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Primary banded RYGB, banded long-limb RYGB, and revisional B-RYGB: weight loss and complications at one-year follow-up

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Abstract

Aim: We aimed to study the effectiveness and safety of primary banded Roux-en-Y gastric bypass (B-RYGB), primary banded long-limb RYGB (B-LLRYGB), and revisional B-RYGB to address insufficient post-RYGB excess weight loss (≤ 50.0%) or weight regain.

Methods: This was a single-center, retrospective, comparative analysis of weight loss and postoperative complications in patients with class III obesity [body mass index (BMI, kg/m²) \geq 40.0 - \leq 50.0] who received the MIDCAL^{*} non-adjustable calibration ring during primary B-RYGB or B-LLRYGB, or as part of a revisional banding procedure.

Results: Between July 2017 and January 2021, the B-RYGB + B-LLRYGB cohort of 104 patients (median BMI 49.3 ± 4.6 [40.6-67.8]) achieved a mean BMI of 30.7 ± 4.8 , total weight loss (TWL) $37.7\% \pm 7.9\%$, and excess BMI loss (EBMIL) of $77.5\% \pm 17.2\%$ at 1-year follow-up (P < 0.001). One-year respective B-RYGB (n = 53) vs. B-LLRYGB (n = 51) analysis: mean BMI 29.4 ± 3.6 vs. 32.4 ± 5.4 (P < 0.005), TWL $38.0\% \pm 7.3\%$ vs. $37.4\% \pm 8.6\%$ (P = 0.746), EBMIL $80.7\% \pm 15.0\%$ vs. $73.6\% \pm 18.9\%$ (P = 0.066). The revisional B-RYGB cohort of 96 patients [baseline BMI 37.6 ± 5.5 (28.0-59.2)] attained a 1-year mean BMI of 31.7 ± 4.6 , TWL $16.2\% \pm 9.7\%$,



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EBMIL 49.3%% \pm 40.2% (*P* < 0.001). There was no mortality. 30-day complication rates: primary group 0.0%, revisional group 3.8%. Longer-term (median 577 days) complication rates: primary group 2.5%, revisional group 17.7%.

Conclusions: At one-year follow-up in patients with class III and IV (\geq 50.0 - \leq 60.0) obesity, B-RYGB, B-LLRYGB, and revisional B-RYGB were effective in attaining weight loss with a low rate of complications. Band-related complications were more frequent in revisions than in primary cases, likely due to the use of smaller-sized bands.

Keywords: Banded Roux-en-Y gastric bypass, B-RYGB, banded long-limb Roux-en-Y gastric bypass, B-LLRYGB, total weight loss, TWL, body mass index, BMI

INTRODUCTION

Half a century after the introduction of the gastric bypass by Mason and Ito in 1967^[1] and its Roux gastrojejunostomy augmentation by Griffen *et al.* (RYGB, 1977)^[2], a vast body of published evidence describes effective RYGB outcomes. However, approximately 20.4% of patients with class III obesity (body mass index [BMI, kg/m²] \geq 40.0 - \leq 50.0) and 34.9% of those with class IV obesity (BMI \geq 50.0 - \leq 60.0) undergoing RYGB have disappointing results in long-term follow-up due to inadequate weight loss or weight regain^[3].

While RYGB remains one of the leading two procedures performed worldwide, banded Roux-en-Y gastric bypass (B-RYGB), introduced in the late 1980s and early 1990s by Linner and Drew, Fobi, and Capella and Capella^[4-9], has become an important bypass variation employed by metabolic/bariatric surgeons. Typically, one to two years after RYGB, the gastric pouch, stoma, and proximal small bowel begin to dilate; this lessens anastomotic restriction, speeds gastric emptying, and often increases food consumption^[3,10-12]. Gastric placement of a non-adjustable band, whether primarily or secondarily, minimizes gastric pouch expansion and facilitates longer maintenance of the substantial early weight loss achieved by the bypass. Primary B-RYGB significantly reduces class III and IV obesity as effectively as biliopancreatic diversion (BPD) over the medium term while improving or resolving most associated medical problems (AMPs)^[13,14].

Alternatively, for patients with a BMI at the high end of class III or class IV obesity^[3], primary banding a *long-limb RYGB* (B-LLRYGB) may accomplish the same goal. When revision of a metabolic/bariatric operation is required, *banding the pouch* and/or pouch alteration with gastrojejunal anastomosis (GJA) resizing typically halts weight regain and may augment the weight loss of the primary procedure^[15-18].

Data comparing primary B-RYGB and revisional banding of the gastric pouch are scarce; to our knowledge, data comparing primary B-RYGB with B-LLRYGB are nonexistent. Our study sought to compare the weight loss and postoperative complications of these banded bariatric procedures in patients with class III and IV obesity. We also aimed to evaluate the outcomes of revisions with band placement to address insufficient excess weight loss (\leq 50.0%) or weight regain post RYGB.

PATIENTS AND METHODS

Study design

The study was designed as a single-center retrospective evaluation of patients who presented for primary bariatric surgery in a large public hospital and who agreed to undergo B-RYGB or B-LLRYGB, or who required a revisional banded RYGB procedure consisting of a gastric pouch or gastro-jejunal resizing with positioning of a non-adjustable band. The study was conducted in accordance with the ethical standards outlined in the Declaration of Helsinki. Approval was obtained from the Hospital AZ Sint-Jan Bruges

Ethical Committee (070121), and informed consent was obtained from all participants.

Patient inclusion and preparation

All patients met international criteria for bariatric surgery study inclusion (i.e., ASMBS and IFSO 2022 Indications for Metabolic and Bariatric Surgery^[19] and 2015 European Guidelines^[20]). The American Society of Anesthesiology (ASA) Physical Status Classification System metric was used to assess a patient's fitness to undergo anesthesia. Patients attended a preoperative meeting with the surgeon, anesthesiologist, dietitian, and internist and provided written informed consent. Ethical standards aligned with the 1964 Helsinki Declaration were ensured throughout the study.

Indications

Primary B-RYGB was recommended for patients with a BMI indicating class III obesity in conjunction with their AMPs and clinical status; primary B-LLRYGB was recommended for patients with a BMI \geq 45.0. Patients were indicated for revision if they had experienced a primary bariatric operation resulting in \geq 50.0% excess BMI loss (EBMIL).

Outcome evaluation

Primary endpoints were weight loss and postoperative complications. Weight evolution was recorded in terms of absolute weight (AW: initial AW [kg] - post-intervention AW); total weight loss [%TWL: (initial weight - follow-up weight) / (initial weight) × 100]; BMI loss (initial BMI – post-intervention BMI); EBMIL [(initial BMI - follow-up BMI) / (initial BMI) - 25]. Complications were graded for severity with the Clavien-Dindo classification system^[21] and time of occurrence in terms of postoperative days (POD).

Technique

Operations were performed under general anesthesia in a single center by the same surgeon (BD). The nonadjustable MIDCAL[™] calibration ring (MID, Dardilly, France) was used in all patients. MIDCAL is made of medical-grade silicone and can be visualized on x-ray [Figure 1]. To avoid narrowing the gastric pouch, the band/ring can be locked into one of four sizes based on the surgeon's desired calibration (available circumferences: 6.5, 7.0, 7.5, or 8.0 cm).

B-RYGB, B-LLRYGB, and revision with band

We previously described our standardized technique for the bypass portion of the RYGB^[22]. Currently, the approach is similar, with the exception that, since 2017, the opening of the entero-enterostomy was transversely closed with a barbed suture (Stratafix, Ethicon, Somerville, NJ). After pouch creation, a small perigastric window was made 2 cm above the gastro-jejunostomy, through which the MIDCAL band was positioned. The diameter was calibrated with the aid of a 32-Fr nasogastric tube (band size 7.5 cm for primary B-RYGB and ≥ 7.0 for revisional B-RYGB). Gastrogastric Ethibond^{*} sutures (Ethicon, Somerville, NJ) were placed between the pouch and gastric remnant, both proximal and distal to the band, in order to secure its position and prevent slippage. This particular fixation technique was applied to diminish the chance of band erosion, as band slippage and erosion are concerns before 18 months and also over the long term. In case of erosion, this fixation permits better endoscopic removal of the band. The alimentary limb (AL) length was 130 cm and the biliopancreatic limb (BL) 50 cm. B-LLRYGB was performed in the same manner as the B-RYGB, using different limb lengths: an AL of 75 cm and BL of 150 cm. The purpose of lengthening the BP limb is to enhance the long-term weight loss results, as has been reported by different authors^[23,24]. This long BP limb bypass was preferred in patients with class IV obesity (BMI > 50) and in patients with BMI > 45 with serious comorbidities (e.g., T2DM and arterial hypertension). When revising a dilated RYGB gastric pouch and anastomosis, the size of the dilated gastric pouch and/or the gastro-jejunal complex had been reduced following the primary procedure. Therefore, stoma size was maintained at

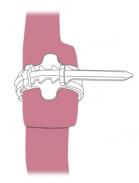


Figure 1. Banded Roux-en-Y gastric bypass. (*Reprinted from*: Heneghan HM, Annaberdyev S, Eldar S, Rogula T, Brethauer S, Schauer P. Banded Roux-en-Y gastric bypass for the treatment of morbid obesity. *Surg Obes Relat Dis*. 2014 Mar-Apr;10(2):210-6.)

approximately \leq 1.5 cm.

Follow-up

Patient follow-up visits were scheduled at 6 weeks, 6 months, 1 year, 2 years, and 3 years for required monitoring, with urgent appointments arranged as needed for suspected complications. Beginning with the first postoperative visit and for the full year after surgery, daily multivitamins were prescribed. Thereafter, vitamins were gradually reduced with the close follow-up of the general practitioner. The patient's attention was focused on sufficient protein intake to promote healing, activities of daily living and exercise, complaints, mental status, and medication. During the COVID-19 pandemic period, this information was discussed by telephone consultation.

Statistical analysis

Analyses were performed using the SPSS statistical package (version 27, IBM, Chicago, IL, USA). Data normality was evaluated using the Shapiro-Wilk test; normality assessments were supplemented by visual inspection of histograms and Q-Q plots. Quantitative demographic and outcome variables were reported as means, standard deviations (SDs), ranges, and/or 95% confidence intervals (CIs). Between-group comparisons along quantitative variables were carried out using the independent-samples t-test or the Mann-Whitney U-test, as appropriate; measures of change from baseline were analyzed with the paired-samples *t*-test. Qualitative variables were presented as frequency and percentage and evaluated using the chi-square test or Fisher's exact test. All statistical tests were two-tailed and statistical significance was set at P < 0.05.

RESULTS

Patient characteristics

Between July 2017 and January 2021, at a single bariatric surgery center of excellence, 200 patients (85.5% female) underwent surgery with the MIDCAL calibration ring. Of these, 104 (52.0%) underwent a primary procedure and 96 (48.0%) underwent revisional B-RYGB surgery, largely as a result of insufficient weight loss and/or weight regain after a prior bariatric procedure. The majority of revisional patients had undergone a prior RYGB with a group mean AW regain of 23.0 ± 18.2 kg. The mean age of primary banded bypass patients was 32.7 ± 12.4 years (18.0-66.0), and 42.9 ± 11.0 years (22.0-73.0) for revisional patients (P < 0.001). Mean BMI (kg/m²) was 49.3 ± 4.6 (40.6-63.8) and 37.6 ± 5.5 (28.0-59.2), respectively (P < 0.001) [Table 1]. Primary and revisional patients differed significantly with respect to ASA physical status prior to surgery, with 100% of primary patients obtaining an ASA score of III (severe systemic disease) *vs.* 33.3 % of revisional patients (P < 0.001). Dyslipidemia was the most frequently recorded AMP in primary patients

Table 1. Patient characteristics

Variable	Primary (<i>n</i> = 104)	Revisional (n = 96)	<i>P</i> -value*
Age, years (mean, SD)	32.7 ± 12.4 (18.0-66.0)	42.9 ± 11.0 (22.0-73.0)	< 0.001*
Height, cm (mean, SD)	167.9 ± 8.5 (149.0-196.0)	166.4 ± 7.7 (151.0-191.0)	0.195*
Weight, kg (mean, SD)	139.3 ± 18.5 (107.3-200.0)	104.2±17.8 (65.0-179.1)	< 0.001*
BMI prior to current procedure, kg/m ² (mean \pm SD)	49.3 ± 4.6 (40.6-63.8)	37.7 ± 5.5 (28.0-59.2)	< 0.001*
BMI prior to 1st surgery, kg/m ² (mean \pm SD)	-	44.2 ± 7.0 (30.0-67.0)	-
Weight at nadir (mean ± SD)	-	81.2 ± 18.6 (52.0-169.0)	-
BMI at nadir, kg/m ² (mean \pm SD)	-	29.2 ± 6.0 (19.5-55.9)	-
TWL at nadir, % (mean ± SD)	-	33.3 ± 9.9 (8.0-56.0)	-
ASA, mean (%)			
I	0 (0.0)	3 (3.1)	< 0.001 [†]
II	0 (0.0)	61 (63.5)	-
111	104 (100.0)	32 (33.3)	-
Female, mean (%)	88 (84.6)	83 (86.5)	0.712 [†]
Associated medical problem, n (%)			
Depression	22 (21.2)	28 (29.2)	0.191 ⁺
Dyslipidemia	32 (30.8)	14 (14.6)	< 0.05 [†]
GERD	28 (26.9)	11 (11.5)	< 0.05 ⁺
Hypertension	26 (25.0)	18 (18.8)	0.286 [†]
OSA	6 (5.8)	6 (6.3)	0.560^{\dagger}
COPD	5 (4.8)	6 (6.3)	0.445^{\dagger}
T2DM	2 (1.9)	1 (1.0)	0.530 ⁺

(30.8%, P < 0.05) [Table 1]. Depression rates were greater than 20% in both groups, and depression was the most frequently recorded AMP in revisional patients (29.2%).

Primary procedure subgroup characteristics (B-RYGB vs. B-LLRYGB)

Characteristics of the primary banded bypass subgroups (B-RYGB *vs.* B-LLRYGB) are presented in Table 2. Fifty-three (50.5%) patients underwent B-RYGB and 52 (49.5%) B-LLRYGB. The principal differentiating variable between groups was baseline weight: mean B-RYGB absolute weight (AW) was 134.3 \pm 16.4 kg (107.3-183.0) with a corresponding mean BMI of 47.4 \pm 3.3 (40.6-55.9); mean B-LLRYGB absolute weight was 145.3 \pm 19.6 kg (108.1-200.0), mean BMI of 51.5 \pm 5.0 (44.0-63.8) (*P* < 0.005 and *P* < 0.001, respectively).

Operative and hospital characteristics

On average, revisional patients spent approximately 40% less time in the operating room than primary patients (P < 0.001) [Table 3]. Their MIDCAL bands were calibrated to a smaller diameter (P < 0.001) and they tended to spend less time in hospital following their procedures [2.4 ± 0.8 days (median: 2 days; range: 2-8) *vs.* 2.9 ± 0.6 days (3 days; range: 2-7), P < 0.001]. There were no differences along these parameters in primary patients.

Table 2. Primary banded bypass subgroup characteristics

Variable	Primary procedures		
	B-RYGB (<i>n</i> = 53)	B-LLRYGB (n = 51)	
Age, years (mean \pm SD)	31.0 ± 12.3	34.6 ± 12.4	0.144*
Height, cm (mean \pm SD)	168.1± 8.5	167.9 ± 8.7	0.879*
Weight, kg (mean \pm SD)	134.3 ± 16.4	145.3 ± 19.6	< 0.005*
BMI (pre-current procedure), kg/m ² (mean \pm SD)	47.4 ± 3.3	51.5 ± 5.0	< 0.001*
ASA, mean (%)			
	0 (0.0)	0 (0.0)	0.999 [†]
I	0 (0.0)	0 (0.0)	-
II	53 (100.0)	52 (100.0)	-
^F emale, mean (%)	46 (86.8)	43 (82.7)	0.559^{\dagger}
Associated medical problem, n (%)			
Depression	14 (26.4)	8 (15.4)	0.165 [†]
Dyslipidemia	15 (28.3)	17 (32.7)	0.625 [†]
GERD	13 (24.5)	15 (28.8)	0.617 [†]
Hypertension	13 (24.5)	14 (26.9)	0.779^{\dagger}
DSA	2 (3.8)	4 (7.7)	0437^{\dagger}
COPD	1 (1.9)	4 (7.7)	0.205 ⁺
T2DM	0 (0.0)	2 (3.8)	0.243 [†]

Table 3. Operative and hospital characteristics

Variable	Primary (<i>n</i> = 104)	Revisional (n = 96)	<i>P</i> -value [*]
Operative duration, mean \pm SD	138.3 ± 23.8	84.0 ± 28.9	< 0.001
Long limb, <i>n</i> (%)	51 (49.0)	-	-
MIDCAL diameter, cm, mean \pm SD	7.6 ± 0.4	7.1±0.5	< 0.001
MIDCAL diameter, cm, median †	7.5	7.0	< 0.001
Time in hospital, days, mean \pm SD	2.9 ± 0.6	2.4 ± 0.8	< 0.001

Weight

At the one-year primary endpoint, the follow-up rate for the primary group was 76.0% (79/104), and 65.0% (62/96) for revisional B-RYGB patients. Although the two groups differed markedly in AW prior to the current procedure (139.3 ± 18.5 kg *vs.* 104.2 ± 17.8 kg, P < 0.001), there were no significant differences in weight or BMI at 1-year follow-up [86.5 ± 15.4 kg *vs.* 87.6±15.6 kg (P = 0.679), and 30.7 ± 4.8 *vs.* 31.7 ± 4.6 (P = 0.215)] [Table 4A]. Indeed, both primary and revisional groups experienced significant within-group change from baseline at 1 year in AW and BMI. For primary patients, mean changes in AW and BMI were 52.4 ± 13.1 kg (95%CI: 49.5, 55.4; P < 0.001) and 18.6 ± 4.2 (17.6, 19.5; P < 0.001), respectively. Mean changes in AW and BMI for revisional patients were 17.5 ± 12.3 kg (14.5, 20.6; P < 0.001) and 6.4 ± 4.3 (5.3, 7.5; P < 0.001), respectively [Table 4B]. These reductions in weight translated to a mean total weight loss (TWL) for primary patients of 37.7 ± 7.9%, and 16.2 ± 9.7% for revisional patients (P < 0.001); mean EBMIL was 77.5 ± 17.2% and 49.3 ± 40.2%, respectively, P < 0.001 [Table 4A]. Comparative frequency distributions depicting the ranges of TWL for primary *vs.* revisional B-RYGB patients are presented in Figure 2A.

The differences in percentage weight reduction correlate to revisional B-RYGB patients on average having already experienced significant BMI loss following their initial bariatric procedure (mean BMI reduction: 6.6 ± 4.4) [Table 1]. Subsequent revisional procedures served to promote their overall weight loss trajectory to approach that of primary patients who lost significant weight. In the last analysis,

Α				
Variable	Primary mean \pm SD (<i>n</i> = 79)	Revisional mean \pm SD ($n = 62$)	P-value*	
AW (kg)	86.5 ± 15.4	87.6±15.6	0.679	
AWL (kg)	52.4 ± 13.1	17.5±12.3	<0.001	
TWL (%)	37.7 ± 7.9	16.2±9.7	<0.001	
BMI, kg/m ²	30.7 ± 4.8	31.7±4.6	0.215	
BMI loss, kg/m ²	18.6 ± 4.2	6.4±4.3	<0.001	
EBMIL, %	77.5 ± 17.2	49.3±40.2	<0.001	
В				
Variable	Preoperative Mean \pm SD	Postoperative Mean ± SD	Mean change ± SD (95%CI)	P-value†
Primary (<i>n</i> = 79)				
AW (kg)	138.9 ± 17.7	86.5 ± 15.4	52.4 ± 13.1 (49.5, 55.4)	<0.001
BMI, kg/m ²	49.3 ± 4.2	30.7 ± 4.8	18.6 ± 4.2 (17.6, 19.5)	<0.001
Revisional (n = 62)				
AW (kg)	105.2 ± 18.6	87.6 ± 15.6	17.5 ± 12.3 (14.5, 20.6)	<0.001
BMI, kg/m ²	38.1±5.6	31.7 ± 4.6	6.4 ± 4.3 (5.3, 7.5)	<0.001

Table 4. Weight outcomes for primary vs. revisional banded procedures at 1 year

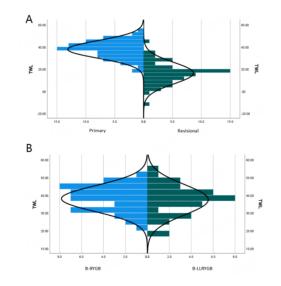


Figure 2. (A) Total weight loss (TWL) frequency distribution by primary and revisional procedures; (B) Total weight loss (TWL) frequency distribution by B-RYGB and B-LLRYGB.

both groups moved from class III or IV obesity prior to their first surgery (BMI > 40) to the low end of the obesity spectrum (BMI 31.7 and 30.7, respectively).

