Patient-Reported Outcomes and Pelvic Organ Prolapse

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Stavros Athanasiou

Learning Objectives

- The assessment of POP should involve objective and subjective measures.
- Subjective measurements of POP are the patient-reported outcomes (PROs).
- PROs should be used in the day-to-day clinical practice as they provide a better understanding of patients' perceptions regarding their situation and their thoughts for the therapeutic management.
- PROs should be used in research for the assessment of therapeutic outcomes and comparison of the various therapeutic modalities.

46.1 Introduction

Pelvic organ prolapse (POP) is "primarily a definition of anatomical change" [1]. It refers to a falling, slipping, or downward displacement of the uterus and/or vaginal compartments and neighboring organs such as the bladder, rectum, or bowel [1]. Thus, POP along with urinary incontinence, voiding dysfunction, fecal incontinence, and defecatory dysfunction belongs in an interrelated group of conditions named pelvic floor disorders (PFD) [2].

The diagnosis of POP includes clinical evidence of POP and symptoms related to the "downward displacement" of a pelvic organ [1]. The clinical evidence of POP is evaluated using the Pelvic Organ Prolapse Quantification (POP-Q) System [3]. POP-Q includes four stages (stage 0 to stage IV). Stages 0 and IV define the absence of POP and the complete eversion, respectively. Stages I, II, and III define the distance between the most distal portion of the prolapse from the level of hymen (≥1 cm above the level of hymen, between 1 cm above and 1 cm below, and ≤1 cm below but at least 2 cm less than the total vaginal length, respectively).

Clinical evidence of POP does not always correlate with the presence of POP symptoms, as up to 80% of women may be asymptomatic [4]. The level of hymen has been estimated to be an important "cutoff point" for symptom manifestation, as women with POP below the hymen are more likely to have bulging symptoms and more PFD symptoms, as well [2, 5–7]. However, the symptoms of POP are diverse and often non-condition specific as they may be the result of a coexisting PFD and not directly attributing to the POP itself. Thus, it is of importance to acknowledge which symptoms reflect the POP and which is a coexisting PFD before choosing the best therapeutic approach. Additionally, the latter allows a thorough patients' counselling aiming to provide information of what to expect (i.e., which symptoms may disappear or persist, etc.) after an intervention. POP in particular and PFD in general rarely result in severe morbidity or mortality but can influence negatively women's quality of life (QOL) and their daily (physical and social) activities and sexual function.

Furthermore, management of PFD involves conservative treatment including vaginal pessaries, behavioral therapy (such as lifestyle modification, bladder training, etc.), pharmacotherapy, and surgical interventions. Definition of treatments' success rates has not been standardized yet. Surgical interventions aim to restore the anatomical changes to an optimum or at least satisfactory result. Objective measures such as "optimal anatomic outcome" (stage 0 according to the Pelvic Organ Prolapse Quantification (POP-Q) System [8]) used to define "cure" which was the priority of surgeons [3]. However, anatomy does not always correlate with the severity or presence of symptoms. POP symptoms may not be present in 75% of patients without an optimum postsurgical anatomic result and in 40% of patients with a satisfactory one [9]. As a step forward, recommendations of reporting surgical outcomes suggest evaluation not only of objective but also of subjective and quality of life measures [10].

S. Athanasiou (✉)
National and Kapodistrian University of Athens, Athens, Greece
e-mail: stavros.athanasiou@gmail.com

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This chapter reviews the currently available patient-reported outcome (PRO) measures that can be used by clinicians and researchers in patients with POP. Specifically, PROs assessing pelvic floor symptoms, their effect on patient's quality of life and sexual function, and what the patients actually think and feel for their condition and what they expect from their therapy will be presented. The aim of this chapter is to present available evidence of research studies and to provide an appropriate patient-oriented clinical practice and a reproduction of comparable results for the research studies.

46.2 Recommendations for Practice

46.2.1 POP Symptomatology

All symptoms that may be directly or potentially associated to POP as described by the International Urogynecological Association (IUGA) and the International Continence Society (ICS) are presented in Table 46.1 [1]. The most commonly described symptoms are the bulge sensation/visualization, feeling of pelvic pressure, bladder storage symptoms (i.e., frequency, urgency, and nocturia), urinary incontinence (UI), recurrent UTIs, and incomplete defecation [1]. Other common symptoms are the low backache, incomplete emptying/urinary retention, slow urine stream, rectal urgency, digitation/splinting, dyspareunia, and vaginal laxity [1].

The presence of POP symptoms may increase from an average of 0.5 symptoms in stage I prolapse to 2.1 symptoms in women with the leading edge of prolapse extending beyond the level of hymen [11]. However, weak correlations have been found between prolapse and individual symptoms [12, 13]. Although bladder, bowel, and sexual symptoms are more common in women experiencing POP than those without, there is a weak correlation between specific prolapsed compartments and individual symptoms [13, 14]. The only symptom that is consistently reported by the patients with severe POP is the vaginal bulge that can be seen or felt [2]. Furthermore, women with mild prolapse may have stress urinary incontinence (SUI) [15], while those with an advanced one may experience voiding difficulties due to obstruction, needing a manual assistance to urine [13]. Nevertheless, in some cases, SUI may be occult, appearing only after reduction of prolapse, and a combined prolapse and anti-incontinence surgical procedure should be considered [16]. In addition, data regarding the appearance of urgency and urge incontinence (UUI) in relation to POP stage are in discordance [13, 15]. Specifically, Romanzi et al. found that urgency and UUI may occur in patients with advanced POP [15], while Burrows et al. demonstrated that patients with

Table 46.1 Prolapse symptoms as defined by the International Urogynecological Association (IUGA) and the International Continence Society (ICS) [1]

Prolapse symptoms		
Vaginal prolapse symptoms	*Urinary tract prolapse symptoms*	*Anorectal prolapse symptoms*
Vaginal bulging (complaint of a" bulge," "lump," or "something coming down" or "falling out") Pelvic pressure Bleeding, discharge, infection Splinting/digitation Low backache	Urethral prolapse (complaint of a "lump" at the external urethral meatus)	(a) Anorectal prolapse (complaint of a "bulge" or "something coming down") (b) Rectal prolapse (complaint of external protrusion of the rectum)
Potential prolapse symptoms		
Related to lower urinary tract symptoms	*Related to anorectal dysfunction symptoms*	*Related to sexual dysfunction symptoms*
Hesitancy Slow stream Intermittency Straining to void Spraying (splitting) of urinary stream Feeling of incomplete (bladder) emptying Need to immediately re-void Post-micturition leakage Position-dependent micturition Splinting to micturate Dysuria Urinary retention Urinary frequency Urgency	Constipation Feeling of incomplete bowel evacuation Straining to defecate Sensation of anorectal blockage Splinting/digitation Fecal (rectal) urgency Post-defecatory soiling	Dyspareunia Obstructed intercourse Vaginal laxity Libido loss or decrease
Other possible associated symptoms		
	Urinary incontinence symptoms Bladder storage symptoms Bladder sensory symptoms Lower urinary tract infection	

less advanced POP are more likely to experience urgency and UUI than those with an advanced one [13].

All the above indicate that the presence or severity of POP may not attribute to specific POP symptoms, while POP symptoms may be experienced by women with adequate pelvic support. Therefore, a detailed documentation of the symptomatology is essential prior to the initiation of any therapy in order to assess its efficacy.

46.2.2 Patient-Reported Outcome Questionnaires

The PFD symptoms can be assessed during the clinical interview. However, the clinical interview relies on the physician's time and knowledge. Usually, there is not enough time to review all problems that may affect patients, while clinical histories do not assess patients' perception regarding their condition neither how their quality of life is impaired by their condition.

Subjective and quality of life measures can be assessed by psychometrically robust, preferably self-administered questionnaires known as patient-reported outcomes (PRO). PRO "is any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" [11]. They represent the most important clinical review of patient's experience, disease, or set of symptoms. Thus, PROs are used to assess effectiveness and quality of treatment, as they evaluate presence and severity of symptoms and their impact in the everyday life [17, 18].

46.2.3 Selecting PRO Instruments

The choice of which PRO instrument to use should be based on three steps: (1) seeking its relativity and consistency to the clinical purpose and objectives of the study, (2) determination of the length and construct of the questionnaire because long questionnaires may be difficult to be completed by the patients, and (3) assessment of the *reliability* (ability to reproduce similar results after repeated assessments), *validity* (ability to measure of what it is expected to), and *responsiveness* of the questionnaire (ability to detect changes) [2, 19].

The smallest change in PROs that patients perceive as important defines the minimum clinically important difference (MCID). The statistically important differences do not always correlate to what is clinically important. Thus, MCID helps physicians to interpret the outcome measures and to decide of whether to continue or modify their management. In addition, it helps researchers to calculate the sample size of clinical trials [20]. However, MCID can vary depending on certain factors such as population, culture, the baseline from which the patients start, etc. [21]. Thus, it should not be overestimated but applied judiciously to clinical practice or research [21].

Table 46.2 Grade of recommendations according to the International Consultation on Incontinence [23]

Grade	Criteria
A. Highly recommended	Valid *and* reliable *and* responsive to change on psychometric testing (published data)
B. Recommended	Valid *and* reliable to change on psychometric testing (published data)
C. With potential	Valid *or* reliable *or* responsive to change on psychometric testing (published data or abstracts)

46.2.4 Categories of PROs

PRO measures are divided into two large categories [22]: (1) *Generic measures* are multidimensional and have been designed to attribute to a broad range of populations as they tend to assess physical, social, and emotional dimensions of life. However, they may not detect MIDs as they do not focus on specific effects of the evaluated therapeutic approach. And (2) *condition-specific measures* are more specific to a certain disease or population and thus may be more precise at evaluating the efficacy of the treatment. Grade of recommendations and their criteria according to the International Consultation on Incontinence [22, 23] are presented in Table 46.2.

In addition, PRO questionnaires may be divided into five other categories: (1) *screeners*, (2) *symptom questionnaires* (measure the presence, intensity, discomfort, and impact of specific symptoms), (3) *quality of life questionnaires*, (4) *sexual function questionnaires*, and (5) measures of patient's satisfaction, expectations, and goal achievements [2, 22]. Some questionnaires may be mixed assessing symptoms, quality of life, and sexual function of the patients.

46.3 PRO Instruments for POP

Many PRO instruments for POP are used, aiming to cover all POP symptoms (directly, potentially, or possibly associated to POP), their impact on patient's quality of life and sexual function, as well as patients' expectations and satisfaction (Table 46.3, Further Reading). Patients initially may not be able to recognize issues associated with bladder or bowel or sexual function. Thus, in research and in clinical practice, these issues should be acknowledged before proceeding to therapy and medical counselling.

PROs for POP may be administered by mail in order to be completed prior the patient's visit or online or via phone or by

Table 46.3 Summary of PRO instruments for POP

Screeners	Symptoms	Quality of life	Sexual function	Patients' expectations and satisfaction
7-item Q [28]	POP-SS [54, 55]	HUI-3 [91–95]	ICIQ-VS [67]	GAS [135–141]
5-item Q [29]	10-cm VAS [56, 57]	EQ-D5 [91, 92, 96]	Australian Pelvic Floor Questionnaire [68]	SAGA [141]
Single-Q [30]	UDI [58–61]	SF-36, SF-12, SF-6 [91, 93, 94, 97, 98]	ePAQ-PF [69–72]	EGGS [138, 143]
POPSSI [31]	UDI-6 [62]	AAS [98]	ICIQ-FLUTS [78]	PGI scales (PGI-S, PGI-B, PGI-I, PGI-C) [144–148]
EPIQ [32]	PFDI, PFDI-20 [63–66]	ICIQ-VS [67]	Golombok Rust Inventory of Sexual Satisfaction [115]	SSQ-8 [149, 150]
B-SAQ [33, 34]	POPDI long and short form [63, 65]	Australian Pelvic Floor Questionnaire [68]	BISF-W [116, 117]	GPI [61, 151]
ICISI [35–37]	ICIQ-VS [67]	ePAQ-PF [69–72]	CSFQ, CSFQ-14 [118, 119]	PSQ [151]
MESA [38]	Australian Pelvic Floor Questionnaire [68]	ICIQ-FLUTS [78]	FSFI [120, 121]	EPI [151]
3IQ [39]	ePAQ-PF [69–72]	OAB-q [81–83]	MSFQ [122]	PPTBQ [130, 152]
OAB-V8/OAB Awareness Tool [40, 41]	BBUS-Q [73, 74] ISI [75]	PFIQ, PFIQ-7 [60, 63–66, 84, 91, 99]	SPEQ [108, 123–126]	PPBC [153, 154]
PUF [42, 43]	BLUTS [76, 77]	P-QOL [100–104]	PISQ, PISQ-12 [127–131]	BSW [130, 155]
BPIC-SS [44]	ICIQ-FLUTS [78]	IIQ, IIQ-7 [63, 99, 105–107]	PISQ-IR [132, 133]	SATMED-Q [156, 157]
QUID [45–47]	ICIQ-UI SF [79, 80]	I-QOL [108–110]	BIPOP [134]	TSQM [158, 159]
3 questions [48]	QUID [45–47]	KHQ [111, 112]		OAB-S [160, 161]
SFQ [49, 50]	OAB-q [81–83]	ICIQ-LUTSqol [111]		
SFQ28 [49–51]	CRADI [63, 84]	FIQL [113, 114]		
SFQ15 [49, 50]	ICIQ-B [85]			
HSDD [52]	Wexner [86, 87]			
B-PFSF [53]	RAFIS [88]			
	FISI [89] Cleveland Clinic Incontinence Score [90]			

AAS Activities Assessment Scale, *BBUS-Q* Birmingham Bowel and Urinary Symptoms Questionnaire, *BFLUTS* Bristol Female Lower Urinary Tract Symptoms Questionnaire, *BIPOP* Body Image in the Pelvic Organ Prolapse Questionnaire, *BISF-W* Brief Index of Sexual Functioning for Women, *B-PFSF* Brief Profile of Female Sexual Function, *BPIC-SS* Bladder Pain/Interstitial Cystitis Symptom Score, *B-SAQ* Bladder Control Self-Assessment Questionnaires, *BSW* Benefit, Satisfaction, and Willingness, *CRADI* Colorectal-Anal Distress Inventory, *CSFQ* Changes in Sexual Functioning Questionnaire, *EGGS* Expectations, Goal Setting, Goal Achievement, and Satisfaction, *ePAQ-PF* Electronic Personal Assessment Questionnaire-Pelvic Floor, *EPIQ* Epidemiology of Prolapse and Incontinence Questionnaire, *FIQL* Fecal Incontinence Quality of Life Scale, *FISI* Fecal Incontinence Severity Index, *FSFI* Female Sexual Function Index, *GAS* Goal Attainment Scaling, *HSDD* hypoactive sexual desire disorder, *HUI* Health Utilities Index Mark, *ICIQ-FLUTS* International Consultation Modular Questionnaire-Female Lower Urinary Tract Symptoms, *ICIQ-LUTSqol* ICIQ-Lower Urinary Tract Symptoms quality of life, *ICIQ-UI SF* ICIQ-Urinary Incontinence Short Form, *ICIQ-VS* International Consultation on Incontinence Questionnaire-Vaginal Symptoms, *ICSI* Interstitial Cystitis Symptom Index, *3IQ* 3-Incontinence Questionnaire, *IIQ* Incontinence Impact Questionnaire, *I-QOL* Incontinence Quality of Life Questionnaire, *ISI* Incontinence Severity Index, *KHQ* King's Health Questionnaire, *MESA* Medical, Epidemiological, and Social Aspects of Aging Questionnaire, *MSFQ* McCoy Female Sexuality Questionnaire, *OAB-S* OAB-Satisfaction, *OAB-V8/OAB* overactive bladder, *OAB-q* Overactive Bladder Questionnaire, *PFDI* Pelvic Floor Distress Inventory, *PFIQ* Pelvic Floor Impact Questionnaire, *PGI* scales Patient Global Impression scales, *PISQ* Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire, *PISQ-IR* PISQ-International Urogynecological Association Revised, *POPDI* Pelvic Organ Prolapse Distress Inventory, *POP-SS* Pelvic Organ Prolapse Symptom Score, *POPSSI* Pelvic Organ Prolapse Simple Screening Inventory, *PPTBQ* Patient Perception of Treatment Benefit Questionnaire, *P-QOL* Prolapse Quality of Life Questionnaire, *PUF* pelvic pain and urgency/frequency, *Q* Questionnaire, *QUID* Questionnaire for Urinary Incontinence Diagnosis, *RAFIS* Rapid Assessment Fecal Incontinence Score, *SAGA* Self-Assessment Goal Achievement, *SATMED-Q* Treatment Satisfaction with Medicines Questionnaire, *SFQ* Sexual Function Questionnaire, *SPEQ* Short Personal Experiences Questionnaire, *SSQ-8* Surgical Satisfaction Questionnaire, *TSQM* Treatment Satisfaction Questionnaire for Medication, *UDI* Urogenital Distress Inventory, *VAS* Visual Analogue Scale.

a member of the medical team or self-administered in the healthcare setting. The method of administration will affect both the response rate and the accuracy of the response. Self-administered questionnaires are the most robust and accurate for assessing patients' perspectives as they are not affected by an inter-observer variability. Computerized questionnaires were also suggested and were found to be comparable to paper questionnaires in reliability and validity with superior response rates, efficiency, and economic advantages [24–27]. In addition, patients may find them easier and more enjoyable to

complete [27] provided they have technological skills. When patients are elderly, as many POP patients, such skills are doubtful resulting in no completion of the questionnaires or needing help from outer observers that may introduce biases.

All PROs for POP are presented in Table 46.3 [28–161] and extensively reviewed in Further Reading. Below, some PROs for POP, as well as considerations and tips for their selection and interpretation, will be discussed.

46.3.1 Screeners

The beginning of screeners in POP lies in 1989 when WHO conducted a meeting to establish specific questions about chronic obstetric comorbidities [28]. Seven questions were chosen that could identify 80–90% of moderate to severe prolapses. Since then many screening tools have been developed [28]. Screeners may be used to detect patients who might have POP or PFD before a clinical examination. Nevertheless, they should not be misinterpreted as diagnostic tools even when cutoff scores have been determined. They usually include few and specific-oriented questions (i.e., "feeling or seeing a bulge in vagina?" etc.). Responsiveness of screeners has not been assessed. However, sensitivity and specificity are extremely important for their interpretation [22]. Sensitivity provides information regarding how likely a patient with a certain condition is to score positive in screeners, while specificity is how likely a patient without a certain condition is to score negative [22].

46.3.2 Symptom Questionnaires

Symptom questionnaires aim to assess the presence, severity, and bothering of particular POP symptoms or groups of POP symptoms. Ideally, they should be valid, reliable, and responsive, with the MCID being of importance especially for the studies assessing surgical strategies. Questionnaires with a wide coverage of POP symptoms are preferable, but when specific symptoms are indicative (such as UI), specific condition questionnaires may be used. Nevertheless, before deciding which or how many questionnaires to use, it should be kept in mind that the goal is to obtain accurate answers from the patients without making it difficult or confusing for them. In addition, the administration of longer questionnaires may result in more missing data than the short ones. Usually for research studies, many features have to be evaluated; thus the long ones may be more appropriate, whereas for the everyday clinical practice, the short ones are considered more user-friendly. Furthermore, the most frequently used PROs are not always the most reliable ones [22]. Another aspect that should be considered before deciding which questionnaire to use is the recall period that allows factors to affect patients' memory. Thus, recall bias may be introduced [22]. Furthermore, parts or certain questions from PROs should not be used alone or in modification or changing the order or content because the psychometric properties may alter, and the scoring is invalidated [22]. If someone wishes to modify, a validated questionnaire should perform a new validation. In addition, some questionnaires are considered companion to others (i.e., PROs evaluating symptoms with PROs evaluating QoL and PROs evaluating sexual function). The advantage of companion questionnaires is that they add the one to another without duplicating questions.

Urogenital Distress Inventory (UDI-6), Pelvic Floor Distress Inventory-20 (PFDI-20, respectively), and Pelvic Organ Prolapse Distress Inventory long and short form (POPDI and POPDI-6, respectively) are PROs for POP with Grade A recommendation and wide coverage of symptoms [22, 23]. The International Consultation on Incontinence Modular Questionnaire on Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) and ICIQ-UI SF, as well as the Colorectal-Anal Distress Inventory long and short form (CRADI and CRADI-8, respectively), are Grade A PROs focusing on LUTS and bowel function, respectively [22, 23].

PFDI-20 is the synthesis of the UDI-6, POPDI-6, and CRADI-8. It has been derived from the PFDI (its long form that consists of 46 questions) a questionnaire designed specifically for women with POP. PFDI-20 is the most commonly used questionnaire in studies assessing therapies (surgical or conservatives) for POP as it includes urinary, colorectal, and POP scales and is reliable, valid, and responsive to change. Its flexibility due to the wide coverage of symptoms allows the postsurgical evaluation of POP interventions with subgroup comparisons of POP women with and without UI or with and without bowel dysfunction. This is of importance because postsurgical complications (i.e., de novo appearance of UI) can be assessed, while modifications of certain types of surgical techniques may be introduced when POP coexist with UI or bowel dysfunction. Furthermore, its recall period of 3 months is considered appropriate for the recollection of symptoms and events [63, 65]. UDI-6, POPDI-6, and CRADI-8 they all can be used separately because they have been validated and designed to be used individually. However, their synthesis forbids possible duplication of concepts or items, offers less patient burden, and takes less time to be administered.

46.3.3 Quality of Life Questionnaires or Health-Related Quality of Life Questionnaires

"Quality of Life is defined as an individual's perception of their position in life in the context of the culture and value systems in which they live in relation to their goals,

expectations, standards and concerns" [162]. "Health-Related Quality of Life (HRQOL) is defined as an individual's or a group's perceived physical and mental health over time" [163].

Usually, QoL or HRQOL is evaluated with multi-item questionnaires aiming to assess various aspects of patients' life such as sleep, energy, physical health, emotions, work life, sex life, and social life. The terms QoL questionnaires or HRQoL questionnaires are used interchangeably in the literature. However, the QoL questionnaires include domains such as personal safety, community connectedness, and future security that usually are not found in HRQoL questionnaires, although these domains may be affected by illnesses [164]. HRQoL measures a broad description of self-perceived health status using functioning and well-being and not of QoL as it is widely known [164].

QoL or HRQoL questionnaires may be interpreted differently by the patients depending on their personality, social and economic status, psychology, etc. In addition, individual symptoms have distinct impact on QoL. For example, women with POP may stop participating in physical or social activities, while women with UI, even though still participating in such activities, usually declare less satisfied than they used to before the condition occurred [7]. In addition, improvements of objective measurements following a POP surgery do not always reflect improvements in the patients QoL. Thus, QoL questionnaires are important outcomes for urogynecological interventions.

As mentioned above PROs assessing QoL or HRQoL are divided into two categories, the generic and condition specific. The condition-specific PROs are preferable, as they allow to estimate the impact of the specific condition in patient's life and to address changes following an intervention.

Short Form Survey (SF) long and short form (SF-36 and SF-12, respectively), Pelvic Floor Impact Questionnaire long and short form (PFIQ and PFIQ-7, respectively), Incontinence Impact Questionnaire long and short form (IIQ and IIQ-7, respectively), King's Health Questionnaire, and International Consultation on Incontinence Questionnaire-Lower Urinary Tract Symptoms quality of life (ICIQ-LUTSqol) are the most commonly used HRQOL with Grade A level of recommendation [22, 23]. The SF is a generic questionnaire that measures concepts such as physical and social functioning, role limitations due to physical or emotional problems, bodily pain, vitality, and mental health and general health perception. The SF short form is frequently used as a gold standard for health-related QoL questionnaires [165, 166]. However, apart from its social functioning scale, it is not responsive to change in women with POP undergoing surgery.

PFIQ is prolapse specific with excellent validity, reliability, and responsiveness that assesses the impact of urinary, prolapse, and bowel function in the everyday life of women with POP [63–66]. Thus, it can be used by researchers and clinicians. It encompasses the Incontinence Impact Questionnaire (IIQ), the Pelvic Organ Prolapse Impact Questionnaire (POPIQ), and the Colorectal-Anal Impact Questionnaire (CRAIQ) [63–66]. It has a 3-month recall period that is considered appropriate to recollection of symptoms' impact in the quality of life [63, 65]. The PFIQ-7 includes the IIQ-7, POPIQ-7, and CRAIQ-7 and is a companion questionnaire to the PFDI-20 [22]. PFIQ-7 and PFDI-20 have been translated and validated in many languages reproducing its reliability and validity [165–171].

Moreover, many mixed questionnaires have been developed aiming to offer evaluation of symptom bothering and simultaneously how this bothering interfere with the patient's everyday life. Such questionnaires are the following: the Australian Pelvic Floor Questionnaire, Electronic Personal Assessment Questionnaire-Pelvic Floor (ePAQ-PF), ICIQ-VS, ICIQ-FLUTS, and Overactive Bladder Questionnaire (OAB-q) are mixed questionnaires. The Australian Pelvic Floor Questionnaire and the ePAQ-PF also include a sexual function domain, while ePAQ-PF is the only electronic prolapse specific questionnaire. Moreover, ICIQ-VS and ICIQ-FLUTS include a 10-cm VAS for the determination of patients' QoL. However, VAS for measuring HRQOL in POP patients has not found to be valid [91].

46.3.4 Sexual Function

Female sexuality is complex, as various aspects, such as psychological, social, and physiological, are involved. Therefore, female sexual dysfunction (FSD) is difficult to diagnose. However, it is very important to be identified and treated appropriately, for establishing women's well-being and quality of life. Two systems are considered "sanctioned with international fluence" for the definition of sexual dysfunction the ICD-10 and DSM-5 [172]. The combination of these two produced the ICD-11 which is currently in the process of modification. The ICD-10 includes sexual dysfunction not caused by an organic disorder or disease, while DSM-5 includes the female sexual interest/arousal disorder, female orgasmic disorder, and genito-pelvic pain/penetration disorder [172]. These systems are not familiar to gynecologists, and screening for FSD in women with PFDs is not consistently performed [173].

However, 50–60% of women with PFD are sexually active [13, 174]. Data regarding the presence of dyspareunia, decreased orgasmic capacity, and libido in women with POP are controversial. Studies have demonstrated that symptomatic POP and UI increase the risk of FSD (due to reduced sexual arousal, infrequent orgasm, and dyspareunia) while UI women are more likely to avoid sexual intimacy due to their fear of urine leakage [123, 129]. In addition, the negative impact of POP in sexual functioning

may be improved or remained unchanged following a PFD surgery [175]. Nevertheless, measures of sexual function have been found to be similar between women with and those without POP [129]. Moreover, FSD was found to be related to the presence of POP and not the grade of POP and can be explained only partly by the presence of POP [176]. Other factors such as aging/menopause or problems with the partner may be involved.

As sexuality is a multi-complex issue, it is essential for the gynecologists to screen and accurately evaluate the presence of FSD in POP patients taking into account all sexuality aspects in order to provide a better patient counselling. The PROs evaluating women's sexuality and its deviations may help them identify the problem without embarrassing neither the gynecologist nor the patients. PROs for sexual function, as PROs for quality of life, are divided into two large categories: the generic and the condition specific.

The Golombok Rust Inventory of Sexual Satisfaction and the Brief Index of Sexual Functioning for Women are generic questionnaires with Grade A level of recommendation [22, 23]. Condition-specific questionnaires with Grade A level of recommendation are not available. However, the most commonly used condition-specific PROs for sexual function in women with POP are the Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire short form (PISQ-12), with a Grade B level of recommendation, and the Female Sexual Function Index (FSFI) with a Grade C level [22, 23]. In particular, the PISQ-12 is a companion questionnaire to the PFDI-20 and the PFIQ-7 [127–131]. It was designed to evaluate the sexual function of heterosexual women with POP or UI. It is a valid, reliable, and responsive to change questionnaire. However, it cannot assess the partner perception of POP and cannot identify the post-surgery-specific negative effects on sexual function. Recently, IUGA revised PISQ-12 to PISQ-IR aiming to attribute in both sexually and nonsexually active women [132, 133]. PISQ-IR correlates with PFDI-20 and FSFI [132, 133].

