



Informed Prostate Cancer Support Group Inc.

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June 2019 NEWSLETTER
P.O. Box 420142 San Diego, CA 92142
Phone: 619-890-8447 Web: <http://ipcs.org>
We Meet Every Third Saturday (except December)



Tuesday, June 11, 2019

Volume 12 Issue 6

Next Meeting— June 15, 2019-10:00 AM to Noon

Location: SBP Auditorium, 10905 Road to the Cure, San Diego, CA 92121

Franklin D. Gaylis, MD, FACS Urologist - Active Surveillance

Active surveillance (AS) is the practice of closely monitoring slow, indolent forms of prostate cancer with prostate-specific antigen (PSA) blood tests, digital rectal prostate exams and, potentially, biopsies. Urologists at Genesis Healthcare and UC San Diego Health jointly developed a reporting mechanism to improve the process of tracking patients with prostate cancer. The research team developed standardized selection criteria based on scientific literature for patients to be followed with AS according to tumor characteristics, including clinical cancer staging, Gleason (pathology grading) and PSA scores. In addition, comparative dashboards were developed to show individual physician AS adoption rates compared to their peers. According to Dr. Gaylis, this new model to be discussed increased rates of surveillance to benefit patients through use of provider education and a standardized report card," Franklin Gaylis, MD, Chief Scientific Officer, Genesis Healthcare first author of a recent paper on the subject will describe this tool.

Last IPCSG Meeting Summary May 2019

Sexual Function Rehabilitation: Revolutionary Breakthroughs in Men's Health

Dr. T. Mike Hsieh, Urologist, UCSD Men's Health Center

Summary by Bill Lewis

As background to his presentation, Dr. Hsieh (pronounced "shay"; has been with UCSD for 7 years) noted that the principles of cancer treatment are safety, cancer control and minimizing side effects. With prostate cancer, cancer control is generally approached through surgery, radiation, or hormones (i.e., ADT). Beyond control, preserving urinary continence and sexual function are principal goals, and are referred to by urologists as the "Trifecta." Quality of life has become very important in patients' choices of treatments.

Potential sexual side effects after cancer treatment include erectile dysfunction, anejaculation (inability to ejaculate, with or without orgasm), penile shortening or curvature, orgasmic dysfunction, orgasm-associated urine leak, and decreased desire/hormonal imbalance. Erectile dysfunction (ED, the inability to obtain a penile erection sufficient for sexual activity) is a problem for one in five men across America, and is now understood to be 90% physical, and (only) 10% psychological. Erections occur when penile erectile tissue fills with blood. There are various physical causes of ED, including diabetes, heart disease, medications, spinal injury, and hormone imbalance, apart from cancer treatment (especially in prostate, bladder,

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Prostate Cancer: GET THE FACTS

Other than skin cancer, prostate cancer is the most common cancer in American men.



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.

Be your own health manager!!

Meeting Video DVD's

DVD's of our meetings are available in our library for \$10ea. Refer to the index available in the library. They can also be purchased through our website: <http://ipcs.org> Click on the 'Purchase DVDs" tab.

The DVD of each meeting is available by the next meeting date.

From the Editor

WE ARE SEEKING REPLACEMENT FOR SOME OF OUR IPCSG TEAM

If you consider the IPCSG to be valuable in your cancer journey, realize that we need people to step up. The current staff are aging in place, and someday the 3rd Saturday may see no meeting of the group. Serving in this team can be rewarding and is a way to pay it forward to the group. To offer your services and/or ask questions about functions, contact any of the individuals at their listed phone number.

FUNCTIONS NEEDED:

1. **President:** IPCSG public relations, research and advice. Lyle LaRosh has performed for 18 years. 619-892-3888
2. **Vice President:** Support all team members, assist in monthly planning and speaker acquisition. *currently vacant* Gene Van Vleet has performed Functions 2, 4, 5 for 11 years. 619-890-8447.
3. **Meeting facilitator:** Monthly planning and speaker acquisition. George Johnson has performed for 8 years. 858-456-2492
4. **Treasurer/Secretary:** Handle banking, accounting, government reporting (see 2)
5. **Hot Line:** Communicate directly with newcomers and handle phone inquiries. (see 2)

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colon and rectal cancer). Cancer treatment results in long-term ED in 40-75% of patients, due to negative effects on blood flow and/or the nerves that control erections. Other major risk factors for ED are lifestyle issues such as depression, obesity, lack of exercise, heavy drinking, recreational drugs, and cigarette smoking.

Current treatment options include hormones (testosterone replacement, often applied topically, but also by injection or implants), oral therapy with PDE inhibitors (drugs that cause penile smooth muscle relaxation, such as Viagra, Cialis or Levitra), intraurethral medication ("MUSE" suppositories), vacuum constriction devices, injections, and a penile prosthesis. Dr. Hsieh noted that oral testosterone is available in Europe, South America and Asia, but not in the US, because of negative effects on the liver.

Whereas testosterone supplementation for prostate cancer patients used to be considered "adding gasoline to a fire," it is now understood that having low testosterone, especially castrate levels, is a significant health hazard, leading to loss of bone density (breaking hips or other bones), or cardiovascular problems (heart attacks or strokes). So doctors now try to limit the length of time that a patient is on anti-testosterone treatment – six months to two years – rather than keeping him on ADT for life, to let the body recover. Intermittent ADT can also help avoid problems from constant ADT. He noted that it is typical that the body's own production of testosterone does not fully recover to pretreatment levels after a long period of ADT.

Furthermore, it has been shown that giving testosterone to prostate cancer patients is safe. It does not make the cancer come back, nor lead to metastatic disease. Dr. Hsieh asserted that he writes more testosterone prescriptions than any other doctor in San Diego, including for men on active surveillance, and men who have had surgery or radiation. However, he does insist that active cancer be treated first, before starting testosterone supplementation. The dose and method of administration are individualized. A too-high dose leads

to excessive red blood cells, which can cause blood thickening and strokes.

For erectile dysfunction (ED), pills such as Viagra, Cialis, or Levitra can be very effective, but must be taken about an hour before sexual activity, and they are usually not covered by insurance (unlike rehab options for breast cancer), but advocacy groups are working to change this. Some success was seen with nightly dosing with 25mg of Viagra after prostatectomy allowing "spontaneous" erections, so low-dose pills have been sold since 2008 as a treatment to preserve erectile function.

The MUSE intraurethral suppositories cause a feeling of burning in the urethra, and are expensive. They turned out to not be as effective as originally predicted, but may be useful in combination with Viagra-like drugs.

Vacuum erection devices suck blood into the penis, and prevent its return with an elastic ring. Use is recommended as a therapeutic exercise after pelvic surgery/radiation, because engorgement gives improved oxygen delivery, and the stretching of the penis prevents some of the shortening that otherwise occurs. It can provide functionality (erections) early after cancer treatments, and may be used when medications fail and getting an inflatable penile prosthesis is unacceptable to the patient.

Intracavernosal injection therapy (ICI) is available as Caverject or Trimix. It works in 90% of men, with an erection in about 5 minutes, lasting about an hour or until climax. The dose is carefully adjusted when prescribed, because overdosing can lead to prolonged erections that cause painful blood clots.

Overall patient satisfaction with ED treatments is reportedly about 40% for penile injections, 51% for oral medications like Viagra, and 93% for penile implants (J Urol. 2003 July; 170: 159-163). That is, implants provide a high level of satisfaction to both the patient and to his partner. They have been on the market for over 30 years, with more than 300,000 implants to date. It is done as an outpatient procedure in appropriate patients. Dr. Hsieh performs 2-3 of these surgeries per week. It takes about an hour, followed by an overnight stay in the hospital. The mechanism is durable for 10-15 years. Then it can be replaced (if erections are still wanted), or

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just be left in the body. Though insurance typically doesn't cover any of the other options discussed above, it usually will pay for the surgery.

Sexual function rehabilitation after cancer surgery may be expected to take 12 to 18 months. Goals would be to preserve penile smooth muscle, endothelial function, and optimize cavernous nerve recovery. The protocol at UCSD is as follows. Pre-op: start nightly Cialis 5mg or Viagra 25 mg. 1 mo. post-op: continue nightly pill, start vacuum device weekly, and use MUSE or full-dose Cialis/Viagra as needed. 3 mo. post-op: start injections if erections not adequate for intercourse. 6 mo. post-op: Check Testosterone and PSA; start TRT (testosterone replacement therapy) if T<300 or if indicated by symptoms; treat anorgasmia if present. 12-16 mo. postop: discuss penile prosthetic surgery if ED persists.

Questions:

Is it true that 50% of men have ED by age 50, 60% by 60, 70% by 70, etc? Yes.

How is anorgasmia treated? It's very complicated to treat, often involving psychological factors. One approach that works for about 1/3 of men is a drug that blocks Prolactin. This hormone is released in the brain during the normal refractory period after orgasm, and blocking it sometimes helps with achieving orgasm.

How do you promote libido during ADT? Can't help you until after ADT.

George Johnson noted that he was able to block dihydrotestosterone with Casodex and Avodart for ten years, with his PSA pushed to zero, his testosterone over 1000, and his sex life active. (More recently, he has been on Firmagon, which he joked means "Firm-is-gone.") Dr. Hsieh responded that hormone therapy protocols are still evolving, including various drugs and intermittent and bipolar approaches. In the latter, testosterone is cycled from low to very high, in an attempt to "shock" the cancer cells. Hormone therapy, such as with Avodart or Proscar has also been tried to prevent prostate cancer, but that doesn't seem to work.

How effective is acoustic shock wave therapy for ED? [See last month's newsletter, or the dvd for

the April IPCSG meeting.] It is commercially promoted, not FDA approved, and therefore expensive. Based on comments from doctors at international meetings, best results are obtained in helping men with mild ED, for whom Viagra no longer works, to be able to get a benefit from the pills again. UCSD is setting up a study, and will notify us when it is open for enrollment. But he really doesn't expect it to be very effective for cancer survivors, due to the complexity of their biology after treatments for their disease.

What about the Priapus or "P" shot (platelet-rich plasma)? Hasn't panned out for ED, though it is still promoted. Neither have stem cells been shown to be effective.

Treating hot flashes? A drug called Megace may help. Generally you need to ride it out, until you finish ADT. Other side effects of ADT include low energy, brain fog, weight gain (due to less physical activity, because of fatigue), irritability, and sleep problems. As noted above, long-term ADT may cause bone and cardiovascular problems. It may also lead to "castrate resistance," where the cancer grows despite the absence of testosterone.

Why don't more doctors prescribe testosterone supplementation? Some are afraid of lawsuits, and others are only prioritizing cancer control, and need to be educated by the patient as to the importance of quality of life.

Does testosterone supplementation affect the body's own production of testosterone? Yes. It also reduces sperm production, so is not used where there is a desire for children.

A member noted that he and others in our group have found that Gabapentin (brand name: Neurontin) is effective for hot flashes.

Is there cumulative damage from injections for ED? (A member has used the Trimix for 10 years, and is 78. Now higher doses are needed.) It's just a matter of the aging body needing increasing assistance. There is a four-component mix available, called Quad Mix, but nothing injectable beyond that. There can be scar tissue, which may actually make the injections less painful.

What is your opinion about proton beam therapy? It is more intense than "regular" radiation, so

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fewer sessions are needed. The cancer control is equivalent. However, side effects tend to be more severe.

How about HIFU? There is a movement toward "ablation" of the prostate, using focal therapy such as HIFU or cryotherapy, to zap specific spots in the prostate, which reduces ED and incontinence side effects. However, treating the whole prostate with HIFU would be equivalent to treating with radiation.

After radiation, with ADT continuing, what can be done for ED? Pills would not work, but injections or surgery (an implant) could be effective.

What is the effect of prostate surgery (prostatectomy) on the size of the penis? The penis will be 2-3 inches shorter due to the tissue removed, and erections are also not as robust, which further shortens the erect result. Rehabilitation helps prevent the extra loss, other than the physical.

What about incontinence? Do Kegel exercises. This does not mean abdominal crunches. You should first practice stopping the urine stream during urination, then practice that same muscle contraction at other times during the day. You only have a year after surgery to affect recovery from incontinence. If you have also received radiation, it's more problematic to avoid leakage. Doctors sometimes use the Sling surgery in those cases. A

synthetic mesh tape is implanted to compress the urethra under it.

Does exercise slow down the decline of testosterone with age? Yes, but it won't stop it. Exercise is especially important to reduce the side effects of ADT. However, patients not feeling well due to ADT have to overcome their reluctance to exert themselves.

Is an implant feasible after brachytherapy? Yes.

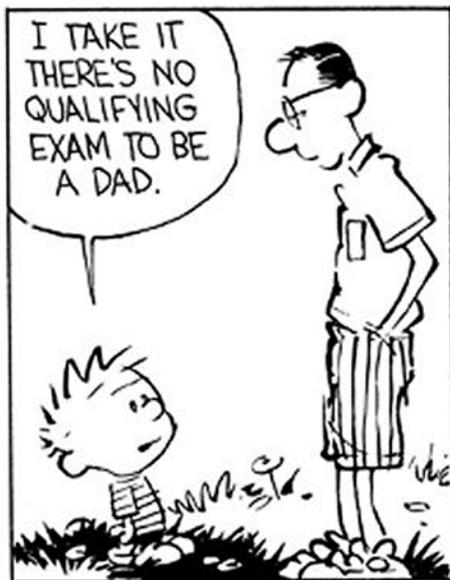
A member has been on intermittent ADT for twenty years with success. Comments? Dr. Hsieh noted that some people are early adopters. Others (doctors) wait for protocols to be more proven before adopting them.

What's a normal testosterone level? He doesn't know! Labs say 300 to 800 is normal. Individual biology is different. We're in the trial-and-error phase.

Can blood pressure medicine cause ED? It lowers blood pressure, so can reduce erections. Likewise, Lasix, a diuretic, can cause more incontinence.

More details are given in the video of this presentation, including the PowerPoint slides, which will be available for purchase via the website shortly before the next meeting, or at the June meeting on the 15th.

On the Lighter Side



Articles of Interest

Prompt Prostate Genetic Score: A New Tool for Targeted Prostate Cancer Screening Summary:

Posted by [Karim Kader, MD, PhD](#) | May 2019

Karim Kader, MD, PhD, presented "Prompt Prostate Genetic Score: A New Tool for Targeted Prostate Cancer Screening" during the 29th Annual [International Prostate Cancer Update](#) on January 26, 2019 in Beaver Creek, Colorado.

How to cite: Kader, Karim "Prompt Prostate Genetic Score: A New Tool for Targeted Prostate Cancer Screening" January 26, 2019. Accessed Jun 2019. <https://grandroundsinurology.com/prompt-prostate-genetic-score-a-new-tool-for-targeted-prostate-cancer-screening/>

Karim Kader, MD, PhD, explains how controversies have led to the decline of PSA screening, and therefore fewer diagnoses and the presentation of more high-grade disease. He suggests that the use of a prostate genetic score, based on SNPs, can more efficiently guide patient selection.

Abstract:

Though PSA screening has saved lives, it may not be the most efficient way to diagnose prostate cancer (PCa). For instance, an [American study](#) found no survival benefit from PSA screening. A [European study](#) found some survival benefit, but in order to prevent one prostate cancer specific death, 1,410 men would need to undergo screening and 48 additional prostate cancer patients would need to undergo treatment. Because of this inefficiency, organizations such as the [United States Preventive Services Task Force \(USPSTF\)](#), American Urological Association (AUA), and National Comprehensive Cancer Network (NCCN) either do not recommend screening at all, or have confusing guidelines regarding patient selection for screening. This has led to a decrease in PCa diagnoses and an increase in presentation of high-grade disease. However, risk-adapted PSA screening could address these concerns and assuage PSA-related controversies.

Age, family history, and racial origin risk factors for PCa are all arguably surrogates for genetic predisposition.

The Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial shows that [patients with a family history of disease see a significant survival benefit from screening](#), whereas patients without that family history do not. Unfortunately, only a small percentage of PCa patients have a family history of the disease.

During the mid-2000s, researchers began investigated [the potential role of single nucleotide polymorphisms \(SNPs\) in prostate cancer screening](#). By 2009, research had identified [over 30 SNPs](#) modestly associated with prostate cancer. The [Prompt® prostate genetic score \(PGS\)](#), which uses these SNPs, outperformed all existing biomarkers for overall PCa risk in the REDUCE study, and outperformed family history. Because PGS delineates a spectrum of risk, it can precisely help identify patients who would or not benefit from PSA screening.

Could Two Drugs Fight Prostate Cancer Earlier?

https://www.webmd.com/prostate-cancer/news/20190602/could-two-drugs-fight-prostate-cancer-earlier?src=RSS_PUBLIC#1

By Dennis Thompson, HealthDay Reporter

SUNDAY, June 2, 2019 (HealthDay News) -- Cutting-edge prostate cancer drugs that help extend life in the toughest cases might also be useful in fighting less aggressive tumors, two new clinical trials suggest.

Two drugs that interfere with cancer's ability to use testosterone for fuel, apalutamide (Erleada) and enzalutamide (Xtandi), are already approved for use against more advanced prostate tumors that don't respond to regular therapy.

But these trials show that the drugs also can improve survival and slow progression in prostate cancers that do respond to regular therapy, which typically involves medication that halts production of testosterone.

Both clinical trials involved patients with prostate cancer that had spread to other parts of their body but who still responded to androgen-deprivation therapy.

"We're slowly starting to see a migration of drugs traditionally saved for advanced stages of disease, where we're incorporating them into earlier stages of disease," said Dr. Bobby Liaw, medical director of the Blavatnik Family Chelsea Medical Center at Mount Sinai, in New York City. He was not involved in the trials.

Apalutamide combined with androgen-deprivation therapy caused a 33% reduction in overall risk of death,

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compared against patients who received a placebo alongside their androgen-deprivation therapy, said the lead researcher of that clinical trial, Dr. Kim Chi.

Apalutamide also delayed progression of the cancer by 52%, and the length of time before patients required chemotherapy by 61%, said Chi, medical director of the Clinical Trials Unit at the BC Cancer Agency-Vancouver Prostate Center in Canada.

Adding the hormone blocker significantly improved patients' outcomes with few side effects, Chi said.

"It's well-tolerated, both from a side-effect profile and from a quality-of-life perspective," Chi said, noting that side effects differ little from a placebo.

The second trial involved adding enzalutamide to androgen-deprivation therapy, and again positive results were found.

About 80% of men treated with enzalutamide were alive after three years, compared with 72% of men who received standard treatment, the researchers said.

Study co-chair Ian Davis is a professor at Monash University in Australia. "The actual result in patients starting hormonal therapy -- noting patients had a 60% improvement in the time it takes to detect the cancer growing again along with a 33% increase chance of survival -- was far higher than we expected," he said in a news release.

In that trial, 1,125 men were randomly assigned to receive either enzalutamide or placebo, the study authors said.

The next step for researchers will be head-to-head comparisons that will help doctors decide which drugs would work best for specific patients, Liaw said.

"We don't yet have any data to compare these drugs side-to-side. That's where we're going to start to see a bit of debate over which one is arguably the best drug to start with first," Liaw said. "We've never had a lot of satisfying data to help us figure out what is the proper sequence, is there an optimal sequence, should we be combining certain drugs to get a better effect?"

Cost will also be an issue in using these new drugs to fight prostate cancer. "These are really expensive drugs," Liaw said. "These are drugs that cost thousands for a month's supply."

Regardless, it is good for doctors to have more drugs on hand to help patients battle prostate cancer, he concluded.

"We're certainly hoping to have their disease controlled, not just now but for the long haul, and that's what these drugs are showing they have the capability of

doing," Liaw said.

Both trials were to be presented at the American Society for Clinical Oncology's annual meeting, in Chicago, this weekend, and they will also be published in the New England Journal of Medicine.

WebMD News from HealthDay

Sources

SOURCES: Bobby Liaw, M.D., medical director, Blavatnik Family Chelsea Medical Center at Mount Sinai, New York City; Kim Chi, M.D., medical director, clinical trials unit, BC Cancer Agency-Vancouver Prostate Center, Canada; June 2, 2019, news release, Dana-Farber Cancer Institute; May 31 and June 2, 2019, New England Journal of Medicine; May 31-June 4, 2019, American Society of Clinical Oncology annual meeting, Chicago

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TITAN Solidifies Place for Apalutamide in Metastatic CSPC

Pam Harrison June 06, 2019
www.medscape.com

CHICAGO — New data show efficacy for the next-generation androgen receptor inhibitor apalutamide (Erleada, Janssen) in the treatment of metastatic hormone-sensitive prostate cancer, which would be a new indication for the drug.

The first efficacy data in this patient population show that the drug extended both radiographic progression-free survival (rPFS) and overall survival (OS) compared with placebo when both were added onto standard androgen deprivation therapy (ADT).

Last year, apalutamide became the first treatment to be approved by the US Food and Drug Administration for use in nonmetastatic, castration-resistant prostate cancer, having shown a benefit on the new endpoint of metastasis-free survival in the SPARTAN study.

The new data comes from the TITAN trial, which was conducted in a later stage of the disease in men with metastatic castrate-sensitive prostate cancer (mCSPC) who were already on ADT.

"The rationale behind the TITAN study was [the idea that] direct inhibition of the androgen receptor by apalutamide may provide a more complete reduction of androgen signaling than ADT alone, leading to improved clinical outcomes," explained study author Kim Chi, MD, medical oncologist at BC Cancer Agency in Vancouver, Canada.

"And the TITAN study met its dual primary end-

(Continued from page 7)

points, demonstrating significant benefit with apalutamide plus ADT in an all-comer population with metastatic CSPC," he concluded.

The study was presented here at the annual meeting of the American Society of Clinical Oncology, and concurrently published online in the *New England Journal of Medicine*.

Commenting on the new data at the meeting, discussant Michael Carducci, MD, AEGON professor in prostate cancer research at Johns Hopkins Kimmel Cancer Center in Baltimore, Maryland, said that this study confirms that the current standard for mCSPC should be a combination of ADT plus chemotherapy or an androgen receptor inhibitor such as enzalutamide (Xtandi, Astellas) and abiraterone (Zytiga, Janssen) and now, also apalutamide.

What About ADT Alone?

Also commenting on the TITAN trial, Celestia Higano, MD, professor of oncology and urology at the University of Washington in Seattle, noted that the oncology community now has a variety of drugs that they can use together with ADT, all of which have been shown to be superior than ADT alone.

"Thus, one of the questions we have is: 'Do we have to eliminate ADT alone as a therapeutic option for patients with mCSPC?'" Higano asked.

In her opinion, the answer to this question is no, at least not for selected patients.

"The patients I would select for ADT alone would be an older man who has recurrent prostate cancer, for example, who has not been on ADT in the past; in such a patient, you start his ADT, and after 7 months his PSA is undetectable on ADT alone," said Higano, who was not involved with the current study.