Focusing on primary patients, Figure 2B depicts comparative frequency distributions of TWL ranges at 1 year for B-RYGB patients *vs.* B-LLRYGB patients. In contrast to the divaricated distribution patterns depicted in Figure 2A, TWL frequency distributions in Figure 2B reflect the high degree of weight loss

parity that existed between B-RYGB and B-LLRYGB patients. Despite significantly higher preoperative and postoperative AW and BMI of the B-LLRYGB group, both groups experienced significant weight reduction (P < 0.001) and corresponding BMI change from baseline (P < 0.001), resulting in nearly identical mean TWL percentages at 1 year ($38.0\% \pm 7.3\% vs. 37.4\% \pm 8.6\%$; P = 0.736) [Table 5A and B]. Analysis of 1-year EBMIL subgroups (i.e., EBMIL < 25%, $\ge 25\% < 50\%$, $\ge 50\%$) further clarifies weight loss between primary and revisional B-RYGB patients, and between B-RYGB and B-LLRYGB. No patient in the primary group experienced a BMIL < 25%, whereas 11 (17.5%) revisional patients fell into that range (P < 0.001) [Figure 3]. Conversely, 73 (93.6%) primary patients achieved an EBMIL ≥ 50 , whereas 26 (41.3%) revisional patients achieved $\ge 50\%$ EBMIL (P < 0.001).

There were no primary patients in the < 25% EBMIL range at 1 year. Two (4.7%) B-RYGB patients reached \geq 25% - < 50% EBMIL, and 41 (95.3%) reached \geq 50%. Similarly, 3 (8.3%) B-LLRYGB patients reached \geq 25% - < 50% EBMIL, and 33 (91.7%) achieved \geq 50% (*P* = 0.655).

Complications

There was no mortality in the study. The 30-day complication rate (Clavien-Dindo grade \geq 3) was 1.7% (3/ 180), 0% (0/101) in the primary group and 3.8% (3/79) in the revisional B-RYGB group (*P* = 0.083). Overall long-term complication rate (median follow-up: 577 days, IQR: 313-930; with 70.5% follow-up rate) was 9.2% (13/141), 2.5% (2/79) in the primary group and 17.7% (11/62) in the revisional group. Complication rates (i.e., number of patients with \geq 1 complication) are presented by Clavien-Dindo class and time point [Table 6].

The only band-related complications were in the revisional b-rygb group, wherein bands were calibrated to a significantly smaller diameter than in the primary group (P < 0.001) [Table 3]. further, revisional patients with band-related complications (n = 10) were calibrated to a significantly smaller diameter than other revisional patients (P < 0.05). all 10 revisional patients with band-related complications had their bands calibrated to 7.0 cm [Figure 4], whereas all 86 revisional patients without band-related complications were calibrated to \geq 7.0 cm.

At 31 to 90-day follow-up, there were no statistically significant between-group differences in the number of grade \geq 3 complications. There were 1 primary and 0 revisional B-RYGB complications, P = 0.554. A 21-year-old female who had undergone B-LLRYGB experienced internal herniation at the entero-enterostomy (POD 55), which was repaired with laparotomy with no resection.

Primary patients

At 91-365 days, the sole complication was in a 46-year-old male experiencing postoperative ileus accompanied by a trocar-site hernia which was surgically repaired (POD 330). At the writing of this report, there have been no \geq 3 Clavien-Dindo complications in primary patients beyond 1-year follow-up.

Revisional B-RYGB patients

At 91-365 days, revisional patients experienced significantly more grade 3b complications than primary patients, 5 vs. 1, respectively (P < 0.05). Revisional B-RYGB patients included: (1) a 35-year-old female with cervical cancer who experienced dysphagia (POD 277); surgery was performed to open the band, and its removal was not necessary; (2) a 57-year-old male experienced excessive weight loss, vomiting, and dysphagia, and total band removal was performed (POD 299); (3) a 48-year-old female with dysphagia; gastroscopy was performed to open the band and extract food (POD 346) with the band remaining intact; (4) a 56-year-old female with dysphagia underwent laparoscopy to calibrate the band more loosely (POD 260) with no band removal; and (5) a 45-year-old female with abdominal pain underwent CT scan; kinking

Α				
Variable	B-RYGB ($n = 43$) mean \pm SD	B-LLRYGB (<i>n</i> = 36) mean ± SD	P-value*	
AW (kg)	83.4 ± 12.8	90.7 ± 17.4	< 0.05	
AWL (kg)	51.5 ± 12.7	54.2 ± 14.1	0.386	
TWL (%)	38.0 ± 7.3	37.4 ± 8.6	0.736	
BMI, kg/m ²	29.4 ± 3.6	32.4 ± 5.4	< 0.005	
BMI loss, kg/m ²	18.1 ± 4.0	19.3 ± 4.5	0.247	
EBMIL, %	80.7 ± 15.0	73.6±18.9	0.066	
В				
Variable	$\begin{array}{c} \text{Preoperative} \\ \text{mean} \pm \text{SD} \end{array}$	Postoperative mean \pm SD	Mean change \pm SD (95%CI)	P -value †
B-RYGB (n = 43)				
AW (kg)	134.9 ± 16.4	83.4 ± 12.8	51.5 ± 12.7 (47.6, 55.5)	< 0.001
BMI, kg/m ²	47.6 ± 3.4	29.4±3.6	18.1 ± 4.0 (16.9, 19.4)	< 0.001
B-LLRYGB (<i>n</i> = 36)				
AW (kg)	144.9 ± 19.0	90.7 ± 17.4	54.2 ± 14.1 (49.4, 59.0)	< 0.001
BMI, kg/m ²	51.6 ± 4.3	32.4 ± 5.4	19.3 ± 4.5 (17.8, 20.8)	< 0.001

