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Minimally invasive synthetic suburethral slings: emerging complications

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The tension-free vaginal tape (TVT) and related suburethral mesh devices have revolutionised the management of urinary stress incontinence worldwide and the available evidence suggests that they are as effective as existing continence procedures. They have been marketed as minimally invasive procedures with low complication rates. Evidence concerning the safety and efficacy of these new products, which include transobturator devices, is gradually emerging, but not before the widespread adoption of these techniques for first-line treatment of stress incontinence. This review explores current evidence of emerging complications associated with these techniques.

REVIEW

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Introduction

Many procedures have been developed for the treatment of stress incontinence. Through the 1980s and 1990s, colposuspension was the most popular and effective choice for primary surgery and appeared to be the most effective treatment for stress incontinence, with cure rates of up to 90%.[1,2] Others reported less than half of patients remaining dry and symptom free in the long term.[3,4] The fascial sling procedure is also associated with cure rates in excess of 85%[2] but may carry an increased risk of operative and postoperative complications compared with other procedures.[1] The tension-free vaginal tape (Gynecare®, Ethicon, Somerville, NJ) was the first of a new generation of devices introduced over the last eight years, which involve the placement of a midurethral synthetic woven tape, usually under local or regional anaesthesia.[5]

The TVT procedure was first described in 1996 as a modification of the intravaginal slingplasty, which was developed by Petros and Ulmsten in the mid 1990s, as a day case procedure that could be performed under local anaesthesia and sedation. It consists of a 10 mm wide polypropylene mesh covered by a plastic sheath and held between two curved needles each measuring 5 mm in diameter. The needles and tape are introduced via a small vaginal incision before perforating the urogenital diaphragm and passing blindly through the retropubic space ('shaving' the back of the pubic bone) to the suprapubic area. Cystoscopy is recommended to detect bladder or urethral damage. The tape is adjusted loosely around the urethra and is designed to remain in place, without fixation, once the plastic sheath is removed.

Data from three early case series,[5–7] suggest objective cure rates of 84–100% up to two years. Few complications were reported. Immediate postoperative voiding difficulty was reported in 2–7%, and there was one bladder perforation and two retropubic haematomas, both treated conservatively. This evidence of efficacy led to rapid, widespread adoption of TVT before its long-term safety and effectiveness relative to existing procedures were known. By 2001, TVT had overtaken colposuspension as the most frequent procedure for stress urinary incontinence in the UK (Figure 1).[8] In this period the total number of operations performed per year for stress incontinence increased from around 7500 to over 8500. This can be accounted for by the increase in TVT procedures over and above the reduction in colposuspension procedures.

Although TVT has been perceived as safe and less invasive, there is little evidence from randomised trials on which to base this. It is difficult to draw conclusions regarding both efficacy and safety of the procedure from the many small retrospective studies that have been published. Reporting bias

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may occur with enthusiasm for a new technique and successful outcomes may be more likely to be reported than failures. Larger studies, such as the national databases reported from Finland[9] and Austria,[10] can be used to estimate the frequency of complications. Estimates of the incidence of infrequent but serious or life threatening complications are difficult to determine. Those reported to the manufacturer, government bodies and in the medical literature should be viewed in relation to the number of procedures that have been performed worldwide. In excess of 550 000 TVT procedures had been performed by May 2004 and eight deaths associated with the procedure have been reported to the manufacturer (personal communication, Gynecare).

Most of the published literature concerns the original TVT device, and hence the recent Health Technology Assessment[11] is restricted to making recommendations on this procedure. A number of other midurethral polypropylene tape devices are now available, utilising alternative polypropylene meshes, introducing devices and operative techniques. The procedures can be broadly categorised into retropubic and transobturator procedures. Polypropylene slings can be made of either monofilament threads (for example, TVT; SPARC®, American Medical Systems, Minnetonka, MN; Uretex®, Bard, UK) or multifilament threads (for example, IVS®, Tyco Healthcare International, Exeter, NH). Retropubic procedures can be performed from an ascending vaginal approach (for example, TVT, IVS, Uretex) or via a suprapubic approach (e.g. SPARC, Uretex), which was suggested might reduce the risk of bowel and bladder injury. The transobturator approach was developed to minimise the risk of trauma to internal organs such as bladder perforation or damage to the bowel, blood vessels and nerves.[12] Transobturator procedures can be performed via the vaginal route or 'inside-out' (TVT-O®, Ethicon) or from the skin into the vagina or 'outside-in' (TOT®, Uratape and Obtape, Mentor-Porges; Monarc®, American Medical Systems). Due to the wide variations in these devices and the properties of the meshes, data from studies on one device cannot necessarily be extrapolated to other midurethral procedures.

