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DECLARATIONS

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ABSTRACT (239 words)

Introduction: Two subtypes of fecal incontinence (FI) are defined in the literature (urge and passive FI). The pertinence of this classification is unknown due to conflicting findings and heterogeneity of definitions. However, no questionnaire is available to clearly classify patients among subtypes. The objective of the present study was to develop and validate a new tool (Fecal incontinence subtype assessment, FI-SA) in order to better classify patients among the different subtypes of FI.

Methods: A prospective monocentric study was conducted in consecutive patients with FI according to Rome IV criteria. To validate psychometric properties of the FI-SA questionnaire, a literature review and qualitative interviews were performed and discussed with an expert panel. A feasibility study was realized to assess acceptability and comprehension of items. The reproducibility was investigated in a validation study.

Results: Comprehension and acceptability were excellent in 90% of patients in the feasibility study (n=30). Validation study (n=100) showed a good reproducibility with an intra-class correlation coefficient of 0.91 and 0.89 for questions 1 and 2. Time to fill the questionnaire was 40.0 seconds. 98.0% patients were classified among subtypes of FI: 34.0% passive FI, 32.0% urge FI and 32.0% mixed FI.

Conclusion: FI-SA is the first questionnaire to classify patients among subtypes of FI with good psychometric characteristics and the first questionnaire introducing the concept of mixed FI. FI-SA could help to determine the pertinence of this classification of FI in the management of these patients.

Key words: fecal incontinence, classification, questionnaire.

INTRODUCTION

Fecal incontinence (FI) is defined by Rome IV criteria¹ as an involuntary loss of feces² occurring more than twice a month in the last 6 months of evolution. In general population, the prevalence of FI varies from 2.0 to 21.0%³. FI can lead to social isolation with a severe impairment of quality of life⁴ and an economic burden⁵. Urge FI and passive FI are the two classical subtypes of FI described by the International Continence Society². Urge FI is described as “the inability to defer defecation once the urge is perceived for long enough to reach a toilet” and passive FI as “the involuntary leakage of faeces without forewarning”². This classification is rather reductive and for example, the concept of mixed incontinence is not taken into account whereas this type of incontinence, both active and passive, is quite frequently encountered in daily practice. Urge FI seems to be more frequent in women than passive FI (35.0% versus 5.0%) in the community⁶ and may be associated with worse quality of life^{6,7}.

If several validated questionnaires are available for FI^{8,9,10,11,12,13,14,6}, all of these questionnaires were developed to assess FI severity or quality of life and not to precise FI type. Only 3 questionnaires^{11,12,13}, explored the notion of “deferring defecation” in their items. The notion of “fecal urgency” was only described in two questionnaires (the Manchester Modified Health Questionnaire¹⁴ and the Fecal Incontinence and Constipation Assessment⁶). This lack of precision in the characterization of FI could be misleading, and an inaccurate patient’s classification among subtypes of FI may be obtained, in particular, by misunderstanding the mixed character of FI. In the literature, there is only a small number of studies that investigated the different characteristics of the different subtypes of FI. However, there is a heterogeneity in the definitions used for both urge and passive FI in these studies^{15,16,17,18}. There is also a lack of methodological explanation regarding how patients were classified among subtypes of

FI^{19,20,21,22}. Finally, patients with mixed FI were commonly excluded from these studies or erroneously classified in one of the two groups^{16,23,24,25,22,26}.

The aim of the study was to develop and validate a new tool, formally the FI-SA (Fecal incontinence subtype assessment), to classify patients in the two subtypes of FI (active, passive) defined by the Rome IV criteria and in a third group defined by a combination of active and passive FI called mixed FI.

MATERIALS AND METHODS

Patients

We conducted a monocentric prospective study in the Neuro-urology Department of a University Hospital. All consecutive patients presenting in the Department with FI between December 2019 and May 2020 were screened for inclusion in the present study. Criteria of inclusion were an age older than 18 years old and symptoms of FI according to Rome IV criteria¹. Exclusion criteria were anorectal fistula, active inflammatory bowel disease, untreated anorectal malignant tumor, rectal or hemorrhoidal prolapses and specific inability regarding the questionnaire (i.e. cognitive disorders, inability to read and to understand questions).

