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Stress urinary incontinence surgery with MiniArc® sling system: Our experience

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A B S T R A C T

Objectives: The objective of this article is to describe, retrospectively, the surgical technique for placing the AMS MiniArc® sling system used for the treatment of urinary incontinence, and evaluate its results and complications.

Material and method: We present a retrospective study about the placement of the AMS MiniArc® tape sling system. From August 2007 to March 2009, we placed the tape in a hammock position in 135 patients, 110 (81.5%) of whom had stress urinary incontinence, and 25 (18.5%) mixed incontinence. The patients' median age was 55 years (range: 27-82 years). All the procedures were performed with local anesthesia and as ambulatory major surgery. The patients were followed up in the outpatient clinic at one month (check-up 1), between 3 and 6 months (check-up 2), and at one year (check-up 3). The clinical history and physical examination were done, and the ICIQ-SF was given, to which we added one question to evaluate satisfaction. A negative stress test with full bladder performed at the office during the physical examination was considered objective cure. The results analysis, descriptive analysis, and means comparison with Student's t-test were done with the SPSS program (V 14.0).

Results: Median follow-up was 495 days (range: 181–777 days). Among the 135 operated patients, the intraoperative complications were two bladder perforations. Early complications included one case of hematoma in the obturator fossa which resolved spontaneously, and four cases (2.9%) with mild, non-incapacitating, inguinal pain. The late complications included four cases (2.9%) of mesh extrusion, and three (2.2%) who required the unilateral cutting of the mesh due to obstruction. In nine patients (6.6%) there was a de novo urgency, five of which (3.7%) were temporary (2–6 months), and four (2.96%) were persistent and treated with anticholinergics.

At one year, 91.9 % of patients were cured. Of the patients with mixed incontinence, 88% were cured, as were 92.7% of those with stress incontinence. The ICIQ-SF and the question about satisfaction showed a mean decrease of 12.7 points, with 90% of patients very satisfied or quite satisfied.

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Conclusion: The AMS MiniArc® sling system is one more surgical tool to treat urinary incontinence; the main advantage over its predecessors is the possibility of operating with local anesthesia, which permits to adjust the sling's tension in situ. However, further studies are required in order to demonstrate long-term results compared to the gold standard TVT

Nuestra experiencia con minicintas MiniArc® en la cirugía de la incontinencia urinaria de esfuerzo

Palabras clave:
Incontinencia
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R E S U M E N

Objetivos: El objetivo de esta publicación es describir de forma retrospectiva la técnica quirúrgica y evaluar las complicaciones y los resultados de la colocación de la cinta AMS MiniArc® sling system para el tratamiento de la incontinencia urinaria.
Material y método: Presentamos un estudio retrospectivo sobre la colocación de cinta AMS MiniArc® sling system. Entre agosto de 2007 y marzo de 2009 colocamos dicha cinta en hamaca a 135 pacientes, 110 (81,5%) tenían incontinencia urinaria de esfuerzo y 25 (18,5%) incontinencia urinaria mixta con una edad mediana de 55 años (rango entre 27–82 años). Todos los procedimientos se realizaron con anestesia local y en régimen de cirugía mayor ambulatoria. Las pacientes fueron controladas en consultas externas al mes (control 1), entre los 3–6 meses (control 2) y al año (control 3). 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 como curación objetiva que la paciente en la exploración física realizada en la consulta con la vejiga llena presentara un test de esfuerzo negativo. Analizamos los resultados y el análisis descriptivo y de comparación de medias con la t de student mediante el programa informático SPSS (V14.0).
Resultados: La mediana de seguimiento fue de 495 días (rango entre 181–777 días). En las 135 pacientes intervenidas registramos como complicaciones intraoperatorias 2 perforaciones vesicales. Como complicaciones precoces registramos 1 paciente con hematoma en la fosa obturatriz que evolucionó espontáneamente a curación y 4 pacientes (2,9%) con dolor leve a nivel inguinal no incapacitante. Como complicaciones tardías, 4 pacientes (2,9%) presentaron extrusión de la malla y 3 pacientes (2,2%) necesitaron corte unilateral de la cinta por presentar obstrucción. En 9 pacientes (6,6%) se presentó urgencia de novo, 5 de las cuales (3,7%) fueron temporales entre 2–6 meses, y 4 (2,96%) persistentes y tratadas mediante anticolinérgicos.

