Taiwanese Journal of Obstetrics & Gynecology 54 (2015) 726–730

Contents lists available at ScienceDirect

Taiwanese Journal of Obstetrics & Gynecology

journal homepage: www.tjog-online.com

Original Article

Comparison of single-incision mini-slings (Ajust) and standard transobturator midurethral slings (Align) in the management of female stress urinary incontinence: A 1-year follow-up

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ARTICLE INFO

Article history:
Accepted 8 June 2015

Keywords:
single-incision mini-slings
standard transobturator midurethral slings
urinary incontinence

ABSTRACT

Objective: To investigate the effectiveness and safety of a new single-incision mini-sling (SIMS)—Ajust—compared with the standard transobturator midurethral sling (SMUS)—Align—for the treatment of female stress urinary incontinence (SUI).

Materials and Methods: A retrospective cohort study was conducted between January 1, 2010 and August 31, 2012. Women with SUI who underwent either SMUS-Align or SIMS-Ajust were recruited. The primary outcomes included operation time, estimated operative blood loss, postoperative pain, and complications. The secondary outcomes included subjective and objective success, defined as an International Consultation on Incontinence Questionnaire (ICIQ) score of 0 or improvement as felt by the patient and a long-term complication, such as dyspareunia and mesh erosion after 6 months and 12 months of follow-up.

Results: A total of 136 patients were enrolled, including 76 receiving SMUS-Align and 60 receiving SIMS-Ajust. Baseline characteristics of the patients in both groups were similar, without a statistically significant difference. Primary outcomes between both groups were similar, except that women treated with SIMS-Ajust had statistically significantly shorter operation time ($p = 0.003$), less intent to treat ($p < 0.05$), and earlier postoperative discharge ($p = 0.001$) than women treated with SMUS-Align. Secondary outcomes were similar without a significant difference between the two groups (93% vs. 88% success rate in each group).

Conclusion: Our results showed that SIMS-Ajust was not inferior to SMUS-Align with respect to success rate, and might have a slight advantage in early discharge. A long-term follow-up or prospective study is needed to confirm the above findings.

Introduction

Urinary incontinence (UI), as a worldwide problem, is a distressing symptom that has a major impact on women's quality of life, because UI leads to embarrassment, anxiety, and in some cases, social isolation [1]. UI affects 10–40% of women, with the most common type known as stress urinary incontinence (SUI) [2]. Risk factors for SUI include increased number of vaginal deliveries,

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http://dx.doi.org/10.1016/j.tjog.2015.10.007

obesity, previous hysterectomy, chronic cough, poor health, depression, and stroke [1]. Nearly 50–70% of women with SUI seek medical help; however, these women often delay doing so. One report showed that the delay in seeking medical care was as long as 6–9 years [3]; moreover, of the women who seek help, only 5% of those who live in the community and 2% of those who live in long-term care facilities will receive appropriate treatment [3].

Behavioral modification as well as physical intervention is the mainstay of conservative treatment, which is considered as a first-line approach. Lifestyle modifications include weight loss, smoking cessation, avoiding caffeine, and prevention of constipation. Physical interventions include pelvic floor muscle exercise (Kegel exercises) or biofeedback to strengthen and improve the function and support of the pelvic floor muscles, and voiding control practice, such as bladder training, voiding at a set time, and establishing the habit of voiding. Medical treatment is often considered as an alternative. If conservative treatment with/without medical treatment does not provide satisfactory improvement, surgery can be contemplated.

Since the description of suprapubic cystotomy by Baker-Brown [4] in 1864, > 160 different surgical procedures (retropubic urethropexy) have been described for the treatment of SUI. There are two conventional routes used to access the retropubic space: the transperitoneal and extraperitoneal [5]. Over the past 30 years, attention has been directed toward developing less-invasive procedures in place of the originally designed surgery (retropupic urethropexy). These less-invasive techniques significantly reduced morbidity, hospital stay, and time taken to return to normal activities. In addition, along with the invention of mesh, midurethral sling procedures, including tension-free vaginal tape (TVT) by Ulmsten et al [6] in 1996 and standard transobturator mid-urethral slings (SMUSs), such as transobturator vaginal tape inside-out (TVT-O) by de Leval [7] in 2003, have been rapidly adopted, due to the simplifying of the Burch procedure and avoiding technical difficulty in laparoscopy. Now, both slings and retropubic urethropexy are considered first-line surgical options [8].

SUI after surgery is sometimes associated with adverse events, including bladder and bowel injury, groin pain and hematoma formation. This led to the development of minimally invasive and third-generation single-incision slings, also referred to as single-incision mini-slings (SIMSs). However, SIMSs are associated with inferior patient-reported and objective cure rates in short-term follow-up, and higher reoperation rates for SUI compared with SMUSs [9,10]. As a result, some SIMSs, for example, the Gynecare TVT Secure (Gynecare, Ethicon Inc., Somerville, MA, USA), were withdrawn from the market [11]. However, not enough evidence has been gathered on other single-incision slings and retropubic or transobturator slings to allow reliable comparisons [9]. In addition, nearly all published articles are obtained from Western countries [9–14]. Finally, no paper comparing the effectiveness of SIMS-Ajust (C.R. Bard, Murray Hill, NJ, USA) and the SMUS-Align Urethral Support System (C.R. Bard) in the management of female SUI has been seen in the literature. The aim of this study was to compare the efficacy and safety of SIMS using Ajust and SMUS using Align Urethral Support System (a retropubic midurethral sling) in the management of women with SUI.

Materials and methods

This was a retrospective cohort study, and followed written operating procedures, Good Clinical Practice guidelines, and applicable regulatory requirements. The study was approved by the Institutional Review Board of Taipei Veterans General Hospital, Taipei, Taiwan (VGHIRB No.: 2014-08-006CC). The board is organized under, and operates according to the International Conference on Harmonisation (ICH)/World Health Organization Good Clinical Practice and applicable laws and regulations. All women who received surgical management of SUI, which was confirmed by urodynamic study at Taipei Veterans General Hospital from January 1, 2011 to August 31, 2012 were enrolled in the study. Women who met the following criteria, including loss to follow-up, history of previous surgery for SUI, pelvic organ prolapse accompanied with or without other surgery, such as hysterectomy and/or other surgery for pelvic organ prolapse, and any additional surgery, were excluded.

To make this study even more uniform and consistent, the following criteria had to be met, including the same anesthesia method, as intravenous general anesthesia with laryngeal mask for operation, and a single operator (H.C.H.) to finish both operations: SIMS-Ajust and SMUS-Align.

Data such as patients' age, body height, body weight, number of births, menopausal status, estimated blood loss during operation, operation time, postoperative pain score using visual analog scale (VAS) scores, and times of postoperative intravenous pain control treatment were recorded. We also recorded the degree of symptom relief, and surgery-related complications, such as difficulty in voiding due to obstruction, wound infection, mesh erosion, or hematoma, at follow-up at the outpatient clinic until 12 months after the operation. We used “cure and improvement” as an endpoint to evaluate surgical success. The cure rate was defined as an International Consultation on Incontinence Questionnaire (ICIQ) score of 0, and improvement was recorded as the patient's impression after 12 months of follow-up.

SPSS for Windows version 15.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. Descriptive statistics were presented as means ± standard deviation or percentages. Means were compared by unpaired t test, and proportions were compared by χ^2 or Fisher's exact tests, as appropriate. All calculated p values were two-tailed, and $p < 0.05$ was considered statistically significant.

Results

Of the 338 patients we followed, 136 fulfilled the inclusion criteria. Seventy-six of these 136 patients received SMUS-Align surgery and 60 underwent SIMS-Ajust surgery. Mean age was 59.9 years and 58.8 years in the SMUS-Align and SIMS-Ajust groups, respectively, without a significant difference ($p = 0.44$). Other background characteristics, including mean number of births, body mass index (BMI), and menopausal status were similar between the two groups (Table 1).

Estimated blood loss was 53.2 mL and 51.2 mL in the SMUS-Align and SIMS-Ajust groups, respectively, without a significant difference ($p = 0.84$). Operation time was significantly longer in the SMUS-Align group than SIMS-Ajust group (31.8 minutes vs. 21.8 minutes, $p = 0.003$), and patients in the SMUS-Align group had a

Table 1
Baseline characteristics of women with stress urinary incontinence treated with SIMS-Ajust or SMUS-Align.

	Study group (SIMS) $n = 60$	Standard group (SMUS) $n = 76$	p
Age (y)	58.5 ± 10.8	59.9 ± 11.2	0.44
Parity	2.7 ± 1.2	2.8 ± 1.7	0.62
BMI (kg/m^2)			0.65
> 25	35 (58.3)	46 (62.2)	
≤ 25	25 (41.7)	28 (37.8)	
Menopause	46 (76.7)	61 (80.3)	0.61

Descriptive statistics are presented as means ± standard deviation or n (%).
BMI = body mass index; SIMS = single-incision mini-sling-Ajust; SMUS = standard transobturator midurethral sling-Align.

longer stay in hospital (4.3 days vs. 3.7 days in the SIMS-Ajust group, $p = 0.001$). Surgical complication rate was similar between the two groups (3.9% in the SMUS-Align group and 5.0% in the SIMS-Ajust group), including two patients with urinary tract infection (UTI) in each group. One patient with a SIMS-Ajust was complicated with hematoma and another with a SMUS-Align had a urinary tract obstruction, and needed surgery to relieve the slings. Postoperative residual volume of urine was 57.6 mL in the SMUS-Align group and 72.1 mL in the SIMS-Ajust group ($p = 0.212$). Patients in the SIMS-Ajust group had less frequency of intent to treat than those in the SMUS-Align group (Table 2).

In both the SMUS-Align and SIMS-Ajust groups, VAS scores were lower when measured at 3 hours than at 30 minutes post-operation ($p < 0.001$), and were also lower when measured at 3 days than at 3 hours post-operation ($p < 0.001$; Table 3). However, no significant difference in VAS scores between the two groups was found after each postoperative follow-up (30 minutes, 3 hours, and 3 days; Table 3).

Secondary outcomes were similar in both groups, regardless of 6- or 12-month follow-up. Both surgical procedures showed nearly 90% success rates, and cure rates were > 70% at the end of the 2-year follow-up (Table 4). Neither dyspareunia nor mesh erosion was found in either group during the 1-year follow-up.

Discussion

Similar to other countries, increasing use of the midurethral sling in the management of female SUI was found in Taiwan in a population-based, nationwide, follow-up descriptive study [15]. However, the effectiveness of SIMS in women with SUI in Taiwan is still uncertain. Only one study from Taiwan has compared the clinical outcome of a SIMS-MiniArc (SIS, American Medical Systems Inc., Minnetonka, MN, USA) and SMUS-Monarc (TOT; American Medical Systems) in the management of female SUI, and the results showed a similar mechanism of action with comparable subjective and objective clinical outcomes [16]. Our current study might be the first comparing two devices from the same company: SIMS-Ajust and SMUS-Align (C.R. Bard) in the management of female SUI, based on our limited knowledge and a literature review, including two recent meta-analyses [14,17], and three previous studies [12–14]. Schellart and colleagues [12] conducted a 1-year randomized clinical trial to compare the efficacy and morbidity of SIMS-MiniArc and SMUS-Monarc and showed that SIMS-MiniArc was non-inferior to SMUS-Monarc with respect to cure, and was superior with respect to pain and recovery. By contrast, Madsen and colleagues [13] found that SIMS-MiniArc was less effective, with more postoperative incontinence, less patient-reported improvement and satisfaction, and higher reoperation rates for SUI, compared with retropubic SMUS-ALIGN. Mostafa and colleagues [18] conducted a multicenter prospective randomized study of SIMS-Ajust and SMUS-TVT-O in the management of female SUI, and showed that SIMS-Ajust was associated with a significantly improved postoperative pain profile and earlier return to work when compared to SMUS-TVT-O, with encouraging results in patient-reported and objective success rates at 4–6 months of follow-up. Grigoriadis and colleagues [19], in a 22.3-month (range, 12–36 months) follow-up, found that SMUS-TVT-O and SIMS-Ajust showed a similar objective cure rate and improvement rate (86% vs. 84.7%, and 5.9% vs. 4.7%, respectively), and concluded that both SMUS-TVT-O and SIMS-Ajust seemed to be safe and effective for the treatment of urodynamic SUI. Our current study design used SIMS-Ajust in place of the SIMS-MiniArc of Madsen et al's [13] study, and compared it with SMUS-Align in place of the SMUS-TVT-O of Mostafa et al's [18] study and Grigoriadis et al's [19] study for the treatment of female SUI. Our results showed that SIMS-Ajust was non-inferior to SMUS-Align, with respect to 6- and 12-month success rates and/or improvement rates, suggesting that both devices could provide similar therapeutic effectiveness for women with SUI.

