

Randomized Comparison of Straight and Colonic J Pouch Anastomosis After Low Anterior Resection

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Objective

The authors compared clinical bowel function and complications of a low anterior resection with either a straight or colonic J pouch anastomosis.

Summary Background Data

Urgency and frequent bowel movements after rectal resection with a low anastomosis have been related to the loss of rectal reservoir function. Reconstruction with a colonic J pouch possibly can obviate some of this dysfunction. Earlier reports have been favorable, but they must be verified in randomized trials.

Method

One hundred patients with rectal cancer in whom a sphincter-saving procedure was appropriate were randomized to reconstruction with either a straight or a colonic J pouch anastomosis.

Results

The incidence of symptomatic anastomotic leakage was lower in the pouch group (2% vs. 15%, $p = 0.03$). Eighty-nine patients could be evaluated after 1 year. The pouch patients had significantly fewer bowel movements per 24 hours, and less nocturnal evacuations, urgency, and incontinence. Overall well-being owing to the bowel function was rated significantly higher by the pouch patients.

Conclusion

Reconstruction with a colonic J pouch was associated with a lower incidence of anastomotic leakage and better clinical bowel function when compared with the traditional straight anastomosis. Functional superiority was especially evident during the first 2 months.

There has been a marked decline of abdominoperineal resections since the rationale for a sphincter preservation has been widely applied.¹ Consequently, most patients with rectal cancer can be offered a restorative resection. Total mesorectal excision currently is widely accepted as a standard procedure to obtain local radicality, requiring that regardless of the level of the tumor, the rectum be transected at the levator plane and the anastomosis be constructed to the anal canal or distal most rectum.² After such a low anastomosis, patients usually experience a varying degree of poor bowel function that may persist even after a year of adaptation. Urgency, frequent bowel movements, and occasional incontinence can be related to the loss of rectal reservoir function and a reduced resting anal pressure, the "anterior resection syndrome."³⁻⁵ Improvement of these symptoms is associated with an increase in "neorectal" capacity.⁶

To compensate for the loss of the rectal reservoir, the use of a colonic J-shaped pouch was first described in 1986.^{7,8} Although the promising results with a colonic pouch have been reproduced,^{9,10} the benefit and safety of this procedure have to be verified in randomized trials. Therefore, the aim of this randomized study was to compare reconstruction with the traditional straight anastomosis and the colonic J pouch anastomosis.

PATIENTS AND METHODS

Four centers, specialized in colorectal surgery, participated in the trial, which was approved by the ethical committees. The inclusion criteria were: 1) rectal adenocarcinoma with a lower margin not more than 12 cm from the anal verge; 2) sphincter-saving resection deemed appropriate on both oncologic and functional grounds; and 3) a curative operation.

Randomization

After informed consent, patients were stratified for center and gender and were randomly allocated to reconstruction with either a straight or a colonic J pouch anas-

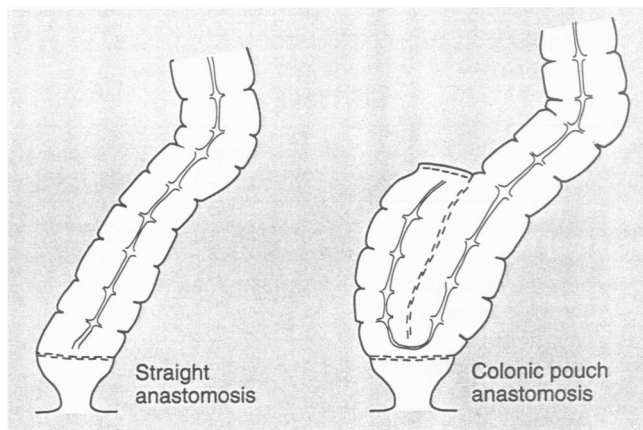


Figure 1. The patients were randomly allocated to reconstruction with either a straight or a colonic J pouch anastomosis.

tomosis (Fig. 1). Randomization was done preoperatively in blocks of four with sealed envelopes in numerical order. The size of the block was unknown by the investigators. A computer was used as the source of random numbers. A sample size of 45 patients in each group was estimated with 80% probability and at the 5% significance level to reduce the proportion of patients with three or more bowel movements per 24 hours from 67% to 40% within 1 year postoperatively. This calculation was based on the original result of Lazorthes.⁷

Patients

One hundred patients were recruited during 3 years until December 1993. Two patients were withdrawn because of inadequate bowel length for pouch construction and one other patient withdrew at her own request after randomization. Thus, 97 patients had surgery within the trial (straight, $n = 52$; pouch, $n = 45$). All patients had adenocarcinoma. Two patients with Dukes' stage D had a simultaneous wedge resection of a solitary liver metastasis. The height of the tumor and the anastomosis was determined with a rigid rectoscope and given in centimeters from the anal verge. Table 1 shows patient characteristics. Preoperative radiotherapy or postoperative chemotherapy was given to a minority of the patients. The use of radiotherapy or chemotherapy was decided according to the routine at each participating center and not governed by the criteria of the trial. None of the variables in Table 1 differed significantly between the two groups. One patient with a straight anastomosis received postoperative radiotherapy (46 Gy during 4 weeks). Ninety-three patients could be evaluated after 2 months, and 89 patients could be evaluated after 1 year. Table 2 shows patient cohorts and withdrawals.

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Table 1. CHARACTERISTICS OF THE 97 PATIENTS WITH SURGERY WITHIN THE TRIAL

	Straight (n = 52)	Pouch (n = 45)
Women:men	25:27	20:25
Median age (range, yrs)	69 (29–82)	67 (40–86)
Tumor stage (Dukes' stage A:B:C:D)	13:21:17:1	8:19:17:1
Median tumor height above anal verge (range, cm)	7 (3.5–12)	7 (4–12)
Median anastomotic height above anal verge (range, cm)	4 (2–6)	3.5 (2–5.5)
Sigmoid (instead of descending) colon for reconstruction	22 (42%)	19 (42%)
Temporary stoma	31 (59%)	32 (71%)
Preoperative radiotherapy (25 Gy 1 wk before surgery)	14 (27%)	7 (16%)
Postoperative chemotherapy	3 (6%)	4 (8%)

Operative Technique

A standardized rectal dissection, including total mesorectal excision, was done in all patients. The level of transection of the distal bowel was determined by the mesorectal excision rather than by the height of the tumor, thus leading to an anastomosis on the top of the anal canal in most of the patients. The use of a temporary

Table 2. STUDY COHORT

	Straight	Pouch	Total
Randomized	52	48	100
Inadequate bowel length for pouch construction		2	
Withdrawn at own request after randomization		1	
Surgery within the trial	52	45	97
Postoperative death from hemorrhage and multiorgan failure		1	
Death from rapid spread of the cancer	1	1	
Declined reversal of loop ileostomy (anastomotic leakage)	1		
Two months follow-up	50	43	93
Death from disseminated rectal cancer		1	
Permanent sigmoidostomy because of poor bowel function	1		
Follow-up not possible because of intercurrent disease	2		
One year follow-up	47	42	89

Table 3. INCONTINENCE SCORE SYSTEM*

	Gas	Liquids	Solids
Never	0	0	0
Less than once a week	1	4	5
More than once a week, but less than daily	2	5	7
Daily	3	6	9

* Maximal score: 18. The score is determined by adding points from the grid, which takes into account the grade and frequency of incontinence of bowel contents.

stoma or the part of colon used for reconstruction was at the individual surgeon's discretion (Table 1). The colonic pouch, 6 to 8 cm in length, was made by folding the colon and creating a side-to-side anastomosis with a stapler introduced through the apex of the pouch. The double stapling technique was used for the anastomosis in 91 patients. In three patients, (straight, n = 2; pouch, n = 1) a distal pursestring suture was used. A circular stapler (28 or 29 mm, n = 50; 31 mm, n = 22; 33 mm, n = 22) was used for the anastomosis, with no significant differences between the two groups. In three patients (straight, n = 2; pouch, n = 1), the anastomosis was sutured transanally.

Follow-Up and Endpoints

Symptomatic anastomotic leakage was evident if any of the following was observed: evidence of abscess on a computed tomography scan or ultrasound; discharge of pus either per anum or through a fistula; and necessity of laparotomy or a transanal drainage procedure. Anastomotic integrity was confirmed by digital and endoscopic examination, and also by a contrast enema, before closure of the temporary stoma in applicable patients. The criteria of an anastomotic stricture was fulfilled when a dilatation under anesthesia was required.

The bowel function was evaluated preoperatively, and at 2 months and 1 year postoperatively (after temporary stoma closure in applicable patients). A questionnaire that included the following items was used:

1. Frequency of bowel movements per day and night. It was calculated as the average noted on a 7-day diary card.
2. Degree of urgency. Ability to defer defecation for 30 minutes: always, often, sometimes, never.
3. Composite score of grade and frequency of fecal incontinence (modified from Miller et al.¹¹; Table 3).
4. Ability to differentiate gas from stool: yes, no.
5. Ability to evacuate the bowel in <15 minutes: always, often, sometimes, never.

Table 4. POSTOPERATIVE COMPLICATIONS

	Straight (n = 52)	Pouch (n = 45)	p
Mortality (in hospital or 30 days postoperatively)	0	1	
Symptomatic anastomotic leakage including pelvic abscess or fistula	8 (15%)	1 (2%)	0.03*
Staple line hemorrhage with transfusion	0	1	
Bronchopneumonia	3	2	
Temporary urinary retention (urinary catheter > 7 days postoperative)	4	5	
Localized wound sepsis	4	4	
Anastomotic stricture requiring dilatation	7	3	0.33*
Deep vein thrombosis	1	1	
Small bowel obstruction with reoperation	1	1	

Values are no. of patients.

* Fisher's exact test.

6. Sensation of incomplete evacuation: never, sometimes, often, always.
7. The patients were asked if the bowel function adversely affected their overall well-being: not at all, a little, quite a bit, very much.
8. Medication for bowel function was noted.

The questionnaire was administered by a nurse blinded to the randomization.

Statistical Methods

Ordinal variables were compared using Wilcoxon's rank sum test or Wilcoxon's signed rank test, as appropriate. Nominal variables were compared using the chi-square test or Fisher's exact test, as appropriate. A two-sided level of 0.05 was accepted as significant.

RESULTS

Surgical Complications

Postoperative complications are shown in Table 4. One pouch patient died due to hemorrhage in the pelvis and subsequent multiorgan failure. There was no evidence of anastomotic complication. One pouch patient required transfusion because of staple line hemorrhage. The incidence of symptomatic anastomotic leakage was significantly lower in the pouch group (n = 1, 2%) versus the straight group (n = 8, 15%; p = 0.03). The single-

pouch patient had a fistula from the circular anastomosis to the vagina. It was repaired successfully before closure of the temporary loop ileostomy. Technical problems were identified during the operation in four patients (straight anastomosis) with leakage. In two patients, the anastomosis was sutured transanally because of erratic double stapling. In one patient, a distal pursestring suture was used because of problems when the distal bowel was closed and divided. In one patient, fecal contamination occurred during preparation of the bowel. No problems could be identified during the operation in the other five patients with leakage. A summary of the technical problems that were identified and recorded during the operation in all patients is shown in Table 5. Occurrence of technical problems was not predictive of anastomotic leakage (p = 0.23, Fisher's exact test). The management

Table 5. ERRATIC DOUBLE STAPLING AND OTHER TECHNICAL PROBLEMS RECORDED DURING LOW ANTERIOR RESECTION IN 97 PATIENTS WITHIN THE TRIAL

	Straight (n = 52)	Pouch (n = 45)	Anastomotic Leakage (n = 9)
Additional sutures at the anastomosis	3	3	0
Anastomosis sutured transanally due to error of the stapling	2	1	2
Distal purse string suture instead of double stapling	2	1	1
Restapling of the anastomosis due to error of the stapling	1	2	0
Staple line hemorrhage (sutured)	0	1	0
Hemorrhage of the middle colic vein (sutured)	0	1	0
Minor tear in the splenic capsule (hemostasis without splenectomy)	1	1	0
Fecal contamination (managed by pelvic lavage)	2	4	1
Total no. of patients with identified technical problem	11 (21%)	14 (31%)	4/25 (16%)
No technical problems identified during the operation	41 (79%)	31 (69%)*	5/72 (7%)†

* Straight vs. pouch: p = 0.35, Fisher's exact test.

† Anastomotic leakage vs. no leakage: p = 0.23, Fisher's exact test.

