The Digital Examiner



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September 2015 -Prostate Cancer Awareness Month

September is prostate cancer awareness across Canada. We have asked Mayor Nenshi of

Calgary and several mayors and reeves in communities and rural areas around Calgary to join us in proclaiming September as Prostate Cancer Awareness Month. We will post their proclamations to our website at www.pccncalgary.org.

PROSTAID Calgary will be busy during September through community activities intended to increase awareness about prostate cancer and to promote baseline and trend PSA testing by all men aged 40 and over. We strongly believe that the early assessment of a man's prostate cancer risk while aged in his 40's is mission critical to making a significant dent to the heavy toll this disease causes.

BETWEEN THE SHEETS in this issue of The Digital Examiner, and in a presentation on September 8 by Dr. Daniel Heng from the Tom Baker Cancer Centre to our General Meeting, we focus attention to the management of advanced prostate cancer. These presentations will interest Warriors and men who have received their primary treatment, and wonder what their options are if they experience rising PSA and recurring disease.

Stewart Campbell, Executive Director

Daniel Heng, MD MPH FRCPC Medical Oncologist



Dr. Daniel Heng is a Medical Oncologist at the Tom Baker Cancer Center in Calgary, Alberta and a Clinical Associate Professor of Medicine at the University of Calgary.

Dr. Heng received his MD from the University of Calgary in 2002.

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- Tuesday, Sept 8th, 2015 Meeting Schedule
- 5:00 PM: Moxie's Grill & Bar 888 7th Ave SW, Calgary, AB
- 6:30 PM: Wives, Partners & Caregivers Room 313 at Kerby Centre
- 6:30 PM: Newly Diagnosed & Active Surveillance Group Room 311 at Kerby Centre
- 6:30 PM: Warriors Group Board Room at Kerby Centre 7:30 PM: General Meeting
- Kerby Centre Lecture Theatre

Advanced Metastatic Prostate Cancer: How We Can Help Daniel Heng, MD Tom Baker Cancer Centre

Our General Meetings are open to the public and free. Cookies, fruit and refreshments will be served.

Come join us at the Kerby Centre at 1133 7 Avenue SW, Calgary, AB T2P 1B2.

Parking is FREE at the Kerby Centre in lots on both sides of 7th Ave. The WEST LRT stops at the Kerby Station, right at the front door of the Kerby Centre.

Ladies, family members and caregivers are always welcome at our meetings.

Dr. Heng completed internal medicine and medical oncology residencies at UBC and received additional training at the BC Cancer Agency in Vancouver. He then completed an Experimental Therapeutics fellowship at the Cleveland Clinic Taussig Cancer Institute. Dr. Heng has also earned a Masters of Public Health from Harvard University.

Dr. Heng is the Chair of the Genitourinary Tumor Group in Calgary and is the Chair of the International mRCC Consortium Database. He has a keen interest in outcomes, prognostic factors and clinical trials research in metastatic renal cell carcinoma and other genitourinary malignancies.

Advanced Prostate Cancer Consensus Conference St. Gallen, Switzerland, March 12—14, 2015

The diagnosis and therapeutic management of men with advanced prostate cancer has been transformed in recent years with new drugs having received regulatory approvals. Registration trials for several drugs have shown significant extension of life and improved or preserved quality of life. Importantly, several drugs for advanced prostate cancer have different modes of action. The therapies include:

- Taxanes—docetaxel and cabazitaxel (both registered in Canada. Funded by Alberta Health Services in prescribed situations);
- An immunotherapeutic agent—sipuleucel T (registered in US. Not registered in Canada. Why not registered?);
- Androgen receptor pathway inhibitors—abiraterone and enzalutamide (both registered in Canada. Funded by Alberta Health Services in prescribed situations); and
- A radiopharmaceutical—radium-223 (the first bone targeting alpha-emitting radionuclide registered in Canada. Funded by provincial health plans in BC and Ontario. Not funded by Alberta Health Services. *Why is this*?).

The approval of these drugs for advanced prostate cancer, and very recent studies of combined chemo-hormonal therapy (ie. androgen deprivation therapy (ADT) plus docetaxel) in men with castration-naïve prostate cancer, have led to considerable uncertainty as to the:

- Best treatment choices;
- Sequence of treatment options; and
- Appropriate patient selection.

To help address this uncertainty, an Advanced Prostate Cancer Consensus Conference was held in St. Gallen, Switzerland March 12—14, 2015 with the objectives of:

- Providing recommendations by clinical experts to complement clinical trial evidence (which take a long to complete and implement into guidelines); and to
- Better frame current discussions between men, their wives and physicians concerning treatment options.

An expert panel of 41 world-renowned prostate cancer specialists from 17 countries was assembled, including:

- Martin E. Gleave, MD, Urology Sciences, Vancouver Prostate Cancer, University of British Columbia, and
- Ian F. Tannock, MD, Department of Medical Oncology and Haematology, Princess Margaret Cancer Centre, University of Toronto.

The panel agreed upon the 10 most important areas of controversy in the management of advanced prostate cancer. Some areas of consensus by the expert panel are listed next.

- 1. Men with castration-naïve metastatic prostate cancer.
 - Castration-naïve is the preferred term as sensitivity to (medical) castration is not known before commencement of androgen deprivation therapy (ADT).
 - Intermittent androgen deprivation therapy (iADT)— is controversial, but 94% of panelists would discuss the option with patients.
 - Combined androgen blockage (CAB) no consensus with older AR antagonists (ie. bicalutamide). Data with newer AR antagonists such as enzalutamide not yet available.
- Men with oligometastatic (consensus for ≤3 sites of metastasis) castration-naïve prostate cancer.
 - No consensus to local treatment of both the primary and all evident metastasis (bone / lymph nodes was appropriate.
- 3. Definition of castration resistance. Consensus to:
 - Measure testosterone (T), target T <1.7 nmol/l) on ADT, and confirm rising PSA with a second test several weeks later.
- 4. Management of men with non-metastatic (M0) castration resistant prostate cancer (CRPC). Consensus that:
 - A PSA-based hurdle should be used to restage asymptomatic patients; a negative CT scan and negative bone scintigraphy are sufficient to diagnose MO disease; and PSA >20 or PSA Doubling Time ≤6 months are sufficient to start imaging.
 - Withholding treatment for men with M0 disease and rising PSA is challenging; options (outside of clinical trials) are older endocrine therapies without proven overall survival benefit.
- 5. Value of endocrine (glands secreting) therapies without proven survival benefit in men with metastatic CRPC. No consensus.
- 6. Treatment choice and sequencing for men with metastatic CRPC. Consensus that:
 - Abiraterone or enzalutamide in addition to ADT are recommended as 'first-line' therapies for otherwise healthy asymptomatic or minimally symptomatic men with CRPC.
- 7. Staging and monitoring of treatment. Consensus that:
 - PSA tests should be conducted regularly; imaging (CT and bone scintigraphy) should be undertaken for men with mCRPC before starting a new line of therapy; and
 - At least 2 or 3 criteria (rising PSA, radiographic progression, or clinical progression) should be fulfilled to stop a therapy.
- 8. Use of bone osteoclast-targeted agents to reduce risk of skeletal-related events (SRE) and symptomatic skeletal-related events (SSE) in men with CRPC. Consensus these agents are not recommended for men without bone metastasis.
- 9. Value and use of predictive markers. Consensus that, at present, predictive markers are not useful in daily clinical practice.
- 10. Multidisciplinary care. Consensus that:Patients should be informed about clinical trials.

Recommendations were based on the experts' collective opinion, and not on a critical review of the available evidence. The recommendations had differing degrees of support. Consensus required that ≥75% of the panel experts agree about a specific item. For many of the 10 topics, clear consensus for specific details of a topic were not resolved.

Radium-223 in an international early access program: Effects of concomitant medication on overall survival in mCRPC patients

On December 12, 2013, Health Canada issued a Notice of Compliance for the therapeutic radiopharmaceutical product Xofigo (Radium-223). Xofigo was authorized for the treatment of men with castration-resistant prostate cancer with symptomatic bone metastases and no known visceral metastatic disease. Xofigo contains the radioactive isotope radium 223 which as a substance acts in a manner similar to calcium, a major component of bones. Xofigo goes to where the cancer has spread in the bone and gives off radiation (alpha particles) which kills the tumor cells without major effects to the healthy cells (Health Canada).

In the pivotal registration trial called ALSYMPCA, men with mCRPC including symptomatic bone metastases were treated with Radium-223 and best standard of care, *versus* best standard of care and placebo. Treatment with Radium-223 and best standard of care resulted in:

- Significantly improved overall survival, at a median of 14.9 *versus* 11.3 months, and
- A delayed time to first symptomatic skeletal event.

The treatment was generally well tolerated, with minimal hematological toxicity.

Recently, results were reported for a Radium-223 early access program (EAP) for men with metastatic castrateresistant prostate cancer (mCRPC) from Europe, Canada, and Israel. A total of 839 men from 14 countries were enrolled. Of these, 696 men were treated with one or more doses of Ra-223. Study objectives were safety and OS.

In post-hoc analysis of the study, overall survival (OS) was:

- Longer for patients who were asymptomatic, or
- Had ECOG performance status of 0 or1, or
- Total alkaline phosphatase (ALP) levels < 220 U/L.

A preliminary post-hoc analysis also found improved survivals among men receiving Ra-223 and concomitant denosumab or abiraterone — results the researchers say call for further study of these combinations in controlled clinical trials.

Pre-planned analyses included time to first skeletal-related event (SRE), changes in ALP activity and PSA levels from baseline, and time to ALP/PSA progression. Post-hoc analyses included OS in subgroup populations based on additional medications taken at baseline (ie. abiraterone, enzalutamide, docetaxel, denosumab, and bisphosphonates), baseline total ALP values, baseline ECOG PS, and baseline pain.

Baseline characteristics of the EAP patients were similar to the men in the ALSYMPCA trial, with the exception of pain at baseline and prior and concomitant treatments. Overall survival was slightly longer in the EAP study than in the ALSYMPCA trial, possibly because men were treated at a slightly earlier stage, suggested Dr. O'Sullivan, Queens University, Belfast. Still, a median survival of 16 months, compared very favorably to the 14-month survival data in the ALSYMPCA trial.

This EAP study also produced some hypothesis-generating analyses. For example, the researchers looked at overall survival according to:

- Baseline total alkaline phosphatase (ALP) levels,
- Whether patients had received prior bisphosphonate therapy (concomitant medications at baseline),
- Baseline ECOG status, or
- Whether men also took abiraterone or enzalutamide.

"It would appear—and again this is hypothesis-generating because patients were not randomized," Dr. O'Sullivan said, "that patients receiving abiraterone or enzalutamide, along with radium, had better survivals. Whether that's a synergistic effect or not is very hard to tell. But the separation of the survival curves certainly merits further study." Some ongoing large, randomized trials are testing the hypothesis of combining abiraterone or enzalutamide with radium-223.

"To me the most reassuring thing, as a clinician treating patients, is that the toxicity profile remains good, and acceptable. And in real-world patients, it looks like the survival is in the range of – or slightly better than – what was seen in the ALSYMCA trial, at a median of 16 months."

He added that additional benefit could arise from new hormonal agents (abiraterone or enzalutamide) which didn't exist or weren't widely available at the time of the ALSYMPCA trial.

"It's interesting how the goal posts are shifting in the castrate-resistant prostate cancer patient. We're seeing better survivals, and I guess we're trying to figure out where all the new therapies fit in a sequence. These data, although they don't answer the question, at least help us think about this and helps us to understand—that it's reasonably safe to combine these agents, without encountering any significant additional toxicity."

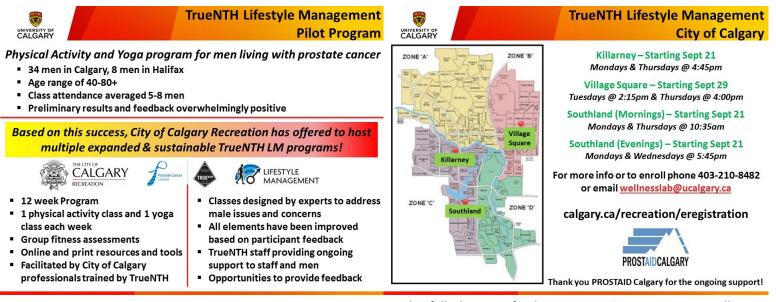
Sources: Urology Today and Saad F, Carles J, et al. . American Society of Clinical Oncology (ASCO) Annual Meeting, May 29 - June 2, 2015 , Chicago, Illinois USA.



We sincerely thank George Brookman and West Canadian Digital Imaging Inc. for their support to print and distribute **The Digital Examiner**.

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Earlier this year, Dr. Nicole Culos-Reed from the U of C started a pilot program for TrueNTH Lifestyle Management (LM). The goal of TrueNTH LM is to provide men across Canada with access to physical activity, nutrition, and stressreduction resources. These three LM components may benefit PCa survivors by decreasing treatment side effects and increasing overall fitness, health and quality of life.

The pilot program offered men evidence-based group physical activity and yoga classes, an individual exercise prescription based upon fitness assessments, and educational sessions and resources.

In Calgary, 34 men enrolled in the program, with 30 deciding to participate in the 12-week program following their initial assessment. Men came from all corners of Calgary, surrounding communities, rural areas, and from Medicine Hat.

Dr. Culos-Reed recently wrote to **PROSTAID Calgary** saying that the success of the pilot program was in large part due to the support received from PROSTAID Calgary, as the majority of men who participated heard about the program through a PROSTAID Calgary meeting, The Digital Examiner, or by word of mouth from a PROSTAID Calgary member.

Volunteer Opportunities

1. PROSTAID Calgary Booths

Calgary Stampeder versus BC Lions

McMahon Stadium, Friday, September 18 Tailgate party, 3PM – 7PM

2. Cowboys Casino

Monday / Tuesday, December 28 / 29, 2015.



This fall, the City of Calgary Recreation Department will offer TrueNTH LM at three facilities. All men living with prostate cancer, regardless of whether they participated in the initial pilot program, are encouraged to sign up for these free programs funded through the TrueNTH LM initiative.

Each participant will receive:

- Two sessions per week: 1 physical activity class and 1 yoga class each week;
- Fitness assessments to help tailor the group-based program to their needs; and
- Access to educational materials and resources.

We hope that all PROSTAID Calgary members will take advantage of these programs and continue to take a lead in helping promote wellness programming for men.

Thank you **PROSTAID Calgary** for your on-going support.

S. Nicole Culos-Reed, PhD, Professor Faculty of Kinesiology, University of Calgary

WWW.GETCHECKED.CA

The Man Van[™] is a resource of the **Prostate Cancer Centre** to increase awareness about prostate cancer and to provide baseline PSA blood tests for men 40 years and older. A Man Van[™] clinic will be held at the Calgary Stampeder *versus* BC Lions game at McMah-



on Stadium on Friday, September 18 from 3PM—7PM. **PROSTAID Calgary** will have two booths at the tailgate party prior to the Sept 18 game which starts at 7PM. We have invited some VIPs to join us at the game in a **Fire-Up for Prostate Cancer** with Darkside Racing's Top Fuel Dragster visibly 'wrapped' with our name and logo. Stay tuned