

Residual rectal mucosa after stapled vs. handsewn ileal J-pouch-anal anastomosis in patients with familial adenomatous polyposis coli (FAP)—a critical issue

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Abstract

Introduction Restorative proctocolectomy has become the standard surgical procedure for familial adenomatous polyposis (FAP) patients. The use of stapler devices has initiated a controversial discussion concerning the ileal pouch-anal reconstruction. Some authors advocate a handsewn anastomosis after transanal mucosectomy. A double-stapled anastomosis leads to better functional results but seems to bear a higher risk of residual rectal mucosa with dysplasia and adenomas. The present study systematically analyses the rate of residual rectal mucosa after restorative proctocolectomy and handsewn vs. stapled anastomosis.

Patients and methods One hundred FAP patients after restorative proctocolectomy undergoing regular follow-up at our outpatient clinic were included in the study. Proctoscopy with standardised biopsy sampling was performed.

Results Of the 100 patients, 50 had undergone a stapled and 50 a handsewn anastomosis. Median follow-up was 146.1 months (handsewn) vs. 44.8 months (stapled) ($P < 0.0001$). Eighty-seven patients received a proctoscopy with standardised biopsy sampling. Thirteen patients had been diagnosed with residual rectal mucosa before. Sixty-three patients (63 %) showed remaining rectal mucosa (42 (66.6 %) stapler, 21 (33.3 %) handsewn, $P < 0.0001$). Patients after stapled anastomosis had higher rates of circular rectal mucosa seams, while small mucosa islets predominated

in the handsewn group. The rate of rectal adenomas was significantly higher in the stapler group (21 vs. 10, $P = 0.02$). **Conclusion** Rectal mucosa, especially wide mucosa seams, as well as rectal adenomas are found significantly more often after a stapled than after a handsewn anastomosis. As the follow-up interval in the stapler group was significantly shorter, the impact of these findings may still be underestimated.

Keywords FAP · Restorative proctocolectomy · Handsewn vs. stapled IPAA · Residual rectal mucosa

Introduction

Familial adenomatous polyposis (FAP) is a genetically inherited disorder that leads to the development of hundreds to thousands of adenomas in the colorectum [1–3]. If left untreated, patients develop colorectal cancer usually during their third to fourth decade of life [4]. Therefore, the surgical therapy aims at preventing the development of colorectal cancer while restoring continence and a good quality of life.

Restorative proctocolectomy (RPC) with ileal pouch-anal reconstruction has become the standard surgical approach for the majority of patients with FAP [5–7]. Since its first description by Parks and Nicholls in 1978, it has been subject to several technical advancements [8]. In the early years of pouch surgery, the pouch shape was modified in various ways until the J-pouch reconstruction, introduced by Utsunomiya in 1980, was adopted as standard in most centres [9, 10].

Apart from the pouch shape, the technique used for the ileal pouch-anal anastomosis (IPAA) has changed. Traditionally, the anastomosis was handsewn transanally after mucosectomy

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[6, 9]. Today, IPAA is mostly accomplished by a circular stapler without transanal mucosectomy [6, 11, 12].

Pros and cons for either technique have been published, including functional analysis and rates of perioperative complications with respect to the technique used for the anastomosis. Three studies specifically addressed septic complications after either technique and found higher rates after a handsewn anastomosis [13–15]. For a stapled IPAA, Lewis and co-workers reported higher rates of anastomotic strictures [16]. Functional outcome and continence tend to be better after a stapled anastomosis due to less transanal manipulation and preservation of the anal transition zone [6, 11–14, 17–19, 21, 22]. On the other hand, a recent meta-analysis by Lovegrove and co-workers revealed higher rates of dysplasia in the anal transition zone (ATZ) after a stapled anastomosis for FAP and UC [19]. This finding is also supported by a recent review on FAP patients [20].

The residual rectal mucosa (RRM) is crucial for the clinical follow-up and safety of FAP patients since it bears the risk of adenoma and rectal cancer development. Some authors even suggest that stapled IPAA should not be performed in FAP patients at all and demand transanal mucosectomy and handsewn anastomosis instead [6, 17, 22–26]. However, a study in the early years of pouch surgery by O’Connell and co-workers showed that even after mucosectomy and handsewn anastomosis, islets of rectal mucosa may remain [27]. Similar results were described by Duijvendijk and colleagues, who estimated a 10 % risk of adenoma development after a handsewn IPAA [28]. Von Roon and co-workers detected adenomas after both surgical techniques, but they occurred significantly earlier after a stapled than after a handsewn anastomosis [29].

