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Original Research

Vaginal Mesh for Prolapse: A Randomized Controlled Trial

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Abstract

OBJECTIVE: To present 3-month outcomes of a double-blind, multicenter randomized controlled trial comparing traditional vaginal prolapse surgery without mesh with vaginal surgery with mesh.

METHODS: Women with pelvic organ prolapse quantification prolapse stages 2–4 were randomized to vaginal colpopexy repair with mesh or traditional vaginal colpopexy without mesh. The primary outcome measure was objective treatment success (pelvic organ prolapse quantification stage 1 or lower) at 3 months. Secondary outcome measures included quality-of-life variables and complication rates.

RESULTS: Sixty-five women were recruited from January 2007 to August 2009, when the study was halted due to predetermined stopping criteria for vaginal mesh erosion at a median follow-up of 9.7 months (range, 2.4–26.7 months). Thirty-two women underwent mesh colpopexy (24 anterior mesh, eight total mesh), and 33 women had vaginal colpopexies without mesh (primarily uterosacral ligament suspension) and concurrent colporrhaphy. There were no statistically significant baseline differences between the mesh and no-mesh groups with respect to demographics, menopausal status, and race. Analysis of the mesh and no-mesh women found no difference with respect to overall recurrence (mesh: 19 [59.4%] compared with no mesh: 24 [70.4%], P=.28). There were five (15.6%) vaginal mesh erosions. Two cystotomies and one blood transfusion occurred in the mesh group only. Subjective cure of bulge symptoms was noted in 93.3% of mesh patients and 100% of no-mesh patients. Furthermore, subjective quality-of-life measurements did not differ between the two groups at baseline or 3 months postoperatively.

CONCLUSION: At 3 months, there is a high vaginal mesh erosion rate (15.6%) with no difference in overall objective and subjective cure rates. This study questions the value of additive synthetic polypropylene mesh for vaginal prolapse repairs.

CLINICAL TRIAL REGISTRATION: Clinicaltrials.gov, www.clinicaltrials.gov, NCT00475540.

LEVEL OF EVIDENCE: I