



Prospective Italian validation of the Vaizey and Wexner and fecal incontinence severity index (FISI) questionnaires

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Abstract

Several objective severity measurement questionnaires of the fecal incontinence (FI), are available to describe type, frequency and degree of FI, and their impact on quality of life, aiming to establish baseline scores measure response to treatment over time and allow comparison among patients treated using different strategies. Presently, despite their widespread use in clinical practice, none of these questionnaire have been validated in the Italian language. The aim is to test the translated Italian version of the Vaizey and Wexner and Fecal Incontinence Severity Index (FISI) questionnaires assessing their reliability and validity among Italian-speaking patients. Two researchers proficient in spoken English and Italian translated both questionnaires in the Italian language. They independently translated the two questionnaires from English and then they met to produce a single version of the two questionnaires, to solve any possible discrepancy. A forward–backward translation was then obtained by a professional bilingual translator, so as to define the final version of the questionnaires. The questionnaires were independently administered twice to 100 Italian-speaking patients by two different and independent raters. Cronbach's α of the first and second Vaizey and Wexner questionnaire was 0.755 and 0.727, respectively. While Cronbach's α of the first and second FISI questionnaire was 0.810 and 0.806, respectively. Spearman correlation and inter-rater reliability were 0.937 and 0.913 for Vaizey and Wexner questionnaire, respectively, and 0.915 and 0.871 for FISI questionnaire, respectively. Italian version of the Vaizey and Wexner and FISI questionnaires proved good consistency, reliability, reproducibility, showing good psychometric properties.

Keywords Italian · Fecal incontinence · Vaizey and Wexner questionnaire · Fecal incontinence severity index (FISI) · Validation

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Introduction

Fecal incontinence (FI) is defined as the uncontrolled passage of stool for a duration of over 3 months in a patient who had previously control [1, 2]. FI is more common in women with a prevalence ranging between 1.4 and 18% [3–5]. Despite many women have coexisting pelvic floor disorders the most bothersome symptoms are frequently related to FI [3, 6]. Regarding men, FI is most frequently reported in nursing home populations, achieving an incidence of 50% and is mainly due to evacuatory dysfunction and rectal hyposensitivity [3, 7].

Several objective severity measurement instruments are available to describe the type, frequency and degree of FI, and their impact on quality of life, aiming to establish baseline scores measure response to treatment over time and allow comparison among patients treated using different strategies [3, 8–12]. Among the available questionnaires, some of the most commonly used are the Vaizey and Wexner [8, 9], Fecal Incontinence Severity Index (FISI) [10], and the Fecal Incontinence Quality of Life Scale (FIQL) [11] questionnaires, that expressly investigate the subjective presence of FI related symptoms and their severity. Vaizey and Wexner and FISI questionnaires are commonly used worldwide due to their easy administration in terms of patients' understandability and acceptability [8–10, 12]. Presently, despite their widespread use in clinical practice, and demonstrated efficacy in reporting changes of the continence condition, none of these questionnaires have been validated in the Italian language.

The aim of the present study is to test the translated Italian version of the Vaizey and Wexner and FISI questionnaires assessing their reliability and validity among Italian-speaking patients.

Methods

This is a prospective study. Institutional review board approval and a signed informed consent form from each patient included in the study were obtained.

From March 2021 to March 2022, all patients, with referred symptoms of FI, who have accessed to the outpatient clinic to our centers (Department of General Surgery, Università Politecnica delle Marche, Ancona, and UOC of General and Minimally Invasive Surgery, Hospital “San Paolo”, Civitavecchia, Rome, Italy) were included in the present study. All included patients spoke fluent Italian and were older than 18 years old. Patients with dementia, mental retardation, and/or other neurological disease were excluded. Eligible patients were informed about this study during the regular outpatient visit. The validation process followed a previously published methodology [13].

Translation and validation of the Vaizey and Wexner and FISI questionnaires

The original Vaizey and Wexner questionnaire is composed by seven questions that investigate the presence of FI (incontinence for solid and liquid stool, gas, alteration in lifestyle, need to wear pad or plug, taking constipation medicine and the inability to defer defecation) [8, 9]. To the first four questions is assigned a score ranges from 0 to 4 based on the frequency of incontinence episodes (0 = never; 1 = rarely; 2 = sometimes; 3 = weekly; 4 = daily) [8, 9]. To the fifth and sixth questions are assigned the score 0 (no symptoms) or 2 (symptoms), and to the last questions are assigned the score 0 (no symptoms) or 4 (symptoms) [8, 9]. The total score of the questionnaire ranges between 0 (perfect continence) to 24 (totally incontinent) (Fig. 1) [8, 9].

The original FISI questionnaire included four questions that investigate the presence of FI for gas, mucus, liquid and solid based on the frequency of incontinence episodes (2 or

Fig. 1 Italian Vaizey and Wexner questionnaire

	<i>Mai</i>	<i>Raramente</i>	<i>Qualche volta</i>	<i>Settimanalmente</i>	<i>Giornalmente</i>
Incontinenza alle feci solide	0	1	2	3	4
Incontinenza alle feci liquide	0	1	2	3	4
Incontinenza ai gas	0	1	2	3	4
Alterazione dello stile di vita	0	1	2	3	4
				<i>No</i>	<i>Si</i>
Necessità di indossare un pannolino o un plug				0	2
Assunzione di farmaci costipanti				0	2
Incapacità di ritardare la defecazione per 15 minuti				0	4

Mai: nessun episodio nelle ultime 4 settimane; **Raramente:** 1 episodio nelle ultime 4 settimane; **Qualche volta:** più di 1 episodio nelle ultime 4 settimane, ma meno di 1 a settimana; **Settimanalmente:** 1 o più episodi a settimana, ma meno di 1 al giorno; **Giornalmente:** 1 o più episodi al giorno.
 Aggiungi un punteggio per ogni riga: punteggio minimo = 0 = continenza perfetta; punteggio massimo = 24 = totalmente incontinente.

more times a day, once a day, 2 or more times a week, once a week, 1 to 3 times a month) [10]. Questionnaire includes patient and surgeon specific rate, but in the present study, the score was based only on patient specific ratings [10]. The total score of the questionnaire ranges between 0 (perfect continence) to 61 (totally incontinent) (Fig. 2) [10].

Two researchers (M.O. and A.B.), proficient in spoken English and Italian translated both questionnaires in the Italian language. They independently translated the two questionnaires in the Italian language and then they met to produce a single version of the two questionnaires, to solve any possible discrepancy in each of these steps. A forward–backward translation was then obtained by a professional bilingual translator, so as to define the final version of the questionnaires (Figs. 1 and 2).

Patient questionnaire administration

Questionnaires were independently administered twice to the Italian-speaking patients by two of the authors, without communicating between them. The questionnaires were administered again no less than 4 days and no more than 30 days after the first administration by the two different raters. During this period, the patients did not change therapy and did not undergo surgery.

Statistical analysis

Categorical variables were expressed as frequencies and percentages and continuous variables as mean ± standard deviation (SD). To evaluate differences between categorical and continuous variables between each question of the first and second questionnaire administration, Fisher's exact and student's *t* test were used. A *p* value lower than 0.05 was considered statistically significant.

For each questionnaire, internal consistency, referring to the expected correlation of two tests that measure the same construct, was assessed by Cronbach's coefficient (Cronbach's α) for both the first and second questionnaire administration [14]. A coefficient ≥ 0.70 supports the construct validity suggesting that the questions within a dimension measure the same construct [14]. Spearman rank correlation coefficient (Spearman coefficient) was employed to assess the questionnaire test–retest reliability between the first and the second questionnaire [14–16]. The correlation coefficient

was employed to assess inter-rater reliability between the two different raters [14–16].

Statistical analyses were carried out with SPSS software 22.0 (SPSS Inc., Chicago, IL, USA).

Results

One-hundred patients (39 women and 61 men) with mean age 62.2 ± 14 years and mean body mass index (BMI) of 23.1 ± 20.1 kg/m², were included in the present study. Patients' clinical characteristics are reported in Table 1.

Tables 2 and 3 show scores observed for each question in the Vaizey and Wexner and FISI questionnaires, respectively. Overall, in the Vaizey and Wexner questionnaire, patients with symptoms were 49 (49%) and 48 (48%) in the first and in the second questionnaires administration, respectively (*p* = 1.000). While for the FISI questionnaire, were 48 (48%) and 44 (44%) in the first and in the second questionnaires administration, respectively (*p* = 1.000). Statistically significant differences did not occur in each question and in the total score between the first and the second questionnaire administration for both Vaizey and Wexner and FISI questionnaire (Tables 2 and 3).

