SUMMARY: In this study we determined the efficacy of TVT for the treatment of female urinary incontinence in a first group of patients (69) of our urogynaecology service from April 1998 to December 2000. The TVT procedure is a minimally invasive technique, using local or spinal anaesthesia, which consists in the implantation of a Prolene tape around the mid-urethra. On the basis of our results (92.3 % success rate) we consider the TVT procedure to be a safe and effective surgical procedure for the treatment of female urinary stress incontinence.

RIASSUNTO: In questo studio si è cercato di identificare l’efficacia della TVT nel trattamento dell’IU femminile in un primo gruppo di pazienti (69) giunte al nostro servizio uroginecologico dall’aprile 1998 al dicembre 2000. La TVT è una tecnica miniminvasiva che si pratica sotto anestesia locale (regionale o spinale) e che consiste nell’impianto di un nastro di Prolene intorno al terzo medio dell’uretra. Sulla base dei risultati (92,3% di successi) consideriamo la TVT una procedura sicura ed efficace per il trattamento dell’IUS femminile.
INTRODUCTION

The TVT (tension free vaginal tape) procedure is a surgical technique, first proposed by Ulf Ulmsten of the University of Uppsala in 1995, that has radically changed surgery for female stress urinary incontinence caused by urethral hypermobility.

The most important innovation proposed by the swedish school, on the basis of in-depth anatomofunctional studies, was to question the supposed theories on which previously proposed female stress urinary incontinence surgery was based.

TVT is in fact a “tension free” surgical procedure that neither displaces nor obstructs the urethra, but supports the intermediary area, preventing the descent and the passive opening under stress (it uses non-absorbable prolene tape), without interfering with the bladder-urethral junction or bladder voiding.

Furthermore, TVT is minimally invasive surgery, to be performed (according to the original technique) under local anaesthesia, which enables the patient to be discharged very quickly and it has an excellent tolerance rate among patients, including excellent long term results.

The aim of this study is to verify the results of our experience.

MATERIALS AND METHODS

From April 1998 to December 2000, in the department of Gynaecology at Como’s Valduce Hospital, 100

MATERIALI E METODI

Dall’aprile 1998 al dicembre 2000, presso la divisione di Ginecologia dell’Ospedale Valduce di Como, 100 pa-
patients underwent corrective operations of SUI using the TVT technique. In particular: in 69 patients the TVT operation was performed exclusively; in 9 the TVT operation was combined with colpohysterectomy.

In the remaining 22 patients the TVT was combined with prolapse correction surgery and these patients were not taken into consideration for this analysis.

The average age of the patients was 58 years (range 36-77), the average parity was 2.3 (range 0-5) of whom only 3 were nulliparous.

Forty patients showed a body mass index over 25.

Fifty-two were already in menopause and they all used hormone replacement therapy or local oestrogen therapy.

Thirteen patients had already had a hysterectomy (12 via abdominal of which 2 sub-total, one via vaginal), 4 patients had already had vaginal anterior repair for a prolapse.

Five patients had previously had treatment using perineal physiotherapy.

Sixty-six patients showed a 1st degree anterior vaginal prolapse and 10 a 2nd degree prolapse, according to Baden and Walker’s classification (H.W.S. 1992).

Inclusion criteria:
• All the patients had complained of stress urinary incontinence for over 2 years.
• Ten had also showed urge symptoms (frequency, nocturia and urgency) without evidence of urodynamic bladder instability, whereas no patient reported difficulties in voiding the bladder or had high residual urine (> 100 ml).
According to Ingelman-Sundberg’s classification, the gravity of the symptoms were 1° degree in 40 patients, 2° degree in 20 and 3° degree in the remaining 18, respectively.

All the patients were evaluated in the Urogynaecology Unit of the Department of Gynaecology following the standard pre and post-operative diagnosis protocol, including:

1. Urocolture and urinalysis (preliminary).
2. Urogynaecological case history gynaecological examination.
3. Stress test performed in the supine and standing positions with a bladder filling of 300 ml.
4. Q tip test (Delta Q tip).
5. Modified PAD test (Standard fill 300 ml, duration—one hour).
6. Urodynamic evaluation with water cystometry, urethral pressure profile and uroflowmetry were performed with Microtip (DUET Multi P-Dantec).
7. Urethral cystoscopy (only pre op).
8. Quality of life evaluation using a questionnaire (King’s Health Questionnaire), and Visual Analogue Scale.

During the urodynamic examination carried out before the operation no patient showed an unstable bladder nor were there signs of bladder retention. Eight patients had a maximum pressure of urethral closure ≤ 20 cm/H20.

