Informed Prostate Cancer Support Group Inc.
"A 501 C 3 CORPORATION ID # 54-2141691"

Tuesday, July 12, 2022

JULY 2022 NEWSLETTER

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

STREAMING ONLINE LIVE

Volume 15 Issue 07

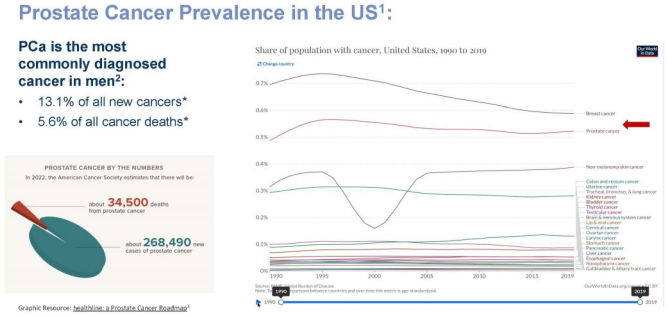
- **Next Meeting Saturday, July 16, 2022 IPCSG—Men Share Their Personal Journey — Live-Stream Event, 10:00am PT**.
- *Here are the men who have agreed to share their personal "prostate cancer journey" with us.*
  - *Patrick Miller. Diagnosed with Gleason 9 in 2018. Had prostate radiation, then followup treatments to spine, femur and recently pubic bone. On Zytiga without Lupron. PSA drifting down since radiation in February, now at 2.2.*
  - *Mike Dibitetto. Diagnosed with Gleason 9 in 2019, with multiple pelvic node tumors. Pelvic radiation brought a clear Axumin scan by Nov. 2021, but now his PSA is rising. Axumin can't find it. Will obtain PSMA scan results before the meeting.*
  - *Bob Stacy. Had proton therapy 3 years ago. Recent PSA's 1.2 to 1.5 to 1.7. MRI w/contrast showed 3.7 mm lesion in pelvis. None seen elsewhere. Will obtain PSMA scan results before the meeting.*
- 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

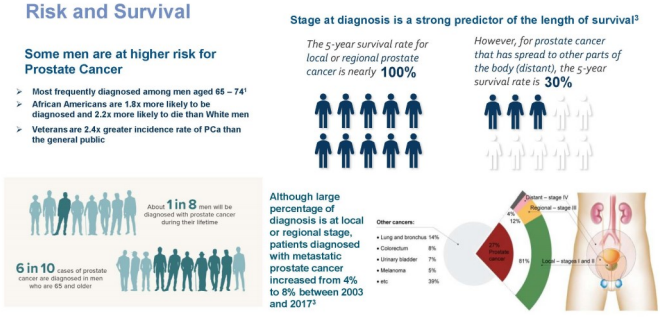
June 2022 Informed Prostate Cancer Support Group Meeting

Selected Slides from Presentation

Mary Hames PhD, Executive MBA - GA68 PSMA and Related Technologies

Dr. Hames holds an interdisciplinary PhD in Biochemistry, Genetics, and Chemical Engineering, as well as an Executive MBA. She is the US Medical Director for Telix pharmaceuticals, and manages the US Field Medical Team which functions to educate US health care professionals on Telix's commercially approved products as well as their pipeline diagnostics and therapeutics. She spoke to us about the technical characteristics of Gallium-68 PSMA and





*male and female 1. National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) Program Cancer Statistics. Cancer stat facts: Prostate Cancer. 2. https://ourworldindata.org/cancer ; 3. https://www.healthline.com/health/advanced-prostate-cancer/prostate-cancer-treatment-a-typical-journey

1. National Cancer Institute Surveillance, Epidemiology, and End Results (SEER) Program Cancer Statistics. Cancer stat facts: Prostate Cancer. https://seer.cancer.gov/statfacts/html/prost.html. Accessed November 2021 2. Urology Times Journal, Vol 48 No 11, Volume 48, Issue 11; 4. . Cancer.net. Prostate Cancer: Statistics. https://www.cancer.net/cancer-types/prostate-cancer/statistics. Accessed November 2021. 5. Graphic from Kang SJ, Int J Nanomedicine. 2015;10:6555-6569

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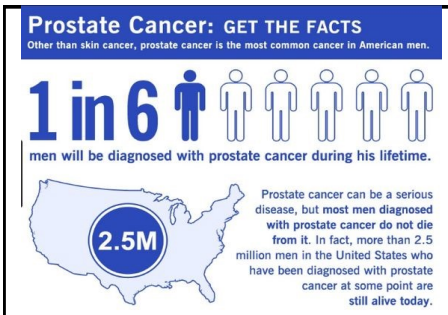

Organization

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

IPCSG

Officers

Bill Lewis President

Additional Directors

Gene Van Vleet

Aaron Lamb

Bill Manning

Honorary Directors

Dr. Dick Gilbert

Judge Robert Coates

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Bill Manning, ...Videographer
John Tassi, ...Webmaster
Bill Bailey, ...Librarian
Jim Kilduff, ...Greeter
Aaron Lamb, ...Meeting Set-up
Stephen Pendergast ..... Editor

