Oncology Investigators Provide Perspectives on the Prevention and Management of Tumor Lysis Syndrome

FACULTY INTERVIEWS

William G Wierda, MD, PhD

Amit Lahoti, MD

EDITOR

Neil Love, MD

OVERVIEW OF ACTIVITY

Tumor lysis syndrome (TLS) is an oncologic emergency characterized by the rapid onset of hyperuricemia, hyperkalemia, hyperphosphatemia, hypocalcemia and/or acute renal failure. Despite the relatively rare incidence of TLS, the clinical landscape of this syndrome changed dramatically with the April 11, 2016 FDA approval of the Bcl-2 inhibitor venetoclax for relapsed/refractory chronic lymphocytic leukemia (CLL) harboring the del(17p) chromosomal abnormality. Given the availability of venetoclax and emerging evidence of its antitumor activity in non-del(17p) CLL and other cancer types, it is likely that concern over TLS will greatly increase in general oncology practice. To bridge the gap between research and patient care, this program uses one-on-one discussions with leading oncology and nephrology investigators to help overcome clinician uncertainties and alleviate current practice gaps surrounding the prevention and management of this potentially devastating complication of effective cancer treatment.

LEARNING OBJECTIVES

- Understand the pathophysiology of TLS, recognize its disease- and treatment-related risk factors and establish an evidence-based approach for the prevention and management of this oncologic emergency.
- Identify patients at increased risk for TLS or its complications (eg, those with increased baseline uric acid, the elderly, those with renal or cardiac dysfunction), and institute appropriate treatment modifications, including early intervention with rasburicase.
- Formulate an approach to manage TLS-associated metabolic abnormalities — hyperuricemia, hyperkalemia, hyperphosphatemia, hypocalcemia and concomitant renal insufficiency — including recognition of when nephrology consultation is warranted.
- Appraise the risk-benefit profiles of chemoimmunotherapy treatments and targeted agents and regimens for CLL, and develop management strategies for the unique toxicities associated with recently approved therapeutics.
- Recognize the increased risk of TLS in patients with CLL treated with venetoclax, and implement approaches to ensure that appropriate administration protocols are followed to mitigate the risk of this potentially fatal toxicity.

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CE INFORMATION

FACULTY AFFILIATIONS

William G Wierda, MD, PhD
DB Lane Cancer Research
Distinguished Professor
Department of Leukemia
Division of Cancer Medicine
The University of Texas
MD Anderson Cancer Center
Houston, Texas

Amit Lahoti, MD
Associate Professor
Department of Nephrology
Division of Internal Medicine
The University of Texas
MD Anderson Cancer Center
Assistant Professor, Department of Internal Medicine
Baylor College of Medicine
Instructor, Division of Internal Medicine
The University of Texas Medical School at Houston
Houston, Texas

EDITOR

Neil Love, MD
Research To Practice
Miami, Florida

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FACULTY — **Dr Lahoti** had no relevant conflicts of interest to disclose. The following faculty (and his spouse/partner) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Wierda** — Consulting Agreement: Sanofi Genzyme; Contracted Research: AbbVie Inc, Acerta Pharma, Genentech BioOncology, Gilead Sciences Inc, GlaxoSmithKline, Juno Therapeutics, Karyopharm Therapeutics, Kite Pharma Inc, miRagen Therapeutics Inc, Novartis, Pharmacyclics LLC, an AbbVie Company, Sunesis Pharmaceuticals Inc.

