BLOOD NEUROFILAMENT LIGHT CHAINS ASSESSED BY CHEMILUMINESCENT ENZYME IMMUNOASSAY: EXPERIENCE IN A LARGE COHORT OF MULTIPLE SCLEROSIS PATIENTS TREATED WITH HIGH-EFFICACY THERAPIES AND CORRELATION WITH SINGLE MOLECULE ASSAY

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INTRODUCTION

Blood neurofilament light chains (NfL) are increasingly used as a biomarker in MS. Several new assays for pNfL have been proposed recently, among which the Lumipulse assay, a fully automated chemiluminescent enzyme immunoassay. More data are needed on the use of these new assays in the clinical setting.

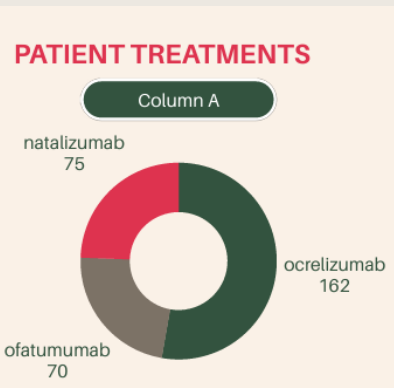
AIMS

The aim of the study was to: **evaluate the Lumipulse™ assay** for pNfL measurement in MS patients treated with high efficacy therapies; assess **correlations with clinical and demographic variables**; compare pNfL levels between patients treated with **anti-CD20 monoclonal antibodies and natalizumab**; evaluate the **degree of agreement between Simoa™ and Lumipulse™** for the determination of NfL levels in a subset of patients.

METHODS

Study population: MS patients treated with anti-CD20 mAbs (ocrelizumab, ofatumumab) and with natalizumab.

PATIENT CHARACTERISTICS	
Number of patients	287
Mean age (y)	48,4
Mean duration of disease (y)	12,4
Median EDSS	3.5

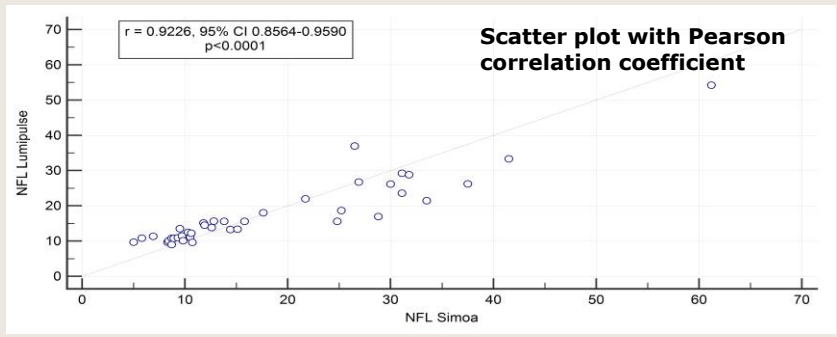


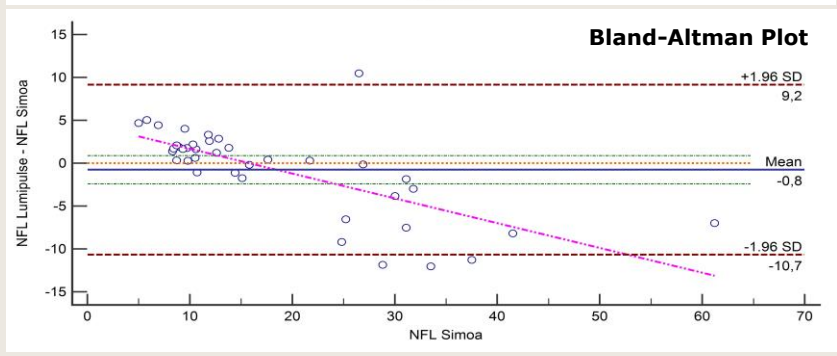
Assessments: Lumipulse™ assay every 6 months over a period of 1 year. Subset of patients: simultaneously Lumipulse™ and Simoa™ assay. Patients treated with anti-CD20 mAbs: lymphocyte subpopulations (CD4+, CD8+, CD19+) count every 6 months over 1 year.

