

Long-term outcome 10 years or more after restorative proctocolectomy and ileal pouch–anal anastomosis in patients with ulcerative colitis

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Abstract

Purpose The aim of this study was to assess quality of life (QOL) in a long-term follow-up of patients with ulcerative colitis (UC) 10 years and more after ileal pouch–anal anastomosis (IPAA) to correlate these results with pouch function and to assess the long-term pouch failure rate.

Methods In a unicentric study, 294 consecutive patients after IPAA between 1988 and 1996 were identified from a prospective database. QOL was evaluated according to the validated Gastrointestinal Quality of Life Index (GIQLI).

Results Overall median follow-up was 11.5 years. Thirty-seven patients experienced pouch failure (12.6%). The rates of ileal pouch success after 5, 10 and 15 years were 92.3%, 88.7% and 84.5%. According to the GIQLI, patients with a functioning pouch achieved a mean score of 107.8, reflecting a decrease of QOL of 10.8% compared to a healthy population. There were significant negative correlations between QOL and an age of >50 years ($p < 0.05$), pouchitis, perianal inflammation and increased stool frequency ($p < 0.0001$).

Conclusions QOL and functional results of patients with UC 10 years or more after IPAA were acceptable; however,

those were reduced when compared to a healthy population. Pouch failure rate still increases up to 15.5% 15 years after IPAA. This result represents an important issue in providing patients with comprehensive preoperative information.

Keywords Long-term quality of life · Ileal pouch–anal anastomosis · Ulcerative colitis · Pouch failure

Introduction

Restorative proctocolectomy and ileal pouch–anal anastomosis has become the standard surgical treatment for patients with ulcerative colitis (UC) over the past 20 years. The main objectives are elimination of the disease and preservation of faecal continence. The procedure is considered a safe operative technique with acceptable functional results and good postoperative quality of life [1–4]. The functional aim of pouch surgery is to achieve an average of five to six bowel movements per day and complete continence without nighttime evacuation [5].

Complications mostly occur in the first few months after surgery and can usually be managed without impairment of quality of life [3, 4].

However, a number of patients suffer from relevant complications which may result in reduced pouch function and limitation of quality of life. The worst consequence of such complications is pouch failure, which is usually defined as a condition leading to the necessity of a permanent diverting ileostomy or a pouch excision. Two different types of pouch failure can be classified, an early postoperative and a late failure. Early pouch failure is mostly a result of postoperative complications after ileal pouch–anal anastomosis (IPAA), whereas late pouch failure

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is usually associated with persisting poor function due to chronic pouchitis or chronic pelvic sepsis. As shown in a recent meta-analysis, 6.8% of all patients need a permanent ileostomy with or without pouch excision with an increase to 8.5% in a follow-up of at least 5 years [4]. This result indicates the importance of long-term follow-up investigations to assess if pouch failure rates tend to further increase or remain stable 10 years or more after the operative procedure. This seems a crucial factor in the long-term assessment of this surgical technique.

Apart from postoperative morbidity and functional outcome, the evaluation of long-term health-related quality of life (HRQOL) is an important parameter used to evaluate the outcome of the ileoanal J-pouch procedure, especially since it is primarily performed in young patients with normal life expectancy. HRQOL is a multifactorial parameter, which is difficult to measure. It is important to consider psychological, emotional, physical and social aspects together with disease-specific symptoms. We used the multidimensional GastroIntestinal Quality of Life Index (GIQLI), designed by Eypasch and coworkers [6, 7]. This questionnaire is a validated instrument for measurement of health-related quality of life in patients with different chronic gastrointestinal diseases [8, 9].

The identification of factors influencing health-related quality of life is an important tool to discern options for improving quality of life in special subgroups of patients. A former study at our institution showed that the duration of the disease, the Colitis Activity Index, the choice of operative procedure and the presence of neoplasia preoperatively had no significant influence on quality of life 5 years after IPAA [10].

So far, the number of studies addressing specifically long-term postoperative results after restorative proctocolectomy and IPAA is limited. Therefore, we only included patients whose IPAA dates back more than 10 years. These results are essential for the collection of valid information on long-term HRQOL status.

The aim of the present study was to assess long-term results 10 years or more after IPAA in a cohort of UC patients. Health-related quality of life, pouch function and pouch failure rate were analysed. Additionally, the correlation of HRQOL and pouch function was investigated.

Materials and methods

Patients

Since January 1988, the data of all patients with ulcerative colitis undergoing proctocolectomy and ileal pouch–anal anastomosis at the Surgical Department of the University of Heidelberg were entered in a prospective database. Patients

who were operated on between January 1988 and January 1996 were included in the present study. All patients received a J-pouch reservoir; reconstruction was performed by a hand-sewn IPAA and protected by a loop ileostomy in a standardized operative technique [11]. There was no patient who was retrospectively diagnosed of having Crohn's or other diseases on the basis of the histological investigation of their colectomy specimen in this study.

In 2006, all patients included in the study received a disease-specific questionnaire on quality of life by mail. Patients who did not respond were contacted by telephone.

Questionnaires

To measure disease-specific quality of life, the GIQLI designed by Eypasch and coworkers [7] was used. This questionnaire is an accepted and validated instrument for measurement of health-related quality of life in patients with chronic gastrointestinal diseases as reported in a recent review by Borgeonkar and Irvine [8].

The questionnaire consists of 36 questions referring to four different dimensions: symptoms, emotions, physical function and social function. Patients answered on a five-point Likert scale for each item (range 0–144, higher score=better QOL). An average result of 120.8 (SD, 15) points is considered normal in a healthy control group of 150 Germans. The GIQLI discriminates well between patient groups stratified by illness severity. The test–retest reliability as well as internal consistency was shown to be excellent [6]. The GIQLI was developed and validated in both German and English [7].

Patients with a secondary permanent ileostomy filled in an additional section of the questionnaire relating to quality of life with an ileostomy.

Pouch function

To assess pouch function, patients had to answer specific questions regarding stool-regulating medication, stool frequency, stool consistency, anal dermatitis and pouchitis. As an indirect parameter, the patients' working status was asked for.

Pouch failure

Pouch failure was defined as the need for a permanent ileostomy (>2 years) after IPAA or pouch excision.

Statistical analysis

SAS software (Release 9.1, SAS Institute, Inc., Cary, NC, USA) was used for statistical analysis. The GIQLI global and dimensional scores are presented as median with interquartile ranges. Mean values with standard deviation

and a *t*-test were used to compare the GIQLI global score of the study group with that of a healthy group present in literature. The mean values with standard deviation and a *t*-test were used. The differences between the global and the dimensional score values of the two study subgroups (functioning pouch versus permanent ileostomy) were compared using the nonparametric Mann–Whitney *U* test. The relationship between the GIQLI global score and the number of bowel movements was examined using the Spearman rho test with the correlation coefficient and the corresponding *p*-value. To compare subgroups of patients with respect to the GIQLI global score, the Mann–Whitney *U* test (to compare two groups) and the Kruskal–Wallis test (to compare three and more groups) were used. Overall survival and the pouch survival from the date of IPAA were estimated using the Kaplan–Meier method. Five-, 10- and 15-year survival rates are shown. Patients alive at the time of the last follow-up as well as patients lost to follow-up were censored and specifically marked in Fig. 1. Two-sided *p*-values were always computed, and an effect was considered statistically significant at $p < 0.05$.