The Delta Q-tip average was 40° before the operation and the average urine loss evaluated on the PAD test was 53 grams (5-100 g).

The operation was performed following the original technique described by Ulmsten and Falconer.

Secondo la classificazione di Ingelman-Sundberg la gravità del sintomo era rispettivamente di 1° grado in 40 pazienti, di 2° grado in 20 e di 3° grado nelle rimanenti 18.

Tutte le pazienti sono state valutate presso il Servizio di Uroginecologia della Divisone di Ginecologia secondo un protocollo diagnostico pre e post-operatorio standard comprensente:

1. Esame urine e urocoltura (preliminari).
3. Stress test in posizione supina e ortostatica a riempimento standard di 300 ml.
4. Q tip test (Delta Q tip).
5. PAD test modificato (riempimento standard di 300 ml, durata di un’ora).
6. Valutazione urodinamica con cistomanometria, profilo pressorio uretrale eseguite con Microtip e uroflusometria (DUET Multi P - Dantec).
7. Uretrocistoscopia (solo pre op).
8. Valutazione della qualità della vita mediante questionario (King’s Health Questionnaire) e scala dell’analogo visivo.

All’esame urodinamico eseguito prima dell’intervento nessuna paziente presentava una vescica instabile né erano presenti segni di ritenzione vesicale. 8 pazienti avevano una massima pressione di chiusura uretrale ≤ a 20 cm/H2O.

Il Delta Q tip medio era di 40° prima dell’intervento e la media della perdita di urina valutata al Pad test è stata di 53 grammi (5-100 g.).

L’intervento è stato eseguito secondo la tecnica originale descritta da Ulmsten e Falconer.
scribed by Ulmsten and Falconer.

In 52 (66.6%) patients the operation was performed under local anaesthesia, in 26 under low spinal anaesthesia.

All the patients were evaluated from a clinical and urodynamic point of view after six months and one year following the operation, and subsequently once a year.

**RESULTS**

The average duration of the operation was 34 minutes (range 20-60 min).

Sixty-two (69.2%) patients were able to micturate spontaneously within 4-6 hours of the operation without the need of catheter.

As a precautionary measure, all the patients had been instructed on how to carry out the self-catheterisation manoeuvre by our nursing staff.

Sixteen (20.5%) patients resumed complete micturition within 3 days of the operation.

Five patients continued with self-catheterisation at home until the 8th day following the operation.

In 3 patients the sub-urethral prolene tape had to be cut one month after the operation due to the persistence of high levels of post micturition residuals.

Of the latter patients 2 remained continent (one at one year from the operation, the other after 6 months). The third patient immediately complained of the resumption of stress urinary incontinence.

The average stay in hospital was 3 days (range 2-8 days).

In 52 (66.6%) patients l’intervento è stato eseguito in anestesia locale, in 26 in anestesia locoregionale (spinale).

Tutte le pazienti sono state rivalutate sia da un punto di vista clinico che urodinamico sei mesi e un anno dopo l’intervento, e successivamente una volta all’anno.

**RISULTATI**

La durata media dell’intervento è stata di 34 minuti (range 20 – 60 min.).

62 (69,2 %) pazienti hanno ripreso ad urinare entro 4-6 ore dall’intervento senza necessità di cateterismo.

Tutte le pazienti sono state preventivamente istruite ad eseguire la manovra dell’autocateterismo dal nostro personale infermieristico.

16 (20.5 %) pazienti hanno ripreso una minzione completa entro 3 giorni dall’intervento.

5 pazienti hanno proseguito con l’autocateterismo domiciliare sino alla 8° giornata post-operatoria.

In 3 pazienti si è dovuto sezionare la benderella di prolene sottouretrale dopo un mese dall’intervento per la persistenza di residui post- minzionali elevati.

Di queste ultime pazienti 2 sono rimaste continenti (una a un anno dall’intervento l’altra dopo 6 mesi). La terza paziente ha subito lamentato la ripresa dell’incontinenza urinaria da sforzo.

La degenza media è stata di 3 giorni (range 2-8 gg).

Il follow up è stato per minimo 6 massimo 36 mesi.
The follow-up ranged from a minimum of 6 to a maximum of 36 months.

Seventy-three patients (93.5%) resulted subjectively (evaluation of the quality of life by means of a questionnaire and visual analogue scale) and objectively (stress test at 300 ml of fill while standing and supine modified PAD test) continent at six months from the operation.

After one year 92.3% of the patients (72/78) were continent and satisfied.

Two patients still complained of SUI; 1 patient, previously described, resumed incontinence after the cut of the tape.

Three (3.8%) patients showed urge incontinence with *de novo* bladder instability that required medical treatment with anticholinergic drugs.

During the operation 3 bladder perforations, which were immediately noted and corrected, occurred without any further consequences for patients. At the end of the operation a Foley bladder catheter was inserted and removed during the 3rd day post-op.

All three patients were continent one year following the operation.

In one patient, as soon as the needle was inserted, immediate and copious bleeding of the venous plexus of the Retzius occurred and this required a suprapubic surgical approach with difficult control of the bleeding.

A retropubic colposuspension following Burch was then performed. The post-operative blood-test showed a drop in the haemoglobin of 3 points (from 13 g/dl to 10 g/dl); the patient was discharged on the 5th day.

73 patients (93.5%) are results subjectively (valutazione della qualità della vita mediante questionario e scala dell’analogico visivo) ed oggettivamente (stress test a 300 ml di riempimento in piedi e supina e Pad test modificato) continent a sei mesi dall’intervento.

Ad un anno sono risultate continenti e soddisfatte il 92.3% delle pazienti (72/78).

2 pazienti lamentavano ancora IUS; 1 paziente, già precedentemente descritta, ha ripreso l’incontinenza dopo la sezione della benderella.

3 (3.8%) pazienti hanno manifestato un’incontinenza urinaria da urgenza, con instabilità vescicale *de novo*, che ha richiesto una terapia medica con parasimpaticolitici per os.

Durante l’intervento si sono verificate 3 perforazioni vescicali, subito individuate e corrette, senza alcuna ulteriore conseguenza per le pazienti. Al termine dell’intervento è stato posizionato un catetere vescicale di Foley, rimosso in 3° giornata.

Tutte e tre le pazienti sono risultate continenti dopo un anno dall’intervento.

In una paziente, al primo passaggio dell’ago, si è verificato un importante ed immediato sanguinamento dal plesso venoso del Retzius che ha richiesto un approccio chirurgico sovrapubico con difficoltoso controllo dell’emorragia.

È stata quindi eseguita una colpopospensione retropubica secondo Burch.

Gli esami ematocimici post-operatori hanno rilevato un calo dell’emoglobina di 3 punti (da 13 g/dL a 10 g/dL); la paziente è stata dimessa in 5° giornata senza ulteriori problemi.
without further problems.

The patient has been continent and without voiding problems for two years since the operation.

Furthermore, a haematoma of the Retzius on the left occurred, which was noticed in a clinical examination and confirmed by ultrasound 12 hours after the operation.

The clinical and haemodynamic stability and absence of subjective symptoms enabled the patient to be monitored carefully without additional measures. There was a 4 point decrease in haemoglobin (12 g/dl- 8 g/dl) and it was not necessary to resort to the use of blood transfusion. After 3 months the haematoma was completely reabsorbed and the patient, who was continent, did not report any symptoms then, nor at one year following the operation.

Finally, in another patient a small erosion of the sub-urethral vaginal mucosa was noted, with exposure of the prolene tape a month following the operation, and this required excising of the vaginal mucosa and re-stitching, without further complications or incontinence.

During a urodynamic examination performed 6 months after the operation, we were able to verify a significant improvement in the transmission rate to the urethra (40% pre op – 87% post-op) without any modification of either maximum urethral closure pressure or the functional length. Finally, there were no modifications in the flow parameters (average flow rate), or significant variations in the delta Q tip performed before and after surgery.

La paziente è continente e senza problemi di svuotamento a due anni dall’intervento.

Si è inoltre verificato un ematoma del Retzius a sinistra, rilevato clinicamente e confermato ecograficamente 12 ore dopo l’intervento.

La stabilità clinica ed emodinamica e l’assenza di sintomi soggettivi hanno consentito un attento monitoraggio della paziente senza ulteriori provvedimenti.

Il calo dell’emoglobina è stato di 4 punti (12 g/dL - 8 g/dL) e non è stato necessario ricorrere all’utilizzo di emotrasfusioni. Dopo 3 mesi l’ematoma era completamente riassorbito e la paziente, continent, non riferiva alcuna sintomatologia, come pure dopo un anno dall’intervento.

In un’altra paziente infine si è verificata una piccola erosione della mucosa vaginale sottouretrale, con esposizione della benderella di prolene un mese dopo l’intervento. Il caso ha richiesto l’escissione della mucosa danneggiata e la risutura senza ulteriori complicanze né compromissione della continenza.

Abbiamo potuto verificare, all’esame urodinamico eseguito a 6 mesi dopo l’intervento, un miglioramento significativo della trasmissione di pressione all’uretra (40 % pre op – 87 % post-op) senza alcuna modificazione sia della massima pressione di chiusura uretrale che della lunghezza funzionale.

