Arab Journal of Urology

ISSN: (Print) 2090-598X (Online) Journal homepage: https://www.tandfonline.com/loi/taju20

Adjustable vs. ordinary transobturator tape for female stress incontinence. Is there a difference?

Mohamed S. Elbadry, Ahmed H. Gabr, Alaa M. Shabaan, Ahmed R. Hammady, Tarek K. Fathelbab, Amr M. Abdelhamid, Wael Gamal Eldin, Mohamed Z. Eldahshoury & Ahmed S. Elhefnawy

To cite this article: Mohamed S. Elbadry, Ahmed H. Gabr, Alaa M. Shabaan, Ahmed R. Hammady, Tarek K. Fathelbab, Amr M. Abdelhamid, Wael Gamal Eldin, Mohamed Z. Eldahshoury & Ahmed S. Elhefnawy (2015) Adjustable vs. ordinary transobturator tape for female stress incontinence. Is there a difference?, Arab Journal of Urology, 13:2, 134-138, DOI: 10.1016/j.aju.2015.02.006

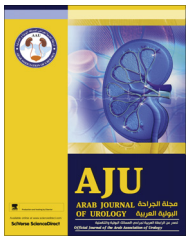
To link to this article: https://doi.org/10.1016/j.aju.2015.02.006

Published online: 05 Apr 2019.

Arab Journal of Urology (2015) 13, 134–138

Arab Journal of Urology
(Official Journal of the Arab Association of Urology)

www.sciencedirect.com



VOIDING DYSFUNCTION/FEMALE UROLOGY
ORIGINAL ARTICLE

Adjustable vs. ordinary transobturator tape for female stress incontinence. Is there a difference?

Mohamed S. Elbadry [a,*], Ahmed H. Gabr [a], Alaa M. Shabaan [a], Ahmed R. Hammady [b], Tarek K. Fathelbab [a], Amr M. Abdelhamid [a], Wael Gamal Eldin [b], Mohamed Z. Eldahshoury [b], Ahmed S. Elhefnawy [c]

[a] *Urology Department, Faculty of Medicine, Minia University, Egypt*
[b] *Urology Department, Faculty of Medicine, Sohag University, Egypt*
[c] *Urology and Nephrology Center, Mansoura University, Egypt*

Received 23 January 2015, Received in revised form 10 February 2015, Accepted 13 February 2015
Available online 12 March 2015

KEYWORDS

Female;
Stress incontinence;
Transobturator;
Adjustable;
Tape

ABBREVIATIONS

TOT, transobturator tape;
TOA, adjustable TOT;
(f)(S)UI, (female) (stress) urinary incontinence;

Abstract ***Objectives:*** To determine whether there are any significant differences in complications and success rate between adjustable transobturator tape (TOA) and ordinary transobturator tape (TOT) in the treatment of female stress urinary incontinence (fSUI), as the TOA was recently introduced for the treatment of female SUI, its advantage being the ability to adjust the tape after surgery to address over- or under-correction.

Patients and methods: In all, 96 women with SUI (mean age 53 years, SD 10) were included in the study. Patients were randomised into two equal groups (group 1, TOA, vs. group 2, TOT). The operative duration, blood loss, intra- and post-operative complications, and the success rate, were compared between the groups.

Results: There was no statistically significant difference between the groups in cure rates (83% vs. 80%, groups 1 and 2, respectively) or in postoperative stay. The mean operative duration in group 2 was significantly shorter than in group 1. No intraoperative bleeding requiring a blood transfusion was recorded, and there were no bladder injuries. Postoperative adjustment of the tape was only required in three patients in group 1.

* Corresponding author at: Urology Department, Faculty of Medicine, Minia University, Minia, Egypt.
E-mail address: mohelbadry6@yahoo.com (M.S. Elbadry).

Peer review under responsibility of Arab Association of Urology.

Production and hosting by Elsevier

http://dx.doi.org/10.1016/j.aju.2015.02.006

PVR, postvoid residual urine volume; Q_{max}, maximum urinary flow rate; ALPP, abdominal leak-point pressure

Conclusions: The TOA is a safe and accurate method for treating fSUI, but with experienced surgeons there was no difference in the cure rate and postoperative outcome between TOA and TOT.

Introduction

Urinary incontinence (UI) is one of the major health problems in women. Stress UI (SUI) is the most common form of this disease and is most commonly treated surgically, aiming to render patients completely continent with no significant morbidity.

The tension-free vaginal tape was introduced by Ulmsten et al. [1] in 1996 and gained widespread popularity, but its potential complications are still a major concern. Since then there have been significant advances in the treatment of female SUI (fSUI), especially in the routes and techniques for using mid-urethral tension-free synthetic slings. More recently, the transobturator tape (TOT) technique and the single-incision mini-sling have minimised the risks when placing a sling [2].

Recent reports noted the excellent long-term effectiveness of the TOT procedure, with published surgical results of this method showing a high success rate of 80–95% [3]. The common cause for the failure of a mid-urethral sling is inaccurate placement of the sub-urethral tape or inadequate tension that is exerted on the tape [4].

In 2007, the adjustable TOT (TOA) was reported as a recent modification of the mid-urethral sling system that allows postoperative re-adjustment of the degree of tension applied during surgery [5]. As recommended by Lee et al. [6], the TOA is readjusted at 1 day after surgery, guided by the standing stress test. If urine leakage is evident, the tape is tightened by traction on one of the inguinal threads. This procedure is repeated until there is no further leakage. If there is a postvoid residual urine volume (PVR) of >100 mL or a maximum urinary flow rate (Q_{max}) of <10 mL/s, the tape is loosened by traction on one of the vaginal threads, followed by a stress test, uroflowmetry and measurement of PVR. However, when the patient is continent in all situations, with a Q_{max} of >10 mL/s, and an insignificant PVR, the threads are cut and removed. The adjustments are made under local anaesthesia [3].

The aim of the present study was to determine if there are any significant differences in the complications and success rate between the TOA and ordinary TOT in the treatment of fSUI.

Patients and methods

After receiving approval from the institutional ethics committee, the study was conducted on 96 women who presented with SUI in the urology outpatient clinic of El-Minia University Hospital, Egypt, between February 2012 and February 2013. The primary goal of the study was to compare the TOA and TOT in the management of fSUI, with the secondary goal of assessing the safety and efficacy of the TOA.

The study included women with pure SUI, but previous surgery or attempts at repair did not exclude patients from the study. All patients were categorised according to the Raz classification [7] as having urethral hypermobility. Patients were excluded if they had urge or mixed UI, had any abnormality in the contractility of the bladder, a small bladder capacity (<300 mL) or a low bladder compliance, had any neurological pathology affecting the bladder, a history of radio- or chemotherapy, antipsychotic treatment, urogenital prolapse of $>$grade I (according to the Baden and Walker classification [8]), any serious medical condition that might affect the postoperative course (bronchial asthma, diabetes mellitus, etc.) and those on anticoagulation therapy or who had active perineal or urethral lesions.

The preoperative evaluation included a detailed medical history with a special emphasis on LUTS, and a physical examination, including a general and focused neurological examination, and detailed pelvic examination. The vagina was examined with the bladder both empty (to check the pelvic organs) and comfortably full (to check for incontinence and prolapse), with the patient in the lithotomy position and repeated with the patient standing. Each patient was investigated by mid-stream urine analysis, culture and sensitivity. Positive urine cultures were treated with culture-specific antibiotics before any intervention.

Abdomino-pelvic ultrasonography was used in all patients to evaluate the kidneys and bladder, and to exclude the presence of a significant PVR. All patients had a urodynamic evaluation, using the Delphis KT system (Labories Medical Technologies, Germany), with uroflowmetry and a pressure-flow study, and a measurement of the abdominal leak-point pressure (ALPP).

