Informed Prostate Cancer Support Group Inc.
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Friday, October 15, 2021

OCTOBER 2021 NEWSLETTER

P.O. Box 420142 San Diego, CA 92142
Phone: 619-890-8447 Web: http://ipcsg.org

STREAMING ONLINE LIVE

Volume 14 Issue 10

- **Saturday, Oct 16, 2021 IPCSG - Live-Stream Event, 10:00am PT**

Updates on Advances in Prostate Cancer

- Presented by **Rana R. McKay, MD**, a board-certified medical oncologist who specializes in treating people with urogenital cancers, including bladder, kidney, prostate and testicular cancer. She leads a multi-disciplinary prostate cancer clinic. She serves as principal investigator of several early phase trials in kidney and prostate cancer. As a clinical investigator, she is committed to advancements in cancer care that will improve the lives of cancer patients. Furthermore, she is interested in understanding mechanisms of response and resistance to specific cancer therapies. Her work has appeared in peer-reviewed publications such as Nature, Lancet, Journal of Clinical Oncology, Clinical Cancer Research, and Cancer, among others.
- Due to COVID-19, no in-person meetings at the Sanford Burnham Prebys Medical Discovery Institute will take place until further notice. This meeting will be live-streamed and will also be available on DVD.
- **For further Reading: https://ipcsg.blogspot.com/**
- **For Comments, Ideas and Questions,** email to Newsletter@ipcsg.org

September 2021 Informed Prostate Cancer Support Group Meeting

Summary by Bill Lewis

Transperineal vs Transrectal Prostate Biopsy

Richard J. Szabo, MD is a clinical associate professor in the Department of Urology at University of California, Irvine and is on staff at Kaiser Permanente Orange County and Riverside, California. He has written extensively about the new transperineal approach and has a special interest in teaching "free-hand" transperineal prostate biopsy under local anesthesia to his colleagues and informing the general public of the technique's advantages over the transrectal approach.

He spoke to the IPCSG online meeting on September 18, 2021, and argued persuasively the benefits of the transperineal approach to prostate biopsies. Two important differences are the reduced incidence of infection, and the improved detection of clinically significant cancer.

Infection from a biopsy can lead to sepsis, which is the presence of harmful microorganisms in the blood or other tissues, potentially leading to the malfunctioning of organs, shock, and death. Severe sepsis complications can include Kidney failure, Tissue death (gangrene) of fingers or toes that may require amputation, Permanent lung damage from acute respiratory distress syndrome, Permanent brain damage, which can cause memory problems or more severe symptoms, Later problems with the immune system, which can raise the risk for future infections, and/

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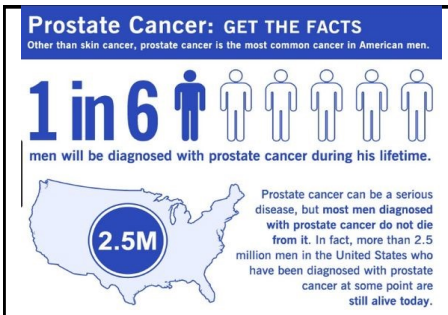

Organization

a 501c3 non-profit organization - all positions are performed gratis

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NEWSLETTER
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PROSTATE CANCER—*2 WORDS, NOT A SENTENCE*

What We Are About

Our Group offers the complete spectrum of information on prevention and treatment. We provide a forum where you can get all your questions answered in one place by men that have lived through the experience. Prostate cancer is very personal. Our goal is to make you more aware of your options before you begin a treatment that has serious side effects that were not properly explained. Impotence, incontinence, and a high rate of recurrence are very common side effects and may be for life. Men who are newly diagnosed with PCa are often overwhelmed by the frightening magnitude of their condition. Networking with our members will help identify what options are best suited for your life style.

Meeting Video DVD's

DVD's of our meetings are available for purchase on our website at https://ipcsg.org/purchase-dvds and are generally available by the next meeting date.

Join the IPCSG TEAM

If you consider the IPCSG to be valuable in your cancer journey, realize that we need people to step up and HELP. Call **President** Bill Lewis @ (619) 591-8670 ; or **Director** Gene Van Vleet @ 619-890-8447.

From the Editor

Due to COVID-19, no in-person meetings will be held until further notice. We will continue to post and distribute the newsletter in the interim. Our speaker this month will be broadcast via the IPCSG website at https://ipcsg.org/live-stream and can be watched by scrolling down and clicking on the "WATCH THE PRESENTATION" button. The broadcast will begin approximately 10 minutes before to the listed start time.

In this issue:

First, we have Bill Lewis's great summary of the last talk by Dr. Richard J. Szabo on different biopsies, followed by Articles of Interest

1. Commentary: Which Cancer Treatment Is Best? Selecting the Right Tool for the Job staging the cancer is key to selecting the right tool to cure or slow cancer
2. 'Gut bugs' can drive prostate cancer growth and treatment resistance: Study unveils mechanism through which the microbiome contributes to prostate cancer progression researchers found that low androgen levels in patients can drive the expansion of gut bacteria, which can become hormone factories to sustain prostate cancer growth
3. Enzalutamide(Xtandi) versus bicalutamide(Casodex) in patients with nonmetastatic castration-resistant prostate cancer: a prespecified subgroup analysis of the STRIVE trial - enzalutamide in reduces the risk of progression or death versus bicalutamide in patients with nmCRPC.

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or Damage to the heart valves (endocarditis), which can lead to heart failure.

There is a rising incidence of infectious complications after TR-Bx (transrectal biopsy), apparently due to increasing microbial resistance to antibiotics. Current rates are 5-7% urine and prostate infections, 1-3% sepsis severe enough to require hospitalization, and about 0.12% death. The increasing difficulty of preventing serious post-TR-Bx infectious complications, stemming from an inherently "transfecal" procedure, has spurred many centers to abandon appropriate antibiotic stewardship as they add antibiotics of last resort (i.e., ertapenem) to their prophylactic regimen.

TR-Bx also leads to rectal bleeding, requiring intervention in 2.5% of cases. So 1 out of 40 go to the ER for observation, rectal balloon "tamponade," or surgery to suture a bleeding vessel.

The inaccuracy of TR-Bx is very significant. Historically, non-MRI targeted TR-Bx has always maintained a high false-negative rate, missing approximately one-third of clinically significant (higher grade) cancers. Also, the findings are understaged (assigned a falsely low Gleason score) in 22-43% of men based on final pathology following radical prostatectomy. The inaccuracy can be reduced by MRI/Ultrasound Fusion Targeting of the TR-BX, so that about 50% better detection of clinically significant cancers is achieved.

Contrary to widely held opinions, TR-Bx is costly, when you consider the total cost to the medical system. That is, the estimated 39,000 cases of post-TR-Bx sepsis and associated hospitalizations cost about $342 to 752 million per year. Inaccuracy leads to repeat biopsies, and the delay in getting accurate results may cause loss of the "window for cure."

Transperineal compared to TR-Bx is much safer, more accurate when MRI/US Fusion targeting is used, and is less costly to the patient and to society. The sepsis rate is essentially zero, and there is no chance of rectal bleeding. Transperineal is 50-60% more accurate than TR-Bx when using MRI/Ultrasound Fusion Targeting, especially in detecting cancer located in the anterior part of the prostate.

Dr. Szabo pointed out errors in meta-analyses of studies in the literature, that missed some of the advantages of the transperineal method – see the video for details. The link is provided below.

The increased accuracy of the transperineal approach leads to an increased chance for cure – less delay in diagnosis of clinically significant cancer (so less delay in adequate treatment), as well as avoiding inappropriate active surveillance, inappropriate focal therapy and inappropriate lack of multimodal therapy. Suffering due to the complications which may occur while not yet cured, include Urinary bleeding, Painful urination, Loss of interest in sex (and impotence), Nausea or other side effects of chronic medications, Bone pain, Depression, and/or Loss of years of life.

There are many misconceptions about the transperineal approach, including a Perceived need for general anesthesia, Increased cost, Needs for a "Stepper Unit" or "Grid", a Much longer procedure time, and More painful. In reality, the transperineal approach can easily be integrated into a normal urologic office workflow using only local anesthesia (see a literature review of 7396 cases of "free-hand transperineal biopsy under local anesthesia without sedation referenced in the video, that show that the Grid and Stepper techniques are not needed).

Sepsis costs add $173-382 for every TR-Bx, and these costs are passed on to all patients via Medicare and insurance companies. To encourage transperineal biopsies, Australia increased remuneration for transperineal by 20%, and decreased for TR-Bx by 50%. In the UK healthcare system, over 70% of biopsies are transperineal, since they appreciate the real cost differences.

Procedure times, based on pooled averages from literature articles, were very similar: Transperineal at 19.1 minutes, and TR-Bx at 14.7 minutes (but they usually took fewer biopsy cores).

Pain scores were very slightly different: 3.17 vs. 2.6, but Wang, et. al. decreased their pain ratings for the transperineal approach to 1.8 by injection of "Branches of Perineal Nerve."

Urinary retention was essentially equivalent to TR-Bx, when fewer than 16 cores were taken by the transperineal approach. And who needs that many, if the biopsy is MRI/US fusion guided?

In summary, based on 12,000 cases of free-hand transperineal biopsies reported in the literature, the approach is superior in safety (virtual elimination of post-biopsy sepsis and rectal bleeding), accuracy (with MRI/US fusion tar-

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geting), and cost. Full adoption of the transperineal approach would save the United States up to $750 million per year! The transperineal approach is closely comparable to TR-Bx in pain score and procedure time.

Questions:

Where can I get a transperineal biopsy? Johns Hopkins, UConn, Fox Chase in Philadelphia, UCSF, USC, UCI, Kaiser Permanente (by Dr. Szabo), and some doctors at UCLA, in orange county and in San Diego who have been trained. See the perineologic website (precision point needle holder manufacturer) for a list. He recommends that patients demand it, for the benefits, and to foster more widespread adoption of the technique.

What is the learning curve for urologists? There is a $10-15,000 investment, and $200 per patient, and it takes about ten cases to learn the technique.

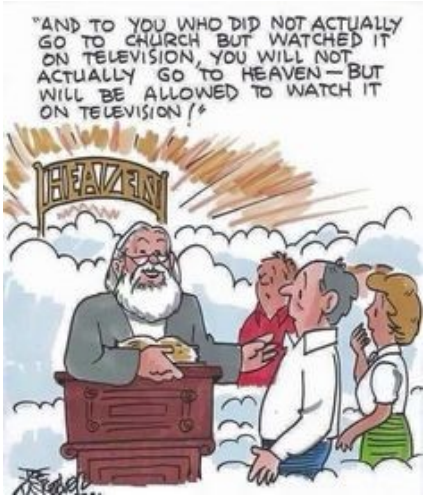
What about having nurses in a urologic practice learn the technique? That's feasible. The procedure is "just a technique," that is relatively easy to learn.