Approval

The study was conducted in accordance with the ethical guidelines of the Declaration of Helsinki (6th revision, 2008) and was registered with clinicaltrials.gov (NCT04410822). The study protocol was approved by the local research ethic committee (N°2018-A01644-51). An oral informed consent was obtained from all subjects in accordance with national legislation. All authors had access to the study data and reviewed and approved the final manuscript.

Phase 1: literature review and qualitative interviews

To determine the dimensions of the questionnaire, a literature review was performed using Pubmed without date limitation until February 2020. The key words used were “active faecal incontinence” OR “active fecal incontinence” OR “passive faecal incontinence” OR “passive fecal incontinence” OR “urge faecal incontinence” OR “urge fecal incontinence”. A second search using the latter one AND (“questionnaire” OR “scale” OR “score” OR “tool”) was made to find all the questionnaires already published. In parallel to this literature review, semi-structured interviews were performed on 20 patients from December 2019 to February 2020. All parts of the interviews were conducted by a single trained gastroenterologist (CD). The first part of the interview was free, in which patients expressed their experience regarding stool leakage. This part explored several dimensions including patient’s awareness, rectal filling sensations, the need to rush to the toilets (when a need to evacuate occurs) and the patient’s efforts to prevent stool leakage (e.g. voluntary contraction of the anal sphincter). If the patient did not talk spontaneously about one of these dimensions, an open question was asked to introduce it. The second part of the interview was used to determine the formulation of items among different propositions for each dimension. During this phase, an expert panel of nine gastroenterologists and neuro-urologists was composed. The gastroenterologist who performed the interviews was part of the panel.

At the term of all interviews, dimensions that were 1/ the most used by patients and 2/ the most discriminative among subtypes of FI, were included in the questionnaire. At the end of qualitative interviews and literature review, we produced six different questions. These questions were validated by the expert panel. Questions were definitively included in the questionnaire when a complete consensus was obtained from all experts. Two questions met these criteria and were finally included in the questionnaire, one question corresponding to one subtype of FI. Each question was then written in 3 versions to allow patients to choose their

preferred version in the feasibility study (Table 1). This stage permitted to choose the wording of question and the answer mode for each question.

Phase 2: feasibility study

The feasibility study was conducted from February to April 2020 on 30 patients. After completion of the questionnaire, each patient was asked to rate each version of the 2 questions. To assess comprehension and acceptance, patients had to answer with a four-point Likert scale (A: very good, B: good, C: difficult, D: very difficult). After the complete reading of the questionnaire, each patient had to choose the version of the 2 questions that they found the most appropriate. A second expert meeting was then performed to validate the definitive version of the questionnaire on the basis of patients' answers.

Phase 3: validation study

To investigate the psychometric properties of the questionnaire, a validation study was performed from April to May 2020 on 100 consecutive patients. In order to evaluate the reproducibility of our questionnaire, patients were asked to answer a second time the questionnaire by mail with a second evaluation from 7 days to 10 days after the first one. The "intra-class correlation coefficient" (ICC) was used to determine test-retest reliability for each question. An ICC > 0.70 was expected to be a very good test-retest reliability²⁷. The first questionnaire was filled at the end of the consultation. Patients were asked to read carefully the questionnaire before answering but were not helped to fill it. Patients had to mail a second questionnaire (filled at home) 7 days after the first consultation.

RESULTS

Phase 1: literature review and qualitative interviews

Qualitative interviews were conducted on 20 patients [18 females, median age: 47.5(33.0-67.8) years] followed for fecal incontinence of various aetiologies (9 patients with upper motor neuron lesion, 10 patients with lower motor neuron lesion, 1 colorectal). Characteristics of patients are summarized in Table 2. Two relevant dimensions of the questionnaire were found based on the literature review and interviews: the notion of “fecal urgency” and the “restraining effort” of the anal sphincter. Indeed, all patients with urge FI (n=9) described the notion of “fecal urgency” that they differentiated from the normal progressive rectal filling sensation. No patient with passive FI (n=6) experienced “fecal urgency” but most described the absence of sensation (4/6). A sensation of rectal fullness is sometimes described by patients as an equivalent sensation of the need to defecate that may appear at a different time from fecal leakage. This symptom was reported by 2 of the 6 patients with passive FI. The concept of “warning time” did not seem to be pertinent for patients with passive FI as it was only mentioned in 1 of 6 patients. All patients with urge FI and 2 of 6 patients with passive FI were “aware” of their stool leakage. These 2 patients with passive FI who were “aware” of the fecal leakage, reported humid perineal sensation or smell immediately after leakage but not any specific ano-rectal sensory warning. Lastly, all patients with passive FI reported that they did not have to “restrain” themselves as they did not perceive stool leakage, in contrary to all patients with urge FI.

