ANNUAL MEMBERSHIP

Please support your support group. PHCSG is run by volunteers. The small annual membership fee of \$20 helps cover incidental costs and upkeep. Members and their partner or support person are encouraged to attend our meetings on the third Tuesday of each month (Feb – Dec).

Prostate Heidelberg

January 2021

Issue 202

For Education, Information and Support

Meeting Hall: Ivanhoe Uniting Church 19 Seddon Street, Ivanhoe POB 241 Ivanhoe Victoria 3079 Email: prostateheidelberg@gmail.com Website: www.prostateheidelberg.info

Next PHCSG Meeting – Tues 16 Feb (via Zoom) 10am – 12:30pm

A HAPPY & HEALTHY NEW YEAR to all our readers...

Welcome to 2021. I hope you've all had a relaxing break over the Christmas period.

RE-OPENING OF UNITING CHURCH HALL: The Banyule Network of Uniting Churches has conducted a detailed review of its facility hire procedures and a new facility hire policy has been developed to include the COVID Safe requirements. They have advised us of the new hirer rates and procedures starting this year. We intend to recommence face-to-face meetings in March but also hope to continue to invite members and guest speakers via Zoom.

In this month's newsletter we highlight:

- page 2 A short Burst of Energy
- page 3 Clinicians Take Note!
- page 4 First Oral Hormone Therapy
- page 5 Prolonged ADT Risks
- page 6 Burden of Out-of-Pocket Expenses
- page 7 BAT Sensitizes CRPCa to Subsequent Therapy
- page 8 & 9 Targeting bone mets in oligrecurrent men
- page 10 & 11 Clinical trials

If there is anything you want to talk through in relation to your treatment or wellbeing please don't hesitate to ring:

Max Shub	0413 777 342
Mike Waller	0438 616 240
Michael Meszaros	0407 837 538

Prostate Heidelberg Cancer Support Group



PHCSG provides information, education and support for those affected by Prostate Cancer. At our meetings we are committed to:

- showing respect to members, speakers and guests
- allowing members to speak without interruption
- respecting confidentiality



Many people have been touched by cancer

Talking openly about cancer and your experiences makes a huge difference in increasing understanding, overcoming stigma and reducing fear.

A Short Burst of Energy

For many, a big hurdle to exercise is the discomfort. No pain, no gain, right? Unfortunately, this is true. Positive changes in the body occur as part of the cycle of stressing your muscles and then subsequently recovering them. But there is some good news. Research has indicated that the benefits of exercise can be imparted by short bursts of energy, followed immediately by short bursts of rest. This type of exercise is called HIIT (pages 44-45 in The Science of Living Well Beyond Cancer) or HIRT. In High Intensity Resistance Training, you lift weight (a barbell, your body weight) in spurts, with rest in between. Interval training has the bonus of the same physiological benefits you get with a longer, less-intense training session in a shorter time frame. Resistance training (e.g., weight lifting) is an important part of a well-rounded exercise routine done right, it builds strength and stability, as well as supporting joints and bones.

HIIT or circuit training (1 minute "on" 1 minute "off") is fairly easy at your local gym. However, many of us don't have or (or want) access to a gym right now. Never fear: almost everything you need is already on-board your body! See the quick infographic below for a short set of 9 exercises (for the 1 in 9 men diagnosed with prostate cancer) that you can do 1-3x/week from the comfort of your own home.

Remember: unless you are an experienced athlete, it is recommended that you consult with a doctor or professional



January 2021



Source: https://pubmed.ncbi.nlm.nih.gov/33 260255/ https://pubmed.ncbi.nlm.nih.gov/33 317523/

The management of sexual dysfunction resulting from radiotherapy and androgen deprivation therapy to treat prostate cancer:

Abstract

Objectives: To establish current urooncology practice in the management of sexual dysfunction (SD) following radiotherapy (RT) and/or androgen deprivation therapy (ADT) to treat prostate cancer. To identify differences in approach to the management of SD according to disease stage.

Subjects and methods: A 14-question mixed methods survey was designed to assess the current UK practice. Closedand open-ended questions were used to quantify results while allowing participants to expand on answers. The survey was distributed to members of the British Uro-Oncology Group at the 2019 annual meeting.

Results: Surveys were completed by 63 uro-oncologists attending the annual

Clinicians – take note!

meeting of the British Uro-Oncology Group (response rate 66%). The major issue highlighted was a difference in approach to managing SD according to disease stage. More than half of the participants (56%) said 'advanced stage of disease' was a barrier to discussing SD. Clinicians were less likely to discuss SD, take baseline assessments, refer to a specialist clinic or offer rehabilitation when dealing with patients with advanced disease. Only a minority said that the management of SD was primarily their responsibility (11%). Nearly all clinicians (92%) had access to SD clinics; however, the majority of clinicians did not routinely refer patients.

Conclusions: This study shows that men with advanced prostate cancer need better support in managing SD. Patients receiving long-term ADT are less likely to be offered any kind of help or intervention. Specific guidance on managing SD in this cohort may result in improvements in sexual function, emotional well-being, quality of life, mental health and confidence.

