Subjective Assessment of the Overactive Pelvic Floor

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10.1 Introduction

An emerging population of female patients is experiencing pelvic hyperactivity that includes voiding symptoms in conjunction with debilitating pelvic pain that can affect gastrointestinal or sexual function. Such patients, deemed as having an "overactive pelvic floor," are currently undergoing comprehensive investigations due to the uncertain etiology of pelvic floor hyperactivity, its alarming prevalence and significant negative impact on quality of life. Pelvic floor overactivity may be associated with neurological or musculoskeletal impairment as well as psychological distress, calling on contributions from medical professionals not only within the field of gynecology. The symptom complex under the "umbrella" of pelvic floor hyperactivity includes overactive bladder syndrome (OABS), chronic pelvic pain (CPP), sexual dysfunction, and associated gastrointestinal disorders. This chapter explores the subjective tools established to assess patients with overactive pelvic floor disorders and aims to characterize the multiple approaches that have been established today.

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10.2 Overactive Bladder Syndrome

OABS is defined by the International Continence Society (ICS) as urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence, in the absence of urinary tract infection or other obvious pathology [1]. This updated definition of OABS is centered around urinary urgency, defined as the complaint of a sudden, compelling desire to pass urine, which is difficult to defer, and must be distinguished from the "normal urge to void" that occurs with normal bladder filling [1–3]. Also, urinary urgency incontinence is no longer essential to the diagnosis of OABS as data from a US study [4] in 2003 indicated that up to 60 % of those with OABS did not actually have urgency incontinence. Reported prevalence rates of OABS in men and women in North America and Europe range between 12 and 17 % [4–6]. Additionally, prevalence of OABS in women in

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North America increases to between 33 and 43 % over the age of 40 years [7]. Not only is the prevalence significant, but the reported health-related quality of life (HRQoL) in these patients is significantly impaired. Symptoms can negatively impact self-esteem, emotional well-being, sexual relationships, and productivity at work [8].

The trio of urinary bladder storage symptoms, which include urinary urgency, urinary frequency, and nocturia, along with urinary urgency incontinence, are subjective findings that can be difficult to measure and rely solely on patients' complaints [2, 3, 9–13]. Thus, OABS is a clinical diagnosis and requires a thorough clinical assessment [2, 3, 10, 12]. Perhaps the most challenging task for physicians is ensuring patients understand the definitions of such urinary symptoms and whether they can accurately recall to what extent they are experiencing them [14]. After working to achieve this goal, physicians can rely on evidence-based instruments that have undergone rigorous validation studies, such as qualitative scales and questionnaires, in efforts to subjectively assess their patients and match the most appropriate and effective treatment method [3, 10, 12–14]. However, physicians and researchers are also continuing to rely on objective measures, such as bladder diaries and urodynamics, to provide insight into pathophysiology, facilitate diagnoses, and evaluate efficacies of treatment measures [3, 12]. Therefore, it is imperative to distinguish between both subjective and objective outcomes as objective assessments may provide results that do not necessarily correlate with or predict such highly individualized subjective outcomes and vice versa.

10.2.1 Evaluating Overactive Bladder Syndrome

Due to its alarming prevalence and impact on quality of life, there continues to be an effort to identify patients with symptoms related to OABS [13]. Studies across Europe and the United States have shown that up to 60 % of patients with bladder symptoms never consulted their physician, an unfortunate statistic that may be due to the stigma associated with bladder problems [13]. Furthermore, a recent study [15] showed that while patients may ultimately consult their physician, they wait a number of years before doing so. This, coupled with its growing prevalence, provides enough evidence to support screening women for symptoms related to OABS. Additionally, screening can help trigger effective communication between patients and health care providers as increased patient education could help eliminate embarrassment and uncertainty about treatment availability associated with bladder problems [13].

One of the first screening tools for lower urinary tract dysfunction, assessing the presence of the four common storage symptoms, was developed and validated in Europe in 2006 [14]. The Bladder Control Self-Assessment Questionnaire's (B-SAQ) first validation study [14] investigated only female subjects from gynecology and urogynecology clinics and was designed to help raise awareness of bladder problems within society and probe patients to seek earlier intervention (see Fig. 10.1). The responses to each symptom and bother item are graded on a 4-point Likert scale: 0 (not at all), 1 (a little), 2 (moderately), and 3 (a great deal). Scores are then added and given an overall score up to 12, which grades severity to either none (0), mild (1–3), moderate (4–6), severe (7–9), or very severe (10–12). Achieving a score greater than 4 on the symptom scale is an indication that seeking medical help may be beneficial to the patient. Assessment of its ease of use, criterion and discriminant validity, and test–retest reliability produced favorable results [14]. Women found the questionnaire to be concise and easy to interpret; there was high internal consistency amongst the questionnaire items, and test–retest analysis showed that the majority of women had the same symptom and bother category assignments [14]. Taken together, these findings support that B-SAQ as a psychometrically robust instrument with good reliability and validity [14]. The sensitivity and specificity were 98 % and 79 %, respectively [14]. Follow-up investigation with male patients demonstrated similar effectiveness, with the exception of a lower specificity (46 %) [16]. Both studies require further assessment in primary care settings.