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

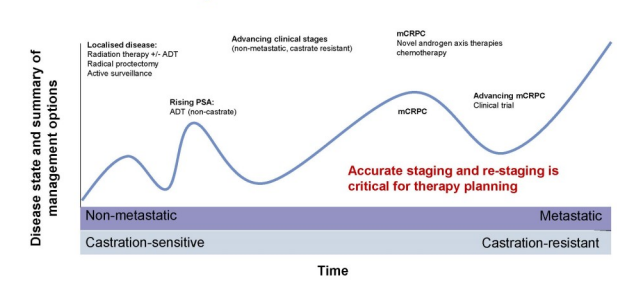
Due to COVID-19, no in-person meetings will be held until further notice. We will continue to post and distribute the newsletter in the interim. Our speaker this month will be broadcast via the IPCSG website at https://ipcsg.org/live-stream and can be watched by scrolling down and clicking on the "WATCH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

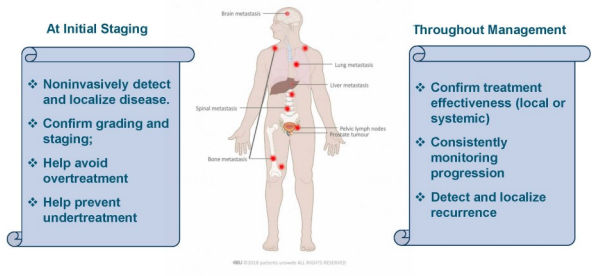
In this issue:

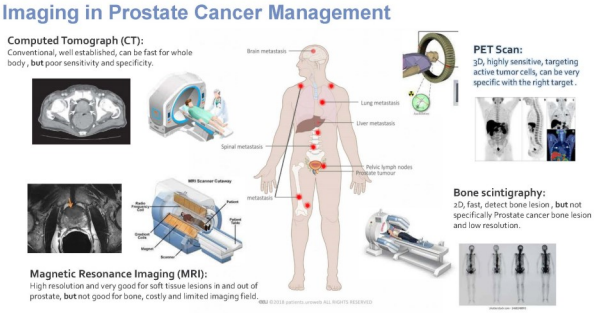
Speaker did not wish to have summary posted, so selected slides are provided.

Articles of Interest:

1. A Healthy Lifestyle in Men at Increased Genetic Risk for Prostate Cancer—if your genes are high risk, lifestyle can better your odds.
2. Yes, Nodal Recurrence of Prostate Cancer is Potentially Curable— previously held uncurable, imaging and radiation can cure some metastatic PCA.
3. Novel Focal Therapy Yields Low Rate of Serious Prostate Cancers—China H-FIRE focal therapy beats other focal techniques.
4. Clinical use of the mRNA urinary biomarker SelectMDx test for prostate cancer test can tell high risk from low PCA
5. Prostate Cancer Cases Are Growing More Serious Some AS cases may delay treatment of risky PCA





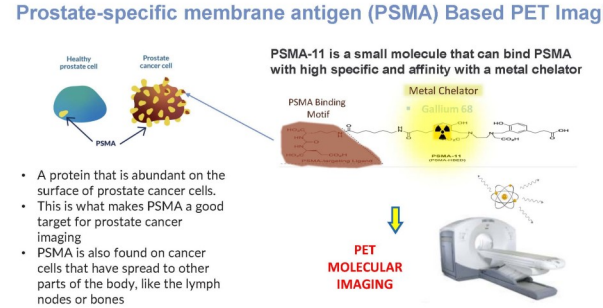


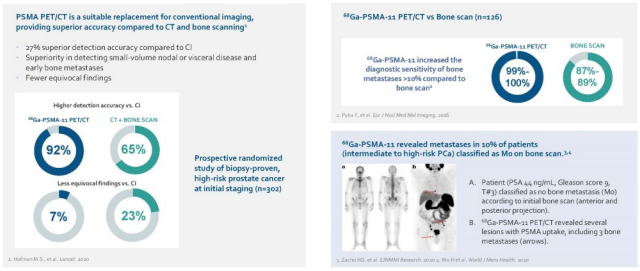
Challenges of Conventional Imaging Techniques

Guidelines recommend conventional imaging methods,[1] but bone scans and CTs result in positive findings in less than 10% of men with biochemical recurrence, particularly those lesions that are less than 1 cm in size with PSA <20 ng/mL[2-6,9]

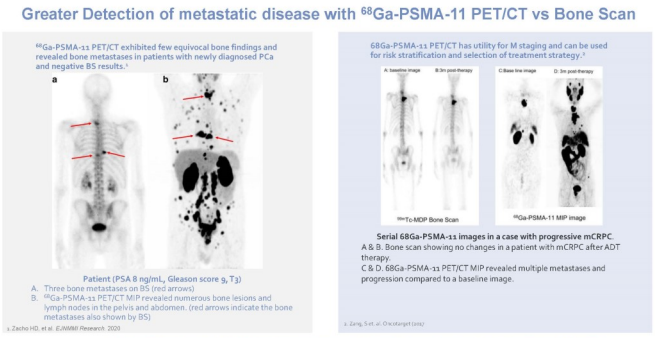
Modality	Standard Use	Challenges
Bone scintigraphy (BS)	• Widely available[7] • Identify bony lesions[7]	• False positives in asymptomatic disease ; limited accuracy for low PSA[1,8]
Computed tomography (CT)	• Use to monitor treatment response (soft tissue/lymph nodes/viscera)[8] • Can detect sclerotic bone and visceral metastases[8]	• Less accurate detecting local recurrence(post RP)[8] • Dependent on size for nodal evaluation, which confers poor sensitivity[8]
Multiparametric magnetic resonance imaging (mpMRI) or standard MRI	• Identification of extra-prostatic margins/recurrence post-radiation therapy (RT)[8]	• Limited utility in staging pelvic lymph nodes[8]

The advent of highly accurate imaging techniques could lead to cost savings in the management of PCa

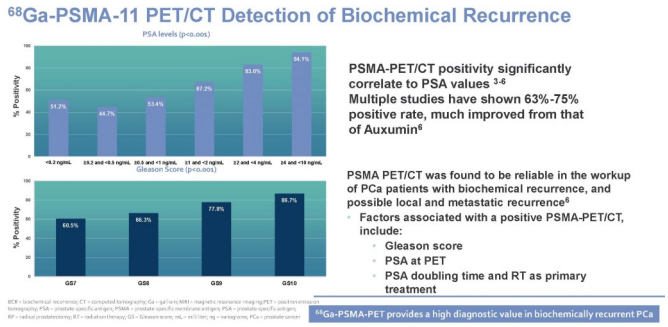




CT = computed tomography; Ga = gallium; MRI = magnetic resonance imaging; PCa = prostate cancer; PET = positron emission tomography; PSA = prostate-specific antigen; PSMA = prostate-specific membrane antigen



CT = computed tomography; Ga = gallium; MRI = magnetic resonance imaging; BS = Bone Scan; MIP = maximum image projection; PCa = prostate cancer; PET = positron emission tomography; PSA = prostate-specific antigen; PSMA = prostate-specific membrane antigen; mCRPC = metastatic castrate resistant prostate cancer



(Continued from page 1)

Lu-177 PSMA, per the slide presentation you can view via the Live-Stream page on the ipcsg.org website. Selected slides are provided below.

^{68}Ga-PSMA impacts Prostate Cancer management in real world

^{68}Ga-PSMA-11 is the **most widely used** radiotracer used for PET imaging of prostate cancer[1]

^{68}Ga-PSMA-11 guided management changes in

up to 43%	up to 68%	up to 70%
Intermediate-High Risk Males at Initial Staging[2-5]	Males at BCR[6,7]	Males at mCRPC[8]

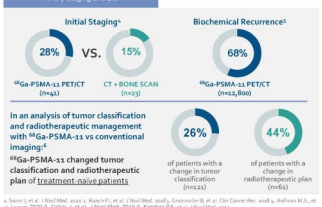
1. Kurash, et al. *Sci Rep* 10, 3109 (2020). 2. Sonni I, et al. *J Nucl Med.* 2020;61(8):1153-1160. 3. Roach PJ, *et al J Nucl Med.* 2018;59(1):82-88. 4. Hofman MS, et al. *Lancet.* 2020;395(10231):1208-1216. 5. Grubmuller B, et al. *Clin Cancer Res.* 2018;24(24):6300-6307. 6. Calais J, et al. *J Nucl Med.* 2018 Mar;59(3):434-441. 7. Koerber SA, et al. *J Nucl Med.* 2018;60(2):234-240. 8. Fourquet A, et al. *Sci Rep.* 2020;10:2104.

^{68}Ga-PSMA-11 Changes in Patient Management

In randomized studies of biopsy-proven, high-risk PCa, ^{68}Ga-PSMA-11 was found to influence management changes by up to 43% of patients at primary staging[1-3]

Management changes were implemented almost 2X more often with ^{68}Ga-PSMA-11 vs. conventional imaging[4]

Patient Management Changes
Primary Staging and BCR

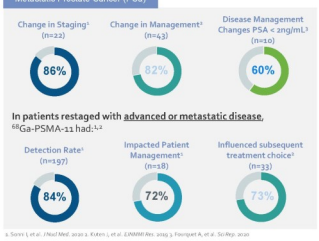


In an analysis of tumor classification and radiotherapeutic management with ^{68}Ga-PSMA-11 vs conventional imaging[4]

^{68}Ga-PSMA-11 changed tumor classification and radiotherapeutic plan of treatment-naive patients

In randomized studies of patients with metastatic PCa, ^{68}Ga-PSMA-11 PET/CT was found to influence[1-3]

Patient Management Changes
Metastatic Prostate Cancer (PCa)



In patients restaged with advanced or metastatic disease, ^{68}Ga-PSMA-11 had:[1,4]

1. Sonni I, et al. *J Nucl Med.* 2020 2. Roach PJ, et al. *J Nucl Med.* 2018 3. Grubmüller B, et al. *Clin Cancer Res.* 2018 4. Hofman M.S., et al. *Lancet.* 2020 5. Calais J, et al. *J Nucl Med.* 2019 6. Koerber SA, et al. *J Nucl Med.* 2019

CT = computed tomography; Ga = gallium; MRI = magnetic resonance imaging; PCa = prostate cancer; PET = positron emission tomography; PSA = prostate-specific antigen; PSMA = prostate-specific membrane antigen

