

## TENSION-FREE VAGINAL TAPE (TVT): MINIMALLY INVASIVE TECHNIQUE FOR STRESS URINARY INCONTINENCE (SUI)

PAULO C. R. PALMA, CÁSSIO L. Z. RICCETTO, MÍRIAM DAMBROS, VIVIANE HERRMANN, MARCELO THIEL, NELSON R. NETTO JR.

*Department of Urology, Medical Sciences College, State University of Campinas (UNICAMP), Campinas, SP, Brazil*

### ABSTRACT

**Objective:** The procedure of tension-free vaginal tape (TVT) was recently introduced in the therapeutic armamentarium of stress urinary incontinence (SUI). It is a pubovaginal sling applied in mid-urethra. The authors describe their experience with this technique.

**Materials and Methods:** During the period of May, 1999 to March, 2001, 110 patients (median age=53 years) were submitted to TVT implant for the treatment of stress urinary incontinence. Clinical exam and urodynamic studies were performed previously to surgery. All patients referred symptoms consistent with stress incontinence, and 35.7% complained of associated voiding urgency. Sixty-eight percent of the group reported previous continence procedure. Urethral hypermobility was diagnosed in 42% of patients (mean Valsalva leak point pressure under median effort of 110 cmH<sub>2</sub>O), and 58% had intrinsic sphincter deficiency (mean Valsalva leak point pressure under effort of 55 cmH<sub>2</sub>O).

**Results:** Mean patient follow-up was 18 months. Ninety-two percent of the patients were submitted to anesthetic blockade and 8% to local anesthesia. Mean length of the procedure was 30 minutes. Dystopy correction, when present, was performed in the same procedure. Mean hospital stay was 24 hours. There was bladder perforation in 13% of cases of TVT. There was no urethral or vaginal erosion. Twenty patients (18%) developed urgency symptoms during post-operative period, and 5 (4.5%) presented urge incontinence. During this follow-up period, 81% remained continent, 9% referred improvement of the symptoms compared to before the procedure and 10% were not satisfied.

**Conclusion:** Our data allow us to conclude that TVT procedure is safe, rapid and promoting adequate levels of continence in mean term.

**Key words:** urinary incontinence, stress; therapeutics; surgical procedures; prostheses and implants  
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### INTRODUCTION

The use of autologous pubovaginal slings has been the preferred approach for treating difficult cases of stress urinary incontinence (SUI) (1). This preference to synthetic material occurs greatly because of two basic issues: implant infection and urethral erosion (2).

On the other hand, the use of synthetic slings transforms a complex surgery in a minimal invasive

procedure, reducing not only surgical time, as well as hospitalization period, post-operative discomfort and time to recovery (1).

Recently, tension-free vaginal tape (TVT) was introduced in therapeutic armamentarium, a synthetic sling applied without tension, eliminating the issue of urethral erosion.

The paradigm's change is not just in eliminating the tension, which was already advocated by many authors, but primarily placing the sling by vagi-

nal route, in mid- or distal urethra, instead of placing it in the bladder neck (3).

According to integral theory of continence (4), pubourethral ligament together with pelvic floor muscles make distal and midurethra the most important regions for urinary continence.

These new conceptions, associated to the fact that sling surgeries are now widely used, makes TVT an alternative for the surgical treatment of SUI.

The authors present their experience with TVT for the surgical treatment of SUI.

## MATERIALS AND METHODS

A prospective, randomized clinical trial was performed with SUI patients. The project was approved by the Committee of Ethics of the Hospital.

In the period of May, 1999 to March 2001, 110 patients with a diagnosis of SUI were submitted to TVT implant. Patients' ages ranged from 42 to 72 years, median of 53 years. Patients were submitted to clinical examination and urodynamic study previously to surgical procedure.

After the surgery the patients returned monthly to the ambulatory for a clinical evaluation. In that moment they were questioned about presence of spontaneous voiding, involuntary urinary leakage, irritative bladder symptoms, vaginal and suprapubic pain, in addition to questions about their satisfaction with the procedure.

