Rounds with the Investigators

National Research Leaders Provide Their Perspectives on the Management of Actual Patients with Multiple Myeloma

A Case-Based Roundtable Discussion

Co-Chair

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Contents

2 Audio CDs

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Rounds with the Investigators: National Research Leaders Provide Their Perspectives on the Management of Actual Patients with Multiple Myeloma

A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY

Multiple myeloma (MM) is a plasma cell neoplasm that accounts for approximately 10% of all hematologic cancers and carries with it the worst death to new cases ratio (3:4) among all the blood cancer subtypes. Patients with smoldering (asymptomatic) myeloma may be cared for by observation only because the course of disease is often indolent for many years without therapy. However, patients with more advanced, active disease require immediate induction therapy in an effort to prepare eligible candidates for autologous stem cell transplant (ASCT). Optimal initial induction therapy for both ASCT candidates and those not eligible remains an area of clinical controversy, and multiple acceptable treatment options appear to merit consideration. Recent clinical research demonstrates an abundance of treatment options now available to patients with both newly diagnosed and relapsed or refractory MM.

To provide clinicians with therapeutic strategies to address the disparate needs of patients with MM, the *Rounds with the Investigators* audio series employs an innovative case-based approach that gathers the perspectives of leading MM investigators and community oncologists as they explore the intricacies of making treatment decisions. Upon completion of this CME activity, medical oncologists and hematologists should be able to formulate an up-to-date and more complete approach to the care of patients with MM.

LEARNING OBJECTIVES

- Employ case-based learning to effectively implement evidence-based diagnostic and therapeutic approaches for patients with newly diagnosed and relapsed/refractory MM.
- Recognize and apply essential patient care considerations that enable the successful delivery of proteasome inhibitor- and/or IMiD-containing systemic therapy for MM.
- Adhere to published guidelines and expert recommendations when selecting frequency of administration and total duration of bisphosphonates for patients with MM.
- Appropriately identify and counsel patients with MM who may experience quantitative and qualitative benefit from stem cell transplantation.
- Recognize treatment-associated side effects and offer patients acceptable alternative dosing/administration and/or supportive management interventions to address them.
- Use biomarkers to assess risk for patients with MM, and recommend systemic treatment commensurate with prognosis and likelihood of therapeutic response in the induction, consolidation and maintenance settings.
- Recall emerging efficacy and safety data with newer-generation IMiDs and proteasome inhibitors currently under investigation in MM.

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TRACKS 1-20

ROUNDTABLE DISCUSSION WITH RAFAEL FONSECA, MD AND RAVI VIJ, MD

Track 1 **Case discussion:** A 51-year-old woman with a painful, disabling hip lesion is diagnosed with ISS Stage II multiple myeloma (MM) with multiple bone lesions

Track 2 Short- and long-term therapeutic options for transplant-eligible patients

Track 3 Reduction in bortezomib-associated peripheral neuropathy: Subcutaneous versus intravenous administration and weekly versus twice-weekly schedule

Track 4 Management of impending bone fractures

Track 5 Cyclophosphamide, bortezomib and dexamethasone (CyBorD) with subcutaneous bortezomib as pretransplant therapy

Track 6 Cereblon: A direct protein target for the immunomodulatory and antiproliferative actions of lenalidomide and pomalidomide

Track 7 Improved long-term outcomes with post-transplant lenalidomide maintenance therapy

Track 8 Risk of second primary cancers with post-transplant maintenance lenalidomide

Track 9 Efficacy of the novel proteasome inhibitor carfilzomib in MM

Track 10 Carfilzomib-associated toxicities

Track 11 Activity and tolerability of the oral proteasome inhibitor MLN9708

Track 12 **Case discussion:** A 79-year-old man with hyperdiploid MM with 80% plasma cells in the bone marrow, trisomy of chromosomes 7, 9 and 11 and multiple lytic bone lesions

Track 13 Viewpoints on duration of treatment and antimyeloma effects of zoledronic acid

Track 14 Preemptive dose reduction and duration of antimyeloma therapy for elderly patients with MM

Track 15 **Case discussion:** A 74-year-old man with a 3-cm right femoral neck lytic lesion diagnosed as a kappa-restricted plasmacytoma has 30% plasma cells in the marrow and an 11;14 translocation and 1q duplication

Track 16 Assessment of cytogenetic abnormalities in the treatment of MM

Track 17 Studies of rituximab-based therapy for patients with CD20-positive MM

Track 18 Novel monoclonal antibodies in combination with lenalidomide- or bortezomib-based therapy

Track 19 New options for patients with amyloidosis

Track 20 Consideration of intravenous versus subcutaneous bortezomib-based therapy for patients with MM and amyloidosis

TRACKS 1-23

ROUNDTABLE DISCUSSION WITH JEFFREY L WOLF, MD AND JEFFREY A ZONDER, MD

Track 1 **Case discussion:** An 86-year-old man with ISS Stage I IgG lambda MM, right femoral fracture and multiple lytic bone lesions receives dose-adjusted melphalan/prednisone/bortezomib (MPV)

Track 2 Perspectives on the use of subcutaneous bortezomib

Track 3 Consideration for and duration of maintenance therapy for patients with MM

Track 4 Clinical experience with injection site discomfort and hyperpigmentation with subcutaneous bortezomib administration

Track 5 Preemptive dose reduction for older patients with myeloma

Track 6 Choice of alkylating agent to combine with novel agents

Track 7 Use of an attenuated RVD regimen for older patients with MM

Track 8 **Case discussion:** A 60-year-old man with mild anemia, weight loss and a 5-cm right clavicular mass is diagnosed with ISS Stage I lambda light chain MM

Track 9 IFM/DFCI 2009: A Phase III study of RVD with stem cell transplant as initial therapy versus stem cell transplant at first relapse in the initial management of MM

Track 10 Perspectives on the inclusion of radiation therapy with systemic treatment for a patient with MM and a clavicular lesion

Track 11 Management of smoldering myeloma

Track 12 **Case discussion:** An 83-year-old man with anemia, hypercalcemia and acute renal failure is diagnosed with ISS Stage III MM and receives MPV

Track 13 Role of bortezomib for patients with acute renal failure secondary to MM

Track 14 Dose-reduced lenalidomide for patients with renal dysfunction

Track 15 **Case discussion:** A 79-year-old woman with MM initially treated with MPV has progressive renal failure

Track 16 Efficacy and toxicity of the third-generation IMiD pomalidomide in patients with prior exposure to lenalidomide and thalidomide

Track 17 Activity and reduced rates of peripheral neuropathy with the second-generation proteasome inhibitor carfilzomib in relapsed/refractory and bortezomib-naïve MM

Track 18 Initial Phase I/II study results with the novel proteasome inhibitor MLN9708 as a single agent for relapsed/refractory MM and in combination with lenalidomide and dexamethasone for previously untreated MM

Track 19 **Case discussion:** A 74-year-old man with a solitary plasmacytoma with monoclonal expression of kappa light chain

Track 20 Management of solitary plasmacytomas

Track 21 Radiation therapy alone or in combination with lenalidomide- or bortezomib-based chemotherapy in the treatment of solitary plasmacytomas

Track 22 Late-line therapy considerations for patients with relapsed/refractory plasmacytoma

Track 23 Mechanism of action and preliminary efficacy data with elotuzumab in relapsed/refractory MM

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Jakubowiak AJ et al. **Carfilzomib, lenalidomide, and dexamethasone in newly diagnosed multiple myeloma: Initial results of phase I/II MMRC trial.** *Proc ASH* 2010;**Abstract 862**.

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Moreau P et al. **Subcutaneous versus intravenous administration of bortezomib in patients with relapsed multiple myeloma: A randomised, phase 3, non-inferiority study.** *Lancet Oncol* 2011;12(5):431-40.

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POST-TEST

Rounds with the Investigators: National Research Leaders Provide Their Perspectives on the Management of Actual Patients with Multiple Myeloma

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **The results of the IFM and CALGB trials failed to demonstrate an improvement in progression-free survival among patients with myeloma receiving maintenance lenalidomide compared to placebo after transplant.**
   a. True
   b. False

2. **The oral proteasome inhibitor MLN9708 in combination with lenalidomide and dexamethasone produced a response rate approaching 100% for patients with previously untreated MM.**
   a. True
   b. False

3. **The irreversible proteasome inhibitor carfilzomib has generated high-quality responses and reduced rates of _____.**
   a. Hyperglycemia
   b. Dyspnea
   c. Neuropathy

4. **The MRC Myeloma IX study reported a survival advantage for patients with newly diagnosed myeloma who received zoledronic acid.**
   a. True
   b. False

5. **In a recent review article by Drs Palumbo and Anderson in *The New England Journal of Medicine*, the authors contend that the novel agents bortezomib and lenalidomide should not be dose reduced at the initiation of treatment for older patients.**
   a. True
   b. False

6. **A publication by Fonseca and colleagues in *Blood* reported rapid and complete responses with CyBorD in patients with amyloidosis.**
   a. True
   b. False

7. **The Phase III IFM/DFCI 2009 study is evaluating _____ with stem cell transplant as initial therapy versus stem cell transplant at first relapse.**
   a. CyBorD
   b. Melphalan/prednisone/thalidomide
   c. Lenalidomide/dexamethasone
   d. RVD

8. **Results published by Hutchison and colleagues indicated that patients with dialysis-dependent acute renal failure secondary to myeloma who received chemotherapy and extended hemodialysis with a high cutoff filter sustained reductions in serum free light chain concentrations and recovered independent renal function.**
   a. True
   b. False

9. **Preliminary data suggest that patients with myeloma who have a high level of cereblon in their bone marrow respond better to IMiDs than those with little or no cereblon in their bone marrow.**
   a. True
   b. False

10. **Which of the following can be attributed to the use of subcutaneous weekly bortezomib administration compared to standard twice-weekly intravenous administration?**
    a. Less neuropathy
    b. Equivalent efficacy
    c. Both a and b

EDUCATIONAL ASSESSMENT AND CREDIT FORM

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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
IFN and CALGB studies of post-transplant maintenance lenalidomide	4 3 2 1	4 3 2 1
Effects of bortezomib schedule and route of administration on peripheral neuropathy	4 3 2 1	4 3 2 1
Potential roles of novel proteasome inhibitors (MLN9708, carfilzomib) and the novel IMiD pomalidomide in MM	4 3 2 1	4 3 2 1
IFM/DFCI 2009: A Phase III study of RVD and stem cell transplant as initial therapy versus stem cell transplant at first relapse	4 3 2 1	4 3 2 1
Bortezomib-based therapy and extended high-cutoff hemodialysis as treatment for acute renal failure secondary to MM	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
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☐ 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.

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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:

- Employ case-based learning to effectively implement evidence-based diagnostic and therapeutic approaches for patients with newly diagnosed and relapsed/refractory MM. .... 4 3 2 1 N/M N/A
- Recognize and apply essential patient care considerations that enable the successful delivery of proteasome inhibitor- and/or IMiD-containing systemic therapy for MM. ..... 4 3 2 1 N/M N/A
- Adhere to published guidelines and expert recommendations when selecting frequency of administration and total duration of bisphosphonates for patients with MM. ..... 4 3 2 1 N/M N/A
- Appropriately identify and counsel patients with MM who may experience quantitative and qualitative benefit from stem cell transplantation. ..... 4 3 2 1 N/M N/A
- Recognize treatment-associated side effects and offer patients acceptable alternative dosing/administration and/or supportive management interventions to address them. ..... 4 3 2 1 N/M N/A
- Use biomarkers to assess risk for patients with MM, and recommend systemic treatment commensurate with prognosis and likelihood of therapeutic response in the induction, consolidation and maintenance settings. ..... 4 3 2 1 N/M N/A
- Recall emerging efficacy and safety data with newer-generation IMiDs and proteasome inhibitors currently under investigation in MM. ..... 4 3 2 1 N/M N/A

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.....

Would you recommend this activity to a colleague?

☐ Yes ☐ No

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

Faculty	Knowledge of subject matter	Effectiveness as an educator
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Ravi Vij, MD	4 3 2 1	4 3 2 1
Jeffrey L Wolf, MD	4 3 2 1	4 3 2 1
Jeffrey A Zonder, 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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