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TRATAMENTO CIRÚRGICO DA INCONTINÊNCIA URINÁRIA DE ESFORÇO FEMININA COM FITAS SUB-URETRAIS DE INCISÃO ÚNICA VAGINAL

SURGICAL TREATMENT OF FEMALE STRESS URINARY INCONTINENCE WITH SINGLE-INCISION VAGINAL SLINGS

RUI MIGUEL DOS SANTOS OLIVEIRA

TESE DE DOUTORAMENTO APRESENTADA
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MEDICINA

Orientador:

Doutor Francisco José Miranda Rodrigues Cruz

Professor Catedrático Convidado
Faculdade de Medicina da Universidade do Porto
Departamento de Doenças Renais, Urológicas e Infecciosas

Co-orientador:

Doutor Paulo Dinis dos Santos Oliveira

Professor Associado Convidado
Faculdade de Medicina da Universidade do Porto
Departamento de Doenças Renais, Urológicas e Infecciosas

Supervised by:

Francisco José Miranda Rodrigues Cruz, MD, PhD

Faculty of Medicine, University of Oporto
Renal, Urologic and Infectious Diseases Department

Paulo Dinis dos Santos Oliveira, MD, PhD

Faculty of Medicine, University of Oporto
Renal, Urologic and Infectious Diseases Department

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DA UNIVERSIDADE DO PORTO

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I- **Oliveira R**, Silva A, Pinto R, Silva J, Silva C, Guimarães M, Dinis P, Cruz F. Short-term assessment of a tension-free vaginal tape for treating female stress urinary incontinence. BJU Int. 2009; 104 (2): 225-8

II- **Oliveira R**, Botelho F, Silva P, Resende A, Silva C, Dinis P, Cruz F. Single-incision sling system as primary treatment of female stress urinary incontinence: prospective 12 months data from a single institution. BJU Int 2011; 108: 1616-1621

III- **Oliveira R**, Botelho F, Silva P, Resende A, Silva C, Dinis P, Cruz F. Exploratory Study Assessing Efficacy and Complications of TVT-O, TVT-Secur, and Mini-Arc: Results at 12-Month Follow-Up. Eur Urol 2011; 59: 940-944

IV- **Oliveira R**, Botelho F, Silva P, Resende A, Silva C, Dinis P, Cruz F. Reply from Authors re: Elisabetta Costantini and Massimo Lazzeri. Surgery for Stress Urinary Incontinence: So Near and Yet So Far. Eur Urol 2011;59:945–6. Eur Urol 2011; 59: 947

V- **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 Urology 2014; 659383

Aos de casa, por terem esperado por mim até eu chegar

LIST OF ABBREVIATIONS

EAU – European Association of Urology

LUT – Lower Urinary Tract

MUS – Mid-Urethral Synthetic Sling

NICE – National Institute for Health and Care Excellence

PDS – Polydioxanone

PFMT – Pelvic-Floor Muscle Training

PVR – Post-Void Residual

QoL – Quality of Life

RCT – Randomized Clinical Trial

RP – Retropubic

RR-Risk Ratio

SD – Sexual Dysfunction

SF – Sexual Function

SIS – Single-Incision vaginal Sling

SUI- Stress Urinary Incontinence

TFS – Tissue Fixation System

TO – Transobturator

TVT^{TM} – Tension-free Vaginal Tape

TVT-O^{TM} – Tension-free Vaginal Tape – Obturator

UI – Urinary Incontinence

UTI – Urinary Tract Infection

VD – Voiding Dysfunction

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INTRODUCTION

URINARY INCONTINENCE: OVERVIEW

Urinary incontinence (UI) is defined by the International Continence Society (ICS) as “the complaint of any involuntary leakage of urine” (Abrams *et al*, 2003). Stress urinary incontinence (SUI) is defined by the same society as “the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing” (Abrams *et al*, 2003). Urinary incontinence is the most prevalent pelvic floor disorder (Lukacz *et al,* 2006 and Coyne *et al,* 2009) and is responsible for silent suffering and social ostracism.

It is a highly prevalent complaint among women living in Western countries, with mean overall reports around 35% of women in large epidemiological surveys, SUI being the most common type of urine loss (Hunskaar *et al,* 2004 and Coyne *et al,* 2009). Estimates of the annual direct costs of UI, in a 1995 study, are around $16 billion (in United States dollars) (Wilson *et al,* 2001). More recently, another American study described that community-dwelling women with severe forms of UI pay up to $1150 (in United States dollars) per year out-of-pocket for incontinence routine care (Subak *et al,* 2007).

Current surgical treatment options are driven by our better understanding of SUI causal mechanisms. The continence mechanism is obtained by the fixation of the middle region of the urethra to the pubic bone, via the pubourethral ligaments and the adequate positioning of the urethra by the

muscle and ligamentory elements of the pelvic brim, assuring adequate coaptation of the urethra wall during coughing or sneezing. The loss of this mechanism results in urethral hypermobility. This integral theory of female incontinence, described in 1990 (Petros *et al,* 1990), remains one of the most important concepts that defines the modern approach to anti-incontinence surgery. The clinical applications of these concepts are evident in the tension-free positioning of the urethral slings in a location beneath the mid-urethra, which reinforces muscle insertion points, ligaments, restores opening and closing muscle forces and, therefore, function (Lee *et al,* 2010).

SURGERY IS THE IDEAL FORM OF TREATMENT

Although being a very prevalent condition, seek for professional help, even in western countries, is very low, with consultation rates of 31% (Hunskaar *et al*, 2004). Active forms of treatment are, unfortunately, requested only by a small fraction of the affected women, with half of them using absorbable pads as the form of treatment (Hunskaar *et al*, 2004).

Conservative treatments are the first management step and include behavioural interventions, life-style changes, pelvic-floor muscle training, pharmacologic treatment and medical devices. Physical exercise and weight reduction can cure up to 27% of the overweight patients with SUI, but requires a prolonged program of diet and exercise, which demands a firm adherence and will not produce readily perceptible improvement (Subak *et al,* 2009).

Pelvic floor muscle training (PFMT) is a first-line therapy for women with SUI (Hay-Smith*,* 2008). PFMT can improve continence in the majority of patients, but cure rates are very low (around 20%) and seen particularly in younger patients with mild forms of SUI (Hay-Smith, 2008 and Shamliyan *et al,* 2008). These treatments are time-consuming, require a firm and long-lasting adherence and their durability is questioned (European Association of Urology, 2013). A recent randomized clinical trial (RCT) comparing treatment of female SUI with initial mid-urethral sling surgery versus initial physiotherapy largely favoured the surgical treatment, with higher subjective, objective cured and improved rates at 1 year follow-up (Labrie *et al,* 2013). Even in the long run, PFMT does not have an important impact on SUI cure, since the vast majority of women incontinent at one trial entry also reported SUI at 12 years follow-up

and more women in the PFMT group have been submitted to surgical SUI treatment (Glazener *et al,* 2014).

Pharmacologic treatment of SUI is still limited. Duloxetine is a serotonin and nor-epinephrine reuptake inhibitor. The increase of these two neurotransmitters in the spinal cord (Onuf's nucleus), intensifies the pudendal nerve activity, increasing the resting and contraction tone of the urethral sphincter (Li *et al,* 2013). However, in a recent meta-analysis, duloxetine is only marginally better than placebo to cure SUI (7.8% *versus* 10.8), while causing high rates of side-effects (Li *et al,* 2013). According to the European Association of Urology (EAU) Guidelines on Urinary Incontinence, duloxetine should not be offered to women who are seeking a cure for their incontinence.

The use of local oestrogens may improve urinary incontinence, particularly in post-menopausal women, although timing, duration, type and route of administration are not clearly defined. Also, long-term effects are not known, as studies are few and not designed to address this matter, as recently has been reported by a Cochrane review (Cody *et al,* 2012). On the other hand, systemic use of oestrogens may worsen incontinence (Cody *et al,* 2012). Concerns about the risk of endometrial and breast cancer after long-term use of systemic oestrogen suggest that treatment should be for limited periods, especially in those women with an intact uterus (Cody *et al,* 2012).

It is therefore without surprise that the EAU Guidelines on Urinary Incontinence peremptory state that the most effective treatment of female SUI is the insertion of a synthetic mid-urethral sling (MUS), which gives equivalent patient-reported cure of SUI, when compared to colposuspension, but at much

lower costs, short and long term complications and time to return to normal activity (European Association of Urology, 2013). These guidelines also report that mid-urethral synthetic sling inserted by either the transobturator (TO) or retropubic (RP) route gives equivalent patient-reported outcome at 12 months (European Association of Urology, 2013).

Peri-urethral and trans-urethral injection of bulking agents is considered by many authors to be a surgical form of SUI treatment. Some studies show promising results in some groups of patients, but evidence for its use is lacking (Kirchin *et al*, 2012). Consensus indicates that bulking agents should not be offered to women who are seeking for a permanent SUI cure (European Association of Urology, 2013), or that are fit for other surgical procedures (Kirchin *et al*, 2012).

MID-URETHRAL SLINGS: INCONVENIENCES AND COMPLICATIONS

The swift success of the mid-urethral tension-free vaginal tape (TVT™, Gynecare, Ethicon, Somerville, New Jersey, USA) (Ulmsten *et al*, 1996) can be estimated by the 1 million cases that had been performed worldwide during the first 10 years that elapsed after its introduction by Ulmsten *et al*, in the middle 1990's (Deng *et al,* 2007 and Schimpf *et al*, 2014). Although considered a safe procedure, TVT™ has, nevertheless been associated with severe complications, such as bladder and bowel perforations and life-threatening vascular injuries. These complications are associated with the blind passage of the needles through the RP space (Deng *et al,* 2007 and Novara *et al,* 2008). This prompted the development of the TO route, by Delorme *et al*, to reduce RP-route associated complications (Delorme *et al,* 2004). Large randomized studies comparing the RP against the TO route established that the two techniques are virtually identical concerning SUI cure, with a percentage of objective cured patients in the range between 75 and 80% (Rechberger *et al,* 2009 and Richter *et al,* 2010). However, TO slings did not decrease all complications, but rather replaced those associated with the incursion through the RP space by others caused by the violation of the obturator foramen. Transobturator tapes have been associated with prolonged and limitative pain referred to the groin and upper thigh, due to peripheral nerve injury and vaginal perforations due to a more horizontal trajectory of the needle passage (Deng *et al,* 2007; Novara *et al,* 2008 and Richter *et al,* 2010). In addition, vascular complications and severe perineal fasciitis were occasionally reported (Deng *et al,* 2007).

As MUS surgeries, performed by the RP or TO route, are currently the preferred surgical treatment worldwide, with millions of women submitted to these surgeries, it is important to describe complications and morbidity associated with these procedures.

Complications associated with MUS can be divided into intra-operative, peri-operative and post-operative ones (Costantini *et al*, 2007) or according to the nature or type of complication (Novara *et al*, 2008).

Hemorrhagic Complications

Hemorrhage is relatively rare. Hemorrhage, defined as blood loss greater than 200 mL or postoperative hematoma, occurs in approximately 2% of patients and can usually be managed by observation or local compression. A recent prospective randomized study comparing the adverse effects after RP and TO MUS surgery reported that intra-operative blood loss (more than 100 mL) was one of the most common intra-operative complication in both surgery groups and occurred twice as frequently in the RP group (4.7% *versus* 2.3%) (Brubaker *et al,* 2011).

Catastrophic complications do occur after RP MUS and may result in mortality, as seven reported deaths exist in the database from 1998 to 2005 (Food and Drug Administration, 2014). Major vascular injuries have not been reported in TO MUS procedures, probably due to the anatomy of TO MUS needle passage (Moore *et al,* 2007).

Injury to the lower urinary tract

Complications consisting of injury to the lower urinary tract (LUT) are bladder perforation and urethral injury. The bladder perforation rate was reported to be between 2.9 and 5% in one large national registry (Kuuva and Nilson, 2002) of RP MUS procedures, although there are reports that reach 23% of cases (Andonian *et al, 2005)*. In a meta-analysis, the numbers are consistently below 10% (Novara *et al,* 2008). The risk of complications was higher in centres where RP MUS are occasionally performed (Kuuva and Nilson, 2002). A recent review assessing the evidence on the effectiveness and complications of RP and TO procedures reported that bladder perforation was significantly more common in the RP group (Long *et al,* 2009). A recent RCT comparing adverse effects after RP and TO MUS surgery reported that intra-operative bladder perforation (5%) occurred exclusively in the RP group (Brubaker *et al,* 2011). In a recent Cochrane Review, the RP bottom-to-top route was more effective than top-to-bottom route and incurred in significantly less bladder perforations (Ogah *et al*, 2011). A recent retrospective review of patients undergoing RP MUS placement complicated by bladder perforation during sling placement showed that the majority of subjects (20 of 25 of patients) were successfully discharged home the day of surgery without catheter drainage (Crosby *et al,* 2013). This risk is much rarer in the TO than it is in RP procedures (Dmochowsky *et al,* 2007) because the planned trocar path during TO sling placement does not enter the pelvis. Case reports of bladder and urethral injuries have led to the current recommendation for routine intra-

operative urethrocystoscopy (Minaglia *et al,* 2004), even with the use of the TO route (American Urological Association, 2009).

Urethral lesion is a rare event. On a review article on this matter (Morton and Hill, 2009), the authors reported urethral perforation during RP procedures in about 0.5% (range 0-2.0%) of the cases and in 1% (range 0-2.5%) after TO procedures.

Infectious complications

The vast majority of the studies address only the most frequent infectious complication, in this case uncomplicated urinary tract infection, with a prevalence situated between 5.5 and 7.5%, and no statistical differences between the RP or the TO route (Rechberger *et al* 2009). These numbers are almost consistently below 10% (Novara *et al,* 2008). In a nationwide analysis of complications associated with TVT^{TM} procedures (Kuuva and Nilsson, 2002), the authors reported that 4.1%, 0.8%, and 0.7% of patients had urinary tract infection, wound infection of the abdominal incision, and defective healing of the vaginal incision, respectively. Nevertheless, there are case series or single-patient reports on serious and life-threatening necrotizing infectious (Johnson *et al,* 2003 and Connolly, 2004). It was speculated that the presence of localized infection and morbid obesity could be possible risk factors for the development of necrotizing infections. Serious infection-related complications after TO procedures have included thigh abscesses requiring drainage and an infected obturator hematoma also requiring exploration and drainage (Dmochowsky *et al,* 2007).

