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Endoscopic vacuum-assisted closure of anastomotic leakage following anterior resection of the rectum: a new method

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Abstract
Background Conservative treatment of anastomotic leakage after anterior resection of the rectum seems to be possible in patients who have no occurrence of generalized peritonitis. This report describes a new method of endoscopic management of large anastomotic leakage in these patients.
Method The main feature of this new method is the endoscopically assisted placement of an open-cell sponge connected to a vacuum device into the abscess cavity via an introducer device. The sponge system is changed every 48–72 h.
Results Twenty-nine patients with an anastomotic leakage after anterior resection were treated with the endoscopic vacuum therapy. The total duration of endovac therapy was 34.4 ± 19.4 days. The total number of endoscopic sessions per patient was 11.4 ± 6.3. In 21 of the 29 patients, a protecting stoma was created at the primary operation. Four patients were treated successfully without the need of a secondary stoma. Definitive healing was achieved in 28 of the 29 patients.
Conclusions Endoscopic vacuum-assisted closure is a new efficacious modality for treating anastomotic leakage following anterior resection due to an effective control of the septic focus. Further studies will show if it is possible to reduce the high mortality rate of patients with anastomotic leakage through the avoidance of surgical reinterventions while at the same time preserving the sphincter function.

Keywords Endoscopic · Closure · Anastomotic · Leakage · Resection · Rectum

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Anastomotic leakage is the most significant complication after anterior resection of the rectum and is the major cause of postoperative mortality and morbidity [1–5]. The reported incidence of symptomatic leakage is between 1.5% and 17.5% [1, 2, 6–9] and is associated with a mortality rate between 6% and 22% [10]. Despite improvements in surgical techniques and surgical devices, colorectal anastomoses are still prone to leakage [11, 12]. Although significant progress has been made in understanding the perioperative factors that predispose to anastomotic leakage [3, 4, 6, 13, 14], little is known about the best treatment for this problem [15–20]. Available treatments range from conservative treatments such as nasogastric suction, broad-spectrum antibiotic coverage, and parenteral nutrition [5], through surgical procedures such as simple drainage or loop colostomy, or resection of the anastomosis with proximal colostomy and closure of the distal stump (Hartmann procedure), or, finally, abdominoperineal extirpation [5]. The particular procedure varies individually depending on the point in time, the extent, and location of the anastomotic leakage, as well as the efficiency of the secretion drainage and the clinical condition of the patient. Controlled studies for the best treatment of anastomotic leakage following resections of the rectum do not exist so far [21].

Conservative treatment by rinsing and drainage of the leakage cavity seems to be possible in patients without generalized peritonitis. However, healing is often very slow and formation of abundant scar tissue often results in a poor functional outcome.

We developed a new endoscopically applicable, minimally invasive method for continuous and effective drainage of the perianastomotic abscess and fistula in the pelvic region in combination with debridement and consecutive mechanical closure of the leakage [22]. The basic feature of this method is the placement of an open-cell sponge into the abscess cavity of the anastomotic leakage by means of a flexible endoscope. An evacuation tube fixed to the sponge exits transanally and is connected to a vacuum system.

Patients and methods

Between 2002 and 2004 34 patients with an anastomotic leakage after (low) anterior resection were treated with the newly developed endoscopic vacuum therapy (endovac). Informed consent was obtained from all patients. Patients were operated on electively after bowel preparation. Pelvis suction drains were routinely placed beside the anastomosis and left for 5–7 days after the operation. All patients were closely followed by the surgeon to detect clinical signs of anastomotic leakage (fecal discharge from wound or drain, fever, pelvic abscess, local peritonitis, discharge of pus per anus). If there were such signs endoscopic examination was performed routinely to verify the existence of a leak. In addition, a CT scan was used mainly to exclude endoscopically not visible and not accessible abscess formations.

