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Prognostic Value of On-Treatment Serum Neurofilament Light Chain for New or Enlarging T2 Lesions in People With Relapsing Multiple Sclerosis: Pooled Analysis of the 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]), baseline serum neurofilament light chain (sNfL) levels were prognostic for on-study lesion formation and brain volume loss in the overall population and in recently diagnosed treatment-naive participants. Here, we assess the prognostic value of on-treatment sNfL levels for future disease activity.
Objectives: To evaluate the prognostic value of 3- and 12-month on-treatment sNfL levels for future disease activity in pwRMS.
Methods: A baseline sNfL cut-off was predefined by the median sNfL value across the ASCLEPIOS I/II trials and participants were stratified into high (≥baseline median [≥9.3 pg/mL]) and low (<median) sNfL groups at Month (M) 3 and M12, irrespective of treatment received. The prognostic value of high versus low sNfL at M3 and M12 was analyzed for the annualized rate of new/enlarging T2 (neT2) lesions. The number of neT2 lesions on the last available scan relative to the M12 scan was analyzed in a negative binomial model with time (in years) between the two scans as offset, adjusting for sNfL category at the respective month.
Results: Of the 1,882 participants randomized in ASCLEPIOS I/II, 1,393 and 1,384 participants had neT2 and sNfL data at M3 and M12, respectively. Participants with high versus low sNfL at M3 had a ~2.2-fold higher mean annualized rate of neT2 lesions (3.67 versus 1.69, rate ratio [RR]: 2.17; p<0.001). Similarly, participants with high versus low sNfL at M12 had a ~3.6-fold higher mean annualized rate of neT2 lesions (4.90 versus 1.37, RR: 3.57; p<0.001).
Conclusions: On-treatment sNfL levels at 3 and 12 months continue to be prognostic for future lesion formation and support the use of sNfL as a prognostic biomarker for MS disease activity in pwRMS on disease-modifying therapy.

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