If this raises any issues for you, you might like to visit "A Touchy Subject" with Victoria Cullen for further reading.

Shared decision making, physicians' explanations, and treatment satisfaction:

Abstract

Background: Hormone therapy is one option for some types of prostate cancer. Shared decision making (SDM) is important in the decision making process, but SDM between prostate cancer patients receiving hormone therapy and physicians is not fully understood. This study tested hypotheses: "Patients' perception of SDM is associated with treatment satisfaction, mediated by satisfaction with physicians' explanations and perceived effective decision making" and "The amount of information provided to patients by physicians on diseases and treatment is associated

with treatment satisfaction mediated by patients' perceived SDM and satisfaction with physicians' explanations."

Methods: This cross-sectional study was conducted using an online panel via a private research company in Japan. The participants in this study were patients registered with the panel who had received or were currently receiving hormone therapy for prostate cancer and physicians registered with the panel who were treating patients with prostate cancer. Measures used in this study included a nine-item Shared Decision Making Questionnaire, levels of satisfaction with physicians' explanations and treatment satisfaction, and effective decision making for patients (feeling the choice is informed, value-based, likely to be implemented and expressing satisfaction with the choice), and a Shared Decision Making Questionnaire for Doctors. The hypotheses were examined using path analysis.

Results: In total, 124 patients and 150 physicians were included in the analyses. In keeping with our hypotheses, perceived SDM significantly correlated with the physicians' explanations and perceived effective decision making for patients, and satisfaction with physicians' explanations and perceived effective decision making for patients were both related to treatment satisfaction. Although the amount of information provided to patients was correlated with the perceived SDM, it was indirectly related to their satisfaction with physicians' explanations.

Conclusions: When physicians encourage patients to be actively involved in making decisions about treatment through the SDM process while presenting a wide range of information at the start of hormone therapy, patients' effective decision making and physicians' explanations may be improved; consequently, the patients' overall treatment satisfaction may be improved. Physicians who treat patients with prostate cancer may have underestimated the importance of SDM before starting hormone therapy, even greater extent than patients.



FDA Approves First Oral Hormone Therapy for PCa

Sour

https://www.pcf.org/news/breaking -news-fda-approves-first-oral hormone-therapy-for-advanced On Friday, December 18, 2020, the US FDA approved the first oral gonadotropin-releasing hormone (GnRH) receptor antagonist, relugolix, for adult patients with advanced prostate cancer. This is an important advance because it offers another option to patients who are taking hormone therapy.

One of the mainstays of treatment for high-risk and metastatic prostate cancer is androgen deprivation therapy (ADT). ADT is designed to stop testosterone from being produced or directly block it from acting on prostate cancer cells, slowing or stopping cancer growth. Most forms of ADT are given as regular injections (e.g., monthly or every 3 months) or as implants under the skin. One disadvantage of commonly use medications is an initial spike in testosterone, as well as a delay in time to lowering the man's testosterone level.

This newly-approved therapy, relugolix, works by blocking the pituitary gland (in the brain) from making hormones that stimulate the testes to make testosterone – thereby lowering a man's testosterone levels. Instead of an injection, the patient takes an oral tablet once daily, at approximately the same time each day, with or without food.

The effects were tested in a randomized clinical trial comparing relugolix to leuprolide, a very common injectable form of ADT, in over 900 patients with advanced prostate cancer. More patients taking relugolix had their testosterone levels fall quickly and remain at a low ("castrate" level) during the study vs those taking leuprolide.

Side effects of ADT can include weight gain, increase in cholesterol levels, and increased risk for heart attack. A striking finding in the clinical trial was a 54% decrease in major cardiac events (such as heart attack and stroke) in the patients taking relugolix vs leuprolide.

What does this approval mean for patients with advanced prostate cancer? They now have an oral alternative to typical ADT that decreases testosterone levels more guickly, and keeps them low, than one commonly used medication. Some patients and doctors may decide that taking an oral medication at home, rather than having to come to the clinic for an injection, may be preferable during the COVID-19 pandemic. Many men with prostate cancer already have risk factors for cardiovascular disease, and relugolix may offer reduced risk of dangerous side effects such as a heart attack. This may be an important consideration when choosing a form of ADT.

PLEASE NOTE: Treatments may vary in Australia. Please ensure you discuss your diagnosis and treatment options with your consulting specialist



Prolonged ADT For Prostate Cancer Reduces Cardiorespiratory Fitness, Increases Risk of CV Death



https://www.jacc.org/doi/10.1016/j. accao.2020.08.011?_ga=2.22452233 4.579713609.1610784576 2135745017.16101708768 In patients with prostate cancer and high cardiovascular risk at baseline, an association was found between prolonged androgen deprivation therapy (ADT) and reduced cardiorespiratory fitness and increased risk of cardiovascular death, according to a single-center retrospective cohort study published Nov. 17 in JACC: CardioOncology.

