Int Surg 2016;**101:**202–211
DOI: 10.9738/INTSURG-D-15-00224.1

Long-Term Functional Outcome and Quality of Life After Restorative Proctocolectomy With Mucosectomy and Hand Suture IPAA: 20 Years' Experience in 326 Patients

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This paper was designed to evaluate the functional outcome and assess the long-term quality of life (QoL) of patients who underwent restorative proctocolectomy with mucosectomy and hand suture ileal pouch-anal anastomosis (IPAA) over 20 years. Restorative proctocolectomy with IPAA is the surgical treatment of choice to all familial adenomatous polyposis (FAP) patients and those with ulcerative colitis (UC) not responding to conservative management. The procedure has been modified from a transanal hand-suture IPAA after mucosectomy to a stapled IPAA without mucosectomy, but the benefits are still debatable. We studied retrospectively all UC and FAP patients subjected to the procedure between 1987 and 2006, using the SF-36 Health Survey, the Wexner score for incontinence, and an additional questionnaire evaluating various aspects of functional outcome and late complications.

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A total of 326 patients (53% male) were included in the study. Pouchitis was recorded in 31% of UC and 5% of FAP patients. Anastomotic stricture was observed in 24% of UC and 8% of FAP patients. IPAA-related pouch failures occurred in 9% of UC and 3% of FAP. The median number of bowel movements per 24 hours was 6 (range: 2–20) with 1 (range: 0–8) bowel motion occurring at night. Wexner score was 3.27 (±0.32) for UC and 1.22 (±0.36) for FAP. The overall norm-based SF-36 score for physical/mental health status was 52.85/50.31 and 57.29/50.05 respectively. Restorative proctocolectomy with mucosectomy and hand suture IPAA is a safe procedure with good functional results and quality of life in well-satisfied patients. Pouchitis, anastomotic strictures, and pouch failures were mainly observed in the UC group.

Key words: Restorative proctocolectomy – Mucosectomy – Hand sewn – IPAA – Functional outcome – Quality of life

Approximately 30% to 45% of patients with ulcerative colitis (UC) will at some point require operative treatment.[1,2] In parallel, for patients who suffer with familial adenomatous polyposis (FAP), surgery is currently the only effective means of preventing progression to colorectal carcinoma.[3] Restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA) is the surgical treatment of choice.[4,5] The procedure has been modified from a transanal hand-suture IPAA after mucosectomy to a stapled IPAA without mucosectomy. Although stapled anastomosis seems to be favored by better functional outcomes, it results in higher rates of persisting adenomas in the residual anorectal mucosa. Mucosectomy is still the procedure of choice in cases of colon or rectal cancer and dysplasia of the lower rectum.[6]

Nevertheless the Greek literature lacks data regarding the functional results of IPAA. This could partially be related to the lack of referral treatment centers with extensive surgical experience. In our institution a large cohort of UC and FAP patients were treated with hand suture IPAA after mucosectomy since the early '80s. The aim of the present study is to retrospectively assess the quality of life in these patients, to evaluate the long-term functional outcome of the procedure and to compare the results with respect to early and late postoperative complications between UC and FAP patients. The secondary endpoint is to identify possible factors associated with good and less satisfactory functional results.

Methods

The medical files of all patients subjected to restorative proctocolectomy with IPAA for a preoperative diagnosis of UC or FAP disease, between January 1, 1987 and December 31, 2006, were reviewed in order to monitor their characteristics and to identify early and late surgical complications. In order to expand on our current understanding of the effect of age, patients were stratified by age at the time of IPAA surgery.[7,8] The surgical procedures were performed at the 1st Surgical Clinic of Evangelismos General Hospital in Athens. The senior author performed all surgical procedures.