Mesh Extrusion

Vaginal extrusion is a rare complication and its incidence is reported to range from 0.5% to 1.1% (Brubaker *et al,* 2011). Some possible reasons for vaginal extrusion include wound infection, impaired wound healing, superficial placement of the sling on the vaginal wall and vaginal atrophy (Tsivian *et al,* 2004). Symptoms of vaginal erosion include vaginal discharge, a palpable rough surface in the vagina, sexual discomfort (usually partner related), and LUT symptoms, including hematuria. However, up to 35% of patients may be asymptomatic (Hammad *et al,* 2005), and the erosion only identified in vaginal examination. This complication is more frequent with the TO approach, reaching almost statistical significance in a recent meta-analysis (Ogah *et al,* 2009), with a Risk Ratio of 1.58 [0.83-3], although the highest incidence series reports a 4% vaginal erosion rate. Domingo *et al* (2005), who used Obtape™ or Uratape™ as the sling material, reported a relatively high vaginal extrusion rate (15%). They attributed this high erosion rate to the reduced pore size of their mesh (50 µm). They concluded that synthetic mesh with larger pore sizes facilitated vascular and tissue ingrowth, thus optimizing mesh incorporation. Because of similar reports, currently, “when offering a synthetic mid-urethral tape procedure, surgeons should use a device manufactured from type 1 macroporous polypropylene tape” (NICE recommendations, 2013).

The management options are not standardized and range from observation to partial and complete tape excision and re-approximation of the vaginal mucosa over the exposed tape (Costantini *et al*, 2007). Initial observation for small vaginal erosions, with the use of local oestrogens creams when appropriate is recommended, while excision should be preferred for large

erosions and those that do not respond to conservative treatment (Costantini *et al*, 2007).

Urethral erosion is defined as the presence of sling material within the urethral lumen. The median rate of urethral erosions at RP tape procedures from 13 studies was 0.88% (range 0.1–5.5%) and for TO foramen tape procedures in ten studies was 1.09% (range 0.0–2.5%), showing there are not substantial differences (Morton and Hill, 2009). Excess tension of the sling on the urethra, and technical error during dissection of the plane underneath the urethra, resulting in compromised thickness of suburethral tissue, were advanced as possible risk factors for urethral erosion (Kobashi and Govier, 2003). The erosion could also be a result of an unrecognized urethral perforation during the original procedure (Wai *et al,* 2004). The vast majority of patients are symptomatic (Costantini *et* al, 2007). Voiding dysfunction is predominant with symptoms of urgency, urge incontinence, obstructive voiding symptoms, and sometimes complete urinary retention. Recurrent urinary tract infection may be the clinical picture. Diagnosis is made by determining the presence of the tape within the urethral lumen during urethrocystoscopy. Conservative observational treatment is not an option. Endoscopic tape transection or transvaginal excision of the tape with closure of the urethrotomy is the treatment option (Madjar *et al,* 2002). A Martius fat pad graft may be used in case of extensive urethrotomies (Costantini *et al*, 2007).

Intravesical tape erosion is the finding of sling material within the lumen of the bladder. The vast majority of this complication is due to inadvertent and unrecognized bladder perforation during the original procedure, usually using a RP route. Thus, complete and thorough cystoscopic evaluation by an

experienced urologist is essential to minimize this complication. Typical symptoms are intermittent gross hematuria, pelvic pain, storage-type LUT symptoms and recurrent UTI. Observational treatment is not an option. The sling material inside the bladder must be removed either endoscopically or by open surgery. Only patients with complete tape removal have been reported to have recurrent stress incontinence (Dmochowsky *et al*, 2007).

Voiding dysfunction

The presenting symptoms of voiding dysfunction (VD) may differ in terms of type and severity in a range between urinary frequency and urinary retention.

A recent study evaluating the long-term results of TVT^{TM} reported *de novo* overactive bladder symptoms in 30.1% and 18.9% of patients at 3 months and 10 years of follow-up, respectively (Serati *et al,* 2012). The incidence of postoperative VD varies between 2.1% and 6.7% after TO MUS (Dmochowsky *et al,* 2007). Although differences appear substantial, some meta-analysis of RCTs report similar rates of *de novo* urgency for both procedures, although urinary retention is marginally more common in women that underwent TVT^{TM} (Long *et al,* 2009). After TO sling surgery, obstructive urinary symptoms are usually transient and are usually managed by short-term intermittent catheterization, although occasionally symptoms do not subside, thus making tape release mandatory. In a meta-analysis, postoperative urinary retention was found to be slightly more common in women undergoing RP MUS than in those undergoing TO MUS (Long *et al,* 2009). Brubaker *et al* (2011) also reported that

VD requiring surgery (and/or catheter use) was more common after RP MUS than after TO MUS.

A recently reviewed 2009 extensive Cochrane Review on minimally invasive synthetic suburethral sling operations for female SUI statistically favors the TO route, when compared with the RP route, concerning *de novo* VD (Mean Risk Ratio of 0.63, [0.44-0.89]). Surprisingly, no statistical difference was proven when considering *de novo* detrusor overactivity, with a Mean Risk Ratio of 1.22 [0.56-2.63] (Ogah *et al*, 2009 and 2011).

Urinary retention stands at the edge of the symptom spectrum of VD seen after MUS surgery. The definition of urinary retention after MUS varies between studies. It may be defined as catheter-dependency for at least 28 days (Patel *et al,* 2012). There is no consensus about the cut-off level of PVR after voiding trials that needs catheterization. For a clinically significant PVR, some authors propose 20% to 50% of the bladder capacity, whereas others use clearly defined levels of PVR ranging from 100 to 150 mL (Elliott and Comiter, 2012). The discomfort of the patient also plays an important role in the decision making for clean intermittent or indwelling catheterization. Even though obstruction appears to be the main etiological factor, there is not a precise method for diagnosing obstruction, and subsequently predicting the patients who will benefit from a urethral release surgery (Carr and Webster, 1997; Petrou *et al,* 1999). Increased outlet resistance by the over-tensioned sling appears to be the main causative factor for urinary retention after MUS. It is still unclear whether preoperative urodynamic findings indicating relatively impaired detrusor contractility may predict postoperative retention. For example, Kleeman *et al* (2002) showed that a preoperatively high PVR was a significant

risk factor in predicting postoperative retention after different types of anti-incontinence and prolapse surgeries.

Urinary retention may be recognized when patients fail to empty their bladder at the first voiding attempt. Kim *et al* (2012) further showed that postoperative VD is common in the early postoperative period but may be transient and associated with the immediate voiding conditions following surgery such as increased fluid load and bladder overdistention. The latter study showed that that even among patients who fail the initial voiding trial, 36.8% can successfully void on subsequent trials. When the patient cannot void after MUS surgery, many surgeons prefer indwelling bladder catheterization up to 1 week (3 to 7 days) and retesting the patient after catheter removal. There is, however, almost no consensus in the literature about the strategy to follow when the voiding trial 1 week after sling surgery fails. In cases of retention lasting longer than 1 week, some surgeons prefer an early surgical intervention to cut the tape, whereas some prefer to switch to clean intermittent catheterization as advocated by Elliott and Comiter (2012). However, there is a paradigm shift among surgeons toward earlier intervention because delayed time to urethrolysis and longstanding obstruction can lead to irreversible bladder dysfunction.

Interference on female sexual function

In the last few years an increasing number of studies have investigated the potential impact of MUS on women´s sexual health. Unfortunately, most are retrospective series that report mainly on dyspareunia as the sole sexual health

complication of these surgeries, ignoring the many areas of female sexual dysfunction. Sexual dysfunction (SD) is present in almost half of the women who complained of UI or recurrent/persistent LUT symptoms (Salonia *et al,* 2006). On the other hand, cure of UI can solve some forms of SD, in particular, those associated with coital incontinence.

Some studies report that dyspareunia is much more common after TO than RP MUS, in 18,5% of the women treated with a TO sling but only in 3.8% of women after RP MUS (Petri and Ashok, 2012). On the contrary, a report on the TVT-O^{TM} (Ethicon, Sommerville, NJ, USA) procedure in women with SUI did not significantly affect sexual function, with more than half (54.5%) of the women reported an improvement in sexual function after surgery and 45.5% reported no change (Xu *et al,* 2011). Some authors report that sexual function (SF) scores improve after surgery for UI (Rogers *et al,* 2006).

A recent meta-analysis exclusively addressing this matter has given important insights into this topic (Jha *et al,* 2012). Coital incontinence is significantly reduced following continence surgery. However, its impact on SF may be limited because at least half of all women undergoing surgery for SUI are likely to experience no change in SF. There is no difference in SF when comparing RP or TO mid-urethral slings.

Post-operative pain

A bothersome complication particularly associated with TO MUS procedures is postoperative leg pain. The etiology of the pain is hypothesized to be due to either subclinical hematoma or to a transient neuropathic

phenomenon (Dmochowsky *et al,* 2007). A recent review assessing the evidence on the complications of RP and TO procedures revealed groin or thigh pain to be significantly more common in the TO group (Moore *et al,* 2007). Neurologic adverse effects such as numbness or weakness in the legs or pelvic area were reported to be more common in the TO group of the TOMUS study (Brubaker *et al,* 2011). Laurikainen *et al*, in a RCT (2007), reported that groin pain was more frequent with the TO route (16% *vs* 1.5%). A recent Cochrane review also considers that the TO approach was associated with more groin pain (12% *versus* 1.7%, RR 6, 95% CI: 3-11) (Ogah *et al,* 2011).

Some authors (Deng *et al*, 2007 and Costantini *et al,* 2007) highlight the importance of voluntary reporting of MUS-related complications, such as that register made by the Food and Drug Administration (FDA) manufacturer and user facility device experience (MAUDE). These authors found a significant discrepancy between scientific reports and this MAUDE database, concerning major MUS-related complications, with up to 4 times as many major complications. These findings gave a false sense of security. Several explanations may be found: (1) reports may understate complications, (2) surgeons who have higher complication rates do not answer questionnaires, (3) differences exist between high- and low-volume surgeons, and (4) underreporting or over-reporting complication rates might be accounted for by surgeons who manage the complications.

SINGLE-INCISION VAGINAL SLINGS

The increased number of incontinence procedures has prompted additional development of lesser invasive procedures aiming to further decrease morbidity and costs related to operating room resources, hospital stay, recovery time, pain and time to return to work. Indeed, a way to increase women's adherence to surgical treatment of SUI is to opt for minimally invasive procedures. Around 2006 appeared the first reports on some new tension-free mid-urethral vaginal slings, known as single-incision vaginal slings (Neuman, 2008; Petros and Richardson, 2005), which were introduced with the concept of a shorter tape, inserted through a single vaginal incision, providing a suburethral hammock, avoiding the blind passage of trocars through the retropubic space or the groin muscles as the previous methods required. The aim of these techniques was to provide an equally effective procedure to tension-free mid-urethral vaginal slings with synchronous reduction in morbidity. Data on these new single-incision slings (SIS) are mainly available in small cohorts, with very short follow-ups. Although results seem comparable to conventional MUS, these new slings need adequate prospective studies in order to adequately clarify their precise indications and utilization limits. These potential advantages, if proven, may be reflected in improving women's quality of life (QoL) and potential cost savings to health providers and society. However, the advantages just cited would be only relevant if SIS are proven to have a similar clinical efficacy compared with traditional MUS.

TVT Secur™

The first widespread SIS to be introduced was TVT-Secur™ in 2006 (Gynecare, Ethicon, Sommerville, NJ, USA). This sling consists of a short (1,1x8 cm) laser cut tape of the same material as TVT™. Specially designed extremities are coated with a fleece of absorbable materials (Vycril™ and PDS™). The latter exerts a velcro effect on host tissues, offering immediate fixation and providing a pull-out force similar to TVT™ (Rezapour *et al,* 2007). The tape comes attached to a steel blade-shaped inserter in each tip, which is released by pulling a metal trigger and gently twisting the inserter. As neither sutures nor inserting needles are necessary for the sling placement, the risks of internal injuries inherent to the blind passage of inserting needles are hypothetically minimized. The system can be fixed in a U-shaped position, resembling the retropubic approach (vertical) or in a hammock (H) position (lateral), resembling the TVT-O^{TM} route (TVT Secur information manual, 2007). As the theoretical advantage of TVT-Secur™ is minimizing complications, surgeons usually do not consider the alternative “U” position, as this position is more susceptible of injuring abdominal viscera, in particular the bladder.

One issue about TVT-Secur™ is the learning curve. Neuman, in an initial series of 100 patients, after dividing the cohort into the first 50 and last 50 patients, found that success rate at 1 month follow-up was 80% in the former and 92% in the latter group (Neuman, 2008). Vaginal perforation was 8% and 0% and mesh extrusion was 12% and 8% in the first and second fifty patients, respectively. Unintended tape removal occurred in 5 patients in the first group and in none in the second. These findings clearly indicate that surgeons must

master the technique in order to optimize results. Points of technique requiring surgeon expertise include the depth of submucosal dissection, the width of the insertion tunnel, a meticulously detachment of the inserter and the adjustment of the sling placement, ideally left abutting the urethra.

Meschia *et al* (2009) prospectively reported on 95 patients treated in 4 Italian centers. After an average follow-up of 15 months subjective cure rate was 78% and objective cure rate 81%. Complications referred were 2 inadvertent removal of tapes during blade inserter disassembly, requiring the placement of a new device. Bleeding over 500 cc occurred in 2 patients and one patient had transient VD which resolved spontaneously.

Taken together, these results indicate that TVT-Secur™ may be effective in the cure of SUI. Morbidity seemed lesser than in classical slings. None of the series reported bowel, bladder or urethral injuries and groin pain appears to be slightly lower than that after standard slings. The long-term outcome of TVT-Secur™ is unknown. Optimization of the results is highly dependent on proper training and attention to technique details, which may require an unexpected long learning curve.

Mini Arc™

Mini-Arc™ (American Medical Systems, Minnetonka, MN, USA) design is very simple. A small elastic 8 cm long polypropylene mesh is attached to two small harpoon-like anchoring extremities. These are easily directed through the para-urethral tissues with a curved metallic handle (2.3mm needle) docked in the anchors.

Gauruder-Burmester and Popken (2009) used Mini-Arc™ in a total of 97 women with mixed or stress urinary incontinence (SUI). The Mini-Arc™ sling was the initial intervention in 37 (38.2%) patients and the second intervention in 60 (61.7%) patients with recurrent incontinence. Six weeks after the sling procedure the cough stress test was negative in 83.1% of the women. This number decreased slightly at 12 months, when 77.8% of the women were cured. *De novo* urgency occurred in 32 women (36.8%). Quality of life was significantly improved at 12-month follow-up in 69.1% of the patients ($p<0.001$). The number of pads decreased significantly, from 2.2 to 0.6 ($p<0.001$) after the procedure. One hematoma and one bladder perforation were reported as complications.

