

Mount Sinai First to Test Gold Nanoparticle Treatment for Prostate Cancer

Dr. Art Rastinehad, Martin Feeney (patient)

and Mrs. JoAnne Feeney

Prostate Cancer specialists at Mount Sinai have treated their first patient in an exciting new clinical trial with the objective of minimizing side effects frequently experienced

after radical prostatectomy or radiation therapy for prostate cancer while still completely eliminating a cancerous tumor.

Martin Feeney, 70, was diagnosed with low grade, low volume prostate cancer four years ago. That was distressing for him, but as scary was his developing sepsis (a potentially life threatening complication of infection), a result of the biopsy he underwent following his diagnosis. Once

recovered, Martin was advised he could follow an active surveillance program to monitor his cancer, but he was nervous about the regimen of biopsies required for this treatment plan. That concern resulted in his delaying his next biopsy for over a year.

Fast forward to earlier this year, when he met Dr. Art Rastinehad, Director of Focal Therapy and Interventional Urologic Oncology and learned he could undergo a biopsy

> using a combination of an MRI of the prostate and a new approach pioneered here at Mount Sinai. This time, the biopsy result was less favorable. Martin was found to have a clinically significant Gleason 3+4 cancer. He was faced with a decision of which treatment (surgery vs. radiation) to choose to treat his prostate cancer.

> Fortunately for Martin, Dr. Rastinehad is leading the national team investigating a new

procedure based on nanotechnology that can treat prostate lesions found on biopsy locally instead of removing or radiating the entire prostate. This option can give men more confidence that their cancer will be successfully removed without worry-Continued on page 4

Insights from Dr. Ash Tewari, Chair

The controversy over when and who to screen for prostate cancer continues to confuse men and their loved ones. In 2012, The United States Preventive Services Task Force came out against screening for prostate cancer for all men, claiming that doing so results in overdiagnosis and overtreatment. The American Urological Association disagreed, but responded by revising their guidelines, recommending screening men at risk at 40 and encouraging men from 55-70 to engage in shared decision making: speaking with their doctors about their personal risk for prostate cancer and the benefits of screening. Most recently, a study out Continued on page 4



Dr. Ash Tewari

more updates inside: **Faculty Introductions** Immunotherapy Active Surveillance Prostate Cancer Awareness Day **Did You Know?**





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Dr. Art Rastinehad

Immunotherapy: Fighting High Risk Cancer with Personalized Defense Systems

Prostate cancer is the second leading cause of cancer death in men. The American Cancer Society predicts there will be an estimated 180,890 new cases of prostate cancer and 26,120 deaths in 2016. There is not yet a reliable method to predict the course of the disease or to distinguish between indolent from aggressive types. Radical prostatectomy (removal of the prostate) is a standard treatment approach for clinically localized prostate cancer and while it is curative in a large proportion of patients, approximately 25% of patients will ultimately develop disease recurrence (metastases). Treatment of metastatic disease is a major clinical challenge as recurrent metastatic tumors eventually develop resistance to androgen deprivation (hormone therapy) and radiation and/or chemotherapy. This is why researchers, including our team at Mount Sinai, are seeking ways to attack high risk cancer before the metastatic stage.

Immunotherapy is treatment that uses a patient's own immune system to fight disease. Immunotherapy treatment has garnered significant interest as a promising option for increasing survival for several cancers. Indeed, the first immunotherapeutic agent approved by the FDA for any cancer was for prostate cancer: in 2010, the FDA approved Sepuleucel-T, a vaccine that was shown to elicit a response against the prostatic acid phosphatase (PAP) antigen, which is expressed in most prostate cancers. Mount Sinai researchers were among the scientists responsible for its development and approval.

The Uro-Immuno-Oncology Program at Mount Sinai is dedicated to cutting edge research in comparative immunotherapy and the development of novel immunotherapy strategies for genitourinary cancers. We have multiple areas of focus:

Development of novel immunomodulatory agents for genitourinary cancers

Our goal is to develop immunotherapy agents with the ability to either accelerate tumor elimination or prolong the stage when there is "crosstalk" or communications between a tumor and the immune system to keep the balance that prevents tumor growth.

Immunomodulators in combination with other treatments

Immunotherapy can be used with traditional types of cancer treatment, including surgery, hormone therapy, chemotherapy, radiation and ablative therapy. We will focus on studies that will evaluate the success of immunotherapy with several of these treatment options.

Immunotherapy of early and clinically localized aggressive cancers

There are several immunotherapeutic agents in clinical trials at this point in time but their focus is on advanced disease and treatment alternatives for high risk prostate cancer patients. There exists a need for new strategies to reset a patient's immune response so that it is able to prevent tumor spread and/or resistance to treatment.

Based upon response to immunotherapeutic agents to date, we believe we can elicit similar responses in patients with localized, aggressive disease and oligometastasis (cancer that has spread beyond its primary site, but is limited to 5 or fewer spots, typically confined to one organ) in addition to metastasis. The benefits of this focus are profound: eliminating the need for invasive treatment such as surgery or the side effects of radiation or chemotherapy and in all cases, preserving of quality of life (i.e., urinary and sexual function).

