Surg Endosc (2002) 16: 1631–1635
DOI: 10.1007/s00464-001-9225-0

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SURGICAL ENDOSCOPY
and Other Interventional Techniques

Abnormal esophageal acid exposure is common in morbidly obese patients and improves after a successful Lap-band system implantation

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Received: 12 March 2001/Accepted in final form: 1 April 2002/Online publication: 20 June 2002

Abstract
Background: The relation between gastro-esophageal reflux disease (GERD) and obesity is controversial. The laparoscopic adjustable gastric band (LAGB) procedure is effective for morbid obesity. Its indication in the presence of GERD, however, is still debated. This study aimed to investigate esophageal symptoms, motility patterns, and acid exposure in morbidly obese patients before and after LAGB placement.
Method: For this study, 43 consecutive obese patients were investigated by a standardized symptoms questionnaire, stationary manometry and 24-h ambulatory pH-metry, and 16 patients with abnormal esophageal acid exposure were reevaluated 18 months after LAGB placement.
Results: Symptom scores and abnormal esophageal acid exposure were found to be significantly higher, Lower Esophageal Sphincter (LOS) pressure was significantly lower in obese patients than in control subjects. After LAGB, esophageal acid exposure was significantly reduced in all but two patients, who presented with proximal of gastric pouch dilation.
Conclusions: There is a high prevalence of GERD in the obese population. Uncomplicated LAGB placement reduces the amount of acid in these patients with abnormal esophageal acid exposure.

Key words: Gastro esophageal reflux disease — Obesity — Laparoscopic adjustable Gastric band — Reflux symptoms — pH Measurements — Esophageal motility

Presented in part at the X European Symposium on Neurogastroenterology and Motility, Bologna, Italy, 14–17 June 2000
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Gastro-esophageal reflux disease (GERD) and obesity are both common conditions in developed countries. The common belief is that obesity represents an important risk factor in GERD [2]. In fact, weight loss commonly is recommended as part of first-line GERD management [3], but few data are currently available to support the assumption that body weight per se predisposes to GERD [13, 20]. Lundell et al. [14] reported that massive obesity is not associated with an increased prevalence of GERD. However, other studies have reported that excessive body weight is significantly associated with esophagitis, largely through an increased incidence of hiatal hernia [23].

Findings have shown surgery to be the only method for achieving significant weight loss maintenance, with reversal of co-morbidities, rehabilitation, and an acceptable complication rate [7]. The laparoscopic Adjustable gastric band (LAGB) procedure is one of the most popular treatment options, but it is not clear whether such a procedure can be performed safe in presence of reflux disease or hiatal hernia [5, 18]. Our preliminary data suggest that LAGB with Lap-band system (Bioenterics, Carpinteria, CA, USA) implantation could be a satisfactory treatment for obesity and GERD [1]. Therefore, for further evaluation of its role in obese patients with GERD, the current study aimed to

- investigate the prevalence of reflux symptoms, esophageal motility patterns, and esophageal-impaired acid exposure in a large series of morbidly obese subjects.
- evaluate the outcome after LAGB in obese patients with abnormal esophageal acid exposure.

Materials and methods

Participants

This study enrolled 43 consecutive obese patients ranging in age from 17 to 59 years. All these patients were referred for Lap-band system implantation because of massive obesity [4].

Table 1. Demographic and clinical parameters and esophageal symptoms of obese patients (mean ± SD)

	Obese patients (n = 43)	Obese patients with abnormal acid exposure (n = 22)	Obese patients with normal acid exposure (n = 21)	Control subjects (n = 44)
Male/female ratio	6/37	5/17	1/20	7/37
Age (years)	33.2 ± 10.7	33.6 ± 11.7	32.7 ± 9.9	33.3 ± 7.4
Weight (kg)	120.0 ± 20.9[a]	124.7 ± 23.9	114.9 ± 16.2	61.4 ± 8.7
Body mass index (kg/m^2)	44.7 ± 5.2[a]	45.6 ± 5.9	43.8 ± 4.3	22.0 ± 2.8
Median (IQR)	44.4 (7.7)	45.4 (8.7)	43.2 (6.7)	21.0 (4.7)
Esophageal symptom score	2.1 ± 2.8[a]	3.3 ± 3.2[b]	0.8 ± 1.6	0.9 ± 2.0

[a] $p < 0.05$ vs control subjects
[b] $p < 0.05$ with abnormal vs normal acid exposure and control subjects
IQR, interquartile range

Surgical intervention

The operation was performed with the patient under general anesthesia, in lithotomy and reverse Trendelenberg (30°–45°) positions, and with closed CO_2 pneumoperitoneum. Five trocars were used in all the procedures. Patients with and without hiatal hernia were treated with gastric Lap-band system implantation (Bioenterics, Carpinteria, CA, USA) with a 15-ml virtual pouch calibration. Two patients experienced hypertension; one underwent cholestystectomy and one had diabetes mellitus. Seventeen patients smoked.

