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NEW CONCEPT

To Band or Not to Band—Early Results of Banded Sleeve Gastrectomy

W. Konrad Karcz · Iwona Karcz-Socha · Goran Marjanovic · Simon Kuesters · Matthias Goos · Ulrich T. Hopt · Tomasz Szewczyk · Tobias Baumann · Jodok Matthias Grueneberger

Abstract Laparoscopic sleeve gastrectomy (LSG) is the procedure with the fastest growing numbers worldwide. Although excellent weight loss can be achieved, one major obstacle of LSG is weight regain due to sleeve dilatation. Banded sleeve gastrectomy (BLSG) has been described as an option to counteract sleeve dilatation and ameliorate weight loss over time. In a retrospective study, we analysed 25 patients who underwent BLSG using a MiniMizer® ring. Twenty five patients who had previously undergone a conventional LSG were selected for matched-pair analysis. Patient follow-up was 12 months in both groups. Mean preoperative BMI was 56.1±7.2 kg/m^2 for BLSG and 57.0±6.3 kg/m^2 for LSG, P=0.522. Operative time was significantly shorter for BLSG (53±27 min vs. 68±20 min, P=0.0025). Excess weight loss (%EWL) was equal in both groups with %EWL at 12 months of 58.0±14.6 % for BSLG patients vs. 58.4±19.2 % for LSG patients. There was no procedure-related mortality in either group. At 12 months postoperative, vomiting was significantly increased in BSLG patients (OR 6.75, P=0.035). New onset reflux was equal in both groups (OR 0.67, P=0.469). Ring implantation does not increase the duration of surgery or early surgical complications. Weight loss in the first follow-up year is not influenced, but the incidence of vomiting is raised after 12 months when patients start to increase eating volume.

Keywords Banded sleeve gastrectomy · BLSG · Restriction · Obesity surgery · Weight loss

Introduction

Laparoscopic sleeve gastrectomy (LSG) is the bariatric procedure with the fastest growing numbers worldwide, and today is the second most-often conducted bariatric operation, exceeded only by Roux-en Y gastric bypass (RYGB). In 2011, almost 95,000 procedures were completed worldwide [1]. The original indication for LSG was primarily to reduce operative risk in the super obese, now it is widely accepted as a stand-alone procedure [2]. Furthermore, early and mid-term weight-loss and resolution of comorbidities is equal to RYGB. At the same time, surgical re-intervention and overall surgery-related morbidity is significantly lower [3, 4]. However, sleeve dilatation with subsequent consumption of larger meals is a drawback for this purely restrictive procedure and can be responsible for insufficient weight loss [5, 6]. The suspicion that sleeve dilatation correlates with weight gain led our group to measure sleeves with three-dimensional computed tomography (CT) in selected patients. Unfortunately, a thoracic sleeve migration was found in approximately 40 % of examined cases. Furthermore, stomach volume analysis surprisingly revealed that migrated sleeves were smaller than formally correctly positioned sleeves [6]. Based on the knowledge that additional "diaphragmatic restriction" prevents sleeve dilatation, we

W. K. Karcz
Department of General Surgery, University of Schleswig-Holstein, Campus, Lübeck, Germany

I. Karcz-Socha
Department of Physiology, Medical University of Silesia, Katowice, Poland

G. Marjanovic · S. Kuesters · M. Goos · U. T. Hopt · J. M. Grueneberger (✉)
Department of General and Visceral Surgery, University of Freiburg, Hugstetter Strasse 55, 79106 Freiburg im Breisgau, Germany
e-mail: jodok.grueneberger@uniklinik-freiburg.de

T. Szewczyk
Department of Gastrointestinal Surgery, University of Łódź, Łódź, Poland

T. Baumann
Department of Radiology, University of Freiburg, Freiburg im Breisgau, Germany

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proposed a banded laparoscopic sleeve gastrectomy (BLSG) using a polyurethane (GaBP) ring. We first performed the operation in June 2007 [7]. Others initiated a similar technique wrapping the sleeve stomach with a piece of AlloDerm® [8].

