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A Prospective Randomized Study Between Laparoscopic Gastric Banding and Laparoscopic Isolated Sleeve Gastrectomy: Results after 1 and 3 Years

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Background: Laparoscopic adjustable gastric banding (GB) is the most popular restrictive procedure for obesity in Europe. Isolated sleeve gastrectomy (SG), is less common, but more invasive and with a higher learning curve. The aim of this prospective randomized study was to compare the results of GB and SG after 1 and 3 years of surgery.

Methods: 80 patient candidates for laparoscopic restrictive surgery were operated consecutively and randomly, between January and December 31, 2002, by GB (7M, 33F) or by SG (9M, 31F) (NS). Median age was 36 (20-61) for GB versus 40 (22-65) for SG (NS). Median BMI was 37 (30-47) for GB versus 39 (30-53) for SG (NS). After 1 and 3 years: weight loss, feeling of hunger, sweet eating, gastroesophageal reflux disease (GERD), complications and re-operations were recorded in both groups.

Results: Median weight loss after 1 year was 14 kg (-5 to +38) for GB and 26 kg (0 to 46) for SG (*P*<0.0001); and after 3 years was 17 kg (0 to 40) for GB and 29.5 kg (1 to 48) for SG (*P*<0.0001). Median decrease in BMI after 1 year was 15.5 kg/m^2 (5 to 39) after GB and 25 kg/m^2 (0 to 45) after SG (*P*<0.0001); and after 3 years was 18 kg/m^2 (0 to 39) after GB and 27.5 kg/m^2 (0 to 48) after SG (*P*=0.0004). Median %EWL at 1 year was 41.4% (-11.8 to +130.5) after GB and 57.7% (0 to 125.5) after SG (*P*=0.0004); and at 3 years was 48% (0 to 124.8) after GB and 66% (-3.1 to +152.4) after SG (*P*=0.0025). Loss of feeling of hunger after 1 year was registered in 42.5% of patients with GB and in 75% of patients with SG (*P*=0.003); and after 3 years in 2.9% of patients with GB and 46.7% of patients with SG (*P*<0.0001). Loss of craving for sweets after 1 year was achieved in 35% of patients with GB and 50% of patients with SG (NS); and after 3 years in 2.9% of patients with GB and 23% of patients with SG (NS). GERD appeared *de novo* after 1 year in 8.8% of patients with GB and 21.8% of patients with SG (NS); and after 3 years in 20.5% of patients with GB and 3.1% of patients with SG (NS). Postoperative complications requiring re-operation were necessary for 2 patients after SG. Late complications requiring re-operation after GB included 3 pouch dilations treated by band removal in 2 and 1 laparoscopic conversion to Roux-en-Y gastric bypass (RYGBP), 1 gastric erosion treated by conversion to RYGBP, and 3 disconnections of the system treated by reconnection. Inefficacy affected 2 patients after GB, treated by conversion into RYGBP and 2 patients after SG treated by conversion to duodenal switch.

Conclusion: Weight loss and loss of feeling of hunger after 1 year and 3 years are better after SG than GB. GERD is more frequent at 1 year after SG and at 3 years after GB. The number of re-operations is important in both groups, but the severity of complications appears higher in SG.

Key words: Morbid obesity, gastric banding, sleeve gastrectomy, weight loss, hunger, sweet eating, ghrelin, gastroesophageal reflux, complications

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Introduction

Gastric banding (GB) is the most popular restrictive procedure for morbid obesity in Europe. It is characterized by minimal invasivity, total possibility of reversibility and good weight loss at long-term.[1-8]

Sleeve gastrectomy (SG), described since 1988 by Hess[9] and Marceau[10] during the procedure of duodenal switch and since 1993 by Johnston[11] in an isolated form, is a less common restrictive operation for obesity, with major invasivity and, in our experience, a longer learning curve than GB.

The aim of this prospective randomized study was to compare the laparoscopic adjustable GB and laparoscopic isolated SG in terms of weight loss, feeling of hunger, craving for eating sweets, gastroesophageal reflux disease (GERD), complications and re-operations, reporting the results after 1 year and 3 years.

Materials and Methods

Between January 1 and December 31, 2002, 80 patient candidates for a laparoscopic restrictive operation were operated consecutively and randomly assigned to a GB (40) or SG (40). The characteristics of the patients were similar for the two groups: 7 males and 33 females (GB) versus 9 males and 31 females (SG) (NS), a median age of 36 years (20-61) for GB versus 40 years (22-65) for SG (NS), and a median BMI of 37 kg/m^2 (30-47) for GB versus 39 kg/m^2 (30-53) for SG (NS). Before surgery, 6 patients (15%) of the GB and 8 patients (20%) of the SG group suffered from GERD, requiring daily medical therapy with proton pump inhibitor (PPI).

