



CHARLES E. MILLER, M.D.

MASTER CLASS

Stress Urinary Incontinence

Until recently, gynecologists and urologists approached stress urinary incontinence differently. Gynecologists were champions of retropubic colpopexy procedures, while urologists performed sling procedures. Through Dr. Ulf Ulmsten's

landmark work on stress urinary incontinence, culminating in the use of tension-free vaginal tape (TVT) in 1996, gynecologists and urologists throughout the world came to agree on a common procedure.

Whereas laparoscopic retropubic colpopexy was the minimally invasive surgical procedure of choice in the late 1990s, the use of TVT has quickly become the preferred minimally invasive technique in the treatment of

stress urinary incontinence. The rapid acceptance of the use of tension-free vaginal tape is quite understandable. Few techniques in gynecologic surgery have been as well studied.

Rapidly accumulating data indicate that the long-term results are at least as good as the standard, retropubic colpopexy. In a large, multicenter, prospective, randomized trial for stress urinary incontinence (*Am. J. Obstet. Gynecol.* 2004;190:324-31), the cure rates at 2 years for TVT and colposuspension were essentially the same (81% vs. 80%).

For this edition of the Master Class, I am proud to have Dr. Mickey M. Karram discussing TVT in the treatment of stress urinary incontinence. As one of the true thought leaders in urogynecology, Dr. Karram helped introduce the use of TVT in the United States.

Dr. Karram is the director of urogynecology and re-

constructive pelvic surgery and the director and founder of the fellowship training program in female pelvic medicine and reconstructive surgery in the department of obstetrics and gynecology at Good Samaritan Hospital in Cincinnati. He is also affiliated with the department of obstetrics and gynecology at the University of Cincinnati and is editor-in-chief of the *International Urogynecology Journal* and *Pelvic Floor Dysfunction*.

Dr. Karram has authored over 90 peer-reviewed publications and 33 book chapters, and has edited five books. I am truly honored to have Dr. Karram introduce the important topic of synthetic midurethral slings for stress incontinence. ■

DR. MILLER, a reproductive endocrinologist in private practice in Arlington Heights, Ill., and Naperville, Ill., is the medical editor of this column.

Synthetic Midurethral Slings: TVT and TOT

Today, there are more published studies on the use of tension-free vaginal tape in the treatment of stress urinary incontinence than on any other procedure that has ever been performed for stress incontinence.

When compared with traditional suspensions and slings, TVT has been shown to be at least as—if not more—efficacious for all types of stress urinary incontinence, from incontinence due to anatomical abnormalities to incontinence resulting from intrinsic sphincter deficiency and mixed incontinence.

Added to TVT's efficacy is the fact that the TVT procedure is simpler, shorter in duration (approximately 20 minutes), and less invasive than other procedures, with extremely low complication rates when the appropriate technique is utilized and retropubic anatomy is appreciated.

Clearly, the TVT procedure is a good treatment of choice.

TVT's Origins

The TVT procedure, which was the first use of the synthetic midurethral sling, was first done in this country in 1998.

The history of TVT is interesting because the procedure went against everything we always thought we understood about surgery for SUI: mainly, that the mechanism for continence was at the proximal urethra and bladder neck, and that surgeries for incontinence needed to either elevate or support this area. TVT, on the other hand, uses a midurethral placement. It provides a backboard under a portion of the urethra that has very little mobility.

In addition to processing this major change in thinking, many of us also thought at the time that synthetic materials should be avoided for sling procedures, and few of us could easily grasp the notion of placing a sling without fixing it to anything.

The TVT procedure was first described

by Dr. Ulf Ulmsten in 1996. In the mid-1980s, he and his fellow, Dr. Peter Petros, set out to identify and describe a new minimally invasive outpatient procedure for stress incontinence.

They described a series of small studies, exploring what they called the "integral theory," in which they looked at different slings or meshes placed at different anatomical sites underneath the urethra.

In the end, they determined that a certain type of polypropylene mesh, placed through a vaginal-to-suprapubic route using specially designed, long stainless steel needles that can be passed under local anesthesia, was the best approach.

According to Dr. Ulmsten's theory, the procedure works by reinforcing the pubourethral ligaments and levator ani muscles, as well as increasing the support of the vaginal hammock.

