7506 **Oral Abstract Session**

Myeloablative versus non-myeloablative consolidative chemotherapy for newly diagnosed primary central nervous system lymphoma: Results of CALGB 51101 (Alliance).

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Background: Optimal consolidative therapy for primary central nervous system lymphoma (PCNSL) is not defined. Avoidance of whole brain radiation may reduce risk of neurotoxicity. Non-radiation consolidative options include myeloablative chemotherapy with autologous stem cell transplantation (HDT/ASCT) or non-myeloablative chemotherapy. **Methods:** This is a randomized phase 2, National Clinical Trials Network study of induction methotrexate (MTX) (8 g/m^2 days 1, 15), temozolomide (TMZ) (150-200 mg/m^2 D7-11), and rituximab (RTX) (C1 D3, 10, 17, 24 and C2 D3, 10) in four 28-day cycles followed by one cycle of cytarabine (ARA-C) (2 g/m^2 BID, D1, 2) (MTRA). After induction, patients (pts) received consolidation with thiotepa (5 mg/kg BID, D -5, -4) plus carmustine (400 mg/m^2, day -6) and ASCT (Arm A) or one cycle of ARA-C (2 g/m^2 BID, D1-4) plus infusional etoposide (40 mg/kg over 96h) (Arm B). Pts were stratified on age and performance status and randomized 1:1 before induction. The primary endpoint was progression-free survival (PFS) from randomization. With 110 pts, there was 84% power to detect an improvement in PFS using a log-rank test (1-sided α= 10%), assuming a median PFS of 3 months for pts who progress during induction, and a median PFS of 2 years (yrs) for Arm B and 4.5 yrs for Arm A consolidation. This report includes the results for the primary endpoint analysis. **Results:** 113 pts (median age 61 yrs, range 33-75) were randomized (Arm A: 57, Arm B: 56) across 27 centers. 108 eligible pts who received induction therapy were included in the primary endpoint analysis (Arm A: 54, Arm B: 54). 72/108 pts started consolidation and 70/72 completed consolidation per protocol (Arm A: 36, Arm B: 34). With a median follow-up of 3.8 years, median PFS from randomization was 6 yrs (95% CI 3.9-not reached) in Arm A vs 2.4 yrs (95% CI 0.6-not reached) in Arm B (p = 0.02). However, more pts randomized to Arm B went off treatment before consolidation due to progression or death (28% vs 11%, p = 0.05). PFS landmarked at start of consolidation demonstrated a trend for improved PFS favoring Arm A (HR 0.58, 95% CI 0.25-1.36; p = 0.21). Median OS was not reached in either arm, and 3-yr estimates were 83% (95% CI 69-91; Arm A) vs 72% (95% CI 57-82; Arm B). Toxicities were similar between arms with no treatment-related mortality during consolidation. **Conclusions:** MTRA induction followed by myeloablative consolidation (Arm A) had improved PFS vs MTRA induction followed by non-myeloablative consolidation (Arm B), though more progressions or deaths leading to treatment discontinuation prior to consolidation in Arm B were noted. Both consolidation regimens were well-tolerated with encouraging PFS and OS in newly-diagnosed PCNSL. Support: U10CA180821, U10CA180882; https://acknowledgments.alliancefound.org. Clinical trial information: NCT01511562. Research Sponsor: U.S. National Institutes of Health.

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