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ORIGINAL ARTICLE

Comparison of Endoscopic Vacuum Therapy Versus Stent for Anastomotic Leak After Esophagectomy

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Abstract
Background Endoscopic vacuum therapy is a novel option for the management of esophageal leaks. This study compares endoscopic vacuum therapy versus placement of covered stents for anastomotic leaks after esophagectomy.
Methods *N*=45 consecutive patients with anastomotic leaks following esophagectomy (including patients referred to our center from other hospitals for complication management) were managed by endoscopic therapy at our institution from January 2009 to February 2015. Outcomes of stent and endoscopic vacuum therapy were analyzed retrospectively.
Results Thirty patients received endoscopic stent placement and 15 endoscopic vacuum therapy. In the stent group, seven patients were switched to endoscopic vacuum and four to surgery. Classified by type of initial endoscopic therapy, the success rate (anastomotic healing, patient recovered) was higher for endoscopic vacuum therapy (endoscopic vacuum 93.3 %, stent 63.3 %; p=0.038). Classified by final endoscopic therapy (after switches in therapy), success rates were 86.4 and 60.9 % (p=0.091), respectively. There was no difference observed in mortality, duration of therapy, and length of hospital stay between the study groups.
Conclusions Endoscopic vacuum therapy might be more effective than endoscopic stent placement in the management of esophageal anastomotic leaks.

Keywords Esophagectomy · Endoscopic vacuum therapy · Stent · Anastomotic leak

Introduction

Esophagectomy is the mainstay of surgical therapy for esophageal cancer. Despite evolving surgical techniques and optimal perioperative management, morbidity of this procedure remains high. Mortality rates of 0–15.4 % have been reported,[1] while experienced centers achieve rates below 10 %.[2] In this context, it is important to consider that centers with very low mortality rates do not have lower postoperative complication rates, but are more successful in managing life-threatening complications.[2] As a consequence, improvements in complication management are most promising in reducing the overall mortality.

Besides pulmonary complications, anastomotic leaks are an important determinant of postoperative morbidity; they occur in up to 35 %[1] and give rise to 40 % of all fatalities following esophagectomy.[3] In patients being stable enough for nonsurgical therapy (Clavien-Dindo classification III/IV),[4] the placement of fully or partially covered self-expanding metal stents (SEMS) has become the standard endoscopic therapy of anastomotic leaks in the past years. In dedicated series, stent therapy achieved clinical success rates (healing of anastomosis) of 80–85 %.[5–7]

Recently, this standard therapy has been challenged by endoscopic vacuum therapy. Since feasibility and efficacy of its application in the upper gastrointestinal tract have been shown in first reports,[8,9] several centers published success rates in the management of esophageal leaks of 84–100 %.[10–18] These

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results lead to the question if this novel therapy is superior to the standard stent therapy, and if management algorithms of anastomotic leakage should be modified.

The aim of this study was to compare the efficacy of endoscopic vacuum therapy and stent placement for anastomotic leak after esophagectomy in a retrospective single-center study.

Patients and Methods

This is a single-center retrospective study conducted at our surgical department. Unlike several other retrospective studies on endoscopic vacuum therapy, this study only includes patients with anastomotic leaks following esophagectomy, this as an effort to ensure the homogeneity between the different study groups. Other esophageal leaks, e.g., spontaneous, iatrogenic, or following gastrectomy, were not included in this report.

The study period was from January 2009 to February 2015; cases before 2009 were excluded in order to make the patients comparable; in older cases, several factors like advances in surgical technique, perioperative management, anesthesiology, or management on the intensive care unit might have changed over time and are hard to incorporate.

We included all consecutive patients with esophageal anastomotic leak following esophagectomy who were managed at our institution, including patients who had esophagectomy in other hospitals and were transferred to our department for the management of complications. Anastomotic leak was proven by endoscopy in all cases. CT scans were routinely performed to assess the extent of possible leakage cavities.

The decision of treatment modality was at the discretion of the responsible surgeon. As this is a retrospective study, no study-related interventions were performed. Written informed consent was obtained for all interventions.

