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DARATUMUMAB-LENALIDOMIDE-DEXAMETHASONE IN PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA NOT CANDIDATES FOR AUTOLOGOUS HEMATOPOIETIC STEM CELL TRANSPLANTATION: EXPERIENCE AT OUR CENTER

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ABSTRACT

Patients with Multiple Myeloma (MM) over the age of 65-70 years or with significant comorbidities are considered not candidates for high-dose chemotherapy followed by autologous hematopoietic stem cell transplantation (ASCT). Daratumumab was used in combination with lenalidomide and dexamethasone (DRd) for the treatment of relapsed MM with better response rates compared to previous treatment regimens. Around 30% of these patients will not have the opportunity to receive a second-line therapy, and the use of different therapies leads to greater disease resistance. The phase 3 MAIA clinical trial incorporates DRd in the first-line treatment of newly diagnosed MM patients not candidates for ASCT, aiming for better responses and increased survival.

Our aim is to evaluate the efficacy and safety of the daratumumab, lenalidomide, and dexamethasone (DRd) regimen in newly diagnosed multiple myeloma patients who are not candidates for autologous hematopoietic stem cell transplantation (ASCT), analyzing the overall response rate, treatment duration, reasons for regimen discontinuation, and progression-free survival outcomes in real-world clinical practice.

This is a descriptive retrospective real-life study of newly diagnosed MM patients not candidates for ASCT treated with DRd at HUVN between October 2022 and February 2025.

RESULTS

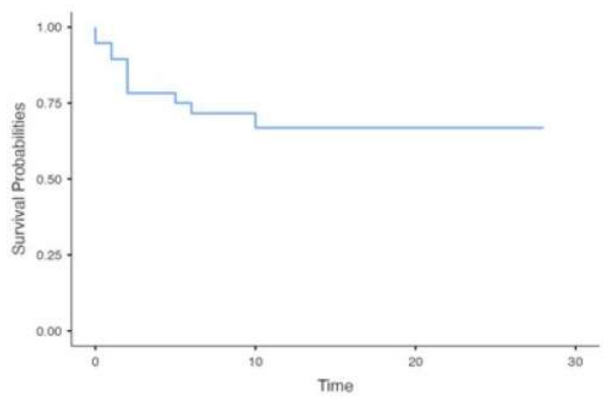
A total of 38 patients were included, with a median age of 77 years (range 64-84), 66% of whom were men. All patients received DRd in the first line. The overall response rate (ORR) was 97%, with 29% achieving complete responses (CR). In patients with high-risk cytogenetic abnormalities, such as del17p (n=6), the ORR was 83%. The median duration of treatment was 7.3 months (range 0.8-28.6). As of the analysis date, the median progression-free survival (PFS) has not been reached in our group due to the short follow-up period with active treatment. 29% of patients (n=11) discontinued the DRd regimen, with 50% of these cases due to lenalidomide toxicity, but maintaining good overall responses (ORR of 91%) and switching to Daratumumab-Bortezomib-Dexamethasone (DVd) regimen.

Table 1. Demographic characteristics and analytical data of the population

Age, median (range)	77	(64-84)
Sex	**n**	**%**
Male	25	66
Female	13	34
Heavy chain	**n**	**%**
Ig G	15	40
Ig A	14	37
Ig D	0	0
Light chain	9	23
Extramedular	4	11
Non-secretory	0	0
Light chain	**n**	**%**
Kappa	19	50
Lambda	19	50
ECOG Scale	n	%
0-1	34	89.5
2-4	4	10.5
R-ISS	**n**	**%**
1	6	16
2	25	65
3	6	16
Not applicable	1	3
Cytogenetic risk	**n**	**%**
Standard	30	79
High	7	18
Not applicable	1	3
Renal function	**n**	**%**
GF<30ml/min	9	24
GF>30ml/min	29	76
Treatment interruption	**n**	**%**
Yes	11	29
No	27	71
Exitus	**n**	**%**
Yes	4	10
No	34	90
Maximun response achieved	**n**	**%**
CR	11	29
VGPR	17	45
PR	7	18
SD	2	5
No response	1	3

Immunoglobuline (Ig), Eastern Cooperative Oncology Group (ECOG), Revised International Staging System (R-ISS), Glomerular filter (GF), Complete response (CR), Very good partial response (VGPR), Partial response (PR), Stable disease (SD)

Figure 1. Progression-free survival (PFS)



CONCLUSION

Our real-life experience with the DRd regimen as a first-line treatment in MM patients not candidates for ASCT has demonstrated excellent ORR (97%), including patients with unfavorable cytogenetic profiles. Half of the patients discontinued DRd due to lenalidomide toxicity without disease progression, maintaining good tolerance to Daratumumab with other combinations. The median PFS in our group has not been reached to date, requiring further follow-up to provide more solid results.

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