ACOG-AUGS Says Limit Use of Mesh for Prolapse

BY ELIZABETH MECHCATIE

FROM OBSTETRICS & GYNECOLOGY

Debilitating pain, abscess formation, and other serious complications associated with the use of vaginal synthetic mesh for pelvic organ prolapse surgery have been addressed in a joint statement issued by the American College of Obstetricians and Gynecologists and the American Urogynecologic Society that recommends the development of a national patient registry for "all current and future vaginal mesh implants."

Other recommendations in the statement include reserving the use of vaginal mesh in the surgical repair of pelvic organ prolapse (POP) to women at high risk "in whom the benefit of mesh placement may justify the risk." These women include those with recurrent prolapse – particularly of the anterior compartment – and those with medical comorbidities that "preclude more invasive and lengthier open and endoscopic procedures," according to the statement which appears in the December issue of Obstetrics & Gynecology (Obstet. Gynecol. 2011;118:1459-64). The statement is an opinion of the Committee on Gynecologic Practice (Committee opinion #513).

Based on the currently available but limited data, a "small but significant" group of women who undergo mesh-augmented vaginal repair of pelvic organ prolapse experience "permanent and life-altering sequelae, including pain and dyspareunia, from the use of vaginal mesh," according to the statement. The estimated complication rates range from less than 1%-15%, but could be higher.

Some women with complications need additional surgery to attempt to correct the problem, but "unfortunately, some women will continue to have pain even after corrective surgery because complete removal of the mesh may not be possible," Dr. Cheryl B. Iglesia, the former chair of the committee, said in a written statement issued by ACOG.

"For this reason, it's important to understand that, in many cases, POP can be successfully treated without mesh, and women and their doctors really need to weigh the risks and benefits before deciding on a course of action," added Dr. Iglesia, director of Female Pelvic Medicine and Reconstructive Surgery at Washington (D.C.) Hospital Center.

In an interview, Dr. Iglesia said that other patients for whom the benefits of using mesh may justify the risks include those with recurrences after a traditional vaginal repair using native tissue without mesh, those with more advanced stages of prolapse who have comorbidities and are not good candidates for an abdominal procedure and anesthesia, and a woman with a collagen vascular disorder.

'Women and their doctors really need to weigh the risks and benefits before deciding on a course of action.'

DR. IGLESIA

The ACOG-AUGS recommendations reflect some of those made by the Food and Drug Administration in a July 2011 safety communication updating the complications associated with transvaginal placement of surgical mesh for POP, which was an update of a 2008 Public Health Notification about these complications ("FDA Warns of Risks With Transvaginal Mesh" August 2011, p. 1). The first surgical mesh product intended for the repair of POP was cleared by the FDA in 2001, based on the agency's review that concluded the product was "substantially equivalent" to surgical mesh used for hernia repairs, without any clinical data. Surgical mesh products are currently regulated by the FDA as a class II device, which requires the manufacturers to show that the product is substantially equivalent to a similar product already on the market. Clinical trials are required for clearance of devices that are regulated as class III devices, and the ACOG-AUGS statement notes that the FDA is considering whether to reclassify mesh products intended for vaginal repair of POP to a class III device. In that case, clinical trials would be required before a product would become available.

The joint statement also recommends that complications and total reoperation rates for recurrence of complications should be reported as outcomes for prolapse surgical techniques, and surgeons should undergo training for each specific surgical mesh product before using it in surgery. In addition, new mesh products "should not be assumed to have equal or improved safety and efficacy unless clinical long-term data are available," and patients "should provide their informed consent after reviewing the risks and benefits of the procedure, as well as discussing alternative repairs."

The statement also says that ACOG and AUGS support the development of a registry "to provide surveillance of all currently available and future vaginal mesh implant products," and describes "rigorous" clinical trials that compare the effectiveness of synthetic mesh and native tissue repair, with long-term follow-up of patients as "ideal."

Most of the outcomes data for vaginal placement of synthetic mesh for POP are case series and prospective cohort studies, and smaller studies "document good short-term success in the hands of individual surgeons, but longer follow-up procedures performed by surgeons from multiple centers is lacking," the statement points out.

Dr. Iglesia noted that a tracking mechanism for the individual products is important because there have "clearly" been some devices with higher complication rates than others. Formal physician training specific to each individual mesh product, and determining how many cases need to be performed to gain and maintain competence is also important to ensure that these devices are used safely, she said.

Dr. Iglesia, associate professor of obstetrics, gynecology, and urology at Georgetown University, Washington, said that while physicians do not need to treat patients who have had vaginal mesh implanted for POP and are asymptomatic, these patients should be monitored for potential complications. Many patients have contacted their physicians in a panic, after hearing about the reports of complications, she said, "but the vast majority of patients are fine, although they do need to be seen by their physician if they develop symptoms," such as bleeding, pain or discharge, or if their partner feels something during intercourse.

The use of vaginal mesh for POP has increased since 2004; only about 20% of the estimated 100 synthetic mesh devices or mesh kits that have been cleared for use for POP surgery are being actively marketed, according to the statement.

The statement does not address the use of synthetic mesh used for abdominal or minimally invasive sacrocolpopexy or for midurethral slings to treat stress urinary incontinence.

All ACOG committee members are required to follow the college's guidelines for relationships with the health care industry, according to the ACOG website. Dr. Iglesia said she had no disclosures. ■

The 2011 FDA advisory is available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm. Adverse events associated with surgical mesh and other medical devices should be reported to the FDA at www.fda.gov/MedicalDevices/Safety/ReportaProblem/FormsandInstructions/default.htm.

Study Supports Hysteroscopy to Diagnose Endometrial Ca

BY DAMIAN McNAMARA

FROM THE AAGL ANNUAL MEETING

HOLLYWOOD, FLA. – Researchers report a good correlation between hysteroscopy and histopathology in the diagnosis of endometrial cancer among women with postmenopausal bleeding.

An estimated 10%-15% of patients with postmenopausal bleeding have endometrial cancer. "In Brazil, this is the eighth most frequent tumor [type]," said Dr. Raquel P. Dibi, a gynecologist at Complexo Hospitalar Santa Casa de Porto Alegre, a teaching hospital in Porto Alegre, Rio Grande do Sul, Brazil.

Dr. Dibi and her associates compared hysteroscopy and biopsy histopathology findings for 507 patients with postmenopausal bleeding. Hysteroscopy identified 41 (8%) cases suggestive of endometrial cancer, and histology confirmed 30 of these (73%). Hysteroscopy for the diagnosis of endometrial cancer was associated with 94% sensitivity, 98% specificity, a 73% positive predictive value, and a 99.6% negative predictive value.

VITALS

Major Finding: Hysteroscopy for the diagnosis of endometrial cancer was associated with 94% sensitivity, 98% specificity, a 73% positive predictive value, and a 99.6% negative predictive value.

Data Source: Comparison of hysteroscopy and histopathology findings for 507 women with postmenopausal bleeding.

Disclosures: Dr. Dibi said she had no relevant financial disclosures.

"A good correlation was observed between hysteroscopy and histological findings," Dr. Dibi said at the meeting.

With hysteroscopy, the most common findings were endometrial polyps (40%) and atrophic endometrium (34%). With histopathology, almost half of reports came back designated "absent material" (47%); the most common findings also were endometrial polyps (17%) and atrophic endometrium (5%).

"Hysteroscopy has demonstrated efficacy for diagnosis of endometrial cancer, agreeing with studies published by other authors," Dr. Dibi said.

Patients ranged in age from 43 to 85 years. The mean age at time of menopause was 48 years. The median time since menopause was 9 years in this study. ■