Celebrating **Prostate Cancer** 28 years of supporting men **Support Association** and their families of New Mexico **PCSANM** Quarterly **July 2019** Volume 26, Issue 3 Annual PCSANM Conference: **Issue Highlights** November 9, 2019 Information 2 "What's New for Diagnosis and Treatment **Recap of Events** 3 for Prostate Cancer" **PET-based Imaging** 4 Put this great event on your calendar! Long-term Androgen Deprivation PCSANM is proud to present our eighth annual, free conference to be held 5 from 9 a.m. to 5 p.m. at Sandia Preparatory School in Albuquerque. **Active Surveillance** 6 9:00-9:15 — Welcome, Intro to Morning Moderator (Joe Diaz): FDA Oks Jatenzo 7 Steve Denning, PCSANM Board Chairman **Testosterone Therapy** 8 9:15–10:15 — Supplements—What Works and What Doesn't: 9 **Recent Studies** Dr. Mark Moyad, University of Michigan and Prostate Cancer **Research** Institute **Book Review - "Cell"** 10 Radium-223 & Abiraterone 11 10:15-10:30 - Break Chairman's Message 12 **10:30–11:15 — PSMA Trial and Radiopharmaceuticals:** Dr. Gregg Franklin, New Mexico Cancer Center **Our website address:** www.pcsanm.org 11:15–12:00 — Updated Treatments for Castration-Resistant Prostate Carcinoma (CRPC): Dr. Pranshu Bansal, **Email us:** New Mexico Cancer Center pchelp@pcsanm.org 12:00-1:00 — Lunch Break **Support Meetings:** 1:00-1:15 — Intro to Afternoon Moderator Dr. Thomas Schroeder, PCSANM meets at Bear Canyon UNM Comprehensive Cancer Center Senior Center, 4645 Pitt St NE in Albuquerque. This is two blocks 1:15–2:15 — Axumin: Speaker TBA, XRay Associates of New Mexico from Montgomery and Eubank; go north one block to Lagrima de 2:15-2:30 — Break Oro St, and east one block to Pitt,

2:30–3:30 — New Diagnostic Tools and Treatments for Initial Stages of Prostate Cancer: Speaker TBA, Lovelace Urology

3:30–4:30 — Regulatory/Insurance Changes and/or Patient Care vs. Treatment: Dr. Barbara McAneny, American Medical Association President, CEO of New Mexico Cancer Center

4:30–4:45 — Thanks/Closing Remarks: Steve Denning

and left 50 yards to the Bear

Canyon parking lot. We are in

room 3 or 5, at the west end of the building. Meetings are

usually the first and third

Saturdays of the month from

12:30-2:45 pm. Map is at http://binged.it/1baQodz

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Special thanks to Presbyterian Healthcare Services for their generous support of this newsletter.

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Prostate Cancer Support Contacts Around the State

City	Contact	Phone
Clovis	Kim Adams	(575) 769-7365
Farmington	Deb Albin	(505) 609-6089
Grants	Dorie Sandoval	(505) 285-3922
Los Alamos	Randy Morgan	(505) 672-3486
Las Cruces	John Sarbo or	(915) 503-1246
	Ron Childress	(575) 522-1083
Silver City		(575) 574-0225 C
	Herb Trejo	(575) 538-3522 H

In Memory of

With deep sympathy and regret, we list these names:

> Peter De Wolf Bill Henderson

James L. Todd

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The PCSA of New Mexico gives education, information and support, not medical advice. Please contact your physician for all your medical concerns.

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PCSANM Lifeline

A quarterly newsletter addressing issues of prostate cancer

Months Published: January April July October

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The Prostate Cancer Support Association of New Mexico, Inc. 2533 Virginia St NE, Suite C Albuquerque, NM 87110

(505) 254-7784 (505) 254-7786 Fax (800) 278-7678 (toll free in NM)

> Office and library open Monday thru Thursday 10 am-2 pm or by appointment

Calls received after hours will be forwarded to a board member

> EMAIL pchelp@pcsanm.org

VISIT OUR WEBSITE http://www.pcsanm.org

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FACEBOOK Rod Geer

EDITORS Lou Reimer/Ann Weinberg

> MEETINGS Lou Reimer

PROGRAM MANAGER Ann Weinberg

Recap of One-on-One Support, Events, and Meetings of Prostate Cancer Support Association of New Mexico March, April, and May 2019

We invite you to review our accomplishments.

