SU‡ AND TVT SECUR SYSTEM: RESULTS OF A PROSPECTIVE OBSERVATIONAL MULTICENTRIC STUDY. MORBIDITY AND SHORT-TERM PERCENTAGES OF SUCCESS

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SUMMARY
The aim of this study was to evaluate perioperative morbidity and short-term efficacy of TVT-Secur in treating female stress urinary incontinence. Data from 147 patients with urodynamic and/or occult SUI who were treated with TVTSecur in each single centre between 1st March 2007 and 31st December 2007 were collected. In positioning the sling, 74.8% of the surgeons chose the transobturator approach (110/147) and the remaining 25.2% chose the retropubic one. In 64.6% of patients (95/147) with urethral hypermobility and cystocele =<2° degree according to POP-Q classification system, only isolated urodynamic SUI was treated (Group A); in 52 patients TVTSecur was used to treat an occult SUI associated

SOMMARIO
Scopo dello studio è stato quello di valutare la morbidità perioperatoria e l’efficacia a breve termine della TVT-secur nel trattamento della incontinenza urinaria da sforzo femminile. I dati raccolti sono relativi a 147 pazienti affette da SUI urodinamica e/o potenziale trattate con TVT secur in ogni singolo centro dal 1 Marzo 2007 al 31 Dicembre 2007. Nel posizionare la sling il 74.8% degli operatori ha scelto l’approccio transotturatorio (110/147) e il restante 25.2% l’approccio retropubico. Nel 64.6% (95/147) delle pazienti con iper mobilità uretrale e cistocele di =<2° sec il POP-Q è stata trattata solo la SUI urodinamica (Gruppo A); in 52 pazienti il TVT-secur system è stato utilizzato in una SUI associata a prolasso genitale
with complex genital prolapse (Group B). Intra-operative complications were observed in the whole population: 2 slings had to be re-positioned; 1 deep vaginal laceration occurred and a new sling was implanted; 5 patients presented PE >=200ml. Post-operative morbidity was represented by 1 haematoma that disappeared spontaneously; 1 case of temporary pain that stopped within 7 days; 8 patients had urinating difficulties (RV>100ml), 5 of whom were in Group B. At the short-term follow up this technique’s success percentage with respect to the total population was 87.5% (119/136), 85.3% in Group A (81/95) and 90.3% (37/41) in Group B. The data collected show that when treating female stress urinary incontinence, TVTsecur represents an innovative, simpler and safer, therapeutic alternative, and its efficacy equals that of retropubic and/or transobturator traditional midurethral slings.

**INTRODUCTION**

The TVT procedure was developed during the early 1990s and introduced as a minimally invasive operation in 1996\(^1\). 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 years.\(^2\)\(^-\)\(^5\)

The tension-free vaginal tape (TVT) procedure for the treatment of female complesso (Gruppo B). Nell’intero campione sono state osservate le seguenti complicanze intraoperatorie: due casi di rimozione accidentale e riposizionamento della sling; un caso di lacerazione vaginale profonda con impianto di una altra sling; 5 pazienti con perdite ematiche >=200ml. In riferimento alla morbidità postoperatoria si è osservato 1 caso di ematoma a risoluzione spontanea, 1 caso di dolore in sede di impianto risoltosi con terapia medica nell’arco di 7 giorni; mentre in 8 pz (5 delle quali appartenenti al Gruppo B) si è manifestata una difficoltà minzionale con RV>100ml. Al follow-up a breve termine la percentuale di successo di questa tecnica è stata nella popolazione totale dell’87.5% (119/136), dell’85.3% nel Gruppo A (81/95) e del 90.3% (37/41) nel gruppo B. I dati raccolti dimostrano che la TVT-secur rappresenta una innovativa alternativa terapeutica più semplice, più sicura e con un’efficacia paragonabile alle tradizionali slings medio uretrali transotturatorie e/o retropubiche.

**INTRODUZIONE**

La procedura della TVT si è sviluppata durante i primi anni 90 e fu proposta come tecnica mini invasiva nel 1996\(^1\). Da allora molti lavori ne hanno dimostrato l’efficacia in diverse popolazioni di pazienti con un rate di cura tra l’80% ed il 90% e follow-up superiori a tre anni\(^2\)\(^-\)\(^5\).

La TVT per il trattamento della SUI è la prima procedura moderna mini invasiva e l’unica con tasso di cura validato
stress incontinence is the first modern minimally invasive midurethral sling operation and the only one thus far with reports on cure rates with follow-up periods of 5 years or more. In one of Nilsson’s studies 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) improved, for 1.3% (1/80) of the patients the operation was a failure, and in his last published study, the mean follow-up time was 141 months (range 127-160), which is an average of 11 1/2 years. The cough stress test was negative in 95.3% (61/64) of the women, and 90.2% had a negative pad test (55/61). 90.2% of these patients had both a negative stress test and a negative pad test and were thus objectively regarded as cured.

Using the PGI, 77% (53/69) of the patients regarded themselves as cured, 20% (14/69) as improved, and 3% (2/69) thought the treatment had failed. When asked if they experienced leakage on straining, 93% (64/69) claimed they were dry. 97% of the patients were prepared to recommend the TVT operation to a friend.

Thus, the Tension-free vaginal tape (TVT) is a safe and effective treatment for stress urinary incontinence (SUI), offering the benefits of a minimally invasive technique with good long-term results.

The complications of the procedure reported in the literature include bladder and vascular injuries and to a lesser extent bowel perforations and mesh erosion.

The transobturator approach (TOT) da follow-up pari o maggiore ai 5 anni. In uno studio di Nilsson la media del follow-up era di 91.1 mesi (78-100) pari 7.6 anni; dai dati soggettivi risultava che l’81.3% (65/80) delle donne si considerava guarita, il 16.3% (13/80) migliorata e l1.3% (1/80) non curata. Nel suo ultimo lavoro Nilsson dichiara che ad un follow-up medio di 141 mesi (127-160) pari ad un tempo medio di 11 anni e ½: lo stress test risultava negativo nel 95.3% (61/64) delle donne mentre il Pad test risultava negativo nel 90.2% (55/61). Nel 90.2% delle pazienti erano negativi entrambi i Test. Dal PGI risultava che il 77% (53/69) si considerava guarita, il 20% (14/69) si considerava migliorata ed il 3% considerava fallito il trattamento. Interrogate circa la presenza di fughe di urina sotto sforzo nel 93% dei casi (64/69) le pazienti riferivano di essere asciutte; il 97% delle pazienti consigliò l’intervento di TVT ad una amica.

