Manitoba Prostate Cancer SUPPORT GROUP

Newsletter

**Vol. 300** 1,300 copies printed/e-mailed **August 2016**

# Focal Therapy for Early Stage Prostate Cancer

**INTRODUCTION:** The progression of clinically localized prostate cancer is usually slower than other cancers, and has confounded the development of a national consensus regarding the optimal treatment for the disease. In addition, most of the observers believe that screening with PSA can result in the over-treatment of prostate cancer. However, the justification for PSA screening and treatment is still accepted by most experts due to the estimated 27,540 death from this disease last year in the United States. Although some prostate cancers are aggressive, the relatively slow growing nature of clinically localized prostate cancer has refuted the current established treatment options for the disease. This argument is supported by the fact that about one third men over 50 years of age will display incidental prostate cancer at autopsy, but only 10 – 16% will develop invasive prostate cancer during their life time, and only 2.5% will die from it.

Current treatment options for prostate cancer (PCa) are either active surveillance or radical intervention treating the entire prostate (surgery, radiation, and others). Radical therapy may maximize the cancer control, but with a certain degree of sexual and urinary complications which may seriously affect quality of life. Active surveillance will not impact a patient's sexual and urinary function, but it can carry the psychological burden of missing the window of opportunity for cure for some men.

This article reviews many forms of novel approaches that are called "focal

*(Continued on page 2)*

## Medical Advisors

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*Thanks!*

**Next meeting:** August 18, 2016
Dr. Eric Saltel, Urologist
**Topic:** Sub-urethral sling option for incontinence.
**Location:** Cindy Klassen Recreation Complex at 999 Sargent Avenue
**Time:** 7:00 General Discussion
8:00 Guest Speaker

SHARING IS CARING SHARING IS CARING

*The Manitoba Prostate Cancer Support Group does not recommend treatment modalities, medications, or physicians.*

**MPCSG – active since 1992.**

*Thought of The Day*

Not to get technical ... but, according to chemistry, alcohol is a solution.

*(Continued from page 1)*

therapy" or "subtotal therapy". The goal of this approach is not only to achieve the same level of cancer control as seen in radical therapy, but also to maintain few or no complications in a selected group of men who have early stage organ-confined disease.

**DEFINITION OF FOCAL THERAPY:**

Focal therapy is a generic term for destroying the tumors only by treating a portion of the prostate, and leaving the prostate gland intact. There is no consensus of opinion on the method of focal therapy. Some researchers treated only areas of known cancer while others have tried to treat the entire one half of the prostate that showed tumor involvement. There was also an attempt to treat the entire gland excluding the neurovascular bundles. Therefore, some advocate the term "subtotal therapy" instead of "focal therapy". But "focal therapy" is the most common term, now spanning over a decade of research.

**The advantages of focal therapy include:**

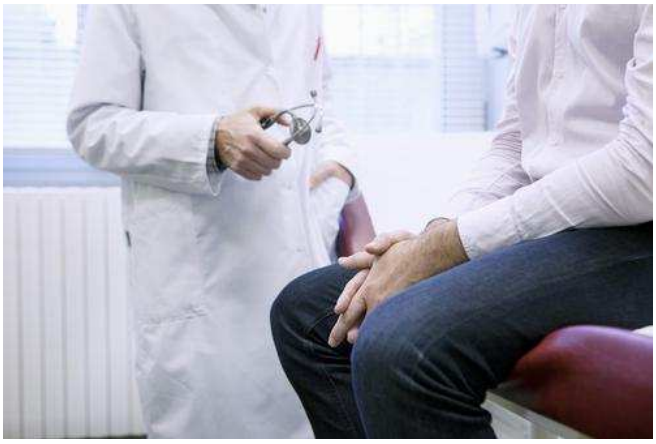
1. It is a minimally invasive procedure using highly accurate imaging to target and destroy only the cancerous tissue within the prostate.
2. The side effects (mainly urinary and sexual dysfunctions) are far less frequent and severe than other conventional therapies.
3. If it fails, other currently available treatment options remain viable. In other words, it will not burn the bridge behind you.
4. It usually performed as an out-patient basis, if not an overnight hospital stay.
5. Recuperation from the procedure is mostly uneventful and quick.

**The disadvantages of focal therapy include:**

1. It is not widely available. The patient may need to travel to find an expert.
2. Parts of the procedure may not be covered by insurance for some men. The patient should ask about cost, insurance, etc.

