

CONTASURE-NEEDLELESS® VS TRANSOBTURATOR-TVT®: CORRELATION BETWEEN ULTRASOUND FINDINGS AND CLINICAL RESULTS

Hypothesis / aims of study

A question arising in incontinence surgery is how all variations of the “tension-free vaginal tape” original technique can achieve good results despite their different forms of application. For this reason it seems interesting to evaluate the anatomical location of the suburethral tape by translabial or introital ultrasound and the correlation of these data with the functional or dysfunctional results obtained.

Main study objective is to compare ultrasonographic findings on tape width, position and angulation following surgical anti-incontinence procedures by Contasure-Needleless® and obturator tension-free vaginal tape (TVT-O®) and correlate with functional outcomes regarding continence, and “de novo” dysfunctional urgency or recurrence of stress incontinence.

Study design, materials and methods

One hundred fifty eight women with primary SUI were scheduled to receive TVT-O® or C-NDL® and followed up during one year after procedure. We evaluated postoperative stress test, quality of life and “de novo” urinary disorders a year after the procedure. All of them were studied with introital ultrasonography.

All patients underwent ultrasound measurement of the tape width, position and angulation. We used a high-frequency transvaginal probe (General electrics, Voluson 730 Pro) placed in the introitus just under the urethral meatus. The location of the mesh was determined in the sagittal plane in relation to the urethrovesical junction, by drawing a perpendicular line from the proximal end of the mesh to the bladder neck. In this plane, we also measured the extent of the mesh, allowing us to calculate the postoperative retraction. The angulation between the arms of the tape was calculated in the frontal plane at rest, at retaining and during maximum Valsalva Maneuver.

Results

The results at 12 months follow-up showed that there was a negative stress test in 87.5% of patients in the C-NDL® group and 90% in TVT-O® group. There are no statistically significant differences in the complication rates in any of the studied items: “de novo” urgency, voiding difficulty, mesh extrusion and recurrent urinary tract infections.

There was no statistically significant difference ($p=0.421$) between the two groups regarding distance from the tape proximal end to the bladder neck. Distance was 17.72 mm in C-NDL® group and 18.17 mm in TVT-O® group. The tape was located in mid-urethra.

Tape width was 5.91 mm and 5.89 mm in C-NDL® and TVT-O® group respectively without differences ($p=0.896$). These values corresponded to a retraction of 48.16% and 46.46% in the first and second group respectively. At rest, angle between tape arms was obtuse of 139.29° in C-NDL® and 137.41° in TVT-O® groups respectively, at rest. This difference was not statistically significant ($p=0.054$). During maximum Valsalva Maneuver, angle was 142.27° in C-NDL® and 140.30° in TVT-O® groups, being this difference statistically significant ($p=0.05$). At retaining, first and second group angles were 134.01° and 135.39° respectively without statistically significant differences ($p=0.235$).

When we analyzed patients with surgical failure we obtained more opened angulations at rest, retaining and at maximum Valsalva Maneuver with statistical significance ($p=0$, $p=0.002$ and $p=0$). Closer angulation, in all measurements, is associated with “de novo” urgency with statistical significant differences ($p=0$, $p=0.002$ and $p=0$).

Distance between proximal tape end to the bladder neck in patients with “de novo” urgency was 18.66 mm with no statistical differences with the distance measured in cured patients ($p=0.29$). In patients with recurrence of the stress incontinence we found a larger distance (19.83 mm), with statistical significant differences, when compared to cured patients ($p=0.026$). Mesh was situated in a distal place from the bladder neck.

Interpretation of results

In cured group, tape arms angle was obtuse, at rest, during Valsalva Maneuver and at retaining that confirms the mesh was placed in a “V”, both in group C-NDL® and in group TVT-O®.

Ultrasound can be useful to study and control postoperative complications. “De novo” urge incontinence can occur after tension-free vaginal tapes despite the transobturator method had lower rate of this complication due to a less compression of the urethra.

Our study showed that in patients with “de novo” urgency, the mesh was located closer to the bladder neck but this difference is not statistically significant. Mesh angle on the urethra was more closed than in cured patients. Alternatively, the mesh could be tighter.

In 12.5% of C-NDL® patients and 10% of TVT-O® group persisted a positive stress test after surgery and was considered a failure. In these cases, we found that the sling was located distal from the bladder neck and the arms angle of the band was more opened than in cured patients, ie the mesh is more “tension-free” than desired. Since less tight slings are more likely to fail, we hypothesize that transobturator slings, with their hammock effect, do not need to maintain the classic concept of “tension-free”, because it is better to give them more tension to be successful than in retropubic slings.

Concluding message

The definitive location of the sling is important to obtain good results in SUI surgery. To further improve results, we believe it would be of interest to intraoperatively study the situation the sling is placed.

References

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<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>Is this a Randomised Controlled Trial (RCT)?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require ethics committee approval because</i>	both techniques used in the study are tested and commercialized.
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes