# CAUSALITY OF ADVERSE DRUG REACTIONS IN HIV-PATIENTS TREATED WITH

# BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE

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### BACKGROUND AND IMPORTANCE

Bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) has been positioned as a preference drug in the main guidelines in the treatment of HIV. BIC/FTC/TAF has demostrated an excelent safety and efficacy profile in pivotal studies.

## AIM AND OBJECTIVES

To assess the causality of adverse drug reactions (ADRs) of HIV-patients treated with BIC/FTC/TAF.

#### MATERIAL AND METHODS

Observational and retrospective study from may 2019 to march 2021 in a general hospital.

#### Characterization of the population

Cohort 1: patients who changed their antirretroviral treatment due to an ADR.

Cohort 2: patients who mantained their antirretroviral treatment despite some ADR.

## Variables analyzed





Sex



**ADRs** 

Age

# Naranjo Algorithm

To assess whether there is a causal relationship between an identified untoward clinical event and a drug.



definite

5-8

probably

1-4

possible

0

doubtful

#### Most common ADRs (Cohort 1) Characterization of the population N = 1,275 patients Nightmares **Cohort 1:** 27 women vs 25 men and median age 56 [IQR 51 – 60] **Cohort 2:** 107 women vs 25 men and median age 45 [IQR 33 – 55] Others Vomiting Dizziness Causality of ADRs (Cohort 1) Causality of ADRs (Cohort 2) Nausea Imsomnia Flatulence Abdominal pai 1.7 % Headache Dyspepsia 17,25 % 17.3 % Diarrhoea Gastro-Nervous Psychiatric Weight gain Asthenia Arthralgias intestinals Rash system disorders 81 % 82.75 % disorders disorders Most common ADRs (Cohort 2) 80 Anxiety Dizziness doubtful probably possible 60 Most common ADRs Cohort 1 Cohort 2 Total 40 Headache Nightmares Total adverse drug reactions 179 266 Others 20 12 Headache 62 74 (27.8%) Abdominal pai Imsomnia Diarrhoea Gastrointestinal disorders 50 (18.8%) Nervous Gastro-Weight gain Psychiatric Asthenia Arthralgias Rash intestinals system 24 43 (16.2%) Insomnia disorders disorders disorders

### CONCLUSIONS AND RELEVANCE

- The frequency of ADRs of HIV patients in treatment with BIC/FTC/TAF is low and most of people who suffer it can continue with their treatment.
- Most ADRs were consider as probably.
- The most common ADRs was the headaches, the gastrointestinal disorders and the insomnia.







