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Prognostic Value of Serum Neurofilament Light Chain for Disease Activity in Patients With Relapsing Multiple Sclerosis: Results From Subgroup Analysis Based on Body Mass Index and Age 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 in people with relapsing multiple sclerosis [pwRMS] aged 18-55 years), serum neurofilament light chain (sNfL) levels were prognostic for on-study lesion formation and brain volume loss in the overall and recently diagnosed treatment-naïve populations. Age and body mass index (BMI) may affect sNfL levels.

Objectives: To evaluate the prognostic value of sNfL for future disease activity according to BMI and age in pwRMS.

Methods: A baseline sNfL cut-off was predefined by the median sNfL value across ASCLEPIOS I/II and participants were stratified into high (\geq median [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 baseline BMI [$<$ 24.5 versus \geq 24.5 kg/m²] and age [$<$ 38 versus \geq 38 years] subgroups. Negative binomial regression model adjusting for sNfL group, and sNfL group by BMI/age subgroup interaction, were used to estimate the lesion rate ratio (RR) for high versus low sNfL levels in each BMI/age subgroup.

Results: Of the 1,882 participants randomized in ASCLEPIOS I/II, 1,678 (89.2%) had baseline sNfL and neT2 data available. In both BMI subgroups ($<$ 24.5 and \geq 24.5 kg/m²), participants with high versus low sNfL had a higher mean annualized rate of neT2 lesions (BMI $<$ 24.5: 4.04 versus 2.10, RR: 1.92; BMI \geq 24.5: 4.14 versus 1.66, RR: 2.49; p $<$ 0.001 for both). In both age subgroups ($<$ 38 and \geq 38 years), participants with high versus low sNfL had a higher mean annualized rate of neT2 lesions ($<$ 38: 5.68 versus 2.91, RR: 1.95; \geq 38: 2.50 versus 0.94, RR: 2.66; p $<$ 0.001 for both).

Conclusions: Baseline sNfL levels were prognostic of future lesion formation irrespective of baseline BMI and age, supporting the use of sNfL as a prognostic biomarker for relapsing multiple sclerosis disease activity.

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