

TVT VS. SPARC: A CASE- CONTROL TRIAL

Aims of Study

Midurethral synthetic slings have achieved widespread popularity since their introduction in the mid- 90's, a development that is all the more remarkable for the high complication rates reported for synthetic slings in the past (1). It appears that both unusual biomechanical properties (2) and implantation technique may be responsible for the high biocompatibility of suburethral slings. Not surprisingly, several competitors now offer alternatives to the original tension- free vaginal tape (TVTTM, Gynecare). The most similar in biomechanical properties (SPARCTM, AMS) is the subject of this case- control series aimed at assessing sling placement and postoperative voiding function as well as subjective and objective cure rates for stress incontinence.

Methods

Patients after TVT and Sparc surgery performed by two of the authors were invited for review in the context of an external postoperative audit conducted by the first author. Insertion technique complied with the manufacturers' instructions (cranio-caudal insertion for Sparc, caudo- cranial insertion for the TVT). Follow-up appointments consisted of a standardized interview, free flowmetry, and translabial ultrasound for estimation of residual urine, position and mobility of tape and bladder neck relative to the inferoposterior margin of the symphysis pubis (3). An interobserver series conducted by two of the authors confirmed good repeatability (%CV of 0.08 to 0.26 for tape position and %CV of 0.12 for total tape mobility).

Results

37 Sparc patients were compared to 69 women who had undergone TVT surgery. They were matched for age, body weight, preexisting urge incontinence, preoperative maximum flow rate centile, concomitant prolapse surgery and length of follow-up which was 0.6 (range 0.1- 1.5) years on average. There were no significant differences for subjective cure/ improvement (92% after Sparc vs 85% after TVT), satisfaction rate (83% vs 86%) and symptoms of stress (24% vs. 19%) or urge incontinence (57% vs. 59%), frequency or nocturia. There were trends towards less symptoms of voiding dysfunction after Sparc, although this reached significance only for the symptom of poor stream ($p= 0.009$).

Parameter	Sparc (n= 37)	TVT (n= 69)	P=
x-r	1.94 (SD .56) cm	.82 (SD .70) cm	< 0.001
y-r	1.80 (SD .43) cm	1.65 (SD .38) cm	0.07
x-s	-.21 (SD .88) cm	-.43 (SD .58) cm	0.17
y-s	1.46 (SD .47) cm	0.91 (SD .55) cm	< 0.001
Tape mobility	2.25 (SD .78) cm	1.57 (SD .64) cm	< 0.001

Table 1: Ultrasound parameters of tape position and mobility after Sparc and TVT placement (2- sample t- test). x-r, yr: vertical and horizontal distance between tape and inferoposterior symphyseal margin at rest, x-s, ys: same measurements on Valsalva.

The clinical stress test was positive in 8/37 Sparc vs. 4/69 TVT patients ($p= 0.019$). Postoperative voiding function differed significantly, with an average drop in maximum flow rate centiles of 21.8 (SD 29) after TVT and an increase of 1 (SD 32.7)

centile point after Sparc ($p= 0.001$). Marked differences were also observed in tape position and mobility: The Sparc is situated more cranial at rest and further from the symphysis pubis on Valsalva, and it moves a greater distance on Valsalva (see Table).

Conclusions

It appears that there are a number of significant differences in medium- term outcomes after TVT and Sparc. Differences in tape position at rest are likely due to the insertion mode (cranio-caudal with the Sparc, caudocranial with the TVT). The absence of voiding impairment and the increased rate of positive clinical stress tests after Sparc is more difficult to explain. The authors would like to hypothesize that the central suture used with Sparc tapes could prevent the pretensioning that is seen with TVT tapes on removing the plastic sheath after tape adjustment. This hypothesis is also supported by the markedly greater tape mobility in vivo despite similar in vitro characteristics (2).

The higher likelihood of a positive clinical stress test with the Sparc does not seem to impact on subjective satisfaction and cure/ improvement rates which may be due to a reduced number of complaints arising from voiding dysfunction.

A randomized controlled trial is planned to further elucidate these matters.

References

- 1 Int Urogynecol J 1997; 8(2):105-115.
- 2 Neurourol Urodyn 2001; 20(4):530-532.
- 3 Neurourol Urodyn 2000; 19 (4); 393- 394