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Original Article

Analysis of outcome and risk factors for failure after single-incision sling procedure

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Abstract

Aim: To assess the effectiveness and safety of a single-incision sling (SIS) and to detect the risk factors for failure after surgery in woman with stress urinary incontinence (SUI).

Materials and Methods: The medical records of the one hundred thirty-two patients were analyzed. Preoperatively, medical history was taken and urogynecological examination was made. Patients were asked to answer Urinary Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7). Objective cure of SUI was defined as the absence of leakage of urine on the cough test. Subjective cure was based on negative response to UDI-6, question 3. Patients were divided into two groups according to objective cure rate: cured patients (Group A) and failed patients (Group B).

Results: The overall objective and subjective cure was 87.8% and 90.1%, respectively. According to the objective cure rate, there were 116 patients (87.8%) in Group A and 16 patients (12.2%) in Group B. In terms of subjective cure, Quality of Life (QoL) scores (IIQ-7 and stress subdomain of UDI-6) of Group B were statistically improved after surgery (p=0.001 and p=0.005 respectively). When two groups were compared, Group B had higher prevalence of severe SUI (IIQ scores ≥15 points) and reduced urethral mobility (Q-tip ≤ 30°) (0.8% vs 87.5%, p=0.0001 and 3.4% vs 68.7%, p=0.0001, respectively). The overall recommendation rate for surgery was 90%.

Conclusion: Our study showed that SIS procedure has high subjective and objective cure rates. The main risk factors for failure were detected as reduced urethral mobility and SUI severity expressed with IIQ scores.

Keywords: Suburetral slings; urinary incontinence; urinary stress incontinence

INTRODUCTION

Midurethral slings (MUS) have been identified to be safe and effective treatment choice for female stress urinary incontinence (SUI). The tension-free vaginal tape (TVT) procedure is the first generation MUS was described earlier (1). According to long term studies, TVT was regarded as the "gold standard" treatment (2). Transobturator sling technique was started to be preferred to place the end of the tape to avoid severe intestinal and vascular complications of TVT. However, this approach brought specific complications as postoperative groin pain due to neural injury (3). Finally, the third generation minimally invasive slings also called single-incision slings (SIS) were developed to decrease the groin pain and to avoid blind passing trocars through obturator canal and Retzius space with using shorter length of mesh (4).

In short-term studies, SIS seems to have similar effectiveness compared to standard MUS procedures (5). However, there have been a few studies investigating long term outcome of SIS (6). In addition, only a few studies have yet focused on risk factors.

The purpose of the study was to evaluate long term outcome of a SIS called Contasure-Needleless (Neomedic International SL, Barcelona, Spain) and to detect the risk factors for failure.

MATERIALS and METHODS

This retrospective observational study was carried out in a tertiary center. The medical records of the patients who underwent SIS procedure for SUI without accompanying pelvic prolapse surgery between 2009 and 2017 were reviewed. The study was approved by the Institutional Review Board and the Local Ethics Committee (102/5.5.2017).

The patients with urodinamically proven detrusor over activity, neurogenic bladder, previous anti-incontinence surgery including MUS, postvoidal residual volume (PVR) >100 ml, previous radical pelvic surgery, and anterior pelvic

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organ prolapse >stage I were excluded from the study (7). Preoperative evaluation included medical history, pelvic examination including POP-Q scoring (8), cough stress test, Q-tip test (3) and urinalysis. The cough stress test was performed in a 300 ml bladder filling in a standing position A strong cough was requested from the patient while urinary leakage was observed by the examiner.

The multichannel urodynamic study was carried out in accordance with the criteria of the International Continence Association. (9). With the patient seated after 150 ml of filling, Valsalva leak point pressure (VLPP) was calculated by asking the patient to perform a Valsalva maneuver until urine loss was directly ob¬served. If there was no leakage at this volume, the test was repeated after every additional 50 mL of filling. The lowest measured VLPP was recorded and patients were asked to answer validated questionnaires such as Urinary Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) (10). The objective cure of SUI was defined as the absence of a significant leak in urine in the cough stress test. Subjective cure was defined as negative response to UDI-6, question 3 (no leakage on coughing, sneezing, or laughing).

