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OUTPATIENT OR INPATIENT: IS THERE AN IMPACT ON THE FUNCTIONAL RESULTS, COMPLICATION OF MIDURETHRAL SLING SURGERY FOR STRESS URINARY INCONTINENCE?

Hypothesis / aims of study
The aim of our study was to compare the long-term functional outcomes, the peri operative complication rate of midurethral sling surgery according the type of hospitalization (ambulatory versus conventional)

Study design, materials and methods
From January 2005 to December 2007, 154 patients have been recruited in fourteen centers (university hospitals and three general hospitals), and 149 were randomly assigned to either the TVT or the TVT-O procedure. The current study is a secondary analysis of this previous randomized trial. Among patients, 31 were outpatient (group 1) and 118 were inpatient (group 2). Inclusion criteria were as follows: isolated or mixed USI (according to the International Continence Society (ICS) classification), positive cough stress test (cough stress test was performed during cystometry in sitting position; volume 200 to 300 ml), and at least 18 years of age. Exclusion criteria were as follows: concomitant pelvic organ prolapse surgery, concomitant hysterectomy, previous incontinence surgery, pregnancy, anticoagulant therapy, higher than first stage urogenital prolapse (POP-Q ICS), and patient unable to understand the purpose of the trial. All participants underwent a standardized evaluation, which included a urogynecological history, pelvic organ prolapse quantification examination, a validated symptom questionnaire (Contilife) and a urodynamic evaluation. The presence of bladder outlet obstruction symptoms was identified during the interview by the presence of one or several altered emptying symptoms: hesitancy, slow or intermittent stream, and straining or feeling of incomplete emptying. Inpatients arrived the morning of the procedure and were admitted for one or more night following the surgery. Outpatients arrived the morning of the procedure and were discharged in the afternoon. The TVT-O (Johnson and Johnson, Ethicon, Gynecare) procedures were all performed using the vaginal approach, from inside to outside, as described by Jean de Leval. Retropubic TVT procedures were all performed using the vaginal approach, in accordance with the technique described by Ulmsten and the manufacturer (Johnson and Johnson, Ethicon, Gynecare). The method of anesthesia was left to the discretion each surgeon. Immediately after surgery, post-void residual urine volumes were measured by catheterization following spontaneous voiding. Post-operative pain was equally assessed at hospital discharge. Follow-up visits were at 1, 3 weeks and 6,12, 24 months postoperatively. At each visit, patients underwent an urogynecological examination and an exhaustive interview which included visual analog scales (VAS 0-100) for dysuria, urgenturia, urinary stress incontinence, post operative pain and satisfaction with the operation. Objective (negative stress test) and subjective (no referred leakage at interview, no use of protection) cure rates were recorded. The overall cure rate was defined as follows: no urine leakage and negative stress test. Follow-up examinations were performed in supine position (bladder full) by operating surgeons. All data were computed in a database and then analysed with SPSS (SPSS Inc., Chicago, IL, USA). Continuous data are presented as median and interquartile (IQR: 25th–75th percentile). Student's t-test and Pearson Chi-square test were carried out for quantitative variables and qualitative variables, respectively. $p<0.05$ was considered statistically significant.