Higano also noted that she chose the 7 months purposely because in the SWOG-9346 trial, "we found that those who became undetectable at the 7-month time frame had a very good long-term outcome, with a median survival of 5 years."

"So it's not clear to me that adding one of these other agents to that type of scenario is really worth some of the additional toxicities that we know are associated with them," she concluded.

Study Details

The TITAN study involved 525 patients who were randomly assigned to apalutamide and another 527 to placebo.

"Patients were required to have continuous ADT," Chi noted, "and prior docetaxel for castration-sensitive

disease" was permitted (and used by 10%).

Patients randomly assigned to active therapy received apalutamide 240 mg/day given in addition to standard ADT, or to placebo plus ADT.

The two groups were evenly balanced both in baseline characteristics and in disease status. For example, the Eastern Cooperative Oncology Group (ECOG) Performance Status was 0 in 64% of patients, most patients had no pain or only mild pain at baseline, and 63% had high-volume disease.

At the time of the current analysis, the median follow-up for OS was 22.9 months in the additional apalutamide group and 22.4 months in the placebo group.

Median treatment duration was somewhat longer for patients receiving apalutamide at 20.5 months, with 66% of patients still remaining on treatment at the time of analysis.

For placebo controls, the median treatment duration was 18.3 months, with 46% of patients remaining on placebo at the same time point.

"Apalutamide significantly reduced the risk of radiographic progression or death by 52% compared with placebo," Chi reported.

In addition, the drug significantly reduced the risk of death by 33% compared with placebo, with OS rates at 2 years being 82% in the experimental group and 74% in the placebo group ($P = .0053$).

The median time to radiographic progression was not reached among those randomly assigned to apalutamide vs 22.1 months for those receiving ADT alone.

At 2 years, there was an absolute 20% difference in the rate of rPFS, with 68% of patients in the apalutamide group remaining free of disease progression vs 48% of those on ADT alone.

"The benefit from apalutamide was consistent across subgroups," Chi noted.

This included whether patients had or had not received prior docetaxel, and those with both high- and low-volume disease.

However, in his discussion of the study, Johns Hopkins professor Carducci disagreed with this conclusion, and he cautioned that the addition of apalutamide to ADT did not seem to benefit certain subgroups of patients, such as those who had visceral disease or who had received prior docetaxel.

Secondary endpoints similarly favored apalutamide, Chi added.

For example, the median time to PSA progression had not been reached at the time of analysis for the apalutamide group compared with a median of 12.9 months for those on ADT alone ($P < .001$).

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At 2 years, 75% of patients in the active treatment group remained PSA progression-free compared with only 36% of those in the control group.

"The incidence of adverse events was roughly the same between apalutamide and placebo," Chi noted, although more patients in the apalutamide group (8%) discontinued treatment than did those on placebo (5.3%), largely because of rash.

Other adverse events, said Chi, included hypothyroidism, which was largely grade 1 and did not require intervention. Incidence rates of fatigue, fall, fracture, and seizures were similar between the two treatment groups.

In keeping with the AE profile, health-related quality of life was preserved from baseline, with no change from baseline in patients who received additional apalutamide; this was similar to that seen among placebo controls, Chi noted.

Chi reports receiving honoraria from Astellas, Bayer, Janssen, and Sanofi, and has served as a consultant or on the advisory board for Amgen, Astellas, Bayer, ESSA, Janssen, Lilly/ImClone, and Sanofi. He also reports receiving research funding from Astellas, Bayer, Bristol-Myers Squibb, Lilly/ImClone, Merck, Roche, Sanofi, and Tokai Pharmaceuticals.

Carducci reports having served as a consultant for Pfizer, Roche/Genentech/ Foundation Medicine, and AbbVie and has received research funding from EMD Serrano, Pfizer, and Effector.

