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SHORT COMMUNICATION

Efficacy and Tolerability of Dolutegravir-Based Dual-Therapies in HIV Naive and Switch Patients

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Objectives: The introduction of dual-therapy both as preferred starting therapy and in switches has been a revolution, allowing the same efficacy results to be obtained as therapies with more Active Ingredients (AI) with a lower risk of toxicity and interactions. The aim of the study is to analyze the efficacy, tolerability and reasons for switching patients to dolutegravir-based dual therapies.

Methods: Single-center retrospective observational single-center study of patients treated with dolutegravir dual-therapies (dolutegravir+lamivudine and dolutegravir+rilpivirine) from January 2019 to 18/02/2020. Variables collected included age, sex, presence of AIDS, mechanism of transmission, current ART, previous ART (number of tablets and daily BP), reason for change and Adverse Drug Reactions (ADRs). Analyses were taken from the consultation prior to the change and the first subsequent consultation [CD4, CD8, Viral Load (VL), lipid profile and creatinine].

Results: Forty-two patients on dolutegravir-based dual-therapies were identified with a median age of 46 years (15-82) and 28.6% (12) female. A total of 73.8% (31) were treated with dolutegravir+lamivudine. AIDS-defining events were detected in 26.2% (11) and as mechanisms of transmission: sexual 59.5% (25), parenteral drug 26.2% (11), vertical 4.8% (2) and unknown 9.5% (4).

23.8% (10) were initiated on dolutegravir+lamivudine and 76.2% (32) switched to dual-therapies (50% dolutegravir+lamivudine and 26.2% dolutegravir+rilpivirine). Reasons for switching were simplification 62.5% (20), renal toxicity 25% (8), concomitant drug interactions 9.4% (3) and cardiovascular toxicity 3.1% (1). 40.6% (13) were from integrase inhibitor-based ART (7 with dolutegravir) and a median of 2 tablets daily (1-5) and 3 AI (2-4).

In the statistical analysis 10 patients were not included due to lack of post-switch data due to the delay in consultations because of the COVID-19 pandemic.

In naive patients median CD4 increased from 447 cell/mcl to 596 cell/mcl ($p = 0.07$) and CD8 from 969 cell/mcl to 1157 cell/mcl ($p = 0.333$). Total Cholesterol (TC), triglycerides and creatinine showed no significant differences ($p = 0.889$, $p = 0.889$ and $p = 0.108$ respectively). In 90% (9) of naive patients, VL became undetectable.

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In switch patients median CD4 increased from 618 cell/mcl to 724 cell/mcl ($p = 0.424$) and CD8 from 773 cell/mcl to 859 cell/mcl ($p = 0.043$). Median TC decreased from 196 mg/dl to 172 mg/dl ($p = 0.011$) and triglycerides from 93 mg/dl to 79 mg/dl ($p = 0.021$). No difference was found in creatinine ($p = 0.292$). VL remained undetectable in 78.1% (25) of the switches, 18.8% (6) could not be analyzed and 3.1% (1) was detectable. No patient developed ADR.

Conclusions: Treatment with dolutegravir-based dual-therapy has proven to be an effective and safe therapy in both naive and switch patients.

The main reason for switching to dual-therapy is simplification, what achieves a reduction in both the number of tablets and AI compared to other single-tablet therapies. In addition, they do not contain enhancers AI, avoiding all interactions with these AI.

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