P612

Improvements Across Functional Systems Are Maintained Regardless of Early VS Late Confirmed Disability Improvement: CARE-MS 6-Year Follow-Up

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Background: In CARE-MS studies (NCT00530348; NCT00548405), alemtuzumab showed significant improvement vs SC IFNB-1a in clinical/MRI outcomes over 2 years in patients with RRMS, including higher rates of confirmed disability improvement (CDI). Efficacy was maintained in a 4-year extension (NCT00930553). In CARE-MS II, 71% of patients with CDI achieved improvements in >1 EDSS functional system (FS) score; improvements were seen across all FS.

Objective(s): The Objective(s) was to assess CDI occurring early/late after alemtuzumab initiation in pooled CARE-MS I and II patients over 6 years, including maintenance of effect and pattern of improvement across FS scores.

Method(s): Patients received two annual courses of alemtuzumab 12 mg/day (baseline: 5 consecutive days; 12 months later: 3 consecutive days) in the core CARE-MS studies, with as-needed alemtuzumab retreatment/other disease-modifying therapies in the extension. CDI was defined as ≥1-point EDSS decrease confirmed over 6 months. Analyses: percentage of patients with improved/stable EDSS scores from baseline to Y6, and with stable/improved or number of improved FS scores at 6 months post-CDI onset.

Result(s): 171/427 (40%) eligible patients achieved CDI, 60% of whom had EDSS scores that remained improved at Y6; 67% of patients without CDI had stable EDSS scores from baseline–Y6. EDSS improvement/stability at Y6 vs baseline was apparent in patients with early CDI (61%/34%) and late CDI (57%/37%), respectively. At 6 months post-CDI onset, improvement/stability in each FS was observed in 90−100% of patients with early/late CDI; improvement was most frequently in sensory, pyramidal, and cerebellar FS. 74%/18% of CDI patients (early) and 67%/13% (late) achieved improvements in >1 FS/≥4 FS, respectively.

Conclusion: CDI, occurring within the first 2 years or later, was maintained at Y6 in absence of continuous treatment and was associated with improvements across multiple FS, indicating a broad and prolonged effect of alemtuzumab on disability improvement, potentially changing the MS disease course.