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ORIGINAL ARTICLE

Evaluation of transvaginal slings using different materials in the management of female stress urinary incontinence

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KEYWORDS

Sling;
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Female;
Stress;
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ABBREVIATIONS

SUI, stress urinary incontinence; TVT, tension-free vaginal tape; VLPP, Valsalva leak-point pressure; BMI, body mass index; ARS, anterior rectus sheath sling; AVS, anterior vaginal wall

Abstract ***Purpose:*** To evaluate tailored polypropylene (prolene) mesh, anterior rectus sheath, and vaginal wall slings positioned under the mid-urethra, to treat stress urinary incontinence (SUI) in women, as SUI is a common pathological condition causing considerable distress and compromising social, physical, psychological, and sexual health, and for which surgical treatment remains controversial.

Patients and methods: This prospective randomised study included 32 patients with SUI, evaluated by SEAPI (Stress, Emptying, Anatomy, Protection, and Instability) symptom score and urodynamics. According to sling material, 12 patients had tailored prolene mesh, 12 had anterior rectus sheath and eight had anterior vaginal wall slings. Operative variables (intraoperative bleeding, duration, complications and hospital stay) were documented, and postoperative complications and continence status were assessed. The follow-up was 12–18 months.

Results: Patients who received tailored prolene mesh slings had a lower operative duration and hospital stay, and less intraoperative bleeding. Postoperative complications, e.g. urinary retention and urgency, were $<12\%$, with no significant differences. There was no significant difference among the three studied groups in the success rate (75%, 67% and 75%).

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sling; ISD, intrinsic sphincteric deficiency; SEAPI, Stress, Emptying, Anatomy, Protection, Inhibition; RU, residual urine

Conclusions: Tailored prolene mesh, anterior rectus sheath and the vaginal wall sling are good alternatives to treat SUI in women, with comparable results in a short-term follow up. The surgeon's experience and the patient's clinical circumstances should be considered when choosing a sling material, as success rates are comparable, being slightly better for the prolene sling in operative duration, bleeding and hospital stay.

Introduction

Stress urinary incontinence (SUI) is a common pathological condition, with reported prevalence rates of 12.8–46% [1], causing considerable distress and compromising social, physical, psychological and sexual health [2,3]. Failure of conservative management strategies, e.g. lifestyle changes, physical therapies, scheduled voiding regimens, and behavioural therapies, mandates surgical intervention [4]. The surgical treatment of SUI remains controversial; previously, bladder neck suspensions were used to correct anatomical abnormalities of the bladder neck and urethral hypermobility [5]. Since first described, the tension-free vaginal tape (TVT) using mid-urethral polypropylene (prolene) tape, has been accepted worldwide as an effective, safe and easy surgical technique, with a low incidence of complications [6]. Several autologous and synthetic materials are used as suburethral slings for treating SUI in women. The use of synthetic materials decreases the duration of surgery, avoids the harvesting process, and seems to have a similar outcome to that from the fascial sling [7]. Special indications for autologous grafts include patients with a history of poor vaginal healing, pelvic bone trauma, pelvic radiotherapy, or previous urethral reconstruction [8]. In the present study we investigated the use of tailored prolene mesh, anterior rectus sheath (ARS) and anterior vaginal wall sling (AVS) positioned under the mid-urethra to treat SUI in women.

Patients and methods

Between May 2008 and May 2010 this prospective study included 32 women from our urology outpatient clinic, with a main complaint of SUI. The diagnosis was established by history-taking, including the Stress, Emptying, Anatomy, Protection, and Instability (SEAPI) subjective questionnaire and a voiding diary, clinical examination including stress and Q-tip tests, and a urodynamic evaluation including the Valsalva leak-point pressure (VLPP), to grade SUI according to Jae et al. [9] (>60 or <60 cm H_2O). On examination, the degree of pelvic organ prolapse was assessed and graded according to Baden and Walker [10]. The body mass index (BMI) was determined and classified according to Garrow [11].

Exclusion criteria were neurological diseases, overactive bladder, other causes and forms of incontinence (overflow or pure urge) recurrent SUI (after anti-incontinence procedure) and any form of prolapse requiring surgery (only cases with grade 1 asymptomatic cysto-urethrocele were included). Basic laboratory investigations (complete blood count, serum creatinine, urine analysis and culture) were used routinely. In selected cases (history of urolithiasis or previous pelvic surgery), ultrasonography, plain X-ray and voiding cystourethrogram were used.

All operations were performed by the same surgical team, using transvaginal tension-free slings under the mid-urethra via a retropubic route. According to the sling material, the patients were randomly divided into three groups; in group 1, 12 received a tailored prolene mesh, in group 2, 12 had an anterior rectus sheath (ARS) fascial sling, and in group 3, eight had an AVS.