The diagnostic workup included an upper gastrointestinal endoscopy and an upper gastrointestinal barium meal with the patient in Trendelenberg position to assess for the presence of esophagitis and hiatal hernia.

As general population sample, 44 volunteers ranging in age from 23 to 47 years formed the control group for symptom questionnaires (Table 1). Their mean age did not differ statistically from that of the patient group.

Nine healthy volunteers (5 women and 4 men; mean age, 32.9 ± 11.3 years; range, 18–46 years) formed the control group for the manometric evaluation. None of these subjects reported gastrointestinal symptoms or had any history of abdominal surgery (except appendectomy). Their age did not differ statistically from that of the study patients. After the aims of the investigation had been carefully explained, informed consent was obtained from all obese patients and control subjects. The study was conducted in accordance with the Declaration of Helsinki and authorized by the Ethical Committee of the Federico II University of Naples.

Protocol

The obese patients underwent an assessment of esophageal symptoms, esophageal motility, gastroesophageal reflux patterns. They then were divided into two groups according to the presence of normal esophageal acid exposure (pH < 4 for less than 4.75% of the total time) or abnormal esophageal acid exposure (pH > 4 for more than 4.75% of the total time) [19]. At 18 months after Lap-band® system implantation, the patients with abnormal esophageal acid exposure were reinvestigated. The control subjects underwent only a basal assessment of esophageal symptoms and motility.

Assessment of the esophageal symptoms

The esophageal symptom score was calculated by administering to the obese patients and control subjects a questionnaire dealing with the frequency and intensity of heartburn, regurgitation, dysphagia, and chest pain. Symptom frequency was scored as 0 (absent), 1 (less than 2 days a week), 2 (3 to 5 days a week), or 3 (6 to 7 days a week). The symptom intensity was scored as 0 (absent), 1 (mild), 2 (moderate), or 3 (severe) [8]. For each obese patient and control subject, the scores for frequency and intensity were calculated for each symptom. When more than one symptom was present, the cumulative score was calculated.

Assessment of the esophageal motility pattern

Esophageal manometry was performed in accordance with a previously described technique [8]. Briefly, a six-lumen standard esophageal polyvinyl chloride (PVC) catheter (Mui Scientific, Ontario, Canada) with the three distal holes arranged radially on the same level at 120° and the proximal holes spaced 5 cm apart 5, 10, and 15 cm from the tip was used. The catheter was perfused with a low-compliance pneumohydraulic infusion pump (SensorMedics, Milan, Italy) at a rate of 0.5 ml/min. Each lumen was connected to an external pressure transducer. The analog signals were recorded on a computer polygraph and analyzed semiautomatically using Menfis software (Menfis, Bologna, Italy).

Lower esophageal sphincter (LOS) pressure was assessed during two stationary pull-throughs. Esophageal body motility and LOS relaxation were tested by at least 10 wet swallows of 5 ml of water at 30-s intervals. Relaxations were considered complete if LOS pressure fell at least 80%. Wave amplitude and duration were measured with the four openings positioned 3, 8, 13, and 18 cm, respectively, above the LOS. The individual values for the recording sites 3 cm and 8 cm above the LOS also were combined and designated as distal esophageal contractile amplitude and duration.

Assessment of gastroesophageal reflux pattern

Esophageal pH measurements were performed on an ambulatory basis over 24 h. A monoglass pH electrode (Mettler-Toledo AG, Greifensee, Switzerland) was passed through, secured to the nose with the electrode positioned 5 cm above the LOS as previously detected manometrically, and connected to a data logger (LEM, Bologna, Italy). The patients were encouraged to adhere to their usual diet and mealtimes. They were carefully instructed to activate the event market and to record on a diary card the timing of symptoms, meals, drinks, and body position. A computer program (Genesi 4, version 8.0) was used to analyzed all pH data. The time that esophageal pH was below 4 (esophageal acid exposure time) was expressed as a fraction (percentage) of the total registration period and as a fraction of the period spent in the upright and supine positions. Abnormal esophageal acid exposure was considered to be present when more than 4.75% of the total time showed a pH less than 4 [19].