Quindi la TVT risulta essere un trattamento sicuro ed efficace nel trattamento della SUI, permettendo un approccio mini invasivo e dei buoni risultati a lungo termine.

Sono riportate in letteratura complicanze che vanno da lesioni vescicali, vascolari, piccole lesioni intestinali ed erosioni della mesh.

L’approccio transotturatorio (TOT) fu proposto con l’intento di minimizzare il rischio delle suddette complicanze durante il passaggio retropubico del device.

Sebbene nella TOT originale, il nastro venisse inserito nel forame otturatorio mediante un approccio out-in, in seguito fu proposto anche un approccio in-out (TVT-O). Il tasso di cura ri-
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, the tape was inserted through the obturator foramen in an 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 was also described. Reported cure rates of incontinence with the transobturator approach are similar to those observed with TVT.

One recent Italian randomised prospective study, comparing TVT and TVT-O with regard to perioperative morbidity and the 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.

The latest French multi-centre study, involving 984 patients, reported similar results: with regards to efficacy, 886 (90%) patients were considered completely cured, 86 (8.7%) improved and 12 (1.2%) not cured, with a second operation in 9 cases (0.9%).

The post-operative complications were: residual pain in 2.7%, urinary retention in 0.8%, vaginal erosion in 0.6% and paravesical hematoma in 0.1% of the cases.

The novel TVTsecur (TVTs) was des-
signed to overcome the perioperative complications reported with use of TVT and TVT-O: bladder perforation, bowel, vessel and nerve injury, infection, thigh pain and bladder outlet obstruction. This new device is composed of an 8 cm long laser cut polypropylene mesh and is introduced into the internal obturator muscle (Hammock position) with a metallic inserter, while no exit skin cuts are needed.

This approach imitates the sub-midurethral support provided with the TVT-obturator (TVTs-O), and imitating the TVT is possible as well, by introducing the TVT-SECUR arms retropubically rather than into the obturator area (TVTs-U). This “U” position approach requires urethral catheterization as well as diagnostic cystoscopy in order to avoid bladder penetration.

The initial pull-out force and successive tissue growth incorporating the tape were studied in the sheep model and the results were satisfactory. The aim of the this study was to evaluate the perioperative morbidity and short-term efficacy of this novel minimally invasive anti-incontinence procedure.

MATERIALS AND METHODS

The study was a longitudinal observational multicentric prospective trial involving 9 Italian urogynaecological centres.

Randomization using another surgical technique was excluded since at the time the study took off no publications were available in the literature on the use of TVTs on human beings.

All patients included in the study were suffering from urodynamic and/or incisioni cutanee. Questo approccio mira il posizionamento della protesi a livello della media uretra che si effettua con la TVT-O, mentre è possibile con l’approccio ad U posizionare il nastro mimando la TVT retro pubica. L’approccio ad U necessita sia di cateterizzazione che di cistoscopia di controllo. L’iniziale forza di trazione e il successivo inglobamento tissutale, studiati in modelli animali, si sono rivelati soddisfacenti.

La scopo di questa analisi è stato quello di valutare la morbilità perioperatoria e la efficacia terapeutica a breve termine di questa nuova procedura mini-invasiva anti-incontinenza.
occult SUI treated with TVTs in each centre from 1st March 2007 to 31st December 2007.

For each single case, the surgeons were free to choose which approach to adopt, transobturator and/or retro-pubic, for placing the tape.

All centres used the same software to enter the main personal, anamnestic and clinical data required by the entry protocol at 0, 3-6 and 12 months after surgery.

For all patients the pre-operative protocol involved careful collection and insertion of the main personal (age), anamnestic (associated medical pathologies, contingent therapies) and urogynaecological parameters (parity, hormonal status, previous intervention, type and severity classification of clinical urinary incontinency and of the possibly associated overactive bladder syndrome), a bi-manual clinical evaluation to highlight any associated benign gynaecologic pathologies, an evaluation and classification of pelvic floor defects according to the POP-Q system, the execution of a Q-tip test, a cotton swab test to assess urethral mobility, a stress-test at low and/or middle bladder filling (200 and 300ml) in supine and/or orthostatic position, before and after reduction of genital prolapse if present, to highlight any occult SUI.

In patients suffering from clinical SUI only associated with urethral hypermobility and cystocele <=2 according to POP-Q system, the protocol required urodynamic tests to exclude urinary incontinency due to emergency and suspected associated intrinsic sphincter deficiency (ISD).

Two parameters were used to assess

namica e/o potenziale e furono trattate con TVT-S in ogni centro dal 1 Marzo al 31 Dicembre 2007. Per ogni singolo caso tutti i centri furono lasciati liberi di scegliere il tipo di approccio da utilizzare (O/Amaca o retro pubico/U) nel posizionare il tape.

Tutti i centri hanno usato lo stesso software per la raccolta dei dati previsti per l’arruolamento nel protocollo al tempo 0, e per l’outcome a 3-6, 12 mesi dall’intervento.

Per ogni paziente il protocollo pre operatorio ha previsto una attenta raccolta dei principali dati anagrafici (età), anamnestici (altre patologie associate, terapie in atto) e dei parametri uroginecologici (parità, stato ormonale, pregressa chirurgia, tipo gravità e classificazione dell’incontinenza e della eventuale coesistenza di sindrome da vesica iperattiva), visita ginecologica per escludere eventuali patologie benigne associate, valutazione e classificazione dei difetti del Pavimento Pelvico sec il POP-Q, Q-tip test per la valutazione della ipermobilità uretrale, stress test a piccolo e/o medio riempimento (200 e 300ml) in clin e/o ortostatismo, prima e dopo riduzione manuale di prollasso concomitante per slatentizzare un eventuale SUI potenziale.

Nelle pazienti affette da SUI clinicamente accertata associata esclusivamente ad ipermobilità uretrale e a cistocele <=2°, sec il POP-Q, fu eseguito Esame Urodinamico completo per escludere la presenza di una ISD (Insufficienza sfiniterica Intrinseca).

Per valutare il grado di severità della SUI sono stati utilizzati due parametri: uno oggettivo (Stress test sec Ferrari) ed uno soggettivo (una scala
severity of the SUI: an objective one (Ferrari’s stress-test) and a subjective one (VAS score between 1 and 4, where 1 was no loss of urine due to stress and 4 was major daily urine loss), plus filling out the PGI-S questionnaire. For the overactive bladder syndrome a urinary diary and the W-IPSS questionnaire were used.

To assess perioperative morbidity the protocol required collection of the following data for all patients: date and kind of surgery, anaesthesia used; intra-and post-operative complications observed, time of recovery of spontaneous urination, any drugs administered.

To assess the therapeutic efficacy of the surgical technique used, the following parameters were collected at 3-6 and 12 months after surgery: Ferrari’s stress-test, subjective VAS, PGI-I and W-IPSS questionnaires, any complications appearing later on (erosion, infection, UTI), medical treatments and any second operations (date and kind).

Statistical Analysis

The data was described using the mean (±SD) for continuous variables and percentages (number of observations) for each category. Continuous variables were compared among groups using a Wilcoxon test for independent samples. Categorical variables were compared among groups using the Exact Monte Carlo test (2000 interactions and 200 burn-in samples), as described by Forster and Zamar. All exact significance values were reported with 3-digit precision, and they were considered as significant if lower than 0.05. The acronim N.S. significa non significativo ad un livello di 0.05.
0.05; in the text, the acronym N.S. means not significant at a 0.05 level. All analyses were performed using the 1R.System.

**RESULTS**

A total of 147 patients took part in the study, 136 (92.5%) of whom took part in the 6-month follow up and 69 in the 12 month follow up (Tab. 1 and 2).

The surgeons adopted both approaches for TVTsecur, but they preferred the transobturator approach (110 patients); the retro-pubic approach was mainly chosen in patients with occult SUI (23/37, 85%) associated with more reconstructive surgery of the pelvic floor.

**Sling positioning comparison (TVTs-O and TVTs-U)**

The analysis of the general characteristics of patients treated with the two different sling positioning approaches (TVTs-O and TVTs-U) (Tab. 2) showed that the surgeons’ random adoption of the retropubic approach in patients with associated complex genital pro-

**Table 1 – General characteristics of the population**

<table>
<thead>
<tr>
<th></th>
<th>Total patients</th>
<th>TVTs-O</th>
<th>TVTs-U</th>
</tr>
</thead>
<tbody>
<tr>
<td>n. patients</td>
<td>147</td>
<td>110</td>
<td>37</td>
</tr>
<tr>
<td>n. patients at 3-6 month follow up</td>
<td>136</td>
<td>110</td>
<td>26</td>
</tr>
<tr>
<td>n. patients at 12 month follow-up</td>
<td>69</td>
<td>62</td>
<td>7</td>
</tr>
<tr>
<td>Urodynam ic SUI (n)</td>
<td>95</td>
<td>81</td>
<td>14</td>
</tr>
<tr>
<td>Occult SUI (n)</td>
<td>52</td>
<td>29</td>
<td>23</td>
</tr>
</tbody>
</table>

**RISULTATI**

In totale 147 hanno preso parte allo studio, di cui 136 (92.5%) hanno completato il follow-up a 6 mesi e 69 il follow-up a 12 mesi (Tab. 1 e 2).

Gli operatori hanno adottato entrambi gli approcci con una preferenza per l’approccio transobturatorio (110 pazienti); l’approccio retro pubico è stato prevalentemente scelto in pazienti con SUI potenziale (23/37 85%) associata ad altra chirurgia ricostruttiva del pavimento pelvico.

**Confronto nel posizionamento della sling**

L’analisi delle caratteristiche generali delle pazienti trattate con i due differenti approcci (Tab. 2) ha mostrato che la preferenza casuale degli operatori per la via retropubica nelle pazienti con prolasse genitale complesso (62.1% vs 26.3% p=0.004) ha determinato la
lapse (62.1% vs. 26.3% p=0.004) involved an averagely older population (65.5 vs. 58.3, N.S.), who were almost all in menopause (97.3% vs. 74.5%, N.S.) and had a higher prevalence of associated irritative symptoms (25% vs. 15.4%, N.S.).

**Urodynamic SUI vs. Cystopecty**

Sixty-five-percent of the population (95/147) were treated for urodynamic SUI associated with urethral hypermobility and <2\(^{nd}\) degree cystocoele according to the POP-Q system classification (Group A); there were also two cases of TVTs associated with laparoscopic surgery for uterus adnexal benign pathology. In the remaining 52 patients TVTs was associated with corrective surgery for complex genital prolapse, which often required a cystopecty with double fasciae + vaginal hysterectomy ± bilateral adnexitomy ± colpoperineoplasty (Group B).

**SUI Urodinamica vs Cistopessi**

Il 65% della popolazione (95/147) è stato trattato per SUI urodinamica associata ad ipermobilità uretrale e cistocele <2\(^{\circ}\)sec il POP-Q (Gruppo A); in due casi la TVT-S fu associata a laparoscopia operativa per patologia annessiale benigna. Nelle rimanenti 52 pazienti la TVT-S fu associata a chirurgia ricostruttiva per prollasso genitale complesso che spesso ha richiesto una cistopessi con duplicazione della fascia + isterecotomia vaginale ± annessiectomia bilaterale ± colpoperineoplastica (Gruppo B).

