Outcomes of Teclistamab (Tec) step-up dosing in outpatient/ hybrid settings among a large sample of relapsed refractory multiple myeloma (RRMM) patients treated with Tec

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Key Takeaway



Teclistamab (Tec) step-up dosing (SUD) is feasible to administer in outpatient or hybrid (OP/HY) settings with appropriate prophylaxis, including pre-medications per label and management of adverse

Conclusions



In this real-world study of relapsed or refractory multiple myeloma (RRMM) patients treated with Tec in primarily community settings, the reported frequency of cytokine release syndrome, immune effector cell-associated neurotoxicity syndrome, and infections was similar between patients receiving Tec SUD in OP/HY settings and the overall cohort



Effectiveness outcomes also appeared similar between patients receiving Tec SUD in OP/HY settings and the overall cohort – best overall response rates were 77.5% and 69.8%, respectively



Introduction

- Teclistamab (Tec) is a first-in-class B-cell maturation antigen (BCMA) x CD3 bispecific antibody approved for the treatment of relapsed/refractory multiple myeloma (RRMM) that demonstrated an overall response rate (ORR) of 63% after a median follow-up of 30.4 months in the pivotal MajesTEC-1 trial.1
- Tec is initiated using step-up dosing (SUD) to mitigate the risk of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS).2
- In real-world practice, Tec SUD initiation is shifting towards outpatient (OP) or hybrid (HY) care models, however, real-world evidence on Tec has been largely collected from academic centers with SUD conducted primarily in inpatient settings.3-6
- The aim of this study was to assess the characteristics, treatment patterns, and clinical outcomes of patients receiving Tec in a large, multicenter dataset of primarily US community practices, including a subgroup of patients who received Tec SUD in OP/HY settings.

Results

Patient and clinical characteristics

- The overall cohort and OP/HY SUD subgroup included 222 and 71 patients (29 OP, 42 HY), respectively (Table 1), with 66.2% of patients in the overall cohort treated by community providers.
- The median patient age was 68 years in the overall cohort and 63 years in the OP/HY subgroup (Table 1).

Table 1: Patient demographic and clinical characteristics

Characteristics	Overall cohort (N=222)	OP/HY subgroup (N=71)
Age, median (range)	68 (49-92)	63 (60-68)
Gender, n (%)		
Female	90 (40.5)	28 (39.4)
Male	132 (59.5)	43 (60.6)
Race, n (%)		
White	166 (74.8)	55 (77.5)
Black	42 (18.9)	13 (18.3)
Asian	7 (3.2)	0 (0.0)
Other/unknown	7 (3.2)	3 (4.2)
Primary insurance, n (%)		
Medicare FFS	85 (38.3)	14 (19.7)
Commercial/Medicare Advantage	112 (50.5)	43 (60.6)
Medicaid	7 (3.2)	2 (2.8)
Military	2 (0.9)	1 (1.4)
Unknown	16 (7.2)	11 (15.5)
High cytogenetic risk, n (%)a	38 (37.6)	28 (42.4)
ECOG PS, n (%)	- (2	
0-1	170 (76.6)	55 (77.5)
2-3	51 (23.0)	15 (21.1)
Unknown	1 (0.5)	1 (1.4)
R-ISS, n (%)		
Stage I	18 (8.1)	9 (12.7)
Stage II	51 (23.0)	23 (32.4)
Stage III	41 (18.5)	12 (16.9)
Unknown	112 (50.5)	27 (38.0)
Extramedullary disease, n (%)	15 (6.8)	1 (1.4)
Prior LOTs, median (range)	4 (1-9)	4 (3-4)
Prior treatment, n (%)		
Prior BCMA exposure	13 (5.9)	4 (5.6)
Triple-class exposed	211 (95.0)	66 (93.0)
Triple-class refractory	179 (80.6)	55 (77.5)
Penta-class exposed	140 (63.0)	36 (50.7)
Penta-class refractory	92 (41.4)	17 (23.9)
Comorbidities, n (%)		
Anemia	81 (36.5)	16 (22.5)
Hypogammaglobulinemia	19 (8.6)	6 (8.5)
Renal impairment or failure	38 (17.1)	9 (12.7)

"High cytogenetic risk was defined as ((4;14), t(14;16), t(14;20), 1q21 gain and/or del(17p). "Extramedullary disease is defined as isolated extraosseous plasmacytomas not associated with bone lesions present or imaging within 3 months prior to the initiation of tecistamab. BCMA, B-cell line of therapy, maturation artigen. ECOG PS, Eastern Cooperative Oroclogy Group performance status. FFS, fee-for-service. HY, hybrid. LOT, OP, outpatient. R-ISS, Revised International Staging System.

