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Operative Complications and Results of the »Sparc« Procedure for Stress Urinary Incontinence

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A B S T R A C T

The aim of this study was to determine the efficacy and operative complications of the suprapubic arc (SPARC) procedure in stress incontinent women with and without previous anti-incontinence surgery. One-hundred and twenty-one patients with stress urinary incontinence (SUI) were treated with SPARC for correction of urethral hypermobility (N=65) and intrinsic sphincter deficiency (N=56) between August 2002 and February 2007. The long-term surgical results, operative complications (bladder injury, retropubic hematoma, de novo urgency and urinary infection) and patients' satisfaction were assessed. The overall complication rate was 9.9% (12/121). The perioperative complication rate was 1.7% including 2 urinary bladder injuries. Significant difference in the overall complications rate was detected between women with and without previous surgery (23/45, 51.1% vs. 6/108, 5.5%, χ^2=49.89, P<0.001). The overall postoperative complication rate was 8.3% (10/121) including 4 de novo urgencies, 4 urinary infections and 2 retropubic hematomas. There were 3 patients with postoperative urinary retention managed conservatively, without voiding difficulties on control visits. The objective cure rate after the follow-up was 86.8% (105/121). In patients with SUI and without preceding vaginal operations SPARC is a good method with low incidence of perioperative complications, promising long-term results and high patient satisfaction.

Key words: *stress urinary incontinence, SPARC, complications, efficacy*

Introduction

The suprapubic arc (SPARC) polypropylene midurethral sling is considered as one of the best surgical treatment methods for women with stress urinary incontinence. The reported success rate of the pubovaginal sling procedures using various materials fluctuated impressively from 80–95%[1,2]. Until recently, the procedure has been reserved for patients who previously failed other surgical treatments, but nowadays the indications are extended and the treatment is widely applied in all types of SUI[2]. Correction of suburethral support with adequate intrinsic urethral resistance is important in achieving continence especially in women with severe intrinsic sphincter deficiency[3,4]. Since the needle passes at the back surface of the symphysis, the risks for lower urinary tract, bowel and vascular injury are outstandingly decreased[5]. In addition, this technique offers the surgeon control of the path of the needle under finger guidance and the exceptional tensioning design allows reducing or increasing the tension after sling positioning. Relatively high percentage of early postoperative complications, well documented in the literature, are mostly associated with the prior abdominal or vaginal surgery[6]. On the other hand, certain dissapointing outcome was correlated with the surgical technique designed to prevent bladder outlet obstruction[7,8]. Some unsatisfactory surgical results of SPARC might derive from the high grade type of SUI coupled with pelvic organ prolapse. Long-term outcome and complications of this surgical procedure regarding the risk of persistent incontinence or bladder outlet obstruction have not been well determined and explained.

The primary objectives of our retrospective cohort study were to establish the safety, efficacy and postopera-

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tive complications of SPARC in women with previous anti-incontinence surgical treatment and in women who underwent SPARC-only operation.

Patients and Methods

A total of 121 women with SUI received SPARC procedure for correction of urethral hypermobility and intrinsic urethral sphincter deficiency. A retrospective cohort study was performed at our institution in the time period between August 2002 and February 2007. All patients were assessed preoperatively by quality of life questionairre, physical examination and urodynamic study. Women were questioned preoperatively with regard to the symptoms of stress and urge incontinence. Out of 121 patients, 65 women had signs of urethral hypermobility, 56 had been diagnosed as intrinsic sphincter deficiency. All types of other vaginal support defects such as cystocoele, rectocoele or uterine prolapse were eliminated from the study. If the urgency was the predominant cause of the incontinence participants were ruled out from the study. All patients had sterile urine before the surgery.

Surgery

The SPARC procedure was performed under general (N=87) or spinal anesthesia (N=34). The propylene sling was positioned under the midurethra into the subcutaneous tunnel which passes at the posterior wall of the symphisis through the endopelvic fascia without fixation to the fascia and without tension until the cystoscopy and provocation test have been completed. After the positioning of the tape the cystoscopy was done to check for the bladder injury. The optimal tension was achieved by two steps afterwards when the bladder was full: first the instrument was placed between the tape and midurethra and then tensioned in order to avoid postoperative retention. Subsequently the continence was attested by deep and intense compression of abdominal wall above the symphisis. If the drops or slight leakage of urine were obtained on the provocation test the tension was clarified as ideal, with no risk for postoperative retention. A Foley catheter was inserted in the bladder for 24 hours in average.

Outcome measures

The incidence of perioperative (bladder injury) and early and late postoperative complications (retropubic haemoatoma, voiding difficulties, infection, urinary retention, *de novo* urgency), operating time, intraoperative blood loss and hospitalization period were obtained. Retention was defined if the residual urine was more than 50 mL after micturition. *De novo* urgency was identified if the frequency, urgency, or urge incontinence developed in patients who lacked urgency before operation and if it persisted more than 30 days after the procedure. Urinary infection was confirmed by the microbiological urine analysis. All patients were followed-up at our Institution 6, 12 and 18 months postoperatively by questionnaire and urogynecologic inspection.

Questionnaire

Objective cure rate was determined from the patients symptoms, physical and urodynamic evaluation at each postoperative visit. Satisfaction rate was assessed from the straightforward questionnaire regarding the postoperative condition, improvement and potential postoperative difficulties. The objective surgical results were classified as cured: without any lower urinary tract symptom, no incontinence on provocation tests; improved: very mild SUI on provocation test at first postoperative visit, frequency, *de novo* urgency and strain to void; failed: moderate to severe incontinence.

Statistical analysis

Statistical analysis was based on Pearson's chi-square test for categorical variables. Probabilities lower than 5% ($P<0.05$) were considered significant. Statistics was done with Statistical Package for Social Sciences, version 11 (SPSS Inc., Chicago, IL, USA) software.

Results

In 98 patients SPARC was the first operation, and the remaining 23 had undergone the abdomino-pelvic operation previously (Table 1). There was no significant difference in the mean age, parity duration of symptoms and hormonal state between the SPARC-only operation group and group with previous surgery. Stress urinary incontinence was identified as either urethral hypermobility (N=65) or intrinsic sphincter deficiency (N=56). The mean operating time was 20 ± 8 minutes (range 11–38 min). After the pubovaginal sling procedure all patients could void volitionally with little residual urine (< 50 mL) on the first postoperative day after the removal of the Foley catheter. The overall complication rate was

TABLE 1
CHARACTERISTICS OF THE PATIENTS WITH SPARC

Patients' characteristics	No (%) of patients (N=121)
Age (mean ± S.D.)	51 ± 8.2
Hormonal age:	
generative age	18 (14.9)
perimenopause	59 (48.8)
postmenopause	44 (36.3)
Parity ± S.D.	2.8 ± 1.4
Previous surgery:	23 (19.0)
abdominal hysterectomy	12 (9.9)
vaginal hysterectomy with colporraphy	6 (5.0)
correction of cystocoele	3 (2.5)
correction of urethral insufficiency	2 (1.7)
Stress urinary incontinence:	121 (100)
urethral hypermobility	65 (53.7)
intrinsic sphyncter deficiency	56 (46.3)

SPARC – Suprapubic arc

9.9% (12/121) (Table 2). Perioperative complications occurred in 2 patients (1.7%) as bladder perforation (N=1) or bladder laceration (N=1) and were both diagnozed during routine cystoscopy. Lacerations were repaired with sutures and perforations were simply drained until the recovery. Bladder catheterization lasted a mean of 2.7 ± 1.9 days. The overall postoperative complication rate was 8.3% (10/121). Early postoperative complications were urinary infection and retropubic hematoma.

