Clinical Management of Patients Presenting with Non-Adjustable Gastric Band (NAGB) Complications

Julius Balogh, MD\textsuperscript{a}; Andrey Vizhul, MD\textsuperscript{b}; Brian J. Dunkin, MD, FACS\textsuperscript{c}; Nabil Tariq, MD, FACS\textsuperscript{c}; and Vadim Sherman, MD, FRCSC, FACS\textsuperscript{c}\textsuperscript{*}

\textsuperscript{a}Houston Methodist Hospital, Houston, Texas; \textsuperscript{b}University of Alberta, Edmonton, Alberta; \textsuperscript{c}Bariatric and Metabolic Surgery Center, Houston Methodist Hospital, Weill Cornell Medical College, Houston, Texas

Background: A number of bariatric surgical procedures have been developed to manage morbid obesity and related co-morbidities. The non-adjustable gastric band (NAGB) was one such procedure that created restriction to food intake by gastric segmentation. Benefits of the procedure included a low risk of perioperative complications and substantial early weight loss. Unfortunately, the long term results of NAGB include a high incidence of complications and failure to maintain weight loss. The purpose of this study was to examine the presentation, workup, and treatment of patients presenting with complications following NAGB placement.

Methods: A retrospective review of the diagnosis and management of 11 patients who presented with complications related to NAGB placement.

Results: All patients presented with some degree of proximal gastric outlet obstruction. The majority of patients (8/11) presented with vomiting as the main complaint. Other complaints included intolerance to solids, liquids, and reflux. Only 2/11 patients presented with weight loss since undergoing NAGB placement, while the remainder had weight regain to their pre-NAGB level and above. Depending on clinical presentation, desire for additional weight loss and co-morbid conditions, patients underwent a variety of treatments. This included NAGB removal (endoscopic, laparo-endoscopic, and laparoscopic) as well as conversion to another bariatric procedure (sleeve gastrectomy, Roux-en-Y gastric bypass).

Conclusion: Patients with NAGB complications present with symptoms related to a proximal gastric outlet obstruction, related to constriction imposed by the band. This may result in severe food and liquid intolerance and subsequent weight loss, but more likely results in maladaptive eating and subsequent weight gain. Optimal therapy involves removal of the NAGB. Laparoscopic conversion to another bariatric procedure, optimally a Roux-en-Y gastric bypass, is warranted to treat morbid obesity and associated co-morbidities.

*To whom all correspondence should be addressed: Vadim Sherman, MD, FRCSC, FACS, Medical Director, Bariatric and Metabolic Surgery Center, Houston Methodist Hospital, Assistant Professor, Weill Cornell Medical College, 6550 Fannin St., SM 1661, Houston, TX 77030; Email: vsherman@houstonmethodist.org.

†Abbreviations: NAGB, non-adjustable gastric band; ePTFE, Gore-Tex; EGD, esophagogastroduodenoscopy; TGER, trans-gastric endoscopic rendezvous procedure; RYGB, Roux-en-Y gastric bypass; UGI, upper gastrointestinal; pGOO, proximal gastric outlet obstruction; LRYGB, laparoscopic Roux-en-Y gastric bypass; LSG, laparoscopic sleeve gastrectomy.

Keywords: bariatric, complications, revision, laparoscopic, non-adjustable gastric band
Bariatric surgery has consistently been proven as one of the most effective means of producing a sustainable weight loss [1]. Unfortunately, since not all bariatric procedures are equal, history has demonstrated the development, proliferation, and subsequent demise of a number of surgical weight loss procedures. For example, non-adjustable gastric banding (NAGB) initially led to excellent short-term outcomes; however, it was ultimately abandoned due to poor long-term success rates and complications.

The non-adjustable gastric band was developed by Marcel Molina in 1980, and over the next decade, it was implanted into at least 7,347 patients [2,3]. The main principle of the operation was to perform gastric segmentation. A strip of prosthetic material would be encircled around the upper stomach, with the assistance of an intra-gastric sizing tube, and sewn to itself to create a band. Since the proximal gastric pouch could be separated from the remainder of the stomach without transecting the stomach, the operation was one of the least invasive bariatric procedures of its time. Figure 1 represents a schematic of the gastric segmentation created by placement of the NAGB. Figure 2 is a representative image obtained from a barium swallow study, demonstrating the post-surgical anatomy of a patient with a non-adjustable gastric band.

