

Results at up to 20 years after ileal pouch–anal anastomosis for chronic ulcerative colitis

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Background: Ileal pouch–anal anastomosis (IPAA) is performed routinely for chronic ulcerative colitis.

Methods: Using data from a prospective database and annual standardized questionnaires, functional outcome, complications and quality of life (QoL) after IPAA were assessed.

Results: Some 1885 IPAA operations were performed for chronic ulcerative colitis over a 20-year period (mean follow-up 11 years). The mean age at the time of IPAA was 34.1 years, increasing from 31.2 years (1981–1985) to 36.3 years (1996–2000). The overall rate of pouch success at 5, 10, 15 and 20 years was 96.3, 93.3, 92.4 and 92.1 per cent respectively. Mean daytime stool frequency increased from 5.7 at 1 year to 6.4 at 20 years ($P < 0.001$), and also increased at night (from 1.5 to 2.0; $P < 0.001$). The incidence of frequent daytime faecal incontinence increased from 5 to 11 per cent during the day ($P < 0.001$) and from 12 to 21 per cent at night ($P < 0.001$). QoL remained unchanged and 92 per cent remained in the same employment. Seventy-six patients were eventually diagnosed with indeterminate colitis and 47 with Crohn's disease.

Conclusion: IPAA is a reliable surgical procedure for patients requiring proctocolectomy for chronic ulcerative colitis and indeterminate colitis. The clinical and functional outcomes are excellent and stable for 20 years after operation.

Presented to the Fifth Annual Meeting of the European Association of Coloproctology, Geneva, Switzerland, October 2004, and published in abstract form as *Colorectal Dis* 2004; 6(Suppl 2): 1

Paper accepted 5 December 2006

Published online 15 January 2007 in Wiley InterScience (www.bjs.co.uk). DOI: 10.1002/bjs.5464

Introduction

Because the goals of eliminating disease and preserving faecal continence are achieved in most patients, restorative proctocolectomy with ileal pouch–anal anastomosis (IPAA) has become the accepted surgical procedure for chronic ulcerative colitis. Since the initial description of the procedure by Parks and Nicholls in 1978¹, several studies have shown that IPAA is a safe and effective operation for chronic ulcerative colitis^{2–8}; bowel function is acceptable, and quality of life (QoL) is good and comparable to that of the general population⁹. Whether these outcomes remain stable over time is unknown. Several studies have examined short-term and limited long-term functional results^{4–7}. Although many have concluded that the short-term functional results are satisfactory and remain constant, others have suggested that function deteriorates

over time. Because patients undergoing IPAA are young and have a life expectancy of 40–50 years after operation, determining function over the longer term is important. The aim of this study was to evaluate the success of IPAA in terms of functional outcome, QoL and durability of results.

Patients and methods

During the 20 years between January 1981 and December 2000, 1885 patients with a preoperative diagnosis of chronic ulcerative colitis underwent IPAA at the Mayo Clinic. Data files were created for each patient in which all preoperative, postoperative and follow-up information was recorded prospectively by an independent observer. Preoperative data included daily stool frequency and sexual function,

and follow-up data included stool frequency, degree of continence, ability to discriminate stool from gas, use of medication and pads, and sexual and urinary abnormalities. Follow-up began 1 year after closure of the ileostomy and was conducted yearly by mailed questionnaire. A data clerk conducted follow-up; surgeons did not participate. Follow-up information is current to January 2005. One, 23, 44, 66 and 74 patients had died by 1, 5, 10, 15 and 20 years of follow-up respectively and corresponding response rates to the questionnaires were 80, 72, 73, 64 and 54 per cent. For analyses comparing diagnosis groups and calendar year of initial surgery, most recent follow-up data were used. For analyses comparing follow-up times, the follow-up closest to the target date within the defined time window was used. If a patient did not return a survey during the time window, the patient had no data included in that interval.

QoL data were acquired by asking patients to enumerate in what manner the operation affected the following 'activity' or 'performance' categories: sport, sexual and social activities, recreation, work around the house, family relationships and travel.

Although it remains difficult to quantify and define precisely, faecal incontinence during the day and night was recorded as never, occasional (one or two episodes per week) or frequent (more than two episodes per week). Pouchitis is a poorly understood syndrome characterized clinically by sudden increased frequency of loose, watery and sometimes bloody stools, faecal urgency, incontinence, lower abdominal cramping, malaise and fever. Although it is preferable to perform endoscopy and biopsy in patients with suspected pouchitis, the authors consider that a patient has pouchitis if symptoms (watery diarrhoea, haematochezia, fatigue and fever) are present for 2–3 days, and such symptoms are alleviated promptly (within 24 h) by administration of metronidazole or ciprofloxacin².

Nearly all patients underwent a two-stage operation. The first stage consisted of abdominal colectomy, complete mobilization of the small bowel mesentery and complete rectal mobilization using a close rectal resection technique. The terminal 24–30 cm of ileum was used to construct an ileal reservoir (1824 J pouch, 44 S pouch and 17 W pouch). The IPAA was completed either by excision of the anal transition zone (ATZ) and handsewing the pouch to the dentate line area, or by preserving the ATZ and double-stapling the pouch to the dentate line. A diverting ileostomy was performed in 98.4 per cent of patients (30 patients had a one-stage procedure). The second stage of the operation, that is closure of the diverting stoma, was accomplished 2–3 months later (mean(s.d.) 3.4(2.9) months). Only nine patients had an emergency operation; all other patients had elective surgery.

Statistical analysis

Patient subgroups defined by year of IPAA and age at IPAA were compared using ANOVA for outcomes with continuous data, and χ^2 tests with ridit scores for discrete, ordinal data. Long-term complications, including pouch failure, were analysed as time-to-event outcomes; the cumulative probability of remaining free from specific complications was estimated using the method of Kaplan and Meier, and survival curves were compared with the log rank test. All statistical tests were two sided and $P < 0.050$ was considered significant. Statistical analysis was performed using SAS version 8.2 (SAS Institute, Cary, North Carolina, USA) and Splus version 6.2 (Insightful Corporation, Seattle, Washington, USA).

Results

The mean(s.d.) age of the 1885 patients at the time of IPAA was 34(11) (range 12–68) years. There were 1023 men and 862 women. The mean number of stools per day before IPAA was 9.5 (range 1–35). Sexual activity before operation was graded as normal in 82 per cent of patients, reduced because of the disease in 8 per cent and absent in 10 per cent. The probability of a successful outcome at 5, 10, 15 and 20 years was 96.3, 93.3, 92.4 and 92.1 per cent respectively.

Functional outcome over time

The mean(s.d.) follow-up was 10.8(5.9) years (range 14 days to 23 years). Stool frequency during the day increased slightly from a mean(s.d.) of 5.7(2.3) at 1 year to 6.4(3.0) at 20 years ($P < 0.001$), whereas night-time frequency increased from 1.5(1.2) to 2.0(1.4) ($P < 0.001$) (Table 1).

At 1 year, 71 per cent of patients never experienced any daytime faecal incontinence. By 10 years this proportion had decreased to 60 per cent, and remained similar at 15 and 20 years (Fig. 1). This decrease in perfect continence was accompanied by an increase in occasional and a smaller increase in frequent episodes of daytime faecal incontinence. Faecal incontinence at night also worsened over time; 43 per cent of patients never had incontinence at 1 year, but this decreased to 32 per cent by 20 years (Fig. 1). The decrease in perfect night-time continence was accompanied mainly by an increase in frequent faecal incontinence. The percentage of patients who recorded their stools as liquid increased over the 20-year period from 7 to 12 per cent, whereas the percentage who described their stools as solid decreased from 31 to 16 per cent.

Table 1 Functional outcome of 1885 patients operated on for chronic ulcerative colitis at 1, 5, 10, 15 and 20 years of follow-up

| | Follow-up (years) | | | | | P* |
|------------------------------------|-------------------|------|------|------|------|---------|
| | 1 | 5 | 10 | 15 | 20 | |
| No. of patients | 1511 | 1306 | 1035 | 637 | 251 | |
| Mean age (years) | 35.2 | 39.4 | 43.8 | 49.1 | 53.8 | |
| Mean stool frequency | | | | | | |
| Per day | 5.7 | 5.7 | 5.8 | 6.2 | 6.4 | < 0.001 |
| Per night | 1.5 | 1.5 | 1.7 | 2.0 | 2.0 | < 0.001 |
| Stool consistency (% of patients) | | | | | | |
| Liquid | 7 | 7 | 9 | 11 | 12 | < 0.001 |
| Semiliquid | 62 | 71 | 74 | 73 | 72 | |
| Solid | 31 | 23 | 17 | 16 | 16 | |
| Can distinguish gas from stool (%) | 76 | 78 | 75 | 74 | 76 | 0.241 |
| Pad use (%) | 34 | 29 | 31 | 43 | 50 | < 0.001 |
| Medication use (%) | 53 | 47 | 44 | 44 | 49 | < 0.001 |

*ANOVA test for continuous data, χ^2 test for discrete data.

Despite these changes, the proportion of patients using medication to alter transit (stool bulking agents, loperamide, Lomotil® (Pfizer, New York, NY, USA) and Questran™ (Bristol-Meyers Squibb, Hounslow, UK)) remained stable at about 50 per cent throughout the follow-up. Importantly, the ability of the patients to discriminate stool from gas remained constant at approximately 75 per cent (Table 1).

Table 2 Functional outcome of 1885 patients operated on for chronic ulcerative colitis by time period of operation

| | 1981–1985 | 1986–1990 | 1991–1995 | 1996–2000 | P* |
|------------------------------------|-----------|-----------|-----------|-----------|---------|
| No. of patients | 431 | 557 | 470 | 427 | |
| Mean age at surgery (years) | 31.2 | 33.7 | 35.4 | 36.3 | < 0.001 |
| Mean follow-up (years) | 16.8 | 13.1 | 8.8 | 5.0 | < 0.001 |
| Mean stool frequency after IPAA | | | | | |
| Per day | 6.4 | 6.1 | 6.2 | 6.4 | 0.232 |
| Per night | 2.1 | 2.0 | 2.0 | 2.1 | 0.473 |
| Incontinence during day (%) | | | | | |
| Never | 57 | 54 | 64 | 70 | < 0.001 |
| Occasional | 31 | 35 | 26 | 21 | |
| Frequent | 11 | 11 | 10 | 9 | |
| Incontinence during night (%) | | | | | |
| Never | 30 | 29 | 34 | 37 | 0.063 |
| Occasional | 48 | 48 | 48 | 41 | |
| Frequent | 21 | 23 | 18 | 22 | |
| Stool consistency (% of patients) | | | | | |
| Liquid | 12 | 11 | 12 | 12 | 0.941 |
| Semiliquid | 70 | 72 | 70 | 69 | |
| Solid | 18 | 17 | 17 | 19 | |
| Can distinguish gas from stool (%) | 77 | 74 | 67 | 67 | 0.002 |
| Pad use (%) | 46 | 44 | 39 | 44 | 0.194 |
| Medication use (%) | 50 | 45 | 43 | 51 | 0.054 |

IPAA, ileal pouch–anal anastomosis. *ANOVA test for continuous data, χ^2 test for discrete data.

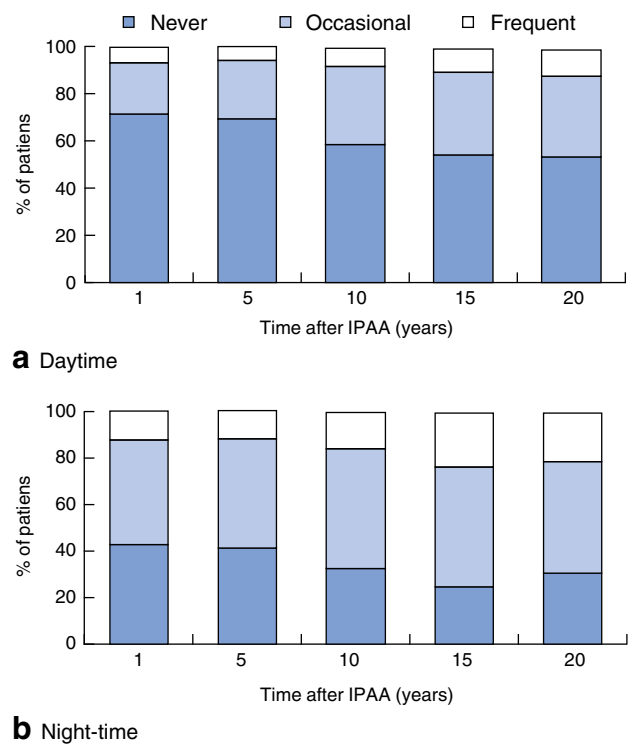


Fig. 1 a Daytime and b night-time faecal incontinence according to time after ileal pouch–anal anastomosis (IPAA). Never, perfect faecal continence; occasional, faecal spotting on underclothes once or twice per week; frequent, more than two episodes per week

Functional outcome by 5-year time periods

The functional outcome of the 1885 patients grouped by 5-year period of IPAA surgery is summarized in *Table 2*. The mean(s.d.) age of patients at the time of the operation increased from 31.2(8.9) years (1981–1985) to 36.3(12.1) years (1996–2000). At last follow-up, the mean numbers of stools per day and per night were comparable. Rates of frequent incontinence remained stable over the different time periods.

