Health-related quality of life and tolerability in treatment-experienced HIV-1-infected patients on tipranavir versus comparator regimens.

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Abstract

BACKGROUND: Antiretroviral therapy including tipranavir boosted with ritonavir (TPV/r) has shown superior viral suppression and immunological response compared with comparator ritonavir-boosted protease inhibitor (CPI/r) regimens in treatment-experienced HIV-1-infected patients. This study assesses the influence of adverse events (AEs) on health-related quality of life (HRQOL) and change in HRQOL in patients treated with TPV/r versus CPI/r regimens.

METHODS: Changes in HRQOL over 48 weeks were assessed using Medical Outcomes Study HIV Health Survey (MOS-HIV) data combined from two randomized, open-label, Phase III studies (RESIST-1 and RESIST-2). Generalized estimating equations (GEE) were used to compare physical health and mental health summary scores and 10 subscale scores, and to compare scores of patients with and without AEs. To compare AE incidences in the two treatment groups, AEs were exposure-adjusted.

RESULTS: There were 984 patients in the HRQOL analysis. AE occurrence and severity resulted in significantly lower MOS-HIV scores across both treatment arms (P<0.05). Overall incidence of AEs was higher in the CPI/r versus TPV/r group (562.8 versus 514.4 per 100 patient-exposure years); treatment-related AEs were more frequent in the TPV/r group (75.0 versus 56.6 per 100 patient-exposure years). HRQOL was maintained in patients on TPV/r over 48 weeks of treatment across all summary and subscale scores. Compared with CPI/r, TPV/r was associated with a significant but small (SD<0.2) improvement in pain scores (+4.8 points; P<0.05).

CONCLUSIONS: HRQOL was maintained across both summary and all subscale scores from baseline to 48 weeks in the TPV/r and CPI/r treatment arms, despite the incidence of treatment-related AEs.

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