Since most of these studies followed a retrospective approach, we hypothesised that the problem of RRM is still underestimated. Therefore, in the presented study, we followed a defined endoscopic approach with standardised biopsy sampling to estimate and compare the actual rate of residual rectal mucosa after RPC and handsewn vs. stapled IPAA in a large number of FAP patients.

Material and methods

Study design

All FAP patients who presented for follow-up at the Surgical Department of Heidelberg University Hospital between May 2005 and October 2009 and had undergone RPC and IPAA more than 12 months before were included in the study ($n=136$). Informed consent was obtained on the day of the examination. A standardised study proctoscopy was performed in addition to regular yearly flexible pouchoscopy. Clinical data was extracted from the Heidelberg Polyposis Register [30].

Proctoscopy

In the majority of patients included in the study, a proctoscopy with a standardised biopsy sampling was performed by a single experienced surgeon. Two patients were examined by a different physician with a comparable experience in performing endoscopic procedures.

Biopsies were taken from all macroscopically suspicious lesions at the anastomotic site. If no macroscopic evidence of RRM or adenomas was found, biopsies were taken from all four quadrants of the anastomosis. Specimens were analysed histologically for rectal mucosa, adenomas, and dysplasia. Proofs of RRM and adenomas in past examinations were included as +RRM, also if biopsies during the recent study did not reveal any RRM. If patients denied a new proctoscopy, older results were used if possible.

Standard proctoscopes with a diameter of 20, 15, and 10 mm and a length of 8 cm and standard 5-mm biopsy forceps were used. Sedation or anaesthesia was not required.

Endpoints

The rate of RRM after IPAA with a handsewn or a stapled anastomosis was defined as the primary endpoint of the study. Secondary endpoints were

- Macroscopic appearance of RRM (seams vs. islets)
- Distribution of RRM (dorsal and ventral circumference of the anastomosis)
- Rate of adenomas
- Rate of carcinomas

Surgical procedure

The surgical approach to the abdomen was open, laparoscopically assisted or entirely laparoscopic. All patients included received a J-pouch with either a handsewn anastomosis after transanal mucosectomy or a stapled anastomosis at the dentate line with a standard circular stapling device. Radical removal of the rectal mucosa was attempted irrespective of the abdominal approach and the reconstructive technique.

Statistics

The SAS software (Release 9.1, SAS Institute, Inc., Cary, NC, USA) was used for statistical analysis. The primary study endpoint was the rate of RRM after handsewn vs. stapled IPAA. The chi-square test was performed to statistically compare the rate of RRM between the two groups. To analyse the defined secondary endpoints, the chi-square test if appropriate and Fisher’s exact test were used. The quantitative parameters age and follow-up were

compared between the two groups using the Mann-Whitney U test. Sensitivity and specificity of the endoscopy were calculated. All tests were used two-sided. P values <0.05 were considered statistically significant.

Results

Between May 2005 and October 2009, 136 patients fulfilling the inclusion criteria presented at our outpatient clinic and were screened for this study. Thirty-six patients had to be excluded from the analysis due to the following reasons:

- Twenty patients due to appointment conflicts for the scheduled examinations.
- Eight patients due to severe anal pain preventing proctoscopy.
- Two patients due to stenosis of the IPAA impairing proctoscopy.
- Two patients suffering from a large pouchocele inhibiting precise evaluation of the anastomotic site.
- One patient due to recent transanal operative revision for a pouch prolapse.
- Three patients refused participation in the study.

One hundred patients (73.5 %) could be included in the study, 50 after a stapled and 50 after a handsewn anastomosis. Eighty-seven patients underwent proctoscopy during the study period; 13 patients had been diagnosed with RRM before and had already undergone secondary mucosectomy. The median follow-up differed significantly between both groups (146.1 months after a handsewn vs.

44.8 months after a stapled IPAA, $P<0.0001$). The frequency of colorectal cancer at the time of proctocolectomy and IPAA did not differ. Detailed patient data is given in Table 1. The laparoscopic approach to the abdomen was significantly more frequent in the stapler group, whereas in the handsewn group, the open approach predominated ($P<0.0001$, Table 2).

Ten patients, 7 in the handsewn and 3 in the stapler group ($P=0.32$), had undergone abdominal surgery prior to restorative proctocolectomy and IPAA. Another 33 patients, 15 after a handsewn and 18 after a stapled anastomosis ($P=0.52$), had had local pouch revisions prior to the present study. Details are given in Tables 1 and 3.