We performed a comprehensive, albeit not formal, systematic review of the literature relating to complications following minimally invasive, synthetic suburethral slings. We classified complications following surgery as immediate (up to 24 hours), early (24 hours to six weeks) and late (six weeks onwards).

Immediate complications

Haemorrhage

Significant bleeding can occur from the peri-vesical venous plexus in the retropubic space during incontinence surgery. Despite limited vaginal dissection compared with other continence procedures, the venous plexus in the retropubic space is vulnerable to damage during the blind passage of an introducer. Bleeding from the retropubic space may present as increased intra-operative blood loss (vaginally or suprapubically) or subsequently as a retropubic haematoma. The symptoms of retropubic haematoma include pain, voiding difficulty,

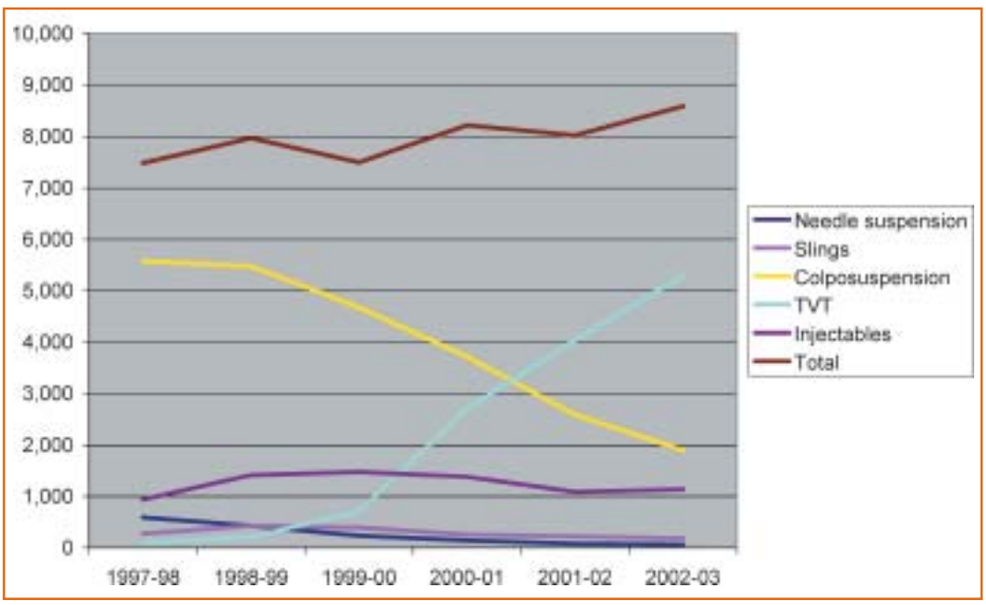

Figure 1. Number of finished episodes of surgery for stress incontinence 1997-2003[8]

Table 1. Complications associated with the TVT procedure in larger series (number [%])

Study	Patients	Haematoma	UTI	Vaginal erosion	Nerve injury	Voiding disorder	*De novo* urge incontinence	Other
Ward, Hilton[13]	165	3 (2)	38 (22)	1 (0.6)		11 (9)		
Tamussino *et al*[10]	2795	19 (0.7)	486 (17)			39 (1.4)		
Kuuva, Nilsson[9]	1455	27 (1.9)	59 (4.1)	10 (0.7)	1 (0.06)[a]	34 (2.3)	11 (0.8)	DVT, seroma
Rardin *et al*[21]	245	5 (2.0)[b]		1 (0.6)		28 (11.4)	63 (25.7)	Death on day 2
Meschia *et al*[49]	404	6 (1.5)		2 (0.5)	1 (0.2)[a]	17 (4)		
Jeffry *et al*[68]	112		12 (10.7)			14 (12.5) <15 days 4 (3.6) >15 days	29 (25.9)	
Deval *et al*[54]	187		16 (8.5)			14 (7.5) <15 days 6 (3.2) >15 days	40 (21.3)	
Debodinance *et al*[57]	256	1 (0.4)	8 (3.1)			13 (5.1)	31 (12)	Renal failure
Bodelsson *et al*[69]	177	1 (0.5)	12 (7)	3 (1.7)		35 (20)	9 (6)	
Karram *et al*[43]	350	8 (2.3)	38 (10.9)	2 (0.6)	3 (0.9)[c]	17 (4.9) >7 days	42 (12)	
Abouassaly *et al*[70]	241	5 (2.1)	25 (11.8)	2 (1)		15 (32) >48 hours	33 (13.6)	
Nilsson, Kuuva[71]	161	2 (1.2)	10 (6.2)			7 (4.3)	5 (3.1)	

[a]Obturator nerve [b]Includes haematoma and abscesses [c]One obturator, 1 ilioinguinal, 1 femoral DVT = deep vein thrombosis UTI = urinary tract infection

pelvic mass and a drop in haemoglobin, although many are asymptomatic and the true incidence is not known.

Median blood loss from TVT was found to be significantly lower than with colposuspension (50 ml from TVT and 128 ml from colposuspension, $P < 0.001$).[13] The Austrian registry[10] report the rate of increased operative bleeding as 2.3% overall and similar in those with and without previous surgery for incontinence or prolapse. Clinically apparent retropubic haematomas occur in 0.4–2.3% of women (Table 1) and can be the cause of significant morbidity.[14] Retropubic haematomas were seen in five out of 140 (3.6%) women undergoing a SPARC procedure in one series.[15]

Major vascular injury during blind retropubic procedures is a rare but potentially fatal occurrence. The true frequency with which this occurs is not known. Forty-eight major vascular complications (including two deaths) have been reported to the manufacturer from over 550 000 procedures (0.009%). In the study from Finland,[9] there was one injury in 1455 patients (0.06%) and an injury to an abnormal obturator artery was reported in the UK and Ireland TVT trial (0.6%).[13] Injuries to the obturator, external iliac, femoral and inferior epigastric arteries have also been reported.[9,13,16,17]

The relationship between the passage of the TVT tape and vascular anatomy has been studied by cadaver dissection.[18] The mean distance of the tape to the vessels in the anterior abdominal wall and retropubic space is shown in Table 2. The study by Muir *et al.*[18] confirms that the major vascular structures are lateral to the ideal placement of the TVT needle and that a small cephalad or lateral excursion of the TVT needle during insertion leaves the arteries vulnerable to laceration. The authors suggest that surgeons may deflect the needle laterally either deliberately to avoid bladder perforation or inadvertently if the patient moves during needle insertion.[16]

Vascular injury has been reported in association with other retropubic devices (SPARC, Uretex and IVS)[17] although there are few large series available with which to compare the frequency of this event with TVT.

There were no major vascular injuries or bleeding complications in 183 women undergoing a transobturator tape (Uratape) procedure in one series,[12] and none have yet been reported for other transobturator devices. Cadaver dissection has been used to determine the relationship between a transobturator sling and anatomical structures within the obturator

Table 2. Mean distance and range from the lateral margin of the TVT needle to the medial edge of vessels in the anterior abdominal wall and retropubic space. Numbers are expressed as mean cm (range).[18]

Vessel	Distance
Superficial epigastric	3.9 (0.9–6.7)
Inferior epigastric	3.9 (1.9–6.6)
External iliac	4.9 (2.9–6.2)
Obturator	3.2 (1.6–4.3)

Table 3. Lower urinary tract injury associated with mid-urethral tape devices

Study	Procedure	Number of patients	Number of bladder perforations (%)	Number of urethral injuries (%)
Ward, Hilton[13]	TVT	165	15 (9)	0
Tamussino *et al*[10]	TVT	2795	75 (2.7)	0
Kuuva, Nilsson[9]	TVT	1455	56 (3.8)	1 (0.06)
Rardin *et al*[21]	TVT	245	8 (3.3)	0
Meschia *et al*[49]	TVT	404	24 (6)	0
Jeffry *et al*[68]	TVT	112	13 (11.6)	0
Deval *et al*[54]	TVT	187	18 (9.6)	0
Debodinance *et al*[57]	TVT	256	14 (5.5)	1 (0.4)
Bodelsson *et al*[69]	TVT	177	25 (15)	2 (1.1)
Karram *et al*[43]	TVT	350	19 (4.9)	0
Abouassaly *et al*[70]	TVT	241	14 (5.8)	0
Nilsson, Kuuva[71]	TVT	161	6 (3.7)	0
Monga *et al*[20]	SPARC	113	8 (7.1)	2 (1.8)
Minaglia *et al*[72]	TOT	61	3 (4.9)	
Costa *et al*[12]	TOT (Uratape)	183	1 (0.5)	2 (1.1)
Delorme *et al*[22]	TOT (Uratape)	150	0	0
Grise *et al*[73]	TOT	141	1 (0.7)	1 (0.7)
Schulman *et al*[74]	TOT	100	1 (1.0)	3 (3.0)
Naidu *et al*[75]	MONARC	62	0	1 (1.6)
Mellier *et al*[40]	MONARC	204	0	0

