SUMMARY: In this study we determined the efficacy and safety of tension free vaginal tape (TVT), a new procedure for the treatment of female stress urinary incontinence. TVT consists in the implantation of a prolene tape around the mid-urethra via a small vaginal incision. The TVT procedure is a minimally invasive technique using local or spinal anaesthesia allowing most women to be discharged from hospital the same day or the day after the operation. In the surgery of SUI with urethral hypermobility, TVT is without doubt one of the most interesting procedure to have changed surgery practice, and is a promising alternative to the traditional techniques. On the basis of our results we consider the TVT operation to be a safe and effective surgical procedure for the treatment of female urinary stress incontinence, having obtained a success rate of 76.5%.
INTRODUCTION

The anatomic structures that perform the duties of support with regard to continence are the uteropelvic and pubourethral ligaments, the tendinous arcus, the levator ani aponeurosis and the urogenital diaphragm. These structures support the third median of the urethra. In fact, this area of the urethra presents the highest closure pressure at the urethral pressure profile.

Under stress in fact, the urethrovesical region is very mobile; this mobility is necessary to empty the bladder suitably. The crucial role of this mobility is very clear in pluripara women and in women suffering from cystocele.

Stress incontinence is caused by impaired collagen function causing a disruption of the elements necessary to maintain the above mentioned anatomical structures that form the closing mechanism of the urethra; this is why in some cases we find a pathology of pelvic static (descensus uteri, cystocele) without incontinence. Therefore, incontinence always appears in association with urethral hypermobility caused by traumatic, dystrophic and constitutional lesions of the third median of urethra.

The aim of modern and effective surgery of incontinence is to support the third median of the urethra and to prevent the passive deployment and the opening of the urethra under stress.

The operation forms a hammock to suspend the third median of the urethra without interfering with the urethrovesical zone, the latter being very important for bladder emptying.

Based on this criteria a new surgical sling procedure was

INTRODUZIONE

Le strutture anatomiche che esercitano una notevole funzione di supporto riguardo la continenza sono i legamenti utero-pelvici, i legamenti pubouretrali, gli archi tendinei, l’aponeurosi degli elevatori ed il diaframma urogenitale: esercitano la propria funzione convergendo tutte nel sostenere e supportare l’uretra nel suo terzo medio.

E’ infatti la zona intermedia dell’uretra che presenta al profilo pressorio la più elevata pressione di chiusura.

Sotto sforzo, infatti, la regione uretrovesicale è particolarmente mobile, essendo tale mobilità necessaria per permettere un adeguato svuotamento vescicale, e tutto ciò è particolarmente evidente nelle pluripare e nelle donne affette da cistocele.

L’incontinenza da sforzo, si manifesta infatti quando si verificano lesioni in questa zona dell’uretra (nell’area cioè dove vanno a convergere le strutture sopra descritte), ciò spiega anche come possa verificarsi una patologia della statica pelvica (prolasso, cistocele) non accompagnato da incontinenza urinaria.

L’incontinenza urinaria stessa proprio per questo motivo, si accompagna clinicamente ad ipermobilità uretrale, dovuta a lesioni specifiche (traumatiche, distrofiche, costituzionali) della zona descritta, cioè del terzo medio dell’uretra.

Per comprendere quindi qualsi dei debbano essere gli obbiettivi per una moderna ed efficace chirurgia dell’incontinenza è fondamentale che essa non dislochi né ostruisca l’uretra, ma ne supporti la zona intermedia impedendole la dislocazione e l’apertura passiva sotto sforzo, non interferendo con la zona uretro-vesicale che possiede notevole importanza riguardo allo svuotamento vescicale.

La chirurgia, quindi, deve costituire un
presented by the Uppsala school headed by Prof. Ulmsten after a long study with the cooperation of biomechanical engineers. This surgical technique obtained astonishing and permanent results also thanks to the particular material used (prolene).

**Surgical technique**

The patient is placed in the lithotomy position with her legs not excessively bent over her pelvis. The patient’s legs must be kept as low and separated as possible. This expedient, that might seem a minor detail, is, instead, very important to remove as many iliac vessels as possible from the median line. The operation is carried out under local anaesthesia (in the suprapubic, paraurethral and retro urethral zone), with mepivacaine at 0.5% 100 ml max or with epidural anaesthesia; recently in our Division we have also used subaracnoidal anaesthesia.

After insertion of a Foley 18 ch and depletion of the bladder we perform a short incision at a distance of 1 cm from the meatus urethrae externi.

Then we proceed with a modest smooth unsticking on both sides toward the endopelvic fascia followed by two small skin incisions above the posterior edge of the horizontal blade of the pubis. A rigid mandrin is inserted to move the bladder neck counter-laterally with respect to the zone of insertion of the sling. At this stage, proceeding with the maximum caution and avoiding rapid manoeuvres, the

La paziente è posta in posizione litotomica; molto importante è che la posizione delle gambe non sia eccessivamente piegata sul bacino. Le gambe devono essere mantenute più basse e più divaricate possibile. Questo accorgimento, che può sembrare un banale dettaglio, è invece molto importante in quanto serve a distanziare ed allontanare il più possibile i vasi iliaci dalla linea mediana.

