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EFFICACY OUTCOMES OF A LOW ELASTICITY POLYPROPYLENE TRANSOBTURATOR MIDURETHRAL SLING FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE: FINAL DATA COMBINED FROM TWO MULTI-CENTER PROSPECTIVE CLINICAL STUDIES.

Hypothesis / Aims of Study

The aim of these two North American multi-center studies is to evaluate the safety and efficacy of the transobturator procedure using a low elasticity polypropylene midurethral sling for the treatment of female mixed and stress urinary incontinence (SUI) over a 1 year time period.

Study Design, Materials and Methods

Patients were prospectively enrolled at 4 centers in each of the two multi-center studies, for a total of 8 centers in the United States. Main eligibility criteria across the two multi-center studies included: women >18 years old, SUI or mixed urinary incontinence, no prior synthetic sling surgery, not pregnant, no urinary or vaginal infection, <150 mL post-void residual. After IRB approval and patient consent, pre-operative data was collected, and a monofilament polypropylene, light weight, macroporous midurethral sling (Aris^{TM}, Coloplast, Denmark) was implanted using the transobturator technique described by E. Delorme[1]. Operative and peri-operative data was recorded. Patients had 4 follow-up visits over the course of one year. Efficacy outcome measures were: cough stress test, Stamey incontinence grade, IIQ-7, UDI-6 and quality of life (QoL). Complications were recorded at each follow-up.

Results

117 women (mean age 55.1 y, range 29–87 y) underwent transobturator sling surgery, with a mean follow-up time of 10.7 $\pm$ 3.9 months. Of these, 57% had SUI and 43% had mixed urinary incontinence, with 49% of the total patient population having had previous anti-incontinence surgery (e.g. including bulking agents, bladder suspension). 79/116 (68.1%) patients were post-menopausal, and 59/116 (50.9%) had pelvic organ prolapse.

Patients were treated with either local (n=37), general (n=46), spinal (n=31) or spinal and local (n=3). Peri-operative measures were blood loss >200 mL (3/116); length of stay: outpatient (66/117), <23 hours (48/117), >1 day (3/117); length of catheterization: none (54/117), <23 hours (54/117), >1 day (9/117).

Post-operative outcomes show significant improvements in objective continence as well as in QoL (Table 1). The incidence of post-operative overactive bladder symptoms was observed in 2 (1.7%) patients. There were 7 patients with vaginal exposure of sling all treated successfully by local excisions.

Table 1. Post-operative Outcomes

	Pre-operative	**6 months**	**1 year**	**p-value**
Negative Cough Stress Test	7/117 (6%)	79/87 (91%)	90/92 (98%)	p<0.0001
IIQ-7	42.3	7.6	6.3	p<0.0001
UDI-6	55.2	15.6	15.2	p<0.0001
Improved QoL	NA	83/88 (94%)	87/92 (95%)	p<0.0001

Interpretation of Results

This final analysis of merged outcome data from two multi-center, prospective studies on a transobturator midurethral sling shows that the procedure is safe and effective in treating mixed and stress urinary incontinence. The results show a low rate of retention with only a small percentage of patients requiring catheterization beyond 1 day, as well as low post-operative overactive bladder symptoms. There is significant improvement in quality of life at 6 and 12 months after surgery compared to the pre-operative values as measured by two validated questionnaires: IIQ-7 and UDI-6. Further, nearly all patients experienced an improvement in their quality of life on a 7-point verbal scale, which is maintained 1 year after surgery.

Concluding Message

The results of this combined analysis from two North American multi-center, prospective studies using the transobturator procedure using a low elasticity polypropylene midurethral sling is both safe and effective in the treatment of female mixed and stress urinary incontinence.

References

1. Delorme E. Transobturator urethral suspension: a minimally invasive procedure to treat female stress urinary incontinence. Prog Urol 2001; 11:1306-13013

Specify source of funding or grant	**Coloplast sponsored studies**
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	**Protocols were approved by the Ethics Committees at each of the 8 total centers involved in these two multi-center studies:** **1) Cleveland Clinic - Florida IRB, Weston, FL** **2) St. Mary's Good Samaritan IRB, Centralia, IL** **3) Univ of Southern California IRB, LA, CA** **4) Schulman Associates IRB, Fort Wayne, IN** **5) Human Research Protection Office, St. Louis, MO** **6) Univ Medical Center of Southern Nevada IRB, LV, NV** **7) LaVeta Surgery Center IRB, LA, CA** **8) HCA-HealthOne LLC IRB, Denver, CO**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**