Non si sono infine rilevate modificazioni dei parametri di flusso urinario, né variazioni significative al delta Q tip eseguito prima e dopo l’intervento.
DISCUSSION

The recovery success rate of 92.3% one year following the operation is certainly encouraging and identical to that reported by other authors with a greater number of surveys and lengthier follow-ups.

In our survey we were also able to verify how long the continence lasted in the patients with follow-up of 24 and 36 months: 90.4% (19/21) and 90.3% (28/31) respectively.

The TVT operation, originally proposed for the cure of genuine stress urinary incontinence from urethral hypermobility, in the absence of prolapse, has been subsequently associated with prolapse surgery and this combination does not seem to create intra operative or follow-up problems and gives identical results to those described with only TVT.

In our 22 patients submitted to TVT operations and vaginal surgery for prolapse the results of continence was 90.9% (20/22) after 8 months. In these patients the operation was always performed under spinal anaesthesia, performing the TVT as first time surgery.

The calibration of the tension of the sub-urethral tape is a critical and delicate task for the positive outcome of the operation and requires the maximum care by the surgeon and the active collaboration of the patient.

Two of the three patients in our survey with post-operative bladder retention had a vaginal operation for prolapse in the past (Kelly-Kennedy) and probably the resulting vaginal scar tissue conditioned the result.
Furthermore, in these three patients the operation was performed under spinal anaesthesia which, as opposed to local anaesthesia, originally suggested by Ulmsten, can interfere with the functionality of the pelvic floor.

Strict adherence to the "tension free" technique and the precise execution of the stress test at the end of the operation should guide the surgeon and guarantee positive results.

The haemorrhaging problems that occurred in two of our patients and which were fortunately resolved without consequences, in Literature cases described in documentation, confirm the fact that the TVT procedure, although being a minimally invasive operation touches on an area of the anatomy that is particularly vascularised and complex.

To reduce to the minimum the risk of these problems, the operation should always be conducted with extreme and rigorous caution and should follow the original technique instructions, which were the results of years of in-depth studies and great experience.

No cases of infection of the lower urinary tracts or creasing of the prolene tape were noted in our patients, and none of the patients who were sexually active complained of problems following the TVT operation.

In addition, the three patients who suffered bladder perforation (3.8%) experienced no further problems.

On meeting the patients during the follow-up they all expressed their satisfaction with the results and the improvement in the quality of life obtained, thanks to a minimally invasive zialli vaginali hanno condizionato il risultato. Inoltre in queste tre pazienti l’intervento è stato eseguito in anestesia locoregionale (spinale), che a differenza dell’anestesia locale originariamente proposta da Ulmsten, può interferire sulla funzionalità del pavimento pelvico. L’attenzione alla tecnica “tension free”, la corretta e precisa esecuzione dello stress test al termine dell’intervento dovrebbero guidare l’operatore ed essere garanzia di un buon risultato. I problemi emorragici occorsi alle nostre due pazienti e fortunatamente risolti senza conseguenze per le stesse, oltre ai casi descritti in Letteratura, confermano il fatto che l’intervento di TVT, pur essendo un intervento mininvasivo interessa una zona anatomica particolarmente vascolarizzata e complessa. Per ridurre al minimo il rischio di questi problemi l’intervento dovrebbe essere sempre condotto in modo attento e rigoroso rispettando le indicazioni della tecnica originale frutto di anni di studi approfonditi e di grande esperienza.

Non si sono verificati nelle nostre pazienti casi di infezione delle basse vie urinarie o rigetti della benderella di prolene e nessuna delle pazienti sessualmente attive ha lamentato problemi dopo l’intervento di TVT. Anche nelle tre pazienti in cui si è verificata una perforazione vescicale (3.8%) non ci sono stati ulteriori problemi. Incontrando le pazienti durante il follow up abbiamo potuto cogliere la loro soddisfazione per il risultato raggiunto e il miglioramento della qualità della vita ottenuto grazie ad un intervento minimamente invasivo che ha comportato solo una brevissima interruzione delle loro attività.
operation that required only a brief interruption in their normal activities.

In conclusion, the TVT operation is a safe and efficient method for the cure of female stress urinary incontinence, which gives excellent results, reduces hospitalisation times (some authors propose it as an ambulatory surgical procedure) and can be combined, with equally good results, with prolapse surgery.

In conclusione, l’intervento di TVT è una metodica sicura ed efficace per la cura dell’incontinenza urinaria da sforzo che dà ottimi risultati, riduce i tempi di degenza (alcuni autori lo propongono come tecnica ambulatoriale) e può essere associato, con altrettanti buoni risultati, alla chirurgia del prolasso.

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