Regarding the primary endpoint RRM, a highly significant difference was found after handsewn and stapled IPAA. RRM was detected in 63 patients (63 %), in 21 cases (33.3 %) after a handsewn and in 42 cases (66.6 %) after a stapled anastomosis ($P<0.0001$, Fig. 1). There was no significant difference in RRM between males and females after either technique for IPAA ($P=1.0$).

Adenomas in RRM were detected in 27 patients (27 %) of the study cohort, 10 patients with a handsewn anastomosis, and the 17 with a stapled IPAA. In another 5 patients with adenomas after a stapled IPAA, histological differentiation between rectal and ileal adenomas was not possible on the basis of proctoscopic biopsies. In 4 of these patients, the secondary mucosectomy specimen, however, clearly revealed rectal adenomas. Thus, the total number of rectal adenomas found in the stapler group ($n=21$) differed significantly from that of the handsewn group ($n=10$) ($P=0.02$). No patient in the study population showed a high-grade dysplasia or developed a rectal carcinoma at the anastomosis during the study period.

Table 1 Demographic data of included patients

	Handsewn IPAA	Stapled IPAA	P value
Total number of patients	50	50	
Male patients	25	26	
Female patients	25	24	
Median age at time of study (IQR)	41.5 (18–69)	32.2 (17–59)	0.0002
Median age at time of IPAA (IQR)	29.3 (7–58)	28.5 (14–56)	0.5059
Median follow-up in months (IQR)	146.1 (24–276)	44.8 (12–99)	<0.0001
Total number of patients with previous abdominal surgeries	7	3	0.3173
Subtotal colectomy with ileorectal anastomosis	5	1	
Subtotal colectomy with ascendrectostomy	0	1	
Rectum resection	1	0	
Proctocolectomy with ileoanal anastomosis	1	0	
Laparoscopic appendectomy	0	1	
Colorectal carcinoma at time of IPAA	9	6	0.4008
Rectal carcinoma	4	3	
Colon carcinoma	4	3	
Double colorectal carcinoma	1	0	

Figures in bold signals statistical significance

Table 2 Abdominal approach used for restorative proctocolectomy and IPAA

Technique for surgical approach	<i>N</i> handsewn group (%)	<i>N</i> stapler group (%)	<i>P</i> value
Open abdominal approach	40 (80)	18 (36)	<0.0001
Laparoscopically assisted approach	10 (20)	2 (4)	
Laparoscopic approach	0	30 (60)	

Figures in bold signals statistical significance

Data on the distribution of RRM at the anastomotic site was available for 38 patients, 11 with a handsewn and 17 with a stapled anastomosis. After a handsewn anastomosis, RRM was found in the dorsal circumference in 5 cases (45.5 %), in the ventral circumference in 1 case (9 %), and in both localisations in another 5 cases (45.5 %). Among patients after a stapled IPAA, RRM was detected in the samples from the dorsal quadrants in 3 cases (11.1 %), from the ventral quadrants in 7 cases (25.9 %), and from both the ventral and dorsal quadrants in 17 cases (63 %) (Fig. 2). The difference in the distribution of rectal mucosa was not statistically significant ($P=0.53$).

Circular seams of RRM were significantly more frequent after a stapled anastomosis, whereas patients with a handsewn anastomosis more often showed islets of RRM ($P=0.01$) (Fig. 2). There was no significant difference in the rate of RRM with respect to the open and laparoscopic abdominal approach ($P=0.24$ for the stapler group, $P=0.49$ for the handsewn group).

Discussion

Until now, data on RRM after RPC was mainly gathered by retrospective analysis. In order to precisely estimate the real rate of RRM, we followed a different approach in the present study using a standardised proctoscopic screening and biopsy sampling. RRM was chosen as the primary endpoint in this study because especially FAP patients require a radical removal of colorectal mucosa in order to prevent the development of rectal cancer.

Our results show that there is a highly significant difference in the rate of RRM after a handsewn and a stapled IPAA, even if total removal of rectal mucosa was attempted irrespective of the abdominal approach and the reconstructive technique.

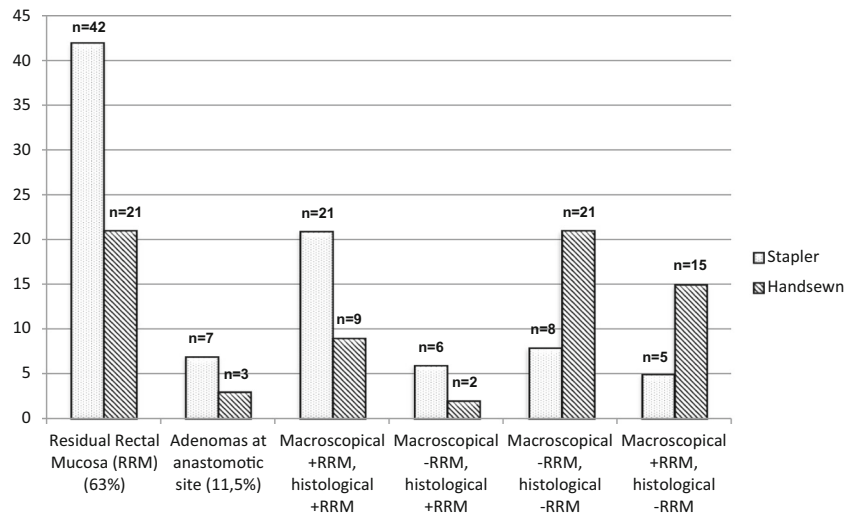
While after a handsewn anastomosis with prior mucosectomy still 42 % of the patients showed RRM, this was the case in 84 % of the patients after a stapled anastomosis. Several studies have addressed the issue of RRM and reported different rates [27, 29, 35, 38–40]. Deen et al. found high rates up to 88.9 % in the distal doughnut after a stapled anastomosis [36]. A subsequent study reported on a much lower rate of only 46.7 % after a stapled IPAA [37]. Our own rates of RRM in the present study clearly support the former study and favour the handsewn anastomosis after prior mucosectomy.

Besides RRM, the development of adenomas in the ATZ is a major point of interest in the follow-up of FAP patients. Remzi and co-workers reported rates of up to 28 % of adenomas after a stapled IPAA [38]. Duijvendijk and colleagues also emphasised the importance of adenoma development at the anastomosis and estimated the cumulative risk of FAP patients for developing polyps within 7 years to be 10 % after a handsewn and 31 % after a stapled IPAA [28]. Von Roon and colleagues reported an even higher risk of up to 22.6 % after a handsewn and 51.1 % after a stapled IPAA for neoplastic transformation [29]. A recent retrospective analysis by Ozdemir and co-workers found similar results with an estimated cumulative risk of developing ATZ polyps after 10 years of 11.6 % after a handsewn and 29.9 % after a stapled IPAA [41]. Further studies by Tsunoda and co-workers aimed at estimating the risk of premalignant and malignant transformations in the epithelium of the ATZ by looking at mucosa strippings from 14 FAP patients. Dysplasia was found in 12 cases; in three cases, it was severe [22]. The difference in the rate of adenomas between the handsewn and stapler group in our own study is statistically significant ($P=0.02$) and underlines previous results. Since the follow-up period in the stapler group was significantly shorter than in the handsewn group, the problem of adenoma and dysplasia development is probably still underestimated. Although none of the patients in the

Table 3 Type of local revision of the IPAA within the included patient population

Surgical procedure	Handsewn group	Stapler group	<i>P</i> value
Total number of patients affected	15	18	0.5232
Transanal mucosectomy and/or polypectomy	7	13	
Excision/drainage of fistula or abscess	4	2	
Transsection of remaining pouch bridge	2	0	
Dilatation of the IPAA	1	2	
Re-insertion of pouch-anal anastomosis	1	1	

Fig. 1 Difference in the rate of RRM and adenomas after RPC with a handsewn or a stapled IPAA ($P<0.0001$) (+RRM macroscopic or histologic evidence of rectal mucosa, -RRM no macroscopic or histologic evidence of rectal mucosa)



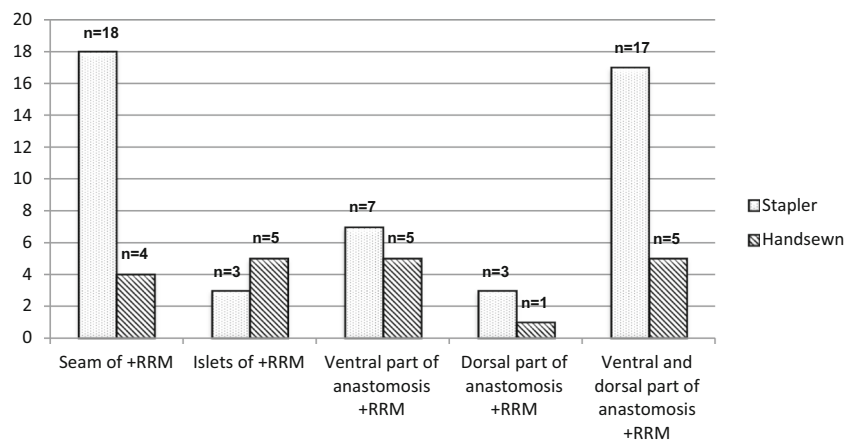
present study showed a high-grade dysplasia, the fairly short follow-up interval for the stapler group leaves a critical view on these findings. Ozdemir and colleagues did not find a difference in the rate for ATZ cancer, yet also in their study, the follow-up interval was significantly shorter in the stapler group [41]. Therefore, the development of dysplasia in large amounts of RRM in FAP patients may only be a matter of time as also suggested by von Roon and co-workers [29].

In our entire FAP patient population, three patients developed true rectal cancer in RRM after RPC, but none in the study population (unpublished results). In two patients, a carcinoma arose at the anastomosis, one after a handsewn and one after a stapled anastomosis. A third patient developed a carcinoma in the muscular cuff 24 years after RPC with transanal mucosectomy and handsewn IPAA. These disease courses underline the risk of malignant transformation in RRM. They further indicate that after either technique, careful surveillance is mandatory.

The discussion whether a stapled IPAA is an option for FAP patients at all or whether mucosectomy and a handsewn anastomosis should be performed instead is still an important issue

today. Results from our own study and from previous literature show an advantage of primary mucosectomy and a handsewn IPAA with respect to RRM as it bears a lower risk of adenomas and premalignant transformation [28, 29, 41]. The higher risk after stapled IPAA mostly results from wide seams of RRM as opposed to small islets after a handsewn anastomosis. On the other hand, as suggested by Reilly and colleagues, a visible seam of rectal mucosa after a stapled IPAA may facilitate surveillance in comparison with small islets of mucosa after transanal mucosectomy and a handsewn anastomosis [12]. Better functional results after a stapled IPAA also favour this technique [6, 11–14, 17–19, 38]. However, the present study suggests that patients after a stapled IPAA will need secondary mucosectomy during follow-up and thus adds another important aspect to the discussion of ileoanal reconstruction after restorative proctocolectomy. The questions of timing for secondary mucosectomy and subsequent pouch function have not yet been addressed adequately. If secondary mucosectomy is inevitable after a stapled IPAA, a comparison of pouch function after primary and secondary mucosectomy seems mandatory and is addressed in a follow-up study.

Fig. 2 Difference in distribution of RRM after RPC with a stapled or a handsewn IPAA; circular seams were significantly more frequent after a stapled IPAA than after a handsewn anastomosis ($P=0.01$) (+RRM evidence of rectal mucosa)



We are aware that the laparoscopic approach predominated in the stapler group. However, we do believe that the significantly higher rate of RRM in the current study is not caused by the abdominal approach but is a true effect of the technique used for the pouch-anal anastomosis. This is supported by the fact that the rate of RRM did not differ between a laparoscopic and an open approach neither in the handsewn nor in the stapler group. Moreover, several other studies did not detect any difference in the morbidity and mortality between open and laparoscopic pouch surgery [31]. The laparoscopic approach is commonly used in rectal surgery. Also here, no difference in the morbidity and mortality could be found. Furthermore, recent long-term results failed to show any difference in the recurrence rates and overall survival after rectal surgery for rectal cancer so that the laparoscopic approach does not seem to limit the extent of resection [32–34].

All data indicate that after either anastomotic technique, careful endoscopic surveillance is essential. We highly recommend both proctoscopy and flexible endoscopy since only the combination allows detailed evaluation of the pouch itself as well as of the pouch-anal anastomosis. In addition, we suggest standardised biopsies of the pouch-anal anastomosis also in case of macroscopically unsuspecting findings. The strategy of pouch-anal reconstruction for FAP patients must be critically discussed.

Conclusion

RRM is a crucial problem after IPAA for FAP patients as it bears the risk for the development of rectal cancer. In the present study, RRM and especially wide rectal mucosa seams were found significantly more often after a stapled IPAA. Moreover, the rate of rectal adenomas was significantly higher after a stapled IPAA, although the follow-up interval in this group was significantly shorter. These findings imply a higher risk of subsequent malignant transformation. In case of pre-malignant transformation or wide seams of RRM after a stapled IPAA, secondary mucosectomy may become necessary for FAP patients. Further studies are mandatory to evaluate whether the functional advantage of a stapled anastomosis persists after secondary mucosectomy or whether primary mucosectomy and a handsewn anastomosis should be favoured in FAP patients.

Conflicts of interest None.

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