

Pouch function and quality of life after successful management of pouch-related septic complications in patients with ulcerative colitis

Rudolf Mennigen · Norbert Senninger ·
Matthias Bruewer · Emile Rijcken

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Abstract

Purpose Restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA) for ulcerative colitis is associated with pouch-related septic complications (PRSC) in 10% of patients. This study questioned if PRSC have a negative impact on pouch function and quality of life.

Patients and methods One hundred thirty consecutive patients undergoing IPAA for ulcerative colitis between 1997 and 2009 were reviewed. At 1-year follow-up, patients were asked to complete questionnaires including a pouch function score (Oresland score, 0–16 points, 0 optimum) and two quality of life scores [Short Inflammatory Bowel Disease Questionnaire (SIBDQ), 1–7 points, 7 optimum; Gastrointestinal Quality of Life Index (GIQLI), 0–144 points, 144 optimum].

Results Twelve out of 130 patients (9.2%) undergoing IPAA developed PRSC. These included anastomotic dehiscence (five), pouch leakage (three, one patient had a combined leak), peripouchal abscess (three), pouch-anal fistula (one), and pouch-vaginal fistula (one). Omission of diverting ileostomy was a risk factor for PRSC (OR 4.62, CI 1.17–18.4). PRSC led to four pouch failures (33%), whereas no failure occurred in the control group ($p < 0.001$). Median 3 (range, 1–10) further operations were necessary until the pouch was salvaged or definitively lost. If the pouch was salvaged, functional Oresland score (8.2 ± 1.3 vs. 6.6 ± 0.5 ; $p = 0.127$), SIBDQ (5.0 ± 0.5 vs. 5.5 ± 0.1 ; $p = 0.203$), and GIQLI (95.8 ± 8.4 vs. 107.3 ± 2.6 ; $p = 0.119$) were not significantly inferior to uncomplicated controls.

Conclusions In case of PRSC, even multiple surgical approaches are worthwhile as the outcome of salvaged pouches in terms of function and quality of life is not substantially inferior to patients without septic complications.

Keywords Ileal pouch-anal anastomosis · Ulcerative colitis · Pouch-related septic complications · Quality of life · Function

Introduction

Restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA) is the standard surgical procedure in the management of patients with ulcerative colitis [1]. It allows a complete removal of the diseased colon, avoids permanent ileostomy, and preserves transanal defecation, this leading to high patient satisfaction. Although the number of bowel movements remains increased compared to a healthy control population, functional results of the IPAA procedure usually are very satisfactory [2–4]. In the recent years, several studies documented excellent quality of life after restorative proctocolectomy basically reaching the values of healthy control populations [2, 3, 5–7].

Despite evolving surgical techniques of IPAA, especially the routine use of double-stapling anastomosis and the widespread use of a protective ileostomy, IPAA is still associated with a relatively high morbidity [8, 9]. Life-threatening pouch-related septic complications, such as anastomotic dehiscence, pouch fistula, or peripouchal abscess, occur in approximately 10% of patients [8, 9]. These complications are difficult to manage, and they ultimately lead to a pouch failure in 14–30% of affected

R. Mennigen (✉) · N. Senninger · M. Bruewer · E. Rijcken
Department of General and Visceral Surgery,
University Hospital Muenster,
Waldeyerstr. 1,
48149 Muenster, Germany
e-mail: rudolf.mennigen@ukmuenster.de

patients [10–13]. Pelvic septic complications account for more than half of all pouch failures [14].

But even in patients in whom the pouch is salvaged, pouch-related septic complications might deteriorate pouch function and quality of life. This issue is not clarified yet, as previous studies showed conflicting results on this topic [13, 15–18].

This study aimed to analyze: (1) the surgical management of pouch-related septic complications at our institution and (2) the outcome of this management in terms of pouch salvage, pouch function, and quality of life compared to controls without septic complications.

Patients and methods

Patients undergoing restorative proctocolectomy and IPAA for ulcerative colitis between 1997 and 2009 were extracted from our prospectively maintained Inflammatory Bowel Disease (IBD) database. Patients with Crohn's disease diagnosed after proctocolectomy ($n=2$) were excluded. Patients awaiting scheduled ileostomy closure, meaning that a multistage procedure was yet incomplete, were excluded. Patients with pouch-related septic complications were included in the study group ($n=12$), whereas the remainder of the study population served as controls ($n=118$).

