



Nonsurgical Management of Luminal Dilatation After Laparoscopic Adjustable Gastric Banding

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Abstract

Background Proximal luminal dilatation (PLD) is one of the most significant challenges following laparoscopic adjustable gastric banding (LAGB). If PLD is identified at an early stage, there is potential to avoid reoperation or irreversible change by implementing nonsurgical measures. The success of these strategies is unknown. The aim of this study was to determine the outcome of how often PLD can be successfully treated nonsurgically.

Methods The records of patients who underwent primary LAGB insertion by a single surgeon from January 2005 to December 2006 were reviewed. Study participants were all patients who had subsequently undergone a postoperative liquid contrast swallow demonstrating a PLD. The severity of PLD, subsequent management, and outcomes were recorded and assessed.

Results There were 354 patients who underwent a primary LAGB insertion during the study period. Seventy-eight patients were found to have varying degrees of PLD and had an attempt at nonsurgical management. Thirty-four of these patients (43.6 %) were successfully managed nonsurgically at a mean follow-up of 2.8 years (33.2 months, CL±3.2). The success with nonsurgical management was lower if the symmetrical pouch dilatation was more severe or gastric prolapse was seen at presentation, and if no improvement in liquid contrast swallow was seen.

Conclusions PLD can often be successfully managed with nonsurgical measures, maintaining good weight loss in the intermediate term. Patients with more significant dilatation are more likely to require revisional surgery. Early recognition may have a role in preventing surgery or more severe abnormalities.

Keywords Proximal luminal dilatation · Symmetrical pouch dilatation · Gastric prolapse · Laparoscopic adjustable gastric banding · Bariatric surgery · Revision surgery · Conservative management · Nonsurgical management · Complication

Introduction

Laparoscopic adjustable gastric banding (LAGB) has been shown to be a safe and effective means of inducing substantial weight loss that can be sustained for at least 15 years [1]. It is one of the most commonly performed bariatric procedures [2–4].

Proximal luminal dilatation (PLD) has emerged as one of the most significant complications of LAGB [5, 6], with incidence rates reported from 1 to 25 % [3, 6–9]. There are several variants of PLD involving the stomach, esophagus, or both. These variants have been previously described by our group (Fig. 1) [6, 7].

It is most likely that all variants of PLD result from chronic luminal hypertension above the LAGB [6]. The intraluminal distending pressure above the LAGB is directly mediated by the volume of saline within the band [10]. Eating behaviors, including the pace of eating and the size and texture of the swallowed bolus, will also determine the distension applied to the supra-band lumen [5]. The expected response to luminal hypertension is dilatation.

Patients with luminal dilatation usually present with reflux or regurgitation, lack of satiety, or poor weight loss. These

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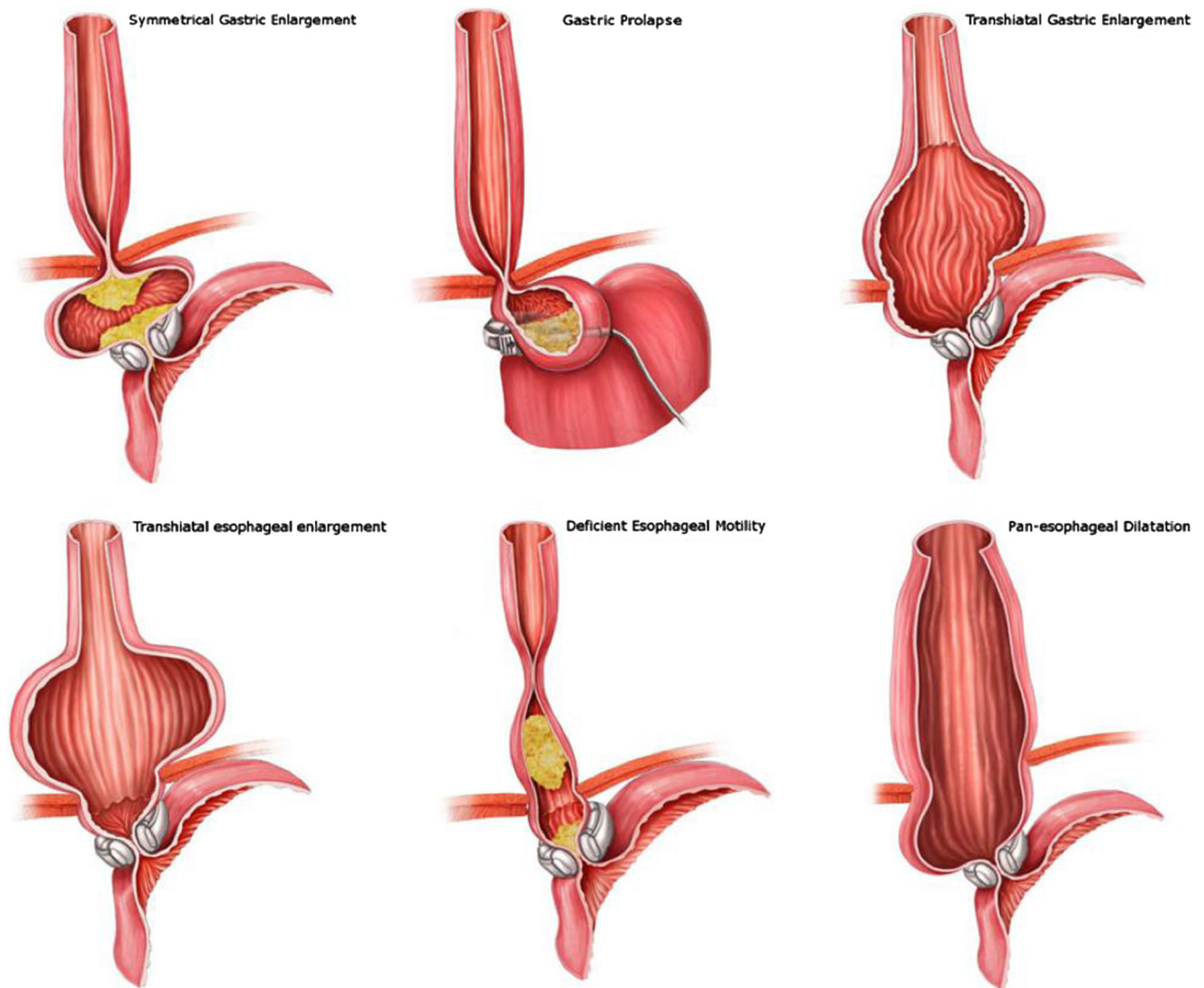


Fig. 1 Schematic representation of the CORE classification. Typical patients represented by the CORE classification are schematically demonstrated. To determine optimal treatment, it is critical to differentiate

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symptoms mandate investigation and intervention if a significant abnormality is identified. The optimal management of PLD has not been defined.

Our current practice, once one of these pathologies is identified, is to remove fluid from the band and provide the patient with reeducation about eating styles and behaviors. Reducing the intraluminal pressure above the LAGB reduces the strain on the luminal wall during eating and theoretically allows a pouch to resolve. Anecdotally, we know that a proportion of our patients have complete resolution of the proximal dilatation with these changes; however, should the PLD not respond to these measures, surgical intervention is usually offered. We have previously shown that symmetrical gastric dilatations respond well to surgical revision and that esophageal luminal dilatations respond poorly to surgery [6, 7].

We do not know the proportion of patients who will subsequently require surgical intervention or what proportion of these pathologies resolve with nonsurgical management.

The literature has varying reports of successful management of pouch dilatations with nonsurgical measures such as removal of fluid from the band, close attention to eating habits, and protocol for careful reintroduction of fluid into the band. In these studies, success ranges from 51 to 77 % in the short term [8, 11, 12]. However, the study population and follow-up period for these studies are limited.

We hypothesized that nonsurgical intervention leads to the successful resolution of the majority of PLD. The aim of this study was to investigate the outcomes (weight, need for reoperation) of patients who developed a PLD and were treated nonsurgically in a large cohort followed in the intermediate term.

Methods

Patients

Patients who underwent laparoscopic adjustable gastric banding performed by a single surgeon between January 2005 and December 2006 were identified for review. The Allergan Lap-Band system was used in all cases. Data on subsequent management were retrieved from LapBase™, a prospective database used to document operative notes, follow-up appointments, investigations, and complications.

Diagnosing Proximal Luminal Dilatation

Liquid contrast studies were performed on patients who presented with symptoms suspicious of pathology during follow-up review (reflux/regurgitative symptoms, restrictive symptoms, poor weight loss, poor satiety). All liquid contrast studies are stored on Lapbase™ and patients who had undergone these studies identified.

The liquid contrast studies were reviewed by two independent reviewers (GO and PB). Abnormal liquid contrast studies were defined as any symmetrical dilatation of the proximal pouch (SPD) or gastric prolapse (Fig. 2). SPD was further divided into mild (less than the diameter of band with band at 45°), moderate (as large as the diameter of the band with band at 45°), and severe (larger than the diameter of band with flattening of band to the horizontal position). Gastric prolapse is indicated by the band being in the vertical or horizontal position, with an asymmetrical dilatation above the band.

Protocol for Nonsurgical Management

The steps of the nonsurgical management are as follows:

1. Reduce the fluid in the band to a point where there is likely to be minimal resistance. For a Lap-Band AP, this generally will be a reduction to 3 ml.
2. Wait for 4 weeks. This is a challenging time for the patients as they will have lost the satiety effect of the band, will be hungry, eat too easily, and subsequently may put on weight.
3. Review at 4 weeks with a repeat barium swallow. On clinical review, expect complete resolution of the symptoms. On barium meal, expect to see total or near total resolution of the enlargement. If this is so, proceed with readjustment of the band and continue reeducation of the patient.
4. Readjustment of the band: Add sufficient saline to possibly start the satiety effect, but expect to take several adjustments to get to full effect.
5. Reeducation of the patient: The major drivers for proximal enlargements are errors in eating. Re-enforcement of

the eating rules is an essential part of the nonsurgical program.

The nonsurgical trial period was defined as the time that measures were attempted to reverse the luminal dilatation until either surgical intervention or symptoms and/or liquid contrast study demonstrated resolution of the dilatation. The decision to proceed to operative management was multifactorial, coming from the patient–clinician interaction, clinician experience, progression of disease and symptoms, and maintenance of successful weight loss. When management progressed to revision surgery, the date of surgery and weight on the day of surgery were recorded.

Outcomes

Outcomes were assessed at different time points of a patient's management. Values of interest were percentage excess weight loss (%EWL), defined as the proportion of weight lost above a BMI of 25; radiological change from the time of initial diagnosis through to last liquid contrast study; change or resolution of symptoms; and progression to surgical management.

The total period of conservative management was recorded for both the nonsurgically managed group and the revision surgery group. This was measured as being until symptom or radiological resolution and recommencement of normal management of LAGB or until surgical intervention was instituted.

Analysis

Data were compiled in Microsoft Excel and analyzed with SPSS (version 20). Unless otherwise stated, all data are expressed as the mean±95 % confidence limit. Values of *p* were calculated with Pearson's chi-square analysis.

Results

Patient Selection

Between January 2005 and December 2006, 354 patients underwent a primary LAGB. In all patients, the initial post-operative barium study was normal. During follow-up, 174 patients had liquid contrast swallows to investigate adverse symptoms or poor progress. Seventy-seven patients had completely normal barium studies (50 %). Abnormal barium studies of varying severity were identified in 97 patients, ranging from mild SPD (*n*=36, 46.2 %), moderate SPD (*n*=25, 32.1 %), severe SPD (*n*=13, 16.7 %), and gastric prolapse (*n*=23, 29.5 %).

Fig. 2 Examples of mild symmetrical pouch dilatation (*top left*), moderate SPD (*top right*), severe SPD (*bottom left*), and gastric prolapse (*bottom right*)



Figure 3 shows the patients with abnormal liquid contrast swallows and patients who were selected for this study.

Twelve patients who had PLD underwent immediate surgical management with no trial of nonsurgical measures and were thus not included. Due to the severity of their liquid contrast swallow in combination with assessment of their weight loss and symptoms, it was decided between patient and clinician that immediate surgical management was required. These 12 patients had various grades of abnormality, ranging from mild SPD ($n=3$), moderate SPD ($n=2$), severe SPD ($n=0$), and prolapse ($n=7$).

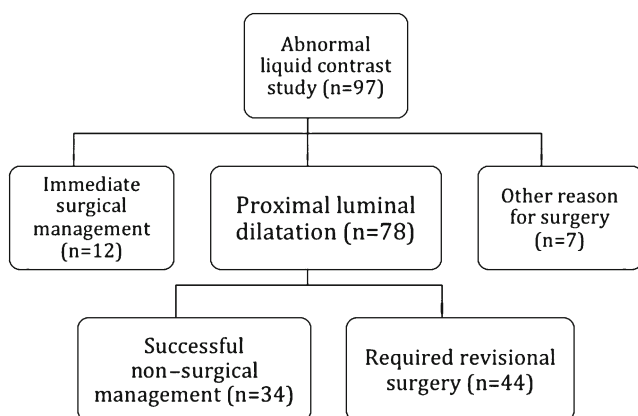


Fig. 3 Patient selection flowchart

In a further seven patients, surgical management was chosen for reasons other than the PLD seen on radiological study, including patient request ($n=1$), emergency removal for complete food intolerance ($n=2$), erosion found on gastroscopy ($n=3$), and coincidental leak from LAGB balloon ($n=1$).

In the remaining 78 study patients, conservative measures were initiated, aimed at reversing the luminal dilatation. These patients were included in the study to see whether these measures were successful in avoiding operative management. Baseline details are as shown in Table 1.

Outcomes of Nonsurgical Management

Since diagnosis of luminal dilatation, the entire study cohort has been followed up for a mean of 2.8 years or 33.2 ± 3.2 months. At the conclusion of data collection, 34 patients (43 %) have successfully been managed with nonsurgical measures. These nonsurgical strategies were implemented for an average of 9.7 ± 3.5 months for this group.

Forty-four patients (57 %) required surgical intervention after a trial of conservative management. Reasons for progression to surgery included a combination of ongoing or worsening abnormality on liquid contrast swallow, ongoing or worsening symptoms, and poor weight loss. The period of nonsurgical treatment in these patients was documented to range from 0.9 to 33.7 months, with an average duration of

Table 1 Demographics of patients in study group

Demographics	Surgical	Nonsurgical	<i>p</i> value
Number	44	34	
Female	97.7 % (43/44)	79.4 % (27/34)	0.02
Initial weight	120.6±3.5 kg	126±3.8 kg	0.08
Initial BMI	43.6±1.8	45.8±1.9	0.05
Excess weight	51.4±4.4 kg	57.2±5.7 kg	0.06
Age	35.1±3.2 years	41.0±4.1 years	0.08
Follow-up ^a	266±3.1 weeks	258±3.7 weeks	0.47

Confidence limits are shown

^a Follow-up from insertion to last appointment prior to January 2011

10.2±2.3 months. Patients underwent surgery at a mean time of 33.2±4.4 months after initial insertion of LAGB.

Liquid Contrast Studies

Routine postoperative liquid contrast swallows were performed on all patients to assess placement of the band and anatomy. In our 78 patients, these initial studies were all normal.

Initial Abnormality

Patients presented with symptoms of concern approximately 26.5±3.0 months after insertion of Lap-Band. They were subsequently formally diagnosed with a PLD soon after, at an average of 4.4±1.8 weeks (1.0±0.4 months) after first presenting with symptoms.

This correlates with an average time to detection of first abnormality on liquid contrast swallow of 27.5±3.0 months after LAGB insertion. Abnormalities observed at this time were mild SPD in 29 patients (37.2 %), moderate SPD in 22 patients (28.2 %), severe SPD in 12 patients (15.4 %), and prolapse in 15 patients (19.2 %).

Change in Liquid Contrast Swallow with Nonsurgical Measures

At the end of conservative management, 11 patients had abnormalities that had completely resolved (14.1 %). Thirty-three patients (42.3 %) had mild SPD, 6 patients (7.7 %) had moderate SPD, 13 patients (16.7 %) had severe SPD, and 15 patients (19.2 %) had prolapse.

When patients' results were assessed individually in sequence, this corresponded to an improvement or resolution in 33 patients (42.3 %), stable abnormality in 31 patients (39.7 %), and deterioration in 14 patients (17.9 %), as shown in Fig. 4.