In the absence of urinary leakage complaint the patients were classified as continent. In the presence of this symptom, the patients were grouped according to the severity of the leakage reported: a)- More than 75% improvement from pre-operative

symptoms; b)- 50-75% improvement from pre-operative symptoms; c)- Less than 50% improvement; d)- No alterations of the symptoms, or worsening, after the surgery.

In addition to the clinical history, we proceeded to physical examination to evaluate the presence of urinary leakage, signs of infection and erosion in vaginal wall.

In urodynamic study diagnosis of SUI due to urethral hypermobility was made for patients presenting Valsalva Leak Point Pressure (VLPP) above 90 cmH<sub>2</sub>O, and intrinsic sphincter deficiency when VLPP was less than 90 cmH<sub>2</sub>O during urodynamic study (Table-1). Patients presenting involuntary detrusor contractions during bladder filling, or bladder outlet obstruction were excluded from the study.

In 35.7%, patients reported voiding urgency associated to the symptoms of urinary leakage, and 68% reported history of previous surgical procedure for the treatment of incontinence, the most frequent procedure being Kelly-Kennedy surgery (86%).

At gynecological examination presence of cistocele was verified in 34 patients (31%), and in 94% of the cases it was grade I and in the remaining it was grade II. For 12 patients (11%) rectocele was diagnosed e for 8 (7%) perineal rupture. For grade I cistoceles repair was not performed; the procedure was executed in grade II cistoceles. Dystopy correction was performed at the same surgical time during TVT implant.

## SURGICAL TECHNIQUE

The procedure was performed with the patient in dorsal lithotomy position and spinal anesthesia for the majority of the patients. One hundred and

**Table1** - Pre-operative urodynamic study of patients submitted to tension-free vaginal tape (TVT) procedure.

	No. of Patients (%)	Mean VLPP cmH <sub>2</sub> O	VLPP variation cmH <sub>2</sub> O
Urethral hypermobility	46 (42)	110	94-121
Intrinsic sphincter deficiency	64 (58)	55	20-82

VLPP: Valsava Leak Point Pressure.

one patients (92%) were submitted to spinal anesthesia and 9 (8%) to local anesthesia and intravenous sedatives. In cases where it was necessary to have surgical correction of dystopy, we choose, primarily, spinal anesthesia. In cases where local anesthesia was used, the patient received intravenous Midazolam™, 1mg before the procedure. For local anesthesia, we used 20mL 1% Marcain™ in 40mL of saline solution, and initially 5mL were applied in skin and subcutaneous on each side, near the superior edge of the pubic bone. Then, with a 22G spinal needle introduced near the pubis in Retzius space, 15mL of the solution were applied bilaterally. Vaginal anesthesia was performed by the injection of 20mL of anesthetic solution on sub- and paraurethral regions, 1cm from urethral meatus, as well as in vaginal pillars.

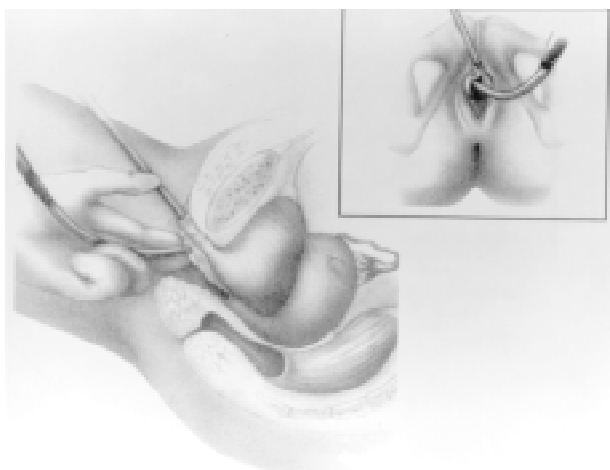
Two small 1cm transversal incisions were performed near each side of the superior edge of the pubic bone to exteriorize TVT trocar in this region. In the sequence, a median vaginal incision of approximately 1.5cm was performed, initiating 1cm from urethral meatus proximally, avoiding the bladder neck. Then, with a Metzenbaum scissor, each side was bluntly dissected laterally, creating a 1cm tunnel, large enough to introduce the tip of TVT trocar, which device was formed by a polypropylene mesh covered by a plastic sheath, a curved trocar at each end, a

metallic introducer, and a straight metallic catheter guide to introduce a Foley 20F catheter.

