Paravaginal Bests Xenograft for Anterior Prolapse

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HOLLYWOOD, FLA. — Paravaginal repair of anterior prolapse with synthetic mesh is associated with a higher anatomic success rate than is xenograft repair; both of these interventions were more successful than standard colporrhaphy, based on interim results of a double-blind, randomized, controlled study.

There were no significant differences in symptomatic prolapse recurrence, operative time, or sexual function outcomes, Dr. Keisha Dyer said.

Recurrence rates of up to 40%-50% are commonly reported after anterior vaginal wall prolapse repair, with about 30% of these women requiring a reoperation, she said.

Although paravaginal repairs and graft augmentation can decrease the number of failures, more data are needed about the optimal material, said Dr. Dyer of the division of female pelvic medicine and reconstructive surgery at the University of California, San Diego.

Dr. Dyer and her associates assessed 99 women with symptomatic prolapse. In the operating room on the day of surgery, 32 were randomized to anterior colporrhaphy; 31, to porcine dermal graft; and the remaining 36, to polypropylene mesh.

At baseline, patients enrolled in this Optimal Anterior Repair Study (OARS) had a mean of stage III anterior prolapse and a mean age of 63 years. They were enrolled from January 2006 to September 2008. The researchers tracked patients' outcomes at 6 weeks and at 6, 12, and 24 months.

Dr. Dyer presented interim results for 78 women followed for at least 1 year (mean, 20 months) at the annual meeting of the American Urogynecologic Society.

Anatomic success was achieved by 14 of 26 women (54%) in the colporrhaphy group, 15 of 24 women (63%) in the porcine graft group, and 25 of 28 (89%) women in the synthetic mesh group. The difference in this primary outcome between the colporrhaphy and synthetic mesh groups was statistically significant, Dr. Dyer said. Anatomic success was defined as prolapse stage I or 0 on the pelvic organ prolapse quantification (POP-Q) examination.

VITALS

Major Finding: Paravaginal repair of anterior prolapse with synthetic mesh had a higher anatomic success rate than xenograft repair; both beat standard colporrhaphy at 1 year after surgery.

Data Source: Interim results of a double-blind, randomized, controlled study in 78 women with symptomatic prolapse.

Disclosures: The study was supported by an unrestricted grant from Boston Scientific Corp. Dr. Dyer and her coauthors said they had no relevant disclosures.

There was no significant difference between groups in symptomatic recurrence, a secondary aim of the study. A total of 12% of the colporrhaphy group, 13% of the porcine graft group, and 4% of the mesh group had a return of prolapse symptoms, such as complaint of "bulge." Two patients in the porcine graft group had reoperations, Dr. Dyer said.

The erosion rate was higher in the synthetic mesh group. This outcome was experienced by four patients in this group (14%), compared with one patient (4%) who received the porcine graft repair.

There were no significant differences in terms of operative time. However, there was a trend toward approximately 50 mL more blood loss with augmentation, Dr. Dyer said. Estimated blood loss was 171 mL in the colporrhaphy cohort, 229 mL in the porcine graft group, and 225 mL in the synthetic mesh patients.

In terms of subjective outcomes, women in all three groups reported a reduction in prolapse and urinary symptoms at follow-up on subscales of the pelvic floor impact questionnaire (PFIQ) and the pelvic floor distress inventory (PFDI). There were no statistical differences between groups.

In addition, postoperative sexual function scores on the pelvic organ prolapse/urinary incontinence sexual questionnaire (PISQ) were not significantly different between groups, Dr. Dyer said.

The randomized, double-blind, multicenter design was a strength of the study, she said. "A major limitation is that a majority of our subjects underwent concomitant procedures," which were permitted at the discretion of the surgeon.

"We look forward to sharing our 2-year data in the future," Dr. Dyer said. Time to failure and any differences in reports of pain are planned to be released with the 24-month data. ■

Prolapse Surgery Now Less Common in Younger Women

VITALS

Major Finding: Fewer pelvic organ prolapse procedures are being performed in women under age 52 years.

Data Source: A study of the National Hospital Discharge Survey database.

Disclosures: The National Institutes of Health funded the study. Dr. Jones said she had no relevant disclosures.

HOLLYWOOD, FLA. — The overall number of inpatient surgeries for pelvic organ prolapse decreased over the past few decades, with some interesting trends according to patient age, based on a 1979-2006 study of the National Hospital Discharge Survey database.

"The decrease in overall numbers likely reflects a large decline in procedures in women younger than 52 years," Dr. Keisha Jones said. "Rates were stable or slightly increased for women 52 and older."

Epidemiologic data for pelvic organ prolapse are lacking, she said at the annual meeting of the American Urogynecologic Society. So she and her associates evaluated more than 5.6 million prolapse procedures performed from 1979 to 2006. There were approximately 228,000 procedures in 1979 and 186,000 in the final year of the study period, according to ICD-9-CM codes in the database.

The researchers stratified women into two groups—those younger than 52 and those 52 years and older. They chose this cutoff point because 52 is the average age of onset of menopause in the United States.

During the study, mean patient age increased by a decade from 47 years in 1979 to 57 years in 2006, said Dr. Jones, who was an ob.gyn. fellow in the division of female pelvic medicine and reconstructive surgery at Magee-Women's Hospital in Pittsburgh at the time of the study. Dr. Jones is currently a urogynecologist at Baystate Medical Center in Springfield, Mass.

Dr. Jones and her associates also looked at age-adjusted surgery rates based on 1990 U.S. census data. The overall rates of prolapse surgery decreased from 2.93/1,000 women in 1979 to 1.56 in 2006. Among younger women, the rate decreased from 3.03 in 1979 to 0.84 in 2006. Among women 52 and older, the rates actually increased slightly, from 2.73 in 1979 to 2.86 in 2006.

The investigators proposed that a dramatic decrease in overall hysterectomies performed for benign indications among women younger than 52 is directly related to the significant decrease in inpatient prolapse procedures in this population.

The overall age-adjusted rates of hysterectomy for benign indications declined from 7.24/1,000 women in 1979 to 4.50 in 2006, most dramatically in women under age 52 (from 9.4/1,000 women to 5.1), Dr. Jones said. In contrast, no significant change was observed for hysterectomies in women aged 52 years and older (from 3.1 in 1979 to 3.3 in 2006).

A total of 29% of the women had surgical complications, most often uterine or vaginal inflammation and anemia. ■

Follow-Up Prolapse Study Finds Mesh Not Superior to Fascia

HOLLYWOOD, FLA. — Follow-up data from a study of prolapse repair, which originally found a significant advantage of synthetic mesh over cadaver fascia at 1 year, revealed no significant difference at 5 years based on a new definition of surgical success that included patient-reported symptoms.

"Although fascia did not seem to work as well as mesh using the original definition, the difference did not reach statistical significance with a new definition using a combination of subjective and objective measures of prolapse," Dr. Susan B. Tate said at the annual meeting of the American Urogynecologic Society.

In the initial study, researchers randomized 100 women with pelvic organ prolapse to receive either mesh or cadaver fascia for abdominal sacral colpopexy (Obstet. Gynecol. 2005; 106:29-37). Among the 89 patients assessed at 1-year follow-up, the success rate was significantly higher with mesh (91%) than with fascia (68%), based solely on anatomic changes as assessed using the pelvic organ prolapse quantification (POP-Q) examination.

Dr. Tate and her colleagues attempted to contact all 100 patients for the follow-up study. She presented 5-year findings for 29 women who received mesh repair and 29 who received fascia repair, all of whom underwent assessment of anatomic changes and completed a questionnaire about subjective outcomes. For example, patients were asked about symptoms using questions such as "I feel as though there is a ball between my legs or that I am sitting on a ball," said Dr. Tate, of the department of obstetrics, gynecology, and women's health, University of Louisville (Ky.).

At 5 years, 100% of the mesh patients and 83% of the fascia patients had achieved success based on a combination of anatomic assessment and patient-reported symptoms. Although all of the failures were in the fascia group, "there was only a trend toward a significant difference," Dr. Tate said.

During the 5 years, there was one mesh erosion and one fascia erosion. Both were removed without complications, Dr. Tate said.

Dr. Tate noted that the new findings can be viewed in the context of a 2007 American College of Obstetricians and Gynecologists Practice Bulletin that cautions against use of cadaver fascia because of a higher risk of relapse, compared with synthetic mesh (Obstet. Gynecol. 2007;110:717-29).

Strengths of the study include its randomized design and long-term follow-up, Dr. Tate said. A lack of validated questionnaire use at the time of the original study and attrition are potential weaknesses, she added. ■

Disclosures: *Dr. Tate, who is a consultant and paid instructor for C.R. Bard, had no relevant disclosures.*