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New Jersey Oncologist Says Ovarian Cancer Test May Catch Disease Early

By Bob Groves, The Record, Hackensack, N.J. Knight Ridder/Tribune Business News

Apr. 13 - A promising test for ovarian cancer is based on a new way of detecting disease that is as plain as the nose on your face, says a New Jersey oncologist who helped research the technique.

OvaCheck could prove to be the first test to detect deadly ovarian cancer in its early stages, when it is most curable. The test could potentially save thousands of lives.

The experimental test works by identifying patterns of abnormal proteins in a patient's blood, like picking out a face in the crowd, said Dr. Charles B. Simone of Lawrenceville.

"Cancer cells have faces different from other cells in our systems. Say that noses are protein A, and ears are protein B ... eyelashes, eyebrows, anything that protrudes off that globe of a face," are all recognizable features, Simone said.

"Our reasoning was, if every cancer cell looked different than other normal cells, they'd have characteristic spikes of protein. So we looked just at the surface of proteins for different patterns," he said.

The process, known as proteomic -- or abnormal -- protein pattern recognition, can identify disease without searching for specific, individual proteins.

Two years ago, Simone supplied patient blood samples and co-wrote a study in the British journal The Lancet that found protein pattern recognition was highly effective in detecting ovarian cancer.

Simone, an oncologist who treats patients and conducts research, is founder of the not-for-profit Simone Protective Cancer Institute in Lawrenceville. He studied pattern recognition for the National Cancer Institute, and said he is interested in research, not commercial ventures such as OvaCheck, an offshoot of that work.

Correlogic Systems Inc. of Bethesda, Md., developed the computer software used in The Lancet study and for the OvaCheck ovarian cancer test. Quest Diagnostics Inc. of Teterboro and another laboratory in North Carolina are testing the new screening process before it is put on the market, reportedly within a few months.

Ovarian cancer has the highest mortality rate for women after lung, breast, and colorectal cancer. This year in the United States, there will be 25,580 new cases and 16,090 deaths from the disease, including 540 women in New Jersey, according to the American Cancer Society

Ovarian cancer is deadly because testing has never been able to detect it early and woman typically have no symptoms in the early stages. Currently, 80 percent of ovarian cancer is diagnosed at a late stage, giving those patients a 35 percent chance of living another five years. But patients whose cancer is diagnosed in stage I of the disease are more than 90 percent likely to be alive after five years and most of them are curable by surgery.

A diseased organ, such as an ovary, undergoes changes and secretes abnormal proteins in unique clusters or patterns into the bloodstream.

The OvaCheck test requires only a drop of a patient's blood. In the laboratory, proteins are separated from the blood serum, the clear fluid part that does not contain cells that carry oxygen or fight infection, or platelets that enable clotting.

The proteins are run through a mass spectrometer, a lab instrument that categorizes the proteins according to their molecular mass and electrical charge. This produces a spectrum of about 15,200 different proteins and protein fragments.

A computer with pattern recognition software then sorts through the spectrum looking for a cluster of several abnormal proteins that match a model of the cancer protein pattern. If there is no match, the person does not have the disease.

Peter Levine, president of Correlogic, compares the process of pattern recognition to opening a combination lock. But while an average lock might require picking three correct combinations out of 40 possible numbers, an

ovarian cancer pattern could involve five or more combinations out of 15,200 exponential choices, Levine said.

In The Lancet study in 2002 of 116 patients who had ovarian disease, pattern recognition accurately identified all 50 of those who had cancer, and 63 of 66 cases of disease that were non-cancerous, with three false positives.

"Pattern recognition is old-fashioned, but it's much more powerful than genetics or the human genome" for detecting cancer, Simone said.

The test is also being adapted for prostate, breast, and other kinds of cancers, he said.

Should a test like OvaCheck prove effective, "it would be a godsend for everyone," said Dr. Daniel Smith, a surgeon and chief of gynecologic oncology at Hackensack University Medical Center.

"We would be absolutely ecstatic. This could well be a standard screen [for ovarian cancer] for people in the general population," Smith said. "Ovarian cancer is a formidable health risk to women. For some malignancies, like cervical cancer, we have early detection methods."

A small percentage of late-stage ovarian cancer cases can be detected by using ultrasound, combined with a test for a protein or biochemical substance in the blood, known as cancer antigen CA125, he said. But "to date, there are no reliable methods of detection for early disease."

"The symptoms of ovarian cancer are very subtle, usually mild gastrointestinal upset, or weight gain, and could be confused with other conditions. Patients will often try to medicate themselves at first or go to a general practitioner who doesn't recognize the pattern that's about to evolve," Smith said.

A spokesman for Quest Diagnostics said it was too early to discuss the test.

"We would love to talk about the test. But it's just not fair to doctors and patients," said Gary Samuels at Quest's corporate headquarters in Lyndhurst. Quest is the world's largest operator of medical testing laboratories.

"We don't want to have them expect something that doesn't exist right now and isn't available. And we don't necessarily want people going to doctors and asking for a test doctors can't order," Samuels said.

OvaCheck will be tested on blood samples from women who either had ovarian cancer, or who did not have it but were at high risk for the disease because of family history, he said.

The validation testing involves more than 1,000 blood samples, said Peter Levine of Correllogic. Levine said he did not know how long it will take.

"Science drives the process, not the calendar," he said. "I don't want to be in a position of creating false expectations.

"When news [about The Lancet study] broke two years ago, we were deluged by calls from anxious patients. We're much closer now, but we wouldn't want people racing" to get the test before it has been proven effective, he said.

Correllogic has kept the same software that was used for The Lancet study, but it upgraded some of the technology for retrieving the proteins in the OvaCheck test, he said.

"Think of The Lancet as being the Wright brothers' first flight, and this is a couple years later. It still has wings, propellers, and an engine, but we've improved the efficiency of all those functions," Levine said.

Simone, the Lawrenceville oncologist, was strictly at the Wright brothers stage when he started studying ovarian cancer without the help of computer software.

"There are 30,000 protein patterns in blood. I got a group of people and started laboriously looking at hundreds of patterns. We had them spread out on my dining room table," recalled the physician.

Now, with new technology, pattern recognition will eventually test for different cancers, as well as other diseases, Simone said. "It will be a major advance in the history of cancer. Heretofore, we've never been able to detect a cancer to make a meaningful difference. We've had the same survival curve since 1930," he said.

"It has many possibilities, not just cancer, but now heart disease and diabetes, any illness" that lends itself to the process, he said. "Finding characteristic protein patterns can alert us to react quicker."

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