

# Pelvic Organ Prolapse

A New Option Offers Effectiveness and Ease of Use

By Diane A. Smith, NP

**W**eakened pelvic floor musculature and pelvic organ prolapse are common clinical problems for women of all ages. Often accompanied by urinary incontinence, these underdiagnosed and underreported conditions produce adverse psychosocial effects and require significant health care expenditures.<sup>1</sup>

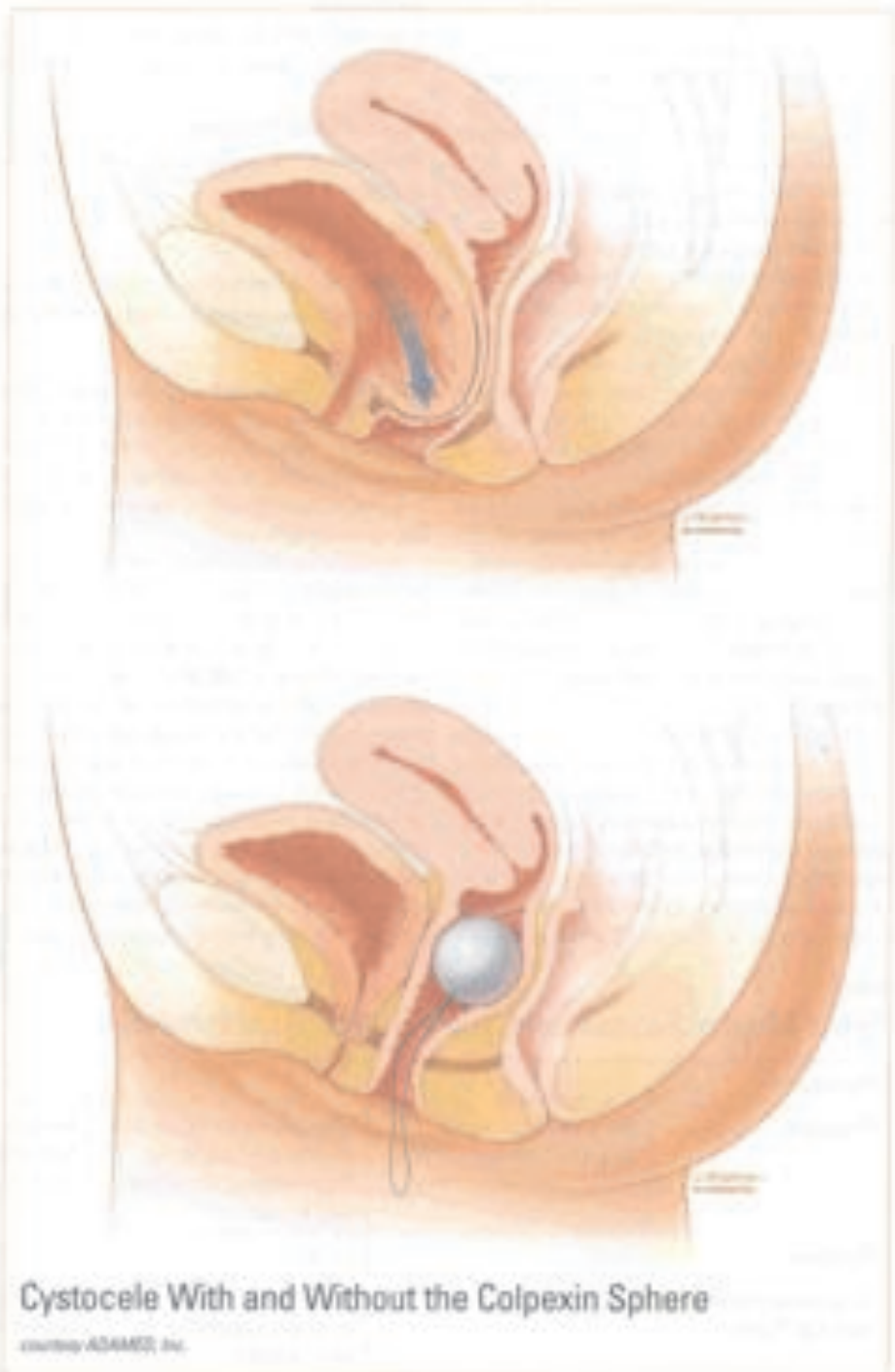
The majority of the more than 13 million people in the United States who experience urinary incontinence are women. Epidemiologic studies show that 47% to 56% of women between the ages of 20 and 80 experience urinary incontinence.<sup>2,3</sup>

While surgical management is considered definitive treatment, many women can benefit from more conservative management strategies.

## Pelvic Organ Prolapse

Pelvic organ prolapse, defined as protrusion of the pelvic organs (uterus, bladder or rectum) into the vagina, is a common but often overlooked problem. Two large epidemiologic studies — the Women's Health Initiative (WHI) and a Kaiser Permanente study — evaluated the incidence of pelvic organ prolapse among a wide range of women. The WHI, which followed more than 160,000 postmenopausal women ages 50 to 70, documented pelvic organ prolapse in 41% of women who had not undergone hysterectomy and in 38% of women who had undergone the procedure.<sup>4</sup> Kaiser Permanente's epidemiologic survey, which used the Epidemiology of Prolapse and

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Cystocele With and Without the Colpexin Sphere

courtesy ADAMCO, Inc.

Incontinence Questionnaire (ITIQ), documented self-reported pelvic organ prolapse in 7% of 4,458 respondents ages 25 to 84.<sup>17</sup>

Pelvic organ prolapse occurs when the pelvic floor muscle (levator ani) weakens and allows the pelvic organs to bulge into the vaginal cavity. In its early stages, the condition often produces no symptoms. As the pelvic floor muscle weakens, prolapse worsens and leads to urinary and fecal symptoms.

The Pelvic Organ Support Study (POSS) reported that the distribution of pelvic organ prolapse by stage among 1,004 women ages 18 to 83 followed a bell-shaped curve. Most subjects had early-stage disease.<sup>18</sup> In the POSS, approximately 25% of parous women demonstrated some degree of prolapse.<sup>19</sup>

Pelvic floor muscle damage may result from any of the following:

- neuromuscular damage that occurs during vaginal delivery or hysterectomy
- increased intra-abdominal pressure resulting from pregnancy, obesity, chronic cough, constipation or heavy lifting
- a metabolic abnormality due to estrogen deprivation associated with menopause or a genetic predisposition due to connective tissue weakness.

As shown in Table 1, the various types of pelvic organ prolapse are defined by the location of pelvic floor muscle weakness and the organ that is displaced. While many staging systems are available, pelvic muscle strength is commonly assessed by digital assessment in most general clinical settings (Table 2).

Obesity and gravidity are consistent risk factors for pelvic organ prolapse and, paradoxically, are the most modifiable preventive factors. Studies show that vaginal parity is directly related to increased risk for prolapse and urinary incontinence, with risk of major defects in the levator ani muscle higher among women with a self-reported

Table 1

## Types of Pelvic Organ Prolapse

**Cystocele**

A central or midline defect in the pubocervical fascia that results in herniation of the anterior vaginal wall and bladder into the vaginal lumen.

**Rectocele**

A break in the rectovaginal septum that results in herniation of the rectum and posterior vaginal wall into the vaginal lumen.

**Enterocele**

Separation of the pubocervical fascia and retrovaginal fascia, which allows herniation of the superior anterior or posterior vaginal wall and underlying peritoneal contents into the vaginal lumen.

**Vaginal Vault Prolapse**

Herniation of the vaginal apex (with or without the uterus) into the vaginal lumen; may result in eversion of the vagina.

**Uterine Prolapse**

A failure of the uterosacral ligaments that allows the uterus to descend into the vagina; complete uterine prolapse causes the uterus to fall outside the vaginal opening and the vagina to evert.

history of forceps delivery (see graph, next page).<sup>20</sup> Cesarean delivery appears to be protective against pelvic organ prolapse when compared with vaginal delivery and is a major contributor to maternal requests for cesarean delivery.<sup>21</sup>

Symptoms commonly associated with pelvic organ prolapse are listed in Table 3. The most common symptom is a palpable bulge in the vaginal vault or a perception that something is falling out of the vagina. Stress urinary incontinence, an involuntary loss of urine during coughing, sneezing, bending or lifting, is also a common consequence of pelvic organ prolapse. Weakened pelvic floor musculature prevents complete closure of the urethra, resulting in urine leakage during moments of physical stress. This problem is not limited to older women. Urinary incontinence and reduced

quality of life have been documented in women of varying ages, including very young women.<sup>22</sup> Moreover, incontinence may not be limited to urine. A population-based study found that 29% of postpartum women reported fecal incontinence.<sup>23</sup>

Although it is not life-threatening, pelvic organ prolapse can cause significant discomfort and can negatively affect daily activities. Women with advanced pelvic organ prolapse have poor body image and a diminished quality of life.<sup>24</sup> Numerous studies of women with stress urinary incontinence show that reduced quality of life is a frequent consequence of this condition and that the severity of incontinence is directly related to greater loss in quality of life.<sup>25-27</sup>

**Management Options**

Surgery is the only definitive therapy for pelvic organ prolapse, but it is often imper-

