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ORIGINAL ARTICLE

Contasure-Needleless® single incision sling compared with transobturator TVT-O® for the treatment of stress urinary incontinence: long-term results

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Abstract
Introduction and hypothesis This study compared transobturator tension-free vaginal tape (TVT-O®) and Contasure-Needleless (C-NDL®) at long-term follow-up.
Methods Non-inferiority, prospective, single-centre, quasi-randomised trial started in September 2006 and finished in April 2011 to compare C-NDL® with transobturator vaginal tape (TVT-O®) mesh in the treatment of stress urinary incontinence (SUI). Epidemiological information, intraoperative and postoperative complications, subjective estimates of blood loss and pain levels were recorded. We also analysed the postoperative stress test, the subjective impression of improvement using the Sandvik Severity Index and the quality of life during follow-up using the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF).
Results Two hundred and fifty-seven women with primary SUI were scheduled to receive TVT-O® or C-NDL® and were followed up at least 3 years after the procedure . One hundred and eleven women in the C-NDL® group (84.7 %) had a negative stress test, compared with 54 women (88.9 %) in the TVT-O® group (p=0.0065 for the non-inferiority test). The postoperative Sandvik Severity Index was 0 or better than the preoperative score in 90.7 % of patients in the C-NDL® group and 95.4 % of patients in the TVT-O® group (p= 0.0022). The complication rate was similar in both groups. There were significant differences (p=0.02) in postoperative pain within the TVT-O® group. The degree of satisfaction was not statistically significant between the two groups.
Conclusions The outcomes for the C-NDL® group were similar to those of the TVT-O® group, adding the concept of "single incision tape" to the tension-free sling option.

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Introduction

Throughout history, different surgical techniques have been devised to treat SUI in women. However, the real therapeutic revolution in this treatment occurred in 1995 [1] when the first midurethral sling technique was created and is now considered the gold standard in the surgical treatment of female SUI [2, 3].

Since then, modifications of the original technique, based on the use of a retropubic polypropylene mesh to support the urethra without tension, have been introduced to achieve the same therapeutic results with fewer complications. First, the transobturator approach was introduced [4, 5] to avoid needle passage through the retropubic space and to minimize the risk of bladder perforation and haematoma formation in this area [6]. However, complications of these midurethral sling techniques are also due to the blind passage of the introducer needles through the obturator foramen. The most common complication is groin pain, with published rates of 2–7.5 % [7, 8], but more serious complications such as vascular injury also occur [9].

Both the retropubic and transobturator techniques have demonstrated high, long-term objective and subjective cure rates [10–14].

The most recent contribution to these technical modifications occurred in 2006 with the introduction of the "single incision" concept, referring to the placement of the slings without needles (SIMS). SIMS were created with theoretical advantages over the midurethral slings (retropubic or transobturator). A shorter length of polypropylene tape is used; therefore, less mesh is inserted into the human body. Additionally, the insertion through a single vaginal incision

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produces a similar suburethral hammock to standard midurethral slings, avoiding both retropubic and groin trajectories, thus theoretically maintaining high cure rates [15].

The Contasure-Needleless® (C-NDL®) is a single incision device. The C-NDL® is made of polypropylene monofilament mesh, with dimensions of 114 x 12 mm, and does not require anchors. The ends are slightly wider and they form a "fascial pocket" (Fig 1) to provide sling tissue ingrowth, thus maintaining stability under the urethra. The wide pocket and the length of the sling are its distinguishing features. A potential advantage of the C-NDL® is that although the surface area in the pelvic floor is almost the same as for the TVT-O®, the obturator foramen and groin are not incised.

The main objective of this study is to update the evidence from the previous non-inferior study, about 1-year follow-up results, comparing the C-NDL® with transobturator vaginal tape (TVT-O®) mesh in the treatment of SUI in patients with or without associated pelvic organ prolapse, with a minimum postoperative follow-up of 3 years.

Materials and methods

This study is a non-inferiority, prospective, single-centre, quasi-randomised trial, conducted in the Pelvic Floor Unit of our institution, a tertiary referral academic centre in Barcelona (Spain). Patient inclusion started in September 2006 and finished in April 2010 and some preliminary results were published in 2011 [16].

All patients affected by urodynamic SUI and a positive stress test, with or without associated genital prolapse, who were candidates for surgical treatment, were eligible for the study.

Patients were assigned to one or other group of treatment depending on the last figure of their medical history number; the last even figure was allocated to technical TVT-O® and last odd figure to C-NDL®. The study was approved by the ethics committee of our institution in 2006 and all patients signed informed consent before surgery. Both techniques have been described in a previous publication [16].