Table 6. POSTOPERATIVE FUNCTIONAL OUTCOME

	Two Months			One Year		
	Straight (n = 50)	Pouch (n = 43)	p	Straight (n = 47)	Pouch (n = 42)	p
Frequency of bowel movements 24 hr [median (interquartile range)]	6.4 (4.5–8.1)	2 (1.5–2.5)	<0.001*	3.5 (2.4–4.5)	2 (1.3–2.3)	<0.001*
Nocturnal bowel movements	31 (62%)	13 (30%)	0.0019†	11 (24%)	3 (7%)	0.042†
Ability to defer defecation > 30 min (%)			<0.001*			<0.001*
Always	8	44		15	49	
Often	22	35		40	44	
Sometimes	36	21		30	5	
Never	34	0		15	2	
Composite score of incontinence, 0–18 [median (interquartile range)]	7 (2.8–13)	1.5 (0–5)	<0.001*	5 (2–9)	2 (0–5.3)	0.0018*
Unable to differentiate gas from stool	22 (44%)	5 (12%)	<0.001†	8 (17%)	4 (10%)	0.36†
Regular use of retarding medication	21 (42%)	3 (7%)	<0.001†	19 (40%)	1 (2%)	<0.001†
Regular use of bulking medication	10 (20%)	18 (42%)	0.026†	10 (21%)	21 (50%)	0.071†

* Wilcoxon rank sum test.

† Fisher's exact test.

of leakage in the group with straight anastomosis consisted of urgent laparotomy and creation of a loop ileostomy (n = 3), transanal drainage (n = 2), spontaneous drainage per anum or treatment with antibiotics only (n = 3). In one of the patients, the leak was diagnosed after 3 months. Three of 21 patients with preoperative radiotherapy developed anastomotic leakage. This proportion was not different from 6 patients of 76 without radiotherapy (p = 0.40, Fisher's exact test). One of the patients (straight anastomosis; preoperative radiotherapy) with anastomotic leakage also had postoperative chemotherapy. The single patient with postoperative radiotherapy had no complications. Three of the nine patients with leakage had a temporary stoma fashioned primarily. Closure of the temporary stoma was done after a median of 3 months (range, 1–5 months) in a total of 60 patients without leakage, but closure was delayed to between 5 and 11 months in the patients with leakage.

Symptomatic anastomotic stricture, precluding the passage of a rigid 18-mm diameter rectoscope, was dilated from below, under anesthesia, in ten patients (pouch, n = 3; straight, n = 7; p = 0.33, Fisher's exact test). Four of these ten patients had previous symptomatic leakage. Reversal of the loop ileostomy was declined in one patient (straight anastomosis) after an anastomotic leak.

Bowel Function

Summary of the postoperative functional outcome is shown in Tables 6 and 7. Frequency of bowel move-

ments and incontinence scores are shown in Figures 2 and 3, including the preoperative findings. The preoperative functional results did not differ significantly between the groups in any of the variables and therefore were omitted from Tables 6 and 7. There was a significant reduction of frequency of bowel movements, nocturnal movements, degree of urgency, and incontinence score in the pouch group at 2 months and 1 year. The ability to evacuate the bowel was not significantly different between the groups, but there was deterioration within the pouch group between 2 months and 1 year (p = 0.031, Wilcoxon's signed rank test). Sensation of incomplete evacuation and the inability to differentiate between gas and stool was more pronounced in the straight anastomosis group after 2 months, but the differences were not statistically significant after 1 year. At 1 year, 51% of the patients used medication to improve bowel function. The use of retarding medication (such as loperamide) was more common in the straight anastomosis group. Bulking agents were used more commonly in the pouch group. Four pouch patients (10%) regularly used enemas or suppositories to evacuate the pouch. At 1 year, overall well-being of bowel function was rated higher by the pouch patients, as shown in Figure 4.

In one patient (straight anastomosis) a permanent sigmoidostomy was fashioned after 14 months because of poor bowel function after anastomotic leakage and subsequent stricture formation. In another patient, the colonic pouch was excised after 2 years because of poor function and symptoms of pouchitis that did not re-

Table 7. POSTOPERATIVE FUNCTIONAL OUTCOME WITH REGARD TO EVACUATION

	Two Months			One Year		
	Straight (n = 50)	Pouch (n = 43)	p	Straight (n = 47)	Pouch (n = 42)	p
Ability to evacuate the bowel < 15 min (%)			0.54*			0.073*
Always	50	56		55	34	
Often	28	23		26	39	
Sometimes	14	21		15	20	
Never	8	0		4	7	
Sensation of incomplete evacuation (%)			0.033*			0.10*
Never	13	32		9	22	
Sometimes	29	39		52	50	
Often	40	21		32	23	
Always	18	8		7	5	
Regular use of enema or suppository to evacuate the bowel [no. (%)]	0	3 (7)	0.095†	0	4 (10)	0.046†

* Wilcoxon rank sum test.
† Fisher's exact test.

spond to medical treatment. The histopathologic examination of the pouch showed only chronic inflammation.

