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BENEFIT-RISK OF MALE SLING. CONTINENCE VERSUS RETENTION IN THE I-STOP® TOMS® TRANSOBTURATOR MALE SLING, A MINIMALLY INVASIVE TREATMENT FOR POST-PROSTATECTOMY INCONTINENCE.

Hypothesis / aims of study
Minimally invasive techniques, such as slings, are becoming standard of care for the treatment of mild to moderate post-prostatectomy incontinence. However slings are applied with tension and may cause urinary retention or low stream after surgery.

Study design, materials and methods
A prospective multicenter study was conducted in 121 patients with post-prostatectomy SUI treated with the I-STOP TOMS® sling and followed for 1 year. Preoperative and post-operative evaluation included daily pad use, pad test, questionnaires evaluating continence and quality of life, adverse effects, subjective low stream, uroflowmetry and post-void residual urine. Statistical analysis were performed with Kruskal-Wallis test and Wilcoxonmatch paired test.

Results
Mean follow-up was 323.3 days. Mean daily pad use significantly decreased from 2.45 to 0.60 at last follow up; with 58% of patients completely dry, 17% needing 1-2 pads/day with improvement compared to baseline, and 11% using >2 pads/day with improvement compared to baseline. All quality-of-life scores (ICIQ-UI-SF and UCLA-PCI urinary function) improved significantly after sling implantation. Before surgery then at 1, 6 and 12 months, the mean rate concerning low stream was respectively 4%, 21%, 11%, 13%. Concerning Qmax (ml/s) it was respectively 23.2, 19.1, 20.7, 21.5 , and concerning post void residual (ml) it was 7.7, 13.3, 10.6, 10.5. Acute urinary retention (AUR) did not occur.

Interpretation of results

When comparing our results on complete continence rate, efficacy rates are comparable to most of the non adjustable male sling series that may vary from 50 to 60%. However the retention rate is lower than the 5 to 20% retention rate reported with other male sling . The bulbar position of the sling and the large surface of the sling could explained the favorable benefit-risk concerning continence-retention.

Concluding message
Up to 12 months, most patients were completely continent with the I-STOP TOMS male sling or had improved continence. The intervention had a minimal retention risk but 10 to 21 % patients reported during the follow-up period a subjective low stream.

References
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Specify source of funding or grant	**no funding**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**ClinicalTrials.gov under the trial registration number NCT00442078.**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Rouen CCPPRBH**

Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**