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

Proceedings from a Clinical Investigator Think Tank

FACULTY
Ketan K Badani, MD
Robert Dreicer, MD, MS
Leonard G Gomella, MD
Daniel P Petrylak, MD
A Oliver Sartor, MD

MODERATOR
Neil Love, MD

 CONTENTS
2 Audio CDs

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Neil Love, MD
Research To Practice
One Biscayne Tower
2 South Biscayne Boulevard, Suite 3600
Miami, FL 33131

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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 responsive 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 radionuclide 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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Release date: June 2015; Expiration date: June 2016
### FACULTY

<table>
<thead>
<tr>
<th>Ketan K Badani, MD</th>
<th>Daniel P Petrylak, MD</th>
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<tr>
<td>Vice Chairman of Urology and Robotic Operations&lt;br&gt;Director, Comprehensive Kidney Cancer Center&lt;br&gt;Mount Sinai Health System&lt;br&gt;Director of Robotic Surgery&lt;br&gt;Mount Sinai St Luke's and Roosevelt Hospitals&lt;br&gt;Professor of Urology&lt;br&gt;Icahn School of Medicine&lt;br&gt;New York, New York</td>
<td>Professor of Medicine&lt;br&gt;Director, Prostate and GU Medical Oncology&lt;br&gt;Co-Director, Signal Transduction Program&lt;br&gt;Yale Cancer Center&lt;br&gt;New Haven, Connecticut</td>
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<tr>
<th>Robert Dreicer, MD, MS</th>
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<tr>
<td>Division of Hematology and Oncology&lt;br&gt;Department of Medicine&lt;br&gt;University of Virginia School of Medicine&lt;br&gt;Charlottesville, Virginia</td>
<td>Medical Director, Tulane Cancer Center&lt;br&gt;Laborde Professor of Cancer Research&lt;br&gt;Professor of Medicine and Urology&lt;br&gt;Tulane Medical School&lt;br&gt;New Orleans, Louisiana</td>
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<th>Leonard G Gomella, MD</th>
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<td>The Bernard W Godwin Professor of Prostate Cancer&lt;br&gt;Chairman, Department of Urology&lt;br&gt;Associate Director, Jefferson Sidney Kimmel Cancer Center&lt;br&gt;Clinical Director, Jefferson Sidney Kimmel Cancer Center Network&lt;br&gt;Editor-in-Chief, Canadian Journal of Urology&lt;br&gt;Philadelphia, Pennsylvania</td>
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### MODERATOR

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<th>Neil Love, MD</th>
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<tr>
<td>Research To Practice&lt;br&gt;Miami, Florida</td>
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Submit them to us via Facebook or Twitter and we will do our best to get them answered for you

Facebook.com/ResearchToPractice or Twitter @DrNeilLove
| 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 Oncotype DX® 17-gene prostate cancer assay and Prolaris® Cell Cycle Progression test |
| Track 11 | Development and validation of the Oncotype 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 Oncotype 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 |
| Track 24 | Case discussion: A 64-year-old man presents with inflammatory colitis and Gleason 7 PC and undergoes an Oncotype DX prostate assay and then active surveillance |
| 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-naive 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 unslected 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 |
| Track 23 | Results of a Phase III trial of docetaxel/prednisone with or without the novel antisense agent custirsen (OGX-011) as first-line therapy for mCRPC |
| 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


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.


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.


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

POST-TEST

The questions are to be answered on the answer sheet following this page. Please circle the letter of your answer to each question and write any additional comments in the space provided. This section contains 10 questions, each with one or more correct responses.

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. Oncotype 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. Oncotype 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
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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?

<table>
<thead>
<tr>
<th>Topic</th>
<th>BEFORE</th>
<th>AFTER</th>
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<tbody>
<tr>
<td>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</td>
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<td>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</td>
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<td>Clinical and biologic factors affecting the selection and sequencing of abiraterone and enzalutamide for patients with CRPC</td>
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<td>Correlation between the presence of AR-V7 and response to enzalutamide and abiraterone</td>
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<td>Safety of radium-223 in combination with other systemic therapeutic approaches (eg, chemotherapy, other bone-targeted agents, hormonal therapy)</td>
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<td>Potential benefits and limitations of active surveillance versus definitive treatment</td>
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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:

<table>
<thead>
<tr>
<th>LO</th>
<th>4 = Yes</th>
<th>3 = Will consider</th>
<th>2 = No</th>
<th>1 = Already doing</th>
<th>N/M = LO not met</th>
<th>N/A = Not applicable</th>
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<td>As a result of this activity, I will be able to:</td>
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<td>• Apply evidence-based decision-making regarding the role of adjuvant versus salvage radiation therapy in patients with adverse pathologic features after prostatectomy.</td>
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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

<table>
<thead>
<tr>
<th>Faculty</th>
<th>Knowledge of subject matter</th>
<th>Effectiveness as an educator</th>
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<tr>
<td>Ketan K Badani, MD</td>
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<tr>
<td>Moderator</td>
<td>Knowledge of subject matter</td>
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<tr>
<td>Neil Love, MD</td>
<td>4 3 2 1</td>
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Please recommend additional faculty for future activities:

REQUEST FOR CREDIT — Please print clearly

Name: ................................................................. Specialty: .................................................................

Professional Designation:
☐ MD  ☐ DO  ☐ PharmD  ☐ NP  ☐ RN  ☐ PA  ☐ Other .................................................................

Street Address: ................................................................. Box/Suite: .................................................................

City, State, Zip: .................................................................

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I certify my actual time spent to complete this educational activity to be _________ hour(s).

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

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Proceedings from a Clinical Investigator Think Tank

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Ketan K Badani, MD
Robert Dreicer, MD, MS
Leonard G Gomella, MD
Daniel P Petrylak, MD
A Oliver Sartor, MD

MODERATOR

Neil Love, MD

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