

SPARC OUTCOME BASED ON BODY MASS INDEX

Hypothesis/ aims of study

To evaluate the clinical outcome of the SPARC- sling procedure for women with stress urinary incontinence according to the WHO body mass index (BMI).

Study design, materials and methods

Between June 2001 and March 2009 a total of 151 women with a mean age of 60±11.9 years underwent SPARC sling placement. Women were divided into three groups according to the BMI. Minimum follow-up of 12 months was required. Thus, data from 93 participants were available for analyses.

25 had normal BMI (18.5 to < 25 kg/m² group A), 33 were overweight (BMI 25 to < 30 kg/m² group B) and 35 were obese (BMI ≥ 30 kg/m² group C).

Detailed patient's history as well as a comprehensive clinical and urodynamical investigation was done preoperatively. Objective cure rate was defined as negative cough test and pad weight 0-1 g. Improvement was defined as positive cough test and/or pad weight 0-5g. Patients who did not meet these criteria were considered to have a treatment failure. Subjective cure rate was defined as no usage of pads. Moreover patients were asked about their satisfaction (satisfied or dissatisfied) with the outcome of the surgery and whether they would recommend it to a friend or undergo the surgical procedure again.

Self-perceived severity of bother was quantified by using a visual analog scale

(VAS 0-10). This retrospective study has been approved by the Ethics Committee of the Medical University of Graz. Statistical analysis was performed by the Wilcoxon rank sum test, a p- value < 0.05 was considered statistically significant.

Results

Mean number of pads/day and pad weight was 4.5; 34 g (A), 4.6; 27 g (B) and 5.2; 44 g(C) at baseline and it decreased to 0.5; 1.2 g (A), 0.4; 0.5 g (B) and 0.7; 4.5 g(C) at date last seen (p<0.001). No significance (n.s.) could be observed between the three groups. Objective cure rate was 76% (A), 76% (B) and 48.6% (C) (p=0.008). Overall success rate (cure and improvement) was 92 % (A), 97 % (B) and 83 % (C) (n.s.). Subjective cure rate was 60% (A), 61% (B) and 40% (C) (n.s.).

Mean perception of severity (VAS) decreased from 7.8 (A, B, C) at baseline to 0.8 (A), to 1.3 (B) and to 2.3 (C) at date last seen (p<0.001; p<0.001; p=0.04). A statistical significance (p=0.009) was found between group A and B versus C. Overall, 94.7% (A), 91.7% (B) and 96.1 % (C) of patients were satisfied with the outcome of SPARC-procedure. All females but one would recommend the procedure to a friend and willing undergo it again.

Only a few minor complications could be observed. Urinary retention was observed in 2 women (A), 1 woman (B) and 2 women (C).

Interpretation of results

SPARC-sling procedure seems to have a potential positive effect on various parameters of incontinence and quality of life regardless of BMI. Nevertheless SPARC-sling procedure outcome is significantly worse in obese women regarding objective cure rate and self perceived severity of bother. Complete dryness is not necessary to achieve high satisfaction.

Concluding message

SPARC- sling procedure can be done safely in normal weight as well as in overweight and obese women.

Specify source of funding or grant	None
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
Is this a Randomised Controlled Trial (RCT)?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Ethics Committee of the Medical University Graz
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes