Treatment of female stress urinary incontinence using suburethral slings: comparative, retrospective, observational study of two surgical techniques

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KEYWORDS
Stress urinary incontinence; Surgical treatment; Transobturator suburethral sling; Mini-sling; Results; Complications

Abstract
Objective: The treatment of female stress urinary incontinence has undergone a revolution in recent years due the emergence on the market of suburethral slings. The aim of this study is to compare two surgical techniques for treating stress urinary incontinence: Monarc™ (transobturator suburethral sling) and MiniArc® (single-incision suburethral mini-sling).

Materials and methods: Comparative, retrospective, observational study from January 2005 to December 2011 on 317 women diagnosed with stress urinary incontinence. Of these, 214 were treated with the Monarc™ transobturator suburethral sling, and 103 were treated with the MiniArc® mini-sling. The results were treated with SPSS v.15 software, and the statistical significance was p ≤ .005.

Results: The two patients groups were homogeneous in terms of age, number of births, presence of urgency urinary incontinence and prior hysterectomy. There were significant differences in hospital stay, surgical time and early complications in favor of the MiniArc®, technique, but overall there were no significant differences in the late complications. Some 84% of the patients treated with the Monarc™ transobturator sling were cured compared with the 72% of patients in whom we implanted a MiniArc®, a difference that was statistically significant.

Conclusion: We need to perform more high-quality, prospective and randomized studies with larger number of patients and longer follow-up times to confirm or disprove the difference that we found in the success rate for the Monarc™ transobturator suburethral sling.

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Tratamiento de la incontinencia urinaria de esfuerzo femenina mediante cintillas suburetrales: estudio retrospectivo comparativo observacional de 2 técnicas quirúrgicas

Resumen
Objetivo: El tratamiento de la incontinencia urinaria femenina ha sufrido una revolución en los últimos años por la aparición en el mercado de las cintillas suburetrales. El objetivo de este estudio es comparar 2 técnicas quirúrgicas para el tratamiento de la incontinencia urinaria de esfuerzo: Monarc™ (cintilla suburetral transobturadora) y MiniArc® (mini-cintilla suburetral de incisión única).

Material y métodos: Estudio retrospectivo observacional comparativo desde enero de 2005 hasta diciembre de 2011 con 317 mujeres diagnosticadas de incontinencia urinaria de esfuerzo. Doscientas catorce fueron tratadas con la cintilla suburetral transobturadora Monarc™ y 103 con la mini-cintilla MiniArc®. Los resultados han sido tratados con el programa informático SPSS y 15 y el nivel de significación estadística ha sido p ≤ 0.005.

Resultados: Los 2 grupos de pacientes son homogéneos en cuanto a la edad, el número de partos, la presencia de incontinencia urinaria de urgencia o histerectomía previa. Diferencias significativas objetivas en estancia hospitalaria, tiempo quirúrgico y complicaciones precoz para favor del MiniArc®, pero no en las tardías donde no hay diferencias significativas globales. El 84% de las pacientes tratadas con la cintilla transobturadora Monarc™ están curadas frente al 72% en las que colocamos un MiniArc® con diferencia significativa.

Conclusión: Debemos realizar un mayor número de estudios de alta calidad de carácter prospectivo y aleatorizados, con mayor número de pacientes y tiempo de seguimiento para confirmar o rechazar la diferencia que hemos encontrado en la tasa de éxito a favor de cintilla suburetral transobturadora Monarc™.

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Introduction

Tension-free sub-urethral slings, both retropubic and transobturator slings, have become the surgical treatment for stress urinary incontinence and have gained popularity in recent years as gold-standard procedure.1

According to the last 2009 update of the International Consultation on Incontinence Guidelines, the surgical treatment of stress urinary incontinence may include the use of autologous slings, midurethral slings, and Burch colposuspension. However, the guidelines do not define a clear priority among these three options.2 Recent prospective studies, reviews, and meta-analyses have highlighted their long-lasting efficacy and safety of midurethral slings.3 In 2006 single-incision mini-slings were introduced for reducing surgical complications and providing surgeons with a more convenient, faster and safer technique.4

However, the lack of long-term results of surgical procedures for stress urinary incontinence is the major topic of discussion in urogynecology. This deserves special attention because life expectancy is increasing.

The objective is to compare the results of 2 types of suburethral slings for the treatment of urodynamic stress incontinence in women: transobturator sling (Monarc™) versus third generation suburethral slings or single incision mini-sling (MiniArc®).

Materials and methods

In this retrospective observational study, we compare the results and complications found in 2 groups of women treated with transobturator sling, Monarc™ (American Medical Systems, Minnetonka, MN, USA) versus single incision mini-sling, MiniArc® (American Medical Systems, Minnetonka, MN, USA).

The study has been performed in Urogynecology and Pelvic Floor Unit, University Hospital “Rio Ortega”, Valladolid, Spain. We assessed 317 women diagnosed of stress urinary incontinence whom were treated surgically from January 2005 to December 2011. In 214 women sub-urethral tension-free transobturator slings (Monarc®) were used and single incision mini-sling (MiniArc®) in 103 patients.

Study inclusion criteria were: women of full age (older women) with clinical and urodynamic symptomatology of stress urinary incontinence.

Exclusion criteria were: women with previous clinical history of radical pelvic surgery or anti-incontinence surgical procedure, neurological or psychiatric disorders, overactive bladder diagnosed by urodynamic study or postvoid residual greater than 100 cm³ and patients with any degree of pelvic organ prolapse. Preoperative exam included: clinical history, physical and gynecological exploration, 3-day void diary, urinalysis with urine culture, abdominal ultrasound and urodynamic study (uroflowmetry, leak point pressure with Valsalva, cystomanometry and pressure-flow test and urethral pressure profile were carried out in patients with leak point pressure with Valsalva lower than 50 cm H2O).

Gynecologic exploration was developed in lithotomy position with full bladder and urine leakage was evaluated with Valsalva maneuver and Ulstem test. Pelvic organ prolapse was graded according to Baden–Walker classification.

All exams, definitions and units were updated according to the last version standardization of terminology of the
International Continence Society which appeared in 'Good Urodynamic Practices Guidelines of the International Continence Society'.

The same surgeons group developed all surgical procedures in accordance to original technique. The type of anesthesia was general, spinal or local depending on the patient’s needs and surgeons. This is the reason because hospital stay varies.

During surgical act, intraoperative complications were recorded. Early postoperative complications are defined as those complications that appear during first month after surgery. We name later postoperative complications the complications appeared after first month.

Follow-up of the patients was scheduled for first month after intervention, at 3 months, at 6 months and finally each year. Follow-up visits included: anamnesis, evaluation of the presence of urinary symptoms of urgency or voiding difficulty, pain or sexual dysfunction. In the exploration, urine leakage, using Valsalva maneuver, and the presence of tape erosions or de novo prolapses were objectified. Subjective assessment was performed by visual analog scale [VAS]: 0 = ‘I feel terrible’ and 10 = ‘I feel great’.

Urodynamic study during follow-up period was conducted in the moment when patient referred void difficulty, urgency symptoms or recurrent urinary tract infections.

Results

317 women diagnosed of stress urinary incontinence have been treated from January 2005 to December 2011: of them, 214 patients were treated with sub-urethral transobturator slings Monarc® and 103 patients with single incision mini-sling, MiniArc.

Complications have been classified into: intraoperative complications, early complications when appeared during first month after surgery, later postoperative complications if they appeared one month or later after surgery. Surgical complications have also been classified according to modified Clavien classification of surgical complications: most of patients were in Grade I (any deviation from normal postoperative course without the need for drug treatment, surgical, endoscopic or radiological intervention) and II (drug treatment requirement); 3 patients were in Grade III because urethrolysis was needed.

The following results have been analyzed with SPSS v.5 software for Windows (IBM Corp., Armonk, NY, USA). Statistical significance level has been estimated in \( p \leq 0.005 \).

As Table 1 shows, there are no significant differences between 2 groups in age, number of births, presence of urgency urinary incontinence and prior hysterectomy. Significant differences have been found regarding hospital stay, surgical time (in favor of the MiniArc®) and follow-up time (in favor of Monarc® suburethral transobturator sling has been implanted more often by our team).

Regarding complications shown in Table 2 we only have found significant differences in early complications in favor of the Miniarc®, because in Monarc® group, postoperative urinary retention is more frequent. By contrast, there are no significant differences between both techniques in lower urinary tract infections, intraoperative bladder perforations, hematomas (vaginal hematoma drainage was required only in one case) or various complications, such as, pain, dizziness, vertigo or thoracic pain.

Among later complications, there was only a significantly higher incidence of tape erosion in the Miniarc® group. No significant differences in de novo urgency symptoms or postoperative voiding difficulties between the two groups have been found. It is remarkable that urethrolysis has been necessary in only 3 patients in whom a Monarc® sling was placed; the other patients were controlled with intermittent catheterization. All patients showing urgency symptoms

<table>
<thead>
<tr>
<th>Monarc®</th>
<th>MiniArc®</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>57.9 (37-87) ± 11.24</td>
<td>59.31 (37-85) ± 11.53</td>
</tr>
<tr>
<td>Parity</td>
<td>2.41 (0-7) ± 1.46</td>
<td>2.27 (0-8) ± 1.44</td>
</tr>
<tr>
<td>Hysterectomy</td>
<td>32 (15%)</td>
<td>16 (15.5%)</td>
</tr>
<tr>
<td>UUI</td>
<td>49 (22.89%)</td>
<td>15 (14.5%)</td>
</tr>
<tr>
<td>Hospital stay (days)</td>
<td>3.83 (1-24) ± 2.46</td>
<td>2.48 (1-8) ± 1.18</td>
</tr>
<tr>
<td>Surgical time (minutes)</td>
<td>27.57 (10-85) ± 11.57</td>
<td>19.52 (5-63) ± 11.05</td>
</tr>
<tr>
<td>Follow-up time (months)</td>
<td>53 (6-94) ± 23.88</td>
<td>30 (6-55) ± 13.85</td>
</tr>
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</table>

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<tr>
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</thead>
<tbody>
<tr>
<td>Early complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AUR</td>
<td>19 (8.87%)</td>
<td>2 (1.94%)</td>
</tr>
<tr>
<td>ITU</td>
<td>1 (0.5%)</td>
<td>1 (1.0%)</td>
</tr>
<tr>
<td>Bladder perforation</td>
<td>0</td>
<td>1 (0.97%)</td>
</tr>
<tr>
<td>Hematoma</td>
<td>3 (1.4%)</td>
<td>0</td>
</tr>
<tr>
<td>Others</td>
<td>6 (2.8%)</td>
<td>2 (1.9%)</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Monarc®</th>
<th>MiniArc®</th>
<th>( p )</th>
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</thead>
<tbody>
<tr>
<td>Later complications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erosion</td>
<td>3 (1.4%)</td>
<td>7 (6.7%)</td>
</tr>
<tr>
<td>SUI sustained</td>
<td>11 (5.14%)</td>
<td>23 (22.33%)</td>
</tr>
<tr>
<td>UUI de novo</td>
<td>16 (7.47%)</td>
<td>8 (7.6%)</td>
</tr>
<tr>
<td>UUI sustained</td>
<td>25 (11.68%)</td>
<td>5 (4.85%)</td>
</tr>
<tr>
<td>Residues &gt; 150 cm³</td>
<td>4 (1.86%)</td>
<td>1 (0.97%)</td>
</tr>
<tr>
<td>Urethrolysis</td>
<td>3 (1.4%)</td>
<td>0</td>
</tr>
<tr>
<td>Others</td>
<td>3 (1.4%)</td>
<td>1 (1.0%)</td>
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<tr>
<th>Monarc®</th>
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<tbody>
<tr>
<td>Success</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VAS</td>
<td>7.06 ± 1.95</td>
<td>6.61 ± 2.13</td>
</tr>
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</table>
are controlled with anticholinergic. Only one of the patients improved after treatment with percutaneous stimulation of the posterior tibial nerve.

The absence of urine leakage with Valsalva maneuver in the physical examination with full bladder, the absence of the novo urgency and the need for intermittent catheterization for at least 6 months after procedure were considered a success of surgical technique. According these parameters, significant differences in cure rate are observed: 84% of patients treated with transobturator sling Monarc™ are cured whilst 72% of patients are cured in MiniArc® group. No significant difference in subjective perception of welfare (VAS) has been found.

Discussion

Efficacy and complications outcomes of 2 different surgical techniques to correct stress urinary incontinence are reported in our study. Although both procedures use the same type of mesh, macroporous polypropylene, length and surgical approach are different. Objectives and subjective results have been evaluated; however we are aware of the limitations of our study. Body mass index has not been considered as a factor in the choice of the mesh, being surgeon preferences the criteria of choice. In obese women, Monarc™ device has been chosen for its greater anchorage lengths. However, there is no corroborating scientific evidence to support our inferences, and thus the results may be biased.

Another limitation is the lack of subjective data recorded from patients by using quality of life questionnaires and specific test of stress urinary incontinence.

Regarding hospital stay, it is remarkable that we did not take advantage of ambulant surgery with local anesthesia. We understand and assume that costs of each procedure are increased comparing with other groups and colleagues.

In literature review we have observed that De Ridder et al.,9 in a 1-year follow-up retrospective and nonrandomized trial comparing both types of mesh, shown equal objective and subjective continence results for both surgical procedures with better surgical time for MiniArc® group. These results are equal to ours. Dr. Pushkar,9 in his commentary and revision of this paper, emphasizes the need to perform high-quality prospective randomized studies in order to help making timely and accurate decisions about mini-slings for treatment of stress urinary incontinence. In this point, it is convenient to know if 10 additional minutes per surgery are economically important.

In the last few years, numerous research studies have been conducted to determine both the effectiveness and complications of different surgical procedures for the treatment of stress urinary incontinence. Recently, Dr. Fattahe8 performed a meta-analysis of all randomized controlled trials comparing single-incision mini-slings versus standard midurethral slings. He included a total of 758 women in nine randomized controlled trials with a mean follow-up of 9.5 months; being mean age, body mass index and parity comparable for both groups. In the conclusions, he determines that single-incision mini-slings are associated with inferior subjective and objective cure rates, as well as higher reoperation rates for stress urinary incontinence recurrent or not cured and higher risk of urgency symptoms.

Regarding complications, no differences between both techniques were found concerning lesions in pelvic organs. Single-incision mini-slings group had shown less postoperative groin pain; tape erosion and de novo urgency incontinence were significantly higher in single-incision group. In contrast, in our study, de novo urgency incontinence rates were similar in both techniques; no differences regarding low urinary tract infections, hematomas, hematuria and other minor postoperative complications were found.

In 2010, Álvarez-Bandrés et al.10 published a review about complications of stress urinary incontinence surgery with mini-sling system (50 TVT-Secur y 105 MinArc). Follow-up period was 6 months and overall complication rates were of 20%, and most of them were mild and could successfully be treated conservatively. These results are coincident with those reported in the last revision about mesh complications in pelvic floor reconstructive surgery and their management, initially conservative, with excellent results.11

In our study, only tape erosions have been found in Miniarc® group. They could be due to that mini-slings implantation was performed, sometimes, without hydrodissection in vaginal wall, because all patients have local estrogens (pre- and postoperatives). However, we have not been corroborating scientific evidence of this hypothesis.

Among recent prospective studies of MiniArc®, in 201212 a 1-year follow-up prospective study in 77 patients was published. The authors reported that one-year after the surgery 44% of the patients stated to be completely dry and 68% stated an improvement in their incontinence.

Reviews comparing both surgical treatments for stress urinary incontinence are lacking, have reduced number of patients, short follow-up period and heterogeneous groups of patients and of surgical techniques.13 Regarding complications, it seems that there is no clear evidence that complications in mini-slings series are lower than in transobturator suburethral sling.14 Therefore, we should wait for making better treatment decisions for stress urinary incontinence in females and, if it is possible, for finding the ideal mesh for the ideal woman.

Conclusion

Major conclusion of this review is that both objective and subjective cure rates are higher with transobturator suburethral sling Monarc™ than with mini-slings MiniArc®, showing, in both cases, similar complication rates. Nowadays, due to limitations of this study, we are carrying out a randomized and prospective study in order to corroborate or deny our retrospectives results; because benefits reported by other studies regarding possibility of ambulant surgery, local anesthesia, patient cooperation during surgery and less postoperative pain would bring us an improvement in the quality of care of patients and would theoretically lead to a reduction in costs.

Long-term follow-up, randomized and prospective studies must be performed in order to determine the best surgical technique and the best mesh as well as to improve the indication of both procedures in order to choose proper
treatment for each patient. The main goal is to improve patients’ quality of life and to match the expectations of patients and surgeons.

Conflict of interest

The authors declare that they have no conflict of interest.

References