

# Real-World Evidence on Patient-Reported Outcomes Among Newly Diagnosed Multiple Myeloma Patients Treated With Daratumumab-Based Regimens in Frontline

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## Introduction

- Patients with multiple myeloma have high symptom burden, including fatigue, neuropathy, and bone pain, leading to high rates of anxiety, depression, and psychosocial burden along with a poor health-related quality of life (HRQoL)<sup>1-4</sup>
- Daratumumab (Dara)-based regimens have demonstrated clinical efficacy as well as improvement in HRQoL in both transplant-eligible (TE) and transplant-ineligible (TIE) patients with newly diagnosed multiple myeloma (NDMM) in pivotal randomized clinical trials<sup>5-14</sup>
- However, the impact of these regimens as frontline treatment for NDMM on patient-reported outcomes (PROs) in the real world is not known
- This study examined PROs among real-world patients with TE, TIE, or transplant-deferred (TD) NDMM initiating Dara-based regimens as frontline therapy

## Methods

- This retrospective study analyzed PROs that were captured as part of the University of Alabama at Birmingham Cancer and Aging Resilience Evaluation in Hematologic Malignancies (CARE-Heme) registry
- PROs were collected between January 2020 and April 2024 among TE and TIE/TD patients with NDMM initiating frontline treatment with Dara-based regimens
- The Patient-Reported Outcomes Measurement Information System (PROMIS) scale v1.2 – Global Health was utilized to assess HRQoL; it consists of global physical health and global mental health domains
  - Higher scores reflect better health
- Anxiety was measured using PROMIS Anxiety Short Form 4a v1.0, and depression was measured using PROMIS Depression Short Form 4a v1.0
  - Lower scores reflect lower symptoms
- PROs were captured at baseline (within 30 days of treatment initiation), and at 3, 6, and 12 months, or at the end of treatment
- Scores were transformed to a 0–100 scale (T-score); general population median T-score is set to 50
- Longitudinal, generalized, linear mixed models adjusted for age, sex, race/ethnicity, and treatment type (triplet vs quadruplet) were used to describe the mean change from baseline to 3, 6, and 12 months
- The proportion of patients with clinically meaningful improvement, defined as ≥3-point T-score difference, was reported

## Results

### Clinical characteristics

- The TIE/TD cohort was older, more frail, had more comorbidities, and had more advanced disease compared with the TE cohort, as expected (Table)

**Table: Demographics and clinical characteristics**

	TE (n=37)	TIE/TD (n=44)
Age group, n (%)		
<65 years	19 (51.4)	8 (18.2)
65 to <75 years	17 (45.9)	19 (43.2)
75 to <85 years	1 (2.7)	10 (22.7)
≥85 years	0	7 (15.9)
Male sex, n (%)	21 (56.8)	20 (45.5)
Race and ethnicity, n (%)		
Non-Hispanic White	20 (54.1)	25 (56.8)
Non-Hispanic Black	16 (43.2)	15 (34.1)
Other	1 (2.7)	4 (9.1)
IMWG frailty index, n (%)		
Robust/fit	19 (51.4)	4 (9.1)
Intermediate frail	11 (29.7)	16 (36.4)
Frail	7 (18.9)	17 (38.6)
Missing	0	7 (15.9)
Quan-Charlson Comorbidity Index, n (%)		
0–1	25 (67.6)	17 (38.6)
2	5 (13.5)	2 (4.5)
≥3	7 (18.9)	20 (45.5)
Unknown	0	5 (11.4)
Cytogenetic risk, n (%)		
High risk <sup>a</sup>	13 (35.1)	8 (18.2)
Standard risk	24 (64.9)	36 (81.8)
CRAB symptoms, n (%)		
Hypercalcemia	8 (21.6)	3 (6.8)
Anemia	11 (29.7)	20 (45.5)
Bone lesions based on fractures	21 (56.8)	16 (36.4)
Renal impairment	4 (10.8)	7 (15.9)
ISS stage, n (%)		
I	12 (32.4)	8 (18.2)
II	13 (35.1)	9 (20.5)
III	10 (27.0)	18 (40.9)
Missing	2 (5.4)	9 (20.5)
ECOG PS, n (%)		
0–1	31 (83.8)	21 (47.7)
2	3 (8.1)	8 (18.2)
3	3 (8.1)	9 (20.5)
Missing	0	6 (13.6)
PROs, mean baseline T-score (std)		
PROMIS physical health	45.2 (8.1)	39.5 (8.4)
PROMIS mental health	49.1 (9.2)	46.3 (8.6)
PROMIS anxiety	50.0 (8.6)	51.5 (9.8)
PROMIS depression	48.6 (8.3)	50.1 (8.9)

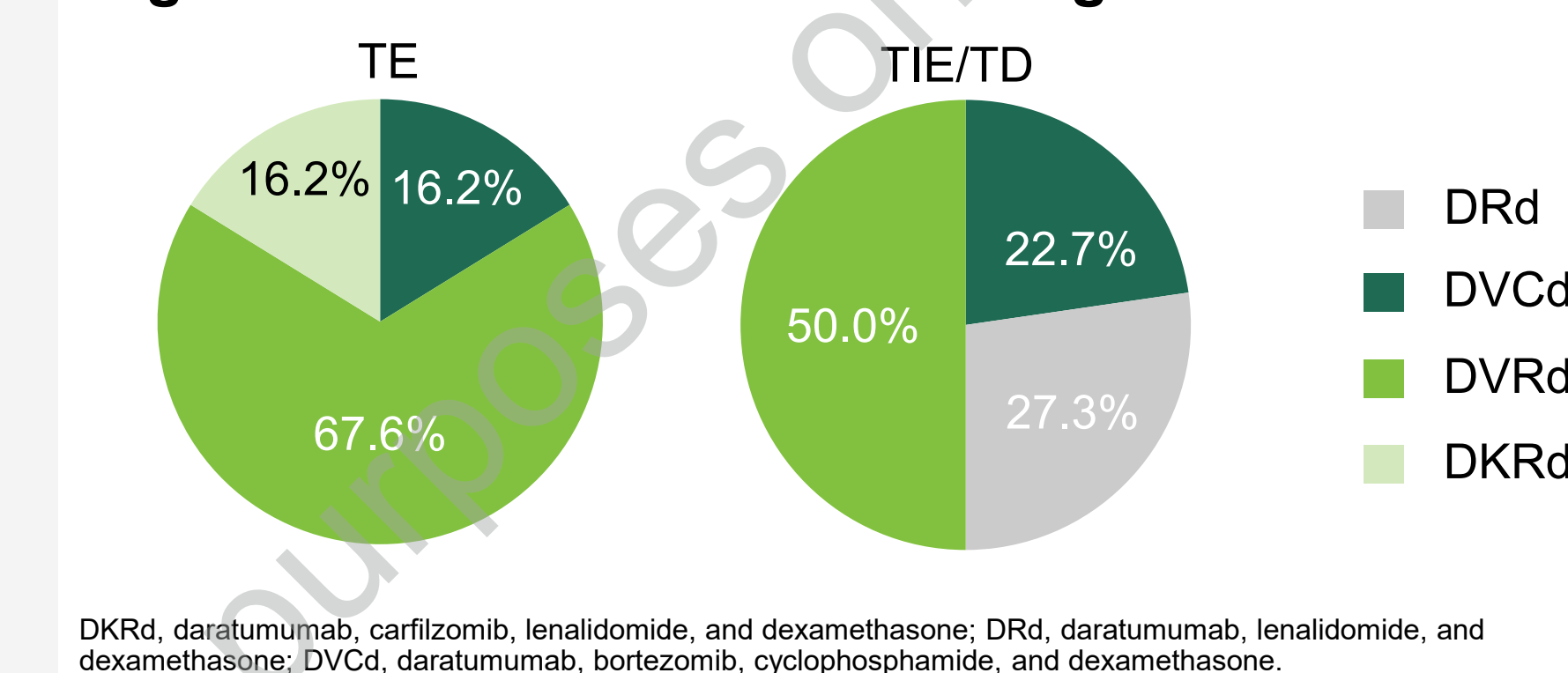
<sup>a</sup>Defined as presence of del17p, t(14;16), t(4;14), t(14;20), or gain/amp 1q21. CRAB, calcium, renal, anemia, bone damage; ECOG PS, Eastern Cooperative Oncology Group performance status; IMWG, International Myeloma Working Group; ISS, International Staging System.

- A greater proportion of TE patients had high-risk cytogenetics
- 57% of TE and 36% of TIE/TD patients had bone lesions or fractures
- 43% of TE and 34% of TIE/TD patients were Black
- TIE/TD patients had worse baseline PRO scores for all 4 domains compared with TE patients
  - Both cohorts had lower mean global physical and mental health scores than the general population median

### Treatment regimens

- Dara, bortezomib, lenalidomide, and dexamethasone (DVRd) was the most common regimen in both cohorts; all TE patients received quadruplet regimens, as did 72.7% of TIE/TD patients (Figure 1)

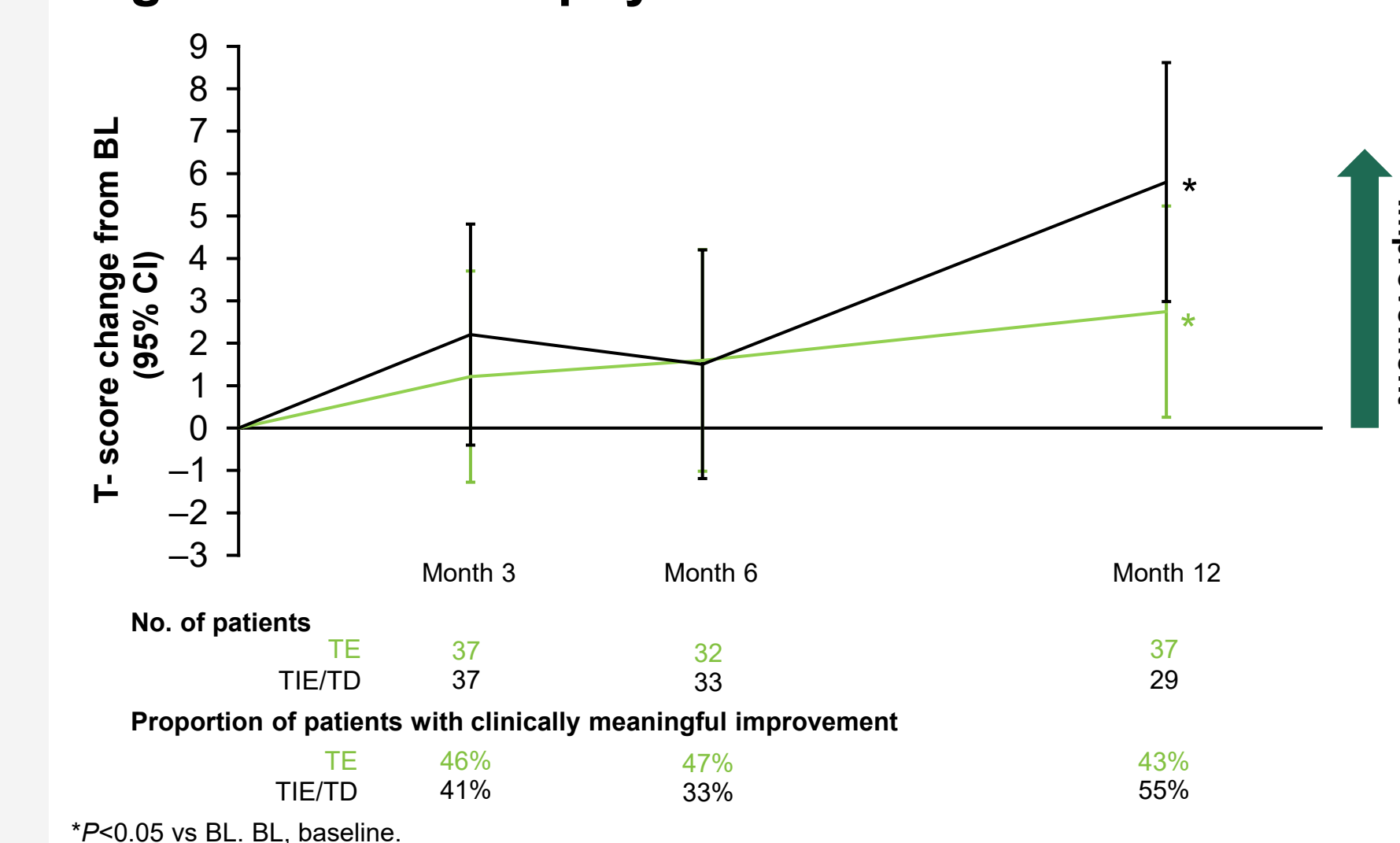
**Figure 1: Dara-based treatment regimens**



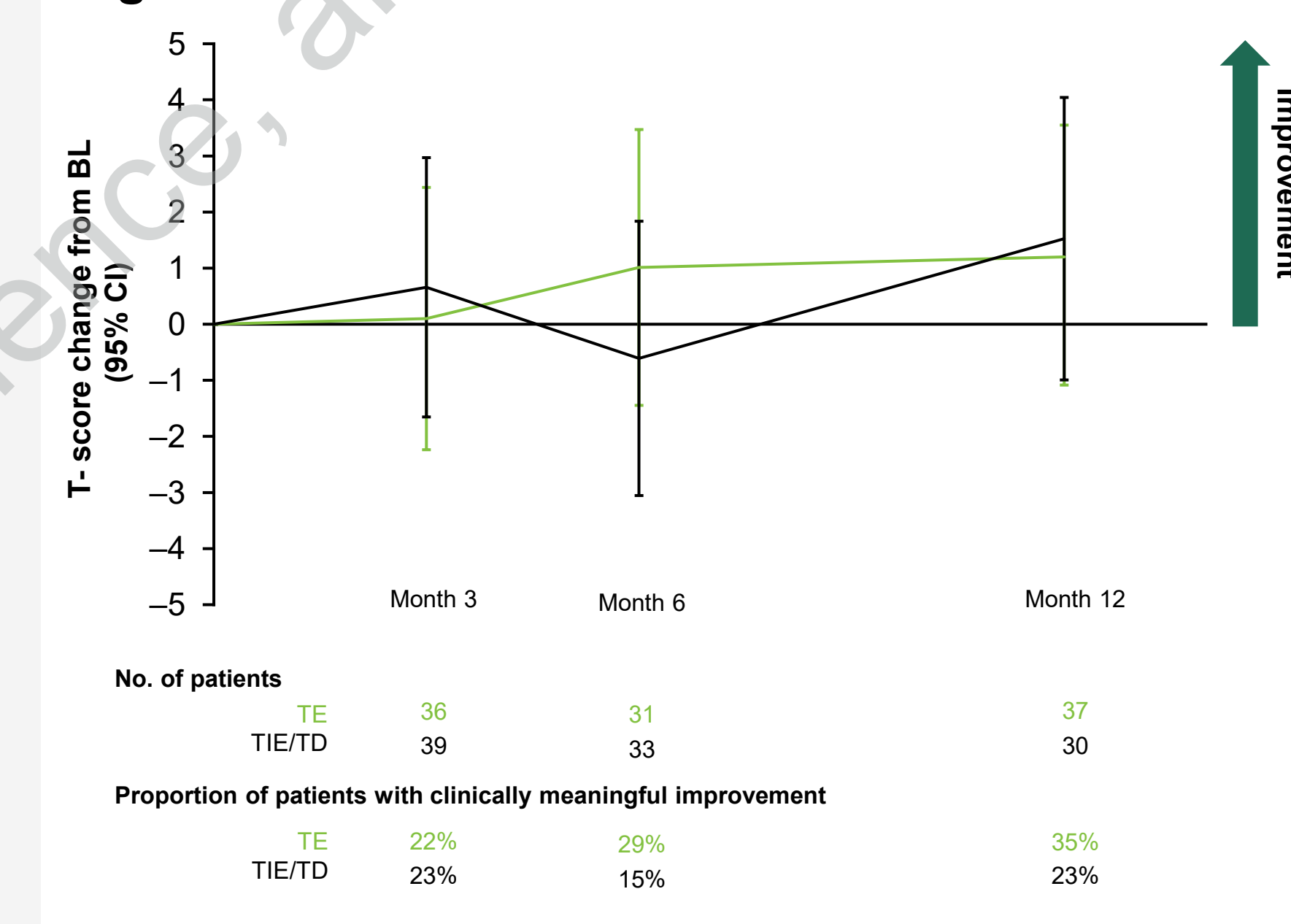
### PROs

- Median follow-up was 359 days (interquartile range [IQR], 345–374) in the TE cohort and 345 days (IQR, 176–361) in the TIE/TD cohort
- TE and TIE/TD patients treated with Dara-based regimens had clinically meaningful improvements from baseline in physical health scores over 12 months (Figure 2)
- About a quarter of patients had clinically meaningful improvements in mental health scores (Figure 3)

