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Comparing the Efficacy of the Contasure-Needleless Sling Technique with a Conventional Midurethral Sling in the Surgical Management of Female Stress Urinary Incontinence

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***Abstract**: Objective: This study aimed to compare the efficacy of the Contasure-Needleless (C-NDL) technique with the Transvaginal Tension Free Vaginal Tape-Obturator (TVT-O) technique in the surgical management of stress urinary incontinence (SUI).*
***Methods:** This prospective observational study was performed on adult women with urodynamic proved SUI who failed or declined conservative treatment between August 2017 to October 2019. The cough Stress test was performed for all patients, and they underwent urodynamic evaluation preoperatively. Follow-up visits were performed at one month, six months, and 12 months after surgery. For statistical analysis, we used the Statistical Packages for Software Sciences (SPSS) version 21.*
***Results:** Forty patients were divided equally into two groups (TVT-O subgroup and C-NDL subgroup). Regarding the operative time and pain scale, there were no significant differences between both groups (p= 0.078 and 0.054). A higher blood loss was observed in the TVT-O group than the C-NDL group (p= 0.001). At three, six, and 12 months of follow-up, no significant difference was observed in terms of the cough test (p= 0.4708, 0.7256, and 0.6644). Moreover, there was no significant difference in terms of complications (all p>0.05). Regarding the relationship between Valsalva leak-point pressure and cough stress reflex at the last follow-up visit, we detected a significant difference among the studied patients (p= 0.001).*
***Conclusions:** C-NDL is a promising technique for treating SUI cases, with low complication rates and a good patient satisfaction level. Furthermore, the procedure's efficacy holds encouraging results that need to be affirmed and tested by long-term outcomes.*

***Keywords:** contasure-needleless; C-NDL; mid-urethral sling; TVT-O; stress; urinary incontinence; surgical.*

INTRODUCTION

Stress urinary incontinence (SUI) is a condition where involuntary leakage of urine occurs with increases in the intraabdominal pressure, such as on the exertion of effort or forceful actions like sneezing and coughing [1]. Nearly 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 pelvic floor anatomy, as a consequence of the trauma associated with vaginal delivery, or due to chronic illness like obesity and diabetes [3]. In such cases, there is a lowering of the urethral closure pressure at stress, which is inversely related to the SUI degree of severity. Subsequently, forceful actions (e.g., cough or exercise) would inevitably raise the abdominal pressure to exceed the urethral closure pressure at stress, eventually causing spontaneous urine leakage [4]. Various non-surgical treatment options are still under investigation, including lifestyle modifications, pelvic floor training approaches, medications (e.g., serotonin or norepinephrine reuptake inhibitors), and even devices (e.g., pessaries and urethral inserts) [5].

Moreover, non-invasive, non-ablative laser treatment and cell therapy are amongst some of the recently suggested strategies to halt the progression of SUI [6]. However, with a median cure rate of approximately 85%, surgical treatment remains the gold standard for treating cases with SUI, especially in cases of failure of the conservative treatment [7]. With over 200 documented procedures, surgery for SUI has gone through numerous phases of evolution, starting with the anterior repair that was first performed by Schultz in the late 1800s, followed by Giordano's novel strategy, which was developed later by Zoedler in 1961, where suspension of the urethrovesical junction into the intraabdominal zone was made through the placement of material beneath the urethra, to provide partial urethral compression [8]. Currently, the most widely-accepted surgical approach for SUI treatment is the mid-urethral sling, where the middle of the urethra is supported from a sub-urethral position, unlike the previous operations, where the support was focused on the urethrovesical junction [9]. This can be done either through a retropubic route (TVT) or a trans-obturator route (TOT). The former implies blindly inserting two needles (trocars) between the vagina and the abdomen, whether through a vaginal incision or suprapubic incisions, to position the synthetic mesh in a U-shape fashion, with the mesh's ends located between the bladder and the pubic bone [10].
Meanwhile, the trans-obturator technique involves horizontally inserting the mesh through the obturator foramina towards the vagina, immediately under the urethra, in an outside-in fashion [11]. Two years later, de Leval introduced a novel adjustment to the technique, Transvaginal Tension Free Vaginal Tape-Obturator (TVT-O), where an inside-out approach was used, sparing any intrapelvic interventions and dispensing the need for cystoscopy [12]. These procedures have shown markedly high cure rates, both on the subjective and the objective scales [13–15]. Regardless, the continuing search for less invasive and safer techniques has led to the development of the single incision mini-slings (SIMSs) in late 2006 [16]. In these procedures, a shorter-length mesh is inserted through a single incision within the vagina, without the need for any needle insertion into the abdomen or groin, which would allow a faster recovery period and a high cure rate [17]. However, some quite-discouraging results were reported as regards the most initial form of SIMSs operations, the TVT-Secur ™, whether in the matter of the long or short-term efficacy outcomes [18,19]. A new type of SIMSs, Contasure-Needleless (C-NDL), is currently being investigated due to its promising results in terms of the high cure rates and fewer complications than conventional techniques [15,20]. 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 [21]. In this study, we compared the efficacy of the contasure-needleless sling technique with a conventional mid-urethral sling in the surgical management of women with urodynamic proved SUI.

