Effect of Transobturator Tape on Overactive Bladder Symptoms and Urge Urinary Incontinence in Women With Mixed Urinary Incontinence

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OBJECTIVE: To estimate changes in overactive bladder (OAB) symptoms and urge urinary incontinence (UUI) in patients undergoing the transobturator tape procedure for urinary stress and mixed incontinence.

METHODS: Telephone interviews were conducted using the International Consultation on Incontinence–Female Lower Urinary Tract Symptoms questionnaire, the International Consultation on Incontinence–Overactive Bladder (ICIQ-OAB) questionnaire, and the Verbal Analogue Satisfaction (VeAS) scale. Preoperative OAB scores were compared with postoperative scores in women with stress incontinence only (group 1), mixed incontinence with predominant stress leakage (group 2), and mixed incontinence with predominant urge (group 3). Case notes were reviewed for preoperative assessment and complications.

RESULTS: At median follow-up of 13 months, significant improvement was noted in ICIQ-OAB scores, from a median of 10 (1–15) preoperatively to a median of 3 (0–11) postoperatively ($P<.001$). Overall, UUI was cured in 19 of 44 (43%) patients, improved in a further 16 (36%), and was persistent in only 9 (21%). In group 2 (stress predominant), UUI was cured in 10 of 23 (43.5%) patients, improved in 10 (43.5%), and persistent in three (13%). In group 3 (urge predominant), UUI was cured in 9 of 21 (43%) patients, improved in six (28.5%), and persistent in six (28.5%). Postoperative lower urinary tract symptom scores were low in all three groups (median 4/48 [0–18]). Stress incontinence was cured in 77%, improved in a further 19%, and unchanged in 4%. Median VeAS score was 9 (2–10); 21% (11/52) of participants had low satisfaction scores (less than 8) owing to persistent urge and slow voiding.

CONCLUSION: Marked resolution or improvement (79%) in urge incontinence after the transobturator tape procedure was noted, and no cases of de novo urge incontinence were identified.

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LEVEL OF EVIDENCE: III

The characteristic symptom of overactive bladder (OAB)[1] is urgency, which is defined as a sudden, compelling desire to pass urine that is difficult to defer.[1] Without the qualifiers of fear of leaking and pain (previous International Continence Society definition)[2] or being an abnormal feeling to be distinguished from a normal urge to void, urgency is a relatively vague term and difficult to quantify.[3] The cause of urgency is not understood fully, and detrusor overactivity often is not found in patients suffering from urge urinary incontinence (UUI),[4] which may be caused by other forms of urethrovesical dysfunction. Definitions of urge and mixed incontinence are also limited to patient-reported symptoms.[1] Attempts to measure urgency and OAB symptoms are confounded by difficulties, although validated patient-symptom questionnaires have the potential to provide a scientific method to quantify severity, assess treatment, and improve communication. The International Consultation on Incontinence–Overactive Bladder (ICIQ-OAB) questionnaire[5] is one such tool that takes into account daytime frequency, nocturia, degree of urgency, and number of urge-incontinence episodes and adds up a numerical value as an index of severity ranging from 0–16, with a higher score indicating increased severity of symptoms.

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Evidence is building that stress incontinence is associated strongly with OAB,[6–8] which is compatible with the theories that urgency originates from a deteriorating neuromuscular ability to close the proximal urethra[9,10] or that the frequency (which leads later to urgency) is a behavioral adaptation to reduce stress incontinence. The majority of women suffering from urinary stress incontinence will have coexisting symptoms of either detrusor overactivity or mixed incontinence.[11] Mixed symptoms seem to be more prevalent in clinical than in population-based epidemiological studies.[12] Symptoms of OAB pose a challenge to the treatment of women with concomitant stress urinary symptoms. Women who undergo surgery have high expectations regarding the outcome, which include resolution of urgency and frequency.[13] Midurethral sling procedures (tension-free vaginal tape [TVT] and transobturator tape [TOT]) provide effective treatment for stress urinary incontinence,[14,15] but, because most women have coexisting symptoms of OAB or mixed urinary incontinence or both, which have a more negative effect on quality of life than stress incontinence alone,[16] it is important to assess the effect of surgery on OAB in these women.

Transobturator tape is gaining popularity because of its relative safety and technical feasibility as a minimally invasive midurethral sling procedure. There are several reports of resolution or improvement of urge incontinence and OAB symptoms after TVT,[17–21] and few reports have addressed the issue as comparative studies of TVT and TOT.[22–24] Our objective was to estimate change in OAB symptomatology and UUI in patients undergoing the TOT procedure for urinary stress incontinence and mixed incontinence, giving consideration to patient satisfaction in the context of overall postoperative lower urinary tract function.

MATERIALS AND METHODS

The study design was reviewed and approved by Luton and Dunstable Hospital's Local Research and Ethics Committee office. All patients who underwent TOT outside in approach for urinary stress incontinence or mixed incontinence were included. Case notes were reviewed for demographic details, previous incontinence surgery, and assessment of urinary incontinence, including OAB severity using preoperative ICIQ-OAB score, operative details, postoperative complications (hemorrhage greater than 150 mL, bladder perforation, urethral injury), and postoperative course (obstructive symptoms leading to catheterization and its duration, groin pain, and urinary tract infections in the follow-up). All patients were to assess lower urinary tract function using the International Consultation on Incontinence–Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) questionnaire, the postoperative ICIQ-OAB questionnaire, and the Verbal Analogue Satisfaction (VeAS) scale. Only those who completed full preoperative and postoperative data sets comprise the final sample.

Patients were categorized into three groups: group 1, women with a history of pure stress incontinence with or without some frequency, urgency, or both; group 2, women having mixed urinary incontinence with a predominant complaint of stress leakage; group 3, women having mixed urinary incontinence with predominant urge leakage.

The diagnostic protocol for stress incontinence included patients complaining of leaking with stress in the context of a full gynecological history and examination, including a supine stress test to confirm stress incontinence objectively and a minimum 4-day bladder diary to assess frequency, nocturia, and frequency of incontinence episodes. Women in group 1 were offered TOT without urodynamics, whereas those in groups 2 and 3 had urodynamic assessment performed by the authors, with definitions conforming to the International Continence Society Standardization of terminology. Recurrent lower urinary tract infections and metabolic disorders associated with polyuria (eg, diabetes) were treated before any surgery was offered. Pelvic physiotherapy was offered before surgery for stress incontinence unless the patient had a history of prior therapy.

Women with mixed incontinence were assessed clinically for the predominant symptom, guided by patients' views of their predominant symptom together with bladder diaries' events. Scores for OAB were recorded, but treatment assignment was not based on these scores. For women having mixed symptoms with predominant stress component (group 2), a TOT procedure was planned as first-line treatment with a forewarning that urge incontinence may persist. Bladder retraining was commenced if the predominant symptom was urge incontinence (group 3) and continued in dedicated weekly clinics by a consultant urogynecologist and a trained nurse. Behavioral techniques to reduce the frequency of micturition gradually and to overcome urgency episodes and exercises to stop leaking on the way to the toilet were taught using individualized regimens.

A polypropylene TOT (Obtryx, Boston Scientific, Natick, MA) was inserted between the two obturator foramen from outside to inside as described by Delorme in 2001.[25] All procedures were performed by the authors or by specialist trainees under

Table 1. Examples of Relevant Questions of the International Consultation on Incontinence–Female Lower Urinary Tract Symptoms and International Consultation on Incontinence–Overactive Bladder Questionnaires

Text of Questions	Options for Response
Female Lower Urinary Tract Symptoms question number	
4: Does urine leak when you are physically active, exert yourself, cough or sneeze?	Never (0), occasionally (1), sometimes (2), most of the time (3), all the time (4)
6: Is there a delay before you can start to urinate?	Never (0), occasionally (1), sometimes (2), most of the time (3), all the time (4)
7: Do you have to strain to urinate?	Never (0), occasionally (1), sometimes (2), most of the time (3), all the time (4)
8: Do you stop and start more than once while you urinate?	Never (0), occasionally (1), sometimes (2), most of the time (3), all the time (4)
9: Does urine leak before you can get to the toilet?	Never (0), occasionally (1), sometimes (2), most of the time (3), all the time (4)
Overactive Bladder question number	
1: How often do you pass urine during the day?	Every 4 hours or more (0), every 3 hours (1), every 2 hours (2), hourly (3)
2: During the night how many times do you have to get up on average?	None (0), one (1), two (2), three (3), four or more (4)
3: Do you have a sudden need to go to the toilet to urinate?	Never (0), occasionally (1), sometimes (2), most of the time (3), all the time (4)
4: Does urine leak after you feel a sudden need to go to the toilet?	Never (0), once a week or less (1), 2–3 times a week (2), once a day (3), several times a day (4), all the time (5)

their direct supervision. Routine cystoscopy was not performed, nor was stress test to adjust tape tension under the urethra, and tape was left comfortably sitting under midurethra. Routine catheterization was not done, and postoperative voided volumes were monitored for three voids. In case of inability to void or low recorded void volumes, residual volume was estimated and a catheter left in situ for 24 hours if required.

Women were examined in clinic 4–6 weeks postoperatively to assess urinary symptoms including voiding and any de novo symptoms (eg, cystitis or persistent groin pain).

A detailed assessment of lower urinary tract function was made in September 2008 using the ICIQ-FLUTS questionnaire, the postoperative ICIQ-OAB questionnaire, and the Verbal/Visual Analogue Satisfaction scale. Telephone contacts initially were made (by S.T., who did not have access to patients' notes at the time of interview), and women were given the option for a postal questionnaire to be sent or to complete data verbally over the phone. All questionnaires were administered by same caller. For patients not contactable by phone, a postal questionnaire was sent, followed by a reminder letter a week later. Participation in the study was voluntary, and women were informed of the choice not to participate. Only those who completed the full postoperative assessment were included in the final sample. Efficacy of TOT for urinary stress incontinence was evaluated by question 4 of the FLUTS questionnaire (Table 1). A response of never (0) was taken as cure of stress incontinence, occasionally (1) as improvement, and all other responses were taken as failure. Voiding function was assessed by questions 6, 7, and 8 of the FLUTS questionnaire (Table 1). The severity index for voiding difficulty was denoted as V-score on the questionnaire, and the range was 0–12. We calculated VeAS scores and correlated these with patient's satisfaction scores.

The ICIQ-OAB questionnaire consists of four domains (Table 1); scores to individual questions were added to calculate a severity index, and preoperative scores were compared with postoperative scores.

Cure of urge incontinence was defined as responses of never (0) to both question 9 of the FLUTS questionnaire and question 4 of the OAB questionnaire. Persistence of urge incontinence was defined as a postoperative response to question 4 on the OAB questionnaire being the same as recorded preoperatively; any response of once a day (3), several times a day (4), or all the time (5); or any responses to question 9 in the FLUTS questionnaire of most of the time (3) or all the time (4). Improvement was defined as urge incontinence episodes reported as less frequent postoperatively in question 4 of the OAB questionnaire than recorded preoperatively as well as being less frequent than daily occurrence (ie, a score of 1 [once a week or less] or 2 [2–3 times a week] on

Table 2. Patient Characteristics in the Three Groups

Patient Characteristics	Group 1 (n=8)	Group 2 (n=23)	Group 3 (n=21)
Age (y)	45 (38–78)	52 (34–69)	50 (41–79)
Parity	2 (1–4)	2 (1–5)	2 (0–4)
Previous vaginal surgery			
Vaginal hysterectomy	2	2	3
Anterior repair	0	1	2
Previous incontinence surgery			
Burch colposuspension	0	0	2
Tension-free vaginal tape	0	0	1
Concurrent vaginal surgery			
Vaginal hysterectomy+ anterior repair	1	1	2
Anterior repair	0	2	1
Posterior repair	0	2	0

Data median (range) or n.

question 4 of the OAB questionnaire and responses of 1 (occasionally) or 2 (sometimes) on question 9 of the FLUTS questionnaire).

