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Real-World Outcomes With Cladribine Tablets Across Race and Ethnicity of People With Relapsing Multiple Sclerosis

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CONCLUSIONS

- **This real-world study presents data through 3 years after initiating cladribine tablets for relapsing multiple sclerosis (RMS) in racially and ethnically diverse patients**
- **A reduction in annualized relapse rates (ARRs) and a reduction in magnetic resonance imaging (MRI) activity were observed through 3 years after cladribine tablet initiation, across all ethnicities and races**
- **MS-related hospitalizations and emergency department (ED) visits were reduced after cladribine tablet initiation, across all ethnicities and races**

INTRODUCTION

- MS is a chronic inflammatory, demyelinating, and neurodegenerative disease of the central nervous system[1,2]
- Effective management of inflammation in early stages has been associated with improved long-term outcomes; therefore, as a primary goal, the available therapeutic options aim to reduce the risk of relapse and disease progression[3,4]
- Cladribine tablets (3.5 mg/kg cumulative dose over 2 years) are indicated for the treatment of RMS in adults in the United States[5]
- There is a paucity of real-world data on the use of cladribine tablets in racially and ethnically diverse patients with RMS as they are typically underrepresented in clinical trials
- Here, we present data from racially and ethnically diverse subgroups of people with RMS, 1 year prior to and up to 3 years after initiating cladribine tablets

OBJECTIVE

- **To describe clinical outcomes in racially and ethnically diverse populations after switching to cladribine tablets in a US real-world cohort of people with RMS**

METHODS

Study Design

- A single-center, longitudinal, retrospective, observational cohort study of de-identified medical records of people with RMS was carried out at the University of Texas Southwestern Medical Center in Dallas, TX, USA

Eligibility Criteria

- People aged ≥18 years with RMS treated with ≥1 course of cladribine tablets from April 2019 to March 2023 were included in this analysis
- People with primary progressive MS or clinically isolated syndrome were excluded from the study

Study Outcomes

- ARRs 1 year prior to baseline and up to 3 years after initiation of cladribine tablets
- MRI activity 1 year prior to baseline and up to 3 years after initiation of cladribine tablets
- Hospitalizations and urgent care/ED visits due to MS relapse/symptoms 1 year prior to and up to 3 years after initiation of cladribine tablets

Statistical Analysis

- Descriptive statistics and frequency counts were used in this subpopulation for patient demographics, and for number of prior disease-modifying therapies (DMTs) used

RESULTS

Baseline Demographics and Disease Characteristics

- The study cohort was composed of 164 people treated with ≥1 course of cladribine tablets (1 year prior to: n=164; Year 1: n=164; Year 2: n=91; Year 3: n=49)
  - The median follow-up time for all patients was 1.8 years
  - The median time between cladribine courses was 1.1 (0.88-2.4) years
- The baseline demographics and disease characteristics by race and ethnicity are presented in **Tables 1** and **2**

Table 1. Baseline Demographics and Disease Characteristics of Patients by Race

Characteristics	White	Black/African American	Asian
n	128	32	4
Mean age, years (SD)	45.5 (10.5)	44.8 (9.8)	46.5 (4.7)
Sex at birth, n (%)			
Female	89 (69.5)	26 (81.3)	4 (100)
Male	39 (30.5)	6 (18.8)	0
Ethnicity, n (%)			
Hispanic	18 (14.1)	0	0
Non-Hispanic	110 (85.9)	32 (100)	4 (100)
Mean disease duration, years (SD)	12.1 (7.3)	12.1 (6.7)	5.8 (5.7)
Median number of prior treatments, n (range)	2 (1-9)	2 (1-6)	1 (1-6)

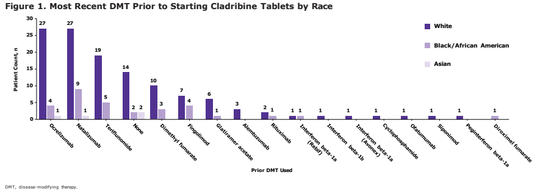
Table 2. Baseline Demographics and Disease Characteristics of Patients by Ethnicity

Characteristics	Non-Hispanic	Hispanic
n	146	18
Mean age, years (SD)	45.9 (10.2)	41.2 (10.2)
Sex at birth, n (%)		
Female	104 (71.2)	15 (83.3)
Male	42 (28.8)	3 (16.7)
Race, n (%)		
White	110 (75.3)	18 (100)
Black/African American	32 (21.9)	0
Asian	4 (2.7)	0
Mean disease duration, years (SD)	12.1 (7.2)	10.9 (6.8)
Median number of prior treatments, n (range)	2.5 (1-7)	2 (1-9)

Most Recent DMTs

- The most common DMTs used prior to initiating cladribine treatment in White people were ocrelizumab (n=27), natalizumab (n=27), and teriflunomide (n=19); in Black/African American people they were natalizumab (n=9) and teriflunomide (n=5); and in Asian people they were ocrelizumab (n=1) and natalizumab (n=1) (**Figure 1**)

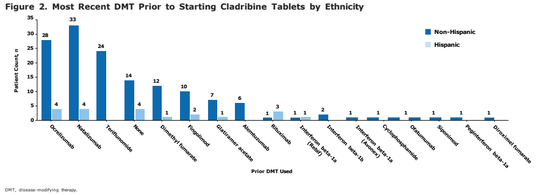
Figure 1. Most Recent DMT Prior to Starting Cladribine Tablets by Race



DMT, disease-modifying therapy.

- The most common DMTs used prior to initiating cladribine treatment in non-Hispanic people were natalizumab (n=33), ocrelizumab (n=28), and teriflunomide (n=24); in Hispanic people they were ocrelizumab (n=4) and natalizumab (n=4) (**Figure 2**)

Figure 2. Most Recent DMT Prior to Starting Cladribine Tablets by Ethnicity



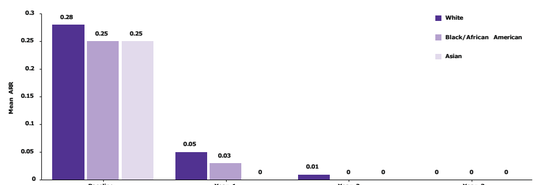
DMT, disease-modifying therapy.

RESULTS (cont.)

Annualized Relapse Rates

- Mean (SD) ARRs decreased following cladribine tablet initiation, regardless of race (**Figure 3**)
  - In White people the mean (SD) ARR at baseline was 0.28 (0.72; n=26 patients with relapse); Year 1 was 0.05 (0.30, n=4 patients with relapse); Year 2 was 0.01 (0.09, n=1 patient with relapse); 0 in Year 3
  - In Black/African American people, the mean (SD) ARR at baseline was 0.25 (0.51; n=7 patients with relapse); Year 1 was 0.03 (0.18, n=1 patient with relapse); 0 in Years 2 and 3
  - In Asian people the mean (SD) ARR at baseline was 0.25 (0.50; n=1 patient with relapse); 0 in Years 1, 2, and 3

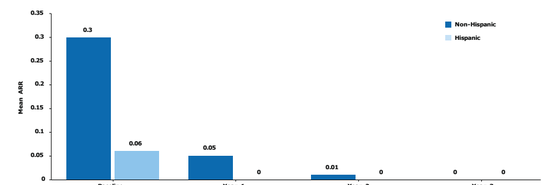
Figure 3. ARRs Through 3 Years After Initiating Cladribine Tablets by Race



*N: Total number of patients. ARRs, annualized relapse rates.

- Mean (SD) ARRs decreased following cladribine tablet initiation, regardless of ethnicity (**Figure 4**)
  - In non-Hispanic people the mean (SD) ARR at baseline was 0.30 (0.71, n=33 patients with relapse); Year 1 was 0.05 (0.30, n=5 patients with relapse); Year 2 was 0.01 (0.08, n=1 patient with relapse); 0 in Year 3
  - In Hispanic people, the mean (SD) ARR at baseline was 0.60 (0.24, n=1 patient with relapse); 0 in Years 1, 2, and 3

Figure 4. ARRs Through 3 Years After Initiating Cladribine Tablets by Ethnicity



*N: Total number of patients. ARRs, annualized relapse rates.

MRI Activity

Race

- The number of people free from any MRI activity increased following cladribine tablet initiation, regardless of race (**Figure 5**)
  - White people free from any MRI activity at baseline were n=104/128 (81.3%); at Year 1 were n=121/128 (94.5%); Year 2 were n=72/73 (98.6%); Year 3 were n=40/41 (97.6%)
  - Black/African American people free from any MRI activity at baseline were n=27/32 (84.4%); 100% in Years 1, 2, and 3
  - Asian people were free from any MRI activity at all timepoints

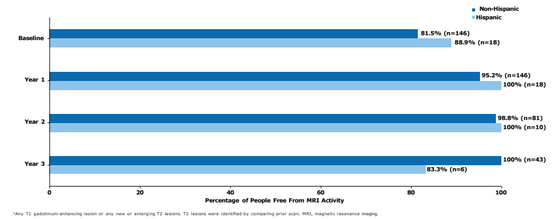
Figure 5. Percentage of People Free From MRI Activity[a] Through 3 Years After Initiating Cladribine Tablets by Race

[a]Any T1 gadolinium-enhancing lesion or any new or enlarging T2 lesions. T2 lesions were identified by comparing to the prior scan. MRI, magnetic resonance imaging.

