

A RANDOMIZED CONTROLLED TRIAL OF FASCIA LATA FOR THE PREVENTION OF RECURRENT ANTERIOR VAGINAL WALL PROLAPSE

Hypothesis / aims of study

Genital prolapse is a common problem with an especially high prevalence among parous women. Successful treatment of anterior wall prolapse remains challenging. Recurrent anterior wall prolapse has been reported to occur in up to 70% of women undergoing standard colporrhaphy (1). We conducted this study to evaluate the efficacy of solvent dehydrated cadaveric fascia lata in preventing recurrent anterior vaginal wall prolapse during reconstructive surgery.

Study design, materials and methods

A prospective, randomized, controlled trial evaluating the impact of a 2x4 cm patch of solvent dehydrated cadaveric fascia lata on recurrent anterior vaginal wall prolapse was performed in women with anterior vaginal wall prolapse to the hymenal ring and beyond. Subjects were randomized to standard colporrhaphy with or without a fascial patch. The patch was sutured in place between the plicated endopelvic connective tissue and vaginal epithelium. Subjects were evaluated by both the Baden-Walker modified halfway and POP-Q systems preoperatively and at 2, 6, 12, 52 weeks postoperatively. Patients were also asked to return for follow-up beyond 1 year. "Failure" was defined as either ICS stage II anterior wall prolapse or prolapse to the introitus. This IRB-approved study was powered to detect a 15% difference in recurrent anterior wall prolapse. Groups were compared using chi-squared or Fisher's exact tests. Multiple logistic regression analysis was used to control for potential confounding variables.

Results

Of 162 subjects enrolled from July 1999 to November 2002, 154 subjects had surgery (76 patch: 78 no patch). 134 subjects (87%) returned for either a 52 week or long term evaluation. The two groups were similar for age, history of previous reconstructive surgery, and concomitant surgeries. Mean age (SD) was 65.2 years (11.6). At entry, 76 patients (49%) had ICS stage II, 72 patients (47%) had stage III, and 6 patients (4%) had stage IV anterior vaginal wall prolapse. Twenty of 68 controls (29%) and 15 of 66 subjects (23%) in the patch group experienced recurrent stage II or greater anterior wall prolapse ($p=0.379$). When defining recurrent prolapse as anterior wall descent to the introitus or beyond, 9 of 69 controls (13%) and 8 of 66 subjects (12%) in the patch group experienced recurrent prolapse ($p=0.872$). 74% with recurrent prolapse were free of symptoms. In multiple logistic regression analysis, a fascial patch did not reduce recurrent anterior vaginal wall prolapse (OR 0.70, $p=0.380$), while the presence of a transvaginal sling was associated with a dramatic decrease in recurrent stage II anterior wall prolapse (OR 0.119, $p<0.0001$).

Interpretation of results

The use of solvent dehydrated fascia lata as a barrier during anterior colporrhaphy does not appear to decrease the rate of recurrent prolapse. This study demonstrates a significant protective effect of transvaginal slings against recurrent anterior wall prolapse.

Concluding message

Surgeons should use adjuvant grafts in reconstructive surgery with caution until efficacy is demonstrated in randomized controlled trials. Future studies on the impact of adjuvant grafts in the anterior compartment should include a stratified randomization for transvaginal sling.

References

1. Anterior colporrhaphy: A randomized trial of three surgical techniques. *Am. J Obstet Gynecol* 2001; 185: 1299-306. **FUNDING: Mentor Corporation**