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## HIFU or HYPE-U? The difficulties of assessing new prostate cancer therapies

According to Dr. Larry Goldenberg, HIFU, or high-intensity focused ultrasound, is a "technology with exciting potential," but, up to now, "there has been a lot of hype and marketing that may be clouding the true potential of HIFU." At CPCN's 2008 National Prostate Cancer Conference, held in Calgary, Dr. Goldenberg used the emergence of HIFU as a treatment for prostate cancer in Canada to unpack some of the difficulties inherent in assessing technological advances in medicine --- and to examine the pressures faced by physicians and their patients when they try to decide how or whether to fit a new technology, drug, or therapy into treatment protocols.



### Limited or short-term efficacy evidence

Goldenberg began by examining the extent of medical knowledge about the efficacy of HIFU as a treatment for prostate cancer. On its website, the NIHR Health Technology Assessment Programme of the UK lists HIFU as one among six interventions for which "conclusions regarding their clinical effectiveness cannot be drawn." Why? The answer is "the paucity and poor quality of evidence identified." The other five interventions are hormonal monotherapy, interstitial microwave thermal therapy (IMTT), transperineal radiofrequency interstitial tumour ablation (RITA), laser photocoagulation, and gene therapy.

One of the largest studies of HIFU technology took place in Europe between 1995 and 2000. It reported in 2003 on the data obtained between 1995 and 1999. (For an abstract of this report, entitled "High-Intensity Focused Ultrasound and Localized Prostate Cancer: Efficacy Results from the European Multicentric Study," click [here](#).) As far as Goldenberg could determine, no data were published since the 2003 publication of the 1999 interim analysis. Why? Questions such as these are important to raise when a person is trying to decide among treatment options.

Another important consideration is that the Canadian importation and sale of HIFU technology was authorized in 2003 under the *Medical Device Regulations of the Food and Drug Act*. Health Canada granted the technology a Class III Medical Device License, which means a rating of "potentially hazardous." (Class I is the lowest risk category, and Class V the highest.) The license was granted because the device met Canadian standards of design, manufacturing, and safety. There was "no reference whatsoever to investigational testing" although there was a listing, not a review, Goldenberg stresses, of public reports addressing effectiveness and safety. "Essentially," Goldenberg quips, "it was licensed on the same grounds as a hairdryer." The important point is that the medical device licensing requirements do not pertain to efficacy so much as to safety.

In a technological review of HIFU's use in the treatment of prostate cancer, Pickles, Goldenberg, and Steinhoff (2005) came to these conclusions:

- "Lack of efficacy data does not allow meaningful assessment as to the benefit/risk ratio of HIFU."
- "It would therefore be inappropriate to offer HIFU as standard therapy for prostate cancer."
- "It could be further explored in a phase1-2 research setting."

When conducting this technology review of HIFU, Goldenberg reports discovering some troubling aspects related to the process, extent, and usefulness of research into HIFU's efficacy. For example, there were no randomized studies comparing HIFU with "gold standard" treatments for prostate cancer. (A randomized study assigns people randomly to separate treatment groups.) Only case-series studies looking at the treatment outcomes of a certain number of men undergoing HIFU treatment were available. "That's okay," Goldenberg explains, "you determine that there is efficacy and safety as a preliminary to going on to a randomized study, which compares it [a new treatment] to the standards of care." Other key points were that

- it was difficult to determine the true numbers of HIFU patients being studied because of the duplicate reporting of patient datasets (e.g., one researcher publishes on 75 patients and a second on 100 patients, so it seems as if 175 men have undergone HIFU therapy but only 100 have because the second researcher has used the first researcher's patient dataset, adding to it only 25 new cases);
- follow-up was either quite short, less than 2 years, on average, or not completely documented;
- technology and protocols kept changing, making comparisons difficult;
- some of the authors did not report conflicts of interest (e.g., they were on the boards of the companies making the HIFU machines); and
- most studies reported mean rather than median follow-up outcomes (e.g., the average cancer-free period after treatment rather than the middle point on a range from the shortest to the longest cancer-free period recorded).

