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

July 2018 NEWSLETTER

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

We Meet Every Third Saturday (except December)

Next Meeting
July 21, 2018
10:00AM to Noon

Meeting at

Sanford-Burnham-Prebys Auditorium

10905 Road to the Cure, San Diego CA 92121

SEE MAP ON THE LAST PAGE

Tuesday, July 17, 2018

Volume 11 Issue 7

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 lifestyle.

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Editor: Stephen Pendergast

PROSTATE CANCER IT'S ONLY 2 WORDS NOT A SENTENCE

IPCSG June 2018 Meeting Summary (by Bill Lewis)

Dr. Mark Schechter -- Diagnostic and Interventional Radiologist at Imaging Healthcare specialists.

Dr. Schechter is an expert in diagnosis and biopsy, but does not do treatments.

Topics in Diagnostic Imaging:

1. X-ray -- not generally used for diagnosis, but incidental findings from X-ray images generated for another purpose may lead to discovery of some diseases or locations of disease not previously iden-

(Continued on page 2)

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://ipcsg.org Click on the 'Purchase DVDs" tab.

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

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tified.

2. Ultrasound (TRUS) -- limited value in diagnosis because many cancers are not visible/detectable using ultrasound. The tumors are "isoechoic," and appear the same as the background image (that is, they reflect back the ultrasound waves the same as the surrounding "normal" tissue). It can assist in TRUS-guided biopsies and it's also useful to measure gland volume.

3. CT (Computed Tomography) -- used for patients who cannot have an MRI, because of implanted devices or other reasons. Not useful for initial detection of cancer, but very useful for staging a patient with known cancer. Good for looking at bones and lymph nodes. It's also used for CT-guided biopsy in bone or lymph nodes.

4. MRI (multiparametric Magnetic Resonance Imaging) has become an amazing tool for diagnosing, for pretreatment "staging," and for evaluating recurrence. Also valuable for guided needle biopsies. More accurate than TRUS for measuring prostate volume. See previous meeting summaries in newsletters on the IPCSG website for more information on mpMRI.

5. Nuclear medicine -- conventional versus "molecular imaging." In conventional nuclear medicine scans, radioactive technetium combined with another substance is taken up by an organ. It's useful for prostate cancer staging for bones only -- in which case, the radioisotope is combined with a phosphate type agent which goes to all bones. It detects areas of increased bone metabolism, whether tumor, fracture (as old as a year or more), infection, or arthritis. It has high sensitivity, but is not specific to just tumors. It is a two-dimensional scan.

There is a PET scan version of a bone scan, using sodium fluoride. It is sharper, and has better spatial resolution (3-D instead of only 2-D imaging), and better signal-to-noise ratio. It has a high negative predictive value. If nothing is seen in the sodium fluoride PET scan, it's a pretty good bet there are no active metastases. It's better at picking up lesions than a technetium bone scan, and because it is combined it with a CT scan, the specificity is really good, in three dimensions. For example, bone spurs and compression fractures visible in the CT scan can show that a hotspot is not cancer, but instead just "normal" bone activity taking up the sodium fluoride.

6. PET (Positron emission tomography) -- First there's a CT (an x-ray) scan for anatomical localization, then the PET image is made. A PET scan is a metabolic scan, showing biological activity ("molecular imaging"), not just structure ("morphology"). There are very many molecular imaging probes for PET scanning. They include carbon-11 choline or acetate, fluorine-18 choline or FACBC derivative (Axumin), and various PSMA ligands (most commonly attached to gallium-68), as well as some ligands with copper-64 or zirconium-89. Axumin seems to be as effective as C-11 choline, and it's much more widely available because of its much longer half-life. PSMA ligands are available in Europe and we are waiting for FDA approval in this country. Gallium and fluorine PSMA ligands are expected to dominate going forward.

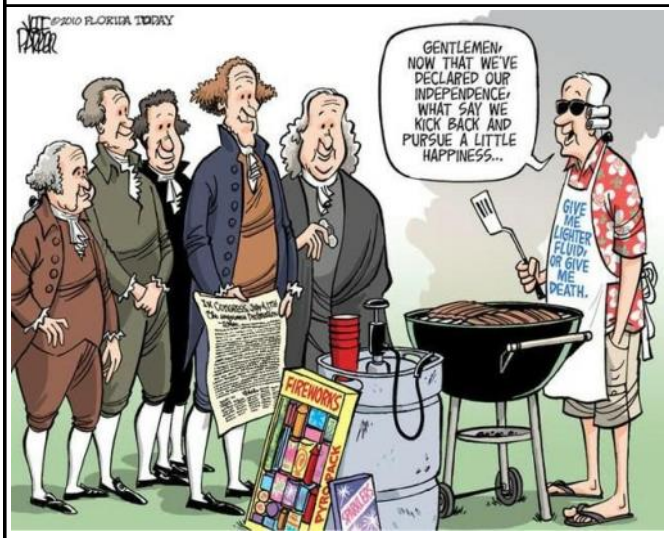
Questions and comments:

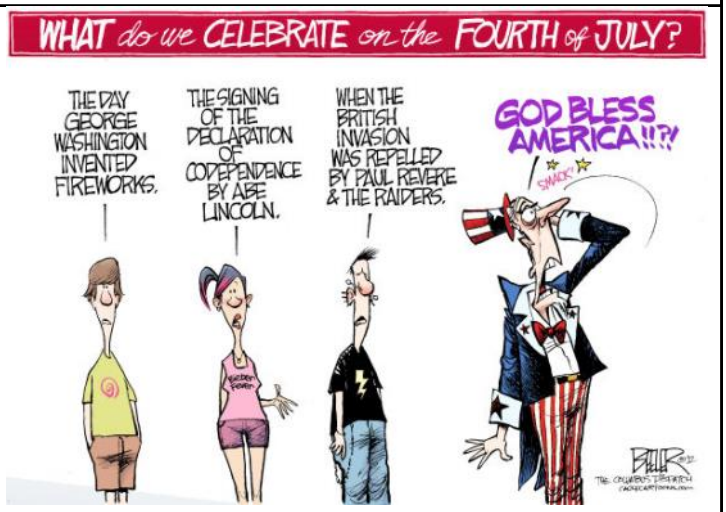
Cost of a sodium fluoride bone scan? It now has a cash price of about $1,400, since the FDA failed to renew its approval late last year. MRI or Axumin scans can be used for treatment planning, for instance for stereotactic radiation. Dr. Schechter also works at Scripps Mercy.

What about cumulative exposure to radiation from scans? There have been many efforts, especially in recent years, for dose reduction. CT is an extremely low dose, like "background." It takes 30 years to develop tumors from the PET part of the scan. In some cases, a patient may need 3-month, then 6-month, then year-interval scans. But the radiation part of it (the CT part) is minimal.

Many images from various scans are shown in the video of this presentation, which, including the PowerPoint slides, will be available via the website shortly before the next meeting, or at the July 21 meeting.

ON THE LIGHTER SIDE





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FUTURE MEETINGS

July 21, 2018 Dr. Michael Kipper will give an in-depth presentation on the question, "When Prostate Cancer Returns, How Soon Can We Find It?" Dr. Kipper is one of the nation's foremost experts in PET/CT imaging technology for the diagnosis of cancer and brain disorders. He is the author of several medical textbooks and numerous professional journal articles on imaging techniques for the evaluation of cancer and other disease processes.

August 18 - DR. Kane – Advances in Surgery

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For Comments, Ideas and Questions, email to Newsletter@ipcsg.org

INTERESTING ARTICLES

BREAKING NEWS: FDA Approves Enzalutamide (Xtandi) for Non-Metastatic Castration-Resistant Prostate Cancer

July 13, 2018 | By ANDREA K. MIYAHIRA, PHD

July 13, 2018 – Today the U.S. Food and Drug Administration (FDA) **approved enzalutamide (Xtandi) for the treatment of non-metastatic castration-resistant prostate cancer (non-metastatic CRPC).** Non-metastatic CRPC is a clinical state in which PSA levels begin to rise in patients being treated with androgen deprivation therapy (ADT), but metastases are not visible yet on conventional imaging (bone or computed tomography (CT) scans). Enzalutamide was previously approved for patients with metastatic CRPC.

This new approval for enzalutamide is based on results from the randomized phase 3 PROSPER clinical trial, which was first presented publicly in February at the 2018 ASCO Genitourinary Cancers Symposium, and was published in June in the New England Journal of Medicine.

The PROSPER trial, led by PCF-funded investigator Maha Hussain, MD (Northwestern University), tested the addition of enzalutamide versus placebo to continued ADT in 1,401 men with non-metastatic CRPC who had rapidly rising PSA levels (doubling time of 10 months or less) but no evidence of disease by bone scans, CT or magnetic resonance imaging (MRI).

The addition of enzalutamide was found to delay the time to metastatic disease or death (whichever came first) by a median of 21.9 months compared with placebo (36.6 months versus 14.7 months) – representing a highly significant 71% reduction of risk for metastasis or death. Enzalutamide also significantly delayed the time before men needed additional cancer therapy, compared with placebo (median of 39.6

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months vs. 17.7 months).

In February 2018, the FDA also approved apalutamide (Erleada) for non-metastatic CRPC. Prior to this year, there were no FDA-approved treatments for non-metastatic CRPC, and these patients typically continued to receive ADT alone, despite a diminishing benefit. Today, men with non-metastatic CRPC have two treatment choices, both of which significantly delay metastatic disease. It is still too early to know if the addition of either enzalutamide or apalutamide to ADT in non-metastatic CRPC improves overall survival.

PCF provided initial funding for the synthesis of both enzalutamide and apalutamide at UCLA by Drs. Michael Jung, PhD and Charles Sawyers, MD. PCF also funded early preclinical studies on both of these agents.

Prostate cancer ultrasound treatment as effective as surgery or radiotherapy -- ScienceDaily: Date: July 5, 2018

Source: Imperial College London

Summary: Using high energy ultrasound beams to destroy prostate cancer tumours may be as effective as surgery or radiotherapy, but with fewer side effects.

Using high energy ultrasound beams to destroy prostate cancer tumours may be as effective as surgery or radiotherapy, but with fewer side effects.

A new study, carried out at six hospitals across the UK, tracked 625 men with prostate cancer who received a type of treatment called high-intensity focused ultrasound (HIFU).

The research, published in the journal European Urology, is the largest ever study of HIFU treatment used to target prostate tumours. The treatment is similar to a 'lumpectomy' for other cancers -- where doctors remove only tumour cells, leaving as much healthy tissue as possible.

The findings, from a number of institutions including Imperial College London and University College London, found that after five years the cancer survival rate from HIFU was 100 per cent. Approximately, 1 in 10 men needed further treatment. The cancer survival rate from surgery and radiotherapy is also 100 per cent at five years.

The research also showed the risk of side effects of HIFU, such as urinary incontinence and erectile dysfunction, were lower than other treatment options, at 2 per cent and 15 per cent respectively.

The study was funded by the Medical Research Council and SonaCare Inc., who manufacture the ultrasound equipment used in the procedure.

Professor Hashim Ahmed, lead author from the department of Surgery and Cancer at Imperial, said: "Although prostate cancer survival rates are now very good, the side effects of surgery or radiotherapy can be life-changing. Some patients are left requiring multiple incontinence pads every day, or with severe erectile dysfunction."

He added: "We need to now focus on improving the quality of life for these men following treatment. This latest trial of focal HIFU -- which is the largest and longest study of the treatment to date -- suggests we may be able to tackle the cancer with fewer side effects."

Prostate cancer is the most common cancer in men in the UK, with around 47,000 cases every year.

