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# Stents for Postoperative Upper Gastrointestinal Leaks

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## Abstract

Anastomotic leaks are the most severe complication after upper gastrointestinal surgery and a major source for mortality and morbidity. Meanwhile, endoscopic procedures, especially the placement of self-expanding stents, are an attractive treatment option to close the leak and to promote the healing process under these conditions. Endoscopic stent placement should be the treatment of choice in patients with symptomatic (septic), non-ischemic and sufficiently drained anastomotic leaks up to 60% of the anastomotic circumference after gastroesophageal surgery. Complete anastomotic healing of postsurgical leaks after stent placement, without the need of further surgical procedures, was reported in 67–100% with an acceptable mortality of 0–33%. The most frequent complications after stent placement seem to be the migration of the graft and strictures after stent removal, which can be treated in the majority of cases sufficiently by an endoscopic reintervention. Surgical reexploration must be considered if clinical improvement of the patient is not achieved with endoscopic treatment.

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Anastomotic leaks after gastroesophageal resection continue to be a major source of mortality and morbidity, especially when leakage follows an intrathoracic anastomosis [1–4]. The incidence of this complication has been reported to be between 4 and 17% and it is responsible for approximately 40% of postoperative deaths [2–4]. The spectrum of manifestations of anastomotic leakage ranges from clinically silent to early fulminant leaks. A key issue is that there are no uniform methods for treating patients with symptomatic anastomotic leakage. Appropriate treatment must therefore be matched to the individual patient. Traditionally, some authors suggest surgical reexploration and repair (e.g. resection and diversion procedures), whereas others recommend a more conservative approach using parenteral nutrition, nasogastric decompression, perianastomotic drainage in the form of intercostal drains, or CT-guided percutaneous drainage and broad-spectrum antibiotics. However, aggressive surgical treatment is often associated with poor results and considerable mortality and morbidity, especially after delayed diagnosis of the leakage [1, 3]. A conservative approach is indicated only in selected patients with asymptomatic, non-septic and small anastomotic leaks, and it is associated with long hospitalization and long time enteral or parenteral nutrition support. Conservative treatment of clinically significant leaks was associated with mortality up to 30–45% and with a high rate of persistent leaks [5, 6].

However, during the past decade, the principles of management of postoperative anastomotic leaks after upper gastrointestinal surgery have shifted increasingly toward a more less surgically invasive but, nevertheless, endoscopically interventional approach, including endoscopic application of fibrin glue injections, use of clips and covered self-expanding stents to seal leakages [7]. Especially the use of stent seems to be a promising treatment option for many patients [7].

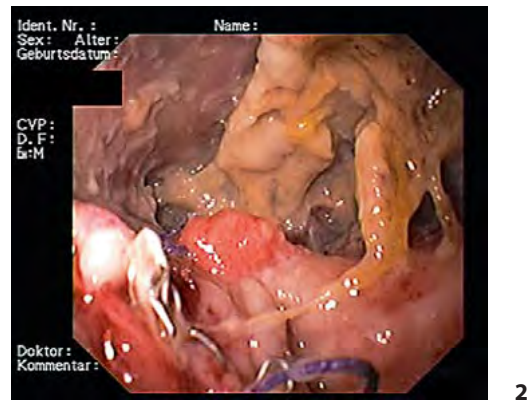
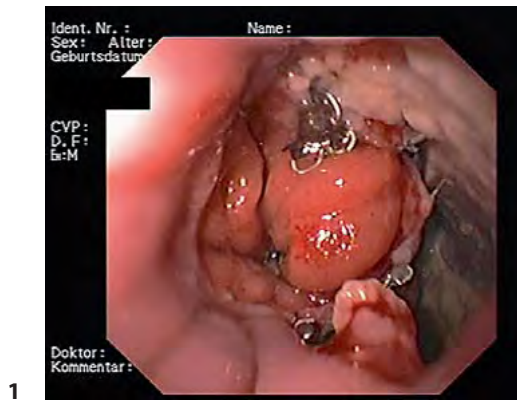
### **Clinical Presentation of Anastomotic Leaks**