After 1 year and 3 years, weight loss, feeling of hunger, craving for eating sweets, GERD, complications and re-operations were recorded in both groups.

Data from clinical visits during follow-up permitted evaluation of the modifications of weight loss (kg), the decrease of BMI and the decrease of %EWL. The feeling of hunger and the craving for sweets were evaluated with a questionnaire completed by the patients regarding their changes during follow-up (Table 1). The modification of GERD was estimated by the number of the patients on PPI before and at 1 year and 3 years after the procedure. Barium swallow and blood tests were performed as needed by the clinical status. In case of re-operation, a totally laparoscopic approach was performed.

Table 1. Patient Questionnaire after 1 year and 3 years

- Your feeling of hunger after surgery is: abolished, diminished, the same, augmented, very augmented.
- Your craving for sweets after surgery is: abolished, diminished, the same, augmented, very augmented.

We performed a descriptive analysis of patients' baseline characteristics per group using frequency tabulations for categorical variables and median and range for continuous variables. Possible differences between groups were assessed using chi-square tests for homogeneity for categorical variables and Mann-Whitney tests for continous variables.

The primary outcome for the study, measured after 1 and 3 years of follow-up, was defined as the relative weight loss compared to the ponderal excess before treatment and treated as a continuous variable.

Secondary outcomes included hunger sensation, intake of sweets and modifications of GERD, that were measured compared to the baseline status using a binary scale: decrease versus stabilization or increase as well as occurrence of complications and need for a new surgical intervention.

The distribution of the primary outcome was compared between groups using Mann-Whitney tests. For the secondary outcomes, we used chi-square tests for homogeneity or Fisher's exact test if required by sample size. All reported *P* values are two-tailed, and a *P* value <0.05 was needed to conclude statistical significance.

Surgical Technique

Laparoscopic Adjustable Gastric Banding

GB was performed by the pars flaccida approach, using the gastric balloon to calibrate the closure of the device on 25 mL. The band of Heliogast (Helioscopie, Vienne cedex, France) or AMI (Medical Innovation, Gotzis, Austria) was placed.

Laparoscopic Isolated Sleeve Gastrectomy

After identification of the crow's foot, the stomach was perpendicularly scored. The greater omentum was sectioned close to the gastric wall and medial to the gastro-epiploic vessels using the Ligasure device (Tyco, New Haven, CT). The dissection reached the base of the left diaphragmatic pillar which was entirely freed as well as the base of the right diaphragmatic pillar. A first firing of a linear stapler (EndoGIA 60 mm, Tyco, New Haven, CT) blue or green load, divided the greater curvature in the direction of the

crow's foot. Other firings of the linear stapler divided longitudinally, from the antrum to the angle of His. The anesthesiologist passed down a nasogastric tube of 34-French, in order to guide the gastric division. A No. 1 polypropylene running suture reinforced the staple-line. A leak-test with compressed air demonstrated the integrity of the gastric tube.

Results

The median weight loss after 1 year was 14 kg (-5 to +38) for GB and 26 kg (0 to 46) for SG ($P<0.0001$); and after 3 years was 17 kg (0 to 40) for GB and 29.5 kg (1 to 48) for SG ($P<0.0001$). The median decrease of BMI after 1 year was 15.5 kg/m^2 (5 to 39) for GB and 25 kg/m^2 (0 to 45) for SG ($P<0.0001$); and after 3 years was 18 kg/m^2 (0 to 39) for GB and 27.5 kg/m^2 (0 to 48) for SG ($P=0.0004$) (Table 2). The median %EWL at 1 year was 41.4% (-11.8 to +130.5) after GB and 57.7% (0 to 125.5) after SG ($P=0.0004$); and at 3 years was of 48% (0 to 124.8) after GB and 66% (-3.1 to +152.4) after SG ($P=0.0025$) (Table 2).

The loss of feeling of hunger (abolished or diminished in the questionnaire) after 1 year was recorded in 42.5% of the patients with GB and 75% of the patients with SG ($P=0.003$); and after 3 years this number dropped to 2.9% of the patients with GB and 46.7% of the patients with SG ($P<0.0001$) (Figure 1).

The loss of craving for sweet eating (abolished or diminished in the questionnaire) after 1 year was reported by 35% of the patients with GB and by 50% of the patients with SG (NS); and after 3 years these numbers dropped to 2.9% of the patients with GB and 23.3% of the patients with SG (NS) (Figure 2).

