LYMPHOMA RESEARCH • FOUNDATION

FRONTLINE

A LYMPHOMA ROUNDS PUBLICATION

Spring 2016 Issue 3

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Frontline is a Lymphoma Research Foundation (LRF) publication that features selected case presentations from LRF's ***Lymphoma Rounds*** professional education program, which provides a forum for local lymphoma healthcare professionals to meet on a regular basis to discuss actual lymphoma cases in a collaborative environment. ***Lymphoma Rounds*** is currently held in six U.S. cities with participation of over 35 academic centers.

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Treatment of Multiply-Relapsed Hodgkin Lymphoma with Immune Checkpoint Inhibitors

Dr. Schuster speaking at Philadelphia Lymphoma Rounds

Presenters

Trent Wang, DO, MPH, *Fox Chase Cancer Center/ Temple Health*
Stefan Barta, MD, MS, MRCP, *Fox Chase Cancer Center/ Temple Health*

Case Background

In 2007, a 35-year-old man presented with a left axillary mass, malaise, and night sweats. He had no significant past medical or surgical history and was not on any medications. His family history included pancreatic cancer in his maternal grandmother, bone cancer in his paternal grandfather, and multiple myeloma in his uncle. His social history included occasional smoking and tobacco use over 20 pack-years that was down to an occasional cigarette at the time of presentation. He was a social beer drinker and worked as a machinist.

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Treatment of Multiply-Relapsed Hodgkin Lymphoma with Immune Checkpoint Inhibitors

Continued from page 1

Dr. Barta and Dr. Wang

Diagnosis

A positron emission tomography/computed tomography (PET/CT) scan revealed lymphadenopathy and avidity in the supraclavicular, cervical, left axillary, and porta hepatis lymph nodes. A left axillary lymph node excisional biopsy revealed Hodgkin lymphoma, nodular sclerosis subtype. His lymphoma was staged as IIIB, with a low International Prognostic Score (IPS) of 1.

Case Evolution

In April 2007, the patient received six cycles of ABVD (doxorubicin, bleomycin, vinblastine, and dacarbazine) but was found to have primary refractory disease, with an increasing left axillary lymph node. He was then given salvage ICE (ifosfamide, carboplatin, etoposide). A PET/CT scan after two cycles of ICE indicated that he had chemotherapy-sensitive disease (Deauville, 2). In May 2008, he underwent an autologous stem cell transplantation (SCT) with BEAM (carmustine, etoposide, cytarabine, melphalan) conditioning, which induced a complete response (CR). Six months later, a PET/CT scan showed new fluorodeoxyglucose (FDG)-avid retroperitoneal lymph nodes. He was then enrolled in a clinical trial of the investigational anti-CD30 antibody XmAb2513. However, after only 1 month on therapy, progressive disease was detected in the mediastinal, abdominal, and pelvic lymph nodes.

Two months later, in March 2009, the patient enrolled in a clinical trial of the NEDD-8 activating enzyme inhibitor MLN-4924. He had stable disease until April 2010, when he was removed from the study due to progression in mediastinal, axillary, and supraclavicular lymph nodes. At this time, the patient was asymptomatic and chose a watch-and-wait approach.

In October 2011, he started brentuximab vedotin, which induced a partial response. His disease progressed to the skeleton in May 2012. A month later, he started gemcitabine and vinorelbine and had a mixed response, with persistent active lesions in the skeleton and minimal residual disease in the spleen and lung. Three months later, he started salvage ICE for three cycles in preparation for an unrelated donor allogeneic SCT. An end-of-treatment PET/CT scan showed response in the osseous-based disease but new involvement in two right cervical lymph nodes.

Five months later, in June 2013, the patient enrolled on a clinical trial of the anti-PD1 antibody nivolumab. Improvement in lung and bony lesions was noted (Figure 1). The treatment was well tolerated aside from joint aches and pruritis. He also developed progressive cytopenias. A bone marrow analysis conducted 5 months after he had started nivolumab revealed therapy-related myelodysplastic syndrome (MDS) (monosomy 5 and complex karyotype), prompting his removal from the protocol. He subsequently started decitabine, which induced a CR of his MDS. A PET/CT scan performed six months after stopping the PD-1 blocker showed persistent but decreasing activity in the right axillary lymph node and an active right inguinal lymph node. Focal uptake in the spleen had resolved and there were no active osseous lesions.

Continued on page 3

Coming Soon: Updated Disease-Specific Videos

The Lymphoma Research Foundation will release new disease and topic-specific video content to its YouTube channel in the coming month. As part of LRF's digital educational resources, the videos will provide an opportunity for viewers to learn more about the various subtypes of the disease, treatment options, research and clinical trials from some of the world's leading experts in lymphoma.

The videos will be featured on the Foundation's YouTube channel (www.youtube.com/lymphomaresearch), and will also be available on its website and mobile app.

Lymphoma Rounds at a Glance

2,200
Professionals Participated in Lymphoma Rounds in 2015

63
Lymphoma Cases Presented in 2015

44
Institutions Presented in 2015

21
Lymphoma Rounds Programs in 2015

Treatment of Multiply-Relapsed Hodgkin Lymphoma with Immune Checkpoint Inhibitors

Continued from pages 1-2

Consolidative radiotherapy (3000 Gy) was administered to the right inguinal lymph node then the patient underwent a matched unrelated donor allogeneic SCT with reduced-intensity conditioning (Flu/Bu/Cy). The post-transplant period was complicated by graft-versus-host disease of the eyes and skin. The patient was offered, but declined, decitabine maintenance treatment for his MDS. A year after SCT, new focal activity was detected in the spleen consistent with relapse of his Hodgkin lymphoma. Additional therapies are now being considered.

Discussion

Immune checkpoint inhibitors have been of significant interest in the treatment of classical Hodgkin lymphoma. The programmed death 1 (PD-1)-blocking antibody nivolumab showed substantial activity, including some durable responses, in a phase 1 study in 23 patients with relapsed or refractory Hodgkin lymphoma.[1] Faculty noted that patterns of response to a checkpoint inhibitor may differ from those observed with chemotherapy in that initially some tumor lesion may appear to get slightly worse on imaging before regressing later. Although CR rates are low, most patients may still attain benefit. There might be an increased rate of post-transplant complications in patients who have received PD-1 inhibitors who undergo an allogeneic stem cell transplant later, such as graft-versus-host disease, however information is limited at this point in time.

Common adverse events in the phase 1 study of nivolumab included rash and thrombocytopenia. [1] Noting the development of MDS during nivolumab treatment in the case patient, attendees suggested that the MDS more likely resulted from prior chemotherapy rather than the nivolumab. In fact, checkpoint inhibition is being evaluated as a treatment for MDS.

In discussing the potential role of checkpoint inhibition in Hodgkin lymphoma, faculty noted the importance of patient selection and the potential of these agents to move further into frontline treatment. In the future, it would be valuable to be able to identify which patients should receive checkpoint inhibitors and which are likely to attain a durable complete remission with chemotherapy alone.

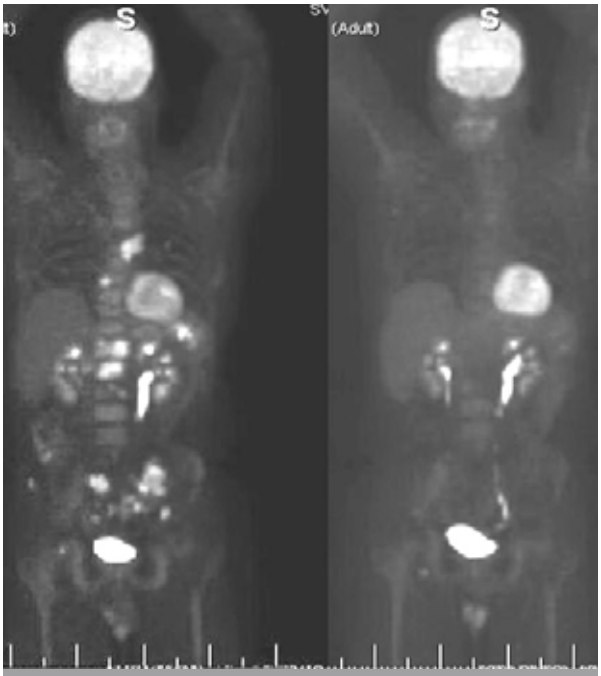

Figure 1. PET/CT Scan Before and After Anti-PD-1 Therapy in Refractory Hodgkin Lymphoma

In terms of other agents, the PD-1 blocker pembrolizumab is also being evaluated in patients with Hodgkin lymphoma, as is the CTLA-4 mAb ipilimumab. A phase 1 study evaluating combination regimens with brentuximab vedotin plus a checkpoint inhibitor (ipilimumab, nivolumab, or both) is ongoing. ■

Reference

1. Ansell SM, et al. *N Engl J Med.* 2015;372:311-319

A Case of ALK-1 Positive Anaplastic Large Cell Lymphoma in Pregnancy

Presenters

Jessica Belmonte, MD, *University of California, Irvine Medical Center*

Sherif Rezk, MD, *University of California, Irvine Medical Center*

Deepa Jeyakumar, MD, *University of California, Irvine Medical Center*

Case Background

Jessica Belmonte, MD, of the University of California, Irvine Medical Center presented the case of a 38 year-old woman who was pregnant with her second child when she presented to her primary care physician with fever and night sweats. Her symptoms had been occurring for 3 weeks. A complete blood count (CBC) showed a white blood cell (WBC) count of 3.4 cells/mm3, a hemoglobin level of 9 g/dL, and platelet count of 115 cells/mm3. Blood cultures were drawn and the patient was started on amoxicillin/clavulanic acid. The patient was referred to an infectious disease specialist, who found progressing bilateral axillary lymphadenopathy. She was hospitalized for an expedited workup.

Diagnosis

The patient's past medical history included antinuclear factor-positive rheumatoid arthritis diagnosed in 2005, which was periodically treated with low-dose prednisone. She had one prior pregnancy that was uncomplicated and resulted in the birth of a healthy infant. There was no significant past surgical history, family history of malignancy, or notable social history.

An extensive infectious disease workup showed no evidence of cytomegalovirus, Epstein-Barr virus, rickettsia, acute parvovirus, or histoplasma urine antigen. A right axillary lymph node biopsy showed no evidence of fungal or bacterial infection.

A CT scan of the chest showed right greater than left axillary adenopathy (largest 3.2 cm) and suspected splenomegaly. CT of the abdomen and pelvis was not done, as this procedure should be avoided during pregnancy. An echocardiogram was essentially normal.

At 28 weeks, 2 days gestation, the patient was transferred to an academic center where she presented with fatigue and fevers. A physical exam revealed a palpable mobile 1-cm left supraclavicular lymph node and a palpable 2-cm fixed axillary lymph node. A CBC showed a WBC of 5.4 cells/mm3, an absolute neutrophil count of 3.4 cells/mm3, a normal differential, a hemoglobin level of 6.9 g/dL, a platelet count of 88 cells/mm3 and a mean corpuscular volume (MCV) of 88 fL. Lactate dehydrogenase, uric acid, liver function tests, haptoglobulin, and coagulation tests were normal. HIV and hepatitis serologies were negative.

A review of the pathology of the case was presented by Sherif Rezk, MD, also of the University of California, Irvine Medical Center. Slides from the right axillary lymph node showed effacement of the nodal architecture by a diffuse high-grade process. Morphology was consistent with anaplastic large-cell lymphoma (ALCL), with hallmark cells showing basophilic cytoplasm and kidney-shaped nuclei. Upon immunohistochemistry, the neoplastic cells were CD3-negative, CD20-negative (aside from reactive B-cells), CD30-positive, EMA-positive, and diffusely ALK-1-positive. Ki-67 staining showed a high proliferation rate (70-80%) (Figure 2). Flow cytometry showed an atypical CD2-positive, CD43-positive population. The bone marrow was markedly hypercellular and extensively fibrotic with reduced hematopoiesis and the presence of lymphoma cells.

A lumbar puncture revealed no malignant cells in the cerebrospinal fluid.

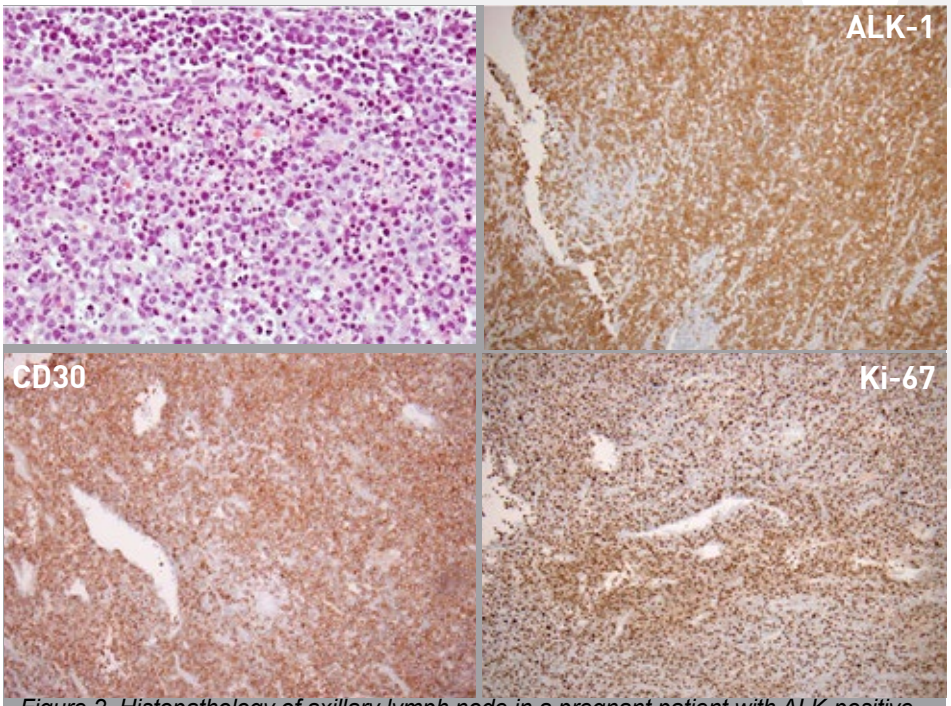

Figure 2. Histopathology of axillary lymph node in a pregnant patient with ALK-positive ALCL

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A Case of ALK-1 Positive Anaplastic Large Cell Lymphoma in Pregnancy

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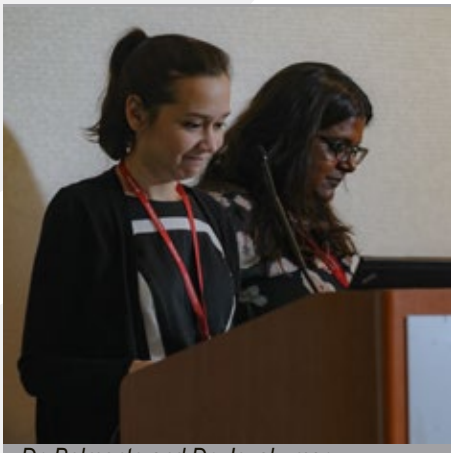

Dr. Belmonte and Dr. Jeyakumar

An MRI of the abdomen and pelvis –done without contrast due to the risk of contrast during pregnancy—showed marked splenomegaly (24 cm) and hepatomegaly (19 cm). The final diagnosis was ALK-positive ALCL.

Case Evolution

Given the poor prognosis of ALCL without treatment, and the favorable outcomes associated with ALK-positive ALCL with treatment, the decision was made to initiate treatment. The patient underwent two 21-day cycles of CHOP (cyclophosphamide, doxorubicin, vincristine, or prednisone) with filgrastim support; the last cycle was given about two weeks before the delivery. The pregnancy was complicated by preterm premature rupture of membranes and a failed induction of labor at 34 weeks, 2 days. The patient underwent primary low-transverse cesarean section and delivered a viable, 2020-g female infant with an Apgar score of 8 and 9 at 1 and 5 minutes, respectively. There were no notable congenital abnormalities; no abnormalities were observed upon pathologic examination of the placenta.

Cycle 3 of CHOP was administered approximately 2 weeks after delivery. A positron emission tomography-computed tomography (PET/CT) scan after cycle 3 showed mild activity in the right axilla and no evidence of FDG-avid lymphadenopathy in the neck, abdomen, or pelvis.

Discussion

Attendees discussed when to proceed with treatment in this patient who was 28 weeks into her pregnancy and what regimen to use. Dr. Belmonte noted that chemotherapy, if needed during pregnancy, should be administered during the second or third trimester if possible. Although there are very few studies on the treatment of ALCL during pregnancy, retrospective data suggest that the treatment of non-Hodgkin lymphoma during the second or third trimester with standard combination chemotherapy is associated with relatively few complications.[1]

CHOP and CHOEP (cyclophosphamide, doxorubicin, etoposide, vincristine, and prednisone) were discussed as potential options; both are commonly used and recommended by the National Comprehensive Cancer Network clinical guidelines.[2]

Delivery of the infant is not recommended until 36-37 weeks due to the risk of fetal prematurity. Moreover, delivery should be planned for 2-3 weeks after the last treatment to allow bone marrow recovery and to enable fetal drug elimination via the placenta, as premature infants have a limited ability to metabolize and clear drugs due to renal and liver prematurity. ■

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1. Evens AM, et al. *J Clin Oncol.* 2013;31:4132-4139.
2. NCCN clinical practice guidelines in oncology (NCCN Guidelines®): non-Hodgkin's lymphomas. Version 1.2016.

