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SURGICAL TREATMENT OF FEMALE STRESS URINARY INCONTINENCE WITH GYNECARE TVT SECUR™ SYSTEM – PRELIMINARY REPORT

Hypothesis / aims of study
Sling procedures were first introduced over 100 years ago in the treatment of stress urinary incontinence. Since then they have evolved to become less invasive and safer. The sling procedure with the use of Gynecare TVT Secur™ system is a new therapeutic option for women with stress urinary incontinence. Aim of the study was to evaluate the safety (intra- et postoperative complications) and early efficacy of TVT Secur™ in the surgical treatment of stress urinary incontinence in women.

Study design, materials and methods
TVT Secur system is a modification of the "classical" TVT device. TVT Secur device consists of 8 X 1.1cm monofilament polypropylene tape with a novel anchoring system. The curved stainless steel inserters and release wire are anatomically designed for both retropubic (the "U") and transobturator (obturator internus muscle and fascia - "Hammock") position. The TVT Secur is less invasive when compare to classical TVT, because it is a shorter sling (8cm), no exit points and minimal only damage to the tissues. The study comprised seventy consecutive female patients admitted to the gynaecological department, who had been qualified for surgical treatment of stress urinary incontinence on the basis of physical signs and symptoms and the findings of a urodynamic study. The procedure was performed with the use of Gynecare TVT Secur™ system with tape introduced in an "Hammock" or U-shape mode.

Results
Between October 2006 and February 2008, sling procedures with the use of Gynecare TVT Secur™ system were performed in 70 women with stress urinary incontinence. Their mean age of the patients was 55.9 (30-86) years, mean BMI 27.4 (20.2-43.8) kg/m^2. Sixty two implants were positioned in H-shape mode, eight in U-shape mode. Forty nine women (70,0%) were menopausal, only one woman currently takes hormonal replacement therapy. Thirteen (18.5%) patients previously had three or more natural deliveries, mean parity was 1,9. Eighteen (25,7%%) had a history of previous gynaecological surgery, including 6 patients with anterior or posterior vaginal wall reconstructive surgery, two had sling procedure - in one case it was complicated by the tape erosion, and the tape was removed. Twenty five procedures were performed under general anaesthesia and 45 under local anaesthesia (maximum 30 ml of 1% lidocaine), usually with good compliance. The mean duration of the surgery was 10,7 (4 - 44) minutes. Sixty two women underwent TVTS procedure alone, 8 women underwent additional procedures (2 conisation of cervix, 3 D&C, 3 pelvic floor repair procedure due to POP stage III). In one case unintended tape removal at the time of inserter removal was observed. It was possible to discharge 35 (50%) women from the hospital on the day of the surgery. Urine retention was observed only in 1 woman. In all cases operated, blood loss was less than 50ml. No other complications were recorded. Fifty seven (81%) patients became completely dry or greatly improved after surgery, but the longest observation time is only 17 months.

Interpretation of results:
The TVT-Secur system seems a promising evolution of the classical TVT (either retropubic or transobturator). This technique is safe, needs short time to perform, can be done easily in most of patients under local anaesthesia. Despite of a slight but clinically insignificant increase in blood loss, it seems to be less invasive than other techniques used so far. This technique can be use with only minimal risks of serious perioperative and postoperative complications. The surgical treatment of urinary incontinence with sling procedures using the TVT Secur™ system shows good immediate efficacy and safety comparable to previous sling techniques.

Concluding message: Considering the short duration, minimal invasiveness of the procedure and its good tolerability under local anaesthesia, the use of TVT Secur™ system in outpatient setting can be advocated. Further studies with longer follow-up are necessary to establish the long-term efficacy of the procedure.

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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 eithics committee approval because	**Retrospective study**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**