METHODS

The study was performed in compliance with the recommendations of Helsinki's declaration [22] 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 2019. We included women aged ≥18 years old with urodynamic proved SUI, who failed or declined conservative treatment. We excluded patients who had an anterior wall or apical prolapse, 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 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 the lithotomy and/or standing position. Small spurts of urine loss immediately with coughing are suggestive of stress incontinence, while the large volume of urine loss suggests that another cause of incontinence should be pursued. All patients underwent urodynamic evaluation preoperatively in the Urodynamic unit in the outpatient clinic in 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. Also, complete blood count, renal function test, liver function test, random blood sugar, and coagulation profile were assessed.

Manipulation

All patients signed informed consent and had a preoperative anesthetic evaluation. Patients were assigned to two groups (odd patient for Contsure, even patient for TVT-O). Both techniques may be performed under regional anesthesia. 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, cough stress test, and completion of the short form of the International Consultation on Incontinence Questionnaire (ICIQ-UI-SF), the Arabic version. The ICIQ-UI-SF is a four-item questionnaire that is used to assess the frequency, severity, and quality of life (QoL) of incontinent individuals. It is universally used for both clinical and research purposes. The frequency item holds five points; the severity/amount component has six points, and the QoL item is graded from zero to ten. The fourth self-diagnostic item is unscored. The scoring is made by adding the points from the first three sections, with a final score range from zero to 21. A lower score indicates less severity and reflects improvement, and vice versa [23].

Surgical Techniques

TVT-O

Three incisions were performed (two small incisions were made in the groin lateral to the inferior pubic ramus, 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 (a)**. 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. 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, **Figure 1 (b)**. The process was repeated on the contralateral side towards the 10 o'clock direction. After adequate locating, the blue centering 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.

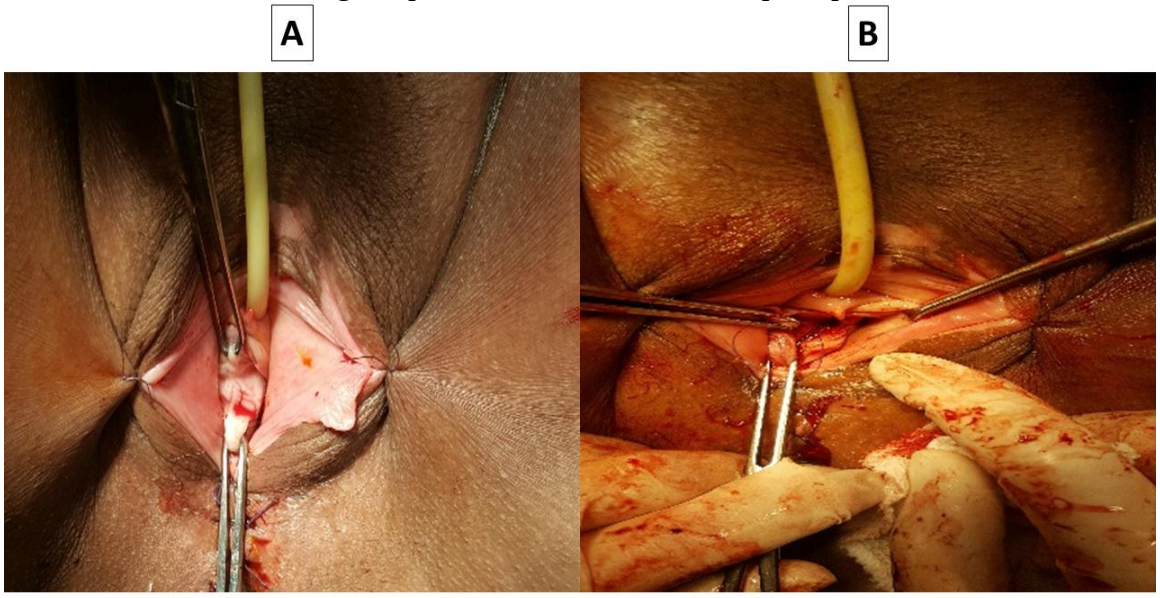

Figure 1 shows (a) the vaginal incision, (b) the blue mark in mid-line

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.

RESULTS

Characteristics of the study population

We included 40 patients in our study. The included women were divided into two groups (20 women in the TVT-O group, with a mean age of 45.9 (±9.29) years and 20 women in the C-NDL group, with a mean age of 44.35 (±6.9) years. The mean body mass index was 28.1 and 27.8 in both groups, respectively. 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= 40 patients)

		TVT-O (n=20)	C-NDL (n=20)	p-value
Age (years), mean ± SD		45.9 ± 9.29	44.35 ± 6.9	0.553 [a]
Body mass index (kg/m2), mean ± SD		28.1 ± 4	27.8 ± 4.84	0.832 [a]
Valsalva leak-point pressure (VLPP), n (%)	>100	6 (30)	7 (35)	0.937 [b]
	60-75	10 (50)	9 (45)	
	80-100	4 (20)	4 (20)	

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 terms of operative time (p= 0.078) and pain scale (p= 0.054). However, the 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.

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

	TVT-O (n=20)	C-NDL (n=20)	p-value
Operative time (minutes), mean ± SD	18.25 ± 2.2	17.1 ± 1.8	0.078 [a]
Blood loss (ml), mean ± SD	77.9 ± 16.53	62.55 ± 6.49	0.001* [a]
Pain scale, median (range)	2 (0 - 6)	1 (0 – 4)	0.054 [a]

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

The cough test follow-up

The cough test was tested at three, six, and 12 months. However, a higher rate was observed in the C-NDL group; we detected no statistically significant difference between both groups at all follow-up visits (p= 0.4708, 0.7256, and 0.6644), **Table 3.**

Table 3 shows the follow-up of the cough test among the studied patients

		TVT-O	C-NDL	p-value
At three months	Negative	16/20 (80%)	14 (70%)	0.4708 [a]
	Positive	4/20 (20%)	6 (30%)	
At six months	Negative	15/18 (83.3)	15/19 (78.9)	0.7256 [a]
	Positive	3/18 (16.7)	4/19 (21.1)	
At 12 months	Negative	15/18 (83.3)	14/18 (77.8)	0.6644 [a]
	Positive	3/18 (16.7)	4/18 (22.2)	

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

Postoperative complications

As shown in **Table 4,** there was no statistically significant difference between the studied groups in terms of the incidence of pain (p= 0.661), groin pain (p= 1), thigh pain (p= 0.487), UTI (p= 0.605), Urine retention (p= 0.231), and dyspareunia (p= 1).

Table 4 shows the postoperative complications between the studied groups

		TVT-O (n=20)	**C-NDL (n=20)**	**p-value**
Pain	No	16 (80)	19 (95)	0.661 [a]
	Yes	4 (20)	1 (5)	
Pain site	Groin	2 (10)	1 (5)	1 [a]
	Thigh	2 (10)	0 (0)	0.487 [a]
Urinary complications	UTI	2 (10)	3 (15)	0.605 [a]
	Urine retention	0 (0)	1 (5)	0.231 [a]
Dyspareunia	Negative	18 (90)	19 (95)	1 [a]
	Positive	2 (10)	1 (5)	

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

The relationship between VLPP and cough stress reflex

Among the seven positive patients for cough stress reflex at 12 months, five patients had a VLPP ranging between 60 and 75. One patient had a VLPP of 80-100, and another patient had a VLPP of >100. **Table 5** shows the relationship between VLPP and cough stress reflex at the last follow-up visit, and a statistically significant difference was observed among the studied patients (p= 0.001).

Table 5 shows the relation between VLPP and cough stress reflex at 12 months among the studied patients

VLPP	**Cough stress test**		
	Negative (N=29)	Positive (N=7)	p
>100	10 (34.5)	1 (14.3)	0.001*
60-75	2 (6.9)	5 (71.4)	
80-100	17 (58.6)	1 (14.3)	

a= p-value has been calculated using the Fisher test; *= Significant at p≤0.05 level.

Preoperative and postoperative ICIQ-IU

As shown in **Figure 2**, the ICIQ-UI-SF decreased from 13.5 to 2.5 in the C-NDL group and 12.5 to 2.5 in the TVT-O group.

Figure 2 shows the comparison between the studied groups regarding ICIQ-UI-SF pre-and postoperatively

DISCUSSION

Despite the promising results of the C-NDL approach, 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 [15,21,24,25]. 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 [26]. 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 [15]. Indeed, the novel C-NDL technique proved to be inferior to conventional methods.

