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Journal of Neurology & Stroke

Research Article

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Natalizumab in relapsing-remitting Multiple Sclerosis: A retrospective case series of 14 patients at Mohammed V Military teaching hospital of Rabat

Abstract

Aims: To describe clinical outcomes and tolerability of natalizumab in patients with relapsing-remitting multiple sclerosis at Mohammed V Military Teaching Hospital in Rabat. Study Design: Retrospective, single-center observational case series.

Place and duration of study: Department of Neurology, Mohammed V Military Teaching Hospital, Rabat, Morocco, January 2013 to March 2023. Methodology: We reviewed records of 14 patients treated with natalizumab and extracted relapse history, Expanded Disability Status Scale (EDSS) scores, magnetic resonance imaging (MRI) findings, JC virus antibody status, and adverse events.

Results: Mean age was 37.6 ± 13.1 years; 10 patients (71.4%) were women. Natalizumab was initiated as first-line therapy in five patients and after interferon beta-1a in nine. Six patients (42.9%) had no documented relapse during natalizumab treatment. In eight patients with available data, mean annualized relapse rate was 2.0 before any disease-modifying treatment and 1.6 during natalizumab treatment. Mean EDSS scores were 3.88 before initial treatment and 2.19 after natalizumab, but these assessments occurred at different treatment stages. Five patients had nonserious adverse events, one had anaphylaxis, and one had MRI findings suspicious for progressive multifocal leukoencephalopathy without documented confirmation. Three patients discontinued natalizumab.

Conclusion: This small retrospective series describes clinical experience with natalizumab in a military teaching hospital. Differences in follow-up and missing paired measurements preclude causal estimates of effectiveness; suspected progressive multifocal leukoencephalopathy should not be counted as a confirmed event.

Keywords: multiple sclerosis, natalizumab, retrospective studies, relapse, disability, progressive multifocal leukoencephalopathy

Volume 16 Issue 4 - 2026

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Received: September 22, 2026 | **Published:** October 07, 2026

Introduction

Natalizumab is a monoclonal antibody directed against α4 integrin that inhibits leukocyte trafficking into the central nervous system. In the randomized AFFIRM trial, treatment reduced clinical relapses and new MRI lesions and delayed confirmed disability progression compared with placebo.[1] Its effectiveness has also been evaluated in the prospective Tysabri Observational Program (TOP), which follows patients treated in routine practice.[2] Treatment nevertheless requires surveillance for adverse events, particularly progressive multifocal leukoencephalopathy (PML). Anti-JC virus (JCV) antibody status, previous immunosuppressant exposure, and treatment duration contribute to PML risk stratification.[3,4] We report the experience of Mohammed V Military Teaching Hospital in Rabat involving 14 patients with relapsing-remitting multiple sclerosis (RRMS), focusing on disease activity, disability, and tolerability.

Methodology

We conducted a single-center retrospective observational study in the Department of Neurology at Mohammed V Military Teaching Hospital, Rabat. The study included 14 patients with RRMS who received natalizumab between January 2013 and March 2023. Eligible patients met the 2017 McDonald diagnostic criteria[5] and received natalizumab 300 mg intravenously every four or six weeks. Patients lost to follow-up and those with insufficient records were excluded. The individual follow-up duration could not be established consistently from the available summary data.

We extracted demographic data, previous treatment, annualized relapse rate (ARR), Expanded Disability Status Scale (EDSS) scores, MRI activity, anti-JC virus (JCV) antibody status, laboratory abnormalities, infusion reactions, and reasons for discontinuation. Counts, percentages, and means are reported as available in the study summary. Comparisons are restricted to patients with available measurements. As paired individual measurements and assessment intervals were not uniformly available, outcomes are presented descriptively without an inferential test. Language editing was assisted by OpenAI ChatGPT (Codex, GPT-6, 2026); the authors retain responsibility for all clinical data and interpretations.

Results

The mean age of the 14 patients was 37.6 ± 13.1 years, and 10 were women (71.4%). All had RRMS at natalizumab initiation. Five patients (35.7%) received natalizumab as first-line treatment for disease considered highly active, whereas nine (64.3%) started it after interferon beta-1a. The mean interval between diagnosis and natalizumab initiation was 35.1 ± 57.7 months. Baseline characteristics are summarized in Table 1.

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Table 1 Baseline characteristics and natalizumab exposure

Characteristic	Result
Patients, n	14
Age, mean± SD, years	37.6±13.1
Women, n (%)	10 (71.4)
RRMS at natalizumab initiation, n	14
First-line natalizumab, n (%)	5 (35.7)
Natalizumab after interferon beta-1a, n (%)	9 (64.3)
Time from diagnosis to initiation, mean± SD, months	35.1±57.7

SD, standard deviation; RRMS, relapsing-remitting multiple sclerosis.

Six of 14 patients (42.9%) had no relapse during treatment, whereas eight had at least one relapse. Among eight patients for whom a comparison was reported, mean ARR decreased from 2 before any disease-modifying treatment to 1.6 during natalizumab treatment. A separate analysis of four previously interferon-treated patients reported a mean ARR of 4 during interferon beta-1a treatment versus 2.5 during natalizumab treatment. These estimates concern different subsets and should not be combined. Clinical outcomes are summarized in Table 2.

