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Prevalence of neuropsychiatric adverse events and associated factors among adult patients on dolutegravir attending Mulago ISS clinic

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Abstract

Introduction: Dolutegravir (DTG) is a second-generation integrase strand transfer inhibitor that is recommended by the World Health Organization as the preferred first-line and second-line antiretroviral therapy (ART) in patients with HIV. In 2018, Uganda started using DTG-based regimens as the preferred first-line ART. However, concerns regarding the potential neurotoxicity of DTG have been increasing. Data on the occurrence of neuropsychiatric adverse events (NPAEs) and the associated factors among adult patients who are initiated on or switched to DTG-based first-line or second-line ART in Uganda are limited.

Objective: This study aimed to determine the prevalence of NPAEs among adult patients on DTG and the factors associated with their occurrence.

Methods: We conducted a cross-sectional study using questionnaires administered by a trained research assistant between 15 November 2021 and 15 December 2021. The study included patients aged ≥18 years with HIV who were either initiated on or switched to a DTG-based ART regimen between 1 January 2018 and 31 October 2021. Informed consent and data were collected from 892 participants attending Mulago ISS clinic, including data on age, sex, marital status, disclosure status, current regimen, duration on ART, concurrent illness, concurrent medications, year of switch to DTG, duration on DTG, whether the onset of NPAEs was immediate or delayed, history of alcohol use or smoking, level of education, report of NPAEs while on DTG, and history of NPAEs while on previous regimen. Data were entered into Epidata version 4.6.0.2 then exported to Stata version 14 for analysis.

Results: Of the 892 adults on DTG attending Mulago ISS clinic, 41.7% (95% confidence interval [CI] 38.5%-44.9%) experienced at least one NPAE. DTG duration in years (adjusted prevalence [aPR] = 1.21, p = 0.024), disclosure status (aPR = 1.40, p = 0.042), concurrent medications (aPR = 1.31, p = 0.026), year of switch to DTG, and concurrent illness were associated with an increased occurrence of NPAEs.

Conclusions: The prevalence of NPAEs was higher than that reported by any clinical trial. About 9.1% of participants had experienced severe to life-threatening NPAEs that required intervention from a healthcare professional to improve tolerability. The high prevalence requires that clinicians screen for NPAEs at very visit and reassure patients to maximize the benefits of long-term ART.

Keywords: antiretroviral therapy; dolutegravir; neuropsychiatric adverse events.

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