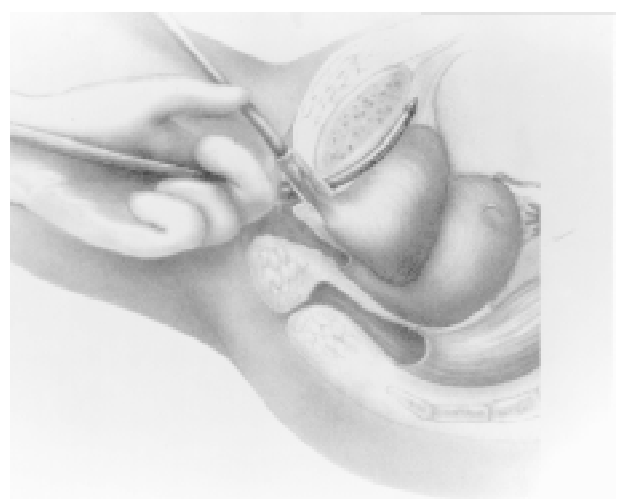
A Foley 20F catheter was introduced and bladder was emptied and, in the sequence, with a metallic guide within this catheter, the bladder was displaced away from the trocar. The sling, that possesses a 5mm trocar at each end, was then prepared, introducing one of these trocars in the introducer, and then guiding in the previous dissected tunnels. Before the trocar, the catheter with the metallic guide was lateralized in the same side where the trocar was introduced.

This trocar must be directed to the ipsilateral shoulder of the patient, through two movements: in the first one, the trocar must progress horizontally until it perforates endopelvic fascia (Figure-1). The second movement consisted in a bascule movement, making the trocar progress through the space of Retzius, tangent to pubis periosteum until attaining suprapubic region, perforating rectus muscle and its fascia, exteriorizing it through the incision previously performed (Figures-2 and 3).

The Foley catheter was removed and a cystoscopy performed to assess possible bladder perforation. In case of perforation, the trocar was removed and a new passage was made. Finally, the introducer was removed and the trocar pulled, leading it to suprapubic region.



**Figure 1** - Fingertip control in the anterior vaginal wall guides the needle cephalad and lateral toward the ipsilateral shoulder, and the endopelvic fascia is perforated.



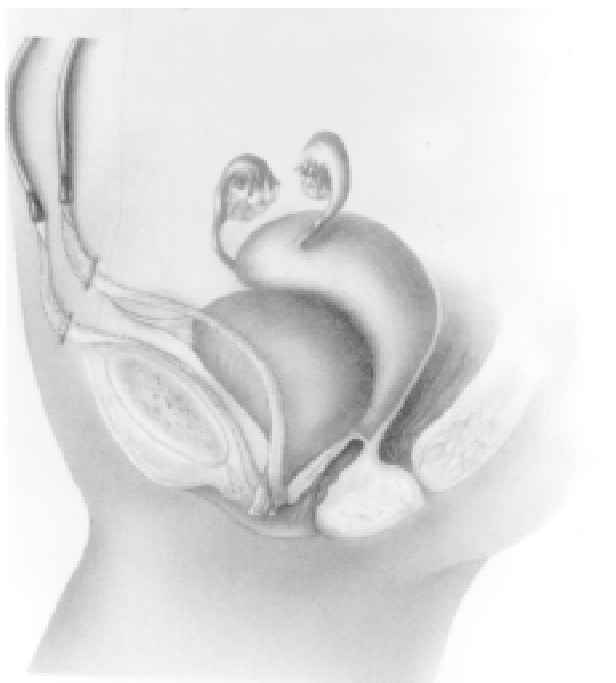
**Figure 2** - After perforation of the endopelvic fascia, the needle is directed through the retropubic space along the inner surface of the pubic bone.



