ACS EXPERT DISPUTES METHODOLOGY OF STUDY QUESTIONING MAMMOGRAPHY BENEFIT

A study published in the Journal of the National Cancer Institute (2005;97:1035–1043) suggests breast cancer screening might not be as effective in community practice as it is in randomized controlled trials. The case-control study led by researchers at the University of Washington School of Medicine did not find a statistically significant survival benefit from mammography in a study of women enrolled in six health plans in five states.

Joanne Elmore, MD, MPH, and colleagues studied 1,351 women who died of breast cancer and 2,501 similar control women without breast cancer. The women with cancer had been diagnosed between 1983 and 1993, and died between 1983 and 1998. The researchers looked at the screening history of each woman with cancer in the 3 years before her diagnosis and at the screening history of her matched control(s) for the same 3 years.

Screening patterns were similar between the two groups.

“Overall, our findings suggest that breast cancer screening in the community was minimally effective in preventing death from breast cancer,” they wrote.

But an American Cancer Society (ACS) expert says the study methodology is not strong enough to call into question decades of previous research that has shown mammography can reduce breast cancer mortality.

“[The] ACS and other organizations, such as the US Preventive Services Task Force, recommend regular screening because well-designed studies conducted in many different settings over the past 30 years, using a range of methodologies, have shown that it can reduce breast cancer deaths by finding tumors when they’re at an early stage and still highly treatable,” said Robert Smith, PhD, Director of Cancer Screening for the ACS.

“It’s important to not let the occasional study that differs from the long-term trend in the scientific evidence question the value of medical advice that is endorsed by leading, evidence-based guidelines,” he added.

ACS screening guidelines call for women at average risk of breast cancer to begin screening with yearly mammography at age 40; women at high risk of the disease may choose to begin screening even earlier.
Although it is important to learn whether screening works as well in the real-world setting as it does in a clinical trial, Smith finds numerous problems with the way this particular study tried to look at that question.

Some of the choices the researchers made in designing the study may have introduced a bias against screening, he said. Case-control studies also have the potential to bias results in favor of screening, he noted, making them a challenging design for investigating the effectiveness of screening.

“There have been a number of studies with a stronger design that have shown that modern mammography not only achieves the benefits observed in the [earlier] trials, but exceeds those benefits,” he said.

That research comes from Sweden, the Netherlands, and other countries that have government-run screening programs that invite all women of the right age to get their regular mammogram. These studies include much larger numbers of women than Elmore’s study and were able to collect much more detailed information about who did or did not get screened. They also followed women for a longer period of time, and their design was less likely to bias their results, Smith said.

In the largest of these studies, breast cancer deaths dropped by about 40% in the women who got screened. Women who did not get screened saw only a 16% drop in breast cancer deaths, presumably due to improvements in awareness and treatment over the period of the study.

Elmore, who is a Professor in the Division of General Internal Medicine, cited several potential reasons for her negative findings. For one thing, about one-third of the women in the study had only a clinical breast exam to screen for breast cancer. However, clinical exams cannot find very small tumors the way a mammogram can and are not as effective a screening method. The quality of clinical breast examination is highly variable and was especially so during the 1980s. Only about one-quarter of the women in the study group, all of whom died from breast cancer, were diagnosed with small tumors (less than 2 cm).

Another possible explanation suggested by Elmore: treatments have gotten better over the years, so survival may have improved regardless of women’s screening practices. Likewise, women are more aware of breast cancer these days, and they are more likely to consult a doctor promptly if they notice something amiss.

And, Elmore said, there’s also a chance that screening in the community really doesn’t measure up to screening done in a clinical trial. “Research trials are often done in academic centers [that have a lot of experience], and the people doing them are experts,” she explained. “There is a lot of variability in clinical practice.”

Smith also points to the low rate of mammography in both groups but does not agree with Elmore’s explanations for the weak findings in her study. “The biggest problem with this study was the study design, which has been shown in other simulations to have a significant bias against seeing a screening benefit,” he said.

In addition, the screening taking place over this period is a poor substitute for a program of modern mammography with high rates of attendance. “The study covers a very long period of time,” Smith explained. “This was a period of considerable change during which mammography use increased (after the mid-1980s) and quality steadily improved (in the 1990s). Mortality began to decline in 1989 to 1990, following a period of rapidly increasing participation in screening.”

Advances in treatment and improvements in awareness will confer a small additional advantage over time, but little compared with the value of detecting a breast cancer early in its natural history, Smith noted.

Whatever the causes, the negative results do not give women license to skip their regular mammograms, both Smith and Elmore said.

“It’s important that women get screened regularly,” Smith said, “because a mammogram can help find a tumor early, it may spare
women from more extensive debilitating treatments, and it could save her life.”

“I want women to continue with current screening as recommended,” said Elmore. “I think they also need to realize that screening is not perfect or foolproof. Women need to pay attention to their bodies and seek medical attention if they notice an abnormality that worries them.”

Smith and Elmore also agree that it is important to find ways to improve the quality of mammography and breast cancer screening in the United States.

“I hope the results of our study will serve as an impetus to investigators and funding agencies,” Elmore said. “We can’t become complacent about screening.”

PHYSICIAN INVOLVEMENT BOOSTS HOSPICE REFERRAL

Nursing home patients are more likely to enroll in hospice care at the end of life if their health care team is involved in the decision to refer them to a program. That was the conclusion of a study published recently in JAMA (2005;294:211–217) that examined an intervention designed to pull physicians into the process sooner.

“Hospice is the gold standard for end of life care,” said David Casarett, MD, MA, lead author of the new study. “For most patients and families in most settings, the single best way to get access to a highly-trained interdisciplinary team is through hospice.”

Hospice services are covered by Medicare for people 65 and older. Yet many patients who could benefit from hospice services never enroll, or only do so within a few weeks—or even a few days—of their death.

“If we could take care of people for longer, we could do more good,” said Casarett, who is director of the Palliative Care Consult Service at the Philadelphia Veterans Affairs (VA) Medical Center.

Casarett has done previous studies of hospice, looking at factors that lead people to enroll. A common theme emerging in the earlier work, he said, is that “patients and families often wait for physicians to begin the hospice discussion—and they wait and they wait and they wait.”

Doctors may be reluctant to bring up the topic of hospice because they are not certain how the patient or family might respond, Casarett said.

“Enough of us as physicians have had that experience where you come into a room and say, ‘Things are looking bad, maybe it’s time to think about hospice,’ and you’re met with a distraught patient or family member who thinks you’re abandoning them,” he said. “All it takes is one bad conversation like that to make a physician gun shy.”

With this latest work, he and his colleagues hoped to find a way to “jumpstart” this potentially difficult conversation.

The study included residents of three nursing homes, including the VA facility where Casarett works, who were randomized into two groups. Trained interviewers spoke with the residents (or the person responsible for making decisions about their care) to identify hospice-appropriate patients. The control group received usual care. Hospice-appropriate patients were given a brief description of hospice services and told they could learn more by speaking with their physician.

But the researchers asked members of the intervention group for permission to contact their doctor directly about enrolling in hospice. Those doctors then got a fax from the researchers letting them know they had a patient who was a good candidate for hospice care and asking them to authorize a consultation.

Of 35 patients in the intervention group who were candidates for hospice, 21 enrolled in a program within 30 days, and six additional patients had enrolled by the 6-month mark. Of 49 hospice-eligible patients in the control group, just one enrolled in a program in the first 30 days, and five additional patients had enrolled by the 6-month mark.

People in the intervention group also spent much more time in hospice (mean 64 days) than people in the control group (mean 14