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ORIGINAL ARTICLE

Contasure-Needleless® compared with transobturator-TVT® for the treatment of stress urinary incontinence

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Abstract
Introduction Single-incision devices for the treatment of stress urinary incontinence (SUI) have been introduced in the last few years. We report a comparison between Obturator Tension-free vaginal tape (TVT-O®) and Contasure-Needleless (C-NDL®).
Methods One hundred and fifty-eight women with primary SUI were scheduled to receive TVT-O® or C-NDL® and follow-up during the first year. Epidemiological information, complications, blood loss, and pain level were recorded. We also analyze stress test and quality of life.
Results Sixty-three (87.5%) C-NDL® presented a negative stress test, compared with 54 (90%) of TVT-O® (p value 0.015 for non-inferiority test). Sandvik Severity Index was 0 in 75.4% in the C-NDL® group and 87.3% in the TVT-O® ($p<0.015$). Complication rate and degree of satisfaction were similar in both groups. Statistically, there were differences ($p=0.012$) in postoperative pain in the TVT-O® group.
Conclusions C-NDL® provides similar outcomes as TVT-O® after 1-year follow-up. It is necessary that long-term data confirm our results.

Keywords Mini-sling · Needleless · Stress urinary incontinence · TVT

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Abbreviations

SUI	Stress urinary incontinence
TVT®	Tension-free vaginal tape
ISD	Intrinsic sphincter dysfunction
C-NDL®	Contasure-Needleless®
TVT®-O	Transobturator-TVT®

Introduction

Stress urinary incontinence (SUI) may be due to changes in the urethral support or changes in the urethral sphincter mechanism [1] therefore, surgical treatment is aimed at stabilizing the urethra in cases of hypermobility or to achieve some degree of additional support of the urethra in patients with intrinsic sphincter dysfunction. We followed the principles of integral theory on SUI, developed by Petros and Ulmsten [2] in 1995, in which they developed a new technique based on the use of a retropubic polypropylene mesh to support the urethra without tensioning it; tension-free vaginal tape (TVT®). [3] Based on published data, we consider the use of the tension-free sling (TVT®), a procedure with the same efficiency in terms of continence when compared to the Burch procedure, both short, [4], [5] and long term, [6], [7] with a level of evidence 1.

Delorme in 2001 devised a new approach, placing the mesh without tension out–in through the obturator foramen (TOT®). This minimized the risk of bladder perforation and hematoma formation at the Retzius space [8]. After mid-term follow-up, results have demonstrated cure rates between 82.8% [9], [10] and 90% [11] with a level of evidence 1.

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Jean Leval in 2003 modified this technique, introducing the sling through the obturator foramen using a technique commonly referred to as inside-out, [12] in order to further reduce the complications with the passage of the needle through this territory (nerve, vascular). The results showed cure rates of short-medium term, between 89% and 95.4%, comparable to the retropubic approach but with a smaller intra- and postoperative morbidity, [13], [14], [15]

Complications of transobturator needle passage are also due to blind passage of the introducer needles through the obturator foramen. The most common complication is groin pain with published rates of 2–7.5%, [16], [17] but failures and extrusion [10] of the sling have also been published along with more serious complications such as vascular injury. [18]

In an attempt to simplify the techniques described and decrease the rate of complications attributable to the passage of needles through the obturator foramen, a new device, Contasure- Needleless® (C-NDL®) was created. This device maintained the principle of the tension-free sling and introduced the concept of "single incision tape", as the placement of the mesh is performed without passing completely through the obturator foramen. The main objective of this study is to assess whether or not the Contasure-Needleless® (C-NDL®) sling is inferior to trans-obturator vaginal tape (TVT®-O) mesh in the treatment of stress urinary incontinence in patients with or without associated pelvic organ prolapse.

Materials and methods

A quasi-randomized prospective study was performed in the pelvic floor unit of our institution from September 2006 to July 2009. We include a total of 158 patients affected by stress urinary incontinence with positive stress test, with or without associated genital prolapse and who are candidates for surgical treatment.

Exclusion criteria were:

- Previous surgical treatment of stress urinary incontinence
- Intrinsic sphincter deficiency: defined in urodynamic testing by valsalva leak point pressure (VLPP)<60 cm H_2O and absence of urethral hypermobility
- Candidates for pelvic floor physiotherapy rehabilitation
- Mixed incontinence with predominance of urge incontinence (major quality of life affectation by the overactive bladder symptoms)

The study was approved by the ethical committee of our institution. All patients submitted to a clinical history during which clinical and demographic data was collected. Patients completed the International Consultation on Incontinence Questionnaire (ICI-Q) short form under the Spanish validated form [19] and the Sandvik test [20] of incontinence severity, also validated in Spanish. Urogynecologic examination was carried out including a stress test, Q-tip test [21] (evaluating the angle of a cotton swab, introduced in the urethra at the level of the bladder neck, and the horizontal plane, at rest and during the Valsalva maneuver), evaluation of the prolapse degree according to the classification of Baden-Walker, (consideration being given to operate on all patients with symptomatic prolapse degree III and IV), and urodynamic testing. All patients signed an informed consent and were subjected to a preoperative study and anesthetic evaluation. Patients were assigned to one or another group of treatment depending on the last figure of their medical history number; last even figure was allocated for technical TVT®-O and last odd figure for C-NDL®.

Both techniques may be performed under several types of anesthesia: local, regional or general. Antibiotic prophylaxis with 2 gr of Cefazolin IV was administered before the procedure.

C-NDL® technique

The mesh used for this technique is made of polypropylene monofilament, with dimensions of 114×12 mm. The ends are slightly wider as they form a pocket (Fig. 1) to provide sling tissue ingrowth which maintains the slings stability under the urethra. These extremes, the wide pocket and the length of the sling, are its' main features. The surface area of the sling in the pelvic floor is almost the same as the TVT-O®.

With the patient in the lithotomy position, we empty the bladder with a Foley catheter. A 1.5-cm longitudinal incision is made at the level of the suburethral vaginal mucosa at a distance of 0.5 cm from the urethral meatus. Lateral to this incision, blunt dissection of the para-urethral

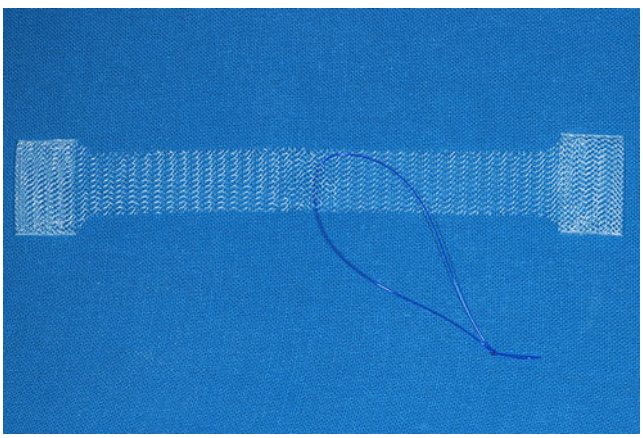

Fig. 1 C-NDL® mesh

spaces is done up to the descending ramus of the pubic bone. Then a pair forceps is introduced into the sling pocket and the sling is perfectly folded by the forceps (Fig. 2). We then introduce both into the paraurethral spaces and continue pushing the forceps in the 2 o'clock direction perforating the urogenital diaphragm and into the internal obturator muscle. Forceps are opened to display the "T" pocket positioning of the mesh. We then semi close the forceps and remove them, leaving the sling anchored at the internal obturator muscle. To control the penetration of the tip of the forceps and the sling, the surgeon can hold the central portion of the sling by means of a blue centering suture affixed to the middle of the sling for this purpose. The process is repeated on the contralateral side towards the 10 o'clock direction. Once the sling is placed, it can be further adjusted to give more support to the urethra by introducing the tip of the forceps in the pocket positioning system and pushing the tip of the mesh up to the desired support level. To reduce the mesh urethral support level, the surgeon can pull the suture at the central part of the C-NDL® sling. After proper positioning, the blue centering suture is removed from the sling with a single cut on one side of the suture while maintaining traction on the suture. Finally, close the vaginal incision with a rapidly absorbable 2/0 suture.

TVT®-O technique

TVT®-O is made of polypropylene monofilament mesh 450 × 11 mm with a plastic cover. Its' ends are attached to stainless steel introducer needle used for its placement. With the patient in the lithotomy position, we empty the bladder through a Foley catheter. A 1-cm longitudinal incision is made at a distance of 0.5 cm from the urethral meatus. A blunt dissection of the paraurethral spaces is made at the level of the middle portion of the urethra. We place the helical needles from the vaginal incision laterally through the obturator membrane, rotating the needle around the obturator foramen and out through the inguinal skin. The same maneuver is performed at the contra lateral side. Then we pull both ends of the mesh while maintaining the placement of a Bengolea forceps between the urethra and the mesh to ensure the sling is tension free. Once the mesh is properly positioned we remove the plastic cover of the mesh. We close the vaginal incision with a rapidly absorbable 2/0 suture and the groin incisions with adhesive skin sutures. The bladder catheter is maintained during the immediate postoperative period, and removed when the anesthesia effects are overcome. In cases associated with prolapse surgery, a bladder catheter is maintained until the second postoperative day. Then we perform a measurement of the residual urine in the bladder after the second spontaneous micturition. If this is 100 cc or less, the patient is discharged.

