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TOPIC PAPER

Making surgery safer through adequate communication with the stakeholders: vaginal slings

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Abstract

Purpose In this review, we explore the evidence behind mid-urethral sling (MUS) surgery, review the rising reports of complications and the subsequent US Food and Drug Administration (FDA) and society statements, and evaluate risk perception and communication with patients, doctors, governing bodies, manufacturers and insurance companies. Our aim was to explore the pitfalls in communication that may be contributing to the decline in MUS use, and develop strategies to make MUS surgery safer.

Methods We searched the English language literature using PubMed for articles related to the management of stress urinary incontinence (SUI), MUS, safety and monitoring of transvaginal mesh (TVM), and reviewed all online FDA publications and international position statements regarding MUS for SUI.

Results Polypropylene mesh has been used in MUS since the 1990s, with robust evidence to support its use. There has been a decline in the use of MUS ever since the FDA notifications. In response to the controversy surrounding TVM, position statements have been released portending the safety of, and advocating for the continued use of, MUS for the management of SUI.

Conclusions MUS is a viable, effective and safe treatment for SUI management. Physicians should obtain and document informed consent, be adequately trained, and monitor and report their outcomes using registries. With publication of registry results and ongoing health advocacy, the perception of the safety of MUS can improve and MUS can still be offered as a treatment option for SUI.

Keywords Mid-urethral sling · Stress urinary incontinence · Transvaginal mesh

Introduction

The use of transvaginal mesh (TVM) for the management of pelvic organ prolapse (POP) and stress urinary incontinence (SUI) increased exponentially from 2005, and the mid-urethral sling (MUS) has become the most popular surgical treatment for SUI. Extensive warnings and restrictions of TVM have occurred since the FDA addressed the increased reporting of TVM complications with a public health notification in 2008, and again in 2011. Although the FDA safety communication in 2011 emphasised that the serious complications do not apply to the use of mesh for SUI or abdominal surgery, there is ongoing confusion amongst the public and stakeholders, evident in the fact that many countries have seen a decline in the use of MUS since the FDA notifications.

The aim of this review is to summarise the current literature and address the potential problems in communication between patients, doctors, governing bodies, manufacturers

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and insurance companies, and suggest ways to improve the status of the MUS and in doing so ensure safer surgery for women with SUI.

Methods

We searched the English language literature using PubMed for articles related to safety, efficacy and monitoring of MUS using the terms "mid urethral sling", "transvaginal mesh", "stress urinary incontinence" and "prolapse". We reviewed the FDA publications and notices of urology, gynaecology and urogynaecology society statements on its use, including articles most relevant to making MUS surgery safer.

Results

Mid-urethral slings for female SUI

SUI is a common, burdensome and costly condition for women with a negative impact on quality of life [1]. In 1990, Petros and Ulmsten described the integral theory of female incontinence and the "mid-urethral sling"—whereby the critical factor in continence mechanisms is the physiological 'backboard' created through fixation of the middle region of the urethra to the pubic bone via the pubourethral ligaments. Loss of this backboard stops urethral closure with increased intra-abdominal pressure resulting in SUI [2].

The MUS, developed in the early 1990s, involves the passage of a length of polypropylene mesh through either the retropubic or obturator space, with entry or exit points at the lower abdomen or groin, respectively [3]. In 1998, Nilsson published initial results for the tension free vaginal tape, finding it to be highly effective and associated with very few intra- and post-operative adverse events (AEs) [3, 4]. Since this initial study, the MUS has been the most extensively researched treatment for SUI, with an excellent safety profile. Irrespective of the routes traversed, they are highly effective in the short and medium term, and accruing evidence in over 15,000 women studied demonstrates their effectiveness in the long term, with over 80% of women cured, or having significant symptomatic improvement [3].

