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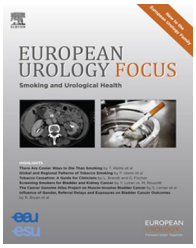

Review-Female Urology - Incontinence

Complications of Transvaginal Mesh for Pelvic Organ Prolapse and Stress Urinary Incontinence: Tips for Prevention, Recognition, and Management

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Abstract

Context: Mesh-related complications following transvaginal management of pelvic organ prolapse (POP) and/or stress urinary incontinence (SUI) have received significant attention in the last decade.
Objective: We sought to identify patient, product, and technical factors associated with an increased risk of complications after mesh-based transvaginal repair of anterior POP and SUI. In this review we clarify the different pattern of complications after POP and SUI repairs. Our aim is to provide a practical evidence-based guide for physicians to prevent and, if necessary, manage product-associated complications in a stepwise manner.
Evidence acquisition: We conducted a comprehensive PubMed search of all English-language articles published from 2010 to June 2016, using these search terms: *mesh, pelvic organ prolapse*, and *stress urinary incontinence*. Expert opinion is also provided.
Evidence synthesis: Mesh-related complications are much lower after repair of SUI compared with POP, despite its more frequent use. Vaginal exposure is the most common mesh-specific complication. Patients may present with vaginal discharge, dyspareunia, pain, recurrent urinary tract infection, and/or hematuria. Conversely, patients may be asymptomatic. Small asymptomatic mesh exposures (<0.5 cm) may be treated conservatively. Larger exposures will require partial, if not complete, excision with reconstruction. Any mesh encountered within the urinary tract must be fully excised. Following excision, pain may persist in up to 50% of patients.
Conclusions: Vaginal extrusion, persistent pain, and urethral and/or bladder erosion are the three most common product-specific complications following mesh-based repair for SUI or POP. Conservative therapies may be attempted, but most patients ultimately require partial or complete mesh excision.
Patient summary: We reviewed the recent literature on mesh-related complications after repair of pelvic organ prolapse (POP) and stress urinary incontinence (SUI). Vaginal exposure, persistent pain, and erosion into the urinary tract are the most common. These often require surgical management, best suited to a urologist with training and experience in this area. Evidence supports mesh use for correction of SUI, whereas the indication for POP repair remains controversial.

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1. Introduction

Pelvic organ prolapse (POP) and stress urinary incontinence (SUI) are quite common among the aging female population. Up to half of parous women demonstrate POP on examination, although only 3–6% note symptoms [1]. As many as 20% of women report SUI by the age of 40, a figure that doubles as they approach the age of 60 [2]. These problems are so common and bothersome that a recent study of national data found that US women have a 1 in 5 lifetime chance of electing surgical correction for either SUI or POP [3].

Following surgical intervention, up to 29% of women experience failure and undergo a subsequent procedure [4]. The rationale for using mesh involves avoiding use of the same native tissue that was structurally deficient in the initial disease presentation. Mesh is an inert, readily available synthetic material that offers the prospect of a durable repair. An off-the-shelf option also avoids the morbidity and time required for fascial harvest.

Mesh used in POP repair can help reduce the risk of anatomic recurrence; however, the rate of complications is increased compared with a native tissue repair. In the 2013 Cochrane review, a meta-analysis by Maher et al. found that women undergoing POP repair without mesh had a 2-fold higher risk of anatomic recurrence [5]. More recently, the definition of "success" has shifted to patient perception of the outcome rather than strict anatomic divisions of POP. Within this new paradigm, functional outcomes of POP repairs with and without mesh appear similar.

In contrast, multiple studies have shown that mesh has improved success rates for the treatment of SUI with similar rates of complications to native tissue repairs. Guerrero et al. compared the tension-free vaginal tape (TVT) sling versus autologous fascia and found that rates of improvement in SUI at 1 yr were similar, 93% and 90%, respectively, as were the rates of postoperative complications [6]. Brito et al. compared the transobturator tape (TOT) sling versus autologous fascia and found that rates of cure at 2 yr were similar (88.7% vs 84.6%, respectively) with fewer postoperative complications in the TOT group [7].

The marketing, availability, and technical simplicity of prepackaged kits contributed to the increased use of mesh, which also meant an increased incidence of complications. The US Food and Drug Administration (FDA) noted a 5-fold increase in complications from the 2005–2007 period to 2008–2010 [8]. In 2008, the FDA issued a public health notification regarding transvaginal placement of mesh, stating that >1000 complications were reported and recorded within the Manufacturer and User Device Experience database during a 3-yr period by nine manufacturers [9]. The notification also urged physicians to inform patients of potential complications and to obtain specialized training in mesh implantation before performing such procedures [9,10]. In 2011, the FDA updated its previous notification and cautioned the continued use of mesh given that it did not find conclusive evidence that mesh improves clinical outcomes [8]. That same year, the International Urogynecological Association/International Continence Society established a standardized classification of mesh-related complications [11]. In 2014, the FDA reclassified transvaginal mesh for POP from a moderate risk to a high-risk medical device [12]. No comment was made in that press release on the use of intra-abdominal mesh or mesh for the treatment of SUI.

In this review we provide a practical guide for urologists regarding the prevention, recognition, and management of mesh-related complications placed for the two most common urologic indications, anterior compartment POP and SUI. We focused on complications due to type 1 polypropylene mesh, now the standard because type 2 and 3 mesh were previously shown to have higher rates of exposure. We also limited our research to transvaginal placement, excluding abdominally placed mesh for sacrocolpopexy. We did not seek to address new-onset postoperative voiding symptoms because these are not exclusive to the product.

2. Evidence acquisition

We conducted a thorough PubMed search of all English-language articles published from January 2010 to June 2016, using these search terms: *mesh, mesh complications, mesh exposure, mesh erosion, pelvic organ prolapse*, and *stress urinary incontinence*. Relevant studies from the references of identified articles were also included for review. Large prospective trials of mesh kits were included to obtain complication rates. Small retrospective reviews were included for the management of uncommon complications, such as calculus formation on intravesical mesh. Case studies were excluded. Editorials and commentaries on articles were referenced for expert opinion on management because no authoritative algorithm has been recognized.

3. Evidence synthesis

3.1. *Vaginal extrusion*

3.1.1. *Incidence*

In the Trial of Mid-Urethral Slings (TOMUS) study, 3–5% of patients undergoing a sling for SUI developed extrusion, consistent with other large series [13–15]. In a review of 388 complications following midurethral sling, vaginal extrusion was the fourth most common complication, seen in 17% [16]. Vaginal extrusion is significantly more common when mesh is used for POP repair. Generally, extrusion after anterior repairs is reported in 10–12% of patients; however, it has been reported as high as 36% [7,15,17,18] (Fig. 1).

3.1.2. *Prevention*

Patient selection is essential to minimize the risk of postoperative complications; diabetes mellitus, smoking, immunosuppression, prior pelvic radiation, and prior vaginal surgery were all shown to elevate risk for mesh extrusion after sling placement [10,14,17,19]. Older age was shown to be associated with extrusion after sling placement, whereas younger sexually active women were shown