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MZL

Phase II study of rituximab and bendamustine shows positive long term results for MALT lymphoma

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A Letter to the editor[1] published in Blood on 12th October 2017 described the positive results of a long-term phase II study on the use of rituximab and bendamustine (RB) for mucosa-associated lymphoid tissue lymphoma (MALT).

MALT 2008-01 (NCT01015248) was a multicenter, prospective and non-randomized study conducted in Spain by the Grupo Español de Linfomas y Trasplantes de Médula Ósea (GELTAMO) network. The primary endpoint of the study was event-free survival (EFS) and the secondary endpoints were overall response rate (ORR), progression-free survival (PFS), overall survival (OS) and toxicities. The long-term results of this study were reported by Antonio Salar, from the Department of Hematology at the Hospital del Mar in Barcelona, Spain, and colleagues.

Study Highlights

- 57 patients with biopsy-proven CD20+ MALT lymphoma were included in the study
- Median age was 62 years (26–84)
- Median observation time was 82 months (7 years)
- Treatment included rituximab 375 mg/m^2 given on Day 1, bendamustine 90 mg/m^2 given on Days 1 and 2 and administered in cycles every 28 days with a maximum of 6 cycles

Efficacy

- 7-year EFS: 87.7% (95% CI, 76.0–94.0)
- 7-year EFS gastric *vs* non-gastric patients: 89.5% (95% CI, 64.1–97.3) *vs* 4% (95% CI, 66.5–93.2) $P = 0.637$
- 7-year estimated PFS: 92.8% (95% CI, 81.9–97.2)
- The presence or absence of the gene mutation t(11;18)(q21;q21) did not impact the efficacy of RB treatment

Safety[2]

- 36 patients (60%) reported adverse events (AE) grade 3 or 4, with the most common toxicities being hematological:
  - Lymphopenia: 20 patients (35%)
  - Neutropenia: 12 patients (21%)
- 3 deaths were reported during the study but were classified as unrelated to lymphoma or RB treatment

Conclusion

The authors stated that long term outcomes of RB treatment showed good efficacy at 7 years for EFS and predicted PFS for patients with MALT lymphoma. Treatment with RB was well tolerated in patients and no new safety risks emerged. Comparison was made with another study IELSG-19[3] previously reportedusing 5-year data with R-chlorambucil treatment and it was found that RB treatment was superior in terms of complete response, EFS and EFS in gastric and non-gastric MALT.

References

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3. Zucca E. et al. Final results of the IELSG-19 randomized trial of mucosa-associated lymphoid tissue lymphoma: improved event-free and progression-free survival with rituximab plus chlorambucil versus either chlorambucil or rituximab monotherapy. Journal of Clinical Oncology. 2017;35(17): 1905-1912