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ORIGINAL ARTICLE

Autologous versus synthetic slings in female stress urinary incontinence: A retrospective study

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KEYWORDS

Stress urinary incontinence;
Autologous sling

ABBREVIATIONS

ALPP, abdominal leak-point pressure;
EGP, Egyptian pounds;
NRS, numerical rating scale;
PVR, post-void residual urine volume;
QoL, quality of life;
SUI, stress urinary incontinence;
TOT, transobturator tape

Abstract ***Objective:*** To evaluate and compare the clinical (patient's morbidity, quality of life [QoL]) and economic impact of autologous vs synthetic slings in female stress urinary incontinence (SUI), as over the last decade, the introduction of synthetic vaginal tapes for managing SUI has gained wide acceptance being quicker with low morbidity. Synthetic vaginal tapes have been progressively replacing the use of autologous rectus fascia. However, the high cost of these synthetic tapes is almost always an obstacle for most patients of limited socio-economic resources in the Egyptian community.

Patients and methods: This retrospective study included 126 women with SUI. Data for patients that matched the study inclusion criteria were collected from the Urology Department of Ain-Shams University Hospitals from March 2011 to May 2013. Patients were categorised into two groups: Group I included 62 patients who underwent an autologous sling procedure using rectus sheath; and Group II included 64 patients that had a synthetic sling, using transobturator tape (TOT). The following variables were compared: operative time, postoperative pain scores, duration of indwelling urethral catheter, hospital stay, cost including the price of the synthetic tape when used, return to normal activity, and QoL assessment (International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form [ICIQ-UI-SF]) before and after discharge from hospital.

Results: Patients amongst the two groups were normally distributed with no statistically significant differences in patient's demographic data and comorbidities. The

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mean hospital stay was longer and the return to normal activity was delayed in Group I compared to Group II. The highest mean postoperative pain score was recorded in Group I. The overall morbidity was 12.9% and 4.68% in groups I and II, respectively. The mean (SD) overall cost was 2571.65 (254.8) and 3502.34 (196.9) Egyptian pounds (local currency) in groups I and II, respectively, being insignificantly lower in Group I when compared to Group II ($P > 0.05$). There were statistically significant differences between groups I and II for operative time, hospital stay, and postoperative pain scores. However, the differences in hospital cost amongst Group I and Group II were in favour of Group I. Post-surgical outcome was categorised into either complete cure (dry) or improved or failed with no significant differences in success rate and QoL amongst the study groups. The mean (SD) change in the QoL score was 10.95 (4.19) and 12.32 (4.1) in groups I and II, respectively. The higher success rate (complete cure) was in Group II, at 93.75%. Also, a statistically significant improvement of >70% of mean ICIQ-UI-SF score was shown in all groups when compared to baseline on both the 1- and 6-month follow-up visits.

Conclusion: Autologous grafts should be considered as a repair option in females with SUI in countries were health insurance policies do not cover the cost of synthetic materials in many instances. The cost-effectiveness of synthetic TOT slings, as a minimally invasive procedure with lower overall morbidity, has yet to be confirmed in larger scale studies with longer periods of follow-up, to confirm the durability of its successful outcomes and be considered as the primary treatment of choice in female SUI.

Introduction

The increased popularity of pubovaginal sling surgery reflects advances in our understanding of the pathophysiology of stress urinary incontinence (SUI). However, it has been associated with high complication rates and therefore reserved for the treatment of recurrent or refractory SUI [1].

Despite the popularity of the tension-free vaginal tape procedure via a retropubic approach, using an elastic polypropylene tape for the management of SUI, the overall safety of the procedure has been questioned due to the high complication rate weighted against its high long-term success rate [2].

The use of the transobturator route (outside–in) was advocated by Delorme et al. [7] to avoid the complications associated with the retropubic route. Insertion through the obturator muscles reproduces the natural suspension fascia of the urethra and is almost identical to the natural position of the pelvic floor hammock, whilst preserving the retropubic space.

Improvement in patients' quality of life (QoL) is a fundamental issue for successful outcomes, as failures and complications can have devastating effects on patients [8]. Moreover, the cost of the whole surgical procedure is vitally important, especially amongst communities of limited resources and income. In the present study, we retrospectively compared both autologous and synthetic slings in female SUI as regards both clinical and financial aspects.