**Figure 3** - After perforation of the rectus fascia, a hand is placed suprapubically to guide the needle tip through the stab incision.

The same procedure was repeated on the contralateral side, obtaining thus a U-loop of the pubovaginal sling in mid-urethra (Figure-4).

The trocars were maintained in suprapubic region and the adjustment of the tension was made

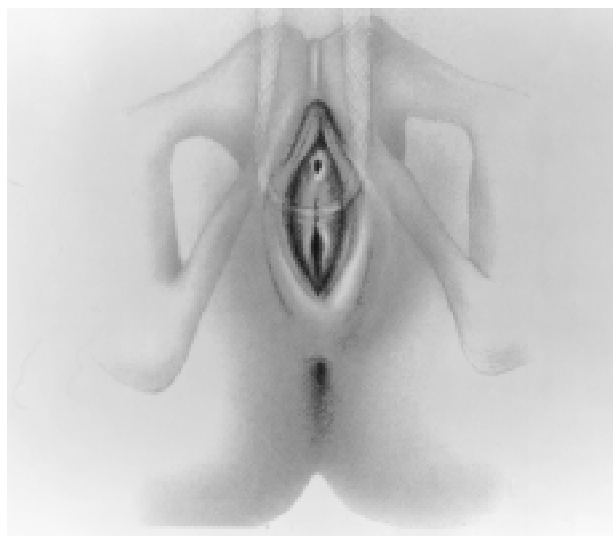


**Figure 4** - Once the technique is repeated on the contralateral side, the TVT sling should lie flat against the posterior surface of the mid-urethra.



**Figure 5** - With long, heavy Mayo scissors placed between the tape and the urethra, gentle tension on each end of the tape sling in contact with the scissors for proper placement.

before the removal of the plastic sheaths (Figures-5 and 6). In patients submitted to local anesthesia, the tape adjustment was made by the injection of 300mL saline solution, asking the patient to cough vigorously and, in cases of presence of urinary leakage, the ends of the sling were slightly pulled until continence was observed. In cases where spinal anesthesia was used, intraoperative adjustment of the tape was not performed.



**Figure 6** - The completed procedure with the sling in place within the tissues at the mid-urethra.

Before removing the plastics sheaths, a scissor was placed between the TVT tape and the urethra. Then the TVT ends were sectioned near to the skin, and suprapubic and vaginal incisions were closed in standard fashion.

No indwelling catheter was left in place, except for the cases of bladder perforation where the catheter was maintained for 48 hours.

Antibiotics prophylaxis was made with sodium cefalexine 1g 1h before the surgery and q6h until completing 24h.

## RESULTS

Patients mean follow-up was 18 months, range from 2 to 24 months. Mean length of procedure was 30 minutes, range from 20 minutes to 1h30min. In cases of dystopy correction, surgical time increased approximately 40 minutes. Mean hospital stay was 24 hours (range from 12 to 36 hrs). Inadvertent bladder perforation, in its superolateral wall, occurred in 14 patients (13%), which maintained bladder catheter for 48 hours, with no further complications. Post-operative urinary retention occurred in 10 patients (9%), among these 9 (90%) voided spontaneously in up to 14 days from the surgical procedure. These patients were treated with bladder catheter in the first 7 days and, then, with clean intermittent catheterization until resolution of the urinary retention. In one patient a surgical lyses of one side of the TVT was required 2 months after the implant, due to persistent retention, and she has progressed without retention and continent.

