Evaluation of the efficacy of mini-sling in the treatment of stress urinary incontinence through patient-reported outcomes and transperineal ultrasonography

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Abstract

Objective: Single-incision slings, such as Contasure-Needleless® (C-NDL), were developed to improve surgical treatment success in stress urinary incontinence (SUI). However, more evidence is needed to describe the outcomes of mini-sling procedures as an alternative to classical mid-urethral slings. The aim was to evaluate the short-term outcomes of the mini-sling procedure using C-NDL in the surgical treatment of SUI patients.

Material and Methods: This was a single-center, prospective study including 24 patients with SUI who underwent C-NDL. Michigan Incontinence Severity Index (M-ISI) questionnaire, the Female Sexual Function Index, and the Patient Global Impression of Improvement (PGI-I) questionnaire were applied, as well as trans-perineal ultrasound evaluations at baseline, one month and six months postoperatively.

Results: The PGI-I index showed that 54.17% of participants described their post-operative recovery as "very much better" and 29.17% as "much better". Significant improvements were observed in all SUI and M-ISI-related results. No significant differences were detected in terms of FSFI. Complications were reported as *de novo* urgency in 4 (16.67%) patients, mesh erosion in 2 (8.33%) patients, and pelvic pain and infection in 1 patient each (4.17%). The mean distance of the mini-sling mesh to the urethra was found to be 5.51±2.3 mm at one month and 4.69±1.85 mm at six months after surgery ($p=0.006$). The mean urethral rotation angle was decreased following surgery ($p<0.001$). No significant differences were observed between patients with and without cure regarding any of the examined variables.

Conclusion: For SUI treatment, the C-NDL procedure is a safe and effective method with few complications and high subjective cure rates on short-term follow-up (6 months). [J Turk Ger Gynecol Assoc. 2025; 26(2): 98-108]

Keywords: Urinary incontinence, stress, suburethral slings, ultrasonography, postoperative complications, patient reported outcome measures

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Introduction

Urinary incontinence (UI) is characterized by involuntary urinary leakage that negatively affects quality of life, including social, emotional, sexual, and professional domains (1). Its prevalence varies widely from 5% to 70% depending on the definition used, and risk factors include advanced age, female sex, parity, race, menopausal status, smoking, constipation, obesity and previous gynecological surgery (2). According to a systematic review, the prevalence of urinary incontinence among Turkish women ranges from 16.4% to 49.7% (3). Patients are often reluctant to seek treatment, with reasons such as the

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perceiving UI as a part of natural aging, hesitation to report complaints, lack of information about treatment methods, fear of surgery, and belief that all kinds of treatment are useless. Therefore, risk factors and complaints should be evaluated in detail to determine the need for treatment. Moreover, therapeutic options should be evaluated comprehensively and surgical interventions should be as non-invasive as possible while restoring quality of life without compromising efficacy.

Stress UI (SUI) is particularly prevalent in middle-aged and postmenopausal women, which is related to abrupt elevation of abdominal pressure (defeating closure pressure), exemplified by incontinence occurring during coughing, laughing, heavy lifting, and exercise (4). Although conservative treatments, such as electrical simulation, laser therapy, urethral bulking, and pelvic muscle training, with or without pharmacotherapy, are used with certain levels of success in patients with SUI, the surgical approaches have advanced rapidly (5). Tension-free vaginal tape (TVT) and transobturator tape (TOT) are common, effective and relatively safe procedures with success rates of 80% to 90% but these surgeries pose a risk for major complications associated with needle insertion through the abdomen or groin, including vascular injury and chronic pain (6). Over the years, third-generation, minimally invasive slings with shorter mesh length single-incision slings (SIS) have emerged, reducing complications and preventing blind manipulation of trocars in the obturator canal and Retzius space (7). However, clinical studies are needed to obtain more evidence regarding the efficacy of mini-slings as an alternative to classical mid-urethral slings.

In this study the short-term effects of the mini-sling procedure using the Contasure-Needleless® (C-NDL) device (Neomedic International SL, Barcelona, Spain) were evaluated in patients with SUI by performing ultrasonographic examinations and validated questionnaires over a 6-months follow-up period.

Material and Methods

Study design

This was a single-center, prospective study conducted between March 2019 and June 2019 in a tertiary center. All patients with clinically proven SUI who were candidates for SI, mid-urethral sling procedure with C-NDL were eligible for study inclusion.

