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NEW CONCEPT

Endoscopic Vacuum Therapy (EVT)—a New Concept for Complication Management in Bariatric Surgery

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Abstract

Background Bariatric surgery is the most efficient therapy for morbid obesity. Staple line and anastomotic leakage are the most feared postoperative complications after Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy (LSG). Traditional treatment options like revisional surgery and endoscopic stent placement are associated with high morbidity and mortality as well as variable success rates. Endoscopic vacuum therapy (EVT) has shown to be a new successful and feasible treatment option for leaks of different etiology after major gastro-esophageal surgery.

Method We report a case of the EVT principle being applied in a patient with three major leaks located apart from each other within the gastric staple line after LSG for morbid obesity (BMI 62.7). EVT was initiated on postoperative day 8.

Results In total, 18 endoscopic interventions were performed in 72 days, the vacuum sponge being replaced endoscopically every 4 days. Hospital length of stay was 106 days. No relevant procedure related complications were observed during the course of therapy and during the follow up.

Conclusion EVT of postoperative leaks in the upper GI tract has been shown to be feasible and safe. It combines defect closure and effective drainage and allows a periodic inspection of the wound cavity. In case of therapeutic failure, it does not jeopardize surgical repair or stent placement. Even though the techniques and materials used in EVT still vary considerably according to local expertise, EVT has the potential to succeed as a nonsurgical, feasible, safe, and effective treatment option for postoperative leaks in bariatric surgery.

Keywords Laparoscopic sleeve gastrectomy · Endoscopic vacuum therapy · EVT · Negative pressure wound therapy · Bariatric surgery · Obesity · Anastomotic leakage · Postoperative complications · Therapeutic endoscopy

Abbreviations

GI	Gastrointestinal
RYGB	Roux-en-Y gastric bypass
LSG	Laparoscopic sleeve gastrectomy
SEMS	Self-expanding metal stent
SEPS	Self-expanding plastic stent
EVT	Endoscopic vacuum therapy
NPWT	Negative pressure wound therapy
CT	Computed tomography

Introduction

Bariatric surgery with its increasing number of procedures is known to be the most efficient therapy for the treatment of morbid obesity. [1] This leads in turn to a mandatory rise of post-bariatric surgical complications. Leaks belong to the most feared postoperative complications in the two most popular bariatric procedures, Roux-en-Y gastric bypass (RYGB) and laparoscopic sleeve gastrectomy (LSG). RYGB is associated with a reported prevalence of postoperative leaks ranging from 0.4 to 4% [2–4], whereas the LSG with its increasing popularity due to the simplicity compared with RYGB, is linked to a reported leak rate ranging from 1.9% to 2.4%. [5, 6]. The life-threatening character of this complication, especially if leading to peritonitis and mediastinitis, requires an effective, safe and fast therapeutic

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response, since delays in treatment for more than 24 h are associated with a threefold increase in mortality rates. [7] Treatment options remain controversial, as the indications for surgical, conservative, and endoscopic therapy still remain non-standardized. [8] The treatment principles for leaks occurring after bariatric surgery include the obligatory medical management, the drainage of any leak-associated fluid collection in order to ensure and to induce a potential closure of the defect. The conventional surgical management of leaks, consisting of external drainage and early revisional surgery to close the gastric or anastomotic defect [9], remains associated with high morbidity and mortality. [10–12] However, revisional surgery remains mandatory in unstable patients in critical condition. In contrast, conservative management based on medical support has been reported to be effective, but is mainly used for acute postoperative small volume leaks in asymptomatic patients [11].

Since revisional surgery is associated with high morbidity and mortality, interventional endoscopy has evolved as a valid alternative to primary surgery. The placement of self-expanding fully or partially covered metal or plastic stents (SEMS or SEPS) can avoid the risk of emergency surgery. However, despite reported success rates of 80% for stent therapy of post-bariatric surgery leaks, complications occur in up to 22% [13] and reported success rates vary widely [14]. Stent-related digestive wall damage due to pressure or impaction is a serious matter of concern. Bleeding, perforations of mucosal ulcers, and post-treatment strictures have been reported in the literature. Stent migration rates have been reported in a range of 25–58% [15] necessitating endoscopic repositioning or extraction which might be associated with even more severe complications such as esophageal wall stripping and perforation, and possibly require surgery in cases of migration of the stent into the distal small intestine [16]. Therefore, stent placement in the gastric sleeve remains to be weighed carefully. [17] Other interventional techniques for direct closure of leaks in the gastric sleeve such as fibrin sealant [18] or suturing devices [19] are associated with poor success rates or are limited to small leaks such as over-the-scope clip placement and plug insertion. Thus, stent therapy is increasingly being challenged by endoscopic vacuum therapy (EVT), which has shown to be a new successful and feasible treatment option for leaks of different etiology after major gastroesophageal surgery. Reported success rates in patient cohorts ranging from 1 to 52 patients (185 patients in total), ranged from 84 to 100% (Table 1) [20–29].

Only one case of successful EVT in a post-bariatric surgery context has been published to date. [28] We report about the EVT principle of continuous negative pressure leading to a decrease of bacterial contamination, secretion, local edema, and promotion of granulation tissue by endoscopic insertion of a polyurethane sponge into the defect zone, connected transnasally to an external vacuum system in one patient after a complicated course of LSG resulting in a successful complete defect closure.

Table 1 Endoscopic vacuum therapy (EVT) for leaks of different etiology (*a. l.* anastomotic leakage, *perf.* perforation, *b. s.* boerhaave syndrome, *b. surg.* bariatric surgery, and *o. o.* other origin). Synopsis of studies up to date reporting EVT with number of treated patients and success rates of closure of the defect in total and percentage

Literature	Patients (*n*)	Indication for EVT	Success rate (Closure of leak by EVT)
Weidenhagen et al. [20]	6	6× a. l.	6/6 (100%)
Wallstabe et al. [21]	1	1× a. l.	1/1 (100%)
Brangewitz et al. [22]	32	30× a. l. 1× perf. 1× b. s.	27/32 (84%)
Schniewind et al. [23]	17	17× a. l.	15/17 (88%)
Bludau et al. [24]	14	8× a. l. 6× perf.	12/14 (87%)
Smallwood et al. [25]	6	1× a. l. 5× perf.	6/6 (100%)
Schorsch et al. [26]	35	21× a. l. 7× perf. 1× b.s. 6× o.o.	32/35 (91%)
Kuehn et al. [27]	21	11× a. l. 8× perf. 2× b.s.	19/21 (91%)
Seyfried et al. [28]	1	1× b. surg.	1/1 (100%)
Laukoetter et al. [29]	52	39× a. l. 9× perf. 4× b.s.	49/52 (94%)
Total	185	134× a. l. 36× perf. 8× b. s. 1× b. surg. 6× o. o.	168/185 90.8%

Case

A 51-year-old male patient underwent LSG for morbid obesity (BMI 62.7) in an outside facility 7 days prior to transfer to our hospital. As stated in the case history, the patient had developed temperatures up to 104 °F and presented with suspicious drain fluids, an elevated white blood cell count (WBC) and markedly elevated C-reactive protein (CRP) level on the third postoperative day. The initial diagnosis of a gastric leakage could not be managed sufficiently by the referring hospital. In domo, computed tomography revealed a leak of orally administered water-soluble contrast agent from the esophagus into the upper abdomen and a fistula to the outside of the abdominal wall in the region of the initially placed drainage (Fig. 1a). A subsequent esophagogastroduodenoscopy (EGD) showed three major leaks located within the gastric staple line in the proximal, middle, and distal part of the gastric tube; 50, 53, and 56 cm

