Disease Aggressiveness Index: A Novel Pre-Infusion Risk Stratification Tool for Idecabtagene Vicleucel in Relapsed/Refractory Multiple Myeloma

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INTRODUCTION

- Idecabtagene vicleucel (ide-cel) is an approved BCMA-directed CAR T-cell therapy for relapsed/refractory multiple myeloma (RRMM).
- Real-world outcomes vary widely between recipients.
- No validated pre-infusion composite tool exists to risk-stratify patients before ide-cel infusion.

OBJECTIVE

- To develop and internally validate a simple, bedside-calculable pre-infusion risk score for survival and response after ide-cel.

METHODS

- Retrospective analysis of 821 adults receiving standard-of-care ide-cel for RRMM (May 2021–June 2023) at CIBMTR-reporting U.S. cellular therapy centers.
- Median follow-up 11.6 months; 813 patients evaluable (≥4 of 6 DAI components available).
- The Disease Aggressiveness Index (DAI) assigns 1 point each for six adverse pre-infusion features (see box below).
- Risk groups: Low (0–1), Intermediate (2–3), High (4–6).
- Outcomes: overall survival (OS), progression-free survival (PFS), overall response rate (ORR), and ≥VGPR.
- Kaplan-Meier and log-rank testing; Cox and logistic regression adjusted for age, sex, ECOG, frailty, and comorbidities.

CONCLUSIONS

- The DAI is a simple pre-infusion tool that risk-stratifies ide-cel recipients with RRMM independently of ISS staging.
- Pending external validation, it may inform patient counseling and post-infusion monitoring intensity.
- It may also support stratified enrollment in CAR T-cell trials.

RESULTS

Key findings

- Each additional DAI point independently predicted worse OS (HR 1.49, 95% CI 1.31–1.68) and PFS (HR 1.37, 1.24–1.51).
- High vs Low: OS HR 3.66 (2.34–5.73); PFS HR 2.70 (1.92–3.79); all p<0.001.
- Median OS fell from 20.8 to 7.5 months and median PFS from 13.2 to 4.2 months across increasing DAI tiers (log-rank p<0.001).
- Response depth declined in parallel: ORR 79.1% → 59.1% (p=0.001); ≥VGPR 66% → 46% (p<0.001).
- DAI remained prognostic after adjustment for age, sex, ECOG, frailty and comorbidities, and independently of ISS stage (per-point HR 1.42, p<0.001).
- Tier-stable subset (n=521): per-point HR 1.46, p<0.001. Harrell's C-index for the adjusted OS model 0.672.

The DAI: 1 point each
- Elevated LDH
- High-risk cytogenetics
- Non-responsive pre-infusion disease (NR/SD/PD/relapse)
- Penta-refractory disease
- Extramedullary plasmacytomas
- Prior BCMA-directed therapy

Low 0–1 • Intermediate 2–3 • High 4–6

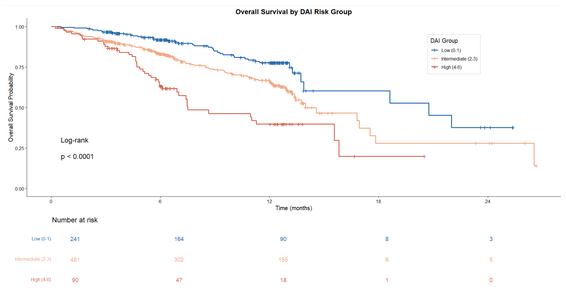

Figure 1. *Overall survival by DAI risk group (n=812 with follow-up).*

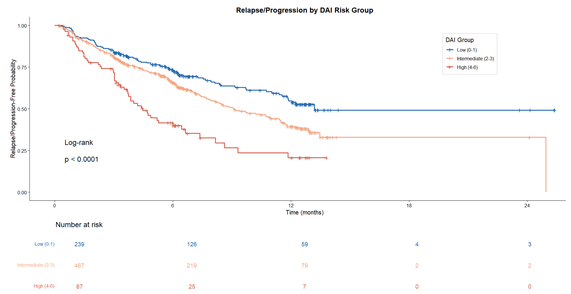

Figure 2. *Relapse/progression-free probability by DAI risk group.*

Outcome	Low (0–1)	Intermediate (2–3)	High (4–6)
Patients, n (%)	241 (29.6)	482 (59.3)	90 (11.1)
Median OS, months	20.8	14.0	7.5
12-month OS	77.7%	66.8%	39.7%
Median PFS, months	13.2	8.6	4.2
ORR	79.1%	72.4%	59.1%
≥VGPR	66%	53%	46%

Table 1. *Survival and response outcomes by DAI risk group. All between-group comparisons p≤0.001.*

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