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STRESS URINARY INCONTINENCE TREATMENT USING A SPECIALLY DESIGNED SUB URETHRAL SUPPORT URETEX ® – RESULTS AT 1 YEAR FROM A MULTICENTER PROSPECTIVE STUDY.

Hypothesis / aims of study

Stress urinary incontinence (SUI) treatment using a tension free urethral support has become a routine procedure. This multicenter prospective study was designed to evaluate the efficacy and safety of a second generation device specially designed for the treatment of Stress Urinary Incontinence. Introduced on the market in 2001, Uretex® combines the validated concept of a macroporous monofilament polypropylene sling to unique properties of stability (minimizing curling and the release of particles) and elasticity (1). Moreover its universal ancillary system allows the placement of the sling through various approaches (2).

Study design, materials and methods

The study included a consecutive series of 256 patients with mean age of 57 years [range 29-94 years], surgically treated for Stress Urinary Incontinence (SUI) between January 2001 and September 2002. 108 patients (42 %) had previous urinary or genital surgery (hysterectomy 59 [23 %], vaginal prolapse 24 [9.4 %], cysto-cervicopexy 20 [7.8 %], sling 5 [2 %]). A specially designed tension-free polypropylene monofilament mid-urethral support (Uretex® Sup – Sofradim) was used via a retropubic implant method. The surgical procedure was carried out under general anesthesia in 145 (56.6%), spinal anesthesia in 93(41.4%) and local anesthesia in 5 (2%).
Concomitant procedures for a variety of prolapse conditions were performed in 43.4 % of study cases.

Results

Peri operative complications were limited to 14 bladder perforations (5.4%), all recognized at the time of the procedure, and 3 blood loss over 200ml (1.2%) . 239 procedures (93.4%) were complication free. No patients experienced blood loss greater than 300 cc. No vascular, bowel or nerve injury was reported.

Peri operative complications	nb cases	%
none	239	93.4 %
Bladder perforation	14	5.4 %
Blood loss> 200 cc	3	1.2 %

During the follow up, no infection and no migration of the tension-free sling support was detected. Post operatively, reported events included 2 haematomas in the space of Retzius (0.8%), 13 urinary tract infections (5.1%), 6 acute or persistent dysurias (2.3%) necessitating sling section in one case at 7 days post procedure and in 5 cases at 3-18 months post procedure (At the end of follow up, 2of these patients were considered cured or significantly improved). All cases of dysuria were observed in the early phase of the study. 36 patients (14%) experienced temporary dysuria, all of which resolved within 2-3 months.
97.2% of patients (249) have achieved one year follow up and were assessed at time of this report. At mean follow up of 16 months [range 8-31 months], 93.6% of patients were cured or significantly improved. 16 patients (6.4%) were considered failures, including 9 urge incontinence, 6 persistent SUI (4 after a sling section related to a sling over tension), and finally 1 sphincteric insufficiency. No pain related to sexual activity was reported

Clinical Results at 12 months		
• Cured or significantly improved	233	93.6%
• Failure	16	6.4 %
- Persistent SUI	2	0.8 %
- Persistent SUI after sling section	4	1.6 %
- Urge incontinence	9	3.6 %
- Sphincteric insufficiency	1	
• Dyspareunia	0	
• Sepsis	0	

Interpretation of results

Urethral support with the Uretex® Urethral Support System is a safe and effective alternative to conventional sling and suspension procedures for SUI. The developed ancillary allows easy detection of peroperative bladder perforation and the specific knitting of the sling reinforce the stability and tolerance of the device (1,2).

Concluding message

The results of this specially designed Urethral Support System favorably compare with those already published and need to be confirmed by long- term follow-up.

References

1. Pariente J.L. et al. Prog. Urol., 2002, 12, supp. 1, 36A
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