ALTIS SINGLE-INCISION SLING: ONE YEAR EFFICACY AND SAFETY

Hypothesis / aims of study
The aim of the surgical treatment of female urinary stress incontinence is to achieve higher success rates with the least number of prosthetic material and minimizing complications. The purpose of our work was to analyze the success rates and safety profile of a single-incision sling (ALTIS® (Coloplast)) for the treatment of female urinary stress incontinence.

Study design, materials and methods
A prospective, observational, single-center study in a cohort of patients undergoing stress urinary incontinence surgery using single-incision sling ALTIS® (Coloplast) was design. All patients underwent urodynamic study prior to surgery. Follow up was carried out with clinical history, validated version in Spanish of the ICIQ-SF questionnaire (International Consultation on Incontinence Questionnaire Short Form), visual scale of satisfaction and physical examination at 1,6 and 12 months. Success was defined as ICIQ-SF=0. Complications were categorized according to Clavien-Dindo classification.

Results
A total of 47 patients were treated between January 2013 and December 2015. The mean age was 63.43 years (S.D. 10.89) with a BMI of 28.43 Kg/m² (S.D. 4.23). 75% of the patients presented two vaginal deliveries or more. The urodynamic study showed mixed urinary incontinence with predominant stress incontinence in 20 patients (42.56%). Categorized Valsalva leak point pressure (VLPP) was <60cmH2O in 2 patients (4.3%), 60-90cmH2O in 9 patients (19.1%) and >90cmH2O in the rest (76.6%). Mean follow-up time was 10.41 months (S.D. 6.78) with a mean satisfaction score of 9.57 points (S.D. 0.72). The subjective cure according to ICIQ-SF at the end of the follow-up was the 93.6%. There was no difference in cure rates or mean satisfaction score in obese patients versus non-obese (p=0.56 and p=0.72 respectively) or in patients with greater or less than 90 VLPP (p=0.81 and p=0.32 respectively). A total of 10 patients (21.27%) presented some type of complication type Clavien I (four (8.51%) patients presented groin pain self-limited and 6 patients (12.76%) voiding dysfunction, 3 of them with postoperative acute urinary retention resolved with 3 days of catheterization). No patient showed extrusion. No urge urinary incontinence de novo was found, in fact two patients (10%), improved from urge urinary incontinence.

Interpretation of results
The emergence of the single-incision slings are an theoretical opportunity to decrease risks in prosthetic vaginal female stress urinary incontinence surgery. The ALTIS® sling (Coloplast) was not included in the main meta-analysis (1, 2) published where the evidence on the effectiveness of the mini-slings is controversial. Our series provides data on efficacy and safety similar to those offered by the transobturator slings (3).

Concluding message
According to our results, the single-incision sling ALTIS® (Coloplast) provides high rates of cure and satisfaction of patients regardless of BMI or VLPP with an acceptable safety profile for one year of follow-up.

References

Disclosures
Funding: NONE Clinical Trial: No Subjects: HUMAN Ethics not Req’d: It was not a random study and the mesh employed has already passed all human test before and it is of common use Helsinki: Yes Informed Consent: Yes