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Can morbidly obese patients with reflux be offered laparoscopic sleeve gastrectomy? A case report of 40 patients

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GERD;
Sleeve gastrectomy;
Hiatal hernia;
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Abstract

BACKGROUND: The incidence of reflux in obesity can reach greater than 35%. Most surgeons recommend Roux-en-y gastric bypass to patients with pre-existing reflux. One alternative to Roux-en-y gastric bypass is the addition of anterior fundoplication (AF) with posterior crural approximation (pCA) to laparoscopic sleeve gastrectomy (LSG) in patients with documented reflux.

METHODS: Between February 2011 and April 2013 we reviewed data from the bariatric registry on weight loss, resolution of symptoms, and quality of life presurgery and postsurgery for all patients who consented to participate in the registry and underwent LSG with AF/pCA.

RESULTS: Forty patients met inclusion criteria; 78% (31) were female. The mean initial weight was 298 ± 64 lbs. with mean BMI of 49 ± 8 kg/m^2. The mean DeMeester score was 36 ± 27 (normal <14.7). Nine (22.5%) patients had esophagitis. Thirty-six (90%) patients had hiatal hernia. There were no intraoperative complications. The mean operative time was 84 ± 20 minutes and the mean hospital stay was 1.6 ± .9 days. Postoperative complications included 1 fluid collection, 1 narrowing, 4 admissions for nausea and dehydration, 1 for pancreatitis, and 1 for deep vein thrombosis . Thirty-eight (95%) patients had immediate resolution of reflux, whereas 2 (5%) patients complained of worsening symptoms. On short-term follow-up of 24 ± 6 months, 55% of patients responded to the gastroesophageal reflux disease-health related quality of life questionnaire with improvement in their median score from 31/75 interquartile range (IQR 25) preoperatively to 0/75 (IQR 6.5) postoperatively ($P < .0001$). Their %excess body mass index loss was 69 ± 27%.

CONCLUSIONS: Morbidly obese patients with documented reflux can be offered LSG with the addition of AF/pCA.

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In the last few years, laparoscopic sleeve gastrectomy (LSG) has been increasing in its popularity as the procedure of choice for the management of morbid obesity. According to data from the Michigan Bariatric Surgery Collaborative, sleeve gastrectomy (SG) in 2013 has surpassed Roux-en-Y gastric bypass (RYGB), which had been the most common

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operation for obesity in Michigan.[1] Reports have shown; however, that LSG is associated with both increased severity of reflux in some patients, and an increase in de-novo incidence of gastroesophageal reflux disease (GERD) in others.[2] In fact, 57% of the International Sleeve Gastrectomy Expert Panel in 2011 believes that GERD is a relative contraindication to SG.[3] As a result, surgeons will typically offer RYGB to these patients, thus potentially overriding their wishes. For patients in our practice with documented GERD who do not wish to undergo RYGB, we offer LSG with the addition of anterior fundoplication (AF) with a posterior crural approximation (pCA). We reviewed registry data for these patients to assess weight loss. In addition, resolution of symptoms and quality of life was assessed using the gastroesophageal reflux disease-health related quality of life questionnaire (GERD-HRQL) questionnaire both presurgery and postsurgery. This questionnaire was developed and validated to measure changes of typical GERD symptoms in response to surgical or medical treatment.[4,5]

