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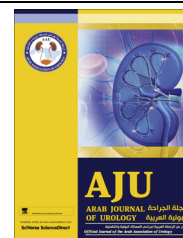
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VOIDING DYSFUNCTION/FEMALE UROLOGY
ORIGINAL ARTICLE

The first Iraqi experience with the rectus fascia sling and transobturator tape for female stress incontinence: A randomised trial



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KEYWORDS

Urinary incontinence;
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Transobturator tape

ABBREVIATIONS

SUI, stress urinary incontinence;
MUI, mixed urinary incontinence;
RFS, rectus fascia sling;
TOT, transobturator tape;
PVR, post voiding residual volume;
US, ultrasonography

Abstract Objectives: To present the first experience in Iraq of autologous rectus fascia sling (RFS) procedures and transobturator tape (TOT) for treating female stress urinary incontinence (SUI), and to review the validity of the RFS in the era of synthetic tapes.

Patients and methods: From December 2004 to July 2012, 80 female patients with SUI were enrolled in the study, and randomly assigned into two types of surgery, with 40 treated by RFS (retropubic route) and 40 by TOT. The surgical results were compared between the groups and with those from previous studies.

Results: The mean operative duration was 80 min for RFS vs. 20 min for TOT. The early cure rate was 98% for RFS (with one failure due to prolonged urinary retention) and 95% for TOT (with two failures due to persistent incontinence). The early complications were mainly abdominal wound problems (20%) for RFS, and groin and upper thigh pain (13%) for TOT. The late complications were the development of postvoid residual urine (8% in RFS vs. 5% in TOT) and de novo detrusor overactivity (5% in each group). There were no vaginal or urethral erosions up to the end of the study.

Conclusions: RFS and TOT have comparable efficacy and safety in treating SUI. Nevertheless RFS, with its more invasive nature and long operative duration, should only be used when synthetic tapes are not available or not preferable.

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Introduction

Stress urinary incontinence (SUI) is an important social and health problem with a significant effect on the quality of life [1,2]. Among the various treatment options, the suburethral sling procedure has become the mainstay of surgical treatment for SUI [3]. Over the last few decades there have been several significant modifications of the sling procedure, among them is the use of different sling materials (natural & synthetic) [2,4]. Until the 1990s autologous fascial slings (rectus fascia sling, RFS, and fascia lata) were the standard options in the treatment of SUI [5]. In 1995, a sling of synthetic material was introduced to the urogynaecological field, termed the tension-free vaginal tape [6]. A few years later another procedure was also introduced, using a synthetic tape, the transobturator tape (TOT) [7]. Both have rapidly gained acceptance. The best material for a sling procedure remains controversial, because each type has its advantages and disadvantages.

In Iraq, most female patients with SUI are managed by gynaecologists. Because of the lack of a urogynaecology subspecialty in Iraq, our gynaecologists generally offer anterior colporrhaphy as the only solution available for patients with SUI and concomitant cystocele.

The present study was conducted to describe the first Iraqi experience with autologous RFS procedures and a synthetic tape procedure (TOT), as a treatment for female SUI, and to review the validity of RFS in the era of synthetic tapes.

Patients and methods

From December 2004 to July 2012 all female patients with UI who consulted the urology clinic at Al-Yarmouk teaching hospital in Baghdad were evaluated. The assessment of these patients included a careful history taking, checking the voiding diary, and a physical examination which included a general examination, a stress test in two positions (lithotomy and standing), an examination and grading of cystocele according to Swift classification [8], and a brief neurological examination.

The severity of UI was assessed according to the history, the number of pads used per day (a uniform type of pad) and the amount of leakage at the stress test (mild degree, 0–1 pad/day, a few drops of urine leaked on stress; moderate degree, ≤ 3 pads/day, a small gush of urine leaked on stress; severe degree, > 3 pads/day, large loss of urine leaked on stress). Basic laboratory investigations and abdominal ultrasonography (US) were also routinely performed.

Some patients had a urodynamic evaluation when the history was inconclusive or indicated mixed UI (MUI) (SUI and urge UI). Cystoscopy was performed at the time of surgery, to exclude other pathologies in the

bladder or urethra before definitive surgery, and to check for any injury in the bladder after inserting the slings.

The inclusion criteria were SUI, whether in a pure form or a major component of MUI, and body mass index of $< 30 \text{ kg/m}^2$. The exclusion criteria were a mild degree of UI, a concomitant cystocele of $>$ grade 1, active vaginal infection or UTI, neurogenic voiding dysfunction, a significant postvoid residual urine volume (PVR), other bladder or urethral pathologies and fistulae.

