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ORIGINAL ARTICLE

The transverse coloplasty pouch is technically easy and safe and improves functional outcomes after low rectal cancer resection—a single center experience with 397 patients

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Abstract

Background Following resection for low rectal cancer, numerous patients suffer from frequent bowel movements, fecal urgency, and incontinence. Although there is good evidence that colonic J-pouch reconstruction, side-to-end anastomosis, or a transverse coloplasty pouch (TCP) improves functional outcome, many surgeons still prefer straight coloanal anastomosis because it is technically easier and lacks the risk of pouch-associated complications. The present single-center study aimed to evaluate the practicability of TCPs in routine clinical practice as well as pouch-related complications.

Method All consecutive patients who underwent low anterior rectal resection with restoration of bowel continuity for cancer during the period September 2008 to June 2018 were included. A TCP in combination with a diverting ileostomy was defined as the hospital standard. The feasibility and safety of TCPs were assessed in a retrospective single-center study.

Results A total of 397 patients were included in the study. A total of 328/397 patients underwent TCP construction (82.6%). Two pouch-related surgical complications occurred (0.6%); one case of pouch-related stenosis and one case of sutural insufficiency. Overall, leakage of the coloanal anastomosis was reported in 14.1% of patients with a TCP and in 18.8% of patients without a pouch (p=0.252). Diverting ileostomy was applied in 378/397 patients (95.2%). The 30-day mortality was 0.25%.

Conclusion The present study is by far the largest single-center experience with TCP construction for low rectal cancer resection. The study shows that a TCP is technically applicable in the vast majority of cases (82.6%). Pouch-associated surgical complications are sporadic events. In our opinion, the TCP can be considered an alternative to J-pouch construction after low anterior rectal resection.

Keywords Transverse coloplasty pouch · Rectal cancer · Low anterior resection · Reconstruction techniques · Surgical complications

Introduction

Low anterior rectal resection with total mesorectal excision (TME) [1], performed in a multidisciplinary setting, is the current standard treatment for rectal cancer [2, 3]. TME has been shown to significantly improve survival and reduce local recurrence [4, 5]. With advancements in oncologic treatment, postoperative quality of life is becoming increasingly important. Particularly, when a low colorectal anastomosis of less than 4 cm from the anal verge is required for reconstruction, most patients will experience a constellation of symptoms, including fecal urgency, frequent bowel movements, bowel fragmentation, and incontinence [6], which is in summary named low anterior resection syndrome (LARS) [7]. From a pragmatic point of view, LARS was recently defined as disordered bowel function after rectal resection leading to a detriment in quality of life [8]. There is evidence that the symptoms of LARS are aggravated by neoadjuvant chemoradiation [9].

Surgical construction of a colonic reservoir has been proposed to improve postoperative bowel function. One option to

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reconstitute a colonic reservoir involves the construction of a J-pouch analogous to the ileal J-pouch after proctocolectomy [10, 11]. Furthermore, side-to-end coloanal anastomosis (CAA) has been suggested to reduce LARS [12, 13]. Another option to reduce LARS symptoms after rectal resection is the so-called transverse coloplasty pouch (TCP) [14]. In a recent meta-analysis comprising data from 1636 patients, colonic J-pouches, side-to-end CAA, and TCPs were found to have a better functional outcome than straight CAA [15]. Likewise, in a Cochrane review from 2008 that included 16 randomized controlled trials [16], a colonic J-pouch was reported to be superior to straight CAA up to 18 months after gastrointestinal continuity was re-established. Considering bowel frequency, urgency, fecal incontinence, and the use of antidiarrheal medication, a TCP and side-to-end CAA were shown to have similar bowel function outcomes compared to colonic J-pouch reconstruction [16].

Overall, there are valid data available indicating that all reconstruction techniques mentioned above lead to a better functional outcome than straight CAA. One challenge in rectal cancer surgery is to avoid straight CAA for the reconstruction of bowel continuity. In clinical practice, every rectal surgeon is occasionally faced with technical difficulties arising from anatomical limitations such as a thick mesocolon or a narrow pelvis, particularly in obese and male patients [14, 15]. Likewise, a long anal canal with a prominent sphincter may turn pouch construction techniques into technically challenging procedures [17]. Due to these technical limitations, the involved surgeons should have different techniques of reconstruction in their armamentarium in order not to be forced to recourse to straight CAA instead of creating a colonic pouch [18].

In particular, J-pouch construction can be technically demanding even in well-experienced hands. Under these circumstances, a TCP may present an acceptable alternative with comparable clinical outcomes [14, 15, 19]. The TCP is technically simple, and usually, the length of the remaining colon after pouch formation is sufficient to reach the pelvic floor for a tension-free anastomosis down to the dentate line, as only the anterior wall of the anastomosed colon is shortened by the formation of the transverse suture [17].

Nevertheless, some rectal surgeons are wary of installing a TCP due to a presumed higher anastomotic leakage rate or pouch-associated surgical complications. In the past, Ho et al. reported that postoperative complications and the anastomotic leak rate were significantly higher in patients who received TCP than in patients who received J-pouch reconstruction [20].

The present single-center study aimed to evaluate the practicability of TCP in daily clinical routine as well as pouch-related complications and anastomotic leakage rates in a large cohort of patients.

Methods

Patients

Consecutive patients with histologically proven rectal cancer who underwent surgical resection at the Department of General, Visceral, and Transplantation Surgery of the Klinikum Stuttgart, Germany, between September 2008 and June 2018 were retrospectively identified from an electronic database. Included were all patients in whom a low anterior rectal resection was performed with total mesorectal excision (TME) and restoration of bowel continuity. Patients who underwent Hartmann´s procedure or abdominoperineal resection (APR) were excluded. Rectal cancer was outlined as a tumor with its lower edge within 15 cm from the anal verge. All patients underwent preoperative endosonography, rigid rectoscopy by the operating surgeon, abdominal and pelvic computed tomography scans (CT), and/or magnetic resonance imaging (MRI) for tumor staging. Clinicopathologic features were assessed with a special focus on surgical complications and postoperative outcomes. Anastomotic leakage was diagnosed when anastomotic dehiscence with pelvic sepsis, transanal discharge of pus, or a fistula arising at the area of the anastomosis was present during follow-up. The definitions also included anastomotic leaks detected by contrast enema before closure of the ileostomy. For statistical evaluation, anastomotic leakage was further classified according to the International Study Group of Rectal Cancer [21].

Surgical procedure and pathologic assessment

All operations were performed or decisively guided by a certified colorectal surgeon. A low rectal anterior resection was conducted according to current guidelines. The left colon was mobilized proximal to the left flexure. High ligation of the inferior mesenteric vessels was performed as a clinical standard. Subsequently, the distal rectum was dissected down to the anorectal junction at the pelvis at the level of the pelvic floor according to Heald [1]. Thus, the level of anastomosis was determined in most patients between 3 and 6 cm from the anal verge. For the sake of convenience, expression coloanal anastomosis (CAA) was used for coloanal and low colorectal anastomosis.

For creation of the TCP, a longitudinal incision of approximately 7–8 cm was made along the antimesenteric side of the descending colon, starting from 4 cm above the distal cut end (Fig. 1). The incision was then closed transversely with a double layer of mucosal and seromuscular sutures with polydioxanone (PDS) threads 5–0 or by a linear stapler combined with an additional PDS overstitching (Fig. 2). Subsequently, the TCP was anastomosed to the stapled anorectal stump by the double stapling technique with the coloplasty facing anteriorly. The anastomosis and TCP suture

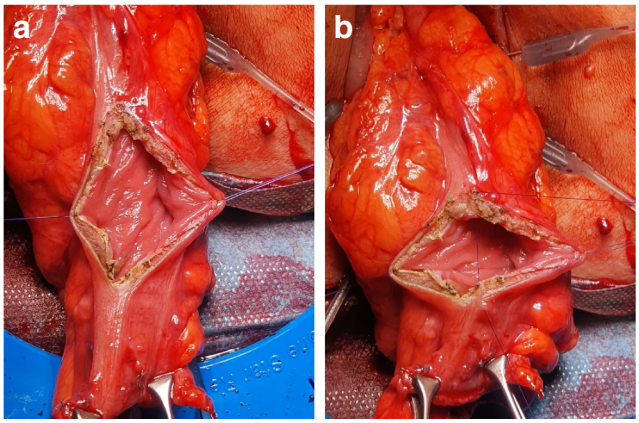

Fig. 1 Construction of the transverse coloplasty pouch (TCP). For creation of the TCP, a longitudinal incision of approximately 7–8 cm was made along the antimesenteric side of the descending colon, starting from 4 cm above the distal cut end (**a**). Subsequently, the cut edges were approximated transversely (**b**)

were tested by air anal air insufflation on a routine basis. Finally, a diverting loop ileostomy was applied routinely in the majority of patients. After an unremarkable contrast conformation of the anastomosis and pouch integrity, the ileostomy was intended to be closed after 6 weeks.

Surgical specimens were evaluated by an experienced team of colorectal pathologists. After macroscopic assessment, the specimen was serially sliced into 0.5 to 1.0-μm thick sections and embedded in paraffin [22]. The TNM stage was determined using the current version of the Union for International Cancer Control (UICC) staging system. The quality of TME resection was graded according to the MERCURY classification [23].

Statistical methods

Statistical analysis was performed using SAS® version 9.1 for Windows® (SAS Institute, Cary, North Carolina, USA). All consecutive patient data were transferred to an Excel file and included in the analysis. Pre- and postoperative data were collected in a standardized prospective fashion. Postoperative complications and in-hospital deaths were recorded.

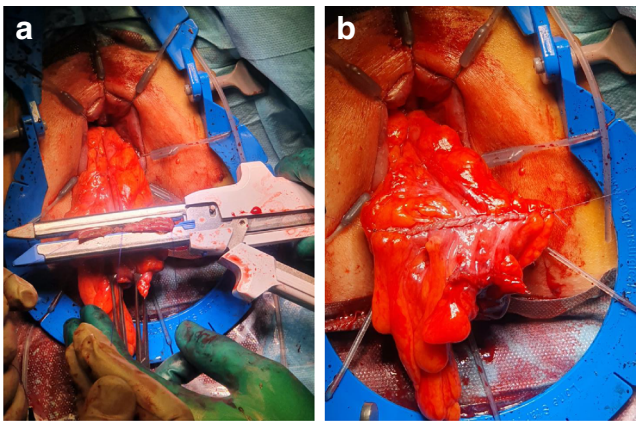

Fig. 2 Construction of the transverse coloplasty pouch (TCP). The incision was then closed transversely with a linear stapler (**a**) combined with additional PDS overstitching (**b**)

Results

Patient demographics

In our institution, three hundred ninety-seven consecutive patients underwent low anterior rectal resection with total mesorectal excision (TME) for histologically proven rectal cancer with immediate restoration of bowel continuity between September 2008 and June 2018 (Table 1). The study cohort included 264 men (66.5%) and 133 women (33.5%). The median age of all patients was 67 years (range: 27–91 years). The mean body mass index of all patients was 25.8 (range: 15.6–43.9), with a body weight ranging from 40 to 130 kg (mean: 76.4 kg). Detailed clinical characteristics and operative risk stratification according to the American Society of Anesthesiologists (ASA) classification of all patients are listed in Table 1.

In line with a preoperative interdisciplinary tumor board decision, 154/397 patients received neoadjuvant therapy (38.8%). According to the department standard, the majority of patients received a combined long-course chemoradiation (CRT) regimen with a total of 50 Gray in 25 fractures and 5-fluorouracil as accompanying chemotherapy.