Complications that are unique to MUS include vaginal mesh exposure, erosion into bladder and/or urethra, and pain, which may require surgery or removal. Less commonly reported AEs include haemorrhage, bowel injury, urinary tract infection, recurrent SUI, de novo bladder overactivity, voiding dysfunction and dyspareunia [5]. A large UK study of 92,246 women estimated that the complication rate within 5 years was 9.8%. 5.9% were readmitted at least once within 5 years for further mesh intervention or symptoms of complications [6]. Voiding dysfunction and bladder perforations occur more commonly with retropubic MUS (3% and 5%), whereas neurologic symptoms (primarily groin pain) are more common following transobturator MUS (5.4% vs 9.7%) [7]. Overall, the reported rate of vaginal tape erosion/exposure/extrusion is low, 2.1–2.4% [3]. Although rare, complications of MUS may be under-reported and more common than they appear in the literature [8]. It was highlighted in the Cochrane review of MUS for SUI that evidence about how safe these procedures are in the longer term is lacking and the authors stressed the need for reporting of longer term outcome data from the numerous existing trials [3].

Transvaginal mesh for POP

The prevalence of POP reaches up to 50% of women across all age groups [9]. 6–19% of women undergo surgery for POP, and up to 29% undergo reoperation within 3–5 years [10]. Native tissue repair (NTR) anterior colporrhaphy is the most common surgery [11]; however, the results are notoriously poor, with anatomic recurrence rates in excess of 40% [12]. TVM, placed between the vaginal epithelium and the underlying endopelvic connective tissue for augmentation of the anterior, posterior or apical vaginal supports, was marketed as a way to improve high recurrence rates [13].

Current evidence does not support the use of TVM repair compared with NTR for the anterior compartment. The 2016 Cochrane review of surgery for women with anterior compartment prolapse found that although TVM repairs have resulted in lower recurrence of anatomical prolapse and marginally reduced subjective symptoms of tissue protrusion compared with NTR, TVM repair was associated with higher risk of de novo SUI, increased bladder injury, and higher rates of repeat surgery for prolapse, SUI and mesh exposure [14]. Novel, and potentially serious complications from TVM for POP management include mesh extrusion, urinary tract erosion, pain and dyspareunia. The Austrian Urogynecology working group established a TVM registry, reporting 12% mesh erosion at 12 months, and 10% dyspareunia at 12 months [15]. TVM exposure rates are as high as 30% in smokers [16].

Safety concerns

The use of TVM for SUI and POP increased exponentially following minimal testing based on the US FDA 501 clearance method, where a product predicated on an existing and approved device, can forgo the usually rigorous process of approval. The first TVM kits for POP were introduced in the USA in 2001, relying on claimed equivalence to the 1985 Mersilene Mesh (Ethicon) and the 1996 ProteGen Sling (Boston Scientific) [17]. Approval of these new devices occurred in the context of extensive industry influence and research funding, creating a potential for bias in study

designs and results [18]. New mesh kits were brought to the market quickly, often before short-term safety data were obtained [13]. The relative simplicity of TVM and MUS placement led to a massive uptake in its use, often performed by inexperienced users and in women with minimal symptoms. Registering of patients receiving TVM implants was not enforced, and warnings from the UK National Institute for Health and Care Excellence (NICE) regarding the safety of TVM date back to 2003 [18].

In 2008, the FDA issued a public health notice prompted by reports of complications with TVM used to repair POP and SUI [19]. More than 1000 complications were reported between 2005 and 2008, including mesh erosion, infection, pain, urinary problems, and recurrent POP or incontinence. The FDA notification noted rare events of more serious complications such a bowel, bladder, and vessel perforation during mesh placement, as well as vaginal scarring leading to vaginal pain and dyspareunia [13]. A 2009 review reported erosion rates of 2–25% for TVM used in anterior compartment prolapse surgery, 3–16% for apical prolapse surgery, and 7–12% for posterior-compartment prolapse surgery [20].

By 2011, more TVM complaints had been reported to the FDA (1503 for POP, 1371 for SUI), and the FDA issued a safety communication, identifying concerns about the use of TVM for repair of POP [21]. In 2016, the FDA reclassified TVM systems from class II (moderate risk) to class III (high risk), and required that device manufacturers conduct pre- and post-market studies of the safety and effectiveness of TVM devices [22], issuing 131 orders to 34 manufacturers of TVM for POP repair [23]. The expense of conducting post-market studies and the impact of litigation made TVM for POP not commercially viable. Consequently, most manufactures elected to stop marketing TVM for POP, with only four ongoing post-market studies in progress for 5 devices.

