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Porta O[1], Targa C[1], Macia M[1], Simo M[1], Perello J[1], Gich I[2]
1. *Obstetrics and Gynaecology Dpt. Hospital de la Santa Creu i Sant Pau. Barcelona (Spain),* ***2.*** *Epidemiology Dpt. Hospital de la Santa Creu i Sant Pau. Barcelona (Spain)*

ONE TO THREE YEAR PROSPECTIVE FOLLOW-UP DATA OF TVT-S PROCEDURE FOR STRESS URINARY INCONTINENCE SURGERY

Hypothesis / aims of study
The purpose of this prospective study was to report data on the efficacy and safety of the TVT-S mini-sling procedure (Gynecare, Johnson & Johnson, Somerville, USA) in the treatment of stress urinary incontinence (SUI) after one year or more follow-up time.

Study design, materials and methods
Forty-seven (47) women were included in the study group and prospectively followed up. Inclusion criteria was urodynamically proven primary stress urinary incontinence. Exclusion criteria were predominant urge incontinence or urodynamic detrusor overactivity, previous anti-incontinence surgery and women with concomitant prolapse surgery. All the procedures involved "hammock" positioning, and were done or directly, supervised by the same surgeon. To intraoperatively determine the tensioning of the tape, a cough stress test with bladder filled with 250 ml of saline solution was performed until it was negative. Information was collected on the type of anesthesia, the days of hospital stay, perioperative complications and the need for major analgesics. Criteria for cure. According to IUGA and ICS recommendations, objective, subjective and patient-centered outcome measures were described. The criteria for objective cure was both a negative standing stress test and 1-hour pad test < 1 gr. Subjective cure was ICIQ-UI-SF=0 and subjective improvement was defined as ICIQ-UI-SF=1-5. Patient-centered outcomes were assessed by means of two five-item Likert scales: patients considering themselves "satisfied" or "very satisfied" with the procedure and those who reported that the procedure fulfilled "quite" or "totally" their expectations were regarded as successful results. A descriptive analysis of the variables was made. The Student's t- and Wilcoxon tests were used for the comparison of paired samples. Analysis was performed using the SPSS (v 15.0) statistical package.

Results
From November 2006 to February 2009, 47 patients were enrolled in the study. Forty-five patients were available for the analysis, as two women were lost to follow-up (one having a progressive Alzheimer's disease and the other one having had a urethra perforation during surgery, her TVT-Secur being replaced by a TVT-O). Five of the remaining 45 patients were only reached by telephone for the follow-up, so objective results data were not available. For personal reasons, only 35 women had both objective tests done. Mean follow-up time was 25 months (12-38). The procedure was performed either under local anesthesia + sedation (86%), local anesthesia (4%), spinal anesthesia (4%) or general anesthesia (6%). All surgeries using general anesthesia had other major non-POP surgical procedures. The average hospital stay was 0.33 days (85% outpatient procedures) (see Table 1). Complications are shown in Table 2. None of the 47 cases needed major analgesia. Objective cure (defined as 1h-pad-test < 1 g + no-leakage standing stress test) was reached in 31/35 (88.6%). Subjective cure (defined as ICIQ-UI-SF=0) was achieved in 21/44 (47.7%), while 9/44 (20.4%) of patients presented subjective improvement (ICIQ-UI-SF=1-5). Thus, the accumulative rate found for subjective cure or improvement (ICIQ-UI-SF≤5) was 30/44 (68.2%). When considering patient-centered outcomes, 2 five-point Likert scales were used: 28/44 (63.6%) of patients were "very satisfied" and 9/44 (20.4%) "satisfied" with the procedure; when asked about their expectations for the surgery, 31/44 (70.4%) felt they had been "totally" accomplished, while 5/44 (11.4%) felt they had "quite" been met (see Table 3). ICIQ-UI-SF at baseline assessment was 15.95±2.11 and significantly decreased after the procedure to a mean 3.98±5.29 (p<0.001). Four of forty-one (4/41) (9.7%) reported *de novo* urge symptoms.

Table 1. Demographics and clinical data

	N	min.	Max.	MEAN	ST. DEVIATION
AGE	47	38	82	61.26	11.626
BMI	47	19.23	36.05	26-3	4.32
MONTHS AT FOLLOW-UP	45	12	38	25.27	7.97
DAYS OF HOSPITAL STAY	46	0	6	0.33	1.09

Table 2. Complications

N=47	**N (%)**
PERIOPERATIVE COMPLICATIONS	**2 (4%)**
Urethral perforation	1 (2%)
Misplacement of TVT-S.	1 (2%)
POSTOPERTIVE COMPLICATIONS	**6 (12%)**
Urinary retention (resolved in >24 h)	1 (2%)
Venous bleeding	1 (2%)
Urinary tract infection	1 (2%)
Transient groin pain	1 (2%)
Button-holing of the vaginal sulcus	1 (2%)
Voiding difficulty	1 (2%)

Table 3. Results

OBJECTIVE CURE no-leakage standing cough stress test + 1h-pad-test < 1 g	31/35 (88.6%)	
SUBJECTIVE CURE (ICIQ-SF = 0)	21/44 (47.7%)	**Total:** 30/44 **(68.2%)**
SUBJECTIVE IMPROVEMENT (ICIQ-SF 1-5)	9/44 (20.4%)	
PATIENT-CENTERED SATISFACTION		**Total**
Comparison with previous situation -Very satisfied - Satisfied	 28/44 (63.6%) 9/44 (20.4%)	 37/44 **(84.1%)**
Achievement of expectations - Totally - Quite	 31/44 (70.4 %) 5/44 (11.4 %)	 36/44 **(81.8%)**

Interpretation of results

Interpretation of outcomes deserves careful attention, and the criteria used to define success should be considered. Objective cure (as defined by negative stress test and 1-hour pad test < 1 gr.) is as high as 88.6%. However, subjective assessment by means of ICIQ-UI-SF questionnaire reveals that, unlike what we, as the surgeons involved, objectively see, less than half of the patients are completely dry, and only 68% have an ICIQ-UI-SF ≤ 5. But subjective complete dryness cannot be considered as the only valid outcome measure. Leakage of some drops and an ICIQ-UI-SF > 5 may not be considered a failure if the patient feels that her quality of life has significantly improved after the procedure. This seems to be represented by the fact that patient expectation-centered outcomes can be considered successful in 84% of patients. In this study, high success rates may be explained in part by the tensioning of the tape. In all cases, the tape was left in close contact with the tissue underneath the urethra. Final positioning of the tape was allowed only after a dry cough test was observed intrasurgery under local anesthesia.
We previously communicated our results with similar objective and subjective success rates at a median follow-up of 8 months in a multi-center study. Success rates show no decline over time in this study.

Concluding message

After a median follow-up period of 2 years, TVT-S appears to be efficacious and safe. It is feasible to perform the procedure under local anesthesia plus sedation in an outpatient setting. Results may differ depending on the outcome measures used to define success (objective, subjective or patient expectation-centered).

Specify source of funding or grant	**None**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Comitè d'Ètica d'Investigació Clínica (CEIC) de la Fundació de Gestió Sanitària de l'Hospital de la Santa Creu i Sant Pau**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**