Validation of the Danish version of Inflammatory Bowel Disease Self-assessment Scale

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ABSTRACT
INTRODUCTION: The Inflammatory Bowel Disease Fatigue Self-assessment Scale (IBD-F) is a multidimensional, disease-specific questionnaire. Patients with inflammatory bowel disease (IBD) took part in the development of the tool. The scale was developed in the UK and comprises 35 questions: five questions about the severity of fatigue and 30 questions about the impact of fatigue. The purpose of this study was to validate a Danish electronic version of the IBD-F in a Danish IBD population.

METHODS: We included IBD outpatients regardless of disease activity. They were invited to answer the IBD-F, the Multidimensional Fatigue Inventory (MFI-20) and the health-related quality of life tool known as the Short Health Scale (SHS). Furthermore, we collected socio-demographic and disease data. A subsample was invited to answer the IBD-F again two weeks later. Spearman analysis was used to evaluate the correlations between the IBD-F, the MFI-20 and the SHS. Reliability was tested by intraclass coefficients.

RESULTS: A total of 325 patients were invited, and 159 patients had complete data. The IBD-F correlated well with the MFI-20 fatigue tool for almost all dimensions. The correlation with the SHS was less marked. The following variables were associated with more fatigue: female, Crohn’s disease, respondent unemployed and comorbidity. The test-retest reliability was excellent.

CONCLUSION: The Danish version of the IBD-F is a valid tool for use in Danish patients with IBD.

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TRIAL REGISTRATION: not relevant.

‘Inflammatory bowel disease (IBD) comprises the two diseases, ulcerative colitis (UC) and Crohn’s disease (CD), and affects approximately 2.5-3 million people in Europe [1].

Some studies have identified fatigue as one of the main concerns for patients with IBD, along with sufficient bowel control [2]. Fatigue in IBD flare is closely related to active gut inflammation. Nevertheless, many patients whose disease is in remission still suffer from fatigue [3]. A systematic review identified a fatigue prevalence ranging from 41-48% in patients with disease in remission to 86% for patients with active disease [4]. In both CD and UC patients, fatigue has been proven to determine health-related quality of life (HRQoL) independently of disease activity [5, 6]. This suggests that measuring fatigue may be a simple way of screening for overall well-being. The concept of fatigue has proven hard to define. While most studies agree that fatigue is a multidimensional construct, a recent review discovered that studies use different definitions of fatigue: low energy, tiredness, decline in vitality and vigour or reduced energy and vitality [7-9].

The Inflammatory Bowel Disease Fatigue Self-assessment Scale (IBD-F) is a multidimensional, disease-specific questionnaire [10]. It was developed in collaboration with an English IBD population and comprises a total of 35 questions about fatigue. The IBD-F is the first disease-specific tool for measuring fatigue in IBD. As patients with IBD are generally young, an online version of the IBD-F questionnaire seems the most rational tool in clinical practice [11]. We hypothesised that an IBD-F electronic questionnaire would be as capable as other fatigue measurement tools in IBD. The aim of this study was to translate and validate an electronic version of the IBD-F questionnaire in a Danish IBD population.

METHODS
The IBD-F comprises five questions about the severity of fatigue (Section I) followed by 30 statements exploring the impact of fatigue (Section II). Questions are graded on a Likert scale: 0-4. Section I yields a total score of 0-20, and Section II a score of 0-120. A higher score indicates a higher level of fatigue. The translation of the IBD-F into Danish was done in accordance with international guidelines and using the following steps. First, a forward translation from English into Danish was done by two independent translators who had English as their native language and who were fluent in Danish. Second, the translated version was discussed and consensus was obtained among the translators, a third, independent party, and the investigators. Third, a back-translation into English was done by two other independent translators who had Danish as their native language and were fluent in English. Finally, the back-translated version was discussed at a consensus meeting and subsequently sent to the developer of the original IBD-F questionnaire for validation.
The final Danish version underwent pilot testing for face validity among nine patients with IBD in our outpatient clinic. The face validity test gave rise to only minor comments. No adjustments were made as a result of the pilot test. The final adjusted version was then back-translated into English and presented to the original authors, and no further changes were made.

