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Original article

Clinical outcomes of single-incision sling procedure (MiniArc)

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ABSTRACT

Objective: To evaluate the clinical outcome among women who had undergone Miniarc™ in the treatment of stress urinary incontinence (SUI).
Study design: In this retrospective study from March 2010 to December 2011 patients with clinically confirmed SUI and urodynamic stress incontinence (USI) underwent Single Incision Sling Procedure (SIS). Objective cure of SUI was defined as no urinary leakage on provocative filling cystometry and 1-hour pad test of <2 g. Subjective cure of SUI was the negative response to UDI-6. Assessment was done at baseline and after 1 year follow-up.
Results: Postoperative data was available for 85 women. Five women were not able to participate in the follow-up schedule and post-op questionnaire. The objective data for post-operative follow-up was available from 80 women. The average period of follow-up was 1.4 years (range 1.0 to 2.1). A total of 14 women had immediate post-operative urine retention at the first 24 hours and 6 cases were due to over-tensioning of the sling after ultrasound assessment. No case of bladder or bowel injury was recorded and no other major complications noted. Pre and post clinical findings revealed a significant improvement after 1 year follow-up based on the response to UDI-6, IIQ-7 (<0.001) and PISQ-1 (0.12). Urodynamic parameters revealed an increase in MUCP however the other urodynamic parameters had no statistical difference ($p > 0.05$).
Conclusions: In conclusion, Miniarc™ was noted to have improvement in both subjective and objective clinical outcomes. Urethral indentation was noted and resolved by tape release on immediate post-operative voiding dysfunction.

Introduction

After the transobturator inside-out or outside-in route, a mini-sling or single-incision sling (SIS) was introduced to create a similar "hammock" support with a shorter trajectory. Its objective was to avoid blind insertion to the retropubic and groin musculature, visceral perforation, vascular injuries, and postoperative groin pain.[1] The MiniArc (AMS, Minnetonka, MN, USA) represented an SIS system. It consists of an 8.5-cm long, macroporous polypropylene sling that is anchored in place via self-fixating tips into the obturator internus muscle with the help of a curved needle via a small vaginal incision at the midurethra. Since its introduction, the efficacy of this technique has been continually evaluated and compared with the standard midurethral sling (MUS); however,

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results have been unsatisfactory and variable levels of efficacy have been stated in the literature.[2]

Correlations between incontinence mechanisms and clinical outcomes can help us understand the variable success rates of the SIS observed in the literature. This study aimed to evaluate the clinical correlations among women who had undergone MiniArc (SIS) in the treatment of stress urinary incontinence (SUI).

Materials and methods

In this retrospective study conducted in Chang Gung Memorial Hospital Linkou from March 2010 to December 2011, patients with clinically confirmed SUI and urodynamic stress incontinence underwent SIS procedure. Patients with neurological bladder dysfunction, pelvic organ prolapse >Stage II based on the International Continence Society grading system, and postvoid bladder residual of >100 mL, as well as those who underwent other types of MUS surgeries were excluded. Initially, 90 patients were included in the study. However, five women dropped out due to incomplete data and various other reasons, such as transportation and geographic factors; a total of 85 patients met the inclusion criteria.

Demographic data, including age, parity, menstrual status, mean body mass index, prior pelvic surgery, and medical comorbidities, were reviewed through the hospital's electronic database. Operative records were obtained for the mean operating time, estimated blood loss, operative time, postoperative complications, and length of hospital stay. Multichannel UDS (Urodynamics) in the sitting position was performed preoperatively and 1-year postoperatively using a six-channel Dantec Menuet recorder (Dantec Medical A/S, Skovlunde, Denmark). Results of uroflowmetry, filling (provocative) and voiding cystometry, and a 1-hour pad test were recorded.

All the procedures were carried out in accordance with the International Continence Society guidelines. Objective cure of SUI was defined as a 1-hour pad test of a weight of <2 g and no urinary leakage demonstrable on provocative filling cystometry. Subjective cure of SUI was defined as a negative response to Question 3 of Urogenital Distress Inventory Six (UDI-6).[3] Patients completed a 72-hour voiding diary and subjective evaluations including the UDI-6, the Incontinence Impact Questionnaire (IIQ-7),[4] and Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12)[5] at baseline and after 1-year follow up.

Assessment of the power for differentiating the surgical outcome in terms of cure rates (70% cure in SIS procedure) and a power analysis revealed that approximately 50–70 women are required to have a power of 80%.

