CLINICAL OBSTETRICS AND GYNECOLOGY
Volume 48, Number 3, 648–661

Symptoms and Outcome Measures of Pelvic Organ Prolapse

MATTHEW D. BARBER, MD, MHS

Director of Clinical Research, Section of Urogynecology and Reconstructive Pelvic Surgery, Cleveland Clinic Foundation, Cleveland, Ohio

Introduction

Pelvic organ prolapse, along with urinary incontinence, fecal incontinence, voiding dysfunction, and defecatory dysfunction, make up an interrelated group of conditions known collectively as disorders of the pelvic floor. These disorders share many common risk factors and often coexist with one another.[1,2] Pelvic organ prolapse, like with other pelvic floor disorders, rarely results in severe morbidity or mortality; rather, it causes symptoms that can impact a woman's daily activities and negatively affect her quality of life.

Loss of normal vaginal support can be seen, to some degree or another, in as many as 43% to 76% of women.[3,4] When this loss of support becomes a condition that causes patients to seek care and/or physicians to offer treatment depends in large part on the development and severity of associated symptoms. Many women with pelvic organ prolapse are asymptomatic and do not require treatment. This is particularly true for women with prolapse that is mild and does not extend beyond the hymen. Women who develop symptoms may present with a single symptom such as vaginal bulging or pelvic pressure or they may present with multiple disorders. Some are the result of the prolapsing vagina itself and some are caused by coexisting or associated dysfunction of the bladder, lower gastrointestinal tract, or pelvic floor. In either circumstance, the evaluation of a patient with vaginal prolapse requires a comprehensive review of the full spectrum of pelvic floor symptoms and an assessment of how these symptoms affect their quality of life.

An understanding of which symptoms are attributable to the prolapse itself and which symptoms suggest the presence of another condition is important. This understanding

Correspondence: Matthew D. Barber, MD, MHS, Director of Clinical Research, Section of Urogynecology and Reconstructive Pelvic Surgery, Cleveland Clinic Foundation, 9500 Euclid Avenue, Desk A81, Cleveland OH 44195. E-mail: BARBERM2@CCF.ORG

allows one to counsel patients appropriately about when prolapse treatment is indicated and which symptoms are likely to improve after treatment and which are likely to persist. It also gives an indication of which patients will require additional evaluation or treatment of disorders other than prolapse. Until recently, the relationship between specific symptoms and the presence and severity of prolapse was largely unknown. Over the last several years, a number of studies have attempted to fill this void. In the first section of this chapter, the current evidence about the relationship between pelvic organ prolapse and the common urinary, bowel, sexual, and pelvic symptoms is reviewed. The second section of the chapter contains a review of the currently available outcome measures that can be used by clinicians and researchers to assess the functional outcomes of prolapse and its treatment on patients with an emphasis on symptom and quality-of-life assessment.

Symptoms

Symptoms that have commonly been attributed to pelvic organ prolapse are listed in Table 1. Also listed are several alternative conditions that can cause similar symptoms, which should be considered when evaluating a patient with prolapse. The relationship between vaginal prolapse and specific pelvic floor symptoms can be complex but in most circumstances can be explained by one of the following scenarios:

1. Pelvic organ prolapse is the direct cause of the symptom (ie, vaginal bulging, pelvic pressure);
2. Loss of vaginal support contributes dysfunction of an adjacent organ system (ie, stress urinary incontinence in women with mild to moderate anterior vaginal prolapse or voiding dysfunction as a result of urethral kinking in women with advanced prolapse);
3. A common pathogenic mechanism is shared by prolapse and the condition causing the symptom (ie, muscular injury and pelvic floor denervation after vaginal delivery as a common cause of pelvic organ prolapse and fecal incontinence);
4. The symptom, or its source, is a contributor to the development of pelvic organ prolapse (ie, chronic straining to defecate); or
5. There is no causal relationship between vaginal prolapse and the condition causing the symptom, but both conditions are common and therefore are seen together in a certain proportion of women (ie, chronic back pain).

This complex relationship between pelvic organ prolapse and pelvic floor symptoms has been investigated in studies that compared symptoms in women with prolapse with appropriately matched women without prolapse and in a number of studies that correlated the degree of pelvic organ prolapse with the development and severity of symptoms in a single population. In general, they have found only weak to moderate correlations between the degree of vaginal prolapse and the presence of specific symptoms such as vaginal bulging, pelvic heaviness, and voiding dysfunction.[4–7] Some have also found that a number of symptoms often attributed to prolapse may, in fact, not be related. This seems particularly true for many bowel symptoms.[7,8] The hymen appears to be an important "cutoff point" for symptom development. Swift et al evaluated symptoms and pelvic organ support in 477 women presenting for annual gynecologic examinations and found that the number of pelvic floor symptoms increased from an average of 0.5 symptoms for patients with stage 1 pelvic support to 2.1 symptoms for women when the leading edge of the prolapse extended beyond the hymen.[3] In contrast, the prevalence of some symptoms, particularly stress urinary incontinence, appears to decline as prolapse extends beyond the hymen, likely from urethral kinking.

