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Mini-Slings: Do They Stand the Test of Time? A 10-Year Cohort

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Stress urinary incontinence · Single-incision slings · Mini-slings

Abstract
Introduction: It is known that failures after midurethral slings increase with the follow-up time. Nevertheless, data concerning mini-slings are sparse. To clarify this statement, we analyze a mini-sling cohort with a median follow-up of 10 years. Although the brand used, MiniArc®, is no longer available, an identical device, Solyx™, can still be used, which makes the analysis of the cohort clinically relevant. ***Material and Methods:*** A total of 172 women with predominant stress urinary incontinence (SUI) were consecutively treated with the mini-sling MiniArc® from 2006 until 2013. They were re-evaluated in 2018. The primary outcome, treatment success, was defined as no self-reported SUI symptoms and no reintervention. Secondary outcomes included the response to patient-reported outcomes. Adverse events were assessed. ***Results:*** After a median follow-up time of 113 months, 115 (66.9%) women were available for reevaluation. Forty-four (38.3%) women self-reported SUI. Seventeen women had been reoperated, 14 (12.2%) due to the reappearance of SUI and 3 due to complications. Altogether, MiniArc® had an overall success rate of 47.0% at 10 years. Among those not reoperated, 63.3% stated that they were much better or very much better in Patient Global Impression of Improvement (PGI-I) and 71.4% affirmed that their continence problem was normal or mild in Patient Global Impression of Severity (PGI-S). Almost 85% would repeat the surgery. Reoperation due to complications was rare (2.6%). De novo urgency appeared in 30.6% of the patients and it was managed with anticholinergic drugs with favorable outcomes. ***Discussion/Conclusion:*** This report adds evidence to the long-term outcomes of mini-slings, confirming that they can cure or improve SUI and give patients high satisfaction rates, at the expense of low morbidity.
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Introduction

Stress urinary incontinence (SUI) is defined as the complaint of involuntary leakage of urine from the urethra, synchronous with exertion, sneezing, or coughing [1]. Despite varying according different populations, SUI overall prevalence ranges from 10 to 25%, making even

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more relevant the scrutiny of its methods of treatment [2].

When conservative management fails, surgery is the preferred option, with midurethral slings (MUS) being the recommended procedure to uncomplicated SUI [3]. First and second generation MUS, inserted either by retropubic or transobturator approach, have been proven to be effective and equivalent [4, 5]. However, the associated complications, as risk of bladder injury during retropubic approach and groin or thigh pain following transobturator route, led to the development of a third generation of MUS, the single-incision slings or mini-slings.

In the long-term, it is known that failures after SUI surgery increase with the follow-up time [6]. This fundamental analysis has been challenged in the case of the mini-slings by the different design of the tapes, some of which have very specific methods of insertion and fixation, making generalizations potentially incorrect. Nevertheless, at short-term follow-up, up to 2 years, standard MUS and mini-slings, TVTSecur® excluded, provide similar cure rates according to several meta-analysis [7–9]. A recent randomized controlled trial revealed an objective cure rate of 89% in the mini-sling group (MiniArc®), comparable to the 87% in the MUS group at 3 years [10]. Data with longer follow-up are very sparse, with few analyses suggesting a sustained efficacy of MiniArc®, 4–5 years after implantation [11, 12]. Therefore, the European Association of Urology (EAU) guidelines of 2019 maintain a strong statement that patients should be informed that the long-term efficacy of mini-slings remains uncertain, essentially similar to the one produced in the 2012 version [3]. To clarify this statement, data from cohorts with long follow-up time are relevant. Here we analyze a mini-sling cohort, MiniArc®, with a median follow-up of 10 years. Although MiniArc® brand was discontinued, a similar device is available under the trade name of Solyx™, which makes the analysis of the cohort relevant.

Materials and Methods

A total of 172 women with predominant SUI were consecutively treated with the mini-sling MiniArc® (American Medical Systems, Minnetonka, MN, USA) from 2006 until 2013 at a tertiary center. Although no longer available with this name, a tape with the same anchoring structure and similar mesh material of MiniArc® is still accessible as the Solyx™ mini-sling (Boston Scientific Corp., Natick, MA, USA). From the 172 women treated with MiniArc®, 115 (66.9%) were available for reevaluation.

