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626.AGGRESSIVE LYMPHOMAS: PROSPECTIVE THERAPEUTIC TRIALS

The ZR2-Minichop Study:Zanubrutinib, Lenalidomide, Rituximab, Cyclophosphamide, Vincristine, Epirubicin and Prednisone in Elderly Patients with Previously Untreated Diffuse Large B-Cell Lymphoma

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Background: Diffuse large B cell lymphoma (DLBCL) is common in the elderly group. New schedules are required due to the toxicity in classic chemotherapy regimens. Previous studies reported that non-germinal center B cell (non-GCB) subtype aggregates in elderly patients with abnormality in the activated B cell receptor signal and nuclear factor kappa-B pathway. We conducted a prospective trial to investigate the efficacy and safety of the ZR2-miniCHOP schedule (zanubrutinib, lenalidomide, rituximab, cyclophosphamide, vincristine, epirubicin and prednisone) in elder patients newly diagnosed with non-GCB DLBCL.

Methods: This multicenter, single-arm, phase II clinical study started in June 2021 at 6 centers in China. Eligible patients were newly diagnosed non-GCB DLBCL, aged 60 to 80 with Eastern Cooperation Oncology Group (ECOG) performance status over 2, or patients aged over 80 with ECOG status of 0-4. The purpose of this study is to discuss the response, safety and long-term survival with the primary endpoint of objective response rate (ORR) and the secondary endpoint of overall survival (OS) and progression free survival (PFS). Patients would receive 2 cycles induction period with zanubrutinib 160mg twice per day on d1-28, lenalidomide 25mg d1-10 and rituximab 375mg/m ^{2} d1, after then combine 4-6 cycles miniCHOP schedule as: cyclophosphamide 400mg/m ^{2} d2, vincristine 1.4mg/m ^{2} d2, epirubicin 35mg/m ^{2} d2 and prednisone 45mg/m ^{2} d2-6. Evaluation is conducted after 6 cycles of treatment including the ORR and CR rate by positron emission tomography-computed tomography (PET-CT) and 2-years OS and PFS.

Results: At the data collection duration from June 2021 to June 2023, 45 patients were recruited in this trial. 34 patients were considered for result analysis as 2 withdrawals and 1 drop-out. 6 patients are still in the process of treatment. The median age of the 45 patients enrolled was 79 (range 65-90) years, with 34 (75.6%) patients over 75 years old. The ORR was 91.2% (31/34). Among the 34 assessable patients, 61.8% (21/34) of them reached CR after 6 cycles routine therapy. Besides, 29.4% (10/34) patients just achieved PR, and for these patients we then continued administered more 2 cycles with ZR2+miniCHOP. Later 5 of these 10 patients achieved CR. One patient stayed SD and 3 patients appeared disease progressing. The most common hematology-relevant adverse events (AEs) were neutropenia (13/34) and thrombocytopenia (10/34). Eleven patients appeared AEs over grade 3 occurred during therapy with neutropenia, thrombocytopenia, infectious pneumonia events. All these patients have been administrated the normal dose as the treatment resistance and the toxicity did not affect therapy. Two patients died of progressive disease. No treatment-associated death was observed. Generally analyzing, this trial achieved acceptable response and safety.

Conclusion: The ZR2-miniCHOP schedule represented satisfactory efficacy and safety in elderly non-GCB DLBCL.

Disclosures No relevant conflicts of interest to declare.

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