Impact of immunotherapy in racial disparity of cancer

Persons of African American descent are the group most at risk for aggressive prostate cancer. Our research will explore immunotherapy in African American patients in the hope of decreasing the disease burden.

Our overarching goal is to develop new immunotherapy agents, personalized to a patient's own tumor, and with increased ability to educate a patient's immune system to eliminate cancer. We believe that when these immunotherapy agents are administered alone or in combination with existing treatments a potent immunologic and tumor-specific effect will be generated and that one or more of these agents will succeed as first-line treatment for clinically localized aggressive disease. We are excited that precision immunotherapy has long-term clinical benefits and potential to dramatically improve prostate cancer outcomes.

Drs. Shalini Singh, Sujit Nair and Nina Bhardwaj (left to right) are working to develop effective immunotherapy agents, personalized to a patient's own tumor, and with increased ability to educate a patient's immune system to eliminate cancer. They believe that precision immunotherapy has the potential to dramatically improve cancer outcomes.







Insights from Dr. Ash Tewari

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of Northwestern University reported an increase of metastatic prostate cancer (cancer not confined to the prostate gland) of 72 percent in the ten years between 2003 and 2013, raising the question whether a trend of fewer men screened might be contributing to this rise or whether the disease has just become more aggressive. More studies need to be conducted to answer this question definitively, but in either scenario, early detection makes sense.

We believe that all men should be screened by the time they are 50 (men at highest risk around 40), or at a minimum, be speaking to their doctors about the screening process. The PSA blood test is not a perfect tool. But, along with a DRE (digital rectal exam), screening with the PSA is the best defense we have to diagnose a cancer that is forecast to account for 26,120 deaths this year. The PSA test gives us a number that can be tracked over time, and does allow us to best predict cancers that are likely to be aggressive. The PSA has resulted in many fewer advanced cases of prostate cancer at the time of diagnosis.

Like a Bengal tiger, prostate cancer can be gentle or vicious. Metastatic prostate cancer is not curable and late stage disease is marked by intense pain, fatigue, weakness and a highly impaired, very poor quality of life. But when prostate cancer is detected early, nearly 100% of men are cured. And in the hands of an experienced surgeon, and with the precision that robotic prostate surgery affords (magnification of the operative field and less blood loss than open surgery), treatment side effects are minimal and can usually be resolved in a reasonable timeframe.

This September, we hope you will start this new season and mark Prostate Cancer Awareness Month by talking to your physician about your risk, getting screened if appropriate, and encouraging family and friends to do the same.

To your health,

Gold Nanoparticle Treatment Continued from page 1

ing about side effects that can impact quality of life.

In May, Martin was the first man to undergo gold nanoparticles directed focal laser ablation (removal) of his lesion. Gold nanoparticles, also known as AuroShell[®] particles, are infused into the blood of the patient where they settle into prostate lesions. These particles absorb laser light and create heat, differentiating the lesions from nerve tissue or blood vessels, allowing for highly targeted ablation.

Follow up imaging of Mr. Feeney's prostate showed no sign of cancer. He is doing well at this point in time and has experienced no side effects. He and Dr. Rastinehad are both elated. "This new treatment may allow men to avoid side effects yet still obtain excellent outcomes," Dr. Rastinehad says. "Mount Sinai is the first hospital in the world to have brought this to patients; we could not be more thrilled."

Prostate Cancer Risk Factors

• Race – African Americans are 1.6 times more likely to be diagnosed with prostate cancer than Caucasians and twice as likely to die from prostate cancer.

• Family History – Family history is a key risk factor for prostate cancer. Having one affected first degree relative (father, brother) has high risk, and the risk jumps if they were diagnosed younger than 65 or if two or more first degree relatives were diagnosed at any age. Second degree relatives (e.g., uncle) count, too.

• Age – Prostate Cancer is not usually seen in men under 40, but is diagnosed increasingly with each passing decade.

• **Diet** – The effect of diet on prostate cancer diagnosis has few clear-cut answers. It appears that men who eat a lot of red meat and high-fat dairy products have a slightly increased chance of getting prostate cancer.

Ash Tewari

Active Surveillance: Treatment Decision Making and Adherence Among Low Risk Prostate Cancer Patients

Active surveillance (AS) is an option for men whose prostate cancer is considered low risk. Active surveillance means that instead of treatment such as surgery or radiation, these patients will be monitored on a regular basis for signs of more aggressive disease. Monitoring comprises PSA blood testing and a digital rectal exam (DRE) every few months (the same tests that are performed for screening), and biopsies at time intervals determined by the physician.

At Mount Sinai, Dr. Ash Tewari has one of the largest active surveillance patient cohorts in the country. Patients under Active Surveillance generally have a PSA blood test and DRE every 3 months, an MRI yearly and biopsy every 3 years. Active surveillance is sometimes referred to as "watchful waiting" or "expectant management", but active surveillance is the favored term for this approach, because it is a proactive, rather than a passive regimen.