Lymphoma Rounds is currently active in six locations:

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- Los Angeles
- New England
- New York
- Philadelphia
- Seattle

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A Case of Secondary CNS Lymphoma

Presenters

Mendel Goldfinger, MD
Rutgers Cancer Institute of New Jersey

Ben Stueben, MD
Rutgers Cancer Institute of New Jersey

Joseph Bertino, MD
Rutgers Cancer Institute of New Jersey

Dr. Bertino at New York Lymphoma Rounds

Case Background

Mendel Goldfinger, MD, of the Rutgers Cancer Institute of New Jersey, presented the case of a 66-year-old man who presented to a community hospital with dizziness and changes in mental status that had been worsening over several months. He was found to have severe hyponatremia with a sodium level of 110 mEq/L. A workup was consistent with syndrome of inappropriate antidiuretic hormone secretion (SIADH), which was treated and resolved. As part of his mental status workup, he underwent a CT scan of the head that showed multiple brain lesions. He had undergone a lumbar puncture in the emergency department due to concerns about meningitis. Flow cytometric analysis of the cerebrospinal fluid showed a CD10-positive monoclonal lambda B-cell population consistent with a germinal center B-cell lymphoma.

Diagnosis

A CT scan of the chest, abdomen and pelvis did not show any evidence of lymphadenopathy or splenomegaly but did reveal a left renal mass that was reported as "suspicious for renal cell carcinoma". A testicular ultrasound and bone marrow biopsy did not reveal any evidence of lymphoma. The patient was subsequently transferred to Rutgers Cancer Institute for treatment of "primary CNS lymphoma".

An MRI of the brain was done which showed multiple brain lesions with two predominant masses in the corpus collosum and hypothalamic area, measuring up to 2 centimeters (Figure 3A). An MRI of the spine showed enhancement in the lumbar spine with characteristics of lymphomatous meningitis (Figure 3B). The patient underwent a core needle biopsy of his renal mass and the pathology of this mass was presented by Dr. Ben Stueben from the hematopathology department at the Rutgers Cancer Institute of New Jersey.

Pathology slides showed morphology consistent with a diffuse large B-cell lymphoma. Immunohistochemistry was strongly positive for C-MYC and BCL2 and weakly positive for BCL6. The Ki-67 proliferation index was 100%. Fluorescence in situ hybridization (FISH) analysis revealed a t(8;14) translocation between *C-MYC* and the immunoglobulin heavy chain and also showed a *BCL6* translocation. No *BCL2* translocation was identified. The final diagnosis was double-hit lymphoma in the left kidney with lymphomatous meningitis and multiple intraparenchymal brain lesions.

Case Evolution

The patient received induction therapy consisting of dose adjusted-EPOCH-R (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin, and rituximab) along with high-dose methotrexate at 3.5 g/m2 and intrathecal liposomal cytarabine.

The lymphoma was cleared from the CSF after the first cycle and imaging done after two cycles showed no evidence of disease. The patient completed six cycles and is currently in complete remission. High-dose chemotherapy with autologous stem cell transplant (ASCT) is being considered for consolidation treatment.

Discussion

A major point of discussion was the need to select an induction regimen that is active for the systemic and CNS disease. This presented a significant challenge because there are almost no data to guide therapy for patients with secondary CNS involvement of lymphoma, as these patients have historically

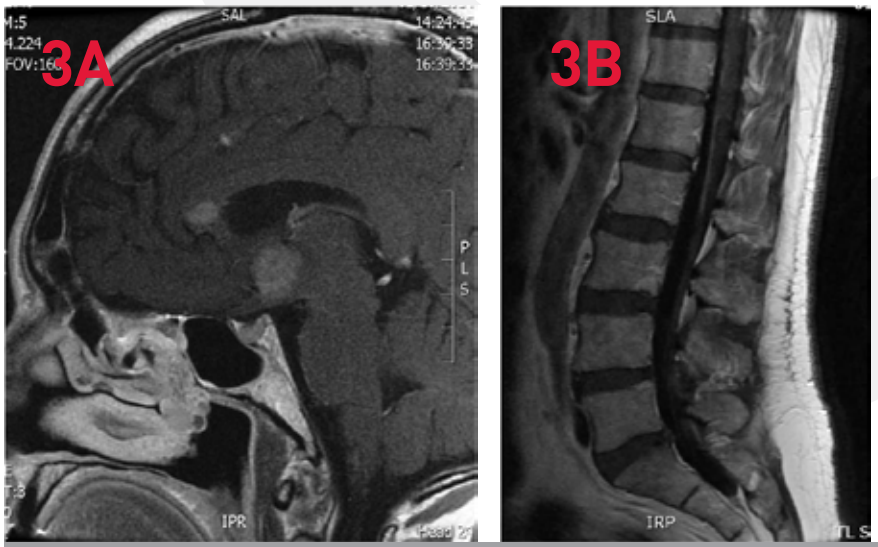

Figure 3. MRI of the brain and spine in a patient with double-hit lymphoma in the left kidney with lymphomatous meningitis and multiple intraparenchymal brain lesions.

