

Early postoperative complications after stapled *vs* handsewn restorative proctocolectomy with ileal pouch-anal anastomosis in 148 patients with familial adenomatous polyposis coli: a matched-pair analysis

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Abstract

Aim Restorative proctocolectomy with ileal pouch-anal anastomosis for patients with familial adenomatous polyposis (FAP) and ulcerative colitis (UC) has been modified from a transanal hand-suture after mucosectomy to a stapled ileal pouch-anal anastomosis (IPAA) without mucosectomy. Better functional results favour stapled anastomosis; however, stapled anastomosis results in higher rates of adenomas in persisting anorectal mucosa. The purpose of this study was to compare the two techniques of pouch-anal anastomosis with respect to early postoperative complications in a collective of FAP patients.

Method The study was performed as a matched-pair analysis. Data were obtained from a prospectively collected database.

Results The overall rate of postoperative complications was higher after stapled IPAA (31% stapled *vs* 23% handsewn), with anastomotic stricture occurring in 24.3% (stapled) and 16.2% (handsewn) ($P = 0.22$). Any leakage or pelvic abscess formation after stapled anastomosis occurred within 30 days in almost all patients, whereas these were mainly diagnosed between 30 days and 6 months after handsewn IPAA. A laparoscopic approach was used in 56.7% of patients in the stapled group but in

only two patients in the handsewn group. Intra-operative blood loss was significantly higher in the handsewn group (mean \pm SD: 699 \pm 511 ml *vs* 369 \pm 343 ml; $P < 0.0001$), as was the volume of blood transfused (mean \pm SD: 205 \pm 365 ml *vs* 8 \pm 49 ml; $P < 0.0001$). Function did not differ between the groups.

Conclusion There was a nonstatistically significant tendency towards a higher rate of early postoperative complications after stapled IPAA. The timing of anastomotic leakage and abscess formation differed between the groups.

Keywords FAP, restorative proctocolectomy, pouch, ileal pouch-anal anastomosis, IPAA

What does this paper add to the literature?

Pouch-related complications after double-stapling and hand-suture of the ileal pouch-anal anastomosis (IPAA) during restorative proctocolectomy were analysed in a large number of patients with familial adenomatous polyposis (FAP) to determine whether disease-related factors might be a cause of postoperative complications. The results showed a trend of a high complication rate after stapled IPAA compared with manual IPAA and, when it occurred, anastomotic leakage was earlier after a stapled IPAA.

Introduction

Restorative proctocolectomy with ileal-pouch anal anastomosis (IPAA) has become the standard surgical procedure in the prophylactic treatment of patients with a classical phenotype of familial adenomatous polyposis

(FAP) [1–6]. Owing to the nature of the disease, removal of the colorectal mucosa as completely as possible is required to minimize the risk of metachronous cancer in the anorectal stump. The operation allows radical removal of the colorectum and the preservation of anal function [7]. Since its first description in 1978 [8], pouch reconstruction has been modified several times. Although various pouch designs have been developed [2], most centres use the J-pouch introduced by Utsunomiya *et al.* in 1980 [9].

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As with pouch design, the ileal pouch-anal anastomosis (IPAA) technique has been modified. In parallel with the introduction of stapling devices in the 1980s, manual IPAA with mucosectomy [2,5,9] has been increasingly replaced with a double-stapling technique without mucosectomy [3–5,10].

Several studies have compared both techniques with respect to function and perioperative complications [11–14]. Three studies specifically addressed differences in perioperative complications and found higher rates of septic complications, fistula formation and anastomotic stricture after a handsewn IPAA [3,14,15]. In contrast, Lewis *et al.* reported a higher incidence of stricture after stapled IPAA [16]. Various authors have shown that stapled IPAA is associated with better function, especially of faecal continence [3,11,13,14]. The underlying reason is assumed to be less trauma to the anal sphincter and preservation of the anal transitional zone (ATZ) [3,4,11,13,14]. A meta-analysis by Lovegrove *et al.* showed a higher incidence of dysplasia in the ATZ after a stapled anastomosis, in line with the results from the same group for FAP, which showed persisting adenomas in the residual anorectal mucosa after a stapled IPAA in up to 28% of patients [4].

Many studies on restorative proctocolectomy have mixed patients with FAP and ulcerative colitis (UC) [3,12,13,16]. However, previous studies have shown differences in complication rates and function between such patients [12,15,17–21]. A recent study by our own group identified septic complications among UC patients as a reason for late pouch failure over a follow-up period of years [22].

For this reason the present study dealt exclusively with patients with FAP and aimed to compare the early complications related to the IPAA performed using stapled or handsewn techniques.

Method

Patients

The Heidelberg Polyposis Register [23] was searched for patients who had undergone restorative proctocolectomy with a stapled IPAA between 2001 and 2006. This time period was chosen because of a major switch of the IPAA technique to double stapling in 2001. According to the matching criteria, patients who had undergone restorative proctocolectomy with a handsewn anastomosis between 1984 and 2001 were extracted from the Polyposis Register.

Seventy-four patients treated with a stapled IPAA during restorative proctocolectomy for FAP were available for analysis. Of the 189 patients treated with a

handsewn IPAA, 74 were matched to those treated with a stapled IPAA according to the following criteria: age at the time of restorative proctocolectomy; gender; and previous colonic surgery. The following clinical data were retrieved from the Polyposis Register and clinical charts: age; weight; height; duration of the surgical procedure; intra- and postoperative blood loss and transfusions; perioperative complications and clinical management; results of follow-up consultations, including endoscopy; and pathology reports.

End-points

Primary and secondary end-points

The primary end-point was the rate of pouch-related complications within the first 2 years after restorative proctocolectomy. Anastomotic leakage was defined as a separation of the IPAA detected clinically, radiographically or endoscopically. Examination of the IPAA was initiated on the basis of features including fever, pain and laboratory results. A fistula was regarded as a significant complication if it was arising from the IPAA. Pelvic abscess formation was detected radiographically by CT scan. Stricture formation of the IPAA was diagnosed only where instrumental dilatation was required, it did not include cases with a membranous web, dilated by digital examination. Secondary end-points included postoperative bleeding, persisting rectal mucosa and function.

Surgical technique

Following open, laparoscopic or laparoscopically assisted proctocolectomy, all patients received a J-pouch reconstruction. Stapling of the IPAA was performed using a circular stapler without mucosectomy. This was carried out in all patients treated with a handsewn IPAA.

With the exception of three patients, all those who had a stapled IPAA received a diverting ileostomy for approximately 3 months. Before closure of the ileostomy, all patients underwent radiography of the pouch, pouchoscopy and anal manometry.

Function

The MSKCC-Incontinence Scoring System, which consists of 18 questions on continence, factors influencing continence and the frequency of defaecation after rectal resection, was used to record the nature and the severity of incontinence [24]. The answers are given in integers, which are added to give a global score with three subscales (Table 3). Four questions are evaluated as single items and are included in the global score. A higher

score equals a better functional result. The questionnaire was translated into German and sent to patients by post in 2006.

Persisting rectal mucosa

Regular follow up of the IPAA and the ileal mucosa in the pouch was performed by flexible pouchoscopy at intervals of 1 year. In patients with possible abnormality of the IPAA, an additional proctoscopy with biopsies, if indicated, was performed.

Statistical analysis

Data were expressed as mean \pm SD or median with interquartile range (IQR), according whether the data were parametric or nonparametric, respectively. Differences between the distributions of quantitative parameters of the stapler and the handsewn groups were analysed using the nonparametric Mann–Whitney *U*-test. To compare the rates of postoperative complications, Pearson's chi-square test or Fisher's exact test was used, where appropriate. A *P*-value of ≤ 0.05 was considered statistically significant. SAS software (Release 9.1; SAS Institute, Inc., Cary, North Carolina, USA) was used.

Results

Two-hundred and seventy-seven patients who underwent restorative proctocolectomy with IPAA for FAP were identified from the Heidelberg Polyposis Register. Of these, 74 had been treated with a stapled IPAA and had complete follow-up data for the required observation period. They were matched with 74 patients out of 189 who had been treated with a handsewn IPAA. The mean ages, at surgery, of the stapled and handsewn groups were 28.0 (14.3–56.4) years and 28.5 (10.9–55.8) years, respectively (Table 1). The body mass index was 23.1 kg/m² in the handsewn group and 22.8 kg/m² in the stapled group, with no statistically significant difference between the groups.

Table 1 Patient data.

	Stapled group (<i>n</i> = 74)	Handsewn group (<i>n</i> = 74)	<i>P</i>
Male: female	40: 34 (54.0%: 45.9%)	40: 34 (54.0%: 45.9%)	
Mean age at RPC	28.0 (14.3–56.4)	28.5 (10.9–55.8)	0.697
Patients with previous colonic surgery	2 (2.7%)	2 (2.7%)	
Median (IQR) body mass index (BMI) kg/m ²	22.8 (19.9–26.1)	23.1 (19.8–25.4)	0.812

BMI, body mass index; IQR, interquartile range; RPC, restorative proctocolectomy.

All but four patients underwent restorative proctocolectomy as the primary surgery. Three had previously had a colectomy with ileorectal anastomosis (one in the stapled group and two in the handsewn group). One patient with a stapled IPAA had previously undergone a segmental colonic resection.

Eight patients in the stapled group and 12 in the handsewn group had colorectal cancer at the time of restorative proctocolectomy. In the stapled group desmoid disease involving the mesentery was found intra-operatively in four patients. Only one of these developed a postoperative complication (haematoma). No patient in the handsewn group had a desmoid tumor at the time of pouch surgery.

In the stapled group, 42 (56.7%) patients underwent laparoscopic or laparoscopic-assisted surgery compared with two (2.5%) in the handsewn group. Conversion from laparoscopic surgery to open surgery was necessary in three (3.6%) patients in the stapled group and in one (1.5%) in the handsewn group.

The median interval from the pouch operation to closure of the ileostomy was 106 (IQR: 86–135) days after stapled IPAA and 112.5 (IQR: 92–138) days after handsewn IPAA (*P* = 0.6206).

Intra-operative blood loss was higher in the handsewn group (mean 699 \pm 511 ml *vs* 369 \pm 343 ml; *P* < 0.0001). Likewise, the mean volume of blood transfused was significantly higher in the handsewn group (205 \pm 365 ml *vs* 8 \pm 49 ml; *P* < 0.0001).

Complications 2 years after restorative proctocolectomy

Twenty-three (31.08%) patients treated with a stapled IPAA had 29 pouch-related complications within 2 years of surgery compared with 17 (22.97%) patients in the hand-sewn group who had 22 complications. Although showing a clear tendency, this difference did not reach statistical significance (*P* = 0.2668, Table 2). Complications after stapled IPAA occurred at a mean \pm SD interval of 97.3 \pm 122.1 days in the stapler group (range, 6–556 days) and at 142.2 \pm 152.7 days

Table 2 Pouch-related complications according to the technique of ileal pouch-anal anastomosis (IPAA).

Complication	Technique of IPAA	Interval from RPC			Total number <i>n</i> (%)	<i>P</i>
		30 days <i>n</i> (%)	6 months <i>n</i> (%)	2 years <i>n</i> (%)		
Anastomotic leakage	Stapler	6 (8.1)	0	0	6 (8.1)	0.512
	Hand suture	1 (1.3)	3 (4.0)	0	4 (5.4)	
Abscess	Stapler	4 (5.4)	0	0	4 (5.4)	0.681
	Hand suture	1 (1.3)	1 (1.3)	0	2 (2.7)	
Fistula	Stapler	0	0	1 (1.3)	1 (1.3)	0.366
	Hand suture	0	2 (2.7)	2 (2.7)	4 (5.4)	
Stricture	Stapler	0	16 (21.6)	2 (2.7)	18 (24.3)	0.220
	Hand suture	1 (1.3)	8 (10.8)	3 (4.0)	12 (16.2)	
Postoperative bleeding	Stapler	8 (10.8)	0	0	8 (10.8)	0.785
	Hand suture	7 (9.4)	0	0	7 (9.5)	

RPC, restorative proctocolectomy.

in the handsewn group (range, 20–579 days) ($P = 0.189$).

To exclude a learning curve effect in the early years of stapler usage, we compared the complication rates between 2001–2003 and 2004–2006. There was no significant difference in the complication rates between these two periods ($P = 0.7072$).

Primary end-points

Anastomotic leakage

In the stapler group, six patients were diagnosed with leakage of the IPAA within 30 days of surgery, compared with only one leak within the same time period (out of four leaks in total) in the handsewn group. This difference did not reach statistical significance (Table 2).

In the six patients having leakage after stapled IPAA, two required major revision with re-creation of the IPAA, two were treated by transanal drainage of a pelvic abscess and two did not require any specific treatment. The patient with an early postoperative leak in the handsewn group did not require any surgical treatment. Of the remaining three patients with anastomotic leakage after a handsewn anastomosis, one did not require specific treatment, one required transanal drainage of a resulting pelvic abscess and one needed major abdominal revision with re-creation of the IPAA.

Pelvic abscess and fistula formation

Pelvic abscess occurred in four patients after stapled anastomosis, within 30 days in all cases; pelvic abscess occurred in one patient after handsewn anastomosis within 30 days and in another patient within 6 months after handsewn anastomosis ($P = 0.6810$) (Table 2). Four patients with pelvic abscess had underlying

anastomotic leakage. Two patients with pelvic abscess after a stapled IPAA had drainage and two required major revision with re-creation of the IPAA. The two patients developing a pelvic abscess after a handsewn anastomosis were treated by interventional external drainage.

One patient developed a fistula within 2 years of a stapled IPAA, following anastomotic leakage in the immediate postoperative period. Of the four fistulae that developed following a handsewn IPAA, two occurred within 6 months and two between 6 months and 2 years ($P = 0.3664$). In three, anastomotic leakage had developed in the immediate postoperative period (Table 2).

Stricture formation

An IPAA stricture occurred in 18 (24.3%) patients in the stapled group and in 12 (16.2%) in the handsewn group. It was diagnosed within 6 months in 16 patients after stapled IPAA, mostly before ileostomy closure. Seven patients required dilatation under anaesthesia. The stapler size was ≤ 29 mm in 34 patients and ≥ 31 mm in 19, with a similar rate of stricture formation between these two sizes (20.6% and 21.1%, respectively). In patients with a handsewn anastomosis, stricture formation occurred in 12 ($P = 0.2199$) of whom only one required dilatation under anaesthesia ($P = 0.0630$).

Secondary end-points

Postoperative bleeding occurred in eight patients after a stapled IPAA and in seven after a handsewn IPAA. Six (three in each group) required abdominal reoperation with evacuation of the haematoma.

Persisting rectal mucosa was found during follow-up proctoscopy or pouchoscopy in 24 patients after a stapled IPAA and in 15 after a handsewn IPAA.

Function

Eight of the 148 patients were excluded from the analysis of function owing to death ($n = 5$), loss to follow up ($n = 2$) and excision of the pouch ($n = 1$). Of the remaining 140 patients, an evaluable questionnaire was received from 98 (70%). The median follow up was 11.4 (IQR: 8.5–15.4) years in the handsewn group and 2.4 (IQR: 1.5–4.7) years in the stapled group.

The global functional scores were 65.4 in the handsewn group and 67.1 in the stapled group ($P = 0.666$) and the mean \pm SD frequency of defaecation/24 h was 7.0 ± 2.1 in the handsewn group and 6.7 ± 2.5 in the stapled group (Table 3). There was no difference in the functional scores in patients with and without postoperative complications (66.7 vs 63.5; $P = 0.308$).

Discussion

The matched-pair analysis revealed no significant difference in the overall rate of pouch-related complications within 2 years after restorative proctocolectomy including a stapled or a handsewn IPAA. The incidence of complications is consistent with those published for stapled anastomosis [13] and is comparable with previously published results for FAP patients after a handsewn IPAA [6,7,25]. However, there was a tendency for fewer anastomotic complications in the handsewn group. The laparoscopic approach was used significantly more often in the stapled group, but because previous studies showed no difference in the overall rate of complications after laparoscopic or open pouch surgery [26,27] it is likely that the integrity of the IPAA was influenced less by the surgical approach to the abdomen than by the anastomotic technique. The literature consistently demonstrates a tendency

towards more bleeding and a greater requirement for blood transfusion with an open approach [26,28] and the difference identified in the present study is probably because of these factors, rather than the anastomotic technique. Manual IPAA was mostly performed in the 1990s, when perioperative transfusion was given more frequently, and in higher volumes, than after 2001 when stapled IPAA began to be performed.

There was a clear tendency towards anastomotic leakage and abscess and stricture formation after stapled IPAA, and the difference in the need to perform dilatation under general anaesthesia very nearly achieved statistical significance. The rates of septic anastomotic complications in the current study are somewhat lower with previously published large series [3,16] and those for fistula formation are lower than previously published [12,14,15]. As the underlying disease – FAP or UC – has been shown to influence postoperative complications and function [15,17–21], the decreased rates of anastomotic complications in the present study may be a result of the fact that all patients had FAP. The rate of pelvic sepsis after restorative proctocolectomy for FAP patients has been reported to be as low as 1.6% [25].

The difference in timing of anastomotic complications in the two groups may be a result of the fact that after a handsewn IPAA the remaining muscular cuff may have some protective function in the case of minor leakage. This is supported by the fact that none of the patients with a pelvic abscess after a handsewn anastomosis required major revision, whereas this was carried out in 50% of those having this complication after stapled IPAA. The most striking complication was stricture formation, with those occurring after stapling being more likely to require dilatation under anaesthesia. The rates reported for stricture formation in the literature

Table 3 The MSKCC-incontinence score.

Dimension according to the MSKCC-Incontinence Score	Technique of anastomosis	<i>n</i>	Results (mean \pm SD)	<i>P</i>
Frequency	Handsewn	39	21.4 \pm 3.5	0.667
	Stapler	59	21.9 \pm 3.3	
Dietary	Handsewn	39	12.6 \pm 4.1	0.380
	Stapler	59	13.3 \pm 3.9	
Urgency/soiling	Handsewn	39	15.6 \pm 4.6	0.219
	Stapler	59	16.7 \pm 3.7	
Total (three subscales)	Handsewn	39	49.5 \pm 10.1	0.375
	Stapler	59	51.9 \pm 8.8	
Total (three subscales + single items)	Handsewn	38	65.4 \pm 12.3	0.666
	Stapler	58	67.1 \pm 10.3	
Frequency of defaecation/24 h	Handsewn	37	7.0 \pm 2.1	0.414
	Stapler	57	6.8 \pm 2.5	

differ widely, with a higher risk for manual IPAA with mucosectomy reported by some authors [14] and a lower risk reported by others [16]. Although the difference between both groups in the present study was not statistically significant, there was a clear tendency for a higher rate of dilatation under anaesthesia after stapled IPAA. This did not appear to be related to stapler size, as previously demonstrated [16] [29]. The lack of any difference in function is in contrast to the findings reported in a larger meta-analysis [4] and may reflect the longer duration of follow up of patients who had a handsewn IPAA.

Rectal mucosa was detected in more patients in the stapled group than in the handsewn group, underlining previous observations indicating the potential risk of more dysplasia and possible invasion [4,5,14,30–32]. The actual risk of these findings still needs to be addressed in further studies, given the report of a large group of patients having stapled and manual IPAA for FAP in which only one patient developed cancer in the anorectal segment, which in any case had been after handsewn IPAA [31]. In our own patients so far three have developed carcinoma in the residual large bowel mucosa: one after a stapled IPAA; one after a handsewn IPAA; and in the third extraluminally, 24 years after restorative proctocolectomy. Mucosectomy is clearly not a guarantee that malignant invasion will be avoided [32], even with endoscopic surveillance. Perhaps other methods of investigation, such as endoscopic ultrasound, should be considered in patients who are difficult to assess using simple endoscopy. Thus, neither technique of IPAA can remove the anorectal mucosa completely. Persisting anorectal mucosa is inevitable and in patients with FAP, close follow up is clearly necessary.

Author contributions

Petra Ganschow-Primary author of manuscript, acquisition of data, analysis and interpretation of results; Ramona Warth-Acquisition of data, analysis and interpretation of results; Ulf Hinz-Statistical analysis of data, interpretation of data, interpretation of results, statistical counselling of study; Markus W. Büchler-Conceptual review of study, critical review of manuscript; Martina Kadmon-Conceptual development of study, analysis and interpretation of results, critical review of manuscript and possible impact on clinical management.

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