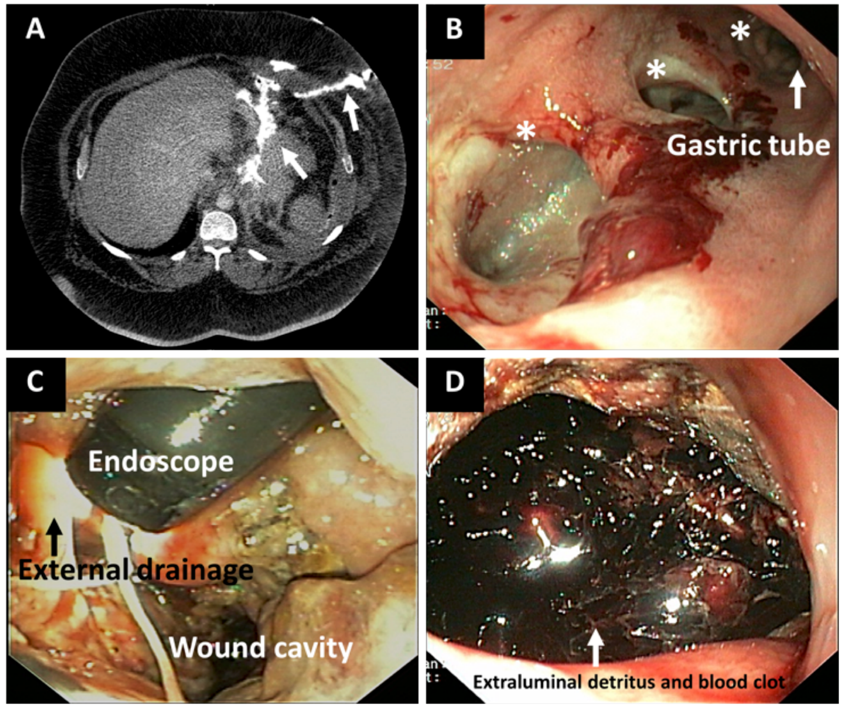

Fig. 1 Initial findings after complicated LSG for morbid obesity. **a** Computed tomography revealing a leak of orally administered contrast agent from the esophagus into the upper abdomen and a fistula into the abdominal wall. **b** Endoluminal endoscopic view on three major leaks located within the gastric staple line. **c** Rendezvous endoscopy showing the extraluminal wound cavity and the second gastroscope coming through the external fistula opening. **d** Extraluminal wound cavity filled with detritus and blood clot

distal to the dental arch, respectively (Fig. 1b), not able to determine if this complication occurred secondary to hemorrhage in the staple line formation or due to a technical failure during the operation. All defects merged into a single, large insufficiency cavity in the upper abdomen filled with hematoma, inflammatory fluid, and detritus, with drainage to the abdominal wall via a fistula (Fig. 1b, c). After initial endoscopic lavage and removal of the detritus, a transnasal enteral feeding tube was placed into the proximal jejunum for decompression and initial enteral feeding. During the ongoing course of therapy, the feeding tube was replaced by complete parenteral nutrition. Broad-spectrum antibiotic therapy with piperacillin/tazobactam had been initiated at the onset of fever and was continued at our hospital. Due to the initial critical septic condition of the patient, the extent of damage to the gastric tube in combination with a large inflamed wound cavity and the time point of transfer to our hospital after initial surgery, revisional surgery was deemed unfeasible at this point.

Encouraged by excellent results of EVT in comparison to conventional methods like stent therapy for upper gastrointestinal leaks in non-bariatric patients at our institution [29, 30], EVT was initiated on day 8 after failed LSG in the present case.

Endoscopic Vacuum Therapy (EVT)

EVT was performed as previously reported and described in detail by our group and as shown in Fig. 2 [29–31]. Briefly, EVT is carried out, by endoscopic insertion of an open-pore polyurethane sponge (e.g., VivanoMed® Foam, Paul Hartmann AG, Heidenheim, Germany) into the abscess cavity (intracavitary) (Fig. 3a, b) and with diminishing size of the defect by placing the sponge in the lumen covering the leak (intraluminal) (Fig. 4c).

The sponge is cut into shape according to the particular size and geometry of the extraluminal cavity as estimated by the endoscopist (Fig. 2b, c). The sponge is sutured to the tip of a conventional polyvinyl chloride gastro-duodenal tube (e.g., Covidien™ Salem Sump™, 14 Fr/Ch (4.7 mm) × 114 cm; Covidien™, MA, USA) with sutures at the proximal and distal ends of the sponge (Fig. 2b). The sponge is grasped by endoscopic forceps, pulled close to the endoscope and placed in the cavity under direct endoscopic vision (Fig. 2d, "backpack-method"). This is further simplified by an additional suture loop (L-loop) at the tip of the sponge (Fig. 2c). Continuous suction of 100–125 mmHg is applied using an electronic vacuum pump (e.g., VivanoTec®, Paul Hartmann AG, Heidenheim, Germany (Fig. 2a)) connected transnasally to the drainage tube. The sponge-drainage-system is endoscopically replaced every 3–5 days, to avoid the ingrowth of granulation tissue and until the cavity appears to be clean and firmly closed. To remove the vacuum drainage, the tube has to be diverted through the mouth and gently pulled out after discontinuation of the applied negative pressure. It is advisable to flush the tube with 0.9% saline solution to dissolve the granulation tissue from the pores of the sponge prior to removal. Initial placement and subsequent changing of sponges are done under conscious sedation (with midazolam and propofol) or general anesthesia, depending on the general condition of the patient in the ICU or the endoscopy unit.

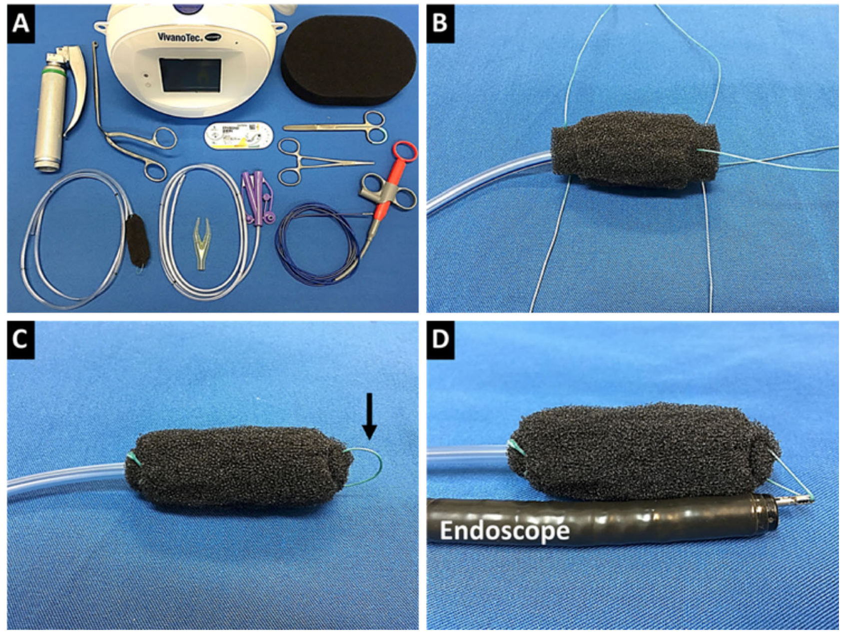

Fig. 2 EVT. **a** Basic set up for sponge preparation. **b** A polyurethane sponge is fixed on the tip of a gastric tube. **c** A suture loop (L-loop) at the tip of the sponge facilitates endoscopic handling. **d** Principle of insertion into the defect zone using an endoscopic forceps in a "backpack-method" allowing the positioning under direct visualization

Depending on the geometry of the wound cavity and the leaks, even two sponges can be placed separately at the same time to allow rapid and sufficient drainage of the defect.

Results

During the course of EVT, after the fourth (Fig. 3c) and seventh (Fig. 3d) change of the sponge, respectively, the extraluminal wound cavity became clean and showed the onset of formation of granulation tissue (Fig. 3d). At this stage, the septic focus was sufficiently controlled due to the diminished defect size accompanied with regeneration of the surface epithelium, and antibiotic treatment was discontinued. The Penrose drain, which had been placed in the area of the abdominal-cutaneous fistula at the onset of EVT to prevent collection of infectious fluids and to facilitate daily wound irrigation was withdrawn gradually, leading to complete wound closure without further infectious complications. After near total consolidation of the large abdominal wound

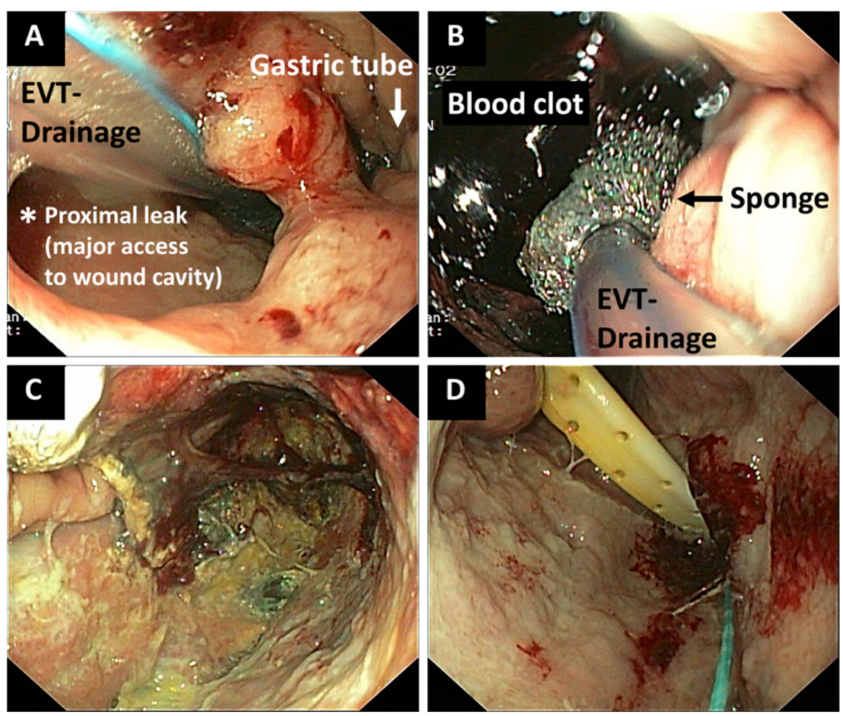

Fig. 3 Course of treatment – 1 month of EVT. **a**, **b** Initial intracavitary placement of the sponge in order to drain the extraluminal cavity. **c** Cavity after the fourth change of the sponge-drainage-system showing start of wound consolidation. **d** Cavity after the seventh change of the sponge-drainage-system showing external drainage and onset of wound regeneration and formation of granulation tissue

