

Practical Strategies in WOMEN'S HEALTH

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PELVIC FLOOR DYSFUNCTION

WHAT AREN'T YOUR PATIENTS TELLING YOU?

Mickey Karram, MD

Accurately diagnosing the cause of pelvic floor dysfunction can be difficult; the condition covers a variety of abnormalities that share symptoms with a host of other conditions. Very commonly these symptoms may not correlate with the anatomic abnormalities seen on physical examination.

Making matters more difficult, many women will not initiate a discussion about their symptoms because they are embarrassed; believe the symptoms are a normal part of aging; or falsely believe the only treatment is surgery, which will likely be unsuccessful.

ination, and testing or refer patients to specialists in female pelvic medicine.

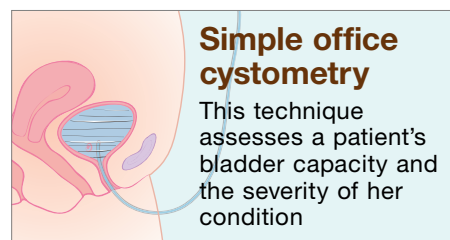
Pelvic floor dysfunction: An umbrella term

The term "pelvic floor dysfunction" has been popularized to describe all of the functional and anatomic problems associated with one or more of the 3 systems in the pelvic floor: the lower urinary tract, the genital system, and the lower gastrointestinal tract. Symptoms may include—but are not limited to—voiding dysfunction, evidence of tissue protrusion,

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Patients need to be screened for pelvic floor dysfunction

Therefore, a critical stage in diagnosis rests with clinicians screening patients. Health care professionals should offer women questionnaires or ask them directly about pelvic floor dysfunction. Clinicians can then proceed with more specific diagnosis through history, exam-



Simple office cystometry

This technique assesses a patient's bladder capacity and the severity of her condition

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WHI WHAT DOES IT MEAN TO YOU AND YOUR PATIENTS?

Vivian M. Dickerson, MD

The Women's Health Initiative (WHI) has changed how we manage menopausal and postmenopausal patients. We must provide initial counseling for patients who may benefit from hormone therapy (HT), and we must regularly revisit the risk-benefit profiles with our patients who are on HT. The American College of Obstetricians and Gynecologists (ACOG), the Food and Drug Administration, and numerous other organizations

recommend that women take the lowest effective dose of HT for the shortest duration of time.

HT and quality of life

Importantly, ACOG guidelines state that HT should not be withheld from women who have menopausal symptoms; severity of vasomotor symptoms is the criterion for initiating and maintaining therapy¹ because of the profound

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Our goal

Improve the
 health care of women



The Foundation for Female Health Awareness is proud to announce the launch of *Practical Strategies in Women's Health*, a newsletter for healthcare providers developed as part of the Women's Health Experience™, a program that educates consumers and helps clinicians better meet the needs of their patients.

The Women's Health Experience™ comprises the following components:

- *Practical Strategies in Women's Health*, the quarterly newsletter you hold in your hands, designed to help you meet everyday challenges in patient care
- *Women's Health Today*, a national magazine for women that delivers authoritative and practical health information for consumers
- *Women's Health Experience™ Online*, an extensive Web site, featuring educational information for consumers and health care providers. Visit www.womenshealthexperience.com
- Hospital-sponsored regional meetings, where local physicians present the educational portions of the program and health-conscious women learn about important health issues

Our National Advisory Board reviews all program materials to ensure that the content is accurate and unbiased and reflects the highest standards of education.

We thank our sponsors—American Medical Systems, Astellas Pharma US Inc, Ethicon Endo-Surgery Inc, and TAP Pharmaceutical Products Inc—for their generous support of the Women's Health Experience™. Revenue generated from the Women's Health Experience™ will be used to support much needed, unbiased medical research in various areas of women's health.

The Foundation for Female Health Awareness, in conjunction with Dowden Health Media, is very excited about bringing the Women's Health Experience™ to you.

Sincerely,

Mickey Karram, MD

Co-founder and Director
 Foundation for Female Health Awareness



WHI WHAT DOES IT MEAN TO YOU AND YOUR PATIENTS?

Hormone therapy from page 1

negative effect such symptoms often have on a patient's quality of life. (QOL). This underscores the importance of evaluating a patient's QOL in determining whether a patient should receive HT. A 1983 study² reported that women who used either estrogen or an estrogen/progestin combination experienced a net increase in the quality-adjusted life expectancy (length of life and QOL). A later study confirmed this finding.³

Both studies were published prior to the WHI; assumptions and data were based on available observational studies. With the loss of protection against cardiovascular events and the increased risk of thromboembolic events clearly demonstrated in the WHI population, one must put these earlier decision analyses in perspective. The only similar decision-making analysis on the subject published since the WHI takes the above issues into consideration.⁴ Paradoxically, it reports that asymptomatic women who used HT for 2 years had a very small (1 to 3 months) loss in quality-adjusted life expectancy, while women with severe symptoms realized 7- to 8-month gains. It seems, therefore, clear that prescribing HT for symptomatic women wishing to use it at least for the short term is a logical and evidence-based approach.

WHI: Study limitations

The WHI has received more intense scrutiny than virtually any other HT study in the past 20 years, and the study had flaws, as is true of any study. Opponents cite the number of smokers and women on medication for hyperlipidemia or hypertension. Proponents cite that the rates for major events such as heart attack or stroke in all arms of the study were significantly lower than in the US population as a whole. Many researchers and clinicians have observed that the WHI was not, in reality, a primary preventive study. The real question is: Does the WHI represent the patient population most likely to have been using HT or to have HT prescribed? The answer to this may, in fact, be "no."



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Who typically uses HT? Who should use it?

Even prior to the WHI, we knew that most women began to take HT (if at all) during early menopause. Less than 20% of women who began therapy were on it at 5 years. Probably less than 50% of women fill their prescriptions, which is a selection bias that may have confounded the observational studies on HT. Most of us know that starting first-time HT use at age 63 (the median age of WHI participants) is not beneficial and may be harmful. Significantly, the WHI did report a trend toward better outcomes in the 50- to 59-year-old cohort.⁵ This finding raises the key questions: Is there an optimal time to initiate HT? Does HT make a difference in short- and long-term outcomes, particularly in cardiovascular disease, the number 1 killer of women in this country?

New investigations, new answers

At least one study—enrollment is now underway—will attempt to answer this question. In 2001, Clarkson reported that in the monkey model, cardiovascular disease and plaque formation may be prevented or reversed if HT is initiated at menopause, but not if initiated later.⁶ The National Institutes of Health has now funded a study that will attempt to look at this phenomenon in human beings. The study, known as ELITE (Early vs Late Intervention Trial with Estradiol), will evaluate the efficacy of estradiol on the prevention of cardiovascular disease in women and attempt to determine whether these effects are altered by the time at which estrogen is initiated. Those of us who see patients every day and those women about to enter menopause will anxiously await the results. ■

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Endometriosis

Tommaso Falcone, MD

DIAGNOSIS AND MANAGEMENT

Endometriosis is a chronic inflammatory disease characterized by the presence of endometrial glands and stroma in areas outside of the uterus. Normally found in the uterine cavity, these glands form the physiologic uterine lining that is shed and extruded each menstrual period. Some of these glands flow upward through the uterine tubes into the peritoneal cavity and may adhere to different sites in and around the pelvis.

Normally, the body can clear these glands from the cavity. However, if there is a dysfunction in this peritoneal clearance mechanism or if there are intrinsic features of the glands that allow them to escape clearance, these glands persist. The inflammatory response that occurs may result in scar tissue and other manifestations of the disease.



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Family history is important when endometriosis is suspected. Several genetic abnormalities found in women with endometriosis predispose them to either the development of the disease or the clinical manifestations of the disease. Chronic exposure to environmental pollutants is also associated with the development of endometriosis. Other immunologic disorders as well as cancers seem to be increased in women with endometriosis.

