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Real-World Characteristics, Step-Up Dosing Patterns, and Early Safety Outcomes of Patients With Multiple Myeloma Treated With Teclistamab Within vs After the First Year of FDA Approval

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Key takeaway

Real-world practice patterns are evolving including treatment of older patients (compared to clinical trials) with teclistamab and increased utilization of teclistamab SUD in the outpatient setting

Conclusions

In this study using nationally representative real-world all payer claims data, we observe that initiators of teclistamab in the real-world, both early (Oct 2022-Sep 2023) and recent initiators (Oct 2023-Jan 2024), were older than the patients from the MajesTEC-1 trial

The early initiators of teclistamab were younger, had a greater baseline comorbidity burden, and were more heavily pre-treated (including prior commercial anti-BCMA therapies) than recent initiators of teclistamab

A higher proportion of recent initiators were observed to have received teclistamab SUD in an outpatient setting as compared to the early initiators; similar rates of CRS were observed in both the groups

These evolving patient characteristics and outpatient SUD models likely reflect the growing familiarity with teclistamab among health care providers and patients

Introduction

- Teclistamab, the first-in-class B-cell maturation antigen (BCMA) x CD3 bispecific antibody, gained US regulatory approval in October 2022 for the treatment of patients with relapsed or refractory multiple myeloma (RRMM)
- To date, published real-world analyses of teclistamab in the US have generally used data cutoffs within one year of its approval[1,2]
- As more patients receive teclistamab at an increasing number of medical centers across the country, there is a growing need to understand changes in patient characteristics, dosing patterns, and early safety outcomes in patients with multiple myeloma (MM) receiving teclistamab

Objective

- To examine real-world patient demographic and clinical characteristics, teclistamab step-up dosing (SUD) patterns, and early safety outcomes among patients with RRMM who initiated teclistamab 'early' (within one year of teclistamab approval) vs 'recent' (after one year)

Methods

- We performed a retrospective observational cohort study using de-identified data from the All-payer Real-world Multiple Myeloma Research-ready Data (ARMMRD) registry, derived from the STATinMED RWD Insights all-payer claims data (covering approximately 87% of the insured population in the US) from January 1, 2014, to January 31, 2024 (the study period)
  - Claims data are used primarily for administrative/reimbursement purposes and are not intended for research. However, claims can provide valuable information on real world practice patterns
  - Although there are inherent limitations with claims such as potential coding errors or omissions, outcomes misclassification, and incomplete information which may cause under-reporting or over-estimation of co-morbidities and outcomes, prior studies have used real-world claims data for analyses of CRS outcmes where results should be interpreted with caution[3]

Study population

- Adult patients (≥18 years of age) with MM who had ≥1 teclistamab claim in the ARMMRD registry between October 26, 2022, and January 31, 2024 (the identification period) were included in this study (**Figure 1**)
- The index date was defined as the date of the earliest outpatient claim of a teclistamab 30 mg/3 mL vial or the admission date of the earliest hospitalization encounter claim that contained teclistamab
- Patients were required to have continuous eligibility for pharmacy and medical benefits for ≥6 months prior to the index date (pre-index period)
- Patients who received teclistamab before or on October 25, 2022 (teclistamab FDA approval date) were excluded

Cohort identification

- Patients who met the following criteria were defined as having a complete SUD period:
  - Had ≥1 inpatient admission containing teclistamab or ≥1 outpatient claim for a 30 mg/3 mL vial for teclistamab. The admission date of the first teclistamab claim (if inpatient) or the administration date of the first teclistamab claim (if outpatient) was defined as the start date of the SUD period
  - All inpatient or outpatient claims for teclistamab with a <5-day gap between claims within a 21-day continuous enrollment period from the SUD start date were rolled up as part of the SUD period. If an index claim was outpatient, an additional outpatient claim for a 153 mg/1.7 mL vial for teclistamab was required unless an inpatient admission containing teclistamab was observed
  - The end date of the SUD period was the discharge date if the last encounter was an inpatient admission, or the claim date +4 days if the last encounter was an outpatient claim for a 153 mg/1.7 mL vial
- Patients were stratified by index date into early initiator (October 2022 through September 2023) and recent initiator (September 2023 to January 2024) cohorts