Age and functional outcome

At last follow-up, 112 patients were aged 65 years or more (mean(s.d.) 69(3.9) (range 65–80) years). Their mean(s.d.) age at the time of IPAA was 56.6(5.8) (range 42–68) years. Daytime and night-time stool frequencies were excellent at 6.1 and 2.6 respectively. Incontinence was described as absent in 55 per cent of patients, occasional in 35 per cent and frequent in 10 per cent during the day; respective proportions at night were 25, 50 and 25 per cent. Stool consistency was solid in 23 per cent of patients and liquid in 12 per cent; 69 per cent of patients were able to discriminate gas from stool. However, a higher proportion required stool-regulating medication (59 per cent) or pads (68 per cent).

Functional outcome and change of diagnosis

Among the 1885 patients operated on for chronic ulcerative colitis, 76 had indeterminate colitis diagnosed after surgery and 47 eventually had Crohn's disease diagnosed. Patients with indeterminate colitis had a much higher chance of having Crohn's disease diagnosed at some point in the postoperative course (15 per cent) than did those with chronic ulcerative colitis (2 per cent). Overall, functional outcome was best in patients with chronic ulcerative colitis and worst in those with Crohn's disease. Patients with Crohn's disease reported higher rates of frequent daytime incontinence than those in the other two groups (*Table 3*). Patients with Crohn's disease or indeterminate colitis reported a higher number of daytime stools than those with chronic ulcerative colitis (*Table 3*).

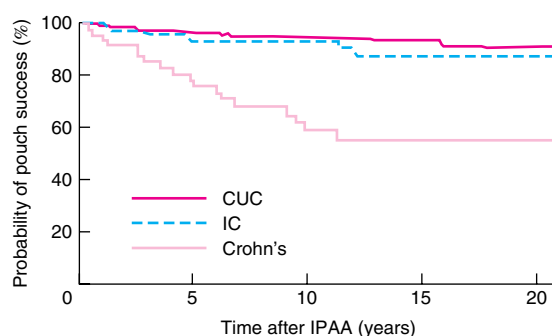
Complications and pouch failure

The final postoperative diagnosis not only influenced functional results, but also rates of pouch failure and complications. Pouch success was highest in patients with chronic ulcerative colitis, with 96, 94 and 94 per cent of patients having a functioning ileal pouch in place at 5,

Table 3 Functional outcome of 1885 patients operated on for chronic ulcerative colitis grouped by final postoperative diagnosis

| | Final diagnosis | | | P* |
|------------------------------------|-----------------|------|---------|-------|
| | CUC | IC | Crohn's | |
| No. of patients | 1762 | 76 | 47 | |
| Mean age at surgery (years) | 34.3 | 31.9 | 31.4 | 0.03 |
| Mean follow-up (years) | 11.2 | 11.9 | 10.2 | 0.33 |
| Mean stool frequency after IPAA | | | | |
| Per day | 6.2 | 7.0 | 7.1 | 0.007 |
| Per night | 2.0 | 2.5 | 2.1 | 0.041 |
| Incontinence during day (%) | | | | |
| Never | 61 | 47 | 55 | 0.010 |
| Occasional | 29 | 39 | 26 | |
| Frequent | 10 | 14 | 19 | |
| Incontinence during night (%) | | | | |
| Never | 32 | 29 | 31 | 0.621 |
| Occasional | 47 | 49 | 48 | |
| Frequent | 21 | 22 | 21 | |
| Stool consistency (% of patients) | | | | |
| Liquid | 12 | 11 | 21 | 0.962 |
| Semiliquid | 71 | 72 | 53 | |
| Solid | 17 | 17 | 26 | |
| Can distinguish gas from stool (%) | 71 | 76 | 62 | 0.263 |
| Pad use (%) | 43 | 46 | 47 | 0.824 |
| Medication use (%) | 46 | 53 | 56 | 0.262 |

CUC, chronic ulcerative colitis; IC, indeterminate colitis; IPAA, ileal pouch–anal anastomosis. *ANOVA test for continuous data, χ^2 test for discrete data.