Results

Patients

There were 294 patients who underwent IPAA for ulcerative colitis in our institution between January 1988 and January 1996 who could be identified from the database. Fourteen patients had died at the time of survey. The median follow-up in this 294 patients' selection was 11.5 years (IQR, 7.5–13.4). There were 280 questionnaires distributed, and 197 patients responded with questionnaires

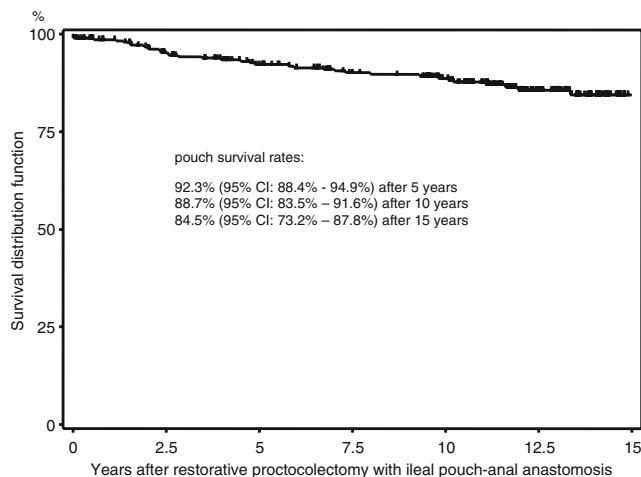


Fig. 1 Pouch survival estimation after IPAA in a time span of 15 years for 294 UC patients with a median follow-up of 11.5 years

that could be analysed corresponding to a response rate of 70.4%. The median follow-up in these 197 patients with utilizable questionnaires was 12.3 years (IQR, 11.3–14.1) and the range was 9.4 to 17.6 years.

In most cases, IPAA was performed as a two-step procedure in an elective setting (66%). Ninety-nine patients (34%) underwent a three-step procedure. The major indication for surgery was lack of response to medical treatment (70.4%). Toxic megacolon and perforation were encountered in 37 patients (12.6%) and dysplasia, DALM or carcinoma in 26 patients (8.8%). Patients' characteristics are listed in Table 1.

Pouch failure

Thirty-seven patients with reported pouch failure (12.6%) were identified in our patient sample. Fifteen patients had their pouch excised (5.1%) and 22 patients had a diverting ileostomy (7.5%) at the time of survey. The reasons for pouch failure were poor function due to chronic pouchitis (35%) and pelvic abscesses or fistulas with and without pouchitis (65%).

In a Kaplan–Meier analysis, the pouch failure rates 5, 10 and 15 years after IPAA were 7.7%, 11.3% and 15.5% (Fig. 1). Median time between the operation and pouch failure among the 37 patients was 4.5 years (IQR, 2.0–9.3). Fifteen of them filled in the questionnaire section on quality of life with a permanent ileostomy.

Table 1 Patients' characteristics

Characteristic	Number
Total	294
Sex, male/female, <i>n</i> (%)	161/133 (55/45)
Median age at operation (IQR, years)	33 (25–45)
Indication for colectomy, <i>n</i> (%)	
Failed medical treatment	207 (70.4)
Colon/rectal stricture	10 (3.4)
Perirectal fistulas	11 (3.7)
Perforation	15 (5.1)
Toxicity	22 (7.5)
Carcinoma	15 (5.1)
Dysplasia	10 (3.4)
Adenoma	1 (0.3)
PSC	1 (0.3)
Drug side effects	2 (0.7)
Surgical procedure, <i>n</i> (%)	
IPAA with temporary ileostomy	195 (66)
Colectomy with Hartmann procedure before IPAA with temporary ileostomy	99 (34)

IQR interquartile range

Pouch function

There was 34% of the patients who required medication for the regulation of bowel function, while 174 patients had answered the questions concerning number of bowel movements. The median number of bowel movements in 24 h was seven (IQR, 5–9; range, 3–20), five at daytime (IQR, 4–7; range, 2–18) and one at night (IQR, 1–2; range, 0–8). Forty-three patients had eight or more stools per 24 h, whereas 131 had fewer defaecations. Sixty-three of the latter subgroup did not have more than four stools every 24 h. There was 32% of the patients who had more than the desired number of bowel movements with more than six defaecations at daytime. Only 10% of the patients had no nighttime evacuation.

Stool consistency was stratified into two different categories, fluid and mushy or formed consistency. One hundred thirty-one patients (75%) reported to have mushy or formed stool consistency; 43 (25%) had fluid stools. Anal dermatitis at the time of investigation was reported by 104 patients (59%). Twenty-eight patients had suffered from an episode of pouchitis in the last 2 weeks (15.5%). Working disability was present in only 28 cases (15%).

Quality of life

The median overall quality of life score in patients with a functioning pouch was 110 (IQR, 93–127), the mean value being 107.8 (SD, 22). In patients with a permanent ileostomy due to pouch failure, QOL decreased to 94 (IQR, 77–116; $p=0.05$). Considering the different dimensions of the GIQLI, this difference was due to a significant decrease in the dimensions emotions, physical functions and social functions ($p<0.05$ each). In contrast, the dimension of symptoms did not differ between patients with a functioning pouch and those with a permanent ileostomy ($p=0.50$) (Table 2).

In comparison to a healthy control group with a mean value of 120.8 (SD, 15), the mean of overall quality of life scores of patients with a functioning pouch was significantly reduced ($p<0.0001$).

Correlation of quality of life with pouch function, age and sex

There was a highly significant negative correlation between overall quality of life and the number of bowel movements at daytime ($r=-0.454$, $p<0.0001$) (Fig. 2) and at night ($r=-0.414$, $p<0.0001$) (Fig. 3). This negative correlation existed in all four dimensions. In further analyses, patients were categorized according to their number of bowel movements at day and night. The QOL overall score in the subgroup of patients with one to four bowel movements during the day did not differ from the overall score of patients with five to six bowel movements ($p=0.50$). QOL overall scores in the subgroup of patients with seven or more bowel movements per day, however, were significantly lower than in both subgroups of patients with one to four and five to six bowel movements per day ($p<0.0001$ and $p<0.0001$, respectively).

There was also a difference in median QOL overall scores of ten score points in the subgroups of patients with no bowel movement at night and one bowel movement, but this difference did not amount to any statistical significance ($p=0.16$). Comparing these two subgroups of patients with those having two or more bowel movements at night, median QOL overall score in the latter group was significantly lower ($p<0.05$ and $p<0.0001$, respectively) (Table 3).

Fluid stool consistency, the need for stool-regulating medication, the presence of anal dermatitis, signs of pouchitis within 2 weeks prior to the investigation and working disability were associated with diminished QOL overall score ($p<0.0001$, $p<0.0001$, $p<0.0001$, $p<0.0001$ and $p<0.0001$, respectively) (Table 3). These negative correlations were highly significant and were reflected in all dimensions of GIQLI.

Moreover, the correlation of GIQLI scores with age revealed a significantly better quality of life for patients of younger age at the time of the survey ($p<0.05$). The group of patients older than 50 years of age had a significantly lower QOL overall score as compared to the group of patients younger than 50 years. Median values of QOL overall scores of female patients were ten points lower

Table 2 Results of the health-related quality of life score (GIQLI) (median values with interquartile ranges) in patients with a functioning pouch and in patients with permanent ileostomy

QoL parameter	Functioning pouch N=182	Ileostomy N=15	<i>p</i> -value
Overall quality of life	108 (93–127)	94 (77–116)	0.0527
Dimensions			
Symptoms	59.5 (52–68)	59 (47–66)	0.5002
Emotions	16 (13–18)	13 (9–17)	0.0309
Physical functions	17 (13–21)	11 (7–17)	0.0031
Social functions	14 (11–16)	12 (7–14)	0.0220

