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MINIARC® ONE YEAR CLINICAL OUTCOME AND QUALITY OF LIFE IN PATIENTS TREATED FOR SUI

Hypothesis / aims of study

MiniArc® is a single-incision, minimally invasive approach to treat women with stress urinary incontinence (SUI). Our objective was to evaluate the long-term efficacy and morbidity in using MiniArc to treat SUI.

Study design, materials and methods

This was a prospective, IRB/EC approved study with 16 centers internationally. To be eligible for inclusion in the study, women had to be ≥ 18 years old, desire surgical treatment for SUI and demonstrate one of the following objective SUI criteria: 1) evidence of SUI on urodynamics; 2) a 1-hour pad weight test (PWT) > 2 grams; or 3) a positive cough stress test (CST). The MiniArc single-incision sling was placed at the mid-urethra along the transobturator trajectory and fixed into the obturator internus muscles bilaterally. Outcomes measured included baseline demographics, intra-operative and peri-operative parameters, efficacy at 12 months via CST, PWT, Urogenital Distress Inventory (UDI-6), Incontinence Impact Questionnaire (IIQ-7), and adverse events (AE's). The 12-month UDI-6 and IIQ-7 scores were compared with baseline values using paired t-test and Wilcoxon signed rank test as appropriate. The CST and PWT were evaluated using the Last Failure Carried Forward (LFCF) method, which carries forward patients' objective failure at 6 months if their 12 month results are missing. The LFCF analysis also considers patients who had a revision for recurrent SUI within 12 months from the initial implant as failures regardless of their 6 month and 12 month test results.

Results

A total of 188 women underwent the MiniArc procedure. The mean age was 51.1 years (25.9-79.6), mean BMI was 27.9 kg/m^2 (17.9-40.1), and mean parity was 2.0 (0-8). A total of 49.5% of subjects were implanted under general anesthesia, 31.9% under intravenous sedation, 17.6% under local anesthesia, and 1% had an epidural. A total of 37 (19.7%) subjects had a concomitant procedure, the majority of which were prolapse repairs. The median procedure time was 11.0 minutes. Median estimated (EBL) blood loss was 25 cc and median length of stay was 3.2 hours. At discharge, median pain score via Wong-Baker pain scale was 0 (0-10). At 12 months, 157 out of the 188 subjects were evaluated. The efficacy rate was 90.6% for CST and 84.5% for PWT. The UDI-6 median score decreased from a baseline value of 44.4 to 11.1 at 12 months ($p<.001$). Of those with urge incontinence at baseline on UDI-6 question #2, 87.3% of patients reported symptom resolution at 12 months. De novo urge incontinence was reported in 7.7% of patients at 12 months based on UDI-6 question #2 (defined by a change of a score at baseline of 0 or 1 to a score of ≥2 at 12 months). Based on UDI-6 question #3, 89.9% reported resolution of SUI symptoms at 12 months. The IIQ-7 median score decreased from a baseline of 40.5 to 0 at 12 months ($p<.001$). Of the 188 implanted subjects, the device or procedure related complications reported by >2% of subjects were: UTI (4.3%), constipation (3.7%), pain/discomfort (3.2%), temporary urinary retention (3.2%), urinary incontinence - de novo (2.7%), vaginal infection (2.1%), dyspareunia (2.1%) and urinary urgency (2.1%). There were no reports of bladder, bowel, or major vessel perforation.

Interpretation of results

At 12 months, our results showed minimal EBL, short LOS, no postoperative pain, and infrequent AE's. In addition to high efficacy rates via objective measurements (90.6% CST and 84.5% PWT), subjects' quality of life showed statistically significant improvements.

Concluding message

MiniArc demonstrated objective efficacy in the treatment of SUI and low morbidity at one-year with follow-up ongoing through 24 months.

Specify source of funding or grant	**American Medical systems funded this study.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Clinicaltrial.gov with reference number NCT00541151**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Each participating center had to have ethical approval by the local IRB/EC since this is a prospective, sponsor-initiated study.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**