Postoperative FLUTS scores were taken as a measure of overall lower urinary tract function along with the Verbal Analogue Satisfaction scores. The patient was considered satisfied if the VeAS score was 8 or above. If scores were less than 8, the reasons for dissatisfaction were explored and detailed questions were asked regarding persistent stress incontinence, voiding difficulty, and OAB symptoms.

Descriptive statistics were used in the reporting of demographic data. Statistical analysis included the Wilcoxon-Rank test for continuous variables and χ^2 for categorical variables. SPSS 12.0 (SPSS, Inc., Chicago, IL) was used for all data analysis. Significance level was set at $P<.05$.

RESULTS

Fifty eight women underwent the TOT procedure from January 2007 to June 2008.

Outcome data were collected in September 2008 at a median follow-up of 13 months (range 4–21 months). Complete follow-up assessment was available for 52 of 58 patients, which comprises the final sample. Forty-nine questionnaires were completed over the telephone; four patients requested to have postal questionnaires, of whom only two returned the completed questionnaires. Five patients were not contactable by phone–one patient had moved out of the area, one patient had no telephone number available either in the hospital or with a general practitioner, and two patients did not have a working telephone line; one women was not contactable for unknown reasons. Only one of these participants returned the questionnaire. Patient characteristics are shown in Table 2. Women in group 1 (8/52, stress incontinence only) had very low preoperative OAB scores as compared with those in group 2 (23/52 mixed incontinence with predominant stress leakage) and group 3 (21/52, mixed incontinence with predominant urge leakage), as shown in Table 3.

Overall, UUI was cured in 19 of 44 (43%) women suffering from mixed incontinence, improved in a further 16 (36%), and was persistent in nine (21%). Scores for OAB for the entire sample improved significantly, as did the scores within subgroups, as shown in Table 3. In group 2 (stress predominant mixed incontinence), cure was noted in 10 of 23 (43.5%) women, improvement in 10 (43.5%), and persistence in three (13%). Similarly, in group 3 (urge predominant mixed incontinence), cure was noted in nine of 21 (43%) women, improvement in six (28.5%), and persistence in six (28.5%). The risk of having persistent urge incontinence after TOT operation in group 3 (urge predominant) was higher compared with group 2 (stress predominant; odds ratio 2.66, confidence interval 0.57–12.4). No cases of de novo UUI were identified, although one woman reported de novo urgency without associated frequency or incontinence.

The patients in group 1 (stress incontinence only, eight of 52) all were cured of stress incontinence. No obstructive voiding was reported by seven of the patients; slow voiding but no straining was reported

Table 3. Comparison of the Preoperative and Postoperative Overactive Bladder Scores and Postoperative Female Lower Urinary Tract Symptoms Scores in the Three Groups

	Preoperative OAB Score	Postoperative OAB Score	Comparison of OAB Scores	Percentage Reduction in OAB Scores	Postoperative FLUTS Score
Group 1 (n=82)	3 (1–4)	1 (0–2)	.03	48	1.2 (0.5–4)
Group 2 (n=23)	10 (7–12)	4 (1–7)	<.00	59	5 (0.5–12)
Group 3 (n=21)	12 (9–15)	4 (0–11)	<.00	66	5 (0–18)
Overall scores (N=52)	10 (1–15)	3 (0–11)	<.00	61	4 (0–18)

OAB, overactive bladder; FLUTS, female lower urinary tract symptoms.
Data median (range) unless otherwise specified.

Table 4. Outcome Analysis in the Three Groups

	Group 1 (n=8)	Group 2 (n=23)	Group 3 (n=21)	Comparison Between Groups 2 and 3 (*P*)
Stress incontinence				
Cure	8 (100)	18 (78)	14 (67)	.18
Improvement	0 (0)	5 (22)	5 (24)	.27
Persistence	0 (0)	0 (0)	2 (9)	.22
Urge incontinence				
Cure	NA	10 (43.5)	9 (43)	.23
Improvement	NA	10 (43.5)	6 (28.5)	.14
Persistence	NA	3 (13)	6 (28.5)	.13
Average Visual Analogue Satisfaction scores	9.4	8.3	8.4	.43
Satisfaction score less than 8	1 (12)	4 (17)	6 (28)	.19

Data are n (%) unless otherwise specified.

by one. Median void score was 0/12 (range 0–3). Overall, patients had very low scores on FLUTS (median 1.5/48, range 0.5–4). Median VeAS score was 10; one woman had a VeAS score of 7 owing to slow voiding.

Of the patients in group 2 (mixed incontinence with predominant stress, 23 of 52), 18 were cured of stress leakage and five improved. Median void score was 0/12 (range 0–5). Score on FLUTS was low as well (median 5, range 0.5–12). The median VeAS score was 9 (range 2–10). Four women reported VeAS scores less than 8; persistent urge incontinence was the reason for dissatisfaction in these four participants. Two also complained of slow voiding.

Of the patients in group 3 (mixed incontinence with predominant urge, 21 of 52), 14 were cured of stress incontinence, five had stress leakage improved, and two did not have any improvement (one owing to erosion and resection). Median void score was 0/12 (range 0–7). Median FLUTS score was low as well (5, range 0–18). Median VeAS score in this group was 10. Six women reported VeAS scores less than 8, two owing to persistent stress and urge incontinence, three owing to persistent urge (one woman also complained of slow voids), and one owing to slow voiding and urinary tract infections.

Those reporting low satisfaction rates (less than 8) comprised 12% of group 1 (1/8), 17% of group 2 (4/23), and 28% of group 3 (6/21). The incidence of slow voiding was seen equally in the three groups, but low satisfaction owing to persistent urge incontinence was reported by 17% in the stress-predominant group (4/23) and 24% in the urge-predominant/mixed-incontinence group (5/21).

Overall cure rate for stress incontinence was 77% (40/52). A further 19% (10/52) had stress leakage improved to only occasional leakage. Two patients (4%) had no improvement in stress leakage; one of these patients lost the cure achieved after midsegmental tape resection owing to midline erosion.

Four women (4/52, 8%) complained of slow voiding, and none of these had to strain to void. Outcome analysis is summarized in Table 4, with comparison within groups 2 and 3.

Intraoperatively, there was one urethral injury (by a trainee) and one bladder perforation. No vascular injury or hematoma formation occurred. Postoperatively, three patients complained of groin pain, which resolved over 4–8 weeks, five had urinary tract infections, one had midline mesh erosion (in a patient with previous TVT and associated midline mesh erosion with TVT), and there was one vaginal forniceal injury with exposed mesh in a patient with previous Burch colposuspension.

Three patients (5.8%) required catheterization for 24–48 hours followed by resumption of normal voiding pattern; tape loosening was not required. No patients required self-catheterization.

DISCUSSION

The transobturator midurethral sling has been shown in this study to improve UUI and OAB symptoms significantly in mixed urinary incontinence and to provide high postoperative patient satisfaction. Overall, 43% of patients had complete resolution of their mixed incontinence, with marked improvement in a further 36%; symptoms persisted in only 21%. Definitions of improvement and persistence of urge incontinence in our study, although arbitrarily chosen, were stringent. Many patients reported reduction in frequency of urge episodes but still had some leakage on a daily basis (eg, from a preoperative leakage of all the time [score 5] or several times a day [4] to once a day [3] postoperatively), and these women still were considered to have persistent urge incontinence in the results analysis. Improvement in urgency symptoms

after antiincontinence surgery long has been noted,[26] moreso after midurethral slings.[17–21] Midurethral sling procedures are better at resolving urgency symptoms owing to a lower incidence of obstructive and de novo urge symptoms and theoretically prevent urine entering into the upper posterior urethra at raised intraabdominal pressure to cause reflex urgency.[8,9] This theoretical advantage of midurethral sling warrants further study.

