Virginia Urology Makes Its Mark In Quality Assurance

Prostate Cancer
How New Technology is Helping Us Target Treatment
Virginia Urology Quality Assurance

The American Urological Association held its inaugural Quality Improvement Summit in January 2014, and this conference focused on reducing infectious complications related to ultrasound guided biopsy of the prostate. At this national summit, Dr. Michael Franks reviewed the Virginia Urology experience using a standardized biopsy and management protocol.

In 2007, the Virginia Urology Quality Assurance Program was developed to internally review prostate biopsy infection and post-biopsy sepsis rates with the goal being to reduce infection rates below one percent. At this time, quinolone resistance was becoming a significant issue, and the local antibiogram was used to guide prophylaxis choices. Beginning in 2010, after collaboration with infectious disease specialists, ciprofloxacin and cefdinir were given orally before and after biopsy. The protocol also included an enema preparation of the rectum. Continued evaluation of the current antibiogram revealed a small increase in the percentage of multi-drug resistant organisms; however, the extended antibiotic coverage was effective with prostate biopsy infection rates remaining low at under 0.5 percent. Compliance with this standard protocol is being continually assessed. As Virginia Urology has been able to attain and maintain extremely low rates of infection, hospitalization, and sepsis rates using the current antibiogram, the benefit of targeted antibiotic prophylaxis based on rectal swab cultures is unknown.

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<th>YEAR</th>
<th>POSSIBLE INFECTIONS</th>
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Increased MDRO, ESBL, E. coli
Michael D. Byrne, MD
Dr. Byrne grew up in New Jersey and attended the Georgia Institute of Technology to study electrical engineering. He worked for several years as an engineer before entering medical school. He obtained his medical degree from Virginia Commonwealth University where he also completed his general surgery internship and urologic residency. Dr. Byrne completed a year fellowship in Endourology and stone disease at the Cleveland Clinic. His clinical interests include endoscopic and percutaneous surgery for stone disease along with the medical management of stone disease. He and his family are glad to be back in Richmond. In his spare time, he enjoys spending time with his family as well as running, fishing and golfing. He will practice at our Stony Point and Reynolds Crossing locations.

Joseph H. Ellen III, MD
Dr. Ellen obtained his undergraduate and medical degrees from the University of Virginia. He then went on to University of Florida in Gainesville where he completed his general surgery internship and urologic residency. Dr. Ellen completed a fellowship in andrology, prosthetics, and urethral stricture repair at Albany Medical Center in New York. His clinical interests include male infertility, vasectomy reversal, hypogonadism, erectile dysfunction, and urethral stricture repair. Dr. Ellen grew up in Richmond and is happy to be back close to his family. In his spare time, he enjoys hiking, golfing and traveling. He will practice at our Prince George, Reynolds Crossing and Stony Point locations.

Treating BPH
Charles A. Seabury, M.D.
Benign Prostatic Hypertrophy (BPH) is a condition that affects roughly half of men over 50 years of age, though symptoms can start many years earlier. Indications of BPH include “obstructive” symptoms of slow stream, straining to void, intermittency of stream, or hesitancy to start urination; as well as “irritative” symptoms of frequency, urgency, sensation of incomplete emptying, and nocturia. Not every man with an enlarged prostate develops symptoms and symptoms occur in a variety of other conditions other than BPH. Most men will begin their prostate journey with their primary care physician. Conservative measures are often been employed, as well as alpha blockers and occasionally other medications before sending them on to an Urologist. Our investigation starts with questions similar to the well-publicized AUA symptom score sheet, and a review of what may have already been attempted. Many times medication is our first step, though occasionally we proceed to more invasive tests or procedures. As for steps beyond medication, like all professions, Urology has been trying to build a better mouse trap for a century. Starting with open incisions for removal of the overgrown adenoma, we have now progressed to the oft-considered “gold-standard” of Transurethral Resection of the Prostate (TURP). (continued on page 4)
Freezing Prostate Cancer
With Cryotherapy

C. Ryan Barnes, M.D.

Localized Cancer Treatment

Cryotherapy uses freezing technology to kill cancerous tissue. Different from radiation, which can require up to 45 treatments, cryotherapy is usually a one-time treatment. As an outpatient procedure, cryotherapy patients typically have minimal pain and are able to return to normal activities shortly after their procedure.

