

SHORT TERM EFFICACY OF THE MINIARCTM SINGLE INCISION SLING SYSTEM FOR THE TREATMENT OF STRESS URINARY INCONTINENCE

Hypothesis / aims of study

The treatment of stress urinary incontinence (SUI) in women has evolved profoundly over the last decade. The introduction and refinement of transvaginal and transobturator sling systems has led to durable objective treatment success with less associated morbidity when compared to traditional methods of operative repair. In keeping with this trend, newer single incision sling systems have been launched and marketed as both efficacious and nearly free of morbidity. However, little data exists to support these claims. We present a prospective clinical non-comparative study with the primary objective to observe the satisfaction and short term efficacy of the implantation of the MiniArc™ single incision sling system for the treatment of female SUI.

Study design, materials and methods

All patients with SUI who were treated with the MiniArc™ sling (AMS) since it was approved by the FDA in October 2007 had data collected in a prospective fashion. Each patient underwent a history and physical examination and completed a preoperative voiding log. Each patient had SUI confirmed by examination evaluating hypermobility and a Marshall-Bonney test. Patients with genuine SUI underwent MiniArc™ placement in an outpatient setting under general anaesthesia. Patients were followed postoperatively for evidence and duration of sling success and for any postoperative complications. Cure was defined as the absence of any urinary leakage at one month. Statistical analysis was performed.

Results

A total of 60 patients with a mean age of 55.4 years (range 26-87 years) with subjective and objective evidence of genuine SUI were treated. Preoperatively, mean daily pad use was 2.22 pads/day \pm 1.32pads/day. 46 patients (75%) were postmenopausal and 34 of 60 (56%) patients had a prior hysterectomy. Mean body mass index (BMI) of the study cohort was 28.7 (range 18-38). Mean follow-up is 3 months (range 1-7 months).

Intraoperative complications included two bladder perforations that required overnight catheter drainage. Two patients experienced urinary retention, once of which resolved on postoperative day one and another that eventually required sling incision. Cure rate at one month was 98%; defined as no pad usage or complains of any leaking. One patient that failed was significantly improved requiring only one pad per 24 hour period. Mean narcotic use postoperatively was 1.6 pills (oxycodone/acetaminophen 10/325); all taken within the first 24 hours. All patients reported that they were pleased with their result and would recommend a friend or family member to have the same procedure performed.

Interpretation of results

Use of MiniArc™ Single Incision Sling System for the treatment of SUI is associated with a high objective cure rate with a modicum of risks. Further research is needed to establish durability of these results as well as objective improvement in quality of life parameters.

Concluding message

The learning curve for this procedure is very short compared to other transvaginal slings. This procedure can be performed quickly (average 10 minutes), requires minimal narcotics and carries a very high patient satisfaction rating

<i>Specify source of funding or grant</i>	None
<i>Is this a clinical trial?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	No
<i>This study did not require ethics committee approval because</i>	this was standard treatment for females with SUI
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes