Impact of Fecal Incontinence and Its Treatment on Quality of Life in Women

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Abstract

Fecal incontinence (FI) is a physically and psychosocially debilitating disorder which negatively impacts quality of life (QOL). It bears a significant burden not only on patients but also on their families, caretakers, as well as society as a whole. Even though it is considered a somewhat common condition, especially as women age, the prevalence is often underestimated due to patients' reluctance to report symptoms or seek care. The evaluation and treatment of FI can be also hindered by lack of understanding of the current management options among healthcare providers and how they impact on QOL. This article provides a comprehensive review on the impact of FI and its treatment on QOL in women.

Keywords

Fecal incontinence; anal incontinence; accidental bowel leakage; quality of life; defecatory disorders; defecation disorders; bowel incontinence; bowel leakage

INTRODUCTION

Fecal incontinence (FI), defined as the complaint of involuntary loss of liquid/solid stool, is a physically and psychosocially debilitating condition which negatively impacts quality of life (QOL). This condition can lead to social isolation, embarrassment, loss of employment, as well as intimate relationships and self-esteem. [1,2] [3] In addition, the impact of FI is influenced not only by severity, but multiple other individual factors, such as gender, age,

lifestyle, occupation, cultural issues and personal values. The prevalence of FI in community dwelling women varies considerably depending on the studied population and the definition of FI with rates of 2.2 to 25 %.[4–11] Approximately, 18 million adults in the US are affected.[12]

The association of gender and FI is controversial. [6,13] Many clinical studies have shown a higher prevalence of FI in women, especially among those seeking gynecologic care (28.4%).[14] Women may be more willing to report FI than men.[15,16] However, recent epidemiologic studies tend to show an equal gender distribution.[11,13,17,18]

Anal incontinence (AI) and FI are often used interchangeably, however, the terms are not synonymous. According to the terminology by International Urogynecology Association (IUGA) and International Continence Society (ICS), AI is the complaint of involuntary loss of feces and/or flatus, whereas FI pertains to involuntary loss of feces.[17] Both conditions cause social or hygienic problems.

SEEKING CARE

The prevalence of FI is often underestimated due to patients' reluctance to report symptoms or to seek care.[19] When women are asked, 51% had spoken to a friend or partner about their FI, whereas only 10–30% had reported symptoms to a physician, often attributing to delayed diagnosis and management. [11,20–26] There appears to be a positive correlation between health seeking behavior and symptom severity. Bharucha et al reported that 48% of women with severe FI had consulted a physician for their symptoms compared to the overall help seeking rate of 10% in his study population.[27] Of those who sought care, women discussed their FI symptoms with a family physician (56%), an internist (19%), a gastroenterologist (27%), and were less likely to talk to surgical specialists, such as a colorectal surgeon (7%) and gynecologist/urogynecologist (7%).[20,28]

Healthcare professionals are often reluctant to inquire about FI not only because of the complexity in evaluation but also because of a lack of clinical experience and knowledge on current management approaches. Only 54 % of primary care providers screen for FI, and of those who do, 40% believed that conservative management is not effective for treatment of FI.[29–31]

Dunivan et al found that 36% of patients presenting for primary care reported FI symptoms in the past month, however, only 2.7% of those with self-reported FI had a clinical diagnosis of FI in the medical record.[32] In another prospective study including patients with symptoms of FI, only 3 % presented with a chief complaint of FI, and the remaining (97%) reported incontinence only on direct questioning.[33] This emphasizes the importance of asking patients directly about FI symptoms to actively identify and engage potential patients who would otherwise suffer in silence.

The National Institute of Health (NIH) released a consensus and state-of-the-science statement regarding incontinence in adults in 2007 that addressed the suffering and burden of incontinence in adults.[13,18] The statement emphasized the importance of efforts to raise public awareness of incontinence and the benefits of prevention and management in

order to eliminate stigma, promote disclosure and care-seeking, as well as to reduce suffering.[13,18] It has been recently reported that women with FI prefer the term, accidental bowel leakage (ABL), to describe their condition.[13,20] As care providers, when speaking with our patients or publically regarding this sensitive subject, it is recommended that we use the term ABL.

Communication by clinicians that is perceived as 'blaming the patient for stool leakage' or 'belittling the impact of FI' discourages further discussion and care seeking. Referring to incontinence as "failure to control" might be perceived as being capable of control leakage if one wanted or tried harder.

SPECIAL POPULATIONS

As most women with FI do not express their complaint, physicians should actively inquire about FI symptoms. Recognizing common risk factors (Table 1) are helpful in identifying high risk patients.

