Functional and quality of life outcome of transobturator tape for treatment of female stress urinary incontinence

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Abstract

Introduction and hypothesis This study aims to evaluate the functional outcome of transobturator tape (TOT) in treatment of female stress urinary incontinence (SUI) and its impact on patient quality of life (QoL).

Methods Sixty female patients with SUI underwent TOT operation, outside-in technique. Forty-eight patients completed the study. Clinical evaluation, urodynamics, and QoL using validated Arabic translation of the International Consultation on Incontinence Questionnaire—Short Form were done both preoperatively and 3, 6, and 12 months postoperatively.

Results The mean follow-up was 16 months. The objective cure rate was 95.83%. There were no cases of urethral injury, bladder perforation, or thigh pain. De novo urgency and urge incontinence was observed in four patients (8.3%). No early or late outflow obstructive symptoms were noted. No difference was observed between pre- and postoperative filling cystometrogram and pressure flow studies. There was significant improvement in the postoperative QoL assessment.

Conclusions TOT (outside–in) appears to have no deleterious effect on storage and voiding functions.

Keywords Functional outcome · Quality of life · Stress urinary incontinence · TOT

Introduction

Over the last few years, the procedure of urethral suspension via the retropubic access (TVT) has become the most common form of surgery for treating female stress urinary incontinence. However, potential immediate surgical complications include bladder perforation [1] and injury to the pelvic vessels [2] and the bowel [3]. Moreover, de novo urge incontinence and voiding dysfunction may occur after overcorrection associated with TVT [2]. Potentially life-threatening complications occurring with this technique were also reported.

In 2001 Delorme introduced the transobturator approach to avoid bladder injury, which was estimated to occur in 7.34% of women treated with TVT. He demonstrated that TOT gave similar success rates to TVT without its complications [4]. This was confirmed later by several studies and meta-analysis comparing the TVT to the TOT which showed similar results but with less storage and emptying problems [5–7].

In a recent prospective study with a 3-year minimum follow-up, TVT-O procedure showed a subjective cure rate of 87.9% and objective cure rate was 91.8%. Globally, these subjective and objective cure rates compare favorably with those obtained at 3 years after TVT procedure [8].

Nevertheless, Lukacz and colleagues showed that maximum flow rates fell by up to 43% after the TVT procedure. Moreover, these authors reported that residual urine volume was doubled postoperatively [9]. Wang and Chen [10] reported similar results after TVT sling placement. They reported a decrease in free maximum flow rates, increased detrusor pressure at maximum flow rates, and an increase in urethral resistance, particularly in women with dysfunctional voiding.
Unfortunately, most of the studies that addressed the outcome of the TOT procedure focused on the cure rates and complications without a real focus on the functional outcome. It is not clear whether this procedure can cause any deleterious effect on the storage and voiding functions of the lower urinary tract similar to that reported in TVT procedure.

Therefore, the aim of this prospective study is to evaluate the functional outcome of transobturator tape in treatment of female stress urinary incontinence both clinically and urodynamically and its impact on quality of life.

Patients and methods

This prospective study was conducted in the Department of Urology, Ain Shams University Hospitals, Egypt on 60 female patients complaining of SUI who were treated by TOT outside–in procedure between February 1, 2008 and December 31, 2009. The patients must be agreeing to the investigational nature of the study.

Inclusion criteria were women older than 21 year with SUI proven by clinical and urodynamic examination. Exclusion criteria were women with previous history of radio or chemotherapy for previous malignancy, pregnant women, incontinent women with significant post-void residual urine and patients in whom urodynamic study shows poor detrusor compliance (less than 12.5 ml/cmH2O) and detrusor hypocontractility. Women with mixed incontinence were not excluded from the study.

Out of the 60 patients, 48 completed the study. The ethical approval of the study was obtained from our research ethics committee in the hospital. The reason for the drop out was mainly due to failure of these patients to comply with the follow-up visits schedule or refusing repeating the UDS sequentially as stated by the study protocol.

A detailed patient history was recorded for each patient prior to physical examination and multi-channel urodynamic study. Evaluations of all patients were done following the recommendations of the international Scientific Committee of the 3rd International Consultation on Incontinence, 2005 [11].

All the women completed a validated Arabic form of the questionnaires on quality of life of the International Consultation on Incontinence Questionnaire–Short Form (ICIQ-UI-SF) which is a validated questionnaire [12].

The TOT operations were done by outside–in technique under spinal anesthesia in 46 cases and local anesthesia in only two cases as most patients did not prefer local anesthesia. The tape used was Aris (Porgés-Coloplast), a macroporous and monofilament polypropylene tape. The procedure was performed as described by Delorme et al. [5]. All patients were subjected to urethrocystoscopy after the procedure to ascertain that there is no bladder or urethral injury. Prophylactic 3rd generation cephalosporin antibiotic was used in all cases.

