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CURE OF WOMEN STRESS URINARY INCONTINENCE WITH THE AJUST SINGLE INCISION SLING: ONE YEAR RESULTS.

Hypothesis / aims of study: Ajust single incision sling for women stress urinary incontinence is a newly described mini-invasive device. However, no results over one year follow-up has been published. Our goal was to prospectively assess the efficacy of Ajust sling with a minimum follow-up of one year.

Study design, materials and methods: From November 2008 to February 2010, patients with SUI or mixed urinary incontinence with predominant SUI were implanted with the Ajust adjustable single incision sling (Bard Urological Division, Covington, GA, USA) in one tertiary reference center. Age, medical history, clinical examination with cough test, TVT and Bonney tests, urodynamics were assessed preoperatively. 97 consecutive patients (mean age 56.7±12 [35-87]) were included in this prospective evaluation. 36 /97 patients had preoperative overactive bladder (OAB) symptoms managed by anticholinergics. No patient had associated pelvic organ prolapse. All had urethral hypermobility and had positive stress test at clinical examination. Twelve patients had maximal urethral closure pressure (MUCP) inferior than 30cm H20. 94 patients were managed on an outpatient basis (local anesthesia), and three patients were hospitalized for 24 hours (general anesthesia). The following efficacy parameters were assessed 1, 6, 12 months and then yearly after surgery: pad usage, clinical examination including a stress test to evaluate SUI, validated patient global impression of improvement (PGI-I) scale, bladder diary, and adverse events. The primary endpoint was focused on efficacy based on the following definition: patients were classified as cured for SUI when wearing no pads, having no stress-related leakage and presenting a PGI-I score of one or two, and as failure otherwise. Durability of the results was assessed through a Kaplan-Meier analysis.

Results: Mean operating time was 14,9 minutes ± 0,6 [10-15]. Blood loss was minimal for all patients. Fifty percent of patients having undergone only the sling procedure did not take any oral medication at home after surgery, and other only used acetaminophen. One patient developed a postoperative vaginal bleeding that was managed surgically eight hours after surgery. One patient presented acute urinary retention after removal of her urinary catheter, necessitating 24 hours of catheterization. No organ perforation or injury occurred.
Mean follow-up was 16±5 months [12-26]. Data showed that 85/97 patients (86%) used no pads, were fully satisfied of the procedure (one or two on PGI-I scale), and had no leakage at last follow-up. These results were durable as shown in figure 1 representing the rate of patients cured during follow-up (months). Pad usage was significantly reduced ($p<0.0001$). Five patients presented with de novo urgency, and did respond to trospium chloride treatment. One patient died one year after the procedure, from a cervical cancer, not known at the time of surgery. One case of lateral erosion the sling was noted at 6 months follow-up. Two patients experienced mild pelvic pain during three months that spontaneously resolved. One patients had mild sensation of dysuria at last follow-up (with normal outflow), and three patients had urinary tract infection treated by antibiotics.

Interpretation of results: Single incision slings may be useful to avoid conventional slings secondary effect because of a reduced rate of complications. The efficacy of this device in our series is comparable to the only published paper [1]. In our series, 12 cases of failure were assessed. One patient was still unsatisfied, although using no pads at last follow-up, 4 patients were those with the lowest maximal urethral closure pressure (under 30 cm H_20), 3 patients were those using more than 6 pads per day and 4 patients failed with no obvious reason. The strength of our study is its prospective design and the long follow-up of patients. However, it is not randomized but should provide critical data , useful to clinicians who should put these data in perspective with their clinical practice.

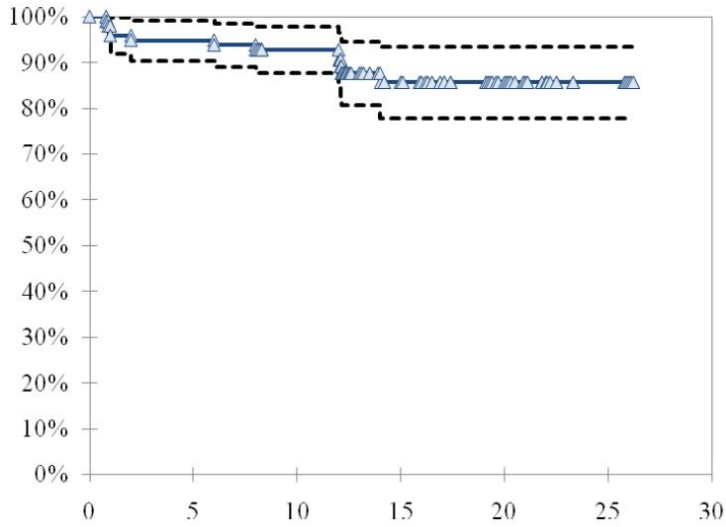

Figure 1: Recurrence of pad-use or leakage during follow-up

Concluding message: Our initial experience using the Ajust single incision sling system for SUI in women shows that this new technique is safe, time efficient, reproducible and associated with limited adverse events. It is easily performed in an outpatient basis and therefore should be cost effective. As a first line treatment, durable results are obtained one year after surgery with a success rate of 85%. These results are in favor of a real clinical advantage of this new device, but have to be confirmed in large, controlled and comparative studies with longer follow-up.

References

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Was informed consent obtained from the patients?	**Yes**