Endoscopic stent placement was the standard therapy in virtually all patients before 2012. In 2012, endoscopic vacuum therapy was introduced into clinical routine use at our institution. Based on good experiences with this technique, endoscopic vacuum therapy has replaced stent placement as standard therapy during the last years. Cases that were managed by primary surgery (all of these were critical patients with organ failure, Clavien-Dindo grade IV) were excluded from further analysis.

All remaining patients were classified into either "stent" or "endoscopic vacuum therapy" groups. Adjuvant endoscopic measures, like endoscopic clipping, or fibrin glue of residual fistulas, were allowed.

Follow-up was complete for all identified patients. By review of charts and recent follow-up visits, the following parameters were extracted: details of esophagectomy, details of anastomotic leak, type of therapy, details of therapy, success rate (anastomotic healing as proven by endoscopy and x-ray contrast study, and patient recovery), complications of therapy, and in-hospital mortality.

Stent Placement

The placement of stents was performed in prone or supine position, either under conscious sedation or general anesthesia. After endoscopic lavage of the mediastinal leakage cavity, a contrast study was performed to evaluate the extent of the leakage. Drainage of the cavity had to be ensured, usually by drainages placed during the initial operation. Under fluoroscopic control, a covered self-expanding stent was placed over the leakage. We used 10-cm-long (7 cm covered) and 23-mm-(shaft) and 28-mm-wide (proximal and distal throat) nitinol stents (Ultraflex®, Boston Scientific Corp., Natick, MA, USA) in 21 patients, and 10-cm- or 8-cm-long (completely covered) and 28-mm-(shaft) and 34-mm-wide (proximal and distal throat) nitinol stents (aixstent® OEL, Leufen Medical GmbH, Berlin, Germany) in nine patients. Correct position and sealing were proven by endoscopy and x-ray contrast study. Our standard procedure includes removal of the stent after a period of 4 to 6 weeks. In cases of stent migration, insufficient sealing, or other problems, endoscopic examinations were performed on demand. If the sealing was complete, oral intake of food was allowed. Some patients needed more than one stent, especially in the era before endoscopic vacuum therapy. With the advent of endoscopic vacuum therapy, most patients were switched to vacuum therapy if the first stent failed.

Healing of the anastomosis was assessed by endoscopy and x-ray contrast study after stent removal.

Endoscopic Vacuum Therapy (EVT)

EVT was done under conscious sedation or general anesthesia, depending on the general condition of the patient. After endoscopic assessment of the geometry of the leakage and the cavity, a polyurethane foam sponge (e.g., V.A.C.® GranuFoam™, pore size 400–600 μm; KCI®—KineticConcepts, Inc., TX, USA, and Wiesbaden, Germany) was cut into the corresponding shape. The sponge was fixed to the tip of a polyvinyl chloride (PVC) gastroduodenal tube (e.g., Covidien™ Salem Sump™, 14 Fr/Ch (4,7 mm)× 114 cm; Covidien™, MA, USA) with a suture at the proximal and distal ends of the sponge. An additional suture loop (L-loop) was placed at the tip of the sponge. This loop was grasped with a forceps (Fig. 1a), pulled close to the endoscope, and the sponge was placed in the leakage cavity under direct endoscopic vision (intracavitary) (Fig. 1b). If the defect entrance was not initially wide enough to accommodate the endoscope, the opening was dilated. After sponge placement, the vacuum drainage tube was diverted through the nose.

