

Vaginal mesh surgery: a review of current practice

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We review the risks and benefits of vaginal mesh surgery for pelvic organ prolapse and compare the existing guidelines and recommendations from different regions and academic bodies. We then provide recommendations on the use of vaginal mesh surgery for pelvic organ prolapse.

Keywords: Pelvic organ prolapse; Surgical mesh

Introduction

Pelvic organ prolapse (POP) is a common but distressing problem in older women, affecting 40% to 60% of women^{1,2}. The risk of recurrence after surgery is 16% to 33%³. Owing to the high rate of recurrence after native tissue repair surgery, a mesh graft material has been used in abdominal sacrocolpopexy since 1960s⁴, and via the transvaginal route since 1990s. In 2002, the transvaginal mesh device was approved by the US Food and Drug Administration (FDA). However, vaginal mesh surgery is associated with serious adverse events and complications^{5,6}. In 2008 and 2011, the FDA released two public health notifications⁷. This study aims to review the risks and benefits of vaginal mesh surgery for POP, compare the existing guidelines and recommendations from different regions and academic bodies, and provide recommendations on its use.

Polypropylene mesh

Polypropylene has been used for >60 years as suture material for repair of hernias in various anatomic locations. In urogynaecology, type I polypropylene mesh is first used as the mid-urethral sling for treatment of urinary stress incontinence. The mesh has been widely used as an adjuvant material for repair of POP for >20 years. However, polypropylene mid-urethral sling induces a minimal inflammatory reaction without significant change in collagen solubility. The polypropylene sling causes more intense and longer-lasting inflammatory reaction and greater visceral penetration than an autologous fascial sling^{8,9}. In animals, normal-weight polypropylene has a negative impact on the metabolism of both collagen and elastin, resulting in catabolic reactions, whereas lighter more-porous and less-stiff meshes have less negative impact¹⁰. However, polypropylene mid-urethral sling surgery for urinary stress incontinence is not associated with an increased cancer risk later in life¹¹. Exposed and

unexposed women are comparable in terms of pelvic organ cancers including ovarian cancer (hazard ratio [HR]=0.8, 95% confidence interval [CI]=0.5-1.2), endometrial cancer (HR=1.1, 95% CI=0.8-1.4), cervical cancer (HR=0.4, 95% CI=0.2-1.0), and bladder and urethral cancer (HR=0.7, 95% CI=0.4-1.2)¹¹. Nonetheless, in 2019, the International Consultation on Incontinence Research Society Meeting was held to discuss alternative materials and tissue-engineering techniques that may improve interactions and host response in vagina¹².

Benefits and risks of vaginal mesh surgery for POP

Benefits

Vaginal mesh surgery is developed owing to the high failure rate of traditional native tissue repair. It has lower risk of recurrence. In a study in 2011, the benefit of synthetic mesh for the anterior compartment was confirmed, but the study was limited by the non-blinded assessment and industry affiliation¹³.

In the multi-centre PROSPECT of women who underwent primary transvaginal anterior or posterior compartment prolapse surgery, the native tissue group and the mesh group were comparable in terms of the patient-reported Pelvic Organ Prolapse Symptom Score and condition-specific quality of life score¹⁴. However, the follow-up was up to 2 years, and longer-term outcomes were not available.

In the Cochrane review of 37 randomised controlled studies involving 4023 women who underwent transvaginal mesh repair or native tissue repair for anterior

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or multi-compartment POP¹⁵, the awareness of prolapse at 1 to 3 years was significantly lower in women with transvaginal mesh repair (risk ratio [RR]=0.66, 95% CI=0.54-0.81). This indicates that only 10% to 15% of women with transvaginal mesh repair are aware of prolapse, compared with 19% of women with native tissue repair. Nonetheless, the two groups were comparable in terms of the extent of repair and the awareness of prolapse. In addition, women with transvaginal mesh repair were less likely to have a stage-2 or greater prolapse (RR=0.40, 95% CI=0.30-0.53) upon examination. This shows that 11% to 20% of women with transvaginal mesh repair have a stage-2 or greater prolapse, compared with 38% of women with native tissue repair. Furthermore, the rate of repeat surgery for prolapse after 1 to 3 years was lower in those with transvaginal mesh repair (RR=0.53, 95% CI=0.31-0.88). This suggests that 1% to 3% of women with transvaginal mesh repair need repeat surgery, compared with 3% of women with native tissue repair. When the PROSPECT data were added, transvaginal mesh repair remains superior in terms of awareness of prolapse (RR=0.83, 95% CI=0.71-0.96) and recurrence (RR=0.42, 96% CI=0.32-0.56). However, there is heterogeneity in the included trials; some trials include women with uterine or vault prolapse; few trials differentiate primary from secondary repairs. There are variations in inclusion criteria regarding concomitant procedures and continence surgery.

In two studies of women with severe POP, transvaginal mesh repair achieved better 5-year outcomes for both anterior compartment and multi-compartment prolapse, compared with native tissue repair^{16,17}. However, the sample size of these trials is small. Further research and systematic review are needed to reach a conclusion.

Risks

The main risks of transvaginal mesh repair are mesh exposure and erosion and hence the subsequent repeated surgery. The reported complication rates vary and may be due to heterogeneity in surgical techniques, definition of exposure, and small sample size. In the PROSPECT¹⁴, in women who received only synthetic mesh as part of anterior or posterior prolapse repair, with no other concomitant mesh procedure or mesh inserted, the mesh complication rate in the first 2 years was 14%. 76% of the complications were asymptomatic mesh exposure and required only conservative or partial removal, except for one case that required complete mesh removal owing to severe infection.

In a New York state database, in 3798 women with vaginal mesh surgery and 5070 women with vaginal mesh

plus sling surgery, the rates of mesh erosion were 1.95% and 2.72%, respectively, and the rate of repeat surgery for mesh erosion were 1.23% and 2.16%, respectively¹⁸.

In the Cochrane review of 19 randomised controlled trials¹⁵, 134 (12%) of 1097 women with transvaginal mesh repair had mesh exposure. In subgroup analysis of women with anterior transvaginal mesh repair, the mesh exposure rate was 10%. Women with transvaginal mesh repair were more likely to have repeat surgery (for prolapse, stress urinary incontinence, or mesh exposure) at 1 to 3 years, compared with those with native tissue repair (RR=2.4, 95% CI=1.51-3.81). However, the rate of repeat surgery for prolapse was lower in those with transvaginal mesh repair (RR=0.53, 95% CI=0.31-0.88). The two groups were comparable in terms of the rate of repeat surgery for stress urinary incontinence (RR=1.07, 95% CI=0.62-1.83). Surgery for mesh exposure was required in 8% of women. The operative time was longer in mesh surgery, but the two groups were similar in terms of the need for blood transfusion and the length of hospital stay. The operative risks for mesh repair were higher, particularly the risk of bladder injury (RR=3.92, 95% CI=1.62-9.50). However, there was no significant difference in serious adverse events or complications during or after surgery. Women with transvaginal mesh repair were more likely to develop de novo stress urinary incontinence (RR=1.39, 95% CI=1.06-1.82)¹⁵. In a study in Scotland, the risk of subsequent incontinence surgery is also higher in women with anterior mesh repair for POP¹⁹. However, in UK, those with mesh, graft, or standard repair were comparable in terms of 2-year urinary outcomes and quality of life related to urinary, bowel, vaginal, and sexual symptoms¹⁴. Long-term data are limited. More robust studies with larger sample size and longer follow-up are needed to determine the benefits and risks of transvaginal mesh repair.

Complications

Vaginal mesh-related complications can result in severe symptoms and necessitate specialised surgical management (from simple transecting the mesh to complete removal of the mesh). The complication rates reported vary and are mostly under-reported.

In a retrospective study in France, the rate of reoperation for mesh-related complications in 1123 patients with POP surgery over 8 years was 2.8%, of which 4.2% after transvaginal mesh operation and 1.3% after sacrocolpopexy²⁰. The most common indication for reoperation was vaginal exposure of mesh (48%), followed by symptomatic mesh contraction (20.3%) with pain,

voiding dysfunction, and overactive bladder symptoms. 83% of reoperations were performed transvaginally and 9% laparoscopically. For treatment outcomes, 78% were cured, 13% were improved, and 7.4% were failed. Of all complications, residual pain or dyspareunia was reported in 11.8% of patients.

In a review of mesh-related complaints at a tertiary referral centre in the United States, of 92 women with mesh revision, 56.5% involved a midurethral sling, 26.1% a transvaginal mesh, 2.2% both, and 13% a sacrocolpopexy mesh⁶. The median interval from mesh implantation to presentation was 2.4 to 3.2 years. In 69.4% of women, the mesh for prolapse repair was revised owing to pain or dyspareunia. Around 85% of women reported improvement of symptoms after surgical intervention.

Thus, pain syndrome can be a serious complication after mesh repair. Other severe complication reported was fistulas, which have a poor prognosis even after surgery. All these complications are rare but difficult to treat. Surgeons must be aware of the specific risks associated with surgery for pelvic floor disorders. Intensive training of new techniques is encouraged. Complications should be recognised promptly to enable subsequent management.

Trends and regulations worldwide

The debate on when, where, and how to use mesh for POP remains controversial, especially regarding the safety of the synthetic mesh. In 2008, the FDA issued a safety concern after receiving >1000 reports of mesh-associated complications. In 2011, another safety concern was issued. In 2016, the FDA reclassified surgical mesh for transvaginal repair of POP as class III (high risk). Multiple class-action lawsuits have been brought against mesh manufacturers, particularly against those of transvaginal mesh. The use of mesh has dramatically reduced since 2008; multiple manufacturers suspended the sale of vaginal mesh devices²¹. In 2019, the FDA issued a public notice to order all manufacturers to stop selling and distributing surgical mesh intended for transvaginal repair of POP. Therefore, fewer vaginal mesh procedure and more native tissue repairs and minimally invasive sacrocolpopexies are performed for prolapse^{22,23}.

In 2014 in the United Kingdom, the Medicines and Healthcare Products Regulatory Agency concluded that the benefits of vaginal mesh outweigh the risks and hence there is no justification to take regulatory action to ban mesh devices from UK hospitals. However, in 2017 a Scottish Independent Review concluded that transvaginal

mesh procedures must not be offered routinely, as it has no extra benefit compared with native tissue repair. However, the review did not consider studies on the long-term safety and effectiveness of mesh surgery. There is a lack of long-term follow-up data such as quality of life and activities of daily living.

In the PROSPECT in 2017, conventional anterior colporrhaphy, anterior mesh repair with synthetic implants, and anterior mesh repair with biological implants are comparable in terms of prolapse-related quality of life and adverse events¹⁴. However, 12% of complications were mesh-related. Thus, in July 2018, a high vigilance restriction was imposed on the use of mesh to treat stress urinary incontinence and POP. This included restriction of the use of synthetic tape and mesh to procedures for stress urinary incontinence and vaginally inserted mesh for POP, as well as high vigilance scrutiny on procedures involving abdominally inserted mesh such as sacrocolpopexy. In March 2019, the high vigilance restriction was extended. In 2019, the National Institute for Health and Care Excellence guideline states that transvaginal mesh in the anterior compartment is only allowed in research, whereas the use of mesh in the posterior compartment is prohibited²⁴.

In the position statement by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, the transvaginal polypropylene mesh is not recommended as the first-line treatment for any vaginal prolapse in September 2017²⁵. Sales of mesh are halted. Transvaginal mesh products with the sole use for treatment of POP via transvaginal implantation are removed from the Australian Register of Therapeutic Goods.

The International Federation of Gynecology and Obstetrics concludes that use of transvaginal mesh for the treatment of POP should be considered only in complex cases, in which the benefits of mesh placement justify the known risks²⁶. Such complex cases include recurrent POP, especially in the presence of poor-quality collagen, increased intra-abdominal pressure, and large anterior compartment prolapse, and cases with contraindication to abdominal surgery. Transvaginal mesh procedure should be performed by a surgeon with expertise in mesh placement techniques who is capable of recognising, diagnosing, and treating potential mesh-related complications. Surgical management of mesh erosion and contraction may be particularly challenging owing to the proximity of the bladder and bowel. Thus, referral to an expert is recommended to avoid further complications such as fistula formation.

In Asia, no restrictions have been imposed on the use of mesh. It remains a treatment option. In 2019 in the Pan Asia meeting of the International Urogynecological Association, urogynaecologists shared their practice of performing mesh repair for POP. Most performed mesh repair only for advanced stage of prolapse or recurrent cases, mainly for older patients and for the anterior compartment only, and operations were performed by trained urogynaecologists or urologists or subspecialty trainees with supervision.

Local experience and recommendations

In 2004, the tension-free vaginal mesh was proposed for repairing POP²⁷. In 2006, commercial mesh kits became available in Hong Kong, and synthetic mesh surgery was more readily available. In a Hong Kong study of 47 women who underwent transvaginal mesh surgery for stage III or IV POP, the mean operating time was 94 minutes, the mean estimated blood loss was 163 mL, and the mean hospital stay was 4 days²⁸. Four (8.5%) patients had visceral injuries, which were identified and repaired intra-operatively, and all recovered uneventfully. POP quantification improved significantly. Nine (19%) patients had recurrent stage-II prolapse but only one was symptomatic. Six (13%) patients had postoperative mesh exposure, three of whom underwent mesh excision. Five (11%) patients had de-novo urodynamic stress incontinence, which was mostly mild and managed conservatively. 91% of patients were satisfied with the outcomes.

Regarding intermediate-to-long-term outcomes, in 183 sexually inactive women aged >65 years who underwent transvaginal mesh surgery with concomitant vaginal hysterectomy or uterine-preserving operation for advanced stage of POP (ie stage III/IV) with or without urodynamic stress incontinence, after a mean follow-up duration of 50 months in 156 of those women, the subjective recurrence rate was 5.1% and the objective recurrence rate was 10.9%²⁹. The re-operative rate for prolapse was 1.3%. The mesh erosion rate was 9.6%. De novo stress urinary incontinence occurred in 12 (7.7%) women. Only one (1.9%) woman underwent tension-free transvaginal tape procedure (transobturator route) for stress urinary incontinence, and the others received pelvic floor training to improve symptoms. The overall satisfaction rate was 98.1%.

Regarding complications, in 134 cases of vaginal mesh surgery with a mean follow-up duration of

40 months, the rate of mesh-related complications was 13.4% and the mesh exposure rate was 11.9%³⁰. The main indication for re-operation was vaginal spotting; no re-operations were related to pelvic pain or dyspareunia. All 13 surgical excisions (in eight patients) of exposed mesh were performed vaginally under local anaesthesia on the same day, except for one patient who opted for general anaesthesia. The median time between primary operation to first surgical excision of exposed mesh was 14 months (interquartile range=8.8-37.3 months); the longest time was 66 months. The mean operating time for surgical excision of the exposed mesh was 20±6 (range, 10-30) minutes, with estimated blood loss of 2 to 10 mL. 95% of patients were well at their latest follow-up. Transvaginal mesh with posterior insertion was associated with increased risk of mesh-related complications (OR=4.3, 95% CI=1.6-11.5, p=0.002). Mesh exposure was associated with total vaginal mesh surgery (OR=5.0, 95% CI=1.8-13.6, p=0.002), coital activity (OR=2.8, 95% CI=1.1-6.9, p=0.03), and obesity (OR=4.7, 95% CI=1.5-14.4, p=0.007). As total vaginal mesh and posterior vaginal mesh are no longer available in Hong Kong, this risk is eliminated.

In 154 Chinese women with stage-III or stage-IV POP who underwent mesh repair or native tissue repair and were followed up to 2 to 5 years, those with mesh repair was associated with a five-fold reduction in the risk of subjective recurrence and a six-fold reduction in the risk of objective recurrence³¹. In women with concomitant levator ani muscle avulsion, mesh repair was associated with a four-fold reduction in both objective and subjective recurrence of POP.

Findings of studies in Hong Kong are consistent with those in the Cochrane review. The rates of recurrence and repeat surgery were lower in women with mesh repair than with native tissue repair. In our unit, sexually inactive women aged ≥65 years with advanced stage of prolapse and levator ani muscle avulsion were offered vaginal mesh repair for anterior compartment. The rate of mesh exposure was just 10%. In our patients with mesh exposure, the symptoms were much milder; most patients were asymptomatic or with mild vaginal spotting. The treatment was thus conservative or minor. The overall satisfaction rate was high. Strict patient selection of mainly sexually inactive women for mesh repair resulted in fewer dyspareunia or coital problems. Operations were performed by urogynaecologists or gynaecologists experienced in prolapse surgery. In Hong Kong, no major litigation has been lodged against mesh manufactures.

Conclusion

The benefits of vaginal mesh surgery for POP outweigh its risks in patients at risk of recurrence, with advanced stage of prolapse, sexually inactive, and with levator ani muscle injury. Vaginal mesh surgery may be performed in selected patients by trained surgeons who can promptly recognise and manage any complications. The recurrence rate is low, and the overall satisfaction rate is high. The mesh-related complication rate is low; most complications are mild and can be resolved by conservative or simple surgical interventions.

Contributors

All authors drafted the manuscript and critically revised the manuscript for important intellectual content.

All authors contributed to the study, approved the final version for publication, and take responsibility for its accuracy and integrity.

Conflicts of interest

All authors have disclosed no conflicts of interest.

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Data availability

All data generated or analysed during the present study are available from the corresponding author on reasonable request.

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