Higano declares she has served as a consultant, or on the advisory board, for Astellas, AstraZeneca, Bayer, Blue Earth Diagnostics, Clovis Oncology, Ferring, Janssen, Myriad Genetics, Pfizer, and Tolmar. She has also received research funding from Aragon Pharmaceuticals, Astellas, AstraZeneca, Bayer, Dendreon, Emergent BioSolutions, Hinoa Pharmaceuticals, Medivation, and Pfizer; and travel expenses from Astellas, Bayer, Blue Earth Diagnostics, Clovis Oncology, Ferring, Hinoa Pharmaceuticals, Menarini, Myriad Genetics, and Pfizer.

American Society of Clinical Oncology (ASCO) 2019 Annual Meeting: Abstract 5006. Presented May 31, 2019.

NEJM. Published online May 31, 2019. Abstract

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Gomella Calls for Increased Genetic Testing in Prostate Cancer

<https://www.onclive.com/web-exclusives/gomella-calls-for-increased-genetic-testing-in-prostate-cancer>

Brandon Scalea

Dr. Leonard G. Gomella

An increased understanding of the genetic makeup of prostate cancer could allow for the introduction of more effective therapies for patients who develop advanced disease, said Leonard G. Gomella, MD. However, how to best use genetic testing to screen potentially at-risk patients early on remains unclear.

The role of genetic testing is finding its way right now. We know much more about using these tests in women with breast cancer," said Gomella, a professor and chair of the Department of Urology and director of the Sidney Kimmel Cancer Center Network and Thomas Jefferson University Hospital. "We are still trying to figure out how to best use these methods in prostate cancer."

Over the years, investigators have identified which traditional genes play a key role in the development of aggressive disease. For instance, BRCA1/2 mutations are particularly important in prostate cancer, as they are known to increase the likelihood of metastases and have been associated with poor prognosis.

"What's happening with BRCA mutations—in particular, the DNA repair gene pathways—is that identifying men with these abnormalities allows us to use more effective drugs when they develop advanced disease," said Gomella. "For example, PARP inhibitors may work better in men who have these alterations in their DNA."

In an interview with OncoLive, Gomella underscored the need for genetic testing in prostate cancer, shed light on important biomarkers in the space, and explained how these tests are helping oncologists facilitate a precision medicine approach.

OncoLive: Could you speak to the importance of genetic testing in prostate cancer?

Gomella: The area of testing men for inherited risk of developing prostate cancer is rapidly evolving. We are learning more about the best way to test the traditional genes that we think about in breast and ovarian cancers, which are proving to also be important in men with prostate cancer. These are the BRCA1/2 genes. It is very important for us to understand that these genes themselves do not cause prostate cancer, but if a man does develop prostate cancer, having these mutated genes appears to cause the cancer to take a very drastic course, becoming more aggressive.

NETWORKING

Please help us in our outreach efforts. Our speakers bureau consisting of Lyle LaRosh, Gene Van Vleet and George Johnson are available to speak to organizations of which you might be a member. Contact Gene 619-890-8447 or gene@ipcs.org to coordinate.

Member and Director, 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://ipcs.org/personal-experience>

Our brochure provides the group philosophy and explains our goals. Copies may be obtained at our meetings. 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!

If you have the internet you can contribute easily by going to our website, <http://ipcs.org> and clicking on "Donate" Follow the instructions on that page. OR just mail a check to: IPCSG, P. O. Box 4201042, San Diego CA 92142



Directions to Sanford-Burnham-Prebys Auditorium 10905 Road to the Cure San Diego, CA 92121

- ◆ Take I-5 (north or south) to the Genesee exit (west).
- ◆ Follow Genesee up the hill, staying right.
- ◆ Genesee rounds right onto North Torrey Pines Road.
- ◆ **Do not turn into the Sanford-Burnham-Prebys Medical Discovery Institute or Fishman Auditorium**
- ◆ Turn right on Science Park Road. Watch for our sign here.
- ◆ Turn Left on Torreyana Road. Watch for our sign here.
- ◆ Turn Right on Road to the Cure (formerly Altman Row). Watch for our sign here.