5PSQ-052 ANALYSIS OF POTENTIAL PROGNOSTIC FACTORS OF EFFICACY IN TISAGENLECLEUCEL TREATMENT IN A COHORT OF PATIENTS WITH DIFFUSE LARGE B-CELL LYMPHOMA

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Background and Importance In the context of B-cell non-Hodgkin lymphomas, the use of CAR T-cell therapy offered new treatment possibilities. The evolution of these therapies can improve the treatment arsenal and patients' life expectancy. However, some patients experience treatment failure: the identification of predictors can be crucial for a cost-effective use of this therapy.

Aim and Objectives The purpose of this analysis was to evaluate the correlation between some possible predictive factors and outcome after tisagenlecleucel infusion in patients with diffuse B-cell lymphoma. A retrospective observational study was conducted on a cohort of 35 patients treated with tisagenlecleucel from clinical practice in an Italian Oncologic Institute from December 2019 to August 2023. Patients were evaluated based on their response to the therapy in terms of overall response rate over an 18-month period following infusion. The analysed factors included age, gender, development of cytokine release syndrome and its grade, tocilizumab administration, steroid administration, lymphocyte count at the time of leukapheresis, lymphocyte count at day 14 and day 30 post-infusion, c-reactive protein at day 0, peak of c-reactive protein within 14 days post-infusion, ferritin at day 0, peak ferritin within 14 days, previous therapy lines, previous autologous marrow transplantation, disease stage, bridge therapy received.

Material and Methods Factors that could influence response were analysed by stratified analysis dividing patients into responders (complete remission, partial remission) and non-responders (death and progression) at 18 months; Mann-Whitney U test for continuous variables and Fisher's exact test for categorical variables were used. Univariate logistic regression was used to assess the independent contribution of each factor on the probability of response to therapy. Statistical significance was considered for a value of $p<0.05$.

Results Elevated baseline levels of c-reactive protein and ferritin increase the risk of therapy failure. Higher ferritin peaks within 14 days also increase the risk of failure. Higher lymphocyte expansion at day 30 is associated with a better response; previous autologous marrow transplantation correlates with a better response.

Conclusion and Relevance The patient's inflammatory status before therapy should be carefully evaluated: elevated levels of inflammatory markers are associated with therapy failure. Previous autologous marrow transplantation correlates with a better response; the analysis of factors that can predict the possibility of treatment failure is important.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-053 EFFECTIVENESS AND SAFETY OF GALCANEZUMAB. REAL-LIFE RESULTS

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Background and Importance Galcanezumab is a monoclonal antibody that binds the calcitonin gene-related peptide, indicated for migraine prophylaxis.

Aim and Objectives To assess the effectiveness and safety of galcanezumab six months after initiation of treatment.

Material and Methods A retrospective observational study including patients treated with galcanezumab, from September 2020 to August 2023 was conducted. Collected variables comprised age, sex, type of migraine, median number of migraine days per month (MDM), HIT-6 score, galcanezumab treatment duration, and adverse effects. Treatment with galcanezumab was considered effective if a reduction of at least 50% in MDM or a reduction of more than 5 points on the HIT-6 scale was achieved at 6 months of treatment. For the assessment of drug safety, adverse effects reported by the patient were considered.

Results A total of 32 cases were reviewed (median age 49 years; 25 women [71.4%]), 75% (n=24) of patients had chronic migraine without aura, 9.4% (n=3) had chronic migraine with aura, and 15.6% (n=5) had high-frequency episodic migraine. The change in MDM before and after six months of treatment was 15 versus 5, and the HIT-6 index was 69 versus 57. Median duration of galcanezumab treatment was 19 months. At the end of the study period, 84.6% of patients continued with the treatment, while 15.4% discontinued it due to side effects or ineffectiveness. Regarding the type of adverse effects, two patients reported dizziness (7.7%), and one reported intense itching (3.8%). The observed frequencies are higher than those reported in pivotal clinical trials, with an incidence of 1.2% for dizziness and itching. The adverse effects reported were in all cases, mild or moderate, and the discontinuation rate awed to this reason was less than 4%.

Conclusion and Relevance Treatment with galcanezumab has proved to be effective and safe in most patients. Despite adequate monitoring at six months from the initiation of monoclonal antibody treatment, further and longer-term studies would be necessary to establish the utility of this drug, its impact on quality of life, and its long-term safety.

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Conflict of Interest No conflict of interest.