The time of the procedure was estimated from the vaginal incision to the last skin suture. The patients were discharged after voiding in first postoperative day and were advised to avoid heavy lifting, exercise, and sexual intercourse for 4 weeks. Patients were seen again 4–6 weeks for clinical evaluation, and later at 3, 6, and 12 months after operation for clinical assessment and urodynamic study.

Functional outcome was evaluated on several levels. Objective cure rate was demonstrated with provocative stress test and urinary leakage during urodynamics in response to Valsalva and cough. Subjective cure rate was determined by their responses in the ICIQ-UI short form and by asking them directly about their satisfaction regarding the outcome. Complete patient satisfaction meaning no urine loss under stress, no voiding difficulty, and no urinary symptoms at filling. Partial patient satisfaction meaning patient had periodic or rare episodes of dribbling at stress but considered themselves cured because incontinence occurred under extreme stress and no pads were required on daily basis. Clinical emptying and storage problems were looked for in addition to measuring residual urine early postoperatively and in the follow-up visits. Urodynamics were done according to recommendations of ICS [13]. Uroflowmetry, filling cystometrogram and pressure flow study were done preoperatively and on the postoperative visits.

Statistics Quantitative data are presented in text as mean ± SD. Qualitative data are presented as number and percentage. Preoperative urodynamics and quality of life data were compared with postoperative data of the same patients at the 3, 6, and 12 months follow-up visits using paired t test. We compared the continence after TOT in patients who had previous anti-incontinence procedures to those who did not and that of patients that had concomitant POP surgery during insertion of the TOT to those who did not using the Fisher exact test. P values are considered significant if less than 0.05 and highly significant if less than 0.01. Statistical Program for Social Science (SPSS version 16) was used to do statistical analysis [14].

Results

The mean follow-up was 16 months with 22 patients exceeding 1 year. Mean age of the patients was 56.8±
12 years and mean parity was 4.5±1.4. Prior history of hysterectomy was reported in four patients (8.3%). History of prior surgery for SUI was reported in eight patients (16.7%) in the form of Burch’s colposuspension in four patients (8.3%), TVT in two patients (4.2%), and multiple procedures in two patients (4.2%).

Clinically, the type of incontinence was defined as pure SUI in 20 (41.6%) and mixed urinary incontinence in 28 (58.4%) patients. Cystocele repair was done in six patients (12.5%) simultaneously. Cystocele and rectocele repair were done in another two patients (4.2%).

The mean operative time was 21±9.5 (10–50) min, and the mean hospital stay was 2.1±1 (0.8–5) days. Urinary catheter was removed on the average of 0.8±0.5 (0.5–2) days and none of the patients needed recatheterization.

Complications

Only four cases (8.3%) of vaginal fornix perforation occurred intraoperatively and were repaired at time of operation. No major complications, notably no injury of major vessels, neurological or gastrointestinal complications, and no pulmonary embolism were reported. There was one case of intraoperative hemorrhage of more than 300 cm³ which was controlled by compression. None of the cases suffered urethral injury or bladder perforation and none of them experienced postoperative thigh pain. Postoperative surgery site pain assessed by numerical rating scale was 0.8±1.4 (0–4) which was relieved by oral analgesics. There were no cases of vaginal or urethral erosions.

Functional outcome

Continence results after TOT

The objective cure rate in these 48 patients after TOT operation was 95.83% by stress test and no urine leakage during urodynamic study with increased intra-abdominal pressure. The subjective level of complete and partial patient satisfaction was 91.67% (44 patients) and 4.17% (two patients), respectively. The two cases that failed had concomitant cystocele repair. One of them had a previous TVT procedure. In other words, the cure rate in patients with concomitant POP surgery is 75% and in cases with previous anti-incontinence procedure is 87.5%. There was no statistical significant difference comparing the outcome of patients with previous anti-incontinence procedures to those that did not. On the other hand, there was statistical significant difference comparing the continence in those patients that had concomitant POP surgery to those that did not. The 12 cases that were excluded from the study were continent in early follow-up with no voiding dysfunction which may be the reason for their negligence to follow-up.

Clinical storage and emptying outcome

None of the women reported either early or late postoperative voiding dysfunction. De novo urgency and urge incontinence was observed in four patients (8.3%) at the first and second visits (1 month and 3 months) which were treated by anticholinergics for 3 months and symptoms were relieved. After 6 months no de novo urgency or urge incontinence were observed. As regards patients with mixed incontinence, overactive bladder symptoms persisted in 14 of them (50%).