In 2017, Australia's FDA equivalent, the Therapeutic Goods Administration (TGA), had received 226 reports regarding TVM complications, and, at the end of 2017, took the internationally unprecedented step to remove all TVM mesh devices used to treat POP from the Australian Register of Therapeutic Goods (ARTG) [24]. The Australian Senate referred the matter of TVM surgery to the Senate Community Affairs References Committee for inquiry and report. Recommendations from the Senate Inquiry included mandatory reporting of AEs to the TGA, establishment of a registry, and that TVM for SUI treatment should be only undertaken as a "last resort" when other options have been properly considered and determined unsuitable [25].

In the UK in 2018, after pressure from mesh victim groups and the all-party parliamentary group on surgical mesh implants, the Independent Medicines and Medical Devices Safety Review announced that an immediate "High Vigilance Pause" (HVP) was to be placed on the use of TVM for POP and SUI pending the outcome of its review and the updated NICE 2019 guidance. The updated NICE guidance was published on 2 April 2019 and recommended strict mandatory requirements prior to any surgery for SUI or POP. Currently, the HVP remains in place due to outstanding issues for fulfilment of the HVP conditions including completion of procurement of the specialist services and a registry of procedures, and identification and accreditation of the specialist centres for SUI mesh procedures [26].

On April 16th, 2019, the FDA had not received sufficient evidence from the manufacturers, Boston Scientific and Coloplast, to assure that the probable benefits of their TVM devices outweigh their probable risks. As such, the FDA ordered an immediate cessation of the distribution or use of mesh for transvaginal repair of pelvic organ prolapse [27]. This statement did not apply to mesh utilised for SUI, specifically MUS.

Litigation

Since the FDA Notifications, there has been increasing litigation against mesh manufacturers. In the US, more than 77,000 cases are being overseen in the federal court [5], and multi-million dollar awards have been granted in punitive damages, with manufacturer settlements recording over USD 3 Billion as of January 2018 [28]. In 2016, the US states of California and Washington filed a suit against Johnson and Johnson, alleging that the company hid its knowledge about potential AEs associated with its TVM devices.

Due to the very large number of litigants in the US, Multi District Litigation (MDL) was implemented, grouping similar claims against common defendants with a "strategy" to guide plaintiff groups into settlements or dismissals. In West Virginia, a MDL trial is ongoing, representing more than 70,000 plaintiffs. Of concern, is a growing industry of medical lending in the US, where financiers invest in operations for patients to remove mesh to be used as evidence, reaping in an inflated share of the payout when cases settle [29].

Souders et al. [30] analysed TVM claims filed in the US and found, in a 1% random sample, 63.3% involved MUS, 13.3% TVM for POP, and 23.2% both, concluding that the rise in lawsuits does not reflect the low complication rates for MUS reported in the literature. These numbers likely reflect the fact that many more MUS are performed annually than TVM. In 2007, 33,880 MUS were performed [31], whereas only 5680 TVM procedures were performed in POP surgery in female Medicare beneficiaries in the United States [32]. It is also recognised that patients who undergo surgery typically receive larger settlements than plaintiffs who do not have devices removed. In May 2019, in New York, a doctor and a surgical funding consultant were arrested on charges that they defrauded women into having unnecessary surgeries to remove TVM to profit from settlements [33]. This begs the question as to whether the number of true TVM and

MUS complications is artificially inflated, and how many patients are undergoing unnecessary mesh removal surgery at the advice of their lawyer or medical financial lender.

Risk perception

The 2008 FDA safety communication did not address MUS surgery and specifically reported complications of TVM in POP surgery, causing confusion. Although the updated 2011 FDA communication emphasised that the serious complications associated with TVM for POP do not apply to the use of mesh for SUI or abdominal surgery, there is ongoing uncertainty within the general population. There is a common misconception that the risk of complications with MUS mesh used for SUI and TVM for POP are equivalent [34]; however, the risk of TVM increases with its surface area and density [35]. As a greater amount of mesh is implanted in patients with POP than in those with SUI, it is important to explain to the patient these crucial differences between TVM for POP and MUS for SUI.