The diagnosis of SUI was made via symptomatic assessment and demonstration of cough test positivity in the supine and standing positions with a saline-filled bladder (300 mL). Participants with diabetes mellitus, major neurological disease or stroke, previous anti-incontinence surgery, acute infection, previous or concomitant pelvic reconstructive surgery, and > Stage I pelvic organ prolapse (POP) assessed by the POP Quantification (POP- Q) system were excluded from the study.

All research procedures conformed to the Declaration of Helsinki and were approved by the Local Research Ethics Committee of the University of Health Sciences Türkiye, Fatih Sultan Mehmet Training and Research Hospital (approval number: 2019/19, date: 14.03.2019). Written and signed informed consent forms were obtained from each study participant prior to enrollment. A comprehensive preoperative evaluation was performed, including medical history, gynecological and ultrasound examinations, urinalysis, and validated condition-specific questionnaires. Baseline data including age, body mass index (BMI), parity, type of birth delivery, history of macrosomic neonate delivery, menopausal status, sexual life, history of gynecological surgery, smoking, concomitant diseases (diabetes mellitus, hypertension, goiter, chronic obstructive pulmonary disease, chronic constipation, urgency), and duration and treatments for incontinence were obtained from patient files. No urodynamic testing was performed on patients before the procedures.

In line with NICE Guideline NG123 (2019) Recommendation 1.4.1-which states that preoperative urodynamic testing is not required in women with uncomplicated, clinically diagnosed SUI, urodynamic studies were omitted in our cohort, and diagnosis relied solely on a positive cough stress test.

Measures

The Turkish-language validated version of the Michigan Incontinence Severity Index (M-ISI) questionnaire, the Hospital Anxiety and Depression Scale (HADS), and the Female Sexual Function Index questionnaire were applied to all participants before and after the mini-sling procedure (8-10). All these questionnaires and the the Patient Global Impression of Improvement (PGI-I) were the validated Turkish-language versions and were administered via face-to-face interview by a physician who was not involved in the surgical procedures and was blinded to study design, rather than being self-completed by participants.

Quality of life associated with incontinence was examined with the M-ISI (11). M-ISI is a Likert-type scale that includes a total of 10 questions, the first three questions examine SUI, the second three questions examine UUI, the 7th and 8th questions examine pad use, and the last two questions examine how much this situation bothers the patient. Responses to each item ranged from 0 to 4; higher values represent more symptoms and more discomfort. Minimal difference values for significance were determined as 4 points for total M-ISI, 2 points for SUI, 2 points for UUI, and 1 point for the use of pads (11).

The FSFI is a 19-item, self-reported questionnaire that provides scores on six subsections, including sexual desire, arousal, lubrication, orgasm, satisfaction and pain, which can be used with women who have had sexual intercourse in the last month (12). The subdomain scores range between 0 and 5, and the

total score was obtained by multiplying the scores obtained from the domains with their own coefficients. The cut-off point for distinguishing sexual dysfunction from normal sexual function was accepted as a total score of 26.55.

The HADS consists of 14 items (4-point Likert) that score anxiety (n=7) and depression (n=7) (13), resulting in subscale values ranging from 0 to 21 points. Anxiety cut-off was 10 and depression cut-off was 7.

In addition, the PGI-I was used as a subjective measure to assess mini-sling success (14). This is a simple, direct and easy-to-use scale that can be intuitively understood by both physicians and patients, and consists of a single question comparing postoperative status with baseline. Responses categorize patients into seven groups ranging from "very much better" to "very much worse". In addition, a 3-item Likert scale was used to describe subjective overall satisfaction. According to the scale, responses were divided into three groups: a response of 3 indicated "cured, very satisfied, no UI"; 2 indicated "satisfied, less UI, an improvement in the condition compared to before"; and 1 was for "not satisfied, condition did not change or worsened compared to pre-operative period".

Complete cure was defined as both (1) objective resolution (negative postoperative cough stress test) and (2) subjective resolution (no leakage episodes, no pad use, and patient-reported "very satisfied" on the 3-point Likert scale or "very much better" on the PGI-I questionnaire.