Oncologic Results

Withdrawals from the trial because of cancer-related deaths are shown in Table 2. At the 1-year follow-up, five patients in each group had evidence of distant metastases,

but none were admitted to the hospital or withdrawn from the follow-up. There were no local recurrences in either group at 1-year follow-up.

DISCUSSION

Experience with pelvic ileal pouches has led to the application of similar pouch techniques after low anterior

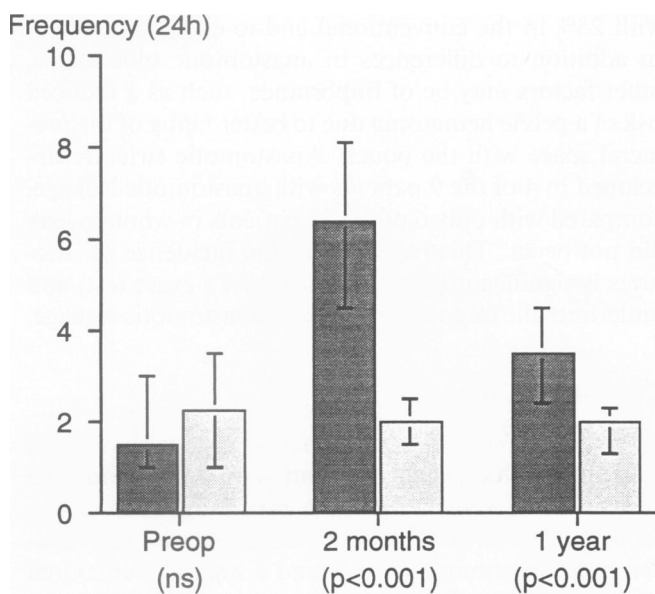


Figure 2. Frequency of bowel movements per 24 hours. Straight anastomosis group (dark gray) and pouch anastomosis group (light gray). Preoperatively, n = 97; at 2 months follow-up, n = 93; and at 1 year follow-up, n = 89. Bars are medians and error bars are interquartile ranges.

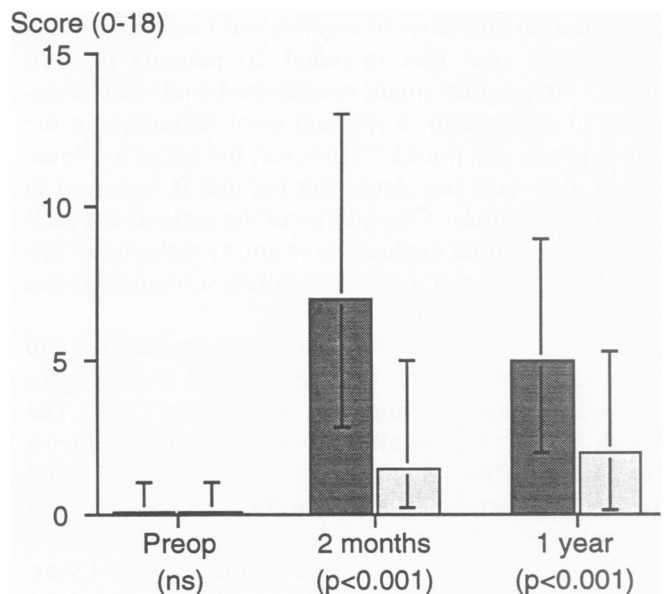


Figure 3. Composite score of grade and frequency of incontinence (0–18, 0 = no incontinence). Straight anastomosis group (dark gray) and pouch anastomosis group (light gray). Preoperatively, n = 97; at 2 months follow-up, n = 93; and at 1 year, follow-up, n = 89. Bars are medians and error bars are interquartile ranges.

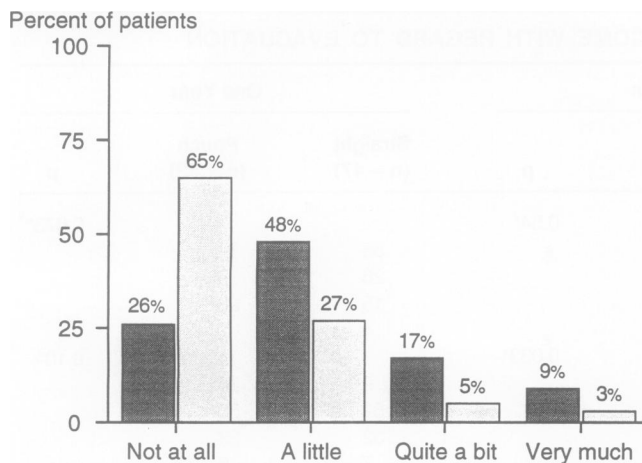


Figure 4. The patients were asked if the bowel function adversely affected their overall well-being. The proportions (%) of the patients' ratings after 1 year are shown. The difference between the groups (straight anastomosis [dark gray], $n = 47$; pouch anastomosis [light gray], $n = 42$) was significant ($p < 0.001$, Wilcoxon's rank sum test).

resection. The use of a colonic pouch in conjunction with a coloanal anastomosis originally was reported by Lazorthes and Parc.^{7,8} The procedure was shown to reduce stool frequency, urgency, and occasional incontinence. Most patients experience satisfactory function shortly after the operation.¹⁰ A randomized comparison between the pouch and the straight coloanal anastomosis was started by Kusunoki et al., but was soon abandoned because of superior results with the pouch.¹¹ A reduced stool frequency and improved continence in the pouch group but no difference in urgency was found in a small, randomized trial that included 20 patients in each group.¹² In another small, randomized trial with 15 patients in each group, a reduced stool frequency in the pouch group was found.¹³ However, the use of a colonic pouch may have one detriment because it may lead to difficult evacuation. One quarter of the patients in Parc's original series used medication to empty the pouch.⁸ Impaired evacuation of the colonic pouch subsequently has been noted by other investigators.^{9,14}

In the current series, 100 patients were randomized to either a straight or the colonic J pouch anastomosis. Eighty-nine patients could be evaluated after 1 year. The pouch patients had significantly less bowel movements per 24 hours, less nocturnal evacuations, urgency, and incontinence, and used less retarding medication. Even if functional superiority was especially evident after 2 months, the differences still were significant after 1 year. Although the advantage with the pouch regarding these variables was apparent, it would appear that some pouch patients experienced impaired evacuation. Although there was no statistical difference in the ability to evacuate the bowel, 10% of the pouch patients regularly used

enemas to elicit evacuation (Table 7). In the pouch group, there was a significant decrease in the ability to evacuate between the 2-month and 1-year follow-up. The volume of the pouch may be crucial for the ability to evacuate. When the colonic pouch procedure was first described, 10- to 12-cm long limbs of colon were used for the construction, but by reducing the length of the limbs to 6 cm, better emptying may be achieved without losing the advantage of low frequency and urgency.¹⁵

An adaptation period of 1 year is too short to draw firm conclusions about the long-term outcome. Follow-up of at least 2 to 3 years probably is necessary, especially regarding evacuation. To determine the optimal size of the colonic pouch, further studies are needed to investigate physiological variables in relation to the clinical function.

The pouch group had lower incidence of anastomotic leakage. This rate compares well with leak rates of less than 5% in previous uncontrolled series with the pouch.^{10,16,17} Occurrence of technical problems during the operation or preoperative radiotherapy seemed not to be significantly predictive of anastomotic leakage. This is in agreement with randomized trials using radiotherapy, in which no adverse effects on anastomotic healing have been found.¹⁸ However, one reason for the difference in leak rate may be that the microcirculation at the apex of the pouch is better preserved compared with the bowel end in the straight reconstruction.¹⁹ The concept of a side-to-end anastomosis in gastrointestinal surgery is well recognized. In a retrospective study,²⁰ the leak rate was only 4% with the side-to-end colorectal anastomosis described by Baker²¹ in 1950, compared with 23% in the conventional end-to-end anastomosis. In addition to differences in anastomotic blood flow, other factors may be of importance, such as a reduced risk of a pelvic hematoma due to better filling of the presacral space with the pouch. Anastomotic stricture developed in 4 of the 9 patients with anastomotic leakage, compared with only 6 of the 88 patients in whom a leak did not occur. This reduction of the incidence of strictures is significant ($p = 0.0058$, Fisher's exact test) and underlines the importance to avoid anastomotic leakage.

CONCLUSION

Patients having surgery for rectal cancer sometimes have limited life expectancy and should be offered the best outcome shortly after the operation. Our results show that the use of a colonic pouch gives a lower incidence of anastomotic leakage and a superior functional result when compared with the traditional straight anastomosis. Despite imperfections of evacuation in some pouch patients, the overall well-being of bowel function was significantly better in the pouch group.

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