Use of the multiple sclerosis functional composite as an outcome measure in a phase 3 clinical trial.

Abstract

BACKGROUND: The Multiple Sclerosis Functional Composite (MSFC) is a multidimensional clinical outcome measure that includes quantitative tests of leg function/ambulation (Timed 25-Foot Walk), arm function (9-Hole Peg Test), and cognitive function (Paced Auditory Serial Addition Test). The MSFC is the primary outcome measure in the ongoing multinational phase 3 trial of interferon beta-1a (Avonex) in patients with secondary progressive MS.

OBJECTIVE: To assess the practice effects, reliability, and validity of the MSFC clinical outcome measure.

DESIGN: Examining technicians underwent formal training using standardized materials. The MSFC was performed according to a standardized protocol. The 436 patients enrolled in the International Multiple Sclerosis Secondary Progressive Avonex Controlled Trial underwent 3 prebaseline MSFC testing sessions before randomization.

RESULTS: Practice effects were evident initially for the MSFC but stabilized by the fourth administration. The Paced Auditory Serial Addition Test demonstrated the most prominent practice effects. The reliability of the MSFC was excellent, with an intraclass correlation coefficient for session 3 (final prebaseline session) vs session 4 (baseline) of 0.90. The MSFC at baseline correlated moderately strongly...
with the Kurtzke Expanded Disability Status Scale. Among the MSFC components, the Timed 25-Foot Walk correlated most closely. Correlations among the 3 MSFC components were weak, suggesting they assess distinct aspects of neurologic function in patients with MS.

**CONCLUSIONS:** The MSFC demonstrated excellent intrarater reliability in this multinational phase 3 trial. Three prebaseline testing sessions were sufficient to compensate for practice effects. The pattern of correlations among the MSFC, its components, and the Kurtzke Expanded Disability Status Scale supported the validity of the MSFC.

Alternate Journal
Arch. Neurol.

PubMed ID
11405811