A study conducted in a single centre in the United States, with 61 patients, evaluated retrospectively at 12 months, reported overall cure rates of 91%, determined by the both physician and patient (Moore *et al*, 2009). There were no intra-operative complications and the only post-operative adverse event was a case of urinary retention requiring sling loosening.

These initial, albeit non-comparative studies, indicate that Mini-Arc™ is safe and easily reproducible, with a short learning curve. Cure rates at a short follow-up are high, in the range of those reported by series using conventional slings.

Tissue Fixation System

The Tissue Fixation System (TFS^{TM}) (TFS Manufacturing PTY LTD, 18 Kincaid Avenue, North Plympton, SA, Australia) consists of an adjustable

polypropylene mesh that uses two small plastic anchors to fix it into the inferior surface of the pelvic muscles and tissues below the retropubic space, in an hammock-like tension-free position.

This SIS was developed by Petros and their report at medium follow-up (3 years) provides data about 36 patients with SUI (Petros and Richardson, 2008). Data were collected by a telephone interview conducted by a nurse and a negative answer to the question “Do you leak when you cough?” was considered as a cure. Cure rates on 31 eligible patients were of 80%. Complication rates are not described.

Another report on TFS^{TM} (Sekiguchi *et al,* 2009), describes a prospective study on 44 women with urodynamic SUI. This cohort had a high percentage of women with poor sphincteric function (34,1%). With a mean follow-up of 16,1 months, success was noted in 91% of patients, with 4 cases considered treatment failures (9%). Pain described at discharge was minimal. No significant blood loss was described. Five patients (11%) had transient voiding difficulties that resolved after 48 hours of indwelling catheterization. Nine patients (20%) had occasional urge incontinence in the post-operative follow-up, that resolved spontaneously or with pelvic floor exercises.

These studies, although including a low number of patients, provide an insight into the results of this SIS, that seem comparable to conventional MUS in terms of success rates, with a small cohort followed at medium-term. Morbidity seems also in accordance with the expected minimally invasiveness of this sling. However, data are scarce and it is not possible to draw convincing conclusions.

This device is not commercially available in Portugal.

Other single-incision slings

These other SIS are evaluated separately because they have a very low number of patients, very limited follow-up or the results are not comparable with the aforementioned SIS.

Arcus to arcus (Palma *et al,* 2008), a transobturator route SIS, has been used in 20 patients, with a 12 month´s follow-up cure rate of 88%.

Contasure Needleless™ (Neomedic International SL, Barcelona, Spain) although being placed through a vaginal single-incision, is somewhat different in terms of invasiveness, as it requires the introduction of a surgical forceps into the urogenital diaphragm, and then it is opened to deploy the mesh into the internal obturator muscle. Preliminary data (Navazo *et al,* 2009) on 120 patients evaluated retrospectively, with 24 months follow-up, show 84% cure and 8% improvement rates, with low and mild morbidity profile. The authors state by themselves that this is not a mini-sling, because it is a 114mm long mesh, with 138% more surface area.

Serels *et al* (2010) reported on preliminary results of Solyx® (Boston Scientific Corporation, Natick, MA, USA), a self-anchoring sling system. This retrospective study on 63 patients, with only 6.5 months follow-up, shows 95% dry rate and 2 cases of transient voiding dysfunction as the sole morbidity. This SIS design resembles, in some aspects, Mini-Arc™

Minitape™ (GyneIdeas, Glasgow, UK) is a 14 cm long mesh with terminal anchors that fixate the tape in the RP space. It was evaluated in an adequately designed multicentre prospective trial, with 24 months mature follow-up (North

et al, 2010). However, results were disappointing, with only 33% and 10% of patients cured at 1 months and 24 months, respectively (n=60).

Current perspective

As discussed before, treatment of female SUI is at a point where a myriad of new devices are being designed and launched into medical practice without adequate clinical evaluation. These innovative surgical procedures are introduced in the market without any specific regulatory framework (Costantini and Lazzeri, 2010). That is the opposite of what happens with a new drug, which is assessed through specific clinical research phases, well characterized and regulated in the vast majority of countries. The Lancet has published a paper on this particular matter (Barkun *et al,* 2009), with the grant of official health authorities, proposing a staged surgical model with 4 phases, resembling the drug development stages in human beings. This paper has also been entitled as the Balliol Colloquia achievements, and surgeons with interest in UI should put adequate emphasis on safety and efficacy of standard treatments, introducing adequate stage research practices into the operating theatre. Only then, surgical innovations can be promptly considered on academic urology institutions, which will support surgical development under rigorous guidelines and encourage early registration of new procedures in public registries (Costantini and Lazzeri, 2010).

It is obvious from the previous descriptions that SIS are not equal to each other, although their potential advantages, if proven, may be reflected in improving women's quality of life and potential cost savings to health providers

and society. Hence, clinical trials are necessary to define which SIS will meet the required criteria of efficacy and safety, in order to be included in the armamentarium of surgical therapies for SUI.

OBJECTIVES

Prospective enrollment of patients submitted to single-incision vaginal sling placement as the initial surgical treatment of SUI, in order to evaluate short-term success rates, post-operative complications and quality-of-life outcomes.

Evaluate both available single-incision slings, TVT-Secur™ and Mini-Arc™.

Long-term follow-up of the initial population.

Randomized clinical trial comparing SIS with the gold-standard mid-urethral sling.

PUBLICATIONS

PUBLICATION 1

Short-term assessment of a tension-free vaginal tape
for treating female stress urinary incontinence

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Short-term assessment of a tension-free vaginal tape for treating female stress urinary incontinence

Rui Oliveira, André Silva, Rui Pinto, João Silva, Carlos Silva, Miguel Guimarães, Paulo Dinis and Francisco Cruz

Hospital de São João, Serviço de Urologia, Porto, Portugal

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OBJECTIVE

To evaluate the short-term surgical complications and results of a tension-free vaginal tape (TVT) system (TVT-Secur™, Gynecare, Ethicon, Somerville, NJ, USA) in the treatment of female stress urinary incontinence (SUI).

PATIENTS AND METHODS

TVT-Secur was applied to 107 women with SUI through a vaginal incision and left abutting the urethra. Postoperative pain, complications, de novo lower urinary tract symptoms, incontinence cure rate and the King's Health Questionnaire (KHQ) score were evaluated.

RESULTS

The operative duration was 12 min; the mean pain score was 2.3 and only one patient had transient voiding difficulties. After a mean follow-up of 15 months, 71% of the patients were dry and 14% improved. The KHQ scores decreased significantly for most subscores. Urgency appeared *de novo* in six patients (5.6%), and vaginal erosion required one TVT-Secur explantation.

CONCLUSION

This study shows that TVT-Secur is a simple and safe treatment for female SUI, but before recommending this sling as a first choice for treating SUI, TVT-Secur must pass the test of time and comparative studies with conventional slings.

KEYWORDS

female stress urinary incontinence, mid-urethral sling, suburethral tape, TVT, mini-sling, TVT-Secur™

INTRODUCTION

Recent epidemiological studies estimate that stress urinary incontinence (SUI) affects 40% of the women in the Western world [1]. At present one of the most successful treatments for SUI is provided by surgery [2], but unfortunately, too few women are receiving appropriate surgery for SUI [1]. One way to increase the adoption of surgery for SUI by these women is to opt for minimally invasive procedures. This was why Burch colposuspension, once the standard technique [2], was progressively discarded in favour of tension-free vaginal tape (TVT), the first mid-urethral sling to be introduced into clinical practice in 1996, by Ulmsten *et al.* [3]. When both procedures were compared by appropriate randomized clinical trials it became clear that the advantage of TVT did not lie in the success rate. At 5 years of follow up, 69% of women after Burch colposuspension and 75% after TVT were cured [4]. However, while Burch colposuspension had a median hospital stay of 5 days and a median time to return to work of 10 weeks, TVT required only 1 day and 4 weeks, respectively [5].

While being considered a highly successful [6], minimally invasive technique, TVT is not devoid of serious complications, in general associated with the 'blind' course of the needles through the retropubic space. A high rate of bladder perforation and occasional severe vascular and bowel injuries have been reported, in a few instances leading to the patient's death [7–9]. In an attempt to obviate the needle passage through the retropubic space, transobturator slings were introduced. Nevertheless, transobturator tapes have been associated with prolonged postoperative pain referred to the groin and upper thigh, after obturator nerve entrapment by the mesh, in many patients [10]. In addition, vascular injuries and perineal fasciitis have also been reported, associated with the death of two patients [11]. Thus, further improvement in mid-urethral slings is still possible.

The novel TVT-Secur™ (Gynecare, Ethicon, Sommerville, NJ, USA) mid-urethral sling is an 8-cm long laser-cut polypropylene mesh that is put in place through a single vaginal incision. Specially designed absorbable ends offer immediate fixation of the mesh to the obturator internus internal fascia. As neither sutures nor inserting needles are necessary for placing the sling the risks of internal injuries inherent to the blind passage of inserting needles are hypothetically minimized. Here we report the surgical complications and short-term results with this device. Preliminary data were presented in abstract form previously [12].

PATIENTS AND METHODS

In a prospective study, 107 women referred to our department for SUI or mixed UI associated with urethral hypermobility were treated with

the TVT-Secur. Written informed consent was obtained from every patient. Patients with previous surgical procedures for SUI, genital prolapse Stage 2 or higher (by the Pelvic Organ Prolapse Quantification system) in any vaginal compartment or obesity (body mass index >30 kg/m^2) were excluded. The preoperative evaluation consisted of a medical history and physical examination with neurological and urogynaecological assessment. All patients had a stress test with the bladder previously filled to 300 mL and a quality-of-life assessment questionnaire (King's Health Questionnaire, KHQ). All patients complaining of urgency, frequency or nocturia besides SUI had a urodynamic evaluation to exclude detrusor overactivity.

The surgery was done by one or more of the authors; the slings were placed according to the technique described by Neuman [13], and always placed in the hammock position. As the theoretical advantage of TVT-Secur is minimizing complications, we did not consider the alternative 'U' position, as this is more susceptible to injuring abdominal viscera, in particular the bladder [13]. The procedure was carried out with the patient in the lithotomy position, with the hips flexed at 90°. A 16 F Foley catheter was introduced into the bladder and urine evacuated. A 1–1.5-cm vaginal incision was made in the midline, 1 cm posterior to the external urethral meatus. Sharp para-urethral dissection using Metzenbaum scissors was extended laterally until the tip of the scissors touched the inferior border of the ischiopubic ramus. Care was taken to avoid any dissection in the area of the obturator foramen or perforation of the internal obturator fascia. The TVT-Secur, mounted on the inserter handle system, was then advanced through the trajectories created. Then, with the TVT-Secur handle firmly grasped on a needle-holder, the device was pushed just behind the ischiopubic ramus to place its extremity in the fibrous attachment of the obturator internus muscle. Usually this procedure was initiated on the right side of the patient and was then repeated on the left side. The position of the TVT-Secur was then checked immediately, to confirm that the mesh was abutting the urethra and to exclude vaginal perforations, in particular in the vaginal cul-de-sac. The right inserter handle was then detached from the mesh by pulling out the release wire and twisting the handle, while gently pushing it into the patient's body. The left handle was then disconnected from the mesh as previously described for the right side. Again, while twisting the handle to disassemble it from the mesh, a gentle pressure was put to maintain the tip of the sling in the correct position. Maintaining a pushing force in the sling while disassembling the handles is essential to leave the mesh in close contact with the peri-urethral tissues, which could eventually be seen protruding from the orifices of the polypropylene mesh. The final tension of the TVT-Secur was therefore identical in every patient, as we did not use an intraoperative stress test to adjust the sling. We feel that the information given by such a test in a patient recovering from general anaesthesia is unreliable. The procedure was concluded with the closure of the vaginal incision with a 3–0 polyglactin (Vicryl Rapide, Johnson & Johnson Intl., Brussels, Belgium) running suture and a vaginal packing with lubricated gauze.

Postoperative analgesia consisted of paracetamol (1 g orally twice daily) and ibuprofen (400 mg, orally twice daily). The Foley catheter and the vaginal gauze were removed on the day after surgery and the postvoid residual urine volume (PVR) was measured by ultrasonography; if the PVR was <100 mL the patient was discharged on prophylactic antibiotics and conventional analgesic treatment (paracetamol, 1 g, orally, 8/8 h). At discharge patients were asked to rate the pain felt in the first 24 h, using a visual analogue scale of 1–10.

Patients were re-assessed by the first author at 1, 6 and 12 months after surgery. For the purpose of the present analysis there was an extra follow-up in July 2008, so the follow-up reported refers to this last assessment. The presence of pain and LUTS, including urine leakage, was elicited at each visit. In addition, patients repeated a cough and Valsalva stress test with the bladder previously filled to 300 mL (considered positive when there was urine leakage) and the KHQ at 1 and 6 months. Treatment was considered successful if the patient ceased to wear continence pads and reported no episodes of UI, and the stress test was negative (patient cured) or if there was at least a ≥50% decrease in daily pad use, and the patient answered 'yes' to the question: 'are you satisfied with the result of the surgery?' (patient improved). All other situations were considered as treatment failures. Student's *t*-test was used for the statistical analysis, with $P < 0.05$ considered to indicate significance.

RESULTS

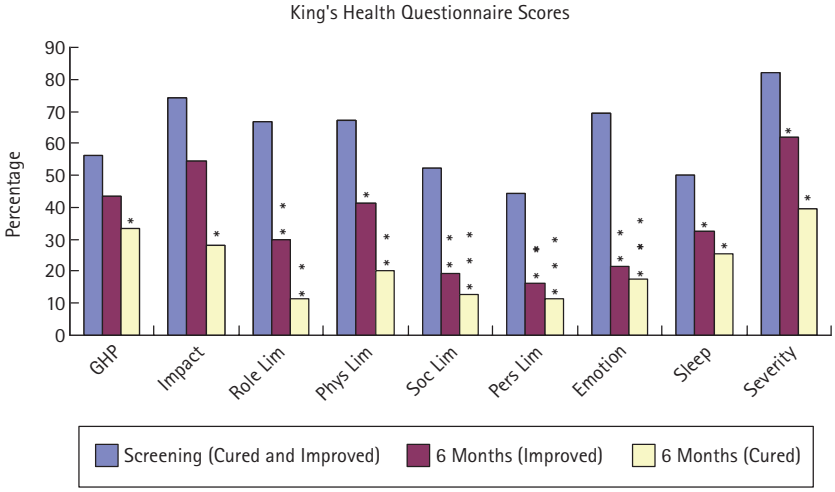
The patients had a mean age of 55 years and a mean parity of two; 91 (85%) had pure SUI and 16 (15%) had mixed UI with predominant SUI symptoms. None of the latter patients had detrusor overactivity. The mean operative duration was 12 min; the surgery was performed under sedation (62 patients, 58%) or spinal anaesthesia (45, 42%). There were no cases of bowel injury, bladder perforation, haematuria, excessive bleeding or haematoma formation.

All patients voided spontaneously and all but one had a PVR of <100 mL. One patient, with a PVR of 300 mL, was discharged with permanent bladder drainage. One week later, at a new voiding trial, the PVR was already <100 mL and the urethral catheter was removed. The mean (median) pain intensity during the first 24 h was 2.3 (2) and usually referred to the vagina. There were no complaints of numbness or pain in the thighs or groin. During the follow-up, one patient was detected to have a major vaginal erosion that dictated removal of the mesh. This was done through an anterior vaginal incision, similar to the one used for sling placement. The mesh was easily identified at the midline, loosened 3 cm to each side and, because there was no evidence of infection, simply cut and removed. Another five patients had minor erosions (<5 mm) that were successfully treated with the application of topical oestrogens. Mild *de novo* urgency appeared in six patients (5.6%), which was easily controlled with appropriate anticholinergic therapy.

One patient never appeared at the follow-up visits, so data are available for 106 women. The mean (median, range) follow-up was 15 (14, 11–22) months. At the last assessment 75 patients (71%) were cured and 15 (14%) were improved, corresponding to an overall success rate of 85%, with the procedure failing in 16 (15%).

The KHQ scores before and after surgery were available for 68 women; this group were demographically similar to that of the whole sample, with a mean age of 57 years and a mean parity of 1.8. The cure rate was 69% (47 patients) and the improvement rate 18% (12 patients), making a success rate equivalent to that of the all patients. At 6 months after surgery there was a significant reduction in the KHQ scores, in both the groups designated

*FIG. 1. The KHQ scores of the cured (47) and improved (12) patients, before and at 6 months after placing the TVT-Secur; P *< 0.05, **<0.01 and ***<0.001.*



cured and improved. Figure 1 shows the partial scores for these two groups, at baseline and at 6 months after surgery.

DISCUSSION

The ideal mid-urethral sling should be simple to place, require a short hospital stay, cause rare and mild complications, provide a rapid return to active life, be reproducible and give a high success rate. The present study evaluating the short-term results of TVT-Secur seems to confirm that this 'mini-sling' might fulfil these criteria.

The procedure is simple, requiring a single 1-cm incision in the anterior vaginal wall, and the extension of the dissection required to create a passage for introducing the sling is very limited. There were no cases of bladder perforation, bowel injury or blood vessel injury leading to severe bleeding or large haematoma formation. Complications as a whole were less than those reported for retropubic or transobturator slings; the reported bladder perforation rates associated with TVT are 0.7–6.5% [10,14,15]. For transobturator tapes, although generally believed to be exempt from such a hazard, can be associated with bladder perforation [16]. The pain reported by patients was mild and easily controlled using common analgesics. Persistent groin pain or severe, eventually lethal complications, associated with retropubic or transobturator slings, are not reported from large series [15,17], but they have occurred with both procedures. In all, 38 cases of bowel perforation were reported to the USA Food and Drug Administration/ Manufacturer and User Facility Device Experience Database, all related to retropubic slings, causing six deaths in all [8]. Thirty-six vascular injuries were reported after retropubic (33 cases) and transobturator slings (three cases), responsible for three deaths [8].

The total operative time necessary for placing a TVT-Secur was 12 min, which compares favourably with times reported for TVT and Monarc™ (American Medical Systems, Minnetonka, MI, USA) slings in the TORP study, at 18.5 min and 14.6 min, respectively [14]. Although cystoscopy was not used systematically in the present study during surgery, there is a report of bladder injury during TVT-Secur placement [18]. Thus, cystoscopy might be recommended at the end of the procedure, especially when surgeons are gaining experience with the technique.

The hospital stay was 1 day; in our centre such a duration was dictated by the process of reimbursement of our local health system, that obligates a minimum hospital stay of 24 h. However, we believe that this procedure can easily be done as an ambulatory procedure. In addition, we only had one case of transient urinary retention (1%) while for retropubic slings the reported rates are 4–17% [14,15] and for transobturator tapes 2.6–11% [10,15].

The reproducibility of a surgical procedure designed to treat female SUI is essential to guarantee the success of the operation worldwide. The technique for placing the TVT-Secur is easily and rapidly learned by the average surgeon qualified to treat SUI. However, caution is required when placing the TVT-Secur absorbable extremities in the fibrous attachment of the internal obturator muscle, as this might not be quickly achieved by inexperienced surgeons [19]. Another important point in the surgery is the disconnection of the inserter from the mesh. This entails a gentle twist of the handle while gently pushing the device into the patient's body. This maintains the ideal tension of the mesh which should be left abutting the urethra, forcing the peri-urethral tissues to protrude slightly through the mesh orifices. This is radically different from what has been taught to surgeons about retropubic or transobturator sling placement. In these cases the mesh must be left tension-free, with 2–3 mm between the mesh and the urethra. A recent study showed that the accumulation of experience affects the success rate with TVT-Secur [13] and thus surgeons should refrain from attempting this surgery before receiving adequate training.

In the present study we used patient-reported symptoms and a stress test to define cure. These variables are commonly used to define cure after surgical treatment for SUI [20,21]. Although theoretically more objective for measuring incontinence, pad tests were shown to lack reproducibility between consecutive examinations [22]. Moreover, there is no direct correlation between this objective measure and subjective measures of improvement [22]. The success rate of TVT-Secur in the present study, at a mean follow-up of 15 months, was 85%; other recent short-term reports on TVT-Secur give success rates of ≈90% [13,23,24]. The success rates offered by TVT-Secur are therefore similar to those offered by other procedures also at a short follow-up. At 3 months the TORP study reported objective cure rates of 79.3% and 84.5% for retropubic and transobtutator slings, respectively [14]. Porena *et al.* [15] reported a rate of 'dry' or 'improved' patients with a 31-month follow-up at 90% for both retropubic or transobturator sling. Only Laurikainen *et al.* [10] obtained objective cure rates greater than those cited here; at the 2-month follow-up the cure rates were 98.5% for the retropubic and 95.4% for the transobturator sling. The important values are

those that reflect the cure rates at ≥5 years of follow-up, and these are still lacking for TVT-Secur.

In conclusion, this initial report on the use of TVT-Secur for treating women with predominantly SUI shows that the technique is simple and free from severe complications. As long as the surgical steps are followed strictly during the operation, a high success rate can be expected, although the reproducibility of this technique might require adequate training [19]. Furthermore, studies are needed to establish the long-term results of the procedure.

CONFLICT OF INTEREST

None declared.

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Correspondence: Francisco Cruz, Department of Urology, Hospital de São João, E.P.E, Alameda Professor Hernâni Monteiro, 4200-319 Porto, Portugal.
e-mail: cruzfjmr@med.up.pt

Abbreviatons: **TVT**, tension-free vaginal tape; **(S)UI**, (stress) urinary incontinence; **PVR**, postvoid residual urine volume; **KHQ**, King's Health Questionnaire.

PUBLICATION 2

Single-incision sling system as primary treatment of female stress urinary incontinence: prospective 12 months data from a single institution.

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Single-incision sling system as primary treatment of female stress urinary incontinence: prospective 12 months data from a single institution

Rui Oliveira, Francisco Botelho, Pedro Silva, Alexandre Resende, Carlos Silva, Paulo Dinis and Francisco Cruz

Hospital de São João, Serviço de Urologia, Porto, Portugal

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Study Type – Therapy (case series)
Level of Evidence 4

What's known on the subject? and What does the study add?
Single-incision slings (SIS), requiring very limited intracorporeal dissection, have been recently introduced on the premise that they might increase safety of female stress urinary incontinence treatment. However, their success rate has been insufficiently evaluated.

This is a large prospective series on Mini-Arc SIS, with data on 105 patients available at a mean follow-up of 12 months. Success rates are comparable while morbidity was lower and milder than that associated retropubic or transobturator slings. This study warrants a large-scale randomized comparative study between Mini-Arc and standard mid-urethral tapes, matured at longer follow-up time.

OBJECTIVE

- To investigate the success and complication rates for Mini-Arc™ single incision sling in the treatment of female stress urinary incontinence (SUI).

MATERIALS AND METHODS

- A total of 119 female patients with pure SUI were enrolled in a prospective study. From these, 105 were available with a minimum follow-up of 6 months and a mean follow-up of 12 months.
- Success, as determined by patient-reported outcomes, and complication rates, as well as impact of learning curve, body mass index (BMI), intrinsic sphincter deficiency (ISD), incontinence severity and age were investigated.

RESULTS

- Cure rate was 80% and improvement rate was 11%. Pain intensity was minimal on a visual analogue scale and transient urinary retention occurred in three patients, one requiring sling section.
- *De novo* urgency was reported by 6% of women. Severe incontinence was less likely to be cured: 70% if >5 pads per day (ppd); 94% if <2 ppd; 94% if 2–4 ppd, $P < 0.05$).
- There was no difference in success rates between the first 50 and the last 50 patients. BMI, ISD and age also did not influence success rate.

CONCLUSION

- Mini-Arc™ attained high success rates at 1 year follow-up. The procedure was easy to learn and was associated with very low and mild morbidity. Severe incontinence was identified as a risk factor for failure.

KEYWORDS

female stress urinary incontinence, mid-urethral sling, suburethral tape, Mini-Arc, mini-sling, single incision sling

INTRODUCTION

Female stress urinary incontinence (SUI) is the most common form of incontinence in the western world. It reduces quality of life, causes important social limitations and represents an important economic burden [1]. Pelvic floor muscle training can improve continence, particularly in younger patients with mild forms of the disease [2]. Prolonged physical exercise associated with weight reduction may achieve cure rates of up to 25% [3]. However, the success of conservative treatments is highly dependent on a patient's persistence with therapy. Therefore, for most women, surgery remains the mainstay of SUI treatment. Simplification of the surgical technique, aimed at reducing morbidity while maintaining a high cure rate, has been a natural evolution, therefore increasing women's adherence to treatment. Retropubic (RP) [4] and transobturator (TO) [5] slings replaced worldwide the previously considered standard procedure, Burch colposuspension [6]. In spite of the excellent success rates achieved with RP and TO tapes, shorter, single-incision slings were designed to further minimize surgical morbidity. TVT-Secur™ (Gynecare, Ethicon, Sommerville, NJ, USA), the first single-incision sling, was launched in 2006 and paved the way [7–10], with only four reports of bladder injury [10,11] and two cases of major bleeding [9,12], in almost 1000 patients treated. No cases of urethral or bowel injuries and persistent groin pain were referred and no deaths occurred [7–11]. This

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low morbidity compares favourably with that reported for RP and TO slings [13,14]. However, TVT-Secur™ cure rates at mid-term appear to be lower than those after standard slings [15], eventually related to the technical complexity of the procedure [7,16].

The second single-incision sling to be introduced worldwide was the Mini-Arc™ (American Medical Systems, Minnetonka, MN, USA). It is an 8.5 cm long monofilament macroporous type 1 polypropylene mesh, with integrated anchor-like self-fixating extremities, and was introduced in 2007. Initial experience was promising with little morbidity and success rates in the short-term are comparable with the conventional RP or TO slings [17,18].

In this paper we present our experience with Mini-Arc™, as a short-term prospective evaluation, analysing success rates and complications. In addition we investigated the influence of incontinence severity, body mass index (BMI), intrinsic sphincter deficiency (ISD), age and learning curve on success rate. Previous data have been presented in abstract form [19].

MATERIALS AND METHODS

A total of 119 consecutive women from our surgical waiting list, with pure SUI, were prospectively enrolled in this study. Preoperative evaluation included a medical history focused on urogynaecological and neurological assessments. All patients were submitted to preoperative cystometry, uroflowmetry and Valsalva leak point pressure (VLPP) measurements. In all cases, SUI was shown urodynamically. Women with previous surgeries for SUI, genital prolapse Grade 2 or higher (by the Pelvic Organ Prolapse Quantification System), complaints of urgency, frequency, nocturia or demonstration of detrusor overactivity were excluded. Terminology used in this manuscript is defined by the ICS Standardization Sub-committee [20]. Written informed consent was obtained from every patient. Preoperative impact of SUI on quality of life was assessed using the King's Health Questionnaire (KHQ) Score [21].

All surgeries were carried out with the patient in the lithotomy position, with hips flexed at 90 degrees. Intravenous sedation was the preferred type of anaesthesia (71 patients, 68%) and spinal anaesthesia was used in the remainder (34 patients). Preoperative antibiotic prophylaxis consisted of a single injection of ceftriaxone. The bladder was evacuated through a 16Fr catheter. A 1.5-cm anterior vaginal wall incision was performed, 1 cm posterior to the urethral meatus. Sharp para-urethral dissection was carried on laterally, until the scissors reached the pubic rami. The direction of needle introduction was towards the point where the medial border of the adductor longus tendon and the inferior pubic ramus met, as determined by palpation. The tip of the needle passer was then keyed to the sling extremity, so that the mesh lay on the convexity of the passer. Slight tensioning of the mesh with the index finger was shown to be helpful. The procedure was performed first on the right side of the patient. The sling was advanced through the created trajectories and was then pushed along the posterior surface of the ischio-pubic ramus, until the midline mark on the mesh was underlying the urethra. Care was taken not to perforate the obturator membrane, as the hook-shaped extremity should lie fixed in the obturator internus muscle and fascia. The procedure was then repeated on the left side, making sure that the mesh was not twisted, and the needle introducer was disengaged as soon as a tension-free positioning under the urethra was achieved. Vaginal perforation was ruled out on either side. We did not use the redocking procedure as described by the manufacturer because we did not perform any intraoperative stress test to assess sling tensioning. The surgical wound was then closed with a 3-0 polyglactin (Vicryl Rapide, Johnson & Johnson Intl., Brussels, Belgium) running suture and a vaginal gauze was positioned. The bladder catheter was left in place.

Postoperative analgesia, comprising paracetamol (1 g, orally, three times daily) and ibuprofen (400 mg, orally, three times daily). On postoperative day 1, the vaginal gauze and the Foley catheter were removed and postvoid residual urine volume was measured after spontaneous voiding. If estimated to be below 100 mL, patients were discharged on conventional analgesics (paracetamol, 1 g, orally, three times daily). At discharge, women were asked to rate the pain felt in the first 24 hours through a 0–10 visual analogue scale.

Routine postoperative assessment of these patients comprised visits at 1, 6 and 12 months after the procedure. Fourteen patients who presented at the 1-month postoperative visit did not respond to the other appointments; 13 of these patients were considered cured at that visit and one had a major acute neurological disability so lower urinary tract symptoms could not be assessed. Therefore data from the 6-month visit, where KHQ and uroflowmetry were re-evaluated, were available from 105 patients. In addition, patients with a follow-up over 6 months were invited for another evaluation to access their lower urinary tract symptoms, including urine leakage, pain and complications. In all, 71 patients had a follow-up between 12 and 21 months. The total mean follow-up of the cohort at the present report is therefore 12 months.

Patients were considered cured only if they did not report any episodes of urine leakage and ceased to wear any protection for incontinence. If a patient reported persistence of urine leakage or maintained the use of incontinence protection but the number of pads used decreased by >50% and if they answered affirmatively to the question 'are you satisfied with the result of the surgery?', then she was considered improved. All other cases were reported as failures.

The BMI was determined using WHO definitions [22]. It was considered that ISD was present if a VLPP <60 mmH_2O was found [23]. The VLPP was determined by the measurement of intravesical pressure in the lithotomy position, at the volume at which patients reported a normal desire to void. Urodynamic evaluations were performed according to the criteria established by the ICS [24]. Incontinence was stratified by number of pads per day (ppd) in three groups according to severity: <2; 2–4; ≥5. Preoperative and postoperative free maximum flow rate (Q_{max}) and KHQ score were compared using a matched Student's *t* test. Age, ppd, BMI and VLPP were associated with success rates using chi-squared (with Yates correction for continuity, if applicable) for the univariate analysis. Success rates of the first and last 50 cases were also compared. Statistical analysis was performed using SPSS version 17.0 (SPSS Inc., Chicago, IL, USA) and $P<0.05$ was considered significant.

RESULTS

Patients had a mean ± SD age of 52 ± 11.1 years, mean BMI was 28.6 ± 4.9 kg/m^2 with 73

patients <30 and 32 patients with BMI ≥30; mean parity was 2.2 ± 1.5. Mean pad usage was 2.8 ± 2.0 ppd with 16, 79 and 10 patients using <2, 2–4 or ≥5 ppd, respectively. Mean duration of SUI was 7.4 ± 6.3 years. Mean VLPP was 101.5 ± 33.5 cm H_2O, with 14 patients having VLPP<60 cm H_2O (13%). Preoperative mean maximum flow rate was 27.0 ± 8.7 mL/s.

There were no cases of bowel injury, bladder perforation, haematuria, vaginal wall laceration, major bleeding or clinical haematoma formation. The mean pain score in the first 24 h was 1.0 ± 1.4. One patient had prolonged pain referred to the right groin that slowly waned over the initial 6 months. Two patients (2%) with an estimated postvoid residual urine volume >100 mL on the day of discharge and one (1%) not able to void spontaneously were discharged with an indwelling catheter. One week later, a voiding trial was repeated. The first two patients had a postvoid residual urine volume <100 mL, so the catheter was removed. The third maintained the incapacity to void and was therefore offered a midline sling section. Four patients (3%) reported the appearance of mild dyspareunia after the procedure, which was managed with lubricating cream until spontaneous resolution. Two patients (2%) had *minor* (<1 cm) vaginal mesh exposure that was successfully treated with sexual abstinence and topical oestrogen application. Mild *de novo* storage symptoms (urgency, frequency, nocturia) were referred by seven patients (6%), but resolved spontaneously over time or were easily controlled with anticholinergic therapy.

With a mean follow-up of 12.4 months (range: 7–21 months), 84 patients were cured (80%) and 12 were improved (11%), amounting to a global success rate of 91%. Success rate in patients using >5 ppd at baseline was 70% whereas in patients who used <5 ppd it was significantly higher, 94% ($P = 0.039$). In contrast, VLPP, BMI and age had no statistically significant influence on success rate (Table 1). No differences were noticed between success rates of the first and last 50 cases (92% vs 90%, $P = 1$).

An additional subanalysis was performed by evaluating cure and improvement rates in those patients who concluded the 6-month and 12-month follow-up visits. At the 6-month visit, the entire cohort, 105 patients, was observed. Eighty-six patients were cured (82%) and 11 were improved (10%). The KHQ scores of the cured patients for the preoperative period and the 6-month observation showed a significant reduction, consistent with SUI cure. The KHQ subscores are displayed in Fig. 1. At the 12-month visit, 71 patients were available of whom 55 were cured (77%) and eight were improved (11%).

Variable (*n*)	% Improved	*P* value
Pads per day		
<2 (16)	93.8	0.039
2–4 (79)	93.7	
≥5 (10)	70.0	
Body mass index		
<30 (73)	90.3	0.718
≥30 (32)	93.8	
Age (years)		
<65 (89)	91.0	1
≥65 (16)	93.8	
Valsalva leak point pressure		
<60 (14)	92.9	0.185
60–90 (23)	81.0	
>90 (68)	93.9	

TABLE 1
Correlation of stratified baseline characteristics with percentage of improved patients (improved and cured)

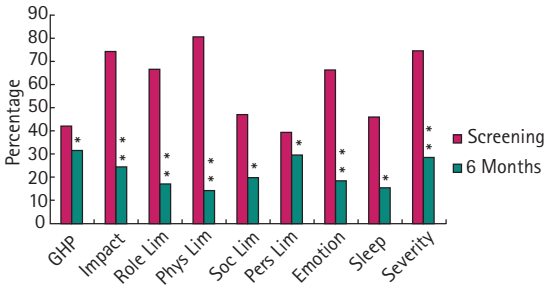

FIG. 1.
*The King's Health Questionnaire scores of the cured patients, before and at 6 months after placing Mini-Arc™; *P < 0.05, **P < 0.01.*

A significant reduction in the mean Q_{max} occurred after Mini-Arc™ placement. Q_{max} was 27.0 ± 8.7 mL/s at baseline and decreased to 23.7 ± 7.5 mL/s at 6-month follow-up ($P < 0.001$).

DISCUSSION

The data after 12 months of follow-up show a success rate of Mini-Arc™ of 91%, associated with a marked overall increase in quality of life. Complications were few and mild in nature. The surgical procedure was shown to be simple and easy to teach and learn by the fact that no differences were noticed between success rates among the first and last 50 cases. In addition, no decrease in success rate with time was observed.

The definition of cure used in this study employed patient-reported outcomes. Although the use of subjective criteria for cure is frequently overlooked in favour of objective tests, as pad weight or cough test, a trend supporting subjective evaluations of cure is gaining advocates [25]. For cure, a statement of no episodes of urine loss and no protection use by the patient is particularly precise when associated with improvement of quality of life determined by an appropriate questionnaire [25]. Interestingly, subjective criteria may even be more demanding than objective parameters, as one can observe from the TVT/Burch [6] and RP/TO [26] comparative studies, where cure rates based on subjective criteria were systematically lower. In addition, the usually considered objective criteria may lack reproducibility. The cough test is frequently negative for incontinence because of patient embarrassment. Large intra-observer and inter-observer variations have been reported concerning pad weight [27,28]. Hence, the high success rate shown in this study, based on patient-reported outcomes and quality of life assessment, is strongly in favour of the value of the surgical procedure.

The follow-up of this study is still short. Although it includes 71 patients with a follow-up time between 12 and 21 months, the mean period of observation is 12 months. Therefore the study cannot fully respond to a pivotal issue when dealing with surgeries for the treatment of female SUI, the capacity of the procedure to remain effective long-term is not evaluated. The follow-up of this study is far from the experience of 11 years with TVT™ or from the 5-year follow-up of the comparative study between TVT™ and Burch colposuspension. It may be argued, however, that studies with conventional RP and TO slings did not show any meaningful decay of efficacy over time. The success rate reported by Rinne *et al.* [29] in a cohort of 267 women randomized to TVT™ or TOT™ and evaluated at a 12-month follow-up was unchanged at the 36-month re-evaluation [30]. Therefore, many large randomized studies comparing RP and TO slings are now using 12-month follow-up a as reasonable minimum time point for reporting the initial results [26,31]. Nevertheless, a longer period of close vigilance of the patients included in this cohort is obviously mandatory before definitive assumptions can be made concerning the durability of Mini-Arc™.

One important goal of SUI management is the identification of risk factors negatively affecting the cure rate of a particular treatment. Commonly admitted risk factors such as failure of a previous anti-incontinence surgery, occurrence of detrusor overactivity or the presence of strong urgency incontinence before operation could not be evaluated [32] in this study because these were exclusion criteria adopted in patient selection. However, other risk factors were investigated including severity of incontinence [31], weak sphincter function [33] or BMI [34]. Women with more severe forms of incontinence (≥5 ppd) had less chance of being cured or improved (70% if ≥5 ppd; 94% if <2 ppd; 94% if 2–4 ppd, $P < 0.05$). Severity of incontinence was also recognized by Rechberger *et al.* [31], in their series. Women with Stamey type III SUI, which was defined as total incontinence or urine loss without any relation to physical activity or position, was shown to decrease the cure rate of TO placed slings but not RP slings [31]. Consequently, it is reasonable in future studies to restrict Mini-Arc™ to women with mild to moderate forms of SUI. In this context, the relevance of sphincter activity was surprising. A low VLPP was not found to be a risk factor for Mini-Arc™ failure. In fact, the 14 women with VLPP <60 cmH_2O, indicative of ISD, had success rates equivalent to those of the global cohort. However, a weak sphincter has been recognized as a risk factor to the success of TO slings [31,35]. Considering the resemblance of Mini-Arc™ to TO sling placement, a word of caution should be sounded about the use of this single-incision sling in patients with urodynamic evidence of ISD before larger studies are conducted.

The BMI is directly associated with the risk for SUI [36]. A decrease of weight associated with programmed physical activity was shown to cure a high percentage of patients with SUI [3]. A very high prevalence of SUI is found among women attending bariatric surgery consultation. Increased intra-abdominal pressure results in increased intravesical pressure, increased pressure at maximum cystometric capacity, and decreased cough pressure transmission from the bladder to the urethra, which may all contribute to SUI in obese patients [37]. As expected, besides being found as a risk factor for incontinence, morbid obesity (BMI > 35) has been identified as a risk factor for the success of SUI surgery [38]. In contrast, a BMI < 35 seems not to influence success rate [39–41]. Likewise no influence of BMI could be detected on the success rate as one-third of the patients had a BMI>30. Yet, we still advise a special counselling of overweight women regarding Mini-Arc™ use because deterioration over time cannot be totally ruled out at this moment.

Mini-Arc™ becomes fixed by the anchor-like extremities inserted in the internal obturator muscles. In contrast, conventional suburethral slings have a process of fixation that depends upon the interaction of a much longer mesh with the pelvic floor and abdominal or upper tight muscles and fascia, depending on the preferred route of placement. Hence, the strength of pelvic floor tissues may influence single-incision sling fixation more than conventional slings. To support this assumption, a recent study with TVT-Secur™ [15] reported a very poor outcome in patients with concomitant pelvic organ prolapses. Patient age is another factor that influences pelvic floor tissue quality. Nevertheless, the success of Mini-Arc™ in the present study was not influenced by age.

Low morbidity is one of the expected advantages of single incision slings. Available reports indicate that few cases of bladder perforation, bowel injury, major bleeding or other life-threatening conditions are to be expected with single-incision slings [7,9]. This study confirms the safety of Mini-Arc™, as the complications reported were few and mild. Two points may deserve further mention. First, bladder perforation did not occur in any woman; if these data are confirmed by larger studies, it may be appropriate to omit cystoscopy after Mini-Arc™ placement. Second, the Mini-Arc™ procedure was virtually painless. This is quite different from studies on RP or TO slings where this complication is commonly reported [42].

Although tension-free, Mini-Arc™ is slightly obstructive as a significant decrease in urinary free flow was found. However, the percentage of *de novo* urgency was low and easily manageable medically, suggesting that obstruction was clinically irrelevant. Likewise, only two cases of high postvoid residual urine volume and one case of urinary retention occurred after the procedure, which is far less than the urinary retention commonly reported in series of conventional slings [13]. Dyspareunia was mild and transient, probably the result of a more superficial insertion of the mesh in these cases. However, the incidence of dyspareunia in this series is far below that reported in TO procedures [43].

The lack of a comparator arm and the follow-up time being restricted to a mean of 12 months limit the findings reported here. However, they still show that Mini-Arc™ is a reproducible technique, simple to perform and easy to learn, that offers high cure rates at 1 year follow-up and that is associated with few and mild complications. Recent initial reports of ongoing trials comparing Mini-Arc™ with conventional slings seem to support these results as no differences in outcome between Mini-Arc™ and TO conventional slings have been reported [44,45].

CONFLICT OF INTEREST

None declared.

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45 **Oliveira R, Botelho F, Silva P, Silva C, Dinis C, Cruz F.** Randomized clinical trial comparing TVT-O™, TVT-Secur™ and Mini-Arc™. Outcome at 12 months follow-up. *Eur Urol Suppl* 2010; **9**: 145

Correspondence: Francisco Cruz, Department of Urology, Hospital de São João, E.P.E., Alameda Professor Hernâni Monteiro, 4200-319 Porto, Portugal.
e-mail: cruzfjmr@med.up.pt

Abbreviations:: **SUI**, strees urinary incontinence; **RP**, retropubic; **TO**, transobturator; **BMI**, body mass index; **ISD**, intrinsic sphincter deficiency; **VLPP**, Valsalva leak point pressure; **KHQ**, King's Health Questionnaire; **ppd**, pads per day.

PUBLICATION 3

Exploratory Study Assessing Efficacy and Complications of TVT-O, TVT-Secur, and Mini-Arc: Results at 12-Month Follow-Up.

