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A MULTICENTER PROSPECTIVE TRIAL ON THE AJUST: A NEW SINGLE INCISION SLING FOR THE TREATMENT OF FEMALE STRESS URINARY INCONTINENCE

Hypothesis / aims of study

The Ajust system is a new single incision sling that looks different from other marketed minimally invasive slings as the tape is secured into the obturator membrane and not into the obturator internus muscle and it is provided with a unique adjustability mechanism allowing the surgeon to set optimal sling tension. The aim of the present study was to evaluate the efficacy and morbidity of the Ajust system in the treatment of primary stress urinary incontinence.

Study design, materials and methods

The study design was a prospective multi-centre trial involving five different hospitals. All patients with primary urodynamic stress urinary incontinence (SUI) and urethral hypermobility were prospectively selected to receive the Ajust sling procedure.
Exclusion criteria from the study were: previous anti-incontinence surgery, pelvic organ prolapse requiring treatment, any coexistent pelvic pathology, urethral hypomobility (Δ Q-tip $\leq$ 20°) and detrusor overactivity. The primary outcome measure was objective & subjective cure of SUI and **t**he secondary outcome measures were intra-and post-operative complications, post-operative pain, long-term complications (including further procedure needed), and patient satisfaction.
The pre- and postoperative protocol included the following: a detailed urogynecologic history, a physical examination, a cotton swab test, a stress test in the supine and standing positions with a comfortably filled bladder (300 ml) and a multichannel urodynamic evaluation. The ICI-SF, W-IPSS, PGI-S questionnaires were used to evaluate the impact of incontinence and voiding dysfunction on QoL and to measure patient's perception of incontinence severity.
The post-operative evaluation included collection of data regarding intra- and postoperative complications, pain assessment by means of a 0-10 validated numerical rating scale (NRS) given to patients at 5 hours postoperatively, and analysis of outcomes. The outcome of surgical treatment was estimated both subjectively and objectively using the same tools as before surgery and the PGI-I questionnaire was added to assess the subjective perception of improvement . Objective cure was defined as no leakage of urine while coughing during the post-operative stress test. Subjective cure was defined as no urine loss during exertion and failure as any reported leakage of urine during 'stress'. All patients were informed about the study and procedure and gave their informed consent. The Statistical Package fo Social Sciences was used for data analysis. Continuous data were reported as means $\pm$ standard deviation (SD)and analyzed with Student's t test. Categorical relationships were analyzed by the χ^2 test with Yates' correction or Fisher exact test, as appropriate. Probability values of < 0.05 were considered statistically significant. With the aim to include 100 patient in the final analysis of outcomes and assuming a 10% drop-out rate during the study period we sought to enrol 110 patients in the trial. Follow-up visits were scheduled after 3, 6, and 12, months from surgery.

Results

From January 2009 and October 2009, 111 consecutive patients with primary stress urinary incontinence and urethral hypermobility were enrolled in the study. Baseline characteristics of the patients are shown in table 1.
Most procedures were performed as day case surgery under light general anaesthesia with i.v. Propofol. No intraoperative complications occurred except for some initial technical difficulty with the fixation of the adjusting anchor on the left side of the patient that required the insertion of a new tape in four women. There were five women with voiding difficulty that resolved spontaneously within the first five days from surgery and one who had urinary retention that required section of the tape after 9 days. The median value for the NRS was 1 (range 0-9) with 24 (22%) women receiving analgesic for pain relief, two of them reported pain at discharge. The average hospital stay was 1 $\pm$ 0.6 days (range 1-5).
One hundred-five women were available for an interim analysis, of whom 79 completed the six months follow-up visit. The last follow-up visit carried forward was used for data analysis. Six women drop-out from the study within the first three months for different reasons: one had a different device inserted at the time of operation for technical difficulty, one had a TOT for persisting incontinence one month later and she was considered among failures, one had a vertebral fracture and did not come to follow-up and three were lost for the inability to contact them recalling the scheduled visit. One more patient was lost at six months for persisting incontinence. Subjectively 90 (85.7%) women were cured by the procedure and objectively the cough stress test was negative in 96 (89.5 %) patients. When considering objective and subjective results together, 87 women (83%) were considered cured by the procedure. The ICI-SF questionnaire symptoms score showed an higly statistical decrease from a mean of 14 $\pm$ 3.3 before surgery to a mean of 3.2 $\pm$ 4.6 at the last follow-up visit forwarded (p=0.000), the W-IPSS decreased from 10 $\pm$ 7.7 to 4.5 $\pm$ 5.2 (p=0.002). Most of the women were satisfied of their post-operative condition with a mean score of 1.5 $\pm$ 0.9 at the PGI-I questionnaire (scale 1-7). Postoperative complications included: voiding difficulty in 4 women (3.8%), recurrent UTI in 8 (7.6%) and dyspareunia for anchor detachment in one patient. Four patients received a new surgery for stress incontinence and one for pelvic organ prolapse within the first 6 months of follow-up. Analysing patients that were considered failures both subjectively and objectively, 8 women reported a score of 1 or 2 at the PGI-I questionnaire (*very much better or much better*) and therefore the rate of cure/improvement can be considered as high as 90.5%

Interpretation of results

Our data show that the Ajust system is effective and safe for the treatment of primary stress urinary incontinence with 86% and 89.5% subjective and objective cure rates associated with an highly significant improvement in incontinence related QoL.

Postoperative pain was in general low with only 22% of women requiring analgesic for pain relief. Most patient were satisfied with the results with a mean PGI-I score of 1.5 at three and six months from surgery.

Concluding message

The Ajust system ia a new promising tool for the treatment of primary stress urinary incontinence.

Table I. Baseline characteristics of 111patients enrolled in the study

Age, y	56 ± 11 (36-79)
Parity, median (range)	2 (0-5)
BMI (kg/h^2)	26 ± 4
Menopausal, n (%)	74 (66%)
Patients with OAB symptoms (n)	30 (27%)
Straining Q-tip angle (∆°)	48 ± 15
ICIQ-SF	14 ± 3.3
PGI-S	2.1 ± 0.9
W-IPSS	10.3 ± 7.7

Specify source of funding or grant	**No disclosure**
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	**Azienda Ospedaliera Ospedale Civile di Legnano**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**