Postoperatively, PVR was checked before discharge with using a urinary catheter. Follow up controls were scheduled for 1 week, 2 months and then annually. Assessment included medical history, detailed pelvic examination for mesh erosion, PVR measurement, validated questionnaires and cough stress test performed at standing position at bladder filling ≥300 ml. Patients were divided into two groups according to objective cure: cured patients (Group A) and failed patients (Group B). Also, the patients were asked to answer the question that "Would you recommend this surgery to others for urinary incontinence?" (Figure 1).

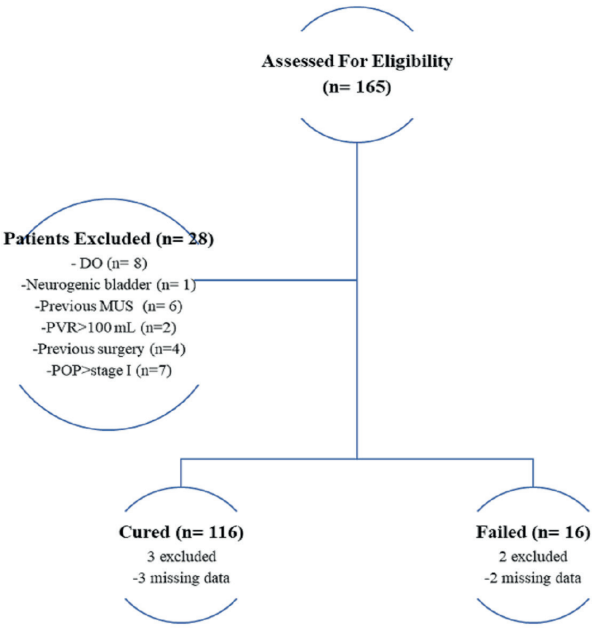

Figure 1. The Flowchart of Study

Operative Procedure

The Contasure Needleless System (Neomedic International SL) is a polypropylene monofilament mesh placed under the mid-urethra and includes the concept of pocket fixation mechanism (11) (Figure 2).

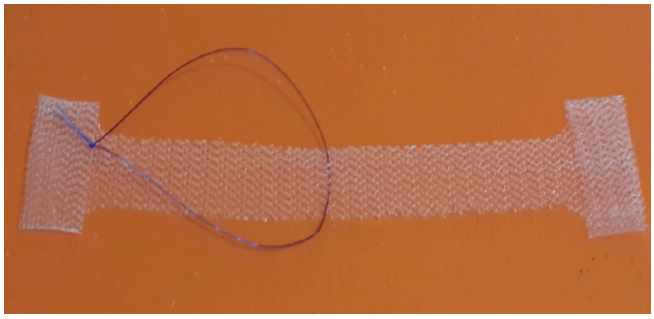

Figure 2. The Contasure Needleless System (Neomedic International SL)

Under general anesthesia, a 16F Foley catheter was inserted into the urethra. A vertical 2 cm incision under the mid-urethra was performed. Lateral to this incision, paraurethral spaces were dissected at 2 and 10 o'clock by scissor. A Kelly clamp was placed inside the "pocket system" of the mesh, and was introduced through para-urethral spaces. The fascia of the internal obturator muscle was perforated. Then, clamp was released and end of the mesh was left in place. After the location of the mesh was confirmed, the tension was adjusted by pulling the blue polypropylene string at the middle of the mesh. Finally, the vaginal incision was closed using 2-0 absorbable suture in running fashion. The edge of string was left in the vagina through the closed vaginal incision for possible adjustment after the operation. No cystoscopy was carried out. The following day, in the absence of signs of outflow obstruction, the strings were cut and removed.

Statistical Analysis

All statistical analysis was performed using SPSS Version 16; SPSS, Inc, Chicago, IL). The distribution of variables was assessed using Kolmogrov-Smirnov test (n ≥30) and Shapiro-Wilk test (n<30).Data were analyzed by descriptive statistical measure of average, standard deviation, median, Q1-Q3 percentage, frequency and ratio were used. Mann Whitney U test was used for comparing the variables that did not show normal distribution between groups. The Wilcoxon signed rank test was used for the intergroup comparison. In comparison of qualitative data, Pearson Chi-Square test and Fisher's Exact test were used. Significance was evaluated at the level of $p < 0.05$

RESULTS

One hundred fifty-four patients who had surgery between 2009 and 2017 were included in the study. Twenty-two patients were lost to follow up in this period. The remaining 132 patients were analyzed. All patients completed follow-up at least 12 months. The overall objective cure was 87.8% (116/132) and subjective cure was 90.1% (119/132) in a follow-up period of 63.6±12.8 months (ranging 12-96 months). Preoperative characteristics of two groups were shown in Table 1.

Table 1. Preoperative Characteristics of Two Groups

	Cured (n=116)	Failed (n=16)	p
Age (years)	55.5 (47.7-65.3)	52.5 (45-65)	[a]**0.644**
Parity	2 (2-3)	2 (2-3)	
Body mass index (BMI)			
Overweight	71 (61.2%)	12 (75%)	[b]**0.284**
Normal	45 (38.8%)	4 (25%)	
Postmenopausal	60 (51.7%)	10 (62.5%)	[b]**0.418**
Diabetes mellitus	13 (11.2%)	2 (12.5%)	[c]**1.000**
Hypertension	26 (22.4%)	4 (25%)	[c]**0.729**
Macrosomia (>4000 g)	13 (11.2%)	2 (12.5%)	[c]**1.000**
Cough stress test			
Positive	61 (52.6%)	9 (56.3%)	[b]**0.783**
Negative	55 (47.4%)	7 (43.7%)	
Q-tip test (degree)	55 (50-70)	20 (15-30)	[a]**0.001****
First desire to void (mL)	176 (127-218)	152 (136-152)	[a]**0.537**
Normal desire to void (mL)	272 (209-311)	183 (181-229)	[a]**0.038***
Strong desire to void (mL)	371 (317.5-417.8)	361 (229- 456)	[a]**0.210**
Maximum cystometric capacity (mL)	604 (360-1041)	583 (341- 1101)	[a]**0.235**
Residual urine volume (mL)	43 (19.5-64.5)	36.5 (30-60.5)	[a]**0.654**
Qmax (mL/s)	19 (13-32)	13 (1-23)	[a]**0.010***

[a] Mann Whitney U test ; results are shown: median (25th-75th percentiles); [b] Pearson Chi Square test; [c] Fisher Exact test *p<0,05 ; **p<0,01

No mesh-related complications were noted. Only two patients (1.5%) had residual urine >200 mL at first voiding trial in postoperative day 1, however, both of them voided without residual urine at postoperative day 2. No intraoperative hemorrhage, bladder perforation, de novo urgency or de novo urge incontinence were observed. The overall recommendation rate for SIS procedure was detected as 90%.

According to the objective cure rate, there were 116 patients (87.8%) in Group A and 16 patients (12.2%) in Group B. When two groups were compared, Group B had higher prevalence of severe SUI (IIQ scores ≥15 points) and reduced urethral mobility (Q-tip ≤ 30°). Regarding low detrusor pressures during voiding phase (pdet Qmax <20 cmH2O, opening pressure <15 cmH2O), there was no significant difference between two groups (Table 2).

Table 2. Determining Factors of Objective Cure Rate After Single-Incision Sling

	Cured (n=116)	Failed (n=16)	p
Q-tip ≤30	1 (0.9%)	14 (87.5%)	[b]**0.0001****
Valsalva Leak Point Pressure ≤60 cmH2O	24 (20.7%)	3 (18.8%)	[c]**1.000**
Detrusor Pressure At Maximum Flow Pdet Qmax <20 cmH2O	61(52.6%)	11 (68.8%)	[b]**0.224**
Detrusor Pressure (Pdet) at opening <15 cmH2O	4 (3.4%)	1 (6.3%)	[c]**0.481**
Preoperative IIQ >15	4 (3.4%)	11 (68.8%)	[c]**0.0001****

[b]Pearson Chi Square test; [c]Fisher Exact test; **p<0,01

Patients had a statistically significant improvement in scores on the IIQ-7 and all subdomains of the UDI-6. In Group B, 16 patients were failed however all of them had significantly improved QoL scores after SIS procedure. Pre- and postoperative IIQ-7 and UDI-6 scores of two groups were shown in Table 3.