**Table 2 – Sling positioning (TVTs-O vs TVTs-U)**

<table>
<thead>
<tr>
<th></th>
<th>TOT CASI</th>
<th>TVTs-O</th>
<th>TVTs-U</th>
<th>p-values</th>
</tr>
</thead>
<tbody>
<tr>
<td>n. patients</td>
<td>147</td>
<td>110</td>
<td>37</td>
<td></td>
</tr>
<tr>
<td>Average age (years)</td>
<td>59.50 ± 9.66</td>
<td>58.30 ± 9.71</td>
<td>65.50 ± 7.90</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>BMI (kg/m(^2))</td>
<td>28.10 ± 6.53</td>
<td>27.92 ± 6.80</td>
<td>28.44 ± 6.53</td>
<td>0.781</td>
</tr>
<tr>
<td>parity</td>
<td>2 ± 0.93</td>
<td>1.80 ± 0.96</td>
<td>0.96 ± 0.94</td>
<td>0.94 ± 0.94</td>
</tr>
<tr>
<td>menopause (n-%)</td>
<td>108 % 73.46</td>
<td>82 % 74.54</td>
<td>36 % 97.30</td>
<td>0.021</td>
</tr>
<tr>
<td>urg. - frequency (n-%)</td>
<td>50 % 34.01</td>
<td>38 % 34.54</td>
<td>12 % 37.50</td>
<td>0.900</td>
</tr>
<tr>
<td>urg. - incontinency (n-%)</td>
<td>25 % 17.01</td>
<td>17 % 15.45</td>
<td>8 % 25.00</td>
<td>0.427</td>
</tr>
<tr>
<td>Urodynamic SUI (n-%)</td>
<td>95 % 64.63</td>
<td>81 % 73.63</td>
<td>14 % 37.84</td>
<td>0.016</td>
</tr>
<tr>
<td>Potential SUI (n-%)</td>
<td>52 % 35.37</td>
<td>29 % 26.36</td>
<td>23 % 62.16</td>
<td>0.014</td>
</tr>
</tbody>
</table>
In Group A 52.2% (48/92) of the patients underwent general anaesthesia ± local anaesthesia and the remaining 44 patients (47.8%) underwent spinal anaesthesia. Seventy-one-percent (37/52) of patients in Group B underwent spinal local-regional anaesthesia whereas the remaining 15 (28.8%) underwent general anaesthesia.

Intra and post-operative morbidity

Intra and post-operative morbidity is reported in Table 3. The following intra-operative complications were observed: 2 cases of TVTs repositioning due to accidental sling removal during surgery, 1 extensive lateral vaginal laceration (LVP) that required the implant of another kind of sub-urethral sling, 5 cases of intra-operative excessive blood loss (according to the protocol adopted every case of blood loss >=200ml was to be considered excessive).

Post-operative morbidity was represented by 1 retropubic haematoma that recovered spontaneously and did not require any therapy, 1 case of temporary pain in the obturator area that recovered spontaneously within 7 days.

Nel Gruppo A il 52.2% (48/92) delle pazienti è stata sottoposta ad anestesia generale ± anestesia locale, mentre il rimanente 47.8% (44/92) fu sottoposta ad anestesia spinale. Il 71% (35/52) delle pazienti del Gruppo B fu sottoposta ad anestesia loco-regionale mentre il rimanente 28.8% (15/52) fu sottoposto ad anestesia generale.

Morbidity intra e post operatoria

La morbidità intra e post operatoria è riportata in Tabella 3. Furono osservate le seguenti complicanze intraoperatorie: 2 riposizionamenti del TVT-S dovute ad accidentale rimozione durante l’intervento, 1 lacerazione vaginale (LVP) estesa che richiese l’impianto di un altro tipo di sling sub uretrale, 5 perdite ematiche intraoperatorie eccessive (in accordo con il protocollo ogni perdita ematica >200ml fu considerata eccessiva).

La morbidità post operatoria fu rappresentata da: 1 ematoma retro pubico risolto spontaneamente che non ha richiesto alcuna terapia, 1 caso di dolore nella regione otturatoria risolto entro una settimana dall’intervento che fu

### Table 3 – Perioperative complications

<table>
<thead>
<tr>
<th>Intra operative Complications:</th>
<th>Post-operative Complications:</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 sling re-positioning</td>
<td>1 haematoma (spontaneous recovery)</td>
</tr>
<tr>
<td>1 LVP with implant of another sling</td>
<td>1 temporary pain recovered within 7 days</td>
</tr>
<tr>
<td>3 PE&gt;= 200</td>
<td>8 urinary difficulties (RV&gt;100ml):</td>
</tr>
</tbody>
</table>

* 5 patients underwent associated surgery

<table>
<thead>
<tr>
<th></th>
<th>4 recovered during 2nd day</th>
<th>2 recovered during 3rd day*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-operative Complications:</td>
<td>2 recovered during 8th day*</td>
<td></td>
</tr>
</tbody>
</table>

* 5 patients underwent associated surgery
and was treated with NSAIDs in the first 48 hours, 8 patients did not completely recover urinary functions within the first 24 hours after surgery with persistent RV>100ml (4 patients recovered during the 2nd day, 2 recovered on the 3rd day and 2 on the 8th day), 5 of them were observed in Group B, and underwent more associated reconstructive surgery.

No intra-operative bladder, urethral, vascular or nervous damage was observed; none of the population analysed (136/147) at the 6 month follow-up showed sling urethral-vaginal erosion or signs of infection in the site of the operation.

Three-six month follow-up

At the short-medium term, the technique’s failure percentage (improved + failed) in the whole population was 12.5% (Tab. 4). The percentage of failures in the 95 patients with urodynamic SUI (Group A) was 14.74% (14/95), whereas in patients with potential SUI (Group B), the ratio was 9.76% (4/41). Nine (6.6%) of the 17 patients who were not cured, improved (resulting in a lower class with Ferrari’s stress-test, VAS of lower degree and PG1-I <=2) and 8 (5.9%) were unchanged; for 5 failures further surgery was required during the first 6 months of follow-up for serious recurring SUI (1 TVTs, 1 TOT, 1 BURCH, 2 periurethral infiltrations), which resulted in complete recovery.

