Little Data on CHD Risk In Bilateral Oophorectomy

ARTICLES BY DOUG BRUNK

LAS VEGAS — A systematic review of the medical literature yielded mixed results concerning the effects of bilateral oophorectomy on the risk of coronary heart disease.

"There's been a concern that bilateral oophorectomy may increase the risk of coronary heart disease because estrogen deprivation might accelerate the rate of atherosclerosis," Dr. Vanessa Jacoby said at the annual meeting of the AAGL.

Dr. Jacoby and her associates sought to identify all of the available related literature on PubMed and Embase between 1966 and 2007, all related abstracts that were presented at the annual clinical meeting of the American College of Obstetricians and Gynecologists between 1996 and 2006, and reference lists from the retrieved articles. Studies were included if they compared women who had bilateral oophorectomy with a hysterectomy to women who had a hysterectomy and ovarian conservation, naturally menopausal women, premenopausal women, or premenopausal women with no history of hysterectomy or bilateral oophorectomy but unreported or unknown menopausal status. The primary outcome was fatal or nonfatal coronary heart disease.

Nearly 2,000 abstracts were reviewed, said Dr. Jacoby of the department of obstetrics, gynecology, and reproductive sciences at the University of California, San Francisco. From these, 16 observational studies were reviewed in full and 7 were used in the final analysis. No randomized trials were located.

Two studies involving women with a hysterectomy and ovarian conservation showed no significant increased risk of coronary heart disease following bilateral oophorectomy.

One of three studies involving naturally menopausal women did show a slight increased risk of CHD, with a hazard ratio of 1.16 (Circulation 2005;111:1462-70). "But in a subsequent analysis that accounted for the effect of all demographic and cardiovascular risk factors like hypertension, diabetes, and smoking, there was no statistically significant increased risk of coronary heart disease," Dr. Jacoby said.

One of two studies involving premenopausal women, the Nurse's Health Study, reported an increased risk of CHD, with a relative risk of 2.2 (N. Engl. J. Med. 1987;316:1105-10). "That was only in women who never took estrogen following bilateral oophorectomy, and only in an analysis that accounted for age and smoking," she said. "But in a subsequent analysis that accounted for other cardiovascular risk factors such as obesity, hypertension, and diabetes, there was no increased risk."

The other study involving premenopausal women found a significantly increased risk of CHD in women aged 40-44 years who had undergone hysterectomy and bilateral oophorectomy, but not in women aged 45 years and older (Ann. Intern. Med. 1978;89:157-61). One of two studies involving women with no history of hysterectomy or bilateral oophorectomy but unreported or unknown menopausal status showed a significantly increased risk of CHD, but only in women younger than age 60 years (Acta. Obstet. Gynecol. Scand. 1981;106 [Suppl.]:11-5).

A limitation of the analysis, she said, is that the observational studies used "are inherently limited by the potential effect of confounding on the outcome. To that end, our goal is to implement a randomized trial of bilateral oophorectomy so we can have the highest-quality evidence to guide our clinical practice for this very common clinical question." ■

Patient Compliance With HSG After Essure Is High

LAS VEGAS — Patient compliance with the recommendation for a hysterosalpingogram after Essure hysteroscopic sterilization can be high in the private practice setting, according to Dr. Larry R. Glazerman, who tracked compliance in a chart review of his practice.

"Since the introduction of Essure in 2003, physician uptake has been substantially less than expected, despite the obvious advantages in terms of no incisions, no general anesthesia, and no hospital stay," Dr. Glazerman said at the annual meeting of the AAGL. "One of the expressed concerns is that the [Food and Drug Administration] requires a 3-month confirmatory hysterosalpingogram [HSG] after the procedure, before the patient is allowed to rely on the device for contraception. In my personal discussions with physicians, I hear all the time that 'my patients don't want to come back for the HSG. They'd rather know right away that they are sterile.' "

Concern about noncompliance with HSG should not deter physicians from offering the Essure procedure.

DR. GLAZERMAN

Dr. Glazerman disclosed that he is a preceptor, speaker, and consultant for Conceptus Inc., which developed the Essure procedure. He is also a preceptor for Karl Storz Endoscopy–America Inc.

To determine the rate of compliance with the FDA recommendation for the hysterosalpingogram, Dr. Glazerman studied the medical charts of 130 consecutive patients who underwent Essure hysteroscopic sterilization in his former private ob.gyn. practice in Allentown, Pa., from December 2003 through May 2008.