The endoscopic vacuum device

The endoscopic vacuum device consists of a sponge connected to an evacuation tube that is endoscopically applicable via an introducer device (Fig. 1). The sponge is an open-cell, polyurethane ether sponge that has been approved by the U.S. Food and Drug Administration for contact with open wounds and has a CE-Label for the European market. The pore size ranges from 400 to 600 μm. The size of the cavity is determined via flexible endoscopy. The sponge dressing is cut to a size ranging from 7.0 cm in length and 3 cm in diameter to 0.5 cm × 1.0 cm according to the size and geometry of the leak and the corresponding cavity of the individual patient for each session. An evacuation tube (12 Ch, 50 cm) with side ports that communicate with the sponge is placed in the middle of the sponge and the proximal and distal ends of the sponge are fixed to it with a nonabsorbable surgical suture (Fig. 1). The end of the evacuation probe is connected to a vacuum wound drainage system via a variable drain connector in which effluent fluid is collected. The open-cell nature of the sponge ensures equal distribution of the applied subatmospheric pressure force to every surface of the cavity in contact with the sponge. The sponge dressing is placed into the abscess cavity using a specially developed introducer system.

The introducer system

The introducer system consists of two coaxially arranged sleeves. The lumen of the outer PVC sleeve is 1 mm larger than the outer diameter of the endoscope in use and is used as the introducer sleeve. The lumen of the inner sleeve is 2 mm larger than the diameter of the evacuation tube and is used as pusher for the sponge dressing. The sponge with the evacuation tube in its inner channel is pushed forward by the inner sleeve to the end of the introducer sleeve (Fig. 2e).

The procedure

At the beginning of the procedure the introducer sleeve is fitted over the endoscope. After the anal sphincter is lubricated the endoscope is placed at the distal end of the cavity (Fig. 2b). A standard hydrogel wound dressing is used as lubricant. The introducer sleeve is advanced under

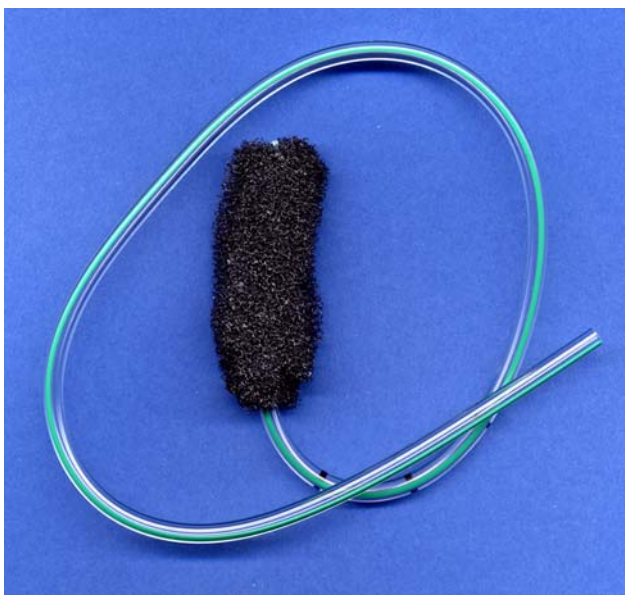

Fig. 1 The endoscopic vacuum device: An open-cell polyurethane sponge connected to an evacuation tube