Using the Raz classification [7], SUI was categorised as either anatomical, due to malposition of an intact sphincteric unit, or as intrinsic sphincter deficiency due to malfunction of the sphincter, with or without hypermobility. SUI was also graded according to the Stamey grading system [9] into grades I–III, where grade

I was loss of urine with severe exertion, grade II was loss with a lesser degree of exertion, such as walking and standing, and grade III was loss of urine continuously, regardless of activity or position.

Operative technique

All 96 patients provided informed written consent, and were randomised into two equal groups, with group 1 treated using the TOA ('outside-in', AMI Company, Vienna, Austria) and group 2 the TOT (Obtyrx, Boston Scientific Co., Natick, USA). All patients were operated under spinal anaesthesia, and placed in the exaggerated lithotomy position, with 1 g of third-generation cephalosporin given at the time of anaesthesia. An 18-F Foley catheter was inserted in the bladder and all urine was evacuated. A small midline vaginal incision was made and the para-urethral spaces were developed. Bilateral skin punctures were made in the genitofemoral fold at the level of the clitoris. The tape was then applied using 'out-in' technique. In group 1 the exteriorised tape was cut and the threads were left outside the skin. The vaginal parts of the threads were crossed and exteriorised through the anterior vaginal surface. The vaginal incision was closed using 3–0 polyglactin sutures. The threads were secured to the skin. The catheter was removed at 12 h after surgery in all patients.

In group 1, one day after surgery and depending on the patient's condition, they had a standing stress test. If there was leakage of urine on this test after filling the bladder with the minimum volume (250 mL), the tape was tightened by traction on one of the inguinal threads by ≈0.5 cm, and the stress test was repeated. This procedure was repeated until there was no further leakage. The urinary flow rate and the PVR were also measured. If the PVR was >100 mL or the Q_{max} was <10 mL/s, the tape was loosened by traction on one of the vaginal threads by 0.5 cm.

We adopted the universal definition of success in the correction of SUI, as the loss of <200 mL of urine or the use of one pad per day, in addition to a negative stress test. All patients were assessed during a strict follow-up for at least four visits at 1, 3, 6 and 12 months, by ultrasonography (to measure PVR), uroflowmetry and a stress test.

Data on the operative duration, type of anaesthesia, postoperative analgesia and duration of hospital stay were collected, and any intra- or postoperative complications were reported if present.

The research sample size was determined by appropriate software (GraphPad Software, La Jolla, CA, USA). Based on previous studies [2–5] of evaluated variables (operative duration, intraoperative complications, postoperative incontinence, etc.), a clinically important difference of 30% in the proportion of these variables was considered acceptable. We expected a withdrawal rate of 10%. To obtain a significance level of 0.05 and a power of 80%, a sample size of 96 patients per group was needed.

The success rate in the two groups was compared using the chi-squared test, and patient data and urodynamic variables were compared using the independent *t*-test, Mann–Whitney *U*-test and Fisher's Exact test, as appropriate.

Results

There was no statistically significant difference between the groups in age distribution, parity and basal urodynamic variables; the demographic data are shown in Table 1. The mean operative duration in group 1 was significantly longer than in group 2, but there was no significant difference between the groups in intraoperative bleeding (Table 1). There was no statistically significant difference between the groups in the cure rate or in early postoperative uroflowmetry (Table 1).

Only three patients in group 1 needed adjustment of the TOA by traction on the sutures to increase the ten-

Table 1 Demographic and intraoperative data, and the postoperative comparison.

