Matsumoto, T. Kitamura

Manuscript review: A. Sugawara, A. Morita

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## Conflicts of interest

There are no conflicts of interest and no financial disclosures.

## Patient consent

Not applicable.

## Ethics approval

This review article is waived for ethical approval.

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# Endoscopic surgical skill qualification and educational system of the Japanese Orthopaedic Association

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## INTRODUCTION

In the field of spinal surgery, the application of minimally invasive endoscopic surgery owes much to advances in high performance optical instruments [charge-coupled device cameras and the latest small diameter (just 2 mm) endoscopes and electronic scopes] and the accompanying improvements in imaging technology and the development of innovations such as ultrasonic incision devices. As far as the manipulation for decompression of the spinal nerve root is concerned, reliability and safety both improved following development and advances in instruments such as robotics and enhanced endoscopic resolution, and further improvement is anticipated henceforth. In Japan, endoscopy began to be applied in 1995

to anterior approach spinal surgery and in 1997 to posterior approach surgery. After this form of surgery began to be covered by the national health insurance, endoscopic spinal surgery spread rapidly. However, as this form of surgery spread rapidly, complications arising from the procedures began to gradually be highlighted as a problem. The steps to establish an endoscopic surgical skill qualification (ESSQ) system were started in 2002 and this system was launched at the Japanese Orthopaedic Association (JOA) in 2004.<sup>[1]</sup> This system, called the “endoscopic spinal surgery skill qualification system”, is aimed at “evaluating the skills of individual surgeon involved in endoscopic spinal surgery in accordance with common criteria and accrediting surgeons satisfying certain high-level standards”, with the ultimate goal of facilitating



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the sound spread and progress of endoscopic spinal surgery in Japan.<sup>[2]</sup>

## COURSE AND METHODS OF QUALIFICATION AND RESULTS

Qualification procedures for skills are as follows. First, the applicant, satisfying the requirements for filing an application for skill qualification, submits the necessary documents and an unedited videotape. On the basis of the submitted materials, the skill of each application is assessed by multiple referees (referee committee on surgical skill qualification). Assessments are based on scoring of each checked item (full score: 100 per item).

During assessment of the videotape, if one referee raises an objection, another referee or all members of the referee committee conduct further evaluations. If two or more referees raise objections, the applicant is automatically judged to be “unacceptable” for qualification. The referee qualification must be updated every fifth year. Each referee applying for renewal of the referee qualification has several obligations, including submission of a certificate of clinical activity for 5 consecutive years.

The first application from surgeons for skill qualification under this system was received in December 2004. Through strict assessment of the documents, DVD and videotape submitted, on April 1, 2005, 6 surgeons were accredited as to the anterior approach skill and 18 surgeons as to the posterior approach.<sup>[2]</sup>

We sent a questionnaire to facilities registered with JOA in advance as spine surgery special hospital. During the period from 2005 to 2014, responses to the questionnaire were collected from 1,148 facilities per year on average. The mean response rate was 56.4% (45.2-63.9%).

The number of facilities providing endoscopic surgery averaged 262.9 (208-297), with the mean percentage being 24.8% (20.3-27.3%).

Under this qualification system, 167 surgeons were qualified in terms of endoscopic surgical skill between 2004 and 2015. The posterior approach skill (MED, PELD) qualification was obtained by 165 surgeons (MED: 141, PELD: 24) and the anterior approach skill qualification by 2 surgeons [Table 1].

The mean percentage of applicants who qualified successfully was 50.6% (39.1-80%) after video assessments. Following the recent increase in endoscopic surgery, the number of complications

arising from this form of surgery has tended to rise annually (from 66 cases in 2005 to 361 cases in 2014). However, the mean incidence of complications per year has remained essentially unchanged at 2.4% (1.57-2.81%) [Table 1].<sup>[3,4]</sup>

## PRINCIPLE AND SIGNIFICANCE OF ENDOSCOPIC SPINAL SURGERY SKILL QUALIFICATION SYSTEM

It loses trust of the whole endoscopic surgery that complications of the endoscopic surgery in the field of spine increase, serving as a major obstacle slowing and even blocking advances in endoscopic surgery at all related specialties. This is a serious problem for all surgeons involved in endoscopic surgery. Every time such complications arise, citizens, the mass media and governmental organs begin arguing about the necessity of establishing an educational system and a qualification assessment organization/system for endoscopic surgeons. The JOA rules on the skill qualification system were drafted taking this viewpoint into account. The rules are based on two principles: (1) the system is aimed at accrediting endoscopic spinal surgeons with sufficient skills through assessment in accordance with high-level standards; and (2) the system is aimed at evaluating the skill level of only surgeons engaged in endoscopic spinal surgery and is not based on the specialist surgeon system set forth by the specialist surgeon accreditation council. The significance of establishing this qualification system lies in: (1) the endoscopic spinal surgeon's skill qualification in accordance with high-level standards makes endoscopic spinal surgeons more acceptable to the public and raises their value; (2) an increase in the number of qualified surgeons and their activities will operate favorably as a mechanism to mitigate

**Table1: Changes over time from 2004 to 2015 in the number of applicants for skill qualification and the percentage of successfully qualified applicants**

Year	Board certified surgeon	Applicant	Success ratio (%)
2004	24	30	80
2005	8	14	53
2006	14	30	45
2007	17	31	55
2008	14	31	45
2009	13	32	41
2010	13	26	50
2011	15	30	50
2012	14	30	47
2013	20	35	57
2014	16	27	59
2015	15	32	47

risk, contributing to the sound spread and progress of endoscopic spinal surgery in Japan; and so on.<sup>[3]</sup>

## ACTIONS RELATED TO THE SKILL QUALIFICATION SYSTEM

### Guidelines on endoscopic spinal surgery

1. Before endoscopic spinal surgery, preparatory steps need to be taken in accordance with the rules prevailing at the facility concerned.

2. Thoracoscopic surgery should be performed under the supervision of a surgeon qualified by JOA to perform endoscopic spinal surgery, who has acquired sufficient skills in open chest surgery and can cope with any complications arising during or after surgery appropriately (hereinafter called “skill-qualified surgeon”).

3. Laparoscopic or posterior laparoscopic surgery should be performed under the supervision of a skill-qualified surgeon who has acquired sufficient skills in open abdominal surgery and the retroperitoneal approach and can cope with any complications arising during or after surgery appropriately.<sup>[5]</sup>

4. If thoracotomy or laparotomy is required during endoscopic surgery, the surgery should be immediately switched to open chest or open abdominal surgery. It must be ensured that cooperation from a thoracic surgeon or an abdominal surgeon is always available, in the event of being needed.<sup>[6]</sup>

5. Preoperative and postoperative patient management is conducted under a system in which the surgeon plays a central role.

6. Requirements before endoscopic spinal surgery.

- (1) Learning open chest/abdominal surgery procedure and perioperative management and how to deal with complications;
- (2) Understanding the anatomical structure and relative position of each organ during endoscopy;
- (3) Mastering the approaches with a thoracoscope, laparoscope and posterior/posterolateral spinal endoscope;
- (4) Mastering the sense of depth under two-dimensional video monitor images;
- (5) Mastering the sense of organ touch by remote control;
- (6) Mastering coordination between visual sense and finger motions under magnified images;
- (7) Mastering how to use special tools/devices;
- (8) Mastering the special skills required for endoscopic

surgery (ligating method, *etc.*).

Of those listed above, 2 through 8 should be studied and fully mastered by attending the endoscopic spinal surgery education/training courses provided or authorized by the JOA.

7. Requirement of surgeons performing anterior approach endoscopic spinal surgery: having experienced the anterior approach spinal surgery in at least 20 cases.

8. Requirement of surgeons performing posterior/posterolateral approach endoscopic spinal surgery: having experienced the posterior/posterolateral approach spinal surgery in at least 30 cases.

9. Informed consent, based on a decision made by the patient after sufficient explanation, must be obtained before endoscopic spinal surgery.

10. In the event of a near-miss or an actual accident during endoscopic spinal surgery, primary emphasis needs to be placed on securing of the patient's safety and appropriate actions must be taken promptly in accordance with all relevant hospital rules. At the same time, an endoscopic spinal surgery near-miss/accident report needs to be submitted to the “Endoscopic Spinal Surgery Skill Qualification Committee” (c/o JOA Secretariat).<sup>[6]</sup>

### Educational system and maintenance of qualified skills

Training methods can be roughly divided into training with the use of animals (pigs, sheep), participation in training courses, supervision by endoscopic surgeons, implementation of existing open chest/abdominal surgery under endoscopic guidance, and so on. Japanese Society for the Study of Endoscopic



**Figure 1:** Animal surgery allows the surgeon to practice important skills needed during actual surgery

and Minimally Invasive Spine Surgery (JESMISS) established in 1999 and changed the name with Japanese Society of Minimally Invasive Spine Surgery (JASMISS) in 2015. JESMISS has been making efforts to implement training with the use of pigs for coping with the qualification system. In the field of orthopedic surgery, 5 *in vitro* training sessions on spinal endoscopy were officially provided, beginning with the 14th Arthroscopy Seminar in July 1996, and an *in vivo* training session was provided during the First Endoscopic Spinal Surgery Seminar in September 1997. To date, 14 JASMISS training sessions and 13 JOA training sessions have been provided, involving a total of 1,020 participants [Figure 1].

## CONCLUSION

This system is designed to provide accreditation of sufficient skills to surgeons for the purpose of facilitating endoscopic spinal surgery progress in an appropriate direction. We believe that this system will ensure the provision of safe and reliable endoscopic spinal surgery.

## Authors' contributions

A. Dezawa contributed solely to this paper.

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None.

## Conflicts of interest

There are no conflicts of interest.

## Patient consent

Written informed consent was obtained from the patient.

## Ethics approval

This article is approved by the Ethical Committee of Teikyo University Mizonokuchi Hospital.

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# Minimal laminectomy using the interlaminar approach for percutaneous endoscopic lumbar discectomy

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## ABSTRACT

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### Key words:

Percutaneous endoscopic lumbar discectomy, lumbar disc herniation, interlaminar approach, minimal laminectomy, minimally invasive

**Aim:** To evaluate the application of laminectomy using the interlaminar approach (ILA) for percutaneous endoscopic lumbar discectomy (PELD). **Methods:** Minimal laminectomy using the ILA for PELD was performed in 13 patients with lumbar disc herniation (LDH). The width of the interlaminar space, shape of the caudal margin of the upper vertebral laminae (CM-UVL), LDH size, and caudal migration grade were radiologically evaluated. Ten LDHs were removed via the shoulder of the corresponding nerve root, and three via the axilla of the corresponding nerve root and dural sac. Bone status was evaluated preoperatively and postoperatively using two- and three-dimensional computed tomography. **Results:** All patients (mean age 46.3 years) underwent PELD at a single spinal level, mostly at L5/S1. Compared with a previous study without laminectomy, the mean operative duration (57.5 min) and operative outcome, evaluated using the modified Japanese Orthopaedic Association and Numerical Rating Scale scores, were similar; no complications were observed. However, the width of the interlaminar space was significantly narrower, and eight cases revealed a narrow interlaminar space (width < 20 mm and/or lost concave shape of CM-UVL). **Conclusion:** Minimal laminectomy using the ILA for PELD is feasible for treating LDH with the narrow space and highly migrated LDH.

## INTRODUCTION

Percutaneous endoscopic lumbar discectomy (PELD)

is one of the most sophisticated operative procedures for the treatment of lumbar disc herniation (LDH).<sup>[1-5]</sup> However, PELD has an anatomical limitation for



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endoscope insertion, and there are three different operative approaches: interlaminar, transforaminal, and posterolateral. Each approach has an adequate pathophysiological status.<sup>[1,6,7]</sup> The interlaminar approach (ILA) is preferred for axillary-type and migrated LDH.<sup>[1]</sup> It is performed under endoscopic visualization, and the visual field is similar to conventional open and/or microsurgical operative views. Therefore, the ILA is preferred by surgeons with experience in performing conventional procedures, rather than other PELD approaches.<sup>[1,8-11]</sup>

Conversely, we have previously experienced and reported on relatively severe complications of the ILA.<sup>[8]</sup> These complications included persistent numbness in the corresponding nerve area, transient muscular weakness, and transient bladder and rectal disturbance, which may be due to excessive compression of the nerve root and/or dural sac by the endoscopic sheath. As a result of these experiences, we have been more careful in performing the ILA and have not experienced such complications. To avoid complications, we proposed the proper use of 2 different operative routes of the ILA (via the shoulder and via the axilla). Furthermore, we suggested that the width of the interlaminar space should be at least 20 mm for the ILA without bone removal.<sup>[8]</sup>

We sometimes experience cases in which the width of the interlaminar space is < 20 mm even in LDH at L5/S1.<sup>[1]</sup> To overcome this limitation, we recently started to use a high-speed drill and/or a small Kerrison rongeur (width 3 mm) for certain ILA cases. We have already experienced 13 such cases and avoided complications. In this study, we retrospectively analyzed these cases, and summarized the features of minimal laminectomy with the ILA.

## METHODS

Thirteen consecutive patients with LDH underwent the ILA for PELD by using a 7-mm diameter spinal full-endoscopic system (Richard Wolf GmbH, Knittlingen, Germany) between March and December 2016. All patients had lateral radiculopathy resistant to medical treatment, epidural steroids, and/or nerve block. To clarify the surgical benefit of minimal laminectomy with the ILA for PELD, we did not exclude patients who previously underwent discectomy at the same vertebral level. However, we excluded patients with spinal canal stenosis who had been operated on using the percutaneous endoscopic translaminar approach.<sup>[12]</sup>

All patients underwent the ILA for PELD at only one vertebral level. Neurological examination, preoperative

computed tomography (CT), and magnetic resonance imaging (MRI) were used to identify the location and type of LDH according to our previous report.<sup>[8]</sup> The width of the interlaminar space and the LDH size were calculated on axial CT and MRI, respectively, as described previously [the width was determined by the widest distance between the bilateral facet joints at the corresponding disc level, and the LDH size was evaluated by the anteroposterior (AP) size ratio calculated from the protruded height against the AP diameter of the spinal canal].<sup>[8]</sup> The extent of migration was evaluated by using T2-weighted sagittal MRI according to previous reports.<sup>[13,14]</sup> High-grade migration was defined as migration exceeding the disc-space height. Conversely, low-grade migration was defined as a migration extent that was smaller than the disc-space height [Figure 1A and B].

The patients were followed postoperatively for an average of 6.2 months (2-11 months). Neurological status was evaluated preoperatively and postoperatively by using the modified Japanese Orthopaedic Association (mJOA) score.<sup>[15,16]</sup> The corresponding leg pain was also evaluated by using the Numerical Rating Scale (NRS) score.<sup>[17]</sup> We compared data for these parameters with our previous ILA data [laminectomy (-) group: 41 cases]. Statistical analysis was performed with student's *t*-test. *P* values < 0.05 were considered statistically significant. The exclusion of high-grade caudal migration is the differentiated background of the laminectomy (-) group.

In addition to these previous parameters, we also evaluated the shape of the upper vertebral laminae. Concave (-) was defined as when the caudal margin of the upper vertebral laminae (CM-UVL) was straight and the interlaminar space appeared as a sharp triangle. Concave (+) was defined as when the CM-UVL had a concave shape and the interlaminar space appeared to have a more rounded form [Figure 1C and D].

The basic operative procedure has already been described in our previous report.<sup>[9]</sup> In addition to the basic ILA procedure, the methods for manipulation of a high-speed drill and/or a small Kerrison rongeur are described below.

First, the endoscope sheath is placed on the surface of the yellow ligament and then tilted toward a direction by which the area requiring bone removal is at the center of the endoscopic visual field. The vertebral laminae are thinned by using a high-speed drill with a diameter of 3.5 mm (NSK-Nakanishi Japan, Tokyo, Japan). Subsequently, the residual thin layer is removed with a small Kerrison rongeur. Naturally thin bone areas, such as the inner border of the superior articular process

(SAP), are directly removed by using the Kerrison rongeur. In such cases, after detachment of the yellow ligament from the bone margin, the cutting edge of the Kerrison rongeur is sledged into the detached space (case 4, [Supplementary Video 1](#)). As exposure of a small part of the protruded vertebral disc is sufficient to remove it, we only perform minimum removal of bone and yellow ligament (final stage of [Supplementary Video 1](#): the white protruded disc surface at the shoulder area of the nerve root can be seen).

## RESULTS

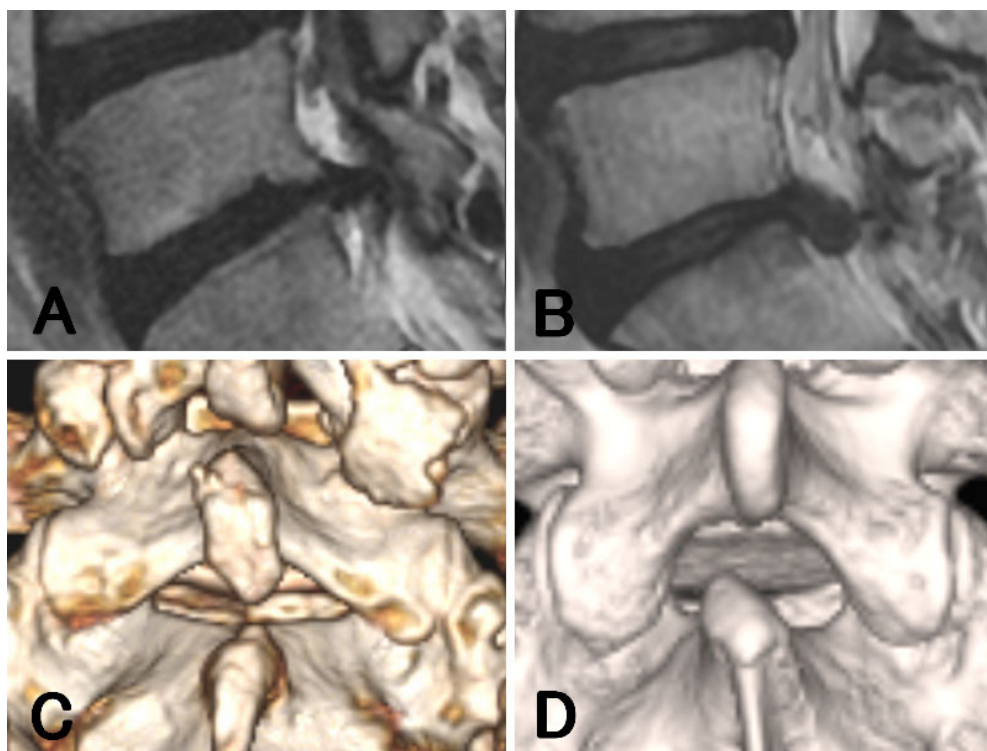
Thirteen patients were registered for this study; 10 underwent the ILA via the shoulder (cases 1-10) and three underwent the ILA via the axilla (cases 11-13). The mean patient age was 46.3 years (range 17-82 years), and the most affected vertebral level was L5/S1 (11 cases), followed by L4/5 (2 cases). The LDH location, AP size ratio, width of the interlaminar space, operation time, postoperative hospital stay, blood loss, and operative outcome (mJOA and NRS scores) for each case are shown in [Table 1](#). Compared with our previous ILA data[laminectomy (-) group], the width of the interlaminar space in the cases that received laminectomy was significantly narrower (25.95 mm vs. 22.46 mm,  $P = 0.003$ ). However, there was no

significant difference between the 2 groups in the AP size ratio, operation time, postoperative hospital stay, blood loss, follow-up period, and operative outcome. We observed no intraoperative complications in this study [[Table 1](#)].

Two recurrent cases (cases 1 and 5) received minimal laminectomy for exposure of the fresh margin of the vertebral laminae and yellow ligament. One case (case 2) received minimal laminectomy to perform ILA under an inappropriate endoscope insertion due to a high level of obesity (body mass index 39.4). Generally, the endoscope is introduced from the caudal to the cephalic direction toward the interlaminar space; however, we could not maintain this slope because of the thickness of soft tissue in this case. We had to remove the CM-UVL, which is one workaround for inappropriate endoscope insertion.

Furthermore, we radiologically analyzed each case that received laminectomy, including the shape of the upper vertebral laminae, extent of migration, and area of laminectomy [[Table 2](#)].

Four of 10 cases (cases 4, 6, 9, and 12) showed an interlaminar space with a width of < 20 mm, and a small extent of SAP removal was mainly required. The



**Figure 1:** Preoperative radiographic findings on the migration and shape of the upper vertebral laminae. The extent of migration was evaluated by using T2-weighted sagittal magnetic resonance imaging. (A) Low-grade migration: defined as a migration extent smaller than the height of the disc space (case 2); (B) high-grade migration: defined as a migration extent exceeding the height of the disc space (case 11); (C) concave (-): caudal margin of the upper vertebral laminae (CM-UVL) is straight, as evaluated by using three-dimensional computed tomography (case 8); (D) concave (+): CM-UVL has a measurable concave and the superior articular process is easy to access (case 9)

preoperative and postoperative radiological changes in case 6, in which we only removed the SAP 4 mm toward the lateral direction, are shown in Figure 2. Six of 10 cases (cases 3, 4, 7, 8, 10, and 12) lost the concave shape of the upper vertebral laminae. Among these, two cases (cases 4 and 12) also showed an interlaminar space with a width of < 20 mm. The preoperative and postoperative radiological changes

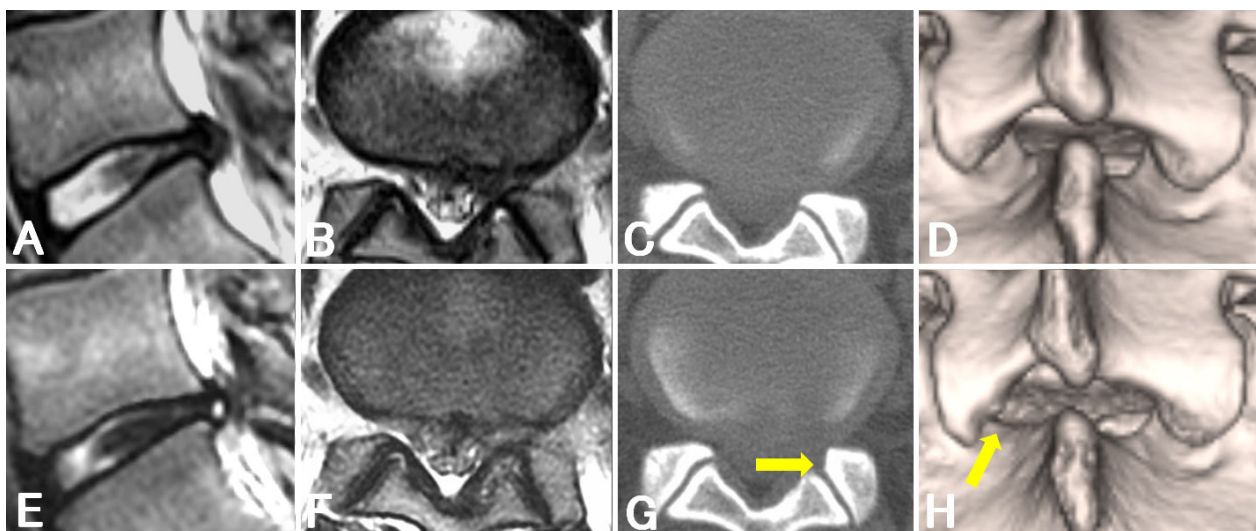
in case 12, in which we removed the SAP and cephalic margin of the lower vertebral laminae and completely removed the highly migrated nucleus, are shown in Figure 3. Taken together, a total of eight of 10 cases required minimal laminectomy for a narrow interlaminar space evaluated by using the width and shape.

The remaining two cases underwent ILA via the axilla.

**Table 1: Comparative surgical outcome of 41 cases without laminectomy<sup>[8]</sup> and 13 cases with laminectomy**

Laminectomy*	(-)‡	(+)	P value
Total cases	41	13	
Age (years)	41.5	46.3	0.260
Gender			
Male	25	11	
Female	16	2	
Level			
L4/5	7	2	
L5/6†	1	0	
L5/S1	23	11	
R/L			
Right	19	5	
Left	22	8	
Type of MRI			
Shoulder	8	1	
Ventral	19	10	
Axilla	10	2	
Central	4	0	
AP size ratio (MRI)	0.44	0.44	0.962
Width of interlaminar space	25.95	22.46	0.003
Operation time (min)	50.7	57.5	0.211
Postoperative hospital stay (days)	2.1	2	0.803
Blood loss	Negligible	Negligible	
Follow-up period (months)	9.2	6.2	0.064
mJOA score			
Preoperative	10.6	12.7	0.211
Postoperative	18.6	18	0.610
NRS score			
Preoperative	5.83	5.46	0.632
Postoperative	1	1.77	0.098
Complication	3	0	

MRI: magnetic resonance imaging; AP: anteroposterior; mJOA: modified Japanese Orthopaedic Association scale; NRS: numerical rating scale; (-) previous data; (+) current data. \*(+) Indicates lumbar disc herniation (LDH) case received minimal laminectomy and (-) indicates LDH cases did not receive minimal laminectomy; †lumbarization of the first sacral segment was designated as L6; ‡this data is cited from<sup>[8]</sup>



**Figure 2: Magnetic resonance imaging and computed tomography findings of a patient with subligamentous lumbar disc herniation (case 6).** Preoperative (A, B) and postoperative (E, F) sagittal (A, E) and axial (B, F) T2-weighted magnetic resonance images. Preoperative (C, D) and postoperative (G, H) axial (C, G) and three-dimensional (D, H) computer tomographic images: arrows indicate the margin of minimal laminectomy

Table 2: Summary of the detailed features of the 13 cases with laminectomy

Case No.	Age (years)	Gender	BMI	Location		Recurrence*	Type of MRI	AP size ratio (MRI)	Width of interlaminar space (mm)	Concave of upper vertebral laminae†	Grade of caudal migration‡	Mainly used instrument	Area of bone removal	Removed width of SAP (mm)
				Level	R/L									
1	43	F	23.1	L5/S1	L	(+)	Ventral	0.47	20	(-)	Low	Drill	CM-UVL	
2	40	M	<b>39.4</b>	L5/S1	L	(-)	Ventral	0.41	27	(+)	Low	Kerrison	CM-UVL	
3	82	M	23.5	L4/5	L	(-)	Ventral	0.5	27	(-)	(-)	Drill	CM-UVL	
4	37	M	21.2	L5/S1	L	(-)	Ventral	0.48	<b>19</b>	(-)	Low	Kerrison	SAP, CM-LVL	3
5	34	M	24.4	L5/S1	R	(+)	Ventral	0.53	23	(-)	Low	Kerrison	CM-UVL	
6	17	M	25.7	L5/S1	L	(-)	Ventral	0.43	<b>17</b>	(+)	(-)	Drill	SAP, IAP	4
7	41	M	20.3	L5/S1	L	(-)	Shoulder	0.47	20	(-)	Low	Kerrison	SAP	4
8	53	M	27.3	L5/S1	R	(-)	Ventral	0.4	26	(-)	(-)	Drill	SAP, IAP	3
9	31	M	16.9	L5/S1	R	(-)	Ventral	0.41	<b>19</b>	(+)	(-)	Drill	SAP, IAP	3
10	50	F	20.9	L5/S1	R	(-)	Ventral	0.19	23	(-)	(-)	Kerrison	SAP	1
11	74	M	26.3	L5/S1	L	(-)	Axilla	0.53	27	(+)	<b>High</b>	Kerrison	CM-LVL	
12	57	M	27.3	L4/5	L	(-)	Axilla	0.6	<b>19</b>	(-)	<b>High</b>	Drill	SAP, CM-LVL	2
13	43	M	27.5	L5/S1	R	(-)	Ventral	0.29	25	(+)	Low	Kerrison	SAP, CM-LVL	3

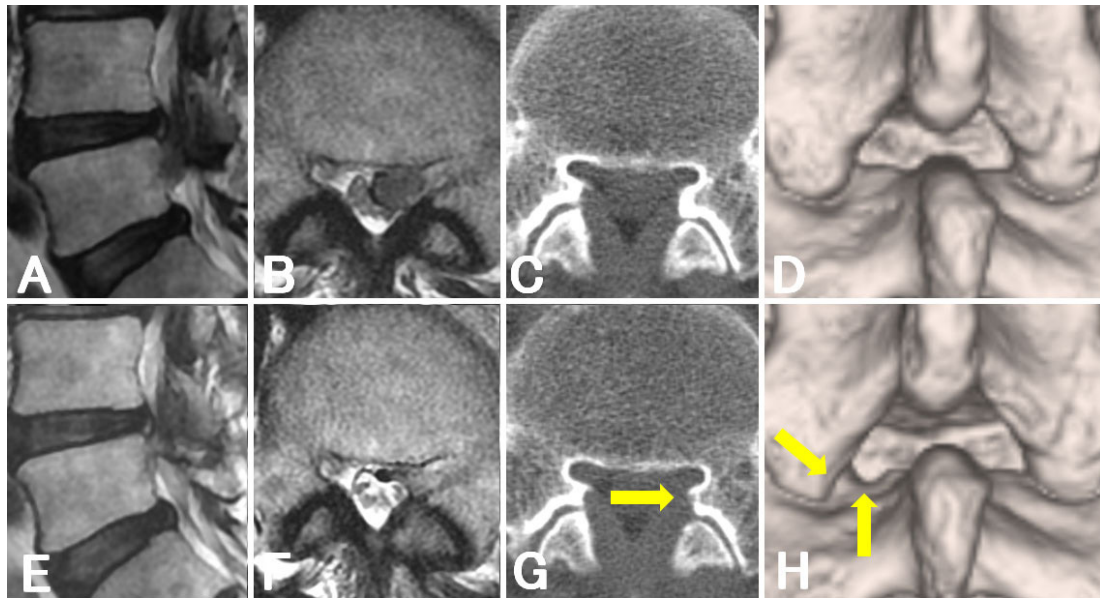
The boldfaced type in columns indicates the main reason for minimal laminectomy. \* (+) Indicates recurrent lumbar disc herniation (LDH) case and (-) indicates fresh LDH cases; † (+) indicates LDH case with concave of upper vertebral laminae and (-) indicates LDH case without the concave; ‡ (-) indicates LDH case revealed no caudal migration. BMI: body mass index; MRI: magnetic resonance imaging; AP: anteroposterior; SAP: superior articular process; IAP: inferior articular process; CM-UVL: caudal margin of the upper vertebral laminae; CM-LVL: cephalic margin of the lower vertebral laminae

Case 11 showed high-grade migration of LDH [Figure 1B], and we only performed laminectomy of the cephalic margin of the lower vertebral laminae. Although case 13 had a small (AP size ratio = 0.29) and low-grade migration of LDH [Figure 4A] (a migration extent that was smaller than the height of the disc space), we noticed an immobile nerve root during the operation. We therefore enlarged the surrounding area of the nerve root toward the lateral and caudal directions and evacuated the LDH via the axilla without traction of the nerve root [Figure 4].

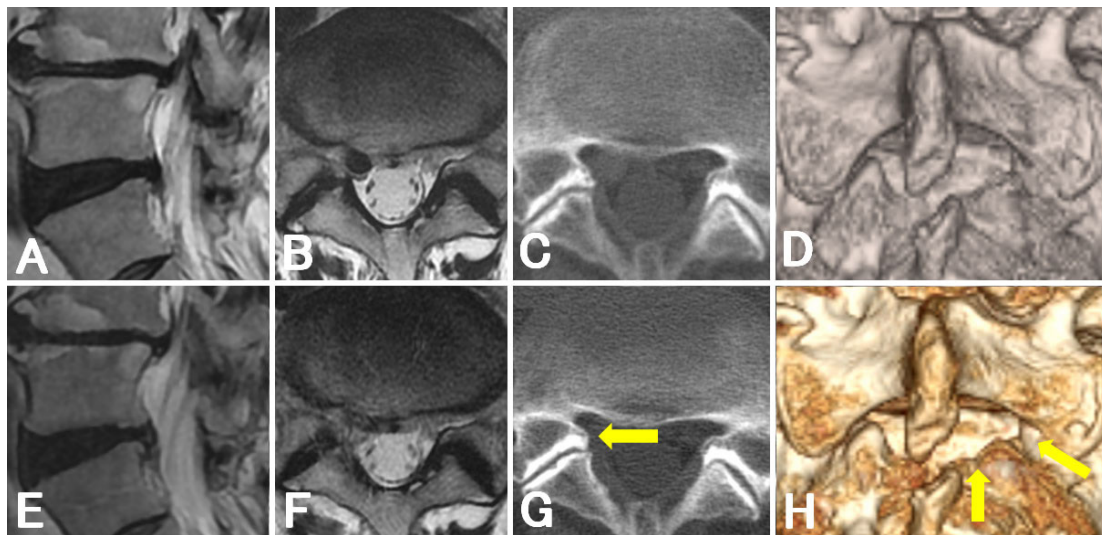
## DISCUSSION

The significance of PELD lies not only in the small skin incision but also in its minimal damage to surrounding structures such as muscle, bone, and ligaments.<sup>[18,19]</sup> Previously, we reported the appropriate operative indication of the ILA without bone removal (equal to laminectomy). In our previous report, we proposed that an ILA without laminectomy can be used to treat LDH cases with an interlaminar space of  $\geq 20$  mm.<sup>[6]</sup> Furthermore, we also proposed that an operative route via the axilla should be considered for large LDHs (AP size ratio  $> 0.5$ ).<sup>[6]</sup> However, laminectomy is necessary in some cases such as those with a small interlaminar space to prevent complications. We therefore analyzed cases in which partial laminectomy was applied, and obtained useful information for selecting laminectomy with the ILA.

We retrospectively analyzed the type of LDH and extent of laminectomy [Table 2]. There were several indications for the requirement of bone removal. The major indication was a narrow interlaminar space; that is, with a width of  $< 20$  mm and/or disappearance of the concave shape of the upper



**Figure 3:** Magnetic resonance imaging and computed tomography findings of a patient with high-grade migration of lumbar disc herniation (case 12). Preoperative (A, B) and postoperative (E, F) sagittal (A, E) and axial (B, F) T2-weighted magnetic resonance images. Preoperative (C, D) and postoperative (G, H) axial (C, G) and three-dimensional (D, H) computer tomographic images: arrows indicate the margin of minimal laminectomy



**Figure 4:** Magnetic resonance imaging and computed tomography findings of a patient with an immobile nerve root (case 13). Preoperative (A, B) and postoperative (E, F) sagittal (A, E) and axial (B, F) T2-weighted magnetic resonance images. Preoperative (C, D) and postoperative (G, H) axial (C, G) and three-dimensional (D, H) computer tomographic images: arrows indicate the margin of minimal laminectomy

vertebral laminae. In these cases, the inner border of the SAP was a main target for laminectomy. In concave (-) cases, removal of the straight CM-UVL was occasionally required. In cases with high-grade migration, the lateral part of the cephalic margin of the lower vertebral laminae was the main target. In addition to the narrow interlaminar space and high-grade migration of LDH, minimal laminectomy was also useful in cases showing recurrent LDH, obesity, or an immobile nerve root.

A high-speed drill is necessary for the laminectomy of

the CM-UVL, because the bone here is thick. However, it is not always necessary to remove the bone of the inner border of the SAP and the cephalic margin of the lower vertebral laminae by using a high-speed drill, because the bone here is thin. In such cases, a small Kerrison rongeur is a powerful tool for laminectomy. Furthermore, PELD allows for removal of the inner margin of the SAP without removing the inferior articular process [Supplementary Video 1]. Around 3 mm (1-4 mm, average 2.9 mm) of laminectomy of the SAP toward the outside was enough to expose the protruded LDH and the lateral margin of the nerve root. Compared with

conventional surgeries such as open, microscopic, and microendoscopic discectomy, the extent of bone removal in the ILA is extremely small. Removal of the yellow ligament to this small extent is also sufficient in the ILA for PELD.

In conclusion, the preliminary results of a small number of cases show that minimal laminectomy with the ILA for PELD is feasible for the treatment of LDH with a narrow interlaminar space and high-grade migration. Furthermore, minimal laminectomy is also useful for cases showing recurrent LDH, obesity, or an immobile nerve root.

### Authors' contributions

Conception and design: H. Koga

Provision of study materials or patients: H. Koga, H. Inanami

Collection and assembly of data: H. Koga

Data analysis and interpretation: H. Koga

Manuscript writing: H. Koga

Final approval of manuscript: H. Koga, H. Inanami

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### Conflicts of interest

The authors have no conflicts of interest to declare.

### Patient consent

Informed consent was obtained from the patients for publication of this study and any accompanying images.

### Ethics approval

This study was approved by the ethics committee of the Iwai Medical Foundation.

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# Outcomes of full-endoscopic posterior cervical foraminotomy for cervical radiculopathy caused by bony stenosis of the intervertebral foramen

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bony stenosis of the intervertebral  
foramen

## ABSTRACT

**Aim:** Full-endoscopic posterior cervical foraminotomy (FPCF) has been utilized to treat cervical lateral disc herniation and provided good surgical outcomes. The authors examined the superiority of FPCF in patients with spondylotic foraminal stenosis. **Methods:** Fifty-nine cases of FPCF were evaluated. Of the 59 patients, 34 had lateral disc herniation (group H) and 25 had spondylotic foraminal stenosis (group S). Operative time, complications, length of hospital stay, visual analog pain scale scores of neck and arm pain, and the amount of facet joint resection were compared between the groups. **Results:** The mean operative times were 96 min (group H) and 100 min (group S). The lengths of hospital stay were 3.0 days and 3.9 days, respectively. No significant differences were observed in pre-operative neck and arm pain between the groups. Average neck pain at the final follow-up was significantly less severe in group H (2.9) than in group S (12). However, postoperative arm pain was the same after surgery in both groups (14). In both groups, 52% of the facet joint was resected. **Conclusion:** The surgical outcome of FPCF in patients with spondylotic foraminal stenosis is equivalent to that in patients with lateral disc herniation.



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## INTRODUCTION

The upper extremity pain experienced by patients with cervical radiculopathy is commonly caused by either lateral cervical disc herniation or stenosis of the intervertebral foramen due to a bone spur resulting from spondylosis. Surgical treatment of cervical radiculopathy can be divided into two procedures: anterior cervical decompression and fusion<sup>[1-4]</sup> or posterior foraminotomy.<sup>[5-9]</sup> The latter option involves three types of procedures: open,<sup>[5-9]</sup> microscopic<sup>[10,11]</sup> and micro-endoscopic surgery.<sup>[12-16]</sup>

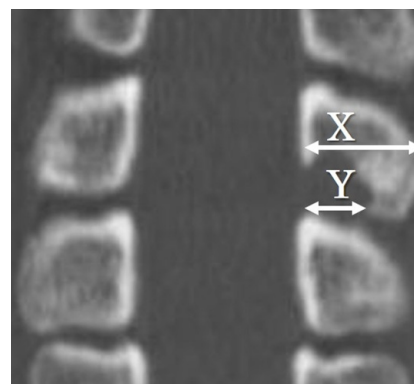
The use of full-endoscopic posterior cervical foraminotomy (FPCF) to treat lateral disc herniation was first reported by Ruetten *et al.*<sup>[17,18]</sup> in 2007. They concluded that FPCF is a sufficient and safe supplement and alternative to conventional procedures. Since then, Kim *et al.*<sup>[19,20]</sup> also suggested FPCF is an alternative to open surgery. However, there has been no comparison of FPCF outcomes in patients with cervical lateral disc herniation versus those with bony stenosis of the intervertebral foramen. Therefore, the aim of this study was to compare clinical outcomes of FPCF in these two groups of patients.

## METHODS

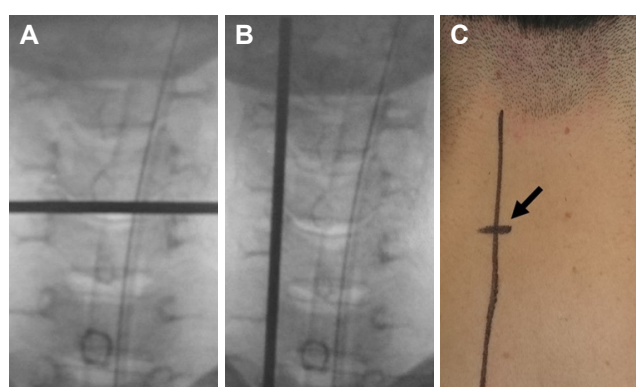
We retrospectively assessed 59 consecutive patients [45 men, 14 women; mean age 53.7 (30-81) years] who underwent FPCF for cervical radiculopathy between October 2014 and July 2016. All patients had either a single-level symptomatic lateral disc herniation or bony stenosis of the intervertebral foramen, none of which were recurrent. Conservative therapy was pursued for at least 3 months before surgery. The indication for surgery was persistent radicular pain or neurological deficits. Among the 59 patients, the affected level was C4/5 ( $n = 16$ ), C5/6 ( $n = 25$ ), C6/7 ( $n = 16$ ), and C7/T1 ( $n = 2$ ). Thirty-four patients had lateral disc herniation (group H), and 25 had bony stenosis of the intervertebral foramen (group S). All diagnoses were confirmed on preoperative computed tomography (CT) scans and magnetic resonance imaging (MRI).

The variables assessed and compared between groups H and S included operative time, complications, length of hospital stay, visual analog pain scale (VAS) scores of pre- and postoperative neck and arm pain, and the amount of facet joint resection. The percentage of facet joint resection was measured on the coronal plane of postoperative CT images that revealed the widest bone removal [Figure 1].

Clinical and radiographic parameters were statistically analyzed with Mann-Whitney  $U$  and chi-square tests.



**Figure 1:** Percentage of resection of the facet joint was calculated by  $Y/X \times 100\%$  which was measured on the coronal plane on postoperative computer tomography scans



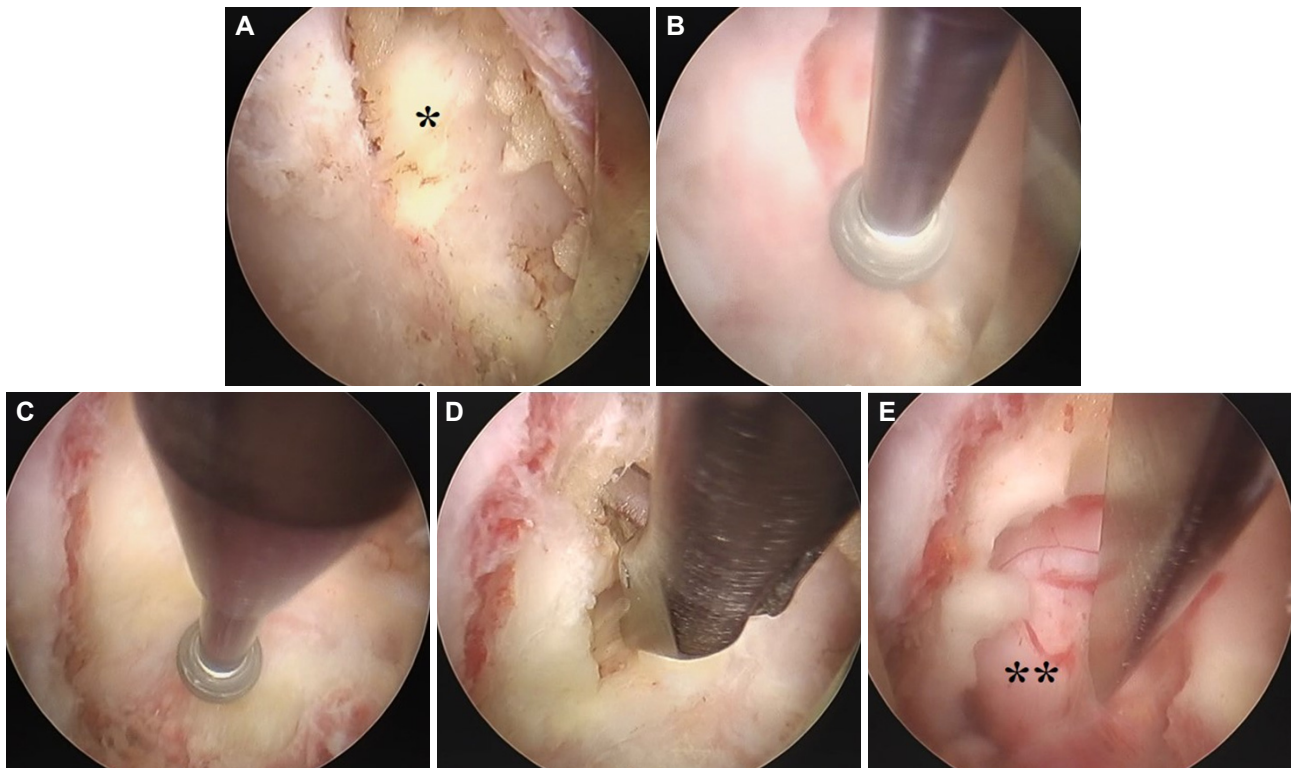
**Figure 2:** Intraoperative images determining the location of the skin incision. Location of the intervertebral disc at the C5/6 level (A) and the medial edge of the facet joint (B) were marked as lines under intraoperative fluoroscopy. A small skin incision (C) approximately 8 mm in length is made at the intersection (arrow)

Statistical significance was defined as  $P < 0.05$  (two-sided).

## FPCF surgical technique

FPCF was performed according to the method of Ruetten *et al.*<sup>[17]</sup> The patient was placed in the prone position under general anesthesia. In patients with pathology on the left side of C5/6, a skin incision was made under fluoroscopy at the intersection of a line at the C5/6 disc level [Figure 2A] and a line at the medial edge of the facet joint on the left side [Figure 2B]. A skin incision approximately 8 mm in length was made at that point [Figure 2C], and a full endoscope was inserted. The outer diameter of the entire endoscope was 6.9 mm; the working channel was 4.2 mm in diameter. The angle of vision was 25°, and the outer diameter of the working sleeve (beveled type) was 7.9 mm. All instruments were made by WOLF (RIWOspine GmbH, Knittlingen, Germany).

After removal of the connective tissue attached to the vertebral lamina, the vertebral laminae at C5 and C6 were clearly exposed, and the interlaminar window



**Figure 3:** (A) Interlaminar window and yellow ligament (\*) are clearly seen; (B) inferior edge of C5 vertebral lamina is partially cut with a high-speed drill; (C) superior edge of C6 vertebral lamina is also resected; (D) the yellow ligament is cut with scissors; (E) lateral edge of dura mater and C6 nerve root (\*\*) should be completely decompressed. Left side: cephalic; right side: caudal; upper side: medial; lower side: lateral

and yellow ligament were visible [Figure 3A]. First, the inferior edge of the C5 vertebral lamina was cut with a high-speed drill (NSK-Nakanishi, Kanuma, Japan) [Figure 3B], and the superior edge of the C6 vertebral lamina was cut [Figure 3C]. The yellow ligament was cut and removed [Figure 3D], and the perineural membrane was carefully removed using a bipolar coagulator (Surgi-Max®Plus, Trigger-flex® System: Elliquence, LCC, Baldwin, New York, USA) with output power set to 20-25 watts. Next, the lateral edges of the dura mater and C6 nerve root were decompressed [Figure 3E]. After complete decompression of the nerve root, irrigation was interrupted to reveal any bleeding. If observed, hemostasis was performed with a bipolar coagulator. The wound was closed without drainage. Ideally, all operations were performed while monitoring the motor evoked potentials of the following muscles: deltoid, brachioradialis, opponens pollicis, tibialis anterior, and gastrocnemius. Patients began walking 3 h after surgery.

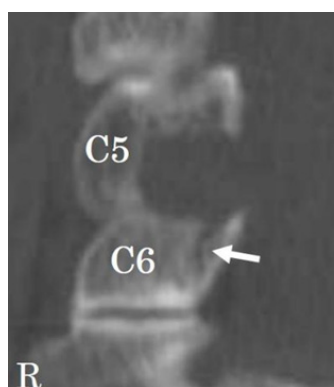
## RESULTS

Gender, age, segment, and postoperative follow-up period are shown in Table 1. No significant differences were observed between the groups in terms of gender, segment, or postoperative follow-up period. However, the mean patient age in group H was significantly

younger than that in group S ( $P < 0.05$ ). The average operative time in group H was  $97.2 \pm 19.5$  min, while that in group S was  $102 \pm 28.9$  min. Only 2 complications occurred, both in group H. One patient had increased radicular pain after surgery because the nerve root was stimulated during epidural hemostasis. The second had a lower lamina fracture due to cutting with the high-speed drill. In this case, a small fracture line on the C6 vertebral lamina was found in the coronal postoperative CT [Figure 4]. Fortunately, the patient had no symptoms. The postoperative hospital stays in group H and Y were 3.0 and 3.9 days, respectively. There were no significant differences in pre-operative neck or arm pain between the groups (neck pain: group H  $51 \pm 24.1$ , group S  $40.1 \pm 33.3$ ; arm pain: group H  $60 \pm 19.3$ , group S  $58.3 \pm 27.1$ ). On average, the neck

**Table 1: Basic data of groups H and S**

	Group H (n = 34)	Group S (n = 25)	P
Gender (M/F)	24/10	21/4	0.15
Age (years)	50 (30-68)	59 (46-81)	0.01
Operated spinal level	C4/5 (n = 6) C5/6 (n = 11) C6/7 (n = 15) C7/T1 (n = 2)	C4/5 (n = 4) C5/6 (n = 14) C6/7 (n = 7)	0.50
Follow-up period (days)	311	339	0.55



**Figure 4:** Postoperative computer tomography shows that vertical fracture line is on the medial side on C6 vertebral lamina (arrow). R: right side

pain VAS score at the final follow-up in group H ( $2.9 \pm 1.4$ ) was significantly lower than that in group S ( $12 \pm 16.4$ ) ( $P < 0.05$ ). However, the postoperative arm pain VAS scores were the same in both groups (group H  $14 \pm 21$ , group S  $14 \pm 18.6$ ). In both groups, 52% of the facet joint (group H  $52 \pm 8.5\%$ , group S  $52 \pm 6.7\%$ ) was resected.

### Case presentation

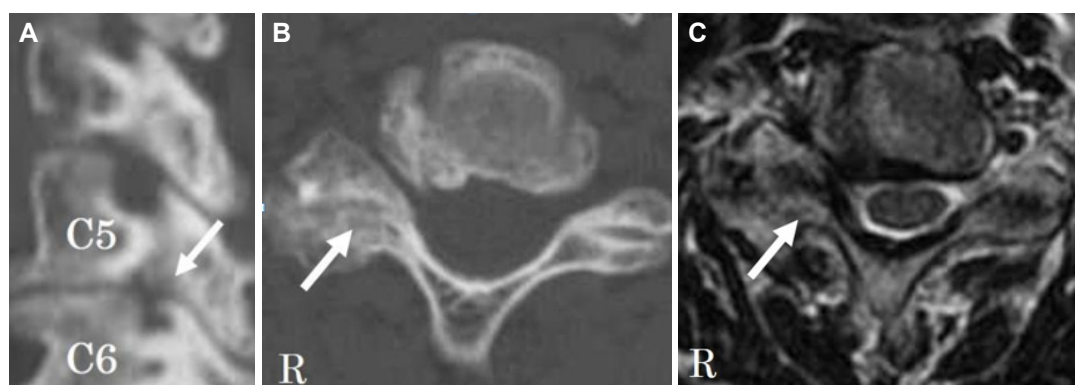
An 84-year-old female presented with very severe arm and neck pain on the right side. Conservative therapy was pursued for 3 months with no improvement in symptoms. Severe bony stenosis of the intervertebral foramen with spondylosis at C5/6 was observed on the sagittal and axial views of CT images [Figure 5A and B] and on the axial view on MRI [Figure 5C], and FPCF was performed. The operation time was 113 min. The C6 nerve root and lateral margin of the dura mater on the right were completely decompressed [Figure 6]. Postoperative CT showed that the intervertebral foramen was successfully decompressed [Figure 7] and that 42% of the facet joint had been resected. The patient's VAS scores for neck and pain improved from 45.2 to 10.1 and from 63.4 to 5.2, respectively.

## DISCUSSION

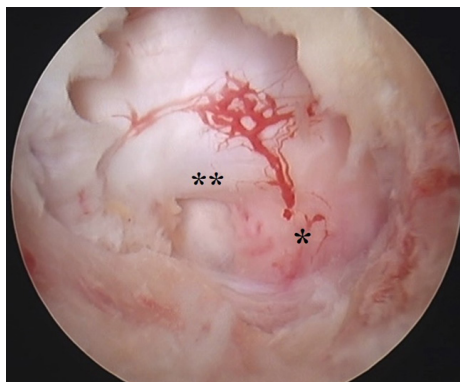
Full-endoscopic spinal surgery, which is called percutaneous endoscopic spinal surgery, was first reported by Mayer and Brock<sup>[21]</sup> for the treatment of lumbar disc herniation. Since then, surgeons have developed a percutaneous endoscopic lumbar discectomy through a transforaminal approach.<sup>[22-24]</sup> In 2010, Choi *et al.*<sup>[25]</sup> devised a new technique that approached the disc herniation through an interlaminar window. Dezawa and Saiyo<sup>[26]</sup> further evolved the procedure using a high-speed drill. Advances in the interlaminar approach procedure have facilitated the application of full-endoscopic spinal surgery to cervical spine disease.

There are two approaches for full-endoscopic surgery in the cervical spine: anterior<sup>[27,28]</sup> and posterior.<sup>[17-20]</sup> Anterior percutaneous endoscopic cervical discectomy requires more careful techniques compared with FPCF.<sup>[28]</sup> Therefore, endoscopic spinal surgeons who have performed percutaneous endoscopic lumbar discectomy find FPCF a relatively easy technique to learn. However, it has been reported that the indication for FPCF is limited to treatment of lateral disc herniation.<sup>[17-20]</sup> To our knowledge, this is the first description of outcomes of FPCF for bony stenosis of the intervertebral foramen.

