ORIGINAL ARTICLE

Use of autologous rectus fascia in a new transobturator hybrid sling for treatment of female stress urinary incontinence: A pilot study

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Abstract

Objective. This article reports the early results of a novel sling used for the treatment of female stress urinary incontinence (SUI). This sling has a piece of autologous rectus fascia in its middle part and two arms of polypropylene mesh. Material and methods. The study included 44 women with SUI. The preoperative work-up involved complete history taking, physical examination, cough stress test (CST) and 1 h pad weight test (PWT). Two questionnaires, the Urogenital Distress Inventory – Short Form (UDI-6) and the Incontinence Impact Questionnaire – Short Form (IIQ-7), were also completed preoperatively. The previously described sling was then inserted via the transobturator route in all patients. Postoperatively, the previous work-up was repeated for objective evaluation of the procedure and the subjective improvement was assessed by the Patient Global Impression of Improvement scale. Results. At the end of the first year, 92.9% of the patients had a negative CST, 85.7% had 1 h PWT < 1 g and the subjective cure rate was 90.5%. In addition, the scores for both UDI-6 and IIQ-7 were found to be decreased significantly ($p<0.001$). The recorded complications included temporary urinary retention, dyspareunia, de novo urge incontinence and groin pain in 4.8%, 4.8%, 7.1% and 11.9% of patients, respectively. Conclusion. This hybrid sling appears to have good short-term efficacy and low cost.

Key Words: stress incontinence, hybrid sling, transobturator sling

Introduction

Stress urinary incontinence (SUI) is included among the top 10 medical problems of adult women owing to its high prevalence rate as well as its direct impact on the physical, psychological and social well-being of affected patients [1]. The treatment of this disease involves a long list of behavioural, medical and surgical therapies. In addition, the surgical procedures in this field have shown significant progress over the past two decades. In 1978, McGuire and Lytton utilized the autologous rectus fascia for the treatment of type 3 SUI, with early promising results [2]. Different types of fascial sling procedure and Burch colposuspension were the most commonly performed operations for SUI until 1996, when Ulmsten et al. introduced the retropubic midurethral tension-free vaginal tape (TVT), which successfully replaced most of the previous procedures [3]. Thereafter, transobturator tape (TOT) was developed to increase the safety of this operation, particularly regarding urinary tract, bowel and vascular injuries. However, TOT was found to be associated with significant postoperative groin and thigh pain [4].

The use of autologous fascial slings has been proven to be as effective as TVT and TOT but with the advantages of lower infection and erosion rates [5]. However, these fascial slings could not compete with the synthetic ones because the continuous modification of the latter resulted in a significant reduction in their complications [4,6].

Because the autologous rectus fascia is cheaper than the conventional slings and the transobturator route is safer than the retropubic one, a novel transobturator hybrid sling has been designed that has a strip of autologous rectus fascia in its middle part. Early results using this sling are reported here.
Material and methods

This study was carried out in Tanta University Hospital, Egypt, during the period from November 2009 to May 2011, and was designed as a pilot clinical trial. The study protocol was reviewed and approved by the institutional review board and informed consent was obtained from all participants. The study included female patients with subjective SUI who were scheduled for surgical treatment after failure of conservative therapy and fulfilled one or more of the following criteria: positive cough stress test (CST), 1 h pad weight test (PWT) >2 g and SUI on urodynamic studies. Only patients who could not afford to pay for the traditional TVT or TOT slings on urodynamic studies. Only patients who could not meet any of the following criteria: virgin; pregnancy; recurrent case; pelvic organ prolapse greater than stage II, according to the Pelvic Organ Prolapse Quantification (POPQ) system [7]; increased postvoid residual urine >100 ml, body mass index >40 kg/m²; or a past history of urogenital malignancy, pelvic radiation or neurological disease.

The Arabic translations of the original American English versions of the Urogenital Distress Inventory–Short Form (UDI-6) and the Incontinence Impact Questionnaire–Short Form (IQ-7) symptom questionnaires were administered to all included patients in the outpatient department. These self-assessment questionnaires were completed with the help of an unbiased research nurse without any influence on the patients’ responses. Then, the patients were subjected to complete history taking, physical examination, CST, PWT, urine analysis, urine culture if indicated and routine blood tests.

