

Preventive drugs for higher-risk women rarely used to treat breast cancer

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The millions of Americans who take a pill each day to drive down their cholesterol or blood pressure do not generally think of themselves as "sick." They believe that they are treating one thing -- high cholesterol or blood pressure -- and helping to prevent something worse: a heart attack or stroke.

For [women](#) who worry about becoming the oft-quoted "1 in 8" who will develop [breast cancer](#) in her lifetime, two well-established drugs can do for breast cancer what statins and blood pressure drugs do for heart attacks and strokes: drive down its odds of happening.

Cardiovascular medications are aggressively advertised, widely prescribed and talked about freely among friends and co-workers. Breast cancer prevention drugs are virtually invisible on the American pharmaceutical landscape.

Those contrasting pictures are a puzzle to many physicians and researchers who have spent their careers working to eradicate the scourge of invasive breast cancer -- a diagnosis handed down to more than 192,000 American women last year. In 2009, about 40,000 women died of breast cancer in the United States.

"It has surprised me continuously," says Dr. Rowan T. Chlebowski, a breast cancer expert at Harbor-UCLA Medical Center in Torrance, Calif. "Physicians get more women asking about medication to increase their eyelashes than they do about drugs that can reduce breast cancer

risk."

This is in spite of the fact that a raft of respected studies has shown that in certain women with higher-than-average risk for breast cancer, two widely available drugs -- tamoxifen and raloxifene -- can cut that probability roughly in half. Tamoxifen is a chemotherapy drug for breast cancer patients; raloxifene, marketed since 1998 as Evista, is better known as an osteoporosis drug that women can take after menopause.

In the coming years, researchers expect a new class of drugs -- aromatase inhibitors -- may prove even more effective than raloxifene and tamoxifen at driving down breast cancer risk, cutting it by 70 percent.

So why, given the fear so many women feel about this particular disease, aren't people flocking to the drugs? The reasons are various -- involving optimism, mistrust and a misunderstanding of how breast cancer risk is calculated.

Neither of the drugs now approved for prevention is a wonder drug that's perfectly effective and side-effect free. Both raise the risk of strokes, blood clots, endometrial cancers and, with tamoxifen, cataracts. Both can come with bothersome side effects such as hot flashes and vaginal dryness. Taking either drug for years is not, therefore, a slam-dunk decision, even for a woman who by virtue of age, family history and past breast disease is more likely than most to develop invasive breast cancer. But for the right woman, one whose lifetime risk is well above average, many breast cancer specialists say these drugs look like a pretty easy call.

Yet, among women who are aware they have a higher-than-average risk and consult a specialist about it, just a little over 3 in 10 opt for medicine to lower their risk.

"These medications have been underutilized to this point by anyone's

standards," says Dr. Larry Wickerham, a professor of oncology at Drexel University School of Medicine in Philadelphia.

That's particularly surprising, experts say, given that women typically overestimate their breast cancer risk. Most women have heard advocacy groups cite the alarming statistic that a woman in the U.S. has a 1 in 8 -- or 12.5 percent -- chance of developing breast cancer over her lifetime. And everyone knows someone -- a relative, friend, neighbor or celebrity -- who's recently gotten a diagnosis. Such factors tend to inflate women's perceptions of their personal risk.

In one telling 2009 study, 632 women considered to be at high risk of developing breast cancer in the next five years received a comprehensive assessment of the risks and benefits they could expect from tamoxifen. While 29 percent said they would probably speak to their doctor about the drug, only 6 percent said they thought they would take it. Three months later, fewer than 1 percent had started to take it, and just 6 percent had asked their doctor about it.

"People weren't always convinced the benefits were real or that those benefits would apply to them," says study co-author Angela Fagerlin, a University of Michigan psychologist. And then there is suspicion. Fagerlin says she was struck recently by online comments posted in response to a newspaper editorial she wrote about the medications.

"They said, 'Look at hormone replacement therapy -- they claimed it was going to help us, and look what happened,'" Fagerlin says. "The hatred and mistrust of the pharmaceutical companies was just astounding."

Becky Gannon, a 58-year-old nurse from Evans City, Pa., is balanced on the knife's edge between hoping for the best and trying to avert the worst. Her mother was diagnosed with breast cancer at 70 and died of a

recurrence 10 years later. Her sister got a diagnosis of invasive breast cancer at 39.

When Allegheny General Hospital in Pittsburgh, where Gannon works, posted a notice seeking women with a high risk of breast cancer to participate in a study, she was intrigued. She got exhaustive briefings on the pros and cons of trying raloxifene or tamoxifen to reduce her risk.

But she has decided, for now, to hold off. She was troubled by her friend's experience with tamoxifen after a diagnosis of breast cancer, including many unpleasant side effects. She says she's more open to raloxifene, which her sister takes for osteoporosis.

But Gannon looks after her health -- eats carefully, works out regularly, drinks alcohol rarely -- and is an avowed optimist. She harbors the hope that breast cancer won't happen to her. Given that mindset, she says, it's hard to see taking a daily pill.

The "risk calculators" that are used to judge a woman's breast cancer vulnerability may also make people skeptical about the need for preventive measures.

Medical professionals largely rely on the Breast Cancer Risk Assessment Tool -- better known as the Gail model -- which estimates a woman's risk of developing invasive breast cancer in the next five years. Because the disease is more likely to strike as women get older, a younger woman often greets her "Gail" number with relief, even if she shouldn't.

For instance, a 50-year-old woman who is told she stands a 1.7 percent chance of developing breast cancer in the next five years may perceive her risk as low. But in fact, such a woman is at higher-than-average risk and deemed a good candidate for preventive drug therapy.

Physicians are a factor too. Many primary care doctors and gynecologists shy from introducing new drug risks to women who seem healthy. They also have little time and are ill-equipped for the complex risk assessment and counseling the decision requires.

Nor do the public profiles of tamoxifen and raloxifene endear them to women. When women like Becky Gannon hear "tamoxifen," many recognize the name of a cancer drug their mother or aunt took. "The fact that it's a cancer drug ... has some stigma," psychologist Angela Fagerlin says. "You think, 'I must be a sick person because I'm choosing to take this drug.'"

Raloxifene doesn't suffer from that problem: Since 1998, it has been widely recommended to many of the 12 million women who have osteoporosis and the roughly 40 million others thought to have low bone mass, or osteopenia.

The Food and Drug Administration gave Eli Lilly & Co. permission in 2007 to market the drug for breast cancer prevention too. But Lilly's approach is remarkably low-key: Its ads have merely billed raloxifene's effectiveness in driving down breast cancer risk as a bonus for women already taking it for their bones.

Finally, the mission of breast cancer prevention suffers from a major missing link: a clear way of showing doctor and patient that a woman's risk is dropping in response to drugs. It's a different situation than the one that exists for statins and blood pressure medications, for which improved cholesterol and blood pressure readings give everyone an accepted measure of whether a drug is working.

Researchers are focusing on breast density as a possible risk indicator. A growing body of evidence shows that women with less fatty, denser breasts are more likely to develop [invasive breast cancer](#). But scientists

have much to learn about that. "The whole concept of chemoprevention of cancer is in its infancy, and it's not perfect," Wickerham says.

Still, he adds, "it wasn't all that long ago we were having the same discussion about heart disease. We're going to get better at this over time."

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