Original Article

Ambulatory MiniArc Precise Sling under Local Anesthesia for Stress Urinary Incontinence: Feasibility and Outcome

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Abstract

Aims: The aim of the study is to assess the feasibility of ambulatory stress urinary incontinence (SUI) surgery using the MiniArc Precise single-incision urethral sling without increasing the number of complications.
Settings and Design: This was a retrospective observational study of prospectively collected data carried out in a Tertiary Referral Hospital in Barcelona, Spain.
Materials and Methods: Forty patients diagnosed with SUI or stress predominant mixed urinary incontinence (MUI) treated surgically between November 2011 and November 2013. The MiniArc Precise® sling was inserted under local anesthesia in the ambulatory setting.
Statistical Analysis Used: Descriptive statistics included frequencies and percentages for categorical variables and mean and range for quantitative variables. The statistical package used was SPSS version 17.0.
Results: Urodynamic studies showed SUI in 78% of cases and stress predominant MUI in 17%. Clinical findings included SUI in 56% of cases and MUI in 44%, with positive stress tests in all participants. The mean intraoperative pain (1–10 Visual Analog Scale) was 2. All patients were satisfied with the use of local anesthesia in the outpatient setting. Perioperative complications did not occur. One case of urinary retention and two cases of urinary tract infection (UTI) developed within this 1st month after operation and were successfully managed conservatively. Midterm complications included eight cases of UTI and four *de novo* urge incontinence.
Conclusions: Placement of the MiniArc Precise sling under local anesthesia is a feasible and safe technique, which when carried out by an experienced surgeon allows to be done as an outpatient basis without increasing the rate of postprocedural complications.

Keywords: Ambulatory surgical procedures, local anesthesia, MiniArc Precise, patient satisfaction, stress urinary incontinence, suburethral slings

Introduction

Single incision of mini-slings has been developed to prevent complications of the standard suburethral transobturator tape (TOT).[1-3] They require fewer incisions, less dissection, less mesh material, and anesthetizing of a smaller area for placement and offer a minimally invasive option, which can be performed on an ambulatory basis under local anesthesia.[4,5]

Because the development of new technologies and materials is faster than the appearance of scientific evidence, organizations such as the National Institute for Health and Care Excellence recommend limiting their use to the context of studies.[6] Conclusions regarding the benefits of mini-slings versus retropubic and transobturator tension-free vaginal tape (TVT) for the treatment of stress urinary

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incontinence (SUI) remain unclear.[7-9] Mini-slings appeared to be associated with inferior objective cure rates on the short term, as well as higher reoperation rates when compared with standard mid-urethral slings.[10] Fixation of the tape to the internus obturator muscle, which is a weaker structure than anchorage of the classic TOT technique,[11,12] may account for the differences.

The MiniArc Precise is a single-incision mini-sling with a length around 8 cm, which incorporates self-fixating tips that provide immediate bilateral fixation of the mesh to the fascia of the obturator internus giving a strong point of support. This procedure is minimally invasive with only one small incision, minimizes the potential for tissue trauma with enhanced patient recovery, and can be performed as an outpatient procedure. The MiniArc Precise design allows theoretically obtaining similar results in the short, mid, and long term than TOT.[11,13,14] In case of confirming the use of the MiniArc in an ambulatory setup without affecting continence outcomes, this new technique would be associated with a greater safety for patients during the surgical procedure, less adverse events, and reduction of costs of treatment related to daycare surgery.

The aim of this study was to assess the feasibility of ambulatory SUI surgery using the MiniArc Precise single-incision urethral sling without increasing the number of complications. Other objectives were to determine the cure rate of SUI and the rate of long-term complications.

Materials and Methods

Study design and participants

A retrospective observational study of prospectively collected data was conducted in 40 women with primary SUI or stress predominant mixed urinary incontinence (MUI) treated with the MiniArc Precise single-incision urethral sling in a single tertiary referral center in Barcelona, Spain, between November 2011 and November 2013. Systematic preoperative investigations included clinical examination of the pelvic floor, urinary stress test, and urodynamic studies. All patients were operated on a minor ambulatory surgery basis and under local anesthesia. In our setting, minor ambulatory surgery unlike major ambulatory surgery used in most centers for this procedure involves performing operation without the attendance of an anesthesiologist in the operating room and without hospital admission, in which the patient remains in a waiting room without specialized recovery services for about 30 min after operation. Minor ambulatory surgery is only possible in well-selected cases. All operations were performed by the same surgeon (M. C-D.) to avoid performance bias, who was previously trained in the theoretical and practical aspects of the surgical technique required for implanting the MiniArc Precise min-sling.

The study inclusion criteria were age ≥18 years, desire for surgical treatment of SUI, evidence of SUI or stress predominant MUI at urodynamic testing, positive cough stress test performed at a bladder volume of at least 200 mL assessed by transvaginal ultrasound, and clear understanding of the procedure. Exclusion criteria were previous use of synthetic sling, pelvic organ prolapse, any coexisting pelvic disease, urodynamic or clinical diagnosis of primary urge incontinence or urge predominant MUI, presence of any underlying disease including psychiatric illness and anxiety disorder that according to the physician's criteria would contraindicate operation in the ambulatory setting, refusal of undergoing the procedure under local anesthesia, and difficulties in clear understanding of the surgical technique. The study was approved by the Ethics Committee of the hospital (PR334/17 obtained on 26th September, 2017) and conformed to the provisions of the Declaration of Helsinki. Written informed consent was obtained from all participants.

Surgical procedure

Preoperatively, 1 h before the procedure, patients were given amoxicillin/clavulanate 1 g or metronidazole 1 g in case of penicillin allergy and 5 mg sublingual diazepam. Patient blood pressure and oxygen levels (pulse oximetry) were monitored, and an intravenous line was maintained during the procedure. For local anesthesia, 10 mL of 2% mepivacaine and 0.5% bupivacaine (without epinephrine) was used. All surgical interventions were performed in the lithotomy position with hips flexed 90°, and a Foley catheter was routinely placed. Xylocaine spray was used as topical anesthesia, and after 1 min, 1 mL of the anesthetic was injected in the mid-urethra using an insulin needle until the appearance of a raised wheal. Then, using an epidural anesthesia needle (Spinocan 22 G × 3 ½) and by directing the needle to the ischiopubic ramus in both sides, approximately 20 mL (10 mL per side) of the local anesthetic was injected. The local anesthetic was injected in both paraurethral spaces following the same direction as the dissection of paraurethral space, instilling the anesthetic throughout the dissected path.

The MiniArc Precise™ single-incision sling (American Medical Systems, Minnetonka, MN, USA) was inserted after the paraurethral tissue was dissected.

At the end of the procedure, the patient remains 30 min in the waiting room to assess the clinical course before discharge home. Postoperative recommendation included avoidance of lifting heavy weights, physical exercise, and sexual intercourse for at least 4 weeks.

Although we do not ask the patients to void and measure residual urine before discharge, we give to all patients specify

instructions on how the bladder emptying should be after surgery. Furthermore, we give a contact telephone number with a specialized nurse to answer possible doubts of patients about it and another question.

Patients were instructed to take oral fosfomycin 3 g every 24 h for 2 days and dexketoprofen 25 mg every 8 h for pain relief, as well as to contact the hospital in case of bleeding, urinary retention, or other relevant symptoms.

Routine postoperatory assessments of these patients comprised visits at 1, 6, 12, and 24 months after the procedure.

Data collection

The International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) was administered before surgery and at 6, 12, and 24 months postoperatively. The ICIQ-SF is a self-administered questionnaire that identifies people with urinary incontinence (IU) and the impact on the quality of life. The ICIQ-SF score ranges between 0 and 21, with higher scores indicating more severe incontinence. A Spanish validated version of the instrument was used.[15] Urinary continence outcome was defined as an objective cure (ICIQ-SF score 0), much improvement (ICIQ-SF score ≤2), and clinical stability (ICIQ-SF score unchanged). Perioperative pain intensity was assessed with a 1–10 Visual Analog Scale (VAS) (1 – no pain and 10 – very severe pain). Perioperative complications included severe pain, vasovagal syncope, intraoperative hemorrhage, and bladder/urethra perforation. Complications within the 1st postoperative month included pain, hemorrhage, hematoma, acute urinary retention (AUR), and urinary tract infection (UTI). Complications recorded at 6, 12, and 24 months were *de novo* urge incontinence, UTI, and SUI. Failure of the procedure was defined as persistent SUI stated by the patient in the ICIQ-SF questionnaire as any urine leakage. The level of subjective satisfaction with the procedure carried out under local anesthesia was evaluated with a standard ten-item questionnaire of patient satisfaction for ambulatory procedures used in our institution.

Statistical analysis

Descriptive statistics included frequencies and percentages for categorical variables and mean and range for quantitative variables. The Statistical Package for the Social Sciences (SPSS Institute Inc., Chicago, IL, USA) version 17.0 for Windows was used for analysis.

Results

A total of 40 patients were included in the study, with a mean age of 55 years. The mean body mass index (BMI) was 29.8 kg/m^2, and only 19% of patients had a normal BMI (18.5–24.9 kg/m^2). Ninety-three percent of participants were multiparous women, with parity ≥3 in 43% of the cases. Preoperatively, urodynamic studies showed SUI in 78% of cases and stress predominant MUI in 17%, and the remaining 5% was normal results. Clinical findings included SUI in 56% of cases and MUI in 44%, with positive cough stress tests in all participants. The mean ICIQ-SF score was 16 (range: 12–20). Previous unsuccessful pelvic floor rehabilitation was recorded in 42% of the patient and anticholinergic treatment in 38%.

The mean intraoperative VAS score was 2. The mean duration of the procedure was 30 min. All patients were satisfied with the surgical operation and stated that they will repeat the procedure in these conditions. Intraoperative complications were not recorded. Complications within the 1st month after surgery were AUR in one patient and UTI in two patients. After the 1st postsurgical month, complications included eight cases of UTI and four cases of *de novo* urge incontinence.

Results of the ICIQ-SF questionnaire at 6, 12, and 24 months are shown in Table 1. In the first control, 6 months after surgery, cure was recorded in 77.5% of the patients and much improvement in 12.5%. Only four patients (10%) remained unchanged. One patient was lost to follow-up at 12 and 24 months. Cure rate was 66.7% at 12 months and 61.5% at 24 months. Furthermore, the percentage of patients with much clinical improvement (ICIQ-SF score ≤2) was 18.0% at 12 months increasing to 25.6% at 24 months. The overall success rates at 6, 12, and 24 months were 90%, 84.6%, and 87.2%, respectively. The percentage of patients in which ICIQ-SF scores did not change as compared with preoperative values was 15.4% at 12 months and 12.8% at 24 months.

No mini-sling procedure needed TOT conversion due to failure of the procedure or complication.

Discussion

This study shows that the MiniArc Precise surgery for the treatment of SUI performed in the office setting under local anesthesia is feasible. The MiniArc Precise Single-Incision

Table 1: Results of the Incontinence Questionnaire-Short Form questionnaire after placement of the MiniArc Precise mini-sling in forty patients with stress urinary incontinence or stress predominant mixed urinary incontinence

ICIQ-SF score	Follow-up, number patients (%)		
	6 months	12 months*	24 months*
0, cure	31 (77.5)	26 (66.7)	24 (61.5)
≤2, much improvement	5 (12.5)	7 (18.0)	10 (25.6)
Unchanged, clinical stability†	4 (10)	6 (15.4)	5 (12.8)

*One patient lost at the 12-month and 24-month assessments, †As compared with baseline ICIQ-SF score. ICIQ-SF: Incontinence Questionnaire-Short Form

Sling System[16] is a modification of the MiniArc device, in which the innovative anchorage system with an arrowhead and release on demand facilitates its anchorage in a single maneuver avoiding lacerating the tissue. In no case was it necessary to use electric scalpel or other materials to perform hemostasis.

A few studies have reported results of MiniArc for SUI as major ambulatory surgery under local anesthesia,[4,5,11,12,17] but as far as we are aware, no previous studies using the MiniArc Precise mini-sling as a minor ambulatory surgery under local anesthesia have been published in the literature. Previous studies have reported the routine use of midazolam instead of diazepam, the presence of an anesthesiologist in the operating room during the procedure, and the fact that patients remain in a specialized recovery room for some hours after the procedure, a situation that does occur in minor ambulatory surgery. Furthermore, in most studies of single-incision MiniArc, the procedure was performed under general or spinal anesthesia.[13,18-20] In our experience, the use of diazepam and local anesthesia allowed the patients to be discharged home approximately 20–30 min after the procedure without the need of hospital admission. Besides different factors that favor the ambulatory setting for mini-sling procedures, costs are less from the payer's perspective. Although in our study this aspect was not assessed, it has been shown that outpatient procedures result in overall savings <35%.[5] In a meta-analysis of single-incision mini-slings versus standard mid-urethral slings in surgical management of female SUI of a total of 758 women in nine randomized controlled clinical trials (RCTs), no studies compared costs to health-care services.[10]