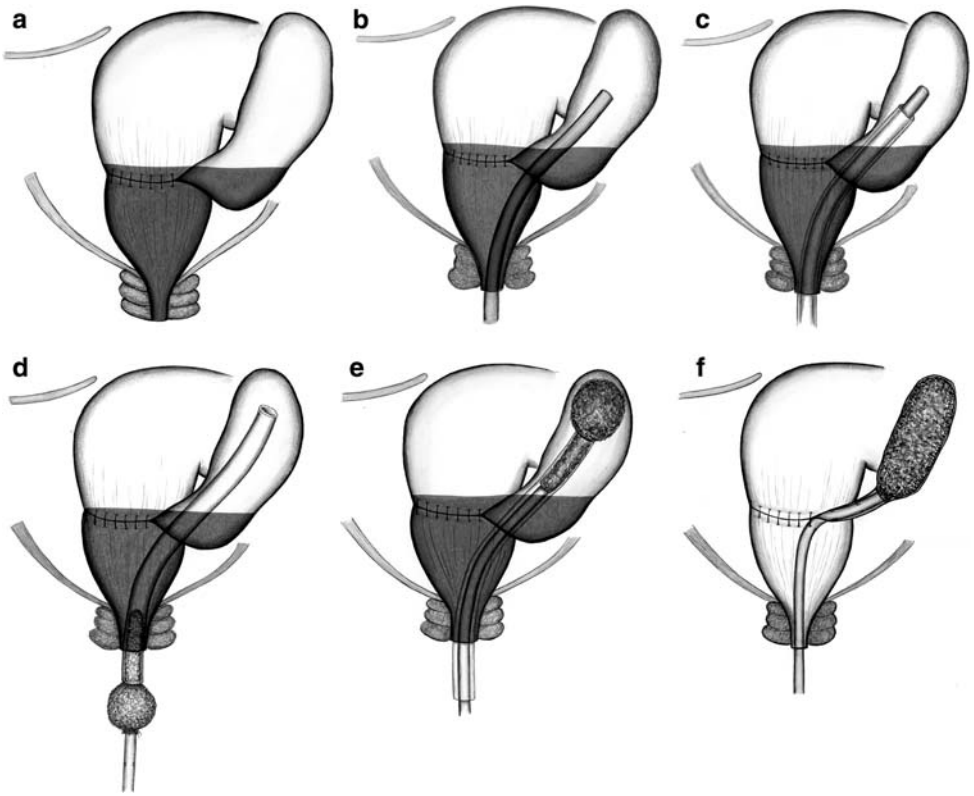

Fig. 2 **a** Anastomotic leakage with gas, pus, and feces in the abscess cavity. **b** The endoscope is placed into the cavity. **c** The outer sheath of the introducer system is advanced under endoscopic control. **d** The endoscope is removed leaving the outer sheath in place.The sponge is introduced into the distal end of the sheath. **e** The sponge is pushed through the outer sheath by the inner sleeve and finally released in the cavity. **f** The evacuation tube coming out of the anus of the patient is connected to a vacuum device

endoscopic control until the end of the cavity is reached using the endoscope as a guide (Fig. 2c). The introducer sleeve is fixed in this position and the endoscope is withdrawn (Fig. 2d). The sponge, which has already been cut to the size of the wound cavity and moistened with the lubricant, is compressed and inserted into the introducer sleeve. The pusher is used to advance the sponge through the introducer sleeve into the leakage cavity and right up to the far end, where it is placed in position. The introducer sleeve is grasped at its distal end and is withdrawn over the pusher. As a result the sponge is fully deployed in the cavity and the introducer system is removed leaving the sponge and evacuation tube in place (Fig. 2e). Care is taken to make sure that the sponge is not located in the rectal lumen but only in the abscess cavity. The position of the sponge is controlled endoscopically and the vacuum can be applied under direct view. The evacuation tube coming out of the anus of the patient is connected to the vacuum wound drainage system (Fig. 2f). Compared with vacuum therapy for open wounds, no sealing is necessary to obtain air tightness.

At the beginning of treatment for very large cavities, two or three sponges are placed in series to get as much sponge contact with the cavity surface as possible. The sponge system is changed every 48-72 h. The removal is facilitated by initial application of 10 ml NaCl 0.9% to dissolve the granulation tissue from the pores of the sponge. The endovac device is removed by pulling the evacuation tube with increasing force until the sponge system comes out of the cavity and can be removed via the anus.

