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ORIGINAL CONTRIBUTIONS

5-Year Results of Banded One-Anastomosis Gastric Bypass: a Pilot Study in Super-Obese Patients

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Abstract

Background The novel banded one-anastomosis gastric bypass (B-OAGB) procedure has not previously been reported in super-obese patients over the long term. In this pilot study, outcomes in patients with a mean baseline body mass index (BMI, kg/m^2) of ≥ 50 who underwent B-OAGB were evaluated through 5-year follow-up.

Patients and Methods Total weight loss (TWL), excess weight loss (EWL), BMI evolution, and changes in type 2 diabetes biomarkers were analyzed prospectively in super-obese patients who underwent B-OAGB. Paired samples *t* tests were used to assess weight outcome change from baseline through 5-year follow-up and 95% CIs were calculated. The Bariatric Outcomes and Reporting System (BAROS) was used to assess surgical success at 3 time points.

Results Between October 2013 and February 2014, a 12-patient pilot cohort (mean baseline BMI 57.5 ± 6.3) underwent B-OAGB. No perioperative complications were observed within 30 days. Five-year mean BMI was 31.2 ± 5.4, a BMI loss of 25.9 (TWL 45.3 ± 7.5%; EWL 72.2 ± 12.8%). Between 11 and 24 months following surgery, 3 patients required band removal; each had one complication (1 stasis esophagitis and recurrent vomiting; 1 hypoalbuminemia; 1 anemia). There was no mortality. Long-term B-OAGB BAROS subscale and composite scores were comparable to other major bariatric procedures.

Conclusions In a pilot study of super-obese patients who underwent B-OAGB, excellent durable BMI loss of 25.9 kg/m^2 (EWL 72.2%) at 5 years was achieved with an acceptable level of reoperation. More B-OAGB long-term follow-up studies are necessary to provide definitive conclusions regarding this combination bariatric procedure.

Keywords Banded one-anastomosis gastric bypass · B-OAGB · TWL · EWL · RYGB · LAGB · MGB · SG · Gastroesophageal reflux · Iron deficiency anemia

Introduction

Super obesity is associated with substantially increased risk of morbidity and mortality. Life expectancy for patients with super obesity (body mass index (BMI, kg/m^2) ≥ 50) is markedly shorter, by up to 9.8 years, than for those with a normal BMI [1]. Yet, published mid- and long-term outcomes for super-obese patients who have undergone bariatric surgery are scant. While Roux-en-Y gastric bypass (RYGB) is an effective treatment for morbidly obese patients, it has been shown to be less successful in the super-obese population [2–4]. The banded RYGB (B-RYGB) leads to significant and sustained weight loss without significant weight regain from 5 to 10 years in both morbidly and super-obese patients [5–7]. Yet, a recent study found that food intolerance increased significantly following B-RYGB, leading to dissatisfaction with food and increased vomiting frequency [8]. These and related findings encouraged surgeons to aim at more satisfying results by innovating variations of the bypass procedure to better aid this population.

One-anastomosis gastric bypass (OAGB)/mini gastric bypass (MGB) was proposed as an effective procedure for super-obese patients [9, 10]. However, concerns about symptomatic

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gastric or esophageal biliary reflux requiring revisional surgery and long-term nutritional risk persist. Surgeons performing the OAGB should be aware of this controversy and counsel their patients appropriately about the need for long-term follow-up with this procedure [11–14]. Prior to 2013, no study had been published on a banded OAGB (B-OAGB) as a possible alternative for the super-obese population. We elected to carry out a pilot study on the long-term safety and effectiveness of B-OAGB in super-obese patients. Long-term surgical outcomes (inclusive of quality of life [QoL]) of super-obese B-OAGB patients were evaluated and compared to that of 3 common bariatric procedures using the standardized Bariatric Reporting Outcomes System (BAROS [15, 16]).

Patients and Methods

Study Design

The study was designed as a single-center prospective investigation of patients with a BMI ≥ 50 who agreed to undergo a B-OAGB surgical protocol. The study was approved by the Ethics Committee (Prot. No: IT 5448081) as a pilot investigation of 12 patients to evaluate the safety and effectiveness of a procedure that had not previously been studied over the course of ≥ 5 years.

Patient Inclusion and Preparation

All patients were required to meet international criteria for bariatric surgery (i.e., European Guidelines [17], US National Institutes of Health 1991 Guidelines [18]) for study inclusion, and each patient provided written informed consent. The ethical standards of the institutional and/or national research committee in alignment with the 1964 Helsinki Declaration and its later amendments were ensured throughout the study. Biochemical and radiological studies (abdominal ultrasound, chest X-ray) as well as endocrine and cardiopulmonary assessments were performed. Each patient attended a preoperative meeting with the surgeon and an anesthesiologist, dietitian, psychologist, and internist.

Outcome Evaluation

Following postoperative care, patients were followed at 6 time points: 6, 12, 24, 36, 48, and 60 months. Effectiveness endpoints included weight loss in terms of BMI, absolute weight, waist circumference, hip circumference, waist-to-hip ratio, percentage of total weight loss (TWL), and percentage of excess weight loss (EWL), and improvement/resolution of obesity-related comorbidities. TWL was calculated using the formula: (initial weight − follow-up weight)/(initial weight) × 100%. EWL was calculated as: (initial weight − follow-up weight)/(initial weight − ideal weight) × 100%.

Specific criteria used to assess improvement in obesity-related metabolic disorders following surgery were remission of hypertension (blood pressure < 140/80 mmHg with medication) and remission of type 2 diabetes mellitus (T2DM; fasting glucose < 120 mg/dL with HbA_{1C} < 6.5%, and HOMA IR index < 5 with medication).

The standardized BAROS [15] was used to obtain an integrative and comparative appraisal of B-OAGB outcomes. The BAROS is based on clinician ratings of weight loss, changes in comorbidities, surgical complications, and a patient-rated measure of QoL. The BAROS generates subscale scores for EWL, comorbidity status, QoL, and a composite outcome score for overall surgical success (range, < 1 = failure – 7–9 = excellent).

Surgical Technique

Preoperative gastroscopy was mandatory. All patients received enoxaparin 60 U the night before surgery and routinely for 14 days post-surgery. Pneumatic antithrombosis stockings were applied. There is as yet no optimized B-OAGB operative technique: All patients in the study underwent B-OAGB according to the procedure standardized at our center. The operation was performed with a typical 5-port laparoscopic technique in reverse Trendelenburg position with the surgeon positioned between the patient's legs. An atraumatic liver retractor (Endo Paddle Retract™ 12 mm; Medtronic, Mpls., MN USA) was positioned from the right costal margin at the anterior axillary line.

The gastric tube was created from the antrum distal to the crow's foot using a 60-mm linear stapler with 4–5-cm staples at a right angle to the lesser curvature. A gastric tube (ch 36) is passed by the anesthetist and held against the lesser curvature. The division of the stomach against the tube is completed with 5–6 lines of staple cartridges to seal the gastric pouch. The last staple line which was proximal to the band was reinforced (Seamguard™, Gore, Flagstaff, AZ). The stomach was divided parallel to the lesser curvature up to the angle of His. A nonadjustable ring (MIDCAL™, MID, Dardilly, France) was placed perigastric, 5 cm distal from the esophagogastric junction, with a band length adjustment of 7.5–8 cm (Fig. 1). The MIDCAL ring is made of medical-grade silicone, is visible on X-ray, and has four locking positions to adjust four sizes (circumferences of 65, 70, 75, and 80 mm) in order not to narrow the gastric pouch. The widest position of 80 mm was used in all patients.

A side-to-side anterior loop gastrojejunostomy of the 200-cm afferent limb was performed with a 4–5-cm linear staple line. The gastrostomy and enterostomy defects were closed seromuscularly with a single-layer running suture (Vicryl 3/0). The afferent jejunal loop was fixed 5–7 cm parallel to

