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Hopper L R[1], Mostafa A[1], Abdel-Fattah M[1]
1. *University of Aberdeen*

THE EFFECTIVENESS OF TRANSOBTURATOR TAPES IN THE SURGICAL MANAGEMENT OF WOMEN WITH MIXED URINARY INCONTINENCE: 3 YEAR OUTCOMES

Hypothesis / aims of study: To assess the 3-years outcomes for transobturator tension free vaginal tapes (TO-TVT) in surgical treatment of women with mixed urinary incontinence (MUI) and to compare the outside-in vs. inside-out techniques in a randomised control trial.

Study design, materials and methods:
83 women with MUI but predominant stress symptoms were randomised to receive outside-in (n=42) or inside-out (n=41) TO-TVT as part of a larger RCT. Women were contacted by post at a minimum of 3-years follow-up. The primary outcome was patient reported success rate, defined as "*much improved / very much improved*" on Patient Global Impression of Improvement (PGI-I); with all other responses considered failures. Secondary outcomes included: symptom severity measured using International Consultation on Continence-Short Form (ICIQ-SF); patient satisfaction measured on a 10-point visual analogue scale (VAS); impact on quality of life (QoL) measure using the King's Health Questionnaire (KHQ); improvement in sexual function on Prolapse Incontinence Sexual Function Questionnaire-12 (PISQ-12) and changes in urgency and urgency incontinence symptoms evaluated by the Birmingham Bowel Urinary symptom Questionnaire (BBUQ-22) and finally, disease recurrence requiring repeat continence surgery. Analysis was performed on an intention-to-treat basis. Outcomes were compared between groups and to the one year outcomes.

Results:
66 women completed the 3-years follow-up; outside-in (n=35) vs. inside-out (n=31). Four women, 2 in each group, underwent further continence surgery and were classed as failures in this analysis. The patient-reported success rate on PGI-I was 73.8% (Table 1) with no significant differences between outside-in and inside-out groups (OR 1.035; 95% CI 0.342-3.134; p=0.951); these results pertained on sensitivity analysis with different assumptions for those lost to follow-up. A clinically significant improvement in QoL (≥18 point improvement in total KHQ scores) was seen in 86.7% of women with no statistically significant differences between groups (outside-in 87.5% vs. inside-out 85.7%; OR 0.857; 95%CI 0.193-3.801; p=>0.999). 30 women were sexually active and completed PISQ-12 both pre-operatively and at 3 years follow-up, 22 (73.3%) women showed an improvement in sexual function (total PISQ-12 scores) with no differences between groups (OR 1.200; 95%CI 0.237-6.065; p=>0.999). Cure of urgency and urgency incontinence was seen in 51.1% (n=34) and 56.5% (n=26) of women respectively, with 31 women taking antimuscarinic treatment at 3-years (Table 2).

Interpretation of results
This RCT provides the first reported medium term outcomes of TO-TVT in women with MUI. The success rate in our RCT (73.8% patient-reported success) was lower than that reported by Jain et al in their systematic review, who found cure of stress symptoms in 85-97% of women and overactive bladder symptoms in 30-85% of women with MUI following insertion of a mid-urethral sling. (1) This difference may be due to the fact that they included observational studies in their review with their inherited methodological bias, and therefore the authors concluded that RCTs with good methodology and long follow-up are needed. Our results showed no significant differences between outside-in and inside-out TO-TVT, however it is important to note that the relatively small cohort could mean that it is not powered significantly to identify differences. Only one previous study compared outside-in and inside-out TO-TVT in women with MUI. However, this was in a RCT that randomised both women with stress urinary incontinence and MUI with predominant stress symptoms and had a short follow-up of only 4months. (2) The cure of urgency symptoms, in our RCT, was comparable to that found by Lee et al who reported 59.7% of women with MUI (and predominant stress symptoms) were cured of urgency symptoms following insertion of a mid-urethral sling with up-to 50 months follow-up. (3)

Concluding message
Transobturator tapes are associated with a reasonable patient reported success rate of 73.8% in women with mixed urinary incontinence which is maintained at 3-years follow-up. The majority of women showed a significant improvement in quality of life and sexual function, with a lower rate of cure in urgency and urgency incontinence.

Table 1: Patient-reported success rates at 3 year follow-up for whole cohort and comparing between outside-in and inside-out techniques

	Total Success/Cured (%)	Outside-in (n=34)	Inside-out (n=31)	OR (95%CI)	p-value
PGI-I	48/65 (73.8)	25/34 (73.5)	23/31 (74.2)	1.035 (0.342-3.134)	0.951
Satisfaction	47/66 (71.2)	25/35 (71.4)	22/31 (71.0)	0.978 (0.336-2.843)	0.967
ICIQ-SF	38/64 (59.4)	23/34 (67.6)	15/30(50.0)	0.478 (0.173-1.319)	0.151

OR: odds ratio; 95% CI: 95% confidence interval; PGI-I: Patient Global Impression of Improvement; ICIQ-SF: International Consultation on Incontinence Questionnaire-Short Form
PGI-I – Success defined as "*very much improved/much improved"*
Satisfaction – defined as score of ≥8 on 10 point VAS
ICIQ-SF – Success defined as "*never leak/ leak few drops once or less per week"* in response to "*How much do you leak?"*

Table 2: Outcomes for urgency and urge incontinence symptoms at 3 years follow-up.

Preoperative Urgency	**Total n=66**	**Outside-in n=35**	**Inside-out n=31**	**OR (95%CI)**	**p-value**
Cure Urgency	34/66 (51.5%)	19/35 (54.3%)	15/31 (48.4%)	1.267 (0.481-3.337)	0.632
Persistence Urgency	16/66 (24.2%)	9/35 (25.7%)	7/31 (22.6%)	1.187 (0.382-3.685)	0.767
Worsening Urgency	16/66 (24.2%)	7/35 (20.0%)	9/31 (29.0%)	1.267 (0.481-3.337)	0.632
Preoperative UI	46/66 (69.7%)	11/35 (31.4%)	9/31 (29.0%)		
Cure UI	26/66 (56.5%)	15/25 (60.0%)	11/21 (52.4%)	1.364 (0.504-3.687)	0.541
Persistence UI	11/66 (23.9%)	5/25 (14.3%)	6/21 (28.6%)	0.694 (0.189-2.548)	0.581
Worsening UI	9/66 (19.6%)	5/25 (14.3%)	4/21 (12.9%)	1.125 (0.274-4.626)	>0.999

OR: Odds ratio; 95% CI: 95% Confidence interval; UI: urge incontinence.

References

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