The Effect of Valsalva Leak Point Pressure on Outcomes of the Needleless® System in Female Stress Urinary Incontinence

Seung Bum Han, Joon Chul Kim, Dong Hwan Lee, Hyo Sin Kim, Jun Sung Koh, Won Sok Hur, Kang Jun Cho*

Purpose: This study aimed to investigate the effects of preoperative Valsalva leak point pressure (VLPP) on the outcomes of the single-incision midurethral sling procedure (Needleless® System) in female stress urinary incontinence (SUI).

Materials and Methods: We evaluated 112 patients who underwent midurethral sling placement for SUI using the Needleless® System. Patients were divided into two groups according to their preoperative VLPP values: VLPP > 90 cmH_2O (group 1) and VLPP 60-90 cmH_2O (group 2). After the postoperative period, SUI status and satisfaction were compared between the two groups. Subjective cure was defined as the absence of any episodes of urinary incontinence associated with conditions that increase intra-abdominal pressure in daily life. Treatment satisfaction was analyzed according to patient responses as 'satisfied', 'neutral', and 'dissatisfied'. Postoperative other lower urinary tract symptoms except SUI were compared between the two groups too.

Results: There were no significant differences in age, body weight, and urodynamic parameters (except VLPP) between the two groups. The mean VLPPs were 105.9 ± 12.3 cmH_2O (range, 93.6–118.2 cmH_2O) in group 1 and 75.4 ± 10.5 cmH_2O (range, 65–85.9 cmH_2O) in group 2. The overall subjective cure rates were 65.0% in group 1 and 62.5% in group 2 (P = .744). The overall satisfaction rates were 58.8% in group 1 and 68.8% in group 2 (P = .600). Complication rates did not differ between the two groups.

Conclusion: When stratified as > 90 cmH_2O or ≤ 90 cmH_2O, preoperative VLPP did not affect Needleless® System outcomes in female SUI patients.

Keywords: urinary incontinence; stress; surgery; treatment outcome; urodynamics; female; suburethral slings.

INTRODUCTION

Midurethral slings that utilize synthetic polypropylene monofilament mesh have been established to be safe and effective in the treatment of female stress urinary incontinence (SUI). This treatment strategy is based on Petros and Ulmsten's[1] suggestion that the main pathophysiology of SUI involves weakening of the pubourethral ligaments and the impairment of midurethral function and anterior urethral wall support. Midurethral sling techniques have progressed rapidly, and they can be classified into three generations, with retropubic transvaginal tape (TVT) representing the first generation, and transobturator tape (TOT) representing the second generation. The third generation technique is the single-incision mini-sling (SIMS), which utilizes a shorter sling and a single vaginal incision to minimize morbidity by avoiding blind passage in the retropubic space or obturator foramen. Although the SIMS offers a shorter operative time and a lower risk of postoperative pain, debate remains over its clinical efficacy compared to standard midurethral slings. A meta-analysis by Mostafa and colleagues[2] found no evidence of significant differences in cure rate between SIMS and standard midurethral slings at a mean follow-up of 18 months, excluding the TVT-Secure (Gynecare, Sommerville, NJ, USA). The TVT-Secure was inferior to standard midurethral slings and has already been withdrawn from clinical use. While there has been insufficient evidence to reveal a difference in outcome between SIMS and standard midurethral slings, SIMS has been considered inferior to standard midurethral slings.[3,4] Various fixation mechanisms and preoperative risk factors may influence the outcomes of SIMS placement. Adequate patient selection would be beneficial in situations in which the efficacy of SIMS is uncertain. Valsalva leak point pressure (VLPP), an objective parameter of SUI severity, is a risk factor for the failure of surgical treatment. Patients with a low VLPP in the preoperative urodynamic study (UDS) are considered to have a greater risk of treatment failure. Some studies found that patients with a low VLPP had a lower subjective cure rate after TVT, but there was no significant difference in outcomes after TOT.[5,6] However, there is a lack of data regarding the relationship between VLPP and SIMS outcomes. We therefore investigated the effects of preoperative VLPP on SIMS outcomes using the Needleless® System (Neomedic International, Spain) in female SUI.

MATERIALS AND METHODS

Study Subjects

After Institutional Review Board approval, we retro-

Department of Urology, College of Medicine, The Catholic University of Korea, Seoul, Korea
*Department of Urology, The Catholic University of Korea, Bucheon St. Mary`s Hospital, 327 Sosa-Ro, Wonmi-gu, Bucheon-city, Gyeonggi-do, 420-717, Korea.
Tel: +82 32 3407730. Fax: +82 32 3402124. E-mail: gift99@catholic.ac.kr.
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Table 1. Comparison of preoperative clinical characteristics and urodynamic parameters between group 1 and group 2.

Variables	Group 1 (n = 80)	Group 2 (n = 32)	*P* Value
Age (years)	54.4 ± 6.9	54.5 ± 8.9	.748
Body weight (kg)	61.9 ± 9.8	58.4 ± 2.8	.274
Mixed UI	33 (41.2)	12 (37.5)	.715
Qmax (mL/s)	20.9 ± 7.5	22.5 ± 7.2	.550
PVR (mL)	28.2 ± 35.1	30.0 ± 27.0	.510
VLPP (cmH_2O)	105.9 ± 12.3	75.4 ± 10.5	<.001
PdetQmax (cmH_2O)	31.7 ± 15.9	21.3 ± 8.3	.095
MUCP (cmH_2O)	60.0 ± 25.9	49.1 ± 11.4	.364
CMG bladder capacity (mL)	329.8 ± 64.1	311.6 ± 60.2	.530

Abbreviations: UI, urinary incontinence; Qmax, maximum urinary flow rate; PVR, postvoid residual volume; Pdet Qmax, detrusor pressure on maximumflow; MUCP, maximum urethral closure pressure; VLPP, Valsalva leak point pressure; CMG, cystometrography.
Data are presented as mean ± standard deviation or as no. (%).

spectively reviewed the clinical data of women who underwent SIMS using the Needleless® System for SUI in two centers from March 2010 to August 2012 and could be followed up by telephone interview. Those who previously underwent other surgeries for SUI, had neurologically caused incontinence, or had stage 3 or greater pelvic organ prolapse were excluded. Techniques of anti-incontinence surgery in patients without exclusion criteria were chosen by surgeon's preference in our institute. Patients were divided into two groups according to their preoperative VLPP values: VLPP > 90 cmH_2O (group 1), VLPP 60-90 cmH_2O (group 2).

Evaluations

All the women underwent clinical evaluations, including complete history taking, physical examination, and UDS. UDS was performed with a 6-French (F) dual-lumen vesical catheter and a 12-F rectal balloon catheter. The bladder was filled with 30–50 mL/min saline with the patient in the sitting position. Patients were asked to void prior to the examination, at which point the maximum flow rate in the sitting position, voiding volume, and postvoid residual urine volume were recorded. During bladder filling, the patients were simply instructed to report their sensations to the examiner. Total bladder capacity was recorded during filling cystometry. A urethral pressure profile was performed, and the detrusor pressure at the maximum flow rate in the voiding phase and the maximum urethral closure pressure were recorded. With the subject seated after 150 mL of filling, VLPP was determined by asking the subject to perform a Valsalva maneuver until urine loss was directly observed. If there was no leakage at this volume, the test was repeated after each additional 50 mL of filling. The lowest measured VLPP was recorded.

Surgical Technique

Placement of the midurethral sling (Needleless® System) was performed by one of two experienced urologists (JCK, DHL) under spinal or general anesthesia. The intervention consisted of placing a polypropylene monofilament mesh measuring 114 mm in length and 12 mm in width under the midurethra; a pocket positioning system was located in the lateral sides of the mesh, anchoring the sling. The patient was positioned in the lithotomy position, and a 16 F Foley catheter was inserted into the bladder for drainage and identification of the bladder neck. A longitudinal 2 cm incision was made in the anterior vaginal wall at the level of the midurethra. Lateral to this incision, the para-urethral spaces were dissected bluntly at 2 and 10 o'clock positions to easily accept the fully extended mesh, but only up to the descending ramus of the pubic bone. A pair of surgical forceps was then introduced inside the pocket positioning system at the edge of the mesh. We hyperextended the jaws of the forceps and closed them to create an arrow with the mesh. The mesh was then introduced through the dissected para-urethral space. We continued pushing the forceps in the 10 o'clock direction, perforating the urogenital diaphragm and into the internal obturator muscle. The forceps were opened widely to extend the pocket inside the muscle. We then withdrew the forceps, semi-closing them. To control the penetration of the tip of the forceps and the mesh, the surgeon could hold the central portion of the mesh by means of a blue centering suture affixed to the middle of the mesh for this purpose. The process was repeated on the contralateral side towards the 2 o'clock direction. Once the sling was placed, it could be adjusted to further support the urethra by introducing the tip of the forceps into the pocket positioning system and pushing the tip of the mesh up to the desired support level. To reduce the mesh urethral support level, the surgeon could pull the blue centering suture on the mesh. After achieving proper positioning, the blue centering suture was removed from the mesh with a single cut on one side of the suture while maintaining traction on the suture. Finally, the vaginal incision was closed using 2-0 rapidly absorbable sutures in a running fashion. All patients were discharged on the same day after voiding.