If there is a meeting noted below that is of interest, please check with the office to see if a video has been prepared and made available for check-out.

One-on-One Support

PCSANM facilitators provided prostate cancer educational guidance and support on 35 occasions to 27 individuals both over the phone and in person. Six individuals became members.

Events Attended

<u>April 12</u> - Cancer Services of New Mexico Spring Retreat: Jan Marfyak and Phil York represented PCSANM and reached 32 individuals.

<u>April 25</u> - Colfax County Health Fair (Raton):

Carol and Lou Reimer represented PCSANM at this community event and spoke to 17 individuals in depth and to 64 casually about prostate cancer.

April 27 - Cibola County Health Fair (Grants):

Eli Maestas and Phil York reached 34 individuals at this health fair.

<u>May 15, 2019</u> - VA2K Walk & Roll Event to

Support Homeless Veterans: Rod Geer and Steve Denning staffed a table and spoke with 24 individuals about prostate cancer.

May 16, 2019 - Sandia Pueblo/Casino Wellness and

Safety Fair: Rod Geer and Lou Reimer visited at length with 24 people and also talked with 40 other attendees generally.

Meetings

We held six regular support meetings during this time period. Meetings drew 154 attendees.

<u>March 2</u> - New Trials and the Future of Prostate Cancer Treatment: Dr. Neda Hashemi,

Hematology and Oncology Specialist, UNM Comprehensive Cancer Center

March 16 - An Intimate Conversation About

Prostate Cancer: Dr. Juhee Sidhu, Medical Oncologist, New Mexico Cancer Center

<u>April 6</u> - Sharing Session: Facilitated by Steve Denning

<u>April 20</u> - DVD, "Update of the Best Imaging Tests for Prostate Cancer Detection and Progression: MRI and Beyond": Dr. Daniel Margolis, Radiologist, UCLA

<u>May 4</u> - Optimal Treatment When Prostate Cancer Has Spread Beyond the Prostate: Dr. Ramesh Gopal, Radiation Oncologist, Presbyterian Medical Group, MD Anderson Cancer Center

<u>May 18</u> - DVD, "Your Pathology Report: What You Have to Know" (Prostate Cancer Research Institute 2017 Conference): Dr. Jonathan Epstein, Professor of Oncology, Pathology, and Urology, Johns Hopkins Medical Center

"The twice monthly PCSANM meetings have been a great source of the latest diagnostic procedures and treatment protocols for reoccurring prostate cancer. This has given me confidence that I am effectively managing my health years after my initial prostate cancer treatment."

– John G.

PET-based Imaging Improves Metastases Detection in Biochemically Recurrent Prostate Cancer

By Marilynn Larkin

NEW YORK (Reuters Health) - Gallium-68 prostatespecific membrane antigen positron emission tomography (Ga-68 PSMA PET) accurately detects metastases in biochemically recurrent prostate cancer, particularly at low prostate-specific antigen (PSA) levels, researchers say.

"Historically, conventional imaging modalities have included computerized tomography and whole body radionucleotide bone scans," Dr. Marlon Perera of the University of Melbourne in Victoria, Australia told Reuters Health by email. "While cost-effective and readily available, these conventional imaging modalities are fraught with limited accuracy."

"Ga-68 PSMA PET is a novel imaging technique," he said. "PSMA is a transmembrane ligand that is expressed on prostatic cells. Excitingly, the expression of PSMA increases with increasing cellular dysplasia (i.e., more malignant). Accordingly, this represents an ideal target for imaging in prostate cancer."

In a 2016 paper in European Urology, Perera's team reported a meta-analysis of 18 studies involving 1,306 patients that showed "significantly superior accuracy, sensitivity and specificity" for Ga-68 PSMA PET compared with conventional imaging (http://bit.ly/2YyIqH1).

For the current study, the researchers expanded the meta-analysis, including 37 articles involving 4,790 patients.

As reported online February 14, also in European Urology, in men with biochemical recurrence, positive Ga-68-PSMA PET scans increased with higher pre-PET PSA levels.

Specifically, for PSA categories 0-0.19, 0.2-0.49, 0.5-0.99, 1-1.99, and 2 ng/ml or greater, the percentages of positive scans were 33%, 45%, 59%, 75%, and 95%, respectively.

No significant differences in Ga-68 PSMA PET positivity and Gleason score were noted. Patients with a Gleason sum of 7 or less had positivity of 72% compared with 80% in patients with a Gleason sum of 8 or more.

"In the biochemical recurrence setting, local recurrence was identified in 22% post prostatectomy and 52% post radiotherapy," Dr. Perera noted. "Radiotherapy cohorts also had higher rates of positivity in extrapelvic lymphadenopathy and bone metastases."

"A further novel finding of our meta-analysis identified interesting patterns of disease based on Ga-68 PSMA PET," he said. "In the primary setting, Ga-68 PSMA PET identified intraprostatic (local) prostate cancer in 90%."

PCSANM is a chapter of Us TOO, International Prostate Cancer Education and Support Network

Us TOO has held several conferences at which speakers have presented talks of potential interest to our members. Links to three of those conferences include:

https://www.ustoo.org/PathwaysChicago https://www.ustoo.org/Pathways-EnglewoodNJ https://www.ustoo.org/Pathways-Seattle-Webcast

Special thanks to Presbyterian Healthcare Services for their generous support of this newsletter. Medscape: March 13, 2019

Long-Term Androgen Deprivation Underused for Prostate Cancer

By Scott Baltic, SOURCE: https://bit.ly/2F3cEJl, Eur Urol Oncol 2019

NEW YORK (Reuters Health) - Long-duration androgen deprivation therapy (ADT) is widely underused in men, especially African Americans, who are undergoing definitive external beam radiotherapy (EBRT) for high-grade prostate cancer, a new U.S. study has found.

Nearly a quarter of patients in the population-based retrospective trial received no long-term ADT, and fewer than one in seven received the recommended 24 to 36 months.

"Overall, this underutilization is concerning, as multiple randomized controlled trials have confirmed a survival benefit to longer durations of concomitant ADT, and thus long-term ADT constitutes the current standard of care," Dr. Amar Kishan of the University of California, Los Angeles, and his colleagues write in European Urology Oncology, online February 1.

The study examined records from the Surveillance, Epidemiology, and End Results (SEER) Medicarelinked database of non-Hispanic white (NHW) and African-American (AA) men with Gleason grade group 4-5 (Gleason score 8-10) prostate cancer treated definitively with EBRT from 2008 to 2011.

In all, 961 men (852 white and 109 African-American) were included in the study. Significant differences at baseline in all covariates between AA and NHW men were largely reduced after adjustment via propensity score.

Of the participants, 23.4% received no ADT, 30.9% received one to six months of treatment, 32.6% seven to 23 months and 13.1% received 24 to 36 months. Use of ADT differed between African-American and non-Hispanic white men, with 33.9% versus 22.1% receiving no ADT, respectively. This difference was significant even after adjusting for covariates.

This racial disparity "is consistent with recent reports of disparities in the delivery of definitive treatments" in African-American men versus non-Hispanic white men and could, in part, explain the inferior prostate cancer-specific mortality outcomes reported for African-American men, the authors write.

"More training on the clear survival benefit of longer-term ADT, and training on minimizing the side effects, may be helpful," Dr. Kishan said. "An alternative approach, which is also ongoing, is trying to learn how to decrease the duration of ADT without compromising survival."

Dr. Ronald C. Chen, associate professor and associate chair for education with the department of radiation oncology at the University of North Carolina at Chapel Hill, told Reuters Health by email that "there are now multiple studies consistently showing underutilization of ADT in patients with high-risk prostate cancer treated with EBRT. This is very concerning."

"While ADT does have side effects, as all cancer treatments do, patients need to be informed that long -duration ADT improves cure rates and prolongs life, as demonstrated by multiple clinical trials," he continued. "Therefore, skipping ADT, or giving short-duration instead of long-duration ADT, for these patients with the most aggressive form of localized prostate cancer, has significant potential negative consequences."

In an email to Reuters Health, Dr. Quoc-Dien Trinh, co-director of the prostate-cancer program at Dana-Farber/Brigham and Women's Hospital in Boston and assistant professor of surgery at Harvard Medical School, called the racial disparity "a notable finding."

"Many investigators (including myself) feel that the racial differences in prostate-cancer outcomes have more to do with access to quality care rather than biological differences," he explained. "To show that African-American men are under-treated for potentially lethal prostate cancer supports that hypothesis." Medscape: February 11, 2019

Active Surveillance for Prostate Cancer Triples in US Another Trend Worries Radiation Oncologists

Nick Mulcahy, Genitourinary Cancers Symposium (GUCS) 2019

Active surveillance for low-risk prostate cancer, which involves forgoing immediate treatment, has increased threefold since such "conservative" management was recommended by major guidelines in the United States.

Specifically, the practice of active surveillance or watchful waiting (AS/WW) increased from 14.5% in 2010 to 42% in 2015, when it became the most common approach for the management of low-risk prostate cancer.

The new figures were published online February 11 in *JAMA* and were also presented at the Genitourinary Cancers Symposium (GUCS) 2019 in San Francisco, California.

The increase in AS/WW over time is "encouraging," said lead author Brandon A. Mahal, MD, a radiation oncologist at the Dana-Farber Cancer Institute in Boston, Massachusetts. This "suggests that clinicians are better adhering to current recommendations and guidelines," and this will reduce rates of overtreatment, he told *Medscape Medical News*.

However, another expert was surprised that the reported numbers are so low.

"Despite these positive trends, it is concerning that as of 2015, still only 42% of low-risk patients were being managed conservatively," said Stacy Loeb, MD, a urologist at NYU Langone Health in New York City, in an email to *Medscape Medical News*.

Loeb and colleagues recently reported much higher rates: 72% of men younger than 65 years and 79% of men 65 or older with low-risk prostate cancer seen in the US Department of Veterans Affairs health system were managed conservatively in 2015.

How could two studies from the United States have such different findings?

The data sources — and what they reflect in terms of treatment settings — could be the explanation, said both Mahal and Loeb.

The new findings are derived from the Surveillance, Epidemiology and End Results (SEER) Prostate Active Surveillance/Watchful Waiting database. These patients were managed in a variety of settings. On the other hand, Loeb's VA study is from just one healthcare system.

Mahal also pointed out that the VA study included a proxy for AS/WW via administrative codes, but not a validated AS/WW variable, which was embedded in the custom SEER database.

Still, Loeb pressed her point that the newly reported rate of AS/WW is still low — given what can be achieved.

Other findings reinforce her argument. For example, data from the National Prostate Cancer Registry of Sweden showed that 74% of men with low-risk prostate cancer there were managed with active surveillance in 2014.

Continued from page 5

"Patients need to be aware of the importance of ADT in conjunction with EBRT for high-risk prostate cancer," said Dr. Trinh, who also was not part of the study. "Policy makers should devise strategies to incentivize physicians (or hospitals) to provide highquality care to ALL men with prostate cancer." Medscape: March 27, 2019

FDA OKs *Jatenzo* Oral Testosterone Replacement for Certain Forms of Hypogonadism

By Megan Brooks

The US Food and Drug Administration (FDA) has approved oral testosterone undecanoate (*Jatenzo*, Clarus Therapeutics) to treat men with hypogonadism resulting from specific medical conditions, such as genetic disorders like Klinefelter syndrome or tumors that have damaged the pituitary gland.

Jatenzo should not be used to treat men with agerelated hypogonadism, even if such patients have symptoms that appear to be related to low testosterone. For patients with age-related hypogonadism, Jatenzo's benefits do not outweigh its risks, the FDA said in a news release announcing approval.

"Jatenzo's oral route of administration provides an important addition to current treatment options available for men with certain hypogonadal conditions who up until now have most commonly been treated with testosterone products that are applied to the skin or injected," Hylton V. Joffe, MD, director of the Division of Bone, Reproductive and Urologic Products in the FDA's Center for Drug Evaluation and Research, said in the release.

