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TRANS-OBTURATOR TAPE: EFFECTS ON CLINICAL SYMPTOMS AND WOMEN WITH QUALITY OF LIFE FOR STRESS URINARY INCONTINENCE.

<u>Hypothesis / aims of study</u> Trans-Obturator Tape (TOT) is a simple, minimally invasive treatment for stress urinary incontinence (SUI). It provides an alternative to Trans-vaginal tape (TVT), avoiding the blind passage of needle carriers and tape through the retropubic space and as a consequence cystoscopy is not required (1).

The Obtape sling (Mentor) is made of non-woven polypropylene and is placed tension free under the mid-urethra (2). The purpose of this study is to determine the efficacy of TOT® using Obtape, on clinical symptoms and quality of life issues.

Study design, materials and methods

This is an ongoing prospective longitudinal cohort study of 48 women with SUI undergoing a TOT procedure between August 2003 and March 2005 in the gynaecology department of a large UK Teaching hospital. All surgery was performed by one operator.

Pre-operatively a detailed history, examination and urodynamic investigation was performed. Women completed the 'Bristol Female Lower Urinary Tract Symptoms' validated symptomatic and quality of life questionnaire, both pre and 3 months postoperatively (3)

Results

86% of women had urodynamic stress incontinence (USI) with a further 6% diagnosed as having both USI and detrusor overactivity (DO). The remaining 8% of women reported symptoms highly suggestive of SUI but had a normal urodynamic study. The demographic details of the women are shown in Table 1. The mean maximum flow rate was 23.5 ml/sec (range 10-30).

Table 1: Demographic data

	Mean	Range
Age (years)	54	32-77
Parity	2.2	0-8
Body Mass Index (BMI)	27.9	18-37.7

The majority of women (61%) had undergone previous gynaecological surgery (e.g. hysterectomy). 55% of them had also undergone prior incontinence procedures (e.g. Colposuspension, Stamey).

Table 2: Additional procedures performed at the time of TOT insertion

None	77%
Anterior colporrhaphy	15%
Posterior colporrhaphy	5%
Vaginal hysterectomy	3%

23% of women underwent TOT with an additional procedure (Table 2). The majority of women who underwent TOT alone were discharged home either the same day or subsequent morning. The mean number of overnight stays (including women who underwent additional procedures) was 1.4 days (range 0-5). 90% of women had no intra or peri-operative

complications. One woman who had a TOT and vaginal hysterectomy developed a vault haematoma. Two women developed post-operative urgency (treated with Tolterodine) and a further woman experienced voiding difficulties with poor flow leading to release of the TOT. Lateral tape erosion occurred in one woman and the eroded section was excised. This woman, who was diabetic, went on to develop a groin abscess that required incision and drainage.

The post-operative questionnaires were completed, on average 4.3 months after TOT insertion

There were significant improvements in symptoms of urgency, urge incontinence (UI) and SUI.

90% of women, pre-operatively, experience SUI either 'all the time or more than two thirds of the time'. Post-operatively 59% of women were completely dry and a further 31% experiencing only occasional SUI i.e <1/3 of the time (p<0.0005).

Symptoms of urgency fell significantly from, a mean of 50% of the time to <1/3 of the time (p<0.005). Similarly symptoms of UI significantly reduced post TOT^{\otimes} , from an average of 'sometimes or most of the time' to 'never or occasionally' (p<0.0005).

There was a significant reduction in the number of women who experienced a 'sense of incomplete bladder emptying' from 78% pre TOT to 43% after TOT® (p=0.04).

Women did describe a mean reduction in the strength of their urinary stream, stating the post-operative flow was 'reduced a little' compared to pre-operatively. This trend did not reach statistical significance (p=0.06).

Pre-operatively 94% of women felt their urinary symptoms interfered with their life, whereas following TOT 76% describe 'no interference in their life, at all, from urinary symptoms' (p<0.0005).

Before undergoing TOT[®] 88% of women stated their urinary symptoms interfered with their physical activity (e.g walking, swimming), with 50% of women describing 'a lot' of interference. Following surgery 72% of women stated their urinary symptoms no longer interfered at all with physical activity and a further 12% described the interference as only 'a little' (p=0.07).

Pre-operatively 84% of women declared that they would feel 'very unhappy' or 'desperate' if they had to spend the rest of their life with their urinary symptoms. Following surgery 71% of women were 'satisfied', 'pleased' or 'perfectly happy' with the improvement in their symptoms (p<0.0005).

Interpretation of results

The majority of women experienced considerable symptomatic improvements following TOT with low complication rates. These results are encouraging especially as most of our women had undergone prior pelvic/incontinence surgery. Further follow up is required (and currently being collected) to determine the long-term efficacy of this treatment.

Concluding message

TOT using Obtape is an effective treatment for SUI generating significant subjective improvements in both urinary symptoms and women's quality of life.

References

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