

Health-Related Quality of Life, EDSS and Timed 25-Foot Walk in a Multiple Sclerosis Population of a Real-World Observational Outcomes Study: Baseline Data from ROBUST



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Background

- The disability in Multiple Sclerosis (MS) patients has been captured by previous studies using physician-assessed and patient-reported outcome measures such as the Short Form-12 (SF-12), the Physical Functioning Scale (PF), and the Kurtzke Expanded Disability Status Scale (EDSS).
- This study examines the Health-related Quality of Life (HRQoL) in MS patients using the association of a patient-reported measure--the SF-12--with two physician-assessed measures--the EDSS and the Timed 25-Foot Walk (T25FW, in seconds).
- Data was obtained from the Real-World Betaseron® Outcomes Study (ROBUST) study; ROBUST is a US, prospective, 12-month, observational, single-arm, open-label, multi-center outcomes study of interferon beta-1b given every other day for multiple sclerosis.

Methods

- A total of 226 patients were registered at 52 neurologists' sites.
- Clinical measures and patient outcomes were reported by physicians and patients via a web-based data capture tool.
- The Kurtzke Expanded Disability Status Scale (EDSS) and the Timed 25-foot Walk (T25FW, in seconds) were measured by the neurologist at baseline to evaluate patient disability and motor functioning.
- HRQoL was measured at baseline for 191 patients via the SF-12 Health Survey.
- EDSS has a scale from 0 to 10, with 0 being normal neurological examination, and 10 being death due to MS.
- For this analysis, EDSS was categorized into five groups (0, 1-2, 2.5-4, 4.5-5.5, 6), and T25FW was categorized into two groups (≤ 7 sec, > 7 sec).
- SF-12 results were summarized by Physical Component Score (PCS-12) and Mental Component Score (MCS-12).
- Analysis of Variance (ANOVA) methods were used to explore the association of baseline HRQoL and clinically measured EDSS and T25FW.

Results

- At higher EDSS scores (i.e., worsening disability), both physical and mental HRQoL were lower.
- This association was statistically significant only in the PCS-12 ($p < 0.001$ for PCS-12, $p = 0.707$ for MCS-12).
- Among adjacent EDSS groups, pairwise differences for the PCS-12 were statistically significant between EDSS=1-2 (44.0) and EDSS=2.5-4 (37.2), $p = 0.0004$; suggesting a marked worsening of physical HRQoL at or above the disability threshold of EDSS=2.5.
- For the MCS-12, no pairwise comparisons were statistically significant between the EDSS groups.
- Both PCS-12 and MCS-12 were higher for the group with better ambulation: T25FW ≤ 7 sec vs. T25FW > 7 sec (43.5 vs. 37.0, $p < 0.001$ for PCS-12; 43.9 vs. 41.0, $p = 0.079$ for MCS-12).

Figure 1. Association of SF-12 Score with Baseline EDSS Score

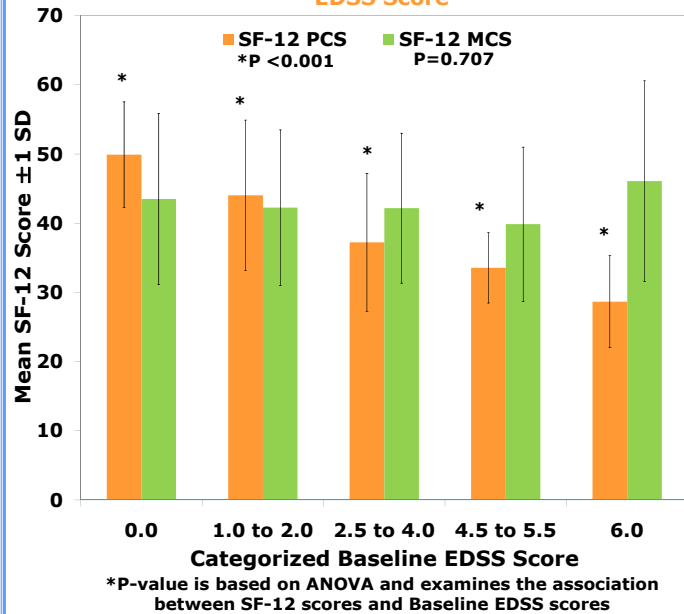
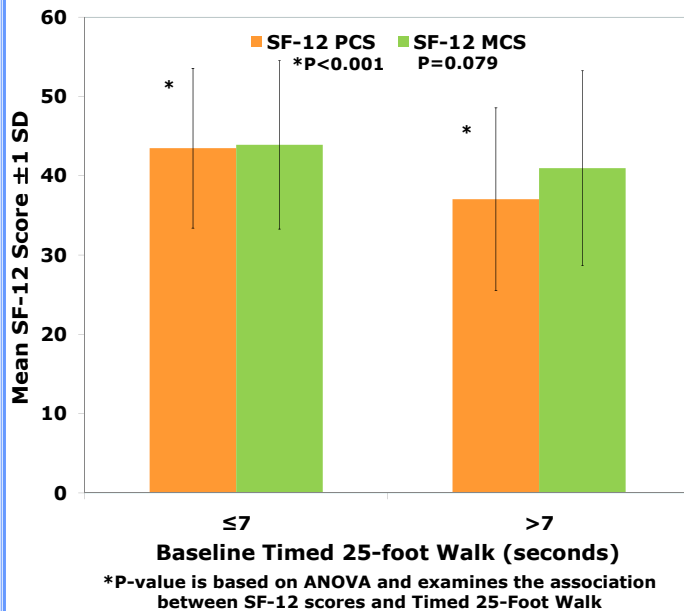


Figure 2. Association of SF-12 Score with Timed 25-Foot Walk



Conclusions

- Physical HRQoL is associated with functional impairment assessed via the EDSS and T25FW.
- These findings suggest that the PCS-12 component of the generic HRQoL tool reflects clinical functional impairment in this population of MS patients.

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