Transanal Tube as a Means of Prevention of Anastomotic Leakage after Rectal Cancer Surgery

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Keywords
Rectal cancer · Low anterior resection · Anastomotic leakage · Transanal tube

Summary
Background: Anastomotic leaks after low anterior resection for rectal cancer remain the most feared complication. The aim of our study was to investigate whether the use of a transanal tube could reduce the leakage rate after this surgical procedure. Methods: This is a retrospective analysis of a single-institution experience. The study includes 66 patients who underwent low anterior resection for rectal cancer without stoma creation between January 2008 and June 2013. Patients were divided into two groups, i.e. those with a transanal drainage tube (TT; n = 9) and those without tube (NTT; n = 57), and evaluated for clinically evident anastomotic leakage and postoperative complications. Results: The postoperative anastomotic leakage appeared in 5 patients (9%) in the NTT group while no single case was observed within the TT group. Despite the disadvantageous background in the TT group (a transanal stent was used in the most high-risk patients), these patients had no postoperative complications. In the NTT group, 23% had some kind of postoperative complications, and 5% died. The difference between the two groups is not significant. Conclusions: Our study showed that the use of a transanal tube in low anterior resection for rectal cancer could potentially be a simple and effective method of reducing anastomotic leakage. In order to prove our observations, larger prospective randomized studies should be performed.

Schlüsselwörter
Rektumkarzinom · Tiefe anteriore Resektion · Anastomoseninsuffizienz · Transanales Darmrohr

Zusammenfassung
Hintergrund: Anastomoseninsuffizienzen bleiben die am meisten gefürchtete Komplikation nach tiefer anteriorer Resektion bei Rektumkarzinom. Das Ziel unserer Studie bestand darin, zu untersuchen, ob die Verwendung eines transanalen Darmrohrs die Leckagerate nach diesem chirurgischen Eingriff reduzieren könnte. Methoden: Es handelt sich hierbei um die retrospektive Analyse einer Single-Center-Erfahrung. Die Studie umfasst 66 Patienten, die sich zwischen Januar 2008 und Juni 2013 einer tiefen anterioren Resektion bei Rektumkarzinom ohne Schaffung eines Stomas unterzogen. Die Patienten wurden in zwei Gruppen, d.h. solche mit einem transanalen Darmrohr (TT; n = 9) und solche ohne Darmrohr (NTT; n = 57), unterteilt und bezüglich klinisch evident Anastosmoseinsuffizienzen sowie postoperativer Komplikationen ausgewertet. Ergebnisse: Die postoperative Anastomoseninsuffizienz trat bei 5 Patienten (9%) in der NTT-Gruppe auf, während kein einziger Fall in der TT-Gruppe beobachtet wurde. Trotz des mit Nachteilen behafteten Hintergrunds der TT-Gruppe (eine transanale Drainage wurde bei den hochnährigsten Patienten verwendet) hatten diese Patienten keine postoperativen Komplikationen. In der NTT-Gruppe, 23% der Patienten hatten einen postoperativen Komplikation, und 5% der Patienten verstarben. Der Unterschied zwischen den beiden Gruppen ist nicht signifikant. Schlussfolgerungen: Unsere Studie belegte, dass die Verwendung eines transanalen Darmrohrs bei tiefer anteriores Resektion bei Rektumkarzinom möglicherweise eine einfache und effektive Methode zur Reduktion von Anastomoseninsuffizienzen sein könnte. Um unsere Beobachtungen zu bestätigen, sollten größere prospektiv randomisierte Studien durchgeführt werden.
Introduction

In recent years, there has been a rapid development in the surgery for rectal cancer. Low anterior resection is more commonly performed for the treatment of middle and lower rectal cancer. Abdominoperineal resection, the previous gold standard in the treatment of rectal cancer, has been regarded as unnecessary in most patients, and more patients can now be treated with sphincter-saving surgery. Total mesorectal excision (TME) has been accepted as the standard method for rectal surgery because it reduces the local recurrence rate, increases the survival rate, and shows better functional results. After laparoscopic surgery was adopted, it has been showing promising results. However, neither laparoscopic nor open surgery is completely safe from the risk of anastomotic leakage.

Actually, anastomotic leakage continues to be the most frustrating and feared complication of colorectal surgery, leading to significant morbidity, fistulas, peritonitis and sepsis, increased mortality, and prolonged hospital stay [1]. It may also affect the patients’ postoperative quality of life and causes substantial extra cost. Conversely, there could be an increased risk of anastomotic dehiscence associated with TME as it potentially endangers the blood supply of the rectal stump [2]. Anastomotic leakage is reported at a rate of 2–20% and is usually higher than 10% [3–11]. A low level of anastomosis and male gender is usually regarded as the significant factor that increases the rate of anastomotic leakage [12]. The postoperative mortality associated with anastomotic complications varies between 6 and 22% [12]. Therefore, the creation of a diverting stoma for proximal fecal diversion has been suggested for patients undergoing low anterior resection. A stoma itself, however, has clinical disadvantages such as patient discomfort, the need for stoma closure surgery, and cost of stoma care aids. A study performed in Austria [13] showed the overall stoma closure-related mortality rate at 3% and a rate of stoma closure-related surgical complications of 20%. From the economic point of view, defunctioning stomas have a major effect on the overall cost of treatment [14].

Therefore, we investigated the usage of transanal tubes in patients who were at a high risk for postoperative anastomotic leakage. Only few studies on the safety or efficacy of such transanal tubes exist [15–18]. The aim of our study was to retrospectively assess the difference in the rate of symptomatic leakage and prove the efficacy of transanal tubes in patients after low anterior resection of the rectum.

Patients and Methods

Patients

This is a single-center, retrospective study. It includes the patients who underwent elective low anterior resection (laparoscopy-assisted or open) for rectal cancer between January 2008 and June 2013. Patients with abdominoperineal resection, partial and total pelvic exenteration, and those who underwent a protective defunctioning stoma procedure were excluded. Rectal cancer was confirmed preoperatively by colonoscopy and biopsy. The tumor located within 10 cm of the anal verge was the primary criterion. A total of 66 patients met these criteria.

Patients were divided into two groups, i.e. those with a transanal drainage tube (TT) and those without tube (nontransanal drainage tube (NTT)). Because of the price of NO COIL® (silicone tube; Sapi Med S.p.A., Alessandria, Italy), we used this transanal drainage only in patients with the highest risk of anastomotic leakage. The average ASA (American Society of Anesthesiologists) status of this group was 3, and the average distant margin of the tumor was 5 cm above the anal verge. Each patient of this group had either diabetes mellitus or atherosclerosis. They were also treated for hypertension (8%), Parkinson’s disease (1%), hepatopathy (2%), coagulation disorders (2%), etc. Two of them received neoadjuvant radiotherapy.

Surgical Procedure

According to the fast-track protocol, our patients do not receive any oral mechanical bowel preparation. Cefuroxime (Axeetine®) is given 30 min prior to the incision. A repeated dose of a prophylactic antibiotic is administered during operations lasting more than 2 h and then stopped within 24 h after the operation. The procedure is conducted in the lithotomy position and starts either with a midline incision or with the placement of four ports. Once the medial white line of Toldt of the sigmoid colon is identified, the incision is performed. The sigmoid colon is then mobilized by the medial-to-lateral approach in Toldt’s space. The inferior mesenteric artery is dissected (below the origin of the left colic artery, i.e. low tie). The inferior mesenteric vein is cut at the same level. The preparation of the sigmoid is completed and then the procedure is continued down to the pelvis along the anatomic space between the visceral and parietal endopelvic fascia. Ultrasonic devices are used for preparation. If necessary, the descending colon and splenic flexure are mobilized. The rectum is transected transversely using a stapler, ideally 2 cm distal to the inferior margin of the tumor. In the case of a laparoscopic approach, we perform a short midline incision to extract the specimen. The proximal colon is transected at a level of about 10–15 cm proximal to the upper edge of the tumor. An end-to-end colorectal or coloanal stapler anastomosis is performed. Anastomotic air tightness is tested by instillation of air. A drain is always placed beside the anastomosis. With high-risk patients, the drainage tube (NO COIL®) is gently inserted into the anus and fixated with a skin suture after the suture of abdominal wall incisions. In most cases, the tube is removed 5–6 days after surgery.

Definitions of Anastomotic Leakage

The suspicion was based on clinical symptoms, i.e. abdominal pain, abdominal distension, leukocytosis, CRP elevation, fever; emission of gas, pus, or feces via the drains, the laparotomy incision, or the vagina; peritonitis. We confirmed the suspicion of anastomotic leakage by computed tomography (CT). If the clinical examination was unambiguous, we verified an anastomotic leakage directly during relaparotomy.

Statistical Analysis

The data were evaluated using descriptive statistical methods. Statistical analyses were performed using the statistical software Six Sigma, version 7. Pearson’s chi-squared test was used for categorical variables. Continuous variables were compared using the Mann-Whitney U test. A value of p < 0.05 was considered statistically significant.

Results

In our study, 69 patients underwent anterior resection for low rectal cancer. Defunctioning stoma was indicated in 3 of
them, and those patients were excluded from the study. The characteristics of the remaining 66 patients are presented in Table 1. Age and sex did not differ significantly between the two groups.

The rate of postoperative anastomotic leakage was 9% in the NTT group and 0% in the TT group. The difference between the NTT and the TT group was found not to be statistically significant. All 5 patients with anastomotic dehiscence underwent surgery, and a diverting stoma was created in 4 cases. In 1 patient, the transanal tube was placed in the rectum and an abdominal drain was fixed to the anastomosis. One of these patients died (32 days after the operation from ischemic stroke). 2 other patients from the NTT group died from metabolic decompensation and pulmonary embolism. Another 10 patients from the NTT group had complications (cardiac decompensation 2×, atrial fibrillation 1×, pneumonia 2×, surgical site infections 5×, disorientation 1×, urinary tract infection 1×). No complications were observed in the TT group. This result, however, cannot be considered as statistically significant due to the limited number of patients in the TT group.

### Discussion

The introduction of TME surgery as a surgical technique of choice for rectal carcinoma has led to a decreased local recurrence of rectal carcinoma and to an improved oncologic outcome. Nevertheless, postoperative morbidity and early mortality after anterior resection of the rectum remain important issues, with symptomatic anastomotic leakage being the most feared complication.

The most important risk factor for leakage is the low anastomosis. Vignali et al. [19], for example, reported that anastomotic dehiscence occurred in 8% after stapling within 7 cm from the anal verge and in 1% after stapling higher than 7 cm (p < 0.001). Similar results were described by Pakkastie et al. [20] who also identified the divide between high and low anastomosis at 7 cm above the anal verge. The high leakage rate associated with low anastomosis is probably due to a combination of anatomical inaccessibility, suboptimal blood supply, tightly closed anal sphincter below a low anastomosis, and an infected hematoma that may discharge through the anastomosis. There are also other contributing factors such as male gender, preoperative steroid use, comorbidities, malnutrition, longer duration of the operation, contamination of the operative field, and preoperative radiation [1–3]. Some studies demonstrated a reduction in leakage rates in patients with diverting stoma; however, other studies revealed that the creation of an ileotransversostomy had no effect on leakage rates although it reduced the severity of consequences of an anastomotic leakage. In contrast, a defunctioning stoma means the risk of another operation, the probability of a permanent stoma (20–25%) [21, 22], a higher cost, and a lower quality of life. This is the reason why a few studies focus on the defunctioning transanal catheter which could play a role in decompression and drainage on the proximal side of the anastomosis and should decrease the incidence of leakage.

In our study, anastomotic leakage occurred in a total of 5 patients (7.6%), whereas none of the leaks occurred in the TT group. Despite the disadvantageous background in the TT group (a transanal stent was used by a surgeon in the most high-risk patients), these patients had no postoperative complications, and nobody died. Although not statistically significant, our results demonstrate that the use of a transanal tube contributed to a decrease in anastomotic leakage, in overall complications, and in the mortality rate after low rectal surgery. In the early postoperative period, the anal sphincter is under tight contraction and spasm due to factors such as pain, fear, inflammation, and trauma. The action mechanism of the transanal tube may result from a reduction in intraluminal pressure, reducing the risk of fecal extrusion through the staple line.

In Great Britain, where 76 patients were randomized into two groups, no difference was reported in the leakage rate (7% in the stoma group compared with 6% in the transanal stent group). The transanal stent was made of a radio-opaque soft silicone tube, 4 cm in length with funnel-shaped flanges [17]. General infectious complications were less frequent in the transanal stent group (17 vs. 35%; p = 0.029) [15]. In this study, 81 patients were included in the group with tube and 77 patients in the group without tube. The transanal catheter was made of an ordinary rubber drainage tube and had a relatively large diameter (26 French) [15].

An older but larger Chinese study dealing with risk factors of an anastomotic leak considered the transanal tube as a risk factor. In this series, 278 patients underwent defunctioning stoma or defunctioning transanal catheter placement, whereas 15 of them had the two procedures at the same time. In the remaining 244 patients, no protective measures were taken. The leakage rate of the transanal catheter placement group was significantly higher than that of the noncatheter group (15.1 vs. 4.9%; p = 0.008). The authors do not mention the type of catheter, while the study is large but retrospective and the groups are not clearly defined [3].