Frail older women

The estimated prevalence of FI is disproportionally higher in the older woman. FI affects 1 in 5 community living women aged 65+.[12] By 2030, more than 20% of women will be 65 years or older. As the older population increases, the burden of healthcare in the community will become even more substantial.[6,12] FI is not an inevitable consequence of aging. Most studies use the definition of age 65 or above, arbitrarily chosen, to describe "old". Many women above the age of 65 continue to be very active and healthy. These people are different from the frail elderly, who are over the age of 65 *with* a clinical presentation or phenotype combining impaired physical activity, mobility, muscle strength, motor processing, cognition, nutrition, and endurance, most often due to multiple comorbid chronic illnesses. Frailty is considered an independent risk factor for FI. [34,35] In addition, the impact of FI in the frail older adult often affects not only the individuals but also their caregivers. As a result, many older women do not volunteer their problems to health care providers not only due to embarrassment but also concerns of being a burden to their caregivers.[29] FI is one of the leading causes for institutionalization of affected individuals often due to the psychological distress on their family and/or caregivers.[30,36–38] The prevalence of FI in institutionalized adults is as high as 50%.[39,40]

Management of FI in the frail elderly woman is challenging, as it is often accompanied by underlying physical and psychological impairments with other geriatric conditions. FI is also a strong factor for debilitating falls.[41] Reduced mobility requiring toileting assistance and accessibility to toilet demands a higher level of care.

Pharmacologic treatment warrants special attention due to altered drug metabolism and polypharmacy seen in this population, as they are more susceptible to adverse effects. For surgical approaches, the question of age itself as a surgical risk factor is controversial. Factors such as age related physiologic changes, underlying disease state, and the type of procedures performed can all contribute to higher surgical mortality and morbidity rates than the general population. Existing reports show that there is limited awareness regarding

appropriate assessment and treatment options of FI especially among primary care physicians, even though there has been a strong emphasis on the importance of identifying treatable causes of FI in frail older women. As a result, physicians often provide passive treatment with incontinence products without identifying treatable causes of FI in the frail older woman.[29,42]

Pregnancy/Childbirth

One of the main risk factors in women with AI is related to pregnancy, childbirth, and obstetric anal sphincter injuries (OASIS). Some women may consider AI as a normal part or inevitable consequence of childbirth, thus many tend not to seek medical treatment. In a British study, 37% of primiparous women reported at least one symptom of AI during the last 4 weeks of pregnancy. Of those with AI, 3–10% reported that their symptoms were affecting their QOL, especially "coping" and "embarrassment" domains being highly impacted.[43] Handa et al found approximately 1 in 5 young primiparous women with FI had a "moderate" to "extreme" life impact. These primiparous women with FI had decreased QOL as evidenced by lower SF-12 mental component summary scores and self-rated health utility index scores.[44] These studies suggest that FI symptoms are a burden, even for young, relatively healthy women within 6 months of delivering their first child. This can psychologically affect new mothers leading to problems with bonding with their newborns, and neglect, affecting the infant's well-being. Similar studies demonstrated that 30–50% of pregnant women experience AI in late pregnancy, and the prevalence decreases 6–12 months postpartum.[43,45–49]

A longitudinal study of 3763 women demonstrated that the rate of FI after childbirth at 12-year follow-up was 6%. However, 43% of women who had reported FI at 3 months postpartum continued to have persistent FI at 12 years. These women with persistent FI had significantly lower SF-12 scores. The authors also demonstrated that forceps assisted vaginal delivery and obesity are strong modifiable risk factors.[45]

Cesarean delivery is often discussed for the purpose to protect pelvic floor functions despite the lack of supportive data. The Cochrane review on cesarean delivery for the prevention of anal incontinence was published in 2010. The authors concluded that no benefit was demonstrated for cesarean delivery over vaginal delivery in the review of 21 non-randomized studies, thus cesarean delivery should not be recommended to women with average obstetric risk, solely for the purpose for the prevention of FI. However, the decision making is often complicated, especially among women with previous sphincter injuries. In this case, it is reasonable to offer cesarean delivery to prevent further trauma to the sphincters.[50]

Obstetricians can play an important role in reducing burdens of expectant and new mothers by routinely discussing AI symptoms in pregnancy and postpartum to increase awareness and possibly promote help-seeking behaviors.

