Evaluation of Transobturator Tension-Free Vaginal Tapes in the Surgical Management of Mixed Urinary Incontinence: 3-Year Outcomes of a Randomized Controlled Trial

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Abbreviations and Acronyms

MUI = mixed urinary incontinence

MUS = mid urethral sling

OAB = overactive bladder

QoL = quality of life

RCT = randomized controlled trial

RP-TVT = retropubic tension-free vaginal tape

SUI = stress urinary incontinence

TO-TVT = transobturator tension-free vaginal tape

UI = urgency incontinence

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Study received local research ethics committee approval.

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Purpose: We evaluate the clinical effectiveness of transobturator tension-free vaginal tape procedures in the surgical management of mixed urinary incontinence in women at 3-year followup.

Materials and Methods: In this secondary analysis of a prospective, single-blind, randomized controlled trial 83 of 341 women (24%) with mixed urinary incontinence were randomized to undergo an outside-in (Aris® transobturator sling system 42) or inside-out (TVT™-O 41) transobturator tension-free vaginal tape procedure. Patients were contacted by postal questionnaire at a minimum of 3 years postoperatively. The primary outcome was the patient reported success rate, defined as very much improved/much improved on the PGI-I (Patient Global Impression of Improvement). Secondary outcomes included improvement in quality of life, impact on preoperative urgency/urgency incontinence and repeat surgical treatment for stress urinary incontinence. Outcomes at 3 years were compared between groups (outside-in vs inside-out) and to 1-year outcomes. Analysis was performed using SPSS® version 20 with significance levels set at $p = 0.05$.

Results: A total of 66 women with mixed urinary incontinence completed the 3-year followup (outside-in 35 vs inside-out 31). In each group 2 women underwent further continence surgery. The patient reported success rate was 73.8% with no significant differences between the groups (OR 1.035, 95% CI 0.342–3.134, $p = 0.951$). Overall 34 (50.1%) and 26 women (56.5%) reported cure of preoperative urgency and urgency incontinence, respectively, and 52 women (86.7%) had a clinically significant improvement in quality of life (18 points or more in total KHQ [King's Health Questionnaire] score) compared to baseline.

Conclusions: Transobturator tape procedures are associated with a good (73.8%) patient reported success rate at a minimum of 3 years of followup in the surgical management of mixed urinary incontinence in women with predominant stress urinary incontinence symptoms. Nearly half of the women reported cure of urgency/urgency incontinence.

Key Words: urinary incontinence, suburethral slings

MIXED urinary incontinence is the second most common type of urinary incontinence and is specifically more common with advancing age. MUI is considered more difficult to treat due to the need to mutually manage stress urinary incontinence and overactive bladder symptoms, with the latter often being unpredictable with evidence of flaring and remission of symptoms over time.[1] Of all incontinent women in the EPICONT study

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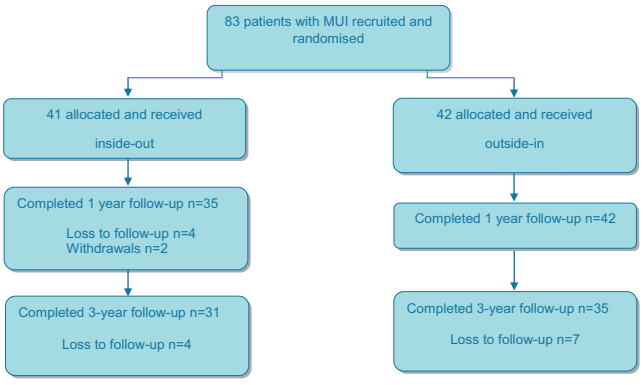
36% reported experiencing MUI.[2] Women with MUI often report that their symptoms are more troublesome in terms of quality of life compared to women with other types of urinary incontinence.[2,3] There is evidence of a reduction in the productivity of working women with MUI and in severe cases urinary incontinence can lead to social isolation.[4,5]