Also, design flaws may have affected the results in some of the studies. Goldenberg argued that HIFU treatment failures, as measured by increases in [prostate-specific antigen \(PSA\)](#), were likely underestimated because some patients were not followed long enough to document rising PSA levels. "Remember the prostate is still in" after HIFU treatment, explains Goldenberg, so the studies used definitions of treatment failure that were developed for radiation therapy, which also leaves the prostate in place. "One of the issues that we had was how can you take a radiation definition of failure and apply it to a procedure that is being touted as an obliterative procedure," Goldenberg remarks.

And what if the procedure fails? At the time of Pickles, Goldenberg, and Steinhoff's review, there was no data whatsoever on what to do if HIFU did not work to stop prostate cancer growth. Should the procedure be repeated? What about operating to remove a prostate after HIFU has failed? What about radiation? Would a man treated with HIFU tolerate secondary therapies?

### **HIFU since 2005**

Since the publication of the HIFU technology review that Goldenberg participated in, there have been many studies investigating how the procedure treats prostate cancer. The current thinking is that the ultrasound waves not only work directly and locally on the tumour but also help stop blood flow to the prostate and cause an anti-tumour immune response at the cellular level. Research has also improved HIFU technology and protocols, making both much safer and more easily tolerated. Still, a new treatment for prostate cancer should be more than safe and tolerable; it should work as well as or better than other treatments. And, as Goldenberg repeats throughout his presentation, "I think this is technology that needs to be further assessed. I think it's great technology; it's got great potential."

One very telling moment of Goldenberg's talk came when he compared the results of two case-series

studies (one from Japan and one from France) with data on the natural progression of untreated prostate cancer. The Japanese study (Uchida et al., 2006) reported a 94 per cent biochemical disease-free survival rate at 3 years for patients with localized prostate cancer whose PSA was 10 or less before they received HIFU treatment. The French study (Poissonnier et al., 2007) estimated a 90 per cent 5-year survival rate for those with a PSA of 4 or less before HIFU treatment. Impressive statistics. But, at 5 years after diagnosis, the survival rate of men with localized prostate cancer who have received *no treatment at all* is very similar. Even at 15 years, most men with low-risk localized prostate cancer are alive, over 80 per cent of them, according to Dr. Peter Albertsen's nomogram. (Visit the [CPCN page on the 2008 conference](#) to view a video of Dr. Goldenberg's presentation.)

### **HIFU today**

If a patient walked into Dr. Goldenberg's office today asking about HIFU, he would not "automatically recommend it." Here is what he would say:

- It is still an emerging technology with exciting potential, but there are also risks of overtreatment.
- The less cancer you have, the more effective this treatment.
- It is still not clear which patients are the best candidates for HIFU and what technology and protocol should be used in specific circumstances.
- Ask very careful questions about some of the new protocols that leave parts of the prostate untreated, either to spare nerves or to lessen the risks of urinary incontinence or blockage.
- It appears that HIFU treatment can be repeated and that it doesn't preclude other treatments either.
- We just don't know whether it is as curative as radical prostatectomy or radiation.
- HIFU may become increasingly useful and effective, for example, as a way of treating only the prostate cancer tumour, once improved imaging technology lets us see the prostate better, or to enhance drug delivery or in the palliation of locally advanced tumours.

"But right now," Goldenberg suggests, "it's buyer beware." And his talk certainly demonstrated a useful way to be wary --- ask questions about studies and statistics offered in support of treatments, consider where the information you collect comes from, and, most important, consult experts you can trust, as well as your own common sense.

### **The new therapies conundrum**

So what should men and their doctors do when promising new drugs or technologies or treatment protocols emerge? Of course, we all want access to the newest and the best therapies for prostate cancer. But what do we do when faced with research that is short-term, non-randomized, sometimes of poor quality or statistically invalid, and offering very limited conclusions? Does a doctor say "Caveat Emptor" or "Primum non Nocere" --- "Buyer Beware" or "First, Do No Harm"?

"This is a moral issue," concludes Goldenberg. "Each of us has different thresholds, moral and ethical, and there are all these pressures brought to bear on us." The medical and pharmaceutical industries promote new devices and drugs, patient advocacy groups push for better or faster access to promising treatments, and the readily available, up-to-the-minute (but sometimes inaccurate) information from the media and Internet seems to focus attention on an exciting "potential cure" every week. Add to these pressures the need to consider the opinions of specialists, colleagues, and the various professional or regulatory bodies in medicine, as well as the necessity of taking into account the level and quality of evidence supporting the use of new therapies, and doctors are often in a tight spot.

But so are men with prostate cancer when it comes to new treatments. Information pours in from books, medical journals, drug companies, private clinics, suppliers of supplements, support groups, television

and radio ads, the Internet, family and friends, and well-meaning but uninformed acquaintances who offer anecdotal evidence that such-and-such will work or so-and-so has found a cure. Of course, the threat of their disease is the main motivator, pushing them, sometimes, to choose a promising therapy without a verified track record because waiting is not an option.

Goldenberg's advice: Find a physician who functions "under the rubric of *the art of medicine*, and call upon common sense to rescue us."

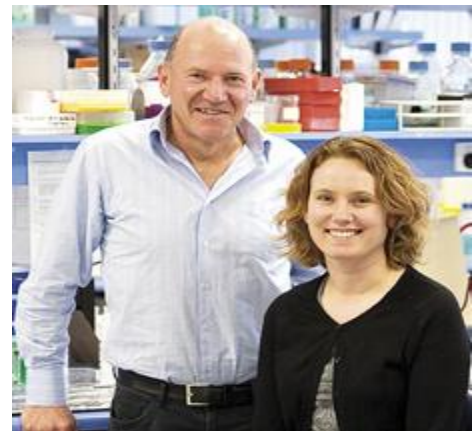
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### New therapy for advanced prostate cancer to be tested in Australia

A new and promising approach to treating advanced prostate cancer will soon be tested on patients in Australia, reported Dr. Wayne Tilley at this year's 4th Pacrim Breast and Prostate Cancer Meeting in Whistler, BC, where he was awarded the meeting's highest honour.

Tilley and colleague Dr. Lisa Butler, researchers at the University of Adelaide, believe that, by combining low doses of bicalutamide (Casodex®) with either 17-AAG or vorinostat, they can expect to treat advanced prostate cancer more effectively and with fewer side effects.



Bicalutamide is an anti-androgen currently used in [hormone therapy](#). It works by preventing testosterone from attaching (binding) to the receptors on the surface of the prostate cancer cells. Without testosterone, the cancer cells either grow more slowly or not at all. Unfortunately, Tilley explains, in spite of an initial response to anti-androgens, cancer cells often develop a resistance to hormone deprivation, and the tumour starts to grow again.

The drug 17-AAG (17-N-allylamino-17-demethoxygeldanamycin) is an anti-tumour antibiotic that has been undergoing phase I/II clinical trials, at least in the United States, since 1999. It works by inhibiting the work of Hsp90, a heat shock protein that acts as a kind of molecular chaperone of other proteins and so plays a supporting role in androgen reception and in the promotion and growth of tumour cells. Recent clinical trials suggest that Hsp90 inhibitors such as 17-AAG re-sensitize cancer cells to drugs to which

they have become resistant.

Vorinostat (suberoylanilide hydroxamic acid) is a drug that inhibits histone deacetylase, an enzyme that plays a key role in the regulation of cell survival, cell growth, and eventual cell death. Consequently, the drug has the potential to affect a tumour's ability to survive. Vorinostat in combination with the chemotherapy drug docetaxel is currently in phase I testing as a treatment for advanced and relapsed prostate cancer. (For information on this clinical trial, click [here](#).)

According to Tilley, bicalutamide and other hormone therapies are currently given at doses that can cause men to experience side effects, such as "reduced libido, impotence, hot flushes, tiredness and sweating, gradual decreases in body hair, reduced bone and muscle strength, and cognitive changes." And 17-AAG and vorinostat, although they block key cancer survival pathways, are "not particularly effective in killing prostate cancer cells if given alone." Combine these difficulties with the more serious possibility that a man's prostate cancer may no longer respond to conventional hormone therapy, and you get an urgent medical research question: Will some combination of drugs work better to combat advanced prostate cancer?