Illuccix® for PSMA-11 Labeling

Illuccix® is approved by U.S. FDA (Dec. 20th, 2021) and by Australian TGA (Nov. 1st, 2021) for PSMA Imaging in Prostate Cancer

Indications and Usage

Illuccix®, after radiolabeling with gallium-68, is a radioactive diagnostic agent indicated for positron emission tomography (PET) of prostate-specific membrane antigen (PSMA) positive lesions in men with prostate cancer:
- with suspected metastasis who are candidates for initial definitive therapy
- with suspected recurrence based on elevated serum prostate-specific antigen (PSA) level

Important Safety Information

Warnings and Precautions

Risk for Misdiagnosis

Image interpretation errors can occur with gallium-68 gozetotide PET. A negative image does not rule out the presence of prostate cancer and a positive image does not confirm the presence of prostate cancer. The performance of gallium-68 gozetotide for imaging of biochemically recurrent prostate cancer seems to be affected by serum PSA levels and by site of disease. The performance of gallium-68 gozetotide for imaging of metastatic pelvic lymph nodes prior to initial definitive therapy seems to be affected by Gleason score. Gallium-68 gozetotide uptake is not specific for prostate cancer and may occur with other types of cancer as well as non-malignant processes such as Paget's disease, fibrous dysplasia, and osteophytosis. Clinical correlation, which may include histopathological evaluation of the suspected prostate cancer site, is recommended.

Radiation Risks

Gallium-68 gozetotide contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. Ensure safe handling to minimize radiation exposure to the patient and health care workers. Advise patients to hydrate before and after administration and to void frequently after administration.

Adverse Reactions

The safety of gallium-68 gozetotide was evaluated in 960 patients, each receiving one dose of gallium-68 gozetotide. The average injected activity was 188.7 ± 40.7 MBq (5.1 ± 1.1 mCi). No serious adverse reactions were attributed to gallium-68 gozetotide. The most commonly reported adverse reactions were nausea, diarrhea, and dizziness, occurring at a rate of < 1%.

Drug Interactions

Androgen deprivation therapy and other therapies targeting the androgen pathway

Androgen deprivation therapy (ADT) and other therapies targeting the androgen pathway, such as androgen receptor antagonists, can result in changes in uptake of gallium-68 gozetotide in prostate cancer. The effect of these therapies on performance of gallium-68 gozetotide PET has not been established.

https://illuccix.com/#safety-information

Efficacy established at initial staging

Illuccix® accuracy demonstrated in a pivotal trial with ^{68}Ga-PSMA-11 by histopathology comparison

The open-label, prostate-specific membrane antigen-preprostatectomy (PSMA-PrePP) study (N=325) compared majority positron emission tomography (PET) reads to pelvis lymph node histopathology results.[1]

In an exploratory subgroup analysis based on summed Gleason score, there was a numerical trend toward more true positives in patients with a Gleason score of ≥8 compared to those with a Gleason score of ≤7.[1]

In an exploratory analysis of pelvic nodal metastasis in all patients, including those without histopathology reference standard, and using an imputation method[1,2]:

- Imputed sensitivity was 47% (95% CI: 38%-55%)
- Imputed specificity was 74% (95% CI: 68%-80%)

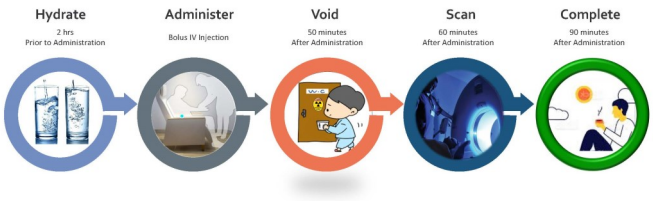
Patient-Level Performance of ^{68}Ga-PSMA-11 for Detection of Pelvic Lymph Node Metastasis (n=123)[1,4]

Among the pool of 6 readers, sensitivity ranged from 36% to 60%, specificity from 83% to 96%, positive predictive value from 38% to 80%, and negative predictive value from 80% to 88%.

Efficacy established at biochemical recurrence (BCR) even at low PSA levels

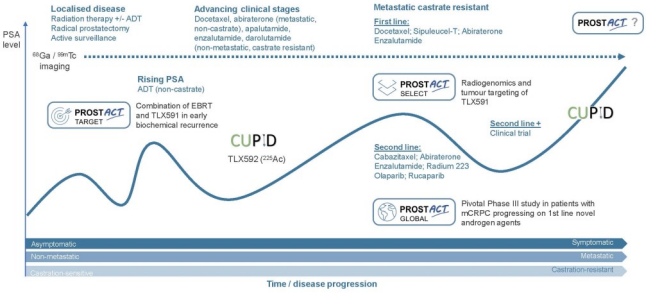
https://illuccixhcp.com/efficacy/#bcr

What to Expect



Summarized from Telix Illuccix Website for HCP, Illuccix Patient Brochure and Outreaching Medical Materials. https://illuccix.com

In the Future: Telix Support the patient every step of the way



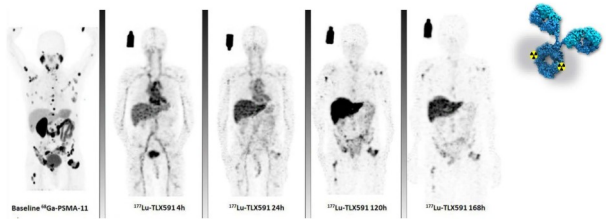
TLX591: Our Antibody based Prostate Cancer Therapy

Lu^{177} labelled with PSMA targeted full monoclonal antibody

Retained in the tumor up to 7 days post injection

Anticipated treatment regiment is two dose, 1 cycle.

