EFFICACY OF TERIFLUNOMIDE IN ACHIEVING NO EVIDENCE OF DISEASE ACTIVITY FROM 6 MONTHS TO 2 YEARS IN THE TEMSO STUDY

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BACKGROUND/OBJECTIVES

Attainment of no evidence of disease activity (NEDA) has been proposed as a therapeutic goal in MS. Treatment with teriflunomide 14mg increased the likelihood of patients achieving NEDA over a 2-year period in TEMSO (NCT00134563). Residual disease activity may occur while full therapeutic efficacy of teriflunomide becomes established. This post hoc analysis of TEMSO evaluated impact of teriflunomide on NEDA using 6 months from treatment initiation as baseline.

METHODS

Patients with relapsing forms of MS (N=1086) were randomized to receive teriflunomide 14mg, 7mg, or placebo for 108 weeks. We evaluated achievement of NEDA (no gadolinium-enhancing T_1 lesions, no new/enlarging T_2 lesions [MRI activity], no relapse, and no 12-week sustained disability progression [clinical disease activity; CDA]) and proportions free from CDA or MRI activity, from 6 months to 2 years.

RESULTS

From 6 months to 2 years, a significantly greater proportion of teriflunomide-treated patients (14mg, 28.1%, *P*0.0001; 7mg, 21.5%, *P*=0.0180) achieved NEDA vs placebo-treated patients (14.3%). The proportion CDA-free was significantly higher in the 14-mg group (61.3%, *P*=0.0022) vs placebo (49.2%). The proportion free of MRI activity was significantly higher with teriflunomide 14mg (45.1%, *P*0.0001) and 7mg (35.4%, *P*=0.0029) vs placebo (24.6%), with 14mg exhibiting superiority over 7mg (*P*=0.0141).

CONCLUSIONS

Teriflunomide is associated with a significant dose-dependent increase vs placebo in proportion of patients achieving NEDA from 6 months to 2 years in the TEMSO study, providing further evidence for efficacy on key measures of CDA and MRI activity.

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