

# Study: 1.3 Million Overdiagnosed Breast Cancers in 30 Years

Nick Mulcahy

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In the past 30 years, an estimated 1.3 million American women had breast cancers that were "overdiagnosed," which means their screening-detected tumors would never have led to clinical symptoms, according to a [study published](#) in the November 22 issue of the *New England Journal of Medicine*.

In 2008 alone, breast cancer was overdiagnosed in an estimated 70,000-plus women, which was 31% of all breast cancers diagnosed that year, assert the study authors, Archie Bleyer, MD, from the Oregon Health and Science University in Portland, and H. Gilbert Welch, MD, MPH, from the Geisel School of Medicine at Dartmouth College in Hanover, New Hampshire.

Overall, about one third of all breast cancers detected in the United States are overdiagnosed, they say.

The authors point out that the advent of widespread mammography screening in the United States led to a "substantial increase" in early-stage breast cancer, but only "marginally reduced" the rate of advanced cancers detected. "The imbalance suggests that there is substantial overdiagnosis."

However, breast screening expert Daniel B. Kopans, MD, from Harvard Medical School in Boston, Massachusetts, believes the study is "outrageous" and "should have never passed peer review."

## **Mammography does not cause 'overdiagnosis'.**

"The paper...is another in a long line of scientifically unsupportable attacks on mammography," he told *Medscape Medical News*.

Dr. Kopans questioned the authors' methodology in his critique of the study. He also dismissed one of its central findings and ideas. "Mammography does not cause 'overdiagnosis'," said Dr. Kopans. "Unfortunately, pathologists are not yet able to distinguish cancers that will be lethal if left untreated from those that do not need treatment."

## **First Prerequisite Not Met**

In their study, Drs. Bleyer and Welch state that "effective" cancer screening programs must increase the incidence of early cancers detected and decrease the incidence of late cancers detected. But mammography screening has not done the latter substantially, they say.

They used Surveillance, Epidemiology, and End Results (SEER) data to examine trends in the incidence of early-stage breast cancer (ductal carcinoma in situ [DCIS] and localized disease) and late-stage breast cancer (regional and distant disease) in women 40 years and older from 1976 to 2008.

They found that the introduction of screening doubled the number of early breast cancers detected annually.

Specifically, the incidence jumped from 112 to 234 cases per 100,000 women — an absolute increase of 122 cases per 100,000 women over the study period.

At the same time, the rate at which women present with late-stage cancer decreased by only a small amount (8%), from 102 to 94 cases per 100,000 women — an absolute decrease of 8 cases per 100,000 women.

However, only 8 of the 122 additional early-stage cancers diagnosed were expected to progress to advanced disease, say Drs. Bleyer and Welch, leaving a large imbalance between detected early-stage and late-stage cancers.

The data suggest that "mammography has largely not met the first prerequisite for screening to reduce cancer-specific mortality — a reduction in the number of women who present with late-stage cancer," the authors state.

The findings suggest that "screening is having, at best, only a small effect on the rate of death from breast cancer," they conclude.

### **Our study raises serious questions about the value of screening mammography.**

"Our study raises serious questions about the value of screening mammography," say Drs. Bleyer and Welch. However, they note that their study does not answer a common question that women ask: "Should I be screened for breast cancer?"

Dr. Kopans suggests that the study delivers the message that screening is not worthwhile. And he sees Dr. Welch as part of a "small group of highly vocal individuals who have decided that they wish to end all screening for breast cancer."

"All responsible groups agree that mammography screening saves lives," said Dr. Kopans, referring to guidelines that recommend screening from major groups such as the US Preventive Services Task Force and the American College of Physicians.

### **Assumptions Questioned**

Drs. Bleyer and Welch chose the 3-year period from 1976 to 1978 to obtain their estimate of the baseline incidence of breast cancer detected without mammography. "During this period, the incidence of breast cancer was stable and few cases of DCIS were detected," they write.