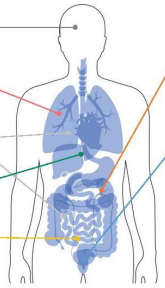
PROSTACT SELECT



Source: Lenzo, N, Meyrick, D, Hayward, C - 177Lu-DOTA-TLX591 Safety, Biodistribution and Dosimetry Study poster - presented at ASCO 2022

Telix is pioneering a new cancer modality

"See it, Treat it" is what we do



Glioblastoma

Ph	Name	Asset	Dx/Tx
I/II	[redacted]	TLX101	Tx

Breast Cancer

Ph	Name	Asset	Dx/Tx
II	OPALESCENCE (IIT)	TLX250-CDx	Dx
I	Emory University (IIT)	TLX591-CDx	Dx

Lung and Ovarian Cancers

Ph	Name	Asset	Dx/Tx
I	Royal Adelaide (IIT)	APOMAB	Dx/Tx

Bone Marrow Conditioning

Ph	Name	Asset	Dx/Tx
I/IIa	TRALA (IIT)	TLX66	Tx

Bladder Cancer

Ph	Name	Asset	Dx/Tx
I	ZIP-UP (IIT)	TLX250-CDx	Dx
I	PERTINENCE (IIT)	TLX250-CDx	Dx

Kidney Cancer

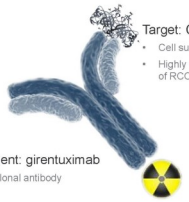
Ph	Name	Asset	Dx/Tx
III	ZIRCON	TLX250-CDx	Dx
I/II	ZIRDAC	TLX250-CDx	Dx
II	STARLITE 1 (IIT)	TLX250	Tx
II	STARLITE 2 (IIT)	TLX250	Tx

Prostate Cancer

Ph	Name	Asset	Dx/Tx
III	University of Linz (IIT)	TLX591-CDx	Dx
II	Emory University (IIT)	TLX591-CDx	Dx
II	ENHANCING (IIT)	TLX591-CDx	Dx
II	Mem. Sloan Kettering (IIT)	TLX591-CDx	Dx
N/A*	NOBLE	TLX599-CDx	Dx
III	PROSTACT	TLX591	Tx
I	CUPID	TLX592	Tx

*Registry study

^{89}Zr-TLX250 -(^{89}Zr-girentuximab) targets hypoxic nature of tumor



Target: CA-IX
- Cell surface antigen
- Highly expressed in >70% of RCC (esp. ccRCC)

Targeting Agent: girentuximab
- IgG1 monoclonal antibody

Payload: ^{89}Zr
- Positron emitter
- $T_{1/2}$ 3.3 days

Description:
- Antibody-based PET imaging agent targeting carbonic anhydrase 9 (CA-IX) for imaging of clear cell renal cell carcinoma (ccRCC)

Clinical Status:
- ZIRCON Phase III (confirmatory/pivotal)

Unmet Need:
- ✓ Better / more cost-effective management of incidental findings
- ✓ Superior staging / re-staging
- ✓ Informing nephron-sparing surgery
- ✓ Rapid treatment response assessment

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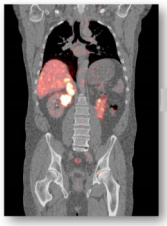
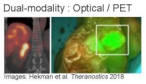
Future Directions



CDx — ZIRCON
- Other malignancies where CAIX might be beneficial for imaging over FDG PET/CT
- Colorectal, testicular, H&N
- Dosimetry for ^{177}Lu

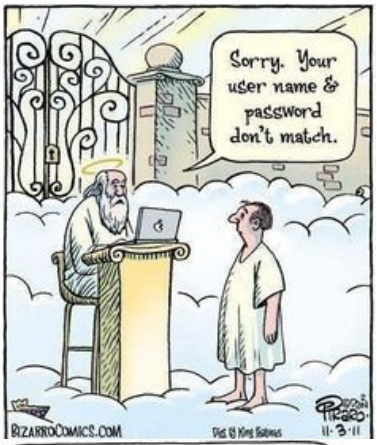
OR — ^{89}Zr-IR-girentuximab
- Dual-modality : Optical / PET



Images: Heikman et al. *Theranostics* 2018

Rx — ^{177}Lu-DFO-girentuximab — STARLITE
- Combination I-O therapy studies
  - STARLITE1: TLX250 + pembrolizumab/axitinib in 1L ccRCC
  - STARLITE2: TLX250 + nivolumab in patients that have progressed on I-O therapy

On the Lighter Side



"I explained the risks to his wife and she thinks we should go for it."

"Okay, Mr. Johnson, during this next part of your exam, you may feel some slight discomfort."

Articles of Interest

A Healthy Lifestyle in Men at Increased Genetic Risk for Prostate Cancer

YiwenZhang[b†]Konrad H.Stopsack[bd]BénédicteDelcoigne[e]FredrikWiklund[c]ChristopherHaiman[f]Stacey A.Kenfield[g]Adam S.Kibel[a]EdwardGiovannucci[h]Kathryn L.Penney[bi†]Lorelei A.Mucci[b†]

https://doi.org/10.1016/j.eururo.2022.05.008Get rights and content

Abstract

Background

Prostate cancer is the most heritable cancer. There is a need to identify possible modifiable factors for men at an increased risk of prostate cancer due to genetic factors.

Objective

To examine whether men at an increased genetic risk of prostate cancer can offset their risk of disease or disease progression by adhering to a healthy lifestyle.

Design, setting, and participants

We prospectively followed 12 411 genotyped men in the Health Professionals Follow-up Study (1993–2019) and the Physicians' Health Study (1983–2010). Genetic risk of prostate cancer was quantified using a polygenic risk score (PRS). A healthy lifestyle was defined by healthy weight, vigorous physical activity, not smoking, and a healthy diet.

Outcome measurements and statistical analysis

Overall and lethal prostate cancer events (metastatic disease/prostate cancer–specific death) were analyzed using time-to-event analyses estimating hazard ratios (HRs) and lifetime risks.

Results and limitations

During 27 yr of follow-up, 3005 overall prostate cancer and 435 lethal prostate cancer events were observed. The PRS enabled risk stratification not only for overall prostate cancer, but also for lethal disease with a four-fold difference between men in the highest and lowest quartiles (HR, 4.32; 95% confidence interval [CI], 3.16–5.89). Among men in the highest PRS quartile, adhering to a healthy lifestyle was associated with a decreased rate of lethal prostate cancer (HR, 0.55; 95% CI, 0.36–0.86) compared with having an unhealthy lifestyle, translating to a lifetime risk of 1.6% (95% CI, 0.8–3.1%) among the healthy and 5.3% (95% CI, 3.6–7.8%) among the unhealthy. Adhering to a healthy lifestyle was not associated with a decreased risk of overall prostate cancer.

Conclusions

Our findings suggest that a genetic predisposition for prostate cancer is not deterministic for a poor cancer outcome. Maintaining a healthy lifestyle may provide a way to offset the genetic risk of lethal prostate cancer.

Patient summary

This study examined whether the genetic risk of prostate cancer can be attenuated by a healthy lifestyle including a healthy weight, regular exercise, not smoking, and a healthy diet. We observed that adherence to a healthy lifestyle reduced the risk of metastatic disease and prostate cancer death among men at the highest genetic risk. We conclude that men at a high genetic risk of prostate cancer may benefit from adhering to a healthy lifestyle.

Yes, Nodal Recurrence of Prostate Cancer is Potentially Curable

redjournal.org

Advances in positron emission tomography (PET) imaging with prostate-specific tracers allow more sensitive and specific detection of low-volume recurrences that were previously indiscernible using conventional imaging. Retrospective data in patients presenting with N1M0 prostate cancer support combined-modality therapy with radiation and androgen deprivation therapy, and preliminary data from the Radiation Therapy Oncology Group 0534 randomized trial suggest that salvage pelvic nodal radiation therapy with androgen deprivation therapy is safe and effective for patients with biochemical recurrence after prostatectomy.

Novel Focal Therapy Yields Low Rate of Serious Prostate Cancers

— Trial's 6-month rate of 6% was superior to historical control

by Mike Bassett, Staff Writer, MedPage Today July 7, 2022

The use of a novel focal therapy technique called high-frequency irreversible electroporation (H-FIRE) for the treatment of localized prostate cancer resulted in a 6-month clinically significant prostate cancer (csPCa) rate lower than previously seen with other energy platforms, according to Chinese investigators.

Among the 100 patients who received H-FIRE and were biopsied at 6 months, the 6-month csPCa rate of 6.0% (95% CI 2.2-12.6) established superiority versus a pre-defined historical control rate of 20%, reported Chuanliang Xu, MD, PhD, of Changhai Hospital in Shanghai, and colleagues.

Among the six cases of csPCa, just one was inside the treatment zone, resulting in an in-field csPCa rate of 1%, "suggesting the reliability of H-FIRE," Xu and colleagues wrote in *JAMA Surgery*.

They contrasted that result with reported in-field recurrence rates of 1.7-26.0% for cryotherapy, 6-100% for high-intensity focused ultrasound, 8-38.0% for laser ablation, and 17-33.0% for photodynamic therapy.

The primary endpoint of 6-month csPCa was defined as any biopsy core with Gleason score of greater than or equal to 7, or Gleason score of 6 plus maximum cancer core length of greater than 3 mm or an increase from the original cancer burden. Treatment superiority was defined by the upper limit of the 95% CI being less than 20%.

The trial was conducted at four medical centers in China between May 2018 and March 2019. Eligible patients were between the ages of 40 and 85, with low- or intermediate-risk PCa, PSA level less than 20 ng/mL, clinical stage of T2c or less, and Gleason score of 7 or less.