L’anestesia praticata può essere effettuata o con infiltrazione locale (in zona sovrapubica, parauretrale e retro uretrale bilateralmente) con mepivacaina allo 0.5% 100ml max o con anestesia epidurale; ultimamente nella nostra Divisione abbiamo utilizzato spesso l’anestesia subaracnoidea.

Dopo aver applicato un Foley 18 ch ed aver accuratamente svuotato la vescica si pratica una piccola incisione a distanza di circa 1 cm dal meato uretrale esterno.

Si procede a modestissimo scollemiento per via smussa sui due lati verso la fascia endopelvica. Vengono praticate quindi due piccole incisioni cutanee a livello del margine posteriore della branca orizzontale del pube. Si inserisce un mandrino rigido per poter spostare il collo vescicale dalla parte controlaterale rispetto alla zona in cui passeremo l’ago portatore della sling, si
smoothed needle is inserted and brought up (without any lateralisation) using as a guide the posterior pubic ramus that must be followed internally with the index finger of the left hand (for right handed surgeons).

Let us now focus on some important considerations about this last passage:

a) avoiding any lateralisation decreases the risk of injuring the big vessels that flow from the pelvis to the lower limbs;

b) following the retropubic zone vertically prevents bladder lesions. Some of these lesions could occur just because of an excessive departure from the inner edge of the pubis;

c) proceeding very slowly and in a smooth and constant fashion allows the smooth needle to avoid possible vessels present in the Retzius cavity and therefore the formation of retropubic haematomae and disturbing bleeding;

After repetition of the same procedure counter-laterally a cystoscopic check of bladder is performed. One then proceeds with the control of urinary continence by smoothly calibrating the sling tension while the patient coughs. It is most important not to apply excessive tension.

Generally no Foley catheter is inserted and discharge occurs 24 hours after the verification of absence of post-micturition residual urine (except for patients who underwent subaracnoidal anaesthesia).
MATERIALS AND METHODS

Ninety-eight patients of average age 62.3 years (ranging from 39 to 78) were operated with the tension free vaginal tape procedure from March 1998 to May 2000. Fifty-three patients had been in menopause for at least two years. Fifty-eight (of these 98) patients were treated with TVT not associated with other vaginal surgery. Twenty-six underwent colpohysterectomy and repairing of cystocele by prolene net. Fourteen underwent TVT and repair of posterior segment by levator myorrhaphy.

We evaluated exclusively the patients undergoing TVT and 23 had a Q-tip test result of 1 degree, 18 a Q-tip test of 2 degree and 17 of 3 degree.

Eighteen patients had nicturia and urgency confirmed by a urodynamical study that showed moderate motor instability.

All the patients of this group underwent a careful urogynaecological work-up with:
- detailed clinical history
- urogynaecological examination with evaluation of vaginal profile
- Q-tip test
- complete urodynamic study (PPU static and dynamic, CMG, UFM)
- endoscopic examination.

RESULTS

At a mean follow-up of 14 months (range 4-24)
  a) 75 patients (76.5%) were completely cured
  b) 10 patients (10.2%) showed moderate detrusor instability (this disappeared however after 10 months)
c) 4 patients (4.1%) improved with rare and irregular urine leakages
d) 5 patients (5.1%) were classified as failures, one of these due to incorrect positioning of the prolene band, solved two months after with dissection of the same and reapplication six months later

e) 1 lesion of external iliac vein
f) 3 bladder perforations (3.1%)
g) 1 haematoma of the Retzius

These failures, in spite of the good experience of our Centre in vaginal surgery, did not occur in early operations, as one would expect in the first passage of the learning-curve, but after the first 15 operations. TVT is not difficult but not banal and must be faced with great precaution, attention and meticulousness, not disregarding the precautions previously described.

CONCLUSIONS

In the surgery of SUI with urethral hypermobility, TVT is no doubt the most interesting procedure to have changed surgical practice, and is a promising alternative to the traditional technique.

On the basis of our results we consider the TVT operation to be a safe and effective surgical procedure for the treatment of female urinary stress incontinence with a success rate of 76.5%. Further studies are in progress to improve the statistics and to determine the long-term efficacy of this technique.

CONCLUSIONI

La TVT nell’ambito della chirurgia della IUS in presenza di iper mobilità uretrale è senza dubbio una metodica interessante, che ha cambiato la condotta chirurgica abbattendone nella nostra esperienza il ricorso ad altre metodiche ampiamente usate fino al suo avvento. Ha inoltre mostrato alto grado di affidabilità e successo terapeutico che andrà controllato nel corso degli anni.
REFERENCES / BIBLIOGRAFIA


