

RANDOMIZED COMPARATIVE STUDY BETWEEN INSIDE-OUT TRANSOBTURATOR TAPE AND OUTSIDE-IN TRANOBTURATOR TAPE FOR URODYNAMIC STRESS INCONTINENCE

Hypothesis / aims of study

To compare the 'inside-out' versus 'outside-in' routes for transobturator tape insertion for urodynamic stress incontinence

Study design, materials and methods

A prospective single-blinded randomised trial.

A cohort of 250 women undergoing transobturator tape procedures between August 2006 and August 2011. Women were randomised to transobturator tape (TOT) 'inside-out' route (n = 125) and transobturator tape (TOT) 'outside-in' route (n = 125).

The primary outcomes were the improvement of stress incontinence symptom and signs, the intraoperative time, the intra and post operative complications. The secondary outcome was the recurrence of stress incontinence within the 1st year post operative.

Results

A total of 250 women were recruited: 125 women to the 'outside-in' group and 125 to the 'inside-out' group; 199 completed the 1-year follow up. The patient-reported success rate was 80% with no statistically significant differences between both groups ('outside-in' 77.6% versus 'inside-out' 81.2%). There was no statistically significant difference between both groups regarding the intraoperative time. Adverse events such as haematomas occurred in 12 cases 5 in the 'inside-out' group and 7 in 'the outside-in' group with no statistically significant difference. Groin/thigh pain occurred in 70% with no statistically significant differences between both groups ('outside-in' 67.3% versus 'inside-out' 72.7%). Mesh erosion occurred in only one case in the inside-out group. After one year follow-up, 2 patients treated with a TOT 'outside-in' approach complained of mild stress urinary incontinence.

Interpretation of results

	Group 1 (outside-in) N=125	Group 2 (inside-out) N=125	P value
Improvement of incontinence	77.6%	81.2%	insignificant*
Intraoperative time	24 min	27 min	insignificant*
Haematoma	5.6%	4%	insignificant*
Groin and thigh pain	67.3%	72.7%	insignificant*
Mesh erosion	0%	0.8%	insignificant*

1 year follow up	Group 1 (outside-in) N=97	Group 2 (inside-out) N=102	P value
Recurrence of incontinence	2.06%	0%	Insignificant*

Concluding message

There are no significant differences in patient reported and objective cure rates between 'inside-out' and 'outside-in' transobturator tapes.

Disclosures

Funding: Kasr Alainy teaching hospital Cairo university **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Kasr elainy ethical committee. **Helsinki:** Yes **Informed Consent:** Yes