Evaluation Of Prolene Mesh As T.O.T. In The Surgical Treatment Of Female Stress Urinary Incontinence

Thesis

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Abstract

Objective: Determination of the short term safety, efficacy and urodynamic effect of the use of Prolene mesh as a midurethral sling for surgical correction of female stress urinary incontinence using trans-obturator vaginal tape inside-out technique as a low cost alternative for available commercial kits in the treatment of female stress urinary incontinence.

Patients and Methods: Since June 2006, thirty female patients with stress urinary incontinence (9 with pure ISD (30%), 18 with urethral hypermobility (60%) & 3 (10%) with combined ISD & hypermobility) underwent Prolene mesh midurethral sling in our institution. Preoperative evaluation consisted of history, examination, ultrasonography, ascending cystography, urodynamic studies, and routine laboratory investigations. SUI was evident clinically in all patients. 2 patients underwent anterior colporrhaphy concomitant to the Prolene mesh procedure for correction of symptomatic grade II cystocele. Prolene mesh was cut into a tapes measuring 10x1.5 cm and sterilized by autoclave. The mesh was placed at the mid-urethra and passed through the obturator foramena by Prolene sutures loaded on specially designed helical passers. The helical passers were passed inside-out. The prolene sutures were anchored to the subcutaneous tissue at the site of exit. Patients were followed up (for a mean of 9 months) by history, examination, urine analysis, pelvic ultrasound to detect residual urine, and urodynamic evaluation at 1, 3, 6, 9 & 12 months post-operatively.

Results: All procedures were completed with no intraoperative complications, no failures or recurrences of stress incontinence. All patients were objectively cured but twenty nine patients were subjectively cured (96.7%). One patient (3.3%) developed obstruction but she could complete her voiding without residual urine. She was satisfied with her results. 3 patients (10%) developed vaginal infection, one patient (3.3%) developed wound infection, two patients (6.7%) developed UTI & one patient complained from dyspareunia. Lower limb & groin pain has been developed in 15 patients (50%), but was controlled by analgesics and has disappeared in all patients within the 1st post-operative month. Subcutaneous non absorbable sutures were felt in one patient. De novo urgency and erosions have not occurred in any patient.

Conclusion: Results of our technique showed that midurethral trans-obturator prolene mesh sling is safe, efficient, reproducible and a low cost technique for treatment of stress urinary incontinence. Our technique does not require disposable instrumentation for placement, and is inexpensive as our modified helical passers have the advantage of being resterilizable & each Prolene strip will cost less than 10 EGP. The price of similar incontinence kits in the market ranges from (3000 − 3500 EGP) per set. Long term follow up is required together with prospective randomized studies with the original TVT-O technique to confirm these results.

Key Words:

Urinary incontinence, stress, Prolene mesh, TVT-O, female.

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ALPP:	Abdominal leak point pressure
ATLA:	Arcus tendineus of the levator ani.
ATFP:	Arcus tendineus fascia pelvis.
AUA:	American urological association
AUS:	Artificial urinary sphincter.
AVWS:	Anterior vaginal wall sling
BOO:	Bladder outlet obstruction
BOOI:	Bladder outlet obstruction index
CaHA:	Calcium hydroxylapatite.
CBC:	Complete blood picture.
CIC:	Clean intermittent catheterization
CMG:	Cystometrogram.
CNS:	Central nervous system
CS:	Caesarian section.
DSD:	Detrusor sphincter dyssynergia
DLPP:	Detrusor leak point pressure
EMG:	Electromyography
EUS:	External urethral sphincter.
F:	French
FDA:	Food and drug administration.
GAX:	Gautaraldahyde cross-linked bovine collagen.
Gh:	Genital hiatus
ICS:	International Continence Society
ISD:	Intrinsic sphincter deficiency
IVS:	Intravaginal slingplasty
LBNS:	Laparoscopic bladder neck suspension.
linPURR:	Linear partial urethral resistance relation
LMA:	Longitudinal muscle of the anus
LP:	Levator plate
LUTS:	Lower urinary tract symptoms.
MMK:	Marshal-Marchetti-Krantz-cystourethropexy.
MRI:	Magnetic resonance imaging.
MUCP:	Maximum urethral closure pressure
MUI:	Mixed urinary incontinence
NE:	Nor-Epinephrine.
Pabd:	Abdominal pressure.
Pb:	Perineal body
PCM:	Pubococcygeus muscle
Pdet:	Detrusor pressure.
PFES:	Pelvic floor exercises.
PFS:	Pressure flow study.
PMC:	Pontine micturition center
POPQ:	Pelvic organ prolapse quantification.
PPA:	Phenylproparolamine
PTFE:	Polytetrafluoroethylene
PUL:	Pubourethral ligaments.
PUV:	Posterior urethro vesical

Pves:	Intravesical pressure.
PVS:	Pubovaginal sling
Qmax:	Maximum flow rate.
SD:	Standard deviation
SUI:	Stress urinary incontinence
TFS:	Tissue fixation system
TOT:	Trans-obturator tape
T.O.T:	Trans-obturator tape outside-in
TVL:	Total vaginal length
TVNS:	Transvaginal needle suspension
TVT:	Tension free vaginal tape.
TVT-O:	Tension-free vaginal tape-outside (inside-out trans-obturator tape)
UCP:	Urethral closure pressure.
UI:	Urinary incontinence
UPP:	Urethral pressure profile
USL:	Uterosacral ligament
UTI:	Urinary tract infection.
UUI:	Urge urinary incontinence
VLPP:	Valsalva leak point pressure
VUDS:	Videourodynamics
VUR:	Vesicoureteric reflux

