

# Esophageal Dysmotility Disorders After Laparoscopic Gastric Banding—An Underestimated Complication

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**Objective:** To evaluate the effects of laparoscopic adjustable gastric banding (LAGB) on esophageal dysfunction over the long term in a prospective study, based on a 12-year experience.

**Background:** Esophageal motility disorders and dilatation after LAGB have been reported. However, only a few studies present long-term follow-up data.

**Methods:** Between June 1998 and June 2009, all patients with implantation of a LAGB were enrolled in a prospective clinical trial including a yearly barium swallow. Esophageal motility disorders were recorded and classified over the period. An esophageal diameter of 35 mm or greater was considered dilated.

**Results:** Laparoscopic adjustable gastric banding was performed in 167 patients (120 females and 47 males) with a mean age of  $40.1 \pm 5.2$  years. Overall patient follow-up was 94%. Esophageal dysmotility disorders were found in 108 patients (68.8% of patients followed). Esophageal dilatation occurred in 40 patients (25.5%) with a mean esophageal diameter of  $47.3 \pm 6.9$  mm ( $35.0$ – $94.6$ ) after a follow-up of  $73.8 \pm 6.8$  months (36–120) compared with  $26.2 \pm 2.8$  mm (18.3–34.2) in patients without dilatation (diameter of  $<35$ mm) ( $P < 0.01$ ). Thirty-four patients suffered from stage III dilatation (band deflation necessary) and 6 from stage IV (major achalasia-like dilatation, band removal mandatory). In 29 patients, upper endoscopy was carried out because of heartburn/dysphagia. In 18 patients, the endoscopy was normal; 9 patients suffered from gastroesophageal reflux disease, 1 from a stenosis, and 1 from a hiatus hernia.

**Conclusions:** This study demonstrates that esophageal motility disorders after LAGB are frequent, poorly appreciated complications. Despite adequate excess weight loss, LAGB should probably not be considered the procedure of first choice and should be performed only in selected cases until reliable criteria for patients with a low risk for the procedures long-term complications are developed.

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Most esophageal motility disorders are related to gastroesophageal reflux disease (GERD), which is the most common pathologic condition of the foregut in the Western world and accounts for about 75% of all esophageal diseases.<sup>1</sup> Primary esophageal motility disorders occur in the absence of GERD and present with specific manometric patterns classified as hypertensive lower esophageal sphincter, hypercontracting esophagus (nutcracker esophagus), diffuse esophageal spasms, and achalasia.<sup>2,3</sup> The prevalence of obesity significantly increased over the past decades and is recognized by the World Health Organization as a global epidemic.<sup>4</sup> Severe obesity is a life-threatening chronic disease with numerous comorbidities such

as coronary heart disease, type 2 diabetes mellitus, hypertension, dyslipidemia, stroke, obstructive sleep apnea, nonalcoholic steatohepatitis, osteoarthritis, and the polycystic ovary syndrome.<sup>5,6</sup> Another obesity-associated morbidity is GERD, for which obesity has been identified as an independent risk factor.<sup>7–10</sup> Thus, weight loss is usually part of the recommendations for overweight patients with GERD.<sup>8</sup>

Since its introduction in 1993, laparoscopic adjustable gastric banding (LAGB) has become one of the most frequently performed surgical procedures for treating morbid obesity.<sup>11–14</sup> This relatively simple, minimally invasive, reversible procedure has been associated with a high success rate and low morbidity and mortality.<sup>15–20</sup> Many longer-term complications such as pouch dilatation and slipping, band migration, band leakage, infection, and obstruction have been described in the literature.<sup>18–29</sup> However, less attention has been paid to esophageal problems after LAGB.<sup>30–33</sup> In fact, concern has arisen regarding esophageal dysfunction, such as esophageal motility disorders, esophageal dilatation, or GERD after gastric banding over the long-term.<sup>32,34–38</sup> The aim of this prospective study was to evaluate the effects of LAGB on long-term esophageal dysfunction, based on a 12-year experience.

## MATERIALS AND METHODS

### Patient Data

Between June 1998 and June 2009, all patients with implantation of an LAGB were enrolled in a prospective clinical trial with a minimum follow-up of 6 months. The preoperative evaluation of patients followed the guidelines of the Swiss Study Group for Morbid Obesity.<sup>39</sup> Patients were seen during a multidisciplinary consultation attended by a surgeon, an internist, a dietitian, a psychologist, and an exercise instructor. Patients were considered as candidates for LAGB placement when the following conditions were met: body mass index (BMI) greater than  $40 \text{ kg/m}^2$  or greater than  $35 \text{ kg/m}^2$  with comorbidities, failure of competent conservative treatment for 2 years, usually not older than 60 years, no significant intake of sweets or alcohol, and no concurrent psychiatric illness. In every patient, upper endoscopy was performed as part of the preoperative protocol. All patients were repeatedly instructed concerning the importance of an adapted diet, disciplined eating habits, and regular exercise. Written informed consent was obtained from all patients. A computerized database was used to prospectively gather patient data. Data are expressed as median and range or as mean  $\pm$  SD. For statistical analysis the Fisher exact test was employed with  $P < 0.05$  taken as the level of significance.

### Operative Technique

A standard 5-trocar pars flaccida technique was used to place the LAGB, as previously described.<sup>18</sup> In all the patients, the Swedish adjustable gastric band (Obtech, Ethicon Endo-Surgery, Johnson & Johnson) was implanted. After an upper gastrointestinal (GI) series of the gastroesophageal region 6 to 10 hours postoperatively (baseline investigation), patients were permitted to start a liquid diet for 3 days and were discharged on the second or third postoperative day. Detailed

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dietary instructions were provided, including a semiliquid diet for days 3 to 8 and solid food (free of fiber) for days 8 to 21.

### Follow-up Protocol

Four weeks after the operation, initial band filling was performed by injecting 2 to 3 mL of a radiology contrast medium (Iopamiro isotonic 200 mg; Bracco) under aseptic conditions. Further follow-up including subsequent band adjustments was carried out after 3, 6, 9, and 12 months and yearly thereafter in patients with an uneventful course. The band filling was carefully adjusted to avoid solid food intolerance and to obtain a reduction of food intake to approximately one-third to one-half of preoperative meal volumes. Indications for inflation were less than 1 kg weight loss per month or absence of fullness reported during follow-up visit. Deflation or no band filling was indicated for obstruction, severe solid food intolerance, nightly aspiration, or vomiting more than twice per week. Band adjustments were done on an outpatient basis; radiological guidance was usually not necessary. Vitamin supplementation was prescribed for 3 months and whenever indicated thereafter. Blood tests were performed every 12 months. All patients were required to undergo a barium swallow every year to evaluate status of the band, pouch size, and esophageal dilatation. Upper endoscopy was performed only when indicated.

### Radiological Examination

Upper GI series were performed using fluororadiographic equipment and a water-soluble contrast agent (Gastrografin; Schering) postoperatively and a barium swallow (Prontobarium HD; Bracco) for subsequent radiological studies and were interpreted by an attending radiologist. Key steps in the radiological technique included (1) supine plain abdominal fluoroscopy to check the band, the tubing, and the position of the access port; (2) upper esophagogastric fluoroscopy showing the pouch size and the passage through the band stoma with the patient upright; and (3) upper esophagogastric fluoroscopy showing the band to measure the maximal vertical diameter of the esophagus in the upright patient.

### Definitions

*Esophageal diameter* was directly measured in the digital x-ray images using CwApiTool (Centricity Enterprise Web, GE Medical Systems) with an internal control. An esophageal diameter of 35 mm or more was considered dilated.<sup>32</sup> *Normal esophageal diameter* was defined as less than 35 mm. *Esophageal dilatation* was classified according to Dargent<sup>33</sup> (stages I–IV). The parameters for the radiological classification were as follows: (1) stage I, moderate dilatation with delayed emptying; (2) stage II, hypercontracting esophagus (nutcracker esophagus); (3) stage III, significant dilatation with anterior/posterior pouch slipping; and (4) stage IV, major achalasia-like dilatation.

## RESULTS

One hundred sixty-seven patients with a mean age of 40.1 ± 5.2 years (range, 19–68 years) underwent LAGB in our department between June 1998 and June 2009; 120 were females and 47 were males. The preoperative mean weight, BMI, and excess weight were 124.7 ± 7.9 kg (range, 79–187 kg), 44.2 ± 4.6 kg/m<sup>2</sup> (range, 33–65 kg/m<sup>2</sup>), and 65.9 ± 7.1 kg (range, 32–116 kg), respectively. Preoperative characteristics of the patients are summarized in Table 1.

Medical history revealed upper GI problems in 11 patients, of whom 5 suffered from GERD and 3 from hiatal hernia. Ninety-five patients had pathological findings in preoperative endoscopy (56.9%), of whom 26 suffered from GERD (mainly grades I and II), 41 from hiatal hernia, and 20 from gastritis (Table 2). *Helicobacter pylori* was

**TABLE 1.** Preoperative Characteristics of the 167 Patients

Parameter	Mean	Range
Age, yr	40.1 ± 5.2	19–68
Weight, kg	124.7 ± 7.9	79–187
Body mass index, kg/m <sup>2</sup>	44.2 ± 4.6	33–65
Excess weight, kg	65.9 ± 7.1	32–116

**TABLE 2.** Pathological Findings in Preoperative Upper Endoscopy (n = 167)

Finding	n	n	%
Gastroesophageal reflux disease		26	15.6
Grade I	17		
Grade II	8		
Grade III	0		
Grade IV	1		
Hiatal hernia		41	24.5
Gastritis		20	12.0
Other		8	4.8
Total		95	56.9

positive in 12% (20 of 167) patients. The postoperative baseline x-ray with upper GI series of the gastro-esophageal region showed a gastric perforation in 1 patient, which was treated conservatively. Overall patient follow-up was 94.0% (157 of 167) with a median follow-up time of 79.9 ± 8.6 months (range, 6–138 months). Duration of follow-up exceeded 2 years in 152 patients (91.0%), 5 years in 114 (68.3%), and 8 years in 66 (39.5%). The follow-up for the available patients at 1, 2, 5, and 8 years was 98.8%, 96.7%, 91.2%, and 84.8%, respectively (Table 3).

Yearly barium swallow studies demonstrated 108 patients with esophageal dysmotility disorders (68.8% of the available patients) at follow-up (Table 4, Figs. 1–3). The average diameter of the esophagus of all patients was 31.6 ± 7.9 mm (range, 18.3–94.6 mm). Esophageal dilatation (diameter of ≥35 mm) occurred in 40 patients (25.5%) with a mean esophageal diameter of 47.3 ± 6.9 mm (range, 35.0–94.6 mm) after a follow-up of 73.8 ± 6.8 months (range, 36–120 months), compared with 26.2 ± 2.8 mm (range, 18.3–34.2 mm) in patients without dilatation (diameter of <35 mm) (*P* < 0.01). Thirty-four patients suffered from stage III dilatation (significant dilatation with anterior/posterior slipping), needing band deflation (Fig. 2). In 6 patients, we found stage IV dilatation (major achalasia-like dilatation), not recovering after band deflation (Fig. 3). Table 5 shows the

**TABLE 3.** Eligible and Available Patients Found at Follow-up

Year After Surgery	Eligible	Total, %	Available	Eligible, %
1	164	98.2	162	98.8
2	152	91.0	147	96.7
5	114	68.3	104	91.2
8	66	39.5	56	84.8

**TABLE 4.** Esophageal Dysmotility/Dilatation at Long-term Follow-up,\* Stages III and IV With Esophageal Diameter of  $\geq 35$  mm

Stage	Description (Radiological Classification)	n	%
I	Moderate dilatation with delayed emptying	26	16.6
II	Hypercontracting esophagus (nutcracker esophagus)	42	26.7
III	Significant dilatation with anterior/posterior pouch slipping	34	21.7
IV	Major achalasia-like dilatation	6	3.8
	Total	108	68.8

\* Staging according to Dargent.<sup>33</sup>**FIGURE 1.** Barium swallow of a 50-year-old patient 7 years postoperatively with stage II esophageal dilatation (hypercontracting esophagus, nutcracker esophagus).

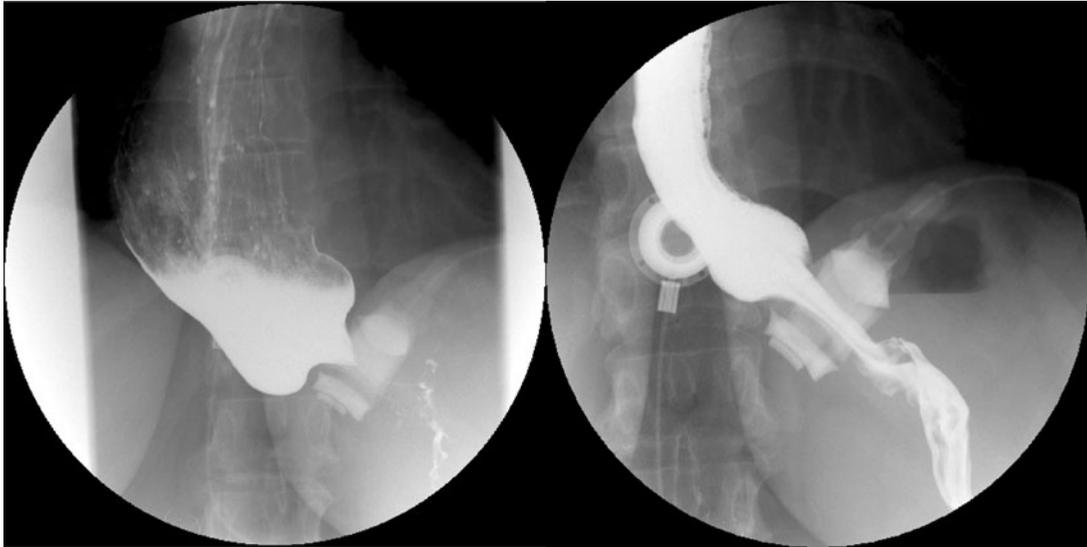
occurrence of esophageal dilatation stages III and IV in relation to the respective year after surgery. In 29.9% of the patients, band deflation had to be carried out; in 7 patients with stage II for obstruction, severe solid food intolerance, nightly aspiration, or vomiting more than twice per week and in 40 with stage III, of whom 6 had to be subsequently classified as stage IV with persistent major achalasia-like dilatation not recovering after band deflation. These 6 patients had to be reoperated with band removal, and in 4 cases a sleeve gastrectomy was carried out; the other 2 patients did not wish another bariatric procedure. The follow-up of these patients was satisfactory; in all of the 6 patients, esophageal dilatation was completely reversible when assessed by radiological examination and endoscopy. The 2 patients not wishing another bariatric procedure gained weight. The final total volume of the band filling was  $4.6 \pm 1.9$  mL. In 18.5% of the patients, upper endoscopy was carried out because of heartburn and/or dysphagia (29 of 157), and in 6 patients more than 1 endoscopy was

performed. The findings are summarized in Table 6. In 18 patients the endoscopy was normal, 9 suffered from GERD, 1 from a stenosis, and 1 from a hiatus hernia.

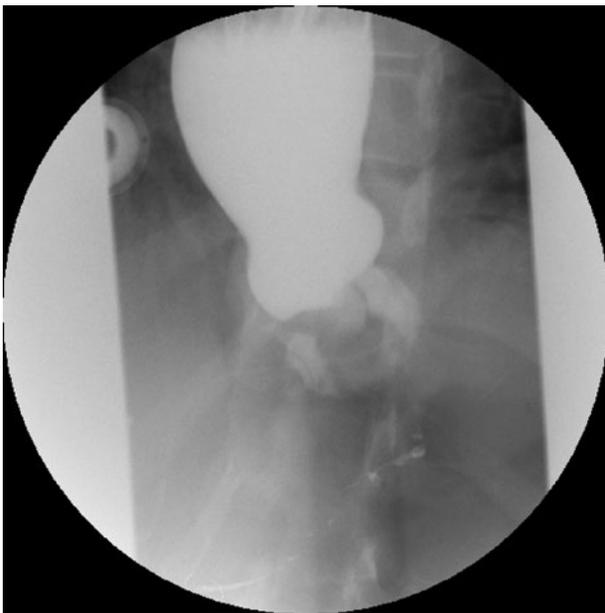
## DISCUSSION

Bariatric surgery has proven to be the only effective and sustained treatment of morbid obesity resulting in long-term weight loss, improved lifestyle, and eliminating or improving obesity-related comorbid risk factors.<sup>6,40</sup> In fact, the practice of bariatric surgery has increased more than 10-fold in the United States between 1994 and 2005. Laparoscopic adjustable gastric banding is one of the most commonly performed bariatric procedures and has been shown to be a safe, effective, and affordable operation for achieving the above-mentioned end-points in the morbidly obese.<sup>16–20</sup> Besides the obvious benefits of laparoscopic surgery, the other major advantages of gastric banding include reversibility (no suturing or opening of the digestive tract) and the possibility of adjusting the band's stoma size.<sup>6,35</sup> Today, more than 250,000 patients in the world have been submitted to this procedure.<sup>32</sup> The early results were encouraging, with low morbidity, almost no reported mortality, and weight loss comparable with other purely restrictive procedures performed.<sup>22</sup> However, most published papers report follow-up data limited to a period of less than 5 years and only a limited percentage of the entire patient group have been followed for more than 5 years. Furthermore, until recently there have been only a few reports concerning esophageal dysfunction and dilatation after LAGB over the longer term.<sup>31–34,37</sup> The present study presents long-term results focused primarily on esophageal dysfunction with a 94% overall follow-up. In fact, almost 70% of the patients are beyond the 5-year limit and the follow-up rates of 91% and 85% after 5 and 8 years repeatedly provide useful long-term outcomes.

In the present series, we found two-thirds of our patients with esophageal motility disorders at long-term follow-up and 25.5% with significant dilatation of the esophagus. Normal esophageal diameter has not been well defined in the literature. On the basis of our personal experience with bariatric surgery of more than 16 years, and supported by a recently published paper, an esophageal diameter of 35 mm or more was considered dilated.<sup>32</sup> We recognize that this is a relatively arbitrary definition. However, change over baseline by 30%, proposed in other publications, seems even more unclear.<sup>30</sup> Dargent proposed a radiological classification with 4 stages in the progression of dilatation, based on peristalsis and resolution after band deflation.<sup>33</sup> Although he gave no size criteria, we find his classification useful, because it gives recommendations for treatment. In esophageal dilatation stage III (significant dilatation with anterior and/or posterior pouch slipping), deflation of the band may lead to a normal radiological situation, but usually at the cost of weight regain, which in our opinion has to be classified as a failure of the procedure. There was a significant difference in esophageal diameters in the dilatation group (47 mm) compared with normal (26 mm). In 87% of our patients with band deflation, esophageal dilatation was reversible. However, in 13% of the cases, the patients did not recover after band deflation, with persistent stage IV dilatation (major achalasia-like dilatation) and removal of the band. Interestingly, in our series, stages III and IV dilatations occurred 3 to 10 years after surgery after a median follow-up of 74 months, emphasizing the need for long-term follow-up to detect these late complications. Because of our strategy to apply a rather slow gastric restriction, we did not find stage III and IV dilatations within the first 2 years and weight loss was quite smooth and still ongoing beyond 2 years after surgery. Indeed, we have reported insufficient weight loss in 18.3% and 16.6% of our patients after 5 and 10 years, but an excess weight loss after 5 and 10 years of 50.3% and 48.8%.<sup>41</sup> There was no difference for excess weight loss between those patients who developed esophageal dilatation and those who did not.



**FIGURE 2.** Barium swallow of a 37-year-old patient 5 years postoperatively with stage III esophageal dilatation and the same patient 3 months after band deflation.



**FIGURE 3.** Barium swallow of a 45-year-old patient 8 years postoperatively with stage IV esophageal dilatation (major achalasia-like dilatation) not recovering after band deflation.

**TABLE 5.** Occurrence of Esophageal Dilatation Stages III and IV in Relation to Year After Surgery

Year After Surgery	3	4	5	6	7	8	9	10	Total
Stage III	6	5	5	4	4	3	4	3	34
Stage IV			1	2		3			6
Total	6	5	6	8	4	6	4	3	40

**TABLE 6.** Postoperative Findings in Upper Endoscopy (n = 157)

Finding	n	n	%
Gastroesophageal reflux disease		9	5.8
Grade I	5		
Grade II	3		
Grade III	1		
Grade IV	0		
Hiatal hernia		1	0.6
Stenosis		1	0.6
Normal		18	11.5
Total		29	18.5

Band adjustments in the first year were carried out every 3 months and yearly thereafter, and band filling was carefully adjusted to avoid solid food intolerance, ending in a final total volume of  $4.6 \pm 1.9$  mL. Indications for deflation or no band filling was obstruction, severe solid food intolerance, nightly aspiration, or vomiting more than twice per week. It is well known from the literature that the reduction of the above-mentioned symptoms by band deflation may prevent the later development of esophageal dilatation.<sup>20,22,34</sup> Little is known with respect to the true incidence of esophageal dysfunction after LAGB.<sup>30,32,33,37</sup> DeMaria et al. found an incidence of 71% with esophageal dilatation after LAGB as part of the first FDA approving trial in the United States, which is consistent with our results.<sup>30</sup> Of these, more than two-thirds of the patients had prominent dysphagia, vomiting, and reflux.<sup>30</sup> On the contrary, Dargent reported only an incidence of 0.6% of his patients having esophageal dilatation, but he gave no information on the evolution over time.<sup>33</sup> In a recently published study, the incidence of esophageal dilatation at 1 year after LAGB was 14%.<sup>32</sup> However, from long-term studies it is well known that failure rates and complications increase with time, up to 40% at 10 years, and each year adds 3% to 4% to the major complication rate.<sup>22–25</sup>

