

Experience of a Latin American Tertiary Center with Donanemab Infusion

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INTRODUCTION

Donanemab is an anti-amyloid monoclonal antibody approved by ANVISA in 2025 for early-stage Alzheimer’s disease. We report the initial implementation experience of Donanemab therapy in a Latin American Tertiary Center.

METHODS

We conducted an institutional experience report and descriptive case series at a Latin American Tertiary Center implementing a multidisciplinary Donanemab infusion protocol. Data were collected through a medical record review, including protocol logistics, eligibility screening, infusion administration, MRI monitoring, and adverse event management. The eligible criteria were: mild cognitive impairment or mild AD dementia with Clinical Dementia Rating (CDR) ≤ 1 and MMSE > 20), AD biomarker positivity (amyloid PET or CSF), baseline MRI Fazekas ≤ 1 , and no anticoagulant use; APOE genotyping was performed and $\epsilon 4/\epsilon 4$ patients were excluded. Donanemab infusions were administered using 2 dose-escalation regimens (Table 1) and were preceded by corticosteroid and antihistamine premedication. Safety outcomes included infusion-related reactions and MRI-confirmed ARIA-E/ARIA-H during surveillance.

RESULTS

Protocol implementation was structured around five pillars: a standardized brain MRI protocol and neuroradiologist training for ARIA surveillance; pharmacist training for medication storage and handling; nursing staff training for drug administration and adverse-event monitoring; and education of emergency department physicians regarding contraindications to thrombolytic agents and the recognition and management of therapy-related adverse events. Fifteen patients were screened for Donanemab therapy; seven met clinical eligibility criteria. However, only four initiated treatment due to high cost barriers. The median time from screening to first infusion was 3 months. To date, three patients have completed the full treatment course, all of whom achieved amyloid PET negativity. The fourth patient is currently receiving their 9th infusion. One patient (an APOE $\epsilon 4/\epsilon 4$ heterozygote) experienced a infusion-related reaction consisting of rash, respiratory stridor, and transient hypertension, along with a headache. Another patient reported transient post-infusion irritability. Surveillance MRI for one patient identified asymptomatic radiological findings consistent with normal pressure hydrocephalus. Crucially, no ARIA-E or ARIA-H events have been observed to date. Clinical presentation remained stable compared to baseline across all patients.

TABLE 1 – Donanemab Dosing Regimens

Infusion Number	Regimen 1 (Dose Escalation)	Regimen 2 (Dose Escalation)
1	1 vial (350 mg)	2 vials (700 mg)
2	2 vials (700 mg)	2 vials (700 mg)
3	3 vials (1050 mg)	2 vials (700 mg)
4	4 vials (1400 mg)	4 vials (1400 mg)
Subsequent infusions	4 vials (1400 mg)	4 vials (1400 mg)

CONCLUSIONS

Early real-world implementation of Donanemab in a Latin American tertiary center was feasible with a structured multidisciplinary protocol. However, high cost substantially limited access, and ongoing surveillance remains essential to ensure safety, particularly regarding ARIA.

REFERENCES

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