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Dietz H P[1], Barry C[2], Lim Y[2], Rane A[2]
1. RPAH, 2. Townsville Hospital

2D AND 3D ULTRASOUND IMAGING OF SUBURETHRAL SLINGS: DATA FROM THE 'SUSPEND' RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

Suburethral slings have become the most commonly peformed anti- incontinence procedure in many developed countries. Three implants account for the majority of such surgery in Australia: TVT (Gynecare J+J), SPARC (American Medical Systems) and IVS (Tyco Healthcare). The aim of this study was to determine whether there are any differences in position and mobility of implants, and whether differences could explain any variations in flowmetry data or subjective cure and satisfaction.

Study design, materials and methods

In a prospective randomized controlled trial, 196 women were randomized to TVT (n=67), IVS (n= 64) or SPARC (n=64). 17 women required a second procedure affecting the original sling- with 5 women undergoing insertion of a second tape, and 12 requiring tape trimming for erosion or division. One infected tape was removed. Of the remaining 179 women, 135 (53 TVT, 47 IVS and 35 Sparc) were seen for an interview and ultrasound imaging within 19 months of their procedure (75%). 2D and 3D pelvic floor ultrasound were performed using a Philips ATL HDI 4000 system with 7-4 Mhz volume transducer. 2D measurements for tape position and mobility were obtained supine and after bladder emptying, with the most effective of at least three Valsalva manouevres used for evaluation. Tape position was determined relative to bladder neck and inferoposterior symphyseal margin. The method has been described elsewhere in detail and is highly reproducible (ICC 0.85- 0.93) (1). 3D analysis was carried out at a later date, on a PC with proprietary software (Kretz 4D View 2000, Kretz Medizintechnik, Zipf, Austria). Assessors of ultrasound data were blinded against group allocation.

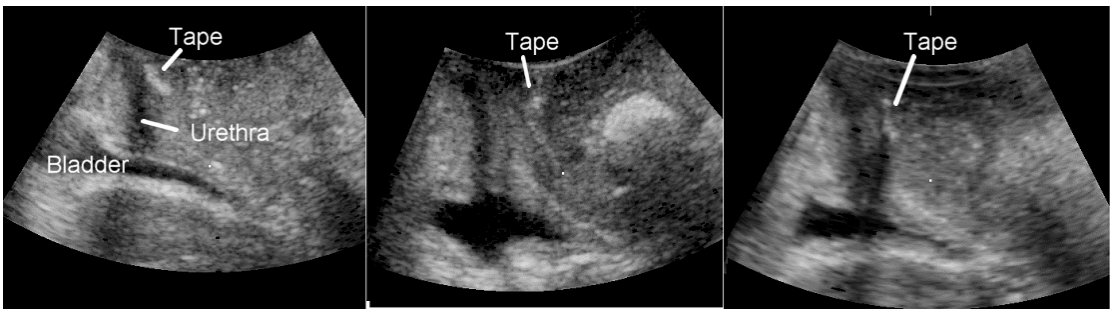

Figure 1: Midsagittal 2D translabial ultrasound of TVT, IVS and Sparc (from left to right).

Results

Randomization resulted in good matching for all significant preoperative parameters (age, parity, previous anti- incontinence or prolapse surgery, preop. urge incontinence and detrusor overactivity, preop. flowmetry indices). The same was true for intraoperative parameters such as type of anaesthetic and concomitant surgery, and length of followup (0.2- 1.6 years, mean 0.79). There were no significant differences in subjective cure of stress incontinence (83-94%) or satisfaction rates. Reported symptoms, including those of voiding dysfunction, did not vary between groups. All tapes could be imaged by translabial ultrasound, although appearances varied. TVT and Sparc are highly echogenic, with the Sparc generally flatter and of wider weave. The TVT often assumes a c shape on Valsalva which is less marked with the Sparc. The IVS seems smaller in craniocaudal dimensions, and generally less echogenic (see Fig. 1). Figure 2 shows appearances in the axial plane.

