OBES SURG (2018) 28:15–24
DOI 10.1007/s11695-017-2808-1

ORIGINAL CONTRIBUTIONS

Large Bariatric-Specific Stents and Over-the-Scope Clips in the Management of Post-Bariatric Surgery Leaks

Hany Shehab[1] · **Emad Abdallah**[2] · **Khaled Gawdat**[3] · **Inas Elattar**[4]

Published online: 12 July 2017

Abstract
Background Endoscopic stents are successful in the management of surgical leaks; however, stent migration remains a significant problem. In this study, we present our approach depending on a large bariatrics-specific stent (Mega stent) and over-the-scope clips in the management of post-bariatric surgery leaks.
Methods A retrospective analysis of all patients with post-bariatric surgery leaks treated at our institution using an approach reliant on Mega stents and over-the-scope clips was conducted. Potential factors associated with procedure success and occurrence of complications were also evaluated.
Results A total of 81 stents were inserted in 62 patients with post-bariatric surgery leaks, 46 sleeve gastrectomies (73%) and 16 Roux-en-Y gastric bypass (27%). Over-the-scope clips were applied in 29 patients (46%). Leak closure was achieved in 51 patients (82%). Median number of procedures per patient was 3 (range 2–8). Complications included the following: stent migration (11/62, 18%), intolerance necessitating premature removal (7/62, 11%), esophageal stricture (8/62, 13%), bleeding (4/62, 6%), perforation (4/62, 6%). One stent-induced mortality was encountered (bleeding). The presence of open surgery (vs laparoscopic) was significantly associated with the occurrence of stent-induced complications (p 0.002).
Conclusion The approach combining Mega stents and over-the-scope clips is highly effective in the management of post-bariatric surgery leaks and is associated with a low rate of stent migration and a low number of procedures and stents per patient. Mega stents, however, should be used with great caution due to the significant morbidity associated with their use.

Keywords Bariatric surgery · Anastomotic leak · Sleeve gastrectomy · Endoscopic · Leak · Esophageal stents · Enteral stents · Mega stent

✉ Hany Shehab
h.shehab@kasralainy.edu.eg

[1] Gastroenterology Department, Kasr-Alainy School of Medicine, Cairo University, Cairo 11562, Egypt

[2] General Surgery Department, Mansoura School of Medicine, Mansoura University, Mansoura, Egypt

[3] General Surgery Department, Faculty of Medicine, Ain Shams University, Cairo, Egypt

[4] Biostatistics and Epidemiology Department, National Cancer Institute, Cairo, Egypt

Introduction

Bariatric surgery has proven a very effective method in the management of morbid obesity; however, staple line leaks remain an ominous complication associated with prolonged hospital stay and significant morbidity and mortality [1]. Over the last two decades, endoscopic stents have proved to be a successful minimally invasive option in such difficult patients [2–4]. Stents seal the site of leak allowing for rapid resolution of infection and acceleration of the healing process. In comparison to uncovered or partially covered stents, fully covered stents have the significant advantage of being easily removable; however, this comes at the expense of a high rate of migration reaching up to 67% in some series [5]. Problems particular to post-bariatric surgery leaks include the absence of a stricture to hold the stent in place and the particular tortuous anatomy for which current standard esophageal stents are not adapted. One of the proposed solutions to overcome the problem of migration is to use much wider and longer stents to increase compression and coaptation against the lumen wall.

The Mega stent™ (MITECH, Seoul, South Korea) is an ultra-large fully covered stent with a braided nitinol mesh and significant flexibility allowing it to conform to the tortuous bariatric surgery anatomy (Fig. 1). We previously published our initial case experience which suggested a low rate of migration and significant success at leak closure with the use of Mega stents [6]. In this study, we present our extended experience with 62 patients to assess the safety and efficacy of such large stents and the factors associated with successful leak closure and occurrence of complications.

Patients and Methods

Study Design

Starting December 2012, all patients presenting with post-bariatric surgery leaks were treated with endoscopic insertion of Mega stents as their primary treatment modality. Our sequence of selection of endoscopic methods has been previously described and is depicted in Fig. 2 [6]. Data prospectively collected and later retrospectively retrieved included the following: age, sex, BMI, type of surgery, site and size of leak, time to diagnosis, time to endoscopic intervention, stent size and duration, adverse events related to the endoscopic intervention and leak outcomes.

Study Definitions

Leak: Dehiscence at the site of suture line or anastomosis.

Late leak: Presenting to endoscopic therapy >28 days after the inciting surgery.

Primary closure: Complete disappearance of the leak both endoscopically and radiologically after removal of the first Mega stent.

Secondary closure: Complete disappearance of the leak both endoscopically and radiologically after further endoscopic attempts after removal of the first Mega stent.

Endoscopic failure: Persistence of the leak after the last endoscopic procedure and when a decision has been made for no further endoscopic attempts.

Migration: Displacement of the stent to a position where it is no longer sealing the site of leak.