Table 5. Weight outcomes for B-RYGB vs. B-LLRYG procedures at 1 year

Table 6. Complications by Clavien-Dindo classification

Time point / grade	Primary n (%)	Revisional n (%)	P-value*
Pre-discharge	(<i>n</i> = 104)	(<i>n</i> = 96)	
Grade 3a	0	0	-
Grade 3b	0	1 (1.0)	0.480
Grade 4	0	0	-
< 30 days	(<i>n</i> = 101)	(<i>n</i> = 79)	
Grade 3a	0	0	-
Grade 3b	0	3 (3.8)	0.083
Grade 4	0	0	-
31-90 days	(<i>n</i> = 97)	(<i>n</i> = 78)	
Grade 3a	0	0	-
Grade 3b	1 (1.0)	0	0.554
Grade 4	0	0	-
91-365 days	(<i>n</i> = 79)	(<i>n</i> = 62)	
Grade 3a	0	1 (1.6)	0.440
Grade 3b	1 (1.3)	5 (8.1)	< 0.05
Grade 4	0	0	-
> 365 days	(<i>n</i> = 79)	(<i>n</i> = 62)	
Grade 3a	0	0	-
Grade 3b	0	4 (6.5)	< 0.05
Grade 4	0	1 (1.6)	0.192

of the AL was identified surgically at the entero-enterostomy and an ulcer at the gastrojejunostomy. A plication stitch was applied (POD 238) to prevent further kinking.

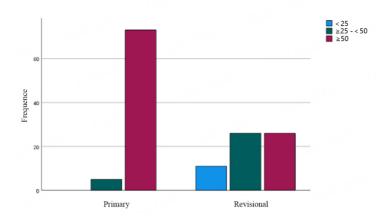


Figure 3. Frequencies within excess body mass index loss (EBMIL) groups (< 25, $\geq 25 - < 50$, ≥ 50) by primary and revisional procedures.

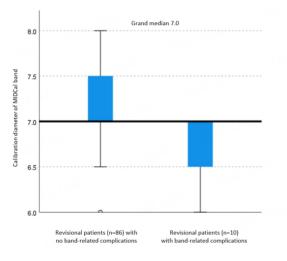


Figure 4. Revisional patients with vs. without band-related complications relative to distribution of MIDCAL band calibration diameter.

Beyond 365 days, two 30-year-old female revisional B-RYGB patients experienced band slippages that led to their removal (PODs 469 and 888). A 45-year-old female experienced dysphagia requiring laparoscopic band opening (POD 413). Beyond 365 days, there were two patients who experienced multiple complications: One 43-year-old female approaching 2-year follow-up experienced an anastomotic ulcer with leakage (POD 689). Her band remained intact, but was later removed (POD 781) due to erosion; anastomotic revision was performed. Exploratory laparoscopy was performed (POD 795) due to the patient's excessive pain with no cause found. The last revisional patient experienced dysphagia and the band was opened (POD 372). An anastomotic ulcer presented (POD 546) and band removal and oversewing were performed; a hemodynamic response ensued, requiring intensive care.

DISCUSSION

Primary B-RYGB was developed for patients with class III or IV obesity to stabilize the RYGB gastric stoma and halt weight regain that results in 10%-20% of patients from gradual dilation of the gastroenterostomy^[25,26]. Banding a primary RYGB often obviates the need for a second procedure^[4,7,9,13]. When a bariatric procedure requires revision, banding the gastric pouch slows, or stops, existing weight

regain and may renew modest weight loss^[13,25].

Recently, Miller *et al.* published outcomes using the intraoperatively calibratable MIDCAL ring in banded one-anastomosis gastric bypass^[27], and Noel *et al.* in re-sleeve gastrectomy^[28]. The current study is the first to report the use of a MIDCAL ring in primary banded RYGB and in the secondary setting of weight gain after RYGB.

Primary B-RYGB and B-LLRYGB: current vs. prior outcomes

In our study, in the 104 patients receiving primary B-RYGB (n = 53) or B-LLRYGB (n = 51), statistically and clinically significant weight loss at 1-year follow-up was attained. In comparing primary subgroups, B-RYGB patients reached $80.7\% \pm 15.0\%$ EBMIL *vs.* 73.6\% $\pm 18.9\%$ EBMIL in the B-LLRYGB group. A very high proportion of patients in each group (95.3% B-RYGB, 91.7% B-LLRYGB) achieved $\geq 50\%$ EBMIL. Although the longer BP limb in B-LLRYGB showed no statistically significant difference in weight loss in comparison to B-RYGB, this might be due to the relatively short follow-up and limited number of patients included. In terms of postoperative complications, the B-RYGB and B-LLRYGB cohorts had no mortality and only one non-band-related complication in each group.

Primary B-RYGB studies prior to 2014 have been summarized by two systematic reviews/meta-analyses. In the B-RYGB sample of patients with class III obesity analyzed by Buchwald *et al.* that included 15 studies spanning 23 years, the pooled weighted mean 1-year excess weight loss (EWL) was 76.0% (95%CI: 69.5, 82.5;); this finding is comparable to the 80.7 EBMIL in the current study. At 5-year follow-up, 1,254 patients (11 studies) in the meta-analysis sustained a slightly lower weighted mean EWL of 72.5% (67.5, 77.4)^[26]. The systematic review of primary B-RYGB by Mahawar *et al.* (17 included studies, total n = 2,254 patients, mean BMI 47.4) found a 1-year EWL of 68.1%, which increased to 75.2% EWL at 5 years^[13]. Although the systematic review B-RYGB weight loss outcome at 1 year was effective, it was somewhat lower than that of the current study and the meta-analysis; however, the difference may simply reflect inherent variation within measures (EWL *vs.* EBMIL). In terms of complications, the meta-analysis found primary patients had a 1-year mean complication rate of 10.9%, with a band-specific reoperation rate of 4.1%, and an erosion rate of 2.3%^[26]. The current study, and no complications (n = 2) were band-related.

Between 2014 and 2021, two randomized controlled trials (RCTs) and six observational B-RYGB studies provide relevant comparisons to the current investigation. Murphy *et al.*, in an RCT comparing primary B-RYGB (n = 56) vs. sleeve gastrectomy (SG) (n = 58) patients with a baseline mean BMI of 42.5 ± 6.2, found 32.2% ± 7.7% vs. 27.1% ± 7.5% TWL, respectively, at 1-year follow-up; however, there were more major complications in the B-RYGB group (i.e., 3 ulcers, 1 abdominal bleed, 1 anastomotic leak)^[29]. Rasera *et al.* performed an RCT comparing primary B-RYGB (n = 200) with RYGB (n = 200) in patients with a median BMI of 47.0 and no significant differences in AMPs. At the 2-year follow-up, the respective median EWL was 75.4% vs. 71.0% (P = 0.002); 1.1% vs. 10.5% experienced weight regain. There were no between-group differences in incidence or severity of complications, but vomiting frequency was higher in the banded vs. nonbanded group: 26.8% vs. 11.6% at 1 year; 26.8% vs. 8.2% at 2 years. At the 2-year endpoint, B-RYGB patients had slightly significantly greater weight loss and less weight regain, but a threefold higher incidence of vomiting^[30].

Bhandari *et al.* retrospectively compared weight loss in their primary B-RYGB (n = 64, BMI 44.13 ± 6.14) and RYGB (n = 101, BMI 42.16 ± 5.97) patients with complete 2-year follow-up; B-RYGB BMI was significantly lower (27.66 ± 2.55 *vs.* 29.45 ± 3.33, P < 0.05). No weight regain was seen in the banded group,

although 10 non-banded patients (9.9%) regained > 5 kg. Most major postoperative complications (bleeding, anastomotic stricture) arose in the non-banded group, with most minor complications occurring in banded patients^[31]. Figueiredo Reis *et al.*'s prospective gastric-emptying scintigraphy and food tolerance study of B-RYGB (n = 47, BMI 44.3) *vs.* RYGB (n = 47, BMI 42.4) found no significant difference in BMI at 2 years (28.8 *vs.* 30.9). A significantly different frequency of vomiting was reported: 13 B-RYGB *vs.* 2 RYGB patients vomited > 2 times/week^[32]. In a retrospective analysis of B-RYGB (using gastric bands fashioned from bovine pericardium) *vs.* RYGB, Moon *et al.* found no significant differences in complications or in weight loss at 1 (72.5% *vs.* 73.5% EBMIL), 2 (78.8% *vs.* 79.0%), and 3 (73.3% *vs.* 74.8%) years^[33].

In 2017, Lemmens's retrospective analysis of 5-year primary B-RYGB (n = 178) vs. RYGB (n = 254) found no significant differences at 1-year follow-up. However, at 5 years, B-RYGB patients attained significantly greater EWL of 74.0% ± 15.1% vs. 65.2% ± 20.0%, and the non-banded group experienced significantly greater weight regain (P < 0.0001). The study saw only a few minor complications in both groups with no band slippage or migration; the authors suggest this is likely due to the loose placement of the band^[16]. Galal *et al.* retrospectively reviewed 106 primary B-RYGB patients (mean BMI 44.8) over the medium term, reporting respective 1-, 3-, and 5-year TWL of 33.9% (n = 95), 34.0% (n = 70), and 31.8% (n = 75). Bandrelated complications within 5 years: 5 persistent dysphagia, 2 erosions, 1 band repositioning^[34]. Lastly, Magro *et al.* compared TWL in primary B-RYGB patients with class III vs. class IV obesity through a 10year follow-up. The greatest weight loss was seen at 18-month follow-up: mean BMI 28.5 ± 3.6, and EWL 79.7% ± 23.4%, neither of which were significantly different at 10 years. Despite a small late weight regain, most patients achieved effective weight loss in the short and long terms^[35].

At 1 year, the current study's primary B-RYGB outcomes (TWL 38.0 ± 7.3 , EBMIL $80.7\% \pm 15.0\%$) as well as those in prior publications, demonstrated a significant, highly effective level of weight loss. Overall complications in B-RYGB in the current study were somewhat less prevalent than those of comparators, probably due to the intentionally loose placement of the band around the pouch.

