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Baseline Serum Neurofilament Light Chain Levels Predict Future Disease Activity Irrespective of Race/Ethnicity: Results From the Phase 3 ASCLEPIOS I/II Trials

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Abstract:
Background: In the Phase 3 ASCLEPIOS I/II trials (ofatumumab versus teriflunomide), baseline serum neurofilament light chain (sNfL) levels were prognostic for on-study lesion formation and brain volume loss. However, the prognostic value of sNfL for future disease activity among diverse racial/ethnic subgroups from the trials has yet to be explored.
Objectives: To evaluate the prognostic value of baseline sNfL for future magnetic resonance imaging (MRI) disease activity in diverse racial/ethnic subpopulations (Asian, Black, and Other) of people with relapsing multiple sclerosis (pwRMS) in ASCLEPIOS I/II.
Methods: A baseline sNfL cut-off was predefined by the median sNfL value across the ASCLEPIOS I/II studies and participants were stratified into high (≥9.3 pg/mL) and low (<9.3 pg/mL) groups irrespective of treatment received. The prognostic value of high versus low baseline sNfL for the annualized rate of new/enlarging T2 (neT2) lesions was assessed in the overall population, and Caucasian and racial/ethnic subgroups from ASCLEPIOS I/II. neT2 lesion number on the last available scan (relative to baseline scan) was analyzed using a negative binomial model with time (in years) between the two scans as offset, adjusting for baseline sNfL groups. The prognostic value was assessed via the lesion rate ratio (RR) attained using this single cut-off threshold for high versus low sNfL.
Results: Of the 1,882 participants randomized, 1,678 (89.2%) had baseline sNfL and neT2 lesion data available. Annualized mean rate of neT2 lesions for participants with high/low baseline sNfL levels in the Asian (n=31/29), Black (n=29/26), and Other (n=39/34) subgroups were 2.59/0.97 (RR 2.68; p=0.042), 5.10/2.04 (RR 2.50; p=0.061), and 7.79/3.07 (RR 2.54; p=0.029), respectively; values for the Caucasian subgroup (n=738/752) and overall population (n=837/841) were 3.91/1.83 (RR 2.14; p<0.001) and 4.08/1.85 (RR 2.20; p<0.001), respectively.
Conclusions: Baseline sNfL levels were prognostic for neT2 lesion development in all pwRMS, including those of diverse racial/ethnic subpopulations.

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