| No. at risk | | | | | |
|-------------|------|------|-----|-----|-----|
| CUC | 1684 | 1404 | 963 | 529 | 163 |
| IC | 74 | 74 | 49 | 27 | 9 |
| Crohn's | 44 | 33 | 20 | 12 | 7 |

Fig. 2 Kaplan–Meier curves showing the probabilities of pouch success with time after ileal pouch–anal anastomosis (IPAA) in patients with an eventual diagnosis of chronic ulcerative colitis (CUC), indeterminate colitis (IC) or Crohn's disease

10 and 20 years of follow-up. Results were similar in patients with indeterminate colitis (93, 93 and 88 per cent respectively). However, in patients with Crohn's disease, the proportion of patients with a functioning ileal pouch

was much smaller (76, 59 and 55 per cent) ($P < 0.001$) (Fig. 2).

The principal complication after IPAA was pouchitis. The 10-year rate of pouchitis was 48 per cent in patients with chronic ulcerative colitis, 49 per cent in those with indeterminate colitis and 56 per cent in patients with Crohn's disease. This rate increased to 70 per cent for chronic ulcerative colitis, 78 per cent for indeterminate colitis and 83 per cent for Crohn's disease by 20 years. Abscesses and fistulas, other typical pouch-related complications, were most frequent in patients with Crohn's disease. The abscess rate at 20 years was 16 per cent for patients with chronic ulcerative colitis, 29 per cent for those with indeterminate colitis and 40 per cent for patients with Crohn's disease ($P < 0.001$). Fistula rates at 20 years were 14, 18 and 73 per cent respectively ($P < 0.001$). Both complications were also the principal cause of pouch failure. Pelvic sepsis, the primary cause of pouch failure in all patients, occurred in one of two settings: early in the post-operative course, probably secondary to a postoperative complication, or some years after operation, the principal cause being Crohn's disease. Episodes of small bowel obstruction occurred in approximately 35–40 per cent at 20 years, with similar probability among the three diseases (chronic ulcerative colitis 42 per cent, indeterminate colitis 33 per cent, Crohn's disease 38 per cent; $P = 0.83$). Strictureing of the anastomosis also occurred with similar probability at 20 years (chronic ulcerative colitis 39 per cent, indeterminate colitis 48 per cent, Crohn's disease 79 per cent; $P = 0.14$). Strictures were usually found early and dealt with by simple dilatation. The numbers of patients in whom handsewn and stapled anastomoses could be compared was small (stapled IPAA was not introduced until 1997) and so no meaningful observations could be made.

Quality of life and satisfaction

QoL after IPAA in terms of various activities is shown in Fig. 3. Severe restriction was observed in very few patients. Restriction in sexual activities was minor or severe in 17 and 5 per cent respectively, at last available follow-up. More women than men described sexual problems ($P < 0.001$). Ninety-two per cent of patients had remained in the same employment and work was not affected by the surgery in 83 per cent. Diet was unchanged in 56 per cent of patients or slightly more restricted in 44 per cent, with a slight difference between men (41 per cent) and women (47 per cent) ($P = 0.01$).

Discussion

When proctocolectomy is indicated for chronic ulcerative colitis, IPAA is the operation preferred by patients, gastroenterologists and surgeons. As the operation has evolved and techniques such as double-stapling and laparoscopy have been introduced, older, larger and sicker patients have more frequently been offered the option of IPAA. In this large group of patients the results were remarkably stable over time; 92 per cent of patients had a functioning pouch at 20 years after IPAA. This study therefore confirms and extends earlier observations that IPAA is safe and appears to achieve stable function over time^{2,3,10}.

The overall rate of pouch success at 5, 10, 15 and 20 years was 96, 93, 92 and 92 per cent respectively. Pelvic sepsis was the primary cause of pouch failure, occurring in about 5 per cent of patients¹¹. Tulchinsky *et al.*¹² reported a cumulative failure rate of 9 per cent at 5 years and 13 per cent at 10 years. Seventy-five per cent of failures occurred after 1 year and were caused by pelvic sepsis in 80 per cent of patients. In a multivariate analysis of 494 patients with chronic ulcerative colitis who had IPAA, Heuschen *et al.*¹³ found that the risk of pouch-related septic complications depended significantly on the presence and dose of long-term corticoid medication at the time of IPAA. In another study, the cumulative probability of pouch failure was 7 per cent at 10 years and strongly correlated with fistula formation¹⁴.

In this study, time since surgery had little adverse impact on the number of bowel movements during the day (mean 6.4) or night (mean 2.0) at 20 years. However, episodes of faecal incontinence were more common after 10 years than in the first 5 years after IPAA. The number of patients with perfect continence during the day or night declined, but remained relatively stable from 10 to 20 years. The type of incontinence likewise changed: daytime faecal incontinence was manifested by increased occasional spotting, but at night frequent incontinence was observed more often. Other authors have shown a similar decline in perfect continence to about 50 per cent at 10 years^{4,6,15}. Whether faecal continence will remain stable or not after 20 years is unclear. What is known is that sphincter strength decreases with age¹⁶, and that occult obstetric sphincter injuries become manifest¹⁷ and irritable bowel syndrome becomes more common with age¹⁸. These observations imply that anal sphincter competence will continue to be challenged as patients with an IPAA age.

When patients aged more than 55 years of age at the time of surgery were compared with younger patients (less than 45 years), several authors reported no significant difference in functional outcome or pouch-related complications^{2–4,19,20}. Moreover, Delaney *et al.*²¹ reported

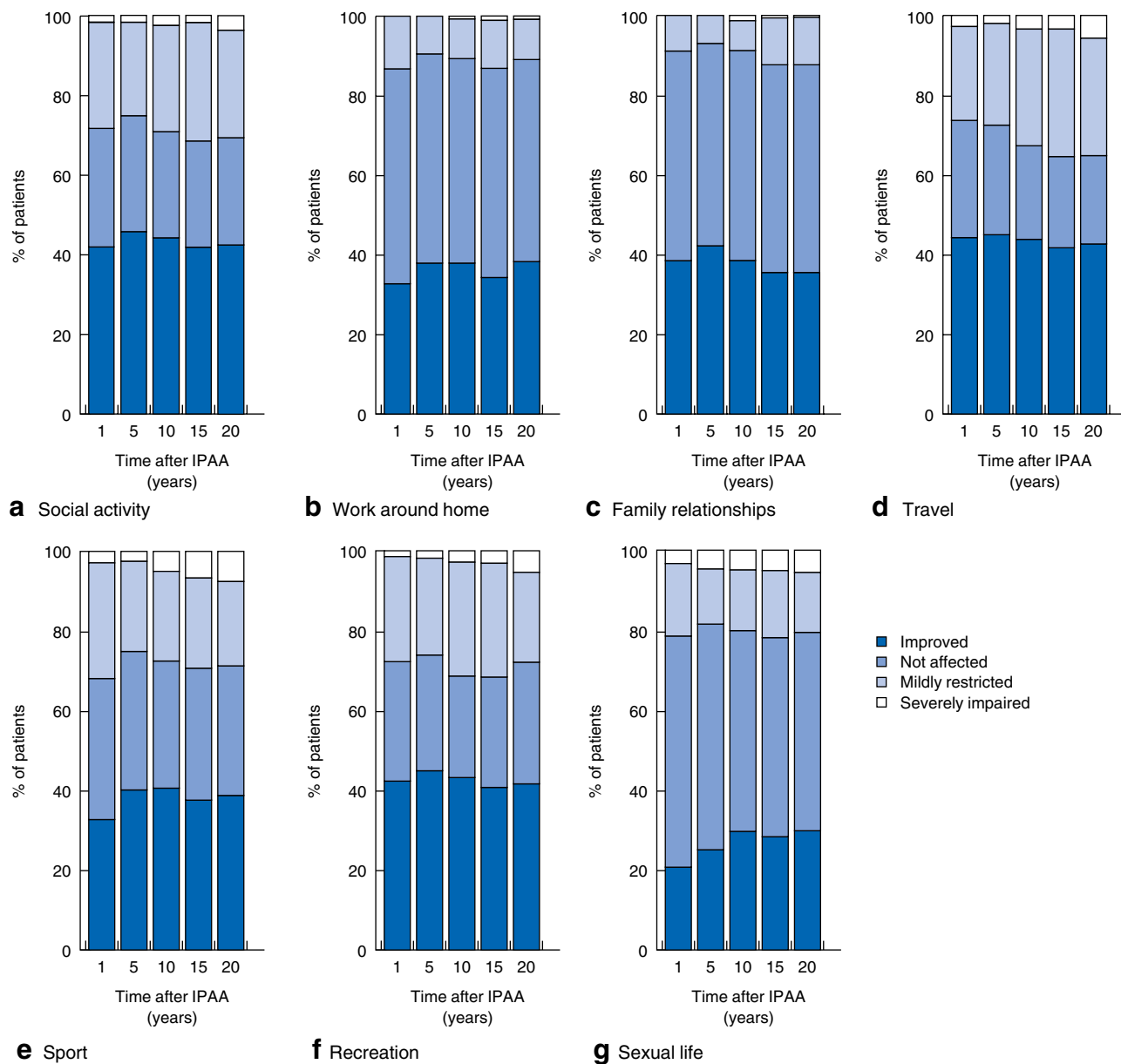


Fig. 3 Quality of life results in relation to **a** social activities, **b** work around home, **c** family relationships, **d** travel, **e** sport, **f** recreation and **g** sexual life after ileal pouch-anal anastomosis (IPAA)

recently that IPAA may be an acceptable surgical option even for healthy, motivated septuagenarians. In the present study, among the 112 patients older than 65 years at last follow-up, stool frequency increased marginally and both daytime and night-time continence deteriorated slightly.

Patients in this study in whom indeterminate colitis was diagnosed had a pouch failure rate comparable to that in patients with chronic ulcerative colitis. Those subsequently diagnosed with Crohn's disease had a much

higher risk of failure^{22,23}. Because of these findings and those of others²⁴⁻²⁷, the authors have not offered IPAA to patients with a preoperative diagnosis of Crohn's disease despite some reports that such patients do well^{28,29}. Indeed, patients who develop Crohn's disease of the pouch experience frequency, incontinence, bleeding, peripouch and perianal abscess, and fistulas and sinuses. This leads to pouch removal in about 50 per cent of patients^{26,30}. However, Remicade® (Centocor Inc., Malvern, PA, USA)

and Imuran® (Prometheus Laboratories, Greenville, NC, USA) hold some promise in the management of patients with these complications³¹.