We recommend that you watch the video online for more definitive information about the talk and slides: https://www.youtube.com/watch?v=4GLr_E6Bvec

A DVD of the talk and Dr. Szabo's slides will be available for purchase from the IPCSG about one month after the meeting.

On the Lighter Side

"Don't bother."



Articles of Interest

webmd.com

Commentary: Which Cancer Treatment Is Best? Selecting the Right Tool for the Job

By H. Jack West, MD

Oct. 7, 2021 -- For patients diagnosed with a cancer that starts in a solid organ like a lung, colon, breast, or prostate, oncologists want to identify the best treatment for each patient.

To figure that out, oncologists must answer a critical question: Has the cancer spread to other parts of the body? The process of determining where the cancer is, called staging, gives doctors a clearer sense of the cancer's biological behavior and prognosis, and it helps define the best treatment strategy.

The most common method of staging a cancer evaluates the size and invasiveness of where the cancer started -- the primary tumor -- as well as whether cancer cells have spread to draining lymph nodes in the region or have traveled through the bloodstream to more distant sites in the body -- advanced or metastatic disease. The contributions of the tumor, nodes, and metastases define the TNM staging system.

Our treatments for cancer tend to work either locally or systemically. Local therapies, like surgery or radiation, are effective in the specific area they are directed. Surgery that removes a tumor is effective at eliminating the risk of disease from that location, and radiation helps kill cancer cells within the "field" in which the radiation is pointed.

Systemic therapies, such as chemotherapy and immunotherapy, work throughout the entire body and can be given intravenously (IV), orally with a pill, or occasionally by injection. Immunotherapy, typically an IV treatment, helps stimulate a patient's immune system to recognize and attack the cancer. The goal of systemic therapies is to treat the disease that's visible on scans or a physical examination as well as any potential microscopic or invisible disease that a scan or exam cannot detect but that may grow over time.

Historically, surgery or radiation has been the cornerstone of managing early-stage cancers, and chemotherapy or other systemic therapies have been the mainstay of advanced cancer care.

Doctors typically use local therapies when the primary tumor is not too large, has not invaded surrounding tissues, and the spread to lymph nodes is limited. In fact, for early stage cancers, local therapies like surgery or radiation can be curative.

However, as the size and number of lymph nodes involved with a cancer increases, the probability that the cancer has or will spread to other areas of the body also increases. Patients with more advanced cancers typically undergo systemic therapy to cast a wider treatment net and catch not only the disease you see but also the disease you can't.

Over time, however, we have found that systemic therapies can also improve results for many high-risk but still earlier-stage cancers, and local therapies may be helpful for specific types of metastatic cancer.

For instance, in some patients with early-stage, localized cancer, chemotherapy may be given before surgery or at the same time as radiation. Combining systemic and local therapies can improve how well the local therapy works against the visible disease we can see and often helps catch the invisible disease before it can take hold. For many cancers, chemotherapy or immunotherapy has been shown to shrink tumors before surgery or during radiation and increase the chance that patients will be cancer free years after treatment.

Local therapies like surgery or radiation may also be appropriate for patients with advanced cancer. If the cancer has metastasized to the brain, for example, a patient may benefit from surgery or radiation directed to the

tumor site because many systemic cancer drugs cannot reach the brain in high enough concentrations to shrink these tumors. Similarly, when a tumor mass is causing symptoms that need to be treated immediately, such as bleeding or difficulty breathing, local therapy targeting the problem are may do the job best. In addition, patients with metastatic disease may only have one or two tumors growing at a concerning rate. This situation, called oligo-metastatic disease (oligo meaning "few"), is unusual but may call for a local treatment directed at that fast-growing tumor.

That is precision medicine -- the concept of identifying the right tools for each individual -- at work.

H. Jack West, MD, is an associate clinical professor and the executive director of employer services at City of Hope Comprehensive Cancer Center in Duarte, CA. West serves as web editor for JAMA Oncology, edits and writes several sections on lung cancer for UpToDate, and leads a wide range of continuing education programs and other educational programs, including hosting the podcast West Wind.

sciencedaily.com

'Gut bugs' can drive prostate cancer growth and treatment resistance: Study unveils mechanism through which the microbiome contributes to prostate cancer progression

Common gut bacteria can fuel the growth of prostate cancers and allow them to evade the effects of treatment, a new study finds.

Scientists revealed how gut bacteria contribute to the progression of advanced prostate cancers and their resistance to hormone therapy -- by providing an alternative source of growth-promoting androgens, or male hormones.

Hormone therapy is the standard of care for advanced prostate cancer and works by lowering levels of androgens. But researchers found that low androgen levels in patients can drive the expansion of gut bacteria, which can become hormone factories to sustain prostate cancer growth.

Bacterial 'fingerprints' identified by scientists may help pick out patients at high risk of developing resistance to treatment who could benefit from strategies to manipulate their 'microbiome'. For example, men could undergo a faecal transplant or take a yoghurt drink enriched with favourable bacteria.

A team of scientists from The Institute of Cancer Research, London, the Institute of Oncology Research in Bellinzona, Switzerland and the Swiss Federal Institute of Technology used mice and patient samples to investigate the role of gut bacteria in prostate cancer growth and progression.

The findings, once further validated in the clinic, could provide new opportunities for the treatment of prostate cancer through manipulation of the microbiome.

The study, published in the journal Science, was funded by the Prostate Cancer Foundation, Movember, Prostate Cancer UK, Cancer Research UK and The John Black Charitable Foundation.

Gut bacteria are part of our microbiome and are usually valuable to humans. However, cancer and other diseases can ruin this mutually beneficial balance -- for example by promoting the expansion of gut bacteria and encouraging them to release toxins or other molecules that affect cancer cells.

Given the role these 'gut bugs' can play in cancer, researchers looked at whether the gut bacteria from men with prostate cancer could also alter patients' hormone metabolism, and so affect cancer growth.

Scientists found that getting rid of all gut bacteria in mice with prostate cancer slowed tumour growth and delayed the emergence of hormone resistance.

They also found that transplanting faeces from mice with hormone-resistant prostate cancer into mice with low androgen levels that had not yet developed resistance encouraged tumour growth.

The researchers demonstrated in mice that gut bacteria were able to make androgen hormones from precursor molecules.

To translate the findings into humans, researchers analysed the gut bacteria from patients who were being treated at The Royal Marsden NHS Foundation Trust. They looked at two different groups of patients -- 19 men whose prostate cancers were still responding to hormone therapy and 55 men with advanced hormone-resistant prostate cancer.

Transplanting stool from prostate cancer patients with hormone-resistant prostate cancer into mice whose cancers were not resistant promoted tumour growth and hormone resistance.

Scientists also analysed microbial genetic material from the stool of men with prostate cancer and identified a specific bacterium -- Ruminococcus - that may play a major role in the development of resistance. In contrast, the bacterium Prevotella stercorea was associated with favourable clinical outcomes.

Researchers incubated mini-tumours called organoids derived from prostate cancer patients with different gut bacteria and attempted to treat them in the lab. This helped them identify favourable and unfavourable bacterial 'fingerprints' linked to prostate cancer outcome, which could help identify men who could benefit from strategies to manipulate the microbiome.

Study author Professor Johann de Bono, Professor of Experimental Cancer Medicine at The Institute of Cancer Research, London, and Consultant Medical Oncologist at The Royal Marsden NHS Foundation Trust, said:

"Our findings reveal that the initiation of hormone therapy for prostate cancer can trigger 'gut bugs' to start producing androgen hormones. These androgens can then sustain prostate cancer's growth and drive resistance to hormone therapy -- worsening men's survival outcomes.

"Excitingly, our research has identified particular signatures among gut bacteria which could indicate that some men with prostate cancer who have these gut bugs are more likely to develop resistance to hormone therapy. The next step will be to further explore how we apply these signatures in patients, with the aim of devising tests to pick out men who would benefit from faecal transplants, antibiotic therapy and other strategies to manipulate the microbiome. In the long-term, our aim would be to produce a 'yoghurt' enriched with favourable bacteria to prevent resistance to treatment."

Professor Kristian Helin, Chief Executive of The Institute of Cancer Research, London, said:

"The influence of the gut microbiome on cancer is a fascinating new area of science that we are just beginning to understand. These exciting findings are the first to unveil a mechanism through which the gut microbiome can drive prostate cancer growth and resistance to hormone therapy.

"Understanding how common, 'good' bacteria in the gut -- which play a vital role in keeping us healthy -- can interfere with hormone metabolism in men with prostate cancer could help us devise new treatment strategies. I look forward to this research moving forward into the clinic and hope that strategies to manipulate the microbiome could make a real difference for patients."

Professor Andrea Alimonti, Head of Molecular Oncology at the Institute of Oncology Research (IOR), Professor at Università della Svizzera italiana (USI), at the University of Padova and at the Swiss Federal Institute of Technology (ETH), said:

"Our discoveries pave the way to adjuvant therapeutic strategies that, through microbiota manipulations, counteract the expansion of androgen-producing bacterial species."

Enzalutamide versus bicalutamide in patients with non-metastatic castration-resistant prostate cancer: a pre-specified subgroup analysis of the STRIVE trial

David F. Penson, Andrew J. Armstrong, Raoul S. Concepcion, Neeraj Agarwal, Carl A. Olsson, Lawrence I. Karsh, Curtis J. Dunshee, William Duggan, Qi Shen, Jennifer Sugg, Gabriel P. Haas & Celestia S. Higano

Prostate Cancer and Prostatic Diseases (2021)Cite this article

Abstract

Background

In the phase 2, randomized, double-blind STRIVE trial, enzalutamide significantly reduced the risk of prostate cancer progression or death versus bicalutamide in patients with metastatic castration-resistant prostate cancer (mCRPC) and nonmetastatic CRPC (nmCRPC). The objective of this protocol-specified subgroup analysis of STRIVE was to investigate the benefit of enzalutamide versus bicalutamide specifically in patients with nmCRPC.

Methods

Patients (N = 139) were stratified by disease stage and randomized to enzalutamide 160 mg/day plus androgen deprivation therapy (ADT; n = 70) or bicalutamide 50 mg/day plus ADT (n = 69).

Results

Baseline characteristics of patients with nmCRPC were comparable between groups. At a median of 17 months follow-up, enzalutamide reduced the risk of progression or death by 76% versus bicalutamide in patients with nmCRPC (hazard ratio [HR], 0.24; 95% CI 0.14–0.42). Enzalutamide reduced risk of prostate-specific antigen progression by 82% versus bicalutamide in patients with nmCRPC (HR, 0.18; 95% CI 0.10–0.34). The most frequently reported adverse events by patients receiving enzalutamide were fatigue (36.2%), hot flush (20.3%), decreased appetite (17.4%), dizziness (17.4%), and nausea (17.4%).

Conclusions

This STRIVE subgroup analysis of patients with nmCRPC illustrates the benefit of enzalutamide in reducing the risk of progression or death versus bicalutamide in patients with nmCRPC.

Trial registration

ClinicalTrials.gov identifier NCT01664923.

ecu.edu.au

Cancer breakthrough: Exercise may stop disease in its tracks

Professor Rob Newton

Forget bedrest, research from Edith Cowan University (ECU) has shown exercise may be a key weapon in cancer patients' battle against the disease.

Exercise causes muscles to secrete proteins called myokines into our blood – and researchers from ECU's Exercise Medicine Research Institute have learned these myokines can suppress tumour growth and even help actively fight cancerous cells.

A clinical trial saw obese prostate cancer patients undergo regular exercise training for 12 weeks, giving blood samples before and after the exercise program.

Researchers then took the samples and applied them directly onto living prostate cancer cells.

Study supervisor Professor Robert Newton said the results help explain why cancer progresses more slowly in patients who exercise.

"The patients' levels of anti-cancer myokines increased in the three months," he said.

"When we took their pre-exercise blood and their post-exercise blood and placed it over living prostate cancer cells, we saw a significant suppression of the growth of those cells from the post-training blood.

"That's quite substantial indicating chronic exercise creates a cancer suppressive environment in the body."

A formidable team

PhD candidate and research lead Jin-Soo Kim said while myokines could signal cancer cells to grow slower – or stop completely – they were unable to kill the cells by themselves.

However, he said myokines can team up with other cells in the blood to actively fight cancer.

"Myokines in and of themselves don't signal the cells to die," Mr Kim said.

"But they do signal our immune cells – T-cells – to attack and kill the cancer cells."

Professor Rob Newton.

Professor Newton said exercise also complements other prostate cancer treatments such as androgen deprivation therapy, which is both effective and commonly prescribed but can also lead to significant reduction in lean mass and an increase in fat mass. This can result in sarcopenic obesity (being obese with low muscle mass), poorer health and cancer outcomes.

All study participants were undergoing ADT and were obese, with the training program seeing them maintain lean mass while losing fat mass.

A fighting future

The study focused on prostate cancer due it being the most common non-skin cancer among men and the high number of patient fatalities – however Professor Newton said the findings could have a wider impact.

"We believe this mechanism applies to all cancers," he said.

ECU is carrying out further studies, including a trial where patients with advanced-stage prostate cancer are put through a six-month exercise program.

Though results are still pending, Professor Newton said preliminary findings were encouraging.

"These men have high disease burden, extensive treatment side-effects and are very unwell, but they still can produce anti-cancer medicine from within.

"It's important as it may indicate why men even with advanced cancer, if they're physically active, don't succumb as quickly."

'Myokine expression and tumour-suppressive effect of serum following 12 weeks of exercise in prostate cancer patients on ADT' was published in Medicine and Science in Sports and Exercise.

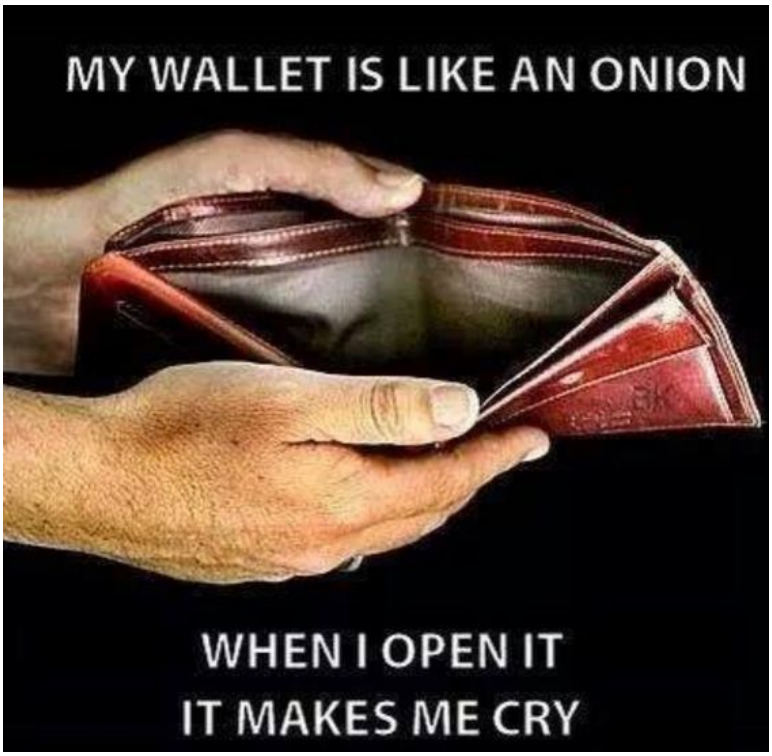
NETWORKING

Please help us in our outreach efforts. Our speakers bureau consisting of Gene Van Vleet is available to speak to organizations of which you might be a member. Contact Gene 619-890-8447 or gene@ipcsg.org to coordinate.

Member John Tassi is the webmaster of our website and welcomes any suggestions to make our website simple and easy to navigate. Check out the Personal Experiences page and send us your story. Go to: https://ipcsg.org/personal-experience

Our brochure provides the group philosophy and explains our goals. Copies may be obtained by mail or email on request. Please pass them along to friends and contacts.

FINANCES



We want to thank those of you who have made special donations to IPCSG. Remember that your gifts are tax deductible because we are a 501(c)(3) non-profit organization.

We again are reminding our members and friends to consider giving a large financial contribution to the IPCSG. This can include estate giving as well as giving in memory of a loved one. You can also have a distribution from your IRA made to our account. We need your support. We will, in turn, make contributions from our group to Prostate Cancer researchers and other groups as appropriate for a non-profit organization. Our group ID number is 54-2141691. Corporate donors are welcome!

While our monthly meetings are suspended, we still have continuing needs, but no monthly collection. If you have the internet you can contribute easily by going to our website, http://ipcsg.org and clicking on "Donate" Follow the instructions on that page. OR just mail a check to: IPCSG, P. O. Box 420142, San Diego CA 92142

Continued Editors Notes:

4. Cancer breakthrough: Exercise may stop disease in its tracks—Exercise causes muscles to secrete proteins called myokines into our blood – myokines can suppress tumour growth and help actively fight cancerous cells
5. Early outcomes and decision regret using PSMA/MRI guided focal boost for prostate cancer SBRT demonstrated promising efficacy and low toxicity with PSMA/MRI guided SBRT focal
6. Disease Control With Cabozantinib Plus Atezolizumab in CRPC— COSMIC-21 results showed 84% with stable disease after combination treatment
7. Too Many Black Men Are Dying From Prostate Cancer— Improving access to screening can reduce racial disparities and save lives
8. New Tests for Colon, Prostate Cancer Show Promise
9. Predicting high-grade prostate cancer at initial biopsy: clinical performance of the ExoDx (EPI) Prostate Intelliscore test in three independent prospective studies
10. Discovery of a new candidate drug to overcome cabazitaxel-resistant gene signature in castration-resistant prostate cancer by in silico screening
11. Prospective phase 2 trial of PSMA-targeted molecular RadiothErapy with 177Lu-PSMA-617 for metastatic castration-reSISTant Prostate Cancer (RESIST-PC): efficacy results of the UCLA cohort
12. Diagnostic Value, Oncologic Outcomes, and Safety Profile of Image-Guided Surgery Technologies During Robot-Assisted Lymph Node Dissection with Sentinel Node Biopsy for Prostate Cancer
13. The impact of the extent and location of positive surgical margins on the risk of biochemical recurrence following radical prostatectomy in men with Gleason 7 prostate cancers
14. NCCN Guidelines Embrace PSMA-PET Imaging for Prostate Cancer Superior Accuracy
15. Metastatic Prostate Cancer Comes in Two Forms, Which Could Guide Treatment
16. Abiraterone acetate versus nonsteroidal antiandrogen with androgen deprivation therapy for high-risk metastatic hormone-sensitive prostate cancer
17. Immunotherapy in treatment of metastatic prostate cancer: An approach to circumvent immunosuppressive tumor microenvironment
18. Chemotherapy-induced peripheral neuropathy and rehabilitation: A review
19. STAMPEDE Will 'Change Practice' in High-Risk Prostate Cancer— Trial showed adding abiraterone to ADT improved metastasis-free and overall survival
20. More than 25 organizations join new Prostate Cancer Impact Alliance
21. Men Give Thumbs Up to Video on Genetic Testing in Prostate Cancer
22. Second Industry Body Updates Guidance for Use of PSMA PET Imaging—Medicare approved

sciencedirect.com

Early outcomes and decision regret using PSMA/MRI guided focal boost for prostate cancer SBRT

Abstract

Purpose

SBRT is a recognised treatment for low and intermediate risk prostate cancer with 36.25Gy in 5 fractions the most commonly used regimen. We explored the preliminary efficacy, patient recorded toxicity and decision regret in intermediate and high risk prostate cancer receiving SBRT with PSMA/MRI guided focal gross tumor volume (GTV) boost to 45Gy.

Methods

Between July 2015 and June 2019, 120 patients received SBRT across 2 institutions with a uniform protocol. All patients had fiducial markers and hydrogel, MRI and PSMA PET scan. All patients received a questionnaire asking the degree of urinary, bowel and sexual bother experienced at set time points, including questions about treatment choice and decision regret.

Results

112 of 120 patients consented, their median age was 72 years and median follow up was 2.3 yrs. As per National Comprehensive Cancer Network guidelines, 78% had intermediate risk and 20% high risk. Androgen deprivation was combined with radiation in 6 patients. Most patients (74%) reported that receiving SBRT significantly influenced their choice of treatment.

Five men (4%) expressed "quite a lot" (n=4) or "very much" regret (n=1) regarding their choice of treatment, whilst 89% expressed "no regret". Similar to pretreatment levels, "Quite a lot" or "Very much" urinary or bowel bother was expressed in 8% and 6% of patients respectively.

Two patients experienced nadir +2 biochemical failure, both found to have bone metastases. A 3rd patient underwent PSMA PET at nadir + 1.7, and had disease at the penile bulb, which was out of field. Three year estimated freedom from biochemical failure was 99% for intermediate and 85% for high risk groups.

Conclusions

We have demonstrated promising efficacy and low toxicity with PSMA/MRI guided SBRT focal boost. Less than 5% of patients expressed significant decision regret for their choice of treatment.

View full text

medpagetoday.com

Disease Control With Cabozantinib Plus Atezolizumab in CRPC

by Greg Laub, Director, Video, MedPage Today October 4, 2021

Meeting Coverage > ESMO Video Pearls: Prostate Cancer

— COSMIC-21 results showed 84% with stable disease after combination treatment

For previously treated patients with locally advanced or metastatic castration-resistant prostate cancer (CRPC), cabozantinib (Cabometyx) plus atezolizumab (Tecentriq) continued to show clinically significant activity, according to results from the phase Ib COSMIC-021 trial, presented during the European Society for Medical Oncology virtual meeting.

In this exclusive MedPage Today video, Yung Lyou, MD, PhD, a medical oncologist at City of Hope in Duarte, California, briefly describes the study and his clinical takeaways.

Following is a transcript of his remarks:

Hi, my name is Dr. Yung Lyou. I am an assistant clinical professor at City of Hope specializing in general urinary cancers, and I am a medical oncologist. So the study I wanted to talk about today is cohort 6 of the COSMIC-21 study, which is a phase Ib study looking at the combination of cabozantinib, which is a tyrosine kinase inhibitor [TKI], combined with atezolizumab, which is an immune checkpoint inhibitor, and seeing how patients with metastatic prostate cancer responded to this particular treatment.

One of the key reasons this study was of particular interest is that it is one of the first studies, or one of the few studies out there, that shows efficacy and metastatic castration-resistant prostate cancer combining a TKI and an IO [immuno-oncology] agent.

The way this study was conducted is that they recruited patients that had radiographic progression in soft tissue after getting an anti-androgen such as enzalutamide and/or abiraterone prednisone. And the other key algebra criteria had to be that the patients had measurable

disease based on RECIST 1.1 in the soft tissues, or extrapelvic lymph nodes, and prior chemotherapy was not permitted with the exception of docetaxel for metastatic castration-sensitive prostate cancer.

So for this clinical trial, a total of 132 patients were enrolled, and 101 of them had visceral and extrapelvic lymph nodes. And all of these patients were metastatic castration-resistant prostate cancer patients. And what this showed was that the treatment of combined cabozantinib and atezolizumab showed significant efficacy with the overall response rate, including all partial responses of 15%, where they had a pretty significant disease control rate -- which includes CR [complete response], PR [partial response], and SD [stable disease] patients -- of 84%.

Furthermore, what was also noticed from this study was that the overall adverse effects were tolerable with having only 20% of patients discontinue, and the adverse effects themselves were consistent with what was expected from administering these agents separately, such as diarrhea, fatigue, and some IRAEs [immune-related adverse events] such as dermatitis and hand-foot syndrome, which comes from the use of cabozantinib.

So the key take-homes I would like to say from this particular study is that it is significant, and that it shows that combining non-cytotoxic chemotherapy for metastatic castration-resistant prostate cancer patients using a TKI and IO agent is beneficial.

And in this phase I study, there was good safety signals and also meaningful clinical responses. And the investigators now are further investigating to see if this combination is effective in a larger phase III study, which is the CONTACT-02 study.

medpagetoday.com

Too Many Black Men Are Dying From Prostate Cancer

by Jonathan Henderson, MD October 3, 2021

— Improving access to screening can reduce racial disparities and save lives

Prostate cancer remains the second highest cancer-related cause of death in men in the U.S., and there has been a worrisome trend of rising metastatic disease at diagnosis. These facts make it increasingly important that the urological community and the patients we serve turn our attention to ways to overcome these challenges.

The Role of Screening

As a urologist practicing in Shreveport, a majority-minority city in Louisiana -- the state with the highest incidence of prostate cancer -- I am well aware that Black men in the U.S. have the highest mortality rate for prostate cancer and are twice as likely to die from it as white men. Consequently, Black men are more likely to be saved by screening.

Prostate-specific antigen (PSA) screening may be more controversial today than decades ago, as more questions have arisen about the balance of benefits versus potential harms of unnecessary treatment. However, there is one aspect of this disease on which the entire healthcare community agrees: for both the diagnosis and treatment of prostate cancer, patient-physician shared decision-making should be optimized. Providers must have the ability to counsel patients on evidence-based best practices, taking into account the individual's risk factors and personal preferences.

Unfortunately, policy changes over the past few years have made access to screening increasingly challenging. This is an issue that must be addressed at a Congressional level.

Consider a recent study on PSA screening in men ages 40 and older released at the 2021 Genitourinary Cancers Symposium. The data suggest that the 2012 decision by the U.S. Preventive Services Task Force (USPSTF) to de-prioritize PSA testing has resulted in a higher proportion of men diagnosed with metastatic prostate cancer in later stages than before the USPSTF policy. This decision was faulty from the beginning, as it was loosely based on an erroneous interpretation of previous data and undermines the benefits of PSA tests. There is a direct relationship between PSA screening and diagnosing prostate cancer at an earlier stage. Despite multiple studies identifying this upward shift of prostate cancer metastatic at diagnosis, the USPSTF still devalues PSA testing by giving it a C grade, suggesting that the balance of benefits and harms is close and that the extent of the net benefit is small. In contrast, a rating of a B or higher would carry the recommendation to providers to offer or provide the service. The USPSTF's current C rating is inappropriate because it not only ne-

gates a physician's expertise and knowledge of a patient's health history, but it also undermines recent breakthroughs in molecular and genomic testing that facilitate personalized precision healthcare delivery. Furthermore, as many insurers and providers use USPSTF ratings as one factor in planning treatment, men cannot be confident their insurance company will cover the cost of their PSA test.

This unacceptable circumstance diminishes the value of adequate access to PSA screening at a time when the number of deaths due to prostate cancer has been increasing. Many lives may not have been lost had people's cancer been detected earlier.

Removing Barriers to Screening

The current rating highlights the essential role government regulators must play in removing barriers to screenings for those at high risk of developing prostate cancer, including Black men; those with a family history of prostate cancer; and professionals and servicemen who may have suffered exposure to cancer-causing toxins.

So, what can be done? Congress -- though often ineffective at passing meaningful piecemeal healthcare legislation -- can begin by reforming the process USPSTF uses to issue recommendations and guidance. Congress should hold this powerful, yet unelected agency to the same standards as other bureaus. The USPSTF Transparency and Accountability Act, introduced in every Congress since 2015, has sought to improve the accountability and processes of this unelected body.

Waiving cost-sharing -- including deductibles, copayments, and coinsurances -- for at-risk patients will help more men, including those affected by regional, economic, and racial disparities, to secure earlier diagnoses and better treatment options. Some states are introducing legislation to require insurers to cover prostate cancer screening, as state action has become increasingly commonplace due to congressional inaction on various issues. But the problem of prostate cancer in the U.S. is bigger than any one state's legislature, and it has gotten worse, especially regarding prevention.

If elected officials in Congress are committed to reducing racial disparities in prostate cancer deaths, expanding access to healthcare, and protecting generations of American men, re-introducing and passing the USPSTF Transparency and Accountability Act is one of the simplest and most impactful actions they can take. As public policy catches up to the medical realities of prostate cancer, the work to educate and update primary care providers on the importance of PSA screening will remain essential.

Jonathan Henderson, MD, is president of the Large Urology Group Practice Association (LUGPA).

Last Updated October 04, 2021

medicinenet.com

New Tests for Colon, Prostate Cancer Show Promise

WEDNESDAY, Sept. 29, 2021 (HealthDay News)

A pair of experimental tests could help doctors detect colon or prostate cancer with just a sample of blood or saliva.

One test examines a person's blood for four biomarkers linked to inflammation. In a small study, it outperformed the fecal blood test now used in colon cancer screening, said lead researcher Dr. Mona Eldeeb, of Alexandria University Medical Research Institute in Egypt.

"These combined blood base markers could detect early cancer [of the] colon, especially if applied in a screening program," she said.

The other test uses a man's saliva to look for genetic material linked to prostate tumor growth, according to the Iranian researchers who developed it.

If approved in the United States, the tests could make screening and diagnosis for these cancers easier on patients, without the need for needle biopsy or colonoscopy, experts said.

"The exciting part of this study is that the [prostate cancer] test truly is noninvasive, requiring no need for needles as it relies on saliva that can be easily and repeatedly obtained," said Dr. Corey Speers, a radiation oncologist at the University of Michigan's Rogel Cancer Center in Ann Arbor.

The colon cancer test uses microscopic, color-coded beads to capture four inflammatory proteins from a blood sample. Laser technology then provides a count of the beads.

Eldeeb and her team tried the test with 35 patients with colon cancer and 52 people who were cancer-free.

They found that the proteins were at higher levels in the

cancer patients, indicating that they could be used to screen for colon cancer without resorting to colonoscopy, Eldeeb said.

"This new test showed higher accurate results than the routinely used stool-based noninvasive test, and if used in combination with the fecal occult blood test gives very strong and accurate sensitivity with less need for colonoscopy," she said.

The prostate cancer test searches saliva for eight RNA samples that indicate whether a man has developed prostate cancer or is simply suffering from age-related enlarged prostate. The research was led by Jamal Amri and Mona Alaee, from Tehran University of Medical Sciences in Iran.

The researchers tried the test on 180 men between the ages of 45 and 50, including 60 diagnosed with prostate cancer and 60 with enlarged prostate.

The study found that the saliva panel accurately sorted the men with prostate cancer from those with an enlarged prostate -- something that up to now has required a needle biopsy.

"Of course, with all such preliminary studies questions still remain as to the accuracy and reliability of the test when you expand to a larger group of patients, and it isn't yet ready for general adoption, but this represents an exciting first step," said Speers, a spokesman for the American Society for Clinical Oncology.

He said future studies would seek to confirm these initial findings in a larger and more diverse set of men. They will also seek to determine appropriate cutoffs for levels of RNA in the saliva samples.

"We look forward to these confirmatory studies being completed," Speers said.

Both reports were presented this week at the American Association for Clinical Chemistry (AACC) annual meeting, in Atlanta. Findings presented at medical meetings are considered preliminary until published in a peer-reviewed journal.

"These reports are very interesting early observations, and it will be exciting to see how they perform in follow-up studies," AACC President Dr. Stephen Master said in a statement. "Of course, it's important to note that both of these studies are preliminary, and both tests will need to be validated in larger studies before we can really know if they can be used in clinical practice or not."

SLIDESHOW

Screening Tests Every Man Should Have See Slideshow

More information

The U.S. National Cancer Institute has more about cancer screening.

