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A prospective randomized trial of different laparoscopic gastric banding techniques for morbid obesity

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Abstract

Background: Slippage of the stomach is the most common postoperative complication after laparoscopic adjustable silicone gastric banding (LASGB) for morbid obesity. Retrogastric placement (RGP) of the band through the lesser sac can cause posterior slippage Incomplete suturing often is responsible for anterior slippage. A randomized prospective study was constructed to determine whether laparoscopic esophagogastric placement (EGP) is associated with a lower incidence of postoperative slippage and pouch dilation than RGP.

Methods: Morbid obese patients presenting for LASGB were randomized to undergo either an EGP ($n = 50$) or an RGP ($n = 51$). Patients were blinded to which procedure they underwent, and follow-up date were obtained by a blinded independent investigator. Standardized clinical and radiologic controls were used to assess pouch enlargement and slippage.

Results: Operating time was similar for the two procedures (54.5 min for EGP vs 58 min for RGP). There was no significant difference in postoperative weight loss (34 kg after EGP vs 37 kg after RGP within 12 months), esophagus dilation, or postoperative quality of life. There were two postoperative slippages and one pouch dilation in the RGP group and no postoperative complication in the EGP group.

Conclusions: The placement of a LAP-BAND adjustable gastric banding system by the EGP technique is safe and results in a lower frequency of postoperative complications than its placement by the RGP technique. Clear anatomic landmarks are a benefit to education and to the learning curve for LASGB.

Key words: Implantation technique — Laparoscopic gastric banding — Pouch dilation — Slippage

Over the past few years, the surgical treatment of severe obesity has gained amazing popularity all over the world, supported by the discouraging intractability of this illness despite a wide variety of conservative therapies. Laparoscopic adjustable silicone gastric banding (LASGB) is the least invasive operation available in the surgical treatment of morbid obesity [3], and its efficacy has been proved through many studies and publications. More than 40,000 LASGB procedures have been performed around the world in the past few years, most of them in Europe. The number of these operations is increasing rapidly. Postoperative slippage of the stomach through the band is the most common complication after adjustable gastric banding. This has led to reoperations and revisions, with subsequent modification and improvement of the technique. To determine whether the incidence of slippage with retrogastric placement (RGP) is lower than with esophagogastric placement (EGP), a prospective randomized study was constructed and carried out.

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Patients and methods

From May 1996 to August 1999, 307 patients (260 females and 47 males) with a mean body mass index of 49,3 kg/m^2 (range, 36–79 kg/m^2) underwent a LASGB at the Nordwest Hospital in Frankfurt a.M., Germany. From February 1997 to February 1998, 101 consecutive patients with morbid obesity were randomized to either laparoscopic retroesophageal placement with creation of an anterior gastric pouch (esophagogastric placement: EGP) or retrogastric placement (RGP) of the adjustable silicon gastric band. Patients were blinded to which procedure they underwent, and follow-up data was obtained by a blinded independent investigator. Quality of life was measured by an anonymous questionnaire [16]. The demographic data for both groups are shown in Table 1. In all cases a LAP-BAND adjustable gastric banding system (BioEnterics Corporation, Carpinteria, CA, USA) was implanted laparoscopically. All surgical procedures were performed by the same surgeon, and all subjects were participants in an interdisciplinary obesity surgery program.

Operative procedures

The patient is placed in the lithotomy position with the operating table in a 30° reverse Trendelenburg tilt. The surgeon stands between the patient's

Table 1. Patients demographics

	RGP group (n = 51)	EGP group (n = 50)	p
Age (years)	35.4 ± 9.3 (18–54)	34.7 ± 10.4 (19–52)	NS
Gender (female/male)	42/8	44/7	NS
Body mass (kg)	142.9 ± 14.3	145.8 ± 17.4	NS
BMI (kg/m_2)	49.5 ± 4.2	48.5 ± 3.4	NS
Excess weight	69.7 ± 12.3	66.2 ± 10.2	NS
Operative time (min)	56.5 ± 5.2	58.2 ± 4.8	NS
Hospitalization (days)	4.5 ± 0.4	4.9 ± 0.8	NS
Intraoperative complications	0	0	NS
Postoperative complications	0	3	<0.001
Port related	0	4	NS
Band related	0	3	<0.001
Slippage	0	2	<0.001
Pouch dilation	0	1	<0.05
Erosion of mi tion	0	0	NS
Material defect	0	0	NS

NS, not statistically significant ($p > 0.05$); RGP, retrogastric placement; EGP, esophagogastric placement; BMI, body mass index

legs, with one assistant on the left side of the patient and one assistant on the right side.

Port placement is comparable with that for laparoscopic fundoplication port sites [15, 18]. The ports (Step System, InnerDyne Inc., Sunnyvale, CA, USA) for the working instruments are placed further cranially. After creation of the pneumoperitoneum, the optic port is introduced into the abdominal cavity. Four ports are placed under visual control with a 30° angle telescope. The subcardiac area is exposed by lifting the left lobe of the liver and by pulling down the gastric fundus. Exploration of the anatomic area is begun using a 30° laparoscope.

Esophagogastric placement

The initial steps for the EGP are similar to those for laparoscopic fundoplication procedures. After the pars flaccida is opened, the right crus is dissected. The procedure involves blunt dissection of the esophageal hiatus, with special care taken to preserve the hepatic branch of the vagus nerve. After dissection of the left crus, the phrenogastric ligament at the angle of His is opened. A blunt articulating dissector is passed under laparoscopic visualization through the retroesophageal opening (Fig. 1).

The EndoLumina II transillumination system (BioEnterics) bougie is used to identify the esophagus and esophagogastric junction during the dissection. The instrument is left in place, and the system's calibration balloon is inflated with 25 ml of water, then pulled back to the gastroesophageal junction by the anesthesiologist. This aids in identifying the correct point of dissection along the lesser curvature. The point at the equator of the balloon is marked by electrocoagulation. This calibration helps in the creation of a small anterior gastric pouch with a volume of 15 ml.

Next, the balloon should be deflated and pushed into the stomach before any dissection. The lesser curvature containing the nerve of Laterjet is dissected from the gastric wall in the direction of the right crus. The band is introduced through the optic port, which is replaced by an 18-mm TEC port (Ethicon Endo-Surgery, Cincinnati, OH, USA).

The end of the tube is transported behind the esophagus from the left to the right side of the hiatus. The articulating dissector is introduced through this opening behind the esophagogastric junction and through the point of dissection at the angle of His, and the end of the tube is inserted into the opening of the instrument (Fig. 2). The next step is to advance the tube along the gastric wall to the marked opening (Fig. 3). After removal of the articulating dissector, the band is pulled into position without force, and adherent tissue can be dissected under laparoscopic view. The closing and calibration procedure is not different from previous techniques.

In addition, five anterior gastrogastric sutures (silk 00) are applied over the band, which, together with the previous point of dissection, are crucial for the creation of a proximal 15-ml pouch. These anterior antislippage stomach-to-pouch sutures are placed as close as possible to the greater curvature to prevent band migration, and posterior stitches are neither necessary nor applicable. After the port is connected to the tube of the band system, the procedure is completed by securing the access port of the LASGB system in a subcutaneous pocket to the musculoaponeurotic fascia.

Retrogastric placement

The RGP technique was developed by Belachew et al. [3]. After exposure of the hiatal region, the calibrating tube balloon is advanced into the stomach by the anesthesiologist. The balloon is inflated with 25 ml of water and pulled back to the gastroesophageal junction. This aids in the correct identification of the point along the lesser curvature at which to start blunt dissection. This reference point on the lesser curvature is the equator of the balloon, which normally is 2 cm from the hiatus. However, this distance and the position of the surrounding vessels have shown a wide variability, and the calibration aids in the creation of a 15-ml pouch. A tunnel is created behind the stomach joining the two dissected reference points. A very small opening in the phrenogastric ligament (His angle) close to the gastric wall of the greater curvature is made for reference and identification.

The bursa omentalis should not be entered because the posterior dissection should be performed through the phrenogastric ligament above the peritoneal reflection of the bursa omentalis. Dissection may go through the bursa omentalis, depending on individual anatomy, especially in patients with hiatal hernias, which often are present in the obese population.

The calibration balloon should be pushed into the stomach before any dissection to avoid injury to the gastric wall. The dissection along the lesser curvature is begun using an electrical coagulation hook or the Harmonic Scalpel, and should be as close as possible to the gastric wall. Great care should be taken not to damage the stomach wall. Under direct vision, the hepatogastric ligament is dissected from the gastric wall to make a narrow opening.

A blunt roticulating instrument is introduced through this tunnel between the lesser curvature and the angle of His and left in place (Fig. 4). The band is introduced through the optic port, which replaces an 18-mm TEC port (Ethicon Endo-Surgery). The band then is placed around the stomach at the level of the dissection. The calibration balloon is reinflated with 15 ml of sterile saline and pulled back to the esophogastric junction, where the band then is closed below the balloon. This procedure is greatly facilitated by the self-locking mechanism the LAP-BAND system provides.

Five anterior gastrogastric retention sutures (silk 00) are applied over the band, which, together with the previous point of dissection, are crucial for the creation of an anterior 15-ml pouch. These antislippage sutures are started as close as possible to the greater curvature to avert migration of the band. In the current study no posterior stitches were applied because no opening in the bursa omentalis was recorded.

The procedure is completed by securing the access port of the LASGB system on the musculoaponeurotic fascia in a subcutaneous pocket. With the use of Step-System ports (InnerDyne), no fascia closure is necessary, which is an important time-saving factor in obese patients.

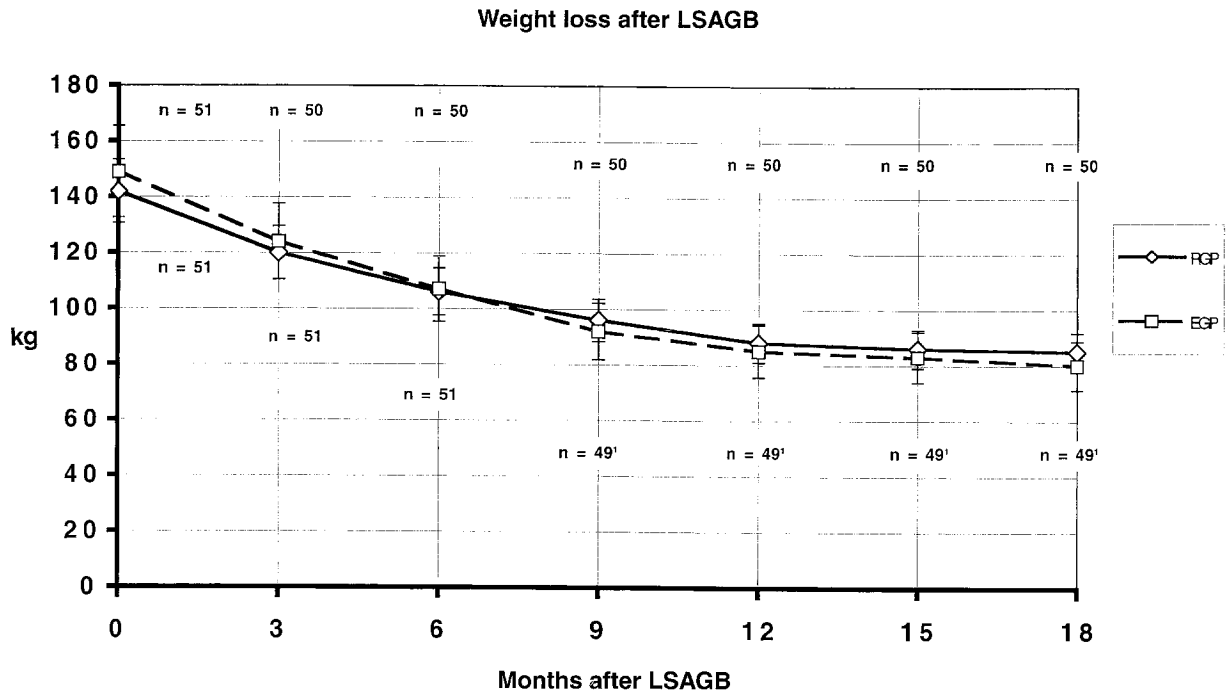

Fig. 1. Postoperative weight loss (kg) after laparoscopic adjustable silicone gastric banding (LASGB) using the following techniques of band placement: esophagogastric placement (EGP) and retrogastric placement (RGP). One patient was lost during follow-up evaluation after 6 months, and one pregnant woman was excluded (weight gain of 14 kg during pregnancy).