Current Generation Technology Has Fewer Side Effects

Early cryotherapy treatments in the 1960s used liquid nitrogen to create an ice ball to freeze tissue. Use of nitrogen, however, lacked precise control and monitoring, resulting in high complication rates.

The treatment has since been revolutionized and has transitioned to argon–based systems, which use ultrathin needles to create precisely controlled ice balls. Ultrasound imaging has also evolved with cryotherapy and provides visualization of the generated ice ball. Cryoablation now incorporates routine use of advanced sensing probes, double freeze–thaw cycles, and urethral warming catheters. When used together, these technical advances, along with improvements in technique, have led to reductions in side effects.

It is important to note, however, as with any treatment for prostate cancer, side effects may occur after cryotherapy. These side effects may include loss of urinary control, injury to the rectum, and loss of sexual function.

Unfortunately, many of the therapies we use to treat prostate cancer come with potential side effects such as incontinence. Fortunately, with the improvements in cryotherapy we’ve seen in the last decade, the occurrence of incontinence has been dramatically reduced and is often only a temporary side effect.

Cryotherapy is also used to treat cancers of the kidneys and lungs, as well as treating liver metastases and providing palliative intervention for cancer.
Prostate Cancer Awareness

Prostate cancer affects more than 220,000 men in the US, and contributes 27,000 deaths (Cancer Stats 2015). It is a relevant problem that requires individualized care, and Virginia Urology with its subspecialty focus has the experience and staff to assist with management of prostate cancer. Prostate Cancer Awareness Month in September focused attention on the screening and diagnosis of prostate cancer in the Richmond Metropolitan area. Virginia Urology was involved in several outreach programs at Retreat Hospital and Petersburg Tri-Cities area, which were well received. No Shave November, Moustache November or “Movember” also promotes men to grow their individual style of moustache to support and raise awareness for prostate cancer. Post your pictures of support on your website, our Facebook page or Twitter.

Treating BPH

(continued from pg. 2)

Over the last 20 years we have attempted to minimize the impact of this “opening-up”, employing a variety of modalities. Currently, we utilize several treatments to “open” the prostate. There does not exist one ideal way to do this. Factors including gland size and anatomy, as well as patient health help us determine the best course of action. We currently utilize several different laser frequencies (Greenlight, Protouch, Thulium, Holmium) for treatment, but also still utilize variations of traditional TURP and open (or in some cases robotic) prostatectomy. The goal now is as it has always been: maximum efficacy with minimum risk or side effects.

Still, new technologies are on the horizon. Some show early promise without impacting sexual function and potentially with even less downtime. This includes new physical devices (Urolift) and new ablative technologies (Rezum). We will continue to pursue these and try to keep our Primary Care partners as informed as possible.
Prostate Cancer Screening

Although currently controversial, screening studies have demonstrated an improved survival in men with prostate cancer screening, but these studies are mostly in Caucasian men. African American men have more advanced tumors and risk on initial presentation, and warrant awareness efforts and rigorous screening. PSA and DRE are the mainstay of prostate cancer screening methods. American Urologic Association (AUA) guidelines recommend starting PSA testing with DRE at age 50 and continuing it biennially until age 70. Virginia Urology also strongly considers checking baseline PSA levels in men in their 40’s, as a PSA > 1 increases risk for prostate cancer at 20 years follow-up. Additionally, men over age 70 with 10-year life expectancy can be considered for PSA testing after an informed discussion.

**African American men and those with family history are 2 subgroups that require annual screening starting at age 40, due to their significantly increased risk for aggressive cancers.** PSA is not a perfect test, with reduced specificity a common problem, however, additional tests are being developed to assist and improve patient selection for biopsy & risks (4KScore, Prostate Health Index – PHI).

Know Your Stats

About Prostate Cancer

1 IN 6 AMERICAN MEN will be diagnosed with prostate cancer IN HIS LIFETIME

1 NEW CASE occurs every 2.2 MINUTES

As men increase in age THE RISK OF DYING FROM PROSTATE CANCER increases exponentially

More than 2.5 MILLION AMERICAN MEN are living with prostate cancer
Prostate Cancer Diagnosis  Michael E. Franks, M.D.