The CST was performed initially in the lithotomy position (with bladder volume about 250 ml), but if no leakage was observed it was repeated in the standing position. The 1 h PWT was also carried out with the same bladder volume (250 ml) and the weight of the dry pad was determined before the test. The patient was then asked to perform some specific standardized physical activities in an hour’s time. These activities included walking, climbing stairs, standing, coughing vigorously, running on the spot, bending to pick up objects and hand washing with running water. At the end of these activities, the pad was reweighed to assess the amount of urine leakage.

Preoperative urodynamic evaluation involved uroflowmetry and water cystometry. Uroflowmetry was repeated at least twice with voided volume >150 ml and PVR with estimated by ultrasonography. Cystometry was carried out with the patient in the sitting position using an 8 F double-lumen urethral catheter and with a medium filling rate (50 ml/s). During this study, it was also confirmed that the involuntary leakage of urine that took place with the increase in the intra-abdominal pressure was not associated with any detrusor contractions, to meet the criteria of urodynamic SUI. The urodynamic study was conducted by a urologist who is expert in this field, using the Delphis-KT system (Laborie, Canada).

Surgical technique

The procedure was performed under spinal anaesthesia and all patients received a single preoperative dose of 500 mg of intravenous levofloxacin. The patient was put in the lithotomy position and after abdominal preparation, a transverse strip, 1.5 × 5 cm, was harvested from the rectus fascia through a small Pfannenstiel incision. The wound was then closed in layers and the isolated strip was prepared to form the hybrid sling. This was achieved via suturing one its short edges (1.5 cm) to a polypropylene mesh (Ethicon®), 1.5 × 10 cm, with continuous zero nylon suture. The other short edge of the isolated rectus sheath was similarly sutured to another 1.5 × 10 cm polypropylene mesh (Figure 1).

Thereafter, the vaginal part of the procedure was carried out as the standard TOT operation to insert this hybrid sling as a midurethral sling via the outside–in technique [8] and the urinary bladder was evacuated completely before insertion of the needles. At the end of the procedure, the sling was manipulated so that its middle part (rectus fascia) rested directly below the urethra (Figure 2). Cystoscopy was not used to look for bladder perforation. After good positioning of the sling (midurethral), an artery forceps was placed between the rectus strip and the urethra to ensure tension-free sling placement. Thereafter, the two polypropylene arms were cut flush with the skin and the rectus fascia was fixed to the underlying periurethral fascia using 4/0 polyglactin sutures at the 6 and 12 o’clock positions. The patients were discharged on the day of operation and the urethral catheter was left indwelling for 48 h. Patients with grade II cystocele underwent the same procedure but anterior colporrhaphy was also performed using three sutures of 2/0 polydioxanone, approximating the pubocervical fascia in the midline, and the catheter was kept for 5 days. When the catheter was removed at its predetermined time (after 2 or 5 days), all patients were asked to urinate twice. The patient was sent home if the residual volume was less than 100 ml. If this was not the case, a Foley catheter was refixed for an extra week.
Follow-up

Patients were evaluated on the seventh postoperative day for any early complications. Thereafter, they were evaluated at 6 and 12 months after surgery with complete history taking, physical examination, UDI-6, IIQ-7, CST and 1 h PWT and the pain was assessed using a visual analogue scale score. Objectively, the patients were considered cured if they had a negative cough test and 1 h PWT of 1 g or less. The subjective cure rate was based on the Patient Global Impression of Improvement (PGII) scale (7 points, from very much worse to very much better) [9]. Patients were considered cured if they were very much better. The presence of urge incontinence was also reported and its diagnosis was based on the response to the second question in UDI-6, “Do you experience urine leakage related to a feeling of urgency?” In addition, symptoms and signs suggestive of urethral erosion (e.g. recurrent urinary tract infection, urethral discharge or bleeding) or vaginal erosion were looked for. Similar outcome measures were also obtained at the end of the first year after surgery and annually thereafter in successful cases.

Figure 1. The isolated piece of the rectus fascia with attached arms of polypropylene mesh.

Figure 2. The hybrid sling in its final position.
Statistical analysis

The data were collected and analysed by the Student’s t test, with p < 0.05 considered statistically significant. The computer software SPSS 17.0 for Windows® (SPSS, Chicago, IL, USA) was used for statistical analysis.

