CHARACTERIZATION OF PATIENTS NON-ADHERENT TO HIGHLY ACTIVE ANTIRETROVIRAL THERAPY (HAART) BETWEEN 2010–2011

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BACKGROUND

Thanks to the introduction of Highly Active Antiretroviral Therapy (HAART), a decrease has been observed in the number of hospital admissions, the incidence of opportunistic infections and mortality associated with HIV/AIDS. However, adherence to treatment continues to play a crucial role. In fact, a failure of HAART often leads to changes in laboratory parameters, development of resistant strains and the need to change treatment regimens. This study aims to analyse the impact of the failure of treatment changes on laboratory parameters and treatment regimens.

PURPOSE

To characterise patients who had been included in the government’s subsidised programme who were later excluded by their inability to follow treatment.

MATERIALS AND METHODS

Retrospective observational study. 50 patients, who had been taking HAART since January 2007 and abandoned it between January 2010 and December 2011, were randomly selected and analysed. The control group consisted of 50 adherent patients who began taking HAART since January 2007.

RESULTS

Preliminary data indicate that our patients are mainly male with a median age range of 40 years old. There was a need to change the treatment regimen in 83% of the patients due to their inability to follow treatment correctly. Even though the viral load was undetectable in 54% of the patients, 70% couldn’t achieve a CD4 count above 350 cells/µL. The main reasons for the lack of adherence are drug and/or alcohol addiction (38%), distance to the hospital (13%), psychological causes (13%), adverse drug reactions (13%) and unknown reasons (25%).

CONCLUSIONS

The patients’ inability to follow HAART correctly often leads to the need to change the treatment regimen. Considering the present data, it’s extremely relevant to characterise the non-adherent population, in order to improve adherence to HAART.

No conflict of interest.

CLINICAL CASE OF AN ADVERSE DRUG REACTION DUE TO THE ADMINISTRATION OF AN ESTROGENE/GESTAGENE COMBINATION DRUG


Background

Different European countries have different Summary of Product Characteristics (SmCP) for the same registered drug, which leads to an unequal level of safety information.

Purpose

To describe an ADR in a child after administration of Fedra (gestodene + ethinylestradiol) not reported in the Italian SmCP case report.

Materials and Methods

The Paediatric Emergency department of our hospital admitted a 15-year-old girl with frequent hand, foot and facial paresthesias on the right side of the body.

The patient had been treated with Fedra for 10 days due to menstrual irregularity.

Results

At admission, the general status of the patient, monitored by blood, clotting test and imaging studies (CT and brain MRI) appeared within the normal. During the hospitalisation oestro-progestin treatment was suspended with gradual resolution of symptoms and negative neurological follow-up.

A report of these ADRs has been submitted to the Agenzia Italiana del Farmaco (AIFA) and to the database of MEAP project (monitoring adverse drug reactions in paediatric patients).

Applying the Naranjo algorithm this ADR (frequent hand, foot and facial paresthesias of the right side of the body) was classified as ‘possible’.

However, in the AIFA database there are 33 ADRs related to the administration of the combo ‘gestodene + ethinylestradiol’ related to the nervous system, including paresthesias.

These reactions are not mentioned in the Italian SmCP, when in the British SmCP they are classified as ‘well-known side effect’ for the same combination, registered under the trade name of Triminulet.

Conclusions

This case study suggests the importance of pointing out all the symptoms, even the minor ones not yet known, especially in the paediatric patients, to better evaluate the safety profile of the drug in this particular population.

No conflict of interest.
Corrections


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