782

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AJUST™: RESULTS FROM OUR PROSPECTIVE STUDY

Hypothesis / aims of study

Mini-slings are a third generation of sub-urethral slings in the treatment of female stress urinary incontinence, innovative by their shorter length and use of a single vaginal incision. The aim is to reduce the morbidity of the procedure by avoiding the retropubic and trans-obturator approach, while maintaining their efficacy.

The Ajust™ is one of these new mini-slings. It provides support to mid-urethra by means of a short polypropylene tape of 4,5 cm length. It differs from other mini-slings by the fact that it is adjustable. It is anchored to the obturator membrane through the obturator internus muscle with the help of a special designed introducer and two polypropylene anchors, one fixed and the other mobile. This allows the tape to be adjusted in a tension free way and to adapt to the inter-obturatory distance without folds or stretches, in what could be considered an advantage over the previous designed tapes.

Our aim is to present our experience with this procedure and clinical outcomes in terms of continence rates and complications after 6 months of follow-up.

Study design, materials and methods

A prospective study was done, and women with stress or mixed urinary incontinence were included. All women were submitted to surgical treatment with Ajust™ after informed consent. Preoperative work-up included clinical history with symptom impact evaluation by means of the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) and pads per day (PPD), physical examination with cough-test, and urodynamic evaluation (free flow uroflowmetry, cystometry, pressure/flow curve and abdominal leak point pressure (ALPP) measurement). The procedure was performed by two experienced surgeons under spinal anaesthesia. Operative time, peri-operative complications and hospital stay were prospectively recorded. Patients were evaluated at one and six months post-operatively, and persistent complications assessed. At the sixth month, the ICIQ-SF score was performed, as well as physical examination with cough-test and assessment of de novo appearance of lower urinary tract or sexual symptoms. Cure was defined as an ICIQ-SF score of 0 (zero), no need to use daily pads and negative cough-test. Statistical analysis was done using SPSS 17.0. Descriptive statistics includes mean±standard deviation. Student's T test for paired samples was used to compare continuous variables pre-operatively and at the sixth month. Differences between independent groups were analysed by Mann-Whitney test. Statistical significance was considered with *P* values <0.05 (two-tailed).

Results

Between January and September of 2009, 49 women were included in the study. Preoperative characteristics are shown on table 1. Mean operative time was 15,4±7 min and additional procedures were an anterior colpoperineoplasty in 2 patients. No intra-operative complications occurred. Bladder catheter was removed at the first post-operative day. Peri-operative complications were noticed in 7 patients (14.2%). Three women had vaginal bleeding treated with conservative measures and 4 had urinary retention solved by 2 to 3 days with a bladder catheter (except in one case that had to perform intermittent catheterization for 3 months). Mean hospital stay was 1.2 days.

At the first month 79.6% (n=39) of patients were cured. Seven patients (14.3%) maintained stress urinary incontinence (SUI) and 3 (6.1%) urgency incontinence (UUI). One patient (2%) had temporary perineal pain and another one (2%) developed de novo voiding symptoms. De novo urgency was noticed in 2 patients (4%). There were no sexual complaints.

At six months, 75.5% (n=37) of patients were cured, 10.2% (n=5) were improved and 14.3% (n=7) had treatment failure. The overall reduction on the ICIQ-SF score was from 15,6±2,9 to 4.2±5.8 (*P* < 0.001) and in relation to the number of PPD it decreased from 2,7±1,4 to 0.4±0.9 (*P* <0.001). Of those who remained incontinent (24.5%, 12 patients), 7 had SUI and 5 UUI. No significant differences were found on the pre-operative ALPP between women cured or not (Median= 96 vs 100 cm H2O, *P*=0.66). De novo urgency was found in 9 patients (18.3%), 4 of which had associated incontinence. Only 5 women with previous MUI maintained urgency. One patient referred voiding symptoms. No sexual symptoms were mentioned.

Interpretation of results

The Ajust™ appears to be an effective option in the treatment of SUI, with minimal intra and peri-operative morbidity profile. We emphasize the absence of sexual complaints and minimal occurrence of voiding symptoms and urinary retention. These findings comply with one the main goals of this new tape, which is avoiding mid-urethral overtension by its adjustability, thus preventing urinary retention and obstructive symptoms. De novo urgency was the most noticed complaint with an acceptable incidence. One the other hand, more than half of women with previous mixed urinary incontinence had their urgency problems solved.

Concluding message

The Ajust™ mini-sling shows promising results in terms of continence rates and morbidity. Its adjustability is an interesting characteristic which seems to work well in the prevention of obstructive complaints. To our knowledge this is one of the first reported series about the clinical outcomes of this procedure, reason why we think that larger randomized series are necessary to confirm these results.

N	49

Age (years)	58.5±11.1
BMI (Kg/m^2)	22.3±4.9
Parity	2.73±1.5
Menopause	38 (79.2%)
Previous hormonal treatment	3 (6.3%)
Hysterectomy	13 (26.5%)
Previous treatments: - Biofeedback - TOT - Colpossuspension	 28 (59.6%) 1 (2%) 2 (4%)
ICIQ-SF	15.6±2.9
Q max (ml/s)	24.2±12
ALPP (cm/H20)	91.1±26.8
PPD	2.7±1.4
OAB (dry/wet)	13 (2/11)

Table 1: Preoperative characteristics. Data are expressed as number of patients and percentage or mean with standard deviation.
BMI: Body Mass Index; PPD: Pads Per Day; TOT: Trans-Obturator Tape; OAB: Overactive Bladder

Specify source of funding or grant	**None**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**No**
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	**Ethics Comittee of Centro Hospitalar do Porto**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**