



Management of complications arising from the use of mesh for stress urinary incontinence—International Urogynecology Association Research and Development Committee opinion

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Abstract

Introduction and hypothesis Management of pain or mesh exposure complications after stress incontinence surgery has become a new issue over the last 20 years with the introduction of mesh techniques to treat stress incontinence. There is much debate regarding the incidence of complications and how best to treat them.

Methods A working subcommittee from the International Urogynecology Association (IUGA) Research and Development (R&D) Committee was formed. An initial document was drafted based on a literature review. The review focused on complications of vaginal mesh inserted for stress incontinence. After evaluation by the entire IUGA R&D Committee revisions were made. The final document represents the IUGA R&D Committee Opinion.

Results The R&D Committee Opinion reviews the literature on the management of complications arising from the use of mesh for stress urinary incontinence. The review concentrated on the assessment and treatment of pain and exposure.

Conclusions Complications after surgery for stress incontinence using mesh may not be common occurrences for individual surgeons. Complications may be difficult to manage and outcomes are variable. Specialist centres and a multidisciplinary approach may optimise treatment and reporting of outcomes.

Keywords Mesh · Mideurethral sling · Complication · Stress incontinence

Introduction

In recent years there has been much debate and controversy regarding the risks of mesh used for mid-urethral sling (MUS) insertion. There have been several reviews of safety and efficacy [1, 2]. In England Hospital Episode Statistics (HES) data suggest that 2.7% of retropubic and 1.9% of transobturator MUSs were removed over an 8-year period [3].

Patients have reported that they were not given adequate information regarding mesh complications before insertion of mesh for urodynamic stress incontinence (USI) and have not received timely treatment [4]. Treatments include pain relief, local anaesthetic nerve blocks or removal of the mesh (depending on the site, symptoms and signs). Unfortunately not all treatments are successful and some patients have persistent pain which may become chronic. In many women removal of the mesh can result in a recurrence of their symptoms of incontinence.

Although there has been widespread media coverage of patients experiencing complications, individual centres may have relatively little experience in managing these complications [5]. This review was designed to evaluate the current literature on this subject and to provide advice for clinicians performing procedures for MUS mesh complications. The primary focus of the review was managing mesh removal required for pain or erosion. IUGA has previously published on the management of voiding dysfunction after MUS surgery and therefore this was not considered in this review [6].

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Methods

The review was aimed at vaginally inserted mesh for stress incontinence. A literature search for the review was performed using the following keywords: suburethral sling or prostheses and implants or suburethral sling or suburethral tape or midurethral sling or midurethral tape or urethral sling or urethral tape or transobturator tape or trans-obturator tape or tensionless vaginal tape or tension-free vaginal tape or tension-free sling or tension-free tape “and” pain, rejection, erosion, extrusion, dyspareunia, hispareunia, survivor, pelvic pain and bleeding. An initial manuscript was drafted, which was then reviewed by the IUGA R&D committee and amended.

Clinical presentation and symptoms

The complications can be attributed to the incorrect indication for mesh surgery, faulty surgical technique (tape positioning, kinking and overcorrection), material properties (biocompatibility) and improper patient selection. Reasons for exposure of the mesh material are categorised into tissue causes and biomechanical mesh properties. Tissue causes include superficial placement, traumatic dissection, tissue healing, and thin and atrophic vaginal epithelium, especially in postmenopausal women. Many women will have no identifiable cause for their complication.

Mesh-related complications are lower after surgery for SUI compared with surgery with mesh for POP. Vaginal exposure is a common mesh-specific complication. Patients may present with vaginal discharge, bleeding, dyspareunia, pain, recurrent urinary tract infection and/or haematuria [7]. Conversely, patients may be asymptomatic and a mesh exposure will be identified during a vaginal examination performed for other reasons [8]. Patients will often have a variety of different symptoms, e.g. mixed bladder symptoms and urinary tract infections, rather than a single complaint. The patient’s partner may also complain of discomfort with intercourse (hispareunia) [9]. Symptoms may be nonspecific with worsening of bladder and bowel symptoms. Rarely patients present with a pelvic or thigh abscess [10], urogenital fistula, discharging sinus or osteomyelitis. The history should include questions regarding the musculoskeletal system such as the hips and back as well as questions regarding bowel function and periods if relevant. A full continence history should be re-evaluated and compared with symptoms (if possible) prior to the index procedure. An assessment of menopausal symptoms is required.

Assessment/diagnostic evaluation of mesh complications

Assessment of various mesh complications generally includes history, physical/pelvic examination, urodynamics, ultrasonography, cystourethroscopy and microbiological studies as determined by the presenting symptoms.

Symptoms should be further assessed with validated questionnaires for pain, bladder, sexual function and continence-related quality of life (QoL). A review of all previous operative and progress notes should be performed (where available).

Examination and investigations

A detailed pelvic examination using a speculum to systematically examine all compartments of the vagina for any mesh exposure or signs of infection or fistula is mandatory. Clinical examination may reveal induration at the vaginal incision, vaginal granulation tissue, draining sinus tracts, and mesh exposure or rejection. The most common location of mesh exposure is in the midline at the previous incision site. This may be due to suture disruption, tissue necrosis, subclinical infection or haematoma [11]. Palpation of the levator ani, the vagina over the sling tract or portions overlying the mesh can help map the areas or points of tenderness.

Examination under anaesthesia, diagnostic cystoscopy [12] and vaginoscopy may be required as part of the patient assessment. Cystometry is important as a baseline because surgical intervention may result in an alteration of bladder function and symptoms.

Ultrasound may be helpful for assessing the presence of mesh, identifying its relationship to the vaginal wall and aid planning for surgical intervention. Some authors advocate pre-operative MRI to locate mesh in the vaginal wall [13]. For midurethral tapes, the mesh in the suburethral space is best visualised using ultrasound. Differentiating residual incompletely removed mesh after an attempted removal from scarring caused by a removal (or insertion of mesh) can be difficult. It may be difficult to differentiate whether the suburethral portion of the mesh is from a transobturator or a retropubic MUS. The more peripheral aspects of the mesh may be visualised by MRI [14]. Translabial ultrasound can identify polypropylene MUS mesh implants in the anterior vaginal wall [15]. Three-dimensional endovaginal ultrasound has been shown to be superior to palpation for identification of vaginal mesh [16]. It should also be noted that a proportion of patients will report having had a mesh inserted but there is no evidence of this on ultrasound [16]. A CT of the abdomen and pelvis is useful in identifying any other cause for the pain, e.g., diverticulitis. All MUS mesh exposures should be graded using the IUGA classification [17].

Pain after MUS mesh insertion

Pain is a common MUS mesh complication requiring surgical mesh removal [18]. MUS mesh-related pain may occur in the presence or absence of mesh erosion. Vaginal pain may be constant or intermittent in nature triggered by activity such as micturition or sexual intercourse. Other sites of MUS-

related mesh pain include urethra, bladder, abdominal, back, thigh, groin and/or generalised pelvic pain [19]. Other causes for pain, e.g. back pain, need to be investigated and local pathology excluded before treatment for suspected MUS pain. Hispareunia is the symptom of pain experienced by the male partner during sexual intercourse from a relatively sharp edge of mesh [9]. Chronic pelvic pain might develop from pelvic floor muscle spasm, pudendal neuralgia and infection [20].

Groin pain after transobturator mesh placement is known to occur from mesh placement through the obturator foramen for SUI or pelvic organ prolapse (POP) surgery. The occurrence of pain is typically localised to the inguinal area and medial thigh along the obturator nerve distribution and is reported in 15–32% of patients [21, 22]. Groin pain is believed to be related to obturator nerve damage or entrapment neuropathy. Pain may also be muscular and related to tension between the mesh and adductor muscles [22]. Dyspareunia/vaginal pain may be secondary to a paraurethral band of transobturator tape [23]. A palpable transobturator tape with pain elicited in the groin was found in a 5-year follow-up study in 12% of patients after a TOT [24]. There is lack of consensus on comparison of inside-out and outside-in transobturator mesh tapes in relation to pain [25].

Pain is more likely to be suprapubic (after a retropubic MUS insertion) and located in the groin (after a TOT) because of the positioning of the trocars for inserting the tapes. Vaginal pain is seen with both TVTs and TOTs. The pain may be described as a “saw like” pain. Groin pain reported after TVT may be due to damage to the ilioinguinal nerve [26, 27] whilst damage to the obturator nerve is implicated after TOT. The aetiology is similar, as are the treatments.

Pathophysiology of pain from MUS vaginal mesh

The pathophysiology of pain provoked by mesh placement is believed to be multifactorial. Pain may arise from direct trauma to pelvic organs, nerves, viscera, abdominal and pelvic walls or haematoma formation and present in the immediate post-operative period [8]. In cases where no mesh exposure or pelvic organ injury is detected, delayed onset pain can be related to mesh contracture/inflammation, mesh exposure and/or erosion, mesh infection, nerve entrapment (obturator/pudendal nerve), tight placement under tension, muscle injury from inappropriately positioned mesh or fistula formation [8]. Infection may contribute to pain and may be present even in cases in which it is not clinically apparent. Placement of a mesh arm or mesh tape through the muscle can result in myofascial syndrome. Acute muscle trauma or repetitive microtrauma leads to pain of varying intensity [28]. Pain is thought to be more common in patients with generalised pain syndromes such as fibromyalgia. Specific care and detailed counselling should be performed prior to any continence surgery in these patient groups.

Severe and debilitating pain is seen as a reaction to mesh. Animal studies have shown an inflammatory reaction (oxidative stress) causes free radical damage to the mesh and in turn causes more inflammation and local fibrosis. Oxidative reactions generated by the influx of neutrophils to the site of polypropylene mesh results in degradation of the mesh; deep fissures in the fibre surface and decreased fibre diameter are evident on scanning electron microscopy on explanted materials [29]. In a study on histological examination of explanted mesh, oxidative damage with increased inflammatory cytokines, increased macrophages and a 4- to 30-fold loss in compliance was observed [30].

Direct injury to a nerve from trocars will be noticeable immediately after surgery [31]. Transobturator mesh tapes (both outside in and inside out) and TVTs may injure the dorsal nerve of the clitoris as it courses along the medial side of the inferior pubic ramus or the obturator nerve [32].

Management of pain

Pain-related issues require multidisciplinary management and can be difficult to cure. Advice and treatment from a musculoskeletal physiotherapist will allow treatments different from the surgical interventions often provided by physicians. Physiotherapy and trigger point massage may be used for pain and may result in surgical intervention not being required. Acupuncture or TENS may be utilised.

Conservative management strategies for pelvic pain after mesh placement include anti-inflammatory medications, local oestrogen therapy and targeted injections of local anaesthetic and steroid [33]. Injections into painful areas may be both diagnostic and therapeutic [26]. A proportion of patients will have resolution of the pain with a steroid injection into a tender area although the pain may return and need further treatment such as MUS removal. Short-term resolution of pain may give the clinician more confidence that removal of the MUS will result in longer term resolution of pain. A steroid injection can be carried out at the same time as a diagnostic cystoscopy performed during the initial assessment of the patient. Neuromodulators such as amitriptyline, gabapentin or pregabalin can be used prior to considering more invasive interventions. Atrophy is a common cause of pain in the post-menopausal group and should be treated with vaginal oestrogens before tape removal is considered. Surgical removal of the mesh is known to improve pain in a significant proportion of women although their selection is crucial to the outcome [34]. Central sensitisation may result in pain which is persistent after the removal of the stimulus causing the pain. In this situation pain will often be persistent despite the removal of the MUS. Pain management programmes may be more appropriate in this situation.