Change in liquid contrast study after non-surgical management

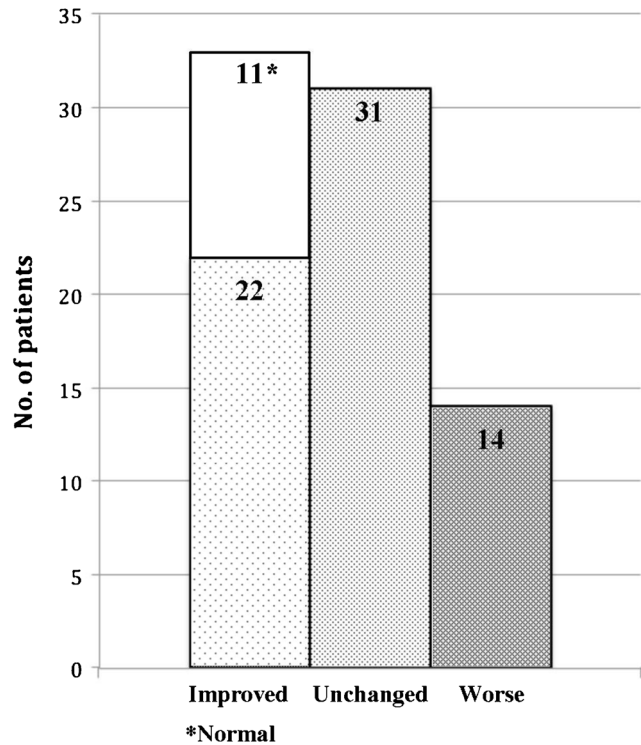


Fig. 4 Progress in individual patients after conservative management—improved or normal follow-up liquid contrast study result, stable, or worsened result. *Eleven patients with liquid contrast swallows that have returned to a normal appearance

Radiological Results Based on Initial Severity of PLD

In those with mild dilatation (*n*=29), the greatest proportion of patients had resolution, with seven patients (24.1 %) returning to normal liquid contrast study at the end of nonsurgical management (*p*=0.29). Thirteen patients continued to have mild SPD (44.8 %), and nine patients (31.0 %) had a worse result.

Those initially with a moderate SPD (*n*=22) showed one patient with normal liquid contrast swallow and 12 with mild SPD (a total of 59.1 % of the patients improved). Four patients' liquid contrast swallows remained stable, and five patients deteriorated.

In the group with severe SPD (*n*=12), two patients had normal liquid contrast swallows, six had mild SPD, and one had moderate SPD (75 % with improved studies).

In patients with gastric prolapse (*n*=15), 11 had ongoing prolapse on follow-up liquid contrast swallow. However, one patient had a normal liquid contrast swallow, and two had a mild SPD after nonsurgical measures were implemented (20 % improved).

Effect of Initial Radiological Appearance on Requirement for Revisional Surgery

The rate of revisional surgery differed depending on the severity of SPD observed and the changes seen on follow-up liquid contrast swallow. Patients with mild SPD showed a 55.2 % success rate with nonsurgical management, moderate SPD had 36.4 %, severe SPD had 58.3 %, and prolapse showed a 20 % rate of success ($p=0.09$; Fig. 5). In patients with follow-up liquid contrast swallows that have shown improvement ($n=22$) regardless of the initial grade of SPD, 59.1 % are successfully managed nonsurgically. In those with stable or worse liquid contrast studies, only 29.0 and 7.1 % have been managed nonsurgically at last follow-up ($p<0.001$).

Weight Loss

At the time of diagnosis, the mean %EWL was 63.8 ± 5.2 %. The progression in weight loss during the period of nonsurgical management is shown in Fig. 6.

At all time points, there was no significant difference in %EWL between surgical and nonsurgical cohorts. From the time of symptom onset to the diagnosis of SPD, there is a mild increase in %EWL. While instituting conservative measures, all patients on average gained weight with an average change in %EWL of -6.5 ± 3.1 %, corresponding to a total %EWL of 58.6 ± 8.3 %.

The average duration of nonsurgical management was 9.7 ± 2.1 months. The surgical group received a total of 10.2 ± 2.8 months and the nonsurgical group a total of 9.7 ± 3.5 months. The period of nonsurgical management is taken