There is currently a lack of evidence on the best management strategy for MUI. Standard practice is to offer women surgical treatment for SUI, most commonly mid urethral sling, if OAB symptoms are well controlled. TO-TVT is theoretically more advantageous in women with MUI compared to RP-TVT due to the more horizontal insertion and less obstructive nature. We have previously shown a patient reported success rate of 75% and an objective cure rate of 90% in women with MUI after insertion of TO-TVT at 1-year followup.[6] There is a paucity of data on long-term outcomes of TO-TVT in general and particularly in women with MUI.[7] A recent systematic review called for RCTs with a long-term followup to determine the effectiveness of MUS in women with MUI.[7] In this study we bridge a gap in the current literature and evaluate patient reported outcomes of 2 types of TO-TVT in women with MUI at a minimum of 3 years of followup. We also compare the results to 1-year outcomes to determine late onset failures.

METHODS

This is a secondary analysis of a prospective single-blind RCT, the E-TOT (Evaluation of Transobturator Tapes) study, performed at a tertiary urogynecology referral center in Scotland between April 2005 and April 2007.[8] A total of 341 women with SUI were recruited and randomized to receive outside-in (TOT-Aris 42) or inside-out (TVT-O 41) TO-TVT. Of these women 83 had MUI symptoms (ie SUI and urgency with or without urinary incontinence) and predominant SUI symptoms, and formed the basis of this secondary analysis (see figure). Ethical approval was received from the local research ethics committee and the trial protocol was registered at www.clincaltrials.gov.



CONSORT flow diagram of recruited patients and followup

Inclusion and Exclusion Criteria

Women were included in this secondary analysis if they had MUI with predominant SUI symptoms (predominant symptoms were self-determined by participants). All women underwent primary or secondary continence surgery after a trial of conservative management. Women were excluded from the study if they had predominant OAB symptoms, were undergoing concomitant surgery, had comorbidities such as multiple sclerosis or diabetes, or had pelvic organ prolapse (pelvic organ prolapse quantification system stage 2 or greater) on examination.

Randomization and Allocation Concealment

Randomization was computer generated and allocation was concealed using sealed opaque envelopes. Women were not blinded to allocation. However, they were asked not to disclose this information at followup.

Preoperative Assessment

This evaluation included history, clinical examination and urodynamic assessment. Women completed several questionnaires preoperatively including the KHQ, PISQ-12 (Prolapse Incontinence Sexual Function Questionnaire) and BBUQ-22 (Birmingham Bowel Urinary symptom Questionnaire).

Postoperative Assessment at 3 Years

Women were contacted by mail at a minimum of 3 years of followup and were asked to complete the same questionnaires as they did preoperatively, with the addition of the PGI-I, patient satisfaction on a 10-point visual analog scale, the ICIQ-SF (International Consultation on Incontinence Questionnaire-Short Form) and questions eliciting whether they had received any further conservative, medical or surgical treatment for urinary incontinence/pelvic organ prolapse. The same assessment was previously performed at 1 year and the results were reported.[6]

Outcome Measures

The primary outcome was the patient reported success rate as defined by very much improved/much improved on PGI-I, with all other responses classified as failures. Secondary outcomes included impact on QoL and sexual function (defined as 18 points or more improvement in total KHQ score and improvement in PISQ-12 score compared to baseline, respectively), cure rates of postoperative urgency and UI (defined as 2 or more points improvement on the relevant question in BBUQ-22, eg improvement from all of the time to occasionally), and patient satisfaction (defined as a score of 8 or greater on a 10-point visual analog scale).

Analysis of Data

Statistical analysis was performed using SPSS version 20. Between group comparisons were made for categorical variables using the chi-square or Fisher's exact test where appropriate. Comparisons of between group improvements in KHQ and PISQ-12 scores were performed using the Mann-Whitney test. The 3-year postoperative scores were compared with baseline scores using the Wilcoxon