

SINGLE INCISION MID-URETHRAL SLING AND TENSION-FREE VAGINAL TAPE PROCEDURE FOR THE TREATMENT OF STRESS URINARY INCONTINENCE: A 12-MONTH FOLLOW-UP RANDOMIZED STUDY

Hypothesis / aims of study

The object of this study was to compare the treatment outcomes of single incision mid-urethral sling (Miniarc™) and tension-free vaginal tape (TVT) procedure in women with stress urinary incontinence (SUI) at 12 months.

Study design, materials and methods

A total 187 women with SUI were randomized to receive Miniarc and TVT. The primary outcomes were objective and subjective cure rates at a 12-month follow-up visit. Objective and subjective cure of SUI were defined as a negative cough stress test and absence of self-reported SUI symptoms. Cure rates of the two groups were compared at 12-month follow-up.

Results

158 (85%) of 187 women originally included in the study (MiniArc: 87, TVT: 71) were evaluated at 12 month follow-up. There were no significant difference found in demographic and clinical preoperative parameters. Objective cure rates for MiniArc and TVT groups were 90% and 94% while subjective cure rates were 84% and 89%. There was no statistically significant difference between groups ($p>0.05$).

Interpretation of results

To our knowledge, this was the first randomized study that compared the objective and subjective outcomes of MiniArc single incision sling and TVT procedures in women with SUI. MiniArc single incision sling may be as effective as TVT procedure, even though displaying a trend toward a lower efficacy.

Concluding message

Our 12-month randomized clinical trial showed that MiniArc single incision sling is not inferior to TVT procedure with respect to objective and subjective cures at 12-month follow-up.

Disclosures

Funding: None **Clinical Trial:** Yes **Public Registry:** No **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Hallym University Ethics Committee **Helsinki:** Yes **Informed Consent:** Yes