De novo urinary tract infection occurred in 4 (3.3%) patients and were immediately treated by appropriate antibiotics. Retropubic hematoma occurred in 2 patients and have been detected on the day after the surgery. In 3 patients urinary retention occurred after removal of catheter so further 10–14 days of catheterisation was necessary. No urinary retention or strain to void occurred on routine check-up controls. The only late postoperative complication, *de novo* urgency was observed in 4 patients (3.3%). Normal vaginal healing has been noticed in all patients. None of the patients required releasing of sling tension and none of them had voiding difficulties or strain to void. Significant difference in the overall complications was detected between women with and without previous abdominal or vaginal surgery (respectively, 9/23, 39.1% vs. 3/98, 3.1%, $\chi^2=39.99$, $P<0.001$) (Table 2).

Bladder injury (perforation and laceration) occurred in patients who had undergone prior surgery. One of them have had prior vaginal hysterectomy and one anterior colporraphy with the correction of sphyncter mechanism. No bladder injury occured in SPARC-only operation group.

De novo urgency and urinary infection appeared more frequently in patients who underwent SPARC as the second operation than in women with SPARC-only operation (3/23, 13.0% vs. 1/98, 1.0%; $\chi^2=6.86$, $P<0.005$) (Table 2).

Hospitalization interval ranged from 2 to 10 days (mean 3.1 ± 1.4).

We achieved the objective cure rate 86,8% (105/121) and improvement was achieved in the remaining 6.7% (8/121). The mean follow-up time was 38 ± 6.4 months. The main postoperative symptom which persisted on the check visits was *de novo* urgency in 4 cases and *de novo* urinary infection in 4 patients. However, patients with *de novo* urgency had higher satisfactory rate on the further follow-up visits. There was no incident of recurrent SUI and none of the patient failed SPARC procedure. Overall satisfactory rate was 81.8% (99/121) including patients with perioperative and postoperative difficulties. When the SPARC was applied to women with pure stress urinary incontinence and no preceding operation the objective cure rate was 87.6% (106/121).

Discussion

According to our results neither persistent urinary retention nor severe SUI were detected after operation in our study. Using the tight instrument, which was placed between the tape and urethra prior to gradual tensioning of the sling we performed routine cystocscopy by stress provocation test. Bladder perforation or laceration in our study occurred in women who previously underwent vaginal hysterectomy and correction of sphyncter mechanism. Altered position of pelvic organs, adhesions, and reduction of retropubic space might give explanation of such feeble consequences. No bladder injury occurred in the patients with SPARC-only operation. Vascular, bowel or nerve injury reported previously, have also not been detected. No infection, erosions or defective healing of the vaginal wall were observed. Two sequels of asymptomatic retropubic hematoma occurred in women with history of abdominal hysterectomy with spontaneous resolution occurring two weeks postoperatively. It is valuable to detect that there were no alterations between the preoperative and postoperative red blood cells count, even in the patients with hematoma or bladder injury. Even though some authors believe that the large size of dilating connector attaching the tape to the SPARC needle is responsible for the increased blood loss[9], we had no such experience. Our most frequent postoperative complications were urinary infection and *de novo* urgency. Previous detrusor instability or chronic inflammation of the bladder enhances the possibility of recurrent infection and need of continuous perioperative antibacterial treatment. Very few cases (3/121) of urinary retention, managed conservatively with no further voiding difficulties, usually reported by prior investigations, were observed in our study[6,10].

Quite contradictory results of the SPARC procedures have been reported by other researchers, mostly regarding the cure rate and perioperative complications[9–11]. High rate of mild to moderate SUI after operation, which was associated with too slight tension of the tape and the fear of outlet obstruction, was observed by some in-

TABLE 2
COMPLICATIONS OF THE SPARC DEPENDING ON HISTORY OF PREVIOUS SURGERY

Group (N)	No (%) of patients with complication				
	overall 12 (9.9)	bladder injury 2 (1.7)	retropubic hematoma 2 (1.7)	*de novo* urinary infection 4 (3.4)	*de novo* urgency 4 (3.4)
SPARC only (98)	3 (3.1)*	0	0	1 (1.0)‡	1 (1.0)‡
Previous surgery (23)	9 (39.1)*	2 (8.7)	2 (8.7)	3 (13.0)‡	3 (13.0)‡

