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TEN YEARS FOLLOW-UP AFTER TENSION FREE VAGINAL TAPE (TVT®): FORTY-NINE CASES

Hypothesis / aims of study

This study is about evaluating results after stress urinary incontinence repair with tension free vaginal tape (TVT®) ten years follow-up.

Study design, materials and methods

This is a prospective observational study performed in a tertiary referral center. We included women with stress and mixed urinary incontinence, underwent a transvaginal pelvic floor repair using a tension free vaginal tape, retropubic via (TVT®) performing check cystoscopy at the end of the procedure. All patients were interviewed and explored before intervention, and all of they presented a confirmative urodynamics. After de surgical intervention, we visited them at 1 and 6 months, and 1 and 2 years. Then, we continued our study by telephonic interview annually so far. All our patients answered ICIQ-SF validated in Spanish and a subjective question: "How do you feel about surgery: cured-improved-equal or worse". We register this information in an Access® database, and we analyze it using SPSS® 18.0.

Results

Between 2000 and 2001 we practiced 61 antiincontinence techniques with tension free vaginal tape retropubic via – TVT© with a mean age of 58.1 years (38-82).Moreover, 21.3% of patients had antecedent of surgery about prolapse and 3.3% about incontinence. About the type of incontinence: 49 patients (80.3%) presented stress urinary incontinence (SUI) and 12 patients (19.7%) presented mixed urinary incontinence. Globally, we practiced 61 TVT© with these associated surgery: 18 hysterectomies (29.5%), 22 anterior colpoplasty (36.1%) and 10 posterior colpoplasty (16.4%). Most surgeries had realized under raquidea anesthesia (91.8%), but 2 were done under general anesthesia and 6 with local anesthesia with sedation. The average of days in hospital was 2.56 days in global, 3.54 days with associated surgery and 1 day without associated surgery. Complications were: bladder perforation 5 cases (8.2%), vascular injury (Retzius) 1 case (1.6%) –required laparotomy and blood transfusion–, acute urinary retention 13 (21.3%), mesh extrusion 2 (3.3%) and recurrent cystitis 3 (4.9%), without intestinal injuries, mesh infections or chronic pelvic pain. Furthermore, we practiced 3 sections for urinary retention persistence and recurrent cystitis and 1 resection for mesh extrusion. Globally, 39 patients no presented complications.

At long term, we followed 49 patients (4 exitus for other causes and 8 missed cases) at 10 years. The mean of ICIQ-SF was 6.9, with a 69.4% under 11. Subjective satisfaction rate described as: cure, improvement, unchanged and worse, was respectively 46.9%, 36.7%, 10.2% and 6.1% at ten years follow up. In the group with SUI, 81.6% consider cured or improved and ICIQ-SF 6.9 too, with 28.9% of urge incontinence de novo (IUU de novo)

(ICQ-SF or 9.45 in this group). In the group with MUI, 10 of 11 patients are cured or improved, with 6 cases with urge component solved, and ICQ-SF of 7.55.

Subjective impression	Cured 46.9%	Improved 36.7%	Unchanged 10.2%	Worse 6.1%
ICIQ-SF	0.26	8.83	10.07	13.9

Interpretation of results

Ten years follow-up presents a high degree of patients' percentage cured or improved and they presented too a low mean of ICIQ-SF. We would indicate a relationship between subjective impression and this standard test.

However, we also would like to highlight the complications occurred: the percentage of bladder perforation was elevated, because included the learning curve, and the rest of complications is similar to literature.

At long term, our rate of IUU de novo is very high at ten years, but with a result of ICIQ-SF 9.45. Actually, the diagnosis rate is high with a low repercussion in quality of life.

Finally, we believe that we must be self-critical by the fact that the study population is not homogeneous, a problem that is otherwise common in the literature due to the complexity of this condition: we analyze patients with very different ages, as different levels of activity, with varying degrees of vaginal prolapse and affected compartments, carrying or not concomitant hysterectomy and incontinence surgery, repair of single or several compartments, previous history of prolapse surgery, etc. All these factors limit the value of the study.

Concluding message

In terms of quality of life, globally, our patients present very safistactory results, but it is very important to inform patients of potential risks and take into account their expectations at long term.

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Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**

This study did not require ethics committee approval because	**This is a prospective observational study, which is the result of a systematic collection of data.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**