The systematic evaluation of the results of conservative therapies is difficult as they are commonly used before

surgical intervention and very little structured evaluation of their efficacy has been performed. They provide a low risk strategy with few side effects and therefore should be used in all patients. The literature concentrates on the evaluation of surgical outcomes rather than on conservative treatments.

Outcomes of MUS mesh removal

Laparoscopic removal of retropubic slings is offered in some centres and this is less invasive than the open abdominal-vaginal approach; 48% reported complete improvement of their presenting complaint and 30% had partial improvement [35]. If a TOT removal is planned for groin pain, it is best performed in conjunction with surgeons who are used to operating in this area, e.g. plastic surgeons.

The possibility of pain returning at some point in the future after mesh removal is a cause for concern and is seen in 20% of patients [34]. Pain recurrence may be seen with incomplete removal, mesh infections [36], secondary scarring and shrinking, chronic pain of a separate aetiology (fibromyalgia, chronic pain syndrome, hormonal changes), and muscle and/or nerve involvement during placement and/or removal of the mesh [37]. The need for full mesh removal over partial mesh removal after stress incontinence mesh surgery should be judged on a patient-by-patient basis but full removal may result in a higher risk of recurrent incontinence [38]. Both partial and complete removal of sling meshes improve pain in the majority of patients [37].

Outcomes of MUS revision surgery are variable and often include a variety of indications with small numbers for any individual complication. A retrospective review of 24 case notes of patients presenting with midurethral tape complications to a mesh complication management service (2011–2017) included 19 urethral perforations including 4 fistulas, 7 bladder perforations and 1 ureteric injury (requiring reimplantation). Of these 23 had mesh formally excised. Five women with bladder perforation had cystotomy to excise the mesh and one had cystoscopic excision. All but 1 (who had cystoscopic excision) of the 19 patients with urethral perforation had vaginal mesh excision and 8 had Martius fat pad flaps to reinforce the urethral repair. No significant post-operative complications were recorded. Of the women who had mesh excision, 57% had recurrent SUI; 46% had further surgery including autologous fascial sling, bladder neck injection and colposuspension [39]. National registries would provide a more structured outcome and allow analysis of more patients.

Summary points

These patients may be difficult to treat and should be managed by a multidisciplinary team including urogynecologists, urologists, pain specialists, psychologists, plastic surgeons, physiotherapists, radiologists, etc.

Other causes of pain should be considered including pain arising from the back, hips and intraabdominal structures.

Conservative treatments should be explored including the use of vaginal oestrogens in post-menopausal women (for small exposures and dyspareunia) for 6–12 weeks and analgesia and physiotherapy to reduce muscular spasms.

Surgical removal of mesh should be performed by a team familiar with the anatomy and experienced in mesh removal. Incomplete removal can make future potentially required procedures more difficult and hence the first procedure of removal needs to be carefully planned. Collaboration with the urologist might be required to optimise outcomes.

Realistic expectations for any intervention should be discussed and the effect of treatment on other symptoms considered. Women should be counselled that pain resolution after surgery is not uniform. The ideal timing of surgery cannot be recommended although logically, the earlier the better.

Exposed vaginal meshes which are causing symptoms should be treated and removed if conservative therapies fail.

Patients with no symptoms should not be offered mesh removal. A mesh which is non-tender on palpation is less likely to be the cause of pain. A woman who is worried that the mesh is harmful needs to be reassured after listening patiently to her concerns.

Mesh erosion into viscera should be removed.

All patients should be registered on a national database such as those provided by national societies. Additional reporting may also be mandatory in some countries.

Pre-existing pain conditions such as fibromyalgia should be assessed prior to the insertion of an MUS as this will represent a prognostic factor for post-operative pain.

Post-operative pain is a common complication of any type of surgery. Thus, women should be made aware of this at the time of pre-operative counselling.

International professional societies should develop guidelines and inclusion criteria for mesh removal.

Compliance with ethical standards

Conflicts of interest None.

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