The media plays a pivotal role in information distribution to the public [36, 37], through television commercials regarding litigation, legal advertisements, news, the internet and consumer reports. Unbalanced, inaccurate and sensationalised information is propagated. Media attention on TVM, without differentiating between TVM for POP and SUI, has the potential to cause confusion and fear in women considering treatment of SUI. This confusion may prevent women from seeking or receiving treatment for SUI. Research has shown that this uncertainty has led to patients developing an aversion to future surgery. Brown et al. looked at the perceptions of TVM in the US and found that 43.1% women would refuse surgery if it were to involve mesh for both POP or SUI, and that women tended to consider all TVM surgery the same surgery, regardless of the indication or type of surgery. They also identified misinformation, including women reporting that TVM can cause cancer, might be "rejected" from the body, needed to be removed immediately due to a recall, or can cause an allergic reaction [34].

Educating patients and the public that polypropylene mesh is safe as a surgical implant is crucial. Correcting misinformation regarding the possibility of cancer or allergic reactions, or that its industrial uses somehow negate its use in a clinical setting need to be refuted. Polypropylene mesh is the consensus graft material for augmenting hernia repairs in a number of areas in the human body and has significantly and favourably impacted the field of hernia surgery [38, 39]. As a surgical implant to treat SUI, the microporous, monofilament, light weight polypropylene has demonstrated long-term durability, safety, and efficacy up to 17 years, although this was in a small cohort of only 90 women. Of the 90 women treated with a MUS, 78% were evaluated at 17 years and only one case of a minimal, symptom-free tape extrusion was seen, and over 90% were objectively continent [40].

FDA fallout

There appears to be a lasting effect of the FDA notifications on practice patterns for treatment of SUI, even though the Safety Communications did not specifically implicate MUS [41]. This is multifactorial; patients have become increasing averse to surgery with TVM, a number of insurance companies now deny coverage for TVM procedures, and hospitals and surgeons have reduced the use of TVM due to fears of litigation.

Clinical practice patterns in the USA have undergone dramatic change over the past decade, with increased TVM use prior to the FDA Notifications and decreased use afterwards. In a 2017 survey sent to American Urogynecological Society (AUGS) members, prior to the 2011 FDA warning, 90% used TVM, 34% used biologic grafts and 99% used MUS. After the FDA warning, only 61% continued using TVM, with 40% reporting a decreased use and 12% ceasing completely [42].

SUI surgery trends in tertiary care academic medical centres between 2007 and 2013 reveal a decrease in the use of MUS and a concurrent increase in the utilisation of pubovaginal fascial slings (PVS) [41]. While there was an increasing number of patients presenting with SUI between 2010 and 2014, there was a progressive decrease in the proportion having anti-incontinence procedures after the 2011 FDA notification, specifically a decrease in the use of MUS but an increase in urethral bulking agents (UB) and PVS [5]. There are clear trends showing similar changes in Australia. Mathieson et al. evaluated Australian Government Department of Human Services data from 2008 to 2018. There was a decline for most SUI procedures (MUS, burch colposuspension (BC), PVS) except UB (Fig. 1), the annual rate for MUS halved (78–36 per 100,000 population) (Fig. 2), and the total number of procedures decreased from 93 to 49 per 100,000 population [43].

Position statements and recommendations

In response to the controversy surrounding TVM, specifically the use of mesh MUS for the management of SUI, position statements have been released supporting the safety of and advocating for the continued use of MUS. There is a strong sense that women wanting surgical treatment for SUI should have the choice to have a MUS or not. In 2016, the American Urological Association (AUA), the American Congress of Obstetricians and Gynaecologists (ACOG), the AUGS, the International Continence Society (ICS), the International Urogynecological Association (IUGA), the Society of Gynecologic Surgeons (SGS) and the Society

