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Randomized Clinical Trial Comparing Suprapubic Arch Sling (SPARC) and Tension-Free Vaginal Tape (TVT): One-Year Results

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Abstract

Purpose: Suprapubic Arch sling (SPARC) has been initially presented as being comparable to Tension-free Vaginal Tape (TVT) without published trials. To test the safety and efficacy of this new product, we designed a prospective, randomized clinical trial with a minimum follow-up of 1 year.

Materials and methods: 84 women presenting with Stress Urinary Incontinence (SUI) were randomly assigned to SPARC or TVT as a minimally invasive mid-urethral sling procedure. All patients were re-evaluated at 1, 6, and 12 months. Symptom assessment, Incontinence Impact Questionnaire (IIQ), physical examination, Uro-Dynamic Studies (UDS) and 1-hour pad test were repeated at 1-year follow-up.

Results: 41 patients were randomized to SPARC and 43 to TVT. The two groups had similar baseline characteristics. Both procedures resulted in similar peri-operative complications: bladder perforation (24% vs. 23%), median estimated blood loss (0–50 ml), median hospital stay (1-night), post-operative analgesia, and persistent urinary retention necessitating tape resection (2 patients in each group). There were three other complications in the SPARC group: tape erosion, infected pelvic hematoma, and urinary tract infection. At 12 months, there was no statistically significant difference between SPARC and TVT, in terms of objective cure rates as determined by 1-hour pad test of less than two grams (83% vs. 95%; $p \leq 0.1$; 12% difference, 95% CI: 25.4% to −1.4%) and subjective cure rates as determined by IIQ scores (49.9 ± 25.6 vs. 45.3 ± 18.4; $p = 0.46$).

Conclusions: At 1-year follow-up, there is no statistically significant difference between SPARC and TVT. Longer follow-up is needed to confirm these results.

Keywords: Stress urinary incontinence; Tension-free vaginal tape; Suprapubic arch sling; Efficacy trial; Randomized clinical trial

1. Introduction

It is estimated that 10.6% of adult women suffer from varying degrees of Stress Urinary Incontinence (SUI) [1]. In addition to the social implications, this condition costs $11.2 billion annually in the USA [2]. A variety of retropubic and transvaginal surgical techniques have been developed to restore support to the urethral sphincteric apparatus. However, there is no consensus about the best procedure [3]. Furthermore, morbidity and convalescence issues have stimulated a search for less invasive procedures. In 1996, Ulmsten developed Tension-free Vaginal Tape (TVT), a minimally-invasive procedure based on the "hammock hypothesis" of DeLancey [4,5]. As new procedures are introduced, the initial results focus on success. Ulmsten, in his sentinel paper, claimed

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a high success rate of 85% with "no complications" [5]. This led to a dramatic increase in the number of TVT procedures performed [6–9]. Recent retrospective data indicate that TVT is not without complications [8,10]. Therefore, modifications of the original TVT procedure have been developed.

Suprapubic Arch sling (SPARC) is one such modification, where needles are driven from the suprapubic region to the vagina, in the opposite direction to TVT needles. The procedure is proposed to reduce the intra-operative complications of TVT, such as bladder perforation and retropubic bleeding, since the needles follow the curvature of the symphysis pubis, and theoretically avoiding important adjacent structures. SPARC has been presented as being comparable to TVT without published trials. To test the safety and efficacy of this new product, we designed a prospective, randomized clinical trial with a minimum follow-up of 1 year.

2. Materials and methods

2.1. Endpoints of the study

The 1-hour pad test was chosen upon the recommendations of the International Continence Society. Weight gain of up to 2 g may result from weighing errors, sweating or vaginal discharge, whereas a loss of <1 g is within experimental error and the patient is considered continent [29]. Therefore, in this trial, 1-hour pad test of ≤ 2 g was considered as an objective cure, and this was the primary endpoint of the study. As a secondary endpoint, we have used the Incontinence Impact Questionnaire (IIQ) of Shumaker, where a score of less than 50 would be representative of good Quality of Life (QoL), between 50 and 70 would be moderate QoL, and greater than 70 would be indicative of poor QoL [11,12,28]. Furthermore, IIQ has been tested in our population with moderate test-retest reliability and good internal consistency [12]. Therefore, the Shumaker IIQ was used to determine subjective cure rates as a secondary endpoint in this trial.

2.2. Sample size determinations and statistical analysis

Since the primary endpoint of the trial was objective cure rate as defined by the 1-hour pad test of ≤ 2 g, the success rate of 90% for TVT was used. It was decided that 30% difference in success rate between the two procedures would be clinically significant. Therefore, to detect 30% difference, with an alpha value of 0.05 and power of 80%, at least 38 subjects in each group is required. This number is increased to 42 per group to account for 10% dropout during the follow-up period.

Sample size determination was performed using PS software version 2.1.31 by Dupont and Plummer [31]. Data were analyzed using the SAS software, version 7. Student's *t*-test and ANOVA were used for continuous variables. Chi square and Fisher exact tests were used for proportions. Two-sided *p* values were calculated.

2.3. Inclusion and exclusion criteria

This prospective, randomized clinical trial was performed at a single institution (Jewish General Hospital). Women were eligible for the trial if they had Urodynamic Stress Incontinence (USI) with or without pelvic organ prolapse. All pre-operative parameters were recorded by a single experienced female urologist (JC). Detailed history was obtained with patient age, menopausal status, parity, co-morbid medical conditions, previous incontinence or pelvic surgery, number of pads per day, hormone replacement therapy, and incontinence history, including incontinence grade and quality of life assessment with IIQ [11,12].

On physical examination, in addition to the Blaivas type of incontinence, estimated by the degree of bladder neck and urethral mobility, the presence of rectocele, enterocele, cystocele and pelvic organ prolapse was assessed [30]. Multichannel urodynamic study (UDS) of each patient included: flowmetry, post-void residual, cystometogram, leak point pressure and 1-hour pad test. These were done to make sure that all patients had stable bladder function and good flow rates without clinically significant post-void residual. Women with previous failed anti-incontinence surgeries or bulking agents treatments were also eligible for the study. Women with mixed urinary incontinence were not excluded as far as their cystometrogram showed normal capacity, compliance and no uninhibited contractions. Women with obstructive, unstable bladder functions, or neurogenic bladders were excluded from the study. Urinary tract infection was temporary exclusion criteria.

2.4. Randomization and follow-up

Patients were blinded to the procedure and had envelope randomization immediately prior to the start of the surgery. Peri-operative information was obtained from pre-printed operative reports filled by the surgeon immediately post-operatively. This included type of anesthesia, operative time (incision to closure), estimated blood loss (0–50 ml, 50–250 ml, and >250 ml), and bladder perforation (one or both sides). In addition, information from anesthesia and nursing reports were also used.

Post-operatively, all patients were re-evaluated by symptom assessment and physical examination at 1, 6 and 12 months. Furthermore, at 12 months, all patients, except 1 TVT patient who had died of an unrelated cause, completed the IIQ and underwent UDS and the 1-hour pad test by a dedicated UDS nurse (BS), who was blinded to the procedure.

2.5. Surgical techniques

The TVT procedure was carried out as described by Ulmsten, with the exception of the type of anesthesia [5]. TVT sets are manufactured by Gynecare, a division of Ethicon, Inc. (Sommerville, NJ, USA). SPARC sets are manufactured by American Medical Systems, Inc. (Minnetonka, MN, USA). Both techniques have been previously described [5,10].

Anterior and posterior colporrhaphy, and vaginal hysterectomy were performed simultaneously in symptomatic women with pelvic organ prolapse. A 16F Foley catheter was left *in situ* until complete patient recovery from anesthesia. Patients were invited to urinate before leaving the hospital, and a bladder scan ensured that post-void residual was <150 ml. In cases of higher residual volumes, an indwelling urethral catheter was re-inserted and the patient was followed at the clinic within 48 hours for a voiding trial and measurement of post-void residual.

3. Results

Out of 93 eligible women with SUI, only 84 agreed to participate and gave informed consent for this study that took place from April 2001 till December 2002. Nine patients declined to participate in the study