Methods

Data were reviewed on all patients who underwent LSG from February 2011 to April 2013. As per standard practice, all patients undergoing LSG were evaluated preoperatively with upper endoscopy. Patients with reflux had a pH monitor using the Bravo capsule (GIVEN, Duluth, GA). Patients with reflux were counseled that they could undergo RYGB as an option for treatment of both the morbid obesity condition and the reflux problem. They were also offered LSG with AF/pCA. They were informed about their dual problem: obesity and reflux. The obesity is treated by SG and the reflux is normally treated by fundoplication; in LSG with AF/pCA we combine the 2 procedures. The potential risks and complications were explained. All patients declined the RYGB option and consented for the LSG and AF/pCA. Esophageal motility was not performed because we were not planning on doing a full wrap. In addition, patients declined undergoing an uncomfortable test especially that the results were not going to change the planned AF. We collected data from the registry on those patients who underwent this procedure and participate in the registry. Data were collected as part of routine follow-up on weight loss, symptom resolution, proton pump inhibitor (PPI) use and GERD-HRQL scores of reflux presuegery and postsurgery. Patients' weight loss was documented and their percent excess body mass index loss was calculated. Data were then retrospectively reviewed and analyzed using paired *t* test. Differences in quality of life (GERD-HRQL) scores were assessed using the Wilcoxon signed-rank test. All data were analyzed using SPSS, v. 22.0, and a *P* value of .05 or less was considered to indicate statistical significance. The registry and subsequent analysis of data from the registry were approved by the institutional review board.

Surgical technique

The procedure was performed using 5 incisions (Fig. 1). The short gastric vessels were transected from an area across from the incisura angularis to the fundus of the stomach. The peritoneum around the esophagus was opened and the esophagus was mobilized bringing a portion of thoracic esophagus intra-abdominally. The posterior crura of the diaphragm were approximated and a blunt tip bougie (36 to 40 fr.) was placed. Nonabsorbable sutures of 0-Ethibond were used to approximate the crura of the diaphragm posteriorly. The approximation allowed the bougie (36 to 40 fr.) to pass into the antrum without difficulty. The stomach was then transected along the edge of the bougie from an area across from the incisura angularis (approximately 6 cm from the pylorus) to the fundus of the stomach leaving a small pouch. In creating the gastric pouch, the stapler stayed at the gastric fat pad at a 45-degree angle with a distance of approximately 4 cm from the gastro-esophageal junction. Care was made not to come close to the incisura angularis (distance 2 to 3 cm) and not to stretch the stomach when stapling especially at the fundus. The staple line was not sutured or inverted to avoid narrowing of the gastric lumen. The bougie was then removed, and the gastric pouch was sutured at the 10 o'clock location on the right side of the esophagus using 3 sutures of 2-0 Ethibond. The sutures were taken at the staple line of the pouch. Additional suture was placed between the top portion of the

Figure 1 Trocars positions.

pouch and the right crus anteriorly to prevent twisting of the esophagus (Figs. 2-6). The cut portion of the stomach was then removed through the 15-mm trocar in the supra-umbilical area. Visual inspection of the staples line was done without any need for an esophago-gastro-duodeno-scopy (EGD) or a leak test.

Results

During the study period we identified 40 patients who underwent the procedure and participated in the registry. Thirty-one (78%) patients were females. The initial mean weight was 298 ± 64 lbs. with mean body mass index (BMI) of 49 ± 8 kg/m^2. Their preoperative DeMeester score was 36 ± 27 (normal <14.7). Nine (22.5%) patients had esophagitis. Thirty-six (90%) patients had hiatal hernia. The remaining 4 patients had esophagitis in 2 patients and severe reflux in the other 2 patients without documented hiatal hernia.

Patients underwent LSG with AF/pCA using a 36 fr. bougie in the first 25 patients, and 40 fr. bougie in the second 15 patients. The mean operative time was 84 ± 20 minutes. There were no intraoperative complications. The mean hospital length of stay was 1.6 ± .9 days.

Postoperative complications included 1 patient who developed a small fluid collection with no evidence of a leak by postoperative imaging. This patient was treated conservatively with computer tomography guided drainage and total parental nutrition. One patient developed narrowing requiring endoscopic dilatation. Six patients were readmitted within 30 days; 4 for nausea/dehydration, 1 for pancreatitis, and 1 for treatment of deep vein thrombosis.

Complete resolution of reflux occurred immediately postoperatively in 38 (95%) patients. These patients stopped their PPI and other antiacid medication immediately postoperatively. Two (5%) patients (both in the 36 fr. bougie) complained of worsening of their reflux symptoms. On short-term follow-up of 24 ± 6 months, 55% of patients responded to the GERD-HRQL questionnaire with improvement in their median score of 31/75 (IQR 25) preoperatively to a score of .0/75 (IQR 6.5) postoperatively ($P < .0001$) without taking any PPI or other antiacid medications. Their BMI was 33 ± 8 kg/m^2 with percent excess body mass index loss of 69 ± 27%.