The primary outcome was to compare the objective and subjective cure rates of the two slings. We hypothesized that the single-incision procedure, C-NDL®, is not inferior to the transobturator midurethral sling, TVT-O®, for SUI treatment at long-term follow-up .

After surgical treatment, all patients were monitored in the Pelvic Floor Unit at 1 month, 3 months, 6 months and then annually. At each visit, a new history of urinary symptoms was obtained and the patient was asked if she was very satisfied, satisfied or dissatisfied with the intervention outcome. An urogynaecological examination was performed, including an assessment of external genitalia, a stress test and two questionnaires, the ICI-Q short form and the Sandvik Severity Index, both validated in Spanish [17, 18].

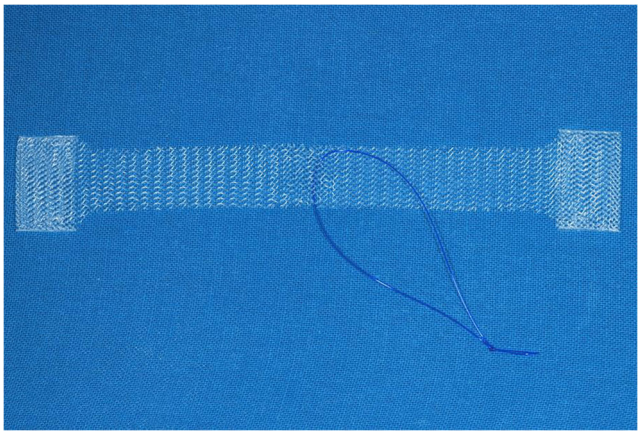

Fig. 1 Contasure-Needleless single incision sling

The secondary objective of our study was to evaluate the effect of both SUI surgeries on the quality of life and to compare possible complications. The improvement in quality of life was assessed by a specific question in the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) questionnaire: "How much does leaking urine interfere with your everyday life?"

The objective cure rate for SUI was analysed using a stress test. We defined cure as the presence of a negative stress test. In the lithotomy position, and with a full bladder, the patients performed a series of forceful coughs [19]. The procedure was considered to have failed when urine was lost.

We analysed the patient's subjective impression of the treatment received through a direct question on satisfaction with the results of the intervention: very satisfied, satisfied or dissatisfied. With the Sandvik Severity Index we defined cure as a post-surgical Sandvik test score of 0 and improvement when the postoperative score was lower than the preoperative score and equal or greater when the postoperative score was equal to or greater than the preoperative score. In this category, we included patients with urinary symptoms, including non-stress-related symptoms, which had appeared after surgery.

Patients who had symptoms of urgency before surgery that persisted after surgery were excluded from analysis because it was not possible to determine whether the origin of the positive Sandvik test was due to pre-existing urgency as this test cannot discriminate urinary symptoms.

The cure rate in short- to middle-term studies of the TVT-O® is approximately 90 %. Assessing similar results in our study with 58 patients in each group (total of 116), we obtain a statistical power of 80 %. This rejects the null hypothesis in favour of the obturator in–out (H_1), which assumes that the single incision technique is not inferior to the transobturator in–out (H_1: single incision TVT-O®<0.15).

Statistical analyses were performed using an asymptotic normal unilateral test for two independent proportions, taking

Table 1 Clinical data

	C-NDL®	TVT-O®	*p* value
Follow-up (months)	54.27 (36–60)	54.11 (36–60)	0.9683
Age (years)	58.99 (35–86)	58.52 (38–85)	0.5678
BMI	28.05 (19.6-41.78)	28.89 (19.57-42.19)	0.1756
Menopausal status	108	77	0.1570
Smoker	11	14	0.2175
Previous conservative treatment	55	35	0.2738
Parity	2.48 (0–7)	2.64 (0–9)	0.9404
Presurgical Sandvik	5.96 (1–12)	6.54 (1–12)	0.2044
Quality of life (ICI-Q)	6.35 (0–10)	6.59 (0–10)	0.6639
Symptoms of urge incontinence	66	48	0.5163

C-NDL® Contasure-Needleless, *TVT-O*® obturator tension-free vaginal tape

into consideration a level of statistical significance of 5 %, and using SPSS package version 18 and SAS 9.3. More details about the study design, statistical analysis and surgical techniques have previously been published [16].

Table 2 Associated surgeries and operative data

	C-NDL®	TVT-O®	*p* value
Vaginal hysterectomy	40 (28.0 %)	42 (36.8 %)	0.1296
Anterior colporrhaphy	72 (50.3 %)	68 (59.6 %)	0.1369
Posterior colporrhaphy	7 (4.9 %)	7 (6.1 %)	0.6621
Intraoperative bleeding	1	1	
Without associated surgery (n=94)	1	0	1
With associated surgery (n=163)	0	1	0.42
Intraoperative bladder injury	1	1	
Without associated surgery (n=94)	0	0	
With associated surgery (n=163)	1	1	1
Urinary infection	1	1	
Without associated surgery (n=94)	0	0	
With associated surgery (n=163)	1	1	1
Postoperative pain>5 on the visual analogue scale (VAS)	1	7	
Without associated surgery (n=94)	1	2	0.56
With associated surgery (n=163)	0	5	0.02
Urinary retention	5	8	
Without associated surgery (n=94)	1	1	1
With associated surgery (n=163)	4	7	0.35
Catheterisation (days)			
Without associated surgery (n=94)	0.84	1	0.048
With associated surgery (n=163)	1.98	2.35	0.038
Hospital admission (days)			
Without associated surgery (n=94)	0.89	0.97	0.09
With associated surgery (n=163)	2.63	2.85	0.11

Results

Eighteen patients (12 in the TVT-O® group and 6 in the C-NDL® group) did not complete the follow-up and were excluded from the analysis, leaving a total of 131 in the C-NDL® group (group 1) and 108 patients in the TVT-O® group (group 2) , with a drop-out rate of 8.39 % and 5.26 % respectively. The mean follow-up was 54.27 (36–60) months in the C-NDL® group and 54.11 (36–60) in the TVT-O®, with no statistically significant difference between the groups (p=0.97)

First, we analysed the epidemiological data and symptoms of urinary incontinence and found no significant differences between the groups. The two groups were therefore homogeneous and comparable. The clinical data are shown in Table 1.

Surgical procedures for pure incontinence were performed in 94 patients (36.57 %), 55 in the C-NDL® group and 39 in the TVT-O® group. The remaining patients underwent genital prolapse-associated interventions. There were no significant differences in the proportion of associated surgeries between the groups (Table 2).

The stress test was negative in 84.7 % of patients in the C-NDL® group and 88.9 % in the TVT-O® group, with an absolute difference of −4.2 % for the TVT-O® group (95 % CI:−12.7 % to 4.4 %, p=0.0065). Thus, we reject the hypothesis of inferiority in favour of the alternative hypothesis of non-inferiority. C-NDL® is not inferior to TVT-O®.

The postoperative Sandvik Severity Index was lower than the preoperative Sandvik test score, including patients with postoperative Sandvik test scores of 0, in 90.7 % of the first group and 95.4 % of the second group, and higher than preoperatively in 9.3 % and 4.6 % respectively. The absolute difference in the number of failures (Sandvik Severity Index was greater postoperatively) was 4.7 % (95 % CI: −2.3 to

Table 3 Objective and subjective cure rate results

	C-NDL® (%)	TVT-O® (%)	Absolute difference (95 % CI)	*p* value
Negative stress test	111/131 (84.7)	96/108 (88.9)	−4.2 (−12.7 to 4.4)	0.0065
Sandvik test<than pre	97/107 (90.7)	83/87 (95.4)		
Sandvik test>than pre	10/107 (9.3)	4/87 (4.6)	4.7 (−2.3 to 11.8)	0.0022
Very satisfied	53/131 (40.5)	42/108 (38.9)		
Satisfied	69/131 (52.7)	60/108 (55.6)		
Dissatisfied	9/131 (6.9)	6/108 (5.6)	1.3 (−4.8 to 7.4)	<0.001

11.8 %). The levels of satisfaction among the C-NDL® patients were not significantly different; 40.5 % were very satisfied with the outcome of the intervention, 52.7 % were satisfied and 6.9 % were dissatisfied. The levels of satisfaction among the TVT-O® group were also not significantly different, with the proportions of patients who were very satisfied, satisfied and dissatisfied being 38.9 %, 55.6 % and 5.6 % respectively (Table 3).

Both surgeries showed a statistically significant improvement in quality of life scores (Table 4).

The rates of surgical and postoperative complications were similar in the two groups, as well as the number of days hospitalized. There were statistically significant differences (p=0.02 and p=0.048) in postoperative pain and catheterisation respectively, within the TVT-O® group. Further analyses of the two subgroups of patients, one with associated surgery and one without, found no statistically significant differences in patients without associated surgery, and there was more postoperative pain in the TVT-O® group (Table 2).

The analysis of complications during follow-up showed that there were no statistically significant differences in any of the items studied: de novo urgency, voiding difficulty, mesh extrusion and recurrent urinary tract infections (Table 5).

Discussion

In the last 15 years, there has been a revolution in the surgical treatment of SUI, and research has explored the before-and-after outcomes of the tension-free vaginal tape (TVT®). Results of comparisons of the TVT-O® technique and the TVT® have found a reduction in complications among patients having the TVT-O® procedure, such as bladder perforation and vessel or bowel injury [12, 13, 20–25].

There is an absence of clinical evidence regarding whether the new synthetic slings, called single-incision mini-slings (SIMS) because they do not pass through anatomical spaces, are comparable in efficacy and safety to previous techniques. The C-NDL® has a similar length, material and the direction of placement relative to the transobturator devices, but also has theoretical advantages based on the method of placement, such as a reduced risk of serious complications and less postoperative pain.

There are a few comparative studies on SIMS [15], but these studies are limited by short-term results and a lack of comparison between the C-NDL® technique and the standard treatments of SUI such as TVT-O®.

It is difficult to imagine that a new device may show statistically significant improvements compared with the good present-day cure rates, which is why we chose a non-inferiority study to demonstrate that the results of the C-NDL® technique are not worse than those obtained with the TVT-O® technique.

One possible limitation of this study was the randomisation method, but we do not think that this introduced bias because a medical history number was automatically assigned the first time the patients arrived at the hospital; thus, all patients had the same probability of receiving an odd medical history number.

Another limitation is that this study was not blinded. It was not possible to blind the process because in the TVT-O group, the patient presents a cutaneous scar at the obturator region. On the other hand, in our hospital the surgeon performed the follow-up visits.

The drop-out rate did not affect the statistical analysis because we calculated the minimum sample size needed to

Table 4 Quality of life (QoL) improvement

	QoL (ICIQ-SF) preoperative	QoL (ICIQ-SF) postoperative	*p* value
C-NDL®	6.15	1.1	0.002
TVT-O®	6.54	0.95	0

ICIQ-SF International Consultation on Incontinence Questionnaire-Short Form

Table 5 Follow-up results

	C-NDL®	TVT-O®	*p* value
De novo urgency	11	14	0.25
Difficulty urinating	1	1	0.54
Mesh extrusion	3	2	0.53
Recurrent urinary tract infections	1	1	1

reject the hypothesis of inferiority to be a total of 116 patients (58 per group).

We presented the short-term results of this study in 2011, and demonstrated that C-NDL® is not inferior to TVT-O® at 1-year follow-up. However, it is more important to determine what happens with a longer follow-up and to see if cure rates are maintained; thus, in this paper, we present an update of the study with a minimum postoperative follow-up of 3 years and our results demonstrate that the non-inferior results are maintained.

The main objective when analysing the results of a surgical technique for SUI should be the cure rate. However, it is difficult to define the cure rate with unique parameters that include both the objective and subjective results [26]. Therefore, in our study, we used a principal parameter of objective cure, the negative stress test, which was negative in 84.7 % of the patients in the C-NDL® group and 88.9 % in the TVT-O® group, but also analysed the post-surgical Sandvik Index score. The Sandvik Index score was 0 or improved in 90.7 % of patients in the first group and 95.4 % in the second group of patients, and it was worse in 9.3 % and 4.6 % respectively, including all patients with de novo urgency.

The subjective cure rate was evaluated with a satisfaction question and the satisfaction level was found to be high in both groups of patients, with no significant differences. This demonstrates that patient expectations are accomplished by both treatments at the same level.

No serious complications were reported, despite the description of serious complications in the literature; thus, both techniques seem to be safe.

One of the potential risks of the passage of the needles in the retropubic or transobturator approach is injuring the neurovascular structures or tissues of the anatomical spaces we use. Although in our study we did not find any cases of injuries of this type, in the literature there are descriptions of injuries related to the needle passage [27]. With the C-NDL technique, this morbidity should not exist, because no anatomical space is crossed for its placement. In our study we have not been able to demonstrate this advantage, owing to the low incidence of these types of injuries, and a greater sample size would be required to find a difference.

Conclusion

Our experience and the results of the non-inferiority study of the C-NDL® compared with the TVT-O® demonstrate that it is a safe, reproducible technique and that it accomplishes the goal of minimally invasive surgery. High objective and subjective cure rates maintained at long-term follow-up indicate that C-NDL® is not inferior to TVT-O®; therefore, single incision tape should be considered in the armamentarium of clinicians who manage women with urodynamic stress incontinence.

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Conflicts of interest None.

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