SOURCES: Mona Eldeeb, MD, Alexandria University Medical Research Institute, Egypt; Corey Speers, MD, PhD, radiation oncologist, University of Michigan Rogel Cancer Center, Ann Arbor; Sept. 28, 2021, statement, Stephen Master, president, American Association of Clinical Chemistry, American Association for Clinical Chemistry, annual meeting, Atlanta, Sept. 28-29, 2021

HealthDay

From WebMD

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Predicting high-grade prostate cancer at initial biopsy: clinical performance of the ExoDx (EPI) Prostate Intelliscore test in three independent prospective studies

Erik Margolis, Gordon Brown, Alan Partin, Ballentine Carter, James McKiernan, Ronald Tutrone, Phillipp Torkler, Christian Fischer, Vasisht Tadigotla, Mikkel Noerholm, Michael J. Donovan & Johan Skog

Prostate Cancer and Prostatic Diseases (2021)Cite this article

Abstract

Background

The ability to discriminate indolent from clinically significant prostate cancer (PC) at the initial biopsy remains a challenge. The ExoDx Prostate (IntelliScore) (EPI) test is a noninvasive liquid biopsy that quantifies three RNA targets in urine exosomes. The EPI test stratifies patients for risk of high-grade prostate cancer (HGPC; ≥ Grade Group 2 [GG] PC) in men ≥ 50 years with equivocal prostate-specific antigen (PSA) (2–10 ng/mL). Here, we present a pooled meta-analysis from three independent prospective-validation studies in men presenting for initial biopsy decision.

Methods

Pooled data from two prospective multi-site validation studies and the control arm of a clinical utility study were analyzed. Performance was evaluated using the area under the receiver-operating characteristic curve (AUC), negative predictive value (NPV), positive predictive value (PPV), sensitivity, and specificity for discriminating ≥ GG2 from GG1 and benign pathology.

Results

The combined cohort (n = 1212) of initial-biopsy subjects had a median age of 63 years and median PSA of 5.2 ng/mL. The EPI AUC (0.70) was superior to PSA (0.56), Prostate Cancer Prevention Trial Risk Calculator (PCPT-RC) (0.62), and The European Randomized Study of Screening for Prostate Cancer (ERSPC) (0.59), (all p-values <0.001) for discriminating GG2 from GG1 and benign histology. The validated cutoff of 15.6 would avoid 23% of all prostate biopsies and 30% of "unnecessary" (benign or Gleason 6/GG1) biopsies, with an NPV of 90%.

Conclusions

EPI is a noninvasive, easy-to-use, urine exosome–RNA assay that has been validated across 3 independent prospective multicenter clinical trials with 1212 subjects. The test can discriminate high-grade (≥GG2) from low-grade (GG1) cancer and benign disease. EPI effectively guides the biopsy-decision process independent of PSA and other standard-of-care factors.

Published: 30 September 2021

Discovery of a new candidate drug to overcome cabazitaxel-resistant gene signature in castration-resistant prostate cancer by in silico screening

Hiroshi Hongo, Takeo Kosaka, Yoko Suzuki & Mototsugu Oya

Prostate Cancer and Prostatic Diseases (2021)Cite this article

Abstract

Background

The taxane cabazitaxel (CBZ) is a promising treatment for docetaxel-resistant castration-resistant prostate cancer (CRPC). However, the survival benefit with CBZ for patients with CRPC is limited. This study used screening tests for candidate drugs targeting CBZ-resistant-related gene expression and identified pimozide as a potential candidate for overcoming CBZ resistance in CRPC.

Methods

We established CBZ-resistant cell lines, DU145CR and PC3CR by incubating DU145 cells and PC3 cells with gradually increasing concentrations of CBZ. We performed in silico drug screening for candidate drugs that could reprogram the gene expression signature of a CBZ-resistant prostate cancer cells using a Connectivity Map. The in vivo effect of the drug combination was tested in xenograft mice models.

Results

We identified pimozide as a promising candidate drug for CBZ-resistant CRPC. Pimozide had a significant antitumor effect on DU145CR cells. Moreover, combination treatment with pimozide and CBZ had a synergic effect for DU145CR cells in vitro and in vivo. Microarray analysis identified AURKB and KIF20A as potential targets of pimozide in CBZ-resistant CRPC. DU145CR had significantly higher AURKB and KIF20A expression compared with a non-CBZ-resistant cell line. Inhibition of AURKB and KIF20A had an antitumor effect in DU145CR xenograft tumors. Higher expression of AURKB and KIF20A was a poor prognostic factor of TGCA prostate cancer cohort. CBZ-resistant prostate cancer tissues in our institution had higher AURKB and KIF20A expression.

Conclusions

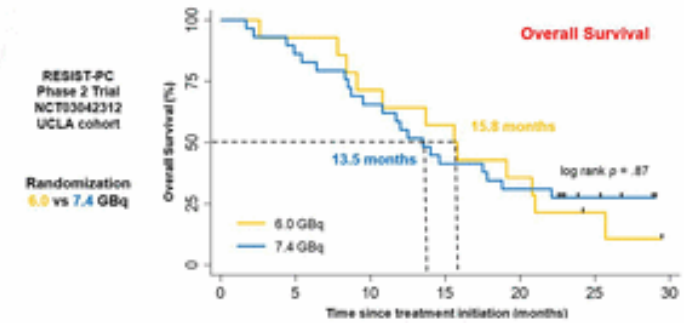
Pimozide appears to be a promising drug to overcome CBZ resistance in CRPC by targeting AURKB and KIF20A.

Prospective phase 2 trial of PSMA-targeted molecular RadiothErapy with ^{177}Lu-PSMA-617 for metastatic castration-reSISTant Prostate Cancer (RESIST-PC): efficacy results of the UCLA cohort

Jeremie Calais, Andrei Gafita, Matthias Eiber, Wesley R. Armstrong, Jeannine Gartmann, Pan Thin, Kathleen Nguyen, Vincent Lok, Laura Gosa, Tristan Grogan, Rouzbeh Esfandiari, Martin Allen Auerbach, Andrew Quon, Shadfar Bahri, Pawan Gupta, Linda Gardner, David Ranganathan, Roger Slavik, Magnus Dahlbom, Ken Herrmann, Ebrahim Delpassand, Wolfgang P. Fendler and Johannes Czernin

Journal of Nuclear Medicine October 2021, 62 (10) 1440-1446; DOI: https://doi.org/10.2967/jnumed.121.261982

Visual Abstract

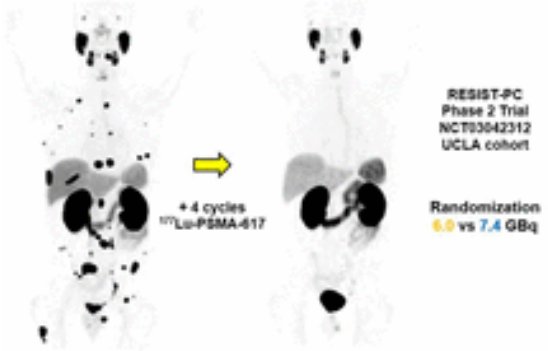


Abstract

The objective of this study was to determine prospectively the efficacy profile of 2 activity regimens of ^{177}Lu-PSMA therapy in patients with progressive metastatic castrate-resistant prostate cancer (mCRPC): 6.0 vs. 7.4 GBq.

Methods: RESIST-PC (NCT03042312) was a prospective multicenter phase 2 trial. Patients with progressive mCRPC after ≥ 1 novel androgen-axis drug, either chemotherapy naïve or postchemotherapy, with sufficient bone marrow reserve, normal kidney function, and sufficient PSMA expression by PSMA PET were eligible. Patients were randomized (1:1) into 2 activity groups (6.0 or 7.4 GBq) and received up to 4 cycles every 8 wk. The primary endpoint was the efficacy of ^{177}Lu-PSMA measured by the prostate-specific antigen (PSA) response rate (RR) after 2 cycles (≥50% decline from baseline). Secondary endpoints included the PSA RR (≥50% decline) at any time (best response), and overall survival (OS).

Results: The study was closed at enrollment of 71/200 planned patients because of sponsorship transfer. We report here the efficacy of the University of California Los Angeles cohort results only (n = 43). The PSA RRs after 2 cycles and at any time were 11/40 (28%, 95% CI 15–44), 6/13 (46%, 95% CI 19–75), and 5/27 (19%, 95% CI 6–38), and 16/43 (37%, 95% CI 23–53), 7/14 (50%, 95% CI 23–77), and 9/29 (31%, 95% CI 15–51) in the whole cohort, the 6.0-GBq group, and the 7.4-GBq group, respectively (P = 0.12 and P = 0.31). The median



OS was 14.0 mo (95% CI 10.1–17.9), 15.8 (95% CI 11.8–19.4), and 13.5 (95% CI 10.0–17.0) in the whole cohort, the 6.0-GBq group, and the 7.4 GBq group, respectively (P = 0.87). OS was longer in patients who experienced a PSA decline ≥ 50% at any time than in those who did not: median, 20.8 versus 10.8 mo (P = 0.005).

Conclusion: In this prospective phase 2 trial of ^{177}Lu-PSMA for mCRPC, the median OS was 14 mo. Despite the heterogeneous study population and the premature study termination, the efficacy profile of ^{177}Lu-PSMA appeared to be favorable and comparable with both activity regimens (6.0 vs. 7.4 GBq). Results justify confirmation with real-world data matched-pair analysis and further clinical trials to refine and optimize the ^{177}Lu-PSMA therapy administration scheme to improve tumor radiation dose delivery and efficacy.

Diagnostic Value, Oncologic Outcomes, and Safety Profile of Image-Guided Surgery Technologies During Robot-Assisted Lymph Node Dissection with Sentinel Node Biopsy for Prostate Cancer

Elio Mazzone, Paolo Dell'Oglio, Nikos Grivas, Esther Wit, Maarten Donswijk, Alberto Briganti, Fijs Van Leeuwen and Henk van der Poel

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Abstract

Despite good sensitivity and a good negative predictive value, the implementation of sentinel node biopsy (SNB) in robot-assisted radical prostatectomy with extended pelvic lymph node dissection (ePLND) for prostate cancer is still controversial. For this reason, we aimed to define the added value of SNB (with different tracer modalities) to ePLND in the identification of nodal metastases. Complication rates and oncologic outcomes were also assessed.

Methods: From January 2006 to December 2019, prospectively collected data were retrospectively analyzed from a single-institution database regarding prostate cancer patients treated with robot-assisted radical prostatectomy and ePLND with or without additional use of SNB, either with the hybrid tracer indocyanine green (ICG)–^{99m}Tc-nanocolloid or with free ICG. Multivariable logistic and Cox regression models tested the impact of adding SNB (either with the hybrid tracer or with free ICG) on lymph nodal invasion detection, complications, and oncologic outcomes.

Results: Overall, 1,680 patients were included in the final analysis: 1,168 (69.5%) in the non-SNB group, 161 (9.6%) in the ICG-SNB group, and 351 (20.9%) in the hybrid-SNB group. The hybrid-SNB group (odds ratio, 1.61; 95%CI, 1.18–2.20; P = 0.002) was an independent predictor of nodal involvement, whereas the ICG-SNB group did not reach independent predictor status when compared with the non-SNB group (odds ratio, 1.35; 95%CI, 0.89–2.03; P = 0.1). SNB techniques were not associated with higher rates of complications. Lastly, use of hybrid SNB was associated with lower rates of biochemical recurrence (0.79; 95%CI, 0.63–0.98) and of clinical recurrence (hazard ratio, 0.76, P = 0.035) than were seen in the non-SNB group.

Conclusion: The implementation of hybrid-SNB technique with ICG–^{99m}Tc-nanocolloid in prostate cancer improves detection of positive nodes and potentially lowers recurrence rates with subsequent optimization of patient management, without harming patient safety.

The impact of the extent and location of positive surgical margins on the risk of biochemical recurrence following radical prostatectomy in men with Gleason 7 prostate cancers

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First published: 27 September 2021

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Abstract

Background

Positive surgical margins (PSM) after radical prostatectomy (RP) have been associated with increased risk of biochemical recurrence (BCR). This is heavily influenced by other clinicopathological factors. This study aims to assess the impact of the extent and location of PSM on BCR following RP for Gleason 7 carcinoma of the prostate (CaP).

Materials and Methods

All men treated with RP between 2008 and 2017 in our region for localized or locally advanced Gleason 7 CaP, were included. Clinical (age, year, preoperative prostate specific antigen) and pathological (prostate weight, positive or negative surgical margins, International Society of Urological Pathology [ISUP] grade, T stage) data were collected. PSM were subcategorised according to Extent into favourable (unifocal and <3 mm in length) or unfavourable (multifocal or ≥3 mm in length), and Location into apical only or others. The outcome was the risk of BCR which was calculated with univariable and multivariable regression models and reported as hazard ratio (HR) with 95% confidence interval (CI).

Results

The cohort constituted of 1433 men. Majority had ISUP 2 (71.2%) or localized (62%) disease. Men with PSM (n = 506) were at greater risk of BCR when compared to those with negative margins (adjusted HR = 1.52, [CI: 1.14–2.04], p = .005). Similar observation was demonstrated for both PSM location subgroups. As for the PSM extent category, only men with unfavourable PSM demonstrated an increase in BCR risk over negative margin (adjusted HR = 1.67, [CI: 1.23–2.28], p = .001).

Conclusions

Within this study settings, PSM were generally associated with increased BCR risk. This, however, was not demonstrated in favourable PSM extent cases. Observation rather than active treatment in these men should be considered.

medscape.com

NCCN Guidelines Embrace PSMA-PET Imaging for Prostate Cancer

Authors and Disclosures Authors and Disclosures Journalist Neil Osterweil

Rarely has a footnote garnered so much positive attention, but a reference in the newly updated prostate cancer guidelines from the National Comprehensive Cancer Network (NCCN) has prostate cancer specialists excited about the prospects for incorporating the highly sensitive imaging modality PSMA-PET into daily practice.

PSMA-PET (prostate-specific membrane antigen positron-emission tomography) involves use of a radiotracer that binds to PSMA and emits positrons that can be detected on PET scans.

The US Food and Drug Administration (FDA) approved the first such imaging agent for use in prostate cancer, Gallium 68 PSMA-11 (Ga 68 PSMA-11), in December 2020.

"Ga 68 PSMA-11 is an important tool that can aid healthcare providers in assessing prostate cancer," commented Alex Gorovets, MD, from the FDA's Office of Specialty Medicine in the Center for Drug Evaluation and Research, at that time. "With this first approval of a PSMA-targeted PET imaging drug for men with prostate cancer, providers now have a new imaging approach to detect whether or not the cancer has spread to other parts of the body."

The footnote in the new NCCN guidelines states that "because of the increased sensitivity and specificity of PSMA-PET tracers for detecting micrometastatic disease compared to conventional imaging (CT, MRI) at both initial staging and biochemical recurrence, the Panel does not feel that conventional imaging is a necessary prerequisite to PSMA-PET and that PSMA-PET/CT or PSMA-PET/MRI can serve as an equally effective, if not more effective, front-line imaging tool for these patients."

Superior Accuracy

The superior accuracy of this type of imaging was shown in the ProPSMA trial, as previously reported by Medscape Medical News. Imaging with PSMA-PET was shown to have 92% accuracy for the primary outcome of firstline imaging for identifying pelvic nodal or distant metastases, compared with 65% for CT and bone scanning, an absolute difference of 27% (P < .0001). Accuracy

was defined as the area under the curve of receiver operating characteristics using a predefined reference standard that included histopathology, imaging, and biochemistry at 6-month follow-up.

Now, with a nod of approval from the NCCN, imaging with PSMA-PET stands ready to gain wider acceptance by clinicians and, equally importantly, by insurers, say experts.

"These molecularly targeted imaging agents are novel, and we're very excited about their prospects," said Sophia C. Kamran, MD, a radiation oncologist and assistant professor of radiation oncology at the Massachusetts General Cancer Center, Boston, Massachusetts.

"PSMA-PET has been shown to have more specificity and sensitivity compared to conventional imaging, such as bone scintigraphy and CT scans of the abdomen and pelvis," she said in an interview.

Jeremie Calais, MD, from the Department of Molecular and Medical Pharmacology at the University of California, Los Angeles, told Medscape Medical News: "it's more sensitive, it's more specific, so overall more accurate to detect a localized prostate cancer lesion, so you see more disease with a higher level of confidence when you see something with PSMA-PET than with other imaging techniques."

cookwithkathy.wordpress.com

Metastatic Prostate Cancer Comes in Two Forms, Which Could Guide Treatment

Eric Hamilton wrote . . . . . .

Scientists have identified two subtypes of metastatic prostate cancer that respond differently to treatment, information that could one day guide physicians in treating patients with the therapies best suited to their disease.

Building off of earlier studies that discovered clinically relevant subtypes of breast cancer and non-metastatic prostate cancer, researchers identified genetic signatures that can divide metastatic prostate tumors into two types known as luminal and basal.

Luminal tumors responded better to testosterone-blocking treatments, while basal tumors did not benefit as much from this hormone treatment. Basal tumors also included the particularly aggressive form of metastatic disease known as small cell neuroendocrine prostate cancer. Further clinical trials will be required before any new diagnostic-based treatment selection is available.

"The reason why these subtypes are important is they respond to hormone therapy very differently," says Shuang Zhao, a professor of oncology in the University of Wisconsin School of Medicine and Public Health who helped direct the research. "In localized prostate cancer, we've shown that luminal tumors had a bigger benefit from anti-testosterone therapy. We wanted to know if the same pattern extended to metastatic disease."

With colleagues at the University of California, San Francisco and other institutions, Zhao published his findings Sept. 23 in the journal JAMA Oncology. The work was co-led by Rahul Aggarwal of UCSF and Nicholas Rydzewski in the Department of Human Oncology at SMPH.

About 20 years ago, scientists discovered luminal and basal subtypes of breast cancer and found that each responds better to different therapies. This has given doctors greater precision in treating their breast cancer patients.

Since breast cancers and prostate cancers share many similarities, including their sensitivity to hormone treatment, in 2016 Zhao's team looked at whether these similarities extended to different prostate cancer subtypes. They published the first report that identified the luminal and basal subtypes in localized prostate cancer, when the disease remains confined to the prostate.

The new study expanded the analysis to metastatic cancer, when the disease spreads from the prostate. Metastatic prostate cancer is much more lethal than its local version. It's also more difficult to study, because small tumors can be in many different parts of the body and are harder to biopsy.

So, to identify enough samples to run their analysis, Zhao's team turned to multiple large, national studies of metastatic prostate cancer patients. The largest of these studies was based out of UCSF and led by two of the current study's senior authors, Eric Small and Felix Feng.

"We pooled all of the data together and assembled the largest metastatic prostate cancer cohort to date,"

says Zhao. The team ended up with a total of 634 patient samples.

The scientists used computational methods to compare the patterns of gene expression in the tumor biopsies. A group of 50 genes determines the basal-or-luminal nature of breast and prostate cancer and, depending on how active each of these genes is, scientists can separate out the two subtypes.

As they had seen for localized prostate cancer, Zhao's team identified luminal and basal types for metastatic cancer as well. They then asked how the subtypes affected patient survival and response to treatment.

Because the doctors treating the study's patients did not know about the subtypes at the time, they had to decide what treatment they thought might work best without this information. The variation in treatment produced a natural experiment that the researchers could analyze.

"And we found that just like in localized prostate cancer, the hormone therapies seemed to work better in the luminal tumors than in the basal tumors," says Zhao.

Although there were two clear subtypes, the researchers also saw that the tumors fell onto a spectrum depending on their degree of luminal-ness or basal-ness. At one extreme were the hormone-treatment-resistant small cell neuroendocrine prostate cancers, which appeared the most basal. At the other end were less aggressive luminal subtypes, which are much more sensitive to hormone therapy. But there were tumors in between the two extremes as well. It's not yet clear how these middle-of-the-road cancers may benefit from different treatments.

Since metastatic tumors are so difficult to biopsy, Zhao is hoping to develop blood tests that could more easily determine the luminal-or-basal nature of metastatic prostate cancer. Such a biomarker test would make clinical trials testing the usefulness of subtyping metastatic tumors much more feasible. Similar clinical trials for local prostate cancer are currently underway.

"Now that we've discovered this pattern, how do we turn this into a test that metastatic patients can benefit from?" says Zhao, who is also the co-director of the Circulating Biomarker Core at the UW–Madison Carbone Cancer Center, which researches how to develop such blood tests. "The only way it can be used widely is if we make it easier."

Source: University of Wisconsin-Madison

Filed under: Health, News and Articles, Study | Tagged: Prostate Cancer |

Abiraterone acetate versus nonsteroidal antiandrogen with androgen deprivation therapy for high-risk metastatic hormone-sensitive prostate cancer

Takafumi Yanagisawa MD, PhD, Takahiro Kimura MD, PhD, Keiichiro Mori MD, Hirotaka Suzuki MD, Takayuki Sano MD, Takashi Otsuka MD, Yuya Iwamoto MD, Wataru Fukuokaya MD, … See all authors

First published: 24 September 2021

https://doi.org/10.1002/pros.24243

Read the full text

Abstract

Background

Although prostate cancer is a very common form of malignancy in men, the clinical significance of androgen deprivation therapy (ADT) with abiraterone acetate versus the nonsteroidal antiandrogen bicalutamide has not yet been verified in patients with high-risk metastatic hormone-sensitive prostate cancer (mHSPC). The present study was designed to initiate this verification in real-world Japanese clinical practice.

Methods

We retrospectively analyzed the records of 312 patients with high-risk mHSPC based on LATITUDE criteria and had received ADT with bicalutamide (n = 212) or abiraterone acetate (n = 100) between September 2015 and December 2020. Bicalutamide was given at 80 mg daily and abiraterone was given at 1000 mg daily as four 250-mg tablets plus prednisolone (5–10 mg daily). Overall survival (OS), cancer-specific survival (CSS), and time to castration-resistant prostate cancer (CRPC) were compared. The prognostic factor for time to CRPC was analyzed by Cox proportional hazard model.

Results

Patients in the bicalutamide group were older, and more of them had poor performance status (≧2), than in the abiraterone group. Impaired liver function was noted in 2% of the bicalutamide group and 16% of the abiraterone group ($p < 0.001$). Median follow-up was 22.5 months for bicalutamide and 17 months for abiraterone ($p < 0.001$). Two-year OS and CSS for bicalutamide versus abiraterone was 77.8% versus 79.5% ($p = 0.793$) and 81.1% versus 82.5% ($p = 0.698$), respectively. Median time to CRPC was significantly longer in the abiraterone group than in the bicalutamide group (NA vs. 13 months, $p < 0.001$). In multivariate analysis, Gleason score ≧9, high alkaline phosphatase, high lactate dehydrogenase, liver metastasis, and bicalutamide were independent prognostic risk factors for time to CRPC. Abiraterone prolonged the time to CRPC in patients with each of these prognostic factors.

Conclusions

Despite limitations regarding the time-dependent bias, ADT with abiraterone acetate significantly prolonged the time to CRPC compared to bicalutamide in patients with high-risk mHSPC. However, further study with longer follow-up is needed.

Immunotherapy in treatment of metastatic prostate cancer: An approach to circumvent immunosuppressive tumor microenvironment

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https://doi.org/10.1002/pros.24213

Read the full text

Abstract

Prostate cancer is the second most common cause of cancer-related death in men in the United States and the fifth worldwide. Most prostate cancer arises as an androgen-dependent tumor but eventually progresses into castration-resistance prostate cancer, incurable by the current androgen deprivation therapy and chemotherapy. The development of immunotherapy in cancer treatment has brought an exciting era of antiprostate cancer therapy through antitumor immune responses. Prostate cancer is recognized as a poorly immunogenic tissue with immunological ignorance showing low levels of antigen-presenting process and cytotoxic T-cell activation, high levels of immune checkpoint molecules and immunosuppressive cytokines/chemokines, and recruitment of immunosuppressive cells. Immunotherapies for prostate cancer have been developed to activate the innate and adaptive immune responses, such as vaccines and adoptive CAR-T cells, or to inhibit immunosuppressive molecules, such as immune checkpoint inhibitors or antibodies. The U.S Food and Drug Administration has approved Sipuleucel-T for the treatment of asymptomatic or minimally symptomatic metastatic castrate-resistant prostate cancer (mCRPC) and immune checkpoint inhibitor pembrolizumab for the treatment of all solid tumors, including prostate cancer, with impaired mismatch repair genes/microsatellite instability; however, the current clinical outcomes still need to be improved. As various immunosuppressive mechanisms coexist and cross-interact within the tumor microenvironment, different immunotherapy approaches may have to be combined and selected in a highly personalized way. It is hoped that this rapidly evolving field of immunotherapy will achieve successful treatment for mCRPC and will be applied to a wider range of prostate cancer patients.

Chemotherapy-induced peripheral neuropathy and rehabilitation: A review

Author links open overlay panelShangmingZhang

https://doi.org/10.1053/j.seminoncol.2021.09.004Get rights and content

Abstract

Chemotherapy-induced peripheral neuropathy (CIPN) is a common complication after chemotherapy that can damage the sensory, motor, autonomic, or cranial nerves in approximately 30%–60% of patients with cancer. CIPN can lead to detrimental dose modifications and/or premature chemotherapy discontinuation due to patient intolerance. The long-term impact of CIPN is particularly challenging and can have a profound impact

on the quality of life (QoL) and survivorship. However, this condition is often underdiagnosed. No agents have been established to prevent CIPN. Pre-chemotherapy testing is recommended for high-risk patients. Duloxetine is considered a first-line treatment, whereas gabapentin, pregabalin, tricyclic antidepressants, and topical compounding creams may be used for neuropathic pain control. Home-based, low-to-moderate walking, and resistance exercise during chemotherapy can reduce the severity and prevalence of CIPN symptoms, especially in older patients. Pre-habilitation and rehabilitation should be recommended for all patients receiving cytotoxic chemotherapies. The purpose of this article is to review common chemotherapeutic drugs causing CIPN, risk factors, diagnosis and treatment of CIPN, and evidence of the benefits of rehabilitation.

medpagetoday.com

STAMPEDE Will 'Change Practice' in High-Risk Prostate Cancer

by Greg Laub, Director, Video, MedPage Today September 27, 2021

Meeting Coverage > ESMO Video Pearls: Prostate Cancer

— Trial showed adding abiraterone to ADT improved metastasis-free and overall survival

At the virtual European Society for Medical Oncology meeting, researchers presented a combined analysis from the STAMPEDE platform assessing androgen deprivation therapy (ADT) alone for high-risk non-metastatic prostate cancer versus ADT plus abiraterone acetate (Zytiga) and prednisolone (AAP), with or without enzalutamide.

In this exclusive MedPage Today video, Inderbir Gill, MD, chair of urology at the Keck School of Medicine at the University of Southern California in Los Angeles, explains why he believes the implications are practice changing.

Following is a transcript of his remarks:

So this is a seminal trial. This trial looked at the M0 population -- high-risk M0 population, metastatic. High risk being defined as either node positive, or high-risk node-negative, which means T3-4 disease, PSA 40 or greater, or Gleason 8-10 grade group 4, essentially, or relapsing.

And so this trial randomized men, almost 2,000 men, at 113 locations in the U.K. and Switzerland. The randomization was about 900 patients to ADT with or without abiraterone plus prednisolone, and 1,000-plus patients to ADT with or without abiraterone and enzalutamide. And the primary endpoint of this trial was metastasis-free survival. And the treatment effect was measured at 2 years.

The baseline of both these groups were well balanced. About 79% had grade group 4 disease in both groups, about 39% were node positive, median PSA was about 34, and median age was about 68 -- so the kind of patient that we would often see in clinic.

And so, upon analyzing the outcomes, metastasis-free survival events occurred significantly more in the control group -- 306 versus 180.

So the abiraterone-based therapy improved metastasis-free survival and also overall survival. For example, 6-year metastasis-free survival improved from 69% to 82%, and 6-year overall survival from 77% to 86%. And these were statistically significant.

And the authors concluded that 2 years of abiraterone-based therapy significantly improves the metastasis-free survival and overall survival in men with high-risk, non-metastatic prostate cancer. And when starting ADT, this study indicates that AAP-based therapy should be added to ADT, and indicates that this should now be considered the new standard of care.

So from my perspective, I want to compliment the authors. This is a lot of work, and a huge advance in the field. For men with non-metastatic high-risk prostate cancer, we all know that the chances of their relapsing, either biochemically or otherwise, are not insignificant, and this shows with clear data that at least at 2 years, the outcomes from the pertinent outcomes -- i.e., overall survival and metastasis-free survival -- were significantly superior.

These are convincing data that will change practice. And I just want to compliment the authors on this seminal study.

prostatecancerinfolink.net

More than 25 organizations join new Prostate Cancer Impact Alliance

A detailed media release about PCIA was issued by the Urology Care Foundation this morning. The full text of that media release appears below.

Prostate Cancer Impact Alliance Seeks to Improve Patient Outcomes through Collaboration

Baltimore, MD, September 22, 2021 – The Prostate Cancer Impact Alliance (PCIA) has brought together a formidable and diverse group of researchers, patient advocacy groups, physicians and health professionals within the prostate cancer community in a dedicated effort to advance education about, research into, and access to high quality care for men with prostate cancer. Convened by the American Urological Association (AUA), PCIA has launched an online presence at UrologyHealth.org/PCIA.

According to the American Cancer Society, prostate cancer is the second leading cause of cancer deaths among American men. In 2021, an estimated 248,530 men will be newly diagnosed with prostate cancer, a nearly 30 percent increase over 2020 statistics. It is estimated more than 34,100 of those diagnosed in 2021 will die from this disease.

PCIA – an alliance of 28 stakeholder organizations – has been working together over the past year to identify a unified vision and pursue projects to advance the mission of the Alliance. Through three workgroups – Health Equity, Patient and Provider Communications, as well as Policy and Advocacy – PCIA members are working to identify immediate barriers standing in the way of better patient outcomes related to education, research, health equity and quality of life.

"This Alliance is about transforming the prostate cancer continuum, as well as reimagining the possibilities for better patient outcomes and equitable access to care for men diagnosed with this deadly disease," said Harris M. Nagler, President of the Urology Care Foundation, a PCIA stakeholder organization, and official Foundation of the AUA. "Members of the PCIA share a bold vision and by joining forces we intend to scale our network, improve health outcomes and make a profound impact on the prostate cancer community, including the millions of men living with the disease."

As part of its' longer-term vision, the alliance plans to continue to identify priorities within the prostate cancer space and develop ways to engage on those issue areas in a strategic, meaningful and collaborative way. This collective community strives to accelerate and optimize progress in the following specific areas:

Equity of access, outcomes and information for the highest possible quality of care;

Shared decision-making for men at risk for, or diagnosed with, prostate cancer;

Patient and caregiver knowledge regarding diagnostic and management options;

Understanding of challenges affecting care and access for patients; and

Research intended to improve health outcomes for patients with prostate cancer across the spectrum of this disease.

"For the past 30 years I have felt strongly that the varied members of the prostate cancer advocacy and patient support community need to work closely together on the most important initiatives that affect the diagnosis and management of men with prostate cancer and their families," said E. Michael D. Scott, President and Executive Director of Prostate Cancer International, a PCIA inaugural steering committee member. "I am honored to be an inaugural member of the PCIA Steering Committee and look forward to working within the alliance to advance our community towards those goals."

PCIA members have already collaborated on a number of issues including a letter to the Biden Administration encouraging prioritization of policy that supports diversity of research and the needs of men living with prostate cancer, as well as the hosting of informational webinars on the Congressionally Directed Medical Research Programs (CDMRP) and implications of the Most Favored Nation drug pricing model.

The PCIA inaugural steering committee has played an integral part in developing and shaping this Alliance. Those members include:

John Fortin, AUA Patient Advocacy Liaison

Susan Friedman, FORCE – Facing Our Risk of Cancer Empowered

Amy Luckenbaugh, MD, Society of Women in Urology

Alexandra Scholz, Prostate Cancer Research Institute

Mike Scott, Prostate Cancer International

For more information about current and future PCIA activities, please visit www,UrologyHealth.org/PCIA.

About the Urology Care Foundation: The Urology Care Foundation is the world's leading nonprofit urological health foundation, and the official foundation of the American Urological Association. Partnering with physicians, researchers, healthcare professionals, parients, caregivers, families and the public, the Foundation supports and improves urological clinical care by funding research, developing patient educvation and pursuing philanthropic support. To learn more about the Urology Care Foundation and its programs visit www.urologyhealth.org

About the American Urological Association: Founded in 1902 and headquartered near Baltimore, Maryland, the American Urological Association is a leading advocate for the specialty of urology, and has nearly 23,000 members throughout the world. The AUA is a premier urologic association, providing invaluable support to the urologic community as it pursues its mission of fostering the highest standards of urologic care through education, research and the formulation of health policy.

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Prostate Cancer Impact Alliance is a collection of diverse stakeholders within the prostate cancer community working together toward increased awareness and access for prostate cancer treatments. The PCIA membership is represented by 28 patient advocacy groups and professional medical and scientific organizations, as well as industry companies. The PCIA events and activities are supported in part by funding from industry companies.

medscape.com

Men Give Thumbs Up to Video on Genetic Testing in Prostate Cancer

Neil Osterweil

What is it about guys and TV? Given a choice between watching a short video about genetic screening for cancer or meeting with a genetic counselor prior to testing, nearly three fourths of the men (71%) in a study opted for the video instead of the face-to-face meeting.

The study involved men who had either received a prostate cancer diagnosis or had a family history of prostate cancer. The information imparted by video or provided by the trained counselor was about germline testing, which can identify patients who have a genetic predisposition to prostate cancer or who may benefit from targeted therapy.

There was no significant difference in how many men decided to undergo testing (94.4% of men who watched the video, and 92% of men who met with a counselor).

However, the video watchers were more likely to be willing to share their test results with others, reported Jessica Russo, MS, and colleagues from the Thomas Jefferson University, in Philadelphia, Pennsylvania.

"Our results support the use of pretest genetic education videos in nongenetic practices to address the shortage of genetic counselors and advance germline testing to capitalize on the progress in precision medicine," they conclude.

The study was published online on September 1 in JCO Precision Oncology.

Germline testing can identify men who are at increased risk for prostate cancer because of BRCA pathogenic variants. It also provides information on hereditary cancer syndromes, such the Lynch syndrome, Russo and colleagues explain.

Pressure to identify men with prostate cancer who are BRCA positive has increased in recent years. Evidence shows that these patients may respond to treatment with PARP inhibitors, and last year the first drug for this indication (rucaparib) was approved by the US Food and Drug Adinistration.

Russo and colleagues note that "with the current increase in men in need of germline testing, there is an increasing need for alternate delivery of pretest informed consent in nongenetic practices as referral of all men to genetic counseling is currently not sustainable."

To see whether video-based patient education could help to narrow the gap, the investigators conducted the Evaluation and Management for Prostate Oncology, Wellness, and Risk (EMPOWER) study. The goal of the study was to streamline delivery of genetic services across a variety of practice types.

The video lasts 11 minutes. It was created by the cancer genetics team at Jefferson University and includes information about cancer heritability, the purpose of testing, risks and benefits, potential results, implications

for blood relatives if hereditary syndromes are identified, laws regarding genetic discrimination, and potential reproductive implications.

Participants were tested at baseline for their knowledge of cancer genetics. They were asked to complete surveys about their experience after watching the educational video or attending a counseling session and after they had received genetic results and recommendations by a genetic counselor.

In the article, the team reports interim results on the first 127 participants.

Many men (71%) chose the video rather than genetic counseling (P < .001). There were no differences between the groups in either decisional conflict about germline testing or in satisfaction, as measured by the validated Genetic Counseling Satisfaction Scale.

For both groups, there was similar improvement in knowledge of cancer genetics following the selected intervention, but men who chose the video more frequently reported that they were willing to share their genetic test results with their families (96.4% vs 86.4%; P = .02).

Russo and colleagues note that the sample was largely White (85%) and that 66.9% of the patients had a bachelor's degree or more education. They write that it is "imperative to study digital solutions to pretest genetic delivery across diverse populations to ensure generalizability."

The study was supported by a SKCC TIPS Pilot Funding Grant and a National Cancer Institute Cancer Center support grant. Russo has stock/ownership interests in Agenus. Her co-authors have reported various industry relationships.

JCO Precis Oncol. Published online September 1, 2021. Abstract

Neil Osterweil, an award-winning medical journalist, is a long-standing and frequent contributor to Medscape. For more news, follow Medscape on Facebook, Twitter, Instagram, and YouTube.

Second Industry Body Updates Guidance for Use of PSMA PET Imaging

MELBOURNE, Australia and INDIANAPOLIS, Sept. 20, 2021 (GLOBE NEWSWIRE) -- Telix Pharmaceuticals Limited (ASX: TLX, Telix, the Company) has today welcomed the Society of Nuclear Medicine and Molecular Imaging (SNMMI) updated Appropriate Use Criteria (AUC) for prostate specific membrane antigen (PSMA) positron emission tomography (PET) imaging.

The updated AUC, developed following a critical review of evidence by leading experts to guide referring and imaging physicians on the appropriate use of imaging agents, recognise a widespread use of PSMA PET in men with prostate cancer including that PSMA PET-based imaging has a higher accuracy in the initial staging evaluation of men with newly diagnosed prostate cancer than conventional imaging (bone scan and CT).

The AUC are based on scientific evidence and were developed collaboratively between SNMMI, the American College of Nuclear Medicine (ACNM), the American Urological Association (AUA), the Australia and New Zealand Society of Nuclear Medicine (ANZSNM), and the American Society of Clinical Oncology (ASCO) for the appropriate use of PSMA PET, specifically for the diagnosis and management of prostate cancer.

It follows updated guidance from the National Comprehensive Cancer Network® (NCCN)1, which recognises the increased sensitivity and specificity of PSMA PET tracers, compared to conventional imaging for detecting micrometastatic disease, at both initial staging and biochemical recurrence.

The systematic review2 also noted:

PSMA PET may have additional use in selecting patients for PSMA directed therapy and assessing response to therapies. PSMA PET radiotracers, similar to other radiopharmaceuticals, have an excellent safety profile, given the sub-pharmacological mass dose and high specific activity administered. Although there may be small differences between each PSMA PET radiopharmaceutical currently approved or being evaluated by the US Food and Drug Administration, there is no evidence to date that one specific radiopharmaceutical has improved diagnostic characteristics compared with another.Integration of AUC into clinical decision support tools may lead to a more efficient reimbursement approval process for advanced diagnostic imaging procedures, including radiology and nuclear medicine procedures, by allowing healthcare providers to track comparisons between the AUC model and the payer's reimbursement strategy.

Dr Colin Hayward, Chief Medical Officer of Telix said, "Alongside recent NCCN updated guidance, this latest endorsement by the SNMMI will further influence the shift in clinical practice to consider PSMA PET imag-

ing as an alternative to conventional imaging of bone and soft tissue for the detection of prostate cancer. These user guidelines are also important in driving private payer reimbursement, as more healthcare providers adopt PSMA PET and demonstrate its benefit to patients, in more accurate staging and diagnosis."

Dr. Jeremie Calais, Director of the UCLA Theranostics Program added, "Along with updated NCCN Guidelines and Medicare coverage, this is great news for patients. Private insurers should follow soon. Access to PSMA PET will be widely available and this game-changer technology will ultimately become part of the routine staging of prostate cancer patients. Like doing a PSA test, I anticipate in a near future that physicians will routinely require a PSMA PET scan before making a treatment plan."

About Telix Pharmaceuticals Limited

Telix is a biopharmaceutical company focused on the development of diagnostic and therapeutic products using Molecularly Targeted Radiation (MTR). Telix is headquartered in Melbourne, Australia with international operations in Belgium, Japan, and the United States. Telix is developing a portfolio of clinical-stage products that address significant unmet medical need in oncology and rare diseases. Telix is listed on the Australian Securities Exchange (ASX: TLX). For more information visit www.telixpharma.com and follow Telix on Twitter (@TelixPharma) and LinkedIn.

Telix's lead investigational product, Illuccix® (TLX591-CDx) for prostate cancer imaging, has been accepted for filing by the U.S. FDA,3 and is under priority evaluation by the Australian Therapeutic Goods Administration (TGA).4 Telix is also progressing marketing authorisation applications for Illuccix® in the European Union5 and Canada.6 None of Telix's products have received a marketing authorisation in any jurisdiction.

Telix Media Contact

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1 https://www.nccn.org/guidelines/category—1 2 https://www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber=38657 3 ASX disclosure 24/11/20. 4 ASX disclosure 14/04/21. 5 ASX disclosure 1/05/20. 6 ASX disclosure 16/12/20.

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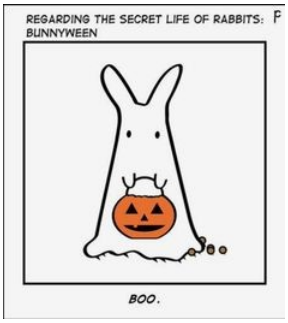
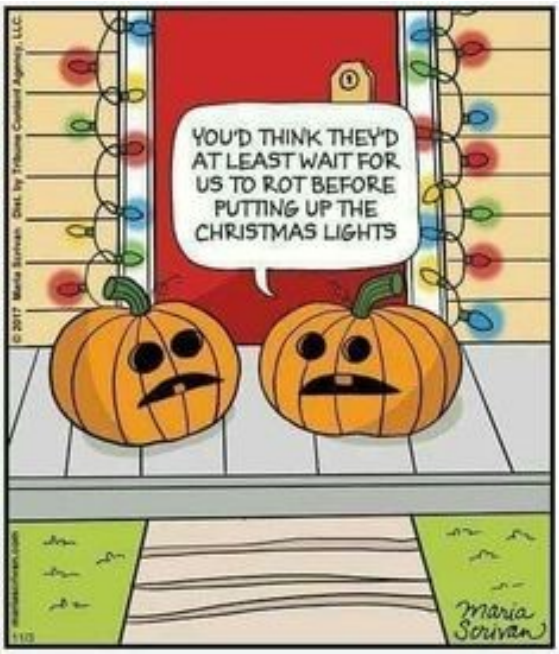
On the Lighter Side

"It can't be healthy for them to be sitting in front of this new technology all day."





WATCHING *GHOST HUNTERS*