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Which sling for which patient?

This roundtable is the first of a series on persistent questions in urogynecology. Future topics: lower urinary tract injury, hysterectomy routes, vaginal vault prolapse.

Slings abound, entering the market faster than research can evaluate every new modification as exhaustively as we would like. How should we determine what is best for a particular patient? That is the question we examine in this discussion—the first in a series of roundtables, *Controversies in Pelvic Surgery*.

Future topics in the series focus on other unsettled issues:

- Preventing and managing lower urinary tract injury
- How best to correct vaginal vault prolapse

- Choosing the right hysterectomy route
- Mesh augmentation in prolapse repair

We decided on a roundtable format for the series because it seems well suited to a review of sometimes spotty data, not to mention the onslaught of new products and procedures that, ironically enough, are intended to simplify our lives.

Mickey Karam, MD

■ Choosing a sling for “uncomplicated” cases

DR. KARRAM: What is your sling procedure of choice for the uncomplicated patient who has primary stress urinary incontinence (SUI), urethral hypermobility, and what appears to be a healthy urethra?

DR. BLAIVAS: I prefer an old-fashioned, autologous, rectus fascial sling, or one made of soft prolene mesh, as described by Rodriguez and Raz¹—although I place the sling a bit more proximal than most and dissect into the retropubic space. The autologous rectus fascial sling has a long-term success rate at least as good as any other procedure. Even though it requires at least a small suprapubic incision, the possibility of serious complication (vascular or bowel injury, urethral or vaginal erosion) is almost nil.

Allograft and xenograft slings do not have as good a long-term success rate, but the chance of serious complication is nearly nil. If I do use a synthetic, I prefer the technique developed by Dr. Raz because it utilizes a time-honored, safe technique and avoids the unnecessary expense of the disposable midurethral sling kits.

I place the autologous sling at the bladder neck because long-term studies confirm its safety and efficacy.

DR. WALTERS: I use the literature as a guide and perform either Burch colposuspension or a synthetic midurethral sling procedure. Although its popularity has waned slightly, the Burch operation—either open or laparoscopic—is very effective.

My midurethral sling of choice for the simplest cases, as well as those with coexistent prolapse, is the Monarc transobturator sling (*American Medical Systems, Minnetonka, Minn*). The outcome data for this procedure are preliminary, and it has not yet been shown to equal a classic tension-free vaginal tape (TVT) technique, but I find that it causes less voiding dysfunction and urgency in my hands.

KARRAM: I would probably use a conventional TVT sling procedure. The reason: There is a tremendous amount of data to

support the use of TVT for all types of SUI. The data and our experience supports a very low erosion or excursion rate with the TVT tape. Since it is really the only synthetic midurethral sling that has been shown to be as effective as—if not more effective than—conventional repairs, it remains my procedure of choice in uncomplicated cases.

■ Preop evaluation

KARRAM: Do you use the same sling procedure for all patients? If so, do you test preoperatively to help determine appropriate tension? If not, how do you decide which sling to use on which patient?

WALTERS: I use 3 types of slings:

- the Monarc transobturator sling for simple primary SUI, SUI with prolapse, and potential SUI,
- TVT placed very loosely for recurrent SUI with leak point pressures over 60 cm H₂O, and
- TVT placed with a little more tension under the urethra for patients who have recurrent SUI with leak point pressures under 60 cm H₂O, but who lack a complete “drainpipe” urethra.

Technically, I also use a fourth sling—a full fascial sling for severe intrinsic sphincter deficiency (ISD)—although I haven’t done one of these procedures in over a year.

CONTINUED

OUR EXPERT PANELISTS

■ **Mickey Karram, MD**, the moderator of this discussion, is director of urogynecology at Good Samaritan Hospital in Cincinnati and professor of obstetrics and gynecology at the University of Cincinnati.

■ **Jerry Blaivas, MD**, is clinical professor of urology, Weill Cornell Medical Center, New York City.

■ **Mark Walters, MD**, is head of the section of urogynecology and reconstructive pelvic surgery, Cleveland Clinic Foundation, Cleveland.

FAST TRACK

“The tension-free vaginal tape is the only synthetic midurethral sling proven to be as effective as conventional repairs”

BLAIVAS: For the uncomplicated case, I use either an autologous rectus fascial sling, an allograft or xenograft, or one made of soft prolene mesh, depending on the patient's preference. zenograft

If I suspect she is at risk for erosion of a synthetic sling due to prior sling erosion, previous pelvic radiation, concomitant urethral diverticulectomy, or pelvic/urethral reconstructive surgery, I avoid synthetics..

"I must emphasize that these are all touchy-feely things"

BLAIVAS: Preoperatively, in addition to a focused history, questionnaire and examination, I make use of diaries, pad tests, video-urodynamics, pressure flow studies, cystoscopy, leak point pressure tests, and the Q-tip test whenever possible.

If the patient has significant urethral hypermobility and a relatively high leak point pressure, I use a bladder neck sling without any added tension. If there is little urethral mobility and a low leak point pressure, I make the sling a bit tighter.

If the woman has impaired detrusor contractility or urethral obstruction according to detrusor pressure uroflow data, I make the sling a bit looser.

I must emphasize that these are all "touchy, feely" things, unsupported by any meaningful data.

I also adjust the tension, depending on the patient's feelings about intermittent catheterization versus persistent sphincteric incontinence.

That said, there is still a lot more art than science to this issue. I almost always tie the slings very loosely, compared with what I see others saying or doing. I do this because, in my own learning curve, I quickly encountered problems of urethral obstruction but almost never made a sling too loose. As I gained experience, I tied them looser and looser without ever losing clinical efficacy.

KARRAM: I don't use the same sling for every patient. Like both of you, I first look

at the leak point pressure and review the patient's subjective complaints. I also consider any chronic systemic disorders, such as asthma or chronic obstructive lung disease, that may put a patient at high risk for failure. The findings help me adjust the tension intraoperatively.

I also try to reproduce the stress incontinence with a cough or Valsalva maneuver if the surgery is performed under local anesthesia, or using suprapubic pressure if it is done under general anesthesia.

Most of my sling procedures involve TVT. Although I recently began to selectively utilize a transobturator approach for women with occult incontinence or mild disease, I am not fully convinced it will be as efficacious as a traditional TVT for SUI.

"No matter how slight the modification, each new sling is encumbered by a learning curve"

KARRAM: Industry aggressively promotes new sling procedures—new materials, new placement techniques, new needles to pass the sling material. There are so many products and procedures that it is difficult to compare them all. Do you think this will become a serious problem, with many procedures lumped together and each assumed as effective as a similar product?

BLAIVAS: Emphatically, yes. Each new sling, no matter how slight the modification seems to be, is encumbered by a new learning curve. That means that the first batch of patients each surgeon operates on will be subjected to a higher complication rate or lower efficacy.

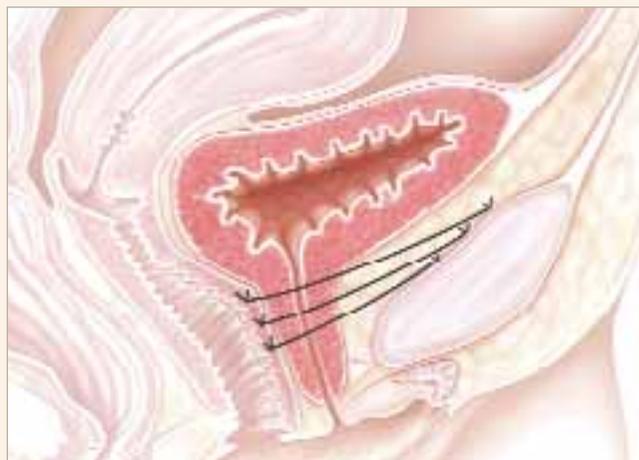
There have been unexpected (and unpublished) deaths due to vascular and bowel injuries and a 1% to 9% vaginal or urethral erosion rate with synthetic slings. Disappointing medium-term efficacy of allograft and xenograft slings were recently published, and recent abstracts suggest that transobturator slings are less efficacious for women with ISD.