Mean (SD) or *n* (%) variable	TOA	TOT	*P*
Age (years)			
<50	34 (72)	38 (80)	0.487
>50	14 (28)	10 (20)	
Parity	4 (1)	4 (2)	0.840[b]
Menopausal			0.472[c]
Pre	32 (68)	36 (77)	
Post	16 (32)	12 (23)	
Previous surgery			0.104[c]
Yes	21 (44)	19 (23)	
No	27 (56)	29 (77)	
Prolapse:			0.014[c]
0, no cystocele	36 (76)	20 (43)	
1, Grade I	12 (24)	18 (57)	
Degree of SUI (Stamey)			0.856[b]
Grade I	22	24	
Grade II	23	19	
Grade III	3	5	
Q_{max} (mL/s)	18 (3.1)	28 (9)	<0.001[a]
ALPP (cmH_2O)	70 (4)	82.5 (41)	0.146[a]
$\leqslant 60$	21 (44)	19 (40)	0.765[a]
>60	27 (56)	29 (60)	
Op. duration (min)	20 (9)	11 (5.5)	0.003[a]
Intra-operative	100.5 (14)	98.4 (13)	0.923[a]
Bleeding (mL)			
Q_{max}, mL/s			0.007[a]
Early	20.0 (2.6)	25.0 (8.6)	
Late	21.0 (3.2)	24.0 (5.3)	
Follow-up (months)	8 (6)	9 (5)	0.777[b]
Cure rate	40 (83)	38 (80)	0.448[b]

[a] Independent *t*-test.
[b] Mann–Whitney *U*-test.
[c] Fisher's Exact test.

sion. No patients needed a decrease in the tension of the tape. There were no major complications in any patient in either group.

Discussion

As of 2005, ≈84% of all procedures used for treating fSUI in Europe used mid-urethral-type synthetic tapes, of which 26.9% were TOT [10]. All these techniques involve placing a synthetic tape at the level of the mid- to distal urethra, and all are commercial products that include the placing of needles or 'passers'. They differ primarily in the approach to placement (from the suprapubic area to the vagina, or vice versa) and in the specific hardware used for insertion. Although simple to perform, these procedures require special instrumentation, and the cost limits their use in many countries [11]. The two most common problems after surgery for SUI are the persistence of incontinence and voiding dysfunction, both of which are related to how loose or how tight the tape is implanted [4].

In a study by Lee et al. in 2010 [4] the mean (SD) age and number of vaginal deliveries in enrolled patients was 57.3 (9.4) years and 2.7 (0.9). In the present study, the mean (SD, range) age was 45.6 (7, 32–60) years in group 1 and 42.9 (5.0) in group 2, and the mean number of vaginal deliveries was 4 (1, 2–7) in group 1 and 4 (2) in group 2, and most patients were premenopausal.

In the recent study [4] there were no intraoperative complications. In another study by Romero Maroto et al. [12] there were no cases of bladder, urethral, bowel, nerve, or major vessel injury. In the present study there was a urethral injury in only one patient, and this might be attributed to a difficult dissection as the result of previous anti-incontinence surgery. None of the present patients had erosions, possibly because tape erosion is a late complication that can arise at any time after surgery, from 6 weeks to 19 months, while the present mean (SD) follow-up was 8 (4) months.

Among the 65 women enrolled in the study of Lee et al. [4], 27 (42%) required readjustments of tension after surgery. Fourteen patients (21%) had the tension released and 13 (20%) had the tape tightened. Also Romero Maroto et al. [12] reported that after using transvaginal adjustable tape, ≈15% of patients still had incontinence, and voiding dysfunction was present in relatively many patients. After adjustment, all patients were rendered continent, and none had a PVR. In the present study three patients (9%) in group 1 had tightness of the tape and none of this group had the tension released.

Davila et al. [13] reported that the cure rate of the TOT procedure was 51–95%, depending on the definition used for success, the instruments used, and discrepancies in the studied populations. Similarly, others [14–16] reported success rates of 96%, 95% and 96%, respectively, for TOT, with variable periods of follow-up of 1–18 months. Lee et al. [4] reported a cure rate for the TOA procedure of 84.6%. Similarly Romero Maroto et al. [12] reported a success rate of 94% for the transvaginal adjustable tape. The mean (SD) follow-up was 40 (13) months.

The results of the present study, where 83% in group 1 and 80% in group 2 were cured objectively, are in agreement with those of previous studies. The mean (SD, range) follow-up was 8 (6, 3–16) months. In the present study the operative duration for the TOT was significantly shorter than for the TAO (11 vs. 19 min, $P = 0.003$), but a mean difference of 9 min could be insignificant from a practical perspective.

