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Trifecta results in Retzius-sparing robotic radical prostatectomy: results of a high-volume center

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Abstract

Aim: We aimed to evaluate trifecta outcomes after Retzius-sparing robot-assisted radical prostatectomy (rs-RARP).

Methods: We evaluated 1488 patients who had undergone rs-RARP at our institution from 2011 to 2019. All patients filled out questionnaires for functional outcomes before surgery, and only patients with baseline continence and IIEF-5 scores of > 16 were included. Biochemical recurrence (BCR) was defined as two consecutive prostatic specific antigen levels of > 0.2 ng/mL after rs-RARP. Postoperative continence was defined as the use of no pads. Potency was defined as the ability to achieve erections for sexual intercourse, with or without phosphodiesterase-5 (PDE-5) inhibitors. A multivariable logistic regression model was performed to identify predictors of trifecta outcome.

Results: In total, 1240 patients were included in the analysis. During the 24-month follow-up time, 149 patients (11.9%) harbored BCR. Urinary continence was observed in 981 patients (79.5%), while 171 (13.8%) still used a safety pad daily after 24 months. Sexual potency was reported in 643 patients (51.9%), of whom 379 (30.6%) had



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spontaneous erections and 264 (21.3%) used a PDE-5 inhibitor. Overall, the trifecta outcome was reached by 42.1% of the study's population. The trifecta outcome was easily reached by younger patients and patients who underwent a full nerve-sparing (NS) prostatectomy. In the multivariable model, age [odds ratio (OR) = 0.89; 95% confidence interval (CI): 0.84-0.90; $P < 0.01$] and type of NS surgery [partial NS (OR = 3.34; 95%CI: 1.01-11; $P = 0.04$) full NS (OR = 4.57; 95%CI: 1.86-12; $P < 0.01$)] resulted as independent predictors.

Conclusion: rs-RARP is associated with optimal trifecta outcome rate. Age and NS technique are independent predictors of trifecta outcomes.

Keywords: Prostate cancer, robot-assisted radical prostatectomy, Retzius sparing, functional outcomes, trifecta outcome

INTRODUCTION

Robot-assisted radical prostatectomy (RARP) was introduced in the early 2000s^[1]. Since its introduction, RARP has gained popularity among surgeons due to the well-known advantages, such as three-dimensional binocular magnification, motion scaling, tremor filtration, and good surgeon ergonomics^[2]. Furthermore, since radical treatment of prostate cancer (PCa) is associated with optimal oncologic outcomes^[3], the focus of the urologist is to improve the quality of life (QoL) after treatment, and urinary continence and sexual potency preservation are the two most frequent QoL alterations that bother patients after RARP^[4].

The three main long-term goals of RARP are complete removal of cancer, recovery of continence, and recovery of potency, which are commonly gathered with the name of “trifecta outcome”^[5]. Various studies have reported the rate of trifecta outcome in RARP^[6,7], ranging from 23% to 86%. This considerable variability is mainly due to the different definitions of trifecta adopted in the literature^[8].

Retzius-sparing robot-assisted radical prostatectomy (rs-RARP) was first proposed by our group in 2010^[9] and is recognized by the European Association of Urology (EAU) guidelines as an effective surgical option for PCa treatment^[10]. The technique's success is due to a shorter continence recovery time than the traditional robotic approach^[11-13]. Recently, it has been demonstrated that the technique is also safe during the learning curve phase^[13-15].

Although urinary continence recovery and other specific outcomes after rs-RARP have been described^[16,17], no series analyzing the trifecta rates extensively after rs-RARP have been previously published, and further research is needed to evaluate both sexual function outcomes and oncologic outcomes^[18].

This study aimed to evaluate trifecta outcome rates at 24 months after rs-RARP and identify possible outcomes predictors.

METHODS

Study population

Data from 1488 PCa patients treated with rs-RARP at a single high-volume European center (ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy) between January 2011 and March 2019 were analyzed. Data were extrapolated from an ongoing prospective database, and all patients had at least 24 months of follow-up.

All patients prior to the surgery answered self-administered validated questionnaire, the International Index of Erectile Function (IIEF-5)^[19], to assess the baseline sexual function.

In the present study, we only included patients with preoperative IIEF-5 scores of > 16. In addition, all patients analyzed were continent before rs-RARP. All patients provided informed consent.

Surgical technique and functional rehabilitation

All RS-RARP procedures were performed with a four-arm da Vinci Si Surgical System (Intuitive Surgical, Sunnyvale, CA, USA) with a transperitoneal approach. Eight different urologists with different grades of experience performed the surgeries. All the surgeons had completed the learning curve and had completed at least 40 cases. The assistant was often a resident or a urologist in the learning curve phase. Patients were placed in the 30° Trendelenburg position. Six laparoscopic trocars were used as previously described^[9]. The type of nerve sparing (NS) performed during the rs-RARP was reported according to the Pasadena Consensus Panel^[20]. In the surgical report, the surgeon defined a grade of NS for each side of the gland (intra-fascial, inter-fascial, or extra-fascial/no nerve-sparing technique). We considered full NS intra-fascial at least on one side and intra- or inter-fascial on the other, partial NS inter-fascial bilaterally, and minimal or no NS for extra-fascial or no NS on one side. Therefore, all types of NS were included in the analysis.

All patients started pelvic floor muscle exercises immediately after the supra-pubic catheter removal and were recommended to continue during the follow-up. In addition, all patients were advised to use phosphodiesterase-5 (PDE-5) inhibitors after surgery regularly, at least three times/week, until recovery of sexual function. A vacuum device was not routinely recommended.

Follow-up and outcomes definition

Our primary goal was to determine the trifecta rate 24 months after rs-RARP.

Urinary continence was defined as the use of no pads (score 0) in the last four weeks.

Potency was defined as the ability to obtain and maintain a proper erection for sexual intercourse in more than 50% of the attempts, with or without PDE-5 inhibitors.

The biochemical recurrence (BCR) was defined as two consecutive prostatic specific antigen (PSA) measurements of > 0.2 ng/mL after the surgery.

During follow-up, serum PSA measurement and clinical evaluation were carried out at 3, 6, and 12 months, and then every six months for three years. Before clinical evaluations, questions about potency and urinary function were assessed.

Statistical analyses

Medians and interquartile ranges (IQR) and frequencies and proportions were reported for continuous and categorical variables, respectively.

To identify predictors of trifecta outcome, a multivariable logistic regression model testing for trifecta outcome was performed. Adjustment variables consisted of age, body mass index (BMI), PSA, comorbidities (reported as the Charlson score), prostate volume, pathological International Society of Urological Pathology (ISUP) grade, pathological tumor stage (pT), and nerve-sparing technique. The R software environment for statistical computing and graphics (version 3.6.3) was used for all statistical analyses. All

tests were two-sided with a level of significance set at $P < 0.05$.

RESULTS

Of the 1488 patients treated, 167 were excluded due to a preoperative IIEF-5 score of < 17 and 81 were excluded because of incomplete data or follow-up. Thus, in total, 1240 patients were included in the analysis.

Preoperative characteristics

Table 1 summarizes the descriptive characteristics of our patients. Median age and BMI were 65 years (IQR: 60-69 years) and 26.1 kg/m² (IQR: 24.2-28.4 kg/m²). Median PSA was 6.9 ng/mL (IQR: 5-9.9 ng/mL). Most of the patients presented a clinical T2a or inferior disease (56.5%). ISUP grade group was 1 in 582 (46.4%), 2 in 322 (25.8%), 3 in 133 (10.5%), 4 in 152 (12.2%), and 5 in 51 (4.1%) of the patients. The median prostate volume was 42 mL (IQR: 32-55 mL).

Overall, 71.7% of the patients underwent a full NS procedure, 4.1% underwent a partial NS surgery, and 24.2% underwent a minimal or non-NS prostatectomy.

Functional and cancer control outcomes

Positive surgical margins were present in 215 patients (17.3%). During the 24-month follow-up period, 149 patients (11.9%) harbored BCR.

Urinary continence was observed in 981 patients (79.5%), while 171 (13.8%) still used a safety pad daily after 24 months. In total, 88 patients (6.7%) did not reach urinary continence.

Sexual potency at 24 months was reported in 643 patients (51.9%), of whom 379 (30.6%) had spontaneous erections and 264 (21.3%) used PDE-5 inhibitor. Overall, 34 patients (2.7%) were able to reach erections with intracavernous injections, while the remaining 563 (45.4%) patients did not reach a satisfactory erection for intercourse. The full results are shown in **Table 2**.

Trifecta outcomes

Overall, the trifecta outcome was reached by 42.1% of the study's population.

Trifecta rate stratified for the grade of NS surgery was 20.7% for minimal or no NS, 38.8% for partial NS, and 49.9% for full NS [**Figure 1A** and **B**].

Trifecta outcome rate stratified for age groups was as follows: 62.2% in patients younger than 56 years, 58.2% inpatient between 56 and 60 years, 45.8% in patients between 61 and 65 years, 34.2% in patients between 66 and 70 years, 26.1% in patients between 71 and 75 years, and 9.1% in patients older than 75 years [**Figure 2A** and **B**].

A multivariable logistic regression analysis predicting trifecta found that age (OR = 0.89; 95%CI: 0.84-0.90; $P < 0.01$) and the grade of nerve-sparing surgery of partial NS (OR = 3.34; 95%CI: 1.01-11; $P = 0.04$) vs. full NS (OR = 4.57; 95%CI: 1.86-12; $P < 0.01$) reached independent predictor status [**Table 3**].

DISCUSSION

High-level evidence evaluating the trifecta outcome rate after rs-RARP is unavailable. Most studies have evaluated the intraoperative outcomes and urinary continence results after rs-RARP^[13]. To improve the

Table 1. Descriptive characteristics of 1240 prostate cancer patients treated with the Retzius-sparing approach at a single European high-volume center

Preoperative variables (n = 1240)	
Age , years, median (IQR)	65 (60-69.3)
BMI , kg/mq, median (IQR)	26.1 (24.2-28.4)
Charlson comorbidity index , n (%)	
0	919 (74.1)
1	141 (11.4)
2	120 (9.7)
3	60 (4.8)
Previous abdominal surgery , n (%)	409 (33)
Previous surgery for BPH , n (%)	57 (4.6)
PSA at RS-RARP , ng/mL, median (IQR)	6.9 (5-9.9)
Clinical tumour stage , n (%)	
≤ cT2a	703 (56.5)
cT2b	305 (24.6)
cT2c	146 (11.8)
≥ cT3	88 (7.1)
ISUP grade group at prostate biopsy , n (%)	
1	582 (46.4)
2	322 (25.8)
3	133 (10.5)
4	152 (12.2)
5	51 (4.1)
EAU risk classification group , n (%)	
Low	412 (33.2)
Intermediate	525 (42.4)
High	303 (24.4)
Prostate volume , mL, median (IQR)	42 (32-55)
Intraoperative variables (n = 1240)	
Nerve sparing technique , n (%)	
Full NS	891 (71.7)
Partial NS	49 (4.1)
Non NS	300 (24.2)

BMI: Body mass index; BPH: benign prostate hyperplasia; PSA: prostate specific antigen; ISUP: International Society of Urological Pathology; RS-RARP: Retzius-sparing robot-assisted radical prostatectomy; IQR: inter-quartile range; NS: nerve sparing; ISUP: International Society of Urological Pathology; EAU: European Association of Urology.

counseling of PCa patients and better inform them regarding what to expect after the surgery, we analyzed the trifecta outcome at 24 months after the surgery. We investigated the possible predictor factors in over 1200 patients who had undergone rs-RARP in a high-volume center. We found that more than 40% of the patients 24 months after rs-RARP reached the trifecta outcome, regardless of the patients' age or the NS-approach used during the surgery.

Moreover, we found that age and NS technique are independent predictors of the trifecta outcome. Lastly, as previously demonstrated, we observed that the potency rate is the item that most influences the trifecta rate as only slightly more than 50% of our group was potent after rs-RARP.

Our findings will help better assess the risk of not reaching the trifecta outcome after rs-RARP and give valuable information for the preoperative counseling of PCa patients.

Table 2. Cancer control and functional outcomes of 1240 prostate cancer patients treated with the Retzius-sparing approach at a single European high-volume center

Functional and cancer control outcomes (n = 1240)	
Positive surgical margins, n (%)	215 (17.3)
BCR, n (%)	149 (11.9)
Urinary continence at 24 months, n (%)	
No pad	981 (79.5)
Safety pad	171 (13.8)
More than 1 pad/day	88 (6.7)
Sexual potency at 24 months, n (%)	
Spontaneous erections	379 (30.6)
PDE-5 inhibitors	264 (21.3)
Intracavernous injections	34 (2.7)
ED	563 (45.4)
Overall trifecta outcome, n (%)	522 (42.1)
Trifecta outcome for age groups, years, %	
Younger than 56	62.2
56-60	58.2
61-65	45.8
66-70	34.2
71-75	26.1
Older than 75	9.1
Trifecta outcome for NS technique, %	
Full NS	49.9
Partial NS	38.8
Non-NS	20.7

BCR: Biochemical recurrence; ED: erectile dysfunction; NS: nerve sparing.

Table 3. Multivariable logistic regression model predicting trifecta in 1240 prostate cancer patients treated with the Retzius-sparing approach at a single European high-volume center

Variables	Trifecta outcome	
	OR (95%CI)	P-value
Age	0.89 (0.84-0.90)	< 0.001
Body max index	0.92 (0.84-1.00)	0.077
Charlson comorbidity score		
≤ 2	Ref.	
≥ 3	0.93 (0.51-1.09)	0.15
Prostate volume	1.01 (0.99-1.02)	0.14
Previous BPH surgery		
Yes	Ref.	
No	2.64 (0.75-9.8)	0.13
PSA	1.01 (0.99-1.01)	0.9
Clinical tumour stage		
≤ cT2	Ref.	
≥ cT3	0.57 (0.1-2.2)	0.4
ISUP grade group at biopsy		
1-3	Ref.	
4-5	1.02 (0.39-2.66)	0.9
Nerve sparing technique		
Non NS	Ref.	
Partial NS	3.34 (1.01-11)	0.04
Full NS	4.57 (1.8-12)	< 0.001

OR: Odds ratio; CI: confidence interval.

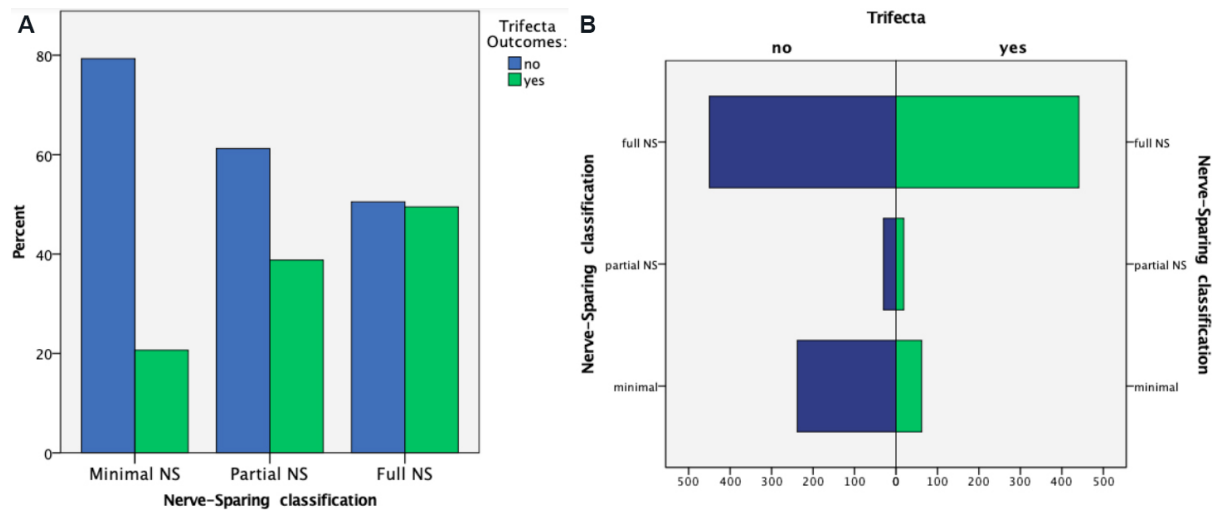


Figure 1. Histogram of distribution of Trifecta outcome rate stratified by NS-approach groups: (A) percentage; and (B) count. NS: Nerve sparing.

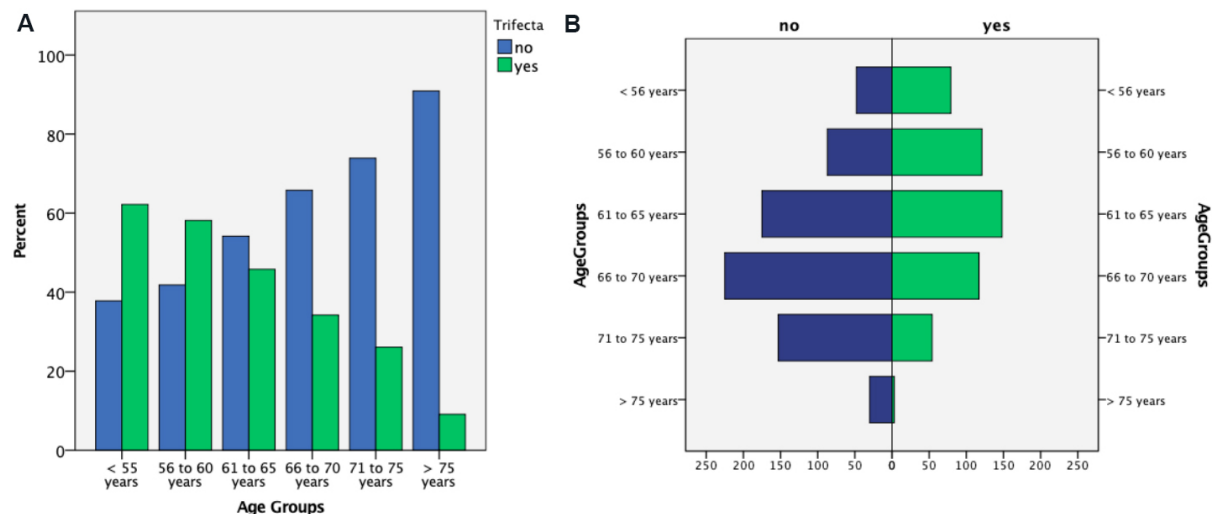


Figure 2. Histogram of distribution of Trifecta outcome rate stratified by age groups: (A) percentage; and (B) count.