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Platinum Priority – Female Urology – Incontinence

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Exploratory Study Assessing Efficacy and Complications of TVT-O, TVT-Secur, and Mini-Arc: Results at 12-Month Follow-Up

Rui Oliveira [a], *Francisco Botelho* [a], *Pedro Silva* [a], *Alexandre Resende* [a], *Carlos Silva* [a], *Paulo Dinis* [a,b], *Francisco Cruz* [a,b,*]

[a] *Hospital de São João, Serviço de Urologia, Porto, Portugal*
[b] *IBMC, Institute of Molecular and Cellular Biology, Porto, Portugal*

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Abstract

Background: Contemporary surgical treatment of female stress urinary incontinence (SUI) includes retropubic and transobturator (TO) midurethral slings (MUS). Case series of single-incision slings (SIS) have shown similar outcomes with lower morbidity.

Objective: Our aim was to assess the cure rates, complications, and quality-of-life impact of one standard TO MUS and two SIS.

Design, setting, and participants: Ninety consecutive patients with clinically and urodynamically proven SUI were enrolled in an exploratory randomised phase 2 trial. Patients with previous SUI surgery, major pelvic organ prolapse, mixed incontinence, or detrusor overactivity were excluded.

Interventions: Patients were treated randomly with TVT-O, TVT-Secur, or Mini-Arc.

Measurements: Postoperative visits were scheduled at 6 and 12 mo. The King's Health Questionnaire (KHQ) was repeated at 6 mo. Cure was defined as the absence of urine leakage, no pad use, and a negative cough test at 12 mo. Pain and other complications were also investigated.

Results and limitations: Cure rate was 83% after TVT-O, 67% after TVT-Secur, and 87% after Mini-Arc. Improvement was found in 10%, 13%, and 7% of the patients, respectively. Failures were 7% after TVT-O and Mini-Arc and 20% after TVT-Secur.

TVT-O and Mini-Arc improved at least 15 points in >80% of the patients in six KHQ domains, whereas TVT-Secur could only achieve improvement in three of the nine domains. The pain score was lower in the Mini-Arc group. Complications were more numerous after TVT-O. This study has the limitations inherent in a phase 2 trial with a follow-up limited to 12 mo.

Conclusions: Mini-Arc offers cure and improvement rates similar to TVT-O, whereas TVT-Secur may yield an inferior outcome. These findings recommend the urgent launch of large randomised phase 3 studies comparing conventional MUS with SIS, with Mini-Arc the advised option.

* Corresponding author. Department of Urology, Hospital de São João, E.P.E., Alameda Professor Hernâni Monteiro, 4200-319 Porto, Portugal. Tel. +351225513654; Fax: +351225513655.
E-mail address: cruzfjmr@med.up.pt (F. Cruz).

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1. Introduction

Midurethral slings (MUS), either retropubic (RP) or transobturator (TO), are the most common contemporary surgical treatment for female stress urinary incontinence (SUI). Two facts have largely contributed to this situation: (1) Without compromising incontinence cure rate, RP MUS cause less morbidity and shorter hospital stays than the Burch colposuspension [1], and (2) RP and TO MUS have been shown repeatedly to have equivalent success rates [2,3]. Nevertheless, neither is free of complications, mainly dictated by the blind course of the introducer devices. The RP course may perforate the bladder, whereas the TO passage is associated with vaginal perforation and neurologic impairment leading to protracted thigh pain and upper leg weakness [4]. Both routes occasionally are associated with life-threatening complications including bowel perforation, major vessel disruption, and perineal gangrene [5]. In addition, voiding dysfunction and vaginal mesh exposures may also complicate MUS [6].

The quest to minimise the morbidity of MUS has determined the appearance of yet another group of shorter MUS, requiring a single vaginal incision for placement. Available data, mainly from case series [7,8], validate that assumption. However, reported success rates are extremely variable, ranging between 40% [9] and 100% [10], suggesting that considerable differences exist among single-incision slings (SIS) in what concerns efficacy. In spite of this evidence, comparative studies of SIS have not been performed up to now.

Our exploratory study assessed two SIS, TVT-Secur (Gynecare; Ethicon Inc., Somerville, NJ, USA) and Mini-Arc (American Medical Systems, Minnetonka, MN, USA), and TVT-O (Gynecare; Ethicon Inc., Somerville, NJ, USA), a conventional TO MUS. Cure and complication rates and quality of life were investigated at 6- and 12-mo follow-up. Previous results were presented elsewhere [11].

2. Patients and methods

We enrolled consecutive patients from our surgical waiting list with clinically and urodynamically proven SUI associated with urethral hypermobility between January and September 2008. The three slings investigated in the study were available in the hospital and could be indicated for any of the patients included. No patients refused randomisation. All patients gave written informed consent before entering the trial, which was authorised by the Ethics Committee of Hospital São João, Porto, Portugal.

Preoperative evaluation included a medical history comprising urogynaecologic and neurologic assessments and a urodynamic evaluation following International Continence Society recommendations [12,13]. Body mass index was determined according to the World Health Organisation definitions [14]. Cystometry and valsalva leak point pressure (VLPP; using intravesical pressure, measured in the lithotomy position, with the bladder filled at the normal desire to void) were performed. Intrinsic sphincter deficiency (ISD) was considered if VLPP was <60 cm H_2O [15].

Women with previous surgeries for SUI, genital prolapse stage ≥ 2 (by the Pelvic Organ Prolapse Quantification System), complaints of urgency, frequency, nocturia, or demonstrating detrusor overactivity were excluded.

Impact of SUI on the quality of life was assessed by the King's Health Questionnaire (KHQ) score [16]. A 15-point reduction in each domain was considered indicative of improvement. The surgeries were performed by the authors with the patient in the lithotomy position, with hips flexed at 90°. All the surgeons had a minimum experience of 30 cases for each procedure. For prophylactic antibiotherapy, intravenous ceftriaxone 1 g was used. A 16F Foley catheter was introduced and urine evacuated.

TVT-O was inserted according to De Leval [17]. TVT-Secur was positioned in the hammock position [7,18]. The Mini-Arc procedure followed the original description [8,19]. The surgical incisions were closed with a 3-0 running suture, and a vaginal gauze was left in place.

Postoperative analgesia included paracetamol (1 g orally three times a day) and ibuprofen (400 mg orally three times a day). On postoperative day 1, the vaginal gauze and the Foley catheter were removed and residual volume measured after spontaneous voiding (postvoiding residual). If <100 ml, patients were discharged on paracetamol 1 g orally three times a day. At discharge (postoperative day 1), women were asked to rate the pain they felt in the first 24 h, in spite of the standard analgesic protocol, using a 0–10 visual analogue scale.

Postoperative evaluations included visits at 6 and 12 mo following the procedure and were performed between January and September 2009. Patients were asked about lower urinary tract symptoms including urine leakage, pain, and complications. KHQ was repeated at the 6-mo visit. A cough test, at the volume the patient referred to as a normal desire to void, was performed at 12 mo.

Patients were considered cured if they did not report any episodes of urine leakage, ceased to wear any incontinence protection, and had a negative cough test. If a patient reported maintenance of SUI or a positive cough test, but the number of incontinence protections necessary decreased by $>50\%$ and she answered affirmatively to the question "Are you satisfied with the result of the surgery?", the patient was considered improved. All other cases were deemed failures. When used, the term *success rate* indicates the sum of cure and improvement rates.

Previous case series have shown that success rates after conventional TO MUS vary from 35% to 98% [20]; success rates reported after Mini-Arc and TVT-Secur vary from 40% to 100% [7,9,10,19]. Sample size was computed considering a one-stage procedure by Fleming. A minimum of 26 patients in each group was needed assuming a higher proportion for acceptance of 0.85, a lower proportion for rejection of 0.6, an α of 0.05, and a β of 0.1.

3. Results

Table 1 lists the demographics and baseline characteristics of the groups. No patients were lost to follow-up. Five patients had a VLPP slightly below 60 cm H_2O. However, surgeons maintained the surgical option because they believed the most important component for SUI was urethral hypermobility. One patient was randomised for TVT-O (VLPP: 59 cm H_2O), two for TVT-Secur (VLPP: 58 cm H_2O each), and two for Mini-Arc (VLPP: 54 cm H_2O and 58 cm H_2O).

At the 12-mo evaluation, 25 of 30 patients (83%) were cured and 3 of 30 patients (10%) were improved after TVT-O. After TVT-Secur, these numbers were 20 of 30 patients (67%) and 4 of 30 patients (13%), respectively. After Mini-Arc, these numbers were 26 of 30 patients (87%) and 2 of 30 patients (7%), respectively. Failures were 2 of 30 patients (7%) after TVT-O and Mini-Arc and 6 of 30 patients (20%) after TVT-Secur (Fig. 1).

TVT-O and Mini-Arc improved $>80\%$ of patients by a minimum of 15 points in six of the nine KHQ domains

Table 1 – Baseline demographics and clinical characteristics of the enrolled patients

	TVT-O	TVT-Secur	Mini-Arc
No.	30	30	30
Age, yr			
Mean ± SD	52.0 ± 11.7	52.7 ± 10.9	52.6 ± 11.8
Median (range)	52 (38–74)	52 (33–72)	51.5 (29–66)
BMI			
Mean ± SD	27.2 ± 5.3	26.3 ± 6.6	29.8 ± 5.4
Median (range)	27.0 (20.5–38.9)	26.2 (20.2–41.1)	29.1 (22.2–43.3)
Pads per day			
Mean ± SD	3.1 ± 2.0	2.5 ± 1.3	2.5 ± 1.8
Median (range)	3 (1–12)	2 (1–9)	2 (1–15)
Parity			
Mean ± SD	1.5 ± 1.1	1.8 ± 2	2.1 ± 2.2
Median (range)	2 (1–4)	2 (0–5)	2 (1–4)
Years of onset			
Mean ± SD	10.8 ± 8.5	8.4 ± 5.9	8.0 ± 6.1
Median (range)	10 (3–20)	6 (2–20)	8 (1–18)
VLPP			
Mean ± SD	109 ± 18.5	82 ± 39	95 ± 41
Median (range)	105 (59–142)	83 (58–126)	93.5 (54–166)

BMI = body mass index; SD = standard deviation; VLPP = Valsalva leak point pressure.

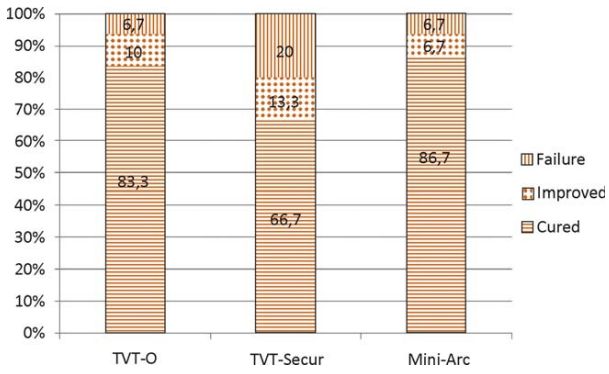

Fig. 1 – Cure, improvement, and failure rates after each midurethral sling at 12-mo follow-up.

(incontinence impact, role limitation, physical limitation, emotion, sleep, severity). TVT-Secur improved >80% of patients by a minimum of 15 points in three KHQ domains (physical limitation, emotion, severity) and very close to 80% in another three (role limitation, sleep, and social limitation) (Fig. 2).

No cases of intraoperative major bleeding, haematuria, urethral injury, or vaginal perforation were observed. No immediate associated surgical procedure was required.

Pain score in the first 24 h had its maximum expression in TVT-O and its minimum in Mini-Arc, and it was intermediate in TVT-Secur (Table 2). Nine patients submitted to TVT-O had some form of complication, and this MUS was, in fact, the sole one that had complications requiring surgical interventions. These surgeries, performed in two patients, consisted of sling transection due to recurrent urinary retention, carried out through a vaginal approach. Five patients developed moderate de novo urgency; two had referred prolonged thigh pain. Concerning TVT-Secur, complications occurred in five patients with one transient urinary retention, one urinary tract infection, and three cases of de novo moderate urgency. Mini-Arc was associated with six complications with one transitory urinary retention, one urinary tract infection, three cases of

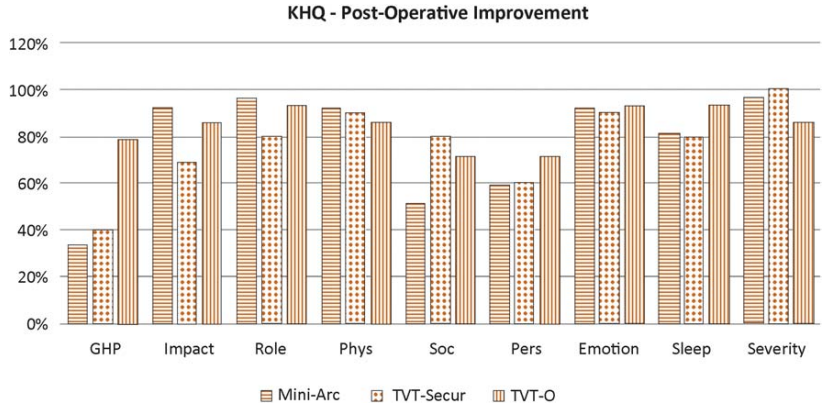

Fig. 2 – Percentage of patients with at least 15 points of improvement on the King's Health Questionnaire (KHQ) domains at 6 mo after placement of each tape. GHP = global health perception; Impact = incontinence impact; Role = role limitation; Phys = physical limitation; Soc = social limitation; Pers = personal limitation.

Table 2 – Postoperative pain score in first 24 h, assessed at discharge by a 0–10 visual analogue scale

	TVT-O	TVT-Secur	Mini-Arc
Postoperative pain			
Mean ± SD	4.5 ± 2.6	2.3 ± 2.3	1.0 ± 1.0
Median (range)	4 (1–10)	3 (0–6)	1 (0–3)

SD = standard deviation.

de novo urgency, and one case of prolonged pain in the thigh.

4. Discussion

This phase 2 study evaluated two SIS, TVT-Secur and Mini-Arc, and TVT-O, a conventional TO MUS, as first surgical treatment for SUI. Data merit two considerations. First, all tested MUS had success rates above the minimum cut-off of 60%. Second, only TVT-O and Mini-Arc overtook the higher cut-off for acceptance.

The in-out TO sling TVT-O was chosen as the standard device due to its resemblance to TVT-Secur and Mini-Arc techniques. The option for TVT, the only MUS compared with Burch colposuspension [1], would introduce the possibility of complications only dictated by the retropubic passage of the needles [3]. In addition, the success rates achieved by RP and TO MUS in patients without ISD are identical [2,3]. As the standard technique, the 93% success rates observed here with TVT-O were similar to those of other studies at 12-mo follow-up. Zullo et al reported an 89% success rate [21], and Rinne et al reported a 93% cure rate [22]. The most common complications, de novo urgency, pain in the thigh, and urinary retention, were also similar to those reported elsewhere [2,3,6].

The 93% success rate attained here with Mini-Arc was identical to that of TVT-O. It should also be stressed that our success rate is in line with those previously reported also after 12-mo follow-up. In a prospective case series, Moore et al reported a cure rate of 91% based on a negative cough stress test ($n = 61$) [8]. Debodinance and Delporte found a success rate of 90% ($n = 68$) [23]. In the two most recent and largest case series, Kennelly et al ($n = 157$) reported a negative cough test in 91% of the patients [13], and Oliveira et al ($n = 105$) accounted for a success rate of 91% [24]. Comparisons between conventional MUS and Mini-Arc are still sparse. De Ridder and Berkers compared Mini-Arc ($n = 75$) to Monarc (American Medical Systems, Minnetonka, MN, USA) ($n = 56$) in a retrospective study [25]. The objective cure rate of 85% at 12 mo was similar with both MUS. These data diverge, however, from those of Basu and Duckett, who randomly assigned 61 patients either to Mini-Arc or to a RP sling (Advantage TVT; Boston Scientific, Natick, MA, USA) [26]. At 6 mo, a failure rate of 41% was found in the Mini-Arc group as opposed to only 3% in the RP sling arm [26]. The limited previous experience of the authors with the TO route may explain such difference, already detected at the first follow-up visit at 6 wk [26]. Thus it may be concluded that the harpoon-like anchoring extremities, once inserted in the internal obturator muscle, provide a grip equivalent to TVT-O. In the latter, fixation is obtained by the passage through the internal obturator muscle, obturator membrane, external obturator, and thigh muscles.

In contrast to Mini-Arc, TVT-Secur offered a success rate of 80%, lower than that observed with the other two MUS. Failures with TVT-Secur amounted to 20%, that is, almost three times higher than in the other groups. In agreement, TVT-Secur only improved (at least 15 points) in >80% of patients in three of the nine KHQ domains. In available case series, TVT-Secur cure rates are highly variable. Our own initial TVT-Secur experience with 105 patients showed success and failure rates at 15 mo similar to those found here [7]. Meschia et al reported similar success rates on 95 patients at 15 mo [27]. Cornu et al, with a mean follow-up of 30 mo ($n = 45$), reported a success rate of 58% [9]. In contrast, in the sole comparative study published up to date, TVT-Secur and TVT-O provided similar outcomes with a cure rate of 83% for TVT-Secur and 81% for TVT-O [28]. The fact that TVT-Secur has been associated with lower success rates deserves some consideration. TVT-Secur has a long learning curve [20]. Even among experienced surgeons, consistent positioning of the TVT-Secur tip may be difficult. Correct placement in some studies was <50% [29]. Moreover, mesh detachment from the introducer blades requires a twisting movement that may enlarge the internal obturator muscle area where the TVT-Secur tip was inserted, compromising mesh adhesion.

The study confirmed the low morbidity of SIS. Pain in the first 24 h was very low in the Mini-Arc group, whereas it was rated four times higher in the TVT-O arm. TVT-O was associated with two cases of urinary retention requiring sling transection. On the contrary, only one case of transient urinary retention occurred in the two SIS patient groups. Two patients in the TVT-O group reported prolonged referred thigh pain. This complication was not observed in the TVT-Secur arm. However, SIS may not be totally exempt from this complication because one patient in the Mini-Arc group complained of thigh pain for 6 mo. As in TVT-O, inadvertent violation of the obturator membrane, nerve lesioning, or haematoma formation could have been the cause of this problem [6]. However, it must represent a rare event because prolonged pain complaints had never been reported with Mini-Arc before [8,13,23–25].

This study has the inherent limitations of phase 2 trials, mainly a small number of patients and a relatively short follow-up time of 12 mo. Although this follow-up time is commonly used in studies investigating the outcome of conventional MUS [2,3], it might be desirable to evaluate SIS at considerably longer follow-up times. Nevertheless, this study clearly indicates the need to conduct well-powered multicentre randomised clinical trials comparing SIS with standard techniques. According to the present results, Mini-Arc should be chosen to be further compared against TO slings. Such comparative studies should probably be compulsory before the introduction of new devices for SUI treatment. A uniform report of outcomes, stating cure and improvement rates, would facilitate comparisons.

5. Conclusions

SIS may offer success rates for SUI equivalent to conventional TO MUS with less morbidity. These exploratory findings should be further investigated in randomised phase 3 studies.

Author contributions: Francisco Cruz had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Oliveira, C. Silva, Dinis, Cruz.
Acquisition of data: Oliveira, Botelho, P. Silva, Resende, C. Silva.
Analysis and interpretation of data: Oliveira, Botelho, Dinis, Cruz.
Drafting of the manuscript: Oliveira, Dinis, Cruz.
Critical revision of the manuscript for important intellectual content: Oliveira, Dinis, Cruz.
Statistical analysis: Botelho.
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PUBLICATION 4

Reply from Authors re: Elisabetta Costantini and Massimo Lazzeri. Surgery for Stress Urinary Incontinence: So Near and Yet So Far. Eur Urol 2011;59:945–6.

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Platinum Priority

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Rui Oliveira [a], *Francisco Botelho* [a], *Pedro Silva* [a], *Alexandre Resende* [a], *Carlos Silva* [a], *Paulo Dinis* [a,b], *Francisco Cruz* [a,b,*]

[a] *Hospital de São João, Serviço de Urologia, Porto, Portugal*
[b] *IBMC, Institute of Molecular and Cellular Biology of Porto, Portugal*

We cannot agree more with Professors Costantini and Lazzeri in their editorial [1], as, in our opinion, they touch on three essential points. First, there is the need to adequately compare new devices with a *gold standard* technique to have sound scientific support ahead of their widespread use for the treatment of female stress urinary incontinence. There is no valid reason to have looser rules for the introduction of slings than for the introduction of new drugs. Second, rigorous and reproducible methods of assessing outcomes must be standardized and obligatory in all published studies, so high-quality evidence can be adequately drawn. These outcome assessments should include objective and subjective (patient-reported outcomes) efficacy evaluations as well as quality-of-life questionnaires. Third, it should be mandatory to investigate materials used to ensure that they remain safe, as they will stay in patients' bodies for many years, most probably the remainder of their lives.

Our contribution is modest [2], but we think these phase 2 studies are crucial in defining which of the new devices should be further compared with standard techniques in well-powered phase 3 clinical trials. Only at this point, if scientific evidence is adequate, should the new devices be available in everyday clinical practice.

Conflicts of interest: The authors have nothing to disclose.

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* Corresponding author. Department of Urology, Hospital de São João, E.P.E., Alameda Professor Hernâni Monteiro, 4200-319 Porto, Portugal. Tel. +351225513654; Fax: +351225513655.
E-mail address: cruzfjmr@med.up.pt (F. Cruz).

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Research Article

Mini-Arc for the Treatment of Female Stress Urinary Incontinence: Long-Term Prospective Evaluation by Patient Reported Outcomes

Rui Oliveira,[1] Alexandre Resende,[1,2] Carlos Silva,[1,2] Paulo Dinis,[1,2] and Francisco Cruz[1,2]

[1] *Faculdade de Medicina da Universidade do Porto, Alameda Professor Hernâni Monteiro, 4200-319 Porto, Portugal*
[2] *Serviço de Urologia, Centro Hospitalar São João, Alameda Professor Hernâni Monteiro, 4200-319 Porto, Portugal*

Correspondence should be addressed to Francisco Cruz; cruzfjmr@med.up.pt

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Single-incision slings were introduced in the surgical treatment of female stress urinary incontinence (SUI) to lessen the morbidity associated with traditional midurethral slings. However, long-term reports on patient satisfaction are still scarce. This study describes the outcome of women treated with Mini-Arc at a mean follow-up of 45 months. In a previous report on 105 women with 15-month mean follow-up, 84 (80%) were found cured and 12 (11%) improved. Now, with a mean follow-up of 45 months, cured/improved patients were reassessed by telephone and completed Patient Global Impression of Improvement (PGI-I), Patient Global Impression of Severity (PGI-S), rated their improvement in a 0–100 scale, and answered if they would recommend the procedure. At 45-month follow-up, 73 women cured/improved were available for evaluation. Over 80% of the cured patients rated the improvement of SUI by the PGI-I as "very much better" or "much better," reported their urinary tract condition to be "normal" on PGI-S, and described their improvement >70%. Ninety percent would recommend this procedure to a friend. The improved-patient population is very small ($n = 7$). This study shows that the majority of patients cured/improved after Mini-Arc placement maintain a high degree of satisfaction at a long-term evaluation.

1. Introduction

According to the European Association of Urology Guidelines on Urinary Incontinence, concerning the treatment of female stress urinary incontinence (SUI), the retropubic insertion of a midurethral synthetic sling (MUS) gives equivalent patient-reported cure of SUI at 12 months, when compared to colposuspension [1]. These guidelines also report that midurethral synthetic sling inserted by either the transobturator (TO) or retropubic (RP) route gives equivalent patient-reported outcome at 12 months [1].

With an obvious trending towards less and less invasive surgical options, single-incision vaginal slings (SIS) have emerged. They require very limited intracorporeal dissection, proposing to further increase safety of suburethral slings, without jeopardizing the success rates reported by conventional RP and TO access [2]. These SIS outcomes are comparable with conventional MUS at short-term follow-up [3–5]. Although sparse, two-year follow-up studies are available and seem to maintain steady success rates over this time [6, 7]. Longer follow-up time reports are needed, to ensure that, in the long run, these SIS offer constant success rates.

The objective of this study is to describe the outcome of women treated with Mini-Arc at a mean follow-up of 45 months, based on a baseline population which has already been reported in a short-term paper [8], after adequate long-term follow-up evaluation. Previously considered cured and improved patients were evaluated to access if their condition remains stable, as reflected in a subjective satisfaction evaluation.

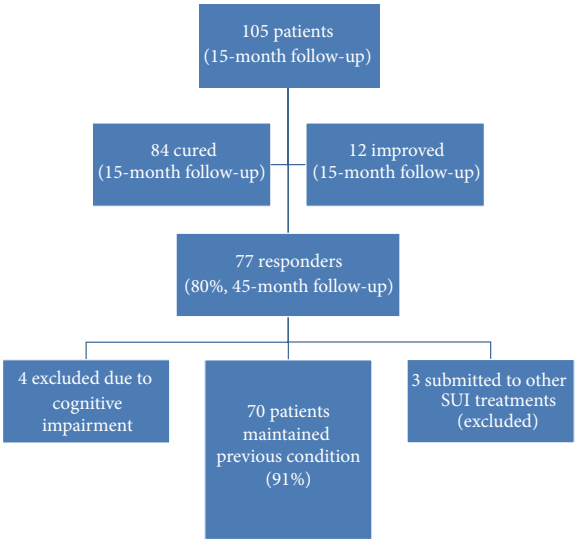

Figure 1: Study subject distribution tree.

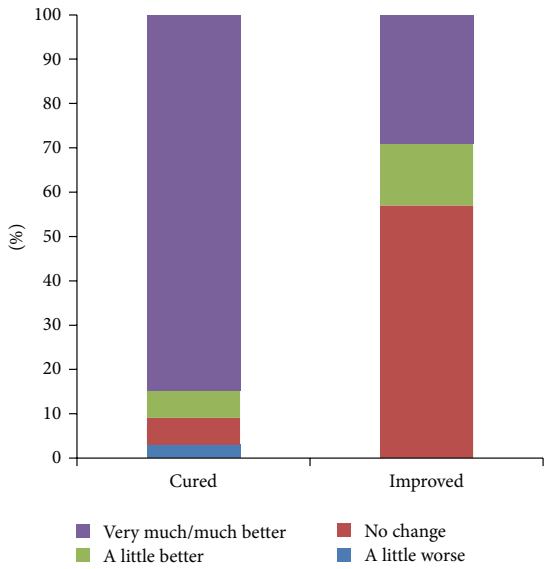

Figure 2: Patient Global Impression of Improvement (PGI-I).

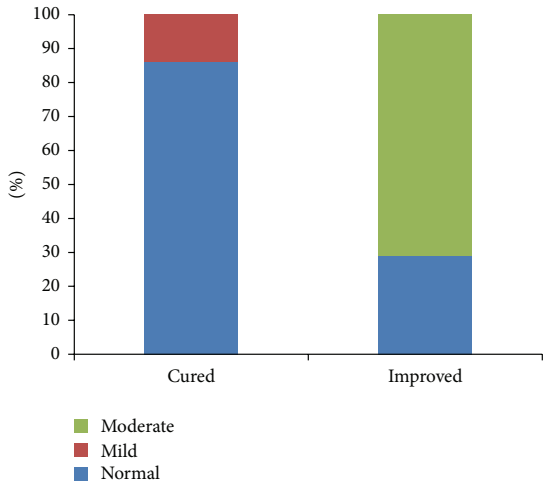

Figure 3: Patient Global Impression of Severity (PGI-S).

2. Materials and Methods

This is a single-centre prospective evaluation of women with urodynamic stress urinary incontinence, which were submitted to Mini-Arc (American Medical Systems, Minnetonka, MN, USA) placement as a primary surgical treatment. Surgical technique, inclusion and exclusion criteria, baseline population characteristics, and short-term outcome and complications have already been described in a previous paper [8]. On this report, on 105 women with a mean follow-up of 15 months (and a minimum follow-up of 6 months), 84 patients (80%) were found cured and 12 (11%) improved. Now, with a mean follow-up of 45 months, cured/improved patients were reassessed by telephone interview and completed Patient Global Impression of Improvement (PGI-I), to access treatment response [9], Patient Global Impression of Severity (PGI-S), to access current SUI condition [9], rated their improvement in a 0–100 scale, and answered if they would recommend the procedure. This study was approved by the institutions' ethics committees and each participant provided written informed consent prior to enrollment.

3. Results and Discussion

At 15-month mean follow-up (initial population of 105 patients), 84 patients were cured and 12 improved. Seventy-seven patients could be contacted (80% of the initial population) and have a current mean follow-up of 45 months (median 43.5 months). Four had to be excluded due to cognitive impairment. Three were submitted to other forms of SUI treatment during the period of follow-up. So, from a total of 77 responders, 70 (91%) maintained the initial cure/improvement situation (Figure 1). Subsequently, 63 previously considered cured and 7 improved were available for analysis.