We assessed the patients' outcome by telephone, by post or face-to-face interview during office examination, according to a structured questionnaire that comprised a list of questions aimed at assessing late complications related to operation, pouchitis, strictures, use of medications, and urgency of defecation.[9,10] It also related to the presence of major or minor leakage, the incident of perineal rash, and frequency of bowel movements.[11] The continence capacity during day and nighttime and the use of protective pads have been evaluated by using the Wexner Continence Grading Scale.[12] This is a simple, widely used questionnaire for assessing fecal incontinence on a scale of 0–20, where 0 represents perfect continence and 20 indicates total incontinence.[13] It is suggested that the Wexner score is most suitable for severity assessment.[14]

Health-related quality of life was assessed by the patient self-rating Short Form-36 Health Survey.[15] This is a generic, not disease-specific, questionnaire consisting of 8 multi-item scales: physical functioning, role limitations due to physical problems, bodily pain, general health perception, vitality, social functioning, and role limitations due to emotional problems and mental health. For each item a score (range: 0–100) is established. A higher score indicates higher well-being. Summary scores

for the physical and mental components were calculated as well. The questionnaire is validated for evaluation of QoL in patients after IPAA.[16] It has also been validated in Greece with a survey that was administered to a stratified representative sample (n = 1426) of the general population residing in the greater Athens area (response rate: 70.6%).[17] The sample was mainly urban with equal distribution between gender and age groups over 18 years. Statistical analysis was performed according to documented procedures developed within the international quality of life assessment (IQOLA) project.

During office follow-up a physical examination was performed with particular attention to digital examination aimed at assessing the status of the IPAA, the anal canal, the sphincter mechanism, and any pouch stricture. When symptoms of pouchitis were suspected a rigid anoscopy with biopsy was added and when ileoanal stenosis was detected, immediate digital dilatation was performed.

Definitions

Pouchitis was defined as the symptomatic inflammation of the ileal reservoir. The diagnosis was mainly based on clinical presentations including increased stool frequency, urgency, incontinence, nocturnal seepage, abdominal cramping, pelvic discomfort, and arthralgia.[18] Pouch failure was defined as the need to replace, reconstruct, bypass, or remove the ileo-anal pouch, or the need for long-term nonclosure of the defunctioning stoma.[19] Small bowel obstruction was defined as any partial or complete obstruction of the small bowel for which the patient had to be admitted in the hospital irrespective of if it was treated conservatively or surgically.

Surgical technique

While mobilizing the right colon, blood supply is ligated close to the bowel wall, thus not sacrificing the marginal branch from the right colic to the ileocolic artery. The mesorectum is being excised by preserving the omentum, which is used as a cover to the bear areas left after the removal of the colon. A tongue of the omentum is always placed between the ileal pouch and the pelvic wall for diminishing the risk of bowel obstruction or "kinking" of the pouch. By using the most distal 40 cm of the terminal ileum, bilateral enterotomies are performed and a linear stapler is fired toward the apex. The terminal ileal bridge is also transected. The linear stapler is finally fired retrograde, thus completing construction of an 18–20-cm-long ileal J-pouch. The anterior enterotomy is closed with the use of TA-60 stapler (Covidien/Medtronic, Minneapolis, Minnesota) in 2 layers. The posterior staple line is inspected for any potential defects and reinforced if necessary. Additional care is taken to avoid tension of the anastomotic line that could further lead to septic complications and potential stricture at a later stage.

Through the anal approach, mucosectomy is performed with the assistance of Lone-Star retractor system (Lone Star Disposable Retractors, Cooper-Surgical, Trumbull, Connecticut). In order to avoid remaining islands of rectal mucosa, we inject methylene blue to stain the mucosa in a "chromography technique," followed by removal of the mucosa layer as a whole tube. The J-pouch is then pulled through the pelvic floor into the anal canal without tension. The most prominent part of the pouch is anastomosed to the squamous epithelium, with extra caution not to incorporate the internal sphincter into the stitches, which may potentially lead to ischaemia and incontinence. To females in their reproductive age, before closure of the abdomen we perform wrapping of the ovaries and the fallopian tubes with INTERCEED Absorbable Adhesion Barrier (Ethicon, Norderstedt, Germany). Two layers of anti-adhesive membranes are also placed below the anterior abdominal wall. The pelvis is drained abdominally and a diverting ileostomy is constructed.

Statistical review

The effect of relevant covariates and their interactions were examined using chi-square analysis via MATLAB's *crosstab* function. These comprised type of disease, gender, age, and the length of follow-up. A value of $P < 0.05$ was considered statistically significant. In order to unveil the main parameters of high impact to the quality of life of the patients we ran a series of tests using N-way analysis of variance (ANOVA) via MATLAB's *anovan* function. This was done for all the possible combinations of study parameters (taken as independent variables) against the SF-36 score parameter (taken as the dependent variable) by using an in-house MATLAB script, which allowed the automation of the numerous statistical tasks. As before a P value < 0.05 was considered statistically significant.

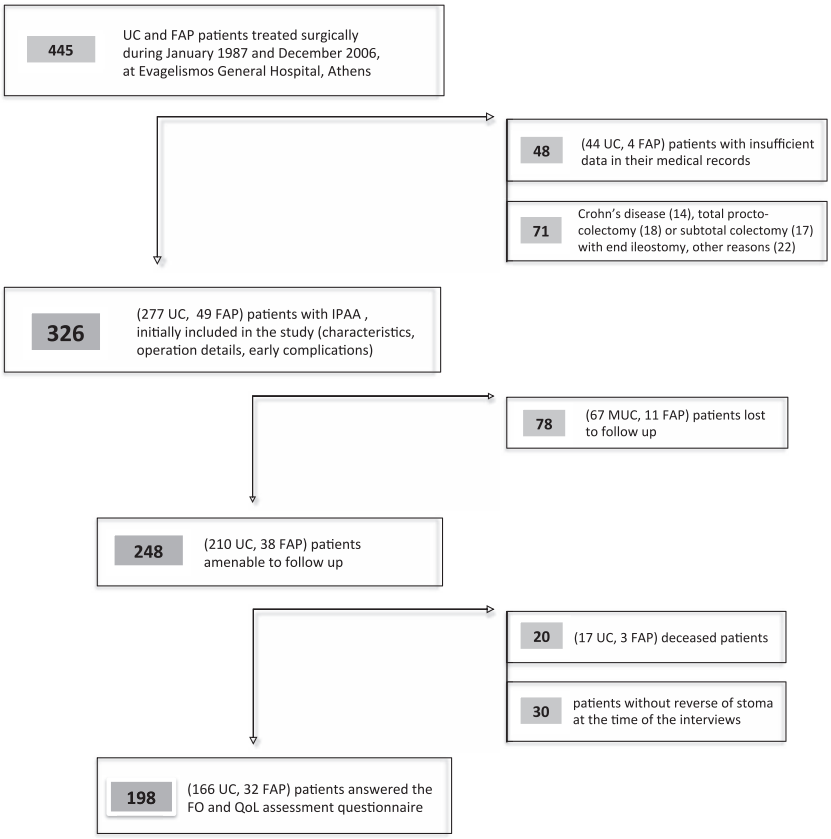

Fig. 1 Study flowchart showing the selection of 326 patients who underwent IPAA at the 1st Surgical Clinic of Evangelismos General Hospital in Athens, Greece.

The ANOVA was performed with the default parameter value of Type 3 sums of squares and its results were submitted to a multiple comparison test by Tukey's least significant difference procedure using MATLAB's *multicompare* function. This test exposed the specific effect each of the categoric predictors had on the dependent variable each time there was an ANOVA result of statistical significance.

Results

In total, 326 (73%) out of 445 UC and FAP patients, treated surgically in our clinic between 1987 and 2006, underwent total proctocolectomy with mucosectomy and hand-sewn ileoanal anastomosis with a J-pouch reservoir. Figure 1 shows the study flowchart where 48 (11%) patients excluded because of insufficient data, 35 (8%) underwent pan-proctocolectomy with end ileostomy or subtotal colectomy with end ileostomy, and 14 (3%) were diagnosed postoperatively with Crohn's disease. The majority of UC patients (65%) and all FAP patients underwent the procedure under elective circumstances. A three-stage procedure was performed in 98 (35%) UC patients, where an urgent operation was needed. Long-term follow-up information is available on 248 (76%) out of 326 patients, while 78 (24%) patients were not found at the time of follow-up. Finally, 198 (61%) patients answered the Functional Outcome and Quality of Life assessment questionnaire, while 20 (6%) patients were excluded because of death and 30 (9%) patients had a defunctioning stoma, which was not diverted at the time of the interview.

The median age at the time of the reservoir construction was 39 (range: 12–73) years for UC and 30 (range: 16–69) years for FAP patients. Mean duration of the time at the diagnosis of the disease up to the operation was 7 (0.1–44) years for UC patients and 2 (0.2–17) years for FAP patients. The indications of surgery and characteristics of patients for each of the diagnostic groups are given in Table 1. The median length of hospital stay was 11 (6–45) days for UC and 10 (6–89) days for FAP patients. To 47% of the patients, the ileostomy was reversed within 3 to 6 months (data not shown). Out of 98 UC patients who underwent the procedure in 3 stages, the majority of them (69%) had the IPAA in 3 months up to 1 year from the time of the mucous fistula formation. The median observational period

Table 1 Characteristics, indications for surgery, and operative details by type of disease. Values are shown as median and range

	UC (n = 389)		FAP (n = 56)		Total (n = 445)		
	Number	% (range)	Number	% (range)	Number	% (range)	ANOVA *P* value (chi square)
Included	277	71%	49	88%	326	73%	
Male sex	142	51%	31	63%	173	53%	(0.120)
Indications							
Cancer	8	3%	10	20%	18	4%	<0.001
Severe bleeding	42	15%	0	0%	42	9%	(<0.001)
Megacolon	112	40%	0	0%	112	25%	(0.001)
Other reasons	115	42%	39	80%	154	35%	(0.001)
Age							
At reservoir construction (yrs)	39	(12–73)	30	(16–69)	38	(12–73)	<0.001
At diagnosis of disease (yrs)	30	(2–70)	28	(14–62)	30	(2–70)	0.082
Duration of disease before surgery (yrs)	7	(0.1–44)	2	(0.2–17)	4	(0.1–44)	<0.001
Observational time (yrs with functional reservoir)	14	(6–25)	10	(6–20)	13	(6–25)	<0.001
Operative details							
Elective (2-stage) procedure	179	65%	49	100%	228	70%	(<0.001)
Emergency (3-stage) procedure	98	35%	0	0%	98	30%	
Duration of IPAA surgical procedure (min)	210	(95–370)	215	(140–465)	210	(95–465)	0.162
Hospital stay after IPAA (days)	11	(6–45)	10	(6–89)	11	(6–89)	0.800

ANOVA, analysis of variance; FAP, familial adenomatous polyposis; IPAA, ileal pouch-anal anastomosis; UC, ulcerative colitis; yrs, years.

Table 2 Early (<30 days) and late postoperative complications of patients who underwent IPAA, by type of disease

	UC		FAP		Total		
	Number	%	Number	%	Number	%	*P* value
Early complications (<30 days)	n = 249		n = 42		n = 291		
Anastomotic leakage/ pelvic sepsis	18	7%	1	2%	19	7%	0.402
Small bowel perforation	6	2%	0	0%	6	2%	0.294
Small bowel obstruction	10	4%	0	0%	10	3%	0.175
2nd operation (<30 days)	13	5%	0	0%	13	4%	0.120
Late complications (>30 days)	n = 210		n = 38		n = 248		
Small bowel obstruction	65	31%	5	13%	70	28%	0.203
Incisional or stoma hernia	18	9%	2	5%	20	8%	0.392
Anastomotic stricture							
Inlet	14	7%	1	3%	15	6%	<0.05
Outlet	38	18%	2	5%	40	16%	0.072
Pouch fistulas (total)	34	16%	2	5%	36	15%	0.422
Vaginal	16	8%	1	3%	17	7%	
Intestinal	4	2%	0	0%	4	2%	
Cutaneous	14	7%	1	3%	15	6%	
Pouchitis	66	31%	2	5%	68	27%	<0.01
Pouch failure	27	13%	2	5%	29	12%	0.236
IPAA related	19	9%	1	2.5%	20	8%	
Crohn's, other reasons	8	4%	1	2.5%	9	4%	
Mean time of failure since IPAA (yrs)	5.9	SD = 4.1	2.7	SD = 3	5.5	SD = 4.1	<0.01
Surgical repair of pouch failure							
i) Removal + reconstruction	15	44%	1	50%	16	55%	0.530
ii) Removal + end ileostomy	9	26%	1	50%	10	34%	0.938
iii) Bypass	3	9%	0	0%	3	11%	0.425
Mortality (overall)	17	8%	3	8%	20	8%	0.781
Disease related	9	4%	2	5%	11	4%	
IPAA related	1	0.5%	0	0%	1	0%	
Other reasons	7	3%	1	3%	8	3%	

FAP, familial adenomatous polyposis; IPAA, ileal pouch-anal anastomosis; SD, standard deviation; UC, ulcerative colitis; yrs, years.

was 14 (mean: 13.7, range: 6–25) years and 10 (mean: 10.3, range: 6–20) years for UC and FAP patients, respectively.

The early (within 30 days after surgery) and late postoperative complications are summarized in Table 2. In total 19 (7%) patients developed pelvic sepsis due to anastomotic leakage as an early complication. Out of them, 13 were treated conservatively, 2 with a CT-guided drainage and 4 underwent an exploratory laparotomy. Of the UC patients, 10 (4%) developed a small bowel obstruction for which they had to be re-operated. None of the FAP patients underwent a second operation because of early complications. There was no early mortality.

Following closure of the ileostomy 70 (28%) out of 248 patients developed at least 1 episode of small bowel obstruction. Of them, 55 (53 UC, 2 FAP) patients were treated conservatively and 15 (12 UC, 3 FAP) patients were treated surgically. Pouchitis, usually mild, with increased frequency of bowel movements, abdominal colic, tenesmus, and partial loss of continence was mainly recorded in UC patients (31% UC, 5% FAP, $P < 0.01$). Anastomotic outlet strictures that usually responded to finger or bougie dilation were observed in 40 (16%) patients. UC patients developed inlet anastomotic strictures in significantly higher rate than the FAP patients (7% UC, 3% FAP, $P < 0.05$). Pouch failures related to IPAA occurred in 9% of UC and 2.5% of FAP patients in the mean period of 5.9 years and 2.7 years after the operation, respectively. Half of the pouch failures in UC patients were treated with a deviating stoma. None of the patients developed severe dysplasia at the anastomotic site. A single case of adenocarcinoma, developed in the anal canal after stapled ileal pouch-anal anastomosis for UC, was reported. In this case a T3N0 cecal cancer was found unexpectedly in the colectomy specimen. Two years later the patient presented with an outlet obstruction of the pouch due to adenocarcinoma of the anal canal and was treated with abdominoperineal excision of the pouch and anorectum.[20] Mortality related to IPAA was recorded in 1 (0.5%) of the UC patients and none of the FAP patients.

The majority of patients (61% UC and 75% FAP) had 5 to 10 bowel movements in 24 hours. The median number was 6 (range: 2–20) with 1 (range: 0–8) bowel movement occurring at night. Fecal incontinence, as reported on the Wexner scale, is summarized in Table 3. The median Wexner score reporting fecal incontinence was 3 (SD = 4.09) for the UC and 1 (SD = 2.01) for the FAP patients with statistical significance ($P < 0.01$). SF-36 norm-based scoring for the physical component was significantly better in FAP patients ($P < 0.01$), but it was similar in both groups for the mental component.