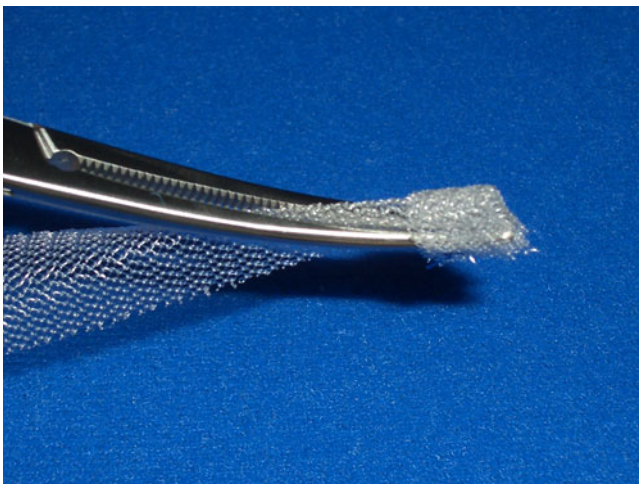

Fig. 2 Pocket folded by the forceps

All patients are monitored in the pelvic floor unit at intervals of 1 month, 3 months, 6 months and annually after surgery. At each visit, a new history of urinary symptoms is obtained and the patient is asked if she is (a) very satisfied, (b) satisfied or (c) dissatisfied with the intervention outcome. Also, a urogynecological examination is performed which includes: assessment of external genitalia, stress test and completion of two questionnaires: the ICI-Q short form quality of life and the Sandvik severity test.

Cure criteria

We analyze the patient subjective impression of the treatment received through a direct question on satisfaction of the results of the intervention; very satisfied, satisfied or dissatisfied.

The cure rate is analyzed in two ways:

- Stress test: we define cure by the presence of a negative stress test. This is performed with the patient in the lithotomy position, bladder full (subjective), and the initiation of a series of forceful coughs. We consider the procedure a failure if there is a loss of urine.
- Sandvik severity test: We define cure when we have post surgical Sandvik test of 0, improvement when the score is smaller compared to the pre surgical one and failure when it is equal to or greater than the patient's pre surgical test. We include in this category patients with urinary symptoms after surgery, even if those are not stress related.

We exclude from this analysis all patients who had symptoms of urge incontinence before surgery and persisted after surgery. In these patients, we do not know if the origin of the positive Sandvik test is the preexisting urgency, because this test cannot discriminate urinary symptoms.

Table 1 Epidemiological data

	C-NDL®	TVT®-O	*p* value
Age (years)	59.9 (37–86)	60.6 (40–85)	0.648
Body mass index	29.13 (20.8–41.1)	29.01 (19.5–42.1)	0.917
Menopausal status	71	52	0.492
Smoker	5	11	0.062
Parity	2.53 (0–6)	2.63 (0–9)	0.589
Maximum weight of newborn (g)	3714.5 (2600–6000)	3755.6 (2900–5200)	0.681
Duration of SUI (years)	7.61 (6 months–40 years)	4.68 (6 months–20 years)	0.042
Previous rehabilatative treatment	30	20	0.492
Sandvik severity index	5.43 (0–12)	5.39 (0–12)	0.961
Quality of life (ICI-Q)	5.39 (0–10)	5.23 (0–10)	0.768
Symptoms of urge incontinence	40	30	0.748
Associated genital prolapse (III–IV Baden grade scale)	53	50	0.184

Statistical analysis

We designed a non-inferiority study, in which the null hypothesis (H0) is the difference in the failure rate. Single-incision techniques are compared with transobturator techniques, and determined to be equal to or greater than 15% (margin of no inferiority) (H_o=unique incision; TVT®-O-OR≥0.15). We chose a non-inferiority margin of 15% [10], because it is widely considered that differences smaller than 15% are not clinically relevant. The cure rate in short–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 favor of

