

Health related quality of life in pediatric patients with inflammatory bowel disease

Calidad de vida relacionada con la salud en pacientes pediátricos con enfermedad inflamatoria intestinal

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Abstract

Introduction: Inflammatory bowel disease (IBD) is a group of chronic pathologies that have implications in several factors that affect the quality of life in pediatric patients. **Objectives:** To describe the health related quality of life (HRQL) in pediatric patients with IBD. **Patients and Methods:** A Multicenter cross-sectional descriptive study was conducted. Patients aged between 8-18 and with IBD diagnosis were included; IMPACT III quality of life questionnaire and a sociodemographic questionnaire were applied between September 2015 and January 2017. **Results:** A total of 30 patients were recruited, 60% male, with an average age of 13.6 years. 80% of patients were diagnosed with Ulcerative Colitis (UC). The predominant pharmacological treatment was combined therapy in 63.3%, being the most frequent aminosalicylates and immunomodulator. The IMPACT III quality of life score had an average of 129,5 points and when analyzing by section, there was no statistically significant difference between the averages. In our sample, there was no correlation between HRQoL and the number of flares, disease duration gender. **Conclusions:** This is a first approach to the study of HRQoL in pediatric patients in Chile. Since HRQoL is an important aspect to be explored in the routine evaluation of IBD patients, the identification of a lower HRQoL is the first step to perform interventions in these patients, thus we recommend performing this measurement as a screening method in all of them.

Keywords:

Health related quality of life;
inflammatory bowel disease;
children;
ulcerative colitis

Introduction

Inflammatory bowel disease (IBD) is a group of chronic pathologies characterized by gastrointestinal mucosal inflammation, which presents periods of exacerbation and remission. It includes Crohn's disease (CD), ulcerative colitis (UC) and indeterminate colitis (IC)¹.

The prevalence and incidence of IBD worldwide have been increasing; an incidence of 4-11 cases/100,000 inhabitants is reported^{1,2}. Approximately 25-30% of CD patients and 20-25% of UC or IC patients will be diagnosed before age 20³. In pediatric age, IBD typically occurs with moderate to severe disease activity⁴, with more extensive gastrointestinal tract involvement at the time of presentation, and the disease may progress more rapidly⁵.

The diagnosis in pediatric age is made in 56% between 10-14 years of age, followed by 19% between 15-17 years of age and 8% before four years of age⁶. There are no epidemiological data on incidence and prevalence in Latin America or Chile.

Given the above, and as a group of chronic pathologies, it has implications for the pediatric patient such as frequent visits to health services, high levels of school absenteeism, limitation in normal activities, discomfort derived from chronic pain, treatments and dietary restrictions that affect the quality of life^{7,8}.

Health-related quality of life (HRQoL) is defined as the impact that a disease and its treatment have on the perception of the patient of his or her well-being; it is a subjective personal experience⁹. HRQoL studies allow to identify and assess health needs, learn about the natural history of diseases, measure therapeutic results, and develop health policy guidelines.

There is a growing consensus on the importance of using instruments to assess the quality of life of these patients in order to provide a comprehensive health care as an essential complement to traditional clinical evaluation¹⁰.

HRQoL studies in pediatric patients with IBD have shown higher rates of depression, anxiety, social isolation, and academic difficulties, especially in adolescent patients treated with corticosteroids^{11,12,13}, thus it is important to clarify what are the aspects associated with quality of life in order to make the corresponding interventions.

There are currently two specific HRQoL questionnaires for children and adolescents with IBD. The most commonly used is the IMPACT-III questionnaire, which is a questionnaire developed in Canada, 2002, adapted from an adult quality of life questionnaire¹⁴.

Considering that in Chile and Latin America there are no studies on HRQoL in pediatric patients with IBD, the objective of this study was to describe the qua-

lity of life in the pediatric population with IBD and the aspects associated with HRQoL.

Patients and Methods

A multicenter cross-sectional descriptive study conducted at the UC-Christus Health Network, Sótero del Río Hospital, and with patients belonging to the Carlos Quintana Foundation, Concepción, and the Foundation *Crohn y Colitis Ulcerosa Junto a Ti*, between September 2015 and January 2017.

Patients between eight and 18 years of age with a diagnosis of IBD of more than six months of evolution were selected, excluding patients with a neurological deficit that prevented them from answering the questionnaires.

The participants, accompanied by their guardian, answered two questionnaires personally, after obtaining their assent and informed consent.

The IMPACT III questionnaire was used for the assessment of quality of life, with the authorization of the authors Otley et al¹⁴. It was used the version validated for Chile in November 2013 by Juanet et al. (unpublished data). This is a self-administered questionnaire on quality of life specifically designed for pediatric patients with IBD. It comprises 35 questions with Likert scale of 0-5 (never-frequent), giving a score of 35-175 points, where the higher the score the better quality of life. It encompasses six areas grouped into sections: intestinal symptoms, systemic symptoms, body image, social functioning/limitations, emotional involvement, interventions/treatments. Its administration takes 10-15 minutes^{14,15}. A socio-demographic questionnaire was also conducted which measured the following variables: age, gender, place of residence, type of disease, previous surgery, number of crises (flares) in the last year, the age of diagnosis, time of disease evolution, and treatment.

During the period from September 2015 to January 2017, patients were recruited in their outpatient check-ups, during hospitalizations, whether due to a flare or for medicine administration, and via e-mail, prior acceptance to participate by telephone.

The study was approved by the Scientific Ethics Committee of the Faculty of Medicine of the Pontificia Universidad Católica de Chile and the Scientific Ethics Committee of the South East Metropolitan Health Service. Patients over ten years of age were asked for their assent and all parents and/or guardians were asked for informed consent.

A description of the study population by number and percentage for nominal variables was considered for statistical analysis. For numerical variables, distribution normality was evaluated with Kolmogorov-

Smirnov Test. In the case of variables with normal distribution, it was used for their description the average $\pm$ standard deviation (SD) or range. Otherwise, median and interquartile range were used. For the comparison of variables without normal distribution, Mann-Whitney U test and correlation analysis of variables through Spearman's rho were used. The results were considered significant with a value of $p \leq 0.05$. Data were analyzed using the SPSS statistical software, version 21.

Results

A total of 63 pediatric patients diagnosed with IBD were identified from patient records. Of this total, 12 patients were excluded from the study because they were younger than seven or older than 18 years.

In total, 31 patients were recruited from the UC-Christus Health Network, nine patients from the S tero del R o Hospital, three patients from the Carlos Quintana Foundation, Concepci n, and eight patients from the Foundation *Crohn y Colitis Ulcerosa Junto a Ti*.

Three patients were recruited in outpatient check-up, five patients during hospitalization, and 22 patients via e-mail. Of the total, six patients declined to participate, and 15 patients agreed to participate but did not respond the questionnaires. Finally, a total of 30 patients were analyzed.

Socio-demographic and clinical characteristics.

Table 1

Of the total number of patients, 60% were male and the predominant disease in 80% was UC. The average age was 13.6 years (range 8.3-17.4 years). The 63.3% used combination therapy, and the most common combination was aminosalicylates and immunomodulators, which was 40%.

The average age at diagnosis was 10.9 years (± 3.9 SD). On average, patients had 33.1 months of disease progression (± 25.1 SD) and had 2.5 flares per year (± 3.1 SD).

Regarding patient residency, 73% live in the Metropolitan Region. No patients had undergone surgery for IBD.

Health-related quality of life

The total score of the IMPACT III questionnaire (35-175 points) had a median of 129.5 points (interquartile range 107-140.3), with no significant differences between men and women, both in the overall score (Mann-Whitney U, $p = 0.765$) and in the different sections.

Table 2 shows the analysis by section of the IMPACT III questionnaire. It was not observed that any section of the questionnaire had more affectation over another.

Table 1. Demographical and medical characteristics of patients with IBD

Characteristics	N (%)
Masculine sex	18 (60)
Type of IBD diagnosis	
Ulcerative Colitis	24 (80)
Crohn's Disease	4 (13.3)
Indeterminate Colitis	2 (6.7)
Place of Origin	
Metropolitan Region	22 (73.3)
Other regions	8 (26.7)
Current medication	
5-Asa	8 (26.7)
Immunomodulator	2 (6.7)
5-Asa + immunomodulator	12 (40)
Immunomodulator + Biological Therapy	4 (13.3)
Steroids + 5-Asa + Immunomodulator	2 (6.7)
Steroids + Immunomodulator	1 (3.3%)
Homeopathy	1 (3.3)

Table 2. Summary of the IMPACT-III subscales

IMPACT-III sub-scales	Minimum	Maximum	Median	p25	p75
IMPACT III (35-175)	87	152	129.5	107	140.3
IBD symptoms (7-35)	15	32	23.5	19	28.3
Systemic symptoms (3-15)	6	15	11	9	13
Body image (3-15)	4	14	12	9	13
Social functioning (12-60)	29	56	47.5	41.5	52
Emotional functioning (7-35)	10	32	23.5	18.8	27.3
Treatment (3-15)	5	15	10	8	13

No correlation was observed between the IMPACT III score and the number of flares (Spearman's $\rho = -0.306$, $p=0.10$) and the duration of the disease (Spearman's $\rho = -0.030$, $p = 0.876$).

Discussion

To our knowledge, this study is the first to describe the clinical and socio-demographic characteristics of a group of pediatric patients with IBD in Chile.

In the studied population, and similar to that reported in the international literature, most of the patients were male and, in contrast to what was published internationally where CD predominated, in our sample the most frequent disease was UC with an 80%^{16,17}.

The age of diagnosis in our patients was lower than published, as 43.3% were diagnosed before the age of ten years⁶.

With regard to the IMPACT III questionnaire, this is a validated tool for measuring the quality of life, but it cannot be classified as bad, regular or good. This does not allow the analysis of cut-off score, but it does seem to be a good tool for the patients follow-up^{14,15}.

In 2002, Otley published the results of the IMPACT questionnaire which showed that the total average score for patients with disease in remission was 180 ± 32 , mild-moderate disease 146 ± 31 , and moderate-severe disease 133 ± 34 ¹⁴. If we compare the IMPACT III questionnaire score of our sample (129.5 points of our patients) with that reported in international studies (with scores between 130-159 on average) it is evident that the quality of life is lower^{10,14,18,19,20}. This may be due to 30% of our patients reported having a flare at the time of the questionnaire application and the fact that five patients were hospitalized at the time of answering the questionnaire.

Associations between HRQoL and type of disease have been described in studies in adults. The study of Casellas et al.²¹, shows that patients with UC have a lower quality of life. Subgroup analyses were not made in our sample due to the low number of CD and IC. However, when comparing average scores of CD 104.2, UC 125.6 and IC 140.5 it is possible to observe a tendency to lower quality of life in CD patients.

In pediatric studies, a higher quality of life associated with biological treatments has been reported versus corticosteroid treatments, however, due to the low number of patients included in our study, it was not possible to make associations between these variables^{15,19}.

Due to the low number of patients with CD and IC, and multiple drug types, there was no subgroup analysis.

We believe that the measurement of HRQoL in

patients with IBD should be applied as a screening method. According to Ryan et al²², presenting low HRQoL is associated with increased medical consultations and health resource utilization, therefore, the early identification and intervention of patients focused on those with low HRQoL is an effective approach in order to improve clinical outcomes and health resource utilization.

Our study has limitations. Since the instrument used only analyzes the symptoms occurred in the last two weeks prior to the questionnaire, the result may be mainly influenced by what the patient is experiencing in that period right before the questionnaire application. The disease activity was not recorded at the time of the questionnaire, therefore, this point cannot be strongly confirmed. In addition, the study has a small sample size, thus it was not possible to make analyses according to type of disease or type of treatment, and correlation with HRQoL.

This study provides relevant information regarding the clinical and socio-demographic characteristics of patients with IBD in the pediatric population and is the first approach to the study of these patients in our country.

The studied population showed a lower quality of life than reported internationally. While it is not possible to categorize the HRQoL in patients as good, regular or bad, it is a method that can be useful as a follow-up in patients by comparing their own scores.

The identification of patients with lower HRQoL will allow proactive interventions and thus improve the use of health resources.

For future studies, it is necessary to include other variables such as disease activity in order to look for factors that are related to HRQoL.

In the future, the knowledge of which factors are related to the quality of life will allow having a basis for carrying out interventions and thus improve the quality of life in our patients. It is therefore important to conduct studies with a larger number of patients that allow us to make associations between variables and HRQoL.

Ethical Responsibilities

Human Beings and animals protection: Disclosure the authors state that the procedures were followed according to the Declaration of Helsinki and the World Medical Association regarding human experimentation developed for the medical community.

Data confidentiality: The authors state that they have followed the protocols of their Center and Local regulations on the publication of patient data.

Rights to privacy and informed consent: The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the correspondence author.

Conflicts of Interest

Authors declare no conflict of interest regarding the present study.

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