DI-046
J05 Antivirals for systemic use

ANALYSIS OF TREATMENT DISCONTINUATION BY IATROGENESIS RELATED TO DOLUTEGRAVIR/ABACAVIR/LAMIVUDINE

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BACKGROUND

Dolutegravir/abacavir/lamivudine (Triumeq®) is a new oral drug to treat human immunodeficiency virus (HIV) offering single-pill regimen. Treatment discontinuations due to adverse events (AE) occurred in our clinical experience concerning drug security.

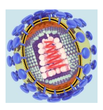
PURPOSE

To determine the proportion of patients who stop Triumeq® due to AE and to analyze its causality.

MATERIAL AND METHODS

JUNE 2015 ← Adult patients treated with Triumeq® → **JUNE 2016**

Sex, age



HIV progression time, previous antiretrovirals, HCV and/or HBV co-infection, liver fibrosis stage

Stop Triumeq® reason, AE risk factors, intervention, results obtained, length of Triumeq ® treatment

Karch-Lasagna algorithm for AE causality

RESULTS

66 patients treated with Triumeq®

11 (16.7%) treatment discontinuations

8 (12.1%) discontinuation due to AE

Characteristics of patients who stopped Triumeq® due to AE:

75% female; median age 50 years. The median HIV progression time was 22.7 years and all of them had received previous HIV treatment. 7 patients HCV co-infected (one F4), and 1 liver transplanted due to liver cancer HBV-related. Median length of Triumeq® was 41 days.

AE / Nº patient	P1	P2	P3	P4	P5	P6	P7	P8
Nausea/vomiting		X			X	X		
Headache			X			X	X	
Cutaneous reaction				X		X		X
Muscle pain				X			X	
Sleepiness				X			X	
Conduct disorder	X							
Acute confusional syndrome				X				
Hospitalization	Yes	No	No	Yes	No	No	No	No

AE resolved after changing HIV treatment, although one cutaneous biopsy was made and 3 cases required specific treatment.
AE were notified to the Pharmacovigilance Center. The causal link between drug and AE was probable.

CONCLUSION

More than 10% of patients suffered AE Triumeq®-related which required discontinuation. Serious psychiatric disorders occurred, recommending attention in patients with mental risk factors treated with Triumeq®. Probable causal link strengths pharmaceutical collaboration, especially in medicines under additional monitoring.