Evaluation, treatment, and clinical follow-up were done by eight different surgeons of the surgical endoscopy unit during the observation time. Treatment procedures and results (text and pictures) are routinely documented immediately after the intervention for all endoscopic procedures of our unit using an electronic documentation system (EundL, Nuremberg, Germany). The clinical course of the patients documented in this system and an additional colorectal database of our institution were analyzed retrospectively.

Results

Data are presented as mean (range). Thirty-four patients with anastomotic leakage were to undergo closure of the leakage using endoscopic vacuum therapy. Mean age was 66.7 years (range = 42–79 years).

One patient died during the treatment due to a craniocerebral injury after falling out of bed. One patient rejected the ongoing therapy and left the hospital at his own risk. In one patient suffering from additional rectovaginal fistula, this treatment modality was used only for a conditioning of the wound bed as a bridging method; reoperation had to be

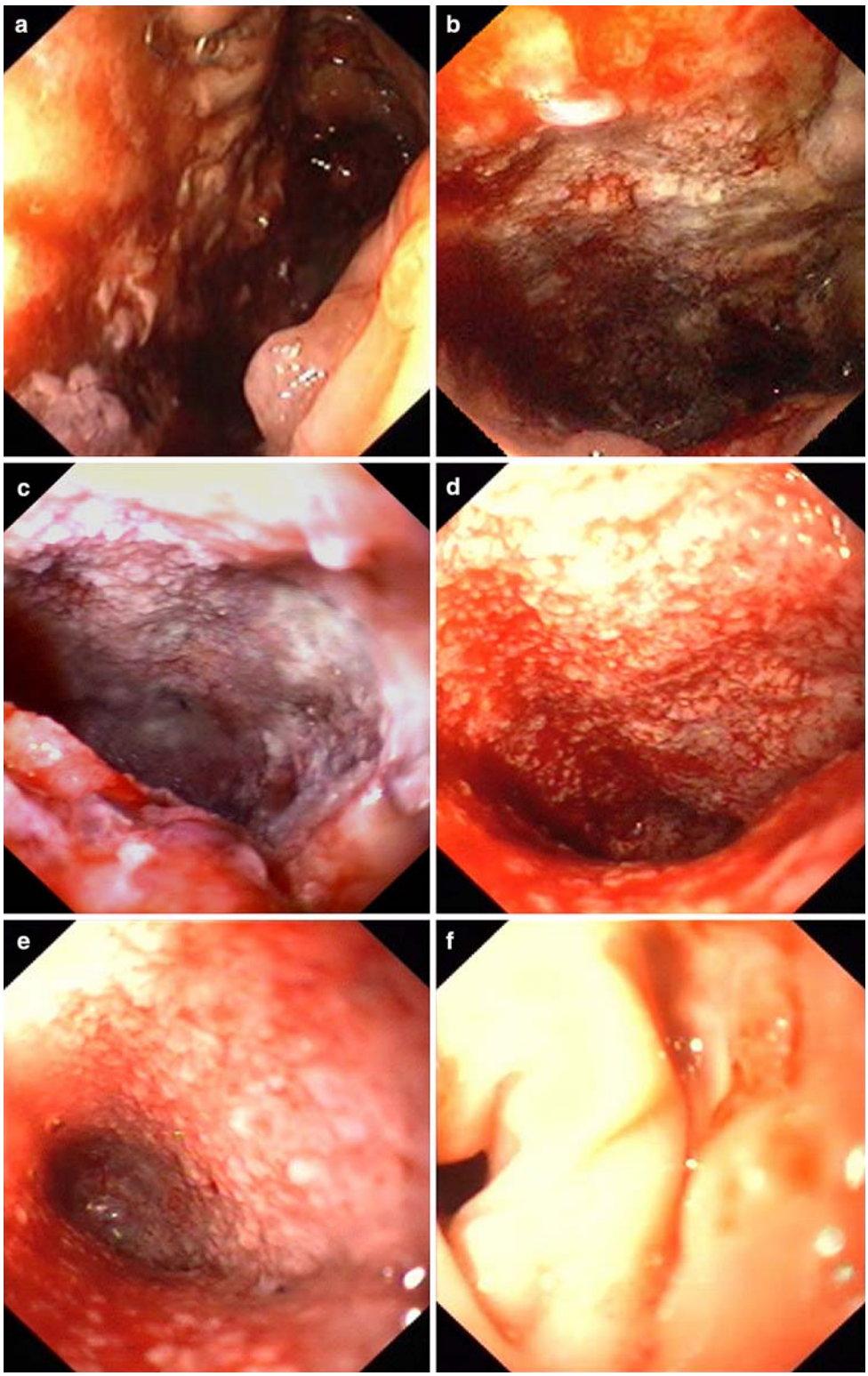

Fig. 3 Example of treatment: F.A., 82-year-old female, suffered from a rectal carcinoma and underwent low anterior resection with total mesorectal excisision. Ten days after the operation anastomotic leakage was diagnosed. **a** Endoscopic view of the anastomotic leakage with pus and feces in the abscess cavity. Nearly the whole circumference was dehiscent. The length of the abscess cavity is 11 cm. The endovac treatment was started and two sponge systems were placed into the large cavity. **b** Day 4 of treatment: Rapid debridement of the cavity and formation of granulation tissue. **c** Day 11 of treatment: No pus and fibrin are left in the cavity. A reduction in size of the cavity is visible. Only one foam system is placed for treatment. **d** Day 18 of treatment: Consecutive mechanical closure. The sponge is reduced in size. **e** Day 21 of treatment: Only a small channel is left as resulting defect. 2 × 0.5 ml of fibrin glue was injected into the wall to close the small defect. **f** Day 28 of treatment: A small scar is left next to the anastomosis; no leakage is visible

done after 7 days. In two patients reoperation and breakdown of the anastomosis and Hartmann's procedure were done after one and two sessions of endoscopic treatment because of ischemic necrosis and progressive complete dehiscence of the anastomosis.