Ethnicity

- The number of people free from any MRI activity increased following cladribine tablet initiation, regardless of ethnicity (**Figure 6**)
  - Non-Hispanic people free from any MRI activity at baseline were n=119/146 (81.5%); Year 1, n=139/146 (95.2%); Year 2, n=80/81 (98.8%); 100% in Year 3
  - Hispanic people free from any MRI activity at baseline were n=16/18 (88.9%); 100% in Years 1 and 2; n=5/6 (83.3%) in Year 3

Figure 6. Percentage of People Free From MRI Activity[a] Through 3 Years After Initiating Cladribine Tablets by Ethnicity



[a]Any T1 gadolinium-enhancing lesion or any new or enlarging T2 lesions. T2 lesions were identified by comparing prior scan. MRI, magnetic resonance imaging.

Hospitalizations and Urgent Care/ED Visits

- Hospitalizations and urgent care/ED visits due to MS relapse/symptoms were infrequent in both subgroups by race and ethnicity and there were no hospitalizations or urgent care/ED visits in Years 2 and 3 (**Tables 3** and **4**)
- Respiratory problems were the most reported reasons for hospitalizations and urgent care/ED visits 1 year prior to and after cladribine treatment in both subgroups by race and ethnicity

Table 3. Hospitalizations and Urgent Care/ED Visits Due to MS 1 Year Prior to and 1 Year After Initiating Cladribine Tablets by Race

	1 Year Prior to Initiating Cladribine Tablets			1 Year After Initiating Cladribine Tablets		
	White (n=128)	Black/African American (n=32)	Asian (n=4)	White (n=128)	Black/African American (n=32)	Asian (n=4)
Hospitalizations due to MS relapse/symptoms, n	8	2	1	3	1	0
Mean (SD)	0.09 (0.49)	0.13 (0.48)	0.25 (0.43)	0.02 (0.15)	0.03 (0.17)	0
Urgent Care/ED visits due to MS relapse/symptoms, n	6	3	0	1	0	0
Mean (SD)	0.05 (0.21)	0.09 (0.29)	0	0.01 (0.09)	0	0

ED, emergency department; MS, multiple sclerosis.

Table 4. Hospitalizations and Urgent Care/ED Visits Due to MS 1 Year Prior to and 1 Year After Initiating Cladribine Tablets by Ethnicity

	1 Year Prior to Initiating Cladribine Tablets		1 Year After Initiating Cladribine Tablets	
	Non-Hispanic (n=146)	Hispanic (n=18)	Non-Hispanic (n=146)	Hispanic (n=18)
Hospitalizations due to MS relapse/symptoms, n	11	0	4	0
Mean (SD)	0.11 (0.52)	0	0.03 (0.16)	0
Urgent Care/ED visits due to MS relapse/symptoms, n	9	0	1	0
Mean (SD)	0.06 (0.24)	0	0.01 (0.08)	0

ED, emergency department; MS, multiple sclerosis.

Treatment Delay in Starting Second Course of Cladribine

- Reduced lymphocyte count was the primary reason for delays in starting a second course of cladribine treatment in both subgroups by race and ethnicity (**Figures 7** and **8**)

Figure 7. Reasons for Delay in Second Cladribine Treatment Course by Race

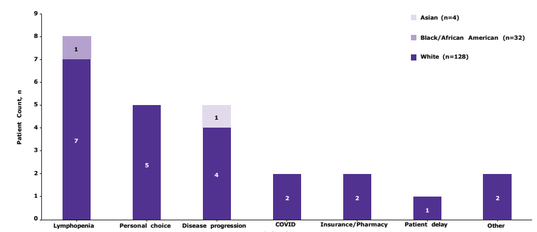
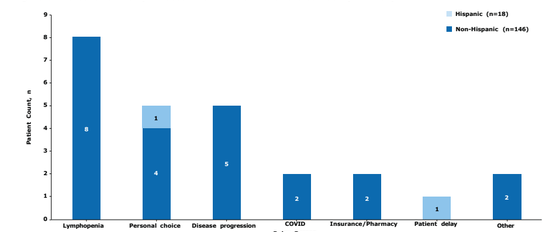


Figure 8. Reasons for Delay in Second Cladribine Treatment Course by Ethnicity



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