Xu and colleagues also reported that a worst-scenario sensitivity analysis (in which patients who underwent H-FIRE, but did not undergo biopsy at 6 months, were assumed to have csPCa) resulted in a 6-month csPCa rate of 11.0% (95% CI 5.8-18.4), still supporting superiority versus the historical control. The same held true with a subgroup analysis that only included the 57 patients with Gleason score of 7 at baseline, which resulted in a 6-month csPCa rate of 3.5% (95% CI 0.4-12.1).

In addition, the authors found:

Prostate cancer of any kind in 14 patients (two with a Gleason score of 7, and 14 with a Gleason score 0f 6)

Median PSA levels of 9.0 ng/mL at baseline and 1.1 ng/mL at 6 months

Median International Prostate Symptom Scores of 9.0 at baseline and 4.5 at 6 months

Median International Index of Erectile Function 5 scores of 2.0 at baseline and at 6 months

Synopsi

In an accompanying commentary, Shawn Dason, MD, of the Ohio State University in Columbus, and colleagues suggested that even though there was no appropriate control group for this study, "the methodology for the question the authors sought to answer was reasonable."

Furthermore, the lack of a control group was likely unimportant given the in-field rate of clinically significant cancer of 1%, Dason and his colleagues observed, adding that while patients with Gleason scores of 6 probably did not need treatment and could have benefited from active surveillance, "results in the remaining cohort are compelling enough."

As for safety, Xu and colleagues reported no intraoperative complications. During the 6-month follow-up, there was an overall complication rate of 37.6%, with the most common complications being elevated white blood cell level in urine (23.9% of 109 patients), followed by epididymitis (4.6%), prolonged gross hematuria (3.7%), urinary retention (2.8%), urinary tract infection (1.8%), and bladder stones (0.9%).

The authors acknowledged that major limitations of the study included the use of a historical control rather than a parallel control group, as well as its relatively small sample size. Thus, "trials that compare H-FIRE with thermal energy platform directly using a larger sample size are needed to verify our preliminary findings," they observed.

In their commentary, Dason and his colleagues wrote that the data presented in the study "are reasonable in

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demonstrating histologic efficacy of the ablation technique they studied."

"Nonetheless, the broader clinical questions essential to establish focal therapy for prostate cancer remain unanswered -- namely in whom is this therapy oncologically effective and how should we define oncologic efficacy?" they added. "Answering these questions will ultimately be critical in supporting focal therapy for prostate cancer as a standard of care."

[Editor's note: see IPCSG newsletter meeting summaries in October 2016 and June 2018 for more information about Irreversible Electroporation as a focal treatment for prostate cancer.]

Clinical use of the mRNA urinary biomarker SelectMDx test for prostate cancer

Schalken, Jack A.
nature.com

Abstract

Background

Molecular biomarker tests are developed as diagnostic tools for prostate cancer (PCa) diagnosis. The SelectMDx (MDxHealth, Nijmegen, The Netherlands) test is a urinary-based biomarker test intended to be used to predict presence of high-grade PCa upon biopsy in men with elevated serum prostate-specific antigen (PSA) levels. Previous validation of the SelectMDx test revealed that 53% of the unnecessary biopsies (biopsies indicating no- or GG1 PCa) could be avoided using the SelectMDx test as a decision-tool to select men for prostate biopsy. The objective of this study is to examine the use of the commercially available SelectMDx test under routine, real-life practice.

Methods

Men that underwent a SelectMDx test between May 2019 and December 2020 and that were originating from countries that perform the SelectMDx test on a regular basis were included in this study, resulting in 5157 cases from 10 European countries. Clinical parameters, urinary RNA scores, and test outcomes were compared between PSA groups, age groups, countries, and the validation cohort (described previously [4]) using the Mann–Whitney *U* test, Chi-Square test, Benjamini–Hochberg and Kruskal–Wallis tests.

Results

40.72% of the cases received a negative SelectMDx result. The test is also used in patients outside the intended-use population (PSA < 3 and >10 ng/mL). Clinical parameters (age, PSA density, DRE outcome) varied between patient population from individual countries and the validation cohort, resulting in differences in the potential number of saved biopsies using the test.

Conclusions

The potential number of reduced biopsies in clinical use was 40,72% using the SelectMDx test, assuming a negative SelectMDx test resulted in the decision not to biopsy the patient. This is higher compared to the validation cohort, which is explained by differences in patient population.

Prostate Cancer Cases Are Growing More Serious

Abdullah Hashmi, MD
July 07, 2022
The study covered in this summary was published on ResearchSquare.com as a preprint and has not yet been peer reviewed.

Key Takeaways

(Continued on page 9)

In the past decade, the incidence of T1a/b prostate cancer has remained stable, but clinically significant T1a/b disease has increased over time.

Across all risk groups and accounting for age and comorbidity status, patients diagnosed with T1a/b prostate cancer are more likely to enter active surveillance/watchful waiting and are less likely to be treated definitively with surgery or radiation.

Why This Matters

The changing recommendations regarding prostate cancer screening in the U.S. during the last decade have led to changes in incidence patterns of prostate cancer, and the appropriate management of T1a/b prostate cancer is not well defined.

