Phase II clinical study of VR-CAP regimen for first-line treatment of marginal zone lymphoma

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BACKGROUND

Marginal zone lymphoma (MZL) is a relatively common group of inert B-cell non-Hodgkin's lymphoma (B-NHL) originating from peripheral memory lymphocytes. Some patients cannot achieve complete remission or relapse quickly after standard first-line treatment.

Studies have shown that the NF-KB signal pathway in MZL is in an abnormally activated state, while bortezomib is a proteasome inhibitor targeting the NF-KB pathway.

This multicenter phase II clinical study evaluated the efficacy and safety of VR-CAP regimen in the first-line treatment of MZL, and explored the best beneficiaries of VR-CAP regimen (rituximab, cyclophosphamide, epirubicin, bortezomib and prednisone).

RESULTS

At present, 23 patients were enrolled, the median age was 58 years (25-74 years). By February 2023, 16 patients had completed all six courses of treatment; 6 patients completed 4 courses of treatment; Two patients stopped treatment by themselves, and 22 patients could evaluate the curative effect. Sixteen patients (72.7%) and five patients (22.7%) achieved CR/CRu and PR respectively. PFS and OS were 82.2% and 82.0% respectively in two years.

Among the 13 patients who have completed all the treatment, the common therapeutic adverse events were anemia (73.9%), gastrointestinal reaction (52.2%), thrombocytopenia (30.4%), pulmonary infection (21.7%), neurotoxicity (8.7%), rituximab-related rash (8.7%).

METHOD

The patient received 6 cycles of VR-CAP first-line treatment. Each cycle lasts for 3 weeks, and rituximab (375mg/m2) is given intravenously on the 0th day, cyclophosphamide (750 mg/m2) and epirubicin (70 mg/m2) are given intravenously on the 1st day, bortezomib (1.3 mg/m2) is given subcutaneously on the 1st and 4th days, and prednisone (100 mg) is given orally on the 1st to 5th days. The primary end point was 2-year progression-free survival (PFS), and the secondary end point was objective response rate (ORR), including complete response (CR) and partial response (PR); Total survival (OS) and security.

CONCLUSIONS

- VR-CAP first-line treatment of lymphoma in the marginal region has a good effect, the objective response rate (ORR) is 95.5%, and the patient is well tolerated. All adverse events are mainly 1-2 grades.

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Figure 1 Time since treatment (months)
Figure 2 PFS and OS
Figure 3 Response Rate
Figure 4 Adverse events