The decision to follow an active surveillance protocol is a highly personal one. Some men, aware of the potential side effects of curative treatment (i.e., sexual and urinary side effects) are elated to have this option. But others are uncomfortable with the idea that cancer, no matter how low risk, is residing in their body. In fact, approximately 90% of patients eligible for active surveillance opt for curative treatment and 25–50% of patients on active surveillance discontinue the active surveillance protocol within 2–5 years without clinical evidence of cancer progression.

Given these statistics, and hoping to better enhance patients' treatment decisions and adherence to active surveillance follow-up tests, Mount Sinai has undertaken the first study to examine an intervention to enhance adherence to active surveillance. Led by Dr. Nihal Mohamed, the study (phase one) interviewed low risk prostate cancer patients on active surveillance at the Mount Sinai Health System between January and May of 2016, and explored:

1) barriers and facilitators of treatment decision making regarding active surveillance

2) patient and physician factors that influence adherence to the AS protocol

3) unmet informational and supportive care needs

The results were enlightening. The majority of patients followed the physician's recommendation (90%) and few patients searched the internet for additional information about active surveillance (30%). Factors that influenced patients' decisions to opt for AS included trust in the physician's expertise, good intentions, and skills in detecting cancer progression in a timely manner; and avoidance of sexual and urinary deterioration associated with other treatment options. Participants expressed no desire to discontinue AS or regret of decision to opt for AS. Participants, however, reported anxiety associated with having cancer that increased around time of clinical testing of cancer progression. Lack of full information about follow-up care, AS management plan, and delays in follow-up surveillance appointments contributed to anxiety levels. Financial and life insurance barriers to AS emerged as significant concerns about patients' ability to stay on an AS protocol in the future despite their willingness to continue AS.

These findings provide evidence for the existence of unmet informational and supportive care needs of low-risk prostate cancer patients making decisions about AS and the barriers and facilitators of patients' decisions, especially adherence to AS. Patient and provider factors that influence adherence to AS protocol include patient education about follow-up care requirement, patient tolerance of anxiety and distress, and the value of and desire to maintain sexual function.

Dr. Mohamed believes educational and psychosocial interventions are needed to enhance AS treatment decision making in both patients and their partners and is developing such programs that she will be evaluating later this year. In the meantime, "physicians could benefit from patient-provider training to enhance their communication skills," she says. "Our study indicates that patients will accept an AS recommendation if they trust the physician's good intentions and skills in detecting cancer progression in a timely manner but the challenge is keeping them on the protocol, so understanding their fears and concerns is paramount."



Dr. Nihal Mohamed discusses Active Surveillance with a patient. She hopes conversations that address a patient's fears and concerns will improve adherence.

Prostate Cancer Awareness Month and Men's Health Day

On Friday, September 23rd, hosted by Dr. Ash Tewari, Chair, the Department of Urology will hold its annual Prostate Cancer Awareness and Men's Health event in the Guggenheim Pavilion Atrium at Mount Sinai Hospital from 10 am to 2:30 pm.

Information about prostate cancer, men's health, urological disease and the role of exercise and diet in disease prevention and survival will be provided by medical professionals, supplemented with printed materials. Free prostate cancer risk consultations will be available from 10 am–1:15 pm. For men who are appropriate candidates and wish to be screened, PSA blood tests will be offered. Guests can also "test drive" the



Did You Know? What are the signs and symptoms of prostate cancer?

Prostate cancer is considered a "blind killer" because there are no symptoms of prostate cancer in its early stages. By the time symptoms appear, cancer is considered advanced. The symptoms include difficulty urinating, pain while urinating, blood in the urine, and pain or stiffness in the back, hips, upper thighs, or pelvis.

Men should keep in mind that some of these symptoms are signs of other conditions, some more serious than others. For example, difficulty urinating can be a sign of benign prostatic hyperplasia (BPH), which is also referred to as an enlarged prostate. Painful urination may indicate a urinary tract infection. Blood in the urine should always be checked out in a timely manner as it can be a symptom of bladder cancer. But it can also indicate a kidney infection or kidney stone or in some cases, is just a result of strenuous exercise. Pain in the hips and back can be the result of strenuous exercise as well. Because there are no early symptoms, the best defense is knowing your risk and speaking with your physician about getting a baseline PSA (along with a DRE) in your 40s. daVinci surgical robot, used by our surgeons to perform prostate, kidney and bladder cancer surgery.

A highlight of the event will be our 2nd Annual Push-Up for Prostate Cancer Challenge at 1:15 pm. Faculty, staff, students and visitors will be invited to test their athletic ability. Last September, a total of 3,576 push-ups were performed by over 60 participants. No one surpassed Dr. Dennis Charney, Dean of the Icahn School of Medicine at the Mount Sinai Health System, who won the Challenge with a total of 106 push-ups.

Prostate Cancer Awareness Month and Men's Health Day Friday, September 23rd 10 AM–2:30 PM Guggenheim Pavilion Atrium Mount Sinai Hospital 1468 Madison Avenue

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