region.[19] Considerable variation in vascular anatomy was found among the six cadavers. The transobturator device passed on average 1.1 cm (range 0.5–1.4 cm) from the most medial branch of the medial division of the obturator vessels.

Urinary tract injury

Bladder perforation is a well documented risk of retropubic continence procedures (Table 3) (2.7–15% of TVTs and eight of 113 [7.1%] SPARC procedures).[20] Data from the Austrian registry suggest bladder perforation rates are higher in patients with previous surgery for incontinence or prolapse (4.4% for those with previous surgery and 2.0% for those without, $P = 0.01$). This finding is not confirmed by Rardin *et al*,[21] who found no difference in rates of bladder trauma following previous incontinence surgery in their series of 245 women. Transobturator slings were designed to minimise the risk of bladder trauma and many surgeons no longer routinely perform cystoscopy following the procedure.[12,22] Bladder perforations have, however, been reported in 0–4.9% of women (Table 3).

Figure 2. Bladder perforation by a TVT needle

Bladder injury recognised by cystoscopy at the time of surgery (Figure 2) and treated by indwelling catheterisation for 24 hours appears to have no long-term sequelae. Unrecognised bladder perforation can lead to immediate postoperative vaginal leakage,[17] and vulval oedema has been reported.[23] In the long term, intravesical mesh can cause pain, recurrent urinary tract infection, urge symptoms and stone formation[24–26] (Figure 3).

Urethral injuries occur infrequently during the TVT procedure (Table 3) although there are few data on injuries as a consequence of the other retropubic procedures. It is likely that a proportion of women presenting late with apparent urethral erosion of tape will have had an undiagnosed perforation at their initial surgery,[27] particularly when symptoms of pain and urinary retention have been present since TVT placement (Figure 4).

Urethral injuries are also seen following transobturator procedures and have been reported in 0–3% (Table 3). It is not known whether the risk of injury to the urethra is reduced as a consequence of the 'inside-out' approach taken by the TVT-O device as there have been no comparative trials.

Bowel injury

Bowel trauma is rare but potentially the most serious complication. Perforation is unlikely to be recognised at surgery and delayed diagnosis can lead to significant morbidity. Six of eight

Figure 3. TVT encrusted with stone, 15 months after insertion (reproduced with permission from Hilton *et al.*[27])

reported deaths associated with TVT were attributed to bowel perforation. One injury to the small bowel was reported in the Austrian registry (0.04%). Bowel injury has been reported as a consequence of both the SPARC and Uretex procedures.[15,17]

Both ileal and colonic perforations have occurred as well as perforation of the small bowel mesentery leading to small bowel obstruction.[28] Bowel injury usually, although not invariably,[29] occurs in patients who have had previous pelvic or lower abdominal surgery. Bowel injury can present with fever, abdominal pain or intestinal obstruction and leakage of bowel contents from the suprapubic incisions has been described following perforation of the ileum.[30]

Bowel complications have been reported several months after surgery. A patient who presented with bowel obstruction five months after surgery was found to have TVT penetrating a loop of ileum. The authors suggest that it had eroded into the bowel.[31]

No bowel injuries have been described following transobturator procedures.

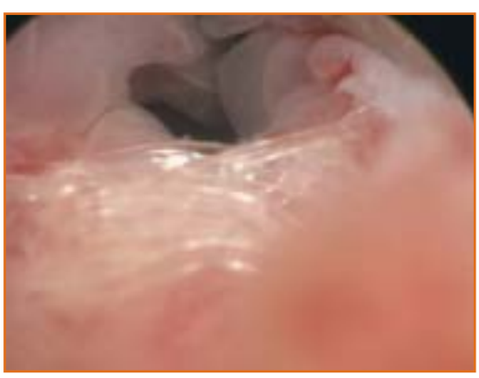

Figure 4. TVT tape sitting across proximal urethra

Early discharge following surgery, together with failure to recognise intra-operative bowel injury, lead to delay in diagnosis with increased morbidity and mortality. The risk of trauma can be minimised by adherence to the technique as described by Ulmsten *et al.*,[5] of keeping close to the back of the pubic bone with the introducer. It is important to consider this diagnosis in patients presenting with pain and/or fever following surgery.