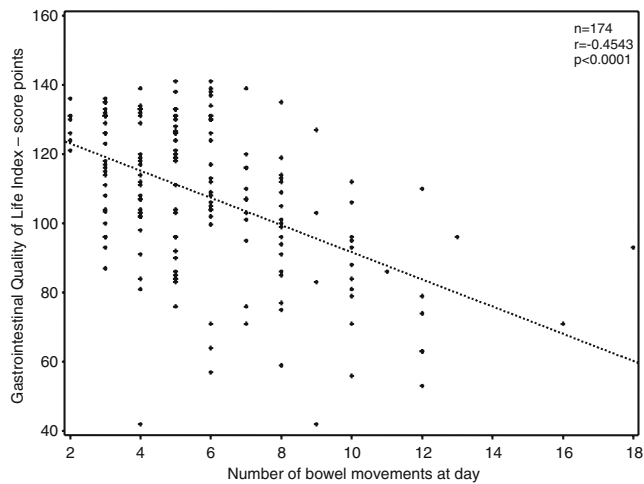


Fig. 2 Correlation of stool frequency at daytime with QOL scores

compared to male patients. This difference, however, did not result in a statistical significance ($p=0.06$) (Table 3).

Discussion

Restorative proctocolectomy with ileal pouch–anal anastomosis has become the standard operative strategy for patients with ulcerative colitis. Apart from the postoperative assessment of morbidity and mortality, the evaluation of postoperative quality of life is an important tool required to assess the success of a surgical technique. Thus, the aim of the present study was to evaluate long-term health-related quality of life, pouch function and pouch failure rates in UC patients who had undergone restorative proctocolectomy with IPAA under standardized conditions more than 10 years before the investigation. Considering the median age at the time of operation of 33 years in our patient sample, the long-term results as measured by the quality of

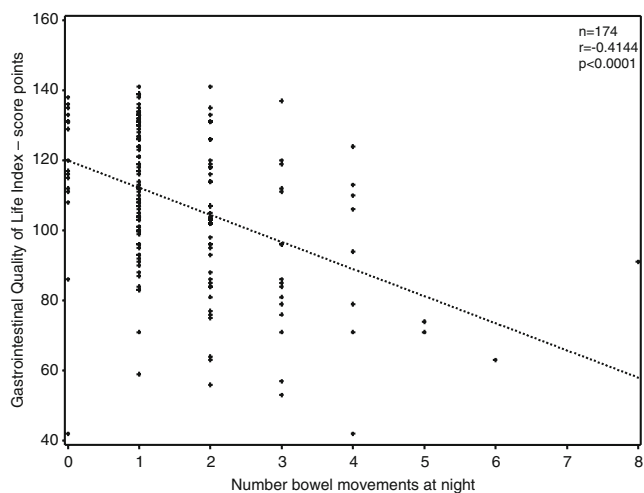


Fig. 3 Correlation of stool frequency at nighttime with QOL scores

life after this major operation as well as the pouch success rate are essential issues relating to the personal and socioeconomic impact of patients. Of the 297 patients identified in our prospective database, 197 responded with analyzable questionnaires which represent an acceptable response rate of 70.4%.

Several former studies have investigated quality of life and functional results after this operation with stable and acceptable results. However, most of them have investigated mixed patient collectives with respect to the follow-up period [4]. To our knowledge, the median follow-up of 151 months in this study is one of the longest reported in the literature to date for patients with ulcerative colitis after IPAA. One study with a comparable long-term follow-up is that of Hahnloser et al. who reported results of patients up to 20 years after IPAA for UC with a mean follow-up of 10.8 years (SD, 5.9) (range 14 days to 23 years) [1]. To avoid a selection bias due to inclusion of patients with short follow-up periods, the present study defined a patient cohort who underwent IPAA at least 10 years or more prior to the survey.

