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ECTRIMS
EUROPEAN COMMITTEE FOR TREATMENT AND RESEARCH IN MULTIPLE SCLEROSIS

Real-World Utilization of a Multi-Proteomic, Serum-Based Assay for Assessing Response to Therapy Change in Persons with Multiple Sclerosis

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Introduction

Routine monitoring of patients with multiple sclerosis (PwMS) is performed using clinical and radiographic assessments. Blood biomarkers are also being incorporated into longitudinal clinical management as an indicator of response to therapy. The Octave Multiple Sclerosis Disease Activity (MSDA) test is a commercially available multi-proteomic blood test with previous clinical validation relative to markers of disease activity.

Objectives

To observe longitudinal MSDA score change in five distinct treatment plan categories defined by disease modifying therapy (DMT) reported at 2 time points:

(1) **initiating DMT:** no DMT reported at time point 1; actively taking a DMT at time point 2

(2) **switching DMT:** actively taking a DMT at time point 1; actively taking a different DMT at time point 2

(3) **maintaining DMT:** actively taking a DMT at time point 1; actively taking the same DMT at time point 2

(4) **maintaining no DMT:** no DMT reported at both time point 1 and 2

(5) **discontinuing DMT:** actively taking a DMT at time point 1; no DMT reported at time point 2

Methods

Data were collected for a multicenter, retrospective chart-review study assessing the impact of the MSDA test on real-world clinician decision-making for PwMS. Each patient had one baseline data point and at least one longitudinal data point. A subset of patients from a single site and first two time points were considered for this case series study. Response to therapy change was defined as change in MSDA score (post minus pre).

Results

A total of 30 patient charts met inclusion criteria. Average age was 41.5 years. 83.3% were female, 73.3% were Caucasian, 16.7% were Black or African American and 3.3% were Native Hawaiian or other Pacific Islander. The rest of the patients preferred to not share race identity. 93.33% were non-Hispanic. All patients had relapsing-remitting multiple sclerosis (RRMS).

- **5** patients **(16.7%)** initiated DMT after baseline, having an average MSDA score change of **2.9**.
- **5** patients **(16.7%)** switched DMT, having an average MSDA score change of **3.3**.
- **12** patients **(40.0%)** maintained DMT, having an average MSDA score change of **0.21**.
- **6** patients **(20.0%)** maintained no DMT, having an average MSDA score change of **-1.34**.
- **2** patients **(6.67%)** discontinued DMT with an average MSDA score change of **-0.50**.

MSDA Use Case: DMT Decision Support
DMT Initiation

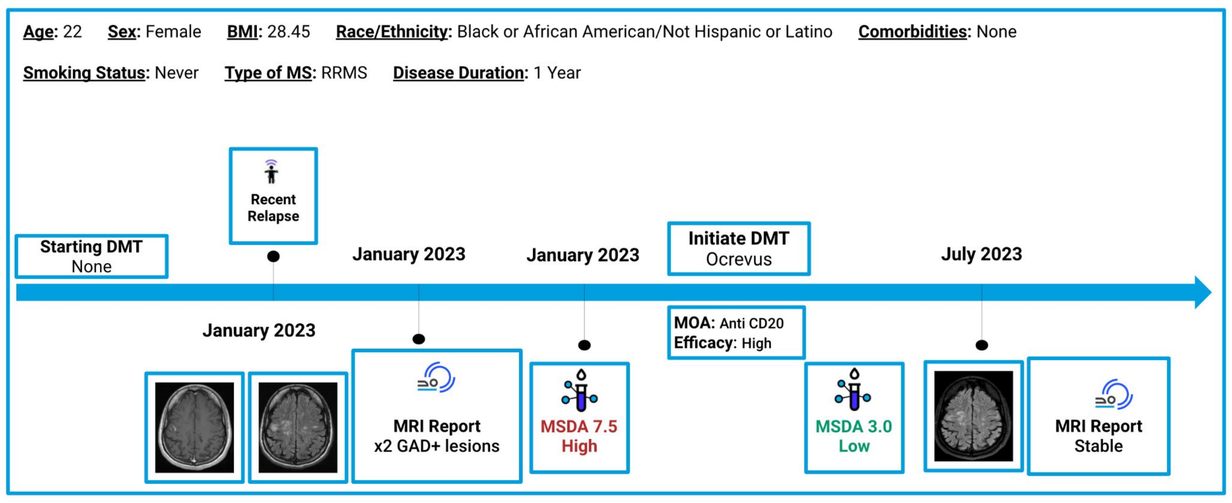

Figure 1. A use case exemplifying using MSDA to support DMT decision-making, specifically DMT initiation in a newly diagnosed PwMS. In the chart review, 5 patients (16.7%) initiated DMT after baseline, having an average MSDA score change of 2.9.

MSDA Use Case: DMT Decision Support
DMT Switch

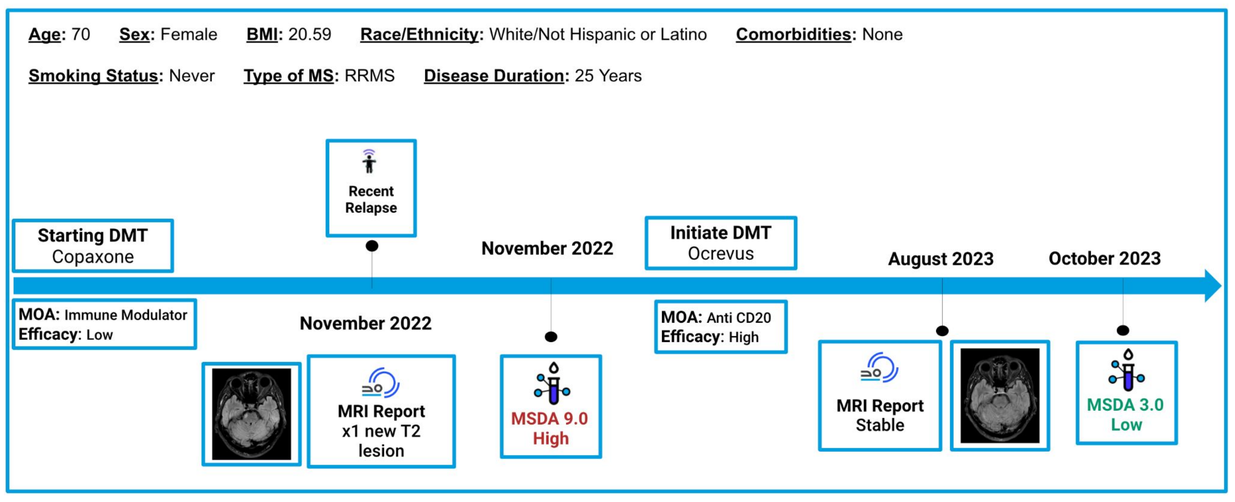

Figure 2. A use case exemplifying using MSDA to support DMT decision-making, specifically a DMT switch. In the chart review, 5 patients (16.7%) switched DMT, having an average MSDA score change of 3.3.

MSDA Use Case: DMT Decision Support
DMT Stability

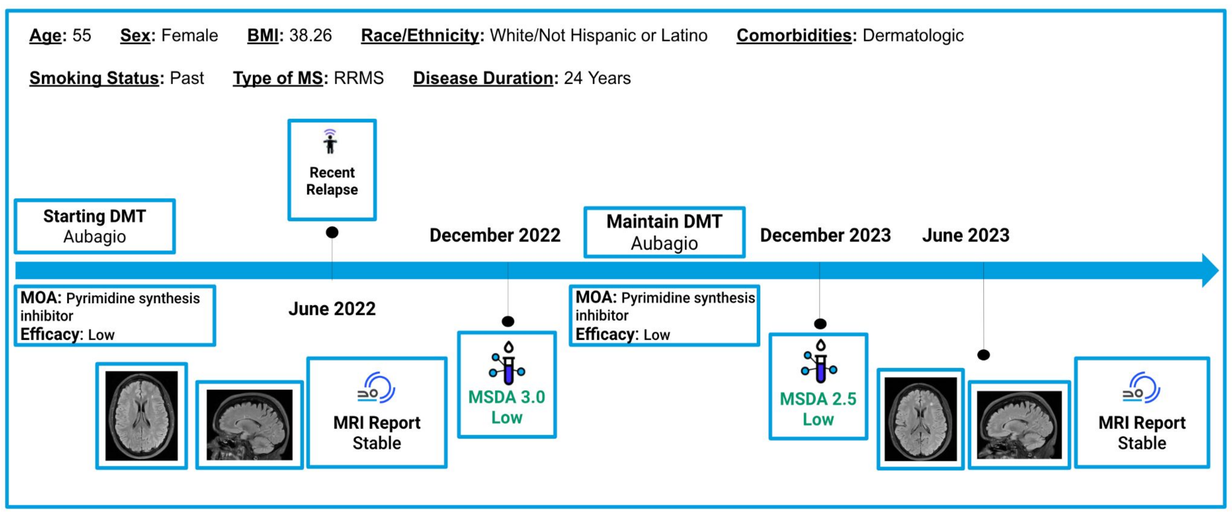

Figure 3. A use case exemplifying using MSDA to support DMT decision-making, specifically assessing DMT stability. In the chart review, 12 patients (40.0%) maintained DMT, having an average MSDA score change of 0.21.