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Interview with William G Wierda, MD, PhD

Tracks 1-27

Track 1	**Case:** A 28-year-old man with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia starts induction hyper-CVAD and dasatinib
Track 2	Diagnostic criteria and identification of patients at risk for tumor lysis syndrome (TLS)
Track 3	Clinical care of patients at high risk for TLS
Track 4	Allopurinol for hyperuricemia in patients at lower risk for TLS
Track 5	Rasburicase for patients at higher risk for TLS
Track 6	Correlation between bulk of disease and clinical course of TLS
Track 7	TLS-associated renal failure
Track 8	**Case:** A 60-year-old man with previously untreated Stage III trisomy 12 chronic lymphocytic leukemia (CLL) harboring an IGHV gene mutation receives FCR and prophylactic allopurinol
Track 9	Relationship between renal function and risk of TLS
Track 10	Management of anti-CD20 antibody-related infusion reactions
Track 11	Infrequency of TLS in solid tumors
Track 12	Gradual dose escalation with venetoclax to mitigate the risk of TLS
Track 13	TLS as an on-target effect of venetoclax in CLL
Track 14	Investigational strategies combining venetoclax with other agents in CLL
Track 15	Tolerability of venetoclax in CLL
Track 16	Complementary activity of venetoclax and ibrutinib
Track 17	**Case:** A 70-year-old patient with previously treated CLL and 17p deletion experiences disease progression and receives venetoclax
Track 18	Risk stratification for TLS in patients initiating treatment with venetoclax
Track 19	Creatinine clearance as a modifier of TLS risk
Track 20	Algorithm for patients at high risk for TLS who are initiating venetoclax treatment
Track 21	Approach for patients at medium risk for TLS who are initiating venetoclax treatment
Track 22	Use of venetoclax in lieu of ibrutinib in patients with atrial fibrillation who are receiving anticoagulation treatment
Track 23	Rates of ibrutinib discontinuation due to toxicity
Track 24	Restarting dose escalation of venetoclax after a treatment hold
Track 25	**Case:** A 72-year-old patient with previously treated CLL and a low creatinine clearance receives salvage venetoclax
Track 26	Potential for fixed-duration or endpoint-based treatment with venetoclax in CLL
Track 27	**Case:** A 62-year-old patient with CLL and a low risk of TLS initiates dose-escalation treatment with venetoclax

Interview with Amit Lahoti, MD

Tracks 1-36

Track 1	Incidence of TLS in patients receiving CAR T-cell therapy
Track 2	Pathophysiology of TLS
Track 3	Monitoring renal function in patients at risk for TLS
Track 4	**Case:** A 46-year-old man with metastatic melanoma and chronic renal disease experiences TLS after initiating nanoparticle albumin-bound (*nab*) paclitaxel

Interview with Dr Lahoti (continued)

Track 5	Renal-associated toxicities in patients receiving immune checkpoint inhibitors
Track 6	Differing mechanisms of action of allopurinol and rasburicase
Track 7	Dosing, administration and tolerability of rasburicase
Track 8	Clinical consequences of hyperkalemia
Track 9	Supportive measures for patients experiencing hyperkalemia

Video Program

View the corresponding video interviews with (from left) Drs Wierda and Lahoti by Dr Love at www.ResearchToPractice.com/TumorLysis17/Video

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Submit them to us via Facebook or Twitter and we will do our best to get them answered for you

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SELECT PUBLICATIONS

A phase II study of venetoclax and ibrutinib in patients with chronic lymphocytic leukemia (CLL). NCT02756897

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POST-TEST

Oncology Investigators Provide Perspectives on the Prevention and Management of Tumor Lysis Syndrome

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **TLS is characterized by the rapid onset of _____.**
   a. Hyperkalemia
   b. Hyperuricemia
   c. Hyperphosphatemia
   d. Hypocalcemia
   e. All of the above
   f. Both a and c
   g. Both b and d

2. **Use of rasburicase is contraindicated in patients with _____.**
   a. 17p deletion
   b. G6PD (glucose-6-phosphate dehydrogenase) deficiency
   c. Trisomy 12

3. **Venetoclax is currently FDA approved for the treatment of _____ in patients who have received at least 1 prior therapy.**
   a. CLL with 17p deletion
   b. CLL without 17p deletion
   c. Both a and b
   d. Neither a nor b

4. **Which of the following is the mechanism of action of venetoclax?**
   a. Bcl-2 inhibitor
   b. CAR T-cell therapy
   c. Immune checkpoint inhibitor

5. **Venetoclax is dosed and administered in which of the following fashions?**
   a. 20 mg once daily
   b. 400 mg once daily
   c. Initiated at 20 mg and gradually escalated to the target dose of 400 mg once daily

6. **Hospitalization for the purpose of inpatient monitoring for TLS is required for all patients initiating therapy with venetoclax.**
   a. True
   b. False

7. **Which of the following is the most common toxicity other than TLS for which venetoclax is dose reduced?**
   a. Diarrhea
   b. Fatigue
   c. Neutropenia

8. **Patients with severe TLS can experience acute renal failure, although this issue is typically reversible.**
   a. True
   b. False

9. **Which side effect is of greatest concern for patients with acute leukemias receiving CAR T-cell therapy?**
   a. Cytokine release syndrome
   b. Renal failure
   c. TLS

10. **A meta-analysis published by Feng and colleagues evaluating the efficacy and cost of single-dose rasburicase versus the FDA-approved daily dosing of rasburicase for 5 days in the prevention and treatment of TLS demonstrated response rates with the single-dose approach to be _____ to those with daily dosing for the prophylaxis of high-risk TLS.**
    a. Inferior
    b. Noninferior/equivalent
    c. Superior

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Oncology Investigators Provide Perspectives on the Prevention and Management of Tumor Lysis Syndrome

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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
Strategies to effectively mitigate TLS in patients initiating venetoclax treatment (ie, dose ramping, prophylaxis, monitoring, et cetera)	4 3 2 1	4 3 2 1
Results of a meta-analysis evaluating single-dose rasburicase versus the FDA-approved daily dosing of rasburicase for 5 days in the prevention and treatment of TLS	4 3 2 1	4 3 2 1
Investigational strategies and ongoing trials evaluating venetoclax-based regimens for CLL	4 3 2 1	4 3 2 1
Risk-benefit ratio for patients with aggressive lymphomas treated with CAR T-cell therapy	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 of your patients develop TLS 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: .....

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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:

- Understand the pathophysiology of TLS, recognize its disease- and treatment-related risk factors and establish an evidence-based approach for the prevention and management of this oncologic emergency. . . . . 4 3 2 1 N/M N/A
- Identify patients at increased risk for TLS or its complications (eg, those with increased baseline uric acid, the elderly, those with renal or cardiac dysfunction), and institute appropriate treatment modifications, including early intervention with rasburicase. . . . . 4 3 2 1 N/M N/A
- Formulate an approach to manage TLS-associated metabolic abnormalities — hyperuricemia, hyperkalemia, hyperphosphatemia, hypocalcemia and concomitant renal insufficiency — including recognition of when nephrology consultation is warranted. . . . . 4 3 2 1 N/M N/A

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

- Appraise the risk-benefit profiles of chemoimmunotherapy treatments and targeted agents and regimens for CLL, and develop management strategies for the unique toxicities associated with recently approved therapeutics. . . . . 4 3 2 1 N/M N/A
- Recognize the increased risk of TLS in patients with CLL treated with venetoclax, and implement approaches to ensure that appropriate administration protocols are followed to mitigate the risk of this potentially fatal toxicity.. . . . . 4 3 2 1 N/M N/A

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. . . . . .

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Faculty	**Knowledge of subject matter**	**Effectiveness as an educator**
William G Wierda, MD, PhD	4 3 2 1	4 3 2 1
Amit Lahoti, 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

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A Continuing Education Audio Program

Editor	Neil Love, MD
Director, Clinical Content and CPD/CME	Kathryn Ault Ziel, PhD
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Contact Information	Neil Love, MD Research To Practice One Biscayne Tower 2 South Biscayne Boulevard, Suite 3600 Miami, FL 33131 Fax: (305) 377-9998 Email: DrNeilLove@ResearchToPractice.com
For CME/CNE Information	Email: CE@ResearchToPractice.com

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

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