

High-tech test not so effective

Computer-aided mammography might not help spot cancer

BY KATHRYN DOYLE
REUTERS

Computer-aided detection, a part of almost all mammograms today, appears not to improve diagnostic accuracy for breast cancer screening, according to a large study.

Computer-aided detection, or CAD, marks areas of concern on mammogram readouts that radiologists might otherwise miss. It was approved by the Food and Drug Administration in 1998 and became common after the Centers for Medicare and Medicaid Services increased reimbursement for the technology in 2002, the authors write.

Since then, it has been hard to measure how much difference CAD actually makes in spotting cancers.

“There’s been a lot of controversy about whether or not CAD improves performance, and the largest studies haven’t supported improvement,” said Dr. Constance Lehman of Massachusetts General Hospital in

Boston, who led the new study.

“Prior studies were done on CAD technology on the very early curve of its adoption,” and radiologists may not have been comfortable using it yet, Lehman told Reuters Health by phone.

For the new study, she and her coauthors only considered mammograms reviewed by radiologists who had been working with CAD for at least a year.

Between 2003 and 2009, the nearly 324,000 women in the study had nearly 626,000 digital screening mammography exams, including 495,818 that were interpreted with CAD and 129,807 that were interpreted without it.

The mammograms were interpreted by 271 radiologists at 66 facilities.

Within a year after mammography, 3,159 women were diagnosed with breast cancer.

Radiologists correctly detected a breast cancer about 85 percent of the time, regardless of whether CAD was involved. In other words, the

cancer detection rate did not change based on CAD technology.

When the researchers looked specifically at about 100 radiologists who interpreted mammograms with and without the computer readout, they found that the radiologists actually detected fewer cancers with CAD mammograms.

CAD now costs more than \$400 million yearly, without an established benefit for patients, the authors write.

“Literally hundreds of thousands of women are undergoing this and in many cases paying out of pocket,” Lehman said.

Radiologists should be thoughtful about how they are using CAD — it may be useful for spotting calcifications, but just because it does not mark an area as concerning doesn’t mean that area should be ignored, she said.

Dr. Joshua J. Fenton of the University of California, Davis Health System in Sacramento, who wrote an editorial published with the findings in JAMA Internal Medi-

cine, doesn’t think patients should be alarmed.

“CAD seems to be having, on balance, little if any effect,” he told Reuters Health by phone.

Fenton said he’s not surprised that CAD did not yield substantial benefits, and he questions whether Medicare should be reimbursing for it.

“If it weren’t reimbursed then a lot of radiologists would have the freedom to say I don’t want to use CAD,” Fenton said.

To change reimbursement, strong political leadership would need to make a compelling argument for why CAD is not a good use of taxpayer money, he said.

“We need to be more rapid in assessing new technology,” Lehman said. “We are advancing so quickly in technology development, we need to get quicker at assessment.”

“In my practice I’m not sure if I’m going to stop using CAD, but I question if it makes sense to charge for CAD if I’m using it to diagnose cancer,” Lehman said.

New analysis refutes 2001 Paxil study

BY KATHRYN DOYLE
REUTERS

According to a reanalysis of the original data from a 2001 study of paroxetine, or Paxil, for teens with major depression, the drug was not effective and led to serious side effects, which is not how the results were presented 14 years ago.

“There have been warnings about paroxetine for a long time,” including a 2007 Food and Drug Administration advisory on the risk of increased suicidality when antidepressants like paroxetine or imipramine are used to treat people age 18 to 24, according to Dr. Jon Jureidini of the University of Adelaide in Australia.

The authors of the 2001 study did not report this side effect, although the evidence was there, said Jureidini, a co-author of the reanalysis.

“A broad community of people around the world have raised concerns,” he told Reuters Health by phone.

The original trial, known as ‘Study 329,’ ran from 1994 to 1998 and included 275 teens with major depression. For eight weeks, about a third of them received 20 to 40 milligrams of paroxetine, another third received up to 300 mg of imipramine (Tofranil), and a third received placebo pills.

The researchers, supported by paroxetine’s maker GlaxoSmithKline, measured the participants’ total Hamilton depression scale score before and after treatment, as well as several other mental

health assessment scales.

The original published results described paroxetine as effective and safe.

In the new analysis, Jureidini and colleagues found that neither paroxetine nor imipramine were better than placebo for any measure of depression. Furthermore, the drugs did not notably increase harms, like suicidal thoughts and behavioral problems in the paroxetine group and heart problems in the imipramine group.

According to Jureidini’s team, the original analysis departed from the stated protocol for the study and included four more clinical endpoints that were not part of the original design, but were introduced after the data had been collected, which allowed the investigators to present the results as positive.

The original number of side effects seemed to be lower because the authors only included problems that affected at least five percent of the study participants.

The reanalysis, published in the BMJ, was part of the “restoring invisible and abandoned trials,” or RIAT, initiative that began in 2013 and is aimed at publishing undisclosed trial outcomes or correcting misleading publications.