SPARC – Suprapubic arc, SUI – Stress urinary incontinence; * $P<0.001$; ‡ $P<0.005$

vestigators[4,8,12]. High rate of perioperative complications, particularly the bladder injury, might be somewhat explained by surgeon's limited experience with the SPARC method. Furthermore, current reports respected that the risk of bladder injury was higher if there is a history of prior anti-incontinence surgery[6,13]. We have to oppose some previous researches[14] and recapitulate that only slight vaginal defects that originate from breaking or weakness of endopelvic fascia could be managed by SPARC, while high grade protrusion of vaginal wall, cystocoella or other genital descensus accompanied with SUI should be coupled by other surgical techniques rather than complementing the SPARC procedure. In addition, during the past several years concept has been evolved toward a spectrum of patients having explicitly intrinsic sphincter deficiency or urethral hypermobility[9,15]. Uncomplicated hematomas have been reported by previous multicenter trails and, as in our trial, had reliable final outcome[6,13]. Urinary infection and *de novo* urgency have been described by other previous investigations[6,10,16]. This complex problem has been described in the literature with a frequency of 3 to 24%[2]. Postoperative detrusor overactivity manifested as urgency, frequency and urge incontinence, according to previous reports, might result from suburethral nervous or myogenic irritation. Other authors point out that the bladder instability originates not only from the age and hormonal status but from the changes in paraurethral collagen metabolism and sclerosis induced by polypropylene tape[17,18]. We consider that the etiology of *de novo* urgency is multifactorial but mainly derives from unrecognized detrusor instability before the operation rather than from newly developed bladder obstruction.

Comparing with the current studies on the SPARC efficiency we achieved promissing objective overall success rate (86.8%). When we respected surgical results of patients with SUI and without preceding abdominal or vaginal operations objective success rate raised up more (87.6%). Approved by our investigation SPARC has shown up to be available, minimally invasive and rather safe method for SUI. It especially refers to patients without history of previous surgery and uncured urgency, offering a low incidence of perioperative complications and exceptional objective results with high satisfactory rate.

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OPERATIVNE KOMPLIKACIJE I ISHOD METODE SPARC U LIJEČENJU STATIČKE INKONTINENCIJE MOKRAĆE

SAŽETAK

U radu je prikazana učinkovitost metode SPARC i usporedba pojave komplikacija u bolesnica koje su prvi puta operirane SPARC metodom i bolesnica koje su već prethodno imale operacije dna zdjelice. Stotinu dvadeset i jedna žena sa statičkom inkontinencijom operirana je SPARC metodom zbog hipermobilnosti uretre (n=65) odnosno intrinzičnog oštećenja uretralnog sfinktera (n=56) u razdoblju između kolovoza 2002 i veljače 2007 godine. Prikazan je dugoročni ishod, operativne komplikacije (ozljeda mjehura, retropubični hematom, *de novo* urgencija, urinarna infekcija) te zadovoljstvo bolesnica. Ukupan udio komplikacija bio je 9,9% (12/121). Perioperativnih komplikacija bilo je 1,7%, što uključuje 2 ozljede mjehura. Zamijećena je značajna razlika u broju komplikacija između bolesnica koje su prethodno operirane odnosno onih kojima je ovo bila prva korekcija inkontinencije (9/23, 39,1% vs. 3/98, 3,1%, P<0,001). Ukupan broj postoperativnih komplikacija bio je 8,3% (10/121) uključujući 4 *de novo* urgencije, 4 urinarne infekcije i 2 retropubična hematoma. Nije bilo slučajeva trajne postoperativne urinarne retencije niti otežanog mokrenja. Ukupna učinkovitost metode bila je 86,8% (105/121). U bolesnica s čistom statičkom inkontinencijom, a bez prethodne operativne korekcije, SPARC je sigurna metoda, s niskim udjelom komplikacija i zadovoljavajućim dugoročnim ishodom.