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Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Prostate Cancer

Proceedings from a Clinical Investigator Think Tank

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Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Prostate Cancer

A Continuing Medical Education Audio Program

OVERVIEW OF ACTIVITY

Prostate cancer is the most frequently diagnosed cancer in men, with an estimated 241,740 new cases in 2012 in the United States. Although virtually all locally advanced or metastatic sites of tumor are initially reliant on androgen stimulation for growth and respond to treatment with androgen deprivation therapy, inevitably resistance to hormone blockade eventually develops, culminating in the recurrence of highly aggressive castration-resistant prostate cancer (CRPC). Recently published randomized controlled studies focused specifically on this population have led to the emergence of novel therapeutic strategies for patients with CRPC and resulted in a paradigm shift to the multidisciplinary care of this disease. A number of pivotal data sets illustrating the benefits of several novel agents indicate that additional therapeutic options may soon be available that will warrant consideration and integration into prostate cancer care. The treatment landscape and available options for prostate cancer have thus broadened, making choices more challenging for many healthcare professionals and patients, and a once-stagnant systemic treatment algorithm, largely confined to medical or surgical castration, has evolved into delivery of cutting-edge antineoplastic therapy necessitating learning opportunities for urologists and medical oncologists. This CME program uses a roundtable discussion with leading prostate cancer clinical investigators to assist practicing clinicians in formulating up-to-date and appropriate clinical management strategies.

LEARNING OBJECTIVES

- Explore the emerging data and active research evaluating novel agents — including radiopharmaceuticals, androgen biosynthesis inhibitors, antiandrogens and clusterin antisense oligonucleotides — in the setting of advanced prostate cancer, and discuss the biologic basis for their clinical activity.
- Recall existing and emerging research demonstrating the effects of secondary hormonal interventions on quality and quantity of life for patients with chemotherapy-naïve and chemotherapy-pretreated CRPC, and use this information to guide treatment planning for these patients.
- Efficiently identify and educate patients with skeletal metastases about the efficacy and safety of emerging systemic bone-directed treatments.
- Employ case-based learning to effectively apply evidence-based research findings in the determination of best-practice sequencing of available systemic agents for patients with metastatic prostate cancer.
- Counsel appropriately selected patients with minimally symptomatic or asymptomatic advanced prostate cancer about sipuleucel-T as a treatment option, and define an approach to patient monitoring after treatment with this agent.

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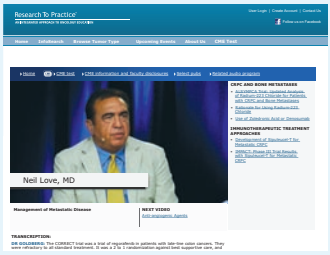
Video Highlights of the Clinical Investigator Think Tank



Check out highlight clips from this fascinating Think Tank featuring our esteemed clinical investigator panel discussing and debating some of the key clinical management issues in the field of prostate cancer. Visit www.ResearchToPractice.com/PCUTT112/Video for more information.

SELECT PUBLICATIONS

AFFINITY: A randomized phase 3 study comparing cabazitaxel/prednisone in combination with custirsen to cabazitaxel/prednisone for second-line chemotherapy in men with metastatic castrate resistant prostate cancer. NCT01578655

Crook JM et al. **Intermittent androgen suppression for rising PSA level after radiotherapy.** *N Engl J Med* 2012;367(10):895-903.

Crook JM et al. **A phase III randomized trial of intermittent versus continuous androgen suppression for PSA progression after radical therapy (NCIC CTG PR.7/SWOG JPR.7/CTSU JPR.7/UK Intercontinental Trial CRUKE/01/013).** *Proc ASCO* 2011;**Abstract 4514**.

George DJ et al. **Safety and activity of the investigational agent orteronel without prednisone in men with nonmetastatic castration-resistant prostate cancer and rising prostate-specific antigen: Updated results of a phase II study.** *Proc ASCO* 2012;**Abstract 4549**.

Gomella L et al. **Estimating the overall survival benefit of sipuleucel-T in the IMPACT trial accounting for crossover treatment in control subjects with autologous immunotherapy generated from cryopreserved cells.** *Proc AUA* 2012;**Abstract 683**.

Halabi S et al. **Prostate-specific antigen decline as a surrogate for overall survival in patients with metastatic castrate-resistant prostate cancer who failed first-line chemotherapy.** *Proc ASCO* 2012;**Abstract 4515**.

Hervonen P et al. **Biweekly docetaxel is better tolerated than conventional three-weekly dosing for advanced hormone-refractory prostate cancer.** *Anticancer Res* 2012;32(3):953-6.

Huber ML et al. **Interdisciplinary critique of sipuleucel-T as immunotherapy in castration-resistant prostate cancer.** *J Natl Cancer Inst* 2012;104(4):273-9.

Hussain M et al. **Intermittent (IAD) versus continuous androgen deprivation (CAD) in hormone sensitive metastatic prostate cancer (HSM1PC) patients (pts): Results of S9346 (INT-0162), an international phase III trial.** *Proc ASCO* 2012;**Abstract 4**.

Kantoff PW et al; IMPACT Study Investigators. **Sipuleucel-T immunotherapy for castration-resistant prostate cancer.** *N Engl J Med* 2010;363(5):411-22.

Kantoff P et al. **Updated survival results of the IMPACT trial of sipuleucel-T for metastatic castration-resistant prostate cancer (CRPC).** Genitourinary Cancers Symposium 2010;**Abstract 8**.

Oudard S et al. **First-line use of cabazitaxel in chemotherapy-naive patients with metastatic castration-resistant prostate cancer: A three-arm study in comparison with docetaxel.** *Proc ASCO* 2012;**Abstract TPS4696**.

Parker C et al. **Updated analysis of the phase III, double-blind, randomized, multinational study of radium-223 chloride in castration-resistant prostate cancer patients with bone metastases (ALSYMPCA).** *Proc ASCO* 2012;**Abstract LBA4512**.

Ryan CJ et al. **Interim analysis results of COU-AA-302, a randomized, phase III study of abiraterone acetate in chemotherapy-naive patients with metastatic castration-resistant prostate cancer.** *Proc ASCO* 2012;**Abstract LBA4518**.

Saad F et al; Canadian Uro-Oncology Group. **Randomized phase II trial of custirsen (OGX-011) in combination with docetaxel or mitoxantrone as second-line therapy in patients with metastatic castrate-resistant prostate cancer progressing after first-line docetaxel: CUOG trial P-06c.** *Clin Cancer Res* 2011;17(17):5765-73.

Sartor AO et al. **Radium-223 chloride impact on skeletal-related events and ECOG performance status in patients with castration-resistant prostate cancer with bone metastases: Interim results of a phase III trial (ALSYMPCA).** *Proc ASCO* 2012;**Abstract 4551**.

Scher HI et al. **Effect of MDV3100, an androgen receptor signaling inhibitor (ARSI), on overall survival in patients with prostate cancer postdocetaxel: Results from the phase III AFFIRM study.** Genitourinary Cancers Symposium 2012;**Abstract LBA1**.

Scher HI et al. **Increased survival with enzalutamide in prostate cancer after chemotherapy.** *N Engl J Med* 2012;367(13):1187-97.

Sheikh NA et al. **Sipuleucel-T immune parameters correlate with survival: An analysis of the randomized phase 3 clinical trials in men with castration-resistant prostate cancer.** *Cancer Immunol Immunother* 2012;[Epub ahead of print].

SYNERGY: A randomized phase 3 study comparing standard first-line docetaxel/prednisone to docetaxel/prednisone in combination with custirsen in men with metastatic castrate resistant prostate cancer. NCT01188187

POST-TEST

Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Prostate Cancer

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **The Phase III SWOG-S9346 trial reported that intermittent androgen deprivation is inferior to continuous androgen deprivation for patients with hormone-sensitive metastatic PC.**
   a. True
   b. False

2. **Which of the following agents are classified as androgen synthesis inhibitors, compounds that work by inhibiting the access of androgens such as testosterone and DHT to the androgen receptor?**
   a. Abiraterone acetate
   b. Orteronel
   c. Both a and b
   d. Neither a nor b

3. **The interim analysis of the results of the COU-AA-302 Phase III trial of abiraterone acetate/prednisone versus placebo/prednisone for patients with chemotherapy-naïve mCRPC demonstrated a statistically significant improvement in _____ with abiraterone acetate.**
   a. Progression-free survival
   b. Overall survival
   c. Both a and b

4. **The Phase III AFFIRM trial for men with mCRPC previously treated with docetaxel demonstrated that enzalutamide was superior to placebo with respect to _____.**
   a. Median overall survival
   b. PSA decline
   c. Median time to progression
   d. Objective response rate
   e. Quality-of-life improvement
   f. All of the above

5. **In the Phase III ALSYMPCA study, radium-223 chloride improved overall survival for patients with symptomatic CRPC with bone metastases.**
   a. True
   b. False

6. **Sipuleucel-T is a(n) _____.**
   a. Third-generation taxane
   b. Immunotherapeutic agent
   c. Antiandrogen with a high affinity for the androgen receptor

7. **The ongoing Phase III PROSELICA trial is evaluating _____ as second-line therapy for patients with mCRPC previously treated with docetaxel.**
   a. Cabazitaxel at 20 mg/m^2
   b. Cabazitaxel at 25 mg/m^2
   c. Docetaxel re-treatment
   d. Both a and b
   e. Both a and c

8. **Phase III trial data have reported a low incidence of treatment-associated seizures with which of the following agents?**
   a. Cabazitaxel
   b. Enzalutamide
   c. Sipuleucel-T
   d. Radium-223

9. **On the Phase II CUOG trial P-06c, which evaluated the novel antisense agent custirsen (OGX-011) in combination with docetaxel or mitoxantrone as second-line therapy for patients with mCRPC progressing after first-line docetaxel, patients who received the custirsen/docetaxel combination experienced a significant improvement in pain relief versus those who received custirsen/mitoxantrone.**
   a. True
   b. False

10. **The ongoing Phase III FIRSTANA trial is evaluating docetaxel versus _____ as first-line therapy for patients with mCRPC.**
    a. Cabazitaxel
    b. Radium-223
    c. Sipuleucel-T
    d. All of the above

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Current Controversies, Recent Developments and Emerging Strategies in the Practical Management of Prostate Cancer

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

PART 1 — Please tell us about your experience with this educational activity

How would you characterize your level of knowledge on the following topics?

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

	BEFORE	AFTER
Results with intermittent versus continuous androgen deprivation in patients with hormone-sensitive metastatic PC — SWOG-S9346 (INT-0162) trial — or rising PSA after radical therapy — NCIC CTG PR.7 trial	4 3 2 1	4 3 2 1
Mechanism of action and available research evidence with enzalutamide in CRPC	4 3 2 1	4 3 2 1
Updated results from a Phase II study of orteronel without prednisone for men with nonmetastatic CRPC and rising PSA levels	4 3 2 1	4 3 2 1
Phase II trial results and ongoing Phase III trials evaluating the novel antisense agent custirsen in mCRPC	4 3 2 1	4 3 2 1
Ongoing trials of cabazitaxel in mCRPC: FIRSTANA — first-line docetaxel versus cabazitaxel — and PROSELICA — 2 doses of cabazitaxel in patients who previously received docetaxel	4 3 2 1	4 3 2 1
Updated analysis of the Phase III ALSYMPCA study evaluating radium-223 chloride in patients with CRPC with bone metastases	4 3 2 1	4 3 2 1

Was the activity evidence based, fair, balanced and free from commercial bias?

☐ Yes ☐ No If no, please explain: .....

Please identify how you will change your practice as a result of completing this activity (select all that apply).

☐ This activity validated my current practice
☐ Create/revise protocols, policies and/or procedures
☐ Change the management and/or treatment of my patients
☐ Other (please explain): .....

If you intend to implement any changes in your practice, please provide 1 or more examples:

.....

The content of this activity matched my current (or potential) scope of practice.

☐ Yes ☐ No If no, please explain: .....

Please respond to the following learning objectives (LOs) by circling the appropriate selection:

4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not met N/A = Not applicable

As a result of this activity, I will be able to:

- Explore the emerging data and active research evaluating novel agents — including radiopharmaceuticals, androgen biosynthesis inhibitors, antiandrogens and clusterin antisense oligonucleotides — in the setting of advanced prostate cancer, and discuss the biologic basis for their clinical activity. ..... 4 3 2 1 N/M N/A
- Recall existing and emerging research demonstrating the effects of secondary hormonal interventions on quality and quantity of life for patients with chemotherapy-naïve and chemotherapy-pretreated CRPC, and use this information to guide treatment planning for these patients. ..... 4 3 2 1 N/M N/A
- Efficiently identify and educate patients with skeletal metastases about the efficacy and safety of emerging systemic bone-directed treatments. ..... 4 3 2 1 N/M N/A
- Employ case-based learning to effectively apply evidence-based research findings in the determination of best-practice sequencing of available systemic agents for patients with metastatic prostate cancer. ..... 4 3 2 1 N/M N/A
- Counsel appropriately selected patients with minimally symptomatic or asymptomatic advanced prostate cancer about sipuleucel-T as a treatment option, and define an approach to patient monitoring after treatment with this agent. ..... 4 3 2 1 N/M N/A

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:

.....

Would you recommend this activity to a colleague?

☐ Yes ☐ No

If no, please explain:.....

Additional comments about this activity:

.....

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☐ Yes, I am willing to participate in a follow-up survey.
☐ No, I am not willing to participate in a follow-up survey.

PART 2 — Please tell us about the faculty and moderator for this educational activity

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

Faculty	Knowledge of subject matter				Effectiveness as an educator			
Tomasz M Beer, MD	4	3	2	1	4	3	2	1
Robert Dreicer, MD, MS	4	3	2	1	4	3	2	1
Mario A Eisenberger, MD	4	3	2	1	4	3	2	1
William K Oh, MD	4	3	2	1	4	3	2	1
Daniel P Petrylak, MD	4	3	2	1	4	3	2	1
A Oliver Sartor, MD	4	3	2	1	4	3	2	1
Susan F Slovin, MD, PhD	4	3	2	1	4	3	2	1
Matthew R Smith, MD, PhD	4	3	2	1	4	3	2	1
Moderator	**Knowledge of subject matter**				**Effectiveness as an educator**			
Neil Love, MD	4	3	2	1	4	3	2	1

Please recommend additional faculty for future activities:

.....

Other comments about the faculty and moderator for this activity:

.....

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