Fingolimod Reduces T1 Hypointense and Gadolinium Enhancing Lesions in Hispanic MS Patients

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Background

Fingolimod (FG) is a sphingosine-1-phosphate (S1P) receptor modulator that is FDA approved for the treatment of Multiple Sclerosis (MS)[1]. MS is frequent in Puerto Rico with an incidence of 5.0/100,000 and affecting individuals in the peak of their life[2]. Following patient's T1 gadolinium (GAD) lesion enhancement and T1 hypo intense lesions or black holes (BH) with MRI imaging have become standard in patient care.

Objectives

To determine if FG can reduce T1 GAD lesions and BH burden in a Hispanic population with MS (Figure 1-4).

Methods

117 Hispanic patients with MS were recruited from a single MS center all diagnosed by a neurologist. Patient recruitment was open enrollment regardless of age. Patients less than 18 years of age had parental consent. Patients had baseline and follow-up imaging at a designated MRI center using a 1.5 T MRI with MS imaging protocol. Three patients had their baseline and follow up MRIs at another MRI center. These 3 images and reports were submitted to the designated MRI center to reduce inter-radiologist bias. All images were interpreted by one neuroradiologist. The neuroradiologist compared baseline and 1 year-follow up images to determine the absence, presence or development of T1 hypointense (BH) and T1 GAD-enhancing (GAD).

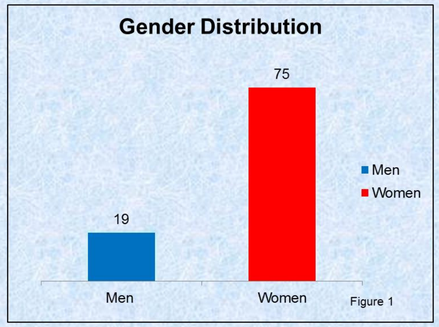

Figure 1. Gender Distribution

Patient Age at Enrollment

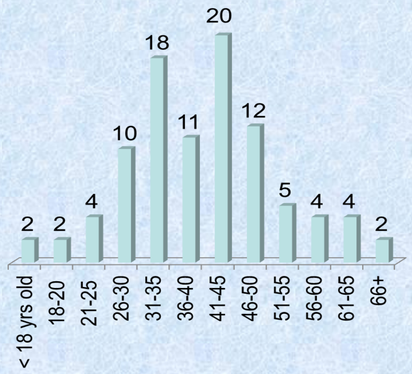

Figure 2. Distribution of Age at Enrollment

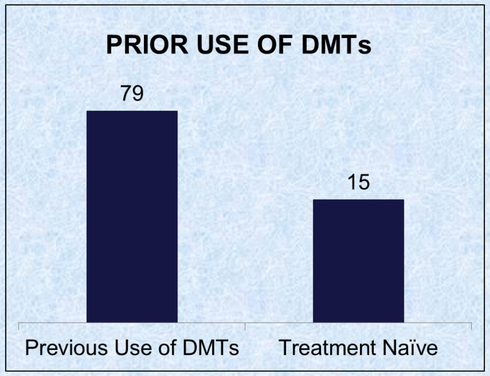

Figure 3. Most patients had prior exposure to DMTs at enrollment

Results

94/117 completed the first year. The majority of patients were Relapsing Remitting (Figure 4) and had prior use of disease modifying therapy (Figure 3). Women composed the majority of patient population (81%). More than 50% of the population had less than 5 years with the disease. 1/3 of the population was diagnosed between the ages of 30-45 years old. At baseline, there were 50 patients without BH and 44 patients with BH. At 1 year follow up, 88% (44) BH negative patients did not developed BH and 87% (43) of patients with BH at baseline did not develop new BH. 1 patient with BH at baseline , had resolution of their solitary black hole at 1 year follow up and was deemed transitory BH. At baseline, there were 71 patients without GAD enhancing lesions and 23 patients with GAD enhancing lesions. At 1 year follow up, 96% of GAD negative patients did not have GAD enhancement and 87% of patients GAD enhancing lesions at baseline did not develop GAD enhancing lesions. 10 patients were lost to follow up and 13 patients discontinued the medication. Reasons for patient discontinuation: 4 headaches, 4 generalized malaise, 1 lack of efficacy, 2 cost of medication, 1 developed psychotic symptoms, 1 developed macular edema.

T1 Gadolinium Enhancement Negative Patients at Baseline		**T1 Gadolinium Enhancement Positive at Baseline**	
GAD negative at baseline	71	GAD positive at baseline	23
GAD negative at 1 year	68	GAD negative at 1 year	20
GAD enhacement lesions at 1 year	3	GAD positive at 1 year	3
% of Patients that remained Gad negative at 1 year	96%	Reduction in GAD enhancement lesions at 1 year	87%
T1 Black Hole Negative at Baseline		**T1 Black Hole Positive at Baseline**	
T1 BH negative	50	T1 BH Positive at Baseline	44
T1 BH positive at 1 year	6	Development of T1 BH at 1 year	0
% of patients that did not develop BH at 1 year	88%	Transitory BH	1
		% of patients with stable T1 BH burden at 1 year	87%

Conclusion

We can conclude that FG is highly effective in reducing both T1 Gadolinium enhancement lesion and development/progression of T1 hypointense lesions. The data suggests that FG can be considered when treating Hispanic patients with MS. More information is needed to study the long-term efficacy of this medication. This 2-year study has finished and is currently being analyzed.

MS SUBTYPE DISTRIBUTION

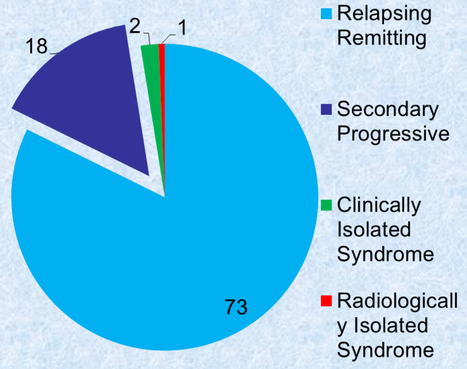

Figure 4. Relapsing Remitting was the common frequent subtype at enrollment. Patients did not progress to another subtype.

References

1. Gilenya [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; April 2014.
2. Chinea AC, Rubi C, Estades E, Rios C, Vicente I, Hernandez Y. Incidence of Multiple Sclerosis in Puerto Rico: A Multicenter Initiative. Poster presented in Ectrims 2015.

ID DX28