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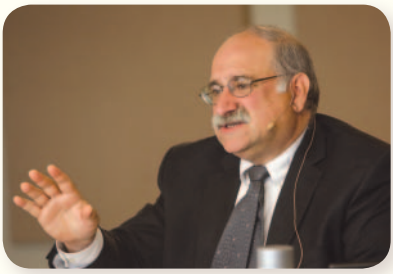
The Application of Existing and Emerging Research Findings to the Practical Management of Prostate Cancer

Proceedings from a Clinical Investigator Think Tank



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MODERATOR

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The Application of Existing and Emerging Research Findings to the Practical Management of Prostate Cancer

A Continuing Medical Education Audio Program

OVERVIEW OF ACTIVITY

Prostate cancer (PC) is the most frequently diagnosed cancer in men, with an estimated 241,740 new cases every year in the United States. Emerging data increasingly allow individualized treatment decision-making for localized PC, including the option of active surveillance and radiation therapy for those with high-risk disease after prostatectomy. In addition, while 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, resistance to hormone blockade inevitably develops, culminating in the recurrence of highly aggressive castration-resistant PC (CRPC). Recently published randomized, controlled studies have signaled the emergence of novel therapeutic strategies for patients with CRPC. This has led to a paradigm shift in the multidisciplinary care of patients with this disease. The treatment landscape and available options for PC 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 PC investigators to assist practicing clinicians in formulating up-to-date and appropriate clinical management strategies.

LEARNING OBJECTIVES

- Review emerging research data and ongoing trials evaluating the use of novel biomarkers and gene signatures to help patients with localized PC refine their risk of recurrence, and use this information to guide clinical decision-making, particularly regarding the role of active surveillance.
- Apply evidence-based decision-making regarding the role of adjuvant versus salvage radiation therapy in patients with adverse pathologic features after prostatectomy.
- Explore emerging data on the use of cytotoxic therapy in the setting of hormone-sensitive advanced PC, and consider this information when designing initial treatment plans for appropriate individuals.
- Recall existing and emerging research demonstrating the effects of secondary hormonal interventions on quality and quantity of life for patients with metastatic CRPC, and use this information to guide treatment planning.
- Consider available research data and expert perspectives on the efficacy and safety of radium-223 as monotherapy or in combination with other treatment modalities, and use this information to appropriately integrate this novel radio-pharmaceutical into clinical practice.
- Effectively apply evidence-based research findings in the determination of best-practice sequencing of available immunotherapeutic, chemotherapeutic and secondary hormonal agents for patients with metastatic PC.
- Explore the emerging data and active research evaluating novel agents in the setting of PSA-only recurrent or advanced PC, and discuss the biologic basis for their clinical activity.

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TRACKS 1-24

Issues in the Management of Localized Prostate Cancer

Track 1 **Case discussion:** A 58-year-old man with Stage T1C, Gleason 7 prostate cancer (PC) undergoes radical prostatectomy, has a steady postoperative PSA rise and receives salvage radiation therapy (RT)

Track 2 Perspectives on the use of ultrasensitive PSA monitoring and early salvage RT

Track 3 Rationale for the ongoing Phase III RTOG-0534 trial of short-term androgen-deprivation therapy (ADT) and pelvic lymph node RT with or without prostate RT for patients with PC with rising PSA after surgery

Track 4 **Case discussion:** A 66-year-old man with Gleason 8 PC undergoes radical prostatectomy followed by a rapid PSA rise

Track 5 **Case discussion:** A 58-year-old man with Crohn's disease and T2C, Gleason 7 PC previously treated with radical prostatectomy who now exhibits PSA-only disease and undergoes ADT

Track 6 Immediate versus deferred initiation of ADT in patients with PSA-only relapse

Track 7 Perspectives on intermittent versus continuous ADT for patients with PSA-only relapse

Track 8 Viewpoint on the use of second-generation endocrine agents for castration-resistant PSA-only disease

Track 9 **Case discussion:** A 62-year-old man with a strong family history of prostate and breast cancer and Gleason 6 PC for whom a multigene assay was used to decide between active surveillance and treatment

Track 10 Pros and cons of the Onco*type* DX® 17-gene prostate cancer assay and Prolaris® Cell Cycle Progression test

Track 11 Development and validation of the Onco*type* DX prostate and Prolaris assays for patients with localized PC

Track 12 Evolving role of genomic assays for patients with PC

Track 13 Potential use of multigene assays and/or multiparametric MRI to reduce the frequency of repeat biopsies for patients on active surveillance

Track 14 Impact of multigene assays on patient care

Track 15 Defining "active surveillance"

Track 16 Importance of multidisciplinary clinics

Track 17 Identification and precision targeting of PC with MRI fusion technology

Track 18 Individualized faculty approaches to counseling patients about active surveillance for localized PC

Track 19 Results of the Prostate Cancer Intervention Versus Observation Trial (PIVOT): A Phase III study of radical prostatectomy versus palliative expectant management for clinically localized PC

Track 20 Use of the Onco*type* DX Genomic Prostate Score (GPS) in decision-making regarding active surveillance for men with very low- to low-intermediate-risk PC

Track 21 Prediction of PC-specific disease progression with the Prolaris assay

Track 22 Limitations of current multigene assays in localized PC

Track 23 Cost effectiveness of active surveillance versus active treatment

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TRACKS 1-24

Current Treatment for Patients with Metastatic Prostate Cancer

Track 1 **Case discussion:** A 58-year-old man with Gleason 9 PC with extensive rib, spinal and pelvic metastases receives ADT and docetaxel

Track 2 Overall survival benefit for men with high-volume disease treated with ADT and docetaxel on the Phase III CHAARTED (ECOG-E3805) trial in hormone-sensitive, newly metastatic PC

Track 3 Perspectives on the lack of overall survival benefit in the Phase III GETUG-AFU 15 trial of ADT with or without docetaxel for noncastration-resistant metastatic PC

Track 4 **Case discussion:** A 65-year-old man with metastatic castration-resistant PC (mCRPC) who receives abiraterone acetate and enzalutamide sequentially

Track 5 Sequencing of second-generation endocrine therapy options for mCRPC

Track 6 Therapeutic options for patients with mCRPC whose disease progresses on abiraterone/prednisone

Track 7 Activity of enzalutamide in patients with mCRPC who experience disease progression after docetaxel and abiraterone

Track 8 Tolerability of enzalutamide versus abiraterone

Track 9 Results of the Phase III PREVAIL trial: Improvements in survival and quality of life with enzalutamide for men with chemotherapy-naïve mCRPC

Track 10 Final overall survival analysis of the Phase III COU-AA-302 trial of abiraterone for patients with mCRPC without prior chemotherapy

Track 11 Potential role of androgen receptor splice variant 7 (AR-V7) in predicting resistance to enzalutamide and abiraterone

Track 12 Detection of androgen receptor splice variants in patients with advanced PC

Track 13 **Case discussion:** A 63-year-old man with mCRPC, a painful hip lesion and multifocal bone metastases with no soft tissue disease experiences an excellent response with external beam RT, abiraterone and radium-223

Track 14 Antitumor and bone-protective activity of radium-223

Track 15 Side-effect profile and incidence of secondary cancers and thrombocytopenia with radium-223

Track 16 Results of TOPARP: A Phase II trial evaluating the antitumor activity of the PARP inhibitor olaparib in unselected sporadic CRPC

Track 17 Response to the MET and VEGFR2 inhibitor cabozantinib on a clinical trial

Track 18 COMET-1: Results of a Phase III trial of cabozantinib for mCRPC

Track 19 Improvements in bone scans and pain with cabozantinib in mCRPC

Track 20 Results of the Phase II ARMOR2 trial: Activity of the multitargeted oral steroid analog galeterone in men with CRPC

Track 21 Activity and safety of enzalutamide in combination with abiraterone in bone mCRPC

Track 22 Rationale for the ongoing Phase III ALLIANCE A031201 trial of enzalutamide with or without abiraterone and prednisone for mCRPC

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Track 24 Factors associated with time to development of neuroendocrine PC (NEPC) and survival from NEPC diagnosis: A systematic review and pooled analysis

SELECT PUBLICATIONS

A phase III trial of short term androgen deprivation with pelvic lymph node or prostate bed only radiotherapy (SPPORT) in prostate cancer patients with a rising PSA after radical prostatectomy. NCT00567580

A randomized phase 3 study comparing cabazitaxel/prednisone in combination with custirsen (OGX-011) to cabazitaxel/prednisone for second-line chemotherapy in men with metastatic castrate resistant prostate cancer (AFFINITY). NCT01578655

Antonarakis ES et al. **AR-V7 and resistance to enzalutamide and abiraterone in prostate cancer.** *N Engl J Med* 2014;371(11):1028-38.

Armstrong AJ et al. **Primary, secondary, and quality-of-life endpoint results from PREVAIL, a phase 3 study of enzalutamide in men with metastatic castration resistant prostate cancer (mCRPC).** *Proc ASCO* 2014;**Abstract 5007**.

Badrising S et al. **Clinical activity and tolerability of enzalutamide (MDV3100) in patients with metastatic, castration-resistant prostate cancer who progress after docetaxel and abiraterone treatment.** *Cancer* 2014;120(7):968-75.

Beer TM et al. **Enzalutamide in metastatic prostate cancer before chemotherapy.** *N Engl J Med* 2014;371(5):424-33.

Bishoff JT et al. **Prognostic utility of the cell cycle progression score generated from biopsy in men treated with prostatectomy.** *J Urol* 2014;192(2):409-14.

