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905.OUTCOMES RESEARCH-LYMPHOID MALIGNANCIES

Real-World Utilization of Daratumumab in Front-Line Treatment of Newly Diagnosed Multiple Myeloma: A Retrospective Observational Study

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Introduction:
Daratumumab (DARA), a CD38 monoclonal antibody, has demonstrated remarkable efficacy among newly diagnosed (ND) and relapsed/refractory multiple myeloma (MM) patients. The introduction of a quadruplet therapy with an addition of DARA per the GRIFFIN trial has improved the treatment paradigm. However, the real-world data on treatment patterns and utilization of DARA in front-line treatment are limited. This study aimed to evaluate the real-world utilization of DARA in front-line treatment and examine factors that may impact the utilization of DARA-based regimen in NDMM.

Methods:
We conducted a retrospective observational study of all patients, age $\geq$ 18, with clinical MM who were newly diagnosed and treated within the Yale New Haven Health (YNHH) system between August 1, 2020 and August 31, 2022. We manually reviewed clinical presentation, age at diagnosis, gender, race, ethnicity, Revised International Staging System (R-ISS) stage, Eastern Cooperative Oncology Group (ECOG) performance status (PS), insurance type, practice setting, immunoglobulin (Ig) isotype, hemoglobin (Hb), creatinine (Cr), and calcium (Ca) at diagnosis, presence of bone lesion, bone marrow plasma cell (BMPC) %, cytogenetic abnormalities, transplant eligibility, and treatment response based on the International Myeloma Working Group (IMWG) criteria at 3 months after front-line therapy. Descriptive statistics were performed with Pearson's χ^2-test using GraphPad PRISM version 9.0.0.

Results:
We identified 241 patients with NDMM during the study period within the YNHH system. Overall median age at diagnosis was 69 years (interquartile range: 61-78). 60.2% (n=145) were male, 68% (n=164) identified themselves as white and 90% (n=217) as non-Hispanic. 51.9% (n=125) had R-ISS stage II and 65.6% (n=158) had ECOG PS of 0-1. 63.1% (n=152) were treated at a community practice setting and 53.9% (n=130) had commercial insurance. 55.6% (n=134) had IgG isotype and 41.1% (n=99) had unfavorable risk cytogenetics which was defined as a 17p deletion, t(4;14), t(14;16), t(14;20), gain or amplification of 1q, 1p deletion, and chromosome 1 translocations. 28.2% (n=68) received front-line quadruplet therapy: DARA+lenalidomide (LEN)+bortezomib (BORTE)+dexamethasone (DEX) (n=54), DARA+cyclophosphamide+BORTE+DEX (n=10), or DARA+LEN+carfilzomib (CARFIL)+DEX (n=4). 58.5% (n=141) received triplet therapy, 8.3% (n=20) received doublet therapy, 0.83% (n=2) received monotherapy, and 4.1% (n=10) opted for hospice care. 41.5% (n=100) received DARA in front-line treatment: quadruplet as above (n=68), triplet of DARA+LEN+DEX, DARA+BORTE+DEX, or DARA+CARFIL+DEX (n=31), and doublet of DARA+DEX (n=1). Factors including gender (male vs. female, p=0.018), practice setting (academic vs community, p=0.014), R-ISS stage (I vs II vs III vs unknown, p=0.003), Ig isotype (IgG vs IgA vs light chain vs other, p=0.006), cytogenetic abnormalities (standard risk vs unfavorable risk, p=0.02), and transplant eligibility (transplant eligible vs transplant ineligible, p=0.001) were associated with the adoption of DARA in front-line treatment. While 51.7% (n=46) of the patients treated at an academic practice setting received DARA in front-line treatment, only 35.5% (n=54) of the patients treated at a community practice setting received such treatment. 69% (n=69) of those who received DARA-based regimen in front-line treatment achieved at least a very good partial response (VGPR) at 3 months compared to 54.6% (n=77) of those who received non-DARA-based regimen. There were no significant differences in age, race, ethnicity, ECOG PS, insurance type, laboratory data (Hb, Cr, and Ca) at diagnosis, presence of bone lesion, and BMPC % between the group treated with DARA-based regimen and the group treated with non-DARA-based regimen.

Conclusion:

This analysis of real-world data from patients with NDMM highlighted underutilization of DARA in front-line treatment, especially at a community practice setting. Gender, practice setting, R-ISS stage, Ig isotype, cytogenetic abnormalities, and transplant eligibility were significantly associated with the adoption of DARA in front-line treatment. Additionally, utilization of DARA in front-line treatment was associated with a better treatment response at 3 months, suggesting that interventions to promote the utilization of DARA will help improve outcomes of NDMM patients.

