Validation of the Short Inflammatory Bowel Disease Questionnaire as an outcome measure in Crohn's disease patients

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Background

Health-related quality-of-life by the self-report, disease-specific Short Inflammatory Bowel Disease Questionnaire (SIBDQ) is increasingly used as an outcome measure in Crohn`s disease (CD) patients in clinical trials.

Higher SIBDQ scores indicate better quality-of-life; the range is 10 to 70. However, the construct validity of SIBDQ and its responsiveness to change of disease status require validation.

Methods:

This study was part of a randomized clinical trial evaluating the effectiveness of mindfulness-based stress reduction (MSR) in CD patients.

Patients, recruited from gastroenterology clinics or self-referral, were randomly assigned to either 3 months of MSR or a 3-month wait-list control condition, beginning at time T1 and ending at T2.

The inclusion criteria were (i) age over 18 years, (ii) verified CD diagnosis, (iii) mild to moderately active based on Harvey–Bradshaw Index (HBI > 5 or < 16), (iv) at least 3-month post diagnosis.

Clinical, laboratory and self-report measures were collected prospectively from a cohort of 108 CD patients. Laboratory markers of disease activity included Calprotectin and C-reaction protein (CRP), while clinical symptoms were assessed using the HBI.

The construct validity of SIBDQ in relation to biomarkers and HBI was determined by Pearson correlations and group comparisons using Student`s t-test.

Results: Sample's Characteristics

Demographic and medical characteristics (median, %) were: age 30 y; females 65%; higher education 83%; BMI 22; disease duration 5 y; Montreal classification A2 89%, L2+L3 89%, B1+B2 89%, perianal disease 18%.

Results:

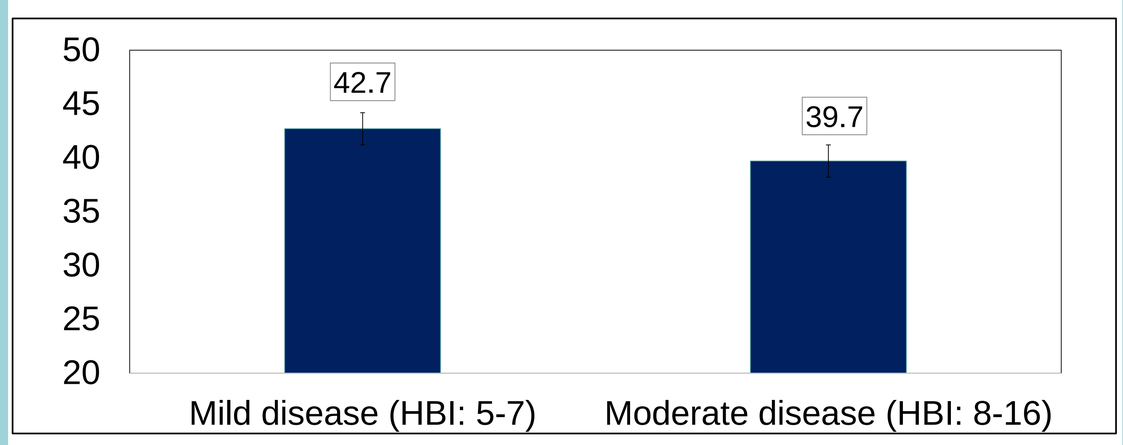
SIBDQ scores correlated inversely with Calprotectin (r=-.395, p=.002), CRP (r=-.208, p=.046), and HBI (r=-.345, p<.001).

Baseline HBI scores were used to divide the cohort into two groups for comparison: mild disease (5–7) vs. moderate disease (8–16). Mild disease patients reported higher SIBDQ scores than those with moderate disease (42.7 vs. 39.7, t=1.96, p=.05; see figure 1).

Regarding sensitivity of SIBDQ to clinical changes between T1 and T2, we found that change in SIBDQ correlated significantly with change in CRP across these two administrations (r = -.232, p = .042).

Defining clinical response in CD as a decrease from baseline HBI score by ≥3 points, SIBDQ change scores were significantly larger in treatment responders (n=51, M=6.25) vs. non-responders (n=30, M=1.13, t=−3.042, p=.003).

Figure 1. Differences in SIBDQ scores for mild vs. moderate disease activity



Conclusions:

- ✓ The SIBDQ is a valid assessment of quality-of-life in CD, correlating with biomarkers of disease activity.
- ✓ The SIBDQ is sensitive to therapeutically-induced change in clinical symptoms of CD.
- ✓ SIBDQ has the potential for use as patient-reported outcome in both clinical practice and as a primary end-point in clinical trials

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