

Nonsurgical and Minimally Invasive Outpatient Treatments for Stress Urinary Incontinence and Pelvic Organ Prolapse

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Urinary incontinence and prolapse are common, distressing, and costly conditions in women. It is estimated that 25 million Americans suffer from urinary incontinence.¹ Stress urinary incontinence (SUI) is the predominant type, and can lead to social isolation and depression. The annual direct cost of managing urinary incontinence in the United States was estimated to be \$16 billion in 1995.^{2,3} Furthermore, about 50% of women over 50 years of age are thought to have pelvic organ prolapse, many of whom will require treatment of their symptoms at some point.⁴ In many cases, pelvic organ prolapse and SUI occur concomitantly.

Over the past decade, there has been increasing interest in the nonsurgical management of SUI. In March 1992, the Agency for Health Care Policy and Research issued the first clinical practice guidelines for urinary incontinence, and an updated version became available in March 1996.^{5,6} Both publications recommend that conservative management of urinary incontinence be undertaken before surgery.

NONSURGICAL MANAGEMENT

Current nonsurgical options for the management of SUI include behavior modification, physiotherapy, pharmacologic therapy, and mechanical devices. Pes-

saries remain the only conservative option available for the treatment of pelvic organ prolapse. The effectiveness of each modality, alone and in combination, has been reported in the literature.

Behavioral Modification

The voiding diary is a helpful tool in diagnosing and managing SUI (Figure 1). By reviewing a patient's voiding habits, the clinician may discover some remarkable behavioral contributors to incontinence. Asking the patient to decrease her fluid intake (especially the intake of carbonated and caffeinated beverages) or her voiding interval may decrease symptoms

FIGURE 1. Voiding diary

INSTRUCTIONS

1. **Voiding**
 - a. Record every time you urinate
 - b. Measure the amount
2. **Accidents / Leakage**
 - a. Record when an accident occurs
 - b. Record the amount of leakage
 - c. Note any activity that may be associated with accidents, i.e. sneezing, coughing, laughing, lifting a heavy object, etc.
 - d. Indicate when pads are changed
3. **Fluid Intake**
 - a. Record the amount of all fluids taken
 - b. Record the type of fluid you drink (such as coffee, tea, pop and water)

Attempt to drink for 3 consecutive days and bring it with you at the time of your appointment.

Day / Time	Voiding Amount	Accident Amount	Activity	Change Pad	Fluid Intake Amount & Type
1 am					
2 am					
3 am					
4 am					
5 am					
6 am					
7 am					
8 am					
9 am					
10 am					
11 am					
12 pm					
1 pm					
2 pm					
3 pm					
4 pm					
5 pm					
6 pm					
7 pm					
8 pm					
9 pm					
10 pm					
11 pm					
12 am					

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TABLE 1. Suggested Pelvic Muscle Exercise Regimen

- During pelvic examination, identify that patient is contracting the correct muscle
 - Ask the patient to “squeeze as if you are trying to stop the flow of urine.”
 - Identify the pubococcygeus by digital palpation.
 - Use a hand on the abdomen to verify abdominal relaxation.
 - Patient should avoid using the abdominal or gluteal muscles.
- Begin with 20 contractions (slow & fast) two times a day
 - Slow: Contract muscle quickly and hard and hold for 10 seconds.
 - Practice exercises when lifting or coughing.
- Increase to three times a day, or add 10 contractions every 4 weeks.
- Follow up every 4 weeks for 3 months.
- Continue beyond resolution of symptoms until conditioned reflex is established.

of SUI, urinary urgency, and frequency. Women with severe thirst and polydipsia should be evaluated for diabetes and hypercalcemia. Restricting fluids after 6:00 PM may help to decrease nocturnal voids.

Obesity and heavy smoking are common modifiable life-style factors that are associated with urinary incontinence.^{7,8} Obese women with urinary incontinence should be enrolled in a weight-reduction program.^{9,10} Smoking cessation should be encouraged, including participation in programs and/or groups designed to facilitate quitting.