Mini-sling procedure

All mini-sling procedures were performed under general anesthesia, based on previously reported approaches (15,16). Briefly, the bladder was emptied with a Foley catheter while patients were in the dorsal lithotomy position. The SI needleless mini-sling mesh (C-NDL) used during the operation has a macropore monofilament mesh structure made of polypropylene material, with dimensions of 114 × 12 mm. The anterior vaginal wall was opened with a longitudinal incision (15-20 mm) at the mid-urethral level. From this incision, a passage/tunnel was opened bilaterally (45°, towards 10 and 2 o'clock) with dissecting scissors until the ischiopubic ramus was felt in the paraurethral area. The T-pocket positioning of the mesh was compressed by folding it concavely using Kelly clamps. The mesh (held with a clamp) was advanced through the tunnel. The fascia of the internal obturator muscle was perforated in a controlled manner. Then, the mouth of the clamp was opened, allowing the mesh T-pocket to be placed, and the clamp was withdrawn in a semi-closed form. Then these processes were repeated contralaterally. The positioning and the tension of the T-pockets were checked by employing a centering suture, which was then cut and removed. The vaginal incision was closed using 2/0 absorbable sutures. Any perioperative complications were monitored; none occurred. Postoperative urinary retention was absent, and discharge was on day 1 for all subjects.

Follow-up

Scheduled at 1 and 6 months, each visit involved pelvic examination, cough stress test, trans-perineal ultrasound, and questionnaires. All signs and symptoms were categorized by the examining surgeons according to the International Continence Society/International Urogynecological Association Complications Classification Code guidelines. No patients underwent additional surgical interventions or routine intraoperative cystoscopy.

A 6-month follow-up was chosen to capture early postoperative efficacy and safety outcomes. As reported in previous meta-analyses, the majority of failures and complications of SI mini-slings typically manifest within this timeframe (17,18).

Ultrasound examinations

Trans-perineal ultrasound (preoperative and postoperative 1 and 6 months) was conducted at rest and at maximum Valsalva, by a single investigator who was not involved in the surgical treatment process. The urinary bladder, urethra, pubic symphysis and sling-associated parameters were evaluated in the mid-sagittal plane. Bladder neck descent, proximal urethral rotation angle, retrovesical angle, and hiatal opening were measured and recorded by Dietz's standard method using 3D convex probes (Mindray DC-8 PRO ultrasound device; Shenzhen, China) (19). The sling was identified as a hyperechoic structure under the urethra. Minimal sling-to-symphysis pubis distance was measured and recorded during the Valsalva maneuver. Sling-urethra distance was determined based on the shortest distance between the sling and the hypoechoic urethra. In order to calculate the urethra-relative sling position, bladder neck-to-center-sling distance was divided by the length of the urethra and defined as a percentage. Proximal urethral rotation angle was described as the angle between the resting and Valsalva states of the proximal urethra.

Statistical analysis

SPSS, version 25.0, was used for data collection and analyses (IBM Inc., Armonk, NY, USA). All p values less than 0.05 were accepted as being significant. Descriptive statistics of continuous data are summarized using mean ± standard deviation for normally distributed data or median (25-75 percentiles) for non-normal distribution. Frequency and percentage were described to summarize categorical variables. Normal distribution assumption was checked using the Shapiro-Wilk test. Normally distributed preoperative and postoperative measurements were analyzed using the paired

t-test or repeated measures analysis of variance (ANOVA) depending on the number of measurements. Non-normally distributed preoperative and postoperative measurements were analyzed using the Wilcoxon signed ranks test or Friedman's ANOVA by ranks, again depending on the number of measurements. Bonferroni correction was used for all pairwise comparisons. Between groups analysis of continuous variables was performed using the Student's t-test or the Mann-Whitney U test, depending on parametricity. Between groups analyses of categorical variables were performed using Fisher's exact test or its Fisher-Freeman-Halton extension.

Results

Thirty patients admitted in the study period were evaluated for eligibility as candidates for surgical treatment. Three were excluded due to missing questionnaires or treatment refusal. Participants who did not attend their follow-up appointments were considered lost to follow-up (n=2). One participant with inaccurate questionnaire responses was excluded. Thus, twenty-four women were included in analyses. Mean age was 45.04±7.37 years. The mean BMI value was 30.33±4.97 kg/m^2, and 37.5% of patients had obesity. Almost a third (29.17%) of women were postmenopausal but none had received hormone replacement therapy. While 70.83% of women had given birth vaginally, 29.17% had undergone Cesarean delivery. The median duration of incontinence complaints was 4 (1.5-5.5) years. According to the HADS score test, the depression subgroup result was found to be 8.04±4.66, while the anxiety subgroup result was 8.96±4.96. In terms of ultrasonography findings, the mean diameter of hiatal opening was 56.43±6.9 mm, urethral length was 31.52±4.12 mm, and bladder neck descent was 15.9±6.46 mm. The mean retrovesical angle was 140.71±23.79°. (Table 1)

