DATTOLI CANCER FOUNDATION

Journey

FALL 2017

Rev. Paul Gruesu of Greensburg, Pennsylvania shares a father and son story.

DATTOLI CANCER FOUNDATION

Time For Transition

FROM THE EDITOR

HERB BOOTH

I am writing this on August 24, 2017 – 25 years since I rode out Hurricane Andrew at South Miami Hospital. I was in my office for four days straight, sleeping on the floor between posting updates to local media and fielding phone calls from national and international press. It was a week that changed my life.

Seventeen years ago another seminal event occurred – I was hired as Marketing Director at Dattoli Cancer Center. Prior to this, I had never worked longer than five years at any one place. Over these years, Dattoli Cancer Center has become a home for me, a place that has made me proud of my role and my contributions. Dr. Dattoli, Dr. Sorace and now Dr. Kaminski are the kind of physicians who make the practice of medicine a noble profession. They are "passionaries" and set the bar high for all staff. Our patients come to us seeking understanding, support and care, and the Dattoli Team is enriched by the trust and respect they give back to us.

Eventually the time comes when it makes sense to scale back and to dip one's toes into the "retirement pool." I am there. By the time you read this, I will have celebrated my 70th birthday. (I don't believe it either, but birth certificates don't lie!) I am so supportive of Dr. Dattoli and the Center that I really don't want to just leave.

Dr. Dattoli has agreed to let me continue to run the Dattoli Cancer Foundation for a few years to keep me busy and in the prostate cancer loop, and to keep my mind sharp! I might even be able to produce our award-winning *Journey* more often this way. It has been my true pleasure to meet so many wonderful people through my association with Dattoli Cancer Center. I just can't say goodbye.

If I have touched your life, a donation to our Foundation in my name would greatly honor me. I plan to catch up with you in spring 2018, in the next issue of *Journey*!

Virginia 'Ginya' Carnahan, APR, CPRC

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What's New?

Remember that odd experience of having your "alpha cradle" made on "Sim Day?" That clunky grey contraption is now a thing of the past. In its place we now are using a "Vac-Lock" Immobilization Device System. As CT Technologist Pam Nelson explains it, "Vac-Lock uses an air compressor to inflate a recyclable, cloth like envelope around the patient."

Patients get an upper and a lower one, for even better position control during treatment. This method does not require a special shoe – you can just wear socks. After the patient has completed his course of daily DART radiation, the air in the cradle is released, the surface is disinfected and it is ready to use again. The Vac-Lock material is more comfortable for the patient, and it comes in a lovely, neutral beige color that coordinates nicely with any attire! - GC

Above: Out with the old (left), and in with the new. Dattoli Cancer Center CT Technologist Pam Nelson shows us the new Vac-Lok Immobilization Device System.

MESSAGE FROM MICHAEL DATTOLI, MD

Why Focal Therapies Won't Work

New prostate cancer treatment theories, therapies and approaches seem to surface every month or so these days. It is a challenge for me to keep up with them all. What must it be like for patients, especially newly diagnosed men?

One idea that I am very clear and passionate about is the expanding and even potentially dangerous approach suggesting that newly diagnosed prostate cancer may be defeated by some variety of focal treatment. "Focal" therapies are those that isolate a specific tumor site and direct treatment only to that area and occasionally to other select areas.

Focal therapy sounds pretty straightforward. After all, we are aware of select tumors of the skin, kidney, extremities (sarcomas) and low-lying ano-rectal cancers that have been treated with organ-sparing focal therapies, often resulting in equivalent rates of cancer control, lower morbidity rates and less disfigurement. Transferring this experience to other sites (e.g., head and neck, esophagus, stomach, bladder and especially the prostate gland), however, is an ill-advised leap of faith.

The term "field effect" or "field cancerization" has been well characterized in cancer medicine dating back to the 1950s, with countless studies focusing on prostate and breast (*Cancer*, Vol 16, No 5, 1953). In essence, it suggests that if a cancer has occurred in one site of an organ, other sites of the same organ are at equal risk for developing cancer.

One only needs to look at breast cancer where focal "lumpectomy" has consistently been found to be inferior to lumpectomy followed by whole breast irradiation or mastectomy (NSABP B-06, Clinical Med Res, Vol 1(4), 2003; 20 Year Follow-up of Randomized Trial, NEJM, 347, 2002).

Prostate cancer is rarely a unifocal disease. It is very complicated. Studies have shown the 86% of men with a unilateral (left or right lobe) diagnosis will actually have bilobar disease following prostatectomy (*Journal of Clinical Oncology*, Vol. 32, No. 13, May 2014).

Data regarding field cancerization of prostate cancer is especially abundant. I can recall long ago, with the advent of PSA and during the early days of seed implantation, I would implant the classic prostate "B-1 Jewett nodule," which would regress (along with the PSA), only for another nodule to develop in the other lobe coinciding with a rise in the PSA.

