

## Original Article Polypropylene Mesh Used as a Pubovaginal Sling in the Treatment of Female Stress Urinary Incontinence – Preliminary Experience

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### ABSTRACT

**Objective:** There is some lack of consensus regarding the best method to treat female patients with stress urinary incontinence (SUI). In the past, pubovaginal slings were reserved for recurrent, complicated cases associated with intrinsic sphincteric deficiency, but this is not the case any more. We report our own experience using the polypropylene mesh in the treatment of all types of SUI in women.

**Patients and Methods:** 25 female patients with a mean age of  $42.1 \pm 9.7$  (range 26–70) years were included in this prospective study. Pre-operative evaluation included a detailed uro-gynecological history, voiding diary, physical examination, laboratory investigations and multichannel urodynamics. A pubovaginal sling procedure using polypropylene mesh was performed in all patients. Post-operatively, the patients were evaluated at 1, 3, 6 months and then at 3-month intervals. Post-operative urodynamic assessment was done only in the presence of urgency or urge incontinence, whether persistent or de novo, recurrent SUI and persistent obstruction.

**Results:** At a mean follow-up of 25.2 (range 20-30) months, 21 patients (84%) were cured, 3 patients were improved (12%) and the procedure failed in one patient. Post-operative urinary urge incontinence was present in 4 patients (16%) including 3 patients with pre-operative urgency/urge incontinence and one patient with de-novo urgency/urge incontinence. Complications included urinary retention in 6 and bladder perforation in 2 patients.

**Conclusion:** The results achieved with the polypropylene sling are comparable to other procedures reported in the literature. It represents an inexpensive, safe and simple alternative treatment for patients with SUI.

**Keywords :** Urinary incontinence, urodynamics, bladder, sling procedure

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### INTRODUCTION

Urinary incontinence afflicts an estimated 13 million adults in the United States of America alone<sup>1</sup>. Due to the prevalence of this condition and a dramatic increase in public awareness, urinary incontinence has come to the forefront and is now one of the most common presenting symptoms in the urological and gynecological daily practice. Recently there has been a considerable

progress in understanding the pathogenesis of stress urinary incontinence (SUI) that has led to improvements of the various surgical and medical treatment modalities, but unfortunately there is still a lot to learn in this field.

SUI has been classified into incontinence due to poor anatomic support mechanisms

(types I and II), or deficiency of the bladder neck and proximal urethral closure mechanism (type III or intrinsic sphincteric dysfunction - ISD)<sup>2</sup>. Classically, types I and II have been treated with retropubic or transvaginal suspension procedures, while type III SUI has been treated with injection of bulking agents or pubovaginal slings<sup>3</sup>. Lately, this algorithm has been questioned and many urologists are using pubovaginal slings to treat all types of SUI.

While the concept of suburethral support was originally introduced in 1907 by Giordano, it was not until its reintroduction in 1978 by McGuire and Lytton that it gained increased clinical use<sup>4</sup>. Unfortunately, the general acceptance of pubovaginal slings by the urological and gynecological communities has been limited by the historically higher incidence of complications with pubovaginal slings, namely sling erosion, de-novo instability and urinary retention<sup>5</sup>.

We herein report our preliminary experience with the polypropylene mesh as a pubovaginal sling in the treatment of SUI.

## **PATIENTS AND METHODS**

In this prospective study, we evaluated the results of the polypropylene mesh as a pubovaginal sling in the treatment of 25 female patients presenting with SUI. Table 1 shows the mean age of the patients, their mean body mass and parity status. Two patients (8%) had undergone previous failed anti-incontinence surgery (one operation), and 6 patients (24%) had undergone previous pelvic surgery other than anti-incontinence surgery.

Pre-operative evaluation included a detailed urogynecological history, voiding diary, physical examination, laboratory investigations and multichannel urodynamics. Each patient underwent urine analysis and culture, kidney and liver function tests, as well as assessment of fasting blood sugar, complete blood picture and bleeding profile. Positive urine cultures were treated with culture-specific antibiotics. All patients underwent pre-

operative urodynamic evaluation (cystometry, pressure flow evaluation, Valsalva leak-point pressure assessment, uroflowmetry and post-void residual urine), while post-operative urodynamics were done only in the presence of persistent or de novo urgency or urge incontinence, recurrent SUI and persistent obstruction.

The mean pre-operative urinary frequency was  $6.8 \pm 3.2$  (range 4-12) times per day. Pre-operative urodynamic studies showed a mean abdominal leak-point pressure of  $112 \pm 22.7$  (range 60 – 130) cm H<sub>2</sub>O. The mean bladder capacity was  $402.4 \pm 20.5$  (range 350-420) ml. None of the patients had involuntary bladder contractions pre-operatively.

The types of SIU in the studied patients are shown in Table 2. Pure SUI was found in 11 patients (44%), while mixed incontinence (urge + stress) was found in 14 patients (56%).

