

# Comparison of tension-free vaginal tape and transobturator tape procedure for the treatment of stress urinary incontinence

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**Current Opinion in Obstetrics and Gynecology**  
2009, 21:342–347

## Purpose of review

The aim of this review was to assess the recent evidence on the effectiveness and complications of tension-free vaginal tape (TVT) and transobturator tape (TOT) procedures for female stress urinary incontinence between January 2008 and March 2009.

## Recent findings

A meta-analysis of recent studies revealed that the short-term objective cure rate was borderline worse in the TOT group compared with TVT [odds ratio (OR) 0.62; 95% confidence interval (CI) 0.37–1.00;  $P=0.05$ ]. Bladder perforation (OR 12.23; 95% CI 2.86–52.34) was significantly more common, whereas groin/thigh pain was significantly less in the TVT group (OR 0.32; 95% CI 0.11–0.92;  $P=0.022$ ). Postoperative urinary retention was slightly more in women undergoing TVT than those undergoing TOT (OR 1.6; 95% CI 0.90–3.12;  $P=0.06$ ). The rates of vaginal erosion (OR 0.34; 95% CI 0.09–1.33), de-novo urgency (OR 1.21; 95% CI 0.52–2.79) and urinary tract infection (OR 0.88; 95% CI 0.56–1.38) were comparable in both procedures. In addition, TVT appeared to be more obstructive than TOT, as evidenced by ultrasonographic and urodynamic findings. Changes in sexual function need further investigation because this issue has not been well studied for either sling procedure.

## Summary

TOT has the advantages over TVT with shorter operative time and a relatively lower complication rate. For women with intrinsic sphincter deficiency, however, TVT appears to be a better option because it is more obstructive.

## Keywords

stress urinary incontinence, tension-free vaginal tape, transobturator tape

Curr Opin Obstet Gynecol 21:342–347  
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1040-872X

## Introduction

Stress urinary incontinence (SUI) is defined as the involuntary leakage of urine on effort, exertion, or coughing [1]. These symptoms are rarely life-threatening but always cause a negative impact on quality of life, such as physical, psychological, and social well being of the affected women. Surgery is the most effective treatment for SUI. There are over 100 types of anti-incontinence surgeries invented by Kelley's placcation reported in 1914 [2]. In the last decade, midurethral synthetic sling has become the most popular procedure for female SUI. The two main categories are tension-free vaginal tape (TVT) and transobturator tape (TOT) procedures.

## Tension-free vaginal tape

In 1995, Petros and Ulmsten [3] introduced a new, minimally invasive surgery for the treatment of female

SUI, namely the TVT procedure. On the basis of the integral theory, continence can be achieved by placing a vaginal tape underneath the midurethra without tension to reinforce the weakened pubourethral ligament [3]. It has become one of the most popular procedures for female SUI because of its excellent results [3,4]. The 11-year follow-up with durable cure rate (81%) has been published [4]. However, the common use of the TVT has been associated with various operative complications, including bladder perforation, major blood vessel injuries [5], and postoperative voiding difficulties [6].

## Transobturator tape

In an attempt to reduce the morbidity of retropubic needle passage, an alternative approach with a transobturator route of prolene tape (UraTape, Porges-Mentor, Lisses, France) (TOT) has been developed by Delorme [7] in 2001. More recently, de Leval [8] designed a TOT

inside-out procedure (TVT-O) (Gynecare TVT-Obturator System, Ethicon, Inc., Somerville, NJ) in 2003. This procedure can be performed more easily than the outside-in technique because an index finger is not put in the vaginal incision to guide the needle coming from the outside. In theory, the TOT sling lies in the midurethra at less of an acute angle compared to the TVT, and it is not likely to obstruct urine flow during voiding. However, this transobturator procedure does not completely eliminate the risks of bladder perforation or nerve injury [9]. A French study of 984 women undergoing TVT-O reported a high cure rate (90%) and acceptably low complication rate at 12 weeks [10].

The review of this literature was performed by searching PubMed listings using keywords of ‘tension-free vaginal tape’, ‘transobturator tape’, ‘stress urinary incontinence’, ‘TVT-O’, and ‘TOT’. The following limits were employed: human, sex (female), language (English), and since January 2008 to March 2009. As a result, 146 articles were retrieved. A total of 11 articles were included in the analysis of our article: three randomized controlled trials (RCTs) comparing TVT and TVT-O [11–13]; three RCTs comparing TVT and TOT outside-in procedure [14,15\*,16]; and five cohort studies reporting on comparison of TVT and TOT (two TVTO and three outside-in procedures) [17,18\*,19–21]. A meta-analysis of RCTs was conducted with the use of the NCSS 2004 and PASS (Number Cruncher Statistical System, Kaysville, Utah, USA). Statistical heterogeneity was tested through the Chi-square test. A *P*-value less than 0.1 was used to indicate heterogeneity. For dichotomous data, results of each study were expressed as an odds ratio (OR) with 95% confidence interval (CI).

### Objective cure rate

The primary outcome in all RCTs was reported in a variety of ways. Three studies reported on objective cure rates [13,14,15\*] and one focused on subjective cure rate [11]. The remaining two studies assessed the changes in quality of life or reoperation rate [12,16]. Figure 1 shows the summary of the effectiveness of TOT (TVT-O and outside-in TOT) in comparison with TVT. The short-term objective cure rate was borderline worse in the TOT group (OR 0.62; 95% CI 0.37–1.00), nearly reaching statistical significance (*P* = 0.05). A possible explanation was that only inclusion of women with intrinsic sphincter deficiency (ISD) in the study of Schierlitz *et al.* [15\*], magnifying the difference of cure rates in both procedures. A number of previous studies obtained similar results in which TOT was more likely to fail than TVT in women with low maximum urethral closure pressure (less than 40 cmH<sub>2</sub>O) [20–24]. Reports of cure rates after a midurethral sling procedure may depend on the type of SUI (urethral hypermobility or ISD) [15\*,20–24], the symptoms of incontinence (pure SUI or mixed incontinence), age, and whether this time was to treat primary or recurrent SUI [25].

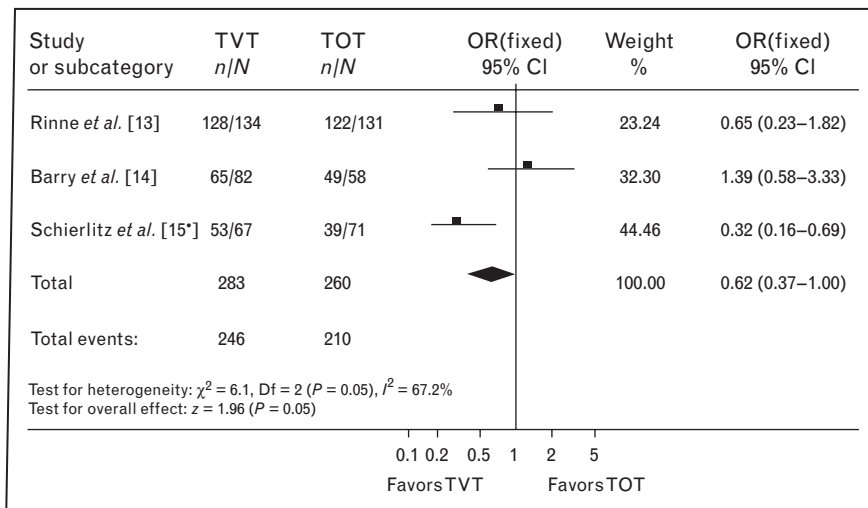
### Complications of tension-free vaginal tape and transobturator tape

Complications of both TVT and TOT procedures may arise.

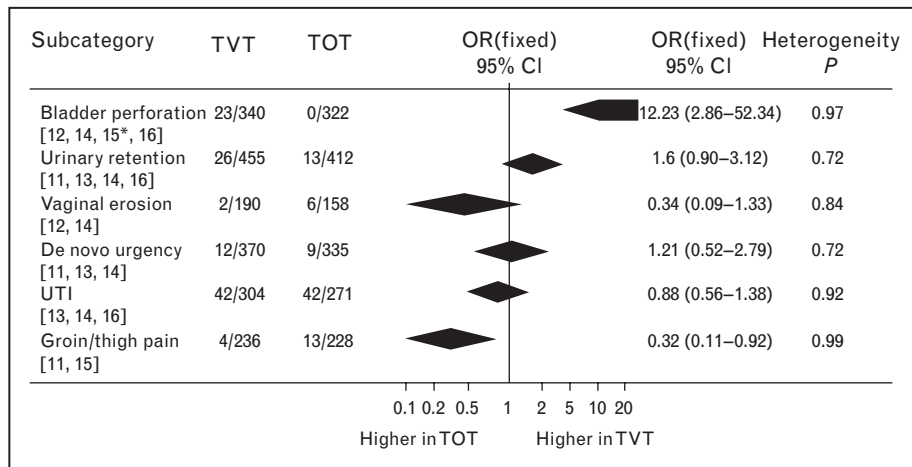
#### Bladder perforation

When compared with TOT, the incidence of bladder perforation (OR 12.23; 95% CI 2.86–52.34) (Fig. 2) was significantly more common in TVT procedure. The necessity for cystoscopy during TOT is controversial,

**Figure 1 Objective cure of stress urinary incontinence after TVT versus TOT procedure**



**Figure 2 Risk of complications with TVT for stress urinary incontinence (compared to TOT)**



TOT, transobturator tape; TVT, tension-free vaginal tape.

as bladder or urethral injuries are rare but not impossible. A retrospective study revealed all injuries of lower urinary tract during the TOT occurred only in the outside-in group, though this difference between the inside-out and outside-in procedures was not statistically significant [26]. Therefore, cystoscopy is still recommended for TOT, especially in women with previous hysterectomy or significant cystocele. Another advantage of routine cystoscopy is the incidental finding of intravesical diseases [27,28].

#### Urinary retention

Postoperative voiding dysfunction, most commonly in the form of urinary retention, was found to be borderline more in women undergoing TVT than those undergoing TOT (OR 1.6; 95% CI 0.90–3.12) (Fig. 2). This may be due to the fact that more horizontally placed tape of TOT may be less obstructive. Therefore, TOT may be more suitable for women with low flow rates preoperatively. Although most urinary retention resolves with conservative treatment including medication, urethral dilation, or intermittent catheterization, refractory urethral obstruction ultimately requires midline or lateral excision of tape [6,29]. Surgical results are comparable in both methods. One study found recurrent SUI is unlikely to occur when the takedown procedure is performed beyond 14 days after the initial operation [6].

#### Vaginal erosion

When compared with TOT, the vaginal erosion was found to be less in the TVT group (OR 0.34; 95% CI 0.09–1.33) (Fig. 2), yet it was not statistically significant. Although the erosion rate of initial TOT tape (UraTape) was much higher due to the microporous material, current rates of vaginal erosion with macroporous monofilament polypropylene do not exceed 3% [30]. A recent review

study found the vaginal erosion rate was doubled in the TOT group [31\*\*]. A possibility is that vaginal wall perforations are more common in the TOT group [12,14], and this may contribute to a higher rate of vaginal erosion. Other factors related to erosion include diabetes mellitus [30], inadequate vaginal mucosa coverage, infection, or radiation [32].

#### De-novo urgency symptoms and urinary tract infection

De-novo urgency symptoms (OR 1.21; 95% CI 0.52–2.79) and urinary tract infection (OR 0.88; 95% CI 0.56–1.38) were similar in both TVT and TOT procedures (Fig. 2). In fact, de-novo urgency may occur after any sling procedure in women with urodynamic stress incontinence [33]. More horizontal tape may cause less urethral compression and irritative symptoms. However, whether the TOT is more beneficial in women with preoperative overactive bladder (OAB) symptoms remains controversial. Interestingly, both TVT and TOT are also associated with resolution of preoperative OAB symptoms in half of those patients with mixed incontinence and predominant SUI [18\*,34]. It is known that frequent appearance of urine in proximal urethra easily induces a reflex detrusor contraction [35]. Absence of urinary leakage may decrease this reflex following anti-incontinence surgery.

#### Groin/thigh pain

As expected, postoperative groin/thigh pain at 6-month follow-up was significantly less in the TVT group than in the TOT group (OR 0.32; 95% CI 0.11–0.92;  $P=0.022$ ) (Fig. 2). On subgroup analysis, this condition seems to be more in the TVT-O (inside-out) procedure [11], not in the outside-in procedure. A recent RCT included 120 women assigned to either TVT-O or outside-in TOT procedure under local anesthesia, and the TVT-O appeared to be more painful [36]. The possible cause

was that the exit point of the TVT-O needle is closer to the adductor muscle and obturator neurovascular bundle, compared with the outside-in TOT [37]. The groin pain may be unilateral or bilateral, and seldom persists beyond 1 year after surgery [13].

### Ultrasonographic comparison

On ultrasound assessment, Long *et al.* [17,18<sup>\*</sup>] compared TVT and TVT-O, showing the middle of the TVT-O tape was localized more distally than the TVT at rest or during straining. A higher rate of urethral kinking during straining was noted in the TVT group compared with the TVT-O group (86.9 versus 23.9%). Another study by Chene *et al.* [38<sup>\*</sup>] was carried out on a frontal plane, and the angles between two arms of suburethral slings at rest were found to be TVT-O (138°) > TOT (outside-in) (131°) > TVT (116°). Moreover, larger angulation at rest appeared to be significantly associated with surgical failure [38<sup>\*</sup>]. As TOT is less obstructive than TVT, the severity or types of SUI may be potentially a parameter that could help surgeons to choose the most appropriate procedure [12].

### Urodynamic comparison

Table 1 shows randomized and nonrandomized studies presenting the urodynamic changes following TVT and TOT. Following the TVT, decreased maximum flow rate was observed in two studies [14,15<sup>\*</sup>], and increased urethral closure pressure area was found in another two studies [18<sup>\*</sup>,21]. These findings also implied that TVT appeared to be more obstructive than TOT, although both procedures had no significant impact on bladder storage and voiding functions.

### Sexual function

Murphy *et al.* [39] examined 239 stress-incontinent women treated with TVT or TVT-O using the Pelvic Organ Prolapse/Incontinence Sexual Questionnaire (PISQ-12), and found no significant difference in sexual function between the two groups. Another study evaluated post-operative sexual complaints following inside-out (TVT-O) and outside-in procedures [40]. Although the outside-in TOT caused more sexual dysfunction than TVT-O, both

operations had, overall, a positive effect on sexual function due to the cure of SUI. Like previous studies, this study also showed that incontinence surgery may have positive and negative effects on sexual function.

### Midurethral tape with biologic materials

The ideal graft should be inert, noncarcinogenic, possess enough strength and flexibility, be noninflammatory, nonmodifiable by ingrowth tissue, and affordable [41]. However, no existing material has all of the above properties. The inflammatory process is different in response to synthetic and biologic grafts. The former induces a T helper type 1 response and the latter activate a T helper type 2 humoral immune response. Biologic grafts may be particularly beneficial for women with urogenital atrophy, history of previous irradiation, or immunosuppression due to the risk of poor vascularization and healing.