A pouch-related septic complication was defined if patients had one or more of the following complications: anastomotic dehiscence, anastomotic fistula, pouch leakage, pouch fistula, or peripouchal abscess (including cases without detectable leakage from anastomosis or pouch). Fistulas or abscesses occurring later than 1 year after surgery were considered as late complications and were recorded separately. Pouch failure was defined as excision of the pouch or permanent diverting ileostomy.

IPAA was performed as one-stage, two-stage (proctocolectomy and IPAA with diverting ileostomy, ileostomy closure), or three-stage procedures (subtotal colectomy, IPAA with diverting ileostomy, ileostomy closure). The choice for either procedure was made by the responsible surgeon taking into account individual patient risk factors. Since 2008, the one-stage procedure has been abandoned at our institution, and a diverting ileostomy was routinely created at IPAA as we and others could show that omission of a temporary ileostomy is a risk factor for pouch-related septic complications [9].

All pouches were created in a J shape using linear staplers with a limb length of approximately 15 cm. Proctomucosectomy and hand-sewn transanal anastomosis were performed in case of intraepithelial neoplasia in the rectum. A double-stapling anastomosis with a short rectum cuff was the standard procedure for the remainder. During

the study period, a small proportion of procedures was performed laparoscopically ($n=10$). Ileostomy closure was scheduled 3 months after IPAA.

Patients were enrolled in a routine follow-up schedule in our outpatient department. Standard follow-up intervals were every 3 months during the first year, then once a year. Evaluation included interview, clinical examination, and pouch endoscopy. All patient characteristics, in hospital complications, and follow-up data were recorded prospectively in our IBD database. At 1 year after ileostomy closure and implementing of the pouch, patients were asked to complete three questionnaires (Oresland score, Short Inflammatory Bowel Disease Questionnaire, and Gastrointestinal Quality of Life Index).

The modified Oresland score [19] is a validated tool for the assessment of pouch function and consists of 12 categories. The calculation of the score is shown in Table 1. The lower the score, the better the function; 0 points indicate the best function possible.

The Short Inflammatory Bowel Disease Questionnaire (SIBDQ) is a widely accepted and standardized disease-specific health-related quality of life questionnaire for patients with IBD [20]. It is composed of ten items each with seven possible responses resulting in 1–7 points in each item. Averaging the score in all ten items gives a score of 1–7, a score of 7 indicating the highest quality of life. The German version of the SIBDQ has been validated in German IBD patients [21].

The Gastrointestinal Quality of Life Index (GIQLI) by Eypasch et al. [22] is an instrument for measuring the quality of life specifically for patients with gastrointestinal disease. The questionnaire contains 36 items with five response categories resulting in 0–4 points for each item.

Table 1 Functional score (modified Oresland score [19])

	Score (0–16)		
	0	1	2
Bowel movements/day	<5	5	>5
Bowel movements/night	No	>1/week	>2/night
Deferral time <30 min	No	Yes	
Evacuation time >15 min	No	Yes	
Spotting	No	>1/week	
Abdominal pain	No		Yes
Perianal skin irritation	No	Sometimes	Always
Protecting pads daytime	No	>1/week	
Protecting pads nighttime	No	>1/week	
Diet alterations	No	Yes	
Use of antidiarrheals	No	Yes	
Social handicap	No	Yes	

The score is added giving a possible range of 0–144 points with 144 points indicating optimal quality of life.

The significance of differences between groups was evaluated using Fisher's exact test, Mann–Whitney *U* test, and *T* test, as appropriate. Probability values less than 0.05 were considered significant. All calculations were made with the SPSS 17.0 software.

Results

During the study period, 130 patients underwent restorative proctocolectomy for ulcerative colitis including scheduled ileostomy closure. Of these, 12 (9.2%) developed pouch-related septic complications necessitating surgical therapy. The remaining 118 patients served as controls. Details of the study groups are summarized in Table 2.

Pouch-related septic complications, pouch failure

Patients with pouch-related septic complications more frequently had one-stage procedures (50 % vs. 17.8%; $p < 0.022$). Omission of a diverting ileostomy (one-stage procedure) had an odds ratio of 4.62 (95 CI, 1.17–18.40) for the development of septic complications. Other demographic and surgical factors were comparable between both groups.