For evaluating the patients we used the classification according to Raz et al.<sup>6</sup>. SUI is either anatomic due to malposition of an intact sphincteric unit or intrinsic sphincteric dysfunction due to malfunction of the sphincter with or without hypermobility. Patients with grade 3 or 4 cystocele were excluded from the study.

Treatment consisted of the placement of a mid-urethral sling similar to the transvaginal tape using hernia polypropylene mesh:

A midline longitudinal anterior vaginal wall incision was done extending 1cm from the external urethral meatus to the bladder neck, and sharp dissection was used along the pubo-urethral and the pubo-cervical fascia to reach the retropubic space. The endopelvic fascia was sharply perforated, thus entering into the retropubic space. 6-8 x 1-1.5 cm polypropylene mesh (Ethicon, Johnson and Johnson BMM3, Egypt) was placed beneath the mid-urethra and secured at both ends with a running no. 1 polypropylene suture.

PUBOVAGINAL SLING IN THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

**Table 1:** Patients' age, body mass and parity status

	Mean $\pm$ SD	Range
Age (years)	42.1 $\pm$ 9.7	26 - 70
Parity	5.3 $\pm$ 2.1	3 - 11
Body mass (kg)	71.1 $\pm$ 6.6	60 - 89

**Table 2:** Types of SUI in the study population

Type of SUI	Number	%
Urethral hypermobility	21	84%
Intrinsic sphincteric dysfunction	1	4%
Combined	3	12%
<b>Total</b>	<b>25</b>	<b>100%</b>

Initially the original hernia mesh was divided into smaller pieces which were stored and sterilized for each case. The sling sutures were passed from the vaginal to the abdominal incision using a Stamey needle. The sling was tacked to the periurethral tissues with a 3-0 delayed absorbable suture. The vaginal mucosa was closed with a 2-0 chromic suture in a running or interrupted fashion. The sling sutures (each suture had 2 ends) were tied together over the rectus fascia without any tension, while the assistant was holding the sheath of a cystoscope inserted per urethram at an angle of 20-30° to the horizontal. The suture ends were tied to prevent them from slipping and moving downwards.

The post-operative management was the same for all patients: The vaginal pack was removed on the morning of the first post-operative day. As soon as the patients were ambulant, they were encouraged to walk. The Foley catheter was usually removed on the afternoon of the same day and the patients were encouraged to attempt to void frequently without straining. When a patient could not void at all or had a post-void residual urine volume >100 ml after voiding, she was catheterized again using a Foley catheter and was discharged the same day with the catheter indwelling. After a week, the catheter was removed and the patient was given another trial

of voiding. If she still had a residual urine volume >100 ml or if she developed urinary retention, she was taught clean intermittent self-catheterization (CISC) using a 14F Nelaton catheter every 4 hours and more often if necessary. When the successive residual urine volumes were 100 ml or less, catheterization was stopped.

All patients were instructed to refrain from sexual intercourse for 4 to 6 weeks post-operatively and to avoid pregnancy for 1 year. They were asked to pay regular visits to the clinic, every 2 weeks during the first month, every 3 months for the first year and then every 6 months. On each visit the patient was asked about any distressing problem (vaginal pain, dyspareunia, vaginal discharge or suprapubic pain) and about the quality of micturition (strength, intermittency, deviation of stream, post-void dribbling). If the patient complained of post-operative de-novo urgency, urge incontinence or frequency with no significant residual urine (i.e. <100 ml), she was given an anticholinergic. In the presence of a residual urine volume >100 ml, she was taught CISC. In either case urodynamic assessment was performed at 3 months. If the patient still complained of persistent urgency, urge incontinence or frequency, the a.m. treatment was repeated.

The success of the treatment was assessed both subjectively via verbal communication and objectively via a stress test, but none of our patients had a pad test pre- or post-operatively. A patient was considered cured when no SUI was present post-operatively, and improved when SUI was still present, but to a milder degree than pre-operatively. The procedure was considered a failure when the patient was still complaining of SUI.

The mean follow-up was 25.2 months (range 20-30 months).

Standard statistical methods were used to analyze the results with  $p < 0.05$  being considered statistically significant

## RESULTS

Twenty-one patients (84%) were cured; 18 of them had pure urethral hypermobility, 2 had mixed hypermobility and ISD and one patient had pure ISD. Three patients (12%) were improved, while the procedure failed in 1 patient (4%). The mean hospital stay was  $2.2 \pm 5.8$  days (range 1 day - 1 month). There was a statistically significant decrease in mean urinary frequency from  $6.8 \pm 3.2$  to  $5.1 \pm 2.1$  ( $p < 0.05$ ), and post-operative urgency was present in only 4 patients (16%), including 3 with pre-operative urgency and one who developed de-novo urgency. These 4 patients had no significant residual urine and were treated medically. After administration of an anticholinergic (Uripin 2-4 tablets / day) for 3 months, 2 of the 4 patients showed improvement. Post-operative urodynamics at 3 months for those 4 patients showed no evidence of involuntary bladder contractions, bladder outlet obstruction or significant residual urine. The pressure-flow study showed non-obstructed curves, and none of the patients had a high voiding detrusor pressure or obstructed uroflowmetry.