Data analysis

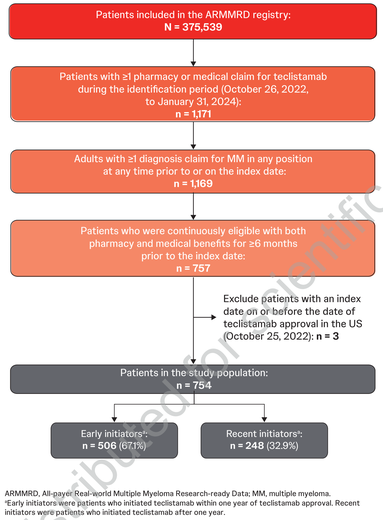
- Patient demographic and clinical characteristics were captured during the 6 months prior to or on the index date among all patients and analyzed descriptively
- Mean, standard deviation (SD), median, interquartile range (IQR), as well as minimum and maximum were reported for continuous variables; counts and percentages were reported for categorical variables
- Cytokine release syndrome (CRS) was evaluated in patients with a complete SUD period
  - CRS was identified in 2 ways: (1) using the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes and (2) using a published algorithm of CRS-related symptoms and treatment codes (Keating algorithm for CRS[3])

Results

Demographics

- Among the 754 patients who met the study criteria, 506 (67.1%) were early initiators and 248 (32.9%) were recent initiators (**Figure 1**)
- Recent initiators of teclistamab were older than early initiators of teclistamab (median age 72 years vs 70 years). A higher proportion of recent initiators were ≥75 years old (41.1% vs 28.3%; **Table 1**). In the real-world, patients in both early and recent initiator cohorts were much older than the MM patients in the MajesTEC-1 trial (median age 64 years)
- Compared to recent initiators, a higher proportion of early initiators had commercial insurance (16.0% vs 10.5%; **Table 1**)
- Median follow up was 7.2 months in early initiators and 2.3 months in recent initiators (**Table 1**)

FIGURE 1: Study population



ARMMRD, All-payer Real-world Multiple Myeloma Research-ready Data; MM, multiple myeloma.
[a]Early initiators were patients who initiated teclistamab within one year of teclistamab approval. Recent initiators were patients who initiated teclistamab after one year.

TABLE 1: Baseline demographic characteristics of patients with MM treated with teclistamab

	Early initiators[a] n = 506	Recent initiators[a] n = 248
Median age (range), years	70 (31–84)	72 (42–85)
Age categories, years, n (%)		
<65	156 (30.8)	53 (21.4)
65 to 70	89 (17.6)	44 (17.7)
70 to 75	118 (23.3)	49 (19.8)
≥75	143 (28.3)	102 (41.1)
Sex, n (%)		
Male	262 (51.8)	126 (50.8)
Female	244 (48.2)	122 (49.2)
Race of patients with race information available, n (%)		
White	314 (81.6)	157 (81.3)
Black	55 (14.3)	31(16.1)
Asian	16 (4.2)	5 (2.6)
Ethnicity of patients with ethnicity information available, n (%)		
Hispanic	62 (16.7)	16 (9.4)
Non-Hispanic	310 (83.3)	154 (90.6)
Region		
Northeast	108 (21.3)	41 (16.5)
Midwest	149 (29.4)	54 (21.8)
South	134 (26.5)	101 (40.7)
West	115 (22.7)	52 (21.0)
Payer type, n (%)		
Commercial	81 (16.0)	26 (10.5)
Medicaid	65 (12.8)	25 (10.1)
Medicare FFS	309 (61.1)	158 (63.7)
Medicare Advantage	51 (10.1)	38 (15.3)
Other insurance	0 (0)	1 (<1)
Median follow up (range), months	7.2 (0–13.8)	2.3 (0–4.8)

FFS, fee-for-service; MM, multiple myeloma.
[a]Early initiators were patients who initiated teclistamab within one year of teclistamab approval. Recent initiators were patients who initiated teclistamab after one year.

Patient clinical characteristics

- Compared to recent initiators, early initiators had a higher mean (SD) Quan-Charlson Comorbidity Index (QCCI) score (4.2 [3.9] vs 3.8 [3.7]), with a higher proportion of early initiators having a QCCI score ≥3 (54.9% vs 51.6%) (**Table 2**)
- Additionally, early initiators had a greater prevalence of baseline comorbidities and relevant conditions, including anemia, infections, peripheral neuropathy, hypogammaglobulinemia, lytic bone lesions, neutropenia, lymphocytopenia, and extramedullary disease

Treatment history

- Among patients with an evaluable treatment history, the median time from the end of the most recent LOT to the index date was shorter for early initiators than recent initiators (31.5 days vs 46.5 days; **Table 3**)
- Prior to teclistamab initiation, higher proportions of early initiators than recent initiators received commercial BCMA-targeted therapy or stem cell transplant (**Table 3**)

TABLE 2: Baseline clinical characteristics of patients with MM treated with teclistamab

	Early initiators n = 506	Recent initiators n = 248
QCCI score		
Mean (SD)	4.2 (3.9)	3.8 (3.7)
Median (IQR)	3 (6)	3 (5)
QCCI categorical scores, n (%)		
0	110 (21.7)	57 (23.0)
1	38 (7.5)	25 (10.1)
2	80 (15.8)	38 (15.3)
≥3	278 (54.9)	128 (51.6)
Key relevant comorbidities and conditions of interest, n (%)		
Hypertension	308 (60.9)	152 (61.3)
Anemia	314 (62.1)	125 (50.4)
Infections[a]	240 (47.4)	91 (36.7)
Renal impairment/failure[b]	215 (42.5)	103 (41.5)
Peripheral neuropathy	196 (38.7)	88 (35.5)
Hypogammaglobulinemia	145 (28.7)	58 (23.4)
Metastatic solid tumor	144 (28.5)	57 (23.0)
Any malignancy[c]	137 (27.1)	61 (24.6)
Lytic bone lesions	133 (26.3)	51 (20.6)
Congestive heart failure	106 (20.9)	60 (24.2)
Chronic pulmonary disease	102 (20.2)	48 (19.4)
Neutropenia	107 (21.1)	37 (14.9)
Osteoarthritis	92 (18.2)	47 (19.0)
Hypercalcemia	69 (13.6)	31 (12.5)
Lymphocytopenia	68 (13.4)	17 (6.9)
COPD	44 (8.7)	22 (8.9)
Extramedullary disease	26 (5.1)	5 (2.0)

COPD, chronic obstructive pulmonary disease; IQR, interquartile range; MM, multiple myeloma; QCCI, Quan-Charlson Comorbidity Index.
[a]Includes COVID-19, pneumonia, upper respiratory tract infection (sinusitis), fungal infections, hepatitis B or C, *C. difficile* infection, bacteremia, *Pneumocystis jirovecii* pneumonia, and tuberculosis.
[b]Includes all stage and unspecified chronic kidney disease, dialysis, end-stage renal disease, kidney transplant, and kidney failure.
[c]Includes lymphoma and leukemia but not malignant neoplasm of the skin.