Transient causes of urinary incontinence, such as side effects of medications, urinary tract infection, or an upper respiratory infection, should be assessed. If present, the exacerbating cause should be eliminated.

Physiotherapy

Physiotherapy has been used for decades to treat incontinence because weak or damaged pelvic floor muscles play a significant role in SUI. Common forms of physiotherapy include pelvic floor muscle exercises, vaginal cones, biofeedback, and electrical stimulation. These modalities are often employed in combination to achieve optimum results.

Exercises to strengthen the levator muscles were originally described by Arnold Kegel in 1948,¹¹ and these

Kegel exercises can be used to regain bladder control. As up to 33% of women perform these exercises incorrectly, ensuring that the patient is adequately instructed in the use of the correct muscles is crucial to the program’s success. Although practitioners have suggested different regimens and reported different efficacy rates, there is fair correlation between success and the intensity of training (Table 1).

Vaginal cones are an inexpensive form of biofeedback available for home use (Figure 2). Cone therapy can be initiated during a regular office visit. Vaginal cones are a series of tampon-sized weights that are held in the vagina for approximately 15 minutes once or twice per day. Holding the cone in place requires contraction of the pelvic muscles. The goal is to perform physically demanding daily activities (eg, climbing stairs, vacuuming, aerobic exercise) while holding the cone in place.

Biofeedback is widely practiced to help patients gain awareness and control of their pelvic muscles. With biofeedback, a variety of instruments are used to record small electrical signals that are produced when the pelvic muscles are squeezed during contraction. These contraction-related signals are instantly converted into audio and visual cues that patients can recognize and use to control muscular activity. With biofeedback, weak muscles can be activated on demand, tense muscles can be relaxed, and overall muscle activity can be coordinated. Biofeedback has several advantages in that it allows patients to learn to stop behaviors that increase abdominal pressures and contribute to leakage, and to master voluntary contractions of the pelvic muscles to prevent leakage. Typically, patients undergo biofeedback sessions twice weekly for 6 to 8 weeks.

Functional electrical stimulation is another physiotherapy modality with success rates ranging from 35% to 70%. A vaginal probe is used to electrically stimulate the pudendal nerve and cause contraction of the pelvic floor and periurethral muscles. The probe is inserted into either the vagina or anus and electrical stimulation is applied at an intensity below the threshold of pain, creating a current that stimulates contraction of the pelvic muscles. Electrical stimulation devices are available for both home and office use.

Pharmacologic Therapy

Currently, there are no medications approved by the US Food and Drug Administration (FDA) to treat SUI.

FIGURE 2. Vaginal cones



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TABLE 2. Pharmacologic Therapy for Stress Urinary Incontinence

Classification	Drug	Dosage (min-max)	Side Effects
Hormone	Conjugated estrogens	Oral: 0.3mg-0.625 mg qd Vaginal: 1-4 g qd, then weekly for maintenance Others: Vagifem, Estring	Irregular vaginal bleeding
α -sympathomimetics	Pseudoephedrine hydrochloride	15 mg bid 30 mg qid	Drowsiness, dry mouth, hypertension
	Phenylpropanolamine hydrochloride	25 mg qd 75 mg qd	Drowsiness, dry mouth, hypertension
Tricyclic antidepressant	Imipramine hydrochloride	25 mg qd 75 mg bid	Anticholinergic effects Orthostatic hypotension Hepatic dysfunction Cardiovascular effects Monoamine oxidase inhibitors contraindicated

bid = twice a day; qd = daily; qid = four times a day.

However, a number of drugs are used off-label to help manage the condition (Table 2). Most of these medications have limited effectiveness due to annoying, and sometimes life-threatening, side effects.

The role of estrogen therapy in the treatment of urinary incontinence has been studied for decades, and remains controversial. Several studies have found that estrogen was not an effective treatment for urinary incontinence, but that it may be of benefit in treating irritative voiding symptoms such as urinary frequency, nocturia, and dysuria.¹²⁻¹⁴ Based on these findings, it is not unreasonable to recommend short-term estrogen therapy for 6 to 8 weeks in hypoestrogenic women with urinary incontinence. If there is minimal or no improvement, therapy can be discontinued.

The new antidepressant duloxetine is currently being explored specifically for the treatment of SUI. It is a selective serotonin and norepinephrine reuptake inhibitor that results in urethral rhabdosphincter contractility. It appears to be both safe and effective in placebo-controlled, randomized trials.^{15,16} The results obtained thus far suggest that duloxetine may be useful in the treatment of mild to moderate SUI. Clinical trials are ongoing.

Mechanical Devices

Pessaries have been used throughout history for the treatment of various gynecologic conditions, including prolapse, cervical incompetence, and uterine retrodisplacement. Specific pessary types have been developed that are designed for the treatment of SUI (Figure 3). Proper insertion and careful follow-up are

recommended to avoid complications such as ulceration and vaginal erosion. The use of topical estrogen or Trimo-San pH-balanced gel may help to minimize ulceration of the vagina with extended pessary use.

Urethral devices that are currently available include the FemSoft insert and the FemAssist cap. The FemSoft insert is a disposable sterile urethral insert or plug that is placed into the urethra by the patient (Figure 4). It is removed before voiding and replaced afterward with a new insert. FemAssist (Figure 5) is a disposable urethral suction cap with a safe, effective profile.¹⁷ It is placed on the external urethral meatus and held there by suction. Available in two sizes, it prevents urine loss by obstructing the external urethral meatus. FemAssist can be reapplied after voids and reused for up to 1 week.

Conclusion

The success of nonsurgical treatments for incontinence and prolapse depends on several factors. Most important is the patient's motivation and compliance. A clinician or physical therapist committed to the success of nonoperative therapy is also helpful. Compliance is better when the patient has a good understanding of the rationale behind therapy and what to expect. All of these factors work together to produce the best possible outcome for the patient. If conservative therapy fails, surgery still remains an option.

MINIMALLY INVASIVE SURGICAL TECHNIQUES

The last decade has seen significant improvements in minimally invasive techniques for the treatment of SUI

FIGURE 3. Pessaries for Stress Urinary Incontinence



Courtesy of © Millex Products, Inc, 2001.

Pessary	Indication (SUI +)
A. Incontinence ring	
B. Incontinence ring with support	1st- or 2nd-degree uterine/vault prolapse and/or mild cystocele
C. Incontinence dish	Mild 1st- or 2nd-degree uterine prolapse
D. Incontinence dish w/ support	1st- or 2nd-degree uterine/vault prolapse and/or mild cystocele
E. Hodge	Narrow vaginal introitus
F. Hodge with support	Narrow vaginal introitus; Mild cystocele
G. Hodge with incontinence knob	Narrow vaginal introitus + stabilization of the UVJ
H. Hodge with incontinence knob and support	Narrow vaginal introitus + stabilization of the UVJ + mild cystocele
I. Gehrung with incontinence knob	Cystocele and/or rectocele
J. Cube	SUI during strenuous exercise (insert just before exercise begins)

SUI = stress urinary incontinence; UVJ = urethrovaginal junction.

and pelvic organ prolapse. Advances in technology and an improved understanding of underlying pathophysiology have led to better cure rates, reduced complications, and shorter hospitalization and postoperative recovery. Due to growing operating-room and hospitalization costs, there has been an increasing shift toward minimally invasive outpatient procedures for the treatment of incontinence and prolapse.

Stress Urinary Incontinence

Outpatient procedures such as paraurethral bulking agents and laparoscopic Burch colposuspensions were frequently utilized for the outpatient surgical treatment of SUI until the mid-1990s. Since then, the introduction of the minimally invasive midurethral sling (MIMUS) procedure using tension-free vaginal tape (TVT) has revolutionized the surgical approach to incontinence. Recent innovations, including radiofrequency (RF) bladder neck suspension, are still being studied with regard to long-term outcome, but are also available to the gynecologic surgeon.

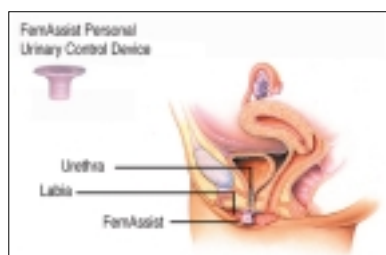
Paraurethral Bulking Agents.—Paraurethral injections of bulking agents attempt to occlude the proximal urethra and restore continence. Injections can be performed via the transurethral or periurethral approach under cystoscopic guidance in the office or ambulatory surgery setting. Currently, bovine collagen and carbon pellets are the only FDA-approved agents for this indication. Although indicated for SUI due to a fixed urethra or intrinsic sphincter deficiency (ISD), previous reports have reported some success with SUI due to urethral hypermobility. Reported success rates range from 33% to 80%.^{18,19} Advantages of the procedure include ease of administration and minimal postoperative complications.²⁰ Disadvantages include suboptimal cure rates, need for repeated injections, and particle migration. Indications include patients with SUI who may be poor surgical candidates, or for persistent SUI following retropubic colposuspension or suburethral sling procedure.^{21,22}

Laparoscopic Burch Colposuspension.—Both the laparoscopic Burch and MIMUS procedures attempt to restore continence by creating paraurethral support of urethral hypermobility, as well as a suburethral platform for compression in case of urethral sphincter compromise (ie, ISD). This is accomplished in the Burch procedure using the vaginal wall with lateral suspension sutures, and a synthetic tape in the suburethral position in the case of the MIMUS procedure.

FIGURE 4. FemSoft insert



FIGURE 5. FemAssist device

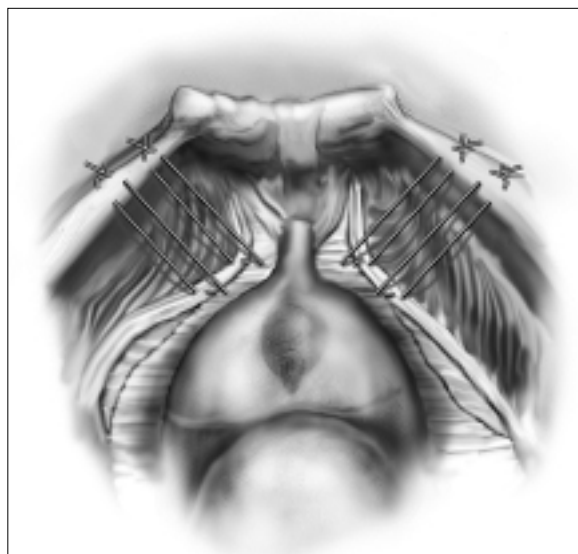


The laparoscopic Burch colposuspension, first described in 1991,²³ has dwindled in popularity following the introduction of TVT. The procedure is a laparoscopic approach to the traditional Burch colposuspension, with entry into the retropubic space via a transperitoneal or preperitoneal route. Although use of mesh/staples have been described, laparoscopic suturing with placement of two suspension sutures on each side is recommended to most exactly replicate the open approach (Figure 6). Cure rates have been reported to range from 70% to 90%, and depend on surgical skill and experience. Advantages include the high cure rates associated with the Burch procedure overall, minimal intraoperative and postoperative complications, and reduced hospitalization.²⁴ Disadvantages include the need for advanced laparoscopic skills and increased cost compared with the MIMUS procedure.²⁵ Indications are for patients with SUI due to urethral hypermobility who need additional intraperitoneal surgery including paravaginal repair, tubal ligation, or laparoscopically assisted vaginal hysterectomy.²⁶

Minimally Invasive Midurethral Sling.—A modification of the traditional suburethral sling, the MIMUS procedure involves passage of a synthetic or biomaterial graft under the midurethra through small incisions with ten-

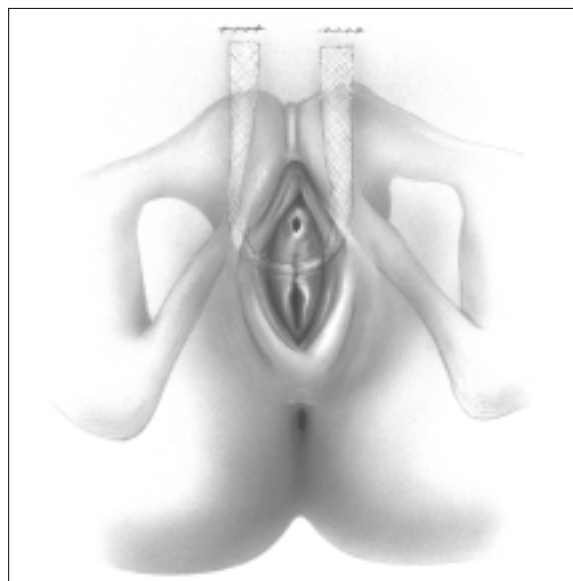
sion-free application (Figure 7). The sling is created via a retropubic approach. The needle can be inserted vaginally using TVT, Advantage, Urotex, intravaginal sling-plasty (IVS), or T-sling. Conversely, if the surgeon prefers, the needle can be inserted abdominally using TVT-Abdominal Guide or SPARC.^{27,28} Finally, transobturator needle insertion has been recommended recently to potentially minimize the risk of injury to the bowel, bladder, and blood vessels, which had been reported with the retropubic approach; the transobturator approach can be accomplished using Monarc, ObTape, or TVT-Obturator.^{29,30} Both approaches can be performed under local, regional, or general anesthesia. Intraoperative adjustment of the tape minimizes the risk of postoperative voiding dysfunction. Success rates for the MIMUS procedures are as high as 95% on 5-year follow-up and 81% on 7-year follow-up.^{27,31} Long-term outcomes data regarding the transobturator approach are lacking. Advantages of the MIMUS procedure include excellent cure rates, a short physician learning curve, and minimal postoperative complications. Disadvantages include complications associated with the use of synthetic materials, and (rarely) bowel or major vascular injury with passage of the needles. Indications include patients with genuine SUI due to either urethral hypermobility and/or ISD.

FIGURE 6. Retropubic view of complete laparoscopic Burch procedure with two sutures on each side



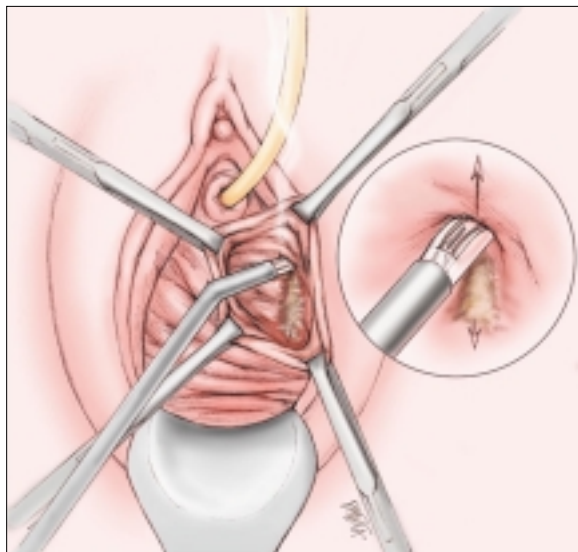
Courtesy of Neeraj Kohli, MD, and John R. Miklos, MD.

FIGURE 7. Placement of tension-free vaginal tape at the level of the midurethra



Courtesy of Neeraj Kohli, MD, and John R. Miklos, MD.