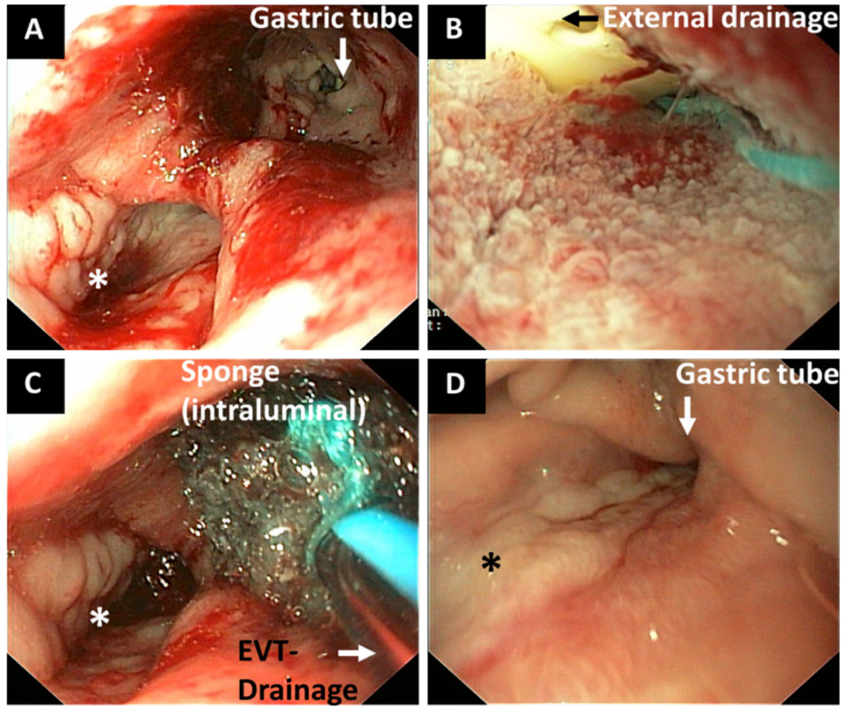

Fig. 4 Final course of EVT. Second month of EVT—**a** Diminishing size of the defect characterized by granulation. **b** Reduction of size of the cavity with regenerated epithelium and granulation tissue. Final 2 weeks of EVT—**c** Intraluminal placement of the sponge covering the defect zone. **d** Consecutive closure of the defects showing remaining fibrin scar

cavity was obtained (Fig. 4a, b), the sponge was subsequently placed intraluminally, covering the defect zone completely during the last 2 weeks of EVT (Fig. 4c). Finally, EVT resulted in a small fibrin scar indicating a successful complete closure of the defect (Fig. 4d).

The inflammatory markers, WBC (pre EVT, 27.84 k/μl) and CRP (pre EVT, 25.7 mg/dl), normalized during the course of EVT and showed an evident reduced level after the first change of the sponge on day 4 (13.89 K/μl and 18.1 mg/dl) with normalization of WBC (8.83 K/μl) and continuously low CRP levels (<6 mg/dl) after the 3rd EVT on day 12. A pleural effusion was drained by a chest tube for 5 days after 9 days of EVT.

In total, 18 endoscopic interventions with subsequent changes of the sponge-drainage-system were performed until the defect was firmly closed. The duration of EVT was 72 days with a changing interval of sponges of 4 days. Hospital length of stay was 106 days.

EVT resulted in a reduction of size and consecutive closure of the cavity by granulation tissue. After closure of the leakages, only a fibrin scar remained (Fig. 4d). After completion of EVT, leak closure was proven by additional x-ray contrast study and the patient was followed-up endoscopically once weekly over the course of 34 days. Oral nutrition was possible immediately after the termination of EVT. The patient could be discharged from our hospital in a good overall condition. After discharge from hospital, the patient was followed-up for additional 3 months. No relevant procedure related complications were observed during the course of therapy and during the follow-up.

Conclusion

Leaks are life-threatening complications associated with LSGs and most leaks occur at the proximal part of the staple line, at the esophagogastric junction. The reported patient suffering from a near total insufficiency of the staple line is surely not a common example for postoperative complications after bariatric surgery but shows imposingly that EVT is even feasible under unpromising circumstances. In case of unlikely failure, EVT does not jeopardize surgical repair rather than being a bridging technique in these rare cases. Although EVT requires multiple endoscopic procedures and is associated with a moderate prolonged hospitalization of the patient, its advantages with regard to previous treatment options like stent therapy are the regular visualization of the wound cavity and the optimal drainage provided by the vacuum system leading to a sufficient successful closure of the defect. Weighed against the numerous advantages of EVT, stent therapy seems to be more profitable concerning health economic aspects which in contrast does not compensate for the superior clinical outcome of EVT. However, the indication for EVT has to be weighted carefully in cases of close contact to major thoracic or abdominal vascular structures. Based on our individual experience, we observed in two patients with delayed leakages after upper GI surgery, an erosive precondition of adjacent vascular structures subsequently leading to severe hemorrhage during EVT. [29] Therefore, exit strategies, such as surgical or radiological insertion of a drainage combined with stent therapy remain considerable options in these patients. Nonetheless and in the light of this, endoscopic management of post-bariatric leaks becomes increasingly accepted in daily routine. While EVT is associated with a considerable learning curve and the preparation and placement of a suitable sponge can be time consuming especially at the onset of the establishment as a new interventional treatment option, procedure duration improves rapidly with forthcoming increased experience. Additionally, pre-assembled EVT sets for the upper GI tract fitting different cavities and endoluminal diameters are increasingly offered commercially, further reducing processing time.