Although no comparison was made between two populations with similar general features, the differences observed in percentages of success for the two sling applications (transobturator treated nelle prime 48h con FANS, in 8 pazienti non vi fu un pieno recupero della minzione spontanea entro le 24h dall’intervento con un RPM (residuo post minzionale) persistentemente >100ml (in 4 pazienti vi fu un recupero in 2°giornata, 2 recuperarono in 3°giornata ed in 2 casi il recupero si ebbe in 8°), 5 dei suddetti casi furono osservati nel Gruppo B ed erano state sottoposte ad altra chirurgia ricostruttiva.

Non furono osservate lesioni uretrali, vescicali, vascolari e nervose; la popolazione totale valutata a 6 mesi (136/147) non presentava erosioni uretro-vaginali o segni di infezione nel sito dell’intervento.

Follow-up 3-6mesi

La percentuale di fallimento (migliorate+fallite) a breve e medio termine in tutta la popolazione fu del 12.5% (Tab. 4). La percentuale di fallimento nelle 95 pazienti con SUI Urodinamica (Gruppo A) fu del 13.68% (14/95), mentre nelle pazienti con SUI potenziale (Gruppo B) fu del 9.76% (4/41). Delle 17 pazienti che non furono curate, 9 (6.6%) risultarono migliorate (presentando una più bassa classe allo Stress Test sec Ferrari, un punteggio VAS più basso ed un PG1-I score <=2), 8 (5.9%) erano invariate rispetto al preoperatorio; per 5 fallimenti fu necessaria un’ulteriore chirurgia entro i primi 6 mesi di follow-up a causa di una grave SUI ricorrente (1 TVT-S, 1 TOT, 1 BURCH, 2 infiltrazioni peri uretrali) che risultò completamente risolta. Sebbene non sia stata effettuata una comparazione nell’ambito di due popolazioni che presentavano le stesse caratteristiche generali, le differenti percentuali di successo tra le due modalità
and retropubic approach) were not statistically significant (Tab. 4).

Among centres with different levels of experience and different numbers of patients, there is a significative difference in the percentage of success depending on the approach chosen (Tab. 4).

In the whole population, this percentage drops 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. (Tab. 4).

**Table 4 – Follow-up at 6 months and center characteristics.** *n. 5 re-operated recurring SUI; 1 TVT-s, 1 TOT, 1 BURCH, 2 infiltrating. No significant differences among groups found*

<table>
<thead>
<tr>
<th></th>
<th>TOTAL PATIENTS</th>
<th>TVTs-O</th>
<th>TVTs-U</th>
</tr>
</thead>
<tbody>
<tr>
<td>N. patients</td>
<td>136</td>
<td>110</td>
<td>26</td>
</tr>
<tr>
<td>Total failures (n.-%)</td>
<td>17*</td>
<td>12.50%</td>
<td>14</td>
</tr>
<tr>
<td>Urodynam ic SUI (n. patients)</td>
<td>95</td>
<td>14.74%</td>
<td>12</td>
</tr>
<tr>
<td>Potential SUI (n. patients)</td>
<td>41</td>
<td>14.81%</td>
<td>2</td>
</tr>
<tr>
<td>Total failure (n.-%)</td>
<td>4</td>
<td>10.34%</td>
<td>1</td>
</tr>
</tbody>
</table>

**Center characteristics**

<table>
<thead>
<tr>
<th>Learning curve</th>
<th>TOTAL PATIENTS</th>
<th>Urodynam ic SUI</th>
<th>Potential SUI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centres with &lt; 10 implants</td>
<td>13</td>
<td>23.08%</td>
<td>3</td>
</tr>
<tr>
<td>Total failures (n.-%)</td>
<td>3</td>
<td>20.00%</td>
<td>1</td>
</tr>
<tr>
<td>Centres with 10-20 implants</td>
<td>33</td>
<td>15.15%</td>
<td>4</td>
</tr>
<tr>
<td>Total failures (n.-%)</td>
<td>5</td>
<td>16.00%</td>
<td>1</td>
</tr>
<tr>
<td>Centres with &gt; 20 implants</td>
<td>90</td>
<td>11.11%</td>
<td>8</td>
</tr>
<tr>
<td>Total failures (n.-%)</td>
<td>10</td>
<td>13.30%</td>
<td>2</td>
</tr>
</tbody>
</table>

**Long term follow-up**

The long term results for the data available are comparable with the short-term results (Tab. 5): for a correct interpretation of the data, one must consider that in the calculation of the long term failure percentages, the patients who were successfully re-operated on during follow-up were nonetheless included in the failure group; thus reported failures are cumulative, since no failure was added after the 6 months follow-up.

**DISCUSSION**

In the cases of long term follow up too, all the mid-urethral slings now used, with either the retropubic or the transobturator approach, are simple, safe and effective.

Thanks to their success percentages, which are on average equal to or above 90% and the low number of perioperative complications in the last decade, TVTs and TVT-Os represent a Copernican revolution in treating urodynamic SUI associated with urethral hypermobility.

**Table 5 – Long-term follow-up. No significant differences have been found among groups**

<table>
<thead>
<tr>
<th></th>
<th>6 MONTHS FOLLOW-UP</th>
<th>12 MONTHS FOLLOW-UP</th>
</tr>
</thead>
<tbody>
<tr>
<td>N. patients</td>
<td>136</td>
<td>69</td>
</tr>
<tr>
<td>Total failures (n.-%)</td>
<td>17</td>
<td>12.50%</td>
</tr>
<tr>
<td>Urodynamic SUI (n. patients)</td>
<td>95</td>
<td>56</td>
</tr>
<tr>
<td>Total failures (n.-%)</td>
<td>14</td>
<td>14.74%</td>
</tr>
<tr>
<td>Potential SUI (n. patients)</td>
<td>41</td>
<td>13</td>
</tr>
<tr>
<td>Total failures (n.-%)</td>
<td>4</td>
<td>9.76%</td>
</tr>
</tbody>
</table>

**Follow-up a lungo termine**

I risultati per i dati ad oggi utilizzabili possono essere confrontati con quelli a breve termine (Tab. 5): per una corretta interpretazione dei dati, va detto che nel calcolo delle percentuali di insuccesso a lungo termine, le pazienti che furono rioperate con successo durante il follow-up tuttavia furono incluse nel gruppo dei fallimenti; quindi i fallimenti riportati sono cumulativi, dal momento che nessun fallimento è stato aggiunto dopo i sei mesi di follow-up.

