Female Urology

Single Incision Mid-urethral Sling for Treatment of Female Stress Urinary Incontinence

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OBJECTIVES

To present the longitudinal outcomes in an observational cohort of patients who had undergone treatment of stress urinary incontinence with a single incision mid-urethral sling (MUS).

METHODS

A prospective, observational study of all female patients who had undergone surgical intervention with the MiniArc MUS was performed. The surgical candidates underwent history and physical examination and urodynamic testing, as indicated. Quality of life questionnaires (Urogenital Distress Inventory [UDI-6] and Incontinence Impact Questionnaire [IIQ-7]) were administered preoperatively. The salient operative data were recorded. The patients were followed up postoperatively for evidence of treatment success and adverse events. The patients completed the UDI-6, IIQ-7, and Female Sexual Function Index questionnaires at 1 and 12 months after treatment.

RESULTS

From September 2007 to October 2008, 120 patients underwent placement of the MiniArc MUS for the treatment of stress urinary incontinence. The mean patient age was 58.4 years. The mean body mass index was 27.2 kg/m². The mean preoperative daily pad use was 2.4. The mean preoperative IIQ-7 and UDI-6 score was 86.58 and 62.5, respectively. Of the 120 patients, 108 (90%) completed a minimum follow-up period of 12 months. Of these 108 patients, 101 (94%) were cured/dry. The mean postoperative pad use was 0.2 (P < .001). The mean IIQ-7 and UDI-6 score was 13.32 (P < .001) and 12.5 (P < .001), respectively. The Female Sexual Function Index results demonstrated no discomfort with intercourse in 49%, occasional discomfort in 9%, and frequent discomfort in 2%. The remaining 40% of our patients were not sexually active.

CONCLUSIONS

Our results have shown that the MiniArc MUS offers excellent outcomes that are durable at 1 year after treatment.

Stress urinary incontinence (SUI) adversely affects the quality of life and well-being of approximately 15% of the female population.1 The treatment options for SUI include retropubic suspensions and slings, transobturator tape procedures, injectable bulking agents, and, less commonly, artificial urinary sphincter placement.2 Among the most significant advances in the treatment of SUI in recent decades has been the introduction of the mid-urethral sling (MUS). Originally proposed by Petros and Ulmsten,3 the integral theory laid the foundation for the myriad of commercially available and highly successful retropubic and transobturator MUSs. A recent meta-analysis demonstrated short- and long-term “cured/dry” rates with the MUS that approached 85%.2 In an attempt to minimize operative morbidity and the complications related to the original retropubic transvaginal tape (TVT) procedure, the MUS has been modified during the past 5 years to include the transobturator tape (TOT) procedures and the more recently introduced single-incision MUSs (TVT-SECUR, GYNECARE/Ethicon, Somerville, NJ; and MiniArc, American Medical Systems, Minnetonka, MN). Although published data have defined the objective outcomes with the TOT and TVT-SECUR, no data have been published to support the role of the MiniArc MUS in the exclusive treatment of primary SUI without concomitant pelvic organ prolapse.4,5 In an attempt to address this gap in knowledge, we have presented our initial results with the MiniArc MUS, with an emphasis on the device’s safety and efficacy and its affect on our patients’ quality of life.

MATERIAL AND METHODS

After institutional review board approval, a prospective, longitudinal study was performed to evaluate the short- and intermediate-term outcomes among women who underwent MiniArc MUS placement to treat primary SUI. All patients...
underwent a complete history and physical examination and urinalysis. Women with concomitant pelvic organ prolapse and/or who had undergone previous surgery for SUI were excluded from the present study. The patients with subjective complaints of SUI underwent an assessment of the postvoid residual volume and Marshall’s/Bonney’s test to objectively demonstrate SUI. Preoperative pad testing was performed. Additional testing, including a 3-day voiding diary, multichannel urodynamics, cystoscopy, and imaging, were used when appropriate. Before intervention, the surgical candidates completed 2 validated quality-of-life questionnaires: the Urogenital Distress Inventory, 6-item questionnaire (UDI-6) and the Incontinence Impact 7-item short form Questionnaire (IIQ-7). Salient demographic data, including age and body mass index, were obtained preoperatively.

For MiniArc MUS placement, the patients were administered general anesthesia and positioned in the extreme dorsal lithotomy position using Allen stirrups. A 16F Foley catheter was inserted into the patient’s bladder for drainage and identification of the bladder neck. A weighted vaginal speculum was placed for exposure. A approximately 3 mL of 0.25% Marcaine without epinephrine was placed in the anterior vaginal wall overlying the mid-urethra. A 1.5-cm vertical incision was made in the anterior vaginal wall and developed with Metzenbaum scissors toward the obturator foramen bilaterally. The sling was inserted into the obturator internus muscle on the patient’s right side, with the midportion of the sling just to the right of the patient’s midline (Fig. 1A). The contralateral side of the sling was next inserted into the obturator internus muscle on the patient’s left side until the midportion of the sling was aligned with the midline of the patient and the sling was flat against the urethra (Fig. 1B). Holding the sling in place, the bladder was filled to capacity through the indwelling Foley catheter. The catheter was removed and a Credé maneuver performed to evaluate the integrity of the sling with increased abdominal pressure. The sling was sequentially tightened by advancing the trocar on the patient’s left side. Once the sling had the appropriate tension, and the tape lay flat against the urethra, cystoscopy was performed to evaluate any potential urethral or bladder perforations. The incision was closed using 3-0 absorbable suture in a running fashion. The patient was awakened and taken to the recovery room. All patients were discharged on the same day after voiding.

