Original article

Effect of adjustable gastric banding on changes in gastroesophageal reflux disease (GERD) and quality of life

George Woodman
MidSouth Bariatrics, Memphis, TN, USA

Robert Cywes
Jacksonville Surgical Associates, Jacksonville, FL, USA

Helmuth Billy
Ventura Advanced Surgical Associates, Ventura CA, USA

Kevin Montgomery
Northwest Weight Loss Surgery, Everett, WA, USA

Christopher Cornell
Ted Okerson
Allergan, Inc., Irvine, CA, USA

The APEX Study Group

Abstract

Objective:
Bariatric surgery is an effective treatment for the reduction of weight in obese patients (BMI ≥ 40 kg/m² or 30 kg/m² with ≥1 comorbidities), who are refractory to behavioral and medical therapies. This study examined the effect of the adjustable gastric band (AGB) system on changes in gastroesophageal reflux disease (GERD) and patient-reported outcomes, including measures of quality of life.

Methods:
Two-year interim analysis of patients (N=171) in the 5 year, prospective APEX study who reported GERD prior to the AGB procedure. An unrecorded number of hiatal hernia repairs were conducted during the APEX study.

Results:
At baseline, 171 of 395 patients (43%) reported GERD requiring daily medical therapy. After 2 years, 122 patients had sufficient data to assess outcome (71%). Complete resolution of GERD was reported in 98 patients (80%), improvement in 13 (11%), no change in 9 (7%), and worsening in 2 (2%). Overall, 91% of GERD patients experienced resolution and/or improvement of GERD. Baseline BMI was not significantly different among the GERD response categories (resolved, improved, and stable/worse), p=0.4581. Mean ΔBMI and percentage excess weight loss (%EWL) were: −8.8 kg/m²/−0.9%, −11.4 kg/m²/−53.9%, 6.4 kg/m²/−36.1%, and −7.1 kg/m²/−31.2%, respectively. There were no significant differences in reductions in BMI or %EWL between responder groups (resolved versus stable/worse ΔBMI p=0.1031, %EWL p=0.0667 OR resolved/improved versus stable/worse ΔBMI p=0.0918, %EWL p=0.0552). After 2 years, resolution or improvement occurred in pre-existing comorbidities: type 2 diabetes (96%), hypertension (49%), hyperlipidemia (77%), obstructive sleep apnea (86%), osteoarthritis (93%), and depression (75%). Patient satisfaction with AGB was assessed as: very satisfied/satisfied (87%), very satisfied (50%), dissatisfied (5.0%). Quality of life measured by the Obesity and Weight-Loss Quality of Life Instrument (OWL-QOL-17) – Quality of life – Weight loss.

Conclusion:
Obese patients with GERD had meaningful improvement in patient-reported outcomes with the AGB system. In addition, other obesity-related comorbidities and measures of quality of life improved.

Introduction

The prevalence of obesity, defined as a body mass index (BMI) of ≥30 kg/m², has been described as pandemic by the World Health Organization, who estimate 400 million people are currently obese worldwide. Accelerated rates of obesity have been demonstrated further in the United States by the Centers for Disease Control and Prevention, who reported the incidence of obesity in 1960 as 13.4%...
of the adult population, increasing in 1980 to only 14.4%, but then doubling by 2000 to 30.4%. The incidence of obesity in the United States has risen further to 33.8% of the population in 2008, and is predicted to reach 44.2% of the population by 2020.

Obesity increases the risk of cardiovascular disease, manifested by the increased incidence of myocardial infarction and stroke, and is a causative or contributing factor to other serious diseases, including type 2 diabetes, hypertension, dyslipidemia, nonalcoholic fatty liver disease, obstructive sleep apnea, and colon rectal and other cancers. In addition, obesity is associated with gastroesophageal reflux disease (GERD), a serious condition in which gastric contents reflux abnormally into the esophagus, resulting in heartburn, acid regurgitation, and damage to the esophageal mucosa, with the potential to cause Barrett's esophagus and the resultant increased risk of esophageal cancer. Significantly, the prevalence of GERD is increasing, with reported incidences of 10%–20% in the Western world and approximately 5% in Asia. Furthermore, incidence rates for GERD have been reported in longitudinal studies as being between 4.5 and 5.4 cases per 1000 people per year.

The pathophysiology of GERD is not completely understood, but is likely to be multifactorial in nature—including functional factors such as hiatal hernia formation, transient lower esophageal sphincter relaxation (TLESR), and genetic factors as indicated by twin studies which suggest that heritability may account for up to 43% of the chance of developing GERD.

The increasing prevalence of both obesity and GERD or GERD-related symptoms is suggestive of a pathogenic link between the two diseases. Evidence supporting this relationship includes a large study suggesting a correlation between obesity and esophageal acid exposure of 13%, with a proposed pathophysiological mode of action of lower esophageal sphincter dysfunction. A meta-analysis of epidemiological studies also suggested a relationship between obesity and GERD symptoms (odds ratio: 1.94). A large cross-sectional study demonstrated a correlation between obesity and GERD symptoms in a white population (odds ratio: 1.85), but not in blacks or Asians. Two population-based studies further support an association between increased BMI and GERD symptoms, with odds ratios: 2.6 (men and women), and 2.11 (women) and 2.15 (men). Although the available information is based upon meta-analyses, and cross-sectional and population-based studies utilizing patient questionnaires, the evidence is suggestive of a causal relationship between obesity—in particular abdominal obesity—and GERD.

The rising prevalence of obesity has not been successfully met by attempts at changes in patient lifestyle or currently available medications. To date, only bariatric surgery has been successful in providing durable weight loss of up to 60% of excess body weight in longitudinal studies of up to 5 years. The laparoscopic adjustable gastric band (AGB) procedure accounts for approximately half of bariatric surgeries carried out in the United States, and has been reported to be a safe, effective and durable method of reducing body weight in severely obese patients. The LAP-BAND AP* (LBAP) system (Allergan, Inc., California, USA) is approved in the United States for use in obese patients (BMI ≥ 30 kg/m²) with one or more obesity-related comorbidity. Of note, the AGB procedure is reported to reduce or eliminate a large percentage of obesity-related comorbidities such as type 2 diabetes, hypertension, and GERD. The LAP-BAND AP* (LBAP) system.* Although the value of the AGB procedure in reducing body weight in severely obese patients is well understood, many clinicians in the broader medical and surgical communities mistakenly view the AGB procedure as a potentially causative factor for GERD. It is therefore important to establish the effect of the AGB procedure on GERD status.

This study reports the effect of the AGB system on changes in GERD after 2 years by patient-reported outcomes accompanied by reduction in BMI, percentage excess weight loss, and improvement of comorbidities and quality of life measures.

**Patients and methods**

The APEX study (NCT00501085) is a 5 year, multicenter, open-label, prospective, observational trial, enrolling 516 severely obese patients undergoing AGB surgery with the LBAP system in the United States. Study protocols were approved by an institutional review board at each site, and patients provided written informed consent.

**APEX study inclusion criteria**

The inclusion criteria were consistent with the LBAP system label, which was typical of all AGB devices at the time of study implementation. Briefly, this included: (1) male or female patients aged ≥18 years; (2) BMI of ≥40 kg/m² or ≥30 kg/m² with ≥1 comorbid condition, or those who are at least 100 lbs over their estimated ideal body weight; (3) willingness to comply with the substantial lifelong dietary restrictions required by AGB implantation; (4) a history of obesity for ≥5 years; (5) a history of demonstrated failures with non-surgical weight loss methods; (6) likely to complete all study visits and comply with protocol requirements; (7) able to provide written informed consent.

*AP-BAND AP is a registered trade name of Allergan, Inc., Irvine, California, USA."
Table 1. Patient demographics: patients with GERD at baseline prior to implantation of the AGB system.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Patients N=171</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²) mean (SD)</td>
<td>44.2 (6.6)</td>
</tr>
<tr>
<td>Range (min, max)</td>
<td>33.1–66.3</td>
</tr>
<tr>
<td>Weight (lb) mean (SD)</td>
<td>270.4 (49.5)</td>
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<tr>
<td>Range (min, max)</td>
<td>187–488</td>
</tr>
<tr>
<td>Age (yrs), mean (SD)</td>
<td>42.4 (11.5)</td>
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<tr>
<td>Race</td>
<td></td>
</tr>
<tr>
<td>Caucasian (%)</td>
<td>148 (86.5)</td>
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<tr>
<td>Hispanic (%)</td>
<td>9 (5.3)</td>
</tr>
<tr>
<td>Black (%)</td>
<td>11 (6.4)</td>
</tr>
<tr>
<td>Missing (%)</td>
<td>3 (1.8)</td>
</tr>
</tbody>
</table>

APEX study exclusion criteria

The exclusion criteria are described in detail in the LBAP system label. Briefly, this included: (1) any surgical procedure or treatment representing an unreasonable risk to the patient; (2) family or patient history of inflammatory disease of the gastrointestinal tract; (3) severe cardiopulmonary disease or other serious organic disease; (4) pregnant or planning a pregnancy within 12 months; (5) alcohol or drug addiction; (6) established infection anywhere in the body at time of surgery; (7) previous bariatric surgery (except adjustable silicone gastric band), intestinal obstruction, or adhesive peritonitis; (8) family or patient history of autoimmune disease; (9) any condition or situation which, in the investigator’s opinion, may put the subject at significant risk, confound the study results, or interfere significantly with the subject’s participation.

In this interim analysis, 395 patients completed the 2 year post-operative visit, with 171 patients (43%) (baseline demographics: Table 1) reporting GERD requiring daily medical therapy at baseline – of which 122 patients (71%) met the 2 year post-intervention criteria, such that they had GERD at baseline, and had sufficient information available in order to assess changes in weight, GERD status, concomitant comorbidities, and other patient-reported outcomes such as quality of life. Patients participating in the APEX study were assessed using the following outcome measures: (1) surgical evaluation; (2) percentage excess weight loss (%EWL); (3) subject-reported quality of life questionnaire (The Obesity and Weight-Loss Quality of Life Instrument [OWL-QOL-17]); (4) surgeon/investigator global assessment questionnaire; (5) patient global assessment questionnaire; (6) incidence of adverse events. Excess weight was defined as the operative weight minus ideal body weight based on the 1983 Metropolitan Life Insurance Tables. The %EWL is defined as the operative weight minus the follow-up weight divided by the excess weight multiplied by 100.

Study visit schedule

Patients in the APEX study were required to participate in the following visit schedule: Visit 1 (screening); Visit 2 (Day 0, surgical procedure); Visit 3 (Week 2±2 days); Visits 4–13 (Weeks 4, 8, 12, 16, 20, 24, 30, 36, 42, and 48±5 days); Visits 14–20 (Semi-annual visits; Months 18–54±14 days); Visit 21 (Final visit; Month 60±14 days).

Patient-reported outcomes

The Obesity and Weight-Loss Quality of Life Instrument (OWL-QOL-17) assessment consists of 17 questions, asked at screening, Week 24, Week 48, and 2 years. The questions were designed to assess quality of life in persons who are overweight and attempting to lose weight. The questions are scored on a 6 point scale ranging from 0: ‘Not at all’ to 6: ‘A Very Great Deal’. Responses were scored for each question and assessed for the overall population completing 2 years of treatment, and by patients with GERD at baseline by response group i.e., resolved GERD, improved GERD, stable GERD, and worsened GERD. In general, decreases in the Obesity and Weight-Loss Quality of Life Instrument (OWL-QOL-17) question scores over time are associated with improvements in quality of life linked with weight loss.

Surgeon/investigator global assessments (satisfaction) with regard to the LBAP system were conducted at 2 years. Surgeon/investigator satisfaction was assessed using the following terms: very satisfied, satisfied, indifferent (not good or bad), or dissatisfied. At Week 24, surgeons/investigators: (1) compared their surgical experience with the LBAP system against other surgical procedures they had performed; (2) described their adjustment experience with the LBAP system; (3) described how satisfied they were, in general with the majority of patients LBAP system results; and (4) described how satisfied their patients were, in general with the LBAP system results. Surgeon/investigator global assessments were conducted using questions 2, 3, and 4 at Week 48 and 2 years.

Patient global assessments with regard to the LBAP system were conducted at 2 years. Patient global assessments were assessed using the following terms: (1) resolved (no symptoms and no medication); (2) improved (reduction of symptoms and/or reduced use of medication); (3) stable (no change in symptoms or the use of medication); or (4) worse (increased symptoms and/or increased use of medication).

Adverse events

Adverse events were classified by investigators as definite, probable or possibly due to use of the LBAP system.
Statistics

Frequencies of GERD response (resolved, improved, stable, or worse) were provided for patients who had GERD at baseline and were evaluable at 2 years. Frequencies were also provided for patients who did not have GERD at baseline and developed symptoms after 2 years. Descriptive statistics of changes in BMI, EWL and %EWL were provided for patients who had GERD at baseline (GERD population).

For all statistical tests, a two-sided p-value of ≤0.05, unadjusted for multiplicity (if applicable), was considered statistically significant.