Surgical procedure

All patients underwent low anterior rectal resection with total mesorectal excision (LAR/TME) by certified colorectal surgeons. Each patient received perioperative single-shot antibiosis. Overall, in 328/397 patients (82.6%), a TCP was constructed as described above. During the anal air insufflation test of the coloanal anastomosis, noticeable air leakage was reported in 8/397 cases (2.0%). Under these circumstances, the suture was overstitched with PDS. In 33/397 cases (8.3%), the coloanal anastomosis was not stapled but transanally pulled-through and hand-sewed. The median operation time was 179 min, with a range from 77 to 545 min. A diverting ileostomy was applied in 378/397 cases (95.2%) either before or during rectal resection. In selected patients without relevant comorbidities and a colorectal anastomosis above 6 cm from the anal verge, the surgeon decided to dispense with a perioperative ileostomy.

The hospital standard rectal reservoir reconstruction was a transverse coloplasty pouch. However, in 69/397 patients (17.4%), no TCP was constructed. The detailed reasons for not creating a TCP are listed in Table 2. In case of a relatively high anastomosis at the level of the lower rectum, the decision

Table 1 Clinical and histopathologic characteristics (n=397 patients)

Feature		N	%
Age (years)	Median: 67		
	Range: 27–91		
Sex	Male	264	66.5
	Female	133	33.5
Body mass index (kg/m^2)	Mean: 25.8		
	Range: 15.6–43.9		
	≤18.5	11	2.8
	>18.5 and ≤25.0	162	40.8
	>25.0 and ≤30.0	163	41.1
	>30.0 and ≤35.0	49	12.3
	>35.0	12	3.0
Body weight (kg)	Mean: 76.4		
	Range: 40–130		
Comorbidity	Arterial hypertension	200	50.4
	Diabetes mellitus type II	71	17.9
	Renal insufficiency	25	6.3
	Cardiovascular disease with therapeutic anticoagulation	41	10.3
	Nicotine	60	15.1
	Alcohol	76	19.1
ASA risk classification	I	36	9.1
	II	268	67.5
	III	91	22.9
	IV	2	0.5
Histopathologic	UICC 0	24	6.0
UICC Staging	UICC I	136	34.3
	UICC II	70	17.6
	UICC III	100	25.2
	UICC IV	63	15.9
	Not determined	4	1.0

was up to the surgeon whether to create a pouch or not. In 41 of these patients, the surgeon decided to dispense with a rectal pouch construction.

In addition to this condition, in 13/69 patients (18.9%), a short mesenterium of the descending colon was the reason for not creating a pouch. In three patients, the surgeon reported that the pelvis was too narrow to create a coloplasty (4.3%). All three patients were males.

In two patients, distinct obesity was the reason for not creating a TCP. Both patients were males with BMIs of 30.5 and 36.9 kg/m^2, respectively. Overall, 61 patients with a BMI >30.0 underwent rectal resection. Among these patients, TCP was created in 50 cases (82.0%). Thus, in the majority of obese patients with a BMI >30.0 kg/m^2, a TCP construction was applicable.

Among 69 patients who did not receive a TCP, four patients underwent alternative reconstruction techniques. Two patients had a side-to-end CAA, and one patient received a J-pouch. One patient had a known status post sigmoidectomy. In this case, resection of the remnant colon was performed, and bowel continuity was reconstructed by ileorectostomy. One patient without pouch construction had Crohn´s disease. In this case, the surgeon decided against a pouch to prevent the potential occurrence of an enteric fistula. Another patient also

Table 2 Reasons for not creating a coloplasty pouch (n=69)

Reason		N	%
Anatomical reasons	Relatively high anastomosis	41	59.4
	Short mesocolon	13	18.9
	Narrow pelvis	3	4.3
	Obesity	2	2.9
Others	Alternative rectal reconstructions	4	5.8
	Palliative care situation	2	2.9
	Other medical reasons	2	2.9
	Not determined	2	2.9

showed a status post sigmoid resection. In this case, the descending colon was already dilated up to more than 6 cm in diameter. Subsequently, the surgeon declined to construct a rectal pouch. Two patients presented advanced oncologic disease with multiple metastases. Due to the palliative care situation, the surgeon decided against pouch creation.

