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EFFICACY AND SAFETY OF TVT-SECUR(IN THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE: A SYSTEMATIC REVIEW

Hypothesis / aims of study
To reduce the complication rate of trans-obturator tension-free vaginal tape, mainly represented by groin pain, the single-incision TVT-Secur™ device was first introduced in 2007. Since then a number of studies have been performed to verify if this minimally invasive device has the same efficacy of the standard retropubic TVT and trans-obturator TVT (TOT and TVT-O™) and if it offers a higher safety profile. Aim of this systematic review was to identify all articles reporting on the efficacy and/or safety of TVT-Secur™ for the surgical treatment of female urinary stress incontinence and to extract data to identify overall cure and success (patients cured plus patients improved) rates, to evaluate TVT-Secur safety and to verify if discrepancies exist between reports from peer-reviewed journals and abstracts presented at international congresses.

Study design, materials and methods
A prospective protocol implemented with recommendations from the Meta-Analysis of Observational Studies in Epidemiology group (MOOSE) (1) for this review was prepared *a priori*. All reports describing studies on the efficacy and/or safety of TVT-Secur™ device were obtained searching the Medline, MeSH, Science Direct, Web of Science databases, and Cochrane Database of Systematic Reviews from January 2006 to March 2011. The following keywords were used for the search as text words or subject headings without language restriction: "TVT-Secur", "TVT-S", "Secur", "Single-incision sling" and "Mini-sling". Furthermore, hand searches of the bibliographies and citation lists of all relevant studies to identify articles not captuered by electronic searches, as well as the proceedings of the International Urogynecological Association and International Continence Society of the last 3 years (2007-2008) were performed. Studies were included if they reported data on the efficacy and/or safety of the TVT-Secur device in the treatment of female urinary stress incontinence whichever their design study and if they included at least 20 patients. Two authors (G.A.T. and C.F.) independently scrutinized full papers of all citations that were likely to meet the predefined criteria. In cases of two or more publications from the same trial group, we selected the most recent and/or complete version, unless it was evident from the paper that the subjects included in two studies were different. The data extracted were input in an excel spreadsheet. These included publication type, number of procedures performed, follow-up time, number of subjects with isolated SUI or urge/detrusor overactivity symptoms, mean operative time, number of associated procedures, objective and subjective cure and success rates (cured+improved) with overall number of patients cured or improved, number and type of complications, number of patients with de novo urge symptoms, re-operation rate (both for failure and complications) and the number of procedure with the "U" or "hammock" approaches. We determined objective and subjective cure and improvement rates for the studies reporting these outcomes, as well as complication, de novo urge symptoms and re-operation rates. We also compared these rates between articles published on peer-reviewed journals and those presented as abstracts in peer-reviewed Congress Proceedings. Non parametric analysis (Mann-Whitney test) was used to compare median follow-up times, Student's t test for uncoupled samples to compare operative times, and χ^2 test to compare objective and subjective cure and success rates, complication, de novo symptoms, and re-operation rates. The 95% CI for cure and success rates were constructed using the exact binomial method (Clopper-Pearson).

Results
A total of 54 studies among 101 evaluated were included in the analysis. Twenty-three were published on peer-reviewed (P.R.) journals and 31 on proceedings of IUGA/ICS congresses. Thirty-five articles were prospective studies (14 on P.R. journals and 20 on congress abstracts), seven were randomized trials (5/4), 12 were retrospective studies (4/8) and 5 were also multicentric (2/3). A total of 4839 procedures were included in the analysis (1947 in studies from peer-reviewed journals and 2892 in studies from abstracts). Overall median follow-up was 12 months [95%CI 6.5-12.3], but studies from abstracts showed a significantly shorter follow-up in comparison with studies on P.R. journals ($p = .04$). Studies from abstracts also had a significantly higher number of subjects with mixed incontinence (42.5% vs. 24.1%, $p< .001$) and associated procedures (24.1% vs 14.2%, $p < .001$). Overall, 66.8% had pure urinary stress incontinence and 33.2% associated urge symptomatology. 19.2% of all women studies underwent an associated procedure. Overall objective and subjective cure rates were 74.5% and 82.6%, while objective and subjective success rates (cured+improved) were 80.8% and 81.4%. Differences between studies from P.R. journals and abstracts reached a statistical significance for both objective and subjective cure rates (76.5% vs. 73.2, $p = .02$ and 76.1% vs. 86.3%, $p = .001$). Overall complication and de novo urge symptoms rates were 9.3% and 7.1%, with studies from abstracts reporting a significantly lower complication and de novo symptoms rates in comparison with studies from P.R. journals (7.5% vs. 11.8 and 4.4% vs. 9.4%, $p < .01$). The most frequent complication was any kind of vaginal exposure of the sling in both abstract and P.R. journals studies (overall 15.2%, P.R. journals 15.9% and abstracts 14.3%). Bladder injuries and pain rates were 3.6% and 3.4%, respectively. Overall, re-operation rate, both for failure and/or complications, was 6.4%, significantly higher in the abstract group (8.3 vs. 5.4%, $p = .01$). The "hammock" approach was used in 72% of cases, with similar percentages between the studies from P.R. Journals (70.2%) and from abstracts (73.7%).

Interpretation of results
The results of this systematic review seems to indicate that TVT-Secur device objective cure rate does not reach 80%. If also improved patients were considered, TVT-Secur showed a satisfactory success rate. Subjective cure rate seems to be somewhat higher, probably reflecting the good acceptability of this procedure. TVT-Secur proved to be a safe procedure with complication rate lower that 10% and limited de novo symptoms and re-operation rate. Discrepancies between published

articles and studies from abstracts may be explained by selection bias, inclusion of the learning curve period, undefined or poorly defined objective cure definition and/or overestimation of subjective cure.

Concluding message

The data from this analysis seems to suggest that TVT-Secur may have lower cure rates in comparison with retropubic and trans-obturator devices, but has limited complication rate.

References

1. Stroup DF, Berlin JA, Morton SC, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting Meta-analysis of Observational Studies in Epidemiology (MOOSE) group. JAMA 2000; 283: 2008-12.

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?	**No**
This study did not require ethics committee approval because	**none required; systematic review**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**No**