BREAST CANCER AWARENESS MONTH

A battle for change

Margie's Army fighting to improve standard of care for Georgia women

BY LORI WYNN
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Margie Singleton is on a mission, and she's got the power of an army behind her.

Singleton, who has been battling an aggressive form of breast cancer since being diagnosed in February, has her sights set on the Georgia Legislature to change the standard of care of how breast density is included on mammogram reports.

"It is statistically known that mammograms are missing cancer in every other patient with dense breast tissue," she said. "Women need to be educated and they need to be given a choice."

Singleton was diagnosed in February, but her story began in August 2017, when she found a lump in her left breast. She went in for a 3-D mammogram, which came back clear. Fast forward six months and she found sensitive knot in her right breast. This time, her doctor ordered a 3-D mammogram and an ultrasound.

"Two different 3-D diagnostic mammograms taken that same day missed a 3.6-centimeter tumor," Singleton said. "The only thing that saw it was an ultrasound, and a biopsy confirmed it … In August and in February, a 3-D diagnostic mammogram – because I have dense breast tissue – missed that cancer."

That was when she learned that not only is cancer more difficult to spot in dense breast tissue on a mammogram, just having dense breast tissue made her four times more likely to get cancer.

"Lo and behold, if you have dense breast tissue, it looks the same as cancer on the mammogram, so it's hard for the radiologist to pick up," she said.

Dr. William Burak is a breast cancer surgeon at Memorial Health and Singleton's doctor. He compared finding cancer in dense breast tissue on a mammogram to finding a golf ball in a pile of snow – because both cancer and dense tissue appear white on a mammogram.

"So every person's different, and for some women mammograms aren't as accurate," Burak said. "And what reduces the accuracy of the mammogram? The No. 1 factor is the density of the breast tissue. So if a woman is very dense, then it's going to hide a cancer."

In radiology, breast tissue density is categorized as either A, B, C or D, with C considered "dense" and D considered "extremely dense," according to densebreast-info.org. In Georgia, mammogram reports may mention the category the patient falls under, but they aren't required to explain what the category means.

"I can go back and look at every mammogram report I have. When I turned 40, I thought I was doing the right thing (getting annual mammograms). It just says, 'You have breast density C.' That's it. Every woman I've spoken to, all they worry about is getting the phone call: 'Hey, your mammogram's clear,'" Singleton said.

"I thought I was good, but no. I have C density and that put me at four times more risk of getting breast cancer. I didn't know what that meant. I didn't know that I could benefit from getting an ultrasound or MRI. It's not standard on any mammograms right now."

New determination

Singleton now lives in Savannah but spent 13 years in Richmond Hill until 2012. Her husband Jason Singleton, owns Singleton Custom Homes in Richmond Hill, and her 12-year-old daughter Jadyn attends Savannah Christian Preparatory School.

Since being diagnosed, Singleton has completed six rounds of initial chemo and had a double mastectomy and reconstruction, followed by 25 rounds of radiation. She is currently cancer free but will still go in for maintenance chemo every three weeks for about a year. For another five to 10 years, she will take a chemo pill to help with recurrence.

Photos provided

Clockwise from top left: Margie Singleton smiles with her husband Jason and daughter Jadyn; Margie Singleton strikes the "We can do it" pose as Rosie the Riveter in April before tackling her third round of chemo; and members of Margie's Army gather for a photo earlier this year.

"It's not pleasant, the whole thing," she said. "Your whole life is turned upside down when you lose every aspect of who you are and what you are."

In addition to her family, a group of 15-20 of Singleton's close friends known as "Margie's Army" has been by her side, from keeping her company during treatments to holding fundraisers to help with all the expenses that come with fighting cancer.

But Singleton sees her journey with cancer as part of God's plan. And that journey has fueled a desire to help other women in Georgia avoid the path she ended up on.

"It has empowered me to research and to help other women," she said. "I've always want to help, anyway. But this has changed me a lot – it really has, I think for the positive. Now that I'm on the other side of it, I wouldn't trade it for anything if I can just help one person to not have to go through this."

With the help of Margie's Army, Singleton hopes to pass legislation that would add Georgia to the list of 36 other states that require language on mammogram reports explaining breast density and the associated risks.

Her surgeon, Dr. Burak, said he agrees a mammogram report should better explain breast density.

"It mandates a conversation," he said. "Also, it's putting it in the patient's hands – this (mammogram report) language – to say, 'Hey, it's your responsibility to talk to your doctor. We're informing you that you have this issue.' And the doctor gets the report, too, so it goes both ways. And I think it's helpful for both people to be reminded."

Singleton said Margie's Army has been in contact with several legislators, including House Majority Leader Jon Burns, R-Newington; Rep. Bill Hitchens, R-Rincon; and Rep. Sharon Cooper, R-Marietta; and even Gov. Nathan Deal to pitch the importance of "Margie's Law."

