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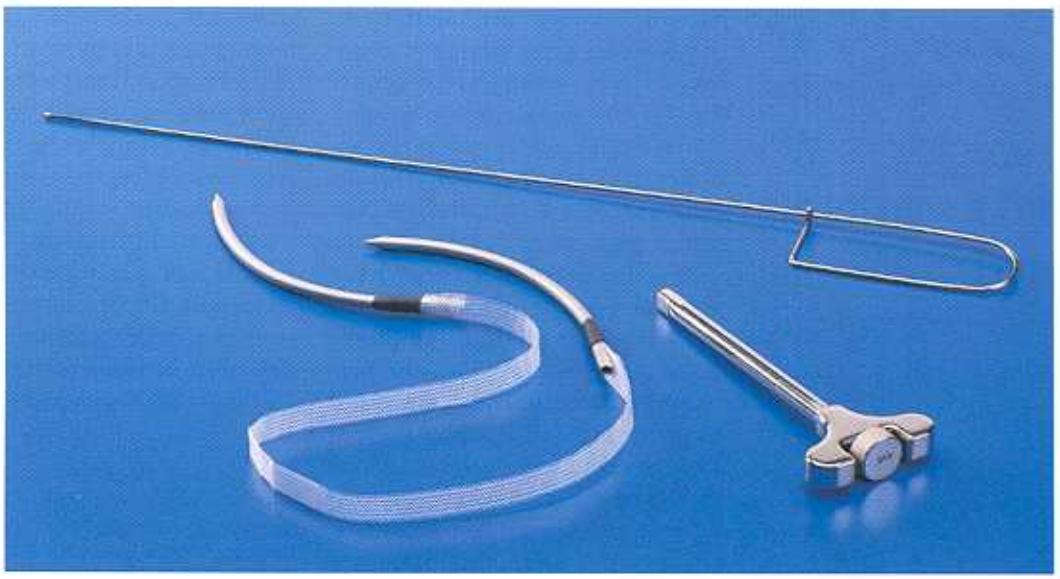
Surgical Techniques

Tension-free vaginal tape: a minimally invasive technique for treating female SUI



By Neeraj Kohli, MD,
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Tension-free vaginal tape: a minimally invasive technique for treating female SUI

By Neeraj Kohli, MD, John R. Miklos, MD, and Vincent Lucente, MD

Long-term data and more extensive clinical experience in this country are needed before we'll know if this promising new contender from Europe fulfills expectations. Will it or won't it surpass the suburethral sling and retropubic urethropexy procedures?

Urinary incontinence, already a significant health-care problem that affects some 25 million Americans at an annual cost of more than $20 billion, is expected to become increasingly more prevalent as the population ages.[1] Despite this and an evolving knowledge of the pathophysiology and anatomy of the normal continence mechanism, the best surgical procedure for treating female stress urinary incontinence (SUI) remains controversial (see "Pathophysiology of female stress urinary incontinence, page 3).

Recent meta-analyses have reported that the suburethral sling and retropubic urethropexy procedures are associated with the best long-term surgical cure rates based on currently available data.[2] Each of these procedures, however, is associated with specific disadvantages that limit their clinical applicability. Although the suburethral sling is a less invasive technique, which can be performed concurrently with vaginal repairs, it is associated with a steep learning curve and a high incidence of postoperative irritative bladder symptoms and voiding dysfunction, as well as the possibility of erosion.[3] In contrast, the retropubic urethropexy, while associated with less postoperative bladder dysfunction, requires an abdominal incision, with resulting increased morbidity and mortality and prolonged hospitalization and recovery. Although the laparoscopic approach to the latter procedure has gained popularity in recent years, it requires a high degree of operative skill and increased medical resources. Clearly, those factors limit its broad application in the current medicoeconomic environment.

Tension-free vaginal tape (TVT) was recently introduced in this country as a minimally invasive technique for the surgical correction of female genuine SUI. First described in Sweden by Ulmsten in 1995, the TVT procedure has been

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Pathophysiology of female SUI

Although a detailed discussion of the pathophysiology of SUI is beyond the scope of this article, a brief review may clarify the clinical applicability and surgical effectiveness of the TVT procedure. The exact mechanism of continence is complex and incompletely understood. The bladder at rest is a muscular reservoir capable of holding increasing volumes of urine while maintaining a low resting pressure, due to the compliance of the bladder wall. Continence is maintained by a high resting pressure in the urethra at the bladder neck due to three factors: a functional urethral sphincter mechanism, mucosal coaptation of the urethral lumen, and sympathetic stimulation of α-adrenergic receptors in the urethra. Whenever intra-abdominal pressure rises, the pressure gradient between the bladder and proximal urethra is maintained by equal transmission of pressure to both structures (zone of abdominal pressure transmission), thus ensuring continence. In addition, the vagina, which is slung hammock-like below the urethra from its lateral fascial attachments, acts as a backboard against which the urethra compresses during valsalva maneuvers.

