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EVALUATION OF PROLENE MESH AS TOT IN THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

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Objective: Determination of the safety, efficacy and urodynamic effect of the use of Prolene mesh as a midurethral sling 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.

Patients and Methods: This was a prospective study that included thirty female patients with stress urinary incontinence (9 with pure ISD, 18 with urethral hypermobility and 3 with combined ISD and urethral hypermobility). All patients underwent Prolene mesh midurethral sling in our institution. Preoperative evaluation included: history, physical examination, laboratory investigations and urodynamic studies. Two patients underwent anterior colporrhaphy concomitant to the Prolene mesh procedure for correction of symptomatic grade II cystocele. Prolene mesh was placed at the midurethra and passed through the obturator foramina 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, physical examination, urine analysis, pelvic ultrasound to detect residual urine at 1, 3, 6, 9 and 12 months. Urodynamic evaluation was done only in patients with persistent SUI or obstruction.

Results: Sixteen patients (53.3%) had pure SUI while 14 patients (46.3%) had mixed SUI and urge incontinence. Eighteen patients (60%) had urethral hypermobility, 9 patients (30%) had pure ISD and 3 patients (10%) had both. Fourteen patients (46.7%) had grade I SUI, 14 patients (46.7%) had grade II SUI and 2 patients (6.7%) had grade III. Seventeen patients (56.7%) had grade I cystocele and 3 patients (10%) had grade II cystocele. All procedures were completed with no intraoperative complications, no failures or recurrence of stress urinary incontinence. All patients were objectively cured. Of the 14 patients with mixed SUI and urge incontinence, 10 patients (71.3%) showed resolution of urge incontinence while 4 patients (28.6%) had persistent urge incontinence. None of the patients developed urinary tract obstructive symptoms, 1 patient (3.3%) had vaginal infection, 1 patient (3.3%) had wound infection, 1 patient (3.3%) developed UTI and one patient complained from dyspareunia. Groin pain developed in 15 patients (50%) but was controlled with analgesics and disappeared in all patients within the first postoperative month. None of the patients had any vaginal erosion.

Conclusion: Results of our technique showed that the midurethral transobturator prolene mesh is safe, efficient, reproducible and at a low cost. Our technique does not require disposable instruments and is inexpensive. Long term follow up as well as randomized studies are needed to confirm our results.

Key Words: Stress urinary incontinence, Prolene mesh, TVT-O, female.

INTRODUCTION

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 the United States in 2000. Stress urinary incontinence is considered one of the most common types of incontinence accounting for about 50% of all cases.[2]

There are two main types of stress urinary incontinence: urethral hypermobility & intrinsic sphincter diffeciency.[3] However both conditions may coexist.[5] 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.[1]

As more women seek treatment for stress urinary incontinence, the demand for safe,

effective, minimally invasive and durable form of therapy has increased.

The surgical treatment for stress urinary incontinence was drastically changed by the description of a new concept, the midurethral support without tension.[4] The widespread use of retropubic TVT has been associated with various peri and postoperative complications including bladder perforation, urinary retention and vessel injury. Thus an alternative approach came out, the transobturator passage of the tape from outside to inside.[7] At the end of 2003, Delaval described the passage of the tape from inside to outside. The aim of this work was to evaluate the safety and efficacy of prolene mesh for treatment of female stress urinary incontinence using transobturator vaginal tape inside-out technique as a low cost alternative to commercially available kits.

PATIENTS AND METHODS

The study was conducted on 30 female patients complaining of stress urinary incontinence in the period of June 2007 to June 2008. The study was designed as a prospective open observational study.

Inclusion criteria:

Female patients with stress urinary incontinence due to urethral hpermobility or ISD. Urge incontinence didn't exclude patients unless it was the only complaint. Previous surgeries or attempts of repair didn't exclude patients. Patients with cystocele were included but repair was done along with the prolene mesh (grade II symptomatic).

Exclusion criteria:

Patients were excluded from the study if they had any abnormality in bladder contractility, reduced bladder capacity or compliance, post void residual urine >100cc, history of radio- or chemotherapy. Women on anticoagulant or antipsychotic treatment were also excluded as well as patients with urogenital prolapse of more than 2nd degree (Baden and Walker, 1992).

Preoperative evaluation included: History, physical examination (stress test, urogenital prolapse assessment), routine preoperative laboratory work up (urine analysis, serum creatinine, liver functions, fasting blood sugar and bleeding profile), abdominal and pelvic ultrasound with post void residual urine assessment and urodynamics studies (uroflometry, cystometry, abdominal leak point pressure, pressure flow study).