Tilley and Butler think so. They have successfully killed prostate cancer cells in laboratory studies using low doses of bicalutamide and either of the other two drugs. "We can now confirm that a very low level of bicalutamide is capable of inhibiting cancer cell proliferation by more than 10-fold when combined with either vorinostat or 17-AAG, making our current treatments much more effective and causing fewer side effects," reports Butler.

But, of course, the most important tests are yet to come. Dr. Christopher Sweeney, a medical oncologist at the Royal Adelaide Hospital Cancer Centre and its Director of Clinical Trials, will lead a team to examine the efficacy of this combination of drugs outside the lab. "The ultimate test of this exciting laboratory breakthrough is to see if it improves outcomes and quality of life for men suffering from advanced prostate cancer," he emphasizes.

### **Male depression under-diagnosed: Why should men with prostate cancer care?**

Fewer men than women are diagnosed with depression. In developed countries, the ratio is 2:1. But men have a much higher suicide rate than women, four times higher, on average. This discrepancy got John Oliffe and Melanie Phillips, medical researchers from the University of British Columbia, thinking. Perhaps male depression was being under-diagnosed. The researchers collaborated to review the literature on male depression, and their recent article "Men, depression, and masculinities: A review and recommendations" is the result. ([See an abstract of this article](#).)



But why should men with prostate cancer care about the possibility that male depression is under-diagnosed? One answer is that this under-diagnosis probably means there are prostate cancer patients experiencing psychological distress and slipping through the cracks of our mental health care system, men struggling to cope not only with their disease but also with depression.

Besides, prostate cancer is often diagnosed at a time when a man and his partner are experiencing considerable stress as a normal part of daily life. Men 60 to 75 may be coping with many traumatic events:

- retirement, which men sometimes perceive as the loss of identity, status, and workplace friendships;
- aging and its effects on strength, stamina, and overall well-being;
- changes in relationships as a consequence of one partner's declining health, reduced virility or desire, or the need to renegotiate family roles; and
- other more obvious stresses, such as trying to live on a fixed income or taking care of both aged parents and young grandchildren.

Add to these the anxiety of a prostate cancer diagnosis, and depression may result. "It can certainly take the gloss off retirement," Oliffe comments. He adds, "A man undergoing prostate cancer treatment who feels depressed may respond by saying 'I'll get through this myself' or 'I'll just tough it out' rather than by seeking help."

### **But what is depression?**

How do you know whether you should look for help? Depression is usually diagnosed when a person reports experiencing symptoms that persist over two weeks or more. And these symptoms relate to mood, feelings, and behavioural patterns. In other words, there are no open wounds, no blood, no swollen or obviously infected body parts, and often no sharp or persistent pains. Given the considerable research suggesting that men are "strongly reluctant" to consult physicians at all and only "go to their doctor when they're extremely sick," it is not a huge leap to theorize that men may not schedule a visit to talk about their symptoms of depression.

And, according to Oliffe and Phillips, some of the generic criteria used to diagnose depression are "not sensitive to depression in men." The usual symptoms used to diagnose depression are

- A persistent sad or "empty" feeling
- Abrupt changes in appetite or weight
- A loss of interest in activities that you usually enjoy
- Feelings of pessimism, hopelessness, guilt, worthlessness, or helplessness
- Fatigue or decreased energy
- Changes in your normal sleep patterns, e.g., trouble getting to sleep, waking in the night, trouble getting out of bed in the morning
- Confusion or difficulty concentrating, remembering, or making decisions
- Irritability
- Persistent thoughts of suicide or death
- Minor physical discomforts, such as aches and pains, headaches, or an upset stomach

But men and women often manifest depression in different ways, according to the research. Of course, there are many individual and diverse manifestations of depression in both men and women. As Oliffe says, "It is difficult to get at the diversity while pointing at the typical patterns." Still, he continues, "Depression doesn't usually look the same in men as it does in women."

