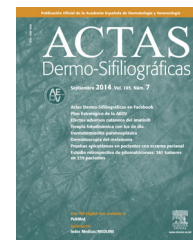




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ORIGINAL ARTICLE

Drug Eruptions Induced by Telaprevir in Patients With Chronic Hepatitis C Virus Genotype 1 Infection: A Prospective Study[☆]



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KEYWORDS

Telaprevir;
Triple therapy;
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Toxicoderma

Abstract

Introduction: When co-administered with interferon and ribavirin, the prescription drug telaprevir significantly improves treatment response in patients with chronic hepatitis C virus (HCV) infection. Its use, however, also increases the likelihood of adverse effects that may lead to discontinuation of treatment. Cutaneous adverse effects are particularly common.

Objective: To determine the frequency and clinical characteristics of drug eruptions induced by telaprevir in patients receiving HCV treatment and to analyze the clinical course of lesions and response to treatment.

Material and methods: We performed a prospective observational study of all patients who started a treatment regimen that included telaprevir between May 2012 and July 2013. We recorded the demographic characteristics of the patients who developed telaprevir-induced eruptions, and analyzed the clinical characteristics of the lesions and their clinical course following the application of guideline-based treatment recommendations.

Results: Twenty (46%) of the 43 patients who received triple therapy with interferon, ribavirin, and telaprevir during the study period developed drug reactions attributable to telaprevir. The reaction was classified as mild or moderate (grades 1 or 2) in 90% of cases and consisted of an exanthem with erythematous-edematous scaling plaques and papules. The rash worsened,

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PALABRAS CLAVE

Telaprevir;
Triple terapia;
Virus hepatitis C;
Toxicodermia

mainly by spreading, in about one-third of cases. The skin lesions led to discontinuation of treatment in 2 patients (4.6%). Sustained viral response was achieved in 34 patients (79%).

Conclusions: Telaprevir-induced eruptions are common and often progress, but they rarely require patients to discontinue treatment.

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Toxicodermias por telaprevir en el tratamiento de la infección crónica por el genotipo 1 del virus de la hepatitis C. Estudio prospectivo

Resumen

Introducción: Telaprevir es un fármaco que administrado junto a interferón y ribavirina incrementa de forma significativa la respuesta al tratamiento de la infección por el virus de la hepatitis C. Sin embargo, su empleo incrementa también la probabilidad de desarrollar efectos adversos, en muchos casos cutáneos que pueden condicionar el mantenimiento del tratamiento. **Objetivo:** Conocer la incidencia, características clínicas y evolutivas y respuesta al tratamiento de las toxicodermias por telaprevir en el contexto del tratamiento de la infección por el virus de la hepatitis C.

Material y métodos: Estudio prospectivo observacional realizado entre mayo de 2012 y julio de 2013 en el que se incluyeron aquellos pacientes que iniciaron tratamiento con telaprevir durante ese periodo. En aquellos en los que se detectaron toxicodermia se recogieron los datos demográficos de los pacientes, las características clínicas de las lesiones y la evolución tras la aplicación de las recomendaciones de las guías clínicas.

Resultados: De un total de 43 pacientes que recibieron tratamiento triple un 46% presentó toxicodermia atribuible a telaprevir. En el 90% de los casos esta fue leve o moderada (grados 1 o 2) y consistió en un exantema constituido por pápulas y placas eritematoedematosas y descamativas. En alrededor de un tercio de los pacientes se comprobó la progresión de la toxicodermia, principalmente en extensión, durante el curso del tratamiento. En 2 casos (4,6%) las lesiones cutáneas condicionaron la suspensión del fármaco. Un 79% de los tratados (34 pacientes) alcanzó una respuesta viral sostenida tras el tratamiento.

Conclusiones: Las toxicodermias asociadas a telaprevir son frecuentes en el curso del tratamiento y a menudo progresivas. Sin embargo, solo de forma excepcional condicionan su suspensión.

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INTRODUCTION

In developed countries, chronic hepatitis C virus (HCV) infection is currently the main cause of cirrhosis, hepatocellular carcinoma, and death from liver-related diseases, as well as a leading indication for liver transplant.¹ Standard treatment, which is based on the combination of pegylated interferon and ribavirin, provides modest rates of sustained virological response (SVR), defined as the absence of viral load in blood 24 weeks after completion of treatment. Since achieving SVR has been associated with a clear improvement in the prognosis of the underlying liver disease and survival,² it is considered the main objective of treatment of HCV infection. During the last few years, efforts to develop new agents to improve the treatment of patients with this disease have yielded a new drug class known as direct-acting antiviral agents.

In 2011, the United States Food and Drug Administration and the European Medicines Agency approved telaprevir for the treatment of chronic genotype 1 HCV infection.³ Telaprevir is a direct-acting antiviral agent that rapidly reduces HCV RNA levels by binding to the protease serine

NS3/4A, an enzyme that is essential for viral replication.⁴ When telaprevir is administered with interferon and ribavirin (triple therapy), a significant increase is observed in the SVR rate in patients infected by HCV genotype 1.⁵ Thus, the SVR rate achieved with telaprevir reaches 75% in previously untreated patients⁶ and up to 70% in previously treated patients⁷ compared with more modest rates of around 50% for pegylated interferon and ribavirin.⁸

The recommended treatment regimen is 12 weeks with triple therapy followed by 12–36 weeks of interferon and ribavirin depending on the viral response and the presence or absence of cirrhosis.

However, adding telaprevir to standard HCV therapy increases the risk of adverse events, among which skin complaints are common. In addition, patients who receive telaprevir suspend treatment more often than those who take standard treatment.⁹

Although telaprevir-associated skin manifestations have been reported in clinical trials and guidelines for management of these manifestations have been drafted, we know little of the incidence, magnitude, clinical expression, and outcome of drug eruptions in daily practice.

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