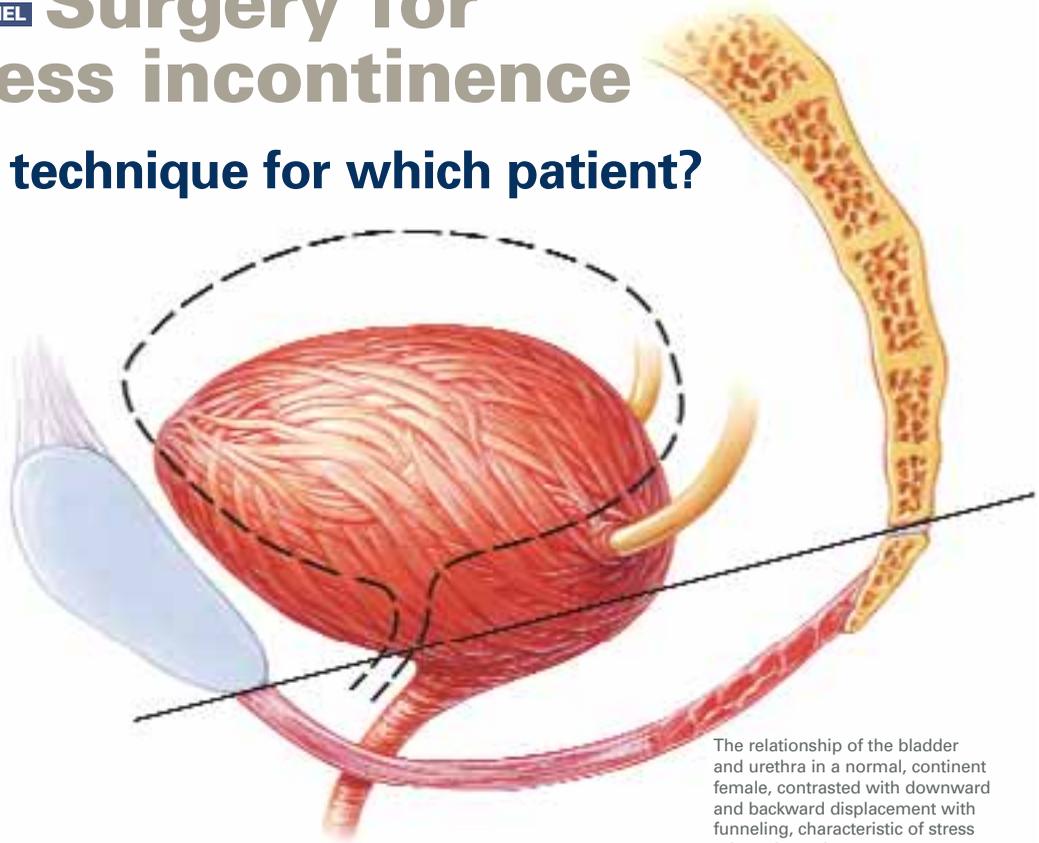


EXPERT PANEL **Surgery for stress incontinence**

Which technique for which patient?



The relationship of the bladder and urethra in a normal, continent female, contrasted with downward and backward displacement with funneling, characteristic of stress urinary incontinence.

When conservative treatments fail, operative therapy may offer better success—and an increasing number of methods are available. Our experts consider the full range of surgical options and offer guidance on tailoring treatment to the patient’s underlying problem, activity level, and desires.

Choosing appropriate surgical interventions is the focus of the second of our 2-part panel on stress urinary incontinence (SUI). The panelists discuss:

- how to weigh the factors that influence choice of technique, including Burch retropubic urethropexy and the various sling operations;
- the challenges of treating “mixed” stress and urge incontinence; and
- when to use bulking agents for intrinsic sphincteric deficiency.

The panelists also share tips on:

- how to help patients accurately describe their symptoms, and
- what issues to review with patients as they consider their options.

Part 1 covered medical therapies such as pelvic floor muscle rehabilitation, occlusive devices, and drugs. (*Stress urinary incontinence: A closer look at nonsurgical therapies.* OBG MANAGEMENT. 2003;15(9):40-51.)

Review surgical options with the patient

SAND: How do you counsel patients about surgical treatments for stress urinary incontinence?

MYERS: After the initial evaluation and diagnosis, I review the conservative options, and I also offer surgery. At this time, I discuss whether an operation is appropriate.

I work with the patient, going over her diagnosis as well as the different types of operations that are performed. Some patients are fairly well educated about their options, having looked up information on the Internet.

Next I explore whether other types of procedures need to be done concomitantly. For instance, does the patient need abdominal hysterectomy for some other reason? That would prompt me to offer an abdominal approach to the SUI. Do other types of vaginal surgery need to be done? Then I would probably opt for a vaginal approach.

I also look at the patient's health status. Is she healthy and physically active? Or is she sedentary with comorbidities? In a woman who is a poor surgical candidate, I would consider less invasive procedures or procedures with less operative risk, such as urethral injections or the newer tape slings.

LUBER: When it comes to surgery for urinary incontinence, I like to reinforce the reconstructive nature of the repair, since patients tend to view surgical procedures as definitive. For example, when the uterus and ovaries are removed, they never bother that patient again. Incontinence procedures are different. Their effect is potentially time-limited, so it's important to reinforce the patient's understanding of their reconstructive and fallible nature.

At the first surgical consultation, I basically go through an informed consent. I do so again preoperatively, but I think it is a very important initial step for a patient who is considering surgery.

SAND: What if a patient isn't sure she wants surgery?

LUBER: When a patient asks, "What should I do, Dr. Luber? Should I have an operation?" I like to use the example of standing in front of the refrigerator and asking, "Gee, am I hungry?" If you have to ask, you probably aren't.

Potential surgical patients should feel extremely comfortable that they have exhausted all the nonsurgical options. Even if they have decided against nonsurgical therapy, they should feel very comfortable with that choice. Then I am confident we can work through any potential problems of surgery.

As for the operation itself, history has demonstrated the irresistible impulse to innovate during surgery for female stress incontinence. Literally hundreds of operations have been described, and dozens are currently in use; this reinforces the supposition that our techniques are imperfect, and the importance of basing what we do upon the available data. The 1997 American Urological Association guidelines are an excellent example. Looking forward, the National Institutes of Health are

PANELISTS



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sponsoring studies comparing, for example, the gold-standard Burch to the gold-standard sling operation. In the next few years, we should have better evidence-based guidance.

Consider patient characteristics when choosing treatment

SAND: How do you select a surgical procedure for a particular patient?

MYERS: Because of all the different variables, I use various treatment arms. Since my institution does a large number of sling procedures, I am very comfortable performing those operations. I still

do retropubic urethropexy. I also do the newer vaginal-tape procedures, and I use bulking agents for patients who have a demonstrated sphincter deficiency with no obvious support problems. Basically, I try to tailor my procedure to the patient.

For example, in a woman who requires a total abdominal hysterectomy for fibroids as well as an anti-incontinence procedure, I would do a Burch operation. For a woman who needed a vaginal hysterectomy, I probably would perform a sling procedure.

DAVILA: Ob/Gyns may be a bit unsure how to proceed at this point. For example, we formerly considered the Burch procedure the gold standard against which other procedures should be judged. Although I continue to view it as the standard, the Burch procedure increasingly is overlooked in favor of tension-free slings—due to increased marketing of the latter—for any form of stress incontinence. I think that has led us down a path that is not entirely beneficial for many of our patients.

In contrast to that approach, I use a basic

TABLE

Stress urinary incontinence treatment choices based on urethral support and urethral sphincteric function

URETHRAL SUPPORT	URETHRAL SPHINCTERIC FUNCTION	
Bladder neck mobility (Q-tip test)	Normal urethral function MUCP >20 cm H ₂ O VLPP >60 cm H ₂ O Negative EBST	Poor urethral function LPP <20 cm H ₂ O VLPP <60 cm H ₂ O Positive EBST
>30 degrees (hypermobility)	Kegel exercises Biofeedback Vaginal device Tension-free vaginal tape Burch urethropexy	Traditional sling
<30 degrees	Kegel exercises Biofeedback	Bulking agents

Source: GW Davila, MD
EBST = empty bladder stress test;
MUCP = maximal urethral closure pressure;
VLPP = Valsalva leak point pressure
NOTE: Urethral plugs may function in all categories

evaluation of the patient to construct a treatment algorithm. In simple terms, 2 factors are taken into account: urethral sphincter function and bladder neck or urethral support. Using those 2 factors, I create a 2 x 2 table to select patients who do or don't have urethral hypermobility and who do or don't have sphincteric deficiency (TABLE).

For example, a patient with hypermobility and normal sphincter function has what we might consider "garden-variety" stress incontinence. Such patients do well with any form of treatment, whether it's conservative therapy, a vaginal device, or a Burch procedure or tension-free sling.

I am more concerned when the patient has hypermobility with a significant degree of sphincteric deficiency. In recent years, the tendency has been to treat such patients with a tension-free sling. Although the literature is not absolutely clear, the success rate of tension-free slings in a patient with intrinsic sphincteric deficiency (ISD) is not as high as in a woman without ISD.¹ So in these patients,

Atrophy can cause significant urgency and nocturia symptoms.

— Dr. Davila

I do a traditional sling.

The other 2 groups of patients have no hypermobility. I think most of us would agree that a woman with ISD and no hypermobility would best be treated with a bulking agent such as Contigen (*C.R. Bard, Murray Hill, NJ*) or Durasphere (*Advanced Uroscience, St. Paul, Minn.*).

I have had good success rates with bulking agents. I do not think current data would support a tension-free sling in these patients.

Finally, there is the patient without hypermobility who has normal sphincter function. These patients do fairly well with conservative therapy, including pelvic floor exercises. They usually have mild forms of stress incontinence to begin with.

Simple method to assess sphincter function

DAVILA: This is the algorithm I tend to follow. It does entail evaluation of the urethral sphincter mechanism, but there are simpler ways to do that than with multi-channel urodynamics. For example, if the patient leaks with a Valsalva maneuver, after voiding, in a supine position, that suggests she has ISD and therefore is likely to have a low-pressure urethra or a low leak-point pressure. Multiple centers have reported on this.^{2,3}

Role of urethral function in choice of treatment

LUBER: There seems to be 2 schools. The first dichotomizes urethral function to reasonable (“good” urethral function) versus unreasonable (“poor” urethral function or ISD) and selects the operation based on that. Thus, a Burch or supportive operation would be used for good

urethral function with hypermobility, and a sling operation would be selected for poor urethral function or ISD.

More recently, some experts have preached an inclusive approach, whereby all patients undergo sling operations. That strategy evolved out of frustration over the difficulty of identifying which patients have poor urethral function. Unfortunately, we lack good long-term data on the potential downside of performing sling procedures on all patients with incontinence. Hopefully, over the next 3 years, the National Institutes of Health data will help clarify whether we need to dichotomize patients in terms of urethral function.

Meanwhile, at our center, we continue to consider urethral function the deciding factor as to whether patients will undergo a gold-standard Burch procedure or a sling. We steer toward a sling procedure when the patient clearly has poor urethral function or ISD. Of course in cases of the fixed immobile and poorly functioning urethra, we also make bulking agents available.

Additional factors in the choice of treatment

SAND: We throw 2 other things into the algorithm at our center: One is detrusor overactivity, which is very important when considering surgical treatment of stress urinary incontinence. The second is voiding function.

Activity level of the patient is an additional measure, as Dr. Myers commented on earlier. I’m not as concerned about age as I am about the patient’s physical activity and expectations for the operation over time. For example, for a woman who is relatively homebound and not physically active and has poor voiding function (underactive detrusor) and prolapse with normal intrinsic urethral function, a Kelly Kennedy procedure at the time of an anterior colporrhaphy may be more appropriate than a Burch procedure.

Detrusor overactivity is important because, in the trial that we performed, the Burch retrop-

ubic urethropexy had a 55% objective cure rate of concurrent detrusor overactivity and a 70% subjective cure rate of the symptom of urge urinary incontinence. In contrast, over the last 12 years, the sling procedure has had a resolution rate of between 20% and 28% for recurrent detrusor overactivity. Recent subjective data at 1 year for midurethral slings fall into the same range: 20% to 30% resolution of recurrent urge incontinence.

Another factor is de novo detrusor overactivity. The rate of de novo detrusor overactivity and urge incontinence in our sling patients seems consistently higher, compared with our retropubic urethropexy patients. We all know that the patient with urge incontinence is far more upset about her condition than the patient who has predictable stress incontinence, because urge incontinence can be far more destructive to quality of life. I try to encourage gynecologists to consider this factor.

Voiding function is less clear-cut. Basically, because intrinsic urethral function declines with age, it is not uncommon to see a woman in her 70s or 80s with ISD who also has absent detrusor contractions during voiding studies. The physician can assess this function by ultrasound or urodynamic testing, or by measuring the postvoid residual volume, which usually falls in the range of 100 to 200 mL, especially if no prolapse is present. Thus, even in cases in which I normally would want to do a sling for ISD, I opt against it if the patient has poor voiding function. That's because the risk of permanent retention may rise as high as 15% to 20% in some of these patients.

Evaluation and treatment of mixed incontinence

DAVILA: I think we all agree that incontinence is easier to address than "hypercontinence" resulting from postoperative urethral obstruction, urinary retention, and irritative voiding symptoms. But what about patients with

I believe in offering all patients both nonsurgical and surgical options.

— Dr. Sand

mixed incontinence? How do you evaluate them? Is there a role for surgical procedures in patients with primary urge incontinence?

SAND: Many centers offer nonsurgical treatment of mixed incontinence, especially if urge incontinence predominates. But I believe in offering all patients both nonsurgical and surgical options. I end up triaging based on what patients select first, regardless of whether they have pure SUI or mixed symptoms, as long as they have been counseled appropriately about the expected outcomes of the various options.

MYERS: In my practice, I treat the urge symptoms first with anticholinergics or other medications. Then, if the stress incontinence continues, I offer a procedure.

This may be difficult in some cases, such as a patient with severe ISD. It is hard to treat detrusor overactivity when the urethral sphincter is weak, as the woman cannot hold increasing volumes of urine in the bladder.

Thus, I approach these cases by treating the stress incontinence first and then the urgency symptoms if intervention is still necessary—which is a 180-degree shift from my previous statement. In these cases, I treat the ISD first. Then, after the stress incontinence resolves, I offer medications for the urgency.

LUBER: I want to throw a little cold water on surgical treatment of overactive bladder. Clearly, this is an enormous issue. Probably 40% of women who come to my office complaining of urinary incontinence have mixed symptoms or mixed disease as determined by urodynamics. For the doctors out there caring for these patients daily, I think it is important to remember, as Dr. Sand mentioned, that in some cases, anti-incontinence operations can provoke detrusor overactivity in patients who were rela-

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Probably 40% of women who come to my office complaining of urinary incontinence have mixed symptoms.

— Dr. Luber

tively asymptomatic previously. Dr. Myers' suggestion that surgery may simply unmask the detrusor overactivity is also possible, of course.

Thus, I think it is reasonable to ask patients reporting mixed symptoms to characterize their urine loss. I usually have them pick a percentage (which isn't always easy). I ask, "Is your urge incontinence 10%, 50% or 90% of your problem?" If urgency is 90% of the problem and stress incontinence is minimal, then naturally that patient's care should be focused on the urge incontinence, and vice versa.

It becomes more problematic in the middle, with that 50/50 group. But I'm old-fashioned in that I like to treat the urge incontinence first and get that under control. Of course, in women with poor sphincter function, this distinction becomes more difficult because of the inevitable overlap of symptoms. But this is a small subset of the whole population.

DAVILA: Even if you operate on these patients to correct sphincter function, you must follow them closely. You shouldn't be saying, "We'll see you in 6 months."

In addition, the cofactor of urogenital atrophy should be addressed. Atrophy can cause significant urinary urgency and nocturia symptoms, although most women may not report vaginal atrophy symptoms.⁴ Local estrogen cream at a low dosage can be used pre- and postoperatively without concern about systemic absorption.⁵

Which patients benefit from bulking agents?

SAND: We touched on the use of periurethral injections of bulking agents. How do you determine when bulking agents are appropriate?

MYERS: I use periurethral injections for demonstrated sphincter deficiency. The ideal patient has a supported bladder neck and true sphincter deficiency—for example, patients whose sphincter deficiency is caused by pelvic radiation or significant surgical scarring.

In recent years, I have loosened the guidelines slightly, in that a number of my patients are elderly women with urethral hypermobility who are not healthy enough to undergo a major operation. In these patients, I use a pessary to support the bladder neck before performing an injection, and I make sure the patient understands that she will need to use the pessary even after the injection. I have better results when there is no hypermobility.

LUBER: The concept of ISD as the sole cause of urinary incontinence is less mysterious than it at first appears. In the typical patient with a fixed poorly functioning urethra, a Q-tip test will be 0 degrees at rest, and will still be 0 degrees with straining. The patient will leak readily with any kind of provocative maneuver, be it coughing or slight straining. With or without urodynamics, we know that patient's urethra is not functioning properly. Such a patient, for me, is the ideal candidate for bulking agents.

Unfortunately, bulking agents tend to have short half-lives of around 2 years. Still, you can improve the quality of life of these patients tremendously in that time by periurethrally injecting bulking agents during a very simple office or outpatient visit.

I have had less satisfaction and success using bulking agents in patients with urethral hypermobility, although I do like Dr. Myers' idea of correcting the hypermobility with an intravaginal support device and then using collagen to improve their urethral coaptation. That's a nice concept.

Improvements being studied

SAND: Currently, we have 2 injectables approved by the US Food and Drug

Administration: collagen and carbon-coated microspheres. Are new agents coming out? Do you expect improvements in the current agents?

DAVILA: The number of bulking agents being studied right now is huge. I think the future will bring one that can be implanted without the need for cystoscopy. A couple of trials under way use a conical urethral template for needle placement, and the injection is performed without cystoscopy. Although we're a number of years away from having enough data to support the widespread implementation of this approach, the momentum is certainly in that direction.

The half-lives of bulking agents also are increasing. Collagen was an excellent start, but we are moving toward permanence. In addition, most of the agents being studied are simpler to inject than collagen. Biotechnology is coming to the forefront with polymers that are either temperature-sensitive or able to reconfigure themselves over time. Thus, they should serve as a nidus for collagen deposition or remain in place longer, enhancing urethral sphincteric function.

It isn't clear which agent will take a leading role in the next few years, but a number of them have great promise. This is an exciting time in the management of stress incontinence as we move from invasive procedures such as retropubic urethropexy to minimally invasive surgery—as well as from the operating room to the office.

Radiofrequency technologies

SAND: What do you think about the new radiofrequency technologies being used to create support in periurethral tissues to correct hypermobility? Is there a role for this evolving technology?

LUBER: The concept of developing scar tissue adjacent to the urethra to provide better support underlies much of what we already do surgically. So there is some logic in the use of radiofrequency technologies to accomplish the same thing.

Still, there is the theoretical risk of further

It is hard to treat detrusor overactivity when the urethral sphincter is weak.

— Dr. Myers

denervating the urethra, which is probably already denervated. Having looked at outcome studies for radiofrequency therapy, I think it's a modality that can be embraced, but that should be done under the auspices of clinical research. Again, I'm old fashioned and am not comfortable integrating untested approaches into routine clinical care until we have adequate evidence of their effectiveness. In caring for incontinence, it is important that this effectiveness be looked at over a reasonable period of time, for example, 48 months.

DAVILA: I have had some experience with radiofrequency therapy, and the tissue changes it stimulates are fairly impressive. I share your concern about the issue of denervation. In fact, my colleagues and I are hoping to initiate a trial in which we plan to look at pudendal latencies to the urethral sphincter in these patients. As of now, with limited experience, it appears that there is no worsening of urethral sphincter function with the therapy.

Tension-free vaginal tape

SAND: What about other new treatments on the horizon?

DAVILA: Like bulking agents, new minimally invasive surgical techniques are also increasing in number. The advent of the tension-free vaginal tape (TVT), a technique that moved from Sweden to the United States a couple of years ago, truly has revolutionized what we do in anti-incontinence surgery. I think we all can agree that it has changed our practice patterns quite significantly, and the modifications or theoretical improvements by different companies are likely to have a further impact.

Polypropylene mesh appears to be very

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well received by the body. It doesn't get rejected or infected at a significant rate, so most physicians are comfortable with it. But I think it has become the surgeon's preference as to which product works better.

For the Ob/Gyn, the primary issue remains the small yet well-recognized risks of retropubic needle placement, beginning with bladder perforation and including vascular or bowel injury. As a result, many Ob/Gyns have probably been hesitant to perform these procedures.

What the future holds is very exciting: the transobturator approach to surgery for stress incontinence. Instead of bringing the needle superiorly behind the pubic bone, the surgeon maneuvers it laterally beneath the pubic ramus and through the obturator membrane. This is an anti-incontinence procedure a gynecologist can embrace. It may not be necessary to perform cystoscopy afterward because the surgery is nowhere near the bladder.

The French have taken the lead in developing this technique and recently presented approximately 2 years of data.^{6,7} A US trial also is being initiated.

LUBER: TVT is billed as a midurethral procedure. However, when you consider where those tapes actually end up after a few months, it probably functions much like a traditional sling. Recent studies are in conflict: Some demonstrate the sling remains at the midurethra while others show that it readily migrates to the bladder neck. So the quest for a less obstructive procedure has not been fulfilled with the TVT.

In fact, in our recent TVT series that Drs. Lukacz and Nager are meticulously following, the voiding time increases and the maximum flow decreases postoperatively in roughly 30% of patients. So it definitely has some obstructive characteristics.

Quest for the Holy Grail continues

LUBER: I think we need to continue to explore these newer, less invasive procedures that offer

wonderful potential. At this point, I might employ them in patients who are not able to tolerate the more invasive procedures or who flatly state that they want a less invasive operation. But I am not ready to embrace them as first-line therapy for all of my patients with stress incontinence.

Over the years, we have all seen various waves of surgical innovation, from the no-incision urethropexies of the mid-1990s to the laparoscopic techniques prominent later in the decade. Now, more minimally invasive techniques are coming to the fore. At some point, we may even find the Holy Grail. But for the most part, we continue to evolve, examining new approaches until we are forced to reconcile with their limitations.

SAND: It is clear that this is a very exciting time to be treating SUI, with continuing innovation and an increased awareness of the problem by the public. While we all treat these women differently, there is a surprising consensus. We all seem to concur that the operation should be tailored to the individual, considering the relative balance of any concurrent urinary urge incontinence, urethral hypermobility, voiding dysfunction, and the woman's health and activity level. We all use midurethral slings and periurethral bulking agents in selected women, but still also rely on Burch procedures and bladder-neck slings. ■

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