Endometriosis is one of the leading causes of hospital admission for non-cancerous gynecologic disorders due to pain, formation of cysts, and infertility associated with the disease.

Diagnostic challenges

The primary manifestations of endometriosis are chronic pain and infertility. The chronic pain can present with constant lower abdominal pain, cyclic menstrual pain (dysmenorrhea) or pain with sexual intercourse (dyspareunia).

Endometriosis is suspected in women with the classic symptoms.

There are several challenges to a definitive diagnosis:

- ▶ No specific blood tests can determine if a patient has endometriosis.
- ▶ Imaging techniques such as ultrasound can detect cysts on the ovary that may be from endometriosis but do not reveal even extensive pelvic disease.
- ▶ Sophisticated imaging technologies may be more sensitive to deeply infiltrating disease but cannot rule out the presence of endometriosis.

Because of these limitations, diagnostic laparoscopy, a surgical procedure that introduces a camera through the umbilicus, is usually required. Experts recommend biopsy of the lesion to confirm the presence of endometriosis. The American Society for Reproductive Medicine established a system to classify disease severity from stage 1 (minimal) to stage 4 (severe). Classification of the patient's stage facilitates communication among all clinicians involved in treating her.

CASE REPORT 1

Longstanding severe, chronic pelvic pain, dyspareunia, and severe dysmenorrhea

Presentation and medical history. A 38-year-old woman complains of 3 years of severe, chronic pelvic pain, dyspareunia, and severe dysmenorrhea. On a presumptive diagnosis of endometriosis, she was treated with an oral contraceptive and nonsteroidal anti-inflammatory drugs, which have failed to improve her condition after 1 year.

Physical examination. Physical examination reveals some nodularity in the posterior cul de sac, which is consistent with endometriosis. She reports severe pain on bimanual examination without any significant pelvic masses.

Diagnosis. Since the patient is primarily interested in symptom relief, diagnostic laparoscopy is not initially ordered, and treatment proceeds on the presumption of endometriosis based on her presentation of classic symptoms.

Treatment and management. This patient should be sent for an ultrasound of her ovaries to check for cysts, which would be consistent with endometriosis. In such cases, medical management is not effective, and surgery is required.

If the ultrasound reveals no cysts or indications of previous pelvic inflammatory disease, this patient has 2 options: empiric medical management or surgery. If she chooses medical treatment, a depot gonadotropin releasing hormone (GnRH) agonist should be prescribed and a follow-up appointment at 2 months should be scheduled, at which time effectiveness of the GnRH agonist can be assessed. If there is improvement in symptoms within 2 months, she should continue with the agonist for 6 months. If hypogonadal symptoms occur, norethindrone can be added, and it will also protect against bone loss. If there is no improvement in 2 months, this patient should have surgery.

Alternatively, this patient could have surgery, which would probably show endometriosis. The extent of disease bears no correlation with the extent of symptoms; however, the fact that she had cul de sac nodularity points to a more advanced stage. Excision requires an experienced surgeon. Typically, two thirds of patients will respond to surgical management. ■

Nonoperative management

Management of endometriosis depends on whether the patient is seeking relief from pain or treatment for infertility. An oral contraceptive agent and nonsteroidal anti-inflammatory drugs (NSAIDs) are usually used initially to manage chronic pelvic pain, to thin the endometrial lining, and to reduce the inflammatory response. No formulation is superior to another. During this drug therapy consideration should be given to ancillary methods of pain relief such as biofeedback, acupuncture, and physical therapy that may help the pain syndrome. Some patients have pain relief only with medication and will require long-term treatment.

If pain persists after 2 to 3 months, simple medical therapy can be considered a failure and more sophisticated treatment consisting of agents that suppress the menstrual cycle or surgical treatment should be initiated.