FAST TRACK

"As I gained experience, I tied slings looser and looser, without ever losing clinical efficacy"

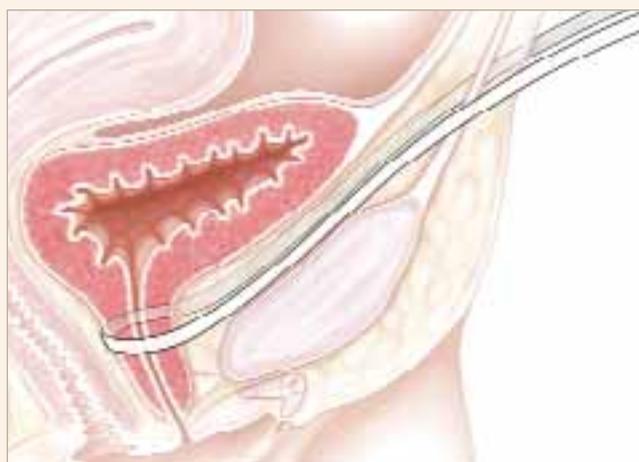
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3 techniques for stress incontinence



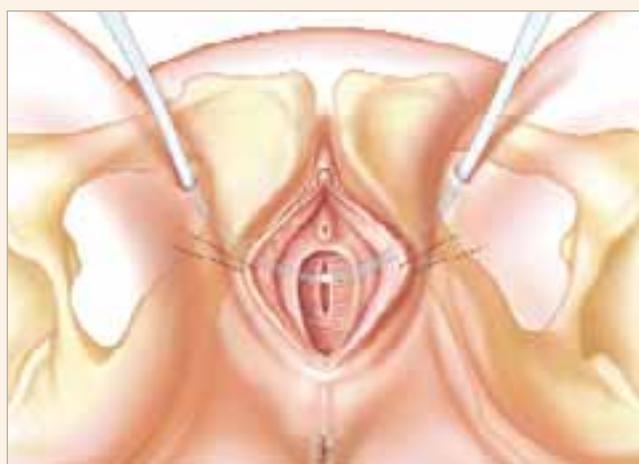
CONVENTIONAL REPAIR Burch colposuspension

- ▮ Proven track record
- ▮ Seems as effective as tension-free vaginal tape
- ▮ Used less than sling procedures
- ▮ More invasive. Requires abdominal or laparoscopic entry



WIDELY USED Transvaginal sling

- ▮ Necessitates passing needles and sling material blindly through the retropubic space
- ▮ Abundant data support use for all types of stress urinary incontinence
- ▮ The only synthetic midurethral sling proven to be as effective as conventional repairs



NEWEST APPROACH Transobturator route

- ▮ Eliminates need to pass needles and sling material through the retropubic space, thereby lowering risk of bowel, bladder, and ureteral injury
- ▮ Lack of long-term efficacy data

IMAGE: MAURA FLYNN

WALTERS: This problem not only exists, it has been worsening over the past several years. We still don't know if the transobturator sling is as effective as TVT, for example, yet we are slowly adopting it because it is easier and probably safer.

The various instruments required for these operations may not be that different, but the absorbable and nonabsorbable prosthetic sling materials are. They should be evaluated constantly and compared with the TVT procedure.

In medicine, we can't control what industry does, but we can continue to study and test the new procedures before we consider them standards.

KARRAM: I agree that the problem already exists. Although we have a substantial amount of data on the TVT mechanism and the Gynecare material (*Ethicon, Somerville, NJ*), we need to derive data for other slings. This may be very difficult, given the number of different materials and kits already on the market.

"We still don't know if the transobturator is as effective as TVT, but we are slowly adopting it because it is easier and probably safer"

KARRAM: The current rage is the transobturator approach, although we have very little data about it. Theoretically, it is safer than TVT, since there is no need to pass the needles through the retropubic space, and thus it is unlikely to lead to vascular and bowel, or bladder and urethral injury.

Should go ahead and adopt it as a primary procedure, or do you recommend waiting for more data on its efficacy?

BLAIVAS: I do not recommend that it be adopted until it is proven safe and effective, but I feel the same way about most of the other slings as well. When performed by experts, almost all these procedures are very safe, but we don't know very much about long-term efficacy. If someone selects the



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transobturator approach out of fear of complications from a different procedure, he or she is probably not skilled enough to perform these operations in the first place.

KARRAM: I agree that we need to wait until efficacy data are established. As slings become less and less invasive, industry is aggressively pushing them into the hands of novices. Most of the time these are gynecologists who have not performed anti-incontinence surgery and may even lack cystoscopy privileges. Do you think this will be a problem down the road?

BLAIVAS: Yes, unless the procedures are dumbed down enough and they are truly safe and effective.

■ Transobturator and TVT learning curves and outcomes

WALTERS: As for the transobturator approach, I am convinced, based on my surgical experience over the past 2 years, that it is easier than TVT and results in less voiding difficulty and urgency.

However, I am not convinced that it is equivalent to retropubic TVT in cure rates for SUI. This issue especially needs to be rigorously tested.

In my experience, TVT has a very high cure rate for SUI, but can cause urgency, including intractable urge and voiding dysfunction requiring transection of the polypropylene tape. This rarely occurs with the transobturator sling, making it attractive for simple SUI.

The transobturator sling also is easier than TVT to learn and teach, and completely avoids any risk of retropubic hematoma and bowel perforation. Also, unless there is extensive prolapse, the risk of entering the bladder and urethra is practically nil, assuming you are able to pass the needle and touch your finger from the lateral side.

The next big, important study will likely be a randomized comparison of transobturator and TVT slings, similar to the way TVT was compared with the open Burch procedure.

“I perform cystoscopy on virtually every patient, and find abnormalities in 2% to 4% of cases a year”

WALTERS: For their own protection, I don't think gynecologists should be doing surgery for prolapse and incontinence if they do not have privileges for cystoscopy.

KARRAM: I agree. It is very important that the gynecologists performing these procedures evaluate the patient thoroughly enough to decide wisely between surgical and nonsurgical management. Certainly they should have the ability to evaluate the lower urinary tract with cystoscopy before doing these procedures.

WALTERS: I perform cystoscopy on virtually every pelvic reconstructive surgery and find abnormalities in the bladder, urethra, or ureters in 2% to 4% of cases a year. Although I encourage gynecologists to learn these operations, cystoscopy is crucial, so an effort should be made to obtain training and privileges for it. .

“I'm glad my partners and I have the ability to perform the Burch procedure when necessary”

KARRAM: You mentioned the Burch procedure, Dr. Walters. Do you think there is still a role for retropubic urethropexy—done laparoscopically or via an open technique?

WALTERS: I perform an open Burch procedure if I have already made a laparotomy incision for another reason, such as abdominal sacrocolpopexy or hysterectomy. I occasionally perform laparoscopic Burch procedures in younger women undergoing laparoscopy for other reasons, such as tubal sterilization or ovarian disease.

KARRAM: I perform retropubic urethropexy if operating in the abdomen for another reason, provided the patient has SUI, urethral hypermobility, and vaginal pliability.

FAST TRACK

“For their own protection, ObGyns should not do surgery for prolapse and incontinence if they do not have cystoscopy privileges”

BLAIVAS: Retropubic urethropexy has a proven track record, but requires skill and experience.

With uncomplicated incontinence, long-term success appears as good as any operation. If a surgeon is skilled, this procedure should be part of his or her armamentarium.

