Review

Complications of mesh application in the surgical treatment of pelvic organ prolapse

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Abstract: Mesh application has recently become popular worldwide. Despite considerable success in pelvic organ prolapse surgery, there is an increasing concern regarding mesh use. Although mesh use-related complications are minor and manageable during and after intervention in most cases, some of complications that seldom occur, such as bladder, bowel, and vascular injuries, may threaten life. According to International Continence Society and International Urogynecology Association, complications related to mesh application can be broadly classified as 1) vaginal complications (prominence-contraction, exposure-extrusion, and pain), 2) urinary tract complications (bladder perforation, urinary retention, *de novo* stress urinary incontinence, detrusor over activity, and vesicovaginal and urethrovaginal fistulas), 3) rectum or bowel complications (rectal or bowel injury, abscess and rectovaginal fistula), 4) skin and/or musculoskeletal complications, 5) patient compromise, and 6) infectious complications. This review describes underlying causes of mesh complications and their management.

Key words: Pelvic Organ Prolapse; Mesh application; Complication Management.

INTRODUCTION

Pelvic organ prolapse (POP) is a common condition, affecting women of all ages. A lifetime risk of prolapse or incontinence surgery is 7-19%.[1] Although there are many approaches to the surgical correction of POP, recently mesh kits have been developed because of high failure rates from traditional vaginal colporrhaphy and surgical suspension procedures using native tissue. Synthetic vaginal mesh was approved for use in the USA by the Food and Drug Administration (FDA) in 2004. According to the 2011 Society of Obstetricians and Gynecologists of Canada (SOGC) Technical Update on Transvaginal Mesh Procedures, anatomic cure from early case series and comparative trials using the first generation mesh kits ranged from 79 to 100%.[2] Despite achievement of appreciable success rate, concerns related to complications of mesh use among surgeons still remain. Complications commonly associated with mesh include cystotomy, bleeding, hematoma, mesh exposure/erosion, *de novo* stress urinary incontinence, dyspareunia, and pelvic pain. Upon more pronunciation of mesh complications, FDA published an article entitled "Public Health Notification and Additional Patient Information on Serious Complications Associated with Surgical Mesh Placed through the Vagina (Transvaginal Placement) to Treat Pelvic Organ Prolapse (POP) and Stress Urinary Incontinence (SUI)" in 2008, which was updated in 2011.[3] The primary goals of this update were to inform that "serious complications with surgical mesh for transvaginal repair of POP are not rare" and "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk".

The present review intends to compile information on risks associated with mesh surgery.

COMPLICATIONS OF MESH SURGERY

All complications associated with mesh surgery in POP have been reviewed and evaluated by International Continence Society (ICS), and International Urogynecology Association (IUGA) in 2011, which are summarized in Table 1.[4]

Vaginal Complications

Prominence-Contraction

Actual incidence of mesh contraction is not really known since these complications are not commonly reported. Most of the time accompanied by pain.[5] Mesh contraction may also cause vaginal shortening and tightening.[6]

Exposure-extrusion

ICS and IUGA offer to use exposure and extrusion of the mesh instead of erosion which is more commonly used in the literature. Graft erosion is one of the most common direct complications of graft materials used in urogynecologic surgery with an incidence of 10.3% (0-29%).[7] Exposures have been reported as early as 6 weeks and as late as 4 years after vaginal mesh surgery, but they usually occur during the first year.[8] Risk factors for mesh exposure vary by surgeons experience, high stage prolapses, smoking, and concomitant hysterectomy.[9-11] There are conflicting data about the age of the patients. Deffieux and colleagues found age over 70 to be a risk factor,[12] but Kaufman et al. reported that younger age and sexual activity were risk factors for mesh exposure.[13] Mesh exposure can be classified as early and late. Early mesh exposure usually is a result of the surgery itself, whereas late exposure may be a result of infections and recurrent trauma. ICS and IUGA suggest using time intervals as follows: T1: intraoperative to 48 hours, T2: 48 hours to 2 months, T3: 2 months to 12 months, T4: over 12 months.[4]

Vaginal discharge, odor, vaginal pain, and dyspareunia expressed by the sexual partner are some of the mesh erosion or extrusion signs. To minimize this type of vaginal mesh complication, the following suggestions have been proposed: making incisions as small as possible, using type I soft mesh, not using T incisions with hysterectomy, using hydrodissection, maintaining thick dissection plane, using pre and post-op estrogen, excising minimal vaginal epithelium and placing the mesh underneath the fascial plane.[14, 15]

Management of mesh extrusion or exposure is usually easy. Most of the time removal of the mesh is not necessary. Local estrogen and antiseptic agents are usually preferred. However, excision or total removal of the mesh and repetitive surgeries may be needed in some cases.[7] FDA highlighted that more than half of the women with erosions

from non-absorbable synthetic mesh required surgical excision in the operation room.[3]

