Tension-free Midurethral Sling Surgeries for Stress Urinary Incontinence

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ABSTRACT

The surgical treatment of stress urinary incontinence (SUI) has undergone a revolutionary change since the launch of tension-free midurethral slings, including the original practices of retro-pubic and modified trans-obturator surgical approaches. Minimally invasive techniques and high success rates have led to an increasing popularity of the procedures. The short-term efficacy of trans-obturator tension-free midurethral slings is comparable to that of the retro-pubic approach. However, preliminary evidence suggests that the trans-obturator approach has a lower success rate for treatment of intrinsic sphincter deficiency (ISD). As for adverse events after different procedures, the trans-obturator route produces fewer bladder injuries and voiding difficulties, but more groin/thigh pain, vaginal injuries or erosion of the mesh as compared with the retro-pubic route. Although the short term reports on the trans-obturator approach look promising, long-term studies and randomized controlled trials (RCTs) are needed to identify the proper indications for the various types of slings and to assess efficacy and complication rates over time. *Keywords:* urinary incontinence, tension-free midurethral slings, trans-obturator vaginal tape (TOT), tension-free vaginal tape (TVT), tension-free vaginal tape- obturator system (TVT-O).

INTRODUCTION

Urinary incontinence, meaning any involuntary leakage of urine (a symptom), is defined as urethral or extra-urethral urine leakage seen during examination (a sign). Stress urinary incontinence (SUI), is the complaint of involuntary leakage upon effort or exertion (a symptom), including sneezing or coughing; it is defined clinically as the observation of involuntary leakage from the urethra synchronous with exertion or effort, sneezing or coughing; it is presumed to be due to increased abdominal pressure (a sign) [1]. With the ability to conduct more objective urodynamic evaluations, the term genuine stress incontinence (GSI) has been replaced by the preferred term urodynamic stress incontinence (USI). USI is defined through filling cystometry as an involuntary leakage of urine during increased abdominal pressure in the absence of a detrusor contraction [1]. A randomly sampled community-based study to evaluate the prevalence of urinary incontinence in a healthy population conducted by Chen et al [1] showed that a total of 53.7% of women suffered from urinary incontinence with or without related symptoms. The prevalence of stress urinary incontinence, overactive bladder, and mixed incontinence, with each category mutually exclusive, was 18.0%, 18.6%, and 17.1%, respectively, based on patients' perceptions. The criteria of the International Continence Society (ICS) yields a lower incidence, with the prevalence of the above three conditions as 4.3%, 2.4%, and 1.8%, respectively. The occurrence of SUI increases with age (reaching 25% in the 50-65-year-old cohort). Approximately two thirds of the incontinent women reported restricting social activities because of embarrassment and inconvenience and approximately 19% reported it affected their sex life. However, only 27.1% of the women with urinary incontinence related symptoms in their study reported seeking medical services to solve these problems [2].

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A brief history of anti-incontinence surgery

There have been more than 100 types of anti-incontinence surgeries invented since Kelly's sub-urethral fascia placation reported in the year 1914 [3]. A brief summary of the history of anti-incontinence surgeries is listed in Table 1. The methods of surgical treatment for urinary incontinence vary according to the type of SUI, patients' conditions, and surgeons' preferences. Tension-free vaginal tape (TVT) (Gynecare, Ethicon Inc, Summerville, NJ), first introduced by Ulmsten in 1995 [4], has gained popularity with both gynecologists and urologists. The International Urogynecological Association (IUGA) surveyed its 152 members, including gynecologists (89%) and urologists (11%), regarding the management of pelvic floor dysfunction in 2002 and found the operations preferred for SUI were TVT (48.8%), and Burch colposuspension (44%). In SUI related to low urethral closure pressure, i.e. intrinsic sphincter deficiency (ISD), the surgery chosen was 44.6% for TVT and 32.3% for the conventional sling [5]. We have summarized the evolution of the types of anti-incontinence surgeries in Fig. 1. A review conducted in Cochrane Library in 2007 indicated that open retro-pubic colposuspension is still considered an effective treatment modality in the long run for SUI. Comparing the results of treatments in the first year, the overall continence rate achieved is approximately 85% to 90%. After five years, approximately 70% of the patients can expect to be dry. However, newer minimally invasive procedures like TVT [6] look promising in comparison to open colposuspension, but their long-term performance is not known [7]. This review will address the mechanisms, efficacy, complications and issues related to tension-free midurethral slings.

