EFFICACY OF TERIFLUNOMIDE IN PATIENTS WITH EARLY MULTIPLE SCLEROSIS: SUBGROUP ANALYSES OF MRI OUTCOMES FROM THE PHASE 3 TOPIC STUDY

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BACKGROUND/OBJECTIVES: Teriflunomide is a once-daily oral immunomodulator approved for relapsing-remitting MS. TOPIC (NCT00622700) evaluated efficacy and safety of teriflunomide in patients with a first clinical episode suggestive of MS. TOPIC demonstrated significant reduction in the risk of relapse determining conversion to clinically definite MS with teriflunomide 14mg. This post hoc analysis evaluated treatment effects of teriflunomide 14mg on MRI outcomes in patient subgroups.
METHODS: Patients were randomized to teriflunomide 14mg (n=216), 7mg (n=205), or placebo (n=197) for up to 108 weeks. MRI scans were performed at screening, 12, 24, 48, 72, and 108 weeks. Effect of teriflunomide 14mg on number of gadolinium (Gd)-enhancing T1 lesions and total-lesion volume (TLV) was analyzed for subgroups defined by gender, age (< or ≥31 years), baseline number of Gd-enhancing lesions (< or ≥1), TLV (< or ≥5mL), and monofocal/multifocal status.
RESULTS: Baseline characteristics were well balanced across treatment groups. Versus placebo, teriflunomide 14mg significantly reduced number of Gd-enhancing T1 lesions (58.5%, $P<0.001$) and TLV increase from baseline ($P<0.05$, all time points). Treatment with teriflunomide resulted in a consistent positive effect on number of Gd-enhancing lesions across all subgroups and on TLV across all but the subgroup defined by gender, where greater effect (albeit inconsistent across time) was observed in females.
CONCLUSIONS: Teriflunomide 14mg was associated with positive effects on number of Gd-enhancing lesions and TLV, which were generally consistent across patient subgroups defined by gender, age, baseline MRI, and monofocal/multifocal status.

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