After evaluating > 400 female patients with UI during the period of study, 80 with the main complaint of SUI fulfilled the inclusion criteria and were assigned randomly. After counselling, they were fully informed of their problem, the surgical treatment needed, the expected results and any possible complications of surgery. An informed consent was obtained from all of them and they were randomly assigned to the two types of surgery. Forty patients were treated by autologous RFS and 40 were treated by the TOT technique, using the synthetic polypropylene tape. Patients were randomised using a random-number table. Both types of surgery were performed by the same surgeon and with the patients under general anaesthesia.

Operative techniques

RFS was performed via a combined abdominal-vaginal approach, with a $12 \times 2 \text{ cm}$ segment of rectus fascia harvested, de-fatted and soaked in gentamycin solution before use. Two 0-nylon threads were sutured at both ends of the harvested fascial sling. After positioning the sling via a retropubic approach, the mid part of the fascial sling was fixed to the underlying periurethral fascia using 4-0 polyglactin sutures, and the two nylon threads, after passing retropubically and piercing the suprapubic part of the rectus muscle and fascia (5 cm apart), were tied together in a tension-free manner.

For TOT, a technique similar to that proposed by DeLorme was adopted [7]. In both procedures, an 18-F Foley catheter was introduced urethrally and maintained for 2–4 days, according to the circumstances of surgery (generally it was 1 day longer in the RFS group). A vaginal pack, soaked with povidone iodine, was inserted at the end of surgery and held for 1 day for sterilisation and to avoid haematoma formation.

The surgical results assessed in the two groups were the operative duration, perioperative blood loss, duration of urethral catheterisation, hospital stay, intraoperative visceral injury and cost. Blood loss was estimated by measuring blood in the aspirate container plus the difference in pack weight before and after usage.

The follow-up visits were scheduled at 1 week, 1 month, 3 months, 6 months and yearly thereafter. The primary outcome was the cure of SUI, as shown

by significant dryness as perceived by the patient, no more use of pads, a negative stress test and an acceptable voiding stream (with a maximum flow rate of ≥ 15 mL/s).

The results were analysed statistically by Student's *t*-test for parametric data, presented as the mean (SD) and the chi-squared test for nonparametric data, presented as the number and percentage, with $P < 0.05$ considered to indicate significance. The study was approved by the ethics committee of the Iraqi Urological Association.

Results

The preoperative patient data are shown in Table 1; the mean (range) age of the patients was 41 (27–62) years. All the patients were multiparous and complaining of incontinence for 1.5–3 years. The reported previous pelvic/or vaginal surgeries were mainly Caesarean section in 21 patients, and anterior colporrhaphy (in 18). Patients with a concomitant cystocele included in this study were only those with a grade 1 cystocele. SUI was the major complaint of all the patients, and only those with a moderate and severe degree were included.

Apart from the age and duration of incontinence, there was no statistically significant difference between the groups in the baseline variables.

For the operative findings (Table 1) there was a significant difference in favour of TOT for operative duration, perioperative blood loss, duration of urethral catheterisation and hospital stay. There was no intraoperative visceral or bladder injury in either group.

The cost of the procedure was higher in the TOT group (because of the price of the tape), but the longer hospital stay in the RFS group was not without cost and should also be considered.

The results were evaluated at 1 week after surgery (after removing the catheter and the resumption of voiding). There was a high cure rate in both groups, with no statistically significant difference between them (Table 1). There was one failure in the RFS group, due to prolonged urinary retention, and two failures in the TOT group, due to persistent incontinence.

The mean (range) follow-up was 1 (0.5–4) years; there were no significant changes in the continence achieved throughout the follow-up period. In both groups patients with MUI reported a complete cure of their

Table 1 The variables assessed before and after surgery in the two groups (40 patients in each).

Mean (SD) or <i>n</i> (%) variable	RFS	TOT	<i>P</i>
Age (years)	42.8 (6.0)	39.2 (4.66)	0.007*
Parity	4.6 (1.11)	4.1 (0.88)	0.044*
Previous pelvic/vaginal surgery	23 (58)	22 (55)	0.822†
Cystocele	33 (83)	31 (78)	0.576†
Duration of incontinence (years)	2.5 (0.55)	2.1 (0.44)	0.007*
<i>Severity of incontinence</i>			
Moderate	28 (70)	26 (65)	0.633†
Severe	12 (30)	14 (35)	
<i>Type of incontinence</i>			
Pure SUI	32 (80)	29 (73)	0.431†
MUI	8 (20)	11 (28)	
<i>Operative findings</i>			
Operative duration (min)	80 (11.11)	20 (4.44)	<0.001*
Urethral catheterisation (days)	3.5 (0.44)	2.5 (0.77)	<0.001*
Hospital stay (days)	2.8 (1.33)	1.2 (0.44)	<0.001*
Per-operative blood loss (mL)	270.4 (30.5)	154.6 (26.0)	<0.001*
Intraoperative visceral injury	0	0	
Cure (at 1 week)	39 (98)	38 (95)	0.556†
Failure	1 (3)	2 (5)	
<i>Complications</i>			
<i>Early</i>			
Abdominal wound problems (pain, ooze, haematoma, infection)	8 (20)	–	
Foot drop	1 (3)	–	
Groin + upper thigh pain	–	5 (13)	
Voiding difficulty	–	1 (3)	
Vaginal bleeding	–	1 (3)	
<i>Late</i>			
PVR	3 (8)	2 (5)	
De novo detrusor overactivity	2 (5)	2 (5)	
No vaginal or urethral erosions in both groups			

* Student's *t*-test.