The pertinent intraoperative and immediate postoperative data were accrued for all patients. The operative time, estimated blood loss, and intraoperative complications were recorded. All patients were followed up for a minimum of 12 months after surgery. At 1 and 12 months postoperatively, all patients again completed the UDI-6 and IIQ-7. In addition, the Female Sexual Function Index validated questionnaire was administered to patients to evaluate adverse outcomes related to sexual function after surgery. Treatment success was determined by the findings from the postoperative interview and follow-up questionnaires. The patients were considered “cured” if they responded “not at all” to question 3 of the UDI-6 ("urine leakage related to physical activity, coughing, or sneezing") and denied stress-related leakage on direct questioning.

The Statistical Package for the Social Sciences (SPSS, Chicago, IL) was used to perform all statistical analyses. Statistical significance was set at \( P < 0.05 \). Descriptive analyses were performed to describe the characteristics of the patient sample (mean, standard deviation, percentages, and frequencies). A Wilcoxon signed rank test was used to evaluate differences in preoperative and postoperative pad use and UDI-6 and IIQ-7 scores.

RESULTS

From September 2007 to October 2008, 120 women underwent MiniArc MUS placement for the treatment of SUI. The mean age of the cohort was 58.4 years (range 26-87). The mean body mass index was 27.7 kg/m² (range 18-50). Of the 120 patients, 42 (35%) reported concomitant symptoms of overactivity that were confirmed on preoperative urodynamics. The mean preoperative daily pad use was 2.4 pads daily. The mean preoperative UDI-6 score was 65 of 100. The mean preoperative IIQ-7 score was 86.58 of 100. All patients were discharged on the same day after voiding.

All patients underwent successful MiniArc placement. The mean estimated blood loss was 37 mL. The intraoperative adverse events included 3 bladder perforations, all of which were identified intraoperatively. All patients who experienced a bladder perforation were treated with a Foley catheter overnight, with removal on postoperative...
tive day 1. No vascular or bowel injuries occurred. The mean oral narcotic use in the first month after surgery was 1.6 tablets of 7.5 mg hydrocodone.

At 1 month after surgery, 113 patients (94%) were “cured,” with 6 patients (5%) significantly improved but not completely dry. The remaining patient reported persistent SUI with demonstrable leakage on the follow-up examination. She subsequently underwent repeat MUS 2 months later and was “cured.” The mean pad use at 1 month after surgery was 0.1 pad daily (P = .001). The mean UDI-6 and IIQ-7 scores at 1 month after surgery was 2.5 of 100 (P = .001) and 3.33 of 100 (P = .001), respectively.

Of the 120 patients, 108 (90%) completed the minimal follow-up of 12 months. Of these 108 patients, 101 (93.5%) were “cured.” Significant improvement was seen in daily pad use (2.4 vs 0.2, P = .001) and UDI-6 (65 of 100 vs 13.32, P = .001) and IIQ-7 (89.91 of 100 vs 12.5 of 100, P = .001) scores. The Female Sexual Function Index results at 12 months demonstrated that 49% of our patients had no discomfort during intercourse, 9% sometimes had discomfort, and 2% always had discomfort; 40% of our patients were sexually inactive.

The adverse events in the 12 months after MUS placement included immediate postoperative urinary retention in 2 patients. Of these 2 patients, 1 responded to temporary indwelling catheter placement with spontaneous voiding on postoperative day 2, and 1 required clean intermittent catheterization with eventual sling lysis 2 months after surgery. De novo overactivity was identified on postoperative urodynamics in 5 patients after sling placement. Persistent overactivity was noted in an additional 30 patients. No patients demonstrated infection, refractory postoperative pain, bleeding, thromboembolus formation, or sling erosion. No patients reported new onset thigh or perineal pain after surgery.

COMMENT

Before 1996, SUI was optimally treated with 1 of several forms of retropubic colposuspension, the pubovaginal sling, injectable bulking agents, and/or needle suspension. Although associated with acceptable “cured/dry” rates, each of these procedures were subject to inherent complications, were cumbersome to perform or difficult to learn, and/or were associated with unacceptable morbidity. The TVT, whose design was determined from the integral theory’s focus on midurethral continence, offered a less-invasive, outpatient-based treatment option for SUI. The long-term success rates with the TVT have been excellent, with “cured/dry” rates comparable or superior to those seen with the Burch colposuspension.