The RIAT organizers identified questionable studies and contacted original study funders and authors asking them to publicize their results or correct their published results.

In the case of Study 329, the original authors and the journal where they published, the Journal of the American Academy of Child and Adolescent Psychiatry, did not agree to make corrections, so another group of researchers set out to reanalyze their now public data.

“This isn’t out and out scientific fraud,” said professor David Henry of the Institute for Clinical Evaluative Sciences in Ontario, Canada, who coauthored an editorial in the BMJ on the importance of clinical data sharing.

“This is a subtle form of manipulation of the analysis of the data and interpretation of the results that may actually happen quite often,” Henry told Reuters Health by phone.

It takes a lot of time and effort to reanalyze this type of data, and academic reviewers are not paid to do it, so it often does not happen, he said.

“Statistical analysis is not black and white, you can make a drug look better than it actually is,” Henry said.

Although paroxetine and imipramine were prescribed for kids and teens following the 2001 publication, this new paper won’t have a big effect on clinical practice, as those prescriptions are much less common now following the FDA advisory and other red flags, he said.

In 2012, GlaxoSmithKline agreed to pay three billion dollars in the largest healthcare fraud settlement in U.S. history, which resolved

claims of introducing misbranded drugs and failing to report safety data for some of their products, including Paxil.

Dr. Martin Keller of Brown University and eight of the 22 authors of the original JAA-CAP paper wrote a letter to the industry site Retraction Watch in response to the reanalysis. Keller shared a copy of the letter with Reuters Health; in it, he and his colleagues express “strong disagreement” with many of the points raised in the BMJ paper.

“That one can do better reanalyzing adverse-event data using refinements in approach that have accrued in the 15 years since a study’s publication is unsurprising and not a valid critique of our study as performed and presented,” Keller and his coauthors write. “In summary, to describe our trial as ‘misreported’ is pejorative and wrong, both from consideration of best research practices at the time, and in terms of a retrospective from the standpoint of current best practices.”

Jureidini says open data sharing could prevent this kind of problem from happening again.

“All of the problems with the [original] paper, none would have been there if their data and protocol were publicly available at publication,” Jureidini said.

“A call has been made for drug companies to publish data, not papers,” he said.

OBITUARIES

In Memoriam

In Loving Memory Of
KATIE M. WINGATE



OUR BELOVED KATIE

Why not I in sadness pass?
Why not I in shadows cast.
Obscure the tragic history,
And take your place to set
you free.

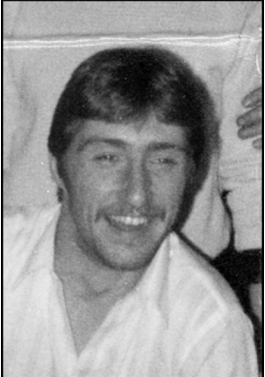
Our eternal remembrance
and love
Dad, Mom, Jenn, Noelle,
Courtney, Justin, Jordan

In Loving Memory Of
MATTHEW H. GILMAN
Feb 12, 1953 - Sep 29, 2013



Forever in our hearts

In Loving Memory Of
GARY FLOYD MARTIN
Dec. 8, 1963 - Sept. 29, 1989



Angels and butterflies fly
together reminding us that
you'll live on in our hearts
forever. Love your family
and all who love you.

Committal Services

PETER J. VANIER

CARIBOU - There will be a committal service for Peter Vanier on Saturday, October 3rd at 10AM at St. Thomas Aquinas Cemetery, Madawaska. A reception for family and friends will follow from 11-1PM at Long Lake Sporting Club, Sinclair. A reception will also be held from 4:30-7PM at The Par and Grille, Caribou. Please join us to Celebrate the Life of Peter Vanier.
www.athutchins.com



FRANCES L. SAWYER

GLENBURN - Frances L. Sawyer, 78, died unexpectedly May 26, 2015, in Ellsworth. She was born in Bangor on April 24, 1936, daughter of the late David and Jessie (Bowden) Lane. She was predeceased by her husband, Charles Sawyer Sr., on Oct. 17, 2011. Both are missed greatly. A graveside service will be held 3:30 p.m. on Friday, Oct. 2, 2015, at Glenburn Cemetery, Lakeview Road.

In Memoriam

In Loving Memory Of
SHARON BARROWS



It was a year ago today Pattie and I held on to you so tight, wanting to never lose the fight. Not a day goes by my friend when I don't think of you. I still shed many tears and my heart still hurts of missing you, but I always end with a smile and special memories. I was so blessed to have you in my life and be able to call you my friend. You were the most generous, giving and kind person I have ever known. You brought so much joy to so many lives. I never see a backpack without thinking of all the ones you bought and filled to help children in need. Even seeing pet food reminds me of all the times you bought it to give to the elderly so they could keep their pets. Every time I hug my children I think of how much you loved yours. You were so giving and loving in so many ways and asked so little in return. How I embrace all the wonderful memories we shared. All the laughs, tears, good times and bad. Until we meet again my friend, I will always have my memories.
Linda

Alligator attack victim shows resilience

BY BETH KASSAB
ORLANDO SENTINEL

ORLANDO, Florida — The moment the alligator clamped down on Rachael Lilienthal’s right arm she softly touched its head with her left, as if to convince herself of what was happening.

“I think it was then that I paused and I prayed,” she remembered in her first interview since the attack seven weeks ago on the Wekiva River. “It was a simple prayer. It was bless us, protect us, keep us well.”

The alligator didn’t let go. So this time Lilienthal, 37, pounded the reptile’s head.

“This made him angry, so he turned me under the water,” she said.

Each time the gator dragged her under — she’s not sure how many — she didn’t know how long it would be until she surfaced.

“At one point I could feel my arm break,” she said. “And I was so upset that I had to deal with a broken arm.”

She looks back now, almost bemused at how in the moment she worried about getting a cast.

The gator let her back up and she looked around and called to the nearest people, a group of women in a canoe.

They were struggling to maneuver their canoe, but had whistles and started blowing them.

“They played a very important part,” she said. “They let everybody know there was a problem.”

Then Krista Karlsen and her boyfriend Casey Spencer paddled their kayak over.

Lilienthal calls them “heroic” and marvels at how they didn’t hesitate or consider their own safety.

Casey began to hit the alligator with his paddle.

The gator then rolled Lilienthal so violently her bathing suit was torn off.

“One last time, Casey got the alligator I think right on the head with the paddle really hard,” she said. “And, I guess luckily because it could have been so much worse, the alligator took off with my arm.”

This is one of the incredible things about Rachael Lilienthal.

Even when reflecting on the most terrifying of moments, she finds the silver lining: It just took her arm.

She is also incredibly grateful.

For the kayakers.

“They saved the day,” she said.

For the Eagle Scout nearby in a canoe who helped get her to the dock at Wekiva Island.

For the powerful man who reached down and pulled her onto land.

“He somehow lifted me out of the water by one arm,” she said. “I do not know who that

man was. I would love to thank him if anybody knows who that is.”

For the person who ran for a towel and covered her. Even in her panic she remembers being terrified that she was naked.

And for the paramedics.

“I was from alligator’s mouth to the operating room in less than one hour,” she said.

She remembers being in the ambulance, and the panic that washed over her.

“Once I was in the hands of the professionals I gave up and I cried for my mommy,” she remembered, looking over at her mother, Cindy Kruger.

They both choked back the emotion of remembering that day.

It’s been seven weeks since Lilienthal went to Wekiva Island with a friend. They canoed. She drank a smoothie (and no alcohol, as some have speculated). He ate a sandwich.

They decided to get in the water to cool off.

Her friend got back out, but Rachael, who has a passion for swimming, decided to stay in a bit longer.

She did a few butterfly strokes and chatted with some people in a canoe — the same women who would later blow the whistle to help save her.

The river was crowded.

She says she didn’t go into any areas where swimming is prohibited. She wasn’t in the weeds.

She was heading back to meet up with her friend when she felt something move over her back. She thought it might have been a canoeist who didn’t see her. It was the alligator.

“I know that alligators live in those waters. That’s their home, I’m aware of that,” she said. “I also had a false sense of security that they don’t attack people.”

One witness told her after the fact that she saw the gator leave the bank on the other side of the river and swim toward Lilienthal.

In a way, she says, it might have been best the alligator got her, a strong swimmer and former lifeguard.

“If that gator had gotten someone else, would they have been as comfortable in the water?” she asked. “I think that most people would not have had such a favorable outcome.”

Those silver linings, again.

The resilience that kept her alive that day still shows.

Lilienthal, a Florida State grad, teaches Spanish at Rollins College and plans to be back in the classroom by January.

But the simplest things are hard now. Like getting dressed, or putting her hair in a ponytail.



JOE BURBANK | ORLANDO SENTINEL | TNS

Rachel Lilienthal, the Orlando, Florida, woman who lost an arm in an alligator attack seven weeks ago, talks to the Orlando Sentinel at her home on Friday.

Once right-handed, she’s learning to write and type with her left.

She is thankful for health insurance, but it’s still unclear if it will cover the kind of prosthetic arm Lilienthal hopes to have one day.

Her friends set up a fundraising account — GoFundMe.com/wekivarachael-com — to help cover her many expenses.

Her occupational therapist helped her find a special cutting board so she can cut fruit and vegetables with one hand for salads.

“This morning I single-handedly made my awesome mother a great cup of coffee with cashew mylk,” she wrote on Facebook last month.

“That was the day she got back from the hospital,” her mother, Kruger, remembered. “She’s done a lot in that amount of time.”

Kruger, who lives in suburban Philadelphia, has stayed with Lilienthal since the accident.

She showed her videos of paralympic swimmers.

And, one day, Lilienthal knows she’ll swim again.

Until then she has decided to tackle the small things.

And, as she puts it, find the peace that comes with being grateful.