Main adverse reactions motivating the substitution of Dolutegravir in Antiretroviral Therapy regimens in Brazil

Authors: Batista CJB; Corrêa RG; Monteiro JC; Sakita K; Benzaken AS
Affiliation: Brazilian Ministry of Health, Brasília, Brazil

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Introduction

The Brazilian AIDS policy has included free distribution of antiretroviral drugs since 1996, and, from 1997 on, Brazil's government has conducted the logistic management of these drugs and patient clinical monitoring through the Medication Logistics Control System (SICLOM), with online access nationwide. In this context, in 2017 the Ministry of Health (MoH) began to distribute antiretroviral drug Dolutegravir (DTG) 50mg to all people living with HIV (PLHIV) beginning first line Antiretroviral Therapy (ART), as well as for third-line PLHIV in substitution to Raltegravir 400mg. Although DTG is widely considered to have better tolerability levels and a smaller possibility of causing adverse reactions, the safety profile of a drug must be continuously assessed among the population. In order to evaluate the safety profile of DTG in Brazil, an active pharmacovigilance project was implemented. It was made up of interviews and online questionnaires that were made available through SICLOM. This research proposes to study the main reactions that motivated the substitution of this drug and the frequency percentage of each one within an active pharmacovigilance project.

Methodology

SICLOM's database was used to verify the list of patients who had DGT substituted in their therapy regimens due to adverse reactions in the period between April and December 2017. Based on this list, the 10 main adverse reactions were identified as well as the percentage frequency of each one.

Results

Out of the 72,032 people on DTG in Brazil, 149 (0.20%) had their therapy regimens changed due to adverse reactions – demographic data can be observed in Table 1. 398 adverse reactions were reported and the most frequent ones are shown in Figure 1.

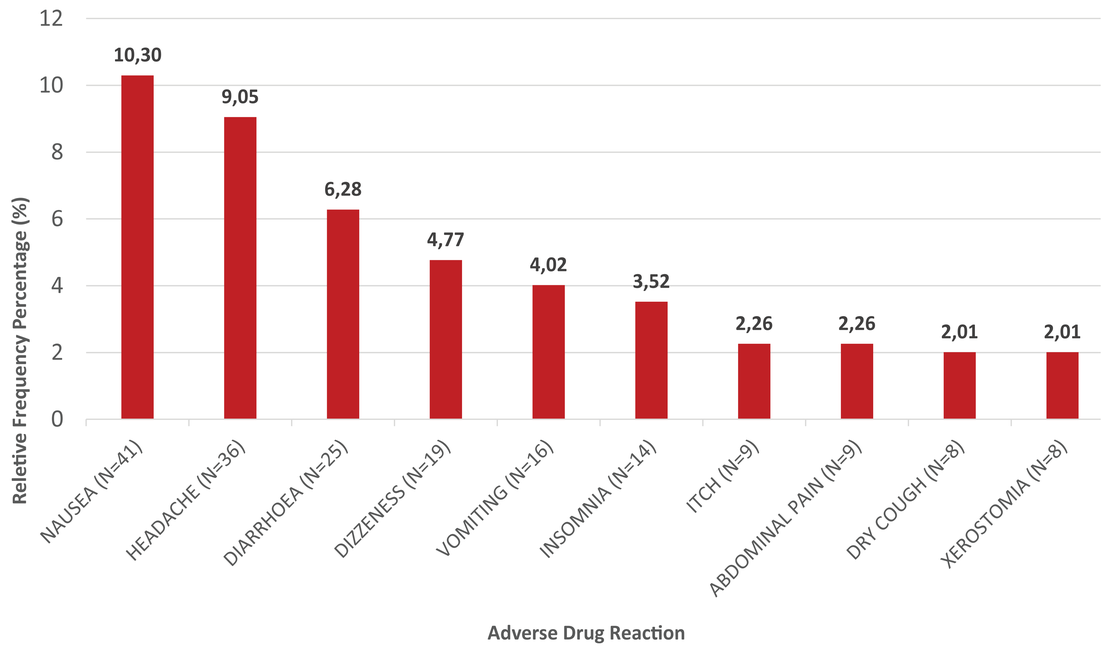
Conclusions

Data indicate that the most of the adverse reactions that motivated the discontinuation of DTG in Brazil are described in the package leaflet. Nausea, diarrhea, and headaches are the most frequent (>10%); dizziness, insomnia, vomiting and abdominal pain are commonly associated with the use of Dolutegravir (1 to 10%); and hypersensitivity presents lower frequency and are considered unusual (0.1 to 1%). This finding, however, corroborates the more consolidated knowledge of the medicinal product and, therefore, for greater patient safety.

Contacts

Author: Cynthia Batista
Mobile: +55 61 3315-7635
email: cynthia.batista@aids.gov.br
Contact and poster at www.aids.gov.br/aids2018

Figure 1: Main adverse reactions that motivated the substitution of DTG in therapy regimens in Brazil



Source: Siclom/SVS/MS

Table 1 – Demographic data of patients who changed antiretroviral therapy due to adverse reactions to Dolutegravir

Characteristic	Male (n = 86)	Female (n = 63)	Total (n = 149)
Age, years			
Median	44	45	45
Mean	45	46	45
Race/color			
White/yellow	47 (59%)	32 (41%)	79
Black/brown	25 (58%)	18 (42%)	43
Indigenous	0	1 (100%)	1
Unknwon	14 (54%)	12 (46%)	26

Source: Siclom/SVS/MS