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SYSTEMATIC REVIEW AND CLASSIFICATION OF COMPLICATIONS AFTER ANTERIOR, POSTERIOR, APICAL AND COMBINED VAGINAL MESH IMPLANTATION FOR PROLAPSE REPAIR

Hypothesis / aims of study
Due to the recent development of alloplastic materials and FDA warnings concerning high complication rates associated with trans-vaginal placement of surgical mesh to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI), a detailed and differentiated evaluation of mesh application is needed (1). In this review we focus on the vaginal meshes used for POP repair and possible changes in application after the first FDA warning 2008.

Study design, materials and methods
A systematic review of the literature using PubMed and the Cochrane Library Database was performed. Randomized controlled and high volume prospective trials (>100 patients) from 2008 to July 2013 on the treatment of vaginal wall prolapse with alloplastic materials were selected. The data was reviewed for reoperation rates and complications based on the ICS-IUGA classification 2010. A sub-group analysis of anterior, posterior, apical and combined compartment vaginal repair was performed. Mesh-related complications and risk factors for occurrence of complications were extracted.

Results
A total of 11 randomized controlled and 9 prospective studies with 2289 patients (most POP-Q≥II, median follow up 12mos) were included. The results showed a mean total complication rate of 27% in anterior, 20% in posterior and 40% in combined mesh repair group (ns). Severe complications (reoperations) occurred in 8% anterior, 3.5% posterior and 13% combined ($p<0.05$) mesh repairs. No differences were found for reoperation rates for POP (2-3%) and de novo dyspareunia (11-17%). A significant higher number of patients in the total mesh repair group needed a second operation for SUI.
Following mesh-related complications were identified: mesh exposure (ICS classification: 2B or 3B/S1 or S2), infection (1, 2 or 3 C/D/S1-S3 or 6C or D/S4), fistula (4B/S1 or S2), prolonged pain (1Be/S1 or S2 or S4 or 6Be/S4) and dyspareunia (1Bc/S1 or S2). Mesh-related complications occurred in 19.9% (0.6-60.3) anterior, 17.3% (0-42.7) posterior, 13.5% apical (no data for dyspareunia) and 26.9% (7.5-45.5) combined mesh repair (ns). The majority of the adverse events related to trans-vaginal mesh surgery took place during the first postoperative year. Following risk factors for complications were identified: operative technique, surgeon experience, previous prolapse repair, concomitant hysterectomy, total mesh repair, mesh properties (light-weight, collagen coating were positive factors), young age, sexual activity and smoking.

Interpretation of results
Six years after the first FDA warning, there is a change in trial conduction but still scant supportive evidence for trans-vaginal mesh implantation. Long-term surveillance studies and randomized controlled trials for the vaginal mesh kits are necessary. Surgical skills, mesh materials and careful patient selection seem to be crucial factors for a good outcome.

Concluding message
Trans-vaginal alloplastic materials are popular for POP repair but are associated with high complication rates, especially mesh exposure, voiding dysfunction and dyspareunia. Our systematic review presents an update on the current literature in the field of vaginal mesh kits for the treatment of prolapse after the first FDA warning 2008. First structured application of the ICS-IUGA classification of complications associated with trans-vaginal mesh implantation in all compartments was conducted. The review is intended to be a help for clinicians to educate their patients about the risks of alloplastic materials and to make an individualized decision based on risk stratification.

References
1. FDA Safety Communication: UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse. Available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm. Accessed July 13, 2011.

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