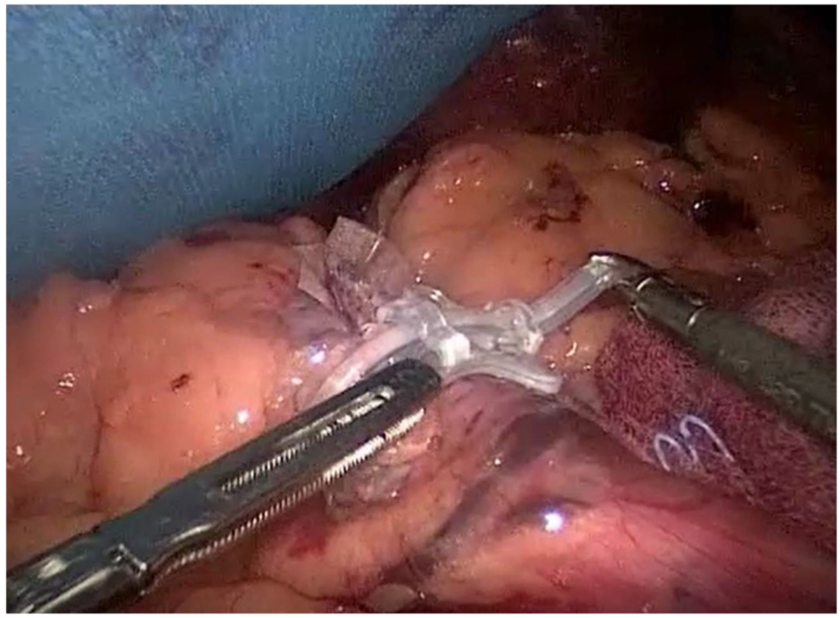

Fig. 1 Banded one-anastomosis gastric bypass anatomy

the gastric pouch, as described by Caballero and Carbajo [19]. An intraoperative leak test was performed in all operations.

Follow-up

Postoperative visits were scheduled for complications as they arose. Three follow-up visits were scheduled in the first year, two in the second, then yearly thereafter, and on demand. Daily multivitamins were prescribed that contained iron (15 mg), B-12, folic acid, and vitamin D. The patients' attention was focused on the intake of sufficient protein. All patient visits were performed in the hospital and included time with a nutritionist.

Statistical Analysis

Analyses were performed using the SPSS statistical package (version 20; IBM, Chicago, IL). Continuous data were presented using means, standard deviations, and/or ranges; 95% confidence intervals (CIs) were calculated for 5-year mean weight outcomes, including mean changes in weight, BMI, and waist circumference. The Shapiro-Wilk's test for

Table 1 Weight evolution through 5-year follow-up

	n	BMI (kg/m^2)	Weight (kg)	TWL (%)	EWL (%)
Female	5	54.4 ± 4.0	149.0 ± 20.6	43.8 ± 10.7*	67.6 ± 11.5*
Male	7	59.7 ± 7.1	184.0 ± 14.8	46.3 ± 4.7*	74.2 ± 11.2*
Baseline	12	57.5 ± 6.3	169.1 ± 24.5	–	–
6 mo	12	47.3 ± 5.2	139.0 ± 20.1	17.6 ± 4.4	28.1 ± 6.9
12 mo	12	39.4 ± 6.0	115.1 ± 18.1	31.4 ± 6.7	50.3 ± 11.6
24 mo	12	29.8 ± 10.4	97.0 ± 16.2	42.6 ± 8.3	67.7 ± 11.9
36 mo	12	31.0 ± 4.7	91.3 ± 20.1	45.8 ± 7.4	73.1 ± 11.7
48 mo	12	31.4 ± 10.3	93.0 ± 15.7	44.9 ± 7.1	71.7 ± 11.5
60 mo	12	31.2 ± 5.4	93.2 ± 18.4	45.3 ± 7.5	72.2 ± 12.8
Mean change ± SD	–	25.9 ± 5.4	76.1 ± 16.4	–	–
95% CI		22.3, 29.5†	65.0, 87.1†	40.5, 50.1††	64.5, 79.9††
p value§		< 0.001	< 0.001	–	–

BMI, body mass index; *TWL*, total weight loss; *EWL*, excess weight loss; *mo*, months

* 60 months

† 95% CI of mean change

†† 95% CI of mean 60-month percent weight loss

§ *p* value = significance of mean change in weight from baseline to 60 months; paired *t* test normality was applied to determine appropriate testing procedures for assessing change from baseline. Categorical data were presented using frequencies and percentages unless otherwise specified. McNemar's chi-square was used to test significance of change in T2DM biomakers at 5 years. Mean BAROS subscale and composite scores were calculated across time points; repeated-measures ANOVA, or Friedman's ANOVA, was used to assess significant change.

Results

Between October 2013 and February 2014, 10 patients (8 women, 2 men) refused the B-OAGB procedure and 12 patients (7 men, 5 women) elected B-OAGB and underwent the procedure. The patients' mean age was 38.2 ± 6.5 years (30.0–50.0), and their mean preoperative BMI was 57.5 ± 6.3 (range 50.5–72.6). All 12 patients studied were available through 5 years of follow-up.

Weight Loss

Demographics and weight-loss evolution across variables are shown in Table 1. Weight-loss trends expressed in %EWL are depicted for the entire sample in Fig. 2, and for individual patients in Fig. 3. At 60 months, paired *t* tests with respect to baseline measures revealed statistically significant reductions in weight-related outcome measures: BMI mean change, 25.9 ± 5.4 (95% CI, 22.3–29.5; $p < 0.001$); absolute weight mean change, 76.1 ± 16.4 kg (95% CI, 65.0–87.1; $p < 0.001$); waist circumference mean change, 46.5 ± 8.6 cm (95% CI, 40.7–52.2; $p < 0.001$). Non-parametric analyses

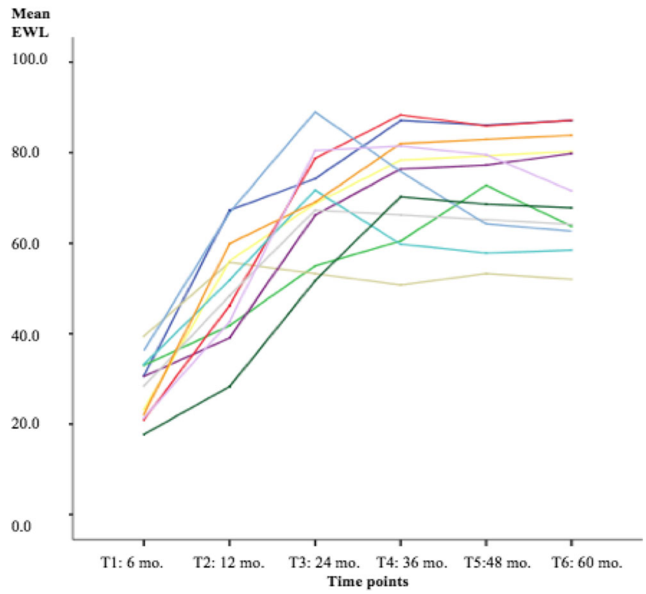

Fig. 3 Weight-loss trends for *individual* patients expressed in % excess weight loss (EWL)

(i.e., Wilcoxon signed rank test) also revealed statistically significant reductions in hip circumference ($p < 0.005$) and waist-to-hip ratio ($p < 0.005$). At 60 months, mean respective TWL and EWL were 45.3 ± 7.5%, (95% CI, 40.5, 50.1) and 72.2 ± 12.8% (95% CI, 64.5, 79.9). Male and female EWL results (Table 1) were excellent; males performed slightly better at 60 months (74.2% vs 67.6%), but with no statistically significant difference between groups.

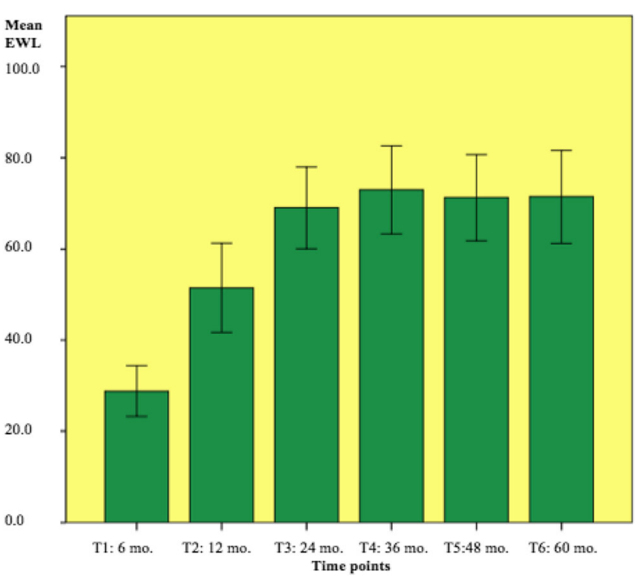

Fig. 2 Weight-loss trends for the *entire sample* expressed in % excess weight loss (EWL). Error bars represent 95% confidence intervals of mean excess weight loss at each time point

T2DM

At long-term follow-up, with a specific focus on T2DM, remission occurred in all patients and there were statistically significant decreases in percentages of patients with associated metabolic markers: T2DM ($p = 0.04$), fasting glucose ($p = 0.01$), HOMA IR ($p = 0.01$), and HbA_{1C} ($p = 0.005$). There was no significant reduction in resting rate blood pressure among patients, but a trend toward that effect was noted ($p = 0.08$) (Table 2). Overall comorbidity was addressed as part of the BAROS assessment (below).