Early complications

Infection

Urinary tract infection is the commonest sequel of incontinence surgery and occurs in 3.1–22% of women following a TVT procedure (Table 1). The rate of urinary tract infection reported in the Austrian registry was higher in those who had indwelling catheterisation following the procedure: 8% among those with intermittent catheterisation, 18% with indwelling urethral catheterisation and 25% with suprapubic catheterisation ($P = 0.01$).

Wound infection and infection of the TVT tape are surprisingly uncommon. Of 12 infections reported by Kuuva and Nilsson[9] in 1455 patients, four developed abscesses requiring surgical drainage. One was suprapubic, one retropubic and in two the location was not stated. Neuman[32] described two infected haematomas in 238 consecutive patients (0.84%). These were treated with antibiotics alone and did not require tape removal. Fournier's gangrene and necrotising fasciitis have been described following TVT.[33,34] The rate of infection following IVS insertion was found to be significantly higher than following TVT in a non-randomised, retrospective study,[35] occurring in 11 of 149 (7.4%) IVS procedures and none of 164 TVTs. In women in whom the sling was removed, four had recurrence of stress incontinence and four reported sexual problems. To date there have been few reports of infection following the use of transobturator tapes.[17,36]

Tape erosion

One of the major concerns about inorganic synthetic sling materials is their potential to erode into the urinary tract and vagina. This complication has been well reported following traditional suburethral sling procedures.

Early erosion into the vagina is most likely to be due to failure of vaginal skin healing rather than

true erosion (Figure 5). It has been reported following all suburethral procedures, both retropubic and transobturator[17] and occurs in 0.5–1.7% of women following TVT (Table 1). Delayed vaginal healing following the SPARC procedure occurred in two out of 113 (1.8%) women in one series[20] and three out of 90 (3.3%) in another.[37] There is evidence from two studies that defective vaginal healing is more common following IVS than TVT. In one non-randomised comparative study, one woman from 127 (0.8%) with TVT and six out of 40 (15%) with IVS experienced defective healing, erosion or extrusion of the tape ($P < 0.001$, χ^2 test).[38] A randomised comparative study also found significantly higher rates of vaginal erosion in the IVS group, with defects in eight of 87 (9%) women following IVS compared with none in 92 TVTs ($P = 0.013$).[39]

Delayed vaginal healing following insertion of transobturator tape occurred in three out of 183 (1.6%) in one series with Uratape, and in two out of 204 (1.0%) women following a Monarc procedure.[40]

Early erosion or defective vaginal healing is usually treated by tape trimming or excision and resuturing, but success with conservative management has been reported for TVT erosion,[37] which includes observation and avoidance of sexual intercourse.

Erosion of TVT has been reported up to 18 months after surgery[41] and the authors are aware of one asymptomatic case found at five years at a scheduled trial follow-up visit, which had not been present at four years (unpublished).

Erosion of synthetic sling materials into the urethra has been well documented.[42] It is difficult to be certain of the extent of problems relating to new procedures, as erosion from synthetic slings may not become apparent until relatively late. The low rate of sling erosion reported in the TVT series may be a reflection of short follow-up intervals rather than low risk of erosion. Of the series listed in Table 1 there was only one urethral erosion (0.6% for this study, 0.015% of the all patients included in studies)[43] and 20 (0.004%) have been reported to the manufacturer. There have been few reports of urethral erosion following other procedures; however, two occurred in a series of 183 transobturator tape procedures.[12]

Figure 5. Edge extrusion of TVT tape

Urethral erosion following TVT has been reported on a number of occasions[44–47] although the incidence appears to be low. In the majority of cases this was associated with severe voiding difficulty, often from the time of surgery, with or without urge incontinence, haematuria and pain. The timing of symptoms in relation to surgery has led to the suggestion that a number of urethral erosions may be missed urethral perforations[27] and that the urethra should be inspected with a 0° or 12° telescope perioperatively or in women presenting with problems.

Excision of the intra-urethral tape with urethral repair (with or without a Martius graft) has been reported with variable effects on continence. Although urethrovaginal fistulae have been reported following TVT, none have been described in association with tape excision.

Nerve injury/pain

Injury to the ilioinguinal nerve,[43,48] the obturator nerve[9,43,49,50] and the femoral nerve[43] have been described following the TVT procedure. Injury to the ilioinguinal nerve is a recognised risk in low transverse abdominal incisions and has been described following needle suspension procedures.[51] The ilioinguinal nerve provides sensory innervation to the skin that overlies the groin, inner thigh and labium majus. Patients with ilioinguinal nerve injury typically have burning pain and altered sensation in this area. Given the anatomical course of the nerve, it is surprising that nerve injury has not been reported more frequently.[52] Some injuries resolve spontaneously over time, while others may require nerve blockade with local anaesthetic or local steroid injections.

Obturator nerve injury is a rare but serious complication of the TVT procedure[9,43,49,50] that can occur following insertion of the TVT tape that is too lateral.

Kuuva and Nilsson[9] reported one obturator nerve injury in their series of 1455 cases. Three patients in this series developed pain in the region of the gluteal muscle and thigh. Two

settled spontaneously and one was confirmed to have obturator nerve compression by electromyography. The pain resolved after cutting the tape. Another obturator nerve injury was reported by Meschia *et al.*[49] in a series of 404 women. In a series reported by Moran *et al.*[50] one woman suffered acute right inner thigh pain at the time of inserting the needle in a procedure performed under local anaesthetic. The needle was removed and placed more medially, leading to resolution of her pain. Postoperatively, she had right adductor weakness with a mild limp and was shown on electromyography to have suffered partial damage to her right obturator nerve. A probable nerve injury occurred following SPARC procedure when a patient complained of inner thigh pain.[17]

Chronic groin pain is described following colposuspension (post colposuspension syndrome) and is often relieved by cutting the stitch on the affected side. Similar occurrences have been described following the TVT procedure.[53,54] Severe pain occurred following surgery and responded to removal of the tape. In both of these cases, pain was relieved and continence was preserved. Groin pain has been reported in three out of 204 women (1.5%) following the Monarc procedure.[40]

Fistulae

One vesicovaginal fistula was reported in the series of 1455 TVTs from Finland[9] and was thought to be caused by an unidentified bladder perforation. Urethrovaginal fistulae following TVT are rare and have been described in women who have had previous continence procedures; one an anterior colporrhaphy with Kelly sutures[55] and the other a woven polyester pubovaginal sling.[56] A urethrovaginal fistula occurred in association with an infected transobturator tape; however, symptoms were apparent on the first postoperative day and this may represent unrecognised urethral perforation.[36]

A ureteric fistula following TVT has been reported in a case series.[57] The procedure was performed in conjunction with prolapse surgery and no further details are given.

Voiding dysfunction

Procedures for the correction of stress incontinence are commonly obstructive and can result in voiding difficulties. Sling procedures are thought to be less obstructive than colposuspension with approximately 10% (range 2–20%) of women developing voiding disorder.[2] The incidence of voiding disorder following incontinence procedures is difficult to determine, as there is a lack of clear definitions. It can vary from transient postoperative retention, obstructive urodynamic findings or the continuing need for catheterisation.

Several studies have demonstrated a reduction in peak flow rate with no significant rise in maximum voiding pressure following TVT,[13,58] although there is some evidence that voiding function improves over time.[59] In the UK and Ireland TVT trial,[13] 5% of women developed transient voiding disorder following TVT, requiring catheterisation up to one month; by six months this had gone down to 3% and by two years no women required clean intermittent self catheterisation. Only one of the 169 women underwent tape division for obstructed voiding.

Tape division is widely described as a treatment for severe voiding difficulty, with the majority of patients (range 61–94%) remaining continent.[60–62]

There is little available evidence on voiding function following other procedures. Pifarotti *et al.*[39] found no difference in rates of voiding disorder between TVT (13%) and IVS (10%). Costa *et al.*[12] reported voiding disorders in seven (3.8%) women following insertion of Uratape (transobturator tape): three underwent immediate surgical release and four were treated with intermittent self catheterisation. Two did not recover voiding function. They also found a reduction in peak flow rate following this procedure.