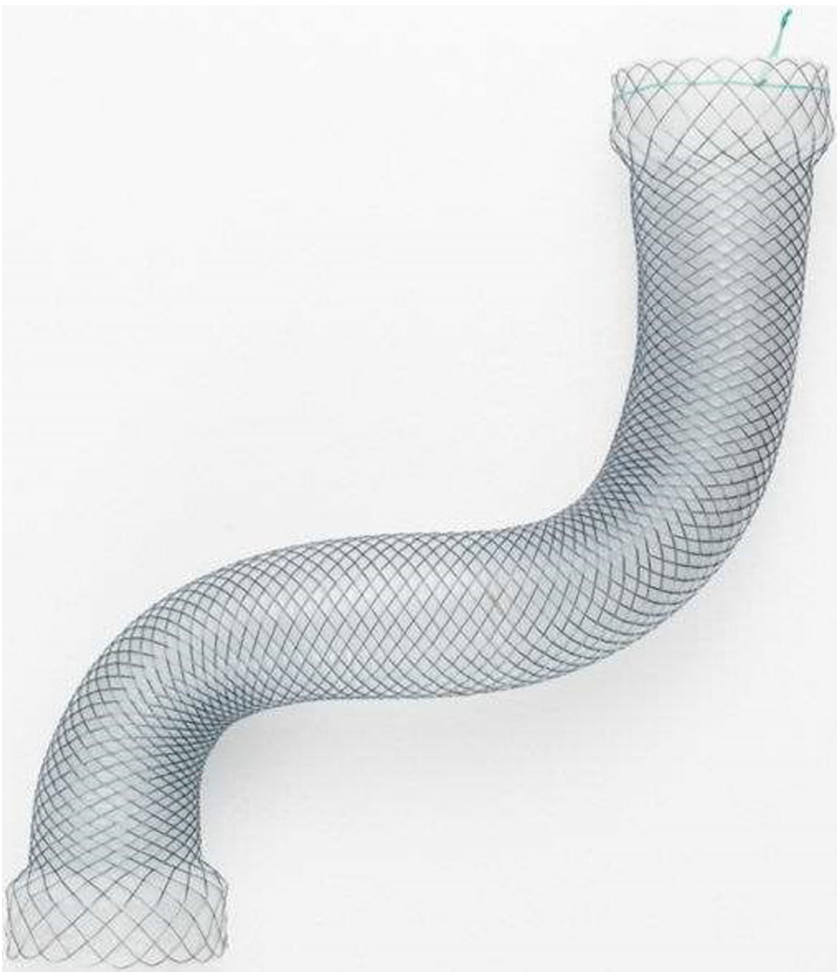

Fig. 1 The Mega stent. A fully covered highly flexible nitinol stent

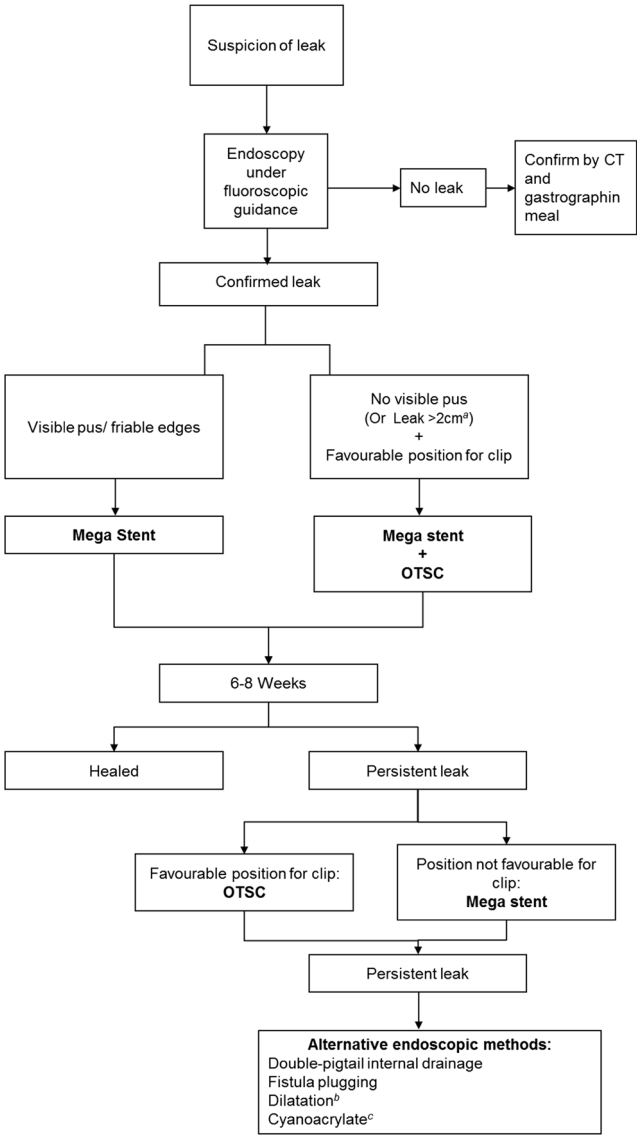

Fig. 2 Approach to post-bariatric surgery leaks. **a** Clips may rarely be used despite the presence of evident infection only in cases with very large leaks aiming to provide some approximation and reduce stenting time. **b** Aggressive dilatation distal to the leak in patients with sleeve gastrectomy (30-mm balloon). **c** Cyanoacrylate was initially an option, but due to repeated failure and widening of some fistulas, it is not used anymore

Procedure Details

In any patient presenting with a leak, the first step was to ensure drainage of any collections, this was achieved either by the original surgical drains, re-laparoscopy or radiologically - guided drainage. Endoscopic procedures were performed by two experienced endoscopists (H.S, E.A). After a written informed consent, endoscopy was performed under fluoroscopic guidance and general anaesthesia. After endoscopic visualization of the leak orifice, contrast injection was performed through the endoscope to confirm and to assess the extent and communication of the leak. Leak orifice diameter was assessed endoscopically according to the endoscopist's judgement and by comparing to the size of an open biopsy forceps. If deemed wide enough, the endoscope was passed through the leak orifice to attempt cleaning any leak cavities. Any collections were aspirated and necrotic debris was removed by Dormia basket (Endoflex, Voerde, Germany) or Roth-net (US endoscopy, Mentor, OH, USA). In cases presenting with late leaks, Argon plasma coagulation (APC) was applied to the orifice edges and track/cavity walls, a setting of 30 W and 1.5 L/min flow was used (VIO200S, ERBE, Limonest, France). Insertion of a Mega stent was the primary endoscopic method of choice in all patients; however, in selected patients with no evidence of frank pus or friable edges and presence of the leak in a suitable position, an over-the-scope clip (OTSC, Ovesco, Tubingen, Germany) was applied followed by insertion of a Mega stent in the same session. To insert the stent, a 0.035-in. metal guidewire was inserted first beyond the 2nd duodenal part (Cook medical, Limerick, Ireland); the stent was then passed over the wire and deployed under fluoroscopic visualization. All stents had a 28-mm shaft diameter and 36 mm flared ends. Stent length (18 or 23 cm) was selected on the discretion of the endoscopist aiming to place the upper edge 5 cm above the cardia. The lower edge was placed in the duodenal bulb or just before the pylorus in patients with sleeve gastrectomy, while in patients with RYGB, it was placed about 10 cm beyond the site of leak but proximal to the first jejunal loop to avoid impaction against the loop.

Patient Follow-up and Stent Removal

Oral intake was restricted for 24 h to allow for full stent expansion, this was followed by a liquid to semi-solid diet throughout the stenting period. Routine IV medications included paracetamol tid (Perfalgan®, Bristol Myers Squibb, Middlesex, UK), hyoscine-butyl-bromide tid (Buscopan®, Boehringer Ingelheim, Ingelheim, Germany), Ondansetron 8 mg tid (Zofran®, GlaxoSmithKline, UK) and esomeprazole 40 mg tid (Nexium®, Astrazeneca, Sodertaije, Sweden). In selected patients with severe pain, IV tramadol was administered in low doses (Tramadol®, Grunenthal Gmbh, Aachen, Germany). Routine medications were shifted to oral form after 48 h if tolerated and gradually stopped according to the patients' symptoms. Oral esomeprazole continued throughout the period of stenting at a dose of 40 mg bid.

Stent removal was scheduled at 6–8 weeks after insertion according to the patient's tolerance. During the stenting period, gastrografin meal or CT with oral contrast was performed routinely after 4–5 days and whenever there was a suspicion of persistent leakage or stent migration leakage. When stent migration occurred, endoscopy was performed to adjust the stent position. To extract the stent, the lasso at the proximal edge was grasped and the stent was pulled under fluoroscopic

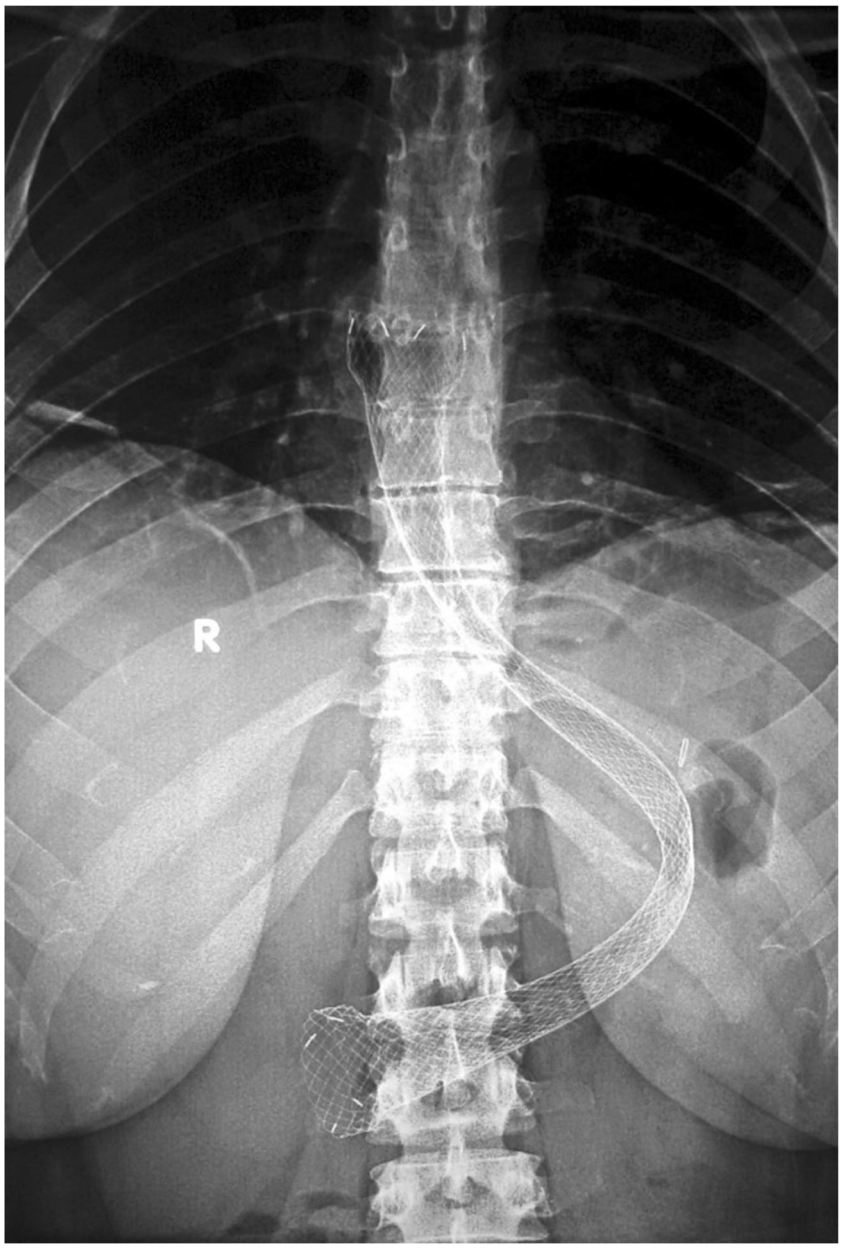

Fig. 3 A Mega stent in a gastric sleeve; the upper edge is in the lower esophagus while the lower edge is in the duodenal bulb

guidance. Healing of the leak was confirmed endoscopically and confirmed by contrast injection. In cases with persistent leakage, endoscopic options included the following: insertion of another stent, application of an OTSC clip or both. In the absence of grossly visible pus or friable edges and presence of the leak in an accessible location, an OTSC was favoured (Figs. 2, 3, 4). Failure of the leaks to heal after insertion of Mega stents and OTSC clips was managed by any of the following techniques on the discretion of the endoscopist: cyanoacrylate injection (Histoacryl; B. Braun, Tuttlingen, Germany), internal drainage by double-pigtail stents, aggressive dilatation by a 30-mm Achalasia balloon (Endoflex, Voerde, Germany) or fistula plugging with polyglycolic acid sheets (Seamguard, Gore, Flagstaff, AZ, USA).

Statistical Methods

Data management and analysis were performed using Statistical Package for Social Sciences (SPSS) vs. 23. Numerical data were summarized using means and standard deviations or medians and ranges, as appropriate. Categorical data were summarized as numbers and percentages. Numerical data were explored for normality using the Kolmogrov-Smirnov test and Shapiro-Wilk test. Exploration of data revealed that the collected values were not normally distributed. Comparisons between the two groups were done by the Mann-Whitney test. The chi-square test was used to compare between the groups with respect to categorical data. All p values are two-sided. p values <0.05 were considered significant.