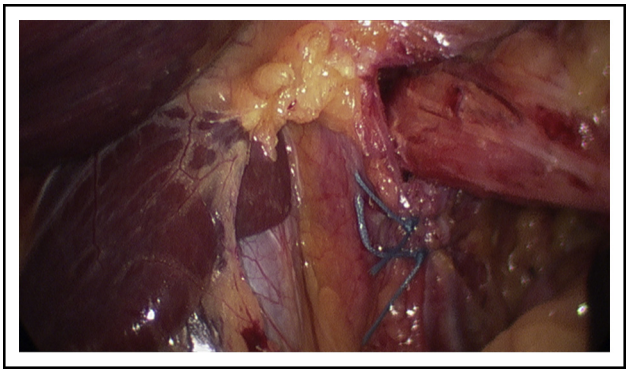

Figure 3 Posterior crura approximation.

Comments

GERD is a recognized obesity-related complication with the prevalence ranging from 39% to 61% among patients undergoing evaluation for bariatric surgery.[6–8] A meta-analysis conducted by Hampel et al[9] showed a trend with BMI with a pooled adjusted odds ratio for GERD symptoms of 1.43 for BMI between 25 and 30 kg/m^2 and 1.94 for BMI greater than 30 kg/m^2. Furthermore, a review of multiple case-control and cohort studies by El-Serag[10] concluded that obesity carried a 1.5 to 2 fold risk increase in GERD symptoms and erosive esophagitis. As LSG becomes an increasingly popular and viable option as a stand-alone procedure in bariatric surgery, special attention to prevalence and incidence of GERD symptoms becomes necessary.

In 2011, The International Sleeve Gastrectomy Expert Panel issued best practice guidelines based on more than 12,000 cases. Of note, 90% of panelists agreed that LSG is a viable stand-alone procedure and 82% believed that hiatal hernias, if found, should be repaired. However, 57% of panelists believed that GERD was a relative contraindication to LSG.[3] Fueling this divisive sentiment no doubt is the

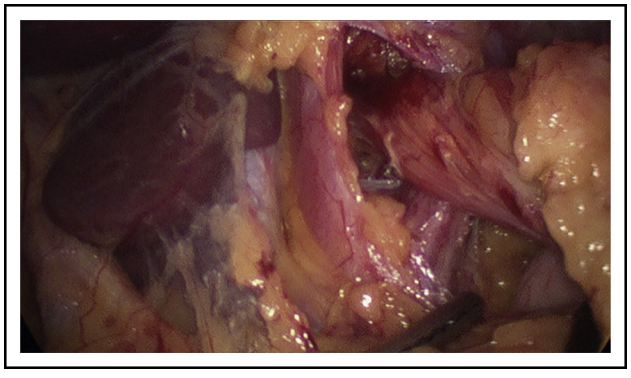

Figure 2 Exposure of the posterior crura of the diaphragm.

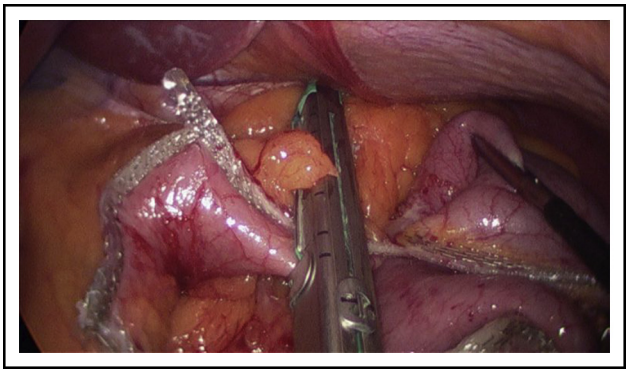

Figure 4 Leaving small fundus for the AF.

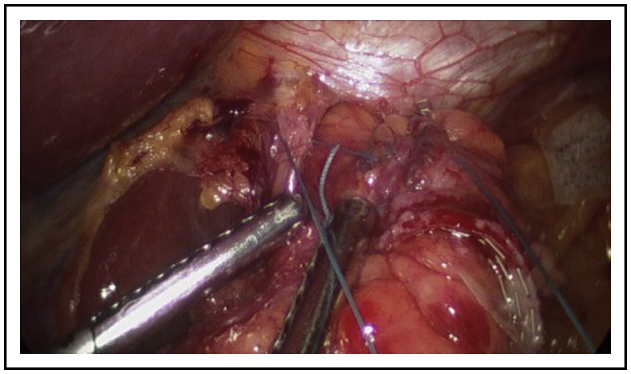

Figure 5 The anterior fundoplication.

realization of increased prevalence of reflux from 34.6% before LSG to 49% after LSG.[11] Howard et al[12] further mirrored these findings in a study that showed a 22% de-novo incidence of reflux after LSG. Given these findings many surgeons are recommending RYGB, potentially overriding patients' wishes, when faced with patients who have GERD.

Weight loss in itself is a well-known factor influencing the resolution of reflux symptoms. Singh et al[13] reported a 65% resolution of reflux depending on the amount of BMI loss over time. The addition of hiatal hernia repair to LSG to address GERD is a relatively new concept with variable results. In a prospective single center study carried out by Daes et al,[14] the addition of hiatal hernia repair to LSG resulted in a 47.5% decreased prevalence of GERD in a short postoperative follow-up at 6 and 12 months. Out of 97 patients, Soricelli et al[15] realized no new cases of GERD when combining LSG and hiatal hernia repair with resolution of reflux in 73.3% with a mean follow-up of 18 months. None of these reports indicated whether the resolution of reflux occurred immediately postoperatively or over the follow-up period giving the possibility that the weight loss may have been a factor in the resolution of the reflux.

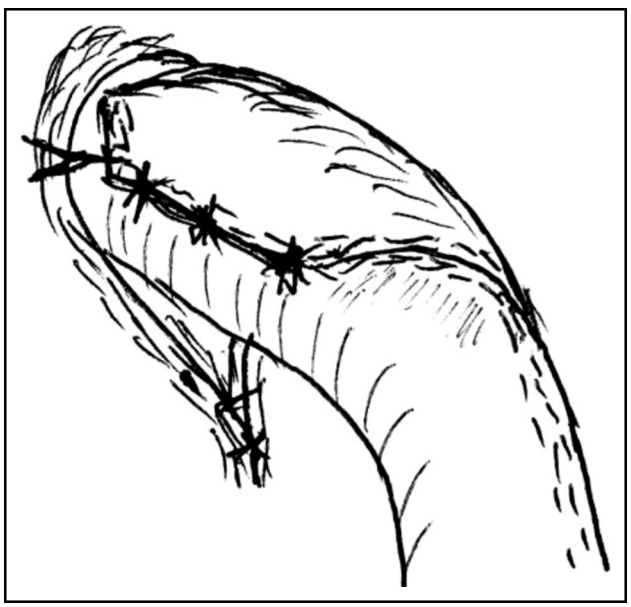

Figure 6 Diagram of the AF.

The traditional treatment of reflux has been centered on the performing of a fundoplication in addition to the repair of the hiatal hernia when present. This is done to address the role of the weak lower esophageal sphincter and its transient relaxations on the etiology of reflux.[16,17] Thus we elected to combine these 2 standard treatments (LSG for obesity and AF for reflux) at the same time in our patients who has both problems to achieve better results in controlling the reflux along with the weight loss.

AF has been recognized as a method to treat reflux since its introduction by Watson, who published his results in 1991.[18] Later, other authors have demonstrated its efficacy in controlling GERD symptoms.[19–21] A meta-analysis by Broeders et al[22] have shown even better results in controlling reflux over Nissen fundoplication. The success of this method in controlling the reflux without the need for too much tissue to do the wrap, in contrast to what is needed in the standard Nissen fundoplication, allowed us to use it in our patients where the fundic tissue was reduced in volume as part of the LSG.

