



The 65th ASH Annual Meeting Abstracts

ORAL ABSTRACTS

905.OUTCOMES RESEARCH-LYMPHOID MALIGNANCIES

Longitudinal Differences By Treatment Arm in Health-Related Quality of Life Among High Risk Pediatric Hodgkin's Lymphoma Patients Treated on the Children's Oncology Group Ahod 1331 Study

Annalynn M Williams, PhDMS¹, Angie Mae Rodday, PhD MS², Qinglin Pei, PhD³, Tara O. Henderson, MD⁴, Frank Keller, MD⁵, Angela Punnett, MD⁶, Kara M. Kelly, MD⁷, Sharon M. Castellino, MD MSc⁸, Susan K Parsons, MDMRCP⁹

¹James P. Wilmot Cancer Institute, University of Rochester, Rochester, NY

²Institute for Clinical Research and Health Policy Studies, Tufts Medical Center, Boston, MA

³University of Florida, Gainesville, FL

⁴University of Chicago Medical Center, Chicago, IL

⁵Aflac Cancer Ctr. & Blood Disorders Svc., Atlanta, GA

⁶The hospital for sick children, Toronto, Canada

⁷Roswell Park Comprehensive Cancer Center, Buffalo, NY

⁸Department of Pediatrics, Emory University School of Medicine, Atlanta, GA

⁹The Center for Health Solutions, Tufts Medical Center, Boston, MA

Introduction: Brentuximab vendotin (BV) with AVE-PC demonstrated superior efficacy to ABVE-PC for pediatric patients with high-risk HL in the AHOD 1331 trial. However, there are no data regarding the impact on health-related quality of life (HRQoL) with the addition of BV into the treatment of pediatric HL.

Methods: Eligibility for AHOD 1331 (NCT 02166463) included previously untreated HL with high risk disease, defined as stage IIB +bulk, IIIB, IVA, or IVB classic HL. Participants were randomized to either BV-AVE-PC ("BV" arm) or ABVE-PC (standard arm). Among the first 309 participants enrolled in a prespecified longitudinal patient-reported outcomes sub study, 280 were age 11+ years and eligible to self-report HRQoL using the seven-item Child Health Ratings Inventories (CHRI)-Global scale. HRQoL was assessed prior to treatment (T1), at cycle 2 (T2), at cycle 5 (T3), and at the end of treatment (T4). A clinically meaningful increase in HRQoL was considered a change of 7 points in the CHRI-Global score (CHRI), translating to a 1/3 standard deviation. Multivariable linear regression estimated the association between demographic/clinical variables and HRQoL at T1. Linear mixed models estimated the change in HRQoL relative to T1 with a time*treatment arm interaction to estimate differences in the change in HRQoL across treatment arm. This model was adjusted for age, sex, race/ethnicity, stage, large mediastinal adenopathy (LMA), B-symptoms at diagnosis, and a time-varying covariate for involved site radiation prior to T4.

Results: Participant and disease characteristics were balanced by treatment arm; mean age at enrollment was 15.6 years (SD=1.9), 52% were female, 60.4% had LMA, and 58% were stage IV. 93% of participants completed the CHRI at T1, 92% at T2, 89% at T3, and 74% at T4. At T1, female sex (mean (SD) 64.1 (20.2) vs 71.3 (23.3) $p=0.004$) and fever (60.8 (23.0) vs. 71.9 (20.4) $p=0.024$) were associated with worse HRQoL. At each time point after pre-treatment (T1), HRQoL was higher, on average, in the BV arm compared to the standard arm (Figure 1). By T2, participants in the BV arm experienced a statistically and clinically significant increase in HRQoL compared to pre-treatment (T1) (Table 1; $\beta=7.3$ 95%CI 3.2, 11.4; $p\leq 0.001$), which was greater than the change experienced in the standard arm (difference in change $\beta=5.1$ 95%CI -0.2, 10.3; $p=0.057$). At T3 and T4 the BV arm continued to experience statistically significant improvements in HRQoL relative to T1 (T3 $\beta=5.3$ 95%CI 0.8, 9.9; $p=0.022$; T4 $\beta=14.6$ 95%CI 10.3, 18.9; $p\leq 0.001$). The standard arm did not experience a statistically or clinically significant increase in HRQoL from T1 until T4 ($\beta=9.3$ 95%CI 4.7, 11.5; $p<0.001$).

Conclusion: Patients with high-risk pediatric HL treated with BV-AVE-PC experienced more rapid and sustained improvement in HRQoL compared to patients treated with ABVE-PC. These data also demonstrate the feasibility and importance of incorporating HRQoL assessments into pediatric clinical trials.

Disclosures Keller: Merck: Consultancy, Membership on an entity's Board of Directors or advisory committees, Other: Scientific advisory council. **Kelly:** Seagen: Other: Scientific Steering Committee; **Merck:** Other: Scientific Steering Committee.

Castellino: Bristol Meyers Squibb: Honoraria, Other: Scientific Advisory Committee; **SeaGen Inc.:** Other: Scientific Advisory Committee - No honoraria, Research Funding. **Parsons:** Seagen: Consultancy.

Figure 1: Mean global CHRIs scores (HRQoL) by treatment arm and time point.

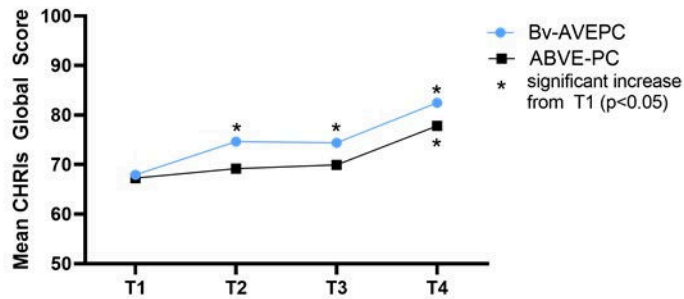


Table 1: Estimated mean difference (95%CI) in HRQoL relative to T1 by treatment arm.

	Mean Difference in HRQoL β (95%CI) ¹	P-value
Comparing T2 to T1		
BV-AVE-PC	7.30 (3.21, 11.38) ²	<0.001
ABVE-PC	2.23 (-1.06, 5.52)	0.182
Change in BV-AVE-PC vs. Change in ABVE-PC	5.07 (-0.15, 10.28)	0.057
Comparing T3 to T1		
BV-AVE-PC	5.32 (0.78, 9.87)	0.022
ABVE-PC	2.41 (-1.36, 6.18)	0.208
Change in BV-AVE-PC vs. Change in ABVE-PC	2.91 (-2.98, 8.79)	0.330
Comparing T4 to T1		
BV-AVE-PC	14.58 (10.26, 18.90)	<0.001
ABVE-PC	9.30 (4.71, 13.90)	<0.001
Change in BV-AVE-PC vs. Change in ABVE-PC	5.27 (-0.99, 11.54)	0.099
Type III effects		
Time	<0.001	
Treatment Arm	0.212	
Time*Treatment Arm	0.222	

¹Model adjusted for adjusted for age, sex, race/ethnicity, stage, large mediastinal adenopathy (LMA), B-symptoms at diagnosis, and a time-varying covariate for involved site radiation prior to T4. ²A clinically meaningful difference in HRQoL is considered a change of 7 points.

Figure 1

<https://doi.org/10.1182/blood-2023-187125>