Statistical analysis

The difference in prevalence of hiatal hernia and complete LOS relaxations was statistically analyzed using the chi-square test. The esophageal symptoms score, LOS pressure, LOS length, esophageal waves amplitude and duration were statistically analyzed using the Mann–Whitney U test. Ages, weight, and body mass index were compared using the Student's t-test for independent samples. For comparisons of data before and after Lap-band system implantation in patients with abnormal esophageal acid exposure, the McNemar and Wilcoxon tests for paired data were used. Spearman rank correlation was used for nonparametric data, as appropriate. Data are presented as mean ± standard deviation unless otherwise indicated. All p values less than 0.05 were considered statistically significant.

Table 2. Reflux parameters of obese patients

Time for pH < 4	Median (IQR) % (range)
Total time	4.9 (1.1–8.9)
Time supine	3.1 (0.4–9.5)
Time upright	3.3 (1.0–10.6)

	Weight		BMI	
Reflux variable	*r*	*p*	*r*	*p*
Time (%) with pH < 4				
Total	0.19	0.3	0.13	0.4
Supine	0.17	0.3	0.11	0.5
Upright	0.3	0.9	0.0	1.0

IQR, interquartile range; BMI, body mass index

Results

Before Lap-band system implantation

The demographic and clinical parameters are shown in Table l. Two patients showed a mild macroscopic alteration of the esophageal mucosa, and 13 patients evidenced hiatal hernia.

Gastro-esophageal reflux pattern

Table 2 shows the influence of morbid obesity on 24-h pH measurements. On an individual basis, 22 of 43 patients (51%) had abnormal esophageal acid exposure. The percentage of total time for a pH less than 4 was 1.1 (ranges, 0.6–2.5) and 8.9 (ranges, 5.9–11.6) median interquartile range (IQR) in patients with normal and abnormal esophageal exposure, respectively. Patients with abnormal esophageal acid exposure had a significantly higher prevalence of hiatal hernia than patients with normal esophageal acid exposure (10/22 vs 3/21; $p < 0.05$). Neither weight nor body mass index were significantly correlated with the percentage of total time for a less than 4 or for the upright or supine position (Table 2).

Esophageal symptoms

The cumulative intensity–frequency symptom score was significantly higher in obese group than in control group (Table 1). The intensity–frequency scores for heartburn and regurgitation were higher than for dysphagia. Obese patients with abnormal esophageal acid exposure showed a higher significant cumulative score (Table 1).

Obese patients with hiatal hernia had a significantly higher cumulative score than obese patients without hiatal hernia (3.62 ± 2.84 vs 1.41 ± 2.64; $p \le 0.05$). A positive rank correlation was present between the cumulative score and the percentage of total time with a pH less than 4 ($r = 0.50$; $p = 0.001$).

Esophageal motility pattern

The LOS pressure for all the obese patients was significantly lower than that for the control group (11.9 ± 5.3 vs 15.9 ± 2.7 mmHg; $p < 0.05$). Obese patients with abnormal esophageal acid exposure showed a significantly lower LOS pressure than patients with normal esophageal acid exposure (9.9 ± 3.8 vs 14.0 ± 6.1 mmHg; $p < 0.05$). Only one patient showed incomplete LOS relaxations. A negative rank correlation was found between LOS pressure and the percentage of total time with a pH less than 4 ($r = -0.41$; $p = 0.007$), and between LOS pressure and the cumulative esophageal symptoms score ($r = -0.32$; $p = 0.027$).

There was no difference in LOS length, esophageal peristaltic waves amplitude, or duration between patients and control subjects, and between patients with normal and those with abnormal esophageal acid exposure.

After Lap-band system implantation

Of 22 obese patients with abnormal esophageal acid exposure, 16 were studied before and 18 months after Lap-band system implantation. The remaining six patients were excluded from analysis: four did not fulfill the inclusion criteria or perform the surgical procedure; one patient underwent laparoscopic band removal for early dislocation; and one patient was pregnant.

