

# Short Health Scale: A Valid, Reliable, and Responsive Measure of Health-related Quality of Life in Children with Inflammatory Bowel Disease

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**Background:** Inflammatory bowel disease (IBD) presents a growing medical and epidemiological problem. In respect to patients, health-related quality of life (HRQOL) emerged as informative means to evaluate the impact of disease burden on health. The Short Health Scale (SHS), a disease-specific HRQOL instrument with only 4 questions (symptoms, functioning, worry, and general well-being), was demonstrated as valid, reliable, and responsive in adults. Aim of this study was to assess its psychometric properties in children with IBD.

**Methods:** In a multicentric prospective study, HRQOL was assessed in 104 children with IBD by generic (PedsQL) and disease-specific questionnaires (IMPACT-III (HR) and SHS), which were cross-culturally adapted for Croatian. Forty-one patients completed the questionnaires at the second visit 6 to 12 months later. Of them, 27 patients changed from remission to active disease or vice versa and were included in responsiveness to change analysis.

**Results:** Patients in remission had significantly better scores for symptoms ( $P = 0.022$ ) and functioning ( $P = 0.003$ ) than those with active disease. Each of the 4 SHS questions was strongly correlated with the corresponding dimensions of PedsQL and IMPACT-III (HR) questionnaires ( $r_s = 0.50-0.72$ ,  $P < 0.001$ ). Reliability was confirmed with Cronbach's  $\alpha = 0.74$ . Patients who changed from remission to active disease or vice versa showed significant change in following SHS scores: symptoms ( $P = 0.032$ ), functioning ( $P = 0.008$ ), and worry ( $P = 0.021$ ).

**Conclusions:** SHS appears to be valid, reliable, and responsive tool to measure HRQOL in children with IBD. Simplicity of use, compactness, and the possibility of immediate interpretation make SHS well suited for both clinical practice and research studies.

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**Key Words:** inflammatory bowel disease, children, health-related quality of life, psychometric validation

Lifelong duration, unpredictable and relapse-remitting course, repeated hospitalizations, and increasing incidence make inflammatory bowel disease (IBD) a growing epidemiological and medical problem.<sup>1</sup> Moreover, debilitating symptoms are common, while increased risk of surgery and treatment complications are to be expected.<sup>2</sup> Therefore, IBD presents a great burden on daily life, particularly in children because of the profound negative effect on growth and development.<sup>3</sup>

Health-related quality of life (HRQOL) measures patients' perception of their health status and how their disease affects

physical, social, and emotional functioning,<sup>3</sup> complementing the information obtained by disease activity indices. Consequently, HRQOL instruments have emerged as an important means of assessing the impact of the disease burden on health and determining the efficacy of treatment.<sup>1,4</sup>

Currently, the only disease-specific HRQOL instrument for children with IBD, proven to be reliable and valid, is the IMPACT-III questionnaire.<sup>3,5–8</sup> In adults, Inflammatory Bowel Disease Questionnaire (IBDQ) has been consistently used for more than 2 decades,<sup>9</sup> accompanied lately with the Short Health Scale (SHS). This is a new, simplified, 4-item questionnaire validated in adult patients with Crohn's disease (CD)<sup>10</sup> and with ulcerative colitis (UC).<sup>11</sup> However, despite being concise and practical HRQOL questionnaire, until now, there is no evidence on the performance of the SHS in pediatric patients. It was, therefore, the primary aim of this study to psychometrically evaluate the SHS in children with IBD, i.e., to investigate whether it is valid, reliable, and responsive instrument of HRQOL in children with IBD.

## MATERIALS AND METHODS

Children aged 9 years and older with confirmed diagnosis of IBD for more than 6 months, according to the established criteria,<sup>12</sup> were prospectively recruited at pediatric gastroenterology units in

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The authors have no conflicts of interest to disclose.

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the 3 tertiary care hospitals in Croatia. Exclusion criterion was history of cognitive or developmental delay. One hundred ten patients were consecutively enrolled between January 2009, and December 2011, within either the inpatient or outpatient clinic. Of them, 104 agreed to participate. Patients were asked to complete the cross-culturally adapted Croatian versions of SHS, IMPACT-III (HR), and PedsQL. Demographic and anthropometric data, as well as disease characteristics, were collected from medical records.

## HRQOL Questionnaires

### SHS

The SHS is a disease-specific 4-item self-administered questionnaire. Each open-ended question corresponds to one of the standard HRQOL dimensions: symptoms, functioning, disease-related worry, and general well-being. Responses are graded on a 100-mm visual analog scale correlating with score range of 0 to 100 with higher result matching worse HRQOL (Table 1). The original and cross-culturally adapted versions were successfully validated in adult patients with CD or UC but not in children.<sup>10,11,13,14</sup>

### IMPACT-III (HR) Questionnaire

IMPACT-III (HR), a cross-culturally adapted version of the original IMPACT-III questionnaire,<sup>3,15</sup> was previously demonstrated as a valid and reliable measure of HRQOL in our pediatric patients with IBD.<sup>7</sup> It is a disease-specific self-report measure with 33 closed questions and 5 domain scores: symptoms (10 items), concerns (9 items), socializing (7 items), body image (4 items), and worry about stool (3 items). The IMPACT-III (HR) uses 5-point Likert scale ranging from 1 to 5 for all answers. The outcome score ranges from 33 to 165, with higher scores suggesting better quality of life.

### Pediatric Quality of Life Inventory, Version 4.0 (PedsQL)

Participants also completed the PedsQL, a generic 23-item measure of pediatric HRQOL.<sup>16</sup> This measure provides a total HRQOL score and 2 summary scores: physical health (comprised of the physical health domain score) and psychosocial health (comprised of the emotional, social, and school functioning domain score). Participants rated the degree to which each item

had been a problem for them during the past month on a 5-point Likert scale ranging from 0 (Never) to 4 (Almost Always). Items were reverse-scored and linearly transformed to a 0 to 100 scale, with higher scores reflecting better HRQOL.<sup>17</sup>

## Disease Activity

Current disease activity was assessed using Pediatric Crohn's Disease Activity Index for patients with CD<sup>18</sup> and Pediatric Ulcerative Colitis Activity Index for patients with ulcerative or indeterminate colitis.<sup>19</sup> To facilitate analysis of all patients with IBD together, Pediatric Crohn's Disease Activity Index and Pediatric Ulcerative Colitis Activity Index scores were converted to categorical groupings ("inactive," "mild," and "moderate/severe") using established cut scores.<sup>20,21</sup> Disease severity groups were used to assess known-group comparison and responsiveness analysis.

## Statistical Methods

Nonparametric statistics were used because the results of the SHS questionnaire did not follow normal distribution. Score results are presented as median and interquartile range values. Independent samples *t* test was executed to evaluate whether demographic, anthropometric, disease-related variables, and mean HRQOL scores differed between recruitment sites. Cronbach's  $\alpha$  was calculated as a measure of internal consistency reliability and item homogeneity. Confirmatory factor analysis was used as a measure of construct validity. Correlations were analyzed by Spearman's rank order correlation ( $r_s$ ). A strong correlation was defined as  $r_s > 0.5$ , a moderate correlation  $r_s \geq 0.3$ , and a mild or weak correlation  $r_s < 0.3$ . The Kruskal-Wallis was used for known-group comparison. The Wilcoxon's signed rank test was used to compare scores after the second evaluation. A *P* value of  $<0.05$  was considered significant. The data were analyzed using Statistical Package for Social Sciences (Windows version 19.0.0.1; SPSS Inc., Chicago, IL) software.

## Psychometric Analysis

To analyze the psychometric properties of the SHS for the pediatric patients with IBD, it was necessary to investigate validity, reliability, and responsiveness to change.

Validity assesses whether the questionnaire measures what it is supposed to measure<sup>22</sup>; in this case, whether SHS measures HRQOL in children with IBD. We assessed the validity with 3 methods. First, factor analysis was used to report the total variance explained, which demonstrates the extent to which differences in patients' SHS scores reflect the differences among the individuals attributable to the varying IBD burden among them.<sup>23</sup> Second, the correlations between the SHS items and the subscales of other validated, age-specific HRQOL instruments (PedsQL and IMPACT-III (HR)) were calculated. To be regarded as valid, each SHS item should correlate more strongly with the subscales covering the same aspect of health (convergent validity) than with subscales covering other aspects of health (discriminant validity). Third, known-group comparison evaluated the ability of SHS to distinguish differences in HRQOL scores between patients with

**TABLE 1.** Items of the SHS

1. How severe are the symptoms you suffer from your bowel disease? No symptoms—0; Very severe symptoms—100
2. Do your bowel problems interfere with your activities in daily life? Not at all—0; Interfere to a very high degree—100
3. How much worry does your bowel disease cause? No worry—0; Constant worry—100
4. How is your general feeling of well-being? Very good—0; Dreadful—100

different disease activity level as rated by established activity indices (Pediatric Crohn's Disease Activity Index and Pediatric Ulcerative Colitis Activity Index). Because the degree of disease activity determines symptom burden in IBD, it can be expected that patients in relapse have worse scores on the SHS when compared with patients in remission.

Reliability refers to the consistency of the instrument, i.e., does the questionnaire elicit similar scores on readministration. Cronbach's  $\alpha$ , as a measure of internal consistency, was calculated to evaluate the reliability and item homogeneity. It measures the correlation between responses to questions and is considered acceptable for group comparisons when above 0.70.<sup>24</sup>

To evaluate responsiveness, a sensitivity to change over time, patients were offered a second evaluation 6 to 12 months after the initial one. All procedures at the first visit were repeated. The changes in SHS score for patients in stable remission and for patients who changed from remission to active disease or vice versa were compared. Patients who had active disease at both visits were omitted from this analysis.

## Ethical Considerations

This study was approved by the Institutional Ethical Board at each recruitment site and by the Central Ethical Board at the School of Medicine, University of Zagreb. Informed consent was obtained from the participants and their legal guardians before study procedures.

## RESULTS

When comparing the 3 recruitment sites, no significant differences between variables of interest were observed (data not shown). As such, all analyses were conducted on the combined sample. All patients (104 of 104, 100%) completed IMPACT-III (HR) questionnaire, whereas 6 (5.8%) and 10 patients (9.6%) did not complete PedsQL and SHS, respectively. Demographics and disease-related characteristics for the 104 patients are presented in Table 2. The most commonly affected site for patients with CD was ileocolonic region (52.7%). Eleven patients (14.9%) had involvement of the upper gastrointestinal tract (from mouth to ligament of Treitz), while perianal disease was present in 3 patients (4.1%). Pancolitis was the most common disease location for patients with colitis (53.3%), with inflammation extending beyond the splenic flexure.

## Validity

A predicted one-factor solution was adequate to represent the data and accounts for 60.4% of the total variance of the sample. All items had high loading on one-factor solution above the set critical level of 0.50 (0.858, 0.840, 0.819, and 0.553 for items 1, 2, 3, and 4, respectively). Spearman's correlations between the SHS scores and subscores of other validated HRQOL measures are shown in Table 3. All tested correlations were significant ( $P < 0.05$ ). Level of disease activity significantly affected SHS scores for the first 2 questions: symptoms ( $\chi^2 = 7.609$ ,  $df = 2$ ,  $P = 0.022$ ) and function

**TABLE 2. Demographic and Disease Characteristics of the Participants**

	CD (N = 74)	UC (N = 30)	Total (N = 104)
Age, mean $\pm$ SD, yrs	14.66 $\pm$ 2.76	14.74 $\pm$ 2.63	14.68 $\pm$ 2.71
Male	38 (51.4%)	11 (36.7%)	49 (47.1%)
Female	36 (48.6%)	19 (63.3%)	55 (52.9%)
Disease duration, mean $\pm$ SD, yrs	3.16 $\pm$ 2.65	2.43 $\pm$ 2.04	2.95 $\pm$ 2.50
Weight (Z score $\pm$ SD)	-0.33 $\pm$ 1.37	-0.35 $\pm$ 1.30	-0.34 $\pm$ 1.34
Height (Z score $\pm$ SD)	-0.60 $\pm$ 1.36	-0.65 $\pm$ 1.04	-0.61 $\pm$ 1.27
BMI (Z score $\pm$ SD)	0.05 $\pm$ 1.22	0.00 $\pm$ 1.34	0.03 $\pm$ 1.25
Disease activity			
Inactive	46 (62.2%)	13 (43.3%)	59 (56.7%)
Mild	26 (35.1%)	11 (36.7%)	37 (35.6%)
Moderate/severe	2 (2.7%)	6 (20.0%)	8 (7.7%)
Extraintestinal disease <sup>a</sup>	6 (8.1%)	5 (16.7%)	11 (10.6%)
Surgical ostomy	1 (1.4%)	1 (3.3%)	2 (1.9%)
Operation <sup>b</sup>	7 (9.5)	5 (16.7)	12 (11.5%)
Referral center for PGN	28 (37.8%)	18 (60.0%)	46 (44.2%)
UHC Zagreb	13 (17.6%)	6 (20.0%)	19 (18.3%)
UHC Rijeka	33 (44.6%)	6 (20.0%)	39 (37.5%)

<sup>a</sup>Including fever, arthritis, uveitis, erythema nodosum, pyoderma gangrenosum, oral disease, granulomatous skin lesions, primary sclerosing cholangitis, ankylosing spondylitis, and sacroiliitis.

<sup>b</sup>Nonresection, resection, or proctocolectomy.

BMI, body mass index; PGN, pediatric gastroenterology and nutrition; UHC, University Hospital Center.

( $\chi^2 = 11.764$ ,  $df = 2$ ,  $P = 0.003$ ). Mann-Whitney tests were used to follow up this finding. A Bonferroni correction was applied, and so all effects are reported at a 0.025 level of significance. Scores for item "symptoms" were significantly higher (worse HRQOL) even when mild level of disease activity was compared with inactive disease ( $P = 0.018$ ). Difference in scores in comparison with remission for item "function" was significantly higher only for moderate/severe levels of disease activity ( $P = 0.001$ ). Results are presented in Table 4.

## Reliability

Analyzing the current sample, SHS demonstrated adequate internal consistency with Cronbach's  $\alpha$  of 0.74. Removing item 3 (disease-related worry) increased Cronbach's  $\alpha$  to 0.81.

## Responsiveness

Responsiveness was analyzed in 41 patients (44%) who participated in the reevaluation (after 6–12 mo). Of them, 14 patients had active disease at both visits and were omitted from this analysis. The median SHS scores from the 2 visits are presented in Table 5. Of remaining patients, 14 patients who maintained their remission during the follow-up period had no

**TABLE 3.** Spearman Correlation Coefficients ( $r_s$ ) Between SHS Items and Scales of Other Validated HRQOL Instruments (N = 90)

Scales of Other HRQOL Measures	SHS Symptoms	SHS Function	SHS Worry	SHS General Well-being
<b>Symptoms</b>				
Physical health (PedsQL)	<b>-0.45</b>	-0.50	-0.44	-0.40
Symptoms (IMPACT-III (HR))	<b>-0.65</b>	-0.62	-0.56	-0.48
Worry about stool (IMPACT-III (HR))	<b>-0.36</b>	-0.32 <sup>a</sup>	-0.30 <sup>b</sup>	-0.27 <sup>c</sup>
<b>Function</b>				
Social functioning (PedsQL)	-0.36	<b>-0.50</b>	-0.38	-0.43
School functioning (PedsQL)	-0.39	<b>-0.41</b>	-0.34 <sup>d</sup>	-0.34 <sup>d</sup>
Socializing (IMPACT-III (HR))	-0.36	<b>-0.58</b>	-0.51	-0.45
<b>Worry</b>				
Psychosocial Health (PedsQL)	-0.38	-0.47	<b>-0.52</b>	-0.45
Emotional functioning (PedsQL)	-0.20 <sup>e</sup>	-0.28 <sup>f</sup>	<b>-0.56</b>	-0.37
Concerns (IMPACT-III (HR))	-0.25 <sup>g</sup>	-0.38	<b>-0.72</b>	-0.35 <sup>d</sup>
Body image (IMPACT-III (HR))	-0.24 <sup>h</sup>	-0.42	<b>-0.51</b>	-0.36
<b>General well-being</b>				
PedsQL total score	-0.43	-0.52	-0.51	<b>-0.50</b>
IMPACT-III (HR) total score	-0.51	-0.61	-0.71	<b>-0.50</b>

Correlations between each SHS question and its corresponding scale in other HRQOL questionnaires are printed in bold. All correlations are significant with  $P < 0.0001$  except for a-h which are 0.002, 0.003, 0.009, 0.001, 0.066, 0.007, 0.015, and 0.019, respectively.

N, number of subjects.

significant change in SHS scores. Change in disease activity was reported for 13 patients: 5 patients changed from remission to active disease and 8 of them contrariwise. These patients showed a significant change in the expected direction in 3 SHS scores ( $P < 0.05$ ), except for the “general well-being.”

### DISCUSSION

In this study, the psychometric properties of the SHS as the measure of the HRQOL were determined for the first time in the pediatric patients with IBD. To assess its validity, SHS was compared with the much more complicated and time-consuming IMPACT-III (HR)—disease and age-specific questionnaire, which was previously psychometrically validated in the same

**TABLE 4.** SHS Scores for Patients in Remission and Patients with Active Disease at Their First Assessment (N = 94)

SHS Items	Remission (N = 52)	Mild Active (N = 34)	Moderate/Severe Active (N = 8)	P
Symptoms	4 (0–16)	13 (2–35)	21 (5–41)	<b>0.022</b>
Function	3 (0–20)	8 (2–52)	50 (14–65)	<b>0.003</b>
Worry	13 (2–45)	21 (5–46)	45 (33–65)	0.085
General well-being	4 (0–15)	5 (0–30)	9 (4–27)	0.251

For each item, responses were scored from 0 to 100, with higher scores representing worse HRQOL. Score results are presented as median and interquartile range values rounded off to integers. Significance of difference in median scores between patients in different disease activity groups was analyzed using Kruskal-Wallis rank test. Significant P values are printed in bold.

N, number of subjects.

group of our patients,<sup>7</sup> and also to the PedsQL. However, SHS was found to be a reliable indicator with the appropriate psychometric properties, which performed as well in children as it was previously shown for the adult patients with CD and UC, both original and culturally adapted version.<sup>10,11,13,14</sup> Total variance explained above 60% is acceptable and shows that SHS explains higher percentage of the variance of the sample than the 35-item IMPACT-III (HR) (60.4% versus 53.7%). Validity was also confirmed by a stronger and significant correlation of SHS questions and the corresponding subscales of other validated and age-specific HRQOL questionnaires. However, SHS question for social functioning was more closely associated with noncorresponding subscales of PedsQL (physical health) and IMPACT-III (HR) (symptoms) than assumed corresponding ones. Identical results were reported in 2 psychometric validations of SHS in adult patients with CD ( $r = -0.72$  with intestinal symptoms of IBDQ questionnaire)<sup>10</sup> and UC ( $r = -0.74$  with intestinal symptoms of IBDQ questionnaire).<sup>11</sup> This finding could be explained by the formulation of the question (“Do your bowel problems interfere with your activities in daily life?”) and the answer range (“Not at all—Interfere to a very high degree”). Here, functional status was examined by seeking an answer to how much does disease symptoms (“bowel problems”) impair social functioning.<sup>10</sup> Incorporating disease manifestations in the formulation directly correlates the item with the “symptom” domains of other concurrent HRQOL questionnaires. Despite that, SHS item for social functioning should not be discarded rather reformulated because correlation with “socializing” subscales of PedsQL and IMPACT-III (HR) was very good (0.50 and 0.58, respectively). These results demonstrate that 4-item SHS evaluates the impact of IBD on health in children about as good as the more extensive HRQOL instruments. Finally, validity was confirmed by significantly worse scores obtained from patients with active disease

**TABLE 5.** Responsiveness to Change in Disease Activity for SHS Items Over a Follow-up Period

SHS Items	Stable in Remission (N = 14)			Change in Disease Activity (N = 13)		
	Remission	Relapse	P	Remission	Relapse	P
Symptoms	3 (0–28)	17 (3–39)	0.374	6 (0–8)	12 (3–27)	<b>0.032</b>
Function	5 (0–22)	8 (3–21)	0.476	2 (0–9)	11 (5–56)	<b>0.008</b>
Worry	13 (2–62)	22 (4–47)	0.480	6 (1–15)	30 (3–45)	<b>0.021</b>
General well-being	3 (0–23)	7 (0–31)	0.262	1 (0–13)	8 (1–18)	0.515

Patients with active disease at both visits were omitted (N = 14). For each item, responses were scored from 0 to 100, with higher scores representing worse HRQOL. Score results are presented as median and interquartile range values rounded off to integers. Significance was tested with Wilcoxon's sign rank test. Significant P values are printed in bold. N, number of subjects.

compared with patients in remission. This has proven that SHS can successfully distinguished patients with active and inactive disease. However, this has not been achieved for the items examining disease-related worry and general well-being. However, for proper positioning of both HRQOL tools, it is important to recognize that the value of the IMPACT-III is in the ability to evaluate more precisely quality of life aspects that are specifically influenced by IBD. This fine-tuning ability cannot be simply compressed into the 4-item instrument, such as SHS.

Along with verifying the validity of the questionnaire, reliability was assessed by means of internal consistency. The test gives reliability estimations based on the average correlation among items in the questionnaire. Obtained Cronbach's  $\alpha$  value above 0.70 indicates an acceptable reliability coefficient for group comparisons.<sup>24</sup>

In addition to validity and reliability analysis, our study has proven sensitivity to change over time for the 3 SHS questions. This was confirmed by reassessment after 6 to 12 months. Patients who had change in disease activity from remission to active disease, and vice versa, had a significant and meaningful change in the scores (with increase in disease activity quality of life was worse). Also, patients who remained in remission had no significant difference in SHS scores at retest. Only exception was the item "general well-being," where significant difference in scores was not reported after change in disease activity.

This study has several strengths: use of well-validated measures to assess disease activity and HRQOL, multicenter data collection (limits shared method bias), and recruitment from both inpatient and outpatient sample. However, several limitations need to be addressed. First, sample size for interpretable factor analysis was just about sufficient.<sup>25</sup> Larger and more representative sample would yield more assuring results for discriminant validity and responsiveness analysis. Second, test–retest reliability was not reported because period to reassessment was too long (6–12 mo). For future studies using the SHS, test–retest reliability analysis is strongly recommended. Third and final, randomization of participants was not performed, and they were enrolled prospectively as they arrived to the recruitment site, which could lead to selection bias.

## CONCLUSIONS

We have demonstrated, for the first time in pediatric patients with IBD, that SHS is valid, reliable, and sensitive HRQOL questionnaire for children with IBD. Easiness of use, compactness, and immediate interpretation make SHS well suited for both clinical practice and research studies.

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Author contributions: S. Abdovic designed the study, acquired data, performed the analysis and wrote the first draft manuscript; A. M. Pavic, M. Persic, and I. Senecic-Cala acquired data, commented in the design and analysis and approved the final manuscript; M. Milosevic performed the analysis and approved the final manuscript; S. Kolacek designed the study, commented in the design and analysis and revised the manuscript.

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