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Table 1. Demographics and Clinical Characteristics of Newly Diagnosed Multiple Myeloma Patients

Demographics/Characteristics	Total (n=241)	Daratumumab-Based Regimen in Front-Line Therapy (n=100)	Non-Daratumumab-Based Regimen in Front-line Therapy (n=141)	p-value
Age at Diagnosis (years), n (%)				
19-64	88 (36.5)	43 (43)	45 (31.9)	0.149
65-75	79 (32.8)	32 (32)	47 (33.3)	
76-94	74 (30.7)	25 (25)	49 (34.8)	
Gender, n (%)				
Male	145 (60.2)	69 (69)	76 (53.9)	0.018
Female	96 (39.8)	31 (31)	65 (46.1)	
Race, n (%)				
White	164 (68)	63 (63)	101 (71.6)	0.517
Black	45 (18.7)	21 (21)	24 (17)	
Asian or Pacific Islander	7 (2.9)	4 (4)	3 (2.1)	
Unknown	25 (10.4)	12 (12)	13 (9.2)	
Ethnicity, n (%)				
Hispanic	17 (7.1)	7 (7)	10 (7.1)	0.264
Non-Hispanic	217 (90)	88 (88)	129 (91.5)	
Unknown	7 (2.9)	5 (5)	2 (1.4)	
Revised International Staging System (R-ISS) Stage, n (%)				
I	37 (15.4)	23 (23)	14 (9.9)	0.003
II	125 (51.9)	55 (55)	70 (49.6)	
III	45 (18.7)	15 (15)	30 (21.3)	
Unknown	34 (14.1)	7 (7)	27 (19.1)	
Eastern Cooperative Oncology Group (ECOG) Performance Status, n (%)				
0-1	158 (65.6)	70 (70)	88 (62.4)	0.338
2-4	68 (28.2)	26 (26)	42 (29.8)	
Unknown	15 (6.2)	4 (4)	11 (7.8)	
Insurance Type, n (%)				
Medicare	83 (34.4)	28 (28)	55 (39)	0.366
Medicaid	19 (7.9)	9 (9)	10 (7.1)	
Commercial	130 (53.9)	59 (59)	71 (50.4)	
Unknown/Uninsured	9 (3.7)	4 (4)	5 (3.5)	
Practice Setting, n (%)				
Academic	89 (36.9)	46 (46)	43 (30.5)	0.014
Community	152 (63.1)	54 (54)	98 (69.5)	
Immunoglobulin Isotype*, n (%)				
IgG	134 (55.6)	53 (53)	81 (57.4)	0.006
IgA	59 (24.5)	17 (17)	42 (29.8)	
Light Chain	43 (17.8)	27 (27)	16 (11.3)	
Other (IgD/IgM/Non-Secretory)	6 (2.5)	3 (3)	3 (2.1)	
Hemoglobin (g/dL), n (%)				
< 10	129 (53.5)	49 (49)	80 (56.7)	0.235
≥ 10	112 (46.5)	51 (51)	61 (43.3)	
Creatinine (mg/dL), n (%)				
< 1.3	139 (57.7)	64 (64)	75 (53.2)	0.094
≥ 1.3	102 (42.3)	36 (36)	66 (46.8)	
Calcium (mg/dL), n (%)				
≤ 11	202 (83.8)	86 (86)	116 (82.3)	0.438
> 11	39 (16.2)	14 (14)	25 (17.7)	
Bone Lesion, n (%)				
Presence of Bone Lesion	165 (68.5)	67 (67)	98 (69.5)	0.680
Absence of Bone Lesion	76 (31.5)	33 (33)	43 (30.5)	
Bone Marrow Plasma Cell Involvement, n (%)				
< 10%	7 (2.9)	3 (3)	4 (2.8)	0.073
10-59%	91 (37.8)	37 (37)	54 (38.3)	
≥ 60%	130 (53.9)	59 (59)	71 (50.4)	
Unknown	13 (5.4)	1 (1)	12 (8.5)	
Cytogenetic Abnormalities, n (%)				
Standard Risk	120 (49.8)	52 (52)	68 (48.2)	0.020
Unfavorable Risk**	99 (41.1)	45 (45)	54 (38.3)	
Unknown	22 (9.1)	3 (3)	19 (13.5)	
Transplant Eligibility, n (%)				
Transplant Eligible	152 (63.1)	75 (75)	77 (54.6)	0.001
Transplant Ineligible	89 (36.9)	25 (25)	64 (45.4)	
Treatment Response at 3 Months After Front-Line Therapy, n (%)				
≥ Very Good Partial Response (VGPR)	146 (60.6)	69 (69)	77 (54.6)	0.023
≤ Partial Response (PR)	59 (24.5)	23 (23)	36 (25.5)	
Unknown	36 (14.9)	8 (8)	28 (19.9)	

*1 patient had both IgG and IgM multiple myeloma.
**Unfavorable cytogenetic abnormalities include a 17p deletion, t(4;14), t(14;16), t(14;20), gain or amplification of 1q, 1p deletion, and chromosome 1 translocations.

Figure 1

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