The mean distance of the mini-sling mesh to the urethra was 5.51±2.3 mm at the 1st month and 4.69±1.85 mm iat the 6th month after surgery (p=0.006). No difference was detected in the sling position relative to the urethra and the sling-symphysis pubis distance between the 1st and 6th months after surgery (p=0.361 and p=0.547, respectively). At the 6th month after procedure, symmetrical mesh arms (sling material) were observed in 19 (82.61%) subjects, and the sling demonstrated a straight shape in 17 (73.91%) subjects. Complications were reported as *de novo* urgency in 4 (16.67%) patients, mesh erosion in 2 (8.33%), pelvic pain in 1 (4.17%), and infection in 1 (4.17%). According to the PGI-I, 54.17% of the participants described their postoperative recovery as "very much better" and 29.17% as "much better". According to the 3-item Likert scale describing subjective overall satisfaction, 14 (58.33%) patients responded with "improved, very satisfied, no incontinence" (Table 2).

While the mean preoperative total FSFI score of sexually active patients (n=18) was 20.17±8.81, the postoperative total mean FSFI score was 20.32±9.1 (p=0.833). No differences were detected in any of the FSFI subdimensions (all, p>0.05) (Table 3). The median total severity M-ISI score was 18 (13.5-26.5) at baseline, 4 (2-8) at the 1st postoperative month, and 5 (1.5-10.5) at the 6th postoperative month (p<0.001). Significant improvements in postoperative M-ISI scores were detected (all, p<0.001) (Table 4). Anatomical measurements showed that the

Table 1. Demographics and clinical characteristics of patients in the preoperative period

Variables	Results
Age, years	45.04±7.37
Body mass index, kg/m^2	30.33 4.97
Parity, n	3 (2-3)
History of vaginal delivery, n	17 (70.83%)
Giving birth to macrosomic infant, n	2 (8.33%)
Menopausal status	
Premenopausal, n	17 (70.83%)
Postmenopausal, n	7 (29.17%)
Sexual life	
Passive, n	6 (25.00%)
Active, n	18 (75.00%)
Gynecological operation	14 (58.33%)
C/S, n	13 (54.17%)
TAH, n	1 (4.17%)
Smoking, n	8 (33.33%)
Diabetes mellitus, n	2 (8.33%)
Hypertension, n	6 (25.00%)
Goiter, n	3 (12.50%)
COPD, n	1 (4.17%)
Chronic constipation, n	2 (8.33%)
Duration of incontinence, years	4 (1.5 - 5.5)
HADS score	
Depression	8.04±4.66
Anxiety	8.96±4.96
Urethral funneling, n	8 (33.33%)
Hiatal opening, mm	56.43±6.90
Retrovesical angle, °	140.71±23.79
Bladder neck descent, mm	15.90±6.46
Urethral length, mm	31.52±4.12

C/S: Cesarean section, TAH: Total abdominal hysterectomy, COPD: Chronic obstructive pulmonary disease, HADS: Hospital Anxiety and Depression Scale. Descriptive statistics are presented using mean ± standard deviation for normally distributed continuous variables, median (25th percentile-75th percentile) for non-normally distributed continuous variables and frequency (percentage) for categorical variables

Table 2. Sling-related measurements and outcomes of the patients

Variables	Results
Sling-bladder neck, mm	22.20±3.53
Relative sling position, %	
1st month	70.64±8.56
6th month	71.79±7.24
p	0.361†
Sling-symphysis distance, mm	
1st month	20.36±3.30
6th month	20.68±3.35
p	0.547†
Sling-urethra distance, mm	
1st month	5.51±2.30
6th month	4.69±1.85
p	0.006†
Sling status	
Symmetrical, n	19 (82.61%)
Asymmetrical, n	4 (17.39%)
Sling shape	
Straight line, n	17 (73.91%)
Curved, n	1 (4.35%)
Folded, "V" shape, n	5 (21.74%)
Complication	8 (33.33%)
De novo urgency, n	4 (16.67%)
Mesh erosion, n	2 (8.33%)
Pelvic pain, n	1 (4.17%)
Infection, n	1 (4.17%)
PGI-I	
Very much better, n	13 (54.17%)
Much better, n	7 (29.17%)
A little better, n	1 (4.17%)
No change, n	2 (8.33%)
A little worse, n	0 (0.00%)
Much worse, n	1 (4.17%)
Very much worse, n	0 (0.00%)
Outcome	
Cured (no leakage), n	14 (58.33%)
Improved (minimal leakage), n	7 (29.17%)
No change or worse, n	3 (12.50%)

