

RANDOMIZED CLINICAL TRIAL COMPARING SPARC AND TVT PROCEDURE FOR THE TREATMENT OF SUI: PRELIMINARY REPORT ON PERI-OPERATIVE AND SHORT TERM COMPLICATIONS

Aims of Study

A randomized prospective clinical trial to compare SupraPubic ARCh tape (SPARC) versus Tension-free Vaginal Tape (TVT) for the treatment of stress urinary incontinence (SUI). Peri-operative and short term complications were analyzed.

Methods

Patients presenting with SUI were evaluated with history, physical examination, cystoscopy and complete urodynamic studies (UDS). They were randomized to undergo SPARC or TVT procedure. Peri-operative information was obtained from standardized operative reports filled by the surgeon immediately post-operatively. In addition, Anesthesia and nursing reports were used. All patients were re-evaluated at 4 weeks, and when possible at 6 and 12 months post-operatively.

Results

Eighty-four women with SUI were recruited and consented for the study. Forty-one patients were randomized into the SPARC group and 43 into the TVT group. Both groups had similar baseline characteristics. The mean ages were 62.6 and 60.4 for SPARC and TVT, respectively (2p=0.4). The number of patients with a particular grade and type of SUI in each group is indicated in the table below. The mean pre-op pad test was 27.8g and 29.3 g for the SPARC and TVT groups, respectively (2p= 0.86). 83% and 72% of patients received spinal anesthesia in SPARC and TVT groups, respectively. There was no difference in mean OR time with 32.3min and 35.6min for SPARC and TVT groups, respectively (2p=0.51). The bladder perforation rate was the same in both groups with 10 patients in each group. The median estimated blood loss was the same for both groups (0-50cc category). More patients in the TVT group 22 (51%) compared with the SPARC 13 (32%) required peri-operative analgesia during their hospital stay. The median hospital stay was the same for both groups with a median of one night. Complete retention was seen in 2 SPARC and 4 TVT patients. However, this was not statistically significant ($\chi^2=0.62$; $p \leq 1$). Two in each group required re-operation to loosen the tape after 3 days. Other complications included: removal of eroded SPARC in a patient; pelvic infection in a patient necessitating intravenous antibiotics and percutaneous drainage. Another patient developed fever on POD#1 and was treated medically.

Table 1: Distribution of patients according to grade and type of SUI:

		SPARC	TVT
Grade of incontinence (Stamey classification)	1	4 (9.7%)	4 (9.3%)
	2	26 (63.4%)	27 (62.8%)
	3	11 (26.8%)	12 (27.9%)
Type of incontinence (Blaivas classification)	1	1 (2.4%)	1 (2.3%)
	2a	27 (65.9%)	22 (51.2%)
	2b	6 (14.6%)	9 (20.9%)
	3	7 (17.1%)	11 (25.6%)

Conclusions

SPARC and TVT have similar peri-operative and short term complications including hospital stay, bladder perforation, operative bleeding, and urinary retention. However, both post-operative infections occurred in the SPARC group.