All the patients showed a normal macroscopic appearance of esophageal mucosa. In two patients, upper gastrointestinal barium meal showed the presence of proximal gastric pouch dilation. The overall complication rate after Lap-band system implantation in patients with abnormal esophageal acid exposure was 3/18 (16.6%). Two patients underwent laparoscopic band removal: one for early dislocation and the other for gastric pouch dilation. The last patient underwent only band deflation

Esophageal symptoms

The cumulative intensity–frequency symptoms score was not modified after Lap-band system implantation (4.19 ± 3.23 vs 2.31 ± 2.57; $p = 0.1$). The heartburn and regurgitation scores were significantly decreased,

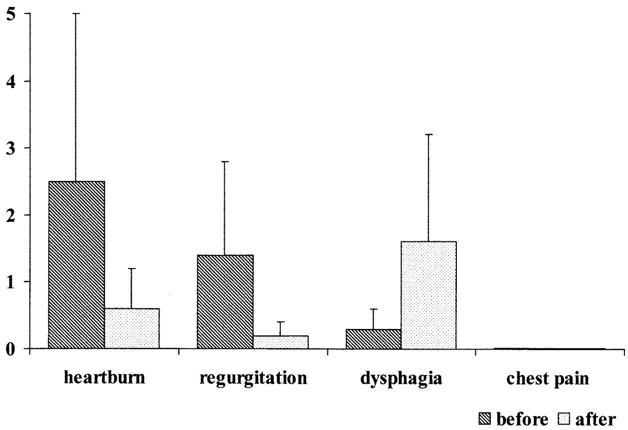

Fig. 1. Reflux symptoms before and after Lap-band system implantation.

Table 3. Esophageal pressure data of obese patients (n = 11) with abnormal acid exposure before and after Lap-band system implantation (mean ± SD)

	Before Lap-band	After Lap-band
LOS pressure (mmHg)	8.6 ± 2.6[a]	14.8 ± 4.8
LOS length (cm)	3.5 ± 1.0[a]	4.7 ± 0.7
Complete LOS relaxations (%)	91	45
Amplitude (mmHg)		
Upper esophagus	67.3 ± 29.0	82.6 ± 43.5
Middle esophagus	41.8 ± 17.4	41.1 ± 11.5
Distal esophagus	79.3 ± 30.4	93.4 ± 35.7
Duration (s)		
Upper esophagus	2.0 ± 0.4[a]	2.4 ± 0.3
Middle esophagus	2.8 ± 0.7[a]	3.7 ± 1.0
Distal esophagus	3.4 ± 0.7	3.9 ± 1.0

LOS, lower esophageal sphincter
[a] $p < 0.05$ before vs after Lap-band system implantation

whereas the dysphagia score was significantly increased (Fig. 1)

Esophageal motility pattern

Eleven patients gave their consent for a further manometric and pH-metry examination. After Lap-band system implantation, the mean pressure as well as the length of LOS and esophageal wave duration were significantly increased (Table 3). There were no differences before and after Lap-band system implantation in any other parameters considered: LOS relaxations, percentage of peristaltic waves, and waves amplitude.

Gastro-esophageal reflux pattern

In the two patients with proximal gastric pouch dilation, the percentage of total time with a pH less than 4 was very high (15.5% and 26.1%). Figure 2 shows the parameters of gastroesophageal reflux before and after Lap-band system implantation in the remaining nine patient. The results showed the significantly decreased

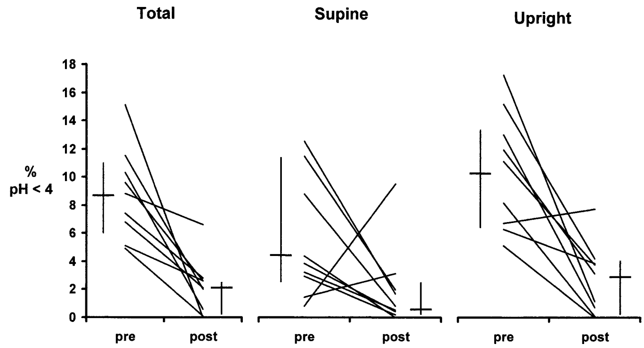

Fig. 2. Esophageal acid exposure before and after Lap-band system implantation.

percentage of total, upright, and supine time with a pH less than 4.

Discussion

Spechler [21] defined gastro-esophageal reflux disease as "any symptomatic condition, anatomic alteration, or both that results from the reflux of noxious material from the stomach into the oesophagus" [21]. The disorder is extremely common, with some studies suggesting that up to 25% of the adult population present the typical esophageal symptoms: heartburn and regurgitation, often in the presence of normal endoscopic findings [9]. The pathogenesis of GERD is multifactorial. Abnormalities include a defective antireflux barrier (impairment of LOS and hiatal hernia), impaired esophageal clearance, altered esophageal mucosal resistance, and delayed gastric emptying [11]. The most sensitive and objective means for assessing reflux is ambulatory 24-h esophageal pH monitoring.

The current study showed that the cumulative esophageal symptom score was significantly higher in obese patients than in the general population, especially in those with hiatal hernia, despite a low prevalence of esophagitis. More than one-half of our patients presented with abnormal oesophageal acid exposure according to criteria of the Italian multicenter GISMAD GOR study group [19]. A higher prevalence of hiatal hernia and a significant correlation between the total time with a pH less than 4 and the intensity–frequency symptoms score were observed in such patients.

The mechanisms underlying GERD in obesity are unknown [2, 3, 13, 14, 20, 23]. Obese patients have higher abdominal pressure than lean individuals (22), which increases the gastro-esophageal pressure gradient. Alternatively, adipose tissue may be laid directly in the diaphragmatic hiatus, thereby adversely affecting the pinch mechanism, which helps to maintain LOS pressure [6].

In our patients, the LOS pressure was significantly lower than in the control subjects and negatively correlated with the percentage of time with a pH less than 4. This significant correlation suggests that although the LOS pressure might not be a reliable indicator of GERD, abnormalities of LOS play some role in increasing esophageal acid exposure. This study did not show that obesity might influence the tendency for acid reflux in a graded fashion, or whether a threshold value exists above which obesity can be of importance. Therefore, we cannot conclude that obesity is a significant predisposing condition for GERD. There is confusion in the literature whether weight loss reduces reflux in patients with GERD [12, 15]. Our data cannot address this point because the presence of Lap-band system implantation itself could be a protection against reflux [10].

The pH measurements 18 months after Lap-band system implantation showed that abnormal esophageal acid exposure was reduced in all but two patients with proximal gastric pouch dilation. Moreover, regurgitation and heartburn had decreased, whereas dysphagia had increased significantly, the pressure and length of LOS risen significantly, and the duration of esophageal waves had increased. These results confirm our preliminary data [1], suggesting that Lap-band system implantation reduces the abnormal esophageal acid exposure frequently present in obesity. As a possible underlying mechanism, the Lap-band system implantation itself could act as an Angelchik prosthesis with an increased LOS pressure and length, but also with the same dysphagia, complication which does not reliably disappear, although most patients do learn to chew their food more carefully, wash it down with fluid, and take particular care with certain foods, especially bread and meat [16].

The LAGB with Lap-band system implantation is one of the most popular treatment options in Europe because of its technical simplicity, lack of stomach invasiveness, good weight reduction, and particularly its complete reversibility [7]. The most frequent complications are pouch dilations and band erosions [17].

Recently, some authors have reported that GERD is more severe after gastric banding, probably because of a partial outlet obstruction followed by pouch dilation and retention of gastric contents. Therefore, they concluded that gastric banding does not demonstrate antireflux properties [18]. In contrast, Dixon and O'Brien [5] demonstrated gastroesophageal reflux improvement soon after surgery and hypothesized that the placement of the band probably acts directly to reduce reflux. Our results support the observation that proximal gastric pouch dilation could lead to retention and reflux of pouch content up to the esophagus. The esophagus cannot propel the refluxate into the stomach against the obstruction imposed by the gastric banding, but in our group of patients, only two had proximal gastric pouch dilations.

Further studies are necessary to investigate any possible alterations in the smooth muscle of the esophagus several years after Lap-band system implantation.

In conclusion, we note that in our obese population, a high prevalence of abnormal esophageal acid exposure was present, without frequent mucosal damage. Uncomplicated LAGB placement reduces the amount of acid in patients with abnormal esophageal acid exposure, probably acting mechanically as an Angelchik prosthesis.

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