PGI-I: Patient Global Impression of Improvement. Descriptive statistics are presented using mean ± standard deviation for normally distributed continuous variables and frequency (percentage) for categorical variables. †Paired t test

mean urethral rotation angle was 71.75±11.38° before surgery, and it decreased to 42.42±10.29° in the 1st month after surgery, and to 37.39±12.90° in the 6th month after surgery (p<0.001). Bladder wall thickness was similar in the preoperative and postoperative periods (p=0.977) (Table 4).

Finally, when those with and without cure after treatment were analyzed (Tables 5, 6), all parameters were found to be similar in these subsets (all, p>0.05).

Discussion

The aim of this study was to assess short-term mini-sling surgery outcomes by comparing pre- and post-operative transperineal ultrasonography results and subjective success rates in SUI patients. Scores assessing quality of life, including the PGI-I, M-ISI, and 3-item Likert scale, showed measurable and patient-reported improvements with the mini-sling surgery. As such, our results demonstrate high satisfaction over short-term follow-up and few complications, suggesting that C-NDL is a reliable management strategy for SUI. Notably, we did not observe any significant differences in terms of demographic and clinical characteristics, ultrasonographic examination results, and mini-sling-related parameters between patients with and without surgical success.

Mini-sling procedures were introduced in 2006 to reduce postoperative complications and improve quality of life (shorter mesh, single incision), but efficacy is still unclear due to limited data and different types of SIS procedures being performed throughout the world. The main indicator used to evaluate the effectiveness of mini-sling procedures is cure rate (subjective and objective). A meta-analysis in 2011 compared TVT-Secure, Mini-Arc, and Ophira to classical midurethral slings. The data showed lower cure rates with the newer approaches (17). In a later meta-analysis performed in 2014, success rates and quality of life scores were similar with mini slings compared to classical midurethral slings after a follow-up of 12-36 months (18). Importantly, these authors observed similar rates of lower urinary tract injury, postoperative micturition, vaginal mesh erosion, and *de novo* urgency, with the exception of TVT-Secure. Luo et al, compared C-NDL and TVT/TOT-O for female patients with SUI in a meta-analysis and found that C-NDL was equally effective in terms of subjective and objective recovery rate, and had advantages of shorter operative times, fewer complications, with the exception of groin pain, and less postoperative pain (20). Our data from mini-sling procedures show an improvement in subjective cure rates and patient satisfaction. The PGI-I revealed that 83% of our patients described their postoperative recovery as "much better" or "very much better". Similarly, Dogan et al. (16) described a cure rate of 89.9% with C-NDL in a 24-month follow-up of 80 SUI patients. Naumann et al. (21) reported that 86.3% of patients

Table 3. Pre- and post-operative FSFI scores of the patients

FSFI score (n=18)	Baseline	6th month	p
Desire	2.90±1.44	3.17±1.36	0.415†
Arousal	3.22±1.62	3.12±1.79	0.728†
Lubrication	3.6 (3.3-4.5)	3.9 (3.0-4.5)	0.207‡
Orgasm	4.0 (2.8-5.2)	4.0 (2.4-5.2)	0.573‡
Satisfaction	3.69±1.47	3.71±1.62	0.917†
Pain	3.24±2.09	2.96±1.73	0.508†
Total	20.17±8.82	20.32±9.11	0.833†

FSFI: Female Sexual Function Index. Descriptive statistics were presented using mean ± standard deviation for normally distributed continuous variables, median (25th percentile-75th percentile) for non-normally distributed continuous variables. †Paired t test, ‡Wilcoxon signed ranks test

Table 4. Michigan Incontinence Symptom Index scores and anatomical measurements of the patients

