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A SYSTEMATIC REVIEW AND META-ANALYSIS OF THE EFFICACY AND COMPLICATIONS OF THE "INSIDE-OUT" VERSUS THE "OUTSIDE-IN" TRANSOBTURATOR TAPES IN MANAGEMENT OF FEMALE STRESS URINARY INCONTINENCE.

Hypothesis / aims of study

To compare the 'Inside-out' vs. 'Outside-in' routes of insertion of transobturator tapes for the treatment of stress urinary incontinence (SUI) in adult women as regards: patient reported outcomes, objective outcomes, impact on women quality of life and peri-operative complications.

Study design, materials and methods

A prospective peer reviewed protocol was prepared as priori. MEDLINE, OVID, EMBASE, CINAHL, AMED(up to Jan 2010), The Incontinence Group Specialised Register, The UK National research Register and Clinical Trials.gov were searched using relevant search terms. Randomised and quasi-randomised controlled trials comparing the 'Inside-out' vs. 'Outside-in' transobturator tapes in the treatment of SUI; diagnosed clinically or on urodynamics, in adult women and in all languages were included in the meta-analysis. Comparative, non-randomised, cohort studies were included & analysed separately. Primary outcome was clinical cure/ improvement in SUI (both patient reported and objective outcomes). The secondary outcomes were Impact on women quality of life and sexual function, surgical outcomes and peri-operative surgical complications, adverse events (such as de-novo detrusor overactivity, de-novo urgency or urgency incontinence, voiding dysfunction, tape erosion into vagina, bladder or urethra) and economic measures.Two reviewers independently assessed the quality of the trials and data were extracted using pre-specified data extraction forms. Any disagreements were resolved by discussion with the senior researcher. A number of authors were contacted for clarifications on their published studies. Meta-analysis was performed using Rev-Man 5 Software from the Cochrane Collaboration.

Results

Five randomised trials comparing the 'Inside-out' vs. 'outside-in' transobturator tapes were included. At 3- 12 months follow-up (fig 1); there was no significant difference in the patient reported cure/ improvement (OR 1.19, 95%CI 0.74, 1.92) and the objective cure/ improvement (fig 2) (OR 1.66, 95%CI 0.8, 3.43) between the 2 groups. Vaginal angle injuries (fig 3) were significantly higher with the outside-in route (OR 0.14, 95%CI 0.05, 0.41) while groin and thigh pain were higher in the inside-out route, but did not reach statistical significance (OR 1.42, 95%CI 0.94, 2.13). Lower urinary tract injuries (fig 4) mesh erosion were insignificantly higher in the outside-in route (OR 0.40, 95%CI 0.06, 2.75 and OR 0.60, 95%CI 0.14, 2.54 respectively). De-novo urgency/ urgency incontinence and postoperative voiding dysfunction were lower with the outside-in route (OR 1.46, 95%CI 0.63, 3.36 and OR 1.07, 95%CI 0.62, 1.86 respectively) but they did not reach statistical significance. Economic analysis was not reported by any of the trials. We were unable to perform meta-analysis for impact on women's quality of life (QoL) due to variety of Qol assessment tools used. Only one trial assessed the impact on sexual function. On meta-analysis of the 3 comparative, non-randomised, cohort studies: 2 studies reported patient-reported cure/improvement and one reported objective cure/ improvement. The subjective cure and improvement (fig 5) were similar between the groups while the composite complication rate (fig 6) was insignificantly lower in the inside-out route (OR 0.64, 95%CI 0.36, 1.12).

