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ORIGINAL ARTICLE

Clinical impact of body mass index on the outcome of the SPARC-sling system for the treatment of female stress urinary incontinence

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Abstract
Purpose Of this observational study was to evaluate the clinical outcome of the suprapubic arc (SPARC)-sling system in women with stress urinary incontinence according to body mass index (BMI).
Materials and methods A total of 151 women underwent SPARC between June 2001 and March 2009 at a single tertiary academic center. A complete urodynamic investigation was performed preoperatively. A minimum follow-up of 12 months was required, which left data of 93 individuals for analyses. Participants were divided into the following: A, non-obese (BMI 18.5 to <25 kg/m^2), B, overweight (BMI 25 to <30 kg/m^2), and C, obese (BMI 30–35 kg/m^2). Objective and subjective cure rates, as well as overall success rate and self-perceived severity of bother, were measured. Moreover, participants were asked about their satisfaction after surgery.
Results Median follow-up was 7.6 years. Mean number of pads/day, pad test, and self-perceived severity of bother were significantly reduced overall, as well as in each BMI category ($P < 0.001$). In multivariable analyses, BMI was not an independent predictor of objective cure rate, coded either as continuous ($P = 0.108$) or as categorical variable (P for trend 0.301). Similarly, BMI was not an independent predictor of subjective cure rate, both coded as continuous ($P = 0.475$) and as categorical variable (P for trend 0.690). Overall, 92% (A), 85% (B), and 80% (C) of participants were satisfied with the surgical outcome at follow-up, respectively.
Conclusions BMI failed to achieve independent predictor status regarding objective and subjective cure rate at follow-up. A high BMI is not a contraindication to SPARC, more studies are recommended to confirm these findings.

Keywords Body mass index · Objective and subjective cure rate · SPARC · Stress urinary incontinence

Abbreviations

WHO	World Health Organization
SUI	Stress urinary incontinence
TVT	Tension-free vaginal tape
SPARC	Suprapubic arc-sling system
BMI	Body mass index
VAS	Visual analogue scale
IQR	Interquartile ranges
MUCP	Maximum urethral closure pressure

Introduction

Obesity tends to become a major global health problem [1]. According to recent World Health Organization (WHO) criteria, more than 30% of adults in the United States are obese [2]. Similarly, obesity is a growing health burden in Western European countries [3, 4]. WHO's projections for 2015 indicate that globally 2.3 billion adults will be overweight, and more than 700 million adults will be obese [5].

Stress urinary incontinence (SUI) is common, affecting up to 41% of the female population [6]. In Austria, one million inhabitants are estimated to suffer from SUI,

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approximately 85% of them being women [7]. Several epidemiological studies demonstrated an association between obesity and urinary incontinence; therefore, the question whether obesity has an impact on the outcome of surgical treatment of pelvic floor disorders, such as SUI, is paramount [8–12].

Since the introduction of the tension-free vaginal tape (TVT) in 1995, several technically modified types of midurethral slings were developed and in the meantime are commercially available [13–16]. Different adverse effects depending on different specific techniques have been reported; nonetheless, all sling types seem to provide efficacious outcomes [17]. The suprapubic arc (SPARC; American Medical Systems, Minnetonka, MN, USA)-sling system, approved by the US Food and Drug Administration in 2001, was designed to overcome complications associated with the blind passage of the TVT through the retropubic space, such as bowel, lower urinary tract, and vascular injuries that can occur with the upward passage of the TVT trocar, but all complications are seen with the SPARC system [18]. The SPARC trocars are passed from a suprapubic approach through two small incisions in an up-down fashion to the vagina [15]. Several systematic reviews and meta-analyses of randomized controlled trials comparing TVT with other surgical procedures have been published [19]. Regarding the impact of obesity in TVT series (within the short-term follow-up) [20–24], the majority of authors found no significant differences in patients' outcome depending on body mass index (BMI). To the best of our knowledge, no studies addressed the direct relationship between BMI and the clinical outcome of SPARC in women with SUI so far. Therefore, the purpose of the present study was to evaluate the impact of BMI (coded either as continuous or categorical variable) on the clinical outcome of SPARC in women with SUI.

Materials and methods

The cohort of our observational study consisted of 151 women suffering from SUI who underwent SPARC (performed by one surgeon, G. P.) between June 2001 and March 2009 at a single tertiary academic center. The study has been approved by the Ethics Committee of the Medical University of Graz. BMI was defined according to WHO classification [weight (kg)/height squared (m^2)] [25]. All participants had urodynamically and clinically proven SUI; individuals who previously underwent failed incontinence, or gynecological surgery, as well as those suffering from mixed urinary incontinence, were included into analyses. Women with neurologic findings or vaginal support defects greater than second stage according to the Pelvic Organ Prolapse Quantification system were excluded [26]. A complete medical history, physical examination, as well as a multichannel urodynamic investigation in sitting position, urinalysis, 3-day micturition diary, and cystoscopy were performed preoperatively in all participants. Individuals with mixed urinary incontinence symptoms in the urodynamic examination were put on anticholinergic medication and then underwent the urodynamic investigation again, as described elsewhere [27]. At baseline and at follow-up, all participants underwent a cough test in standing position with a filled bladder volume of 250 ml, as well as a pad test according to Hahn and Fall [28], a free uroflowmetry, and a sonographic post-void residual volume measurement. Postoperative follow-up was scheduled at 1 week after discharge, then 6, 12 months and yearly thereafter. Only records of women who completed all investigations were evaluated in the study, those patients with a follow-up shorter than 12 months were excluded, which left data of 93 (61.6%) individuals, who are the subject of the current analysis.

Objective cure rate was defined by a negative cough test and a pad weight $\leq$1 g, improvement as pad weight >1 to $\leq$5 g at with or without a positive cough test. Subjective cure rate was defined as no usage of pads at all. Self-perceived severity of bother was quantified by visual analogue scale (VAS 0–10). Moreover, participants were asked by an independent urologist about their satisfaction (satisfied/dissatisfied) after surgery and whether they would be willing to undergo the procedure again or recommend it to a friend.

For the purpose of the present analysis, BMI was measured at baseline and at follow-up, and it did not change at follow-up. BMI was measured as continuous variable; moreover, patients were categorized according to the preoperative BMI as follows: normal weight (BMI 18.5 to <25 kg/m^2), overweight (BMI 25 to <30 kg/m^2), and obese (BMI 30–35 kg/m^2), respectively.

Statistical analyses

Continuous variables are reported as median values and interquartile ranges (IQR). The Kruskal–Wallis, Wilcoxon signed rank, and Pearson χ^2 tests were used to compare continuous and categorical variables where appropriate. A Cox proportional hazard model is a regression model to analyze time of survival; time was not a relevant factor in our study. A Cox proportional hazard model was used for univariable and multivariable analyses for predicting objective, subjective, and overall cure rate, as well as patients' satisfaction rates. A two-sided $P < 0.05$ was considered statistically significant. All statistical analyses were performed using the Statistical Package for Social Sciences version 16.0 (SPSS Inc., Chicago, IL, USA).

Results

Table 1 summarizes the clinical and follow-up characteristics of the 93 patients treated with SPARC. Specifically, 25 (27%) patients were categorized as normal weight, 33 (35%) as overweight, and 35 (38%) as obese. No statistically significant differences were identified among the three categories according to the BMI-strata (all $P > 0.05$).

The median follow-up time of the overall cohort was 7.6 years. (IQR 6.5–8.3), which was similar across the three BMI categories ($P = 0.288$). At follow-up, mean number of pads/day, pad test, and self-perceived severity of bother were significantly reduced in the overall cohort and in each BMI category, compared to the preoperative values (Wilcoxon signed rank $P < 0.001$).

At follow-up, objective cure rate was 76, 76, and 49% in patients with normal weight, overweight, and obesity, respectively ($P = 0.08$). Table 2 summarizes univariable and multivariable analyses for objective cure rate. In univariable analyses, BMI coded as continuous variable was statistically significantly associated with objective cure rate (HR 1.1; $P = 0.018$). In multivariable analyses, after adjustment for the effects of patients' age, parity, prior treatment for SUI, presence of mixed urinary incontinence symptoms, and maximum urethral closure pressure (MUCP), BMI was not an independent predictor of objective cure rate, coded either as continuous (HR 1.1; $P = 0.108$) or as categorical variable (P for trend 0.301). At follow-up, subjective cure rate was 60, 61, and 40% in patients with normal weight, overweight, and obesity, respectively ($P = 0.163$). Table 3 summarizes univariable and multivariable analyses for subjective cure rate. In univariable analyses, BMI was not statistically significantly associated with subjective cure rate, coded either as

Table 1 Association of BMI with clinical and follow-up data of 93 patients suffering from SUI treated with SPARC-sling system

Variable	Overall	Normal weight ($n = 25$, 27%)	Overweight ($n = 33$, 35%)	Obese ($n = 35$, 38%)	P value
Age (years)	62 (51–68)	57 (48–67.5)	65 (56–70.5)	62 (50–68)	0.12
Parity	2 (1–3)	2 (1–3)	2 (2–3)	2 (1–3)	0.72
BMI (kg/m^2)	28.1 (24.8–31.2)	22.6 (21.5–23.7)	27.4 (26.2–28.7)	31.7 (30.8–34.1)	<0.001
No prior pelvic surgery	48/93 (51.6%)	18/48 (37.5%)	17/48 (35.4%)	13/48 (27.1%)	>0.05
Prior pelvic surgery	45/93 (48.4%)	12/45 (26.7%)	17/45 (37.8%)	16/45 (35.5%)	0.89
Abdominal surgery	20/45 (44.4%)	10/20 (50.0%)	6/20 (30.0%)	4/20 (20.0%)	>0.05
Vaginal surgery	25/45 (55.6%)	17/25 (68.0%)	4/25 (16.0%)	4/25 (16.0%)	>0.05
No prior incontinence surgery	68/93 (73.1%)	34/68 (50.0%)	20/68 (29.4%)	14/68 (20.6%)	>0.05
Prior incontinence surgery	25/93 (26.9%)	5/25 (20.0%)	9/25 (36.0%)	11/25 (44.0%)	>0.05
TVT	5/25 (20.0%)	1/5 (20.0%)	2/5 (40.0%)	2/5 (40.0%)	>0.05
Burch	20/25 (80.0%)	4/20 (20.0%)	7/20 (35.0%)	9/20 (45.0%)	>0.05
Preoperative duration of incontinence (years)	8 (3.5–14.5)	8 (4.5–14.5)	8 (3–10.5)	10 (4–15)	0.54
Recurrent SUI	28 (30%)	8 (32%)	10 (30%)	10 (29%)	0.96
Mixed urinary incontinence	11 (12%)	3 (12%)	3 (9%)	5 (14%)	0.80
Preoperative number of pads/day	4 (3–6)	4 (3–6)	4 (3–5)	4 (3–6)	0.24
Preoperative pad test (grams)	17 (5.5–41.5)	17 (5–40)	12 (5–41)	18 (8–44)	0.54
Preoperative VAS	7 (6–9)	7 (7–8)	8 (6–10)	7 (6–9)	0.99
MUCP (cm H_2O)	44.8 (32–69)	41.5 (27–70)	44 (32–65)	46 (33–74)	0.67
Follow-up duration (years)	7.6 (6.5–8.3)	8 (6.5–8.3)	7.2 (5.1–8.2)	7.5 (6.5–8.3)	0.29
No. of pads/day at follow-up	0 (0–1)	0 (0–1)	0 (0–1)	0 (0–1)	0.07
Pad test (g) at follow-up	0 (0–1)	0 (0–0)	0 (0–0)	0 (0–1)	0.01
VAS at follow-up	0 (0–2)	0 (0–1)	0 (0–2)	2 (0–4)	0.01
Objective cure rate at follow-up					
Cured	61 (66%)	19 (76%)	25 (76%)	17 (49%)	0.08
Improved	23 (25%)	4 (16%)	7 (21%)	12 (34%)	0.10
Failed	9 (10%)	2 (8%)	1 (3%)	6 (17%)	
Subjective cure rate at follow-up	49 (53%)	15 (60%)	20 (61%)	14 (40%)	0.163
Satisfaction at follow-up	79 (85%)	23 (92%)	28 (85%)	28 (80%)	0.440

BMI body mass index, *SUI* stress urinary incontinence, *MUCP* maximum urethral closure pressure, *SPARC* suprapubic arc-sling system, *VAS* visual analogue scale

Table 2 Univariable and multivariable regression analyses for objective cure rate

Covariates	Univariable analyses			Multivariable analyses					
	HR	95% CI	*P* value	HR	95% CI	*P* value	HR	95% CI	*P* value
Age (continuous)	1.02	0.9–1.05	0.130	1.05	1.01–1.09	0.044	1.05	1.005–1.1	0.028
Parity (continuous)	1.0	0.7–1.3	0.998	1.0	0.8–1.4	0.827	1.03	0.8–1.4	0.857
BMI (continuous)	1.1	1.015–1.2	0.018	1.1	0.9–1.2	0.108	–	–	–
BMI			0.194	–	–	–			0.301
Normal weight	1	Reference	–				1	Reference	–
Overweight	1.3	0.5–3.8	0.603				0.9	0.3–2.97	0.796
Obese	2.2	0.9–5.5	0.099				1.6	0.6–4.3	0.336
Recurrent SUI	1.2	0.6–2.6	0.598	1.2	0.5–2.8	0.741	1.1	0.5–2.7	0.750
Mixed urinary incontinence	0.9	0.3–2.8	0.978	0.7	0.2–2.2	0.546	0.8	0.3–2.4	0.684
MUCP	1.01	0.9–1.02	0.125	1.02	0.9–1.04	0.065	1.02	1.005–1.04	0.011

