

Quality of life of ulcerative colitis patients treated surgically with proctocolectomy and J-pouch formation: a comparative study before surgery and after closure of the defunctioning ileostomy

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Abstract

Background Ulcerative colitis (UC) is a lifelong disease with a relapse-remission pattern that affects patients' social and psychological wellbeing. Restorative proctocolectomy and J-pouch formation is the gold-standard surgical procedure in cases where symptoms are refractory to currently available medical treatment. The aim of this study was to assess patients' quality of life (QoL) in order to evaluate the efficiency of surgery and patients' symptomatology.

Methods We performed a prospective comparative study of the QoL of 47 patients with UC, treated surgically. As research tools, we used the Inflammatory Bowel Disease Questionnaire (IBDQ) and the Cleveland Global Quality of Life (CGQL) questionnaire. Parametric and non-parametric tests were used in order to correlate areas of QoL and other selected factors, such as marital status, sex, age, and education.

Results The mean scores before and after closure of the ileostomy were 153.29 and 178 for the IBDQ ($P=0.0025$), and 17.4 and 23.42 for the CGQL ($P<0.001$), suggesting an overall improvement in QoL. The research showed that there was no specific QoL factor, such as intestinal, systemic, emotional or social life symptoms, that improved significantly more than the others ($P=0.99$). The IBDQ showed that patients aged less than 20 years ($P<0.001$), female patients ($P=0.03$) and patients with secondary education ($P<0.001$) reported the greatest improvement.

Conclusions The QoL in UC patients treated surgically improved following closure of the defunctioning ileostomy. QoL studies are encouraged to optimize and maintain high standards of surgical care, and they could potentially be used for assessment of therapeutic efficacy.

Keywords Inflammatory bowel disease questionnaire, ulcerative colitis, Cleveland global quality of life questionnaire

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Introduction

Ulcerative colitis (UC) is the commonest type of inflammatory bowel disease (IBD) worldwide; its cause is unknown and it has an incidence of 10 per 100,000 people

annually in Europe [1]. It may develop at any age, with a peak incidence between 15-25 years and a second peak between 55-65 years of age.

The main symptom of UC is hematochezia, reported in more than 95% of cases of active disease. Rectal urgency, tenesmus and occasionally severe constipation represent the classical complaints of rectal involvement, while chronic diarrhea with nocturnal defecation and crampy abdominal pain are typical of left-sided or extensive UC [2].

Evaluation of quality of life (QoL) is of great importance because it can lead to better patient care and the consideration of treatment modifications [3]. Health-related QoL (HRQoL) is an important measure of illness perception from the patient's point of view. The IBD Questionnaire (IBDQ) is a widely used questionnaire for HRQoL assessment in IBD patients. This questionnaire has been adapted and validated in several languages and cultural milieus [3-8]. We used as reference the Greek version of the questionnaire, introduced by Pallis *et al* [7-9].

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Similar well-accepted assessment tools of QoL that have been used in UC patients undergoing restorative proctocolectomy are the Short Form Health Survey-36 (SF-36) questionnaire and the Cleveland Global QoL (CGQL) questionnaire. The SF-36 is a generic measure of health status, consisting of 36 statements, and has been used to provide a population-based measure by evaluating the physical and the psychological status of patients. However, it is more difficult to use and requires complicated analysis [10].

CGQL, first introduced in 1999 by Fazio *et al* [11], is a short questionnaire composed of 3 questions that provide a gross impression of the QoL. The CGQL has not been validated in the Greek language before. In comparison, the IBDQ includes a more detailed spectrum of questions, leading to broader and more interesting results.

The aim of our research was to evaluate the QoL in UC patients treated surgically and analyze specific areas of the QoL affected following surgical intervention. Furthermore, we wanted to compare the scores of the CGQL, a simpler tool and easier to use [12], with the IBDQ results, to assess whether they are concordant.

Patients and methods

During the period 2010-2016, 57 UC patients underwent proctocolectomy and J-pouch formation at Aretaieion University Hospital in Athens, Greece. We carried out a prospective comparative study of 47 of those patients, assessing their QoL before surgery and after closure of the defunctioning ileostomy. Ten patients had invalid data and were therefore excluded. As a research tool, we used the Greek version of the IBDQ validated by Pallis *et al* and a Greek version of the CGQL score that had not yet been validated in Greece.

Questionnaires were sent to patients with an enclosed consent form; the first one a week before their preoperative assessment and the second one 6-8 weeks after closure of the ileostomy. Information sheets describing our research project objectives were also attached. All patients gave informed consent and the study protocol was approved by the hospital's committee on human research.

The IBDQ consisted of 32 questions organized into 4 groups, assessing the biological and psychological aspects of the patient's lifestyle. Each question was scored from 1 (worst outcome) up to 7 (best outcome). The range of the results varied between 32 (worst) and 224 (best), with a high score indicating a good QoL. The questions from group 1 (10 questions) were related to intestinal symptoms (score range from 10-70 per patient); group 2 questions (5 questions) were focused on systemic symptoms (score range from 5-35 per patient); emotional aspects were evaluated in group 3 (12 questions) (score range from 12-84 per patient); and group 4 questions (5 questions) assessed the social aspects (score range from 7-35 per patient) [13].

The total IBDQ scores of each patient before and after the surgery were divided into a further 4 categories. Those with a score >200 were considered to have an "Excellent" QoL, those with a score of 151-199 a "Good" QoL, those with a score

101-150 as a "Regular" QoL and finally, those with a score <100 as a "Bad" QoL. We also evaluated the relationship of QoL before and after the operation with selected factors, such as sex, education and marital status, and the improvement that patients showed in the biological and psychological aspects of QoL, based on their response to the same questions after the treatment.

The CGQL score was composed of 3 questions related to the QoL, the health status and the energy status at present. Each question was scored from 1 (worst outcome) up to 10 (best outcome) and the results varied between 3 (worst) and 30 (best) per patient.

Statistical analysis

The following measures of descriptive statistics were calculated: absolute and relative frequency, arithmetic mean, and standard deviation. The Kolmogorov-Smirnov test was used to determine the type of distribution of our sample. Parametric and non-parametric tests, including randomized two-factor analysis of variance (ANOVA) without replication, *t*-test preceded by Levene's test (to verify the homogeneity of variance), paired *t*-test or signed-rank test, Mann-Whitney and the chi-square test were used as appropriate to analyze the differences in various areas of the IBDQ and CGQL. All calculations were carried out using Microsoft Office Excel Pro Plus 2016 software.

Table 1 Patients' age, sex, level of education and marital status

Age range	No. of patients	%
<20	7	14.89
20-29	8	17.02
30-39	3	27.66
40-49	5	10.64
50-59	7	14.89
60-70	7	14.89
Total	47	
Sex		
Female	17	36.2
Male	30	63.8
Total	47	
Education		
Primary	6	12.8
Secondary	22	46.8
University	19	40.4
Total	47	
Marital Status		
Married	29	61.7
Single	18	38.3
Total	47	

Results

Patients were between 14 and 70 years old, with mean age 36 (median 26). Fifteen percent were aged <20 years, 17% were aged 20-29, 28% were aged 30-39, 11% were aged 40-49, 15% were 50-59, and 15% 60-70 years (Table 1).

The majority of patients who responded to the questionnaires were men 30/47 (64%) (Table 1). Among respondents, 13% had primary education, 47% had secondary education, and 40% had completed higher education. More than half of the respondents were married (62%) (Table 1).

The mean of the IBDQ scale before the operation was 153.29, and the median was 164. After the operation, the mean was 178 and the median 183 (P<0.001 with level of significance $\alpha=0.05$) (Table 2). In this scale, a higher score indicates better QoL. When the scores were divided into 4 groups based on the ranges of the scores (Excellent, Good, Regular, and Bad QoL), before surgery 17.6% of the patients had Bad QoL (score <100), 11.8% Regular (score 100-150), 61.8% Good (score 150-199), and only 8.8% had Excellent QoL (score >200) (P<0.001). After closure of the ileostomy, none of the patients had a Bad QoL, 9.1% had Regular, 72.7% Good, and 18.2% had Excellent QoL (P<0.001).

The mean CGQL score was 17.42 before the operation and 23.42 after, with a mean QoL improvement of 6 (P<0.001) (Table 2).