Table 3. Comparison of Preoperative and Postoperative Scores

Questionnaire	Preoperative	Postoperative	[d]p
IIQ-7			
Total	10 (7-15)	1 (0-6)	**<0.0001****
Failed	18 (15-19.7)	13 (5.3-18)	**0.001****
UDI-6			
Irritative (UDI 1-2)			
Total	3 (1-5)	1 (0-1)	**<0.0001****
Failed	1.5 (1-3)	1 (0-2)	**0.024***
Stress (UDI 3-4)			
Total	4 (3-6)	0 (0-1.75)	**<0.0001****
Failed	6 (5-6)	5 (1-5.75)	**0.005****
Obstructive (UDI 5-6)			
Total	1 (0-3)	0 (0-0)	**<0.0001****
Failed	1 (0-2.75)	0 (0-1)	**0.024***

[d]Wilcoxon Signed Rank test; *p<0,05; **p<0,01

DISCUSSION

At the end of 8 years, the overall objective and subjective cure rate was 87.8% and 90.1% in our study, respectively. When compared preoperative and postoperative QoL scores, we found that patients had statistically significant improvement after surgery. The main risk factors for failure were detected as SUI severity and reduced urethral mobility.

In the literature, SIS were reported to have similar effectiveness compared with conventional MUS in short-term (12). There are a few studies investigating long-term cure rates of SIS. Martinez-Franco et al (13) reported outcome of Needleless procedure at least 3 years after surgery. In their study, objective and subjective cure rate was 84.7% and 90.7% respectively. They also showed that 8.4% of patients experienced de novo urgency and 0.8% experienced voiding difficulty. Lo et al (6) reported outcome of MiniArc single-incision sling in a follow-up period of 74.1±15.1 months. They found that overall subjective cure rate was 80% and objective cure 84.7%. In consistent with our findings, they were reported no mesh-related complications.

Several studies have investigated risk factors associated with failure of mid-urethral slings. Some studies showed risk factors, such as age, overactive bladder symptoms, obesity, urethral immobility whereas no association has been found by others (14-17). Despite increasing popularity, very few studies focused on predictors of failure after SIS (6,12). Palmieri et al (12) showed that International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) score > 18 points and detrusor pressure at maximum flow < 20 cmH2O are independent risk factors for SUI persistence after MiniArc sling. In another study, failure rate after MiniArc single-incision sling was 15.3% and cure rates were affected by only age, especially those older than 66 years (6). Additionally, Mira Gon et al (18) found that 15% of patients have failed after the Ophira minisling procedure. Age and parity were not related with outcomes whereas previous surgery history rise failure rate with 5.66 OR.

In this study, severe SUI (preoperative IIQ scores ≥ 15 points) and reduced urethral mobility were found to be significantly related with failure after SIS procedure. In previous studies, it was more likely to experience treatment failure after the TVT women who use more than 2 pads per day (15). Contrary, the most successful women after surgery were those who did not leak at first cough or did not need to wear pads during the day. Moreover, Richter et al (19) showed that the only significant clinical measure associated with treatment failure was greater pad weight before surgery.

The reduced urethral mobility (Q tip ≤ 30º) may increase failure after MUS (17,20). This finding may arise from that these women may have a deficient urethral function or that dynamic kinking mechanism does not work in case of urethral immobility. Kinking mechanism is highly important as indicated by many studies showing that success rate after sling is maximized when it is placed in the mid-urethra compared to proximal or distal urethra (21). On the other hand, VLPP, an objective parameter of intrinsic sphincter deficiency, is considered as a risk factor for treatment failure (22). A few data exists regarding the relationship between SIS outcomes and VLPP. Bum Han et al (23) reported that success rate of SIS procedure did not affected by preoperative VLPP, when divided as > 90 cmH2O or ≤ 90 cmH2O. However, patients with lower VLPP, which is associated with more severe SUI, were more satisfied by a relatively minor improvement of their symptoms through surgical treatment in their study. Therefore, the urethral mobility is relatively more important than sphincter deficiency for the success of MUS or SIS procedures.

The main limitations of the study are its retrospective design and the fact that only objective cure was taken into account to determine the groups. The strengths of the study are that all operations performed by a single surgeon in single center, long-term follow up, selection of a pure SUI population and moderate sample size.

CONCLUSION

In conclusion, our study showed that SIS procedure has similar objective and subjective cure rates compared with MUS. The main risk factors for failure were detected as reduced urethral mobility and SUI severity expressed with IIQ scores. Therefore, preoperative assessment of patient may play a key role in improving preoperative counseling and predicting outcome of SIS. In future, a well-designed, prospective randomized controlled trial using evaluation protocol using urodynamic study and questionnaires is needed to validate these results.

Competing interests: The authors declare that they have no competing interest.

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