Late complications

Detrusor overactivity

Detrusor overactivity occurring *de novo* following continence surgery has been well described, with an incidence following sling surgery of 16.6% (4–29%),[2] and it occurs more frequently following previous continence surgery. The aetiology of this complication is not known; however, it is likely that a number of cases reflect pre-existing detrusor overactivity, which is not detected at preoperative cystometry. The results of colposuspension in women with co-existing detrusor overactivity are known to be poorer than when there is urodynamic stress incontinence alone.[63] The incidence of *de novo* detrusor overactivity in patients undergoing TVT is 8% based on a single trial.[13] There have been very few studies that include full postoperative urodynamic evaluation. A similar proportion of women

(6.2%) developed detrusor overactivity following the SPARC procedure.[20]

Urge incontinence following TVT has been reported in 0.8–25.9% of women. This wide variation is likely to reflect variation in the definition and questions concerning urge symptoms rather than differences in outcomes between the centres. A reduction in urgency and urge incontinence and the degree of bother associated with these symptoms has been reported following both TVT and conventional surgery (colposuspension).[13] In patients undergoing TVT, troublesome urgency was reported by 82% preoperatively and 33% two years after surgery.

Pregnancy

There are now several reports of pregnancy in women following TVT; all have remained dry throughout and after pregnancy, although all of those so far described have been delivered by caesarean section.[13,64,65]

Sexual dysfunction

There are conflicting data on the effect of the TVT procedure on sexual function. In the UK and Ireland TVT trial,[13] in 169 patients who had TVT there was a significant reduction in the number of women whose sex life was spoilt due to incontinence and in the number experiencing incontinence with intercourse. There was no significant difference in the reporting of dyspareunia and there were no questions concerning libido. The findings did not differ from those in the colposuspension group. In contrast, deterioration in sexual function has been noted in other studies of TVT.[66,67] In one study, 11 out of 55 (20%) women reported worsening of sexual function, with dyspareunia in eight (14.5%).[67]

Conclusion

The TVT and related suburethral mesh devices have revolutionised the management of urinary stress incontinence worldwide and the available evidence suggests that they are as effective as existing continence procedures. They have been marketed as minimally invasive procedures with low complication rates that can be safely performed by the generalist gynaecologist or urologist.

The TVT procedure has been extensively investigated but among the wealth of literature there are few randomised trials or large cohort studies. Many of the studies are of poor quality, with small patient numbers and non-standard outcome measures. Evidence of the safety and efficacy of the newer procedures, such as transobturator tapes, is gradually emerging, but not before the widespread adoption of these techniques for first-line treatment of stress incontinence.

The overall rate of complications following the TVT procedure appears to be comparable to conventional treatments such as colposuspension. The majority of these are minor, with bladder injury and urinary tract infection the most common. Bladder perforations appear to have no long-term sequelae if recognised at the time of surgery but are the cause of significant morbidity if overlooked. Perioperative cystoscopy has been abandoned by many surgeons performing transobturator procedures without convincing evidence of a reduced rate of urinary tract perforation.

Life threatening complications of surgery are rare (0.009–0.04%) and include vascular and bowel injury. These injuries have yet to be described following transobturator procedures. Evidence concerning erosion into the vagina and urinary tract is incomplete as long-term follow-up is required. All of the polypropylene meshes included in this review have been reported as having eroded into the vagina; however, the IVS has a significantly higher risk of vaginal erosion than TVT.

Adherence to the described operative techniques should reduce the risk of injury to nearby structures such as bladder, bowel, nerves and blood vessels. The technique of the TVT and related procedures is relatively straightforward for those surgeons accustomed to operating in the retropubic space; for example, during sling or needle suspensions, but may be less so for inexperienced surgeons. Knowledge of the anatomy of this area should reduce the complication rate and aid diagnosis of complications when they arise.

High quality research in this rapidly expanding area is urgently required to assess the efficacy and safety of new procedures. The difficulty and expense of performing large randomised trials means that comparative data are unlikely to be available for the majority of new operations. National registries of surgical procedures can provide important additional information about the incidence of adverse outcomes. Suburethral polypropylene tape has been implanted into over half a million women and long-term follow-up studies are clearly needed to quantify the risk of tape erosion in these women.

Declaration of interest

Paul Hilton was principal investigator and Karen Ward trial coordinator for a multi-centre randomised controlled trial of TVT versus colposuspension funded by Gynecare. Paul Hilton has also been involved in development work on another midurethral tape, funded by Gyneideas. Neither author has personal financial interest in these or other companies.

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