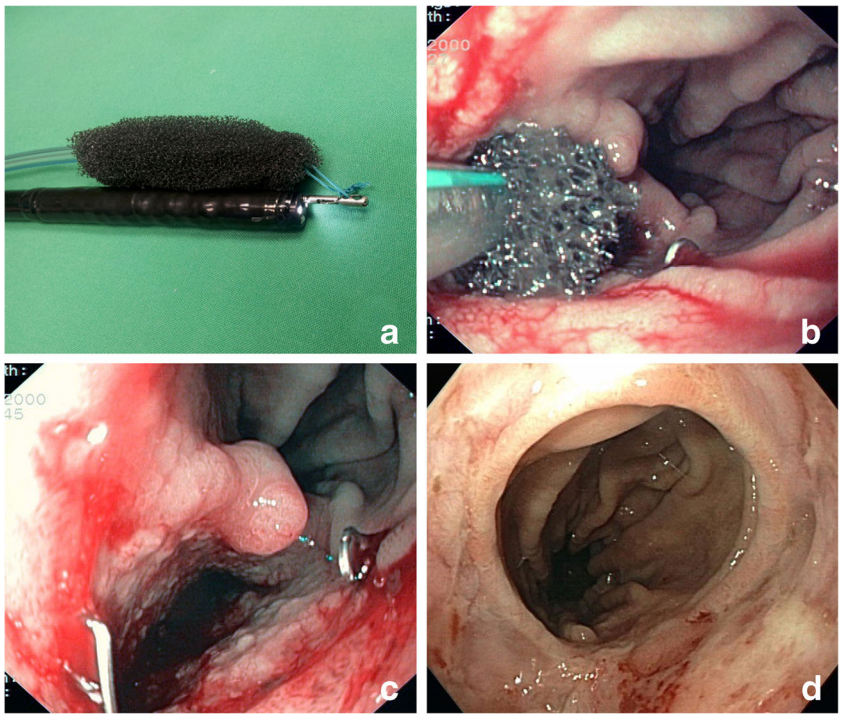

Fig. 1 Endoscopic vacuum therapy. **a** A polyurethane sponge is fixed on the tip of a gastric tube, and a suture loop is grasped by endoscopic forceps. **b** The sponge is placed into the cavity of the anastomotic leakage under direct endoscopic vision. **c** Extensive granulation within the cavity after 10 days of endoscopic vacuum therapy. **d** Completely healed anastomosis 4 weeks after completed endoscopic vacuum therapy

Continuous suction of 100–125 mmHg generated by a vacuum pump (e.g., activ.a.c® or v.a.c.ulta® KCI; VivanoTec®, Hartmann) was connected to the drainage tube. Additionally, a transnasal enteral feeding tube could be placed in the same session to ensure full enteral nutrition. With the sponge placed intracavitary, patients were allowed oral intake of fluids.

We routinely perform CT scans after first sponge placement in order to rule out direct contact to the heart, large vessels, trachea, or bronchus, as direct contact and continuous suction might lead to an injury of these structures.

Sponges were changed every 3–5 days. After discontinuation of suction, the tube was diverted through the mouth and removed simply by pulling. In some cases, remnants of the sponge had to be removed by endoscopic forceps. Endoscopic vacuum therapy was stopped when the defect size became too small for further foam placements (approximately 1 cm radius and 2 cm depth; Fig. 1c). The residual defect was controlled by endoscopy every 5–7 days, usually the defect completely closed within 1–2 weeks (Fig. 1d). In some cases, this was accelerated by clipping the residual defect with an over-the-scope clip (OTSC®; Ovesco Endoscopy AG, Tübingen, Germany).

Complete healing of the anastomosis was assessed by endoscopy and x-ray contrast study.

Statistics

Values are given as median (range), unless indicated otherwise. Comparisons between groups were performed by Fisher's exact test, chi-square test, and Mann-Whitney *U* test, where appropriate.

Results

Study Population

During the study period, $n=52$ consecutive patients with anastomotic leaks following esophagectomy were treated at our department. Seven patients were managed by surgery as first-line therapy and were excluded from further analysis. Details of the study population are given in Table 1. Most patients had esophageal malignancies (including one gastrointestinal stromal tumor and one metastasis of a malignant melanoma); however, two patients had a benign esophageal stenosis as a consequence of gastroesophageal reflux disease. All patients underwent abdomino-thoracal esophagectomy with a stapled intrathoracic anastomosis (end-to-side, circular stapler) to the gastric conduit. All leaks involved the anastomosis itself (not the conduit tip or the conduit staple line). In two cases, an associative conduit necrosis at the anastomosis was present. One of these cases was managed by stent, one by endoscopic vacuum therapy.