The mechanism of action of weight loss is through restriction of food intake. Food fills the small gastric pouch and is delayed from passing into the remainder of the stomach due to a narrowing imposed by the NAGB. This mechanism was later adapted for use in other surgical weight loss therapies, such as vertical-banded gastroplasty, banded gastric bypass, and adjustable gastric banding [4-6]. A number of prosthetic materials were employed to create the band, which included polypropylene, silastic tubing, Dacron, and Gore-Tex [7]. Many of the early NAGB placed by Molina used Dacron as the band material. A significant inflammatory reaction would result at the site of the Dacron band, resulting in dense adhesions that prevented band migration but also resulted in gastric stenosis and erosion of the band into the lumen of the stomach [3]. Subsequently, Molina altered the band material to Gore-Tex (ePTFE), which did not lead to the same localized inflammatory reaction. In our study of patients, six presented with Dacron bands, while the other five presented with ePTFE bands.

Low mortality rates, coupled with a low risk of perioperative complications led to a...
wide adoption of the NAGB. Oria reported Molina’s 28-year experience with 7,650 gastric segmentations, noticing 68 percent and 50 percent of excess weight loss at 1 and 10 years, respectively, but the follow-up rate was less than 20 percent [3]. Reversals were performed in 719 (9.4 percent) and revisions in 311 patients (4 percent). Band erosion was seen in 128 (1.7 percent) patients. The technique was also employed by Westgate, who reported his results in 300 cases. Short term weight loss was successful in that 54 percent of patients experienced a 30 percent weight loss, and 68 percent of patients had at least 25 percent weight loss. Perioperative complications rates were 1 percent, and mortality was 0 percent; however, reoperation or reversal was performed in 12.7 percent of patients [8]. Fried also reported encouraging early outcomes with his 10-year experience of 931 NAGB patients. Perioperative complications were seen in 1.1 percent, and only 6.3 percent of patients underwent reoperation [9]. Despite low rates of perioperative complications and good short-term weight loss, it became readily apparent that with longer follow-up, these outcomes could not be sustained. After following up 92 patients for 7 to 12 years, Naslund and colleagues, one of the first institutions to adopt NAGB, concluded that the method cannot be recommended [10]. Weight regain and incidence of persistent vomiting were unacceptably high, and only 31 percent of their patients did not undergo reoperation.

The same obstructive mechanisms that led to weight loss were also responsible for long-term complications. Despite the abandonment of the NAGB, patients continue to present with a spectrum of gastrointestinal complications related to previously undergoing an NAGB, even decades following the index operation. The purpose of this paper is to examine the spectrum of clinical presentation and treatment options in patients presenting with complications due to non-adjustable gastric band placement.

METHODS

NAGB were not performed at Houston Methodist Hospital Bariatric and Metabolic Surgery Center; however, the center acts as a tertiary referral center for patients with complications related to a previous bariatric surgical procedure. A retrospective chart review was performed, encompassing the period from January 1, 2010, to December 31, 2013, for patients presenting to our center with a history of non-adjustable gastric band placement.

A total of 11 patients were identified. Each case was examined to determine presenting symptoms, results of diagnostic testing, clinical management, and outcomes of therapeutic procedures. Symptoms related to proximal gastric outlet obstruction were defined as vomiting, regurgitation, dysphagia, intolerance to solids, intolerance to liquids, reflux, and heartburn.

Diagnostic testing included upper endoscopy and barium swallow. Oftentimes, patients presented with diagnostic testing already performed by their referring physician. In the remainder of the cases, diagnostic testing was performed as necessary to confirm the patient’s gastric anatomy and confirm the diagnosis. With respect to upper endoscopy, special attention was paid to the presence of esophageal findings such as esophagitis and hiatal hernia, degree of stenosis imposed by the band, and any erosion of the band.

All 11 patients underwent interventions to treat their symptoms. These included both endoscopic and surgical procedures. Details of each therapy and outcomes are discussed below.

RESULTS

Patient Presentation

Six of the 11 patients presented with Dacron bands, while the remaining five had Gore-Tex bands. The primary reason for consultation was either due to weight regain, proximal gastric outlet obstruction symptoms, or both. Eight of 11 patients (72.7 percent) presented with vomiting as the main complaint. All eight patients also had difficulty tolerating solids, although there was variability of the food to which they were intolerant. Six of 11 (54.5 percent) were intolerant to meats,
5/11 (45.4 percent) were intolerant to breads, and 5/11 (45.4 percent) were intolerant to vegetables. Two out of 11 patients (18.2 percent) complained of regurgitation of undigested food, and 1/11 (9.1 percent) was unable to tolerate liquids, in addition to inability to tolerate solids. Three of 11 patients (27.3 percent) also complained about dysphagia, and 5/11 (45.4 percent) had persistent nausea related to meals. Upon detailed questioning, 7/11 patients (63.6 percent) admitted to symptoms of reflux and heartburn. Despite a preponderance of proximal gastric outlet obstruction related symptoms, only two patients had demonstrated a significant weight loss since undergoing the non-adjustable gastric band placement. The remainder of patients had either regained weight lost after the index operation or had a minimal change in weight overall (Figure 3). All 11 patients indicated they had modified their diet to various degrees in response to the proximal gastric outlet obstruction symptoms.

