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IS TRANS-OBTURATOR TAPE (TOT) AS EFFECTIVE AS TENSION-FREE VAGINAL TAPE (TVT) IN THE TREATMENT OF WOMEN WITH URODYNAMIC STRESS INCONTINENCE? RESULTS OF A MULTICENTRE RCT

Hypothesis / aims of study
That the Monarc® TOT is equivalent (but not inferior) to Gynecare® TVT in the treatment of female urodynamic stress incontinence (USI). The aim is to compare the percentage of patients in the two treatment groups who are cured of stress urinary incontinence (SUI) at 12-month follow-up. Cure is defined as the absence of SUI symptoms according to the patient's statement. Other outcomes include semi-objective, objective and Quality of Life measures.

Study design, materials and methods
A Multi-centre randomised controlled trial. A power calculation suggested a sample size of 82 in each group would have an 80% power to reject the null hypothesis i.e. the test be standard or not equivalent. Assuming a 10% loss to follow-up the total sample size was 182. Women aged over 21 years complaining primarily of SUI who had had a failed trial of conservative therapy (and in whom USI had been confirmed) were invited to take part. Patients were randomised and stratified by study sites to either TVT (Gynaecare®) or TOT (Monarc®).

The primary outcome was cure of SUI at 12 month follow-up as judged by symptoms using the ICIQ-FLUTS long form questionnaire, semi objective and objective measures including frequency/volume chart, pad usage and pad test and the ICIQ satisfaction questionnaire. Quality of life was assessed using the ICIQ-LUTS qol (KHQ). Secondary outcomes included a change in lower urinary tract symptoms (LUTS) and impact on sexual life.

Results
191 women were recruited and randomised in 11 centres and 180 attend the 12-month postoperative follow-up visit (85 had a TVT while 95 had a TOT procedure). There were no significant differences at baseline in patient characteristics e.g. age, BMI and urodynamic parameters.

There was no significant difference in patient-reported SUI at 12 months between the two groups (p=0.75). The overall success rate i.e. absence of any SUI on the ICIQ-FLUTS, was 35.3% and 37.6% for TOT and TVT; respectively. For those patients classified as 'not cured', symptom scores were significantly improved at 12 months compared with baseline (p<0.0001) and only 13 (16%) women in the TVT and 10 (13%) in the TOT group thought they required further treatment. Likewise, patient satisfaction at one year on the ICIQ satisfaction questionnaire was high in both groups with no significant difference between groups.

The differences in operation time, blood loss and the 6-hour postoperative pain scores were not significant. However, pain scores of women in the TOT group 24 hours postoperatively were significantly lower compared to TVT (p=0.015).

Significantly more patients in the TVT group documented pad usage on their post-operative frequency/volume chart (p=0.024). However, the number of patients who leaked 5 or more grams during the pad test was similar between the 2 groups as was the number of women reporting pad usage on the ICIQ LUTSqol. Comparative improvements were observed in the impact on sexual QOL scores in the 2 groups.

Interpretation of results
Both TVT and TOT produced comparable results in terms of the primary outcome i.e. subjective stress incontinence at 12 months. This is in keeping with other authors (1). While the overall success rates using strict outcome measures are lower than previously published, the patient reported satisfaction was high.

Concluding message
Mid urethral tapes, whether retropubic or transobturator, seem to produce high levels of satisfaction, which should be considered at the optimum outcome measure.

References
1- Eur Urol. 2006 Jan;49(1):133-8.

Specify source of funding or grant	**American Medical Systems (AMS)**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Central Manchester Local Research Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**