With the increasing use of ADT regimens of increased intensity and longer duration in high-risk prostate cancer patients, Jingyi Gong, MD, et al., sought to examine the impact of ADT exposure and the influence of short-term (\leq six months) and prolonged (> six months) duration on cardiorespiratory fitness and cardiovascular mortality.

The study cohort consisted of 616 patients who had an exercise treadmill test (ETT) for clinical indications between March 7, 2002, and August 18, 2015. The median time from prostate cancer diagnosis to ETT was 4.8 years. Cardiorespiratory fitness was calculated from peak treadmill speed and grade achieved during ETT.

Nearly a quarter of the patients (n=150) had received ADT; 99 patients had long-term exposure and 51 short-term exposure. The majority of study patients (n=504; 81.8%) had two or more cardiovascular risk factors; of the patients with prolonged exposure to ADT, 92.2% had two or more cardiovascular risk factors.

The results showed that prolonged ADT exposure was associated with reduced cardiorespiratory fitness (odds ratio [OR], 2.71; 95% confidence interval [Cl], 1.31-5.61; p=0.007) and increased cardiovascular mortality (hazard ratio [HR], 3.87; 95% Cl, 1.16-12.96; p=0.028) in adjusted analyses.

With short-term ADT exposure, the association with reduced cardiorespiratory fitness was of borderline significance (OR, 1.71; 95% Cl, 1.00-2.94; p=0.052), and no association was found for cardiovascular mortality (HR, 1.60; 95% Cl, 0.51-5.01; p=0.420) in adjusted Cox regression models.

"While prolonged ADT certainly plays a role in the treatment of prostate cancer, these findings emphasize the need to consider cardiovascular surveillance/risk modification during and after ADT exposure," said study author John D. Groarke, MBBCh, MSc, MPH.

In an accompanying editorial comment, Vivek K. Narayan, MD, MSCE and Alicia K. Morgans, MD, MPH, write that this study adds value to our existing clinical knowledge base, but caution that further attention to the cardiovascular complications of varying ADT exposure durations is critical as oncologic treatment strategies evolve.

"By improving our understanding of the patient- and treatment-related factors contributing to ADT-related cardiac toxicity, oncology and cardiology providers can work collaboratively to optimally employ therapy modifications and cardiovascular risk mitigation strategies," they conclude.

Sourc

https://www.mccabecentre.org/n ews-and-updates/reducing-theburden-of-out-of-pocket-cancercosts-with-informed-financialconsent.html

There are so many questions that come with a cancer diagnosis. A family's financial future shouldn't be one of them.

Yet that was the reality for the family of a 72-year-old Sydney pensioner whose daughter had to withdraw money from her superannuation fund to help pay for his liver cancer surgery.

The man received a bill of several thousands of dollars for surgery done through the private health system – even though he didn't have private insurance. His surgeon had told him he couldn't get surgery quickly enough through the public hospital system, leading him and his family to believe the private system was their only option.

A Medical Professional Standards Committee has since found that wasn't the case. The surgery could have been performed in the public system free-ofcost within 30 days. The immense financial impact on this family could have been avoided if they had been made fully aware of all treatment and care options and the associated costs beforehand — a process known as informed financial consent.

Unexpected cancer costs and "bill shock"

In this case, this family's financial burden was largely the result of one doctor's poor conduct. Complaints were made to the <u>Health Care Complaints</u> <u>Commission</u>, and the surgeon was reprimanded for unsatisfactory professional conduct in how he managed the decision to treat the man in the private hospital system.

But the problem of out-of-pocket medical expenses in Australia goes far beyond the actions of one doctor. Australians pay out-of-pocket for about 20% of health care costs, including for medications, testing, and doctor's fees that aren't fully covered by Medicare. That's more than many comparable countries, and it's expected to rise.

The cost of treatment and care can

really add up for cancer patients, who face a complex and unpredictable illness that can require years of tests and treatments. The associated out-ofpocket expenses can lead to "financial toxicity" and "bill shock" that can impact their health and well-being. The McCabe Centre for Law & Cancer wrote about the issue of out-of-pocket cancer costs back in 2018, and the situation hasn't improved.

Reducing the burden of out-ofpocket cancer costs with informed financial consent

But the burdens of out-of-pocket costs can be reduced when patients are empowered to make informed choices about their treatment and care options through informed financial consent. That is why Cancer Council, Breast Cancer Network Australia, CanTeen and the Prostate Cancer Foundation of Australia have jointly created the Informed Financial Consent Standard.

Launched on 26 October, this voluntary standard provides health professionals and health services with practical guidance on how to discuss the costs of treatment and care options with patients, and how to obtain patient consent before any chosen treatment and care is given. It acknowledges that discussing the costs of treatment is an essential component of quality care, and that health professionals are best placed to lead these discussions.

About informed financial consent

Informed financial consent is not a new idea. The expectation to obtain informed financial consent is outlined in health professional standards of practice, including the Medical Board of Australia's Code of Conduct for Doctors. Failing to discuss the costs of treatment options and obtain consent to treatment decisions may be a breach of these professional standards, and could result in disciplinary proceedings and reprimand for health professionals – just like the Sydney liver surgeon.