Outcome Measures

After the postoperative period, SUI status and treatment satisfaction were compared between the two groups. Subjective patient outcomes were defined as follows: "cure" was defined as the absence of any episodes of urinary incontinence associated with conditions that increase intra-abdominal pressure in daily life, "improvement" was defined as reduced frequency and amount of urine leakage, and all other outcomes were regarded as "failure". Treatment satisfaction was analyzed according to patient responses as 'satisfied', 'neutral', and 'dissatisfied'. Other lower urinary tract symptoms new-

Table 2. Comparison of subjective outcomes between group 1 and group 2.

Variables	Group 1 (n = 80)	Group 2 (n = 32)	*P* Value
Cured	52 (65.0)	20 (62.5)	.744
Improved	22 (27.5)	9 (28.1)	
Failed	6 (7.5)	3 (9.4)	
Satisfied	47 (58.8)	22(68.8)	.600
Neutral	25 (31.2))	6 (18.8)	
Dissatisfied	8 (10.0)	4 (12.4)	

All data are presented as no. (%).

ly detected during follow-up were recorded and compared between the two groups. Urgency incontinence was evaluated with urinary sensation scale.

Statistical Analysis

All statistical analyses were carried out using IBM Statistical Package for the Social Science (SPSS) version 20.0 (IBM Corp., Armonk, NY, USA). Continuous variables were reported as the mean ± standard deviation and categorical variables were expressed as frequencies with percentages. Continuous variables were evaluated using Student *t*-test. Categorical variables were evaluated with the Chi-Square test. A *P* value < .05 was considered statistically significant.

RESULTS

A total of 112 patients were enrolled in the study. Table 1 presents the preoperative clinical and urodynamic characteristics of group1 (n = 80) and group 2 (n = 32). The mean follow-up was 28.1 ± 4.9 months (range 25–40) for group 1 and 27.8 ± 3.5 months (range 24–36) for group 2. No significant differences were found between the two groups in terms of age, body weight, mixed urinary incontinence rates and urodynamic parameters (except VLPP). The mean VLPP values were 105.9 ± 12.3 cmH_2O (range, 93.6-118.2 cm H_2O) in group 1 and 75.4 ± 10.5 cm H_2O (range, 65-85.9 cm H_2O) in group 2. The overall subjective cure rates were 65.0% in group 1 and 62.5% in group 2 (*P* = .744). The overall satisfaction rates were 58.8% in group 1 and 68.8% in group 2 (*P* = .600) (**Table 2**). Twenty-five patients (31.3%) in group 1 and nine patients (28.1%) in group 2 complained of voiding symptoms, such as a weak stream, straining to void, and intermittency, but there were no severe voiding difficulties requiring urethral catheterization (*P* = .745). Overall 45 (40.1%) patients had mixed urinary incontinence preoperatively, whereas, 29 (25.9%) patients had urge incontinence at follow up for more than 24 months. Five patients (6.2%) in group 1 and six patients (18.8%) in group 2 complained of postoperative de novo urgency incontinence (*P* = .073). There was not any other early or late postoperative complication such as vaginal tape erosions and urinary tract infection related with anti-incontinence surgery.