We can also gain insight into the relationship between prolapse and pelvic floor symptoms by evaluating symptom resolution after prolapse surgery. Unfortunately, the majority of studies investigating the outcomes of vaginal reconstructive

TABLE 1. Symptoms Associated With Pelvic Organ Prolapse

Symptoms	Other Possible Causes
Bulge Symptoms	
Sensation of vaginal bulging or protrusion	Rectal prolapse
Seeing or feeling a vaginal or perineal bulge	Vulvar or vaginal cyst/mass
Pelvic or vaginal pressure	Pelvic mass
Heaviness in pelvis or vagina	Hernia (inguinal or femoral)
Urinary Symptoms	
Urinary incontinence	Urethral sphincter incompetence
Urinary frequency	Detrusor overactivity
Urinary urgency	Hypoactive detrusor function
Weak or prolonged urinary stream	Bladder outlet obstruction (ie, postsurgical)
Hesitancy	Excessive fluid intake
Feeling of incomplete emptying	Interstitial cystitis
Manual reduction of prolapse to start or complete voiding	Urinary tract infection
Position change to start or complete voiding	
Bowel Symptoms	
Incontinence of flatus or liquid/solid stool	Anal sphincter disruption or neuropathy
Feeling of incomplete emptying	Diarrheal disorder
Hard straining to defecate	Rectal prolapse
Urgency to defecate	Irritable bowel syndrome
Digital evacuation to complete defecation	Rectalinertia
Splinting vagina or perineum to start or complete defecation	Pelvic floor dyssynergia
Feeling of blockage or obstruction during defecation	Hemorrhoids
	Anorectal neoplasm
Sexual Symptoms	
Dyspareunia	Vaginal atrophy
Decreased lubrication	Levator ani syndrome
Decreased sensation	Vulvodynia
Decreased arousal or orgasm	Other female sexual disorder
Pain	
Pain in vagina, bladder, or rectum	Interstitialcystitis
Pelvic pain	Levator ani syndrome
Low back pain	Vulvodynia
	Lumbar disc disease
	Musculoskeletal pain
	Other causes of chronic pelvic pain

surgery focus primarily on anatomic outcomes and do not report functional results. In those that do, many use nonspecific terms such as "prolapse symptoms" or "constipation" that give very little information about specific symptoms. Additionally, most do not use validated instruments for symptom or quality-of-life assessment. However, in the studies that provide useful information about symptoms outcomes, it appears that vaginal reconstructive surgery effectively reduces many prolapse-related symptoms.

BULGE SYMPTOMS

Bulge or herniation symptoms that have been attributed to worsening pelvic organ prolapse include a sensation of bulging or protrusion in the vagina, a sensation of "something falling out" of the vagina, actually seeing or feeling a vaginal or perineal bulge, as well as pelvic pressure, fullness, and heaviness. Although many of these symptoms demonstrate some correlation with the presence and severity of prolapse, the only one that is consistently acknowledged by patients with severe prolapse is the presence

of a vaginal bulge that can be seen or felt. Less specific symptoms like pressure and heaviness appear to have a much weaker relationship to loss of vaginal support.

Figure 1 demonstrates the relationship between the extent of vaginal support and the development of several bulge symptoms in 160 women presenting to a tertiary care urogynecology clinic.[5] In this group, the proportion of patients who were able to see or feel a vaginal bulge increased substantially as the maximal extent of prolapse extended beyond the hymen. Subjects who did not have prolapse that extended beyond the hymen noted this symptom less than 10% of the time, whereas those whose prolapse extended 1 cm or more beyond the hymen almost universally reported this symptom. Although there is a steady increase in the overall proportion of subjects reporting a bulging sensation as the maximal extent of prolapse increases from normal support to 4 cm or more beyond the hymen, there was no relationship between pelvic pressure and extent of maximal prolapse in this population. In general, the proportion of patients bothered by their bulge symptoms increased with worsening prolapse in this study. Ellerkmann et al found a moderate correlation between patients being able to visualize a vaginal bulge and worsening prolapse on physical examination in a cohort of 237 women presenting to the Johns Hopkins Urogynecology Clinic.[6] However, symptoms of pelvic pressure, discomfort, and heaviness correlated only weakly with worsening prolapse. Samuelsson et al evaluated pelvic organ support in 487 women presenting for a regular

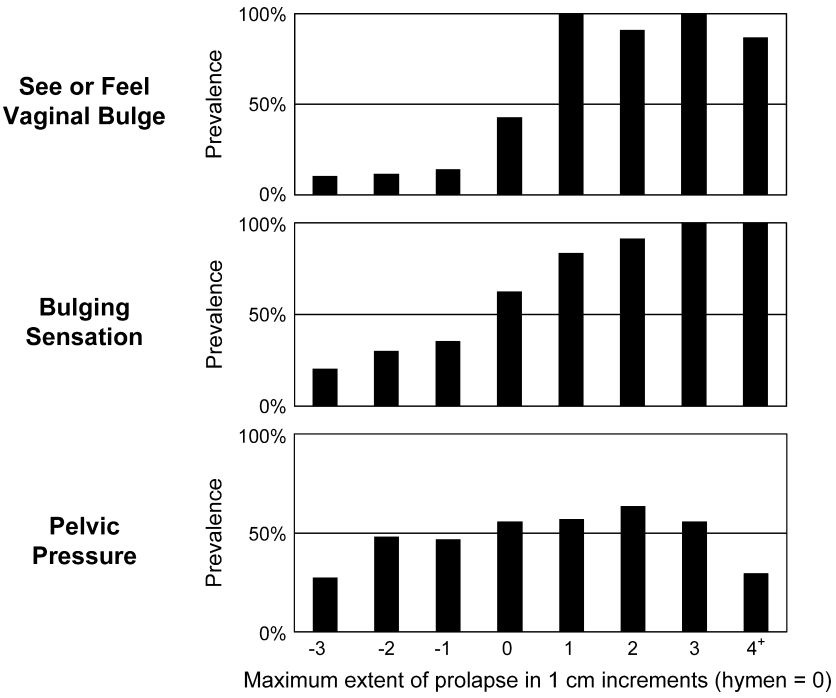

FIGURE 1. Relationship between bulge symptom and maximal extent of prolapse in 160 women presenting to a tertiary care urogynecology clinic.[5] x-axis, maximal extent or prolapse measured in 1-cm increments with the hymen = 0. Prolapse in which maximal extent is proximal to the hymen is in negative numbers and beyond the hymen positive numbers; y-axis, prevalence of subjects indicating that they have the listed symptom.

gynecologic health examination.[4] Some degree of prolapse was noted in 30.8% of subjects, with only 2% having prolapse that reached the introitus. A sense of heaviness in the lower abdomen was noted in 9.7% of women with some degree of vaginal prolapse compared with 7.5% in the group with normal vaginal support, a nonsignificant difference. A sense of heaviness was reported more often among women who had a prolapse that reached the introitus (40%) and among women with uterine prolapse (20%), however.