After this phase, a first expert meeting permitted the writing of 2 questions exploring both of these 2 dimensions (Appendix). Three versions of these questions (Table 1) were made to allow patients to choose their preferred version for each question. Binary answers were used for each of these questions (i.e. “yes” and “no”). After answering to these 2 questions, the patient could be classified among 4 subtypes: urge FI (“yes” and “no”), passive FI (“no” and “yes”), mixed FI (“yes” and “yes”) or unclassified (“no” and “no”). Mixed FI was thus considered as an association of urge and passive FI.

Phase 2: feasibility study

Thirty patients were included in this part of the study [23/30 females, median age: 57.0(46.8-68.3) years]. Causes of FI were mainly lower motor neuron lesion (13/30) and upper motor neuron lesion (10/30). Patients characteristics are summarized in Table 2. The acceptance of the 2 questions was “very good” (A) or “good” (B) for all patients. For question 1, comprehension of the versions 1 and 3 were “good” (B) and “very good” (A) in 29/30 (97.7%), but 28/30 (93.3%) for version 2. For question 2, comprehension for the version 2 and 3 were “good” (B) and “very good” (A) for 28/30 (93.3%), but 27/30 (90.0%) patients for version 1. No patient answered “very difficult” (D) for comprehension for each version of the 2 questions. Most patients preferred the version 1 of the question 1 (14/30; 47.7%): “*When you have a stool leakage, are you warned by an urgent need to defecate and do you then try to restrain yourself?*”. The version 1 of question 2 was the most chosen by patients (12/30; 40.0%): “*Do you have stool leakage without feeling the slightest need beforehand and therefore without even trying to restrain yourself?*”. A second expert meeting allowed to validate the versions 1 of question 1 and question 2 as definitive items.

Phase 3: validation study

One hundred patients were included in the validation study (Figure 1). Patients characteristics are summarized in Table 2. The original version of the FI-SA and its corresponding version in English are given in the Appendix. The median time to fill the questionnaire was 40.0 (30.0-60.0) seconds. Ninety-six patients were included for test-retest reliability and 93 (96.9%) questionnaires were returned by mail from day 7 to day 10. No retest questionnaire was excluded for missing data. For question 1 and 2, the ICC was respectively of 0.88 and 0.91.

At the term of the validation study, 98/100 (98.0%) patients were classified among subtypes of FI: 34 (34.0%) patients with passive FI, 32 (32.0%) with urge FI, 32 (32.0%) with mixed FI. Only 2/100 patients remained unclassified in our study, due to equivalent rectal filling sensations.

DISCUSSION

To our knowledge, the present study is the first one to formally validate a questionnaire which precisely classifies patients among three different subtypes of FI (active, passive and mixed). The FI-SA questionnaire has been found to be easy to understand and well accepted by patients. With only 2 questions, the FI-SA questionnaire is quickly done. Moreover, good psychometric properties revealing the good reproducibility of the questionnaire were found (intraclass correlation coefficient for question 1 and 2 respectively 0.88 and 0.91).

To validate the questionnaire, patients were consecutively screened and included, with a small number of rejections, hence allowing the creation of a large and representative population sample. However, most patients presented a neurological disease (upper or lower motor neuron lesion), with consequently a limitation regarding the application of this questionnaire to a global population of patients with FI. Criteria of inclusion comprised the Rome IV criteria to define FI in order to limit bias of memorization among patients regarding the mechanisms of FI¹. Indeed, the threshold of 2 episodes of fecal leakage in a 4-week time during more than 6 months excluded patients who experienced only a few numbers of stool leakage and who cannot properly remember the circumstances of these episodes. Criteria of exclusion were those commonly used in studies on FI. Consequently, there is a need for further studies to validate the questionnaire FI-SA in a non-neurogenic population.