A postoperative leakage of the anastomotic suture is the most frequent and severe surgical complication following upper gastrointestinal surgery and the major source for surgical mortality [8]. For that reason, not only obvious clinical and laboratory signs suggestive of an anastomotic complication, such as body temperature  $>38^{\circ}\text{C}$ , significant leukocytosis and increasing levels of C-reactive protein and procalcitonin and/or purulent exudation from the local drain, postoperative psychosyndrome, but also every disturbance of a normal postoperative course should lead to the suspicion of the presence of an anastomotic leak, which will require immediate diagnostic interventions. Endoscopy should be the first diagnostic step to detect a suspected postoperative leakage. The detection rate of postoperative anastomotic leaks and the sensitivity of endoscopy in experienced hands are superior to conventional radiological contrast studies in this context [9, 10]. For that reason, routine contrast studies after upper gastrointestinal surgery are not currently recommended [9, 10]. Endoscopy should clarify the following therapeutically relevant points: (1) size of the leakage (percent of the anastomotic circumference); (2) vitality and perfusion of the anastomotic line and interponate; (3) distance of the anastomosis from the mouth; (4) approximate luminal diameter, and (5) degree of contamination of the perianastomotic region, e.g. perianastomotic abscess formation, putrid fluid retention.

Non-ischemic anastomotic leaks up to 60% (two thirds) of the anastomotic circumference are suitable for endoscopic stent placement (fig. 1). Endoscopic treatment cannot be recommended for dehiscences of more than 60–70% of the anastomotic suture, complete dehiscences and anastomoses with an ischemic and devitalized anastomotic line (or interponate). A reoperation in these cases is mandatory. Furthermore, an early leakage occurring within the first 48–72 h postoperatively is mostly the result of relevant technical or surgical defaults (problems with the stapling device, difficulties with the suture line). An immediate surgical reexploration and revision of such early leaking and well-drained anastomosis can be effective and helpful, prior to a relevant perianastomotic inflammation.

In selected patients with non-symptomatic minor leaks (up to 10% of the anastomotic circumference, without septic signs), fibrin glue injection or endoscopic clipping could be an alternative and inexpensive treatment option for rapidly leak closure.

In many cases of larger dehiscences (more than 30% of the anastomotic suture), and especially after delayed leak diagnosis, an advanced putrid pleural or mediastinal inflammation of the perianastomotic region is seen (fig. 2). If possible, large dehiscences should be passed with an endoscope in order to explore the perianastomotic pleural or mediastinal cavity with regard to the degree of contamination. In those cases an endoscopic lavage and debridement of the perianastomotic region, prior to endoscopic leak closure, is useful, whenever significant putrid pleural inflammation is endoscopically detectable [11, 12]. This procedure, which equates traditional surgical cleansing of infected wounds, results in elimination of bacteria,



**Fig. 1.** Anastomotic leakage 5 days after an extended gastrectomy. Note that nearly 50% of the circumference is dehisced, without ischemia and tension. This is a good scenario for an endoscopic management.

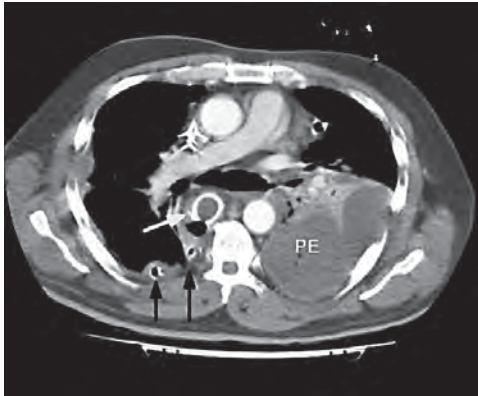
**Fig. 2.** Anastomotic leakage 5 days after extended gastrectomy (same patient as in figure 1). Endoscopic view into the perianastomotic mediastinum with purulent surface and necrotic tissue. As is mandatory, endoscopic debridement was performed prior to stent placement in this patient.

noxious necrotic tissue and remains of gastrointestinal fluids from the fistula and the perianastomotic mediastinum and should thus lead to an improvement of the clinical situation and of local as well as systemic inflammation [11–14]. Endoscopic lavage and debridement should be performed daily or at 2-day intervals until the anastomotic fistula is sufficiently cleaned and incipient granulation and no more putrid tissue are seen. If these criteria are fulfilled, the anastomotic leak can be closed by stent placement [11, 12].

Radiological diagnostics, i.e. CT scans (mostly repetitive CT scans) and, if necessary, conventional contrast studies should resolve the following points in addition to endoscopy: (1) sufficient external drainage of the leak; (2) non-drained mediastinal/pleural or abdominal effusions, and (3) advanced pleural or abdominal infection, i.e. empyema or abscesses.

Appropriate external drainage of an anastomotic leak to minimize contamination of the perianastomotic region is a crucial precondition for endoscopic leak closure via stent placement. Endoscopic leak closure of non-drained leaks cannot be recommended. The stent would prevent the transit of internal effluent of toxic and infectious material from the contaminated perianastomotic region into the intestinal tract, resulting in perianastomotic fluid retention, abscess formation, pleura empyema, and in the worst case, mediastinitis.

In cases of non-drained or insufficiently drained leaks, the additional placement of drains or catheters (pigtailes or chest drains) under CT guidance should be pursued in order to eliminate infectious fluid retentions prior to or in addition to endoscopic stent placement. However, there are some exceptions for such minimally invasive and interventional leak management, where surgery is still needed, in addition to endoscopic stent placement. Interventional external drain placement is mostly not suitable and sufficient in septic patients with pleural abscesses or empyema, due to intrathoracic leakages. In this scenario a radical surgical approach, i.e. evacuation of empyema and pleural decortication, for septic focus clearance should be considered (fig. 3). Relaparotomy, lavage and drainage of the abdominal cavity is inevitable in undrained intraabdominal esophageal leaks (e.g. after gastrectomy), which often lead to a diffuse contamination of the peritoneal cavity or when peritonitic signs are seen.



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**Fig. 3.** CT scan of a septic patient with an anastomotic leakage after esophageal resection, with left-sided pleural empyema (PE) communicating with the leakage. The leak was covered by stent placement (white arrow). The right pleural cavity and mediastinum is sufficiently drained by intraoperatively placed chest drains (black arrows). The patient required an additional surgical evacuation (thoracoscopy) of the PE and placement of additional drainage of the left-sided pleura.

**Fig. 4.** First contrast swallow after stent placement for an anastomotic leak following esophageal resection. The swallow suggests a complete leak closure (see also figure 5).

**Fig. 5.** After 3 contrast swallows (same patient as in figure 4), with progressive filling of the gastric pull-up, retrograde regurgitation of the contrast medium from distal, alongside the stent into the pleura is seen (arrow), demonstrating persistent leakage in this patient.

**Fig. 6.** A specially designed, fully covered SEMS (ECO Cardia Umbrella®, Leufen Medical, Aachen, Germany) was placed for best anchorage and for leak closure and to decrease the reflux of gastric fluids from distally. This patient had undergone resection of the esophagogastric junction and developed an incongruent, leaking esophagogastric anastomosis. This specially designed stent allows for complete leak closure and prevents persistent leaks due to stent influx and reflux.

## Technique of Endoscopic Stent Placement

The patient is placed in a supine position and endoscopy is performed under analgosedation. In cases where additional surgical procedures are contemplated (e.g. evacuation of pleural empyema, peritoneal lavage and drainage), the stent placement should be performed simultaneously under general anesthesia. Use of fluoroscopy (i.e. C-arm) is strongly recommended. However, in emergency settings, stent placement is feasible too, without fluoroscopic guidance, alongside the endoscope under direct visualization [15].

A standard guidewire is placed endoscopically crossing the anastomotic line. The anastomotic leak should be identified with radiopaque markers. All stents used for closing anastomotic leaks should be partially or fully covered (please refer to the Results section for an overview of different types of stents used for the closure of gastrointestinal anastomosis leaks). The unreleased stent is advanced over the guidewire and placed with its proximal and distal radiopaque markers above and below the leaking anastomosis. Now, the stent is delivered under fluoroscopic guidance or under direct visual control with the endoscope according to the instructions for use of the manufacturer. The stent should be deployed with at least 3–4 cm overlap proximal and distal to the leak with its covered part. Stents with a *proximal* release mechanism are recommended for this approach. After stent deployment, endoscopy is performed once again, to confirm correct stent placement and adequate leak closure. Additional nasojejunal tubes are not mandatory in cooperative patients, but very useful in ventilated patients: the nasojejunal tube helps for decompression and enteral feeding. However, oral fluid nutrition is feasible 4 h after stenting.

### *Technical Notes*

Some differences and aspects regarding to esophageal anatomy and configuration of leaking upper gastrointestinal anastomoses need to be addressed. Complete leak closure is not seen in every leaking anastomosis in spite of technically perfect stent placement. This fact may be explainable due to esophageal anatomy and physiology, which may result in stent migration due to the contraction waves occurring during deglutition. In contrast to the bile duct, the esophagus is a non-rigid, motile tube, and it is technically demanding to seal a very contractile leaking tube with a less flexible stent graft completely. Nevertheless, in those cases the implanted stents reduce contamination of the perianastomotic region to a considerable extent, which is an essential precondition for the healing process of leaking anastomoses. Presumably, another advantage of stents is their pressure on the esophageal wall, which induces rapidly granulations and promotes accelerated physiological tissue repair for the definitive leak closure. Dehiscent esophagojejunal end-to-end or end-to-side anastomoses (e.g. after gastrectomy) are optimally suitable for stent placement. The inner diameter of the esophagus is approximately identically to the jejunal lumen. This fact allows mostly direct and complete leak closure for esophagojejunal inflow as well as for jejunoesophageal reflux, due to optimal stent adaption at the inner esophageal and jejunal walls with a minimal risk for stent dislocation. Stent placement is much more difficult in incongruent esophageal anastomoses with a gastric or colonic interponate or a jejunal pouch. The wider inner diameter of the interponate decreases stent anchoring ability distally and leak closure from the interponate site. Complete leak closure for regular influx but not for reflux from the interponate back into the stented esophagus is often seen in those cases (fig. 4, 5). Additionally, the migration rate is higher. It is important to use a large covered stent with its maximal diameter configuration under these conditions. For best anchorage, the stent should be placed as far as possible at the esophageal site. Partially covered stents, to minimize migration, or

custom-made grafts with larger diameters or stents with specifically designed distal ends (tulip ends, mushroom shape, umbrella design) (fig. 6–8) are very useful in this situation.

### *Adjunctive Therapy*

For an interventional-endoscopic approach to be successful, close cooperation between surgeon, ICU specialist, endoscopist and radiologist is required. Most patients with anastomotic leaks following upper gastrointestinal surgery require intensive care treatment due to septic and multiorgan failure. The early initiation of supportive systemic strategies to decrease the dire consequences of sepsis and mediastinitis is mandatory. The use of broad-spectrum antibiotics is essential under these conditions. An intensive monitoring of systemic inflammation and immunologic competence, i.e. leukocyte counts, C-reactive protein level, interleukin and procalcitonin, is required. If the clinical situation and systemic inflammation is not improving under endoscopic treatment, immediate reevaluation, i.e. endoscopy and radiologic diagnostics (repetitive CT scans), or surgery is required.

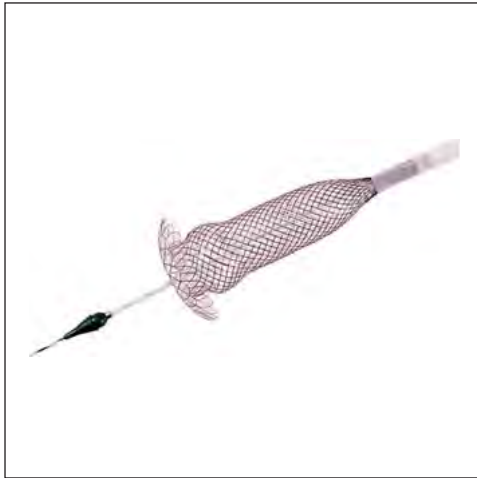
### **Endoscopic Stent Removal**

Because of their long-term complications, like stent ingrowth or overgrowth with resultant secondary strictures, fistulization and upper gastrointestinal hemorrhage, stents should be removed when definitive anastomotic healing is expected. Nevertheless, general recommendations for the optimal duration of stenting for an anastomotic leak do not exist and are not easy to define due to various factors influencing patient recovery and definitive anastomotic healing. The reported time for stent retrieval after placement for anastomotic upper gastrointestinal leaks ranges from 2 up to 20 weeks [15–20]. Leak closure will generally be heralded by an absent inflammatory response. We believe that anastomotic healing can be expected at the earliest 2 weeks after stent placement in smaller leaks and should be completed at the latest after 10 weeks in most of the larger or complicated leaks, depending on initial leak size, patients course and stent type (fully or partially covered) etc., so that stent removal should be conducted within this period in the majority of cases [11, 12]. Infrequently, a second stent therapy is needed in the presence of a persistent leak.

Stent removal (or replacement) can be accomplished in a safe and easy way preferably within 6 weeks (partially covered SEMS) [21] or 3 months (fully covered SEMS or plastic stents) [18, 19, 22] after placement. Stent retrieval becomes more and more difficult after this period, when the ends of the stent (mainly partially covered stents) become embedded in the esophageal mucosa. Further alterations of the anastomoses and esophageal wall, like secondary fistulization, can be expected after delayed stent removal. In cases of persistent leaks after stent removal, the defect can be sealed by fibrin glue, endoscopic clipping or by placement of a new stent (larger diameter and length or different design) [12].

### *Technique*

Stent removal is performed using a standard gastroscope and a rat-toothed forceps under anal-gosedation and direct visualization. To pull out the stent, the proximal stent end or the retrievable thread is grasped with the forceps. However, in our opinion, it is easier and safer to grasp the distal end of the stent (or the distally located retrievable thread) and to invaginate the stent up into itself to extract it from the esophagus. The invagination technique is particularly safe and



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**Fig. 7.** ECO Cardia Umbrella Stent® (Leufen Medical, Aachen, Germany) with specially designed distal stent end (umbrella design) for optimal leak closure from distal in incongruent anastomoses.

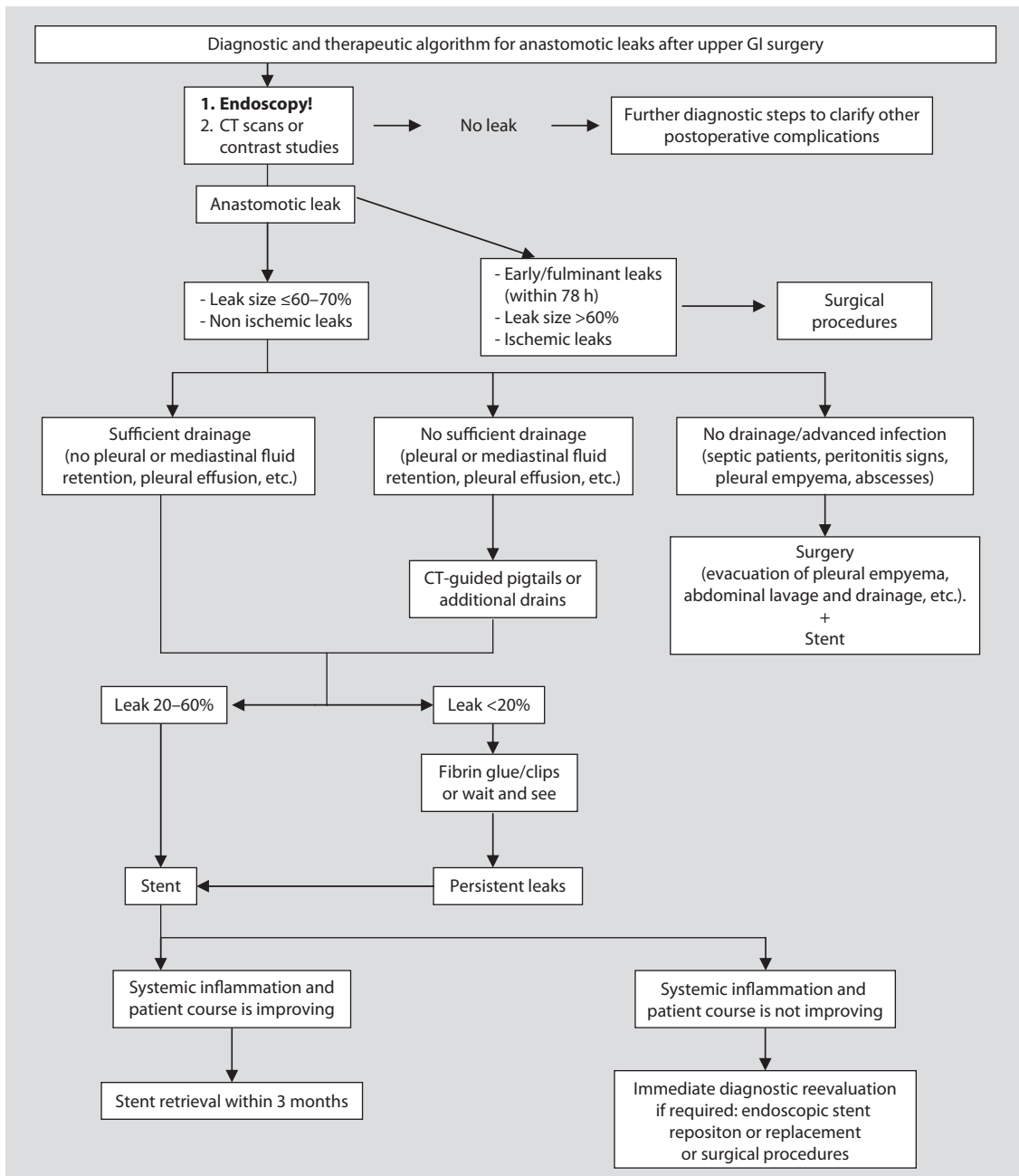
**Fig. 8.** Two partially covered SEMS.

effective for the retrieval of proximal ingrown stents. Sometimes, in cases of stent ingrowth or overgrowth, it is useful to reduce granulation tissue at the proximal stent end using argon plasma coagulation. Endoscopy should be always performed after stent removal to rule out complications such as bleeding or persistent fistulization. A contrast swallow using water-soluble contrast should be performed to confirm complete leak closure.

## Procedure-Associated Complications

### *Stent Migration*

Stent migration is the most frequent procedure-associated complication after stent placement for leaking anastomoses. It should be pointed out that stents were originally designed for (malignant) strictures, and stent adhesion in a non-stenotic, contractile esophagus is not always possible. Distal migration is the commonest problem after stenting, especially in incongruent esophageal anastomoses with a wider gastric or colonic interponate or jejunal pouch. After incomplete distal migration (the stent migrates distally underneath the anastomotic dehiscence, but not completely into the interponate) the proximal stent end can be grasped firmly with a forceps, in order to pull up the graft and to correct its position. This maneuver is usually successful. In cases of repeated distal migrations, the stent should be replaced by a stent with a larger diameter and length, or a fully covered stent should be replaced by a partially covered one for better anchorage. Complete distal stent migration into the interponate requires mostly stent retrieval and placement of a new stent, but endoscopic stent removal can be difficult under these conditions. The fully expanded stent ends are not easy to pull through a relatively narrower



**Fig. 9.** Diagnostic and therapeutic algorithm for anastomotic leaks after upper gastrointestinal surgery.

anastomosis. In those cases it is easier to pass the migrated stent completely with the endoscope and to grasp the distal end with a forceps, in order to invaginate the stent up into itself for removal. Sometimes it is useful to place at first a new larger diameter stent. Subsequently, the complete migrated stent can be removed by pulling it through the previously placed stent using the invagination technique.

In contrast, proximal migration is infrequent. Endoscopic reposition, by pulling down the stent, often fails. Removal of the migrated graft and placement of a larger stent are frequently needed to cover the leakage.

#### *Gastrointestinal Bleeding*

Gastrointestinal bleeding after stent placement or stent retrieval is a rare complication which requires usual endoscopic treatment options for hemostasis. An extremely rare and fatal complication is gastrointestinal bleeding resulting from an esophagoaortic fistula, with a mortality rate of nearly 100%. Merely, additional vascular stenting of the thoracic aorta may be a treatment option in individual cases.

#### *Anastomotic Strictures*

Anastomotic strictures after stent placement are less frequent than stenoses following conventional treatment or fibrin glue injections for anastomotic leaks. This fact is another argument for the use of stents for the treatment of anastomotic leaks. Anastomotic strictures can be treated endoscopically with good results. Usually, surgery is not required.

## **Results**

The use of stents to seal non-malignant esophageal leaks has been increasingly described during the last years [11, 16–28]. Up to now, there are various series about the successful placement of covered stents to close anastomotic leaks after esophageal or gastric, and more recently, bariatric surgery [11, 16–29]. Complete anastomotic healing of postsurgical leaks after stent placement, without the need of further surgical procedures, has been reported in 67–100% of selected cases with an acceptable mortality of 0–33% (table 1). Hereby, stent placement was technically correct in nearly 100% of the patients without difficulties (table 1). The commonest problem after stenting seems to be the migration of the graft, with a recurrence of a symptomatic leakage, which can be treated in the majority of cases sufficiently by endoscopic reposition of the stent or by stent replacement.

Both fully and partially covered metallic stents and covered plastic stents have been found suitable to seal anastomotic leakages in various studies [11, 16–29]. But the crucial question, what stent type should be preferred, cannot be answered yet and further technical innovations of current stents are needed. However, it is clear that all stents should be partially or completely covered, and have an adequate diameter, preferably with larger distal expansion. The cover will decrease leakage into the fistula and the dilated proximal end will help anchor the stent proximally, and thus decrease the chances of distal migration. Currently available stents show different features and have both advantages and disadvantages. The commonly used Polyflex® stent is completely covered by a soft silicon layer, which may result in less proliferation and inflammatory tissue. In contrast, metal stents (partially covered) mostly become strongly embedded in the esophageal mucosa, and stent retrieval is often more tricky. Another advantage of the Polyflex® stent is that it narrows under pressure, this is in contrast to, for example, metal stents, and can thus be removed more easily. But an important disadvantage of those stents, in this context, is an increased risk for migration (up to 37%) [24] in contrast to metal stents. In addition, the diameter of the delivery device is larger than that of the most commonly used metal stents, i.e. 12–14 mm, and the Polyflex® stent needs to be loaded into the delivery device before placement.