The questionnaire internal consistency, the Spearman coefficient and the correlation coefficient are reported in for the Vaizey and Wexner and FISI questionnaires in Tables 4 and 5, respectively. Cronbach's α of the first and second Vaizey and Wexner questionnaire was 0.755 and 0.727, respectively. While Cronbach's α of the first and second FISI questionnaire was 0.810 and 0.806, respectively. Spearman correlation and inter-rater reliability were 0.937 and 0.913 for Vaizey and Wexner questionnaire, respectively, and 0.915 and 0.871 for FISI questionnaire, respectively.

Discussion

The present study was conducted with the aim to validate in Italian two of the most popular questionnaires regarding FI (Vaizey and Wexner and FISI questionnaires) in order to obtain an appropriate cultural and linguistic adaptation [8–10].

To assess patients' understanding of the questionnaires, and reproducibility, the obtained score from the first and

Fig. 2 Italian Fecal Incontinence Severity Index (FISI) questionnaire

	2 o più volte al giorno	Una volta al giorno	2 o più volte la settimana	Una volta alla settimana	1 o 3 volte al mese	Mai
a. Gas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a. Muco	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a. Feci liquide	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a. Feci solide	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Table 1 Patients' clinical characteristics

Sex ratio (F:M)	39:61
Mean age \pm standard deviation, years	62.2 \pm 14
Mean body mass index \pm standard deviation, kg/m ²	23.1 \pm 20.1
Mean Charlson Comorbidity Index score \pm standard deviation	3.2 \pm 2.2
Comorbidities, n (%)	
Hypertension	33 (33)
Smoke habitus	21 (21)
Diabetes mellitus type 2	9 (9)
Dyslipidemia	7 (7)
Diverticular disease	7 (7)
Heart arrhythmia	6 (6)
Ischemic heart disease	6 (6)
Chronic obstructive pulmonary disease	5 (5)
Chronic heart failure	5 (5)
Haemorrhoids	5 (5)
Inflammatory bowel disease	3 (3)
Chronic renal failure	3 (3)
Cysto-rectocele	1 (1)
Liver cirrhosis	1 (1)
Previous abdominal surgery, n (%)	
Appendectomy	24 (24)
Cholecystectomy	9 (9)
Inguinal hernia repair	7 (7)
Hysteroansectomy	5 (5)
Surgery for rectal prolapse	4 (4)
Pfannestiel for Caesarean section	3 (3)
Right hemicolectomy	2 (2)
Surgery for hemorrhoids	2 (2)
Nephrectomy	2 (2)
Total colectomy	1 (1)
Prostatectomy	1 (1)
Monolateral ovariectomy	1 (1)
Bilateral ovariectomy	1 (1)

the second questionnaires administration should be similar, without statistically significant differences. For this reason, to avoid biases deriving from the patients' recollection of the answers given in the first administration of the questionnaires, we administered both questionnaires for a second time not before at least 4 days have passed from the first administration. Similarly, to avoid any changes in patients' continence status, and consequently in questionnaires score, the second administration took place no later than 30 days from the first one. Moreover, to avoid biases deriving from symptoms modification, the patients neither changed therapy nor underwent surgery during the study period.

The high coefficients achieved with Cronbach's α , Spearman and inter-rater reliability coefficients, similar to those reported in literature for other questionnaire validations [14–17], confirms the consistency, reliability and reproducibility of both questionnaires. In fact, Cronbach's α was higher of ≥ 0.70 in both questionnaire at the first and second administration, as well as for Spearman coefficient.

Moreover, questionnaires were administered by two different and independent raters and the high value of the inter-rater reliability coefficient obtained for the Vaizey and Wexner (0.913) and FISI (0.871) questionnaires, proved their high reproducibility. This suggests that the questions were well understood in the same way by most patients, during the second administration, and that the Italian translation is in agreement with patients' condition.

The only questionnaire validated in Italian language aimed to investigate on FI is the FIQL questionnaire, validated in 2005 by Altomare et al. [18]. Recently, the low anterior resection syndrome (LARS) score was validated in Italian language [19], even if the anterior resection syndrome is not directly related to the FI. Anyway, in our opinion, both of the above-mentioned questionnaires have some limitations. The FIQL questionnaire, which investigates on the quality of life related to FI symptoms, including 29 items, and it may

Table 2 Mean score of each question and total score of the first and second Vaizey and Wexner questionnaire

Question	1st questionnaire		2nd questionnaire		p value	
	Patients with symptoms, n (%)	Mean score \pm SD	Patients with symptoms, n (%)	Mean score \pm SD	Patients with symptoms	Score
Incontinence for solid stool	17 (17)	0.43 \pm 1.07	16 (16)	0.34 \pm 0.9	1.0000	0.5199
Incontinence for liquid stool	25 (25)	0.57 \pm 1.12	27 (27)	0.60 \pm 1.15	0.8720	0.8523
Incontinence for gas	35 (35)	0.81 \pm 1.30	36 (36)	0.86 \pm 1.35	1.0000	0.7898
Alteration in lifestyle	25 (25)	0.65 \pm 1.24	28 (28)	0.78 \pm 1.38	0.7488	0.4850
Need to wear a pad or plug	12 (12)	0.24 \pm 0.65	13 (13)	0.26 \pm 0.68	1.0000	0.8317
Taking constipating medicines	9 (9)	0.18 \pm 0.58	9 (9)	0.18 \pm 0.58	1.0000	1.0000
Lack of ability to defer defecation for 15 min	18 (18)	0.72 \pm 1.54	15 (15)	0.60 \pm 1.44	0.7037	0.5699
Total score	49 (49)	3.60 \pm 4.98	48 (48)	3.99 \pm 5.40	1.0000	0.5964

SD standard deviation

Table 3 Mean score of each question and total score of the first and second fecal incontinence severity index (FISI) questionnaire

Question	1st questionnaire		2nd questionnaire		p value	
	Patients with symptoms, n (%)	Mean score ± SD	Patients with symptoms, n (%)	Mean score ± SD	Patients with symptoms	Score
Gas incontinence	37 (37)	2.88 ± 4.34	34 (37)	2.81 ± 4.42	0.7677	0.9102
Mucus incontinence	27 (27)	1.85 ± 3.57	27 (27)	1.91 ± 3.58	1.0000	0.9057
Liquid incontinence	25 (25)	3 ± 5.62	25 (25)	3.22 ± 6.04	1.0000	0.7900
Solid incontinence	12 (12)	1.60 ± 4.51	10 (10)	1.41 ± 4.33	0.8217	0.7615
Total score	48 (48)	9.33 ± 14.59	44 (44)	9.35 ± 14.89	1.0000	0.6705

SD standard deviation

Table 4 Results of the Italian Vaizey and Wexner questionnaire

Question	Cronbach’s α 1st questionnaire	Cronbach’s α 2nd questionnaire	Spearman coefficient	Inter-rater reliability coefficient
Incontinence for solid stool	0.736	0.705	0.830	0.845
Incontinence for liquid stool	0.714	0.676	0.840	0.810
Incontinence for gas	0.700	0.658	0.960	0.918
Alteration in lifestyle	0.776	0.678	0.894	0.869
Need to wear a pad or plug	0.755	0.716	0.772	0.772
Taking constipating medicines	0.762	0.726	0.756	0.756
Lack of ability to defer defecation for 15 min	0.715	0.699	0.751	0.751
Total score	0.755	0.727	0.937	0.913

Table 5 Results of the Italian Fecal Incontinence Severity Index (FISI) questionnaire

Question	Cronbach’s α 1st questionnaire	Cronbach’s α 2nd questionnaire	Spearman coefficient	Inter-rater reliability coefficient
Gas incontinence	0.771	0.764	0.927	0.906
Mucus incontinence	0.809	0.810	0.959	0.953
Liquid incontinence	0.729	0.720	0.838	0.846
Solid incontinence	0.788	0.796	0.707	0.726
Total score	0.810	0.806	0.915	0.871

limit the patients’ understandability and acceptability [11]. On the other hand, the LARS score evaluates instead the presence and severity of FI symptoms after rectal anterior resection, narrowing the applicability of the questionnaire to a specific and restricted population of patients suffering from FI [19].

To the best of our knowledge, Vaizey and Wexner questionnaire has not been validated in any language other than the original one. On the other hand, the FISI questionnaire has been validated in Dutch and Turkish [16, 20]. Both validations proved good consistency, reliability, reproducibility, as the present one. The validation of the Vaizey and Wexner and FISI questionnaires in our opinion constitutes a valid tool to complete the available armamentarium to evaluate symptoms solely related to FI.

The main limitations of the present study are the number of patients included, and the fact that not all patients were affected by FI. However, the aim of the present study was to validate two already existing questionnaires [8–10] for Italian-speaking patients.

Conclusions

The Italian version of the Vaizey and Wexner and FISI questionnaires proved good consistency, reliability, reproducibility, showing good psychometric properties. They seem comparable to questionnaires validated in other languages. It could be a valid tool for evaluating the FI and it may be useful in clinical practice and research area.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Consent to participate Informed consent from all participants was obtained.

Consent for publication All authors approved the publication of the manuscript in the Journal.

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