Although most of UC patients had always complete control of solid stool (90%) and gas (88%), one third (34%) reported rarely or sometimes lack of fecal continence in liquid and 25% had often or always to wear a pad. None of the FAP patients mentioned any losses of solid stool or gas and 34% of them rarely or sometimes experience leakage during either day or night. Out of the 198 patients who were asked, 187 (94%) would undergo this procedure again and 193 (97%) would recommend IPAA to someone else with the same disease.

The relation between median values of Wexner score and SF-36 score with the age at IPAA is shown in Table 4. Wexner score was lower and SF-36 score was better for those under 55 years, when compared with older patients, with statistical significance (1-way ANOVA; $P = 0.006$). Norm-based scoring for physical health status was better in FAP patients (52.85 UC and 57.29 FAP, 1-way ANOVA; $P = 0.001$) but mental health was equal in both groups (50.31 UC and 50.05, 1-way ANOVA; $P = 0.799$). The mean values for each item of the SF-36 in both UC and FAP patients were then compared with the published SF-36 norms of the general Greek population and the results are shown in Fig. 2.

In univariate analysis (data not shown), none of the various clinical and surgical parameters were significantly associated with a better QoL score ($P < 0.05$).

Discussion

The data presented shows low operative mortality and an acceptable rate of early and late complications, which is comparable to the one of the double-stapled techniques.[21] It also indicates that functional outcome and long-term quality of life is highly satisfactory, being well compared with that of the general Greek population.

The majority of patients had 5 to 10 bowel movements per 24 hours and only 1 bowel movement at night. Although true fecal incontinence was rarely noticed, episodes of soiling (incontinence in liquid) were reported by one third of patients. The patient's subjective assessment of quality of life shows overall satisfaction and adjustment with the lifestyle imposed by the procedure. Scores similar to those of the Greek general population were noticed in all different

Table 3 Functional outcomes and QoL of 198 patients who responded to the questionnaire. SF-36 scales are scored to have a mean of 50 and standard deviation of 10 in the 1998 US general population

	UC (n = 166)		FAP (n = 32)		
	Number	% (range)	Number	% (range)	*P* value
Median number of bowel movements	6	(2–20)	6	(3–15)	0.193
<5x	44	27%	6	19%	
5–10x	102	61%	24	75%	
>10x	20	12%	3	9%	
Median number of bowel movements at night	1	(0–8)	1	(0–4)	0.533
Wexner score	3	SD = 4.09	1	SD = 2.01	<0.01
Type of incontinence					
Solid					0.071
Never	149	90%	32	100%	
Rarely/sometimes	15	9%	0	-	
Usually/always	2	1%	0	-	
Liquid					<0.01
Never	76	46%	21	66%	
Rarely/sometimes	57	34%	11	34%	
Usually/always	33	20%	0	-	
Gas					0.039
Never	146	88%	32	100%	
Rarely/sometimes	20	12%	0	-	
Usually/always	0	-	0	-	
Wear pad					<0.01
Never	109	66%	29	91%	
Rarely/sometimes	15	9%	1	3%	
Usually/always	42	25%	2	6%	
Lifestyle altered					0.254
Never	104	63%	24	75%	
Rarely/sometimes	49	30%	6	19%	
Usually/always	13	8%	2	6%	
SF-36 norm-based score					
Physical Component Summary	55.16	SD = 7.26	57.77	SD = 3.68	<0.01
Mental Component Summary	51.5	SD = 3.82	51.9	SD = 6.45	0.799
Level of satisfaction					
I would undergo the same procedure again.	156	94%	31	97%	0.512
I would recommend IPAA to someone else with the same disease.	161	97%	32	100%	0.320

FAP, familial adenomatous polyposis; IPAA, ileal pouch-anal anastomosis; QoL, quality of life; SD, standard deviation; UC, ulcerative colitis; yrs, years.

Table 4 Median values of Wexner and SF-36 norm-based score in 198 patients with functional J-reservoirs, by age at operation. SF-36 scales are scored to have a mean of 50 and standard deviation of 10 in the 1998 US general population

	WEXNER score					SF-36 PCS					SF-36 MCS				
	UC		FAP		1-way ANOVA	UC		FAP		1-way ANOVA	UC		FAP		1-way ANOVA
	Median	SD	Median	SD	*P* value	Median	SD	Median	SD	*P* value	Median	SD	Median	SD	*P* value
<25	0	3.3	0	1.1	0.006	56.7	6.4	58.7	3.7	0.001	52.3	5.1	49.7	5.7	0.799
25–34 yrs	0	3.4	0	1.5		56.5	4.7	58.5	4.6		51.6	6.0	51.8	8.4	
35–44 yrs	2	4.1	0	0.5		54.9	6.2	52.7	2.8		51.7	6.8	52.3	2.9	
45–54 yrs	3	5.0	na	na		53.4	7.6	na	na		49.4	7.5	na	na	
55–64 yrs	5.5	4.2	4	5.7		48.0	9.8	56.1	3.5		51.4	5.7	50.0	7.9	
>64 yrs	6.5	3.2	4.5	3.5		51.2	4.5	53.5	1.3		50.7	5.4	57.0	2.9	

ANOVA, analysis of variance; FAP, familial adenomatous polyposis; MCS, mental component summary; PCS, physical component summary; SD, standard deviation; UC, ulcerative colitis.