Prostate Biopsy is a commonly performed procedure at Virginia Urology (VU) Ambulatory Surgery Center (ASC), with over 20,000 biopsies done in the last 10 years. Our infection rate is < 1% and favorable in comparison to other large groups in the US. The procedure itself involves 12 core biopsies of the prostate obtained under ultrasound guidance. VU carries all anesthetic options at its accredited ASC for patient comfort and reduced anxiety - local, twilight/sedation, or general anesthesia. Complication rates including bleeding and infection are low, and most men return to normal activity in 24 hours. Results of the biopsy are communicated personally by VU staff in 1 week. VU now has the capability to fuse MRI images with real time ultrasound of the prostate and obtain targeted biopsies of prostate dominant lesions to better stage and grade prostate cancers before considering additional therapies. This information forms the basis of the new Active Surveillance model that can help men with low grade disease avoid unnecessary treatment and overtreatment.

Did You Know: Virginia Urology’s prostate Biopsy infection rate is among the lowest in the country!

Prostate Cancer Quiz

With PSA screening, what percentage of prostate cancers are organ confined?

A. 25%  B. 50%  C. 90%  D. 100%

Which patient with Prostate Cancer is a potential candidate for Active Surveillance strategies?

A. 50 yo Gleason 3+4, PSA 13
B. 60 yo Gleason 3+3, PSA 3.5
C. 40 yo Gleason 4+4, PSA 8
D. 65 yo Gleason 4+5, PSA 22

Answers: C, B
Prostate Cancer Treatment

Michael E. Franks, M.D.

With the diagnosis of prostate cancer, the number of affected biopsies, Gleason Score, and exam findings contribute to a risk profile for each patient diagnosed. CT scan and bone scan are really only require for high risk cases for staging. MRI is a new technology with improved sensitivity that can provide a better “road map” of prostate cancer and extracapsular extension or neurovascular involvement.

**Active surveillance (AS):** is essentially deferring treatment until the prostate cancer biology becomes clear that warrants therapy. Most men with Gleason 6 cancers of low volume can take this AS approach if comfortable. MRI is often used to rule out aggressive therapy prior to this observational strategy, especially in younger men, and upstaging occurs in 20-30% of men with MRI. About 30-40% of men on observation will go on to definitive therapy in 5 years (JHU). Monitoring by DRE, PSA every 6 months with judicious use of biopsy and MRI is part of this strategy – at this time, no clear-cut guidelines on AS are published, so patients and Urologists discuss this in a shared decision strategy.

**Surgery:** 50% of men at VU choose to have surgery, whether robotic or open radical prostatectomy (RP). Prostate removal is associated with a short hospital stay. Review of VU Urologists who perform RP show excellent safety records at our Richmond Hospitals and high volumes nationally (Propublica website). ED and Incontinence are adverse events after surgery that may require additional medical or surgical management.
Radiation: Intensity modulated radiation therapy (IMRT) is commonly used for local prostate cancer therapy, combined in intermediate and high risk patients with Lupron or LHRH agonist. Placement of prostatic seeds (brachytherapy) also provides local control of tumor in men with low risk prostate cancer and is a good outpatient option. Collaboration with Dr. Taryn Torre and Dr. T.J. Wallace provide a multidisciplinary management strategy that serves our patients in Metropolitan Richmond well.

Cryotherapy: Dr. Ryan Barnes performs prostate cryotherapy or freezing the prostate as an outpatient hospital procedure for men with recurrence after radiation approaches and in men who elect primary therapy. Erectile dysfunction is a common side effect with this modality. MRI localization of prostate lesions may allow for focal cryotherapy option for men, which is being researched nationally at this time.

Advanced Prostate Cancer Treatments: Dr. Kinloch Nelson, Dr. Charlie Jung, and Dr. Michael Franks are spearheading management of men with advanced or metastatic prostate cancer at VU. Traditionally, hormone therapies were used in metastatic prostate cancer and with progression or resistance to therapy, men then went on to chemotherapy or palliative options. In the last 3 years several FDA approved treatments have improved survival in men with advanced disease which allow for Urologic management. Provenge is a novel immunotherapy given biweekly for three treatments which improves survival in men, and this is well tolerated. Oral therapies such as Zytiga or Xtandi are well tolerated options even in older men, and they have been given to over 100 VU patients in the last 2 years. Chemotherapy is done by medical oncology, and we collaborate with our trusted friends regularly with these advanced patients.

Our Comprehensive Cancer Clinic provides a venue for patient care that allows for management of patients with high risk or metastatic disease. All options are discussed for their complex individualized care which includes bone health, cancer care, and hospice services. It has generally been well received and care pathways continue to evolve at VU.

Did You Know:
Virginia Urology conducts clinical trials of treatments for advanced prostate cancer.
A Smarter Way To Look For Prostate Cancer  Thomas D. Henry, M.D.

Prostate cancer diagnosis is traditionally done using transrectal ultrasound-guided biopsy approach, and 12 samplings are done (6 left, 6 Right). The downside of this often used protocol is that this is a “blinded” technique where 2-4% of prostate tissue is sampled, and ultrasound is not good at seeing lesions clearly at times. This leads to a high false negative rate for cancer diagnosis, and also diagnosis of low volume Gleason 6 cancers which may lead to overtreatment.

For these reasons, MR-guided prostate fusion biopsy was developed to utilize multiparametric MRI prostate (MP-MRI) with real time targeting of prostate dominant lesions, which likely better correlate to the prostate cancer risk. Traditional biopsies are a “snapshot” of the prostate, while MP-MRI gives a “global” view, and if a lesion is present, and adequate “roadmap” for targeted biopsy. Better information is obtained.

Fusion biopsy of the prostate utilizes the powerful anatomic and functional imaging capabilities of multi-parametric MRI (MP-MRI) combined with the real-time convenience and efficacy of ultrasound to target those lesions deemed most likely to be aggressive. Most prostate cancers are not visible with ultrasound and random prostate biopsies by their nature will only sample very limited portions of the gland, inevitably missing higher grade tumors as well as inadvertently identifying low-grade tumors of no clinical significance.

Virginia Urology (VU) was the first site in Virginia to offer this technology to patients, and our urologists have performed over 250 fusion biopsies since 2013. Dr. Michael Franks is presenting an update of the VU fusion biopsy experience at the Mid-Atlantic AUA meeting this fall.
The Technology involves the radiologist marking any suspicious lesion(s) on the MP-MRI images and the urologist and fusion biopsy team then review the targets prior to the procedure (Figure 1B). In the ultrasound suite, a transrectal probe is used to sweep the prostate so that the unit can fuse the real-time ultrasound data with the previously performed MRI, while the patient is sedated. This allows the urologist to view the real-time ultrasound images overlaid on the MRI images (Figure 1C) so that lesions identified on MRI can be targeted for direct biopsy.

**CASE STUDY**

The images on the right are of a 50-year-old patient with unexplained rising PSA and prior standard 12 core biopsies revealing premalignant change (PIN) but no cancer or inflammation. MRI identifies a suspicious target lesion in the anterior mid medial transition zone just left of midline consistent with a Gleason 7 cancer (Figure 1A, arrows). Anterior tumors are notoriously difficult to detect by exam and reach during standard biopsy, but in this case using fusion technology, the target lesion was successfully biopsied (Figure 1C, 1D) and pathology confirmed to be relevant Gleason 3+4 cancer. The standard cores (what would have been previously done) showed some areas of atypia but no diagnosis of cancer. This targeted approach allowed a clinically significant cancer to be found in a more logical manner than “blind” standard biopsies done previously. This patient did well with definitive treatment of his prostate cancer after counselling and shared decision strategy.
**Locations**

Stony Point, Richmond, VA
Reynolds Crossing, Richmond, VA
St. Francis Cancer Institute, Midlothian, VA
Hanover Medical Park, Mechanicsville, VA
Puddledock Medical Center, Prince George, VA
Emporia, Virginia
Tappahannock, Virginia

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