Review Article

Midurethral slings in the mesh litigation era

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Abstract: Stress urinary incontinence (SUI) has always been a major health issue for women. With the progression of technology and surgical techniques, mid urethral slings (MUS) used in both transvaginal and transobturator routes have become the gold standard in the treatment of SUI. There is ample short to mid-term data confirming the efficacy and safety in using MUS in treating SUI in women. However, long-term data supporting the use of MUS in women to treat SUI is scarce. There has been much controversy surrounding the US Food and Drug Administrations' (FDA) public notification of potential complications surrounding the use of transvaginal mesh, which has been magnified and generalised by the media; but despite this there has still been substantial growth and uptake of MUS for treating SUI. In this review, we aim to explore some of the issues with MUS, the factors around litigation with mesh use, the impact of FDA's notification on the uptake of MUS and ultimately, the results and efficacy of MUS for the treatment of SUI.

Keywords: Mesh sling; complications; female urinary incontinence; FDA warning

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Introduction

Stress urinary incontinence (SUI) is the involuntary leakage of urine whilst under increased abdominal strain (e.g., sneezing, coughing and laughing). This is a very prevalent condition that affects the health of up to 35% of women (1). It has been estimated that 11% of women by the age 80 will undergo surgery for pelvic organ prolapse (POP) or urinary incontinence (2), which can lead to detrimental effects on the quality of life (QoL) for women; creating anxiety, depression and social isolation (3).

Pathophysiology of SUI is due to one of two problems; (I) urethral hypermobility and (II) intrinsic sphincter deficiency (ISD). In urethral hypermobility, the descent of the bladder neck and proximal urethra is thought to be caused by the laxity or weakness of the surrounding pelvic floor. This descent produces unequal pressures between the bladder and proximal urethra and thus, urine leakage occurs (4). This concept was first elaborated by Petros and Ulmsten in their Integral theory (5), which led to the concept of midurethral support without tension for SUI correction.

ISD is another cause of SUI. The loss of urethral tone that keeps the urethra lumen closed creates a situation where urinary incontinence can occur. This is thought to be mainly from neuromuscular damage and is often seen in women who have had repeated pelvic, incontinence operations or radiation damage.

Surgical treatments of SUI have advanced over the years from the first described use of a gracilis muscle flap in 1907 (6) to the previous gold standard Burch colposuspension in 1961 (7). The modern mesh sling was first introduced in 1995, and was refined and coined by Ulmsten as the tension free vaginal tape (TVT) (8). This quickly became the new gold standard in many surgeons' opinions as the number of studies and short and medium-term outcome data accumulated and showed positive results. However, due to the retropubic passage of the introducer and mesh, past studies have stated that up to

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7% of surgeries can produce complications (9). These complications, as described in literature can include bladder perforation, bowel perforation, vessel damage and voiding dysfunction (9,10). Bladder perforation is quite common as evident by the reported rates of up to 24% (11). On the other hand, urethral injury during a TVT insertion is less common but has also been reported in the literature (12).

The path of TVT trocars can be affected by the lateral or cephalad angulation from the usual insertion technique resulting in the marked deviation in the trajectory. This could be disastrous, as the mean distance from the trocar to the major vessels has been shown to be less than five centimetres (13). Bowel perforation is another adverse event, which can result from TVT placements. The Manufacturer and User Facility Device Experience (MAUDE) database has noted that these occurrences are rare but do occur. Up until 2008, there have been at least nine bowel perforations in which six cases resulted in mortality (14). However, due to the voluntary nature of reporting in this database, the statistic quoted is likely to be under-reported.

In a retrospective study, voiding dysfunction has also been described in the literature with de novo urgency after TVT occurring in up to 25% of patients (15). Voiding dysfunction has been theorised to arise from both irritation from the proximity of the tape to the urethra as well as mild obstruction from the mesh.