Although 7–41% of primiparous women may sustain an OASIS, not all are symptomatic immediately after delivery. As many as 70% of sphincter defects related to OASIS were asymptomatic.[51–53] Bharucha et al reported that the median age of FI onset in women

was 55 years old, a few decades after OASIS. This may be due to the "multiple-hit hypothesis" where the OASIS (the initial "hit") is compounded by other factors such as pelvic laxity resulting from stretch-induced pudendal neuropathy and menopause, in addition to aging. [27]

Double incontinence

Women with urinary incontinence (UI) are more likely to have concomitant AI than those without UI.[23,54,55]The presence of UI symptoms in women with AI (double incontinence, DI) can further decrease QOL.[55,56] Selcuk et al demonstrated that women with DI scored worse on the Incontinence Impact Questionnaire – Short Form 7 and Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire, compared to women with UI only.[23] Other studies demonstrated similar findings that sexual life is more adversely affected, and severe anxiety is more common in women with DI compared to single incontinence.[23,57] The prevalence of AI was 28 %, and DI was 9% among women presenting for gynecologic care.[14] Given the negative impact on QOL in women with DI, healthcare providers treating women with UI should also inquire about FI symptoms as an opportunity to reach out to more women.

IMPACT OF FI

Living with FI

For women with FI, going out or traveling causes great anxiety and much planning. Many women fast for hours or days as a strategy to avoid bowel leakage when they have to leave their house. The availability and accessibility of a restroom is a major concern. They are acutely aware of bowel control and are conscious of where the nearest toilets are when they are away from home. This process is known as "toilet mapping" to reduce the risk of a bowel accident.[58] Many women either postpone or avoid meetings and trips. FI has limited women's ability to concentrate on work, reduced productivity, and eventually forced early retirement for some of those who suffer with their condition.[59]

Women with FI are very self-conscious about their body-image, often choosing clothing to conceal pads and to hide stains in case of accidents. Many wear only small pads not large diapers because of visibility through clothing.[59,60] For these reasons, they feel that they have succumbed to the condition and are often hopeless.

Psychological impact

There is a significant association between FI and major depression with worsening scores on the Patient Health Questionnaires (PHQ) predicting worse QOL scores.[24,61,62] The effects of treatment can affect psychological status. Subjects with FI who have had an unsuccessful surgical intervention for FI appeared to have significantly higher scores on anxiety and depression scales than those who had successful surgical outcomes. [63] In addition, psychological symptoms may hinder treatment of FI. Heyman et al noted that mild depression on the Beck Depression Inventory (BDI) predicted treatment failure using biofeedback therapy (p=0.017). Subjects who discontinued treatment before completion scored in the moderate depression range on the BDI. [63]

Factors impacting QOL

Bowel urgency appears to be an independent factor impacting QOL in women with FI in existing studies. Other factors include stool consistency, UI, and multiple chronic illnesses. [12,14,27,64]

Impact on female sexual function

When asked about sexuality, many women are reluctant to bring up the issue with their healthcare providers. Women with FI symptoms tend to have intercourse less frequently. Reports on correlations between FI severity and sexual satisfaction are somewhat inconsistent. Some studies have demonstrated that woman with FI have lower sexual desire, satisfaction, and worse sexual functioning compared to those without FI.[65,66] Imhoff demonstrated that women with FI episodes once weekly or more tended to report lower sexual satisfaction and greater limitation of sexual activity compared to those with FI episodes less than once a month.[65] However, Patel et al reported symptoms of AI were not associated with worse sexual functioning demonstrated using the PISQ-12 after controlling for prolapse stage and age.[67] Healthcare providers should ask directly about the impact of FI on their sexual life, as patients are unlikely to initiate the conversation. They should approach the patient with compassion and provide empathy in a stigma-free environment without being judgmental.

Economic impact

Limited data are available on the direct and indirect health care cost associated with FI. Healthcare costs are estimated 55% higher in people with FI than those without, roughly accounting for $11 billion US dollars annually.[32,68] FI is one of the leading causes of nursing home admission.[2,69]

Direct costs include physician and clinic fees, hospital fees, costs for medications and continence supplies (absorbent pads, barrier or moisturizer, cleansing products, other appliances) as well as transportation costs for the purposes of obtaining healthcare. Indirect costs include work absenteeism, impaired work performance, and changes in job status (choosing a lower wage job to limit contact with the public, the lost wages related to leaving work or retiring prematurely). A survey of 5400 US adults noted that 13.2% of those with FI reported being "too sick to work or go to school." This rate increased to 29.4% with those having large-volume FI.[70] People with large-volume (>400 grams stool per day) FI reported missing an average of 50 days from work in the past year compared to 4.9 days among those without FI.[70] In addition, indirect costs also account for family members missing work to care for the patients and the disability claim payment to people with FI.[71] Thus, estimating indirect costs for FI is challenging.

The average annual cost per person including direct medical and nonmedical costs, as well as lost productivity was $4110 (in 2010 US dollars). Of these costs, direct medical and nonmedical costs averaged $2353 and $209 respectively, whereas the indirect cost associated with productivity loss averaged $1549 per patient annually.[72] FI severity was significantly associated with higher annual direct costs. Dunivan et al [32] reported that the average annual direct medical costs for patients with FI were $2897 higher than those

without FI (in 2005 US dollars). This study excluded costs related to surgical procedures and hospitalizations, possibly contributing to the lower estimates. A Dutch study estimated an annual total cost of €2169 ($2628 in 2004 US dollars) per FI patient, of which €714 was for direct medical cost, €337 for direct nonmedical cost, and €1118 for indirect costs.[73]

Of the medical expenses, the average cost for evaluation and treatment for FI was estimated to be $17,166 per patient.[2,74] Community-dwelling women spend a substantial amount of money for supplies including diapers, absorbent pads, and medications.[2] Four hundred million dollars per year are spent on adult diapers, which are usually not covered by insurance. The costs for conservative treatment have not been well-studied. Sung et al estimated that inpatient procedures for female FI alone cost $24.5 million (in 2003 US dollars).[75] Other study findings are similar reflecting medical costs, including surgical and inpatient care, which are substantial.[71,76]

CONTINENCE MECHANISM

The FI mechanism is dependent upon anal sphincter function, rectal sensation, adequate rectal capacity and compliance, colonic transit time, stool consistency, cognitive and neurologic factors. Incontinence occurs when any one or more of these factors are impacted. Proper diagnosis and treatment of FI requires an understanding of the complex pelvic floor musculature, innervation, and function, as well as compensatory mechanisms. Discussion of the specific mechanism of continence is beyond the scope of this article, and can be found in other reviews.[4,68,77,78]

EVALUATION – HOW TO MEASURE THE IMPACT OF FI

Patient vs physician reported outcomes

One of the goals of evaluation is to ascertain symptom severity and impact on the patient's QOL. Patient impact can be evaluated in several ways. The traditional method is to obtain a clinical history documented by healthcare providers. However, patient-reported outcomes, such as bowel diaries and questionnaires, are an important part of impact evaluation representing the patients' perspective. Assessment of outcomes reported by healthcare providers has been shown to underestimate the degree of symptom bother perceived by patients.[79]

How patients and physicians rank the severity of FI are different. Surgeons have been shown to put greater importance on incontinence of solid stool over other types of leakage (liquid stool and gas). In addition, physicians emphasize a physiological interpretation of events (frequency, amount of lost stool, type of FI), whereas patients are more conscious of leakage that can affect personal hygiene and provoke social embarrassment.[80,81] As the focus of patients may differ from that of physicians, it is important that a combination of severity scale and patient-reported QOL measures be used.

Continence diary

Continence diaries to document bowel habits and episodes of incontinence are a very useful tool to measure the severity of symptoms and are more reliable than patient verbal self-

reporting.[77,82] One limitation of diaries is that it is highly influenced by the individual's willingness to do them and level of commitment.

It is interesting to note that total FI severity scores based on recall (from patient history) compared to daily report (from bowel diary) are different. The total FI severity score based on recall was significantly lower than the score based on their diary. In addition, many women with FI have to rely on caregivers, who may not understand the magnitude of incontinence that the patients are suffering. Fisher et al found that caretakers reported lesser severity on recall compared to their patients.[82] The results of this study support the use of bowel diaries in order to accurately obtain information about the severity of FI symptoms.

Validated questionnaires

Most agree outcome measures reflecting treatment of FI should be a combination of incontinence severity and incontinence-related QOL. Characterizing the severity of FI is important in order to choose a treatment modality as well as to assess the treatment outcomes. The Fecal Incontinence Severity Index (FISI) was developed by surgeons with patient input for assessment of severity independent of direct clinical assessment.[82]

The importance of qualitative research on the impact of FI on QOL gained support in the 1990's. Current data support that disease-specific health-related QOL (HRQOL) questionnaires, instead of general questionnaires, have been shown to best quantify the impact of FI.[83,84] The existing questionnaires for QOL were recently evaluated by the International Consultation on Incontinence (ICI), using 3 grades of recommendation (Table 2). [85] Although multiple instruments are available to evaluate HRQOL, healthcare providers need to carefully choose an instrument that is not only appropriate for the purpose (clinical vs. research settings) but also valid (measures what it intends to measure) and reliable (demonstrate consistency when the assessment is repeated). In addition, for an instrument to be useful in clinical practice, it must be responsive (sensitive to detect change in a patient's condition and that change has to be meaningful to the patient).[86–88]

The Fecal Incontinence Quality of Life index (FIQOL) is a validated quality outcome measure consisting of 29 questions divided into 4 individual scales of lifestyle, coping/ behavior, depression/self-perception, and embarrassment.[87] The Manchester health questionnaire (MHQ) comprises 31 items with subscales of role limitations, physical/social limitations, personal relationships, emotions, and sleep/energy to measure HRQOL in women with AI.[87] The modified MHQ (MMHQ) which includes all the questions from FISI is a valid tool for assessing severity of FI and its impact on QOL, and has been shown to meet standards for both validity and reliability.[89]

The International Consultation on Incontinence Questionnaire – Bowel Symptoms (ICIQ-B) was most recently developed to evaluate symptoms of AI and impact on HRQOL in a single scale for a general adult population.[19] This tool has been shown to have all three factors (validity, reliability, and responsiveness), making it one of the most valid tools assessing the impact of FI.[88]

Multiple validated questionnaires have both long and short-forms. The short-forms of the Pelvic Floor Distress Inventory (PFDI) and Pelvic Floor Impact Questionnaire (PFIQ) provide a reliable and valid alternative to those of the long-forms.[90,91] Interestingly, a higher correlation between long and short form versions was noted with the Colorectal-Anal scales of PFDI than the other 2 scales (UI and POP).[91] Using the short-forms should lower the burden of completing the questionnaires by patients as well as interpreting by clinicians. This promotes more frequent use of these questionnaires. It was traditionally believed that the more severe the condition is, the higher the impact of the condition has on a patient's QOL, thus the two measures (severity and QOL) should correlate. However, more recent data demonstrate a weak correlation between severity and some QOL measures. [24,64,80,92–94]

IMPACT OF TREATMENT ON QOL

As FI is a complex condition, it is best managed by a multidisciplinary team comprised of primary care, continence specialist (urogynecologists, colorectal surgeons, and gastroenterologists), nurses, physical therapists, secondary care specialists such as neurologists and often geriatricians.

Prevention

Preventive measures for FI are categorized into primary, secondary, and tertiary. The goals of primary prevention should focus on eliminating modifiable risk factors for FI. Those factors include controlling diarrhea, preventing as well as treating obesity, and using surgical and obstetrical practices to avoid future sphincter damage. Episiotomy, specifically median episiotomy has been associated with a higher rate of OASIS. Thus, routine practice of episiotomy should be avoided. Whether cesarean delivery should be performed to protect against OASIS is controversial, especially as primary prevention.[2,18,95]

Rey et al demonstrated that urgency is one of the strongest independent risk factors (OR 24.9, 95% CI 10.6, 58.4) for becoming incontinent in community dwelling women. Among those reporting urgency, 72% actually suffered FI. In this study, 37% of those who developed new urgency became incontinent during the 10-year study period, compared to the 7% overall 10-year incident rate of FI.[96] This information can be helpful as a possible marker in screening women to determine who may be more likely to develop FI in subsequent years.

Secondary prevention focuses on screening and identifying women with FI at earlier stages, to avoid invasive treatment before progression of the condition. To reduce the gap between the high prevalence of FI and low rate of seeking care, healthcare providers should initiate the conversation by simply asking patients about their bowel health.

Tertiary prevention focuses on reducing or minimizing the consequences of a condition. The goal of tertiary prevention is to delay or avoid the onset of complications and disability related to the condition. Most medical and surgical interventions are classified as tertiary prevention. All 3 preventative approaches are necessary to reduce impact on women's health and QOL.

Conservative management

Conservative treatment can be very effective for the management of FI. Healthcare providers should share coping strategies such as having cleansing kits, as well as coaching patients how to plan for and reduce unpredictable bowel accidents. Many women are unaware of the effect of dietary modifications to reduce incontinence episodes.[97,98] Certain foods, such as sweets, chocolate, caffeine, alcohol, rich and spicy foods, fried foods and dairy, can aggravate stool leakage, whereas fiber supplementation can alleviate FI symptoms.[97] The timing and portion of meals should also be included in a bowel management program. Bowel diaries can be helpful in predicting when accidents may occur.