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A Case of Secondary CNS Lymphoma

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been excluded from most clinical trials. In addition, extrapolating from primary CNS lymphoma is not optimal, as it has been shown that systemic lymphomas do not have the same response to high-dose methotrexate, despite having a similar biology.[1]

Attendees first discussed several potential induction treatment regimens for double-hit lymphoma. The use of an aggressive chemotherapy regimen was recommended, as retrospective data in patients with double-hit lymphoma have shown better progression-free survival (PFS) with intensive induction regimens than with standard treatments such as R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone).[2] However, despite the improvement in PFS, the effect of intensive induction on overall survival is less clear. Preliminary prospective data presented at ASH 2014 was discussed which demonstrated support for the use of DA-EPOCH-R in patients with *MYC*-rearranged B-cell lymphomas.[3]

For the CNS disease there was unanimous agreement on the need to include high-dose methotrexate in this patient's treatment regimen. Data on methotrexate dosing was discussed. Studies in primary CNS lymphoma have used doses anywhere from 1 g/m2 to 8 g/m2. Retrospective studies and subset analyses have shown a survival benefit for patients who achieve a higher area under the curve (AUC), regardless of the dose given. [4,5] Thus, tailoring the therapy to a specific AUC was suggested as a useful strategy. Part of the discussion focused on whether there is a benefit to administering intrathecal chemotherapy in addition to high-dose systemic therapy. Data on the pharmacokinetics of intrathecal versus systemic administration of methotrexate were reviewed.

Attendees also debated the role of consolidation with stem cell transplantation in this clinical scenario. While some clinicians supported the use of a transplant, others noted that there are scarce data to support the role of ASCT in patients with lymphoma and CNS involvement. Results of a recently published small phase II study were reviewed which showed favorable outcomes using high-dose chemoimmunotherapy followed by ASCT in patients with secondary CNS involvement of B-cell lymphoma. [6] Although this is the largest study to date to have prospectively evaluated the role of ASCT in secondary CNS lymphoma, it was agreed that the small sample size and lack of a control arm are major limitations and more data from larger trials would be needed to support this approach in daily practice.

Dr. Goldfinger then went on to review several novel agents which may potentially be relevant to the case discussed. First, he reviewed early data demonstrating efficacy of ibrutinib in patients with CNS involvement of lymphoma. [7] He then showed preclinical data demonstrating synergistic cell killing with the combination of BCL-2 and MYC inhibitors in double-hit lymphoma cell lines. [8] ■

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Researcher Spotlight

Sean M. Post, PhD

Dr. Sean M. Post is an Assistant Professor at The University of Texas M.D. Anderson Cancer Center and a recipient of the Lymphoma Research Foundation's Chronic Lymphocytic Leukemia (CLL) Collaborative Grant in 2012. His grant project studied the impact of a mutation on the protein TP53 (p53) in CLL, which has long been known to be a critical genetic alteration in CLL (17p deletion).

In December 2015, the results of Dr. Post's research were presented at the Annual Meeting of the American Society of Hematology (ASH). Working with a preclinical mouse model of CLL, Dr. Post and his colleagues tested whether the effectiveness of ibrutinib (Imbruvica) was affected by the presence of a p53 mutation. Their results revealed that ibrutinib, which targets the Bruton's tyrosine kinase (BTK) pathway and other gene sets outside of the p53 pathway, was an effective therapy regardless of whether the CLL sample had mutated p53.

Dr. Post's research, begun prior to the United States Food and Drug Administration's (FDA) approval of ibrutinib for patients with relapsed/refractory CLL or patients with 17p deletion, provides evidence of the biologic mechanism that makes this therapy an important advance for this population, while identifying the p53 mutation as a contributor to resistance to treatment. Going forward, Dr. Post and his colleagues plan to expand their research, testing combination therapies against p53 mutations in the lab. "If successful," he adds, "this work will guide our clinical collaborators, within our department and institute, in the design of clinical trials for TP53-mutant CLL."

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