Pouch-related septic complications were significantly associated with long-term pouch failure (pouch excision or permanent ileostomy; $p < 0.001$). All four pouch failures occurred in the pouch-related septic complication group (failure rate 33.3%).

During long-term follow-up, four patients developed perianal abscesses, and two patients developed late pouch-anal fistulas (occurring later than 1 year after surgery). These late complications were not included in the study group.

Management of pouch-related septic complications

Details of the 12 patients with pouch-related septic complications are given in Table 3. In eight patients, the pouch could be salvaged (66.7%), whereas four patients had pouch failure during long-term follow-up.

Routine endoscopy of the pouch and the anastomosis were done in every patient before demission. If pouch-related septic complications were suspected clinically, pouch endoscopy and computed tomography with contrast enema were performed for the detection of leakages and peripouchal abscesses. Median time until diagnosis of pouch-related septic complications was 14 days (range, 3–56). Most septic complications were diagnosed during the initial hospital stay. However, in patient nos. 4, 6, and 11, the symptoms were initially absent or mild, and the diagnosis was delayed (56, 26, and 20 days, respectively).

Table 2 Demographic data of study population

	Pouch-related septic complications	Controls	<i>P</i> value
Demographic details			
<i>n</i>	12	118	
Male/female	6/6	74/44	0.53
Age (years)	34.5 (21–50)	38.5 (17–73)	0.251
Simple clinical colitis activity index	8.5 (2–12)	8 (2–16)	0.679
Prednisolone dose (mg)	30 (0–60)	20 (0–112.5)	0.379
Immunosuppressive therapy	6 (50%)	40 (33.9%)	0.344
Extraintestinal manifestation	3 (25%)	22 (18.6%)	0.7
Backwash ileitis	0 (0%)	15 (12.7%)	0.358
Body mass index	23.0 (17.6–27.2)	22.8 (15.6–38.8)	0.615
Preexisting diseases	3 (25%)	25 (21.2%)	0.72
Surgical details			
Type of surgery			0.022
One-stage	6	21	
Two-stage	6	81	
Three-stage	0	16	
Laparoscopic surgery	2 (16.7%)	8 (6.8%)	0.231
Hand-sewn anastomosis	3 (25%)	48 (40.7%)	0.364
Outcome			
Follow-up (months)	23.5 (12–75)	25.0 (3–154)	0.67
Pouch failure	4 (33.3%)	0 (0%)	<0.001

Values given as number of patients (percent) or median (range)

Table 3 Details of patients with pouch-related septic complications

Patient	Gender	Age	Diverting ileostomy	Type of anastomosis	Type of pouch-related septic complication	Diagnosis (days)	Management	Follow-up (months)	Outcome
1	Female	38	No	Double-stapling	Anastomotic dehiscence, peritonitis	19	1. Ileostomy, transanal repair of anastomosis; second look laparotomy 2. Ileostomy closure	12	Salvage
2	Female	32	Yes	Hand-sewn	Pouch-vaginal fistula, peripouchal abscess	17	1. CT-guided drainage of peripouchal abscess 2. Transanal/transvaginal fistula repair (3×, with fistula recurrences) 3. Pouch advancement, new anastomosis, vaginal fistula repair 4. Transanal/transvaginal repair of small residual fistula 5. Ileostomy closure 6. Protective ileostomy (fistula recurrence, pregnancy) 7. Transvaginal fistula repair (after delivery) 8. Ileostomy closure (no signs of persistent fistula)	58	Salvage
3	Male	40	No	Double-stapling	Pouch leakage, peripouchal abscess	7	1. Ileostomy, transabdominal pouch repair 2. Ileostomy closure	61	Salvage
4	Male	37	Yes	Hand-sewn	Anastomotic fistula, perianal abscess	56	1. Transanal repair of anastomosis, perianal abscess excision (3×) 2. Ileostomy closure (no signs of persistent fistula) 3. Perianal abscess excision (recurrent abscess) 4. Protective ileostomy 5. Ileostomy closure (no signs of persistent fistula)	21	Salvage
5	Male	31	No	Double-stapling	Peripouchal abscess (no leak detected)	6	1. Transabdominal drainage, ileostomy 2. Transabdominal drainage (recurrent abscess) 3. Ileostomy closure (initially good pouch function) 4. Ileostomy (30 months after ileostomy closure: chronic pouchitis)	76	Failure (initial salvage)
6	Male	50	No	Double-stapling	Peripouchal abscess (no leak detected)	26	1. Transabdominal drainage	23	Salvage
7	Female	26	No	Double-stapling	Anastomotic dehiscence, peripouchal abscess	11	1. Transabdominal drainage, pouch advancement with new anastomosis; ileostomy; second look laparotomy 2. Closure of rectal cuff, pouch-ostomy (recurrent anastomotic dehiscence) 3. Multiple laparotomies (small bowel fistulae due to peritonitis and adhesions; patient recovered with definitive pouch-ostomy)	16	Failure