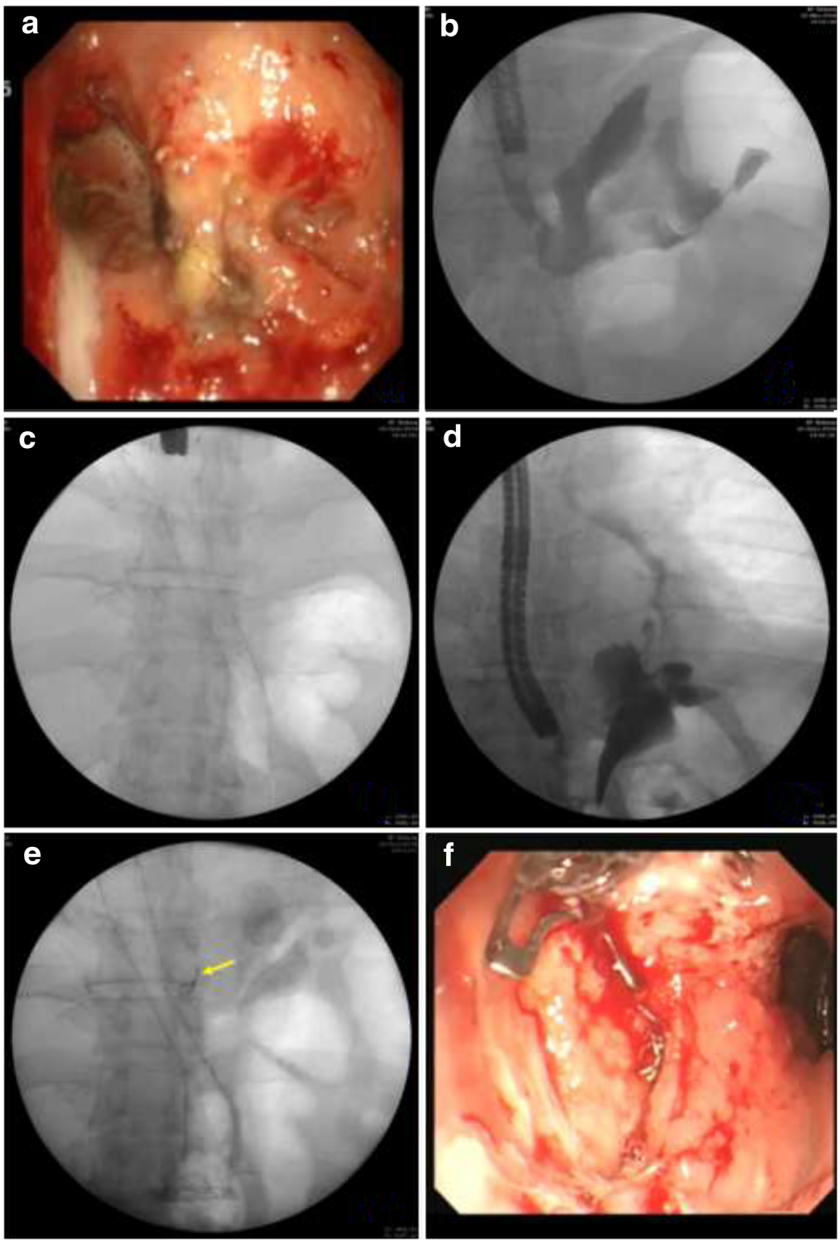

Fig. 4 **a** A large leak cavity from a leak at the gastroesophageal junction in a patient with a gastric bypass. **b** Extensive leak in the left subphrenic space, fluoroscopic view. **c** A 23-cm Mega stent inserted. **d** Three weeks later, leak cavity reduced in size but a gastro-cavitary-bronchial fistula developed. **e** An OTSC clip applied (*arrow*) and another Mega stent inserted. **f** Six weeks later, complete healing of the leak and fistula

Results

Sixty-two patients with post-bariatric surgery leaks were treated by Mega stents as their primary endoscopic modality. Patient characteristics are summarized in Table 1. Forty-six (74%) had a sleeve gastrectomy while 16 (26%) had a RYGB, 10 (16%) were revisional procedures. The main presentation was abdominal sepsis (fever, tachycardia, abdominal and shoulder pain, rising CRP) in 44 patients, abnormal drain output in 17 patients, while one patient presented with a left-sided pleural effusion. Surgical procedures (laparoscopy or open surgery) were performed to establish drainage in 35 patients (56.4%), 8 of which also included an attempt at leak repair, while ultrasound-guided drainage of collections was performed in 19 patients (30.6%).

The median time to diagnosis of the leak was 3 days (1–28 days) postoperatively, while the median time to the first endoscopy was 8.5 days (1–90 days). The first endoscopy was performed within the first 48 h postoperatively in 3 patients (4.8%), between 3 and 7 days in 25 patients (40.3%), 8–28 days in 23 patients (37.1%) and beyond 28 days after the surgery (late leaks) in 11 patients (17.7%). Details of the endoscopic procedures are demonstrated in Table 2. Median leak size was 8 mm (2–33 mm), 45 (72.6%) were located at the gastroesophageal junction, 10 (16.1%) at the gastrojejunal anastomosis and 7 (11.3%) in the middle of the gastric sleeve.

Table 1 Patient characteristics

Age (years)	34 (19–65)[a]
Sex	
Male	21 (34)
Female	41 (66)
BMI (kg/m^2)	48 (36–65)[a]
Type of surgery	
Sleeve	46 (74)
RYGB	16 (26)
Presentation	
Abdominal sepsis (fever, pain, rising CRP)	44 (71)
Pleural effusion	1 (2)
Excessive/coloured drain output	17 (27)
Surgical interventions	
Laparoscopic drainage	36 (53)
Attempt at leak closure	8 (13)
Time to diagnosis (days)	3 (1–28)[a]
Time to endoscopy (days)	8.5 (1–90)[a]
<3 days	3
3–7 days	25
8–28 days	22
>28 days (late)	11

Categorical data are presented as number (percent)

[a] Median (range)

Table 2 Endoscopy characteristics and outcomes

Leak site		
GE junction		45
Mid-sleeve		7
Gastrojejunostomy		10
Leak size, mm		8 (2–23)
≤10		40 (65)
>10		22 (35)
Stents		81
Length	18 cm	27 (43)
	23 cm	35 (57)
Stents per patient		1 (1–3)[a]
OTSC		29 (46)
Simultaneous with stent		11
After stent removal		18
APC		11
Endoscopic procedures/patient		3 (2–8)[a]
Complications		
Migration		11 (18)
Intolerance (pain/vomiting)		60 (97)
Intolerance necessitating removal		7 (11)
Esophageal stricture		8 (13)
Bleeding		4 (6)
Perforation		4 (6)
Successful leak closure		
Primary closure		31 (50)
Secondary closure		20 (32)
Total		51 (82)

Categorical data are presented as number (percent)

[a] Median (range)

All patients had a Mega stent inserted successfully during the first endoscopic procedure. A total of 81 stents were inserted in the 62 patients (mean, 1.3 stents/patient; median, 1). Median stent duration was 6 weeks (1–14 weeks). Stent extraction was successful in all patients (100%). OTSC clips were applied in 29 patients (46.7%), 11 were applied simultaneously with the stent during the first procedure, while 18 were applied after removal of the first stent. In 11 patients (17.7%), APC was applied to the leak edges before stent insertion. In total, 189 endoscopic procedures were performed (median, 3 endoscopic procedures/patient; range, 2–8).

Significant pain and vomiting occurred almost universally (60/62, 97%). Narcotic analgesia was necessary in three patients (4.8%), while intolerance necessitating premature removal of the stent occurred in seven patients (11.3%). Deep ulcers at the site of impaction of the distal edge of the stent were detected in 58 patients (93.5%) at the time of stent removal. Stent migration occurred in 11 patients (17.7%). Migration was managed first by an attempt at stent repositioning in all patients, insertion of longer stents (23 cm) in four patients and insertion of an additional overlapping stent within the migrated one in two patients. Strictures in the lower or mid-esophagus occurred in eight patients (12.9%), all were successfully managed by endoscopic balloon dilatation. Major adverse events (bleeding and perforation) occurred in eight patients (12.9%). Bleeding occurred in four patients (6.5%); one was caused by compression of the upper edge of the stent against the cardia, while three were due to erosion by the distal edge of the stent into the duodenal bulb. Bleeding was successfully managed endoscopically by stent repositioning in two patients and by conservative management in one; however, one patient deceased due to severe uncontrollable bleeding and aspiration. Perforation occurred in four patients (6.5%): two in the duodenal bulb in patients with sleeve gastrectomy and two in the jejunal loops in patients with RYGB (Fig. 5). Two duodenal and one jejunal perforations were successfully managed by early surgical repair, while one jejunal perforation was managed conservatively by inserting a longer stent (23 cm) bypassing the site of perforation.