Fig. 2. Step 1 of esophagogastric placement (EGP) created by Weiner: The end of the tube is transported behind the esophagus from the left to the right side of the hiatus. The articulating dissector is introduced through this opening behind the esophagogastric junction and through the point of dissection at the angle of His. The end of the tube is inserted into the opening of the instrument.

Fig. 3. Step 2 of esophagogastric placement (EGP) created by Weiner: The tube is advanced along the gastric wall to the marked opening.

Results

The mean hospital stay was 5.5 days, depending on the health care system in Germany. In the first 4 weeks, only fluid nutrients and drinks were allowed. Approximately 1 month after the operation, the LAP-BAND was inflated under radiologic control (mean fill volume, 3.1 ml). Thereafter, normal nutrition started under the supervision of a dietician.

Clinical controls and band adjustments were performed every 1st, 3rd, 6th, 9th, 12th, and 18th month. Body weight

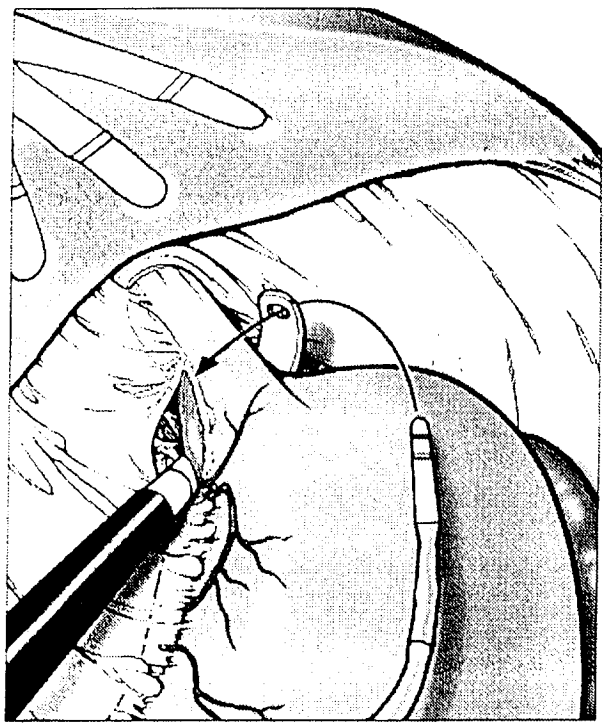

Fig. 4. Retrogastric placement (RGP) created by Belachew and Cadiere: A retrogastric tunnel is created. A blunt roticulating instrument is introduced through this tunnel between the lesser curvature and the angle of His and left in place.

(kg) and the results of an anonymous questionnaire concerning quality of life [16] were documented. The quality of life questionnaire contained 46 questions with four answers. Radiographic evaluations of the distal esophagus, pouch size, band position, and fluid passage through the stoma were performed 1 month, 6 months, 12 months, and 18 months after LASGB. During the first investigation 4 weeks after LASGB, adjustment of the LAP-BAND was performed. Diameters of the esophagus (cm) were measured after the Gastrografin was emptied during all radiologic evaluations. As a comparison for measurement, the same size LAP-BAND was used.

The contrast medium follow-up times in both groups was 1, 3, 6, 9, 12, and 18 months after LASGB. One patient was lost to follow-up evaluation after 6 months. In one case, radiologic evaluation 6 and 12 months after RGP of the LAP-BAND were not performed because the 27-year-old woman became pregnant during the fourth postoperative month.

Gastroscopy was performed only in patients with symptoms of esophagitis (5 in the EGP group and 6 in the RGP group). No intraoperative complications were observed, and there were no conversions to open surgery. No deaths occurred as a result of the operative technique. The operating time was similar for the two procedures (mean, 54.5 min for the EGP and 58 min for RGP), and all procedures were performed by a single surgeon with experience from more than 200 LASGB.

There were two postoperative slippages and one pouch dilation in the RGP group, as compared with no postoperative complication in the EGP group (H-test: $p < 0.01$). The only slippage that occurred was that of the posterior fundus.

Table 2. Comparison of results after esophagogastric placement (EGP) and retrogastric placement (RGP) of the LAP-BAND

	Months after LASGB							
	RGP				EGP			
	1	6	12	18	1	6	12	18
Slippage	0	1	0	0	0	0	0	0
Pouch dilation	0	1	1	1	0	0	0	0
Dilation of esophagus (>30 mm)	0	0	1	1	0	0	1	1
Pouch size								
15–20 cm	50	49	47[a]	47[a]	50	50	50	50
20–25 cm	1	0	0	0	0	0	0	0
>25 cm	0	2	2	2	0	0	0	0
Angle of band position								
<45°	0	0	0	0	50	50	50	50
45–90°	51	50	48[a]	48[a]	0	0	0	0
>90°	0	1	1	1	0	0	0	0
Affections								
Hunger feeling	7	2	3	3	5	3	1	1
Dysphagia	0	1	1	1	0	1	1	1
Recurrent vomiting	0	2	1	1	0	0	1	1
General improvement of QoL								
Excellent and well	51	51	47[a]	47[a]	50	50	50	50
Fair	0	0	2	2	0	0	1	1
No improvement	0	0	1	1	0	0	0	0
Esophagitis (gastroscopy)								
degree I		1		1		1		1
degree II			2				1	
degree >III								

[a] In one patient, radiologic control was not performed (pregnancy 7 months after surgery), and one patient was lost to follow-up evaluation after 6 months (both in RGP group)
LASGB, laparoscopic adjustable silicone gastric bonding; QoL, quality of life

Clinical presentation of the slippage problems were manifested 5 months and 13 months after the operation. Pouch dilation was observed 6 months after surgery, and there was no need of revision at this time because the weight loss of the patient was sufficient. Slippage was treated laparoscopically by opening the band, removing it from the original path, and placing it above the primary path.

At this writing, no recurrence has been reported. There has been no significant difference in postoperative weight loss between the two groups (Fig. 1). The follow-up rate was 100% at 6 months in both groups. One patient in the RGP group was lost to follow-up evaluation after 6 months and at the following control assessments. Radiologic evaluation of the esophagus, pouch size, positioning of the band, and fluid passage produced the results depicted in Table 2. Discomforts such as feelings of hunger and vomiting also were similar between the two groups, and there were no differences in the occurrence of esophagitis and esophageal dilations.

Discussion

Over the past few years, the surgical treatment of morbid obesity has gained amazing popularity in Europe, supported by the discouraging intractability of this condition despite a wide variety of conservative therapies. In Europe, LASGB has become the bariatric procedure of choice, with a continuing increase in numbers. The most frequent complica-

tion is dilation of the upper stomach (pouch) with narrowing of the gastrogastric junction. This process, which can occur within a few days, is attributed to a stenosing inflammatory process under the band, slippage of the stomach through the band, or a combination of both problems.

The rate of slippage depends on patient selection (compliance), surgical technique, and postoperative care. The surgical technique is the most important factor contributing to the development of postoperative complications. The frequency of slippage is 5% to and 10% after the learning curve, according to data published by experienced surgeons [3, 5, 7–10, 13, 18]. Several publications have reported slippage in up to 30% of patients during the learning curve [13]. A recent report by Morino et al. [12] described disappointing long-term results of 60% slippage after LASGB when fixation was not performed.

The time of diagnosis usually is 3 to 8 months after surgery, and O'Brien et al. [13] found a median interval of 8 months. Therefore, the follow-up period of 18 months in the current study is representative of this time frame.

There are three forms of slippage: anterior slippage of the fundus (type 1), posterior slippage of the stomach (part of the bursa omentalis; type 2), and complete slippage of the anterior and posterior part of the stomach (type 3).

Slippage can occur for different reasons. The most common causes are incomplete anterior suturing of the lateral posterior part of the gastric fundus, use of absorbable sutures, and suture disruption due to vomiting. Because of the potential for slippage, the degree of anterior fixation has been extended, and at least four sutures are now used to ensure that all the ventral surface of the band is covered. Importantly, these sutures must be placed in the muscle of the gastric wall above the band. Placing these sutures with the balloon of the calibration tube filled greatly facilitates this step. Without this distension, some sutures may be placed only into the fat pad over the esophagogastric junction.

If the band is placed through the bursa omentalis without posterior fixation, posterior slippage can occur.

In our experience with 307 patients, 12 cases of slippage occurred (3.9%), four of which were of an anterior type (type 1), seven of a posterior type (type 2), and only one of a total slippage anterior and posterior (type 3). The type 3 slippage developed because of a band placed through the bursa and after a large dissection on the lesser curvature. Primary malpositioning of the band can be a second reason for this type of slippage. The only way to avoid this complication completely is to put the band around the cardia or the distal esophagus, thus averting the formation of a proximal gastric pouch.

In cases of pouch dilation, early desufflation of the LAP-BAND and insertion of a tube into the pouch will prevent slippage. Pouch dilation is reversible if recognized and treated at an early stage [17]. However, the pouch should be considered an early sign of slippage.

If the slippage occurs, treatment can be carried out laparoscopically by reconstruction or band removal, which is the least desirable. Depending on the surgeon's laparoscopic experience, repositioning with and without opening of the band is a viable option. Opening of the band and retroesophageal placement of a new band is the safest and most effective technique.

Careful preoperative selection of the patients and prudent postoperative management are vital for normalization of body mass and prevention of complications. There is a lack of objective criteria for patient selection, and the risk–benefit ratio must be considered in every case. Patients whose history of obesity is longer than 5 years, and whose body mass index exceeds 39 are potential candidates if they are ready to face an operation and change their nutritional habits and way of life. Patient compliance is of major importance for lasting success.

Bulimia in the patient's history is one possible contraindication for LASGB because patients with this condition exhibit recurrent overeating with consistent vomiting. In these patients, abundant fixation of the band would seem necessary. Our population of 307 patients included two cases of bulimia with early postoperative slippage. In both cases, the stomach was fixed after it was repositioned at the right and left crus by means of two nonabsorbable sutures. The postoperative courses were uneventful, with follow-up evaluations at 24 and 27 months.

Alvarez-Cordero et al. [1] reported similar results using this technique of fixation during laparoscopic placement of the LAP-BAND around the esophagus ("Mexican technique"). They did not create a real gastric pouch, so dilation of the esophagus occurred much faster than after classic gastric restrictive procedures (LASGB). In addition, no cases of slippage were reported after the Mexican technique.

With the necessary experience in laparoscopic surgery, LASGB is a feasible and safe procedure with excellent early postoperative results. The fact that it can be carried out laparoscopically provides high-risk patients with significant advantages: less pain, faster recovery, rapid return to normal activities, better cosmetic results, and a lower rate of postoperative complications. The frequency of complications can be lowered with increasing experience, and possibly by changing the operative technique of band placement and fixation. Longer follow-up periods are needed to determine whether this is the true rate of complications.

It seems that EGP is simpler and safer than RGP. Most of the surgeons starting with LASGB have experience with fundoplication, and there clearly are anatomic landmarks in the EGP technique. With dissection of the posterior esophageal hiatus, a standardized posterior position of the band can be achieved. This is comparable with the conventional open technique.

Gastric perforation during retrogastric tunnel dissection should not occur. Howewer, injury to the esophagus, the posterior vagus nerve, or both is possible. Nevertheless, the high position of the band may have other drawbacks such as development of dysphagia, and band erosion in this position may be very difficult to handle at reoperation.

With the use of EGP, approach problems with the posterior aspect of pouch dilation and slippage are avoided. This technique was developed to prevent posterior slippage. Considering the overall difficulty of LASGB, EGP is simple and rapid to perform and has been associated with a marked reduction in the frequency of a problem that otherwise could prove to be the Achilles heel [13] of LASGB. With the EGP approach, LASGB is effective in producing weight loss, and prospective studies should analyze the incidence of pouch dilations and surgical management using this technique. It is too early to determine whether fewer late dilations of the

pouch will occur with this approach, but if they do occur, surgical management is easier.

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