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Genotypic susceptibility to tipranavir (TPV) and darunavir (DRV) in a cohort of treatment-experienced patients (TEP)

J Baxter*[1], L Bhatti[2], J Scherer[3], M McDonough[3] and P Piliero[3]

Address: [1]Cooper University Hospital/UMDNJ-Robert Wood Johnson Medical School, Camden, NJ, USA, [2]AIDS Healthcare Foundation, Los Angeles, CA, USA and [3]Boehringer Ingelheim Pharmaceuticals Inc, Ridgefield, CT, USA

* Corresponding author

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Purpose of the study

TPV and DRV are ritonavir-boosted HIV protease inhibitors (PI) indicated for use in TEPs with PI resistance. Both agents have shown superior virologic and immunologic responses in TEPs compared with first-generation PIs. In the Utilization of HIV Drug Resistance in Treatment-Experienced Patients (UTILIZE) study, we assessed the presence of resistance to tipranavir, darunavir, and other antiretroviral agents among HIV-1 isolates in treatment-experienced patients.

Methods

UTILIZE was an observational study at 40 US sites that examined clinician use of HIV drug-resistance testing in TEPs failing a PI-based regimen. Patients were randomized to have either a genotype (GT; Monogram GeneSeq) or combined phenotype-genotype test (PGT; Monogram Phenosense GT) to assist with treatment decision-making. For this analysis, only genotypic resistance data were evaluated to assess PI cross-resistance.

Summary of results

246 patients enrolled and 236 had resistance testing, of whom 139 (59%) had evidence of HIV-1 resistance to at least one PI. Median HIV-RNA and CD4 count were 30,538 copies/mL and 197 cells/mm^3, with no significant differences between GT and PGT groups. Of the 139 patients with evidence of PI resistance, 28% of isolates were resistant to all PIs; 58% and 55% remained sensitive to TPV and DRV, respectively. In contrast, isolate susceptibility to indinavir, lopinavir, atazanavir, saquinavir, or nelfinavir was 21.6%, 20.1%, 19.4%, 16.5%, and 7.9%, respectively. TPV-DRV discordance rates were similar: 15.1% TPV sensitive/DRV resistant and 12.2% TPV resistant/DRV sensitive. 50% (7/14) of isolates from TEPs failing TPV remained sensitive to TPV, while 3% (1/29) of isolates from TEPs failing DRV remained sensitive to DRV.

Conclusion

In this cohort of TEPs failing a PI-based regimen, 59% of HIV-1 isolates demonstrated PI resistance. Of these isolates, over 50% remained sensitive to either TPV or DRV, with 27.3% sensitive to only one of the two drugs. In PI-experienced patients, TPV and DRV remain the most likely available PIs to use in constructing a new regimen.