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THE SUBURETHRAL SLINGPLASTY EVALUATION STUDY IN NORTH QUEENSLAND (SUSPEND): A RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

To compare the safety and efficacy of 3 different types of suburethral slings (TVT, IVS and SPARC) for the treatment of urodynamic stress incontinence.

Study design, materials and methods

Following ethics approval and informed consent, 195 (3x65) patients with urodynamic stress incontinence were randomly assigned to undergo suburethral slingplasty with TVT (Johnson & Johnson), IVS (Tyco Healthcare), or SPARC (American Medical Systems). The subjects were blinded to the type of sling implanted.

The suburethral slings were implanted with the method described by Ulmsten et al [1] with exception to the following: (1) most cases were performed under general anaesthesia and, (2) the cough test was not performed and a space wide enough to allow the passage of Metzenbaum scissors was left between the sling and the urethra.

The main outcome measures were: (1) operative and short-term complications, (2) pre- and post-operative symptomatology and (3) pre- and post-operative urodynamic studies findings.

Randomization proved to be successful in that the 3 groups of patients were comparable in terms of age, vaginal parity, menopausal status, past history of anti-incontinence or prolapse surgeries, mode of anesthesia, concomitant procedures and pre-operative urodynamic parameters.

Results

There was no significant difference between the incidence of urethral injury, bladder injury or prolonged catheterisation between the 3 groups. However, in the SPARC group there was a trend for urethral injury to occur more frequently (4.9% vs 0% & 0%; p=0.11), and also a statistically significant increased rate of sling protrusion (13.1% vs 3.3% & 1.7%; p=0.04) when compared to TVT and IVS. Subjectively, there was no significant difference between stress urinary incontinence cure rates (78.7%, 78.3%, 75.0%; for TVT, IVS and SPARC respectively; p=0.83), patient satisfaction rates (83.6%, 83.3%, 85.9%; p=0.99) or incidences of de novo urinary urgency (3.3%, 8.3%, 5.0%; p=0.90) and urge urinary incontinence (6.6%, 1.7%, 10.0%; p=0.06). In patients who underwent postoperative urodynamics studies ($\geq$90%), no significant differences in urodynamic stress incontinence cure rates (87.9%, 81.5%, 72.4%; p=0.11); incidences of de novo detrusor overactivity (3.4%, 3.7%, 1.7%; p=0.26) or dysfunctional voiding (5.2%, 3.7%, 6.9%; p=0.76) were observed. Patients in all 3 groups were found to have slight reductions of maximal and average urinary flow rates following suburethral slingplasty.

Interpretation of results

The overall cure, as well as subjective outcomes, demonstrate a high success rate for all 3 slings. As the TVT and SPARC slings are very similar in vitro [2], we postulate that the increased incidence of sling protrusion and the trend for SPARC patients to have slightly lower objective cure rates to be related to the implantation method of the SPARC sling. Due to the elasticity of the TVT, when the plastic sheath is being removed after sling placement, there is a “pre-tensioning” effect that causes the tape to “spring” back up in a caudal direction. The tensioning suture of the SPARC sling limits this effect, and hence when placed with similar tension as the TVT, tended to become looser. With the IVS tapes which are much less elastic than TVT and SPARC slings, the surgeon would naturally leave it in a more “snug-fit” fashion under the urethra, and thus not become as loose as a SPARC sling.

Although there was a trend for slight differences in overactive bladder symptoms between the 3 groups, the number of patients affected was small and the clinical significance is unclear.

Otherwise, no significant differences could be observed between the monofilament (TVT, SPARC) and multifilament (IVS) slings.

Concluding message

All 3 slings are generally quite successful for the treatment of urodynamic stress incontinence. The SPARC tapes showed more sling protrusion complications, probably as a result of the insertion method used in this study. We recommend the cough test to be performed for SPARC sling placement to allow for more accurate sling tensioning.

Reference:

1. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J* 1996; 7:81-6
2. Mechanical properties of urogynecologic implant materials. *Int Urogynecol J* 2003; 14:239-43