Intrinsic sphincter deficiency. Female genuine SUI can result from static or dynamic changes in the continence mechanism at the bladder neck. A decrease in resting urethral tone due to sphincteric muscle dysfunction, denervation injuries, or decreased coaptive forces (secondary to hypoestrogenism, mucosal atrophy, radiation, or iatrogenic injury) results in intrinsic sphincter deficiency (ISD) Patients with ISD often present with severe incontinence with minimal stress or even leakage at rest.

Urethral hypermobility. In contrast, SUI due to urethral hypermobility is caused by relaxation of the pelvic floor musculature and fascial supports. Whenever abdominal pressure increases, this relaxation allows rotational descent of the proximal urethra outside the zone of abdominal pressure transmission—with no fixed backboard for mechanical compression. Patients with SUI were previously characterized as having either ISD (Type III Incontinence) or urethral hypermobility (Type II Incontinence), but recent data suggest that many may have a combination of the two. Preoperative multichannel urodynamic evaluation is helpful in determining the correct diagnosis.

used extensively in Europe since clinical trials established its safety and effectiveness as an ambulatory surgical procedure for the treatment of genuine SUI in women.[4]

Recent studies suggest that the TVT procedure is associated with high success rates comparable to the traditional suburethral sling procedure, yet may lower the incidence of intra- and postoperative complications. The procedure is routinely done via the vaginal route under local or regional anesthesia with a hospital stay of less than 24 hours. Moreover, the learning curve is short and outcome results seem to be uniform and independent of operator bias. These characteristics make the procedure suitable for patients with SUI due to either intrinsic sphincter deficiency (ISD) or urethral hypermobility. Conceptually similar to the suburethral sling, the procedure offers modifications that shorten the learning curve and minimize postoperative complications (Table 1). This paper reviews the technique, complications, and surgical outcomes of TVT.

TABLE 1

Potential advantages of TVT sling modification

- Shorter learning curve
- Possibility of concurrent vaginal repairs
- Shorter operative time
- Regional or local anesthesia options
- Shorter hospital stay and recovery
- Reduced incidence of postoperative complications*
  - ➤ urinary retention and incomplete bladder emptying
  - ➤ irritative bladder symptoms
  - ➤ infection
  - ➤ hemorrhage
- Cure rates comparable to traditional sling procedure*

*Long-term studies needed

The suburethral sling debate

Traditionally, anti-incontinence procedures such as the anterior colporrhaphy, needle-suspension modifications, and retropubic urethropexies have been used to treat SUI due to urethral hypermobility. On the other hand, injection of bulk enhancing agents and suburethral sling procedures have been reserved for the surgical treatment of ISD or recurrent incontinence. Recently, the suburethral sling has gained increased popularity for primary SUI, regardless of the underlying pathophysiology. Its proponents argue that the suburethral sling procedure corrects both urethral hypermobility and ISD by increasing resistance at the urethrovesical junction and creating a suburethral backboard (which prevents rotational descent during increased abdominal pressure). Outcomes data do support the clin-

ical effectiveness of the suburethral sling as a primary procedure; however, critics cite the high incidence of postoperative voiding dysfunction with this approach.

Presurgical procedure

We have performed this procedure on more than 50 women. Preoperatively, all patients undergo a complete history and physical examination (including detailed pelvic and lower neurologic exams). Initial office tests include a urinalysis, urine culture, and measurement of a postvoid residual (PVR) volume. Simple cystometry and cotton-swab testing are also routinely performed (Table 2). Information from these tests, together with the pre-visit 24-hour voiding diary and incontinence questionnaire, is then reviewed. Further evaluation, including multichannel cystometry, is performed as indicated. All patients should have objective documentation of SUI. TVT is contraindicated in women (1) who are pregnant or plan to be pregnant in the future, (2) who are on anticoagulation therapy, and (3) who have an acute urinary tract infection.

TABLE 2

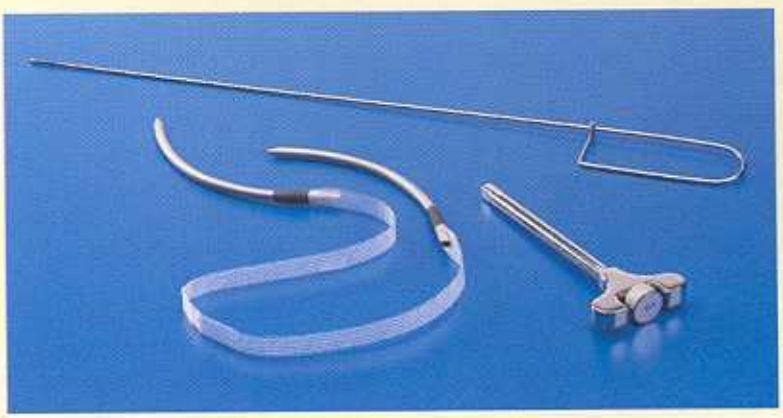
Suggested presurgical diagnostic workup

History (present illness, past medical/surgical history, review of systems, medications)
Physical exam (detailed pelvic exam and focused neurologic exam of perineum and lower extremities)
Urinalysis and urine culture
Measurement of postvoid residual (catheterization or bladder ultrasound)
Cystometry
Cotton swab test
Multichannel urodynamics (as indicated)

Anesthesia options. The TVT procedure can be performed under various types of anesthesia, depending upon patient preference and the need for concurrent surgical procedures. Initially, we recommend regional or local anesthesia with IV sedation, so that a cough stress test can be done intraoperatively. This simple step allows adjustment of the tape, maximizing efficacy and minimizing postoperative voiding dysfunction (PVD). Only after the surgeon has sufficient technical expertise to determine correct sling tension and position should the technique be done under general anesthesia. We recommend the routine use of prophylactic IV antibiotics and antiembolic compression stockings.

Essential tools. The TVT instrumentation consists of a reusable stainless-steel introducer, a reusable rigid catheter guide, and the TVT device, a single-use apparatus composed of a 1 × 40-cm strip of polypropylene mesh (Prolene, Ethicon, Inc., Somerville, N.J.) covered by a plastic sheath and held between two stainless-steel needles (Figure 1). The design of the plastic sheath has two purposes: to cover the synthetic mesh during placement of the sling (thereby reducing postoperative infection or graft rejection) and to allow easy passage/placement of the tape, which is configured to stay fixed in place once the smooth protective cover is removed (before the procedure is completed.)

FIGURE 1



Tension-Free Vaginal Tape system (Gynecare, Somerville, N.J.) consists of (clockwise from top) rigid catheter guide, stainless steel needle introducer, and TVT device with polypropylene mesh attached to stainless steel needles.

Surgical technique

The procedure is performed with the patient in the dorsal lithotomy position. An 18F Foley catheter is inserted into the urethra and the bladder emptied. Local anesthetic

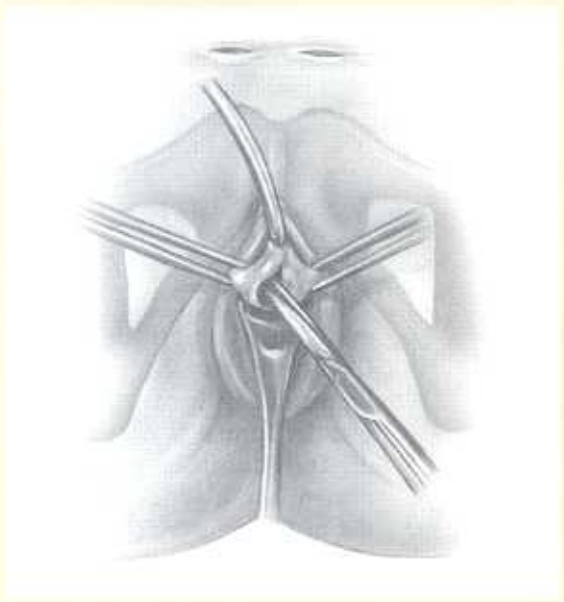
is injected suprapubically into the skin, the rectus fascia, and along the inner aspect of the pubic bone in the space of Retzius on both sides of the midline. The lower half of a Simms speculum is inserted into the vagina, allowing visualization of the anterior vaginal wall. Using gentle traction on the Foley catheter to identify the location of the bladder neck, local anesthetic is injected into the vaginal mucosa and submucosal tissues in the midline and bilaterally at the level of the midurethra.

Two small abdominal skin incisions (0.5 to 1.0 cm) are made on each side of the midline just above the pubic symphysis. A small sagittal incision (1.5 cm) is then made in the midline of the anterior vaginal wall approximately 1 cm proximal to the external urethral meatus. The edges of this incision are grasped using tissue clamps and minimal dissection is used to free the vaginal wall from the urethra and develop a small paraurethral space bilaterally (Figure 2). The rigid catheter guide is then inserted into the Foley catheter, facilitating identification of the urethra and the bladder neck during passage of the suspension needles. To minimize the risk of bladder or urethral perforation, the handle of the guide is deflected to the ipsilateral side just before inserting the suspension needle (Figure 3).

Adequate patient selection, knowledge of the relevant anatomy, and proper surgical technique are integral to performing the procedure safely and effectively.

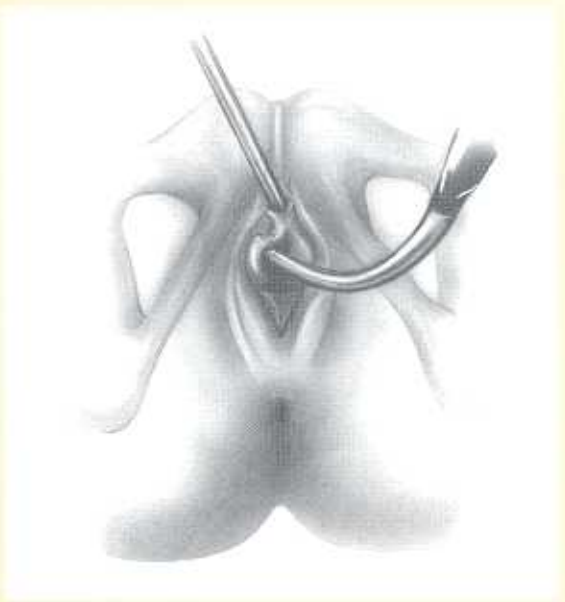
Before placing the sling, the introducer is attached to one of the stainless-steel needles and the

FIGURE 2



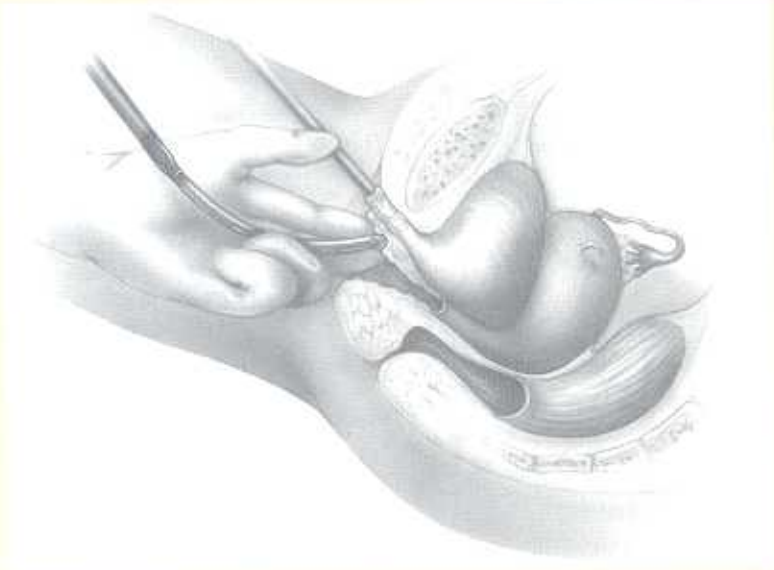
Paraurethral dissection is performed after an initial midline incision on the anterior vaginal mucosa at the level of the midurethra. Note the small suprapubic abdominal stab incisions bilaterally.

FIGURE 3



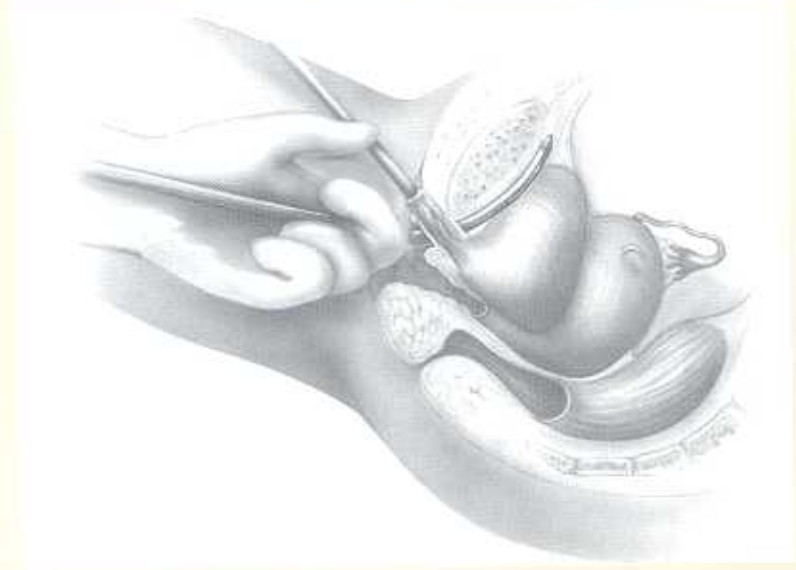
After bilateral dissection of the paraurethral space, the rigid catheter guide is inserted into the urinary catheter. The handle of the guide is deflected to the ipsilateral side and the needle is inserted into the paraurethral space.

FIGURE 4



The tip of the needle is angulated laterally and the endopelvic fascia is perforated just behind the inferior surface of the pubic symphysis.

FIGURE 5



After perforation of the endopelvic fascia, the tip of the needle is guided through the retropubic space along the backside of the pubic symphysis.

speculum removed from the vagina. The surgeon grasps the shaft of the introducer and then inserts the tip of the needle into the previously developed paraurethral space. The needle is angulated slightly laterally and the endopelvic fascia is perforated just behind the inferior surface of the pubic symphysis (Figure 4). Upon entering the retropubic space, the surgeon guides the needle up to the abdominal incision, maintaining contact with the back of the pubic bone and minimizing the risk of vascular or hollow viscous injury (Figure 5). A second layer of resistance is felt as the needle passes through the muscular and fascial layers of the abdominal wall. Passage of the needle is completed once the needle tip passes through the small abdominal incision on the corresponding side (Figure 6).

Unintentional bladder perforation should be excluded before completely extracting the suspension needle. The surgeon removes the rigid catheter guide and empties the bladder via the indwelling catheter. After catheter removal, cystoscopy is performed to confirm integrity of the bladder lumen. If needle penetration of the bladder lumen is noted, the needle-introducer assembly is withdrawn, the bladder drained, and the needle reinserted slightly more laterally. Once correct needle placement is confirmed, the needle is detached from the introducer and passed completely through the abdominal incision. This technique is then repeated on the contralateral side, ensuring that the

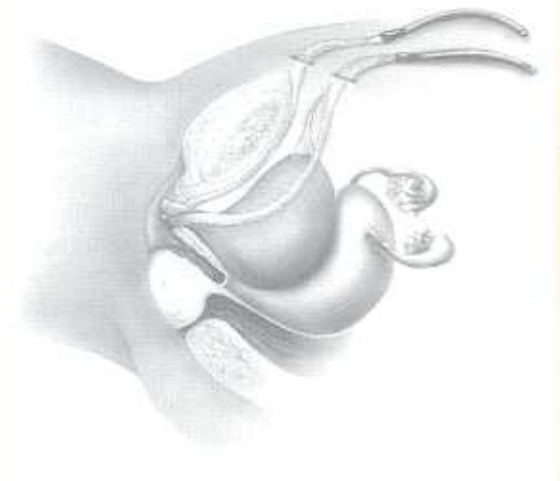
FIGURE 6

After perforation of the rectus fascia, a hand is used to palpate the needle tip suprapubically and guide the needle to the abdominal incision.

tape lies flat against the suburethral tissue at the level of the midurethra (Figure 7).

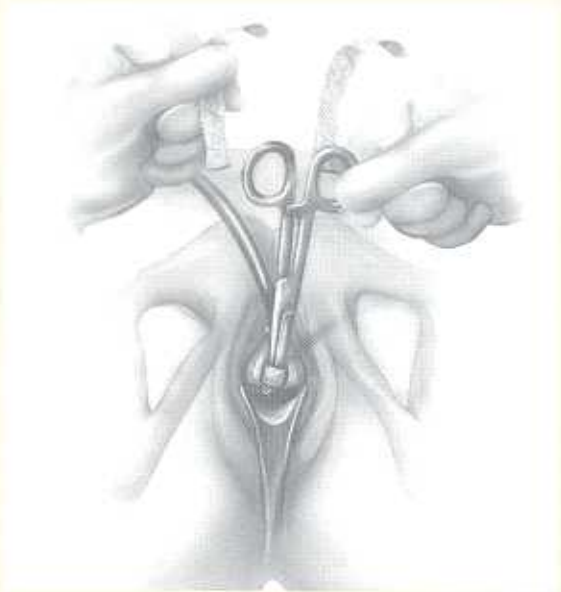
After passage of the needles is complete, a clamp or scissors is inserted between the suburethral portion of the tape and the urethra. Gentle traction on the abdominal ends of the tape relieves any excess tape material and brings the tape into contact with the instrument (Figure 8). Both ends of the tape are then cut where they attach to the needles. All instruments are removed from the surgical field and the patient, if awake, is asked to perform a cough stress test to ensure continence without overcor-

