

Why some Minnesota men travel abroad for their prostate cancer treatment

By Thomas J Stormont MD

"What do you know about HIFU?" This is the question my patient, 64 year old Gary Urban asked me after I had just discussed how we were going to treat his newly diagnosed prostate cancer. Even though my urologic practice focuses on prostate cancer, after a brief uncomfortable silence, I admitted to Gary that I didn't know a lot. I did understand that HIFU (Hi Intensity Focused Ultrasound) was a minimally invasive treatment for prostate cancer not available in the US. I told him that it was expensive and would require going to Canada, Europe or Mexico, and that it was still considered experimental. I told him some other patients of mine were considering this option, but with no encouragement from me. A couple of weeks later, after more research on his own, Gary informed me he was going to undergo HIFU therapy and didn't want to wait for it to be available in the US. He asked if I would support him on his decision. I was stunned-what was so attractive about this treatment that would compel Minnesota men to swim against the mainstream recommendations of their doctors, travel abroad for a \$25,000 procedure which didn't have a lot of long term supporting data? Up for the challenge, I agreed that I would assist Gary as best I could, help him choose a time and place for treatment, only if it appeared safe and that he was a good candidate. Over the next few months, I was going to find out 1st hand about this new procedure and why Gary, and subsequently 3 other patients of mine, has chosen HIFU for their prostate cancer treatment.

The proponents of HIFU make the procedure look attractive and relatively simple on their website and printed literature. It is portrayed as a 'no touch' procedure that is safe and effective with a rapid recovery which minimizes the bladder and rectal irritation unique to radiation, and the delay in getting back to work and the long term urinary incontinence that plagues radical prostatectomy. Also, it leaves a man with every treatment option afterwards, including repeat HIFU. Probably most intriguing claim is that HIFU may have the lowest rate of erectile dysfunction (ED) of all therapies. While complication and cancer control data are sparsely recorded for HIFU, maturing results from the last 5 years did look promising, and at least it appeared to be relatively safe. One of the devices had more worldwide literature and long term experience, so this led both Gary and I, independently via internet, to the same HIFU center. This center had an attractive and compelling web site, was reasonably close and had a reputable treating urologist and Joint Commission approved treating site. After a discussion with the physician about Gary's prostate cancer specifics, it was determined he was an appropriate candidate. While I remained skeptical I was intrigued enough by the procedure and its claims to accept an invitation from the treating urologist to observe Gary's surgery in Toronto, Canada in the near future.

The first detail that Gary needed to be worked out was financial. The center had a price that covered 2 nights in a hotel next to the treatment center, the treatment itself and the postoperative visit. The total cost needed to be paid upfront; with an understanding there would be a total refund if the procedure was cancelled. He also had to consider the non-financial costs: being away from home, the flight, missing work and the unpleasant thought if the procedure didn't go exactly as prepared, Gary knew the trip could take longer. It helped for him to have his wife along, and to have a local urologic clinic that understood what he was going through and was willing to help him out if he had problems afterwards.

By the time I had arrived, Gary had already been to the center for a day for preoperative testing. The next day, with me observing, Gary received a general anesthetic and lay on his side with after a foley catheter was inserted in his urethra. A probe connected to the HIFU machine was inserted about 6 " into his rectum. Ultrasound images were then used to devise a treatment plan, with care to avoid the rectum and external sphincter. After this, Gary was not touched again until the 1.5 hour procedure was over. The urologist turned his attention to the console, watching and occasionally adjusting the controls. I observed as the focused ultrasound beam swept across the entire prostate, turning the gland essentially

into scar tissue. Impressively, there was very little operator input once the procedure started, as it was directed and monitored by software that controlled the treatment probe, guiding the pulses of energy and accounting for subtle patient movement. Gary was eating and walking within a couple hours of the procedure, with no significant pain or bleeding. The next day he returned to Minnesota, and shortly afterwards his catheter was removed and he returned to full activity within a week or so, his fears of a complication laid to rest. Overall, he described his entire HIFU experience as a 'piece of cake' and he is now 6 months following treatment. He has no bladder or bowel problems and is regaining his sexual functioning. There is no evidence of active prostate cancer, based on stable PSA values near zero.