The value of SIMS in the management of female SUI could be supported by a recent meta-analysis [14]. Mostafa and colleagues [14] investigated 26 randomized controlled trials, including 3308 women, comparing SIMS versus SMUS in the surgical management of SUI, and found no evidence of significant differences between SIMS and SMUS in patient-reported cure rates, with a risk ratio of 0.94 (95% confidence interval, 0.88–1.0) and objective cure rates with a risk ratio of 0.98 (95% confidence interval, 0.94–1.01) at a mean follow-up of 18.6 months.

In fact, SIMS fundamentally differs from SMUS because it has a shorter trajectory of insertion and therefore needs a robust mechanism anchoring it to the obturator complex with a strong post-

Table 2
Primary outcome of women treated with SIMS-Ajust or SMUS-Align.

	Study group (SIMS) $n = 60$	Standard group (SMUS) $n = 76$	p
EBL (mL)	51.2 ± 48.9	53.2 ± 67.1	0.844
Operation time (min)	21.8 ± 17.7	31.8 ± 19.8	0.003
Intent to treat[a]	0.5 ± 0.3	1.2 ± 1.1	<0.001
PVR	72.1 ± 55.0	57.6 ± 74.8	0.212
Hospitalization (d)	3.7 ± 0.8	4.3 ± 1.2	0.001
Complications	3 (5.0)	3 (3.9)	0.767

Descriptive statistics are presented as means ± standard deviation or n (%).
EBL = estimated blood loss; PVR = post-voiding residual urine; SIMS = single-incision mini-sling-Ajust; SMUS = standard transobturator midurethral sling-Align.
[a] Patients requested extra postoperative pain relief.

Table 3
Comparison of intervention effects on [a]VAS scores in patients treated with anti-incontinence surgery (SIMS-Ajust or SMUS-Align).

Variables	Regression coefficient	Standard error	t value	p
Intercept	5.50	0.13	43.54	< 0.001
SIMS/SMUS	0.15	0.15	0.98	0.326
3 h/30 min	−2.49	0.14	−17.94	< 0.001
3 d/30 min	−4.51	0.14	−32.56	< 0.001
Group*3 h	0.17	0.21	0.82	0.415
Group*3 d	−0.07	0.21	−0.34	0.737
Intent to treat	−0.10	0.05	−1.99	0.047

SIMS = single-incision mini-sling-Ajust; SMUS = standard transobturator mid-urethral sling-Align; VAS = visual analog scale.
[a] VAS = 5.50 + 0.15*(group) − 2.49*(3 h/30 min) − 4.51*(3 d/30 min) + 0.17*(interaction of 3 h and groups) − 0.07*(interaction of 3 d and groups) − 0.10*(intent to treat).

Table 4
Secondary outcome of women treated with SIMS-Ajust or SMUS-Align.

	Study group (SIMS) $n = 60$	Standard group (SMUS) $n = 76$	p
6 mo			
Success	57 (95.0)	70 (92.1)	0.421
Cure	50 (83.3)	59 (77.6)	0.374
Improvement	7 (11.6)	11 (14.5)	0.634
1 y			
Success	56 (93.3)	67 (88.2)	0.311
Cure	49 (81.7)	56 (73.7)	0.273
Improvement	7 (11.6)	11 (14.5)	0.634

Descriptive statistics are presented as means ± standard deviation or n (%).
Cure = ICIQ-UI Short Form score = 0; ICIQ-UI = International Consultation on Incontinence Questionnaire-Urinary Incontinence; SIMS = single-incision mini-sling-Ajust; SMUS = standard transobturator midurethral sling-Align; Success rate = 1-year follow-up with relief of symptoms.