Table 2 Surgical data

	C-NDL®	TVT®-O	*p* value
Vaginal hysterectomy	26 (29.9%)	30 (42.3%)	0.133
Anterior vaginoplasty	47 (54%)	45 (63.4%)	0.259
Posterior vaginoplasty	4 (4.6%)	5 (7%)	0.732
Intraoperative bleeding (>500 ml)	1	0	1
Without associated surgery (*n*=55)	0	0	1
With associated surgery (*n*=103)	1	0	1
Intraoperative bladder injury	1	1	1
Without associated surgery (*n*=55)	0	0	1
With associated surgery (*n*=103)	1	1	1
Urinary infection	1	0	1
Without associated surgery (*n*=55)	0	0	1
With associated surgery (*n*=103)	1	0	1
Postoperative pain>5 in Visual Analog Scale	1	7	0.023
Without associated surgery (*n*=55)	1	2	0.551
With associated surgery (*n*=103)	0	5	0.024
Urinary retention	4	3	1
Without associated surgery (*n*=55)	1	1	1
With associated surgery (*n*=103)	3	2	1
Catheterization (days)	1.72	1.86	0.491
Without associated surgery (*n*=55)	0.98	1.14	0.296
With associated surgery (*n*=103)	2.18	2.16	0.916
Hospital admission (days)	2.02	2.39	0.064
Without associated surgery (*n*=55)	1.04	1.04	0.982
With associated surgery (*n*=103)	2.65	2.96	0.098

Table 3 Complication at 12 months follow-up

	C-NDL®	TVT®-O	*p* value
De Novo urge incontinence	7	10	0.298
Difficulty in urination	0	1	0.202
Mesh extrusion	0	1	0.451
Recurrent urinary tract infections	1	1	1

the obturator in–out (H_1) that assumes that the single-incision technique is not inferior to the transobturator in–out (H_1: single incision; TVT®-O<0.15).

These calculations have been carried out by means of an asymptomatic normal unilateral test for two independent populations, taking into consideration the level of statistical significance is 5%. Taking into account an abandon rate of 10% of the cases during the follow-up, 158 patients are recruited.

Statistical analyses are performed using the SPSS package version 16 and NCSS 2007.

Results

Twenty-six patients (eleven in the TVT®-O group and fifteen in the C-NDL® group), did not complete the follow-up schedule and thus were considered excluded from the study. This left a total of 60 patients in the TVT®-O group and 72 in the C-NDL® group, with a drop-out rate of 15.5% in the first group and 17.24% in the second one. It does not affect the statistical analysis because we calculated the minimum sample size needed to refuse the hypothesis of inferiority in 116 patients (58 each group).

First, we analyzed the epidemiological data and symptoms of urinary incontinence, which do not show significant differences between both groups. Therefore those are comparable, homogeneous groups (Table 1).

Surgical procedure of pure incontinence was performed in 55 patients (34.8%), 34 in the C-NDL® group and 21 in the TVT®-O group. The remaining patients underwent genital prolapse associated interventions. There were no significant differences in the proportion of associated surgery between both groups (Table 2).

The rates of surgical and post operative complications are similar in both groups as well as the days of catheterization and hospitalization. Statistically, there are differences (p=0.012) in postoperative pain in the TVT®-O group, assessed by the visual analog scale during the first day after the procedure.

Analyzing further into two subgroups of patients, one with associated surgery and one without, no statistically significant differences were found in patients without associated surgery. In patients with concomitant genital prolapse surgery, there was more postoperative pain in the TVT®-O group (Table 3).

The results at 12-months follow-up showed that there are no statistically significant differences in any of the items studied, i.e., emergence of de novo urgency, voiding difficulty of mesh extrusion and recurrent urinary tract infections (Table 4).

The main objective is to study the cure rate of both procedures 1 year after surgery. There is a negative stress test in 87.5% of patients in the C-NDL® group and 90% in TVT®-O group, with an absolute difference of 2.5% for TVT®-O (95% from −9.2% to 13.7%). The p value for non-inferiority test was calculated using the asymptomatically normal test for two independent unilateral populations. Given that the significance level is 5% and using a non-inferiority margin of 15% is 0.015, it was indicated that we reject the hypothesis of inferiority in favor of the alternative hypothesis of non-inferiority. That being said, C-NDL® is not inferior to TVT®-O. The Sandvik Severity Index is 0 in 75.4% of patients in C-NDL® group and 87.3% of patients in the TVT®-O group, scoring lower than preoperatively in 13% of the first group and 3.6% of second and higher than preoperatively in 11.6% and 9.1%, respectively. The absolute difference in the number of failures (Sandvik severity test is greater postoperatively) is 2.5% with a confidence interval 95% from −9.4% to 13.7%. The 39.7% of C-NDL® patients are very satisfied with the outcome of the intervention at 12-months follow-up, 53.4% satisfied and 6.8% dissatisfied. In the TVT®-O group, ratios show no statistically significant differences being 33.3%, 58.3% and 8.3%, respectively.

Table 4 Results at 12 months follow-up

	C-NDL®	TVT®-O	Absolute difference (IC 95%)	*p* value
Negative stress test	63/72 (87.5%)	54/60 (90%)	2.5(−9.2–13.7)	0.015
Sandvik test<than preoperatively	61/69 (88.4%)	50/55 (90.9%)		
Sandvik test>than preoperatively	8/69 (11.6%)	5/55 (9.1%)	2.5(−9.4–13.7)	0.015
Very satisfied	29/73 (39.7%)	20/60 (33.3%)		
Satisfied	39/73 (53.4%)	35/60 (58.3%)		
Dissatisfied	5/73 (6.8%)	5/60 (8.3%)	−1.5 (−12.1–8.1)	0.001

Discussion

In the last 15 years, there has been a revolution in the surgical treatment of SUI, pre and post introduction of the tension-free vaginal tape (TVT®). Recent studies show similar results comparing the TVT®-O technique versus the TVT® with fewer complications with the TVT-O, such as bladder perforation and vessel or bowel injury [15], [22], [14], [23]

Recently, a new class of single-incision slings has emerged. They are aptly named because they don't pass through the obturator foramen but they maintain the hammock approach and the principle of tension free. They are becoming widely used in spite of the absence of clinical evidence attesting to their comparability in efficacy and safety to previous techniques. C-NDL® maintains the length, material and the direction of placement of the transobturator devices, with some advantages based in its way of placement, such as reduced risk of serious complications and less postoperative pain.

There are few studies, [24], [25], [26] but none comparing C-NDL® technique with the standard treatments of SUI like TVT-O®. Comparing different surgical techniques is always difficult in a study, due to many different variables, especially when the results obtained (cure rate, complications, etc.) from one of the techniques being compared is meeting the expectations of the patients and surgeons.

Therefore, it is difficult to think that a new device could show statistically significant differences with good present day cure rates. [17] That is why we chose a non-inferiority study to demonstrate that the results of the C-NDL® technique are not worse than the ones obtained with the TVT®-O technique. A possible draw-back of this study is the random method of patient selection. However, we do not think this causes bias because medical history numbers are automatically assigned when patients initially arrive at the hospital. Everybody has the same probability of even versus odd last number in the selection process based on their medical history number.

The principal objective when analyzing the results of a surgical technique for SUI should be the cure rate. While this has been our objective, it continues to be challenging to isolate and analyze this parameter alone, and to define the proper "cure" parameters. [27]

The assessment of cure in these patients can be seen from different points of view, either objectively (urodynamics, pad test, stress test) or subjective parameters (clinical history, patient satisfaction). In this study, we used as a principal parameter of objective cure, the negative stress test being negative in 87.5% of the patients in the C-NDL® group and 90% in the group of TVT®-O.

The parameters used to evaluate the subjective cure or improvement of the patients was the clinical history (Sandvik severity test, ICI-Q, and satisfaction degree). The Sandvik test showed cured or improved in 88.4% of patients of the first group and 90.9% in the second group of patients, and was worse in 11.6% and 9.1% respectively, including all patients with de novo urgency.

The satisfaction level has been high in both groups of patients, without significant differences. This demonstrates that patient expectations are accomplished by both treatments at the same level.

In consideration of the large population, no serious complications were reported, despite previously reported complications in the literature. The transobturator technique has the potential risk of obturator nerve or vascular damage due to the passage of needles [28]. By using the C-NDL® device we theoretically reduce this risk. Furthermore, the C-NDL® device and associated technique eliminates skin incisions, thus avoiding infections at this level and minimizing the mesh contamination risk.

In conclusion, our experience and the results in 1-year follow-up of non-inferiority of the C-NDL® compared to TVT-O®, demonstrate that it is a safe technique, reproducible, and accomplishes the goal of minimally invasive surgery. Additionally, it widens the surgical armamentarium to treat urinary stress incontinence. More studies are needed and a long-term follow-up will confirm our results.

Conflicts of interest None.

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