775

Lucente V[1], Cornu J[2], Sèbe P[2], Peyrat L[2], Ciofu C[2], Haab F[2]
1. *Institute for Female Pelvic Medicine,* ***2.*** *Department of Urology, Tenon Hospital, Groupe Hospitalo-Universitaire EST, Assistance Publique-Hôpitaux de Paris (AP-HP), University Paris VI*

AJUST SINGLE INCISION TRANSOBTURATOR SLING PROCEDURE FOR STRESS URINARY INCONTINENCE IN WOMEN: ONE YEAR RESULTS.

Hypothesis / aims of study

Suburethral slings are widely used for management of stress urinary incontinence associated to urethral hypermobility, with a high success rate and few complications. Since 2006, a so-called third generation of mid-urethral slings have appeared, avoiding exit skin incisions to pull through and "tension" the sling.These single incision push-in "mini-sling" devices demonstrated a decrease in postoperative related discomfort, yet have shown somewhat controversial if not disappointing results over time compared to other three incision retropubic or transobturator tension-free techniques [REF].To our knowledge, no prior publication has reported on the use of Ajust™, a new single-incision transobturator mid-urethral sling. Our goal was to describe the surgical technique and detail our initial experience with this new device.

Study design, materials and methods

From November 2008 to September 2009, 43 patients who presented with SUI were evaluated for consideration of undergoing the Ajust™ procedure. A prospective observational evaluation was conducted, with NO NEED of formal ethical approvement. The following data were preoperatively collected: age, complete medical history, results of clinical examination with cough test, TVT and Bonney test, preoperative urodynamics (with maximal urethral closure pressure, cystomanometry, and Q_{max}). Overall, 23 out of 43 patients presented clinically with mixed incontinence with overactive bladder syndrome, six of them had objective detrusor overactivity (DO) and were treated by anticholinergic drugs. No patient had pelvic organ prolapse greater than stage 1 in the pelvic organ prolapsed–quantification (POP-Q) classification, and all presented with urethral hypermobility. Four patients were considered to have intrinsic sphincter deficiency based on a urethral closure pressure less than 30cm H_20. All patients did appropriate pelvic floor muscle exercises that failed to improve symptoms.

40 patients were managed on an outpatient basis, received the sling under local anesthesia, and were discharged without a catheter on the day of surgery. Three patients were hospitalized for 24 hours and operated under general anesthesia with 24 hours catheterization.

The Ajust system consists of an introducer, a flexible stylet, and the sling implant with a fixed anchor and an adjustable anchor. After local infiltration, a 1.5 cm incision is made at the midurethral level on the anterior vaginal wall, and a horizontal tunnel is created up to the bonny edge of the inferior pubic ramus. The device is then inserted horizontally towards the cephalad margin of the inferior pubic ramus, and into the obturator internus muscle. This is achieved with a straight "push" provided by the surgeons thumb on the heal of the introducer, while the index finger remains within the vagina guiding the direction of passage. Once the fixed anchor passes the inferior ramus, the surgeon must pause from the original push while pivoting the introducer handle pass the midline, then resume a second straight push maneuver to place the anchor completely through the obturator muscle and membrane. The midline indicator must be deviated past the midline toward the fixed anchor side to confirm proper depth of placement. The fixed anchor is then released and traction is applied to the sub-urethral portion of the sling to confirm proper placement. The adjustable anchor is then loaded into the introducer and the steps are repeated on the opposite side. Once the adjustable anchor is correctly placed, the adjustment tab and tubular mesh is then pulled until the surgeon achieves the desired "set-point" of the sub-urethral sling. Once optimal setting has been achieved, the flexible stylet is used to advance the sling lock into the adjustable anchor, locking it in place. The system is designed to permit tension adjustability after the sling implantation. That is to say, adjustment does not involve further insertion of the device. The vaginal incision is then closed with re-absorbable suture.

Perioperative data collected included: duration of the procedure, blood loss, duration of catheterization, day of discharge, estimation of post-operative pain by visual pain scale. Immediate complications were assessed including: infection, bleeding and hematoma formation, acute urinary retention. Follow-up occurred during office visits 1, 3, 6 and 12 months after surgery with evaluation of pad usage, side effects possibly related to the procedure, clinical examination including a stress test to evaluate SUI, validated patient global impression of improvement (PGI-I) scale and a bladder diary.