FIGURE 7



After the technique is repeated on the other side, the TVT sling is in place with the tape lying flat against the posterior surface of the midurethra.

FIGURE 8



The needles are detached and an instrument is placed between the tape and the urethra. Gentle traction on each end brings the tape in contact with the urethra and correct tension is adjusted with an intraoperative cough stress test.

FIGURE 9

The incisions are closed. The completed procedure allows fixation of the tape below the midurethra with the ends just below the skin level.

rection. The tension on the tape is adjusted as appropriate. Once identified, the plastic sheath of the abdominal ends of the tape is grasped with a forceps. After inserting an instrument between the urethra and the tape, the plastic sheath is removed, leaving the Prolene tape secured under the mid-urethra without tension. The vaginal incision is closed. Next, the surgeon cuts the abdominal ends of the tape just below the surface of the skin. Suture fixation is unnecessary because the friction between the tissues and the Prolene mesh holds the tape in place while maintaining adequate suburethral support. Finally, the abdominal tape incisions are closed using either subcuticular stitches or surgical tape (Figure 9).

Postoperative procedure

The indwelling urinary catheter is removed within the first 24 hours postoperatively and PVRs are checked by intermittent catheterization or bladder ultrasound. PVD, while uncommon, is easily managed. An indwelling Foley catheter is placed, then removed within 3 to 7 days postoperatively. As most patients experience minimal discomfort, adequate pain control can be achieved using oral nonsteroidal anti-inflammatory agents or narcotics. Although postoperative hematomas in the space of Retzius are extremely rare following the TVT procedure, we recommend ordering a postoperative hematocrit prior to discharge since the procedure involves blind passage of a suspension needle through the retropubic space.

Most women are discharged within 24 hours of surgery. Detailed instructions and postoperative precautions are discussed before discharge and a handout reviewing this information is given to the patient. Patients usually resume normal daily activities within 1 to 2 weeks of the procedure but are cautioned to avoid heavy lifting and strenuous exercise for up to 6 weeks postoperatively to promote adequate healing around the suspension graft. Patients are also instructed to abstain from sexual intercourse and avoid tampon use during this time. Patients are seen for routine follow-up 6 weeks postoperatively.

Potential complications

A recent multicenter study of 131 patients who underwent TVT reported a total complication rate of 3%.[3] Although rare, complications associated with the procedure include transient urinary retention, hemorrhage or hematoma formation, perforation of the bladder, and infection. Complications typically associated with the use of synthetic materials such as graft rejection or erosion, fistula or sinus formation, abscess, or hypersensitivity reactions were not reported in the most recent multicenter trial.

Urinary retention. Rarely, urinary retention or incomplete bladder emptying persists beyond the first 48 hours following TVT. In Ulmsten's original series of 75 patients who underwent TVT over a 2-year period, only five failed to void immediately after surgery but all subsequently voided normally within the first 48 hours, after overnight placement of an indwelling catheter. Wang and Lo reported a 17% (12/83) incidence of immediate postoperative voiding difficulty, which was easily corrected by inserting a Hegar dilator into the urethra with downward traction. All patients subsequently resumed normal voiding and none required long-term self-catheterization.[6] In the recent Swedish multicenter trial of 131 patients, all women voided within 24 hours postoperatively except for three who required an indwelling catheter for 3 days and one who performed intermittent self-catheterization for more than 10

FIGURE 10

TVT placement consists of *(left)* perforating the endopelvic fascia in an avascular space, *(center)* passing the needle through the retropubic space, and *(right)* pulling the Prolene tape through to the suprapubic incision.

days. The incidence and severity of PVD following TVT is significantly lower than that reported after traditional suburethral sling (2% 40%) or transvaginal needle suspension (2% to 50%) procedures.[7-10]

