

ADR AND INTERACTIONS OF NEW DIRECT ANTIVIRAL AGENTS FOR HEPATITIS C TREATMENT

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Background

New treatment regimens for hepatitis C virus infection have radically changed the care of patients. Those that are recently commercialized, are subjected to intensive monitoring by AIFA with the aim to evaluate both the effectiveness and safety in clinical practice. The purpose of this retrospective observational study was the analysis of the incidence and severity of adverse reactions (ADRs) reported in the Region of Calabria regimens with antiviral agents Direct (DaaS), as well as evaluation of their effectiveness.

Material and Methods

All forms of reporting of ADRs by new DaaS present in the Calabria National Pharmacovigilance Network were extracted and analyzed from March 2015 until May 2016. From AIFA database were extrapolated monitoring registers containing data on treatment started together with socio-demographic characteristics of the patients. For multi-treated patients we analyzed the possible interactions.

Results

In the Region of Calabria were started 1457 treatments with new regimens based DAA. Patients are most of the male gender (52%). The most represented age group is between 70-79 years (34%). According to the therapeutic program 59,2% of the analyzed treatments are completed with success. In 1,1% of cases were observed adverse drug reactions and for which reporting cards were compiled. Results from cards analysis: mean age 64.86 years (range 35-77); male (60%); drug regimen associated to RBV (50%). Sovaldi + Olysio, Harvoni, Daklinza, Sovaldi, Viekirax regimens were associated with ADR in 37.5%, 31.2%, 12.5%, 6.5% and 6.25% of the cases respectively . By comparing the ADRs and their treatments started it shows that they have an equally significant weight in treatments with Sovaldi + Olysio (1.46%) and Harvoni(0.90%). In 12,5% ADRs are reported to Harvoni load were considered serious for the occurrence of urosepsis and pneumonia. The remaining 87.5% of ADRs were not considered serious. In the other therapeutic regimens there have been marked: fatigue, insomnia, hives, cough, dermatitis. Anemia was the principal adverse event reported for therapeutic regimens associated with the use of RBV (58%). In the 25% of the cases the ADRs are verified in subjects who were administered polytherapies ; analysis has not noticed any possible interaction to which to impute the risen up ADRs.

Conclusions

The data of the study provide a comprehensive view of the safety of new DAAs. The presence of ADR in the elderly subject to polytherapy would require the activation of a careful monitoring of the appropriateness prescriptive and the interactions of the therapies that only management by a multidisciplinary team can implement.