**DISCUSSIONE**

Anche in casi di follow-up a lungo termine, tutte le sling medio uretrali attualmente utilizzate (sia con approccio transotturatorio che retropubico) sono sicure ed efficaci.

Grazie alla loro percentuale di successo che è mediamente pari o maggiore al 90% e al basso numero di complicanze perioperatorie nell’ultima decade, la TVT e la TVT-O hanno rappresentato una rivoluzione Copernicana nel trattamento della SUI Urodinamica associata ad ipermobilità uretrale. Tutti
All the trials published in the literature confirm the therapeutic validity of both techniques, with 1,000,000 and 193,773 implants performed respectively by the end of the year 2007. Although they are uncommon, it is worth mentioning the following complications, which are not always easy and simple to solve: bladder perforation, bowel, vessel and nerve injury, infection, thigh pain and bladder outlet obstruction.20

TVTsecur system is a technique involving the application of a mid-urethral mini-sling through a single incision, and was introduced in 2006 in order to replace traditional mid-urethral slings in treating women SUI.32

This system was designed to reduce the risk of intra- and post-operative complications reported with the use of TVT and TVT-O: the small sling (only 8 cm long) is made of the same material and has had over a decade of experience. The surgeon avoids passing it through the whole thickness of the obturator muscle, as well as through the fascia-muscle spaces of the thigh abductors (in the hammock-like transobturator implant, TVTs-O) and the passage through the whole thickness of the endopelvic fascia, the perivesical and Retzius' spaces, as well as the muscle-fascia structures of the abdominal wall (retropubic approach, TVTs-U), making sure the device does not transit in highly vascularised and nerves areas. Neither approach requires a transcutaneous passage (thus reducing the risk of pain and implant infection); the surgeon only has to partly use, in a protected way, some access points already known and tested with tradition-
al mid-urethral slings.

Despite the methodical limits linked to the study used, which is not a randomized one, the experience collected by the authors, confirms the premises.

Intra- and post-operative morbidity observed in the 147 cases was limited and had a low clinical impact:
- Vaginal wall perforation: 0.68%
- Intra-operative haemorrhage: 1.91%
- Haematoma: 0.68%
- Retention: 0%
- Urinating difficulties (without associated surgery): 1.91%
- Pain: 0.68%

All complications resolved spontaneously (only pain in the obturator site was treated with NSAIDs for 48 hours) and with no clinical recurrence.

No major intra-operative complications (vesical, urethral, vascular and nervous damages) or mid-term post-operative ones (sling erosions and/or infections) were observed.

These percentages are on average all significatively lower than those reported by the authors for traditional mid-urethral slings: in the retropubic approach, there is an average of 4-6% of haemorrhagic complications and vesical perforations, urinary difficulties reach 4-5%, and dangerous damages of the intestinal and nervous great vessels are only rarely reported. In the transobturator approach, post-operative pain is observed in 4-5% of patients, with a long-term persistency in almost 2% of treated patients, urinary difficulties are observed in 2-5% of cases, and vesical, urethral, and nervous lesion or serious infection in the intervention site are only rarely described.7-15, 23-31

basso impatto clinico:
- Lesioni parete vaginale: 0.68%
- Emorragia intraoperatoria: 1.91%
- Ematomi: 0.68%
- Ritenzione: 0%
- Difficoltà minzionale: 1.91%
- Dolore: 0.68%

Tutte le complicanze (tranne il dolore in regione otturatoria che ha richiesto l’uso di FANS per 48h) si sono risolte spontaneamente.

Non sono state osservate complicanze intra-operatorie (lesioni vescicali, uretrali, vascolari e nervose) post-operatorie maggiori a medio termine (erosione della sling e/o infezioni).

Le percentuali delle complicanze sono mediamente più basse di quanto riportato in letteratura con le sling medio-uretrali classiche: con l’approccio retro-pubico, complicanze emorragiche e perforazioni vescicali sono riportate mediamente nel 4-6%, difficoltà urinarie nel 4-5%, raramente sono riportate lesioni gravi a livello intestinale, vascolare e nervoso.

Con l’approccio tran-sotturatorio sono riportate: dolore post-operatorio nel 4-5% dei casi, con una persistenza a lungo termine almeno nel 2% delle pazienti trattate, difficoltà minzionale nel 2-5% dei casi, sono descritte raramente lesioni vescicali, uretrali e nervose o infezioni gravi nel sito dell’intervento.7-15, 23-31

La acquisizione di una corretta tecnica chirurgica nell’impiantare la sling richiede una inevitabile curva di apprendimento.

In 2 delle pazienti trattate fu necessario un riposizionamento della bendella, dovuto ad una accidentale rimozione durante l’intervento e, in 1 caso fu
The correct surgical technique in implanting TVTs requires an unavoidable “learning-curve”.

In 2 of the patients treated re-positioning of the sling was necessary because it was unintentionally removed during implantation, and for 1 patient a different surgical approach was required since an extensive laceration of the lateral vaginal wall had occurred.

All the surgeons found it difficult to apply the sling in the first patients they treated. Neuman, in a total of 100 TVTs implants, reports an average 5% of accidental sling removal during surgery, but this is 14.2% for the first 35 patients and then 0% for the following 65; the same author reports 4% vaginal wall perforation, that is 11.4% in the first 35% patients and again 0% in the following ones.

The surgeons’ experience has in fact led to the introduction of changes in the application of the sling, which because of its technical characteristics, requires greater tension while being inserted compared to the TVT, a wider sub-urethral tunnel compared to the TVT-O, and slower, more delicate and controlled removal of the device after the positioning the implant.

In fact Neuman, reports 20% of failures in TVTs in the first patients (7/35) and 3% (2/65) in the following ones.

The analysis of this study’s results also shows a significative difference in the success percentages of this method among centres with different experience and a different number of patients treated.