In conclusion, our results show that the TOA provides a feasible, safe, accurate, quick and simple surgical procedure for treating fSUI, but with experienced surgeons there is no difference in cure rate and postoperative outcome between the TOA and TOT.

Conflict of interest

None.

Source of funding

None.

References

[1] Ulmsten U, Henrixsson L, Johnson P, Morrows V, Arhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J* 1996;**7**:81–6.
[2] Seok NS, Suh HJ, Lee DH. Clinical outcome of transobturator Monarc procedures for treating of women with stress urinary incontinence: the 2-year follow up. *Korean J Urol* 2006;**47**:835–40.
[3] Davila GW, Johnson JD, Serels S. Multicenter experience with the Monarc transobturator sling system to treat stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2006;**17**:460–5.
[4] Lee YS, Lee HN, Lee KS. The evolution of surgical treatment for female stress urinary incontinence: era of midurethral slings. *Korean J Urol* 2010;**51**:223–32.
[5] Lee KS, Han DH, Choi YS, Yum SH, Song SH, Doo CK. A prospective trial comparing tension-free vaginal tape and transobturator vaginal tape inside-out for the surgical treatment of female stress urinary incontinence: 1-year follow up. *J Urol* 2007;**177**:214–8.
[6] Lee KS, Choo MS, Lee YS, Han JY, Kim JY, Jung BJ. Prospective comparison of the 'inside-out' and 'outside-in' transobturator-tape procedures for the treatment of female stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2008;**19**:577–82.
[7] Raz S, Caine M, Zeigler M. The vascular component in the production of intraurethral pressure. *J Urol* 1972;**108**:93–6.
[8] DeLancey JO. Anatomy. In: Cardozo L, Staskin D, editors. *Textbook of female urology and urogynecology*, vol. 1. Abingdon, UK: Martin Dunitz; 2000.
[9] Stamey TA. Urinary incontinence in the female. In: Harrison JH, Guittes RF, Perlmutter AD, editors. *Campbell's Urology*. 4th ed. Philadelphia: WB Saunders; 1979. p. 2272–93.
[10] deTayrac R, Deffieux X, Droupy S, Chauveaud-Lambling A, Calvanèse-Benamour L, Fernandez H. A prospective randomized

trial comparing tension-free vaginal tape and transobturator suburethral tape for surgical treatment of stress urinary incontinence. Am J Obstet Gynecol 2004;**190** :602–8.

[11] Rodriguez LV. Distal urethral polypropylene sling. In: Vasavada RA, Appell RA, Sand PK, Raz S, editors. *Female Urology, Urogynecology, and Voiding Dysfunction*. New York: Marcel Dekker; 2005. p. 417–27.

[12] Romero Maroto J, Ortiz Gorraiz M, Prieto Chaparro L, Pacheco Bru JJ, Miralles Bueno JJ, Lopez Lopez C. Transvaginal adjustable tape: an adjustable mesh for surgical treatment of female stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2008;**19** :1109–16.

[13] Davila GW, Johnson JD, Serels S. Multicenter experience with the Monarch transobturator sling system to treat stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2006;**17**:460–5.

[14] Cindolo L, Salzano L, Rota G, Bellini S, D'Afiero A. Tension-free transobturator approach for female stress urinary incontinence. *Minerva Urol Nephrol* 2004;**56**:89–98.

[15] Mellier G, Mistrangelo E, Gery L, Philippe C, Patrice M. Tension-free obturator tape (Monarc Subfascial Hammock) in patients with or without associated procedures. *Int Urogynecol J Pelvic Floor Dysfunct* 2007;**18**:165–72.

[16] Queimadlos MA, Cimadevillau GA, Lema GJ. Monarch transobturator suburethral sling: Eighteen months' experience. In: Paper presented at The Joint Meeting of the International Continence Society and The International Urogynecological Association. Paris, France. Abstract 559, August 23–27, 2004.