The type of questions included in the IBDQ scale covered 4 major categories, based on the intestinal and systemic symptoms, and the social and emotional aspects. The arithmetic means per question, before and after the operations of each category of QoL were calculated and compared. As seen in Table 3, the social life symptoms showed the best mean

improvement (0.89 per question), followed by the emotional aspect (0.87), the systemic symptoms (0.78) and final the intestinal symptoms (0.58), but those changes in each category were not statistically significant (P=0.994).

Other factors were also taken into account for assessing the QoL in both the questionnaires; these included level of education, sex, and marital status. Patients' level of education was divided into 3 groups: university level, secondary level, and primary education. Single-factor ANOVA testing of the statistical values of the IBDQ scale before and after operation was performed. For the IBDQ, the mean QoL scores before and after operation were 156.4 and 172.45 for people with university education, 142.6 and 182.5 for patients with secondary education, and was 174 and 176.4 for patients with primary education, respectively (Table 4) (P=0.3 prior surgery, P=0.49 post-surgery). Although education did not show any significant effect on QoL, patients with secondary education showed the highest mean improvement in their QoL after the operation (39.9), followed by patients with higher education (16.3) and those with primary education, who showed the least improvement (2.4) (P<0.001). However, for the CGQL, the statistical analysis showed no relation between the QoL and the level of education (P=0.29) (Table 4).

The patients' sex also showed no statistically significant effect on the IBDQ score. The mean value in the questionnaire for women was 149.83 pre- and 184.43 post-surgery, while for men it was 155.18 pre- and 175 post-surgery (P=0.75 and P=0.59 before and after surgery). However, the improvement in QoL after surgery was greater in female (34.6) compared to male (19.8) patients (P=0.02) (Table 5). On the other hand, for the CGQL the statistical analysis showed no relation between sex and

Table 2 Mean scores of the inflammatory bowel disease (IBDQ) and Cleveland questionnaires before and after surgery

Questionnaire	Pre-surgery	Post-surgery	Improvement	P-value
IBDQ mean score per patient	153.29	178	24.71	0.0025
Cleveland mean score per patient	17.42	23.42	6	<0.001

Table 3 Scores for the inflammatory bowel disease questionnaire (IBDQ) pre- and post-surgery. The patients' answers to each question were graded from 1 (worse) to 7 (best). The questions in group 1 (10 questions) were related to intestinal symptoms (scores ranging from 10-70 in total for each patient). In group 2 (5 questions), the questions were focused on systemic symptoms (scores ranging from 5-35 in total for each patient). The emotional aspects were evaluated in group 3 (12 questions) (scores ranging from 12-84 for each patient) and the 4th group (5 questions) assessed the social aspects (scores ranging from 7-35 in total for each patient)

Group	Scale	Mean		Improvement
		Prior-surgery (per Q)	Post-surgery (per Q)	Total (per Q)
1	Intestinal symptoms: 10Q (range 10-70)	52.24 (5.22)	58.00 (5.8)	5.76 (0.58)
2	Systemic aspects: 5Q (range 5-35)	22.24 (4.45)	26.16 (5.23)	3.92 (0.78)
3	Emotional aspects: 12Q (range 12-84)	55.38 (4.62)	65.93 (5.49)	10.55 (0.87)
4	Social aspects: 5Q (range 7-35)	23.44 (4.69)	27.91 (5.58)	4.47 (0.89)
	Total per patient (per Q)	153.29 (4.74)	178.16 (5.25)	24.71 (0.58)
	P-value	0.995	0.999	0.994

Q, question

Table 4 Patients' mean inflammatory bowel disease questionnaire (IBDQ) and cleveland scores in relation to level of education

IBDQ/ education	Pre-surgery	Post-surgery	Improvement
Primary	174	176.4	2.4
Secondary	142.6	182.5	39.9
University	156.4	172.7	16.3
P-value	0.3	0.49	<0.001
Cleveland/ education			
Primary	19.6	21.83	2.23
Secondary	17.64	24.27	6.64
University	16.56	22.88	6.33
P-value	0.85	0.93	0.29

Table 5 Patients' mean inflammatory bowel disease questionnaire (IBDQ) and cleveland scores in relation to their sex

IBDQ/sex	Pre-surgery	Post-surgery	Improvement
Female	149.83	184.43	34.56
Male	155.18	175	19.82
Total mean	153.29	178	24.71
P-value	0.75	0.59	0.026
Cleveland/sex			
Female	18.50	24.71	6.21
Male	16.83	22.64	5.82
Total mean	17.42	23.42	6.00
P-value	0.77	0.76	0.91

improvement in QoL after the surgery (mean score improvement 6.21 for females and 5.82 for males, $P=0.91$) (Table 5).

