

## Endoluminal vacuum-assisted therapy as a treatment for anastomotic leakage in colorectal surgery

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### Abstract

Anastomotic leakage (AL) has a wide range of clinical features ranging from radiological only findings to peritonitis and sepsis with multiorgan failure. An early diagnosis of AL is essential in order to establish the most appropriate treatment for this complication. Despite AL continues to be a dreadful complication after colorectal surgery, there has been no consensus on its management. However, based on patient's presentation and timing of the AL, there has been a gradual shift to a more conservative management, keeping surgery as the last option. Reoperation for sepsis control is rarely necessary especially in those patients who already have a diverting stoma at the time of the leak. A nonoperative management is usually preferred in these patients. There are several treatment options, also for patients without a stoma who do not require a reoperation for a contained pelvic leak, including recently developed endoscopic procedures, such as clip placement or endoluminal vacuum-assisted therapy. More conservative treatments could be an option in patients who are clinically stable or in presence of a small defect.

**Key Words:** Anastomotic leakage; Colorectal cancer; Colorectal surgery; Mortality; Morbidity

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**Core Tip:** The authors of the review have a remarkable clinical experience and scientific authority in colorectal surgery and related complications. The authors focus their attention on endoluminal vacuum therapy to treat anastomotic leakage in colorectal surgery. The authors highlight that most studies are heterogeneous in term of success rate definition, salvage and long-term results. Furthermore, there is paucity of comparative studies and thus definitive conclusions are not warranted at present time, as pointed out by the authors in their narrative review.

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## TO THE EDITOR

We were pleased to read the high-level article on treatment of colorectal anastomotic leakage (AL) with endoluminal vacuum therapy (EVT), published by Vignali and De Nardi[1]. The authors have a remarkable clinical experience and scientific authority in colorectal surgery and related complications[2-4].

We agree with the authors that AL is still the worst complication of colorectal surgery today. The consequences of AL can severely alter functional outcomes and oncological results[5]. In the case of AL, the severity of the clinical picture is extremely variable. Some AL have no impact on the patient, while others present with sepsis and can be fatal[6-8].

The incidence of AL is variable[1,5,9]. We believe that this variability in incidence is related to several factors. In accordance with the literature data, we believe that variables such as neoplastic or inflammatory disease, timing of the operation, the distance of the tumor from the anal merge, the clinical presentation with signs of visceral perforation or intestinal obstruction, the local characteristics of the tumor and the surgery performed are important for the postoperative onset of AL. In this context, the need for a common definition appears to be fundamental. AL occurs when a surgical anastomosis fails. In this circumstance, the intestinal contents leak out of the surgical connection. A pelvic abscess close to the anastomosis must be considered as AL. The classification of severity degrees proposed by the International Study Group of Rectal Cancer (ISREC)[10] is the most widely adopted. ISREC[10] proposes a classification of AL into three types (A, B and C) of increasing severity according to the therapeutic management it requires (conservative management in type A; non-surgical management in type B; surgical treatment in type C).

We believe that the onset of AL is important. The time to onset of AL affects both the severity of the complication and also the treatment of the complication itself. Colonic or rectal stump ischemia due to excessive preparation of the stump itself with consequent interruption of the perianastomotic supply of microvascular blood or tension in the anastomotic site is usually responsible for the early onset of AL [11]. On the other hand, the late presentation of AL is not linked to surgical technique problems but rather to clinical conditions of impaired tissue healing, such as local sepsis, malnutrition, the intake of immunosuppressive drugs, severe obesity and exposure to radiation[9,12]. In most patients, AL that occurs early is associated with more severe clinical symptoms. Faecal contamination of the peritoneum is frequently observed in these patients and the incidence of emergency laparotomies is higher. In conditions of worsening sepsis, mortality rates increase. By contrast, in late forms of AL, clinical manifestations will be characterized by the appearance of a pelvic abscess[13,14].

Furthermore, we believe that early diagnosis of AL is essential in order to establish the most appropriate treatment for this complication[15]. Despite AL continues to be a dreadful complication after colorectal surgery, there has been no consensus on its management[5]. Today, however, there is an increasing use of more conservative management. It is preferred to keep surgery as a last resort. Obviously this attitude is related to the presentation of the patient and the timing of the AL[16-18]. In agreement with Vignali and De Nardi[1], we believe that saving the anastomosis through the use of conservative treatments represents a valid therapeutic option to be used especially in clinically stable patients or in the presence of a small defect.

The authors focus their attention on EVT. Its principle is based on the application of topic negative pressure to drain the cavity and to prevent the development of chronic sinus. The paragraph on the description of the device is interesting and exhaustive, too. We agree with Vignali and De Nardi[1] that several reviews, and meta-analyses have been published so far with promising results. Nevertheless, the analysis of most documents yields mixed results, especially when the success rate, anastomosis salvage rates, and long-term outcomes are taken into account. Furthermore, the paucity of comparative studies does not allow definitive conclusions to be drawn, as pointed out by the authors in their narrative review.

There are several treatment options, including recently developed endoscopic procedures, such as stent or clip placement or EVT. These procedures can be used primarily in patients who already have a diverting stoma at the time of the leak. These treatments also find application in patients with extraperitoneal anastomosis and in those without ostomy who do not require further surgery due to a contained pelvic loss (type B of the ISREC classification). EVT is performed endoscopically. An open-pored polyurethane sponge is positioned in the leakage cavity through the anastomotic defect. The main advantages of the treatment are represented by a less invasive approach and continuous drainage. Treatment favors granulation and vascularity; furthermore, it determines a mechanical reduction in the size of the abscess cavity[19-21]. The main indication for the use of the EVT are extraperitoneal, low leaks that are difficult to drain. A disadvantage to the systematic adoption of EVT is the fact that the sponges must be periodically changed, usually more than 8 times in 4-6 wk. Anastomotic necrosis and stricture are the most common complications of the procedure.

The AL treatment should be tailored taking into consideration many factors, giving that there is no universally accepted management flowchart for the optimal treatment of this complication. Non-operative management is usually preferred in patients with extraperitoneal anastomosis without sepsis and peritonitis and in those who underwent proximal faecal diversion at the initial operation[5]. Excluding complications directly related to the endoluminal device, the factors associated with the failure of a conservative approach using EVT are mainly represented by neoadjuvant therapy, lack of a protective stoma before treatment and male sex. However, it must be emphasized that most of these are well known risk factors for AL in general. The timing of EVT can influence success, significantly. A high success rate occurs when endoluminal therapy is started early (within 6 wk) after the onset of AL[22, 23]. Riss *et al*[24] found that 25% of patients assessed after primary successful EVT in a multicentre study developed recurrent abscesses after a median follow-up of 17 mo. No study in the literature has focused attention on oncological and functional outcomes.

It seems obvious to us that in case of AL it is better to prevent its complications rather than treat them once they have arisen. Unfortunately, we believe that complications after colorectal surgery are still inevitable. We are sure that also Vignali and De Nardi[1] agree with our orientation.

Moreover, surgeons have employed several intraoperative techniques to assess integrity of the colorectal anastomoses in order to minimize the risks of postoperative complications. Basic mechanic patency tests (traditional air leak testing, saline leak, and methylene blue leak tests), endoscopic visualization techniques, and more recently, micro perfusion assessment technology are the most commonly used methods. Other methods commonly adopted to evaluate the blood perfusion of the intestinal segments to be used for the creation of the anastomosis are the visual evaluation of the color of the intestinal wall, the presence of visible peristalsis and bleeding from the marginal arteries. These tests are limited. None of these tests allow viewing of the lumen. The anastomosis is assessed by occluding the proximal lumen and then filling the intraluminal cavity with air or fluid and checking for leakage[2,25].

Intraoperative endoscopy was used to visualize the anastomosis. However, the use of the method is not so widespread. Furthermore, the results of intraoperative endoscopy are not of univocal interpretation. A recent systematic review evaluating the results of five non-randomized controlled trials, in which a total of over 900 patients were enrolled, documented an incidence rate of AL of 7.7% in patients with documented AL at intraoperative endoscopy, with no significant difference in postoperative AL rate compared to patients with negative intraoperative endoscopy for AL[26].

Nowadays, a promising and increasingly used new technology is intra-operative fluorescence angiography with indocyanine green[2,27-29]. Evidence for the impact of intraoperative fluorescence angiography in reducing AL after colorectal anastomosis is growing. The procedure allows direct visualization of tissue perfusion. It may help to prevent AL. The use of indocyanine green fluorescence angiography leads to a significant reduction in AL compared to standard intraoperative methods to assess anastomotic blood perfusion in colorectal surgery. Moreover, especially in patients with low or ultra-low rectal resection, the use of indocyanine green fluorescence decreases the need for surgical reintervention for AL.

A diverting stoma ideally protects a low colorectal anastomosis. However, there is a lot of controversy surrounding the use of a protective stoma. The first controversy is certainly about which is the most optimal type of ostomy, an ileostomy or a colostomy[30]. We believe that ostomy is useful to reduce clinical symptoms of AL by increasing the percentage of sub-clinical dehiscence, but not modifying the overall percentage. Moreover, no significant benefit of a diverting stoma for reducing the risk of AL has been showed in some large-volume studies. Usually, we tend to protect with an ostomy the patients who underwent neoadjuvant radiotherapy and those with an ultralow colorectal anastomosis. In recent years, this dogma has been challenged. Several authors questioning the need of an ostomy for all patients with an ultralow anastomosis.

We believe that the use of a transanastomotic drainage tube (TDT) may be useful in preventing the onset of AL. Regarding the TDT, several studies showed no difference in AL rate between patients with and without one[31]. Other literature observations, instead, have documented a reduction in frequency of AL in patients with TDT[32-35]. Prophylactic TDT presents fewer risks of complication than derivative stoma. It was thought to lower the risk of AL, *per* as documented in a systematic review and meta-analysis pooling 1772 patients undergoing rectal anterior resection[36]. The same conclusions were obtained in another systematic review and meta-analysis, including patients with diverting stoma[37].

Therefore, prophylactic TDT could constitute an efficient method to prevent AL in high-risk patients without exposing them to the complications of a diverting stoma. However, it is necessary to conduct an RCT on a large number of patients in order to obtain definitive results from the comparison of the two techniques.

AL after rectal surgery is a fearsome complication with considerable mortality and morbidity. Many factors are related to the onset of AL in the postoperative period. Some of these factors cannot be changed in the least by medical intervention. It is paramount to identify leaks early to minimize the potential morbidities of this complication. Despite advances in combating surgical infections, new devices for bowel reapproximation, better understanding of risk factors for anastomotic complications, and improved perioperative care, we continue to struggle with the occurrence and management of this complication. Technology will likely never be developed that would allow surgeons to prevent the onset of AL in the postoperative period. The use of the TDT prevents the formation of AL. This is a simple method that could avoid performing diverting ileostomies. AL can be further reduced by fluorescence angiography. This method, while bringing significant intraoperative changes in surgical strategies, allows the direct evaluation of the vascularization of the intestinal segments. In the meantime, it's necessary promptly diagnose AL. Likewise, the knowledge of all the therapeutic possibilities, from the least invasive ones to surgery, is necessary in order to treat AL and improve patient outcomes by reducing the incidence of functional disorders or the impact on survival.

## FOOTNOTES

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