† Chi-squared test.

SUI component, and even an improvement in their urgency component. A few patients required antimuscarinic drugs after surgery (three of eight in the RFS group and three of 11 in the TOT group).

The postoperative complications, also shown in Table 1, were generally minimal and all were managed conservatively. As late complications, a PVR was detected in three patients in the RFS group and two in the TOT group, whilst de novo detrusor overactivity was reported by two patients in each group. There were no vaginal or urethral erosions in either group up to the end of the study.

Discussion

UI affects large proportion of adult women and is associated with considerable distress and social disability [1,2,9]. Suburethral sling procedures can be used to both re-position the bladder and to provide a stronger suburethral support mechanism, which is why they are generally effective for all types of SUI [1,2,4,10,11].

Patients with a concomitant cystocele included in the study were only those with grade 1, because this type usually requires no further gynaecological intervention. In this study, two different sling materials were inserted using two different techniques, the traditional autologous RFS (natural tape) inserted through the retropubic route, and the relatively new macroporous polypropylene tape (synthetic tape) inserted through the transobturator route.

The ideal sling material should be inert, not carcinogenic, non-inflammatory, with enough strength and flexibility, not modifiable by the ingrowth of tissue, and affordable [12]. However, no existing material has all of the above properties. Autologous fascial slings have many advantages, including availability, minimal cost, reasonable morbidity and being a natural material (with less tissue reaction, less erosion and less infection) but harvesting a fascial graft from an extra-abdominal incision increases the operative duration and blood loss, and causes greater postoperative pain and lengthens recovery, as shown in the present study (Table 1) and in others [2,5,13].

Synthetic tape slings have the advantages of a minimal dissection needed for insertion and the absence of an additional abdominal incision with its sequelae. Hence they are fast techniques with a shorter hospital stay, but they have a relatively high cost and are less available (as in Iraq), and are foreign to the human body (with a theoretically higher incidence of vaginal and urethral erosions and infections) [14,15].

The transobturator route was chosen for the insertion of synthetic tapes in the present study because it is an effective, rapid technique, with less possibility of bladder and other visceral injury than with the retropubic approach, as mentioned in other studies [7,16]. All the

TOT operations in the present series were performed by the outside-in technique, using the Halo type tunneller, which is a matter of the surgeon's preference and experience.

The early cure rate was 98% for RFS and 95% for TOT ($P > 0.05$). These results are comparable and even higher than in other studies on autologous RFS [3,11,15,17] and TOT [16,18,19]. This high cure rate might be attributed to the proper selection of patients and meticulous technique, especially in placing both types of slings in the correct place and in a tension-free manner. The three failures (one in the RFS and two in the TOT group) were all early in the experience, in patients with a preoperatively severe type of SUI, and all were related to insertion of the sling with an incorrect tension.

The improvement in the urge UI component after both types of surgery might be because in patients with MUI, the frequent appearance of urine in the proximal urethra will easily induce reflex detrusor contractions, whilst the absence of urinary leakage, after sling surgery, might decrease this reflex [20].

All the complications (early and late) with both types of slings were marginal, treated conservatively and were comparable to those reported in other studies [3,4,15,16,19,21]. The early postoperative complications were mainly related to the technique used, abdominal wound problems in RFS, and groin and upper thigh pain in TOT.

It was hypothesised that placing the suburethral sling more horizontally (as in TOT) might cause less urethral compression, so that there would be fewer obstructive and irritative symptoms [16]. However, in the present study there was no statistically significant difference between the groups in the incidence of de novo detrusor overactivity or the development of a significant PVR (Table 1).

There were no vaginal or urethral erosions in the present series, which might be attributable to the careful dissection at the vaginal incision, keeping suitable thick vaginal flaps over the tape, the careful insertion of the tunneller to avoid perforations in the vaginal wall or urethra, the use of macroporous monofilament polypropylene tape (in TOT), and no infections at the site of surgery.

In conclusion, RFS and TOT have comparable efficacy and safety in treating SUI. However, RFS, with its more invasive nature and long operative duration, should only be used when synthetic tapes are not available, expensive for the patient, or not preferable, as for diabetic patients or those with a history of previous irradiation, because of the risk of poor vascularisation and healing.

Conflict of interest

None declared.

Source of Funding

None.

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