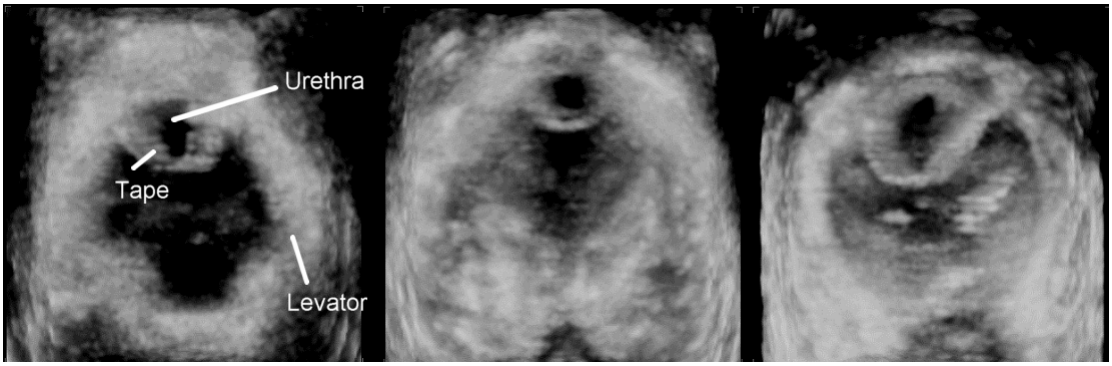

Figure 2: 3D pelvic floor ultrasound of TVT, IVS and Sparc (from left to right) in the axial plane.

Imaging parameters such as tape position and mobility were also similar (see Table), with a trend towards greater horizontal distances between tape and symphysis pubis and greater horizontal tape mobility in the SPARC group. Total tape mobility did not differ. These results did not change when all reoperated patients were included.

Parameter	***TVT (n=53)***	***IVS (n= 47)***	***Sparc (n=35)***
x	*1.71 (.55)*	*1.80 (.47)*	*1.65 (.35)*
y	*1.15 (.63)*	*-.99 (.63)*	*-1.34 (.48)**
x-r	*1.09 (.60)*	*.94 (.54)*	*1.13 (.47)*
y-r	*1.66 (.34)*	*1.82 (.45)*	*1.78 (.34)*
x-s	*-.69 (.47)*	*-.78 (.64)*	*-.68 (.48)*
y-s	*.80 (.57)*	*.79 (.42)*	*1.06 (.53)**
total tape mobility	*2.03 (.65)*	*2.06 (.79)*	*2.02 (.41)*

Table 1: *Translabial imaging of suburethral tapes. X and y refer to distances between inferior tape margin and bladder neck,x -r and y-r to distances between tape and symphysis pubis at rest; x-s and y-s refer to same on Valsalva. *P<0.05 for ANOVA and comparison IVS- Sparc.*

Interpretation of results

In view of previous data demonstrating in vitro properties (2) and significant differences of tape position and mobility between SPARC and TVT (3), the results of this randomized controlled trial at first appear puzzling. As the IVS is less elastic than the other implants (2), one would expect a less mobile tape and greater voiding impairment. This was not the case. However, the insertion technique in this trial did not include the cough test for adjustment. Tapes were left very loose, with enough space between tape and urethra for the passage of Metzenbaum scissors. This results in placement significantly looser than with adjustment according to the Ulmsten/ Nilsson technique, and TVT insertion in this study resulted in less reduction of flowmetry indices than previously reported.

As regards the SPARC, the data obtained in this study is more consistent with previously published results. The SPARC carries a central suture which prevents pretensioning of the tape on adjustment. Consequently, one would have expected the SPARC to be at the mobile end of the spectrum.

Concluding message

Under the conditions of loose insertion without cough test adjustment, the three tested implants result in comparable clinical and anatomical outcomes.

References

1 Ultrasound Obstet Gynecol 2004; 23: 80-92
2 Int Urogynecol J 2003; 14: 239- 243.
3 Int Urogynecol J 2004, in print