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Real-life effectiveness and safety of lopinavir/ritonavir in HIV-infected adults who experienced prior different antiretroviral treatments

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Purpose of the study

The purpose of the study was to assess virologic and immunologic effectiveness of lopinavir/ritonavir in HIV-infected adults who are antiretroviral (ARV) naïve, protease inhibitor (PI) naïve or PI-experienced but naïve to lopinavir/ritonavir.

Methods

This is an ongoing 96-week, observational, open-label, multicenter study. Patients were prescribed the standard dose of lopinavir/ritonavir (400 mg/100 mg) twice a day. Other ARV medications were prescribed at the discretion of the physician according to usual clinical practice.

Summary of results

Of the 142 patients enrolled, 47.2% had not received any previous ARV treatment (ARV-naïve), 19.0% have not been treated with PI-based regimen (PI-naïve), and 31.7% have been exposed to PI-based regimen with the exception of lopinavir/ritonavir (PI-experienced). The mean (SD) age was 44.6 (9.5) years, 123 (86.6%) were male and 109 (76.8%) were Caucasian. The mean (SD) duration of HIV disease was 4.3 (0.7) years. Of the 35 (25.6%) patients discontinued, 13 withdrew due to adverse event (AE). The virologic results after 48 weeks of treatment are available for 106 patients (53 ARV-naive; 19 PI-naïve; 34 PI-non-naive). There were 34 (64.2%) ARV-naïve, 14 (73.7%) PI-naïve, and 22 (64.7%) PI-experienced patients with HIV-RNA viral load < 50 copies/mL after 48 weeks of treatment. There were 116 patients included in the immunologic analyses. Linear regression was performed to estimate the CD4 cell counts at 48 weeks of treatment. Mean (SD) change in absolute CD4 cell counts between baseline and 48 weeks of treatment was 196.9 (52.0) ($p < 0.001$) in ARV-naïve, 110.8 (52.8) ($p < 0.001$) in PI-naïve and 13.0 (78.0) ($p = 0.513$) in PI-experienced patients. Of the 142 patients enrolled, none developed >6 protease resistance mutations. At the time of the analysis, there were 171 AEs probably/possibly related to lopinavir/ritonavir reported by 70 out of 142 patients, 29 ARV-naïve, 16 PI-naïve and 25 PI-experienced patients. Hypercholesterolemia was reported by one ARV-naïve and one PI-experienced patient who were not receiving lipid-lowering agents. Of the 17 serious AEs reported by three ARV-naïve and four PI-experienced patients, 12 were probably not/not related to study drug and none led to discontinuation.

Conclusion

After 48 weeks of treatment in a clinical setting, lopinavir/ritonavir is effective in achieving virologic control and immunologic improvement in ARV-naïve, PI-naïve or PI-experienced patients, with more significant immunologic benefit in ARV and PI-naïve patients.