Chi KN et al. **A randomized phase 3 study comparing first-line docetaxel/prednisone (DP) to DP plus custirsen in men with metastatic castration-resistant prostate cancer.** *Proc ESMO* 2014;**Abstract 755O**.

Cooperberg MR et al. **Validation of a cell-cycle progression gene panel to improve risk stratification in a contemporary prostatectomy cohort.** *J Clin Oncol* 2013;31(11):1428-34.

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

Cullen J et al. **A prospectively-designed study to determine the association of a 17-gene genomic prostate score with recurrence following surgery for localised prostate cancer.** *Proc ESMO* 2014;**Abstract LBA22**.

Dransfield DT et al. **Identification of a companion diagnostic (CDx) that utilizes circulating tumor cells (CTCs) to detect an androgen receptor splice variant (AR-V7) in metastatic castrate resistant prostate cancer (mCRPC).** *Proc Prostate Cancer Foundation* 2014;**Abstract 036**.

Efstathiou E et al. **Enzalutamide in combination with abiraterone acetate in bone metastatic castration resistant prostate cancer.** *Proc ASCO* 2014;**Abstract 5000**.

Garcia-Albeniz X et al. **Immediate versus deferred initiation of androgen deprivation therapy in prostate cancer patients with PSA-only relapse.** *Proc ASCO* 2014;**Abstract 5003**.

Gravis G et al. **Androgen-deprivation therapy alone or with docetaxel in non-castrate metastatic prostate cancer (GETUGAFU15): A randomised, open-label, phase 3 trial.** *Lancet Oncol* 2013;14(2):149-58.

Hoskin P et al. **Efficacy and safety of radium-223 dichloride in patients with castration-resistant prostate cancer and symptomatic bone metastases, with or without previous docetaxel use: A prespecified subgroup analysis from the randomised, double-blind, phase 3 ALSYMPCA trial.** *Lancet Oncol* 2014;15(12):1397-406.

Klein EA et al. **A 17-gene assay to predict prostate cancer aggressiveness in the context of Gleason grade heterogeneity, tumor multifocality, and biopsy undersampling.** *Eur Urol* 2014;66(3):550-60.

Mateo J et al. **Antitumour activity of the PARP inhibitor olaparib in unselected sporadic castration-resistant prostate cancer in the TOPARP trial.** *Proc ESMO* 2014;**Abstract LBA20**.

Parker C et al. **1.5-year post-treatment follow-up of radium-223 dichloride safety in patients with castration-resistant prostate cancer and symptomatic bone metastases from the phase 3 ALSYMPCA study.** *Proc ASCO* 2014;**Abstract 5070**.

Ryan CJ et al. **Final overall survival analysis of COU-AA-302, a randomized phase 3 study of abiraterone acetate in metastatic castration-resistant prostate cancer patients without prior chemotherapy.** *Proc ESMO* 2014;**Abstract 753O**.

Sartor O et al. **Effect of radium-223 dichloride on symptomatic skeletal events in patients with castration-resistant prostate cancer and bone metastases: Results from a phase 3, double-blind, randomised trial.** *Lancet Oncol* 2014;15(7):738-46.

Smith MR et al. **Cabozantinib in chemotherapy-pretreated metastatic castration-resistant prostate cancer: Results of a phase II nonrandomized expansion study.** *J Clin Oncol* 2014;32(30):3391-9.

Sweeney C et al. **Chemohormonal therapy versus hormonal therapy for hormone naïve high volume newly metastatic prostate cancer: ECOG led phase III randomized trial.** *Proc ESMO* 2014;**Abstract 756O**.

Taplin M et al. **Galeterone in 4 patient populations of men with CRPC: Results from ARMOR2.** *Proc ESMO* 2014;**Abstract 757O**.

POST-TEST

The Application of Existing and Emerging Research Findings to the Practical Management of Prostate Cancer

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **The Phase III CHAARTED trial evaluating hormonal therapy with or without docetaxel for patients with hormone-sensitive newly metastatic PC demonstrated that the combination of standard ADT and 6 cycles of docetaxel significantly improved overall survival compared to standard ADT alone in _____.**
   a. Men with low-volume disease
   b. Men with high-volume disease
   c. Both a and b

2. **The Phase III GETUG-AFU 15 trial evaluating ADT with or without docetaxel for noncastrate metastatic PC demonstrated that the combination of ADT and 10 cycles of docetaxel significantly improved overall survival compared to ADT alone.**
   a. True
   b. False

3. **Which of the following multigene assays designed to assist physicians in choosing the most appropriate treatment options is included in the NCCN guidelines?**
   a. Onco*type* DX prostate assay
   b. Prolaris assay
   c. ConfirmMDx® test
   d. ProMark™ assay
   e. Both a and b
   f. All of the above
   g. None of the above

4. **Which of the following multigene assays incorporates elements of the patient's NCCN risk category along with the patient's GPS to generate risk of adverse pathology?**
   a. Onco*type* DX prostate assay
   b. Prolaris assay
   c. Both a and b
   d. Neither a nor b

5. **What is the mechanism of action of olaparib?**
   a. Androgen receptor inhibitor
   b. Immunotherapeutic agent
   c. PARP inhibitor

6. **Of patients with mCRPC initially treated with abiraterone, responses have been reported in approximately _____ of those who subsequently received enzalutamide.**
   a. 0%
   b. 50%
   c. 100%

7. **The Phase III PIVOT trial evaluating radical prostatectomy versus palliative expectant management for clinically localized PC reported that radical prostatectomy was associated with a reduction in all-cause mortality for which of the following groups of patients?**
   a. Those with low-risk disease
   b. Those with high-risk disease
   c. Both a and b
   d. Neither a nor b

8. **A recent paper published in *The New England Journal of Medicine* analyzing the presence of AR-V7 in circulating tumor cells from men with advanced PC reported that patients with AR-V7-positive disease had lower PSA response rates, suggesting that the presence of AR-V7 may be associated with resistance to enzalutamide and abiraterone.**
   a. True
   b. False

9. **The Phase II TOPARP trial evaluating the antitumor activity of olaparib for patients with unselected sporadic CRPC reported _____ for those who received this agent.**
   a. Significant declines in PSA
   b. Reductions in levels of circulating tumor cells
   c. Both a and b

10. **A presentation at ASCO 2014 evaluating the feasibility of enzalutamide in combination with abiraterone in bone mCRPC reported the combination to have a favorable safety profile without any clinically meaningful pharmacokinetic drug-drug interactions.**
    a. True
    b. False

EDUCATIONAL ASSESSMENT AND CREDIT FORM

The Application of Existing and Emerging Research Findings to 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
Rationale for use of the Onco*type* DX GPS in decision-making regarding active surveillance for men with very low- to low-intermediate-risk PC	4 3 2 1	4 3 2 1
Comparative results from the Phase III CHAARTED and GETUG-AFU 15 trials and implications for the use of standard ADT in combination with docetaxel for high-volume, hormone-sensitive PC	4 3 2 1	4 3 2 1
Clinical and biologic factors affecting the selection and sequencing of abiraterone and enzalutamide for patients with CRPC	4 3 2 1	4 3 2 1
Correlation between the presence of AR-V7 and response to enzalutamide and abiraterone	4 3 2 1	4 3 2 1
Safety of radium-223 in combination with other systemic therapeutic approaches (eg, chemotherapy, other bone-targeted agents, hormonal therapy)	4 3 2 1	4 3 2 1
Potential benefits and limitations of active surveillance versus definitive treatment	4 3 2 1	4 3 2 1

Practice Setting:

☐ Academic center/medical school ☐ Community cancer center/hospital ☐ Group practice
☐ Solo practice ☐ Government (eg, VA) ☐ Other (please specify).....

Approximately how many new patients with prostate cancer do you see per year? ..... patients

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:

- Review emerging research data and ongoing trials evaluating the use of novel biomarkers and gene signatures to help patients with localized PC refine their risk of recurrence, and use this information to guide clinical decision-making, particularly regarding the role of active surveillance. . . . . 4 3 2 1 N/M N/A
- Apply evidence-based decision-making regarding the role of adjuvant versus salvage radiation therapy in patients with adverse pathologic features after prostatectomy. . . . . 4 3 2 1 N/M N/A
- Explore emerging data on the use of cytotoxic therapy in the setting of hormone-sensitive advanced PC, and consider this information when designing initial treatment plans for appropriate individuals. . . . . 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 metastatic CRPC, and use this information to guide treatment planning. . . . . 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

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

- Consider available research data and expert perspectives on the efficacy and safety of radium-223 as monotherapy or in combination with other treatment modalities, and use this information to appropriately integrate this novel radiopharmaceutical into clinical practice. . . . . 4 3 2 1 N/M N/A
- Effectively apply evidence-based research findings in the determination of best-practice sequencing of available immunotherapeutic, chemotherapeutic and secondary hormonal agents for patients with metastatic PC. . . . . 4 3 2 1 N/M N/A
- Explore the emerging data and active research evaluating novel agents in the setting of PSA-only recurrent or advanced PC, and discuss the biologic basis for their clinical activity. . 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: . . . . . .

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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
Ketan K Badani, MD	4 3 2 1	4 3 2 1
Robert Dreicer, MD, MS	4 3 2 1	4 3 2 1
Leonard G Gomella, 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
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:

. . . . . .

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Professional Designation:

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Signature: . . . . . Date: . . . . .

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