In relation to the type of anesthetic used in our study (2% mepivacaine and 0.5% bupivacaine), 10 mL injected into each periurethral space was sufficient for performing the procedure with total comfort for the patient, with a mean pain intensity on the VAS scale of 2.

Comparative studies of TVT/TOT tapes and MiniArc for patients with SUI have generally demonstrated similar subjective and objective clinical outcomes.[21-25] In a systematic review and meta-analysis of RCTs comparing single-incision mini-slings versus standard mid-urethral slings in the surgical management of SUI, with 3308 women from 26 RCTs, there was no evidence of significant differences in patient-reported and objective cure at midterm follow-up although results should be interpreted with caution due to the heterogeneity of the trials included.[26]

A recent review of the Cochrane library analyzed 31 randomized or quasi-randomized clinical trials involving 3290 women to assess the effectiveness of mini-sling procedures for treating urodynamic clinical stress or MUI.[27] It is concluded that TVT-Secur (one of the first mini-slings introduced in the market) is inferior to standard mid-urethral slings (retropubic TVT and TOT) possibly due to differences in fixation mechanisms. However, there is not enough evidence allowing reliable comparisons between other single-incision slings developed later (Adjust, MiniArc Precise) and retropubic or transobturator slings. However, two studies reported no difference in clinical outcomes between single-incision slings and transobturator mid-urethral slings, but single-incision slings may be more cost-effective.

Cure rates based on scoring 0 in the ICIQ-SF questionnaire were 77.5% at 6 months, 66.7% at 12 months, and 61.5% at 24 months. However, when patients with much clinical improvement (ICIQ-SF ≤2) were added, the overall success rate was 90% at 6 months, 84.6% at 12 months, and 87.2% at 24 months, which are similar to data reported for other suburethral slings.[4,11,28,29] The number of patients with unchanged ICIQ-SF score at follow-up was 4 at 6 months, 6 at 12 months, and 5 at 24 months. Worsening of urgency for reasons unrelated to the study in patients with MUI may account for these differences.

Intraoperative complications were not recorded. Early complications during the 1st postoperative month included AUR in one patient and UTI in two patients, which were successfully treated conservatively as were eight cases of UTI (urine infection) that occurred after the 1st postoperative month. *De novo* urge incontinence was recorded in four patients. In a series of 105 patients treated with the MiniArc, a complication rate of 17% was reported, with one intraoperative bladder perforation managed conservatively with catheterization.[14] Other complications described were obturator hematoma, groin pain, urge symptoms, recurrent UTI, and urethral obstruction requiring mesh cutting.[14]

Limitations of the study include the open-label design, the small number of patients, and the follow-up limited to 24 months after surgery. All of the findings are exploratory and need to be confirmed in a controlled prospective study. Of note, the authors are experienced mini-slings users and have previous experience in performing minor ambulatory in-office procedures. Therefore, the present results may not be able to be generalized to all ambulatory practices. Although in 2016 this type of mini-sling has been withdrawn from the market by the manufacturer for reasons unrelated to clinical outcome, it is possible to place any type of mini-sling with similar characteristics to those of the MiniArc Precise using the procedure here described. The relevance of the present study is to show the feasibility of placement of mini-slings under local anesthesia in a minor ambulatory surgery setting resulting in acceptable cure rates and patients' satisfaction without increasing the rate of complications. The use of the ICIQ-SF instrument as an objective measure of effectiveness of the MiniArc Precise implantation and the homogeneous group of patients with uncomplicated SUI are strengths of the study.

The use of the MiniArc Precise mini-sling under local anesthesia for SUI is a feasible, effective, and safe technique, which when carried out by an experienced surgeon allows to be done as an outpatient basis without increasing the rate of postprocedural complications.

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Conflicts of interest

There are no conflicts of interest.

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