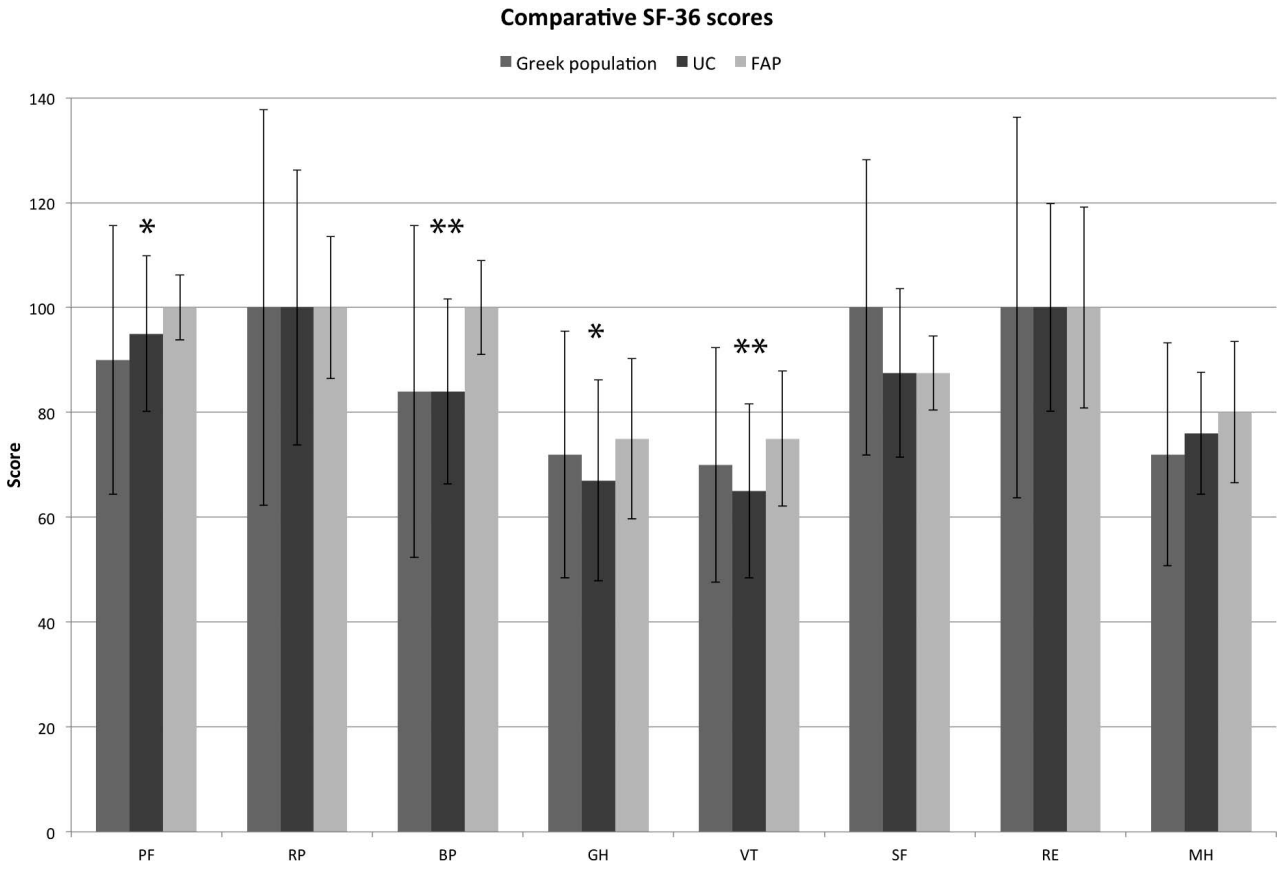

Fig. 2 SF-36 Quality of Life score in 198 patients compared with the Greek general population normative data. Minimum score is 0; maximum score is 100. A higher score indicates higher well-being. BP, bodily pain; GH, general health perception; MH, mental health; PF, physical functioning; RE, role limitations due to emotional problems; RP, role limitations due to physical problems; SF, social functioning; VT, vitality. Values are median with SD. *$P < 0.05$. **$P < 0.001$.

components of the SF-36 scale except of the social function that was lower for both UC and FAP patients. This is most probably related to the frequency of the bowel movements and the episodes of incontinence reported. Additionally, in UC patients, both general health and vitality scores were affected, which may be explained by the recurrent episodes of pouchitis.

Functional results were not as good in patients in the older groups. This was manifested by a slight reduction in the percentage with perfect continence, and a slight increase in the number with seepage of stool at night. Although many patients did not classify this as incontinence, it could be interpreted as age related and not as a technique related one.

UC patients reported pouchitis with a statistically significant difference than the FAP patients. Although not all cases of urgency in the present series were the result of pouchitis, occasional pouchitis may represent a significant proportion. UC patients also developed inlet anastomotic strictures in significantly higher rate than the FAP patients and later pouch failures. This is in agreement with findings in literature showing that late complications are mostly related to the disease than the technique of the anastomosis.[22,23] In our cases, attention is always paid on the way we stitch the top of the pouch to the anus by avoiding full-thickness bites of the internal anal sphincter that could result in ischemia of the sphincter and increased incontinence.

Regarding the pouch failure, a meta-analysis of 43 observational studies comprising 9317 patients showed a rate of 8.5%, when patients were followed up for more than 60 months.[24] This is in accordance with our results where postoperative pelvic sepsis and anastomotic leak often led to pouch failure. High number of bowel movements, stenosis in the pouch, and episodes of pouchitis were associated with lower functional outcome.

Unpublished preliminary data showed also a remarkable decrease of the small bowel obstruction rates at those patients who operated after the mid-'90s, which can be linked to improvements of the technique such as the placement of omental segment in the presacral space and the use of anti-adhesion films. In addition, the use of anti-adhesion membranes for covering both ovaries in young female patients may also be proved of having a positive impact in fertility.

While this is a retrospective study, the number of patients is significant for the Greek standards and shows that in a tertiary referral center, restorative proctocolectomy with mucosectomy and IPAA is a safe procedure with good functional outcome and quality of life. Urgent preoperative conditions, such as intractable hemorrhage, toxic megacolon, or perforation, are best handled in 3 stages by performing subtotal colectomy with ileostomy and mucous fistula, followed by proctocolectomy and IPAA usually 3 to 12 months later. In most other cases, the safest choice of procedure is a combined total colectomy and IPAA with temporary defunctioning loop ileostomy.

Acknowledgments

We did not receive any financial or material support for the research and the work. There were no conflicts of interest. The paper was approved by the Greek ethical committee. The first two authors have full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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