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RANDOMISED TRIAL OF TVT AND TVT-O FOR THE TREATMENT OF URODYNAMIC STRESS INCONTINENCE IN WOMEN

Hypothesis / aims of study

To compare the efficacy and complications of retropubic (TVT, Gynecare) and transobturator (TVT-O, Gynecare) midurethral tapes TVT-O as surgical treatment for urodynamic stress incontinence.

Study design, materials and methods

Women with USI, no DOA, no prior continence surgery and no prolapse >stage1 (POPQ) were randomised to have either TVT or TVT-O insertion (no concomitant surgery). TVT and TVT-O procedures were performed under local anaesthetic and sedation according to published techniques[1, 2].The primary outcome measure was objective cure rate 6 months after surgery, defined by a 24-hour pad test of <5g. Secondary outcome measures included quality of life and symptom severity scores (KHQ and ICIQ respectively), leakage episodes based on a 3-day urinary diary and rate of complications. Ethical committee approval was obtained and the study was conducted according to CONSORT guidelines. All patients provided written, informed consent.

Calculation of the sample size was performed based on a subjective cure rate for TVT at our institution of 89%. To detect a 20% difference in cure rate with 80% power, 70 participants were required in each arm (significance at 5%). Taking an objective cure rate for TVT of 65%[3], 100 participants were required in each arm to detect a 20% difference in cure rate. We aimed to recruit a total of 200 participants over 2 years.

Results

66 women had TVT and 61 had TVT-O. The study was terminated early, after discussion at an investigators' meeting, because other trials had been published in abstract at International meetings. These described significant incidences of leg pain in the TOT groups, so clinical equipoise was deemed to have been lost.

Results are summarised below.

Table 1. Baseline characteristics

	TVT	TVT-O	P
Age (years)	52.4 (±11.8)	50.9 (±11.4)	0.46*
BMI (kg/m^2)	27.7 (±4.4)	29.6 (±5.7)	0.06*
Parity	2 (0-8)	2 (0-8)	0.15**
Previous hysterectomy	17 (25.8%)	17 (27.9%)	0.83***
Premenopausal	25 (37.9%)	25 (41%)	
Postmenopausal	24 (36.4%)	19 (31.1%)	
Previous prolapse surgery	3 (4.5%)	0	0.09***
Pad test (g)	39 (1-513)	27 (1-367)	0.61**
KHQ score	384 (122-814)	399 (106-814)	0.42**
ICIQ score	15 (7-21)	14 (3-21)	0.58**
Leakage episodes (diary)	3 (0-13)	3 (0-18)	0.48**

*Independent samples T test
**Mann-Whitney U test
***Chi squared test.

Table 2. Operative data/complications

	TVT	TVT-O	P
Operating time (min)	20 (15-30)	22 (17-36)	0.02**
Blood loss (ml)	20 (20-200)	50 (20-400)	0.97**
2 hr pain VAS (cm)	1 (0-7.5)	2 (0-8)	0.005**
1 week pain VAS (cm)	1 (0-8.5)	1.5 (0-8.5)	0.26**
Discharge time (days)	0 (0-1)	0 (0-1)	0.9**
Return to normal activity (days)	14 (1-90)	14 (0-60)	0.58**
Haemorrhage	1 (1.6%)	1 (1.5%)	0.95***
Intermittent self catheterisation	3 (4.5%)	1 (1.6%)	0.62***
Bladder perforation	0	0	
Vaginal injury	0	3 (4.9%)	0.12***

*Chi squared test
**Mann-Whitney U test
***Fisher's Exact test

At 6 months, data were available for 59 TVT and 53 TVT-O. Table 3 shows cure rate and problems experienced at 6 months.

Table 3. 6 month cure rate/problems

	TVT	TVTO	P
Objective cure (pad test <5g)	46 (78%)	44 (83%)	0.5*
Subjective cure "very much better"	48 (81.4%)	41 (77.4%)	0.6*
ICIQ "no leakage"	26 (45.6%)	27 (57.4%)	0.28*

KHQ score	58 (0-647)	58 (0-825)	0.82**
ICIQ score	1 (0-18)	0 (0-20)	0.72**
Pad test (g)	1 (0-84)	1.5 (0-135)	0.78**
Diary leakage episodes	0 (0-8)	0 (0-10)	0.49**
Leg pain	1 (1.7%)	14 (26.4%)	0.0001*
De novo/worsening OAB	3 (5.1%)	6 (11.3%)	0.3***
Erosion	3 (5.3%)	1 (2%)	0.43***

*Chi squared test
**Mann-Whitney U test
***Fisher's Exact test

Interpretation of results

The objective and subjective cure rate for TVT and TVT-O were equivalent. TVT caused significantly less postoperative pain. The level of pain was similar between groups soon after 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 retropubic and transobturator tapes. Given the comparable efficacy of the procedures, it seems preferable to recommend retropubic tape placement to avoid a high incidence of leg pain.

Although the study was underpowered to detect differences in cure, the loss of equipoise from publication of results from similar trials necessitated the early termination of the study. The data presented can be added to systematic reviews of published trials to provide a robust assessment of cure and complications of the two procedures.

References

1. Eur Urol (2003) 44; 724-730.
2. Int Urogynecol J (1996) 7; 81– 86.
3. BMJ (2002) 325;67-73.

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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	**Study was approved by Leicestershire, Rutland & Northamptonshire Research Ethics Committee 2, study number 2502/36.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**