A one-way analysis of variance (ANOVA) was performed to analyze differences of mean baseline BMI among Year 2 GERD response categories (resolved, improved, and stable or worse). A two-sample t-test with the Satterthwaite approximation was performed to analyze the difference in baseline BMI between patients with and without GERD at baseline. The differences of change in BMI and %EWL from baseline at 2 years between GERD response categories (resolved versus stable or worse OR resolved or improved versus stable or worse) were analyzed using two-sample t-tests. In addition, Pearson’s correlation coefficients were calculated for change in BMI (and %EWL) and GERD response. The change in %EWL from Year 1 to Year 2 was analyzed for differences between GERD response categories (resolved versus stable or worse OR resolved or improved versus stable or worse) using two sample t-tests.

A repeated measures analysis of variance (ANOVA) model was performed for the GERD population to analyze the within-group and between-group differences for mean QOL scores. The fixed effects in the model were GERD assessment (resolved, improved and stable or worse), QOL (17 individual items), and time point (baseline and Year 2), and the interaction among these three factors was also included. Subjects were repeated on question and time point. GERD assessment was omitted in modeling the total group. Least-squares (LS) means were calculated to evaluate the differences. A two-sided Pearson’s correlation coefficient between change in total OWL-QOL-17 score and %EWL was performed.

The associations between baseline GERD status and the frequencies of various adverse events groupings were analyzed using Fisher’s Exact Test.

Results

After 2 years of treatment, 80% (98/122) of patients experienced resolution of GERD, 11% (13/122) experienced improvement in symptoms, 7% (9/122) experienced no change in symptoms (stable), and 2% (2/122) experienced worsening of GERD symptoms. Overall, 91% of patients experienced resolution or improvement of GERD symptoms (Figure 1). In the population of patients who completed 2 years of treatment, but did not have GERD symptoms at baseline (n = 224), four patients (1.8%) developed symptoms of GERD, all of whom lost weight (mean weight change: −54.8 lbs; range: −102.5 lbs to −20 lbs).

Of patients with GERD at baseline, the mean baseline BMI was 44.6 (SD: 6.7) kg/m². After 2 years, BMI decreased to 35.0 (SD: 16.8) kg/m², representing a mean BMI change of −8.9 (SD: 5.8) kg/m² (Figure 2). Patients with GERD at baseline had mean excess weight loss of 118 lbs (SD: 43.4 lbs), with mean percentage excess weight loss (%EWL) of 49.8% (SD: 31.2%) after 2 years (Figure 3).

Change in mean BMI and mean %EWL in the GERD population was further analyzed by response group (resolved, improved, stable, or worse). There were no significant differences in baseline BMIs among the GERD response categories (resolved, improved, and stable/worse) (range: 45.2 kg/m² to 42.5 kg/m², p = 0.4581), or in baseline BMIs between patients with and without GERD (p = 0.7547). In the GERD population there were no statistically significant differences in the amount of weight lost (BMI change or %EWL) after 2 years (resolved versus stable or worse BMI change p = 0.1031, %EWL p = 0.0667 OR resolved or improved versus stable or worse BMI change p = 0.0918, %EWL p = 0.0552; range, BMI [SD]: −11.4 [7.4] kg/m² to −6.4 [4.1] kg/m², %EWL: −33.9% [23.2%] to −31.2% [27.6%], Figure 4). After 2 years, mean weight change (SD) for each GERD response group was as follows, resolved: −53.2 lbs (26.3 lbs); improved: −69.2 lbs (46.7 lbs); stable:
-36.1 lbs (26.0 lbs); worse: -42.3 lbs (50.6 lbs). In addition, Pearson correlation coefficients indicated no significant correlation between changes in either %EWL or BMI and reported GERD status after 2 years ($p = 0.1250$ and $p = 0.5502$, respectively). There were no significant differences in change in %EWL between 1 year and 2 years (resolved versus stable or worse $p = 0.2504$ OR resolved or improved versus stable or worse $p = 0.2553$).

In addition to improvements in GERD associated with weight loss, several comorbidities also resolved or improved, including: type 2 diabetes (96%), hypertension (91%), hyperlipidemia (77%), obstructive sleep apnea (86%), osteoarthritis (93%), and depression (75%) after 2 years.

The satisfaction of GERD patients with the AGB procedure was assessed after 2 years, with 87.4% of patients...
Device-related adverse events (AEs; defined as definite, probable or possibly related to the device) were reported in 25% of patients (56/224) without GERD at baseline; the proportion of patients with GERD at baseline experiencing these AEs was also 25% (43/171), indicating that the AGB system does not increase the risk of device-related AEs in patients with GERD compared to the overall population (p = 1.0). Device-related serious adverse events (SAEs) were reported in 7.8% of patients (31/395) in the overall population; 8.8% (15/171) of patients with GERD at baseline compared to 7.1% (16/224) of patients without GERD. The incidence of SAEs were not statistically different between these two groups (p = 0.58). These data suggest that the AGB system does not increase the risk of SAEs in the overall population compared to patients with GERD at baseline.

Adverse events, defined as any or combination of nausea, vomiting, heartburn, or GERD, that required therapy were reported in 7.0% of patients (12/171) with GERD at baseline, compared with 9.8% of patients (22/224) without GERD at baseline after 2 years (p = 0.37). Adverse events defined as any of the previously mentioned symptoms that required explant or revisional surgery were reported in 2.9% of patients (5/171) with GERD at baseline, compared with 0.45% of patients (1/224) without GERD at baseline after 2 years, a difference which was also not statistically significant (p = 0.09). Pouch dilation was reported in 2.3% of patients (4/171) with GERD at baseline, and 2.7% of patients (6/224) without GERD at baseline after 2 years (p = 1.0). Adverse events defined as any of the previously mentioned symptoms and pouch dilation were reported in 1.2% of patients (2/171) with GERD at baseline and 1.8% of patients (4/224) without GERD at baseline after 2 years (p = 0.7).

Discussion

The key finding of this study is the high resolution or improvement of GERD (91%) in a refractory population of patients 2 years after implantation of the AGB system. A clear relationship between weight loss and reduction in the prevalence and severity of GERD was not conclusively demonstrated in this study, given that there was no significant difference in baseline weight or weight loss between the four categories (resolved, improved, stable, and worse). Furthermore, Pearson correlation coefficients indicated no significant correlation between changes in BMI or %EWL and reported GERD status after 2 years.

Weight loss in obese patients has been linked to improvement of GERD or GERD-like symptoms, and although resolution or improvement of GERD has been previously reported with the AGB procedure, and is further supported by this study, other studies utilizing bariatric surgery have reported mixed results.
regarding GERD. In addition, misconceptions regarding the AGB procedure exist within the medical and surgical communities, where a belief often exists that the AGB procedure may cause GERD, particularly in patients with weak esophageal body motility, where the AGB procedure is believed to result in esophageal dilation and GERD-like symptoms. A limitation of the APEX clinical trial is the unknown medical histories of these new cases of GERD. For example, GERD symptoms may have been caused by over-tightening the AGB system as a result of patient failure to lose weight. Failure of adequate weight loss in AGB is often due to the consumption of inappropriate quantities and/or types of food, such as liquid calories; as a result, patients may request a (inappropriate) tightening of the AGB system when a better dietary history and behavioral feedback would be the correct therapeutic approach. In such cases where this history and instruction fail to be elicited and communicated, an unnecessary over-tightening of the AGB system may lead to heartburn and incidents of nausea and vomiting.

The misconception that the AGB procedure is causative for GERD necessitates a brief examination of the effects of alternative bariatric surgical treatments on GERD, including fundoplication, vertical gastroplasty, and Roux-en-Y gastric bypass (RYGB). Currently, the main treatment for refractory GERD with hiatal hernia is fundoplication. However, equivocal results have been reported concerning long-term durability and efficacy of fundoplication in obese compared to non-obese patients, suggesting that fundoplication may be less effective in obese patients who may require alternative treatments. Similarly, mixed results have been reported on the efficacy of vertical gastroplasty on GERD, with little long-term data available. In contrast, RYGB has been reported to have positive effects on GERD in severely obese and non-severely obese patients, and in severely obese patients undergoing RYGB after failed fundoplication. Given the high rate of patient-reported resolution of GERD observed in the refractory population herein studied, consideration for the adjunctive utilization of the AGB procedure in patients with the obesity related comorbidity GERD appears warranted.

Although bariatric surgery has been successfully practiced for several decades, the mode of action by which each type of procedure achieves weight loss is not completely understood. With regard to the AGB procedure, the mode of action appears to be the induction of satiety and satiation by the proposed mechanism of compressing vagal afferents of the gastric cardia; this is achieved by placing the band around the very top of the stomach, such that there is a small proximal gastric pouch above the band. Although the AGB procedure is reported to briefly delay semi-solid transit of food into the infraband stomach without physically restricting meal size, it does not affect the overall rate of gastric emptying.