In this variable cohort of patients and symptoms, our results have shown an overall cure for stress incontinence in 77%, improvement in a further 19%, and failure in 4%. Women were more likely to have continuing symptoms of stress leakage if they also had continuing urge incontinence; 10 of 52 patients with occasional postoperative stress incontinence and two of 52 with no change in stress incontinence all reported some continuing urge incontinence. Moreover, it already has been reported that greater preoperative urge incontinence symptoms result in less improvement in stress incontinence postoperatively.[27,28] Our results concur with this observation—those in group 2 (stress-predominant mixed incontinence) had higher success rates for stress incontinence (78% cure and 22% improvement) as compared with those in group 3 (urge-predominant mixed incontinence,) who had only 67% cure, a further 24% improvement, and 9% failure. Because postoperative incontinence of any kind reduces patient satisfaction,[29] persistence of urge incontinence was the main reason for women's dissatisfaction in our series as well; 21% (11/52) of women had low satisfaction scores of less than 8, with persistent urge being the main reason for low scores in nine women.

The weaknesses of the study were small sample size, short follow-up duration, and the subjective nature of follow-up. However, subjective (ie, patient-reported) outcome measures are most relevant to clinical practice. Moreover, ICIQ-OAB is a validated, sensitive, psychometrically robust symptoms-assessment questionnaire that provides rapid assessment of patient-reported disease[4] and is preferred over physician assessment of disease burden of OAB, which has been shown to be inaccurate and nonreproducible.[30] Efficacy of TOT for stress incontinence was based on question 4 of the FLUTS questionnaire. Although not validated for presence of stress incontinence, it defines stress incontinence as well as gives a range of response options from never (0) to all the time (4), facilitating consistency in assessment. Outcome analyses after antiincontinence surgery and for treatment of mixed incontinence are affected by the definitions of success used, which have varied from total absence of leakage to a change in the pattern of pad usage.[31] This further points to a need for clarity in definitions, which a detailed, systematic, validated symptoms questionnaire can provide. Follow-up was short but averaged 1 year. Sample size was small, but this is a single-center study and all patients were managed by a uniform management protocol that avoids the variation in practices observed in multicenter studies. The ICIQ-FLUTS and ICIQ-OAB questionnaires originally were validated for self administration. There is potential for bias owing to telephone administration of these questionnaires; however, patient response to telephone administration was very positive—49 of 53 women contactable by phone preferred to have the questionnaire completed over the phone. On the other hand, only three of nine patients returned the mailed questionnaires.

Recently, there has been a shift in emphasis in urge-incontinence and mixed-incontinence disorders from urodynamically diagnosed unstable detrusor to symptoms-based OAB syndrome/frequency–urgency syndrome (previous[2] and current[1] International Continence Society definitions). In our view, the latter approach is pragmatic and more representative of women's perspectives; however, symptoms need to be quantified for appropriate comparison before and after treatment and between studies. In reality, a substantial proportion of women with mixed symptoms will not have evidence of detrusor overactivity during the filling phase of traditional urodynamics.[32–34] This group was noted as having sensory urgency in the previous International Continence Society classification. As urodynamics is of limited value in assessment in these patients, a standardized symptoms assessment tool is particularly valuable.

Patients with mixed incontinence are likely to be cured of both the stress and urge components by TOT surgery, with only a few patients continuing to have urge incontinence and OAB symptoms. However, it is not yet clear how to predict who will benefit and remain free of urge after the surgery.

Transobturator tape surgery appears to be associated with cure of or significant improvement (79%) in urge incontinence in patients with mixed urinary incontinence (in conjunction with bladder retraining in urge-predominant cases). Only 21% of patients had persistent urge leakage, and no patient reported de novo urge incontinence. Larger outcome studies of TOT with longer follow-up are needed, ideally using standardized, validated assessment tools, focusing on the common problem of mixed incontinence, with clear reporting criteria, and assessment at baseline

and after surgery, keeping in mind the subjective nature of these symptoms.

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