Table 3 (continued)

Patient	Gender	Age	Diverting ileostomy	Type of anastomosis	Type of pouch-related septic complication	Diagnosis (days)	Management	Follow-up (months)	Outcome
8	Male	46	Yes	Hand-sewn	Pouch leakage, anastomotic dehiscence	3	1. Transabdominal pouch repair 2. Transanal drainage, EndoVac therapy (outpatient basis) 3. Perianal drainage (recurrent peripouchal abscess) 4. Pouch excision (severe chronic pouchitis, insufficient compliance of pouch)	18	Failure
9	Male	45	Yes	Double-stapling	Anastomotic dehiscence, peripouchal abscess	17	1. Transanal drainage 2. EndoVac therapy (outpatient basis) 3. Ileostomy closure (intact anastomosis)	27	Salvage
10	Female	28	No	Double-stapling	Peripouchal abscess (no leak detected)	10	1. Transabdominal drainage, ileostomy; second look laparotomy 2. Ileostomy closure	16	Salvage
11	Female	21	Yes	Double-stapling	Pouch leakage, peripouchal abscess (manifestation after scheduled ileostomy closure)	20	1. Transabdominal pouch repair ileostomy; 2× second look laparotomy 2. Ileostomy closure	27	Salvage
12	Female	27	Yes	Double-stapling	Pouchchanal fistula, peripouchal abscess	7	1. Perianal drainage (no fistula detectable, anastomosis intact) 2. Dilation of anastomosis in anesthesia (2×; detection of pouch-anal fistula) 3. Pouch excision (refractory stenosis due to chronic fistula and perianal inflammation, insufficient compliance of pouch)	24	Failure

There were five anastomotic dehiscences or fistulae, three pouch leakages (patient no. 8 had both anastomotic dehiscence and pouch leakage), one pouch-anal fistula, and one pouch-vaginal fistula. These complications usually were associated with a perianal/peripouchal abscesses or peritonitis. Three patients developed peripouchal abscesses without evidence of a leakage from anastomosis or pouch.

Median 3 (range, 1–10) re-operations were necessary until the pouch was salvaged or definitively lost. Of six

patients that initially had no ileostomy (one-stage procedure), five (83.3%) had a diverting ileostomy created for the control of sepsis.

Anastomotic dehiscences or fistulae were managed by transanal procedures (in part combined with transabdominal drainage) in four of five patients, while one patient (patient no. 7) received transabdominal pouch advancement with new ileal pouch-anal anastomosis. Two of five (40%) patients with anastomotic dehiscences finally had a pouch

Table 4 Functional outcome, quality of life

	Pouch-related septic complications	Controls	<i>P</i> value	Mean difference (95% CI)
Öresland (0–16; 0 optimum)	8.2 (1.3)	6.6 (0.5)	0.127	1.6 (–1.4–4.6)
SIBDQ (1–7; 7 optimum)	5.0 (0.5)	5.5 (0.1)	0.203	–0.5 (–1.9–0.9)
GIQLI (0–144; 144 optimum)	95.8 (8.4)	107.3 (2.6)	0.119	–11.5 (–32.9–9.9)

Values given as mean (SEM)

SIBDQ Short Inflammatory Bowel Disease Questionnaire, *GIQLI* Gastrointestinal Quality of Life Index, *CI* confidence interval

failure. All three cases of proximal pouch leakages were managed by transabdominal pouch repair. Failure rate was 1 of 3 (33.3%).

Three cases of peripouchal abscesses without evidence of a leak were surgically drained from a transabdominal access. Interestingly, in patient no. 5 having a peripouchal abscess without anastomotic dehiscence, pouch salvage was initially successful. The Oresland score was 11, he had seven bowel movements per day, and continence was intact. However, this patient developed relapsing chronic pouchitis with massive deterioration of pouch function, which finally necessitated permanent diverting ileostomy 30 months after pouch salvage. It remains unclear if the postoperative septic complications triggered the chronic pouchitis. The remaining two cases could be salvaged (failure rate 1 of 3, 33.3%).

