

Cancer device gets OK for more tests

Charlotte company hopes to bring prostate surgery alternative to U.S.

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A Charlotte company that shares ownership of a device used to treat prostate cancer in other countries has received approval to expand testing of the treatment in the United States.

The device, called Sonablate 500, uses high-intensity focused ultrasound (HIFU) as an alternative to surgery.

The treatment is approved in Japan, China and other countries, including most of Europe. But it is still considered experimental for prostate cancer in the United States and can be used here only as part of a clinical trial.

This month, the U.S. Food and Drug Administration approved the Charlotte company's device for use in a Phase III study to determine effectiveness. The study will involve 466 patients at 24 sites, possibly one in Charlotte.

To qualify, patients must be newly diagnosed with early-stage prostate cancer that has not spread from the walnut-sized gland. Half the patients will receive HIFU, and half will receive cryosurgery, which destroys tissue by freezing it.

Patients will be followed for two years, and results could be available in three years, after which FDA approval will be sought.

"This is the last hurdle toward our goal of bringing HIFU to the United States," said Steve Puckett Jr., chief executive of Charlotte-based U.S. HIFU. Puckett, 25, is a recent graduate of Vanderbilt University with a bachelor's degree in history. He has the backing of his father and company founder, Steve Puckett, who also founded two hospital chains, MedCath Corp. and Hospital Partners of America, after working at Carolinas Medical Center in the 1980s.

The younger Puckett became interested in HIFU after meeting Dr. George Suarez, a Miami urologist who had investigated alternative treatments that would be less likely to cause impotence and incontinence.

HIFU delivers focused ultrasound waves to the prostate through a probe inserted into the rectum. A physician at a computer monitor controls the probe, which sends ultrasound waves through the rectal wall to produce intense heat that destroys the targeted cancerous tissue.

Puckett Jr. said HIFU patients recover more quickly than surgical patients, who remain in the hospital for two or three days and take six to eight weeks to recover. "These guys are off the table and two hours later, they're walking around," he said.

Suarez, who helped start U.S. HIFU, is medical director of the company and performs the treatment in other countries.

Several Charlotte-area patients have traveled to Mexico and the Dominican Republic for the treatment, and several local doctors have gone there to learn the technique.

Darrell Bunch, 50, of Fort Mill, S.C., said he chose HIFU even though his urologist recommended radical prostatectomy because he wanted to reduce the risk of becoming incontinent. "I was only 48," Bunch said. "It was a quality-of-life issue."

Since the treatment, his level of PSA (prostate specific antigen) has dropped from 10 to 0.01. "You can't get any lower than that," he said.

"Considering what my options were, I really think I chose the best," Bunch said. "It's a shame that I had to go outside the country. They've been doing this in Europe, Germany and Japan for a long time."

Dr. Chris Teigland, a urologist and researcher at Carolinas Medical Center, spent a weekend in Mexico this spring learning the technique and is negotiating with U.S. HIFU to be part of the Phase III study.

The treatment is "easy on the patients," Teigland said. "One thing that's remarkable is how quickly they bounce back."

Teigland predicted HIFU will be approved for prostate cancer, but whether it becomes the preferred treatment for all patients remains to be seen. "I think it will be a part of the future of treatment choices for patients with prostate cancer. ... We need data to show us how effective it is."

A second clinical trial of HIFU for early-stage prostate cancer is being conducted at Duke University using a second device called Ablatherm HIFU.

HIFU is also approved outside the United States for treating pancreatic, breast, liver and kidney cancer. Charlotte Realtor Barbara Tate died in July while in China, where she had traveled to receive the treatment for pancreatic cancer.

HIFU Clinical Trials

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