For each year after 1978, the authors calculated the absolute change in the incidence of early- and late-stage cancer relative to the baseline incidence. They then summed the data across the 3 decades.

However, they had a challenge for the years 1990 to 2005, during which many women used breast cancer-causing hormone replacement therapy. To remove the excess breast cancer incidence from that period, they "truncated" or lowered the incidence of the various types of breast cancers.

They estimated the current incidence of breast cancer on the basis of the 3-year period from 2006 to 2008. This was deemed a good time period because it is believed that the effect of hormone-replacement therapy ended at 2006.

Drs. Bleyer and Welch calculated 4 different estimates of the excess detection or "overdiagnosis" of breast cancer for the 30-year period. The estimates varied with regard to the "underlying incidence" of breast cancer, which is an estimate of the number of cases that would be found without mammography detection.

They calculated that the underlying incidence of breast cancer was increasing by 0.25% with each passing year. They describe this as a "best-guess" estimate, and used it as the basis for their conclusion that 1.3 million women had overdetecting/overdiagnosed breast cancer. They also had an "extreme-assumption" estimate that assumed a 0.5% annual increase, resulting in an estimated 1.2 million overdiagnosed cases.

Dr. Kopans said that both of these estimates are too low. He explained that there has been an "underlying 1% per year increase in breast cancer incidence...that has been going on since at least 1940."

He also criticized other elements of the calculations. "They also underestimated the effects of lead time and ignored prevalence screening, which adds to incidence every year as new women begin screening. They also combined DCIS with early-invasive lesions in an effort to dilute the results," he noted.

Drs. Bleyer and Welch anticipated most of these criticisms.

"There has been plenty of time for the surplus of diagnoses of early-stage cancer to translate into a reduction in diagnoses of late-stage cancer — thus eliminating concern about lead time," they write.

They acknowledge that their best-guess estimate of the frequency of overdiagnosis — 31% of all breast cancers — did not distinguish between DCIS and invasive breast cancer. However, they say that invasive disease accounted for about half the overdiagnoses in their estimates, and that about 20% of invasive breast cancers were overdiagnosed. "These findings replicate those of other studies," they write.

They state that reliable estimates of overdiagnosis would "ideally" come from long-term follow-up after a randomized trial. One such trial from Sweden with that long-term follow-up supports these new findings, say the authors. "Among the 9 randomized trials of mammography, the lone example of this is the 15-year follow-up after the end of the Malmö Trial, which showed that about a quarter of mammographically detected cancers were overdiagnosed," they write.

### **Treatment Deserves Credit Too**

Over the study period, "the rate of death from breast cancer decreased considerably," they note, citing other research.

They also cite other research to assert that among women 40 years or older, deaths from breast cancer decreased from 71 to 51 deaths per 100,000 women — a 28% decrease.

But screening is not the sole reason for this drop in the death rate, Drs. Bleyer and Welch note.

"This reduction in mortality is probably due to some combination of the effects of screening mammography and better treatment," they write.

The math suggests that early detection from screening is not the biggest reason for the reduction in disease-specific death, they say.

"Because the absolute reduction in deaths (20 deaths per 100,000 women) is larger than the absolute reduction in the number of cases of late-stage cancer (8 cases per 100,000 women), the contribution of early detection to decreasing numbers of deaths must be small," they write, combining incidence data from their study with those from a death rate study.

Better treatment for breast cancer lessens the need for screening, they suggest.

"Ironically, improvements in treatment tend to deteriorate the benefit of screening. As treatment of clinically detected disease (detected by means other than screening) improves, the benefit of screening diminishes. For example, since pneumonia can be treated successfully, no one would suggest that we screen for pneumonia," they argue.

Dr. Kopans also addressed this issue, saying that "early detection is the main reason that the death rate from breast cancer has declined by over 30% since screening became widely available." He noted that "therapy has improved, but therapy saves lives when cancers are found earlier."

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