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Original Article

Is the anchor matter? A short-term follow-up of the effect of mini-invasive mid urethra sling without anchor for urinary incontinence women

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ABSTRACT

Objective: Stress urinary incontinence (SUI) is a common disease in aged women, and some of them need surgical correction. Recently, the mid-urethral sling is an accepted surgical approach for SUI. However, complication may occur in this surgery, and some of them are needle-related. Therefore, the needleless system may diminish this-type complication.

Materials and methods: We conducted a retrospective study to evaluate the feasibility of women with SUI undergoing needleless sling surgery in 2017. Assessments were performed by two independent special urogynecologists before, during and post operation periods. We used a category-time-site-pain code following the International Continence Society and International Urogynecological Association (ICS/IUGA) Complication Classification Code (CCC) guidelines.

Results: Thirty-eight women were analyzed. The characteristics of the patients were 66.3 ± 12.8 years old (mean \pm standard deviation) of age, 2.8 ± 1.2 of parity, and 25.6 ± 4.2 kg/m² of body mass index. All had history of vaginal delivery for term. The objective cure rate at 2- and 4-week follow-up was 97.4% ($n = 37$) and 94.7% ($n = 36$), respectively. The subjective cure rate at 2- and 4-week follow-up was both 89.5% ($n = 34$). Both objective and subjective cure rates remained constant and similar to the end of 4 weeks. There were 6 patients (15.8%) who had complications according to ICS/IUGA CCC guidelines.

Conclusion: This needleless mid-urethral sling procedure seemed to be feasible in the management of women with SUI in this small series and short-term follow-up study, suggesting that a further prospective, randomized, comparative study with other tension-free procedures and mini-sling systems can be conducted.

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Introduction

Stress urinary incontinence (SUI), a common but bothersome disease, not only deteriorates the quality of life in women but also constitute a huge global problem worldwide affecting approximately 20% of women, increasing with age and times of vaginal

delivery [1–8]. There are many strategies in the management of women with SUI, including behavior and lifestyle modification, medication, pelvic floor training with surface electromyography feedback [9–11], physiological therapy, laser therapy [12,13], urethral bulking agent [14], etc.; however, there is a trend in surgery of women with SUI [7,15–19], estimating to increase by 47.2% from 210,700 in 2010 to 310,050 in 2050 [20]. Historically, many types of surgery have been performed to treat women with SUI [15,16,21]. During the last decade, the accepted standard technique has been the standard midurethral sling (SMUS) operation, whereby an artificial tape or mesh is placed directly beneath the urethra and is anchored to the tissues in adjacent parts of the groin or just above the pubic bone [15,16,21]. Nevertheless, the mid-urethral sling was

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shown to exhibit a good safety profile and to be highly effective in the short and medium term irrespective of the placement route [16]. Although SMUS procedure is popular and feasible, surgery-related complications, such as bladder perforation caused by tape insertion, erosion of the tape into the urethra during the healing period, pelvic hematomas, difficult voiding due to too tight of the sling or chronic thigh/groin pain are nightmare for both physicians and patients [22–24]. Recently, these single-incision mini-slugs (SIMSs) have been optimized to overcome the above-mentioned complications [25]. The first device that used a single incision was tension-free vaginal tape (TVT)-Secur® was developed in 2006 [26]. This device was based on the use of shorter polypropylene laser-cut tape (8 cm × 1 cm) through a single vaginal incision and no need of the use of needles without passage through the retro-pubic space, obturator foramen, or groin muscles, attributable to avoid the injury of the structures related nerves and blood vessels [26,27]. Without fixation by two barbs, the efficacy might be questionable. In fact, the manufacturer (Ethicon) decided to withdraw TVT-Secure® in 2013 [25,26]. In our previous report [17], we have already reported the effectiveness and safety of SIMS-Ajust® in the management of women with SUI. The current study attempted to evaluate the shorten outcome of a new SIMS- Contasure- Needleless® (C-NDL®, Neomedic International) for the single-incision hammock-shaped midurethral sling in the management of women with SUI.

Materials and methods

We conducted a retrospective study to evaluate the outcome of women with SUI undergoing needleless sling surgery in 2017. The study was approved by the ethical committee of our institution. All patients submitted to a clinical history during which background data was collected. All patients had been evaluated by preoperative urodynamic testing. All surgeries were performed under general anesthesia by two experienced urogynecologists (Drs. Chang and Horng). Antibiotic prophylaxis with 1 g of cefazoline was administered before the surgery. No planned concomitant surgery and routine intraoperative cystoscopy were performed. C-NDL® technique was done strictly according to the manufacturer's instructions as previously described before [27,28]. In brief, the patient in the lithotomy position with empty of urinary bladder by Foley catheter received a 1.5-cm longitudinal incision at the level of the suburethral vaginal mucosa at a distance of 0.5 cm from the urethral meatus. The paraurethral space was dissected sharply up to the descending ramus of the pubic bone. A pair forceps hold the sling pocket and push them by 2 and 10 o'clock direction to perforate the urogenital diaphragm and into the internal obturator muscle. Then open the forceps to display the "T" pocket positioning of the mesh, and leaving the sling anchored at the internal obturator muscle. Further adjust of mesh can be done by introducing the tips of the forceps in the pocked positioning system and pushing the tip of the mesh up to the desired support level. After proper positioning, the blue centering suture is removed from the sling with a single cut on one side of the suture, and close the vaginal incision wound.