In patient no. 2, a pouch-vaginal fistula required multiple perineal approaches under coverage of an ileostomy. After an uneventful pregnancy and transvaginal delivery, fistula repair finally was successful, and the ileostomy could be closed.

Finally, in patient no.12, a fistula originating from the distal third of the pouch (with intact anastomosis) led to a chronic inflammatory process with pelvic fibrosis, stenosis of the distal pouch, and insufficient pouch compliance. The pouch was finally excised.

Functional outcome, quality of life after salvage surgery

Questionnaires were completed by all patients with a salvaged pouch in the septic complications group ($n=8$). Twenty-three patients of the uncomplicated control group have not been terminally evaluated yet, thus leaving 95 eligible patients for 1-year follow-up questionnaires. Patients ($N=66$) (69%) of this group completed the questionnaires.

The values for pouch function (Oresland score) and quality of life (SIBDQ and GIQLI), assessed at 1 year after surgery, are summarized in Table 4. There were no significant differences in function or quality of life between the groups. Mean differences between the groups are given with 95% confidence intervals as smaller differences might remain undetected due to the relatively small number of pouch-related septic complications (beta error). The median number of bowel movements per day was 6 (range, 3–13) for the control group and 7 (range, 6–10) for the pouch-related septic complications group ($p=0.377$).

Discussion

Pouch-related septic complications remain a significant issue after restorative proctocolectomy and IPAA. In our series, 9.2% of patients developed pouch-related septic complications. This is in line with the findings of two

recent meta-analyses that calculated a pooled incidence of about 10% [8, 9]. Importantly, this rate seems to stabilize and does not decrease in more recent publications [9]. This means that one out of ten patients will develop a potentially life-threatening septic complication, and every colorectal surgeon performing IPAA procedures will face the surgical management of these patients.

Our data clearly demonstrate that pouch-related septic complications are a significant risk factor for pouch failure. While all four pouch failures occurred in the study group, no pouch failure was observed in the control group. This strong correlation has already been demonstrated by several other studies [11, 13–15, 23, 24].

The omission of a diverting ileostomy (one-stage procedure) was significantly associated with pouch-related septic complications. As a recent meta-analysis could show, a diverting ileostomy can effectively reduce the rate of anastomotic leaks and pelvic sepsis [9]. Therefore, the routine creation of an ileostomy is recommended, and this practice has been adopted by most colorectal surgeons [25]. Including a population of more than 3,000 patients undergoing IPAA at the Cleveland Clinic, Kiran et al. identified a body mass index >30 , final histological diagnosis of Crohn's disease, need for transfusions, and surgical experience as further risk factors for pouch-related septic complications [26]. These factors, however, did not reach significance in our study population probably due to the smaller sample size.

Nowadays, increasing expertise and a multimodal management of pouch-related septic complications allow to salvage an increasing proportion of pouches [10]. The specific therapy of pouch-related septic complications depends on various factors, e.g., the severity of sepsis, presence of a diverting ileostomy, and presence of a leakage at the anastomosis or pouch.

In the case of pouch-related septic complications, patients without diverting ileostomy usually receive parenteral nutrition, and the pouch is drained transanally by a catheter. However, the creation of an ileostomy may be necessary to control the pelvic sepsis. This was the case in five of six patients without initial ileostomy in our series. Perianal or peripouchal abscesses have to be drained. This can be done by interventional, CT-guided drainage, and by transanal or transabdominal surgical drainage. Leaks of the proximal pouch usually mandate a laparotomy and direct pouch repair. The management of anastomotic dehiscences and fistulae includes a wide spectrum of surgical approaches including transanal drainage, transanal repair of the anastomosis, transanal pouch advancement with new anastomosis, and transabdominal approaches, such as pouch advancement, or the formation of a new pouch.

Several centers have published their experience with the management of pouch-related septic complications [10–13].

Although standardized algorithms of management have been proposed [26], surgical approaches are very variable within and between centers [10–13]. The rate of pouch failure after pouch-related septic complication ranges from 14% to 30% in high-volume centers, which is comparable to the pouch failure rate in our series. Both management and outcome are somewhat difficult to compare between different centers as the severity of observed pouch-related septic complications is variable. For example, in the series of Raval et al. from the Mount Sinai Hospital, New York, 100 patients out of 141 could be managed nonoperatively as opposed to 100 % operative management in our series.

In our patient series, many of the abovementioned surgical strategies have been applied. Patients needed median 3 (range, 1–10) operations until final salvage or definitive loss of the pouch. Our experience demonstrates that even after multiple surgical interventions, a final salvage can be achieved.

Our series does not allow any pooled analysis of certain types of pouch-related complications or management modalities as patient numbers were too small. Authors from other high-volume centers, however, have analysed possible factors influencing the outcome. Heuschen et al. reviewed 131 patients with pouch-related septic complications [11]. They demonstrated that the vertical localization of a fistula and the involvement of the anal sphincter had a significant impact on the failure rate. Raval et al. [10] stratified their data of 141 pouch-related septic complications according to the type of complication and the type of management. They demonstrated that less severe cases being managed nonoperatively had a better outcome than cases necessitating surgery. Sagap et al. [12] reviewed a series of 157 patients with pouch-related septic complications at the Cleveland Clinic and identified the following risk factors for a pouch failure: hypertension, hand-sewn anastomosis, need for transanal drainage, need for laparotomy, delayed ileostomy closure, and the need for a new diverting ileostomy.

As pouch salvage surgery is so challenging, it is of great importance to learn about the functional outcome for those patients that finally have their pouch salvaged. Concerns have been raised about a possible bad function and quality of life after salvage surgery [13, 16, 27].

Our results show that pouch function after salvage surgery is comparable to patients without septic pouch complications, although there was a non-significant tendency towards worse postoperative function. In this regard, the Oresland score, which includes various aspects of continence and pouch function, is a well-validated functional score that allows a good discrimination of functional differences. Furthermore, quality of life, as measured by SIBDQ and GIQLI, is not inferior in patients recovering from pouch-related septic complications. Some previous

studies came to the same conclusion [15, 17, 18]. Chessin et al. provided the largest data pool on this topic including 60 patients with pouch-related septic complications [15]. Fecal Incontinence Severity Index score and the Cleveland Global Quality of Life score were not different compared to 314 patients without septic complications [15]. However, other authors found a deterioration of function or quality of life [13, 16]. In a series of 73 patients with pelvic abscesses at the Mayo Clinic [13], several functional parameters and quality of life were significantly poorer than in patients without septic complications. A recent smaller series including nine patients with pouch-related septic complications detected significant decreases in pouch function but not quality of life compared to patients without complications [16].

There are some limitations of our study that need to be addressed. The study group including 12 patients is rather small, thus a minor difference in pouch function or quality of life might remain undetected due to insufficient statistical power. However, the 95% confidence intervals of mean differences provide a reasonable estimation of the true differences. For example, even in the worst case, the deterioration of quality of life should not exceed 1.9 points (SIBDQ, 1–7 points) and 33 points (GIQLI, 0–144 points) in the study group, respectively. This indicates that patients with pouch-related septic complications reach a reasonable pouch function and quality of life, even if it should be gradually inferior to controls.

One has to consider that much of our knowledge about function and quality of life following pouch salvage surgery is derived from studies with identical or even lower patient numbers than in our study [16, 17]. Furthermore, the response to a mailed questionnaire always includes a certain selection bias. The response rate of about 70% in our study is within the generally accepted rate reported in the literature. For the clarification of quality of life and function, no better tool is available at present.

Questionnaires were mailed at 1 year follow-up. At this time point, pouch function and quality of life usually have reached a stable state. Our data on pouch function and quality of life do not allow conclusions concerning long-term results beyond this time point. However, in our experience, all eight patients having their pouches saved after septic pouch-related complications had a stable pouch function and quality of life during further follow-up.

Conclusion

Pouch-related septic complications occur in about 10% of restorative proctocolectomies with IPAA. The management of these complications is demanding and may necessitate multiple surgical approaches, and two of three of pouches

can be salvaged. If salvage is successful, patients reach a reasonable pouch function and quality of life that probably is not substantially inferior to patients without history of pouch-related septic complications. This means that about 96% of patients finally have successful IPAA with satisfactory function and quality of life; this is a useful estimation when informing patients about a planned IPAA procedure.

Conflicts of interest None.

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