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Ombitasvir, paritaprevir, and ritonavir, with or without dasabuvir, plus ribavirin for patients with hepatitis C virus genotype 1 or 4 infection with cirrhosis (ABACUS): a prospective observational study.

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Abstract

BACKGROUND:

We ran a compassionate use nationwide programme (ABACUS) to provide access to ombitasvir, paritaprevir, and ritonavir, with dasabuvir, plus ribavirin for hepatitis C virus (HCV) genotype 1 infection and ombitasvir, paritaprevir, and ritonavir, plus ribavirin for HCV genotype 4 infection in patients with cirrhosis at high risk of decompensation while approval of these regimens was pending in Italy.

METHODS:

In this prospective observational study, we collected data from a compassionate use nationwide programme from March 17, 2014, to May 28, 2015. Patients with HCV genotype 1 infection and cirrhosis at high risk of decompensation were given coformulated ombitasvir (25 mg), paritaprevir (150 mg), and ritonavir (100 mg) once daily and dasabuvir (250 mg) twice daily for 12 weeks (patients with HCV genotype 1b infection) or 24 weeks (patients with HCV genotype 1a infection). Patients with HCV genotype 4 infection were given coformulated ombitasvir (25 mg), paritaprevir (150 mg), and ritonavir (100 mg) once per day for 24 weeks. All patients were given weight-based ribavirin. The primary efficacy endpoint was sustained virological response at week 12 after the end of treatment (SVR12), analysed by intention-to-treat. Univariate and multivariate logistic regression analyses were used to

identify baseline characteristics associated with SVR12. Adverse events were recorded throughout the study.

FINDINGS:

728 (96%) of 762 patients with cirrhosis who were given ombitasvir, paritaprevir, and ritonavir, with or without dasabuvir, plus ribavirin therapy for 12 or 24 weeks achieved SVR12. Logistic regression analyses identified that bilirubin concentrations of less than 2 mg/dL were associated with SVR12 (odds ratio [OR] 4·76 [95% CI 1·83-12·3]; p=0·001). 166 (23%) of 734 patients included in safety analyses had an adverse event. 25 (3%) patients discontinued treatment because of adverse events. Asthenia was the most commonly reported adverse event, occurring in 36 (5%) patients.

INTERPRETATION:

Our findings suggest that the safety and effectiveness of ombitasvir, paritaprevir, and ritonavir, with or without dasabuvir, plus ribavirin in patients with HCV genotype 1 or 4 infection and cirrhosis at high risk of decompensation in a real-life setting are similar to those reported in clinical trials. The concordance with clinical trials provides reassurance that the reported efficacy of this treatment in clinical trials will translate to its use in routine clinical practice.