The resulting 29 patients (24 male, 5 female) were treated continuously with the endovac method to close the leakage. Twenty-two patients were suffering from rectal cancer, three patients from rectosigmoidal cancer, two patients from large rectal adenoma, one patient from

diverticulitis, and one patient from rectal infiltration of endometrial cancer. Nine patients received preoperative radiochemotherapy, five patients were suffering from diabetes, and one patient had a chronic intake of oral steroids. All patients initially had clinical signs and symptoms that suggested an inflammatory complication in the pelvis. None of the patients had clinical signs of a generalized peritonitis when starting the endovac therapy.

Anastomotic leakage was diagnosed between the 3rd and 17th postoperative day (8.2 ± 3.6 days). The mean height of the anastomosis (measured by flexible endoscopy) was 5.3 cm (range = 1–12 cm) above the anal verge. The anastomotic leakage was determined as the percentage of the dehiscence of the whole circumference of the anastomosis and ranged from 20% to 75%. The length of the cavity measured at the beginning of the treatment was between 2 and 20 cm (mean = 7.4 ± 5.1 cm). The endovac therapy started after informed consent was obtained from the patient. The initial management of all patients included intensive nutritional support and broad-spectrum antibiotics.

Patients received parenteral nutrition when adequate oral food intake was not possible. Oral food intake was supplemented by normocaloric balanced diet drinks up to 3 × 200 ml per day. In patients without a stoma, total parenteral nutrition initially was given and only clear fluids orally. At the first sign of granulation tissue in the cavity, normal food was given.

The endoscopic placement was done with the patient under sedation and in the left lateral position. The changing of the sponge system was usually done without analgesia; sedatives were used (2–5 mg of midazolam per session) occasionally. The total duration of endovac therapy was 34.4 ± 19.4 days (range = 4–79 days). The total number of endoscopic sessions per patient was 11.4 ± 6.3 (range = 1–27) until the depth of the resulting cavity was less than 1 cm (mean).