The Entry of Transobturator Slings

The TVT procedure required blind passage of needles through the retropubic space, a process that potentially brings the needle into close proximity with vascular structures as well as bowel and the bladder.

And indeed, there were rare reports of very serious complications related to vascular and bowel injuries.

These complications led a Frenchman, Dr. Emmanuel Delorme, to describe the first transobturator tape (TOT) procedure. The theory behind this technique, which represented a second generation of midurethral slings, was that it avoided the retropubic space and thus avoided these potential vascular, bowel, and bladder injuries.

The procedure became quite popular, and techniques to place the transobturator sling from the

vaginal side or from the inner thigh were described. Experience with these modifications has grown over the last few years.

Complication rates with TOT have been low, but some complications, particularly those related to the inner thigh, have been described.

The next generation of synthetic midurethral slings, which will be available in the next year, will be even less invasive than TOT, as the sling will not have an exit site.

To date, we lack data from any long-term, randomized comparison of the two procedures, and we should not draw any conclusions until we have such long-term data. I believe we need to see a minimum follow-up of 2 years.

The data should accumulate quickly, however. In fact, a prospective, randomized comparison of TVT versus TOT has just been completed, so data should be forthcoming.

Regarding TVT specifically, we have

long-term data (up to 7 years) showing that TVT maintains its high cure rate of greater than 80%.

I sometimes use TOT in my practice; at this time, it seems especially reasonable

in patients at high risk for pelvic adhesions and in patients who have milder degrees of incontinence or SUI that is felt to be occult.

Performing TVT

The TVT procedure begins with the administration of a hemostatic agent and

an anesthetic. (We prefer lidocaine with epinephrine.) The anterior vaginal wall is injected at the level of the distal-to-midurethra.

It is important to appreciate that this portion of the anterior vaginal wall is fused to the posterior urethra. No clear plane of dissection exists between these two structures.

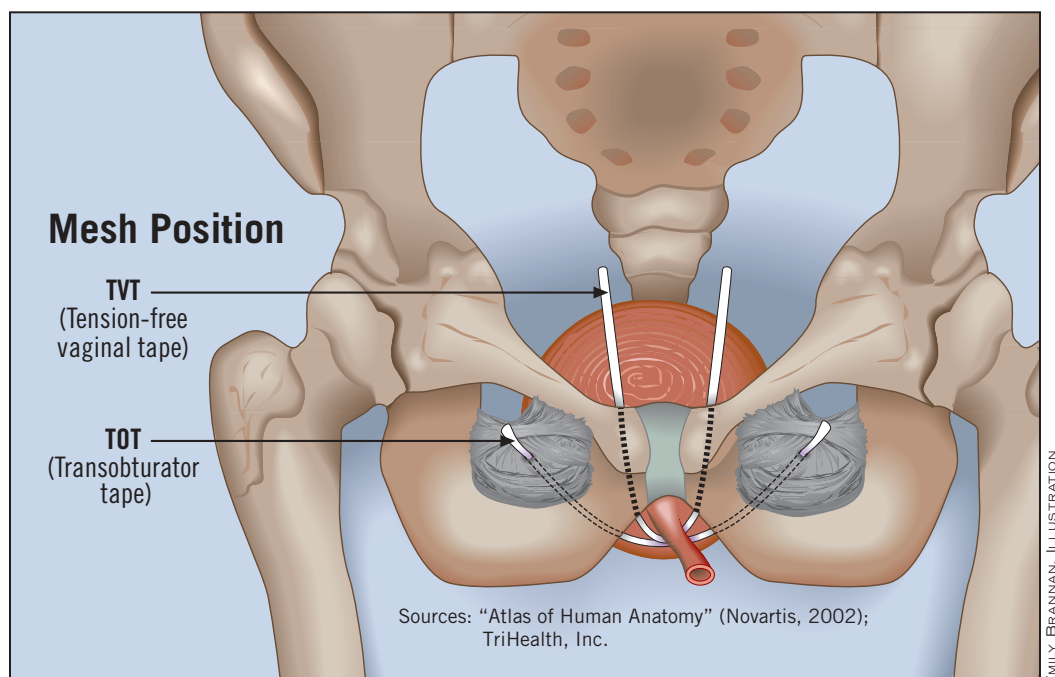
The tips of the scissors are then used to create two tunnels to the level of the in-

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MICKEY M. KARRAM, M.D.