Intra-operative complications in the form of bladder perforation or penetration by the needle were encountered in 2 (8%) patients. The needle was removed and repositioned. In both patients a post-operative indwelling ure-

thral catheter was left for one week with no long-term adverse effects.

Post-operative complications in the form of urinary retention occurred in 6 (24%) patients. It resolved in 2 patients after recatheterization for 1 week. The other 4 patients were taught CISC until their residual urine volume was less than 100 ml which was achieved after 2 weeks in 2 and after 3 and 5 weeks in one patient each.

## DISCUSSION

According to Appell, all women with SUI have some form of ISD<sup>7</sup>. Because many women with hypermobility of the bladder neck and proximal urethra do not have SUI, some credence must be given to the thought that the presence of SUI implies some deficiency in the bladder outlet function, not just an anatomic deficit, so that it would seem that patients would benefit from a sling procedure providing suburethral support during increases in intra-abdominal pressure. The outlet is exposed to two forces for the expulsion of urine, the detrusor pressure and the abdominal pressure. These are never the same, and SUI occurs when increases in intra-abdominal pressure overwhelm the outlet, whether there is hypermobility of the outlet or not. Thus, all patients with SUI have ISD to a greater or lesser degree, determined urodynamically, whether the abdominal leak-point pressure (ALPP) be 140 cm H<sub>2</sub>O or 40 cm H<sub>2</sub>O, the difference being the severity of their incontinence.

There are many treatment options for female patients with SUI, including medical treatment, mechanical devices, pelvic floor exercises and surgical interventions. The large variety of anti-incontinence operations, such as abdominal retropubic cystourethropey, transvaginal cystourethropey, urethrovaginal suburethral slings, artificial sphincters and peri-urethral injection procedures, has resulted in a medical literature containing descriptions of more than 100 surgical procedures to correct SUI. The various techniques, variations and submodifications,

as well as the many paramedical reasons for the selection of one particular procedure over another, all tend to leave one with feelings of confusion rather than clarity. The best results are always described by the inventor of the new procedure. In addition, success rates are always subjective without clearly defined parameters, and often the follow-up is quite short. The other problem is that the original authors always seem to be modifying their own procedure, for which they had originally claimed anywhere from 96% to 100% success rates. In the end it appears that the choice of the operation is dependent primarily upon the experience of the surgeon. Generally it has been stated that there is an 85% cure rate of SUI regardless of which procedure is used. There has been no prospective randomized study with controls for age, parity, degree of anatomical defect, operator's skill, duration of follow-up, previous surgical history, suture material used etc. The wide variability in reported success rates of various techniques, even when narrowed to a particular procedure, seems to demonstrate that comparisons between procedures are untenable. Patient selection is another important factor determining treatment success.

With regard to polypropylene mesh in the treatment of female SUI, the factors in favor of it being the procedure of choice include its usefulness in the treatment of hypermobility and/or ISD, the fact that repair is done with supplementation of innate support not approximation of tissue which has already failed the patient, its versatility in combination with procedures for prolapse, its successful long-term outcomes in complex cases and finally the fact that it is an easy, simple, effective, relatively cheap and easily reproducible procedure. A review of the literature reveals an 81%-98% cure rate, which is comparable with our results<sup>8</sup>.

Urinary retention after sling surgery is generally a temporary event; surgical pain, post-operative edema, extensive and tight

plication of the periurethral tissues and tension on the sling are all factors impeding normal voiding. The most important preventive measure in this regard is to avoid tension on the sling<sup>9</sup>. In our study, retention occurred in 6 patients (24%); it resolved in 2 patients after re-catheterization for 1 week, while the other 4 were taught CISC until their residual urine volume was less than 100 ml. Obstruction was considered in patients with a large amount of post-void residual urine (>100 ml), an obstructed uroflowmetry or an obstructed curve on pressure-flow studies during urodynamics. A suprapubic cystostomy tube was not used, because patients who were obstructed were taught to perform CISC.

Persistent urgency or the development of post-operative urgency and urge incontinence is much more common than frank retention occurring in 8 to 25%<sup>10</sup>. McGuire et al. reported de novo urgency/urge incontinence in 20% of women with a 3% incidence of persistent urge incontinence<sup>10</sup>. In our study, post-operative urgency was present in 4 patients (16%), including 3 patients with pre-operative urgency and one patient with de-novo urgency. None of them had significant residual urine.

According to Amundsen et al. sling erosion can be a drawback with this type of sling<sup>11</sup>, however none of our patients showed sling erosion on follow-up. This was probably attributed to the use of a longitudinal midline rather than a transverse anterior vaginal wall incision and the avoidance of any tension on the sling during fixation.

We conclude that in this preliminary study the polypropylene sling showed results comparable to other procedures reported in the literature. It represents an inexpensive, safe and simple alternative treatment for patients with SUI. However, a prospective randomized study of a larger number of patients with longer follow-up will be required to establish the long-term efficacy, durability and complications of the procedure.

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