

Use of Natalizumab in Hispanic Patients with Relapsing Remitting Multiple Sclerosis

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BACKGROUND

Multiple Sclerosis (MS) is a complex disease. Several etiologic factors play a role in disease severity and frequency, particularly genetic susceptibility. Similar to what is reported worldwide, MS prevalence in Texas is higher in non-Hispanic white women with a female to male ratio of 4:1. Nevertheless, according to US and Latin American studies, MS prevalence in Hispanic population has apparently increased over the last 20 years. In 19 Texas counties, Hispanics were the third most common group affected with MS with a prevalence of 11/100,000.

Immunomodulatory treatments have demonstrated efficacy in treating relapsing remitting MS. Natalizumab has been shown to reduce relapse rate (RR) and progression of disability in relapsing forms of MS. However, little information is available regarding inter-racial variability in treatment response, particularly in Hispanics.

OBJECTIVES

To describe disease characteristics and treatment efficacy of natalizumab in Hispanic patients with relapsing forms of Multiple Sclerosis.

METHODS

Review of medical records of MS patients on natalizumab at Maxine Mesinger MS Comprehensive Care Center.

RESULTS

Of the one hundred and forty two patients with relapsing Multiple Sclerosis receiving natalizumab in our center, seven are Hispanic. Figure

All the patients have relapsing remitting MS and the F:M ratio was 6:1. The clinical presentation leading to diagnosis was limb weakness, paresthesias and brainstem involvement in the same frequency followed by fatigue. One patient had prior history of ON. Over the course of disease, six patients developed weakness, three developed ataxia and all of them experienced paresthesias. The mean age at first attributable symptom was 24.14 (14-31) years.

Prior to natalizumab, six patients had been treated with two or more DMT and two had received chemotherapy. Table 1. The decision to start natalizumab was based on clinical and radiographic response to prior treatment.

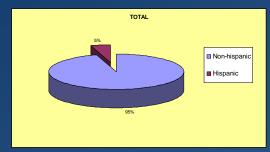


Figure 1. Seven of the 142 patients receiving natalizumab were Hispanic

Patient	Previous treatment
1	Betaseron, Avonex, Rebif, Copaxone
2	Copaxone, Avonex
	Copaxone, Cyclophosphamide, Rebif
4	Betaseron, Avonex, Rebif, Mitoxantrone
5	Rebif, Tysabri
6	Copaxone, Rebif
7	Avonex

Patient	Number of Natalizumab doses	
1	29 Doses	
2	20 Doses	
3	37 Doses	
4	43 Doses	
5	12 Doses	
6	10 Doses	
7	29 Doses	
Table 2 Number of doses		

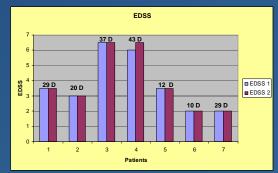


Fig 3, EDSS, D: number of doses

RESULTS

The mean disease duration prior to the first natalizumab dose was 8 years (3 -13y) and mean treatment duration was 25.7 (10-43) doses. Table 2. One patient stopped natalizumab after the 20th dose because of infection and concerns of PMI risk

Clinically, six patients remained relapse free and one patient developed a pseudo exacerbation. Figure 2. The EDSS remained stable in 6 patients. Figure 3.

The initial MR images demonstrated brain T1 hypointensities in 6 patients, spinal cord involvement in 5 and brain gadolinium enhancing lesions in 3. Subsequent images (every 6-12 months) showed no Gadolinium enhancing lesions and 3 patients developed new T2 lesions at some point.

The adverse events recorded were ovarian cyst infection, subclavian vein thrombosis, UTI and rash.

CONCLUSIONS

- The prevalence of Multiple Sclerosis in Hispanic population seems to be increasing. Many reasons may account for the current tendency: better diagnostic assessment, increase in availability of resources, patient education and genetic mix.
- The clinical presentation that led to diagnosis in our group was different from what is usually described in the literature. Our patients had limb weakness and brainstem involvement as commonly as sensory changes. Further studies should address aggressiveness of disease in Hispanics.
- Baseline MRI demonstrated T1 hypointensities in 87% and spinal cord lesions in 71% of the patients.
- In response to treatment, our series showed 100% relapse prevention and 85.7% EDSS stabilization in a mean follow up of 25 months (10-43).
- MRI T2 lesions remained stable in 57% patients and no Gad-enhancing lesions were documented. MRI T2 lesion behavior was less effective than in the original trial.
- Our observations have limitations (retrospective, possible selection bias and sample size). However, overall treatment efficacy in our Hispanic population was similar to the original trials.

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^{3.-} Hebert J, Rivera V, Pace A, Hyde R. Effects of Natalizumab on Relapses and MRI Outcomes in Hispanic patients with Relapsing Multiple Sclerosis. European Committee for Treatment and Research in Multiple Sclerosis. September 2009

^{4.-} Polman CH, O'connor P, Havrdova E, et al. A Randomized, Placebo-Controlled Trial of Natalizumab for Relapsing Multiple Sclerosis. NEJM March 2006.