No vaginal wall infection neither tape erosion for the urethra or vagina was observed. Irritative post-voiding symptoms were reported by 32 patients (29%) during early post-operative period (until 4 weeks after the surgery), 20 (18%) maintained urgency symptoms, and 5 (4.5%) had urge incontinence complaints sustained. This group of patients was submitted to a new urodynamic evaluation, evidencing detrusor instability in 38 patients (35%), urinary incontinence with VLPP less than 60 mmH O in 33 (30%), and absence of significant alterations on the remainder. Patients with detrusor instability were fol-

lowed and treated with oral anticholinergic agents. No case required the removal of TVT due to failure of drug therapy.

Until the follow-up described, we observed that 89 patients (81%) were continent, 10 (9%) reported improvement over 75% and 11 (10%) were unsatisfied with the procedure.

## DISCUSSION

There is a consensus in recent studies that pubovaginal sling and retropubic urethrocystopexy are the therapeutic techniques of stress urinary incontinence offering the best continence results after long term follow-up (1). However, slings imply a considerable time of surgical training, presenting the inconvenience of requiring a donator region for harvesting the fascia to be used, besides the risk of bladder outlet obstruction and other bladder dysfunctions (3). On the other hand, retropubic urethrocystopexy imply performing an abdominal incision, with increases in morbidity and hospital stay and, when performed by laparoscopy, promotes important cost elevation, in addition to the required learning curve (4). Thus, the need for the development of minimal invasive techniques is warranted.

TVT corresponds conceptually to a sling and, thus, promotes an increase of urethral resistance because of the creation of a suburethral support zone, avoiding rotational and descending urethral movement, when elevation of abdominal pressure occurs. In addition, it facilitates the coaptation of urethral lumen at rest and with straining. However, contrarily to classical pubovaginal slings, TVT is applied in mid-urethra, where pubourethral ligaments are inserted, responsible for natural stabilization of the urethra (5). Maintenance of the tape in an adequate position may be explained by its saliencies and indentations, and by the "nipping" effect of pelvic fascias and rectus muscle, and of local inflammatory reaction (6,7).

Until today, no specific problems were described to this technique, but blood dyscrasia is considered a contraindication because retropubic space dissection is performed without direct vision, and there is risk of vascular lesion. Thus, as in other techniques for treating SUI and, specially, because it deals



with synthetic material, a careful vaginal antisepsis is required, as well as excluding urinary tract infections and vulvovaginitis. Although in our study there is a predominance of patients with previous continence surgeries for stress urinary incontinence, no significant complications or difficulties were observed during the surgery. Contrarily to that previously described with the use of synthetic sling (2), no rejection of the implanted material was observed. This may be due by the minimally invasiveness of the procedure, associated to a small surgical time and the use of prophylactic antibiotics before the surgery.

Although our series does not show post-operative urodynamic evaluation, we may suppose that this technique does not alter voiding pressure, as it happens with periurethral injections. TVT is applied without tension and does not limit bladder neck opening, as conventional slings do (7). Though our series present 9% of urinary retention, this may be due to spinal anesthesia used in 90% of patients, and have no direct relation to the surgical technique used. We have chosen spinal anesthesia because we are in an faculty service where resident doctors are trained, and that makes patient manipulation easiest, bringing as minimal discomfort as possible.

Consistency with physiological principles of urinary continence in women, and cure rates above 80% in 2 years mean follow-up (8,9) warrant stating that this procedure is a promising progress in SUI surgical treatment. This is a less invasive surgery that may be performed on an ambulatory basis and with good cost-benefit profile.

## CONCLUSION

TVT is a minimal invasive surgical procedure for the treatment of stress urinary incontinence. Although a recent and costly procedure for the majority of our patients, it has been presenting satisfactory and lasting results that encourage its use in surgical practice.

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## Correspondence address:

Dr. Míriam Dambros  
Rua Engenheiro Edward de Vita Godoy, 966 / 12  
Cidade Universitária, Distrito de Barão Geraldo,  
Campinas, SP, 13084-090, Brazil  
E-mail: miriamdambros@hotmail.com