The growth of granulation tissue in the cavity was observed in all cases after the initial treatment. This is accompanied by a reduction of fibrin and necrotic tissue in the cavity (Fig. 3). The continuous filling of the cavity with granulation tissue is followed by a decrease in the diameter and the length of the cavity during subsequent treatment sessions. The size of the sponge was reduced according to the decrease in the cavity size. The endovac therapy was stopped when the size of the cavity was less than 0.5 cm × 1.0 cm. In nine patients, for definitive closure of the resulting tissue defect (length <1.5 cm) fibrin was injected into the surrounding tissue to close a resulting small channel. In all other cases the resulting small defect at the end of therapy healed spontaneously. Duration of postoperative hospital stay was between 10 and 69 days (mean = 30.5 ± 12.8). In 25 of 29 patients therapy was continued as an ambulatory treatment.

None of the patients reported an increase in discomfort due to the foreign body during the treatment intervals. Removal of the sponge sometimes resulted in minor bleeding from the granulation tissue that stopped spontaneously. No major bleeding occurred in this series of patients. No additional adhesive tape was used in any patient for an airtight sealing of the system. The sponge system is fixed in the cavity due to its own suction. No additional suturing or taping for fixation of the evacuation tube is necessary. There was no dislocation of the sponge system under continuous vacuum therapy.

The improvement of the systemic inflammatory response is shown by a significant decrease of clinical and serologic signs of infection after 7 days of treatment. The C reactive protein (CRP) decreased from 14.0 mg/dl (median) to 2.9 mg/dl (median) ($p < 0.05$, Kruskal-Wallis one-way analysis of variance on ranks) after 7 days of treatment. Leukocytes decreased from 9.8 to 7.8 g/L (not significant, Kruskal-Wallis one-way analysis of variance on ranks).

As reported by the patients themselves and their household community, the odor due to the abscess cavity was significantly better within 24 h after initial treatment.

A definitive healing was achieved in 28 of the 29 patients. In one case, after radiochemotherapy and an operation with a J-pouch, a persistent presacral scarred fistula could not be closed (79 days of treatment). After six months this patient underwent a Hartmann's procedure, closure of the ileostomy, and creation of a descendostoma.

During follow-up of ten patients, a therapy-relevant stenosis of the anastomotic region occurred. Treatment was done by bougienage or balloon dilatation. Therefore, 5.8 ± 2.2 dilatation procedures were necessary.

In 21 of the 29 patients a protecting stoma was created during the primary operation (19 protecting ileostomies, 2 colostomies). Eight patients had no primary protecting stoma created. Three of these patients showed signs early on of a generalized peritonitis and were operated on immediately; a stoma was created without takedown of the colorectal anastomosis. The leakage was secondarily treated by the endovac method. In five patients who had no primary protecting stoma created, the endovac therapy was the first treatment of the anastomotic leakage. In one patient the secondary creation of a stoma was necessary to get control of the infection.

In 22 of 25 patients with a protecting stoma, closure after successful treatment was possible. Time to closure was 168.9 ± 81.7 days (range = 9–321 days). Two patients died before closure because of progression of malignant disease (distant metastases). One patient was converted to a Hartmann's procedure after 6 months.

One patient was treated during the ICU stay after the initial operation. One patient needed a cardiac pacemaker

due to symptomatic bradyarrhythmia and subsequent monitoring at the ICU. One patient received surveillance at the ICU for only one day after the initial treatment. No bleeding from larger blood vessels or appearance of small intestinal fistulas were observed in this series.

Discussion

The most dreaded complication after colorectal surgery is anastomotic leakage [5, 17]. Patients typically show the triad of pelvic or perineal pain, temperature elevation, and serologic inflammation parameters [5]. Early attention to these clinical findings was shown to improve the outcome [5]. In several clinical studies most of the patients were reoperated on after the diagnosis of anastomotic leakage [17]. This extendive procedure carries considerable risks for a critically ill patient resulting in high mortality and a high risk (25%) of a need for a permanent stoma [11]. Therefore, the ultimate aim of all treatment should be to close the anastomotic leakage and to drain the perianastomotic abscess in the shortest possible period of time with the least trauma to the patient. Where an anastomotic leak with generalized peritonitis exists, the primary indication is for open revision. However, if an anastomotic leake is suspected clinically and there are no signs of generalized peritonitis, our patients are first of examined with a flexible endoscope. The flexible endoscope examination in our view offers essential advantages over rigid rectoscopy: much smaller quantities of air are required because the air can be applied in a very controlled manner and according to need. Furthermore, flexible endoscopy provides a better overview and places less mechanical strain on the anastomotic region.

In anastomotic leakage, pressure builds up above the anus and gas and feces follow the path of least resistance out of the colonic lumen into the pelvic cavity. A high bacterial load of up to 10^8–10^9 aerobic and anaerobic germs per gram of feces contaminates the pelvic cavity. As a result, an effective and continuous drainage of the abscess is needed. Pelvis suction drains alone are often not effective enough because they do not have direct contact with the abscess in all cases and often get blocked by debris [23]. Computed tomography-controlled placement of additional catheters is often possible. However, there is still a backflow out of the colonic lumen through the leak into the cavity with whatever type of standard drain is used. For treatment of the abscess cavity, endoscopic lavage of the defect can be used to get local control on the infection. A problem with this method is the discontinuous drainage of the abscess due to the physiologic action of the sphincter next to the anastomosis. The ideal drainage of this type of abscess cavity would be an internal drain in combination with a "bypass" of the physiologic obstruction of the anus by continuous transsphincteric drainage. This avoids additional contamination and laceration of adjacent structures.

Endoscopic vacuum-assisted closure of anastomotic leakage was developed to overcome the limitations of intermittent endoscopic treatment and conventional drainage therapy. This method provides continuous and effective drainage of the perianastomotic abscess and fistula in the pelvic region in combination with debridement and consecutive mechanical closure of the leak. The open-pore structure of the sponge used in endovac therapy in combination with topical negative pressure provides a very effective method of drainage. Damage to neighboring structures is avoided.

Vacuum-assisted closure (VAC) therapy is a well-established treatment for open chronic wounds in which the sponge is placed into the wound, sealing the site with an adhesive drape and applying subatmospheric pressure. The precise mechanism for accelerated wound treatment with the VAC is still unclear [24]. Several studies have shown that vacuum therapy promotes healing of chronic wounds by an enhanced formation of granulation tissue. An increase in vascularity and associated decrease of bacterial colonization with standard vacuum therapy has also been shown before [25, 26].

Using the sponge intracorporally for endoscopic vacuum-assisted therapy also enhances the formation of granulation tissue in the cavity. However, several other factors are responsible for the success of this method in treating anastomotic leaks after low anterior resection. The transanal drainage allows effective and continuous drainage of the abscess cavity while bypassing the physiologic obstruction of the anus without additional trauma to the patient. Any backflow out of the colonic lumen through leakage into the cavity is blocked. Enlargement of the cavity is avoided. Negative pressure leads to a mechanical reduction of the volume of the abscess cavity. However, unlike sutures or other mechanical tension devices, the topical negative pressure of a sponge is applied uniformly to every point on the inner surface of the wound in a controlled manner [26]. No fixation such as sutures or tapes is necessary for the endovac drain. Fixation is via the sponge by its own under negative pressure. No adhesive drape has to be used as in standard vacuum therapy in treating open wounds. Air tightness is maintained by the anus and the sphincter of the patient. A comparative study between transanal drainage alone versus vacuum-assisted drainage has not been done so far. Nevertheless, the effects we could show (granulation tissue, reduction of wound size) are similar to the effects that have already been shown in other large series of patients whose open wounds were treated with vacuum therapy.

