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MINIARC VS TVT ABBREVO MIDURETHRAL SLING IN WOMEN WITH STRESS URINARY INCONTINENCE – AN RCT – 6 AND 12MONTH FOLLOW UP.

Hypothesis / aims of study

Single incision slings (SIS) were introduced in an attempt to decrease the complications associated with retropubic and transobturator slings. The FDA has requested ongoing studies to determine the efficacy of single incision slings. The TVT Abbrevo is a modification of the TVT-O with a reduced length and less immediate postoperative pain[1]. The Miniarc SIS has been shown to be equivalent to outside-in transobturator sling, Monarc at 12 month follow-up[2].

OBJECTIVE: To evaluate objective and subjective outcomes of MiniArc SIS and TVT Abbrevo midurethral sling (MUS) in women with stress urinary incontinence

METHODS: Female subjects who were assessed and referred for stress urinary incontinence surgery were eligible to participate in this study. Women with intrinsic sphincter deficiency (maximum urethral closure pressure (MUCP) of 20 cmH_2O or less and/or abdominal leak point of 60 cm H_2O or less), previous failed midurethral or fascial sling, untreated detrusor overactivity or significant voiding dysfunction (maximum flow rate < 15 mL/s or < 10% Liverpool nomogram and/or postvoid residual > 100 mL) were excluded.

Patients had equal probability of allocation to TVT Abbrevo or MiniArc sling; randomisation was performed with computer-generated blocks of 4-8, with concealed allocation. Surgeons or patients were not blinded once allocation was revealed. Assuming an objective cure rate of 90% for TVT Abbrevo™ with a power of 80%, a sample size of 79 in each arm was required to detect a clinical difference of 15%, using a one sided of 0.05.
The target recruitment number was 220 allowing for an attrition rate of 15%. Institution ethics approval (11261B) was obtained and the trial was registered with the national clinical trial registry.

Routine preoperative assessment (symptom evaluation, clinical examination, urodynamics and perineal ultrasound, urinary diary) was conducted for objective data, whilst patient reported outcome tools (PRO) were utilised for subjective outcomes. These include ICIQ UI SF, ICIQ OAB, IIQ7, EQ5D, PISQ12, PGIs & PGII.

TVT Abbrevo™ or Miniarc™ were performed in a standardized fashion, together with any concomitant prolapse surgery, followed by routine post operative care including voiding trial and assessment of post operative pain. Review was conducted at 6 weeks and at 6 and 12 months at which time, uroflowmetry, a clinical cough stress test and examination were performed in addition to symptom and quality of life questionnaires.

Objective cure was defined as a negative cough stress test with a comfortably full bladder. Subjective cure was defined as no report of leakage with physical exertion. All Data was collected on a standardized proforma including patient characteristics. Outcomes were compared with exact binomial tests (eg, Fisher exact test for dichotomous data) for categorical data and Student *t* test or exact versions of Wilcoxon tests for numerical data as appropriate.

RESULTS: Between 2011 and December 2015, a total of 246 women were randomized to receive MiniArc (121) or TVT Abbrevo (125) with 21 withdrawals over the first 12 months. Baseline characteristics were clinically balanced in both groups as shown in Table 1.

At the current time-point, 178 women were assessed. There were significant differences in subjective cure at 12 months though no differences were seen in objective cure rates and patient reported outcomes, as shown in Table 2.
Five MiniArc patients had failed surgery in the first 12 months requiring a second sling at 3, 12, 13, 14 and 14 months. Two of these were in Miniarc pro (newly introduced tensioning device).
There were 4 failures, in the Abbrevo group, one of them had to be removed due to pain. One had to be loosened. No sling had to be divided.
There were 2 mesh exposures in the Abbrevo group, one required excision at 6 month causing recurrence of SUI and the need for a repeat sling.
OAB symptoms at 12m were reported in 16 TVT abbrevo (4 requiring treatment), 11 Miniarc (6 requiring treatment).
Sixty patients (44 Abbrevo vs 16 MiniArc) complained of transient groin pain varying between 1 to 6 weeks; all self resolved.

CONCLUSION: There were no significant differences in objective cure rates at 6 and 12months between MiniArc and TVT Abbrevo.
Subjective cure rate was significantly higher for TVT Abbrevo compared with MiniArc at 12months but not at 6 months.

Table 1: MiniArc TVTAbbrevo outcomes at 6 and 12 months

Subjective and Objective SUI cure rates	Abbrevo (n: 111) 6m	MiniArc (n: 105) 6m	P value 6m vs 6m	Abbrevo (n: 82) 12m	MiniArc (n: 88) 12m	P value 12m vs 12m
Reported SUI (Subjective) **ICIQ UI : c/e/ce** **SUI: 1 (yes)**	10/105 (10%) 16/111 (14%)	31/102 (30%) 20/108 (18%)	**0.00016** 0.41	21/86 (24%) 10/84 (12%)	24/86 (27%) 22/88 (25%)	0.6 **0.027**
Cough Stress Test negative (Objective)	106/111 (95%)	97/105 (92%)	0.33	79/82 (96%)	82/88 (93%)	0.35
PGII	1 (1-2)	1 (1-2)	0.3	1 (1-2)	1 (1-2)	0.2
ICIQ UI	3 (0 - 5)	3 (0 – 6)	0.6	3 (0 - 5)	3 (0 – 6)	0.9
ICIQ OAB	3 (2 - 4)	3 (1 – 4)	0.43	3 (2 - 4)	3 (1 – 4)	0.9
IIQ7	0 (0 – 3)	0 (0 – 2)	0.3	0 (0 – 2)	0 (0 – 2)	0.93
EQ5D	5 (5 – 5)	5 (5 – 5)	0.64	5 (5 – 6)	5 (5 – 6)	0.85
PISQ 12	37 (33 – 40)	37 (32 – 41)	0.82	37 (34 – 40)	37 (31 – 41)	0.56

References
1. Shaw JS, Jeppson PC, Rardin CR. Decreasing transobturator sling groin pain without decreasing efficacy using TVT-Abbrevo. Int Urogynecol J. 2015 Sep;26(9):1369-72.
2. Lee JK-S, Rosamilia A, Dwyer PL, et al. Randomizes trial of a single incision versus an outside-in obturator midurethral sling in women with stress urinary incontinence: 12 months results. Am J Obstet Gynecol 2015;213:35.e1-9

Disclosures
Funding: N/A **Clinical Trial:** Yes **Registration Number:** Australian New Zealand Clinical Trials Registry (ACTRN12611001151921). **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Human Research Ethics Committee Research Support Services I Monash Health Level 2, I Block, Monash Medical Centre, Clayton, 3168 **Helsinki:** Yes **Informed Consent:** Yes