REAL WORLD EXPERIENCE WITH TEMSIROLIMUS IN PATIENTS WITH RELAPSED OR REFRACTORY MANTLE CELL LYMPHOMA: RESULTS FROM THE SPANISH EXPERIENCE


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Aim: Temsirolimus (TEM) is an mTOR inhibitor approved for the treatment of patients (pts) with relapsed or refractory mantle cell lymphoma (MCL). In a phase III trial TEM 175mg weekly for 3 weeks followed by 75mg weekly significantly improved progression free survival (PFS) and objective response rate (ORR) compared with investigator’s choice. TEM has also been tested in combination with rituximab (RTX) in a phase II trial with encouraging efficacy. However, few data have been reported on the use of TEM in clinical practice.

Methods: A retrospective, observational and multicenter study of TEM used following routine clinical practice in pts with MCL was carried out. Pts treated with TEM between 2010 and 2013 were included. The objective of the study was to analyze the efficacy and safety of TEM. The study was approved by the Regulatory Authorities.

Results: A total of 24 pts were included, 22 were male and the median age was 71 years. 15 pts were treated with TEM in monotherapy and 9 in combination with RTX. The median number of prior therapies in the TEM monotherapy cohort was 2 (range 1 to 7) and 4 (range 2 to 8) in the combination cohort. According to the simplified MIPI prognostic score, 26.1% of the pts had low risk, 43.5% intermediate risk and 30.4% high risk. The ORR was 60% in the TEM monotherapy cohort and 78% in the TEM plus RTX one. Median PFS for patients in the TEM monotherapy cohort was 7.3 months and 4.57 months in the combination cohort. Two pts underwent autologous stem cell transplantation after TEM treatment. In terms of tolerability, 87% of the pts developed at least one adverse event (AE) in the TEM monotherapy cohort and 55% in the combination cohort. The most common G3/4 AE in both cohorts was thrombocytopenia (33%).

Conclusions: TEM is effective and well tolerated in heavily pretreated patients with MCL. Despite the small sample size, TEM efficacy in monotherapy seems to be higher in this study when compared to previous phase II and III trials. The median PFS in the combination therapy cohort was surprisingly low probably due to the differences in clinical features between both groups and to the fact that this cohort was more heavily pretreated.

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