And their efforts seem to be gaining traction.

Cooper, who chairs the House Health and Services Committee, said last week she'd been in contact with Burns and Hitchens about such a bill. While a bill isn't likely to be introduced before next legislative session in January, she said she thinks it would get passed.

"I think we can get a bill that will let women with dense breast tissue know there is another option (for screenings) if they want to discuss it more with their physician," Cooper said. "We'll find a way, and I'm pretty sure we can get a bill passed."

She said legislators are everyday citizens who may not know about an issue if they don't hear about it from someone else.

"It's people like Margie that can make a real difference because they bring these issues before us," Cooper said. "It's a great and wonderful goal, and I appreciate her coming to us."

Study zeros in on patients who don't need chemo

STAFF REPORT
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A majority of women with the most common type of breast cancer can to opt out of chemo without changing their outcome, according to research published this summer in the New England Journal of Medicine.

New findings from the groundbreaking Trial Assigning Individualized Options for Treatment (Rx), or TAILORx trial, show no benefit from chemotherapy for 70 percent of women with the most common type of breast cancer.

The study found that for women with hormone receptor (HR)-positive, HER2-negative, axillary lymph node-negative breast cancer, treatment with chemotherapy and hormone therapy after surgery is not more beneficial than treatment with hormone therapy alone.

The new data, released at the American Society of Clinical Oncology (ASCO) annual meeting in Chicago, will help inform treatment decisions for many women with early-stage breast cancer.

Photo provided by St. Joseph's/Candler

Dr. Mark Taylor is a trial investigator for the Nancy N. and J.C. Lewis Cancer and Research Pavilion in Savannah.

Dr. Mark Taylor, an oncologist with Summit Cancer Care in Savannah, was the investigator for the trial at the Nancy N. and J.C. Lewis Cancer and Research Pavilion at St. Joseph's/Candler, which was one of 1,182 trial sites in the U.S. Australia, Canada, Ireland, New Zealand and Peru.

"We're thrilled to get further and further away from chemo," he said. "We're getting further away from chemo in all kinds of cancers, and breast is no exception. And the TAILORx study was important in sort of furthering that movement."

He explained that the goal of the trial was to focus in on a specific subset of women that previously would have been given chemo by default to err on the side of caution.

"There was a group of women we knew already didn't get chemo, so that was no revelation. And there was a group that's high risk that would still get chemo. The TAILORx was just looking at that intermediate group," Taylor said.

"It was basically just trying to move the goalposts narrower – figuring out more women in that intermediate group that don't need chemo and making sure you're clearly identifying women who do need chemo."

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>
> **Dr. Mark Taylor, Summit Cancer Care**

TAILORx was a phase 3 clinical trial that opened in 2006 and used a molecular test that assesses the expression of 21 genes associated with breast cancer recurrence to assign women with early-stage, HR-positive, HER2-negative, axillary lymph nodenegative breast cancer to the most appropriate and effective post-operative treatment.

The trial enrolled 10,273 women with this type of breast cancer. When patients enrolled, their tumors were analyzed using the 21-gene expression test and assigned a risk score, on a scale of 0100, for cancer recurrence. Based on evidence from earlier trials, women who had a score in the low-risk range, 010, received hormone therapy only. and those who had a score in the high-risk range, 26 and above, were treated with hormone therapy and chemotherapy.

Women who had a score in the intermediate range, 1125, were randomly assigned to receive hormone therapy alone or hormone therapy with adjuvant chemotherapy. The goal was to assess whether women who received hormone therapy alone had outcomes that were as good as those among women who received chemotherapy in addition to hormone therapy.

Five years after treatment, the rate of invasive disease-free survival – women who had not died or developed a recurrence

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BREAST CANCER AWARENESS MONTH

Trial seeks better breast cancer screening

By Lori Wynn
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Dr. Howard Zaren with St. Joseph's/Candler is excited. And he wants others to be excited, too.

Zaren is the medical director for the Nancy N. and J.C. Lewis Cancer and Research Pavilion and the principal investigator in a trial comparing 2-D and 3-D mammography to hopefully learn the best ways to find breast cancer in women who have no symptoms.

The Tomosynthesis Mammographic Imaging Screening Trial (TMIST) is the first randomized trial to compare the two types of digital mammography for breast cancer screening, 2-D and 3-D, also known as tomosynthesis. Even though both are FDA-approved and in use, no one knows whether the newer 3-D technology tops conventional mammography at early detection of aggressive breast cancers.

Zaren explained that when breast cancer is found in women, 60 percent of the time is from an abnormal mammogram, while roughly 40 percent is from breast self-exams or physician exams.

"So screening is really important since 60 percent of patients will find (cancer) from an abnormal screening process," Zaren said during a phone interview. "That's pretty impressive, right?"

