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focus on

Comparison between three mini-sling surgical procedures and the traditional transobturator vaginal tape technique for female stress urinary incontinence

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SUMMARY: **Comparison between three mini-sling surgical procedures and the traditional transobturator vaginal tape technique for female stress urinary incontinence.**

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Objectives. *To compare mini-sling and traditional tension-free operations for female stress urinary incontinence.*

Study design. *A systematic review of articles in the Literature published between 2002 and 2012, was conducted. A Pubmed search was performed. Primary outcomes were subjective and objective cure rates at 12 months comparing the three single-incision mini-slings techniques (TVT-Secur, MiniArc and Monarc systems) with the standard mid-urethral sling procedure TOT (Transobturator Vaginal Tape). Secondary outcomes included peri-operative (vaginal and/or bladder perforation, urine retention, urinary tract infection, bleeding, pain) and post-operative (mesh exposure, de novo urgency, and dyspareunia) complications.*

Results. *In term of objective cure rate at 12 month after surgery, it is evident that TOT at first, and MiniArc are the most effective procedures. The incidence of post-operative urgency and UTI was lower in TOT technique, while vaginal perforation was described in equal frequency both in TOT and in MiniArc procedures. The advantages of the three above described mini-invasive techniques seem to consist into lower cases of urinary retention, pain and bleeding. Furthermore, bladder perforation and bleeding are not described in the Literature for TVT-Secur and Monarc systems.*

Conclusions. *Some single-incision slings look promising and as effective as conventional sub-urethral slings at short term evaluation. However, at this moment a clear statement in favor of the widespread use of single-incision slings cannot be made. More studies must define the efficacy of these techniques.*

KEY WORDS: Stress urinary incontinence - Mid-urethral sling - Single-incision mini-sling.

Introduction

Stress urinary incontinence (SUI) is the most common type of urinary incontinence in pre-menopausal women in almost 50% of cases (1). Initial management of SUI includes conservative therapy such as pelvic floor muscle training, and electrical stimulation with or without pharmacotherapy (2).

Surgical procedures have been continuously evolving over the last four decades with the ultimate aim of providing an effective and ambulatory surgical procedure with reduction of peri-operative morbidity, shorter hospital stay, less postoperative pain and a quicker recovery period (2).

The last decade of the 20th century witnessed significant improvements in surgical approach to SUI with the introduction of sub-urethral tension-free slings. Of the surgical treatments available, standard mid-urethral slings (SMUS), both retropubic tension-free vaginal tapes (RP- TVT) and transobturator tension-free vaginal tapes (TO-TVT), are the most commonly performed procedures for SUI (3-6).

TVT was the first device of this kind to be introduced in clinical practice, in 1996 by Ulmsten (3). TVT demonstrated a high success rate, identical to that of Burch colposuspension in long follow-up observations, together with low invasiveness, short hospital stay, reduced risk of prolonged catheterization and low risk of causing future pelvic organ prolapse (7). All together, these characteristics were responsible for the swift replacement of Burch colposuspension as the preferred surgical approach to female SUI (7).

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 retropubic space (8, 9). This prompted the development

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of the transobturator route by Delorme in 2001, to reduce retropubic route-associated complications (10). Large randomized studies comparing the retropubic against the transobturator route established that the two techniques are virtually identical in what concerns SUI cure (11, 12). However, TOT slings did not decrease complications but rather replaced those associated with the incursion through the retropubic space by others caused by the violation of the obturator foramen. In fact, 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 (8, 9, 12). In addition, vascular complications and severe perineal fasciitis were occasionally reported (8).

Single vaginal incision slings requiring very limited intracorporeal dissection have been recently introduced proposing to further increase safety of sub-urethral slings, without decreasing the success rates reported by conventional retropubic and transobturator access (2). They include TVT-Secur, Mini-Arc, Monarc, Ajust, Arcus-to-Arcus and Tissue Fixation Systems. As the experience with the latter three devices is still very limited, this review will mainly evaluate the evidence available for TVT-Secur, Mini-Arc and Monarc Systems.

Surgical techniques

All surgical interventions were performed in the lithotomy position under general anesthesia, and a Foley catheter was placed.

Standard mid-urethral slings (SMUS)

THE TRANSOBTURATOR PROCEDURE (TOT)

Three incisions are made: two small incisions in the groin lateral to inferior pubic ramus, and one vaginal incision in the midurethral area. The needles are inserted in the groin incision and passed into the mid-urethral incision (out-in) or vice versa (in-out). The direction of the wings is horizontal. Once the tape is in place, it is adjusted to the appropriate tension. The sheath is then removed, the excess mesh trimmed from the surgical site, and the incisions closed with sutures.

Single-incision mini-sling procedures (SIMS)

TVT-SECUR MINI-SLING TECHNIQUE

The vagina was incised approximately 1.5-2 cm below the external urethral orifice. Next, the paraurethral tissue was dissected with scissors, creating a tunnel up to the inferior ramus of the pubic bone. The sling was then advanced into the obturator internus muscle and obturator membrane below the inferior pubic ramus with a needle. Tension-free positioning of the sling was ensured by inserting a forceps handle between the tape and the urethra. The insertion angle was 45 degrees in the direction of the adductor longus muscle tendon. The TVT-S "U-type" is fixed to the urogenital diaphragm (similar to the original retropubic TVT), and the TVT-S "H-type" is fixed to the obturator internus muscle in a Hammock position (more analogous to the second generation transobturator approaches like the Monarc-slings) (13). The vaginal incision was closed with vicryl sutures.

MINI-ARC SINGLE INCISION SLING TECHNIQUE

It is a novel procedure for female SUI that uses a single-incision approach and self-fixating anchoring tips in the obturator internus muscle and membrane.

MONARC TECHNIQUE

It is the second generation of transobturator approach. The vagina was incised approximately 1.5 - 2 cm below the external urethral orifice. Next, the paraurethral tissue was dissected with scissors, creating a tunnel up to the inferior ramus of the pubic bone. The sling was then advanced into the obturator internus muscle and obturator membrane below the inferior pubic ramus with a needle. Tension-free positioning of the sling was ensured by inserting a forceps handle between the tape and the urethra. The insertion angle was 45 degrees in the direction of the adductor longus muscle tendon. The type" is fixed to the obturator internus muscle in a Hammock position (more analogous to the TVT-Secur mini-sling technique). The vaginal incision was closed with vicryl sutures.

Material and methods

A systematic review of articles in the Literature published between 2002 and 2012, was conducted. A Pubmed search was performed. Primary outcomes were subjective and objective cure rates at 12 months comparing three SIMS procedures (MiniArc, TVT-Secur and Monarc) to the corresponding SMUS techniques such as TOT. Secondary outcomes included peri-operative (vaginal and/or bladder perforation, urine retention, urinary tract infection, bleeding, pain) and post-operative (mesh exposure, de novo urgency, and dyspareunia) complications of SIMS versus TOT procedure.

In TOT procedures the objective cure rate at 12 months from surgery ranged from 80% to 97% (2,14-25). De novo post-operative urgency was reported from 3,3% to 10% (2, 20, 21), UTI from 0% to 2% (20, 21), and urinary retention in 0-8% (2, 14, 25). Pain was reported in 5% of Mostafa's series (2) and in 8% in Debodinance's series (25). Only few cases of bleeding and bladder/vaginal/urethral perforation are described in the Literature (2, 20, 26-28).

In the TVT-Secur system the objective cure rate at 12 months after surgery ranged from 76% to 90,9% (24, 29); de novo post-operative urgency was reported in 6,45-10% (29, 30), UTI in 1,3-4,4% (29-31), and urinary retention in 0,64-3,8% (29, 30). Pain was reported in 1-2,5% (24, 30). The incidence of vaginal or urethral perforation was assessed from 1,5% to 5% (29, 30). No cases of bleeding nor bladder perforation were reported.

MiniArc Sling System reported an objective cure rate at 12 months after surgery ranging from 55,8% to 96,7% (31-39), an incidence of bladder perforation ranging from 0% to 0,8% (31, 32, 34), and of vaginal/urethral perforation in 0-2,6% (33, 36, 37, 39). Post-operative de novo urgency ranged from 0% to 36,8% (32, 35, 36, 39), while the incidence of UTI ranged from 1,4% to 4,8% (31, 36, 37). The incidence of urine retention was reported in 0- 3,2% (31, 33, 37, 39), bleeding in 0-1,4% (31, 36), and post-operative pain in 0-2,8% (33, 39).

In the Monarc system the objective cure rate at 12 months after surgery ranged from 80,8% to 95,3% (25, 31, 40-43); de novo post-operative urgency was reported in 2,7-20,5% (40, 42), UTI in 6% (25), and urinary retention in 0,9-6,8% (25, 40, 42). Pain was reported in 6% (25). The incidence of vaginal or urethral perforation was assessed from 1,9 to 2% (25, 43). No cases of bleeding (44) nor bladder perforation were reported.

Results

Results obtained from this review are summarized in Table 1.

In term of objective cure rate at 12 month after surgery, it is evident that TOT at first (45), and MiniArc are the most effective procedures.

The incidence of post-operative urgency and UTI are lower in TOT technique, while vaginal perforation is described in equal frequency both in TOT and in MiniArc procedures.

The advantages of the three above described mini-invasive techniques seem to consist into lower cases of urinary retention, pain and bleeding, compared to the traditional TOT technique. Furthermore, bladder perforation and bleeding are not described in the Literature for TVT-Secur and Monarc systems.

Without ignoring the low number of studies, results obtained in this study seem to indicate that the TOT procedure is more effective than the mini-invasive techniques, but it has not the specific advantages due to the mini-invasiveness, such as lower incidence of bleeding, bladder perforation and post-operative pain.

Discussion and conclusions

Traditional abdominal surgery has been used in the past for the repair of perineal prolapses. With the advent of laparoscopic surgery, thanks to the advantages of this technique (46-49), repair has been also attempted through this mini-invasive abdominal approach.

Differently from the abdominal approaches, the SIMS techniques utilize a single vaginal insertion approach and aim to avoid the blind passage of the trocars through the retropubic area and the groin/adductor muscles, consequently reducing the incidence of peri-operative morbidity compared to SMUS (2). The main advantages of single-incision mini-sling are attributed to the lower incidence of postoperative pain, with shorter hospital stay, quicker recovery, and early resumption of day-to-day activities (50). Furthermore, SIMS procedures showed higher tolerability when performed under local anesthesia that SMUS techniques, which were initially described under local anesthesia and sedation, but the British Society of Urogynaecologists' surgical database reported that SMUS are predominantly performed under general anesthesia (45).

Very few works are available in the Literature about SIMS procedures and about the comparison among SIMS and SMUS procedures. A recent systematic review and

TABLE 1 - COMPLICATIONS OF TOT, TVT-SECUR, MINIARC AND MONARC TECHNIQUES.

	OBJECTIVE CURE RATE	URINARY URGENCY	URINE RETENTION	UTI	BLADDER PERFORATION	URETRAL OR VAGINAL PERFORATION	PAIN	BLEEDING
TOT	80 - 97%	3,3 - 10%	0 - 8%	0 - 2%	Rare	Rare	5 - 8%	Rare
Authors	Mostafa[2], Holly[14], Liapis[15], Mellier[16], Lee[17], Falker[18], Schierlitz[19], Palma[20], Tanuri[21], Giberti[22], Cindolo[23], Neuman[24], Debodinance[25]	Mostafa[2], Palma[20], Tanuri[21],	Mostafa[2], Holly[14], Debodinance[25]	Palma[20], Tanuri[21], Debodinance[25]	Palma[20], Mostafa[2], Ryhammer[26], Agresti[27], Debodinance[25]	Palma[20]	Mostafa[2], Debodinance[25]	Palma[20]
TVT - SECUR	76 – 90,9%	6,45 – 10%	0,64 – 3,8%	1,3 – 4,4%	--	1,5 – 5%	1 – 2,5%	--
Authors	Neuman[24], Colin[29]	Colin[29], Alvarez[30]	Colin[29], Alvarez[30]	Colin[29], Alvarez[30], De Ridder[31]		Colin[29], Alvarez[30]	Neuman[24], Alvarez[30]	
MINIARC	55,8 – 96,7%	0 – 36,8%	0 – 3,2%	1,4 – 4,8%	0 – 0,8%	0 – 2,6%	0 – 2,8%	0 – 1,4%
Authors	De Ridder[31], Annett[32], Moore[33], Barber[34], Oliveira[35], Debodinance[36], Kennelly[37], Prethus[38], Sottner[39]	Annett[32], Oliveira[35], Debodinance[36], Sottner[39]	De Ridder[31], Moore[33], Kennelly[37], Sottner[39]	De Ridder[31] Debodinance[36], Kennelly[37]	De Ridder[31], Annett[32], Barber[34]	Moore[33], Debodinance[36], Kennelly[37], Sottner[39]	Moore[33], Debodinance[36], Sottner[39]	Debodinance[36], De Ridder[31]
MONARC	80,8 – 95,3%	2,7 – 20,5%	0,9 – 6,8%	6%	--	1,9 – 2%	6%	0%
Authors	Debodinance[25], De Ridder[31], Liapis[43], Sun[40], Tomoe[41], Davila[42]	Sun[40], Davila[42]	Sun[40], Davila[42], Debodinance[25]	Debodinance[25]		Debodinance[25], Liapis[43]	Debodinance[25]	Lo[44]

meta-analysis (51) showed that earlier types of SIMS were associated with inferior objective and subjective cure rates when compared to standard mid-urethral slings (52, 53). SIMS appear to be a valid option to offer to patients with SUI. The low morbidity associated with these small devices and the good success rates generally reported by non-comparative and comparative studies are to be considered as promising (35) in most series and even as effective as conventional sub-urethral slings at short term evaluation. However, no experience reported by independent authors can be found.

Nevertheless, SIMS have not come of age, evidence available favoring their use being still very weak. In addition, it is unclear if single-incision slings can be offered to patients with high BMI, severe forms of SUI, including intrinsic sphincter deficiency and concomitant pelvic organ prolapses. The effect of age on success rate is also uncertain, although the kind of fixation systems in all single-incision slings requires good quality host tissues for firm anchoring. Thus, SIMS should be preferentially used in the context of clinical trials in order to rapidly define their role in SUI treatment.

It appears clear that larger studies using conventional slings as comparators to SIMS, and longer follow-ups are needed. Randomized comparative controlled trials and long term results are still required to define the role of the new sling systems in comparison with mid-urethral tape techniques for treating SUI (32, 54). Therefore, at this moment a clear statement in favor of the widespread use of single-incision slings cannot be made. More studies must define the efficacy of these techniques against conventional sub-urethral slings. In addition, comparisons among available SIMS should define one ideal model.

Finally, although as simple as the SIMS techniques look, a careful learning process is still strongly recommended.

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