Be certain that the needle tip maintains contact with the back of the pubic bone. This is a very important landmark, and using it will help avoid migration of the needle into dangerous areas.



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terior pubic ramus. The bladder is emptied and, using a catheter guide, the urethra is deflected in the direction opposite to the direction in which the needle is going to be passed.

The TVT needle is then directed toward the ipsilateral shoulder, and the tip of the needle is used to penetrate the urogenital diaphragm. No more than 0.5-0.75 inch of the needle should be passed in a lateral direction.

Once the urogenital diaphragm has been penetrated, the handle of the needle is dropped, and the tip of the needle is moved in a medial and superior direction. Be certain that the needle tip maintains contact with the back of the pubic bone. This is a very important landmark, and using it will help avoid migration of the needle into dangerous areas.

The next resistance that you will feel at the tip of the needle is the undersurface of the rectus muscle.

The needle is then used to penetrate the anterior abdominal fascia, and the tip comes up through the previously created stab wound. Cystoscopy is performed with the needle in place.

It is very important to overdistend the bladder and make sure that every millimeter of the bladder wall is visualized. Subtle penetrations can be easily missed if the bladder is not overdistended. Once it can be determined for certain that the needle has not penetrated the bladder, the needle is passed and the same procedure is repeated on the opposite side.

With the plastic sheath in place, you can achieve tensioning of the sling either through a cough stress test or suprapubic pressure. Some clinicians—believing that it's unnecessary to perform any sort of stress test—prefer just to place the sling loosely below the urethra, and that's fine.

If at all possible, I like to recreate SUI with suprapubic pressure or a cough, but at times this is not possible. With experience, you'll realize that the sling is placed very loosely most of the time. My end point in the majority of cases is being able to easily pass a right-angled clamp between the sling and the posterior urethra.

Preventing Complications

The most common complication of the TVT procedure is inadvertent penetration of the bladder. However, as long as this is diagnosed and the needle is withdrawn, the bladder emptied, and the needle repassed safely, penetration will rarely, if ever, cause any significant sequelae. In my opinion, these patients really do not even require any prolonged drainage, assuming that the penetration site is in a high, nondependent portion of the bladder.

Vascular injuries occur when the tip of the needle migrates away from the back of the pubic bone. Most commonly, this occurs when the needle is continued in a lateral direction and comes in close proximity with the obturator neurovascular bundle. If the needle is continued in a lateral direction, it may come in close proximity to the external iliac artery and vein.

Regarding bowel injuries, I strongly be-

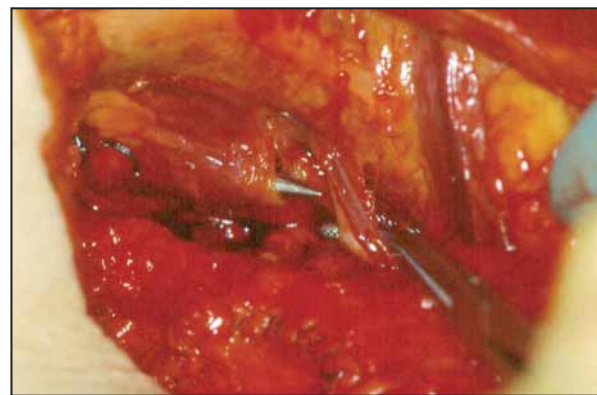
lieve that this procedure should be avoided in patients who are at high risk for significant pelvic adhesions. This category includes patients who have had a ruptured appendix with peritonitis, patients who have had severe endometriosis and are known to have significant pelvic adhesions, and any patient you feel might be at high risk for having bowel adhered very low in the pelvis.

And again, we must not underestimate the importance of maintaining the contact of the needle on the back of the pubic bone. It

is attention to specific anatomical landmarks such as this that make the operation both safe and successful.

A small percentage (less than 1%) of patients will have erosion of the tape. This outcome can be easily managed by either excising the eroded part of the tape or recovering it with healthier tissue.

Rates of partial or complete retention postoperatively—a problem after any operation for SUI—have been very low and can be managed by either stretching or cutting the tape. ■



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COURTESY DR. MICKEY M. KARRAM

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