

Retropubic, transobturator and intraobturator tape procedures: how, when and why

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Abstract: The tension-free vaginal tape (TVT) procedure for treatment of female stress incontinence is the first modern minimally invasive midurethra sling operation and the only one thus far with reports on cure rates with follow-up periods of 5 years or more. The TVT is a safe and effective treatment for stress urinary incontinence (SUI), offering the benefits of a minimally invasive technique with good longterm results . Reported complications of the procedure include bladder and vascular injuries and to lesser extent bowel perforations and mesh erosion.

The transobturator approach (TOT) was developed as an alternative technique to minimise the risk of bladder and vascular injuries during the retro-pubic passage of the needle.

Reported cure rates of incontinence with the transobturator approach were similar to those observed with TVT; comparing retropubic and transobturator tapes, bladder perforations, pelvic haematoma and storage LUTS were significantly less common in the patients treated by transobturator tapes. Viceversa, the performances of retropubic and transobturator tapes were similar for all the other evaluable parameters (vaginal erosions, urinary tract infections, reoperation rates).

New minimally invasive procedures , like the novel TVT-SECUR (TVTs), were designed and introduced to overcome the peri-operative complications reported with use of TVT and TOT/TVT-O (bladder perforation, bowel, vessel and nerve injury, infection, thigh pain and bladder outlet obstruction) but their use needs again further evaluation with respect to efficacy and morbidity.

Key words: Urinary incontinence; TOT; Transobturator procedures; TVT; Complications.

Stress urinary incontinence (SUI) is a highly prevalent symptom that has been estimated to be among the top ten medical problems of adult women.¹ Worldwide about 200 millions women suffer of urinary incontinence (UI) (2-3 millions in England, 10-12 in the USA and 3 millions in Italy). In Thelma Thomas' epidemiological survey, one of the most frequently cited article in literature, prevalence of UI varies, based on population age, from 4.5% to 37%, with an average of 18%.² These data are confirmed in subsequent epidemiological studies also at a national level.³⁻⁴ Although not life-threatening, SUI may seriously impair the physical, psychological, and social wellbeing of the affected patients⁵. Several procedures have been proposed for the surgical treatment of SUI, both in the hypermobility associated kind (type I-II) and in the Intrinsic Sphincteric Deficiency kind (ISD type III), as described by Blaivas and Olsson in 1988.⁶

This dicotomous view of SUI pathophysiology has been discussed so far, though it still plays a relevant clinical and prognostic role in the decision process on what kind of surgery to perform for each single patient. Since the first half of 90's almost 150 different surgical procedures have been described, among those the Burch colposuspension has been the gold standard in the treatment of type I and II SUI for the last 20 years, showing long term results of 80-90% success rate.⁷⁻⁸

The TVT procedure was developed during the early 1990s and introduced as a minimally invasive operation in 1996.⁹ Many reports since then have shown that the TVT procedure is effective in many different groups of patients, with cure rates between 80% and 90% during follow-up periods of more than 3 years¹⁰⁻¹¹⁻¹²⁻¹³ (Tab 1 e 2).

The tension-free vaginal tape (TVT) procedure for treatment of female stress incontinence is the first modern minimally invasive midurethra sling operation and the only one thus far with reports on cure rates with follow-up periods of 5 years or more.¹⁴⁻¹⁵ In one Nilsson's study the mean follow-up time was 91.1 months (range 78-100) which is 7.6 years. According to the women's own opinion, 81.3 % (65/80) were cured, 16.3 % (13/80) were improved and 1.3 % (1/80) was a failure,¹⁴ and in his last published study the median time of follow-up was 141 months (range, 127-160), which is an average of 11 1/2 years: the cough

TABLE 1. – TVT results.

	Wang 1998	Ulmsten 1999	Olsson 1999	Meschia 2001	Jeffry 2001	Nilsson 2001
Patient number	70	50	53	404	112	85
Primary/ secondary	primary	primary	both	both	both	primary
Anaesthetic	epi	LA	LA/epi	LA/epi	LA/epi	LA
Follow-up (mo.)	12	36	36	21	25	60
Subjective cure	87%	86%	90%	92%	66%	85%
Objective cure	83%	86%	90%	90%	89%	85%

stress test was negative in 95.3 % (61/64) of the women, and 90.2 % had a negative pad test (55/61). Of these women, 90.2 % had both a negative stress test and a negative pad test and thus regarded objectively cured. By PGI, 77 % (53/69) regarded themselves as cured, 20% (14/69) as improved, and 3% (2/69) thought the treatment had failed. Asked if experiencing leakage on straining 93% (64/69) claimed they were dry; 97% were prepared to recommend the TVT operation to a friend.¹⁵

To date it is estimated that more than 1 million cases have been performed worldwide.¹⁶

After the success of TVT, several retropubic devices,

TABLE 2. – TVT results.

author	condition	n°	follow-up	results
Nilsson 2001	Primary SUI	85	5 years	85% cured 11% improved
Rezapour 2001	Recurrent SUI	34	4 years	82% cured 9% improved
Rezapour 2001	ISD	49	4 years	74% cured 12% improved
Rezapour 2001	Mixed incontinence	80	4 years	85% cured 4% improved
Meschia 2001	SUI and prolapse	86	2 years	88% cured 6% improved

including suprapubic arc (SPARC) sling, intravaginal slingplasty (IVS) sling, were introduced on the market to make the midurethral sling procedures even less invasive and to reduce the complications.¹⁷ Many studies and also one recently published meta-analysis⁹ showed that TVT outperformed both Burch colposuspension and other retropubic tension-free midurethral slings in terms of continence rates.¹⁸⁻¹⁹⁻²⁰⁻²¹⁻²²⁻²³ Complication rates following placement of TVT are usually considered low.

With regards to the intraoperative complications, bladder perforations have been reported to occur in 2.5–11.7% of cases, whereas significant bleedings are less common (0.5–2.5%). Postoperative complications included urinary tract infections (0.4–31.5%), de novo urgency (3.1–29%), transient or persistent voiding dysfunction (2.8–38%), vaginal and/or bladder erosions (0.6–5.4%), and so on.²⁴ Despite those encouraging figures, some cases of major complications have been reported, including bowel, vascular, and nerve injuries, sepsis, and patient deaths.

For these reasons, the transobturator approach (TOT) was developed as an alternative technique to minimise the risk of bladder and vascular injuries during the retro-pubic passage of the needle.

Although in the original TOT procedure,²⁵ the tape was inserted through the obturator foramen from the outside-to-inside direction, later, the inside-to-outside approach (TVT-O) with the passage of the tape from the vaginal incision to the obturator foramen has also been described.²⁶ Reported cure rates of incontinence with the transobturator approach are similar to those observed with TVT.²⁷⁻²⁸⁻²⁹ One recent Italian randomised prospective study that compared TVT and TVT-O with regard to peri-operative morbidity and short-term surgical outcome in women undergoing primary surgery for stress urinary incontinence showed that subjective and objective cure rates were 92% and 92% in the TVT group and 87% and 89% in the TVT-O group and that both procedures were equally effective in the short-term for the treatment of stress urinary incontinence with a highly significant improvement in incontinence-related QoL.²⁹

Also the last French multi-centre experience reported similar results: with regard to efficacy, the surgeon assessed 886 (90%) patients as completely dry, 86 (8.7%) as improved and 12 (1.2%) as similar with a re-intervention only in 9 cases (0.9%). The post-operative complications in a series of 984 women were: residual pain in 2.7% of cases, urinary retention in 0.8%, vaginal erosion in 0.6% and paravescical hematoma in 0.1%.³⁰

One meta-analysis of six trials that compared TVT and TVT-O (a macroporous polypropylene mesh, to be inserted inside-to-out through the obturator foramen), three RCTs comparing TVT with transobturator outside-to-in tape and a further study compared TVT with Monarc (a knitted macroporous polypropylene mesh to be placed outside-to-in through the transobturator route) concluded that comparing retropubic and transobturator tapes, bladder perforations (OR, 2.33; 95% CI OR, 1.26–4.32; $p = 0.007$), pelvic haematoma (OR, 4.83; 95% CI OR, 1.22–19.15; $p = 0.03$) and storage LUTS (OR, 1.81; 95% CI OR, 1.13–2.91; $p = 0.01$) were significantly less common in the patients treated by transobturator tapes. Viceversa, the performances of retropubic and transobturator tapes were similar for all the other evaluable parameters (vaginal erosions, urinary tract infections, reoperation rates). The observed success rates were similar in both groups of TVT and transobturator approaches.³²

In order to obtain the less invasive surgical approach, to reduce the risk of intra-operative complications, to use a mid-urethral sling in safe conditions with local anaesthesia and in a day surgery ward due to the minimal post-operative

TABLE 3. – TVT Secur results

	Neuman 2008	Oliveira 2009	Debodinance 2009	Meschia 2009
Patient number	100	107	154	95
Primary/secondary	primary	primary	primary	primary
Type	IUS	IUS/ IUM	IUS/ IUM	IUS
Follow-up (mo.)	12	12	12	12
Objective cure	88/93%	85%	81%	81%

pain, in 2006 the first mid-urethral mini-sling requiring a single vaginal incision was introduced. The novel TVT-SECUR (TVTs) is designed to overcome the peri-operative complications reported with use of TVT and TVT-O: bladder perforation, bowel, vessel and nerve injury, infection, thigh pain and bladder outlet obstruction.³³ This new device is composed of an 8 cm long laser cut polypropylene mesh and is introduced to the internal obturator muscle (Hammock position) by a metallic inserter, while no exit skin cuts are needed. This approach imitates the sub-mid-urethral support provided with the TVT-obturator (TVTs-O), yet imitating the TVT is possible as well, by introducing the TVT-SECUR arms retropubically rather than to the obturator area (TVTs-U). This “U” position approach requires urethral catheterization as well as diagnostic cystoscopy for recognition of possible bladder penetration. The initial pull-out force of the tape and further tissue ingrowth were studied in the sheep model, revealing satisfactory figures.³³ At the moment there is no prospective randomised trial comparing TVT and traditional transobturator slings, therefore no evidence can prove the clinical effectiveness of this new surgical approach. Nevertheless data from published studies seem promising. Success rates reported in literature range widely from 60 to 90%. Between the years 2007-2009 over 4000 implants have been performed and described in numerous international abstracts. Four prospective observational studies with a minimum follow-up of 12 months show satisfactory results (tab. 3).

Study populations are not comparable among the different articles but overall success rates range between 81 and 93%. Results are strongly dependent on surgical learning curve for each surgeon as shown by Neumann et al. In his article he compared the first consecutive 50 and the last consecutive 50 procedures, drawing some interesting conclusions regarding the number of intraoperative complications and success rate.³⁴ Similar results were reported by a recent observational multicentric prospective study on the use of TVT Secur system in urodynamic and/or

TABLE 4. – Perioperative complications

Intra-operative complications	2 sling re-positioning 1 LVP with implant of another sling 3 PE \geq 200	
Post-operative complications	1 haematoma (spontaneous recovery) 1 temporary pain recovered within 7 days 8 urinary difficulties (RV > 100 ml):	4 recovered during 2 nd day 2 recovered during 3 rd day* 2 recovered during 8 th day* * 5 patients underwent associated surgery

TABLE 5. – Follow-up at 3.6 months and Centre characteristics. * n° 5 re-operated recurring SUI; 1 TVT-s, 1 TOT, 1 BURCH, 2 infiltrating. No significant differences among groups found.

	TOTAL PATIENTS		TVT-s-O		TVT-s-U	
N° patients	136		110		26	
Total failures (n°-%)	17*	12.50%	14	12.73%	3	11.54%
Urodynamic SUI (n° patients)	95		81		14	
Total failures (n°- %)	14	14.74%	12	14.81%	2	14.29%
Potential SUI (n° patients)	41		29		12	
Total failure (n°- %)	4	9.76%	3	10.34%	1	8.33%
Centre characteristics						
Learning curve	TOTAL PATIENTS		Urodynamic SUI		Potential SUI	
Centres with < 10 implants	13		10		3	
Total failures (n°-%)	3	23.08%	2	20.00%	1	33.33%
Centres with 10-20 implants	33		25		8	
Total failures (n°-%)	5	15.15%	4	16.00%	1	12.50%
Centres with > 20 implants	90		60		30	
Total failures (n°-%)	10	11.11%	8	13.30%	2	6.67%

occult SUI associated to pelvic prolapsed pathologies. The study involved nine national urogynecological centres and a total of 147 patients, of which 136 (92.5%) took part to the 6-month-follow up and 69 to the 12 month-follow up. For each single case, operators were free to adopt the two different TVT-Secur system approaches, transobturator and/or retro-pubic.

Intra and post-operative morbidity is reported in Table 4.

No intra-operative bladder, urethral, vascular or nervous damage was observed; the total analysed population (136/147) at 6 months follow-up did not show sling urethral-vaginal erosion or signs of infection in the intervention site.

At the short-medium term, technique's percentage of failure (improved + failed) in the whole population was of 12.5% (Tab.5). The percentage of failures in the 95 patients with Urodynamic SUI (Group A) was of 14.74 (14/95), whereas in patients with potential SUI (Group B), the ratio was 9.76% (4/41). Of the 17 patients that were not cured, 9 (6.6%) resulted improved (resulting in a lower class with Ferrari's stress-test, VAS of lower degree and PGI-I \leq 2) and 8 (5.9%) were unchanged; for 5 failures a further surgery intervention was required during the first 6 months of follow-up for serious recurring SUI (1 TVTs, 1 TOT, 1 Burch, 2 peri-urethral infiltrations) that resulted in complete recovery. Although no comparison has been made between two populations having similar general features, differences observed in percentages of success for the two sling applications (transobturator and retro-pubic approach) were not statistically significant.

Among centres with different level of experience and different number of patients, indeed there is a significant difference in the percentage of success according to the chosen approach (Tab. 6).

In the whole population, these percentages drop from 23.08% of failure observed in centres with less than 10 implants carried out, to 11.1% of those with more than 20 treated patients and the trend is the same both for Urodynamic SUI and Occult SUI (Table 5).

The analysis of study results show how, though applied in many urogynecological centres having a quite different learning-curve for this technique, TVT Secur System is a surgical method of treating Urodynamic and Occult SUI resulting to be safe (with low and minimal peri-operative

morbidity), versatile (with the possibility of applying sling through different techniques according to each operator's choice), effective (with high percentages of success similar to traditional mid-urethral slings, both for retro-pubic and transobturator approaches).

Observed short-mid term percentages of success seem to be maintained also on long-term.

More than with other mid-urethral slings, results of this study underline the importance of the learning curve for each single centre, and the need of adopting a new and original way of positioning and put under tension the sling.

The need of re-intervention for recurrent SUI already at mid-term follow-up observed in the population of treated patients (5/136) has to be highlighted as significantly higher than percentages reported in literature with traditional mid-urethral slings, and also at long-term (3-11 years) is slightly higher than 1% both for retro-pubic and transobturator approach.¹⁴⁻¹⁵⁻³⁰

This study demonstrate feasibility, reliability and effectiveness of the used single incision mini-sling (TVT Secur System); the analysis of collected data shows how TVTs resulted in being an innovative therapeutic method for patients suffering from Urodynamic and/or Occult SUI: it is simpler, safer and its efficacy is similar to that of mid-urethral, retro-pubic and/or transobturator "traditional" slings. The data available in the international literature do not allow yet an evaluation on the real possibilities of this technique to be a safe alternative to mid-urethral traditional slings, and additional extensive randomised prospective comparative studies are needed.³⁵

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