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# Safety and efficacy of tipranavir co-administered with low-dose ritonavir in patients with advanced HIV-1 infection and limited treatment options

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## Purpose of the study

To assess the safety and efficacy of tipranavir co-administered with low-dose ritonavir (TPV/r) in clinical settings.

## Methods

Data from the German open-label study (EAP). To be included in the study, adult patients (pts) had to be triple antiretroviral (ARV) class experienced having failed at least two previous PI-based regimens. TPV/r 500/200 mg, twice daily, was added to a background regimen chosen by the treating physician. All adverse events (AE) were reported regardless of causal relationship and degree of seriousness.

## Summary of results

Data of 254 HIV-1 infected pts (median age 44 years; 229 males, 25 females) from 70 centres were available for analysis. Most pts were in advanced stages: CDC B3 (28%) and C3 (57.1%). Hepatitis B and C co-infection was reported for 12.6% and 3.9% of the pts, respectively. Median baseline HIV-RNA (VL) was 4.7 log10 copies/mL and median CD4157 cells/μL. After 12 months of TPV/r treatment, median change from baseline in VL was -1.9 log10 copies/mL and +71.5 CD4 cells/μL. Median TPV/r exposure was 35.4 weeks (1.1–76). 117 (46.1%) pts experienced AEs considered related to TPV/r; 53 (20.9%) pts developed serious AEs; 47 (18.5%) pts discontinued TPV/r due to AEs. Most commonly reported AEs in 33.5% of pts were gastrointestinal disorders, the majority of which were mild or moderate intensity. In regard to ALT and AST elevations, 4.3% and 2% of pts had a maximum Grade 3 and 3.1% and 0.2% of pts had maximum Grade 4 elevation, respectively. No cases of jaundice or liver failure were reported.

## Conclusion

Patients treated in the TPV EAP had advanced HIV-1 infection and were heavily pretreated. Nevertheless, they show remarkable decrease in VL and increase in CD4 cells/μL The analysis of AEs did not reveal any new safety findings or change in the known AE profile of TPV/r. Notably, in this real world treatment setting, the rate of TPV/r discontinuations due to AEs was relatively low.