

Characterizing fatigue in US, European and Latin-American adults with relapsing multiple sclerosis: a real-world study conducted using a novel disease specific scale

Valentine Ficara¹, Julie Laurent¹, Lise Radoszycki¹ – ¹ Carenity, Paris, France

CONTEXT & OBJECTIVES

Fatigue is one of the most common symptoms of relapsing multiple sclerosis (RMS).² Considering its subjective aspect, using MS-specific patient reported outcomes to characterize it would grant a better understanding of its impact on patients' quality of life (QoL).^{3,4}

This study aimed to measure fatigue in RMS patients from multiple countries using the Fatigue Symptoms and its Impacts Questionnaire-Relapsing Multiple Sclerosis (FSIQ-RMS).

METHODS

- Data Collection:
 - o US: March 17th September 27th 2020
 - o EU5: November 3rd 2020 March 17th 2022
 - LATAM: December 15th 2021 March 15th 2022
- Adult patients from the US (n=300), EU (n=362) and LATAM (n=60) recruited via an online questionnaire.
- Self-reported data were collected via an online patient community of patient with MS (Carenity platform).
- The 20-item FSIQ-RMS addresses MS fatigue, rated for severity based on the mean daily ratings over 7 days, and the corresponding impacts of fatigue on 3 subdomains: physical, cognitive/emotional, and coping.
- The FSIQ-RMS domain scores range from 0-100 (higher score=greater severity).
- FSIQ-RMS were compared to a 7-day lookback scores using Pearson's correlation coefficient (r) for all regions.

Fig 1: Design: An ongoing, non-interventional, prospective study

Day 1 (Mandatory)

- Screening criteria
- Sociodemographic and clinical characteristics
- Fatigue characteristics
- Impact on professional life
- Expectations and solutions to manage fatigue
- FSIQ-RMS symptom items (7)

Day 2 to 6 (At least 2/5)

FSIQ-RMS symptom items (7)

Day 7 (Mandatory)

- FSIQ-RMS symptom items (7)
- FSIQ-RMS impact items (13)
- 7-day lookback on fatigue symptoms
- Current relapse
- Quality of sleep
- Unusual factors influencing fatigue

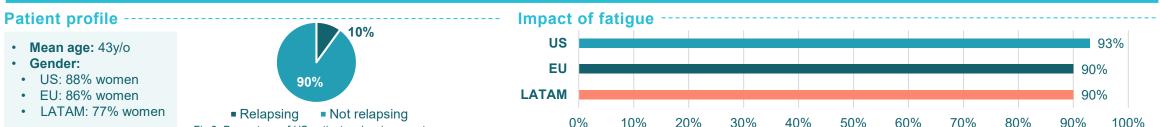
References: 2. Flensner G, BMC Public Health. 2013;13:224; 3. Hudgens S. Value Health. 2019;22(4):453-466; 4. Food and Drug Administration. Guidance for Industry. Patient-reported outcome measures: use in medical product development to support labeling claims http://www.fda.gov/downloads/Drugs/Guidances/UCM193282.pdf



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RESULTS



<u>Fig 2</u>: Percentage of US patients relapsing or not. (Similar figures in EU and LATAM (not relapsing 88%, 92%)

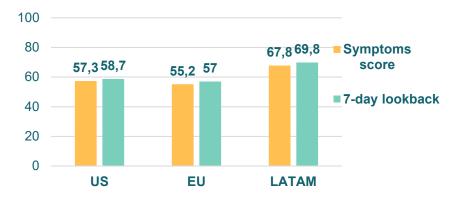
Fig 3: Percentage of patients with an impact of fatigue on their QoL, almost all patients reported being impacted on their QoL by fatigue.

FSIQ-RMS score summary

<u>Fig 4:</u> Symptoms score, physical impacts score, cognitive/emotional score and coping impacts score for US, EU and LATAM patients according to FSIQ-RMS tool. Overall high score reported, especially for coping impact score and symptoms score.



<u>Fig 5:</u> FSIQ-RMS symptoms daily assessment and 7-day lookback. High similarity between the FSIQ-RMS daily symptom score and its 7-day retrospective assessment (r close to 1).



- Using an RMS specific tool, the FSIQ-RMS, this survey helped quantify the severe levels of fatigue experienced by a multi-country cohort of RMS patients, even outside of relapses. Plus, given the high similarity between the FSIQ-RMS daily symptom score and its 7-day retrospective assessment in different regions, the results suggest that the 7-day lookback assessment is reliable.
- However, it is important to note a few **limitations**: in this type of study, there is a **severity bias**, as patients with a greater impact tend to participate more, which may explain the relatively high level of fatigue.
- These findings provide new insights into patients' perspective on the impact of fatigue-related symptoms and supports the integration of patient-reported instruments into clinical practice.

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