

## EVALUATION OF THE EFFICACY AND SAFETY OF THE AJUST SLING PROCEDURE IN THE MANAGEMENT OF FEMALE URODYNAMIC STRESS URINARY INCONTINENCE PERFORMED UNDER LOCAL VERSUS EPIDURAL ANESTHESIA

### Hypothesis / aims of study

Ajust sling (C.R Bard, Inc., Murray Hill) belongs to a new category of single-incision mini-slings for the surgical treatment of female urodynamic stress urinary incontinence that are directly inserted into the obturator internus muscle with a minimally invasive technique, in an ambulatory setting. The aim of this study was to assess the efficacy and safety of the Ajust sling procedure performed under local versus epidural anesthesia.

### Study design, materials and methods

All medical records of patients diagnosed with urodynamic stress urinary incontinence who underwent surgical treatment with Ajust adjustable single incision sling procedure between November 2008 and December 2011 were examined in this retrospective clinical study. The patients were divided in two study groups according to the type of anesthesia they received during the operation: Group L was subjected to the Ajust sling procedure under local anesthesia, using 15 ml of lidocaine 2% with 1:200.000 epinephrine, performed by the surgeon, while Group E underwent the same procedure receiving epidural anesthesia with 12 ml of 0.75% ropivacaine plus 100µg fentanyl. Subjective and objective cure, improvement and failure rate, mean operative time, intraoperative and postoperative pain scores and side effects, postoperative analgesic requirements and hospital stay were examined. Exclusion criteria were: previous surgical procedures in the anterior vaginal wall, recurrent stress urinary incontinence or cases of failed epidural block that led to general anesthesia. Descriptive statistic included the mean and standard deviation for continuous variables with parametric distribution, the median and range for continuous variables with nonparametric distribution and the frequency for categorical variables. One-way analysis of variance (ANOVA) was used to compare the mean values of continuous parametric variables among groups. The ANOVA test for repeated measures was used to calculate differences in the VAS pain score scale. P values <0.05 were considered statistically significant.

### Results

Totally, 167 women were included in the study. In 86 cases the Ajust sling placement was performed under local anesthesia, while in the rest 81 cases under epidural anesthesia. In all patients the urodynamic study performed preoperatively, after patients' medical interview and clinical examination, was diagnostic of urodynamic stress urinary incontinence. There were no statistically significant differences in patients' basic characteristics (age, body mass index, parity, menopausal status), mean operative time and hospital stay between the two groups. No severe intraoperative complications occurred. No patient had urinary tract injury or required blood transfusion. Analysis of the VAS results in the two groups showed that pain decreased significantly from the first hour after surgery ( $P < 0.01$ ). No significant differences between the two groups were observed in intraoperative pain scores. Postoperative analgesic requirements were similar in both groups and only minor intraoperative side effects were recorded 7 patients of group E, including nausea ( $n=4$ , 4.9%) and hypotension ( $n=3$ , 3.7%). No postoperative urinary retention was diagnosed in any patient. Postoperative incomplete bladder emptying (residual urine >100ml) was reported in 5 patients (5.8%) of group L and 4 patients (4.9%) of group E. 10 patients (12.3%) of group E and 8 patients of group L (9.3%) complained for early postoperative symptoms of frequency and urgency. Rejection of the tape did not occur in any patient. The objective, subjective rate and improvement rates were not statistically different between the two groups.

### Interpretation of results

The Ajust sling procedure can be safely and effectively performed both under local and epidural anesthesia. Spontaneous voiding, analgesic requirements, patient satisfaction as estimated by the VAS scoring scale and surgical complications were not statistically different between the two groups, suggesting that local anesthesia was successful and comparable to epidural anesthesia for the treatment of urodynamic stress incontinence with the Ajust sling procedure.

### Concluding message

The efficacy and safety of the Ajust sling procedure under local anesthesia is comparable to the efficacy and safety of the operation performed under epidural anesthesia.

### Disclosures

**Funding:** none **Clinical Trial:** No **Subjects:** HUMAN **Ethics Committee:** Aretaieion Hospital Ethics Committee **Helsinki:** Yes **Informed Consent:** Yes