Modern PCa surgery aims to achieve cancer control while minimizing its impact on patients' QoL^[21]. Since the introduction of robot-assisted radical prostatectomy, there has been constant research on technical improvements and technique refinements to improve functional outcomes^[22-24]. Trifecta outcome is considered a valuable tool to summarize the result of radical prostatectomy^[5], and, since its introduction, various series reported rates of achieving the outcome ranging from 23% to 86%^[2,6,7,25]. The vast range reported is a direct consequence of the heterogeneity adopted in defining the single outcomes. While the definition of BCR as two consecutive PSA values of ≥ 0.2 ng/mL is standardized in the literature, the definitions proposed for urinary continence and sexual function are various^[8]. Several authors used "no leak" to define continence^[7], while others classified continence according to the number of pads used daily^[6]. The use of a single daily safety pad was often debated as an achievement of urinary continence and has been adopted as a definition in several studies^[26,27]. In our study, we chose to use only completely dry patients to fulfill patients' expectations; this led us to reduce our continence rate from 93.3% to 79.5%.

Several definitions have been proposed to evaluate erectile function after surgery: partial recovery, adequate rigidity, the ability for intercourse, and sexual satisfaction. Some authors also expanded the definition from couple sexual intercourse to sexual activity, including masturbation^[4]. We used the most used definition as “erection sufficient for intercourse with or without the use of a PDE-5”^[25-27].

Another substantial difference of our work from the literature is that we included all patients submitted to rs-RARP without selecting for NS-technique or age. As shown in the figures, trifecta outcome resulted inversely proportional to patient’s age and correlated to the grade of NS adopted; ideally, in a selected population of young patients treated with full NS, we can report trifecta rates around 66% in accordance with the best results published.

A recent systematic review found a role in the recovery of continence and consequently in the trifecta rate for the various anatomical reconstructions after RARP, finding that anterior and posterior reconstructions together facilitate continence recovery in comparison to only one approach^[28].

Our study is the first to investigate trifecta outcome after rs-RARP extensively. We relied on a significant number of patients and sufficient follow-up time. In addition, we overcame the potential bias of the single operator ability by including different surgeons.

Another strong point of this study is that other authors included very few high-risk prostate cancer cases^[6,7,26]. In our group, more than 24% of patients were classified high risk according to EAU risk group. These are the patients who historically do not reach the trifecta outcome, and such a rate could limit the result in our cohort.

Our study must be interpreted considering some limitations. First, our findings derived from a retrospective review of prospectively collected observational data. Thus, our results must be interpreted considering the limitations of such data. Second, the follow-up time of 24 months is relatively short, and only early intermediate oncological results can be deducted.

Third, this study reports single-center experience where rs-RARP was ideated. In our center, only the posterior approach is performed; this may not be translated to other centers where surgeons are not so experienced in the Retzius-sparing approach. Confirmation studies in other centers and confrontation studies between rs-RARP and anterior approach may be needed to obtain Level 1 evidence.

In conclusions, rs-RARP is associated with promising trifecta outcome rate. Age and NS technique are independent predictors of trifecta outcomes. The Retzius-sparing approach should be considered a valid surgical treatment for all PCa patients who want to optimize the balance between oncological and functional outcomes.

DECLARATIONS

Authors’ contributions

Data analysis and manuscript drafting: Olivero A, Dell’Oglio P, Ambrosini F

Data research technical, and material support: Barbieri M, Palagonia E, Napoli G, Di Trapani D, Buratto C, Martiriggiano M

Manuscript revision: Bocciardi AM, Galfano A, Petralia G, Strada E, Secco S

Availability of data and materials

Not applicable.

Financial support and sponsorship

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Conflicts of interest

All authors declared that there are no conflicts of interest.

Ethical approval and consent to participate

The study has been designed and performed in accordance with the Declaration of Helsinki. An informed consent to utilize the data for research purposes was obtained from all participants. According to Italian regulations, an Ethical Approval Number is not required for this kind of study.

Consent for publication

Not applicable.

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