Journal of the International AIDS Society

Poster presentation

Safety personalisation of ART therapy: what treatments do patients receive with the knowledge of their HLA-B*5701 status?

R Rubio*[1], MA Johnson[2], BJ Haas[3], EA Loeschel[4], C Granier[4], F Jackson[4] and HC Pearce[4]

Address: [1]Hospital 12 Octubre, Madrid, Spain, [2]Royal Free Centre for HIV Medicine, London, UK, [3]LKH Graz West, Med 1, Infectious Disease Clinic, Graz, Austria and [4]GlaxoSmithKline, London, UK

* Corresponding author

from Ninth International Congress on Drug Therapy in HIV Infection
Glasgow, UK. 9–13 November 2008

Published: 10 November 2008

Journal of the International AIDS Society 2008, **11**(Suppl 1):P83 doi:10.1186/1758-2652-11-S1-P83

This abstract is available from: http://www.jiasociety.org/content/11/S1/P83

Purpose of the study

The PREDICT-1 study has recently proven the clinical utility of prospective genetic screening of HLA-B*5701 to reduce the incidence of abacavir hypersensitivity reactions (ABC HSR). Here we report an observational study that aimed to describe the clinical management and adverse events in HLA-B*5701 positive subjects excluded from PREDICT-1. We evaluate the clinical outcome of these subjects, specifically the choice of ART and resulting adverse events, to explore how clinicians use pharmacogenetic information to guide practice.

Methods

Subjects who were enrolled into PREDICT-1 but withdrew before start of study treatment due to a positive HLA-B*5701 screening result, were consented for further follow-up. PREDICT-1 patients could be ART naive or experienced, but were abacavir naïve. Patients in this study were followed for a 6-week observation period following treatment initiation or switch, or decision not to change the current therapy, based on the notification of the HLA-B*5701 status.

Summary of results

55 subjects withdrew from PREDICT-1 with a positive HLA-B*5701 result; 32/55 patients consented to participate in this study. An additional three subjects were enrolled in the UK under a country-specific protocol amendment of PREDICT-1, and are also included in this analysis. Baseline demographics were similar to the PREDICT-1 study population, except for race where a greater proportion of the study population was white. 32/35 patients received ART during the observation period. The most common NRTIs were TDF/FTC (12) and AZT/3TC (11); the most common third drugs were EFV (13) and KAL (six). Seven subjects initiated ART and seven subjects changed their ART regimen following notification of a positive HLA-B*5701 result; 22 subjects did not change ART during the observation period. One subject mistakenly received abacavir-containing therapy for 9 days prior to awareness of their HLA-B*5701 status, but did not suffer an ABC HSR during this time. Four subjects reported AEs (Grade 1 or 2 only). Two subjects experienced AEs that were related to current treatment, one leading to discontinuation of Combivir.

Conclusion

HLA-B*5701 positive patients and their clinicians chose treatment options that actively avoided exposure to abacavir. Mistakes can happen, highlighting the need for accurate reporting of screening results. Physicians and patients accept pharmacogenetic screening, and use the result to guide patient management, showing that pharmacogenetic screening allows for personalisation of therapy.