



MEDICAL INNOVATION: PROSTATE-SPECIFIC ANTIGEN (PSA) SCREENING TEST (MEDICAL DEVICE: DIAGNOSTIC)

Physician: T. Ming Chu, PhD, DSc

Organization: Roswell Park Cancer Institute, Buffalo, New York

Situation

The equivalent of a death sentence

Prostate cancer is the second most common type of cancer affecting men and stands as the third leading cause of male cancer-related deaths, after lung and colorectal cancer. One in six men will have prostate cancer in their lifetime.

Like most cancers, the earlier prostate cancer is discovered, the better chance patients have of surviving the disease and the lower cost it takes to treat it. That said, scarcely a quarter century ago, the diagnosis of prostate cancer was the equivalent of a death sentence, since only 4% of prostate cancers diagnosed were curable, and there was no easy way to detect the disease in an early state in men. Most were diagnosed with prostate cancer only when it had spread to their bones and caused pain, and the average survival for men with the disease was three years.

Physician-Industry Collaboration

Finding a marker for abnormal prostate function

In the early 1970s, several researchers began to identify proteins in the prostate, and the idea of using these proteins in a test for prostate cancer came to the fore. The problem, though, was that the prostate contains hundreds of proteins, and identifying one that would be a marker for abnormal prostate function was no easy task.

At that time, Taiwan-born T. Ming Chu, PhD, DSc, a researcher at the Roswell Park Cancer Institute (RPCI) in Buffalo, New York, and his team of more than 20 scientists set out to find a protein linked directly with prostate cancer. "From the beginning," said Chu, "we set up the goal of detecting this difficult disease with a simple blood test. It was a challenging task, but we had a critical mass of dedicated researchers, graduate students and technicians."

Working with human prostate tissue from cancer and benign prostatic hyperplasia (non-cancerous enlargement of the prostate), they ran thousands of tests before they finally found what they were looking for, a "prostate-specific antigen," a protein "specific" to the prostate. Then, they had to purify the protein antigen and develop a test to detect that protein in blood, so a simple diagnostic test could be made.

They published their first major paper in 1979 in the Journal of Urology. A patent was issued in 1984 to the state of New York and RPCI. The technology was transferred to the biomedical industry for preparing testing kits. The PSA test received FDA approval in 1986 as a monitor for treatment response and disease recurrence, and in 1994, as a screening aid for diagnosis.



Innovation Benefits

More than 20 million tests annually

Since it was approved, more than one billion PSA tests have been given worldwide, and more than 20 million American men take the test each year. The PSA test has become the centerpiece in the early warning system for prostate cancer, and, as a result the death rate from the disease has dropped significantly.

Now, while one man in six will be diagnosed with prostate cancer during his lifetime, only one man in 35 dies from it. A recent study found that the cost per year of a life saved by prostate cancer screening in the U.S. was between \$3,500 and \$4,500.

Patient Benefits

Keeping on track to accomplish a life-long goal

As described in AdvaMed's [Profiles in Progress You Can See](#), Matt M. loves a challenge, which is why, at age 55, he decided to pursue a life-long ambition to run a marathon. He began training for the Marine Corps Marathon in Washington, DC in March 2005, and was making significant progress. However, just one month later, a routine physical including a PSA revealed some abnormality in his prostate.

His doctor ordered a prostate biopsy – the only means to diagnose prostate cancer with certainty. Using a sonogram to pinpoint the sampling points, the physician took several small tissue samples from his prostate. It was indeed cancer, and although it was caught early, the tumor stood a chance of growing rapidly.

After consulting with several doctors, Matt decided that the best course of action would be a radical prostatectomy, or surgery to remove the entire prostate and some surrounding tissue. The traditional approach to this procedure is invasive and requires lengthy surgery and recovery times. However, since 1999, patients like Matt have benefited from a new option – minimally invasive radical prostatectomy – in which the surgeon uses a robotic surgical tool that allows for greater precision and a much smaller incision, translating into a much shorter procedure and recovery time.

Although it took Matt several weeks to recover, he was back training within two weeks of his surgery. During his first workout after surgery, Matt walked 20 miles without stopping and felt very little discomfort – from the surgery, at least.

Four months after surgery, Matt finished the Marine Corps Marathon alongside two of his four children. “The combination of an early diagnosis and minimally invasive surgery allowed me to accomplish a life-long goal,” he said.