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REAL-WORLD 20-YEAR PFS AND OS DATA FROM TURKEY ON THE IMPACT OF THE INTRODUCTION OF DARATUMUMAB INTO THE TREATMENT OF AL AMYLOIDOSIS

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INTRODUCTION

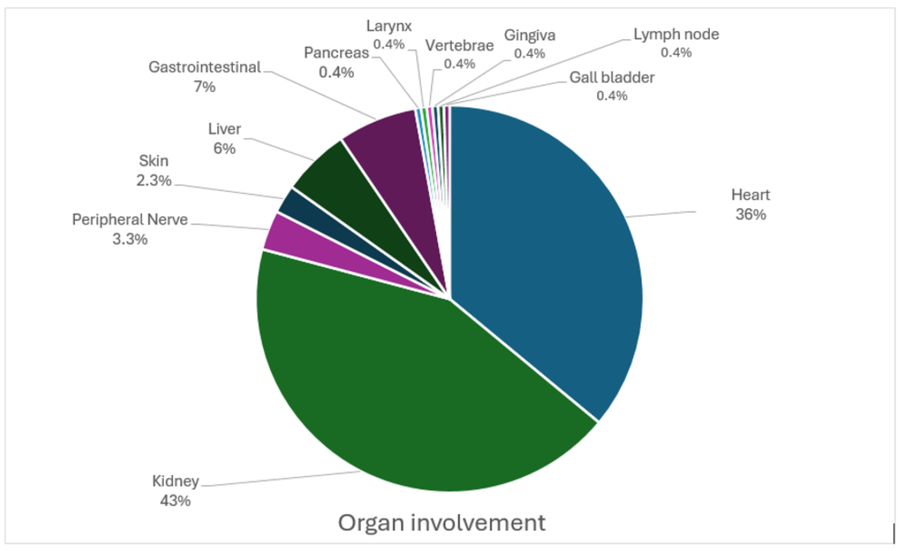
Systemic AL amyloidosis is a plasma cell disease characterized by the deposition of insoluble amyloid fibrils, causing organ dysfunction and death. Results from the ANDROMEDA study showed that the addition of daratumumab to bortezomib, cyclophosphamide, and dexamethasone (VCD) was associated with higher frequencies of hematologic complete response and survival free from major organ deterioration or hematologic progression. In our single-center retrospective real-life case series, we aimed to evaluate the role of AHCT in the era of anti-CD38 monoclonal antibody-based treatments for AL amyloidosis

PATIENTS & METHODS

Consecutive patients newly diagnosed with AL amyloidosis at three centers between 2007-2025 were included retrospectively. As staging, Mayo 2024 the European modification prognostic staging system for AL amyloidosis was used. Statistical analyses were performed with SPSS software version 27.0 (SPSS, Inc., IBM, Armonk, NY). Variables were retained in the model for levels of significance $p \leq 0.05$.

