

THE "NEW" PROSTATE CANCER INFOLINK

The Misleading Promotion of HIFU as a Treatment for Prostate Cancer by Sitemaster

We were recently made aware of a video on Facebook promoting high-intensity focused ultrasound (HIFU) as a treatment for prostate cancer. The video promotes the services of a particular group of physicians who specialize in this form of treatment. They are, of course, entirely entitled to do this.

Now your sitemaster wishes to be **very** clear — right up front — that he believes HIFU **may well** be a highly appropriate form of first-line therapy for **some** men with **some** forms of early stage prostate cancer (and it **may** also be an appropriate form of second-line therapy for **some** men with **some** forms of progressive disease after first-line radiation therapy). He is also aware that HIFU can be used appropriately in carefully selected patients as a form of focal therapy for prostate cancer. Indeed, he actively recommends discussion of HIFU with experienced HIFU providers to **some** patients. However, your sitemaster also finds the promotional approach that is being used by the provider group in question to be distasteful, inaccurate, and misleading, and he would caution men considering HIFU as a form treatment for **any** type of prostate cancer to ask **very** hard questions of any provider about reasonable clinical expectations.

Why?

Because here is what is **not** mentioned on the video (although some of the items are mentioned on the provider group's web site):

- There is no clear statement that HIFU has **not** been approved by the FDA for the treatment of prostate cancer. The video does state that HIFU has been approved for the "ablation of prostate tissue", which is accurate. Most newly diagnosed patients will not really understand this careful and important distinction.
- There is no clear statement that the patient will be responsible for many of the costs associated with this form of treatment that are **not** covered by Medicare or by any commercial insurance company.
- There is no clear statement that [current guidelines](#) from the American Urological Association (AUA), the American Society for Radiation Oncology (ASTRO), and the Society for Urologic Oncology (SUO) do **not** recommend HIFU as a treatment for prostate cancer; in fact, these guidelines state very clearly the things that patients should be made aware of about the use of HIFU in the treatment of prostate cancer (see recommendations 56 to 60)

- There is no clear statement that [the same set of guidelines](#) — and the guidelines issued by the National Comprehensive Cancer Network (NCCN) — now state that active surveillance is the most appropriate form of initial management for men with very low-risk disease (see recommendation 7) and is a recommended form of management for men with low-risk disease (see recommendation 8).
- There is no clear statement about the side effects and complications associated with HIFU (used either as a focal or a whole-gland procedure) as a treatment for localized prostate cancer. These complications and side effects are known to have included
 - The necessity for repeat procedures (which the patient would again need to pay many of the costs for, unless there is a clear statement from the provider that he/she will cover all costs associated with such repeat procedures)
 - The occurrence of post-operative urinary tract infections (short-term and recurrent)
 - The need for subsequent endoscopic interventions (for a whole range of possible reasons)
 - The occurrence of [epididymo-orchitis](#)
 - The **very rare** occurrence of recto-urethral fistula (basically, the development of a hole between the urethral and the rectum)
 - The common occurrence of significant loss of erectile function compared to baseline function in men who had good erectile function prior to treatment (although complete erectile dysfunction after HIFU is rare in men who had good erectile function prior to HIFU)
 - The occurrence of some degree of urinary incontinence (i.e., the continued use of urinary pads over time) in a small percentage of men treated by HIFU

The point here is that: (a) HIFU is not always effective as a treatment for prostate cancer and (b) it is not always safe in terms of the risk for complications and side effects. Many carefully selected patients will do very well; others may have real problems. And it is also imperative to appreciate that the men who will do best after treatment with HIFU may well be the men who never really needed treatment in the first place because they would have done just as well (or actually better) on active surveillance.

If HIFU was a drug being promoted by a pharmaceutical company, the manufacturer would be required to provide full details about the complications and adverse effects associated with its use and the manufacturer would be required to provide complete data about the outcomes of the drug in clinical trials. The same is true for the manufacturer of the equipment that this group of providers state that they use in treating men with HIFU. No such information appears in this video or on the provider's web site. Nor are there any data about the outcomes achieved by this particular group of physicians in treatment of men with prostate cancer (although such data are rare for pretty much all physicians treating prostate cancer in any manner whatsoever).

The one thing that The "New" Prostate Cancer InfoLink would definitely praise the provider group for doing is explaining **exactly** what is and what is not covered by Medicare and other

payers in relation to the use of HIFU in the “ablation of prostate tissue” ([see here](#)). The **only** thing that Medicare covers is the actual operational costs of the approved facility (hospital, outpatient facility, etc.) where the procedure takes place (which can **not** be just a physician’s office). Thus, under Medicare, when the HIFU procedure is done at an approved facility, the patient is still responsible for all of the following:

- The time of the physician who performs the HIFU procedure (and the time of any and all associated clinical support staff)
- The time of the anesthesiologist who administers anesthesia (and perhaps a certified and registered nurse anesthetist or CRNA)
- Any and all follow-up patient care and support services post-treatment

As far as your sitemaster is currently aware, almost no commercial insurance provider covers even the facility costs associated with treatment of prostate cancer using HIFU.

The “New” Prostate Cancer InfoLink has long been disturbed by the way that some hospitals and provider groups have gone about the promotion of specific forms of treatment for prostate cancer over the years. (The way that robot-assisted laparoscopic surgery was promoted in the past was particularly sad.) However, he had hoped that, with the coming of understanding that active surveillance is probably the most appropriate form of first-line management for as many as half of all men being diagnosed with prostate cancer in America today, we would see the promotion of specific forms of treatment placed in a more appropriate context and with fuller disclosure of the risks as well as the benefits of each form of treatment. This is particularly the case when the treatment in question has not even been approved for the treatment of prostate cancer!

To learn more about the Prostate Cancer Info Link click on the link below

<https://prostatecancerinfolink.net/site-map/about/>