FIGURE 8. Vaginal application of RF probe to paraurethral tissue



Courtesy of Neeraj Kohli, MD, and John R. Miklos, MD.

Radiofrequency Bladder Neck Suspension.—First introduced in 2000, RF bladder neck suspension attempts to restore bladder neck support by applying RF energy to the paraurethral tissue via a laparoscopic or vaginal approach (Figure 8). The RF energy causes the collagen fibers to unravel and shrink, reestablishing support. Subsequent postoperative wound healing is essential to strengthening the support.³² Short-term cure rates range from 70% to 85%. Advantages of the procedure include ease of use with a short physician learning curve, no foreign-body implantation, minimal postoperative complications, and no need for cystoscopy. Disadvantages include slightly lower success rates and limited follow-up data. Indications include patients with mild to moderate incontinence, and those still desiring future childbearing.^{33,34}

Pelvic Prolapse

Although various surgical procedures, including colporrhaphy, vault suspension, and vaginal hysterectomy, can be performed on an outpatient basis in selected cases, outpatient

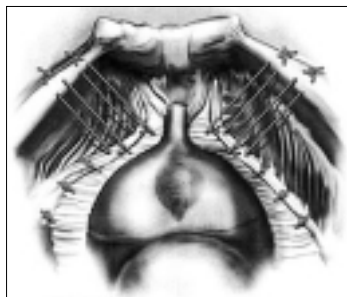
treatment options for pelvic prolapse usually entails laparoscopic pelvic floor reconstruction, including paravaginal repair and laparoscopic vault suspension.

Paravaginal repair for treatment of displacement cystocele is often performed in conjunction with laparoscopic Burch colposuspension, with entry into the retropubic space (Figure 9). A series of sutures are placed from the ischial spine to the bladder neck, reattaching the pubocervical fascia to the arcus tendineus fascia pelvis to correct lateral defects. Success rates vary depending on follow-up and technique. Advantages and disadvantages are identical to those of the laparoscopic Burch colposuspension, and strong laparoscopic surgical skills are required. Indications include a displacement cystocele or paravaginal defect noted on pelvic examination.³⁵

Laparoscopic vault suspension can be performed by attaching the vaginal vault to either the uterosacral ligaments, or via laparoscopic sacrocolpopexy. Uterosacral ligament suspension requires superior knowledge of the pelvic anatomy, while laparoscopic sacrocolpopexy requires advanced laparoscopic surgical skills and thorough knowledge of the anatomy of the presacral space.³⁶ Advantages include reduced hospitalization and recovery, while disadvantages include need for high-level laparoscopic surgical skills and increased cost compared with the open approach. Long-term data regarding these vault suspension techniques are lacking, but should approximate the open approach if performed in an identical fashion.³⁷

Recently, novel techniques have been introduced for vaginal vault and uterine suspension. The posterior IVS procedure involves threading a synthetic tape through the ischiorectal fossa on either side, with a suspensory band created at the level of the ischial spines to which the vault, mesh, or graft can be attached. The needles are inserted lateral and inferior to the rectum, and exit through the levator muscle medial and distal to the ischial spine. Long-term results regarding this procedure are lacking, but initial experience is promising and may allow a minimally invasive vaginal approach to apical prolapse. The Uplift procedure involves laparoscopic uterine suspension with fixation of the round ligaments, and may be useful in women desiring uterine preservation. Long-term outcomes for this procedure are not yet available.

FIGURE 9. Completed laparoscopic colposuspension and paravaginal repair



Courtesy of Neeraj Kohli, MD, and John R. Miklos, MD.

Conclusion

Further advances in technology and knowledge of pathophysiology should continue to improve cure rates, reduce complications, and shorten operative times, hospitalization, and postoperative recovery. Physicians will face ongoing challenges from new technology and techniques requiring continuing education and surgical training to provide the best conservative and minimally invasive treatment alternatives for their patients with SUI and pelvic organ prolapse.

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