Table 2 Clinical and radiological outcomes

Outcome	Before natalizumab	During or after natalizumab
Relapse-free patients, n/N	—	6/14 (42.9%)
ARR in the reported subset, mean (n = 8)	2.0 before any disease-modifying treatment	1.6
ARR in the previously interferon-treated subset, mean (n = 4)	4.0 during interferon beta-1a	2.5
EDSS, mean± SD	3.88± 1.94 before initial treatment	2.19±1.71
New MRI lesions, n	8 on pre-natalizumab follow-up MRI	1 with nonenhancing lesions and suspected PML*
Contrast-enhancing MRI lesions, n	6 on pre-natalizumab follow-up MRI	Not reliably quantified

ARR values were calculated in distinct patient subsets and observation periods. EDSS measurements were taken at different treatment stages. One radiological finding raised suspicion for PML without an established final diagnosis. ARR, annualized relapse rate; EDSS, Expanded Disability Status Scale; MRI, magnetic resonance imaging; PML, progressive multifocal leukoencephalopathy.

The mean EDSS score was 3.88 ± 1.94 before the first disease-modifying treatment and 2.19 ± 1.71 at the assessment after natalizumab initiation. Because these measurements do not represent a uniform pre- and post-natalizumab interval, and nine patients received interferon beta-1a between assessments, the change is descriptive and cannot be attributed to natalizumab alone (Table 2).

Before natalizumab initiation, follow-up MRI identified new lesions in eight patients and contrast enhancement in six. During treatment, new nonenhancing lesions in one patient prompted an evaluation for possible progressive multifocal leukoencephalopathy (PML). The available study summary does not establish a final PML diagnosis. MRI acquisition intervals and the number of evaluable post-treatment scans were not uniform, precluding a comparative estimate of radiological activity.

Five patients experienced at least one nonserious infusion-related adverse event, including headache, a cutaneous reaction, or throat irritation. Anaphylaxis in one patient led to treatment discontinuation. Seven patients had at least one laboratory abnormality recorded during monitoring; individual abnormality categories could not be tabulated consistently from the available aggregate data (Table 3).

Table 3 Tolerability and treatment discontinuation.

Finding	Patients
At least one nonserious adverse event	5/14
Anaphylactic shock requiring discontinuation	1/14
At least one laboratory abnormality	7/14*
Anti-JCV antibody negative at baseline	13/14
Anti-JCV antibody positive at baseline	1/14
Discontinued natalizumab	3/14
Reasons for discontinuation	Suspected PML (1); anaphylaxis (1); anti-JCV seroconversion (1)

At baseline, anti-JC virus antibodies were negative in 13 patients and positive in one. One patient subsequently had a positive anti-JC virus test and discontinued natalizumab. The antibody index at that time is omitted because two different values were recorded in the source document. Overall, three women discontinued natalizumab following an MRI finding suspicious for PML, anaphylaxis, and anti-JC virus seroconversion, respectively; two later received fingolimod. Laboratory abnormalities were recorded in seven patients; individual abnormality categories are not shown because their denominators were not consistently available. JCV, JC virus.

Discussion

This series describes natalizumab use as first-line therapy in patients with highly active disease and as subsequent treatment after interferon beta-1a in the remaining patients. Six of 14 patients had no relapse during natalizumab treatment. The descriptive reductions in ARR in the analyzed subset and in EDSS are consistent with observed clinical improvement; however, sample size, patient selection, and the assessment periods preclude causal attribution. AFFIRM demonstrated a reduction in relapses and sustained disability progression compared with placebo,[1] while long-term TOP data describe outcomes in a larger routine-practice population.[2] Neither provides a directly comparable estimate for this small series without harmonized baseline characteristics and observation periods. A separate TOP analysis examined disability improvement during treatment.[6]

Safety assessment is central to treatment decisions. A large risk-stratification analysis associated anti-JCV seropositivity, previous immunosuppressant use, and longer natalizumab exposure with different levels of PML risk;[3] the anti-JCV antibody index can further refine risk estimates in selected patients.[4] Expert recommendations describe the role of MRI surveillance when PML is suspected.[7] In this series, MRI findings raised suspicion of PML, but no confirmatory evidence was available in the study summary. If available, the clinical course, follow-up MRI, and cerebrospinal fluid JCV testing should

Citation: Alloussi H, Benmouh Y, Mouloudi N, et al. Natalizumab in relapsing-remitting Multiple Sclerosis: A retrospective case series of 14 patients at Mohammed V Military teaching hospital of Rabat. *J Neurol Stroke*. 2026;16(4):174–176. DOI: 10.15406/jnsk.2026.16.00668

be reported before assigning a final diagnosis. Anaphylaxis and anti-JCV seroconversion illustrate distinct reasons for discontinuation. In patients considered for six-week administration, the randomized NOVA trial provides evidence on extended-interval dosing, but our single patient with a prolonged interval cannot inform its comparative efficacy or safety.[8] Disease activity after natalizumab interruption has also been described in pooled clinical trial analyses, emphasizing the importance of documenting post-discontinuation follow-up.[9]

This study is limited by its retrospective single-center design, small sample, absence of a comparator group, heterogeneous treatment and observation periods, and incomplete paired outcome data. Relapse and EDSS estimates refer to different subsets or assessment windows. MRI activity and individual categories of laboratory abnormalities could not be compared consistently across all patients. These factors limit quantitative assessment of treatment effects and should be considered when interpreting the descriptive findings.[10]

Conclusion

In this retrospective series of 14 patients treated at Mohammed V Military Teaching Hospital in Rabat, six had no documented relapse during natalizumab treatment. Three patients discontinued treatment for distinct safety-related reasons. A radiological finding prompted evaluation for possible PML, but the available study summary does not establish that diagnosis. These observations describe local clinical experience; the available data do not permit a comparative estimate of natalizumab effectiveness.

Acknowledgements

None.

Conflicts of interest

The authors declare that there are no conflicts of interest.

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