Little is known about the risk factors for esophageal dilatation, which have been hypothesized to be due to an overly tight band, underlying esophageal motility problems or both.<sup>32</sup> Furthermore, esophageal dilatation seems to occur mainly in patients who overeat and use their distal esophagus as a reservoir. The prevalence of esophageal dysmotility in the morbidly obese population is significantly higher than that among nonobese individuals.<sup>9,10</sup> However, a majority of these patients have been shown to be asymptomatic, suggesting that morbidly obese patients may have abnormal visceral sensation.<sup>9,42</sup> In our series, 57% of the patients had pathological findings in preoperative endoscopy, suffering mainly from GERD and hiatal hernia. The LAGB is an adjustable low-pressure silicone band that is placed around the cardia of the stomach. Indeed, secure placement 1 to 2 cm beneath the gastroesophageal junction forming a small pouch seems critical to its success.<sup>43</sup> It has been suggested that it may be a satiety inducing procedure. However, the exact mechanism of action has not been clearly defined.<sup>43</sup> There are limited and conflicting data concerning the impact of the LAGB on esophageal motility and the lower esophageal sphincter (LES). It is conceivable that the gastric band may partially act as a reflux barrier, preventing acid and duodenogastroesophageal reflux.<sup>37,44</sup> It causes an outlet obstruction, especially during follow-up after band filling. Indeed, it has been shown that LAGB placement increased the LES pressure and the length of the high-pressure zone, although the LES relaxed normally.<sup>43,44</sup> Contractions in the lower esophagus weakened after gastric banding and esophageal motility were disrupted by overfilling the band.<sup>36,43</sup> Furthermore, esophageal acid exposure tended to decrease after LAGB in the short term, but pouch formation increased reflux symptoms over time.<sup>36,44</sup> Preoperative esophageal manometry did not predict either GERD nor weight loss outcomes after LAGB.<sup>44,45</sup> In patients with preoperative defective esophageal motility, hiatal hernia, or GERD, LAGB may aggravate GERD symptoms and promote esophageal dilatation.<sup>36–38</sup> However, some authors found that the outcomes after gastric banding in terms of esophageal dilatation were similar whether esophageal motility disorders were present preoperatively or not.<sup>45,46</sup> To date, there are no convincing data that preoperative esophageal manometry may predict the occurrence of these esophageal complications or that it should be a routine preoperative procedure.<sup>44,46</sup> Furthermore, GERD may develop in patients with band slipping or pouch dilatation, which was the major problem in early series occurring in 15% to 20%.<sup>29,44</sup> We have found only 1.2% of our patients needing a reoperation because of band slipping.<sup>41</sup> It is well known that the surgical technique is a key factor influencing the incidence of these adverse effects (pars flaccida approach).<sup>15,16,18</sup>

On the basis of the available literature and the results from the present study, we suggest the following conclusions and recommendations.<sup>18,20–23,32,36,38,41,44,45,46</sup>

- Esophageal dysmotility disorders and dilatation after LAGB, whether symptomatic or asymptomatic, are a common finding and probably underestimated, especially over the longer term.
- They contribute to the major complications leading to reoperations and failures after LAGB in a significant number of our patients.
- Preoperative esophageal manometry should be performed if a clinical suspicion of esophageal motility disorder is present or at the time of preoperative pathological endoscopy.
- Alternative bariatric surgical procedures such as Roux-en-Y gastric bypass (RYGB), though technically more demanding, should be considered in patients with defective esophageal motility detected by the preoperative investigations.
- It has been suggested that the choice of operation for morbid obesity should be tailor-made for each individual patient, and no single operation is ideal for all obese patients. In our opinion, LAGB should probably not be considered the procedure of first choice in

treating morbidly obese patients and should be performed only in selected cases, until reliable criteria for patients with a low risk for the procedures long-term complications are developed.

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