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Myelodysplastic Syndromes™

UPDATE

Conversations with Oncology Investigators

Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

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Myelodysplastic Syndromes™ UPDATE

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OVERVIEW OF ACTIVITY

The clinical management of myelodysplastic syndromes (MDS) remains a challenge from both a diagnostic and a treatment standpoint, despite recent gains in the understanding of this heterogeneous disease. Determining which treatment approach is most appropriate requires careful consideration of patient characteristics, physician expertise and available health-system resources. To bridge the gap between research and patient care, this issue of *Myelodysplastic Syndromes Update* features one-on-one discussions with leading hematology-oncology investigators. By providing information on the latest clinical developments in the context of expert perspectives, this activity assists medical oncologists, hematologists and hematology-oncology fellows with the formulation of evidence-based and current therapeutic strategies, which in turn facilitates optimal patient care.

LEARNING OBJECTIVES

- Recognize the key cancer-defining features of MDS, and counsel patients accordingly regarding their prognosis and treatment goals and options.
- Appraise the role of molecular testing for MDS to facilitate diagnosis, prognostication and treatment decision-making.
- Formulate a treatment algorithm for lower- and higher-risk MDS, considering patient- and disease-related factors, including cytogenetic abnormalities.
- Consider the available efficacy and safety data with lenalidomide, with or without erythropoiesis-stimulating agents, in patients with low- to intermediate-risk MDS with and without del(5q), and identify patients with MDS appropriate for this treatment.
- Evaluate the potential advantages of oral administration compared to the standard parenteral administration of hypomethylating agents.
- Ascertain the utility and consider the future role of novel agents such as luspatercept in the management of anemia in patients with MDS.
- Recall promising investigational agents (eg, anti-PD-1/PD-L1 monoclonal antibodies, venetoclax, IDH1/2 inhibitors) and combination strategies, and counsel appropriately selected patients regarding clinical trial enrollment.

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Interview with Mikkael A Sekeres, MD, MS

Tracks 1-19

Track 1	Clinical utility of molecular testing for myelodysplastic syndromes (MDS)
Track 2	Genetic alterations in different subtypes of MDS
Track 3	Clonal evolution underlying the long-term course in the development of MDS
Track 4	Frequency and prognostic significance of cytogenetic abnormalities in patients with therapy-related MDS
Track 5	Mechanism of action of the transforming growth factor-beta (TGF-β) inhibitor luspatercept and its potential role for patients with MDS and ring sideroblasts
Track 6	**Case discussion:** A 76-year-old man with lower-risk MDS and del(5q) receives an erythropoiesis-stimulating agent
Track 7	Misperception of MDS as a benign disease
Track 8	Prognosis for patients with MDS
Track 9	Clinical trial options for patients with lower-risk MDS
Track 10	Pharmacodynamic, pharmacokinetic and quality-of-life considerations with the use of oral hypomethylating agents
Track 11	Perspective on the preliminary activity observed with anti-PD-1/PD-L1 checkpoint inhibitors in MDS
Track 12	**Case discussion:** A 60-year-old woman with a history of β-thalassemia and mutations in SF3B1 and CEBPα is diagnosed with an MDS/myeloproliferative neoplasm (MPN) overlap disorder
Track 13	Approach to treatment for patients with MDS/MPN overlap disorders
Track 14	**Case discussion:** An 84-year-old man who has refractory anemia with ring sideroblasts and thrombocytosis receives lenalidomide
Track 15	Mechanism of action and activity of lenalidomide in patients with lower-risk MDS without del(5q)
Track 16	**Case discussion:** A 65-year-old woman with anemia and ring sideroblasts without significant dysplasia for whom a definitive diagnosis cannot be made receives darbepoetin and subsequently requires red blood cell transfusions
Track 17	**Case discussion:** An 89-year-old man who lived in Hiroshima, Japan for 18 months after the nuclear bomb explosion during World War II develops high-risk MDS and experiences relapse with acute myeloid leukemia (AML) while receiving azacitidine
Track 18	Challenges in hospice care for patients with MDS/AML requiring red blood cell and platelet transfusions
Track 19	Incorporation of molecular abnormalities into the prognostic scoring systems for MDS

Interview with Steven D Gore, MD

Tracks 1-19

Track 1	Global perception of MDS as a disease
Track 2	Prognostic scoring systems for MDS
Track 3	Spectrum of mutations in MDS
Track 4	Heterogeneity in treatment goals among patients with MDS
Track 5	Treatment algorithm for patients with MDS
Track 6	Key clinical question: Are erythropoiesis-stimulating agents useful for patients with lower-risk MDS?
Track 7	Role of lenalidomide and timing of administration for patients with lower-risk MDS and del(5q)
Track 8	Activity of hypomethylating agents in patients with disease progression on lenalidomide
Track 9	Mechanistic explanation for the lack of activity of pomalidomide in MDS
Track 10	Lenalidomide in combination with erythropoiesis-stimulating agents for lower-risk MDS without del(5q)

Interview with Dr Gore (continued)

Track 11	**Case discussion:** A 79-year-old woman with rheumatoid arthritis and chronic anemia is diagnosed with MDS with del(5q) and receives lenalidomide
Track 12	**Case discussion:** A 59-year-old man diagnosed with a myeloid neoplasm and mutations in IDH2, SRSF2, RUNX1 and ASXL1 is considered for an allogeneic stem cell transplant
Track 13	Clinical development of orally administered isocitrate dehydrogenase inhibitors in MDS and AML
Track 14	Promising early results with the combination of venetoclax and hypomethylating agents
Track 15	Potential for pulmonary complications in patients receiving hypomethylating agents and anti-PD-1/PD-L1 antibodies on clinical trials
Track 16	**Case discussion:** A 69-year-old man with refractory cytopenia with multilineage dysplasia and ringed sideroblasts receives darbepoetin/G-CSF but is now transfusion dependent and enrolling on a clinical trial of luspatercept
Track 17	Mechanism of action of the TGF-β superfamily inhibitor luspatercept and its impact on anemia
Track 18	Clinical development and potential advantages of oral azacitidine (CC-486) compared to the standard parenteral agent
Track 19	**Case discussion:** A 70-year-old man and heavy smoker who received radiation therapy for prostate cancer is diagnosed with AML with MDS-related changes and mutations in IDH2, SRSF2, DNMT3A, WT1 and RUNX1

Related Video Program

Visit www.ResearchToPractice.com/MDSU117/Video to view video highlights of the interviews with (from left) Drs Sekeres and Gore by Dr Love and earn additional *AMA PRA Category 1 Credit™*.

Topics covered include:

- The role of molecular testing for patients with MDS
- Treatment options for patients with low- and high-risk MDS
- Potential advantages of oral versus standard parenteral administration of hypomethylating agents
- Activity of lenalidomide in patients with MDS with and without del(5q)
- Emerging data with novel agents (eg, anti-PD-1/PD-L1 antibodies, venetoclax, luspatercept) for patients with MDS

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Chen N et al. **Pharmacokinetics and exposure-response of luspatercept in patients with anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS): Preliminary results from Phase 2 studies.** *Proc ASH* 2016;**Abstract 1990**.

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QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Epidemiological studies from the Atomic Bomb Disease Institute in Japan observed a 17-fold increase in the rate of MDS occurrence among people exposed to the atomic bomb explosions during World War II compared to the general population.**
   a. True
   b. False

2. **Use of the TGF-β inhibitor luspatercept may result in improvements in which of the following cytopenias observed in MDS?**
   a. Thrombocytopenia
   b. Anemia
   c. Neutropenia
   d. None of the above

3. **Which patients with lower-risk MDS who have not yet required blood transfusions are more likely to respond to erythropoiesis-stimulating agents?**
   a. Those with higher erythropoietin levels
   b. Those with lower erythropoietin levels
   c. Neither a nor b

4. **What is the response rate with hypomethylating agents for patients with lower-risk MDS?**
   a. Less than 10%
   b. Between 30% and 40%
   c. Higher than 60%

5. **Approximately what proportion of patients with lower-risk del(5q) MDS who are blood transfusion dependent can achieve transfusion independence with lenalidomide treatment?**
   a. Less than 20%
   b. 40%
   c. 60%

6. **Approximately 25% of patients with lower-risk MDS without del(5q) respond to treatment with lenalidomide.**
   a. True
   b. False

7. **The rate of cure for patients with MDS undergoing transplantation is approximately 30% to 40%, whereas the mortality rate associated with transplantation is 1% to 3%.**
   a. True
   b. False

8. **The IPSS-R prognostic scoring system comprises which of the following risk categories for patients with MDS?**
   a. High, intermediate and low
   b. Very high, high, intermediate, low and very low
   c. Neither a nor b

9. **For patients with lower-risk MDS and del(5q) who experience disease progression while receiving lenalidomide therapy, the response rate to subsequent treatment with a hypomethylating agent is _____.**
   a. Similar to the response rate for patients with higher-risk MDS initiating treatment with a hypomethylating agent
   b. Lower than the response rate for patients with higher-risk MDS initiating treatment with a hypomethylating agent
   c. Neither a nor b: The response rate in this setting is unknown and subject to evaluation in clinical trials

10. **Which patients with MDS and otherwise similar prognostic indicators are likely to have better treatment outcomes?**
    a. Patients with a secondary, therapy-related myeloid neoplasm
    b. Patients with a primary, de novo myeloid neoplasm
    c. Neither a nor b

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Myelodysplastic Syndromes Update — Volume 1, Issue 1

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
Evidence for the long-term course of the clonal evolution underlying the development of MDS	4 3 2 1	4 3 2 1
Activity of lenalidomide with or without erythropoiesis-stimulating agents in patients with lower-risk MDS with or without del(5q)	4 3 2 1	4 3 2 1
Mechanism of action of the TGF-β inhibitor luspatercept and its impact on anemia	4 3 2 1	4 3 2 1
Biologic rationale for the potential efficacy benefits of more frequent and protracted scheduling of oral hypomethylating agents	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).....

How many new patients with MDS 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:

- Recognize the key cancer-defining features of MDS, and counsel patients accordingly regarding their prognosis and treatment goals and options. ..... 4 3 2 1 N/M N/A
- Appraise the role of molecular testing for MDS to facilitate diagnosis, prognostication and treatment decision-making. ..... 4 3 2 1 N/M N/A
- Formulate a treatment algorithm for lower- and higher-risk MDS, considering patient- and disease-related factors, including cytogenetic abnormalities. ..... 4 3 2 1 N/M N/A
- Consider the available efficacy and safety data with lenalidomide, with or without erythropoiesis-stimulating agents, in patients with low- to intermediate-risk MDS with and without del(5q), and identify patients with MDS appropriate for this treatment. ..... 4 3 2 1 N/M N/A
- Evaluate the potential advantages of oral administration compared to the standard parenteral administration of hypomethylating agents. ..... 4 3 2 1 N/M N/A
- Ascertain the utility and consider the future role of novel agents such as luspatercept in the management of anemia in patients with MDS. ..... 4 3 2 1 N/M N/A

- Recall promising investigational agents (eg, anti-PD-1/PD-L1 monoclonal antibodies, venetoclax, IDH1/2 inhibitors) and combination strategies, and counsel appropriately selected patients regarding clinical trial enrollment. . . . . 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:

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

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

Faculty	Knowledge of subject matter	Effectiveness as an educator
Mikkael A Sekeres, MD, MS	4 3 2 1	4 3 2 1
Steven D Gore, MD	4 3 2 1	4 3 2 1
Editor	**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 editor for this activity:

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