Assessments during the preoperative period and postoperative weeks 2 and 4, and months 6 were done by two independent experienced urogynecologists. Every complaint was categorized in the postoperative period by the examining surgeon using a category-time-site-pain code following the International Continence Society and International Urogynecological Association (ICS/IUGA) Complication Classification Code (CCC) guidelines [29–32]. Objective cure was defined as the negative cough-stress test and subjective cure was defined as no urine leakage by the answer of International Consultation on Incontinence Questionnaire-Short

Form (ICIQ-SF) question 6 "when dose urine leak?" was "never/urine dose not leak" or "leaks before you can get to the toilet" or "leaks when you are asleep" rather than leaks while cough or sneezing. Failure of the surgery was defined as the need for reoperation for difficult voiding needs sling revision or persisted urinary incontinence needs reoperation [17].

Result

A total of 38 patients were enrolled into the current study. The characteristics of the patients are shown in the Table 1, including 66.3 ± 12.8 years old (mean \pm standard deviation) of age, 2.8 ± 1.2 of parity, and 25.6 ± 4.2 kg/m² of body mass index. Three of them have been treated with sling surgery before (one was Ajust® and two were unknown). The mean operation time was 17 min, ranging from 13 min to 25 min. The objective and subjective cure rate after 2 weeks follow-up was 97.4% (n = 37) and 89.5% (n = 34), respectively. However, passing addition two weeks, objective rate was decreased to 94.5% (n = 36) but subjective cure rate remained 89.5% (Table 2). Six months later, cure rate of both remained constant of 94.5% and 89.5%, respectively, without further declining. A total of 6 patients had complications according to the ICS/IUGA CCC guidelines (Table 3). Overactive urinary bladder (OAB) syndrome occurred in 12 patients after surgery, and majority of them responded well to medication treatment.

Discussion

The synthetic SMUS surgery (a tape made of polypropylene placed mid-urethra under tension) has been established as the golden standard surgery for SUI treatment [16,33–35]. Recently, a new class of SIMSs has emerged [17,27,28]. This modification included shortening of mesh length, no passing through the obturator foramen, maintaining the hammock approach, and stating in the tension free status. With negative reports from the previous studies of TVT-Secure®, there is much concern about the efficacy of these SIMSs.

In 2015, we reported the feasibility and safety of one of SIMSs, naming Ajust® in the management of women with SUI (n = 60) comparing with traditional standard SMUS-Align and found that women treated with SIMS-Ajust had statistically significantly shorter operation time (22 min versus 32 min), less intent to treat (0.5 versus 1.2), and earlier postoperative discharge (3.7 days versus 4.3 days) than women treated with SMUS-Align® without compromising the therapeutic efficacy (83.3% versus 77.6% at 6-month follow-up and 81.7% versus 73.7% at 12-month follow-up, respectively), suggesting that this SIMS-Ajust® could be used in the management of women with SUI based on a slight advantage [17]. The above-mentioned report [17] is also supported by recent systematic review and meta-analysis, which confirmed the benefits of SIMS-Ajust® in the management of women with SUI, because of

Table 1

The general characteristics of the patients (number 38) undergoing single incision midurethral sling- Contasure- Needleless® surgery.

General characteristics	
Age (years)	66.3 \pm 12.8
Parity	2.8 \pm 1.2
Body mass index	25.6 \pm 4.2
Previous operation history	
Hysterectomy	10 (26.3%)
Pelvic organ prolapse surgery	1 (2.6%)
Previous anti-incontinence surgery	3 (7.9%)

The data was presented as mean \pm standard deviation or number (percentage).

Table 2

The objective and subjective cure rates during the 6-month follow-up period.

Time	Objective cure rate Number (%)	Subjective cure rate Number (%)
2 weeks	37 (97.4%)	35 (89.5%)
4 weeks	36 (94.7%)	34 (89.5%)
6 months	36 (94.7%)	34 (89.5%)

The data was presented as number (percentage).

no significant difference between SIMS-Ajust® and other SMUS in subjective and objective cure rates and complication rate but of a significantly shorter operative time and lower postoperative pain score (mean difference [MD] −1.35; 95% confidence interval [CI] −2.24 ~ −0.46, $P = .003$) when comparing SIMS-Ajust® with other SMUS, suggesting that SIMS might have clinical benefits and worthy of supporting the clinical application based on equally efficacy and the significantly shorter operation time and lower postoperative pain score [36].