Table 2. Median decrease of BMI and %EWL after 1 and 3 years

	1 year	3 years
BMI		
BAND	15.5 kg/m^2 (5-39)	18 kg/m^2 (0-39)
SLEEVE	25 kg/m^2 (0-45)	27.5 kg/m^2 (0-48)
%EWL		
BAND	41.4% (-11.8 - +130.5)	48% (0-124.8)
SLEEVE	57.7% (0-125.5)	66% (-3.1 - +152.4)

%EWL = percent of excess weight lost, using the Metropolitan Tables.

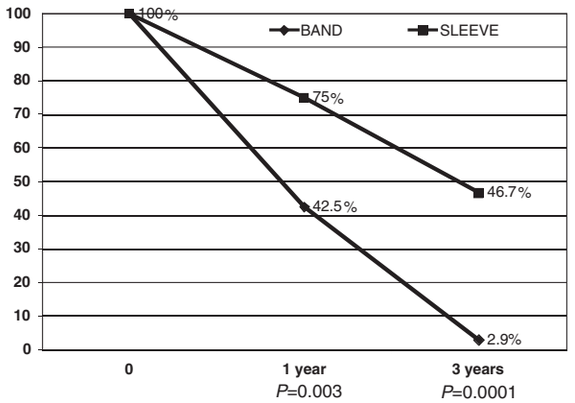

Figure 1. Loss of hunger sensation after 1 and 3 years.

GERD appeared *de novo* after 1 year in 3 out of 34 patients (8.8%) with GB and in 7 out of 32 patients (21.8%) with SG (NS); and after 3 years, in 7 out of 34 patients (20.5%) with GB and in 1 out of 32 patients (3.1%) with SG (NS) (Figure 3). Patients who had been affected by GERD before surgery, noticed its disappearance after 1 year and 3 years, respectively in 5 out of 6 patients (83.3%) with GB and in 6 out of 8 patients (75%) with SG (Figure 4).

The complications not requiring an operation at 1 year after GB were shoulder pain in 3 patients (7.5%), frequent vomiting in 6 patients (15%), poor choice of alimentation in 2 patients (5%); and after SG, gastric pain in 2 patients (5%), frequent vomiting in 1 patient (2.5%) and deficiency of minerals in 2 patients (5%). Complications not requiring an operation at 3 years after GB were shoulder pain in 3 patients (8.5%), frequent vomiting in 10 patients (28.5%), poor choice of alimentation in 17 patients

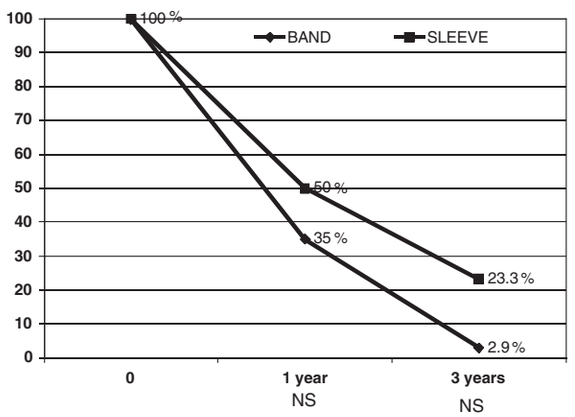

Figure 2. Loss of craving for sweets after 1 and 3 years.

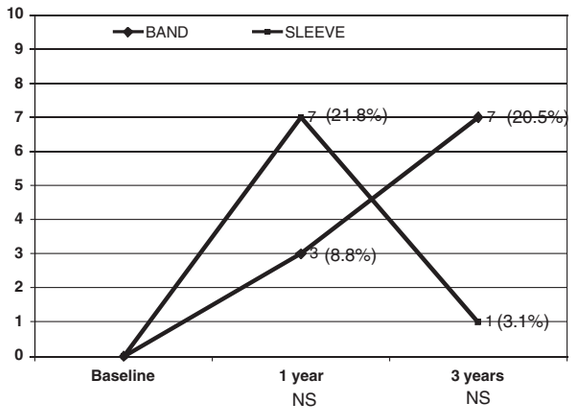

Figure 3. Patients' intake of PPI after 1 and 3 years. (At baseline, 34 patients who underwent GB and 32 patients who underwent SG had GERD).

