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POSTER ABSTRACTS

652.MULTIPLE MYELOMA: CLINICAL AND EPIDEMIOLOGICAL

Unravelling Transplant-Ineligible Newly Diagnosed Multiple Myeloma Treatment in Real-World Practice in Spain. Carinae Study

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Introduction: There is little data regarding real-world treatment patterns and outcomes of transplant-ineligible newly diagnosed multiple myeloma patients (TIE-NDMM) in Spain. In recent years, several treatment regimens have been authorized as effective options for TIE-NDMM, providing patients with better outcomes and quality of life, as evidenced in clinical trials (Mateos et al. *Lancet* 2020). However, the contribution of incorporating these new treatments into the daily therapeutic arsenal has not been widely explored.
Methods: Observational, ambispective, multicenter ongoing study on TIE-NDMM patients who started antineoplastic treatment in the context of daily clinical practice in Spanish hospitals. Group A: started treatment with a combination of ≥2 drugs, between Sep/01/2018 and Aug/31/19. Group B: started treatment with daratumumab in combination with bortezomib, melphalan and prednisone (DVMP group), between Sep/01/19 and Nov/30/20. Here, we present the efficacy and safety outcomes obtained in the second interim analysis after ≈24-month study initiation.
Results: 117 patients were recruited, and 108 were evaluable for efficacy in this interim analysis (group A n=51; group B n=57). No significant differences were observed in basal clinical and demographics characteristics between groups (table 1): mean age 76.9 years; male (53.7%); cardiopathy 28.7%; renal failure 25%; pulmonary obstructive disease 8.3%; peripheral neuropathy 2.8%; median ECOG PS 1; most common myeloma type was IgG (49.5%); 13.9% had a high-risk cytogenetic profile, defined by one of the following alterations: t(4;14), t(14;16) and del 17p13; plasmacytoma 24.3 %. More than 90% of the patients in group A started treatment with schemes based on bortezomib, lenalidomide, or both. Median follow-up was 36.3 versus 23.3 months for groups A and B, respectively, since the initiation of first-line treatment (p<0,0001). Probably in relation to the different follow-ups, the median PFS for Group A was 32.78 months and not reached for Group B (p=0,1129), figure 1. The progression rate at 18 months was 27.5% and 10.5% for Group A and B respectively (p=0,0238). Rates of ≥VGPR and ≥CR, were 60% and 30% in Group A whilst 75.4% and 33.3% in Group B, table 2. 36.9% of the patients showed adverse drug reactions (ADR) related to the first-line treatment during the prospective period. 10.6% of the reported ADRs were serious with no significant differences between groups. No unexpected ADRs were observed. Additional data will be presented at the Congress.
Conclusions: In this interim analysis, a significant clinical benefit has been identified in patients treated with DVMP, with improved PFS indicators vs. other treatment alternatives. Along with the deeper hematological responses observed, we expect this benefit to be consolidated in the final PFS analysis of the *Carinae* study. These real-world practice data continue to support the choice of daratumumab regimens in frontline TIE-NDMM patients.

Disclosures Casanova Espinosa: *Abbvie:* Membership on an entity's Board of Directors or advisory committees; *Roche:* Honoraria; *Pfizer:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees; *Takeda:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees; *Sanofi:* Consultancy, Hono-

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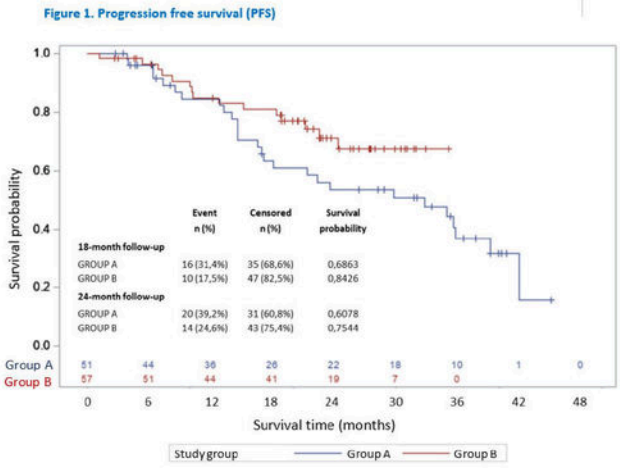
Table 1. Demographic and multiple myeloma characteristics at diagnosis

Characteristics	Total	Group A	Group B	p¹
N	108	51	57	
Age				
Median [range]	75,0 [72,0 ; 79,0]	77,0 [72,0 ; 81,0]	75,0 [73,0 ; 78,0]	0,1951[a]
Sex n (%)				0,8135[c]
Male	58 (53,7%)	28 (54,9%)	30 (52,6%)	
Female	50 (46,3%)	23 (45,1%)	27 (47,4%)	
Comorbidities n (%)				
Cardiopathy	31 (28,7%)	17 (33,3%)	14 (24,6%)	0,3144[c]
Obstructive pulmonary disease	9 (8,3%)	3 (5,9%)	6 (10,5%)	0,4953[f]
Peripheral neuropathy	3 (2,8%)	3 (5,9%)	0 (0,0%)	0,1020[f]
Renal failure	27 (25,0%)	16 (31,4%)	11 (19,3%)	0,1480[c]
ECOG PS n (%)				0,0618[c]
0	23 (21,3%)	7 (13,7%)	16 (28,1%)	
1	40 (37,0%)	22 (43,1%)	18 (31,6%)	
2	23 (21,3%)	8 (15,7%)	15 (26,3%)	
3	8 (7,4%)	4 (7,8%)	4 (7,0%)	
4	1 (0,9%)	0 (0,0%)	1 (1,8%)	
NA	13 (12%)	10 (19,6%)	3 (5,3%)	
Creatinine clearance (mL/min) n (%)				0,1104[c]
<30	13 (12,0%)	8 (15,7%)	5 (8,8%)	
30-60	32 (29,6%)	18 (35,3%)	14 (24,6%)	
>60	52 (48,1%)	23 (45,1%)	29 (50,9%)	
NA	11 (10,2%)	2 (3,9%)	9 (15,8%)	
Myeloma type n (%)				
IgG[2]	50 (40,5%)	22 (48,9%)	28 (50,0%)	0,8026[c]
IgA[2]	35 (34,7%)	15 (33,3%)	20 (35,7%)	
NA	16 (15,8%)	8 (17,8%)	8 (14,3%)	
Oligosecretory	3 (2,8%)	1 (2,0%)	2 (3,5%)	1,0000[f]
Cytogenetic profile (FISH)[3,4] n (%)				
t(4;14) (p16;q32)	8 (16,0%)	5 (19,2%)	3 (12,5%)	0,7041[f]
t(14;16) (q32;q23)	2 (4,0%)	1 (3,8%)	1 (4,2%)	1,0000[f]
Del(17p)	5 (10,0%)	2 (7,7%)	3 (12,5%)	0,6615[f]
NA	15 (13,9%)	5 (9,8%)	10 (17,5%)	
Lytic bone lesions[5] n (%)				0,4651[c]
Yes	66 (61,7%)	29 (58,0%)	37 (64,9%)	
No	41 (38,3%)	21 (42,0%)	20 (35,1%)	
Plasmacytoma[6] n (%)				0,6035[c]
Yes	26 (24,3%)	11 (22,0%)	15 (26,3%)	
No	81 (75,7%)	39 (78,0%)	42 (73,7%)	
Disease staging ISS				0,2435[c]
I	24 (22,2%)	8 (15,7%)	16 (28,1%)	
II	39 (36,1%)	19 (37,3%)	20 (35,1%)	
III	40 (37,0%)	20 (39,2%)	20 (35,1%)	
NA	5 (4,6%)	4 (7,8%)	1 (1,8%)	
Disease staging R-ISS				0,3084[c]
I	18 (16,7%)	6 (11,8%)	12 (21,1%)	
II	54 (50,0%)	28 (54,9%)	26 (45,6%)	
III	17 (15,7%)	10 (19,6%)	7 (12,3%)	
NA	19 (17,6%)	7 (13,7%)	12 (21,1%)	

ECOG PS: Eastern Cooperative Oncology Group Performance status; FISH: Fluorescence in Situ Hybridization; Ig: immunoglobulin; ISS: International Staging System; ISS-R: International Staging System revised.
[a]Comparison between treatment groups: Mann-Whitney U test (u) for numeric variables, Chi-square (c) test or Fisher's exact test (f).
[2]n=1 with biclonality: classified within "Myeloma IgA + IgG".
[3]Based on n=50 patients with detected cytogenetic abnormalities.
[4]n=1 could have more than one type of specified cytogenetic abnormality
[5]n=1 patient without information about specified lytic bone lesions.
[6]n=1 patient without information about plasmacytomas specified. Extramedullary disease was defined as para-skeletal soft tissue masses, soft tissue masses extending beyond the bone marrow, or both.

Figure 1. Progression free survival (PFS)



PFS: Time in months between the date of initiation of first-line treatment and the date of disease progression or death from any cause, whichever comes first. Those patients who did not reach it were censored on the date of the last follow-up.

Table 2. Best response to treatment by group

		Total	Group A	Group B	p¹
N		107	50	57	
Response[2] n (%)					0,1823
≥CR		34 (31,8%)	15 (30%)	19 (33,3%)	
≥VGPR		73 (68,2%)	30 (60%)	43 (75,4%)	
	sCR	15 (14%)	10 (20%)	5 (8,8%)	
	CR	19 (17,8%)	5 (10%)	14 (24,6)	
	VGPR	39 (36,4%)	15 (30%)	24 (42,1%)	
	PR	21 (19,6%)	12 (24%)	9 (15,8%)	
	MR	3 (2,8%)	2 (4%)	1 (1,8%)	
	SD	8 (7,5%)	5 (10%)	3 (5,3%)	
	PD	2 (1,9%)	1 (2%)	1 (1,8%)	

SD: stable disease; PD: progression disease; VGPR: very Good partial response; sCR: strict complete response; CR: complete response; PR: partial response; MR: minimum response.
[a]Comparison between treatment groups: Mann-Whitney U test (u) for numeric variables. [2]n=1 Group A patient with the best inconsistent response at the time of the database cut-off for this interim analysis, which has not been considered for this analysis.

Figure 1

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