HIGH-INTENSITY FOCUSED ULTRASOUND

Research is ongoing on long-term outcomes

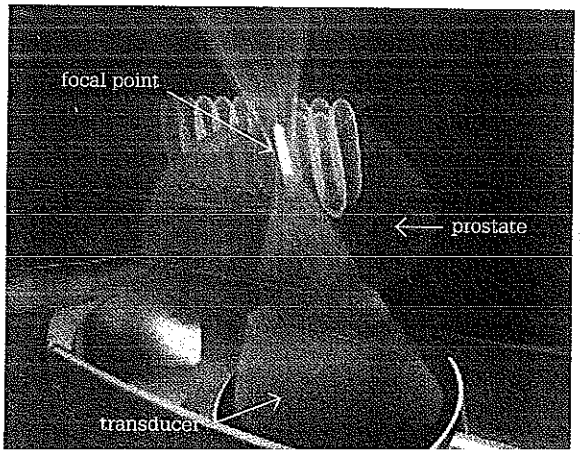
The decision about which prostate cancer treatment to choose depends on many variables, including your PSA level, the stage and grade of your cancer, your age and overall health status. Standard treatments for early-stage, localized prostate cancer include surgery (radical prostatectomy), external beam radiation therapy (EBRT) and brachytherapy (radiation seed implants). Since these generally offer similar outcomes in terms of cancer control, the choice may often come down to personal preference, taking into account side effects and quality of life. Another option for patients who have life expectancy of less than five to 10 years or whose likelihood of disease progression is small may be active surveillance (i.e. choosing not to have any treatment until evidence of higher-risk cancer appears).

Newer treatments include cryosurgery (freezing of the prostate to eliminate the cancer) and high-intensity focused ultrasound (HIFU).

HIFU is now being used extensively to treat localized prostate cancer in Europe, Russia, Japan and other Asian countries. Sanctioned by Health Canada in 2005, it's currently available in private centres in Ontario, Québec and Manitoba. In the United States, HIFU is still under investigation in clinical trials and hasn't received the stamp of approval by the Food and Drug Administration (FDA). Research is ongoing to determine HIFU's long-term effectiveness as well as any lasting side effects.

How HIFU works

HIFU is a highly precise, minimally invasive, image-guided procedure. A probe (transducer) inserted in the rectum focuses high-frequency sound (ultrasound) waves into the prostate, destroying targeted cancer cells by rapidly raising the temperature of the tissue (up to almost 90 degrees Celsius in a few seconds). Clean (non-ionizing) energy ultrasound beams are pulsed systematically into very small zones mapped out in the prostate, until the whole gland has been treated. Cold water circulates around the transducer to cool the rectum and minimize rectal wall heating. HIFU destroys cells at the focal point without harming healthy surrounding tissue.



HIFU is an outpatient procedure that takes two to three hours (depending on the size of the prostate). Spinal or epidural anesthesia is administered with sedation to keep the patient from shifting position during the operation, and most men experience no pain. A catheter is placed in the bladder through a small abdominal incision, and remains in place for two to three weeks or until the patient can urinate on his own. Most men can resume a normal diet and routine almost immediately.

Who's eligible?

HIFU may be an option for men with low- or intermediate-risk disease who aren't interested in or candidates for active surveillance. The cancer must not have spread outside the prostate gland.

Low risk (favourable)

- PSA less than or equal to 10 ng/mL
- Stage T1c–T2a: no nodules felt on DRE, or small nodule in less than half of one side of the prostate
- Gleason score: 6 (3+3)

Intermediate risk

- PSA 10–20 ng/mL
- Stage T2b: larger nodule confined to one lobe
- Gleason score: 7 (3+4 or 4+3)

HIFU may also be used as salvage therapy for patients whose cancer recurs locally after radiation therapy, or as repeat therapy.

Controversies

Like other treatments for prostate cancer, HIFU has both advantages and disadvantages (see HIFU pros and cons). The procedure has been practised for over two decades, but reports on the overall risks and benefits are conflicting. Many practitioners claim excellent results in terms of cancer control with virtually no side effects; others report high failure rates necessitating repeat treatments, with significant morbidity of almost 50%, including incontinence, impotence and uretro-rectal fistula. Lesser risks involve urinary obstruction, infections and catheter-associated issues.

The discrepancies between these findings are likely the result of variations in patient selection, device sophistication, surgery experience and competence (learning curve).

HIFU pros and cons

On the plus side:

- The procedure is minimally invasive (it doesn't involve an incision in the skin) and extremely precise.
- It doesn't involve an overnight hospital stay, and recovery time is short.
- It can be repeated.
- It can be used for radiation treatment failure.
- It doesn't preclude other treatment options if HIFU is unsuccessful.

Disadvantages include:

- More research is needed on HIFU's long-term safety and effectiveness.
- It's difficult to compare it to other standard therapies.
- Not all patients are eligible.
- The procedure is costly (approximately $22,000), and isn't covered by provincial health insurance plans.

Earlier versions of the technology lack some of the more sophisticated safety and monitoring components, which may have contributed to some of the less favourable results. Differences may also be due to the difficulty in monitoring the exact effect of heating on the various components of the prostate and surrounding tissue.

To try to understand the true benefit of HIFU technology, cancer agencies in British Columbia and Ontario have commissioned studies to examine its effects on prostate cancer (see www.bccancer.bc.ca [search under "HIFU"]; www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=47392). The most recent study suggested that HIFU should be considered an "investigational" treatment since it has never been subjected to standard clinical trials comparing it to conventional therapies. As such, it was not recommended as an alternative to conventional treatments of localized prostate cancer.

In a sense, however, all treatments for prostate cancer are "under investigation," as researchers are still evaluating the outcome of even the most established therapies like surgery and radiation.

One proponent's view

Dr. Laurence Klotz is Chief of Urology at the Sunnybrook Health Sciences Centre in Toronto, Ontario, and Professor of Surgery at the University of Toronto. He is one of the partners in Can-Am HIFU, a private clinic that offers HIFU therapy for localized prostate cancer with the Sonablate® 500 system. Can-Am HIFU