Our study found no significant difference between the two groups regarding the intraoperative data (i.e., operative time and the degree of pain). However, higher blood loss was observed amongst patients who underwent the TVT-O technique (the mean volume in milliliters (SD) of intraoperative blood loss was 77.9 (16.53) and 62.55 (6.49) for TVT-O and C-NDL groups, respectively, indicating significantly less bleeding in the experimental group, p= 0.001). This was in concordance with the results published by Gaber et al. (2016), where such an observation was thought to have a possible impact on the applicability of the C-NDL procedure in clinical practice [24]. Nevertheless, the between-group difference (about 15 mL), though statistically significant, was lacking any proof of clinical relevance. Generally, a significant intraoperative hemorrhage is defined by a blood loss of more than 1 Liter, or a drop in a patient's hemoglobin level by 2 to 3 g/dL, which was estimated to correlate to nearly 700 mL and 1000 mL of blood loss in average-weight females and males, respectively [27–30]. Meanwhile, concerning the operative time, our results are in dispute with those of Gaber et al. (2020). While much shorter time (nearly 50% less time consuming) was reported in that study within the C-NDL group in relation to TVT-O (mean operative time was 8.3 and

16.4 minutes, respectively), our results showed the two groups to have almost equal mean operative times. There is no clear justification for such an observation. However, variations in the experience levels between the performing surgeons in the two experiments might have played a role.

In terms of objective cure outcomes, we assessed the number/percentage of patients with negative cough stress test at three different follow-up points. Despite the absence of a statistically significant difference in the rates of negative stress tests between the two groups, a higher percentage of patients experienced spontaneous and involuntary urine leakage on coughing. Similar findings were reported by Fernandez et al. (2016), who found C-NDL to be inferior to the TVT-O technique with reference to the number of negative stress tests. The findings from our trial can be ascribed to the same fundamental factor that Fernandez et al. used for explaining their observation, which is the technique for performing the cough stress test itself, where the lithotomy position is utilized, along with a full bladder, to simulate the daily stresses propagating incontinence. Indeed, practices and activities implemented during everyday life are usually done in the context of a standing or sitting position [21]. Interestingly, the number of negative stress tests increased by one in the C-NDL group, while similarly reduced in the TVT-O group. This might be an indicator of the long-term efficiency of the novel approach.

Further investigation should be conducted for better visualization of the long-term potential of C-NDL. As for the subjective cure measures, the ICIQ-UI-SF postoperative scores of the two groups were equivalent. This reflects a significant satisfaction level amongst the 20 patients who underwent the C-NDL procedure in our study. This was in line with the findings from Gaber et al. (2016) and Martinez Franco et al. (2014), where both surgeries achieved a statistically significant reduction in their ICIQ-UI-SF scores, and in opposition to the observation made by Fernandez Gonzalez et al. (2016), as the C-NDL group participants had significantly higher scores in the postoperative period [15,21,24].

Regarding the postoperative complications, there was no significant difference in the rates of any of the reported complications between the two groups. In general, the complication rates were quite similar to previous findings in the literature [15,21,25]. Expectedly, the most common complication was postoperative pain (both groin and thigh pain in the TVT-O group), followed by UTI (15% in the C-NDL group and 10% in the TVT-O group). Appealingly, there were no cases with thigh pain in the C-NDL group. A possible explanation for this is the different methodology and surgical approaches utilized in the C-NDL technique, probably the absence of the lateral incisions.

There are several limitations to our study. First, the small sample size included might have played a role in the lack of significance observed between the two groups. Larger sample sizes would have enabled a wider range of variations and would have allowed for a well-illustrated comparison. In the same context, adding more items to the objective and subjective cure outcomes and the list of postoperative complications would have strengthened and increased the reliability of such a correlation. Eventually, a set of efficacy outcomes restricted to only the short-term perspective might have limited our ability to appropriately recognize the true value of such a new entry into the world of SUI correction surgeries. Therefore, we recommend that well-designed clinical trials with larger samples and more detailed measures should be conducted in the future.

CONCLUSION

In summary, our findings did not demonstrate significantly different intraoperative data between the two groups, except for the intraoperative bleeding. The cough stress test results in both groups were statistically distinct; however, at a six-month follow-up, a negative stress test was obtained from a further case, indicating a potential capacity for C-NDL to perform well according to long-term measures. Postoperative complications were analogous between the two study groups, with pain and UTI as the most prevalent events. C-NDL is a comparable candidate to the conventional procedures, with few complications, easy applicability, and a significant level of patient satisfaction.

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

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