**TARGETED FOCAL (SUBTOTAL) CRYOABLATION:**

Focal (subtotal) cryotherapy is defined as the less than complete ablation of the prostate gland with freezing or ice. A known tumor site (lobe) is aggressively treated, but the contralateral (opposite side) lobe of prostate tissue and surrounding structures are spared. This method offers targeted local cancer control, while preserving urinary continence and sexual potency for most. In the PSA era, many cancers are detected at an early organ contained stage, and may be confined in one lobe of the prostate. As many as 35% of clinically localized prostate cancers are unifocal and may be candidates for focal therapy. A tumor less than 0.5cc is used as a criterion for low-volume disease; this may not require any type of intervention. Others argue that even tumors smaller than 0.5 cc may be clinically aggressive and may require intervention. It is indeed a burden to identify the proper candidates for focal therapy.



**PATIENT SELECTION FOR FOCAL CRYOABLATION:**

Optimal patient selection criteria are not clearly defined nor agreed upon within the urology field. However, it is essential that the patient have unifocal (1 focus lesion) or unilateral (1 side of gland) prostate cancer. We perform a color Doppler transrectal ultrasound and staging biopsy (in addition to the initial extended blind biopsy that usually was already performed by the patient's physician). Some centers advocate more invasive saturation biopsy to confirm the known tumor site but more importantly to reconfirm the absence of any additional tumor in the other lobe. If an unexpected clinically significant cancer is found in the other lobe by repeated biopsy, the patient is excluded as a candidate for focal therapy. In general, low-risk prostate cancers are preferred but moderate to high-risk cancers in men with medical co-morbidities can also be considered. Only unilaterality, not pre-operative PSA level or tumor differentiation (Gleason grade), are the defining issue. Men with extracapsular extension or seminal vesicle invasion can also have focal therapy.
Focal cryotherapy can also be offered as a salvage therapy (failure after any type of organ preserving treatment, such as radiation, cryotherapy, HIFU, and photodynamic therapy) as long as the recurrent disease is unilateral in location.

**METHODS:**

The cryoablation procedure uses extremely cold temperature (ice) to ablate the tissue. The third generation technology uses argon gas for cooling and helium for warming. It consists of two freeze and thaw cycles after the placement of a urethral warming device. Under general anesthesia or spinal block, cryoprobes are placed

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percutaneously under ultrasound guidance at strategic locations to be frozen. If seminal vesicle invasion is present, it would also be frozen by placing one of the probes in the lumen of the seminal vesicle. Usually 2-4 cryoprobes are used, depending on the size of the lesion and the size of the prostate. A single probe may be placed in the contralateral lobe close to the urethra and external sphincter in case heating is necessary to protect these organs (simultaneous heating and cooling). This can be a useful technique if the prostate gland volume is small. This combination of aggressive freezing at targeted locations within the prostate while maintaining the integrity of the urethra, external sphincter, and contralateral lobe, including the neurovascular bundle, is the premise of focal cryoablation.

Cryotherapy is an outpatient based procedure performed as same day surgery. However, if the patient visits from long distance he will have overnight observation in the hospital and discharged following day with a Foley catheter in place. The catheter is usually removed in 3-5 days.
As a follow up PSA levels should be checked once every three months for one year and every six months thereafter. Biopsy is encouraged at one year, two years, five years, and anytime there is a PSA elevating trend.

**RESULTS:**
Based on multiple publications in the literature, the overall oncologic outcome of focal cryoablation therapy is encouraging. We recently published focal cryotherapy data for clinically unilateral, low-intermediate risk prostate cancer in 73 men with a median follow up of 3.7 years (1-8.5 years). Complete follow up was available in 70 patients. No patient died or developed metastasis. Pre-cryotherapy PSA was 5.9 ng/ml and Gleason score was 6 (n=30) and 7 (n=43). More patients had Gleason 7 (Intermediate risk) than Gleason 6 (Low risk) cancers. Post-cryotherapy mean PSA was 1.6 ng/ml (70% reduction). Of 48 patients undergoing post-cryotherapy biopsy, 36 (75%) had negative biopsies and 12 had positive biopsy for cancer. Reviewing the 12 cases with positive biopsies, 11 cancers were seen in untreated lobe and one in the treated lobe. Complete urinary continence and potency sufficient for intercourse were documented in 100% and 86% of patients, respectively. Matched-pair comparison of focal cryotherapy and robot assisted laparoscopic prostatectomy revealed similar oncologic outcome, defined as needing salvage treatment.