Only a few studies have previously addressed the incidence of T1a/b prostate cancer. It has remained unclear which patients with T1a/b disease benefit from definitive treatment or expectant management.

This is the largest study examining trends in incidence, clinical significance, and treatment patterns for T1a/b prostate cancer regardless of risk group, age, and comorbidity status.

Study Design

Using the National Cancer Database, the study looked at a dataset of 24,679 patients diagnosed with T1a/b prostate cancer between 2010 and 2017.

Patients with missing data for pathological T stage, prostate specific antigen (PSA), or Gleason score were removed from analysis.

Clinically significant disease was defined as Gleason grade group ≥ 2.

Treatment modalities were assessed for primary treatment after diagnosis only. To reduce treatment bias, a second analysis of treatment modality proportions for patients between 62 and 68 years of age was completed. Patients in this age group were eligible for all treatment modalities.

Key Results

Of the 24,679 patients identified, 15,186 had T1a disease and 9493 had T1b disease.

T1a/b prostate cancer represented 3.5% of all prostate cancer without a change in incidence over time.

The likelihood of T1a/b prostate cancer being clinically significant increased over time, from 38.8% in 2010 to 44.1% in 2017 ($P < .001$). Similarly, the chance of being diagnosed with T1a/b non-clinically significant disease decreased from 61.3% in 2010 to 55.9% in 2017.

Patients diagnosed with T1a/b disease were significantly older (mean age 72.2 ± 9.6 vs 64.2 ± 8.1; $P < .001$) than patients diagnosed with T1c disease.

Accounting for age and risk, patients with diagnosed T1a/b disease were less likely to be treated definitively with surgery or radiation compared with patients with T1c disease (low risk — 6.9% [T1a] vs 17.6% [T1b] vs 67.5% [T1c]; $P < .001$); (intermediate risk — 21.6% [T1a] vs 30.4% [T1b] vs 86.2% [T1c]; $P < .001$); (high risk — 28.4% [T1a] vs 26.3% [T1b] vs 78.2% [T1c]; $P < .001$).

Across all risk groups, patients with T1a/b disease were more likely to enter active surveillance/watchful waiting compared with T1c patients. In comparison to T1b, patients with T1a disease across all risk groups were more likely to enter active surveillance/watchful waiting.

Limitations

Variations between institutions for the National Cancer Database reporting and coding may have affected the analyzed dataset.

Long-term oncological outcomes and functional outcomes were not obtained because the data was not coded in the National Cancer Database.

The National Cancer Database only included data for Commission on Cancer-accredited facilities and may not have been generalizable to other countries.

Disclosures

The study received no commercial funding.

The authors disclosed no relevant financial relationships.

This is a summary of a preprint research study, "Trends in Diagnosis and Treatment of T1a, T1b Prostate Cancer in the United States, 2010-2017," led by Eyal Kord, MD, MPH, Virginia Mason Medical Center, Seattle, Washington, and published on ResearchSquare.com. This study has not yet been peer reviewed. The full text can be found on ResearchSquare.com.

- **For further Reading: https://ipcsg.blogspot.com/**

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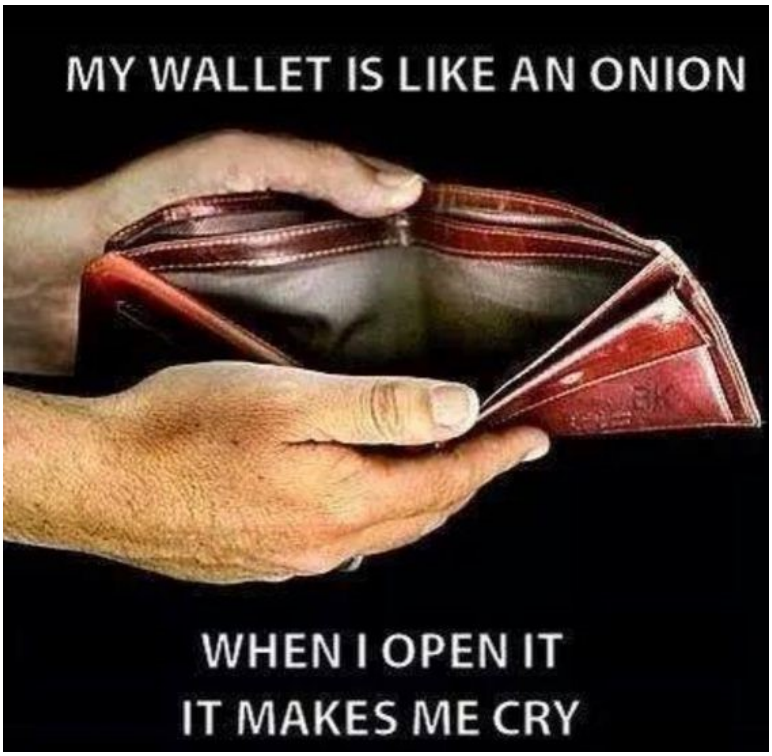
Member John Tassi is the webmaster of our website and welcomes any suggestions to make our website simple and easy to navigate. Check out the Personal Experiences page and send us your story. Go to: https://ipcsg.org/personal-experience

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!



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