Statistical analysis: pNfL levels were correlated with clinical and demographic variables in a generalized linear regression model. In patients treated with anti CD20 mAbs, lymphocyte subpopulations were additionally included in the model. Patients treated with natalizumab and anti-CD20 mAbs were matched for sex, age and EDSS using propensity score; patients with recent disease activity were excluded. In patients tested with both Lumipulse™ and Simoa™ assays, NfL levels were compared to assess the agreement between the two methods.

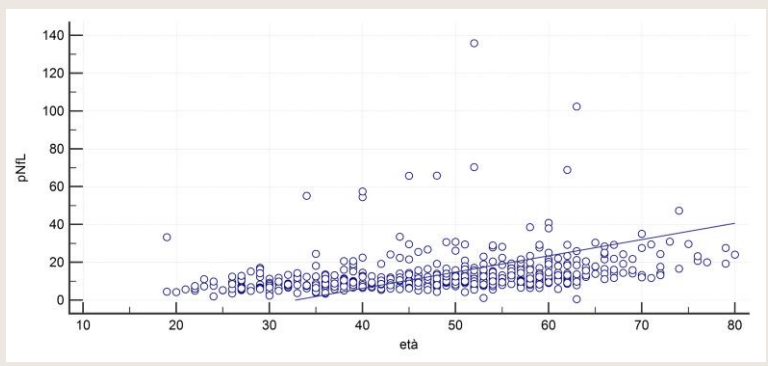
RESULTS

In 40 patients simultaneously tested with both the Simoa™ and Lumipulse™ assay on the same blood sample, Nfl levels were strongly correlated and high agreement in Nfl levels between the two assays was demonstrated.

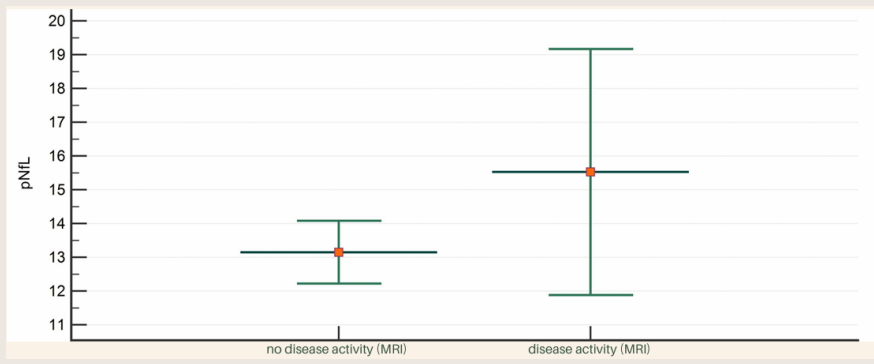




In the linear regression models, pNfl were correlated with age (p<0.001).



Comparing patients treated with anti-CD20 mAbs and patients treated with natalizumab (60 vs 60 after propensity score matching), no significant differences in pNfL levels were found. **No statistically significant relationship was found between pNfL levels** and the **lymphocyte subpopulations** studied (CD4+, CD8+, CD19+) in patients treated with antiCD20 mAbs.



CONCLUSION

Plasma pNfL levels measured using Lumipulse™, in a population of MS patients treated with high efficacy therapies, confirm the known correlations with age and recent disease activity. Comparison of the **Lumipulse™ and Simoa™ assays** shows **high agreement in the measurement of NfL.**

DISCLOSURE

CB, PG, VG, SM, AR, MLV, GM: nothing to disclose. CIB: personal compensation for consulting by Novartis. ADS: personal compensation for speaking and consulting by Biogen, Novartis, Roche, Sanofi, Merck Serono, Bristol Meyer Squibb, Janssen, Alexion, Alnylam and Amgen, reimbursement by Merck Serono, Biogen, Sanofi, Novartis and Roche for attending conferences. MV: honoraria as speaker or travel grants to attend national and international conferences or consultation for advisory boards from Alexion, Almirall, Biogen, BMS, Merck-Serono, Roche, Novartis, Sanofi-Genzyme, Janssen, Sandoz. PC: honoraria as speaker or travel grants to attend national and international conferences or consultation for advisory boards from Alexion, Almirall, Biogen, BMS, Merck-Serono, Roche, Novartis, Sanofi-Genzyme, Janssen, Sandoz; principal investigator in clinical trials for Roche, Sanofi-Genzyme, Novartis and Merck Serono.

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