Urodynamic storage and emptying outcome

The urodynamic assessment of bladder storage function in the 48 patients before and after TOT operation is shown in Fig. 1. The mean preoperative values of first sensation, first desire, strong desire, cystometric capacity, and the compliance at urgency were not significantly different from values at 3, 6, and 12 months after TOT operation. In addition, idiopathic detrusor overactivity (DOA) was observed in eight patients with mixed incontinence preoperatively and none of the patients of the pure SUI group. Postoperatively, only three patients demonstrated idiopathic detrusor overactivity. None of the four patients that demonstrated de novo urge demonstrated DOA in their urodynamic studies.

Data of urodynamics assessing the voiding function is shown in Fig. 2. The mean preoperative values of average flow rate, maximal flow rate, residual urine amount, and the detrusor pressure at peak flow during voiding cystometry (Pdet, Qmax) showed no significant differences compared with values at 3, 6, and 12 months after TOT. The URA value was not obstructed preoperatively and did not change in the follow-up postoperatively.
Quality of life before and after TOT procedure

Semiquantitative evaluation of QoL by ICIQ-UI-SF showed a significant improvement in the total score. These improvements were noted at the first postoperative visit and remained stable thereafter (Fig. 3).

Discussion

Despite the success of many anti-incontinence procedures in females with SUI using suburethral tapes, definite functional changes occur in these patients that may denote that these patients may get partially obstructed by the procedures [7, 8]. This point has not been extensively studied in the literature in patients treated with TOT. It was not intended in this work to study the outcome regarding the success of the technique as anti-incontinence procedure for female SUI but rather to examine the voiding and storage functional changes both clinically and urodynamically after the use of TOT. We have demonstrated in this study the absence of significant voiding and storage functional changes in patients with SUI treated with TOT. This was true both clinically and urodynamically. The absence of these voiding and storage problems in association with the good results of the technique has been clearly demonstrated in our study to result in a high patient satisfaction.

The flat positioning of the suburethral tape when using such technique may have played an important role in preventing the obstructive symptoms. This flat support has been shown to decrease the tension exerted by the tape as compared to a more vertical positioning as in TVT [15]. It is clear now from the integral theory for continence [16] that these suburethral tapes do not function through compressing the urethra but rather through preventing the posterior displacement of the posterior urethral wall during increased intra-abdominal pressure which prevents opening the posterior urethra preventing stress incontinence.

De novo urgency is another bothersome symptom that some patients may suffer after suburethral tapes. Only four cases (8.3%) suffered de novo urgency in this study and were relieved by anticholinergics. This rate is lower than that reported in other studies involving the retropubic approach [17]. The reason for that is not clear since the cause of de novo urgency after suburethral tapes is not clearly understood. Nevertheless, one can speculate that this may be related to the partial obstruction created by the retropubic tapes since the incidence of both obstructive and irritative complications decreased simultaneously with the TOT.

It is not clear from our work whether the brand of the tape has played any role in these results. Apart from its safety features being macroporous monofilamentous polypropylene tape, its non-stretchability and having no memory may have made it easier to adjust its tension. To reach any conclusion regarding this point, head to head comparisons should be made involving different tape brands.
The sequential urodynamic assessment in this study is in our opinion of great importance as it delineates any changes, even if subtle, over the postoperative course. It is clear from our study that no deleterious storage or voiding complications appear over time that does not appear early in the postoperative follow-up. This is of a significant importance in designing future studies and in following up these patients. In other words, one should not expect any voiding and storage problem to develop late in postoperative follow-up that were not evident in the early postoperative period (in our study the first urodynamic study was at 3 month postoperatively). Similar findings were found in a similar study that followed up TVT patients with sequential urodynamic study [18].

Finally, this study is, to our knowledge, one of very few to use the Arabic ICIQ/UI-SF quality of life questionnaire to assess QoL changes after TOT procedures in an Arabic community. This validated instrument proved to be very useful in addressing this issue. The questionnaire proved to be easy to administer and readily understandable by the patients in our area. This is of paramount importance as quality of life issues are new to our medical and patient community in Arab countries or at least not widely dealt with. We have shown that the good success rate of the TOT when associated with no deleterious functional outcome results is significant quality of life improvement.

**Conclusion**

The results from our series showed that the TOT method is a simple, effective, and safe procedure for treating stress urinary incontinence. This was not associated with any detrimental functional drawbacks that may be seen in other anti-incontinence procedures. This was reflected on patient satisfaction and quality of life.

**Conflicts of interest** None.

**References**