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Use of lopinavir/ritonavir in first-line therapy or second-line therapy: 48-week results from the German prospective STAR cohort

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Purpose of the study

Treatment guidelines are mainly based on the evidence of efficacy in clinical trials. However, treatment outcomes may differ in observational cohort studies. We analysed data from the STAR cohort, a German prospective, multicentre, observational study, which includes HIV+ patients (pts) starting a lopinavir/ritonavir (LPV/r)-based regimen. Our goal was to compare treatment outcomes in ART-naïve pts compared to pre-treated, but PI-naïve pts.

Methods

48-week analysis: comparison of treatment responses to LPV/r-based regimens in ART-naïve and PI-naïve pts using on-treatment (OT), intent-to-treat (ITT) and Kaplan-Meier (KM) analyses. Primary outcome parameters were reaching a confirmed viral load (VL) <50 copies/ml, % with VL <50 copies/ml, and time to reaching a confirmed CD4 count >500/μl.

Summary of results

1,079 HIV+ pts (74% ART-naive) have been included in the STAR cohort. Median age was 41 years (range: 20–76). Currently, baseline values were available of 872 pts (76% [662] ART-naïve). Median baseline VL and CD4 cell counts differed significantly between ART-naïve and PI-naïve pts (125,500 vs. 3,746 copies/ml, $p < 0.001$; 198 vs. 310/μl, $p < 0.001$).

At 48 weeks, VL was <50 copies/ml in 79% of ART-naive and in 75% of PI-naive pts (OT) (ITT: 62% of ART-naive and 60% of PI-naive pts). Median changes in CD4 cells were +201/μl in ART-naïve and +135/μl in PI-naïve pts ($p < 0.001$). In 60% of ART-naive pts, CD4 cells increased to levels >350/μl and in 34% to levels >500/μl. In 73% of PI-naive pts, CD4 cells increased to levels >350/μl and in 48% to levels >500/μl.

The probability of remaining of treatment was 78 vs. 77% in ART-naïve vs. PI-naïve pts at 48 weeks (KM-analysis, p = ns). The median time to confirmed VL <50 copies/ml was 25 weeks in ART-naive and 13 weeks in PI-naïve pts; time to >500 CD4 cells/μl was 73 weeks in ART-naïve and 48 weeks in PI-naive pts.

Conclusion

In this cohort study, virological outcomes of LPV/r-based regimens were comparable in ART-naïve and in pre-treated PI-naïve pts, reflecting good efficacy and durability also in second- or third-line use of LPV/r. The probability of remaining on treatment for 48 weeks was high in both groups (78 and 77%); VL was <50 copies/ml in 79% of ART-naive and in 75% of PI-naive pts (OT) (ITT: 62% and 60%). In 34% of ART-naive pts and in 48% of PI-naïve pts, CD4 cells increased to levels >500/μl, demonstrating an ongoing CD4 increase also in pre-treated PI-naïve pts.