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Title
A Functional Composite Endpoint to Characterize Disease Progression in Patients with Active or Non-active SPMS

Introduction
Composite endpoints (CEPs) capture disease progression more comprehensively as they account for functions not, or not optimally, captured by Expanded Disability Status Scale (EDSS) alone. A previous analysis, combining SDMT and EDSS, demonstrated high sensitivity in determining treatment effects. Here, 9-Hole Peg Test (9HPT) and Timed 25-Foot Walk Test (T25FWT) are included with SDMT and EDSS in the construction of CEPs. By exploring novel CEPs more relevant to secondary progressive multiple sclerosis (SPMS), we may be able to better characterize progressive disease including differences in active and non-active SPMS.

Methods
In this post hoc analysis, two definitions for time to 6-month confirmed disease progression (6mCDP) were applied for all SPMS patients participating in the EXPAND Core study and in subgroups with active and non-active disease: CEP1 based on EDSS (1-point/0.5-point worsening from baseline of ≤5/>5, respectively), or ≥4-points worsening on SDMT, or 20% increase in 9HPT; and CEP2 that in addition to CEP1 included the component of 20% increase in T25FWT (only for patients with baseline EDSS ≤5.5, since T25FWT was unstable in patients with higher baseline EDSS in the EXPAND study).

Results
Risk reductions of 6m-CDP in the overall, active and non-active SPMS patients assessed by EDSS alone, CEP1 and CEP2 are presented in the table.

Conclusion
Adding SDMT and 9HPT to the EDSS assessment (CEP1) allows detection of treatment effects on a broader spectrum of symptoms in SPMS compared with EDSS alone, including in patients with non-active disease. Addition of T25FWT in CEP2 did not increase precision of HR ratio estimates.

Disclosure
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