M-ISI score	Baseline	1st month	6th month	p
SUI	7 (5-10)	0 (0-2)*	0 (0-3)*	<0.001‡
UUI	7.5 (4-10)	2 (0-4)*	3 (0-4.5)*	<0.001‡
Pad usage	4.5 (3-6)	2 (0.5-2)*	2 (0.5-3)*	<0.001‡
Bother	5.5 (4-6.5)	0 (0-2)*	0 (0-2)*	<0.001‡
Total severity	18 (13.5-26.5)	4 (2-8)*	5 (1.5-10.5)*	<0.001‡
Bladder wall thickness, mm	5.47±0.69	5.45±0.75	5.49±1.11	0.977†
Urethral rotation angle	71.75±11.38	42.42±10.30*	37.38±12.90*	<0.001†

M-ISI: Michigan Incontinence Symptom Index, SUI: Stress urinary incontinence, UUI: Urgency urinary incontinence. Descriptive statistics were presented using mean ± standard deviation for normally distributed continuous variables, median (25th percentile-75th percentile) for non-normally distributed continuous variables. †Repeated measures analysis of variance, ‡Friedman's analysis of variance by ranks, *Significantly different from baseline

experienced improvement in incontinence after an average of 29 months, following SIS. We observed significantly improved M-ISI scale results in our study, indicating that C-NDL improved patient-reported results, satisfaction, and life quality in women with SUI.

Regarding postoperative complications, many previous studies have demonstrated that major complications may occur during mid-urethral sling procedures, such as bleeding into the retropubic space and obturator muscle, as well as damage to the bowel and vascular system (22). However, reductions in complication rates have been observed with the use of SIS. Stanford and Paraiso (23) in their complication-related review of 20 studies and 1950 patients undergoing mid-urethral sling procedures, found a postoperative urge incontinence frequency of 15.4% (1.7-42%), and reported that preoperative anticholinergic use and advanced age were risk factors for the emergence of over-active bladder. We observed *de novo* urgency in two patients (8.3%) postoperatively, and an increase in overactive bladder symptoms in two patients. These patients received pharmacological treatment with anticholinergics, and a regression in their complaints was observed during their follow-up. A randomized controlled study reported less groin pain after SIS compared to the classical mid-urethral sling technique (24). Consistent with previous studies, groin pain was detected in only one patient (4.14%) in the early postoperative period, and the pain spontaneously regressed in the first postoperative month. Dyspareunia rates after SIS procedure are reported to be between 3-8% (25). Only one patient (4.14%) in our study group complained of dyspareunia, and during the gynecological examination, an eroded area and visible mesh were detected, explaining the dyspareunia. The incidence of urination difficulty, which is one of the important complications observed after mid-urethral sling operations, is reported to be between 0-8% in meta-analyses

Table 5. Demographics and clinical characteristics of the patients with regard to outcome

	Outcome		
Variables	**Cured (n=14)**	**Other (n=10)**	**p**
Age, years	44.79±7.60	45.40±7.43	0.846†
Body mass index, kg/m²	29.73±5.19	31.18±4.80	0.493†
Parity, n	3 (2-3)	3 (2-3)	0.756‡
History of vaginal delivery, n	11 (78.57%)	6 (60.00%)	0.393§
Giving birth to macrosomic infant, n	1 (7.14%)	1 (10.00%)	1,000§
Menopausal status			
Premenopausal, n	10 (71.43%)	7 (70.00%)	1,000§
Postmenopausal, n	4 (28.57%)	3 (30.00%)	
Sexual life			
Passive, n	3 (21.43%)	3 (30.00%)	0.665§
Active, n	11 (78.57%)	7 (70.00%)	
Gynecological operation	8 (57.14%)	6 (60.00%)	1,000§
C/S, n	8 (57.14%)	5 (50.00%)	0.651¶
TAH, n	0 (0.00%)	1 (10.00%)	
Smoking, n	5 (35.71%)	3 (30.00%)	1,000§
Diabetes mellitus, n	2 (14.29%)	0 (0.00%)	0.493§
Hypertension, n	4 (28.57%)	2 (20.00%)	1,000§
Goiter, n	2 (14.29%)	1 (10.00%)	1,000§
COPD, n	0 (0.00%)	1 (10.00%)	0.417§
Chronic constipation, n	2 (14.29%)	0 (0.00%)	0.493§
Urgency, n	7 (50.00%)	4 (40.00%)	0.697§
Duration of incontinence, years	3.5 (1-5)	4 (2-10)	0.313‡
HADS score			
Depression	7.00±4.99	9.50±3.92	0.201†
Anxiety	8.29±5.72	9.90±3.73	0.444†
Urethral funneling, n	5 (35.71%)	3 (30.00%)	1,000§
Hiatal opening, mm	56.84±6.66	55.87±7.54	0.743†
Retrovesical angle,°	137.71±16.68	144.90±31.79	0.478†
Bladder neck descent, mm	17.59±7.76	13.53±2.97	0.092†
Bladder wall thickness, mm	5.38±0.62	5.61±0.78	0.428†
Urethral rotation angle,°	71.57±12.18	72.00±10.81	0.930†
Urethral length, mm	31.37±4.94	31.72±2.84	0.843†

