Validation of the Fecal Incontinence Severity Index in a Turkish Population

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Aim: The aim of this study was to validate the Turkish-translated version of the Fecal Incontinence Severity Index (FISI) for Turkish-speaking patients.

Methods: This prospective cohort study included 58 patients: 22 (37.9%) scored 0 (no incontinence), and the remaining 36 (62.1%) scored at least 1 (any level of gas, mucus, liquid, solid incontinence, pad wear, or lifestyle alteration). Test-retest reliability analysis, internal consistency analysis, content-face validity, and criterion validity were used to evaluate the Turkish version of the FISI. Validity of the criteria was assessed through correlation analyses between patient and surgeon scores of FISI and manometric measurement between patients with or without anal incontinence symptoms.

Results: The 2-week test-retest revealed significant correlation ($P < 0.001$). The Cronbach α values of the translated version for total scores of the scale were 0.735 and 0.734 for patient-rated scores and surgeon-rated scores, respectively, and indicate a high degree of internal consistency in each item of the questionnaire. Total and all subgroup scores of the FISI scale showed significant correlation with the maximal squeeze pressure and resting pressure values. Comparison of maximal squeeze pressure and resting pressure values of both groups showed significant differences between women with no incontinence and women with any form of incontinence.

Conclusions: The Turkish-translated version of the FISI is a reliable, consistent, and valid instrument for assessing the patient-rated symptom severity among women with anal incontinence in a Turkish-speaking population.

Key Words: anal incontinence, Fecal Incontinence Severity Index, validation

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Anal incontinence (AI) is common and can severely impair the quality of life (QOL) of affected women.[1] Although significant improvements have occurred in the understanding of the condition, debates about the methods of measuring the severity of incontinence still continue.[2] The identification of the severity of a condition is fundamental for the successful study of outcomes and important in comparing the effectiveness of alternative management strategies,[3] but selection of various available measure scales may still be a problem for the clinician.[4]

Anal incontinence is defined as the impaired ability to control gas, liquid, or formed stools, ranging in severity from mild to complete loss. The severity of symptoms of AI must be measured through subjective assessment.[2] Self-reported measuring instruments differ in some important aspects, with significant implications for assessing severity. One of the most important differences is the use of weighting.[2] In nonweighted assessment instruments, respondents are presented with various numbers of items and instructed to rate the frequency of the symptoms through the use of vague quantifiers such as never, rarely, sometimes, usually, and always. The total numerical value of the quantifiers generates the score of the instrument.[5] In weighted instruments, responses are multiplied by a weight that reflects the average severity, and the weighted responses are added to compile a total score.[6] However, arbitrarily chosen weight values by the researcher may not reflect the subjective experience of the patient. Lack of subjective perception of the patient's perspective in creating weight values restricts the ability of measuring the severity of the scale.[2] To address this problem, the Fecal Incontinence Severity Index (FISI) was developed as a severity measure. The FISI assigns values to various frequencies and types of incontinence on the basis of subjective ratings of severity.[3]

In the Turkish language, there is no validated weighted instrument measuring the severity of AI. The aim of this study was to validate the Turkish-translated version of FISI for Turkish-speaking patients.

MATERIALS AND METHODS

Questionnaire

The original questionnaire developed by Rockwood et al[3] has 6 frequency categories. To develop the questionnaire, a type-X frequency matrix was used based on the 4 types of incontinence: gas, mucus, liquid stool, and solid stool. The frequency dimension used 5 time frames: 2 or more times per day, once per day, 2 or more times per week, once per week, and 1 to 3 times per month. This matrix was administered to both colorectal surgeons and patients who were asked to rate the severity of various frequencies and to assign values such as "1" to the most severe cell in the table and a "20" to the least severe. With one based on patient ratings and one on surgeon ratings, 2 separate severity-weighting systems were developed. For calculation of the FISI scores, the original responses have been reverse-coded so that a higher score indicates greater severity.

To develop the Turkish version of the instrument, 2 professional English-Turkish translators not familiar with the FISI worked independently to produce the Turkish version of the questionnaire. The translated version was reverse-translated by 2 bilingual translators whose native languages were English. No discrepancies were found between the original and reverse-translated version of the questionnaire. At the first meeting, a common draft of the Turkish version was produced, with a list of alternatives for the controversial items and response choices. At the second meeting between the 2 translators and Turkish physicians with experience in "health and QOL terminology," some revisions were made as needed, and a second draft was produced. One item needed revision. The item "liquid" was replaced with "diarrhea" because culturally, the word liquid represents "something to drink" rather than something to pass out the anus. Ten symptomatic women were asked to self-complete the second draft, and then they were interviewed for possible ambiguous questions. At the third meeting, the final Turkish version was completed. The

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original questionnaire of the Turkish version also consisted of 4 questions about AI (mucus, gas, liquid, and solid). The final Turkish version is presented in the appendix.

Study Population and Data Collection

Initially, a pilot study was carried out for the evaluation of the internal consistency and test-retest reliability of the Turkish version of the questionnaire. Fifty-eight women completed the final version at the beginning of their first visit at the urogynecology outpatient clinic of Zeynep Kamil Hospital (a tertiary referral teaching institution, Istanbul, Turkey) before meeting a physician. The women who participated in the study were selected using the convenience sample method. Questionnaires were printed in large fonts (>16 points) so that women with poor eyesight could read and self-complete them. If a particular woman could not read or write, a relative or companion of hers, when available, helped her to complete the questionnaire. If not, support personnel not familiar with the concepts of urogynecology and QOL provided nondirective assistance to those patients.

To measure the test-retest reliability of the final version, a 2-week test-retest analysis was used. Twenty women were asked to complete the questionnaire at their initial visit and repeat the procedure 2 weeks later in the same clinic. All the women completed the 2-week retest. The responses of the 2 completed questionnaires were then analyzed, which revealed a significant correlation.

After the test-retest analysis of reliability, 58 patients were enrolled into the study. The enrollment followed a sequential basis. Patients who attended our urogynecology clinic were asked to complete the questionnaire. Manometrical investigation was performed on the women who completed the questionnaire regardless of the score of their questionnaires. Among 65 participants, a total of 58 women were available to validate the questionnaire. Seven patients with no incontinence declined to answer the questions and were excluded from the study. Mentally incapacitated patients were excluded from the study. The participants completed the questionnaire, and the same scoring system as described in the original questionnaire was used; total FISI scores were calculated, with the original surgeon-weighted and patient-weighted ratings done separately. Two surgeons experienced in AI in our urogynecology clinic rated the scores. Scores obtained with patient ratings were used for statistical purposes.

After completing the questionnaire, all the participants underwent anal manometric assessment, which was performed by the same investigator (C.C.) who was blinded to the questionnaire scores of the patients. Anorectal manometry measurements were measured with a water-perfused, 4-mm, 4-channeled, polyvinyl chloride manometric catheter. A continuous pull-through technique was used to perform the manometry in all 4 quadrants.

Statistical analysis was performed using SPSS for Windows version 11.0 (Chicago, IL). The paired *t* test was used to assess the difference between paired data sets. A value of $P < 0.05$ was considered to be statistically significant.

The institutional research board approved the study, and written informed consent was obtained from all of the participants.

Statistical Analysis

Data were collected and analyzed using SPSS (Statistical Package for Social Sciences) for Windows 15.0 software (Chicago, IL). To assess the internal consistency for the evaluation of the overall correlation between the items within each scale, the Cronbach α test was performed. The content/face validity, which indicates whether the questionnaire makes sense to the patients and experts and whether all the important and relevant domains were included, was assessed by an expert panel that included 2 urogynecologists and 1 psychometrician. Levels of missing data were used as the indicator of inappropriate questions.[7]

Validity of the criteria, which describes how well the questionnaire correlates with existing standards,[7] was assessed by comparing the scores with the results of manometric investigations. For statistical purposes, patients were divided into 2 groups according to their scores. The first group consisted of women who scored 0 (without any type of incontinence of any degree), and the second group consisted of women who scored at least 1 point (any degree of any type of incontinence).