Patients and methods

This retrospective study was conducted in the Urology Department of Ain Shams University from March 2011 to May 2013. The study was approved by the Ethics Committee of Ain Shams University and all patients signed an informed consent for the details of the procedure. The study included 138 female patients with the diagnosis of SUI, as diagnosed from a standardised history, clinical examination (including stress test), numbers of pads/24 h, cystogram (in supine and erect positions with and without straining), and objectively confirmed by complete urodynamic evaluation with abdominal leak-point pressure (ALPP) recording according to the standards recommended by the ICS [9]. Both uroflowmetry results and post-void residual urine volume (PVR) were retrieved for comparison and assessment of postoperative voiding dysfunction and urethral obstruction. We used the validated Arabic translation of the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI-SF) questionnaire to assess QoL before surgery, and at the 1- and 6-month postoperative visits [10]. The overall score range was from 0 to 21 for the

three questions and the mean values were compared postoperatively to baseline scores.

Of 138 patients, 126 were included in the final analysis, as seven women did not complete the preoperative questionnaire, another four were lost to follow-up, and the remaining one died from another medical cause.

Patients were included in the study if they had SUI as defined by the symptom of involuntary urine leakage on any increase of intra-abdominal pressure (e.g. coughing, exertion, etc.) and confirmed objectively by clinical evaluation, with no associated detrusor overactivity and/or detrusor overactivity UI as confirmed by urodynamics. Patients who had significant pelvic organ prolapse that required surgical correction or had a history of previous prolapse repair of <6 months before, or active UTI, or having evidence of voiding dysfunction by urodynamics, were excluded from enrolment into the study. Also patients with a PVR >100 mL were excluded.

The women with SUI were categorised into two groups after inclusion: Group I included 62 who underwent an autologous rectus sheath sling procedure ($n = 62$) and Group II included patients who had a synthetic sling using a suburethral transobturator route (transobturator tape [TOT] sling) ($n = 64$). The aims of this retrospective study were to evaluate postoperative pain, perioperative complications, and the immediate functional outcome of the autologous rectus sheath and TOT for the treatment of female SUI, together with the economic impact of each procedure.

All the procedures were performed in the modified dorsal lithotomy position under either general or regional anaesthesia. Antibiotic prophylaxis (i.v.) was given to all patients with induction of anaesthesia. The autologous rectus sheath fascial sling procedure was performed as described by Blaivas and Jacobs [11], and TOT (outside–in) was performed as described by Delorme et al. [7]. The procedure was timed from the vaginal incision to the last skin suture, including cystoscopy in autologous sling patients (Group I). At the end of each procedure a vaginal haemostatic pack soaked with local anaesthetic was left for 12–24 h postoperatively, whilst an indwelling urethral Foley's catheter (16 F) was fixed for ≥ 1 day according to the situation. Blood loss was also monitored and recorded for comparison.

Intraoperative and immediate postoperative complications, morbidity, pain (numerical rating scale [NRS]: 0 = 'no pain', 10 = 'unendurable pain'), the postoperative hospital stay, and return to normal activity were retrieved. Data from the 1- and 6-month postoperative visits were compared with the perioperative variables and QoL. Patients' follow-up data records ranged from 6 to 24 months.

The total cost of the surgical procedure was calculated from patient admission until discharge including TOT price when used. Descriptive statistical data of patients' demographics, perioperative variables were recorded as mean ± SD, whilst postoperative surgical outcome in percentage (proportion) for comparison between the groups. Statistical analysis was performed using paired *t*-test and *z* test, with a $P \leq 0.05$ considered to indicate statistical significance.

Results

Epidemiological characteristics of the groups

The mean (SD) age of patients included in the two study groups (age range 32–69 years) was 56.8 (12) and 54.6 (11.5) years for groups I and II, respectively; with no statistically significant difference between them.

Mean body mass index and parity are given in Table 1, with no statistically significant difference between the groups. The epidemiological characteristics and surgical histories of the women in the rectus sheath sling group (Group I) and TOT group (Group II) were not significantly different (Table 1).

Five patients had a past history of surgery for SUI other than sling procedures amongst the whole study group, with no significant difference between groups I and II, at 4.83% and 3.23%, respectively. Only nine of the 126 patients had a past history of hysterectomy (Table 1).

Table 1 Epidemiological characteristics of the study groups.

Variable	Group I (rectus sheath)	Group II (TOT)	*P*
Number of patients	62	64	
Mean (SD, range):			
Age, years	56.8 (12)	54.6 (11.5)	0.18
Body mass index, kg/m^2	25 (4, 19–30)	27 (7, 20–34)	0.48
Parity, *n*	2.1 (1.9, 0–4)	2.9 (2.1, 0–5)	0.56
ICIQ-UI SF score	14.6 (5.5, 8–20)	14.5 (5.95, 8–21)	0.51
N (%)			
Null parity	6	4	0.34
Post-menopausal status	18	12	0.42
Prior surgery for SUI	3	2	0.90
Prior hysterectomy	4	5	0.44

The mean (SD) preoperative ALPP was 81.70 (22.63) cmH_2O. The mean (SD) preoperative maximum urinary flow rate was 19.63 (4.52) mL/s, and the preoperative PVR was 32.47 (21.96) mL.

Operating time and perioperative complications

The operating time was significantly longer in the autologous rectus sheath group (Group I), at a mean (SD; range) of 100 (30.6; 50–200) min vs 17 (6.6; 8–22) min in the TOT patients (Group II) (Table 2 and Figs. 1 and 2).

There was no statistically significant difference in the postoperative PVR between the study groups ($P > 0.05$) and none of the women required bladder self-catheterisation postoperatively (Table 2).

The mean time to return to normal activity was significantly shorter in Group II patients compared to those in Group I ($P < 0.05$), at a mean (SD) of 9.3 (1.2) vs 2.3 (0.1) days.

Intra- and postoperative complications, and postoperative pain intensities (Table 3)

The overall complication rate was higher in Group I. Vaginal injury was encountered in three patients in Group II, in the form of transfixation of the vaginal wall and the needle was withdrawn and re-inserted without complications. Vaginal injury was significantly more frequent in Group II than in Group I ($P = 0.02$), whereas the rate of bladder injury was significantly higher and recorded only in Group I patients ($P = 0.03$) (Table 3). Bladder injury was recorded in four patients, where the needle caused bladder perforation, which was diagnosed through intraoperative cystoscopy. Urethral catheterisation was prolonged in these patients to 5 days. No vascular, nervous or intestinal injuries were encountered in either group. There was no statistically significant difference between the groups for mean intraoperative blood loss. Two women in Group I developed retropubic haematoma, which was complicated by an abscess in one case and necessitated re-admission and ultrasonography-guided placement of a pig-tail drain but further surgery was not necessary. Urinary retention and sling erosion (vaginal/urethral) were not recorded postoperatively or during the entire follow-up period in either of the study groups.

Table 2 Mean operating time and postoperative outcomes.

Variable	Group I (rectus sheath)	Group II (TOT)	*P*
Number of patients	62	64	
Mean (SD)			
Operating time, min	100 (30.6)	17 (6.6)	0.03
Duration of bladder catheterisation, days	2 (0.5)	0.8 (0.5)	0.56
PVR, mL	68 (58)	28 (19)	0.63
Time to return to daily activity, days	9.3 (1.2)	2.3 (1.3)	0.02

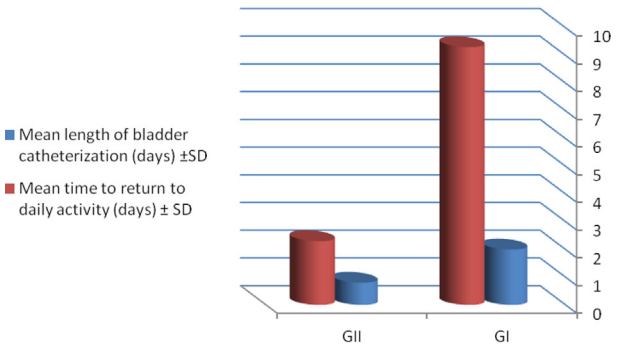

Fig. 1 Comparison of both mean duration of bladder catheterisation and time to return to daily activity for Group I (GI) and Group II (GII).

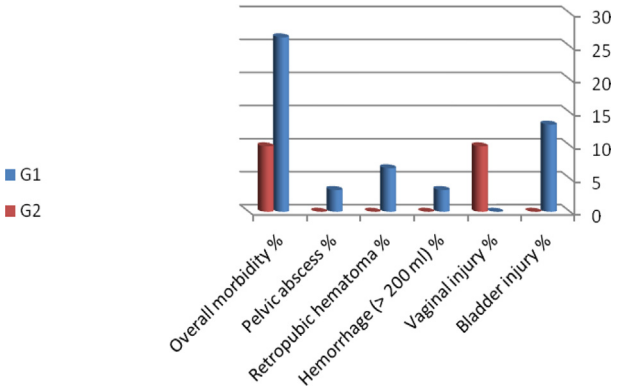

Fig. 2 Intra- and postoperative variables for Group I (GI) and Group II (GII).

