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TVT-SECUR: AFTER THE LEARNING CURVE. SHORT-TERM FOLLOW-UP AND SURGERY COMPLICATIONS.

Hypothesis / aims of study

The TVT-secur (TVT-S) was designed for reducing the invasiveness of the surgical procedure in the treatment of stress incontinence. The aim of this study was to compare the objective and subjective cure rates as primary outcome and other secondary questions: Surgery complications and changes in O.A.B. symptoms. The surgeries performed were both, the stress incontinence one isolated or associated to prolapse surgery. TVT-S technique has been described different to other tension free vaginal tape procedures, with an important number of patients including in the learning curve (+/- 10 per surgeon).

Study design, materials and methods

From January 2009 to December 2009, **124 TVT-S** were made in our hospital. The type of TVT-S performed was "H" approach in everyone. Previously, all the surgeons in our service took part in a session about the specifics of the technique. All of them had made at least 5 TVT-S procedures before the beginning of this study. Preoperative evaluations included history, ICIQ-SF questionnaire, physical examination, standing stress test with filling of 250 ml. of saline and urodynamic evaluation in 29% of patients. Urodynamics were only performed in case of non-evident history of stress incontinence. At post-operative 1-2 months the same evaluation was re-made and surgery complications were collected. The inclusion criteria was the visualisation of leaking urine from the urethra with cough. The only exclusion criteria was the previous surgery of stress incontinence.

Results

124 surgeries were collected. Mean age 59.6 years (+/- 13.1). **30 different surgeons**, including residents of second, third and fourth year. The type of incontinence referred by patients was: Stress (38.3%), mixed (55.5%) and urgency (6.06%). Urodynamics were performed in 29% with the same percentage of types of incontinence (no statistical differences). Pelvic organ prolapse was associated in 55.65% : POP-Q Stage 1 (6,45%), Stage 2 (15.32%), Stage 3 (29.03%) and Stage 4 (4.8%). Stage 0 (44.35%). **38 vaginal hysterectomies were performed (30.40%).**

	PRE-OPERATIVE	POST-OPERATIVE	
Follow-up		1.61 months (+/- 0.64)	
ICIQ-SF	12.7 (+/- 7.62)	3.67 (+/- 6.54)	t student: 14.55 p: <0.000
Subjetive cure		91.2 % "Absolutely dry or better"	
Objective cure		83.06% no leakage	
O.A.B. symptoms		Novo 5.64 % 57,37% (With previous symptoms) "Absolutely absence or better"	

The objective cure was defined as no leakage at all in the standing test, with 250 ml. of saline in the bladder and repetitive cough.

Complications:

Directly associated with the TVT-S procedure

Bladder perforation	3/ 127 (2.36%)
Vaginal perforation	2/ 124 (1.61%)
Vaginal erosion	5/124 (4.03%)
Acute retention	2/124 (1.61%)

Both cases of acute retention needed of temporary drainage, the first one during 48 hours and the second one for 33 days. Finally both cases performed a successfully evolution, with no voiding dysfunction in this moment.

3 erosions were asymptomatic. All of them were treated in the office, been cut with scissors and oestrogen local therapy.

Interpretation of results

We think that 83.06% of objective cure rate with a statistical difference in the ICIQ-SF, is a great result, as good as other T.V.T. procedures. The complication rates are similar to those in the literature. The improvement in O.A.B. symptoms achieved is an important secondary goal. The importance of these results is that no selection of patients was made and the big number of surgeons implicated. In our hospital the TVT-S is now a usual procedure, and it is the first line technique for stress incontinence, regardless of the type of surgery associated, with the only exclusion criteria of previous surgery of stress incontinence performed.

Concluding message

After the learning curve, we have accepted the TVT-S as a good and reproducible technique, and now is our main procedure in stress incontinence. In future we'll try to perform this technique as an office procedure. The short term follow-up is an important objection, our results at one year follow-up are similar with no statistical differences, but we didn't present them because of the short number of cases is this moment, only 35.

References

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<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>	no it didn't
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes