Stress urinary incontinence surgery with sling Miniarc: A 4-year results

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Received 13 December 2013; accepted 1 March 2014
Available online 9 December 2014

Abstract

Objectives: The aim of this publication is to describe retrospectively the results of the surgical technique of AMS MiniArc for the treatment of female urinary incontinence, evaluate its results at 4 years follow-up.

Material and methods: We present a retrospective cohort study of 135 patients, 110 (81.5%) had urinary incontinence and 25 (18.5%) mixed urinary incontinence. All these procedures were performed with local anesthesia and in "out patient surgery". Patients were monitored in the outpatient clinic at 6 months (control 1), one year (control 2) and annually (control 3, 4, and 5). During the following up, clinical history was made in every woman with ICIQ-SF questionnaire, that included a fourth question to evaluate the degree of satisfaction after surgery, as well as physical examination. We considered objective cure when negative stress with full bladder. We use the SPSS program (V19.0) for statistical analysis of the results.

Results: The mean follow-up was of 59 months (range from 33 to 72 months). When evaluating the success rate of anti-incontinence surgery, 86.7% of patients showed objective cured (80.8% with MUI and 89.2% with SUI). The ICIQ-SF decreased average of 12.7 points, 85.7% patients were very or fairly satisfied.

Conclusion: The AMS MiniArc is an optim anti-incontinence procedure a medium term. But the results should be interpreted with caution given the limitations of the study.

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PALABRAS CLAVE
MiniArc;
Sling de incisión única;
Incontinencia

Tratamiento de la incontinencia urinaria de esfuerzo femenina con minicintas
MiniArc: resultados a 4 años

Resumen
Objetivos: El objetivo de esta publicación es describir de forma retrospectiva los resultados de la colocación de la cinta AMS MiniArc a 4 años de seguimiento como tratamiento de la incontinencia urinaria (IU).

Material y método: Presentamos un estudio de cohortes retrospectivo de 135 pacientes, 110 (81,5%) tenían incontinencia urinaria de esfuerzo y 25 (18,5%) incontinencia urinaria mixta. Todos los procedimientos se realizaron con anestesia local y en régimen de cirugía mayor ambulatoria. Las pacientes fueron controladas en consultas externas a los 6 meses (control 1), al año (control 2) y una vez al año (control 3, 4 y 5). Se les realizó una historia clínica y el cuestionario ICIQ-SF, al que le añadimos una pregunta para cuantificar el grado de satisfacción, así como la exploración física. Consideramos curación objetiva que la paciente en la exploración física con vejiga llena presentara un test de esfuerzo negativo. Para valorar la curación subjetiva evaluamos las respuestas al cuestionario ICIQ-SF y la pregunta de satisfacción de los resultados de la cirugía. Para el estudio estadístico de los datos descriptivos y de los resultados se aplicó la comparación de media t de Student utilizando el programa SPSS (V 19.0).

Resultados: La mediana de seguimiento fue de 59 meses (rango entre 33–72 meses). Observamos que el 86,7% de las pacientes presentaban curación objetiva a los 4 años. Si analizamos los resultados según el tipo de incontinencia que presentaban las pacientes, con incontinencia urinaria mixta estuvieron curadas en el 80,8% y las pacientes con incontinencia urinaria de esfuerzo en el 89,2%. Con el cuestionario ICIQ-SF y la pregunta de satisfacción observamos un descenso medio en la puntuación de 12,7 puntos, con un 85,7% de las pacientes muy satisfechas.

Conclusion: La colocación de AMS MiniArc supone un dispositivo eficaz para el tratamiento quirúrgico de la incontinencia urinaria femenina a medio plazo, pero los resultados deben interpretarse con precaución dadas las limitaciones del estudio.

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Introduction

In 1990 Petros and Ulmsten1 published their integral theory, in 1994 de Lancey formulated the hammock theory and in 1998 Petros proposed the theory of the middle urethra. In all of these, the key aspects in the physiopathology of urinary incontinence are the following: providing suitable suburethral support at the level of the middle urethra; restitution of the urethral ligament complex, such as the urethropelvic ligament and the pubourethral ligament; and the absence of tension.

During the years between 1990 and 1995, Ulmsten et al. managed to design and develop the TVT® procedure. In 1996 they published their first series with excellent short-term outcomes2 by placing this sling under local anesthesia and a regimen of major surgery on an outpatient basis. These good results have been corroborated in long-term studies; with a follow-up of over 11 years objective cure rates of 90% and subjective ones of 77% were achieved.

In the year 2001, de Lorme published his first series using the out-in transobturator tape and in 2003 de Leval described the in-out transobturator approach.

This kind of approach allows to perform the procedure via the perineal route and reduces the risk of visceral (bladder, loop of bowel), vascular (Santorini’s plexus, iliofemoral vessels) and neurological complications (obturator and pudendal nerves), as well as the risk of postoperative dysuria. Between the years 2005 and 2011, different meta-analyses were published which showed that the obturator route was less favorable than the retropubic route in terms of objective cure (84% versus 88%; RR: 0.96; CI 95%: 0.93–0.99; 17 trials; n = 2434), although there were no differences in subjective cure rates.3

In October 2006, the third generation of mid-urethral tapes emerged with a shorter length than the previous ones, moving from 20–21 cm to 8–9 cm, with TVTSecur, Women’s Health & Urology, Ethicon, Johnson & Johnson and, in 2007 with the AMS MiniArc sling system and Needleless. These mini-slings or single-incision mini-slings (SIMS) can be placed in a V*-shaped position (as in the case of the transobturator vaginal tape (TOT/TVT-O)), with the tape being anchored onto the internal obturator muscle, or in a U-shaped position (as in the case of TVT), with the tape being anchored onto the retropubic space.

The aim of this study was to retrospectively analyze the outcomes of using the AMS MiniArc sling system tape; to do this we used the first 135 patients out of over 500 who were treated in our service.

Materials and methods

In this retrospective cohort study, we analyzed the outcomes of the first 135 patients treated (this group of patients had a greater follow-up and have been the subject of previous publications4) between the years 2007 and 2009 by placing
the AMS MiniArc sling system and anchoring the tape onto the internal obturator muscle.

As part of the preoperative study, clinical history and physical examination were carried out in all cases and in the case of MUI urodynamic test was requested. As part of their clinical history, patients filled the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF questionnaire) validated in Spanish. The median follow-up was 59 months (range between 33 and 72 months). Surgery was performed under local anesthesia, the intrasurgical mesh being fixed using the cough test with full bladder and on a regimen of major surgery on an outpatient basis. We required blood testing with a coagulation study as the only preoperative study. Postoperative controls were performed after 6 months (control 1) and annually thereafter (control 2–5). These included clinical history, ICIQ-SF questionnaire and physical examination with stress test with full bladder.

We considered objective cure when the patient had a negative stress test with full bladder at the physical examination conducted in the medical office. In order to assess subjective cure, we evaluated the results of the ICIQ-SF questionnaire as well as the question on post-surgical satisfaction.

We used Student’s t comparison test and SPSS software (V 19.0) for the statistical analysis of descriptive data and results.

Results

The median age was 55 years with a range between 27 and 82 years. 81.5% (110/135) had pure stress incontinence (SUI) and 18.5% (25/118) mixed urinary incontinence (MUI). 11.1% (15/135 patients) had a history of previous vaginal surgery (hysterectomy versus cystocele correction) and 2.2% (3/135) anti-incontinence surgery via the abdominal route.

The mean preoperative ICIQ-SF score of patients was 15.6 (SD 2.64). According to the type of incontinence, it was 15.52 (SD 3.41) for MUI and 15.58 (SD 2.43) for SUI, with no significant differences among both groups (p = 0.242). Regarding the impact on quality of life (question 3 of the ICIQ-SF), we observed that the mean was 7.3 out of a maximum of 10, with a standard deviation of 1.8. By groups, according to the type of incontinence, the mean was 7.44 (SD 2.2) for MUI and 7.29 (SD 1.44) for SUI, with no statistical differences among both groups (p = 0.3).

When observing the evolution of the different controls after 6 months, 95% of them were objectively cured, 94.4% after a year, 93.2% at year 2, 90.7% at year 3 and 86.7% at year 4 (there were 1, 5, 6, 9 and 12 lost cases from controls 1 to 5, respectively) (Fig. 1). If we analyze the results according to the type of incontinence, MUI patients were cured in 80% of cases and SUI patients in 89.2%.

In order to evaluate subjective cure, we used the ICIQ-SF questionnaire and the question of post-surgical satisfaction (Fig. 2).

Subjective results measured by using ICIQ-SF in all the periods analyzed varied between 2.53 and 1.53, both for SUI and MUI, as shown in Fig. 3, and although the score for SUI patients was lower, there were no significant differences among both groups (p = 0.253).
In terms of satisfaction, results varied from 92.6% of quite or very satisfied patients in the first control to 89.7% in the last control conducted at year 4 (Fig. 4).

If we analyze the ICIQ-SF questionnaire and look at question 1 (how often do you leak urine?), we can observe how in control 1 73% of patients were totally dry and 19% had occasional leaks once, twice or 3 times a week, generally coinciding with a great effort and a full bladder. In the controls at year 1, 2, 3 and 4, the percentages of dry patients were 71.1, 66.7, 63 and 61.5%; and 20, 26.7, 26.6 and 27.7% for those having occasional leaks, respectively (Fig. 5).

Discussion

The first generation of suburethral tapes was TVT® with retropubic placement, and its long-term efficacy has been proven in publications with a follow-up of over 11 years, and in fact the 2010 European Urology guidelines and the subsequent 2012 update give it a grade A recommendation.

As a consequence of the potential serious injuries this technique might entail, and the possible bladder injury at the moment of needle traversing which a cystoscopy entails, in the year 2001 a second generation of transobturatory tapes emerged with a lower percentage of serious injuries and obviating the need for a cystoscopy. In the years 2006 and 2007, a third generation of tapes known as mini-slings or single-incision mini-slings (SIMS) emerged. In the study published by Rezapour in 2006, it was proven that, despite reducing the size of the tape, the same effect was obtained at the level of the middle urethra, maintaining strength 10 times more than sustained tension on the fascia and prolonging these physical effects on the urethra over time.

Although suburethral tapes were designed for placement without tension, we adjusted them depending on the cough test throughout the procedure, which is made possible by the use of local anesthesia, so the tape is fixed to the urethra (it is not tension-free). In 2013, the American Medical System (AMS) released onto the market a system which controls and measures the tension exerted by the mesh on the urethra in an attempt to standardize the procedure (MiniArc Pro).

Our study included the efficacy results to correct SUI and MUI by using the MiniArc mesh placed under local anesthesia. We are aware of the weakness of the study, given that it is a retrospective cohort study, but it also has strengths such as progression time, the use of the questionnaire validated for results, the surgical technique under local anesthesia and the adjustment of the intrasurgical mesh, which could justify the good results when compared with other authors.

Regarding results with the MiniArc® sling after 1-year follow-up, we obtained cure rates ranging from 69 and 91%, although there are also studies with lower success percentages, such as in the case of Hogewoning, who only achieved 44%. In studies published after 2-year follow-up, we found among others the prospective, multicenter, single-arm study by Kenelly et al. who achieved 85% of objective cures and 90% of subjective cures, or the study published by Moore et al. whose objective cure rates ranged from 81 to 86% after 2 years, depending on whether the patients were obese or not, though the differences among both groups were not statistically significant. The results presented by our group at the 2012 congress of the American Urological Association (AUA) after two and a half years showed an objective cure rate of 92% in patients with pure stress incontinence and of 81% in those with mixed incontinence. Within the few studies with a follow-up of over 2 years, we found the one presented by Basu and Dukett with failure rates of 52% after 3-year follow-up, and we found 2 studies with a follow-up of more than 3 years, the same study with a mean follow-up of 4.8 years (2.7–5.9 years) with objective cure rates of 89% for SUI and 80% for MUI and with subjective cure rates of 86% and the one carried out by Ahmet Akin, comparing the outcomes of TFS (another type of mini-sling) with those of TOT after 5 years, and obtaining objective cure rates of 83%, with no significant differences among both groups. In our hands, these results, regarding objective cure, were similar to the ones we obtained with TVT® and TVT-O® tapes.
Comparative studies between MiniArc® and other types of slings have also been published, such as the one conducted by Ridder evaluating the results compared to Monarc®, with no significant differences between both techniques, or the one by Oliveira comparing TVT Secur®, TVT-O®, and MiniArc®, obtaining cure rates of 66, 84 and 86% respectively with 1-year follow-up. Other studies have shown poorer results for MiniArc compared to Monarc, such as the ones by Castroviejo-Royo, with cure rates of 72% versus 84% at 1-year follow-up, or by Basu and Dukett where, after 3 years, 52% of patients with MiniArc failed to recovery compared to only 9% in the case of TVT. In 2011, Fattah and Ford published their first and only meta-analysis comparing the results of mini-slings (SIMS) with traditional slings (SUMS) (TVT®, TVT-O®, TOT). They included 6 studies on 548 patients with TVT Secur®, 2 on 140 patients with MiniArc® and one on 50 patients with Ophira®. The authors concluded that the results obtained with mini-slings were worse than those with traditional slings. In response to this article, Coruñ stated that this study had limitations due to both the low number of studies analyzed and the already shown mediocre medium-term results of TVT Secur®. He also noted that the MiniArc® and Ophira® systems were poorly evaluated. This same author presented in 2013, at the ICS congress held in Barcelona, a systemic review and a meta-analysis of the results with mini-slings versus traditional slings in the management of SUI, concluding that objective cure rates after 12–24 months of follow-up did not show significant differences with the exclusion of TVT Secur®.

**Conclusion**

The placement of this mini-tape AMS MiniArc sling system is an effective system for the surgical treatment of female urinary incontinence in the medium term, its main advantage with respect to its predecessors being the possibility of performing surgery under local anesthesia, thus enabling a more adequate tension of the tape in situ. Results need to be interpreted cautiously, given the limitations of the study.

**Conflict of interest**

The authors declare that they have no conflict of interest.

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