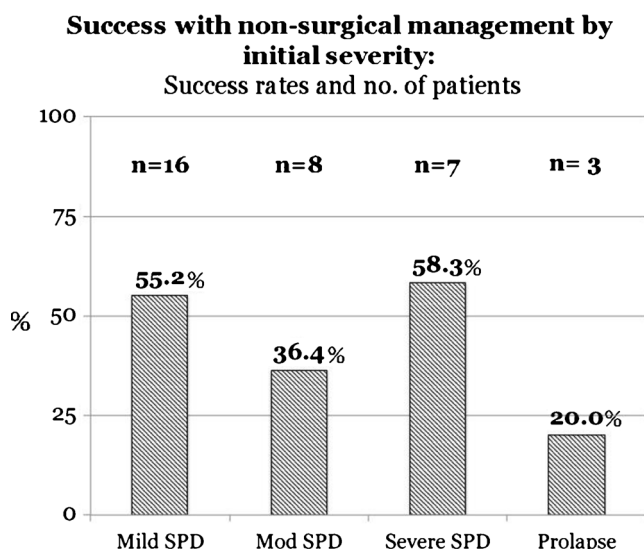


Fig. 5 Percentage of patients and number of patients who have successfully avoided surgery with nonsurgical protocol management, subdivided into the abnormality seen on initial contrast swallow

as the time from nonsurgical intervention until surgery or, for those managed nonsurgically, until liquid contrast study resolves or symptoms improve to allow the addition of fluid to the band as per normal protocol.

At their last follow-up (an average of 57.9 months from LABG insertion), the entire study cohort achieved a mean %EWL of 50.2 ± 6.1 %. There is no significant difference in weight gain in comparing those managed with surgical revision and those managed nonsurgically (49.2 vs. 51.2 %, $p=0.60$).

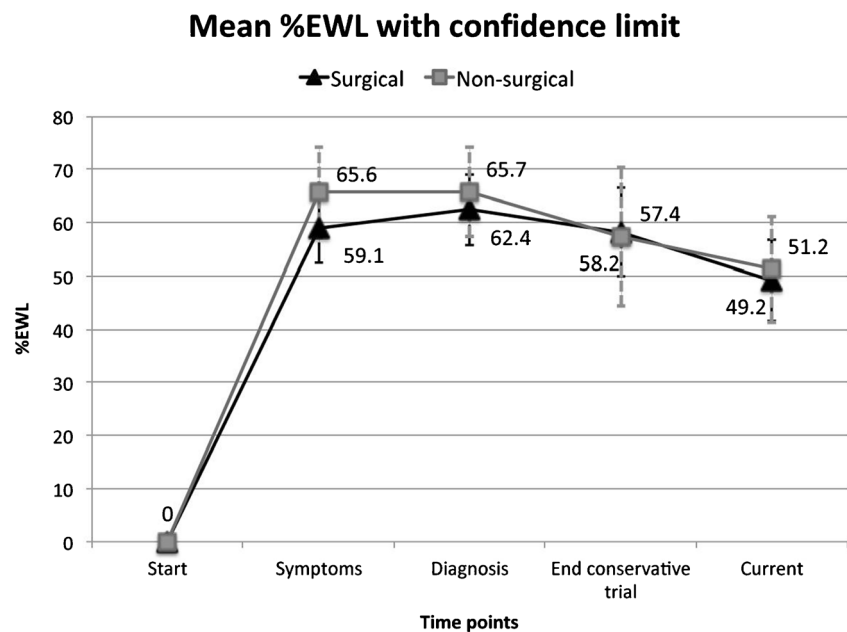
Discussion

Proximal luminal dilatation is the most common complication of LAGB [6]. These data have demonstrated that nonsurgical management consisting of reduction of fluid and patient reeducation is successful in 43.6 % of patients, with a mean follow-up of 2.8 years from the diagnosis of PLD. Importantly, patients who were treated nonsurgically maintained good weight loss (>50 % EWL). We also noted that the severity of luminal dilatation on the initial liquid contrast study and the initial response to nonsurgical management significantly influenced the probability of successful nonsurgical management.

Nonsurgical management has been proposed and studied by various groups. Angrisani et al. [12], in 1999, first described their experiences with deflation of the band as the primary treatment modality for proximal gastric pouch dilatation. They achieved a 57.2 % success rate, with complete deflation in seven patients with pouch dilatation. In 2003, Vertruyen [11] described a 51 % success rate in 51 patients with pouch dilatation. The follow-up period for these two studies is unclear, with focus on the surgically managed patients. Most recently, Moser et al. [8] reported a 77 % success rate in 61 patients with a follow-up of 5 ± 4 months. Although the proportion of our patients successfully managed with conservative measures is lower than in previous reports, our follow-up duration has been longer with a larger patient cohort, accounting for patients who have recurrent problems with proximal luminal dilatation.

