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Outcomes of Patients With Extramedullary Disease and Relapsed or Refractory Multiple Myeloma From Historical Clinical Trials

Shaji Kumar[1], Saad Z Usmani[2], Jing Christine Ye[3], Yaël C Cohen[4], Peter M Voorhees[5], Emma Scott[6], Robin L Carson[7], Christoph Heuck[6], Ryan Gan[8], Colleen Kane[6], Eleanor Caplan[9], Hemanth Kanakamedala[10], Trilok Parekh[10], María-Victoria Mateos[11]

[1]Mayo Clinic, Rochester, MN, USA; [2]Memorial Sloan Kettering Cancer Center, New York, NY, USA; [3]MD Anderson Cancer Center, University of Texas, Houston, TX, USA; [4]Tel Aviv Sourasky (Ichilov) Medical Center, Faculty of Medical & Health Sciences, Tel Aviv University, Tel Aviv, Israel; [5]Atrium Health Levine Cancer Institute, Charlotte, NC, USA; [6]Janssen Research & Development, Spring House, PA, USA; [7]Janssen Research & Development, Wayne, PA, USA; [8]Janssen Research & Development, Brisbane, CA, USA; [9]Janssen Research & Development, Titusville, NJ, USA; [10]Janssen Research & Development, Raritan, NJ, USA; [11]University Hospital of Salamanca/IBSAL/CIC/CIBERONC, Salamanca, Spain

Key Takeaway

Patients with EMD have worse outcomes compared with patients without EMD in trials comparing standard and novel highly effective regimens

Future clinical trials with innovative therapies are essential to address the unmet medical need in patients with EMD

Conclusions

Response rates were uniformly lower for patients with EMD compared with those without EMD across 7 clinical trials, 5 evaluating standard of care vs novel treatment regimens for RRMM

In all but 1 study (that had only 2 patients with EMD), the 12-month mortality rate was higher for patients with EMD

These data highlight the unmet need for patients with EMD, as their prognosis is consistently worse with standard of care and novel regimens

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Poster

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Disclosures
SK has served in a consulting/advisory role for AbbVie, Amgen, Apizyme, ArcellX, Beigene, BMS, Carsgen, Glycostem, GSK, K36, Menarini, Moderna, Pfizer, Regeneron, Roche-Genentech, Sanofi, Takeda, Telogenomics, Trillium, and Window Therapeutics (no personal payments), and Antengene, Calyxm, and CVS Caremark (with personal payments), and has received research funding from AbbVie, Amgen, BMS, Carsgen, GSK, Janssen, Roche-Genentech, Sanofi, Takeda, and Telogenomics.

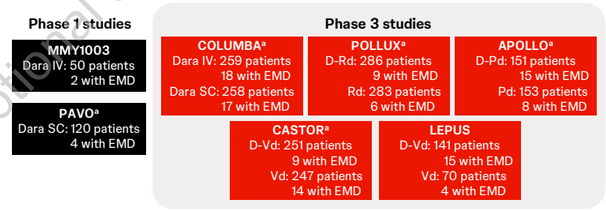
Introduction

- Extramedullary disease (EMD), or plasmacytomas outside the bone marrow in soft tissues or organs, represents an aggressive form of multiple myeloma (MM)[1,2]
- The incidence of EMD in patients with relapsed/refractory MM (RRMM) specifically has been reported to be 3–14%[1]
- With currently available treatments, reported outcomes among patients with RRMM and EMD are worse than those among patients without EMD, highlighting an unmet need in this high-risk population[1,2]
- The aim of this study was to assess the outcomes of patients with RRMM with and without EMD diagnosed with RRMM from historical clinical trials

Methods

- This was a retrospective, descriptive analysis involving secondary use of historical data from 7 clinical trials in patients with RRMM with and without EMD (**Figure 1**)
- Patients were categorized based on EMD at baseline (0=no, ≥1=yes)
- Primary endpoint was overall response rate (ORR) according to International Myeloma Working Group criteria; 95% CIs were estimated using binomial CIs
  - Time-to-event endpoints included progression and death; percent and 95% CIs 12 months after initiation (phase 1 trials) or randomization (phase 3 trials) were estimated using binomial CIs
  - Kaplan-Meier estimates of median progression-free survival and overall survival were not feasible given the small sample size of the EMD subpopulations

Figure 1: Clinical trials included in the analysis[3-9]



[a]EMD defined in these studies as soft tissue plasmacytomas only, excluding paramedullary lesions or soft tissue lesions contiguous with medullary lesions.
Dara, daratumumab; D-Pd, daratumumab, pomalidomide, and dexamethasone; D-Rd, daratumumab, lenalidomide, and dexamethasone; D-Vd, daratumumab, bortezomib, and dexamethasone; IV, intravenous; Pd, pomalidomide and dexamethasone; Rd, lenalidomide and dexamethasone; SC, subcutaneous; Vd, bortezomib and dexamethasone.

Results

Patients and baseline clinical characteristics

- A total of 2274 patients with RRMM (121 [5.3%] with EMD) were analyzed
- Ranges for baseline characteristics across all treatment cohorts for patients with and without EMD are shown in the **Table**

Table: Ranges of baseline characteristics for all treatment cohorts[a]

Characteristic	With EMD (n=121)	Without EMD (n=2153)
Median age, years	53–74	61–69
Female, %	25–65	39–56
Baseline hemoglobin, g/L	99–130	105–118
Baseline creatinine clearance, mL/min/1.73 m^2	70–104	67–82
Prior ASCT,[b] %	0–78	20–75
Refractory status, %		
None	0–50	0–41
Last LOT[b]	0–100	27–84
PI only	0–50	3–71
IMiD only	0–80	11–91
PI and IMiD[c]	0–100	6–54
Median no. of prior lines of therapy		
Across 2 phase 1 studies	4–5	3–4
Across 5 phase 3 studies	1–5	1–4
Race,[d] %		
White	33–100	66–89
Asian[e]	0–56	1–18
Black/African American	0–11	0–10
ECOG PS, %		
0	0–60	24–60
≥1	40–100	40–76
ISS stage[f]		
I/II	67–88	69–84
III	12–33	16–31

[a]Includes all studies unless otherwise noted. [b]Excludes APOLLO, which did not report prior ASCT or refractory status to last LOT. [c]Excludes LEPUS, which did not report patients refractory to both a PI and an IMiD. [d]Excludes MMY1003 and LEPUS, in which all patients were Asian. [e]PAVO did not report an Asian population. [f]Excludes MMY1003, which did not report ISS stage.
ASCT, autologous stem cell transplant; ECOG PS, Eastern Cooperative Oncology Group performance status; IMiD, immunomodulatory drug; ISS, International Staging System; LOT, line of therapy; PI, proteasome inhibitor.

ORR, progression, and death in patients with and without EMD

- Across the 7 trials, ORRs were numerically lower for patients with EMD than in patients without EMD (range, 0–50.0% vs 42.7–92.8%, respectively) (**Figure 2A**)
- Patients with EMD generally had higher rates of progression and/or death over the first year of treatment vs patients without EMD (range, 33.3–100% vs 14.8–69.5%, respectively; death: 0–66.7% vs 6.9–29.2%, respectively) (**Figures 2B** and **2C**)

Figure 2A: Estimated ORR

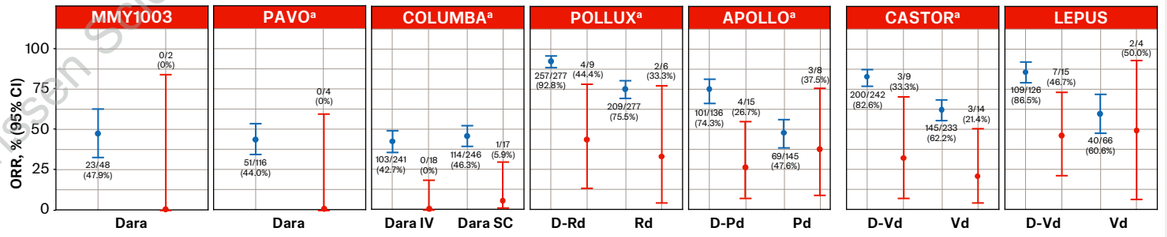


Figure 2B: Estimated proportion of patients who progressed or died in the first year of treatment

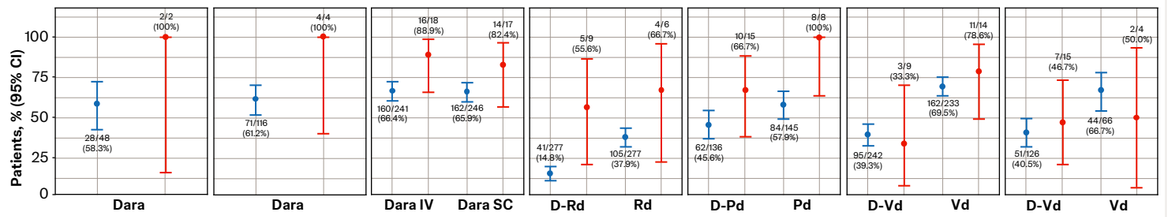
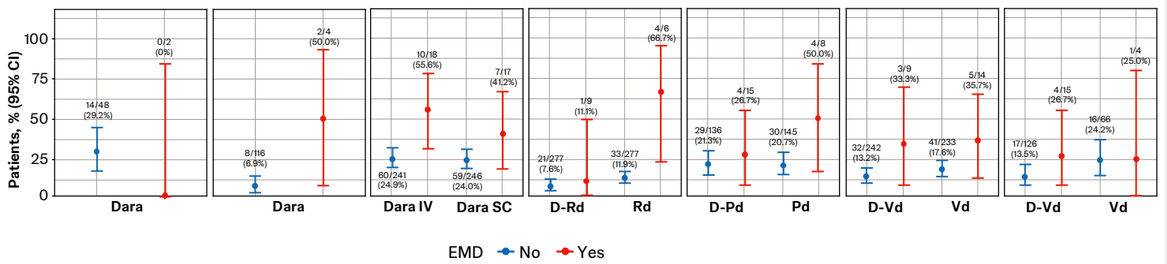


Figure 2C: Estimated proportion of patients who died in the first year of treatment



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