Results

In total, 44 patients were included in this study but two of them were lost to follow-up and were excluded from the statistical analysis. The demographic data of the patients are shown in Table I. The urodynamic study also revealed nine cases with detrusor overactivity. The procedure was performed easily with no intraoperative complications, and all seven patients with grade II anterior vaginal wall prolapse had an anterior colporrhaphy as well as the sling operation. The operative time for the sling operation ranged from 28 to 36 min including the time for harvesting the graft, and the cystocele repair was completed in 15–20 min. The postoperative course was smooth in all patients except for two, in whom a temporary urinary retention was detected and an extra week of Foley catheterization was needed. Following this catheterization, these two patients showed a good voiding pattern with not much residual (<100 ml). In this project the urodynamic studies were not repeated postoperatively, because of the satisfactory voiding in all of the patients. However, seven cases with lower urinary tract infection were detected, all of whom responded to the appropriate treatment.

At 12 months of follow-up, 39 patients (92.9%) reported a subjective cure of their SUI, while the remaining three patients showed some improvement but were not satisfied with the results (less than very much better on the PGII scale) and were considered failed cases. Meanwhile, 92.9% of patients had a negative CST and 85.7% had a 1 h pad weight of less than 1 g. The latter patients (85.7%) had both a negative CST and a 1 h pad weight less than 1 g and, therefore, they met the criteria of an objective cure. In addition, the scores for the UDI-6 and IIQ-7 showed a statistically significant decrease (p < 0.001) compared to the baseline (Table II). Of the nine patients with preoperative urge incontinence, seven (77.8%) reported significant improvement in this symptom after surgery. No cases of vaginal or urethral infection or erosions were reported until the last follow-up (12 months). Complications recorded during follow-up included temporary urinary retention in two patients (4.8%), dyspareunia in two patients (4.8%), groin and mild thigh pain in five patients (11.9%), and de novo urge incontinence in three patients (7.1%). However, the women with groin and thigh pain showed spontaneous resolution of their pain within 3–5 months postoperatively.

Discussion

This study evaluated a novel sling to be included among the different options for treatment of female SUI. The procedure was carried out under spinal anaesthesia in all cases, although it can be also performed under local anaesthesia; spinal anaesthesia was used to allow for easier harvesting of the rectus graft. In addition, the same type of anaesthesia was used in all patients to avoid bias in the intraoperative and postoperative assessments. The preliminary data on the success rate of this technique showed that it is as effective as the previous procedures. At the end of the first year, 92.9% of the patients had a negative

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<th>Table I. Patient characteristics (n = 42).</th>
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<td><strong>Mean ± SD</strong></td>
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<td>1 h pad weight</td>
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<td>Type of incontinence</td>
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<tr>
<td>Stress only</td>
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<td>Mixed stress and urge</td>
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<td>No</td>
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<td>Grade I</td>
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<td>Grade II</td>
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BMI = body mass index; UDI-6 = Urogenital Distress Inventory – Short Form; IIQ-7 = Incontinence Impact Questionnaire – Short Form.

<table>
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<th>Table II. Twelve-month results (n = 42).</th>
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<td><strong>Baseline</strong></td>
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<td>UDI-6</td>
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UDI-6 = Urogenital Distress Inventory – Short Form; IIQ-7 = Incontinence Impact Questionnaire – Short Form; IQR = interquartile range.
patients (4.8%) and de novo urge incontinence in
follow-up in this study included dyspareunia in two
patients (77.8%) showed a significant improvement in their urge incontinence.
This observation was also demonstrated in the previous TVT and TOT studies and was explained
by Petros and Ulmsten [12]. These authors demonstrated that in patients with mixed urinary inconti-
ience, there is a sudden decrease in urethral pressure following the onset of urge symptoms with a rising
detrusor pressure, and this can lead to urge inconti-
nence. Therefore, they suggested that when the urethra is supported with the sling this symptom
can be improved [12].

In the present study, all of the patients with grade II anterior vaginal wall prolapse underwent an anterior
colporrhaphy together with their sling operation. However, there is some controversy about the need
for the sling operation in these cases. Brostad et al. found that when the women with anterior vaginal wall
prolapse and SUI underwent anterior colporrhaphy alone, 29% of them were cured of their preoperative
SUI [13]. Therefore, the authors suggested that this group of patients can be treated initially by anterior
colporrhaphy alone.