The previously validated Multidimensional Fatigue Inventory (MFI-20) and the Short Health Scale (SHS) questionnaire were used to validate the IBD-F. The MFI-20 is a fatigue-specific instrument that consists of five dimensions: general fatigue, mental fatigue, physical fatigue, reduced motivation and reduced activity. It contains total of 20 statements each rated on a 1-5 Likert scale, yielding a total fatigue score of 20-120. The subgroups yielded a score of 4-20. A higher score indicates a higher level of fatigue. The MFI-20 was initially validated in a cancer and chronic-fatigue population in the Netherlands [13]. The MFI-20 has been used frequently in other IBD fatigue studies [6]. The SHS is a disease-specific HRQoL instrument that consists of four questions: symptom burden, functional status, disease-related worry and general well-being. Participants grade the four questions on 100-mm visual analogue scales. A higher score indicates a negative experience for the dimension. The SHS has been validated in patients with IBD in Sweden and is frequently used in IBD outpatient clinics in Scandinavia [14, 15]. Furthermore, the SHS is short and well tolerated by both patients and physicians. In the present study, patients were excluded if they did not complete at least the IBD-F and the MFI-20.

Patients had to be older than 18 years, have a verified IBD diagnosis, speak Danish fluently and have access to the Internet. Patients were included regardless of current disease activity. Patients eligible for inclusion were recruited consecutively in May and June 2016 during routine follow-up visits at the outpatient clinic of the Department of Hepatology and Gastroenterology at Aarhus University Hospital, Denmark. In addition to the completing IBD-F, the MFI-20 and the SHS questionnaires, participants were also asked to fill out a survey covering socio-demographic information, IBD diagnosis, current disease activity (classified as either disease flare or disease in remission) presence of comorbidity (physical or psychiatric) and any use of antidepressants. All items were self-reported. The electronic questionnaire was designed to impede progression if no answer was given, except for the socio-demographic items. There was, however, a “not relevant” option for every item. All responders were invited to participate in a retest of the IBD-F tool two weeks later.

Patients who reported changes in disease activity between the test and the retest were excluded from the re-test analysis. The sample size followed the recommendation that a method comparison study should have a minimum of 50 subjects [16]. The possibility of floor or ceiling effects was examined; effects were considered present if more than 15% of subjects achieved either the highest or the lowest score [17]. Associations between clinical/basic socio-demographic data and the IBD-F values were tested with a t-test for binary variables or a one-way ANOVA. Since Section II contained the ‘not relevant’ option for each item, an adjusted score was calculated:

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\text{Adjusted score} = \frac{\text{Total score}}{\text{Max possible score} - \left(\text{number of NR’s} \times 4\right) \times \text{max possible score}}
\]

NR = questions answered “not relevant”.

Spearman analysis was used to evaluate correlations between the IBD-F, the MFI-20 and the SHS. Correlations above 0.7 were considered indicative of a significant correlation [18]. Data are presented as medians, ranges and interquartile ranges (IQRs) or as numbers and percentiles with 95% confidence intervals (CIs). Analysis of internal correlation was assessed using Cronbach’s $\alpha$. Test-retest reliability was calculated and assessed by intraclass coefficients (ICC) and their corresponding 95% CIs.

All tests were two-sided and a 5% significance level was used. All data were analysed using STATA v.13.1 (StataCorp, College Station).

Trial registration: not relevant.
RESULTS
A total of 325 patients with an IBD diagnosis gave consent to participation in the study, and 177 responded (54%). Figure 1 shows the process of inclusion in the main study and the retest. Patients were excluded from the analysis if they failed to complete both the IBD-F and the MFI-20. Due to the design of the electronic questionnaire, there were no single missing items. In the retest, 74 responded (78% of the invited patients, 42% of the total number of participants). Primary socio-demographic and clinical data at study entry are presented in Table 1. There were no statistically significant differences between the UC and the CD subgroups in the test group. No floor or ceiling effects were present in either Section I or Section II of the test or the retest.

Different factors were associated with high fatigue. The median fatigue in Section I for males was 5 (IQR: 3-11), whereas the median for females was 10 (IQR: 6-12; p < 0.01). The median fatigue score in Section I for patients with CD was 10 (IQR: 6-13), whereas the median fatigue score for patients with UC was 8 (IQR: 5-11; p < 0.01). The median fatigue scores in Section I for employed versus unemployed subjects was 9 (IQR: 5-11) and 11 (IQR: 6-13; p < 0.05), respectively. The median score in Section I for subjects with comorbidity was 11 (IQR: 6-12), whereas subjects without comorbidity had a median score of 8 (IQR: 5-11; p < 0.05). The results for Section II were also significant for all of the above-mentioned variables. Cohabitation, disease activity, age, length of education and number of working hours were not found to be significantly associated with higher fatigue scores. The correlations between the IBD-F sections, the SHS and the MFI-20 are presented in Table 2. All correlations between the MFI-20 and the IBD-F exceeded 0.7, except for mental fatigue in Section I and reduced motivation in both sections. No correlation between the SHS and the IBD-F exceeded 0.7, except for that of the sub-group IBD flare with SHS item 2. The test-retest reliability results are presented in Table 3. In the present study, we found ICC scores of 0.88 and 0.94 for Section I and Section II, respectively.

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**Table 1**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Test CD (N = 74)</th>
<th>Test UC (N = 78)</th>
<th>Retest CD (N = 30)</th>
<th>Retest UC (N = 31)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age group, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-29 yrs</td>
<td>14 (18.9)</td>
<td>21 (26.9)</td>
<td>6 (20.0)</td>
<td>8 (25.8)</td>
</tr>
<tr>
<td>30-39 yrs</td>
<td>22 (29.7)</td>
<td>17 (21.8)</td>
<td>9 (30.0)</td>
<td>3 (9.7)</td>
</tr>
<tr>
<td>40-49 yrs</td>
<td>13 (17.6)</td>
<td>18 (23.1)</td>
<td>4 (13.3)</td>
<td>8 (25.8)</td>
</tr>
<tr>
<td>50-59 yrs</td>
<td>12 (16.2)</td>
<td>15 (19.2)</td>
<td>4 (13.3)</td>
<td>8 (25.8)</td>
</tr>
<tr>
<td>&gt; 60 yrs</td>
<td>13 (17.6)</td>
<td>7 (9.0)</td>
<td>7 (23.4)</td>
<td>4 (12.9)</td>
</tr>
<tr>
<td>Gender, male, n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical illness</td>
<td>21</td>
<td>29</td>
<td>9</td>
<td>14</td>
</tr>
<tr>
<td>Psychiatric illness</td>
<td>2</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Treated with antidepressants</td>
<td>2</td>
<td>1</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Physical and psychiatric illness</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>25 (35.2)</td>
<td>37 (48.0)</td>
<td>11 (36.7)</td>
<td>16 (51.6)</td>
</tr>
</tbody>
</table>

CD = Crohn’s disease; IQR = interquartile range; UC = ulcerative colitis.

**Table 2**

Correlations between Inflammatory Bowel Disease Fatigue Self-assessment Scale, Short Health Scale and Multidimensional Fatigue Inventory.

<table>
<thead>
<tr>
<th>IBD-F, Spearman correlation coefficient, median (IBD flare)</th>
<th>Section I, total fatigue</th>
<th>Section II, total fatigue</th>
</tr>
</thead>
<tbody>
<tr>
<td>General fatigue</td>
<td>0.88 (0.81) [0.89]</td>
<td>0.85 (0.73) [0.87]</td>
</tr>
<tr>
<td>Physical fatigue</td>
<td>0.73 (0.66) [0.75]</td>
<td>0.80 (0.82) [0.79]</td>
</tr>
<tr>
<td>Mental fatigue</td>
<td>0.66 (0.62) [0.66]</td>
<td>0.74 (0.75) [0.73]</td>
</tr>
<tr>
<td>Reduced activity</td>
<td>0.73 (0.57) [0.74]</td>
<td>0.79 (0.71) [0.79]</td>
</tr>
<tr>
<td>Reduced motivation</td>
<td>0.66 (0.73) [0.65]</td>
<td>0.69 (0.61) [0.69]</td>
</tr>
<tr>
<td>Total fatigue</td>
<td>0.84 (0.78) [0.85]</td>
<td>0.85 (0.85) [0.89]</td>
</tr>
<tr>
<td>SHS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Item 1, symptom burden</td>
<td>0.38 (0.59) [0.32]</td>
<td>0.36 (0.41) [0.33]</td>
</tr>
<tr>
<td>Item 2, functional status</td>
<td>0.61 (0.74) [0.59]</td>
<td>0.67 (0.77) [0.62]</td>
</tr>
<tr>
<td>Item 3, worries</td>
<td>0.31 (0.43) [0.29]</td>
<td>0.35 (0.46) [0.31]</td>
</tr>
<tr>
<td>Item 4, well-being</td>
<td>0.54 (0.55) [0.53]</td>
<td>0.54 (0.51) [0.55]</td>
</tr>
</tbody>
</table>