Observamos que el 91,9% de las pacientes estaban curadas al año. Si analizamos los resultados según el tipo de incontinencia que presentaban, las pacientes con incontinencia urinaria mixta estuvieron curadas en el 88% y las pacientes con incontinencia urinaria de esfuerzo en el 92,7%. Con el cuestionario ICIQ-SF y la pregunta de satisfacción, observamos un descenso medio en la puntuación de 12,7 puntos, con un 90% de las pacientes muy o bastante satisfechas.
Conclusión: La colocación de esta minicinta AMS MiniArc® sling system es una herramienta más para el tratamiento quirúrgico de la incontinencia urinaria, y la ventaja fundamental respecto a sus predecesoras es la posibilidad de realizar la cirugía con anestesia local consiguiendo dar la tensión adecuada a la cinta in situ. Pero debe demostrar sus resultados a largo plazo teniendo como referencia al «gold standard» de la TVT.

Introduction

Since the development of the tension vaginal free tape (TVT) in 1996, several minimally invasive techniques have been developed for the surgical treatment of stress urinary incontinence (SUI), all of which are based on holistic theories. With the goal of simplifying the TVT technique, midurethral transobturator tapes were developed in 2001. The third

generation of shorter midurethral tapes includes TVT Secur® by Etichon Women's Health & Urology (Johnson & Johnson), which emerged in October 2006; in 2007, the AMS MiniArc® sling system and Needeless® appeared. These minitapes can be placed in a V position (like the transobturator vaginal tape [TOT/TVT-O]) anchoring the tape in the internal obturator muscle, or in a U position (like the TVT), with the tape in the retropubic space.

The objective of this article is to analyze retrospectively our experience with these minitapes, specifically the AMS MiniArc® sling system.

Material and method

In this retrospective study conducted between August 2007 and March 2009, we operated 135 patients; we placed an AMS MiniArc® sling system and anchored the tape in the obturator foramen. The median age of patients was 55 years (range: 27–82 years). Of these patients, 81.5% (110/135) had SUI, and 18.5% (25/118) had mixed urinary incontinence (MUI).

As part of the preoperative procedures, a clinical history and a physical examination was done to all patients; for patients with MUI, a urodynamic testing was ordered. As part of the clinical history, patients filled the International Consultation on Incontinence Questionnaire Short Form (ICIQ-SF).

Median follow-up was 495 days (range: 181–777 days).

Surgery was done with sedation and analgesia as major ambulatory surgery. A coagulation test was the only preoperative test ordered.

Surgical and anesthetic technique

Monitoring and antibiotic prophylaxis with cafazolin 2g was provided before placing the patient in a lithotomy position with 90° thigh-abdomen flexion.

Aerosol lidocaine was applied to the vaginal introitus. Midazolam 1 mg IV was administered, and an infusion of 50 mg meperidine diluted in 100 cm^3 of saline solution was initiated. During the last year, we did the procedure without midazolam; the only analgesic administered was intravenous acetaminophen.

Urology Service (HVC)

QUALITY OF LIFE QUESTIONNAIRE

Patient's chart No. and first and last name:
Your urologist has indicated surgery for your stress urinary incontinence. In order to assess the results, we are asking you to fill this survey about quality of life **before and after surgery**.

1.º How often do you leak urine?
Check one box:
- 0/ Never
- 1/ once or twice a week
- 2/ two or three times a week
- 3/ once a day
- 4/ several times a day
- 5/ all the time

2.° How much urine do you think you leak (whether you wear protection or not)?
Check one box:
- 0/ None
- 2/ A small amount
- 4/ A moderate amount
- 6/ A large amount

3.° How much does leaking urine interfere with your everyday life?
Circle a number as if it were a grade:

1 2 4 5 6 7 8 9 10
Not at all A great deal

4.° After the surgery, you feel:
- 1/ Much better
- 2/ Quite better
- 3/ A little better
- 4/ The same
- 5/ A little worse
- 6/ Quite worse
- 7/ Much worse

Final score:
Add the numbers of questions 1, 2, and 3

Figure 1 – ICIQ-SF and satisfaction question.

