Original Article

Validation of Bengali version of functional digestive disorders quality of life questionnaire

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ABSTRACT:

Background: *Most people have functional bowel disorders, and the most common ones are irritable bowel syndrome (IBS) and functional dyspepsia (FD). These disorders can make daily life very difficult. A lot of people use the Functional Digestive diseases Quality of Life Questionnaire (FDDQL) to measure the health-related quality of life (HRQOL) of people who have functional bowel diseases. However, there cannot be a Bengali form of FDDQL, even though it is accepted in many countries. The point of this study was to make a Bengali FDDQL that fits the culture and check its validity and reliability.*

Methodology: *The survey questionnaire was initially written into Bengali and changed to fit the social and cultural situation in the area, as suggested by Beaton et al. At Dhaka Medical College, we looked at 130 people who had IBS and FD. We used updated kappa (k*) and item- and scale-level content reliability indices (I-CVI and S-CVI) to check the improved Bengali version. To prove convergent validity, Pearson's correlation values were used to look at the relationship between the FDDQL and the SF-36. Cronbach's alpha was used to measure internal uniformity. The patients were given the questionnaire 14 days after the first interview, and the coefficient of intraclass correlation was used to see how reliable the tests were when they were given again.*

Results: *The six-step process for translating and adapting to different cultures did not find any major problems with the material or the language. The I-CVI was higher than 0.75, the k* was higher than 0.67, and the S-CVI was 0.91. A Pearson's association value of more than 0.74 showed that FDDQL and SF-36 were related in a good way. Strong internal concordance (Cronbach's alpha = 0.86) and high reliability among tests (ICC = 0.93) were shown for the scale.*

Conclusion: *The Bengali version of the FDDQL works well, can be relied on, and is useful for measuring health-related quality of life in people with functional bowel diseases in both clinical and study settings.*

Key Words:
Functional bowel disorders,
Bengali version FDDQL

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Introduction

The functional gastrointestinal disorders (FGIDs) are a collection of conditions characterized by unique symptoms related to the gastrointestinal tract (GIT) that cannot be explained by any detectable organic cause through conventional studies (1). Despite being a non-lethal condition, they can have devastating effect on the quality of life (QOL) (2). QOL assessment includes the impact of a disease condition in daily activities and living as described by the patients themselves (3). Choosing a questionnaire that is pertinent, reliable, and elicits appropriate responses, while also being accessible in multiple languages, is a critical consideration when organizing a clinical trial pertaining to quality of life (4).

The FDDQL, developed by Chassany et al, (5) contains 43 questions, which measures the perceived impact of FD and functional dyspepsia (FD) and irritable bowel syndrome (IBS) in patient's quality of life. The tool employs a 5-point Likert scale to measure the self-perceived effect in eight domains namely: 8 items exploring activities, 9 items for discomfort, 6 items for perceptions, 3 items for coping mechanism, 3 items for disease related stress, 5 items for disease induced anxiety, 6 items for dietary habit, and 3 items for quality of sleep. Higher score indicates higher quality of life (6).

There is limited data regarding the prevalence of FGIDs in Bangladesh. A community-based survey found the prevalence of IBS and FD 12.9% and 8.3% respectively(7), indicating a possible high disease impact. However, till date no valid and culture sensitive tool in Bangla is available to objectively determine the quality of life due to FGIDs. This study aims to translate FDDQL into Bengali language and validation in Bangladeshi patients with Functional dyspepsia and IBS.

Methodology

A cross-sectional observational research took place among participants attending in Department of Gastroenterology of Dhaka Medical College Hospital, Bangladesh from May 2020 to April 2020. Through purposive sampling patients 18 years and above, diagnosed with FD and IBS according to Rome IV criteria(8), and not suffering from any serious mental illness, alcohol, or other substance abuse were included in this study.

This research consisted of two phases. Translation study and cross-culture adaptation study of the English FDDQL into Bangla was done in first phase, and validity of the translation was evaluated in second phase according to the criteria described by Beaton et al. (9).

Phase I: Translation and cross-cultural adaptation of the FDDQL

Translation study and cross-culture adaptation study were accomplished in the following six stages:

Stage I: Forward translation

First forward translation was conducted by two native Bangla translators. Only one translator was informed of the research concept. We designated the translators by T1 and T2 respectively. The author (IG) was one of the translators. Each of the translators submitted a written report to the expert committee.

Stage II: Synthesis of Bangla version (Ts)

The two translators and a recording observer (a third unbiased person was added to the team) sat together to synthesize the results of translations. By incorporating modifications influenced by regional traditions, routines, word pattern, and other factors, a synthesized modified Bangla version (Ts) was generated from the initial T1 and T2.

Stage III: Back translation

Two other translators, designated BT1 and BT2, back-translated the synthesized version. Blinding to the original version was ensured. Both BT1 and BT2, who were skilled in the English language, did not possess any medical background, neither were made aware of the research concept.

Stage IV: Expert committee review

One methodologist, one recording observer, one gastroenterologist, one language specialist, and four translators (forward and backward translators) comprised this committee. The committee received the following materials: the initial English FDDQL, two forward translations (T1 and T2) of the FDDQL, a modified synthesized version of the English translation (Ts), and two backward translations (Ts), in addition to all relevant reports.

The English FDDQL was compared to each translation by the committee. Semantic, idiomatic, experiential, and conceptual equivalence were authenticated across all

Bangla and English iterations. On each item, unanimity had been reached, and an initial Bangla questionnaire was formulated.

Stage V: Test of the preliminary Bangla version

It is advisable that a questionnaire be comprehensible to a child of 12 years of age or older. A preliminary Bangla version of the FDDQL questionnaire was therefore distributed to twenty 12- year-old school-aged pupils. In Gazipur, a cohort of twenty students (10 females and 10 males) was surveyed by the investigator during a visit to Chandona High School. He engaged in conversation with the institute's director and described the study procedure. The candidates were selected at random by the institute's director. The subjects were presented with a questionnaire comprising 43 inquiries. The participants were requested to articulate their comprehension, and their statements were documented by an observing observer. The pre-final Bangla version was revised in light of the feedback provided by the 12-year-old children. These revised versions were then administered to a cohort of thirty adult patients diagnosed with FD and IBS. The patients were selected in a random manner from the Gastroenterology outpatient department at Dhaka Medical College Hospital in accordance with predetermined inclusion and exclusion criteria. Regarding their comprehension, interviews were conducted with each of the FD and IBS patients, and the items were modified in accordance with their feedback.

Stage VI: Submission and appraisal of all written reports

Every written report was submitted to the guide for verification to ensure that reasonable translations were achieved and that the recommended stages were adhered to. The components of the adapted version were selected from the prefinal version based on participant feedback and the items that were most well-received (100 percent agreement) upon comprehension and pretesting.

Phase II: An evaluation of the psychological features of the pre-final Bangla form of the FDDQL:

The second step was when the researchers checked the changed Bangla questionnaire for its validity and reliability. To check the content validity, the item-level content reliability index (I CVI) alongside the scale-level material purity index (S CVI) were used. Four gastroenterologists looked at signs of material truth.

The experts used a four-point scale to rate the validity: four meant "extremely relevant," three meant "quite relevant," two meant "somewhat relevant," and one meant "not relevant." After proving to have good content validity, the Bangla form of the FDDQL was given to 130 adults with functional dyspepsia as well irritable bowel syndrome. To check for convergent validity, the same set of FD and IBS licenses were used to look at the link between the FDDQL and the SF 36. With the Pearson correlation value, you could see how closely each thing was linked. Cronbach's alpha was used to check the scale's internal consistency, and the Bangla form of the FDDQL was given again seven days after the first interview to see how reliable it was. We used the coefficient of intraclass correlation (ICC, [r]) to check how reliable the total and item results of the FDDQL were from one test to the next. (SPSS) version 25 (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp) was used to find the Intraclass Correlation Coefficient (ICC) and its 95% confidence interval.

Results

Phase I: Translation and validation

The forward and back translation of the FDDQL questionnaire in phase one was conducted without significant challenges. Minor discrepancies were addressed during the expert committee review. The items that were most comprehensively understood (100%) and most appropriately selected by the 12-year-old children and 30 patients during the probing phase were chosen for the pre-final adapted version. No modifications were required for cultural adaptation of any item.

Phase II: The Functional Digestion Disorders Quality of Life Questionnaire in Bangla and its psychometric qualities

Thirty people with FD along with IBS who met the requirements were accepted into Phase II. The people who took part were, on average, 33.6 years old (±9.7 SD). 52.3% of the people who took part were women, and 53.0% had at least a primary school education. 38% of the people who took part were women, and 11.7% were students. 55.4% lived in cities or towns. Demographic information is shown in Table 1.