insertion pullout force [14]. Ajust, a recently developed SIMS, has an added advantage that allows post-anchorage adjustment of the sling tension [14]. This polypropylene anchor design has been shown in independent animal studies assessing its immediate and delayed extraction forces to be associated with the strongest and most robust mechanism anchoring it to the obturator complex [14,20]. Our current study confirmed the security of the use of SIMS-Ajust in the management of female SUI, compared with conventional standard transobturator midurethral slings (SMUS-Align), suggesting that SIMS-Ajust is one of the best choices in the management of female SUI during at least the 1-year follow-up period.

The use of SIMS-Ajust in the management of female SUI has been reported before. Cornu and colleagues [21] conducted a prospective study enrolling 95 patients implanted with SIMS-Ajust and showed a success rate of 80% after a mean follow-up of 21 months (12–32 months); however, there were some postoperative complications, including one case of vaginal hematoma, one case of acute urine retention, two cases of UTI, one case of mesh erosion, and two cases of dyspareunia. The study from China found that the subjective cure rate and objective cure rate of women with SUI treated by SIMS-Ajust was 82.3% and 91.2% after 1 year follow-up, respectively, and 3.2% of women had sling exposure [22]. Another study from Italy showed the subjective and objective cure rates of 81.5% and 83.7%, respectively, in 92 women with SUI treated with SIMS-Ajust during 2-year follow-up, and one woman had referred pain in the right leg, three had mesh extrusions, and one had recurrent UTI [23]. A report from Brazil shows that thigh pain was significantly increased in the SMUS group compared with the SIMS group (7.1% vs. 0%, $p = 0.045$) [24]. In our current study, a 5% short-term complication rate was noted in women treated with SIMS-Ajust, including one case of vaginal hematoma and two cases of UTI. Abdel-Fattah and colleagues further indicated the advantages of SIMS-Ajust in the management of female SUI, reporting that half of the patients could be offered the procedure under local anesthesia, and SIMS-Ajust had an 80% patient-reported success rate at the 1-year follow-up [25]. In our current study, SIMS-Ajust had a 93% patient-reported success rate at 1 year follow-up, which showed no significant difference from the standard transobturator midurethral slings, Align (88%). Because SUI is a common and relatively troublesome disease in aged women [26,27], less invasive with a similar effectiveness is more acceptable, suggesting that the use of SIMS-Ajust in place of SMUS-Align might be a trend in the management of women with SUI in the future.

Although there was no significant difference between the SIMS-Ajust and SMUS-Align groups in VAS scores at each of the same postoperative time points (30 minutes, 3 hours, and 3 days) in our study, patients in the SIMS-Ajust group did have fewer instances of intent to treat, suggesting that subjectively, patients in both groups had similar degrees of pain, as measured by VAS score, but objectively, patients in the SIMS-Ajust group had less pain, as reflected by fewer instances of intent to treat.

Conclusion

Our current study showed that SIMS-Ajust was non-inferior to SMUS-Align with respect to success rate, and might have a slight advantage in early discharge among women with SUI. More evidence is needed, and will be provided when larger case numbers and longer follow-up times are available.

Conflicts of interest

The authors have no conflicts of interest relevant to this article.

Acknowledgments

Supported by grants from the Ministry of Science and Technology, Executive Yuan (MOST 103-2314-B-010 -043 -MY3), and Taipei Veterans General Hospital (V103A-016; V102C-141; V103C-112; V104C-095; V102E4-003; V103E4-003). The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript. No additional external funding was received for this study. We thank the Medical Science & Technology Building of Taipei Veterans General Hospital for providing experimental space and facilities. The authors thank the Task Force on Gyn-Urodynamic Research Group, including Chi-Mu Chuang, MD; Yen-Hou Chang, MD; Hua-Hsi Wu, MD; Hei-Yu Lau, MD; Jen-Yu Tseng, MD; Hsiao-Wen Tsai, MD; Nae-Fong Twu, MD; and Hsiang-Tai Chao, MD, PhD.

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