BLADDER CONTROL SELF-ASSESSMENT QUESTIONNAIRE

ARE YOU: MALE ☐ FEMALE ☐

Please put the NUMBER that applies to you in the boxes shown by the arrows based on the following:

NOT AT ALL = 0 A LITTLE = 1 MODERATELY = 2 A GREAT DEAL = 3

SYMPTOMS **BOTHER**

☐ ← Is it difficult to hold urine when you get the urge to go?

\+ How much does it bother you? → ☐

☐ ← Do you have a problem with going to the toilet too often during the day? +

\+ How much does it bother you? → ☐

☐ ← Do you have to wake from sleep at night to pass urine? +

\+ How much does it bother you? → ☐

☐ ← Do you leak urine? +

= How much does it bother you? → ☐

=

☐ NOW ADD THE TWO COLUMNS DOWNWARDS AND PUT THE SCORES IN THESE BOXES ☐

My symptom score My 'bother' score

THIS SYMPTOM SCORE MEANS:

SYMPTOM SCORE	THIS SYMPTOM SCORE MEANS:	THIS 'BOTHER' SCORE MEANS:	'BOTHER' SCORE
0	You are fortunate and don't have a urinary problem	You aren't bothered by a urinary problem	0
1-3	Your symptoms are mild	You are bothered slightly by your symptoms	1-3
4-6	You have moderate symptoms	You are moderately bothered by your symptoms	4-6
7-9	You have significant symptoms	Your symptoms are of significant bother for you	7-9
10-12	You have very significant problems	Your symptoms are a major problem for you	10-12

if your symptom score (above) is 4 or over you should seek help.

if your bother score (above) is 1 or over you may benefit by seeking help.

IMPORTANT - if you have blood in your urine, have difficulty passing urine, or pain on passing urine. you MUST talk to your doctor about it.

Fig. 10.1 The Bladder Control Self-Assessment Questionnaire (B-SAQ)

Recently, a group of investigators [13] in the United States set their sights on validating a new screening tool aimed at identifying individuals experiencing overactive bladder symptoms in the female population that incorporates current best practices and up-to-date regulatory standards. Originally developed for screening use in patients with multiple sclerosis experiencing urinary problems [17], the Actionable Bladder Symptom Screening Tool (ABSST) was assessed via a prospective, observational study that involved 100 female patients experiencing lower urinary tract symptoms recruited from various gynecology clinics [13]. Each subject completed the eight-item

ABSST that includes questions relating to urgency, micturition frequency, leakage, nighttime voiding, impact on social relations, work interference, and embarrassment over a 7-day recall period [13]. Grading for each item is based on a 4-point Likert scale, similar to the B-SAQ. The questionnaire also includes a question on whether the subject would like to receive help for their bladder problems. Scores greater than or equal to 3 (range 0–8) were indicative of need for further evaluation and/or treatment. Results of the study showed that the ABSST is a reliable, valid, and sensitive tool, which demonstrated an internal consistency coefficient range between 0.88 and 0.91 [13]. The questionnaire was easy to understand and respond to. Analysis of the correlation between ABSST scores and severities of symptoms amongst patients was significantly different, indicating that the ABSST appropriately reflects the severity of symptoms relating to OABS [13]. Sensitivity and specificity were 79 % and 98 %, respectively, which is consistent with the sensitivity and specificity findings in the multiple sclerosis population and supports use of the cut-off score [13]. Additional studies are underway in validating the use of the ABSST in wider population pools [13].

10.2.2 Evaluating Urgency and Its Severity

With the most recently established definition of OABS in 2011, urgency is now regarded as the most pivotal symptom of OABS and, therefore, is essential to evaluate and often the focus of further physician investigations [2, 3, 10, 12]. Possible etiologies for urgency include spontaneous smooth muscle cell contractions, structural changes in the bladder wall, altered release of neurotransmitters acting on smooth muscle or nerves, and altered central nervous system communication with the bladder [18]. Like all symptoms that may be present in OABS, however, urgency poses a challenge for physicians due to its subjective nature and the difficulties associated with ensuring that patients understand what it really means [2, 3, 9–12]. While the exact mechanisms of how urgency is perceived remain unclear, it is critical to differentiate between pathological "urgency" and the physiological "desire to void" that occurs during normal bladder filling [2, 3]. As the bladder fills with volume, an appropriate physiological response (urge) takes place as individuals without symptoms are able to tolerate increases of intensity in their desire to void and defer voiding up to a certain point [3]. At maximal bladder volume, and thus maximal intensity to void, voiding will take place and the regular cycle continues [3]. However, once a sudden, compelling desire to void occurs, which is difficult to defer, patients are experiencing urgency, begin to urinate more frequently (with smaller volumes and at nighttime) and may do so involuntarily [3]. Thus, it is essential to evaluate urgency appropriately so that effective treatment methods can relieve patients of these bothersome symptoms.

The first two subjective tools developed were the Indevis Urgency Severity Scale (IUSS) and the Urgency Perception Scale [10]. Based on the perception that urgency can be perceived differently amongst patients, efforts were made via the IUSS to help distinguish how severe the urgency was on a 4-point qualitative scale. During a clinical trial performed in 2003 [19], patients were asked to rate the severity of their urgency before voiding on a scale from 0 to 4 where 0 represented no urgency, 1 represented mild severity with awareness of urgency but easily tolerated and interruption of daily activities, 2 represented moderate severity with enough urgency/discomfort to interfere with daily activities, and 3 represented the most severe with extreme urgency discomfort that stops the ability to perform all activities [19]. Inclusion criteria for the trial included patients who voided greater than ten times per day and had greater than one urgency incontinence episode per day [19]. The IUSS was later validated in a 12-week randomized controlled clinical trial of trospium chloride in 658 patients with overactive bladder symptoms [20].

The Urgency Perception Scale, which must not be confused with the Urgency Perception Score, represents a subjective assessment of a patient's perception of urgency (with or without incontinence) using a 3-point scale [21]. Patients are asked to describe what they feel when they

experience the desire to pass urine [10]. The three responses can be described either as (1) where the patient reports they are usually not able to hold urine (urgency incontinence), (2) where the patient reports they usually able to hold their urine until they reach the toilet if they go immediately (urgency), and (3) where the patient reports they are usually able to finish what they are doing before going to the toilet (first desire to void) [10]. Although not validated in patients with urinary symptoms, construct validity of the Urgency Perception Scale was established by correlating scores with clinical and patient assessment data from three different clinical trials assessing efficacy of tolterodine in patients with overactive bladder symptoms [21–23].

More recently, other subjective tools have been developed. The Urgency Perception Score is a single-item questionnaire developed to grade urgency based on determining why individual patients choose to void as opposed to use as an index of severity and frequency of urgency episodes [10]. Patents are asked "What is the reason that you usually urinate?" and each response represents a 5-point grading scale that includes 0, which represents voiding out of convenience (no urgency), 1, which represents voiding with delay of an hour (mild urgency), 2, which represents voiding with delay of 10–60 min (moderate urgency), 3, which represents voiding with delay no longer than 10 min (severe urgency), and 4, which represents voiding because of desperate urgency (must stop and go void immediately) [10]. The UPS has been validated in asymptomatic volunteers, patients with lower urinary tract symptoms and patients with OABS through clinical trials evaluating the efficacy of tolterodine extended-release capsules and tolterodine with tamsulosin [24]. With proven test–retest reliability, the UPS represents a clinically useful measure of grading urgency [10].

Perhaps the most used and validated subjective tool for assessing urgency in drug development programs has been the Patient Perception of Intensity of Urgency Scale (PPIUS). The PPIUS asks patients to rate the level of urinary urgency for each void using a 5-point scale [10]. With each void recorded, patients rate the degree of associated urgency ranging from 0, described as no urgency—no feeling of need to empty bladder, but did for other reasons, to 3, described as severe urgency—could not postpone voiding, but had to rush to the toilet in order to avoid wetting oneself, or 4, described as urge incontinence—leakage before arriving to toilet [10]. The content validity and test–retest reliability of PPIUS has been tested in both non-interventional [25] and interventional [26–28] studies including healthy volunteers and patients with urinary symptoms/overactive bladder. Clinical trials assessing the efficacy of solifenacin, mirabegron, and the oxybutynin patch have used the PPIUS and indicated it shows good test–retest reliability and responsiveness [26–28]. Also it was demonstrated to have good value in assessing improvements in major OAB symptoms through correlated changes in PPIUS scores related to patients' perception of bladder condition [26–28]. A recent group from the United Kingdom has worked on incorporating the PPIUS with frequency in efforts to assess two of the major storage symptoms as a single measure [29]. This combination of a subjective urgency assessment with the objective count of urinary voids, termed a Total Urgency and Frequency Score (TUFS), has been tested and validated in patients with OAB [10]. Patients report urgency intensity using the PPIUS with every void and record the number of voids per day in their urinary diary [10]. The PPIUS scores are added to every void and then divided by the total number of days recorded in their diary [10]. While relying on patients to complete their diaries accurately, TUFS has produced favorable results in ongoing clinical trials. Through use in the BLOSSOM [27], SUNRISE [29], SATURN [30], and NEPTUNE [31] trials, TUFS has been shown to have good psychometric properties with high responsiveness and is a useful tool for assessing improvements in major OAB symptoms [10].

Lastly, a unique questionnaire has been developed that couples the assessment of severity of urgency with its impact on quality of life, regardless of the patient's continence status [2]. The Urgency Severity and Life Impact Questionnaire (USIQ) is a 13-question instrument that is divided into a 5-question part examining symptom severity and another 8 question part evaluating the impact of urgency of quality of life (see Fig. 10.2).

URGENCY SEVERITY AND IMPACT QUESTIONNAIRE (USIQ)

I. Urgency is a sudden compelling desire to void, which is difficult to defer due to fear of leakage. Please answer the following questions about your experience of urinary urgency.

During the last month, have you experienced any urinary urgency?

Yes ☐ No ☐

IF YOU ANSWERED NO, PLEASE STOP HERE

The following questions are only about your experience of urinary urgency, NOT about other urinary symptoms.

1. During the last month, what proportion of your urinations had urgency associated with them?

☐ None or almost none of the urinations
☐ About half of the urinations
☐ All or almost all of the urinations
☐ Some of the urinations
☐ Most of the urinations
☐ Don't know

2. When you have urgency, is it typically

☐ Extremely Mild
☐ Moderate
☐ Extremely Severe
☐ Mild
☐ Severe
☐ Don't know

3. Check the best answer for how long can you wait to urinate once you have urgency.

☐ Half an hour or more
☐ Less than 5 minutes but more than 1 minute
☐ I cannot wait at all
☐ Less than half an hour but more than 5 minutes
☐ Less than 30 seconds
☐ Don't know

Fig. 10.2 (**a**–**c**) The Urgency Severity and Impact Questionnaire (USIQ)

4. During the last month, how much has urinary urgency bothered you?

☐ None ☐ Moderate ☐ Extensive

☐ Slight ☐ Considerable ☐ Don't know

5. In an average 24 hour period how much of the time is urinary urgency present?

☐ Never ☐ Sometimes ☐ Always

☐ Rarely ☐ Usually ☐ Don't know

II. The following statements are about the impact of urinary urgency on your life.

		Not at all	Somewhat	Moderately	Quite abit	Always
1	**How much does urinary urgency affect your:** Ability to do household chores, do your work or schoolwork?					
2	**How much does urinary urgency affect your:** Ability to do physical activities such as walking, swimming or other exercise?					
3	**How much does urinary urgency affect your:** Ability to have an intimate relationship or sexual intercourse?					
4	**How much does urinary urgency affect your:** Entertainment activities such as going to a movie or concert?					
5	**How much does urinary urgency affect your:** Ability to travel by car or bus for a distance greater than 30 minutes away from home?					
6	**How much does urinary urgency affect your:** Participating in social activities outside your home?					

Fig. 10.2 (continued)

7	**How much does urinary urgency affect your:** Emotional Health (nervousness, depression, etc)?					
8	**How much does urinary urgency affect your:** Feeling Frustrated?					

Fig. 10.2 (continued)

For both assessments, scores range from 0 to 100 where higher scores correlate with more severe urgency symptoms and a greater impact of such symptoms on quality of life [2]. Validation studies have shown that the USIQ has excellent internal consistency as well as good construct, face, and discriminatory validity [2]. Also, after testing the questionnaire in a controlled trial of symptomatic patients receiving treatment with tolterodine, it was found that the USIQ had excellent test–retest reliability and demonstrated responsiveness following OAB treatment [2].

10.2.3 Evaluating Quality of Life

The effect of OABS on quality of life is significant. Over the past 20+ years, there have been several questionnaires developed and targeted towards assessing the impact of disease on quality of life. Many are used across a wide variety of disease spectrums while others are tailored specifically to urinary tract symptoms. This assessment is essential for physicians to help identify patients in need of immediate therapy, improve their symptoms with various treatment methods, and follow how successful their course of therapy is.

The Urogenital Distress Inventory (UDI), one of the first significant questionnaires developed in the United States in the early 1990s, assesses the amount of distress associated with incontinence and other urinary symptoms [32]. The subjective tool asks about 19 urinary symptoms and patients rate the degree to which these symptoms are troubling to them [32]. The UDI is highly recommended and has been shown to have high validity, reliability, and responsiveness in various populations of women with bladder symptoms before and after treatment [32–34]. A shorter form, UDI-6, has also been developed and has shown equal efficacy in trials [35, 36]. Continued improvements to the UDI are ongoing, and it is now being tested in the male population.

The King's Health Questionnaire (KHQ), available in 26 languages, is another tool that was first developed in London and consists of three major parts [37]. The first part tests the patient's general health and health related to urinary symptoms [37]. The second part includes 19 questions divided into seven domains of quality of life: incontinence impact, role limitations, physical limitations, social limitations, personal relationships, emotions, sleep and energy, severity of coping measures, and symptom severity [37]. The third part includes 11 questions assessing the impact/severity of such symptoms [37]. Similar to the UDI, the KHQ is highly recommended and has been shown to have excellent reliability and validity for women [38–40]. The KHQ also has proven reliability and validity for use in assessing lower urinary tract symptoms in men.

A questionnaire targeted towards the psychosocial impact of urinary symptoms in women was developed and named the Incontinence Impact Questionnaire (IIQ) [32, 41]. The tool consists of 30 questions, 24 related to the degree to which the symptoms affect regular activities and 6 related to feelings caused by them. Scores

Interstitial Cystitis Symptoms Index (ICSI)

During the past month:

How often have you felt the strong need to urinate with little or no warning:

0.__ Not at all
1.__ Less than 1 time in 5
2.__ Less than half the time
3.__ About half the time
4.__ More than half the time
5.__Almost always

Have you had to urinate less than 2 hours after you finished urinating?

0.__ Not at all
1.__ Less than 1 time in 5
2.__ Less than half the time
3.__ About half the time
4.__ More than half the time
5. __Almost always

How often did you most typically get up at night to urinate?

0.__ Not at all
1.__ Once per night
2.__ 2 times per night
3.__ 3 times per night
4.__ 4 times per night
5.__ 5 or more times per night

Have you experienced pain or burning in your bladder?

0.__ Not at all
1.__ A few times
2.__ Fairly often
3.__ Usually
4.__ Almost always

Add the numerical values of the checked entries:

Total score _____

Interstitial Cystitis Problem Index (ICPI)

During the past month:

How much has each of the following been a problem for you.

Frequent urination during the day?

0.__ No problem
1.__ Very small problem
2.__ Small problem
3.__ Medium problem
4.__ Big problem

Getting up at night to urinate?

0.__ No problem
1.__ Very small problem
2.__ Small problem
3.__ Medium problem
4.__ Big problem

Need to urinate with little warning?

0.__ No problem
1.__ Very small problem
2.__ Small problem
3.__ Medium problem
4.__ Big problem

Burning, pain, discomfort, or pressure in your bladder?

0.__ No problem
1.__ Very small problem
2.__Small problem
3.__ Medium problem
4.__ Big problem

Add the numerical values of the checked entries:

Total score _____

Fig. 10.3 The Interstitial Cystitis Symptoms Index (ICSI) and Interstitial Cystitis Problem Index (ICPI)

are added and divided into clusters pertaining to effect on physical activity, travel, social relationships, and emotional health [32]. The IIQ has been tested in several studies including use in incontinent women treated with oxybutynin, tolterodine, or behavioral interventions and has been shown to have good levels of reliability and validity [42, 43].

10.3 Evaluating Pain and Sexual Dysfunction

CPP is defined by the American College of Obstetricians and Gynecologists (ACOG) as localized, noncyclic, pain that persists for 6 months or more and causes a loss of function [44]. CPP affects up to 24 % of women who are

of reproductive age and often requires pharmacologic or surgical intervention, which may not ultimately treat the patient's complaints as pain recurrence is likely [45–47]. The etiology of CPP is unclear as it is thought to result from a complex interplay between gynecologic, urinary, gastrointestinal, neurological, musculoskeletal, and psychological systems [45]. What is certain, however, is the negative effect of CPP on quality of life. Patients with CPP suffer tremendously and have associated stress that affects their marital, social, professional, and sexual lives [45, 46, 48]. Thus, improvement of quality of life is the primary goal in treating patients with CPP [48]. With the aid of subjective instruments such as questionnaires, physicians can appropriately assess the impact of CPP in patients and manage outcomes of their therapeutic interventions. The most recent systematic review of quality of life instruments used in studies of CPP identified a need for the development and evaluation of more specific instruments to assess pelvic pain [48]. Only 19 eligible articles studying use of questionnaires were identified from the 187 articles retrieved after a thorough electronic database search. Of those identified, three of the reports had been studying disease-specific instruments, which were not patient generated and instead developed based on reports from other health professionals [48]. It was determined that, in general, the quality of life instruments reviewed have poor clinical face validity [48]. With regard to the disease-specific questionnaires, compliance with matters of importance to patients varied and only one demonstrated reasonable compliance with quality criteria [48, 49].

Painful bladder syndrome (PBS)/interstitial cystitis (IC) was initially defined by the International Society of Bladder Pain Syndrome in 2005 as "the complaint of suprapubic pain related to bladder filling, accompanied by other symptoms, such as increased daytime and nighttime frequency, in the absence of proven urinary infection or other obvious pathology" [50]. Currently, the European Society for the Study of Bladder Pain Syndrome favors the use of the term "Bladder Pain Syndrome" instead of PBS or IC [51]. This syndrome may be included as a form of CPP in patients and differs from OABS such that pain is the predominant symptom and is occurring in association with bladder symptoms. Parsons and colleagues [52] surveyed several studies in 2007 and reported that BPS has a prevalence of 197 for every 100,000 women over the last 10 years, which was deemed a substantial underestimation of its true prevalence, and affects women more often than men. However, the specific etiology is still uncertain as there is still no absolute definition on how to classify BPS. Genetics, prior pelvic surgery, glycosaminoglycan layer defects, nitrogen oxide metabolism, and autoimmunity have all been linked as possible causes [50].

Various subjective tools have been used and evaluated in the assessment of patients complaining of symptoms of BPS. In efforts to address the initial need for developing broad symptom indexes specifically for BPS, O'Leary and colleagues [53] developed the Interstitial Cystitis Symptoms Index (ICSI) and Interstitial Cystitis Problem Index (ICPI) (see Fig. 10.2). Based off of a 10-year clinical experience with over 400 patients at a New England IC clinic and after statistical validation, these tools were believed to be beneficial in IC management and facilitate clinical research [53, 54]. Both indexes contain questions that address each of the symptoms of frequency, urgency, nocturia, and bladder pain. The two indexes differ, however, in that the ICSI assesses the level of severity of symptoms directly while the ICPI assesses the degree of problem caused by each symptom [53, 54]. Questions such as "have you experienced pain or burning in your bladder" versus how much has "burning, pain, discomfort or pressure in your bladder" been a problem for you, are answered based on a scale of 0–4 where 0 represents either "not at all" or "no problem at all" and 4 represents "almost always" or "big problem," respectively [53, 54]. Both the ICSI and ICPI have been shown to demonstrate excellent ability to differentiate characteristics between patients and controls [54]. The ICSI has also been shown to be responsive to changes in patient condition after use in a clinical trial with pentosan polysulfate sodium [55].

While condition-specific tools such as the ICSI or ICPI exist, few address additional associated symptoms such as dyspareunia or pelvic pain other than bladder pain [56]. In 2009, a single instrument was developed and reported by Clemens and colleagues [56] in Michigan that assessed genitourinary pain symptoms in women using symptom-based criteria. Referred to as the Genitourinary Pain Index (GPI), the 9-question tool initially asks patients to report if they experience pain or discomfort in pelvic areas or in association with bladder activities and sexual intercourse [56]. The GPI also asks patient to quantify how often such symptoms occur (including a scale from never to always) and also challenges patients to assess the average pain on a scale from 1 to 10, 10 being as bad a pain as imaginable [56]. Lastly, the GPI assesses the impact of symptoms on quality of life: how much do patients think about their symptoms, whether it interferes with their daily routine and how patients would feel if they experienced symptoms for the rest of their life [56]. A total score of 0–45 is determined based on each patient's scores from the pain, urinary, and quality of life questions. After a thorough evaluation, the GPI was determined to be a valid and reliable instrument that can be used to assess symptom severity and impact in women, demonstrating excellent internal consistency and responsiveness to change [56]. Similar positive results were found with a gender-specific GPI used when assessing pain and symptoms in males [56].

In addition to CPP and lower urinary tract symptoms, women with hyperactive pelvic floors may experience sexual dysfunction. It has been reported that 43 % of women complain of at least one sexual problem [57]. In accordance with the growing prevalence of sexual dysfunction in women, new instruments for assessing patients' complaints are being devised. Sexual dysfunction in women is complicated, involving both psychological and organic processes, and may draw attention from health care providers outside the realm of female pelvic medicine [57]. In efforts to improve the diagnostic framework for assessing and treating female sexual dysfunction, Rosen and colleagues [57] developed the Female Sexual Function Index (FSFI) questionnaire (see Fig. 10.4). The FSFI is a 19-item self-report questionnaire split between the six domains of desire, arousal, lubrication, orgasm, satisfaction, and pain [57]. Each item has a 5-point response scale (1–5) that correlates with variations in frequency, intensity or degree of satisfaction. For 15 of the 19 items, there exists a zero category that codes for either "no sexual activity" in 12 of them or "did not attempt intercourse" in three. The "satisfaction" domain pertains to global sexual and relationship satisfaction and can be viewed as the "quality of life" domain of the scale [57]. Questions assess patients' satisfaction with amount of closeness with partner, sexual relationship, and overall sex life. The "pain" domain is also a crucial one for investigation in women with coinciding CPP or BPS and assesses patients' pain frequency during and following vaginal penetration as well as pain level during or following vaginal penetration [57]. The FSFI has undergone studies assessing its validity, reliability, and replicability in other languages [58]. Overall, results have shown that the questionnaire has excellent reliability and discriminant validity while also being clear, concise, and easy for patients to answer [57–59]. The FSFI has rapidly found acceptance as a screening tool with use in diverse medical conditions and treatments such as bladder reconstruction, spinal cord injuries, vaginoplasty, vulvodynia, and in correlation with hormonal variations [58].

10.4 Screening for Anxiety, Depression, and Posttraumatic Stress Disorder

There are numerous, validated screening and assessment measures for depression, anxiety, and posttraumatic stress disorder (PTSD), some of which have been specifically developed for use in primary care or general medical (i.e., non-mental health) clinics. The majority of widely used and well-established measures were developed and validated using diagnostic criteria established in the fourth edition of the Diagnostic

Female Sexual Function Index (FSFI) ©

Subject Identifier _____ Date _____

INSTRUCTIONS: These questions ask about your sexual feelings and responses during the past 4 weeks. Please answer the following questions as honestly and clearly as possible. Your responses will be kept completely confidential. In answering these questions the following definitions apply:

Sexual activity can include caressing, foreplay, masturbation and vaginal intercourse.

Sexual intercourse is defined as penile penetration (entry) of the vagina.

Sexual stimulation includes situations like foreplay with a partner, self-stimulation (masturbation), or sexual fantasy.

CHECK ONLY ONE BOX PER QUESTION.

Sexual desire or interest is a feeling that includes wanting to have a sexual experience, feeling receptive to a partner's sexual initiation, and thinking or fantasizing about having sex.

1. Over the past 4 weeks, how **often** did you feel sexual desire or interest?

   ☐ Almost always or always
   ☐ Most times (more than half the time)
   ☐ Sometimes (about half the time)
   ☐ A few times (less than half the time)
   ☐ Almost never or never

2. Over the past 4 weeks, how would you rate your **level** (degree) of sexual desire or interest?

   ☐ Very high
   ☐ High
   ☐ Moderate
   ☐ Low
   ☐ Very low or none at all

Fig. 10.4 (**a**–**e**) The Female Sexual Function Index (FSFI)

Sexual arousal is a feeling that includes both physical and mental aspects of sexual excitement. It may include feelings of warmth or tingling in the genitals, lubrication (wetness), or muscle contractions.

3. Over the past 4 weeks, how **often** did you feel sexually aroused ("turned on") during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

4. Over the past 4 weeks, how would you rate your **level** of sexual arousal ("turn on") during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Very high
- ☐ High
- ☐ Moderate
- ☐ Low
- ☐ Very low or none at all

5. Over the past 4 weeks, how **confident** were you about becoming sexually aroused during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Very high confidence
- ☐ High confidence
- ☐ Moderate confidence
- ☐ Low confidence
- ☐ Very low or no confidence

6. Over the past 4 weeks, how **often** have you been satisfied with your arousal (excitement) during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

Fig. 10.4 (continued)

7. Over the past 4 weeks, how **often** did you become lubricated ("wet") during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

8. Over the past 4 weeks, how **difficult** was it to become lubricated ("wet") during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Extremely difficult or impossible
- ☐ Very difficult
- ☐ Difficult
- ☐ Slightly difficult
- ☐ Not difficult

9. Over the past 4 weeks, how often did you **maintain** your lubrication ("wetness") until completion of sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

10. Over the past 4 weeks, how **difficult** was it to maintain your lubrication ("wetness") until completion of sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Extremely difficult or impossible
- ☐ Very difficult
- ☐ Difficult
- ☐ Slightly difficult
- ☐ Not difficult

Fig. 10.4 (continued)

11. Over the past 4 weeks, when you had sexual stimulation or intercourse, how **often** did you reach orgasm (climax)?

- ☐ No sexual activity
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

12. Over the past 4 weeks, when you had sexual stimulation or intercourse, how **difficult** was it for you to reach orgasm (climax)?

- ☐ No sexual activity
- ☐ Extremely difficult or impossible
- ☐ Very difficult
- ☐ Difficult
- ☐ Slightly difficult
- ☐ Not difficult

13. Over the past 4 weeks, how **satisfied** were you with your ability to reach orgasm (climax) during sexual activity or intercourse?

- ☐ No sexual activity
- ☐ Very satisfied
- ☐ Moderately satisfied
- ☐ About equally satisfied and dissatisfied
- ☐ Moderately dissatisfied
- ☐ Very dissatisfied

14. Over the past 4 weeks, how **satisfied** have you been with the amount of emotional closeness during sexual activity between you and your partner?

- ☐ No sexual activity
- ☐ Very satisfied
- ☐ Moderately satisfied
- ☐ About equally satisfied and dissatisfied
- ☐ Moderately dissatisfied
- ☐ Very dissatisfied

Fig. 10.4 (continued)

15. Over the past 4 weeks, how **satisfied** have you been with your sexual relationship with your partner?

- ☐ Very satisfied
- ☐ Moderately satisfied
- ☐ About equally satisfied and dissatisfied
- ☐ Moderately dissatisfied
- ☐ Very dissatisfied

16. Over the past 4 weeks, how **satisfied** have you been with your overall sexual life?

- ☐ Very satisfied
- ☐ Moderately satisfied
- ☐ About equally satisfied and dissatisfied
- ☐ Moderately dissatisfied
- ☐ Very dissatisfied

17. Over the past 4 weeks, how **often** did you experience discomfort or pain during vaginal penetration?

- ☐ Did not attempt intercourse
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

18. Over the past 4 weeks, how **often** did you experience discomfort or pain following vaginal penetration?

- ☐ Did not attempt intercourse
- ☐ Almost always or always
- ☐ Most times (more than half the time)
- ☐ Sometimes (about half the time)
- ☐ A few times (less than half the time)
- ☐ Almost never or never

19. Over the past 4 weeks, how would you rate your **level** (degree) of discomfort or pain during or following vaginal penetration?

- ☐ Did not attempt intercourse
- ☐ Very high
- ☐ High
- ☐ Moderate
- ☐ Low
- ☐ Very low or none at all

Thank you for completing this questionnaire

Fig. 10.4 (continued)

and Statistical Manual of Mental Disorders (DSM-IV), the standard classification of mental disorders developed and published by the American Psychiatric Association and used by mental health providers in the United States [60]. Note that the DSM was revised in 2013 [61], and new or revised measures consistent with new diagnoses and revised diagnostic criteria are likely to be developed.

10.4.1 Depression

The Patient Health Questionnaire-9 (PHQ-9) [62] is the depression module of the PRIME-MD Patient Health Questionnaire, a self-administered questionnaire specifically developed to diagnose DSM-IV mental disorders in a primary care setting [63]. The PHQ-9 asks patients to rate the frequency of each of the 9 DSM criteria for a Major Depressive Episode on a 4-point scale ranging from "0" (not at all) to "3" (nearly every day). These core criteria have not changed from DSM-IV to DSM 5. PHQ-9 scores can be used both for diagnosis and for determination of symptom severity. The PHQ-9 has demonstrated good reliability and validity with patients in primary care and obstetrics/gynecology clinics [62] and in the general population [64], and is strongly associated with functional impairment and quality of life.

10.4.2 Anxiety

A 2-page version of the PRIME-MD PHQ, described above, is also available. The Brief PRIME-MD PHQ can be used in varied ways: the first page includes questions assessing panic disorder in addition to depression; the second page includes questions about psychosocial stressors, one item about physical or sexual violence, and questions about menstruation, pregnancy, and childbirth [65]. This measure was validated in a sample of 3000 patients in 7 outpatient obstetrics/gynecology clinics. The GAD-7 is a brief self-report measure assessing the presence of Generalized Anxiety Disorder (GAD) [66]. This seven item scale has demonstrated good reliability and validity in both primary care and general population samples [66, 67].

10.4.3 Posttraumatic Stress Disorder

PTSD was reclassified in DSM 5 from an anxiety disorder into the new class of trauma and stressor-related disorders, all of which require exposure to a traumatic or highly stressful event. In addition, the diagnostic criteria were reorganized, with some new criteria added. The only currently available screening measure that incorporates these changes is the 20-item PTSD Checklist for DSM 5 (PCL-5), which can be used for provisional diagnosis and for assessment of symptom severity [68]. The PCL asks respondents to indicate "how much they have been bothered" by each of the DSM 5 specified symptoms of PTSD in the prior month, using a scale ranging from "0" (not at all) to "4" (extremely). The PCL-5 can be administered with brief instructions if trauma exposure has already been assessed or disclosed, with a brief assessment of any trauma exposure, or with the Life Events Checklist for DSM 5 (LEC-5), which asks the respondent to indicate any exposure to a list of potentially traumatic events, such as natural disaster, physical and sexual assault, and serious accidents.

10.5 Conclusion

Pelvic floor muscle hyperactivity, as discussed above, can be detrimental to patients and negatively affect many aspects of their quality of life. Thorough evaluations of bladder symptoms, pelvic pain, sexual dysfunction, gastrointestinal dysfunction, and mental health are crucial when evaluating these patients. In order to alleviate such related symptoms, it is important to be well acquainted with the several validated subjective tools with which one can evaluate the different aspects of symptoms that patients experience. Once the diagnosis is made, a multidisciplinary team is often needed to help and treat women suffering from pelvic floor muscle hyperactivity.

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