In general, vaginal mesh used for SUI has an erosion rate of up to 1.6% of cases (16). Uratape™, and the replacement, Obtape™ have had an unexpectedly high mesh erosion rate, which has been reported to be as high as 14% (17). This was due to the different construct of the mesh; Obtape is quite microporous (18) which meant a decrease in host integration and subsequent increased of risk of infection and extrusion (19); as compared to the usual type I polypropylene meshes. Obtape has since been removed from the market in 2006 (20) due to the above factors.

Consequent to the increasing complications reported through literature of the TVT technique, the innovation of the transobturator approach was introduced by Delorme (outside-in) in 2001 (21) and a variation of this approach was introduced in 2003 by de Leval where the tape was inserted in a reverse order (inside-out) (22). Despite the variation and innovation of Delorme and de Leval, the approaches introduced were not without their own associated complications.

The more horizontal passage of needle introducer created a set of separate complications including persistent thigh and groin pain which has become an issue (23). Other rarer adverse events such as obturator nerve injuries, ischiorectal fossa abscess, large blood loss and peroneal tendon fasciitis have also been described in the literature (24) as complications which have arisen from Delorme and de Leval's approach. Despite these somewhat catastrophic albeit rare complications, the recently updated Cochrane's review on MUS did not indicated a decline in its use in favour of TVT by pelvic floor surgeons in general (25).

A retrospective study of 390 patients who underwent transobturator tape (TOT) insertions also reported complications such as bladder injuries (0.5%) and urethral injuries (0.5%). It was noted that these complications all arose in the outside-in group but that the difference however was not statistically significant (26). A prospective multicentre trial demonstrated the overall perioperative complication rate to be at 2.2% with no vascular, nerve or bowel injuries (16). In general, transobturator slings have been evaluated to have less voiding dysfunction compared with TVT (27).

The single incision mini sling (SIMS) was introduced in 2008 with the aim to further decrease potential complications from retropubic and transobturator approaches. There is no blind passage of the needle introducer through the retropubic space when inserting the TVT nor the passage of trocars through the obturator or adductor muscles when inserting the TOT. Instead, the SIMS requires only a single suburethral incision and the adjacent creation of a tunnel in either a "U-type or H-type" where the sling would lie. This therefore eliminates the potential complications associated with these trajectory paths.

Litigation

Since the mid 2000s, there has been a rapid uptake of the various new synthetic midurethral sling and trocar based vaginal mesh POP kits. Part of the reason for this rapid expansion of new kits and mesh is due to the US Food and Drug administration FDA 501(k)'s premarket notification approval system for Class II medical devices.

Medical devices under this class only require that the manufacturers demonstrate the new device is comparable to existing or previous products. In theory, these new devices should provide similar outcomes and favourable results. However, in practice, this is not always the case, which is explored further below. Based on the FDA's classification of the various slings and trocar based vaginal mesh POP kits, there was a significant uptake of the various repair kits

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around the world from different manufacturers.

With the increased uptake of repair kits worldwide, there has also been a significant increase in numbers of adverse events reported post the FDA's Class II approval of this medical device. The Class II nature of these new mesh devices meant an extremely rapid roll out of new meshes and kits available (28). This was in part, fuelled by aggressive marketing techniques of these products usually directed at surgeons, limited training of the correct placement of these meshes; often only via a weekend workshop and the paucity and limited long term data on these products. The culmination of the above factors meant large numbers of unproven newly designed mesh and kits were placed in patients without a complete suite of knowledge and consequences. Thus, the rise of complications not previously encountered, with the smaller population receiving mesh corrective surgery emerged as a result. Market data suggests that in 2010 approximately 75,000 women received POP mesh repair and at least 208,000 women had mesh for SUI surgeries (29).

In 2008, the FDA issued a public heath notification regarding the "serious complications associated with transvaginal placement of surgical mesh in repair of POP and stress urinary incontinence" (30). In the notification, they described that in the three years prior, there had been over 1,000 reports from nine surgical mesh manufacturers regarding complications associated with the use of these meshes. The most frequent complications included vaginal epithelium erosions, infections, pain, urinary dysfunction or incontinence as well as the recurrence of prolapse. Less frequent complications included bowel and bladder perforations as well as vascular vessel damages, of which unfortunately some were fatal.

Treatment of these complications ranged from simple conservative management to high morbidity laparotomies and corrective surgeries. These complications have been well documented in the literature (31-33). In 2011, the FDA further updated the notification stating that serious complications associated with surgical transvaginal mesh repair of POP were not rare. Since the initial notification, the FDA had further received 2,874 additional reports of complications associated with mesh use in POP and SUI repairs (29). Post the 2011 statement, the FDA has mandated more than 650 post market surveillance studies for transvaginal mesh POP, slings and mini slings (34).

In early 2016, the FDA reclassified transvaginal mesh used for POP as a Class III device (35). This reclassification did not include mesh for SUI. In the 2013 update the FDA had clearly stated "the safety and effectiveness of multi-incision slings is well-established in clinical trials that followed patients for up to one-year".

The landmark case of successful litigation against Bard's Avaulta Plus BioSynthetic Support System™ was in 2012. A 53-year-old female was awarded a USD$5.5 million compensation for POP mesh erosion (36). This set a powerful precedent for many other litigations to follow. Some other examples of litigation include the Coloplast case in 2014 where 400 claims were settled totalling payments of USD$16 million (37). The American Medical Systems/ Endo International also settled many cases with payments totalling around USD$1.3 billion (38).

The attractiveness of big payouts and sensationalization reports of "vaginal mesh" in the media created a damning image for all transvaginally inserted meshes whether they are used for POP or SUI. Patients became aware of the issues associated with vaginal mesh through the litigation lawsuits, legal advertisements and media reporting. These media reports may not always be a hundred percent accurate nor did they provide enough specific information to differentiate on a case by case basis. Considering this, the public's knowledge of the vaginal mesh is likely to be negatively skewed.

Literature has subsequently found that many patients had heard of MUS but only a quarter had received in depth education on the topic by a medical professional (39). In a cross section study by Koski *et al*., they found that only 12% of women understood the difference in mesh use of SUI versus POP repair. It is alarming to note that 33% of those interviewed stated that legal advertisements, more so than medical professionals, had been a major factor in shaping their opinion regarding transvaginal mesh (40).

As a result of media reports, there is an unbalanced and overly negative perception of mesh used in SUI caused by the reporting of this issue in the media. The media has lacked emphasis on clarifying the use of mesh in SUI and has generically grouped the specific use of mesh in SUI with vaginal mesh as a whole.

Many professional bodies have published position statements on this issue to assist in clarifying the ambiguous perception caused by legal and media outlets. For instance, the American Urological Association, Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) have all published their support for placement of multi-incision monofilament mid urethral slings (MUS) for the treatment of SUI in appropriate patients by surgeons trained in this area (41).

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These professional bodies have aimed to calm the public perception that all mesh kits will result in negative results.

Impact of use of slings (Medicare data)

As part of the Urologic Disease in America project, Anger *et al*. (42) took a 5% national random sample of female Medicare beneficiaries aged 65 years and older in the period between 1992 and 2001. This data was obtained from the Centers for Medicare and Medicaid services carriers. The procedural count was then multiplied by 20 to estimate the true number of procedures carried out. Over this 10-year period, they found overall surgical procedures performed for SUI had nearly doubled from 18,820 to 32,480. In the early 1990s only a small number of slings [640] were being placed in patients but by year 2001 it had become the most popular procedure for SUI with 17,680 procedures being carried out in that one year. This rapid rise in numbers was balanced out by the steady decline of other procedures in treating SUI such as the needle suspension or the anterior urethropexy.

In the period from 2002 to 2007, Rogo-Gupta conducted a study using the same methods described by Anger *et al*. Rogo-Gupta found that while there was a relatively stable number of total surgical procedures carried out for SUI (49,340 in 2002 versus 49,900 in 2007), there was a definitive rise in the number of slings placed (25,840 in 2002 versus 33,880 in 2007). There was also a corresponding decrease in other procedures including injectable urethral bulking agents, urethropexy, Raz-type suspension, hysterectomy with colpo-urethropexy, laparoscopic repairs, Kelly plication and Pereyra procedure over this six year period (43).

A recent online survey by the American urogynaecology society (AUGS) of its members between December 2011 and January 2012 after the 2011 Food and Drug Administration (FDA) safety update reported no change in synthetic mesh sling use (P=0.10), although there was a statistically significant decrease in transvaginal prolapse mesh use with 40% reported decreased use and 12% stopped use altogether (P<0.001) (44).

Using the Marketscan commercial claims and encounters database, Geller *et al*. analysed the numbers of SUI procedures carried out both as an inpatient and outpatient setting. It was found that between the year 2000 and 2009 the most common procedure was a sling with a 27% increase in sling procedures over that 10-year window. It was interesting to note that there was a corresponding drop in Burch colposuspension and other procedures within the same period. There was a definitive drop in the sling procedure during 2008 which was the same year that the FDA released their safety communication regarding transvaginal mesh complications (45).

Whilst in Australia, Lee *et al*. (46) analysed the data from Medicare Australia between the period of January 1994 to December 2009. They reported that the MUS over the 16-year period has progressively become more popular year by year. It had become the most common SUI procedure by 2002. By 2009, the MUS procedure made up 85.5% of all SUI surgeries. Recently Brown *et al*. aimed at identifying surgical treatment patterns of women with SUI in Australia stratified by age from January 1994 to December 2014. This data extracted from the Medicare data registry showed a peak in total SUI surgeries following the introduction of the MUS in 2002, a plateau between 2006 and 2011, and a new decline from 2012 onwards. Interestingly, there is a steady increase in total SUI operations for women between 75- to 84-year-old and those over 84 years old but a decrease below pre-MUS baseline in 2014 in those aged 45- to 64-year old. They reported this decline as being contributed by 2 raison d'etre: (I) a shift of SUI management to nonsurgical options with pelvic floor rehabilitation and a larger uptake by local general practitioners where once it would have been referred on to specialty care; and (II) a reaction to the negative publicity of synthetic mesh complications generated by the transvaginal mesh debacle for prolapse repair (47).

Outcomes of synthetic slings

In terms of absolute long term outcome, the longest follow up study to date is the one conducted by Nilsson *et al*. which evaluated the SUI outcomes with a TVT over some 17-year follow up. The study found that over 90% of women were objectively continent and 87% of women subjectively cured or improved (48).

In comparing transvaginal tape and transobturator tape mesh slings, Laurikainen *et al*. conducted a randomised controlled trial. The 12-month outcome showed that in 267 women, there was no difference in objective cure rates (95.5% versus 93.1%, P=0.40) (49). Barber *et al*. showed a non-inferiority of TOT compared with TVT in the 168 patients with a mean follow up of 18.2 months. Barber *et al*., however, did find bladder perforations were more common in the TVT group (7% versus 0%, P=0.02) (50).

Zullo *et al*. ran a randomised trial of 70 patients for SUI

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to TVT or TOT. These patients were assessed at 12 months follow up and no significant statistical differences were found in terms of cure rate. They did however find a significantly shorter operative time for the TOT group (51).

Whilst the mini sling has become more popular in recent years, the long-term evidence for non-inferiority has yet to be accumulated. Barber *et al*.'s randomised control trial showed similar cure rates at the one year follow up (55.8% mini sling versus TVT 60.6%, mean difference interval contains 0). However, they did find a proportion of participants whose definition of severe incontinence was higher in the mini sling group (16% compared with 5%; P=0.025) (52). Mostafa *et al*. found that 137 women in a multicentred randomised control trial to SIMS or TVT-O had comparable patient reported success rates, objective success rates and reoperation rates at one year follow up. Improvements in urgency, QoL and sexual function were also similar (53).

In 2015, the Cochrane mid-urethral sling systematic review was updated. This study did not include any analysis for SIMS. From the 55 trials, 8,652 patients were used to compare the use of TOT versus TVT. The short-term data collected concluded that the rate of subjective cure of TOT versus TVT were similar (RR 0.98; 95% CI: 0.96–1.00). Short term objective cure was also similar in TOT versus TVT (RR 0.98; 95% CI: 0.96–1.00). There were less trials reporting on medium and long-term results, which meant the quality of data was lower but nevertheless, both had similar subjective cure results. TVT was found to have higher rates of morbidity including bladder perforation, major vascular or visceral injury, mean operating time, operative blood loss, length of hospital stay and suprapubic pain. TOT approach was found to have statistically significant higher rates of groin pain. A bottom to top route TVT was more effective than top to bottom route in terms of subjective cure as well as having significantly less voiding dysfunction, bladder perforations and vaginal tape erosions. Short to medium term subjective cure rates of TOT versus TVT-O were again similar. Whilst there was evidence that voiding dysfunction was more frequent in the medial to lateral group, vaginal perforation was more common in the lateral to medial route. The systematic review concluded that despite the route of sling insertion, they are highly effective in the short to medium term with growing evidence that they continue to be effective in the long term. Transobturator approaches have lower morbidity profile except the occurrence of groin pain. There is no difference in the outcomes in terms of the direction of insertion of transobturator slings, whilst in the TVT, bottom to top approach is more effective and has less morbidity (25).

Fascial slings

For those seeking an alternative to MUS, the pubovaginal slings (PVS) have been in existence for decades and provides a suitable primary alternative or as a salvage option to those that have failed initial MUS surgery. Small strips of detached rectus fascia or tensor fascia lata permitted low morbidity slings and were popularised in a similar time frame to synthetic MUS though arguably the learning curve is greater owing to the need for tissue harvest. In recent years, its popularity has waned due to its more invasive nature and prolonged recovery. However recent concerns with synthetic mesh complications has seen a resurgence in its use. Although controlled trials comparing such an approach to synthetic slings are lacking, the largest multi-center RCT to date comparing autologous rectus fascia PVS to Burch colposuspension was reported by Albo *et al*. in 2007 (54). Success (defined as no self-reported symptoms of SUI, a negative stress test and no retreatment for SUI) at 24 months, was higher in the PVS group compared to Burch colposuspension group (66% versus 49%; P<0.001). However, there was a significantly higher rate of UTI, voiding dysfunction, and postoperative urge incontinence requiring treatment in the PVS group. At 5 years, continence rates had decreased substantially in both groups but better outcomes were still reported in the PVS group (30.8%,) compared to Burch (24.1%) and patient satisfaction remained high at 5 years for both groups with similar adverse events (55).

Conclusions

SUI is a bothersome condition that plagues many women in their lifetime. Whilst many surgical procedures have been invented to try and combat this condition, MUS has become, in many surgeons' opinion, the gold standard surgical treatment. There have been set backs with litigations over mesh use primarily in the POP field. This has negatively impacted on the perception of mesh use in SUI repair due to skewed media releases of the topic. Despite this, the data and the literature so far have not shown any decline in MUS mesh use. With robust short and medium-term data and slowly accumulating long-term data, the use and acceptance of TVT and TOT will continue to grow. Attention is now being focused on newer technologies

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and techniques such as the mini slings in the treatment of SUI. The medical profession must remember the lessons learnt over the years and evaluate all new techniques and implants with the utmost scrutiny. New practices should only be adopted in a trial setting or clinically if there are evidence to support these endeavours to reduce morbidity and mortality in our patients.

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Footnote

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