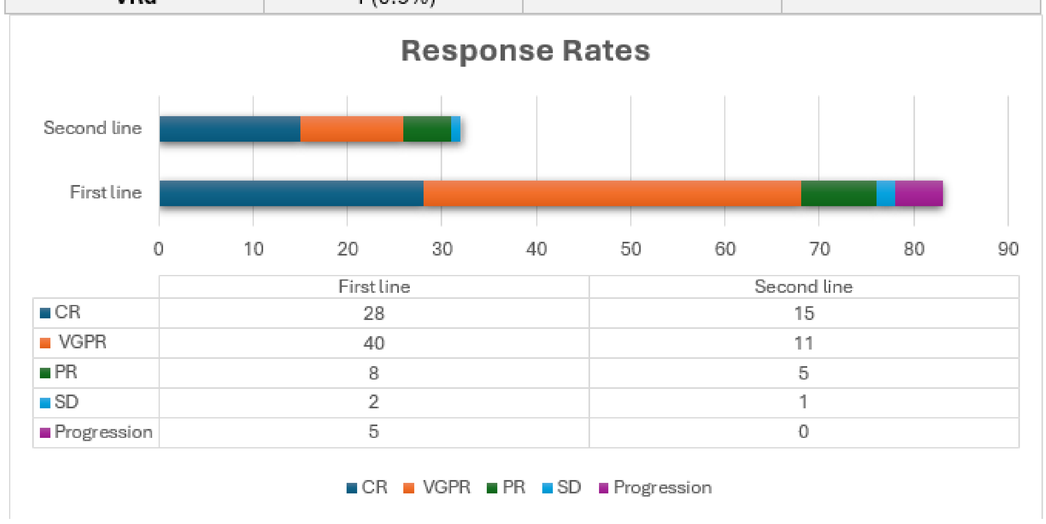
RESULTS

A total of 115 patients with AL amyloidosis (median age: 61 years (29-86); Male/Female: 58/57; median marrow plasma cell 10 %(1-80); Cardiac stage (I/II/IIIA/IIIB:18/13/36/22); renal stage (I/II/III:14/47/26) were included in the analysis. Renal (n=91, 79.8%), cardiac (n=76, 66.7 %) and more than one organ (n=81, 70.4%) involvement were observed. Frontline ASCT (77%) was the treatment of choice, mainly before 2017. After Daratumumab (DARA) approval DARA-based treatments without ASCT consolidation became the first choice in 19 patients out of 61 patients (31.1%) between 2018 and 2025. In patients who received DARA-based induction treatment, renal and cardiac responses were observed in 59% and 55%, respectively. Alongside the markedly increased use of DARA in our center over the last 7 years, the proportion of early deaths (within 3 months after diagnosis) gradually declined (Figure-1). There were significant differences in median OS according to DARA administration (NR vs 23 mos; p<0.001) (Figure-2); even better without ASCT (n=40) compared to others (n=73) (NR vs 23 mos (95% CI 0-55.8); p<0.001) (Figure 3). There were also significant differences in median PFS among patients who received DARA as induction treatment wo ASCT (78.7 vs 18.3 mos, 95% CI 12.7-144.6; p<0.001) (Figure 4). If the Cox proportional hazards model, including Revised Mayo Clinic Stage, w/wo ASCT, w/wo DARA induction, diagnosis year, marrow plasma cell infiltration % was used, DARA administration (HR: 2.0 (95% CI: 1.0-4.0); p=0.04) and wo ASCT (HR: 3.1 (95% CI: 1.5-6.4); p=0.03) were associated with better PFS.