Tarishi Desai, Acting Manager of Treatment & Supportive Care

In that surgeon's case, the Medical Professional Standards Committee found he failed to obtain informed financial consent and failed to consider the financial impact of not obtaining consent on his patient and his patient's family. It found this behaviour was both unethical and unacceptably below the standards one would expect of a doctor under health practitioner regulation law.

Cases like this show that patients have a right to expect health professionals to discuss the costs of their proposed care with them. But they also show that some health professionals need more guidance on the potential financial impacts of treatment options, and how to discuss them with patients. The Medical Professional Standards Committee found that the Sydney liver surgeon "appeared unaware or disinterested in any of the alternative ways of financially assisting private patients without health insurance".

This is where the new Informed Financial Consent Standard can make a difference. The standard aims to help doctors (and can be used by other health professionals) to meet their existing obligations around discussing the cost of care. It does so by setting out a series of principles for informed financial consent, describing the purpose of each principle, and detailing key tasks that individual doctors and health services can follow to make sure treatment fees and charges are understood by patients prior to treatment.

These key tasks include informing patients about Medicare rebates, the benefits and trade-offs of being treated in the private health system, and no- or lowcost alternatives available through the public system. Ultimately, it is the patient's choice about how they are treated.

Empowering people with cancer and health professionals

Cancer Council is currently working with doctors and practice staff to develop resources to help implement the Informed Financial Consent Standard and ensure it benefits cancer patients, their families, and the dedicated doctors who treat them. For health professionals, the standard could offer more clarity and guidance in how to have difficult conversations with patients. Through use of the standard, it is hoped that regulators will see fewer complaints from patients about costs, bill shock, and a lack of informed financial consent.

This standard is one way to deal with the many problems associated with the costs of cancer care and there are further options which could be explored to reduce costs and bill shock.

But for people with cancer, uptake of this standard by health professionals could offer hope that the stress of cancer treatment and care won't be compounded by financial distress about unexpected or unnecessary out-of-pocket costs. Armed with knowledge about the costs of their proposed treatment, and empowered by health professionals who obtain their consent for their chosen treatment and care options, people affected by cancer can better plan for and manage their cancer journey.

Learn more about the Informed Financial Consent Standard at <u>Cancer Coucil</u> <u>Australia's website</u>.



Bipolar androgen therapy sensitizes castration-resistant prostate cancer to subsequent androgen receptor ablative therapy

Sourc

European journal of cancer (Oxford, England : 1990). 2020 Dec 28 [Epub ahead of print] 4 Jan 2021 https://www.urotoday.com/rec <u>ent-abstracts/urologiconcology/prostatecancer/126951-bipolarandrogen-therapy-sensitizescastration-resistant-prostatecancer-to-subsequentandrogen-receptor-ablativetherapy.html</u> Cyclical, high-dose testosterone administration, termed bipolar androgen therapy (BAT), can induce clinical responses and restore sensitivity to androgen signalling inhibition in patients with previously treated castration-resistant prostate cancer (PCa) (CRPC). This trial evaluated whether BAT is a safe and effective first-line hormonal therapy for patients with CRPC.

In cohort C of this single-centre, open-label, phase II, multi-cohort trial (REsensitizing with Supraphysiologic Testosterone to Overcome REsistance study), 29 patients with CRPC received first-line hormonal therapy with 400 mg of testosterone cypionate intramuscularly every 28 days concurrent with a luteinising hormone-releasing hormone agonist/antagonist. The primary endpoint of the study was the PSA50 response rate to BAT treatment.

After treatment with BAT, four of 29 patients (14%; 95% confidence interval [CI]: 4-32%) experienced a PSA50 response. The median radiographic progression-free survival to BAT was 8.5 months (95% CI: 6.9-15.1) for patients with metastatic CRPC. After progression on BAT, 17 of 18 patients (94%; 95% CI: 73-100%) achieved a PSA50 response and 15 of 18 patients (83%; 95% CI: 59-96) achieved a PSA90 response on abiraterone or enzalutamide. Twelve of 15 patients (80%; 95% CI: 52-96) with metastatic CRPC remain on abiraterone or enzalutamide with a median duration of follow-up of 11.2 months.

As first-line hormonal treatment for CRPC, BAT was well tolerated and resulted in prolonged disease stabilisation. After progression on BAT, patients had favourable responses to second-generation androgen receptor-targeted therapy.

ClinicalTrials.gov NCT02090114.

PLEASE NOTE: Treatments may vary in Australia. Please ensure you discuss your diagnosis and treatment options with your consulting specialist



Targeting Bone Metastases with Radiation in Oligorecurrent Men has No Survival Benefit in Mayo Study

Oligometastases in bones

Metastasis-directed therapy (MDT) when there are only a few bone metastases (called "oligometastatic") is controversial. It can certainly relieve pain, and prevent fractures and spinal compression. It can also provide good "local control" (cancer in the irradiated metastasis is permanently destroyed) and reduce the PSA that those metastases put out. But is there any survival benefit?

Patients often ask radiation oncologists (ROs) for radiation of those metastases using targeted radiation (which I'll call "zapping"), and they ask their ROs to treat new metastases as they are detected. This is called "metachronous treatment," but I'll call it "whack-a-mole" Sometimes metastases appear in places where radiation treatment may be problematic, such as near vital organs or deep in the spine. The nagging question is whether such treatment really does the patient any good. With the approval of ever more sensitive PET scans, like the PSMA PET scan approved [last month in the USA], patients will undoubtedly detect more metastases.

The Mayo Clinic has been one of the cheerleaders for MDT. They have posted a deceptive youtube video featuring their C-11 Choline PET scans showing only how good the local control is. What the video can't show is how those patients would have done without MDT - there was no control group ever used or shown in their video.

Perhaps to partially correct for the misleading video, Boeri et al. at Mayo retrospectively looked at 115 patients who had an oligometastatic recurrence to the bones (1-5 metastases):

- 115 patients were treated with SBRT. They had a median of 1 bone metastasis.
- 47 patients were treated with ADT-only. They had a median of 2 bone metastases.

This was not a randomized study, so it is entirely likely that there was "selection bias" -those who received ADT-only may be because it was felt they would not be able to benefit from SBRT or that it might be unsafe. Patients who received ADT-only had a higher number of bone metastases and a higher PSA. All of those receiving MDT for bone metastases were also receiving ADT.

- The 5-year prostate cancer mortality was no different between the two groups
- The 5-year radiographic recurrence-free survival was no different between the two
 groups
- Among those with 5 years of follow-up, the time remaining free of the next significant systemic therapy (e.g., chemo, Zytiga, etc.) was longer for those getting zapped. However, it should be noted that the decision to give an additional significant therapy is a physician decision based on many factors, including patient status, number of metastases, and PSA. Because number of metastases and PSA are changed by MDT, and those receiving MDT started with one less metastasis, the physician may feel pressured to start a new therapy sooner in patients receiving ADT-only.

Pending confirmation from long-term randomized clinical trials of MDT to oligometastases in bones, there is no evidence of oncological benefit.

Oligometastases in Pelvic Lymph Nodes (PLNs)

MDT of oligorecurrent metastases that are only in pelvic lymph nodes (PLNs) is less controversial. Lymph is a slow-moving fluid, and metastatic cancer cells emerging

Source

https://www.prostatecancer.news/2 020/12/targeting-bone-metastaseswith.html

(continued)

from the prostate might get trapped in the lymph nodes that drain the prostate. So it has been hypothesized that treatment of the PLNs when a few are found to be cancerous may still provide a cure. This has not yet been proven in a randomized clinical trial, but there is observational evidence of a significant benefit to salvage wholepelvic radiation.

What is controversial about the way they are treated at the Mayo Clinic is that only those cancerous PLNs and a small margin around them were surgically removed, and whole pelvic salvage radiation wasn't routinely given. They were treated in any of three ways:

- Salvage Pelvic Lymph Node Dissection (sPLND). Jeffrey Karnes at Mayo is one of the few top surgeons in the US who does this difficult surgery. It is difficult because PLNs detected on a PET scan can be very small. They are invisible, can be hidden in fat deposits, and are very difficult to find. There are innovative techniques like fluorescent or gamma-ray PSMA indicators that can facilitate detection. Patients treated with sPLND also received 6 weeks of bicalutamide.
- External Beam Radiotherapy (EBRT) to PLNs as part of salvage radiation treatment (SRT). At Mayo, 72% received salvage IMRT to the identified PLNs plus a large margin around them, while 28% received SBRT to just the identified PLNs plus a small margin around them. This was typically done along with 12-18 months of ADT.
- ADT-only, Patients treated with either of these two forms of MDT were compared to patients who received ADT-only, which is the current standard-of-care. Again, this was not part of a randomized clinical trial, so it is likely that the ADT-only patients were not offered MDT for a reason. Most importantly, about half had cancerous LNs in the retroperitoneum or abdomen (Stage M1a) - already outside of the prostate drainage area (Stage N1), and they had more positive LNs. In contrast, only 9% of the sLND group and 19% of the EBRT group had cancerous LNs outside the pelvis. The ADT-only group had much further progression at the time of treatment.

After a median follow-up of 47 months:

Prostate Cancer-specific mortality

was 13.5% for ADT-only, 9.5% for EBRT, and 6.3% for sLND (the difference between ADT-only and sLND was statistically significant)

- Radiographic recurrence was 65% for ADT-only, 40% for EBRT, and 61% for sLND.
- Castration-resistance was 39% for ADT-only, 19% for EBRT, and 21% for sLND.
 - The median time until castrationresistance set in was 59 months for ADT-only, 73 months for EBRT, and 98 months for sLND.
- Second-line systemic therapies were offered to 43% for ADT-only, 29% for EBRT, and 24% for sLND.
 - The median time until the therapies were offered was 28 months for ADT-only, 32 months for EBRT, and 44 months for sLND.
- Inexplicably, the percent of cancerous lymph nodes outside of the pelvis (% M1a) was not included as a variable to correct for in their multivariable analysis, and was largely ignored.

The authors found an association between MDT and radiographic progression in their retrospective sample of patients. However, it leaves unanalyzed how much of that association is due to the extraordinarily high rate of out-of-pelvis progression already present in the ADT-only treated patients. In fact, it seems likely that that is the reason they didn't receive MDT.

They also make the same error with respect to castration-resistance and use of second-line therapies that they made in their bone MDT analysis; i.e., they "treated PSA" with their MDT, so they can't use castration-resistance and time to second-line therapy as useful endpoints. Tellingly, radiographic recurrence is similar for ADT-only and sLND, while EBRT is lower, possibly only because of the longer use of adjuvant ADT with EBRT.

Another open question is whether whole pelvic salvage radiation might have been more effective than the limited margins they used at Mayo. With the more accurate PSMA PET scans, ROs are able to treat the entire PLN area with radiation boosts given to the detected ones. The RTOGconsensus treatment area has recently been expanded (see this link). It's important that patients understand the detection limits of even the best PSMA PET scan: metastases smaller than 4 mm, and those that put out only small amounts of PSA remain invisible. PLEASE NOTE: Treatments may vary in Australia. Please ensure you discuss your diagnosis and treatment options with your consulting specialist

New Prostate Cancer Trials

PEACE V: Salvage Treatment of OligoRecurrent Nodal Prostate Cancer Metastases (STORM)

Detailed Description:

A proportion of prostate cancer (PCa) patients develop a local, regional (N1) or distant (M1) relapse following curative local treatment. For both local and distant relapses, different treatment recommendations are made in the guidelines (EAU guidelines 2016) However, the entity regional nodal recurrence is not mentioned in the guidelines but is an emerging clinical situation since the introduction of choline and more recently PSMA PET-CT in the restaging of recurrent prostate cancer. More specifically, a subgroup of these patients is being diagnosed with a recurrence confined to the regional lymph nodes and limited in number (oligorecurrence) using choline or PSMA PET-CT. As there are no specific treatment recommendations for these type of patients, different treatment approaches are currently used, mostly focusing on local ablative treatments using radiotherapy or surgery. These treatments are coined metastasisdirected therapy (MDT). MDT in combination with or without temporary ADT could delay the subsequent risk of metastases, and even cure limited regional nodal recurrences. Consequently, lifelong palliative ADT, with its toxicity and excess in non-cancer mortality might be postponed.

The proposed trial randomizes patients with oligorecurrent nodal prostate cancer following primary PCa treatment to either metastasisdirected therapy (MDT) (sLND or SBRT) or MDT plus WPRT. In the recurrent PCa setting, 2 recent trials have suggested a progression-free and even survival benefit of adding temporary ADT to local salvage prostate bed radiotherapy. Consequently, this positive effect might also be applicable for regional recurrences. Although the optimal duration of ADT is unknown, a minimal duration of 6 months of ADT seems advisable in this setting and will be mandatory for both arms.

This trial will improve our insights in the pattern of recurrence following these treatment modalities with the expectation that WPRT will reduce the number of nodal relapses, improving metastasis-free survival and postponing the need for palliative systemic treatments while maintaining quality-of-life. The current phase II trial will try to establish a golden standard in the treatment of oligorecurrent nodal PCa.

The proposed trial randomizes patients with oligorecurrent nodal prostate cancer following primary PCa treatment to either metastasisdirected therapy (MDT) (salvage lymph node dissection, sLND or stereotactic body radiotherapy, SBRT) or MDT plus whole pelvis radiotherapy (WPRT: 45 Gy in 25 fractions).

Epworth Healthcare, Melbourne

Contact: Shankar Sive PhD; Nathan Lawrentschuk PhD

ClinicalTrials.gov Identifier: NCT03569241

UpFrontPSMA Trial Phase II

Most prostate cancer cells have a molecule on their surface called prostate cancer specific membrane antigen (PSMA). PSMA can be targeted with Lutetium-177 PSMA (Lu-PSMA), a radioactive drug that kills prostate cancer cells anywhere in the body. This investigational drug is not approved for use in Australia by the Federal Government's Therapeutic Goods Administration (TGA). It is a new form of treatment that is effective in some patients with metastatic prostate cancer. It is a radioactive substance that, after injection into a vein, attaches to prostate specific membrane antigen (PSMA). The treatment enables delivery of highly targeted radiation to cancer cells. The emitted radiation only travels about 1mm, which means it mainly causes the killing of cancer cells, while avoiding healthy cells, and seems to be well

tolerated with few side effects. This is called radionuclide therapy or theranostic therapy.

The purpose of this randomised controlled clinical trial is to compare the effectiveness of Lu-PSMA therapy followed by docetaxel chemotherapy versus docetaxel chemotherapy on its own. Previous clinical trials have shown promising activity of Lu-PSMA in treatment of patients with metastatic prostate cancer.

Docetaxel is a chemotherapy drug that is approved by the TGA to treat prostate cancer and has been used for many years in the treatment of metastatic prostate cancer.

Since Lu-PSMA radiotherapy and docetaxel chemotherapy are both effective in treating metastatic prostate cancer, it is possible that using Lu-PSMA in addition to standard docetaxel chemotherapy at the beginning of the treatment course may improve patient outcomes when compared to treatment with docetaxel alone. A recent phase 2 clinical trial, showed the effectiveness of Lu-PSMA when used as a last treatment option and helped control disease progression. This study brings the use of Lu-PSMA forward as a first option to patients, with the hope of disease eradication and potential cure.

The trial is open and recruiting including:

Peter MacCallum Cancer Centre &

Austin Health in Melbourne

https://clinicaltrials.gov/show/NCT04 343885

New Prostate Cancer Trials

The NINJA Clinical Trial: Novel Integration of new prostate radiation schedules with adjuvant androgen deprivation for patients with intermediate or lowhigh risk prostate cancer

Trial Overview

This trial is comparing the effectiveness of two schedules of radiotherapy for the treatment of patients with prostate cancer.

This trial is treating patients with prostate cancer. This is a radiation therapy. You may be able to join this trial if:

- Your cancer has not spread to other parts of the body.
- You may be excluded from this trial if:
- You have been diagnosed with a prior or secondary type of cancer.
- You have had certain treatments, surgical procedures or drugs.

Clinical trials have complex eligibility criteria - talk to your doctor about your interest in this trial.

Clinical Summary

Patients eligible to participate in this study will receive radiation therapy, which will be delivered by one of two schedules. The first schedule will involve 40 Grays (Gy) of radiation delivered in five fractions 1-3 times per week. The second schedule will involve 20Gy in 2 fractions delivered once per week, followed by a two week break and 36Gy in 12 fractions, delivered 4-5 times per week. All patients will receive injections of androgen deprivation therapy for 6 months, commencing 3-4 months prior to radiation.

Recruiting Hospitals

Peter MacCallum Cancer Centre Moorabbin Moorabbin Research <u>moorabbin.research@petermac.org</u> 03 9928 8994 Peter MacCallum Cancer Centre, Radiation Oncology Parkville Smitha Sithara <u>Smitha.sithara@petermac.org</u> 03 8559 8771

> Learn to be your own researcher to make the best treatment decisions, by being proactive and an advocate for your own health

Prostate Heidelberg Cancer Support Group Meetings

While we are having to distance ourselves and are unable to hold face-to-face group meetings we are engaging speakers via video conferencing.

We are planning to recommence our regular monthly meetings at Ivanhoe Uniting Church. When this happens we will also try to continue to provide for attendance via Zoom for those who cannot attend in person.

Internet Resources

Members have found the following websites useful Prostate Cancer Foundation of Australia for guides & help https://www.pcfa.org.au https://onlinecommunity.pcfa.org.au/

Australian Cancer Trials Information on clinical trials https://www.australiancancertrials.gov.au

USA Prostate Cancer Foundation (Guide) PDF guide for men newly diagnosed with PC https://www.pcf.org/guide/

Us TOO International PCa Education (USA) USA PC support groups' information & newsletter https://www.ustoo.org

Cancer Council Victoria for general support services https://www.cancervic.org.au

ExMed Cancer Program Melbourne based 'best practice' exercise medicine program https://www.exmedcancer.org.au

ProstMate (PCFA) A companion to record PC results

Beyond Blue for help with depression and anxiety <u>HELPLINE 1300 22 4636</u>

Continence Foundation of Australia for assistance with incontinence aids <u>HELPLINE 1800 33 0066</u>

PCRI Prostate Digest (USA) Prostate Cancer Research Institute supporting research and disseminating information to educate and empower patients, families and the medical community https://pcri.org/insights-newsletter

PAACT Newsletter (USA) Patient Advocates for Advanced Cancer Treatments http://paact.help/newsletter-signup/

PHCSG Correspondance

Prostate Heidelberg POB 241 Ivanhoe Vic 3079 prostateheidelberg@gmail.com prostateheidelberg.info

PHCSG Correspondance

Mike Waller Convenor Max Shub Co-Facilitator Peter Anderson Treasurer Spiros Haldas Library David Bellair Web Site Michael Meszaros Welfare Officer Sue Lawes Secretary/Newsletter

PHCSG Meetings 2021 10am – 12:30pm

Tues 16 Feb Tues 16 March Tues 20 April Tues 18 May Tues 15 June Tues 20 July Tues 17 August Tues 21 September Tues 19 October Tues 16 November Tues 14 December (including Xmas lunch)

Please note that all face-to-face meetings have been cancelled until further notice. Please check your email regularly for updates from the PHSCG Committee.

The internet is a good source for research but it should not be trusted to give you answers for your personal care. Always speak to your doctor to clarify any medical advice.

Disclaimer: Information in this newsletter is not intended to take the place of medical advice. Please ask your doctor to clarify any details that may be related to your treatment. PHCSG have no liability whatsoever to you in connection with this newsletter.

2021 PHCSG Articles

If you have any feedback or wish to include articles on specific aspects of Prostate Cancer please contact Sue at: prostateheidelberg@gmail.com February 2021

- Exercise Infographic
 - Sexual Dysfunction & Shared Decision Making
 - FDA Approves first Oral Hormone Therapy
 - Prolonged ADT Reduces Cardio Fitness
 - Reducing the Burden of Out-of-Pocket Expenses
 - BAT Sensitizes CRPCa to Subsequent Therapy
 - Targeting Bone Mets with Radiation in Oligorecurrent Men
 - Prostate Cancer Trials
 - PEACE V:STORM
 - UpFront PSMA Phase II
 - NINJA

Disclaimer: Information in this newsletter is not intended to take the place of medical advice. Please ask your doctor to clarify any details that may be related to your treatment. PHCSG have no liability whatsoever to

2020 PHCSG **Articles**

If you have any feedback or wish to include articles on specific aspects of Prostate Cancer please contact Sue at:

prostateheidelberg@gmail.com

March 2020

PCFA Consumer Advisory- Coronavirus and Cancer

April 2020

- Telehealth & Delayed Hospital Treatments due to COVID-19
- Fexapotide Triflutate (FT) injection a new kind of focal treatment to extend time on active surveillance Prostate Cancer Trials
- DASL-HiCaP Trial
- · Evaluation of a mainstream model of genetic testing for men with prostate cancer

May 2020

- ADT May Offer Some Protection From COVID-19 in Men with Prostate Cancer
- TULSA Novel MRI-guided ultrasound treatment destroys prostate cancer
- Whack-a-Mole A Treatment of Oligometastasis
- · Long-term adjuvant ADT improves results of brachy boost therapy in unfavorable-risk prostate cancer patients

 Harnessing the immune system to control prostate cancer spread to the bone Prostate Cancer Trials

- A study to see whether PET scans using a chemical called Exendin can detect metastatic PC

Evaluation of a mainstream model of genetic testing for men with prostate cancer

June 2020

- Evaluating the Outcomes of AS in Gleason Grade 2 Prostate Cancer
- Advancing precision medicine for metastatic prostate cancer
- Impact of Primary Prostate Cancer Treatment with Subsequent Metastatic Disease
- Comparative Analysis & Survival Outcomes in a Real-World Practice Setting
- Fexapotide Triflutate (FT) injection a new kind of focal treatment to extend time on AS
- Prostate Cancer Trials

· Impact of 18F-DCFPyL PET scanning in patients undergoing post-prostatectomy Radiotherapy July 2020

- Testosterone Therapy does not Increase the Risks of PCR or Death after Definitive Treatment for Localised Disease
- Association of Pre-Salvage Radiotherapy PSA Levels after Prostatectomy with Outcomes of Long-term Antiandrogen Therapy in Men with Prostate Cancer
- Testosterone Replacement in the treatment of Advanced Prostate Cancer
- Memorial Sloan Kettering Cancer Center PCa nomograms Prediction Tools

August 2020

- Advanced Prostate Cancer Algorithm
- Blood Test Predicts Response to PC Treatment (liquid biopsy)
- The Perils and Pitfalls of Treating PSA in PCa
- Reprogramming Immune Cells could Switch Defence into Attack in PCa
- Maintenance of Sexual Activity Following ADT

September 2020

- Protect Trial showing patient outcomes after AM, RP & EBRT
- Changes in Penile Length after RP
 Active Surveillance for PC is it right for you?
- The final part of The Perils and Pitfalls of "Treating PSA" in Advanced Prostate Cancer
- Managing Erectile Dysfunction A Patient Guide
- Prostate Cancer Trials
- Efficacy and Safety of Pembrolizumab (MK-3475) Plus Enzalutamide Plus Androgen Deprivation Therapy (ADT) Versus Placebo Plus Enzalutamide Plus ADT in Participants with (mHSPC)
- Navigate: An online treatment decision aid

October 2020

- World Osteoporosis Day
- Lifestyle Factors and Chronic Disease
- Hormone Therapy for PC
- Early ADT for Recurrent PC Challenged
 Unexpected aPC weakness can be targeted by drugs
- Hijacking an Epigenetic Program
- New PC Research: Immunotherapy; Gut Microbiome
- · Veyonda New Research on Survival Rates
- Prostate Cancer Trials
- MIndonline mindfulness

November 2020

- · Life insurance & Genetic Testing
- World First Surgery in NZ
- Melatonin increases survival
- SBRT disease control
- Public vs Private Hospitals
 Early ADT for Recurrent PC challenged
- Enzamet trial results
- Prostate Cancer Trials
- Randomised Phase 2 of sequential 177Lu-PSMA & Docetaxel
- Exercise for Heart Health
- December 2020
 - ACTA Trial Award
 - Rethinking Metastasis
 - ESMO Phase 1 AMG160
 - Five Ways to Get it Right
 - Immunotherapy Offers Hope
 SBRT Doubles Pain Response

 - Elevated Streess Hormone Levels
 - Prostate Cancer Trials

your doctor to clarify any details that may be related to your treatment. PHCSG have no liability whatsoever to

newsletter is not intended to take the

place of medical advice. Please ask

Disclaimer: Information in this