We have found that patients with milder luminal dilatation were more likely to succeed with nonsurgical management and that the radiological appearance was more likely to normalize. Seven patients with mild dilatation reverted to a normal appearance on liquid contrast swallow compared to one, two, and one patient(s) with moderate PLD, severe PLD, and gastric prolapse, respectively. Additionally, patients with improved follow-up barium swallows were more likely to subsequently be managed conservatively, with 59.1 % avoiding surgery compared to 29.0 % in those with stable imaging and 7.1 % in those with worse follow-up studies.

Fig. 6 Average %EWL of surgical (red) and nonsurgical (blue) patients, with 95 % confidence limits. Four time points are represented: (1) start of significant symptoms, (2) time of diagnosis with liquid contrast study, (3) end of conservative trial (at surgery or at time of resolution), and (4) current weight (last reading before January 2011)



Patients gained weight after diagnosis of luminal dilatation, with an average change in %EWL of -5.2 %. As noted in other studies [6], this appears to be due to an initial excess weight loss attributable to the pathophysiology, as seen in our patient data in Fig. 6, by an increasing trend (albeit not statistically significant) of the %EWL between patients noticing symptoms and subsequent diagnosis. This culminated in a mean EWL of 59.1 % in the surgical group and 65.6 % in the nonsurgically managed group at the time of diagnosis. Additionally, it is expected that without the satiety effect provided by an adequately inflated LAGB, patients will naturally experience increased hunger and may subsequently gain weight. Current weight loss in these patients of a mean %EWL of 50.2 % is similar to the mean %EWL reported weight loss for LAGB at 5 years postinsertion and comparable to other effective bariatric procedures [13].

This study is limited by its observational nature. Undoubtedly, decision making was influenced by the radiological appearance, although the extent of this bias is unclear. Review of the case notes, however, indicates that symptoms were the primary determinant of decisions to intervene.

Another limitation is the duration of follow-up after treatment. The 2.8-year follow-up period of the study is, however, a significantly longer duration of follow-up and occurring in a larger cohort of patients than has previously been reported. While the results were good during this time, it is unclear whether the presence of luminal dilatation affects longer-term outcomes that are the key to measuring success in bariatric surgery. It would seem unlikely to have a major impact as we have recently reported a 15-year mean %EWL of 47 % [1].

Luminal dilatation is likely caused by chronic luminal hypertension, resulting in the expansion of the weakest point of the luminal wall. This has been hypothesized to be the

result of poor eating behavior, with frequent episodes of obstruction and regurgitation causing recurrent and persistent intraluminal hypertension in the lumen above the LAGB [6]. Reducing the transmission of force to the luminal wall is a logical preventive strategy.

In general and in particular, if a luminal enlargement is identified, meticulous attention to follow-up is required. Firstly, adjustments should target satiety [14] rather than restriction, ensuring only a modest level of restriction is produced by the LAGB. Increasing the volume within the LAGB by only 20 % has been shown to significantly increase the pressures in the esophagus and stomach above the LAGB [10]. A second important preventive strategy is to ensure that patients are well educated about appropriate eating behavior. The avoidance of blockages by consumption of small meals slowly with each limited bolus chewed well prior to swallowing, should be emphasized. Foods of inappropriate texture must be avoided.

We hypothesize that luminal dilatation transitions between an acute reversible phase before becoming established and chronic, invariably requiring revisional surgery or, in some cases, representing unsalvageable change in the luminal wall.

Animal studies modeling the effects of more acute luminal obstruction have shown that there is recovery after short periods of obstruction [15, 16]. Alternatively, if obstruction is more prolonged, irreversible changes supervene. These models support the hypothesis that if an early stage of luminal dilatation can be identified and saline removed from the LAGB, potentially, a future, more significant problem could be avoided.

We have previously reported that in a group of 30 patients over a wide range of follow-up times, liquid contrast swallows did not identify luminal dilatation [10]. This indicates that stable patients in an appropriate follow-up system do not generally demonstrate significant luminal dilatation.

Future research should focus on whether screening of patients for subclinical luminal dilatation is worthwhile and whether intervening at an earlier stage can affect the outcome.

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Conflict of Interest Geraldine Ooi, Paul Burton, Cheryl Laurie, and Geoff Hebbard have no conflict of interest declaration.

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