

Jill Margo

A new blood test for prostate cancer has become available in Australia. Although not perfect, the test is said to be an improvement on what is currently available. Its primary aim is to help men decide whether to take the next step and have a biopsy.

Since the PSA was approved in the 1990s as the first blood test for prostate cancer, many new markers have been proposed and have fallen away.

This new test, however, comes with an impeccable pedigree. It was devised by William Catalona, professor of urology and director of the clinical prostate cancer program at Northwestern University, Illinois.

Catalona is the father of PSA testing. Although he did not discover PSA, he determined it could be used as a screening tool for prostate cancer.

He directed the research that eventually led the US Food and Drug Administration to approve PSA in 1994 as a test for prostate cancer.

At the time, the test was acknowledged to be flawed but was the best tool available.

Catalona worked assiduously on improving it and in 1997 saw the FDA approve a more accurate version that measured the ratio between free and total PSA.

For the past 10 years he has been working on another refinement which uses a component of free PSA.

This is called phi, the prostate health index. Although it is still being assessed by the FDA, it has been approved for use by Australia's Therapeutics Goods Administration. Laboratories are now gearing up to use it. Until it receives a Medicare rebate it will cost about \$95.

Phi was launched early this month at the Australasian Prostate Cancer Conference. This Melbourne conference, which began 12 years ago as a modest gathering, is now one of the premier prostate cancer conferences in the world.

This year it attracted some of the giants of prostate cancer, including Catalona. He used a baseball analogy to describe phi saying: "It's not a home run. It's a single or a double but it is better than anything else out there."

The original total PSA test can indicate there are problems in the prostate but can't identify what they are.

Blood levels of PSA can rise in response to an infection, a cancer or a benign enlargement of the gland.

At best, total PSA's diagnostic accuracy for cancer is 55 per cent. The free to total test raised this to about 65 per cent. Now, phi lifts it another notch, probably to about 75 per cent.

It does this by measuring an immature form of PSA which it then combines in an algorithm with free PSA and total PSA to determine the probability of cancer being present.

Catalona says it has fewer false positives than existing tests and is more specific for aggressive prostate cancer.

He explains that it preferentially

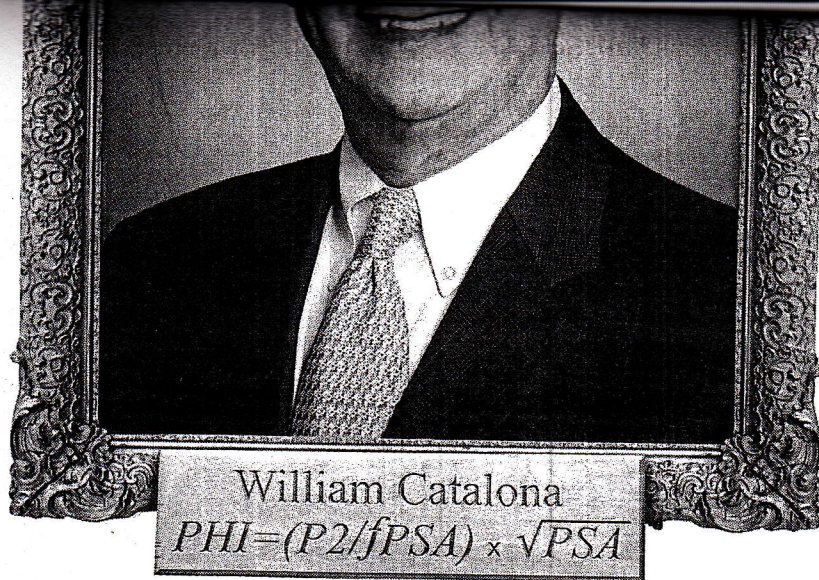


Photo Illustration: KARL HILZINGER

Abstain before taking the plunge

The prostate contracts during ejaculation and this process sends the protein, prostate specific antigen (PSA), into the blood stream.

Pathologist and PSA expert Ken Sikaris says one hour after ejaculation, PSA levels in the blood are increased by 60 per cent.

For this reason, it is advisable not to ejaculate before a PSA test. He recommends abstaining for two days.

As the main component entering the

bloodstream is free PSA, this would affect the free to total ratio and the phi test.

It is also advisable to wait a day after a rectal examination or after participating in sport that puts pressure on the perineum, such as cycling or doing a spin class at the gym.

If your PSA is high and you would like to check it, repeat it in two weeks. If it is normal and you want to double check it, repeat in three months.

detects if the cancer is life-threatening.

Prostate cancer is traditionally graded using a Gleason score with 2 as the least aggressive and 10 the most.

Unlike existing tests, phi can preferentially detect a Gleason 7 or higher which, Catalona says, makes it "significantly superior". This provides clearer information on making a decision about a biopsy.

He explains this with the example of

Multi-drug resistant organisms are making biopsies more dangerous.

William Catalona
Northwestern University

two men in their 50s who walk into his consulting rooms, both having recently received a PSA score of 4. Both then have a phi.

The first man's phi score is 23. This means he has less than a 3 per cent chance of having a potentially life-threatening Gleason 7.

The second man has a phi of 52. This means a 22 per cent chance of Gleason 7, which may incline him towards a biopsy.

Catalona is cautious about performing unnecessary biopsies because multi-drug resistant organisms are making them more dangerous.

"Some men have been exposed to antibiotics, have a biopsy and then develop sepsis because of multi-drug resistant e-coli," he says.

"They end up in intensive care for a month. Biopsies are not trivial things."

In those who have already had a biopsy, he says phi can be used to guide a decision about whether they should opt for active surveillance or for active treatment.

Australia's expert pathologist on PSA, Ken Sikaris, describes phi as another incremental improvement in PSA.

Sikaris, director of chemical pathology at Melbourne Pathology, which is part of Sonic Health, has been working with PSA for 20 years in which time there have been hundreds of new markers proposed.

"None have worked out to be better than PSA, so the best option seems to be improving PSA rather than finding an alternative to it," he says.

Sikaris says the advantage of phi is its measure of a premature form of PSA, which can indicate the presence of cancer more reliably.

"Phi is definitely an improvement but is still not a perfect test so we shouldn't get our hopes too high," he says. "That said, personally I would never have a PSA alone. I would have free to total and if I wanted the best parameter available, I would have phi."

He estimates it will be three weeks before laboratories are ready to process the new test.