

Contasure-Needleless mini-sling for female stress urinary incontinence: a review of outcomes at 12 months

Randomized control trial

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ABSTRACT

Objective: *This study aimed to evaluate Contasure-Needleless (C-NDL) technique in the surgical management of female stress urinary incontinence (SUI).*

Methods: *This prospective observational study was performed on 80 women with urodynamically proven pure SUI (40 underwent Contasure® + 40 underwent TVT-O KIM®) at Zagazig university hospital, obstetrics and gynecology department from August 2017 till October 2020, then they had 12 months follow up with 9 drop out cases (4 in TVT-O group, 5 in C-NDL). Detailed history, investigations, urodynamics and physical examination were done before. Contasure® was implanted through small anterior vaginal wall incision to both obturator muscles. Postoperatively, we evaluated patients' pain, status of continence, satisfaction rate.*

For statistical analysis, we used the Statistical Packages for Software Sciences (SPSS) version 21.

Results: *Mean age of patients was 45.9 & 44.3 years old, BMI was 28.1 & 27.8 kg/m² in TVT-o & Contasure respectively. Mean operative time was 18.25 & 17.1 minutes, blood loss was estimated as 77.9 & 62.55 ml, there was statistically non-significant difference between two groups regarding presence of pain, urinary complications or dyspareunia in favor of Contasure. Both techniques have similar success rate*

Conclusions:

Success and satisfaction rates of Contasure mesh is hopeful without significant different lower complications, but with higher cost 415\$ versus 340\$ KIM TOT. Furthermore, the procedure's efficacy holds encouraging results that need to be affirmed and tested by long-term outcomes.

INTRODUCTION

Stress urinary incontinence in women (SUI) is a timid condition where involuntary urine leakage with any increase in the intra-abdominal pressure, such as staining, sneezing and coughing [1]. Nearly 35-50% of women occasionally report urinary incontinence, with ten percent of the middle-aged group experiencing severe symptoms [2]. SUI usually results from disruption of the normal designed anatomy of pelvic floor muscle and tissues, as a consequence of aging process, the trauma of bad managed vaginal delivery, or due to chronic illness like obesity and diabetes [3]. Various non-surgical treatment options are still under investigation, including lifestyle modifications, pelvic floor training approaches, medications (e.g., norepinephrine reuptake inhibitors, or Duloxetine), and even devices (e.g., pessaries and urethral inserts) [4].

Surgery by the time had been the gold standard for treatment of female SUI and had reached 85-90% success rates [5]. Numerous phases of evolution of surgery of SUI, starting with the anterior repair, going by Burch surgery and lastly laparoscopic Burch and laparoscopic paravaginal repair [6]. Currently, the most cost effective accepted surgical approach for SUI treatment is the mid-urethral slings (TVT,TOT) which depend on hammock theory on mid-urethra, unlike the previous operations, where the support was focused on the urethrovesical junction [7]. Continuous development and updates of minimal invasive surgeries ;the single incision mini-slings (SIMSs) in late 2006 evolved [9]. In these procedures, a shorter-length mesh foreign body is inserted through a single vaginal incision, without the need for any needle blind insertion into the abdomen or groin, which would allow a faster recovery period, less pain and a high cure rate [10]. Contasure-Needleless (C-NDL) is a new type of SIMS which is currently being investigated due to its promising results of high cure rates and fewer complications than other techniques [8,11]. In this technique, a polypropylene monofilament mesh is used (114 mm in length and 12 mm in width), with T-pocket-positioning systems at its ends, allowing for the proper positioning and stability of the mesh into the obturator muscles [12]. In this study, we compared the efficacy of the contasure-needleless sling with TVT-O sling in surgical management of women with urodynamic proved SUI.

METHODS

The study was performed in compliance with the recommendations of Helsinki's declaration [13] and was approved by the ethics committee of Zagazig University (IRB approval no. ZU-IRB #705-3-3-2013). We followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for reporting our study.

Study Design, Setting, and Eligibility Criteria

We conducted a prospective observational study at Zagazig University Hospitals, Egypt, between August 2017 and October 2020. We included eighty women aged ≥ 18 years old with urodynamic proved pure SUI, who failed or declined conservative treatment. We excluded patients who had mixed incontinence, VLPP less than 60 cm H₂O, previous SUI surgery, neurological conditions, or prior pelvic irradiation.

Study procedures

After assessing the eligibility criteria, all patients were subjected to a complete history taking as well as physical, gynecologic, neurological, and rectal examinations. A vaginal examination was performed to exclude genitourinary fistula and any associated pelvic organ prolapse. The Standing Cough Stress test was performed for all patients, where the patient was asked to cough repetitively with a bladder volume of at least 300 ml or a subjectively full bladder in standing position. Small spurts of urine loss immediately with coughing are suggestive of stress incontinence. All patients underwent urodynamic evaluation only preoperatively in the Urodynamic unit in the outpatient clinic of Zagazig University Hospitals using Multichannel Urodynamics System (Triton, LA BORIE, Toronto, Canada). Laboratory investigations included mid-stream urine analysis as well as culture and sensitivity tests in cases of pyuria to be treated before any intervention.

Manipulation

All patients signed informed consent and had a preoperative anesthetic evaluation. Patients were random assigned to two groups (odd patient for Contsure, even patient for TVT-O). Both techniques may be performed under regional anesthesia-saddle block-. Antibiotic prophylaxis with intravenous 2 gm Cefotax was administered before the procedure. All patients were asked to come for a follow-up in the gynecology outpatient clinic at one month, six months, and 12 months after surgery. At each visit, data on urinary symptoms and complications were obtained. Also, we performed a urogynecological examination, including the assessment of external genitalia and standing cough stress test.

Surgical Techniques

TVT-O

After injection of vasopressor (diluted Epinephrine) at vaginal incision site ; Three incisions were performed (two small incisions were made in groin lateral to genito-femoral fold at level of clitoris, and one vaginal incision was done in the mid-urethral area with paraurethral tunneling till inferior pubic ramus). The needle was inserted through the vaginal incision laterally to the obturator membrane, rotating the needle around the obturator foramen and out through the inguinal skin. The same maneuver was performed at the contralateral side. Then we pulled

both ends of the mesh while maintaining the placement of artery forceps between the urethra and the mesh to ensure the sling was tension free.

C-NDL

The vagina was incised approximately 1.5-2 cm below the external urethral orifice, **Figure 1** . Then, the paraurethral tissue was dissected with scissors and tunneled up to the inferior pubic ramus. The sling was advanced into the obturator internus muscle and obturator membrane in the 2 o'clock direction with pointed artery forces, **Figure 3**. The artery forceps was partially opened and removed to free the “T” pocket of the mesh. We controlled the positioning by a blue centering suture of the sling. The process was repeated on the contralateral side towards the 10 o'clock direction. After accurate locating, the blue suture was removed, and the incision was closed with vicryl 2/0 rapidly absorbable sutures.

The catheter and vaginal pack were left for 24 hours postoperative in both techniques



Figure 1 shows the blue suture in mid-line

Figure 2 shows the vaginal incision



Figure 3 shows insertion of contasure

1.1 Statistical Analysis

For statistical analysis, we used the Statistical Packages for Software Sciences (SPSS) version 21. Descriptive analysis was performed to describe the patients' characteristics. We reported the qualitative data as frequencies and percentages, while the quantitative data were reported as mean and standard deviation (SD). We used the Fisher test to compare the categorical variables. We used the t-test to compare the continuous outcomes between the two studied groups. A P-value of ≤ 0.05 was considered statistically significant.

2 Results

2.1 Characteristics of the study population

We included 80 patients in our study. The included women were divided into two groups (40 women in the TVT-O group, with a mean age of 45.9 (± 10.29) years and 40 women in the C-NDL group, with a mean age of 44.35

(± 7.9) years. The mean body mass index was nearly equal in both groups. Data on the baseline characteristics of the included patients, as well as Valsalva leak point pressure, are presented in **Table 1**.

Table 1 shows the demographic characteristics of the studied groups (n= 80 patients)

	TVT-O (n=40)	C-NDL (n=40)	p-value
Age (years), mean \pm SD	45.9 \pm 10.29	44.35 \pm 7.9	0.553 ^a
Body mass index (kg/m ²), mean \pm SD	28.1 \pm 4	27.8 \pm 4.84	0.832 ^a
Valsalva leak-point pressure (VLPP), n (%)	>100	12 (30)	0.878 ^b
	60-75	20 (50)	
	80-100	8 (40)	

a= P-value has been calculated using the t-test; b= P-value has been calculated using the Fisher test.

Intraoperative data

As shown in Table 2, the intraoperative data showed no statistically significant differences between both groups in operative time (p= 0.078). TVT-O group had a higher blood loss than the C-NDL group (77.9 vs. 62.55), with a p-value of 0.001. Three patients after C-NDL had urinary retention versus only one patient in TVT-O.

Table 2 shows the comparison between the studied groups regarding intraoperative data

	TVT-O (n=40)	C-NDL (n=40)	p-value
Operative time (minutes), mean \pm SD	18.25 \pm 2.2	17.1 \pm 1.8	0.078 ^a
Blood loss (ml), mean \pm SD	77.9 \pm 16.53	62.55 \pm 6.49	0.001* ^a
Pain scale, median (range)	2 (0 - 6)	1 (0 - 4)	0.054 ^a
Urinary retention	1(2.5%)	3(7.5%)	□□□□□

a= p-value has been calculated using the t-test; *= Significant at p \leq 0.05 level.

The cough test follow-up

Table 3 shows the follow-up of the cough test and subjective cure rate among the studied patients at 12 month follow up:

	TVT-O	C-NDL	p-value
Cough test	Negative	32/36* (88.8%)	0.4708 ^a
	Positive	4/36 (11.2%)	
Subjective	Negative	33/36 (91.67%)	0.7256 ^a
	Positive	3/36 (8.33%)	

a= p-value has been calculated using the Fisher test,* 4 missed cases at follow up,**5 missed cases.

Postoperative complications

Pain (thigh & groin) was reported in 5.72% of C-NDL patients versus 22.22% in TVT-O. Dyspareunia was complained in 8.57% & 19.44% of patients with C-NDL & TVT-O respectively.

Table 4 shows the postoperative complications between the studied groups after 12 month

	TVT-O (n=36)	C-NDL (n=35)	p-value
Pain	No	28 (77.78)	0.661 ^a
	Yes	8 (22.22)	
Dyspareunia	Negative	29 (80.56)	1 ^a
	Positive	7 (19.44)	

a= p-value has been calculated using the Fisher test.

DISCUSSION

Despite the optimistic results of the C-NDL procedure, in terms of efficacy and complication rates, only a few reports have compared this technique and the second generation of MUS, the TVT-O method [8,12,14,15]. The most recent systematic review and meta-analysis to study the differences in short-term efficiency, operation time, and incidence of adverse events was conducted by Luo et al. (2020). Such a study was considered the first systematic review and meta-analysis comparing C-NDL to MUSs. In their analysis, no statistically significant difference was found between the two groups, TOT/TVT-O and C-NDL, regarding the cure and complication rates. However, C-NDL was superior regarding the incidence of postoperative pain and the intraoperative duration [16]. Owing to the C-NDL procedure's novelty, most of the studies concerned with the subject were non-inferiority trials, as the current interventions' cure rates are already satisfying [8]. Indeed, the novel C-NDL technique proved to be inferior to conventional methods. Stress urinary incontinence is obstacle against female quality of life. Understanding midurethral role of continence open ways to introduce midurethral slings (TVT) as gold standard method in treating SUI, which were upgraded continuously till reaching Contasure single incision minisling. Contasure had introduced with less complications, only one small vaginal incision, small mesh introduction and nearly equal efficacy [17]. Baseline characteristics showed no difference between the two group as in Mean age that was 45.9 ± 10.29 & 44.35 ± 7.9 , mean BMI 28.1 ± 4 & 27.8 ± 4.84 (kg/m²) in TVT-o & Contasure® respectively. Thus both groups are considered homogenously selected. In this study, we used negative Cough stress test as objective cure parameter was negative in 85.7 % & 88.8 % in Contasure and TVT-O® group respectively. these result nearly equal to Franco E. & Tardiu L.2011, who had negative cough test in 88.9 & 84.7 % [15] The subjective cure rate was 91.4% in Contasure & 91.67% TVT-O® group, That was accepted by Tsia-Shu Lo et al who had subjective cure rate 93% [16] There is statistically non-significant difference between the studied groups regarding operative time (TOT took non-significantly longer time 18.25 minutes versus 17.1 minutes in mini-sling operation. Also, There is statistically significant difference between the two techniques regarding blood loss (significantly higher by 15.35 ml in TOT), these results were not constant with Tommaselli GA et al., 2013 who had average operative time 12 & 7.8 minutes in TVT-O & SIS respectively, but their average BMI was 19.5 and the SIMS was TVT-secure [18]. There is statistically non-significant difference between the two techniques regarding early postoperative pain scale. No serious complications were reported, no urgency developed, despite the description of serious complications in the literature; thus in our opinion; both techniques seem to be safe. these data were accepted by Grison P., et al who compared two methods on 92 case [19]. Only three cases (7.5%) reported urine retention after SIS and one case after TVT-O insertion. Retention was relieved after 1 day from re-catheterization in 2 ladies and other 2 patients needed vaginal examination and compression of paraurethral spaces around supported urethra by Foley's catheter, that incidence is accepted with Novara G. et al, who had urinary retention incidence after SUI sub-urethral sling operations between 2.7 to 11.2% of patients [20].

CONCLUSION

In conclusion, our experience and the results in 1-year follow-up of non-inferiority of the Contasure® compared to TVT-O Kim®, demonstrate that it is a safe technique, reproducible, and accomplishes the goal of minimally invasive surgery, but considered more expensive as C-NL mesh only costs about 415 dollar in comparison to TVT-O Kim® mesh only which costs about 340 dollar.

Ethics approval and consent to participate: The study protocol was approved by the Institutional Review Board (IRB) of the Faculty of Medicine, Zagazig University, Egypt (IRB approval no. ZU-IRB #705-3-3-2013).

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List of Abbreviations

SUI	Stress urinary incontinence
SIMSs	Single-incision mini-slings

C-NDL	Contasure-Needleless
TVT-O	Transvaginal Tension Free Vaginal Tape-Obturator
VLPP	Valsalva leak-point pressure

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