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Sacco E[1], Bientinesi R[1], Recupero S[1], Racioppi M[1], Pinto F[1], Gulino G[1], Palermo G[1], D'Agostino D[1], Bassi P[1]
1. *Urology Department, Gemelli Hospital, Catholic University Medical School of Rome*

EVALUATION OF SAFETY, TOLERABILITY AND EFFICACY OF TILOOP®, A TITANIZED INSIDE-OUT TRANSOBTURATORY SLING FOR MALE STRESS URINARY INCONTINENCE

Hypothesis / aims of study
To evaluate safety, tolerability and efficacy on urinary continence and quality-of-life of a new titanized sling for male post-surgical stress incontinence

Study design, materials and methods
Interventional single-armed prospective study. From 11/2012 to 12/2014, 25 patients with stress urinary incontinence after radical prostatectomy (21) or TURP (4) underwent transobturator sling implantation with the inside-out DeLeval technique [1]. The implanted sling was the TiLoop® (pfmmedical, Köln, Germany), a polypropylene mesh coated with titanium to improve biocompatibility, 40x1,5 cm in dimension.
Patients were assessed preoperatively and every three months after surgery with uroflowmetry, pads use/day, urodynamic study (pre-operatively), International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) and Patient-reported Global Impression of Improvement (PGI-I; score 1-7) and Satisfaction (yes/no).
The success was defined as no pad use, while a reduction of at least 50% of the number of pads has been considered as an improvement.
Complications and postoperative adverse effects have been prospectively collected.

Results
Final evaluation included 23 patients (92%), excluding two (previous radical prostatectomy) lost to follow-up. Preoperatively, 11 (48%) and 12 (52%) patients used two or three to five diapers, respectively. Two patients were previously treated with pelvic radiotherapy. After a median follow-up of 12 months (4-26 months), 14 (61%) patients were cured, 5 (22%) were improved and 4 (17%) reported no benefit (patients with use of 4-5 pads/day, two had radiotherapy). The mean ICIQ-SF score improved from 17.3 preoperatively to 7.6 postoperatively ($p < 0.01$), whereas the QoL score (question 5: "Overall, how much does leaking urine interfere with your everyday life?", score 0-10) improved from 8.8 to 3.2 ($p < 0.01$). At PGI-I, 19 (82.6%) patients reported an improvement and 17 (74%) patients were completely satisfied. The Qmax and the post-voiding residual volume were statistically unchanged postoperatively. There were no perioperative complications and no patient experienced urinary retention requiring catheterization. Ten (43.5%) patients reported mild perineal pain which resolved spontaneously within maximum 3 months.

Interpretation of results
These preliminary results on TiLoop® transobturatory sling are satisfactory and consistent with those reported in literature for similar fixed male sling. The inside-out technique is safe and well tolerated. Failure has been associated with severe incontinence or previous pelvic radiotherapy suggesting that patient selection may further improve these results.

Concluding message
The TiLoop® sling appears effective and safe in patients with mild to moderate postprostatectomy incontinence, although prospective long-term and larger studies are needed to confirm these results and to prove the supposed better tolerability of titanized slings.

References
1. De Leval J, Waltregny D. The Inside-Out Trans-Obturator Sling: A Novel Surgical Technique for the Treatment of Male Urinary Incontinence . Eur Urol 54 (2008) 1051–1065.

Disclosures
Funding: none **Clinical Trial:** No **Subjects:** HUMAN **Ethics not Req'd:** The methods were the routine at our institute. **Helsinki:** Yes **Informed Consent:** Yes