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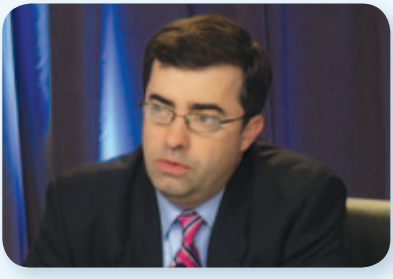
Renal Cell Cancer and the General Medical Oncologist: Where We Are and Where We're Headed

Proceedings from a Clinical Investigator Think Tank



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MODERATOR

Neil Love, MD

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Renal Cell Cancer and the General Medical Oncologist: Where We Are and Where We're Headed

A Continuing Medical Education Audio Program

OVERVIEW OF ACTIVITY

Renal cell carcinoma (RCC) is by far the most common primary tumor known to develop within the kidney and renal pelvis. Although RCC may present as diverse histologic subtypes, more than 85% of these are clear cell cancers. Historically, treatment of advanced clear cell RCC — resistant to conventional chemotherapeutics — had been limited to cytokine immunotherapy. Beginning in 2005, this paradigm shifted rapidly and dramatically, culminating in the FDA approval of 7 new therapeutic agents or regimens for advanced-stage disease. Thus, practicing oncologists must maintain current knowledge of the benefits and risks of the multiple acceptable treatment approaches. To bridge the gap between research and patient care, this program features a case-based roundtable discussion with leading investigators to assist medical oncologists, hematology-oncology fellows and other allied healthcare professionals involved in the treatment of RCC with the formulation of up-to-date clinical management strategies.

LEARNING OBJECTIVES

- Identify patient characteristics that may help to distinguish the individualized utility of cytoreductive nephrectomy in the era of effective targeted therapies for metastatic RCC (mRCC).
- Recall criteria for identification of patients with asymptomatic mRCC who may be suitable for watchful waiting or treatment holidays, and apply these to therapeutic decision-making.
- Educate patients with mRCC about the safety and tolerability of multikinase VEGF tyrosine kinase inhibitors, mTOR inhibitors and VEGF monoclonal antibody therapy.
- Recommend supportive measures to enhance the tolerability of targeted therapeutic agents for RCC, including the use of dose reductions, schedule changes or alternative therapies.
- Apply the results of existing and emerging clinical research to the evidence-based selection of front-line and subsequent therapy for mRCC.
- Recall the scientific rationale for and efficacy of approved and novel investigational immunotherapeutic agents demonstrating activity in RCC.
- Counsel appropriately selected patients with RCC about the availability of ongoing clinical trial participation.

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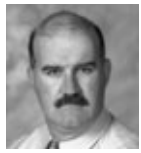

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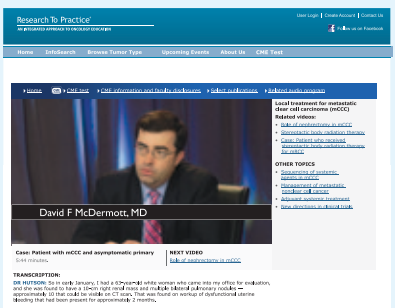
Track 41 **Case discussion:** A 64-year-old patient with clear cell RCC and sarcomatoid differentiation receives late-line cabozantinib therapy on a clinical trial

Video Highlights of the Clinical Investigator Think Tank



Visit www.ResearchToPractice.com/RCCUTT113/Video to access a number of short video segments and corresponding transcripts from the Think Tank featuring the faculty discussing and debating some of the key clinical management and research issues in the field of renal cell cancer.

SELECT PUBLICATIONS

A randomized Phase II study of Afinitor (RAD001) vs Sutent (sunitinib) in patients with metastatic non-clear cell renal cell carcinoma (ASPEN). NCT01108445

Angevin E et al. **Phase I study of dovitinib (TKI258), an oral FGFR, VEGFR, and PDGFR inhibitor, in advanced or metastatic renal cell carcinoma.** *Clin Cancer Res* 2013;19(5):1257-68.

ATLAS: Adjuvant axitinib treatment of renal cancer: A randomized double-blind Phase 3 study of adjuvant axitinib vs placebo in subjects at high risk of recurrent RCC. NCT01599754

Bailey AS et al. **Pdl-1/pdl-3 (programmed death ligand-1/3) tissue expression and response to treatment with IL2 and antiangiogenic therapies.** *Proc ASCO* 2013;**Abstract 4521**.

Belldegrun AS et al. **ARISER: A randomized double blind phase III study to evaluate adjuvant cG250 treatment versus placebo in patients with high-risk ccRCC: Results and implications for adjuvant clinical trials.** *Proc ASCO* 2013;**Abstract 4507**.

Blesius A et al. **Are tyrosine kinase inhibitors still active in patients with metastatic renal cell carcinoma previously treated with a tyrosine kinase inhibitor and everolimus? Experience of 36 patients treated in France in the RECORD-1 trial.** *Clin Genitourin Cancer* 2013;11(2):128-33.

Cho DC et al. **Clinical activity, safety, and biomarkers of MPDL3280A, an engineered PD-L1 antibody in patients with metastatic renal cell carcinoma.** *Proc ASCO* 2013;**Abstract 4505**.

Drake CG et al. **Survival, safety, and response duration results of nivolumab (anti-PD-1; BMS-936558; ONO-4538) in a phase I trial in patients with previously treated metastatic renal cell carcinoma: Long-term patient follow-up.** *Proc ASCO* 2013;**Abstract 4514**.

EVEREST: EVErolimus for Renal cancer Ensuing Surgical Therapy, a Phase III study. NCT01120249

Hutson TE et al. **Axitinib versus sorafenib as first-line therapy in patients with metastatic renal cell carcinoma.** Genitourinary Cancers Symposium 2013;**Abstract LBA348**.

Hutson T et al. **Temsirolimus vs sorafenib as second line therapy in metastatic renal cell carcinoma: Results from the INTORSECT trial.** *Proc ESMO* 2012;**Abstract 918**.

Kirkwood JM, Tarhini AA. **Biomarkers of therapeutic response in melanoma and renal cell carcinoma: Potential inroads to improved immunotherapy.** *J Clin Oncol* 2009;27(16):2583-5.

Motzer RJ et al. **A phase III comparative study of nivolumab versus everolimus in patients with advanced or metastatic renal cell carcinoma previously treated with antiangiogenic therapy.** *Proc ASCO* 2013;**Abstract TPS4592**.

Motzer RJ et al. **Record-3: Phase II randomized trial comparing sequential first-line everolimus (EVE) and second-line sunitinib (SUN) versus first-line SUN and second-line EVE in patients with metastatic renal cell carcinoma.** *Proc ASCO* 2013;**Abstract 4504**.

Pal SK et al. **Impact of age on treatment trends and clinical outcome in patients with metastatic renal cell carcinoma.** *J Geriatr Oncol* 2013;4(2):128-33.

Porta C et al. **Efficacy and safety of everolimus in elderly patients with metastatic renal cell carcinoma: An exploratory analysis of the outcomes of elderly patients in the RECORD-1 trial.** *Eur Urol* 2012;61(4):826-33.

Procopio G et al. **Sorafenib tolerability in elderly patients with advanced renal cell carcinoma: Results from a large pooled analysis.** *Br J Cancer* 2013;108(2):311-8.

PROTECT: A randomized, double-blind, placebo-controlled Phase III study to evaluate the efficacy and safety of pazopanib as adjuvant therapy for subjects with localized or locally advanced RCC following nephrectomy. NCT01235962

Sabatino M et al. **Serum vascular endothelial growth factor and fibronectin predict clinical response to high-dose interleukin-2 therapy.** *J Clin Oncol* 2009;27(16):2645-52.

Silberstein JL et al. **Systematic classification and prediction of complications after nephrectomy in patients with metastatic renal cell carcinoma (RCC).** *BJU Int* 2012;110(9):1276-82.

SORCE: A Phase III randomised double-blind study comparing sorafenib with placebo in patients with resected primary renal cell carcinoma at high or intermediate risk of relapse. NCT00492258

Sunitinib Treatment of Renal Adjuvant Cancer (S-TRAC): A randomized double blind Phase 3 study of adjuvant sunitinib vs placebo in subjects at high risk of recurrent RCC. NCT00375674

POST-TEST

Renal Cell Cancer and the General Medical Oncologist: Where We Are and Where We're Headed

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **A retrospective analysis by Silberstein and colleagues evaluating patients with RCC who underwent cytoreductive nephrectomy at Memorial Sloan-Kettering Cancer Center (MSKCC) reported which of the following to be the factor most likely to lead to patients suffering a complication during the perioperative period?**
   a. Poor risk by MSKCC criteria
   b. Lactate dehydrogenase level
   c. Patient performance status

2. **The ongoing S-TRAC trial is evaluating the efficacy and safety of _____ versus placebo for patients with localized RCC who are at high risk for disease recurrence.**
   a. Axitinib
   b. Sorafenib
   c. Sunitinib
   d. All of the above

3. **Results from the Phase II RECORD-3 trial, which compared sequential first-line everolimus and second-line sunitinib to the standard therapy of first-line sunitinib and second-line everolimus for patients with mRCC, indicated that the treatment paradigm in this setting should remain sunitinib followed by everolimus.**
   a. True
   b. False

4. **The Phase III INTORSECT trial of temsirolimus versus sorafenib for patients with mRCC for whom prior sunitinib therapy had failed reported a statistically significant progression-free survival advantage for temsirolimus compared to sorafenib.**
   a. True
   b. False

5. **A Phase III trial of axitinib versus sorafenib as first-line therapy for mRCC reported a 3.6-month improvement in median progression-free survival in favor of axitinib, but this improvement was not statistically significant.**
   a. True
   b. False

6. **The Phase II ASPEN trial is evaluating _____ versus sunitinib for patients with nonclear cell mRCC.**
   a. Everolimus
   b. Temsirolimus
   c. Both a and b

7. **Results from a retrospective analysis of patients with mRCC treated on the single-arm IL-2 SELECT trial reported that _____ may predict better response to IL-2 therapy.**
   a. Clear cell histology
   b. Nonclear cell histology
   c. PD-L1/PD-L3 tissue expression

8. **Which of the following metabolic abnormalities may be associated with the administration of everolimus?**
   a. Hyperglycemia
   b. Hypercholesterolemia
   c. Hypertriglyceridemia
   d. All of the above

9. **Although results from the Phase III ARISER trial of the anti-G250 antibody girentuximab versus placebo as adjuvant therapy for high-risk clear cell RCC were negative, a post hoc analysis suggested that patients with a higher carbonic anhydrase score fared better with regard to disease-free survival and overall survival than patients with a low carbonic anhydrase score.**
   a. True
   b. False

10. **The ongoing Phase III PROTECT study is evaluating pazopanib versus placebo as adjuvant treatment for localized RCC.**
    a. True
    b. False

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Renal Cell Cancer and the General Medical Oncologist: Where We Are and Where We're Headed

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
Criteria for identification of patients with asymptomatic mRCC suitable for watchful waiting or treatment holidays	4 3 2 1	4 3 2 1
RECORD-3: Results of a Phase II trial comparing sequential first-line everolimus and second-line sunitinib to the opposite sequence for mRCC	4 3 2 1	4 3 2 1
Results from the Phase III ARISER trial of the anti-G250 antibody girentuximab versus placebo as adjuvant therapy for high-risk clear cell RCC	4 3 2 1	4 3 2 1
PD-L1/PD-L3 tissue expression as a potential predictor of response to IL-2 therapy	4 3 2 1	4 3 2 1
Results of a Phase III trial of axitinib versus sorafenib as first-line therapy for mRCC	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:

- Identify patient characteristics that may help to distinguish the individualized utility of cytoreductive nephrectomy in the era of effective targeted therapies for metastatic RCC (mRCC). . . . . 4 3 2 1 N/M N/A
- Recall criteria for identification of patients with asymptomatic mRCC who may be suitable for watchful waiting or treatment holidays, and apply these to therapeutic decision-making. . . . . 4 3 2 1 N/M N/A
- Educate patients with mRCC about the safety and tolerability of multikinase VEGF tyrosine kinase inhibitors, mTOR inhibitors and VEGF monoclonal antibody therapy. . . . . 4 3 2 1 N/M N/A
- Recommend supportive measures to enhance the tolerability of targeted therapeutic agents for RCC, including the use of dose reductions, schedule changes or alternative therapies. . . . . 4 3 2 1 N/M N/A
- Apply the results of existing and emerging clinical research to the evidence-based selection of front-line and subsequent therapy for mRCC. . . . . 4 3 2 1 N/M N/A
- Recall the scientific rationale for and efficacy of approved and novel investigational immunotherapeutic agents demonstrating activity in RCC. . . . . 4 3 2 1 N/M N/A
- Counsel appropriately selected patients with RCC about the availability of ongoing clinical trial participation. . . . . 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:

.....

As part of our ongoing, continuous quality-improvement effort, we conduct postactivity follow-up surveys to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey.

☐ 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
Robert A Figlin, MD	4 3 2 1	4 3 2 1
Thomas E Hutson, DO, PharmD	4 3 2 1	4 3 2 1
David F McDermott, MD	4 3 2 1	4 3 2 1
Robert J Motzer, MD	4 3 2 1	4 3 2 1
David I Quinn, MBBS, PhD	4 3 2 1	4 3 2 1
Walter Stadler, 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:

.....

Other comments about the faculty and moderator for this activity:

.....

.....

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