Table 1: Patient demographics of phase II participants (n=130)

Characteristics		Frequency	Percentage
Age (mean ± SD) in year=33.6±			
Gender	Male	62	47.7
	Female	68	52.3
Education	Illiterate	29	22.3
	Capable of reading	5	3.8
	Capable of both reading & writing	5	3.8
	Primary level	24	18.5
	Secondary level	25	19.2
	Bachelor's/ Master's degree and higher	42	32.3
Occupation	Housewife	50	38.5
	Govt. Service	14	10.8
	Private Service	26	20.0
	Businessman	9	6.9
	Cultivator	4	3.1
	Rickshaw puller	5	3.8
	Student	15	11.5
	Others	7	5.4
Residence	Rural	58	44.6
	Urban	72	55.4

Four gastroenterologists looked at the modified version to make sure it was still accurate. I-CVI, which stands for item-level content validity index, was found to be 1 for 28 items along with 0.75 for 15 items. It was found that the modified kappa (k*) value was 1 for 28 items and 0.67 for 15 items. We found that the scale-level content validity index (S-CVI/Ave) was 0.91 by combining the scores.

We can see that there is a strong positive relationship within the FDDQL in addition the SF-36 (r=0.74, p <.001), and this is also seen in the FDDQL areas (Figure 1).

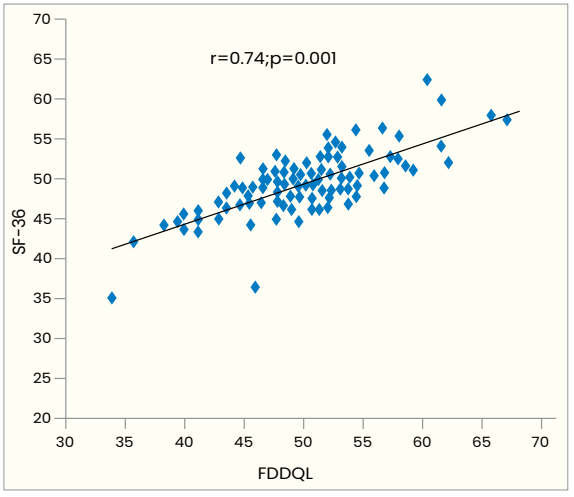

Figure 1 : Pearson's correlation coefficients between the FDDQL and the SF-36

Daily tasks and dealing with illness were the two FDDQL categories that were most strongly linked to SF-36 domains. There was a strong link between the daily tasks area and both physical role limitation and body pain, with Disability coefficients of r = 0.64 (p <.001) and r = 0.89 (p <.001). There is a strong link (r = 0.96) between the dealing with disease domain as well the general health areas. The results can be seen in Table 2.

Table -2: Pearson's correlation coefficients between the FDDQL and the SF-36 domains

		SF-36							
		Physical functioning (r)	Physical role limitation (r)	Emotional role limitation (r)	Mental Health (r)	Social functioning (r)	Energy (r)	Bodily Pain (r)	General health (r)
FDDQL	Daily activities	0.14	0.64*	0.11	0.17	0.23*	0.11	0.89*	0.16
	Anxiety	0.09	0.10	.07	0.31*	0.36*	0.29*	0.33*	0.36*
	Health perceptions	0.02	0.20*	0.25*	0.24*	0.14	0.14	0.19	0.20*
	Coping with disease	0.05	0.11	0.02	0.02	0.14	0.07	0.15	0.96*

* P number less than 0.05. All of the sites are linked in a good way. If the correlation coefficient (r) is greater than 0.50, between 0.35 and 0.50, or less than 0.35, it will be called strong correlation.

Cronbach's alpha showed that the Bengali version of the FDDQL total score was internally consistent at 0.86, which is higher than the accepted level of 0.70.

Out of the 130 people who were tested the first time, 122 could be tested again after 14 days, but 8 people could not be reached for a redo. The rate of dropping out was 6.15 percent. The intraclass correlation coefficient (ICC) gave a value of 0.93 for the test-retest dependability of the Bengali form of the FDDQL overall score.

Discussions

One estimate says that functional gut problems affect about 20% of the world's population (10). Because functional gut problems are so bad, it is very important to measure their health-related quality of life. A group of researchers from France, England, and also Germany worked together to make the FDDQL scale, which is now used a lot in many countries. This tool can be used in many situations, but it hasn't been translated and checked to work in Bengali yet.

The study's main goals were to translate and change the FDDQL for people who speak Bengali and to test the psychological features of this version in people who have FD and IBS. The FDDQL questionnaire was translated and adapted for use in different cultures according to the steps outlined by Beaton et al.(9), and there were no major problems noted. Several problems came up during the agreement meeting, but they were solved after several changes were made. We worked hard to make the cross-cultural version of the FDDQL English assessment semantically, conceptually, and experientially equivalent. Since the English poll items don't use any idioms, they didn't need to be changed to get an informal form of equality. After testing and making sure it was easy to understand, the things from the pre-final version that were easiest to understand (100%) and that participants liked the most were chosen to make the modified version.

Content validity was shown by an ICVI range of 0.75 to 1 for each item and an S-CVI/Ave of 0.91 for the modified version of the scale. The adjusted kappa (k*) value was also between 0.67 and 1. These are the factors used to judge kappa: A kappa number between.40 and.59 means the quality is fair,.60 to.74 means the quality is good, and more than.74 means the quality is excellent. An ICVI higher than 0.78 and an S-CVI/Ave greater than 0.9 show that the information is highly true. Since all scores were above 0.50, it looks like none of the things were turned down. It was very easy to read the changed Bengali form.

The Bengali version that was changed showed strong construct validity, as shown by the fact that the FDDQL and SF-36 had a high positive association. There was a strong link found between the FDDQL along with the GERDPRO-CG, which shows that the constructs are valid (6). The FDDQL scores that were most strongly linked to the SF-36 were those that measured daily tasks and how well people dealt with their illness. The daily tasks scale has a strong relationship with the physical role restriction alongside body pain scales ($r= 0.64$, $p <.001$ and $r = 0.89$, $p <.001$ for Disability).

However, the relationship with the emotional role limitation as well mental health scales is not as strong ($r =.11$ and $r =.18$). There is a strong link ($r = 0.96$) between the dealing with disease measure and the general health scale. Most of the time, the strongest relationships (r values between 0.57 and 0.75 were found between IGQ bloating and global scores and between FDDQL Discomfort (DT) and global scores in a similar study. There was a moderate relationship between the two IGQ scores and the FDDQL categories of Diet (DI), Daily Activities (DA), Anxiety (AN), and Sleep (SL). The values ranged from 0.38 to 0.56. The strongest link was found between FDDQL Discomfort and the other IGQ variables, especially FL ($r = 0.46$), SR ($r = 0.43$), and DGE ($r = 0.44$). The measure of bad breath had the weakest link to FDDQL, with a correlation value that didn't go above 0.22 (Lauffer et al., 2013). It was found that the Bengali form of the FDDQL had strong internal consistency (Cronbach's alpha = 0.86, $P <.001$), which is similar to what other studies have found (Feng-bin et al., 2014). The high level of internal uniformity shows that the things in the FDDQL are all the same.

The test-retest reliability was found to be excellent (ICC = .93, $P < .001$), aligning with findings from other studies which reported an ICC of 0.9 (6). The elevated ICC likely resulted from the brief interval between the initial and subsequent completion of the questionnaire. Values of the ICC exceeding 0.9 indicate that a tool is appropriate for the individual assessment of patients (11).

While our study demonstrated satisfactory validity and reliability of the Bengali version of the FDDQL, several limitations were identified. The study, conducted in a tertiary-level hospital and restricted to a single health center, does not fully represent the entire population of Bangladesh. Due to the absence of translated and validated functional bowel disorder-specific questionnaires in Bangladesh, convergent validity was evaluated using generic health-related questionnaires (e.g., SF-36) instead of functional bowel disorder-specific instruments. Discriminant validity was not evaluated.

Conclusion

The Bengali form of the FDDQL works well with adult patients in Bangladesh who have FD and IBS. It has good content validity, construct validity, internal consistency, as well as test-retest reliability. The changed Bengali form of the FDDQL has been demonstrated to be useful for both clinical and study purposes with Bangladeshi patients. This Bengali form of the FDDQL is suggested for checking the quality of life and keeping an eye on how well treatment is working in Bengali-speaking people who have functional bowel disorders.

Author contribution

a. Conception and design: [Md. Ma.R.]

b. Acquisition, analysis, and interpretation of data: [P.R, H.U, Md. Mu.R. Md. Q., S.K.M, H.A.]

c. Manuscript drafting and revising it critically: [M.K.P, F.C., H.A.]

d. Approval of the final version of the manuscript: [Md. Ma.R., F.C., H.H]

e. Guarantor accuracy and integrity of the work: [Md. Ma.R]

Informed consent

Informed consent was obtained from all participants subjects.

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Conflicts of interest

There are no conflicts of interest

Ethical approval

This study was approved by the institutional review board, Dhaka Medical College, Dhaka, Bangladesh. The IRB clearance Memo No. ERC-DMC/ECC/2020/114.

Data availability statement

The authors confirm that the data supporting the findings of this study are shared upon reasonable request

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