During the validation of the questionnaire, qualitative interviews revealed interesting findings regarding the dimensions that were kept in the final version. It seems that “fecal urgency” and the “restraining effort” are the most cited and discriminative dimensions among patients. In the literature, the definitions in use of FI subtypes are heterogeneous²⁸. The patient’s awareness is the most cited dimension in the studies^{15-17,20,23-26,29-30} to discriminate subtypes of FI. One limit to its employment, when used alone, is that the notion of timing is not clearly precised in the

definition. In our study, some patients were immediately alerted at the time of fecal leakage by scents or humid perineal sensations in underwear (2/6). Some patients with passive FI experienced equivalent rectal filling sensations that they considered as a warning, even if it had happened a long time before fecal leakage (2/6). Consequently, this dimension can be misleading when classifying patients among subtypes. Only 2/100 patients remained unclassified in our study, due to these equivalent rectal filling sensations. Another dimension is the warning time before stool leakage, expressed as “defer defecation”^{31,24,32,18} or the “need to rush to the toilets”^{31,17,25,18,26,33} in the literature. Even if, in most interviews, this notion was evident for patients with urge FI, it was more difficult to understand in some patients with passive FI (2/6) due to the limitations regarding patient’s awareness. In contrary, the “restraining effort”, found in definitions of urge FI in a minority of studies^{15,23,34,30}, was the most discriminative among patients in the present study, as it concerned none of the patients with passive FI. This notion was always associated with the one of “fecal urgency” in patients with urge FI in our study. The latter could also be found in definition of urge FI in previous studies^{16,17,18,26,35,7}. Moreover, the results of the present study also revealed that the subtype of mixed FI is commonly found in patients with FI, with a not negligible prevalence of 32.0% among our cohort of patients. This subtype is probably largely underestimated. Firstly, this mixed FI type is not even mentioned in the definitions of ICS regarding subtypes of FI². Secondly, this subtype does not appear in several prior publications^{16,23,24,25,22,26} which investigated clinical and paraclinical characteristics of subtypes of FI, representing a major bias in the interpretation of their results. Therefore, the definitions given by the ICS regarding subtypes of FI does not seem to reflect reality and it could be interesting to lead further work on this area in the future.

As the present study led to the creation of a new questionnaire, there is no gold standard tool to evaluate the correctness of the classification of our patients among subtypes after answering FI-SA. Therefore, other dimensions of validity were not explored with FI-SA questionnaire, representing a limitation of the present study. Subtypes of FI are not associated with the severity of FI to our knowledge^{26,33,16,22} as there are contradictory findings. Consequently, we did not choose to use the correlation between the severity of FI assessed by validated questionnaires and the patients' answers to FI-SA to assess psychometric characteristics of FI-SA. A limitation of the present study could be the lack of comparison with anamnesis led by an expert-physician in blind of the questionnaire results. This parameter will be included in the evaluation of the questionnaire in a further validation study. After completion of the questionnaire, 2 patients remained unclassified. The first one was a 19-year-old man with T12 spinal cord injury ASIA Impairment grade scale A, with therefore a complete anesthesia under T12 level. The second patient was a 50-year-old female with motor and sensory dysfunctions secondary to a Charcot-Marie-Tooth neuropathy. She had a complete perineal anesthesia with a decreased anal sphincter tone and absence of voluntary contraction. Both patients did not describe fecal urgency before stool leakage but a diffuse and confusing abdominal sensation of a colic movement or peristalsis that was not located in the rectum and consequently answered "NO" to both questions.

Lastly, the use of FI-SA questionnaire might allow more homogeneity among studies in the future, especially in those which investigate the clinical and instrumental relevance of the different subtypes of FI. The absence of homogeneity in definitions of types of FI could have led to a wrong classification of patients among the subtypes of FI in previous studies^{15,16,17,18}. This important limitation could explain part of conflicting findings from these studies. Therefore, there are currently no guidelines available regarding the management of patients

with FI based on the type of FI. The use of FI-SA could help to determine the pertinence of this classification and the possible therapeutic consequences in the management of patients with FI.

CONCLUSION:

The present study is the first one to validate a questionnaire classifying patients among different subtypes of FI (active, passive and mixed) defined by Rome IV criteria. FI-SA was well accepted, easy to understand and quickly filled by patients. Moreover, it had good psychometric properties with a good intraclass correlation coefficient, revealing good reproducibility of the questionnaire. The creation of FI-SA might help to better classify FI and thus allow more specific therapeutic strategies.