The AGB procedure therefore allows the patient to adhere to the follow-up eating guidelines, which require the consumption of small amounts of food at a slow rate.

As previously described, the causes of GERD are not completely understood, but are probably multifactorial and include hereditary and functional factors with more frequent transient lower esophageal sphincter relaxation (TLESR) episodes which may be combined with reduced basal tone of the lower esophageal sphincter (LES), or with esophageal or gastric motor dysfunction. The mechanism by which obesity leads to GERD is also not completely understood; however, obesity is reported to increase intra-gastric pressure (IGP), frequency of TLESR episodes, and the gastroesophageal pressure gradient, potentially leading to GERD. An alternative mechanism in which obesity may result in GERD is the separation of the LES from the extrinsic crural diaphragm, leading to the development of hiatal hernia. The coincidental association of GERD and hiatal hernia is well established, and it is possible that higher IGP, associated with separation of the LES from the extrinsic crural diaphragm may lead to hiatal hernia and GERD. With this potential GERD mechanism in mind, it is important to acknowledge that hiatal hernia repair, though seldom documented, is carried out at a rate of 25% to 40% during AGB procedures. Consequently, an unrecorded number of hiatal hernia repairs were carried out during the APEX study, with unknown consequences for the interpretation of the study data.

Although strong evidence supports the causal effect of obesity on GERD, it is currently unclear if the suppression of GERD by the AGB procedure is a function of weight loss, thereby reducing the previously described phenomena of higher IGP and more frequent TLESR, or essentially an anatomical augmentation of the gastroesophageal sphincter; most likely, it is a combination of both factors.

The present 2 year post-implantation analysis of the large prospective APEX study in severely obese patients (baseline BMI: 44.6 kg/m²) also demonstrates significant and sustained reductions of mean BMI of −8.9 kg/m² and mean %EWL of 49.8%. There was no significant difference in baseline BMI between patients with GERD at baseline and patients without GERD at baseline, showing the even distribution of patients in the study. In the population of patients without GERD at baseline, only 1.8% developed GERD after 2 years, providing strong evidence that the AGB system does not cause GERD. Moreover, these patients lost a similar amount of weight compared to patients with GERD at baseline. This coupled to the observation that weight loss was not correlated with GERD status suggests that reduction in GERD was achieved by a combination of weight loss and other factors.
such as anatomical augmentation of the gastroesophageal sphincter. Furthermore, although crucial approximation data was not available, it seems unlikely that this was routinely performed in most cases. In addition to the resolution or improvement in GERD, weight loss after 2 years was associated with resolution or improvement of several comorbidities associated with obesity, including type 2 diabetes, hypertension, hyperlipidemia, obstructive sleep apnea, osteoarthritis, and depression. Furthermore, high levels of patient satisfaction (87.4% of patients were satisfied or very satisfied with the AGB procedure), and significant improvements in the Obesity and Weight-Loss Quality of Life Instrument (OWL-QOL-17) total score and score for patients reporting resolution of GERD were achieved after 2 years. A significant correlation was demonstrated between change in total OWL-QOL-17 score and %EWL, suggesting that weight loss was associated with improvements in patient-reported quality of life. In patients with GERD at baseline, the incidence of serious device-related adverse events, and non-serious device-related adverse events was low after 2 years. Moreover, the incidence of SAEs and AEs was similar in patients with and without GERD at baseline after 2 years. However, patients with GERD at baseline had more AEs such as nausea, vomiting, heartburn, or symptoms of GERD, required explant or revisional surgery, or experienced pouch dilation. This analysis of the APEX study, as well as previous studies using the laparoscopic AGB procedure have demonstrated the system to be a safe and durable method of reducing body weight in obese patients.

Conclusion

In this 2 year interim analysis from the APEX study, the incidence and severity of GERD was significantly reduced in severely obese patients after surgical intervention with the AGB system. In addition, patients experienced concomitant decreases in weight and other obesity-related comorbidities. Patients reported high levels of satisfaction and improvement of quality of life measures, with a low incidence of adverse events. Consequently, laparoscopic placement of the AGB system could be considered as an adjunctive treatment option for frequent GERD in obese patients.

Transparency

Declaration of funding

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Disclosure of financial/other relationships

G.W., R.C., H.B., and K.M. are investigators and advisors for Allergan, Inc. C.C. and T.O. are employees and stock option/stock holders of Allergan, Inc.

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