A precondition for the applicability of the method for large leaks is a cavity that is accessible by endoscope. In low anastomosis, a proctoscope can be used to insert the foam system. Using a rectoscope is also possible; the rectoscope replaces the introducer sleeve in this setting, and a pusher to advance the foam in the rectoscope to its distal end is still necessary. Handling issues, minimum stress to the anastomosis for the safety of the procedure, and the possibility of documentation were our reasons for using a flexible introducer system in combination with a flexible endoscope.

Because the anastomotic leak and the corresponding cavity has a high bacterial load, sterility of the procedure is not necessary. The sponge dressing is provided sterile, but we used nonsterile gloves and instruments for trimming and placing the sponge. A contraindication to this should be major vessels exposed to the sponge due to the risk of an erosion. Direct contact of parts of the small or large intestine with the sponge should be avoided.

The length of hospital stay of our patients with anastomotic leakage was in the range of 24–35 days as reported in the literature. Our patients were hospitalized for a longer time on purpose for a very intensive clinical follow-up at the beginning. Thus, we cannot show a reduction in length of hospital stay. Further studies will have to show if this is possible with more experience with this method. We could show a high rate of definite healing of the anastomotic leakage. The definite outcome of patients with anastomotic leakage is often not mentioned in the literature (persistent presacral sinus, rate of stenosis, closure of ileostomy). In our experience, a number of leaks "heal" after conservative treatment with a chronic presacral sinus as a residuum next to the anastomosis. As a result closure of the diverting stoma is often not possible. Closure rates of 30% are reported for "clinical leaks." We have quite a high rate of closure of the ileostomies compared with data from the literature (22 of 25 patients) [27, 28].

Endoscopy is often seen as an option only for clinically unapparent, small, and/or "radiographic" leaks [29]. We could show that the endoscopic treatment of large anastomotic leakage by the endovac therapy is a suitable method for the management of this serious complication. The endoscopic closure of large anastomotic leaks and deep abscess cavities was possible within one or two months. Because we do not have a control group or comparative data so far, we have to discuss our results in view of the literature. In recent publications clinical anastomotic leakage is still the major cause of postoperative death after anterior resection. When symptomatic leakage is present, the risk of postoperative death increases to between 6% and 22%. This shows us that there is still a problem in handling these patients. Also, reported closure rates of diverting stomas of 30% after "clinical leaks" are quite low. Data in the literature about the outcome of patients with anastomotic leakage depending on the therapy performed is quite rare [21]. Thus, comparison of our results with results from the literature is limited. Although our study was not randomized, our results show an improved outcome compared with data about anastomotic leakage reported in the literature. Further prospective evaluation that compares this method's effectiveness and safety with those of common procedures managing anastomotic leakage is needed.

Conclusion

Until now endoscopic treatment of anastomotic leakage was limited to small and clinically unapparent dehiscences due to an inadequate septic focus control. Endoscopic vacuum-assisted closure is an extremely efficacious modality for treating anastomotic leakage following anterior resection because of its effective control of the septic focus. In our patient group we showed that larger dehiscences in particular were also suitable for the treatment by endoscopic vacuum-assisted therapy. Close cooperation between the surgeon and the endoscopist is required. Reoperation can be avoided in most patients. Now, as before, where generalized peritonitis exists, there is a clear indication for surgical revision. We believe that endoscopic vacuum-assisted closure of clinically apparent anastomotic leakage is a safe and minimally invasive therapeutic option. Further studies will show if it is possible to reduce the high mortality of patients with anastomotic leakage through the avoidance of surgical reinterventions while at the same time preserving the sphincter function.

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Conflict of interest Worldwide patent is pending for this method (R. Weidenhagen and U. Grützner). A license agreement for this method with KCI, San Antonio, Texas, was signed in 2002 and terminated in 2004. A new license agreement is signed in 2007 with BBraun Melsungen AG, Germany.

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