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A CLINICAL EVALUATION OF THE GYNECARE TVT OBTURATOR SYSTEM FOR THE TREATMENT OF STRESS URINARY INCONTINENCE

Hypothesis / aims of study

The obturator approach for placement of mid-urethral slings for the treatment of stress urinary incontinence (SUI) was developed to avoid the potential serious complications reported with retropubic placement. This procedure provides transobturator inside-out tension-free urethral suspension using specifically designed surgical tools, in which a polypropylene tape is passed through the obturator foramina, towards the thigh, without entering the suprapubic region at any time during the procedure. The tape is positioned without tension at the midurethra.

The primary study objective was to demonstrate that the overall incidence of treatment success was more than 75% among women undergoing surgery utilizing the transobturator tension-free vaginal tape (TVT-O) for the treatment of SUI.

Study design, materials and methods

Women from 19 centers in North America (12), Europe (4) and Asia (3) with objective, demonstrable signs of SUI, including those with Intrinsic Sphincter Deficiency (ISD) were invited to participate in this prospective, single-arm study. The study was to include 300 women, 150 having SUI only with no previous SUI surgery and no planned concomitant surgery (Group A) and 150 having SUI or mixed incontinence (Group B) who did not qualify for Group A, including those who had undergone previous SUI surgery. ISD subjects were defined according to criteria set at individual centers.

After obtaining written informed consent, each subject underwent a baseline assessment, comprising objective evaluation of incontinence by standing stress test (SST), pad test or urodynamics. Subjects completed symptom-specific questionnaires (Urinary Distress Inventory [UDI-6], Incontinence Impact Questionnaire [IIQ-7]) pre-procedure and at 8 weeks, 6 and 12 months. Visual Analogue Scale (VAS) assessing subjective symptom assessment (0=none; 100=unbearable) was completed pre-procedure and repeated at 8 weeks, 6 and 12 months. A pain VAS was completed at 8 weeks (0=no pain; 100=worst imaginable). A SST was completed at 6 and 12 months. Other evaluations included return to usual activities and complications.

The primary effectiveness variable was percentage successes at 12 months post surgery. Success was defined as a negative SST. The primary variable was analyzed using 2 analysis sets: 1) Per Protocol (PP) was considered primary, defined as all subjects who underwent the TVT-O procedure and completed the SST at 12 months; and 2) Intent to Treat (ITT) was considered confirmatory, defined as all subjects who underwent the TVT-O procedure; missing data were handled as last observation carried forward for subjects with 6 month SST data, treating those without any post-procedure SST as failures. Additional subgroups were analyzed using Groups A and B, and ISD subjects.

Results

In total, 301 subjects participated in the study: 158 in Group A and 143 in Group B of whom 26 had undergone previous surgery for SUI. Forty-six subjects had ISD. The mean age of the women was 52.5 years (10.7 Standard Deviation [SD]) with mean BMI 27.8 (5.9 SD).

General anesthesia was used in 47.3% procedures; 40.0% under local with sedation and 12.3% under regional. In Group B, 72 subjects underwent concomitant surgery. Mean procedure duration was 21.8 minutes (18.5 SD). Median estimated blood loss was 25 ml, ranging from 0-500 ml. Discharge occurred on day of procedure for 40% of subjects, with 33.7% discharged the following day, and 16.7% two days after the procedure. At the time of discharge, a normal voiding pattern was reported in 92.0% of subjects with 7% experiencing abnormal voiding that required an indwelling catheter, however these resolved without further intervention.

By 8 weeks, 93.4% of subjects had returned to housework and resumed their social life; 54.5% had resumed employment, with 36.5% not working, and 9.0% yet to return to work; 51.7% had returned to their sex life, with 25.7% yet to return; this was not applicable to 22.6% of subjects. Median value of symptom assessment using VAS reduced from 70 (range 2-100) at baseline to 1 (range of 0-95) at 8 weeks, and this remained stable at 6 and 12 months. Median pain score was 10 (range 0-100) at 8 weeks.

Of the 267 subjects returning at 6 months, 248 (92.9%) had a negative SST. Table 1 presents results of the primary effectiveness variable of negative SST results at 12 months. In the PP analysis, the lower 95% Confidence Interval (CI) was greater than 75% for the overall study population, Groups A and B and the subset of ISD subjects.

Table 1 - Success Rate at 12 Months Post-Procedure (PP and ITT Populations)

		All Subjects	Group A	Group B	ISD
PP	Successes	231 / 246 (93.9%)	128 / 136 (94.1%)	103 / 110 (93.6%)	34 / 35 (97.1%)
	95% CI	0.90, 0.97	0.89, 0.97	0.87, 0.97	0.85, 1.00
ITT	Successes	256 / 301 (85.0%)	141 / 158 (89.2%)	115 / 143 (80.4%)	37 / 46 (80.4%)
	95% CI	0.81, 0.89	0.83, 0.94	0.73, 0.87	0.66, 0.91

Table 2 presents summary scores (0=best score, 100=worst) for UDI-6 and IIQ-7 at baseline and 12 months; differences from baseline were statistically significant ($p<0.0001$) for the overall study population, and for the subgroups.

Table 2 – Mean (SD) Summary Score Results of UDI-6 and IIQ-7

		All Subjects n=301	Group A n=158	Group B n=143	ISD n=46
UDI-6	Baseline	53.1 (18.8)	48.0 (16.6)	58.7 (19.5)	54.9 (20.4)
	12 months	11.8 (15.6)	7.6 (11.0)	17.1 (18.7)	11.7 (18.9)
IIQ-7	Baseline	47.1 (24.8)	45.4 (23.0)	49.1 (26.7)	48.6 (25.3)
	12 months	4.1 (13.2)	2.0 (7.8)	6.8 (17.4)	5.4 (18.1)

Complications included: 16 (5.3%) subjects with leg, thigh or groin pain; 3 (1.0%) subjects with mesh erosion, which required trimming of the exposed mesh; 7 (2.3%) had voiding dysfunction, with tape release required in 2 (0.7%) subjects.

Interpretation of results

Twelve-month results demonstrated the success rate was greater than 75% in total population, and in all 3 sub-groups. Significant improvements were observed in all the patient reported outcomes. Complication rates were low.

Concluding message

The TVT-O procedure is safe, and highly effective in terms of objective and subjective cure in women with SUI, mixed incontinence and ISD.

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HUMAN SUBJECTS: This study was approved by the Research Ethics Board Sunnybrook & Women's College Health Sciences Centre

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Toronto, Ontario, Canada M4N 3M5 and followed the Declaration of Helsinki Informed consent was obtained from the patients.