In a literature search on reports where fundoplication was added to LSG to address the lower esophageal sphincter (LES) role in reflux resolution, we found 1 report by Santoro et al[23] where a partial AF was done in addition to the hiatal hernia repair. Their results showed 61.4% resolution of reflux. Unfortunately, they did not indicate whether this was achieved immediately postoperatively or over time where the weight loss may have been a factor in the resolution of the reflux.

In contrast to Santoro et al[23]; however, we did a complete AF where we sutured the wrap over the anterior esophagus to the 10 o'clock location to augment the weak LES (Fig. 6).

We believed that addressing the weight loss and the repairing of the hiatal hernia alone without addressing the LES, was bound to have partial success in achieving resolution of the reflux as proven by the previously mentioned literature. We felt that treating the reflux in the obese population, who needed a weight reduction procedure, should be the same as in the nonobese population, which is by adding the fundoplication to the hiatal hernia repair at the same time of the weight reduction procedure to achieve the best results. Tissue limitation by the LSG dictated the use of the AF.

Our result of 95% complete and immediate postoperative resolution of GERD after LSG supports our theory. In the 2 (5%) patients in whom GERD actually worsened, the LSG was done with a 36 fr. bougie. We cannot be sure whether this smaller size bougie contributed to the worsening of the reflux symptoms because of a higher mid body pressure of the stomach, or it was just a failure of the LSG or the fundoplication technique.

Our data suggest that the addition of complete AF to the approximation of the posterior crura does have an added value to the repair of the crura alone by improving the effectiveness of controlling the reflux from 61.4% (achieved by Santoro with partial AF) and 73.3% (the

highest achieved by Soricelli by repairing the hiatal hernia alone) to 95% complete and immediate resolution of the reflux. In addition, our results compares favorably with those reported on the effectiveness of RYGB in controlling reflux in a study by Pallatti et al[24] on 116,136 patients where all patients had repair of the hiatal hernia at the time of their bariatric procedure which showed improvement in their reflux score in 56.5% (7,955 of 14,078) after RYGB and 41% (240 of 586) after SG in a 6 months follow-up. The immediate postoperative resolution of reflux points to the effectiveness of this technique independently of the weight loss. The additional effect of the weight loss over time would hopefully help in keeping the reflux from recurring with better lasting results.

In view of our early results and the promising outcome that we saw in the early follow-up period we began to offer this technique to our patients who developed de-novo reflux after LSG in October 2012. Using bariatric registry data, we previously reported our results on a case series of 6 patients who declined RYGB and consented to undergo the AF in addition to posterior crura approximation. All 6 patients did well and had immediate postoperative resolution of their reflux.[25]

Our report has several limitations which include; a retrospective review of the data from registry of those patients who underwent this procedure; a small sample size; the relatively short follow-up period, and the lack of using more objective methods to assess the resolution of reflux other than the cessation of PPI use and the GERD-HRQL questionnaire. Ideally a preoperative and postoperative pH monitor and LES pressure documentations, as part of the evaluation of the effectiveness of this technique, would be helpful. We hope that the results of our case series will lead to randomized prospective multicenter controlled studies comparing LSG/pCA vs RYGB in controlling reflux in the morbidly obese population.

Conclusions

Morbidly obese patients, who are suffering from reflux, can still be offered LSG by adding AF/pCA to the operation.

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Discussion

Discussant

Dr. Gus slotman (Vineland, NJ): The work presented today actually is built on a pilot by this group that was published online just 11 days ago where they used this same technique to treat de-novo reflux that developed after SG. Now they have taken it a step earlier in the process and treating morbid obesity and preoperative existing reflux again with the crural approximation and AF. If this catches on, one would hope to see prospective randomized trials. I have 3 questions for the authors.

The 1st question is that, in addition to being morbidly obese and having reflux, the main criteria in these patients refuse to have laparoscopic gastric bypass. I'm wondering in this highly self-selected group whether they perhaps were different than any other patients in your population with reflux who had gastric bypass. Was there less esophagitis, was the DeMeester score lower, anything that might make the group that actually was presented here to be more likely to be successful? The 2nd question is, you have a golden opportunity in your practice to do case matched 40 patients by age, sex, BMI, comorbidities, DeMeester score, pH testing against the 40 that you have here. And I wondered, have you done that and how does this actually match up to gold standard of gastric bypass? And, thirdly, including the four patients who had to be readmitted for nausea, vomiting, and dehydration, the 20% seems a bit higher than we expect from, sleeve alone or gastric bypass alone? Is there a learning curve with this procedure?

Dr. Hawasli: To answer your first two questions, actually we don't have the Roux-en-Y gastric bypass case match. Patients are offered the Roux-en-Y bypass by other groups if they want to have that, and they opted not to. So they were not forced or pre-selected to the sleeve. However, the literature is really filled with a lot of papers comparing the Roux-en-Y gastric bypass to sleeve in the resolution of reflux. And, actually, there was a article by Pulatti in 2014 of 116,000 patients with 32 percent, which is 36,000 patients, who showed that adding the hiatal hernia repair to the Roux-en-Y bypass improved the reflux in 56% whereas adding the hiatal hernia to the sleeve the reflux was improved by 41%. Our number of 95% resolution of reflux with adding the anterior fundoplication to the hiatal hernia repair is really better than these 2 findings, and their follow-up was only for 6 months. Our follow-up was 24 months.

Also, in 2014, we published the article with Dr. Verban from the Michigan Bariatric Surgical Collaborative on the use of antireflux medication a year after using any of the bariatric procedure from the collaborative study, and we showed that even with the Roux-en-Y gastric bypass, patients who are using antireflux medication before the surgery and had the Roux-en-Y gastric bypass, 44% of them continued to use the antireflux medication and there was 17% new users. That means, even Roux-en-Y bypass does not resolve the reflux in a 100%.

In regard to complication, I agree with you, it is a little high; however, there're 2 factors. One of them is bougie size; 6 of the patients who had nausea and vomiting postop and readmission were in the 36 French bougie size sleeve. So I know some of you will argue what's the difference between 36 French and 40 French is only 1.3 millimeter; however, we have seen before that smaller French bougie can cause more nausea. The second factor is discharging the patients within 1 day or 1.6 days, which can contribute to the readmissions where another 24 hours or 48 hours was needed to resolve their nausea. Some institutions have an outpatient infusion center that they have the patient come to and they are not considered as complication on their data collection.

Dr. Peter Hallowell (Charlottesville, VA): On your patients with the reflux, was that self-reported that triggered the work-up or are you doing a work-up on everybody that's getting a sleeve for reflux? And then how do you assess the size of your pouch? Most of us come along the bougie and bring it within a half centimeter or a centimeter at the gastro-esophageal junction, but you look like you're curving out. So, technically, how are you gaging the size of the pouch to make this AF? And then, finally, Jack Kinpins from the European group, when we originally started doing sleeves, it was shown that reflux begins to occur at 3 years follow-up. So I think we are going to need a little bit more long-term data on this to show whether it's effective or not.

Dr. Hawasli: We perform an EGD on all patients undergoing SG. So if the patient complained of reflux, we do a Bravo test to document the reflux. on them. Every patient we have to document the reflux by Bravo test. And a number above 14.7 is considered positive. If on EGD we find a hiatal hernia or esophagitis, then we did a Bravo, as well, On the size of the bougie, we use the visual inspection of how much we need to wrap anteriorly. So if you stay outside the fat pad of the fundus, most likely you get enough length. So it is a matter of gaging by experience how your size should be to be able to wrap it around.

And, finally, you mentioned about the reflux occurring after two, three years. That's correct for those patients who develop the de novo reflux. Our study was on patients who presented with reflux at time of the sleeve. Actually in our article that was published 11 days ago, the de-novo reflux did occur about 2 or 3 years after the sleeve. I agree with you, we need about two, three years follow up to see if reflux is going to re-occur.