Continence products and QOL

Using appropriate continence products improves QOL even though cure is not achieved. The purpose of continence products is to contain and conceal stool. The fear of smelling is a major concern for many who suffer from FI, and women are least satisfied with odor control among different aspects of absorbent products.[99] Thus, there have been efforts to develop products to prevent, absorb or control odor associated with stool or flatal leakage.[100] If successful, women with FI will feel more confident in public, reduce embracement, maintain hygiene, reduce skin irritation, infection, and becomes less dependent to caretakers.[101]

There is a wide variety of products commercially available which may be overwhelming and confusing to caretakers and patients. The goal of healthcare providers is to identify the needs of patients and give guidance to which products will be effective. However, this is challenging as current recommendations are based on expert opinion and experiences by patients and caretakers, and are also influenced by manufacturers. A Cochrane review of absorbent products for moderate to heavy incontinence identified only 2 eligible trials.[102] Both trials were limited by an insufficient sample size to draw definite conclusions about which product designs were best for FI. No particular design of absorbent products was found to be better for protecting skin against incontinence-associated dermatitis and secondary infection.[103] Skin damage appeared to be dependent on the concentration and length of exposure to feces. Frequent cleansing of skin soiled with feces should occur immediately after leakage.[104] For skin irritation and protection, barrier products such as moisturizers, barrier cream, and ointment are commonly used.

Anal plug and QOL

The most common complaint with anal plug use is discomfort and failure to retain the device. Discomfort rates range widely from 10% to 33%. Many patients use them on a limited basis.[105] The reported outcomes of existing data on anal plugs are limited to frequency of FI episodes, patient satisfaction, and tolerance.[106] The impact of the anal plug use on QOL has not been well documented. Currently, there has been a great deal of effort to develop an anal plug that is more tolerable.

Behavioral therapy/biofeedback

Pelvic muscle exercises and biofeedback alleviate FI symptoms by improving pelvic floor muscle strength, sensory-motor coordination, and enhancing the ability to perceive rectal distension.[107] Currently, there is no standardized biofeedback treatment protocol, likely

contributing to the wide range of reported success rates of exercises and/or biofeedback from 38 to as high as 100 %.[21,78,108] Existing data show that most methods of biofeedback and pelvic floor exercise are equally effective, either alone or combined. [109,110]

Pelvic floor therapy requires the patient and therapist to commit to treatment for a number of weeks to months. One study found that only 44% of patients with FI who were recommended biofeedback therapy completed the treatment.[111] However, it is important to note that those who completed biofeedback reported an 80% positive response to treatment. Other studies confirmed over 70% improvement in both severity and QOL scores. [107,111]

Conservative treatment also includes use of medications such as fiber supplementation, anti-motility drugs (loperamide, diphenoxylate and atropine), anticholinergics (hyoscyamine), amitriptyline, and bile-acid binders. [112] The current literature on pharmacological treatment focuses on the efficacy of drugs by assessing the changes in FI symptom severity, frequency, consistency of stool, as well as physiological measures.[113] Well-designed controlled trials are needed to assess the impact of pharmacological treatment of FI on QOL.

SURGICAL MANAGEMENT

Sphincter Repair and QOL

In general, surgery should be considered in selected patients who have failed conservative measures. In most patients with FI due to sphincter trauma, overlapping sphincter plication is effective, at least in the short-term.[21,114] Initial symptom improvement has been seen in 70–80% of patients, however, success rates deteriorate over time with long-term (≥5 years) success ranging 20 – 58%.[21,94] No patients remained completely continent to liquid and solid stool at 10 years.[21] Zutshi et al reported no difference in FIQOL scores between 5 and 10 years post-operatively, despite a significant worsening of incontinence severity.[115] Existing studies consistently show that there appears to be a weak correlation between long-term QOL and FI severity scores. Patients' QOL and satisfaction remained relatively high despite the fact that sphincter function deteriorates over the long-term following sphincteroplasty. [25,94,116]

Sacral Nerve Stimulation and QOL

Sacral nerve stimulation (SNS) was first introduced as a minimally invasive surgical option for treatment of patients with refractory FI in 1995 in Europe.[117] In the US, Interstim® was approved by the FDA for treatment of refractory chronic FI in April, 2011. SNS improves FI symptoms in patients even with disrupted sphincters, including previously failed sphincteroplasty.[60,118]

In the pivotal US multicenter trial of Interstim® treatment for FI, 90% of subjects proceeded from temporary to permanent implantation.[119,120] This study was extended, and the long-term durability of SNS was published in 2013 reporting 36% complete continence and 89% therapeutic success at 5 years.[121] Other studies have demonstrated over 80% of patients achieving a ≥50% reduction in incontinence episodes per week with sustained long-term

results (up to 14 years).[117,120] Matzel et al showed that FIQOL scores were significantly improved in all 4 scales, and SF-36 scores improved in 7 out of 8 scales.[122] Of the SF-36 scales, the highest impacts were social functioning and mental health, however, only the former was statistically significant.[122] In 2011, a meta-analysis including 34 studies (790 patients) was published with the FIQOL data from 9 studies (199 patients) and general QOL SF-36 outcomes from 7 studies (102 patients). Both the FIQOL and SF-36 scores improved significantly in all categories post-treatment after SNS placement.[123] QOL scores of patients followed for at least 5 years appear to be improved both in the short- and long-term with SNS.[119,124–128]