Methods, definitions, and units conform to the standards jointly recommended by the International Urogynecological Association and the International Continence Society, except where specifically noted. Descriptive statistics was used for patient demographics, preoperative data, as well as subjective and objective clinical outcomes. Paired *t* test was used for computing continuous variables, and chi-square test and Fisher's exact test for categorical variables with a p value <0.05. All statistical analyses were performed using commercial software SPSS, version 17 (SPSS Statistics for Windows, Version 17.0. Chicago: SPSS Inc.). A p value <0.05 was considered statistically significant.

Results

A total of 85 women had clinically confirmed SUI and urodynamic stress incontinence during the study period (Table 1). Five women were not able to participate in the follow-up schedule and postoperative questionnaire. The objective data for postoperative follow up were available from 80 women. The average period of follow up was 1.4 years (range 1.0–2.1 years).

A total of 14 women had immediate postoperative urine retention during the first 24 hours, and six cases were due to overtensioning of the sling upon introital ultrasound evaluation. The sling was loosened in patients with urethral indentation upon introital ultrasound.[6] Intermittent catheterization was done for the eight remaining patients. Spontaneous resolution of the above symptom was noted after 1 day. None needed further treatment. No case of bladder or bowel injury was recorded, and no other major complications were noted (Figure 1).

Pre- and post-operative 1 year findings on Urodynamics and subjective evaluation including UDI-6, IIQ-7 and PISQ-12 were available for 80 patients, and are shown in Table 2.

Post surgery, urodynamic parameters revealed that the maximum urethral closure pressure was noted to increase. Other urodynamic parameters had no statistical difference ($p > 0.05$). Subjective cure of SUI, based on the responses to UDI-6, IIQ-7 ($p < 0.001$), and PISQ-1 (0.12), revealed a significant improvement after 1-year follow up.

Discussion

Objective and subjective success in terms of the clinical correlations was evaluated in this study. To the authors' knowledge, this study adds to the paucity of information comparing clinical outcomes of MiniArc, utilizing validated questionnaires and urodynamics. The popularity of MiniArc stems from its ability to minimize morbidity combined with the absence of a visible wound, compared with the standard MUS. Variable success rates for MiniArc have been reported, ranging from 69% to 91%.[7] In a recent meta-analysis, MiniArc has been found to have an inferior patient-reported and objective cure rate when compared with the standard MUS.[8]

In our study, immediate postoperative urinary retention was noted in 14 patients, with the majority of them having urethral kinking (16.3%). Urethral impingement was noted upon ultrasound analysis. This may be due to the placement technique, wherein no space was allowed in between the sling and the urethra. Sling location has been demonstrated to be associated with recurrent SUI, with the transobturator, inserted through the outside-in route, placed more proximal to the urethra.[9] However, it was not apparent when SIS was placed at 40–70% of the urethra yielded optimal outcome.[10] There has been a report that the exact location of the sling relative to urethral length does not seem to affect outcomes.[11]

Table 1
Patient demographics.

	MiniArc ($n = 85$)
Age (y)[a]	57.9 ± 11.7
BMI	24.9 ± 3.6
Menopausal	58 (68.2)
Parity (n)[a]	3.1 ± 1.4
Previous surgery	13
VTH + Prolift total + A-P	3
VTH + Perigee + SS + A-P	5
Laparoscopic burch	1
Midurethral sling	3
Needle suspension	1
Operating time (min)[a]	31.1 ± 7.2
Overtensioning of the sling	6 (7.1)
Intraoperative blood loss (mL)[a]	25.6 ± 29.6
Complication	0
Postoperation hospital stay (d)[a]	1.23 ± 0.50
Objective cure	73/80 (91.2)
Subjective cure	72/80 (90.0)

BMI = body mass index; VTH = Vaginal Hysterectomy; SS = Sacrospinous ligament fixation; A-P = Anterior and Posterior Colporrhaphy.
[a] Data are presented as mean ± standard deviation or n (%).

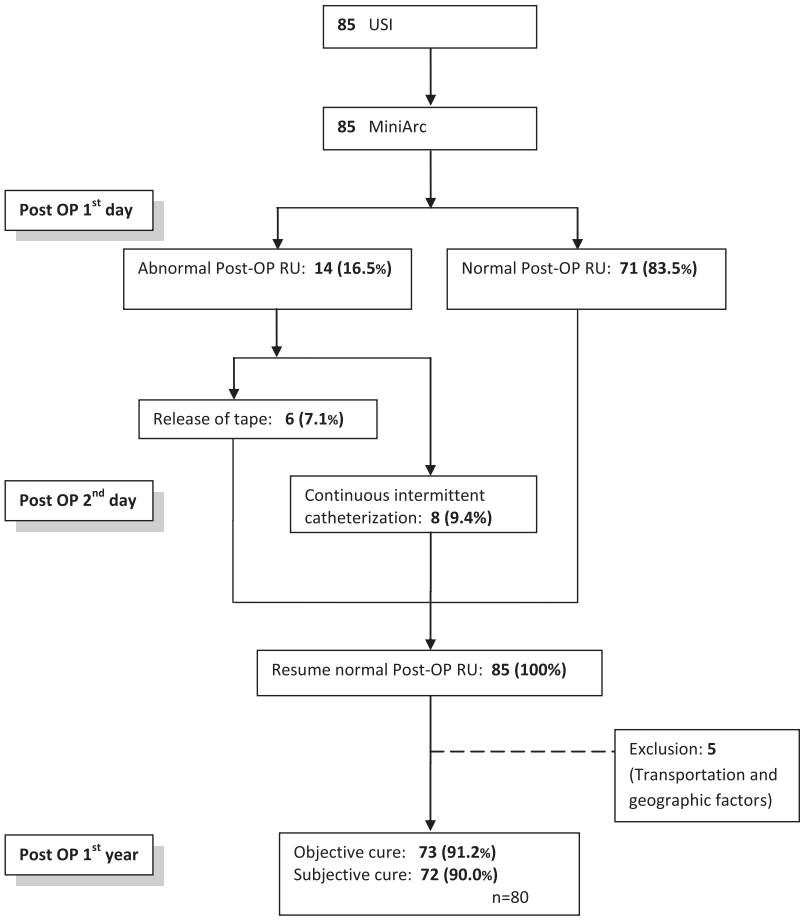

Figure 1. Patients' flow chart with urodynamic stress incontinence (USI) who underwent Single Incision Sling Procedure (SIS). USI, urodynamic stress incontinence; Post-OP RU: post voided residuals urine.

Table 2
Comparison of pre- and postclinical outcomes.

	Preop	Postop	Within group
			p
Subjective	$n = 80$		
Q_{max}	28.1 ± 11.4	26.4 ± 11.4	0.133
RU	31.8 ± 30.9	31.2 ± 21.7	0.855
CC	412.1 ± 128.5	396.3 ± 118.8	0.238
MUCP	70.2 ± 31.5	81.6 ± 39.5	0.012
FUL	22.0 ± 6.1	22.4 ± 6.0	0.607
D_{max}	14.6 ± 8.4	15.6 ± 11.9	0.496
Objective	$n = 41$		
UDI-6	11.8 ± 4.2	4.4 ± 3.5	<0.001
IIQ-7	14.5 ± 5.0	4.0 ± 3.0	<0.001
PISQ-12	24.1 ± 4.9	26.9 ± 4.1	0.012

Data listed as mean ± standard deviation.
CC = cystometric capacity (mL); D_{max} = detrusor pressure at maximum flow (cmH_2O); FUL = functional urethral length (cm); IIQ-7 = Incontinence Impact Questionnaire; MUCP = maximum urethral closure pressure (cmH_2O); PISQ-12 = Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire; Q_{max} = maximum urinary flow (m/second); RU = postvoid residual urine (mL); UDI-6 = Urinary Distress Inventory.

A higher maximum urethral closure pressure (Table 2) was also noted among these patients. During maximum valsalva, mobility of the sling exerted an increased mechanical compression toward the urethra.[11] More studies should be conducted to better explain this phenomenon.

The focus of this study was on the clinical differences in urethral function following SIS. The weakness of our study was its retrospective and single-arm nature, as well as a short-term comparison of the outcomes. Baseline preoperative sonological evaluation was not available for this study. The strengths included the following: a surgeon experienced with SIS interventions, utilization of introital ultrasound imaging for assessment, urethral kinking, and tension between the bladder and the urethra. Further evaluation with a longer follow-up period and a larger cohort in a randomized fashion is needed to determine the validity of the findings of the present study. In conclusion, dynamic urethral kinking and the urethral compression effect of slings are two main components that attribute to continence after SIS placement. There was improvement in both subjective and objective clinical parameters after SIS placement.

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