URINARY SYMPTOMS

Lower urinary tract disorders are common among women with pelvic organ prolapse. In some circumstances, the loss of vaginal support directly influences bladder or urethral function resulting in symptoms. In other cases, the relationship between prolapse and lower urinary tract dysfunction is less clear. The anterior vaginal wall supports the bladder and urethra. Loss of this support results in urethral hypermobility and cystocele formation, which is thought to contribute to the development of stress urinary incontinence. It is therefore not surprising that pelvic organ prolapse and stress urinary incontinence often coexist, particularly when the prolapse is mild.

In contrast, women with pelvic organ prolapse that extends beyond the hymen are less likely to report stress incontinence and more likely to have obstructed voiding symptoms such as urinary hesitancy, intermittent flow, weak or prolonged stream, feeling of incomplete emptying, the need to manually reduce (splint) the prolapse to initiate or complete urination, and, in rare cases, urinary retention.[4–7,9] The mechanism for this appears to be mechanical obstruction resulting from urethral kinking that occurs with progressively worsening anterior vaginal prolapse. Large posterior vaginal prolapse can also cause mechanical obstruction by direct urethral compression rather than kinking. A retrospective analysis of 352 women presenting to the Cleveland Clinic for evaluation of urinary incontinence or prolapse found that worsening prolapse was associated with an increasing need to splint to urinate and that women reporting stress urinary incontinence had less advanced prolapse than those who did not.[7] Romanzi et al evaluated lower urinary tract symptoms and urodynamics in 60 women with varying degrees of anterior vaginal prolapse.[9] Women with grade 3 or 4 cystoceles were significantly more likely to have symptoms of voiding dysfunction than those with lesser degrees of prolapse (44% vs. 9%). Urodynamic evaluation revealed that 72% of women with advanced prolapse had objective evidence of urethral obstruction compared with 6% of those with grade 1 or 2 prolapse. None of the patients with grade 3 or 4 cystoceles demonstrated urodynamic stress incontinence, whereas 86% of those with grade 1or 2 cystoceles did. As many as 30% of women with stage 3 or 4 prolapse have elevated postvoid residuals (PVR $>$100 cc) and women with advanced prolapse have lower mean and maximum flow rates than women with urinary incontinence.[10] Despite this objective evidence of voiding dysfunction in women with advanced prolapse, the correlation between specific voiding symptoms such as hesitancy, weak stream, and feeling of incomplete emptying and severity of prolapse is weak.[5,6] Voiding dysfunction symptoms, particularly the need to splint to urinate, appears to resolve after prolapse surgery in the majority of women who report these symptoms preoperatively.[11]

Studies evaluating the relationship between advancing vaginal prolapse and overactive bladder symptoms such as urgency, frequency, and urge urinary incontinence have been inconsistent. Romanzi et al found that women with grade 3 and 4 cystoceles were more likely to have urinary urgency and frequency and a urodynamic diagnosis of detrusor overactivity than women with lesser degrees of prolapse (56% vs. 20% and 52% vs. 20%, respectively).[9] However, other studies demonstrated that worsening

prolapse was associated with a decline in the symptoms of urgency, frequency, and urge incontinence.[7] Few studies have evaluated effect of vaginal reconstructive surgery on the resolution of overactive bladder symptoms in women with prolapse. Nguyen and Bhatia retrospectively reviewed the medical records of 38 women with grade 2 or greater prolapse and urge incontinence secondary to detrusor overactivity who underwent vaginal reconstructive surgery.[12] Detrusor instability resolved after surgery in 63% of subjects after surgery. Unfortunately, the authors did not comment on specific irritative symptoms other than urge incontinence. The mechanism for the resolution of detrusor overactivity in these patients is unclear, but it is thought to result from the relief of urethral obstruction after restoring normal vaginal support.

Twenty-three percent to 50% of women with advanced prolapse without symptoms of urinary incontinence will demonstrate urinary leakage during urodynamics if their prolapse is reduced.[13] These women are said to have "potential" or "occult" incontinence and are thought to be at greater risk of developing new-onset stress urinary incontinence after prolapse surgery. A detailed review of occult incontinence and its management is beyond the scope of this chapter. Nonetheless, clinicians must be aware of this condition and counsel patients accordingly.

BOWEL SYMPTOMS

Women with pelvic organ prolapse frequently report symptoms related to bowel dysfunction, including feeling of incomplete rectal emptying, hard straining to defecate, the need to apply digital pressure to the vagina or perineum (splint) to start or complete defecation, fecal urgency, and incontinence of flatus or stool. Interestingly, studies that have investigated the relationship between bowel dysfunction and the presence and severity of pelvic organ prolapse have found either weak correlation between posterior vaginal wall support and specific anorectal symptoms or no correlation at all.[5–8] The defecatory symptom that appears most consistently related to posterior vaginal prolapse is the need to splint the vagina or perineum to defecate.[5–7] However, most women with rectoceles do not have this symptom and some women without rectoceles also use manual pressure to accomplish defecation.[8,14]