INTRODUCTION

Urinary disorders in women are common place. Among the most distressing of these are the various forms of incontinence. [1&2]

Urinary incontinence is a significant health problem worldwide with considerable social and economic impact on individuals and society. It was estimated that urinary incontinence in women was the primary cause for more than 1.1 million office visits in 2000 in the United States. The total direct and indirect cost of incontinence in the United States in the year 2000 was estimated to be approximately $19.5 billion.[3] It accounts for approximately 2% of health care costs in USA.[4] Despite its prevalence, morbidity and cost, incontinence remains largely neglected.[5] Furthermore urinary incontinence is with wide spread human and social implications, causing discomfort, shame and loss of self-confidence, and may negatively affect the quality of life. It can result in a loss of self-steam and decreased ability to maintain an independent life style. In elderly women, urinary incontinence may lead to possible rejection on the part of a relative and may be an important factor in the decision on whether to institutionalize an elderly person. [4&6]

Stress incontinence is the involuntary loss of urine during maneuvers that increase intra-abdominal pressure (for example coughing), and reflects urethral hypermobility or intrinsic sphincter weakness.[7] Stress urinary incontinence (SUI) is considered one of the most common types of urinary incontinence accounting for about 50% of all cases. [8&9]

There are two main types of sphincter abnormality: urethral hypermobility & intrinsic sphincter deficiency (ISD).[10] However, both conditions may co-exist, especially when subjective loss of urine is high.[11] Urethral hypermobility occurs when there is a defect in the pelvic support of the bladder neck, while intrinsic sphincter deficiency is defined as loss of bladder outlet closure potential.[12]

As more women seek for SUI, the demand for safe, effective, minimally invasive and durable form of therapy has increased.[13]

Understanding of the physiopathological concepts of female stress urinary incontinence (SUI) has consistently improved over the past decades and their application has lead to the development of numerous surgical techniques aimed at curing this disorder.[14]

The surgical treatment of female stress urinary incontinence caused by urethral hypermobility was drastically changed in 1995 by the description of a new concept, the mid-urethral support without tension, by ***Ulmsten and Petros***.[15] Among the numerous surgical techniques aimed at curing female stress urinary incontinence (SUI), retro-pubic tension-free vaginal tape (TVT) has probably been the most revolutionary.[16–22]

The wide use of retro-pubic TVT has been associated with various peri- and post-operative complications, including bladder perforation, temporary or persistent retention, pain, urinary infection, and de novo instability.[19] Other rare but severe—and possibly under-estimated— complications have been reported with this approach. Indeed, the blind passage of the needle in the retro-pubic space can result in injuries to other organs than the bladder, in particular the urethra, vessels, nerves and bowel.[23&24]

A new surgical approach has been introduced maintaining the position under the mid-urethra of the tension-free vaginal tape but reducing or even eliminating complications related to the penetration of the retro-pubic space by placing the tape between the two obturator foramena.[25] Anatomic studies ruled out the risk of lesion to the obturator pedicle in theory.[26] The alternate approaches with a trans-obturator passage of the tape have continence rates roughly similar to those after the 'classic' retro-pubic TVT at least on the short term.[26–28]

The original design of this new technique described by ***Delorme*** in 2001, called trans-obturator tape (T.O.T.), was to place the tape between the two obturator foramena, from outside to inside.[26] The reported results are very close to those reported in most of the observational series of tension-free vaginal tape.[29,30,31&32] No vascular, nerve or bowel injuries have been reported, justifying the interest in the trans-obturator route.[25] At the end of 2003, a novel surgical technique was described by ***de Leval***, with the passage of the tape through the obturator foramena from inside to outside, which was called tension-free vaginal tape-outside (TVT-O).[33] Clinicians, who have been convinced that the trans-obturator approach is safer than the retro-pubic approach, now have the possibility to choose between outside in TOT and inside out TVT-O. Results obtained in a series of 107 consecutive patients in that study indicate that this surgical procedure is feasible, accurate, quick, and simple. In addition, this technique avoids damage to the urethra and bladder and, for this reason, makes cystoscopy not necessary.[33]

Various materials were used in the slings, from autogenous tissues to synthetic materials, and the choices were based upon well-defined criteria, in which the cost was one of the most important factors for the selection of materials, mainly in countries with limited public health resources.[34]

Studies confirmed that the choice of a tension free polypropylene mesh allows high success rates and simplified the SUI therapy. The TVT and the TOT are becoming one of the most common options for the treatment of this disease. Thus, the industry has offered different kits to make the slings, but most of the time the costs are prohibitive for public health systems with few financial resources.

The aim of this article is to evaluate the safety & efficacy of Prolene mesh for surgical correction of female stress urinary incontinence (SUI) using trans-obturator vaginal tape inside-out technique as a low cost alternative for available commercial kits in the treatment of female stress urinary incontinence (SUI). The principal difference lies in the cost of the material used, since in this study the polypropylene mesh (PROLENE© Polypropylene Mesh; Ethicon Ltd UK) was used, however it was prepared, instead of the specific commercialized material for this procedure.