ABSTRACT

Polytetrafluoroethylene Mesh , Concurrent Hysterectomy and Smoking are Risk Factors for Mesh/Suture Erosions Following Sacrocolpopexy

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Objectives: To investigate risk factors for mesh and/or suture erosions within two years following sacrocolpopexy in women enrolled in a randomized surgical trial.

Study Design: This is an ancillary analysis of the CARE trial, an IRB-approved multicenter randomized surgical trial of sacrocolpopexy with and without concomitant Burch colposuspension in stress continent women. Surgeons were allowed to select graft and suture material for the sacrocolpopexy, allowing study of a large range of materials. Concomitant hysterectomy was allowed, based on clinical indications. All participants were followed carefully with standardized physical examination that included assessment of surgical materials complications over the two years after the index surgery. Mesh and/or suture erosions were identified by adverse event reports which were submitted to the Data Coordinating Center. DSMB intervention early during the study precluded subsequent use of polytetrafluoroethylene (PFTE) based on excess erosion rates. For this analysis, two surgical reviewers read each adverse event report to ensure that it was correctly identified as a surgical material complication. Suture erosion was defined as erosion with visualized suture that resolved after removing the suture without further intervention.

Results: Three hundred one of 322 randomized women completed two-year follow-up. Synthetic mesh was the most common material used for the sacrocolpopexy (83%) with common use of Mersilene (43%) and Polypropylene (39%) and minimal use of PFTE

(Gore-tex) (6%). PFTE suture was used most often for anchoring the mesh to the vagina (54%). Twenty subjects (7%) experienced an erosion of mesh and/or suture. The risk of mesh complications was significantly higher in women who had a synthetic PFTE meshes than those without PFTE mesh (4/18, (22%) versus 16/281, (5.6%): OR 4.7 (95% CI 1.4,16.0)). Concurrent hysterectomy was performed in 88/301 women and increased the risk of erosion (14% versus 4% (OR 4.0 (CI 1.6,10.3)). Women who currently smoked were also at increased risk for erosion (5/21(24%) versus. 15/280 (5%)(OR 5.5 (CI 1.8,17.1)).

Two of three patients with suture erosions healed after simple removal of suture. The third patient likely had a suture erosion, but we have not confirmed healing after suture removal. Of the remaining events, 17 were mesh erosions; 4 were managed without surgery, of which 1 was lost to follow-up and the other 3 had no resolution. Thirteen patients with mesh erosion underwent at least one surgery, for mesh removal. Two patients had resolution, 6 had persistent erosions and 5 were lost to follow-up. One subject had two partial resection procedures and one had three; both had subsequent chronic sinus tracts. **Conclusions:** For women undergoing abdominal sacrocolpopexy, PFTE mesh should be avoided. Concurrent hysterectomy and smoking are modifiable risks for mesh/suture erosion.