**DISCUSSION:**
Appropriate patient selection and standardized follow-up protocols remain controversial issues in focal therapy for prostate cancer. In our opinion, image visibility of prostate cancer is extremely important for proper patient selection, precise cancer mapping that allows accurate therapeutic targeting. We believe the encouraging oncologic outcomes (cancer responses) of our study were a result of accurate TRUS-based sextant and color Doppler targeted biopsy and mapping.

Follow-up biopsies in the treated side confirmed no evidence of cancer in 98% (47 of 48). Ohori et al reported that the index (primary) lesion typically accounts for 80% of the tumor bulk, with the remaining 20% comprising smaller secondary lesions. Removing or destroying the index tumor might eliminate the possibility of distant metastasis in the future and overall tumor burden by 90%.

Similarly, Villers et al. reported that 80% incidental cancers were <0.5 ml. In our series, the follow-up systemic biopsies from the untreated, contralateral, previously negative lobe revealed newly diagnosed cancers in 11 patients: most were small volume Gleason 6, but two were Gleason 7 = 3+4 and one was Gleason 7 = 4+3. However, 8 of 11 patients elected to undergo active surveillance for these newly diagnosed relatively low risk cancers. Consequently, only 4 (5.7%) of 70 patients underwent salvage treatment. Three patients chose focal cryotherapy and one had radiation therapy. In matched-pair radical prostatectomy series, 6 patients (8.8%) underwent salvage therapy.

Given the potential for cancer mutifocality (more than 1 tumor) and/ or bilaterality (both sides of prostate), as well as potential under-diagnosis at the entry biopsy, follow-up biopsies for the untreated lobe are mandatory. Following focal cryoablation, current PSA criteria have a limited role in predicting local recurrence in the treated lobe or progression in the untreated lobe. It is noteworthy that in our series, even patients with biopsy-proven recurrence had well controlled PSA levels (range: 0 – 1.5ng/ml). In other words, our mandatory post-cryotherapy biopsies revealed cancer before a significant PSA rise. Interestingly, percent decrease of PSA from pre to post-cryotherapy was 70%. Since untreated tissue remained in the contralateral lobe, this 70% PSA decrease after hemi-ablation seems a reasonable benchmark to indicate successful ablation of the index lesion, based on prior data that the index cancer accounts for 80% of entire cancer volume in a given patients.

A major limitation of our study includes the fact that 22 patients (33%) refused follow-up biopsy, mainly due to their negligible post-treatment PSA level (<1 ng/ml).

**CONCLUSION:**
Imaging visibility on scanning is

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necessary to achieve precise cancer mapping. Focal cryotherapy represents a modification of the whole gland approach and appears to offer acceptable oncologic effectiveness with reduced treatment related adverse events. The risk of incomplete eradication of cancer is likely to be small in appropriately selected men. It is precisely those types of patients who are presently confounded by the choice between active surveillance and a more complex whole-gland treatment. There are other competing technologies that can be applied to focal or subtotal therapy. Some of them are not ready for clinical use, but are intriguing. The most important component in any focal therapy is the precise imaging. Without clear identification of the tumor, its location and stage of the disease, focal therapy can be a blind approach with potential for suboptimal outcome.

**Other Competing Focal Ablation Technologies:**

**HIGH INTENSITY FOCUSED ULTRASOUND (HIFU)**

In HIFU, ultrasound beam is focused at a small fixed point to create high power that produces heat ranging from 80 to 100 degrees C. It is proven to be lethal temperatures that will create tissue ablation. It has been applied towards organ-confined, localized prostate cancer treatment as a primary treatment or as salvage therapy (after failed any organ preserving therapy, such as radiation, cryoablation, etc). Recently the help of MRI scan is applied to enhance the targeting the cancer in addition to the ultrasound imaging. It is a quite popular procedure in Europe and Asia. This technology just received the FDA clearance, although patients should still ask about insurance coverage and costs.

HIFU is performed as an outpatient procedure, usually under spinal anesthesia. Real-time ultrasound imaging guidance and/or magnetic resonance guidance is used to position the probe and to monitor the procedure. Pulses of HIFU are directed at the targeted section of the prostate, inducing tumor necrosis.

A few published outcome data show fairly good cancer control and acceptable rates of complications. The study populations in the studies are all small and all had short follow up. One study reported the treatment failure (defined as any positive biopsy and/or need for salvage therapy prompted by rising PSA levels) was observed in 42%. Other studies reported the rates of positive biopsy at 12 months were in the range of 8-23%. The sexual and urinary dysfunction rates are fairly low (< 10%)

**FOCAL BRACHYTHERAPY: LOW-DOSE RATE (LDR) AND HIGH-DOSE RATE (HDR)**

LDR brachytherapy is typically used to treat the entire prostate by implanting permanent radioactive seeds that allow the delivery of high dose radiation to the prostate while limiting the collateral damages. The use of whole-gland brachytherapy for localized prostate cancer has been well established. Focal LDR brachytherapy is to target the cancerous area only in the prostate while sparing the rest of the prostate tissue. It will further reduce the radiation toxicity related complication. It usually performed under transrectal ultrasound guide.

HDR brachytherapy (temporary placement of radioactive material in the prostate) can be also used as a focal therapy modality. There is only limited information in the literature related to the clinical outcome of focal brachytherapy, either as LDR or HDR.

**PHOTODYNAMIC THERAPY (PDT) OR VASCULAR-TARGETED PHOTODYNAMIC THERAPY (VPD)**

This technique describes the destruction of a target tissue via the administration of an inactive, light sensitive agent (photosensitizer) and the local application of light in the presence of oxygen. The photosensitizer absorbs a laser light and transfers this energy to the tissues, creating cell destruction. One recently developed photosensitizer has a tendency of staying within the tumor vascular network. Due to this reason, when PDT is applied, extensive vascular damage is created that leads to tissue necrosis. It is referred to "Vascular-Targeted PDT." One small study of 13 patients who had salvage VPD reported 8/13 biopsies negative at 6 months. Two patients experienced urethro-rectal fistulae. This therapy is not approved for prostate cancer in the US, but there are a few clinical trial sites.

**NANOKNIFE**

NanoKnife technology is known as an Irreversible Electroporation. Instead of using extreme heat or cold, the NanoKnife system uses electrical currents to treat the tumors. The device known as the NanoKnife passes an electrical current through the tumor. The expected electric injury is a creation of permanent nano-meter sized very small holes (pores) in the tumor cells, leading to the death of the cells. Ultrasound or other imaging techniques such as CT or MRI is used to focus the electric current precisely on the tumor. One study in the literature reported about 75% disease free survival at 10 years.

***Source:*** *http://www.paactusa.org/*

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## Timing of ADT in patients with a rising PSA: results of a phase 3 trial.

Androgen-deprivation therapy (ADT) is offered to men with prostate cancer who have a rising PSA after curative therapy or who are considered not suitable for curative treatment. However, the optimal timing for its introduction is uncertain. We aimed to assess whether immediate ADT improves overall survival compared with delayed therapy.

In this randomised, multicentre, phase 3, non-blinded trial, we recruited men through 29 oncology centres in Australia, New Zealand, and **Canada**. Men with prostate cancer were eligible if they had a PSA relapse after previous attempted curative therapy (radiotherapy or surgery, with or without postoperative radiotherapy) or if they were not considered suitable for curative treatment (because of age, comorbidity, or locally advanced disease). The trial closed in 2012 but data collection continued for 18 months until Feb 26, 2014. It is registered with the Australian New Zealand Clinical Trials Registry.

Between Sept 3, 2004, and July 13, 2012, we recruited 293 men (261 with PSA relapse and 32 with non-curable disease). 142 men were assigned to the immediate therapy arm and 151 to the delayed therapy arm. 16 (11%) men died in the immediate therapy arm and 30 (20%) died in the delayed therapy arm.

5-year overall survival was 91% in the immediate therapy arm vs 86% in the delayed therapy arm. The most common serious adverse events were cardiovascular, which occurred in 13 (9%) in the immediate therapy arm vs 9 (6%) patients in the delayed therapy arm.

Immediate receipt of androgen-deprivation therapy significantly improved overall survival compared with delayed intervention in men with PSA-relapsed or non-curable prostate cancer. The results provide benchmark evidence of survival rates and morbidity to discuss with men when considering their treatment options.

Australian National Health and Medical Research Council and Cancer Councils, The Royal Australian and New Zealand College of Radiologists, Mayne Pharma Australia.

***Source:*** *The Lancet. May 2016.*

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# Immunotherapy for Prostate Cancer

Immunotherapy is a promising treatment for prostate cancer, including advanced or recurrent forms of the disease. Your care team at CTCA uses a variety of immune-based strategies to eliminate a prostate cancer tumor and prevent its recurrence.

This treatment method may be used alone or in conjunction with other treatments, such as radiation therapy and hormone therapy.

**Provenge**

Provenge is an FDA-approved immunotherapy treatment for prostate cancer that harnesses the power of the patient's own immune system to identify and target prostate cancer cells. This is also known as autologous cellular immunotherapy. The immune system is made up of immune cells that are found in your own blood. These cells work as the body's natural defense against all types of illness, including prostate cancer.

Since Provenge is an immunotherapy treatment that helps the immune system fight disease, each dose is made specifically for each patient. The personalized dose of Provenge consists of the patient's own immune cells that have been trained to seek and attack prostate cancer cells. By stimulating the natural ability of immune cells already in the blood, Provenge may improve a patient's prognosis.

**What types of prostate cancer does Provenge immunotherapy treat?**

- Asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer
- Patients cannot have moderate to severe prostate cancer pain (or be on narcotics for cancer-related pain)
- Metastases must be limited to bone or soft tissue only (no lung, liver or brain metastases)
- Patients cannot have had chemotherapy in the previous three months
- The patient must be able to perform tasks necessary for daily living

Provenge immunotherapy treatment typically takes six weeks, and is administered in three infusions every two weeks.

**What is immunotherapy?**

Immunotherapy is a broad category of anti-cancer therapies that use the body's immune system to fight cancer cells. These cells are different from normal cells, in that they do not die normally. Think of these rapidly-dividing cells like an out-of-control copy machine that won't stop creating images. These abnormal cells frequently change, or "mutate," to evade the immune system. Immunotherapy drugs are designed to alert the immune system about these mutated cells so it can locate and destroy them.

**How does immunotherapy spark the immune system to help fight cancer?**

The immune system is always on patrol, like a police force charged with ridding the body of foreign invaders, such as viruses, bacteria or fungi. Lymph nodes, which make up most of the immune system, serve as police stations throughout the body. White blood cells, such as "T cells," fight infection and cancer. They are the police officers. When a foreign invader is detected, the entire immune system is alerted through chemical signals, just as a police station would radio police officers to alert them about a problem.

Cancer cells are not recognized as invaders because they are the body's own cells, only they've mutated and changed so that once-healthy lung cells no longer behave like lung cells. The immune system doesn't recognize this distinction, allowing these dangerous cells to grow, divide and spread throughout the body. One way cancerous cells stay hidden is through the PD-1 receptor, which tricks the body's police force into thinking cancer cells are normal. Certain immunotherapy drugs work by blocking this evasive maneuver with a PD-1 inhibitor, which quiets the PD-1 receptor, allowing the cancer cells to be exposed as invaders, and triggering the immune system to send out an alert and launch a system-wide attack.

**Experienced care team**

With our team approach to care, our doctors and clinicians work together to come up with treatment options that meet your needs. Immunotherapy may be an option for you if you have breast, prostate, brain, kidney or spinal cancer, along with non-Hodgkin lymphoma, leukemia or melanoma. The treatment may work better for some cancers, so your doctor would monitor your progress closely and may pair immunotherapy with other treatments.

**Personalized treatment approach**

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Patients and their caregivers are the ones who ultimately decide which treatment they want to pursue. Our clinicians are sensitive to your concerns and work to design treatment options that are appropriate for your needs and goals. We will provide you with the information you need to make an informed decision about immunotherapy.

**Managing side effects**

Immunotherapy can cause a variety of side effects, including fatigue, nausea, mouth sores, diarrhea, high blood pressure and fluid buildup, usually in the legs. Breast cancer patients, in particular, may experience fever, chills, pain, weakness, vomiting, headaches and rashes. The side effects of immunotherapy generally become less severe after the first treatment. Throughout your treatment, your care team will provide integrative oncology services, including nutrition therapy, naturopathic medicine, pain management, oncology rehabilitation, mind-body medicine and spiritual support. These therapies can help reduce side effects and improve your overall quality of life during immunotherapy.

*Source: Cancer treatment centres of America www.cancercentre.com*

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## What is a "PSA bounce?"

**I had brachytherapy to treat my prostate cancer and my PSA had dropped to 0.3 ng/ml. But six months ago, my PSA had gone up to 0.5, and now it's up to 0.8 ng/ml. I'm worried that the cancer is back; my doctor said it could be a "PSA bounce." What's that?**

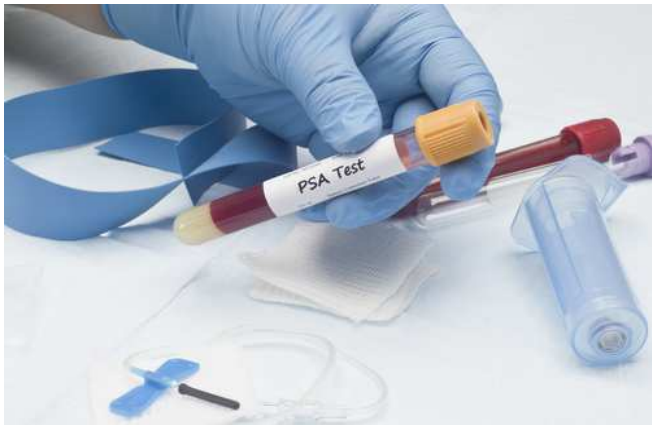
*William C. DeWolf, M.D., Chief of the Division of Urology at Beth Israel Deaconess Medical Center, answers:*

Your concern is understandable. The last thing a prostate cancer patient wants to hear after treatment is that his prostate-specific antigen (PSA) level is on the rise!

However, as your doctor points out, you may be experiencing nothing more than a temporary, benign rise in PSA, a phenomenon often called a PSA bounce, spike, or bump. It's defined as an increase in PSA of 0.1 to 0.5 ng/ml — or a rise in PSA of 15% or greater over the prebounce level — followed by a quick drop to prebounce levels without treatment.

As many as one-third of men who choose brachytherapy, or seed therapy, to treat their prostate cancer may experience this transient rise in PSA, usually about 18 to 24 months after the seeds are implanted. In one study, approximately 12% of men who underwent treatment with external beam radiation therapy were reported to have a PSA bounce about nine months after treatment, on average.

Doctors aren't sure what causes a PSA bounce, though several theories exist.




Studies have shown an association between recent ejaculation and higher PSA levels, for example, as well as proctitis (inflammation of the rectum) and the insertion of a catheter. Age and radiation dose may play a role as well. There can also be variability among laboratories in determining PSA levels. Another theory is that a patient may be experiencing a late reaction to the radiation, such as radiation prostatitis.

The challenge for clinicians is to determine whether the rising PSA represents a bounce or cancer progression. With radiation, treatment is generally not considered a failure until a patient experiences three consecutive increases in PSA; you've had two. Another definition of treatment failure following radiation is an increase of 2 ng/ml over the PSA nadir, or low point, at any time. For you, that would mean a PSA of 2.3 ng/ml.

Not knowing whether your cancer is advancing can certainly be a tremendous source of anxiety. But your physician probably wants to wait to see what your PSA level is in six months, especially since it's still relatively low. Armed with more information, he or she will be able to make a better recommendation about treatment — or reassure you that the rise in PSA was indeed nothing more than a bump in the road.

SOURCE: Satoh T, Ishiyama H, Matsumoto K, et al. Prostate-Specific Antigen "Bounce" After Permanent 125I-Implant Brachytherapy in Japanese Men: A Multi-Institutional Pooled Analysis. *BJU International* 2009;103:1064–68. PMID: 19040526.

***Source:*** *http://www.harvardprostateknowledge.org/what-is-a-psa-bounce*

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## 2016 MEETINGS

**August 18** Dr. Eric Saltel, Urologist
**Topic:** Sub-urethral sling option for urinary incontinence

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The September meeting will be held at the Caboto Centre at 1055 Wilkes Avenue
**Sept. 15 Prostate Cancer Awareness Evening**
**Presenters:** Dr. D. Drachenberg & Dr. M. Kristjanson
**Topic:** General overview of prostate cancer & treatments

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**Oct. 20** Dr. Timothy Hiebert, Internist/Geriatrician
**Topic:** WRHA Palliative Care Program
**Nov. 17** Party Time with musician Kirk Leavesley
Pizza, Cookies, Coffee and Conversation
Dec. No Meeting. No Newsletter.

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All meetings (except September) will be held at our new location: Cindy Klassen Recreation Complex at 999 Sargent Avenue
All meetings are 7 – 9 pm. *Everyone Welcome*

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