KARRAM: You are correct. Data suggest the retropubic operation and TVT procedure are equally effective.^{2,3}

WALTERS: I find it somewhat amusing that I am increasingly considered “old-style” when I continue to recommend the Burch procedure.

All I can say is that I’m glad my partners, fellows, and I have the ability to perform this operation when necessary.

KARRAM: Unfortunately, since retropubic urethropexy is performed much less frequently in the past, residents no longer learn retropubic anatomy.

This has become a problem because a many synthetic midurethral slings require blind passage of a needle through the retropubic space.

“I don’t think TVT complications will increase because of lack of experience with the Burch procedure.”

KARRAM: Are we going to see more complications with these procedures because of a lack of clear understanding of the anatomy? If so, how do you think this can be resolved?

WALTERS: Although TVT works very well for SUI, I think our specialty abandoned Burch colposuspension prematurely, ignoring all the evidence supporting its efficacy. I wish residents were still being taught Burch procedures on open cases. I can see that general Ob/Gyns are slowly forgetting how to do the operation, making it more difficult for them to manage complications such as hematomas and infections.

That said, I don’t think TVT complications will occur more often because of this lack of experience with the Burch procedure. On the contrary, I expect them to remain rare. Use of transobturator

slings avoids retropubic anatomy completely, but we need more outcome data before making a wholesale switch from TVT.

KARRAM: More injuries to blood vessels and other structures are inevitable when novice surgeons unfamiliar with anatomy attempt to blindly pass large needles.

BLAIVAS: I agree, but the developers of the new techniques are trying to make them idiot-proof—and maybe they will! It's a sad day, though, when surgeons don't know anatomy. Too many don't!

KARRAM: The only solution is to aggressively teach anatomy in residency and demand preceptorships that teach anatomy before allowing inexperienced surgeons to adopt the procedure.

BLAIVAS: If enough mistakes are made, we'll be forced to teach anatomy again. The best solution, in my judgment, is subspecialization to the point where all surgeons doing these procedures have sufficient experience.

"No definitive data suggest doing procedures differently based on ISD tests"

KARRAM: Intrinsic sphincter deficiency has become a common term for severe forms of stress incontinence, although there is no widely accepted definition.

How do you define ISD? Is it important to detect it preoperatively? If so, how does ISD alter surgical management?

BLAIVAS: ISD was initially used to describe weakened sphincter mechanism, as distinct from incontinence because of urethral hypermobility.

For practical purposes, all patients with sphincteric incontinence have some degree of "intrinsic sphincter deficiency," but I no longer use the term. Instead, I characterize the sphincter by vesical leak point pressure and the degree of urethral mobility as measured by a simple Q-tip test. The lower the leak point pressure, the weaker the sphincter, the more likely it will be designated ISD.

WALTERS: I still follow the rough guidelines I was taught: ISD exists at leak point pressures below 60 cm H₂O on cystometrogram., although this is probably not that accurate. There is no cutoff defining ISD, but a gradually increasing weakness of the urethral sphincter that correlates roughly with severity of symptoms.

I doubt the concept of ISD would hold up to rigorous scientific scrutiny as a condition or prognostic factor. However, I still use it.

KARRAM: Although intrinsic sphincter deficiency is a vague concept, I believe there are cases that exhibit it—eg, patients who have had multiple operations, been radiated, or have neurologic disease, who essentially have a urethra that is open at rest, doesn't move, and leaks urine with minimal increases in intraabdominal pressure. In situations such as these, I select procedures that bulk up or obstruct the urethra to correct or improve the incontinence.

Most cases identified as having ISD are based on a urethral function test that measures either leak point pressure or static urethral closure pressure. Unfortunately, little data prove that these tests truly measure urethral function.

There are no definitive data suggesting that a procedure needs to be done any differently based on these tests. So I think the term is presently used in a very cavalier fashion and requires a more objective mechanism to define the condition. Only then can its potential impact on clinical management be evaluated. ■

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FAST TRACK

"The best solution is to subspecialize to the point where all surgeons doing these procedures have sufficient experience"