



ASCO and ACOG Update: Breast Cancer Screening and Prevention

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ASCO and ACOG Update: Breast Cancer Screening and Prevention

by Walter Alexander

The 35th Annual Meeting of the American Society of Clinical Oncology and the American College of Obstetrics and Gynecology's 47th Annual Clinical Meeting included many presentations focusing on breast cancer screening as well as prevention. Highlights from these presentations, as well as a discussion of malpractice cases arising out of missed or delayed diagnoses, are presented here.

MAMMOGRAPHY AND WOMEN AT 40

"I believe very strongly in the 'minority report' position that a 17 percent reduction in breast cancer mortality in younger women should not be considered trivial," stated David H. Moore, M.D., associate professor of obstetric/gynecology and chief of gynecologic oncology at Indiana University School of Medicine, Indianapolis, Ind. Moore strongly opposes the NIH consensus panel's recommendation against universal mammography for women in their forties.

Speaking at ACOG, Moore pointed out that familial breast cancer has an earlier age of onset, with detection most common among women in their late forties—ten to fifteen years earlier than in the general population. "That is significant when you sit down and start thinking about screening programs," Moore commented.

Moore acknowledged the downside of mammography, which includes an 8-12 percent

false positive rate. In addition, one-quarter of all breast cancers are missed by mammograms. However, he maintained, the additional procedures and anxiety provoked by screening are justified by the end result of earlier detection leading to reduced mortality and morbidity with less need for radical mastectomy.

Moore pointed out further that the incidence of breast cancer doubles between the ages of 40 to 44 and 45 to 49; at the same time mammography finds earlier and slower growing cancers with generally better prognoses. Optimal frequency of mammographic screening for women in their forties has not been determined, Moore noted, adding: "I offer mammograms on an every-other-year basis to all women in their forties. For those with a strong family history of breast or ovarian cancer, I suggest annual exams."

MALPRACTICE FOR DELAYED DIAGNOSIS

"Misdiagnosed breast cancer accounts for the greatest number of on-going malpractice claims, the largest number of paid claims, and the greatest overall litigation expense," stated Kenneth A. Kern, M.D., of the University of Connecticut School of Medicine and Dartmouth Medical School.

Often the suit involves diagnostic delay. When it does, three-fourths of patients fulfill three criteria: age less than 45, a false-negative mammogram, and a self-discovered breast mass, Kern said at an ACOG satellite symposium.

Physicians frequently lose these often costly misdiagnosis suits, because after the patient's discovery of her own breast mass, the

physician uses no diagnostic methods beyond mammography. In three-fourths of cases, physicians found a palpable mass, but in half the cases the mammogram was negative.

How does it happen? According to Kern: "Physicians are lulled into the misdiagnosis of breast cancer by the young age of patients and false-negative readings of mammography, not by vague findings or difficult diagnostic situations." Kern advised liberal use of fine-needle aspiration, and core and open-surgical biopsy when a palpable mass exists to help avoid diagnostic delays and lawsuits.

Kern also said that patients are increasingly asking their physicians, "At what level of risk do I need tamoxifen?" Kern recommended use of widely available breast cancer risk calculators to help answer that question. Kern drew his data from several studies including the Physician Insurers Association of America Data Sharing Reports and the National Cancer Institute's Surveillance, Epidemiology, and End-Results Reporting Program (SEER).

ONE YEAR AFTER BCPT: ASSESSING RISKS

Agents such as tamoxifen have great potential for reducing the risk of breast cancer in women at increased risk, stated Lori Goldstein, M.D., of the Fox Chase Cancer Center in Philadelphia, Pa. Goldstein moderated the *Breast Cancer Risk Reduction: One Year Later* press conference, which presented an ASCO Technology Assessment Working Group report evaluating all available data

continued on page 27

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continued from page 13

on tamoxifen and raloxifene one year after the Breast Cancer Prevention Trial (BCPT) P-1 trial results showed breast cancer risk reduction for tamoxifen.

The working group's chairperson, Rowan T. Chlebowski, M.D., noted that 175,000 new cases of breast cancer are reported each year in the United States with more than 40,000 deaths. He stated that the current evidence supports offering tamoxifen to women with risk comparable to those women in the BCPT trial, who had at least a 1.67 percent five-year risk. "We felt there was insufficient evidence to determine the effect of tamoxifen on breast cancer-associated survival or overall survival, and also insufficient evidence to determine the effects of tamoxifen on general health, broadly defined," Chlebowski added. He noted that despite tamoxifen's favorable effects on lipids, evidence for favorable effects on cardiac events is insufficient.

Moving to raloxifene, for which much less information is available, Chlebowski said, "We felt there was currently insufficient evidence to support its use at the present time in a general clinical setting for breast cancer risk reduction. We also felt that there wasn't any indication for substitution of this agent for tamoxifen in any kind of breast cancer therapy setting."

TAMOXIFEN: RISK AND BENEFIT

Risk for the subsequent development of invasive breast cancer is substantially elevated among women with prior history of either lobular carcinoma in-situ (LCIS) or atypical hyperplasia. Among the 13,388 women in the BCPT trial, more than 6 percent

had prior history of LCIS and about 9 percent had atypical hyperplasia, for a total of about 1,900 women, according to D. Lawrence Wickerham, M.D., associate chairperson with the National Surgical Adjuvant Breast Cancer Project (NSABP) Foundation, Inc.

Relative breast cancer risk for women with prior history of LCIS treated by excision alone compared with women of the same age and race without additional risk factors is reported in the literature as increasing fifteen-fold, Wickerham stated at an ASCO presentation. Atypical hyperplasia confers a 1.9 relative risk.

Last year's analysis of results from the overall BCPT population had shown the five-year cumulative breast cancer incidence rate of 4.3 percent for the placebo group to be reduced by 49 percent in the tamoxifen group to 2.2 percent. Wickerham reported that in the current analysis, for women with LCIS histories, the five-year cumulative incidence was 6.8 percent in the placebo group and 2.5 percent in the tamoxifen group. "That [the tamoxifen rate] is actually very similar to the rate for women receiving tamoxifen in the overall population and represents a 56 percent reduction," Wickerham said. The incidence curves began to separate in the first year of the trial and continued well into the sixth year.

The breast cancer rate for women with histories of atypical hyperplasia was reduced from 10.1 per thousand per year in the placebo group to 1.43 per thousand per year, an 88 percent reduction.

COST-EFFECTIVENESS ANALYSIS

As a prevention strategy for breast cancer, tamoxifen is cost-effective,

especially in women aged 35-49 years, and those of all ages with a previous hysterectomy, according to Les L. Noe, R.Ph., M.P.A., Ovation Research Group, Highland Park, Ill.

Noe derived a "cost of life-year saved" for tamoxifen therapy and compared it with other therapies already accepted as cost-effective. The cost was derived through economic modeling taking into account savings from disease avoided and additional costs associated with administration of therapy plus potential side effects including endometrial cancer, Noe reported in an ASCO presentation.

Under the most conservative assumptions from base-case analysis, the incremental cost-effectiveness of tamoxifen was \$41,372 per life-year gained for women aged 35 to 49 years, and \$68,349 and \$74,981, respectively for women aged 50 to 59 years and 60 to 69 years. Cost-effectiveness was as low as \$10,196 per life-year gained under what Noe termed "more reasonable scenarios" where tamoxifen's effects persist beyond five years and health benefits are not discounted. In women with a previous hysterectomy receiving tamoxifen, regardless of age, cost-effectiveness was \$46,060 per life-year gained.

Tamoxifen's cost was within range of other therapies commonly accepted as cost-effective. For example, the cost per life-year gained of zidovadine treatment for HIV is about \$85,000, about \$80,000 for the ACE inhibitor captopril in hypertension, and about \$230,000 for screening mammography. Cholesterol-lowering with lovastatin costs between about \$105,000 and \$210,000 per

continued on page 28

continued from page 27

life-year saved depending on the dose taken and the recipient's age. Coronary artery bypass surgery costs just over \$10,000 per life-year saved.

EXPANDING THE PRIMARY CARE ROLE

Managed care payers will naturally turn to primary care physicians (PCPs) and OB/GYNs for the cost benefit of supervising years-long tamoxifen therapy and other breast cancer treatments requiring periodic monitoring. Beyond that, according to James Hall, M.D., clinical associate professor at Indiana University School of Medicine, Indianapolis, the PCP/OB-GYN role in breast cancer screening will expand if physicians use a triad of diagnostic procedures: physical examination, mammography and fine-needle aspiration. Speaking at an ACOG presentation, Hall said that physicians will "reach the correct diagnosis in almost every case."

Fine-needle aspirations refine diagnostic accuracy, emphasized Hall, a surgeon. He suggested that surgeons likely to benefit from increased referrals will offer to supervise cases with those needing training. The advantage of in-office aspiration is quick diagnosis and resolution of some benign cysts. "The results are immediate, and patients are extremely grateful," Hall said.

Hall speculated that because OB-GYNs perform such large numbers of examinations, adopting this triad of office diagnostic procedures may become the informal standard of care in some regions. Certainly, he concluded, OB-GYNs will become increasingly involved in long-term treatment of breast cancer. Hall also urged wider use of mammography. "If someone 80 years old has a good quality of life, I see no reason not to screen her," Hall said. "There isn't an age when women don't benefit from mammograms." ■

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