Fig 1: Patient- reported cure and improvement

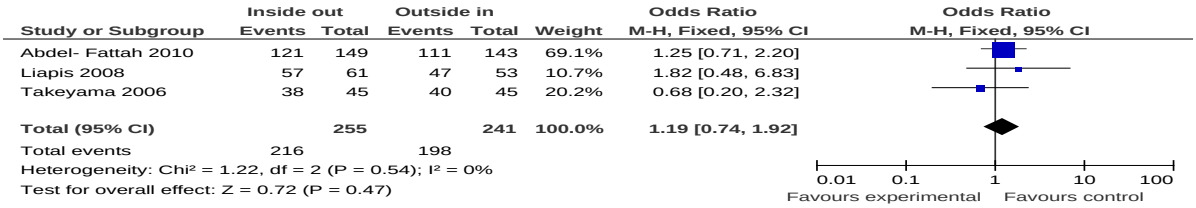


Fig 2: Objective cure & Improvement

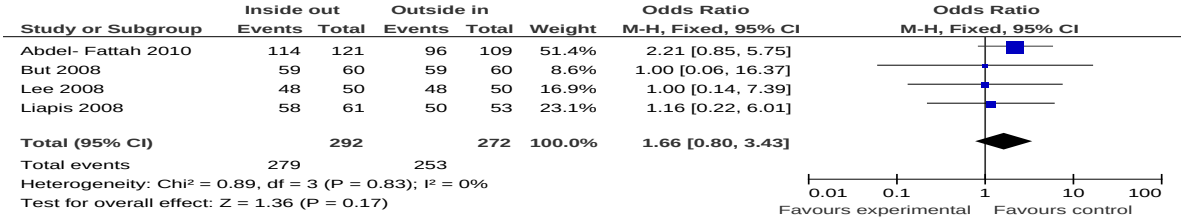


Fig 3: Vaginal injuries

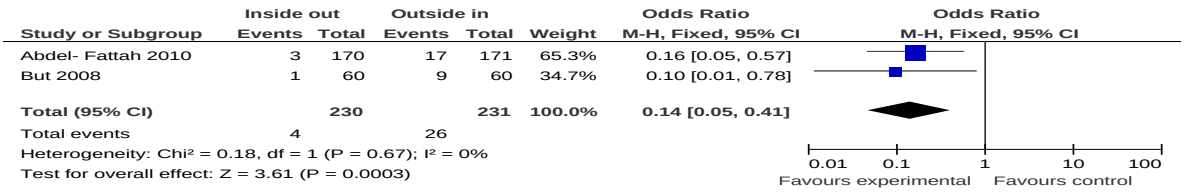


Fig 4: Bladder and urethral injuries

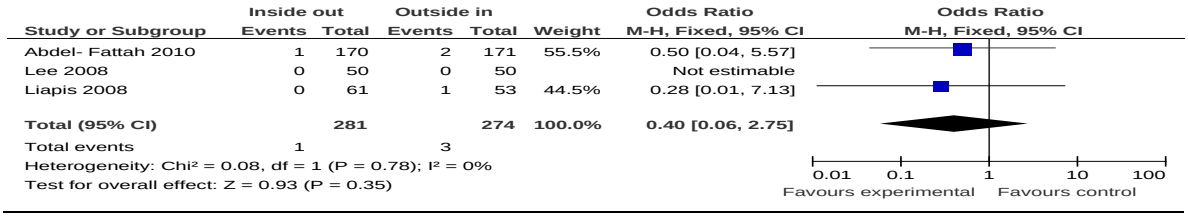


Fig 5: Cohort studies: Subjective cure and improvement.

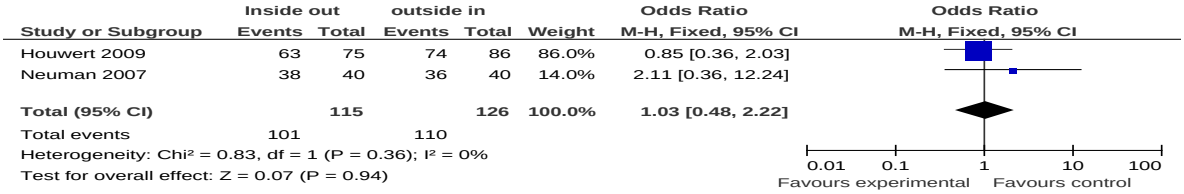
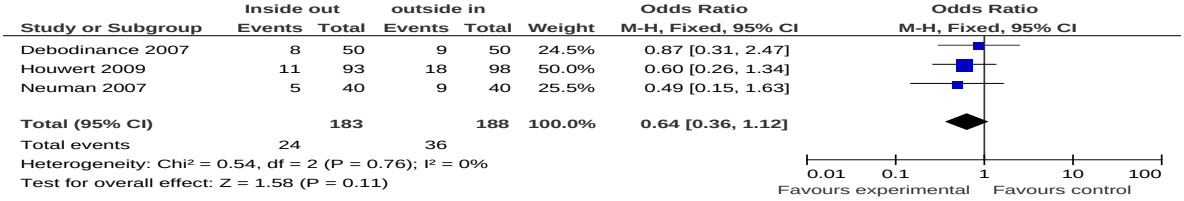


Fig 6: Cohort studies: Risk of composite complication.



Interpretation of results

High quality clinical trials are quite expensive and require a huge clinical and academic effort for prolonged durations hence the number of randomised trials comparing the outside-in vs. inside-out routes of transobturator tapes are limited. All studies, except one, were underpowered and hence the need of such meta-analysis to reach a firm conclusion. Despite its importance, only 2 studies assessed the impact of the operation on women's QoL and only one study assessed the sexual impact. Most of the studies had a short to a medium term follow-up with high risk of bias in 2 studies. This meta-analysis has confirmed the absence of significant difference in the patient reported and objective cure/ Improvement between the outside-in & inside-out routes of transobturator tapes. Although vaginal angles injuries were more common in the outside-in route however this is of limited clinical significance. The higher chance of groin/thigh pain in the inside-out route may affect the choice of this procedure during an informed patient counselling. Economic evaluation would have been of paramount importance in this situation as it could have a big significance on the surgeons/ institution choice. Long term follow up of adequately powered, high quality RCT's incorporating standardised outcome measures and reporting using CONSORT guidelines are needed.

Concluding message

There was no significant difference in the efficacy of the "outside-in" compared to the "inside-out" transobturator tapes. Vaginal angles injuries are significantly lower in the inside-out route however there is a trend towards higher risk of postoperative groin pain although not statistically significant. .

Specify source of funding or grant	**None**
Is this a clinical trial?	**No**
What were the subjects in the study?	**NONE**