EVT has the potential to succeed as a nonsurgical, feasible, safe, and effective treatment option of choice for complication management of postoperative leaks in bariatric surgery, especially in regard to revisional surgery and stent-based therapy.

Compliance with Ethical Standards

Conflicts of Interest Fabian Schmidt, Rudolf Mennigen, Thorsten Vowinkel, Philipp A. Neumann, Norbert Senninger, and Daniel Palmes declare that they have no conflicts of interest to disclose. Mike G. Laukoetter is a member of the expert panel of negative pressure wound therapy of the Paul Hartmann (AG) holding company. He received fees for invited speeches on endoscopic vacuum therapy.

Informed Consent Informed consent was obtained from all individual participants included in the study. Additional informed consent was obtained from the individual participant for whom identifying information is included in this article.

Human and Animal Rights 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.

References

1. Sjöström L, Narbro K, Sjöström CD, et al. Effects of bariatric surgery on mortality in Swedish obese subjects. N Engl J Med Massachusetts Medical Society. 2007;357:741–52.
2. Fernandez AZ, DeMaria EJ, Tichansky DS, et al. Experience with over 3,000 open and laparoscopic bariatric procedures: multivariate analysis of factors related to leak and resultant mortality. Surg Endosc. 2004;18:193–7.
3. Jones KB, Afram JD, Benotti PN, et al. Open versus laparoscopic Roux-en-Y gastric bypass: a comparative study of over 25,000 open cases and the major laparoscopic bariatric reported series. Obes Surg. 2006;16:721–7.
4. Ballesta C, Berindoague R, Cabrera M, et al. Management of anastomotic leaks after laparoscopic Roux-en-Y gastric bypass. Obes Surg. 2008;18:623–30.
5. Zellmer JD, Mathiason MA, Kallies KJ, et al. Is laparoscopic sleeve gastrectomy a lower risk bariatric procedure compared with laparoscopic Roux-en-Y gastric bypass? A meta-analysis. Am J Surg. 2014;208:903–10. discussion909–10
6. Aurora AR, Khaitan L, Saber AA. Sleeve gastrectomy and the risk of leak: a systematic analysis of 4,888 patients. Surg Endosc. Springer-Verlag. 2012;26:1509–15.
7. Biancari F, D'Andrea V, Paone R, et al. Current treatment and outcome of esophageal perforations in adults: systematic review and meta-analysis of 75 studies. World J Surg. 2013;37:1051–9.
8. Schaheen L, Blackmon SH, Nason KS. Optimal approach to the management of intrathoracic esophageal leak following esophagectomy: a systematic review. Am J Surg. 2014;208:536–43.
9. Livingston EH. Complications of bariatric surgery. Surg Clin North Am. 2005;85:853–68. vii
10. Madan AK, Lanier B, Tichansky DS. Laparoscopic repair of gastrointestinal leaks after laparoscopic gastric bypass. Am Surg. 2006;72:586–90. discussion590–1
11. Gonzalez R, Sarr MG, Smith CD, et al. Diagnosis and contemporary management of anastomotic leaks after gastric bypass for obesity. J Am Coll Surg. 2007;204:47–55.
12. Durak E, Inabnet WB, Schrope B, et al. Incidence and management of enteric leaks after gastric bypass for morbid obesity during a 10-year period. Surg Obes Relat Dis. 2008;4:389–93.
13. Eisendrath P, Cremer M, Himpens J, et al. Endotherapy including temporary stenting of fistulas of the upper gastrointestinal tract after laparoscopic bariatric surgery. Endoscopy. 2007;39:625–30.