FSFI, although with Grade C level of recommendation, is often used in the assessment of POP patients, especially when undergoing surgical approaches. It may detect patients with hypoactive sexual desire disorder (HSDD), female orgasmic disorder (FOD), and female sexual arousal disorder (FSAD) [120]. It has also a particular threshold discriminating patients with from those without FSD [121]. Thus, it may help clinicians and researchers understand whether POP or another factor contributes to the FSD and identify sexual problems arising de novo postsurgical.

46.3.5 Patients' Expectations and Satisfaction

PROs for patients' expectations and satisfactions have been developed to evaluate directly the patients' perceptions regarding the effectiveness of their therapy and whether their therapeutic goal has been fulfilled. Patient's perceptions of outcomes associated with urogynecologic health are greatly influenced by their personal beliefs about their condition and their understanding of the availability of various treatments. Patients' expectations and satisfaction are two separate subjective instruments. Specifically, patients' expectations may be positive (goals) or negative (fears) [177]. Important goals prior to POP surgery are symptom release and improved lifestyle (including physical capabilities and improved sexual life), while the most important fears are de novo symptoms, POP recurrence, and surgical complications [177]. However, goals are not always in alignment within what reasonably expected in terms of efficacy. For example, disagreement between the patients' goals and the objectively demonstrated success of the surgical procedure may cause patient's dissatisfaction. Thus, it is of great importance for the clinicians during the pretreatment counselling to identify and understand what the patient regard as the main problem and what they actually expect as a feedback from their therapy in order to suggest the optimum therapy for them.

The Goal Attainment Scaling (GAS) is the oldest PRO that is widely used in the medicine aiming to identify the therapeutically goals of each patient. In urogynecology it can be used to evaluate treatment outcomes following surgery for PFD [139, 140]. The Goal Attainment Scaling (GAS) is a PRO evaluating the extent to which patient's individual goals are met by thepeutic interventions. (1) It augments information received from standardized outcomes. A disadvantage of standardized outcomes is that patients answer questions that are not adjusted for the individual or a particular situation. In contrast, GAS is specifically tailored for individuals and evaluates only what is important to the patient. (2) Patients' expectations are central for GAS, providing all the information needed for the physician to know what is regarded as treatment benefit to the patients. Thus, unrealistic goals may be separated from the realistic ones, and physicians can explain to the patients what their treatment can actually achieve. In this way, patients may understand that their goals are unrealistic and determine new ones, more realistic, while physicians may select an alternative therapeutic option instead of their initial plan. (3) It may be used in clinical trials. Its individualized approach may be overcome using a summary score of all goals of patients utilizing standardized z-based scoring.

Disadvantages of GAS may include [178] the following: (1) risk of bias at setting goals because physicians may lead the patients to easy achievable goals; (2) success depends on physician to select appropriate goals and accurately predict outcomes, while observable changes may not correspond to the pre-defined outcomes; (3) it's time-consuming, especially the initial step; (4) difficulties performing double-blind trials; and (5) unresolved statistical issues regarding the calculation of the summary score. Thus, some researchers suggest being a complementary outcome and not a primary one [179].

Patients' satisfaction is achieved when the results of the therapeutic interventions are in alignment with patients' expectations. As an outcome measure, patients' satisfaction allows healthcare providers to assess the appropriateness of treatment according to patients' expectations. Patients' satisfaction is a complicated issue because various aspects such as treatment's efficacy, side effects, accessibility, and convenience, availability of resources, continuity of care, cost, availability of information on the disease, information giving, pleasantness of surroundings, and facilities may play an important role, on patients' thoughts leading them to over- or underestimate the therapeutic results. The assessment of patients' satisfaction has many advantages [22]: (1) may be the only distinguishing outcome between treatments in chronic diseases, where realistic objective is not the cure but living with the treatments, (2) may be the distinguishing outcome for therapies with the same mechanism of actions, (3) has better sensitivity to changes than QoL PROs, and (4) helps in defining MIDs for other types of PROs.

Patient Global Impression (PGI) scales are valid and reliable measures for patients' satisfaction. Specifically, the PGI-Improvement (PGI-I) is a single-question PRO, responsive to change, that can be used to evaluate the satisfaction of patients following a pelvic floor surgery. Moreover, all patient-centered outcomes are combined in Expectations, Goal Setting, Goal Achievement, and Satisfaction (EGGS) PRO [138]. Specifically, EGGS has been suggested to become the fourth dimension for the assessment of PFD along with the physical findings, symptoms, and QoL outcomes [143].

46.4 Future Directions

As we move to a more patient-centered approach, PROs provide a better understanding of what is mostly important to the patients. Taking into account patients' expectations, goals, and satisfaction with the treatments, clinicians have an enhanced understanding of the needs and treatment results of the patients. They also help to organize a therapeutic plan better catered to the individual needs of the patient. On the curator side, PROs help clinicians to communicate better with the patients and facilitate sharing clinical information and outcomes between researchers. There is ongoing research on the field, and hence guidelines on the use of specific PROs are not available. Recommendations exist and should be applied on the everyday clinical practice and in clinical studies but are in an ever-changing process due to the continuous research on the field. New studies regarding the use, application, and content of PROs are always in need in the modern approach to the patient with POP.

Take-Home Messages

- Patient-reported outcomes (PROs) are objective measures for subjective phenomenon such as symptom presence and bothering, quality of life, sexual function, and patients' expectations and satisfactions.
- Before deciding which PRO to use, validity, reliability, responsiveness, and interpretability should be taken into account.
- PROs are of critical value for the everyday clinical practice as they help physicians decide the best therapeutic option for each patient individually and perform a better patient counselling.
- PROs are also of critical value for the research studies as "treatment's success rates" have not been standardized and the optimum anatomic result does not correspond to the patients' satisfaction or perception of symptom presence. In addition, they provide comparable results for evaluating therapeutic approaches especially the surgical reconstructive procedures.

Further Reading

Screeners

Detection of Patients with POP Symptoms Before a Clinical Examination

A 7-item questionnaire by the World Health Organization (WHO) [28]: In 1989 WHO conducted a meeting to develop specific questions about chronic obstetric morbidities. Thus, seven questions were selected for POP that could identify 80–90% of moderate to severe prolapses. These questions were the following:

- "Do you feel anything coming out of your vagina?"
- "Do you have pain or difficulty in urinating?"
- "Is it uncomfortable down below?"
- "Do you have a feeling of heaviness?"
- "Do you feel any swelling down below when you urinate or move your bowels?"
- "Do you need to manipulate it to urinate or defecate?"
- "Do you have any difficulty with intercourse?"

Short form questionnaire of five items for genital prolapse [29]: It has 92.5% sensitivity with 94.5% specificity when POP was confirmed and 66.5% sensitivity with 94.2%

specificity when objective signs of prolapse in clinical examination were not present.

Single-question screening [30]: The question is: "Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?" Affirmative answer to this question has 96% sensitivity and 79% specificity for prolapse beyond the level of hymen.

Pelvic Organ Prolapse Simple Screening Inventory (POPSSI) [31]: It is based on Pelvic Floor Disorder Inventory (PFDI) and includes the following four questions:

- "Urinary incontinence following laughing, sneezing or coughing?"
- "Urinary urgency?"
- "Feeling pain during defecation?"
- "Feeling or seeing bulge in vagina?"
- In the general population, POPSSI has 45.5% sensitivity and 87.4% specificity.

Epidemiology of Prolapse and Incontinence Questionnaire (EPIQ) [32]: It is a validated screener that may detect women at high risk to develop PFD (POP, SUI, OAB, and anal incontinence). Its positive and negative predictive value for POP is 76% and 97%, respectively, while for SUI 88% and 87%, respectively, for OAB 77% and 90%, respectively, and for AI 61% and 91%, respectively.

Detection of Patients with LUTS

Bladder Control Self-Assessment Questionnaires (B-SAQ) [33, 34]: It has been developed to identify patients with general LUTS and not solely symptoms of specific condition. Thus, it assesses presence and bothering of urgency, frequency, nocturia, and incontinence. Bothering scoring has a range between 0 (not at all) and 3 (a great deal). The final score is calculated by the sum of scoring of each symptom. It is quick and easy to complete, with 98% sensitivity and 79% specificity for bothersome LUTS.

Interstitial Cystitis Symptom Index (ICSI) [35–37]: It includes four questions assessing the severity of day-time frequency, nocturia, urgency, and bladder pain over the past month. Severity scoring ranges from 0 to 20. A score of 0–6, 7–14, and 15–20 are indicative for mild, moderate, and severe symptoms, respectively. It has a good test-retest reliability, internal consistency, validity, and responsiveness. It may be used to distinguish which patients should be further examined for interstitial cystitis, as it has not a sufficient specificity to be used as a diagnostic tool.

Medical, Epidemiological, and Social Aspects of Aging Questionnaire (MESA) [38]: It includes 15 questions with four possible answers: "rare," "rarely," "sometimes," and "often," applying to "0," "1," "2," and "3" scoring, respectively. Questions 1–9 are targeted to stress urinary incontinence (SUI) with a maximum total score of 27, while questions 10–15 to urge incontinence with a maximum total score of 18 (UUI). However, data regarding its sensitivity and specificity are not available.

3-Incontinence Questionnaire (3IQ) [39]: It has been designed to distinguish patients with SUI and UUI. It includes three questions, with the first one being "During the last 3 months, have you leaked urine (even a small amount)?" Affirmative answer leads to the other two questions. The type of UI is defined based on the third question. The classification of UUI has a 75% sensitivity and 77% specificity, while the classification of SUI has 86% sensitivity and 60% specificity. However, due to low specificities the 3IQ should not be used as a diagnostic tool, as many as 23% and 40% of women may be treated inappropriately for UUI and SUI, respectively.

OAB-V8/OAB Awareness Tool [40, 41]: It includes eight questions, based on OAB Questionnaire (OAB-q), involving frequency, nocturia, urgency, and UUI with bothering scores ranging from 0 to 5. A score greater of 8 may indicate presence of bothersome OAB symptoms. It has a 98% sensitivity and an 82.7% specificity. However, OAB-V8 in comparison to B-SAQ is worst in detecting SUI symptoms.

Pelvic Pain and Urgency/Frequency (PUF) [42, 43]: It includes eight questions addressing to frequency, nocturia, symptoms related to sexual intercourse, and pain in the bladder or the pelvis. Each answer may receive a score from 0 to 4. A cutoff score $\geq$13 has been found to provide the best sensitivity-specificity ratio for PUF. The sum of scores defines the total score. It correlates directly with the likelihood of the intravesical positive potassium results that have been estimated in about 80% of patients with bladder pain syndrome and interstitial cystitis. However, it should not be used as a diagnostic tool. In addition, it has been designed by clinicians without patient input. It includes medical terms that may not be adequately comprehended by the patients. Thus, its validity as a PRO instrument is questionable.

Bladder Pain/Interstitial Cystitis Symptom Score (BPIC-SS) [44]: It is an eight-item questionnaire designed to select BPS/IC patients for clinical trials. A cutoff score $\geq$19 has a 72% sensitivity and 86% specificity for clinical trial inclusion. However, it should not be used as a diagnostic tool.

Questionnaire for Urinary Incontinence Diagnosis (QUID) [45–47]: It may distinguish accurately patients with SUI or UUI with only six questions, and it is considered as one of the few available questionnaires that may add to office diagnosis of UI type. Each item may receive scores from 0 to 5. Items 1–3 and 4–6 correspond to stress and urge score, respectively. Thus, the minimum and maximum scores for both stress and urge are 0 and 15, respectively. The diagnosis of SUI or UUI is proposed when stress score is $\geq$4 or urge score $\geq$6, respectively. Its sensitivity and specificity for SUI are 85% and 71%, respectively. For UUI both sensitivity and specificity are 79%.

Detection of Patients with Sexual Dysfunction

Three questions [48]: The following specific questions have been found to be as effective as detailed interview:

- "Are you sexually active?"
- "Are there any problems?"
- "Do you have any pain with intercourse?"

Sexual Function Questionnaire (SFQ) [49, 50]: It consists of 34 questions detecting the presence or absence of hypoactive sexual desire disorder (HSDD), female sexual arousal disorder (FSAD), female orgasmic disorder (FOD), and dyspareunia. It has an excellent internal consistency and validity (discriminant and longitudinal) and moderate to good reliability.

Sexual Function Questionnaire 28 [49–51]: It includes six domains and 28 questions for recognition of HSDD, FSAD, FOD, dyspareunia, enjoyment, and partner issues using a five-point Likert scale. It has a good test-retest reliability and validity and excellent internal consistency. A cutoff score of 5 determines the arousal cognitive domain.

Sexual Function Questionnaire 15 [49, 50]: It includes four domains and 15 questions for recognition of HSDD, FSAD, FOD, and dyspareunia using a five-point Likert scale.

HSDD [52]: It is a four-item questionnaire with a five-point Likert scale designed to detect presence or absence of HSDD.

Brief Profile of Female Sexual Function (B-PFSF) [53]: It is a seven-item instrument based on the Profile of Female Sexual Function and Personal Distress Scale. Each item has a six-point Likert scale ("always" to "never"). Sum of scores results in a final score ranging from 0 to 35. A cutoff score ≤20 defines the presence of HSDD with 97% sensitivity and 96% specificity.

Symptom Questionnaires

PROs with Wide Coverage of POP Symptoms

Pelvic Organ Prolapse Symptom Score (POP-SS) [54, 55]: It is a seven-item questionnaire that patients report how often they experience POP symptoms. Possible answers apply to a five-point Likert scale: "never," "occasionally," "sometimes," "most of the time," and "all the time" receiving scores of 0, 1, 2, 3, and 4, respectively. Thus, the total score ranges from 0 to 28. It has a good internal consistency, construct validity, and sensitivity to change. In particular, it was able to detect changes when surgical or pelvic floor muscle training (PFMT) was applied, with a different magnitude of changes depending on intervention. An MID of 1.5 has been considered to correspond better to patients' satisfaction.

Visual Analogue Scale [56, 57]: It is a valid, repeatable, single-item continuous scale, usually with a length from 0 to 10 cm, that assesses bothering of each POP symptom using a sliding indicator. The highest the score, the more intense are the symptoms. Initially, it was validated for the assessment of quality of life in urogynecologic research. Lately, an association between VAS and POP grade on clinical and ultrasound examination was found. However, studies performing comparisons between VAS and other standard validated POP questionnaires, or studies evaluating its sensitivity to change following therapeutic interventions, currently are not available. Additionally, MID has not yet been determined.

Urogenital Distress Inventory (UDI) (Grade B) [58–61]: It is a reliable, valid, and sensitive 19-item questionnaire including irritative symptoms, obstructive/discomfort symptoms, and stress symptoms. Answers assess the presence of symptoms and the degree of bother on a four-point scale ("not at all," "a little bit," "moderately," and "greatly" applying to 0, 1, 2, and 3, respectively). Initially, it was designed to assess women with UI but has also been used for the assessment of lower urinary tract function in women with POP. However, the validity in women with UI without urodynamic diagnosis is questionable. MID for the UDI and UDI-stress, in women with stress-predominant UI, is considered reasonable at −11 and −8 points, respectively. MID for the UDI and UDI-irritative, in women with urge-predominant UI, is −35 and −15, respectively.

Urogenital Distress Inventory-6 (UDI-6) (Grade A) [62]: It is the short form of UDI. It has a high correlation with the long form, but it is patient friendlier as it includes only six questions. The total score is calculated using the following algorithm: sum of scores/6 × 25. As with the long form, UDI-6 has a questionable validity for women with UI without a urodynamic diagnosis.

Pelvic Floor Distress Inventory (PFDI) (Grade B) [63]: It is based on two validated questionnaires the UDI and the Incontinence Impact Questionnaire (IIQ) and assesses symptom distress in women with PFD. Overall it includes 52 items (19, 17, and 16 for UDI, Colorectal-Anal Distress Inventory (CRADI), and Pelvic Organ Prolapse Distress Inventory (POPDI), respectively). It is reliable, valid, and condition-specific. However, it is time-consuming as it takes an average of 23 min to be completed. It may be used to predict the outcome of pelvic reconstructive surgery [64]. In particular, a cutoff value of 62/300 pre-surgery, in women with pelvic organ prolapse that was repaired with synthetic mesh, may predict a failure to improve quality of life at 36 months post-surgery. The positive predictive value and specificity of the latter cutoff value were 83.6% and 62.1%, respectively.

PFDI-20 (Grade A) [63]: It is the short-form of PFDI with 20 items and three scales (UDI-6, POPDI-6, and CRADI-8). It is reliable and responsive to change and has an

excellent correlation with the long form of PFDI. Total score is calculated by adding the scores of the three scales with a possible range from 0 to 300. Each scale item could receive values from 0 to 4 applying to a score ranging from 0 to 100 for each scale. The higher the score, the more intense are the symptoms. A change of ≥45 points (15%) was determined as MID. PFDI-20 correlates well with the PFDI [66]. Additionally, PFDI-20 can be converted using a certain formula to PFDI [66].

Pelvic Organ Prolapse Distress Inventory (POPDI) long and short form (Grade A) [63, 65]: It is a specific condition questionnaire and has been included in PFDI. Its short version has six questions and it is part of PFDI-20: "Do you usually experience pressure in the lower abdomen?", "Do you usually experience heaviness or dullness in the pelvic area?", "Do you usually have a bulge or something falling out that you can see or feel in your vaginal area?", "Do you ever have to push on the vagina or around the rectum to have or complete a bowel movement?", "Do you usually experience a feeling of incomplete bladder emptying?", and "Do you ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?". Negative answers receive 0 score, while affirmative ones' score ranges from 1 to 4 depending on degree of bothering. Each scale score ranges from 0 to 100.

International Consultation on Incontinence Questionnaire-Vaginal Symptoms (ICIQ-VS) (Grade C) [67]: It is a valid, reliable, consistent, and responsive PRO. Initially it included 27 items for vaginal symptoms (14 items and 13 subquestions (corresponding to the degree of bother)), sexual matters (ten items and nine subquestions corresponding to the degree of bother)), and quality of life (one item). Responses of vaginal symptoms and sexual matters have 4–5 points, while the quality of life question and the subsequent questions of vaginal symptom and sexual matters a 10 VAS. The short form includes 14 items corresponding to the evaluation of vaginal symptoms, sexual matters, and quality of life. Vaginal symptoms and sexual matters are calculated separately using specific algorithms.