Gonadotropin releasing hormone agonist. Gonadotropin releasing hormone (GnRH) agonists suppress the menstrual cycle and create a pseudo-menopausal state for the patient. The medication is the most commonly used cycle suppressant and is very effective in relieving symptoms. However, significant side effects include hot flashes and decreased bone density. The initial treatment cycle is usually for 6 months, and recurrence of pain after discontinuing the drug is quite common. A repeat treatment with the medication is possible.

Add-back therapy. When patients are treated with a GnRH agonist for 6 months or longer, norethindrone, a progestin, should be added to prevent side effects, including bone loss.

Danazol. Danazol, an androgen derivative, has shown benefit in relieving symptoms but is not as popular because of the side effects of weight gain and some increase of facial or body hair. Newer forms of medication are presently under investigation.

Endometriosis

During a menstrual period, endometrial glands, normally found in the uterine cavity, may flow upward through the uterine tubes. Once in the abdominal cavity they may adhere to different sites in and around the pelvis.

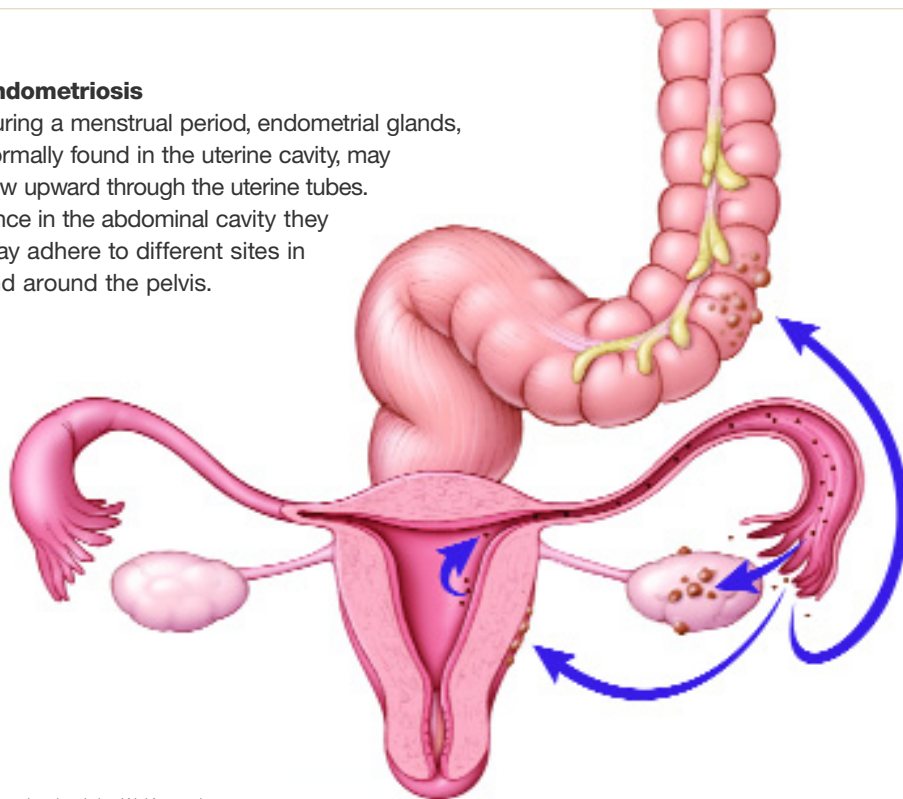


Illustration by John W. Karapelou

Surgical management

Surgical management of chronic pelvic pain is also quite effective. The procedure is performed laparoscopically by an experienced gynecologic surgeon, who ablates or excises the endometrial glands. Most studies have shown that the majority of patients will respond.^{1,2} Many patients will have recurrent symptoms that may require further surgery.

Endometriosis and infertility

Endometriosis associated with infertility is treated somewhat differently, because cycle-suppressing drugs like GnRH agonists will not improve fertility. Surgery can improve pregnancy rates, although not dramatically, and a couple may need to try for up to a year to achieve a spontaneous pregnancy without the use of fertility drugs.

If the surgery fails or the surgical option is not acceptable because of the delay in achieving a pregnancy, then fertility drugs can be used. These drugs are very effective and have a high pregnancy rate in women in the early reproductive

years. In vitro fertilization (IVF) is another good option for women with endometriosis. However, there are data to suggest that results are less in women with endometriosis, especially in women with advanced disease, than IVF results in women without endometriosis.³

Conclusion

Endometriosis is a very common inflammatory disease that usually causes debilitating pain and infertility. Present pharmacologic therapy has significant recurrence rates, and surgical management fails in a portion of patients as well. Ongoing research on new medical interventions may offer more hope of long-term relief. ■

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defecatory dysfunction, sexual dysfunction, and certain types of pelvic pain and may take such forms as:

- ▶ Incontinence of urine or stool
- ▶ Incomplete bladder emptying
- ▶ Pelvic pain, including pain with intercourse; discomfort or heaviness; or pain/burning
- ▶ Irritation from protrusion of vaginal tissue
- ▶ Irritative bladder symptoms such as urinary frequency, urgency, nocturia, or dysuria
- ▶ Pelvic pain of bladder origin
- ▶ Difficulty evacuating stool
- ▶ Fecal urgency

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CASE REPORT 2

Urinary frequency and urgency with bouts of urge incontinence

Presentation and medical history. A 76-year-old woman reports urinary frequency and urgency with rare bouts of urge incontinence. She also complains of some vaginal pressure and pain when she is on her feet for prolonged periods of time. She admits to some mild stress incontinence as well. She has had two vaginal deliveries. She is approximately 25 years postmenopausal and does not use hormone therapy. During the initial interview, she claims that she voids in the range of 15 to 20 times per 24 hours. As a result, she is very reluctant to leave her house and has little social interaction. She takes no medications that influence the lower urinary tract, she is not sexually active, and she denies any defecatory dysfunction.

Physical examination. General physical and neurologic exams yielded normal results. A review of systems is unremarkable. Pelvic exam reveals a normal-size uterus that is mobile and in the mid-plane. She has mild descent of the anterior and posterior vaginal walls into the middle to lower third of the vagina when she strains in a supine position. There is mild descent of the uterus. Gross appearance of the vaginal mucosa is consistent with urogenital atrophy.

Assessment of the pelvic floor musculature is performed by placing two fingers in the vagina and asking the patient to contract her levator muscles at the level of the mid vagina. She is able to only slightly contract her muscles. However, she can completely relax these muscles. Massage of the area as a form of biofeedback to reacquaint her with the location of the muscle is performed, and she is able to contract her muscles more strongly. The muscle contraction strength is upgraded from 1/5 to 3/5. With a subjectively full bladder the patient is asked to cough and strain, first in the supine and then in the standing position. No leakage occurs. When asked to use the toilet, she voids 175 cc. Catheterization reveals a residual

The 3 most common types of pelvic floor dysfunction encountered clinically are urinary incontinence, fecal incontinence, and pelvic organ prolapse. It is estimated that at least one third of adult women are significantly affected by at least one of these conditions.

A survey by Olson et al noted that a woman who lives to be 80 years old has an 11.1% lifetime risk of undergoing an operation for incontinence or prolapse with 29% requiring a second operation.¹

With the steady increase in the population of older women, the national cost burden related to pelvic floor disorders is enormous regarding lost productivity, decreased quality of life and direct health care costs. The prevalence of various types of pelvic floor dysfunction is:

Urinary incontinence. Severe urinary incontinence (at least one bout of incontinence per day) may affect as many as 7% of women younger than age 60, as many as

of 15 cc of urine (a bladder scan may also be used for this purpose). A urine dipstick is negative for bacteria or leukocytes.

Diagnosis. This patient was diagnosed with overactive bladder (OAB) and urogenital atrophy. Most of this woman's pressure symptoms are likely related to urogenital atrophy. Her atrophy may also be contributing to her irritative lower urinary tract symptoms.

Treatment and management. This patient should begin behavioral therapy in the form of timed voiding and pelvic-floor rehabilitation. An anticholinergic and local estrogen therapy should be prescribed.

The patient should follow up in approximately 4 to 6 weeks. If she does not report significant improvement, her clinician should inquire about compliance with behavioral therapy and about possible anticholinergic side effects. If she reports significant side effects, switching to a different pharmacologic agent may be of benefit. If she reports no side effects, the dosage should be increased. If no improvement results, pharmacologic therapy may be assumed to have failed.

If symptoms of urinary frequency, urgency, or urge incontinence continue with no improvement, further evaluation with urodynamics and possibly cystoscopy should be considered (**see Office Cystometry Technique, page 8**).

Symptoms of urogenital atrophy typically improve with local estrogen administration, which can be safely administered in a woman who still has her uterus. No more than 4 g of local estrogen cream should be applied each week. Up to 6 weeks of treatment may be necessary before any significant improvement occurs.

If the patient continues to have OAB symptoms on this therapeutic regimen, then neuromodulation (placement of an interstim device) could be considered. ■

14% of women between the ages of 60 and 85 years, and 17% of women 85 years or older.^{2,3}

When defined as any leakage of urine in a woman, the prevalence is much higher, between 20% and 45%.^{3,4}

Defecatory dysfunction. As it relates to the pelvic floor, defecatory dysfunction most commonly takes the form of fecal incontinence or outlet obstruction secondary to a rectocele. The prevalence of fecal incontinence has been reported in the range of 10% for women older than age 50 and as high as 50% in women who are in tertiary care facilities or nursing homes.⁵

Pelvic organ prolapse. Few studies evaluate the prevalence of pelvic organ prolapse. In one study, 497 women scheduled for routine gynecologic care were examined for prolapse based on a standardized grading system. These investigators noted that 51% of the women had stage 2 or stage 3 pelvic organ prolapse.⁶

Treatment options

Nonsurgical management. Nonsurgical management begins with education and behavioral modification, such as timed voiding and exercises to strengthen, retrain, and relax the muscles of the pelvic floor. Local estrogen and certain medications for overactive bladder may be prescribed. A pessary, or small device inserted in the vagina, can be offered to women with symptomatic prolapse who want to avoid surgery.

Surgical intervention. Surgical intervention includes a variety of anti-incontinent and reconstructive procedures. As previously mentioned, Olsen et al studied a population in a managed care facility and extrapolated that a US-born woman has an 11% lifetime risk of undergoing surgery for prolapse and/or incontinence by the age of 80. Sixty-one percent of these surgeries were done for prolapse with or without incontinence, giving

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CASE REPORT 3

Symptoms of stress incontinence and asymptomatic uterine prolapse

Presentation and medical history. A 35-year-old woman complains of symptoms of stress incontinence. A mother of 3, she exercises frequently but wears a pad during physical activity. She denies significant frequency, urgency, or nocturia. She voids approximately 8 times per 24 hours. She has no pertinent past medical history and is taking no medications.

Physical examination. General physical and neurologic exams yielded results within normal limits. When she strains in a standing position, there is mild descent of the uterus and anterior vaginal wall descending to just inside the hymen. She readily demonstrates the sign of stress incontinence as she leaks urine when asked to cough in the supine position. She voids to completion and results of her urinalysis are negative. Assessment of her pelvic floor reveals her pelvic muscle strength to be 5/5. She is very interested in discussing the most definitive therapy for her problem.

Diagnosis. This woman most likely has straightforward stress incontinence. At a minimum, the clinician should document the sign of stress incontinence prior to discussing surgical options. Office cystometry will assess the patient's bladder capacity and subjectively assess the severity of her condition (see **Office Cystometry Technique, page 8**). Full urodynamic assessment could be performed, which will most likely involve subtracted cystometry and urethral function tests.

Treatment and management. If the patient chooses an anti-incontinence procedure, the next consideration is the asymptomatic prolapse. Some procedures will not alter the vaginal axis (ie, a synthetic midurethral sling). If one of these is selected, it may be prudent to ignore the prolapse. However, if a suspension at the level of the bladder neck via retropubic repair or a traditional proximal sling is performed, the vaginal axis may be altered, potentially worsening the prolapse. This should be discussed with the patient, and the surgeon should individualize treatment. ■

CODING TIPS

Screening for pelvic floor dysfunction

- If pelvic floor dysfunction is suspected, a follow-up visit should be scheduled for a more specific diagnosis. If the consultation is performed appropriately, a Code 99244 consult can be billed. Medicare reimbursement for this is \$168.39, based on Midwest reimbursements. This coding requires approximately 60 minutes of face-to-face time with the patient. Reimbursement has very specific requirements that must be fulfilled and should be reviewed in advance by the clinician.
- A simple cystometrogram requiring only a red, rubber catheter, asepto syringe and water is coded as 51725 (see **Office Cystometry Technique, page 8**). Medicare reimbursement is \$261.86.
- Neuromuscular re-education is coded 97112, which is matched with pelvic floor muscle weakness, code 728.2 with Medicare reimbursement at \$28.88.
- If only a specimen is needed, a straight catheterization coded at 51701 will be reimbursed at \$76.59.
- A dipstick urine sample is coded 81002, reimbursed at \$3.30.
- If a revisit is required, it usually can be billed at Level 3, 99213 (see Medicare guidelines), which is reimbursed at \$51.03.

PELVIC FLOOR DYSFUNCTION

WHAT AREN'T YOUR PATIENTS TELLING YOU?

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women an approximate lifetime risk of 7% for prolapse surgery.⁶

Surgical therapy involves a variety of reconstructive procedures for prolapse that can be performed vaginally, abdominally, or laparoscopically. Most incontinence procedures that are performed for stress incontinence can be done in a minimally invasive fashion as an outpatient procedure.

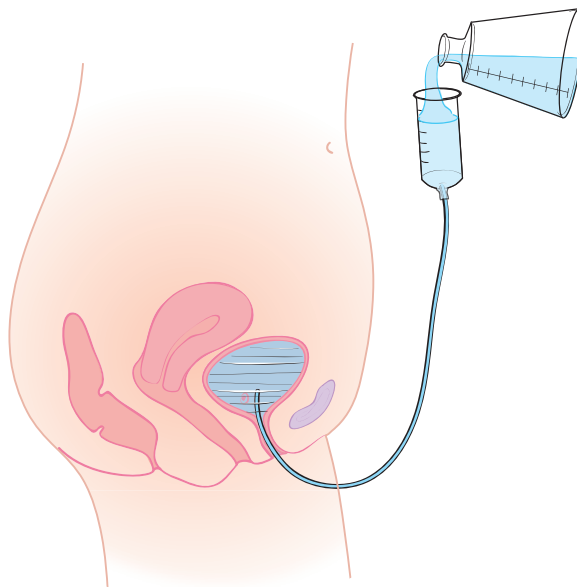
The accompanying case studies (see pages 6 and 7) review pertinent points regarding evaluation and management and provide practical strategies to help clinicians critically evaluate and manage patients who may have pelvic floor dysfunction. ■

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Office Cystometry Technique

1. The patient is asked to void in a Texas Hat and the amount voided is recorded.
2. A red rubber catheter is inserted to obtain a postvoid residual.
3. While the patient remains sitting, sterile water is poured into a syringe attached to a catheter, which allows the bladder to be refilled using gravity. The patient is asked to notify the clinician when she first perceives a sensation, is full, and is at maximum capacity.
4. It is critical that the clinician note any rises in the column of water in the syringe during the procedure. This could indicate uninhibited bladder contraction.
5. The catheter is removed when maximum capacity is reached.
6. The patient is then asked to cough, bounce on her heels, or listen to running water in an attempt to reproduce and confirm reported incontinence.



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Illustration by Mary K. Bryson