



Long-term outcomes following endoscopic stenting in the management of leaks after foregut and bariatric surgery

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Abstract

Introduction Endoscopic stenting has been shown to be effective in treating leaks after bariatric surgery. However, concerns remain regarding its long-term efficacy. The purpose of this study was to assess the evolution of endoscopic stenting and its efficacy over time, as well as the impact of stent fixation on migration rates and long-term outcomes. In addition, the effect of stenting on long-term weight loss and chronic reflux was also evaluated.

Methods A retrospective review was conducted including 37 patients from 2005 to 2017 who had undergone placement of stents after various bariatric procedures. Stents were placed endoscopically and, after 2012, secured with a figure-of-eight overstitch. Demographics, weight loss data, stent migration rates, incidence of revision surgery, chronic PPI use, and chronic symptoms of reflux data were obtained and analyzed.

Results Thirty-seven patients from 2005 to 2017 required endoscopic stenting for leaks. 43.24% patients underwent sleeve gastrectomy, 40.54% gastric bypass, 5.40% patients underwent duodenal switch, and 10.81% underwent miscellaneous foregut procedures. The overall success rate was 94.59% (35 of 37 patients). The incidence of stent migration before 2012 was 41.18% versus 15% after 2012 ($p = 0.136271$). There were 2 treatment failures, one treated successfully with re-stenting and another other requiring revision surgery. Overall, the percent of excess body weight lost was 57.21% over an average of 21 months. 58.82% of patients used PPI chronically; however 41.17% noted actual symptoms of reflux. 16.22% (6 of 37) patients ultimately underwent revision surgery.

Conclusion Endoscopic stenting is a safe and effective treatment for leaks after bariatric surgery. While complications can include stent migration, newer stent technology and endoscopic overstitching techniques show promise in reducing the incidence of stent migration. Despite undergoing treatment with stenting, these patients had successful weight loss with relatively low rates of chronic PPI use and reflux symptoms.

Keywords Endoscopic stenting · Revision bariatric surgery · Leaks after bariatric surgery

Leaks are a feared complication after bariatric surgery, with an incidence of between 1 and 6% [1, 2, 4] in the United States. Leaks were associated with significant morbidity, as patients required complex surgical intervention, triggering a cascade of events, leading to prolonged use of parenteral nutrition, chronic sequelae, and sometimes mortality. Early identification and surgical intervention has been a hallmark of therapy for patients presenting with acute leaks.

Less invasive interventions were reserved for hemodynamically stable patients with more chronic fistulas [3]. The

use of endoscopic therapy and stenting for the management of acute leaks was first reported in 2006 [3] in a small series of patients. Since then, this approach has been shown to be effective in numerous studies [3–6]. However, several problems were identified with the use of these stents, such as stent migration [4–6], patient tolerance of the stent, and failure of stent therapy. As a result, questions regarding the safety and efficacy of stenting have been raised, prompting the suggestion of alternative endoscopic approaches such as endoscopic vacuum therapy and endoscopic internal drainage. Over the past 12 years, stenting technology has improved, and the development of endoscopic suturing techniques have allowed for stents to be secured, theoretically minimizing stent migration. In addition, most studies that have evaluated the efficacy of endoscopic stenting have

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focused on early results. The purpose of this study was to assess the evolution of endoscopic stenting and its efficacy over time, as well as the impact of stent fixation on rates of migration and long-term outcomes. In addition, the effect of stenting on long-term weight loss and chronic reflux was also evaluated.

Methods

Study population

This was a retrospective review of patients who underwent endoscopic stenting after various foregut procedures from 2005 to 2017. Prior to 2012, stents were not secured; however after 2012, the development of endoscopic suturing techniques allowed stents to be secured via a figure of eight overstitch. The EndoMaxx silicone-coated, plastic, covered stent was used. 37 patients were included in this study. 17 patients were before 2012 and 20 patients were after 2012.

Intervention

Leaks were initially confirmed via upper gastrointestinal series by radiology. Associated intra-abdominal fluid collections/abscesses were drained either percutaneously (prior to stent placement) or laparoscopically (concurrent with stent placement). All stents were placed in the operating room under general anesthesia using upper endoscopy and fluoroscopy. Initially, endoscopy was performed to visualize the exact location of the leak and markers were placed to indicate proximal and distal endpoints of the stent. A guidewire was inserted and used to place the stent via an endoscopic overtube. Proper positioning of the stent was confirmed with endoscopy and fluoroscopy and, after 2012, the stent was endoscopically secured with one figure-of-eight overstitch. The stents were removed endoscopically, and the resolution of leaks was confirmed with endoscopy after removal of the stent. In the cases of early migrations, the stents were repositioned. They were replaced if a persistent leak was identified on endoscopy.

