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Female Urology - Incontinence

The Suprapubic Arch Sling Procedure for Treatment of Stress Urinary Incontinence: A 5-Year Retrospective Study☆

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Abstract

Background: Up to now, numerous similar products concerning the surgical treatment of female stress urinary incontinence (SUI) have been developed.
Objective: To assess the long-term efficacy and safety of the suprapubic arch (SPARC) sling system in women with SUI.
Design, setting, and participants: This was a long-term retrospective study. All patients underwent a comprehensive pre- and postoperative evaluation. Forty-six women were available for clinical follow-up investigation after SPARC sling placement.
Intervention: Eighty-six women with SUI and a positive cough test underwent SPARC sling placement between June 2001 and January 2004.
Measurements: At follow-up all 46 patients underwent a cough test, a pad test, uroflowmetry, and sonographic postvoid residual volume measurement. Women rated their subjective continence status (continent, slightly incontinent, incontinent) and were asked if they would undergo the procedure again and if they would recommend it to a friend. Objective cure was defined as a pad weight 0–1 g and a negative cough test. Subjective cure was defined as no use of pads.
Results and limitations: The median follow-up was 5.2 yr. The objective cure rate was 76%; the subjective cure rate was 52%. Sixty-three percent of the patients rated themselves as continent, 33% as slightly incontinent, and 4% as severely incontinent. Most of the women (98%) would recommend the SPARC procedure to a friend and would undergo the procedure again.
Conclusions: The SPARC sling system is an effective and safe procedure for the treatment of female SUI. Patient satisfaction is independent of complete dryness.

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1. Introduction

Stress urinary incontinence (SUI) is the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing [1]. Surgical treatment of SUI in women offers relatively high success rates and immediate improvement of SUI symptoms. The Female Stress Urinary Incontinence Clinical Guideline Panel of the American Urological

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Association found that pubovaginal slings, midurethral tapes, and retropubic suspensions were the most effective surgical techniques for SUI in women [2]. Up to now, numerous similar products have been developed, which always raises the question of the ideal procedure. Several long-term outcome data about the efficacy and safety of the tension-free vaginal tape (TVT) technique [3–6] and only a few short-term outcome data concerning the suprapubic arch (SPARC; American Medical Systems, Minnetonka, MN, USA) placement are currently available [7–13]. The SPARC sling system, approved by the US Food and Drug Administration in 2001, represents an advancement of the TVT, which is the most popular and widely used sling system [14]. Both sling materials consist of a loosely woven monofilament polypropylene mesh. The major difference between SPARC and TVT is trocar size and route of delivery. TVT trocars are passed through a vaginal to a suprapubic route, whereas the thinner SPARC trocars are passed from a suprapubic approach through two small incisions in an antegrade fashion to the vagina. The SPARC sling procedure was developed to decrease bowel, lower urinary tract, and vascular injuries that sometimes occur with the upward passage of the TVT trocar [15]. The aim of this study was to generate long-term outcome data concerning the SPARC sling system.

2. Materials and methods

This retrospective study was approved by the Ethics Committee of the Medical University of Graz. We reviewed a total of 86 cases with urodynamically and clinically proven SUI who underwent SPARC sling placement between June 2001 and January 2004. Women were eligible for surgery if they had predominant SUI symptoms, a positive cough stress test, and a bladder capacity >200 ml. Patients with previous failed incontinence surgery, mixed urinary incontinence (MUI), or previous gynaecological surgery were included. Women with neurologic findings or vaginal support defects greater than second grade according to the Pelvic Organ Prolapse Quantification system were excluded [16]. All patients underwent a comprehensive preoperative evaluation including medical history, physical examination, complete multichannel urodynamic study in sitting position, urinalysis, and a 3-d micturition diary. Additionally, a cystoscopy, which is a standard procedure at our department prior to surgery, was performed. Patients who showed MUI symptoms in the urodynamic examination were put on anticholinergic medication and then underwent the urodynamic investigation again. If these women still had marked predominance of stress incontinence symptoms during their second urodynamic investigation, they continued with anticholinergic treatment. As soon as the urgency component resolved, even if the stress incontinence symptoms remained, they went on to surgery. Our study cohort consisted of 46 of 86 women who were available for follow-up investigation in 2007. At follow-up all patients underwent a cough test in standing position and a validated pad test according to Hahn and Fall with an ultrasound-controlled bladder volume of approximately 200 ml at the beginning of the investigation [17], a free uroflowmetry, and a sonographic postvoid residual (PVR) volume measurement. A 3-d micturition diary was also evaluated. A urologist who had not taken part in the original surgery assessed the questionnaire. Women assessed their subjective continence status using a simple questionnaire (continent, slightly incontinent, incontinent). Additionally, we asked two separate questions regarding whether they would undergo the surgery again and whether they would recommend this procedure to a friend.