Table 3 Intra- and postoperative complications, and pain.

Complication	Group I (rectus sheath) ($n = 62$)	Group II (TOT) ($n = 64$)	*P*
Bladder injury, *n* (%)	4 (6.45)	0	0.03
Vaginal injury, *n* (%)	0	3 (4.68)	0.02
Haemorrhage (>200 mL), *n* (%)	1 (1.6)	0	0.13
Retropubic haematoma, *n* (%)	2 (3.22)	0	0.13
Pelvic abscess, *n* (%)	1 (1.6)	0	0.28
Postoperative pain NRS, mean (SD; range)	4 (3, 0–9)	1.4 (0.8, 0–5)	0.03
Overall morbidity, *n* (%)	8 (12.90)	3 (4.68)	0.28

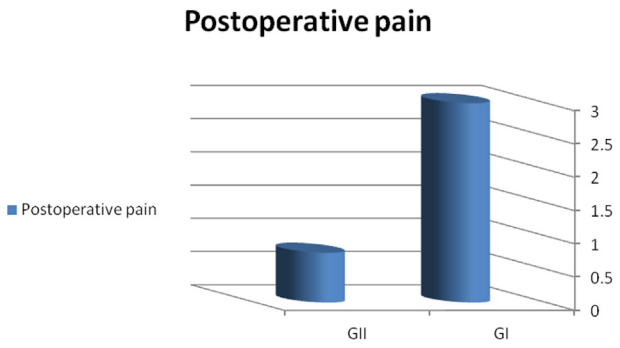

Fig. 3 Postoperative pain scores for Group I (GI) and Group II (GII).

The lowest overall morbidity was recorded in Group II (TOT) at 4.68% vs 12.9% in Group I, which was not statistically significantly different.

The mean postoperative pain score according to the NRS was significantly less in Group II than in Group I, at a mean (SD; range) of 1.4 (0.8; 0–5) vs of 4 (3; 0–9) ($P < 0.03$) (Table 3, Fig. 3). The mean hospital stay was significantly longer in Group I than in Group II, at a mean (SD) of 3.7 (0.8) vs 1.8 (1.7) days ($P < 0.05$).

Functional results, QoL, and cost

The impact of surgery on urinary status at the 1-month postoperative visit is shown in Table 4. The cure rate (defined as no more episodes of SUI or pad use) was insignificantly higher in Group II than in Group I. On comparing the groups, we did not find any statistically significant difference between them, which suggest comparable efficacy of the two procedures ($P > 0.05$). The rates of postoperative nocturia, urgency, and urge incontinence were higher in Group I, but not found to be significantly different from Group II.

There was no statistically significant difference between the groups in the postoperative mean score analysis of the ICIQ-UI-SF questionnaire. Whilst, a statistically significant improvement of >70% in the mean score was seen in both groups when compared to baseline at both the 1- and 6- month follow-up visits, with mean (SD) score changes of 10.95 (4.19) and 12.32 (4.1) in the two groups, respectively, at 6 months.

The postoperative PVR was insignificantly higher in Group I vs Group II, at a mean (SD) of 68 (58) vs 28 (49) mL.

The mean total cost was >35% more in Group II (Table 4). The relatively high efficacy with lower overall morbidity was clearly shown in Group II patients but with a statistically insignificantly higher cost, at a mean (SD) of 3502.34 (196.9) Egyptian pounds (EPG, local currency).

Table 4 Cure rates and voiding problems at the 6-month postoperative visit.

Variable	Group I (rectus sheath) ($n = 62$)	Group II (TOT) ($n = 64$)	P
Outcome, *n* (%)			
Dry	52 (83.87)	60 (93.75)	0.58
Improved	4 (6.45)	3 (4.68)	0.71
Failed (unchanged or worsen)	6 (9.67)	1 (1.56)	0.29
De novo nocturia	6 (9.67)	2 (3.13)	0.16
De novo urgency	8 (12.9)	1 (1.56)	0.48
Cost, mean (SD)			
Cost/case, EGP	2571.65 (254.8)	3502.34 (196.9)	0.59

Discussion

Suburethral slings along with retropubic bladder suspensions are reported to be the most effective procedures for long-term success in the treatment of SUI. With a >80% probability of improvement in SUI at ≥48 months, the pubovaginal sling has become the 'gold standard' for surgical correction of SUI [1]. In a preliminary study, Delorme [7] showed that the transobturator route was associated with a high success rate, no bladder injury, and few perioperative complications in women with SUI.