All patients received spinal anaesthesia and were put in the lithotomy position. A Foley catheter (18 F) was fixed to empty the bladder and identify the urethra during the dissection. A third-generation cephalosporin was given intravenously before surgery.

In group 1, a 7×1.5 cm tailored prolene strip (Ethicon, Inc., UK) was prepared by placing a 0 prolene suture at each end to be used as a sling (Fig. 1a). A 2-cm midline incision in the anterior vaginal wall was made 1 cm from urethral meatus. Peri-urethral dissection was advanced to the retropubic space. Two suprapubic punctures were made to advance the TVT needle and pull the prolene suture at each end of the tailored prolene sling. Cysto-urethroscopy was used after every advance of the TVT needle to exclude urethral or bladder injuries before tying both sutures, while putting an arterial clamp between the sling and the mid-urethra to ensure tension-free positioning.

In group 2, a 5×1.5 cm ARS sling (Fig. 1b) was harvested, with the patient supine, via a $\approx$7 cm Pfannensteil incision, and prepared by defatting and placing a 0 prolene suture at each end to be pulled up, as done with the tailored prolene sling. In group 3, a rectangular anterior vaginal wall patch (Fig. 1c) of $\approx 5 \times 1.5$ cm was harvested and placed under the mid-urethra using prolene sutures, in the same manner. The vaginal and suprapubic incisions were closed with absorbable 3/0 polyglycolic sutures. A vaginal pack and a Foley catheter were left for 1 and 2 days after surgery, respectively.

Operative variables assessed included intraoperative bleeding (estimated by measuring blood in the vacuum container, plus the difference between towel weight before and after surgery), operative duration, complications and hospital stay. All patients were instructed to avoid heavy exercise, straining and sexual intercourse for 1 month after surgery. Follow-up visits were scheduled at 1 and 3 months, then every 3 months, to give a mean (range) follow-up of 18 (12–36) months; patients were evaluated using the urinary symptom questionnaire, a clinical examination (including stress test), ultrasonography to measure residual urine (RU), uroflowmetry, cystometry if there was urgency, a pad test and an estimate VLPP in patients who were not cured.

Postoperative complications (urinary retention and de novo urgency) and treatment outcome were assessed and analysed. The outcome was defined as cured, i.e. no leakage reported by the patient or noticed at examination (stress test); improved, leakage occurs only with severe exertion unlike before

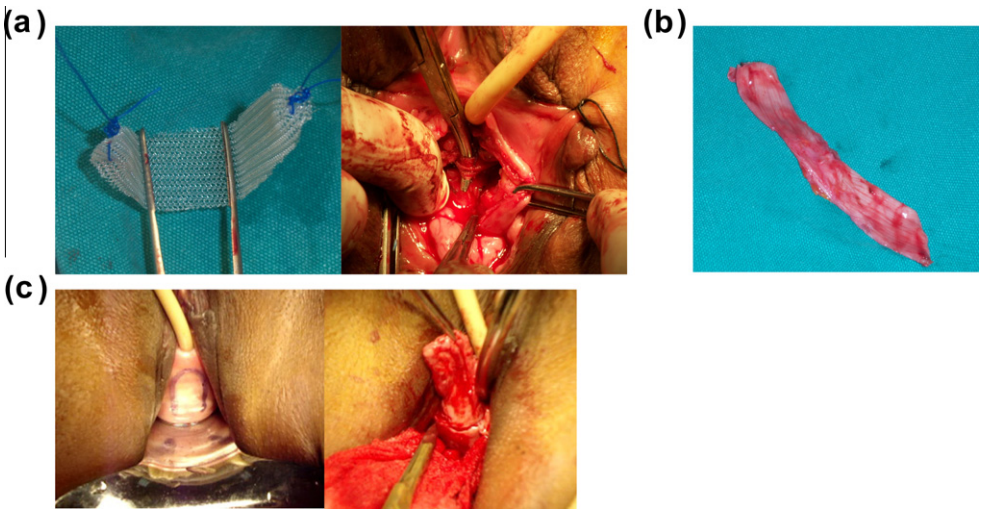

Figure 1 (a) The tailored prolene sling; (b) the rectus sheath sling, and (c) a vaginal wall sling.

surgery; or failure, the persistence of the same degree of preoperative incontinence.

The data were analysed using chi-squared or a paired *t*-test, as appropriate, with $p < 0.05$ considered to indicate statistical significance.