Complications

No perioperative complication, mortality, reoperation, or readmission within 30 days was observed. Between 11 and 24 months, one postoperative complication followed reoperation to remove the band in 3 out of 12 patients (i.e., stasis esophagitis with recurrent vomiting, hypoalbuminemia, anemia) (Table 3). Other than the shortening of the afferent limb, no conversion of the B-OAGB to normal anatomy was necessary. No B-OAGB patients reported symptoms of gastroesophageal reflux. There was no mortality.

Table 2 Change in T2DM biomarkers through 5-year follow-up

	n	BMI mean ± SD	Weight mean ± SD	T2DM* n (%)	FGluc↑ n (%)	HOMA IR↑ n (%)	HbA_{1c}↑ n (%)	RR↑ n (%)
Female	5	54.4 ± 4.0	149.0 ± 20.6	2 (40)	3 (60)	1 (20)	4 (80)	4 (80)
Male	7	59.7 ± 7.1	184.0 ± 14.8	2 (29)	4 (57)	6 (86)	4 (57)	4 (57)
Baseline	12	57.5 ± 6.3	169.1 ± 24.5	4 (33)	7 (58)	7 (58)	8 (67)	8 (67)
6 mo	12	47.3 ± 5.2	139.0 ± 20.1	0 (0)	2 (17)	2 (17)	2 (17)	3 (25)
36 mo	12	31.0 ± 4.7	91.3 ± 20.1	0 (0)	1 (8)	1 (8)	0 (0)	4 (33)
60 mo	12	31.2 ± 5.4	93.2 ± 18.4	0 (0)	1 (8)	1 (8)	0 (0)	5 (42)
p value†	–	–	–	0.04	0.01	0.01	0.005	0.08

**T2DM*, type 2 diabetes mellitus, on medication; *FGluc*↑, fasting glucose > 120 mg/dl; *HOMA IR*↑, HOMA index > 5; HbA_{1c}↑, > 6.5 mmol/mol; *RR*↑, systolic > 140 mmHg and/or diastolic > 80 mmHg

† p value = significance of change in T2DM biomarkers from baseline to 60 months; McNemar's chi-square

BAROS

Complete patient BAROS [15] data was obtained on all patients at 3–6, 6–12, and 48–60 months (Table 4a). Consistent statistically significant weight loss occurred at each time point. All medical comorbidities were improved or resolved by 6 months, and these health gains remained at a constant level over time. Overall QoL was also significantly improved by 6 months and was sustained throughout the course of the 5-year follow-up.

The composite BAROS score significantly increased at each time point (Table 4a), and this effect was largely driven by parallel significant increases in EWL. At nearly 1 year (11 months), there were no complications or reoperations, and 7/12 (58%) of B-OAGB patients had achieved > 50% EWL. At final follow-up, 12/12 (100%) of B-OAGB patients had achieved > 50% EWL. Also, at final follow-up, 9/12 (75%) received a composite BAROS rating for surgical success ranging from very good to excellent.

Final B-OAGB BAROS scores are presented in (Table 4b) juxtaposed with BAROS scores derived from prior research into bariatric surgery success [16]. B-OAGB BAROS subscale and composite scores compare favorably to those of vertical banded gastroplasty (VBG), adjustable gastric banding (AGB), and Roux-en-Y gastric bypass (RYGB). The final B-OAGB composite score was second only to that of RYGB.

Table 3 Complications

Complication	Patients n (%)	Treatment
Severe iron deficiency anemia	1 (8)	Patient #3 = IV ferritin
Vomiting > 2×/wk. and esophagitis	1 (8)	Patient #3 = band explantation at 11 mo.
Hypoalbuminemia (< 2.5 g/dl) and anemia (iron µmol/L and ferritin < 10 µg/L)	1 (8)	Patient #6 = band explantation at 18 mo.; shortened afferent limb from 200 to 160 cm
Stasis esophagitis	1 (8)	Patient #9 = band explantation at 15 mo.
Mild hypoalbuminemia (2.5–3.5 g/dl)	3 (25)	Dietary counseling
Dumping	2 (17)	Dietary counseling
Mortality	0 (0)	
30-day complications and readmission	0 (0)	
Anastomotic or staple-line leak	0 (0)	
Anastomotic ulcer	0 (0)	
Excess weight loss < 50%	0 (0)	
Gastroesophageal reflux disease (alkaline reflux)	0 (0)	
Internal hernia	0 (0)	
Weight regain > 10% total body weight	3 (25)	