Of the 62 treated patients, 51 (82.3%) achieved healing of the leaks by solely endoscopic procedures. In 31 patients (50%), primary closure was achieved (after one endoscopic attempt), 24 of these patients had a Mega stent alone inserted while 7 had an OTSC clip applied simultaneously with the stent at the first endoscopic procedure. Additional endoscopic

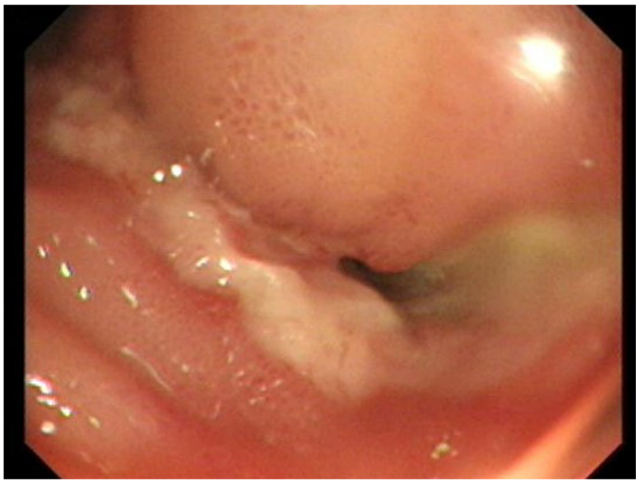

Fig. 5 Deep jejunal ulcer and perforation at site of stent impaction

Table 3 Factors associated with endoscopic success

	Healed (n = 51)	Failure (n = 11)	p value
Age (years)[a]	33 (19–65)	39 (20–57)	0.70
Female sex	35 (69%)	6 (55%)	0.37
Sleeve (vs RYGB)	37 (73%)	9 (82%)	0.52
Open surgery	5 (10%)	2 (18%)	0.21
BMI (kg/m^2)[a]	46 (36–65)	52 (39.5–62.9)	0.22
Leak size (mm)[a]	8 (2–25)	12 (3–33)	0.25
Time to diagnosis (days)[a]	3 (1–21)	4 (1–28)	0.65
Time to endoscopy (days)[a]	7 (1–90)	14 (3–30)	0.22

Categorical data are presented as number (percent)

[a] Median (range)

interventions for failures after Mega stent and OTSC included the following: Histoacryl injection in four patients (none succeeded), endoscopic internal drainage by 7Fr double-pigtail stents in three patients (two succeeded), endoscopic dilatation by 30 mm Achalasia balloon in two patients (one succeeded) and plugging a chronic gastrocutaneous fistula by polyglycolic acid sheets in one patient (succeeded). For failures of endoscopic therapy, surgical intervention was performed in one patient (total gastrectomy) and was successful. Radiological intervention and insertion of a vascular plug (Amplatzer vascular plug, Plymouth, MN, USA) to seal the leak was performed and was successful in one patient. Three patients deceased due to sepsis not related to the endoscopic procedures.

None of the assessed variables were associated with success of endoscopic therapy (Table 3). When assessing for factors associated with the occurrence of significant complications (stricture, bleeding, perforation), only the presence of open surgery (vs laparoscopic) was statistically significant (p 0.002). Out of the seven patients who had an open surgery, five (71%) suffered a significant complication (three perforations, two strictures), Table 4.

Discussion

Despite the paucity of studies directly comparing conventional and endoscopic management of leaks, endoscopic interventions are now accepted as the primary therapeutic modality for post-bariatric surgery leaks [3, 7–9]. This growing belief in endoscopic therapy is based on the logical advantages which include the following: minimal invasiveness, allowing early enteral nutrition, shorter hospital stay, cost savings and improving local infection especially with stents. Expandable stents have been the mainstay of endoscopic therapy with significant success; however, stent migration remains the Achilles tendon of this technique [7–9]. Partially covered stents significantly migrate less than fully covered stents; however, their drawbacks include the following: (a) difficult and sometimes impossible extraction, (b) need of an additional procedure and another stent to allow stent removal (stent-in-stent technique), (c) the occurrence of significant tissue hyperplasia and stenosis necessitating dilatation in about 20% of patients, (d) reflux of food and liquids around the stents due to their short length and small diameter and thus impairing leak healing [2, 10]. Fully covered stents have the major advantage of ease of removal in a single endoscopic procedure; however, this comes at the expense of a much higher rate of migration [2]. The hypothesis behind using ultra-large stents is that they would migrate less due to better coaptation and compression against the lumen wall. Our results show a migration rate of 18% which is still not as good as partially covered stents (about 10%) but much better than the average of other fully covered stents (50–67%) [5, 9–11]. We believe an important factor that reduces the migration is not just the diameter but the long length of the stents, as it appears that the distal edge abuts against the duodenum (in sleeve gastrectomies) or jejunal loops (in gastric bypass) preventing distal migration of the stent.

