SAFETY ANALYSIS OF DARATUMUMAB BASED REGIMENS IN RELAPSED/REFRACTORY MULTIPLE MYELOMA IN A HOSPITAL IN COLOMBIA:REAL LIFE RESULTS

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FUNDACIÓN VALLE DEL LILI

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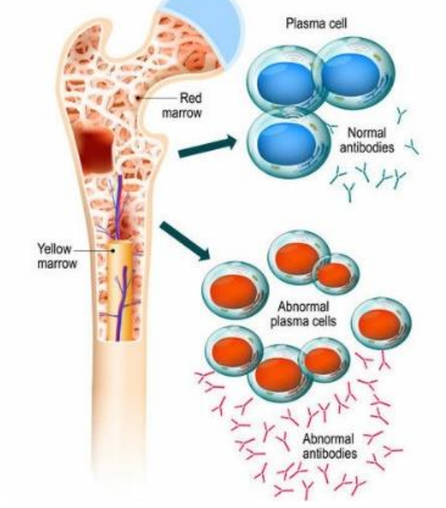
INTRODUCTION

Daratumumab is a humanized IgG1κ monoclonal antibody targeting the CD38 protein, with antibody-dependent cellular cytotoxicity (ADCC) and complement fixation (1).



Daratumumab-based protocols are an alternative for patients refractory to triplet or doublet therapy. However, the presence of adverse reactions may limit its use.

The purpose of this study was to describe the occurrence of adverse events in patients diagnosed with refractory multiple myeloma treated with Daratumumab-based regimens.

METODOLOGY AND RESULTS

Selection of patients over 18 years of age diagnosed with multiple myeloma with clinical relapse or high-risk biochemical relapse, candidates for salvage chemotherapy treated with Daratumumab, from January 2018 (year of approval in Colombia) to January 2024.

Collection of clinical and functional characteristics of the patients.

A total of 131 patients were assessed

127 patients were included

4 patients were excluded due to incomplete information

25 patients treated with regimen "POLLUX"

89 patients treated with regimen **"CASTOR"**

2 patients treated with regimen "CANDOR"

11 patients treated with Daratumumabmonotherapy

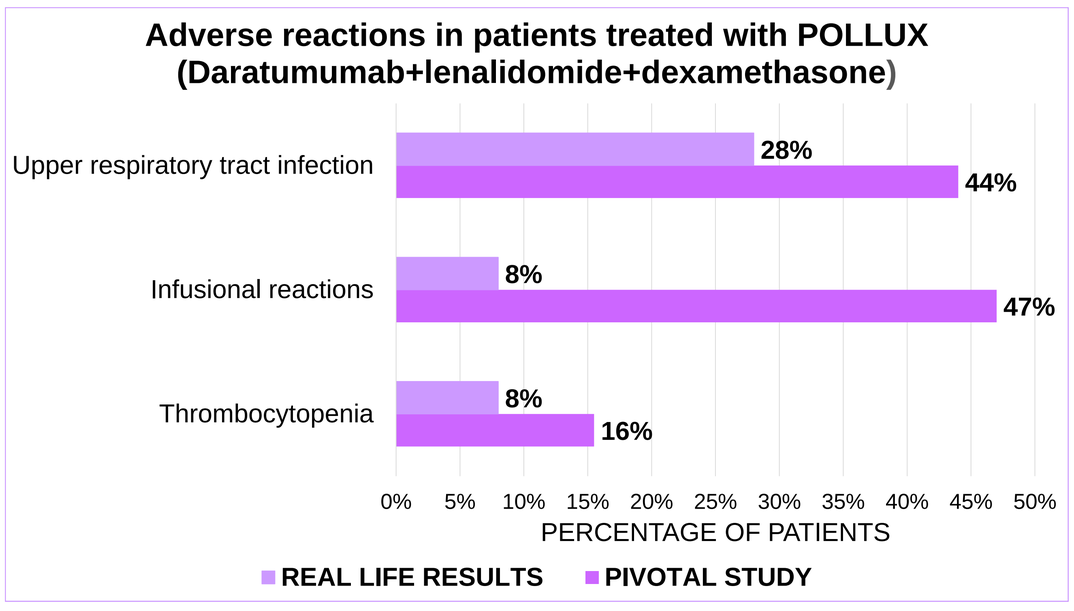


Figure 1. Incidence of adverse effects associated with the POLLUX regimen.