Hemorrhage. Although hemorrhage or hematoma formation may occur during the superficial vaginal dissection, bleeding in the retropubic space is a more significant potential complication during blind passage of the placement needles through the space of Retzius. Avoid surgery on patients with bleeding disorders or those currently taking anticoagulant medications and follow general surgical principles of hemostasis. Recent observation of needle passage through the retropubic space during TVT reveals a relatively avascular space if the procedure is performed as described (Figure 10). Disruption of the perivesical venous plexus, however, may cause excessive intraoperative bleeding that may require suture ligature, manual compression, or vaginal packing. An alternative technique, described by Katske and Raz during transvaginal needle suspension procedures, is the placement of a Foley catheter with a 30-mL balloon into the bleeding space to achieve transvaginal tamponade.[11]

Postoperative hematomas usually present within the first 12 hours and should be considered if the patient complains of increased suprapubic discomfort or has a significant decrease in hematocrit. Diagnosis can be confirmed by bimanual exam or U/S. Most hematomas resolve spontaneously without complication but U/S-guided drainage can be performed if necessary.

Bladder injury. Bladder perforation with the TVT placement needles is uncommon (<1%), and its incidence can be minimized by adequate paraurethral dissection, correct needle insertion, and the proper use of the rigid catheter guide after complete bladder drainage.[5] Performing intraoperative cystourethroscopy after the passage of each needle excludes bladder or urethral injury. If bladder perforation is noted, the needle is withdrawn and then introduced in a more lateral position. The unintentional cystotomy should be a safe distance from the trigone and ureteral orifices and equivalent in size to the defect left after removal of a suprapubic catheter. We recommend initiating a voiding trial after an indwelling Foley catheter has been in place for 2 days. The perforation will heal spontaneously.

Infection. Wound infection following the procedure is rare due to the use of preoperative IV antibiotics and the plastic sheath design, which protects the Prolene tape from contamination during passage, placement, and adjustment. Furthermore, Prolene has been associated with less risk of infection and rejection compared with other synthetic materials.[12] Current data suggest that wound infection occurs in less than 1% of patients and can be associated with vaginal atrophy or localized irritation of the vaginal wall. The use of preoperative estrogen cream may help reduce the incidence of this complication further. In patients with a wound infection, treatment with antibiotics, estrogen cream, and pelvic rest is usually sufficient and surgical intervention is rarely required.

Although the incidence of complications following TVT is extremely small, adequate patient selection, knowledge of the relevant anatomy, and proper surgical technique are integral to performing the procedure safely and effectively. Risks of the procedure are explained in detail to all patients and compared with similar data available for the traditional anti-incontinence procedures. As clinical experience with TVT increases,

A caveat from Luis E. Sanz, MD

The use of suburethral slings for long-term success in the treatment of genuine stress urinary incontinence, especially cases involving intrinsic sphincteric defect, is superior to any other method. However, complications of the synthetic suburethral procedure include urinary retention, refractory detrusor instability, and the most dreaded of them all—urethral erosion, which can lead to urethro-vaginal fistula. Any new suburethral sling procedure involving synthetic material requires careful prospective, well-controlled studies involving experts in the fields before it is attempted by other surgeons.

Also any new method has to be compared to the standard of care: the Burch retropubic colposuspension. The Burch procedure has an 85% to 90% success rate. Any new procedure has to have less serious morbidity than the standard Burch procedure.

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further information may change the incidence of complications. Of course, preoperative counseling will need to be adjusted accordingly.

Surgical outcomes

Because the TVT procedure has arrived only recently in this country, there is limited data regarding results in the United States. Clinical and basic science studies are currently in progress. Although European studies would suggest that the TVT procedure has 2-year cure rates comparable to both the retropubic urethropexy and suburethral sling, long-term results of this technique are still pending. Ulmsten's initial report on 75 women with urodynamically proven SUI cited a cure rate of 84% (63/75) with significant symptomatic improvement in another 8% (6/75) at 2-year follow-up. No improvement was seen in the remaining six patients, who all manifested surgical failure at the first postoperative checkup at 2 months. The average operative time was 22 minutes (range 16 to 42 min). All 75 patients were discharged within 24 hours of surgery and mean recovery time was 10 days.[13]