Pathologic characteristics

The results of the pathologic findings are listed in Table 1. In summary, 56 tumors were stage (y)pT1, 127 were stage (y)pT2, and 170 were stage (y)pT3. Fifteen patients had (y)pT4 tumors. In 28 patients who underwent preoperative chemoradiotherapy, no tumor was detectable in final histopathology (ypT0). One surgical specimen was lost during workup. Overall, 148/397 patients had a positive mesorectal lymph node status (37.3%). According to the MERCURY classification, the majority of resected specimens were rated as grade 1 (91.2%), 31 were rated as grade 2 (7.8%), and 4 specimens were classified as grade 3 (1.0%). Overall, 11/397 patients were histologically revealed to have a positive circumferential resection margin (2.8%).

Postoperative outcomes

Overall, pouch-related surgical complications were seen in two patients (0.6%). A 44-year-old female patient developed pouch-associated stenosis 2 months after rectal resection with TCP reconstruction and therefore underwent dilation with Hegar's dilators. Another patient developed suture insufficiency of the pouch. This patient was a 62-year-old male with primary hepatic metastasis. The coloanal anastomosis was located 4 cm from the anal verge.

To discriminate between suture insufficiency of the pouch and anastomotic leakage of the colorectal anastomosis, we performed rigid rectoscopy and radiological investigation of the anastomosis by applying contrast medium rectally. Insufficiency of the anorectal anastomosis as defined above was observed in 56/397 cases (14.1%). While the insufficiency rate among patients with TCP was 13.1% (43/328), the insufficiency rate of the CAA among patients without TCP was 18.8% (13/69). Among all 56 patients with anastomotic insufficiency, four did not need any further treatment (7.1%). In these cases, the diagnosis of anastomotic leakage was exclusively diagnosed by radiological means. In eleven cases, antibiotics were administered during the postoperative clinical course without the necessity of a more invasive treatment (19.6%). Seven patients received a radiologic intervention including external abscess drainage (12.5%). Twenty patients were rectally explored in the operation theater under general anesthesia (35.7%). When indicated, transanal lavage was administered, and a rectal endosponge was placed (n=12). Overall, 14 patients were surgically reexplored (25.0%), either laparoscopically or via abdominal laparotomy. In summary, according to the classification of the International Study Group of Rectal Cancer [21], 42 patients (75.0%) had grade A or B anastomotic leakage, including antibiotic therapy, radiologic placement of a pelvic drain, and/or transanal lavage. A total of 14 patients had grade C leakage and needed abdominal surgical reexploration (25.0%).

The median postoperative stay was 13 days (range: 6–96 days). Death before hospital discharge occurred in one patient as a result of septic multiorgan failure. Thus, the overall 30-day and in-hospital mortality was 0.25% (Table 3).

Discussion

Low anterior resection with total mesorectal excision is the standard surgical therapy for rectal cancer. Up to 80% of patients undergoing resection and reconstruction with a low anastomosis postoperatively suffer from LARS, a symptom complex including frequent bowel movements, fragmental stool patterns, fecal urgency, and incontinence [24]. The etiology of LARS is without doubt multifactorial. On the one hand, there are potential injuries of the sphincter or the lumbar plexus due to surgery and postoperative anatomy-caused alterations in anorectal physiology. Both aspects are aggravated by neoadjuvant chemoradiation and in cases of associated anastomotic sepsis [9, 24].

The symptoms of LARS may be obviated at least in part by the construction of a neorectal reservoir or by applying an interruption of the peristaltic wave [24, 25]. Today, there is good clinical evidence that pouch reconstruction and side-to-end anastomosis lead to a better functional outcome than straight anastomosis [15, 26]. Different surgical techniques and colonic pouch constructions are available and established in clinical practice.

It is well proven that colonic J-pouches may provide functional benefits over straight CAAs without increasing postoperative complications [27]. However, J-pouch construction is surgically demanding and not always feasible. In particular, it requires enough space in the pelvis and enough length of the remaining colon to create a tension-free anastomosis. In the case of a narrow pelvis in combination with a thick mesocolon and a long anal canal, this technique can be extremely challenging or even impracticable [14, 17, 27]. In the study of Fazio, in 96 of 364 patients, the formation of a J-pouch was impossible. In this study, this feasibility was not differentiated between the sexes, but it can be assumed that most of the problems arose in male patients.

There are data available that side-to-end CAA may be a viable alternative to colonic J-pouch construction in terms of morbidity and functional outcomes [15, 27, 28]. .Regarding functional outcome, side-to-end CAA does not seem to be equivalent to colonic J-pouch construction, but given that

Table 3 Postoperative outcomes

Feature		*N*	%
Pouch-associated complications	TCP-related stenosis	1/328	0.3
	TCP-related suture insufficiency	1/328	0.3
Anastomotic leakage	Patients with TCP	43/328	13.1
	Patients without TCP	13/69	18.8
Mortality	30-day mortality	1/397	0.25

side-to-end anastomosis was technically less demanding, the authors justified this as an alternative to J-pouch reconstruction in sphincter-saving surgery [16, 28].

The TCP is technically simple and, for the most part, can be performed even in the presence of a short or thick mesocolon or narrow male pelvis [18, 29]. In the present study, we found that a TCP was technically achievable in the vast majority of patients (82.6%). This is in accordance with the statement of Rubin et al. that a TCP can be created in over 95% of patients [27]. A TCP seems to be especially applicable when colonic J-pouch anastomosis is technically impracticable [17, 30].

There are few technical and anatomical limitations in creating a TCP. Obesity was a limitation in the present study that prevented the creation of a pouch in two patients. Nevertheless, in 50/61 patients with BMI>30 kg/m^2 (82.0%), a TCP was feasible without problems. We conclude that in the majority of obese patients, TCP construction is applicable. In only three cases of the present series, the reported reason for not creating a pouch was a narrow pelvis. We believe that for stringent rectal surgeons, a TCP is almost always applicable, even in cases of a narrow pelvis or a thick mesocolon.

There have been several studies comparing TCP to J-pouch construction. The TCP has a significantly smaller capacity than the J-pouch. Nevertheless, TCPs have been shown to be effective in preventing LARS [14, 15]. In our opinion, the fundamental functionality of a TCP is based more on its interruption of the colonic peristaltic wave than on its reservoir function. In a randomized multicenter trial, Fazio et al. found that, compared to patients receiving straight CAA or coloplasty, patients with a colonic J-pouch had a significantly lower stool frequency per day and significantly better results concerning the Fecal Incontinence Severity Index (FISI). The authors concluded that the colonic J-pouch offered advantages in function over straight CAA and coloplasty and therefore recommended a J-pouch for all patients in whom pouch construction was practicable [31]. However, as the authors themselves stated, the study arm comparing coloplasty versus straight anastomosis might have been underpowered. In a recent meta-analysis, the results of this trial were not included because the number of patients evaluated at different time points was unclear and because the measures of variability presented in the report were not suitable for meta-analysis [15]. Although the results of the study of Fazio et al. were controversial, this study, together with the fear of pouch-related surgical complications, has led to a certain unpopularity of TCP.

In contrast to this trial, a more recent study by Biondo et al. showed similar stool frequency and functional parameters up to 3 years after stoma closure, except for nocturnal bowel movement, which was less frequent in the TCP group [32]. Likewise, Fürst et al. found similar functional results in the coloplasty group compared to the J-pouch group. In this study, neorectal sensitivity was even increased in the coloplasty group [33]. Likewise, the meta-analysis of Hüttner et al., which included 1636 patients with rectal cancer, and the meta-analysis of Liao et al., which included 648 patients, showed similar results for the two intervention groups (receiving a TCP versus a colonic J-pouch) at different time points [15, 34].