However, the TVT has been associated with specific risks, including bladder, bowel, and vascular injury, owing to the blind passage of trocars through the retropubic space. In response to these risks, the TVT was modified, and the TOT was introduced in 2001. In contrast to transgressing the retropubic space, the TOT procedure passes trocars blindly through the obturator foramen in an “inside-out” or “outside-in” fashion that thus obviates the risk of injury to the retropubic organs. The short- and long-term data have demonstrated comparable efficacy for the TOT and the TVT, with an attendant decreased risk of major complications. Although promising, the TOT has been associated with a small, but defined, risk of prolonged leg pain, ostensibly owing to passage of the transvaginal mesh through the obturator foramen proper.

The single-incision MUS was designed to support the mid-urethra in the same fashion as is accomplished with the TVT and TOT but without the passage of a trocar or mesh through the retropubic space or obturator foramen. Instead, the trocars of the single-incision slings pierce the fascia of the obturator internus muscle and are held in position by 1 of several proprietary designs. The goal of the single-incision sling is to provide comparable “cured/dry” rates, with fewer side effects and adverse events.

A modicum of published data exists regarding the first commercially available single-incision MUS, the TVT-SECU R system. Dmochowski et al reported the 12-month outcomes for 642 women who had undergone TVT SECU R placement at 8 international sites. In that industry-sponsored study, 87.5% of patients were “cured/dry” 1 year after treatment. The adverse events included bladder perforation in 1 patient (0.2%), postsurgical retention in 1 patient (0.2%), de novo urgency in 5 patients (2.3%), and mesh exposure in 5 patients (0.8%). Additional studies, primarily in Europe, have demonstrated similar results.

To date, no published data exist to support the use of the MiniArc MUS compared with alternative commercially available MUSs. The explicit goal of our study was to define the expected objective “cured/dry” rate and the risk of adverse events with the MiniArc MUS. With a minimal follow-up of 12 months, our patient cohort had a “cured/dry” rate of approximately 94%, which compared favorably with the rates from recently published meta-analysis reports. Additionally, significant improvement was seen in our patients’ quality of life after treatment, as determined by 2 validated questionnaires. Adverse events were relatively uncommon, with 3 bladder perforations and 2 episodes of urinary retention constituting our most significant adverse events. In retrospect, these adverse events occurred during the learning curve with this device and were due to technical error, rather than an inherent flaw with the sling itself. The incidence of de novo overactivity in our series was acceptably low at 5%.

Although our study was not designed to directly compare the outcomes with the MiniArc MUS with those of other commercially available TOT and TVT devices, several reassuring conclusions can be cautiously drawn from our results. First, as was previously stated, the TOT was initially viewed as a safer and equally effective alternative to the TVT because of its avoidance of the retro-
pubic space. However, a small, but defined, percentage of patients who undergo TOT placement have reported significant thigh and leg pain postoperatively for previously described reasons. Additionally, and perhaps anecdotally, we have found the transobturator approach to be associated with a potentially greater risk of “button-holing” at the lateral sulci owing to the curvature of the trocars. Using the single-incision MUS, we have had no reports of thigh or leg pain and no issues related to tape exposure along its lateral course. We are performing a matched cohort study to compare the outcomes of patients who underwent TOT with those who underwent MiniArc MUS to better define the outcomes in this regard.

Our study warranted several qualifications. First, although the patients completed a minimal follow-up of 12 months, longer term follow-up is needed to determine the durability of the procedure. However, when analyzing the collective published data and, even more so, a recent meta-analysis published by the American Urological Association, the “cured/dry” rates appeared comparable at 12 months and at 48 months. Athough speculative, it is, therefore, reasonable to assume that our success rates will remain durable with prolonged follow-up. Second, although sexual dysfunction was infrequently reported after surgery, we did not obtain preoperative Female Sexual Function Index scores. Our ability to draw meaningful conclusions regarding sexual dysfunction was therefore limited. Specifically, we could not determine whether the presence of occasional or consistent discomfort during sexual intercourse had resulted from the placement of the MUS, was pre-existing, and/or was unrelated. Third, we are uncertain of the outcomes of the patients who were lost to follow-up. However, a recent study by Ballert et al demonstrated comparable outcomes among patients who did and did not have complete follow-up data. Athough speculative, we have surmised that our patients lost to follow-up experienced results comparable to those included in our final cohort. Finally, the preoperative IIQ-7 scores in our cohort were, admittedly, extremely high. Athough objective, validated, and seemingly devoid of ambiguity, patient-recorded data always introduce some level of inaccuracy and response bias. We are confident that our patients experienced a significant improvement in their quality of life with this procedure. Whether this degree of improvement in quality of life found in our study can be duplicated is speculative.

CONCLUSIONS

From our initial experience, the MiniArc MUS offers excellent “cured/dry” rates and a significant improvement in quality of life among women with primary SUI, without concomitant pelvic organ prolapse. Adverse events, sexual dysfunction, and de novo overactivity were uncommon after sling placement. Long-term follow-up and prospective comparative studies are needed to determine the durability and role of the single-incision MUS in the treatment of recurrent SUI and SUI with associated pelvic organ prolapse.

References