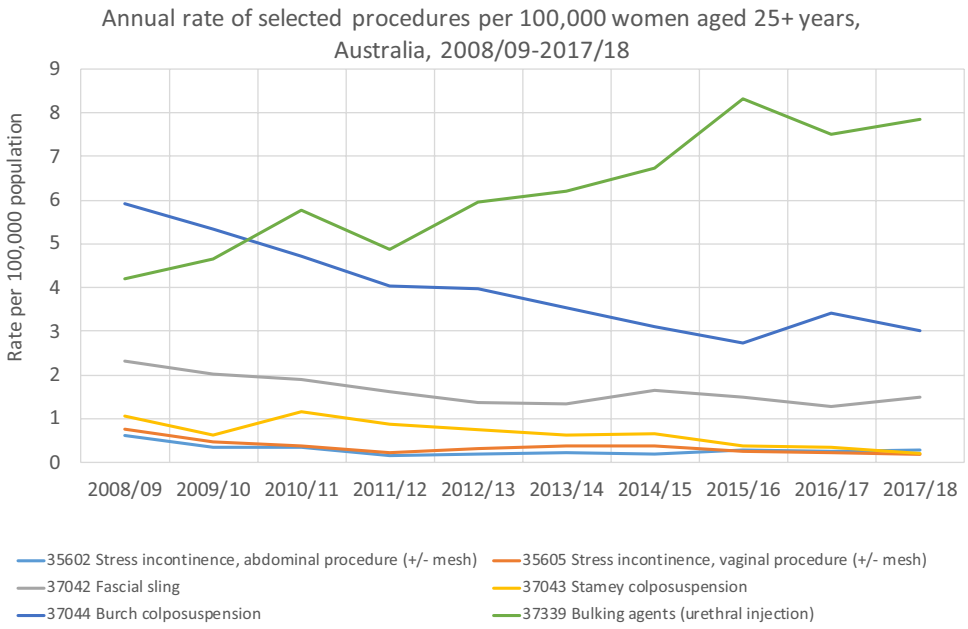

Fig. 1 Annual rate of SUI procedures performed in Australia, 2008–2018 [43]

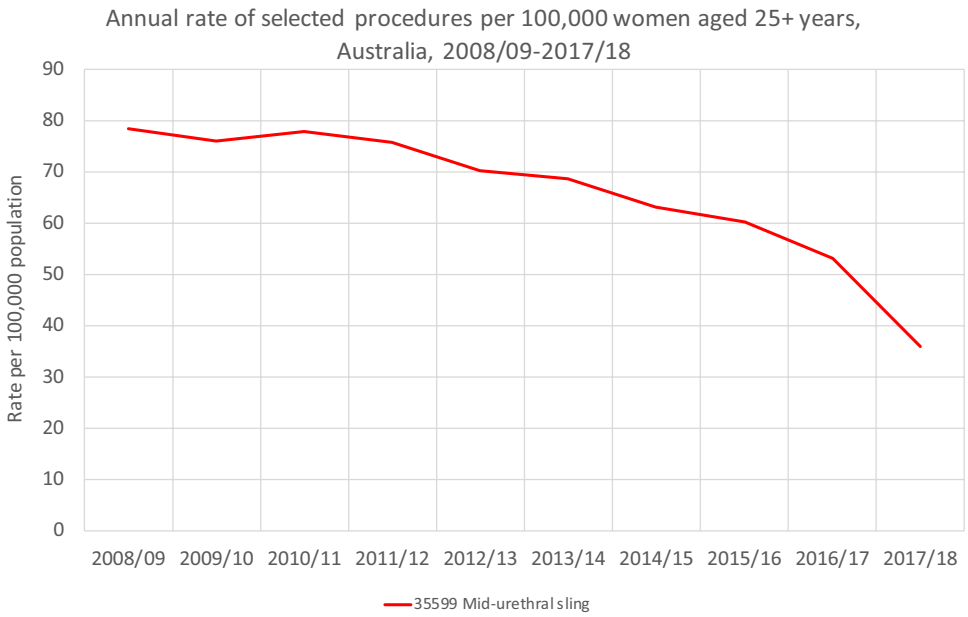

Fig. 2 Annual rate of MUS procedures performed in Australia, 2008–2018 [43]

of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) together representing more than 84,000 healthcare professionals that provide care to women with SUI, reaffirmed their collective support for the use of MUS for the surgical treatment of SUI [44].

