

## RANDOMISED TRIAL OF TENSION-FREE VAGINAL TAPE AND TRANSOBTURATOR TAPE FOR THE TREATMENT OF URODYNAMIC STRESS INCONTINENCE IN WOMEN

### Hypothesis / aims of study

This prospective randomised study compared the effectiveness and complication rate of retropubic tension-free vaginal tape (TVT, Gynecare) and inside-out transobturator tape (TVT-O, Gynecare) for the treatment of urodynamic stress incontinence in women.

### Study design, materials and methods

With local ethics approval, women with USI, no detrusor overactivity and no prior continence surgery were randomised to have either TVT or TVT-O insertion. The primary outcome measure was objective cure rate at 6 months post surgery as defined by a 24 hour pad test of <5g. Secondary outcome measures included change in quality of life and symptom severity, absence of leakage based on a 3-day urinary diary and the incidence of intra/postoperative complications. Validated questionnaires used included the King's Health Questionnaire (KHQ) and International Consultation on Incontinence Questionnaire (ICIQ). Both TVT and TVT-O were performed under local anaesthetic and sedation according to published techniques (1, 2).

Taking an objective cure rate for TVT of 65% (3), 100 participants are required in each arm to detect a 20% difference in cure rate with 80% power (significance at 5%). Data are presented as the mean ( $\pm$ SD), median (range) and n (%). Independent samples T test or Mann-Whitney U test was used to compare continuous data between groups. Proportions were compared with either the chi squared test or Fischer's exact test. Significance was set at P<0.05.

Patients were recruited between Jan 2005 and Jan 2007. At this time, several other studies had been published in abstract form and it was decided that equipoise had been lost and that it was no longer ethical to continue to randomise women. Data on the women recruited are presented, and these can be entered into meta-analyses using data from other published studies.

### Results

52 women had TVT and 39 had TVT-O. Baseline characteristics are shown in Table 1. Outcome data at 6 months are shown in Table 2.

Table 1. Baseline characteristics

|                           | TVT                  | TVT-O                   | P       |
|---------------------------|----------------------|-------------------------|---------|
| Age (years)               | 53.44( $\pm$ 11.83)  | 51.31( $\pm$ 12.01)     | 0.61*   |
| BMI (kg/m <sup>2</sup> )  | 27.57 ( $\pm$ 4.24)  | 29.76 ( $\pm$ 4.71)     | 0.37*   |
| Parity                    | 2 (0-8)              | 2 (1-8)                 | 0.04**  |
| Previous hysterectomy     | 13 (25%)             | 12 (30.8%)              | 0.72*** |
| Premenopausal             | 19 (36.5%)           | 15 (38.5%)              |         |
| Postmenopausal            | 20 (38.5%)           | 12 (30.8%)              |         |
| Previous prolapse surgery | 3 (5.8%)             | 0                       | 0.13*** |
| 24 hr pad test (g)        | 30 (1-513)           | 27 (1-250)              | 0.91**  |
| KHQ score                 | 394 (122-814)        | 397 (106-814)           | 0.75**  |
| ICIQ score                | 14 (7-21)            | 14 (7-21)               | 0.93**  |
| Leakage episodes (diary)  | 2.33 (0-13.33), n=41 | 3.67 (0.33-17.67), n=31 | 0.15**  |

\*Independent samples T test

\*\*Mann-Whitney U test

\*\*\*Chi squared test

Table 2. 6 month comparisons

|                                    | TVT              | TVTO               | P      |
|------------------------------------|------------------|--------------------|--------|
| Objective cure (<5g)               | 41 (78.8%), n=52 | 30 (76.9%), n=39   | 0.83*  |
| Subjective cure "very much better" | 43 (82.7%)       | 29 (74.4%)         | 0.68*  |
| ICIQ "no leakage"                  | 23 (46%), n=50   | 18 (51.4%), n=35   | 0.62*  |
| KHQ score                          | 67 (0-647), n=50 | 59.5 (0-825), n=36 | 0.66** |
| ICIQ score                         | 1 (0-14), n=50   | 1 (0-20), n=35     | 0.62** |
| Pad test (g)                       | 1.15 (0-84)      | 1.5 (0-135)        | 0.94** |
| Diary leakage episodes             | 0 (0-8), n=45    | 0 (0-10), n=35     | 0.44** |
| No leakage - Diary                 | 33 (73.3%), n=45 | 29 (82.9%), n=35   | 0.31*  |
| Operating time (min)               | 20 (15-30), n=52 | 22 (17-22), n=39   | 0.03** |

|                                   |                   |                    |         |
|-----------------------------------|-------------------|--------------------|---------|
| Blood loss (ml)                   | 20 (50-175), n=52 | 50 (20-350), n=39  | 0.93**  |
| 2 hr pain VAS (cm)                | 0.9 (0-7.5), n=51 | 2 (0-8), n=39      | 0.03**  |
| 1 week pain VAS (cm)              | 0 (1-8.5), n=43   | 1.55 (0-8.5), n=36 | 0.57**  |
| Discharge time (days)             | 0 (0-1), n=52     | 0 (0-1), n=39      | 0.52**  |
| Normal activity (days)            | 14 (1-90), n=48   | 14 (0-60), n=32    | 0.88**  |
|                                   |                   |                    |         |
| Intermittent self catheterisation | 3 (5.8%), n=52    | 0                  | 0.26*** |
| Bladder perforation               | 0                 | 0                  |         |
| Vaginal injury                    | 0, n=52           | 3 (7.7%), n=39     | 0.08*** |
| Leg pain                          | 1 (1.9%), n=52    | 13 (33.3%), n=39   | 0.0004* |
| De novo/worsening OAB             | 3 (5.8%), n=52    | 4 (10.3%), n=39    | 0.46*** |
| Erosion                           | 3 (5.8%), n=52    | 1 (2.6%), n=39     | 0.63*** |

\*Chi squared test

\*\*Mann-Whitney U test

\*\*\*Fisher's Exact test

#### Interpretation of results

At 6 months, the objective and subjective cure rates and complication rate for TVT and TVT-O were equivalent. TVT was quicker to perform and caused significantly less immediate postoperative pain. The level of pain was similar between groups by 1 week post surgery and the time taken to return to normal activity was not significantly different. Significantly more women reported leg pain in the TVT-O group.

#### Concluding message

Although efficacy at 6 months is similar, TVT-O results in higher levels of postoperative pain and leg pain. These findings are similar to other studies comparing suburethral to trans-obturator tape. Given the comparable efficacy of the procedures, it seems preferable to recommend suburethral tape placement to avoid a high incidence of leg pain. The theoretical concerns about bladder injury when using suburethral placement seem unfounded.

#### References

1. Eur Urol (2003) 44; 724-730.
2. Int Urogynecol J (1996) 7; 81– 86.
3. BMJ (2002) 325; 67-70.

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**HUMAN SUBJECTS:** This study was approved by the University Hospitals of Leicester and followed the Declaration of Helsinki Informed consent was obtained from the patients.