Stent and Endoscopic Vacuum Therapy

The actual therapy for all 52 patients is shown in Fig. 2. Thirty patients had an endoscopic stent placement as first-line therapy, 15 patients had endoscopic vacuum therapy, and seven

Table 1 Study population (classified by initial endoscopic therapy)

	Total	Stent	EVT	*p* value
Number of patients	45	30	15	
Male : female	35:10	21 : 9	14:1	0.129
Age	64 (40–92)	65.5 (40–92)	56 (42–76)	0.035
Indication				0.155
Adenocarcinoma	29 (64.4 %)	21 (70.0 %)	8 (53.3 %)	
SCC	12 (26.7 %)	7 (23.3 %)	5 (33.3 %)	
Other malignancies	2 (4.4 %)	0 (0.0 %)	2 (13.3 %)	
Benign disease	2 (4.4 %)	2 (6.7 %)	0 (0 %)	
Neoadjuvant therapy (total)	24 (53.3 %)	13 (43.3 %)	11 (73.3 %)	0.085
Chemotherapy	12 (26.7 %)	8 (26.7 %)	4 (26.7 %)	
Radiotherapy+chemotherapy	12 (26.7 %)	5 (16.7 %)	7 (46.7 %)	
Time (days) to diagnosis of leakage	7 (1–41)	7 (1–20)	7 (1–41)	0.448
Endoscopic distance from front teeth (cm)	29 (18–44)	27 (18–37)	29 (20–44)	0.420
Follow-up (days)	339 (10–1507)	503 (10–1507)	250 (69–1298)	0.172

Values given as number (percentage), or median (range)

SCC squamous cell carcinoma, *EVT* endoscopic vacuum therapy

patients were managed by surgery. It is important to note that a substantial number of patients of the stent group switched into other therapy groups during the therapy. Failure of stent therapy (including insufficient sealing of the leakage, clinical deterioration of the patient despite stent therapy, persisting leakage after planned stent removal) was the reason for this switch in all of these cases. Seven patients switched to endoscopic vacuum therapy; four switched to surgery. There was no switch of therapy in the endoscopic vacuum therapy group.

Details of Stent Therapy

Stent placement was used as first-line therapy in 30 patients. Technical placement of the stents was successful in all cases, and there were no complications related to the stent placement procedure. Each patient received in median one stent; however, due to insufficient sealing of the leak, or stent migration, single patients needed up to six stents (range 1–6). The median duration of stent therapy was 36 days (1–560). Total hospital stay was in median 53 days (13–195).

Small residual fistulas persisting after stent removal were successfully managed by OTSC placement in one patient and application of fibrin glue in one patient.

Details of Endoscopic Vacuum Therapy

In 15 patients, endoscopic vacuum therapy was used as first-line therapy; in further seven patients, endoscopic vacuum therapy was used as second-line therapy after stent failure. There were no complications related to endoscopic vacuum therapy. In median, 6.5 sponges (1–18) were used per patient. The median duration of therapy was 26.5 days (3–75), and the median hospital stay was 58 days (23–106).

In four patients, the small residual cavity after successful endoscopic vacuum therapy was closed by an OTSC.

Outcome of Endoscopic Vacuum Therapy and Stent: by Final Endoscopic Therapy

For this analysis, patients were grouped according to their last endoscopic therapy. As seven patients were switched from

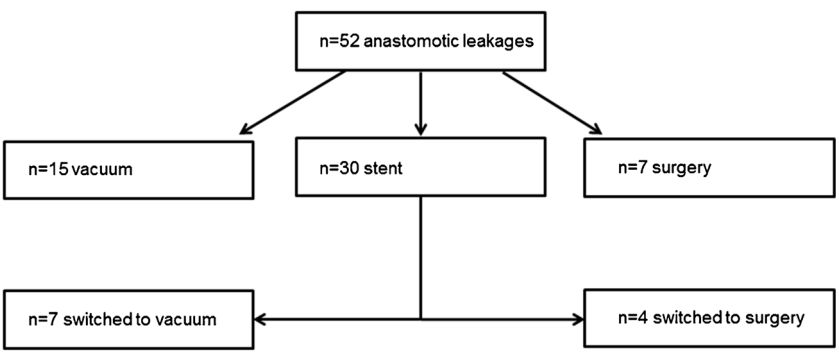

Fig. 2 Groups of therapy. In the stent group, seven patients were switched to endoscopic vacuum therapy during the course of therapy, and four to surgery

stent to endoscopic vacuum therapy, there were 23 patients in the stent group and 22 patients in the endoscopic vacuum group. For the interpretation of this analysis, it has to be taken into account that the seven patients switched from stent to endoscopic vacuum therapy were not counted as stent failure, as they were solely included in the vacuum group.

