Feasibility and Safety of Outpatient Model for Teclistamab Step-Up Dosing Administration: A Single Center Experience

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Introduction:

Teclistamab is a BCMA/ CD3 bispecific T cell engager, FDA approved in relapsed/refractory multiple myeloma (RRMM) after 4 prior lines of therapy, based on the results of MajesTEC-1 study [1]. Early toxicities of teclistamab include CRS and ICANS. To mitigate the risk of CRS/ICANS, teclistamab is administered in a step-up dosing approach. 48h inpatient observation after each of the 3 step-up doses is recommended, although not mandated by FDA. Based on our outpatient CAR-T program experience, we implemented an outpatient teclistamab step-up dosing administration program.

Objectives:

To evaluate safety of outpatient teclistamab administration.

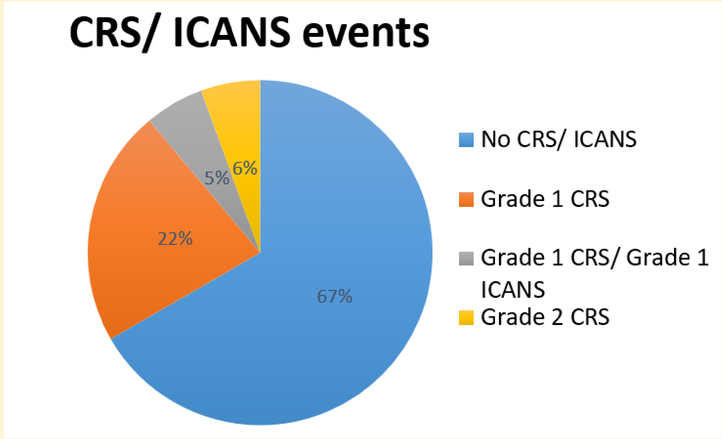
Methods:

This is a retrospective review of toxicity outcomes of patients treated in outpatient teclistamab program at Fox Chase.

Eligible patients were required to stay within 1h from Fox Chase with a caregiver during the observation period (days 1-10).Patients and caregivers received education on CRS & ICANS. Teclistamab was administered on days 1, 3, and 8. Safety monitoring protocol included daily evaluation in the outpatient clinic, home monitoring of vital signs, and 8 pm physician phone call on days 1-5 and 8-10, within 48h window after each step-up dose. CBC, CMP, CRP, ferritin were monitored at each visit. Patients with CRS/ ICANS of any grade were admitted for observation and management.

Results:

- Between 12/2022-5/2023, 18 patients completed outpatient teclistamab step-up dosing. The median age was 66y (46-81).
- 12(66.7%) patients did not have CRS/ICANS. 5(27.8%) patients had grade 1 CRS, of which 1(5.6%) had concurrent grade 1 ICANS. 1(5.6%) patient had grade 2 CRS.
- Of the 6 CRS events, 3(50%) occurred after the first dose and 3(50%) after the second dose.
- 5 of 6 patients with CRS received 1 dose of tocilizumab, and the patient with concurrent ICANS also received dexamethasone, with prompt resolution of symptoms.
- All patients completed step-up dosing with no recurrent CRS/ ICANS.



Conclusions:

Outpatient teclistamab step-up dosing administration with close monitoring and prompt hospitalization for toxicity management is safe and feasible in heavily pre-treated RRMM patients. This approach allows a significant reduction of inpatient stay, resulting in significant healthcare resource savings and improvement of patients' experience.

References:

1. Teclistamab in Relapsed and Refractory Multiple Myeloma. Moreau et al., N Engl J Med 2022; 387:495-505DOI: 10.1056/NEJMoa2203478