Table 2

Pelvic Muscle Assessment Scale (Digital Assessment)<sup>28</sup>

Parameter	1	2	3	4
Pressure	No response; cannot perceive on finger surface	Weak squeeze, felt as flick at various points along finger surface; not all the way around	Moderate squeeze; felt all the way around finger surface	Strong squeeze; full circumference of fingers compressed over it
Duration	None	<1 sec	>1 to <2 sec	>2 sec
Displacement of Vertical Plane	None	Finger tips may move anteriorly (pushed up by muscle bulk)	Whole fingers move anteriorly	Whole fingers move anteriorly, are gripped and pulled in

fect. That's because the repair of one vaginal compartment may predispose another compartment to develop prolapse. In addition, the integrity of pelvic floor innervation and muscle strength can affect surgical outcome. This conclusion is supported by the fact that approximately one-third of procedures for pelvic organ prolapse are repeat operations.<sup>16</sup>

Non-surgical treatment options for pelvic organ prolapse are listed in Table 4. These methods have varying rates of success, and some are associated with challenges in insertion and compliance (pessary), service accessibility and insurance coverage (biofeedback) or self-direction (pelvic floor muscle exercises or PFME).

#### The Colpexin Sphere

A new intravaginal device, the Colpexin Sphere, offers a unique option for conservative management. The Colpexin Sphere, which became available in the United States in 2006, supports the pelvic floor muscle and facilitates performance of PFME. The device is a medical-grade polycarbonate sphere with a locator string that is fitted above the hymenal ring to support the pelvic floor muscle (see images on first page).

The Colpexin Sphere has a number of characteristics that distinguish it from pessaries (Table 5). Fundamentally, the active mechanism of the Colpexin Sphere — support of the prolapsed organ with constant flexion of the pelvic floor muscle — differs from the passive support provided by pessaries. Although pessaries may support a prolapsed pelvic organ, they do not allow for concomitant rehabilitation of pelvic floor muscles.

Fitting for a Colpexin Sphere can take place during a routine gynecologic visit. The fitting procedure consists of determining the optimal sphere diameter using custom fitting tools that correspond with five sphere diameters (32 mm to 44 mm). A clinic visit should be scheduled 1 week after the initial fitting, again 4 weeks to 12 weeks later, and every 6 to 12 months thereafter. These follow-up visits provide opportunities to adjust sphere size to accommodate improved pelvic floor muscle tone. Proper sizing is critical to allow the patient to maintain the position of the device in the vagina.

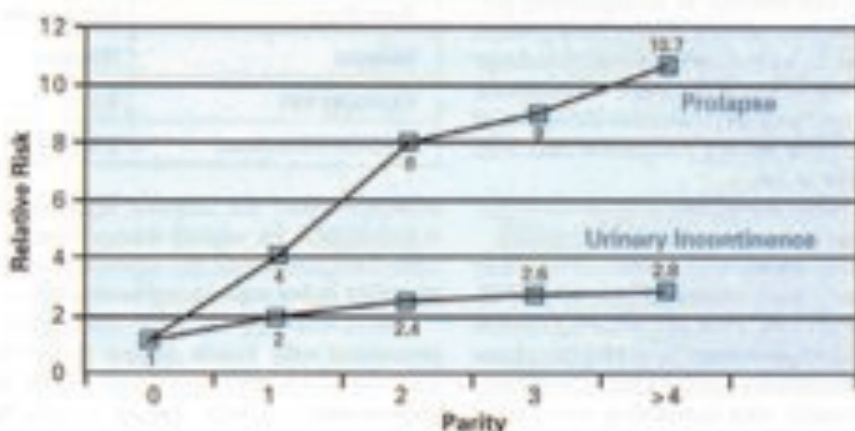
Initial therapy is guided by the patient's ability to contract the pelvic floor muscles and maintain the sphere in place while ambulating. The sphere is used in conjunction with pelvic floor muscle exercises, which should be performed daily. Patients with advanced prolapse may initially only

be able to hold the sphere in the vagina when they are performing PFME in the supine position. As their pelvic floor muscle tone improves, patients will be able to ambulate with the sphere in place.

Insertion of the Colpexin Sphere is

accomplished by hand or using a custom applicator. To remove the device, the woman relaxes her pelvic floor muscles and gently pulls on the string until the sphere slides out of the vagina. The sphere must be removed daily for cleaning with mild unscented soap

### Effect of Parity on Relative Risk\* of Prolapse and Urinary Incontinence



\*Relative risk is a measure of the extent to which a particular risk factor (in this case, parity) influences the risk of a specified outcome (in this case, urinary incontinence or prolapse). This figure shows that women who have had one child have a risk of urinary incontinence that is two times higher than the risk in nulliparous women and a risk of genital prolapse that is four times higher than that in nulliparous women. More than four births confers a risk of urinary incontinence that is 2.8 times higher than the risk in nulliparous women and a risk of genital prolapse that is 10.7 times higher than in nulliparous women. Adapted from reference 7.

Table 3

#### Common Symptoms of Pelvic Organ Prolapse<sup>19,21</sup>

- Palpable bulge in the vaginal vault
- Perception of something "falling out"
- Pelvic pressure, lower back pain
- Urinary incontinence
- Urinary retention
- Spontaneous improvement of urinary incontinence
- Sexual dysfunction
- Difficult evacuation of the rectum, splinting
- Fecal incontinence

Table 4

#### Nonsurgical Treatment Options for Pelvic Organ Prolapse

- Pelvic floor muscle exercises (PFME)
- For women who are unable to perform PFME, biofeedback
- Space-occupying devices (tampons, pessaries, etc.)
- Behavioral modification
  - Avoidance of heavy lifting
  - Avoidance of constipation
  - Maintenance of a healthy weight
  - Avoidance of chronic coughing

or detergent in water water. It is also necessary to remove the sphere during intercourse and menstruation. If the patient chooses, she can also remove the device during urination or bowel movements. Daily use of the Colpexin Sphere with a PTME regimen is recommended for maintenance.

A multicenter, prospective study of 39 women with advanced pelvic organ prolapse demonstrated that the Colpexin Sphere was effective in strengthening pelvic floor musculature and reducing urine leakage in women who reported leakage at the beginning of the trial.<sup>16</sup> Of particular note, significant improvement was reported in four of six urinary parameters after only 16 weeks of use:

- daytime urinary frequency ( $P < 0.001$ )
- urge urinary incontinence ( $P = 0.002$ )
- stress urinary incontinence ( $P = 0.0007$ )
- loss of small amounts of urine ( $P = 0.002$ )

In addition, 75% (15 of 20) patients reported improvement in urinary symptoms on a satisfaction questionnaire, including four women who stated they were "completely dry." These results have been validated in clinical use, as illustrated in the following three patient cases.

#### Case Examples

**Case 1:** A 41-year-old para 2, gravida 2 has had two vaginal deliveries and no other significant medical history. She works as an athletic trainer and runs marathons. She is approximately 61 inches tall and weighs 134 pounds. She complained of urinary incontinence during training and running, which forced her to restrict fluid intake and to wear absorbent pads or an adult diaper during races. She was concerned that restricting fluid intake while racing would result in dehydration or renal damage. In addition, she was embarrassed by having to use incontinence support. While training for a recent marathon, she was fitted with a Colpexin Sphere and experienced complete resolution of incontinence. When she wore the device during the race, she was able to maintain hydration and complete the marathon without using incontinence support.

**Case 2:** A 50-year-old active nurse presented with mixed stress and urge urinary incontinence. She has type 2 diabetes and is being treated with oral metformin (Glucophage) twice daily. Physical exam findings included third-degree cystocele and atrophic vaginal changes. She stopped menstruating about 1 year prior to evaluation and does not use hormone replacement therapy. Urinary evaluation revealed a normal postvoid residual and urinalysis. The

**Table 5**

### Colpexin Sphere vs. Pessary<sup>®</sup>

	Pessary	Colpexin Sphere
Mechanism of action	passive	active
Fitting	challenging	easy
Size options	many	few
Effect on bladder function	good	good
Ease of use	low to moderate	high
Removal	difficult	easy
Expulsion rate	low	moderate to high
Mucosal abrasions	common	rare

patient received the Colpexin Sphere and a prescription for vaginal estrogen cream. After 3 months of use, she reported a sharp reduction in her urgency and incontinence.

**Case 3:** A 92-year-old active retired nurse presented with fourth-degree cystocele and stress urinary incontinence. She is approximately 60 inches tall and weighs 98 pounds. Her overall health was good; she was oriented and walked with a cane during the last visit. Her past medical history includes mild hypertension treated with hydrochlorothiazide, hysterectomy more than 20 years ago, and pelvic heaviness and incontinence for 1 year prior to evaluation. Her postvoid residual was 45 cc, and her urinalysis was negative. She was diagnosed with atrophic vaginitis and was treated with estrogen cream for 2 weeks prior to being fitted with the Colpexin Sphere. After using the device for 8 months, she experienced total resolution of incontinence and pelvic heaviness. Of note, electromyographic muscle examination showed a doubling of pelvic muscle strength after 8 months of treatment. The patient reported that she was able to insert and remove the device independently and use it in conjunction with estrogen vaginal cream.

#### Putting It Into Practice

Pelvic organ prolapse is a significant clinical issue among women of all ages, and it often results in discomfort, altered lifestyle and urinary incontinence. The Colpexin Sphere, which provides pelvic organ support and facilitates pelvic floor muscle strengthening, is an efficacious and conservative management option that should be considered for women with urinary incontinence and pelvic organ prolapse. ♦

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