البحث الرابع

العنوان:

Study of Adverse Drug Effects of Direct-Acting Antivirals for Chronic HCV Infection at Fayoum Governorate, Egypt - A Pharmacovigilance Study

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Abstract:

Background: Different combinations of Direct Antiviral Agents (DAAs) have been used against different Hepatitis C Virus (HCV) genotypes and in different types of patients. Despite being effective and characterized by a very low rate of adverse effects in clinical trials, few data are available on adverse events in real life studies. **Objectives:** The aim of this study was to identify the incidence and pattern of Adverse Drug Reactions (ADRs) caused by DAAs; daclatasvir and sofosbuvir and their combination with ribavirin and to assess the causality and the severity of the reported ADRs. **Methods:** A prospective observational study was conducted over six months at treatment HCV center of Health Insurance Hospital in Fayoum Governorate, Egypt. A pre-tested, interviewed structured questionnaire was used by authors to gather required data from 345 enrolled patients regarding demographics, co-morbidity and ADRs. Causality and severity of ADRs were assessed. **Results:** According to our data. we have found that 75.7% (261out of 345) patients reported 36 different ADRs involving different systems, of these 1.2% experienced Serious Adverse Events (SAEs), including three deaths (0.9%). A majority of ADRs were more significantly reported with ribavirin-containing regimen. Out of 345 patients, 23.5% have comorbidities. Among them, 92.6% reported ADRs. Causality assessment of ADRs by WHO-UMC criteria revealed that 38.89% were probable while 61.11% were possible.

Conclusion: New antiviral drugs require careful follow-up of any significant adverse event that may occur and can affect adherence. Special population as the elderly and those with comorbidities should always be managed with caution to avoid development of serious side effects.