"But it's important to emphasize that this drug should not, like other testosterone treatments, be used to treat older men with 'age-related hypogonadism.' The benefits of testosterone therapy, including Jatenzo, have not been established for this use, and Jatenzo's effects on raising blood pressure can increase the risks of heart attack, stroke and cardiovascular death in this population," said Joffe.

An FDA advisory panel previously voted against approval of oral testosterone undecanoate and a similar product (*Tlando*, Lipocine), citing concerns that ease of use – and the potential for cardiovascular side effects – could expose millions to unnecessary risk. Jatenzo was assessed in a 4-month clinical trial that involved 166 men with hypogonadism. Participants were initially given Jatenzo at a dose of 237 mg twice daily. The dose was adjusted downward or upward to a maximum of 396 mg twice daily, depending on testosterone level.

Results showed that 87% of men treated with Jatenzo achieved an average testosterone level within the normal range (the primary endpoint), the FDA said. Side effects seen in trials of Jatenzo included headache, an increase in hematocrit level, a decrease in HDL cholesterol level, high blood pressure, nausea, and an increase in prostate specific antigen (PSA) level. For patients taking Jatenzo, hematocrit, cholesterol, and PSA levels should be monitored regularly, and patients with benign prostate hyperplasia should be monitored for worsening of symptoms, the FDA said.

Jatenzo's label contains a boxed warning about blood pressure elevations. Healthcare providers should consider individual patients' risk for heart disease and ensure that blood pressure is adequately controlled before prescribing Jatenzo, the FDA said. Blood pressure should be periodically monitored during treatment.

The FDA requires that all manufacturers of testosterone products conduct blood pressure postmarketing trials to more clearly address whether these products increase blood pressure.

USQTOO® PROSTATE CANCER EDUCATION & SUPPORT

Testosterone Therapy for High-Risk Prostate Cancer Survivors

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Abstract:

A systematic review and meta-analysis were performed to determine the relationship between testosterone therapy and the risk of recurrence in testosterone-deficient survivors of curatively treated high-risk prostate cancer. Primary outcome was the risk of biochemical recurrence (BCR) in 109 high-risk patients in 13 included studies (1997-2017). Biochemical and symptomatic effects of therapy were also reviewed. The BCR rate was 0.00 (0.00-0.05), lower than the expected rate for high-risk prostate cancer survivors, suggesting that testosterone therapy may not increase their BCR risk. However, this is uncertain as the available evidence is of very low quality. Testosterone therapy remains investigational in this group.

Urology Journal **TAKE-HOME MESSAGE -** Gautam Jayram, MD

A systematic review and meta-analysis were conducted to determine the relationship between testosterone therapy and the risk of recurrence in testosterone-deficient survivors of curatively treated high-risk prostate cancer. In all, 13 studies were reviewed including a total of 109 patients. With of a median follow-up of 2 to 3 years, the authors found a biochemical recurrence rate of 0.00 (0.00–0.05), lower than the expected rate for high-risk prostate cancer survivors.

The authors concluded there was no increased rate of biochemical recurrence in high-risk prostate cancer patients receiving testosterone following curative treatment. Although the body of evidence is small, these data suggest that testosterone therapy may be safe in this group of men.

From Us TOO - NEWS YOU CAN USE

Recent Studies from University of Colorado Add New Data to Prostate Cancer (Abiraterone Acetate to Treat Metastatic Castrationresistant Prostate Cancer in Combination with Prednisone)

Published: by University of Colorado Tuesday, March 12, 2019

Current study results on Oncology - Prostate Cancer have been published. According to news reporting from Aurora, Colorado, by NewsRx journalists, research stated, "Prostate cancer is one of the most common cancers in the United States, with an estimated incidence of 164,690 cases, accounting for 9.5% of all new cancer diagnoses. The mainstay of therapy for metastatic prostate cancer involves suppressing testosterone production through androgen deprivation therapy."

The news correspondents obtained a quote from the research from the University of Colorado, "However, nearly all patients on androgen deprivation therapy will develop resistance to hormone therapy. An improved understanding of the biology of castration resistance has allowed for the development of novel inhibitors of the androgen axis. Agents such as abiraterone acetate, which provides additional androgen suppression by inhibiting cytochrome P450 17A (CYP17A), have improved survival outcomes of patients with advanced prostate cancer. The longest experience with abiraterone acetate is in the metastatic castration-resistant setting. However, more recent trials have demonstrated that abiraterone acetate is an option for treatment earlier in the prostate cancer paradigm."

