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AN EARLY CLINICAL EVALUATION OF THE MINIARC PERFORMED UNDER GENERAL OR LOCAL ANESTHESIA FOR THE TREATMENT OF STRESS URINARY INCONTINENCE

Hypothesis / aims of study

The MiniArc sling is designed for the treatment of Stress Urinary Incontinence (SUI) in women. The MiniArc single-arm, multi-center, prospective study is designed to collect baseline, operative, peri-operative, and follow-up data on this new less invasive procedure. This report compares the intra and peri-operative parameters of MiniArc procedures performed under general anesthesia or local anesthesia (Oral or IV sedation/local injection).

Study design, materials and methods

We are reporting on 96 subjects who had only the MiniArc procedure performed. The average age was 51.0 years (32-79) and mean body mass index was 27.8 kg/m^2 (20-40) and parity 2 (± 1.1) for these subjects. 29% (28/96) of subjects were implanted under general anesthesia and 71% (68/96) under local anesthesia. The procedure requires a single mid-urethral vaginal incision (1.5cm) and placement of the sling (polypropylene monofilament) along a transobturator trajectory into the obturator internus muscles. Intra operative parameters collected included length of stay (LOS), estimated blood loss (EBL), length of catheter placement, pain scores at discharge, and intra-operative complications. Data on voiding function and pain level were collected via phone interview 7 days after the procedure.

Results

The LOS (defined as time from administration of first procedure medication to discharge) was 13.2 ± 26.5 hours for general anesthesia and 2.7 ± 3.3 hours for local anesthesia. The EBL
(in ml) for the MiniArc procedure under general anesthesia was 27.68 ± 27.66 versus 30.51 ± 30.03 for local anesthesia. At discharge, subjects reported a mean pain score of 0.8 ± 1.5 per Wong-Baker Faces Pain Scale (range from 1-10) after general anesthesia versus 0.6 ± 1.1 after local anesthesia. 57% (16/28) of subjects had a catheter placed after general anesthesia (range 1-24 hours) and 7% (5/68) after local anesthesia (range 8- 72 hours). 3 out of the 5 subjects for local anesthesia had a catheter placed longer than 24 hours but no more than 3 days post-procedure. There were no reported intra-operative complications. A peri-operative complication of a broncho spasm with bradycardia occurred after general anesthesia and resolved on the day of the procedure. This event was deemed not related to the MiniArc device.
Post-procedure data were collected on 90 subjects at 7 days and on 60 subjects at 6 weeks. At the 7 days follow-up phone call, 100% (90/90) of subjects reported having normal voiding. Subjects reported a mean pain score of 0.48 ± 1.00 for general anesthesia and 0.29 ± 1.00 for local anesthesia. No pain medication was used by 32.2% (29/90) of subjects. 12/25 (48%) and 49/65 (75%) of subjects reported using pain medication for general anesthesia and local anesthesia respectively. 55.7% (34/61) of medications were narcotic pain killers used by subjects. The medications were not taken for more than 7 days post-procedure. A total of 9 reported adverse events were reported 7 days post-procedure. 16% (4/25) of subjects reported adverse events (cough congestion, worsening pre-existing pain in right knee, sore throat, and fatigue) in the general anesthesia sub-group and 8% (5/65) reported adverse events (vaginal yeast infection, dizziness, pelvic pain, uterine bleeding, and gastroenteritis) in the local anesthesia sub-group. All reported adverse events were deemed not related to the MiniArc device.

Interpretation of results

The relative comfort of patients was excellent with both methods of anesthesia, and indicates that the minimally invasive nature of this procedure, along with the low peri-operative complications and minimal blood loss noted, make it a potentially viable "in office" procedure.

Concluding message

The early data suggests that MiniArc™ can be performed under local anesthesia. The results of subjects under local anesthesia in comparison to those under general anesthesia showed shorter facility stay with no serious complications, and minimal post-operative pain. There have been no reported peri-operative mesh related complications and no bladder, bowel, urethral, or major vessel perforations reported. In addition to the long term results we intend to show, we should also emphasize that the safety and efficacy of the procedure in a subset of subjects who underwent the procedure in an office setting will be assessed. Subjects in the MiniArc™ study will continue to be followed for twenty-four months.

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Is this study registered in a public clinical trials registry?	**Yes**
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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Carolinas Healthcare System Institution Review Board, Allina Hospitals and Clinic Institutional Review Board, and Commissie Medische Ethiek Van De Universitaire Ziekenhuizen Kuleuven**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**