In this study, two complications were observed in group H, both of which occurred soon after we began to perform FPCF for lateral disc herniation at our institution. There were no significant differences in the clinical parameters of operation time, length of postoperative hospital stay, arm pain VAS at the final follow-up, or percent of facet joint resection between the groups. These results suggest that FPCF is suitable for patients with bony stenosis of the intervertebral foramen. When FPCF is performed in these patients, it is very important to be careful when drilling the lamina



**Figure 5:** (A) Sagittal computer tomography (CT) reveals that the intervertebral foramen is markedly narrowed on the right side at C5/6 (arrow); (b) foraminal stenosis and deformity of the facet joint on the right side are also observed in axial CT image (arrow); (C) axial magnetic resonance imaging image also reveals that the foraminal stenosis on the right side is severe compared to that on the left (arrow). R: right side



**Figure 6:** On the final endoscopic view in this surgery, the C6 nerve root (\*) and lateral margin of the dura mater (\*\*) can be clearly observed. Left side: caudal; right side: cephalic; upper side: medial; lower side: lateral

because the surface of vertebral lamina is not smooth due to osteoarthrosis of the facet joint.

An average of 52% of the facet joint was resected in both groups. Although the percentage of facet joint resection affects postoperative outcomes, removing the perineural membrane of the nerve root in patients with bony stenosis of the intervertebral foramen is also key for obtaining good results because it increases nerve root mobility. The most important factor when removing the perineural membrane is to remove it piece by piece while using a bipolar coagulator.

In conclusion, we recommend that FPCF be considered for patients with radicular pain resulting from bony stenosis of the intervertebral foramen.

### Authors' contributions

Conception and design: K. Ohmori

Provision and study materials or patients: K. Ohmori, K. Ono

Collection and assembly of data: K. Ohmori, K. Ono

Data analysis and interpretation: T. Hori

Manuscript writing: K. Ohmori

Final approval of manuscript: K. Ohmori, K. Ono, T. Hori

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None.

### Conflicts of interest

There are no conflicts of interest.

### Patient consent

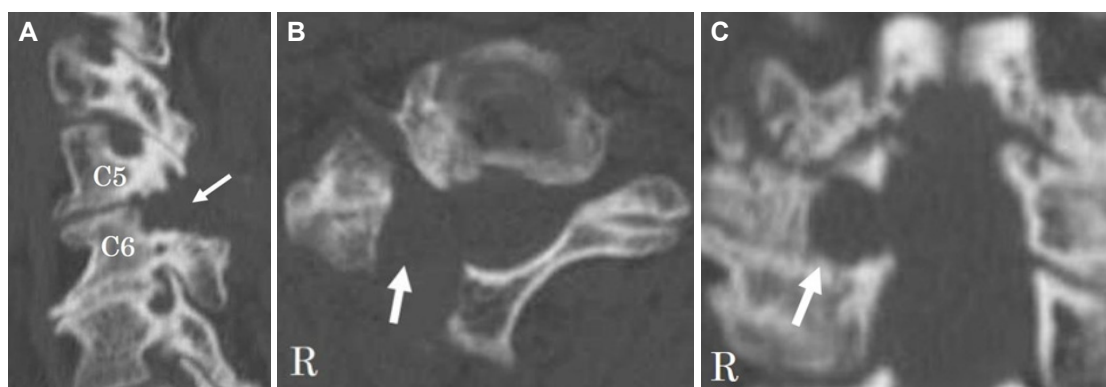
We obtained the patients' consent for publication of the present literature.

### Ethics approval

All procedures used in the present literature approved by the Ethical Committee of Nippon Koukan Hospital.

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**Figure 7:** (A) The osteophyte, which is seen in the sagittal plane on preoperative computer tomography [Figure 5A], is completely resected (arrow); (B) the intervertebral foramen has expanded satisfactorily (arrow); (C) the percent of facet joint resection is 42% (arrow). R: right side

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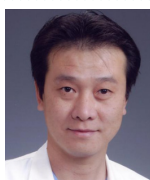
# Percutaneous endoscopic cervical laminectomy

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## ABSTRACT

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### Key words:

Percutaneous endoscopic cervical laminectomy,  
cervical spinal canal stenosis,  
myelopathy,  
minimally invasive

**Aim:** This study aimed to document the use of percutaneous endoscopic cervical laminectomy (PECL) and the treatment results. **Methods:** Eleven patients with a limited cervical spinal canal stenosis were indicated for the surgery. Under general anesthesia, the interlaminar space between the affected vertebrae was approached from 5 mm outside the midline. Laminectomy was performed using a 2.5-mm or 3.5-mm high speed drill, and an endoscope. Subsequently, the bilateral yellow ligament was removed and sufficient decompression of the dural sac was confirmed. Surgery was completed after the placement of an indwelling drain. Pre- and postoperative statuses were evaluated using the modified Japanese Orthopedic Association (mJOA) score. **Results:** The mean operation time was 87.1 min, and no complications were observed. During the mean follow-up period of 16.6 months, the mJOA score improved significantly from  $10.9 \pm 0.7$  to  $14.3 \pm 1.3$  ( $P = 0.0000002$ ). **Conclusion:** PECL is a minimally invasive surgical technique for cervical posterior decompression. This is a useful procedure, although it is technically demanding, and must be carefully performed under strict indication by a surgeon with sufficient experience of endoscopic techniques.

## INTRODUCTION

Cervical posterior decompression is an accepted surgical method to treat cervical spinal canal stenosis, although the technique has various problems.<sup>[1]</sup> For example, postoperative axial neck pain is reported in 30% of patients at a mean follow-up of 51 months.<sup>[2]</sup> The

current study aimed to investigate minimally invasive cervical spine surgery and the use of endoscopy for this spinal surgery.

Recently, because of advances in endoscope resolution and digital processing capabilities, percutaneous endoscopes that are used at the lumbar



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level can also be used safely at the level of the cervical spine.<sup>[3]</sup> Therefore, the use of such endoscopes has been expanded to the level of the cervical cord, and surgeons have begun to carry out this procedure in Japan. This procedure is expected to be adopted more widely in the future. Surgeon at the current institution has performed percutaneous endoscopic cervical laminectomy (PECL) and has obtained good results. Here, this surgical technique and treatment outcomes are reported.

## METHODS

### Operative indication

Indication for the surgery included one vertebral disc level of cervical spinal canal stenosis, with the factor for stenosis being the thickening of the yellow ligament from the posterior, or stenosis because of protrusion of a cervical disc. This procedure has not been applied to complicated and/or widely extended canal stenosis and re-operative cases.

### Preparation

An angled endoscope (15 and 25 degrees: Karl Storz GmbH, Tuttlingen, Germany) was used, which was also used to treat lumbar diseases in this department. A square endoscopic sheath and a high-speed drill (the burr head diameter is 2.5 mm or 3.5 mm, NSK-Nakanishi Japan, Tokyo, Japan) were also used. For excision of the yellow ligament, a punch (cutter), forceps, and curette, or a small bipolar radio-frequency electrode system (Elliquance, Baldwin, NY, USA) was used.

General anesthesia is recommended because the surgery time and drill usage time are long and a strict rest is necessary for safe surgery. Combined use of free run motor evoked potential for transcranial irritation is also recommended.<sup>[4]</sup>

Perfusion pressure is important because the surgery is performed near the cranial epidural space. The optimal perfusion pressure is 100 cmH<sub>2</sub>O and the height of free drip is kept at 150 cm during the surgery.

### Operative procedure

The surgical position is similar to that of a cervical laminoplasty. After fixation of the head using a Mayfield clamp, the posture is the Concorde style. The cervical spine is fixed in the neutral position. The approach is outside-in from the back, similar to the percutaneous endoscopic lumbar discectomy interlaminar approach.<sup>[5]</sup> The approach side is the side where myelopathy is dominant, but if there is no difference between the left and right, it is recommended to approach from the left

side, because a right-handed surgeon stands on the patient's left side for surgery.

In the interlaminar space between the affected vertebrae, a skin incision of 6 to 8 mm is made 5 mm outside the midline, with an incision of 6 to 8 mm made on the fascia. While gently rotating and vertically piercing the dilator to this incision, either the upper or lower margin of the arcus vertebrae is checked by sensing contact with the bone using the tip of the dilator. At this position, the operating sheath is replaced using a dilator.<sup>[6,7]</sup> A small amount of muscle tissue in the interlaminar space is retracted using the bipolar coagulator or resected with forceps to expose the face of the yellow ligament of the interlaminar space. As this yellow ligament acts as a protector when the drill slips, it should be preserved as much as possible until bone removal is completed. Bone removal is started from either the lower margin of the superior arcus vertebrae or the upper margin of the inferior arcus vertebrae. Because the purpose of decompression is release from the pincer mechanism of the thickened yellow ligament on the spinal cord, bone removal in the part covering the thickened yellow ligament region is sufficient.<sup>[8]</sup>

Although it depends on gender and physique, the anatomical range of existence of the yellow ligament is usually exposed by removing 5-6 mm of the superior vertebrae and 3-4 mm of the inferior vertebra. It is normally unnecessary to remove the contralateral arcus vertebrae. Because the approach is 5 mm away from the median, it is possible to pull down the operating sheath so that the region under the contralateral arcus vertebrae can be sufficiently observed. However, in the event that it cannot be pulled down sufficiently, it is necessary to remove the bone in the ventral inner edge of the contralateral arcus vertebrae [Figure 1I and J].

Leaving the yellow ligament on the approach side, remove the yellow ligament on the contralateral side at first, because if the ligament on the approach side is removed first, the dura is exposed and expanded and this is dangerous and also hinders the visual field. If the yellow ligament is resected by approximately 5 mm from the median to the contralateral side, the half spinal cord on the contralateral side is decompressed. Subsequently, resection of the approach side yellow ligament is performed. Except for cases in which stenosis of the vertebral foramen on the approach side is complicated, the bone removal range and resection range for the yellow ligament on the approach side are sufficient up to the inside of the facet joint. If it is difficult to stop bleeding, a head-up position is effective. Surgery is completed after the placement of an indwelling drain, which is considered essential.<sup>[9]</sup>

**Table 1: Summary of the detailed features of the 11 cases with PECL**

Case No.	Age, years	Gender	Original disease	Affected level	Approach side	Operation time, min	Hospital stay, days	Follow-up periods, months	Complication	mJOA score pre-op	mJOA score post-op	Recovery rate, %
1	59	Male	HYL	C5/6	Left	96	5	28	No	11	15	66.7
2	61	Male	HYL + Disc	C4/5	Left	81	5	25	No	10.5	13	36.5
3	67	Male	OPLL	C5/6, 6/7	Right	141	5	24	No	11	15	66.7
4	72	Female	HYL + Disc	C4/5	Right	85	8	20	No	10	13	42.9
5	58	Male	HYL	C3/4	Left	70	3	17	No	11.5	16	81.8
6	65	Female	HYL	C3/4	Right	74	5	17	No	12	15	60.0
7	71	Female	OPLL	C4/5	Right	75	8	13	No	11.5	16	81.8
8	76	Male	HYL + Disc	C5/6	Right	82	8	12	No	11	13	33.3
9	69	Male	HYL	C5/6	Left	95	8	10	No	10	13	42.9
10	52	Male	OPLL	C6/7	Left	88	3	10	No	11	15	66.7
11	59	Female	HYL	C5/6	Left	71	5	7	No	10	13	42.9

PECL: percutaneous endoscopic cervical laminectomy; mJOA: modified Japanese Orthopaedic Association; HYL: hypertrophic yellow ligament; Disc: cervical disc protrusion; OPLL: ossified posterior longitudinal ligament

### Data analysis

Pre- and postoperative neurological statuses were evaluated using the modified Japanese Orthopaedic Association (mJOA) score for cervical myelopathy. Recovery rate was calculated as follows: recovery rate = postoperative mJOA - preoperative mJOA/17 (full score) - preoperative mJOA score × 100.<sup>[10,11]</sup> Statistical analysis was performed using Student's *t*-test. *P* values less than 0.05 were considered statistically significant.

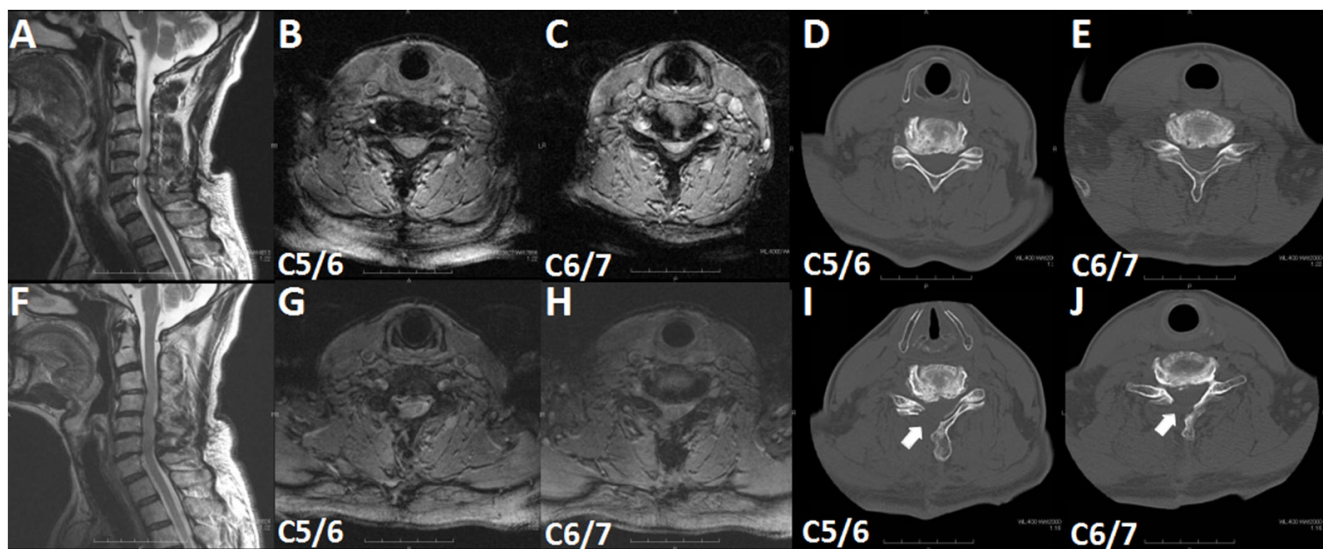
This retrospective study was approved by the ethics committee of the Wakayama Koyo Hospital, and informed consent was obtained from the patients for publication of this study and any accompanying images. The procedures were in accordance with

the ethical standards of the committee and with the Helsinki Declaration.

### RESULTS

Eleven patients were registered for this study. The mean age was 64.5 years (range 52-76 years) and the male/female ratio was 7/4. The most affected vertebral level was C5/6 (5 cases), followed by C4/5 (3 cases). Detailed information on each case, such as operation time, follow-up period, and hospital stay, is shown in Table 1.

During the mean follow-up period of 16.6 months (range 7-28 months), the mJOA score improved significantly



**Figure 1:** T2-weighted magnetic resonance imaging (A, B, C, F, G, H) and computed tomography (D, E, I, J) findings of a patient with ossified posterior longitudinal ligament (case 3). (A, B, C, D, E) Preoperative images; (F, G, H, I, J) postoperative images. (A, F) Sagittal images; (B, C, D, E, G, H, I, J) axial images. Arrows in (I, J) indicate the removed right vertebral laminae

from  $10.9 \pm 0.7$  to  $14.3 \pm 1.3$  ( $P = 0.0000002$ ). The mean recovery rate was  $56.6 \pm 17.6\%$ . The mean operation time was 87.1 min (range 70–141 min), and neither intra- nor postoperative complications were observed. The mean hospital stay was 5.7 days (range 3–8 days), and all patients were discharged.

A representative case (case 3) is shown in Figure 1. A 67-year-old man complained of progressive worsening of numbness of both upper extremities and impairment of skillful movement and walking. A neurological examination revealed an increase in all tendon reflexes, moderate muscle weakness (grasp strength: right, 18 kg; left, 27 kg), and a sensory disturbance. Sagittal cervical magnetic resonance imaging (MRI) revealed central canal stenosis at the C5/6 and C6/7 intervertebral disc levels [Figure 1A–C]. PECL was performed, and all symptoms improved to some extent (grasp strength: right, 24 kg; left, 29 kg) 4 weeks after PECL. Postoperative MRI revealed enlargement of the corresponding spinal canal [Figure 1F–H]. A comparison of preoperative [Figure 1D and E] and postoperative [Figure 1I and J] computed tomography findings demonstrates the extent of the laminectomy (arrows).

## DISCUSSION

PECL is a surgical technique that can be used to enlarge and shape a narrowed spinal canal without destroying the spinal structure and supporting elements more than conventional microscopic laminoplasty, namely cervical micro endoscopic laminectomy.<sup>[12–15]</sup> However, the technique does have some disadvantages and requires a drill to be used in a surgical field of approximate  $1 \text{ cm}^3$  and resection of the yellow ligaments is performed via this small bone window. Therefore, this operation takes a lot of time and causes some operator fatigue. It is recommended that PECL should be carefully performed by the surgeon using a sufficient endoscopic technique. In this study, case 3 was the only case involving multilevel stenosis. The operation time was 141 min and is significantly longer than surgeries involving single level stenosis (mean operation time is 81.7 min). Therefore, it is also recommended that PECL should currently be performed only for single level stenosis.

In conclusion, the current study has reported on the experience of surgeon in this department with PECL, a minimally invasive cervical posterior decompression surgical technique. This is a useful procedure, although it is a surgery that surgeons with sufficient endoscopic technique must perform carefully under strict indication.

## Authors' contributions

Y. Nishimura contributed solely to the paper.

## Financial support and sponsorship

None.

## Conflicts of interest

There are no conflicts of interest.

## Patient consent

Informed consent was obtained from the patients for publication of this study and any accompanying images.

## Ethics approval

This study was approved by the ethics committee of the Wakayama KOYO Hospital and the procedures were in accordance with the ethical standards of the committee and with the Helsinki Declaration.

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# Percutaneous endoscopic lumbar laminectomy

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## ABSTRACT

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### Key words:

Percutaneous endoscopic lumbar laminectomy,  
lumbar canal stenosis,  
single port endoscope

**Aim:** Percutaneous endoscopic lumbar laminectomy or laminotomy (PELL) is a minimally invasive surgical technique to treat lumbar canal stenosis. The procedure is undertaken using a single port endoscope, as with percutaneous endoscopic lumbar discectomy (PED). PED has become popular with spinal surgeons in Japan as a suitable surgery for lumbar disc herniation patients. Because PED has the powerful advantage of structural preservation, it allows for short hospital stays and early recovery of the patient. PELL and PED are conceptually very similar, in that they are both minimally invasive. PELL is not as popular as PED, however. The aim of the current study was to explore the reasons why. **Methods:** The current study reports the early experiences of surgeons at this institution in using the PELL technique, and its limitations. **Results:** The goal of PELL is total flavectomy and decompression of the bony structure. Currently, there are difficulties and limitations in achieving decompression using PELL with small tools. **Conclusion:** PELL requires much more skill than PED and the learning curve is not steep. PELL is minimally invasive for the patient, but further developments of the endoscope or procedures are required to achieve widespread use.

## INTRODUCTION

Percutaneous endoscopic surgery for spinal degenerative diseases is carried out using a special single-port endoscope under irrigation, making the invasiveness of this surgery extremely low.<sup>[1-5]</sup> Percutaneous endoscopic lumbar discectomy (PED) has been extensively reported, and the development of drills and bipolar coagulators has broadened its application.<sup>[6-10]</sup> In particular, the ability to use drills has expanded the surgical indications for the interlaminar approach (PED-IL) to include patients with an insufficiently wide interlaminar space and those with concomitant osseous stenosis.<sup>[11,12]</sup> Attempts have been made to use PED-IL to perform posterior

decompression for lumbar canal stenosis (LCS), in a procedure referred to as percutaneous lumbar laminectomy (or laminotomy) (PELL). However, no studies concerning this method using a single-port endoscope have yet been published. This report describes the PELL procedure and its limitations, based on the initial clinical experiences of surgeons at this institution.

## METHODS

### Surgical indication

Currently, PELL is only performed in this institution to treat LCS at a single vertebral level. In the case of multiple stenosis, after obtaining consent from the



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patient, single-level decompression is only performed if it is likely to affect the patient's symptoms; if the patient requests treatment of all the vertebral levels potentially causing the symptoms, microscopic surgery is performed instead. This procedure is used to treat all types of central canal stenosis and lateral canal stenosis.

### Surgical instruments

A special single-port endoscope is used for PELL, as with PED. In this institution, a scope 7 mm or 8 mm in diameter is used (VERTEBRIS, Winnova Richard Wolf Medical Instruments Corporation, Germany). The 7-mm endoscope has an 8-mm sheath and is easily manipulated, even in a narrow interlaminar space, but is incompatible with some of the instruments that can be used for an 8-mm endoscope. An 8-mm endoscope can be used with drill sizes up to 3.5 mm, which is useful for drilling large areas of bone. The 8-mm endoscope also enables the use of a larger Kerison punch, as well as curved and curved basket punches (Winnova Richard Wolf Medical Instruments Corporation, Germany). The 8-mm endoscope is easier to use at first, until proficiency in the procedure has been achieved. A special drill (Primade 2; Nakanishi, Japan), and a bipolar flexible radiofrequency probe (Elman Trigger-Flex probe; Elman International) are also used.

### Surgical procedure

As PELL requires a longer operation time compared with PED, PELL is currently performed under general anesthesia. In most cases, the approach is performed on the side with the most prominent symptoms, but the opposite side may be chosen if preoperative images indicate that decompression of the osseous stenosis is likely to be easier. If the operator is right-handed and no laterality of the symptoms is present, an approach from the left is used as it allows the surgeon to control the endoscope to drill the lower edge of the upper lamina easily. Discography is not performed if only the posterior component should be decompressed, but if disc manipulation may be required, discography is undertaken from the opposite side. After set-up of the equipment, a frontal fluoroscopic image is used to check the extent of decompression during the procedure. Physiological saline is used for irrigation, which is delivered at low pressure through instillation from a height of 30–40 cm above the operating table.

A 7-mm skin incision is made just beside the spinous process under the affected level. An obturator is advanced from this location along the base of the spinous process above the lamina below, as far as the interlaminar space. In patients with a narrow

interlaminar space and a thick ligamentum flavum, the obturator cannot be inserted into the interlaminar space. Therefore, obturator and sheath should be inserted until they reach the bone surface. However, if the obturator is not inserted deeply along the surface of the bone, the soft tissues will be more difficult to deal with after endoscope insertion. In this institution, a bevel-type sheath at a 30° angle is typically used.

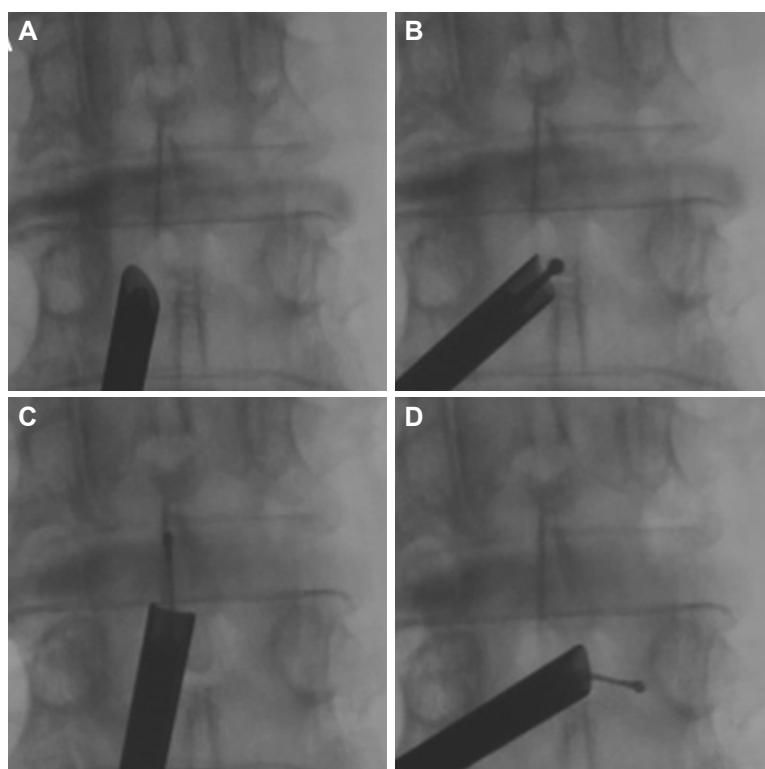
After the soft tissues have been dealt with, drilling is initiated at the center of the superior edge of the lamina under the lesion [Figure 1]. Epidural fat tissue may persist at this site even in patients with severe LCS, meaning that the depth of the epidural space can be safely confirmed. After confirming the epidural space, drilling is performed as far as the attachment of the ligamentum flavum on the approach side of the lamina under the lesion, to enable the dissection of the ligament at its attachment.

The superior facet process is then also drilled, and the stenosis of the lateral recess on the same side is treated in this step. If the ligamentum flavum cannot be detached from its attachment, its complete removal is difficult. As only limited kinds of instruments can be used, flavectomy cannot be performed unless either the attachment of the ligamentum flavum at the lamina is dissected using a drill, or laminotomy itself is carried out as far as the attachment of the ligament, as in a conventional lumbar surgery. Debulking of the ligamentum flavum can be carried out using a punch or basket punch. Therefore, the bone shape and the lesion responsible for the symptoms should be established using preoperative images.

The use of a single-port endoscope makes it difficult to perform a flavectomy on both sides, particularly a superolateral flavectomy on the contralateral side. If the insertion angle of the endoscope is limited, making manipulation on the opposite lateral side problematic, the base of the spinous process of the superior lamina must first be drilled to secure the pathway for insertion. If widespread laminotomy of the ipsilateral lamina above the lesion is required, drilling is easier if a straight-type sheath is initially used, as this helps to prevent soft tissue from entering the sheath. Once a sufficient interlaminar space has been obtained, switching to a 30° bevel or duck-bill type sheath for subsequent operations is necessary to treat the opposite side, as these cannot be carried out using a straight-type sheath. When changing the sheath, an obturator is inserted as a guide.

### Postoperative management

Hemostasis of bleeding from soft tissue and resected



**Figure 1:** Intraoperative frontal fluoroscope images. A: Insertion of 30-degree bevel-type sheath on the obturator; B: starting point of laminectomy with drill; C, D: confirmation of decompressed area

bone stumps can be achieved using a bipolar coagulator. However, the decompressed area after this surgery is very narrow. As in other minimally invasive surgeries, there is no large space to avoid dural compression if a small hemorrhage occurs. A negative-pressure drain is therefore used. The amount of postoperative fluid drainage is only approximately 10 mL, but dull pain in the legs may persist for around a week after drain removal in some cases, possibly as a result of leachate or tiny hematomas. After the endoscope has been withdrawn, the drain tube is advanced inside the sheath and placement of the tip is confirmed using fluoroscopy.

## RESULTS

Using PELL for the treatment of LCS has some advantages compared with conventional surgery. First, PELL requires a small skin incision and produces less muscle damage, thereby resulting in a shorter hospital stay. Second, the greatest advantage of this technique is the good field of view on the opposite side, as once the superior tip of the lamina has been drilled, the opposite side lateral recess can be decompressed. After decompression, the transverse root is visible as far as the vicinity of the intervertebral foramen. Drilling of the lateral recess can be carried out relatively easily. However, training is needed for this method, because of the limited kinds of operative tools.

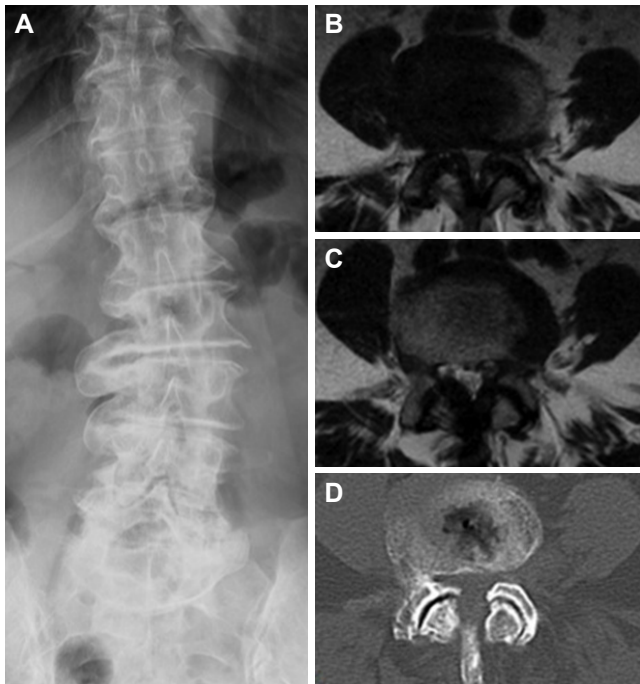
## Complications

In addition to the same sort of dural damage that may occur during conventional surgery, other potential complications include elevated intracranial pressure caused by a long period of high-pressure irrigation, as may also occur in PED. As previously described, irrigation is delivered at comparatively low pressure, and the risk is not great in the absence of complications such as dural damage. The treatment of dural laceration varies depending on its size. If the damage is minor, cerebrospinal fluid leakage is not a problem, because of the narrow surgical space. However, a laceration that exceeds 2 mm and includes the arachnoid membrane may lead to nerve root herniation, causing pain, and will require treatment. As in conventional surgery, caution is required with respect to dural adhesion. Although the wide variety of instruments used in conventional surgery cannot be employed in dissection, this procedure does enable direct visual observation. Areas that cannot be viewed must be treated with greater caution.

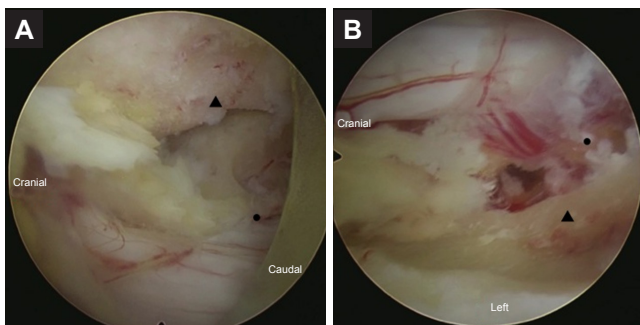
## Illustrated cases

### Case 1

A 76-year-old woman had been attending this hospital for several years complaining of pain in the left leg. Pain was also present at rest, over an area in the left L5 region. Intermittent claudication with numbness in both legs

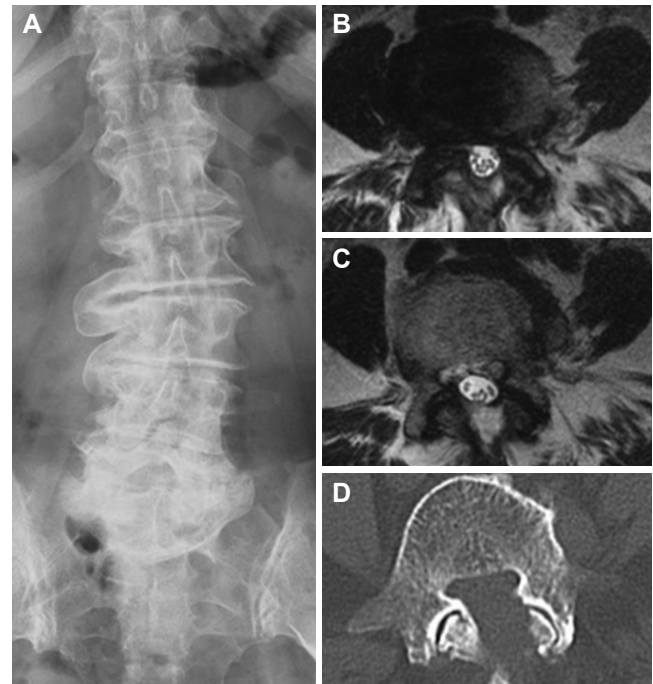


**Figure 2:** Preoperative neuroimages reveal degenerative lumbar scoliosis and remarkable bilateral canal stenosis with hypertrophied ligamentum flavum and superior facet joint at L4/5. A: Roentgram (A-P); B, C: magnetic resonance imaging T2WI axial image at L4/5; D: computed tomography axial image at L4/5



**Figure 3:** Intraoperative endoscopic images (left side approached percutaneous endoscopic lumbar laminectomy). A: Contralateral view. Right side is the caudal of the patient. Triangle: facet joint (already drilled out) of right side; dot: right side L5 nerve root. B: Ipsilateral view. Left side of the figure is the caudal of the patient and lower side is the left side of the patient. Triangle: residual superior facet which medial side was drilled out to decompress the L5 root; dot: left L5 root

was also evident when she walked for approximately 10 m. Preoperative neuroimaging revealed severe LCS at the L4/5 level caused by a hypertrophied ligamentum flavum and superior facet, and degenerative scoliosis was present [Figure 2]. PELL was performed via a left approach, and bilateral decompression was performed [Figure 3]. The operation was finished after confirmation of the decompressed area by using frontal fluoroscope. The negative pressure drain tube was inserted and confirmed the position by frontal fluoroscope. Postoperatively, the pain improved. Dull

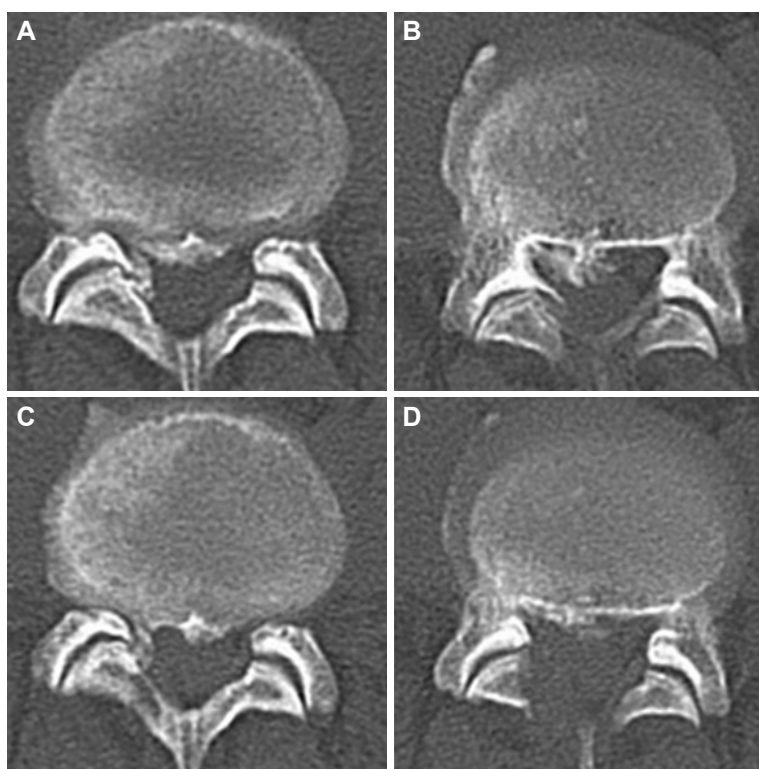


**Figure 4:** Postoperative neuroimages show reasonable decompression of the spinal canal at the L4/5 level and no deterioration of the scoliotic change. A: Roentgram (A-P); B, C: magnetic resonance imaging T2WI axial image at L4/5; D: computed tomography axial image at L4/5

pain was present for several days after drain removal, but this pain improved to 0 on a visual analog scale at postoperative day 7. Postoperative neuroimaging showed that adequate decompression had been achieved [Figure 4]. Six months after surgery she could walk without any limitation and all sensory disturbance was gone.

## Case 2

A 48-year-old man developed pain in the right leg after lifting a heavy object at work. Treatment using conservative therapy for 3 months had not produced any improvement. The painful area was in the L5 region, and was aggravated by load-bearing on the right side. Preoperative neuroimaging revealed stenosis of the right lateral recess caused by ossification of the posterior longitudinal ligament (OPLL) and an ossified ligamentum flavum (OLF) at the L4/5 level [Figure 5A and B]. Preoperatively discography was performed with left side needle insertion. PELL with a right-side approach was performed, and the OLF was drilled out and the hypertrophied ligamentum flavum was resected. After the decompression of the posterior elements, the subligamentous disc was resected and the OPLL under the L5 root was drilled out. The lesion under the theca can not be drilled out but the compression of the right L5 root was improved. The operation was finished with the negative pressure



**Figure 5:** Preoperative computed tomography (CT) images (A, B) at L4/5 show right side ossification of ligamentum flavum and ossification of posterior longitudinal ligament. Postoperative CT images (C, D) at the same level show reasonable decompression of the spinal canal

drain insertion. Postoperatively, the pain completely improved, and numbness also resolved after 2 weeks. Postoperative imaging revealed good decompression [Figure 5C and D].

## DISCUSSION

The gold standard for surgical treatment of LCS is bilateral laminotomy, medial facetectomy, and flavectomy using a microscope.<sup>[13]</sup> Although some studies have stated that bilateral decompression via a unilateral approach is less invasive,<sup>[14]</sup> this approach may cause muscle damage through detachment of the muscles attached to the spinous processes. Microendoscopic laminectomy (MEL) is another method that causes less muscle damage and enables a visual field to be obtained on the opposite side by changing the orientation of the tube retractor.<sup>[15,16]</sup> However, this procedure is associated with problems such as a higher incidence of dura mater damage and other complications.<sup>[17,18]</sup> Furthermore, intraoperative fogging of the camera with blood and other fluid requires cleaning of the camera on a regular basis.<sup>[16]</sup>

In PED IL, if LCS is located on the approach side, then lateral recess decompression is performed together with discectomy. In cases with central lumbar canal stenosis, PELL is used as an additional option to perform

decompression on the opposite side. As with PED, this method minimizes the destruction of tissue during the surgical approach and entails less tissue invasion than the MEL approach described previously. However, in practice it has not yet become as popular as PED. The main reason for this is the difficulty of the surgical procedure.<sup>[19,20]</sup> PELL requires the use of limited kinds of small instruments to perform decompression entirely within the interlaminar space. Although operations on the same side enable exposure of the attachment of the ligamentum flavum by expanding the extent of bone removal, this procedure requires more time.

As pinpoint decompression of the responsible lesion is enabled, this method might have advantages with respect to postoperative instability.<sup>[19]</sup> Eun *et al.*<sup>[21]</sup> showed that there is less chance of instability in patients with PED compared with open lumbar microdiscectomy. The advantage of PELL is that the field of view on the opposite side is superior to that offered by microscopic surgery and MEL. First, the endoscope tip is close to the objective, the endoscopic view is enlarged, and the fact that the operation is performed under irrigation using physiological saline ensures that the field of view is clear. Second, the viewpoint is located beyond the midline structures that disturb the field of view during other procedures. Therefore, the operator can clearly view the area, and even that of the opposite nerve root

[Figure 3]. However, the fact that only limited kinds of instrumentation can be used during PELL tends to make operations more difficult. Drilling of the lateral recess can be carried out relatively easily. Although the corresponding top part of the lamina should be drilled before insertion of the endoscope, the ligament must be dissected from the surrounding bone. Complete detachment of the ligament on the opposite side is particularly difficult. If the detachment is difficult, the bone area attaching to the ligament should be drilled to remove the ligament together with the surrounding bone.

The technical difficulty of PELL using a single-port endoscope has already been described, as have the facts that additional time is required for the procedure and the end result might be incomplete decompression.<sup>[19]</sup> Other studies have also emphasized that the learning curve for PELL is more gradual than those for MEL or PED. This technique should not be started without first achieving a certain level of proficiency in PED IL. Unless adequate technical skills have been acquired, the procedure can hardly be described as minimally invasive.

Some studies have described a method involving use of a second port to increase the number of instruments that can be used and remove the restrictions on field of view and usable instrumentation.<sup>[19,20,22]</sup> In arthroscopy, surgery is performed using the triangle technique. Different reports have detailed the application of this technique to the spinal field and use different terms; irrigation endoscopic decompressive laminotomy (IEDL),<sup>[19]</sup> percutaneous biportal endoscopic decompression (PBED),<sup>[20]</sup> and two-portal percutaneous endoscopic decompression.<sup>[22]</sup> In all these techniques, the arthroscope is inserted via the first port and the instrumentation is inserted via the second port, with the operation being performed under irrigation. All authors concluded that these methods resolve the restrictions on the size of instrument that can be inserted via the second port, enabling the use of drills, Kerison punches, and curettes employed in conventional laminectomy. In addition, no special equipment is required, as the surgery can be performed using an arthroscope and normal spinal surgery instrumentation. However, these second-portal technique may also need special training.<sup>[22]</sup> Eum *et al.*<sup>[20]</sup> reported that this technique is similar to a knee arthroscopic surgery or thoracoscopic surgery. All of these techniques used arthroscope but now we can use the single port endoscope that can allow using the instrumentation through the endoscope. Then the modification might be able to apply the second port method. Basically single port method is applied. And

second port might be able to use for only the large instrumentation like Kerison punch that is used for the conventional surgery. Despite the requirement for technical proficiency described above, adaptations like this may offer one possible direction for the development of this method.

In conclusion, PELL is a method of treatment that minimizes soft-tissue damage caused by invasion associated with the surgical approach. However, because of its technical difficulty, PELL has not yet been become a popular procedure. Nevertheless, this technique offers a range of advantages if the operator acquires a sufficient level of technical proficiency to complete the procedure in approximately the same time required for microscopic lumbar laminotomy. Further developments in the procedure will be required to encourage more widespread use, such as using a larger endoscope to enable the use of a wider range of instrumentation, or use of a second port.

### Authors' contributions

Study conception and design, performing the surgical technique: Y. Ohara

Critical revision: S. Shimizu, J. Mizuno

### Financial support and sponsorship

None.

### Conflicts of interest

There are no conflicts of interest.

### Patient consent

Obtained.

### Ethics approval

The ethics committee of ShinYurigaoka General Hospital approved this retrospective study.

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# Modified parasternal approach is a good alternative for aortic valve surgery

Kuan-Ming Chiu<sup>1,2,3</sup>

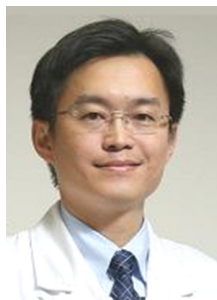
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Prof. Kuan-Ming Chiu, Vice President in Far Eastern Memorial Hospital (FEMH) and Chief of Cardiovascular Center, Taiwan. He is the Council member of the Thoracic and Cardiovascular Surgeons of Asia (ATCSA), and also serves as the Board member of several societies in Taiwan. Dr. Chiu has performed more than 5,000 cardiac operations, including over 3,000 CABG, more than 1,500 valve surgeries, and 54 heart transplants. The core competencies of his team at FEMH are in off-pump coronary artery bypass (OPCAB) and minimally invasive cardiac surgery (MICS). In August 2010, Dr. Chiu and his team initiated the Da Vinci cardiac surgery procedures and performed 52 such operations in past years. FEMH is considered a leader in endoscopic vessel harvest (EVH) procedures (more than 2,100 cases of EVH experience, including 130 endoscopic radial artery harvests) and is also a premier training center in Asia. Several foreign cardiac surgeons have been to FEMH for EVH and MICS training. More than 85% of the isolated CABG procedures he performed were OPCAB. More than 85% of valve procedures at FEMH are performed via the sternum-sparing approach (MICS). Dr. Chiu has been invited for oral presentations and live demonstrations of his OPCAB and sternum-sparing MICS techniques in Japan, China, Hong Kong, Macau, Vietnam, Malaysia, Singapore, India, Philippines and Korea. His expertise includes endoscopic mitral valve surgery, parasternal aortic valve (multi-valve) surgery, and sternum sparing coronary artery bypass.

## ABSTRACT

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### Key words:

Parasternal approach,  
aortic valve surgery,  
modified parasternal incision,  
sternum-sparing aortic valve surgery,  
minimally invasive aortic valve  
surgery

**Aim:** Cardiac surgery, as with other surgical specialties, has moved toward minimally invasive procedures. Currently, since the cardiopulmonary bypass machine remains necessary for most cardiac surgery procedures, efforts have focused on decreasing surgical trauma by limiting vascular access sites and any unnecessary dissection. This study presents the authors' approach for less invasive valve surgery, which aimed to avoid a conventional midline sternotomy and reducing the length of incision. **Methods:** For patients with aortic valve involvement, parasternal approach was the primary choice. A longitudinal 5-6 cm incision was made one fingerbreadth lateral to the sternal border. The 3rd rib was cut at the chondrosternal junction and bent into the right pleural cavity. After either central aortic or peripheral cannulation, all procedures were completed under surgeon's direct vision and conventional instruments. The rib was reduced into position with a wire to offer stability and eliminate postoperative chest deformity. **Results:** The authors' experience of more than 500 cases with the minimally invasive approach showed that bypass time and ischemic time for parasternal valve surgery were compatible with to a full-sternotomy approach. In this series, postoperative ventilation



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time, blood product consumption and overall mortality were reduced. **Conclusion:** Reviewing the parasternal aortic valve series of more than 500 cases, parasternal approach is safe, effective, and reproducible. The surgical trauma and blood product consumption were minimized with this approach. Multiple valve procedures and ablation for atrial fibrillation are also feasible. Stable sternoclavicular joints could facilitate early and aggressive activity of upper extremities for improved postoperative recovery. This approach could be a good alternative option in aortic or multiple valve surgical procedures.

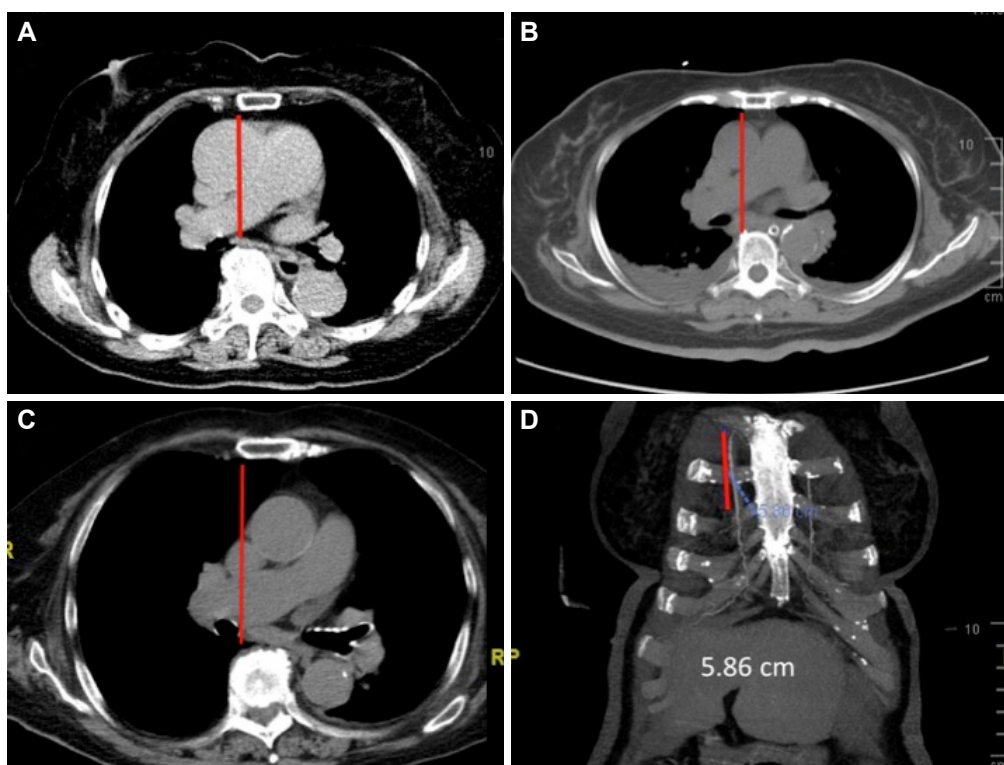
## INTRODUCTION

Minimally invasive cardiac surgery (MICS) has been widely adopted.<sup>[1]</sup> Partial sternotomy for aortic valve replacement is the most common MICS for aortic valve replacement.<sup>[2]</sup> For multiple valve procedure, full sternotomy still remains the choice for most cardiac surgeons. There are several sternum-sparing approaches, such as the anterior thoracotomy,<sup>[3,4]</sup> lateral thoracotomy<sup>[5]</sup> and right parasternotomy.<sup>[6]</sup> Among these three approaches, we modify the Cosgrove's parasternal approach to avoid the paradoxical chest movement and make it usable for most cardiac surgeons. In this series, improved cosmetic results, lower wound infection rates, shorter hospital and intensive care unit stay were found with the minimally invasive approach.

## METHODS

In 2003, our institution adopted the minimally invasive

approach. Patients with isolated mitral procedures or mitral and tricuspid procedures were done through right lateral mini-thoracotomy. For patients with aortic valve involvement, Cosgrove's idea<sup>[7]</sup> was adopted and modified with no rib resection. Initially, the two-rib approach was initiated with the following major selection criteria: adult single aortic valve cases, without chest wall deformity, without severe chronic obstructive pulmonary disease, and without aneurysmal or aortoiliac occlusive disease. Every single patient considered for this approach had pre-operative chest, abdomen and pelvis computed tomography (CT) scans to exclude aneurysmal aortic disease, dense calcifications, or occlusive aorto-iliac disease, which were considered to be contraindications to peripheral cannulation. In addition, the axial and frontal CT scans helped to identify the distance and relative position between skin incision and aortic annulus [Figure 1]. The patient was placed supine and intubated with double-lumen endotracheal tube for temporary one-lung ventilation during costo-chondral flap preparation. One pillow was



**Figure 1:** (A-C) Cross-sectional views of ascending aorta. The red lines indicate the planes of right sternal borders. Axial CT scan revealed relative position of ascending aorta versus sternal border. Aortic valve exposure is less favorable from A to C. Frontal reconstruction of CT scan offers the estimation of longitudinal length; D: distance from the lower margin of second rib to the upper margin of fourth rib. Less than 4 cm would be less favorable for one-rib approach. CT: computed tomography

put under right scapula, which tilted the patient left approximately 30 degrees. External defibrillation pads were applied routinely preoperatively.

The skin incision was made longitudinally one fingerbreadth parallel to right lateral sternal border from the lower margin of 2nd rib to the upper margin of 5th rib. A subcutaneous pocket was created for better detachment of the underlying muscle. The pectoralis major muscle was cut in a reversed C shape from the sternal border attachment to allow lateral retraction naturally. The intercostal muscle was cut underneath the 2nd rib and above the 5th rib. The right internal mammary artery and veins were encountered at both intercostal spaces and carefully divided after clip ligation. The 3rd and 4th ribs were cut at sternochondral junction with a rib cutter. The sharp margin was trimmed with a bone file to prevent inadvertent lung injury. The myocostal flap was bent into right pleural cavity after manual fracture. The fracture point was adjusted based on the width needed for surgical exposure, which was approximately at the junction between rib and costal cartilage. Care was taken to maintain the periosteum and soft tissue attachment to ensure the bony healing and future wound stability. Then, a small-sized rib or sternal spreader (retractor) was inserted to keep constant exposure. The two blades of sternal or rib retractor could be asymmetric. The short blade was good for the sternal side and the longer blade was suitable for the lateral myocostal flap. Pericardium was opened longitudinally after removing the epicardial fat pad. Stay sutures were placed to bring the mediastinum right. Placement of the sternal retractor inside the pericardial cradle provided adequate exposure. If the ascending aortic exposure was adequate enough to accommodate aortic cannulation, crossclamp, cardioplegic needle, aortotomy and prosthetic manipulation, central cannulation could be performed. Otherwise, peripheral cannulation, mainly femoral and occasionally axillary cannulations were used. Femoral vein cannulation was routinely utilized to ensure better exposure under limited skin incision. Wire-reinforced aortic cannula was chosen for better positioning without the risk of kinking. Single femoral venous cannulation plus vacuum assisted venous drainage usually provided adequate drainage. From our experience, left neck central venous line was preferred. Right neck was preserved for surgeon manipulation. Echo-guided 4-Fr introducer sheath was inserted via right internal jugular vein before commencement of cardiopulmonary bypass (CPB). This strategy was helpful when inadequate venous drainage was encountered in order to insert a superior vena cava cannula or a transvenous pacemaker wire when needed.

After commencing CPB, the aortopulmonary window was dissected to facilitate ascending aorta looping using vascular tape. This step was helpful not only for securely cross clamping the aorta but also for adding sutures for hemostasis at both ends of aortotomy. A malleable left ventricular venting catheter was inserted via the right upper pulmonary vein through mitral valve into left ventricle. It was helpful to maintain constant bloodless exposure of aortic valve, to decompress left ventricle and to de-air after crossclamp was removed and before CPB was weaned off.

Using the traction sutures on the pericardium and fixing the cross clamp rightward, the aortic exposure was usually adequate enough for having an aortotomy and delivering cardioplegic solution, even with coronary ostia balloon catheters. Aortic leaflets and annulus could be well-exposed for inspection. Decalcification and trimming of leaflets were then performed meticulously. Repair or replacement of the aortic valve was done by conventional techniques and instruments [Figure 2A]. For mitral valve procedures, three approaches could be chosen according to patient's anatomy and complexity of mitral procedures. By using femoral bicaval cannula and snaring of both superior and inferior vena cava, trans-septal approach offered the best mitral exposure. Through Waterston's groove, the trans-lateral approach was a viable alternative, but the mitral valve would be farther away than trans-septal exposure. For a simplified suture annuloplasty, the left atrial dome approach was an attractive option. Meanwhile, tricuspid valve procedures could be straightforwardly done. Ablation for atrial fibrillation (AF) could be performed both endocardially and epicardially by cryoprobe or unipolar radiofrequency probe.<sup>[8]</sup> Closure of left atrial appendage was feasible. In brief, most valvular procedures could be achieved through our two-rib parasternal approach, except for pulmonary valve procedures. If temporary ventricular pacemaker wires were considered, insertion under total decompression of heart chambers over right ventricle was highly recommended. Transvenous pacemaker wire through right internal jugular or right subclavian vein approach was an alternative.

After our first hundred cases, a single-lumen endotracheal intubation was employed to simplify anesthetic induction process. Temporary cessation of mechanical ventilation would suffice for pleural entry and bending of the myocostal flap. This approach ensured the same prep as a conventional sternal one, except for left-tilted position and external defibrillation pads.

For the next stage of our experience, we moved to

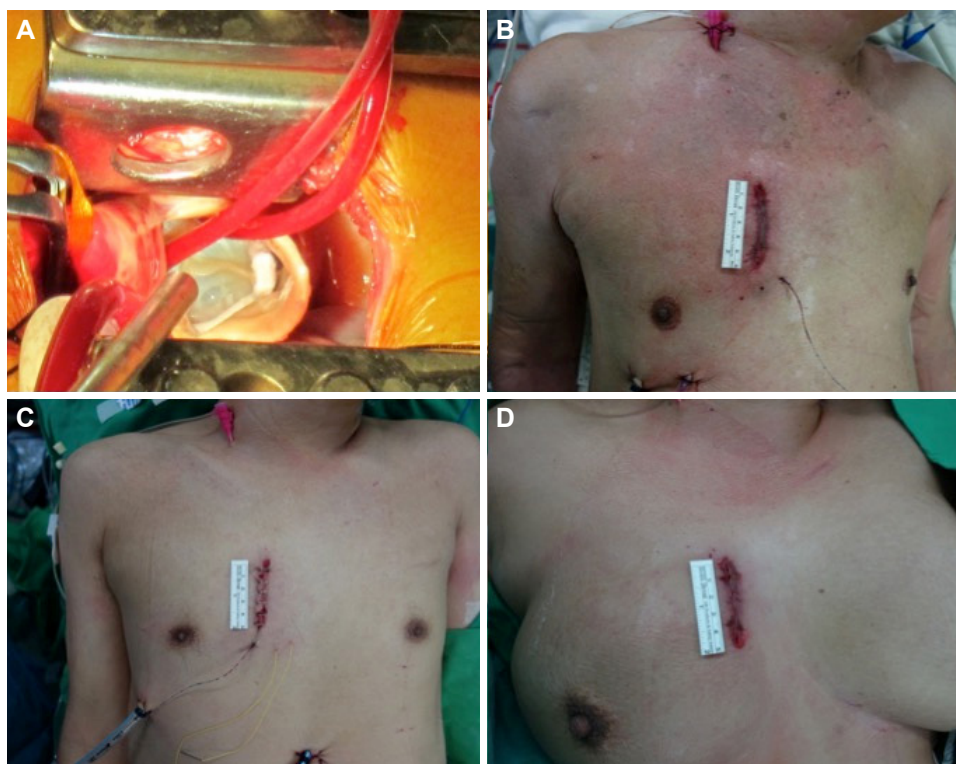
one-rib parasternal approach. All surgical details were similar, except for a smaller incision and only the 3rd rib was cut. A one-rib approach was usually aimed for an isolated aortic procedure. The major determinant for this approach would be the length between the lower margin of 2nd rib and upper margin of 4th rib. For patients with a narrow 2nd intercostal space, this would be difficult to proceed [Figure 1D]. For more than two thirds of these patients, central aortic cannulation could be achieved. Some patients had concomitant mitral repair as well. We also developed epicardial cryoablation for AF using pulmonary vein isolation through this limited incision.

After the completion of valvular procedures, CPB was weaned off and hemostasis was achieved. Two Jackson-Pratt drains were inserted into pericardial and pleural space, respectively. Pericardium was closed with interrupted sutures. The myocostal flap was reduced back into the anatomical position. Any partially broken ribs was fixed with a pediatric wire to sternum. For patients with widened 2nd intercostal space, several interrupted, braided, non-absorbable sutures were used as a fence to divide the space and prevent lung herniation. Mesh for abdominal hernia and ePTFE patch had been placed in selective cases. The pectoral major muscle was brought back centrally and fixed with interrupted sutures. Subcutaneous fascia and skin were closed [Figure 2B-D]. Our postoperative pain

management consisted of controlled local anesthetic infusion and a patient-controlled analgesia pump.

## RESULTS

From 2004 to 2016, 543 parasternal cardiac operations were performed at our institution. The cases included 297 isolated aortic valve, 124 aortic and mitral, 45 aortic, mitral and tricuspid procedures and miscellaneous applications. Nine percent were redo procedures. Average time for parasternal cross clamp, CPB, operation were 61.84, 101.43 and 243.00 min, respectively [Table 1]. Average ventilation time and intensive care unit stay were 13 h and 2.4 days [Table 2]. Surgical mortality was 1.9%. There was one conversion to sternotomy for persistent bleeding. Five patients had perioperative central nervous complications. Retrograde flow from femoral cannulation and inadequate de-airing were considered to be potential causes. Parasternal wound complications were rare and self-limited. The well vascularized pectoralis muscle coverage potentially decreased local infection. Eight patients had a wound infection that required additional limited surgical debridement without the entry of mediastinum. Three of them had local infection related to temporary pacemaker wires [Table 3]. Pain analogue scale was usually less than 2-3 under our aggressive pain management. More than 90% patients were satisfied with their operative wounds.



**Figure 2:** (A) Surgical exposure revealed the well-seated bioprosthesis and two coronary ostia balloon catheters for cardioplegic solution delivery; (B-D) the other three pictures showed the final skin closure immediately after the completion of surgery

**Table 1: Demographic data of the parasternotomy patient group**

Chareacteristics	Total (n = 543)	Male (n = 339)	Female (n = 204)
Age, years			
Average	62.63 ± 14.00	61.58 ± 14.20	64.39 ± 13.50
Median	64	62	65
BMI	24.22	24.56	23.66
Euro score			
< 1	70	54	16
1-5	230	136	94
6-10	57	28	29
11-20	29	18	11
> 20	12	7	5
Concomitant disease, n (%)			
Diabetes	88 (16.2)	51 (15.0)	37 (18.1)
Dyslipidemia	124 (22.8)	74 (21.8)	50 (24.5)
Hypertension	279 (51.4)	172 (50.7)	104 (51.0)
COPD	46 (8.5)	33 (9.7)	13 (6.4)
Status of the procedure			
Elective	536	335	201
Urgent	2	2	0
Emergent	5	2	3
Cardiac surgery			
First	501	313	188
Second	35	22	13
Third	7	4	3
Fourth or more	0	0	0
LVEF distribution			
LV dysfunction poor or LVEF < 30%	25	17	8
LV dysfunction moderate or LVEF 30-50%	99	70	29

BMI: body mass index; COPD: chronic obstructive pulmonary disease; LVEF: left ventricular ejection fraction

No iatrogenic and retrograde aortic dissections or phrenic nerve injuries were identified. Groin complications like seroma were common, although the majority were self-limited. In the latter half of patients, a self-closure device and echo-guided femoral artery puncture were employed to minimize groin complications significantly. Lung complications were rare. Some patients develop right hilar haziness in the first few days which might result from local compression of myocostal flap during the operation. However, lung recruitment by pressure controlled lung expansion during wound closure helped to improve atelectasis and facilitate early extubation. No evidence of non-union, pseudojoint, or chest cage deformity were identified. Any broken ribs were fixed with pediatric wire and lateral soft tissue attachment. Paradoxical movement and lung herniation were rare and typically happened at the 2nd intercostal space. This was well-controlled since interrupted sutures were used for 2nd intercostal space. Local dimpling due to pectoralis muscle atrophy occurred in our series. Therefore, an inverted C incision for pectoralis muscle instead of cutting straightforward muscle following skin incision was performed. Upper

**Table 2: Operative and hospital data**

Chareacteristics	Para (n = 543)	Full (n = 2,991)	P
Hospital stay (days)	14.18 ± 8.17	20.55 ± 19.58	< 0.001
Intensive care unit stay (h)	57.54 ± 23.70	131.49 ± 197.90	< 0.001
Cross clamp time (min)	61.84 ± 25.60	71.10 ± 46.63	< 0.001
Perfusion time (min)	101.43 ± 41.72	135.78 ± 78.41	< 0.001
Operative time (min)	243.73 ± 68.77	283.14 ± 114.85	< 0.001
Ventilation time (h)	13.77 ± 13.90	75.73 ± 202.72	< 0.001

**Table 3: Complication rate, n (%)**

Complications	Para (n = 543)	Full (n = 2,991)
Wound infection	3 (0.6)	37 (1.2)
Stroke	3 (0.6)	116 (3.9)
Renal failure*	11 (2.0)	186 (6.2)

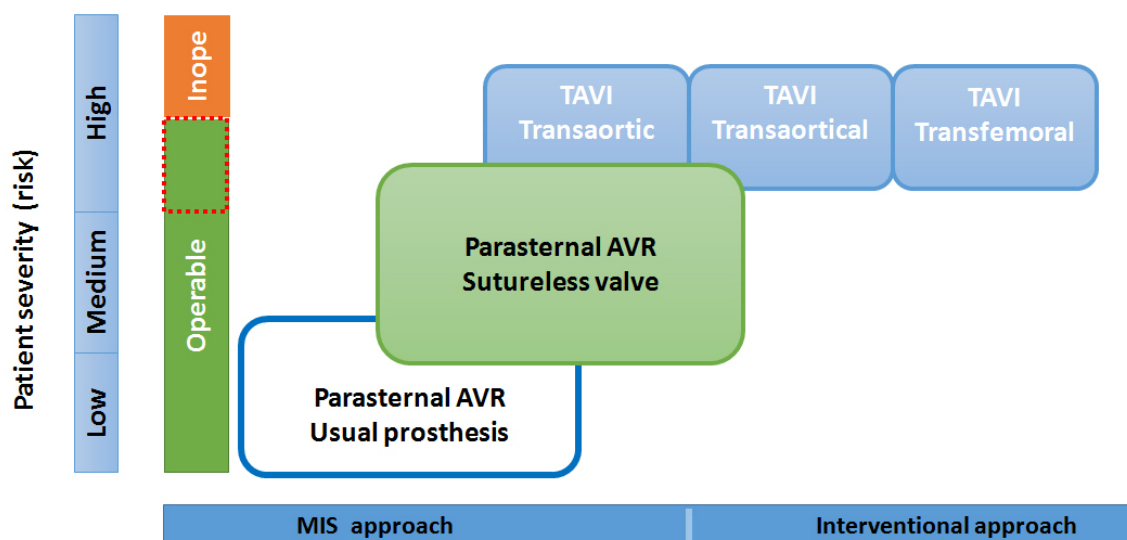
\*Creatinine elevation > 2 times of baseline level

extremity exercise was also encouraged after patients were transferred out of intensive care unit. Instructions were given to patients on how to protect the wound. Simple one-hand compression over the wound offers stability and pain reduction, especially while coughing. Two or even one small Jackson-Pratt drains rather than chest tubes also made early ambulation easier.

## DISCUSSION

MICS is a growing field with the goals to eliminate cardiopulmonary bypass and to avoid a sternotomy. Among the three sternum-sparing approaches, anterior thoracotomy gains the most acceptance especially in Europe when dealing with single aortic valve replacement. It takes advantage of the anatomic proximity to aorta. However, the elliptical spread of intercostal space and its perpendicularity to the ascending aorta limits the exposure. Even though the 3rd rib is transected at sternochondral junction, it still provides limited access to the aortic valve annulus.<sup>[9]</sup> Skin incision of lateral thoracotomy is usually made close to axilla and is intended to be hid under anterior axillary fold. The incision is the largest among these three approaches. Sizable wounds of the intercostal muscles need to be cut in order to gain better exposure. Besides, extended-length instruments and knot-pusher are required to finish the valve replacement.<sup>[5]</sup> This is only reserved for most experienced and highly skilled surgeons. Here, we share our experience of the parasternal approach.

The treatment of aortic valve diseases are based on patients' risk categories and invasiveness or complexity of procedures [Figure 3]. The original parasternal approach developed by Cosgrove was aimed for a sternum-sparing purpose. Although the take-down of costal cartilages facilitated wide exposure, however, it resulted in anterior chest deformity, lung herniation, and



### Procedure

**Figure 3:** Our surgical strategy for aortic valve procedures were mainly categorized by patients' risk severity and the complexity/invasiveness of procedures. MIS: minimally invasive surgery; AVR: aortic valve replacement; TAVI: transcatheter aortic valve implantation

paradoxical movement. Cosmetic results and patients' satisfaction may not be attained.<sup>[10]</sup> In our series, these adverse outcomes were significantly improved.

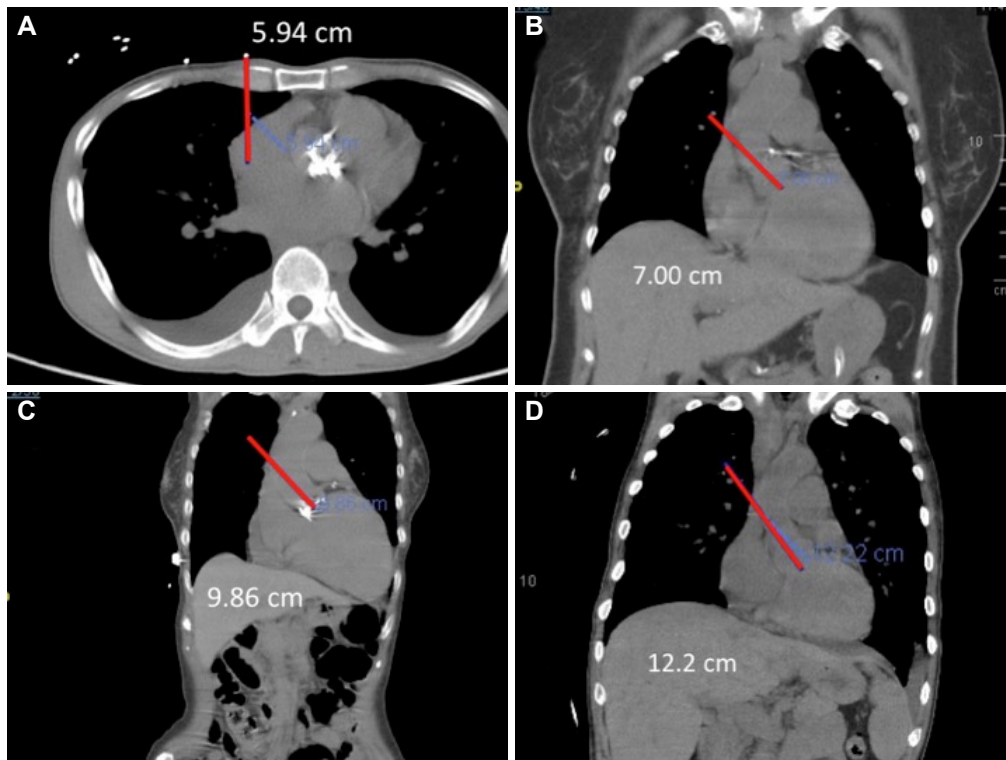
For surgeons considering to employ our parasternal approach, they should be familiar with conventional aortic valve surgery and have a certain amount of experience independently. Team members' orientation is usually simple. No additional effort is needed from anesthesiologists. Operative nurses and surgical assistants are well instructed in advance since they may not be able to view the details through limited exposure. Head-mounted camera from the surgeon's headlight would be helpful to keep crews on the same page and also for educational purpose. Extended length instruments are only needed for deeply seated mitral valves. There is limited or even no additional investment.

For patients who are considered for our parasternal approach, correct diagnoses are crucial. Intention for surgical intervention should be limited to mainly aortic valve procedures. Associated procedures, like mitral valve, tricuspid valve, and AF ablation could be considered following the progress of learning curve. Physical examination is important. The width of 2nd, 3rd and 4th intercostal space tells us the potential working space [Figure 1D]. Chest wall deformities, like pigeon chest or funnel chest, and narrow intercostal space may not be suitable. Preoperative images are extremely helpful for defining the accessibility or searching the contraindications. Absolute contraindications would be defined as poor exposure which precludes the completion of proposed procedures, complex

procedures in early learning process, and ascending aortic or arch aneurysm.

Chest films help us to have ideas of proximity of proposed incision and aorta. However, CT scan from neck to pelvis offers the most information.<sup>[11]</sup> Contrast medium is usually not required, especially for patients proposed to have operations within 48 h.<sup>[12]</sup> Aortic aneurysm and aorto-iliac disease are contraindications for peripheral cannulation, although thigh-brachial index or ankle-brachial index could offer the extent of severity. However, central aortic cannulation is usually possible and axillary artery cannulation could be an alternative if inadequate exposure is a concern. Elevated stroke risk is always a concern for certain patients with MICS using femoral arterial cannulation.<sup>[13,14]</sup>

The location of the ascending aorta in relation to sternum is crucial. More than half of ascending aortic circumference are located right lateral to right sternal border.<sup>[15]</sup> The measurement from the center of proposed skin incision, usually 2 cm right lateral to sternum border over the 3rd rib, to aortic annulus is very helpful. This is a three-dimensional distance consisting of the root of square sum of three parameters which could be acquired from both axial and frontal reconstruction of CT scan [Figure 4]. However, it tends to be closer due to the difference between full inspiration during CT scanning and full muscle relaxation during operation. The distance in between 6 to 12 cm would be acknowledged as friendly for our parasternal approach. Space for all ascending aortic interventions should be considered, including central aortic cannulation, cross clamp,



**Figure 4:** The three-dimensional distance consisting of the root of square sum of simplified two parameters (A: depth from skin to the level of annulus; B-D: oblique distance from the projection of 3rd rib to annulus) which could be acquired from both axial and frontal reconstruction of computed tomography scan. The distance offers surgeons the feasibility and difficulty of this approach

cardioplegic or de-airing needle and reasonable room for aortotomy and prosthesis manipulation. Shorter distance usually indicates limited or shorter exposure of ascending aorta which necessitates peripheral cannulation and very low aortotomy. Farer distance clearly indicates difficulty in exposure, suturing and knot tying. Exposure may be acceptable after commencement of CPB and aortic cross-clamp. However, care should be given for meticulous suturing and hemostasis for aortotomy, especially at both ends. For those with limited exposure, additional stitches for overt bleeding may not be easy once CPB is weaned off and the heart is fully loaded. Complex procedures, like remodeling procedure, reimplantation procedure, Bentall operation, annular enlargement, peri-annular abscess patch repair for infective endocarditis and redo aortic valve replacement have been performed using two-rib parasternal approach in our series. Hemostatic products would be helpful for those suture lines without second chance of hemostasis.

Compared with anterior thoracotomy, similarly, both approaches may need peripheral CPB and have divided or torn right internal mammary artery, broken costal cartilage, lower conversion rate, and limited lung herniation. The advantage of “so-called” intact chest cage often counteracts by its limited exposure. Therefore, its application is limited to highly selected

cases. Most surgeons prefer upper partial sternotomy rather than anterior thoracotomy. Conversely, the parasternal approach offers better exposure to the aortic root, annulus, and is technically easier for beginners initiating sternum-sparing approaches. It is more anatomically oriented and could be a good alternative for aortic valve surgery, especially for patients with the need for better exposure. Additionally, this approach offers opportunity for multi-valve surgery (including mitral and tricuspid).

Our parasternal approach carries additional benefits. Wound complications are rare, mainly due to the stability and muscle flap coverage. It maintains the integrity of sternum, manubrium, and sternoclavicular joints. From anatomical experience, upper extremities (UE) are connected to axial skeleton through clavicles, sternoclavicular joints and chest cage. Our approach reduces pain from UE movement. Early return of full range of UE motility improves post-operative lung function and quality of life.

With the availability of sutureless aortic prostheses, the aortic valve replacement could be facilitated.<sup>[16,17]</sup> High transverse aortotomy is easily achieved. Decalcification of the annulus and nadir sutures could be easily accomplished. The parasternal approach offers a versatile platform for wide-range of aortic valve

procedures. After we developed this technique, it has become our standard practice and primary choice for aortic valve surgery. Our propensity-adjusted analysis shows that the parasternal approach may be a good minimally invasive alternative to full sternotomy for cardiac valve operations.<sup>[6]</sup>

In conclusion, improved cosmetic results, less pain and anagelsic use, and faster recovery have been reported. It has been generally well-accepted by patients and also by surgeons performing minimally invasive aortic valve replacement.<sup>[18]</sup> We agree that full sternotomy procedures have achieved excellent surgical outcomes. It may not be easy to elaborate the differences in outcomes simply through various surgical incisions. Also, new approaches, if not been well conducted, could be detrimental due to unfamiliar and unexpected complications. Open mindedness and curiosity, on-site case observations, and proctor guided practices by well-experienced surgeons are key elements in adopting new approaches that can offer true benefits to selected patients. Preoperative images help us to plan carefully and avoid potential complications. Starting with simple, isolated and straightforward procedures is always the rule of thumb to negotiate the learning curve of new techniques. From our experience, our parasternal approach is an easily learned and performed procedure.<sup>[6]</sup> Our long-term follow up also proves that this a durable procedure.

### Authors' contributions

K.M. Chiu contributed solely to this article.

### Financial support and sponsorship

None.

### Conflicts of interest

There are no conflicts of interest.

### Patient consent

Patients' informed consent were obtained before operations.

### Ethics approval

This study is waived for ethical approval from the author's institution review board.

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# Single-incision laparoscopic closure of inguinal hernia in female children: a simplified technique

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## ABSTRACT

### Article history:

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### Key words:

Single incision,  
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laparoscopic hernia repair,  
simplified technique,  
female hernia

**Aim:** Single-incision laparoscopic hernia repair (SILHR) is a popular technique, especially in female children, as it reduces the number of incisions while achieving a better cosmetic outcome. However, intracorporeal suturing and knotting remains a major obstacle during SILHR and it requires a relatively long learning curve. Conversely, extracorporeal suturing and knotting is straightforward, though it has several drawbacks. The purpose of this report is to describe a simple technique for SILHR in female children. **Methods:** Between May 2014 and December 2016, 100 girls with 120 hernias of the Canal of Nuck (34 with right-side inguinal hernia, 46 with left-side hernia, and 20 with bilateral hernia) underwent SILHR. The opened internal inguinal ring was closed using a complete purse string suture fashioned by epidural needle with intracorporeal knot tying. The main outcomes were feasibility, operative time, complications and cosmetic outcome. **Results:** The mean age was  $2.0 \pm 2.2$  years, and the mean operative time was  $8.0 \pm 2.2$  min for unilateral hernia repair and  $16.0 \pm 4.3$  min for bilateral cases. All cases were completed laparoscopically without intraoperative complications. During follow-up, there were no recurrences and umbilical scars were almost invisible. **Conclusion:** This simplified technique is feasible, quick, achieves better cosmetic results in female children, and avoids the drawbacks of extracorporeal knotting.



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## INTRODUCTION

Over recent years, a variety of techniques have been used for laparoscopic inguinal hernia repair in children, involving both extra- and intracorporeal suturing and knotting.<sup>[1,2]</sup> Single-incision laparoscopic hernia repair (SILHR) is an excellent and increasingly popular technique for children, and is supported by a number of publications describing its feasibility, efficacy, and outstanding cosmetic results.<sup>[3-6]</sup>

However, intracorporeal suture tying and knotting remains one of the most difficult and complicated step for most pediatric surgeons during SILHR, and remains the main causative factor for increased operative time. It is possible that the apparent cause for this obvious problem is that the instruments used for SILHR lie almost parallel to each other without triangulation (this triangulation creates an environment in which instruments can be moved comfortably during conventional laparoscopic surgery), thus making intracorporeal suture tying and knotting a very challenging task.<sup>[7-10]</sup>

During SILHR, many pediatric surgeons prefer extracorporeal suture ligation with subcutaneous knotting, under laparoscopic guidance. However, some authors have reported that this approach may be associated with some drawbacks, such as stitch sinus, infection, granuloma, puckering or dimpling of the skin and entrapment of the abdominal wall muscles with the suture, which may result in later loosening of the suture with an increased recurrence rate.<sup>[11-15]</sup>

Here, we introduce a simplified technique for SILHR in female children. This technique entails the use of gauge-18 epidural needles (EN) to fashion a complete purse string suture around the internal inguinal ring (IIR), accompanied by intracorporeal knotting using extracorporeal self-sliding clinch knot. We have named this as the “Helal technique”. Our purpose here, is to demonstrate the feasibility, safety and efficacy of this new surgical technique.

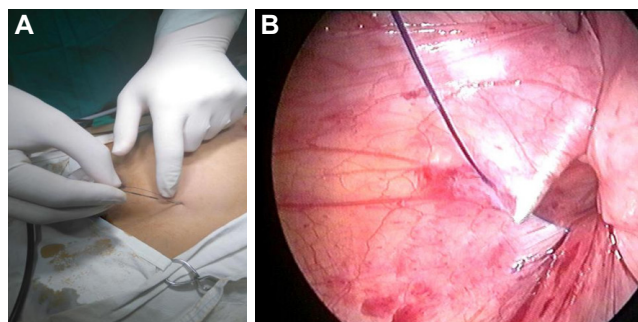
## METHODS

This prospective study was conducted and followed-up at the Pediatric Surgery Department, Al-Azhar University Hospitals, Cairo, Egypt, between May 2014 and December 2016. A total of 120 inguinal hernias were repaired with SILHR in 100 female children. Inclusion criteria included female gender and unilateral or bilateral inguinal hernia. Exclusion criteria included recurrent hernia, hernia in morbid obese female child, complicated hernia (e.g. incarcerated ovary), and children who could not tolerate pneumoperitoneum

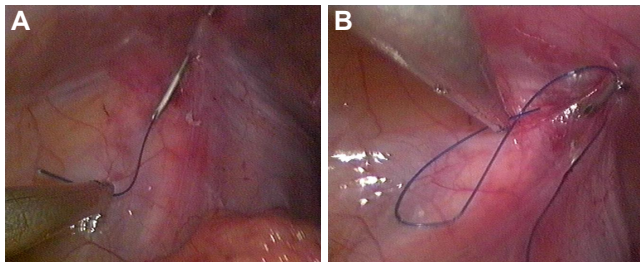
(e.g. those with congenital heart disease). All children were subjected to full history taking, thorough clinical examination, and routine preoperative investigations (complete blood count, bleeding time, clotting time, and liver and renal profiles). All cases were performed by the author and his team. The primary outcome measurements included feasibility of the procedure, operative time, complications and cosmetic outcome. The secondary outcome measurements included parent satisfaction with the cosmetic results.

## Operative steps

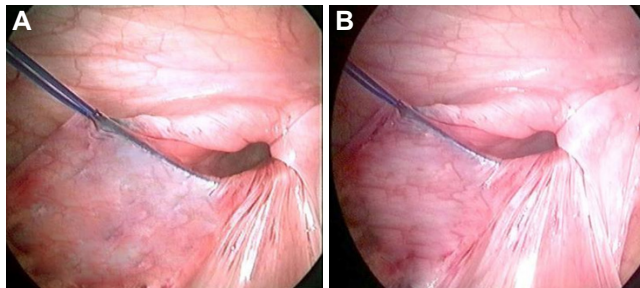
1. The patient was placed in a supine Trendelenburg's position with tilting to the opposite side of the hernia.
2. A longitudinal trans-umbilical incision (0.5-0.9 mm) was made with elevation of the skin flaps.
3. A camera port was inserted for the telescope (5 mm, 30 degree) and a 3-mm laparoscopic needle holder was inserted through a separate facial incision within the same umbilical skin incision.
4. A pneumo-peritoneum was created and pressure was adjusted according to age (from 8 to 10 mmHg).
5. The pelvis, adnexa and both IIRs were carefully inspected. If a contralateral patent processus vaginalis was identified, it was repaired.
6. An EN (gauge-18) was threaded with a 3/0 prolene suture and introduced percutaneously at the level of the IIR [Figure 1A].
7. The EN was manipulated extraperitoneally around the margin of the IIR starting at 3 o'clock meridian (on both sides). It was then advanced along the lower margin of the IIR beneath the peritoneum to breach the peritoneum at 9 o'clock meridian on the margin of the IIR [Figure 1B].



**Figure 1:** (A) An epidural needle (EN) threaded with a 3/0 prolene suture was percutaneously introduced into the extra-peritoneal cavity by direct puncture of the anterior abdominal wall; (B) the EN was then advanced in an extraperitoneal direction to complete a purse string around the internal inguinal rings



**Figure 2:** (A and B) Both ends of the thread was picked out from the epidural needle using a trans-umbilical laparoscopic needle holder and pulled outside of the abdomen



**Figure 3:** (A and B) Complete extra-peritoneal purse string around the internal inguinal ring

8. The end of the thread was picked out from the EN using a trans-umbilical laparoscopic needle holder, and pulled outside of the abdomen [Figure 2A]. The thread was held outside of the abdomen and the needle holder was reintroduced.

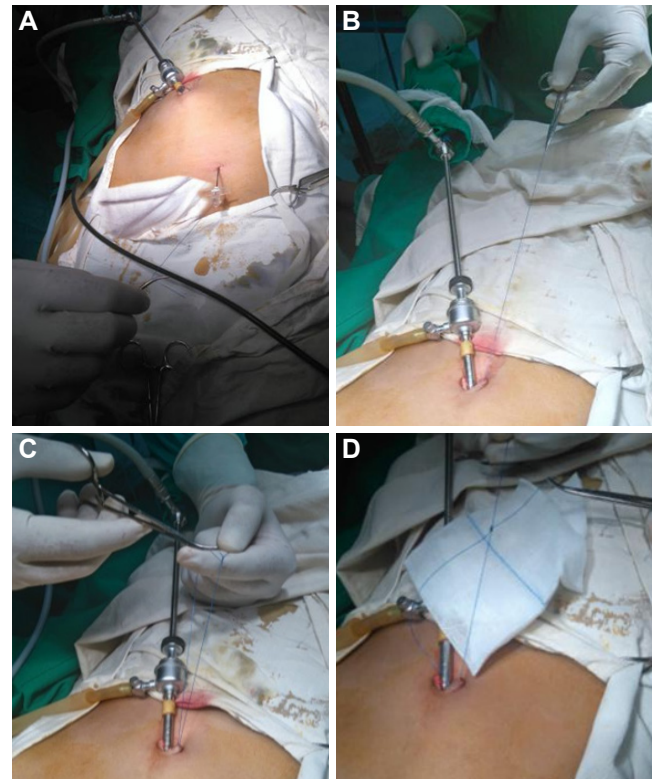
9. The EN was withdrawn backwards to the starting point at 3 o'clock meridian, and then advanced along the upper margin of the IIR beneath the peritoneum to come out from the same peritoneal puncture at 9 o'clock meridian, where the other end of the thread was picked out of EN by the needle holder and also pulled outside of the abdomen [Figures 2B and 3].

10. The suture was tied using a self-sliding extracorporeal clinch knot, as described by Weston,<sup>[16]</sup> and this was reinforced with single instrument intracorporeal knot tying, as described by Ismail and Shalaby [Figures 4 and 5A].<sup>[13]</sup>

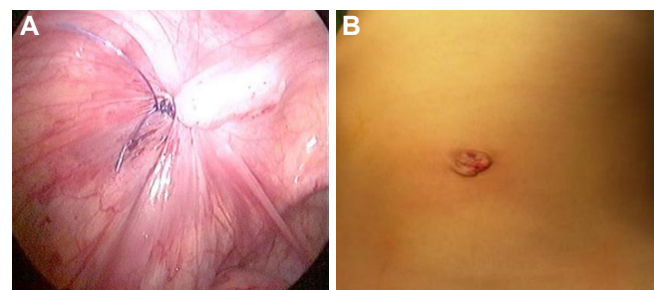
11. Finally, the umbilical incision was closed [Figure 5B].

## RESULTS

One hundred female children with 120 inguinal hernias



**Figure 4:** (A and B) The end of the thread was pulled out through the trans-umbilical incision; (C and D) the self sliding extracorporeal clinch knot was tied



**Figure 5:** (A) Complete closure of the internal inguinal ring with intra-corporeal knotting; (B) finally the umbilicus was closed leaving an almost invisible scar

underwent SILHR. Demographic, preoperative, intraoperative, and postoperative data were collected and analyzed. The mean age was  $2.0 \pm 2.2$  years (range 6 months to 7 years). The demographic data of all patients are shown in Table 1. All cases were completed laparoscopically. The mean operative time was  $8.0 \pm 2.3$  min for unilateral cases and  $16.0 \pm 4.3$  min for bilateral cases. All patients achieved full recovery

**Table 1: Patient demographic data**

No. of patients	Gender	Age		Clinical presentation		Operative presentation	Complications	
		Mean	Range	Left inguinal hernia	Right inguinal hernia	Bilateral inguinal hernia	Intraoperative	Postoperative
100 (100%)	Female	$2 \pm 2.2$ years	6 months - 7 years	46 (46%)	34 (34%)	20 (of clinically left)	Nil	Nil

without intraoperative or postoperative complications. There was no recurrence. All children returned home on the same day. The mean hospital stay was  $7.79 \pm 1.28$  h (range 5-19 h). All parents were satisfied with the cosmetic outcome with an almost invisible scar. The mean postoperative follow-up period was 12 months (range 8-24 months).

## DISCUSSION

In 2015, we published a paper describing a novel technique for the repair of inguinal hernia in female children using a single laparoscopic instrument (needle holder).<sup>[12]</sup> However, we observed that the entry for this single instrument required a separate port in the abdominal wall, plus the camera port. As a consequence, this particular technique was not cosmetically optimal for a female child. Moreover, closure of opened IIR using a single laparoscopic instrument technique requires special laparoscopic skills to manipulate the needle easily around the IIR, and to develop the back-hand movement skills, with protection of the inferior epigastric vessels. Consequently, this technique requires a long learning curve.

Therefore, we continued our research in order to identify a single-incision access technique, which was more feasible for children and required a relatively short learning curve. This research culminated in the novel technique described in this paper. From the author's point of view, there is no doubt that this new technique represents a simpler procedure with a relatively short learning curve. Moreover, the new technique achieves better cosmetic outcomes in female children.

Over recent years, laparoscopic inguinal hernia repair for children has progressively developed from conventional laparoscopic surgery with 2 working instruments (with or without ports) and a camera port, to become single laparoscopic instrument repair with a camera port. Most recent studies have described and supported the feasibility and safety of pediatric single-port and single-incision pediatric laparoscopic hernia repair.<sup>[12,17-19]</sup>

However, there is still debate over which laparoscopic technique is the most appropriate and beneficial for pediatric hernia repair. Becmeur *et al.*<sup>[20]</sup> concluded that pediatric inguinal hernia must be treated in the same manner as that carried out for open surgery; this is achieved with complete separation of the sac at the IIR, and suturing of the peritoneum at the IIR. Giseke *et al.*<sup>[21]</sup> further reported that laparoscopic hernia repair in children should be a reproduction of the open inguinal approach with dissection of the sac at the IIR. In 2015, Lee *et al.*<sup>[22]</sup> reappraised one critical concern in their

publication entitled "A purse-string suture at the level of internal inguinal ring, taking only the peritoneum leaving the distal sac: is it enough for inguinal hernia in pediatric patients?" These authors concluded that laparoscopic purse-string suture of the hernia sac at the IIR, taking only the peritoneum and leaving the distal sac intact, is a safe, effective, and reliable course of treatment for pediatric inguinal hernia.

At the moment, SILHR appears to be taking the upper hand as a very important development in minimal access surgery, with most pediatric surgeons tending to use the simple and rapid percutaneous extraperitoneal closure of opened IIR with subcutaneous suture knotting. However, the major concern of percutaneous closure is the unavoidable inclusion of tissues between the skin and the hernia sac, including nerves and muscles, which may result in unnoticed injury and may be reflected by a subsequent increase in postoperative morbidity.<sup>[23-26]</sup> Moreover, the subcutaneous sutures may cause stitch sinus, infection, granuloma, puckering or dimpling of the skin; or it may cut through the muscles with subsequent loosening of the suture around the IIR, thus resulting in the recurrence of hernia.<sup>[27-29]</sup> Therefore, from the author's point of view, one of the major advantages of our new technique, is that the knot was sutured and tied using an extracorporeal clinch knot with an intracorporeal knotting. Thus, we avoided subcutaneous placement of the suture and associated complications.

Yang *et al.*<sup>[29]</sup> reported that the rate of recurrence following laparoscopic inguinal hernia repair in children was still a matter of controversy. Shalaby *et al.*<sup>[30]</sup> published a description of 150 patients treated with SILHR, and reported one case of recurrence and three cases of hydrocele. It appears that the cause of recurrence may have been related to a weak point (the superficial purse) in the area above the vas and vessels. Helal<sup>[12]</sup> published an investigation of a further series of 60 girls with 68 hernias, treated by laparoscopic single instrument closure of inguinal hernia, and reported only one case of recurrence (1.47%). Furthermore, Helal<sup>[12]</sup> explained that this recurrence may have occurred due to skip areas around the IIR during his learning curve.

In the present study of SILHR, we observed no recurrence during the postoperative follow up (up until the time of writing). We believe that this is because we used an EN to easily fashion a complete, secure and tight purse string suture around the IIR with intracorporeal knotting (i.e. no abdominal wall muscles were included within the knot) without any skip areas (no vas or vessels need to be protected in female children). Furthermore, we performed SILHR after gaining significant prior experience in performing different laparoscopic

procedures for inguinal hernia repair.

One of the major limitations of SILHR is that the instruments lie almost parallel to each other without triangulation (unlike conventional laparoscopic surgery).<sup>[16]</sup> In our new technique, the percutaneous insertion of a complete purse string suture using EN is a straightforward procedure for female children (no vas or vessels need to be protected) with easy retrieval of thread from the EN. Moreover, withdrawal of the thread from the same facial opening of the needle holder entry acts as a guide for reinsertion of the needle holder and avoids trial and error during blind re-entry. Furthermore, the use of a laparoscopic needle holder allows us to stretch the peritoneum in front of the EN and thus avoid the presence of any skip areas. The use of a self-sliding clinch knot avoids the need for a tie pusher, unlike many other extracorporeal knots.<sup>[16]</sup> One well-known disadvantage of laparoscopic knot tying is the reduced sensation of the tension applied to the tissues and the knot. Tightening of the knot in our technique, using a self-sliding extracorporeal clinch knot, and its reinforcement with a laparoscopic single instrument tie, preserves tactile sensation and allows for accurate adjustment of the tension applied to the tissues, thus ensuring the firm and secure closure of the IIR.<sup>[11,12,16,19,20,30,31]</sup>

In conclusion, this simplified technique is feasible, only requires a short operative time, does not lead to recurrence, and yields better cosmetic outcomes in female children. In addition, this technique extends the benefits of single-incision endosurgery and avoids the drawbacks of extracorporeal knotting.

### Author's contributions

A.A. Helal contributed solely to this paper.

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None.

### Conflicts of interest

We have no conflicts of interest and no financial disclosures.

### Patient consent

Written informed consent was obtained from parents.

### Ethics approval

The study protocol was approved by the ethical committee of our hospital.

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# The influence of total bowel length on gastric bypass outcomes

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Dr. Bekheit received his surgical training in several internationally renowned institutions and by eminent surgeons in the field of minimally invasive, bariatric, and HBP surgery. Dr. Bekheit is a Board Member of the Minimal Invasive Bariatric Surgery Program delivered by the Alexandria Endoscopic Association (ALEXEA), where many other courses are delivered. He founded a few educational programs for the Faculty of Medicine, the University of Alexandria during his appointment as teaching assistant in the early stages of his training. Currently, he is practicing in surgery in the Aberdeen Royal Infirmary and conducting first class research with an honorary contract at the University of Aberdeen. He sits on the editorial board of several peer-reviewed journals.

Bariatric surgery is the only long-term solution to obesity-related comorbidities when other conservative measures have failed.<sup>[1,2]</sup> Diversional surgeries often offer the highest success rates when compared to restrictive procedures such as sleeve gastrectomies or gastric banding.<sup>[3]</sup> Of these, the Roux-en-Y gastric bypass (RYGBP) is the commonest diversional procedure because though it does not achieve quite the same amount of weight loss as the biliopancreatic diversion and duodenal switch, it does offer a better complication rate and mortality.<sup>[4,5]</sup>

Gastric bypass achieves weight loss not only by restriction of gastric capacity and therefore earlier

patient satiety but also by the diversion of digestion leading to malabsorption of nutrients and modulation of the metabolic system. It is a combination of these effects that contribute to its success rate in both weight loss and reversal of comorbidities.<sup>[6]</sup>

There are variations between the constructed limb lengths of RYGBPs described in the literature, and these are designed by the surgeon's preference.<sup>[7,8]</sup> Most surgeons create a restricted gastric pouch from which the alimentary limb (AL) (100-150 cm) follows to join the biliopancreatic limb (BPL) (usually 50-100 cm in length) to form the common limb. The remaining common limb (CL) length is of an indeterminate



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length based on the length of small bowel left, and the patient's anatomy,<sup>[7]</sup> and this configuration is known as the proximal or standard gastric bypass.<sup>[9,10]</sup> A distal gastric bypass differs by having a fixed CL length of 100-150 cm which leaves a variable AL and BPL length that may end up being very long or conversely very short.

The hypothesis is that a distal bypass can lead to better weight loss outcomes due to a longer diversion of the digestive tract and a shorter section of common bowel for absorption.<sup>[11]</sup> The small intestine has a huge variability in length among patients and can vary between 300 to 1,000 cm.<sup>[12]</sup> Because of this, the CL length can theoretically range from 50 to 850 cm in a proximal gastric bypass as intestinal lengths are not routinely measured before reconstruction of the digestive continuity.

Despite the RYGBP's success rate in reversing obesity and its comorbidities, the outcomes can be variable. An RYGBP may fail when its primary outcome is not achieved, whether this is resultant from either an insufficient weight loss from what is predicted<sup>[13-15]</sup> or the patient regains weight shortly after the procedure is performed.<sup>[16-18]</sup> Conversely, other patients may develop significant malnutrition when there is not enough absorption of key nutrients<sup>[19-21]</sup> which may even lead to a functional short bowel syndrome which despite its rarity is a far more severe complication and can occur more frequently the shorter the CL length is.<sup>[22-24]</sup>

Studies have assessed the effect of the limb lengths on weight loss, while others have addressed the malnutrition effect. Many studies concur that the CL length and AL length do not affect the amount of potential weight loss that a patient can achieve<sup>[25-28]</sup> though Tran *et al.*<sup>[29]</sup> has suggested the use of a distal bypass is an effective revision for a failed loss of weight on a standard bypass. There is certainly a range of results on whether proximal or distal bypasses have more pronounced effects on the metabolic and endocrine systems as reported by Risstad *et al.*<sup>[9]</sup> and Ramos *et al.*<sup>[30]</sup> Distal bypasses may also be related to increased rates of complication.<sup>[10,31]</sup> Longer BPL lengths have been found to result in both higher weight loss and malnutrition rates with the two are often correlating.<sup>[21,32,33]</sup>

The reasons for failure may have a technical component and could be related to constructed bowel length from diversion, but studies by Maleckas *et al.*,<sup>[16]</sup> Shantavasinkul *et al.*<sup>[34]</sup> and Perrone *et al.*<sup>[35]</sup> allude to a more complex etiology and suggest patient factors play a significant role in determining the outcome. What is

currently unknown is whether there is an impact of the total/bypassed bowel length on the incidence of complications and failure. A patient's preoperative total bowel length may indeed have an effect on the potential weight loss achievable with an RYGBP and also whether they are at risk of regaining weight with a very long bowel that minimizes the effect of the diversion or developing malnutrition with a very short one that has the very limited absorptive capacity. As such knowing a patient's total bowel length may be useful in the future as a predictor of outcomes and would be useful in patient selection when choosing diversion options and limb lengths to maximize benefit and minimize adverse outcomes.

Future studies aim to set a standard into intestinal lengths for optimal outcomes,<sup>[11]</sup> but very few studies seek to examine the patients' total bowel length and whether this has an influence on the success rates of proximal and distal bypasses.<sup>[28]</sup> Navez *et al.*<sup>[26]</sup> and Savassi-Rossa *et al.*<sup>[36]</sup> show that there may be no relation between CL length and weight loss though there is a small sample size and follow-up time to assess weight regain or the occurrence of malnutrition is short.

Further studies are required to assess if bowel length has a long-term influence on outcomes and whether routine measurement of bowel length can optimize this. Several studies have mentioned the technical challenges in measuring bowel length<sup>[37-39]</sup> and in the superobese patient, a high level of visceral fat will only complicate this further. A standardized method of bowel measurement should, therefore, be agreed upon to make accurate comparisons possible, and this could be a combination of preoperative radiographic bowel measurements and intraoperative laparoscopic measurements.

These studies have the potential to answer a fundamental question on the way we perform diversion surgeries in an attempt to optimize the outcome. There is no doubt that there are several other variables that might influence the outcome - such as genetic factors. However, we believe that the question raised - which cannot be ignored - is at the core of understanding the pathophysiology of the procedure, which is not fully understood until now.

## Authors' contributions

Manuscript concept: M. Bekheit

Literature search and drafting: V. Quan, F.P.M. Cooper

Critical revision and approval: V. Quan, F.P.M. Cooper, M. Bekheit

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## Conflicts of interest

There are no conflicts of interest.

## Patient consent

Not applicable.

## Ethics approval

Not applicable.

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# Anatomical relationship between Kambin's triangle and exiting nerve root

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## INTRODUCTION

Percutaneous endoscopic lumbar discectomy (PELD) was introduced by Kambin and Brager<sup>[1]</sup> and Hijikata *et al.*<sup>[2]</sup> prior to the 1980s and is a minimally invasive technique for lumbar disc herniation. Many clinical reports have indicated that PELD is preferable to conventional open techniques.<sup>[3-5]</sup>

There are three approaches for PELD: transforaminal, interlaminar, and posterolateral. Transforaminal and interlaminar approaches are mainly used for intracanal disc herniation. The transforaminal approach is also used for foraminal disc herniation, while the posterolateral approach is used for extraforaminal lesions. The transforaminal approach is typically used to access intervertebral discs through the foramen without sacrificing the paravertebral muscles and facet joint. In 1983, Kambin and Gellmann<sup>[6]</sup> described a safety triangle called "Kambin's triangle" for the

transforaminal approach.

Kambin's triangle is a three-dimensional anatomical right triangle located over the dorsolateral intervertebral disc of the lumbar spine. This concept is widely accepted for not only PELD but also epidural injection and interbody fusion techniques. In an L4-L5 disc herniation, the L4 nerve root forms the hypotenuse of the Kambin's triangle, which maybe at potential risk for injury.

## ANATOMY OF KAMBIN'S TRIANGLE

Kambin's safety zone is the area surrounding the superior endplate of the inferior vertebral body, superior articulating facet, and exiting nerve root (ENR) [Figure 1]. Based on specimens from cadavers, this review discusses the anatomical orientation, area, and diameter of Kambin's safety zone and limitations of the transforaminal approach.<sup>[7]</sup>



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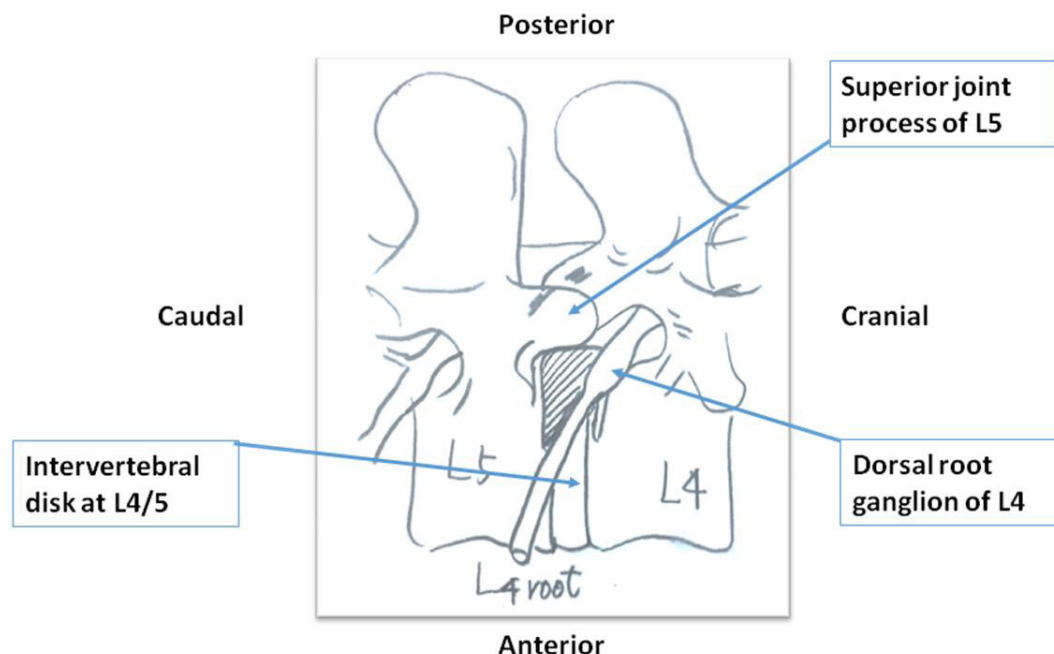
In 1995, Mirkovic *et al.*<sup>[8]</sup> clarified that a working cannula could be safely placed in line with the medial one-third of corresponding pedicle. Min *et al.*<sup>[9]</sup> reported an average distance of 11.6 mm between the ENR and the superior articulating process. Hoshida *et al.*<sup>[10]</sup> also measured the height and width of 16 Kambin's safety triangles from 2 cadavers by closely penetrating intervertebral discs using a standard posterolateral approach with a Kirschner wire under fluoroscopic assistance. At the time of open dissection, there was no ENR injury from the wire insertion. They showed averaged Kambin's safety zone areas of 60, 71.5, 93.5, and 108 mm<sup>2</sup> at L1-L2, L2-L3, L3-L4, and L4-L5 levels, respectively. Hardenbrook *et al.*<sup>[11]</sup> also analyzed Kambin's safety zone areas by removing the top of a superior facet from 8 fresh-frozen female cadaveric specimens, and reported averaged areas of 115, 120, 119, and 116 mm<sup>2</sup> at L1-L2, L2-L3, L3-L4, and L4-L5 levels, respectively. They concluded that Kambin's working triangle was a relatively large area for minimally invasive transforaminal interbody fusion. On the other hand, Ozer *et al.*<sup>[12]</sup> performed both cadaveric measurements and surgical observations of Kambin's safety zone. They observed only 17.6% and 10.8% of "wide" safety zones of cadaveric measurements and surgical observations, respectively and concluded that there were large variations in Kambin's triangle. Furthermore, there was no space inside the triangle in approximately one-third of L2-L5 in cadaveric (15/48) and surgical specimens (11/34). They suggested using a partial superior facetectomy to avoid ENR injury [Figure 2].

Arslan *et al.*<sup>[13]</sup> also showed anatomical variation in the distance between the ENR and pedicle and the height and width of intervertebral foramen from L1-L2 to L5-S1 in 14 male formalin-fixed cadavers.

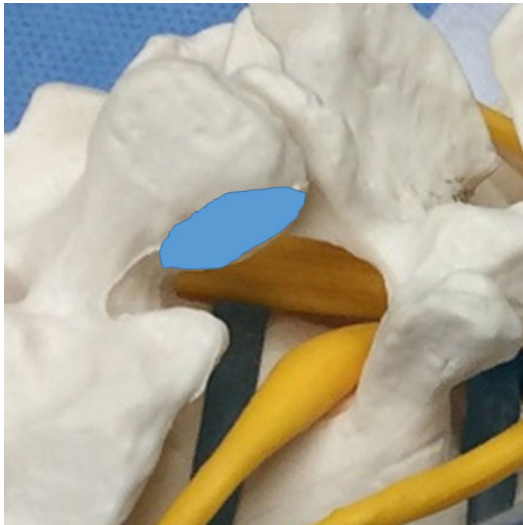
## ENR INJURY

ENR injury is the most devastating complication of transforaminal PELD. In 2002, Yeung and Tsou<sup>[3]</sup> reported on surgical outcomes and complications. The rate of postoperative dysesthesia (POD) was 1.9% (6/307) with a 6-mm scope. Ruetten *et al.*<sup>[4]</sup> reported POD in 1 (1.8%) out of 41 patients with an 8-mm cannula under general anesthesia. Ahn *et al.*<sup>[14,15]</sup> reported that POD occurred as a complication of PELD under local anesthesia and sedation in 4.7% of recurrent herniated cases and in 6.7% of upper lumbar lesion cases. In their early case series of transforaminal PELD with an 8-mm diameter scope, Abe *et al.*<sup>[16]</sup> reported that 2 (9.6%) and 4 (19%) of 22 patients experienced POD after surgery under general and local anesthesia, respectively. Although they used a contrast material injection technique in the epidural space to determine the ENR anatomy during surgery, it did not prevent nerve irritation.<sup>[17]</sup>

Choi *et al.*<sup>[18]</sup> evaluated clinical-radiological features indicating a risk of root injuries for proposed transforaminal endoscopic discectomy. In their retrospective analysis of 233 patients treated with PELD for lumbar disc herniation, 20 (4.7%) patients exhibited postoperative exiting root-related dysesthesias or motor weakness. They did not



**Figure 1:** Kambin's safety triangle (shaded area) at L4/L5



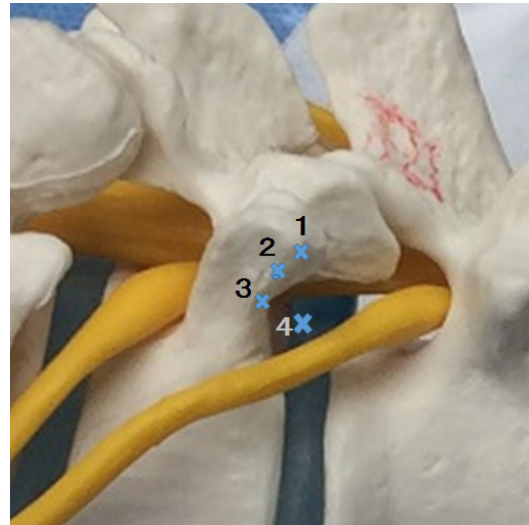
**Figure 2:** Partial facetectomy to widen transforaminal space. An area of partial facetectomy is colored by blue

describe about the type of anesthesia used during the surgery. Magnetic resonance imaging (MRI) revealed that patients sustaining ENR injuries had a shorter distance between the ENR and the lower facet. They recommended that measuring this distance during preoperative MRI studies may allow surgeons to choose more optimal approaches. Recently, the diffusion tensor imaging technique has been used for the structural and functional diagnosis of lumbar nerve damage before and after surgery.<sup>[19-23]</sup>

Regarding surgical procedures, Cho *et al.*<sup>[24]</sup> demonstrated that their floating technique reduces complications during PELD. In their series of 154 patients, none had ENR injury. They recommended that the guide needle should be attached to the lateral aspect of the superior facet for the insertion of dilators and cannula before accessing the annulus.

Sairyo *et al.*<sup>[25]</sup> have reported on their initial 100 cases of PELD under local anesthesia. In this series, 2 patients (2%) complained of leg pain and dysesthesia 2 days after surgery, although the pain disappeared within 3 months after conservative treatment. They proposed 2 etiologies of POD, direct exiting nerve injury with the needle and/or cannula insertion and irritation of the dorsal root ganglion due to compression by the cannula. They also emphasized that the guide needle should touch a caudal pedicle before needling Kambin's triangle, as this "walking technique" prevents POD [Figure 3].

Using a surgical bur through the working portal of the endoscope, full endoscopic partial laminectomy has been performed more frequently. Converting from a translaminar to an interlaminar approach is a reasonable option. In 2015, Li *et al.*<sup>[26]</sup> evaluated



**Figure 3:** Walking technique. A guide needle is place on the superior facet (X1). Then surgeon moves needle on the X2, X3, and X4 point to avoid touching the exiting nerve root

the efficacy of fully endoscopic interlaminar L5-S1 discectomy in 72 patients with axillary, ventral, or shoulder types/locations of disc herniation. They used postoperative MRI to confirm the extent of resection. Complications included 1 disc recurrence, but there were no nerve root injuries and infections.

## DISCUSSION

PELD has the advantages of shorter hospital stay and a lower risk of infection compared with standard surgical procedures, such as open or micro discectomy for lumbar disc herniation.<sup>[27]</sup>

However, the large spine patient outcomes research trial conducted by Desai *et al.*<sup>[28]</sup> showed the frequency of nerve root injury following an open discectomy ranged from 0.13% to 0.25%. For open laminectomy or stenosis with or without fusion, it was 0% and for open laminectomy or stenosis or degenerative spondylolisthesis with or without fusion it was 2%.

Most minimal invasive surgeries for lumbar disc herniation have higher frequencies of radiculitis and/or nerve root injuries compared with conventional open surgery. ENR injury is the most devastating complication of transforaminal PELD, and rates of injury up to 20% have been reported.

ENR injury causes POD and motor weakness and reduces physical function and overall satisfaction of the patient. Therefore, the prevention of ENR injury is important for achieving a higher rate of clinical success.

Under fluoroscopy, surgeons are not able to see one border of ENR in Kambin's triangle. Careful

preoperative neurological examination combined with MRI helps to characterize three-dimensional anatomy of the Kambin's safety zone and to choose between transforaminal and interlaminar techniques.

During transforaminal endoscopic surgery, precise needle placement and the use of additional techniques, such as foraminoplasty using a high-speed bur, to widen the bottom line of Kambin's triangle would help in safely approaching intervertebral discs with short prolongation of operative time.

## DECLARATIONS

### Authors' contributions

M. Sakane contributed solely to the paper.

### Financial support and sponsorship

None.

### Conflicts of interest

There are no conflicts of interest.

### Patient consent

Not applicable.

### Ethics approval

Not applicable.

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# Establishment of the Japanese training system for percutaneous endoscopic lumbar discectomy: from the stand point of neurosurgery

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Historically, lumbar laminectomy and fusion is the traditional surgical intervention for lumbar degenerative diseases such as herniated discs or canal stenosis with or without spondylolisthesis. Although this procedure was once the most commonly performed technique, serious complications were frequent. The most common complications included instability and severe back pain due to destruction of the biomechanical stability of the lumbar spine. To compensate for these complications, an operating microscope was introduced to the field of spinal surgery in the 1950s. Currently, microdiscectomy, the so-called "micro-Love method" based on the classic technique that Dr. Love reported<sup>[1]</sup> has been established as the gold standard procedure for herniated lumbar discs. Due to the less invasive approach and the fine surgical manipulations, conventional complications dramatically decreased and surgical outcome have significantly improved.

In the beginning of this century, microendoscopic discectomy (MED) was developed by using a less than 20 mm tubular retractor.<sup>[2]</sup> Serial dilators also are used to avoid detachment of the paraspinal muscles from

the spinous process. This procedure was considered to be a less invasive, but it still requires the removal of the ligamentum flavum as well as to drill the lamina and the medial portion of the facet joint. Thus, this procedure gained popularity among some spinal surgeons, however the outcomes were not superior to the micro-Love technique. Invasion of the spinal canal by either micro-Love or MED can destabilize the spinal segment and create scarring in and around the spinal nerves. Destruction of soft tissues and bony structures is inevitable when approaching the compressed spinal nerves in micro-Love and MED.

Percutaneous endoscopic lumbar discectomy (PELD) and percutaneous endoscopic lumbar laminectomy (PELL) can avoid a significant portion of approach-related complications.<sup>[3,4]</sup> Third generation systems, such as the Yeung Endoscopic Spine System,<sup>[5]</sup> include a cannula set with slotted openings that allow instruments to exit the cannula for surgical work while a protruding tongue protects and retracts adjacent structures. The beveled cannula allows for visualization of the disc and epidural space simultaneously, thus



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facilitating the removal of subligamentous, extruded, and sequestered disc fragments. Foraminoplasty can enlarge the foramen to decompress the spinal canal and lateral recess stenosis.

PELD allows for targeted fragmentectomy of the herniated disc by performing the “inside-out” technique. Unlike the knee or hip joints, the spinal canal has no fluid cavity. Continuous irrigation of the endoscope is necessary. Basic techniques of PELD includes transforaminal approach and interlaminar approach. The route to the spinal canal or spinal nerves is different in these two approaches, and the spinal surgeons must select the best approach in each case. Once the cannula is placed inside the spinal canal, the “inside-out” technique is performed to remove the herniated disc.

In 2009, the first hands-on training course of spinal endoscopic procedure was organized at the 16th Annual Meeting of Japanese Society for Neuroendoscopy (JSNE) in Toyama (<http://www.med.u-toyama.ac.jp/nsurgery/jsne2009/>). Spinal endoscopic training was officially accepted as one of the neuro-endoscopic training courses by JSNE the following year. In 2014, the first hands-on training course was organized at the 34th Annual Meeting of Japanese Congress of Neurological Surgeons (<https://www.jcns-online.jp/en/>) in Osaka. In 2016, Neuro-Spinal Society of Japan (NSSJ) approved to start the official training system of PELD and PELL. Japanese Society Orthopedic Surgery had started the official training system prior to our training system, and there are 131 board-certified MED, surgeons and 23 board-certified PELD surgeons on November, 2016. NSSJ initially approved 5 board-certified PELD surgeons, Dr. Junichi Mizuno, Dr. Yasuhiko Nishimura, Dr. Yukoh Ohara, Dr. Yoshihiro Kitahama and Dr. Hisaaki Uchikado to initiate the training system. All of these 5 surgeons have experienced various techniques of PELD and PELL through huge volumes of knowledge and surgical techniques. Interested individuals who want to apply the certification system must be an official member of NSSJ and an official member of Japanese Society of Neurological Surgery. Ten clinical experience of either PELD or PELL as a major operator in the past are required. The lectures and hands-on training courses (both anatomical model and cadaver) are also mandatory to attend. This certification system restricts laser disc decompression or percutaneous endoscopic cervical discectomy. Additional, the member can only apply to this certification system after the number of attendance has reached the specified number of times. The applicants must send the operative summary of previous experiences of PELD and operative video record which is not edited

together with their curriculum vitae, recommendation letter by any of previously certified members to the PELD office in Shin-Yurigaoka General Hospital (office.peld@lesnm.ac). An investigation committee which consists of previously certified 5 members has a role of the judgment of the application form and the operative video record. The review process by the committee is closed to the general public but applications are strictly assessed. If applicant does not pass the examination, points for improvement will be conveyed to the applicant.

The learning curve for endoscopic spine surgery is very steep, however it can be grasped by every endoscopic surgeon with proper training. As with novel surgical procedures, the complication rate may be relatively higher during the learning curve. Proper inclusion and exclusion criteria for PELD is the first step for a successful operation. Correlation of the preoperative image and patients' subjective pain must be well understood by the surgeon who performs PELD. For the safer endoscopic operation, the importance of the intraoperative neurophysiological monitoring, anesthesia or surgical tools and techniques should be discussed for the future advances of endoscopic spine procedures.

Finally, several academic meetings related to the minimally invasive spinal operations including PELD or MED are listed below:

Less-Invasive and Endoscopic Spinal Neurosurgery (LESNM)  
 Japanese Society of Minimally Invasive Spinal Surgery (JASMISS)  
 Pacific and Asian Society of Minimally Intervention Spinal Surgery (PASMISS)  
 International Society of Minimally Intervention in Spinal Surgery (ISMISS)  
 World Congress of Minimally Invasive Spine Surgery and Techniques (WCMISSST)

## DECLARATIONS

### Authors' contributions

J. Mizuno contributed solely to this paper.

### Financial support and sponsorship

None.

### Conflicts of interest

There are no conflicts of interest.

### Patient consent

Not applicable.

## Ethics approval

Not applicable.

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# Training system of percutaneous endoscopic lumbar discectomy in China

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Percutaneous endoscopic lumbar discectomy (PELD) is by far the most minimally invasive technique for lumbar disc herniation. The small incision, short recovery time, relatively low cost and low surgical morbidity make this technique attractive for both doctors and patients. However, the technique is still unfamiliar to doctors, even those with many years of experience in spine surgery. In brief, the core of this technique is "placing the working cannula in right location and forceping out the herniated disc" based on our own experience. However, surgeons, especially beginners, sometimes get "lost" in their operations, which can result in complications such nerve damage, disc fragment left over, etc.

For many surgeons, the PELD technique is challenging to learn because the training process is different

from open surgery. In the open operation, the close collaboration between responsible and assistant doctors gives the assistant a lot of opportunities to practice during the operation. PELD operation is an one person performance, the forcep holder deal with everything and assistant does not have any real practice. However, once the beginner stands by the patient and holds the instruments, he has to rely mostly on himself. Consequently, the initial learning process is a technical challenge that it is thought to be insurmountable for some surgeons. The slow learning curve, long hands-on training time, together with insufficient training source, discourages doctors to adopt PELD technique. Therefore, quite a few doctors chose open surgery rather than PELD to treat lumbar disc herniation, because they were more confident with their open surgery techniques instead of PELD.



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After two decades of developing the surgical approach and visible technique, Yeung<sup>[1]</sup> introduced his “inside-out” technique (YESS) with a rigid rod-lens, water flow-integrated, and multichannel spinal cannula that combined a camera, light and the working channel together. He introduced this technique into China in 1997. More doctors in China began to learn the YESS technique, and they began to practice this technique more routinely. They became mentors for other surgeons in China who wanted to learn the technique. In 1999, Hoogland *et al.*<sup>[2]</sup> started a new technique of a lateral transforaminal approach to the spinal canal (THESSYS). The THESSYS technique was introduced to China in 2007<sup>[3]</sup>. After mastering the PELD technique, surgeons began to spread this technique, and a formal training system was soon developed.

Before the PELD training program, minimally invasive spinal surgery workshops involving MED technique appeared in China as early as 2004. In 2007, PELD technique was introduced in seminars. In 2010, PELD cadaver workshop advertisements appeared in meeting notices. Currently, more than 20 seminars were held in China annually. As other surgical technique trainings, the training of PELD for Chinese doctors was in two stages. The first consisted of training abroad in which pioneers were educated abroad and returned to their home country to start practice. The second was training at home in which overseas returnees introduced PELD technique and held workshops to spread the techniques. For a surgeon without a background in endoscopic surgery, seminar, cadaver workshop and hands on practice are the stepwise way to learn the technique. The important areas that help the surgeon to understand the PELD technique include a clear understanding of the anatomical structure and image pictures, accurate judgment of different tissue under endoscopy, and correct 3D positional imprints. Therefore, training and learning are heavily focused on these three aspects.

For a typical training class, teaching modules generally include an introduction of PELD technique, working cannula placement, endoscopic performance, and pitfalls that might be encountered. After lectures, cadaver workshop let each attendee practice the working cannula insertion and practice operations under endoscopy. An operation demonstration with instant explanation would come before or after workshop. Then, before practicing operations on patients, an intensive watching and hands-on operations needs to be finished. Many surgeons have expressed interest in attending a mid-career training program to focus on the PELD technique. They would have an opportunity to get hands-on operation training

during that period. In addition, some physicians have expressed a desire to invite experts to their local hospitals in order to have hands on demonstrations.

Chinese teachers have invented a couple of methods to boost the learning<sup>[4]</sup>. They guide the trainees to combine X-ray, magnetic resonance imaging and computed tomography images to 3D models to help the trainees build 3D images. The learning curve is 60 operations for the surgeon to be skilled to perform PELD<sup>[5]</sup>. In a transforaminal approach, the L4/5 technique was easier to master than L5/S1<sup>[6]</sup>.

In order to standardize the application of minimal invasive spinal surgery in China, a Spinal Endoscopic Diagnosis and Treatment Management Standards (edition 2013) was established by National Health and Family Planning Commission in 2013<sup>[7]</sup>. It established detailed requirements for medical institutions, doctors and ancillary staff. It also set the standard for endoscopic diagnosis and treatment. Most importantly, the detailed requirements of medical education and training bases for spinal endoscopic activities were clearly defined. The education bases must be:

1. Class 3A ranked hospitals;
2. No less than 10 years experience in spinal diseases treatment, with grade 4 (highest) surgical ability to perform spinal endoscopic activities; no less than 1,500 spinal cases were surgically treated in the past 3 years, and 50 cases of endoscopic operations annually;
3. No less than 2 doctors have grade 4 spinal endoscopic surgery ability, and at least 1 is a consultant doctor;
4. The institution fulfills the entire requirement including staffs, techniques, instruments and facilities;
5. The institution has held national spinal endoscopy meeting or finished national continuing medical education program.

After establishment, it served as a solid protocol, but updates are absolutely required, especially as more and more doctors obtained the ability to perform good PELD.

In China, physicians not working in spinal surgery units have performed the PELD technique in treating lumbar disc herniation. It is difficult to determine the training qualifications of the doctors who perform PELD in pain clinics. An Internet search of renowned physicians in the Pain department with their showed that some doctors switched from the Orthopedic Department and some had switched from the Anesthesia Department. In the beginning, they all received training from an orthopedist and now they collaborate with spine orthopedist to open training programs. The Association of Chinese Spine

Pain and Minimal Invasive Technique was established in 2016 and provided a new communication platform for all kind of doctors who performed PELD technique.

Although progress has been achieved, short-term training programs were still not enough for attendees to start practicing PELD. Even after a couple of training classes, many doctors were hesitant to undertake their first operation. This reason can be summed up by the Chinese expression: “easy when watching and hard while doing”. In the future, the training system should focus on “hands on” practice in the operating room.

The PELD technique has become more and more widely accepted by doctors and patients. New indications for the procedure include: spinal canal stenosis, infections, and tumors. In addition, new instruments have been developed. Systematic training or re-training of surgeons is necessary. First, the trainees need to be classified according their background and experience on endoscopic practice. For example, spinal surgeons are familiar with anatomical structure of lumbar spine and more skilled in handling possible pitfalls whereas anesthetists are familiar with punctures. Some doctors come to learn from how to perform the technique and others come to resolve problems in their practice. Accordingly, the teaching methods and courses need to fulfill the different expectations. Second, training system needs to be focused on both quantity and quality. Besides short-term training, trainees and trainers should also focus on long-term hands on clinical training. Third, training needs to be separated into basic and advanced stages. Two types of training facilities should be established. Certificated regional training center focused on short-term training including lecture, cadaver practice and operation observation. Certificated clinics focused on hands-on training. Fourth, the old protocol needs to be revised. Strict rules should be applied to standard certification

system to guide the training facilities and to make sure only qualified doctors perform PELD.

## DECLARATIONS

### Authors' contributions

D.H. Yang contributed solely to the paper.

### Financial support and sponsorship

None.

### Conflicts of interest

There are no conflicts of interest.

### Patient consent

Not applicable.

### Ethics approval

Not applicable.

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# Posterolateral percutaneous endoscopic discectomy with free-running electromyography monitoring under general anesthesia

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Percutaneous endoscopic lumbar discectomy, electromyography, lumbar disc herniation, posterolateral approach, numeric rating scale, MacNab's criteria

## ABSTRACT

**Aim:** Posterolateral percutaneous endoscopic discectomy (PLPED) is commonly performed under local anesthesia, but patients and surgeons are concerned about intraoperative uncontrolled pain. The purpose of this study was to evaluate the safety of the PLPED under general anesthesia with free-running electromyography (EMG) monitoring. **Methods:** The clinical outcomes of consecutive 48 cases of lumbar disc herniation (LDH) were evaluated by numeric rating scale (NRS) score and MacNab's criteria. Hospital stay and time to ambulation and return to work were also assessed. **Results:** NRS score for the affected leg significantly improved from 6.4 to 0.9 immediately after the operation. MacNab's criteria were 91.5% for a follow-up period of 13.5 months. Although no serious complication occurred, 3 patients (6.3%) had transient paresis that completely disappeared by 3 months. No recurrences were observed during the follow-up period. **Conclusion:** PLPED combined with EMG monitoring under general anesthesia is a safe and efficacious procedure for the treatment of LDH.

## INTRODUCTION

Local anesthesia permits the performance of the posterolateral approach for percutaneous endoscopic discectomy (PLPED).<sup>[1]</sup> In some cases, deep sedation is required for uncontrolled intraoperative pain.<sup>[2]</sup> Uncontrolled intraoperative could lead to the early termination of the operation.

Local anesthesia is helpful to avoid exiting nerve

root (ENR) injury from the patient's complaints during operative manipulation.<sup>[3]</sup> Even under general anesthesia, free-running electromyography (EMG) monitoring succeeds in preserving the lumbar plexus for the extreme lateral approach.<sup>[4-7]</sup>

The purpose of this study was to evaluate the safety of PLPED under general anesthesia with EMG monitoring.



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## METHODS

### Ethics and patient consent

This study was approved by the Ethics committee of the Omaezaki Municipal Hospital and all involved patients gave consent.

### Anesthesia and EMG monitoring

Propofol and remifentanyl hydrochloride-based general anesthesia was performed and muscle relaxants were only used at the initial stage for intubation. For free-running EMG monitoring, the needle electrodes were placed on 5 muscles (bilateral gluteus medius, hamstrings, quadriceps, tibialis anterior muscle, and gastrocnemius rect) and the EMG was continuously recorded by Neurovision® free-running EMG monitoring system (NuVasive Inc., San Diego, CA, USA) [Figure 1].

### Preoperative measurement

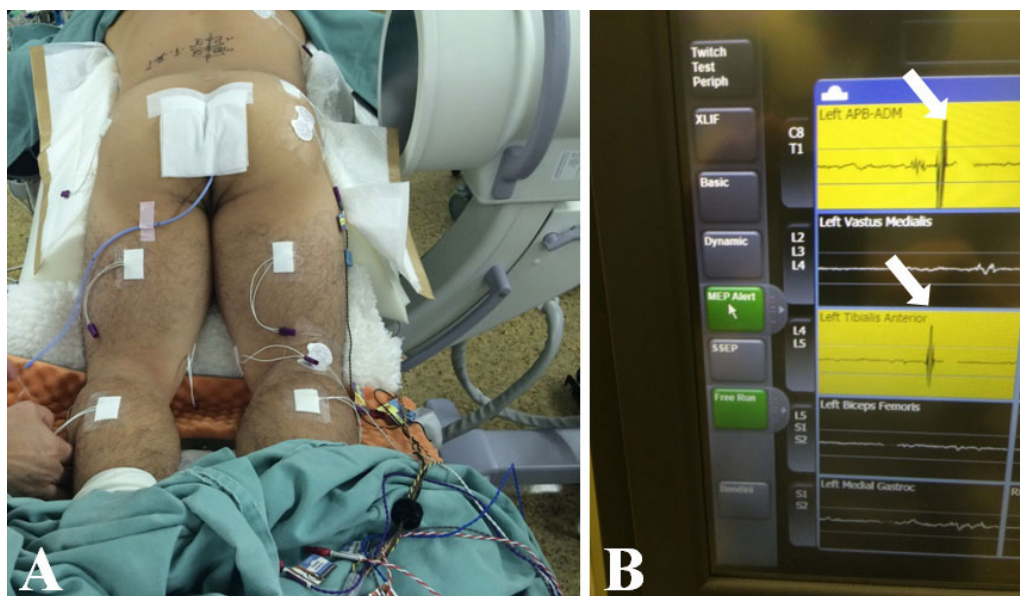
The direction and position of needle puncture were preoperatively designed by plain roentgenography (4 dimensional and 2 functional views), magnetic resonance imaging and computed tomography (CT) scan. Prone positioned CT scan enabled reproducibility and measured the actual operative situation. Axial CT image scanned paralleled with intervertebral disc provided information regarding entry points of the skin (P) and the annulus fibrosus (O) [Figure 2A and B]. A right angled triangle (P-O line is the hypotenuse) was made and designated as the intersection of the base and midline as I [Figure 2B]. The distances of P-I(x) were then calculated. Cranial (y) and dorsal (z) deviations from entry point of the annulus fibrosus (O) were also

calculated from CT and plain roentgenography (both anteroposterior and lateral views) [Figure 2B and C]. The calculated points on were drawn on patient's skin along with the anatomical landmarks (vertebral body, spinous process, transverse process, and iliac crest) to avoid incorrect puncture [Figure 3].

### Basic operative procedure

The patients were carefully log rolled into the prone position. During the operation, a fluoroscope was placed across the center of the operating table to ensure appropriate positioning. An 8-mm skin and fascia incision were simultaneously made on calculated entry points of the skin (P), and then an 18-gauge spinal needle was inserted into the annulus fibrosus. Epidurography with 1-2 mL of a contrast medium was first performed and then discography with 1.5 mL of liquid mixture (contrast medium:lidocaine:indigo carmine = 2:2:1) was performed using the same needle. Following insertion of an obturator, a 7-mm diameter working sheath was inserted. Then, an endoscope [two different systems were used in this study: VERTEBRIS lumbar-thoracic® (Richard Wolf GmbH, Knittlingen, Germany) and Spine TIP® (KARL STORZ GmbH, Tuttlingen, Germany)] was inserted and the lateral edge of the posterior longitudinal ligament (PLL) was confirmed in the center of the endoscopic operative field [Figure 4A].

Under endoscopic discectomy, herniated fragments were disconnected from the nucleus pulposus under the PLL. From the viewpoint of the PLL, preservation and consequently protection of the cauda equine, this procedure is important and an advantageous



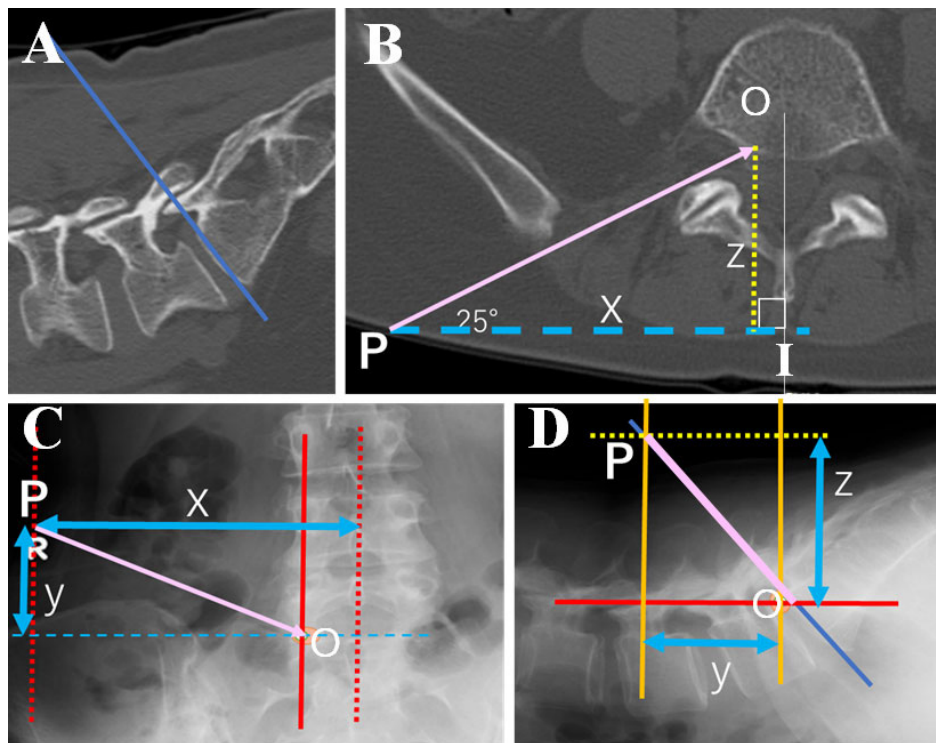
**Figure 1:** Intraoperative view of free-running electromyography (EMG) monitoring. (A) The needle electrodes are located on bilateral gluteus medius, hamstrings, quadriceps, tibialis anterior, and gastrocnemius; (B) exact waves of EMG from gluteus medius (upper) and tibialis anterior muscle (lower) are shown. Note that the waves reach the level of warning alarm (white arrows)

operative step. To make the tunnels under the PLL, it is necessary to repeat 2-3 times of hand-down technique.<sup>[8]</sup> When a piece of the fragment becomes visible from hiatus of the annulus fibrosus, it is possible to remove the fragment by an endoscope inserted from a horizontal direction. Although bleeding can cloud the view during discectomy and fragmentectomy, pin point and short time (within 6 s) bipolar coagulation using a bipolar radio-frequency electrode system (Elliquence, Baldwin, NY, USA) allows hemostasis to be achieved. Microbubbles during operative manipulation can also cloud the view. Upward and downward motion of the

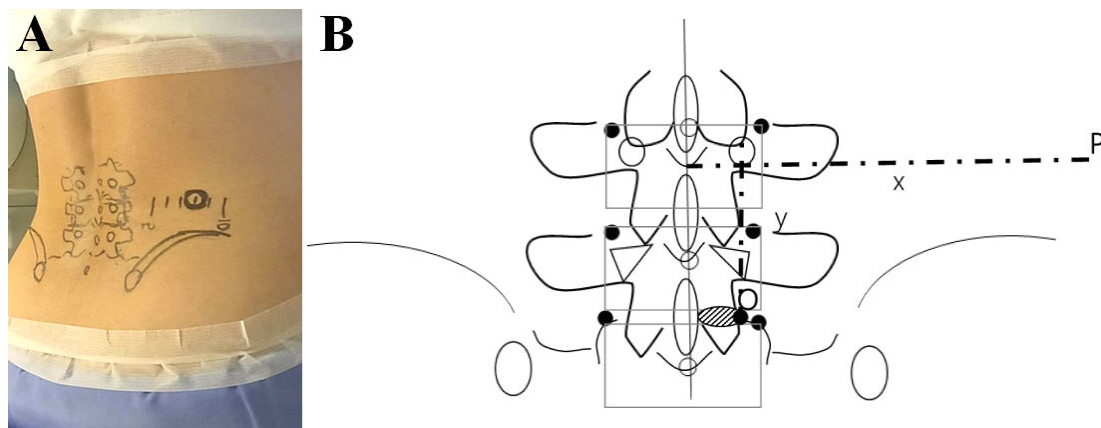
endoscope in the outer sheath removes the bubbles and provides clear visualization. After decompression, the working sheath was carefully removed, and skin was closed with a single suture.

### Optional advanced procedures

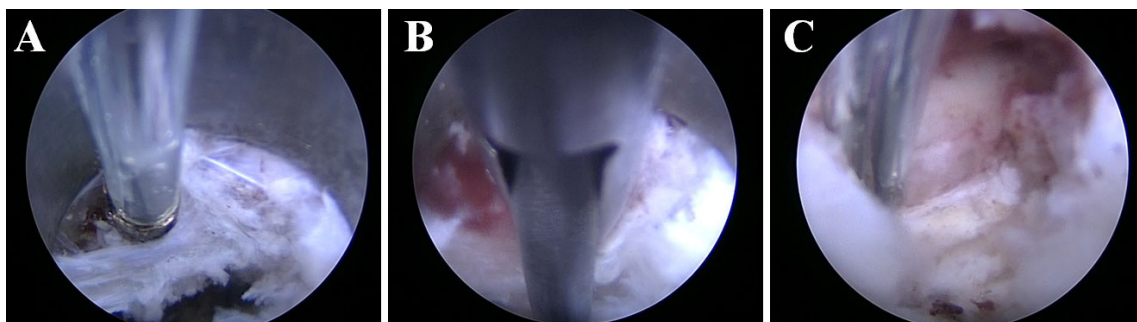
Partial facetectomy<sup>[9,10]</sup> and pediculotomy<sup>[11]</sup> were performed for total removal of the foraminal type LDH. For these techniques, an electrical high speed drill Primado 2® with Super Slim Attachment 200® (NSK-Nakanishi medical, Tochigi, Japan) was utilized. For the medial type of LDH, beak forceps were used for sharp



**Figure 2:** Preoperative design of entry points of skin (P) for L5/S1 lumbar disc herniation. (A) Axial computed tomography paralleled with target intervertebral disc (blue line) is scanned; (B) axial trajectory (pink line) is drawn with 25 degree angle against P-I line; (C, D) cranial (y) and dorsal (z) deviations of P from the entry point of annulus fibrosus (O) are also calculated



**Figure 3:** The entry points of skin (P) and annulus fibrosus (O) calculated by each distance (x, y, and z) were draw together with anatomical bone structure (vertebral body, spinous process, transverse process, facet joint, and iliac crest) (A: intraoperative photograph; B: enlarged schematic drawing)



**Figure 4:** Upper half of the operative field is epidural space, lower half of that is disc spaces, and posterior longitudinal ligament (PLL) is consisting of the boundary of these spaces (A: PLL locates the tip of bipolar coagulator); (B) sharp dissection of the lateral margin of PLL is performed by beak forceps; (C) after that total removal of medial type lumbar disc herniation is achieved

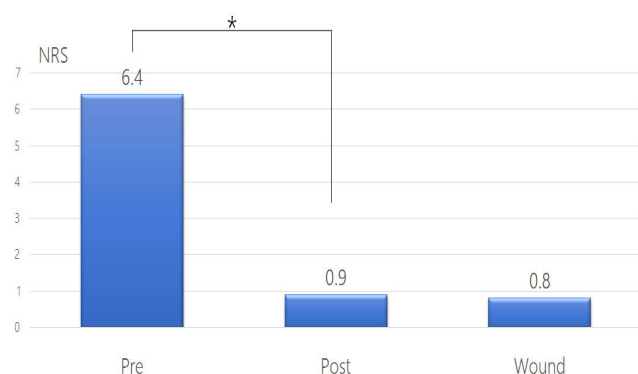
dissection of the lateral part of PLL and subsequently electro-coagulation of the PLL [Figure 4B and C].

### Date analysis

The operative outcomes were evaluated by two methods: (1) the change of pre- and postoperative numeric rating scale (NRS) scores of affected leg pain and NRS score of operative site pain;<sup>[11]</sup> (2) MacNab's criteria rating activities of daily life at the most recent examination. According to the criteria, the results were described as excellent (completely pain free), good (minor intermittent discomfort, not interfering with normal activities), fair (improvement in symptoms but persistent backache or sciatica interfering with capacity to engage in full normal activities) and poor (no change in symptoms).<sup>[12]</sup> Statistical analysis was performed with Student's paired *t*-test. *P* values < 0.05 were considered statistically significant.

## RESULTS

A single level of PLPED for consecutive 48 cases was examined. The mean age of patients (23 men, 25 women) was 50.7 (range 17-88) years old. One patient underwent PLPED at L1-2 level, 3 at L2-3, 7 at L3-4, 29 at L4-5 and 8 at L5-S or L5-6 [Table 1].



**Figure 5:** The short term operative outcome evaluated by numeric rating scale (NRS) score. Left and middle bar show the significant change of NRS score of affected leg pain (\**P* < 0.05). Right bar is NRS score of operative site on the day following the operation

The short-term operative outcome was evaluated by NRS score. Post-operatively, NRS score of the affected leg significantly improved from 6.4 to 0.9 (*P* < 0.05) [Figure 5]. To evaluate wound pain, we also examined NRS score of operative site on the day following the operation. The mean NRS score was 0.8 in the next morning [Figure 5].

The long-term operative outcome was evaluated by MacNab's criteria. The patient was asked to rate the level of well-being at an average of 13.5 months after the operation (range: 1-30 months). "Excellent" or "good" ratings were obtained from 91.5% patients. "Fair" was obtained from 8.5% patients and no patient chose "poor" as per the MacNab's criteria [Table 2].

Mean operative time was 66.7 (range 38-152) min and intraoperative blood loss was negligible in all cases. Mean time to ambulation was 7.2 (range 2-20) h. Mean hospital stay was 4.4 (range 1-33) days and the average duration of return to work was 17.2 (range 5-56) days [Table 3]. Although no serious complication occurred, 4 cases had minor transient neurological deficits. One patient (2.1%) complained of dysesthesia of affected ENR area, but the dysesthesia has been gradually improving. Three patients (6.3%) had a transient paresis that had completely disappeared after 3 months [Table 4]. No recurrence LDH was

**Table 1: Background data of the patients**

Characteristics	Data
Gender	
Male	23
Female	25
Age (years), mean (range)	50.7 (17-88)
Level	
L1-2	1
L2-3	3
L3-4	7
L4-5	29
L5-S, L5-6	8
Type of herniation	
Medial	13
Foraminal	32
Lateral	3

**Table 2: The long term operative outcome evaluated by MacNab's criteria**

MacNab's criteria	Data, n (%)
Excellent	5 (10.6)
Good	39 (80.9)
Fair	4 (8.5)
Poor	0 (0.0)

**Table 3: The commencing times of walk and work**

Characteristics	Time, mean (range)
Start to walk	7.2 (2-20) h
Hospital stay	4.4 (1-33) days
Return to work	17.2 (5-56) days

**Table 4: Complication of posterolateral percutaneous endoscopic discectomy**

Complications	Data, n (%)
Infection	0 (0)
Dysesthesia	1 (2.1)
Dural tear	0 (0)
Vascular injury	0 (0)
Transient palsy	3 (6.3)
Death	0 (0)

observed during the average 13.5 months follow-up (range 1-30).

## DISCUSSION

As presented in this study, we describe the routine performance of detailed mapmaking for needle puncture of PLPED. This map includes entry points of skin (P) and that of annulus fibrosus (O) calculated by each distance (x, y, and z). Anatomical landmarks (spine, sacral ara, and iliac crest) are drawn together with these points. The map enables one to imagine underneath anatomical structures and to estimate obstruction of the puncture by iliac crest.

Accurate needle puncture of annulus fibrosus at the initial stage of PLPED requires significant experience, as inaccurate puncture may lead to the ENR injury. The position of entry points and the direction of the puncture is carefully designed by preoperative radiological images to achieve accurate and safe puncture. Especially for posterolateral approach to L5/S1 LDH and/or high iliac crest, this map is essential. Even for the lateral type of L5/S1 LDH, which is a good indication for PLPED, high iliac crest disturbs removal of the medial part and the high grade migrated part of LDH.<sup>[13,14]</sup> Sometimes partial facetectomy and outside-in technique is required for LDH combined with foraminal stenosis to prevent ENR injury.<sup>[15-19]</sup> From our experience, these cases represented less than one third of the total cases and all successfully completed PLPED. The posterolateral approach is able to remove the migrated foraminal LDH except for the high grade upward migration at L5/S1 affected by iliac

crest.<sup>[20]</sup> The design strategy presented in this study utilizing preoperative images enables one to exclude the contraindicated cases. Those cases should be treated with the other posterior approaches, such as interlaminar and translaminar approaches.<sup>[20]</sup>

Discography and epidulography are very helpful to determine the trajectory of subsequent obturator insertion. Discography reveals the target disc space itself. Epidulography reveals the surface of the nucleus pulposus and the fragment and draws the Kambin's safety triangular zone closely located with ENR. These radiological intraoperative findings also support the preoperative mapping of the trajectory.

The complication rate of ENR injury in this study was 8.3% ( $n = 4/48$  cases). This rate seems high, however most of the complications were transient neurological deficits and not prolonged. Even under general anesthesia, the majority of the patients could walk 2 h after surgery without lumbosacral orthosis. Furthermore, the long-term operative outcome as evaluated by MacNab's criteria, no patient chose the rating of "poor". Even under local anesthesia, ENR injury has been reported and the failure rates of percutaneous endoscopic lumbar discectomy range from 5% to 22%.<sup>[21-24]</sup>

Free-running EMG monitoring has a potential to prevent ENR injury during percutaneous endoscopic lumbar discectomy. Although the EMG monitoring has been applied for to prevent motor deficits, the prevention of sensory deficits is lacking. Moreover, an exact value of free-running EMG monitoring has a diverse range amongst patients. In general, a threshold value of Neurovision® of 80  $\mu$ V is chosen. Depending on the patient's body habitus and the muscle mass, the threshold value may have to be changed (range: 10-300  $\mu$ V). One case demonstrating post-operative transient motor palsy was combined with foraminal stenosis of entry site (L5/S1). The obturator might compress the ENR at this site. No EMG changes were detected during the procedure, and the threshold of the EMG monitoring for this case should be decreased.

The end point of PLPED for the beginners is appearance of a pulsatile movement of ventral surface of dural sac just above the manipulated PLL. This situation shows at least a partial decompression that improves symptoms. Especially at the initial stage of this case series, several cases remained partial removal. However, a similar outcome was obtained even with cases compared to previously reported outcomes of total removal by microdiscectomy and microendoscopic discectomy.<sup>[25]</sup>

In conclusion, PLPED combining free-running EMG

monitoring under general anesthesia is a safe and efficacious procedure for the treatment of LDH. The strict free-running EMG monitoring under general anesthesia makes both patients and surgeons comfortable and contributes to an improvement in operative skill.

## DECLARATIONS

### Authors' contributions

Operated this series: Y. Kitahama

Suggested the idea of PED under general anesthesia: G. Matsui

Supported set-up of EMG monitoring: M. Minami, T. Kawaoka

Managed the general anesthesia of PED with EMG: K. Otome, M. Nakamura

### Financial support and sponsorship

None.

### Conflicts of interest

There are no conflicts of interest.

### Patient consent

All involved patients gave their consent forms.

### Ethics approval

This study was approved by the ethics committee of the Omaezaki Municipal Hospital.

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# Achalasia management: the South American viewpoint

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Achalasia is usually quoted as a rare primary esophageal disorder with an unknown etiology.<sup>[1]</sup> This rarity leads to frequent misdiagnosis as shown by high rate of patients with achalasia referred for antireflux surgery.<sup>[2]</sup> The two affirmatives that achalasia is rare and lacks an etiology; however, may not be true in South America. In this continent, a local disease - Chagas disease or American trypanosomiasis - caused by the inoculation of a parasite through a bug bite leads to an esophagopathy almost indistinguishable from idiopathic achalasia found in other continents, as shown in the paper by Dr. Dantas in this seminar.

Chagas disease currently affects 5-18 million people and an estimated 15-20% will develop Chagasic esophagopathy.<sup>[3]</sup> More than this, autochthonous cases of Chagas disease have been reported up to Southern United States<sup>[4]</sup> and an uncountable number

of immigrants carry the disease worldwide.<sup>[5]</sup> This high incidence of the disease in endemic areas brought a large experience in the management of these patients by South American gastroenterologists and surgeons. Unfortunately, most of this experience is published in local languages making it grey literature for international readers.

Despite several similarities, Chagas disease esophagopathy is characterized by massive dilatation of the esophagus a finding rare in idiopathic achalasia.<sup>[6]</sup> The treatment for non-advanced achalasia is well established and based on cardiomyotomy (surgical or recently endoscopic) or forceful dilatation of the cardia.<sup>[7]</sup> The therapy for end-stage disease is; however, controversial and the familiarity of these conditions by South American physicians may be useful. Some unconventional or long-forgotten surgical



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procedures are still in use in Brazil and some surgeons acquired a large experience with these techniques. Esophageal resection is also a popular choice for dilated megaesophagi.

This seminar reflects the lessons learned by different Brazilian centers highly experienced in the treatment of Chagas disease esophagopathy. Different treatment options are discussed in the light of personal experiences emphasizing aspects not frequently adopted by North American and European surgeons.<sup>[6]</sup>

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Conception and design, writing the manuscript, review of the final version: F.A.M. Herbella

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# Differences between idiopathic and chagasic achalasia

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## ABSTRACT

Idiopathic and Chagas' disease achalasia are characterized by absent or partial lower esophageal sphincter relaxation, absence of peristaltic esophageal contraction, food retention in the esophagus and esophageal dilatation. The most frequent symptoms are dysphagia, regurgitation, heartburn, weight loss and non-cardiac chest pain. The diagnosis is made by radiologic examination and esophageal manometry, which is considered the most accurate exam to characterized achalasia. In both diseases there is destruction of the esophageal myenteric plexus. Despite similarities in clinical and manometric presentation there is evidence of greater loss of inhibitory neurons of the myenteric plexus in idiopathic achalasia, whereas in Chagas' disease there is a loss of both excitatory and inhibitory neurons. Such differences, though do not affect patients' clinical presentation, and hence treatment options should be the same for both diseases.

## INTRODUCTION

Achalasia is a disease characterized by absent or partial relaxation of the lower esophageal sphincter, absence of peristaltic esophageal contraction, food retention and esophageal dilation<sup>[1,2]</sup>.

The most common symptoms are dysphagia,

regurgitation, heartburn, weight loss and non-cardiac chest pain<sup>[1]</sup>. The diagnosis is made by radiologic examination of the esophagus and esophageal manometry, which is the most accurate exam to characterized achalasia. In this test, achalasia is characterized by increased integrated relaxation pressure of the lower esophageal sphincter and absence of peristaltic contraction in the esophageal



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body<sup>[3]</sup>. Using high resolution manometry achalasia patients may be classified as type I, when there are no contractions in esophageal body during swallows, type II, characterized by pan-esophageal pressurization, or type III when there are high-amplitude simultaneous contractions in the distal esophagus<sup>[3]</sup>.

The etiology of achalasia is unknown in most cases around the world, and may be multifactorial, including autoimmune, genetic and viral factors<sup>[2]</sup>. In idiopathic achalasia, there are evidences of autoimmune, genetic and viral etiology, due to the presence of specific autoantibodies associated with neuronal damage, occasional incidence in members of the same family, and presence of previous viral infection in these patients<sup>[2]</sup>. The disease occurs with an annual incidence of 1 in 100,000 and a prevalence of 10 in 100,000<sup>[4]</sup>.

Achalasia may be caused by infection by the hemoflagellate protozoan *Trypanosoma cruzi*<sup>[5,6]</sup> which affects millions of people in Latin America and has been increasingly reported in the United States<sup>[7]</sup> and Europe<sup>[8]</sup>. This parasitic infection is the cause of Chagas' disease, and is characterized by myenteric inflammation, absent myenteric ganglion cells and myenteric neural fibrosis. These lesions are restricted to the esophagus in idiopathic achalasia<sup>[2]</sup>, and may be seen in all digestive tract in Chagas' disease<sup>[5,6,9,10]</sup>. In Latin America Chagas' disease has an incidence from 1,000 in 100,000 to 4,000 in 100,000, however the number is decreasing, as 18 million in 1991 to 5.7 million in 2010<sup>[9]</sup>. It is estimated that 300,000 infected immigrants are living in United States<sup>[9]</sup>. From 7% to 10% of the infected individuals will have achalasia<sup>[5]</sup>.

## DIFFERENCES BETWEEN IDIOPATHIC AND CHAGAS' DISEASE ACHALASIA

Although both diseases cause the same alteration in the

esophagus, including absent or partial relaxation of the lower esophageal sphincter, esophageal aperistalsis, and megaesophagus the loss of esophageal intrinsic innervations may not be the same<sup>[11-13]</sup>.

While in idiopathic achalasia neural destruction has been suggested to be more intense in inhibitory nerves than in excitatory nerves, in achalasia caused by *Trypanosoma cruzi* infection neural impairment involves both inhibitory and excitatory innervations. Consequently lower esophageal sphincter pressure is frequently increased in idiopathic achalasia<sup>[14-17]</sup> and frequently decreased in Chagas' disease<sup>[16-19]</sup> which may explain the variation in the lower esophageal sphincter pressure<sup>[20]</sup>, and the heterogeneity seen in these patients<sup>[21]</sup>.

Previous studies have reported differences in esophageal response to gastrin<sup>[14,15,18]</sup> and to atropine<sup>[15,22]</sup>. These mechanisms have not been completely elucidated in Chagas' disease<sup>[11,13]</sup> [Table 1]. Although studies on idiopathic achalasia have demonstrated a partial opening of the upper esophageal sphincter with increased residual pressure during swallow<sup>[23]</sup>, these features have not been fully demonstrated in Chagas' disease<sup>[12,13]</sup>. The time between pharyngeal contraction and proximal esophageal contraction (5 cm distance) after wet swallows in patients with megaesophagus is increased in Chagas' disease but not in idiopathic achalasia<sup>[24]</sup>. Contractions in the esophageal body are not of the same intensity, and tend to be more intense in patients with idiopathic achalasia<sup>[19,25]</sup>. In addition epiphrenic diverticula is more frequent on idiopathic achalasia (3.6% to 7.4%) than in Chagas' disease (1.5%)<sup>[13]</sup>. Also, high prevalence of circulating antibodies against M2 acetylcholine muscarinic receptor has been found in Chagas' disease patients with achalasia (84%), compared with patients with idiopathic achalasia (28%)<sup>[26]</sup>.

**Table 1: Differences between idiopathic achalasia and Chagas' disease**

	Idiopathic achalasia	Chagas' disease
Gastrin action	Hipersensitivity	Hiposensitivity
Inhibitory innervation	Loss	Loss
Excitatory innervation	Present	Loss
$\alpha$ -adrenergics receptors	Predominating	Predominating
VIP	Decreased	Not investigated
Dopamine D2 receptors	Decreased	Not investigated
LES basal pressure	Increased	Decreased
Bothinun toxin response	LES pressure reduction (32% to 45%)	LES pressure reduction (23%)
Edrophonium response	Increase in esophageal pressure	Increase in esophageal pressure
Atropine response	Present	Partial
Circulating gastrin	Normal	Increased
Anti M2R antibody	Low prevalence (28%)	High prevalence (84%)
Epiphrenic diverticula	3.6% to 7.4%	1.5%

VIP: vasoactive intestinal polypeptide; LES: lower esophageal sphincter

## CLINICAL PRESENTATION AND TREATMENT

Despite differences in pathophysiology of Chagas' disease-related and idiopathic achalasia, the clinical presentation in both diseases is the same, with dysphagia as a common complaint, affecting more than 90% of the patients. However, the symptoms occurs later in patients with Chagas' disease achalasia, a long time after the infection, and may be associated with aging-related changes in esophageal motility<sup>[10]</sup> in addition to impairment of esophageal myenteric plexus caused by the disease. In the evaluation of the water ingestion dynamics patients with dysphagia caused by Chagas' disease or idiopathic achalasia have the same behavior<sup>[27]</sup>.

Taken together, both Chagas' disease-related and idiopathic achalasia have similar clinical and radiologic manifestations, including nonrelaxing or partially relaxing lower esophageal sphincter and esophageal aperistalsis, although the pathophysiology of the diseases should not be the same. Therefore, treatment of both conditions is similar, and include pneumatic dilation of the esophageal-gastric transition, laparoscopic Heller myotomy and, the more recent peroral endoscopic myotomy (POEM)<sup>[28-30]</sup>. Drugs and botulinum toxin may be used in special cases<sup>[31]</sup> and esophagectomy for advanced cases. There is no cure for the disease, and the objective of treatment is relieve the symptoms and permit an adequate food ingestion<sup>[31]</sup>. Drugs cause benefit for a short time and have side effects which may be intense. The remission of the symptoms with pneumatic dilatation may last for 5 to 10 years, but the most effective treatment is laparoscopic or endoscopic myotomy, with an improvement of the symptoms for 6 to 10 years<sup>[31]</sup>. The patients who have a better response to treatment, pneumatic dilation or Heller myotomy, are them who has isobaric panesophageal pressurization after swallowing.

## DECLARATIONS

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R.O. Dantas contributed solely to the paper.

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# One size fits all: laparoscopic Heller's myotomy for the treatment of achalasia irrespective of the degree of dilatation

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## ABSTRACT

Laparoscopic Heller's myotomy is the most common surgical procedure to treat achalasia. It is the most accepted therapy for non-advanced stages of the disease. In the setting of advanced disease with marked esophageal dilatation or sigmoid-shaped esophagus the ideal surgical procedure is debatable. Esophagectomy is believed by several authors to be the operation of choice in these cases. Others; however, opt for less invasive alternatives. Laparoscopic Heller's myotomy has been shown to be a safe and resourceful alternative in end-stage achalasia as well.

## INTRODUCTION

Achalasia is a rare neurodegenerative primary esophageal motor disorder characterized by abnormal lower esophageal sphincter relaxation and aperistalsis<sup>[1]</sup>. The disease may be idiopathic<sup>[2]</sup> or secondary to Chagas' disease - a tropical disease common in Latin America<sup>[3]</sup>, although both forms have distinct etiology they share the same pathophysiology. End-stage disease with marked esophageal dilatation or sigmoid-shaped esophagus is; however, more frequent in Chagas' disease patients [Figure 1]<sup>[4]</sup>.

The degree of esophageal dilatation is used to grade

the severity of the disease and may be used as a guide to tailor treatment according to some authors<sup>[5]</sup>. There is no consensus on the threshold of esophageal diameter to consider the disease as end-stage. While some adopt the limit in 6 cm<sup>[6]</sup>, others prefer 7 cm<sup>[7]</sup>. In Brazil, 4 different stages of esophageal dilatation are considered<sup>[8]</sup> and end-stage disease is defined by diameter over 10 cm<sup>[9]</sup>.

Laparoscopic Heller's myotomy (LHM) is the most common surgical procedure to treat achalasia. It is the most accepted therapy for non-advanced stages of the disease<sup>[10]</sup>. In the setting of advanced disease



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**Figure 1:** Massive dilated megaesophagus in a patient with Chagas's disease esophagopathy

with marked esophageal dilatation or sigmoid-shaped esophagus the ideal surgical procedure is debatable<sup>[9]</sup>. Esophagectomy is believed by several authors to be the operation of choice in these cases<sup>[11]</sup>. However, others advocate for less invasive alternatives<sup>[6]</sup>.

This review discusses the role of LHM as the preferred treatment for achalasia irrespective of the degree of esophageal dilatation.

### LAPAROSCOPIC HELLER'S MYOTOMY ROLE IN NON-ADVANCED ACHALASIA

LHM was described in the early 1990s<sup>[12,13]</sup> and since became a widely accepted procedure for non-advanced achalasia<sup>[14]</sup>. Forceful pneumatic dilatation of the cardia is also a widespread primary therapy<sup>[15]</sup> but recent meta-analyses showed inferior results to dilatation as compared to LHM<sup>[10,16]</sup>. Indeed, a shift to LHM to endoscopic dilatation has occurred<sup>[17]</sup>. LHM is associated to low rates of complications, null mortality, and excellent and long-lasting outcomes superior to 90% of dysphagia relief in most series<sup>[18-20]</sup>. LHM is still the gold-standard treatment for non-advanced achalasia that must be used to compare the outcomes of other treatments such as the newly developed peroral endoscopic myotomy (POEM)<sup>[21,22]</sup>.

### LAPAROSCOPIC HELLER'S MYOTOMY ROLE IN END-STAGE ACHALASIA

Esophageal dilatation is more frequent in Chagas' disease esophagopathy compared to idiopathic achalasia with esophageal diameter over 10 cm found from 10% to 37% of the cases<sup>[4]</sup>. This observation may explain the lack of international literature on the treatment for massive dilated esophagi. Moreover, end-stage achalasia is defined by esophageal dilatation superior to 10 cm in Brazil, thus esophagi between 6-10 cm will not be defined as advanced in the Brazilian series and will probably undergo a LHM.

Esophageal resection is the procedure historically established for end-stage achalasia in Latin America as well as globally<sup>[11,23-27]</sup>. The number of esophagectomies for the treatment of achalasia has been decreasing after the 1990s<sup>[28]</sup> in favor of less invasive methods since esophagectomy is associated with significant complications and mortality<sup>[29]</sup>. Moreover, surgical risk is directly linked to the degree of esophageal dilatation<sup>[30]</sup>. Minimally invasive techniques decreased morbidity although they are still especially considering achalasia is a benign disease<sup>[31]</sup>. Other conservative surgical techniques were tried to minimize complications, such as cardioplasty + gastrectomy (Holt and Large procedure, known in Brazil as Serra-Dória operation<sup>[32-34]</sup>), esophageal mucosectomy and endomuscular gastric tube reconstruction<sup>[35]</sup> and laparoscopic cardioplasty<sup>[36,37]</sup>. Long term results for these procedures in a significant number of patients are lacking.

Few series evaluated the results of LHM for the treatment of end-stage achalasia [Table 1]. Some advocate LHM as the primary option for advanced diseases based on the idea that an esophagectomy could be avoided. Others believe that a massive and tortuous esophagus does not empty well if only the obstacle at the esophagogastric junction is alleviated<sup>[45-47]</sup> and found worse results for LHM when the esophagus is dilated<sup>[48,49]</sup>.

There are no prospective comparative studies comparing LHM with other techniques for end-stage achalasia. Some authors show similar outcomes (complications and dysphagia control) for LHM irrespective of the degree of esophageal dilatation<sup>[9,38,42,45]</sup>. In general, excellent results may be obtained from 54-100% of the cases, with an average of almost 80% [Table 1].

