

High-intensity focused ultrasound (HIFU) can control prostate cancer with fewer side effects

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Behfar Ehdaie said the new treatment approach is like a "male lumpectomy." Instead of removing all the tissue in a breast or prostate, doctors have learned "it is safe and effective to treat specific areas and greatly reduce the burden on patients.". Credit: Memorial Sloan Kettering Cancer Center

In recent years, a new treatment strategy known as focal therapy (partial gland ablation) has emerged for prostate cancer considered to be "intermediate risk"—mostly, small tumors confined to one area of the prostate. At Memorial Sloan Kettering Cancer Center (MSK), researchers have been working closely with an advanced focal therapy approach known as high-intensity focused ultrasound (HIFU), guided by magnetic resonance imaging (MRI).

Now a landmark clinical trial has demonstrated this less-invasive method works well for many patients. The phase 2 trial, led by MSK urologic cancer surgeon Behfar Ehdaie, looked at a particular type of HIFU treatment, also called MR-guided focused ultrasound (MRgFUS), in men with intermediate-risk cancer. The novel approach effectively controlled the disease in patients and greatly reduced adverse side effects of treatment. This suggests many men with intermediate-risk [prostate cancer](#) can avoid surgery, chemotherapy, and radiation.

"We believe this novel treatment strategy will improve the lives of many prostate cancer patients," Dr. Ehdaie says. "To draw a parallel with how [breast cancer treatment](#) changed 30 years ago, you could think of focal therapy as a 'male lumpectomy.' Instead of removing all the tissue in a breast or prostate, we have learned that it is safe and effective to treat specific areas and greatly reduce the burden on patients."

Results from the clinical trial, published June 14, 2022, in *Lancet Oncology*, represent a major step toward having the new HIFU approach become part of widespread prostate cancer treatment.

When the cancer is confined to the prostate gland, the main treatment options have traditionally included active surveillance (close monitoring), surgery, and radiation. But men who needed surgery or radiation often had persistent side effects, such as urinary and sexual problems, that could reduce quality of life.

"Advancements in prostate cancer over the past two decades have been headlined by successes that have benefited all patients, and now focal therapy provides another exciting area that can move the needle in prostate cancer management," Dr. Ehdaie says.

How does HIFU for prostate cancer work?

The MR-guided focused ultrasound (MRgFUS) is an outpatient treatment that takes about two hours. Patients under anesthesia are placed in an MRI machine that covers the lower half of the body. After the machine takes an image of the prostate, the doctors outline the treatment area and deliver the focused ultrasound waves, guided by the MRI. The ultrasound waves come from different directions, intersecting to attack and kill the cancer by heating the cells to more than 158 °F (70 °C).

"While you are imaging, you are getting temperature feedback as well to make sure the right spots are being treated," Dr. Ehdaie says. "The patient wakes up from the anesthesia and goes home. There's no incisions or wounds on the body to heal. We have demonstrated the procedure is safe for patients, and they can return to normal activity right away."

Prostate cancer HIFU treatment patient success story

John Brannan is one of the success stories. In 2016, when he was 65, his prostate-specific antigen (PSA) began rising steeply. Although prostate cancer is largely not hereditary, he was alarmed because his father, uncle, and two cousins all died from the disease. A doctor in Boston suggested surgery to remove the cancer as soon as possible. But that night at a dinner party, John spoke with two of his wife's friends who had surgery for prostate cancer and discussed some of the side effects

that had persisted. One friend knew about the clinical trial and connected John with MSK medical oncologist Howard Scher, who referred him to Dr. Ehdaie.

John was eager to enroll. "In addition to personal reasons for wanting this treatment, I also hoped to help the next generation who might benefit," he says. "I've seen the effect this disease can have on my own family."

John says the process was easy. Dr. Ehdaie scheduled the MRgFUS treatment in the Center for Image-Guided Interventions at Memorial Hospital in September 2016. John walked out several hours later and went back to the hotel with his wife and had dinner. "It was pretty much back to normal right away," he says. "No cutting, no stiches, no lying in a hospital bed for days or weeks. I wore a catheter for the first 24 hours and was a little tired, but that was it. The treatment was actually less painful than the biopsies I have had."

Making HIFU available for more patients

Dr. Ehdaie says that using MRgFUS for intermediate-risk cancers became possible due to two important developments over the past 15 years. First, there was an acceptance by experts of using active surveillance for low-grade tumors. The second advance was new imaging technology that enabled MRIs to be incorporated into ultrasound treatment.

In the phase 2 clinical trial, 101 men received the novel MRgFUS treatment and then were biopsied six months and 24 months later. There was no intermediate- or higher-risk [cancer](#) left in the treated area for 88% of the patients.

"Probably most important was the lack of side effects," Dr. Ehdaie says.

"Nobody in the study reported urinary incontinence or experienced bowel problems. Most men were able to achieve erections."

Based on this data, the FDA in December 2021 granted approval for the technology, called Exablate Prostate, to treat prostate tissue. The FDA also approved an investigator-initiated trial designed by Dr. Ehdaie and surgeon Peter Scardino to compare MRgFUS focal therapy to [active surveillance](#) and demonstrate a clinical benefit for patients with [prostate cancer](#).

'A new lease on life'

More than five years later, John is still doing well and has avoided surgery and radiation treatment. He has yearly follow-up checkups and periodic surveillance biopsies at MSK to make sure the disease has not returned. Now 70, he lives in Florida with his wife and stays active by buying and renovating properties.

Since his treatment, he has gotten calls from friends and acquaintances all over the country asking how they can get it too. MSK will be offering this novel [treatment](#) to select men and is hoping to launch the phase 3 clinical trial soon as well.

"I feel like I was given a new lease on life, so I'm trying to make the most of it," John says. "It's a phenomenal use of technology, and I think it's going to absolutely take off across the world."

More information: MRI-Guided Focused Ultrasound (MRgFUS) Focal Therapy for Intermediate-Risk Prostate Cancer: A Phase 2b Multicenter Study, *The Lancet* (2022).

Provided by Memorial Sloan Kettering Cancer Center

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