Posterior Tibial Nerve Stimulation and QOL

Posterior tibial nerve stimulation (PTNS), initially used in the treatment of overactive bladder symptoms, is now gaining ground as a treatment for FI, but is not currently approved by the FDA. Compared to Interstim®, PTNS requires repetitive treatments to maintain effectiveness. However, PTNS is a minimally invasive outpatient technique with almost no associated morbidity.[129,130] Most studies on PTNS have demonstrated an improvement in both objective and QOL measurements, where success rates of up to 60% have been reported.[129,130] Most recently, the largest prospective study with 115 patients and a median follow-up of 26 months (range, 12–42) reported that 52% of patients with FI demonstrated   50% reduction in FI episodes.[131] However, all studies are limited by short-term follow-up. In these studies, objective success was sustained at 12-month follow-up, whereas subjective success, improved significantly at 3- and 6-month follow-up.[132–134] The ideal treatment protocol (interval and duration) has not been established. A potential disadvantage of PTNS includes frequent returns to clinic. A randomized controlled trail comparing SNS and PTNS in the treatment for FI is currently being performed (NCT01069016).[131]

Perianal injectables, "bulking agents" and QOL

The treatment of women with passive FI and internal anal sphincter (IAS) dysfunction remains challenging. Injection of a bulking agent to augment the closure of the proximal anal canal was first introduced in 1993.[135] Ten materials have been introduced (Table 3). [136] The advantage of anal bulking is its simplicity and minimal invasiveness. The newest injectable agent is sodium hyaluronate dextranomer microspheres (Solesta™). Graf et al demonstrated the short-term efficacy of Solesta™ vs sham injection for FI where 52% of subjects in the treatment group had a   50% reduction in incontinence episodes compared to 32% in the control group at 6 months. The placebo effect demonstrated in the study are compatible with other trials and cannot be negated, as there was no difference between arms observed at 3 months.[135,136] The treatment response increased to 69% at 12 months in this study population. The mean relative change compared with baseline in FIQOL scores for coping and behavior were significantly improved in the active treatment group vs placebo at 6 months. In addition, the mean FIQOL scores for all four subscales improved significantly between baseline and 12 months in the active treatment group.[135] The current data show that the majority of patients treated with injectables have good QOL improvement as reported on both global and FI QOL scores. A recent Cochrane review noted that the absence of long-term studies as well as limited data based on a single

randomized controlled trial with a small sample size made definitive conclusions about the utility of injectables difficult.[136] While it may not offer complete resolution, anal bulking agents can alleviate symptoms and improve impact on QOL in some patients especially with mild to moderate FI.[22]

Secca® procedure and QOL

The Secca® procedure is an application of a temperature-controlled radiofrequency (RF) energy to the IAS, and was approved by the FDA for the treatment of refractory FI in 2002. RF-induced injury to the IAS is thought to cause collagen deposition and fibrosis, potentially tightening the anal canal.[137,138] A five-year follow-up study published in 2008 showed 84% had   50% symptomatic improvement.[137] A study with 12 month follow up reported that the mean FIQOL score improved overall as well as all subsets except for the depression subscale (trended toward improvement but did not reach significance). Other existing reports also noted that patient satisfaction and QOL scores showed improvement after Secca® treatment.[137,139] However, no study had greater than 50 patients or follow-up longer than 5 years.[137] Further study is needed to define the indication and long-term QOL and impact outcomes.

Diversion – colostomy and QOL

Diversion with colostomy is often considered as a last resort for treating FI. However, it is an effective treatment which significantly improve QOL in patients who failed all other options. No randomized trials have been reported on colostomy, however, a cross-sectional survey by Colquhoun et al revealed significantly higher scores both with the SF-36 and FIQOL among patients with colostomy compared to those without.[140] Questionnaire-based surveys have also shown that the majority of patients (83%) felt that living with a stoma did not restrict their QOL, and 84% would either probably or definitely choose to have the stoma again. When evaluating changes in QOL post-stoma compared to pre-stoma on a scale of −5 (much worse) to +5 (much better), the median score was +4.5. [140,141] A colostomy is a viable option for patients with severe FI and offers a definitive cure with improved impact on QOL. Healthcare providers should discuss the option of a stoma with patients having severe refractory incontinence as diversion provides a positive impact on QOL.