The FISI scores were given as mean (SD). The Spearman correlation test was used for evaluating the correlation between FISI scores and the maximal squeeze pressure (MSP) and resting pressure (RP) values. The pressure values were also compared between patients with or without any complaint of incontinence (FISI = 0 or ≥1, respectively) using the Student *t* test. Comparisons of the demographics of these 2 groups were performed using the Student *t* or χ^2 tests, as appropriate. The level of significance was set at $P = 0.05$, and all given *P* values were 2-tailed.

RESULTS

Among 58 participants, 2 patients needed assistance by support personnel, and 56 participants self-answered the questionnaire. A total of 22 (37.9%) scored 0 (no incontinence,), and the

TABLE 1. Demographic Characteristics of the Participants

	Anal Incontinence (n = 36)	No Abnormality (n = 22)	*P*
*Age, mean (SD), y	50.97 (9.54)	55.47 (11.727)	0.214
*BMI, mean (SD), kg/m^2	29.145 (6.12)	30.07 (4.49)	0.584
*Parity, mean (SD)	3.26 (1.63)	3.75 (3.11)	0.501
§Menopause, n (%)	19 (52.8)	13 (59.1)	0.639
†Urinary symptoms, n (%)	5 (13.9)	2 (9.1)	0.586
‡Prolapse symptoms, n (%)	4 (11.1)	3 (13.6)	0.775

Significant at $P = 0.05$

*Student *t* test

†stress, urge or mixed incontinence, voiding difficulty.

‡POP-Q greater than stage II, any compartment.

§ χ^2 test was used to indicate the statistical analysis of comparison of "menapouse status" between two groups.

BMI indicates body mass index; POP-Q, pelvic organ prolapse quantification.

TABLE 2. Cronbach Alpha of the FISI Scale Scores

	Patient-Rated Scores	Surgeon-Rated Scores
Gas	0.837	0.835
Mucus	0.783	0.785
Liquid stool	0.745	0.739
Solid stool	0.747	0.728
Total score	0.735	0.734

remaining 36 (62.1%) scored at least 1 (any level of gas, mucus, liquid, solid incontinence, pad wear, or lifestyle alteration).

The characteristics of both groups were shown in Table 1. Both groups were similar with respect to age, body mass index, parity, and menopausal status. No woman was on hormone replacement therapy. There were no differences in other pelvic floor symptoms (urinary and prolapse) between the groups. The number of missing items was nil (0%). The responses of the 2 completed questionnaires of the 2-week test-retest revealed significant correlation ($P < 0.001$). The Cronbach α values of the translated version for total scores of the scale were 0.735 and 0.734 for patient-rated scores and surgeon-rated scores, respectively. A high degree of internal consistency was also present in each item of the questionnaire (Table 2).

The total and all subgroup scores of the FISI scale showed significant correlation with the MSP and RP values (Table 3). A comparison between the MSP and RP values of both groups was shown in Table 4. The MSP values of women with no incontinence (as indicated by a total score of 0) were significantly higher than those of the patients with any form of incontinence (as indicated by any score greater than 0).

DISCUSSION

According to the results of this study, the Turkish version of the FISI scale has a high internal consistency and test-retest reliability. Both scores of the scale, either patient rated or surgeon rated, showed significant correlation with the objectively assessed pressure values. Overall, asymptomatic women were associated with higher pressure values compared with those with any degree of AI symptoms.

TABLE 3. Correlation of FISI Domain Scores and Anal Manometric Measurements

		Patient-Rated Scores		Surgeon-Rated Scores	
		RP	MSP	RP	MSP
Gas	*r*	0.346	0.275	0.346	0.275
	P	0.008	0.036	0.008	0.036
Mucus	*r*	0.416	0.517	0.415	0.516
	P	0.0001	0.000	0.0001	0.000
Liquid stool	*r*	0.358	0.374	0.358	0.374
	P	0.006	0.004	0.006	0.004
Solid stool	*r*	0.291	0.326	0.291	0.326
	P	0.027	0.013	0.027	0.013
Total score	*r*	0.432	0.464	0.438	0.466
	P	0.001	0.000	0.001	0.000

Significant at $P < 0.05$

TABLE 4. Comparison of Mean Manometric Measurements Between Symptomatic and Asymptomatic Women

FISI Scale	Score (n)	MSP (mm Hg)	*P*	RP (mm Hg)	*P*
Gas	0 (n = 24)	157.92 (39.63)	0.006	71.33 (16.49)	0.008
	≥1 (n = 34)	130.75 (36.17)		59.45 (18.63)	
Mucus	0 (n = 40)	153.80 (36.18)	0.000	68.98 (17.29)	0.000
	≥1 (n = 18)	111.39 (30.06)		52.67 (17.27)	
Liquid stool	0 (n = 40)	150.10 (39.78)	0.005	68.28 (18.56)	0.003
	≥1 (n = 18)	119.61 (30.20)		54.22 (16.22)	
Solid stool	0 (n = 45)	147.44 (39.26)	0.013	66.67 (18.27)	0.008
	≥1 (n = 13)	117.08 (31.13)		54.38 (18.46)	
Total	0 (n = 22)	161.09 (37.75)	0.001	72.18 (16.98)	0.002
	≥1 (n = 36)	128.14 (35.46)		58.86 (18.38)	

Mann-Whitney *U* test was used.
Significant at $P < 0.05$.

The use of weighted methods was recommended for assessing the severity of fecal incontinence,[6] and FISI was developed.[3] The FISI was suggested to increase the understanding of patient values; but it was also advised to be replicated in other populations.[1] In a Turkish population, the Wexner score[5] was validated[8] and used in clinical trials,[9] but a weighted instrument for AI does not exist.

We used the original ratings of the patients and surgeons as originally published and did not rate the items again in Turkish patients and surgeons, because this would create a different severity measuring instrument than originally proposed. On the other hand, the incorporation of patient values into severity measurements may not be equal in different populations and may end up in inconclusive scores. Therefore, the step of assessing the content/face validity, which indicates whether the questionnaire makes sense to the patients and experts, carries a special major importance in validating patient-weighted instruments in different populations. İf difficulties are present in the step of assessing content/face validity, or if the internal consistency of the translated version is poor, rating the items again in the new population should be taken into account.

To assess the construct validity of our translated version of FISI, we compared the scores with anal manometric pressure measurements. Our data showed that worsening of the symptoms correlated with lower pressures, and women with any degree of AI symptoms had lower pressure measurements. These findings are also in concert with published data that showed that pressures at manometry correlate with the FISI.[10]

Anal incontinence in women with urogynecological problems is often overlooked, but one may expect that more than half of these may also experience AI. It is clear that evaluating women with pelvic floor complaints without assessing her anal functions may be suboptimal. However, manometric evaluation of such

patients is not justified and is not always easy to be accomplished when required. Therefore, these instruments should be used to screen patients with lower urinary tract symptoms.

The FISI has the advantage of weighing the severity of the symptoms and is relatively easy to complete by the patient. The subjective perception of the patient must be the foundation of any evaluation of incontinence or the impact of incontinence.

One of the limitations of our study is the relatively small sample size of the participants compared with the original study conducted by Rockwood et al.[3] The selection of the participants may be considered as another limitation of the study. The convenience sampling method is a statistical method of drawing representative data by selecting people because of the ease of their volunteering or selecting units because of their availability or easy access. Although this type of sampling has the advantages of availability and the quickness with which data can be gathered, it may carry the disadvantage that the sample might not represent the population as a whole.

CONCLUSIONS

To our knowledge, this is the first and only international validation of the FISI. Like the original English questionnaire, the Turkish-translated version of the FISI is a reliable, consistent, and valid instrument for assessing the patient-rated symptom severity among women with AI. The scores correlated and are associated with objective measures obtained during manometric investigations. In conclusion, it seems to be a reliable, consistent, and valid instrument for assessing AI in Turkish-speaking women.

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