"Men typically arrive in the doctor's office miserable, angry, introverted, and uncommunicative; they don't usually arrive crying or expressing feelings of falling apart," states Oliffe. And research supports this generalization. Although men who are depressed may experience many of the symptoms already listed,

their depression might manifest itself in other ways as well. The symptoms of male depression often include

- Anger and frustration
- Violent behaviour, aggression, or other difficulties controlling impulses
- Alcohol or substance abuse
- Risk-taking behaviours, such as reckless or drunk driving, binge drinking, or having extramarital sex
- Escaping behaviours, such as over-involvement in work or sports
- Isolation from family and friends resulting in impoverished relationships
- Inability or unwillingness to express emotion or a kind of emotional numbness
- Persistent thoughts of suicide

### **Why is male depression under-diagnosed?**

We have already examined, briefly, two reasons for the under-diagnosis of male depression --- doctors can't diagnose illnesses that aren't reported to them, and depression in men may look very different from depression in women. Other factors are at play, however. According to Dr. Don McCreary, co-chair of the Toronto Men's Health Network, "We have inculcated a culture in our society that men have to be tough, men have to be strong. Weakness is not considered to be masculine." Simply put, "real men" don't get depressed, and, if they happened to feel depressed, they would certainly not admit it to anyone or seek help. As Oliffe and Phillips explain, in a much more accurate description of the situation, "Both depression and seeking professional help for depression are not only at odds with masculine ideals, they are also explicitly situated as feminine affliction and action."

This view---that it is somehow not masculine to admit to being ill---has to change so that men can get the help they need and deserve.

### **What about depression and prostate cancer?**

A small but growing body of research suggests that prostate cancer is associated with elevated rates of depression (Bennett & Badger, 2005). Some studies indicate that men generally report high levels of psychological stress about a month before and during the first stages of treatment for prostate cancer but that they report significantly less anxiety and feelings of depression about six months after treatment begins (Korfage et al., 2006). A few studies have found that men undergoing [radiation therapy](#) experience higher rates of depression than men treated by [brachytherapy](#) or [radical prostatectomy](#) (Hervouet et al., 2005). However, some researchers, after examining survey and questionnaire data, conclude that "psychological distress in men with prostate cancer ... is not very high" and that "most of the prostate cancer patients do not need special help from mental health professionals" (Hinz et al., 2008).

Nevertheless, a significant factor to consider is that research results concerning the level of depression or anxiety felt by men with prostate cancer are, of necessity, based on what men *report*. As we have seen, there are reasons for men to avoid reporting feelings that they may consider unmanly. As Oliffe says, "It is a brave person who concludes that men don't need professional help for depression with the male suicide rate what it is." He thinks that "fellas should be more disregarding of the stats" and more in tune with their feelings and experiences.

And prostate cancer, as well as its various treatments and their side effects, may leave men vulnerable to depression. "Men may experience prostate cancer as the first threat to their mortality," Oliffe explains. Fear of recurrence and regret associated with missed opportunities to seek medical help can further complicate men's feelings, as can temporary or more permanent treatment side effects, such as fatigue,

incontinence, or erectile dysfunction.

Men on [hormone therapy](#) should be aware that some research links depression and minor changes in cognitive ability to androgen deprivation. A 2002 pilot study found that 45 men receiving androgen deprivation therapy as a prostate cancer treatment had 8 times the national rate when it came to the prevalence of a major depressive disorder (Pirl et al.). Recently, a report published in the July 28 online edition of *Cancer* concluded that "androgen depletion therapy can potentially have some subtle, adverse cognitive effects," including difficulty in remembering, thinking quickly, or holding several pieces of information in the mind at one time. ([See an abstract of this article.](#))

The answer, of course, is not to avoid the treatment for prostate cancer that you and your doctors decide is optimal for you but *to be aware of the possibility that you might experience depression or other forms of psychological distress and seek help.*

### Getting help

Your family doctor, oncologist, and urologist can be excellent advisors, guiding you to specialists in the treatment of depression. Many men receive help from the counselling services of their cancer centres or clinics. And, even if you live in a small town or in the country, your medical team can usually arrange for you to receive help from counsellors or psychologists in private practice in your area, from programs run by community health agencies, or from local hospital-based social work programs. And don't forget support groups, telecare programs, or employee assistance programs. Often, talking with another man who knows from experience what you are going through is a great first step to getting the help you need.