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TABLES

TABLE 1: English translated version of the three versions of the two questions in the feasibility study. Questions were answered by YES or NO.

Question 1: urge FI

1. When you have a stool leakage, are you warned by an urgent need to defecate and do you then try to restrain yourself?
2. When you have a stool leakage, are you warned just before by an urgent need to defecate and do you then try to restrain yourself?
3. When you have a stool leakage, are you alerted just before by an urgent need to defecate and do you then try to restrain yourself?

Question 2: passive FI

1. Do you have stool leakage without feeling the slightest need beforehand and without even trying to restrain yourself?
2. Do you have stool leakage without feeling the slightest need and without even trying to restrain yourself?
3. Do you have stool leakage without being warned by a need and without even trying to restrain yourself?

Table 2: Patients characteristics of the validation study.

	Qualitative interviews ; N(%)	Feasibility study ; N (%)	Validation study; N (%)
Age (yo)	47.5 (29-53)	57 (45-72)	54.5 (46.0-69.0)
Female sex, n (%)	18 (90.0%)	23 (76.7%)	77 (77.0%)
BMI (kg.m⁻²)	25 (24-32)	26 (25-34)	23.6 (20.8-27.7)
Etiology of FI*, n (%)			
Upper motor neuron lesion	10 (50.0%)	10 (33.3%)	48 (48.0%)
<i>MS</i>	6 (30.0%)	5 (16.7%)	31 (31.0%)
<i>SCI</i>	3 (15.0%)	4 (13.3%)	9 (9.0%)
<i>Other</i>	1 (5.0%)	1 (3.3%)	7 (7.0%)
Lower motor neuron lesion	9 (45.0%)	13 (43.3%)	44 (44.0%)
<i>Equina syndrome</i>	5 (25.0%)	7 (23.3%)	26 (26.0%)
<i>Pudendal neuropathy</i>	4 (20.0%)	4 (13.3%)	16 (16.0%)
Pelvic RT	1 (5.0%)	1 (3.3%)	4 (4.0%)
CCR	1 (5.0%)	4 (13.3%)	3 (3.0%)
Sphincter defect	1 (5.0%)	2 (6.6%)	3 (3.0%)
Constipation, n (%)	18 (90.0%)	25 (83.3%)	78 (78.0%)
Diarrhea, n (%)	1 (5.0%)	1(3.3%)	2 (2.0%)
Cholinergic therapy, n (%)	5 (25.0%)	11 (36.7%)	38 (38.0%)
Laxative therapy, n (%)	16 (80.0%)	18 (60.0%)	62 (62.0%)

*One patient could have more than one aetiology of FI.

yo: years old; BMI: body mass index; FI: fecal incontinence; MS: multiple sclerosis; SCI; spinal cord injury; RT: radiotherapy; CCR: colorectal cancer.

Cholinergic therapy included all medication with cholinergic effect.

FIGURES

Figure 1: Flow chart of the validation study.

APPENDIX 1: Fecal incontinence subtype assessment (FI-SA) questionnaire

This questionnaire covers the different possible circumstances of stool leakage. Please read both questions carefully and then circle for each question the answer (YES or NO) that best describes how stool leakage episodes occur in the last months. It is possible to answer YES to questions 1 and 2.

1. When you have a stool leakage, are you warned by an urgent need to defecate and do you then try to restrain yourself?
 - a. YES
 - b. NO

2. Do you have stool leakage without feeling the slightest need beforehand and without even trying to restrain yourself?
 - c. YES
 - d. NO

**APPENDIX 2: French version of the Fecal incontinence subtype assessment (FI-SA)
questionnaire**

Ce questionnaire porte sur les différentes circonstances possibles de fuites de selles. Veuillez lire attentivement les deux questions puis entourez pour chaque question la réponse (OUI ou NON) qui décrit au mieux la façon dont se produisent les épisodes de fuite de selles. Il est possible de répondre OUI aux questions 1 et 2.

1. Quand vous avez une fuite de selles, êtes-vous prévenu(e) par un besoin urgent d'aller à la selle et tentez-vous alors de vous retenir ?
 - a. OUI
 - b. NON

2. Avez-vous des fuites de selles sans ressentir auparavant le moindre besoin et donc sans même avoir pu essayer de vous retenir ?
 - a. OUI
 - b. NON