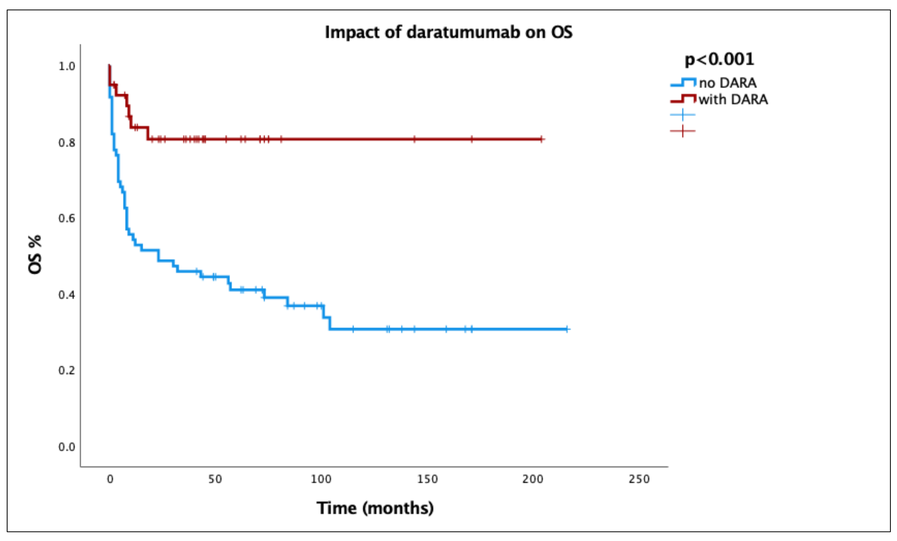


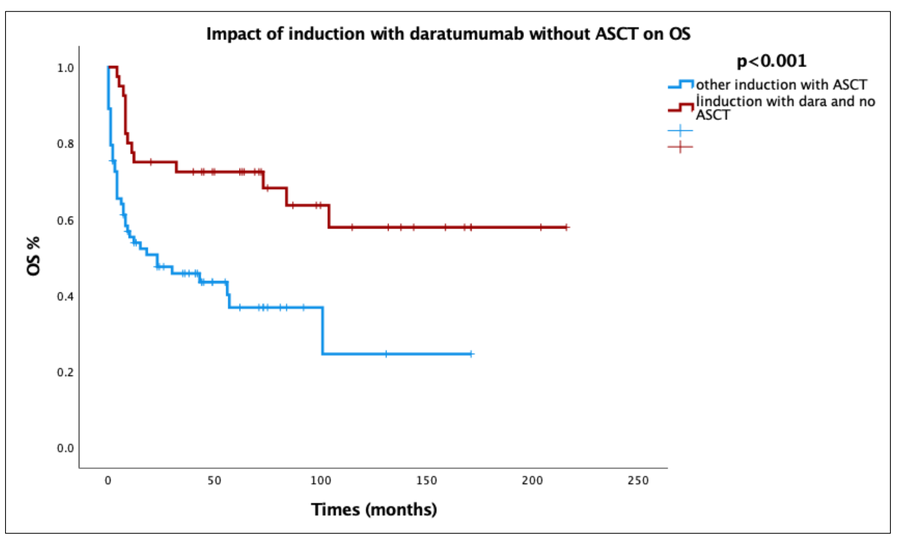
Organ	Kidney	Heart	GIS	Liver	Peripheral Nerve	Skin	Gall Bladder	Gingiva	Larynx	Lymph Node	Pancreas	Vertebra
N	91	76	14	12	7	5	1	1	1	1	1	1

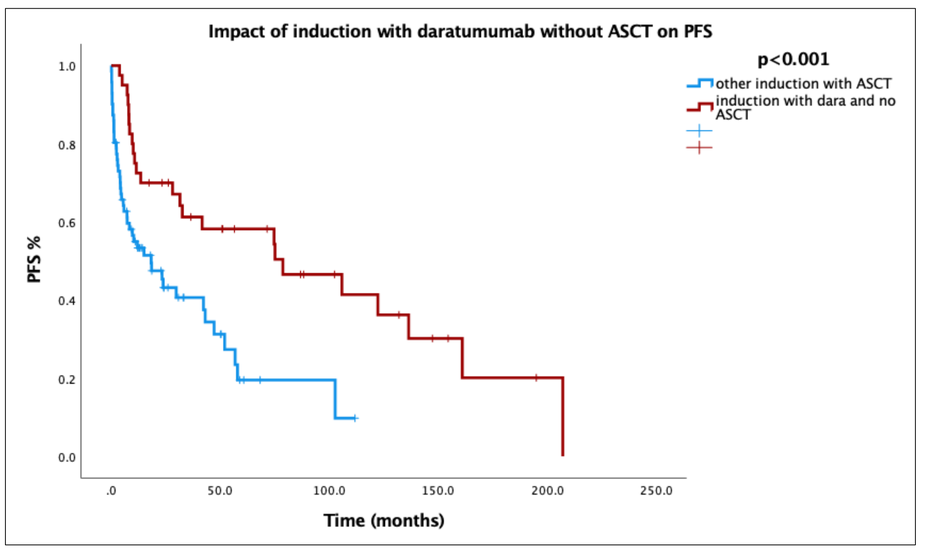
FIRST LINE	N (%)	SECOND LINE	N (%)
VCd	35 (31%)	**ASCT**	11 (34.4%)
DVCd	21 (18.6%)	**DVd**	6 (18.8%)
Vd	14 (12.4%)	**DVCd**	5 (15.6%)
No treatment	14 (12.4%)	**Vd**	3 (9.4%)
ASCT	10 (8.8%)	**VenVd**	3 (9.4%)
DVd	7 (6.2)	**D (monotherapy)**	1 (3.1%)
Md	5 (4.4%)	**DRd**	1 (3.1%)
VAD	2 (1.8%)	**Ixazomib**	1 (3.1%)
MP	1 (0.9%)	**VCd**	1 (3.1%)
Rd	1 (0.9%)		
VMd	1 (0.9%)		
VMP	1 (0.9%)		
VRd	1 (0.9%)		



	First line	Second line
CR	28	15
VGPR	40	11
PR	8	5
SD	2	1
Progression	5	0







CONCLUSION

Our real-world data show a major cardiac and renal response and an improvement in early mortality, PFS, and OS with DARA-based induction treatments even in the absence of ASCT.

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