MSDA Use Case: DMT Decision Support
No Current DMT

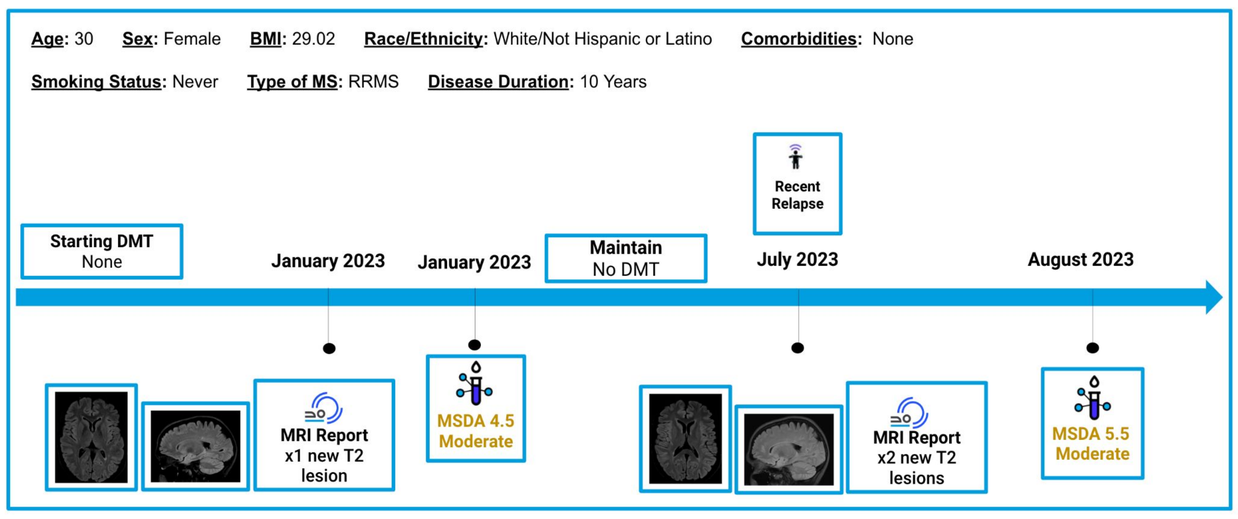

Figure 4. A use case exemplifying using MSDA to support DMT decision-making, specifically assessing disease activity when a PwMS is currently not on DMT. 6 patients (20.0%) maintained no DMT, having an average MSDA score change of -1.34.

Conclusions

We document real-world utilization of longitudinal MSDA testing in PwMS. Clinically meaningful decreases in MSDA were observed for some patients, which may exemplify utility of MSDA testing for measuring response to therapy. Limitations include, but are not limited to, not accounting for age, previous DMT, and variable lengths of time between baseline and follow-up MSDA testing. The application of the MSDA test as a clinical tool for monitoring response to therapy will be further investigated through a prospective study.

Disclosure: PI, EE, AS, JE, FQ are employees of Octave Bioscience, Inc. JD has acted as a consultant for TG Therapeutics.TG has acted as a consultant for Horizon Therapeutics, Sanofi, Genentech and EMD Serono. WB has received research support from Biogen, EMD Serono, Sanofi, and Genentech. He received speaker's honoraria and acted as a consultant for Biogen, Bristol Myers Squibb, Sanofi, and Octave Bioscience. MB has received research support from Biogen, EMD Serono, Sanofi, and Genentech. He received speaker's honoraria and acted as a consultant for Biogen, EMD Serono, Sanofi, Genentech, Alexion, Bristol Myers Squibb, TG Therapeutics, and Octave Bioscience.

References: (1) Qureshi F, Hu W, Loh L, et al. *Proteomics Clin Appl*. 2023;17(3):e2200018. (2) Chitnis T, Foley J, Ionete C, et al. *Clin Immunol.* 2023;253:109688. (3) Chitnis T, Qureshi F, Gehman VM, et al. *Nat Commun*. 2024;15(1):4297.