Incontinence in our patients was classified as pure SUI or mixed (SUI and urge incontinence). SUI was classified according to Raz, 1992 (urethral hypermobility or ISD or both). SUI was graded according to Stamey, 1980 (grade I, II, III).

We performed the transobturator tape inside out using prolene mesh with specially designed helical passers. These are pairs of instruments, specific for the left and right sides. They are stainless steel instruments comprising a spirally shaped section and a handle. The spiral section comprises an open circular segment having a 3cm radius terminated by 2 linear segments with a tapered blunt tip. On a horizontal plane perpendicular to the handle's axis, the gap between the extremities of the spiral section is 2cm. The passer is fenestrated at the tip, which allows the insertion of a non-absorbable monofilament polypropylene sutures that are attached intra-operatively to both ends of the synthetic mesh strip. These passers are resterilizable using the autoclave.

Surgical Technique:

Polypropylene strips of about 10cm length and 1.5cm width were handly prepared by dividing the commercially available 30x30 prolene mesh. Each strip was packaged and sterilized by autoclave. Each end of the mesh was anchored with a zero prolene suture in a figure of eight fashion. The suture end was then inserted into the eye at the end of the passer.

All patients had spinal anesthesia, placed in the dorsal lithotomy position and thighs in hyperflexion. A 16F Foley catheter was inserted per urethra and the bladder emptied.

The labia were retracted laterally. A median sagittal incision of the anterior vaginal wall was started 1cm proximal to the urethral meatus and continued 1cm proximally. Minimal para-urethral subvaginal dissection was carried out laterally sharply towards the upper part of the ischio-pubic ramus on either side. The obturator membrane was perforated sharply. Groin incisions were done.

The points where the needles will exit were identified by tracing a horizontal line at the

level of the urethral meatus. The exit points were located 2cm above this line and 2cm outside the thigh folds. The helical passer was pushed in the preformed dissection pathway at a 45degree angle relative to the midline sagittal plane until it reaches and perforates the obturator membrane. The skin was incised over the pointed tip of the passer. The prolene sutures were extracted from the passer. The passer was removed by a backward rotational movement. The same technique was applied to the other side. Cystoscopy was done to exclude bladder or urethral injury. The tape was aligned at the midurethra. The tape tension was adjusted so that a clamp could be easily passed between the tape and the urethra. The prolene sutures attached at both ends of the tape were fixed to the deep fascia on both sides at the exit points using French eye needle. The anterior vaginal wall incision was closed using interrupted 3-0 vicryl suture.

The urethral catheter was removed the next day and patients were asked to void. Patients were instructed to abstain from sexual intercourse for 4-6weeks and pay regular visits every 2 weeks during the first month and then every 3 months for the first year.

Post-operatively patients were assessed at 1, 3, 6, 9 and 12 months by: History and physical examination, urine ananlysis, residual urine evaluation on ultrasound, uroflometry and urodynamis.

Finally patients were categorizes as cure if no SUI occurred postoperatively (the absence of subjective complaint of urine leakage, and the absence of leakage on cough stress test and urodynamics). The patients were considered improved if SUI was still present but to a milder degree and failed if the patient was still complaining of SUI. (Whether the same or worse than before surgery).

Data were statistically described in terms of range, mean ±standard deviation, frequencies (number of cases) and relative frequencies (percentages) when appropriate. All statistical calculations were done using computer programs Microsoft Excel version 7 and SPSS (Statistical package for the social science, SPSS Inc. Chicago, IL, USA).

RESULTS

Table I shows mean age of patients in the study and parity status. Two patients (6.7%) had previous vaginal anti-incontinence surgery, 3 patients (10%) had previous abdominal hysterectomy and 2 patients (6.7%) had previous vaginal prolapse repair. Seven patients (23.3%) were postmenopausal.

