Re: Patient Safety in Vaginal Mesh Surgery
Anonymous

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Experts' summary:
The Lancet editorial echoes a number of recent newspaper headlines in the UK quoting the National Institute for Health and Care Excellence (NICE) guidelines suggesting that mesh should be used as a last resort for pelvic organ prolapse (POP) repair. The editorial comments were based on number of patient-reported complications with the implication that the absolute number is very high. It ends with the statement that "such evidence should have been more energetically accumulated before vaginal mesh surgery became so irresponsibly fashionable".

The NICE draft guidelines are carefully stated and really do not differ in any large measure from the guidelines of major urological and gynecological associations and the US Food and Drug Administration (FDA) in relation to surgical management of urinary incontinence and POP. The guidelines emphasize that women should explore the range of nonsurgical treatments such as lifestyle interventions, physical therapies, and medications before considering surgical treatments. They state that if mesh is to be used in prolapse surgery, women should be given detailed information including short- and long-term complications, as well as details of the implant material. Importantly, the restrictive comments regarding mesh utilization are confined to POP repair and not stress urinary incontinence (SUI).

Experts' comments:
Mesh may be viewed in a nicer light. Both the Cochrane database [1] and a systematic review by the Society of Gynecologic Surgeons Systematic Review Group [2] found a benefit from mesh utilization in the anterior compartment, with lower recurrence rates than for native tissue repair (relative risk [RR] 1.50, 95% confidence interval [CI] 1.09–2.06; three randomized controlled trials [RCTs]; $n = 268$; $I^2 = 0\%$; moderate-quality evidence). Mesh exposure rates ranged from 1.4% to 19% at the anterior vaginal wall and operative mesh revision rates ranged from 3% to 8%. There was no difference in de novo dyspareunia rates between groups (RR 0.54, 95% CI 0.27–1.06; eight RCTs; $n = 583$; $I^2 = 0\%$; low-quality evidence). The 5-yr outcomes from the OPTIMAL trial [3] reveal a propensity for failure (60–70%) of native tissue repairs for uterine prolapse. Our review of mesh complications [4] showed the potential interactions of host factors (patient), product (mesh), and the surgical training and technique of the implanting surgeon. According to a number of laboratory and clinical experiences [5] the take home points are as follows:

- There are an increasing number of women with POP because of the aging population.
- Lifestyle (phenotypic) factors contribute to POP occurrence (age, body mass index, childbirth, and smoking, among others).
- There is also a genetic and familial link (greater breakdown of collagen, higher level of proteolytic enzyme, genetic upregulation).
- Tissue-based repair has been challenging (bladder neck suspension for SUI and tissue plication for POP) with high rates of recurrence.
- Use of mesh in POP has had better anatomic success in level 1 prospective trials; however, complications and reoperations for mesh are >10%.
- Complication rates are much lower for surgeons and centers with female pelvic health training and a high volume of cases.
- Cell-based and biomaterials with polymers conceptually offer an option but no meaningful data are available (costs and FDA approval are prohibitive) and they do not solve the patient based tissue defect to replace this material. There is no commercially viable alternative to large-pore, lightweight polypropylene for patients with recurrent POP.
- Mesh material is widely accepted for SUI and abdominal (laparoscopic/robotic) use in women and for hernia repair in men, but is controversial for a vaginal approach for repair of POP.
- The FDA, European Association of Urology [6], American Urological Association, Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction, and American Board of Obstetrics and Gynecology policy statements all suggest a dialogue with the patient and informed consent. There are high-risk women who benefit from mesh augmentation, and shared medical decision-making is advocated.

Conflicts of interest: The author has nothing to disclose.

References

[1] Maher C, et al. Cochrane Database Syst Rev 2016;2016, CD004014.
[2] Schimpf MO, et al. Obstet Gynecol 2016;128:81–91.
[3] Jelovsek JE, et al. JAMA 2018;319:1554–65.
[4] Sah HN, , et al. Indian J. Urol 2012;28:129–53.
[5] Coaco M, et al. BJU Int 2015;115:859–66.
[6] Chapple C, et al. Eur Urol 2017;72:424–31.

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