Health-related overall quality of life at least 10 years after IPAA is significantly diminished by 10.2% compared to the quality of life of a general healthy population. In our patients, the median overall QOL score was 107.8 with 120 being considered as normal. Only patients with none or one bowel movement at night which was the case in only 10% of our patient sample (124 and 115 score points, respectively) as well as patients with one to four and five to six bowel movements at daytime (68.2%) (118 and 118.5 score points, respectively) achieved comparable QOL scores. An evacuation frequency of five to six bowel movements at daytime and no bowel movement at night is considered to be the functional aim of pouch surgery [5]. Our data support this hypothesis since this group of patients achieves the highest QOL scores, while those with worse functional results show significantly lower scores.

A comparison of the results of the present study with recently published data of our group [10] reveals that life quality remains rather stable (overall QOL score 5 years after IPAA=110) at a high level over a period of 10 years or more after IPAA. In the present study, the median number of bowel movements was seven in 24 h, one of them occurring at night. These figures are consistent with other reports of large series [1, 12–16] describing stool frequencies between five and nine in 24 h after an initial period of adjustment lasting 12–18 months and remaining constant in the first decade after IPAA. In a recent meta-analysis, the mean defaecation frequency was 5.2 per 24 h with a mean nighttime frequency of 1.0 and a median follow-up of 37.2 months (range, 12–120) [4].

However, Cima et al. reviewed that episodes of incontinence, particularly nocturnal incontinence, increase

Table 3 Correlation of demographic parameters and pouch function with QOL

Parameter	Number	Overall QoL, median (IQR)	<i>p</i> -value
Sex			0.0568
Female	87	104 (87–123)	
Male	95	114 (96–130)	
Age at survey			0.0142
≤30 years	10	118.5 (105–124)	
30–40 years	44	114 (106.5–129.5)	
40–50 years	53	117 (96–130)	
50–60 years	35	96 (84–118)	
≥60 years	40	104.5 (87.5–120)	
Working disability			<0.0001
No	153	114 (98–130)	
Yes	28	89.5 (80–106.5)	
Stool-regulating medication			<0.0001
No	61	100 (83–110)	
Yes	119	117 (101–131)	
Stool consistency			<0.0001
Consistent/mushy	131	115 (101–131)	
Fluid	43	96 (79–108)	
Anal dermatitis			<0.0001
No	71	124 (109–132)	
Yes	104	100.5 (85–117)	
Pouchitis			<0.0001
No	153	114 (99–130)	
Yes	28	87 (76–107)	
Stool frequency at day			<0.0001
1–4	63	118 (104–131)	
5–6	56	118.5 (101–130.5)	
≥7	55	95 (79–109)	
Stool frequency at night			<0.0001
0	18	124.5 (112–131)	
1	84	115 (101–130.5)	
≥2	72	100 (81–115)	

slightly over time [16]. Even with the slight decline in function over time, most patients report a high degree of satisfaction with their ileal pouch function and quality of life [16]. In our analysis, increased stool frequency during the day and night as well as fluid stool consistency, pouchitis, anal dermatitis and the need for stool-regulating medication were significantly correlated with a decrease in quality of life. These parameters represent an impairment of pouch function and identify a subgroup of patients with lower benefit after IPAA.

Another interesting finding is that higher age at survey was significantly correlated with reduced quality of life scores, especially between the ages of 50 to 60. IPAA in older patients is a controversially discussed issue in the literature. There are some studies showing that increasing age is associated with a deterioration of pouch function

after IPAA [15, 17]. However, no significant differences in quality of life at the age of 65 or more are reported, despite a worse functional outcome [2, 3].

Another important objective factor influencing quality of life is the working status of patients with chronic diseases, as working disability does not only influence disease-related concerns but also affects the patients' everyday life. Being on sick leave or disability pension turned out to be the strongest factor associated with decrease in HRQOL in IBD patients [18]. We, therefore, analysed the present working status in correlation with QOL at the time of investigation. Our results show consistent findings with significant reduction of QOL in patients with working disability (15.5% of all patients) in all tested dimensions.