Pain

Pain is an important complication of mesh placement, which will not be resolved even after mesh removal.[3] Pain after mesh surgery manifests itself as dyspareunia, vaginal pain, thigh pain, buttock pain or suprapubic pain. For POP, dyspareunia rate up to 38% has been reported with mesh use.[16] According to the literature, it is not accurate to denote that mesh use in urogynecology may increase dyspareunia or other pain syndromes.[14] To minimize the risk of pain with the use of mesh kits tension free surgical approach should be used as well as rectal and vaginal examination should be performed. Although women may develop pain syndromes without mesh exposure or extrusion, these two are important risk factors for pain syndromes.[8,14] Pain may also arise if the graft is placed too superficially or too close to the nerves. Often all or a portion of the graft requires removal. This can technically be difficult and may not resolve all pain issues. In the management of pain syndromes anti-inflammatory agents, vaginal estrogen, steroid injections, pelvic floor rehabilitation therapy may be used conservatively. In some instances surgical interventions to release tension, partial or total removal of the mesh may be needed.

Urinary tract complications

ICS and IUGA classified urinary tract complications as follows: A)Small intraoperative defect (e.g., bladder perforation), B) Lower urinary tract complication (other lower urinary tract complications or urinary retention), C) Uretheric or upper urinary tract.[4] Hung et al reported that compared to traditional methods, the mesh use in anterior prolapse surgery was associated with increased *de novo* stress urinary incontinence (10 vs. 23%).[17] de Landsheere et al. investigated 524 patients and they reported a 6.9% reoperation rate due to stress incontinence after vaginal mesh surgery in their retrospective study.[18] Detrusor over activity may be seen after urogynecologic operations. Milani et al reported 34% detrusor over activity rate after anterior vaginal repair with polypropylene synthetic mesh.[19] In the literature, the rate of *de novo* urgency after sling operations is reported to be as high as 25.9%.[20,21]

Vesicovaginal and urethrovaginal fistulas are two of mesh related urinary tract complications after vaginal surgeries.[22] Skala et al reported 2 vesicovaginal and 1 urethovaginal fistulas after vaginal tape operations in 179 patients.[23] There were also 62 (34.6%) cases of bladder outlet obstruction and 3 (1.7%) cases of intravesical graft extrusion. The overall rate of urgency was 45.3% and it was mostly seen after vaginal tape operations.[23]

Bladder injury is one of the other intraoperative complications, which is mostly occurring during needle insertion. Caquant et al reported bladder injury in 5 of 684 patients (0.73%).[6] Bladder perforation during needle passage may vary between 0.7 and 24% in retropubic sling operations.[20,24] Failure to recognize intravesical needle passage of mesh can lead to irritative bladder symptoms, pelvic and urethral pain, fistulas, recurrent urinary tract infections, and a return to the operation room. Erosion of mesh into the

TABLE 1. – New classification of mesh related complications.

	CATEGORY General Description	A (Asymptomatic)	B (Symptomatic)	C (Infection)	D (Abscess)
1	**Vaginal:** no epithelial separation include prominence (e. g., due to wrinkling or folding), mesh fiber palpation or contraction (shrinkage)	**1A:** Abnormal prosthesis or graft finding on clinical examination	**1B:** Symptomatic e.g. Unusual discomfort / pain; dyspareunia (either partner); bleeding	**1C:** Infection (suspected or actual)	**1D:** Abscess
2	**Vaginal:** smaller ≤ 1 cm exposure	**2A:** Asymptomatic	**2B:** Symptomatic	**2C:** Infection	**2D:** Abscess
3	**Vaginal:** larger > 1 cm exposure or any extrusion	**3A:** Asymptomatic 1-3Aa if no prosthesis or graft related pain	**3B:** Symptomatic 1-3B(b-e) if prosthesis or graft related pain	**3C:** Infection 1-3C/1-3D (b-e) if prosthesis or graft related pain	**3D:** Abscess
4	**Urinary tract:** compromise or perforation including prosthesis (graft) perforation, fistula and calculae	**4A:** Small intraoperative defect e.g. Bladder perforation	**4B:** Other lower urinary tract complication or urinary retention	**4C:** Ureteric or upper urinary tract complication	
5	**Rectal or bowel:** compromise or perforation including prosthesis (graft) perforation and fistula	**5A:** Small intraoperative defect (rectal or bowel)	**5B:** Rectal injury or compromise	**5C:** Small or Large bowel injury or compromise	**5D:** Abscess
6	**Skin and/or musculoskeletal:** complications including discharge pain lump or sinus tract formation	**6A:** Asymptomatic, abnormal finding on clinical examination	**6B:** Symptomatic e.g. Discharge, pain or lump	**6C:** Infection e.g. sinus tract formation	**6D:** Abscess
7	**Patient:** compromise including hematoma or systemic compromise	**7A:** Bleeding complication including hematoma	**7B:** Major degree of resuscitation or intensive care	**7C:** Mortality*	
			TIME		
T1: Intraoperative to 48 hours		**T2:** 48 hours to 2 months	**T3:** 2 months to 12 months	**T4:** over 12 months	
			SITE		
S1: Vaginal: area of suture line		**S2:** Vaginal: away from area of suture line	**S3:** Trochar passage (except intra-abdominal)	**S4:** Other skin or musculoskeletal site	**S5:** Intra-abdominal