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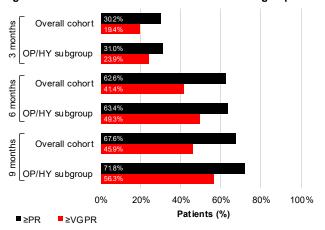
Methods

- This was a retrospective, multicenter chart review study. Data were extracted from electronic medical charts of eligible patients from Cardinal Health's Oncology Provider Extended Network.
- Adult patients with RRMM initiating Tec from October 25, 2022, were included. The follow-up period was from Tec initiation until January 5, 2025, or date of death.
- Data were analyzed for the overall cohort and in a subgroup of patients who received Tec SUD in OP/HY settings (patients who completed SUD fully in the OP setting, and patients who completed SUD in a HY setting that was defined as ≥1 SUD dose in the OP
- Descriptive statistics were calculated to summarize patient characteristics, treatment history, rates of CRS, ICANS and infections. and ORR. Kaplan Meier methods were used to analyze time to event
- · The overall cohort and OP/HY subgroup represented broad patient populations including penta-class exposed patients (likely difficult to treat); at Tec initiation, 23.0% of the overall cohort had an Eastern Cooperative Oncology Group performance status of 2-3 (OP/HY: 21.1%), and 37.6% had high-risk cytogenetics (OP/HY: 42.4%; Table 1).

Effectiveness

- At a median (range) follow-up of 5.4 months (0.3-22.6) and 5.0 months (1.1-22.6), ORR was 69.8% and 77.5% in the overall cohort and OP/HY subgroup, respectively.
- · At 9 months, ORR continued to increase along with deepening of response (Figure 1).
- The median DOR was 14.2 (95% confidence interval [CI]: 14.1, not estimable [NE]) months in the overall cohort and not reached (95% CI: NE, NE) in the OP/HY subgroup.

Figure 1: ORR in the overall cohort and OP/HY subgroup



HY, hybrid. OP, outpatient. ORR, overall response rate. PR, partial response. VGPR, very good partial response

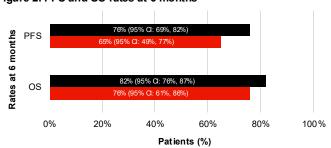
 PFS and OS rates at 6 months were comparable between the overall cohort and the OP/HY subgroup (Figure 2).

Safety

- During SUD, CRS events were reported in 33.3% of the overall cohort (grade 3: 2.3%) and in 26.8% of the OP/HY subgroup (grade 3: 2.8%) and were primarily grade 1/2 (Figure 3).
- ICANS was reported in 5.4% of the overall cohort (grade 4: 0.9%) and in 4.2% of the OP/HY subgroup during SUD (Figure 3).
- Following SUD, 2 CRS events (grade 1 and grade 4) and 1 ICANS event (grade 3) were reported in the overall cohort.
- Treatment discontinuations during SUD due to CRS and ICANS occurred in 1.8% and 1.4%, respectively, of patients in the overall
- Infections were reported in 14.9% of patients in the overall cohort and in 18.3% of patients in the OP/HY subgroup during the follow-up

- CRS and ICANS were described separately during SUD and the maintenance period, while infection frequency was captured over the entire follow-up period, irrespective of timing of the event.
- Clinical outcomes were captured during the follow-up period:
 - ORR (partial response or better, provider-reported according to International Myeloma Working Group criteria);
 - Duration of response (DOR: time from first response to disease progression [PD] or death). Patients who did not have PD or die due to MM were censored at the start date of the next line of treatment or the date of the last patient visit, whichever came first;
 - Progression-free survival (PFS; time from Tec initiation to PD or
 - Overall survival (OS: time from Tec initiation to death).
- For PFS and OS, patients without an event were censored at the date of the last patient visit.

Figure 2: PFS and OS rates at 6 months

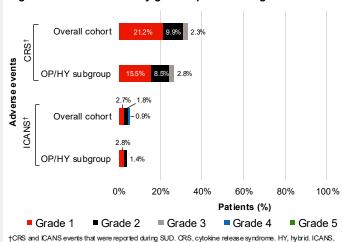


■ Overall cohort ■ OP/HY subgroup

CI, confidence interval. HY, hybrid. OP, outpatient. OS, overall survival. PFS, progression-free survival

- The median (interguartile range) time from Tec initiation to first infection was 70.0 days (49.0, 95.0) in the overall cohort and 59.0 days (49.0, 64.0) in the OP/HY subgroup
- Reported infections were primarily grade 1/2 (overall cohort: grade 1: 5.9%, grade 2: 7.2%, grade 3: 0.9%, grade 5: 0.9%; OP/HY subgroup: grade 1: 8.5%, grade 2: 5.6%, grade 3: 2.8%, grade 5: 1.4%).
- Primary prophylaxis to prevent infections were administered to 80.6% of patients in the overall cohort (intravenous immunoglobulin [IVIG]: 30.6%, granulocyte colony-stimulating factor [G-CSF] therapy: 1.8%, antibiotics: 27.9%, anti-virals: 65.8%, anti-fungals: 21.6%) and 71.8% of patients in the OP/HY subgroup (IVIG: 49.3%, G-CSF therapy: 1.4%, antibiotics: 16.9%, anti-virals: 33.8%, anti-fungals: 18.3%)
- Treatment discontinuations due to reported infections occurred in 2.3% of patients in the overall cohort and two deaths were caused by grade 5 infections (1 COVID-19, 1 unspecified).
 - Of the two patients who died, one received IVIG, one received antibiotics, and both received anti-viral medication as primary prophylaxis to prevent infections during treatment with Tec.

Figure 3: Adverse events by grade reported during SUD



Multiple Myeloma