The 2017 consensus statement of the European Association of Urology (EAU) and the European Urogynaecological Association (EUGA) concluded that MUS can be safely used to treat SUI [35]. Reflecting this statement, EAU guidelines recommend MUS in women with uncomplicated SUI as the preferred surgical intervention, and BC or PVS if MUS cannot be considered [45]. The Urological Society of Australia and New Zealand (USANZ) acknowledges that the use of monofilament polypropylene MUS is a reasonable treatment option for female SUI [46]. The Australian Commission on Safety and Quality in Health Care states that the "MUS is the recommended surgical treatment for SUI, and is highly effective…large, long-term studies show women are satisfied with this operation and the improvement in their SUI symptoms…more data about MUS exists than any native tissue repair" [47].

As emphasised in the FDA notification of 2011, patients with MUS who do not have complications should be reassured and not be advised to undergo MUS explantation [48].

Improved safety for the patients

Established recommendations to improve the safety for patients being treated with MUS include:

- Registries to monitor patient outcome and reporting.
- Creating checklists as part of the informed consent process.
- Surgeon accreditation.

Since the 2008 notification, the FDA has been warning providers to report all AEs and cautioning them to consider mesh in specific cases only and only with patient counselling [49]. To better compare complications between procedures, the Standardization and Terminology Committees of IUGA and ICS published in 2010 a new classification system of complications directly related to prosthesis placement in female pelvic floor surgery. This new classification system should standardise AE reporting, which will hopefully facilitate an understanding as to how these complications occur [50]. The next crucial step is the development of surgical registries for all SUI surgeries (mesh and non-mesh), that can harness the power of uniform data collection from varied sources to assess real-world clinical outcomes, treatment efficacy, and patient safety [51]. In 2019, the Australian Government allocated 2.3 million AUD for the establishment of a Pelvic Floor Surgery Clinical Quality Registry to make this surgery safer for women [52].

The 2011 FDA update recommended questions for patients to ask their surgeon regarding mesh, including alternative options, handling of complications, and follow-up [13]. Informed consent is paramount to the delivery of safer surgery, and all surgeons should obtain and document adequate informed consent. Prior to selecting MUS procedures for SUI, surgeons must discuss the specific risks and benefits of mesh, as well as alternatives to mesh which include nonsurgical options, PVS, BC and UB [7]. Serious morbidity with MUS is uncommon, approximately 4% [35], and should be discussed in detail. It is important to document the discussion of the known risks of using TVM (mesh exposure/erosion/pain). Surgeons should provide the patient with a written copy of the manufacturer's patient labelling information [22]. Clinicians can confirm the patient's understanding using a checklist.

Safer surgery requires appropriate patient selection and counselling [35], particularly for MUS for SUI. Surgeon credentialing for SUI and TVM removal surgery, through formalised training and supervision, is recommended by surgical societies. Surgeons who wish to perform MUS require rigorous training in pelvic anatomy/surgery, specific MUS device techniques, and be able to recognise and manage complications associated with MUS placement [53]. An in-depth understanding of the relevant product information for each MUS device is required and should be communicated to the patient undergoing the MUS surgery.

Conclusion

With the removal of multiple mesh products from the market, well-publicised class actions relating to TVM and increased regulation for surgeons using mesh, there are clear trends showing a reduction in the number of patients seeking treatment for SUI. The current legal environment involving TVM should not deter surgeons from offering mesh or MUS for SUI to those patients who, using their clinical judgement, may best benefit from the procedure. To not offer all the possible options for surgical management of SUI is a disservice to patients and perpetuates the very issue we are seeking to redress.

How do we make vaginal sling surgery safer? By communicating with the key stakeholders, clinicians must engage and educate patients regarding the safety of the MUS, and the availability of other SUI treatment modalities. Regulators and industry should support the collection and publication of registry results. Key groups such as ICS, SUFU, AUGS, IUGA, EAU and EUGA need to engage in ongoing health advocacy and publicly support the MUS. By involving all the key stakeholders, the perception of the safety of MUS will improve and women will still have access to choose this life-changing minimally invasive procedure. Good communication is paramount to ensuring a future with the MUS and avoiding undertreating SUI.

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Compliance with ethical standards

Conflict of interest None to declare.

Research involving human participants and/or animals Not applicable.

Informed consent Not required.

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