

Study Questions Computerized Breast Cancer Detection

By GINA KOLATA

A highly promoted and widely used computerized system for examining mammograms is leading to less accuracy, not more, a new study finds.

The system, known as computer-aided detection, or CAD, did not find more breast cancer, researchers are reporting today. But it did lead to many more false alarms that resulted in additional testing and biopsies for spots on mammograms that turned out to be harmless.

Such detection systems, approved by the Food and Drug Administration in 1998, are sold by several companies, including Hologic of Bedford, Mass.; iCAD of Nashua, N.H.; and Kodak. According to the National Cancer Institute, the systems are now being used in about 30 percent of mammography centers.

The equipment is expensive, costing \$50,000 to \$175,000, but Medicare, assuming it would improve the outcome, pays an extra \$20 for each mammogram read with it. That made it profitable for large centers to use it. Doctors also worried about lawsuits if they were not using it and missed a cancer.

Along with all other, as more and more mammography centers bought the software, the assumption was that the computer would find cancers that radiologists would miss, saving women's lives.

The new findings are likely to surprise radiologists, said Dr. Ferris M. Hall, a radiology professor at Harvard Medical School. Dr. Hall wrote an editorial accompanying the paper, which was published today in *The New England Journal of Medicine*.

"I was surprised," he said. "A lot of people will be amazed."

But executives at the company whose equipment was used in the study, Hologic, said they interpreted the results differently.

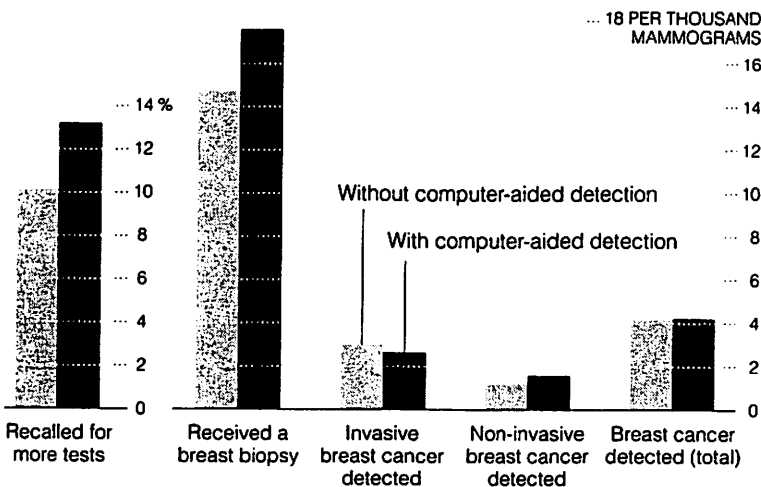
If there is a suspicious spot on a mammogram, women will want to have a biopsy to rule out invasive cancer, said Robert A. Cascella, the company's president and chief operating officer. And the study showed that computer-aided detection was finding proportionately more very early precancerous growths. "That's a valuable finding," he said.

The company has improved its software since the study was conducted, Mr. Cascella added.

The study's lead author, Dr. Joshua Fenton of the University of California, Davis, emphasized that women should continue to have mammograms. But, Dr. Fenton said, they may want to ask if their mammography center uses computer-aided

False Positives

A study of mammography screening at 43 medical facilities found that the use of computer-aided detection resulted in a 20 percent increase in the rate of breast biopsies, but no significant increase in the overall cancer detection rate.



Source: Dr. Joshua J. Fenton

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detection. His study, he said, "does raise concerns that technology is causing harm without clear benefit."

The new look at computer-aided detection is the latest question mark in the changing era of breast cancer detection. New technology — like computer-aided detection, digital mammography, magnetic resonance imaging and ultrasound — can be so sensitive that doctors have trouble deciding which findings are worrisome. The only screening method that has been rigorously evaluated is old-fashioned X-ray film mammograms, but it is likely to be replaced by something, or some combination of things, whose benefits and risks are largely unknown.

"We are getting ourselves out on thinner and thinner ice," said Dr. Suzanne W. Fletcher, an emerita professor of ambulatory care and prevention at Harvard Medical School.

"With mammography, we have multiple studies showing what happens to mortality rates if you get this versus if you don't," Dr. Fletcher said. "With these newer technologies, we don't."

The new study of computer-aided detection was an analysis of 429,345 mammograms obtained from 1998 to 2002 at 43 mammography centers. During that time, seven of the centers switched to computer-aided detection. That enabled the investigators to compare results with and without computer software to help radiologists find suspicious spots.

Computer-aided detection, the re-

searchers wrote, "was associated with significantly higher false positive rates, recall rates, and biopsy rates and with significantly lower overall accuracy."

With computer-aided detection, 31 percent more women were called in for additional tests and 20 percent more had biopsies. And there was another potential problem: CAD did not clearly increase the detection of breast cancer. If anything, it seemed to increase the detection of a precancerous condition, D.C.I.S., for ductal carcinoma in situ.

A technology is found to raise more false alarms in diagnoses.

While all invasive breast cancer is believed to start as D.C.I.S., D.C.I.S. is often harmless. At times, it either never develops into cancer or it grows so slowly that it is not a danger during the woman's lifetime.

But, unable to tell which lesions will become deadly, doctors generally treat them all.

When computer-aided detection was introduced at the seven centers, the number of cancers detected did not change. But the percentage of cancers that were D.C.I.S. increased significantly, to 37.4 percent from

28.1 percent.

One way of looking at the data is to say that if the point of screening is to find cancers early, before they are dangerous, then finding more D.C.I.S. is good. That is the view of Mr. Cascella of Hologic, for example.

But, Dr. Fenton says, doctors had hoped computer-aided detection would find more invasive cancers that were on a road to metastasis. "We didn't find that," he said.

Others were more adamant, saying that the detection of D.C.I.S. was unlikely to have much effect if any on the breast cancer death toll but would lead to more women being told they had cancer and undergoing treatment.

"There is enormous uncertainty about what the significance of these lesions is," said Dr. Rebecca Smith-Bindman, an associate professor of radiology at the University of California, San Francisco. When a test finds more D.C.I.S. and less invasive cancer, Dr. Smith-Bindman added, "personally, I consider it a harm, not a benefit."

In a sense, it might be expected that computer-aided detection performed the way it did, researchers said. The computer program marks four or five spots on the average screening mammogram. A radiologist then looks at those marks and decides if they are cause for concern. Because cancer is so infrequent in a healthy population, a radiologist will see about 2,000 computer marks that are inconsequential for every one that is a real cancer. And to the computer software, tiny flecks of calcium, which are hallmarks of D.C.I.S., are much easier to spot than invasive cancers.

"If you put five extra dots on every mammogram, radiologists will call or will be tempted to call many more things abnormal," Dr. Smith-Bindman said.

"One way to put the whole package together is to say CAD really is not helping us much," she said. "It's tricky, because places have invested in this technology." But, she said, if other studies confirm the results, "I think you have to take it as a loss and move on."

Dr. Hall, however, doubts that many centers will abandon their expensive investment, especially when it is so profitable. He expects that CAD will be refined and improved while breast cancer screening keeps changing with new technologies.

"The primary reasons we got CAD are that it was financially good for us and that everyone else was getting it," he said. "It was a competitive thing." Even now, he said, "there is no way CAD is dead."