B-LLRYGB

The current evaluation of B-RYGB vs. B-LLRYGB appears to be unique in the literature. In this study, B-LLRYGB, which had a greater mean baseline BMI, was an effective approach to weight loss for higher-BMI patients comparable to B-RYGB. Still, the current study's findings were limited to 1-year follow-up, whereas weight regain does not typically present until 12-18 months post procedure. In prior studies of nonbanded *RYGB* in patients with a BMI \leq 50, the question of whether longer limb lengths make a significant difference in efficacy was inconclusive. Prior nonbanded long-limb RYGB studies comparing longer AL than BL limbs^[36,37], longer BL than AL limbs, and still others comparing both^[24,37-39] found a slight difference in outcomes over the early and longer terms. Two 2011 systematic reviews (Stefanidis et al.^[40], Orci et al.^[41]) and an RCT by Choban *et al.*^[42] suggest that longer AL limbs (\geq 150 cm) facilitate a modest short-term weight-loss advantage in class IV obesity, but no significant difference in class III obesity. Nijland et al.'s 2021 retrospective cohort study^[23] comparing short- and long-limb standard RYGB procedures (AL 150 cm, BL 50 cm vs. AL 75 cm, BL 150 cm, respectively) found significantly greater TWL as early as 6 months continuing through 4-year follow-up after the long-limb variant. There is no consensus yet regarding whether primary nonbanded RYGB and LLRYGB results in greater efficacy. By extension, and without published studies to consider, we cannot know yet whether B-LLRYGB will provide greater efficacy for patients.

Revisional RYGB banding: current vs. prior outcomes

In the current study, total weight loss (the sum of weight loss achieved by the primary RYGB and the secondary revision with a band) of the 96 revisional banding patients trended towards that of their primary

patient counterparts, achieving significant \geq 1-year weight loss, moving from class III or IV obesity to mild obesity (BMI 30.7). At 1 year, the revisional group reached 49.3% EBMIL, although with significantly more complications than the primary group [revisional 11/62, 17.7% *vs.* 2/79, 2.5% (*P* < 0.05); median follow-up 577 days].

In the 2014 meta-analysis, revisional B-RYGB group (n = 160) weight loss was comparable to primary RYGB at 2 years (70.0% vs. 68.0% EWL) and markedly greater at 5 years (65.0% vs. 58.0% EWL). Additionally, weight regain was less in B-RYGB vs. RYGB patients between 3- and 5-year follow-ups. Revisional banding complications reported in the meta-analysis were limited to those of Fobi *et al.* in their large series of primary and secondary transected banded vertical gastric bypasses (n = 2,949; 563 revisional): the focus was on a revisional banding erosion rate of $4.5\%^{[7]}$. Boerboom *et al.*, in 2020, reported on revisional banding of 79 patients after inadequate RYGB weight loss or weight regain. Total weight loss improved from 7.0%–26.0% at 1-year follow-up; in 75.0%, additional weight regain was prevented and remained stable through 2 years. However, there were 18 band removals (23.0%) mainly due to dysphagia; the authors cautioned against too-tight band placement around the pouch as the likely cause of patients' dysphagia^[43]. Lastly, Galal et al. in 2020 studied 17 revisional B-RYGB patients secondary to primary RYGB (mean BMI 40.8 ± 6.01) with inadequate weight loss and/or weight regain, reporting a respective 1-, 3-, and 5-year BMI of 28.1 (n = 15), 29.8 (n = 9), and 30.9 (n = 12). One revisional patient's band was removed due to erosion; the authors adjusted their protocol to use larger band sizes for revisional cases^[34]. Although long-term studies suggest primary B-RYGB effects greater weight loss than RYGB, band-related complications remain important factors to be considered.

Limitations

This study's utility for guiding procedure selection was limited by its retrospective design and short-term follow-up. As dilation of the B-RYGB gastric outlet typically does not occur until 12-18 months, the full effect of B-RYGB in relation to weight regain will not likely be seen until mid-term follow-up. The ongoing current study, and other longer studies, will more precisely determine indications for primary B-RYGB and B-LLRYGB *vs.* standard RYGB and other bariatric procedures. Comparison of the B-RYGB to a larger body of literature was limited by the lack of availability or regulatory approval of non-adjustable gastric bands in many countries. An additional parameter that would have contributed to this report is that of nutrition and nutritional issues over the long term after surgery.

Conclusions

At one-year follow-up in patients with class III and IV obesity, B-RYGB, B-LLRYGB, and revisional RYGB band placement were all effective in attaining weight loss with a low rate of postoperative complications. There were no band-related complications in the primary group. Bands placed in the revisional group were all calibrated to a significantly smaller diameter than in the primary group. This factor may be related to the higher percentage of band-related complications in the revisional group, suggesting the advisability of calibrating the MIDCAL band to a wider diameter.

DECLARATIONS

Authors Contributions

Conceived the design of the study, and performed the surgery: Dillemans B

Made substantial contributions to the conceptualization, plan of analysis, and interpretation of the study: Van Huele A, Buchwald JN, McGlennon TW

Assisted in surgery and performed the acquisition, organization, and summation of the data: Van Huele A

Performed the statistical analysis of data and outcome reporting: McGlennon TW

Performed the literature review, outcome interpretation in the context of the scientific literature, and wrote the manuscript: Buchwald JN

Substantively reviewed, edited, and approved the manuscript and take responsibility for its contents: Van Huele A, Buchwald JN, McGlennon TW, Dillemans B

Availability of Data and Materials

The datasets generated or analyzed during the current study are available from the senior author/principal investigator upon reasonable request. Requests should be directed to: Bruno.Dillemans@azsintjan.be

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Conflicts of Interest

B. Dillemans and A. Van Huele have no conflicts of interest. J. Buchwald and T. McGlennon received an M.I.D. grant for independent data analysis and manuscript development.

Ethical Approval and Consent to Participate

Informed consent was obtained from all participants. The study was performed in accord with the ethical standards of the Declaration of Helsinki and approved by the Hospital AZ Sint-Jan Bruges Ethical Committee (070121).

Consent for Publication

Not applicable.

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