MECHANISMS AND THEORIES OF URINARY CONTINENCE

Traditionally, the pathophysiology of stress urinary incontinence emphasized the bladder neck and proximal urethral hypermobility [8]. When performing retro-pubic urethropexy for SUI, e.g. the Marshall-Marchetti-Krantz (MMK) procedure or the Burch colposuspension, the goal of the procedure is to lift the urethra up to a higher retro-pubic position [9]. Burch colposuspension attaches the endopelvic fascia at

the level of the bladder neck to the ipsi-lateral ileal-pectineal (Cooper) ligament, and fixes the bladder neck high in the retro-pubic space. With good results both short term (85%-90% within the first year) and long term (70% for over 5 years), it has been regarded as the gold standard of treatment [7]. Yet, the emergence of tension-free midurethral slings, designed according to integral theory [10,11] and supported by hammock theory [12], has challenged this traditional solution.

Hammock theory

The urethra lies on a supportive layer that is composed of endopelvic fascia and the anterior vaginal wall, The stability of the sub-urethral layer depends on the intact connection of the vaginal wall and endopelvic fascia to the arcus tendineus fasciae pelvis (ATFP), i.e. "white line" and levator ani muscle [12]. The increases in urethral closure pressure (the difference between bladder and urethra) during a cough arises because the urethra is compressed against a hammock-like supportive layer, rather than being truly "intra-abdominal" [12].

Integral theory

Tension-free midurethral slings have revolutionized the treatment of SUI [6,13]. The successful outcomes of the TVT procedure have been attributed not to restricting the hypermobility of the urethra and bladder neck, but to the principles of integral theory [10,11]. This theory indicates that the consequences of SUI are detachment of the pubourethral ligament (PUL) supporting the urethra, weakened support of the anterior vaginal wall to the midurethra and impaired function of the pubo-coccygeal musculature (PCM) adjacent to the urethra. During increased abdominal pressure, e.g. coughing, laughing, etc, the PCM fast twitch contraction pulls forward the upper vagina tightly around the urethra with PUL. This contraction closes the urethra off and immobilizes it while the levator plate (LP) and longitudinal muscle of the anus (LMA) pulls the bladder down and back to create a "zone of critical elasticity". Loss of elasticity here may cause the forward movement of the vagina to fail, leaving the bladder neck in the incontinent "open position" [10,11].

Dynamic kinking with "urethral knee"

Various radiologic studies demonstrating functional kinking of the midurethra during stressful maneuvers have been described. Lo et al performed ultrasound assessment of the TVT sling at 3-year follow-up, which revealed midurethral dynamic kinking for which they coined the term "the urethral knee" [14].

DIFFERENT APPROACHES FOR TENSION-FREE MIDURETHRAL SLINGS: RETRO-PUBIC VERSUS TRANS-OBTURATOR

Tension-free midurethral sling operations include the implantation of a suburethral tape of differing materials without tension under the midurethra. It is aimed to correct the inadequate urethral support and the suburethral vaginal wall [7]. We have summarized the outcome of TVTs performed in essential institutions in various countries (Table 2).

Tension-free midurethral sling procedures can be performed using different approaches with different kinds of implants. These implants differ not only with respect to the material (polyester, polyethylene,

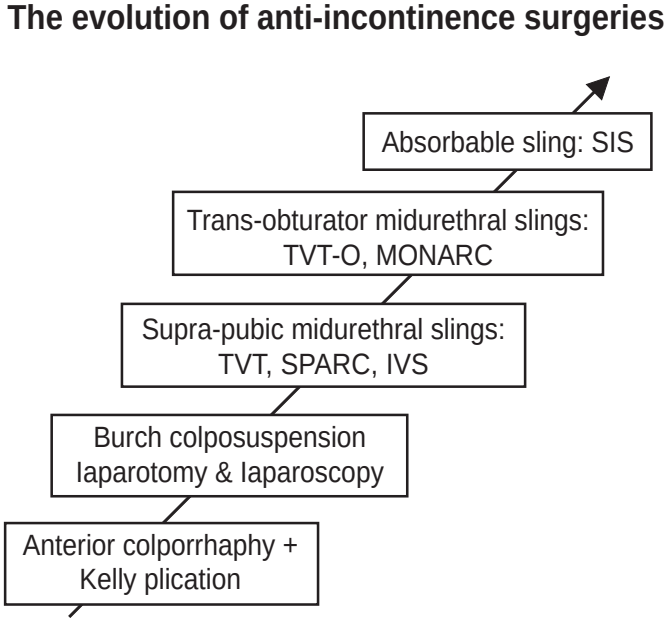

Fig. 1. A brief summary of the evolution of anti-incontinence surgery. IVS: intravaginal slingoplasty; SIS: small intestine submucosa; SPARC: supra-pubic arc; TVT: tension-free vaginal tape; TVT-O: tension-free vaginal tape-obturator system.

Table 1. Brief Summary of Chronological Anti-incontinence Surgeries

Year	Author	Types of Surgeries
1914	Kelly HA [3]	Suburethral fascia plication
1917	Goeball R & Stoeckel W [56]	Using a strip of rectus fascia to encircle the urethra
1949	Marshall VF, Marchetti AA & Krantz KE [57]	Retro-pubic urethropexy (pubis periosteum)
1959	Pereyra AJ [58]	Needle-assisted transvaginal bladder neck suspension
1961	Burch JC [9]	Retro-pubic colposuspension (Cooper ligament)
1973	Stamey TA [59]	Endoscopic bladder neck suspension
1980s	Raz S [60]	Raz bladder neck suspension
1995	Ulmsten U [4]	Tension-free Vaginal Tape (TVT) (Gynecare, Ethicon Inc, Summerville, NJ)
2001	Delorme E [23]	Trans-obturator Subfascial Hammock, MONARC (American Medical System)
2003	Deval B [17]	Supra-pubic arc (SPARC) (American Medical System, Minnetonka, MN)
2003	Petros P [61]	Intra-vaginal Slingplasty (IVS) Tunneller (Tyco Healthcare- United States Surgical, Norwalk, CT)
2003	deLeval J [24]	Trans-obturator vaginal tape (TVT-O) (Gynecare, Ethicon Inc)
2005	Mostow EN [17]	Extracellular matrix graft: absorbable sling (SIS) (Cook Biotech Inc., W. Lafayette, IN)

polypropylene, polytetrafluoroethylene, PTFE, polyethylene terephthalate, PETP, etc), but also in terms of structure (woven, knitted, monofilament and multifilament), pore size, mechanical properties, shape and surface characteristics [15]. The classification of synthetic prostheses was listed in Table 3 [16]. Type I macroporous, monofilamentous mesh is regarded in surgery as the most suitable material for stress urinary incontinence and pelvic floor reconstruction. Most commercially available tension-free midurethral slings use type I polypropylene mesh tape, with the exception of intra-vaginal slingplasty tunneller (IVS tunneller) (Tyco Healthcare-United States Surgical, Norwalk, CT), which is a type III mesh. It is also worth noting for its newly developed absorbable materials, called small intestinal submucosa (SIS) (Cook Biotech Inc., W. Lafayette, IN) [17]. SIS is a natural biomaterial harvested from the porcine small intestine and made into a biocompatible medical product using a patented process. The emergence of absorbable material may mark the beginning of a new era, however, due to limited literature on the topic, the long-term effects are still unknown.

Retro-pubic approach: top-down (TVT) or bottom-up (SPARC)

The retro-pubic approach can be done through a bottom-up vaginal approach, e.g. TVT sling (Gynecare, Ethicon Inc, Summerville, NJ); or through a top-down low abdominal approach, e.g. suprapubic arc (SPARC) sling (American Medical System, Minnetonka, MN). Two types of retro-pubic approaches are illustrated in Fig. 2. Nilsson et al reported their results after 7 years of follow-up involving 90 women. A cure rate of 81.3% was noted after a follow-up period of 91 months [13, 18]. Two randomized trials (RCTs) have reported no differences in efficacy between SPARC and TVT at 2 years. The success rates for SPARC and TVT were 83% (n=41) vs 95% (n=43), $0.05< p < 0.1$ (12 months) [19]; and 80.7% (n=31) vs 87.1% (n=31), $p= 0.706$ (2 years) [20], neither one being significant.

Trans-obturator approach: outside-in (TOT) or inside-out (TVT-O)

TVT has been regarded as a very safe procedure. However, reports from Scandinavia, Austria and other places have drawn attention to severe surgical complications relating to the penetration of the retropubic space [21,22]. In 2001, a trans-obturator approach was proposed for the surgical placement of sub-urethral tapes under the middle urethra, with the aim of reducing or even eliminating complications by sparing the retro-public space [23]. Clinical results and anatomic studies suggest this approach may be safer. The tapes pass from the thigh fold, through the obturator foramens, underneath the urethra, towards the anterior vaginal wall, without entering the pelvic region at any time during the procedure. It can be performed via an outside-in approach (TOTs), e.g. ObTape, UraTape, Monarc (American Medical System, Minnetonka, MN), etc. [23], or an inside-out approach, i.e. TVT- obturator system (TVT-O) (Gynecare, Ethicon Inc, Summerville, NJ) [24]. Two types of trans-obturator approaches are illustrated in Fig. 3. As for the efficacy for the two trans-obturator approaches, the reported results are very similar; 90% for Monarc (n=50) versus 94% for TVT-O (n=50) at 1 year follow-up, with no significant differences [25]. Although short-term data show no difference in cure rates or complications, there are no long-term studies comparing the inside-out and outside-in trans-obturator approaches [26].

Efficacy of retro-pubic versus trans-obturaor approaches

According to a recent review article by Latthe et. al based on five RCTs for TVT-O versus TVT and six RCTs for TOT versus TVT, the subjective cure rates were as follows: TVT-O vs TVT (OR 0.69; 95% CI 0.42-1.15); TOT vs TVT (OR 1.04; 95% CI 0.64-1.70); total TVT-O/TOT vs TVT (OR 0.85; 95% CI 0.60-1.21), all not significant [27]. However, the trans-obturator approach is less successful in patients with ISD [28]. According to the pre-operative maximal urethral closure pressure (MUCP), the cure rates were noted as 86% if the MUCP was greater than 30 cmH_2O; compared 81% if the MUCP was 20-30 cmH_2O; and 70% if the MUCP was less than 20 cmH_2O [28]. In summary, the short-term efficacy of trans-obturator tension-free midurethral slings is comparable to the retro-pubic approach. However, preliminary evidence suggests that trans-obturator tension-free midurethral slings may have a lower success rate for treatment of ISD [27].

Table 2. Outcomes Using Tension-free Vaginal Tape (TVT) at Major Institutions in Various Countries

	Case No.	Successful	Follow-up (Mons)
Ulmsten U (Sweden) [62]	50	86%	36
Olsson U (Sweden) [63]	51	90%	36
Wang AC (Taiwan) [64]	70	84%	3-18
Jacquetin B (France) [65]	156	89.1%	12-36
Soulie M (France) [66]	120	86.7%	15.2 (6-36)
Nilsson CG (Finland) [18]	85	85%	56 (48-70)

Table 3. Classification of Synthetic Prostheses [16]

Type	Characteristics	Pore size	Brand names
Type 1	Monofilament, macroporous	> 75 μ	Gynemesh, TVT, TVT-O SPARC, Monarc, Perigee, Apogee, Prolift
Type 2	Monofilament, microporous	< 10 μ	GORE TEX
Type 3	Macroporous with multifilaments or microporous		IVS tunneller, URATAPE, SURGIPRO, MERSILENE, PARIETEX
Type 4	Submicronic	< 1 μ	

