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#### Chapter

# Quality of Life Considerations on Fecal Incontinence

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#### **Abstract**

Traditionally, it has been assumed that tests like anorectal manometry and endoanal ultrasound are essential in the evaluation of fecal incontinence (FI). However, in daily practice, this testing rarely helps in the decision-making, as are mainly based on the patient's symptoms. Moreover, indications and outcome evaluation should not be decided by only considering the symptom severity but the impact on QoL and patient satisfaction. Nowadays, patients tend to be active consumers of health care, so they may participate on the medical decision-making. On the other hand, monitoring treatment results are mandatory in current practice. Finally, considering the cost of some of the current treatments for FI, changes in QoL should be demonstrated before implementing some procedures. For all these reasons, the QoL scales should be used, and readers encouraged to become familiar with QoL instruments and their limitations. The following chapter will cover almost all areas on existing knowledge about QoL in patients with FI: from how many types of QOL scales have been described, to the different ways to measure our patients' satisfaction, passing through the difference between severity and QOL, going deep on if the improvement of patients treated for FI is reflected enough in the current used QOL scales.

**Keywords:** Quality of Life, Fecal Incontinence, Evaluation, Severity, Patients' satisfaction

#### 1. Introduction

1

Quality of life (QoL) is the general well-being of an individual including all the emotional, social and physical aspects. A half century ago, the WHO defined QoL as an "individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" [1]. Therefore, the concept was already multidimensional including physical, mental and social domains. Health-Related Quality of Life (HRQoL) has been defined as the "physical, psychological, and social domains of health, seen as distinct areas that are influenced by a person's experiences, beliefs, expectations and perceptions" [2]. In other words, it would be an assessment of how the individual's well-being may be affected over time by a disease, disability or disorder.

Patients should be actively involved in the treatment decisions, and therefore, the assessment of health perception is essential. Therapeutic outcomes are not meaningful if they are not balanced with the patient's perception of QoL, thus

asking patients about their health and QoL before and after a procedure is crucial to improve the quality of care. Patient-reported outcomes are reports coming directly from patients about how they feel or function in relation to a health condition and its treatment without any interpretation by healthcare professionals or anyone else [3].

In the last 30 years, different instruments assessing HRQoL and the broader concept of patient-reported outcomes have been developed. These instruments do not substitute the physical, physiological or biochemical evaluations, as they are complementary and represent the patient's general perception of the effect of illness and treatment in different aspects of life such as physical, psychological and social [4].

Fecal incontinence (FI) is a social and emotionally devastating condition that significantly affects the QoL of patients and their families, and the ultimate goal of treatment should be to improve it, being essential to obtain direct data from the patient. Considering that it is a symptom, the subjective perception is essential in assessing the impact of incontinence on QoL. Patients commonly experience embarrassment, and some people limit their social life to assure an easy access to a toilet. Unfortunately, given the social stigma associated with the condition, many patients do not seek treatment. It has been suggested that the prevalence in the general population has been systematically underestimated, to the point that it has been proposed that healthcare professionals should improve detection by actively enquiring about symptoms of FI in high-risk groups [5]. The fact that only 5–27% of people report their symptoms to their physicians may justify the low number of published studies assessing the QoL in patients with FI [6].

This chapter will cover almost all areas on the existing knowledge about FI patients' QoL.

#### 2. Types of QoL scales

There are two ways of administering questionnaires: by a face-to-face interview or in a self-administered way. Traditionally, face-to face surveys have been considered the gold standard because of their ability to obtain high response rates and valid data. However, in QoL questions, it seems that less bias in responses is produced by self-administered questionnaires due to the embarrassing situation of confessing such sensitive questions to an interviewer [7]. Furthermore, face-to-face surveys are more expensive.

Having an alternative viewpoint on a patient's QOL provided by family caregivers or other proxies is important to avoid excluding patients who cannot respond for themselves due to some cognitive impairment, of in case of very young children. Furthermore, proxy assessment of health utility may also supplement critical information for clinical decision-making on economic evaluations of patients care and health of cost-effectiveness and cost-utility analyses [8]. Proxy-patient agreement is lower for more subjective measures (e.g., expectations and satisfaction with social activities) compared with more objective ones (e.g., the frequency of social participation) [9].

In case of children, parent-proxy rapport can often be a limitation in the assessment of QOL [10], with only a few studies evaluating the level of agreement between parents and children on a child's QOL over time. A large study [11] showed low to moderate levels of parent-child agreement at baseline and lower agreement at follow-up; child's age and parent's self-perceived health were the primary factors associated with parent-child disagreements over time. Based on these findings,

authors recommended direct self-assessment of QOL among children and adolescents as much as possible.

Most QoL questionnaires are self-administered and they take into account both the physical and the emotional aspects, which are usually divided in different dimensions, the domains.

For the development of a questionnaire, several questions have to be considered:

- 1. *Validity*: it is the degree to which evidence and theory support the interpretations of test scores entailed by the proposed uses of tests [12]. Validity refers to whether the questionnaire actually measures what it is intended to measure and not something else, so it has to be established whether the questions and the responses are phrased appropriately. Thus, it has to be determined how representative the questions are (content validity), an association between the test scores and the prediction of a theoretical trait has to be demonstrated (construct validity), and if the questionnaire is measuring what it is intended to measure (criterion validity).
  - 2. *Reliability*: it is the ability of the questionnaire to yield reproducible and consistent estimates of true treatment effect [12]. Reliability means that the responses to the questionnaire are reproducible and that it has internal consistency as well.
  - 3. Responsiveness: the instrument should be able to detect the changes in the expected outcomes. For instance, if a questionnaire is determining the QoL of certain condition, then it should be able to predict the QoL after treating that condition.

Furthermore, in order to avoid erroneous research conclusions, the translation of questionnaires should undergo an appropriate and rigorous validation process, as it was done by the International Quality of Life Assessment (IQOLA) project to translate the S-36 Health Survey [13]. Questionnaires must adapt in a culturally relevant and comprehensible form while keeping the original meaning and intention [13, 14].

Studies assessing the QoL in patients with FI have used three types of questionnaires: generic QoL scales, specialized scales and condition-specific scales.

Generic QoL Scales try to cover all aspects of life and are summarized in an overall score. They are commonly used to measure QoL in patients with more than one disease, and they permit comparison of QoL across groups of patients with different medical conditions. Generic scales enable researchers to look at the target population relative to other populations. They are usually adequate for detecting gross changes in a specific population, but they often lack the specific questions to detect subtle changes and, in the case of FI, many remarkable aspects may not be reflected. For FI, the most widely used generic questionnaire is the Short Form 36 Health Status Questionnaire (SF-36) [15].

Specialized scales have been developed for a specific condition or symptom, not a specific population. These scales focus on the measurement of a particular aspect of QoL, such as the assessment of sleeping disorders in patients with irritable bowel syndrome [16] or depression in patients with FI [17]. Specialized scales provide two advantages. First, there is a lower probability that other dimensions of life will emerge, and the instrument will therefore probably be more responsive to change. Second, as with general QoL measures, specialized scales allow for comparison across different populations (for instance, comparing the presence of depression in FI versus depression in multiple sclerosis). The main disadvantage of specialized scales is that the global sense of QoL is not reflected [18].

Condition-specific scales are specially designed to go deep into QoL aspects in each group of patients and its main advantage is that they can be used to detect changes in the treated population. However, as expected, these instruments cannot be used to compare QoL between different diseases. Four different types of condition-specific scales have been used to assess QoL in FI, each of them with strengths and weaknesses that will be further explained. The first one, the Fecal Incontinence Quality of Life Scale (FIQL), has been used as an evaluation tool for patients with FI and it has been widely translated [19]. The second one, the Gastrointestinal Quality of Life Index (GIQLI) [20], is an instrument for measuring QoL specifically in patients with gastrointestinal disorders, which has the additional advantage of looking at FI relative to other gastrointestinal diseases. Finally, the third type would be condition-specific quality instruments, which are designed to assess QoL in specific populations. The Manchester Health Questionnaire (MHQ) [21] was adapted to measure the condition-specific QoL related to FI from a validated measure of urinary incontinence (the King's Health Questionnaire [22]). Subsequently, the Modified Manchester Health Questionnaire (MMHQ) [23] was developed by combining the Fecal Incontinence Severity Scale (FISI) and the MHQ.

#### 3. Measuring the impact of FI: the difference between severity and QoL

Initial scores to assess FI did not include questions about QoL [24, 25]. The most frequently used questionnaires, the Cleveland Clinic Continence Score (CCCS) [26] and the St Mark's score [27], have demonstrated and excellent intra and interobserver reliability [28] and they added a question about lifestyle alterations, with answers ranking in time frequency. However, ranking limitations in daily activities on the basis of time frequency may be difficult for patients. Furthermore, a person who has adapted oneself to deal with episodes of FI over a long period of time may not realize the magnitude of the impact that these episodes have been having on the activities of daily living.

Moreover, severity scores in FI were developed to be as objective as possible but introducing variables such as coping mechanisms and lifestyle changes tends to add subjective aspects, thus they should be interpreted with caution [29].

Additionally, some limitations in applying some scores should be mentioned. Both the CCCS and the St Mark's score characterize the frequency of each type of incontinence separately (i.e. solid, liquid or gas). However, other authors consider that it is difficult for patients to specify and, consequently, their scale has been developed using a different grading system, as in the Fecal Incontinence and Constipation Assessment (FICA) scale [30].

Moreover, health professionals have an additional difficulty scoring the frequency of liquid stool incontinence. In patients never experiencing liquid stools, score could be considered both in the CCCS and the St Mark's score, but if the question is what patient think that it would happen in case that they had liquid stools, score could be 4.

Other significant limitations when assessing FI are: (a) most scores do not include urgency, with the exception of the FICA and the St Mark's score and (b) the FICA score is the only one that quantifies the amount of leakage, thus in other questionnaires the severity of FI would be identical for a minor staining or a large bowel leakage once a week [31].

For all the reasons mentioned above, we need to be aware that severity alone may not be sufficient to establish a therapeutic decision.

As a result, some authors have tried to correlate the QoL assessments with the severity scores. Eypasch et al. [20] determined that patients with a CCCS over 9 had

a severe alteration in their QoL measured by the Gastrointestinal Quality of Life Índex (GIQLI), and that they rested home with very poor social activities.

Bharucha et al. correlated the FICA symptom severity score and a modification of the FIQL scale, and concluded that the FICA score is a simple instrument to use in the office, and that it demonstrates reasonably both the physical manifestations of FI (i.e. symptom severity) but also the impact on QOL [31].

However, the correlation between severity and QoL questionnaires is still a controversial issue. Impact on QoL varies between patients depending on daily activity, work, personality and many other dimensions. While one episode of solid FI might represent a significant trauma leading to changes in personal and working life for one patient, another one might consider it significant just in the case that it happened frequently. Consequently, gas incontinence may be a significant problem for a young person with an active social and working life, but it may not be considered as important for other people.

Rockwood et al. reported that patients acknowledged gas incontinence being more severe than what their doctors considered, being the opposite regarding solid FI [19]. This difference is due to the fact that severity scores are constructed under a pathophysiologic point of view mainly reflecting the doctor's perspective. Thus, gas incontinence is considered less severe by doctors, as they don't expect to find a significant structural or functional disorder when compared with a patient with solid stool incontinence.

Furthermore, FI assessment of the outcome of treatments for FI measurement should take into account the impact on lifestyle. For instance, improving gas incontinence in a young person with an active working life, could decrease the severity score less than 20%, but, however, have a significant impact on QoL.

#### 4. Measuring QoL in fecal incontinence

The Short Form-36 (SF-36) is a multidimensional questionnaire constructed to survey health status in the Medical Outcomes Study [15]. It is used in clinical practice and research, as well as health policy evaluations and general population surveys.

The questionnaire includes 36 items grouped in 8 dimensions: limitations in physical activities, limitations in social activities, limitations in usual role activities because of physical health problems, bodily pain, general mental health, limitations in usual role activities because of emotional problems, vitality (energy and fatigue) and general health perceptions. The SF-36 is scaled from 0 to 100, where higher scores represent a better health status. The questionnaire was designed for self-administration as well as for administration by a trained interviewer either by telephone or in person. The questionnaire has been sufficiently validated and its main advantage is that it is easy and relatively fast to fill in, taking 10–20 minutes as an average. It is the most used instrument to validate other questionnaires subsequently designed and to assess the specific questionnaires.

The SF-36 allows us to compare FI populations with urinary incontinence patients or to compare FI populations with altogether different populations, such as healthy persons or persons with other chronic diseases [13].

As other generic scales, the main disadvantage of the SF-36 is that while the "role physical" measurement might be sufficient to detect changes among persons with FI, the "role social" measurement is probably not sensitive enough to detect such changes (i.e. going to a movie or travelling) [32].

The Gastrointestinal Quality of Life Index (GIQLI) [15] is a "systemic", but not generic, QoL instrument designed to be administered across all populations with

gastrointestinal conditions, which has also been used to assess FI. The questionnaire was designed in three phases and it was also validated against other generic measures of QoL. The GIQLI contains 36 questions, each with 5 response categories, in 5 areas: a symptom list, physical issues (function and perception of functional ability), psychological issues (primarily affect), social issues and disease-specific items (items tied directly to a specific condition, such as bowel urgency for FI). The significant advantage of this type of instrument over condition-specific QoL measures is its ability to look at FI relative to other gastrointestinal conditions [18].

The FIQL scale is the most widely used condition specific QoL instrument in FI. It was developed by a panel of experts, including colorectal surgeons and health service researchers, that selected aspects (or domains) of QoL likely to be affected by FI [19, 33]. The study included 190 participants (118 patients with FI and 72 controls) from 5 different clinics. The psychometric evaluation showed that the questionnaire produced a reliable and valid measurement of QoL in patients with FI. The questionnaire is self-administered, and it includes questions regarding the limitations in their activities caused by FI during the last month.

The FIQL scale includes 29 items that are grouped into 4 scales or domains:

- Lifestyle: comprising 10 questions about the limitation in social activities such as dining out, travelling, or even basic activities such as shopping.
- Coping/behaviour: including 9 questions relating to the level of concern of FI in daily thoughts, and the limitation that represents on sexual relations, work, etc.
- Depression/self-perception: comprising 7 questions about the impact of FI on their feelings, and how they see themselves in their environment.
- Embarrassment and feeling of social rejection, including 3 questions.

Possible answers range from 1 to 4, where 1 indicates a low functional status. The score of each domain is obtained from the mean of all items. The scale includes a "not applicable" category that is coded as a null value in the final sum, although the author recommends not to use it as a response option [33]. Thus, the four domains are scored from 1 to 4, and the higher score better QoL.

The main advantages of the FIQL scale are that it can be used in all adult populations with FI regardless their particular characteristics, and that it is sensitive to the dynamic relationship between the condition, the treatment, and QoL. A recent study re-evaluated the FIQL and confirmed several strengths but also has pointed out some limitations warranting a revision [34].

The Manchester Health Questionnaire (MHQ) [21] was made up of items adapted from the King's Health Questionnaire [22], a condition-specific HRQOL to evaluate urinary incontinence. The MHQ contains 31 items that are grouped into 9 subscales: general health, physical limitations, social function, role limitations, emotional problems, sexual function, sleep/energy, incontinence impact and incontinence severity. Scores range between 0 and 100, a higher score indicating impairment of HRQOL. The questionnaire was evaluated for content validity by 15 females with known FI, and pre-tested for ambiguity and ease of comprehension in a group of 15 females without known FI and in 20 midwives. Interestingly, during pre-testing, it was found that women had difficulty understanding words such as "fecal" and "stool" and thus, wording was replaced with the term "bowel leakage." The final questionnaire showed excellent internal consistency, test-retest reliability, criterion validity and construct validity.

Scores on the MHQ were compared with scores on the SF-36 reaching modest to strong correlations depending on the domain, but the pattern of correlation between the individual scales of the measures was not specified.

As the instrument appeared promising, it has been suggested that further research is required to validate the measure and test sensitivity to change, before it could be used as a primary end point for studies. Moreover, research comparing the MHQ and the FIQL scale would be also useful as the sampled content is similar [32].

The Modified Manchester Health Questionnaire (MMHQ) [23] is a telephone-administered version of the Fecal Incontinence Severity Scale (FISI) [29] and the Manchester Health Questionnaire [21]. Questions from the FISI were combined with similar questions from the MHQ, and some of the MHQ questions, which had been validated in the UK, were rephrased to make them more consistent with American English. Although the authors planned to collect data from 50 female patients, they achieved a relatively small sample as only 30 patients provided data, being incomplete in 4 of them. The MMHQ includes 8 subscales: overall impact, role limitations, physical/social limitations, personal relationships, emotions, sleep/energy, sexual activity and lifestyle adaptation. The MMHQ is scaled from 0 to 100, for total and subscale scores, where higher scores represent a negative impact on HRQOL. In an invited commentary in the same article, Rockwood considered that whether the MMHQ is a viable instrument for a telephone assessment of QoL in FI remains to be established due to the risk of measurement error [23].

The International Consultation on Incontinence Questionnaire–Bowel Symptoms (ICIQ-B) [35] was developed by a multidisciplinary team of clinical experts in order to evaluate symptoms of FI and impact on HRQOL in a general adult population. The goal was to design an instrument including the patient's input that could be used globally in clinical practice or research. The ICIQ-B has 21 items evaluating bowel pattern, bowel control and HRQOL. Scores are generated for each section; the higher the score, the greater the symptom severity and bother to the patient. The instrument has undergone psychometric evaluation and deemed to be valid, reliable and responsive, and it is well suited to clinical practice. The questionnaire also queries the patient to rank issues that are most bothersome.

There are other types of impact measures less frequently used that need to be mentioned. Although further investigation is required, they might prove to be useful tools in the future.

The TyPE specification designed by Wexner and colleagues [36] was developed to measure the fear of incontinence and how activities were affected by using a single question: "During the past 4 weeks, did fear of bowel accidents or leakage limit your participation in the following activities?". Listed activities are: walking, vigorous exercise, household chores, visiting friends, driving, sexual relations, employment, traveling, church or temple attendance and shopping. There are no summary scores for the measure, and thus, each item is evaluated individually. Very little information is available about the development of the measure and information on reliability is not available.

The Direct Questionning of Objectives (DQO) measure consists of a highly personal assessment, constructed on the basis of each patient's feelings. To calculate the DQO, patients list different objectives that are important for them, such as travelling or working, rate the importance of each objective on a scale and also rate their ability to perform that objective in another scale, both from 0 to 10. The product of ability and performance for each objective is calculated and divided by 10. This number is added for all objectives and divided by the importance scores for all objectives, resulting in a score from 0 to 1.0. The main disadvantages of this system of ranking the impact are: (a) the initial generation of objectives and importance

ratings require assistance by trained personnel; (b) it is a cognitively more complex task than completing a questionnaire and (c) measuring only certain individualized objectives may decrease the validity of the measure when groups of patients are to be compared. However, on the other side, the result is directly relevant to a specific person, so it would be more useful when deciding the treatment of an individual patient. This measure has been used to assess the QoL in patients on home parenteral nutrition after surgery for inflammatory bowel disease and also to assess the impact of neuropathic FI on QoL [37].

A study [38] analyzing the validation of QoL measures in FI concluded that the scales with the strongest degree of validity are the GIQLI, FIQL and the ICIQ-B although all of them have some deficiency. The FIQL is the most widely used by far, the main reason for this probably being that it was constructed on a strong methodological basis, being useful and sensitive to change. However, there may be other factors such as habit and the easiness to use it, as it has fewer domains than other questionnaires. Furthermore, the FIQL scale has been translated into many languages (French, Portuguese, Italian, Spanish, Turkish, German, Norwegian and Japanese).

#### 5. What do we know about QoL in patients with FI?

Over the last 25 years, there have been improvements in the understanding, diagnosis and treatment of FI. Although FI has a major impact on QoL, it was not discussed in the literature until 15 years ago.

Few studies in elderly patients showed alterations in specific domains of the SF-36 questionnaire, such as the emotional role, mental health and physical role [39, 40]. However, in younger populations, the assessment of the impact of FI on QoL including specific questions such as change in eating patterns, work, social and sexual activities, only began when disease-specific measures were designed (**Table 1**).

Initially, aspects concerning QoL came from epidemiological studies performed in the general population. Perry and colleagues [41] designed a population-based study using a postal questionnaire that was mailed to almost 16,000 subjects aged 40 years or more. Although it was published in 2002, the study was designed before the development of the FIQL scale, and QoL was measured using general questions: Do your bowel symptoms: bother you?; cause you any physical discomfort?; interfere with your daily activities?, interfere with your social life?; affect your relationships with other people?, upset or distress you?, affect your sleep? and affect your overall QoL? Overall, the prevalence of at least a monthly leakage was 3.3% and the prevalence of soiling was 2.7%. Half of the patients with major FI and, interestingly, 16% of patients with minor FI reported that their bowel symptoms had a significant impact on their life. Nearly two thirds of this group reported to need help for their symptoms.

A panel of experts including colorectal surgeons and health service researchers, was invited to identify QOL-related domains adversely affected by FI, leading to the development of the FIQL scale [19]. An extensive research in two distinct populations demonstrated that patients with FI had a significantly lower QoL than the control population (patients with other gastrointestinal problems). The study demonstrated that these patients reduce activities that other people take for granted such as shopping, going to the cinema, dining out or having sexual intercourse. They suffer from embarrassment, shame and sometimes depression. This was the first evidence that specific daily activities are affected in patients with FI.

Author	Year	N	Population studied	Questionnaires	QoL alterations
O'Keefe et al. [39], Edwards and Jones [40]	1995 2001	704 2818	Elderly patients	SF-36	-Emotional role, mental health, and physical role
Perry et al. [41]	2002	16.000	Population- based study, >40 years old Postal questionnaire	Specific questions "Do your bowel symptoms:?"	-50% with major F and 16% with mino FI reported that bowel symptoms had a negative impact on their life -Nearly two thirds of this group said they wanted help with symptoms
Rockwood et al. [29]	2000	190	FI vs. other gastrointestinal disorders	FIQL	-FI patients reduced shopping, going to the cinema, dining out or having sexual intercourse -FI patients suffer from embarrassment, shame and sometimes depression
Bordeianou et al. [42]	2008	502	Patients referred to a Pelvic Floor Centre because of FI	FIQL + SF-36	-All domains of FIQL significantly altered -Coping-behaviour and embarrassment the two most affected -SF-36 scores decreased as the severity of FI increased, with the exception of the scales on pain
		G			the scales on pain, physical role and physical functioning. FI patients were worse than those with rheumatoid arthritis or diabetes and as severely affected as patients with inflammatory bowel disease
Bharucha et al. [30]	2006	2800	Population- based study Postal questionnaire	FIQL adaptation FICA score	-Urgency affect more QoL -<1 episode/month had important impact on QoL -More affected activities in which toilet access was unpredictable or activities that involved eating

Author	Year	N	Population studied	Questionnaires	QoL alterations
Boreham et al. [43]	2005	457	Women presenting for gynecologic care	FIQL FISI	-Embarrassment the most affected domain -Almost 50% thought that there was no treatment available -Few of them had previously sought care
Bartlett et al. [44]	2009	154	Patients attending a urogynecology and colorrectal clinic for other conditions	FIQL	-QoL severely affected by FI in all four scales -Increased bowel frequency, quantity of fecal loss, type or incontinence and fecal urgency -No difference in QOL when comparing weekly and monthly incontinent episode
Markland et al. [45]	2010	155	Women presenting with FI in a specialty clinic	MMHQ FISI	-Younger women have worst QoL -Increased bowel movement frequency and urgency worst QoL -Urinary incontinence, prior cholecystectomy and prior hysterectomy worst QoL -Loose or watery stool was not a factor for increased MMHQ scores

**Table 1.**What do we know about QoL in patients with FI?

Some years after the development of the FIQL scale, Bordeianou and Rockwood published a prospective analysis of the correlation between severity and QoL, using two tools designed for the same group, the FISI for severity and the FIQL scale, and also the SF-36 [42]. All the domains of the FIQL were significantly altered, being coping-behaviour and embarrassment the two most affected subscales. Furthermore, SF-36 scores decreased as the severity of FI increased, with the exception of the scales on pain, physical role and physical functioning, which was expectable as usually alterations in the QoL of patients with FI are social and emotional. Moreover, the authors reviewed the SF-36 alterations in other chronic diseases managed in an outpatient setting and reported that patients with FI were worse than those with rheumatoid arthritis or diabetes, and as severely affected as patients with inflammatory bowel disease.

Since the publication of the FIQL scale, most studies have used this tool to measure the QoL in FI. Bharucha et al. [31] mailed a questionnaire to an age-stratified random sample of 5300 women treated at two primary care centres covering 80% of a population of 100.000 inhabitants. Subjects with FI during the previous year were assessed by a symptom severity validated scale (Fecal Incontinence and Constipation Assessment, FICA) [30] and a QoL scale consisting in 15 domains adapted from the FIQL scale. The survey was answered by 2800 women and the prevalence of FI was 18.5%. FI had a moderate or severe impact on one or more of the 15 QoL domains in 23% of the women with FI. The study demonstrated that urgency affects more QoL than passive FI alone, being worse if both types of FI are associated, probably due to the anxiety generated by the urgency. Interestingly, women with less than one episode of leakage per month had more impact on their QoL than those patients with the lowest QoL. Furthermore, they found that scores for activities in which toilet access was unpredictable (i.e. going to the cinema, shopping, recreational activities or sports, leaving home, travelling by car, plane or train) and for activities that involved eating (i.e. eating before leaving home, going out to eat) were higher (indicating worse QoL) than scores for activities associated with predictable toilet access (i.e. employment, working home, sex life, visiting friends or relatives, staying overnight away from home and family relationships).

Boreham [43] studied FI in 457 women presenting for gynaecologic care on benign conditions, and reported that prevalence of FI was 28.4%. Moreover, even when the authors considered FI that had an impact on the QoL (answering anything except "never" on the FIQL scale), the prevalence of FI reached 21.7%. Of the 130 women with FI, 76.2% scored very low in the FIQL scales, being also embarrassment the most affected domain. Women with liquid stool leakages reported the largest impact on QoL. Another important aspect that impacts the QoL of patients with FI is the feeling that they are compelled to adapt to their poor situation for the rest of their lives. This study showed several interesting facts: (a) almost three quarters of women reported that FI symptoms were present for 3 years or less; (b) only 11.4% of them had previously sought care; (c) predictors of health care seeking included loss of solid stool and lower scores on the FIQL embarrassment scale and (d) 44.7% of women thought that there was no treatment available.

The findings of this study explain why this condition has been referred to as "the silent affliction" or "the unvoiced symptom" [46, 47] because of the associated stigma. Moreover, we must consider that the overall prevalence of FI is also underestimated because health professionals do not ask about this problem. Aitola et al. reported that only 27% of patients had discussed FI with their physician [48]. Dunivan et al. found that 36% of primary care patients reported FI but only 2.7% carried FI as a medical diagnosis, thus suggesting a lack of knowledge by health professionals [49].

Bartlett and colleagues [50] studied the major reasons for non-disclosure of FI symptoms in patients attending a urogynaecology and colorectal clinic for other conditions. They identified that main reasons were: FI historical but not current; problem not considered as FI by the patient; administrated questionnaires too long; embarrassing condition; doctor considered too busy; patient wanted to focus on the primary reason for consultation and the doctor explained that a one-off bout of uncontrollable diarrhoea was not FI. Nevertheless, interviewees reported that patients would respond to FI questions initiated by their general practitioner during regular consultations.

Later on, the same group [44] reported that more than 22% of patients that attended urogynaecology and colorectal clinic for other conditions than FI, had

a QoL severely affected by FI in all four scales. Factors affecting the QoL were increased bowel frequency, quantity of fecal loss, type of incontinence and fecal urgency. Patients with both solid and liquid incontinence reported a poorer QoL than those with either only solid or liquid incontinent episodes. Given the relationship between the FIQL scales and the quantity of fecal leakage, the authors suggested that the quantity of fecal loss as well as frequency, type, urgency and pad wearing should be included in the definition of FI severity [44]. Another interesting aspect of this study was the small difference found in the FIQL scales when comparing weekly and monthly incontinence episodes, as other authors have previously reported [29], probably because infrequent incontinence episode are always unexpected, and hence, similarly distressing.

Several studies have assessed a potential difference between genders concerning the impact on QoL, with women experiencing a greater impact when compared with men [51, 52]. However, this has not been supported by other reports which failed to find significant differences [44, 53].

Studies using other scales such as MMHQ have been also reached interesting conclusions. Markland [45] studied women presenting with FI and reported a weak correlation between the FISI severity score and the MMHQ. Younger women (<65 years) had higher MMHQ scores, representing a negative impact on HRQoL and the authors suggested that young patients were more likely to report their limitations and seek treatment. However, other studies found that older women had worse QoL than younger women, and justified that a delay in treatment resulted in poorer QoL [50]. Thus, further studies are needed to address the impact on QOL depending on the age. In the same study [45], increased bowel movements and urgency were associated with significantly higher MMHQ scores. After controlling for age and comorbid disease, women reporting more bowel urgency had increased MMHQ score. Urinary incontinence, prior cholecystectomy and prior hysterectomy were also associated with increased QoL scores. Interestingly, loose stool or diarrhea was not a significant factor for increased MMHQ scores in the multivariate analysis.

A prospective study including women with FI investigated the relationship with depression and abdominal pain [54]. Depression was assessed by the Patient Health Questionnaire (PHQ) [55]. Diabetes, prior hysterectomy, abdominal pain, history of previous health care for FI and higher FISI scores were associated with more severe QoL scores. Furthermore, higher PHQ scores predicted worse QoL scores overall and in all four of the FIQL subscales. Other studies have reported a relation between FI and depression [56]. This is an important fact to take into account, because patients with FI are required to cooperate in the management plan, and those suffering from major depression will be less likely to follow a rigorous program. Obviously, FI itself may be the main factor for a depression status; therefore, being aware of it and helping patients is likely to improve the overall treatment.

A study [57] with a cross-sectional design including 2269 ethnically diverse women aged 40–80 years, investigated the impact of FI on sexual QoL. The majority (60%) was sexually active despite having FI, but their sexual function was impaired. The multivariate analysis showed that women with FI experienced significantly lower sexual desire, lower sexual satisfaction, and limitation of sexual activity. Women with isolated gas incontinence reported sexual functioning similar to women without FI. The authors concluded that sexual life should be evaluated and prioritized during therapeutic management, as it is important to women with FI.

In conclusion, key points could be summarized as follows:

1. FI is a frequent condition with a higher prevalence of that reported in previous studies.

- 2. FI has been a neglected problem worldwide. Reasons for non-disclosure and non-detected FI are multifactorial and related to the fear of embarrassment, but also to the lack of professionals dealing with the problem.
- 3. QoL of patients with FI is severely affected in almost all life domains.
- 4. The FIQL scale seems to be a useful and essential tool to assess QoL. Alterations in almost all domains have been demonstrated, especially in coping and embarrassment scales.
- 5. The relationship between severity and QoL in FI is a complex matter, but it has been suggested that the quantity of loss, bowel urgency and increased bowel frequency should be measured and taken into account.
- 6. More specific aspects, such as depression or sexual activity, should also be introduced in the evaluation of these patients in order to improve the quality of health care.

### 6. Is the improvement of patients treated for FI reflected enough in the QOL scales?

For the last 10 years, most studies regarding FI treatments have analyzed its impact on QOL. The FIQL scale has been the most used score to evidence such improvement, thus responsiveness of this score has been widely demonstrated.

A systematic review [58] about outcomes after anal sphincter repair showed that, although continence deteriorates in the long-term, QoL and satisfaction remained relatively high. The scales used in the studies were heterogeneous and, despite most studies were published after the development of the specific QoL scores, less than half used them.

Since the first multicentre European study about the feasibility of sacral neuro-modulation [59], most centres regularly use the FIQL scale and some of them also add the SF-36. Consequently, most articles on this treatment mention the improvement in the four domains of the FIQL scale correlating with the FI improvement, as well as some changes in the generic questionnaire. However, few studies go deeper into the details of the meaning of these changes.

A report about the long-term outcome and QoL in patients treated by sacral neuro-modulation showed a significant and stable improvement in all four categories of the FIQL scale, in contrast to the SF-36 score, which only showed a significant improvement in the social functioning, emotional and mental health subscales, probably due to its generic profile [60]. On the other hand, other studies have demonstrated the quick onset on this QoL improvement, which is already present at 3 months follow-up [61–63].

The Sacral Nerve Stimulation Study Group in the USA [64] reported in-depth details about changes in QoL from baseline through 4 years of follow-up. They reported that not only the four FIQL scales were significantly improved but there was also an improvement in each of the component questions. Before the treatment, patients tended to stay close to a toilet, thought about the impact of food on their bowel function, disliked their body image, and were very limited in their personal intimate life. After sacral neuromodulation, less patients were worried about the proximity to a toilet, were fearful to sleep elsewhere than at home, avoided travelling by plane or train, disliked their body image. Patients also reported an improvement in their sexual life. Moreover, patient-reported overall health was significantly improved, demonstrating a general perception of improvement in wellbeing

beyond the mere restoration of continence. Furthermore, they demonstrated that Embarrassment and Copying-Behaviour were the most affected dimensions, and that correlated better with clinical improvement than Depression and Lifestyle subscales. This fact could be explained because even if patients are not fully continent, their QoL is better secondary to less episodes of FI, but they still remain affected by all the changes that altered their lives during the time that they suffered FI.

Other reports have highlighted the impact of different surgical treatments, such as injectable bulking agents, artificial bowel sphincter or dynamic graciloplasty, on the QOL of patients with FI [44].

#### 7. Measuring patient satisfaction

The current role of clinicians has changed from helping patients through their illness, to have higher expectations that include both cure and alleviate chronic symptoms. Moreover, patients tend to be active consumers of health care, so they may participate on the medical decision-making. On the other hand, monitoring treatment results is mandatory in current practice. For all these reasons, the QoL scales should be used, at least when treatment outcomes are measured.

Nevertheless, the question is whether they are practical and whether its use in the clinical practice is realistic. On certain occasions, decisions based on clinical improvement and patient satisfaction need to be made, and sometimes is impossible to score a QOL scale, in the outpatients' clinic context.

Some studies have reported simple ways to measure patient satisfaction, which are complementary to the application of QOL scores. This implies the addition of study-specific customized questions, typically focusing on subjective measures of satisfaction or QOL (i.e. "Would you recommend a sphincteroplasty to a friend?" or "Are you pleased with the results of your surgery?"). Other authors have used a Likert Scale or Visual Analogue Scales (VAS) to measure patient's satisfaction with the outcome [58].

A study [28] measuring the efficacy of different tools used in FI patient's evaluation, demonstrated and excellent intra and interobserver reliability of both CCCS and St Mark's score. Moreover, all domains of the FIQL demonstrate excellent intraobserver reliability, although a simple quality of life assessment tool such as VAS still maintains a better intraobserver agreement.

The relationship between patient's satisfaction and clinical outcome, assessed by bowel diaries and symptom scores, was evaluated in a study on sacral neuromodulation [65]. Patients were asked to indicate if they were satisfied with their current treatment results, with a simple question (yes/no) that simplified the analysis of predictive factors of outcome. It was evident that this relationship is complex and does not match the traditional used success criteria.

In another study [64], patients were asked to rate his/her own bowel health on a scale from 0 to 10, 0 indicating the worst imaginable situation and a 10 indicating the best one.

There is no consensus on what is the best way to measure patient satisfaction easily, but it is clear that the way to evaluate patients must improve and its validation must be a future line of research.

#### 8. Final comments

Traditionally, it has been assumed that testing is essential in the evaluation of FI. Anorectal manometry and anal ultrasound have been considered the most

useful and available tests to assess FI. Investigations would be clearly useful for patients with a sphincter injury that could benefit from surgical repair. However, in daily practice, the reality for the majority of patients is that testing rarely helps in the decision-making, as decisions are mainly based on the patient's symptoms. It is commonly known that some patients with mild clinical symptoms may have a severe dysfunction when tested, and on the contrary, there are patients experiencing severe FI but showing minor structural and functional alterations. Moreover, treatment decisions and outcome evaluation after treatment should not be decided only considering the symptom severity but the impact on QOL and the patient satisfaction. Finally, considering the economic cost of some of the current treatments for FI, changes in QoL should be demonstrated before implementing certain procedures.

Society is evolving, which implies changes in lifestyle and the possibility of new treatments in the future. Therefore, it might be necessary to rethink the way of assessing QoL, and that questionnaires will need to evolve as well, to adapt to the new circumstances. Readers must be encouraged to become familiar with QoL instruments and their limitations.

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#### Conflict of interest

The authors declare no conflicts of interest.

#### Nomenclature

FI	fecal incontinence
QoL	quality of life
HRQoL	health-related quality of life
IQOLA	international quality of life assessment
SF-36	short form 36 health status questionnaire
FIQL	fecal incontinence quality of life scale
GIQLI	gastrointestinal quality of life index
MHQ	Manchester health questionnaire
MMHQ	modified Manchester health questionnaire
FISI	fecal incontinence severity scale
CCCS	Cleveland Clinic continence score
FICA	fecal incontinence and constipation assessment
ICIQ-B	international consultation on incontinence questionnaire-bowel
	symptoms
DQO	direct questionning of objectives
PHQ	patient health questionnaire
VAS	visual analogue scales

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