You may wish to do a little research on the topic of male depression. CPCN recommends the following websites:

[The Canadian Association of Psychosocial Oncology](#)

[The Canadian Mental Health Association](#)

[Men and Depression, National Institutes of Mental Health \(USA\)](#)

[Beyond Blue: The National Depression Initiative \(Australia\)](#)

[Mensheds: Addressing Men's Health, Isolation, Loneliness and Depression \(Australia\)](#)

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## From Switzerland to Aukland and all points in between: The WWPCC in Geneva

"The most important thing was the opportunity to present the credentials of the Worldwide Prostate Cancer Coalition (WWPCC) to a group of international doctors and medical professionals," said CPCN President Bob Shiell about his recent speech to the 20th UICC World Cancer Congress in Geneva, Switzerland. "It was historic," agrees CPCN Executive Director Wally Seeley, "arguably the first time in the history of survivor-professional relations that survivors were invited to participate directly in an international conference of this standing."



The UICC World Cancer Congress has gathered regularly since its inaugural meeting in 1933, which took place in Madrid. Many other nations --- France, Argentina, Russia, Japan, Hungary, Brazil, and India --- have provided the setting for this prestigious conference, which focuses on transforming the latest cancer research and knowledge into strategies that countries, communities, institutions, and individuals can employ to reduce the burden of this disease.

At the 2008 Congress, Bob Shiell and Wally Seeley, respectively the secretary and treasurer of the WWPCC, were part of a session describing the global problem presented by prostate cancer and how "moving forward together" is the only solution, a solution that will point all men with prostate cancer and their loved ones toward "a future of hope." Virgil Simons (United States), Tom Hudson (Ireland), and Barry Young (New Zealand) also took part in the session.

Virgil Simons outlined the global burden of prostate cancer, mentioning that health care costs as a percentage of the GDP were on the rise internationally and that the aging population of many European and North American countries would exacerbate this trend. Tom Hudson described the WWPCC as part of the solution, sketching out the group's "work in progress" and listing its membership. Currently, it has representatives from 29 countries on 5 continents.

But to "unite the world in the battle with prostate cancer" is a great challenge. Information, medical expertise, and other resources are not equally available worldwide. There are discrepancies in drug availability and medical coverage, screening accessibility, and treatment modalities, both within and between countries. Consequently, high-risk patients do not always get the life-saving support they need.

Barry Young and Wally Seeley also commented on the uneven distribution of the resources that are necessary in the fight against prostate cancer. There are whole areas of the world, for example, without any survivor support. And many countries have particular challenges. In Guyana between 2000 and 2004, prostate cancer ranked second when it came to incidence (326 cases), but it had the highest mortality rate of any cancer. Far away in the heart of the South Pacific, there is a different problematic situation. "Cook Islands men are reluctant to talk about health problems, and they are particularly reluctant to talk about a health problem that affects one of their sexual organs," reports Barry Young, who has been instrumental in extending some of the services of the Prostate Cancer Foundation of New Zealand to

these men.

The WWPCC aims to organize survivors in a worldwide response to prostate disease, enlisting the help of global organizations, national and local support networks, medical and public health professionals, and leaders in industry. And it has taken a number of significant steps. As Bob Shiell explains, "WWPCC has brought together the world's best prostate cancer advocates, and, united under the WWPCC banner, we can share information, ideas, visions, and dreams; set goals and priorities and develop action plans; and minimize the impact of prostate diseases in the global community."

As you can imagine, the WWPCC faces some special challenges when it comes to operationalizing these laudable goals. Communication is sometimes difficult. "Our executives are all in different time zones, and New Zealand is a whole day ahead of Calgary," quips Bob Shiell. "Not to mention all the different tax laws" and other regulations governing the incorporation or registration of organizations and support groups.

Still, the WWPCC is moving ahead with establishing its actual and virtual address and building on the partnerships it has already instituted. "To be effective, though, the organization has to go beyond its present borders," says Wally Seeley. And this development is important given the WWPCC's key goals:

- to ensure that men receive the same opportunities for prostate cancer prevention, detection, and treatment regardless of where they live and
- to save as many men's lives as possible.

For more information on the WWPCC session at the 2008 UICC World Cancer Congress, [visit the UICC website](#).