Overall, it is possible that the J-pouch might show slight advantages, particularly in short-term functional outcomes, compared to the TCP [31, 35]. However, according to current data, in the long term, this advantage is not clinically relevant [15, 30, 35].

Anastomotic leakage is an unsolved problem after low anterior rectal resection, which is reflected by the fact that the routine application of a diverting stoma is the worldwide well accepted standard. Although the reported overall leakage rate of 14.1% of colorectal anastomoses in this study is in line with the current literature [36], the number seems to be relatively high. In our opinion, the reason for this lies in the established stringent and early complication management in the department. To prevent a severe and prolonged postoperative course, a clinical or radiologic assessment of the anastomosis was performed whenever the patient had conspicuous clinical signs or unexplained elevated levels of inflammatory parameters in blood. Using this approach, on the one hand, a number of otherwise clinically inapparent leakages were detected (grade A or B fistulas). On the other hand, if necessary, an intervention was performed early, and the rate of failure to rescue was minimized [37]. Subsequently, the in-hospital mortality rate of our series (0.25%) was far below the average of nationwide reported series, which ranged from 3.9 to 7.5% [38, 39]. We believe that mortality rates below 1% somehow reflect our engagement using early and sophisticated

complication management. However, of utmost importance in this discussion is the fact that we had only two serious pouch-related complications in a series of 328 TCPs. In one patient, during construction of the transverse suture with a stapler, the posterior wall of the neorectum was partially captured, which led to stenosis and the need for repetitive dilatation. In another patient, insufficiency of the transverse suture occurred, which healed under conservative treatment.

With regard to surgical outcomes such as mortality, reoperations, anastomotic leakage, and stricture, no significant differences were seen between patients with and without TCP. This is in accordance with the findings of Hüttner et al. [15] We therefore conclude that the construction of a TCP does not increase the risk of anastomotic leakage or the overall complication rate.

Outcomes and limitations of this study

Reviewing the current literature, we found that the J-pouch is probably the best studied surgical technique to prevent LARS. However, this technique requires specific anatomic preconditions. In many cases, the operating surgeon is limited by a narrow pelvis, possibly in combination with a thick mesocolon. Since straight CAA should be omitted due to a worse clinical outcome, we believe that a TCP offers an adequate alternative with comparable functional outcomes that can be performed in daily routine.

In the present study, we showed that TCPs can be created in the majority of patients (82.6%) with only very rare complications (0.6%). A shortcoming of the present study is the missing control group and its observational fashion. However, the aim of this investigation was to evaluate the clinical practicability of the TCP technique and complications in a large series of experienced tertiary rectal centers. The present study clearly showed that it is feasible to construct a TCP in a high percentage of patients without additional pouch-related complications.

Conclusion

LARS significantly impairs quality of life after low anterior rectal resection, with this effect lasting beyond the first year after surgery. In addition to complete removal of the tumor, care should be taken to reduce LARS using the optimal surgical technique. Colonic J-pouch reconstruction has reliably been shown to be effective, but in a relevant proportion of patients, especially in men, it is not feasible to bring the pouch down to the pelvis.

The present study is by far the largest single-center experience with TCPs. Analysis of the data proves that construction of a TCP is applicable in the vast majority of patients (82.6%). In experienced hands, TCP creation is a safe procedure, with only two pouch-related complications found in our series of 328 patients (0.6%).

In our opinion, TCP can therefore be considered an additional standard reconstruction technique after low anterior rectal resection.

Authors' contributions RH, CK, and SF were responsible for data collection. SF, RH, and CK analyzed and interpreted the patient data. SF, RH, and JK were major contributors in writing the manuscript, and KF, HK, and AS contributed significantly by proofreading. All authors have read and approved the final manuscript.

Data Availability The datasets used and analyzed during the current study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval and consent to participate The study was designed as an observational retrospective analysis. The study did not influence the therapy in any way.

Consent for publication The present manuscript does not contain any individual person's data in any form.

Competing interests The authors declare no competing interests.

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