In the total population, these percentages drop from 23.08% of observed failures in the centres with less than 10 necessary un altro approccio chirurgico a causa di una estesa lacerazione della parete vaginale laterale verificatasi durante l’impianto.

Tutti gli operatori hanno osservato una certa difficoltà di applicazione della sling nelle prime pazienti trattate. Neuman, su un totale di 100 impianti, riporta una percentuale di accidentale rimozione durante l’intervento del 5% ma essa è del 14.2% nelle prime 35 pazienti per scendere a 0 nelle successive 65; lo stesso autore riporta una percentuale di lesioni vaginali del 4%, con un 11.4% nelle prime 35 pazienti e 0% nelle successive. L’esperienza degli operatori infatti ha portato alla introduzione di alcune modifiche nella applicazione della sling, che per le sue caratteristiche intrinseche, richiede una maggiore tensione quando viene inserita rispetto alla TVT, un tunnel sub-uretrale più largo rispetto alla TVT-O ed un più lenta, più delicata e controllata rimozione del dispositivo dopo l’impianto della sling.

Neuman infatti riporta una percentuale di fallimento del 20/0% nelle prime TVT-S (7/35) e del 3% nelle successive (2/65).

Anche dai risultati di questo studio si evince una significativa differenza nelle percentuali di successo nei vari centri correlata alla loro differente esperienza ed al numero di casi trattati. Nella popolazione totale, la percentuale di fallimenti cade dal 23,08% dei centri con meno di 10 impianti effettuati, al 10% dei centri con più di 20 pazienti trattate, sia per la SUI uro dinamica che per la SUI potenziale.

Queste variabili probabilmente spiegano il largo range di percentuali di
implants performed, to 11.1% of failures in those with more than 20 patients treated, and this trend is the same both for patients with urodynamic SUI and those with occult SUI.

These variables probably explain the wide range of success percentages, 62% to 88%, reported nowadays in the literature.\textsuperscript{30-33}

In this study, the objective and subjective mid-term cure rate of SUI for the total population (119/136, 87.5%; 120/136, 88.2%) and for the cases of only urodynamic SUI (82/95, 86.3%; 81/95, 85.26%), are statistically similar to those observed on average in the literature with traditional mid-urethral slings and in particular, with those reported in a recent randomized Italian multicentric trial comparing retropubic slings (TVT) and transobturator slings (TVT-O) (Tab. 6).\textsuperscript{14}

The success percentages in occult SUI are also comparable to those reported in literature using mid-urethral slings used up to now.

These success percentages are similar at follow-up, even 12 months after successo, nelle pazienti trattate (tra il 62% e l’88%), ad oggi riportato in letteratura.\textsuperscript{30-33} In questo studio il rate di cura della SUI a medio termine per la popolazione totale (119/136, 87.5%; 120/136, 88.2%) e per la popolazione con sola SUI Urodinamica (82/95, 86.3%; 81/95, 85.26%) è statisticamente simile a quello mediamente osservato in letteratura con le tradizionali sling medio uretrali e, in particolare, con quelle riportate in un recente studio italiano multicentrico randomizzato di confronto tra la TVT retro pubica e la TVT-O (Tab. 6).\textsuperscript{14}

Anche le percentuali di cura della SUI occulta sono simili a quelle, riportate in letteratura, ottenute utilizzando le sling tradizionali.

Queste percentuali sono costanti all’attuale follow-up, anche a 12 mesi dall’intervento, sebbene per un numero di pazienti più limitato rispetto alla popolazione totale.

La percentuale di casi di fallimento e di casi invariati sono certamente più difficili da interpretare clinicamente; 8 pazienti sono state registrate a medio successa, nelle pazienti trattate (tra il 62% e l’88%), ad oggi riportato in letteratura.\textsuperscript{30-33} In questo studio il rate di cura della SUI a medio termine per la popolazione totale (119/136, 87.5%; 120/136, 88.2%) e per la popolazione con sola SUI Urodinamica (82/95, 86.3%; 81/95, 85.26%) è statisticamente simile a quello mediamente osservato in letteratura con le tradizionali sling medio uretrali e, in particolare, con quelle riportate in un recente studio italiano multicentrico randomizzato di confronto tra la TVT retro pubica e la TVT-O (Tab. 6).\textsuperscript{14}

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### Table 6 – TVTs vs TVT vs TVTO. No significant differences have been found among groups

<table>
<thead>
<tr>
<th></th>
<th>TVTs total patients</th>
<th>TVTs-IUS urodynamic</th>
<th>TVT*</th>
<th>TOT-O*</th>
</tr>
</thead>
<tbody>
<tr>
<td>n. patients</td>
<td>136</td>
<td>95</td>
<td>108</td>
<td>110</td>
</tr>
<tr>
<td>Success percentage</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Objective (n-%)</td>
<td>119</td>
<td>87.50%</td>
<td>81</td>
<td>85.26%</td>
</tr>
<tr>
<td>subjective (n-%)</td>
<td>120</td>
<td>88.24%</td>
<td>82</td>
<td>86.32%</td>
</tr>
</tbody>
</table>

Data from * Meschia et al, Int Urogynecol J 2007
surgery, although for a more limited number of patients than the whole population studied.

The percentages of failures and unchanged cases observed during this study are certainly more difficult to interpret clinically; 8 patients were recorded at mid-term (5.8%), 5 of whom quickly underwent further surgery for serious recurrent SUI.

These percentages are definitely higher than those reported in literature both for TVT and TVT-O: with these surgical procedures, the percentage of patients whose situation does not change or who undergo further surgery is rarely above 1-2%. 4,7,14-15

The number of cases and the type of trial adopted are certainly inadequate to allow for a correct clinical interpretation of this data, and at the moment no randomised prospective studies have been published that could help us in this direction.

CONCLUSIONS

The analysis of study’s results show how, although the TVTSecur System is applied in many urogynaecological centres that have different learning-curves for this technique, this method of treating urodynamic and occult SUI is safe (with low and minimal perioperative morbidity), versatile (with the possibility of applying the sling with different techniques depending on the surgeon’s choice) and effective (with success percentages similar to those achieved with traditional mid-urethral slings, both with retropubic and transobturator approaches).

termine (5.8%) di cui 5 sono state rapidamente sottoposte a reintervento per SUI ricorrente grave.

Tali percentuali sono chiaramente più alte rispetto a quelle riportate in letteratura sia con la TVT che con la TVT-O: con queste procedure la percentuale di pazienti con un reperto clinico invariato o che sono state sottoposte a reintervento, raramente è maggiore dell’1-2%. 4,7,14-15 Il numero di casi ed il tipo di studio utilizzato in questo trial è sicuramente inadeguato a permettere una corretta interpretazione clinica di questi dati né tantomeno sono presenti ad oggi dati in letteratura che ci possano aiutare in questo senso.

CONCLUSIONI

L’analisi dei dati dello studio mostra che, sebbene la tecnica sia stata effettuata in molti centri con differenti livelli di esperienza e curva di apprendimento, il TVT-Secur System è una metodica sicura (con una minima morbilità perioperatoria) versatile (con la possibilità di applicare la sling con modalità differente a seconda della discrezionalità dell’operatore), efficace (con percentuali di successo simili a quelle ottenute con le sling tradizionali sia con l’approccio retro pubico che transsottomuscolare). Le percentuali di successo a breve e medio termine sembrano essere confermate.
The short and mid-term success percentages of seem to be confirmed over a long period.

The technique does not always seem to be simple, intuitive or easily repeatable even for surgeons who have experience in mini-invasive procedures: the sling had to be re-positioned or substituted intra-operatively in 3 patients.

Compared to data concerning other mid-urethral slings, the results of this study underline the greater importance of the learning curve for each centre, and the need to adopt a new and original way of positioning and putting the sling under tension.

All this confirms the data available in the literature, which show extremely variable success percentages with TVT-secur that are significatively influenced (in the only multicentric prospective study present at the time being) by the compliance of the individual surgeon and by the method’s particular technical requirements.  

The percentage of cases of further surgery for recurrent SUI already observed at the mid-term follow-up in the population of patients treated (5/136) is significatively higher than the percentages reported in the literature with traditional mid-urethral slings, and at the long-term follow up (3-11 years) it is also slightly higher, around 1%, than both the retropubic and the transobturator approach.  

This study demonstrates the feasibility and effectiveness of the single incision mini-sling (TVTsecur System); the analysis of the data collected shows that VTsTs is an innovative method for treating patients with urodynamic
and/or occult SUI: it is as simple, safe and effective as the traditional mid-urethral, retropubic and/or transobturator slings.

Although this study is prospective, it has all limits of observational studies, so it is not possible to express a definitive judgement on whether this technique can become a safe alternative to the traditional mid-urethral slings. There is therefore the need for further randomised prospective comparative studies.

References

1. ULMSTEN U., HENRIKSSON L., JOHNSON P., VARHOS G.:
Int Urogynecol J 7: 81-85.

2. REZAPOUR M., ULMSTEN U.:

3. REZAPOUR M., FALCONER C., ULMSTEN U.:

4. ULMSTEN U., JOHNSON P., REZAPOUR M.:

5. OLSOSON I., KROON U.:
(1999) *A three-year postoperative evaluation of tension-free vaginal tape.*
Gynecol Obstet Invest 48: 267-269.

6. NILSSON C.G., KUUA N., FALCONER C., REZAPOUR M., ULMSTEN U.:
Int Urogynecol J 12 (Suppl 2): 5-8.


16. REZAPOUR M., NOVARA G., MEIER P.A. et al.:
Int Urogynecol J Pelvic Floor Dysfunc; 18: 183-187.

17. FORSTER J.J., McDONALD J.W., SMITH P.W.F.:
Markov Chain Monte Carlo Exact Inference for Binomial and Multinomial Logistic Regression Models.

18. ZAMAR D., MCNEN EY B. GRAHAM J.:
Software Implementing Exact-like Inference for Logistic Regression Models.
Journal of Statistical Software 2007, 21 (3).

19. DEVELOPMENT CORE TEAM:
A Language and Environment for Statistical Computing.

20. KUUVA N., NILSSON C.G.:
A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure.

21. PARAISO M.F.R., MUIR T.W., SOKOL A.I.:
Are mid-urethral slings the gold standard surgical treatment for primary genuine stress incontinence?

22. WAETJEN L.E., SUBAK L.L., SHEN H. et al.:
Stress urinary incontinence surgery in the United States.

23. NEUMAN M.:
Tension-free vaginal tape bladder penetration and long-lasting transvesical Prolene material.

24. NEUMAN M.:
Post tension-free vaginal tape voiding difficulties – prevention and management.
25. MESCHIA M., BUSACCA M., PIFAROTTI P., DE MARINIS S.:  
Int Urogynecol J Pelvic Floor Dysfunct 13: 263-265

26. NEUMAN M.:  
TVT-Obturador: Short-term data on an operative procedure for the cure of female stress urinary incontinence performed on 300 patients.  

27. HERMIEU J.F., MESSAS A., DELMAS V. et al.:  
Bladder injury after TVT transobturator.  

28. MINAGLIA S., OZEL B., KLUTKE C. et al.:  
Bladder injury during transobturator sling.  

29. MARTAN A., MASATA J., SVABIK K.:  
TVT SECUR System – tension free support of the urethra in women suffering from stress urinary incontinence – technique and initial experience.  

30. Neuman M.:  
Pelviperineology 26: 121-123.

31. VALENTIM-LOURENCO A., HENRIQUES A. BERNARDINO M., RIBEIRINHO A.:  
Int Urogynecol J Pelvic Floor Dysfunct 19 (Suppl 1): S1-S166

32. DEBODINANCE P., LAGRANGE E., AMBLARD J., YAHI H., LUCOT J., 
COSSON M., VILLET R., JACQUETIN B.:  
(2008) TVT SECUR: prospective study and follow-up to 1 year about 150 patients.  
Int Urogynecol J Pelvic Floor Dysfunct 19 (Suppl 1): S1-S166.

33. MESCHIA M., BARBACINI P., PIFAROTTI P., AMBROGI V., RICCI L., 
SPREAFCO L.:  