Of those patients, 128 were at least 3 months post procedure and 2 were not, said Dr. Glazerman, who is now director of minimally invasive surgery in the department of obstetrics and gynecology at the University of South Florida, Tampa. Of the 128 patients, 116 (91%) underwent hysterosalpingography, and 100 (86%) of those 116 showed bilateral tubal occlusion on their first hysterosalpingogram. Of the 16 patients who failed their initial HSG, 13 had documented tubal occlusion on their second HSG; 2 had a previous unilateral salpingectomy; and 1 had unilateral placement, and subsequently conceived.

Based on the findings, Dr. Glazerman concluded that concern about noncompliance with HSG "should not deter physicians from offering hysteroscopic sterilization. The way I present the Essure procedure to patients is like this: 'If they have a laparoscopic tubal failure (a rate of 0.5%-1%), the only way they know if it fails is if they get pregnant. On the other hand, if they have a hysterosalpingogram after the Essure that shows bilateral occlusion, there's a pregnancy rate of less than 1 in 200,000 cases. My patients seem to like that. In addition, they like the fact that there's no hospital stay, no incision, and no general anesthesia." ■

Paracervical Block Has Little Effect on Essure Placement

LAS VEGAS — Paracervical block decreases the pain associated with cervical manipulation, but has little effect on the pain associated with hysteroscopic placement of the Essure device for sterilization or on the technical success of the placement, a single-center randomized trial showed.

"The management of the pain should be individualized between the patient and the physician, and attention to technique and patient reassurance are key to successful in-office placement of Essure devices," Dr. Scott Chudnoff said at the annual meeting of the AAGL.

Although several researchers have performed assessments of pain during hysteroscopy, as well as during the Essure procedure, "most of these studies have significant methodological flaws, or they focused on diagnostic hysteroscopy," noted Dr. Chudnoff of the department of obstetrics and gynecology and women's health at Albert Einstein College of Medicine, New York. "None focusing on Essure were randomized, placebo-controlled studies."

To determine if paracervical block at the time of hysteroscopic placement of the Essure device provides clinical pain relief, he and his associates randomized 40 women to receive 10 cc of 1% lidocaine, and another 40 to receive 10 cc of normal saline, as a paracervical injection prior to the start of the procedure. The 10-cc dose of lidocaine "is the amount we used in a pilot study and is the recommended dose to be used based on the clinical indications for lidocaine in a paracervical block," Dr. Chudnoff said in a later interview.

Patients were asked to complete the 8-point Visual Analog Scale to assess pain during ketorolac (Toradol) injection and at the conclusion of the placement of the Essure device.

Patients also used the VAS to report the average level and the highest level of pain during the procedure.

Dr. Chudnoff reported that there were three unsuccessful placements in each group.

The average pain score for hysteroscope placement into the cervix was 4.5 in the saline group, compared with 2.6 in the lidocaine group, a difference that was statistically significant. Similar findings were noted for transversing the external orifice of the cervix uteri (3.8 for the saline group vs. 1.5 for the lidocaine group) and for transversing the internal orifice of the cervix uteri (4.1 vs. 1.8).

However, there were no significant differences between the saline group and the lidocaine group in the average pain scores for placement of the Essure device (3.7 vs. 3.2).

For the procedures, which were performed between March 2007 and March 2008, all patients also received 60 mg IM ketorolac in the buttocks before the procedure to reduce tubal spasm. The researchers placed the speculum into the vagina, prepped the area, injected 1 cc of lidocaine into the anterior lip of the cervix, and placed a single-tooth tenaculum on the anterior lip.

Patients received 5 cc of 1% lidocaine or saline injected at the 4 o'clock location on the cervix and 5 cc of 1% lidocaine or saline injected at the 7 o'clock location. The researchers allowed for a 3- to 5-minute rest period to permit the block to set before the introduction of the hysteroscope and subsequent placement of the Essure device.

All subjects and investigators were blinded to the treatment groups, and no errors in randomization occurred. The average age of the patients was 35 years, and 62% were Hispanic.

Dr. Chudnoff disclosed that one of his associates, Dr. Mark Levie, serves on the medical advisory board and is on the speakers bureau for Conceptus Inc., which developed the Essure procedure. ■