Before the surgery, we verified the leak with the Valsalva maneuver.

After voiding the bladder, 3 vials of lidocaine were mixed with 30 cm^3 of saline; this solution was injected into the anterior vaginal wall; the trajectory of the tape up to the internal obturator muscle was infiltrated with an epidural needle, as was the periostium of the ischiopubic ramus.

Once the local anesthesia was injected, a longitudinal vaginal incision was made 1 cm from the meatus; the paraurethral dissection was done with scissors, and the MiniArc® tape was placed in the hammock position; the tapes were anchored in the internal obturator muscle.

Next, the bladder was filled (250 cm^3), the catheter removed, and the tension of the tape adjusted until the Valsalva maneuver caused no leaks. The bladder was emptied and the vaginal incision sutured with Vycril® 3/0.

Patients returned to the Ambulatory Surgery Unit without bladder catheter or vaginal tampon; here, two postvoid residual volumes were measured. If they were over 100 cm^3, the patient was released with a bladder catheter.

The complications were classified as intraoperative, early postoperative (during the first month after surgery), and late postoperative (more than one month after surgery).

The patients were followed up in the outpatient clinic at one month (check-up 1), between 3 and 6 months (check-up 2), and at one year (check-up 3). The clinical history was taken, and the ICIQ-SF was given (to which we added a question to evaluate satisfaction (fig. 1), and a physical examination was done.

The objective criterion to assess healing was a negative stress test with a full bladder at the office; subjective healing was quantified with the ICIQ-SF plus the satisfaction question.

We analyzed the results and did the descriptive analysis and the comparison of means with Student's t-test using the SPSS program (V 14.0).

Results

The intraoperative complications among the 135 patients were 2 (1.4%) bladder perforations. One was diagnosed during surgery because urine was leaking through the vagina; it was resolved by removing and replacing the tape. A cystoscopy verified that the bladder was unharmed. The other case was not diagnosed until 4 months later, when the patient presented with repeat urinary infections; the cystoscopy revealed a calcified intravesical tape (fig. 2), which was endoscopically removed; the symptomology receded, but there was a relapse of the SUI, for which reason a new MiniArc® was placed in September 2009, with a good final result.

Early complications included 1 patient (0.7%) with hematoma in the obturator fossa which resolved spontaneously, and 4 patients (2.9%) with mild, non-incapacitating inguinal pain.

As late complications, 4 patients (2.9%) presented with extruded mesh, three of which cases were resolved with surgery and one with local estrogens (one of these patients had also an intravesical mesh). Three patients (2.2%) required a unilateral cut of the tape due to obstruction: one patient was diagnosed by urodynamic testing, and had de novo urgency; the other two had postvoid residual urine. Nine other patients (6.6%) presented with de novo urgency, 5 of which (3.7%) were temporary (2–6 months), and the other 4 (2.96%) were persistent and treated with anticholinergics.

The mean preoperative ICIQ-SF score was 15.6 (SD 2.64). By type of incontinence, the score of patients with MUI was 15.52 (SD 3.41) and that of patients with SUI was 15.58 (SD 2.43); the differences between the two groups were not significant (p=0.242). Regarding effect on quality of life (ICIQ-SF question 3), the mean was 7.3 over a maximum of 10, with a standard deviation of 1.8. The mean for patients with MUI was 7.44 (SD 2.2), and for patients with SUI it was 7.29 (SD 1.44); there were no differences between the two groups.

Figure 2 – Intravesical mesh.

Table 1 – ICIQ-SF question 1

How often do you leak urine?	1 month		6 months		12 months	
0. Never	98	74%	89	72%	71	69%
1. Once a week	14	85%	18	87%	19	87%
2. 2–3 times a week	12	94%	9	94%	10	97%
3. Once a day	0	94%	1	95%	1	98%
4. Several times a day	5	98%	5	99%	2	100%
5. All the time	3	100%	1	100%	0	100%
	132		123		103	

A negative stress test with a full bladder performed at the office during the physical examination was considered objective cure; according to this criterion, 91.9% of patients were cured at one year: 88% of those with MUI, and 92.7% of those with SUI.

Subjective healing was assessed with the ICIQ-SF[1] and the satisfaction question. At the first check-up (1 month), the mean ICIQ-SF score was 2.4 (SD 3.03), and 93% were quite or very satisfied, according to the satisfaction question. At check-up 2 (3–6 months), the mean ICIQ-SF was 2.6 (SD 3.29), and 93.3% of patients were very or quite satisfied. Finally, at check-up 3 (one year), the mean ICIQ-SF was 2.52 (SD 2.52), and 95.1% were very or quite satisfied.

If we look at question 1 of the ICIQ-SF (How often do you leak urine?), at check-up 1, 74% were completely dry, and 11% had occasional leaks once a week. At check-up 2, 72% were completely dry, and 15% had occasional leaks; at check-up 3, 69% never had leaks, and 18% had leaks once a week (table 1).

Discussion

The first generation of suburethral tapes was the retropubic TVT[2]; its long-term efficacy has been proved with follow-up studies longer than 7 years[3,4]; in fact, TVT is today's gold standard for surgery for SUI. Due to the potentially serious injuries that may result from this technique, and the possible injury to the bladder by the needles, which mandate cystoscopy, the second generation of transobturator tapes appeared in 2001 (Delorme)[5] and 2003 (De Leval)[6], which have a lower rate of severe injury and obviate the need for a cystoscopy.

In 2006, TVT Secur, the third generation of tapes appeared; MiniArc® and Needeless® appeared in 2007. Their length is shortened by 2/3 (from 20–21 to 8–8.5 cm), for which reason they are also known as minitapes. These tapes offer the following advantages:

- Two possible positions: "U" position (similar to TVT), or "V" position (Hammock TOT/TVT-O).
- Penetrate tissues less than their predecessors.
- Fewer complications compared to our series of TVT and TVT-O[7,8].
- Less postoperative pain[9].
- It is possible to operate with local anesthesia in an ambulatory setting[10].

The study published by Rezapour et al[11] in 2006 shows that despite the smaller size of the tape, the same effect is achieved in the mid-urethra, and a force 10 times stronger than the tension supported by the fascia is maintained; in time, these physical effects extend to the urethra.

Theoretically, suburethral tapes must be placed without tension; in fact, when our group placed TVT or TOT tapes, to avoid tension, we introduced scissors in order to prevent direct contact between the tape and the urethra. In contrast, with MiniArc® tapes we adjusted the tape over the urethra; since we did this procedure with local anesthesia, we adjusted the tape until we could verify *in situ* that the Valsalva maneuver did not cause urine leak[10].

This being a new surgical technique, there are only three publications indexed in PubMed[12-14], and two non-indexed publications[15,16]; consequently there are limitations in the comparison of results and complications in our article. Some papers have been presented at various conferences, including one by Dr. M. Basu at the International Urogynecological Association in Como, Italy, this year. In this paper, TVT (currently the gold standard of surgical treatment of SUI) is compared to the MiniArc® tape; the results are frankly better for TVT, with significant differences in terms of both objective and subjective healing[17].

We found that our results with MiniArc® are similar to those published, but our series enjoyed a longer mean and minimum follow-up. The only published article with a follow-up comparable to ours is Moore's, which shows a healing percentage of 91.4%; however, the complications are not described (they are in our study).

We had objective healing results similar to those we have had with TVT and TVT-O tapes[7,8].

The complications were similar to those published: extrusion and cuts due to obstruction. However, we had 6.6% (9/135) cases of de novo urgency, with a wide variation from 0 to 36%. Additionally, 3.7% of our patients (5/135) had this problem temporarily and required anticholinergic treatment; the condition disappeared in 2–6 months without requiring further medication. In only 2.96% (4/135) was the urgency permanent and required continued treatment with anticholinergics.

Conclusion

These minitapes are a new tool to treat SUI; they have clear advantages over TVT and TOT/TVT-O, on account of a lower risk of serious complications, less postoperative pain, and most importantly, the possibility of operating with local anesthesia, which permits providing adequate tension *in situ* to the tape. The good medium-term results require more follow-up in order to compare this product with the TVT gold standard.

Conflict of interest

The authors state that they have no conflicts of interest.

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