

## RETROPUBIC VERSUS TRANSOBTURATOR MID-URETHRAL SLINGS: IN A RANDOMISED CONTROLLED TRIAL PREOPERATIVE VLPP MAY NOT PREDICT MID-TERM OUTCOME

### Hypothesis / aims of study

Since the tension-free vaginal tape (TVT) procedure was first described by Ulmsten et al in 1996, mid-urethral sling procedures have been recognized as safe, effective treatment for female stress urinary incontinence (SUI). The long-term follow-up showed high cure rates, ranging from 81% to 95% for TVT and for the recently introduced tension free transobturator tape procedure [1]. Most studies analyzed safety and efficacy of mid-urethra slings, outcome, and complication rate; a few tried to address the controversy about identifying factors predicting long-term outcomes.

The present study investigated the prognostic value of VLPP on mid-urethral sling outcomes using data from a randomized controlled study of 145 women affected by stress or mixed urinary incontinence who underwent either a TVT or TOT technique.

### Study design, materials and methods

From May 2002 to November 2005, 145 patients affected by SUI, who were candidates for the mid-urethral sling procedure, were prospectively randomized, using a predetermined computer-generated randomization code, to the retropubic route (TVT) or the transobturator route (TOT). Inclusion criteria were stress urinary incontinence associated with urethral hypermobility; exclusion criteria were: > grade II prolapse in any vaginal compartment, previous continence surgery, urinary retention, neurogenic bladder and psychiatric disorders. All patients completed two validated questionnaires on quality of life, the Urogenital Distress Inventory (UDI-6) and the Impact Incontinence Quality of life (IIQ-7) before surgery, at 3, 6, 12 months post-operatively and then annually. Patients' perception of satisfaction was investigated on a VAS of 0-10, where 10 was the maximum satisfaction and 0 the least. Before surgery patients performed 1-h pad test and completed a bladder diary for three days. Patients were stratified by VLPP > 60 cmH<sub>2</sub>O or VLPP ≤ 60 cmH<sub>2</sub>O on the basis of urodynamic assessment.

The primary outcome variable was considered the continence status: dry and wet as deduced by clinical examination, stress test and patients' interview. Patients were allocated to two main categories: *dry (no leakage during clinical and/or stress test and/or reported by patients)* vs. *wet*. Secondary outcome variables were the quality of life questionnaires and the VAS scale.

Statistical Analysis. *The Mann-Whitney and Wilcoxon tests were used to compare ordinal and non-normally distributed continuous variables. Deviations from Gaussian distribution were checked using the Kolmogorov-Smirnov test with the Lilliefors method. Categorical data were analysed by the McNemar test, X<sup>2</sup> test or Fisher's exact test, as appropriate.*

### Results

The mean follow-up was 32 ± 12 (range 12-55) months for TVT group and 31 ± 15 (range 12-61) for TOT. When patients were analyzed according VLPP stratification, 95 (65.5%) patients showed a VLPP > 60 cmH<sub>2</sub>O and 50 (34.5%) patients had a VLPP ≤ 60 cmH<sub>2</sub>O. The overall objective rates were 75.8% (patients with VLPP > 60 cmH<sub>2</sub>O) and 72% (patients with VLPP ≤ 60 cmH<sub>2</sub>O) (p < 0.619). No significant differences in objective cure rates emerged when patients with VLPP > 60 cmH<sub>2</sub>O were matched for TOT or TVT procedures (82 % vs. 68.9% p < 0.172); similar results were found for patients with VLPP ≤ 60 cmH<sub>2</sub>O (68% vs. 76% p < 0.528).

### Interpretation of results

Our findings seem to indicate that preoperative VLPP has no bearing on the outcome of mid-urethral sling, regardless of the technique which was used to treat SUI.

Several authors have used the VLPP to choose treatment in patients with SUI, suggesting the VLPP could provide prognostic information. In evaluating 174 patients who underwent distal-urethral sling procedure, Rodriguez found that objective outcomes and patient reported outcomes were similar after the surgery regardless VLPP [2]. Different conclusions were drawn by O'Connor who evaluated 43 patients with SUI and divided them into two VLPP categories based on preoperative study: VLPP > 60 and VLPP ≤ 60 [3]. He reported that when stratified for preoperative VLPP, 77% of patients with VLPP greater than 60 were cured while only 25% of patients with VLPP ≤ 60 were cured.

### Concluding message

The present data show that when patients were stratified for preoperative VLPP (≤ or > of 60 cmH<sub>2</sub>O) outcomes of mid-urethral sling procedure did not change whatever surgical procedure was chosen. Further studies remain, however, mandatory to confirm these data and to investigate other outcome independent variables.

### References

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**FUNDING:** NONE

**CLINICAL TRIAL REGISTRATION:** This clinical trial has not yet been registered in a public clinical trials registry.

**HUMAN SUBJECTS:** This study was approved by the Ethical Committee of the University of Perugia and followed the Declaration of Helsinki Informed consent was obtained from the patients.