Table (1): Patients' age and parity status

Parameter	Mean ± SD	Range
Age	43.63 ±8.4	31-61
Parity	4.2 ±1.6	2-8

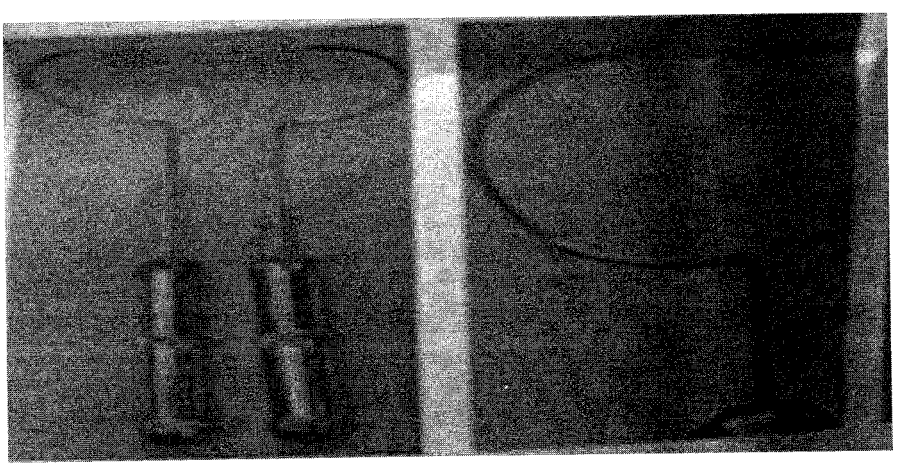

Figure (1): Specially designed helical passers.

Sixteen patients (53.3%) had pure SUI, while 14 patients (46.7%) had mixed SUI and urge incontinence. Fourteen patients (46.7%) had grade I SUI, 14 patients (46.7%) had grade II SUI and 2 patients (6.7%) had grade III SUI. Table 2 shows the different types of SUI encountered in the study population.

Table (2): Type of SUI in the study population

Type of SUI	Number	%
Pure urethral hypermobility	18	60
Combined urethral hypermobility and ISD	3	10
Pure ISD	9	30
Total	**30**	**100**

Prolapse was classified according to Baden and Walker. Thirteen patients (43.3%) had no cystocele and 17 patients (56.7%) had grade II cystocele. Twelve patients (40%) had no rectocele, 9 patients (30%) had grade I rectocele and 9 patients (30%) had grade II rectocele. Table 3 shows preoperative urodynamic findings. None of the patients had involuntary bladder contractions.

Table (3): Urodynamics in the study population

	Mean	Range
Abdominal leak point pressure	82.5±40.9	40-150
Capacity	478±74.1	372-690

Transobturator tape (inside-out) Prolene mesh sling was done for the 30 patients. Additional anterior colporraphy was done for 2 cases with symptomatic grade II cystocele. No intra-operative complications occurred. No injury to the urethra, bladder or bowel was noted. In none of the cases was the vaginal wall perforated during the procedure.

The mean follow up period for the patients was 9.34±5.31 months (range 3-24 months). Twenty nine patients (96.7%) were subjectively cured. This increased to 100% objectively. Only one patient showed improvement, however there was no leakage during stress test, urodynamics with full bladder and while patient was standing. None of the patients had urinary retention postoperatively. Urgency and urge incontinence improved from 14 patients (46.7%) preoperatively to 4 patients postoperatively. The 4 patients had no obstructive symptoms or significant residual urine. They were given an anti-cholinergic (oxybutinin 2-3 tablets per day) on which they improved. Postoperative urodynamics at 1, 3, 6and 12 months for those four patients showed no evidence of involuntary bladder contractions, bladder outlet obstruction or significant residual urine. None of the patients reported denovo urge incontinence. None of the patients had obstruction as assessed verbally (symptoms), residual urine and at urodynamics at follow up.

Fifteen patients (50%) complained of moderate pain or discomfort in the thigh folds and groin early after surgery; however it was controlled within 1 month in all patients with nonsteroidal anti-inflammatory agents. One patient (3.3%) developed vaginal discharge which was treated with the appropriate antibiotic. One patient (3.3%) had wound infection at site of cutaneous sutures. One patient (3.3%) had urinary tract infection which was treated according to culture and sensitivity.

DISCUSSION

Midurethral tesion free synthetic slings such as the tension free vaginal tape (TVT) has become the most popular procedure worldwide for the treatment of female SUI. In Europe, as of 2005, approximately 83.9% of all procedures were midurethral synthetic slings of which 26.9% were TOT.[12] Many procedures had been described, Sparc, Safyre and Sabre. They differ primarily in the approach to placement and hardware necessary for their placement. Although simple to perform, these procedures require special instruments and their price is prohibitive in some parts of the world.

The aim of our study was to evaluate the safety and efficacy of prolene mesh for surgical correction of female stress urinary incontinence using trans-obturator vaginal tape inside out technique as a low cost alternative to commercially available kits. Polypropylene strips of about 10cm length and 1.5 cm width were handly prepared by dividing the commercially available 30x30cm prolene mesh. This will give about 60 tapes. Each strip was packaged and resterlized by autoclave. Each tape will cost about 10 Egyptian Pounds. Our modified helical passers have the advantage of being reused since they were sterilized by the autoclave (they cost less than 200 Egyptian Pounds). The price of similar incontinence kits in the market ranged from 3000-3500 Egyptian Pounds.

Since the initial description by Delorme in 2001, continence rates had been satisfactory

although follow up had been short. Reported continence rates ranged from 80.5% to 96% on the basis of a variety of subjective (questionnaire and quality of life single item assessment) and objective (cough stress test, uroflometry, physical examination) measures.[17]

Delmore and coworkers reported 90.6% cure rate. The mean follow up was 17 months. Meillier and coworkers reported 95% cure rate. The mean follow up was 12.8 months in their study. Twenty nine patients (96.7%0 were subjectively cured in our study, 1 patient (3.3%) reported improvement however, there was no leakage during stress test even when the test was done at full bladder capacity while the patient was standing. No failure was reported in our study at a mean follow up of 9.3 months (range 3-24 months). The success rate in our study was a bit higher than reported in the literature which may be due to decreased severity of incontinence in our patients. The SUI was Grade I in 14 patients, II in 14 patients and only 2 patients had Grade III. In our study, eighteen patients had urethral hypermobility, three patients had combined urethral hypermobility and ISD and nine patients had pure ISD. All patients were objectively cured. Only one patient reported improvement, she had VLPP <60 cm H2O; however the remaining nine patients with ISD were all cured.

Evidence suggests that mid urethral slings had successful outcome for women with mixed incontinence. Pre-existing urge incontinence resolved in 50-80% of patients after correction of SUI, Kwong et al, 2005. In our study, 16 patients (53.3%) had pure SUI while 14 patients (46.7%) had mixed incontinence. Of these 14 patients, only 4 patients showed persistent urge incontinence postoperatively. Those 4 patients had no obstructive symptoms or significant residual urine. Postoperative urodynamics at 1.3, 6 and 12 months showed no evidence of involuntary bladder contractions, bladder outlet obstruction or significant residual urine. They were given an anti-cholinergic on which they improved. The resolution of urge incontinence in our study was 71.4%. None of our patients reported denovo urgency or urge incontinence. Deval and coworkers reported denovo urge symptoms in 12 women (9.3%) using TOT (outside in). Jimenez and coworkers reported denovo urgency in 2.3% of their patients. The low incidence of denovo urgency in our study might be due to small number of patients and high incidence of preoperative urgency.

It is generally accepted that anti-incontinence procedures may have an obstruction effect in the urethra. The female stress urinary incontinence clinical guidelines panel noted a prolonged retention rate and denovo urgency rate in 6-11% and 3-11% in sling procedures, 3-7% and 8-16% in retropubic suspensions and 4-8% and 3-10% in needle suspensions. Definitive evidence of obstruction in females on urodynamics studies had proven to be very difficult. Farrar et al, diagnosed obstruction if Qmax was <15ml/sec with 200cc voided volume. Massey and Abrams defined female bladder outlet obstruction if two or more of the following were present: Qmax <12ml/sec, detrusor pressure at Qmax>5ocm H2O, urethral resistance (PdetQmax/Q2max)>0.2, or significant residual urine with high pressure or resistance. Delmore et al, reported bladder outlet obstruction after TOT in 0.6% of their patients. None of our patients were obstructed using the second criteria.

Infection related complications in the TOT serried have included thigh abscess and an infected obturator hematoma, Game et al, 2004. In our study, 1 patient (3.3%) developed wound infection at site of cutaneous sutures. Deval et al reported 5.4% incidence of post-operative urinary tract infection. In our study, 1 patient (3.3%) developed post-operative urinary tract infection that was treated medically according to culture and sensitivity.

Boustead and Singh reported 2% incidence of dyspareunia after TOT, while Krauth and coworkers, reported 0.3% in their series. In our study, only one patient (3.3%) complained of dyspraeunia postoperatively.

De Laval described 15.9% of patients with temporary groin pain postoperatively. Krauth and coworkers reported 2.3% of patients with postoperative perineal and groin pain that was transient and responded to nonsteroidal anti-inflammatory drugs. They reported that persistent pain might denote erosion. None of our patients developed erosion during follow up. In our study, fifteen patients (50%) reported postoperative groin pain which resolved in all patients within 1 month using nonsteroidal anti-inflammatory agents.

We finally conclude that the Trans-obturator inside-out prolene mesh showed results comparable to other commercially available kits in the market at a lower cost, however, a prospective randomized study with the original TVT-O and a longer duration of follow up is needed to confirm these results.

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