14. Dasari BVM, Neely D, Kennedy A, et al. The role of esophageal stents in the management of esophageal anastomotic leaks and benign esophageal perforations. Ann Surg. 2014;259:852–60.
15. Eubanks S, Edwards CA, Fearing NM, et al. Use of endoscopic stents to treat anastomotic complications after bariatric surgery. J Am Coll Surg. 2008;206:935–8. discussion938–9
16. Hirdes MMC, Vleggaar FP, Van der Linde K, et al. Esophageal perforation due to removal of partially covered self-expanding metal stents placed for a benign perforation or leak. Endoscopy. 2011;43:156–9.
17. Murino A, Arvanitakis M, Le Moine O, et al. Effectiveness of endoscopic management using self-expandable metal stents in a large cohort of patients with post-bariatric leaks. Obes Surg. 2015;25:1569–76.
18. Papavramidis TS, Kotzampassi K, Kotidis E, et al. Endoscopic fibrin sealing of gastrocutaneous fistulas after sleeve gastrectomy and biliopancreatic diversion with duodenal switch. J Gastroenterol Hepatol. 2008;23:1802–5.
19. Overcash WT. Natural orifice surgery (NOS) using StomaphyX for repair of gastric leaks after bariatric revisions. Obes Surg. 2008;18:882–5.
20. Weidenhagen R, Hartl WH, Gruetzner KU, et al. Anastomotic leakage after esophageal resection: new treatment options by endoluminal vacuum therapy. Ann Thorac Surg. 2010;90:1674–81.
21. Wallstabe I, Plato R, Weimann A. Endoluminal vacuum therapy for anastomotic insufficiency after gastrectomy. Endoscopy. 2010;42(Suppl 2):E165–6.
22. Brangewitz M, Voigtländer T, Helfritz FA, et al. Endoscopic closure of esophageal intrathoracic leaks: stent versus endoscopic vacuum-assisted closure, a retrospective analysis. Endoscopy. 2013;45:433–8.
23. Schniewind B, Schafmayer C, Voehrs G, et al. Endoscopic endoluminal vacuum therapy is superior to other regimens in managing anastomotic leakage after esophagectomy: a comparative retrospective study. Surg Endosc. 2013;27:3883–90.
24. Bludau M, Hölscher AH, Herbold T, et al. Management of upper intestinal leaks using an endoscopic vacuum-assisted closure system (E-VAC). Surg Endosc. 2014;28:896–901.
25. Smallwood NR, Fleshman JW, Leeds SG, et al. The use of endoluminal vacuum (E-Vac) therapy in the management of upper gastrointestinal leaks and perforations. Surg Endosc. 2016;30:2473–80.
26. Schorsch T, Müller C, Loske G. Endoscopic vacuum therapy of perforations and anastomotic insufficiency of the esophagus. Chirurg. 2014;85:1081–93.

27. Kuehn F, Schiffmann L, Janisch F, et al. Surgical endoscopic vacuum therapy for defects of the upper gastrointestinal tract. J Gastrointest Surg. 2016;20:237–43.
28. Seyfried F, Reimer S, Miras AD, et al. Successful treatment of a gastric leak after bariatric surgery using endoluminal vacuum therapy. Endoscopy. 2013;45(Suppl 2 UCTN):E267–8.
29. Laukoetter MG, Mennigen R, Neumann PA, et al. Successful closure of defects in the upper gastrointestinal tract by endoscopic vacuum therapy (EVT): a prospective cohort study. Surg Endosc. 2016;
30. Mennigen R, Harting C, Lindner K, et al. Comparison of endoscopic vacuum therapy versus stent for anastomotic leak after esophagectomy. J Gastrointest Surg. 2015;19:1229–35.
31. Mennigen R, Senninger N, Laukoetter MG. Endoscopic vacuum therapy of esophageal anastomotic leakage. Gastrointest Endosc. 2015;82:397.