Results

There were no significant differences among the three groups in preoperative demographical (age, BMI, menopause), clinical (associated cystocele, urge incontinence, subjective SEAPI score) or urodynamic variables (Table 1). Patients treated with tailored prolene slings had significantly lower operative duration, less intraoperative bleeding and a shorter hospital stay (Table 2), but no difference in postoperative analgesic requirement. Bladder perforation occurred in one patient each in group 1 and 3; both had undergone previous pelvic surgery, and were managed by catheterisation for 1 week. There was urinary retention in one patient in group 1, managed by urethral dilatation (using Hegar dilators) and re-fixation of a wide-bore (24 F) urethral catheter for 5 days. De novo urgency occurred in one patient of each group and was treated by anticholinergics (tolterodine orally).

Postoperative uroflowmetry and RU measurements showed no statistically significant difference among the three groups, as tension-free positioning of slings was ensured in all patients (Table 2).

Treatment outcome was determined subjectively by the SEAPI symptom questionnaire and objectively by a stress test. Success was considered only in completely cured, but not improved, patients, with no significant difference (9/12, 8/12, 6/8) among the groups. The overall satisfaction rate was 10/12, 9/12 and 7/8 in groups 1, 2 and 3, respectively (Table 2). There was no change in the continence state in all categories (cured, improved and failed) during the study.

Most of cured (21/23) and improved (4/6) patients had grade I preoperative SUI (VLPP >60 cm H_2O), while in the three patients (one in each group) who had grade II SUI (VLPP <60 cm H_2O) the procedure failed, and they remained incontinent with no improvement from the situation before surgery (Table 3).

The mean follow-up was 18.5, 18 and 18 months (range 12–36) for the three studied groups, respectively. Eleven patients (of 32) had completed 36 months of follow up (four in group 1, four in group 2 and three in group 3).

Table 1 Demographical, clinical and urodynamic data before surgery.

Mean (SD, range) or *n* variable	Group			
	1	2	3	*P*
Age (years)	41.8 (8.2, 30–55)	41.4 (7.8, 28–53)	44.4 (9.4, 31–57)	0.72
BMI (kg/m^2)	30.2 (3.5, 24–35)	29.5 (3.4, 25–34)	30.7 (3.1, 23–35)	0.56
SEAPI score	5.8 (1.7, 3–9)	6.1 (1.5, 4–9)	6.3 (1.8, 4–10)	0.61
Menopause				
Before	6	7	4	0.84
After	6	5	4	
Cysto-urethrocele	5	6	5	0.65
Q_{max} (mL/s)	26.2 (3.6, 22–32)	26.4 (2.8, 23–31)	27.2 (3.3, 23–33)	0.78
RU (mL)	10.2 (3.5, 5–18)	13.6 (4.8, 6–22)	11.2 (4.5, 5–20)	0.17
MCC (mL)	387.5 (38.2, 320–450)	383.3 (37, 330–440)	398.7 (46, 350–470)	0.7
VLPP (cm H_2O)	76.3 (20.8, 25–100)	73.1 (21.4, 32–105)	76.9 (21.2, 40–100)	0.99

MCC, maximum cystometric capacity.

Table 2 Operative blood loss, duration and hospital stay, urodynamic variables at 3 months, and treatment outcome and satisfaction.

Mean (SD, range) or n/N variable	Group			
	1	2	3	*P*
Blood loss (mL)	149.2 (28.8, 100–200)	181.2 (33.1, 130–230)	200.8 (28.1, 160–360)	< 0.001
Duration (min)	35.7 (3.4, 30–40)	52.1 (4.4, 45–60)	42.2 (4.5, 35–50)	< 0.001
Hospital stay (h)	33 (9, 24–48)	58 (12.3, 48–72)	36 (9.1, 24–48)	< 0.001
Q_{max} (mL/s)	22.6 (3.3, 18–27)	23.5 (3.1, 17–30)	21.5 (4.3, 15–27)	0.99
RU (mL)	27.6 (14.4, 12–65)	26.7 (12.1, 15–60)	28.5 (16.2, 15–65)	0.93
Treatment outcome				
Cure (23)	9/12	8/12	6/8	0.87
Improvement (6)	2/12	3/12	1/8	0.76
Failure (3)	1/12	1/12	1/8	0.90
Patient satisfaction				
Satisfied (26)	10/12	9/12	7/8	0.76
Dissatisfied (6)	2/12	3/12	1/8	

Table 3 Correlation between procedure outcome and preoperative SUI grade in all patients.

Outcome	Preoperative grade of SUI	
	I (25)	II (7)
Cured (23)	21	2
Improved (6)	4	2
Failed (3)	0	3
p	< 0.001	

Discussion

Anatomical SUI occurs as a result of hypermobility of the urethra. Intrinsic sphincteric deficiency (ISD) is a second aetiological type of SUI, characterised by severe incontinence. Some authors [12] believe that all women with SUI have some degree of ISD and the severity of the symptom is directly related to the ISD component.

There are many anti-incontinence procedures, but sling procedures are better than other traditional abdominal colposuspension techniques. Because of the higher efficacy and lower morbidity [13] several autologous (e.g. rectus fascia, vaginal wall and fascia lata) and synthetic (prolene or mersilene) materials are used as suburethral slings for the treatment of SUI in women [7]. Since its production, TVT has been shown to be as effective as fascial slings [14]. Although TVT procedures are simple and minimally invasive, they are not free of complications, e.g. bladder or bowel perforation, urinary retention, urethral erosion and wound infection [6]. Because we had anecdotal data showing comparable results from the three materials, we conducted the present study.

We used the prolene sling following the principles of TVT by Ulmsten and Petros [15] in 1995, but as a tailored prolene patch, not full-length tape. The ARS procedure was carried out as described by Blaivas and Jacobs [16] in 1995. The AVS was used as described by Raz et al. [17] in 1989, but using a TVT semicircular needle, not the Stamey one.

There were no significant differences among the three groups in preoperative demographical (age, BMI, menopause), clinical (associated cystocele, urge incontinence, subjective SEAPI score) or urodynamic variables. Although nine (28%) patients had mixed incontinence, urodynamic testing was done for all patients to provide full data. However, we agree with other authorities [18] that this is not a basic requirement for pure SUI [19].

For intraoperative bleeding, operative duration and hospital stay there were significant differences favouring the prolene sling, then AVS and ARS. Bladder perforation occurred in two patients (groups 1 and 3), giving an overall rate of 6%, higher than the 3.8% reported by others [20,21], who noted that previous pelvic surgery is a risk factor for urethral and bladder injuries [22], although a rate of < 10% was reported by others [23].

Tension-free placement of the sling lowers the incidence of urinary retention [22], while de novo urgency complicates synthetic slings more than autologous ones [24]. In the present study, urinary retention occurred in only one patient (in group 1), while de novo urgency occurred in three (one patient in each group). These were relatively low rates, possibly due to tension-free placement of slings in all cases.

To overcome the possible gap between the physician-based and patient-based definition of success [25], both subjective and objective determinants of the outcome were used, and this reduced the success rate of the three groups, compared to that of > 80% in other reports [5–7,18], which considered success as 'cured plus improved' patients and not the cured patients only.

Cross et al. [25] stated that clinical outcomes do not always translate into patient satisfaction. An example is the pubovaginal sling, for which physicians report success rates of 70–100%, compared with subjective cure rates of 46–55%. The King's Health Questionnaire was used to measure satisfaction and postoperative quality of life [26]. In the present study, the overall satisfaction rates were higher than success rates (possibly due to the strict definition of success used for only cured cases) with no significant difference among the three groups.

All patients deemed as failures (one in each group) had severe subjective SUI and a low VLPP (< 60 cm H_2O) before surgery. In agreement with other authorities [21,27], our study states that whatever the sling material, mid-urethral support is not enough to treat higher degrees of ISD, implying severe stress incontinence, unlike mild to moderate cases with mainly anatomical defects that had very good results.

This study has some limitations, i.e. the relatively few patients and lack of a long-term follow-up. Further studies with

more patients followed for longer periods might be possible through a multicentre collaborative study, and is required to yield a more reliable comparison between these three techniques for managing SUI.

In conclusion, tailored prolene mesh, ARS and AVS are good alternatives to treat SUI in women, giving comparable results in a short-term follow-up. The surgeon's experience and the patient's clinical circumstances should be considered when choosing sling materials. The success rates are comparable, but slightly better for the prolene sling in operative duration, bleeding and hospital stay. A longer follow-up is needed to assess the durability of each material.

Conflict of Interest

The authors have no conflict of interest to declare.

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Editorial comment

With the present plethora of publications on the surgical management of SUI in women, this prospective randomised study compares the results of three different types of mid-urethral sling. There is no doubt that SUI in women represents a substantial medical, social and economic burden [1]. A wide variety of surgical techniques, materials and routes has been described to achieve better success rates and to minimize the potential complications. Changing the reference standard of the surgical techniques used for treating SUI with time might reflect the logical way of science development, but it might also indicate the deficiency in understanding the actual pathogenesis of such disease. Do we treat the same disease in every patient? Or are there phenotypic issues and should treatment be individualized? The decrease in success rates over the long-term follow-up of any procedure for this condition might indicate the latter concept.

Despite the good design of the current study it has the same pitfalls of similar trials. The authors conclude that ''Tailored prolene mesh, ARS and AVS are good alternatives for treating SUI in women, with comparable results in a short-term follow-up''. Nevertheless, the authors cannot answer the question 'which sling for which patient?' and this traditional problem