Table 4 BAROS [15] quality of life distribution (a) over 5-year follow-up in B-OAGB patients; (b) over 3–8-year follow-up in B-OAGB, VBG, ASGB, and RYGB patients [16]

(a)				
	3–6 months	6–12 months	48–60 months	*p* value
% EWL	0.6 ± 0.5	1.6 ± 0.5	2.4 ± 0.5	0.000†
Comorbidities	2.4 ± 0.8	2.4 ± 0.8	2.3 ± 1.2	NS†
QoL	2.0 ± 0.3	1.9 ± 0.5	2.1 ± 0.4	NS†
Total BAROS (range)	5.0 ± 1.1 (2.8 ± 6.4)	5.9 ± 1.1 (4.0–7.8)	6.3 ± 2.4* (1.6–8.6)	0.02††
Overall rating	Good	Very good	Very good	
(b)				
	B-OAGB ($n = 12$)	VBG ($n = 30$)	AGB ($n = 30$)	RYGB ($n = 30$)
% EWL	2.4	1.6	1.5	2.7
Comorbidities	2.3	2.57	2.48	1.9
QoL	2.1	1.96	2.01	2.55
Total BAROS	6.3	6.13	5.99	7.15
Overall rating	Very good	Very good	Very good	Excellent

(a) *EWL*, excess weight loss; *QoL*, quality of life; *BAROS*, Bariatric Analysis and Reporting Outcome System psychometric questionnaire

No complication or reoperation up to 11 months post-surgery

*Deductions factored into total score

† Repeated-measures ANOVA

†† Friedman's ANOVA

(b) *B-OAGB*, banded one-anastomosis gastric bypass; *VBG*, vertical banded gastroplasty; *AGB*, adjustable gastric banding; Roux-en-Y gastric bypass

Discussion

Optimum bariatric surgical management of super-obese patients remains controversial due to the risk of their increased morbidity and mortality. Although, entering the year 2020, standard OAGB is the third most performed bariatric surgical procedure worldwide [20], few reports of the B-OAGB have been published, and almost none at long-term in the super-obese population.

To our knowledge, the current pilot study is the only report to focus on B-OAGB in super-obese patients at ≥ 5-year follow-up. While the cohort was small, the durable effectiveness and safety demonstrated suggest that B-OAGB may be a safe and successful option for super-obese patients with an acceptable level of reoperation. There was no mortality over the course of the study, weight loss was excellent and durable through 5 years, and T2DM remission occurred in all patients presenting with the disease. In addition, comparative analysis of BAROS scores showed B-OAGB compared favorably to other primary bariatric procedures in surgical efficacy over the long term.

There are some concerns about the B-OAGB's long-term safety profile in terms of biliary reflux, marginal ulcer, and esophagogastric malignancy [21]. The vast majority of bariatric procedures seem to present a negligible relationship with any esophagogastric malignancy. Only a small number of gastric cancers have been reported after gastric bypass, but the majority of them were in the excluded stomach (remnant) [22]. These remnant cancers may not be related to an OAGB operation. No gastric pouch cancer has been reported after MGB/OAGB at this time, and the very few publications citing post-OAGB cancer have been reported in the excluded part of stomach [22]. In conclusion, gastric cancer due to OAGB has not been demonstrated yet.

Gastroesophageal reflux disease is a rare problem after OAGB when the anastomosis is performed on the lower part of the stomach. Chevallier et al. found foveolar hyperplasia in 4.6% of patients at the 4-year postoperative point without any dysplasia or metaplasia [23]. However, in the current study, no B-OAGB patients reported symptoms of gastroesophageal reflux.

B-OAGB in Morbidly Obese Patients

In the only other two recent studies identified that are similar to the current report of B-OAGB in super-obese patients with ≥ 5-year follow-up, a 2013 study by Clarke et al. [24] evaluated outcomes in *morbidly obese and super-obese* patients. Of 156 total patients (78% female, 22% male), with a mean baseline BMI of 46.0 (35.0; 0–64), mean 5-year EWL was 89.0 ± 16.1%, although a separate weight loss outcome for the super-obese subgroup was not reported. No difference in bile reflux incidence or stomal ulceration between patients in the 2 groups was observed. While excellent EWL was achieved, in this study, there was a high incidence of food intolerance and vomiting, likely associated with the band, and 12.8% required reoperation within 5 years [24]. Typically, food intolerance requiring treatment occurs in the early postoperative period; however, in the current pilot study, we did not observe food intolerance over the early or long term. Also, a 2017 study by Sheikh et al. of long-term (11-year) B-OAGB follow-up in morbidly obese patients (mean BMI 46.0 (35.0–64.0)) reported similar excellent weight-loss results although without disclosing outcomes specific to the super-obese subgroup [25].