Health resource utilization during SUD

- As of the data cutoff date, 269 early initiators and 115 recent initiators had an observed complete SUD period. Among these patients, a higher proportion of recent initiators than early initiators had >1 outpatient administration for teclistamab SUD (31.3% vs 17.8%)
- During the SUD period, higher proportions of early initiators than recent initiators had ≥1 intensive care unit visit (22.3% vs 10.4%) and teclistamab-related admission (96.7% vs 91.3%)

Real-world CRS during SUD

- During SUD, similar proportions of early initiators and recent initiators observed a CRS event (**Table 4**). Among patients with ≥1 CRS event, the majority of CRS events were grade 1 or 2 (86.5% and 84.6%, respectively, per ICD codes) or mild (77.7% and 79.4% per Keating classifications) among both early and recent initiators

TABLE 3: Treatment history of patients with MM treated with teclistamab

	Early initiators[a] n = 165	Recent initiators[a] n = 98
Patients with prior LOT information available, n (%)[b]	148 (89.7)	88 (89.8)
Prior BCMA-directed therapies, n (%)[c]	27 (18.2)	9 (10.2)
CAR-T therapy	14 (9.5)	5 (5.7)
Idecabtagene vicleucel	0 (0)	1 (1.1)
Ciltacabtagene autoleucel	14 (9.5)	4 (4.5)
Belantamab mafodotin	17 (11.5)	4 (4.5)
Stem cell transplantation, n (%)[b]	66 (44.6)	32 (36.4)
Time from the end of the most recent LOT to the index date, days		
Median (range)	31.5 (1–1,688)	46.5 (1–2,648)
Duration of the most recent LOT, days		
Mean (SD)	174 (205.9)	153.1 (142.8)
Median (IQR)	111 (139)	106 (144)

ADC, antibody-drug conjugate; BCMA, B-cell maturation antigen; CAR-T, chimeric antigen receptor T cell; IQR, interquartile range; LOT, line of therapy; MM, multiple myeloma.
[a]Includes all patients with an evaluable treatment history. [b]Among patients with prior LOT information available.
[c]Among patients who met the criteria for evaluation of treatment history.

TABLE 4: CRS among patients who completed SUD

	Early initiators n = 269	Recent initiators n = 115
rwCRS events per ICD-10 codes		
Patients with ≥1 CRS event, n (%)	111 (41.3)	39 (33.9)
Patients with grade 1 events, n (%)[a]	75 (27.9)	25 (21.7)
Patients with grade 2 events, n (%)[a]	21 (7.8)	8 (7.0)
Patients with grade ≥3 events, n (%)[a]	2 (<1)	1 (<1)
Patients with CRS grade unknown or unspecified, n (%)	13 (4.8)	5 (4.3)
rwCRS events per Keating classifications		
Patients with any grade CRS (loose definition)	94 (34.9)	34 (29.6)
Patients with mild CRS	73 (27.1)	27 (23.5)
Patients with severe CRS	21 (7.8)	7 (6.1)
Patients with specific rwCRS symptoms per Keating algorithm		
Fever	61 (22.7)	21 (18.3)
Fatigue	30 (11.2)	14 (12.2)
Hypotension	11 (4.1)	5 (4.3)
Hypoxia	2 (<1)	2 (1.7)
Headaches	1 (<1)	0 (0)

CRS, cytokine release syndrome; ICD-10, International Classification of Diseases, 10th Revision; rw, real-world.
[a]If there was more than 1 grade of CRS event, the event with the highest grade was counted.

Limitations

- This is a descriptive study with limited follow-up, especially in the recent initiator cohort. No statistical tests were conducted to compare differences between cohorts
- Proportions of patients with complete SUD could have been underestimated. The data from this study indicate that half of teclistamab patients are not able to complete SUD, which is not true per prior EHR and chart reviews in the literature[4]
- Data are primarily from US insured populations, which may not be generalizable to other populations
- Claims data may under- or over-estimate outcomes due to coding errors, misclassification, omissions, or incomplete information, and therefore, these results should be interpreted with caution
- ICANS events were not reported as ICD-10 codes were not developed until 2022 and there is a lack of algorithm to evaluate ICANS using claims data; both of these could lead to inaccurate estimation

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Poster

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