

## **EFFICACY AND SAFETY OF A NEW MINI SLING (ALTIS): RESULTS OF A RETROSPECTIVE COMPARATIVE STUDY VERSUS TRANS-OBTURATOR CONVENTIONAL ROUTE (TVT-ABBREVO)**

### Hypothesis / aims of study

The objective of this original study was to compare the effectiveness of a mini-sling ALTIS versus traditional mid-urethral sling (MUS) TVT ABBREVO for stress urinary incontinence treatment in female, resistant to conservative measures.

### Study design, materials and methods

A single-center study, retrospective, with prospective collection of data, between June 2015 to May 2016, compared short-term success rate of two MUS (39 patients in ALTIS group and 53 in ABBREVO group) using clinical criteria and quality of life scores (cf figure 1). Success rate was defined, 3 months after surgery, as proportion of patients having no leakage of urine defined as a negative cough test during clinical examination. Improvement in quality of life defined by a PGI-I score (Patient Global Impression of Improvement) between 1 and 3, and absence of stress urinary incontinence related to USP Questionnaire (urinary Symptom Profile) were evaluated as secondary criteria. Pain, morbidity and intraoperative data were also listed.

### Results

The mean follow-up was 13.55 months. The two groups were comparable in terms of demographics. No significant difference was found for proportion of patients with a negative cough test (89.7% in ALTIS group vs 94.3% in ABBREVO group,  $p=0.45$ ), and for proportion of patients reporting no urinary leakage in USP questionnaire (87.2% in ALTIS group vs 90.6% in ABBREVO group,  $p=0.61$ ) or having an improved quality of life with a score PGI-I between 1 and 3 (82.1% in ALTIS group vs 86.8% in ABBREVO group,  $p=0.53$ ). However, there were more patients who felt very much better after surgery (corresponding to PGI-I score=1) in ABBREVO group compared to ALTIS group (67.9% vs 46.2%,  $p=0.03$ ). The immediate post-operative pain was significantly less intense in ALTIS group than in ABBREVO group (mean VAS score 0.5 vs 1.3,  $p=0.01$ ) but this difference disappeared one week after surgery. Rates of other complications were similar in both groups. The mini-sling ALTIS was significantly associated with a shorter duration of surgery (11.36 vs 14.85 minutes,  $p=0.01$ ).

### Interpretation of results

In this first study evaluating a new adjustable mini-sling for stress incontinence surgery, the mini-sling ALTIS is associated with poor outcomes in terms of quality of life despite a shorter operative time and an immediate lower pain.

### Concluding message

Since traditional MUS have demonstrated their superiority for many years, we suggest using mini-sling ALTIS carefully before more extensive randomized studies.

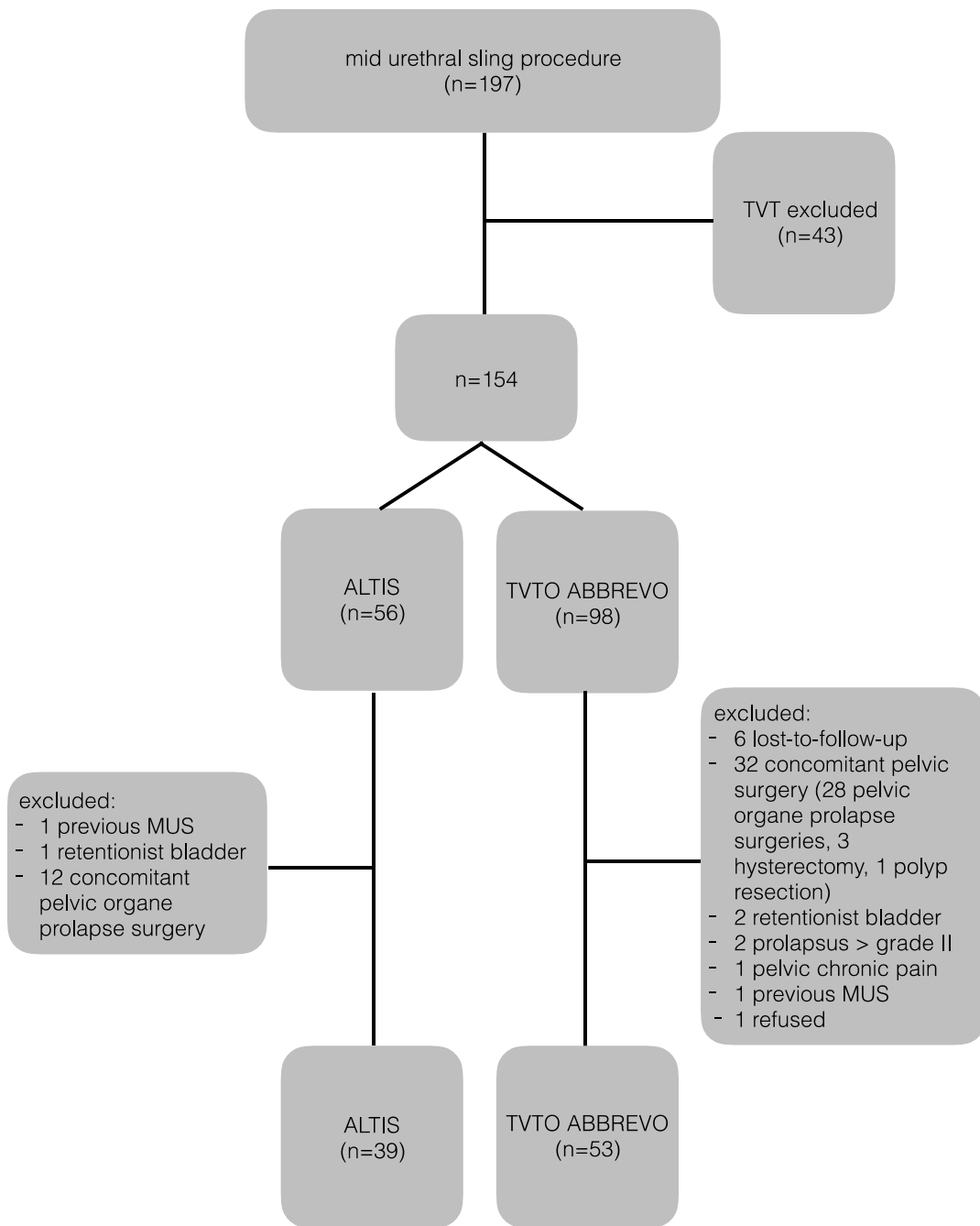


Figure 1 : Flow Chart

#### Disclosures

**Funding:** none **Clinical Trial:** Yes **Public Registry:** No **RCT:** No **Subjects:** HUMAN **Ethics Committee:** CEROG Helsinki: Yes **Informed Consent:** Yes