Our final success rate is 82% which coincides with or is even superior to many reports from studies using conventional stents [4, 5, 9–12]. Importantly, this success was achieved with a low number of procedures per patient (three), in comparison to four to six procedures in other large series [10, 11]. Also, a lower number of stents were used per patient (1.3) in comparison to three to four stents in other series [10–12]. This can be attributed to the lower rate of migration and possibly the better sealing of the leaks not allowing any food/liquid to reach the leak site. Another explanation, however, may be our strong dependence on OTSC clips which were not available in earlier studies where a stent failure could only be managed by inserting another stent. The low number of procedures and stents used per patient is a major advantage due to the low

Table 4 Factors associated with major complications[a]

	Not complicated (n = 47)	Complicated[a] (n = 15)	p value
Age (years)[b]	34 (19–65)	33 (23–50)	0.32
Female sex	30 (64%)	11 (73%)	0.50
Sleeve (vs RYGB)	35 (74%)	11 (73%)	0.93
Open surgery	2 (4%)	5 (33%)	*0.002*
BMI (kg/m^2)[b]	48 (36–65)	46 (39–63)	0.92
Leak size (mm)[b]	8 (3–33)	8 (2–25)	0.88
Time to diagnosis (days)[b]	3 (1–28)	3 (2–21)	0.84
Time to endoscopy (days)[b]	7 (1–90)	10 (2–50)	0.28

Categorical data are presented as number (percent)

[a] Strictures, bleeding, perforation

[b] Median (range)

cost and lower exposure of the patient to further possibly morbid procedures. Patients (and the endoscopists) also tend to get impatient, depressed and anxious after several endoscopic procedures. We believe a technique that reduces the number of procedures and stents is thus highly appreciated.

Our algorithm favours stents over clips as the first endoscopic method of choice. Leaks are initially surrounded by friable tissue and the presence infection is almost universal; this renders clips much less effective. Moreover, if clips are applied and fail to seal the leak, they actually act as a foreign body that will deter adequate healing. Even in the rare cases where a leak is in a favourable position and there is no gross pus and apparently healthy edges, when a clip is applied, we prefer also inserting a stent simultaneously. The stent provides additional sealing, and more importantly, these wide stents dilate any concomitant stricture. Strictures are a frequent occurrence in bariatric surgeries (whether frank strictures or gastric sleeve twists) and their presence is a major contributor to the persistence of leakage. If a leak persists after the removal of the stent, our preference then shifts towards the use of clips; this is because infection at this point has usually been treated and any stenosis has been resolved by the previously inserted stent. Leaks that persist after stents and clips remain very difficult to treat, the different techniques used were variably effective (double-pigtail stents for internal drainage, polyglycolic acid sheets, dilatation, radiological intervention); however, cyanoacrylate was a notable failure in all four cases where it was used. We noted also that in these cases the fistulous tracts actually widened by the presence of the solidified cyanoacrylate. We hence no longer use cyanoacrylate in the management of leaks and fistulas.

The rate of stent-induced complications is not negligible. Despite our intense regimen of IV medications to reduce pain and vomiting, intolerance necessitating stent removal was encountered in seven patients (11%). Pain and vomiting are reported widely with almost all conventional stents; however, intolerance necessitating removal of the stents is rarely encountered [9]. Esophageal stricture formation occurred in eight patients (13%), this compares to about 5% with partially covered stents and almost never with conventional fully covered stents [9]. This significant rate of stricture formation can be explained by the large upper flare (36 mm) causing ulceration and severe inflammation which is followed by fibrosis. We noted also that biliary reflux is remarkable with these stents as they usually bypass the pylorus. Biliary reflux in the esophagus may contribute to the esophageal stricture formation; this is why recently we have been trying to position the lower edge just proximal to the pylorus rather than distal to it. The lower edge of the stent abuts against the lumen wall thus preventing migration, yet this comes at the expense of deep ulcers in almost all patients. Despite that the majority of the ulcers eventually healed with no consequence, some led to bleeding and perforation which occurred in four patients each (6.4%). In a pooled analysis by Van Helsma et al., out of 295 patients treated by conventional fully covered stents, bleeding was encountered in 25 (8.5%), while only 4 (1.3%) suffered a stent-induced perforation [9]. The significant occurrence of such major complications necessitates high vigilance throughout the stenting period, any change in the pattern, site or intensity of pain or recurrence of vomiting after a period of quiescence should alarm to the presence of an impending major complication.

Interestingly none of the assessed variables significantly correlated with success of endoscopic therapy. This concurs with our practical experience where we still find it very hard to predict the prognosis of a certain leak. However, this conflicts with some logical expectations especially for variables such as time of intervention and leak size. The small sample size could be a simple explanation as it did not allow the exposure of statistical significance. However, we also believe that there are many factors that affect healing of leaks; these act as confounders making a clear statistical differentiation of a single variable very difficult. These factors include the following: site of leak, perfusion of the surrounding tissues, general

patient condition and nutrition, infection, presence of distal stenosis, adequacy of drainage, time to intervention and many more. Nevertheless, despite the absence of statistical evidence, we still believe that earlier intervention is associated with a better outcome; the conventional fears of early endoscopic intervention are not warranted as we have never encountered an endoscopy-induced widening of the leak or disruption of the staple lines. Early endoscopic aspiration and debridement of any leak cavities and sealing of the leak by a stent can only be beneficial. We also believe that large leak size should not be a deterrent for endoscopic intervention; from our experience we do find very small leaks resistant to healing and on the other hand very large staple line dehiscence that heals with a single endoscopic attempt. The build up of experience with a larger number of patients, we hope, would eventually elicit the true factors affecting success of endoscopic therapy.

