

**QUALITY OF LIFE OF PATIENTS WITH CROHN'S DISEASE IN SLOVAKIA
WITHOUT BIOLOGICAL TREATMENT EVALUATED BY INFLAMMATORY
BOWEL DISEASE QUESTIONNAIRE**
**KVALITA ŽIVOTA U PACIENTOV S CROHNOVOU CHOROBOU NA SLOVENSKU
NELIEČENÝCH BIOLOGICKOU LIEČBOU A HODNOTENÝCH DOTAZNÍKOM
NA ZÁPALOVÉ ČREVNÉ OCHORENIE**

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ABSTRACT

Background: A survey of the available literature showed only rare papers focusing on the health related quality of life of patients with Crohn's disease without biological treatment from Central and Eastern Europe has been published as yet.

Methods: Health related quality of life was studied in a group of 60 patients with Crohn's disease without biological treatment using the „Inflammatory Bowel Disease Questionnaire“. The study was realised in 2002. The following parameters were evaluated with regard to quality of life: Age, Marital status, Religion, Duration of disease, Course of disease, Extraintestinal symptoms, Histological evidence, Locality, Drug treatment, Surgery, CDAI, Socioeconomic status, Disability, Future expectations.

Results: The average value of IBDQ-measured health related quality of life for the group was 174.4 points (170.5 and 179.1 points for females and males, respectively). The most important results were documented in these parameters: Duration of the disease: a) up to 3 y. – 181.2; b) between 3 and 6 y. – 182.6; c) more than 6 y. – 160.9. CDAI: a) up to 150 (average 55.7) – 179.4; b) 151 and more (average 213) – 152.1. Surgery: a) no surgery – 179.8; b) undergoing surgery – 165.6; ba) one surgery – 178.1; bb) two and more interventions – 137.3. Faith: a) non-believers – 191.1; b) believers – 170.2; ba) mild believers – 182.9; bb) moderate believers – 163.4; bc) strong believers – 169.5.

Conclusions: The following parameters were found to have a significant (at the $p < 0.05$ level) impact on the health related quality of life: duration of the disease, multiple surgical interventions, CDAI and faith.

Key words: Crohn's disease. Quality of life. Inflammatory bowel diseases. Health-related quality of life.

ABSTRAKT

Východiská: V krajinách strednej a východnej Európy bolo dosiaľ publikovaných len málo štúdií zameraných na kvalitu života vo vzťahu ku zdraviu u pacientov s Crohnovou chorobou, ktorí neboli liečení biologickou liečbou.

Metódy: Kvalita života vo vzťahu ku zdraviu sa zisťovala v súbore 60 pacientov s Crohnovou chorobou neliečených biologickou liečbou a to prostredníctvom dotazníka „Inflammatory Bowel Disease Questionnaire“. Štúdia bola realizovaná v roku 2002. Hodnotené boli nasledujúce parametre a to vo vzťahu ku kvalite života: vek, rodinný stav, náboženstvo, trvanie ochore-

nia, priebeh ochorenia, extraintestinálne príznaky, histologický nález, lokalita postihnutia, medikamentózna liečba, chirurgický výkon, aktivita ochorenia, sociálno-ekonomický stav, pracovnosť, očakávania do budúcnosti.

Výsledky: Priemerné hodnoty IBDQ vo vzťahu kvality života ku zdraviu dosiahli 174,4 bodov, pričom priemer u žien bol 170,5 bodu a u mužov to bolo 179,1 bodu. Najviac významné výsledky boli dokumentované v týchto parametroch (v bodoch): Trvanie ochorenia: do 3 rokov 181,2; b, od 3 do 6 rokov – 182,6; c, viac ako 6 rokov – 160,9. CDAI: a) do 150 bodov (priemer 55,7) – 179,4; b) 151 a viac bodov (priemer 213) – 152,1. Chirurgický výkon: a) žiadny – 179,8; b) chirurgický výkon (spolu) – 165,6; ba) jeden chirurgický výkon – 178,1; bb) dva a viac chirurgických výkonov – 137,3. Viera: a) neveriaci – 191,1; b) veriaci (spolu) – 170,2; ba) mierne veriaci – 182,9; bb) stredne veriaci – 163,4; bc) silno veriaci – 169,5.

Záver: Signifikantný vplyv na kvalitu života vo vzťahu ku zdraviu (na úrovni $p < 0,05$) mali nasledovné parametre: trvanie ochorenia, opakované chirurgické intervencie, aktivita ochorenia a viera.

Kľúčové slová: Crohnova choroba. Kvalita života. Zápalové ochorenia čriev. Kvalita života vo vzťahu ku zdraviu.

INTRODUCTION

Quality assessment of the health condition of human individuals started to get increasingly to the foreground since the 1980s. This was due on the one hand to longer duration of chronic diseases connected with extended average life expectancy [1]. In spite of the initial problems concerning the application of appropriate and reliable measurement methods quality of life started to be used as an aspect of the assessment of the health care under various health care programmes [2]. The focus was shifting towards specific illnesses in the subsequent years. Among the diseases of the digestive tract, non-specific inflammatory diseases, and in particular Crohn's disease and ulcerative colitis, gastroesophageal reflux disease, malignant diseases of

the digestive tract and liver diseases got into the centre of attention [3].

Attention has been paid to quality of life of patients with Crohn's disease since effectively the early days of this trend becoming apparent. One of the first papers in this respect studied the quality of life in patients with Crohn's disease who underwent surgery [4].

Epidemiologic data characterize Crohn's disease as a disease with annual incidencies ranging between 1 and 10 per 100,000, depending on the geographical localisation [5]. The values for European countries are as follows: Belgium 5.5 [6], France 4.9 [7], Norway 5.3 [8], Sweden between 5 and 7 [9], Italy between 1.9 and 6.6 [10], and/or 2.8 after gender- and age-adjustments [11]. In Slovakia, the approximative incidence of Crohn's disease is 7.4 per 100,000 per year [12].

As a rule, health-related quality of life (HR-QoL) studies use standardized questionnaires. MOS 36 and/or its abbreviated version MOS SF-36 are examples of generally oriented accepted questionnaire that have proven acceptable under a variety of conditions as well as for the general population [13]. The Guyatt's IBDQ is an example of a questionnaire specifically focusing on non-specific inflammatory bowel diseases; it seems to be the most frequently used specific questionnaire at present [14].

The aim of the present work has been to identify the overall level of quality of life of patients in Slovakia suffering from Crohn's disease, identification of the relationships of the various factors to quality of life, and last but not least, verification of the use of IBDQ in the conditions of Slovakia.

PATIENTS AND METHODS

Patients

The group of patients comprised 60 (81%) out of the total 74 patients with Crohn's disease registered with 2 offices of gastroenterology in District Trenčín (population 115,000) and District Nové Mesto nad Váhom (population 65,000). Fourteen patients could not be included into the study because of time constraints on the part of the gastro-enterologist who registered and followed up the patients. There were 33 males (average age 44.9 years) and 27 females (average age 48.6 years). The average duration of the disease was 8.7 years - 7.5 and 10.1 years for females and males, respectively. In 45 cases

(75%), Crohn's disease was confirmed histologically; the histological diagnosis was non-specific in 11 cases (18.3 %). One case (1.7 %) was associated with a negative finding. No histology was performed in 3 cases (5 %). In all the cases, the clinical picture and the course of the disease suggested Crohn's disease. The sites involved were as follows: ileum 40x, caecum 18x, ascendent colon 10x, hepatic flexure 7x, transversal colon 19x, lienal flexure-9x, descendend colon 10x, sigma 29x, rectum 17x. The pharmacotherapeutical profile of the patients was as follows: a, causal monotherapy (5-ASA) – 21 patients; b, combination causal therapy (5-ASA + corticosteroids, 5-ASA + corticosteroids + entizol, 5-ASA + corticosteroids + entizol + immunosuppressants, 5-ASA + immunosuppressants; 5-ASA + corticosteroids + immunosuppressants, corticosteroids + entizol) – 27 patients; c, combination causal and adjuvant therapy – 7 patients; d, adjuvant or no therapy- 5 patients. There were 21 patients in the group with a mild course of the disease, 13 in the group of moderate course and 26 patients with a severe course of the disease. Extraintestinal symptoms were experienced by 23 patients. Twenty-three patients underwent surgery, 7 patients underwent multiple surgical interventions. The study was realised in 2002.

Methods

A specific questionnaire focusing on the evaluation of quality of life in patients with inflammatory bowel diseases, IBDQ, was used in the original form comprising 32 items. The replies were evaluated using the 7-point Likert scale [14]. IBDQ is oriented towards the evaluation of the perceived quality of life in 4 areas: intestinal symptoms – 10 items, general symptoms- items, emotional functions – 12 items, and social functions – 5 items. The patients received information from their doctor on the purpose of the study. After giving their consent with the inclusion in the study, the patients received explanation as to how to work with the questionnaire. Completed questionnaires were checked by the doctor. If some items in the questionnaire were missing, the doctor asked the patient and filled in the respective answers if the patient agreed. Patient's opinion was respected if refusing to fill in certain items. A total of 1,824 replies went into the evaluation stage (99.0 %). The clinical disease activity index, CDAI, was evaluated using the questionnaire according to Best [15].

Quality of life was evaluated with respect to the following parameters: A) Group of basic data: sex, age, marital status; B) Group of clinical data: duration of disease – course of disease – clinical disease activity index – site of involvement – histological finding – extraintestinal symptoms – type of health care – character of pharmacotherapy; C) Group of socio-economic data: ability to undertake working activities – socio-economic status; D) Group of mental data: faith – nature of future expectations. The above mentioned structure and the respective results IBDQ of CDAI are shown in Table 2.

The non-parametric Kruskal-Wallis' test was used for statistical evaluation. Two-sample test was used in some cases. The Kruskal-Wallis' test was based on comparison of median values. Average, minimum and maximum values, top and bottom quartils and standard deviations were calculated for the various levels of the factors studied. The value of $p < 0.05$ was taken as the significance level of differences.

The study followed the recommendations of the Helsinki II Declaration. Both the study design and the protocol were approved by the Hospital Ethics Commission.

RESULTS

The average value of quality of life for the whole group was 174.4 points, the corresponding values for females and males being 170.5 and 179.1 points respectively. The average value of CDAI for the whole group was 84.5 points.

The other most important results were documented in these parameters: Duration of the disease: a) up to 3 y. – 181.2; b) between 3 and 6 y. – 182.6; c) more than 6 y. – 160.9. CDAI: a) up to 150 (average 55.7) – 179.4; b) 151 and more (average 213) – 152.1. Surgery: a) no surgery – 179.8; b) undergoing surgery – 165.6; ba) one surgery – 178.1; bb) two and more interventions – 137.3. Faith: a) non-believers – 191.1; b) believers – 170.2; ba) mild believers – 182.9; bb) moderate believers – 163.4; bc) strong believers – 169.5.

Table 1 shows the results obtained for all the parameters studied. Table 1 Results obtained for all the parameters studied.

The overall evaluation confirmed the logical assumption that there is a certain indirect correlation between CDAI and quality of life ($p = 0.008$), and that among the other parameters it is repeated surgical interventions only that have a significant

effect on the quality of life ($p = 0.0146$). From among the other parameters studied, duration of disease of more than 6 years and faith were under the significance level of $p < 0.05$ ($p = 0.038$ and $p = 0.0163$, respectively). Faith was only evaluated with respect to claiming no faith, because of the low numbers of respondents in the group of so-called strong believers [2].

From other parameters neither the course of the disease, the presence of extraintestinal symptoms or the method of conservative therapy showed any significant effect on the quality of life. Neither the site of involvement, even in the case of pancolitic involvement, had any effect. There was no significant difference between cases in whom the histological finding specifically confirmed Crohn's disease and those whose histological finding was non-specific or those who had no report in their documentation on such an examination or those in whom no such examination had ever been performed.

The socio-economic status, the degree of the limitation of working activities or the character of future expectations showed no impact on the quality of life.

DISCUSSION

The choice of the right tool seems to be crucial to realizing studies oriented on quality of life. IBDQ was chosen because its translations have proven useful (sometimes with negligible modifications) in various countries, including the Netherlands [16], Germany [17], the United Kingdom [18], Greece [19] as well as South Korea [20].

Using IBDQ, the range of values assigned to quality of life is between 32 and 224 points; the scores for patients in remission usually reach more than 170 points [14]. IBDQ was confirmed as a valid, reliable method to evaluate significant changes in the health condition of patients. [21]. The reliability of the method could also be confirmed in comparing the results of evaluation made by qualified nurses and the patients themselves. This applied to both the overall results and those relating to the 4 above mentioned partial areas [22]. IBDQ has proven adequate with respect to also relatively stable outpatients [23]. From this point of view we would like to assume the high ratio of our results validity.

Also, IBDQ has been used in studies that evaluated efficacy and tolerance of drugs, such as 5-ASA [24], cyclosporine [25], oral budesonide [26] or

methotrexate [27]. It may also be useful in testing efficacies of new forms of medication: e.g., budesonide released in the ileum showed a significant change in the IBDQ scores as early as after 2 weeks of administration, both in doses of 9 mg and 15 mg budesonide [28]. No kind of conservative therapy showed any significant effect on the quality of life in our study. These results indirectly suggest that the patients were receiving adequate therapy in dependence upon their clinical condition.

The original authors of IBDQ have not attempted to consider the results obtained using it as absolute. The differences observed may be due to the age structure of the patient groups, coincident occurrence of other diseases, various frequencies of active and inactive diseases, differences in the approach to health care, differences in socio-economic status, etc. [29]. A better awareness of the disease, i.e. a higher degree of patient's education in the same environment had however no effect on the level of the perceived quality of life [30].

Frequently, also the questionnaire monitoring the disease activity index (CDAI) is used in parallel with IBDQ. Values of up to 150 points are typical of remission, 150 points suggest active disease, and levels above 450 points are typical of extremely severe disease [15]. A high correlation between CDAI and IBDQ has been illustrated by surveys which reported IBDQ and CDAI values of 169 and 133 points, respectively, for stable patients with Crohn's disease [21], with values of 131 and 293 points, respectively for active ileocolic Crohn's disease [24].

In our patient's file the 82 % of patients were in clinical remission. This could be the reason, why only the disease activity, repeated surgical interventions and duration of the disease for more than 6 years were the factors with influence of quality of life.

Differences between results obtained by IBDQ and/or its modified version may also be evaluated using the so-called delta score. The differences observed in this score were most pronounced in patients during recurrence of the disease (0.9), being 0.3 during relapse. These differences were even smaller than expected. On the other hand, disease activity correlated with quality of life [31]. This parameter was confirmed as a significant in our study, too.

The results of a survey focusing on the quality of life after surgery confirmed the need of aggressive

therapy in selected patients with Crohn's disease: after resection, the health related quality of life almost achieved the level of that in the general population, and remained there throughout the period of monitoring of 6 years [32]. This outcome was in strong correlation to our results regarding to repeated surgery interventions and duration of the disease.

CONCLUSIONS

Our study confirmed the usefulness of the translated version of IBDQ in the conditions of the public health system of the Slovak Republic. The questionnaire thus may be used as a proven component of projects or studies focusing on non-specific inflammatory bowel diseases.

A significant effect on the health related quality of life of patients with Crohn's disease without biological treatment could be demonstrated with respect to disease activity, repeated surgical interventions and duration of the disease for more than 6 years. It is difficult to interpret the relationship between faith and quality of life – it would require a separate study. The other parameters studied could not be demonstrated to impact upon the health related quality of life, and this may point to a good diagnostic, monitoring and therapeutical approach to patients with Crohn's disease.

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