

## EFFECTIVENESS OF TVT-SECUR COMPARED WITH MINIARC FOR STRESS URINARY INCONTINENCE: A RANDOMIZED CONTROLLED TRIAL WITH MINI-SLING.

### Hypothesis / aims of study

During 1996 Ulmsten presented the first sling based on the theory of tension-free hammock: the TVT.<sup>1</sup> After several systems based on the same principle were mainly intended to reduce the potential risk and complications. These new techniques were based on the principle of minimally invasive surgery simplifying the devices. In recent years were introduced the mini-tape for the treatment of the stress urinary incontinence. The MiniArc and the TVT-Secur are two representatives of these new systems.<sup>2,3</sup> Then the question arises about if both have the same effectiveness. We hypothesise that both mini-sling techniques have similar results in terms of effectiveness in curing stress urinary incontinence. This study aims to compare the effectiveness of TVT-Secur with MiniArc tape in terms of cure of stress urinary incontinence at 12 months postoperatively.

### Study design, materials and methods

Prospective randomized controlled study with 110 women admitted for symptomatic urinary incontinence study, at Clínica Las Condes, Santiago, Chile. The study was between January 2008 and February 2009. Inclusion criteria: all patients admitted to the study due to stress urinary incontinence at least one year and permanent. Criterion of cure, improvement and failure: the outcome of surgery was classified according to the number of incontinence episodes recorded during the observation period. Cure was considered to the absence of incontinence. Partial cure or improvement was considered to the presence of incontinence episodes less than one every two weeks. Failure when the incontinence episodes were more than once in a week. The randomization was: each physician explained the pathology and the technique to use offering only one. One physician used the MiniArc and the other two used only TVT-Secur. All women signed the informed consent. 50 women were operated with MiniArc and 60 with TVT-Secur. In MiniArc group: the media age was 53 years old (range 36 to 72), with a weight of 64 kg (53 to 82). BMI was 28 (23 to 34) and vaginal parity 3 (0 to 5). In TVT-Secur group: the media age was 55 years old (range 31 to 65), with a weight of 62 kg (51 to 80). BMI was 29 (23 to 35) and vaginal parity 3 (0 to 5). The diagnosis of stress urinary incontinence was realized by clinical evaluation and urodynamic test. The stress urinary incontinence was classified according to the McGuire et al classification of urinary stress incontinence. All patients had mixed urinary incontinence or stress urinary incontinence type II, II+III (with intrinsic sphincter deficiency) and urethral hypermobility. The TVT-Secur tape was applied in "U" in the women of this group. The results of both techniques were compared in order to determine the cure of stress urinary incontinence at twelve month after surgery.

### Results

The media surgical time for MiniArc technique was 10 minutes (range 8-17 minutes); for TVT-Secur was 10 minutes (range 8-15 minutes). Intraoperative complications were registered in 2 (3%) cases corresponding to bladder perforation in the TVT-Secur group. This complication not was observed in cases with MiniArc. During the immediate postoperative time 2 cases (3%) of obstruction were resolved with mesh adjustment in the TVT-Secur women and in 1 case (1%) in the MiniArc group. The mesh adjustment was realized in operating room. At twelve months, 92% (46/50 cases) of the women in the MiniArc group were cured compared with 91.7% (55/60 cases) in the TVT-Secur group. The partial cure or improvement was 8% (4/50 cases) in MiniArc women and 5% (3/60 cases) in TVT-Secur group. Two cases (2/60, 3.3%) of failure were detected in TVT-Secur group. No cases of failure were observed in MiniArc (0/50, 0%). A novo urge-incontinence was observed in the MiniArc women in 4% (2 cases) compared with 3% (2 cases) in TVT-Secur group.

### Interpretation of results

Both mini-sling techniques are similar to treat stress urinary incontinence according our results observed at twelve months. But the comparison was realized only between the "U" positions in the TVT-Secur compared with MiniArc. The TVT-Secur has versatility to apply the mesh in "V" or "U" position. In our series we observed good results of cure at twelve months but long follow-up is required to determine the persistence of these results in the long time. Other series demonstrated similar percentage of patients with cure in both group without significant differences in short follow-up.<sup>2</sup> Both techniques corresponding to third generation meshes for treatment of stress urinary incontinence are minimally invasive or less invasive comparing to classic retropubic TVT, but we must not forget that these new techniques also have complications that we must be vigilant to detect and correct. In our series we observed bladder perforation with TVT-Secur technique for example. We not observed bladder perforation with MiniArc probably due to the position of the tape. In the TVT-Secur the mesh in "U" is closer the urethra and bladder unlike MiniArc in which the sling is away from de bladder, therefore should have less risk of perforation. In the TVT-Secur group we observed two cases of urethra obstruction in which cases was necessary an adjustment of the sling. This may also explain by the mesh position in "U" closest to the urethra.

### Concluding message

According our experience at twelve months both new system corresponding to the mini-sling are safe and effectiveness for stress urinary incontinence treatment. Both techniques have similar rates of cure. Both new techniques require a long follow-up to determine the persistence of good results.

### References

1. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct.* 1996;7(2):81-85.
2. Jiménez Calvo J, Hualde Alfaro A, Raigoso Ortega O, et al. Our experience with mini tapes (TVT-Secur and MiniArc) in surgery for stress urinary incontinence. *Actas Urol Esp.* 2008;32(10):1013-1018.

3. Debodinance P, Delporte P. Miniarc: prospective study and follow-up at one year about 72 patients. J Gynecol Obstet Biol Reprod (Paris).2010;39(1):25-29.

<b><i>Specify source of funding or grant</i></b>	<b>Clinica Las Condes</b>
<b><i>Is this a clinical trial?</i></b>	<b>Yes</b>
<b><i>Is this study registered in a public clinical trials registry?</i></b>	<b>No</b>
<b><i>Is this a Randomised Controlled Trial (RCT)?</i></b>	<b>Yes</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Clinica Las Condes Ethics Committee</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>