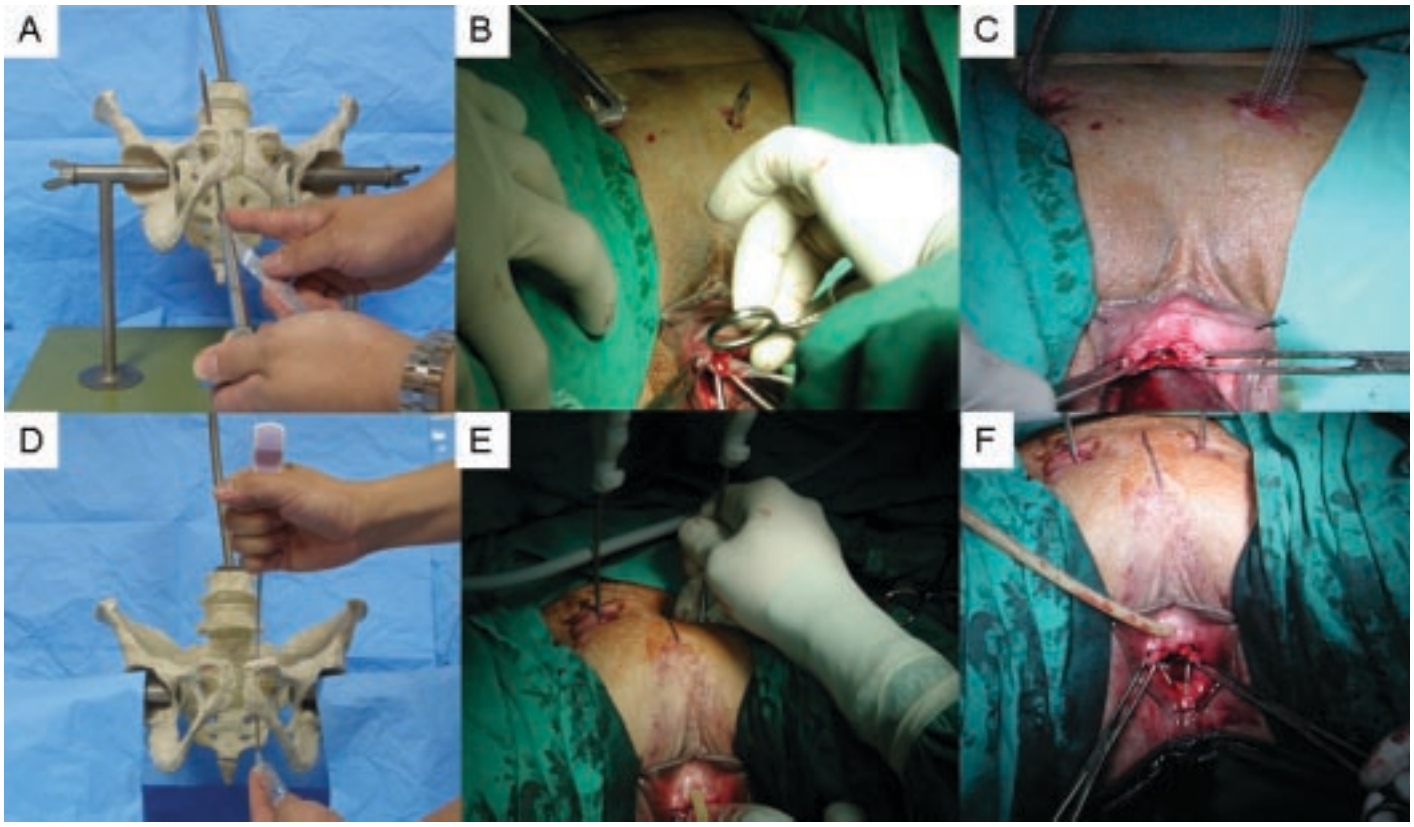

Fig. 2. Retro-pubic tension-free midurethral slings can be performed via a bottom-up vaginal approach (upper panel), e.g. TVT (A, B, C), or via a top-down low abdominal approach (lower panel), e.g. SPARC (D, E, F).

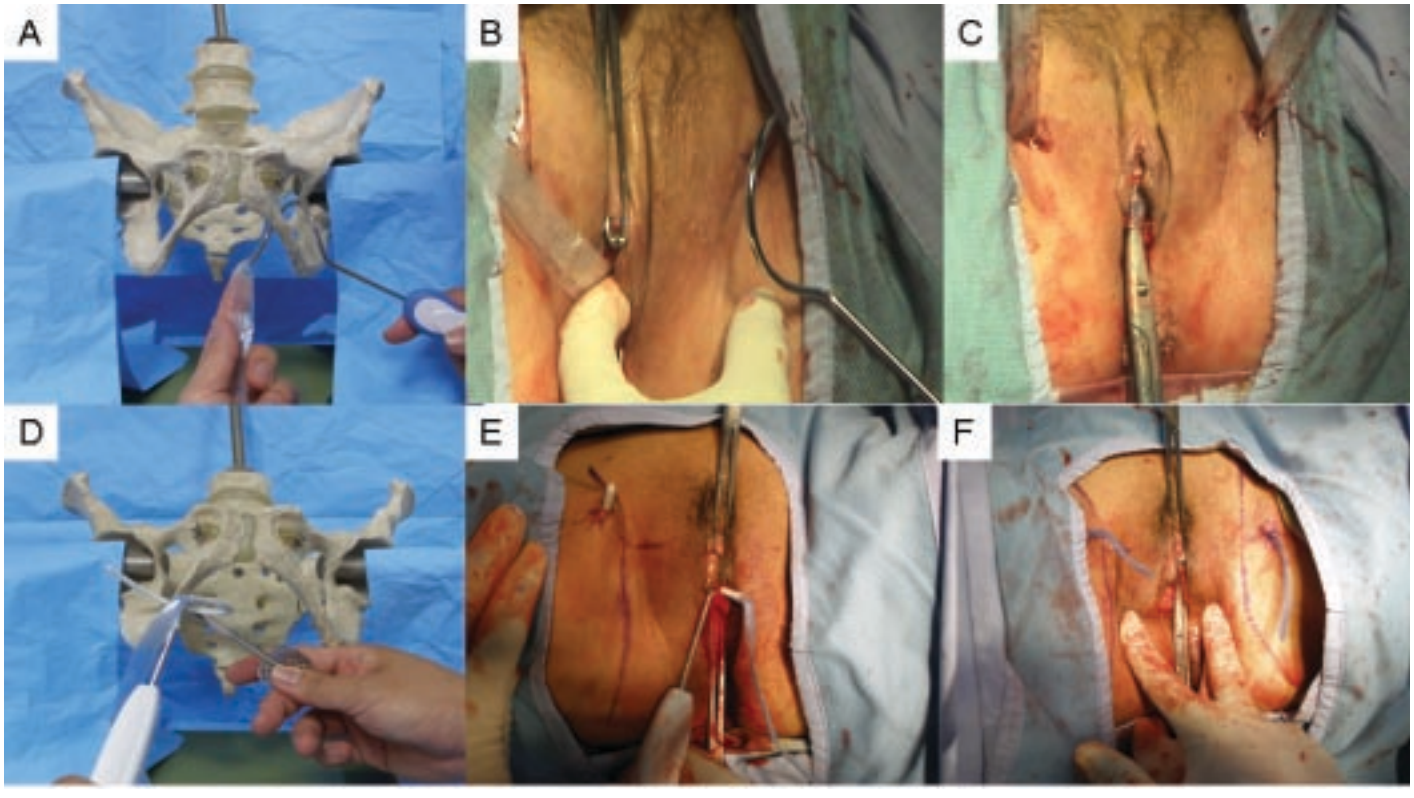

Fig. 3. The trans-obturator approach can be done outside-in with initial incisions at the groin/thigh (A, B, C), or inside-out with initial incisions at the anterior vaginal wall (D, E, F).

