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PROSPECTIVE EVALUATION OF THE TRANS-OBTURATOR APPROACH FOR THE CORRECTION OF STRESS URINARY INCONTINENCE IN WOMEN.

Hypothesis / aims of study

To evaluate peri-operative morbidity, continence outcome, changes in quality of life (QOL) parameters and sexual function in women undergoing placement of a polypropylene trans-obturator tape (TOT) for the correction of stress urinary incontinence (SUI)(1).

Study design, materials and methods

In November 2003 we undertook a prospective observational study evaluating the role of the TOT (Obtape® – Porgés, Mentor) for SUI. We aimed to recruit a cohort of 120 women - 60 with primary and 60 with recurrent SUI over 12 months with follow-up at 6 weeks, 6, 12 and 24 months. This report represents an interim analysis of this study. All women with urodynamically proven primary or recurrent SUI in the absence of any significant genital prolapse (<Grade 2), were considered eligible. Pre-operative assessment included clinical evaluation of vaginal support (POP-Q and Baden Walker) and completion of a continence questionnaire, urinary diary, 1-hour pad test, urethral pressure profilometry (UPP) and uroflowmetry. Each UPP was performed 2-3 times and mean and absolute values calculated. QOL assessment evaluated general health status (SF36), disease specific (SUDI, SIIQ, ICIQ-SF) and sexual function (ASFQ). TOT placement was performed in an identical manner in each patient under local anaesthesia. Cystoscopy was performed in all cases. No catheter was left in-situ at the end of the procedure. Recorded peri-operative parameters included – duration of surgery, estimated blood loss, intra-operative complications, duration to first void (volume voided and residual), voiding dysfunction, urinary infection and in-hospital stay. Post-operative follow-up at 6 weeks included all pre-operative investigations. In addition, they completed a visual analogue score (0-100) and genitourinary treatment satisfaction score (GUTSS) to evaluate satisfaction with continence outcome and delivery of care. Six month follow-up was identical but omitted UPP and uroflowmetry.

Results

At the time of writing 62 women had been recruited. 36 had undergone surgery and 31 completed a minimum of 6 weeks follow-up. Of these 36 women, 28(78%) had primary USI [mean age 55yrs, R36-83] and 8(22%) recurrent USI [mean age 61yrs, R 50-70]. In the latter group – 5 underwent previous retropubic suspension, 4 retropubic slings and 4 underwent more than 2 incontinence procedures. Mean parity was 2(R 0-6) and BMI 30(R 20-48). 34(94%) were performed under local and 2(6%) general anaesthesia. Median duration of surgery was 30mins(IQR 25-40) and EBL 25mls(IQR 15-50).There was one vaginal perforation at the time of surgery. Median duration to first void was 120mins(IQR 73-240), 4(11%) required catheterisation for a mean duration of 25 hours (R12-44). None of the women developed a UTI and the majority were discharged within 24 hours. Changes in pre and postoperative incontinence symptoms, urodynamic parameters, severity of urinary loss assessed by urinary diary and 1-hour pad testing and VAS scores evaluating satisfaction with continence outcome for primary and recurrent USI cases are listed in Table 1. Of the 8 women with persistent incontinence symptoms, 5 had undergone previous incontinence surgery. Six of the 8 women report postoperative urge rather than stress incontinence symptoms. Five reported this preoperatively and one had de-novo symptoms. They have not yet undergone repeat urodynamics. Significant improvements were observed in general, disease specific and sexual QOL parameters ($p<0.001$). Overall patients were also highly satisfied with delivery of care and continence outcome.

Table 1	Pre-op (n=36)	Post-op (n=31)	p
Incontinence symptoms	36(100%)	8(26%)	0.001^
Incontinence severity(VAS 0-10)	7(6-8)	0(0-5)	0.0001*
Urge incontinence symptoms	18(50%)	10(32%)	0.2^
Voiding difficulty symptoms	9(25%)	9(29%)	1.0^
Diary mean stress leaks	4(2-6)	1(0-4)	0.06*
Diary minimum stress leaks	2(1-4)	0(0-2)	0.6*
Diary maximum stress leaks	5(3-11)	3(0-6)	0.09*
Pad weight(grams)	25(5.8-61.2)	0.4(0-1.27)	0.04*
Flow rate(mls/sec)	19(7.3-25.2)	21(15.6-27.4)	0.3*
Residual(mls)	0(0-20)	8(0-35)	0.06*
UPP Mean FL(mm)	27(22-34)	25(21-31)	0.006*
UPP Max FL(mm)	27(22-34)	27(23-34)	0.002*
UPP Mean MUCP(cmH20)	39(20-51)	35(22-44)	0.01*
UPP Max MUCP(cmH20)	42(23-54)	38(24-46)	0.01*
Satisfaction with outcome VAS(0-100)		99.5(72.5-100)	

Values expressed as median (IQR), p* = paired samples t, and p^= Chi-squared tests. FL = functional urethral length, MUCP = maximum urethral closure pressure.

Interpretation of results

TOT is easily performed under local anaesthesia with minimal peri-operative morbidity and avoids the problem of bladder injury particularly with recurrent SUI following previous retropubic surgery. Subjective (symptom resolution) and objective (1-hour pad test <1 grammes) continence outcomes were both 74% and are comparable to TVT. Significant improvements were observed in all QOL parameters and satisfaction with surgery was high. The mechanism of action of the TOT is unclear as UPP parameters including FL and MUCP values were significantly lower following surgery.

Concluding message

TOT is a safe, rapid, minimally invasive technique for the correction of both primary and recurrent SUI. While long-term follow-up is required the short-term outcome and improvement in QOL parameters are comparable to mid-urethral retropubic tape procedures.

References

1. Trans-obturator urethral suspension: mini-invasive procedure in the treatment of stress urinary incontinence in women. Prog Urol 2001;11:1306-13.

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