Experience with this new technique is sparse to date. With the aim to establish and to further develop and facilitate the technique, we performed BLSG using a MiniMizer® ring in 25 patients and here present initial results with critical analysis of benefits and risks in the first follow-up year.

Material and Methods

From January to August 2012, 25 patients underwent BLSG at one institution. Data recording included length of hospital stay, preoperative BMI, presence of medical comorbidities such as arterial hypertension and type 2 diabetes (T2DM), intra- and postoperative surgical complications as well as postoperative comorbidities in form of reflux and frequency of vomiting. Furthermore, management of complications, total operative time and weight loss were noted. All data were entered prospectively into a custom-designed database. The same follow-up protocol was used for all patients at the outpatient clinic at 1, 6 and 12 months after surgery. Patients were specifically asked preoperatively and on every visit about clinical signs of reflux and frequency of vomiting. Missing data were obtained via a telephone questionnaire.

In order to perform a retrospective matched-pair analysis, 25 patients who had previously undergone an LSG at the same institution were selected and matched for preoperative BMI, age, gender and presence of metabolic disorders. All patients underwent routine gastroscopy prior to operation. Apart from additional ring implantation, the operative technique was identical in both groups. Indications for BLSG and LSG equally were patients with a failed conservative treatment for weight loss with an initial BMI above 50 kg/m^2. Written informed consent was obtained from all patients. Patients for BLSG were explicitly informed about the novelty of the procedure and low data availability. The institutional Ethics Committee approved data evaluation of all patients (Ref. number: 321/13).

Operative Technique

Laparoscopic sleeve resection is performed as published earlier [7]. In brief, the operation is performed in a two-surgeon technique with the patient in the lithotomic position and the operating table in a 30° reverse Trendelenburg tilt.

Following exposition, the dissection begins on the greater curvature 4-5 cm from the pylorus. Once the bursa omentalis is entered, the dissection is continued in a cephalic direction using a LigaSure vessel-sealing device (Covidien, Dublin, Ireland) until the left crus of the diaphragm is well visualized. A routine repair of pre-existing hiatal hernias was not conducted. Resection is started about 4-5 cm from the pylorus over a 35 F gastric calibration tube, using violet linear tri-staplers (GIA Roticulators, Covidien, Dublin, Ireland) up to the angle of His. A gastric sleeve less than 100 ml in volume remains.

For MiniMizer® ring implantation, the peritoneum of the lesser curvature is inserted 4 cm from the gastro-esophageal junction. The MiniMizer® ring is then pushed through the omentum minus at the point of dissection and closed to leave a circumference of 6.5 cm. The introducer of the MiniMizer® ring is then removed and the ring is fixed in position using two single Vicryl 3/0 sutures. Sleevopexy was performed in all patients [9].

Statistics

Statistical analysis was conducted using Prism 5 for Mac OS X (GraphPad Software, Inc.). The Mann-Whitney *U* test was used for group comparison; curves were analysed with a two-way ANOVA. All patients were included in the statistical analyses. $P<0.05$ was considered significant.

Results

Twenty five patients underwent BLSG with a mean operative time of 53.2 min (Table 1). Mean follow-up was 11 months in both groups. Compared to conventional LSG, additional ring implantation did not prolong the duration of surgery. Rather, duration of BLSG surgery was significantly shorter (Mann-Whitney $P=0.0025$, Table 1). Five patients with BLSG had undergone previous abdominal surgery, but none in the upper gastrointestinal tract.

Morbidity, Mortality and Complications

One patient in the BLSG group needed operative revision due to staple line bleeding on the first postoperative day. Revision

Table 1 Patient characteristics

	BLSG	LSG	*P* value
Patients	25	25	
Male / Female	7/18	8/17	1.0 $^{\tau}$
Age	42.6	43.6	0.93 $^{\pi}$
Preoperative BMI (kg/m^2)	56.1	57.0	0.52 $^{\pi}$
T2DM	6	6	1.0 $^{\tau}$
Arterial hypertension	12	15	0.57 $^{\tau}$

Values are expressed as absolute numbers

$^{\tau}$ Fisher's exact test

$^{\pi}$ Mann-Whitney test

was conducted laparoscopically. Just exceeding 12 months, 2 patients with BLSG underwent laparoscopic removal of the MiniMizer® ring due to uncontrolled vomiting (Table 2). Whereas one of these two patients showed typical signs of stenosis upon preoperative imaging (Fig. 1), the other patient had no abnormal anatomical findings with a regular sleeve volume of 137 ml measured in CT-volumetry 13 months postoperative (Fig. 2). Ring migration did not occur in any patient.

One patient in the BLSG group with a preoperative BMI of 51.8 kg/m^2 and unremarkable early follow-up died 4 months postoperative due to congestive heart failure with underlying arrhythmia.

At 12-month follow-up, BLSG patients presented with an increased incidence of frequent vomiting (≥ 1/week). Interestingly, the risk for new onset reflux was considerably lower for BLSG patients (OR 0.46, Table 3). Furthermore, BLSG patients had a greater chance of improvement or stable development of pre-existing reflux (OR 4.0). In preoperative gastroscopy, a hiatal hernia was diagnosed in 4 patients in the BLSG and 10 patients in the LSG group. Patients with a pre-existing hiatal hernia in the LSG group were more likely to develop new-onset reflux (OR 4.3). In the BLSG group, hiatal hernias had a stronger implication on new-onset reflux development (OR 20).

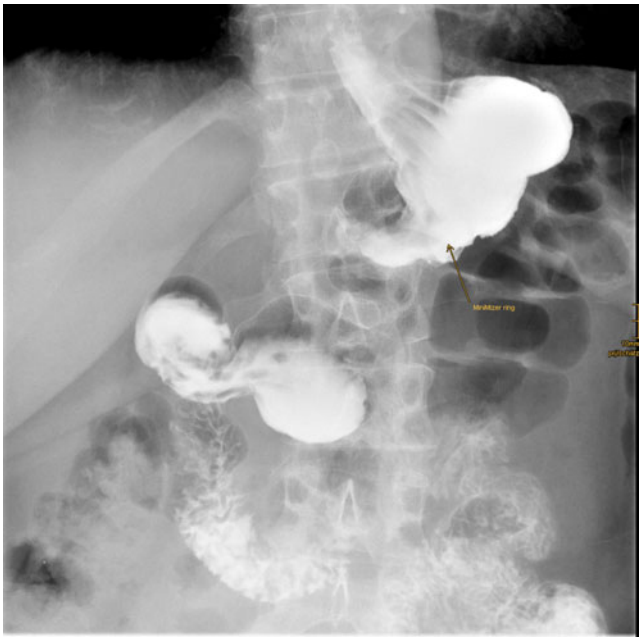

Fig. 1 Image of a gastrografin swallow of a dilated upper sleeve with *arrow* pointing at MiniMizer® ring

Weight Loss

The mean preoperative BMI was 56.1 in the BLSG and 57.0 in the LSG group. Early follow-up showed equal weight loss in both groups at all recorded times (%EWL BLSG vs. LSG after 12 months 58.02 vs. 58.36, two-way ANOVA P=0.787, Fig. 3). Eighty eight percent of BLSG patients reported a good feeling of satiety.

Discussion

Additional circular reinforcement of a gastric pouch has been shown to improve weight loss in vertical gastroplasty and gastric bypass surgery [10, 11]. In the current series, 25 patients underwent BLSG. Data were compared to conventional LSG in matched-pair analysis.

Whereas Alexander et al. applied human dermis to form a BLSG, an artificial silicone ring was used in the current series [8]. Dissection at the lesser curvature may dangerously influence the stomach's blood supply once the gastroepiploic vessels have been dissected for pouch formation. Contrary to earlier "rings", only very limited dissection at the lesser curvature is necessary on the insertion of the MiniMizer® ring, since it contains a blunt, inflexible angled introducer that is removed after ring closure. This is reflected in the fact that additional MiniMizer® ring implantation did not lead to prolonged duration of surgery. On the contrary, BLSG operation times were significantly shorter. Restrictively, this most likely reflects a selection bias since due to the novelty, BSLG procedures were performed to a higher number by a senior surgeon.

Table 2 Perioperative data

	BLSG	LSG	Overall	*P* value
Early operative revision	1	0	1	1.0 $^{\tau}$
Late (>12 m) operative revision	2	0	2	0.49 $^{\tau}$
Duration of surgery (min)	53.2 (22-153)	68.0 (33-111)	60.6	0.0025 $^{\pi}$
Mortality	1	0	1	1.0 $^{\tau}$

Values are expressed as absolute numbers or means with range in parentheses

$^{\tau}$ Fisher's exact test

$^{\pi}$ Mann-Whitney test

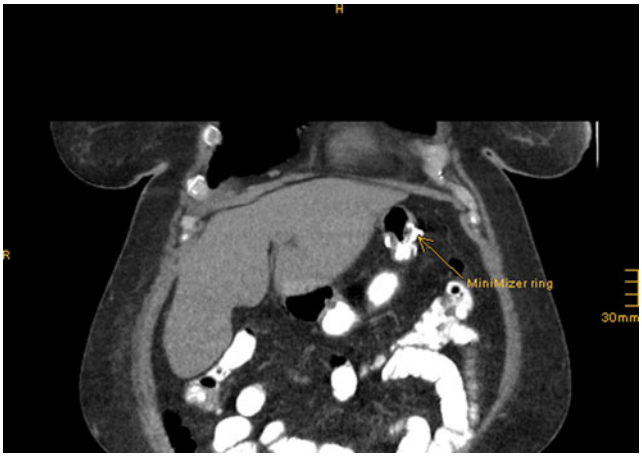

Fig. 2 CT image with oral contrast with *arrow* pointing at MiniMizer® ring. No dilatation of the sleeve stomach can be observed

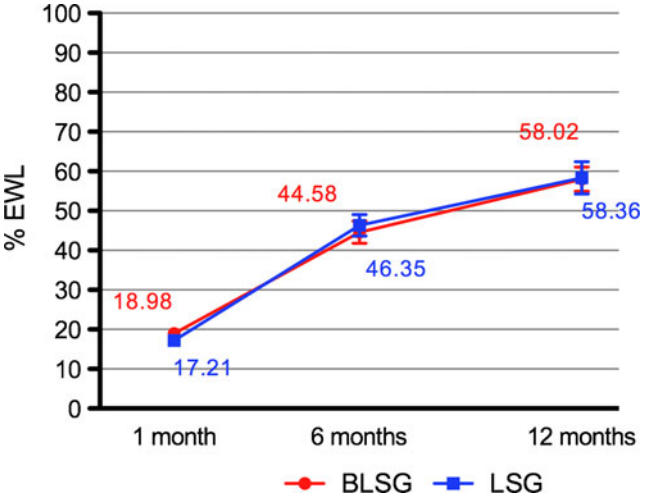

Fig. 3 Plot of excess weight loss after 1, 6 and 12 months with additional display of group means at all time points

Overall weight loss after BLSG and LSG in the current series is within the range reported earlier for LSG, which is noteworthy considering the fact that the preoperative BMI was considerably above 50 kg/m^2 [12]. The authors note that additional banding does not increase %EWL 12 months after LSG when most weight loss has usually occurred, but is it reasonable to expect additional weight loss in this early follow-up period?

On the one hand, our group showed earlier that sleeve volume almost doubles within the first postoperative year [6, 13]. This goes along with findings of sleeve dilatation to a similar extent on CT imaging 2-3 years after LSG [14]. Analysing the mechanisms of weight loss after laparoscopic adjustable gastric banding, Burton and Brown recently reasoned that weight loss is mainly due to satiety and not restriction [15]. As conventional LSG suppresses fasting hunger to a lesser extent than other bariatric procedures, the authors speculated that ring implantation would improve this effect [16]. Furthermore, continued restriction might prolong a slow food transportation in the longitudinal part of the sleeve and therefore amplify satiety [17]. In the current series, 88 % of patients reported an excellent feeling of satiety after BLSG.

On the other hand, using a 35 F calibration tube, the estimated sleeve circumference is approximately 5 cm, assuming a stomach wall thickness of 2 mm. As the ring is closed at 6.5 cm in order to prevent sleeve stenosis, it might primarily have little impact on gastric restriction. Additional restriction will only occur once the sleeve has dilated. Furthermore, randomized controlled and retrospective trials comparing banded with conventional RYGB showed that patients who had received a banded operation only experienced increased weight loss beginning at 36 months [11, 18].

Based on these considerations, the authors speculate that it is reasonable to assume that BLSG does not lead to additional weight loss in the first year, but a difference in %EWL may be noted in longer follow-up. When drawing a parallel to BRYGB, it has to be noted that additional rerouting of the intestine is known to substantially influence appetite, which might effect pouch dilatation, as smaller meals are consumed [19].

In the current series, while all other complication rates are equal, ring implantation comes at the cost of a higher

Table 3 Morbidity (12 months)

	BLSG	LSG	Overall	*P* value; OR
Reflux				
Pre-existing reflux	9 (36 %)	6 (24 %)	15 (30 %)	
Improvement/ no effect	8	4		*P*=0.53 $^{\tau}$; OR 4 $^{\Psi}$
Worsening	1 (4 %)	2 (8 %)	3 (6 %)	
New-onset reflux	3 (12 %)	6 (24 %)	9 (18 %)	*P*=0.45 $^{\tau}$; OR 0.46 $^{\Psi}$
PPI treatment	9 (36 %)	13 (52 %)	22 (44 %)	
Vomiting (≥1/week)	10 (40 %)	2 (8 %)	12 (16 %)	*P*=0.017 $^{\tau}$; OR 8.1 $^{\Psi}$

Values are expressed as absolute numbers and percentages (parentheses)

$^{\tau}$ Fisher's exact test

$^{\Psi}$ Odds ratio (OR) for BLSG

frequency of vomiting. Again, the comparison of BRYGB with conventional RYGB reflects the current constellation. After BRYRG, the rate and severity of vomiting is significantly increased compared to conventional RYGB [18, 20]. Furthermore, the frequency of regurgitation and subsequent band removal strongly correlates with ring size, although at the same time weight loss was equal for all examined ring sizes [21]. Testing rings from 5.5 to 6.5 cm, Stubbs et al. therefore recommended using the largest ring size evaluated [21]. In dealing with ring-related problems in BRYGB, primarily dietary modifications should be undertaken [22]. In case of persisting problems, band removal is recommended after thorough diagnostic workup including endoscopy and upper GI series [22]. Overall, about 5 % of rings are removed after BRYGB [21]. In contrast to BRYGB, Mason et al., who have considerable experience with vertical banded gastric pouches, describe that a stricture due to the Marlex band is an extremely rare incident, yet recommend band removal in such cases [23]. A larger study with a 10-year follow-up confirms these findings with a reoperation rate of 1.3 % due to band-related problems [24]. Pouch enlargement with subsequent relative outlet obstruction due to malcompliance has furthermore been described as a relevant cause of uncontrolled vomiting after vertical banded gastroplasty (VBG) [23]. Aiming to technically improve VBG, Mason recommended forming a short (5 cm) pouch to prevent pouch enlargement, as they observed that large, poorly emptying pouches usually have both excessive volume and length [23].

