

CLINICAL OUTCOME OF TVT-O SURGICAL PROCEDURE IN PATIENTS WITH INTRINSIC SPHINCTER DEFICIENCY. A FIVE YEARS FOLLOW UP.

Hypothesis / aims of study

The free Tension Transvaginal Tape (TVT) procedure seems a highly effective treatment in women whose Intrinsic Sphincter Deficiency (ISD) was documented and the recent literature conclude that TVT procedure has a significantly higher efficacy in cure rates than Burch colposuspension^(1,2). In the current reports there is no long-term follow up with free Tension Transvaginal Tape Obturator (TVT-O) in patients with ISD, neither studies comparing its results with other surgical procedures in the same group of patients⁽³⁾. The purpose of this study was to evaluate the clinical outcome of the TVT-O procedure, in women with urodynamic stress incontinence diagnosed as having ISD. The maximal urethral closure pressure (PCUmax) < 20 cm H₂O was considered as diagnostic of ISD. We consider that success rate of the TVT-O surgical procedure is adequate in patients with ISD at short, medium and long term follow-up.

Study design, materials and methods

In a prospective, long term follow up study, we included 120 women with clinical and urodynamic diagnosis of stress incontinence with ISD. All the patients had an initial evaluation, which includes complete physical examination, cough, q-tip, and urodynamic test. An analogue visual scale to quantify the severity of the stress incontinence was also realized. In all patients we performed TVT-O surgical procedure, by an expert and familiarized surgeon, as treatment for stress incontinence. It was made a Wilcoxon rank-sum test to evaluate the symptoms before and after the surgical procedure. Follow up was conducted by a complete physical examination, urodynamic test and an analogue visual scale for the symptoms. This was made at 3 and 6 months after surgery, and then annually to complete 5 years (range 3-5 years)

Results

The severity of the symptoms before the surgical procedure was 8.4 (evaluated by the analogue visual scale). After the treatment and during the follow up, the severity of the stress incontinence had statistically decreased (8.4 vs 2.1, z= -6.42; p=0.0001). In the urodynamic follow up there were no differences in all the parameters. During the follow up we observed overactivity bladder de novo in 5 patients, infection in 1 patient, exposition of the mesh in 1 patient and dyspareunia in 1 patient.

Interpretation of results

In the follow-up, the TVT-O surgical procedure demonstrated to have an excellent cure rate in patients with ISD. The complications presented in our surgical procedures had no differences with the previous published in the literature⁽³⁾.

Concluding message

In the current available literature, there is no evidence for the efficacy of TVT-O in patients with Intrinsic Sphincter Deficiency. In patients with ISD, our study demonstrates and concludes good clinical outcomes at long-term follow up, and confirms TVT-O to be an ideal surgical procedure in patients with ISD, with the advantages of minimal risk of complications compared to other surgical procedures.

References

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Specify source of funding or grant	No funding
Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
Is this a Randomised Controlled Trial (RCT)?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Local Ethic Committee of "Luis Castelazo Ayala" Hospital, INSTITUTO MEXICANO DEL SEGURO SOCIAL
Was the Declaration of Helsinki followed?	Yes
Was informed consent obtained from the patients?	Yes