A notable finding is the significant association of open surgery with the occurrence of complications; five out of the seven patients who had open surgery suffered a significant complication. Three out of the four perforations encountered during the study were in patients with open surgery. Our explanation is that after open surgery, the stomach (and jejunal loops in case of bypass) are pulled and fixed towards the abdominal wall by intense adhesions. This fixation and lack of pliability makes the tissues more prone to the traumatic edges of the stent. Fortunately, open surgery is not commonly encountered anymore; however, in a case with known open surgery, we now strongly recommend against the use of stents especially the large stents. Other options such as clips and endoscopic internal drainage should be considered in these cases.

Our study has some notable limitations. First, the restrospective nature and lack of a comparative group that includes conventional stents. The low number of patients with leaks and their critical nature renders such a comparison difficult to perform, yet we believe this should be the next step and should also include a comparative arm of double-pigtail internal drainage which now seems to be advocated by many authors as a primary therapeutic modality [13]. Second, it could be argued that we did not formally assess the efficacy of Mega stents as OTSC clips were used in several cases; however, we are here describing our global approach to bariatric leaks which largely depends on Mega stents and OTSC clips; this is our practical approach with its pros and cons clearly described. Even if it could be argued that due to our combined approach the efficacy could not be fairly attributed to either the stents or the clips, one of our main outcomes and possibly the main message of this study is the apparently high rate of stent-induced complications; this fact is not affected by the concomitant use of OTSC clips.

In conclusion, the use of the large Mega stents in post-bariatric surgery leaks is associated with significant success with a low rate of migration and low number of procedures and stents used per patient. However, these stents are associated with significant morbidity in more than a negligible portion of patients, most importantly bleeding, perforation, stricture formation and intolerance necessitating premature removal. Such stents should be used with caution and high vigilance for the occurrence of complications; this should only be done in adequately prepared expert centres. Large stents should not be used in patients who underwent open surgery due to the higher risk of complications. Alterations in stent design are recommended to make these stents less traumatic while maintaining their beneficial large size.

Compliance with Ethical Standards All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of Interest Dr. Abdallah and Dr. Gawdat and dr. Elattar have no relevant conflicts of interest to disclose.

Dr. Shehab had consulted for stent designs not included in this study.

References

1. Sakran N, Goitein D, Raziel A, et al. Gastric leaks after sleeve gastrectomy: a multicenter experience with 2,834 patients. Surg Endosc. 2013;27:240–5.
2. van Boeckel PG, Dua KS, Weusten BL, et al. Fully covered self-expandable metal stents (SEMS), partially covered SEMS and self-expandable plastic stents for the treatment of benign esophageal ruptures and anastomotic leaks. BMC Gastroenterol. 2012;12:19.
3. Puli SR, Spofford IS, Thompson CC. Use of self-expandable stents in the treatment of bariatric surgery leaks: a systematic review and meta-analysis. Gastrointest Endosc. 2012;75:287–93.
4. Leenders BJ, Stronkhorst A, Smulders FJ, et al. Removable and repositionable covered metal self-expandable stents for leaks after upper gastrointestinal surgery: experiences in a tertiary referral hospital. Surg Endosc. 2013;27:2751–9.
5. Orive-Calzada A, Calderón-García Á, Bernal-Martínez A, et al. Closure of benign leaks, perforations, and fistulas with temporary placement of fully covered metal stents: a retrospective analysis. Surg Laparosc Endosc Percutan Tech. 2014;24:528–36.
6. Shehab HM, Hakky SM, Gawdat KA. An endoscopic strategy combining mega stents and over-the-scope clips for the management of post-bariatric surgery leaks and fistulas (with video). Obes Surg. 2016;26:941–8.
7. Willingham FF, Buscaglia JM. Endoscopic management of gastrointestinal leaks and fistulae. Clin Gastroenterol Hepatol. 2015;13:1714–21.
8. Kumar N, Thompson C. Endoscopic therapy for postoperative leaks and fistulae. Gastrointest Endosc Clin N Am. 2013;23:123–36.
9. van Halsema EE, van Hooft JE. Clinical outcomes of self-expandable stent placement for benign esophageal diseases: a pooled analysis of the literature. World J Gastrointest Endosc. 2015;7:135–53.
10. Swinnen J, Eisendrath P, Rigaux J, et al. Self-expandable metal stents for the treatment of benign upper GI leaks and perforations. Gastrointest Endosc. 2011;73:890–9.

11. Feith M, Gillen S, Schuster T, et al. Healing occurs in most patients that receive endoscopic stents for anastomotic leakage; dislocation remains a problem. Clin Gastroenterol Hepatol. 2011;9:202–10.
12. Bège T, Emungania O, Vitton V, et al. An endoscopic strategy for management of anastomotic complications from bariatric surgery: a prospective study. Gastrointest Endosc. 2011;73:238–44.
13. Donatelli G, Dumont JL, Cereatti F, et al. Treatment of leaks following sleeve gastrectomy by endoscopic internal drainage (EID). Obes Surg. 2015;25:1293–301.