Biologic grafts, either allografts (cadaveric dura mater, fascia lata) or xenografts [porcine dermis, small intestine submucosa (SIS)], have been available for clinical use. Some xenografts have been shown to have favorable results with efficacy comparable to autologous fascia [42]. Porcine collagen has a 95% homology to human collagen and it was developed to overcome the possibility of erosion and rejection. It had been shown that the porcine SIS implantation is typically associated with tissue acceptance rather than rejection because it is an acellular, nonimmunogenic, and resorbable biomaterial [43]. However, a graft-versus-host disease following TOT with SIS was reported recently [44]. The information for biologic materials is far less than that for synthetic mesh slings. There are still some concerns about the safety and durability of nonautologous biologic tissues.

## Discussion

Recent studies showed that the TVT-O procedure presents success rates and complications comparable to the outside-in TOT technique at 1-year follow-up [36,45,46]. Thus we combined these two types of transobturator tape into the same group (TOT), compared with the TVT procedure. The figures of newly published (within 1 year)

**Table 1 Urodynamic studies following TVT and TOT**

Study	Slings	F/U	n	Uroflowmetry	Cystometry	Urethral profile
Barry <i>et al.</i> [14]	TVT	3 months	82	Q <sub>max</sub> decreased	N	N
	Monarc	3 months	58	N	N	N
Schierlitz <i>et al.</i> [15 <sup>*</sup> ]	TVT	6 months	82	Q <sub>max</sub> decreased, RU increased	N	N
	Monarc	6 months	82	Q <sub>max</sub> decreased	V <sub>fst</sub> increased	N
Long <i>et al.</i> [18 <sup>*</sup> ]	TVT	1 year	46	N	V <sub>fst</sub> increased	MUCP increased, UCA increased
	TVT-O	1 year	28	N	V <sub>fst</sub> increased	N
Hsiao <i>et al.</i> [21]	TVT	1 year	24	N	N	UCA increased, CA increased
	Monarc	1 year	26	N	N	N

CA, continence area; F/U, follow-up; Monarc (AMS, Minnetonka, Minnesota), outside-in TOT; MUCP, maximum urethral closure pressure; N, no significant change; n, number; Q<sub>max</sub>, maximum flow rate; RU, residual urine; TOT, transobturator tape; TVT, tension-free vaginal tape; UCA, urethral closure pressure area; V<sub>fst</sub>, volume at first desire to void.

literature summarized in our meta-analysis revealed that there is currently no evidence to conclude which one approach has superiority over the other. Bladder perforation was rare, but groin/thigh pain was greater in the TOT group. Voiding dysfunction and urinary retention were slightly more common among women undergoing a TVT procedure, suggesting the obstructive nature of a U-shaped sling, as evidenced by the ultrasonographic [17,18\*,38\*] and urodynamic findings [14,15\*,18\*,21]. Changes in sexual function need further investigation because this issue has not been well studied for either sling procedure.

The TOT is a less obstructive V-shaped sling, making it preferable in patients with low flow rates, although this issue needs to be studied specifically. The rare occurrence of bladder injury might make TOT more suitable in women who have had previous pelvic surgeries such as hysterectomy or prolapse repair in which the bladder anatomy could be altered. In addition, transobturator route also avoids the risk of bowel and vascular injuries. For women with low maximum urethral closure pressure, however, the TOT approach appears to be more likely to fail than the retropubic route [15\*,20–23].

## Conclusion

Transobturator tape has the advantages over TVT with shorter operative time and a relatively lower complication rate. However, TOT tape is at a less acute angle, resulting in less urethral compression and a lower rate of urethral kinking. It is unclear whether women undergoing TOT will remain continent in the long term, especially in patients with intrinsic sphincter deficiency. Future RCTs of midurethral slings comparing techniques and materials in women with good and poor urethral function are awaited to realize whether and how the continent results of various tension-free procedures sustained. Then physicians could tailor an appropriate procedure in individual patients.

## References and recommended reading

Papers of particular interest, published within the annual period of review, have been highlighted as:

- of special interest
- of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (pp. 361–362).

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