### Table 1. Comparison of the TT and NTT groups

|               | TT group (n = 9) | NTT group (n = 57) | p value |
|---------------|-----------------|-------------------|---------|
| Mean age, years | 65              | 64                | 0.6     |
| Gender (female: male ratio) | 3/6             | 28/29             | 0.4     |
| Anastomotic leak | 0               | 5 (9%)            | 0.4     |
| Complications | 0               | 13 (23%)          | 0.1     |
| Death         | 0               | 3 (5%)            | 0.5     |

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The third study of the same Chinese origin is more optimistic. The authors randomized 398 patients into groups with and without transanal stent. Patients with a transanal tube (200 patients) had leakage in 4.0% and those without a tube (198 patients) in 9.6% (p = 0.026). A shorter length of hospital stay was also associated with the use of a transanal tube [16].

A Japanese publication claims that the placement of a transanal tube is effective in decreasing the rate of anastomotic leakage. Patients who received a transanal tube (36 patients) had a lower risk of anastomotic leakage compared to the control group, which did not receive a transanal tube or diverting stoma (140 patients; 1 (2.7%) vs. 22 (16%); p = 0.04). They used a 24 French Ficon tube (Fuji Systems, Tokyo, Japan) which was inserted per anus, and the tip was placed approximately 3–5 cm from the oral side of the anastomosis [4].

A randomized multicenter trial with 194 patients was carried out in Denmark. The surgeon decided to use protective ileostomy, and after completion of the operation the patients were randomized into two groups, i.e. with and without a transanal tube (transanal silicone stent [17]). The analysis showed no significant protective effect of the catheter on forming localized erosion of the rectal wall or anastomosis. The localized erosion resulted in ischemia and perforation [23].

In Germany, Sterk et al. [24] used a 40-cm long transanal rubber drain in 50 patients. 10% of the patients developed an anastomotic leakage, 4% with a clinically evident anastomotic leakage and 6% with an asymptomatic anastomotic leakage detected by CT. The authors consider the transanal drain as at least equivalent to a conventional colostomy in terms of reducing symptomatic anastomotic leakage [24].

An Italian study that used the same transanal tube as we did in our study (NO COIL) considers this catheter as an alternative option to diverting stoma. First, with a transanal tube, they measured the intraluminal rectal pressure which was strongly reduced from 14 to 5 mm Hg (p < 0.01). Then they performed surgery on 184 patients with just the transanal stent, i.e. no stoma was created. The leakage rate reported by the authors was 4.8%. They did not have any control group [25].

Publications concerning this topic are summarized in table 2.

**Table 2. Studies on transanal tubes aimed at preventing anastomotic leakage**

| Study [Ref]    | Year | TT group | Controls | Type of study                  | Anastomotic leak, % | p value |
|----------------|------|----------|----------|--------------------------------|---------------------|---------|
| Amin et al. [17] | 2003 | 41 (– stoma) | 35 (+ stoma) | prospective randomized | 6 | 7 | ns |
| Zhao et al. [15] | 2013 | 81 (– stoma) | 77 (– stoma) | prospective nonrandomized | 3 | 8 | ns |
| Cong et al. [3] | 2009 | 62 (± stoma) | 676 (± stoma) | retrospective nonrandomized | 15 | 4 | 0.000 |
| Xiao et al. [16] | 2011 | 200 (– stoma) | 198 (– stoma) | prospective randomized | 4 | 10 | 0.026 |
| Nishigori et al. [4] | 2014 | 36 (– stoma) | 140 (– stoma) | retrospective randomized | 3 | 16 | 0.04 |
| Bulow et al. [23] | 2006 | 98 (± stoma) | 96 (± stoma) | retrospective randomized | 17 | 8 | ns |
| Sterk et al. [24] | 2001 | 50 (– stoma) | 5 | | 4 |
| Montemurro et al. [25] | 2012 | 184 (– stoma) | 5 | | 5 |

ns = Not significant.

**Conclusions**

We are well aware of the fact that our groups are small and that the results are not statistically significant. Nevertheless, they are quite optimistic, demonstrating that the use of a transanal tube could contribute to the decreasing rate of anastomotic leakage after low rectal surgery, especially when the transanal tube is used in the most high-risk patients. Based on a search of the literature, although there is currently not much high-level evidence, we believe that the use of the transanal tube in anterior resection for rectal cancer could be a simple and effective method of reducing the occurrence of anastomotic leakage. Larger randomized prospective studies should be performed in the future.

**Disclosure Statement**

No conflict of interest.
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