In 2019, Cazzo et al. [26] published short-term randomized controlled trial (RCT) findings for a B-OAGB group ($n = 10$) vs an OAGB group ($n = 10$) in *morbidly obese* patients (average BMI 37.9). At 1- and 2-month follow-up, EWL following B-OAGB in morbidly obese patients was significantly higher than that following standard OAGB (17.2 ± 3.4% vs 9.6 ± 5.5%, $p < 0.0001$; 46 ± 7% vs 34.2 ± 9%, $p = 0.0045$, respectively), as was the result for EBMIL (9.7 ± 1.1% vs 5.8 ± 0.8%, $p < 0.0001$; 15 ± 1.4% vs 11.5 ± 2.1; $p = 0.0002$). At 3-month follow-up, B-OAGB patients achieved significantly greater EWL and EBMIL than standard OAGB patients [26].

Yet, 8 months later, the same author published a study with 12-month follow-up (also, only in morbidly obese rather than super obese patients) that showed no difference in weight-loss outcomes between banded and non-banded OAGB [27].

Standard OAGB in Super-Obese Patients

In 2018, Parmar and Mahawar [28] systematically reviewed OAGB outcomes for 12,807 *morbidly obese and super-obese* patients with a mean BMI of 46.6 (26.0–8.0). At ≥ 5-year follow-up, their EWL was 76.6% (based on 7 available studies) although, as in the B-OAGB study by [24], an independent EWL for the super-obese subgroup was not reported.

Banded RYGB in Super-Obese and Morbidly Obese Patients

In a systematic review and meta-analysis, Buchwald et al. [5] studied medium- and long-term outcomes in *morbidly obese and super-obese* patients who underwent B-RYGB. As is often the case in patients with super-obesity, B-RYGB patients ($n = 156$) comprising the 3 studies reporting a *super-obese* patient subgroup lost significantly more weight at 5-year follow-up than those ($n = 1098$) in the 8 studies with a baseline BMI < 50 [5]. In reports by Awad et al. [29], Lemmens et al. [30], and Magro et al. [6], long-term outcomes for *morbidly obese* patients undergoing B-RYGB showed EWL peaking around the 2-year postoperative time point and, at 4–12 years of follow-up, being maintained at around 70.0–80.0%, with significant TWL of 32.5%.

In summary, at both early and late follow-up, results from recent studies of standard OAGB and B-RYGB show greater weight loss in super-obese patients relative to morbidly obese patients and greater weight loss in the banded versions of each procedure. Results of the current B-OAGB pilot study in super-obese patients lend support to these prior findings. Placing a band on an OAGB in super-obese patients may enhance and preserve excess weight loss over the long term, although further investigation with RCTs is needed as available observational studies are inconclusive.

Limitations

Although the current cohort of 12 was appropriate for a pilot study, a limitation of the study's utility is the small number of patients included. The safety and effectiveness of B-OAGB over the course of 5-year follow-up suggest that further research in larger cohorts, preferably RCTs, is justified and may result in evidence that can be considered predictive for this procedure.

Conclusion

To our knowledge, this is the first study to specifically study and describe long-term outcomes in super-obese patients following the B-OAGB procedure. At 5-year follow-up, B-OAGB was safe and durably effective for weight loss and reduction of obesity comorbidities in super-obese patients.

Compliance with Ethical Standards

Informed Consent Informed consent was obtained from all participants.

Human and Animal Rights The study was performed in accordance with the ethical standards of the Declaration of Helsinki.

Conflict of Interest The authors declare that they have no conflict of interest. The study is an investigator-initiated study in which the authors received no financial or product support. Karl Miller has been head of the Surgical Department, State Hospital Hallein, Salzburg, Austria from 2000 and joined Johnson & Johnson as Chief Medical Officer for the Middle East in 2015, part-time. JN Buchwald, Medwrite Medical Communications, WI, USA, received a grant for manuscript development.

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