Wang reported a subjective cure rate of 87% and an objective cure rate of 83% in 70 women with follow-up ranging from 3 to 18 months. Mean operative time was 29 minutes (range 20 to 51 min) and average intraoperative blood loss was 75 mL (range 20 to 280 mL).[6] In the most recent prospective multicenter trial (involving 131 patients at six centers who had had SUI for an average of 3 years), a cure rate of 91% (119/131) was noted at a minimum of 12-month follow-up. Nine other women (7%) were significantly improved. Postoperative evaluation included a cough stress test at 250 mL, a quality-of-life questionnaire, 24-hour pad test, and—when possible—multichannel urodynamics. Mean operating time was 28 minutes (range 19 to 41 min) and six complications were noted: one bladder perforation, one wound infection in the vaginal-wall incision, three cases of immediate postoperative voiding dysfunction, and one small retropubic hematoma that spontaneously resolved. Although there's limited comparative data on the efficacy of TVT in women with urethral hypermobility vs. ISD vs. mixed incontinence, studies to date have included women with clinical parameters that suggested ISD. These patients' results have been comparable, with no significant decrease in surgical cure rate due to coexisting sphincteric dysfunction.

Mechanism of action. The clinical effectiveness of the TVT procedure is hypothesized to result from positioning of the sling material in the area of the mid-urethra, as well as possible changes in the collagen properties of the periurethral connective tissues induced by the synthetic tape. The Prolene tape is placed in the area of the mid-urethra in order to simulate the support mechanism of the pubourethral ligament and create support closest to the high pressure zone of the urethra. In addition, the specific needle instrument used to implant the sling creates narrow canals in the endopelvic fascia, which foster considerable adhesive forces. These fix the sling into the correct position once the plastic sheath is removed and minimize subsequent migration. The same forces theoretically act at the point of contact between the Prolene tape and the rectus fascia/retropubic space to provide tension-free fixation and suspension.[4]

Basic science. Histologic studies postulate that changes in the connective-tissue metabolism may reinforce the support function around the synthetic tape. Falconer and colleagues performed trans-

vaginal punch biopsies in the paraurethral area preoperatively and 2 years postoperatively following TVT. Histologic analysis with determination of collagen concentration and extractability revealed a significant increase in collagen metabolism postoperatively. Possibly alterations in the collagen metabolism induced by the TVT change the biochemical and biomechanical properties of the endopelvic fascia and restore the supportive properties of the connective tissue along the sling.[14] Although initial clinical and basic science studies on the TVT procedure are encouraging, further research is required to obtain more data supporting clinical effectiveness and further enhance understanding of its underlying scientific principles.

Conclusion

Surgical management of female SUI continues to challenge the gynecologic surgeon. Some current anti-incontinence procedures are associated with various postoperative complications that are often dependent on operator experience. Although controversy continues concerning the best surgical approach to female SUI, TVT appears to be a safe and effective minimally invasive surgical technique associated with a shortened learning curve and reduced risk of complication. As with any new sling procedure involving synthetic materials, more clinical research is needed. While clinical studies have demonstrated TVT cure rates comparable to currently practiced procedures, additional long-term data and clinical experience in the US are essential before the procedure can achieve widespread acceptance. □

Drs. Kohli, Miklos, and Lucente are all members of the Speaker's Bureau for Gynecare. Drs. Kohli and Miklos are paid consultants for the company, while Dr. Lucente serves as clinical instructor for its physician-training certification program.

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Tension-free Vaginal Tape (TVT) System

TVT Single Use Device
TVT Reusable Introducer
TVT Reusable Rigid Catheter Guide

INDICATIONS

The TVT device is intended to be used as a pubourethral sling for treatment of stress urinary incontinence (SUI), for female urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The TVT introducer and rigid catheter guide are available separately and intended to facilitate the placement of the TVT device.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE polypropylene mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

Do not use TVT procedure for patients who are on anticoagulation therapy.
Do not use TVT procedure for patients who have a urinary tract infection.

- Users should be familiar with surgical technique for bladder neck suspensions before employing the TVT device. It is however important to recognize that TVT is different from a traditional sling procedure in that the tape should be located without tension under mid-urethra.
- Acceptable surgical practice should be followed for the TVT procedure as well as for the management of contaminated or infected wounds.
- The TVT procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of needles will minimise risks.
- Retropubic bleeding may occur postoperatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The rigid catheter guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley Catheter.
- When removing the rigid catheter guide, open the handle completely so that the catheter remains properly in place.
- Do not remove the plastic sheath until the tape has been properly positioned.
- Ensure that the tape is placed with minimal tension under mid-urethra.
- PROLENE mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material.
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Post-operatively the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.
- Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilize TVT device. Discard opened, unused devices.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE mesh is designed to minimize the risk of contamination.
- Over correction i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.