Objective cure was defined as pad weight 0–1 g and a negative cough test in a standing position. Subjective cure was defined as no use of pads according to the micturition diary. Improvement was defined as urine loss only during cough test, a pad weight of >1–5 g, and overall patient satisfaction. Patients who did not meet the criteria just described were considered surgical failures. The evaluation of missing data on objective and subjective cure rates was done by calculating the cure rates, with the assumption that all patients lost to follow-up were continent or were surgical failures.

A written informed consent was obtained from all patients. The recruited population was consecutive and therefore without selection bias.

2.1. Statistical analysis

Patients' characteristics are described with mean and standard deviation for normally distributed data and with median and percentile for not normally distributed data, respectively. To assess differences between initial values and date last seen, χ^2 and Wilcoxon signed rank tests were performed. The p values (two sided) ≤ 0.05 were considered significant. Statistical analysis was performed using SPSS 16.0 (SPSS Inc, Chicago, IL, USA).

3. Results

Mean age was 59 ± 11 yr at surgery. Mean preoperative duration of incontinence was 10 ± 9 yr. Of the 46 patients, 3 were nullipara (6.5%), 11 unipara (23.9%), and 32 multipara (69.6%). Median follow-up was 5.2 yr (first quartile: 4.9 yr; third quartile: 5.8 yr). Thirty of 46 women (65.2%) suffered from primary SUI only. Five of 46 (10.9%) had a MUI with remaining predominant stress incontinence symptoms under anticholinergic treatment, and 11 of 46 (23.9%) had recurrent SUI after previous incontinence surgery (Table 1). Table 2 lists the preoperative characteristics and demographics of the 46 patients. The objective cure rate of the 46 patients available for follow-up was 76.1% (35 of 46). Overall, 87% (40 of 46) of patients improved and 13% (6 of 46) deteriorated. The analysis of outcome due to missing data showed an objective cure rate of 40.7% (35 of 86) when assuming that all missing patients were failures, and an objective cure rate of 87.2% (75 of 86) when assuming that all missing patients were cured. The subjective cure rate was 52.2% (24 of 46). The analysis of outcome due to missing data showed a subjective cure rate of 27.9% (24 of 86) when assuming that all missing patients were failures, and 74.4% (64 of 86) when assuming that all missing patients were cured. At follow-up investigation, 78.3% (36 of 46) showed a negative cough test. Of the remaining 10 patients who had a positive cough test, 5 were slightly positive (only a few drops of urine loss during vigorous coughing) and 5 were markedly positive (urine loss during normal coughing). The mean weight of the pad test decreased from 31 ± 37 g at baseline to 1 ± 2 g at follow-up ($p < 0.001$). Pad use per day decreased from an average of 5 ± 2 pads per day preoperatively to 1 ± 1 pad per day at follow-up ($p < 0.001$). Maximum flow rate decreased from 41.3 ± 15.2 ml/s at baseline to 28 ± 11.9 ml/s at date last seen ($p < 0.001$), and no patient had PVR urine. As to the subjective continence status, 63.1% of the patients rated themselves as continent, 32.6% as slightly incontinent, and 4.3% as severely incontinent. Most of the women (97.8%) would recommend the SPARC procedure to

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Table 1 – Previous surgeries

Type of prior incontinence procedure	*n*	%
Anterior colporrhaphy	8	17.4
TVT	1	2.2
Burch	1	2.2
Fascial colposuspension sling	1	2.2
Total	11	24.0
Type of prior pelvic surgery		
Vaginal hysterectomy	9	19.6
Abdominal hysterectomy	6	13.0
Wertheim procedure	3	6.5
Cesarean section	3	6.5
Ovariectomy	3	6.5
Paravaginal repair	1	2.2
Total	24	54.3

TVT = tension-free vaginal tape.

Table 2 – Preoperative characteristics of the patients (*n* = 46)

Characteristics	Mean ± SD (range) or %
Positive cough test	100%
Pads per day	5 ± 2 (2–12)
Pad test, g	31 ± 37 (2–190)
Maximum flow rate, ml/s	41.3 ± 15.2 (16.1–77.6)
Postvoid residual, ml	5 ± 18 (0–80)
Height, cm	165 ± 6 (150–178)
Weight, kg	77 ± 14 (51–105)
BMI, kg/m^2	28.2 ± 5 (17.8–40.1)
Previous incontinence procedures	24%
Prior hysterectomy	32.6%

BMI = body mass index; SD = standard deviation.

a friend. Also, 97.8% would undergo the procedure again. After surgery, the urgency component resolved without need for additional medication in four of the five patients with MUI previously treated with anticholinergic agents, but persisted in one patient, who is still on anticholinergic medication and free of symptoms 5 yr postsurgery. Additionally, 5 of 46 patients (10.9%) reported mild de novo urgency symptoms but refused any medication. One woman had a stroke 3 yr after sling placement and developed a neurogenic overactive bladder with incontinence episodes due to her suprapontine lesion. This patient went on to perform timed voiding. One patient (2.2%) showed an asymptomatic vaginal sling erosion (approximately 1 mm) 4 yr postoperatively. Because of the unexpected finding as part of the study examination, the small size of the lesion, her advanced age, and the total lack of symptoms, no treatment is necessary at this stage, but yearly cystoscopy controls and gynaecological examination will be performed in the future.