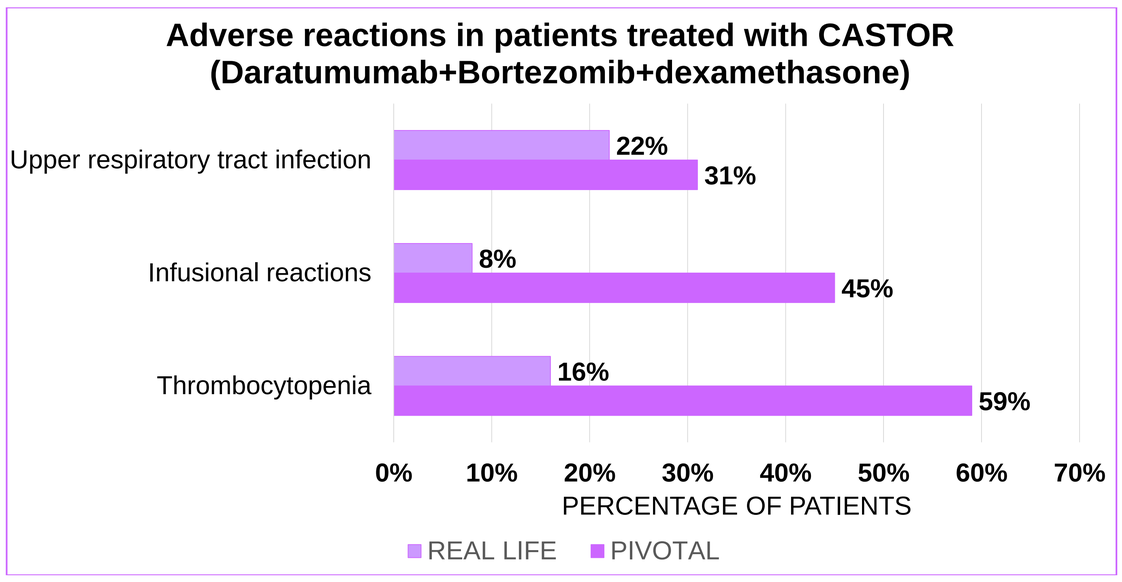


Figure 2. Incidence of adverse effects associated with the POLLUX regimen.

Variable	Pollux, N=25	Castor, N=89	Candor, N=2	Daratumumab monotherapy, N=11	p-value
Upper respiratory tract infection	**7 (28%)**	**20 (22%)**	2 (100%)	1 (9.1%)	0.80
Bronchitis	2 (8.0%)	1 (1.1%)	1 (50%)	0 (0%)	0.03
Pneumonia	**5 (20%)**	**12 (13%)**	0 (0%)	1 (9.1%)	0.60
Urinary tract infections	0 (0%)	3 (3.4%)	0 (0%)	0 (0%)	>0.9
Sepsis	4 (16%)	9 (10%)	1 (50%)	1 (9.1%)	0.08
CMV infection	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.30
Covid-19	2 (8.0%)	1 (1.1%)	0 (0%)	0 (0%)	0.30
HBV	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0.40
Osteomyelitis	0 (0%)	2 (2.2%)	0 (0%)	1 (9.1%)	0.40
Tuberculosis	0 (0%)	2 (2.2%)	0 (0%)	0 (0%)	>0.9
Colitis	0 (0%)	1 (1.1%)	0 (0%)	0 (0%)	0.03

Table 1. Infections occurred in patients treated with Daratumumab-based regimens.

CONCLUSIONS

Among the study population, ***27 patients developed upper respiratory tract infections and 17 developed pneumonia***. Pneumonia was reported at a slightly higher rate compared to the proportion of events observed in the POLLUX (3) and CASTOR (4) clinical trials. The POLLUX regimen was associated with a higher incidence of respiratory infections, making the ***CASTOR regimen a preferred option for patients with a history of respiratory conditions***. However, the CASTOR regimen showed a higher incidence of thrombocytopenia compared to POLLUX.

In this real-world study, Daratumumab-based chemotherapy regimens demonstrated lower rates of thrombocytopenia, peripheral neuropathy, and upper respiratory tract infections

REFERENCES

1. de Weers, M., Tai, Y. T., van der Veer, et al. (2011). Daratumumab, a novel therapeutic human CD38 monoclonal antibody, induces killing of multiple myeloma and other hematological tumors. Journal of immunology (Baltimore, Md. : 1950), 186(3), 1840–1848. https://doi.org/10.4049/jimmunol.1003032

2. Rajkumar SV. Multiple myeloma: 2022 update on diagnosis, risk stratification, and management. Am J Hematol. 2022 Aug;97(8):1086-1107. doi: 10.1002/ajh.26590. Epub 2022 May 23. PMID: 35560063; PMCID: PMC9387011.

3. Dimopoulos MA, Oriol A, Nahi H, et al. Daratumumab, lenalidomide, and dexamethasone for multiple myeloma. N Engl J Med. 2016;375: 1319-1331

4. Palumbo A, Chanan-Khan A, Weisel K, et al. Daratumumab, bortezomib, and dexamethasone for multiple myeloma. N Engl J Med. 2016;375:754-766

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