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Effectiveness, Safety, and Tolerability Profile of Stribild® in HIV-1-infected Patients in the Clinical Setting

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Abstract : Objectives: The efficacy of Stribild®, an integrase strand transfer inhibitor (INSTI) -based STR, has been evaluated in randomized clinical trials and it has demonstrated durable capability in terms of achieving sustained suppression of HIV-1 RNA-levels. However, differences in monitoring frequency, existing selection bias and profile of patients enrolled in the trials, may all result in divergent efficacy of this regimen in routine clinical settings. The aim of this study was to assess the virologic outcomes, safety and tolerability profile of Stribild® in a routine clinical setting. Methods: This was a retrospective monocentric analysis on HIV-1-infected patients, who started with or were switched to Stribild®. Virological failure (VF) was defined as confirmed HIV-RNA>50 copies/ml. The minimum time of follow-up was 24 weeks. The percentage of patients remaining free of therapeutic failure was estimated using the time-to-loss-of-virologic-response (TLOVR) algorithm, by intent-to-treat analysis. Results: We analyzed the data of 197 patients (56 ART-naïve and 141 treatment-experienced patients), who fulfilled the inclusion criteria. Majority (95.9%) of patients were male. The median time of HIV-infection at baseline was 2 months in treatment-naïve and 70 months in treatment-experienced patients. Median time [IQR] under ART in treatment-experienced patients was 37 months. Among the treatment-experienced patients 27.0% had already been treated with a regimen consisting of two NRTIs and one INSTI, whereas 18.4% of them experienced a VF. The median time [IQR] of virological suppression prior to therapy with Stribild® in the treatment-experienced patients was 10 months [0-27]. At the end of follow-up (median 33 months), 87.3% (95% CI, 83.5-91.2) of treatment-naïve and 80.3% (95% CI, 75.8-84.8) of treatment-experienced patients remained free of therapeutic failure. Considering only treatment-experienced patients with baseline VL<50 copies/ml, 83.0% (95% CI, 78.5-87.5) remained free of therapeutic failure. A total of 17 patients stopped treatment with Stribild®, 5.4% (3/56) of them were treatment-naïve and 9.9% (14/141) were treatment-experienced patients. The Stribild® therapy was discontinued in 2 (1.0%) because of VF, loss to follow-up in 4 (2.0%), and drug-drug interactions in 2 (1.0%) patients. Adverse events were in 7 (3.6%) patients the reason to switch from therapy with Stribild® and further 2 (1.0%) patients decided personally to switch. The most frequently observed adverse events were gastrointestinal side effects (20.0%), headache (8%), rash events (7%) and dizziness (6%). In two patients we observed an emergence of novel resistances in integrase-gene. The N155H evolved in one patient and resulted in VF. In another patient S119R evolved either during or shortly upon switch from therapy with Stribild®. In one further patient with VF two novel mutations in the RT-gene were observed when compared to historical genotypic test result (V106I/M and M184V), whereby it is not clear whether they evolved during or already before the switch to Stribild®. Conclusions: Effectiveness of Stribild® for treatment-naïve patients was consistent with data obtained in clinical trials. The safety and tolerability profile as well as resistance development confirmed clinical efficacy of Stribild® in a daily practice setting.

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