The primary outcome for this study was the success rate defined as no self-reported SUI symptoms and no reintervention for SUI or sling removal due to complications. Secondary outcomes included the response to patient-reported outcomes: Patient Global Impression of Improvement (PGI-I) and Patient Global Impression of Severity (PGI-S) questionnaires, and the question "would you repeat the surgery" [13]. Adverse events were also evaluated. For statistical analysis we used SPSS® software, version 25.0.

Results

A total of 115 women from the initial population were available to determine the success rate of the mini-slings, 66.9% of the total MiniArc® patients. Lost patients either had deceased or were no longer available in the contacts available in the hospital. The patients were evaluated between May and July 2018 with a median follow-up of 113 months. The mean age of women at the time of surgery was 52 ± 11 years.

When inquired about symptoms of SUI, 44 (38.3%) women self-reported SUI. Seventeen women had been reoperated, 14 (12.2%) due to the reappearance of SUI and 3 due to complications. This led to a success of MiniArc® at 10 years in 54 women making an overall success rate of 47.0%. Figure 1 summarizes patients' distribution.

Among those not reoperated (98 women) in the PGI-I, 63.3% stated that they were much better or very much better. In 17.4%, some improvement was still found. Only 3% declared they were much worse or very much worse (Fig. 2). In the PGI-S, the continence problem was normal or mild in 71.4% of the patients, while only 8.2% reported that the situation was severe (Fig. 3). When asked "would you repeat the surgery," 83.7% answered affirmatively.

Reoperation due to complications was rare (2.6%). Acute urinary retention led to cut the MiniArc® tape in 2 women, and in one the MiniArc® was removed due to vaginal exposure/erosion. Ten out of the 17 women reoperated due to reappearance of SUI or complications had the second surgery within the first 24 months after the mini-sling placement, in the majority of the cases with a standard MUS. De novo urgency appeared in 30.6% of the patients and it was managed with anticholinergic drugs with favorable outcomes.

There were no differences in all these parameters when patients with less or more than 113 months of follow-up were compared.

Discussion/Conclusion

The long-term efficacy between standard MUS and mini-slings has remained a non-solved issue in the last editions of EAU guidelines. The most recent meta-analy-

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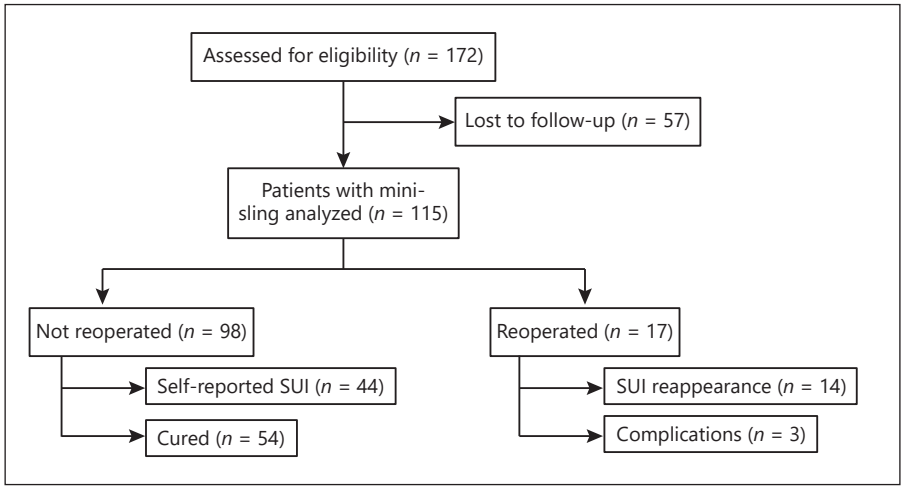

Fig. 1. Patients' distribution. SUI, stress urinary incontinence.

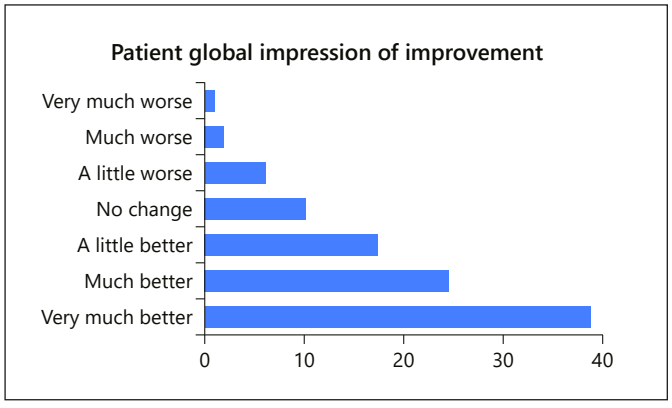

Fig. 2. PGI-I. PGI-I, Patient Global Impression of Improvement.

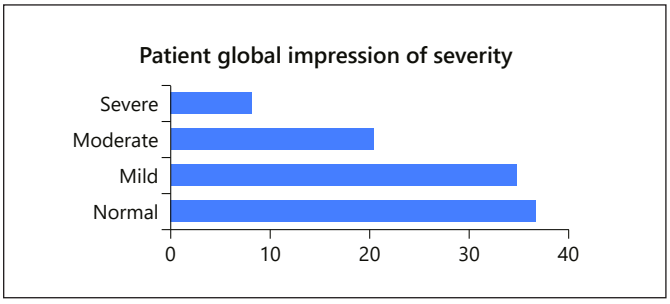

Fig. 3. PGI-S. PGI-S, Patient Global Impression of Severity.

sis with an average follow-up of 2 years concludes that objective cure rates were inferior in mini-slings, emphasizing, however, the similar outcomes between the 2 types of tapes when subjective cure rates were compared [14, 15].

Regarding overall objective cure rate, after 10 years, 47.0% of our population was dry. These results are very similar from those of the TOMUS trial for MUS at 5 years (retropubic with 51.3% and transobturator with 43.4% of success), which used the same outcome measures for success [6]. They were adopted at the design of the study in order to make comparisons more trustworthy.

Subjective cure rates, measured through patient-reported outcomes, are becoming increasingly relevant in clinical trials since patient perception of cure is the ultimate purpose of incontinence surgery. In the MiniArc® cohort, after 10 years of median follow-up, 71.4% of the women that had no reoperation stated their continence problem was normal or mild in PGI-S and 63.3% stated that they were still much better or very much better in PGI-I. Furthermore, >80% of our patients would repeat the surgery knowing the current results.

According to the TOMUS trial, notwithstanding with its decreased efficacy over time, the satisfaction rates at 5 years also remained high with MUS (retropubic with 79% and transobturator with 85%) [6]. Also, in a randomized clinical trial comparing MiniArc® and a MUS, the values in the PGI-I were identically high after 3 years for the mini-sling (86%) and MUS (87%) [10]. Altogether, these data demonstrates a high patient satisfaction at 10 years after the placement of MiniArc® and stresses the fact that eventual small losses, without significant interference in the quality of life, may also be perceived by patients as positive outcome.

Only 3 (2.6%) women had complications requiring intervention, highlighting the good safety profile of these devices. It was, actually, the need for a simpler procedure

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(one small incision and a limited tissue dissection), with less postoperative complications (bladder perforation or inguinal pain), that motivated the single-incision sling development. In addition to its simpler technique, the mini-sling provides a device with less synthetic material in the body of women. In recent meta-analysis, mini-slings were associated with significantly shorter operation times, lower immediate postoperative pain, lower intraoperative blood loss, and lower postoperative voiding dysfunction [14, 15]. The amount of synthetic material may be increasingly important as more studies suggest that it is related with some of the potential complications including the mentioned inguinal pain and the negative effect on sexual function. That would explain why the improvement in sexual life is higher with mini-slings than with standard MUS, as stated in EAU guidelines [3].

The literature available for standard MUS after 10 years of follow-up disclosed much higher cure percentages after transobturator MUS insertion, of nearly 90% based on negative cough stress test, which may give higher rates than criteria based on no reoperation and no self-reported outcome measure here used [16]. However, for the same type of sling and similar follow-up time, other authors did not reproduce these results. The objective cure rate based on a negative cough stress test was 78.9% while the subjective one was only 62.6%, again highlighting that the cough stress test may show unexpected better outcome rates [17]. In another cohort with 10 years follow-up in which only retropubic MUS were used, the satisfaction rate was also of 62.6%, after a slow decline along the years [18]. The subjective assessment of the patients reported by these cohorts is, therefore, comparable with our rates of satisfaction in PGI questionnaires.

In this series, patients developed de novo urgency in 30.6%, a percentage that, although high, can be expected in a population followed-up 10 years. To the de novo urgency may concur not only the increase of overactive bladder symptoms after MUS placement but also the increasing incidence of such symptoms with aging [19]. It is, therefore, surprising that long-term studies regarding MUS do not reflect this incidence that is similar across the world [20–22]. A recent study reported de novo urgency in only 14.4% of their patients at 10 years after a retropubic MUS, despite the annual incidence of overactive bladder symptoms that, in the lowest range, overpasses 3% per year [18, 23]. Eventually, we cannot exclude that the placement of the mini-sling meshes, abutting the urethra, may increase de novo urgency, an aspect that should be object of investigation in the future.

This report adds evidence to the long-term outcomes of MiniArc® mini-sling, confirming their capacity to cure or improve SUI and give patients high satisfaction rates, at the expenses of a low morbidity. The latter aspect is particularly relevant because the Solyx™ device has a similar anchoring system and same mesh material. Moreover, the small amount of artificial mesh that is used in a MiniArc®-like mini-sling may further increase the safety of the procedure. In fact, in a recent consensus meeting the amount of artificial mesh used in the treatment of pelvic organ prolapse was recognized by all experts as a main reason for the severe complications reported worldwide [24]. Similar complications have not been reported after placement of MUS, which use smaller amounts of mesh. Using the same rationale, the probability of such dreadful events after a mini-sling, which were not seen in our patients, should be even less likely. Moreover, if their cost-effectiveness is contemplated, it stands no question that this surgical approach should be considered as potential superior to standard MUS. Eventually the possibility of performing the mini-sling surgery as an ambulatory procedure and under local anesthesia may contribute for that and may contribute to decreasing the costs associated with the treatment of SUI [15, 25].

As strength of this study we should highlight the fact that we considered cure as a strict objective measure, while most trials measure subjective outcomes, contemplating both cure and improvement, with consequent higher success rates. There are some limitations of this study though: it is a single center study and the overall information includes a device already withdrawn from the market, MiniArc®, despite the fact that Solyx™ is similar in what concerns the design of the anchoring system and the type of mesh used. Mini-slings might be offered to women seeking long-term cure of SUI through a minor surgery virtually free of severe complications, as cure of SUI and a high degree of satisfaction were reported by almost 50% and by >75% of women 10 years after the procedure, respectively.

Statement of Ethics

Subjects treated with single-incision slings have given their written informed consent, and the study protocol was approved by the Ethics Committee of the institution in 2010, when a short-term prospective study was conducted. To perform this long-term retrospective analysis, no written consent was obtained, in line with the policies of the institution.

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Conflict of Interest Statement

Francisco Cruz has been a consultant to Boston Scientific. The other authors have no conflict of interests.

Author Contributions

Margarida Manso: data collection and manuscript writing; Francisco Botelho: data analysis; Carlos Silva: data collection and project development; Francisco Cruz: data analysis and manuscript writing.

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References

1 Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, et al. The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. Neurourol Urodyn. 2002; 21(2):167–78.
2 Wein A, Kavoussi L, Partin A, Peters C. Campbell-Walsh urology. 11th ed. St Louis: Elsevier; 2016.
3 Burkhard F, Bosch J, Cruz F, et al. Guidelines on urinary incontinence. European Association of Urology; 2018.
4 Rechberger T, Futyma K, Jankiewicz K, Adamiak A, Skorupski P. The clinical effectiveness of retropubic (IVS-02) and transobturator (IVS-04) midurethral slings: randomized trial. Eur Urol. 2009;56(1):24–30.
5 Richter HE, Albo ME, Zyczynski HM, Kenton K, Norton PA, Sirls LT, et al. Retropubic versus transobturator midurethral slings for stress incontinence. N Engl J Med. 2010; 362(22):2066–76.
6 Kenton K, Stoddard AM, Zyczynski H, Albo M, Rickey L, Norton P, et al. 5-year longitudinal followup after retropubic and transobturator mid urethral slings. J Urol. 2015;193(1): 203–10.
7 Jiao B, Lai S, Xu X, Zhang M, Diao T, Zhang G. A systematic review and meta-analysis of single-incision mini-slings (MiniArc) versus transobturator mid-urethral slings in surgical management of female stress urinary incontinence. Medicine. 2018;97(14):e0283.
8 Bai F, Chen J, Zhang Z, Zheng Y, Wen J, Mao X, et al. Adjustable single-incision mini-slings (Ajust®) versus other slings in surgical management of female stress urinary incontinence: a meta-analysis of effectiveness and complications. BMC Urol. 2018;18(1):44.
9 Mostafa A, Lim CP, Hopper L, Madhuvrata P, Abdel-Fattah M. Single-incision mini-slings versus standard midurethral slings in surgical management of female stress urinary incontinence: an updated systematic review and meta-analysis of effectiveness and complications. Eur Urol. 2014;65(2):402–27.
10 Schellart RP, Zwolsman SE, Lucot JP, de Ridder DJMK, Dijkgraaf MGW, Roovers JWR. A randomized, nonblinded extension study of single-incision versus transobturator midurethral sling in women with stress urinary incontinence. Int Urogynecol J. 2018 Jan;29(1): 37–44.
11 Tutolo M, de Ridder DJ, Montorsi F, Castagna G, Deprest J, Schellart RP, et al. A minimum of 1-year follow-up for MiniArc single incision slings compared to Monarc transobturator slings: an analysis to evaluate durability of continence and medium-term outcomes. Neurourol Urodyn. 2017 Mar;36(3): 803–7.
12 Oliveira R, Resende A, Silva C, Dinis P, Cruz F. Mini-arc for the treatment of female stress urinary incontinence: long-term prospective evaluation by patient reported outcomes. ISRN Urol. 2014;2104:659383.
13 Yalcin I, Bump RC. Validation of two global impression questionnaires for incontinence. Am J Obstet Gynecol. 2003;189(1):98–101.
14 Kim A, Kim MS, Park YJ, Choi WS, Park HK, Paick SH, et al. Clinical outcome of single-incision slings, excluding TVT-Secur, vs standard slings in the surgical management of stress incontinence: an updated systematic review and meta-analysis. BJU Int. 2019 Apr; 123(4):566–84.
15 Nambiar A, Cody JD, Jeffery ST, Aluko P. Single-incision sling operations for urinary incontinence in women. Cochrane Database Syst Rev. 2017;7(7):CD008709.
16 Serati M, Braga A, Athanasiou S, Tommaselli GA, Caccia G, Torella M, et al. Tension-free vaginal tape-obturator for treatment of pure urodynamic stress urinary incontinence: efficacy and adverse effects at 10-year follow-up. Eur Urol. 2017 Apr;71(4):674–9.
17 Natale F, Illiano E, Marchesi A, La Penna C, Costantini E. Transobturator tape: over 10 years follow-up. Urology. 2019 Jul;129:48–53.
18 Schauer I, Bock H, Eredics K, Wallis M, Scholz M, Madersbacher S, et al. 10 years follow-up after mid-urethral sling implantation: high rate of cure yet a re-occurrence of OAB-symptoms. Neurourol Urodyn. 2017 Mar; 36(3):614–9.
19 Marcelissen T, Van Kerrebroeck P. Overactive bladder symptoms after midurethral sling surgery in women: risk factors and management. Neurourol Urodyn. 2018;37(1):83–8.
20 Milsom I, Abrams P, Cardozo L, Roberts RG, Thüroff J, Wein A. How widespread are the symptoms of an overactive bladder and how are they managed? A population based prevalence study. BJU Int. 2001;87(9):760–6.
21 Irwin D, Milsom I, Hunskaar S, Reilly K, Kopp Z, Herschorn S, et al. Population-based survey of urinary incontinence, overactive bladder and other lower urinary tract symptoms in five countries: results of the EPIC study. Eur Urol. 2006;50(6):1306–15.
22 Coyne KS, Sexton CC, Vats V, Thompson C, Kopp ZS, Milsom I. National community prevalence of overactive bladder in the United States stratified by sex and age. Urology. 2011; 77(5):1081–7.
23 Irwin DE, Milsom I, Chancellor MB, Kopp Z, Guan Z. Dynamic progression of overactive bladder and urinary incontinence symptoms: a systematic review. Eur Urol. 2010 Oct;58(4): 532–43.
24 Chapple CR, Cruz F, Deffieux X, Milani AL, Arlandis S, Artibani W, et al. Consensus Statement of the European Urology Association and the European Urogynaecological Association on the use of implanted materials for treating pelvic organ prolapse and stress urinary incontinence. Eur Urol. 2017 Sep; 72(3):424–31.
25 Boyers D, Kilonzo M, Mostafa A, Abdel-Fattah M. Comparison of an adjustable anchored single-incision mini-sling, Ajust, with a standard mid-urethral sling, TVT-O (TM): a health economic evaluation. BJU Int. 2013 Dec;112(8):1169–77.

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