The other type of SIMS- MiniArc® is also evaluated in the management of women with SUI. A recent systematic review and meta-analysis also showed its effectiveness, because when compared with other SMUS, this SIMS-MiniArc® not only has similar high objective and subjective cure rates (risk ratio [RR] 0.98, 95% CI 0.94–1.03, $P = 0.43$; RR 0.97, 95% CI 0.91–1.04, $P = .38$, respectively), but also has shorter operation time (MD −6.12, 95% CI −8.61 ~ −3.64, $P < .001$), less blood loss (MD −16.67, 95% CI −26.29 ~ −7.05, $P < .001$), more favorable recovery time (MD 1.30, 95% CI −1.74 ~ −0.86, $P < .001$), lower postoperative pain scores (MD −1.70, 95% CI −3.17 ~ −0.23, $P = .02$), less postoperative groin pain (RR 0.42, 95% CI 0.18–0.98, $P = .04$), less

urinary retention (RR 1.15, 95% CI 0.46–2.87, $P = .77$), and absence of a visible wound [37].

Consistent with other types of SIMS (Ajust® and MiniArc®), the feasibility of current type of SIMS-C-NDL® seemed to be acceptable, because of higher cure rate of 89.5%, which is not inferior to that (83.3%) in our previous report using SIMS Ajust® [17]. The feasibility and safety of the current study is similar not only to the early report in 2011 (87.5%) [27] but also to the recent reports in 2015, 2017, and 2018, respectively [28,32,38,39].

In detailed discussion about the postoperative lower urinary tract disorders, which are common after surgical management of women with various kinds of pelvic organ disorders, including SUI [40–45], there are 4 patients complaining of difficult empty, slow flow or urinary retention, but only one of them had the above-mentioned troubles needing further surgery (sling cut surgery). Eventually, the remaining 3 patients were totally free of symptoms during the follow-up period.

Two patients had pelvic pain during physical activities and among both, one patient was treated with the Obtryx® TO SMUS System (Boston Scientific) for persisted SUI during the follow-up period. The re-operation rate was 5.3% ($n = 2$). Interestingly, 12 patients had OAB symptoms, including frequency, and urge incontinence or even nocturia after surgery and 4 patients had completely absence of OAB symptom during the follow-up. Eight patients received medicine treatment. Because 2 patients had OAB symptoms before surgery, de novo OAB rate was 15.8% ($n = 6$), which is similar to other reports from SMUS or SIMS [17,27,36–46].

The strength of the current study, it may be the first domestic article addressing the feasibility of the use of Needleless system in the management of Taiwanese women with SUI. However, there are several limitations in the current study, such as a small series, a

Table 3

The detailed complications in the current study according to the International Continence Society and International Urogynecological Association (ICS/IUGA) Complication Classification Code (CCC) guidelines.

	IUGA/ICS classification of complications
Category	
1. Vaginal: no epithelial separation	2 (5.3%)
2. Vaginal: smaller ≤ 1 cm exposure	0 (0)
3. Vaginal: larger > 1 cm exposure, or any extrusion	0 (0)
4. Urinary tract: compromise or perforation, including Prosthesis (grift) perforation and fistula	4 (10.5%)
5. Rectal or bowel: compromise or perforation, including Prosthesis (grift) perforation and fistula	0 (0)
6. Skin or musculoskeletal: complications, including discharge, pain, lump or sinus tract formation	0 (0)
7. Patient: compromise, including hematoma or systemic compromise	0 (0)
A (asymptomatic)	2 (5.3%)
B (Symptomatic)	4 (10.5%)
C (Infection)	0 (0)
D (Abscess)	0 (0)
Time (clinically diagnosed)	
T1: Intraoperative to 48 h	0 (0)
T2: 48 h to 6 months	5 (13.2%)
T3: Over 6 months	1 (2.6%)
Site	
S1: Vaginal: area of suture line	4 (10.5%)
S2: Vaginal: away from area of suture line	0 (0)
S3: Trocar passage	0 (0)
S4: Other skin site	0 (0)
S5: Intra-abdominal	2 (5.3%)
Pain	
U: Unspecified	4 (10.5%)
a: Asymptomatic	0 (0)
b: Provoked pain only (during vaginal examination)	0 (0)
c: Pain during intercourse	0 (0)
d: Pain during physical activities	2 (5.3%)
e: Spontaneous pain	0 (0)

The data was presented as number (percentage).

short follow-up. However, based on the current study, we can reinforce the feasibility of SIMS in the management of women with SUI in Taiwan.

In conclusion, the experience about the use of Needleless system in the management of women with SUI is shared. Based on relatively promising results and acceptability of the SIMS- Contasure-Needleless® for women with SUI, a comparison study or a prospective study is welcome to test the efficacy and safety of this relatively new SIMS Contasure- Needleless® in the management of women with SUI.

Conflicts of interest

The authors declare that they have no competing interests.

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