4. Discussion

Due to the low number of available comparative studies, very limited information is at hand regarding cure and complication rates associated with different sling materials and techniques [14]. The only available long-term outcome data up to now is on the TVT [3–6]. When comparing the TVT with other retropubic devices such as SPARC, the meta-analysis and comparative studies suggest that the original TVT is slightly more effective in short-term follow-up [7,14,18,19]. Regarding the available short-term SPARC studies, Nazemi et al [10] published an analogue objective success rate of 75.9% according to our objective cure rate (76%). Deval et al [9] reported an objective cure rate of 90.4% and a subjective cure rate of 72%. Rapp et al [20] showed a success rate of 77%. Hodroff et al [11] reported similar results to those found in our study concerning repetition (91%) and recommendation (84%) of the SPARC procedure. Based on our 1-yr results, we can confirm a stable long-term outcome regarding efficacy and safety. Preoperatively, 100% of our patients had a positive cough test. A negative cough test was seen in 76% after 1 yr and in 78% after 5.2 yr. Mean pad weight was 31 g and number of pads was five pads per day at baseline and 1 g and one pad per day after 1 and 5.2 yr. The objective cure rate was 67% at 1 yr and 76% after 5.2 yr. Subjective cure rate was 65% at 1 yr and 52% after 5.2 yr. Our main goal was to compare baseline and long-term results; therefore we refrained from comparing different sets of postoperative results over time to avoid statistical mistakes. Concerning complications found in our current study, we found in 5 of 46 patients(10.9%) de novo urgency after SPARC sling procedure, but none had urge incontinence, which was rather frequently found in other studies [3,4]. Only one woman had an asymptomatic small vaginal sling erosion that did not require any therapy. Complications that occurred directly after SPARC sling procedure and other short-term results have been already published elsewhere [8,12].

Another interesting fact found in our study was the difference of 26% between objective (76%) and subjective (52%) cure rates. Deval et al [9] also noted a difference of almost 20% between objective and subjective cure rates. Nilsson et al [6] reported a difference of 13% in his TVT study. Rodriquez and Raz [21] reported that the distal urethral sling procedure provides high objective (89%) and physician-determined cure rates but a significantly lower patient self-reported subjective cure rate (69%). A possible explanation for these findings might be that objective cure rate gives us a description of patients' continence status at one specific moment, whereas the subjective cure rate represents everyday life.

In our study, there appeared to be a difference between the patients' subjective cure rate (52%) and the percentage of patients who rated themselves as continent (63%) in terms of subjective continence status too. This is probably because our definition of subjective cure rate was much stricter than the patient's subjective impression. Subjective cure was defined as no use of pads during daily activities. However, many women use pads for safety reasons and still feel continent. We were not surprised to see that quite a number of women rated themselves as continent even though they failed to meet the continence criteria. The patients' judgement of being cured may not mean achieving complete dryness but rather reflected the impact of reduction of urine loss on their daily life. We are convinced that this is one of the main conclusions of our study: Patient satisfaction is independent of achieving complete dryness.

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A limitation of our study was the modest follow-up rate because we lost track of nearly half of the 86 patients. One had died; the vast majority (31 of 86) had changed their landline telephones, mostly to mobile phones. These numbers as a rule are not listed in phone books. Therefore, if patients did not respond to letters, we were unable to contact them at all. Eight women refused to participate because they were too frail to come to our clinic for follow-up. Due to the loss of so many patients for follow-up, we felt that an intention-to-treat (ITT) analysis might be appropriate and helpful. The analysis of outcome due to missing data showed an objective cure rate of 40.7% (35 of 86), assuming all missing patients were failures, and an objective cure rate of 87.2% (75 of 86), assuming all missing patients were cured. In relation to our ITT analysis, the results reported for the TVT were similar [3–6]. A further limitation of our study is lack of information regarding female sexual function and quality of life, but these data are on the way and will be reported later. Wide variations in outcomes of new surgical procedures due to different definitions were seen in a literature review [22]. Strict guidelines for evaluation of new surgical procedures would have been preferable. In evaluating the positive and negative aspects of our current study, further investigation is still needed, and the long-term efficacy of all new surgical incontinence procedures remains an important point of interest.

5. Conclusions

Our results indicate that the SPARC sling system is an effective and safe method for the treatment of female SUI with low long-term complication rates and a stable long-term outcome. Furthermore, patient satisfaction is independent of achieving complete dryness.

Author contributions: Stefan Heidler had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Heidler, Primus.
Acquisition of data: Heidler, Primus, Puchwein.
Analysis and interpretation of data: Heidler, Primus.
Drafting of the manuscript: Heidler, Primus.
Critical revision of the manuscript for important intellectual content: Pummer.
Statistical analysis: Ofner-Kopeinig.
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Administrative, technical, or material support: None.
Supervision: Primus.
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