According to the news reporters, the research concluded: "This review will cover the current use of abiraterone acetate in combination with prednisone for the treatment of castration-resistant prostate cancer."

See For More Information page 9

Sipuleucel-T Could Be More Widely Used for Advanced Prostate Cancer (Commercially = Provenge. ed)

By Will Boggs, MD

NEW YORK (Reuters Health) - More men with advanced prostate cancer could benefit from immunotherapy with sipuleucel-T, according to researchers who found use of the drug was influenced by income and other factors.

"Prostate cancer is a disease that affects men of every race, income level, and in every part of the country," Dr. Megan V. Caram of the University of Michigan, in Ann Arbor, told Reuters Health by email. "Therefore, it is important that future work be done to investigate and identify disparities in use of therapies for prostate cancer. Identifying disparities is an important first step in working toward ensuring that treatment of a patient is based on their disease and not their income, race, the doctor that they see, or where they live."

Sipuleucel-T was approved by the U.S. Food and Drug Administration (FDA) in 2010 for use in metastatic castration-resistant prostate cancer (mCRPC) with minimal or no symptoms. It met with considerable initial skepticism as the first treatment of its kind, and its use has remained controversial despite evidence of its efficacy and safety.

Dr. Caram's team used data from the Clinformatics Data Mart Database to investigate patient, physician and regional factors associated with the adoption of sipuleucel-T.

Among the 7,272 men included in the study who received treatment for mCRPC, only 730 (10.0%) received sipuleucel-T, a fraction that increased from 0.6% in 2010, peaked at 15.1% in 2012, and then fell to 8.6% by 2016.

Most patients who received sipuleucel-T (69.0%) received it as first-line treatment, and most (68.2%) received subsequent therapies, the researchers report in JAMA Network Open, online April 19.

Nearly 10% of men treated with sipuleucel-T received it concurrently with other therapies, which is a nonevidence-based practice. After adjusting for all other variables, Hispanic ethnicity and living in the Pacific region were independently associated with lower odds of receiving sipuleucel-T. Meanwhile, higher household income, having preferred provider organization insurance and being treated by a urologist were independently associated with higher odds of receiving the drug.

"In my opinion, the most important take-home point is the difference in use of sipuleucel-T at different income levels," Dr. Caram said. "This difference may be explained by an element of financial toxicity since many patients are still required to pay a significant amount out-of-pocket for this therapy. It's also possible that patients of lower income do not have access to centers that offer sipuleucel-T or are not being offered this therapy by their provider. Future studies will help elucidate the reason behind the income level difference."

"It is encouraging that we found most providers are using sipuleucel-T as first-line therapy in patients, the period of their disease when we would expect most patients would have the fewest symptoms and the lowest volume of their disease," she said. "However, it is still unknown when the optimal time will be and in which patients sipuleucel-T will provide the most benefit."

Continued from page 8

For more information see: Abiraterone Acetate To Treat Metastatic Castration-resistant Prostate Cancer In Combination With Prednisone. *DRUGS OF TODAY*, 2019;55(1):5-15. *DRUGS OF TODAY* can be contacted at: Prous Science, Sau-Thomson Reuters, 398 Provenca, 08025 Barcelona, Spain.

Our news journalists report that additional information may be obtained by contacting A. Jimeno, University of Colorado, Cancer Center, Dept. of Med, Div Med Oncol, Aurora, CO 80045, United States.

PCSA LIFELINE

Review of Robin Cook's book "Cell"

By Lou Reimer

I have just finished an audiobook version of this Robin Cook novel and found it fascinating. I suggest others might find it as fascinating as well.

This 2014 book features George Wilson, a 4th year Radiology Resident in the fictitious LA University Hospital. The "CELL" in the title refers to cell phones; i.e. Smartphones.

A bit of the plot.

George wakes up one morning and finds his fiancee, Kasey, dead alongside him. Kasey was a participant in the "beta" testing of a new smartphone App called iDoc. iDoc is a personal primary physician for the participants. Through the App, the person's general health can be monitored. The phone can test blood and saliva when placed on the screen. The phone can be used to have a video visit with a physician. Once the App has gathered the information about the patients' medical condition, iDoc can give advice for the patient to do some self -help, can prescribe medications to be picked up at the pharmacy, consult with a virtual physician, or direct the patient to go to the hospital or otherwise command a visit to a live physician. iDoc's power is that it is a computer program that can learn and compile information and conclude that A+B = C and then apply it to the diagnosis and treatment of the patient. iDoc can compile these findings over a suite of patients and make better diagnoses and therefore better prescribe treatments. iDoc can go beyond an individual doctor's or group's, knowledge and expertise.

As the story continues, George finds that some of his patients who learn of fatal illnesses, are dying sooner that they would normally die due to the fatal illness. All the dead patients who George knows about were iDoc participants. What is the relationship between these patients and iDoc? The other element in the plot is that all the patients who died were diabetics with an implanted insulin reservoir which kept their diabetes under control. The smartphone tested their blood sugar levels regularly and added just the right amount of insulin to keep the patient healthy.

What I found so intriguing is that many of the functions of iDoc are available today through smartphones. For example, I can test my blood pressure, track my exercises, have a video conference with a doctor, and access my medical records from my smartphone. A Fitbit might be capable of more functions. Apple has released its Series 4 watch that sends out an alert if you fall and don't respond to a signal, and it also monitors for heart problems with an installed electrocardiogram App.

It took only a very small leap of faith to imagine how all the medical functions described in the novel could be implemented.

I don't want to reveal the plot but the novel raises some questions for today and the future. iDoc is developed by an insurance company whose stated purpose is to reduce the number of doctor visits by nipping in the bud medical problems that might spiral out of control. Or is it just to lower their cash out go?

Would iDoc alleviate the current primary care physician shortage?

What about the patient/doctor relationship? Will it be as responsive as our current in-person relationships?

Can we trust a computer program to make life and death decisions about our health?

Can this sort of program help us rein in burgeoning medical costs?

Can it help our gov't provide efficient ACA and Medicare services?

Will the program be able to weigh the costs of prolonging life for a terminal patient vs quality of life considering the assumed short time before death?

Where will all the information stored and used by an iDoc be? How accessible would that info be to unauthorized persons/institutions?

What would government's role be in the development and implementation of an iDoc type App?

There are ethical and practical questions for an iDoc. We probably would be ahead if we, as a society, thought about them now because I anticipate such computer programs looming on the horizon. It will be a debate that needs to involve doctors, patients, hospitals, insurance companies, pharmaceutical companies and the government. The anticipated effort needed to address these ethical questions reminds me of what I have read about the initial efforts to develop the ACA program, it started out to develop a sleek race horse and instead created a three-legged camel. July 2019

The Lancet / Oncology / Volume 20, ISSUE 3, P408-419, March 01, 2019

Addition of radium-223 to abiraterone acetate and prednisone or prednisolone in patients with castration-resistant prostate cancer and bone metastases (ERA 223): a randomized, double-blind, placebo-controlled, phase 3 trial

Prof Matthew Smith, MD, Prof Chris Parker, MD, Prof Fred Saad, MD, Prof Kurt Miller, MD, Prof Bertrand Tombal, MD, Quan Sing Ng, MD, et al.

Background

Abiraterone acetate plus prednisone or prednisolone improves progression-free survival and overall survival in patients with metastatic castration-resistant prostate cancer. Radium-223 improves overall survival and delays the onset of symptomatic skeletal events in patients with castration-resistant prostate cancer and bone metastases. We assessed concurrent treatment with abiraterone acetate plus prednisone or prednisolone and radium-223 in such patients.

