ABSTRACT

Objective: The aim of this trial is to describe the use of surgeon tailored ordinary prolene mesh (STPM) and available resterlizable helical or S shaped passers to do transobturator tape (TOT) as a low cost alternative to available commercial kits (CK) in treatment of stress urinary incontinence (SUI ) in female with evaluation of its safety and short term efficacy.

Patient and methods: STPM tape (15 x 1.5 cm) was inserted as outside-in TOT procedure done alone in 22/30 (73%) and with other prolapse procedures in 8/30 (26%). No major complications, lower urinary tract injuries or mesh erosion were reported. Improvement of SUI symptom score postoperatively was significantly (p<0.0001), urinary symptoms impact on quality of life (QOL) was significantly (P<0.0001) improved after STPM insertion also the visual analogue scale urinary incontinence severity was also significantly (P<0.0001) improved postoperatively, but the Q-MAX were significantly (P<0.0001) reduce by STPM insertion

Conclusion: surgeon tailored prolene mesh insertion as outside-in trans obturator procedure was easy, safe, effective treatment for women with stress urinary incontinence.

ABBREVIATIONS:
SUI: Stress urinary incontinence .
TOT: Trans obturator tape
QOL: Quality of life
Q-MAX: Maximum flow rate
CUA: Complete urine analysis
CIC: Clean intermittent catherization
PVRU: Post void residual urine volume
LUT: Lower urinary tract
TVT: Tension-free vaginal tape
CST: Cough stress test
VLPP: Valsalva leak point pressure
STPM: Surgeon tailored prolene mesh

INTRODUCTION

Stress urinary incontinence (SUI) prevalence is quiet high, ranging from 4 to 35% of adult females (Luber, 2004). The cost of treatment of incontinence and related disorders is approximately 19.5 billion dollars annually in USA (Hu, et al., 2004). The high costs are due to both the increased cost of treatment and the high prevalence. SUI surgical correction big market has driven the development of many available commercial kits (CK). This CK advantage is simplifying and standardizing the treatment and outcomes while its disadvantage is their high cost. An alternative to the prefashioned kits is to use ordinary prolene mesh and tailor it to tape suitable for midurethral support. surgeon tailored prolene mesh (STPM) for treatment of SUI in female has been previously described and has robust long term outcomes (Shah, et al., 2004; Amrute, et al., 2007). The purpose of this study is to report our short term outcomes results of use the ordinary prolene mesh tailored by surgeon as TOT in treatment of female SUI.

PATIENTS AND METHODS

From May 2013 to May 2014, in Benha University Hospital, obstetrics and gynecology department after obtaining approval from Benha University ethical committee, 35 women diagnosed with SUI underwent a TOT procedure with a sling fashioned from the ordinary surgical prolene mesh (EGYMIX, PM 160 mesh) this mesh is composite of nonabsorable prolene and co polymers of poly glycolid co-caprolactone (Taisier–Med, Elobour city, Cairo, Egypt). All women after giving their consent, were subjected to full history, physical examination, including cough stress test (CST), urine culture and sensitivity and preoperative urodynamics. The CST was done with full bladder (≥ 300 ml measured with ultrasound) the women was asked to cough and bear down, if urine is escaped in small spurts with each cough, SUI diagnosis was made but if delayed urine leakage of large volume had occurred after coughing; unstable bladder activity was highly suspected if cystocele and or rectocele was associated, the test was done before and after inseaction of a vaginal pack (Ghoniem, et al.; 1994). Patients with PVRU > 100 ml, bladder capacity <300 ml, impaired bladder compliance, neurological lesions or evident urge incontinence were excluded if there was a defect in pelvic floor support, it was corrected with an appropriate technique. A strip of 15 cm in length and 1.5 cm in width was manually tailored from EGY MIX 10X15 cm, this type of mesh used for herniorrhaphy with idea that absorbable part will be faded a way within 90 days but the prolene part will remain for ever and sense of hardness with classic heavy prolene mesh will be reduced, each end of the 15X1.5cm tape was threaded with a number 1 prolene suture to form closed loop i.e the both ends of prolene thread were tied to each other, this prolene loop could be fitted into retrieval groove of obtryx II handle of Boston scientific TOT (figure 1 a,b) ( as we found this handle could be resterilized in autoclave with the usual surgical instruments). The procedure was done under spinal anesthesia in lithotomy position with thighs in hyperflexion (120°) During
induction of anesthesia and positioning of the patient, the tape was prepared. Before the procedure a 2 gram of third generation cephalosporin were administered. After insertion of a Foley catheter and injection of adrenalinized saline into vaginal submucosa for hydrodissection a 2 cm midline anterior vaginal wall incision was preformed starting 1 cm proximal to external urethral meatus the vaginal mucosa was dissected bilaterally at the ischio pubi ramus. Two small cutaneous incisions were made in the inferior internal part of the obturator foramen at a horizontal at the level of the clitoris.

The TOT needle of obtroxy II either helical passer or s shaped needle (figure 1 a,b) was inserted through the obturator membran and guided by the surgeon’s index finger into the vaginal incision, the loop of the prolene suture was fitted to tip of the needle and guided back to the obturator incision the same technique was done at the other side. So at the end we have the two prolene loop brought out of the obturator incision, we aslo marked the midway part of tape by folding with Allis clamp pulling on both prolene loops applying tension on the TOT which was adjusted by insertion of heager’s dilator number 8 in urethrea and heager’s number 4 between urethrea and tape. After tension was adjusted cut one theard of the closed prolene loop to remove it and vaginal incision was closed with vicryl 2/0 while the obturator incision only dressed. The patient was discharged from the hospital the next day after removal of vaginal pack, urethral catheter and spontaneous urination was confirmed when there was avoiding difficulty. Program of clean intermittent catheterization (CIC) was started. Any operation events and postoperative complication were recorded follow up evaluation was performed at 3,6,12 months including physical examination, cough stress test, complete urine analysis and uroflowmetry with measuring the PVRU. Postoperative events were recorded including urinary retention, avoiding difficulty, denovo urgency, vaginal or urethral erosion recurrent urinary tract infection and dyspareunia the surgical cure of SUI were assessed objectively as follow: a) Cure: if there no urine leakage during cough stress test with ≥ 300 ml of urine with in the bladder .b) Improvement when significantly fewer leakage episodes during stress than the preoperative status. C) Failure: All other patients than in a and b. Data were presented as mean ± standard deviation (range ) for continuous variables while categorial were presented as number (percentage). Paired student’s t test were used to compare preoperative to postoperative status including symptoms, quality of life (QOL) and visual analogue scale score, Q-max. p<0.05 was considered statistically significant analysis were performed by medcalc easy –to –use statistical software for windows desktop (www.medcalc.org) 2015 (medcalc, software, bvba).
RESULTS

In this trial 35 female patients were enrolled, five patients were lost in follow up, while complete data were available only for 30 patients Table 1 summarized the demographic and clinical criteria of patients with complete follow up in this trial. In all women included in this trial, even those with cystocele after insertion of vaginal pack, the CST with a bladder volume ≥ 300 ml was positive. In 22 (73.3%) the STMP procedure was performed alone while in 5 (16.7%) repair for cystocele was done, and in 2 (6.7%) rectocele repair was performed and 1 (3.3%) cystorectocele repair was done. When STPM was performed alone the mean operative time was 30±10 (25-50) min, while where accompanied with other repair procedure the mean operative time was 60±15 (50-80) min, Pre-operative SUI symptoms score versus postoperative showed a statistically significant (p <0.0001) decrease in the severity of these symptoms after the STPM procedure (table 2). Moreover there was a significant decrease in postoperative Q-max. Incontinence severity and impact of urinary symptoms on Qol was analysed by a visual analogue scale and divtrovei QOL self-questionnaire, respectively, showed a significant decrease in urinary leakage and significant improvement in QOL (table 2). There were no major complications, or need for blood transfusion. Most of women, 25 (83.3%), in this trial resumed normal voiding in the first postoperative day. While 3 women (10%) with difficulty for 1 week, but only 2 women (6.7%) were with voiding difficulty for 3 weeks, in all women the PVUR were not more than 50 ml. no mesh erosion reported during

Fig (1): Surgeon tailored prolene mesh STPM mounted on obtux II helical needle (a) , S shape passer (b) of restrelizable Boston scientific TOT

Egypt. J. Med. Sci. 36 (1) 2015
follow up period which was up to 2 years in some women. Of the 7 women with mixed urinary incontinence 5 (71.4%) showed significant improvement from the preoperative status while the other 2 (28.6%) women still had persistent detrusor over activity and need medical treatment, while 2 out of 25 patients (8%) with SUI developed denovo detrusor instability but they improved within 3 months postoperatively. According to predefined success, improvement and failure, 24 (80%) patients were significantly improved but in 2 (6.7%) patients the procedure was failed.

Table (1): Demographic and clinical characteristic of female patients in STPM trial for SUI (no=30)

<table>
<thead>
<tr>
<th>ITEMS</th>
<th>VALUE</th>
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<tbody>
<tr>
<td>Age (years) *</td>
<td>42 (±7.5 ) (29-58)</td>
</tr>
<tr>
<td>BMI (Kg/m2)*</td>
<td>29.8 (±5.6) (26.6-34.2)</td>
</tr>
<tr>
<td>Parity**</td>
<td>4.3 (±1.6) (3-9)</td>
</tr>
<tr>
<td>Type of incontinence:**</td>
<td></td>
</tr>
<tr>
<td>• Pure SUI</td>
<td>32/30 (76.7%)</td>
</tr>
<tr>
<td>• Mixed a</td>
<td>7/30 (23.3%)</td>
</tr>
<tr>
<td>Pelvic organ prolapse:***</td>
<td></td>
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<tr>
<td>• Cytocele</td>
<td>5/30 (16.7%)</td>
</tr>
<tr>
<td>• Rectocele</td>
<td>2/30 (6.7%)</td>
</tr>
<tr>
<td>• Cystorectocele</td>
<td>1/30 (3.3%)</td>
</tr>
<tr>
<td>Preoperative VLPP (cm H2O)*</td>
<td>72.3 (±16) (46-98)</td>
</tr>
<tr>
<td>Preoperative Q-max (ml/s)*</td>
<td>23.8 (±2.6) (18-29)</td>
</tr>
</tbody>
</table>

Abbreviations BMI: Body mass index, STPM :surgeon tailored prolene mesh, SUI: stress urinary incontinence.
*The values were given as mean (±SD) (Range)
** the values were given as numbers (%)
a-The stress component was the predominant component with no involuntary bladder contractions during cystometry.
DISCUSSION

Based on theory of midurethral role in urinary continence mechanism Ulmsten and Petors, (1995) introduce trans vaginal tape (TVT). Later Delorme et al. (2004) introduced the outside – in TOT to reduce the complication associated with classic retropublic TVT and de Le Val, (2003) introduced inside- out TOT technique minimal vaginal dissection. The number of patients enrolled in this study was relatively small, despite that the prevalence of SUI relatively high in developing countries as fewer women with SUI are seeking for treatment due to embarrassment and the relative high prices of commercial kits (CK) for SUI. The current study introduce the utilization of ordinary prolene mesh used for herniorraphy after tailored with surgeon to be fitted for the mid urethral support, this composite mesh was chosen as it has relative wide pores which allow the circulation of macrophages, fibroblasts, deposition of collagen and angiogenesis. the integrated copolymers part of polyglycolid -co-caprolactone is absorbed with time which allows more integration of the tape in the host tissue this may explain good healing, high success rate, absence of vaginal or urethral erosion than expected as well as absence of sense of hardness that may occurred with the usual, prolene mesh. Also, in this study the absence of complication may be due to the prior experience of surgeon with TOT procedure by handle of Boston scientific obturyx II. In this study the outside in TOT with surgeon tailored prolene mesh was preformed alone in 22 (73.3%) or in combination with other repair procedure in 8 (26.7 %) and with use of strict criteria for defining success, the cure rate was recorded in 80 % and improvement in 13.3% but failure oc-

Table (2): Comparisons between preoperative and postoperative urinary symptoms score, Q-max, incontinence severity score, Qol scale score in patient of STPM trial (no=30).

<table>
<thead>
<tr>
<th></th>
<th>Preoperative (no=30)</th>
<th>Postoperative (no=30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SUI symptom scale (max=8)</td>
<td>6.2±1.46 (0-8)</td>
<td>0.42±0.92(0-8)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Urinary incontinence visual</td>
<td>4.66±2.5 (0-10)</td>
<td>0.79±1.3(0-8)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>analogue scale (max=10)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impact of urinary symptoms</td>
<td>26.8±7.8 (10-45)</td>
<td>10.3±5.38(10-45)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>on QOL (10-50)</td>
<td></td>
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</tr>
<tr>
<td>Q-max (ml/s)</td>
<td>23.2±2.6 (18-28)</td>
<td>19.2±4.2 (6-28)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Abbreviation: STPM: surgeon tailored prolene mesh, Q-max: maximum flow rate, SUI: Stress urinary incontinence, QOL: quality of life values were given as mean (±stander deviation) (range). p<0.05 statistically significant.
curred in 6.7%, similar results were reported with TOT of other trials (Waltregny et al., 2006; Morey et al., 2006; Deval et al., 2006; Elqamasy et al., 2008). In this study, after tape procedure for women with mixed incontinence (23.3% of study patient), the bladder preoperative symptoms improved in up to 71.4% of patients, similar results reported by other authors (Waltregny et al., 2006; Elqamasy et al., 2008; Tahseen et al., 2007).

The voiding difficulty reported after all TOT procedures ranging from 7 to 11% (Waltregny et al., 2006; Morey et al., 2006; Elqamasy et al., 2008) and this could be attributed to over correction but in this trial due to standardized adjustment by hager's number 8 in urethral and hager's number 4 in plane between tape and urethral over correction was eliminated, so low rate of voiding difficulty and aslo of short duration. The Q-max in this trial after tape insertion was significantly decrease as that reported with prior trials of TOT (Waltregny et al., 2006; Morey et al., 2006; Elqamasy et al., 2008; Domingo et al., 2005).

The reported rate of vaginal erosion after TOT procedures varies greatly ranging from zero (Waltregny et al., 2006) to 13.8% (Domingo, 2005). In our study it was zero, this may be secondary to type composite mesh. The reported rate of bladder and urethral injuries in this trial was zero this may be secondary to absence of recurrence cases of SUI and with cases prior pelvic surgery inclusion in this trial, this like results of other trial(Silva, 2007) while other study reported urinary tract injuries use to it (Abdel-fattah et al., 2006). Other injuries were not reported in this trial as vessels and nervosas in other trial of TOT (Hinou et al., 2007; Zahn et al., 2007; Achtari et al., 2006).

CONCLUSION

From this study results, it could be concluded that the manually designed transobturator composite prolene mesh tape (STPM) is an easy, cheap, safe, effective procedure for treatment of female stress urinary incontinence.

REFERENCES

1. Abdel-fattah, M.; Ramsay, I.; Bringle, S. (2006): Lower urinary tract injuries after transobturator tape insertion by different routes a large retrospective study, BJOG 113:1377-1381


النتائج الأولية لأجراء التشريط المسد الجزار عن طريق استخدام جزء من شبكة البرونين المفصلة بواسطة الجراح لعلاج سلس البول الإجهادي عند السيدات،
شرف مصطفى محمود المنطاوي - تامر محمود عصر
قسم النساء والتوليد كلية طب بنها - جامعه بنها

لجريت هذه الدراسة في كلية طب بنها قسم النساء والتوليد بين مايو 2014 و2015 بهدف تقييم درجة قابلية وامان التشريط المفصل بيد الجراح أثناء العملية كشريطة مار من قطعه عظم الحوض واجريت الدراسة بين 35 سيدة تعاني من سلس البول الإجهادي وتحدي نتائج كلها لـ 30 حالة فقط وكانت النتائج جيدة جدا وكان المعامل الإحصائي جيد جدا لنجاح هذه العملية بهذا التشريط المفصل بيد الجراح اثناء العملية بدون حدوث مضاعفات من العملية مثل: اصابات للقناة البولية أو تورم مكان التشريط. لذلك ينصح في البلاد النامية باستخدام هذه الطريقة لعلاج السلس البولي الإجهادي حيث أنها طريقة سهلة وامنة وفعالة وقابلة للتكرار.