**Table 1.** Outcome after stent placement for anastomotic leaks and non malignant esophageal perforations

Reference (first author)	n	Stent	Correct stent placement, %	Complete leak healing, %	Mortality %	Migration %	Retrieval %
Doniec [16]	21	SEMS partially covered	90	80.1	23.8	5	56.5
Freeman [23]	21	Polyflex	100	95	5	24	100
Gelbman [18]	9	Polyflex	100	67	33	30	100
Han [22]	8	SEMS fully covered	100	100	0	0	100
Hunerbein [19]	9	Polyflex	100	88.9	0	22	100
Kauer [20]	10	SEMS fully covered	100	70	20	40	62.5
Leers [21]	31	SEMS partially covered	100	92	6.5	3	100
Ott [30]	12	Polyflex	100	42	n.a.	33	100
Radecke [15, 26]	15	Polyflex	100	73	n.a.	20	n.a.
Langer [24]	24	Polyflex	92	89	25	37.5	50
Evrad [17]	4	Polyflex	100	100	0	0	100
Roy-Choudhury [27]	14	SEMS partially covered	100	93	7	0	0
Tueberger [27]	32	SEMS fully covered	100	78	15.6	n.a.	70
Own patients	17	Polyflex	100	82	12	35	100
Own patients	21	SEMS fully covered	100	86	14	10	95

n.a. = No data available.

**Table 2.** Characteristics of recently used stent types for sealing of anastomotic leaks and non-malignant esophageal perforations (- low, + high)

	SEMS (partially covered)	SEMS (fully covered)	Polyflex
Delivery device, diameter in mm	5–10	5–10	12/14
Costs	+(++)	+(++)	-
Effectiveness in leak sealing	+(++)	+(++)	+(++)
Induction of stenoses	++	+	+
Risk for migration	-	+	++
Easy to removal	-	+	++

Initially, we used the Polyflex® stent for treating anastomotic leaks. Recently, we changed our initially endoscopic approach, due to frequent migrations of these plastic stents and repetitive incomplete leak closure, by using the new generation of fully covered metallic stents, which are also easy to remove within 3–4 months. The pros and cons of current available stent types are summarized in table 2.

Evidence-based guidelines for endoscopic treatment of anastomotic upper gastrointestinal leaks do not exist up to now, because of lacking prospective studies comparing different stent types, i.e. plastic versus metallic stents and partially covered versus fully covered stents, and different treatment strategies, i.e. endoscopic versus surgical or conservative treatment under defined conditions.

## **Conclusion**

Anastomotic leaks are the most severe and feared complication after gastroesophageal surgery and a major source of mortality and morbidity. Successful management of an anastomotic leak after upper gastrointestinal surgery requires sufficient drainage of the leakage to eliminate the contamination of the perianastomotic region and to control ongoing sepsis. It is also important to secure the intestinal passage and enteral feeding during the healing process. The optimal therapeutic strategy depends on a variety of influencing factors, such as size of the leakage, perfusion of the interponate, patient's condition, degree of sepsis and drainage of the leak, and ranges from a strict conservative approach in selected patients with small, well-drained and asymptomatic leaks to aggressive surgery (resection and diversion procedures) in septic patients with early and fulminant undrained leaks.

Despite the lack of prospective, randomized studies, the temporary placement of self-expanding and covered stents seems to be a very effective and safe, minimally invasive modality to treat these leaks, and it can reduce morbidity and mortality of this life-threatening complication after upper gastrointestinal surgery. With regard to published studies and our own experience, endoscopic stent placement should be the treatment of choice in patients with symptomatic (septic), non-ischemic and sufficiently drained anastomotic leaks involving up to 60% of the anastomotic circumference. Adequate drainage of the leakage must be established prior to sealing the leak with a stent, because once covered by a stent, the leak no longer allows internal drainage of infectious fluid into the intestinal tract and septic complications of the perianastomotic region are to be expected. In addition, endoscopic lavage and debridement, prior to stent placement, can be helpful to reduce pleural and mediastinal contamination in selected patients. To prevent mechanical and other stent-related complications, the stent should be removed or replaced preferably within 6 weeks (partially covered SEMs) or 3 months (fully covered SEMs and plastic stents). An interventional-endoscopic management of anastomotic leaks should be based on a multidisciplinary approach involving the surgeon, endoscopist, radiologist and ICU specialist. Surgical reexploration must be immediately considered if clinical improvement of the patient is not achieved with endoscopic treatment.

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