IBD = inflammatory bowel disease; IBD-F = Inflammatory Bowel Disease Fatigue Self-assessment Scale; MFI-20 = Multidimensional Fatigue Inventory; SHS = Short Health Scale. a) N = 24. b) N = 135.
The IBD-F was successfully translated into Danish and showed a good validity and reliability. The IBD-F seems to be a reliable tool for evaluation of fatigue in patients with IBD in a Danish population. We found that female gender, CD and presence of comorbidity were adversely associated with the IBD-F score, which is in accordance with previous research, suggesting that these factors influence fatigue and HRQoL [19]. We were unable to compare our results to those of others, as this is the first validity and reliability study of the IBD-F in Danish. Furthermore, we could not compare our results to fatigue values in the general population, as normative IBD-F values do not exist.

The correlations between Section I, Section II and the MFI-20 were excellent, especially for general fatigue and total fatigue. In contrast, the correlations between the IBD-F and the SHS were generally poor. Interestingly, when sub-divided into flare or remission, the flare group showed a significant correlation with SHS item 2. However, further research is needed to substantiate this correlation as we did not have sufficient data. The association may be explained by the fact that the terminology between the simple HRQoL questions and the more specific fatigue questions does not fully overlap. Strong internal correlation between Sections I and II may suggest that only section I alone may be used as a screening tool rather than the whole questionnaire, which may be deemed too long. However, further research is needed to support this. We used an interval of two weeks between the test and the retest. Some authors propose a longer interval to minimise recall bias. However, this time interval was chosen to ensure a minimal change in disease activity [17]. Despite the two-week interval, we had to exclude eight patients (11%) due to a change in disease activity as the purpose was to assess test-retest reliability.

One possible limitation of the study is that all patients were recruited from a single outpatient clinic at the Aarhus University Hospital. It is possible that patients with more disease-related problems visit the outpatient clinic more often and thus might represent a larger proportion in the study than is the case in the full Danish IBD population. Furthermore, we included patients consecutively regardless of the level of disease activity. However, in our study, the main aim was not to evaluate IBD fatigue but to validate the IBD-F questionnaire. In addition, no baseline data were collected for non-responders. Thus, we have no way of describing this group and cannot completely exclude the possibility of bias. Another possible limitation is that we did not collect biochemical data, e.g., markers for anaemia, disease activity, iron or vitamin D deficiency. In addition, future research should investigate responsiveness as we did not have enough participants with a change in disease activity to perform the needed calculations. Lastly, with the option of “not relevant”, some patients might have achieved a lower total score on the grounds that they would have scored high on an item if it were relevant. To minimise this possibility, we calculated Section II as an “adjusted score”, which eliminates the irrelevant questions individually.

This study has several strengths: we used well-validated measures of fatigue and the HRQoL to compare with the IBD-F, the data were collected from an outpatient clinic that covers patients from a large area, and we included a large variety of socio-demographic data. It is questionable whether we could have increased the response rate by using paper versions of the IBD-F. Some studies have been able to improve response rates by sending non-responders a paper version. However, as
the aim was to validate an electronic version, we did not send out a paper version to non-responders [20]. Reminders to non-responders were e-mailed after one week. By using an electronic version only, we were able to reduce missing data and test the questionnaire in the situation that most resembles a possible clinical implementation.

CONCLUSION
This is the first study to validate the IBD-F questionnaire in Danish. The IBD-F is easy to administer electronically, it is disease-specific and may serve as a valid tool for measuring fatigue in IBD in daily clinical practice.

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LITERATURE