DISCUSSION

We found that preoperative VLPP did not affect cure rate, satisfaction, or postoperative de novo urinary symptoms after SIMS using the Needleless® System in female SUI patients with a preoperative VLPP > 60 cmH_2O. A VLPP ≤ 60 cmH_2O in SUI is suggestive of an intrinsic sphincter deficiency etiology.[7] Some authors demonstrated a correlation between VLPP and risk factors for standard midurethral sling success[5,8] while others have not.[6,9] The VLPP threshold reported in the literature is generally 60 cmH_2O. Some studies with varying VLPP thresholds used VLPP values of 60 and 90cmH_2O.[6,10] In a study seeking to identify preoperative factors affecting the SIMS cure rate, a VLPP < 60 cmH_2O was associated with a lower cure rate for the TVT-Secure [11] and severe incontinence was a risk factor for failure of the Mini-Arc (American Medical Systems, Minnetonka, MN, USA).[12] A previous study of Needleless® System outcomes by Amatand colleagues[13] did not include patients with intrinsic sphincter deficiency, defined as a VLPP < 60 cmH_2O and the absence of urethral hypermobility. Although we did not propose the exclusion of patients with a VLPP < 60 cmH_2O initially, all patients enrolled in our study had VLPP values ≥ 60 cmH_2O. This indicates that surgeons tend to avoid using SIMS in patients with intrinsic sphincter deficiency. Thus, we used a VLPP of 90 cmH_2O as the threshold for investigating the effect of preoperative VLPP on Needleless® System outcomes. A VLPP ≥ 90 cmH_2O is usually not associated with intrinsic sphincter damage and is related to urethral hypermobility, while a VLPP of 60-90 cmH_2O indicates the possible coexistence of intrinsic sphincter damage and urethral hypermobility.[14] Agarwal and colleagues[15] reported no significant differences in quality of life and incontinence assessment tools at both 6 and 12 months postoperatively when comparing TOT outcomes by stratifying preoperative VLPP as 60-90 or > 90 cmH_2O. However, SIMS procedures such as the Needleless® System have basic anchoring mechanisms different from those of standard midurethral sling procedures such as TOT. SIMSs have a shorter trajectory of mesh insertion and need to be soundly anchored to the obturator internus muscle with a strong post-insertion pullout force.[2] We hypothesized that these different anchoring mechanisms could influence SIMS outcomes when comparing patients with a preoperative VLPP of 60-90 versus > 90 cmH_2O. However, we did not find any significant differences in Needleless® System cure rate between the two groups. Rather, the treatment satisfaction rate seemed to be higher when the VLPP was lower (68.8% vs. 58.8%), although the difference of satisfaction rate was not significant. Patients with a lower VLPP, which is associated with more severe SUI, were more satisfied by a relatively minor improvement of their symptoms through surgical treatment.

In this study, the total cure rate and total satisfaction rate for the overall study cohort more than 24 months after the Needleless® System procedure were 64.3% (72/112) and 61.6% (69/112), respectively. Amat and

Martinez Franco [13,16] reported outcomes for SUI women who underwent the Needleless® System procedure. In their study, 87.5% of patients were cured, 39.7% were very satisfied, and 53.4% of patients were satisfied at 12 months after treatment. In addition, 84.7% of patients were cured, 40.5% were very satisfied, and 52.7% were satisfied at 36 months after treatment. The outcomes for the Needleless® System were not different to those of the TVT-O. The differences in cure and satisfaction rates between our study and previously reported studies may be due to these studies' exclusion patients who had symptoms of urgency before surgery that persisted after surgery.

Among the most troublesome outcomes following anti-incontinence surgery is the development of voiding dysfunction. A long-term study of the Needleless® System showed that 8.4% of patients experienced de novo urgency and 0.8% experienced voiding difficulty.[16] A study of SIMS utilizing the Ophira Mini Sling (Promedon, Cordoba, Argentina) found that 7.3% of patients experienced de novo urgency and 3.2% experienced voiding difficulty.[17] In our study, 9.8% (11/112) of patients experienced de novo urgency and 30.3% (34/112) experienced voiding symptoms, and there were no significant differences in de novo voiding dysfunction between groups 1 and 2. Although urgency incontinence prior surgery would influence the outcomes of anti-incontinence surgery, overactive bladder symptoms could decrease significantly by surgical treatment for SUI.[18] Our study showed the similar results.

Our study has some limitations. First, this study was a retrospective study and the outcomes were entirely based on patient self-reports of incontinence rather than objective outcomes. This had a relatively small sample size that did not have statistical power sufficient to show the relationship of VLPP with outcome of SIMS. Further prospective research with adequate power and improved design are needed to provide more information. In addition, there is a lack of consensus regarding the specific threshold of VLPP that correlates with the surgical outcomes of SIMS. We acknowledge that selecting slightly different VLPP thresholds could result in slightly different outcomes.

CONCLUSIONS

Although we could not identify preoperative factors for adequate SIMS patient selection, preoperative VLPP stratified as 60-90 cmH_2O or > 90 cmH_2O did not affect outcomes after SIMS performed using the Needleless® System. Further studies are necessary to confirm these data and to identify preoperative factors predicting the outcome of SIMS.

CONFLICT OF INTEREST

None declared.

REFERENCES

1. Petros PE, Ulmsten UI. An integral theory and its method for the diagnosis and management of female urinary incontinence. Scand J Urol Nephrol Suppl. 1993;153:1-93.
2. Mostafa A, Lim CP, Hopper L, Madhuvrata P, Abdel-Fattah M. Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: an updated systematic review and meta-analysis of effectiveness and complications. Eur Urol. 2014;65:402-27.
3. Cornu JN, Sebe P, Peyrat L, Ciofu C, Cussenot O, Haab F. Midterm prospective evaluation of TVT-Secur reveals high failure rate. Eur Urol. 2010;58:157-61.
4. Nambiar A, Cody JD, Jeffery ST. Single-incision sling operations for urinary incontinence in women. Cochrane Database Syst Rev. 2014;6:Cd008709.
5. Kawasaki A, Wu JM, Amundsen CL, et al. Do urodynamic parameters predict persistent postoperative stress incontinence after midurethral sling? A systematic review. Int Urogynecol J. 2012;23:813-22.
6. Ryu JG, Yu SH, Jeong SH, et al. Transobturator tape for female stress urinary incontinence: preoperative Valsalva leak point pressure is not related to cure rate or quality of life improvement. Korean J Urol. 2014;55:265-9.
7. McGuire EJ, Fitzpatrick CC, Wan J, et al. Clinical assessment of urethral sphincter function. J Urol. 1993;150:1452-4.
8. Iancu G, Peltecu G. Predicting the outcome of mid-urethral tape surgery for stress urinary incontinence using preoperative urodynamics - a systematic review. Chirurgia (Bucur). 2014;109:359-68.
9. Costantini E, Lazzeri M, Giannantoni A, Bini V, del Zingaro M, Porena M. Preoperative MUCP and VLPP did not predict long-term (4-year) outcome after transobturator mid-urethral sling. Urol Int. 2009;83:392-8.
10. Feldner PC, Jr., Bezerra LR, de Castro RA, et al. Correlation between valsalva leak point pressure and maximal urethral closure pressure in women with stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct. 2004;15:194-7.
11. Han JY, Park J, Choo MS. Efficacy of TVT-SECUR and factors affecting cure of female stress urinary incontinence: 3-year follow-up. Int Urogynecol J. 2012;23:1721-6.
12. Oliveira R, Botelho F, Silva P, Resende A, Silva C, Dinis P, et al. Single-incision sling system as primary treatment of female stress urinary incontinence: prospective 12 months data from a single institution. BJU Int. 2011;108:1616-21.
13. Amat ITL, Martinez Franco E, LaillaVicens JM. Contasure-Needleless compared with transobturator-TVT for the treatment of stress urinary incontinence. Int Urogynecol J. 2011;22:827-33.
14. Prieto Chaparro L, Garcia Lopez F, Llorens Martinez F, et al. [Valsalva minimal leak point pressure: a useful approximation to type III female urinary incontinence]. Arch Esp Urol. 1998;51:783-9.

15. Agarwal A, Rathi S, Patnaik P, et al. Does preoperative urodynamic testing improve surgical outcomes in patients undergoing the transobturator tape procedure for stress urinary incontinence? A prospective randomized trial. Korean J Urol. 2014;55:821-7.

16. Martinez Franco E, AmatTardiu L. Contasure-Needleless(R) single incision sling compared with transobturator TVT-O (R) for the treatment of stress urinary incontinence: long-term results. Int Urogynecol J. 2015;26:213-8.

17. Palma P, Riccetto C, Bronzatto E, Castro R, Altuna S. What is the best indication for single-incision Ophira Mini Sling? Insights from a 2-year follow-up international multicentric study. Int Urogynecol J. 2014;25:637-43.

18. Ciftci S, Ozkurkcugil C, Ustuner M, Yilmaz H, Yavuz U, Gulecen T. Comparison of transobturator tape surgery using commercial and hand made slings in women with stress urinary incontinence. Urol J. 2015;12:2090-4.