

SHORT TERM OUTCOMES OF ALTIS® SINGLE-INCISION SLING PROCEDURE FOR STRESS URINARY INCONTINENCE IN AN AMBULATORY SETTING

Hypothesis / aims of study

Available data on Altis® (Coloplast), a new adjustable single-incision sling procedure for the treatment of female stress urinary incontinence (SUI) remain scarce. The aim of our study was to evaluate the effectiveness and safety of this procedure and to identify predictors of treatment failure.

Study design, materials and methods

In a single centre prospective observational study, a total of 112 women with clinical SUI (confirmed with urodynamic study in 93.8% of patients) were implanted with Altis® sling between April 2012 and December 2013. Surgeries were carried out in an ambulatory setting, using a combined anaesthesia protocol of sedoanalgesia and local anaesthesia.

Patients were excluded if they had pelvic organ prolapse stage >2 (POP Quantification classification), previous failed sling surgery, predominant overactive bladder (OAB) symptoms, any coexistent neurologic disease, or were to undergo a concomitant surgery.

Before and after intervention (at 3, 6 and 12 months), women completed the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF). In addition, patients underwent a cough stress test at each evaluation and a post-voiding residual urine volume estimation at 3 months follow up.

The main outcomes measured were: subjective cure (ICIQ-SF=0), subjective improvement (ICIQ-SF >0 and < preoperative ICIQ-SF) and objective cure (negative cough stress test and no pad usage, excluding a dry security pad or pad usage for vaginal discharge) rates. Secondly, *de novo* OAB symptoms, changes on voiding habits and adverse events were also analyzed.

Odds ratios (ORs), adjusted in a multivariable logistic regression model (to age, body mass index (BMI), presence of cystocele [grade 1-2], menopausal status and number of used pads per day before intervention) were calculated to identify predictors of treatment failure.

Results

The mean age of the cohort was 53.1±10.8 years old, the mean BMI of 28.0±4.6 Kg/m², with a median pad usage of 2 and a mean pre-intervention ICIQ-SF score of 14.0±2.8. 51.9% of patients were menopausal and 47.3% had concomitant OAB symptoms. Urodynamic data showed intrinsic sphincter deficiency in 25.3% and detrusor overactivity in 20.2%.

71.4% of patients attended the three follow-up consultations, with 20.5% and 8.0% of patients only completing the 6 and 3 months' follow-up, respectively. The subjective cure rate was 82.1%, with an additional subjective improvement rate of 13.4% (an average reduction of 9.5 ± 3.8 points on ICIQ-SF score). The objective cure rate was 92.5%.

Postoperative complications are shown in table 1:

Postoperative complications	IUGA/ICS complication classification	n (%)
<i>Early postoperative</i>		
Vaginal bleeding	7Aa/T1/S1	3 (2.7%)
Transient urinary retention	4Be/T1/S1	6 (5.4%)
<i>Late postoperative</i>		
Vaginal mesh extrusion	3Aa/T3/S2	1 (0.9%)
Exposure of the adjustment thread	2Bc/T2/S2	4 (3.6%)
Urinary infection		7 (6.3%)
<i>De novo</i> OAB symptoms		10 (9.1%)
Dyspareunia	1Bc/T2/S1	5 (4.7%)

Minor changes in the urinary stream were described by 18.7% of women (significant reduction of flow in two patients). The post-voiding residual urine was <50cc in 93.3% of patients (>100cc in 3 patients).

There were no significant differences in the subjective cure rate (ICIQ-SF=0 vs. ICIQ-SF>0) with the number of vaginal deliveries, menopausal status, preintervention ICIQ-SF score, intrinsic sphincter deficiency, presence of pelvic prolapse grade 1 or 2, OAB symptoms or urodynamic hyperactivity. Older and more obese women were more likely to have a ICIQ-SF >0 after sling placement.

Data from the multivariate analysis, showed that a higher BMI (OR 1.17 per each 1Kg/m² increase [CI 95% 1.02-1.33], p=0.02) and menopausal status (OR 11.0 [CI 95% 1.28-94.0], p=0.03) were significant predictors of treatment failure.

Interpretation of results

The obtained results in terms of objective and subjective cures are consistent with the short term results for similar commercial procedures, namely the MiniArc® (AMS) and Ajust® (Bard), the two single incision sling procedures more widely studied [1,2]. Moreover, the rate of complications was low and the procedure proved feasible for execution in an ambulatory setting.

Concluding message

The Altis® sling was safe and effective on a short-term follow-up. Menopausal status and a higher BMI were identified as independent predictors of treatment failure.

References

1. Gauruder-Burmester A, Popken G, The MiniArc Sling System in the treatment of female stress urinary incontinence, Int Braz J Urol 2009, 35(3):334-43.
2. Meschia M, Barbacini P, Baccichet R et al, Short-term outcomes with the Ajust system: a new single incision sling for the treatment of stress urinary incontinence, Int Urogynecol J 2011, 22(2):177-82.

Disclosures

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