Australian Pelvic Floor Questionnaire [68]: It is a reproducible and valid questionnaire with a wide coverage, as it assesses presence, bothering, and impact on quality of life of all pelvic floor symptoms (bladder, bowel, and sexual function) and prolapse symptoms. It has 42 items and four sections (bladder, bowel, prolapse, and sexual function corresponding to questions 1–15, 16–27, 28–32, and 33–42, respectively). Scores are calculated separately for each section giving values from 0 to 10 for each section. Thus, the maximum global dysfunction score is 40. The bladder, bowel, prolapse, and sexual function domains correlate with the UDI-6, established bowel questionnaire, International Continence Society Prolapse Quantification, and McCoy Female Sexuality Questionnaire, respectively.

Electronic Personal Assessment Questionnaire-Pelvic Floor (ePAQ-PF) [69–72]: It is reliable, valid, and web-based questionnaire consisting of urinary (12 questions), bowel (20 questions), vaginal (11 questions), and sexual (15 questions) domains. All domains evaluate quality of patients' life. Moreover, urinary domain assesses pain, overactive bladder and SUI, bowel domain constipation, evacuation, and incontinence, while vaginal domain sensation and prolapse. Sexual domain includes aspects of urinary, bowel, and vaginal symptoms in relation to sex. The time for its completion has been estimated between 12–103 min providing medians of 26 and 33 for the "non-interactive" version and primary care, respectively. Additionally, its responsiveness to change has been indicated in the relative domains of prolapse and quality of life, in women undergoing POP surgery. The electronic over paper administration of PROs is considered to offer many advantages. However, patients should have technological skills, but the vast majority of POP patients are elderly, and such skills are doubtful.

Birmingham Bowel and Urinary Symptoms Questionnaire (BBUS-Q) (Grade B) [73, 74]: It is a valid, reliable, and responsive, 22-item questionnaire assessing constipation (Q1 and 2), evacuation (Q7–13 and 15), incontinence (Q3–6), and urinary symptoms (Q16–22). Question 14 is not encompassed in any domain. Responses apply to a four-level scale, while scores range from 0 to 100 for each domain. Cutoff scores to define abnormal domains are ≥64%, ≥17%, ≥17%, and ≥20%, for constipation, evacuation, incontinence, and urinary symptoms score, respectively.

PROs Focusing on LUTS

Incontinence Severity Index (ISI) [75]: It is a valid, reliable, sensitive measure with only two questions ("how often do you experience urine leakage" and "how much urine do you lose each time"). The total score is calculated by multiplying the score of the first question (from 0 to 4) by the score of the second question (from 1 to 2). It can be used in routine clinical practice.

Bristol Female Lower Urinary Tract Symptoms Questionnaire (BFLUTS) [76, 77]: It is a valid and reliable questionnaire that includes 6 domains involving frequency, voiding, incontinence, sex, and quality of life with scores ranging from 0 to 15, 0 to 12, 0 to 20, 0 to 6, and 0 to 18, respectively. However, it has been found that women may score higher on self-completion than interview [65].

International Consultation on Incontinence Modular Questionnaire-Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) (Grade A) [78]: It is the short form of BLUTS. It is a valid, reliable, and responsive, 12-item questionnaire evaluating nocturia, urgency, bladder pain, fre-

quency, hesitancy, straining, intermittency, UI (urge, stress, and unexplained), frequency of urinary incontinence, and nocturnal enuresis. Filling, voiding, and incontinence symptom subscales range from 0 to 15, 0 to 12, and 0 to 20, respectively. Additionally, it evaluates impact of individual symptoms with bothering scales that are not incorporated in the overall scores.

ICIQ-UI SF (Grade A) [79, 80]: It is a valid, reliable, responsive questionnaire with four items, including frequency, prevalence and cause of UI, and impact on everyday life. The cause of UI is not included in the total score calculation. The total score ranges from 0 to 21. The recommended MIDs for women undergoing surgery due to SUI are −5 and −4 at 12 and 24 months postoperatively, respectively.

Questionnaire for Urinary Incontinence Diagnosis (QUID) [45–47]: It is a valid, reliable, and responsive to change with 6-item UI symptom questionnaire. It may distinguish accurately the type of UI and may be offered as a screener, as presented above. It correlates strongly with the UDI as it assesses symptoms' intensity and bothering. In addition, it may detect differences following a non-surgical intervention. Thus, it may be used in research as UI outcome measure of clinical trials.

Overactive Bladder Questionnaire (OAB-q) [81–83]: It is a valid, reliable, and responsive symptom bother and quality of life questionnaire attributable in both continent and incontinent patients. Initially, 62 items (13 symptom items, 4 general, and 44 health-related quality of life (HRQL)) were included, while a reduction to 33 items (8 symptom items and 25 HRQL) was performed in order to become user-friendlier and more accurate. It includes scales of symptom bother (frequency, nocturia, urgency, and urge incontinence), coping, concern/worry, sleep, social interaction, and HRQL. Each question corresponds to a six-point Likert scale, from "none of the time" to "all the time," applying to 1–6, respectively. The total score for each domain ranges from 0 to 100, with MID recommended at ≥10 points. In addition, two versions of 4- and 1-week recall period with similar factor structures are available.

PROs Focusing on Bowel Function

Colorectal-Anal Distress Inventory (CRADI) long and short (CRADI-8) form (Grade A) [63, 84]: The long form has 17 items and is included in the PFDI, while CRADI-8 has eight items and is included in the PFDI-20. However, they can be used apart from the PFDI and PFDI-20 as independent questionnaires for women with fecal incontinence. MIDs for the long and short form are 11 and 5, respectively.

International Continence Consultation-Bowels (ICIQ-B) [85]: It is a valid, reliable, and responsive 35-item questionnaire (25 symptom items and 10 HRQL items). It has three scored domains involving bowel pattern, bowel control, and quality of life with scores ranging from 1 to 21, 0 to 28, and 0 to 26, respectively. Additionally, it includes four unscored items for the assessment of clinical or patient perspective.

Wexner Scores (Grade C) [86, 87]: It is a scoring system for both fecal incontinence and constipation. The incontinence score ranges from 0 to 20, while the constipation score from 0 to 30 with values >15 defining constipation's presence. Zero defines absence of symptoms while 20 and 30 severe ones.

Rapid Assessment Fecal Incontinence Score (RAFIS) [88]: It is a valid and reliable two-item tool for assessing fecal incontinence. The total score ranges from 0 to 20.

Fecal Incontinence Severity Index (FISI) [89]: It includes four items involving incontinence to gas, mucus, liquid stool, and solid stool with scores ranging from 0 to 12, 0 to 12, 0 to 19, and 0 to 18, respectively.

Cleveland Clinic Fecal Incontinence Score [90]: It is a five-item questionnaire assessing leakage of solid, liquid, and gas, the use of pads, and the lifestyle restriction. Responses apply to "never," "rarely," "sometimes," "usually," and "always."

Quality of Life Questionnaires

Generic Questionnaires

Health Utilities Index (HUI)-3 [91–95]: It includes eight attributes (vision, hearing, speech, ambulation, dexterity, emotion, cognition, and pain) with five or six levels. The scoring attribute to morbidity scale is from 0.00 (worst level) to 1.00 (best level). It can receive negative scores representing health states worse than death. Difference in mean HUI total score ≥0.03 has been suggested as MID. It is a valid tool of HRQOL in women with POP or other PFDs (i.e., UI).

EuroQol (EQ-5D) [91, 92, 96]: It includes five attributes (mobility, self-care, usual activities, pain/discomfort, and pain) with five or six levels. The score of EQ-5D ranges from −0.59 to 1.00. Difference in utility score of 0.03 has been suggested as MID. It is a valid measure of HRQOL in women with POP and UI (urge, stress, and mixed).

Sort Form Survey (Grade A) [91, 93, 94, 97, 98]: It has various versions including 36 (SF-36), 12 (SF-12), and 6 (SF-6) items. SF-36 measures eight concepts: physical and social functioning, role limitations due to physical or emotional problems, bodily pain, vitality, mental health (psychological distress and well-being), and general health perception. The number of response levels varies between 4 and 21, depending on domain. The MID for the physical functioning scale is 2 and 3 points for functioning scores <40 and >40, respectively. SF-12 also includes eight concepts,

while SF-6 is derived from SF-12 with six concepts (physical and social functioning, role limitation, pain, mental health and vitality). SF-6 is scored on a scale from 0.29 to 1.00, and each of the six attributes has five or six levels of responses. In addition, SF-6, as with HUI-3 and EQ-5D, is valid and reliable for women with POP or UI of any type, with MID of 0.03.

Activities Assessment Scale (AAS) [98]: It is a valid, reliable, and responsive measure for the assessment of physical activities following vaginal reconstructive surgery for POP and SUI. It includes 13 items for the evaluation of the ability regarding lying in bed, sitting, getting in or out of bed or chair, reaching or stretching, lifting 3–5 pounds, walking around inside, climbing up or down stairs, walking outside or at work, engaging in sedentary activities (i.e., typing, talking on the phone, playing cards, watching TV), engaging in light physical activities (i.e., cooking, dusting, clerical work, visiting friends), engaging in moderate physical activities (i.e., sweeping, washing the car, dancing, playing golf, hiking), engaging in vigorous physical activities (i.e., construction work, shoveling, playing tennis or basketball, weight lifting), and engaging in sexual intercourse. Responses may receive scores from 1 "no difficulty" to 6 "did not do it for other reasons." The total score is calculated using a transformation algorithm to produce a range from 0 to 100. Higher total score indicates greater physical functioning.

Condition Specific

Pelvic Floor Impact Questionnaire (PFIQ) long and short form (PFIQ-7) (Grade A) [60, 63–66, 84, 91, 99]: It is a valid, reliable, and responsive measurement assessing the impact in HRQOL of related, possibly related, and potentially related POP symptoms. The short form correlates well with the long one, while a conversion formula from the short to the long form, with an excellent goodness of fit, has been published. The long form includes three domains (Incontinence Impact Questionnaire (IIQ), Pelvic Organ Prolapse Impact Questionnaire (POPIQ), and Colorectal-Anal Impact Questionnaire (CRAIQ)) with 93 items (31 items in each domain). The PFIQ-7 includes three domains (IIQ-7, POPIQ-7, and CRAIQ-7) with 21 items (seven items in each domain). The total score of PFIQ-7 ranges from 0 to 300 (each domain may receive scores from 0 to 100). A change of ≥36 points (12%) has been suggested as MID for PFIQ-7. In addition, the generic questionnaires of HUI-3, EQ-5D, and SF-6D correlated significantly but moderately with the prolapse subscale of PFIQ-7. The long and short forms of IIQ, POPIQ, and CRAIQ can also be used individually from the PFDI long and short form, respectively. MID for IIQ has been estimated at −16 points. MID for CRAIQ long and short form is −18 and −8, respectively. However, a study evaluating these long forms of PFIQ in women undergoing pelvic floor reconstructive surgery (PFR) or receiving vaginal pessary resulted in different MIDs in the respective subscales depending on type of intervention. In particular, MID for POPIQ is −40 to −27 and −29 for PFR and vaginal pessary, respectively. MID for CRAIQ is −34 to −6 and −29 for PFR and vaginal pessary, respectively.

Prolapse Quality of Life Questionnaire (P-QOL) [100–104]: It is a simple, valid, and reliable measurement that includes nine domains (general health perceptions; prolapse impact; role; physical, social, and personal limitations; emotions; sleep/energy; and severity measures) with responses having a four-point scoring system. This scoring attributes to how much the POP symptoms are affecting women's life ranging from "none/not at all" to "a lot." Each domain ranges from 0 to 100. Higher score indicates greater negative impact on women's life. Thus, it is a reliable and valid tool for the recognition of women who need a therapeutic intervention, as symptom severity and their impact on quality of women's life can be defined. Additionally, P-QOL has been used in surgical studies, detecting significant improvement of the quality of life of women undergoing a pelvic reconstructive surgery, such as vaginal mesh implantation. In particular, MID difference was met in all domains. Nevertheless, the latter MID was defined only by a statistical model using the "half standard deviation," as studies with the recommended methods for determining MID have not been published [94].

Incontinence Impact Questionnaire long (IIQ) and short form (IIQ-7) (Grade A) [63, 99, 105–107]: The long form includes 30 items with 4 subscales (physical activity, travel, social relationships, and emotional health) and a possible score of 0–400. Mild, moderate, and severe levels of UI are defined when IIQ is <50, 50–70, and >70, respectively. In addition, MID for women undergoing continence surgery or PFR or receiving vaginal pessary is −28 to −14 or −37 to −31 or −17, respectively [88]. IIQ-7 consists of seven questions and a possible score of 0–100. Good, moderate, and poor QoL is indicated when IIQ-7 is <50, 50–70, and >70, respectively.

Incontinence Quality of Life Questionnaire (I-QOL) [108–110]: It is a valid and reproducible measure of UI that is more closely related to overall well-being of patients than bodily pain. Initially, it was designed for use in clinical trials and in-patient care centers. It has 22 items with three subscales (avoidance and limiting behavior, psychosocial impact, and social embarrassment). MID for patients with SUI has been proposed to be 2.5 and 6.3 points for between and within treatment, respectively. MID for patients with neurogenic bladder ranges from 4 to 11 points.

King's Health Questionnaire (KHQ) (Grade A) [101, 102]: It is a valid, reliable, and responsive measure of UI regardless of type. It has three sections: (1) general health and overall health related to urinary symptoms with two

questions; (2) incontinence impact, role limitations, physical limitations, social limitations, personal limitations, emotions, sleep and energy, and severity coping measures with 19 questions; and (3) bother or impact of urinary symptoms with 11 questions. MID is indicative when change from baseline to posttreatment is ≥5 in each domain.

International Consultation on Incontinence Questionnaire-Lower Urinary Tract Symptoms quality of life (ICIQ-LUTSqol) (Grade A) [111, 112]: It is a valid, reliable, and responsive measurement that has been derived from KHQ, with 22 items. The total score of all items ranges from 0 to 76, and the overall impact on everyday life subscale from 0 to 10 that is not incorporated in the overall score. The MID has been suggested to be 3.71.

Fecal Incontinence Quality of Life Scale (FIQL) (Grade B) [113, 114]: It includes 29 items with four scales (lifestyle, coping/behavior, depression/self-perception, and embarrassment). It may distinguish patients with fecal incontinence from patients with other gastrointestinal problems. Additionally, it has significant correlations with the SF-36 subscales. However, limitations have been found, and suggestions for revisions have been made. In particular, there is a lack of contrast validity, a highest reliability in patients with low QoL, and a minimal differential functioning. Thus, it has been suggested formatting, scoring, and instructions to be simplified, items with higher difficulty to be developed, and embarrassment domain to be revised. Furthermore, it has not been tested in asymptomatic controls. Thus, its capability as a screening tool is unknown.

Sexual Function

Generic PROs

Golombok Rust Inventory of sexual satisfaction (Grade A) [115]: It is a valid, reliable, and responsive measure that has 56 items (28 for women and 28 for men) for the assessment of heterosexual couples' sexual relationship and individual's functioning, as well. It includes 12 domains that are divided in five domains for women (anorgasmia, vaginismus, avoidance, nonsexuality, and dissatisfaction), five for men, and two non-gender oriented (frequency of sexual contact and non-communication).

Brief Index of Sexual Functioning for Women (BISF-W) (Grade A) [116, 117]: It includes 22 items initially covering levels of sexual functioning (interest/desire and sexual activity) and satisfaction suitable for both clinical and nonclinical samples. However, a new scoring algorithm was created for clinical trial use, encompassing seven domains (thought/desire, arousal, frequency of sexual activity, receptivity/initiation, relationship satisfaction, pleasure/orgasm, and problems affecting sexual function). This scoring was compared between normative and surgically menopausal women, and it was able to quantify the nature and degree of impaired sexual function in surgically menopausal women.

Changes in Sexual Functioning Questionnaire long form (CSFQ) and short form (CSFQ-14) (Grade C) [118, 119]: It is a 35-item questionnaire that evaluates changes related to sexual function with an underlying cause (such as medications for illness). It encompasses five domains (sexual desire/frequency, sexual desire/interest, sexual pleasure, sexual arousal, and orgasm) with scoring of individuals' domains and an overall CSFQ score. It may be used in both clinical and nonclinical patients (i.e., depressed ones) with responsiveness. A short form with 14 items and three scales has been suggested as a global measure of sexual dysfunction. It addresses desire, arousal, and orgasm but also the scales of the long form with a strong internal reliability.

Condition-Specific PROs

Female Sexual Function Index (FSFI) (Grade C) [120, 121]: It is a valid and reliable 29-item questionnaire with six domains (desire, arousal, lubrication, orgasm, satisfaction, and pain). It may detect patients with HSDD, FOD, and FSAD. In addition, a cutoff value of 26.55 may distinguish patients with sexual dysfunction from those without. However, a possible disadvantage is that the evaluation refers in the last 4 weeks. Cases where sexual intercourse has not been performed for reasons other than sexual dysfunction cannot be detected, as the response of "not having sexual intercourse" does not include the possible reasons. Furthermore, the partner's sexual problems cannot be addressed.

McCoy Female Sexuality Questionnaire (MFSQ) (Grade C) [122]: Various versions have been tested using 7, 9, 10, or 17 items that were all valid, reliable, and consistent. Responses are retrieved with seven-point Likert scales. It is able to identify levels of sexual interest and response in relation to levels of estrogens and androgens. In particular, a differentiation of sexual response between women with hormone replacement therapy (HRT), oral contraceptives, and presence or absence of ovaries may be detected by certain items of MSFQ.

Short Personal Experiences Questionnaire (SPEQ) [108, 123–126]: It includes nine items with eight of them being adapted from the MSFQ. The first half attributes to all women irrespectively to partner status, while the second one to women with partners (females or males). Sexual desire (one item), arousal (two items), orgasm (one item), dyspareunia (one item), passion for the partner (1 item), and difficulties of partner in sexual performance (one item) are evaluated. A cutoff score of ≤7 detects women with sexual dysfunction (79% sensitivity and specificity). In addition, SPEQ scores correlate with estradiol levels and, thus, menopausal status, indicating that from early to late menopause,

sexual dysfunction may rise from 42% to 88%. Furthermore, SPEQ may detect the arousal, orgasm, and dyspareunia changes in relation to PFDI scores. Thus, it has been found that POP is associated with decreased sexual arousal, infrequent orgasm, and dyspareunia.

Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire long (PISQ) and short form (PISQ-12) (Grade B) [127–131]: It has been developed to evaluate sexual functioning in heterosexual women with UI or POP and discriminate patients with sexual dysfunction from those without. Two versions (long form and short form) have been published. The long form measures 31 items, while the short one (PISQ-12) only 12 items. PISQ-12 scores may predict the PISQ-31 scores. For both versions the items correspond to behavioral-emotive, physical, and partner-related. Likert scale ranging from always (0 score) to never (4 score) is encompassed. Scores are obtained for all domains individually. The sum of all scores creates a total PISQ score. PISQ total score ranges from 0 to 125. Higher values indicate better sexual functioning, while MID is set at 6 points. Furthermore, it has a sensitivity of 78% and specificity of 72% for the detection of women with depression. However, PISQ has defaults. The partner-related domain does not evaluate the response of partners to POP and UI but the women's perception regarding her partners' response. In addition, its capability to address sexual function following a pelvic surgery is inadequate, because it cannot identify most surgery-specific negative effects on sexual function.

PISQ-International Urogynecological Association (IUGA) Revised (PISQ-IR) [132, 133]: It is a valid, reliable, and responsive measure of sexual function that developed from the PISQ-12 and attributes to both sexually and nonsexually active women. It includes 42 items evaluating both sexual activity status and sexual function. It is the only PRO for sexual function that has been validated not only in women with POP and/or UI but also in women with anal incontinence (AI). It has been found to correlate with the PFDI-20, ISI, and EPIQ question 35, for both sexually and nonsexually active women, and for the sexually active ones additionally correlate with FSFI and POPQ. Results of the PISQ-IR may be calculated using the transformed summation or the mean calculation. Guidelines for both methods have been published. In addition, a summary score is not recommended, as explaining or understanding relationships between items is not feasible.

Body Image in the Pelvic Organ Prolapse Questionnaire (BIPOP) [134]: It is a valid, consistent, and reliable 21-item questionnaire developed to identify the impact of POP on body image. It has two versions, one for women with a sexual partner and one for those without. In particular, this measurement aims to identify how women feel or might have felt regarding their attractiveness, confidence, femininity, and sexual intimacy due to their anatomical changes when they have or have not a sexual partner, respectively. It is calculated using a mean value with the intention to automatically account of missing data. Better body image is indicated when BIPOP is scored higher.

ICIQ-VS [67], **Australian Pelvic Floor Questionnaire** [68], **and Electronic Personal Assessment Questionnaire-Pelvic Floor (ePAQ-PF)** [69–72]: They are mixed questionnaires as they address symptoms, sexual functioning, and quality of life of women with POP, as presented above.

Patients' Expectations PROs

Goal Attainment Scaling (GAS) [135–141]: GAS is a multistep approach which begins with the identification of goals by the patients. Initially, patients list their goals and the importance of each goal to them (fairly important, very important, and extremely important). Afterward, anticipated or expected outcome levels are discussed with the urogynecologist. Thus, unrealistic goals may be eliminated. After the completion of therapy, assessment of goal attainment is rated. The scores may be "0" when the goal is achieved as predicted, "+1" or "+2" when achievement is above the level predicted ("somewhat better than expected or predicted" or "much better than expected or predicted," respectively), "−1" when achievement is below the expected level, and "−2" when there is worsening of the target function.

Self-Assessment Goal Achievement (SAGA) [141]: It is a patient-completed questionnaire designed to assess goal attainment in behavioral or pharmacologic treatment of LUTS/OAB. It is a comprehensive and easy-to-understand questionnaire. At baseline, SAGA includes nine fixed treatment goals and up to five additional treatment goals specified by the patients. The five most important goals are ranked, and the criteria for successful achievement of the most important goals are identified. At follow-up, the degree of achievement of each individual (fixed and additional) goal, as well as the overall goal, is rated.

Expectations, Goal Setting, Goal Achievement, and Satisfaction (EGGS) [138, 143]: It combines all patient-centered outcomes (expectations, goal setting, goal achievement, and satisfaction). It has been suggested to become the fourth dimension for the assessment of PFD along with the physical findings, symptoms, and QoL outcomes. Specifically, it was found that women who did not chose surgical intervention had as primary goal information seeking, while patients with a primary goal other than the symptom goal were more likely to choose alternative to surgery interventions.

Patients' Satisfaction PROs

Patient Global Impression (PGI) Scales [144–148]: Valid and reliable measurements for LUTS and POP that include a single item aiming to evaluate a certain condition overall and not sepa-

rately its components. Thus, patients may rate the severity (PGI-S) or bothering (PGI-B) of their condition and the change (PGI-C) or improvement (PGI-I) following a therapeutic intervention. Depending on type of PGI, responses may involve four- to seven-point scales. PGI-S and PGI-I correlate significantly with number of UI episodes, stress pad test, and QoL questionnaires. Moreover, PGI-C and PGI-I are valid, reliable, and sensitive to change measures that can be used following a prolapse surgery. Furthermore, PGI-I is a single question that is answered post-surgery with an excellent positive correlation with POP-Q and pQoL and a negative correlation with self-documentation in goal achievement. Thus, it may be considered a tool for the definition of surgery "success" for POP, as it reflects the objective, subjective, QoL, and patients' goal. However, it may score higher than ICIQ in women undergoing surgery for UI or POP, overestimating the surgical results.

Surgical Satisfaction Questionnaire (SSQ-8) [149, 150]: It is a valid and reliable tool for the patient satisfaction following pelvic surgery. It includes eight items with five- or six-point scale responses (from "very satisfied" to "very unsatisfied" or "very satisfied" to "N/A" or "yes" to "never"). In women with advanced POP that underwent reconstructive or obliterative surgery, the postoperative answers of SSQ-8 are comparable with the improvements from preoperative to postoperative IIQ and UDI.

Global Perception of Improvement (GPI) [61, 151], **Patient Satisfaction Questionnaire (PSQ)** [151], **and Estimated Percent Improvement (EPI)** [151]: GPI is similar to the PGI-I, but it includes five-point scale responses (from "much better" to "much worse") instead of seven-point scale responses. PSQ is a single-item questionnaire that evaluates the level of satisfaction following a therapeutic intervention. It may receive responses using a five-point scale (from "very satisfied" to "very dissatisfied"). GPI, PSQ, and EPI are valid measurements for outcomes of behavioral treatment for UI. They all correlate positively with the reduction of the number of UI episodes in the bladder diary and the change in the IIQ. They all correlate negatively with the desire of another treatment. In addition, GPI along with the PSQ and the incontinence episodes (IE) has been used for the determination of the MID of UDI and OAB-q.

Patient Perception of Treatment Benefit Questionnaire (PPTBQ) [130, 152]: It evaluates whether patients perceive a benefit from the treatment. Responses vary from "no benefit," "little benefit," and "much benefit"). PPTBQ along with bladder diaries, PPBC, OAB-q, and IIQ-7 has been used for the definition of the MID of PISQ. PPTBQ, bladder diary, and PPBC all set the MID at five points. Finally, the six-point MID for PISQ was derived taking into account the nine and seven points of OAB-q and IIQ-7, respectively.

Patient Perception of Bladder Condition [153, 154]: It is a valid and responsive to change measurement that may be used as a global assessment of bladder condition of patients with UI and/or OAB. It is a single-item questionnaire with six possible responses evaluating the problems (from "none" to "many severe") due to the bladder condition. PPBC correlates with the bladder diaries, OAB-q, and KHQ. Specifically, higher PPBC improvement indicates greater reductions in frequency, urgency episodes, and symptom bother and significantly greater improvement in HRQL in comparison to a minor PPBC improvement.

Benefit, Satisfaction, and Willingness (BSW) [130, 155]: It is a three-item questionnaire designed to evaluate the perception of patients regarding the benefit, satisfaction, and willingness to continue with the therapy. It was validated by three randomized controlled trials for the assessment of tolterodine in OAB patients. In these studies correlations between BSW and the improvements of OAB-q, KHQ, and bladder diaries were evident.

Treatment Satisfaction with Medicines Questionnaire (SATMED-Q) [156, 158]: It is a valid, reliable, and responsive 17-item questionnaire with six domains (treatment effectiveness, convenience of use, impact on daily activities, medical care, global satisfaction, and undesirable side effects that have been evaluated in chronically ill patients). The MID has been suggested at 13.4 for total score. For domains the MID ranges from 10.3 (medical care) to 20.6 (impact on daily living/activities) points.

Treatment Satisfaction Questionnaire for Medication (TSQM) [158, 159]: It is a sound and valid measure for patients' satisfaction with two versions, an initial long with 55 items and a second shorter with 31 items. Both versions include four scales: side effects, effectiveness, convenience, and global satisfaction.

Overactive Bladder Satisfaction (OAB-S) Questionnaire [160, 161]: It is a valid questionnaire with five scales involving OAB Control Expectations (ten items), Impact on Daily Living with OAB (10 items), OAB Control (ten items), OAB Medication Tolerability (six items), and Satisfaction with Control (ten items). In addition, it includes five single-item overall assessments of patient's fulfillment of OAB medication expectations, interruption of day-to-day life due to OAB, overall satisfaction with OAB medication, willingness to continue OAB medication, and improvement in day-to-day life due to OAB. OAB-S has better test reliability than TSQM, discriminating patients by severity level and detecting change in satisfaction levels in OAB patients.

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