The patients' age also had no association with the IBDQ scale before surgery, but was statistically significantly related with the improvement in symptoms after surgery, with the greatest improvement in patients aged <20 years ($P<0.001$). No such result was seen for the CGQL score ($P=0.95$) (Table 6).

Marital status showed no influence on either of the IBDQ and CGQL scores. Additionally, we observed that single and married patients showed no differences in the improvement of their symptoms after surgery ($P=0.80$ and $P=0.68$, respectively) (Table 7).

In the IBDQ question assessing sexual life, patients reported how much their sexual life was limited by their symptoms (1=major limitation to 7=minimal limitation). The mean value of their responses was 4.18 before and 5.73 after surgery. Although there was an improvement in the score following surgery, it was not statistically significant ($P=0.21$).

Six patients had delayed postoperative complications (three patients diagnosed with ileus, one with pouchitis, one with tubo-ovarian abscess caused by acute endometritis, and one with intraperitoneal collections, drained under ultrasound guidance). Those complications developed beyond the time interval of the questionnaire and thus had no impact on our study.

Summary Box

What is already known:

- Questionnaires such as the Inflammatory Bowel Disease Questionnaire (IBDQ) and the Cleveland Global Quality of Life (CGQL) are used as research tools to evaluate the quality of life (QoL) in ulcerative colitis (UC) patients
- The QoL in UC patients shows improvement after surgical treatment with proctocolectomy and J-pouch formation
- Evaluation of QoL is of great importance because it can lead to better patient care and an appreciation of the need for treatment modifications

What the new findings are:

- Both CGQL and IBDQ do show improvement in QoL after surgical treatment with proctocolectomy and J-pouch
- CGQL failed to prove statistically significant changes based on specific factors such as age, sex or level of education
- Patients less than 20 years old, female patients and patients with secondary education showed better improvement in their symptoms after the surgical treatment

Discussion

Our research using both the 32-question IBDQ and the 3-question CGQL showed that the QoL improved in UC patients treated surgically with proctocolectomy and J-pouch formation (Table 2); this is concordant with other studies [14-17]. Lorenzo *et al* reported a 20-year follow-up study in UC patients treated with J-pouch and showed that surgery was an excellent option with improvement of symptoms overall, apart from the sexual aspect, where it seemed to have a worsening effect [18]. Our study also showed that there was improvement in all symptoms following surgical treatment and this was reflected by scores from both the IBDQ (mean improvement 24.71, 0.77 per question) (Table 2) and the CGQL (mean improvement 6, 2 per question) (Table 2). With regard to sexual life, our results showed that there was a small improvement, with mean scores 4.18 before and 5.72 after treatment, but that it was not statistically significant ($P=0.2$).

Although our research did not show any relation between the sex and QoL scores in general, it showed that females had better improvement in their symptoms after surgery compared to males (Table 5). A cross-sectional Danish population study showed that the total IBDQ score was higher in male patients than in female patients, who reported more urgency with a higher frequency of defecation and higher pad usage [19].

Table 6 Patients' mean inflammatory bowel disease questionnaire (IBDQ) and cleveland scores in relation to age

IBDQ/age range	Pre-surgery	Post-surgery	Improvement
<20	136.25	184.43	48.18
20-29	149	171.88	22.88
30-39	157.09	180.73	23.64
40-49	152	166.2	14.2
50-59	152	180.67	28.67
60-70	163.5	180.43	16.93
Total mean	153.29	178.00	24.70
P-value	0.73	0.93	<0.001
Cleveland/age range			
<20	20.86	25.43	4.57
20-29	14.75	20.75	6.00
30-39	17.42	23.25	5.83
40-49	19.00	25.40	6.40
50-59	19.50	24.86	5.36
60-70	14.14	21.67	7.52
Total mean	17.42	23.40	6.00
P-value	0.86	0.976	0.98

Table 7 Patients' mean inflammatory bowel disease questionnaire (IBDQ) and cleveland score in relation to their marital status

IBDQ/marital status	Pre-surgery	Post-surgery	Improvement
Married	153.26	178.63	25.37
Single	153.36	177	23.64
Total mean	153.29	178	24.76
P-value	0.995	0.93	0.80
Cleveland/marital status			
Married	16.86	23.33	6.47
Single	18.43	23.56	5.12
Total mean	17.42	23.42	6.00
P-value	0.78	0.97	0.68

In addition, Kamrowska *et al* concluded that female sex is associated with a low QoL [20], while a pediatric study by Hirata *et al* highlighted that, although there was no sex-related difference in QoL following pouch failure after restorative proctocolectomy, being a girl was an independent risk factor for pouch-related complications [21]. On the other hand, as mentioned in Kozłowska *et al*'s paper [22], men had worse QoL outcomes, whereas Han *et al* [23] and Casellas *et al* [24] found no such relation.

Our study also showed that there was no relation between the QoL and patients' age. However, patients aged less than

20 years had a greater mean improvement in their QoL following surgical treatment (Tables 6) in comparison with elderly people (over 60s). Although some studies [25,26] have reported that older patients have a worse QoL after surgery, our project showed that even in the older age groups there was an improvement in QoL (Table 6). Older age together with obesity are considered risk factors for postoperative complications and impaired QoL [25-27], but in this study we did not evaluate body mass index as an additional factor that could influence the outcome of surgery and consequently the QoL.

Our study showed that there was no relation between QoL and level of education; however, patients with secondary education had a better improvement in their QoL following surgical treatment (Table 4). Andrzejewska *et al* studied 60 individuals with UC regarding their QoL and its relation with sex and education. Their research showed that female patients with low education had a significantly worse QoL [19] compared to males with higher education. Kozłowska *et al* [3] found that there is a relationship between education and QoL, showing that university-educated patients had a better QoL, most likely because of their ability to access information more easily and apply it to their everyday habits.

One might assume that married patients in a stable relationship would have a better QoL, because of the emotional and social support derived from their partners compared to single patients. However, that was not shown by either the IBDQ or the CGQL in our study (Table 7).

The CGQL showed an improvement in QoL following surgical treatment (Table 2) and this is concordant with similar studies in the literature that showed the same outcome [28,29]. However, compared to the IBDQ, it failed to detect any change in QoL in relation to age, sex or education. It was easier to interpret the results of the CGQL, as it dealt with only 3 questions, which all the patients answered, whereas the IBDQ analysis was time-consuming and complicated and some patients declined to answer all 32 questions.

The QoL of all patients is a major factor that needs to be taken into consideration when a treatment plan is decided upon, pharmacological or surgical. Thus, assessment tools that can evaluate the vital privilege of the human being enjoying a good life, no matter what health issues exist, are of great importance. Therefore, questionnaires may represent a kind of therapy efficacy parameter, estimating the improvement in QoL when an interventional procedure is chosen, rather than conventional treatment with medication. They might help us achieve better insight into our patients' emotional and social status and allow the modification of treatment based on their needs. For instance, psychologically vulnerable patients could be identified and guided accordingly. The strategy in our department is to continue using our questionnaire in UC patients and to expand our research to other fields that define the QoL.

This study was limited by its small sample size. As the IBDQ includes some sensitive questions concerning the responder's sexual life, a few patients declined to answer the whole spectrum of the questionnaire in one or both of the two phases (pre- or post-surgery) and thus had to be excluded from the

analysis. The main limitation of the CGQL questionnaire is that it had not been previously validated in the Greek language, so we did not have a comparative reference value. In addition, the patients' body mass index, a confounding factor as it can differentiate the postoperative outcome, was not included in the study. Finally, although this was a prospective study, there may have been some information bias.

In conclusion, both IBDQ and CGQL scales showed that there is improvement (both P values were <0.001) in the QoL of UC patients treated surgically with proctocolectomy and J-pouch formation. However, there was no evidence that any specific biological or psychological parameter of the QoL showed greater improvement following surgery. The IBDQ scale showed that the QoL of patients UC is not influenced by their age, sex, level of education or marital status. Nevertheless, we noticed that patients aged less than 20 years, female patients and patients with secondary education showed better improvement in their symptoms after surgical treatment. Given the limited information in the literature, further research is needed regarding the QoL in UC patients treated surgically.

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