Moreover, the analysis of pouch failure rates is of major interest for the evaluation of long-term results after IPAA.

Pouch failure is an uncommon event that occurs either early in the first two postoperative years due to technical complications or later due to severe pouch dysfunction. The main reason for early pouch failure is pelvic sepsis due to fistulae or abscesses. Late failure due to severe pouch dysfunction regularly leads to increased stool frequency, incontinence or perianal irritations and may be the result of chronic pouchitis or the accidental diagnosis of Crohn's disease after the operation [1, 4, 5, 16, 19]. Pouch failure rates in the literature range from 1% up to 20% in different time periods [1, 15, 19–29]. In the meta-analysis of Huetting et al., the pooled pouch failure rate was 6.8% and increased to 8.5% after 5 years [4]. In our patient sample, pouch failure rate with permanent proximal diversion or pouch excision after 5 years was 7.7%, increasing to 11.3% after 10 years and 15.5% after 15 years. Pouch excisions were necessary in 5.1% of these patients. The reasons for pouch failure were pouchitis, incontinence, pelvic abscesses or fistulae. Pouch failure after more than 10 years was mainly attributed to long-standing pouch dysfunction in patients with chronic pouchitis and/or persisting or recurrent pouch–anal fistulae. On the one hand, pouch failure rates in the literature seem to have significantly decreased with increasing experience of surgeons and the technical development of this operation in the last decade; on the other hand, this study shows that pouch failure rates may still increase beyond 10 years after IPAA. This result is in contrast to the results of Hahnloser et al. who reported pouch failure rates of 6% at 10 years as well as 20 years after IPAA [1].

The QOL of patients with a secondary permanent ileostomy due to pouch failure with or without pouch excision was significantly reduced with a median score of 94. Interestingly, there was no significant difference in the dimension “symptoms” but in all other dimensions as emotions, physical and social functions. In contrast, patients receiving a primary ileostomy before IPAA have a significantly improved QOL in comparison to preoperative results—comparable to QOL of patients receiving primary IPAA [10]. These findings suggest that not the ileostomy itself but the conditions leading to pouch failure and the creation of a secondary ileostomy, i.e., long-standing or recurrent chronic pouchitis and perianal fistulas, lead to the impairment of QOL. Thus, it seems important to define the management guidelines for the improvement of the condition of the subgroup of patients with pouch failure. In some cases, pouch salvage surgery can be performed in experienced centres with good results [30–32].

From our long-term results presented here, we can conclude that for patients with UC restorative proctocolectomy with ileal pouch–anal anastomosis is an appropriate surgical procedure, with acceptable long-term functional results and an acceptable quality of life, although the latter parameter is reduced when compared to a healthy general

population. Only 15.5% of all patients have the status of being incapable of working. Considering the QOL impairment of CU patients prior to surgery [10], QOL in general cannot be considered to be normal, as was concluded by Lichtenstein et al. [3]. In 42.9% of our patient sample, the QOL score of 115 and more was comparable to that of a healthy general population.

Especially for young patients, there is a clear indication for this surgical technique, whereas the indication for older patients with worse QOL results should be considered carefully. Furthermore, our data revealed that patients who need ileostomy diversion because of pouch complications have a significantly reduced quality of life in comparison to patients with functioning pouches. This result emphasizes the need for a competent pouch complication management. Treatment options, especially for patients with long-standing chronic pouchitis and pouch–anal or pouch–vaginal fistulas, are important issues that should be investigated in future studies. Besides, patients with an increased stool frequency, anal dermatitis, pouchitis, fluid stools and the need for stool-regulating drugs should be identified and actively managed in regular follow-up investigations since these factors seem to have a major negative influence on quality of life in the long run.

Additionally, an interesting result of this analysis is the still increasing pouch failure rate between 10 and 15 years after surgery. The analysis of pouch failure rates represents an important issue in providing patients with comprehensive preoperative information.

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