SC21

Ethnicity and Patient Outcomes in the TOP MS Study

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INTRODUCTION

- Multiple sclerosis (MS) is recognized in almost all ethnic groups around the world.[1]
- Worldwide prevalence data imply that racial and ethnic differences are important in influencing the distribution of MS.[1]
- Recent studies in the United States, Europe and Brazil have suggested there is faster clinical progression and greater disability in MS patients of African descent.[2-5]

OBJECTIVES

- To investigate the characteristics of two ethnic groups, African Americans (AA) and Caucasians (C) and the relationship of therapy adherence to MS relapses and disability, among patients who have completed the Therapy Optimization in MS (TOP MS) study.

METHODS

- Enrollees in TOP MS, a prospective, open-label, observational study had a diagnosis of MS and were prescribed glatiramer acetate (GA) or an interferon β (IFN-β) dispensed by a participating specialty pharmacy.
- Additional Inclusion Criteria for these analyses:
  - Relapsing forms of MS
  - Self-reported EDSS scores at baseline and Month 24 without simultaneous confirmed relapses.
- Exclusion Criteria for TOP MS included:
  - Any condition that might interfere with participation or with assessments for the full duration of the study;
  - Any contraindication to GA or IFN-β therapy, including pregnancy, trying to become pregnant or breast feeding;
  - Receiving any experimental drug in the 30 days prior to enrollment.
- Participants submitted signed informed consents to their respective pharmacies.
- Study enrollment produced log-on instructions for the study website where responses were entered at regular intervals throughout the study.
- Disease-modifying therapy (DMT) shipment dates for study participants were uploaded to the study database by the pharmacies at regular intervals and the adherence measure, medication possession ratio (MPR), was calculated each quarter.
  - MPR is a ratio of days that the subject has drug to take at the prescribed frequency (syringe counts) compared to the number of days in the interval (i.e., 24 months). [Expressed as decimal 0.1 to 1.0 in this presentation.]
- Logistic regression was used to examine the association between physician confirmed relapses, ethnicity and DMT MPR.
  - Relapses were counted for these analyses only if they were confirmed by a physician and/or were treated with corticosteroids.
- Linear regression was used to examine the association of 24-month EDSS, ethnicity and DMT MPR accounting for baseline EDSS.

RESULTS

- Of the 2,243 eligible TOP MS completers, 127 (5.7%) reported AA and 2,116 C ethnicities.
  - There were no baseline differences between the ethnic groups in the distribution of DMT used (50.8% GA and 49.2% IFN-β), prior use of another DMT (34.6%) or reasons for changing therapies.
  - At the start of the study, there were more AA patients on disability due to MS and their self-reported EDSS was higher with a shorter duration of disease and a younger age than the C cohort (**Table 1**).
- The AA cohort self-reported missing 40% more DMT doses each month (p <0.001) than the C cohort and this is reflected in the MPR from drug shipments.
  - **Table 2** presents the MPR by ethnic group.

Table 1. Demographic Characteristics

	African American Cohort (n = 127)		Caucasian Cohort (2116)	
Characteristic	Mean	SD	Mean	SD
Age (Yrs)	46.2	10.5	50.0	9.8
Time since First Symptoms (Yrs)	8.2	7.6	11.9	9.4
Duration of Same DMT (Yrs)	3.4	3.5	4.9	4.2
Self-Reported EDSS (Baseline)	3.7	2.6	2.9	2.5
Characteristic	n	%	n	%
Gender (n/% Female)	111	87.4	1704	80.5
Employment Status:				
Full Time	54	42.5	975	46.1
Part Time	4	3.1	216	10.2
Unemployed	8	6.3	75	3.5
Disabled due to MS	47	37.0	440	20.8
Other*	14	11.1	410	19.4

All comparisons are statistically significant: Gender p = 0.05; all others: p <0.0001
SD = standard deviation; DMT = Disease-Modifying Therapy
*Other (Employed at Home 2 vs. 49; Homemaker 1 vs. 149; Student 2 vs. 12; Workers Comp. 0 vs. 1; and Retired 9 vs. 199).

Table 2. Percentage of Each Ethnic Group by MPR Category When Remaining on the Same Therapy*

MPR	African American Cohort (n = 106) %	Caucasian Cohort (n = 1806) %	Total (n = 1912) %
0 to 0.5	8.5	5.2	5.4
>0.5 to ≤0.8	43.4	30.8	31.5
>0.8 to 1.0	48.1	64.0	63.1

*Includes only those remaining on the same therapy for 24 months.
MPR = Medication Possession Ratio

- There were no significant differences between the ethnic cohorts on study in the number of physician-confirmed relapses, proportion relapse-free (**Figure 1**) or change from baseline in EDSS (**Figure 2**).
- Regression Results:
  - Odds of relapse for a patient in the MPR >0.9 group was 0.6073 or 61% of that of a patient in the MPR <0.5 category (p = 0.038) regardless of ethnicity.
  - Ethnicity and levels of MPR were not significantly related to 24-month EDSS changes.

Figure 1. Percentage of Physician-Confirmed Relapses by Ethnic Category

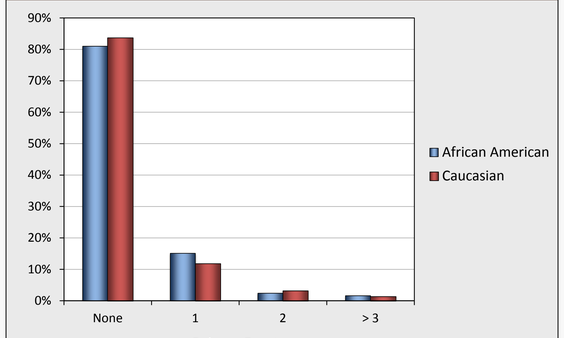
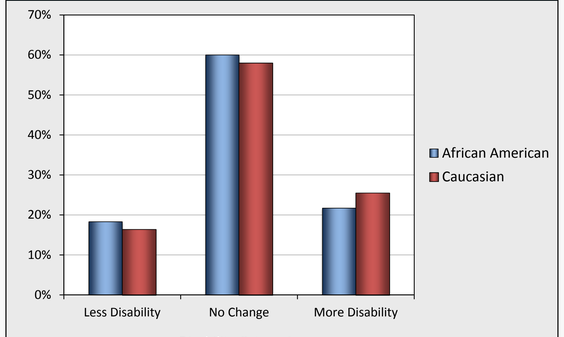


Figure 2. Percentage of Disability Change (EDSS) by Ethnic Category



CONCLUSIONS

- The AA vs. C group in the TOP MS Study showed a more severe disease profile at entry and reported poorer DMT adherence during the two-year study.
- Although mean relapse and EDSS change on study did not differ, relapse rate was significantly less in patients with DMT adherence greater than 90% regardless of ethnicity.

REFERENCES

1. Rosati G. *Neurol Sci* 2001;22:117-39.
2. Weinstock-Guttman B, Jacobs LD, Brownscheidle CM, et al. *Multi Scler* 2003;9:293-98.
3. Kaufman MD, Johnson SK, Moyer D, Bivens J, Norton HJ. *Am J Phys Med Rehabil* 2003; 82:582-90.
4. Ferreira Vasconcelos CC, Cruz Dos Santos GA, Thuler LC, et al. *ISRN Neurol* 2012; Epub 2012 Nov 25. doi: 10.5402/2012/410629.
5. Langer-Gould A, Brara SM, Beaber BE, Zhang JL. *Neurology* 2013;80:1734-9.

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