The evaluation was based on tolerance, with assessment of post-operative side effects needing subsequent rehospitalisation. Secondary endpoints included other adverse events, and efficacy data. Efficacy was subjectively assessed with the PGI-I scale, by pad usage, reports of SUI episodes on a bladder diary and stress test at clinical examination. Patients were defined as cured for SUI when wearing no pads, having no stress-related leakage and presenting a PGI-I score of one or two. Otherwise patients were classified as failure. Quantitative values were compared with the Mann-Whitney test. We evaluated the durability of the results by assessing a Kaplan-Meier analysis about the recurrence of pad use or SUI episode on bladder diary during the follow-up period.

Results

None of the 43 patients were lost to follow-up. Forty patients were managed on an outpatient basis and three patients were hospitalized for 24 hours. The mean operating time was 14,9 ± 0,6 [10-15] minutes. Blood loss during surgery was minimal for all patients. All patients described their post-operative pain as under 5/10 on visual pain scale. 52% of patients did not take any oral medication at home after surgery. For the remaining 48%, only oral medication for pain was utilized being acetaminophen in all cases.One patient developed a postoperative vaginal bleeding that was managed surgically 8 hours after surgery. One patient presented acute urinary retention after removal of her urinary catheter. This patient was discharged with a catheter at home that was removed at day one, without any further complication. No organ perforation or injury occurred.

The mean post-operative follow-up was 8,4±3 [4-14] months. Evaluation of efficacy show that 39 patients (91%) wear no pads, are fully satisfied of the procedure (one or two on PGI-I scale), and did not report experiencing SUI episodes during normal activity at the time of last follow-up. In all these 39 patients, a stress test during clinical examination did not reveal any urinary

incontinence. These results were durable, with no degradation over time as shown in figure 1. Pad usage was significantly reduced ($p<0.0001$). Six patients presenting with OAB symptoms before surgery were still experiencing urgency during follow-up, although they were effectively managed by anticholinergics. One patient presented with *de novo* urgency, and did respond to trospium chloride treatment. One patient died 1 year after the procedure, from a cervical cancer, not known at the time of surgery.

No patient developed any severe complication such as urinary retention, infection or erosion of the sling. Two patients experienced mild pelvic pain, during three weeks and one month respectively, that spontaneously resolved. Three patients had mild sensation of dysuria; two patients had urinary tract infection treated by antibiotics.

Interpretation of results

Overall, 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 and mild complications or adverse events. It is easily performed in an outpatient basis and therefore should be cost effective. In selected cases and as a first line treatment, durable results are obtained one year after surgery with a success rate of 91%. These preliminary 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. Some limitations certainly apply to this study. First, these results have to be considered as preliminary because of the limited follow-up. Secondly, the patient's characteristics in our series are homogeneous. Only one patient had undergone a previous surgery for SUI and no patient had significant pelvic organ prolapse which is commonly associated to SUI. Furthermore, all patients had pure SUI or mixed incontinence with only four patients presenting mild ISD. Thus the results presented here from these selected cases, may carry limited external validity when extrapolated to larger more heterogeneous populations.

Concluding message

The Ajust™ sling is a minimally-invasive, safe and effective procedure for SUI management in women. However, larger trials are required to definitively establish efficacy of this new device.

References

1. 1. Neuman M. Perioperative complications and early follow-up with 100 TVT-SECUR procedures. J Minim Invasive Gynecol 2008;15:480-4
2. 2. Debodinance P et al. TVT Secur: prospective study and follow up at 1 year about 154 patients. J Gynecol Obstet Biol Reprod (Paris) 2009;38: 299-303
3. 3. Basu M, Duckett J. A randomised trial of a retropubic tension-free vaginal tape versus a mini-sling for stress incontinence. BJOG 2010 Feb 22

Specify source of funding or grant	**none**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require ethics committee approval because	**A prospective observational evaluation was conducted, with NO NEED of formal ethical approvement**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**