Prostate cancer is so common that in 2007 approximately 1 in 6 US men have been diagnosed with it. However, it is an especially vexing disease-many tumors grow so slowly they are not life threatening and treatments can be tough on men, thus the decision whether to treat must be dealt with. In fact, for lower risk prostate cancers, watchful waiting (active surveillance) is becoming an increasingly valid option. Also, how to treat can present a medical conundrum, because for many prostate cancers there is often no clearly superior treatment for cancer control, and the different treatments have varying side effects and recovery times. The pressure to treat is enormous, not only from family and friends, but from physicians, device makers and even hospitals, acknowledging the financial incentives that are present. With newer, less invasive treatments especially, there is often significant marketing involved, depending on what urologist, clinic, web site or literature a patient is exposed to. Many claims from these sources are unsubstantiated or misleading, further obfuscating the decision making process. Watchful waiting was not appealing to Gary, so his treatment options included Radical Prostatectomy (open and robotic), radiation (external beam and seeds) and Cryoablation. After research, Gary joined a growing number of men looking for a treatment with less potential harm that still gave him options if it failed. In the past 10 years since HIFU has been used for prostate cancer, the technology has improved and the worldwide experience has matured so that it is now estimated that over 20,000 men have been treated for prostate cancer with HIFU.

Like all of its mainstream counterparts, HIFU has its downsides. Because there are no long term studies (5 year data at best), its cancer control remains invalidated. Probably the most dreaded of all short term complications of all prostate cancer therapies, rectal fistula, fortunately occurs in < 1%, comparable to the other procedures. Regarding ED and urinary incontinence, HIFU may hold an advantage over other treatments, but legitimate comparisons are difficult to make currently. HIFU does require a catheter, usually for days, but sometimes for weeks and there is a significant chance a subsequent TURP may be necessary. Also, there are limitations to the size of the prostate that is treatable with HIFU. Despite these shortcomings, it is estimated that 700 US men will pay for their own healthcare and travel to a foreign country for HIFU prostate cancer treatment in the coming year.

It is remarkable phenomena that so many American men are compelled to seek this non FDA approved therapy at great personal cost, and emphasizes the dilemma that they are faced with. Being diagnosed with any cancer is stressful, but for prostate cancer clear decision making can be particularly difficult, due to the variety of therapies and their side effects, compounded by the marketing trends especially seen with the new minimally invasive treatments. This makes it important for the patient to be wary and adopt a consumerist approach, by gathering information and seeking multiple physician opinions if needed, until a comfort level is reached that all treatment options (including watchful waiting) have been explored. While HIFU internet promotion warrants scrutiny, it is encouraging that it appears to be safe, enjoys a short learning curve and has promising short term results. If eventually FDA approved, HIFU should be covered by insurance and Medicare and will probably be available in the US for the appropriate patient within several years. Until then, except for the rare patient who may qualify for a US clinical trial, HIFU is now only an option for a subgroup of internet familiar, motivated and economically advantaged travelers with newly diagnosed prostate cancer.

THE SCIENCE BEHIND HIFU

HIFU works like "slowly frying an egg with a magnifying glass", using hi powered ultrasound focused at a single point, raising the temperature within seconds to 212F, denaturing protein and melting cellular lipid membranes, while sparing adjacent healthy tissue. Using no incision or needle, a small volume of prostate tissue destruction can be created with an energy pulse from an ultrasound crystal delivered by a thumb sized rectal probe. The ultrasound waves do not damage the rectal wall as it passes through it. Treatment of prostate cancer is accomplished by systematically pulsing energy through the entire prostate at different and overlapping locations, monitored by ultrasound imaging. There are 2 available devices- the Ablatherm (EDAP-TMS, Lyon, France) and the Sonoblate 500 (Focus Surgery, Indianapolis, IN). While the basic physics is similar, there are unique mechanical differences that do slightly affect the treatment, and possibly also the outcome and side effects-this is unclear from the literature as there are no comparison studies between the two devices. Neither device is FDA approved for use in the US, but both are involved in independent phase III clinical trials. FDA approval of one or both devices is anticipated sometime after 2010.