C/S: Caesarean section, TAH: Total abdominal hysterectomy, COPD: Chronic obstructive pulmonary disease, HADS: Hospital Anxiety and Depression Scale. Descriptive statistics were presented using mean ± standard deviation for normally distributed continuous variables, median (25th percentile-75th percentile) for non-normally distributed continuous variables and frequency (percentage) for categorical variables. †Student's t-test, ‡Mann Whitney U test, §Fisher's exact test, ¶Fisher-Freeman Halton test

Table 6. Sling-related measurements of the patients with regard to outcome

	Outcome		
Variables	**Cured (n=14)**	**Other (n=10)**	**p**
Sling-bladder neck, mm	22.07±4.36	22.37±2.06	0.825†
Relative sling position, %			
1st month	70.51±9.74	70.81±7.08	0.934†
6th month	71.21±7.76	72.69±6.68	0.644†
Sling-symphysis distance, mm			
1st month	19.54±2.97	21.51±3.55	0.154†
6th month	21.20±3.36	19.87±3.37	0.170†
Sling-urethra distance, mm			
1st month	5.86±2.11	5.02±2.58	0.387†
6th month	5.31±1.36	3.72±2.16	0.071†
Sling status			
Symmetrical, n	13 (92.86%)	6 (66.67%)	0.260§
Asymmetrical, n	1 (7.14%)	3 (33.33%)	
Sling shape			
Straight line, n	11 (78.57%)	6 (66.67%)	0.762¶
Curved, n	0 (0.00%)	1 (11.11%)	
Folded "V", n	3 (21.43%)	2 (22.22%)	
Complication, n	5 (35.71%)	3 (30.00%)	1.000§

Descriptive statistics were presented using mean ± standard deviation for normally distributed continuous variables, median (25th percentile-75th percentile) for non-normally distributed continuous variables and frequency (percentage) for categorical variables. †Student's t-test, §Fisher's exact test, ¶Fisher-Freeman Halton test

(26). In our study, no urination difficulties were observed in any of the patients. Our low complication rates indicate that C-NDL is a safe technique and achieves the goal of minimally invasive surgery.

A potential relationship has been shown between obesity and incontinence (particularly SUI), and it is thought that excessive body weight increases intra-abdominal pressure. However, the effect of BMI on surgical results is still controversial, and the comparability of research examining this factor is limited due to differences in follow-up, surgical approach, and cure definitions (27). Frigerio et al. (28) found that the subjective success rates were similar in different BMI categories. More than half (54.17%) of the patients in our study group were overweight and 37.50% were obese, and we did not observe a relationship between treatment success and BMI values. The absence of severely obese cases may have contributed to our results, and must be addressed in future studies.

Several clinical studies have reported a decrease in coital incontinence and an improvement in sexual activity following incontinence surgery (29). Golbasi et al. (30) demonstrated increased FSFI scores in 62 patients with SUI treated with the SIS (Ophira, Argentina) after 30 months of long-term follow-up. Contrary to the literature, no significant improvements in sexual functions were observed in our study group, as measured by baseline and sixth month FSFI scores, possibly because of the small sample size. In addition, evaluating sexual life over a specific period of time may limit understanding of how the quality of an individual's sexual experience may be affected by relational, interpersonal, situational, mood, hormonal, and habitual factors. There is a need for prolonged follow-up, including assessment of these features.

Sonographic assessment has become a crucial component of the urogynecological diagnostic examinations of patients presenting with UI in recent years. Slings can be easily visualized with perineal or introital sonography and can yield insights concerning surgical results. Ultrasonographic examination has been integrated into the postoperative evaluation of SUI patients undergoing TVT or TOT (31). Chen et al. (32) in a cumulative meta-analysis of 1,563 SUI patients, demonstrated that urethral rotation, rest and Valsalva angles, bladder neck descent, hiatus area, and bladder neck funneling were notable factors in the trans-perineal ultrasound evaluation of patients with SUI. There

are far fewer studies reporting ultrasonography findings in SIS. García-Mejido et al. (33) in their comparison of SIS patients with and without symptoms at postoperative assessment, reported significant differences in movement compliance between the sling and the urethra and in the axial tape angles at rest and at Valsalva (33). We found the urethral rotation angle value as high as 71.75±11.38° in our study group before the C-NDL procedure, and this value decreased significantly in the 1st and 6th months after surgery. However, these values were similar when compared between clinical outcome groups. This was consistent with previous studies (34). Notably, Turkoglu et al. (35) reported a mean urethral rotation angle of 86.66±11.01° in SUI patients and described that the urethral rotation angle and bladder neck descent values exhibited high specificity and sensitivity for SUI detection. In addition, we did not observe a positive relationship between the position and distance of the sling relative to the symphysis, which have been reported in TVT or TOT. For instance, mid-urethral sling success has been associated with the relative position of the sling to the urethra, and shorter sling-urethra distances have been associated with low cure or high complication rates (36). As a result, the authors suggested that the sling should be placed at least 2 mm from the urethra and between 40-70% of total urethral distance. For SIS, Kluz et al. (37) found that the relative sling position to the urethra did not differ between successful and unsuccessful cases at 36 and 50 months of follow-up. We observed that the sling-urethra distance decreased in the 6th month after surgery compared to 1 month (5.51±2.30 mm vs. 4.69±1.85 mm), but this value was not related to treatment success. Furthermore, we did not find any significant relationships between success and other ultrasonographic variables. We observed that the ultrasonography-detected outcomes of SIS were very different compared to mid-urethral slings, indicating that the classical ultrasound measurements would not be useful to assess SIS surgery outcomes; however, the low sample size and patient characteristics of our cohort should be considered before accepting this as a definite conclusion. Prospective studies with larger homogeneous sample sizes and different surgical methods are required.

The lack of correlation between USG-measured sling parameters and clinical success in our cohort may reflect several factors. First, the consistently standardized surgical technique likely minimized positional variability, reducing the ability of ultrasound to discriminate between outcomes. Second, urinary continence is determined by multiple anatomical and functional factors, including intrinsic sphincter competence and neuromuscular control, beyond sling position alone. Third, SIS such as the C-NDL have unique anchoring systems and shorter tape lengths, which may attenuate positional effects observed with retropubic or transobturator slings. Notably, prior studies of SIS have reported inconsistent or weak associations between USG parameters and clinical outcomes (33,37).

The prospective design is an inherent strength of the present study, as well as the application of all interventions by the same experienced urogynecologist. Furthermore, we used transperineal ultrasonography as well as patient-reported outcomes at follow-up examinations.

Study limitations

Several limitations should be noted. First, our cohort was limited to 24 patients-a consequence of the single-center pilot design with stringent inclusion/exclusion criteria. However, this sample size aligns with other early feasibility studies of SISs. Second, follow-up was restricted to six months to capture early efficacy and safety outcomes so long-term data are needed to confirm durability and late complications. Finally, this single-arm prospective design without a control group reflects standard practice in early-phase evaluations of novel surgical devices that prioritize feasibility and safety assessments before undertaking randomized comparisons.

Conclusion

It was demonstrated that the mini-sling procedure using the C-NDL was a reliable approach with low complications and high cure rates for SUI in women. These results indicate that short-term outcomes with SIS and C-NDL are beneficial based on quantifiable measures and patient satisfaction. However, impact on sexual functions remain unclear and there appear to be no baseline factors or ultrasonography data capable of identifying treatment success.

Ethic

Ethics Committee Approval: *All research procedures conformed to the Declaration of Helsinki and were approved by the Local Research Ethics Committee of the University of Health Sciences Türkiye, Fatih Sultan Mehmet Training and Research Hospital (approval number: 2019/19, date: 14.03.2019).*

Informed Consent: *Written and signed informed consent forms were obtained from each study participant prior to enrollment.*

Footnotes

Author Contributions: *Surgical and Medical Practices: M.Y., A.B.T., Concept: M.Y., A.B.T., Design: E.A., M.Y., Data Collection or Processing: E.A., O.S.G., Analysis or Interpretation: N.T., O.S.G., Literature Search: E.A., K.S., Writing: E.A., K.S.*

Conflict of Interest: *No conflict of interest is declared by the authors.*

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