CONCLUSION & FUTURE PROSPECTIVE

FI is a debilitating condition which negatively impacts women's QOL. The prevalence of FI approaches 25% in older community dwelling women. However, prevalence is often underestimated due to patients' reluctance to report their symptoms or seek care. Evaluation and treatment can be hindered by a lack of clinical experience and knowledge on current recommendations regarding FI management among healthcare providers.

Continence education includes raising awareness of FI in order to reduce the stigma associated with incontinence and to promote help seeking behaviors. There is an urgent need to evaluate current continence education programs, not only for the general public but also healthcare providers, as data are limited. Future research should focus on the content of

educational materials, as well as evaluate effective means to educate health professionals. Implementing research outcomes to clinical practice is also a key to improve quality of care. Continued effort is needed to eliminate barriers to healthcare and reduce the burden of FI on women, their family, and on society.

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Executive Summary

- FI is a physically and psychosocially debilitating condition affecting up to 25 % of community dwelling women.

- Healthcare professionals are often reluctant to inquire about FI not only because of the complexity in assessment but also because of lack of clinical experience and knowledge on current management. It is important to actively screen for women with FI as the reported prevalence is often underestimated due to patients' reluctance to report symptoms or to seek care.

- Living with FI causes psychological distress. Many women feel that they have succumbed to the condition and suffer from anxiety and depression. FI can also affect female sexual function. These women avoid having intimate relationships.

- Both direct and indirect costs associated with FI are substantial. The economic impact of FI is a huge burden not only to individuals with FI, but also their family, as well as society as a whole.

- Evaluation of FI entails ascertaining symptom severity and impact on patients' QOL. Perceptions of symptom severity are different between patients and physicians. The use of validated questionnaires along with bowel diaries and direct interviews are encouraged to fully understand the patient's symptoms.

- As it is a multifactorial condition, FI is best managed by a multidisciplinary team. Prevention is the key to success in managing FI. Primary prevention focuses on eliminating modifiable risk factors whereas secondary prevention is to identify women with FI at earlier stages to avoid a worsening condition. Prevention will reduce impact on women's health and QOL.

- Healthcare providers should fully understand current recommendations and options of FI treatment. Conservative treatment is first-line and can be very effective. In general, surgery should be offered to patients who have either failed other therapies or are not ideal for conservative measures. In addition to sphincteroplasty, new surgical interventions have been introduced over the last couple of decades. As new interventions become available, healthcare providers need to critically evaluate the objective and subjective outcomes of each procedure to tailor treatment plans based on individuals' symptoms and expectations.

Table 1

Risk Factors[68]

Age
Abnormal stool consistency
- diarrhea, loose stool, fecal impaction
Pregnancy, Parity
Birth Trauma
- operative vaginal delivery, high degree laceration, episiotomy
Perianal surgery or trauma
- sphincterotomy, hemorrhoidectomy, anal dilation
Neurologic causes
- dementia, stroke, spina bifida, spinal cord lesions, neuropathy, multiple sclerosis, cauda equina
Inflammation
- inflammatory bowel disease, fistula, radiation
Hemorrhoids
Prolapse
- pelvic organ, rectal
Congenital anorectal abnormality
Obesity
Bariatric surgery
Limited mobility
Urinary incontinence

Table 2

FI HR-QOL Questionnaires and the International Consultation on Incontinence Committee Recommendation [19,85–88]

Questionnaires	Severity	QOL	Reliability	Validity	Responsiveness	Gender	Grade[*1]
FIQL		+	+	+		M/F	A
MHQ[*2]	Some[*3]	+	+	+		F	B
ICIQ-B	+	+	+	+	+	M/F	A+

[*1] Grade A: Highly Recommended

Grade B: Recommended

+: additional evidence of published content validity

[*2] The Committee recommendation for the MMHQ is currently not available.

[*3] + for the MMHQ.

Table 3

Anal Bulking Materials[22]

• Autologous fat
• Teflon
• Bovine glutaraldehyde cross-linked collagen (Contigen®)
• Carbon-coated zirconium beads (Durasphere®)
• Polydimethylsiloxane elastomer
• Dextranomer in non-animal stabilized hyaluronic acid (Solesta™)
• Hydrogel cross-linked with poly-acrylamide (Bioplastique®)
• Porcine dermal collagen (Permacol™)
• Synthetic calcium hydroxylapatite ceramic microspheres
• Polyacrylonitrile in cylinder form