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Access to Advanced Therapies for Multiple Myeloma in a Referral Hospital in Guatemala

Case Series on the Introduction of Monoclonal Antibodies at Instituto Guatemalteco de Seguridad Social

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Introduction

Multiple myeloma (MM) is a hematological malignancy characterized by the clonal proliferation of plasma cells, associated with organ damage and monoclonal protein production [1]. It accounts for approximately 10% of all hematologic cancers and is the second most common after non-Hodgkin lymphoma [2]. In Guatemala and most Latin American countries, MM is often diagnosed at advanced stages, with high rates of anemia, renal impairment, and bone disease at presentation. Limited access to autologous stem cell transplantation and innovative therapies contributes to worse outcomes compared with high-income countries [3].

For over a decade, standard treatment included combinations based on alkylating agents, thalidomide, lenalidomide, bortezomib, and dexamethasone [4]. The introduction of monoclonal antibodies, particularly daratumumab, has transformed the management of MM, demonstrating significant improvements in response rates, progression-free survival (PFS), and overall survival (OS) [5–8].

The ALCYONE trial showed that adding daratumumab to bortezomib–melphalan–prednisone reduced the risk of progression or death by 50% [5]. The MAIA trial reported similar results with daratumumab–lenalidomide–dexamethasone in transplant-ineligible patients [6]. In relapsed MM, the CASTOR and POLLUX studies confirmed the efficacy of daratumumab combined with bortezomib or lenalidomide [7,8].

This study describes the experience of the Guatemalan Social Security Institute (IGSS), the main public referral center in the country, regarding the progressive introduction of daratumumab-based regimens in the management of MM between 2014 and 2024.

Methods

We conducted a retrospective, descriptive case series including all patients with a confirmed diagnosis of MM according to International Myeloma Working Group (IMWG) criteria, treated at IGSS whit monoclonal antibody between January 2014 and December 2024.

Variables analyzed included: type of light chain, baseline hemoglobin, renal function, initial treatment regimen, use of daratumumab (first line or relapse), clinical response (non-progression, relapse, complete remission), and vital status at last follow-up.

Descriptive statistics were used (frequencies and percentages).

Results

A total of 63 patients were included.Baseline characteristics

- 53% presented with kappa light chain.
- 87% (55 patients) had hemoglobin <10 g/dL.
- 37% had estimated glomerular filtration rate (eGFR) <60 ml/min.

Initial Treatment Regimens

- • 53% received CyBorD (cyclophosphamide, bortezomib, dexamethasone).
- • 47% received lenalidomide–dexamethasone (Rd) or bortezomib–dexamethasone (Vd).
- • 33% received daratumumab-containing regimens (triplet or quadruplet).

Clinical Outcomes

- 27% of patients did not progress during follow-up; among them, 58% had received daratumumab in first line.
- Among relapsed patients, 50% received daratumumab.
- At the end of follow-up, 84% of patients treated with daratumumab remained in complete remission and alive.

Discussion

Our findings provide a valuable contribution to the scarce literature on real-world use of novel therapies in multiple myeloma (MM) in Latin America. While pivotal clinical trials such as MAIA, ALCYONE, POLLUX, and CASTOR have demonstrated the efficacy of daratumumab-containing regimens in controlled environments [5–8], real-world cohorts are essential to confirm reproducibility in routine clinical practice, particularly in resource-limited settings.

The high rate of complete remission (CR) and survival in our cohort (84% of patients treated with daratumumab) is particularly noteworthy given the unfavorable baseline characteristics observed. Nearly 9 out of 10 patients presented with anemia (Hb <10 g/dL) and more than one-third had impaired renal function (eGFR <60 ml/min). Both factors are traditionally associated with poor prognosis and shorter survival [3]. The sustained responses observed suggest that the incorporation of monoclonal antibodies may help mitigate the adverse prognostic impact of such clinical features.

Another relevant aspect is the timing of daratumumab introduction. In our series, patients who received daratumumab in first line accounted for 58% of the non-progressors. This observation echoes findings from MAIA and ALCYONE, where early integration of daratumumab yielded superior long-term outcomes [5,6]. By contrast, patients who received daratumumab at relapse still achieved durable responses, consistent with CASTOR and POLLUX results [7,8], highlighting its versatility across disease stages.

Our study also underscores the challenges of drug access in middle-income countries. Unlike clinical trial populations with standardized access to all active agents, the treatment landscape in Guatemala remains restricted. Options such as carfilzomib, pomalidomide, or autologous stem cell transplantation are not uniformly available within the public system. Under these circumstances, daratumumab represented a major breakthrough in our institution, providing patients with a therapeutic opportunity closer to international standards of care.

The implications extend beyond clinical efficacy. Introducing novel therapies requires overcoming logistical, financial, and regulatory barriers. Incorporation of daratumumab at IGSS was possible thanks to institutional commitment, careful patient selection, and multidisciplinary coordination. This experience highlights the potential of collaborative strategies between healthcare providers, policymakers, and patient advocacy

groups to expand access to life-prolonging treatments in resource-constrained environments.

Nevertheless, several limitations should be acknowledged. First, the retrospective and single-center design precludes establishing causality. Second, response assessments were not uniformly standardized using IMWG criteria, which could lead to variability in reported outcomes. Third, survival endpoints such as progression-free and overall survival were not systematically captured, limiting comparisons with clinical trials. Future prospective, multicenter studies are warranted to validate these observations and to better characterize prognostic subgroups in the Guatemalan population.

Despite these limitations, our work provides novel insights that bridge the gap between controlled trial data and real-world outcomes in a Latin American context. This reinforces the value of generating local evidence to guide treatment decisions and resource allocation.

Conclusion

In conclusion, this case series represents the first institutional report from Guatemala describing the real-world experience with monoclonal antibodies in MM. Our results demonstrate that incorporating daratumumab into routine clinical practice at IGSS led to high rates of remission and survival, despite the unfavorable clinical profile of most patients at baseline.

These findings confirm the clinical benefit of daratumumab across treatment lines, both as part of upfront regimens and in relapsed settings, aligning with results from pivotal international trials. Importantly, they provide robust local evidence that can inform decision-making processes in the Guatemalan healthcare system.

Beyond the clinical outcomes, this experience highlights the broader health policy implications of introducing advanced therapies in public institutions of middle-income countries. Ensuring sustainable access to innovative agents requires strategic planning, negotiation of drug pricing, strengthening of infusion capacities, and training of oncology/hematology teams.

Looking forward, our Experience Sets the Foundation for Several Priorities:

- Establishing prospective registries to systematically capture treatment outcomes in MM.
- Expanding access to complementary therapies such as proteasome inhibitors, immunomodulators, and autologous transplantation.
- Encouraging regional collaborations across Latin America to harmonize treatment protocols and share outcome data.
- Advocating for public policies that guarantee equitable and timely access to novel therapies for all patients with MM.

Ultimately, the successful integration of daratumumab at IGSS demonstrates that even in resource-limited settings, it is possible to achieve outcomes comparable to those of high-income countries when access to innovative therapies is ensured. This reinforces the urgent need to continue reducing disparities in cancer care across Latin America.

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