The authors observed two cases of recurrent vomiting, markedly influencing the patient's quality of life 13 months after BLSG. In one case, malcompliance with subsequent pouch enlargement as described by Mason et al. was the most probable underlying cause of the symptoms presented. After dietary modifications had been implemented without success, laparoscopic ring explantation was conducted in both cases. Whereas band removal after BRYGB has been described as a challenging task, MiniMizer® ring explantation was technically simple [22]. Most importantly, there was no relevant scar tissue around the ring and no scar tissue-associated stenosis remained. The authors assume that the limited amount of dissection necessary upon ring implantation and the small implant size are responsible for the little scar formation. Symptoms resolved immediately after operation in both patients, yet weight regain occurred within the first months after revision. As an alternative to laparoscopic revision, Ferraz et al. recently suggested that aggressive balloon dilatation might lead to band rupture thus avoiding the risk of reoperation [25]. As MiniMizer® silicone rings are formable and possess a high opening pressure, endoscopic dilatation does not represent an adequate option in the current patient collective.

The fact that two patients needed operative revision for ring removal somewhat counterbalances the report of Alexander et al., who did not note such incidences [8]. Possibly the AlloDerm® ring stretches with time and therefore allows for a relatively larger flow through. However, data from incisional hernia repair with biologic grafts such as AlloDerm® show that hernia recurrence rate in clean wounds is lower than 3 % and laxity occurs in about 10 % overall [26]. Therefore, the majority of AlloDerm® BLSG should still have a stable implant (ring).

Nevertheless, patient selection and postoperative guidance is crucial when performing additional ring placement, as patients need to maintain a high level of compliance with respect to life-long oral ingestion.

Interestingly, despite an increased rate of vomiting, the incidence of new-onset reflux was equal for BLSG and LSG, with the odds ratio showing a lower risk for BLSG. Beside the pouch shape, thoracic sleeve migration has been shown as a possible risk factor [6, 27]. Furthermore, patients with a pre-existing hiatal hernia were more likely to develop new-onset reflux postoperatively, especially in the BLSG group, yet there was no correlation with band removal. Possibly, patients with pre-existing hiatal hernia should not be considered for BLSG. While reflux is a common phenomenon after conventional LSG, gastric banding may lead to a relief of pre-existing GERD [27–29]. Nevertheless, about 26 % of patients suffer from GERD 12 months after LAGB, mainly because of acidic fermentation in a slow-emptying pouch [30]. Furthermore, VBG may have an anti-reflux function [31]. Whereas BLSG with AlloDerm® was associated with a higher incidence of reflux at 12 months, the data presented here show first evidence that additional ring implantation may improve postoperative reflux as relevant comorbidity after LSG [8].

To the best of our knowledge, the current examination for the first time shows data for BLSG with a silicone ring, and is one of few studies presenting data after this new procedure at all. The strength of this study is perioperative data and early follow-up of a new method with potential impact on long-term outcome after sleeve gastrectomy. Most importantly, no band-related mortality was shown. Although there was one death in the BLSG group, the authors find no reason to assume that this incident was ring related, as the patient died of congestive heart failure due to a pre-existing heart rhythm disorder. Furthermore, the study clearly shows that long-term complications such as reflux or vomiting have to be regarded and the indication for a ring implantation has to be made carefully. Limitations of this study are the small sample sizes, retrospective design, non-randomization and 12-month follow-up.

Follow-up examinations revealed that additional band implantation does not provoke extra weight loss in the first follow-up year. Additional ring implantation leads to a higher rate of vomiting after 12 months, when compliance typically declines and patients start to consume larger meals. Ring implantation did not prolong the operation time or increase

complication rate. Importantly, no band migration was observed. In the future, randomized controlled multicenter trials focusing on a longitudinal morbidity analysis, especially regarding the incidence of vomiting, %EWL, resolution of comorbidities and patients' quality of life are planned to further clarify the safety and efficacy of the novel procedure.

Conflict of Interest W. Konrad Karcz, Iwona Karcz-Socha, Goran Marjanovic, Simon Kuesters, Matthias Goos, Ulrich T. Hopt, Tomasz Szewczyk, Tobias Baumann and Jodok Matthias Grueneberger declare to have no conflicts of interest.

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