Treatments include surgery to remove the gland, or radiotherapy, which uses radiation to the entire prostate. However, these treatments can cause collateral damage to surrounding sensitive tissues like

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nerves, muscles, urine passage, bladder and rectum. The prostate is roughly the size of a walnut and sits between the bladder and the penis.

Surgery and radiotherapy to the entire prostate are effective treatments but can lead to long term risk of urinary problems, like incontinence, of between 5-30 per cent. They also carry a risk of erectile dysfunction of between 30-60 per cent. Radiotherapy can also cause rectal problems like bleeding, diarrhea and discomfort in 5 per cent of patients.

HIFU is a newer treatment, performed under general anaesthetic, which delivers beams of high energy ultrasound directly into the prostate gland, via a probe inserted up the back passage. This allows a surgeon to precisely target tumour cells within the gland to millimetre accuracy, with less risk of damage to surrounding tissues. There are no needles or cuts to skin.

In the new HIFU study, conducted on men with an average age of 65 and whose cancer hadn't spread, the risk of urine incontinence (defined as requiring pad use) at five years after the treatment was 2 per cent, and the risk of erectile dysfunction 15 per cent. The team say the results include patients with medium to high risk cancer.

The scientists also tracked the number of patients who needed further treatment following HIFU, (such as surgery or radiotherapy), to treat any cancer cells that had returned. They found 10 per cent of patients needed further treatment by five years, which is comparable to number of patients needing further treatment after surgery or radiotherapy (5-15 per cent).

The team add that prostate cancer patients should talk through all possible treatments with their healthcare team, so they can consider their options fully.

Further follow-up trials are needed to track progress of the patients after ten years, as well as trials that directly compare HIFU with surgery and radiotherapy.

Anthony Murland underwent HIFU treatment in November last year to treat his prostate cancer. "I first heard of the treatment from a friend, who had the procedure a few months before. My GP hadn't heard of HIFU, but was very interested, so I ended up educating him about it. He then referred me for the treatment on the NHS," explained the 67-year-old from Suffolk.

"I liked the sound of the treatment as it seemed the least invasive option, with low risk. The treatment was over in a day -- I went in first thing in the morning and was out by the evening. I didn't have any pain, but needed a catheter for five days, which was a bit uncomfortable. "I'm closely monitored by my GP, and so far the cancer has not returned."

The work was funded by the Medical Research Council and SonaCare Inc.

Story Source: Materials provided by Imperial College London.

Original written by Kate Wighton. Note: Content may be edited for style and length.

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https://www.onclive.com/web-exclusives/sequencing-challenges-persist-in-metastatic-prostate-cancer

Sequencing Challenges Persist in Metastatic Prostate Cancer

Caroline Seymour

Scott Samuelson, MD

Frontline treatment of patients with metastatic prostate cancer typically includes a taxane-based chemotherapy with docetaxel or an androgen receptor–blocking agent, such as abiraterone acetate (Zytiga). But beyond that, Scott Samuelson, MD, explained that there is no definitive evidence to support the use of one agent over another in subsequent lines of therapy.

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However, Samuelson said he encourages providers to talk with their patients about the various costs, comorbidities, and side effects of each treatment.

"One of the good challenges is that we have a lot of options," said Samuelson, a medical oncologist at Utah Cancer Specialists.

In an interview during the 2018 OncLive® State of the Science Summit™ on Prostate Cancer, Samuelson discussed frontline treatment of patients with prostate cancer and subsequent sequencing.

OncLive: What are the biggest challenges in treating patients with metastatic prostate cancer?

Samuelson: I have been taking care of patients with prostate cancer for the last 9 years. The management is very different now than it was before because we have so many other options. Figuring out the right way to sequence them is an issue. The costs of the medications, especially the oral medications, is another significant challenge for a significant portion of my patients.

What are some challenges that we have with sequencing?

There are a lot of opinions on what should be done without any real data to necessarily tell us that one agent is better than another. We certainly know what to do in the first-line metastatic setting for most patients.

It is not so clear what to do when patients progress on that because we have a number of options. It is a challenge. It is also an opportunity to talk with our patients about the different side effects and costs. Most patients with prostate cancer end up getting most of the available drugs, but we do not know what the proper sequence is at this point.

What is your preferred frontline therapy, and what factors do you take under consideration when making this decision?

A lot of the decision depends on a patient's performance status and whether or not they are a candidate for chemotherapy. Considering a patient's eligibility for chemotherapy is very important, as it is a very effective therapeutic agent. However, abiraterone acetate and enzalutamide (Xtandi) are also great options.

For a lot of patients, the decision comes down to cost. I take care of a number of patients who live several hours from our clinic. For them, an oral agent tends to be preferable. The costs of some of the oral agents, though usually not prohibitive, do pose an additional challenge for some patients. Those are the patients who would prefer an intravenous agent, which tends to be covered better by insurance.

Are there any comorbidities that may affect treatment?

Absolutely. Abiraterone is a very well-tolerated drug, but it has significant issues with high blood pressure. That is a common problem I have seen. Enzalutamide is also a wonderful drug, but, compared with abiraterone, it tends to have more fatigue issues. A lot of patients complain about that.

With docetaxel, there is certainly preexisting neuropathy; diabetes is fairly common in that population. When I am trying to decide the initial therapy or subsequent therapy, I always look at comorbidities.

Does olaparib (Lynparza) have a role in treatment for these patients?

The addition of olaparib will be great, at least for the 10% to 15% of patients who carry an actionable mutation such as BRCA or ATM. It will be another tool for those patients. PARP inhibitors tend to be well tolerated; I will be excited if that becomes an option.

What other topics presented at this meeting would you like to highlight?

One of the talks centered around nonmetastatic castrate-resistant prostate cancer. In that setting, we have the recent approval of apalutamide (Erleada) as well as enzalutamide. We have all been waiting for an agent to use in that setting. It is very exciting and very helpful, but those drugs have their own set of toxicities. Practitioners need to be careful that they do not immediately jump on those medications without having an extended discussion with their patients about the toxicities. Because we do not yet

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have an overall survival benefit, toxicity is a big deal.

As more approvals enter the space, what role do you see chemotherapy having?

Chemotherapy will continue to have a significant role. Most patients prefer to not have chemotherapy, either from the toxicities that we talk to them about or the experiences family members have had. They tend to prefer oral agents. The oral agents, as a rule, tend to have less toxicity. I do not see a future without chemotherapy, specifically docetaxel, anytime soon because it is such an effective drug. Although it has toxicities, most of them are manageable.

Does radium-223 dichloride (Xofigo) still have a role in treatment?

Radium-223 definitely has a role, as well, especially in patients who are no longer candidates for chemotherapy or who are not fit enough to get chemotherapy. It certainly has an excellent palliative benefit. It is nice to be able to tell patients that we are still doing something that potentially prolongs their life.

https://www.onclive.com/web-exclusives/yu-shares-insight-on-recent-advances-in-castrationsensitive-prostate-cancer

Yu Shares Insight on Recent Advances in Castration-Sensitive Prostate Cancer

Angelica Welch

Evan Ya-Wen Yu, MD

The prognosis for patients with castration-sensitive prostate cancer continues to improve, with the recent FDA approval of abiraterone acetate (Zytiga), an agent that has shown promising survival signals. Results from the LATITUDE and STAMPEDE trials have contributed to this dramatic shift, said Evan Ya-Wen Yu, MD.

Abiraterone was approved in February 2018 for use in combination with prednisone for patients with metastatic highrisk castration-sensitive prostate cancer. This approval was based on findings from the phase III LATITUDE trial, in which the addition of abiraterone and prednisone to androgen deprivation therapy (ADT) demonstrated a 38% reduction in the risk of death compared with ADT alone.1

The STAMPEDE trial also investigated abiraterone, showing that it lowered the relative risk of death by 37% when added to standard ADT. Additionally, abiraterone improved progressionfree survival by 71% in metastatic and nonmetastatic patients with high-risk hormone-naïve prostate cancer.2

In an interview during the 2018 OncLive® State of the Science Summit™ on Genitourinary Cancers, Yu, a professor in the Division of Oncology at the University of Washington, and member of the Clinical Research Division at Fred Hutchinson Cancer Research Center, discussed the evolution of treatment for patients with castration-sensitive prostate cancer and how he decides between treatment with abiraterone and docetaxel for this population.

OncLive: Please discuss how treatment has changed for patients with castration-sensitive prostate cancer.

Yu: The field has recently changed dramatically after the [results of the] CHAARTED and STAMPEDE trials showed that 6 cycles of docetaxel, when added to standard ADT, led to a dramatic survival benefit for men with newly diagnosed metastatic prostate cancer. There were some patients in the STAMPEDE trial who did not have metastatic disease, but in regard to subsets, we still have to see the long-term benefit. For metastatic disease, it is very cut and dry; there is benefit with docetaxel, especially for those with high-volume disease.

More recently, the LATITUDE and STAMPEDE trials showed that adding abiraterone to ADT also leads to a dramatic survival benefit. This increases the number of choices that one has. We certainly do not know whether abiraterone or docetaxel is better. Personally, I am using abiraterone for my low-volume–disease patients. For high-volume disease, I offer both. I recognize that there are many considerations in regard to the number of doses of docetaxel, duration of therapy of abiraterone, and financial toxicity. All of these things need to come to light.

The other thing regarding treatment intensification is the future of these diseases. There are many clinical trials with combination therapy as well. Additionally, there are many trials that are now thinking about doing metastases-directed therapy, removing oligometastatic disease surgically or with radiation, and also studies looking at re-

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moving the primary lesion of the prostate or providing radiation to the prostate. Those trials are underway, and we look forward to seeing the results of that.

Finally, I spoke about identifying metastases early for patients with biochemical recurrence using next-generation imaging such as prostate-specific membrane antigen-PET to identify early metastases to then do metastases-directed therapy. This is early ongoing research, but it is generating a lot of excitement in the field.

What else would you like to highlight from LATITUDE, CHAARTED, and/or STAMPEDE?

If you look across cancer studies, regardless of the malignancy or agents, it is not uncommon to see a 2-, 3-, 4-, or 5-month median survival benefit. With these agents, we are seeing survival benefits in terms of 1 to 2 years in certain subsets. These are incredibly dramatic and convincing data. There is really no doubt about it.

What other agents are promising other than abiraterone and docetaxel?

There are a lot of studies going on right now that take the same theories—adding chemotherapy earlier. There will be a study coming out looking at cabazitaxel chemotherapy in this setting. There are studies looking at enzalutamide (Xtandi) and apalutamide (Erleada) in this setting, and there are studies that allow combinations of chemotherapy with a second-generation androgen-targeted agent.

Now that we have seen the survival benefit with docetaxel and abiraterone, the question is, "Should we be sequencing them or possibly combining them?" There will be some studies with other related types of agents out there that will sequence and combine these agents. That will teach us the best thing to do in the future.

What are the factors that you take into consideration when treating a patient with low-volume disease?

Certainly, comorbidities are always important. Duration of therapy, financial toxicity, and patient comorbidities are all important. Patient side effect profiles are important; certainly, docetaxel has its unique side effect profile with neuropathy, hepatic issues, and some patients needing to take high doses of steroids prior to dosing.

One nice thing is that they don't have to take chronic steroid dosing. For instance, in metastatic castration-resistant prostate cancer trials, [the regimens] are all accompanied with 5 mg of prednisone twice daily. In the CHAARTED trial, they did not use prednisone. Whereas when you give abiraterone, that might be a consideration for someone who is a brittle diabetic. There are multiple comorbidity associations that may push you one way or another.

What would you say is the prognosis for castrationsensitive prostate cancer?

The prognosis has improved over time. Traditionally, [findings from] older studies in this setting have shown a prognosis ranging from 3.5 years to 5 years. We have not had long-term outcomes, because a lot of these patients from these studies that we are talking about are still alive. A lot of the data that have come out are from interim analyses. Plus, with all of the new drugs available for metastatic castration-resistant prostate cancer (mCRPC), I would be shocked if the prognosis overall wasn't better.

Is there anything coming up on the horizon that you would like to mention?

There is a lot of excitement in this area. When it comes to treating patients with castration-sensitive disease, the challenge is trial development. This is actually a good challenge, because the prognosis is good—these patients live for years. But, it takes a long time for the data to mature.

I would say that the more immediate things occurring in the field that will garner a lot of press are the use of immunooncology agents such as PD-1/PD-L1 antibodies and selecting patient populations for that. Also, the introduction of PARP inhibitors for homologous recombination deficient patients. Should we be combining immunooncology agents with PARP inhibitors? These are the things that are the most immediate because they are already being tested in patients with mCRPC. We will get to an answer soon.

References

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James ND, DeBono JS, Spears MR, et al. Adding abiraterone for men with high-risk prostate cancer (PCa) starting long-term androgen deprivation therapy (ADT): Survival results from STAMPEDE (NCT00268476). J Clin Oncol. 2017;35 (suppl; abstr LBA5003). doi: 10.1200/JCO.2017.35.18_suppl.LBA5003.

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@ipcsg.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://ipcsg.org/personal-experience

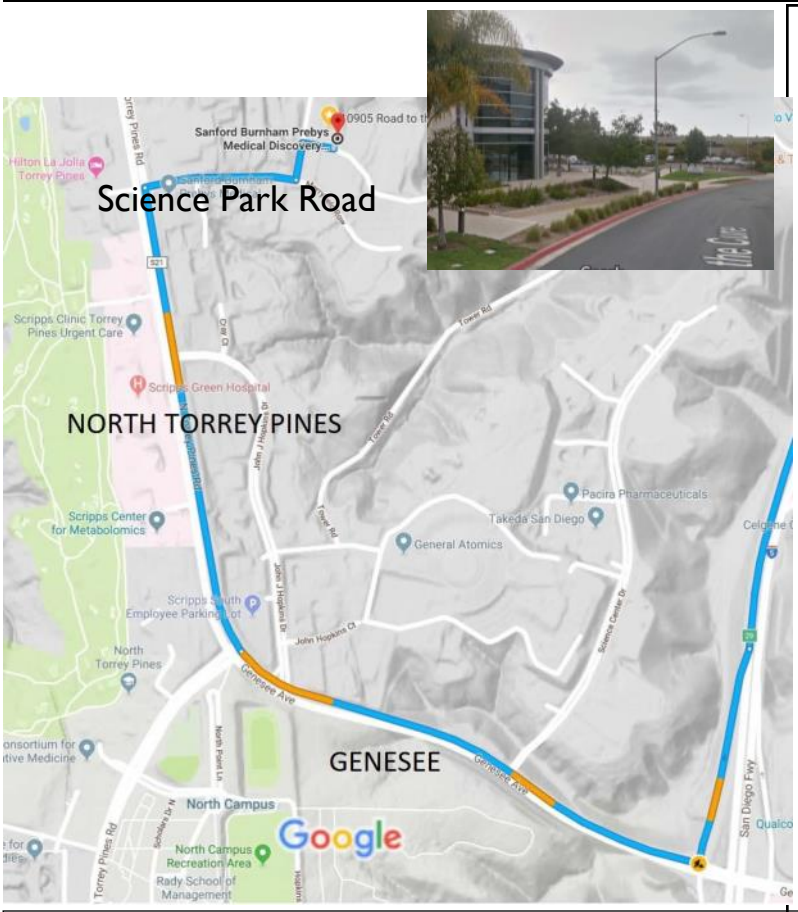
Our brochure provides the group philosophy and explains our goals. Copies may be obtained at our meetings. Please pass them along to friends and contacts.

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://ipcsg.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.