Proposed Indication for retro-pubic versus trans-obturator approaches

There is a paucity of data in the literature to direct physicians regarding the best indications for the use of various tension-free midurethral slings. In addition, the indications are often dependent on clinical experience and the level of comfort with the use of the various techniques. Indications for the better choice among these approaches were proposed by Silva based on common sense principles rather than rigorous study as RCTs [29].

The retro-pubic approach may be preferred over the trans-obturator approach in young, physically active patients or patients with ISD, because it helps prevent thigh/groin discomfort with exercise and the vectors of support create more urethral tension [30,31].

The trans-obturator approach may be preferred over the retro-pubic approach for obese patients, elderly patients, patients with previous retro-pubic or major abdominal surgery, or with mixed incontinence. It can make passing needles easier, reducing the risk of organ injury, reducing the risk of voiding dysfunction, and the risk of urethral obstruction [29].

Until now, there are no conclusive data to recommend the inside-out (TVT-O) over the outside-in (TOT) approach; or the bottom-up (TVT) versus the top-down approach (SPARC). Usually, surgeon preference and training plays a significant role in this decision.

COMPLICATIONS FROM TENSION-FREE MIDURETHRAL SLINGS

A nationwide analysis to evaluate the therapy-associated morbidity from TVT operations was conducted in Finland, where 1,455 patients who underwent TVT from 38 hospitals were recruited [21]. Intra-operative complications were as follows: bladder perforation; 38/1,000; active bleeding (blood loss>200 mL): 19/1,000; injury to major vessels: 0.7/1,000; nerve injury: 0.7/1,000; urethral lesions: 0.7/1,000. Post-operative complications included: retro-pubic hematoma (19/1,000); minor post-operative voiding difficulty (76/1,000); post-operative urine retention (23/1,000); post-operative urinary tract infection (41/1,000); defect in vaginal healing (7/1,000); and complications requiring laparotomy (3.4/1,000) [21]. The study concluded that the TVT procedure is a safe method for the treatment of SUI provided that appropriate training is offered [21]. Lower urinary tract (LUT) injuries from the trans-obturator approach were reported to be 1% in a retrospective cohort study based on 390 procedures, with 241 using the outside-in and 148 using the inside-out technique. Four LUT injuries occurred; two urethral injuries (0.5%) and two bladder injuries (0.5%). All LUT injuries occurred in the outside-in group, although this difference did not reach significance (p= 0.146) [32]. When comparing adverse events according to different approaches, the trans-obturator approach resulted in fewer bladder injuries (OR 0.12; 95% CI 0.05-0.33), and fewer voiding difficulties (OR 0.55; 95% CI 0.31-0.98); however, it was also associated with more groin/thigh pain (OR 8.28; 95% CI 2.7-25.4), vaginal injuries or erosion of the mesh (OR 1.96; 95% CI 0.87-4.39), as compared with the retro-pubic route [27].

Urine retention and/or voiding dysfunction

Urine retention is one of the most common complications following application of tension-free midurethral slings. It is usually caused by undue tension. The symptoms include hesitancy, straining to void, incomplete emptying, urine retention, and increased post-voidal residuals [33]. It can manifest as bladder outlet obstruction, and high pressure with low flow in urodynamic studies [34]. The reported incidence ranges from 1%-17% for voiding disturbances, and

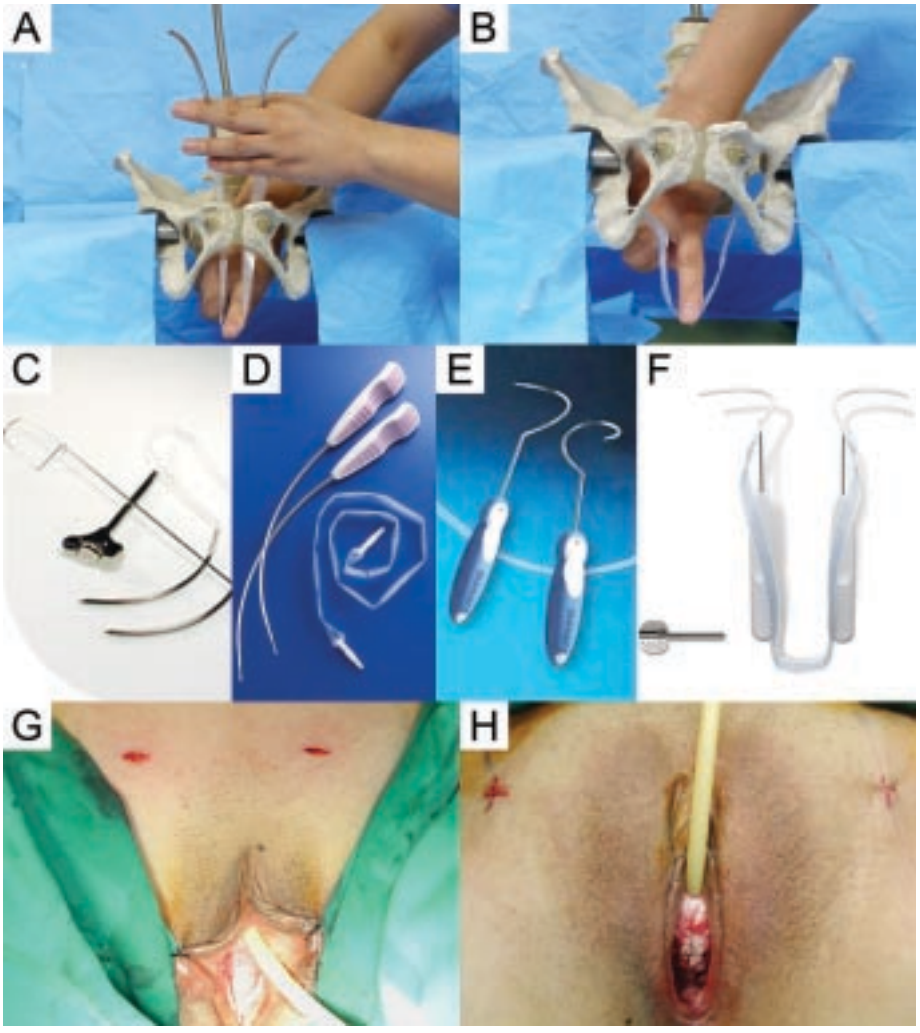

Fig. 4. Comparison of retro-pubic versus trans-obturator approach. The retro-pubic approach (A), e.g. TVT (C), SPARC (D) as the two most common commercially available kits, passes the tape through the retro-pubic space with the incision wounds located low on the abdominal wall (G). The trans-obturator approach (B), e.g. Monarc (E), TVT-O (F), passes the tape through the obturator foramen with the incision wounds located in the groin/thigh areas (H).

0%-3% for urinary retention [35]. The recommended surgical management of urine retention consists of transvaginal transaction or loosening [33], urethral dilataion using Hegar dilatation [36], or lateral excision [37]. Various surgical approaches may be used to treat voiding dysfunctions following an anti-incontinence procedure. Following a vaginal or retro-pubic urethrolysis or removal of a synthetic suburethral sling, obstructive symptoms are likely to improve, symptoms of irritation may remain unchanged, and almost half will develop a recurrence of SUI. Additionally, there was a statistically significant improvement on both quality of life (QoL) questionnaires [38].

Bladder perforation

A variable and high incidence of bladder injury has been reported in the literature, ranging from 0 to 25% [6,39]. It was also reported as 0.8% (5/600) in a study by Wang [40]. There are risk factors responsible for perforation, such as previous pelvic surgery, repeated anti-incontinence surgery, esp. previous colposuspension [41]. Meanwhile, a learning curve is also evident as regards bladder injury; the relationship between the incidence of cystotomy and the cumulative number of cases performed is inversely correlated. As the number of cases a resident completed increased, there was a slight tendency for cystotomy to decrease (p= 0.033) [42]. Therefore, correct insertion of the trocar and intraoperative urethrocystoscopy is imperative in TVTs [40].

A prospective RCT showed that bladder injury was significantly more frequent with the retro-pubic approach compared with the trans-obturator approach (9.5 vs. 0.0%, P= 0.03) [43]. However, unrecognized bladder injuries have also been reported with the trans-obturator approach [28]. Although intra-operative cystoscopy was not recommended for routine use, instead recommended only for selected cases in the original study design [32], some cases of inadvertent cystotomy were noted during routine cystoscopy. Therefore, some authors recommended routine cystoscopy for the trans-obturator procedure, particularly if the outside-in approach is used [44].

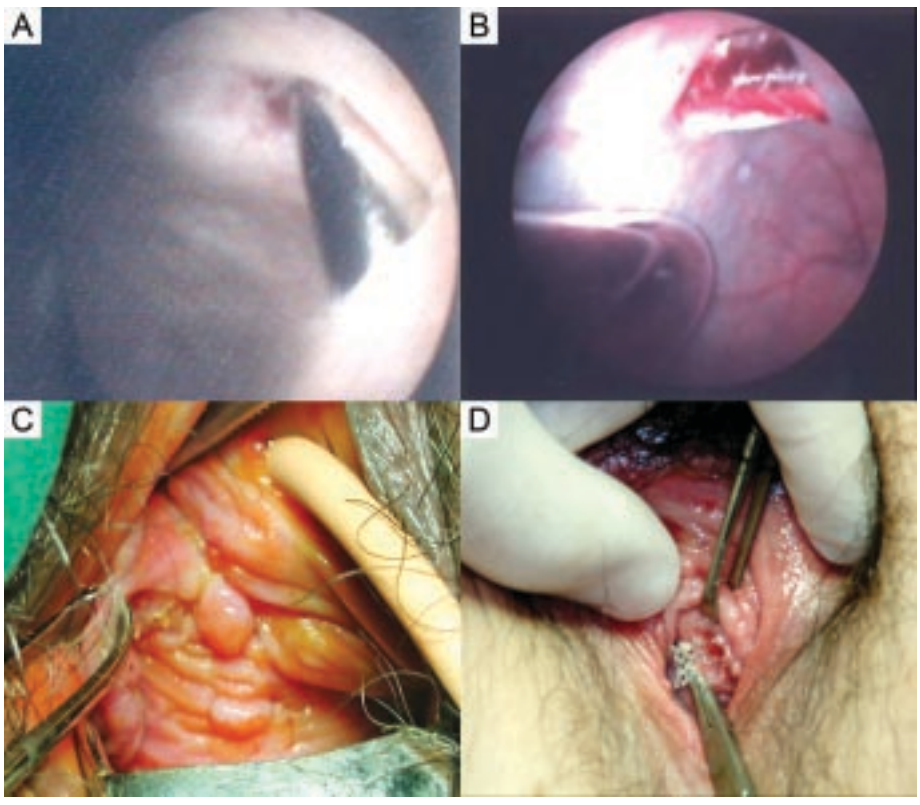

Fig. 5. Two common complications of tension-free midurethral sling surgery include bladder injury and sling erosion. Bladder perforation can either be detected (A) or undetected (B) intra-operatively in a patient with concomitant pelvic organ prolapse. Partial (C) or complete vaginal exposure (D) of sling erosions are illustrated here.

Sling erosion

"Erosion" is defined as the presence of foreign material within the genitourinary tract. A foreign body initially present outside the genitourinary tract and may gradually erode into the bladder, urethra, or vagina [45]. It can present as persistent vaginal discharge, partner discomfort during sexual intercourse, or even be completely asymptomatic [46]. Vaginal erosion of the TVT tape was reported as 0.9% (3/350) [47], and 1.1% (6/546) in our series [48], with incidence varying from 0. 3% to 23% [49]. Sling erosions can manifest as vaginal exposure (Fig. 5C, D), or bladder exposure. The erosion rate was reported to be 2% for TVT-O, as compared with 1.5% for a TVT comparison group [50]. Concerning sling materials, complications from type I mesh, macroporous monofilament polypropylene tape (TVT) are rare 0.2%-1.2% [21]. The complication rate for ObTape (Mentor-Porges, Le Plessis Robinson, France), a non-woven polypropylene tape, is 6.1%-20% [51, 52]. With type III multifilament woven polypropylene tape, vaginal erosion occurs between 7.5%-14% of the time [53].

Most studies suggest complete removal of the eroded tape [54], but conservative treatments are available as alternative options. The exposed vaginal polypropylene slings may be managed with cautious observation. Spontaneous healing can be anticipated in some cases [46]. Sling preservation with urinary continence and patient satisfaction is a possibility for those with vaginal exposure of polypropylene mesh of less than 1 cm [46]. Vaginally exposed polypropylene mesh will become re-epithelialized within 6 weeks. If no overgrowth is evident by 3 months, excision for the eroded slings should be seriously considered [48]. Even with excision of the suburethral sling, the urethral continence function will still be effective [33,55].

CONCLUSION

The tension-free midurethral sling is a revolutionary surgical treatment for SUI. Its minimally invasive approach and success rates have led to increasing popularity of the technique. The trans-obtuturator approach is a potentially safer method as it spares the retro-pubic space. Although the short-term results of tension-free midurthral slings are comparable to retro-pubic colposuspension, long-term studies and RCTs are needed to

identify the proper indications for the various types of slings and to assess efficacy and complication rates over time.

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