Data collection/outcomes

Demographics, stent type, stent migrations, complications, incidence of revision surgeries after stenting, success rate, weight loss data, presence of reflux symptoms, and chronic PPI use data were collected. Success of endoscopic stenting was defined as a lack of a persistent leak after removal of the endoscopic stent. Treatment failure was defined as a recurrent leak after stenting therapy. Percent excess body weight loss (%EBWL) was defined as the ratio of the amount of total weight lost over the difference between the patient's

Table 1 Demographics

	2012–2017 group (<i>N</i> = 20)	2005–2012 group (<i>N</i> = 17)
Age (average)	42.04	39.00
%Female	15 (75%)	11 (64.70%)
Preoperative BMI (average)	42.67	47.00
ASA category		N/A
1	0 (0%)	
2	9 (45%)	
3	10 (50%)	
4	1 (5%)	
DM	2 (10%)	3 (17.65%)
HTN	5 (25%)	4 (23.53%)
OSA	3 (15%)	3 (17.65%)
HL	2 (10%)	N/A
Asthma	1 (5%)	N/A
COPD	0 (0%)	N/A

Table 2 Procedures performed on study population

Type of operation	Number (%) <i>N</i> = 37
Sleeve gastrectomy	16 (43.24%)
Roux-en-Y gastric bypass	15 (40.54%)
Duodenal switch	2 (5.41%)
Miscellaneous foregut procedures	4 (10.81%)

preoperative weight and their ideal bodyweight. Statistical comparisons between groups were conducted using the Fisher Exact *T* Test. This study was reviewed and approved by the IRB of Northwell Health.

Results

Thirty-seven patients from 2005 to 2017 required endoscopic stenting for leaks. Demographics are shown in Table 1. There were no significant differences between the 2 groups. Table 2 shows the types of procedures performed. 16 (43.24%) patients underwent sleeve gastrectomy, 15 (40.54%) underwent gastric bypass, 2 (5.41%) patients underwent duodenal switch, and 4 (10.81%) patients underwent miscellaneous foregut procedures including 2 gastrectomy, 1 esophagectomy, and 1 paraesophageal hernia repair.

When comparing migration rates before 2012 to those after 2012 (Table 3), the incidence of stent migration before 2012 was 41.18% versus 15% after 2012 ($p = 0.136271$). Of those that had stent migration, only 3 patients required the stent to be replaced. These were ultimately removed with successful healing. Average duration of stent therapy was

Table 3 Comparison of patients before and after 2012

	Before 2012 (N=17)	After 2012 (N=20)
Migration rate	7 (41.18%)	3 (15.00%)
Success rate	17 (100%)	18 (90%)
Revisional surgery	3 (17.65%)	3 (15.00%)

44 days. The average number of stents used per patient was 1.19. When comparing sleeve gastrectomy to gastric bypass, 3 migrations (20.00%) were noted in patients who had gastric bypass as their index procedure, while 2 patients (12.50%) with stent migrations had a sleeve gastrectomy as the index procedure (Table 4).

With respect to revision surgery, 3 patients before 2012 and 3 patients after 2012 underwent revision surgery after stenting ($p=1.00$). Of these 6 patients, 2 patients had a sleeve gastrectomy and 4 patients had a gastric bypass. The indications for revision for the sleeve gastrectomy to gastric bypasses included chronic reflux and persistent leak. With respect to gastric bypasses, indications for revision surgery included a chronic stricture requiring a revision of the gastrojejunal anastomosis, intussusception requiring revision of the jejunojejunal anastomosis, and failure to thrive requiring reversal of gastric bypass.

Overall there was a 94.59% success rate (35 of 37 patients). Of the 2 patients (5.40%) who failed stent therapy, both had a sleeve gastrectomy as their index procedure. One patient was successfully treated with repeated stenting while the other patient had a revision of his sleeve to a gastric bypass. 5 of 20 patients (25%) were readmitted for PO intolerance necessitating stent removal in 3 of the 5 patients. All patients were fed orally after stent placement and none of our patients required TPN. There was 1 death in the study population due to fungal sepsis 1 year after successful stent therapy.

With respect to secondary endpoints (Table 5), long-term data on weight loss were available for 21 patients. Overall, these patients had a %EBWL of 57.21% with a range of 2–70 months of follow-up with an average of 21 months. Out of these patients, 17 patients had long-term PPI use and reflux symptom data available. 10 (58.82%) of these patients reported taking a PPI in the long term, while 7 (41.17%) reported chronic symptoms of reflux. The incidence of

Table 4 Comparison of sleeve gastrectomy and gastric bypasses

	Sleeve gastrectomy (N=16)	RYGB (N=15)
Failure rate	2 (12.50%)	0 (0%)
Migration rate	2 (12.50%)	3 (20.00%)
Revisional surgery	2 (12.50%)	4 (26.67%)

Table 5 Secondary outcomes

Outcome	
%EBWL (N=21)	57.21%
#Month follow-up (N=21)	21 months
Chronic PPI use (N=17)	10 (58.82%)
Symptoms of reflux (N=17)	7 (41.17%)

gastroesophageal reflux in general may be impacted by the very nature of the procedure. It is difficult to determine whether stenting had an impact in our patients. When we further analyzed our data comparing sleeve gastrectomy to gastric bypass, the %EBWL was 69.34% vs 43.95% with an average of 21-month follow-up for sleeves (range 2–71 months) versus 16 months (range 3–35 months) for bypasses. With respect to sleeves, 7 of 12 patients (58.3%) reported chronic PPI use, while 4 out of 12 patients (33.3%) reported having symptoms of reflux. With bypasses, 3 of 5 patients (60%) reported chronic PPI use with 3 of 5 patients (60%) reporting symptoms of reflux. Our numbers are too small to draw any conclusions regarding sleeve gastrectomy versus gastric bypass with respect to secondary endpoints.

Discussion

Management of bariatric complications remains a difficult challenge. Urgent surgical interventions often remained unsatisfactory. The introduction of endoscopic techniques has provided a significant alternative in managing these patients. Stenting was first introduced in 2006. Since then, several authors have reported its efficacy in the literature. Eubanks et al. [8] treated 19 patients with leaks, strictures, and fistulas with endoscopic stents, and found that 16 of the 19 patients (84%) demonstrated complete healing of the leak, fistula, or stricture. However, they noted that 3 patients had stent migrations requiring retrieval and 3 treatment failures requiring surgical intervention. They concluded that endoscopic stenting provides successful healing of leaks while simultaneously allowing the patients to have oral nutrition without the need for parenteral nutrition. Shehab et al. [9] demonstrated similar results. They examined leaks in 62 patients (46 sleeve gastrectomy and 16 gastric bypasses) who were treated with endoscopic stenting and/or over-the-scope clips. Ultimately they noted an 82% leak closure rate as seen in prior studies. The main complications they noted were a 17.7% rate of stent migration and an 11% rate of intolerance requiring stent removal. Of note, these studies did not report use of stabilization techniques such as suturing the stent in place.

Similarly, our retrospective review of 37 patients showed a 94.59% (35 of 37 patients) success rate. Complications

encountered in our group were similar to other studies of endoscopic stenting and included PO intolerance and stent migration. In our longitudinal analysis, it appeared that the newer technologies of endoscopic suturing have helped stabilize the stent and have reduced the incidence of stent migration. In our study, the patients before 2012 had a 41.18% migration rate and a 15% migration rate in the patients after 2012. While this number did not reach statistical significance in our study, larger population studies may reveal this to be statistically significant. It is important to note that stent migration did not adversely impact failure rates in our study. In addition, there was no correlation between stent migration and the need for revision surgery. Finally, there have been concerns regarding whether the specific anatomy has an effect on stent migration. However, our data show no difference in migration rates between sleeves and bypasses. Thus the advantage of stenting is that it spares patients the morbidity of a re-operation as well as allowing patients to resume a clear liquid diet post-stent placement, preventing the need for long-term parenteral nutrition.

With respect to the 2 patients who failed endoscopic therapy, it is interesting to note that both had a sleeve gastrectomy as the index procedure. One of these patients was treated with repeated stenting while the other patient was treated by conversion to gastric bypass. The one death in our study group was at a patient who was successfully treated with endoscopic stenting 1 year prior to her death. She expired of fungal sepsis likely unrelated to her stenting therapy given the time course between the removal of the stent and her death.

Although numerous studies have corroborated the findings of our paper, no one has truly investigated the impact of endoscopic stenting on long-term weight loss. In our study, those patients who underwent stenting had appropriate amounts of long-term weight loss (average of 57.21% over an average 21-month follow-up). It is also a concern whether stenting across the lower esophageal sphincter leads to increased rates of reflux; however our data do not support this conclusion as there were relatively low rates of long-term reflux symptoms in our patients after stenting. Of the 17 patients for whom these data were available, 58.82% were taking a PPI long term. However, it is important to note that many of these patients were taking a PPI in the absence of reflux symptoms, mainly because they reported that they were never told to stop taking them.

Other therapies, such as endoscopic internal drainage (EID) and endoluminal vacuum (E-Vac) have also been proposed as alternatives to endoscopic stenting in the treatment of anastomotic leaks. Donatelli et al. [10] studied 67 patients with leaks following sleeve gastrectomy who were treated with endoscopic internal drainage. They reported a success rate of 78.2% (50 of 64) with 5 (7.8%) failures taking on average 57.5 days to completely heal and involving

a range of 2–16 endoscopic sessions. They report that 2 of the 5 failures were related to recurrent pigtail migration and required an average of 368 days to heal, while 3 of the 5 failures ultimately needed a total gastrectomy for chronic sepsis. Endoscopic internal drainage was associated with a significant complication rate including a 10% readmission rate (5 of 50 patients), 3 perforations noted during the first endoscopic drainage procedure, one of which required surgical intervention, and a 12% incidence of stenosis (6 of 50 patients). The authors theorize that the stenoses were due to the granulation tissue and scar contraction induced by the pigtail drains. These 6 patients required balloon dilation of these stenoses with 1 patient ultimately requiring an expandable stent placement to resolve the stenosis. In contrast, our data do not show any stenoses as a complication of stenting therapy. While internal drainage may be useful in treating the abscess cavity associated with the leak, internal drainage may not actually address the root cause of the leak, such as stenosis or twisting of the gastric tube. Stenting provides the opportunity to simultaneously bypass the area of disruption of the staple line, and also address the high pressure environment caused by a stenosis or a helical twist of the gastric pouch. Furthermore, each patient required enteral feeding via a nasojejunal tube until at least the first endoscopic treatment. In our experience, another major benefit of stenting over other proposed therapies is the ability to return the patient to an oral diet immediately after intervention which impacts the patient's psychological outlook and nutrition. However, poor oral intake and postoperative nausea is sometimes associated with stenting. This can be effectively managed with pharmacologic agents such as steroids and anti-nausea medications, and is possibly secondary to stent design. Newer stents may potentially resolve these complications.

Leeds et al. [11] examined E-Vac therapy for treating 9 patients with leaks after sleeve gastrectomy and found an 89% success rate (8 of 9) patients. However, the limitations included the need for multiple interventions to replace the vacuum sponge (10.5 procedures on average with a range of 2–18 procedures) as well as the need for either a feeding jejunostomy tube or total parenteral nutrition throughout the course of treatment. This modality may be a viable alternative for patients who are chronically intubated in the ICU or for those with very large defects not amenable to endoscopic stenting or internal drainage.

It is possible that these therapies may be used in conjunction to stenting. Nedelcu et al. [12] suggested a treatment algorithm for patients with leaks after sleeve gastrectomy. They noted that for patients with a leak size of < 10 mm and no stenosis they would use an endoscopic internal drain. However, they would treat those with either luminal stenosis or a leak size of 10 mm or larger with an endoscopic stent. In their study of 19 patients, they note a 100% success rate

after an average of 3.4 months. In an editorial, Vargas et al. [13] suggested another algorithm for the approach to post-sleeve gastrectomy leaks. Their approach divided patients into 3 categories: unstable, leaks with a walled-off fluid collection, and fistulas. For the unstable patient they recommended surgical treatment with or without an endoscopic stent placement and note that they would use self-expanding stents in patients with acute leaks and no obvious abscess. For patients with subacute or chronic leaks and an organized collection, they would use endoscopic internal drainage with serial pneumatic dilations of any distal stenosis. Those with fistulas would undergo a hybrid endoscopic and laparoscopic approach.

Limitations of our study included the retrospective single, institutional nature of this study. Additionally, our sample size (while large compared to other similar studies) was too small to detect a statistically significant difference between the groups. Ideally, a randomized controlled trial would be useful; however, this type of study would be impractical in the acute setting. Additionally, the low overall incidence of leaks makes a randomized trial difficult to conduct. Future studies are needed to validate these findings and the long-term implications of stent therapy.

Conclusion

Our data demonstrate that endoscopic stenting is a highly effective and safe alternative therapy for the treatment of leaks after bariatric surgery. While complications can include stent migration, newer stent technology and endoscopic suturing techniques show promise in reducing the incidence of stent migration. Furthermore, it is important to note that current stents were not designed specifically for post-bariatric esophagogastric anatomy. It is possible that future stent designs or new materials may further reduce the incidence of stent migration. Much still needs to be learned about stent selection and deployment including size, diameter, anchoring, and placement, which may further improve the safety and efficacy of this technology. At this time, it is unclear as to which patient would benefit from endoscopic suturing, however, our data suggest that endoscopic suturing leads to improved stability of the stent. In our longitudinal analysis, patients who underwent endoscopic stenting had successful weight loss with relatively low rates of chronic reflux symptoms.

Compliance with ethical standards

Disclosures Varun Krishnan, Kevin Hutchings, Andrew Godwin, Jonathan Wong, and Julio Teixeira have no conflicts of interest or financial ties to disclose.

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