Methods

We did a randomised, double-blind, placebocontrolled, phase 3 trial at 165 oncology and urology centres in 19 countries. Eligible patients were aged 18 years or older, and had histologically confirmed, progressive, chemotherapy-naive, asymptomatic or mildly symptomatic castration-resistant prostate cancer and bone metastases, Eastern Cooperative Oncology Group performance status of 0 or 1, life expectancy of at least 6 months, and adequate haematological, renal, and liver function. Participants were randomly assigned (1:1) according to a permuted block design (block size 4) via interactive response technology to receive up to six intravenous injections of radium-223 (55 kBq/kg) or matching placebo once every 4 weeks. All patients were also scheduled to receive oral abiraterone acetate 1000 mg once daily plus oral prednisone or prednisolone 5 mg twice daily during and after radium-223 or placebo treatment. The primary endpoint was symptomatic skeletal event-free survival, which was assessed in the intention-to-treat population. Safety analyses were done in all patients who received at least one dose of any study drug. This trial is registered with ClinicalTrials.gov, number NCT02043678. Enrolment has been completed, and follow-up is ongoing.

Findings

Between March 30, 2014, and Aug 12, 2016, 806 patients were randomly assigned to receive radium-223 (n=401) or placebo (n=405) in addition to abiraterone acetate plus prednisone or prednisolone.

The study was unblended prematurely, on November 17, 2017, after more fractures and deaths were noted in the radium-223 group than in the placebo group (in an unplanned ad-hoc analysis), but all patients had completed radium-223 or placebo before this date. At the primary analysis (data cutoff Feb 15, 2018), 196 (49%) of 401 patients in radium-223 group had had at least one symptomatic skeletal event or died, compared with 190 (47%) of 405 patients in the placebo group (median follow-up 21.2 months [IQR 17.0-25.8]). Median symptomatic skeletal event-free survival was 22.3 months (95% CI 20.4–24.8) in the radium-223 group and 26.0months $(21 \cdot 8 - 28 \cdot 3)$ in the placebo group (hazard ratio 1.122 [95% CI 0.917–1.374]; p=0.2636). Fractures (any grade) occurred in 112 (29%) of 392 patients in the radium-223 group and 45 (11%) of 394 patients in the placebo group. The most common grade 3–4 treatment-emergent adverse events were hypertension (43 [11%] patients in the radium-223 group vs 52 [13%] patients in the placebo group), fractures (36 [9%] vs 12 [3%]) and increased alanine aminotransferase concentrations (34 [9%] vs 28 [7%]). Serious treatment-emergent adverse events occurred in 160 (41%) patients in the radium-223 group and 155 (39%) in the placebo group. Treatment-related deaths occurred in two (1%) patients in the radium-223 group (acute myocardial infarction and interstitial lung disease) and one (<1%) in the placebo group (arrhythmia).

Interpretation

The addition of radium-223 to abiraterone acetate plus prednisone or prednisolone did not improve symptomatic skeletal event-free survival in patients with castration-resistant prostate cancer and bone metastases, and was associated with an increased frequency of bone fractures compared with placebo. Thus, we do not recommend use of this combination.

Funding

Bayer



PCSANM *Lifeline* Newsletter Celebrating 28 years of supporting men and their families

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A Message from the Chairman

July 2019

We continue to see new faces at our Saturday meetings which is bittersweet. We love that they've found us but don't love the reason. Prostate cancer continues and will continue to affect men when they least expect it. That's why we are so firmly in favor of screening via the PSA test. Ever since the US Preventive Services Task Force made their fateful recommendation in 2012, many men stopped getting PSA added to their blood work panel. Many didn't even notice the change but now that is coming back to haunt them and us.

Prostate cancer is the only cancer that has a simple marker that is detected in the blood to let us know that something is happening that needs looking into. All other cancers require much more extensive and sometimes invasive procedures for detection. Why not use the PSA test? Opponents say it leads to unnecessary treatment and anxiety. That used to be the case but now more level heads are popping up and realizing that education and support is what's really needed. The education needs to be extended not only to men starting around age 45 but also to the medical professionals about the need for screening and how to interpret the results so as not to alarm patients. We, at PCSANM, are making efforts to expand our education programs to include not only health fairs and presentations to groups of men and women, but we are also starting a communications effort to medical professionals including mailings, presentations and invitations to our conference in November.

This is big task and we need your support. Next time you visit your doctor, tell them about the work we're doing and let them know how PCSANM is helping not only men with prostate cancer but medical professionals through our education efforts and support activities. Thank you for your continued support.

Steve Demi

Chairman of the Board, PCSANM