Fifty-three of the cured patients (84%) rated the improvement of SUI by the PGI-I as "very much better" or "much better" and 4 (6%) considered it to be "a little better." Four patients (6%) answered "no change" and two (3%) "a little worse" (Figure 2). The mean rate of improvement in a 0–100 scale was 81 ± 15, 52 patients (83%) rating improvement >70. Fifty-four patients (86%) reported their urinary tract condition (UTC) to be "normal" on PGI-S (Figure 3). Fifty-seven (90%) would recommend this procedure to a friend.

When analyzing improved patients ($n = 7$), 2 (29%) considered their PGI-I as "very much better" or "much better," 1 (14%) "a little better," and 4 (57%) "no change" (Figure 2). Only 3 patients (43%) rated their improvement

to be equal or superior to 70% in a 0–100 score or would recommend the procedure to a friend. Five patients (71%) answered "moderate" on PGI-S, with only two patients (29%) considering their UTC to be "normal" (Figure 3).

Female urinary incontinence is a very common condition, which can affect around 35% of women; SUI is the most prevalent type, but the consultation and treatment rates are very low [10].

The conservative management is the first treatment option and it usually includes pelvic floor muscle training, which can be very successful in around a fourth of the patients, especially in younger patients with mild forms of the condition [11]. Obese women can adopt a program of weight reduction associated with physical exercise, which can offer a 25% cure rate, since they stay firmly devoted to the program over time and are willing to wait for the improvements [12]. As a result, surgery is the most common form of SUI treatment worldwide. During the last 2 decades we have observed the development of promising SUI surgical techniques and the introduction of suburethral, tension-free slings. TVT (Gynecare, Ethicon, Somerville, New Jersey, USA) was the first device of this kind to be introduced in clinical practice, in 1996 by Ulmsten et al. [13].

According to the European Association of Urology Guidelines on Urinary Incontinence, the RP insertion of a MUS gives equivalent patient-reported cure of SUI at 12 months, when compared to colposuspension [1]. Nonetheless, TVT shows low invasiveness, short hospital stay, reduced risk of prolonged catheterization, and low risk of causing future pelvic organ prolapsed [14]. All together, these characteristics were responsible for the swift replacement of Burch colposuspension as the preferred surgical approach to female SUI [14]. TVT has become the gold standard in the surgical treatment of SUI with high cure rates that subsist at long time follow-up [15]. The blind passage of needles through the RP space was associated with severe complications, such as bladder and bowel perforations and life-threatening vascular injuries [16, 17]. These concerns led to the development of the TO route in 2000, a relatively avascular space for the passage of trocars [18]. However, TO tapes have been associated with prolonged and limitative pain referred to the groin and upper thigh, due to the obturator foramen violation and vaginal perforations due to a more horizontal trajectory of the needle passage [16, 17, 19].

To our knowledge, this is the longest follow-up prospective report on Mini-Arc single-incision sling. At roughly four-year follow-up, the majority of patients cured or improved at short-term evaluation maintain a high degree of satisfaction at long term.

Short- and midterm reports on Mini-Arc have, on the majority, been consistent with the initial results of this series [6, 7] and comparable to conventional MUS [20, 21], with a low morbidity profile [20, 21].

The number of patients available for this evaluation, with 80% responders at almost 4-year mean follow-up, permits having an adequate idea of the long-term outcomes of the initial population, in a reliable way.

Patient Global Impression of Improvement questionnaire addresses the SUI treatment outcomes when compared with baseline condition and the results among the cured patients describe a 90% (57 patients) positive result, with 84% of the patients considering their actual condition to be "very much better" or "much better," which is usually assumed to be equal to a cured situation. These numbers are certainly reliable, as the 0–100 improvement scale results mean score is over 80%, with over than 4/5 of the cured patients rating this improvement >70%. On the other way, the actual urinary tract condition, addressed by PGI-S, is considered "normal" by 86% of the cured women. Only 10% of the cured women did not recommend the procedure to a friend.

The improved-patient population is very small ($n = 7$), and interpreting their results would not prompt solid conclusions.

These reports on long-term evaluation are very important to assure that SIS are a valid technique, with fair and comparable results at short- and middle-term evaluations, and that over time the results are maintained stable.

4. Conclusions

This study shows that the majority of patients cured/improved after Mini-Arc placement maintain a high degree of satisfaction at a long-term evaluation.

Conflict of Interests

Professor Francisco Cruz has received honoraria from AMS (American Medical Systems, Minnetonka, MN, USA) for lecturing. The other authors declare that there is no conflict of interests regarding the publication of this paper.

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DISCUSSION

The ideal MUS should be simple to place, require short hospital stay, a quick return to active life, have rare and mild complications, be reproducible and give a high success rate. The studies included in this thesis clearly show that SIS can be considered a safe and promising option for SUI treatment. The final positioning of SIS among the surgical alternatives for SUI treatment is, however, unknown and was not the objective of this study. This work should be interpreted as an initial insight, which now must be followed by many other studies, meta-analysis and, at last, by the test of time.

DIFFERENT SINGLE-INCISION VAGINAL SLINGS, DIFFERENT OUTCOMES

Our prospective case series reporting on TVT-Secur™, on a short-term follow-up, showed it as a minimally invasive procedure, with less complications than those reported after similar case-series on traditional MUS, either peri-operative, either post-operative (Oliveira *et al*, 2009). To be mentioned no bladder perforation, major bleeding, or persistent groin pain occurred. However, the percentage of dry patients was only slightly over 70%, lower than Mini-Arc™ or TVT-O™. We have advanced some issues regarding this procedure reproducibility, although in our hands the long-term results were reasonable (Silva *et al*, 2010). However, two recent meta-analysis on SIS, carried out in 2011 and 2014 demonstrated a general poor outcome of this SIS (Abdel-Fattah *et al*, 2011a and Mostafa *et al*, 2014). In addition, the TVT Worldwide Registry Investigators (Tincello *et al*, 2011) compared TVT™, TVT-O™ and TVT-Secur™

Investigators (Tincello *et al*, 2011) compared TVT™, TVT-O™ and TVT-Secur™ (both vertical and horizontal routes) in a multicentre trial, recruiting more than 1300 patients. Almost half of them received the SIS procedure. TVT-O™ was more efficacious than the other comparators, with failure rates reaching 3.6% for TO, 12.8% for RP and 15.8% for SIS (p=0,0039). Taken together, these studies led the manufacturer to withdraw TVT Secur™ from the market.

Following our short-term prospective evaluation of Mini-Arc™, which showed a dry rate of 80% and global success over 90%, with consistent QoL related improvements and minor morbidity (Oliveira *et al*, 2011a), fully confirmed by other cohort studies (Kennelly *et al*, 2010 and Pickens *et al*, 2011), we launched the first comparative study between Mini-Arc™ and other slings (Oliveira *et al*, 2011b). In a total of 90 women, Mini-Arc™ was shown to be as effective as the conventional TO MUS, but with much less complications, mainly post-operative pain, urinary retention requiring surgical revision or transient voiding dysfunction (Oliveira *et al*, 2011b). As mentioned above, Mini-Arc™ was more effective than TVT-Secur™ (Oliveira *et al*, 2011b). This pilot study was corroborated by the SIMS Italian Group, which compared 3 SIS, and also favored Mini-Arc™ *versus* the others (p<0,05) in terms of patient's satisfaction and *versus* TVT-Secur™ in the morbidity profile (p<0,05) (Palomba *et al*, 2012 and 2014). Also, Mini-Arc™ showed a significantly (p<0.05) higher feasibility to be performed under local anesthesia and in ambulatory setting (Palomba *et al*, 2012 and 2014).

The longest prospective follow-up currently available for Mini-Arc ™ is the prolonged evaluation of our series (Oliveira *et al*, 2014), with a mean follow-

the initial follow-up (12 months) maintained a high degree of satisfaction, as assessed subjectively on 73 patients. Only 3 patients were submitted to other SUI treatments (4%). These data are consistent with other author's observations (Kennelly *et al*, 2012 and Moore *et al*, 2013).

The meta-analysis by Mostafa *et al* (2014) showed that Mini-Arc^{TM} is equivalent to conventional MUS in terms of objective cure rates.

MORBIDITY AND COMPLICATIONS OF SINGLE-INCISION VAGINAL SLINGS

The recent meta-analysis (Mostafa *et al*, 2014), concluded that SIS are, indeed, a major evolution in female anti-incontinence surgery. This study confirmed that SIS, once TVT-Secur^{TM} is excluded, offer quicker operative times, less post-operative pain, faster return to normal activities and to work. Also, SIS are associated with less groin pain and a tendency towards less post-operative voiding difficulties. Even though, SIS are associated with more probability of vaginal tape erosion and need for repeated anti-incontinence surgery, although these data were contaminated by TVT-Secur^{TM} data.

Lopes *et* al (2011), further explored the cohort used in our RCT (Oliveira *et* al, 2011b) in order to investigate the impact of sling surgeries on female sexual function. Applying the questionnaire FSFI (Female Sexual Function Index), it was concluded that there were no differences between SIS and conventional MUS. Mostafa *et al* (2014), in a meta-analysis that included 2 studies addressing this matter, withdrew the same conclusion.

BEYOND TVT-SECUR™ AND MINI-ARC™

Although the initial reports with Tissue Fixation System (TFS™) were quite enthusiastic, no more relevant data was published.

Ajust™ (Bard Urological Division, Covington, GA, USA) is a new SIS, consisting of an adjustable mesh with polypropylene anchor-like extremities, designed to consistently place the sling in the obturator membrane. It was commercialized after the beginning or our studies, a fact that prevented us from including it in our work. It consists of a sub-urethral mesh and an adjustable mesh; (Bard Medical Division, 2009). Initial 12 months reports were only recently published. A 2011 report (Abdel-Fattah *et al*, 2011b) on 90 patients, showed a 80% subjective cure rate and reduced morbidity, in a painless procedure. Cornu *et al* (2012) involved 95 women in their case-series and, at a mean range of 21 months, showed a success rate of 80% (no wet pads), with minimal morbidity. Although SIS suggest the gain obtained from the fast recovery of patients to their normal and active life is obvious, there are not many studies that account for the economical benefits of SIS. One study, however, has shown that Ajust™, performed under local anesthesia, as an out-patient procedure, was more cost-effective than TVT-O™ with up to 1 year follow-up (Boyers *et al*, 2013). The meta-analysis by Mostafa *et al* (2014) already includes an evaluation of Ajust™, with consistent results eliciting it as an evolution towards mini-invasiveness and cost-effectiveness.

Solyx™ sling system (Boston Scientific Corporation, Natick, MA, USA) has a similar design to Mini-Arc™, but the available data (pilot RCT) do not permit, yet, any firm conclusion.

Contasure Needleless™ and Ophira™ Mini Sling System (Promedon, Córdoba, Argentina) are SIS that do not user anchor-like fixation methods. Although they seem effective, data are scarce, and their results should be interpreted with caution.

Mini-Arc™ Precise is the newer version of Mini-Arc™, with exactly the same anchoring system, that is designed to be easily adjustable during insertion. By maintaining the fixation anchor on the extremity of the insertion needle till the final positioning of the mesh, Mini-Arc™ Precise has gradually replaced the previous design.

CONCLUSIONS

Single-incision vaginal slings are here to stay. The simplicity of the procedures, associated with safety and efficacy are highly attractive for many surgeons and patients. Our work shows beyond any doubt that SIS cannot be looked at as one single type device. Currently, SIS that offer robust fixation systems, particularly hook-like ones, seem to provide the most efficacious results, concerning success rates (Mostafa *et al*, 2014). This is the case of Mini-Arc™ and Ajust™. Any new SIS or equivalent device should be, nevertheless, adequately compared with conventional MUS, in order to clearly define its efficacy, safety and cost-effectiveness. Only then, should these new devices be commercially available.

One important point still to define is the long-term results of SIS as form of treatment for SUI. The meta-analysis by Mostafa *et al* (2014), although assuming the maturity of these devices, warned about the relatively short follow-up time, 18 months only. This issue can only be solved by the test of time and adequate follow-up of available cohorts.

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SUMMARY

This work investigates the efficacy and safety of single-incision vaginal slings (SIS) for the treatment of female stress urinary incontinence.

Two SIS were investigated, the TVT-Secur™ and Mini-Arc™. Both were studied in prospective cohorts, including long-term evaluations and in a phase 2 randomized clinical trial, in which these SIS were compared with a conventional mid-urethral sling.

We concluded that SIS are easy to insert and extremely safe. However, TVT-Secur™, due to its complex design, may offer some difficulties to position, raising questions about reproducibility.

In terms of efficacy, Mini-Arc™, with its harpoon-like fixation system, offers cure rates comparable to the gold standard mid-urethral slings. Its effectiveness was confirmed up to 4 years after implantation.

In contrast with Mini-Arc™, TVT-Secur™ provides lower cure rates of SUI than traditional mid-urethral slings. In part, the poorer outcome of TVT-Secur™ is related to the fixation system, which is a Velcro-like extremity that needs to interact with host tissues.

In conclusion, SIS with robust anchoring systems are a promising treatment of female SUI.

RESUMO

Este trabalho investigou a eficácia e segurança das fitas sub-uretrais de incisão única vaginal no tratamento da incontinência urinária de esforço feminina.

Foram investigadas duas fitas sub-uretrais de incisão única vaginal, o TVT-Secur™ e o Mini-Arc™. Ambas foram estudadas em séries prospectivas, incluindo avaliações a longo prazo e um ensaio clínico randomizado de fase 2, no qual estas fitas foram comparadas com uma técnica convencional.

Este trabalho concluiu que as fitas sub-uretrais de incisão única vaginal são fáceis de colocar e extremamente seguras. No entanto, o TVT-Secur™, devido à sua concepção mais complexa, pode oferecer mais dificuldades para um adequado posicionamento, levantando questões no que diz respeito à sua reproducibilidade.

Em termos de eficácia, o Mini-Arc™, com as suas extremidades em arpão, permite taxas de cura comparáveis às técnicas padrão. A sua eficácia foi confirmada até aos 4 anos após a cirurgia.

Em contraste com o Mini-Arc™, o TVT-Secur™ tem taxas de cura de incontinência urinária de esforço inferiores às fitas convencionais. Em parte, os piores resultados do TVT-Secur™ estão relacionados com o seu mecanismo de fixação, cuja extremidade exerce um efeito tipo Velcro, necessitando de interagir com os tecidos da doente.

Em conclusão, as fitas sub-uretrais de incisão única vaginal com mecanismos de ancoragem robustos são um tratamento promissor para a incontinência urinária de esforço feminina.