Currently available studies evaluating the relationship between pelvic organ prolapse and defecatory symptoms have several limitations. First, assessment of posterior compartment support is challenging. There is no clear consensus about whether physical examination or radiologic evaluation should be used to determine the anatomic and functional relationship of the posterior compartment.[13] Many studies rely on physical examination alone to evaluate posterior vaginal support and comparisons to defecography have demonstrated high sensitivities (91%–94%) for the detection of rectocele. However, physical examination fails to detect enteroceles or sigmoidoceles detected during proctography in approximately 50% of cases in patients with severe prolapse.[13] How the presence of an enterocele or sigmoidocele influences bowel disorders in women with posterior vaginal prolapse is currently unknown. Using defecography as the "gold standard" for anatomic evaluation of women with posterior compartment defects is also not ideal, because many normal asymptomatic women demonstrate focal defecographic abnormalities. The radiographic criteria used to define significant rectocele at proctography ($\geq$3 cm) do not correlate with defecatory symptoms, nor does the presence or absence of barium trapping.[13]

A second limitation is that available studies, particularly those evaluating the effect of prolapse surgery on bowel function, often use broad, poorly defined terms such as "constipation" or "defecatory dysfunction," and there is currently no standard definitions of constipation or its subtypes that have been accepted in women with pelvic floor disorders. Constipation is a symptom with many different definitions based on stool

frequency, consistency, the need for straining, incomplete emptying, and other characteristics in various combinations. The ROME II criteria are expert consensus guidelines adopted by gastroenterologists and other healthcare providers in 2000 for making the clinical diagnosis of the various types of functional bowel disorders, including constipation.[15] These criteria categorize constipation into subtypes, including 1) constipation—predominant irritable bowel syndrome (IBS), 2) functional constipation, and 3) pelvic floor dyssynergia. Functional constipation may include patients who demonstrate slowed transit times on colonic transit studies or patients with idiopathic constipation because it is a symptom-based diagnosis. Patients with pelvic floor dyssynergia (the older term for this was "anismus") have paradoxic contraction or failure to relax the pelvic floor muscles during attempts to defecate. Some experts have added another subtype, outlet-type constipation, for patients who fulfill criteria for either constipation—predominant IBS or functional constipation who also report 1 of the following: a sensation that stool cannot be passed when having a bowel movement, a need to press on or around their bottom or vagina to try to remove stool to complete a bowel movement, or having difficulty relaxing or letting go to allow the stool to come out at least one fourth of the time.[15] Based on the Cleveland Clinic experience, outlet-type constipation seems to be the predominant subtype seen in patients with pelvic organ prolapse and urinary incontinence[16] (Fig. 2). Interestingly, the prevalence of all types of constipation, and outlet-type in particular, were not different between those patients with stage 3 or 4 pelvic organ prolapse and those with urinary incontinence without prolapse.

Some evidence suggests that bowel dysfunction may in itself be a contributor to pelvic organ prolapse. A case–control study comparing women with uterovaginal prolapse and urinary incontinence with normal control women found that 61% of women with uterovaginal prolapse reported straining at stool as a young adult compared with 30% of women with stress incontinence and 4% of normal control women.[14] Chronic straining to defecate is thought to contribute to pelvic floor neuropathy. It is, therefore, important to consider the multiple causes of defecatory symptoms when caring for women with pelvic organ prolapse for 2 reasons: 1) defecatory dysfunction may be a cause of prolapse rather than a consequence, and 2) specific bowel symptoms correlate poorly with worsening prolapse. Furthermore, patients should be counseled that surgical correction of prolapse may not improve defecatory symptoms. For instance, an abnormal colon transit study is seen in approximately 20% of women with evacuation disorders and is the most consistently cited risk factor for failure of rectocele to relieve evacuatory symptoms regardless of the surgical technique used.[13]

Studies estimate that 7% to 31% of women pelvic organ prolapse also have symptoms of fecal incontinence.[1,2] Although rectal prolapse is a recognized cause of fecal incontinence, it is unlikely that vaginal prolapse contributes to the development of fecal

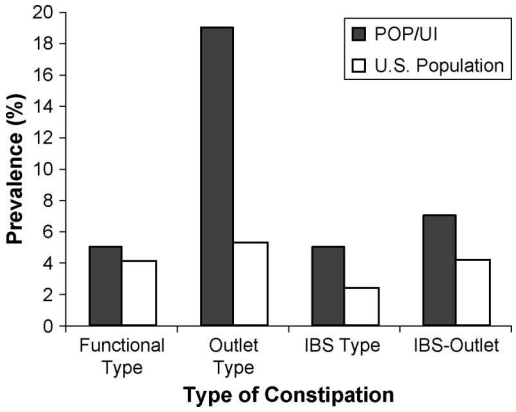

FIGURE 2. Prevalence of subtypes of constipation in 302 consecutive patients presenting to the Cleveland Clinic Foundation for pelvic organ prolapse (POP) and urinary incontinence (UI)[16] versus the U.S. population data from Stewart et al.[15]

incontinence. Rather, fecal incontinence and pelvic organ prolapse often coexist because they share common risk factors such as neuropathic and muscular injury to the pelvic floor after vaginal delivery and the effects of aging. Nichols et al assessed anal incontinence symptoms and performed endoanal ultrasound on 100 consecutive women presenting with urinary incontinence and/or pelvic organ prolapse.[2] Twenty-three percent of subjects reported incontinence of flatus and 31% reported incontinence of liquid or solid stool. Endoanal ultrasound revealed defects in the anal sphincter complex in 52% of women. The presence of an anal sphincter defect correlated significantly with the presence of anal incontinence and severity of fecal incontinence as measured by the Fecal Incontinence Severity Index (FISI). Severity of fecal incontinence correlated significantly with the extent of anal sphincter disruption ($r = 0.81$), but did not correlate with increasing degree of pelvic organ prolapse. Women with both urinary incontinence and pelvic organ prolapse were more likely to report fecal incontinence (odds ratio [OR] 2.7) and have an anal sphincter defect (OR 4.0) than patients with pelvic organ prolapse or urinary incontinence only. Thus, women with multiple pelvic floor disorders are more likely to have experienced a greater degree of injury to the muscles, connective tissue, and nerves of the pelvic floor than those who have a single pelvic floor disorder.

SEXUAL FUNCTION

When assessing the relationship between pelvic organ prolapse and sexual function, it is difficult to separate the effects of pelvic organ prolapse from the normal changes associated with aging and menopause. Additionally, existing studies that evaluate sexual function in women with pelvic organ prolapse are often limited by their small sample size, retrospective nature, and failure to use validated sexual function questionnaires. Very few studies have compared sexual function in women with prolapse with similarly aged women without prolapse. However, existing evidence suggests that, in general, women with pelvic organ prolapse have similar rates of sexual activity as similarly aged women without pelvic organ prolapse.[17] The most common reason for sexual inactivity in this population is absence of a male partner.[18,19] Of those with a partner, male sexual dysfunction, particularly erectile dysfunction, is the most often cited reason for inactivity.[19] In 1 study, women with prolapse or detrusor instability were more likely to cite their pelvic floor symptoms as a reason for sexual inactivity than women with stress urinary incontinence or mixed incontinence.[19] Among sexually active women with prolapse, approximately one third report that their prolapse interferes with their sexual function.[17,19] Ellerkmann et al found that impairment of sexual activity was moderately associated with worsening prolapse in all 3 vaginal compartments, with the apical prolapse being the most pronounced.[6] However, the only study thus far that has compared sexual function in women with prolapse with that of women without prolapse using a validated sexual function questionnaire found no difference in frequency of intercourse, libido, vaginal dryness, dyspareunia, orgasmic function, or overall sexual function between the 2 groups.[17] Furthermore, there is a high rate of sexual satisfaction (81%–84%) in women with pelvic organ prolapse who are in an intimate relationship.[17,19]

The majority of studies of sexual function in patients with prolapse have focused on the effect of vaginal reconstructive surgery on vaginal length and caliber or on postoperative sexual functioning, particularly dyspareunia. Most prospective studies demonstrate that sexual function either does not change or improves in the majority of women after vaginal reconstructive surgery for pelvic organ prolapse.[18,19] Vaginal length and caliber appear to have little relationship with postoperative sexual satisfaction.[18] However, women who undergo posterior colporrhaphy,

especially in conjunction with Burch colposuspension, are at increased risk of developing dyspareunia, with rates as high as 38%.[18]

PAIN

Although it is common for patients with pelvic organ prolapse to attribute back and pelvic pain to their prolapse, there is very little evidence that pelvic organ prolapse causes pain aside from vague symptoms such as pelvic pressure and heaviness. Heit et al performed a cross-sectional study of 152 women with pelvic organ prolapse to determine if there was an association between low back pain or pelvic pain as measured by a visual face scale and severity of pelvic organ prolapse.[20] After adjusting for age and prior prolapse surgery, they found no relationship between prolapse and pelvic or low back pain. Similarly, Swift et al found that report of low back pain and groin pain was common among 477 women presenting for annual gynecologic examinations and had no relationship to the presence or severity of pelvic organ prolapse.[3] The report of pain in a patient with pelvic organ prolapse should prompt clinicians to search for other sources of the pain before attributing it to prolapse (Table 1).

Outcome Measures

Outcome measures are the tools used to determine the efficacy, safety, and side effects of a treatment. Researchers assess outcome measures before and after treatments to determine their relative efficacy. Clinicians can use outcome measures to track the success of their treatments and/or longitudinally follow the outcomes of individual patients. Pelvic organ prolapse, like all pelvic floor disorders, is a multidimensional phenomenon and "success" of treatment is often difficult to define. Because of this, outcomes of treatment should be evaluated in multiple domains. Unfortunately, most studies evaluating the treatment of pelvic organ prolapse have focused exclusively on anatomic success without considering other important areas such as symptoms, quality of life, or socioeconomic outcomes. For an individual patient, the most important outcome of a surgical procedure is the relief of her symptoms and improvement in her quality of life, yet until recently, these areas have largely been ignored. The remainder of this chapter reviews the currently available outcome measures that can be used by clinicians and researchers to assess pelvic floor symptoms and their effect on patients' quality of life.

CHOOSING A QUESTIONNAIRE

Pelvic floor symptoms can be assessed in a number of ways. Obviously, taking a thorough clinical history is an important method of assessing patient's symptoms and their effect on patients' lives. However, in situations in which a standardized, reproducible assessment is desired, clinical histories can be problematic, because they typically take on a different form for each clinician and patient encounter. The most valid way of measuring the presence, severity, and impact of pelvic floor symptoms on a patient's activities and well-being is through the use of psychometrically robust self-administered questionnaires.[21] An increasing number of questionnaires for women with pelvic floor disorders are now available. Most are intended to evaluate lower urinary tract symptoms, but recently, questionnaires have been developed for women with fecal incontinence and pelvic organ prolapse. In general, these questionnaires can be separated into 1 of 3 categories: 1) those that measure the presence of particular symptoms and their severity (Symptom questionnaires); 2) those that measure quality of life (Quality-of-Life [QOL] questionnaires), and 3) those that measure sexual function (Sexual Function questionnaires).

Questionnaire development is a complex process that is governed by the principles of psychometrics. Psychometrics is the science of the measurement of responses to phenomena that are not easily quantifiable. For a

questionnaire to be useful in research or in practice, it must demonstrate 3 important psychometric properties: validity, reliability, and responsiveness. The validity of a questionnaire is simply whether it measures what is intended. The reliability of a questionnaire refers to its ability to measure in a reproducible fashion. Responsiveness refers to a questionnaire's ability to reliably detect the overall effect of treatment and ability to detect clinically meaningful change. When studies have been performed to demonstrate that a particular questionnaire has good psychometric properties, that questionnaire is said to be "validated." Other characteristics that are desirable in a questionnaire include being easy to understand and feasible to implement.

When choosing a questionnaire for use in clinical practice or in research, the first step is to determine if the questionnaire actually measures what you desire. A brief review of the questionnaire's content and structure will provide important information in this regard. It is important to keep in mind the purpose for which a questionnaire was originally designed and the population in which it was validated. Before questionnaires are used in populations or contexts other than those they were designed for, further validation is usually necessary. The second step should be to assess the reliability, validity, and responsiveness of the questionnaire. Use of nonvalidated questionnaires may provide misleading information or fail to detect import clinical changes. Whenever possible, it is desirable to use a validated questionnaire that is widely accepted and has been used many times in the population you want to evaluate. The final step is to determine whether the length and construct of the questionnaire is such that it is feasible to administer in your practice or research study. Long questionnaires may be desirable for research studies in which more detail is needed but are likely too burdensome and time-consuming to be used effectively in clinical practice. In general, using only part of a validated questionnaire or changing the order or content of a questionnaire is discouraged because this can change its psychometric properties.

SYMPTOM QUESTIONNAIRES

Symptom questionnaires are used to assess the presence, severity, and impact of particular symptoms or groups of symptoms. A list of valid and reliable symptom questionnaires developed for women with various pelvic floor disorders is listed in Table 2.[21–23] Questionnaires that have been used in women with pelvic organ prolapse are noted. One of the most widely used symptom questionnaires in the study of pelvic floor disorders is the Urogenital Distress Inventory (UDI).[21] The UDI contains 19 questions about lower urinary tract symptoms separated into 3 scales: Irritative Symptoms, Obstructive/Discomfort Symptoms, and Stress Symptoms. Respondents are asked if they have a particular symptom and, if they do, to assess the degree it bothers them on a 4-point scale from "not at all" to "greatly." A shortened version of the UDI is the UDI-6, a 6-question instrument that

TABLE 2. Recommended Symptom Questionnaires for Women With Pelvic Floor Disorders*

Urinary Incontinence
Sandvik Incontinence Severity Index†
International Consultation on Incontinence Questionnaire (ICIQ)
Urogenital Distress Inventory (UDI)†
Urogenital Distress Inventory short form (UDI-6)†
Kings Health Questionnaire†
Fecal Incontinence
Wexner Continence Scale
Fecal Incontinence Severity Index (FISI)†
Cleveland Clinic Fecal Incontinence Score
All Pelvic Floor Disorders (UI, FI, POP)‡
Pelvic Floor Distress Inventory (PFDI)†
Pelvic Floor Distress Inventory short form (PFDI-20)†

* All instruments listed have been shown to be valid, reliable, and responsive.

† Denotes instruments that have been used in patients with pelvic organ prolapse.

‡ The Pelvic Floor Distress Inventory (PFDI) and its short form (PFDI-20) are intended to be used in women with all forms of pelvic floor disorders and each as urinary, anorectal, and pelvic organ prolapse scales.

correlates well with the longer version. Both the UDI and the UDI-6 were originally designed for use in women with urinary incontinence but have been used extensively in studies of women with pelvic organ prolapse to assess the effects of treatment on lower urinary tract function. A simple urinary incontinence symptom severity questionnaire that has been used frequently, particularly in epidemiology studies, is the Sandvik Incontinence Severity Index.[21] It is comprised of 2 questions: "How often do you experience urine leakage" (4-level response) and "How much urine do you lose" (2-level response). This index has been shown to have good validity and reliability and is responsive to both behavioral and surgical treatment. It is able to accurately distinguish between women with incontinence and those without and has good correlation with the pad test and bladder diary results. The brevity and simplicity of this questionnaire makes it ideal for use in clinical practice.

To date, the only valid and reliable symptom questionnaire designed for specifically for use in women with pelvic organ prolapse is the Pelvic Floor Distress Inventory.[23] This comprehensive symptom questionnaire is intended for women with all forms of pelvic floor disorders. It assesses 46 pelvic floor symptoms and has 3 scales: a urinary scale (identical to the UDI), a colorectal scale, and a pelvic organ prolapse scale. Its structure is similar to that of the UDI; patients are asked to indicate if they have a particular symptom and if so, they are asked to assess how much it bothers them on a 4-point scale. Recently, a short version of the PFDI has been developed, the Pelvic Floor Distress Inventory short form 20 (PFDI-20), which also has urinary, colorectal, and pelvic organ prolapse scales.[24] The urinary scale of the PFDI-20 is identical to the UDI-6. Both the PFDI and the PFDI-20 have good reliability and validity and have demonstrated excellent responsiveness in patients undergoing surgery for pelvic organ prolapse.

QUALITY-OF-LIFE QUESTIONNAIRES

Health-related quality of life (HRQOL) refers to a person's total sense of well-being and considers multiple dimensions, including (but not limited to) their social, physical, and emotional health. Measures of HRQOL can be classified into 2 types: generic and condition-specific. Generic HQOL instruments are used to assess quality of life in a broad range of illnesses or populations. Generic instruments have the advantage of allowing comparisons across different groups or illnesses but may lack sensitivity to the unique aspects of a specific disease and how it impacts the life an affected patient. The 2 generic HRQOL instruments that have been used frequently in women with pelvic floor disorders are the SF-36 and EuroQOL ED-5Q[21] (Table 3). Both instruments are widely used, have been translated into several languages, and have reached the highest levels evidence relating to psychometric testing. Unfortunately, in patients with pelvic floor disorders, they tend to be relatively unresponsive to change.

Condition-specific HRQOL instruments are designed to measure the impact of a specific disease on HRQOL. Condition-specific instruments provide a more in-depth assessment of specific issues and concerns critical to the disease process they were designed for. They also tend to be more responsive to change than generic instruments. Their primary disadvantage is that they can only be used in the particular patient group they were designed for and data cannot be compared with norms for a general population or other groups. Condition-specific HRQOL questionnaires for women with pelvic floor disorders with established reliability and validity are listed in Table 3.[21–24] Questionnaires that have been used in women with pelvic organ prolapse are noted. The Incontinence Impact Questionnaire (IIQ) is a condition-specific quality-of-life questionnaire for women with urinary incontinence that is a companion to the UDI.[21] This questionnaire has 30 questions and assesses the degree to which lower urinary tract

TABLE 3. Recommended Quality-of-Life (QOL) and Sexual Function Scales for Women With Pelvic Floor Disorders*

Generic Quality-of-Life Questionnaires
SF-36†
Euroqol EQ-5D
Condition-Specific Quality-of-Life Questionnaires
Urinary Incontinence
Incontinence Impact Questionnaire (IIQ)†
Incontinence Impact Questionnaire short form (IIQ-7)†
Incontinence quality of life Questionnaire (I-QOL)
Kings Health Questionnaire†
Urge Incontinence Impact Questionnaire (Urge IIQ)
Fecal Incontinence
Fecal Incontinence QOL Scale (FIQL)
Gastrointestinal QOL Index (GIQLI)
All Pelvic Floor Disorders (UI, FI, POP)‡
Pelvic Floor Impact Questionnaire (PFIQ)†
Pelvic Floor Impact Questionnaire short form (PFIQ-7)†
Sexual Function Questionnaires§
Female Sexual Function Index (FSFI)
McCoy's Female Sexual Function Questionnaire (MFSQ)
Prolapse and Incontinence Sexual Function Questionnaire (PISQ)†
Prolapse and Incontinence Sexual Function Questionnaire short form (PISQ-12)†

* All instruments listed have been shown to be valid and reliable; all have demonstrated adequate responsiveness, except for the PISQ-12 whose responsiveness has yet to be evaluated.

† Indicates questionnaires that have been used in patients with pelvic organ prolapse.

‡ The Pelvic Floor Impact Questionnaire (PFIQ) and its short form (PFIQ-7) are intended to be used in women with all forms of pelvic floor disorders and each as urinary, anorectal, and pelvic organ prolapse scales.

§ The FSFI is a general sexual function questionnaire; the McCoy Sexual function Questionnaire is designed for use in postmenopausal women only; the Prolapse and Incontinence Sexual Function Questionnaire (PISQ) and its short form (PISQ-12) are designed for use in sexually active women with prolapse and/or urinary incontinence.

symptoms affect a range of daily activities and emotions. It has 4 scales: Travel, Social, Emotional, and Physical Activity. Like the UDI, it is a valid, reliable, and responsive questionnaire that was originally designed for use in women with urinary incontinence but has been used extensively to measure the affect of lower urinary tract symptoms on the HRQOL of women with pelvic organ prolapse. The IIQ-7 is a shortened version of the IIQ that is a companion to the UDI-6.

The Pelvic Floor Impact Questionnaire is currently the only condition-specific questionnaire that assesses the impact pelvic organ prolapse on quality of life.[23] It is a companion questionnaire to the PFDI and can be used by clinicians and researchers to measure the extent to which lower urinary tract, lower gastrointestinal tract, and pelvic organ prolapse symptoms affect the quality of life of women who experience the full spectrum of pelvic floor disorders. Like the PFDI, it has urinary, colorectal, and pelvic organ prolapse scales, and has good reliability and validity. It also has demonstrated responsiveness in women undergoing surgery for pelvic organ prolapse. The PFIQ-7 is a short version of the PFIQ that includes within it the IIQ-7 and colorectal and prolapse scales.[24]

SEXUAL FUNCTION QUESTIONNAIRES

Sexual function is an important outcome to consider when evaluating treatment of pelvic organ prolapse. Although a number of valid and reliable sexual function questionnaires exist, until recently, their use in women with pelvic organ prolapse or other pelvic floor disorders has been limited.

A recent systematic review identified 14 valid and reliable self-reported sexual function measures for men or women; however, only 2 met the highest standards and were recommended for general use: the McCoy Female Sexuality Questionnaire (MFSQ) and the Female Sexual Function Index (FSFI).[25] The MFSQ is a 19-item questionnaire for use in postmenopausal women that aims to assess a woman's level of sexual interest and response. The FSFI is also a 19-item questionnaire and has 6 domains: desire, arousal, lubrication, orgasm, satisfaction, and pain. The FSFI can be used in any age group. The main difference between these questionnaires is that the MFSQ includes social and relationship factors, whereas the FSFI is more focused on individual function. Both measures contain questions that are only applicable for people with a current sexual partner.

Currently, the only condition-specific sexual function questionnaire for women with pelvic organ prolapse or urinary incontinence is the *Pelvic* Organ Prolapse and Incontinence Sexual Function Questionnaire (PISQ).[26] The PISQ is valid and reliable and contains 31 items and 3 domains: Behavioral/emotive, Physical, and Partner-related It is designed for use in sexually active women with pelvic organ prolapse and/or urinary incontinence and assesses the impact of these diseases on sexual function. The PISQ-12 is a short version of the PISQ that correlates well with its long form.

Conclusion

Women with pelvic organ prolapse can present with a wide variety of bladder, bowel, and pelvic symptoms. With the exception of vaginal bulging symptoms, however, none are specific to prolapse. There is considerable overlap with other pelvic floor disorders and clinicians should be cognizant of other potential sources for the patient's complaints. The hymen appears to be an important landmark for symptom development. When pelvic organ prolapse extends beyond the hymen, the number of symptoms and the degree of bother caused by these symptoms increases substantially. Additionally, the nature of the symptoms can change. For instance, in women with prolapse that does not extend beyond the hymen, stress urinary incontinence is a common complaint; however, in women with prolapse beyond the hymen, voiding dysfunction symptoms are more prevalent.

The most valid way of measuring the presence, severity, and impact of pelvic floor symptoms on a patient's activities and well-being is through the use of validated self-administered questionnaires. An increasing number of questionnaires for women with pelvic floor disorders are now available, many of which were reviewed in this chapter. Widespread adoption of these questionnaires into research and clinical practice will provide a valid, reproducible, and standardized method of capturing the presence and impact symptoms in women with pelvic organ prolapse and its associated conditions, and hopefully aid in the improved care and outcomes of women with these disorders.

References

1. Jackson SL, Weber AM, Hull TL, et al. Fecal incontinence in women with urinary incontinence and pelvic organ prolapse. *Obstet Gynecol*. 1997;89:423–427.
2. Nichols NM, Gill EJ, Nguyen T, et al. Anal sphincter injury in women with pelvic floor disorders. *Obstet Gynecol*. 2004;104: 690–696.
3. Swift SE, Tate SB, Nicholas J. Correlation of symptoms with degree of pelvic organ support in a general population of women: what is pelvic organ prolapse. *Am J Obstet Gynecol*. 2003;189:372–379.
4. Samuelsson EC, Victor FTA, Tibblin G, et al. Signs of genital prolapse in a Swedish population of women 20 to 59 of age and possible related factors. *Am J Obstet Gynecol*. 1999;180:299–305.
5. Barber M, Walters M, Bump R. Association of the magnitude of pelvic organ prolapse

and presence and severity of symptoms. *Jrnl of Pelvic Med & Surg*. 2003;9:208.
6. Ellerkmann MR, Cundiff GW, Melick CF, et al. Correlation of symptoms with location and severity of pelvic organ prolapse. *Am J Obstet Gynecol*. 2001;185:1332–1338.
7. Burrows LJ, Meyn LA, Walters MD, et al. Pelvic symptoms in women with pelvic organ prolapse. *Obstet Gynecol*. 2004;104: 982–988.
8. Weber AM, Walters MD, Ballard LA, et al. Posterior vaginal prolapse and bowel function. *Am J Obstet Gynecol*. 1998;179: 1446–1449.
9. Romanzi LJ, Chaikin DC, Blaivas JG. The effect of genital prolapse on voiding. *J Urol*. 1999;161:581–586.
10. Coates KW, Harris RL, Cundiff GW, et al. Uroflowmetry in women with urinary incontinence and pelvic organ prolapse. *BJU*. 1997;80:217–221.
11. Weber AM, Walters MD, Piedmonte MR, et al. Anterior colporrhaphy: a randomized trial of three surgical techniques. *Am J Obstet Gynecol*. 2001;185:1299–1306.
12. Nguyen JK, Bhatia NN. Resolution of motor urge incontinence after surgical repair of pelvic organ prolapse. *J Urol*. 2001;166: 2263–2266.
13. Brubaker L, Bump R, Jacquentin B, et al. Pelvic organ prolapse. In: Abrams P, Cardozo L, Khoury S, Wein AJ, eds. *2nd International Consultation on Incontinence*. Plymouth, UK: Health Publication Ltd; 2002:243–265.
14. Spence-Jones C, Kamm MA, Henry MM, et al. Bowel dysfunction: a pathogenic factor in uterovaginal prolapse and urinary stress incontinence. *BJOG*. 1994;101:147–152.
15. Stewart WF, Liberman JN, Sandler RS, et al. Epidemiology of constipation (EPOC) study in the United States: relation of clinical subtypes to sociodemographic features. *Am J Gastroenterol*. 1999;94:3530–3540.
16. Jelovsek JE, Barber MD, Paraiso MF, et al. Functional bowel and anorectal disorders in patients with pelvic organ prolapse and urinary incontinence. *Am J Obstet Gynecol*. 2005. In press.
17. Weber AM, Walters MD, Schover LR, et al. Sexual function in women with uterovaginal prolapse and urinary incontinence. *Obstet Gynecol*. 1995;85:483–487.
18. Weber AM, Walters MD, Piedmonte MR. Sexual function and vaginal anatomy in women before and after surgery for pelvic organ prolapse and urinary incontinence. *Am J Obstet Gynecol*. 2000;182:1610–1615.
19. Barber MD, Visco AG, Wyman JF, et al., and the Continence for Women Research Program. Sexual function in women with urinary incontinence and pelvic organ prolapse. *Obstet Gynecol*. 2002;99:281–289.
20. Heit M, Culligan P, Rosenquist C, et al. Is pelvic organ prolapse a cause of pelvic or low back pain? *Obstet Gynecol*. 2002;99: 23–28.
21. Naughton MJ, Donovan J, Badia X, et al. Symptom Severity and QOL scales for urinary incontinence. *Gastroenterology.* 2004; 126:S114–S123.
22. Rockwood TH. Incontinence severity and QOL scales for fecal incontinence. *Gastroenterology.* 2004;126:S106–S113.
23. Barber MD, Kuchibhatla MN, Pieper CF, et al. Psychometric evaluation of 2 comprehensive condition-specific quality of life instruments for women with pelvic floor disorders. *Am J Obstet Gynecol*. 2001;185: 1388–1395.
24. Barber MD, Walters MD, Bump RC. Short forms for two condition-specific quality of life questionnaires for women with pelvic floor disorders (PFDI-20 & PFIQ-7). *Am J Obstet Gynecol*. 2005. In press.
25. Daker-White G. Reliable and valid self-report outcome measures in sexual (dys)-function: a systematic review. *Arch Sex Behav.* 2002;31:197–209.
26. Rogers RG, Kammerer-Doak D, Villarreal A, et al. A new instrument to measure sexual function in women with urinary incontinence and pelvic organ prolapse. *Am J Obstet Gynecol*. 2001;184:552–558.