Results
The characteristics of the patients were not significantly different between both groups. The maximum cloture urethral pressure (MUCP) was the same in both group with respectively 53 (36-72) cm H20 vs. 61 (50-69) cm d'H20 in the group 1 and 2, respectively (p=0.256). In the group 1 6.4% of the patient have a Qmax<15ml vs. 12.8 in the group 2, (p=0.551). In both group the prevalence of transobturator sling and retropubic slings were equivalent (p=0.966). In the group 1, 38.7% of the patient have mixed USI vs. 45.8% in the group 2, (p=0.677). The overall rate of per operative complications was equivalent in both groups: 1 in the group 1 vs. 12 in the group 2, (p=0.388). The median operative time was shorter in outpatients with 10 (9-20) minutes vs. 20 (15-25) in the group 1 and 2, respectively (p=0.003) Concerning the method of anesthesia, the general anesthesia cases were equivalent in both groups while there was more local anesthesia in the group 1 than in the group 2 (41.9% vs. 11%, p<0.005) and less loco regional spinal anesthesia in the group 1 (9.7% vs. 53.4%, p<0.005). Seven patients required intermittent catheterization or indwelling urinary catheter in the immediate post operative follow up in the group 2 vs. 1 in the group 1 (p=0.883). The post void residual seems to be not significantly higher in the group 2 than in the group 1 (60 ml (20-125) vs. 30 ml (14.5-58.5), p=0.054). Per operative complication were similar in both groups (3.2% (1/31) in the group 1 vs. 10.1% (12/118) in the group 2, p=0.39). One urethral injury was observed in the ambulatory group and 6 vaginal wound and 6 bladder wound were observed in the inpatient group. Each case of bladder or urethral injury was diagnosed during the per-operative cystoscopy. At 24 months follow-up, 1 patient of the group 1 and 5 in the ambulatory group had a vaginal sling exposure (p=0.86). The re-intervention rates were similar in both groups. No patient has been re-admitted in the ambulatory group. In both group, we observed an improvement of the question number 28 of the CONTILIFE questionnaire (which evaluated the global quality of life) between the pre operative consultation and the last evaluation (p<0.05). There was no difference between both groups for the question 28 of the CONTILIFE at the pre operative evaluation (p=0.932), at 6 months (p=0.906), at 12 months (p=0.542) and 24 months (0.322). At the 3 weeks follow-up visit, the VAS of satisfaction was equivalent in both groups (100(80-100) in the group 1 vs. 95(80-100) in the group 2, p=0.773). In contrast, the VAS satisfaction was higher in the group 1 than in the non ambulatory group at 12 and 24 months: 100(93.5-100) vs. 96.5(80-100), (p=0.003); 95(90-100) vs. 95(80-100), (p=0.0035), respectively. At 24 months follow-up, we

observed 88% (22/25) dry outpatients and 83.1% (89/107) dry inpatients, respectively (p=0.953). Only 3/107 (2.8%) inpatients reported a persistence of urinary leakage (p=0.953).

Interpretation of results

Mid-urethral sling (MUS) procedures are considered to be the first-line technique for the surgical management of urinary stress incontinence (USI) in women. This surgical approaches are minimally invasive and can be performed as a day-case procedure. Many studies have already evaluated the cost-effectiveness of these day surgeries and make these an attractive form of treatment to purchasers of healthcare. As an example, in Spain, Moreno et al found that the mean cost for MSU ambulatory surgery was 42.43% lower than for the hospitalized patient [1]. In this background, during the last decade, ambulatory procedures to treat USI have widely increased in the United States. Between 2001 and 2009 Suskind found that the rate of ambulatory MUS have increased significantly by fourfold [2]. Few studies have already evaluated the feasibility and functional results of the MUS outpatient procedure [3]. They concluded that the ambulatory management of MSU surgery is a safe procedure with good results for selected patient. To our best acknowledge, this is the first study which compared functional outcome, peri operative complication in function of the type hospitalisation. We observed that outpatient was not associated with higher complication rate and that none of these patients was re-admitted. Even if objective and subjective functional results are equivalent in both groups, satisfaction rate seemed to be better in outpatient group.

Concluding message

Objective and subjective functional long term results of midurethral sling are independent of the type of hospitalisation.

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Disclosures

Funding: none **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** This research was found to conform to the generally accepted scientific principles and ethical standards of medical research. This research was found to be in agreement with the laws and regulations of the country in which the research experiment was performed (comité de protection des personnes, CPP-Hôpital Cochin, Paris, France no. 2207/15-11-04). **Helsinki:** Yes **Informed Consent:** Yes