Although it is preferable to perform endoscopy and biopsy in patients with suspected pouchitis, up to 70 per cent of patients in this study had pouchitis at some point, defined as watery diarrhoea, haematochezia and fever for 2–3 days that responded well to antibiotics. Nearly all of these patients have only one or two episodes. Chronic unrelenting pouchitis occurs in less than 5 per cent of patients. Importantly, episodes of pouchitis are typically quite short and did appear not to alter overall QoL and functional results. The incidence of pouchitis ranges from as low as 12 per cent to more than 50 per cent^{2,3,32–34}. Although patients with extraintestinal manifestations of chronic ulcerative colitis are more likely to develop pouchitis than those without, no other factors are predictive of pouchitis. Interestingly, a recent study of 22 patients with antibiotic-dependent or antibiotic-refractory pouchitis showed a possible association between use of non-steroidal inflammatory drugs and pouchitis³⁵. Another study found a genetic marker, the *interleukin 1 receptor antagonist* gene allele 2, to predict the development of pouchitis; however, such tests are not readily available³⁶.

QoL has become an important measure of operative outcome, perhaps because more conventional measures of quality such as morbidity and mortality have declined steadily. Many attempts have been made to define and assess QoL³⁷. Because there are no generally accepted QoL measurements after surgery for chronic ulcerative colitis in general, or after IPAA in particular, most studies use a combination of validated general QoL scores and simple wellbeing questions^{4,7,9}. All patients in this study enjoyed an excellent QoL after IPAA, with good health and good performance scores in all categories, confirming findings of other studies^{7,9,15,38,39}. It has been reported that patients with an IPAA have a better QoL than those with a Koch pouch or Brooke ileostomy⁴⁰. Although the methodology used to determine the impact of IPAA on QoL in this study has not been validated, the same questions have been asked in the same manner every year for more than 20 years, so trends towards improvement or deterioration would be expected if significant changes occurred. Improvement in QoL is sustained in the same patients for 15 years after IPAA³.

IPAA for chronic ulcerative colitis achieves the goals of eradicating the disease, protecting the patient from future malignant disease and, most importantly because patients are for the most part young, preserves reliable control of stool function and QoL. The long-term results of this large study demonstrate that the clinical and functional

outcomes after IPAA are excellent and stable for 20 years. IPAA has matured into a reliable and preferred operation for chronic ulcerative colitis, but patients with Crohn's disease do not fare as well.

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