**Esophagogastroduodenoscopy (EGD) Findings**

All 11 patients underwent EGD. Five patients (45.4 percent) had severe stenosis at the site of the NAGB, which hindered the passage of the endoscope. Two of these patients had significant esophageal dilation that was readily apparent on EGD and likely secondary to the chronic obstruction imposed by the band. Hiatal hernias were found in six patients (54.5 percent), and band erosion was found in three of the 11 patients (27.3 percent). Esophagitis was seen in only one patient and was classified as minor. Three patients had previously undergone an EGD at outside institutions. In two of these procedures, a balloon dilatation at the band site was attempted, without subsequent relief of symptoms.

**Barium Swallow Findings**

Barium swallow studies were performed selectively for 4/11 patients. The test was used to delineate gastric anatomy in patients presenting without operative reports or adequate knowledge regarding their surgical history. These patients subsequently went on to have an EGD. All four patients were found to have strictures imposed by the band, although contrast was able to flow past the stricture, albeit with a delay.

**Therapeutic Intervention**

All 11 patients required therapeutic intervention to address their symptoms. Two patients underwent therapeutic endoscopy. The remaining nine patients underwent surgical procedures. The detailed management plans follow below.

The three patients who presented with erosion of the non-adjustable gastric band underwent removal of the eroded band. Two
such patients underwent totally endoscopic removal, and one underwent a trans-gastric endoscopic rendezvous procedure (TGER). Totally endoscopic removal was achieved by a combination of endoscopic scissors and electro-cautery to divide the band, followed by its eventual removal. The TGER procedure involved endoscopic visualization of the eroded band, in combination with trans-gastric trocars that were placed laparoscopically. Details of the procedure have been previously reported in a separate group of patients [11].

The remaining eight patients were all treated using laparoscopic surgery. Four patients underwent simple removal of the non-adjustable gastric band, with no additional procedures. Three patients underwent band removal and laparoscopic partial gastrectomy and Roux-en-Y gastrojejunostomy. One patient underwent band removal and conversion to sleeve gastrectomy. In patients where the procedure involved partial gastrectomy and conversion to Roux-en-Y gastric bypass (RYGB), the gastric transection was performed proximal to the level of stenosis.

**Outcomes Following Therapeutic Intervention**

All 11 patients underwent a post-operative upper gastrointestinal (UGI) series, and there was no leak identified in any patient. Totally endoscopic NAGB removal was performed as an outpatient procedure. For patients undergoing laparoscopic intervention, average length of stay was 2.1 days. There were no instances of surgical site infection, leak, pneumonia, venous thromboembolism, or need for blood transfusion. Three of the 11 patients were readmitted within 30 days postoperatively, for reasons including abdominal pain and dehydration.

Ten of 11 patients (90.9 percent) experienced resolution of their proximal gastric outlet obstruction symptoms at the time of the first postoperative visit (7 to 30 days postoperatively). One patient continued to suffer from nausea and vomiting as well as inability to tolerate certain solids and liquids at the 30-day postoperative visit; however, this resolved by the 90-day postoperative visit, without any diagnostic testing or therapeutic intervention.

Of the seven patients who underwent sole removal of the NAGB, two gained weight within the first month postoperatively. The patients who gained weight (7 and 10 lbs, respectively), were the two patients who had presented with BMI of less than 30. The remainder of the band removal patients had no change in weight at the 30-day postoperative visit. These seven patients were not followed up beyond the 30-day visit. The three patients who had undergone conversion to a RYGB demonstrated excellent weight loss. Average excess weight loss was found to be 61 percent at 2 years follow-up. The patient who underwent conversion to sleeve gastrectomy experienced an excess weight loss of 45 percent at the 1-year follow-up; however, she experienced weight regain and return of reflux symptoms by the 2-year follow-up, where excess weight loss was now 32 percent.

**DISCUSSION**

In our study, the limited group of patients presented overwhelmingly with symptoms related to proximal gastric outlet obstruction (pGOO). The spectrum of pGOO involves varying tolerance to solid foods, liquids, reflux, and dysphagia. All patients presented with at least one of these symptoms, with the majority of patients presenting with intolerance to solids and reflux. The tight stoma created by placement of the NAGB, combined with the local tissue reaction that further narrows the stoma, invariably leads to a degree of obstruction of the proximal stomach. Patients may experience dysphagia and intolerance to certain foods as the first symptom. Should the obstruction become severe enough, an intolerance to liquids will also result. If the proximal pouch dilates in response to the chronic obstruction, stasis of food products and upper gastrointestinal secretions will lead to symptoms akin to heartburn and esophageal reflux. Meanwhile, six patients were found to have a concurrent hiatal her-
nia. Owing to the high number of hiatal hernias identified, it is theorized that these are in response to the chronic proximal gastric obstruction and likely contribute to the patient’s reflux symptoms. Lastly, should the stenosis become severe enough, the band may erode into the stomach, which actually provides some relief, but unlikely resolution, of the obstruction.

Diagnostic testing may provide information related to the extent of pGOO; however, patient symptomatology is usually enough to make the diagnosis. Barium swallow is useful to confirm the gastric anatomy, ensure that liquids can be tolerated, and visualize the extent of spontaneous reflux into the esophagus. Upper endoscopy will readily confirm the gastric anatomy as well; however, the added benefit is the diagnosis, and possible treatment, of an eroded gastric band. Although it is tempting to perform dilatation at the stricture site, this is rarely useful as the gastric band creates a fixed obstruction that is not amenable to any dilatation. Upper endoscopy will also provide anatomical landmarks that are useful when considering revisional surgery, such as pouch size and distance of the band from the gastro-esophageal junction.

The presence of an eroded band makes a therapeutic endoscopic intervention possible. In this situation, the exposed portion of the band can be transected intraluminally, using either a solely endoscopic technique or combination endoscopy and transgastric resection. In both situations, the capsule that has formed around the gastric band and stomach is not disturbed. On the contrary, using laparoscopy to open the capsule and retrieve an eroded band results in the need to close the resulting gastrotomy in inflammatory tissue.

Relief of pGOO symptoms, secondary to a NAGB, can only be definitely achieved by removal of the NAGB and/or bypassing the strictured segment by performing a Roux-en-Y gastric bypass. In our study, four patients underwent simple laparoscopic removal of the NAGB without any additional procedures. In addition to band removal, the capsule that had formed between the band and the stomach was also dissected and removed. Failure to remove this capsule is unlikely to completely resolve pGOO symptoms, since the capsule itself forms a concentric ring that perpetuates the stenosis. All four patients experienced an immediate resolution of symptoms. In the two patients who presented with a normal-low BMI, resolution of the symptoms was also met with an intentional early weight gain. The other two patients who had concurrent obesity did not experience any substantial change in weight once their pGOO symptoms resolved.

An interesting finding of this study is that the overwhelming majority of patients who presented with pGOO due to NAGB also presented with morbid obesity and weight regain following their NAGB. Despite an intolerance to many foods, patients will actually present with a continued weight gain. In essence, this is a bariatric paradox, but can be explained by maladaptive eating. Foods that are not tolerated are avoided, and instead, the diet is composed of soft and liquid foods that tend to have a high calorie density. Therefore, removal of the NAGB and conversion to another bariatric procedure is optimal to treat both the symptoms of pGOO, as well as the morbid obesity. Other reports, such as Hedberg’s study, described 121 Roux-en-Y gastric bypasses being performed for failed restrictive procedures, 21 of which were in patients with an NAGB [12]. Jones described six NAGB failures undergoing RYGB, from a group of 414 revision procedures [13].

In our study, four patients with concurrent morbid obesity underwent a conversion to another bariatric procedure. Despite the added complexity of these revisional procedures, there was no incidence of major complications or anastomotic leak. One of the four patients underwent a conversion to sleeve gastrectomy and had delayed resolution of pGOO symptoms. The other three patients underwent a conversion to RYGB, with immediate resolution of pGOO symptoms. Furthermore, these three patients experienced a postoperative weight loss comparable to patients undergoing a primary
RYGB and was increased compared to the sleeve gastrectomy patient. A Roux-en-Y gastric bypass is the preferred procedure, as the site of the stricture can be definitively bypassed. When converting a NAGB to a sleeve gastrectomy, a dilated gastric pouch may result proximal to the level of the band, which may incompletely resolve the pGOO. However, success has been reported, albeit in a group of three NAGB failures [13].

The biggest limitation of this study is the number of patients. Considering how many patients have undergone placement of a non-adjustable gastric band, it is conceivable that there should be a significantly higher number of patients with complications and weight gain. However, it is incorrect to believe that lack of patient presentation implies success of these restrictive procedures. On the contrary, patients are often loathe to present to a bariatric surgeon, due to feelings of failure, shame, and financial reasons. The patients described in this paper were forced to make dietary changes for a prolonged period of time and were thankful once they experienced relief of their symptoms.

Despite the small group of patients, the study describes the spectrum of symptoms associated with proximal gastric outlet obstruction secondary to non-adjustable gastric banding, as well as the variety of findings on diagnostic testing. Endoscopy is a vital diagnostic tool and may occasionally be used as a therapeutic option. Lastly, these complex revisional cases can be performed laparoscopically. Figure 4 represents the algorithm for management and treatment of patients presenting with NAGB complications. One important consideration is that a conversion to Roux-en-Y gastric bypass should be considered for patients with pGOO and morbid obesity, as this bariatric procedure is founded on metabolic changes, rather than simple restriction to food intake.

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