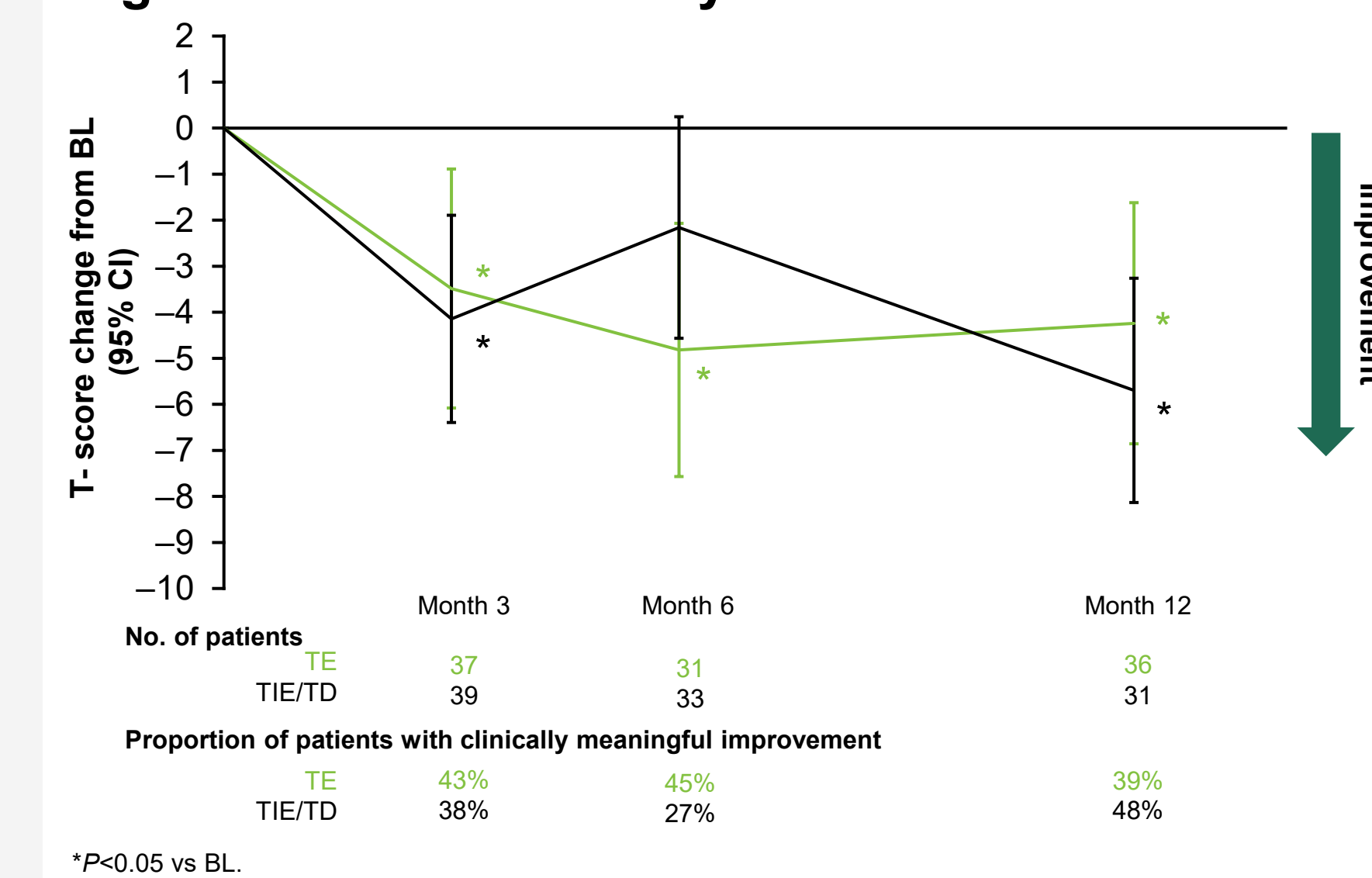
**Figure 2: PROMIS physical health**



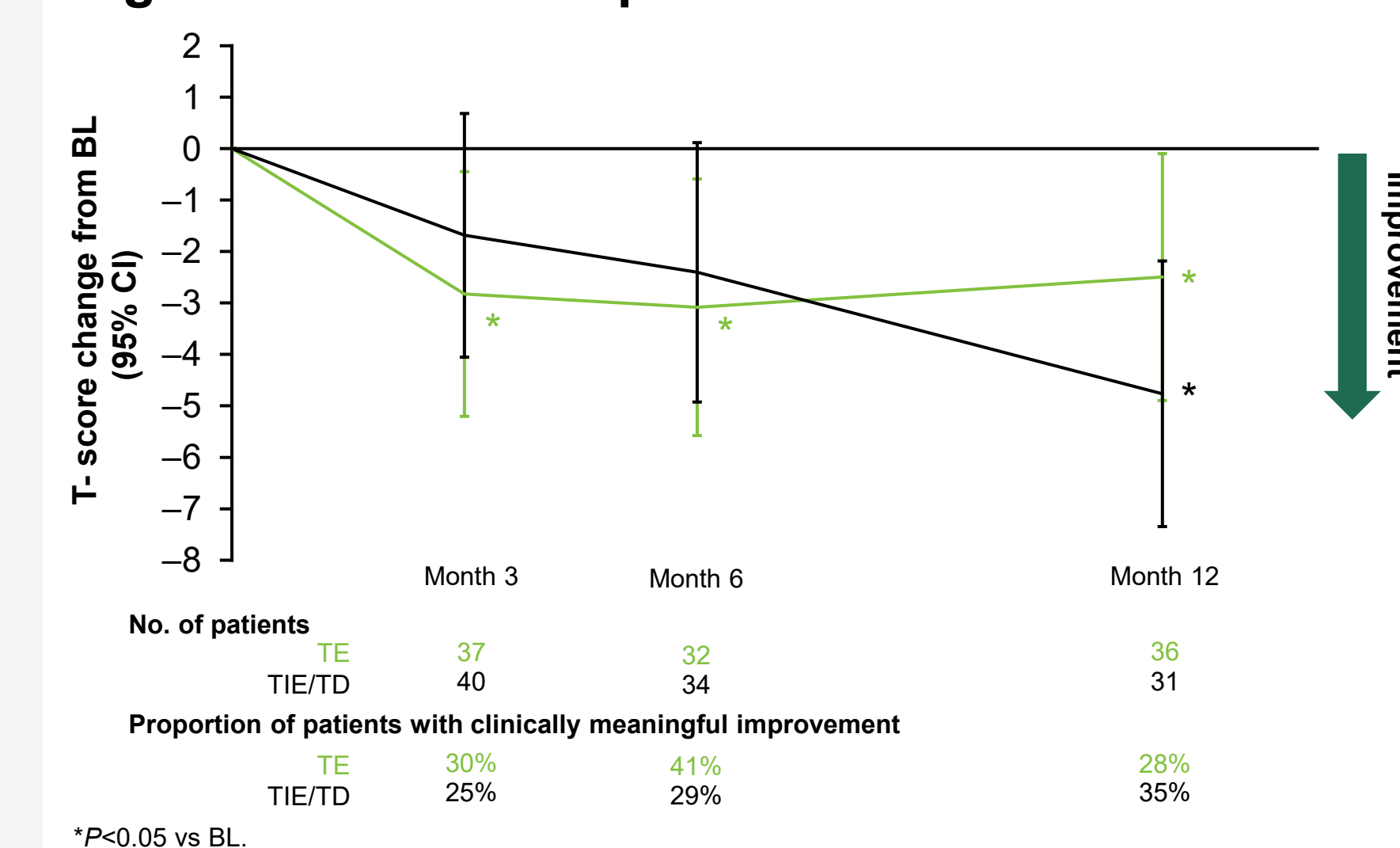
**Figure 3: PROMIS mental health**



**Figure 4: PROMIS anxiety**



**Figure 5: PROMIS depression**



## Key Takeaway

- In this real-world study, significant and clinically meaningful improvements in PROs were observed in TE and TIE/TD patients with NDMM treated with Dara-based regimens, consistent with the PROs observed in the clinical trials employing similar instruments

## Conclusions

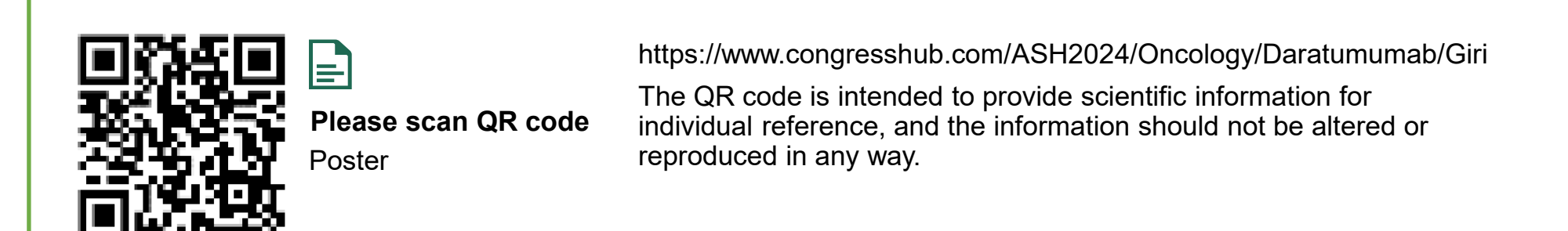
- TIE/TD patients had greater improvements in physical health, anxiety, and depression than TE patients despite being older and more frail
- Improvements in PROs were seen within 3 months of treatment initiation, and were sustained or enhanced with longer treatment
- These findings further support the use of Dara-based regimens in the frontline setting regardless of transplant eligibility, age, or frailty

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