The present retrospective study shows that the suburethral sling procedure by the transobturator route (TOT) is associated with less postoperative pain but a higher risk of vaginal injury than the retropubic route using rectus sheath. In contrast, bladder injury was more frequent in Group I. The autologous rectus sheath (Group I) and TOT groups (Group II) showed similar rates of immediate success in treating the SUI. The success rate of 90% for pubovaginal rectus sheath sling in Group I patients, in our present study is comparable to the Cross et al. [12] study. Moreover, Group II patients in our present study had a higher success rate when compared to other publications [2–8], which may be related to our strict inclusion criteria. The rectus sheath sling procedure had a longer mean (SD) operative time of 100 (30.6) min, which was nearly five-times longer than the TOT procedure, at a mean (SD) of 17 (6.6) min. This difference is probably attributable to rectus sheath graft harvest and preparation in Group I.

The most striking finding was the lower postoperative pain scores amongst the women in Group II compared to those in Group I, which may be explained by the minimal dissection used in the TOT sling procedure. All the Group I patients needed postoperative narcotic analgesics during the immediate postoperative period, in comparison to none of the Group II patients, in agreement with previous reports by other investigators [8,11–12].

In the present study, the TOT procedure was associated with a lesser incidence of voiding problems than the rectus sheath sling. In our Group I patients, *de novo* urgency was found in 13.3%, which is higher than that reported by Morgan et al. [13]. Symptoms of voiding dysfunctions could be due to a more invasive surgical procedure with marked dissection of the periurethral facial support, with its inherent risks of traumatisation of the nerve supply to the bladder and urethra.

The present study suggests that tape insertion via the obturator route (TOT) results in better voiding patterns than others and we can hypothesis that with the transobturator route the tape is inserted on each side at 45° to either vertical and horizontal planes, which is wider than that of other slings. A 90° angle appears to be optimal, because it is in the region of the pubourethral ligaments, which were described and highlighted by Delancey [14] to have an essential role in the physiological mechanisms of urinary continence. With the TOT procedure, the tape forms a neohammock under the urethra, and thus during coughing, we suggest that the urethra may be squeezed against the tape in the same way as it is normally squeezed against the pubourethral ligaments [13].

In the present study, perioperative complications, pain, QoL, and the immediate functional results (surgical outcome and voiding dysfunction) were evaluated at the 1- and 6-month postoperative follow-up visits, without significant differences between the groups. These results also confirm TOT (Group II patients) as minimally invasive procedure with low morbidity, at least in the short term, and in agreement with other investigators [6–7,12–13]. However, TOT is more expensive than a fascial sling, which is considered a burden for patients of limited income and deficient insurance policies.

The mean hospital stay and consequently return to normal activity were significantly shorter for Group II patients [mean (SD) 2.3 (0.1) days] compared with Group I [mean (SD) 9.3 (1.2) days], thus indicating that the TOT procedure is the simpler operation. However, the durability and cost effectiveness of TOT, as a minimally invasive procedure with low morbidity, comparable surgical outcome, and insignificantly higher cost have yet to be confirmed by further studies.

There was no urethral/vaginal erosion in any of the present study groups, which is contrary to the Abdel-Fattah et al. [15] report of their retrospective analysis comparing synthetic slings, which could be attributed to other concomitant surgeries done and intraoperative morbidities (vaginal injuries and/or haematomas) reported in their study.

Furthermore for recurrent SUI after vaginal or urethral erosion, it is advisable to use classic pubovaginal or hemi-slings constructed with rectus fascia, which still show less erosion rates than synthetic slings [16].

TOT was also associated with the complaint of groin pain in 51% of our patients ($n = 33$), which is consistent with results of Nazari et al. [17] and this resolved in all the patients at $\leq$2 weeks of the procedure.

In conclusion, this retrospective study shows that the TOT procedure is associated with less pain compared to the autologous rectus sheath procedure. Bladder injury, haematoma and abscess formation were only recorded in the rectus sheath group, whilst vaginal injury only occurred in the TOT group. In our country, especially in patients with poor socioeconomic status, the autologous sling can be considered a valid and robust option for managing cases of SUI. There must be a rationale to choose between increased cost with high QoL and less intra- and postoperative complication with the synthetic sling and the lower cost with more intra- and postoperative complication with the autologous rectus sheath sling.

Conflict of interest

We have no conflict of interest to declare or funding to disclose.

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Further reading

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