We have since gained tremendous insight into the complexity of cancer mechanics as a result of the fast-paced progress in histopathology, molecular biology and biotechnology as it relates to prostate field cancerization.

What we do know: At the time of diagnosis of an isolated prostate cancer, 90% of the remainder of the gland contains 2 or more cancerous foci (*Human Path*, Vol 41, No 6, 2010). So, while multi-focality most commonly pre-exists at the time of initial diagnosis of a single lesion, the entire prostate gland is subject to the same micro- and macro-environments which resulted in the initial cancerous lesion. Additionally, acquired genetic mutations further compound the rate of additional future malignant tumor disposition within the gland over time ("metachronous disease"). Fascinating data suggests that the initial tumor itself even influences glandular

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Why Focal Therapies Won't Work

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tissue (via molecular alteration) to induce further oncogenesis within the prostatic glandular tissue, and even cancer progression at sites beyond the prostate (*J Mol Diag*, Vol 8, No 3, 2006).

Simply put, at the time of initial diagnosis, the entire prostate gland is at enormous risk for harboring additional malignancies ("synchronous disease").

The plethora of focal (and other) treatment options is likely a direct result of increased screening for prostate cancer. While the objective of wide-spread, annual screening is to find prostate cancer early enough to offer "cure," the challenge becomes delineating those men who actually need treatment from those who theoretically could survive without treatment. There has been righteous criticism of the fallout from screening – including too many unnecessary biopsies, too many unnecessary surgeries and radiation treatments, and the associated morbidities of these procedures, as well as the huge impact on healthcare costs. But is Focal Therapy the answer? Let's examine this in greater detail.

Focal therapies currently being offered for prostate cancer include the following.

Cryotherapy

Also known as "freezing," cryotherapy has been available long enough that there is now third generation technology in use. The original liquid-filled probes have been replaced with smaller probes filled with gas. The procedure involves regional or general anesthesia, and inserting probes via the perineum into the gland under ultrasound and thermosensor guidance. Activating the gas rapidly chills the tissue around the probe, causing cell destruction. Long-term disease-free follow-up data is sketchy, but high incidences of impotence (as high as 87% in early studies) and incontinence have dogged the therapy. Increased rates of recurrence in the vicinity of the "warmed" urethra is all too common. Treating only a portion of the gland with focal therapy theoretically reduces the unwanted complications of total gland ablation, although no substantive long-term data exists.

HIFU (High Intensity Focal Ultrasound)

Whereas cryotherapy uses freezing to treat prostate cancer tumors, HIFU uses thermal (heat) energy. Please note that HIFU is no different than hyperthermia, which has been used for whole-gland treatment since the 1980s. Long ago, and including in my own experience, it was determined that increased thermopathy was necessary (>90° Celsius) in an attempt to improve local control. Despite this, recurrences were still extremely common and complications were not uncommon (rectal/urethral fissures and fistulas, incontinence and erectile dysfunction). Using HIFU focally is new enough that few studies are available to report its success. Based on the high recurrence rates treating whole gland, results using focal HIFU would be predictable.

As an aside, normal tissue obliteration which occurs with Cryosurgery and HIFU makes for extremely damaged tissues, compromising future salvage treatment options (in contrast to radiation, whereby normal tissues are repaired).

MRI LITT (Laser Interstitial Thermal Therapy)

Integrated with multi-parametric MR imaging, LITT is now being used as a treatment for focal, low-grade, organ confined prostate cancer. This modality is still in phase I trials, that is, investigational, so no long-term data exists.

FLA (Focal Laser Ablation)

This option, currently under investigation, uses laser energy to ablate lesions identified by MRI. A recent study involving 9 men found that MRI-guided biopsy post-FLA treatment found prostate malignancy to remain in 22%.

Bipolar RFA (Radiofrequency Ablation)

Also under investigation, RFA can be performed under ultrasound guidance. A specially designed "driver mechanism" is used to position probes that emit radiofrequency waves to the target. As of 2015, no trials had reported RFA outcomes.

Photodynamic Therapy (PDT)

PDT uses a topical or systemically administered photosensitizer which accumulates in a target tissue, where it can be activated by light – which leads to generation of active radicals that attack cancer cells. A phase I trial using PDT in 15 patients with recurrent prostate cancer, using Foscan® as a photosensitizer, saw PSA decrease in 9, but almost all eventually failed and required androgen deprivation therapy. Urethral damage and erectile dysfunction developed in approximately 30%.

Nanoknife (IRE)

Irreversible Electroporation with/without Cryosurgery is a new, minimally invasive modality for the ablation of solid tumors. IRE takes advantage of the electric potential gradient that exists across cell membranes to create permanent pores in the cell membrane. The IRE generator sends electrical energy pulses that alter the cell's transmembrane potential, creating permanent nano-sized pores that irreversibly increase the permeability of the cell membrane, ultimately causing cell death. As with all new therapies, the value of this approach must be evaluated based on clinical research and publication of results. Combining this with cryosurgery will necessitate even further investigation.

Prostate Brachytherapy (seed implant)

Prostate brachytherapy is, of course, the most practiced and studied "focal" therapy of all. Brachytherapy allows for intraprostatic tumors to receive much higher dose levels than other regions, while nearby non-malignant regions can be sub-selected to receive microscopic dose levels or even a nil dose, if planned. It is well documented that the DNA of normal irradiated cells undergoes complete repair, in contrast to the other aforementioned focal treatment options.

Proponents of focal therapies believe that their approaches offer the patient with low risk/low volume, low PSA, low Gleason score (≤6), an alternative to Active Surveillance and the accompanying stress and uncertainties it can put upon the man. **I would make the argument that any man who is deemed a candidate for focal therapy should not be treated at all!**

These patients often make their treatment decision based on the standard 10-12 core ultrasound guided biopsies with or without fused multi-parametric MRI (mpMRI), although studies have determined that saturation biopsies are necessary for the most accurate staging.

In conclusion, focal therapy would be a waste of time, resources and effort for virtually every man. Moreover, these men will succumb to multiple future intra-prostatic recurrences, further biopsies, testing, etc., and the focal therapies' compounding side effects – which are the very things they hoped to avoid by choosing "focal treatment" in the first place!

The Talk

WHEN THIS FATHER AND SON HAD "THE TALK," IT WASN'T ABOUT THE BIRDS AND THE BEES.

BY DAVID CHESNICK

Paul Gruesu relaxing during his recent visit to the Dattoli Cancer Center.

PHOTO BY ALEX STAFFORD

When we hear of a dad having "the Talk" with his son, we assume it's about "the birds and the bees." For Joe Gruesu and his son Paul, the talk involved PSA numbers and Gleason scores.

The conversation – one every man should have with his doctor as well as his sons – began for Joe and Paul in 1992 when a blood screening program at Joe's Johnsonburg, Pennsylvania, Rotary Club revealed that his PSA count was 13.2, three times higher than "normal." It was the beginning of a long journey for Joe and his wife, Bernice.

Joe visited a local urologist who did a biopsy that produced a negative result, despite the high PSA number. Unable to reconcile the disparity between his high PSA score and the negative biopsy result, Joe continued to have the biopsy procedure every year for the next seven years. And the results remained the same, until 1999. By then, Joe's PSA had reached 21.53. This time the biopsy was positive and Joe's Gleason score was reported to be six. Finally diagnosed with prostate cancer, his urologist recommended a radical prostatectomy.

TREATMENT

The proposed solution didn't satisfy the determined father of sons, but Joe knew he had to act. After doing extensive research, he sent his medical records to five of the top prostate clinics in the United States, including Dattoli Cancer Center. When he mentioned to a Virginia doctor that he was considering a clinic in Florida, the doctor asked, "Dattoli?"

"When I said yes, he said, 'Go there. You'll be properly taken care of.' He should know, I thought, because he'd been treated there for his cancer."

A deeply religious man, Joe told the Lord he was putting his life in His hands. Then he called Dr. Michael Dattoli and spoke with him at length. His questions answered, Joe made the decision to undergo treatment in Florida, and in November 1999, he made the trip from Western Pennsylvania to Sarasota.

Joe's road to recovery began with a two-day physical exam that was followed by 23 radiation treatments, each precisely targeting the cancerous tumors while leaving the healthy tissue intact. Happily, after 17 years his cancer had not spread.

"I went home for the holidays and then came back in February. Dr. Dattoli implanted 71 Palladium 103 seeds. In March, I returned for three more radiation treatments. Since then, I've been back once a year for 17 years. My PSA is now a barely detectable 0.008, and all my bodily functions are normal," he reports, "with no incontinence or impotence."

TIME TO TALK

In the years since, Joe has fielded calls from all over the world asking him about his experience. He also schedules his yearly follow-ups for Tuesdays, so he can attend the "Beamers" meetings for new Dattoli patients, to talk to them about his experience and the happy results.

"I always speak with both the husband and wife, so I can share information about my experience with both, because this is a disease that touches both," Joe says.

It was a talk he would soon have with one of his three sons.

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LIKE FATHER, LIKE SON

Now 81, the former metals industry executive still consults and works as a manufacturers' rep. But the years have not proved all that smooth. While oldest son, Stephen, has escaped cancer, middle son Donald passed away in 2013 after a five-year battle with colon cancer. Then came youngest son Paul's diagnosis.

"It was scary to get the news about Dad," says Paul, a Lutheran pastor in the Evangelical Lutheran Church in America. "When Dad was diagnosed, I was unfamiliar with the disease. But even though I was only 30 at the time, I started having my PSA checked as part of my yearly checkup."

In 2016, at the age of 46, Paul's PSA was elevated and a diagnosis of prostate cancer was delivered.

"After talking with Dad all those years about his experience, I knew without hesitation I was going to see Dr. Dattoli."

Paul's experience closely paralleled his father's. Diagnosis at Thanksgiving, a New Year's trip to Florida, two months of radiation, then seed implants and a trip in June for follow-up radiation. And like his Dad, there were no side effects for the married father of one daughter. He was able to carry on his pastoral duties even while being treated in Florida.

Of course, it helped that he was able to stay with his folks at their Central Florida home while undergoing treatment. "I would commute two hours each way every day. On the way home, I'd stop at Planet Fitness and exercise. In the evenings, I was on the phone

doing pastoral work." After the seeds had been implanted, Paul returned to his home in Greensburg, Pennsylvania, to lead his congregation during Easter week.

"The message I want to pass on because of Dad and Don is that, with all the advancements in technology and treatment, early detection is the key to survival, particularly for prostate cancer," Paul says. "Dattoli Cancer Center has a 3-D Color Flow Doppler Ultrasound machine that allows the doctors to see exactly where the cancerous tumors are, so they can target them with pinpoint accuracy without destroying healthy tissue.

"As a pastor, I have a lot of colleagues and parishioners, and by extension a larger community, that I serve. People hear from Pastor Paul, just as I heard from my father, to get a yearly checkup.

"The way I deliver the message is to say that if you're not going to do it for yourself, then do it for your wife and children. Helping wives, children and grandparents have the man in their life around longer is going to improve the quality of their lives as well as your own. So, do it for the ones you love."

It's an important message – especially when delivered from father to son.

"It was scary to get the news about Dad. When Dad was diagnosed, I was unfamiliar with the disease. But even though I was only 30 at the time, I started having my PSA checked as part of my yearly checkup." *- Paul Gruesu*

Three generations – Rev. Paul Gruesu, his father, Joe, and Paul's daughter, Lindsay – tend the community gardens at St. Matthias Evangelical Lutheran Church.

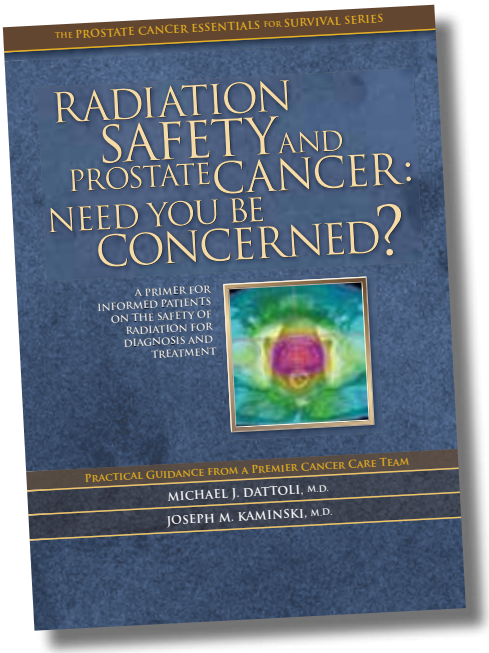
PHOTO BY GARY YON

FROM THE BOOKSHELF

Radiation Safety and Prostate Cancer: Need You Be Concerned?

PRACTICAL GUIDANCE FROM A PREMIER CANCER CARE TEAM

"The use of radiation in medicine has a long history to which scientists from diverse fields, such as physics, chemistry, engineering and medicine, have contributed over many decades."



This statement introduces the latest publication in *The Prostate Cancer Essentials for Survival Series*. Authored by Drs. Michael Dattoli and Joseph Kaminski of the Dattoli Cancer Center, the booklet begins by defining exactly what radiation is and how it is used. It looks at the various types of scans – CT, MRI PET, Bone – and compares their benefits, striving to answer the nagging questions that patients and others have about the safety of radiation when used for the diagnosis and treatment of prostate cancer.

Little more than a century ago, Madame Marie Curie was experimenting with radiation and the use of X-rays at a time when no one knew that this discovery carried health risks. In fact, Madame Curie's death in 1934 was due to her many years of exposure to radioactive materials. It is interesting to note that her daughter, Irene Joliot-Curie, discovered what was called "induced" or "artificial" radioactivity, which became a milestone in the development of nuclear medicine.

If you would like a copy of this new booklet, please send a note to that effect on or in your donation envelope, and we will be happy to send one to you.