HR hazard ratio, *95% CI* lower/upper 95% confidence interval, *BMI* body mass index, *SUI* stress urinary incontinence, *MUCP* maximum urethral closure pressure

Table 3 Univariable and multivariable regression analyses for subjective cure rate

Covariates	Univariable analyses			Multivariable analyses					
	HR	95% CI	*P* value	HR	95% CI	*P* value	HR	95% CI	*P* value
Age (continuous)	1.02	1.0–1.05	0.053	1.05	1.02–1.1	0.003	1.06	1.02–1.1	0.002
Parity (continuous)	0.9	0.8–1.2	0.850	0.9	0.7–1.2	0.823	1.0	0.8–1.2	0.851
BMI (continuous)	1.0	0.9–1.1	0.101	1.0	0.9–1.1	0.475	–	–	–
BMI			0.573	–	–	–			0.690
Normal weight	1	Reference	–				1	Reference	–
Overweight	1.2	0.5–2.8	0.645				0.8	0.3–1.9	0.584
Obese	1.5	0.7–3.2	0.303				1.1	0.5–2.3	0.862
Recurrent SUI	1.3	0.7–2.3	0.500	1.0	0.5–2.1	0.961	1.0	0.5–2.1	0.975
Mixed urinary incontinence	0.9	0.4–2.3	0.825	0.7	0.3–1.9	0.474	0.7	0.3–1.9	0.045
MUCP	1.0	1.0–1.02	0.049	1.02	1.01–1.04	0.003	1.02	1.01–1.04	0.001

HR hazard ratio, *95% CI* lower/upper 95% confidence interval, *BMI* body mass index, *SUI* stress urinary incontinence, *MUCP* maximum urethral closure pressure

continuous (HR 1.0; $P = 0.101$) or as categorical variable (P for trend 0.573). In multivariable analyses, after adjustment for the effects of all other covariates, BMI failed to achieve independent predictor status regarding subjective cure rate, both coded as continuous (HR 1.0; $P = 0.475$) and as categorical variable (P for trend 0.690).

Finally, 92, 85, and 80% of patients with normal weight, overweight, and obesity declared to be satisfied with the outcome of surgery at follow-up, respectively ($P = 0.440$). Again, BMI failed to achieve independent predictor status in multivariable analyses, both coded as continuous (HR 1.0; $P = 0.116$) and as categorical variable (P for trend 0.676). Analysis regarding effects of prior pelvic surgery as well as prior incontinence surgery was done which showed no difference in subjective as well as objective cure rate ($P > 0.05$) (see Table 1).

Discussion

Several epidemiological studies implicated elevated BMI as an important risk factor for urinary incontinence [8–12, 29], whereas the association between increasing weight and SUI (including mixed urinary incontinence) seems to be stronger, than for urge incontinence and overactive bladder syndrome [9]. In a detailed systematic review on overweight and obesity as risk factors for urinary incontinence in women, Hunskaar [29] concluded that in addition to BMI, waist-hip ratio and thus abdominal obesity may be an independent risk factor for female incontinence.

Lovatsis and colleagues reported a matched-pair analysis on 35 obese (BMI $\geq$35 kg/m^2) women who underwent TVT for SUI between 1999 and 2001 in MB, Canada, and the authors were not able to demonstrate a difference in

cure rates in obese versus non-obese patients after a maximum follow-up of 24 months [30]. Skriapas et al. [31] matched 31 patients with BMI >40 kg/m^2, who underwent TVT for urodynamically confirmed SUI, with 52 patients with BMI <30 kg/m^2 who underwent the same procedure. After a mean follow-up of 18.5 months, the reported continence rates were 87 and 92% for morbidly obese women and the control group, respectively.

While a growing body of literature, including meta-analyses of randomized controlled trials, comparing the surgical outcomes and complication rates of TVT and other tension-free midurethral retropubic and transobturator slings has been published [19], much lesser reports on the clinical outcome of midurethral slings (predominantly TVT) in overweight and obese women suffering from SUI can be found [30, 32, 33], and data on the clinical outcome of SPARC according to WHO–BMI–strata are scant [34]. In a prospective, non-randomized multicenter study on 104 consecutive women undergoing SPARC for genuine SUI between 2001 and 2002, Deval et al. [15] reported a difference of almost 20% between objective and subjective cure rates, albeit the BMI distribution in their study cohort differed from ours, with only 12 (11.5%) patients having a BMI >30 kg/m^2. After a mean follow-up time of 11.9 months, the authors found an objective cure rate of 90.4%, wherein no difference could be observed between patients with genuine stress incontinence and those with mixed urinary incontinence.

Objective and subjective cure rates, as well as patients' satisfaction rates in our present study, are significantly lower than in Deval et al.'s report, but still good; moreover, the results are difficult to compare regarding the differences in follow-up time and BMI distribution. In our study, patients' outcome was only marginally affected by BMI, which failed to achieve independent predictor status regarding cure rates in multivariable analyses, and identical findings were obtained in subgroup analyses excluding the patients who had recurrent SUI or mixed urinary incontinence.

In a retrospective single center study by Hellberg et al. [20] on 970 consecutive women who underwent TVT between 1995 and 2001, the authors reported an overall cure rate of 81.2% in non-obese women compared to 52.1% in very obese (BMI ≥35 kg/m^2) individuals. As stated by Heidler et al. [27] in a recently published report on the long-term outcome of SPARC, one reason for the observed differences between objective and subjective cure rates across the published literature might be that subjective cure rate reflects everyday life, whereas objective cure rate captures patients' situation at a certain point of time.

Regardless of the lower objective cure rate in obese women (49%) in our study cohort, nevertheless 80% of obese participants were satisfied with the outcome of SPARC, which might indicate that complete dryness is not necessarily mandatory to achieve high satisfaction. This finding is in agreement with other series, such as a report by Mukherjee et al. [32] who demonstrated similarly high satisfaction rates in 87 obese (BMI ≥30 kg/m^2) and 98 overweight (BMI range 25–29 kg/m^2) women suffering from SUI who were treated with TVT. This group found no statistically significant difference in cure rates according to BMI after a minimum follow-up of 6 months. On the other hand, Lovatsis et al. [30] reported a matched-pair analysis on 35 obese (BMI ≥35 kg/m^2) women who underwent TVT for SUI between 1999 and 2001 in MB, Canada, and were not able to demonstrate a difference in cure rates in obese versus non-obese patients after the same follow-up time.

The present study is important for several reasons. First of all, we report on a homogeneous cohort of patients, evaluated according to a standardized complete protocol and treated by a single surgeon. Moreover, we report data at a long-term follow-up, which might allow drawing more reliable conclusions about the SPARC-sling system over time. Discrepancies among studies may be attributed to different lengths of follow-up, variations in the type of anti-incontinence surgery and different definitions of cure [20]. According to Hellberg, the overall cure rate in women of normal weight was 81.2% as compared to 52.1% in the very obese; this is in agreement with our results. Possible theory to explain our results is that there is a strong correlation between intra-abdominal pressure and BMI; an increased intra-abdominal pressure may be etiological factor. Moreover, we do not believe that very obese women should be compared with overweight women and normal weight women; on the other hand, the study population must be large enough to give a reasonable power to detect differences. It is the responsibility of the physician to provide accurate information to the patients [35]. The US Food and Drug Administration published and update on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse, this update may help patients who are considering or have received a surgical mesh implant regarding the outcome of the surgical repair.

Conversely, several limitations apply to our findings. The biggest limitation is the relatively small sample size, which might have resulted in some statistical analyses being underpowered. Other limitations are related to the nature of our study population. Specifically, our findings only apply to populations where BMI distributions are similar to the one that we observed. Conversely, different BMI distributions may be associated with different clinical outcomes of SPARC in women with SUI. The fact that BMI represents only one of several measures of body fat might represent another limitation. BMI might overestimate body fat in individuals who are very muscular, and it

might underestimate body fat in individuals who have lost muscle mass [29]. Other measures include lean body mass, waist-to-hip ratio, and waist circumference. These alternative coding schemes may represent a better way to quantify the effect of body fat on the clinical outcome of SPARC. In consequence, studies relying on these alternative definitions may show different results.

Conclusions

In multivariable analyses, BMI failed to achieve independent predictor status regarding objective and subjective cure rate, as well as satisfaction at follow-up (coded either as continuous or categorical variable). A high BMI is not a contraindication to SPARC, but more large studies are highly recommended to confirm these findings.

Conflict of interest None of the contributing authors have any conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript.

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