In this study, the urethral catheter was left in place
for a longer duration than in the conventional TOT
technique. This was done because all of the patients
were sent home on the day of surgery and many of
them did not live near the hospital. An addition
consideration is that the duration should be com-
pared to that of the traditional fascial slings, not to
that of the synthetic ones. The postoperative course
was smooth in all cases, but two patients (4.8%) had
temporary urinary retention. This complication was
also reported in the previous TOT studies with
varying incidences from 3.1% to 7.3% [14]. How-
ever, the TOT procedure is usually associated with a high risk of postoperative groin and thigh pain. This
pain was observed in 11.9% of the patients in the
present study, which is in agreement with the prev-
alence reported by Wang et al. (12.9%) [15]. The
exact etiology of this pain remains unknown but it
may be related to the presence of the tape in the
adductor muscles or a foreign body reaction to the
tape lying in proximity to peripheral obturator
nerve branches, or it may be secondary to the trauma
to the obturator membrane and muscles during the
procedure [16].

Delayed complications in the first year of follow-up in this study included dyspareunia in two
patients (4.8%) and de novo urge incontinence in
three patients (7.1%). These results are in accordance
with the previous TOT studies that reported dyspar-
eunia in 7.3% and de novo urge incontinence in 8.9%
of patients [10,17]. The mechanism of de novo urgency after midurethral sling procedures is poorly
understood. Bladder outlet obstruction has com-
monly been used as an explanation and the TOT
procedure is usually associated with a lower rate of
de novo urgency than TVT [18]. This complication
does not usually improve with time. Holmgren et al.
reported 14.5% de novo urgency after long-term follow-up of 5.2 years following TVT [19].

The most distressing complication after any sling
operation is vaginal and/or urethral erosion [20]. The
aetiology of this erosion is usually multifactorial and
includes inadequate closure of vaginal wall incision,
extensive or incorrect plane of dissection, wound
infection, early sexual activity, tape rolling and abnor-
mal vaginal epithelium, as in postmenopausal women
or after previous vaginal surgery [21]. The sling
material also plays an important role in this compi-
lcation. Therefore, most authors agree that the ideal
slings should be made of polypropylene, and be mono-
filamentous and macroporous (pore size >75 μm)
[22]. These criteria have dramatically decreased the
erosion rate in these operations. However, autologous
fascial slings are usually associated with low infection and erosion rates [5,23].

In this project, no cases of vaginal or urethral
erosions were reported after a year of follow-up, in
agreement with previous results using the traditional
rectus sling [5]. In the technique used here, the
urethra was supported by the rectus fascia strip and
as the sling was inserted via the transobturator route,
the two polypropylene arms were related neither to
the urethra nor to the urinary bladder. This advantage
would be missed if the retropubic route were used.
The same principle has been applied before, in the
BioArc® sling, where the urethra was supported by a
strip of a biological mesh and the two arms were
formed of polypropylene mesh. However, there was
a report of bladder erosion with this sling when it was
inserted via the retropubic route due to contact of the
bladder with the polypropylene mesh [24].

This study recruited only those patients who could
not afford to pay for conventional slings. Although
this selection did not seem to affect the outcome of
the tested procedure, it should be considered as a
selection bias and should be avoided in future studies.
This technique is being presented not to replace
traditional tape for the treatment of female patients
with SUI, but as an option for the treatment of such
cases. The main drawbacks of this sling are the
abdominal incision and the relative increases in the
operative time and the duration of the urethral
catheter compared to the traditional TOT sling. In addition, groin and thigh pain is still a significant complication of this technique, as with the traditional TOT sling \[4\]. However, it has the following advantages: first, theoretically, the presence of the rectus fascia strip in contact with the patient’s urethra and vagina and the polypropylene arms away from the bladder wall may help to decrease erosion rates, especially in susceptible patients; and, secondly, it has low cost, because the polypropylene mesh is much cheaper ($45) than the traditional TOT tape ($550) and only a few minutes were spent in harvesting the rectus fascia.

In conclusion, this new technique shows good short-term efficacy for the treatment of female SUI. However, a longer follow-up and a randomized trial with the traditional TOT tape are warranted before firm conclusions can be reached. In addition, it appears that it could be a viable option for patients at risk of urethral or vaginal erosions, such as those with multiple prior vaginal or retropubic surgical interventions and patients with a history of pelvic irradiation, but more studies should be performed in this subset of patients.

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