Focal Therapy – Brief Overview and Focal Cryo Experience at PIOA

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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 (PC) 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 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.

Dr Bahn has been targeting prostate cancer with color Doppler ultrasound for almost 2 decades.

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. (See Table 1)

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 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. (See Figure 1) 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. (See Figure 1)
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 (See Table 1.), 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).

TABLE 1 - FOCAL CRYO PUBLICATIONS

Author	Onik	Bahn	Lambert	Ellis	*Ward
n=No of Patients	(n=48)	(n=73)	(n=25)	(n=60)	(n=1160)
Average age	n/a	64	68	69	68
Average Follow up Years	4.5	3.7	2.3	1.3	1.8
Gleason: No. of patients (%)	n/a	6: 30 (41) 7: 43 (59)	6: 13 (52) 7: 12 (48)	<7: 47 (78) 7: 12 (20) >7: 1 (2)	<7: 844 (74) 7: 240 (21) >7: 64 (6)
Clinical Stage: No. of patients (%)	n/a	T1c: 41 (56) T2a: 31 (43) T2b: 1 (1)	T1c: 25 (100)	T2a: 55 (92) T2b: 5 (8)	T2a: 1013 (87) T2b: 147 (13)
Stable PSA (%)	94	85	85	80.4	75
Incontinence (%)	0	0	0	3.6	1.6
Potency Maintained (%)	90	86	71	71	58

*Data from CCLD registry

CONCLUSION:
Imaging visibility on scanning is 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.

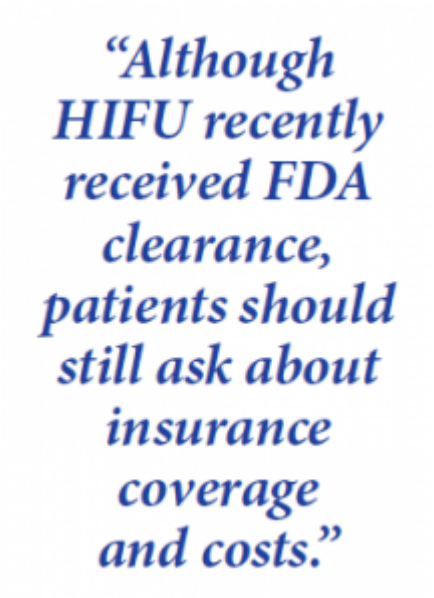
Other Competing Focal Ablation Technologies

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.

SUGGESTED READING

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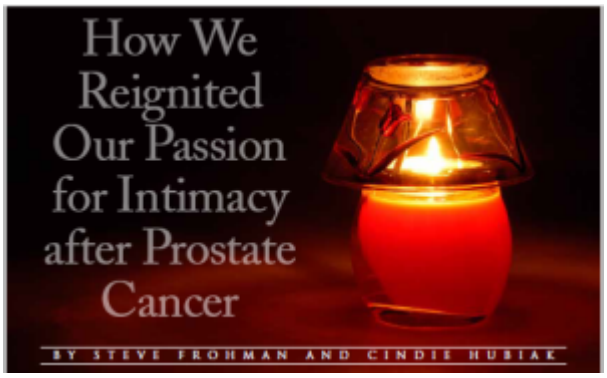
How We Reignited Our Passion for Intimacy after Prostate

Cancer – Steve Frohman and Cindie Hubiak, 2012



Steve

One in six men in America today is affected by prostate cancer. According to the American Cancer Society, more than two million men living in the United States have been diagnosed with prostate cancer at some point in their life. I am one of those.

Women are impacted by prostate cancer at an exponential rate. After all, most men relate to more than one woman. In addition to being a husband/lover, men connect to women as fathers, brothers, uncles, colleagues and friends. Almost every woman could tell you a story about a man in her life
diagnosed with prostate cancer. I am one of those stories.

Cindie
Steve and I learned early on that the survival rate from prostate cancer is extremely high, which we found comforting. We also learned that even with the latest nerve-sparing surgery techniques or the most accurate delivery of radiation treatment, there was a high possibility that Steve's physical ability to engage in an intimate relationship

would be negatively impacted, at least to some degree.

Our journey from just surviving cancer to living a sexually fulfilled life was full of challenges we didn't anticipate.

Many of the physical aspects we enjoyed in our relationship disappeared after Steve's prostate was removed. This negatively impacted our entire relationship, until we learned to look at sex in a whole new way.

At first, Steve and I focused on all the traditional medical solutions with little success. The breakthrough came when we were able to better define the problem as a lack of intimacy and sexual fulfillment. We expanded the "playing field" and created dozens of solutions for intimacy.

It didn't start that way though. We took many wrong turns and lived in survival mode longer than needed. Soon after Steve's diagnosis, he withdrew. Using a laser-like focus, he researched his options to remove the cancer from his body. I didn't know how to reach him, and his distance caused me to withdraw from the relationship as well.

As we reflect back, we see how we approached Steve's diagnosis and our less than satisfying sex life from our own unique perspectives. In the beginning Steve and I didn't fully appreciate how men and women approach and solve problems in different ways.

We were also very good at avoidance, a common human trait. Too often it was easier to ignore our lack of intimacy rather than address it. We found ourselves growing apart because of the cancer
diagnosis and treatment, rather than allowing the experience to bring us closer together. Based on conversations with other men and women impacted by prostate cancer, this happens frequently.

Fortunately, Steve and I kept exploring ways to improve our intimacy until we found what worked. I didn't want to be like a woman I had met who had divorced after 16 years of marriage because of the isolation and lack of sexual fulfillment in her marriage. Our individual stories follow, along with five tips for reigniting passion for intimacy after prostate cancer.

Steve's Story
It was May of 2007, early on a Friday evening at the Jefferson Hotel in Richmond, Virginia. The mood of the group was festive as we were celebrating the retirement of a business associate.

I felt apprehension, as it was still late afternoon in Phoenix. I nervously anticipated a phone call from my urologist with my latest biopsy results. This was my third biopsy over a 15-year period. I had a history of an enlarged prostate and high PSA score ever since my first PSA test in my mid 40's. When my cell phone vibrated, I quickly stepped into the ballroom foyer to take the call.

Dr. Bans let me know that the results of the biopsy were positive, indicating cancer had been found. Although

no cancer is good, he explained that my cancer was a less aggressive form. This meant there was time to evaluate and select the best treatment method for my situation. I know he intended this information to be somewhat comforting, and it was, in a small way; though the fact
still remained…I had cancer.

Over the next few weeks and months, I worked closely with Dr. Bans, Cindie and a close friend to put a plan in place. I wanted to further understand and evaluate my situation, select a treatment option and undergo treatment. I ultimately selected surgery, and my prostate was removed six months later.

I asked Cindie to keep my diagnosis private. She resisted, but I insisted. I'm a private person and didn't want anyone to know. I didn't realize, at the time, how painful she would find this seemingly
simple request. I wasn't overly interested in sex after treatment. I'm embarrassed to say I just ignored our lack of intimacy. We lived a busy life and everything seemed okay. What I didn't realize is that we were drifting apart and living more like roommates. I also didn't realize how unhappy Cindie had become.

Cindie's Story

I didn't engage a great deal in Steve's search for treatment options. He answered my questions, I went to San Francisco with him for a second opinion and I met his surgeon once before the surgery. Early attempts to engage more with Steve didn't work. He seemed to prefer to handle the situation alone, so I gave up and went on with my life.

Initially we focused on Steve’s recovery, ignoring my growing unhappiness. After all, I didn’t have cancer and my body hadn’t undergone an intense surgical procedure. Although, after several quarterly zero PSA tests, I still found myself struggling in a relationship that didn’t work for me.

Steve’s diagnosis and treatment impacted me physically, emotionally and spiritually. I didn’t like myself after Steve’s recovery. I didn’t feel desired as a woman and my self confidence plummeted. Steve wasn’t interested in sex; something we learned later that is quite common in men treated for prostate cancer.

Eventually, I discovered that I had to address my issues if I wanted to find happiness. I would have to take the lead if I wanted to save our marriage. When I began to take responsibility for my situation and stopped blaming Steve, our relationship improved. When I got over feeling sorry for
myself and settling for an unhappy marriage, I discovered ways to take the initiative to create a life where Steve and I looked at sex differently than we did before prostate cancer.

Steve – Reigniting Our Passion for Intimacy
When Cindie and I began looking for ways to increase our intimacy, we started by defining sexual fulfillment. My definition included emotional closeness, physical intimacy and mental intensity. I used words like trust, passion, vulnerability, oneness and excitement.

Cindie used a technique called circle drawing to uncover her definition of sexual fulfillment. She discovered sexual fulfillment meant aliveness, freedom, becoming one with God and an opportunity to get to know herself better.

Cindie and I didn’t possess the skills necessary to reach sexual fulfillment, so we sought outside assistance. Cindie started an intensive study of men, improving her ability to communicate with me in order to get her needs met. We both uncovered destructive childhood patterns that required breaking.

We spent time with a tantrika, a woman who honors the beauty and fullness of sexuality and uses her knowledge to assist others. We learned how to move energy, the importance of slowing down and the necessity of scheduling time for intimacy.
Cindie and I also realized we each needed to go through a grieving process before we could completely heal and experience sexual fulfillment. We talked about our own mortality; the elephant in the room cloaked with our unspoken fears about death and being alone.

As we got to know ourselves better and took responsibility for ourselves—voila—we achieved sexual fulfillment and saved our marriage. Today we live a thriving life, filled with appreciation from our prostate cancer journey that brought us closer together than we had ever imagined. We followed
five steps to reignite the passion in our life and in our relationship:

• Grieve. Anyone impacted by prostate cancer experiences immense change. Change means loss, which goes hand in hand with grief. You need to go through the process of the five commonly accepted stages of grief: anger, denial, bargaining, depression and acceptance. Then go through the process of these emotions again. Your experience will be unique. You may skip a stage or bounce backand- forth between several stages. Cindie and I live in the acceptance stage most of the time, assisting each other to grieve more when needed.

• Explore different solutions. Rely on a combination of resources, both traditional and non-traditional, to achieve a fulfilling sex life. Traditional resources include your urologist, other medical professionals and the use of pharmaceuticals. Non-traditional resources include a naturopathic physician, a psychologist, a hypnotherapist, a tantrika and a chiropractor. By balancing the benefits of high-technology Western medicine with the practices of a more holistic approach, Cindie and I ultimately achieved a more fulfilling relationship than we had ever imagined.

• Define and devote time to intimacy. Too often couples define intimacy as achieving a physical destination, i.e. an orgasm. Explore how you can broaden that definition. Learn how to look at your intimate relationship as a journey, one without a destination. You can do this best by scheduling intimate time together each week. Get to know each other's bodies without an expectation of
orgasm. Use all five senses during your intimate time and slow down. Christie and I amazed ourselves at the increased levels of pleasure we experienced simply by slowing down and expanding our awareness.

• Excellent communications. You achieve high levels of intimacy results when you, as partners, share feelings rather than thoughts. Learn what makes a safe environment for each

other to make sure feelings are shared easily. Recognize the different communication styles of men and women. When I learned to just listen to Cindie without fixing the problem, she relaxed and felt closer to me. When Cindie learned to get my attention and make requests using a specific formula, I began to
meet her needs every time.

• Believe in a thriving life. Know that you can do it. Commit to taking the journey. Be open to experiment. If you want a different result you must take a different action. You'll find things that don't work for you as a couple, stop doing them. You'll also find things that do work for you in your relationship, so make sure you do those things more often. By doing this you'll be creating the journey of a lifetime. Let Cindie and I know what works for you. Today, we celebrate Steve living cancer-free for more than four years. We also celebrate living a sexually fulfilled life.

Steve Frohman and Cindie Hubiak, co-founded Solutions For Intimacy™ to help men, women and couples get to the root of their intimacy struggles and enable them to live a sexually fulfilled life after prostate cancer. The program's cornerstone – The Personal Approach – addresses the physical, emotional and spiritual aspects of intimacy.

Cindie recently published a book titled "A Woman's Guide to Thriving after Prostate Cancer." It helps women and men gain new ideas, understanding and skills from her journey through what's typically considered a man's disease.

They can be reached at 480-607-6850 or www.SolutionsForIntimacy.com.

The Importance of Belonging to a Support Group, Gene Van Vleet, COO, IPCSC, San Diego CA, 2011

Following the recent consternation provoked by the recommendation of the U.S. Preventive Services Task Force (USPSTF) panel to discontinue PSA testing, it is fitting that we address the benefits provided by support groups in dealing with Prostate Cancer.

Commonly a man visits his general practitioner on an annual basis for a general physical. This can include **bloodwork that includes a PSA test and a digital rectal exam (DRE). Make sure you keep a log of your results.** Too often the patient is not informed of the results, but rather is informed "everything is OK." If the PSA test and/or the DRE is of concern to the physician the patient is referred to an urologist for further diagnosis. All too often the next step is a biopsy. Once a biopsy is performed, the roller coaster of treatment options begins. WAIT A MINUTE!!! What is missing here? Patient knowledge and understanding!

As principal of a highly active support group it is my experience that I am most commonly contacted by patients either after a biopsy or after a relapse following treatment. I can help fill the knowledge gap and **lead men to information with which they can learn to be their own case managers rather than be reliant on physicians' recommendations.** I am by no means a medical professional but I have the knowledge of collective experience to aid men through the confusion of

dealing with our troublesome disease. Further, I bring specialists in dealing with our disease to our group meetings to keep us informed of the latest developments without the restrictions of learning and protocol too often suffered within the medical community.

Let us begin with the myth of the PSA test. It was never intended to be utilized as an indicator of the seriousness of the cancer. Its best value is as a marker to monitor elevation over time. Concerns should develop if the score doubles within a year. Simple logic must be used if the score begins rising. It could be because of an ancillary infection. It could be because the test was performed by a different laboratory. It could be because of strenuous exercise prior to the test. One should first verify the test before proceeding. If the PSA is proved to be validly escalating, be real careful about the usual next step—Biopsy.

There has been significant progress lately in prostate imaging that can analyze the condition of the prostate BEFORE an invasive biopsy is performed. Should such imaging indicate the need, a biopsy can then be performed aided by that imaging. Please, no more random biopsies that may miss the troublesome area! Where do you get these tests? Your support group is a good place to find where such imaging is available in your area.

If you have reached the stage of having a biopsy performed, a Gleason score results, which has been the landmark for determining the seriousness of the cancer. Other tests are arising and being validated that can assist in this determination as well. Your support group will likely know their status or can lead you to sources that will know.

We hear too often of cases where a patient is given treatment without a complete medical check-up. Pity the poor man who saw his urologist because his PSA was rising rapidly. He was given a hormone injection and consequently suffered

atrial fibrillation and, later, a mild stroke. His physician failed to check his overall physical condition. Incomplete medical training associated with proper health investigation before treatment can be a problem.

Once a Gleason score is rendered, too often treatment is implemented before a thorough understanding of the possible effects on the patient's life are achieved. Surgery? Radiation? Cryoablation? HIFU? Hormone Therapy? et al. What a maze of possibilities exist. Get involved with your support group and benefit from their knowledge and experience.

We think one of the major oversights in treatment possibilities is no treatment at all or Active Surveillance (often called Watchful Waiting). Dr. Duke Bahn has quantified those tests that can be monitored by a patient over time in concert with his doctor without undergoing invasive treatment (see PAACT article in March, 2011 issue). An important element of this choice is the mental capacity to overcome a man's natural urge to do something to "cure" the disease. Be careful of that word. When someone uses it, make them define to you what they mean. It might be that they consider you "cured" if you don't experience signs over a much shorter time span than you expect.

If you are faced with making a treatment choice, be sure you develop an understanding of the possible side effects of the chosen treatment. Another unfortunate issue in dealing with prostate cancer is that it is difficult to predict how a patient will react to the treatment. Your physician may cite percentages of success, but there is yet no way to ensure what your experience will be. Be sure to check the experience of the doctor treating you. The most experienced doctor will achieve the best results. And, for sure, seek second opinions from unassociated doctors. This can be difficult because of insurance coverage limitations, but it will be in your best interest. Remember, you are your own case manager. Have confidence that unless you are diagnosed at a late stage the

disease is generally slow moving. You have time to assess your treatment possibilities before committing.

Stay involved with your support group. You will find comfort in networking with others to help them as you are being helped. The natural tendency is to be involved through treatment and then disengage. There is value in continuing to stay involved to learn of advances in diagnosis and treatment. It keeps you aware of monitoring your own condition. Too many of the newcomers to our group are experiencing recurrence. Staying abreast of your condition and what is developing in the treatment of the disease will surely give you the opportunity to deal with it successfully. Remember, YOU CAN LIVE WITH PROSTATE CANCER!

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ProstVac for Newly Diagnosed or AS Patients? Check this out….

By Jan Manarite, VP of Advocacy & Education

This has to be one of the most *interesting* clinical trials I've seen for prostate cancer patients in a long time. This trial is for men who have **low risk or intermediate risk prostate cancer**, and are on **Active Surveillance** (AS), or **Newly Diagnosed,** and **have not had treatment yet.**

This trial offers the **immunotherapy ProstVac** to these patients, who would otherwise have no access to it at all.

Remember that most immunotherapy treatments have very few side effects. One of the most common side effects with ProstVac, for example, is irritation at the injection site and short term nausea or fatigue. (Ref, Ref)

Here are some of the benefits of this trial:

- ProstVac is NOT FDA Approved yet, so it is unavailable anywhere, except in a clinical trial like this one.
- If and when ProstVac receives FDA Approval, it will be for men who are advanced prostate cancer patients, not AS, or low risk. So it will still be unavailable for these men, except in a clinical trial like this one.
- There are VERY FEW clinical trials with immunotherapy for men on AS. For me – I have never seen one before.
- ProstVac is in the same class of drugs as PROVENGE, called immunotherapy. It does not have a lot of side effects usually, but is intended to boost your own immune system.
- There is placebo in this trial, but 2/3 of the patients receive ProstVac. Only 1/3 receive placebo.

Here is the Link, and Basic Eligibility Criteria for the clinical trial,
Prostvac (PSA-TRICOM) in Preventing Disease Progression in Patients With Localized Prostate Cancer Undergoing Active Surveillance
(Currently in Baltimore, San Diego, and Irvine. Other sites pending – check link above.)

Basic Eligibility Criteria:

- PSA less than 15.0
- Gleason 3+4=7, or less
- DRE (Clinical Stage) T1c or T2a
- At least 10 cores taken on biopsy
- No more than 50% of the (random) cores are cancerous
- No previous prostate cancer treatments

Check Contacts and Locations Here

As always, research first, then discuss with your physicians and nurses.