LHM is not more demanding in patients with massive dilated esophagus<sup>[38]</sup>. A careful dissection of the

**Table 1: Results for laparoscopic Heller's myotomy in patients with end-stage achalasia**

Author	n	Follow-up (months)	Mortality (%)	Good and excellent results for dysphagia relieve (%)
Patti <i>et al.</i> <sup>[6]</sup> 1999	19	NR	0	91.5
Herbella <i>et al.</i> <sup>[38]</sup> 1999	12	40	0	97.6
Faccani <i>et al.</i> <sup>[39]</sup> 2007	33	89	0	69.7
Mineo and Pompeo <sup>[40]</sup> 2004	14	85	0	72
Gaissert <i>et al.</i> <sup>[41]</sup> 2006	12	154	0	54
Schuchert <i>et al.</i> <sup>[31]</sup> 2008	22	31.6	0	NR
Sweet <i>et al.</i> <sup>[42]</sup> 2008	12	45	0	91
Scott <i>et al.</i> <sup>[43]</sup> 2009	4	NR	0	100
Shuchert <i>et al.</i> <sup>[44]</sup> 2009	24	30.5	0	62.5
Pantanali <i>et al.</i> <sup>[9]</sup> 2013	11	31.5	0	72.8
<b>Average</b>	<b>16</b>	<b>83</b>	<b>0</b>	<b>79.3</b>

NR: not reported

mediastinal esophagus allows a straightening of the axis of the organ facilitating esophageal emptying<sup>[42,44]</sup>.

Finally, LHM does not preclude a subsequent reoperation with a different technique. Recurrent dysphagia after LHM may be treated by endoscopic dilatation<sup>[50]</sup>, POEM<sup>[50,51]</sup>, redo LHM<sup>[50]</sup>, cardioplasty with or without gastrectomy<sup>[33,34,36]</sup>, or esophagectomy<sup>[10,50]</sup>. If a bigger operation is needed, the patient would need a better overall clinical and nutritional status.

## CONCLUSION

LHM is a valuable therapy for advanced achalasia although data comes from retrospective case series. The procedure is associated with a low rate of complications and good/excellent results in the majority of patients. LHM is not technically more demanding and it does not preclude a subsequent reoperation with a different technique if necessary.

## DECLARATIONS

### Authors' contributions

Acquisition of data, drafting the article, analysis and interpretation of data, final approval of the version to be published: L.M. Del Grande

Conception and design, acquisition of data, analysis and interpretation of data, drafting the article, final approval of the version to be published: F.A.M. Herbella

Analysis and interpretation of data, review for intellectual content, final approval of the version to be published: M.G. Patti

Acquisition of data, final approval of the version to be published: F. Schlottmann

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There are no conflicts of interest.

### Patient consent

Not applicable.

### Ethics approval

Not applicable.

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# Laparoscopic skills training of surgical residents: a comparison of two proficiency-based independent approaches

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## ABSTRACT

**Aim:** Current financial and work hour constraints make proctored on-site laparoscopic simulation training challenging. An independent learning approach utilizing proficiency-based training is a potential solution. The purpose of this study was to determine if an independent approach using a portable, laparoscopic training device within one's home environment could effectively train novices in laparoscopic procedural skills. **Methods:** After baseline testing, laparoscopic novices ( $n = 16$ ) were randomized to one of two study groups. The on-site group ( $n = 7$ ) received unlimited access to the workplace laparoscopic trainers and the home group ( $n = 9$ ) received portable laparoscopic trainers for home. Both groups underwent self-directed, proficiency-based training for three months then were retested. Results were compared with parametric and non-parametric statistical tests. **Results:** Baseline characteristics were similar between groups. The practice rate (56%) and practice time (range, 0.18 to 2.6 h) were poor in both groups during the training period. At post-test, the number of participants who demonstrated an improvement (86% on-site, 78% home) on the peg task was not different between groups. The successful completion of the suturing task post-test had significantly improved compared with pre-test in both groups (71% vs. 29% on-site; 44% vs. 22% home,  $P < 0.001$ ). Although the majority of participants reported it was difficult to practice on a regular basis (86% on-site, 89% home), 56% of the home group participants agreed that the at-home trainer was a helpful teaching modality. **Conclusion:** Learning of laparoscopic skills by novice trainees can be augmented by an independent learning approach using either home or on-site laparoscopic trainers. Although over half the candidates found it was useful to have the training device at home, none of the participants practiced more than an hour or two in the three month training period. Thus, the solution to conducting training does not lie in merely providing home training, but rather to understand the work-related stressors and reconfigure jobs.



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## INTRODUCTION

To maximize the benefit of time in the operating room, laparoscopic skills training outside the operating room has become the gold standard for educating surgical residents. It is well documented that residents benefit from this form of training and can lead to improved operative performance. In fact, training is an integral and essential component of a trainee's job. However, there is no consensus regarding the optimal method or learning environment for teaching laparoscopic skills in order to maximize trainees' education while maintaining an equitable and sustainable work-life balance. Recently, several studies have suggested that mandatory, proctored, proficiency-based goal-directed training is the best method for training.<sup>[1-3]</sup> However, this approach is not without disadvantages. For example, this type of training requires a significant amount of practice time per trainee in a workplace environment where shortened work hours are being mandated.<sup>[4-6]</sup> This laborious process of proctored, on-site training programs is time consuming and significantly impinges on the residents' pre-existing didactic requirements, patient care responsibilities, and overall operative experience.<sup>[7-9]</sup> In fact, duty-hour limitations have led to a significant re-evaluation of the traditional surgical education paradigm, with emphasis on increased efficiency of educational efforts. Accordingly, a disadvantage of these on-site training facilities is that they are often not readily accessible to the resident. Unless dedicated training time is made mandatory for residents, few residents independently take advantage of these costly facilities during their already busy week.<sup>[10]</sup> If educators seek to facilitate laparoscopic learning, they should provide the trainees with the opportunities for extracurricular practice. Finally, there is also an economical aspect to consider as the use of surgical educators can be costly, time consuming, and difficult to achieve for smaller institutions.

An independent learning approach where trainees are given self-study resources (i.e. video/didactic tutorials) as well as unlimited access to the on-site training facility and encouraged to practice at their own pace is one alternative strategy.<sup>[6]</sup> The advantages of such self-directed training method are reduced instructor time and simplified scheduling. Moreover, several studies have shown that learning can be facilitated if learners are able to self-direct their own training experience.<sup>[11-13]</sup> However, in the United States, the training time on-site within the workplace environment is counted toward the already restricted resident duty hours. A hybrid approach that employs an independent learning approach using at-home, portable laparoscopic trainer outside the time constraints of the

hospital environment, has not been fully investigated. As medical educators and mentors, the best methods of teaching laparoscopic skills and the most efficacious learning environment where trainees feel motivated and allocate a high priority to practice needs to be the standard for resident education. Clearly, laparoscopic training should not be considered after exhaustion from work-related activities. In fact, there is evidence to suggest that motor training during periods of exhaustion can deteriorate and may create an environment that promotes poor technique.<sup>[14]</sup> This is precisely why home training may be beneficial. It would be portable, accessible, convenient, flexible and inexpensive once initiated. Indeed, trainees could practice the laparoscopic skills at their preferred time, for example when are well-rested and away from work stressors, and not at a time that fits others' schedules. Therefore, we hypothesized that an at-home independent, proficiency-based laparoscopy training method using a low-cost device will improve the laparoscopic skills of novice trainees and that this training method-environment combination would be equivalent to traditional, independent hospital-based, laparoscopic training. The primary endpoint of the study was to compare trainee performance before and after at home practice training.

## METHODS

### Participants

Novice laparoscopists [First and Second Post Graduate Year (PGY-1 and 2) general surgery residents, ( $n = 8$ ) and medical students ( $n = 9$ ), at any year of training] were recruited into the study through word of mouth at Tulane University Medical Center. Prior to beginning training, all participants completed a questionnaire assessing demographics and previous exposure to laparoscopy. The Tulane University Institutional Review Board approved this study, and all subjects gave informed consent prior to participation.

### Apparatus

The Minimally Invasive Surgical Trainer (Joystick SimScope™; 3D Med, Franklin, Ohio) was used in this study for the home training device. This training device is a self-contained, lightweight (15 lbs), and portable box equipped with a camera and 10 inch LCD color monitor, which offered good visual resolution, and optics with all the close-up and rotation options. The trainer is also equipped with seven ports fitted with grommets designed to hold an instrument or a trocar. Tasks were carried out with the monitor at eye level and the laparoscopic instruments at a standard surgical height between the monitor and the participant.

The on-site “standard” conventional trainer (Karl Storz Endoscopy, Culver City, CA) used in this study included a 15 inch video monitor (Sony Corporation, New York, NY), Xenon-nova light source, Telecam SL camera system, Hopkins II laparoscope and a Plexiglas box trainer. Tasks were carried out using a 0° Storz 10-mm laparoscope connected to a light source and with the images directed to the Sony television monitor.

### Training and testing protocol

After an orientation and viewing a introductory video on the “Fundamentals of Laparoscopic Surgery” (FLS) peg board transfer and intra-corporal suturing and knot tying tasks,<sup>[15]</sup> all trainees completed a baseline assessment (pre-test) on these tasks using the on-site “standard” video-trainer. The peg transfer and an FLS-type video-trainer laparoscopic suturing model were used to assess their baseline skills. Performance scores were calculated and recorded for each peg transfer attempt using time (s) and for each laparoscopic suturing and knot tying attempt using the previously published formula:  $600 - [\text{time (s)} + 10 \times \text{accuracy error} + 10 \times \text{security error}]$ .<sup>[16]</sup> If there was failure to complete the later task (i.e. tie a functional knot) within the time limit (10 min), the task was terminated and the participant was given a score of 0. Baseline performance was defined as the mean score of the first three repetitions at the beginning of training (in the absence live, proctored instruction). Subjects were then ranked according to the sum of the overall scores for the three attempts, stratified into blocks of two and randomized into two groups. On-site group received unlimited 24-h access to the on-site skills laboratory for independent practice. Home group received a self-contained, portable laparoscopic - minimally invasive training system box (Joystick SimScope™; 3D Med, Franklin, Ohio).

Both groups were then allowed to self-direct their training for a three months period of time. During this independent training period, both groups were given access and allowed unlimited viewing of the didactic tutorials on the two tasks. The peg transfer model, an FLS-type video-trainer laparoscopic suturing model, and 6-inch pre-cut 3-0 silk sutures were provided to each participant. All participants were given previously established task specific proficiency levels for the peg transfer (48 s)<sup>[17]</sup> and the laparoscopic suturing model (score 512)<sup>[16]</sup> at the start of the training period to guide practice. To further foster goal-directed learning, all participants were encouraged to train as long as they needed in their spare time until they reached the pre-defined proficiency criterion. Both groups were given a journal to record number of practice days, and time spent practicing on each task over the 3-month

independent training period. After training completion, all participants underwent repeated evaluation (post-test) on the same initial two laparoscopic tasks using the on-site “standard” video-trainer.

### Questionnaire

Each participant completed a questionnaire on the educational experience, at the completion of the study investigating the perceived benefit of the training method. One set of issues concerned the opportunity for practice during the study period while another concerned the usefulness of the home training device in term of the learning of surgical skills. Participants in the home group were asked to evaluate using 10-point Likert scale (1-10) their satisfaction regarding the home training with higher numbers being more positive responses.

### Statistics

Data are expressed as means  $\pm$  standard error of the mean. Comparisons of the pre-training and the post-training continuous variables for each domain within groups were performed using a Wilcoxon matched pairs test. Comparisons of continuous variables between groups were conducted by using an unpaired two-tailed *t*-test. Categorical variables were compared using Fisher's exact or chi square test. Computer software (GraphPad InStat software, San Diego CA) was used for all statistical analyses. A *P* value of less than 0.05 was considered significant.

## RESULTS

### Study population

Seventeen subjects were enrolled, but one subject (medical student) dropped out secondary medical reasons during the training period, and this individual was not included in the final study analysis. Therefore, the subsequent analysis was per protocol. The mean age of the study population was  $31.0 \pm 1.5$  years (range 24-47 years). Nine subjects were female (52.9%) and 15 were right-hand dominant (88.2%). There were no significant differences in age, gender, or self-reported laparoscopic experience, between groups. Moreover, trainee baseline simulator performances for the two groups were equal (*P* > 0.05).

### Training period

As a group, only 56 % (*n* = 9/16) of the participants actually practiced the laparoscopic tasks during the training period (*n* = 4 in on-site group, *n* = 5 in home group). Of the participants that practiced (50% of medical students, 40% of PGY-1, and 33% of PGY-2 residents) only one subject (on-site group; medical student) practiced on a regular basis with a total

training time of over 29 h. For the other participants who practiced the average total recorded training time was just 1.0 h (range 0.18–2.6 h), over 5 different days (range 1–15 days) during the entire 3-month training period.

The task-specific practice was as follows: for the pegboard task, only one subject (a medical student) in the on-site training group actually trained on this task during the training period. By comparison, 4 out of 9 (44.4%) subject in the home group practice this task. For the suturing task, nine people (56%) practiced during the 3-month training period (4 in the on-site group with total training time  $5.0 \pm 4.3$  h; 5 in the home group with total training time  $1.0 \pm 0.8$  h).

### Post-test skills assessment performance

Since the number of participants in each group that actually practiced during the study period was small, this situation precluded any meaningful statistical breakdown for this subgroup. Therefore, for the post-test analysis all participants (i.e. those who did and did not train at all) were included. Interestingly, most participants achieved improvements regardless of which group they were initially assigned for training or the amount of practice they recorded. For the pegboard task, post-training times for the participants in the on-site group improved on average 65 s (37%) compared to pretest scores ( $177.7 \pm 23.8$  s pre vs.  $112.2 \pm 9.3$  s post,  $P = 0.047$ ). By comparison, the home group improved on average 41 s (22%), compared to pretest scores ( $183 \pm 21.5$  vs.  $142.9 \pm 16.6$  s,  $P = 0.039$ ). The most marked improvement was noted with one participant improving the pegboard time by 196 s (on-site group). Interestingly, the number of participants who improved on the pegboard task (86% vs. 78%) and the average time to task completion after training was not statistically significantly between the home and on-site groups, respectively ( $P = 0.47$ ). Importantly, despite these improvements no participants, in either group, achieved proficiency at re-testing for the pegboard task.

As expected, the more complex task (suturing) provided the greater training challenge, however an improvement was noted in both groups. The suturing task completion rate for both groups had significantly improved after the training period (71% vs. 29% on-site group;  $P < 0.001$  and 44% vs. 22% home group;  $P < 0.001$ ). Finally, at re-test, the on-site group score improved by an average of 113 points ( $114.9 \pm 74.6$  pre vs.  $228.4 \pm 83.6$  post,  $P > 0.05$ ) compared to 39 points for the group trained at home on the portable device ( $80 \pm 53.5$  pre vs.  $118.7 \pm 60.2$  post,  $P > 0.05$  Wilcoxon matched pairs test). Although the magnitude

of improvement on the suturing task was significantly greater for the on-site trained group on both forms of assessment, no statistically significant difference could be demonstrated ( $P = 0.54$ ). Only one participant from the on-site group achieved proficiency on the suturing task. However, this individual practiced significantly more than all other participants (18 h) during the independent training period.

### End-of-study questionnaire

In total, 93% reported no or minimal exposure to laparoscopic surgery during the study period. The ease of use of the home training device was evaluated using a 10-point Likert scale with anchored end points; 1 being easy and 10 being difficult. Many respondents felt that the home box trainer was easy to use with a median score of 2. According to half of participants, the study experience was beneficial to their laparoscopic skills education. Importantly, regardless of the training location, a majority of each group stated they had difficulty practicing regularly (86% in on-site group, 89% in home group). The 44% who do not practice cited the following reasons: lack of time (57%), away rotations (29%), and the remaining 14% cited various other reasons. Of the 56% who did practice still cited a lack of time (56%) as the major reason they did not practice more often.

### DISCUSSION

Laparoscopic training is an integral and essential component of a surgical trainee's job. However, within a changing surgical environment alternative methods for laparoscopic training must be sought for training which incorporate opportunities to practice. In this un-blinded, randomized study, two proficiency-based independent approaches were employed to teach laparoscopic skills to beginners, with one tactic employing standard on-site physical box trainers at the workplace and the other relying on a similar device used in the trainee's home, outside the stress of the work environment. Both methods allowed trainees to practice their laparoscopic skills at their own pace. In the beginning, pre-training skills were homogenous with minimal baseline experience in the two groups. In the end, novice trainees showed improvement in their laparoscopic skills using our self-directed, proficiency-based home training program. However, at most, it was comparable to our on-site program in terms of feasibility and rates of participation. Several studies have shown that learning can be facilitated if learners are able to self-direct their own training experience<sup>[11–13]</sup> while other studies have shown that low cost, portable training device can improve laparoscopic skills.<sup>[18,19]</sup> However, the ability of a self-

directed laparoscopic training experience using low-cost portable training devices to improve laparoscopic procedural skills with the home environment has not been investigated. We used a proficiency-based, self-directed training approach both within the home and workplace environment. Both groups were instructed to practice at their discretion to achieve expert proficiency on each task with no ramifications if they did not succeed. We believed this would be successful based on the observation that surgical trainees and those interested in surgery are highly motivated to learn the required skills and invest the necessary time. In addition, there seems to be natural selection within the surgical population itself. Trainee motivation is essential for learning because it promotes deliberate practice and persistent efforts to improve objective performance.<sup>[20]</sup> Without motivated learners, any educational efforts will have limited achievements and the skills laboratories will be attended infrequently. At the end of the day, our method was met with mixed results. First of all, the self-directed training approach did enhance the novices' laparoscopic skills in both groups. But, we also observed that few subjects attended the on-site skill laboratory during their independent training period. More surprising, was the observation that when subjects were given the training device to use at home, they still did not find the time to frequently train independently. Interestingly, on average, the home trainees found only about 1-2 h to practice within a three-month period of time and 44% never practiced once during this period. These results demonstrated that one of the most important factors in getting trainees to practice and hone their laparoscopic skills was providing them with enough free time during their work week not changing their learning environment. This ultimately disproved our original hypothesis that moving practice opportunities out of the busy and stressful clinical environment to "free time" would be beneficial. Thus the hard, but unavoidable truth appears to be that there are barriers to practice in both settings that need to be better understood.

The fact that the groups demonstrated improvement despite low recorded practice rates during the training period may indicate that this is due to random effects, rather than due to the amount of deliberate practice. However, there are many different components for procedural skills learning besides the time spent practicing on physical simulator with specific tasks such as utilizing didactic, and video-based instruction, reflection and supervised practice with feedback and formative assessment.<sup>[21-25]</sup> In our study, all subjects most likely received learning from the video-based instruction and during the practice for the

period of the pre-test scoring. Indeed, video-based instruction has been shown to be efficacious in the development of laparoscopic skills.<sup>[26,27]</sup> It has been recently demonstrated that under prescribed practice conditions, video based instruction is equally effective as faculty instruction in teaching basic surgical skills to novice trainees.<sup>[23,24,28]</sup>

Supervised practice-feedback is believed to be another foundation of effective learning. Feedback and formative assessment refer to information about performance that is intended to guide learning. The purpose of giving feedback is to encourage learners to think about their performance and how they might improve. However, feedback in practice is often vague and evaluative (e.g. "good suturing").<sup>[29]</sup> While direct intensive practice feedback was not given in our study, the use of pre-set task-specific proficiency criteria to guide practice was utilized. This has been shown to give the informative feedback and opportunity for error correction vital for deliberative practice and can improve laparoscopic training.<sup>[6]</sup> This may be another reason for the observed skill improvements in both groups.

Our study has several limitations and must be viewed cautiously as they may not apply for other simulators or other subjects with different motivation, interests, and backgrounds. If all of our subjects were surgical residents that were required to achieve proficiency prior to being allowed into the operating room, we believe that nearly 100% would attain the pre-defined proficiency levels as opposed to the 6% noted in the current study.<sup>[30]</sup> Another limitation of our study was that we assumed that the participants knew how to self-direct their learning. Perhaps with more oversight, including feedback and good practice reinforcement, the path to greater task improvements would have been identified. Another limitation was that the number of participants in our study was small. Interestingly, for both tasks the greater improvements were with the on-site training - although statistical significance between the two groups could not be demonstrated this may be a function of small numbers. A larger cohort might result in statistically significant differences between the two groups. A further limitation of this study is it did not attempt to correlate improvement in task performance with improved performance in live human operations. Despite these limitations, this study has provided the foundation for additional assessment of the home trainer as a means of improving operative performance.

Essentially, our investigation is a feasibility study

evaluating if home training is viable, however it was not performed to determine if programs can “avoid obligations” and “negate” work hours regulations. Our study found that novice individuals trained on either the home or the on-site training device were able to improve their laparoscopic skills objectively and subjectively using an independent proficiency-based training method. However, none of the participants practiced for more than 1 or 2 h in the 3-month training period. Therefore, we feel that the only valid conclusion that can be drawn is that when overworked and exhausted trainees who are expected to train on their own time, do not regularly engage in training exercises, regardless of whether these are provided at home or in the workplace. The solution to conducting training in a stressful work environment may not be to simply “suggest” that trainees practice at home, but rather to understand the work-related stressors and reconfigure jobs, and perhaps even to increase staffing, to minimize stress exposure.

## DECLARATIONS

### Authors' contributions

Study design and manuscript preparation: C.F. Bellows  
Manuscript preparation and data analysis: A.A. Smith

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None.

### Conflicts of interest

There are no conflicts of interest.

### Patient consent

All study subjects provided appropriate consent as per the Institutional review board protocol prior to participating in the study.

### Ethics approval

Institutional review board approval was obtained prior to initiation of the study.

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# Mini-invasive distal pancreatectomy: a feasible and cost-effective technique

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## ABSTRACT

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### Key words:

Mini-invasive,  
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cost

**Aim:** Laparoscopic pancreatic surgery is a minimally invasive technique that has been widely applied only in the past decade. The purpose of this study was to evaluate its safety and assess whether laparoscopic distal pancreatectomy (LDP) is cost-effective compared with open distal pancreatectomy (ODP). **Methods:** The medical records of patients treated for left-sided pancreatic lesions were retrospectively analysed, and the analysis of costs for hospital stay, operative time, and equipment were analysed. Twelve patients underwent LDP, while 12 patients underwent ODP. **Results:** The two groups were homogeneous according to age, ASA score, BMI, and distribution of pathological findings. Both the size of the specimen ( $5.33 \pm 3.2$  vs.  $5.58 \pm 2.57$  cm) and the number of removed lymph nodes ( $10.5 \pm 4.3$  vs.  $12.1 \pm 3.1$ ) did not differ. Although LDP required a longer operative time ( $197.5 \pm 33.7$  vs.  $122.5 \pm 35.4$  min), intraoperative bleeding, postoperative pain intensity (measured by VAS scale) and hospital stay were significantly reduced. **Conclusion:** The mini-invasive approach offers several advantages compared with open surgery, including a significant reduction of blood loss and postoperative pain, and an earlier recovery. The global costs of laparoscopic surgery should be carefully re-evaluated, considering the saving that arises from these advantages.

## INTRODUCTION

Advances in laparoscopic technologies have greatly expanded the use of this technique in general surgery. The benefits of laparoscopic or minimally invasive surgery (better cosmesis, reduced postoperative pain, and faster recovery) are well known for many diseases, but reduced trauma to the abdominal wall is particularly evident in pancreatic surgery.<sup>[1,2]</sup> However, surgery of

the pancreas is still challenging, and although the first reported case of laparoscopic approach in pancreatic disease was in 1994, it has been widely applied only in the past decade.<sup>[3-5]</sup> Open surgery is still performed because of the anatomy of pancreas, limitations of team skills, and some early concerns regarding oncologic outcomes.<sup>[6]</sup> Nevertheless, minimally invasive surgery has been increasingly adopted, particularly for benign or low-malignancy pancreatic



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tumours of the left pancreas. Several retrospective studies confirmed laparoscopic distal pancreatectomy (LDP) as a feasible and safe technique, even if no randomized controlled trials (RCTs) comparing open distal pancreatectomy (ODP) and LDP are available. Furthermore, it has been argued that costs for reduced hospital length of stay (LoS) are counterbalanced by the increased operative costs of LDP.<sup>[7]</sup>

The purpose of our study was to evaluate the safety of our standardized minimally invasive technique and assess if LDP is a cost-effective procedure compared to ODP.

## METHODS

### Study design and population

The medical records of all patients treated for left-sided pancreatic lesions (with or without splenic preservation), between April 2013 and March 2015, at the Department of Oncologic Surgery at the Humanitas Gavazzeni Institute of Bergamo (Italy), were retrospectively analysed. Patients with both benign and malignant lesions were included in the study. Cases with insufficient data for analysis or that entailed simple tumour enucleation were excluded, as were those in which additional organ resections were performed during the same operation. All cases were discussed in a multidisciplinary gastrointestinal tumour board prior to surgery. Demographics and intraoperative and postoperative data were recorded in an *ad hoc* database.

The American Society of Anaesthesiologists (ASA) score was reported,<sup>[8]</sup> and body mass index (BMI) was calculated for each patient. Intraoperative blood loss, operative time, hospital LoS, postoperative morbidity, perioperative mortality (within 30 days from surgery), and 30-day readmission rates were also recorded. The level of pain reported was recorded three times per day on postoperative days 1 and 2, using the standard visual analogic scale (VAS). The presence of a postoperative pancreatic fistula was assessed according to the 2005 International Study Group on Pancreatic Fistula (ISGPF) criteria.<sup>[9]</sup> Analysis of costs included the expenses for the hospital stay, operative time and equipment (surgical staplers and energy devices), pharmaceutical treatment, nursing, and laboratory and pathology fees. No post-discharge care or home-nursing costs were included.

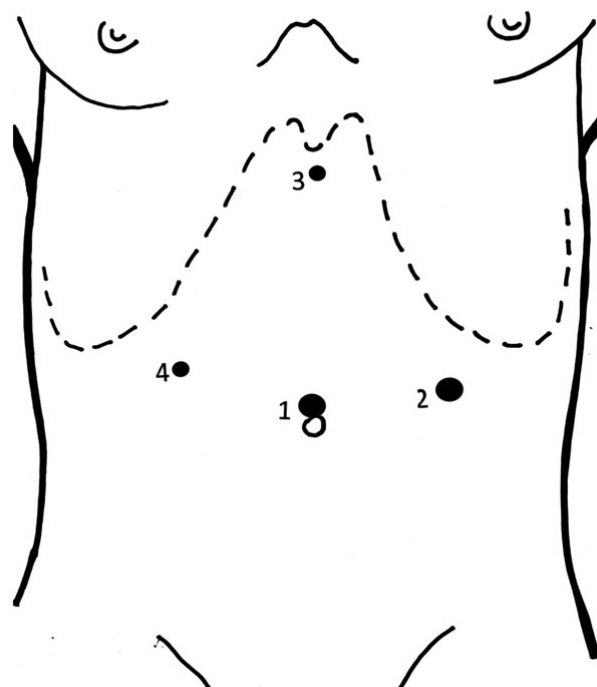
### Surgical technique

All pancreatic resections were performed by experienced surgeons using a standardized technique. The LDP patients were placed in the

lithotomic position, with the operator placed between the patient's legs. The operation was performed through four ports: umbilical, subxyphoid, and both subcostal positions in the mid-clavicular line so as to avoid trauma to the epigastric vessels [Figure 1]. The devices included a harmonic scalpel (Harmonic ACE®, Ethicon EndoSurgery, Cincinnati, OH, USA) used for dissection. Intraoperative ultrasound was used if needed to localize the tumour. In cases without splenic preservation, a vascular stapler was used to divide the splenic vein and two Hem-o-lok® (Teleflex Medical Europe Ltd., IDA Business and Technology Park, Athlone, Ireland) clips were applied on the splenic artery. Division of the pancreas was performed using a stapler. The specimen was placed in an Endopouch Retrieval Bag® (Ethicon EndoSurgery, Cincinnati, OH, USA) and removed through a slightly enlarged periumbilical incision or a Pfannenstiel incision for large specimens.

For the open approach, patients were placed in the supine position and a left subcostal incision was used. The additional cost for the use of Harmonic Focus + Long Shears® (Ethicon EndoSurgery, Cincinnati, OH, USA) was calculated. The pancreatic stump was treated with a stapler, similarly to the laparoscopic approach.

A close suction drain was placed in all cases and



**Figure 1:** Position of trocar sites. (1) 10/12 mm umbilicus; (2) 10/12 mm left anterior axillary line between the costal margin and the iliac crest; (3) 5 mm subxyphoid area; (4) 5 mm lateral right rectus sheath under the right costal margin

removed when the presence of a pancreatic fistula was ruled out, according to the clinical and laboratory findings.

The enhanced recovery-after-surgery (ERAS) programme, including early oral intake, mobilization, and specific instructions for the management of drains and nasogastric tubes, was applied in all patients.<sup>[10]</sup>

### Statistical analysis

The data are reported as mean  $\pm$  standard deviation (SD). To compare continuous and dichotomized variables, we used the Mann-Whitney *U*-test (assuming that the data were not normally distributed) and the Fisher exact probability test (because most cell frequencies were  $\leq 5$ ), respectively. The relationship between parameters was evaluated using Pearson's correlation coefficient calculation, and the relation line equations were also obtained. A *P*-value  $< 0.05$  was considered statistically significant.

## RESULTS

Twelve patients (6 men and 6 women, median age 68, range 57 to 78 years) underwent LDP (group A), while 12 patients (5 men and 7 women, median age 71, range 59 to 79 years) underwent ODP (group B), for benign or malignant diseases.

Table 1 reports the main population characteristics and shows that the two groups were homogeneous (*P* = NS) with respect to age, male/female ratio, ASA score, and BMI. In addition, the pathological findings did not differ (*P* = NS) between groups. Pancreatic neuroendocrine tumour (NET) was the main diagnosis (5 in LDP group and 4 in ODP), followed

by cystic tumours (2 serous and 1 mucinous in LDP vs. 2 serous and 2 mucinous in ODP). Other findings in the LDP group included two intraductal papillary mucinous neoplasms (IPMN), one hematoma, and a lymphoepithelial cyst, whereas one ductal adenocarcinoma, one IPMN, an epithelial cyst, and an inflamed pancreas were found in the ODP group. The intra- and postoperative results are displayed in Table 2. Both the size of the specimen ( $5.33 \pm 3.2$  vs.  $5.58 \pm 2.57$  cm, *P* = 0.8033) and the number of the removed lymph nodes ( $10.5 \pm 4.3$  vs.  $12.1 \pm 3.1$ , *P* = 0.3071) were similar (*P* = NS). In three cases of LDP, the size of the lesion was more than 8 cm and required a Pfannenstiel incision for extraction of the surgical specimen. None of the patients in the LDP group were converted to an open approach.

Laparoscopic pancreatectomy required a longer operative time ( $197.5 \pm 33.7$  vs.  $122.5 \pm 35.4$  min, *P* = 0.00034). However, in this group of patients both postoperative pain intensity measured by a VAS scale (*P* = 0.0009) and the hospital stay (*P* = 0.0014) were significantly reduced, and the patients had an earlier bowel canalization ( $48 \pm 23$  vs.  $92 \pm 17$  h, *P* = 0.001) [Table 2].

Table 3 summarizes correlations between operative time (OT) or hospital LoS and age, BMI, and intraoperative bleeding (IB), to evaluate whether there is any relationship between main variables. In both groups (LDP vs. ODP) the age did not affect operative time (*R* = 0.338, *P* = 0.226 vs. *R* = 0.9002, *P* = 0.996), which was related to the intraoperative bleeding (*R* = 0.797, *P* = 0.002 vs. 0.616, *P* = 0.003). A significant relationship between LoS and age (*R* = 0.578, *P* = 0.040) and between the operative time and BMI (*R* = 0.787, *P* = 0.002) was found only in group ODP [Figure 2A and B].

**Table 1: Population's characteristics**

Parameters	Laparoscopic distal pancreatectomy	Open distal pancreatectomy	<i>P</i> -value
Number of patients	12	12	-
Age (years)	$68.08 \pm 6.73$	$70.5 \pm 6.9$	0.2531
Male/female ratio	6:6	5:7	0.6801
ASA	$2.08 \pm 0.51$	$2.33 \pm 0.49$	0.2247
BMI (range)	$26.92 \pm 2.97$ (24-35)	$27.83 \pm 4.02$ (22-37)	0.7843

ASA: American Society of Anaesthesiologists; BMI: body mass index

**Table 2: Intra- and postoperative results**

Results	Laparoscopic distal pancreatectomy	Open distal pancreatectomy	<i>P</i> -value
Length of surgery, min (range)	$197.5 \pm 33.74$ (160-285)	$122.5 \pm 34.54$ (90-215)	0.00034
Estimated blood loss, mL (range)	$100.83 \pm 32.04$ (60-180)	$180 \pm 39.77$ (120-250)	0.0001
Tumor size, cm (range)	$5.33 \pm 3.2$ (1.2-12.5)	$5.58 \pm 2.57$ (3-11)	0.8033
Number of removed lymph nodes (range)	$10.55 \pm 4.3$ (6-19)	$12.08 \pm 3.12$ (8-18)	0.3071
Post-operative VAS (on days I-II)	$4.08 \pm 1.16$	$5.92 \pm 1.24$	0.0009
Resumption of canalization, hours after surgery (range)	$48 \pm 22.88$ (24-96)	$92 \pm 17.23$ (72-120)	0.001
Resumption of solid oral feeding, days after surgery (range)	$2.42 \pm 0.67$ (2-4)	$3.4 \pm 1.38$ (2-6)	0.1403

VAS: visual analogue scale

**Table 3: Correlations between OT or hospital LoS and age, BMI, and IB**

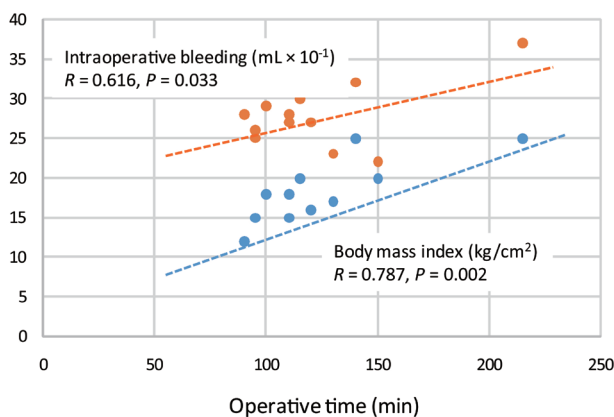
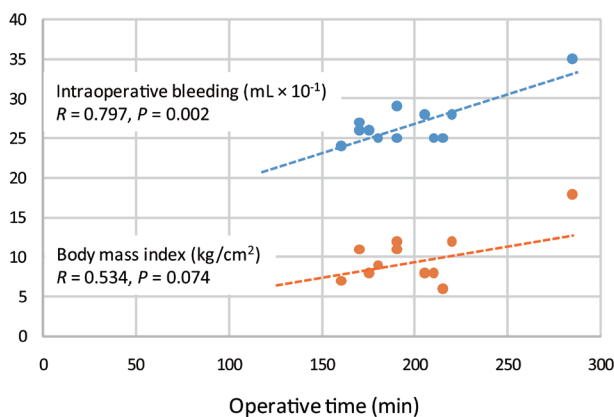
Parameters	ODP			LDP		
	R	Regression line equation	P-value	R	Regression line equation	P-value
OT/age	-0.0015	Age = 68.6746 - 0.0029 OT	0.9963	0.3378	Age = 61.2656 + 0.0754 OT	0.2259
OT/BMI	0.7873	BMI = 13.2375 + 0.0692 OT	0.0024	0.5337	BMI = 20.2266 + 0.0620 OT	0.0739
OT/IB	0.6159	IB = 0.5848 OT - 14.6706 OT	0.0330	0.7973	IB = 67.5333 + 0.9181 OT	0.0019
LoS/age	0.5780	Age = 43.3988 + 2.4269 LoS	0.0490	0.1556	Age = 50.6381 + 1.5396 LoS	0.6291
LoS/OT	0.4487	OT = 17.1067 + 9.4382 LoS	0.1434	0.5979	OT = 110.7816 + 10.7280 LoS	0.0399
LoS/IB	0.1482	IB = 98.0898 + 5.8427 LoS	0.6357	0.8284	IB = 14.1113 - 3.2334 LoS	0.0009

OT: operative time; LoS: length of stay; BMI: body mass index; IB: intraoperative bleeding; ODP: open distal pancreatectomy; LDP: laparoscopic distal pancreatectomy

**Table 4: Hospital length of stay, median operative costs, and total costs according to the type of pancreatectomy**

Parameters	LDP	ODP	P-value
Hospital length of stay (days)	8.08 ± 1.88	11.17 ± 1.64	0.0003
Estimated median operative costs (Euros):			
Spleen-preserving	1,401	863	
No spleen-preserving	1,641	986	
Estimated hospital stay costs (Euros):			
Median (range)	3,768 (2,355-5,652)	5,416.5 (4,239-6,594)	
Mean	3,807.25 ± 885.92	5,259.5 ± 773.5	0.0004
Estimated median total costs (Euros)	5,169	6,279.5	

ODP: open distal pancreatectomy; LDP: laparoscopic distal pancreatectomy

**A****B**

**Figure 2:** Relationship between operative time (min), body mass index (kg/cm<sup>2</sup>) and intraoperative bleeding (mL) in (A) laparoscopic distal pancreatectomy patients and (B) open distal pancreatectomy patients

The patients were started on a fluid diet on the 1st postoperative day and the diet was advanced to soft food as tolerated (LDP 2.4 ± 0.7 vs. ODP 3.4 ± 1.4 days). The hospital LoS was 8.1 ± 1.88 days (median 8, range 5 to 12) in LDP vs. 11.2 ± 1.6 (median 11, range 9 to 14) days in ODP, and the readmission rate was 8.3% in both groups. One patient in both groups developed a pancreatic fistula (Grade B), but no perioperative mortality occurred.

For a single LDP, a cost of €1,401 was calculated (energy devices, disposable trocars, and Endopouch), increased to €1,641 in cases of no spleen-preserving LDP (9 patients), which required a vascular cartridge and Haemoclips. For the open approach, an additional cost of €863 was required for the use of the Harmonic Focus, sutures, and more gauzes (€986 for non-spleen-preserving procedures). The global cost for LDP was €537 more than for an open surgery for each procedure. Calculating intra- and post-operative costs, we found an additional cost of €402 per patient for the minimally invasive technique.

The cost for a single day of hospital stay was on average €471 in our region (Lombardy). Thus, calculating the costs for the longer LoS in ODP vs. LDP (median 11.5 vs. 8.0), showed that there is a cost advantage favoring the minimally invasive approach vs. the open technique (€3,807.25 ± 885.92 vs. €5,259.5 ± 773.5). Table 4 summarizes LoS and total costs of patients who underwent LDP vs. ODP.

## DISCUSSION

The laparoscopic approach to pancreatic surgery has been utilized increasingly in the last decade, as a result of the evolution of minimally invasive technologies and the increasing numbers of pre-malignant and incidentally detected pancreatic lesions.<sup>[11]</sup> However, a population-based analysis on the Nationwide Inpatient Sample (NIS) found that, during the period 1998 to 2009, only 4.3% of distal pancreatectomies were performed with a minimally invasive approach.<sup>[12]</sup> Technical difficulties, due to the retroperitoneal location of the pancreas and the scarcity of high-volume skilled surgical teams, as well as the need to maintain oncologic standards, were major obstacles to the adoption of the laparoscopic approach.<sup>[5]</sup>

More recently, several studies and meta-analyses have shown that LDP is a safe procedure, with improved outcomes and reduced hospital stays.<sup>[13–16]</sup> Cao *et al.*<sup>[12]</sup> in their population-based retrospective cohort study reported a reduction of 1.22 days in LoS associated with minimally invasive surgery, with no differences in the perioperative mortality and total hospital costs. Furthermore, lower rates of infectious complications (30.1% vs. 39%) and bleeding complications (13.1% vs. 20.6%) were reported in LDP vs. ODP. Unfortunately, no randomized controlled trials (RCTs) comparing the two approaches are available, and all favourable results are reported in retrospective cohort-like or case-control studies.<sup>[17]</sup>

Our retrospective analysis was performed on a series of well-matched patients, with comparable demographics and similar histologic findings [Table 1]. In our experience, pancreatic NET and cystic tumours were the main result at definitive histology, and a distal minimally invasive pancreatic resection was the surgical approach of choice for such indolent malignancies. The treatment of these rare diseases requires expertise in both pancreatic surgery and advanced laparoscopy, but unfortunately, the number of retrospective reports is limited, and the complete information, including tumour size and margin status, are often missing.<sup>[18]</sup>

However, the progressive centralization of the surgical treatment of patients with pancreatic disease in specialized and high-volume centres will favour implementation of the procedure and data availability. A multicentre analysis, performed in 2010 by Kooby *et al.*,<sup>[6]</sup> reported similar oncologic results between LDP and ODP, with no differences in terms of overall survival and lymph node yield. Similarly, DiNorcia *et al.*<sup>[19]</sup> in 130 resections for PNET, reported no differences in morbidity, mortality, or overall survival

(OS), between the laparoscopic and open approach.

An important issue concerning oncologic effectiveness of minimally invasive surgery is that of achieving microscopically negative margins (R0) and an adequate number of harvested lymph nodes. Several reports have addressed this topic, and different comparative studies found no significant differences of R0 rates between laparoscopic and open techniques (74–97% vs. 73–96%).<sup>[20]</sup> Abu Hilal *et al.*<sup>[21]</sup> reported a 76% of R0 and a median of 15 sample nodes, suggesting that their standardised technique was a reasonable and safe procedure in left-sided malignancies. Shin *et al.*<sup>[22]</sup> reported a rate of R0 resections of 82.9% in 152 left pancreatic lesions, with a median size of 3 cm, removed with minimally invasive access. Another recent series of distal pancreatectomies showed similar results in terms of R0/R1/R2 rates, and a median of 16 harvested lymph nodes in LDP vs. 14 in ODP.<sup>[13]</sup> Fernandez-Cruz *et al.*<sup>[23]</sup> performed 27 LDP, achieving an R0 resection in 90% of ductal adenocarcinomas, and removing a median of 6 lymph nodes in the LDP group vs. 8 in the ODP group. Interestingly, in our series, the number of removed lymph nodes was similar and adequate in both groups, despite benign and malignant diseases having been included ( $10.55 \pm 4.3$  vs.  $12.08 \pm 3.12$ ,  $P = \text{NS}$ ). Notably, data on pancreatic ductal adenocarcinoma suggest that a minimum of 12 lymph nodes should be excised to ensure adequate nodal assessment.<sup>[24]</sup> However, this point is still debated, and the oncologic effectiveness of the minimally invasive approach still worries some surgeons. In the USA, high-volume centres perform distal pancreatectomies with minimally invasive techniques, either laparoscopic or robotic, unless there are clear contraindications present. However, according to a recent survey, 31% of European surgeons still prefer ODP for oncologic purposes.<sup>[12,25]</sup>

In our series, ASA score and BMI were similar in the two groups and, in contrast to other studies, patients who were treated with LDP had similar tumour size as those treated with open approach ( $5.33 \pm 3.2$  vs.  $5.58 \pm 2.57$  cm,  $P = \text{NS}$ ). In previous studies, the laparoscopic approach was primarily used for small benign lesions or indolent malignancies. In a series of 360 distal pancreatic resections, 71 were totally laparoscopic but had a significantly smaller median tumor size (2.5 cm in LDP vs. 3.6 cm in the ODP group).<sup>[26]</sup> Similarly, another systematic review reported a mean tumor size of 3.5 cm in LDP vs. 3.9 cm in ODP.<sup>[27]</sup> In our experience, the size of the specimen was not a contraindication or a major obstacle to laparoscopic approach, but had an impact on the duration of surgical intervention. It is noteworthy that there is a recent trend toward an increased size of the excised lesions ( $4.0 \pm 2.8$  cm vs.  $3.3 \pm 1.5$  cm) noted in the literature.<sup>[20]</sup>

Consistent with previous studies,<sup>[14,15]</sup> our operative time for LDP was longer than for ODP (median 195.5 vs. 112.5 min). Shin *et al.*<sup>[22]</sup> reported a median operative time of 195 min for LDP, whereas Braga *et al.*<sup>[28]</sup> reported a median duration of surgery of 239 min for LDP, significantly higher than that for ODP (213 min), but their series included a high rate (30%) of adenocarcinomas. Another group reported a longer operative time for LDP (376 min vs. 274 min).<sup>[29]</sup> In our series, the higher operative time was related to one operation (285 min) in an obese patient with diffuse adhesions, and three cases in which the size of the specimens necessitated a Pfannenstiel incision, also lengthening the duration of surgery. Interestingly, we found that in both groups age did not affect operative time, which was related to intraoperative bleeding, whereas a significant relationship between the operative time and BMI only occurred in the ODP group.

Undoubtedly, standardization of the technique and expertise of the surgical team is crucial. Another systematic review found no difference in operative time on 488 patients treated laparoscopically and 573 cases with open approach (mean 220.4 vs. 208.6 min).<sup>[27]</sup>

In agreement with previous studies and meta-analyses, we encountered lower intraoperative blood loss in the minimally invasive group. A wide population-based analysis reported a lower rate of bleeding complications in LDP (13.1% vs. 20.6%) and also a reduction of transfusion rate (11.3% vs. 18%).<sup>[12]</sup> However, the reported blood loss varies widely between studies, and may be related to the surgical technique or to the accuracy of the quantification of the bleeding. Jusoh *et al.*<sup>[27]</sup> reported a mean operative blood loss of 237.4 mL in LDP versus 562.4 mL in ODP, whereas Limongelli *et al.*<sup>[30]</sup> found a blood loss of 160 ± 185 mL vs. 365 ± 215 mL, respectively. Interestingly, Rutz *et al.*<sup>[7]</sup> reported an estimated blood loss of 113 ± 155 mL in LDP vs. 210 ± 274 mL in ODP, further differentiating blood loss between a totally laparoscopic approach (LDP, 76 ± 71 mL) and laparoscopic hand-assisted distal pancreatectomy (LHDP, 197 ± 244 mL). Very recently, a meta-analysis of short-term outcomes between LDP and robotic-assisted distal pancreatectomy (RADP) found a lower blood loss and a higher rate of spleen-preserving procedures in RADP.<sup>[31]</sup> Thus, the technological improvements and the magnified view during laparoscopy are crucial for control of bleeding. Nevertheless, lower rates of bleeding were found in a surgical series that excluded malignancies, suggesting a major role for the size and histology of the tumor.<sup>[32]</sup>

Concerning morbidity, a large population-based analysis reported a 25% reduction of overall perioperative complications, particularly related to a lower rate of postoperative infections (30.1% vs. 39%) and bleeding complications (13.1% vs. 20.6%).<sup>[12]</sup> Similarly, Venkat *et al.*<sup>[14]</sup> reported a reduction in overall morbidity after the minimally invasive approach (33.9% vs. 44.2%), including a lowering of the percentage of surgical site infections (2.9% vs. 8.1%). However, most of the reports found no differences in complication rates between the two approaches.<sup>[13]</sup> Magge *et al.*<sup>[33]</sup> reported equal rates and severity of complications (39% vs. 50%) in 62 patients undergoing distal pancreatectomy for early-stage ductal adenocarcinoma, and found that conversion to an open procedure was associated with poor outcome. Similarly, Jayaraman *et al.*<sup>[34]</sup> compared 343 LDP vs. 236 ODP and found that patients who required conversion had more complications and pancreatic leaks. These findings confirm the need for accurate preoperative patient selection, to identify patients at high risk for conversion and to choose the best approach for each patient and disease presentation.

Post-operative pancreatic fistulas (POPF) remain the most feared complication, but the incidence is variable among different surgeons, partly because of different definitions of POPF. We strictly applied the International Study Group for Pancreatic Fistulae (ISGPF) definition of POPF and, considering only grade B and C fistulae, we found no differences between the two groups, with one case of POPF in both (8.3%).<sup>[9]</sup> A large multicenter study, using the same ISGPF criteria, found no difference in pancreatic leaks between the laparoscopic and the open approach.<sup>[35]</sup> Similarly, a meta-analysis of 18 studies reported a similar incidence of grade B-C fistulae after either the laparoscopic or the open approach.<sup>[14]</sup> Velanovich *et al.*<sup>[36]</sup> reported a rate of POPF of 13% in both groups, whereas Kooby *et al.*<sup>[37]</sup> reported 26% POPF in LDP and 32% in ODP. Another series showed 14% POPF in LDP ( $n = 70$ ) vs. 13% after open surgery ( $n = 45$ ), similar to the report of Corcione *et al.*<sup>[38]</sup> (10.4% in LDP). In contrast, Fox *et al.*<sup>[39]</sup> reported a higher incidence of POPF in LDP (28.57%) compared to ODP (13.16%), but LDP led to only grade A fistulae, while all the grade B-C fistulae occurred in the ODP group. The occurrence of POPF varies widely between surgeons, and this may be attributable to the criteria adopted for definition rather than to the surgical technique. A meta-analysis of the most popular techniques (sutures, stapled closure, combination of both, with or without fibrin glue) did not identify one as being the most safe.<sup>[40]</sup> A multicenter RCT performed in 21 European hospitals found that hand-sewn sutures and closure with stapler

were equally effective after distal pancreatectomy, but the identification and suture of a transected pancreatic duct is the only technique able to reduce the incidence of POPF.<sup>[41,42]</sup> Our standardized technique and the use of a stapled closure of the pancreatic remnant, despite the low number of patients, has proven to be safe, without significant morbidity or mortality, and with similar re-admission rates between groups.

In our experience the LDP group showed reduced pain intensity measured on the standard VAS scale (median 4 vs. 6) during the first 2 postoperative days, allowing reduced use of analgesics and earlier mobilization. Similarly, resumption of bowel canalization (median 48 vs. 96 h) and solid oral feeding (median 2 vs. 3 days) were shortened with LDP, compared with ODP.

An ERAS protocol was applied in all patients, as previously reported.<sup>[10]</sup> These programs, introduced for colorectal surgery, have been progressively adopted by other surgical specialities, leading to a reduction of postoperative morbidity and a shortening of LoS.<sup>[43]</sup> Pancreatic surgery is still a high risk procedure, but several non-randomized trials have demonstrated that ERAS in pancreatic resections is safe and feasible.<sup>[44]</sup> In our study, the use of minimally invasive surgery together with recommendations of the ERAS programme have shown complementary roles, speeding recovery and shortening LoS.

Consistent with previous studies, the hospital LoS was significantly reduced in patients treated with minimally invasive approach (median 8 vs. 11.5 days in LDP and ODP groups, respectively). Venkat *et al.*<sup>[14]</sup> found a 4 days reduction in LoS with LDP, whereas Cao *et al.*<sup>[12]</sup> in a large population-based analysis, reported a mean LoS of 8.62 days in the laparoscopic group vs. 10.76 days in the open one. Pericleous *et al.*<sup>[15]</sup> in their meta-analysis of case-matched studies, reported a reduced LoS of 2.7 days, similar to other groups, who reported a reduction of LoS of 2.7 to 5 days for LDP, compared with ODP. Very recently, a Cochrane review found that mean LoS was shorter by 2.43 days in the minimally invasive group compared with the open surgery group.<sup>[17]</sup> Hospital stay is considered an important evaluation index in laparoscopic surgery. Thus, our finding is interesting and probably related to the implementation of ERAS protocol, with earlier weaning from i.v. analgesia and earlier canalization. Interestingly, a significant relationship between LoS and age was found only in the ODP group.

Cost effectiveness of a procedure has become important, given that resources are limited and cost control is necessary, particularly in the Italian health system. Unfortunately, our analysis is not generalizable

to different countries, because of variations in the different health systems' reimbursements and practices.<sup>[12]</sup> A simplistic trade-off between operative costs and LoS may lead to a rough estimate, resulting in higher cost for the minimally invasive approach.<sup>[45]</sup> Furthermore, technologic advances and availability of new stapler and vessel-sealing devices, have improved the minimally invasive approaches, but simultaneously increased the costs of the procedure. We found an additional cost of €537 for each minimally invasive distal pancreatectomy, compared with a traditional open operation (see Results). However, in their meta-analysis, Nigri *et al.*<sup>[46]</sup> argued that devices are often equally used in LDP and ODP, but other practices or habits may influence results. A Korean single-centre study found significantly higher total costs for LDP, but LoS in this series was higher than any other published study ( $11.5 \pm 4.1$  days for LDP and  $13.5 \pm 4.9$  days for ODP), reflecting the importance of different practices.<sup>[47]</sup> All subsequent studies found that although the operative costs were higher for minimally invasive procedures, decreased LoS after laparoscopic resection balanced, at least, overall costs.<sup>[30,48]</sup> Rutz *et al.*<sup>[7]</sup> found a mean operative cost of \$4,900 for ODP and \$5,756 for LDP, but calculated a mean total cost of care of \$13,900 for the open procedure vs. \$10,480 for the laparoscopic one. In this study, we accurately evaluated the overall expenses of the procedures, calculating device, equipment and all disposable costs as electronically cataloged. Similar to other studies, we calculated the costs for a longer LoS in ODP vs. LDP (median 11.5 vs. 8 days), and we found an advantage of costs for the hospital stay favoring the minimally invasive approach vs. the open technique (mean cost, €5,169 vs. €6,279.5).

Undoubtedly, reduction of hospital stay impacts expenses, lowering the overall cost of postoperative management. Furthermore, the minimally invasive approach contributes to reduction of postoperative pain and earlier ambulation, favouring an earlier discharge of patients. Consistent with our findings, Fox *et al.*<sup>[39]</sup> found a shorter LoS and a reduction of total hospital costs for LDP ( $n = 42$ ), compared with ODP ( $n = 76$ ), showing that LoS was directly proportional to total costs. Interestingly, Braga *et al.*<sup>[28]</sup> suggested that the cost-benefit analysis should consider not only the hospital charges, but also the cosmesis and quality of life of the patients to fully evaluate the minimally invasive approach. Notably, in our study the postoperative complications and readmission rate were similar. Ahmad *et al.*<sup>[49]</sup> found that postoperative complications and higher transfusion requirements, or the presence of chronic pancreatitis, had a significant impact on 30- and 90-day readmission rates.

Our study has several limitations. The main one is that it utilized retrospective data, which may introduce selection bias and allow missing information. Demographics, histology, and tumour size were similar in both groups, despite the absence of randomization. However, the number of patients in our series was low, but all available studies are similar cohort-like or case-control studies from single centres, with few patients. Unfortunately, no long-term data are available in our series, but a lack of long-term results and follow-up is common, as a result of the rarity of this type of disease and heterogeneity of the studies. Particularly, long-term data on recurrence of pancreatic carcinomas are scarce, and larger comparative studies are needed.<sup>[20]</sup>

Rehman *et al.*<sup>[28]</sup> found no significant differences in 3-year OS between laparoscopic ( $n = 8$ ) or open ( $n = 14$ ) distal pancreatectomy for pancreatic adenocarcinoma (82% vs. 74%). Similarly, Hu *et al.*<sup>[50]</sup> compared 11 LDP and 23 ODP and found a mean OS  $42.0 \pm 8.6$  months vs.  $54.0 \pm 5.8$  months. The Central Pancreas Consortium reported the same median OS (16 months) after both procedures, in matched cohorts, suggesting that oncologic outcomes are similar and independent of the surgical approach.<sup>[6]</sup>

In conclusion, our experience confirms that the minimally invasive surgical treatment of tumours of the distal pancreas is safe and feasible. Laparoscopic pancreatectomy offers several advantages compared with open surgery, including a significant reduction of estimated blood loss, reduced postoperative pain intensity, and earlier bowel canalization. However, implementation of minimally invasive pancreatectomy requires specific skills and adequate training, both in advanced laparoscopic surgery and in pancreatic surgery. Additional research and adequate RCTs are needed before the technique can be considered the “gold-standard” for distal pancreatectomies, to assess oncologic results and long-term outcomes. Finally, the costs of laparoscopic surgery should be carefully re-evaluated before concluding that they are greater than those of open surgery.

### Authors' contributions

Designed the study: S.M.M. Basso, P. Ubiali

Acquired the data: F. Maffei, A. Patanè

Analyzed and interpreted the results: S.M.M. Basso, F. Maffei, F. Lumachi

Drafted the manuscript: S.M.M. Basso

Revised the manuscript: S.M.M. Basso, F. Lumachi, M. Ciocca Vasino, P. Ubiali

Approved the final version: S.M.M. Basso, F. Maffei,

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### Conflicts of interest

There are no conflicts of interest.

### Patient consent

Informed consent was obtained from all patients.

### Ethics approval

The present study is a retrospective review of anonymized clinical records, and ethical permission was obtained.

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# The role of delayed laparoscopic suction for intra-abdominal collection or abscess post appendectomy in paediatric patients: case series and review of literature

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## ABSTRACT

**Aim:** Intra-abdominal collection or abscess (IAA) is a dreaded complication post open or laparoscopic appendectomy for perforated appendicitis. There have been many discussions on the role of laparoscopic irrigation during laparoscopic appendectomy for perforated appendix but not its role for patients who subsequently developed IAA post-surgery. **Methods:** All patients who developed clinical symptoms and radiological evidence of IAA of more than 5 cm × 5 cm post appendectomy from January 2014 to May 2016 were subjected to delayed laparoscopic suction (DLS) of the IAA. Days to resolution of fever and improvement of symptoms post the DLS were recorded. Complications during DLS like bowel injury, bleeding and conversion to open surgery were documented and analysed. Patients were followed up for 1 month to a year to look for potential adhesive intestinal obstruction. **Results:** Seven patients who met the criteria of large IAA were subjected to DLS at post-operative day 3 to day 5 post appendectomy. Six of the cases were post laparoscopic appendectomy and one case was post open appendectomy from another institution. Ports were inserted via the same sites as used during the first surgery. Turbid intraperitoneal fluid and abscesses were laparoscopically sucked without irrigation. There was no bowel injury, bleeding or conversion in any of the cases. All patients were afebrile within 24 h post procedure and their associated symptoms improved significantly. All patients were discharged within three days of DLS and have not returned with adhesive obstruction. **Conclusion:** Early recognition of IAA is important and early attempt at DLS resulted in better outcome of patients and lesser hospital stay. DLS is a safe and feasible technique.



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## INTRODUCTION

Laparoscopic appendectomy (LA) for perforated appendicitis had shown favorable outcomes in terms of length of hospital stay, antibiotic usage, return of oral intake and rate of wound infection in comparison with open appendectomy (OA). With regards to infection rate, Lin *et al.*<sup>[1]</sup> in 2006 showed that the rate of wound infection was lower than the OA group i.e. 15.2% vs. 30.7%. However, there was no mention of the more dreaded complication of intra-abdominal abscess (IAA) especially after LA for perforated appendicitis. This issue was later addressed in subsequent literature and it became a major concern when deciding to perform LA for perforated appendicitis for many surgeons. The European guideline recommends thorough peritoneal lavage (6-8 L of warm saline) and aspiration to minimize the IAA rate in complicated appendicitis. However, this practice was controversial as it was postulated that lavage itself might help to spread the infectious materials.<sup>[2-4]</sup>

There are many published articles on the role of LA and lavage and OA and peritoneal washout in the formation of IAA, however there has not been any discussion on the management of these patients with IAA post-surgery except for placement of drains and antibiotics in some series.<sup>[5-9]</sup> The aim of this study is to document feasibility and effectiveness of delayed laparoscopic suction (DLS) at tackling IAA. The hypothesis is that DLS is a feasible and effective technique for treatment of IAA post perforated appendectomy in children.

## METHODS

This study was based on a comprehensive review of audit on paediatric patients who underwent laparoscopic appendectomy at our institution for acute and perforated appendicitis for the recent three and a half years; we looked at the occurrence of IAA and the management strategy to resolve this problem i.e. percutaneous drainage or DLS. All patients with acute or perforated appendicitis at our institution would undergo laparoscopic appendectomy unless there was presence of distended abdomen from a dilated bowel i.e. suggestive of intestinal obstruction secondary to the pathological appendix. Suggestion of intestinal obstruction would be evident clinically and supported radiologically (AXR and/or ultrasound abdomen). We documented the type of appendicitis (suppurative or perforated), whether irrigation and suction was done intraoperatively, days of persistent and cessation of fever, presence of abdominal pain and poor appetite and disappearance of these symptoms, ultrasound findings of the measurement of the IAA, days of

administration of standard antibiotics (and additional antibiotics if any) and days to discharge. We also documented clinical evaluation of these patients during follow-up, specifically looking for symptoms to suggest adhesive intestinal obstruction. We also included in this series, cases referred to our centre for management of IAA. Parental consent was taken prior to DLS procedure.

The laparoscopic approach to appendectomy was the 3-port technique using 11 mm Hasson trocar for camera insertion and 2-6 mm working ports. The antibiotics of choice were intravenous second generation cephalosporin group and metronidazole. The surgical technique was standardised for all patients. All appendiceal stumps were ligated using loop polypropylene suture. All perforated cases would have suction and irrigation with unspecified amount of warm saline till the effluent was clear. Patients who have persistent fever at day 3 of post-surgery with or without symptoms of abdominal distension, pain or poor appetite would be subjected to ultrasound assessment to look for presence of IAA, its complexity and size. Intraabdominal abscess of less than 5 cm × 5 cm were treated conservatively by adding intravenous gentamycin (aminoglycoside). For cases with IAA of more than 5 cm × 5 cm, we documented the procedures chosen to manage the IAA i.e. either percutaneous drainage or DLS and the clinical progress based on factors mentioned earlier.

## RESULTS

Out of the 49 cases of LA at our institution, 20 cases were for perforated appendicitis and 29 were for suppurative appendicitis. None of the cases underwent conversion to open surgery. Intraoperatively, all cases with perforated appendicitis had laparoscopic peritoneal lavage with unspecified amount of warm saline and suction. Out of 20 patients, 9 developed IAA.

All 9 patients with suspected IAA were febrile at post-operative day 3 with temperature of more than 38 °C. They were subjected to ultrasound abdomen for confirmation of IAA. Ultrasound showed 8 patients had IAA larger than 5 cm × 5 cm at the right iliac fossa and in the pelvis region. Two patients underwent percutaneous drainage under ultrasound guidance and a pigtail catheter insertion, the tip of the catheter was placed in the pelvic cavity to drain the residual IAA into a sterile bag. The aspirated pus was sent for culture and sensitivity and the bacterial involved was confirmed to be *Escherichia coli*. In these 2 patients, intravenous antibiotic gentamycin was added. Both patients remained febrile till over a week post-surgery.

They also complaint of pain at the site of the pigtail-catheter and difficulty to mobilise, having to carry the catheter and drainage bag all the time. However, their appetite improved after the percutaneous drainage. They were discharged at POD10 and POD14 respectively after repeat ultrasound showed complete resolution of IAA and removal of the pigtail-catheter. At follow up, 1 patient complaint of pain at the right iliac fossa with no symptoms to suggest adhesive obstruction. A repeat ultrasound was done for him which was normal. The second patient remained well at follow-up.

One patient with IAA of 3 cm × 4 cm was treated conservatively; intravenous Gentamycin was added and she became afebrile 48 h later. This patient's appetite took longer time to resolve, however she did not complain of abdominal pain. She was subsequently discharged well at POD7. Repeat ultrasound was not done on her before discharge; at follow-up, she was also well.

Six other patients with IAA of more than 5 cm × 5 cm on were subjected to DLS. All of them were febrile with temperature of 38 °C or more at POD3. Three patients had no abdominal pain and their appetite were normal. Three other patients have either one or more combination of symptoms e.g. fever, abdominal pain, poor appetite and refusal to mobilise [Table 1]. All 6 patients underwent DLS at POD3 to POD5 via the same port-sites used during first surgery. No additional antibiotics was given. During DLS, intraoperatively, only laparoscopic suction was carried out without irrigation. Post procedure, fever resolved within 24 h of DLS in all 6 patients. Patients who had complaints had complete resolution of their symptoms. They were discharged as early as second to third day post-DLS. The 7th patient included in this review was a patient who underwent open appendectomy for perforated appendicitis at another institution. The appendectomy scar was consistent with a standard Lantz incision about 5 cm in length. The patient was referred to us at POD3 after abdominal ultrasound revealed an 8 cm × 5 cm

collection in the pelvis; the patient also had persistent high-grade fever (39 °C). DLS was performed at POD4; the fever settled within 24 h and patient was discharged two days after DLS. All 7 patients who underwent DLS did not have any complications such as bowel injury, serosal tear or any difficulty in suctioning out the IAA during procedure.

Comparing the patients who underwent DLS and those who had percutaneous drainage, the DLS-group had early cessation of fever (a day after the procedure); they also went home earlier than the percutaneous group (at about 2-3 days post-DLS and total length of stay in the ward did not exceed more than a week). The percutaneous-drainage-group took longer time to become afebrile (fever was settled after more than a week); they also had additional pain and discomfort from the pigtail-insertion. They also stayed longer in the ward (10 and 14 days).

Follow-up was carried out at 1-month post-surgery, all DLS-grouped patients remained well clinically and backed to their normal selves. The histopathological examinations of their appendix confirmed perforated appendicitis. None of the patients had symptoms for adhesive obstruction.

## DISCUSSION

A study published in 2014 by Taguchi *et al.*<sup>[5]</sup> from Nagoya Red Cross Hospital, Japan, showed no significant difference in the incident of IAA formation between LA and OA in treating complicated appendicitis i.e. 17 vs. 20. This single-centre randomized-controlled trial was conducted with the development of an infectious complications including IAA formation as primary outcome. In this study, the operating surgeon performed thorough peritoneal lavage using several liters of warm saline regardless of whether an abscess or peritonitis was present. This study showed the safety and feasibility of the usage of LA for complicated appendicitis. Most importantly

**Table 1: Summary of clinical presentations and progress**

No. of patients	Associated symptoms				Day of performing DLS from original surgery	Time post-DLS that fever settled	Day of discharge post-DLS	Total length of stay in ward (days)
	Persistent fever at POD3 and temperature (°C)	Abdominal pain	Poor appetite	Refusal to mobilise				
1	Yes, 38.7	Yes	No	Yes	POD3	POD-DLS 1	POD-DLS 3	6
2	Yes, 38.5	Yes	No	No	POD4	POD-DLS 1	POD-DLS 3	7
3	Yes, 39.0	No	Yes	Yes	POD4	POD-DLS 1	POD-DLS 3	7
4	Yes, 39.0	Yes	Yes	Yes	POD3	POD-DLS 1	POD-DLS 3	6
5	Yes, 38.5	No	No	Yes	POD5	POD-DLS 1	POD-DLS 2	7
6	Yes, 39.0	No	No	Yes	POD4	POD-DLS 1	POD-DLS 2	6
7	Yes, 39.0	Yes	Yes	Yes	POD4	POD-DLS 1	POD-DLS 2	6

DLS: delayed laparoscopic suction; POD: post-operative day; POD-DLS: post-operative day- delayed laparoscopic suction

it showed that it was not the type of approach (LA vs. OA) that determined the rate of IAA formation post appendectomy, but some other factors that yet to be determined. In this study, all the patients with infected wound underwent open surgery to obtain optimal drainage followed by lavage with a water shower. Drain was then placed in most of the cases. It did prolong the healing time but was comparable in both groups.<sup>[5]</sup>

In 2015, Cho *et al.*<sup>[6]</sup> conducted a study with the aim to identify the risk factors for IAA formation in patients receiving LA; 1,817 patients were enrolled in this study. During the LA, when the surgical findings revealed generalized peritonitis or pus, or if faecolith were spilled during the procedure, the operative surgeon would routinely perform cleansing procedure using laparoscopic gauze and suction; no irrigation water was involved. However, if the routine cleansing procedure was incomplete, peritoneal irrigation using sterile isotonic saline with minimum volume of 200 mL would be carried out. Result showed that 27 patients (1.5%) developed IAA formation; 21 of them had received peritoneal irrigation intra-operatively and this was the only factor that was statistically significant to raise the incident of IAA formation in this study. Not even the type of appendicitis (suppurative vs. complicated) or metabolic factor (diabetes vs. non-diabetes) or use of antibiotics could significantly contribute to the higher incidence of IAA formation. IAA was suspected when patient developed fever and abdominal pain post operatively. Computed tomography scan abdomen was performed to confirm the IAA formation. Among the 27 patients who developed IAA postoperatively, only 1 patient received a re-operation. However, the type of operation (laparoscopic or open) and procedure done was not explained in this paper. The remaining 26 cases of IAA, 12 of them underwent percutaneous drainage, and the rest received antibiotic treatment only, no mortality was reported.<sup>[6]</sup>

A comparative study done by Moore *et al.*<sup>[7]</sup> published in 2011, documented a higher abscess rate when irrigation was used during appendectomy for perforated appendicitis including LA. In this study, the data of 176 patients who underwent appendectomy (39% open and 61% laparoscopic) were reviewed retrospectively. More than 50% of patients in both groups received intra-operative irrigation. The amount of irrigation was not quantified in this study due to inconsistent amount of irrigation used between surgeons. Perforation was observed in 28% (50/176), of which 86% (43/50) of patients received intraoperative irrigation. Eleven patients (9.6%) with irrigation developed postoperative abscess compared with 2 (3.3%) patients without irrigation ( $P = 0.22$ ). The result showed no decrease in postoperative intra-abdominal abscess with use of

intraoperative irrigation. They concluded that routine use of intraoperative irrigation for appendectomies does not prevent intra-abdominal abscess formation. This paper did not mention specifically the subsequent management of postoperative IAA among their patients.<sup>[7]</sup>

A prospective randomised trial study conducted by St Peter *et al.*<sup>[8]</sup> in 2012, concluded that there is no advantage to irrigation of the peritoneal cavity over suction alone during laparoscopic appendectomy for perforated appendicitis; 220 patients with perforated appendicitis were enrolled in this study. They were randomised to irrigation (minimum of 500 mL of saline with no maximum limit), or to suction only group (no irrigation). There were 110 patients treated in each arm of this study. There were no differences in age, weight, body mass index percentile, gender distribution, duration of symptoms, presenting leukocyte count, or temperature between the 2 groups. All patients were managed with the same antibiotic regiment and protocol. The primary outcome variable was the development of a postoperative abdominal abscess. The result showed no difference in abscess rate, which was 19.1% with suction only group and 18.3% in irrigation group ( $P = 1.0$ ). From these data, it's clearly demonstrated that the outcome in patients with perforated appendicitis will not be affected by the use of a moderate amount of irrigation during laparoscopic appendectomy. The authors did not mention regarding the management of postoperative IAA among their patients.<sup>[8]</sup>

Similar result was found in recent randomised, controlled equivalence trial done by Snow *et al.*<sup>[9]</sup> that was published in 2016. Eighty-two patients with suppurative or perforated appendicitis were enrolled in this study; 41 patients were randomised to the suction only (SO) group and 40 patients to irrigation and suction (IS) group. Procedure was performed using standard laparoscopic technique. Primary end point was the rate of IAA formation. A median volume of 675 mL of irrigation was used in the IS group. Result showed equal number of patient who developed IAA in both groups (5% in IS group and 4.9% in SO group). From the 4 patients with IAA, 3 required re-operation, in which 2 were laparoscopic (1 SO, 1 IS) and 1 by laparotomy (SO). Another patient (IS) was planned for percutaneous drainage but this was cancelled due to decreasing size of the collection. The rate of IAA in this study was lower than other studies, which had shown closer to 20%. The reason being is most likely due to the case definition for enrollment. This study included suppurative appendicitis as their subjects while other studies focused more on perforated appendicitis.<sup>[9]</sup> In our series, persistent fever was the most

reliable symptom to suspect IAA or collection post appendectomy. Ultrasound was the only radiological tool needed for our patients to confirm the diagnosis of IAA compared to the other series. There was no IAA following appendectomy for suppurative appendicitis in our series. From our review, DLS was easy to do. It provided us with immediate cessation of fever for the patients and relieved of their symptoms (abdominal pain poor appetite and refusal to ambulate). Patients were able to mobilise faster post-DLS too, compared to those who had percutaneous drainage. Patients were also able to be discharged earlier than those who underwent percutaneous drainage. Technically, DLS did not require any additional port insertion and the technique of DLS was quite straight forward, the ease is probably because the abscesses were still early in their phase and less complicated. This technique was also feasible for patient who had undergone open appendectomy; provided the scar did not interfere with area for port insertion.

Following success of this series, we would like to propose a simple guideline on laparoscopic management of IAA post-appendectomy [Figure 1]. Intraabdominal abscess post appendectomy is not a complication that any centre would like to have in high numbers, as a result of the low incidence, we were not able to show statistical significance to compare results between DLS and percutaneous drainage of IAA. However, we were able to demonstrate how a surgeon would be able to resolve this complication quickly. There has not been any literature describing this technique. In conclusion, we believe DLS is a safe, fast and feasible technique to treat IAA. We recommend

this technique for all centres which advocate minimally invasive technique in children.

## DECLARATIONS

### Authors' contributions

Original idea and drafting of text: D.A.A. Aziz, Z.A. Latiff

Literature review and data collection: S. Said, F. Lim, M. Mohd Nor

Data analysis: M. Osman, F. Mohd Zaki

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### Conflicts of interest

There are no conflicts of interest.

### Patient consent

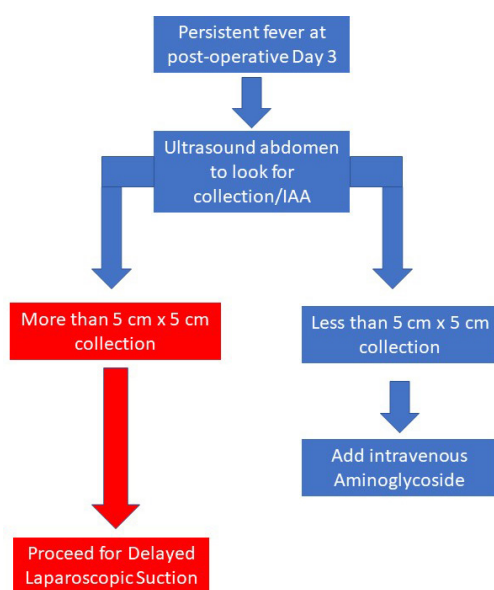
Parental consent was obtained for all patients.

### Ethics approval

Reviews based on our existing audit is waived for ethical approval.

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**Figure 1:** Pathway for management of intra-abdominal abscess (IAA) post-appendectomy

# Endoscopic pneumatic dilatation and peroral endoscopic myotomy in dilated megaesophagus

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## ABSTRACT

Achalasia is a primary esophageal disorder with variable causes, with an incidence between 0.03 to 1/100,000 people, and prevalence of approximately 10/100,000, with no difference between gender. It is more frequent in South and Central America, where Chagas disease is endemic. There are several methods to treat achalasia including endoscopic and surgical procedures, however, all of these methods are palliative. This article discusses 2 different endoscopic methods to treat advanced megaesophagus in Chagas disease, pneumatic balloon dilatation (PBD), and peroral endoscopic myotomy (POEM). Although varying between studies, PBD has an average symptom relief in 93% of patients in 6 months and 44% in 6 years. Some risk factors for failure of PBD are: younger age, male gender, a wider esophagus, poor emptying on post-treatment barium esophagogram and Eckardt scale < 3 before the treatment. Despite relatively short-term follow-up of an average of 3 years, POEM has excellent results. The clinical success achieved in 98% with the Eckardt score decreased from 6.9 preoperatively to 0.77. Regarding sigmoid-shaped esophagus, only a few papers have been published on POEM. The largest population was 32 patients with a follow-up of 2 years. There was an efficacy of 96%, with the Eckardt scale decreasing from 7.8 to 1.4. In conclusion, PBD, is still widely used mainly due to its availability, especially in patients with a higher surgical risk and in patients who already had a Heller myotomy who persist or develop dysphagia. POEM has already demonstrated excellent results, but it requires advanced technical skills and Long-term results and randomized clinical trials are needed to validate the use of POEM in routine clinical practice.

## INTRODUCTION

Achalasia is a primary esophageal disorder of variable causes, with an incidence between 0.03 to 1/100,000 people, and a prevalence of approximately 10/100,000, with no difference between gender<sup>[1-4]</sup>.

It is more frequent in South and Central America, where Chagas disease is endemic. In addition to infectious etiology, other causes of achalasia are idiopathic, autoimmune, or drug-related<sup>[5]</sup>.

Chagas disease is an incurable disease where there



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is total or partial destruction of the intramural motor plexus (Auerbach plexus and Meissner plexus), leading to esophageal aperistalsis and relaxation of the lower esophageal sphincter (LES).

With this underlying pathology, the patients present with progressive dysphagia, retrosternal pain, regurgitation, and weight loss<sup>[6]</sup>.

There are several treatments for this pathology, including medication, surgical and endoscopic treatments. All are palliative because the disease has an unknown pathogenesis with an evolutionary characteristic.

In patients with chagasic disease, the esophagus can dilate to a large caliber. In this circumstance, a well-renowned Brazilian doctor, Ferreira-Santos<sup>[7]</sup>, developed a radiological classification defined by the transverse diameter of the esophagus image contrasted in the antero-posterior incidence, and by the stasis time, that helps with the orientation of the treatment to be used.

Grade I - Moderate dilatation, up to 4 cm of transverse diameter. Small stasis at 5 min.

Grade II - Dilation up to 7 cm of transverse diameter. Stasis at 30 min.

Grade III - Dilation up to 10 cm of transverse diameter with sigmoid-shaped esophagus. Persistence of stasis after 30 min.

Grade IV - Dilation greater than 10 cm of transverse diameter with deviation of the longitudinal axis of the esophagus.

The sigmoid-shaped esophagus (Grade III and Grade IV) is considered to be the advanced stage of achalasia, in which the esophageal lumen is significantly dilated, swerved, and rotated. Up to 10% of all patients with long-standing achalasia (defined as more than 10 years after first diagnosis) developed a sigmoid-shaped esophagus and/or megaesophagus. Endoscopic treatment of advanced achalasia with sigmoid type esophagus is still controversial. Most of the people recommend esophagectomy, mainly in Grade IV, while others recommend myotomy as the first step. Successful treatment of sigmoid-shaped esophagus with laparoscopic Heller myotomy has been demonstrated by several studies<sup>[8-10]</sup>.

A Brazilian group led by Crema *et al.*<sup>[11]</sup>, published a paper that assists physicians in managing patients with sigmoid-shaped esophagus Grade III. They analyzed

the radiologic and manometric findings of 43 patients suffering from chagasic megaesophagus with positive tests for Chagas disease. There was a significant reduction in the high pressure levels of the body of the esophagus related to the stage of the disease: stage I/II - 42.9 mmHg, stage III - 23.6 mmHg, and stage IV - 15.6 mmHg. It was observed that five (35.7%) stage III patients had high pressure levels below 20 mmHg presenting with advanced megaesophagus and underwent a subtotal esophagectomy following esophagogastroplasty instead of cardiomyotomy with anti-reflux valve. The manometric study in stage III patients with chagasic megaesophagus was considered helpful to indicate which surgical procedure would be best for these patients.

Several methods to evaluate the efficacy of the procedure, such as high resolution or conventional manometry to measure the LES pressure and the body motility, upper endoscopy, and emptying timed barium esophagogram (to measure the width and the height of barium column) pre and post-treatment should be done.

In addition, some scales can also be used to evaluate the efficacy of the treatment, such as: the Eckardt *et al.*<sup>[12]</sup> scale [Table 1], visual analog scale<sup>[13]</sup> and quality life SF 36 questionnaire<sup>[14]</sup>.

In regards to endoscopic treatments, there are three types available: injection of botulinum toxin in the LES, pneumatic balloon dilatation (PBD) and peroral endoscopic myotomy (POEM).

The use of botulinum toxin is not common outside the USA and Europe due to its high cost and also because the durability is very low, lower than the PBD. Some authors defend that esophageal botox injections seems particularly appropriate for high-risk patients, but should not be considered a completely safe procedure, with complications rates up to 7.9% in the largest case series available<sup>[15]</sup>.

In this chapter we will discuss the most available and used two types of endoscopic treatment for achalasia: PBD and POEM.

**Table 1: Grading system for evaluating clinical symptoms of achalasia, Eckardt *et al.*<sup>[12]</sup>**

Score	Weight loss	Dysphagia	Retrosternal pain	Regurgitation
0	None	None	None	None
1	< 5 kg	Occasional	Occasional	Occasional
2	8-10 kg	Daily	Daily	Daily
3	> 10 kg	Each meal	Each meal	Each meal

## PNEUMATIC BALLOON DILATATION

PBD uses a pneumatic balloon for low compliance, which is a balloon with minimal deformity and uniform distension throughout its extension. This design promotes the rupture of the muscular fibers of the LES, diminishing its hypertonia. Consequently, this facilitates passage of the alimentary bolus from the esophagus to the gastric chamber<sup>[16]</sup>.

The first balloon built was by Hurst in 1898. Different manufactured models of balloons were developed by Witzel in 1970, the first balloon was used with the gastroscopy. Physical characteristics of the balloons, such as the high complacency, defined as high non-uniform balloon deformity, could increase the risk of perforation in the healthy area of the esophagus because the balloon reached its greatest distension diameter in the area of the minimal resistance.

With the advent of pneumatic balloons with low complacency, balloons with minimal deformity and uniform distension throughout its length, the risk of complications, particularly perforation, was minimized. Currently, the low-compliant balloon is used, which has different sizes (30, 35 and 40 mm) and are much larger than the standard through-the-scope balloons. As a result, the pressure generated by PBD is significantly more effective in fracturing the muscularis propria of the LES.

The dilatation can be done under direct endoscopic view, in which the balloon is placed at the height of the LES and the insufflation was performed under endoscopic vision until the maximum balloon measurement or until the patient begins to feel pain. It can also be done under radiological vision, in which the balloon is placed at the height of the LES. Under continuous radioscopy, the balloon is inflated to its maximum extent, visualizing the formation of a radiological waist in the balloon. Some groups interrupt the inflation after radiological waist loss, while other groups inflate the balloon to its maximum size.

The treatment of achalasia over the years has been carried out mainly through PBD due to its greater availability. However, PBD, although an effective method, has variable durability in different studies. It is also associated with a theoretical higher risk of gastroesophageal reflux disease occurrence between 15-35% of patients due to the total rupture of the circular and longitudinal muscular layers of the LES<sup>[16]</sup>. However, this modality presents a low risk for major complications and deaths compared to surgery. It is currently the most effective non-surgical option for the

treatment of achalasia.

Initial dilatation is performed using a 30-mm balloon and an objective evaluation of the symptoms after 4-6 weeks. For patients who continue to remain symptomatic, dilatation with next-sized balloon should be made. This serial pneumatic dilation approach has been shown to have excellent success rates. Although varying between studies, with relief of symptoms in up to 93% of patients in 6 months to 44% in 6 years<sup>[17,18]</sup>. Additionally, the risk of perforation may be lower with the serial pneumatic dilation approach.

Some risk factors for failure PBD are: younger age, male sex, wider esophagus, poor emptying on post-treatment timed barium esophagogram and Eckardt *et al.*<sup>[12]</sup> scale < 3 before treatment.

Balloon dilatation of the cardia is not indicated for advanced megaesophagus, since the reduction of symptoms is less compared to the non-advanced form and its durability is less than 6 months. Although, a paper published from Pakistan<sup>[19]</sup> showed that 9 patients with dilated megaesophagus (Grade > II) with transverse diameter > 7 cm, were treated using a 35 mm balloon without complications and with symptomatic improvement at 12-month follow-up.

## PERORALENDOSCOPICCARDIOMYOTOMY

POEM introduced by Ortega *et al.*<sup>[20]</sup> in 1980 and later standardized by Inoue *et al.*<sup>[21]</sup> in 2010, is a new type of endoscopic treatment, which has been widespread in the past seven years.

This procedure performed with the upper digestive endoscopy is an esophageal and gastric myotomy with submucosal layer dissection under general anesthesia.

A cushion is formed in the submucosal layer of the esophagus, followed by a 2-cm incision in the mucosa to access the submucosal layer through the anterior or posterior wall. The creation of a submucosal tunnel is carried out to the esophagogastric junction, entering about 2-4 cm into the stomach.

Next, the myotomy of the gastric part is performed, followed by myotomy of the esophageal muscular layer. Some groups perform the total myotomy of the circular and longitudinal layers of the esophagus, while others perform only the myotomy of the circular layer. It is important to vary the extent of the esophageal myotomy from 6 to 10 cm towards the middle esophagus to the gastroesophageal junction (GEJ). Finally, the incision of the mucosal layer is closed with the placement of endoclips or by endoscopic suture.

The first publication on POEM was by Inoue *et al.*<sup>[21]</sup> in 2010 with 17 patients. The mean myotomy was 8 cm, 6 cm from the esophageal part and 2 cm from the gastric portion, with a significant decrease in the pressure of the lower esophageal sphincter (52.4 to 19.9 mm). There was no recurrence of dysphagia with a short follow-up of 5 months.

Initial published experience in humans<sup>[22]</sup> with non-sigmoid megaesophagus is more encouraging despite a relatively short-term follow-up (3 years). The largest series case<sup>[22]</sup> of 500 patients had Eckardt *et al.*<sup>[12]</sup> score decreasing from  $6.0 \pm 3.0$  to  $1.0 \pm 2.0$  and lower esophageal sphincter (LES) pressures from  $25.4 \pm 17.1$  to  $13.4 \pm 5.9$  mmHg with a mean follow-up of 3 years post-POEM. Gastroesophageal reflux was seen in 16.8% of patients at two months and 21.3% at 3-year follow-up.

The most recent meta-analysis<sup>[23]</sup> involved 2,373 patients with a clinical success of 98% after the procedure. On one hand, the mean Eckardt *et al.*<sup>[12]</sup> score decreased from  $6.9 \pm 0.15$  pre-operatively to  $1.0 \pm 0.08$  within 12 months of treatment. In addition, there were significant decreases in the average lower esophageal sphincter pressure, integrated relaxation pressure and the average heights of the barium column following a timed barium esophagogram after the procedure. On the other hand, a mean follow-up of 8 months post-procedure shows symptomatic gastroesophageal reflux in 8.5% and esophagitis on esophagogastroduodenoscopy in 13%.

Only a few papers<sup>[24]</sup> have been published about POEM for sigmoid-shaped esophagus. The dilated and tortuous esophagus lumen may make the endoscopic dissection and separation of tissue more challenging and time consuming. The largest population was published by Hu *et al.*<sup>[25]</sup> with 32 patients and follow-up of 2 years with an efficacy of 96%. The Eckardt *et al.*<sup>[12]</sup> scale decreased from 7.8 to 1.4 and the LES pressure from 37.9 to 12.9 mmHg. No serious complications were observed. However, the most common complication was clinical reflux with an average of 25.8% of the patients.

Recent studies have shown that POEM results in better improvement of dysphagia and reduction of LES pressure and lower complication rates compared to PBD.

However, recent studies have shown that gastroesophageal reflux is more common in POEM, ranging from 15% to 35% in some studies, and myotomy in the posterior wall is more susceptible to

reflux. Moreover, the formation of adhesions between the submucosal layer and the longitudinal musculature after POEM may make it challenging if surgical revision is necessary for recurrence or persistent dysphagia after POEM.

## CLINICAL PRACTICE

At Clinicas Hospital University of São Paulo, one of the most experienced centers that treat patients with achalasia caused by Chagas disease, the endoscopic treatment through the pneumatic dilatation of the cardia or POEM is indicated in degrees I and II based on Ferreira-Santos classification.

In grade III, the option for POEM is questionable and in grade IV, dilation is indicated only with the intention to preparing the patient (providing greater nutritional intake) for surgical treatment.

From the surgical point of view, Heller's cardiomyotomy is indicated in degrees I, II and III, whereas in grade IV esophagectomy is the preferred technique.

At present, both gastroenterologists and surgeons do not know which modality of treatment is better to patients with degrees II, comparing POEM, PBD and Heller's cardiomyotomy and I.

At our institution, the first line treatment to patients degree I is PBD. In degrees II and III, patients up to 70-year-old without high-risk comorbidities are referred to POEM or Heller and in degree IV esophagectomy as the preferred technique. However, if the patient does not have surgical conditions, PBD is performed to provide greater nutritional intake and to relieve symptoms. The botulinum toxin is not currently available at our institution.

## CONCLUSION

In conclusion, in spite of promising results, POEM requires significant qualifications, and because it is a recent procedure, lacks reproducibility. Long-term results and randomized clinical trials before validating the use of POEM in routine clinical practice for the treatment of esophageal achalasia.

In relation to balloon dilatation of the cardia, even with variable durability mainly in advanced megaesophagus, it is still widely used in older patients, with a higher surgical risk, and in many cases in patients already submitted to Heller's surgery who persist or develop dysphagia.

## DECLARATIONS

### Authors' contributions

Literature review: E.T.H. de Moura

Wrote, revised and approved the manuscript and the final version: E.T.H. de Moura, E.G.H. de Moura

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There are no conflicts of interest.

### Patient consent

Not applicable.

### Ethics approval

Not applicable.

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# Heller-Pinotti, a modified partial fundoplication associated with myotomy to treat achalasia: technical and final results from 445 patients

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## ABSTRACT

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### Key words:

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**Aim:** The need for an antireflux procedure after myotomy is no longer as controversial as it used to be. However, the choice of the best fundoplication after myotomy is still controversial. The authors present the results of laparoscopic myotomies associated with postero-latero-anterior fundoplications (Heller-Pinotti). **Methods:** Medical records and endoscopic findings were reviewed for achalasia patients that had submitted to the procedure following 5 years of follow-up. **Results:** In total, 445 patients were enrolled: 39 (8.7%) presented erosive esophagitis, the Los Angeles classification being A-21, B-12, C-2 and D-4 (2 with peptic substenosis and 2 Barrett); 41 (9.2%) patients had dysphagia, 4 needed reinterventions; 49 (11%) presented a migration of the fundoplication wrap to the thorax due to hiatal hernia, this was correlated with a higher risk of present erosive esophagitis ( $P = 0.047$ ) and dysphagia ( $P < 0.001$ ). **Conclusion:** Laparoscopy myotomy postero-latero-anterior fundoplication (Heller-Pinotti) produces a good long-term outcome for dealing with dysphagia and in terms of reflux prevention.

## INTRODUCTION

Myotomy of the esophageal lower sphincter is the best way to treat achalasia. It is expected that gastro esophageal reflux occurs after this procedure because one of the mechanisms of defense against reflux is withdrawn. The incidence of postoperative reflux and related complications following open cardiomyotomy without fundoplication varies between 20%-32%<sup>[1,2]</sup>.

There is therefore a consensus that an antireflux procedure should be performed at the time of the myotomy.

The choice between a total fundoplication, anterior or posterior, has already been the subject of studies and meta-analysis in the literature, though the methods for improvement are still controversial.

Some modifications were made over time in our unit.

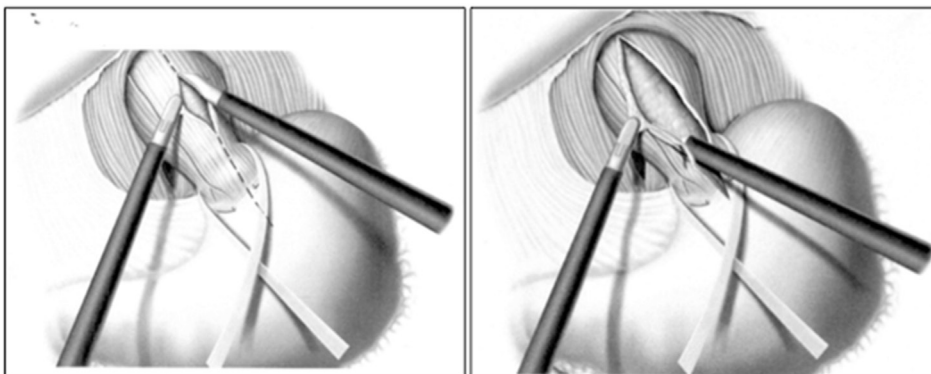


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**Figure 1:** Laparoscopic myotomy

Pinotti *et al.*<sup>[3]</sup> added a posterior suture line to the Dor fundoplication thus creating a postero-lateral-anterior fundoplication that encompassed more than the anterior fundoplication and enhanced reflux control. This type of fundoplication is widely used in Brazil and is known as the Heller-Pinotti procedure.

In this article, we demonstrate the long-term results of myotomy associated with this type of fundoplication and compare it with results from world literature.

## METHODS

### Technique

The arrangement of the ports for laparoscopy, as well as whether the patient is positioned with legs spread open or aligned together in the midline, is a personal choice and depends on the experience and preference of the surgeon. Our preference is to position the patient with legs spread open and the monitor positioned by the patient's head. The surgeon is positioned between the patient's legs, the first assistant is on the left side and the second assistant who is responsible for the camera, is positioned on the patient's right side.

In this position, the trocar receiving the camera is placed 3 to 5 cm above the umbilicus to facilitate the exposure of the gastric fundus and the hiatus. The trocar for the liver retractor is positioned in the epigastrium. In the right hypochondrium is the access to the surgeon's left hand and the portal for the right hand is in the left hypochondrium. An additional trocar can be placed into the left hypochondrium if needed.

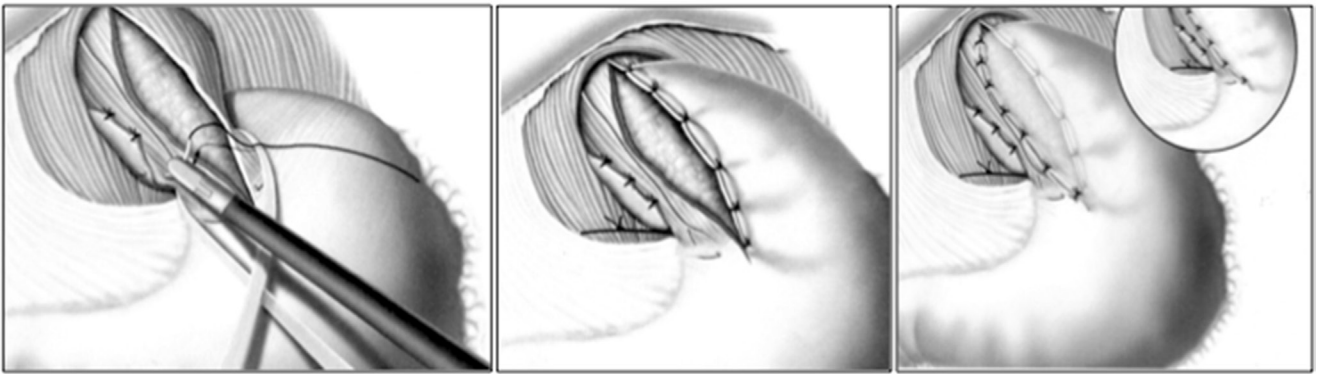
The technical steps are as follows:

1. Mobilization of the gastric fundus: the procedure begins with the complete mobilization of the gastric fundus. It is important to divide as many short gastric

vessels as possible in order to leave it free from adhesions when the fundoplication is constructed. A cause of early postoperative dysphagia is a fundoplication without a complete release of gastric fundus that results in traction and torsion of the esophagogastric junction when the stomach is distended.

2. Dissection of the esophagogastric junction: it begins with a downward movement of the stomach by an assistant and the opening of both the hepatogastric ligament and phrenoesophageal membrane preserving the hepatic branch of the vagus nerve. This allows for better traction of the distal esophagus into the abdominal cavity. The following step is the identification and dissection of the diaphragmatic pillars and separation of the esophagus from the hiatus. At this point it is important to identify the anterior and posterior vagus nerves to avoid their injury. In chagasic patients it is very common to find a twisted and dilated distal esophagus. All the adhesions of the distal esophagus in the mediastinum are released to create a safe, open area for the myotomy and to straighten the esophageal axis.

3. Cardiomyotomy: the myotomy of the distal esophagus and the cardia is performed with the surgeon's preferred instrument (hook, scissors, harmonic scalpel) by bluntly gripping and sectioning the muscle fibers, with or without force to avoid the splitting of the lower esophageal sphincter fibers. The myotomy is advanced upwards in the esophagus for a minimum length of 6 cm and at least 3 cm down in the stomach [Figure 1]. An inadvertent mucosal injury during myotomy is not uncommon, particularly at the beginning of the learning curve with the procedure. If the mucosa is opened, the defect must be closed immediately with a monofilament absorbable suture and coverage of



**Figure 2:** Laparoscopic myotomy and fundoplication

the area should be provided by the fundoplication itself. Such mishap does not increase the risk of failure of the procedure and fistula is rare.

4. Hiatoplasty: for release of the distal esophagus into the mediastinum, the hiatal defect is usually opened wide. If the defect is larger than the diameter of the esophagus, it is recommended to perform the hiatoplasty with separate stitches and approximate the second diaphragmatic.
5. Fundoplication: it is our preference to perform an anterior-lateral-posterior fundoplication with 3 suture lines between the gastric fundus and the esophagus. The 1st suture line is placed between the posterior region of the esophagus and the posterior wall of the stomach, usually with 3 to 4 stitches [Figure 2]. The second suture line is performed by joining the left lateral border of the esophageal myotomy with the gastric fundus in the transition between the anterior and posterior wall. The last suture line is placed in the right lateral border of the myotomy with the anterior face of the gastric fundus covering the entire myotomy.

### Patients

Over the past several years, the 1st choice of treatment for achalasia in our institution has been the myotomy with fundoplication. Of the 849 patients submitted to laparoscopic surgery between 2000 and 2012, 445 had regular follow-ups at our hospital for more than 5 years and underwent routine upper endoscopies. The examinations were performed every 2 years, or less if the patient presented any symptoms.

### Data collection

The medical records of these patients were reviewed and the following data were obtained: age, gender and follow-up time. Regarding the endoscopy examinations, it was decided to analyze

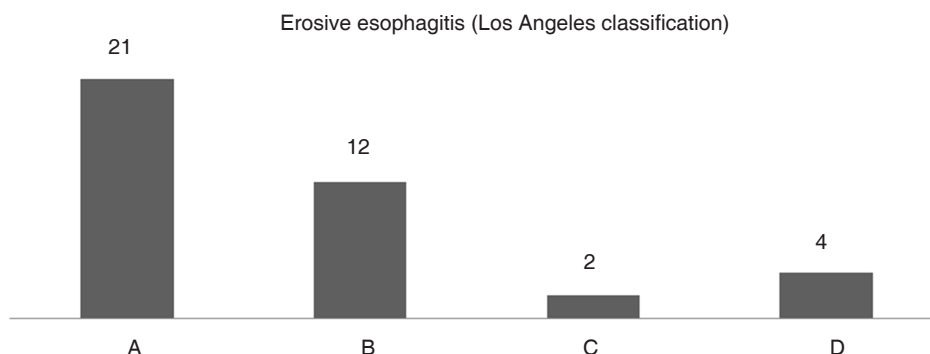
the 1st examinations 5 years after the surgery, thus standardizing the endoscopic findings regarding the follow-up time. All patients were tested for serology and for the presence of Chagas disease. The etiology between chagasic and idiopathic conditions was evaluated. Presence of erosive esophagitis and complications of gastro esophageal reflux (stenosis or barret) were investigated with an endoscopy at a 5-year follow-up. It was also assessed whether funduplications that had migrated due to hiatal hernia were intra-abdominal or intrathoracic. The seriogram was analyzed (barium swallow) before surgery to quantify the degree of dilation of the esophagus. The Rezende classification stages were used. Patients with a dilation of less than 4 cm were classified as in grade I, between 4 and 7 - grade II, between 7 and 10 - grade III and greater than 10 - grade IV. Patients with a dolichomegaesophagus and a degree of dilation greater than 10 cm were excluded from this study. The medications used by the patients were obtained from their electronic medical records. It was assessed whether a patient used a proton pump inhibitor and routinely used 20 mg twice daily. Postoperative dysphagia was defined when the patient reported difficulty in oral intake that required some type of intervention to improve quality of life. Presence of dysphagia reported by the patient was also recorded, as well as how many years after the operation these symptoms persisted.

### Statistical analysis

Calculated odds ratio and chi square between the variables.

## RESULTS

Of the 445 patients, 244 were women and 201 men. The mean age was 45.6 ( $\pm$  12.7) years. The mean follow-up time was 10.2 ( $\pm$  3.4) years. The degree of dilation was grade I in 44 (9.8%), grade II in 226



**Figure 3:** Number of patients with erosive esophagitis. Distribution according to Los Angeles classification

(50.7%) and grade III in 175 (39.5%). Thirty-nine (8.7%) patients presented erosive esophagitis 5 years after surgery. In relation to the Los Angeles classification, 21 presented esophagitis A, 12 B, 2 C and 4 D [Figure 3]. Two patients with esophagitis Los Angeles D also presented peptic sub stenosis, while the other 2 patients were identified with Barrett esophagus without atypia. With regard to the situation surrounding the fundoplication wrap, all remained detectable on endoscopic examination. However, 49 (11%) were partially migrated to the thorax due to hiatal hernia. It was observed that 81 (18%) patients had regular use of a proton pump inhibitor. However, it was noted that 42 patients were taking it per their cardiologist's prescription. These patients were chagasic and used various medications and presented dyspepsia and epigastric pain secondary to medication. The other 39 were precisely the patients who had erosion seen on endoscopy. Forty-one (9.2%) patients had dysphagia and required some type of intervention to improve this condition: 37 had experienced clinical improvement with endoscopic dilation and 4 required reinterventions; 1 case of dysphagia being considered due to gastric migration and the other 3 due to myotomy fibrosis. We can see the dispersion of cases of dysphagia by time [Figure 4].

The odds ratio was calculated and a chi-square test conducted to determine the presence of erosive esophagitis in relation to the degree of dilatation, etiology, and valve migration [Table 1]. The same was done for the presence of dysphagia in relation to the degree of dilatation and migration of the wrap [Table 2] and finally to the presence of migration in relation to the degree of dilatation [Table 3].

It can be observed that when the fundoplication migrated there was a higher risk of developing erosive esophagitis ( $P = 0.047$ ) and dysphagia ( $P < 0.001$ ). There was no higher risk of migration when the esophagus was more dilated.

## DISCUSSION

The need for an antireflux procedure after myotomy is no longer as controversial as it used to be. The presence of a myotomy in the distal esophagus counteracts the physiological function of the lower esophageal sphincter that prevents the gastric contents from going back to the esophagus. It is expected that gastro-esophageal reflux will occur and become more severe postoperatively<sup>[4-6]</sup>.

In a meta-analysis in 2009, Campos *et al.*<sup>[7]</sup> demonstrated an incidence of gastroesophageal reflux disease (GERD) among 31.5% of patients submitted to myotomy without fundoplication. It is very difficult to completely suppress gastroesophageal reflux after laparoscopic myotomy even when some antireflux procedure is associated. The rate of gastroesophageal reflux may range from 0% to 44%<sup>[7]</sup>.

The type of anti-reflux procedure varies according to the circumferential extension of the fundoplication. The most frequently used are the 180° anterior (Dor), 270° (Toupet) and 360° (Nissen). Despite the good control of reflux, the Nissen technique and its modifications are associated with a higher incidence of postoperative dysphagia (up to 75%) and therefore it is not recommended for patients submitted to myotomy<sup>[8-10]</sup>. The choice of the best fundoplication post myotomy is still controversial. The Dor repair uses 2 lines of suture anchored in both borders of the myotomy. The coverage of the exposed submucosa in the myotomy with the Dor fundoplication allegedly has the advantage of blocking an eventual perforation of the myotomy. On the other hand, the Toupet fundoplication theoretically distances the edges of the myotomy, decreasing the risk of dysphagia recurrence<sup>[2,11,12]</sup>. The fundoplication performed in our procedure has some advantages of both. It covers the exposed submucosa because the gastric fundus is fixed at both edges of the myotomy and keeps contact to the anterior face.

**Table 1: Presence of erosive esophagitis in relation to the degree of dilatation, etiology and fundoplication status**

Characteristics	Odds ratio	95%CI	P
Dilatation			
I	1		
II	0.58	(0.22-1.55)	0.274
III	0.55	(0.2-1.53)	0.246
Etiology			
Idiopathic	1		
Chagasic	1.85	(0.96-3.58)	0.065
Fundoplication status			
Intra-abdominal	1		
Wrap migration	2.3	(1-5.33)	0.047

Additionally, it has a latero-posterior component with another suture line in the posterior part of the esophagus, resulting in 270° of circumferential contact with the esophagus and thereby providing a reflux control similar to Toupet. Both anterior (Dor) and posterior (Toupet) are associated with good control of dysphagia after myotomy with results ranging between 77% and 96%<sup>[13-15]</sup>. In a review involving more than 3,000 patients, dysphagia was resolved on average 89.3% of the time<sup>[7]</sup>. With our technique, we demonstrated a long-term dysphagia resolution rate of 91%. In contrast, issues related to reflux are less reported after a Heller myotomy associated with a partial fundoplication.

Clinically, it is often difficult to accurately diagnosis gastro-esophageal reflux because of the reflux-like symptoms resulting from stasis and fermentation of esophageal contents retained in the esophageal lumen by ineffective or incomplete myotomy. One component believed to contribute to this is the severity of the esophageal dilatation. Once the obstacle in the distal esophagus is removed, the reflux of the gastric contents will find an atonic esophagus with literally no contractility capable of promoting esophageal clearance, relying mostly on gravity for emptying<sup>[16,17]</sup>.

The use of pH metry for the evaluation of reflux in patients with achalasia after myotomy with fundoplication is the main tool for quantitative analysis. However, due to the production of lactic acid secondary to the stasis of food and saliva in the distal esophagus the results can be misinterpreted. Tsiaoussis et al noted that up to 66% of reflux events may be secondary to this phenomenon. Additionally, they noted that the diameter of the esophageal lumen showed a positive correlation with a distal pH < 4<sup>[18]</sup>.

Ortiz *et al.*<sup>[19]</sup> evaluated pH results in 136 patients with a median 6-year follow-up after open myotomy; Toupet

**Table 2: Presence of dysphagia in relation to the presence of esophagitis and fundoplication status**

Characteristics	Odds ratio	95%CI	P
Esophagitis	1		
No esophagitis	1.14	(0.38-3.38)	0.814
Fundoplication status			
Intra-abdominal	1		
Wrap migration	3.54	(1.64-7.61)	< 0.001

**Table 3: Presence of migration in relation to the degree of dilatation**

Dilatation	Odds ratio	95%CI	P
I	1		
II	1	(0.39-2.58)	0.989
III	0.46	(0.16-1.32)	0.143

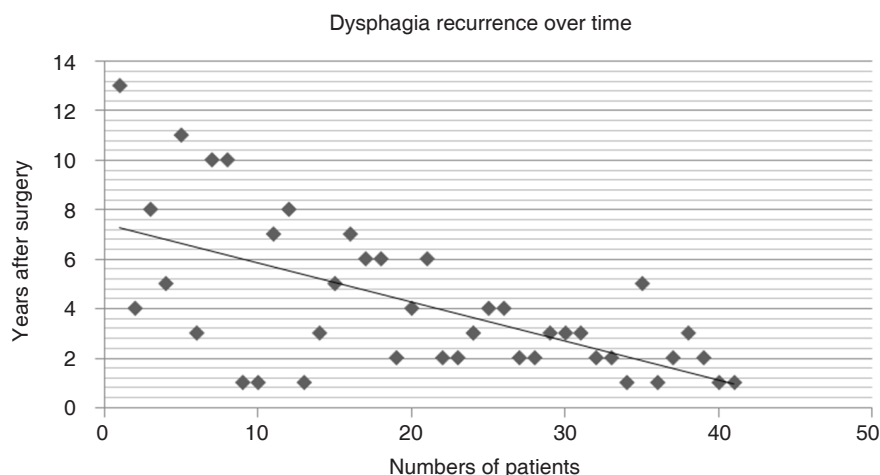
FP and abnormal pH results were found in 19 patients (14%) overall, while abnormal acid exposure increased over the course of follow-up from 8.1% at 1 year to 18.5% at 5 years and 23.7% at 10 years.

We used, as a marker of reflux, the presence of erosive esophagitis because of the alteration in the pH metry of these patients, and also because it is not routine to perform this test on patients with megaesophagus under our care.

There is still no consensus as to the best fundoplication after this procedure. There are few controlled multi-centric studies because it is a rare disease. The only randomized, multi-institutional study comparing the 2 types of partial fundoplications showed gastroesophageal reflux in 41.7% of patients in the Dor group vs. 21% in the Toupet group. It was not possible to demonstrate a statistical difference due to sample size and follow-up<sup>[20]</sup>.

A meta-analysis of more than 2,500 patients showed an approximate 14.3% rate of reflux with anterior fundoplication and 15.8% with posterior and dysphagia indexes of 10% and 5.8%, respectively<sup>[21]</sup>. We had with our antero-latero-posterior fundoplication a reflux rate of only 8.1% after more than 5 years of follow-up.

This meta-analysis study demonstrated that both partial fundoplications are associated with an equivalent control of GERD. However, anterior fundoplication is associated with higher reintervention rates for postoperative dysphagia compared with posterior fundoplication. The authors note that one of the reasons for this difference is that posterior fundoplication keeps the edges of the myotomy open and avoids potential adhesions that



**Figure 4:** Dispersion of patients with recurrence of dysphagia over time

may develop between the myotomy and anterior fundoplication, resulting in fewer reinterventions for postoperative dysphagia<sup>[11,21,22]</sup>. Our fundoplication covers the exposed mucosa, and we only had 4 cases requiring reintervention. There are few studies evaluating endoscopic results. In a study comparing a Dor fundoplication group with a Toupet group, Katada *et al.*<sup>[23]</sup> demonstrated that the pHmetry study was similar in both groups. However, both symptoms and endoscopic findings were different; reinforcing the importance of endoscopic and clinical findings for the evaluation of these cases.

Erosive esophagitis was found in 38.5% of the Toupet group and 8.8% of the Dor group, which was similar to the Toupet group in the same study<sup>[23]</sup>. Our study is not a comparative one, however we find better results with our fundoplication, even taking into account that more than half of our cases were erosive esophagitis Los Angeles A, which is a rather mild complication. In our procedure, we performed a dissection of the entire circumference of the hiatus to create a large segment of intra-abdominal esophagus and a large area for the myotomy. Simić *et al.*<sup>[24]</sup> found that Dor fundoplications in the setting of a complete hiatal dissection had a higher degree of abnormal esophageal acid exposure (23.1%) than if a limited hiatal dissection was performed (8.5%). However, when we performed a more extensive fundoplication than the Dor, we achieved a good success rate (8.1%).

One factor not routinely reported in other studies is the migration of fundoplication to the thorax. Though we advocate the closure of the diaphragmatic hiatus after esophagus dissection, we nevertheless observed a 11% rate of hiatal herniation. This event correlated with the presence of reflux esophagitis ( $P = 0.047$ ) and also

with dysphagia ( $P < 0.001$ ). Gastric migrations through the hiatus have a tendency to decrease the function of the fundoplication due to the negative pressure in the thorax. Perhaps this alteration of the anatomy also allows the edges of the myotomy to approach, and may be related to the difficulty of passage of the bolus due to the ensuing deformities by the hiatal hernia itself. We had 3 cases in which the reintervention was due to myotomy fibrosis and one where the deformity of the hernia clearly originated with dysphagia.

First, we thought that it was important to classify the etiology of achalasia as chagasic or idiopathic because Chagas disease is very common in Brazil. However, we observed that these two groups of patients behave in a similar manner during the treatment, with no difference in outcome. Our study has the limitation of being a retrospective, non-comparative study. Because only medical records were obtained, it was not possible to apply any specific questionnaire regarding reflux or dysphagia. Only information reported by the patient was used and the severity of the reflux or dysphagia was unable to be quantified. The use of a proton pump inhibitor for reasons other than reflux symptoms may also be a bias in the number of patients with endoscopic alterations. However, this number was small and patients had no reported reflux symptoms in their history.

In conclusion, we have demonstrated that laparoscopy myotomy postero-latero-anterior fundoplication (Heller-Pinotti) has a good long-term outcome in relation to dysphagia and in terms of reflux prevention. Furthermore, it could produce better results than other partial fundoplications, however it requires both a prospective and comparative study.

## DECLARATIONS

### Authors' contributions

Concept and design: E.T. Bianchi, R.A.A. Sallum, S. Szachnowicz

Manuscript preparation: E.T. Bianchi, R.A.A. Sallum, J.R.M. da Rocha

Data and statistical analysis: E.T. Bianchi, A.F. Duarte

Manuscript editing: S. Szachnowicz, F.C.B.C. Seguro, A.F. Duarte

Literature search: E.T. Bianchi, F.C.B.C. Seguro, A.F. Duarte

Manuscript review: R.A.A. Sallum, J.R.M. da Rocha, I. Cecconello

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### Conflicts of interest

There are no conflicts of interest.

### Patient consent

Patient informed consents were obtained before the operation, as in all procedures.

### Ethics approval

This retrospective data collection was approved by the Ethical Committee of our hospital.

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# Minimally invasive esophagectomy in achalasia: a more liberal approach to esophageal resection

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## ABSTRACT

**Aim:** The advent of minimally invasive abdominal and thoracic surgeries has led to a meaningful reduction in complication and mortality rates among patients undergoing esophagectomy, especially when used for the treatment of benign diseases such as megaesophagus. **Methods:** Two hundred thirty-one patients, 152 (65.8%) men and 79 (34.2%) women, with a mean age of 52.46 (19-80) years, were treated for advanced megaesophagus between September 1996 and October 2016. Two hundred ten patients (90.91%) had chagasic megaesophagus and 21 patients (9.09%) had idiopathic megaesophagus. **Results:** Immediate complications were observed in 37 patients (16.01%): hemopneumothorax in 22 cases (9.52%), gastric stasis in 11 (4.76%), cervical fistula in 11 (4.76%), dysphonia in 18 (7.8%), and mediastinitis in 1 case (0.43%). Two patients (0.86%) died: 1 patient with a pacemaker died of cardiorespiratory arrest on postoperative day 12 and the other patient died of mediastinitis on day 28. Our standardized protocol includes nutritional and pulmonary outpatient care. **Conclusion:** With a standardized multidisciplinary protocol and a team adequately trained in laparoscopy, minimally invasive esophagectomy is an excellent option for the treatment of advanced megaesophagus. The technique is easily standardized and reproducible, and provides excellent postoperative outcomes.

## INTRODUCTION

The scientific rationale for choosing the best surgical treatment for a condition is to offer patients a procedure that removes or abrogates the symptoms and adverse risks of the condition, thus reducing the number of complications and the mortality rate. The advent of minimally invasive abdominal and thoracic surgeries has led to a meaningful reduction in complication and mortality rates among patients undergoing

esophagectomy, especially when used for the treatment of benign diseases such as megaesophagus<sup>[1]</sup>.

Advanced megaesophagus mainly affects young male adults. It is a chronic progressive motor disorder of esophageal peristalsis that results in dilatation, tortuosity, and elongation of the esophagus. Megaesophagus is commonly associated with pulmonary complications due to acute or chronic bronchoaspiration, and with a higher frequency of epidermoid esophageal



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## Quick Response Code:



cancer<sup>[2,3]</sup> secondary to stasis, chronic esophagitis, intraesophageal pH changes<sup>[4]</sup>, and the presence of bacteria<sup>[5]</sup> and viruses such as human papilloma virus (HPV)<sup>[6]</sup>, in addition to a high prevalence of *Helicobacter pylori* in the esophageal mucosa<sup>[7]</sup>.

Esophagectomy for the treatment of advanced megaesophagus, consisting of right thoracotomy, laparotomy, and cervicotomy, was reported by Camara Lopes and Ferreira-Santos in 1963. Also, in Brazil, DePaula *et al.*<sup>[8]</sup>, Crema *et al.*<sup>[9]</sup> and Crema *et al.*<sup>[10]</sup> published their first results of full laparoscopic transhiatal esophagectomy for the treatment of megaesophagus, including removal of a surgical specimen and esophagogastric anastomosis through cervical incision. As megaesophagus affects the myenteric plexus that is located between the smooth muscle layers, subtotal resection of the organ theoretically cures the disease because striated muscles, which are not innervated by myenteric plexuses, predominate in the proximal third. Analysis of radiologic-manometric correlations showed an amplitude of esophageal body contraction of < 20 mmHg in all cases radiologically classified as megaesophagus grade IV and in 35.7% of cases classified as grade III, defined by us as functionally advanced<sup>[11]</sup>.

In a study investigating 31,769 patients with achalasia in the United States between 2003 and 2010, esophagectomy was performed in 785 cases (2.5%), with an associated intrahospital mortality rate of 1.96%, similar to that with endoscopic treatment (1.17%), and Heller myotomy was performed in 15,567 cases (49.0%)<sup>[12]</sup>. Various authors recommend esophageal resection in the case of recurrence or persistence of symptoms after Heller surgery<sup>[13-17]</sup>. Csendes *et al.*<sup>[18]</sup> reported poor results of Heller surgery in 20% of patients after 10 years of follow-up and in 35% after 20 years. Furthermore, 4.5% of these patients developed esophageal cancer. In a 15-year follow-up study of 448 patients after Heller surgery, Leeuwenburgh *et al.*<sup>[19]</sup> found epidermoid cancer in 2.7% and adenocarcinoma in Barrett's esophagus in 0.7%.

Crema *et al.*<sup>[6]</sup> observed changes in esophageal pH (4 and 5) and a high prevalence of HPV subtypes 16 and 18 in the mucosa of patients with megaesophagus. These subtypes are directly associated with epidermoid esophageal cancer<sup>[20]</sup>.

Using a transhiatal approach in 94% of cases, Devaney *et al.*<sup>[21]</sup> observed mortality in 2%, complications in 30%, and anastomosis dehiscence in 10% of cases, whereas 88% of the patients were satisfied with the procedure. Molena and Yang<sup>[22]</sup> reported excellent results of using a transthoracic approach in esophagectomy and the

stomach as the plasty organ. In Brazil, resection of the esophageal mucosa is preferentially performed for the treatment of advanced megaesophagus, in which a muscular tube is preserved through which the stomach is transposed to the cervical region<sup>[23]</sup>.

In cases of advanced and recurrent megaesophagus, minimally invasive transhiatal esophagectomy is an excellent surgical approach to eliminate dysphagia and prevent pulmonary complications resulting from bronchoaspiration and from the occurrence of tumors associated with chronic esophageal stasis.

## METHODS

During the study period, 660 patients were treated. Of these, 346 (52.42%) underwent Heller surgery combined with an antireflux valve, 231 (35.01%) underwent transhiatal esophagectomy, and 83 (12.57%) underwent esophageal dilatation due to possible clinical conditions for any surgical procedure.

Two hundred thirty-one patients, 152 (65.8%) men and 79 (34.2%) women, with a mean age of 52.46 (19-80) years, were treated for advanced megaesophagus at the Department of Surgery, School of Medicine, Federal University, Uberaba, Brazil, between September 1996 and October 2016. Two hundred and ten patients (90.91%) had chagasic megaesophagus and 21 patients (9.09%) had idiopathic megaesophagus. The mean duration of the surgical procedure was 165 (100-235) min, and all procedures were performed by the same team, with the responsible surgeon being one of the authors of the present study (Crema E). Of the 231 patients, 98 (42.43%) had undergone at least some type of esophagogastric transition surgery 8-20 years before the study. All patients received information about the surgical procedure to be performed, and the protocol was approved by the Ethics Committee on Human Research of the School of Medicine of the Federal University, Uberaba, Brazil<sup>[9]</sup>.

## Surgical technique

The patients were placed in the dorsal decubitus position on the operating table with the legs abducted. The surgeon was positioned between the legs, and an assistant (camera), on the left side of the patient. The monitor, when there was only one, was positioned on the right and at the head of the operating table. Five entry ports were used: 2 of 10 mm diameter and 3 of 5 mm diameter. One of the 10-mm ports was situated in the midline between the xiphoid appendix and the navel for a 30° eyepiece and the other was positioned in the left hemiclavicular line 5 cm from the costal margin (right hand of the surgeon). The 5-mm

ports were positioned in the right hemiclavicular line (left hand of the surgeon), 1 cm left from the xiphoid appendix (aspirator) and 15 cm left from the umbilical scar (esophageal separator).

Using a 12-mmHg pneumoperitoneum (CO<sub>2</sub>), the procedure was started through ample dissection of the esophagogastric transition, restoring the abdominal esophagus with a Penrose drain or a flexible separator (EndoFlex, Medline, Mundelein, IL, USA). Dissection was continued with the esophageal body under direct vision, with preservation of the vagus nerves [Figure 1] and identification of the pleurae and pericardium. Hemostasis was achieved with monopolar cauterization or with UltraCision (UltraCision Inc., Smithfield, RI, USA) and/or clipping of the esophageal branches until the cervical region. The surgical dissection plane was close to the esophagus, thus preventing damage to the pleurae and mediastinal structures.

To obtain better access to the mediastinum during dissection of the thoracic esophagus, we routinely performed median transection of the diaphragm and placed the operating table in the Trendelenburg position.

After dissection of the abdominal and thoracic esophagus was completed, the stomach was prepared with release

of the greater curvature. Monopolar electrocauterization and UltraCision were used for sectioning of the short gastric vessels and gastrocolic omentum. The gastroepiploic and left gastric vessels were ligated by double clipping, with preservation of the arch of the greater and lesser curvature. No pyloroplasty was performed during surgical treatment of advanced megaesophagus. After preparing the stomach, the cervical esophagus was dissected through a left cervicotomy. Owing to the delicate traction of the surgical specimen, the esophagus and proximal part of the stomach in the cervical region were exteriorized and the esophagogastric transition was sectioned with a cutting linear stapler with a 75-mm green load. The passage of the esophagus and stomach was monitored during cervical traction of the esophagus under direct vision, using an eyepiece positioned in the inferior mediastinum.

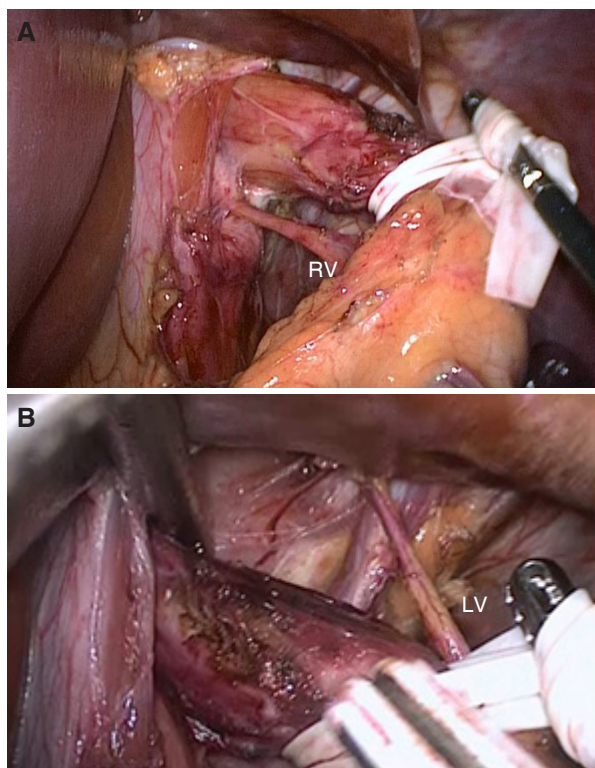
An esophagogastric anastomosis was performed with manual continuous 3.0 monofilament sutures on a single plane between the posterior wall of the gastric fundus and a segment of the cervical esophagus, whose extension was approximately 4 cm so that the esophagogastric anastomosis would remain in the cervical region. No cervical or abdominal drainage was used.

The use of the whole stomach as the plasty organ is justified by the maintenance of better vascularization of the gastric body and fundus because of non-interruption of the rich vascular submucosal network. We therefore do not fabricate a gastric tube and do not interrupt the arcade of the greater and lesser curvature of the stomach. In addition, the stomach of patients with advanced megaesophagus is hypotrophied and has a tubuliform shape [Figure 2], which facilitates the transposition to the cervical region without the need for fabrication of a gastric tube.

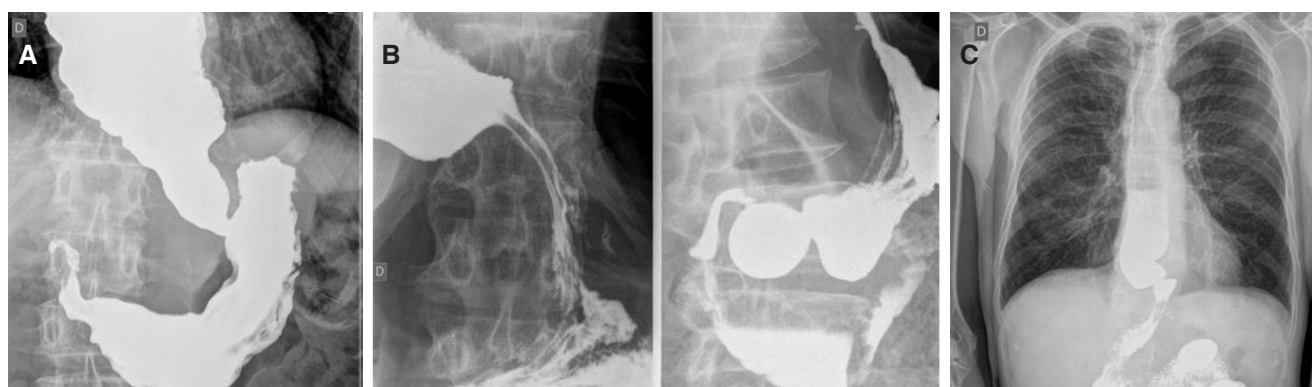
During surgery, a nasoenteric tube was placed in the duodenum or gastric antrum for enteral nutritional support. Enteral diet was started on the second postoperative day and was maintained until the seventh day, when an oral diet was administered after radiologic confirmation of the absence of fistulas and good passage of contrast dye through the anastomosis.

A chest roentgenogram was obtained from all patients at the end of surgery in the operating room. In addition, all patients underwent radiologic contrast examinations and upper digestive endoscopy 12 months after surgery.

To analyze gastroesophageal reflux and esophagitis in the esophageal stump, 126 patients later (7 months



**Figure 1:** Completely dissected esophageal segment. Details of the right (A) and left (B) vagal trunks. RV: right vagal trunk; LV: left vagal trunk



**Figure 2:** Preoperative images (A and B). Postoperative control after 30 days (C). All images show the tube-shaped stomach

to 20 years) underwent endoscopic submucosal dissection with a biopsy, esophagogastric manometry, and 24-h pH measurement in the esophageal stump. The sensor was placed 2 cm above the esophagogastric anastomosis, and its precise position was determined at the time of endoscopic examination<sup>[9]</sup>.

## RESULTS

Immediate complications were observed in 37 patients (16.01%): hemopneumothorax in 22 cases (9.52%), gastric stasis in 11 (4.76%), a cervical fistula in 11 (4.76%), dysphonia in 18 (7.8%), and mediastinitis in 1 case (0.43%). Two patients (0.86%) died: 1 patient with a pacemaker died of cardiorespiratory arrest on postoperative day 12 and the other patient died of mediastinitis on day 28.

Late complications occurred in 23 patients (9.95%). Ten patients (4.33%) who developed stenosis were treated with endoscopic dilatation. Reoperation and anastomosis plasty were necessary in 1 case. Dysphonia occurred after 3 months in 8 patients (3.46%). Gastric stasis occurred in 4 patients (1.73%), and in 1 patient (0.43%) who had an acute obstructive abdomen due to herniation of the transverse colon in the mediastinum. There was no case of severe esophagitis during a follow-up period of 7 months to 20 years.

Among the 136 patients (58.87%) in whom the vagus nerves were preserved, only 3 (2.2%) had gastric-emptying problems during the immediate postoperative period vs. 8 (8.42%) among the 95 patients (41.13%) in whom vagus nerves were not preserved. Late gastric-emptying problems were observed in 4 cases (4.21%) in the group without vagal nerve preservation and in none of the cases with vagal preservation.

We highlight some important technical details of this procedure, including the use of the total stomach that,

anatomically, owing to the chronic condition, already has a tubuliform shape. Pyloroplasty should not be performed to prevent duodenal alkaline reflux to the stomach and hyperchlorhydria. Preservation of the vagus nerves with maintenance of parasympathetic innervation permits maintaining irrigation of the stomach, thus reducing the rate of dehiscence and maintaining storage capacity, secretion, and gastric emptying. Another important technical detail is that the esophagogastric anastomosis is always located in the cervical region, a region characterized by positive pressure, thus preventing acid reflux from the stomach to the esophagus.

The patients had a nasogastric tube introduced into the stomach and received an industrialized enteral diet (1.5 g/kg body weight per day) for at least 14 days. After clinical and spirometric pulmonary evaluation, the patients underwent expiratory and inspiratory muscle training with a threshold device for 2 weeks.

Routine ultrasonography of the abdomen is important in the identification of cholelithiasis, as this association is found in 28.4% of patients with chagasic megaesophagus as a result of parasympathetic denervation of the gallbladder<sup>[24]</sup>. If present, cholecystectomy is performed during surgery.

On the day before surgery, a thick Fouchet or Levin oroesophageal tube is introduced, and the esophagus, which usually contains large amounts of food remnants, is cleaned mechanically with 0.9% saline.

It is important to point out that the anterior and posterior vagus nerve should be dissected before esophageal dissection and stomach preparation to avoid inadvertent sectioning of the vagal trunks in the cervical region. Pyloroplasty is not performed in patients with esophagopathy who do not have a megastomach to avoid reflux from the duodenum to the stomach, now positioned in the posterior mediastinum, a region of

negative pressure. Another important factor is that the esophagogastric anastomosis remains in the cervical region, which is characterized by positive pressure, thus preventing reflux of gastric juice into the esophagus and consequent esophagitis. The latter occurs in the case of intrathoracic location of the anastomosis.

## DISCUSSION

The minimally invasive technique is considered the gold standard for the treatment of megaesophagus. In its early stages, modified Heller surgery combined with a partial antireflux valve has been used with good results. In advanced stages of megaesophagus, minimally invasive transhiatal esophagectomy has been the technique of choice in most centers in Brazil.

Preoperative preparation is also of fundamental importance for good outcomes in these patients, who are usually malnourished and have pulmonary alterations. Chagasic patients exhibit different types of cardiac arrhythmias that should be corrected during the preoperative period. Our standardized protocol includes nutritional and pulmonary outpatient care for this purpose.

A standardized interdisciplinary protocol that comprises the preoperative, perioperative, and postoperative management of patients with megaesophagus is of fundamental importance to obtain satisfactory results in the treatment of this disease. Zamuner *et al.*<sup>[25]</sup> evaluated the use of standardized protocols by multidisciplinary teams in the state of São Paulo, and concluded that the number of centers applying preestablished multidisciplinary protocols is small.

There is clear evidence that preservation of the vagus nerves permits maintenance of gastric emptying, acid secretion, and storage capacity of the stomach, as well as long-term weight maintenance. The results of minimally invasive approaches are consistent with the reduced number of major complications and low mortality rate.

Wang *et al.*<sup>[4]</sup> observed atrophic gastritis in patients who underwent gastropasty after esophagectomy without vagal nerve preservation.

Anatomically, the vagus nerves exhibit 2 trunks (83.4%); these trunks are separated in 26.7% of patients, a communication between them is detected in 56.7%, and 1 or 2 bifurcations occur in only 13.3% of patients<sup>[26]</sup>. Clinical and experimental studies have reported several benefits of preserving the vagus nerves. Using Congo red staining, Banki *et al.*<sup>[1]</sup>

demonstrated acid secretion in the stomach and maintenance of gastric emptying when the vagus nerve was preserved during esophagectomy. Preservation of the vagus nerves also permits the maintenance of parasympathetic irrigation of the stomach, reducing the rate of dehiscence in esophagogastric anastomoses. Furthermore, maintenance of the control of gastric emptying by preserving the vagus nerves reduced the rate of dumping episodes and diarrhea.

The benefit of vagal integrity goes beyond the maintenance of secretory function and gastric motility. Several experimental studies have demonstrated the importance of integrity of the vagus nerves for protection against bacterial translocation. Vagal nerve preservation significantly reduces infectious complications<sup>[27]</sup>. Experimental studies have reported sepsis and faster death in vagotomized animals when compared to controls<sup>[28]</sup>. An increased degree of peritonitis and higher levels of inflammatory cytokines were also observed in vagotomized animals<sup>[29]</sup>.

Evidence of the physiological preservation of the vagus nerves is obtained by measuring the levels of pancreatic peptide after stimulation. Banki *et al.*<sup>[1]</sup> observed a significant increase in pancreatic peptide levels when the vagus nerve was preserved during esophagectomy.

The objective of not performing pyloroplasty or pyloromyotomy is to avoid reflux of alkaline secretion from the duodenum to the stomach after gastric transposition to the mediastinum, a region of negative pressure, which would cause an increase in acid secretion from the stomach.

Crema *et al.*<sup>[30]</sup> compared patients undergoing esophagectomy with and without vagotomy. The results showed a significant increase in pancreatic peptide levels after insulin-induced hypoglycemia in the group with preserved vagus nerve, which was not observed in vagotomized patients.

Our sample of patients undergoing esophagectomy included 21 patients (9.09%) with idiopathic megaesophagus for whom serology and polymerase chain reaction results of esophageal tissues were negative for *Trypanosoma cruzi*. In a study conducted in Campinas-SP in which only serology was used for the diagnosis of Chagas disease, 21% of the patients had idiopathic megaesophagus<sup>[31]</sup>.

Esophagectomy with preservation of the vagal trunks has been used for the treatment of chagasic megaesophagus, although denervation of the entire

parasympathetic autonomic nervous system occurs in this condition (digestive tract myenteric and submucosal plexuses). It is known that the chronically denervated stomach develops intrinsic mechanisms that maintain motility and emptying. In patients with idiopathic megaesophagus undergoing vagotomy, impairment of gastric emptying is observed during the first months after surgery. Previous studies have shown better gastric emptying after esophagectomy even in patients with chagasic megaesophagus and vagal nerve preservation.

With a standardized multidisciplinary protocol and a team adequately trained in laparoscopy, minimally invasive esophagectomy is an excellent option for the treatment of advanced megaesophagus. The technique is easily standardized and reproducible, and provides excellent postoperative outcomes.

## DECLARATIONS

### Authors' contributions

Surgical procedures: E. Crema, J.A.T. Júnior, A.A. da Silva

Monitoring of patients: G.A. Terra, C.J. de Oliveira Teles

### Financial support and sponsorship

None.

### Conflicts of interest

There are no conflicts of interest.

### Patient consent

All patients were guided by the surgical technique and the risks inherent in the procedure.

### Ethics approval

The procedure was approved by the Human Research Ethics Committee of the Federal University of Triângulo Mineiro.

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# Non-conventional surgical approach to achalasia: mucosectomy and endomuscular pull-through

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## ABSTRACT

**Aim:** Transhiatal esophagectomy is a therapeutic option for the treatment of end-stage achalasia that avoids the complications of a thoracotomy. This technique; however, is still linked to some degree of morbimortality especially due to pleuromediastinal complications. Esophageal mucosectomy and endomuscular pull-through could avoid these complications. This study aims to evaluate the short and long-term outcomes of esophageal mucosectomy and endomuscular pull-through in a series of patients with advanced megaesophagus. **Methods:** We retrospectively studied 115 patients with end-stage achalasia that underwent esophageal mucosectomy and endomuscular pull-through. Digestive tract reconstruction was accomplished most times using the stomach through the muscular tunnel. Outcomes were evaluated in a short and long-term follow-up based on clinical, endoscopic and tomographic evaluation. **Results:** Anastomotic leak or stenosis was present in 27%. Pleural effusion was noticed in 11% and pneumonia in 9%. Mortality was 1.7%. Long-term follow-up (over 10 years) was possible in 42 patients. Excellent and good clinical results were obtained in 83% of the patients. **Conclusion:** Esophageal mucosectomy and endomuscular pull-through is a valuable procedure for the treatment of end-stage achalasia. It shows a low rate of complications and good outcomes at long-term follow-up.

## INTRODUCTION

Idiopathic and chagasic achalasia have different etiology but, apart from this fact, both diseases share the same clinical, radiologic, endoscopic and manometric presentations. Thus, any therapeutic modality may be applied equally irrespective of etiology.

Different approaches have been proposed to treat this disease, such as endoscopic dilatation, esophageal caliber-reducing operations, operations on the diaphragm or esophageal extrinsic innervation, cardiectomy, cardioplasties, transthoracic and transhiatal esophagectomy. Neither treatment; however, seems to be ideal since they do not act directly on the physiopathology of the disease<sup>[1-5]</sup>.



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## Quick Response Code:



The aim of the treatment for achalasia is to relieve dysphagia and avoid long-term complications of food stasis.

This study aims to describe the technique and results of esophageal mucosectomy and endomuscular pull-through for the treatment of advanced achalasia.

### History and indications

Kirschner<sup>[6]</sup> in 1914 pioneered the idea of esophageal complete mucosectomy with muscular preservation through invagination. The authors were concerned at that time about mediastinal hemorrhage and pleural lesions. They tried to strip the esophagus through neck and abdomen incisions in dogs but the idea was not popular and an adequate way of reconstructing the tract with the stomach was not developed simultaneously.

Latter, others proved the possibility of the technique in humans showing acceptable results in patients with caustic stenosis, esophageal carcinoma and proximal gastric cancer<sup>[7,8]</sup>.

Aquino<sup>[9]</sup> pioneered the technique in Brazil, a country with a large incidence of achalasia. The technique was employed in patients with advanced megaesophagus since transhiatal esophagectomy may be associated to complications such as accidental pleural lesion, tracheal injury and hemothorax<sup>[10-13]</sup>. Pleural and tracheal injury, as well as hemorrhage, may occur during mediastinal dissection due to severe periesophagitis leading to adhesions between the esophagus and mediastinal structures. It is also well known that stasis esophagitis observed in end-stage disease predisposes to premalignant lesions or even carcinoma<sup>[14-17]</sup>. Based on this premises, the idea of striping the esophageal mucosa and submucosa through cervical and abdominal incisions in the absence of thoracotomy came to mind. Thus, premalignant lesions could be prevented and complications related to mediastinal esophageal dissection avoided.

We operated dogs as a preliminary study before applying the technique in clinical practice<sup>[18]</sup>. Posteriorly, human cadavers were dissected to show the feasibility of the operation. Our clinical experience started after this training and showed good outcomes<sup>[9]</sup>. Recently, a series of 115 cases was published depicting good results and less morbidity than a transmediastinal esophagectomy<sup>[19]</sup>. All patients had an end stage achalasia defined by diameter larger than 10 cm.

## METHODS

### Surgical technique

Surgical technique follows standardization proposed by Aquino<sup>[9]</sup>.

### Mucosal resection

#### Abdominal stage

The operation starts with a midline laparotomy from the xiphoid process to 5 cm below the umbilicus flowed by dissection of the abdominal esophagus and division of vagi nerves. Longitudinal myotomy in the anterior esophagus from the cardia to the hiatus and circumferential dissection of the mucosa/submucosa in an extension 5 to 7 cm.

#### Cervical stage

Left lateral cervicotomy following the anterior border of the sternocleidomastoideus from the sternum to 10 cm upwards. Dissection of the esophagus free of the posterior and prevertebral fascia and trachea. Longitudinal myotomy in the anterior esophagus from 5 cm bellow the pharynx to the sternum and circumferential dissection of the mucosa/submucosa layer.

#### Combined stage

After a cylindrical segment of mucosa is dissected free of the muscular in the abdomen and neck, a small mucosectomy is made in the abdomen and neck to allow the passage of a rectal tube upwards. Cervical esophageal mucosa is circumferentially transected and tied to the rectal tube attached to a long and resistant surgical thread to allow pulling the replacement viscera to the neck. The mucosa is slowly striped downwards and inverted in the abdomen. The esophagus is completely sectioned at the level of the esophagogastric junction and in the neck.

#### Digestive tract reconstruction

Digestive tract was reconstructed in all patients with the stomach after division of the left gastric, gastroepiploic and short vessels. Two different routes for stomach transposition were used based on accessibility to the neck. The muscular tunnel was used in 81 (70%) patients while in 34 (30%) patients the retrosternal route was the option<sup>[19]</sup>. Esophagogastrostomy was performed in the cervical level in all patients. Circular stapler end-to-side esophagogastrostomy was done in 73 (63%) patients and manual end-to-side posterior esophagogastrostomy in 42 (37%) patients<sup>[19]</sup>. A feeding jejunostomy was always added to the procedure. Drains were left in the abdomen and neck.

**Table 1: Clinical evaluation**

Swallowing status	Regurgitation	Bowel movements	Weight variation	Satisfaction with the procedure	Return to work	Grade
Normal	Absent	Unchanged	Gain			2
Occasional dysphagia	Ocasional	Diarrhea/constipation occasional	Unchanged	Yes	Yes	1
Frequent dysphagia	Frequent	Diarrhea/constipation frequent	Loss	No	No	0

The sum of these grades was defined as a global clinical evaluation and classified as: 10 and 9 - excellent; 8 and 7 - good; 6 and 5 - regular; < 4 - bad

**Table 2: Computerized tomography evaluation - retrosternal transposition of the graft**

Medestinal fluid	Compression of the graft	Medestinal esophageal muscular layer	Grade
Absence	Absence	Observed	1
Present	Present	Not observed	0

The sum of these grades was defined as a global clinical evaluation and classified as 3 - excellent; 2 - good; 1 - regular; 0 - bad

### Short-term follow-up

Patients were kept in the intensive care unit (ICU) for 24-48 h after the operation. Early feeding through the jejunostomy was started as soon as bowel motility returned and progressed to 2,500 to 3,000 calories/day according to standard pathways by dedicated nutritionists.

Oral feeding was introduced after anastomotic integrity was confirmed through an esophagram between the 7th and 10th postoperative day. This routine was changed; however, in the event of clinical suspicious of anastomotic leak when the test was repeated or done in variable periods. Chest X-Ray was performed routinely in all patients 24 h after the operation and every 72 h during the first week or in case of necessity.

### Long-term follow-up

Forty-two patients were followed for more than 10 years. Variables used to assess outcomes are depicted in [Tables 1-4<sup>\[9\]</sup>](#).

## RESULTS

### Short-term results

#### *Pathologic examination of the specimen*

A complete removal of the mucosa was observed in all 115 patients. Microscopic examination showed mild to severe inflammation of the mucosa and submucosa. Leukoplakia was found in 18 (15.7%) cases. Carcinoma was not observed.

#### *Clinical evaluation*

One hundred thirteen (98%) patients out of the 115 total had an uneventful recovery and they were

**Table 3: Computerized tomography evaluation - intraesophageal transposition of the graft**

Medestinal fluid	Compression of the graft	Medestinal esophageal muscular layer	Displacement of the graft	Grade
Absence	Absence	Observed	Absence	1
Present	Present	Not observed	Present	0

The sum of these grades was defined as a global clinical evaluation and classified as 4 and 3 - excellent; 2 - good; 1 - regular; 0 - bad

discharged from the ICU during the first 48 h. Oral diet was started between the 7th-10th postoperative days in 82 (72%) patients after the esophagram attested absence of leaks. Jejunostomy tube was removed after 3-4 weeks after the operation when a solid diet was possible. Oral feeding was postponed in 31 (27%) patients due to anastomotic leakage and reintroduced between days 18-29 after the esophagram attested absence of leaks.

#### *Radiologic evaluation*

Chest X-Ray was unremarkable in 92 (80%) patients. In the remaining patients, discrete to mild pleural effusion was noticed in 13 (11%) patients and pulmonary infiltrate in 10 (9%) patients. Barium esophagram was performed in 86 (76%) patients with unremarkable findings in 82 of them. Anastomotic leak was detected in 4 patients. All patients had the test repeated between 18-26th postoperative day to show absence of leak and strictures.

#### *Complications*

Mortality was 2%. Two patients died due to sepsis after graft necrosis in the 3rd postoperative day and other due to pulmonary embolism in the 5th postoperative day. A tube thoracostomy was necessary in 9 out of 13 (11%) patients with pleural effusions and moderate volume. Only observation was enough in the 4 remaining. Pneumonia was diagnosed and treated in 10 (9%) patients with satisfactory outcomes. Anastomotic leak in 31 (27%) patients was managed conservatively with resolution in all cases. In 22 cases, however, an anastomotic stenosis was present and treated satisfactorily in all patients with endoscopic dilatation.

**Table 4: Upper digestive endoscopy evaluation**

Esophagostomy patency	Gastrododenal junction patency	Macroscopic esophageal mucosa evaluation	Macroscopic gastric mucosa evaluation	Grade
Stenosis not present	-	Normal mucosa	Normal mucosa	3
Mild stenosis	-	Esophagitis grade A*	Mild gastritis	2
Moderate stenosis	Patency	Esophagitis grade B*	Moderate gastritis	1
Severe stenosis	Not patency	Esophagitis grade C/D*	Severe gastritis	0

The sum of these grades was defined as a global endoscopic evaluation and classified as 10 and 9 - excellent; 8 and 7 - good; 6 and 5 - regular; < 4 - bad. \*: Los Angeles classification

**Table 5: Long-term follow-up**

Evaluation method	Patients number	Evaluation results			
		Excellent	Good	Regular	Bad
Clinical	42	21 (50%)	14 (33%)	4 (9%)	3 (7%)
Upper endoscopy	42	17 (40%)	20 (47%)	3 (7%)	2 (5%)
Ct scan RTN - graft	16	-	16 (100%)	-	-
Ct scan I - esophageal graft	26	24 (92%)	2 (8%)	-	-

## Long-term results

Results of this evaluation are showed in the following Table 5.

## DISCUSSION

Few authors described clinical experience with esophageal mucosectomy and endomuscular pull-through. Most of these authors used a phrenotomy and even resection of the diaphragmatic crus to obtain better exposure of the mediastinum and avoided the use of the technique in dilated megaesophagus<sup>[7,8]</sup>. A phrenotomy (diaphragm division) to allow a better dissection of the mediastinum hurts the principle of minimal mediastinal dissection. In our study, we avoided this step. We were able to perform a complete dissection of the mucosa. The mucosa is easily extracted from the muscular layer due to histologic features of these layers. The mucosa is a resistant epithelium but the submucosa has few collagen fibers and abundant elastic fibers allowing flexibility and tearing<sup>[7,8]</sup>.

Other objective of this described technique is to resect the esophageal mucosa that frequently shows inflammatory findings due to long-term food stasis and brings a risk for malignization between 3% to 10% according to different series<sup>[14,15,19]</sup>. Cancer was not observed in the resected mucosa in our series but severe inflammation was noticed in all cases and leukoplakia in 15.7%.

Mediastinal hemorrhage is not a common occurrence after esophagectomy without thoracotomy irrespective of the technique: transhiatal dissection, stripping or mucosectomy. However, a high level of morbimortality is expected when a hemorrhage occurs<sup>[11,12,20,21]</sup>. Large vessels such as the azygos vein or direct

branches from the aorta may be injured and in case of pleural lesion may lead to hemothorax in 25% of the cases. This complication usually requires a conversion to thoracotomy.

Other complications can occur after a transhiatal esophagectomy, such as pleural effusions and hemothorax. Pleural lesion may occur from 22-83% of the cases<sup>[11,13,18,20]</sup>. The low rate of pleuropulmonary complications in our study justify the option for esophageal mucosectomy that we believe prevented this type of complication avoiding extensive mediastinal dissection.

Recently, Aquino *et al.*<sup>[19]</sup> compared the intra and postoperative complications associated to either esophageal mucosectomy and endomuscular pull-through or transhiatal esophagectomy in 229 megaesophagus patients. Pleural effusions (including hemothorax) were more common in patients that underwent a transhiatal esophagectomy. Other severe complication found only in the transhiatal group was massive hemothorax that occurred in 6 (5%) patients and led to 2 deaths. Three (2%) patients from the group transhiatal had a tracheal injury, one of them died. This complication did not happen in the mucosectomy patients.

Pneumonia and cardiovascular complications are common after esophagectomy in patients with achalasia due to the basal clinical status in these patients that usually have comorbidities and are undernourished. Mucosectomy once more proved to have low morbidity as noticed by a reduced rate of pulmonary and cardiovascular complications as compared to conventional transhiatal esophagectomy<sup>[19]</sup>. This advantage may be linked again to a lesser degree of mediastinal dissection.

Esophagogastrostomy leak was found in this technique in a rate similar to other series<sup>[14,21,23]</sup>. Leakage seems not be linked to the resection procedure but to other topics such as absence of serosa in the esophagus, deficient vascularization, constant movement with swallow, and low nutrition status of some patients<sup>[2,13,21,24]</sup>.

The risk for bleeding in the muscular tunnel is small. All patients had hemodynamic stability after the procedure and only few required transfusion. Parrilla Paricio *et al.*<sup>[7]</sup> showed in his series no more than 100 mL of blood collected after external drainage of the muscular tunnel in 3 patients that underwent mucosectomy due to cardia cancer. Other series; however, showed a higher level of bleeding (700-800 mL) but without hemodynamic instability nonetheless<sup>[8,25]</sup>. Aquino *et al.*<sup>[18]</sup> showed - in an experimental study in dogs - absence of active bleeding 2 h after mucosectomy. Spontaneous hemostasis occurs due to anatomic characteristics of the vessels that branches in the submucosa<sup>[26]</sup>.

Early results for mucosectomy are very acceptable. Only 12% of the patients had intraoperative complications and in a significantly lower rate compared to transhiatal esophagectomy in the own author's experience (69%). Early postoperative complications were also lower for mucosectomy compared to transhiatal esophagectomy<sup>[19]</sup>.

Long-term follow-up (between 10-15 years) in 42 patients showed excellent and good results in over 80%<sup>[30]</sup>. Quality of swallow was lower in a long-term follow-up to those patients with a retrosternal reconstruction of the digestive tract. The constrict space, development of local fibrosis and angulation of the stomach may lead to these results. Some authors opted to resect the manubrium and part of the clavicle in order increase this space<sup>[13,21]</sup>.

Regurgitation was a symptom with significant incidence after mucosectomy (31%). Gastroduodenal junction patency was compromised in some of the patients with regurgitation. In others without demonstrable anatomic obstruction, the symptom may occur due to consequences of the vagotomy in gastric physiology.

Patients should be closely followed after the operation based on the elevated risk for metaplasia, dysplasia and even carcinoma transformation in the esophageal stump<sup>[27-29]</sup>. Some authors opt for chronic use of proton pump inhibitors after esophagectomy to prevent acid esophagitis in the stump<sup>[27]</sup>.

Functional asocial parameters had satisfactory outcomes as shown by weight gain, quality of life, satisfaction and return to work.

In conclusion, esophageal mucosectomy and endomuscular pull-through seems to be a valuable alternative to esophagectomy in patients with end-stage achalasia.

## DECLARATIONS

### Authors' contributions

Conceived and designed the study, wrote and reviewed the manuscript: J.L.B. De Aquino  
Collected and tabulated data, participated in manuscript writing: M.M. Said  
Participated in manuscript writing and review: J.G.T. De Camargo

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None.

### Conflicts of interest

There are no conflicts of interest.

### Patient consent

The patient consent was obtained.

### Ethics approval

This study was approved by the local Research Ethics Committee.

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# Short-term outcomes of laparoscopic colorectal resection in psychiatric patients

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## ABSTRACT

**Aim:** To investigate the short-term outcomes of laparoscopic colorectal resection compared with open surgery in psychiatric patients with colorectal cancer. **Methods:** The authors retrospectively reviewed the medical records of 31 consecutive patients who underwent open surgery (OS) or laparoscopic surgery (LS) for colorectal cancer between April 2013 and September 2015. All patients were involuntarily admitted to the hospital, because of anosodiaphoria. The clinicopathological characteristics, intraoperative outcomes, and postoperative data of the two groups were analyzed. Categorical data were compared using the  $\chi^2$  test or Fisher exact test, as appropriate. Continuous variables were compared using the Student *t* test or Mann-Whitney *U* test, as appropriate. Statistical analyses were performed using the statistical software program, SPSS, version 22 (SPSS Japan, Tokyo). *P*-values < 0.05 were considered statistically significant. **Results:** Sixteen patients underwent LS, and 15 underwent OS. Blood loss was lower in the LS group than in the OS group (*P* = 0.001). LS was associated with the earlier resumption of psychiatric drug treatment (*P* < 0.001) and a shorter hospital stay (*P* = 0.021) compared with OS. **Conclusion:** Laparoscopic colorectal surgery is safe for psychiatric patients. The main advantages of LS include a shorter washout period and reduced hospital stay.

## INTRODUCTION

Laparoscopic colectomy has become accepted as an alternative to conventional open surgery (OS) for treating colon cancer because it results in earlier recovery. For patients with colorectal cancer, the benefits of laparoscopic surgery (LS) include fewer postoperative complications, shorter periods of hospitalization, and a more rapid recovery<sup>[1,2]</sup>. Therefore, LS may achieve

better short-term outcomes than OS in psychiatric patients with colorectal cancer.

Patients with serious mental illnesses are at a significantly increased risk of death from cardiovascular, gastrointestinal, or respiratory disease<sup>[3-5]</sup>. Furthermore, clinical data suggest that patients with such conditions exhibit worse surgical outcomes than other patients<sup>[6]</sup>.

Patients with psychiatric disorders who develop cancer



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often present with complicated medical and psychiatric problems<sup>[7]</sup>. Such patients have difficulty coping with the diagnosis and treatment of cancer, and they may ignore warning signs and symptoms of the disease because of their cognitive impairment<sup>[8]</sup>, which can result in riskier treatments having to be performed.

Herein, we report the surgical outcomes of psychiatric patients with colorectal cancer. The aim of this study was to evaluate the surgical feasibility and safety of LS. Thus, we compared the operative, pathological, and functional outcomes of LS with those of OS in this patient population.

## METHODS

A retrospective analysis was performed using a colorectal cancer database. Information in the database was prospectively collected between April 2013 and September 2015 at the Tokyo Metropolitan Matsuzawa Hospital. Thirty-one patients underwent LS or OS for primary colorectal cancer. We investigated the short-term outcomes of laparoscopic colorectal resection compared with OS in psychiatric patients with colorectal cancer. All patients examined in this study were eligible for either approach. OS was performed between April 2013 and March 2014, and LS was started in April 2014. The exclusion criterion for LS was acute surgery due to perforative peritonitis. No patients were excluded from the present analysis because palliative surgery was performed or advanced disease was present. Informed consent was obtained from all patients or their relatives or guardians. This study was approved by the institutional review board of Tokyo Metropolitan Matsuzawa Hospital (approval number: 28).

Preoperative evaluations included colonoscopy with biopsy; chest, abdominal, and pelvic computed tomography examinations; and magnetic resonance imaging. Patients were staged using the Japanese Society for Cancer of the Colon and Rectum (eighth edition)<sup>[9]</sup>. An American Society of Anesthesiologists (ASA) grade was assigned to each patient by an anesthesiologist preoperatively.

All patients were involuntarily admitted to the hospital because of anosodiaphoria. They were diagnosed as having colorectal cancer, but it was difficult to admit them to a general hospital for treatment other than psychiatric care. Tokyo Metropolitan Matsuzawa Hospital is one of the biggest hospitals in Tokyo that has a surgical and psychiatry department.

## Psychiatric disorders

Details of the patients' psychiatric disorders are

specified in Table 1. Schizophrenia ( $n = 17$ ) and dementing disorders ( $n = 6$ ) were overrepresented. The median disease period of all psychiatric disorders was 24 years (range: 0–58 years). Twenty-four patients had received psychotropic drugs orally, including at least one major psychotropic drug (a functional category of neuroleptic drugs that are helpful in treating psychosis and have the capacity to ameliorate thought disorders), and 19 had received minor psychotropic drugs (a drug that reduces anxiety). Psychotropic drugs include benzodiazepine derivatives and a few less widely used non-benzodiazepines, such as meprobamate and hydroxyzine hydrochloride). Seven patients had received epileptic agents, and 5 had taken donepezil. All patients had received at least one psychiatric medication. All patients were involuntarily admitted to the hospital; i.e. they were subjected to hospitalization for medical care and protection under Sections 1, 3, and 4 of the Mental Health and Welfare Act in Japan<sup>[10]</sup>. At our hospital, patients with psychiatric problems can be referred to psychiatrists at any time postoperatively, and 24-h psychiatric care is available, which enabled us to manage the study subjects in an unlocked surgical ward.

## Surgical technique

No patients underwent mechanical and chemical bowel preparation. All laparoscopic and open procedures were performed by a single gastrointestinal surgical team. Laparoscopic procedures started to be performed in April 2014. The exclusion criterion for LS was acute surgery due to perforative peritonitis. All patients were operated on under general anesthesia. All laparoscopic and open procedures were performed according to the relevant guidelines<sup>[11]</sup>, and the extent of the resection was the same in both groups. All laparoscopic procedures were performed by the same surgeon, who was a proven expert, as defined by the Japan Society for Endoscopic Surgery. Conversion from LS to OS was allowed at the surgeon's discretion to ensure the patient's safety or because of technical difficulties, the presence of associated conditions, or findings of advanced disease or inadequate oncological margins. Reconstruction was performed with a hand-sewn straight colonic anastomosis or stapled anastomosis. A temporary ileostomy was created in selected patients. The same postoperative care was provided in all patients.

## Outcome assessment

Postoperatively, the bowel motility recovery time, washout period, and length of the hospitalization period were assessed. The washout period was defined as the duration of days between the surgery and start of psychiatric medicine postoperatively. Postoperative

**Table 1: Psychiatric disorder of 31 patients**

Characteristics	LS (n = 16)	OS (n = 15)	P-value
Disorders			0.461
Schizophrenia	9 (56.3%)	8 (53.3%)	
Dementing disorder	4 (25.0%)	2 (13.3%)	
Manic-depressive illness	0 (0%)	2 (13.3%)	
Drug addiction	1 (6.3%)	0 (0%)	
Alcoholism	2 (12.5%)	1 (6.7%)	
Bipolar affective disorder	0 (0%)	1 (6.7%)	
Growth retardation	0 (0%)	1 (6.7%)	
Disease duration (years) (range)*	20 (0-53)	15 (0-58)	0.626
Internal medicine			
Major tranquilizer	12 (75.0%)	12 (80.0%)	0.739
Minor tranquilizer	11 (68.8%)	8 (53.3%)	0.379
Antiepileptic	5 (26.7%)	2 (13.3%)	0.233
Anti-dementia drug	3 (18.8%)	2 (13.3%)	0.982
Others	4 (25.0%)	4 (26.7%)	0.916
More than two major tranquilizer	6 (37.5%)	5 (23.3%)	0.809
Kind of hospitalization			
Involuntary admission <sup>#</sup>	16 (100%)	15 (100%)	–

\*Value are the median (range); <sup>#</sup>hospitalization for medical care and protection under (section 1, 3, 4) of Mental Health and Welfare for Act in Japan

morbidity was defined as a complication that occurred within 30 days of the operation, and it was stratified as recommended by the Clavien-Dindo classification<sup>[12]</sup>. All pathological specimens were examined to determine the extent of the microscopic surgical margins.

## Statistical analysis

Basic clinical characteristics, operative outcomes, and pathological results of the two groups were compared. Categorical data were compared using the  $\chi^2$  test or Fisher exact test, as appropriate. Continuous variables were compared using the Student *t* test or Mann-Whitney *U* test, as appropriate. Statistical analyses were performed using the statistical software SPSS, version 22 (SPSS Japan, Tokyo, Japan). *P*-values < 0.05 were considered statistically significant.

## RESULTS

### Patients' characteristics

There were 16 patients in the LS group and 15 in the OS group. Demographic characteristics of both groups are shown in Table 2. No significant differences were observed between the two groups with respect to age, gender, body mass index, ASA score, or clinical stage (staging was performed before the surgical resection). The clinical and pathological stage was defined by the Japanese Classification of Colorectal Carcinoma, July 2013 (eighth edition)<sup>[9]</sup>.

### Perioperative outcomes

Patients' intraoperative and postoperative data are listed in Table 3. Estimated blood loss was lower in the LS group than in the OS group (*P* = 0.001), and intraoperative transfusions were required less often in

**Table 2: Clinicopathological characteristics**

Characteristics	LS (n = 16)	OS (n = 15)	P-value
Age at surgery (years)*	67 (48-89)	75 (53-91)	0.318
Gender (n)			0.901
Male	5 (31.3%)	5 (33.3%)	
Female	11 (68.8%)	10 (66.7%)	
BMI (kg/m <sup>2</sup> )*	19.6 (15.5-32.5)	19.8 (15.0-24.9)	1.000
ASA score (n)			0.311
I	2 (12.5%)	0 (0%)	
II	11 (68.8%)	13 (86.7%)	
III	3 (18.8%)	2 (13.3%)	
Previous abdominal surgery	4 (25.0%)	3 (20.0%)	0.561
Preoperative intestinal obstruction	2 (12.5%)	3 (20.0%)	0.884
Tumor location			0.127
Ascending colon	2 (12.5%)	5 (33.3%)	
Transverse colon	2 (12.5%)	2 (13.3%)	
Descending colon	1 (6.3%)	0 (0%)	
Sigmoid colon	7 (46.7%)	4 (26.7%)	
Rectum	4 (25.0%)	4 (26.7%)	
No. clinical T stage			0.103
T2	3 (18.8%)	0 (0%)	
T3	5 (31.3%)	9 (60.0%)	
T4	8 (50.0%)	6 (40.0%)	
No. clinical N stage			0.563
N0	7 (43.8%)	5 (33.3%)	
N1-3	9 (56.4%)	10 (66.7%)	
No. clinical stage			0.212
I	1 (6.3%)	0 (0%)	
II	5 (31.3%)	5 (33.3%)	
III	7 (43.8%)	10 (66.7%)	
IV	3 (18.8%)	0 (0%)	

\*Value are the median (range). LS: laparoscopic surgery; OS: open surgery; ASA: American society of anesthesiologist; BMI: body mass index

the LS group than in the OS group (*P* = 0.015). Two patients were converted from LS to OS. One of these patients had direct invasion into the urinary bladder, whereas the other had direct invasion into the splenic vein.

Compared with the OS group, the washout period, frequency of early postoperative recovery, and length of the hospitalization period were all significantly improved in the LS group. One patient in the LS group and 2 patients in the OS group who died were excluded in the length of postoperative hospital stay analysis. All patients except one (93.8%), who did not have a drain inserted postoperatively, were subjected to temporary physical restraint; therefore, none of the patients removed their abdominal drains by themselves. A drain was removed the day after the first defecation postoperatively.

No patients received epidural anesthesia. The LS group required less frequent additional analgesia postoperatively, albeit not significantly. Postoperative delirium developed in 7 patients of the OS group, and 4 of the LS group. Unscheduled intravenous

**Table 3: Intraoperative and postoperative outcomes**

Characteristics	LS (n = 16)	OS (n = 15)	P-value
Operation time (min)*	193.5 (125-459)	155 (78-483)	0.188
Blood loss (mL)*	27 (10-1907)	330 (34-2197)	0.001
Intraoperative transfusion	2 (12.5 %)	8 (53.3 %)	0.015
Type of resection			0.171
Right hemicolectomy	3 (18.8%)	6 (40.0%)	
Transverse colectomy	1 (6.3%)	1 (6.7%)	
Left hemicolectomy	1 (6.3%)	0 (0%)	
Sigmoidectomy	7 (43.8%)	3 (20.0%)	
Low anterior resection	3 (18.8%)	1 (6.7%)	
Abdominal perineal resection	0 (0%)	3 (20.0%)	
Total pelvic exenteration	1 (6.3%)	0 (0%)	
Colostomy	0 (0%)	1 (6.7%)	
Conversion to open surgery	2 (12.5%)	–	–
Stoma	1 (6.3%)	4 (26.7%)	0.122
Duration of drainage (days)*	8 (0-13)	8 (7-27)	0.175
Physical restraint	15 (93.8%)	15 (100%)	0.325
Physical restraint (days)*	19.5 (0-96)	28 (9-141)	0.110
Recovery of bowel motility (days)*	2 (1-6)	7 (2-25)	< 0.001
Washout period (days)*	2.5 (1-6)	8 (4-35)	< 0.001
Return to diet (days)*	5.5 (2-12)	9 (7-39)	0.155
Incidence of using additional analgesia, n (%)	3 (18.8%)	6 (40.0%)	0.252
Unscheduled Intravenous injections of psychotropic drugs	4 (25.0%)	7 (46.7%)	0.208
Duration of hospital stay after surgery (days)*	43 (18-144)	69 (29-423)	0.021

\*Value are the median (range). LS: laparoscopic surgery; OS: open surgery

injections of psychotropic drugs were required for these patients. Such injections usually involved haloperidol, levomepromazine maleate, or diazepam or a combination of these drugs, as determined by the attending psychiatrist. The proportion of patients who needed unscheduled intravenous injections of psychotropic drugs did not differ significantly between the OS and LS groups. Physical restraints were applied for median periods of 19.5 days in the LS group and 28 days in the OS group; the difference was not significant ( $P = 0.110$ ).

## Complications

Postoperative complications occurred in 6 patients (37.5%) in the LS group and 9 (60.0%) in the OS group ( $P = 0.318$ ). Major complications, which were defined as those that were more severe than Clavien-Dindo class III, occurred in 2 patients in the LS group and 4 in the OS group. One patient died (of pulmonary embolism 2 days postoperatively) in the LS group, and 2 patients died (one died of sepsis due to anastomotic leakage 105 days postoperatively, and the other died of acute liver failure due to liver metastasis 80 days postoperatively) in the OS group. Mortality rates of the two groups did not differ significantly [Table 4].

## Pathological outcomes

Table 5 shows the pathological outcomes of both groups. There were no significant differences between the groups with respect to the tumor size, histological grade, or final

stage. Eighteen of 31 (58.1%) patients were diagnosed as having stage III or IV disease. Four patients in the LS group had macroscopic residual tumors. Three of these patients had liver metastasis, and the other patient had para-aortic lymph node metastasis. No patients received adjuvant or postoperative chemotherapy.

In the OS group, 4 patients had macroscopic residual tumors. Three of these patients had peritoneal metastasis. The remaining patient underwent colostomy because of direct invasion of the sacrum.

## DISCUSSION

The number of patients receiving medical treatment from psychiatrists in Japan has increased over the past three decades. Moreover, the number of elderly patients with psychiatric disorders has increased nine-fold during the same period. Psychiatric patients are not considered to be at greater risk of digestive disease that requires operation than the general population<sup>[13]</sup>. Therefore, Japanese surgeons are increasingly having to perform operation in psychiatric patients. We have performed various surgical procedures for digestive disease in patients with psychiatric disorders, and we started performing LS at the Tokyo Metropolitan Matsuzawa Hospital in 2014.

There have only been a few reports about digestive surgery in patients with psychiatric disorders, and none

**Table 4: Postoperative morbidity**

Characteristics	LS (n = 16)	OS (n = 15)	P-value
Grade of morbidity			0.643
Clavien-Dindo I-II	4 (25.0%)	4 (26.7%)	
Clavien-Dindo III-IV	1 (6.3%)	2 (13.3%)	
Clavien-Dindo V	1 (6.3%)	2 (13.3%)	
Postoperative morbidity <sup>*</sup>			0.802
Anastomotic leakage	2 (12.5%)	1 (6.7%)	
Intra-abdominal infection	0 (0%)	1 (6.7%)	
Ileus	0 (0%)	2 (13.3%)	
Wound infection	1 (6.3%)	1 (6.7%)	
Others	3 (18.8%)	3 (20.0%)	

<sup>\*</sup>Total number of patients who suffered from postoperative morbidity. LS: laparoscopic surgery; OS: open surgery

of these studies focused on the safety and feasibility of laparoscopic colorectal surgery in psychiatric patients. It has been suggested that the mortality rate of psychiatric patients is higher than that of comparable non-psychiatric populations<sup>[14]</sup>. In addition, it has been reported that the hospitalization of patients with schizophrenia for medical or surgical reasons doubles the odds of several types of adverse events compared with the risk of such events in non-schizophrenic patients<sup>[6]</sup>. However, Bernstein and Offenbartl<sup>[15]</sup> found that although patients with cognitive impairments have a higher than average mortality rate after general operation, they exhibit a similar incidence of non-fatal complications than surgical patients as a whole, and their increased mortality is mainly due to delays in diagnosis and their inability to withstand the technical surgical complications.

In the present study, we obtained similar overall morbidity and mortality rates to those described in a previous report<sup>[13]</sup>. However, our morbidity rate was higher than that reported for non-psychiatric patients<sup>[16]</sup>. As noted in the Introduction section, individuals with schizophrenia have higher pain thresholds than patients without mental illness, and they have more cognitive deficits, disorganized thinking, and other functional difficulties. Thus, they may have an impaired ability to recognize and communicate potentially important medical symptoms; thus, they may present with more advanced disease, resulting in the need to use riskier treatments<sup>[17]</sup>. In the current study, 58.1% of patients were diagnosed as having stage III or IV disease.

Estimated blood loss was lower in the LS group than in the OS group. However, the operative time was similar in both groups. Our results differ from those of previous studies<sup>[16]</sup>, and this is possibly because our study included a small number of patients. There were no significant differences in morbidity or mortality between the LS and OS groups. Our findings confirm that laparoscopic colectomy for psychiatric patients are not associated with a significant increase in the overall

**Table 5: Pathologic characteristics**

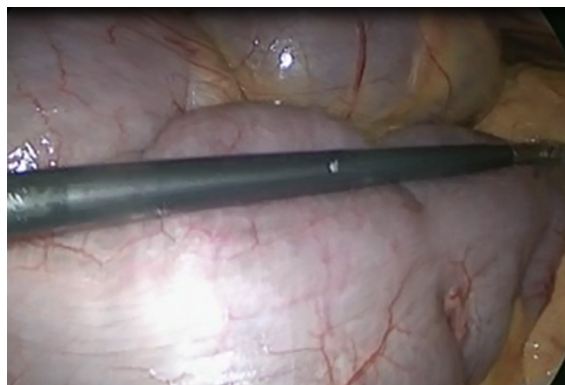
Characteristics	LS (n = 16)	OS (n = 15)	P-value
Tumor size (mm) <sup>*</sup>	44.5 (19-100)	56.0 (34-130)	0.240
Retrieved LN (n) <sup>*</sup>	17 (5-39)	16 (0-29)	0.423
Histological differentiation			0.138
Well	9 (56.3%)	3 (20.0%)	
Moderate	7 (43.8%)	10 (66.7%)	
Poorly	0 (0%)	1 (6.7%)	
Tage			0.363
I	2 (12.5%)	0 (0%)	
II	6 (37.5%)	4 (26.7%)	
III	4 (25.0%)	7 (46.7%)	
IV	4 (25.0%)	3 (20.0%)	
Residual tumor <sup>#</sup>			0.992
R0	11 (62.5%)	10 (66.7%)	
R1	1 (6.3%)	1 (6.7%)	
R2	4 (25.0%)	4 (26.7%)	

<sup>\*</sup>Value are the median (range); <sup>#</sup>R0: no residual tumor; LN: lymph node; R1: microscopic residual tumor; R2: macroscopic residual tumor. LS: laparoscopic surgery; OS: open surgery

complication rate. In the present study, anastomotic leakage occurred more frequently in the LS group, but not significantly. Colostomy was performed in 4 patients (3 with sigmoid colon cancer and 1 with rectal cancer) in the OS group, which prevented anastomotic leakage, whereas in the LS group, colostomy was only required in 1 patient who underwent pelvic exenteration. Colostomy is a safe procedure, because it does not require anastomosis. However, it is difficult to ensure that the resultant stoma is treated appropriately in psychiatric patients. Thus, the presence of a stoma can increase the risk of longer physical restraint, and it can be difficult to provide adequate stoma care after the patient has left the hospital. Therefore, the quality of life of psychiatric patients may be compromised by a lack of stoma care; hence, clinicians should be wary of performing colostomy in psychiatric patients.

Two patients were converted to OS from LS. One patient had a huge tumor that directly invaded the urinary bladder and rectum. The other patient had a tumor embolism in his inferior mesenteric vein and splenic vein. Psychiatric patients usually have megacolon due to a long disease period and psychiatric medicine [Figure 1]<sup>[17]</sup>. No patient was converted to OS, owing to megacolon and other psychiatric reason. As mentioned previously, patients with mental illness may present with more advanced disease<sup>[17]</sup>, resulting in anemia, obstruction, or infiltration of other organs. Advanced cancer may have made the surgical technique complex. For psychiatric patients, it was not difficult to continue and complete LS in the present study. Thus, LS should be performed by an expert who has passed an endoscopic surgical skill qualification system.

The hospitalization period was significantly shorter in the LS group than in the OS group ( $P = 0.021$ ). LS may



**Figure 1:** Almost all of patients had megacolon, owing to psychiatric medicine and some purgative medicine

have several short-term advantages compared with OS, e.g., it may contribute to reducing the hospitalization period. According to some reports, institutionalized patients tend to be hospitalized for longer, increasing the cost of surgical treatment for this population<sup>[6,18]</sup>. In our study, the median hospitalization period was 43 days in the LS group. One of the factors delaying the discharge of psychiatric patients is the difficulty that such patients have with adjusting to their environment. Patients with psychiatric problems cannot return to the psychiatric department or support facilities immediately after recovering from surgical stress. Collaboration with social workers may help reduce the hospitalization period by increasing clinicians' understanding of the optimal management methods for patients with psychiatric disorders.

The washout period was significantly shorter in the LS group than in the OS group. This suggests that psychiatric medications should be continued, if possible, during the perioperative period<sup>[6]</sup>. Until LS was introduced, patients at our hospital routinely received a nasogastric tube for a week postoperatively. The recovery of bowel motility is more difficult in psychiatric patients than in general patients. After starting LS, the nasogastric tube was removed immediately postoperatively<sup>[19]</sup>. The recovery of bowel motility postoperatively was assessed by a surgeon, auscultation, or other physical findings. Therefore, psychiatric medications were resumed as soon as possible. Increased rates of delirium and confusion in the postoperative period have been reported in psychiatric patients. In surgical, medical, and critically ill patients, delirium is associated with higher mortality, a longer hospital stay, and impairment at discharge<sup>[4,5]</sup>. Some studies have suggested that the postoperative development of confusion, delirium, or cognitive disorders may have important consequences for health care utilization and patient outcomes<sup>[20,21]</sup>. LS may lead to a more rapid recovery of intestinal

peristalsis, even for psychiatric patients.

This study had several limitations. First, it had a retrospective study design that has the inherent weakness of being observational or non-experimental. Second, the follow-up period was too short to enable us to draw any conclusions regarding the long-term outcomes of the LS or OS group. However, by continuing to enroll and follow-up with patients, we hope to obtain more valuable information in the future. Third, the small number of subjects is the main limitation, as this may have affected the results of the parameters. The Tokyo Metropolitan Matsuzawa Hospital is one of the largest mental hospitals in Tokyo. Yet, there are about 20 patients who have colorectal cancer in 1 year, so it was difficult to include more psychiatric patients with cancer in our study.

In conclusion, in agreement with a previous study that found that patients with psychiatric disorders do not represent a high-risk group during surgical treatment<sup>[13]</sup>, we consider that such patients do not have worse outcomes after LS than after OS for colorectal cancer. Our study demonstrated that LS for psychiatric patients is safe, and it has comparable short-term outcomes and oncological results compared to OS. Psychiatric patients might not need special postoperative managements, excluding treatment for psychiatric problems. Further studies involving more patients and a longer follow-up period are needed to confirm the present study's results.

## DECLARATIONS

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### Authors' contributions

Concept, design, definition and intellectual content of this study: K. Yuu, M. Tada

Operated this series: K.Yuu, Nasry Baongoc, M Tada  
Analysis, statistical analysis of this study: K. Yajima, K. Yuu

Manuscript preparation: K. Yuu

Data acquisition: K Yuu, K Tsuchihashi, M Ogawa, M Kawasaki and M Kameyama

The paper was coauthored by Kazuhito Yajima, Masanori Tada, Nasry Baongoc, Kurumi Tsuchihashi, Masao Ogawa, Masayasu Kawasaki and Masao Kameyama. All authors' meets the authorship criteria detailed in the Authorship section of this guideline and

all authors are in agreement with the content of the manuscript.

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## Conflict of interest

There are no conflict of interest.

## Ethical approval

We have approval of the research protocol by an institutional Review board. The study was reviewed and approved by the Tokyo Metropolitan Matsuzawa Hospital institutional review board. All study participants, or their legal guardian, provided informed written consent prior to their enrollment.

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# Percutaneous nephrostomy step by step

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## ABSTRACT

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Percutaneous renal access remains the cornerstone initial step in varied clinical settings. For obtaining the best surgical outcome and minimizing patient morbidity, an appropriate access to the target calyx is needed. Though the site of entry depends upon anatomy of pelvicalyceal system and indication for access, a proper technique should be used for gaining access and at the same time minimizing the associated complications. This article describes our technique of gaining access to the pelvicalyceal system and subsequent percutaneous nephrostomy placement in a stepwise manner.

## INTRODUCTION

Percutaneous nephrostomy (PCN) is a widely used interventional procedure for upper urinary diversion and decompression of the renal collecting system in varied clinical settings. Despite it being a basic urological procedure, it remains technically challenging to insert it in the right way and in the right place. Most of the time it's because of lack of exposure of the urologist/interventional radiologist to correct technique of PCN placement in a stepwise manner. Goodwin *et al.*<sup>[1]</sup> first reported placement of percutaneous trocar (needle) nephrostomy in a hydronephrotic kidney. Since then, many direct and wire guided methods of PCN placement has been elucidated in literature. PCN can be done under fluoroscopy, ultrasound

(USG) or computed tomography guidance. In this chapter we will describe the USG guided technique of PCN placement in a stepwise manner which is safe, effective and easily reproducible.

## INDICATION FOR PCN

### Obstructive uropathy

Benign causes: impacted ureteric/pelvis calculi with secondary hydronephrosis (HN), ureteric stricture disease, pelvic ureteric junction obstruction, HN associated with pregnancy, in transplant patients (e.g. HN due to anastomotic stricture), retroperitoneal fibrosis, urosepsis, pyonephrosis. Malignant causes: HN secondary to tumor of urinary tract, HN secondary to carcinoma cervix/prostate<sup>[2,3]</sup>.

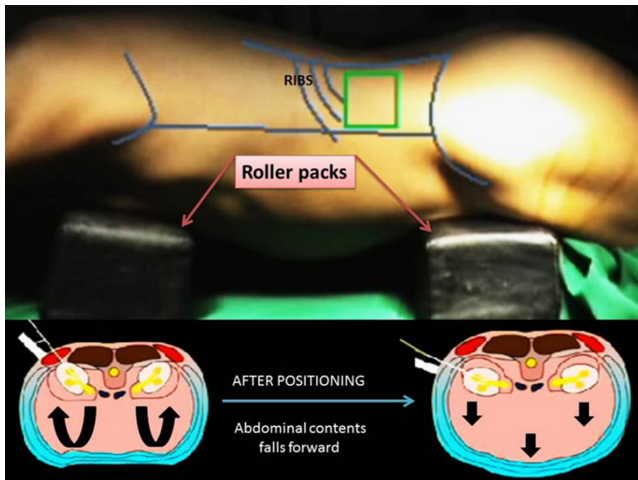


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**Figure 1:** The patient in prone position with roller pack underneath upper abdomen and chest, abdominal contents falls forward so as to give proper access to the kidneys

Urinary diversion in an attempt to heal conditions such as malignant/inflammatory fistula, urinary leak or fistulas resulting from trauma, and hemorrhagic cystitis etc.<sup>[2,3]</sup>.

#### For providing route of access

Chemotherapy, antifungal/antibiotic therapy, benign stricture dilatation, antegrade ureteral stent placement, stone retrieval, endopyelotomy<sup>[2,3]</sup>.

#### For diagnostic procedures

Whitaker test, antegrade pyelography, biopsy<sup>[3]</sup>.

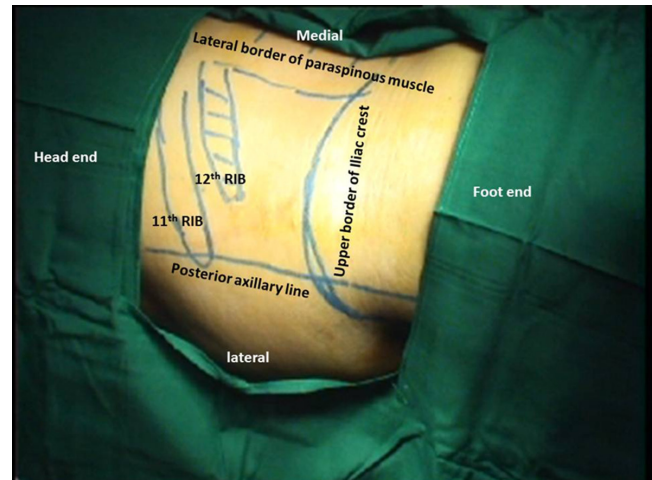
### PRE-OPERATIVE PREPARATION AND A COUNSELING OF THE PATIENT

Commonly, this procedure is done in local anesthesia (LA). Patient should be well explained about the procedure in detail. Informed consent should be taken beforehand. Bleeding parameters should be within normal limits. Attain intravenous (IV) access and antibiotics should be given half an hour prior to procedure particularly in patients presenting with urosepsis. For uncooperative but willing patient, procedure should be performed under general anesthesia. Relevant radiological images should be reviewed again in order to decide an optimal approach for renal access.

### DETAILED STEP-BY-STEP NUMBERED MEDICAL ILLUSTRATION

#### Step 1: patient positioning

With patient in prone position, a roller pack is placed



**Figure 2:** Surface marking (concept of Quadrangle of safety): with the patient in prone position, Quadrangle of safety is formed by posterior axillary line as lateral limit, upper margin of iliac crest as lower limit, lateral margin of paraspinous muscle as medial limit, the 11th and 12th rib border as upper limit

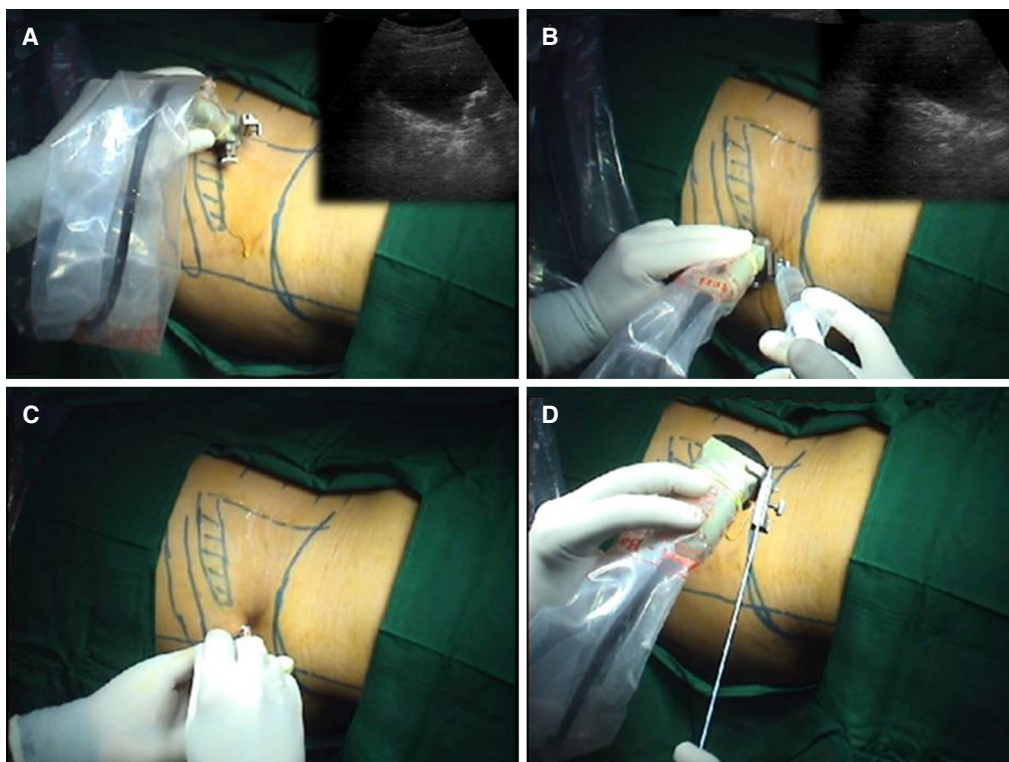
underneath pelvic bone and another under upper abdomen and chest region (as shown) so as to give adequate stretching around flank region<sup>[4,5]</sup>. The side to be operated should be brought at the edge of operating table. The area should be cleansed with povidone iodine and draped [Figure 1]. In case of relative contraindication to prone position (compromised cardiorespiratory system etc.), this procedure can be done in supine position as well.

#### Step 2: surface marking

If we place PCN in quadrangle of safety formed by posterior axillary line as lateral limit, upper margin of iliac crest as lower limit, lateral margin of paraspinous muscle as medial limit, the 11th and 12th rib border as upper limit, there are less chances of associated intrabdominal visceral injuries [Figure 2]<sup>[4,5]</sup>.

#### Step 3: USG to decide site of percutaneous puncture

USG of the diseased kidney should be done starting from medial aspect (Para spinal), advancing laterally until the posterior axillary line so as to see posterior calyces first followed by lateral calyces thereafter and thus to have an idea of degree of HN, type of pathology in the renal unit [Figure 3A and B]. We in our institute use 3.5 MHz convex transducer focused at 5-9 cm for adults and 5 MHz transducer focused at 5-7 cm for children. Exact site of puncture depends primarily on the cause of hydronephrosis (HDN) and anatomic landmarks. For simple urinary drainage a lower pole posterior calyx is usually best which can be easily accessed via subcostal approach. For accessing pelvoureteric junction (PUJ) or upper ureter,



**Figure 3:** (A) USG of the diseased kidney started from medial aspect and advancing laterally; (B) local anesthetic injected at the site selected for percutaneous access directing along the intended line of tract placement (puncture guide - dotted line in inset); (C) skin incision is made using No. 11 surgical scalpel; (D) a 15-cm, diamond-tipped, 18-gauge two-part trocar needle is engaged in needle attachment connected with the USG probe. USG: ultrasound guidance

upper or middle posterior calyx provides easy access and may require supracoastal puncture. Whenever possible aim should be to puncture posterior calyces and to avoid direct pelvic puncture especially in case of HN due to stone disease. Better visualized area of dilated renal pelvis (in mild HDN) and both renal pelvis and calyx (in moderate to severe HDN) is chosen and marked. The electronic dotted puncture line centered over that area and directed into selected calyx/pelvis. The shortest skin to calyceal distance is chosen keeping skin, renal parenchyma and cup of the calyx, infundibulum, and pelvis in a straight line. USG guided puncture can be done “free hand” but at our institute we always do it with help of puncture guide as it helps in guiding the puncture needle in the right plane and depth<sup>[4,5]</sup> [Supplementary Video 1].

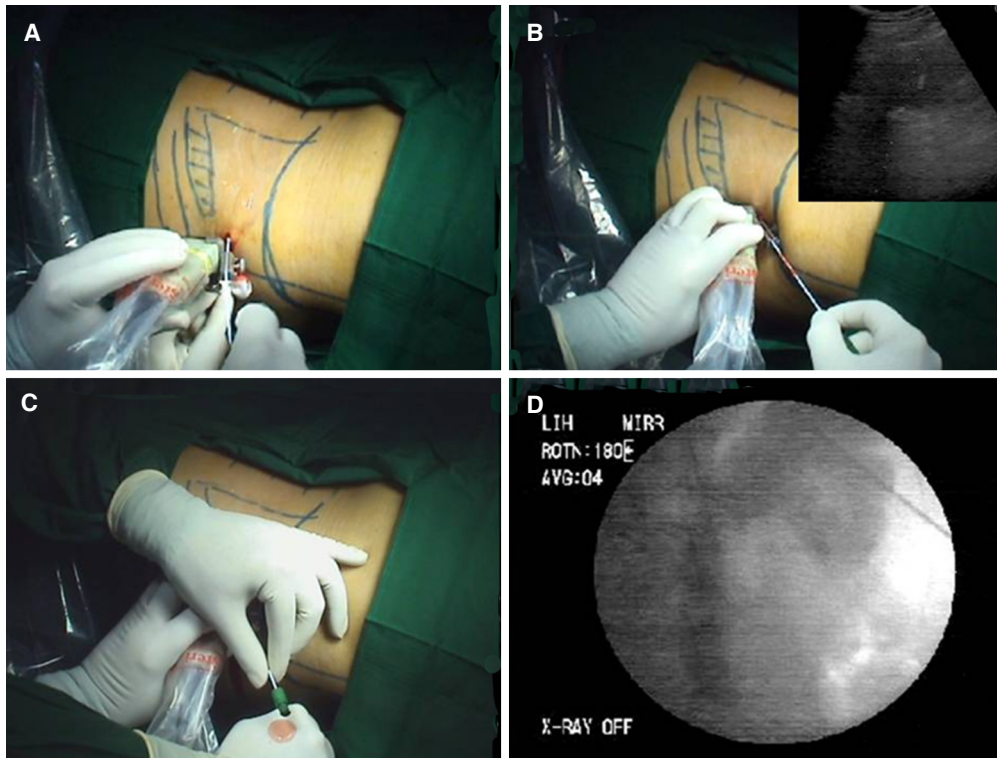
#### Step 4: puncture technique

The 5 mL LA in form of 2% lignocaine is injected at the site selected for percutaneous access and directed in deeper planes along the intended line of tract placement guided by puncture guide [Figure 3B]. Small incision is made with No. 11 surgical scalpel [Figure 3C]. A 15-cm, diamond-tipped, 18-gauge two-part trocar needle is then engaged in needle attachment connected with the USG probe [Figure 3D]. The tip of the needle should be introduced first through

the incision site [Figure 4A] and then advanced into deeper plane with needle guide (electronic dotted line on USG screen) turned on and beveled edge of the needle facing the probe (as beveled edge is echogenic and can be easily differentiated on USG). One should appreciate needle advancement along the dotted line into the desired calyx [Figure 4B]. If the needle is angled away from transducer or is off center, it will not be visualized on USG. During passage, one can appreciate two tactile “pops”. The first one corresponds to give way of renal capsule/thoracolumbar fascia and the second one when needle enters collecting system. Needle tip will move corresponding to renal outline during respiration suggesting entry into renal system. As soon as needle stellate is removed urine will egress (nature depends upon etiology), else gently aspirate while coming out of renal system until urine is observed [Figure 4C]. At this point urine sample should be collected and should be sent for appropriate tests. If urine is clear, we proceed with dye study for calyceal delineation [Figure 4D]. Target calyx will be opacified first followed by pelvis and other calyces. If however urine is turbid or pus is coming, we should avoid dye study to prevent bacteremia.

#### Step 5: guide wire insertion

Once position of needle is ensured, guide wire (0.038-inch



**Figure 4:** (A) Tip of the needle is engaged first through the skin incision site; (B) as the needle is advanced its tip is seen along the dotted line; (C) egress of urine after removing needle stellate; (D) dye study for calyceal delineation as seen on fluoroscopy

diameter) is introduced through the needle under fluoroscopy guidance, trying to negotiate it into the ureter [Figure 5A] or in upper calyx if possible.

### Step 6: tract dilatation

With help of No. 11 surgical scalpel, tract is incised by sliding scalpel over needle until dorsolumbar fascia is incised. Tract then is dilated up to 14 F using single step fascial dilator over the guide wire using rotatory screw movements of hands [Figure 5B]. Care should be taken to avoid kinking of guide wire or buckling of kidney [Figure 5C].

### Step 7: insertion of nephrostomy over guide wire

In a similar fashion and direction as used during tract dilatation nephrostomy tube is inserted with screwing movement of hands (avoid pushing) over the guide wire until it reaches well into the pelvis. We generally prefer to use 14 F Malecot catheter as nephrostomy tube, as it is self-retaining and less chances to get blocked due to its large diameter even in infective conditions like pyonephrosis. Once in place Malecot catheter inner occluder is opened and flower rotation should be appreciated under fluoroscopy guidance [Figure 5D]. Though it's self-retaining, we still prefer to further stabilize nephrostomy with skin using non-absorbable suture material and adhesive strapping.

Once done occluder is taken out with the guide wire and attached to an external drainage bag. Final position of Malecot catheter is confirmed by repeating dye study. USG should be done at the end to see decompression of pelvic calyceal system as well position of nephrostomy tube.

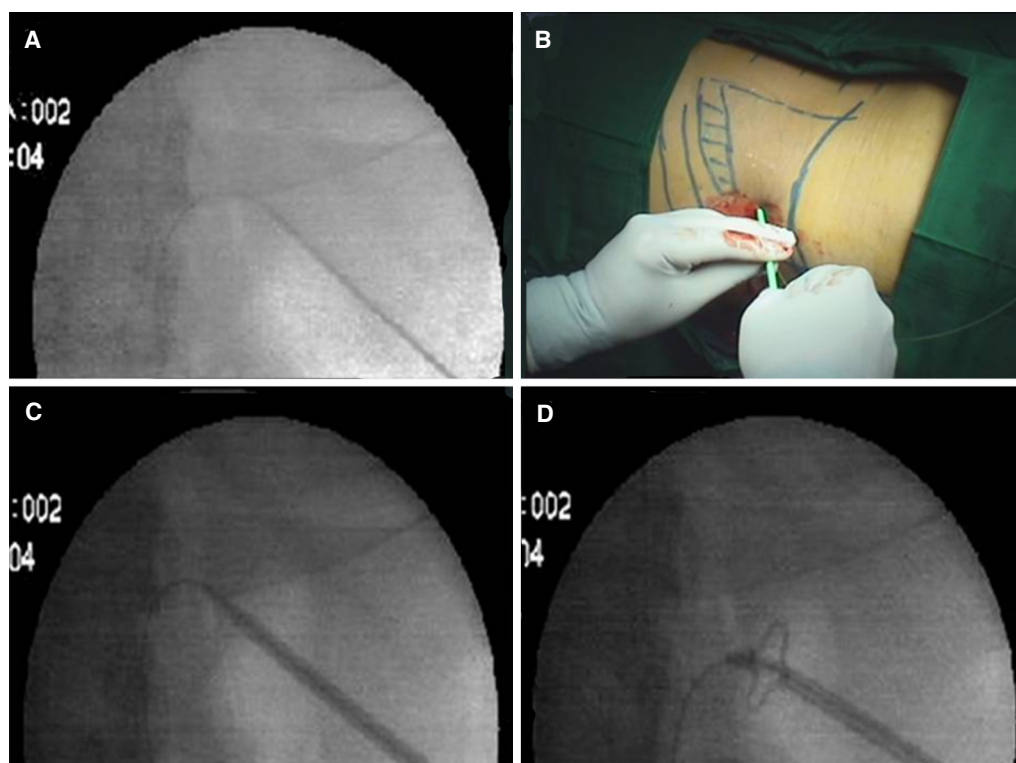
## POST PROCEDURE CARE

Vitals should be recorded every half hourly for first 6 h post procedure. As the most important indication for nephrostomy placement is obstructive uropathy, so after decompression diuresis is expected in these patients mandating close monitoring of urine output and electrolytes. Bed rest should be advised for around 4 h with recommencement of the preprocedural diet. If sepsis is suspected, a broad spectrum injectable antibiotic is started round the clock. Nephrostomy tube should be checked for its patency periodically and if blocked can be gently washed with diluted 5 mL betadine/antibiotic solution.

## OTHER METHODS FOR GAINING ACCESS

### Fluoroscopy guided access

A complete opacification of the system is done using the chiba needle and thereafter access is gained in



**Figure 5:** (A) Guide wire is introduced and parked into ureter under fluoroscopy; (B) tract dilatation using single step fascial dilator (14 Fr) over the guide wire using rotatory screw movements of hands; (C) dilator and guide wire should be in straight line and any guide wire kinking or buckling of kidney is avoided; (D) Malecot in place with its opened flower end

the appropriate calyx<sup>[6]</sup>.

### MDCT guided access

In cases where the collecting system is complicated with difficult anatomy MDCT guided access is valuable with added advantage of delineating abnormal anatomy with respect to surrounding viscera and access site. Main limitations are its availability and radiation exposure<sup>[7]</sup>.

### Advantages of ultrasound guided technique

(1) Reduces radiation exposure both for operating staffs and patients; (2) decreases need for contrast media; (3) decreases chances of major adjacent viscera organ or major vessel (color doppler) injury; (4) can be performed in supine position; (5) can be done safely in pregnant, pediatric patients; (6) method of choice in transplant kidney and ectopic kidney (reduces chances of bowel injury); and (7) overcomes the problem of unsuccessful retrograde ureteral catheterization that is required for contrast media injection in fluoroscopic guidance.

### Disadvantages of ultrasound guided technique

Technically challenging for novice as well in case of mild or no hydronephrosis.

### Tips and tricks of successful ultrasound guided puncture

(1) Proper positioning and surface marking as described; (2) correct identification of posterior calyx; (3) use puncture guide during puncture of desired calyx; (4) use diamond tipped needle instead of beveled tipped needle during puncture; (5) in case of inadequate dilatation of pelvicalyceal system diuretic can be given preoperatively; (6) during puncture one should appreciate full course of needle along the puncture guide; (7) once calyx is punctured and dye is instilled, the target calyx should be opacified first followed by pelvis and other calyx; (8) placement of guidewire through the target calyx into ureter or upper calyx; and (9) always perform repeat ultrasound at end of procedure to see for any residual hydronephrosis which may require another PCN placement.

### COMPLICATIONS

(1) Hematuria: virtually every patient have some amount of transient hematuria but only 1-3% of those patients require transfusion, surgery, or embolization. If noted at the time of nephrostomy itself, can be controlled by applying tamponade over the nephrostomy tract<sup>[8]</sup>; (2) pain: this is also one of the common complications, can be controlled by oral/IV

analgesics; (3) sepsis: PCN insertion in pyonephrotic kidneys can result in severe bacteremia and sepsis; (4) injury to adjacent organs: pneumothorax and colonic injury are rare but are known complication especially in supracostal punctures; (5) extravasation of urine; (6) catheter dislodgement; and (7) inability to remove nephrostomy tube due to crystallization.

## CONCLUSION

USG guided technique of PCN placement is safe, effective and easily reproducible if done with correct technique though it requires some degree of learning curve to overcome to become competent in this technique.

## DECLARATIONS

### Authors' contributions

Study conception and design, drafting of the manuscript: A. Jairath  
Drafting of the manuscript, critical revision: A. Ganpule  
Critical revision: M. Desai

### Financial support and sponsorship

None.

### Conflicts of interest

There are no conflicts of interest.

### Patient consent

Not applicable.

### Ethics approval

Not applicable.

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Case Report

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# Endovesical instillation of platelet rich fibrin for treatment of interstitial cystitis: case report of two patients

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## ABSTRACT

Interstitial cystitis, also called painful bladder syndrome, is a chronic condition causing bladder pain and sometimes pelvic pain. The exact cause of interstitial cystitis is not known. Often, signs and symptoms are hard to elucidate and no single treatment works for everyone. We report two cases of patients affected by interstitial cystitis treated with endovesical instillation of platelets rich fibrin (PRF). PRF is an autologous component that promotes angiogenesis, tissue growth and repair. This report presents the safety and the efficacy of PRF instillations in controlling clinical symptoms and restoring quality of life.

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## INTRODUCTION

Benign diseases of bladder such as interstitial cystitis (IC) and complex hemorrhagic radiation-induced cystitis are highly disabling. IC is not a specific disease but represents a complex set of symptoms also called "bladder pain syndrome". This differs from common bacterial cystitis as it is a non-infective bladder inflammation. IC is caused by cellular alteration

of bladder wall. The etiology causing the mucosal damage is still unclear. The urothelium sustains multiple injuries in contact with the acidic urine and this leads to an increase in local nervous sensibility for pain regulation. Patients are more sensitive to voiding stimuli and suffer chronic pelvic pain, urgency and predisposition to urinary infections. These symptoms dramatically impact quality of life. Females are more affected than males. In 90% of cases, the patients are



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**Table 1: Preoperative SF-36 questionnaire score**

Patient	Preoperative SF-36 score physical health (baseline 50)	Preoperative SF-36 score mental health (baseline 50)
1	35	25
2	22	25

SF-36: Short Form-36

20-40 years old. Prevalence is increasing. In 1999, the Nurses' Health Study has published a paper on over one million women affected by IC in the United States<sup>[1]</sup>. Pathogenesis is still unclear and could be multifactorial including: urothelium dysfunction, mast cell activation and neurogenic inflammation<sup>[2]</sup>. Mast cells accumulate into the sub-urothelium, proliferate forming pericapillaries cluster and release numerous inflammatory molecules (histamine; cytokines; prostaglandins; platelet-activating factor and proteolytic enzymes (tryptase and kinase). The process may result in ulcerative cystitis<sup>[3]</sup>. The "up-regulation" of bladder sensitive afferents is the cause of symptoms such as urgency, frequency and/or pain.

There is no standard treatment. The 2011 AUA Treatment Guidelines include a treatment protocol ranging from conservative treatments to more invasive interventions<sup>[4]</sup>. The aim of that study was to test the efficacy of platelets rich fibrin (PRF) in patients affected by IC in controlling the clinical symptoms and restoring the correct functioning of urothelium coating. PRF<sup>[5-9]</sup> is a blood component for local use. It can be obtained from fresh frozen plasma or bought in synthetic form. It has hemostatic properties replicating the final phase of the coagulation cascade leading to the fibrin coat. PRF is composed of fibrin glue and threefold the number of platelets than normal human blood<sup>[10]</sup>. PRF is stable and biocompatible. It is safe and functional. It promotes angiogenesis, tissue growth and repair through multiple growth factors such as transforming growth factor-beta, vascular endothelial growth factor and platelet-derived growth factor. PRF applications do not induce inflammatory processes, adverse reactions and tissue fibrosis. PRF is nowadays widely applied in different clinical scenarios, such as orthopedics, ophthalmology and healing therapies, as a growth factor pool for improving tissue regeneration.

## CASE REPORT

The ethics committee of Campus Bio-Medico University of Rome approved the study (REC number: 27/14 PAR) on March 2014. From March 2014 to September 2014, we enrolled two women affected by IC who presented clinical symptoms such as pain,

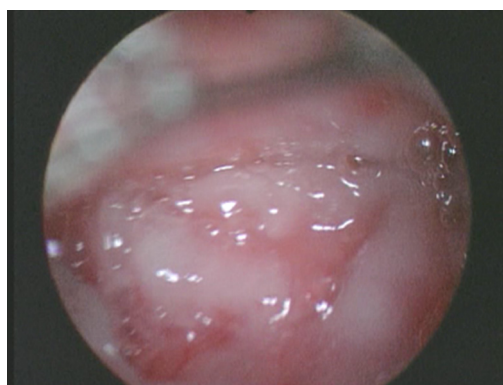
overactive bladder, dysuria, recurrent urinary infections previously treated by conventional drugs without any responses. The mean age was 60 years (range 57-63 years). The exclusion criteria were: patients with Performance Status Karnofsky index  $\leq 50\%$ ; patients who needed major surgery; patients affected by cancer disease; patients presenting platelets counts  $\leq 100,000$  or affected by coagulopathy; pregnancy. Both patients were negative for coagulation pathway alteration or urinary infection.

Patients underwent flexible diagnostic cystoscopy and biopsy 1 to 4 weeks before the application of PRF to exclude bladder cancer. One patient had a histopathological diagnosis of IC due to a previous transurethral resection of the bladder for suspicious carcinoma *in situ* of the bladder. Each patient filled in the urinary symptoms questionnaire for IC<sup>[11-15]</sup> and the SF (Short Form)-36 questionnaire<sup>[16-18]</sup> before the endoscopic procedure and application of PRF. The urinary symptoms questionnaire was composed of 73 questions covering the following domains: urinary symptoms, pain symptoms, sexual function, menstrual variability, and general health status. The SF-36 questionnaire was used to test the quality of life, using a baseline of 50 represented the general health of the unaffected Italian population. The results of SF-36 questionnaire are shown in Table 1. Summary score of IC symptom index was higher than 6 for both patients. This score indicates that patients affected by IC present significant voiding and pain symptoms.

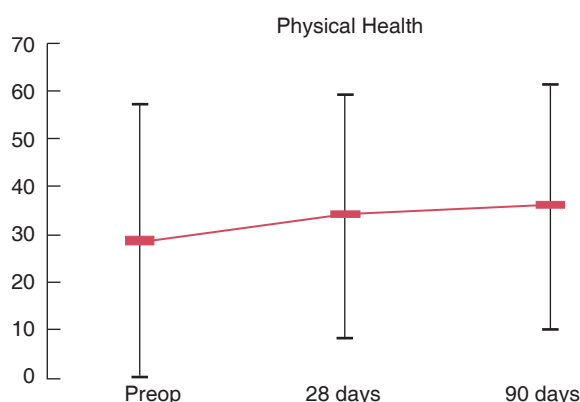
After the written informed consent was obtained, we took 120 mL of autologous blood sample about 1 h before the procedure from a peripheral vein (30 min is the time for preparing about 6 mL of PRF). PRF was obtained from autologous patient's blood through the Vivostat system (Vivolution, Birkerød, Denmark)<sup>[19]</sup> according to the standards for autologous donation (Ministerial Decrees of March 2005). Vivostat system is composed of 3 parts: an automated processor unit, an automated applicator unit and a sterile unit for dispensing which includes a set of preparation and an endoscopic applicator. PRF was controlled for hepatitis B virus, hepatitis C virus, and human immunodeficiency virus. We obtained about 6 mL of PRF from each patient through the Vivostat system. Thereafter, we performed an operative rigid cystoscopy with Carbon Dioxide Insufflation. One patient was treated under sedation, the other one received subarachnoid anesthesia due to serious asthma condition. We instilled 6 mL of PRF in a spray fashion all over the bladder walls [Figures 1 and 2] through the endoscopic applicator. Then we placed the vesical catheter and monitored the urine output.



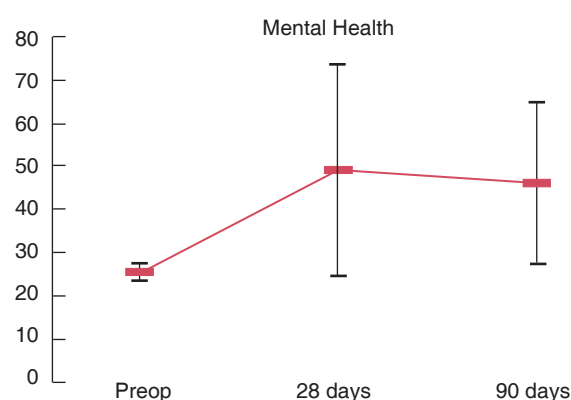
**Figure 1:** Instillation of platelets rich fibrin during operative cystoscopy



**Figure 2:** Appearance of bladder walls at the end of the procedure



**Figure 3:** Physical health improvement after platelets rich fibrin instillation (Short Form-36 questionnaire score)



**Figure 4:** Mental health improvement after platelets rich fibrin instillation (Short Form-36 questionnaire score)

Both patients maintained the vesical catheter postoperatively and presented good urinary output. We discharged patients after removal of the catheter and spontaneous urination.

The follow-up was performed at 28 days, and 3 months through clinical visits and patients were asked to fill in the SF-36 questionnaire again. During the last follow-up at 3 months, patients filled in also the Patient Global Impression of Improvement (PGI-I) questionnaire<sup>[20]</sup>. PGI-I is a 1-item questionnaire designed to assess the patient's impression of changes in urinary symptoms on a 7-point scored scale. Global clinical response was evaluated through clinical examinations and postoperative questionnaires that patients filled in during the follow-up. Patients reported significant improvement of symptoms (pain and dysuria) and quality of life especially regarding the mental health at the SF-36 questionnaire [Figures 3 and 4]. Both patients answered the PGI-I questionnaire to feel "much better" after PRF instillation. Neither patient treated with PRF experienced any short- or long-term side effects.

## DISCUSSION

During the 2003 Kyoto workshop, the IC was defined to be a syndrome characterized by 3 main symptoms: frequency; urgency; pain<sup>[21]</sup>. The discomfort<sup>[22]</sup> significantly alters the quality of life of patients. The etiology and pathogenesis of this condition are still unknown and it remains diagnosed by exclusion. According to the European Society for the study of IC/BPS (ESSIC) recommendations<sup>[23]</sup>, the first line of diagnosis is patient selection based on symptoms and exclusion of other diseases with similar presentation. During the cystoscopy, little pink ulcerations (ulceration of Hunner<sup>[24]</sup>) described in 1914 and "glomerulation" described by Keene in 1920 as sub-mucosal capillary bleeding can be found. The histologic findings are also neither specific for diagnosis nor correlated with symptoms. The histologic sample of bladder biopsy can show the coating involution, the urothelium thinning, the inflammatory sub-urothelium infiltration and the mast cells presence<sup>[25]</sup>. While a patient's history and examination are important, bladder biopsy is not essential. The most common indication for

bladder biopsy is a search for urothelial carcinoma/ carcinoma *in situ* of the bladder, which may be confused with IC<sup>[26]</sup>.

We enrolled patients according to their typical and highly disabling symptoms. Once we excluded the presence of bladder cancer, the aim of this study was to test the safety and the efficacy of endovesical instillation of PRF to stimulate tissue regeneration and control the clinical symptoms. Because standardized treatment for IC does not exist, patients usually try many kinds of procedures such as many drugs (pentosan polysulphate, antidepressants); endovesical instillation of hyaluronic acid or Bacillus Calmette-Guerin; sacral neuromodulation or surgery (laser ablation of ulceration, cystectomy, bladder augmentation). Instillation therapy has a direct action on the urothelium and sub-urothelium to restore the normal bladder lining. Endovesical fibrin glue has been successfully used also for refractory hemorrhagic cystitis occurred after unrelated marrow, cord blood, and haploidentical hematopoietic stem cell transplantation<sup>[27]</sup>. Campus Bio-Medico University (Urology and Hematology Departments) has already conducted, as coordinating center of Rome Transplanta Network in 2009, a study on 35 patients affected by severe hemorrhagic cystitis after allogeneic hematopoietic stem cell transplantation. All 35 patients showed clinical response and pain resolution. In this new study, we treated patients affected by IC and we demonstrated that the typical urothelium coating involution can be successfully helped by PRF that promotes angiogenesis, tissue growth and repair through multiple growth factors as showed for transplanted patients.

A significant number of patients with ulcerative IC show ulceration, severe inflammation, and granulation tissue<sup>[28]</sup>. The inflammatory infiltrates are usually superficial, and restricted to the lamina propria<sup>[29]</sup>. The lamina propria is edematous, with stromal hemorrhage and congested venules. In these patients, the rupture of the bladder mucosa subsequently resulted in reparative granulation tissue<sup>[30]</sup>. Hemorrhage is present in 90% of nonulcerative IC. While generally localized, the hemorrhage may extend into the urothelium<sup>[25]</sup> and causes the mucosal rupture. Usually inflammation is mild, but edema and vascular congestion are frequently seen. In both cases (ulcerative and non-ulcerative IC) the urothelium is particularly fragile. Baseline symptom assessment and regular symptom level reassessment are essential to document efficacy of single and combined treatments<sup>[31]</sup>. We used different types of questionnaires to compare the entity of patients' discomfort before and after the endoscopic application

of PRF. Questionnaires score showed a significant improvement of patients' symptomatology during the follow-up. Our patients presented improvement in quality of life and symptoms especially regarding the mental health. Both the mental and the physical health increased significantly and remained stable after 28 days and 3 months. PGI-I and SF-36 questionnaires can provide an overall appraisal of a patients' condition and they are practical for clinical use by their simplicity in administration and interpretability. The interstitial cystitis symptom index has been designed to capture the most important voiding and pain symptoms and to assess how problematic patients find them. Almost no IC patients score less than 6 while almost no controls score as high as 6. In our study, the symptom index was higher than 6 for both patients and this value is comparable to the score of O'Leary *et al.*<sup>[11]</sup>. No further clinical improvements were seen after the first weeks after PRF instillation. This may justify reevaluation during the follow-up for new endovesical treatments even though they presented partial or no response. PRF is an autologous blood component and it is safe and biocompatible. Patients treated with PRF did not present any immediately or long term side effects. The small series represents the major limitation of the study. Further cases are needed to achieve stronger results.

In conclusion, PRF is an autologous component that promotes angiogenesis, tissue growth and repair through multiple growth factors. It is safe and biocompatible; it is widely applied in different clinical scenarios to promote the tissue regeneration. Our preliminary data show that patients affected by IC who underwent endovesical application of PRF over the damaged urothelium, present significant improvement in clinical symptoms and quality of life. Further studies are needed to obtain more data.

## DECLARATIONS

### Authors' contributions

Study conception and design: F. Cristina  
PRF production: M.C. Tirindelli  
Data collection: A. Nicotera  
Analysis and interpretation of data: T. Petitti  
Drafting of manuscript: M. Buscarini  
Critical revision: G. Avvisati

### Financial support and sponsorship

None.

### Conflicts of interest

There are no conflicts of interest.

## Patient consent

Obtained from both patients.

## Ethics approval

The ethics committee of Campus Bio-Medico University of Rome approved the study (REC number: 27/14 PAR) on March 2014.

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In the second paragraph: concisely explain what was done, the main findings and why they are significant;

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Manuscript Type	Definition	Abstract	Keywords	Main Text Structure
Original Article	An Original Article describes detailed results from novel research. All findings are extensively discussed.	Structured abstract including Aim, Methods, Results and Conclusion. No more than 250 words.	3-8 keywords	The main content should include four sections: Introduction, Methods, Results and Discussion.
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The title of the manuscript should be concise, specific and relevant, with no more than 16 words if possible. When gene or protein names are included, the abbreviated name rather than full name should be used.

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Journal articles ahead of print	Odibo AO. Falling stillbirth and neonatal mortality rates in twin gestation: not a reason for complacency. <i>BJOG</i> 2018; Epub ahead of print [PMID: 30461178 DOI: 10.1111/1471-0528.15541]
Books	Sherlock S, Dooley J. Diseases of the liver and biliary system. 9th ed. Oxford: Blackwell Sci Pub; 1993. pp. 258-96.
Book chapters	Meltzer PS, Kallioniemi A, Trent JM. Chromosome alterations in human solid tumors. In: Vogelstein B, Kinzler KW, editors. <i>The genetic basis of human cancer</i> . New York: McGraw-Hill; 2002. pp. 93-113.
Online resource	FDA News Release. FDA approval brings first gene therapy to the United States. Available from: <a href="https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm574058.htm">https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm574058.htm</a> . [Last accessed on 30 Oct 2017]
Conference proceedings	Harnden P, Joffe JK, Jones WG, editors. Germ cell tumours V. Proceedings of the 5th Germ Cell Tumour Conference; 2001 Sep 13-15; Leeds, UK. New York: Springer; 2002.
Conference paper	Christensen S, Oppacher F. An analysis of Koza's computational effort statistic for genetic programming. In: Foster JA, Lutton E, Miller J, Ryan C, Tettamanzi AG, editors. <i>Genetic programming. EuroGP 2002: Proceedings of the 5th European Conference on Genetic Programming</i> ; 2002 Apr 3-5; Kinsdale, Ireland. Berlin: Springer; 2002. pp. 182-91.
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