The values for success (anastomotic healing, patient recovered) and mortality are given in Table 2. Success rates were 86.4 % for endoscopic vacuum therapy and 60.9 % for stent therapy; this difference did not reach significance. Mortality was not significantly different between groups.

In the stent group, four patients died due to septic complications despite technically correct sealing of the stent. The four patients switched to salvage surgery were counted as stent failure; of these, two recovered after surgery, and two died. One patient developed a chronic esophagobronchial fistula. Taken together, this accounts for six deaths and nine failures in the stent group.

Two mortalities in the endoscopic vacuum group occurred in patients that were treated by stent placement in first instance and were switched to endoscopic vacuum therapy later on. One of these two patients died due to severe pneumonia while the anastomosis was completely healed. The third patient died due to myocardial infarction during the therapy (with good local response to vacuum therapy).

Considering the two patients with associative conduit necrosis, the patient receiving endoscopic vacuum therapy achieved complete healing. The patient receiving initial stent therapy was switched to endoscopic vacuum therapy later on; this latter patient died.

Outcome of Endoscopic Vacuum Therapy and Stent: by Initial Endoscopic Therapy

For this analysis, only the first-line therapy is considered for classifying the patients. This leads to $n=30$ in the stent group, and $n=15$ in the endoscopic vacuum group. The values for success and mortality are given in Table 2. For the interpretation of the respective values, it is important to note that the success rate of the stent group includes five patients that were finally salvaged by endoscopic vacuum therapy. Success rate of endoscopic vacuum therapy was significantly higher than of stent therapy. Again, mortality did not differ significantly.

Duration of Therapy and Length of Hospital Stay

Duration of therapy and length of hospital stay were not significantly different between the two groups.

Discussion

This study indicates that the novel endoscopic vacuum therapy is superior to stent placement in terms of success (defined as complete healing of the anastomosis, and patient recovery) in a cohort of patients with anastomotic leak following esophagectomy. However, patient numbers were too small to detect significant differences in mortality between the groups.

For many years, the placement of self-expanding stents has been the mainstay of endoscopic management of esophageal anastomotic leaks. Many publications have shown that this therapy is effective and safe.[5–7] However, even in dedicated centers, the failure rate of stent therapy is about 15–20 %,[5–7] including both mortalities despite stent therapy, and failures of anastomotic healing.

Endoscopic vacuum therapy was first used in the rectum and colon,[19,20] and based on convincing results, this technique has become the standard therapy in the management of rectal anastomotic leaks. In 2008, first reports on endoscopic vacuum therapy in the upper gastrointestinal tract were published.[8,9] In contrast to stent placement, endoscopic vacuum therapy requires multiple endoscopic procedures (every 3–5 days). Nevertheless, endoscopic vacuum therapy has several advantages compared to stent therapy. It allows visualizing the wound cavity on a regular basis, so deterioration can be detected early, and the cavity can be rinsed extensively at each endoscopy. The most important advantage is the optimal drainage provided by the vacuum system; in our experience, this leads to a very effective sepsis control in case of mediastinitis.

Several series have been published on endoscopic vacuum therapy of esophageal leaks and perforations.[10–18] However, most series include heterogeneous types of leaks and are not focused on anastomotic leaks. All publications report excellent success rates (healing of leaks and perforations in 84–100 %) and virtually no procedure-related complications.[10–18]

Table 2 Outcome of endoscopic therapy

		Stent	Endoscopic vacuum therapy	*p* value
By final therapy (seven patients switched from stent to endoscopic vacuum therapy)	Success	14/23 (60.9 %)	19/22 (86.4 %)	0.091
	Mortality	6/23 (26.1 %)	3/22 (13.6 %)	0.459
By initial therapy	Success	19/30 (63.3 %)	14/15 (93.3 %)	0.038
	Mortality	8/30 (26.7 %)	1/15 (6.7 %)	0.234

Based on these reports, a comparison with the actual "gold standard" stent placement is essential.

The outcome analysis based on the initial treatment (stent or endoscopic vacuum therapy) revealed a significantly higher success rate of endoscopic vacuum therapy compared to stent placement. However, when study groups were classified by the final endoscopic treatment, this advantage was not significant. Both analyses have their own limitations. From a scientific point of view, the classification by initial treatment surely is the most accurate analysis. However, stent failure led to a switch to endoscopic vacuum therapy in seven patients, five of which could be successfully managed by endoscopic vacuum therapy. These successful cases are attributed to the stent group (although stent failure was the reason for the switch of therapy). Conversely, analysis by final endoscopic therapy has to be interpreted with caution as well. First, two mortalities in the endoscopic vacuum group have initially been treated by stent, and one could argue that endoscopic vacuum therapy might have been more successful if started earlier. Second, all seven stent patients switched to endoscopic vacuum therapy were not counted as failure, although problems with stent therapy were the reason for these switches. All these aspects are in favor of the success rates of stent therapy. Therefore, we feel that the advantage of endoscopic vacuum therapy might even be larger than shown in the actual values.

Small residual fistulas (1–2 cm deep) following stent (two patients) or endoscopic vacuum therapy (four patients) were closed by additional OTSCs ($n=5$) or fibrin glue ($n=1$). In all cases, complete healing was expected with or without additional measures, and these optional measures aimed to accelerate complete closure and to allow food intake. Decisions on these adjuvant techniques should be made on individual basis.

The main limitation of this retrospective comparison is the rather low success rate of stent therapy. Compared to our own previous series on stent therapy (success rate 81 %),[6] the actual success rates (by initial therapy 63.3 %, by final therapy 60.9 %) are clearly inferior, leading to statistical significance compared to endoscopic vacuum therapy. In our series, the low success rate of the stent therapy can be attributed to two circumstances. Fist, four patients died as a consequence of prolonged sepsis, despite technically correct stent sealing. One might speculate that these patients would have needed further measures for sepsis control, e.g., additional drainages, redo operations, or other. Second, as soon as endoscopic vacuum therapy was available, stent therapy was disrupted at an early stage, if any problems occurred (like insufficient sealing, deterioration of the patient). Without this alternative, these patients would probably have received further stent therapy.

Interestingly, both previous studies on the comparison of stent therapy versus endoscopic vacuum therapy have the same limitation.[11,14] *Schniewind* studied 62 patients with anastomotic leaks following esophagectomy, comparing stent therapy, endoscopic vacuum therapy, surgery, and conservative management in terms of mortality.[14] After matching for APACHE scores, mortalities for endoscopic vacuum therapy and stent therapy were 12 and 83 %, respectively ($p=0.003$). This mortality rate of 83 % clearly is not in line with all previous reports on stent therapy.

Brangewitz analyzed the outcomes of 71 patients with esophageal leaks managed by stent placement or endoscopic vacuum therapy; unlike our present study, various etiologies were included.[11] Successful closure of defects was achieved in 53.8 % of patients with stent placement and in 84.4 % of patients with endoscopic vacuum therapy ($p<0.05$). Again, this success rate of stent therapy does not bear comparison with previously published rates.

Taken together, the present study and both previously published studies were performed in centers with great experience in stent therapy, and all found that endoscopic vacuum therapy was superior to stent therapy. This indicates that endoscopic vacuum therapy has the potential to replace stent therapy as gold standard for the treatment of esophageal anastomotic leaks. Controlled randomized studies comparing stent therapy and endoscopic vacuum therapy are desirable.

Conclusion

Endoscopic vacuum therapy might be superior to stent placement in the management of anastomotic leaks following esophagectomy. It leads to higher rates of anastomotic healing and has the potential to reduce overall mortality in larger series. In our own algorithms for the management of esophageal leaks and perforations, endoscopic vacuum therapy has replaced stent placement as first-line therapy.

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Conflict of Interest Dr. Laukoetter is a member of the expert panel of negative pressure wound therapy of the Paul Hartmann AG company. He received fees for invited speeches on endoscopic vacuum therapy.

All other authors declare that they have no conflicts of interest to disclose.

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