*Additional complication- no site applicable-S 0.

urethra can rarely occur, as well. In a retrospective series of transvesical tape, urethral erosion was reported in 0.3% of cases.[25]

Rectum or bowel complications

ICS and IUGA classified rectum or bowel complications as A) Small intraoperative defect (rectal or bowel), B) Rectal injury or compromise, C) Bowel injury or compromise (small or large bowel injury or compromise), and D) Abscess. These complications usually occur in posterior prolapses surgery. Dwyer et al revealed 1 case of rectovaginal fistula in 50 patients.[26] Erosion of mesh into the rectum is uncommon, but potentially a serious complication of this class of repair that can lead to rectovaginal fistula, and consequently the need for fecal diversion with colostomy construction and significant morbidity. Rectal perforation during the needle passage is usually self limited because the perforation site is frequently extraperitoneal.

Reported bowel injuries usually occur within hours to days after performing the sling procedure. Most bowel injuries involve perforation of the bowel by the needles used during the procedure. Management of a bowel perforation at the time of sling placement usually covers resection of the injured segment and primary re-anastomosis, followed by a complete removal of the mesh.

Skin and/or musculoskeletal

Skin complications after urogynecologic surgery are rare but if occurs they are usually secondary to trocar entries or sinus tract, fistula formations. These are usually accompanied by infectious complications.

Musculoskeletal complications are more common after trans obturator tape (thigh pain), and abdominal or laparoscopic sacrocolpopexy (sacral pain, back pain). Anti-inflammatory agents are usually the first option in the management but in some cases these complications may persist even after mesh removal. Since these complications may be related to some other serious complications including pelvic abscess, fistulas, mesh erosion, and infections, detailed examination of the patients is necessary.[27,28]

Patient compromise

The severity of complication varies by the location of mesh placement and/or affected site as well as by the patient. Altman et al reported that compared with posterior repair, anterior repair was associated with a longer operating time, greater blood loss, and more frequent complications as well as a greater rate of vaginal hematoma (1.9%), despite similar patient characteristics.[29] This could be related to using four supportive arms in the anterior mesh, compared with two in the posterior procedure. Retroperitoneal hematoma is an important complication of urogynecologic surgery, Sivaslıo lu et al reported one case after abdominal sacrocolpopexy treated surgically with relaparotomy.[30]

Vaginal mesh surgeries may compromise life. FDA revealed that there were seven reported deaths associated with POP repairs. Three of the deaths associated with POP repair were related to the mesh placement procedure (two bowel perforation and one hemorrhage).

Infective complications

In the new classification of ICS/IUGA infectious complications are not categorized separately but used as a division of each category. Infectious complications after vaginal mesh surgeries may be accompanied by exposure, extrusion, urinary or bowel complications. The incidence of mesh-related infections and erosion ranges from 0 to 8%.[31] Mesh type, pore size, bacterial contamination, comorbid conditions (*i.e.*, diabetes mellitus and immune suppression) may affect infectious complications. Various types of infections have been associated with the use of vaginal mesh including retropubic abscess with cutaneous sinus, vesicovaginal fistula, rectovaginal fistula, pelvic abscess, perineal necrotizing infection, and vertebral osteomyelitis.[22,32,33] Common symptoms of infections are non-specific pelvic pain, persistent vaginal discharge or bleeding, dyspareunia, and urinary or fecal incontinence. Clinical examination can reveal tightening of the vaginal incision, vaginal granulation tissue, draining sinus tracts, and prosthesis erosion or rejection. A mesh-related infection can sometimes manifest as a pelvic abscess in the retropubic space, pararectal abscess, ischiorectal abscess, vesicovaginal fistula, rectovaginal fistula, abdominal fistula, sigmoid bowel-vaginal fistula, enterocutaneous or enteroperineal fistulas, and osteomyelitis.

In summary, synthetic mesh application has been replaced by conventional surgical intervention in POP surgery due its greater success. Synthetic mesh use-related complications are mostly minor and manageable. However, some of these complications, such as bowel and vascular injuries as well as uncontrollable infectious complications may risk the patient life in few occasions. To minimize complications, adequate surgery training and knowledge is needed and patients should be informed of possible complications. As more experienced surgeons are available and biocompatible materials with free-needles are developed, the risk of mesh-related complications will further decrease in the future.

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