And the idea of improving that statistic is what he finds so exciting.

"I can't look you in the eyeball, but I want you to be excited about this because that's a big deal."

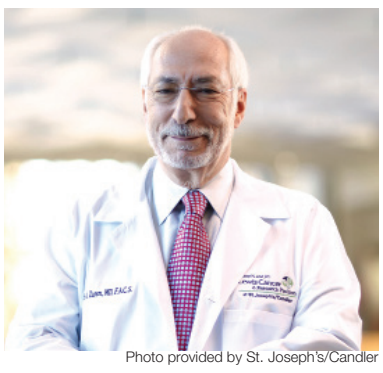

Photo provided by St. Joseph's/Candler

Dr. Howard Zaren is the medical director of the Nancy N. and J.C. Lewis Cancer and Research Pavilion in Savannah.

Zaren said there hasn't been a breast cancer screening trial since the 1980s despite how much technology has changed over the last three decades, so there's a need for newer technology in the screening process.

2-D mammography takes pictures from two sides of the breast to create a flat image. 3-D mammography, or tomosynthesis, images are taken from different angles around the breast and then built into a 3-D like image.

"Tomosynthesis is a much more in-depth evaluation of the breast – it's almost like doing a CAT scan of the breast," he said.

Zaren said he believes the 3-D technology is much more accurate than 2-D mammograms, but he noted tomosynthesis has its own drawbacks.

"With tomosynthesis there's a little more radiation given to the patient, it costs more, takes more time to interpret then digital mammography – there's no free lunch with this new technology," he said.

Additionally, while 3-D mammography is likely to detect more findings that require follow-up, it also is likely to lead to more procedures and treatments, according to a press release from St. Joseph's/Candler. It is not known if this technology is reducing the chances for women to develop a life-threatening, or advanced, cancer compared with 2-D mammography.

"So the whole point of this trial is: Does tomosynthesis find more life-threatening cancers than digital mammography?" Zaren said.

St. Joseph's/Candler is just one of 100 mammography clinics across the U.S. and Canada participating in the study. Researchers hope to get information from 165,000 patients age 45-75, who will be told about the opportunity to enroll in the trial when they schedule a routine mammogram. Once enrolled, they will be assigned to either a 2-D or 3-D mammography screening for five years. Most women enrolled in the trial will be screened annually while postmenopausal women with no high-risk factors will be screened every two years.

During the study, the results of every mammogram from every woman will be collected, whether the mammograms are normal or not. Information about any medical follow-up, such as more imaging or a biopsy, also will be recorded. All women will be followed until the end of the study for breast cancer status, treatment and results from treatment.

Photo provided by St. Joseph's/Candler

A mammography technician watches a 3-D image of a breast come through on her computer. 3-D mammograms, also known as tomosynthesis, are available at several cancer clinics in the Savannah metro area.

If a woman does receive a diagnosis of any kind of breast cancer while in the trial, she will receive treatment just as she would if she was not part of TMIST, while continuing to be part of the trial.

St. Joseph's/Candler has already enrolled 200 patients, Zaren said.

"Saint Joseph's/Candler and Louis Cancer and Research Pavilion is in the top five (clinics) in the country now in recruitment and accrual for patients in this trial. That's a big deal for patients in this area," he said.

Both 2-D and 3-D mammography are available at the Telfair Pavilion, located at Candler Hospital, SJ/C Imaging Center-Pooler and Telfair Breast Imaging-Eisenhower. Both screenings are also available at Memorial Health in Savannah, though Memorial is not participating in this trial.

"We're passionate about this. This is all about doing something good for women," Zaren said. "And it's not just like a hello-goodbye thing – this is going to go on for a while because there are lots of women to be included in this trial. So I'm hopeful that, from this screening point of view, we will make a difference and have a better technology for women."

Patients

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or a second primary cancer – was 92.8 percent for those who had hormone therapy alone and 93.1 percent for those who also had chemotherapy.

At nine years, the rate was 83.3 percent for those with hormone therapy alone and 84.3 percent for the group that had both therapies.

None of these differences were considered statistically significant.

The rates of overall survival were also very similar in the two groups. At five years, the overall survival rate was 98.0 percent for those who received hormone therapy alone and 98.1 percent for those who received both therapies, and at nine years the respective overall survival rates were 93.9 percent and 93.8 percent.

There is one caveat to the new findings.

When the researchers analyzed premenopausal women and those younger than 50 years old at the higher end of the intermediate-risk range (16-25) separately, the results showed there may be a small benefit from chemotherapy, and thus these women should consider chemotherapy with their doctor.

"This is still not cut and dry. You have to talk to your oncologist, and there will be nuances that may make the overall headline (of the trial) not apply to you," Taylor said. "But there's no doubt about it, it was a good study."