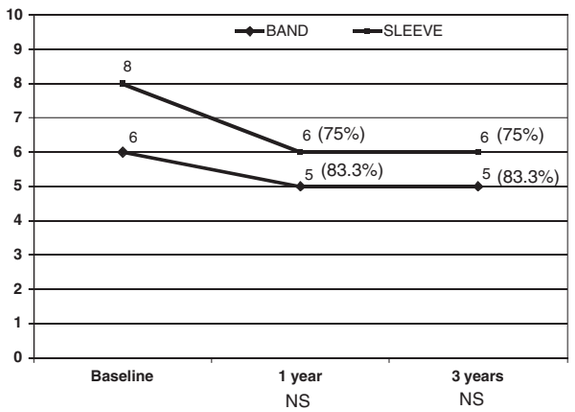

Figure 4. Patients' cessation of PPI after 1 and 3 years.

(48.5%), gastric ulcer in 1 patient (2.8%); and after SG, were frequent vomiting in 5 patients (16.6%), poor choice of alimentation in 8 patients (26.6%), and deficiency of minerals in 3 patients (10%).

The complications requiring re-operation (Table 3) were registered postoperatively in 2 patients with SG: 1 intraperitoneal bleed during the first 24 hours (re-treated by laparoscopy), and 1 ischemia of the sleeve on the 4th postoperative day (requiring a laparoscopic total gastrectomy). Concerning the late complications in the group of GB, 3 patients had a gastric pouch dilation treated by band removal in two and one laparoscopic conversion to Roux-en-Y gastric bypass (RYGBP), 2 patients presented an insufficient weight loss treated by conversion into RYGBP, 1 patient presented a gastric erosion treated by conversion into RYGBP, and 3 patients had a disconnection of the port treated by reconnection. In the group of SG, 2 patients presented insufficient weight loss treated by conversion to laparoscopic duodenal switch (DS).

Discussion

Laparoscopic SG is considered more invasive than GB, and does not have the possibility of "restitutio ad integrum", because of vertical subtotal gastrectomy, where the antrum is conserved besides a small part of the upper stomach. %EWL obtained at 1 and 3 years after GB, are in accordance with data from the literature.[4,6,8] Our results at 1 year after SG are similar to those reported by Langer,[12] Baltasar[13] and Johnston.[11]

Hormonal issues could, firstly explain the differ-

Table 3. Postoperative late complications and weight loss failure

		No.	Treatment
BAND	Postoperative complications	(–)	
	Late complications	(7)	
	-pouch dilation	(3)	2 band removal, 1 RYGBP
	-gastric erosion	(1)	conversion to RYGBP
	-disconnection	(3)	reconnection
	Inefficacy	(2)	conversion to RYGBP
		No.	**Treatment**
SLEEVE	Postoperative complications	(2)	
	-intraperitoneal bleeding	(1)	re-laparoscopy
	-gastric ischemia	(1)	total gastrectomy
	Late complications	(–)	
	Inefficacy	(2)	conversion DS

ences in our study between the two procedures in terms of weight loss and of loss of sensation of hunger. Ghrelin, an acylated upper gastrointestinal peptide, is the only orexigenic hormone, where circulating levels decrease with feeding and increase before meals, achieving concentrations sufficient to stimulate hunger and food intake.[14] This hormone is primarily produced by the enteroendocrine cells of gastric mucosa and to a lesser extent from the duodenum. The procedure of SG involves resection of the gastric fundus, the predominant part of the stomach in the production of ghrelin, resulting in less stimulation of the hunger center. A recent study by Langer[15] compared the ghrelin levels in patients submitted to SG and to GB, showing in patients with SG a significant decrease in plasma ghrelin at day 1 after surgery, confirmed also after 1 and 6 months, in contrast to no change found in patients with GB. Moreover, in patients with GB, the plasma ghrelin levels 1 and 6 months after surgery appeared increased compared with the preoperative levels of the same group. Kotidis[16] measured the serum ghrelin in patients submitted to a SG with DS, before surgery and after 18 months, and concluded that the marked suppression of the hormone seems to be the main cause for the postoperative lack of appetite.

Another mechanism explaining weight loss and differences in loss of hunger sensation between the two groups is a mechanical process, where the appetite is related to gastric emptying. A randomized and double blind trial reported by Bergmann,[17] showed an association between echographic gastric emptying and appetite, where the more the antrum is expanded the less the feeling of hunger. This mechanism is represented by the new anatomy of the stomach after the procedure of SG (Figure 5).

Gastric emptying may be a significant factor in the evolution of GERD after these procedures. In the group after SG, patients were more affected than patients after GB at 1 year and at 3 years these results were reversed. After SG, a lack of gastric compliance and emptying appeared at 1 year, whereas an increased gastric compliance and clearance was present after 3 years, likely resulting in the reduced incidence of GERD.[18] Additional factors involved in GERD after SG could be the anatomical changes in the angle of His, which is one of the gastroesophageal protective mechanisms.[19] During the procedure of SG, this angle is usually blunted. The frequent consequence is the immediate appearance of GERD in previously asymptomatic patients, as shown by our results. After 3 years, a smaller number of patients with SG complained of GERD, probably because of restoration of the angle of His, as evidenced on barium swallow (Figure 6).

On the other hand, Dixon et al[20] have demonstrated a rapid and major improvement of GERD in patients submitted to GB, probably because the GB directly acts as an antireflux mechanism. In our series, patients submitted to GB and affected by GERD before surgery, showed an improvement after 1 year, which was confirmed also after 3 years. However, late *de novo* GERD appeared in 20.5% of patients with GB. This agrees with the literature, where a high incidence of long-term GERD and esophagitis is reported in patients after GB.[21,22]

A frequent cause of failure of restrictive surgery is said to be sweet eating, appearing *de novo* or persisting despite the procedure. In our study, craving for sweets reappeared after 3 years, which was more pronounced (but not statistically significant) for GB than for SG.

We divided the complications into minor and major (requiring re-operation). Our results demonstrated a higher number of minor complications after GB than

Figure 5. Barium swallow in a patient 1 month after SG.

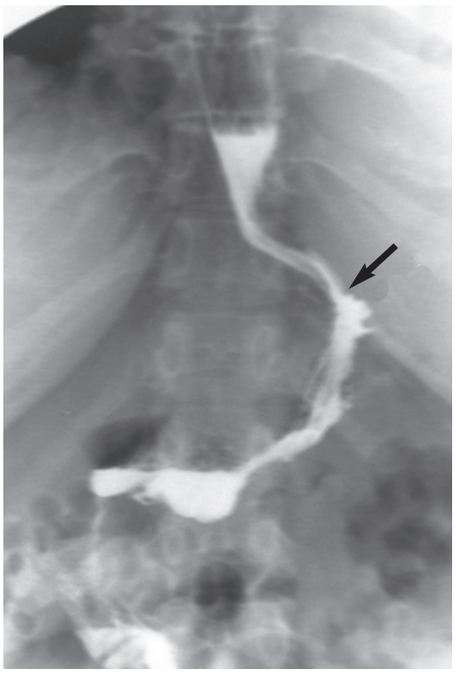

Figure 6. Barium swallow in a patient 3 years after SG. Arrow points to restored angle of His.

SG. The shoulder pain can be explained by radiation of pain from the left upper quadrant, where the port is positioned just distal to the costal margin. Frequent vomiting is related to poor alimentary education and less loss of hunger, characterized by the sudden and fast filling of the gastric pouch. Regarding the SG, frequent vomiting and poor choice of alimentation are probably related to the same mechanism as with GB, but the mineral deficiency for vitamin B_{12} and iron is most likely from lower production of intrinsic factor and acid by the reduced stomach.

Both groups encountered major complications, requiring re-operation during the early and late postoperative period. However, whereas the number of major complications was higher after GB than SG, the importance of these complications is less after GB than after SG. After GB, one case of gastric pouch dilation and three cases of disconnection of the system occurred, concurring with the literature.[1,4] In the SG group, there were two major complications: one intraperitoneal bleed and one ischemia of the sleeve. The first was treated by relaparoscopy with control of bleeding, and the other was life-threatening and required a total gastrectomy. This ischemia was related to poor vascularization to the sleeve, caused by damage of the left gastric vessels during the initial surgery. To obtain a narrow gastric tube it is mandatory during gastric resection to perform an accurate adhesiolysis between the posterior wall of the stomach and the pancreatic body and tail, and the left gastric artery is at danger during this dissection.

The most important late problem presented in our series was insufficient weight loss, more pronounced after GB than after SG. In cases of GB, one possible treatment is re-operation to a RYGBP. Reports have found good results with RYGBP after failure of GB.[23-27] Conversion of GB to RYGBP can also be an alternative in cases of other complications, such as gastric pouch dilation and gastric erosion, encountered in 2 of our patients in the GB group. On the other hand, in the case of insufficient weight loss after SG, it appears logical to add a malabsorptive process to the already performed restrictive operation. SG is often considered as the first step of a DS in cases of super-obese patients.[28-30] We were fortunate not to encounter a case of staple-line dehiscence, which can require challenging treatment.[31]

In conclusion, weight loss and loss of feeling of hunger after 1 year and 3 years were better after SG than GB. GERD was more frequent at 1 year after SG but at 3 years after GB. The number of re-operations was important in both groups, but the severity of complications were higher after SG.

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