

1 Abstract

Title

Real World Evidence of the Effectiveness of Paritaprevir/r – Ombitasvir, ± Dasabuvir, ± Ribavirin in Patients with Chronic Hepatitis C - An Observational Study in the Netherlands (3DUTCH)

Keywords

Chronic hepatitis C (CHC), non-interventional study, paritaprevir, ritonavir (r), ombitasvir, dasabuvir, ribavirin (RBV), sustained virological response (SVR), Patient Reported Outcome (PRO), EuroQol 5 dimension 5 level (EQ-5D-5L)

Background

The interferon-free combination regimen of paritaprevir/ritonavir (r) and ombitasvir with or without dasabuvir (ABBVIE REGIMEN) ± ribavirin (RBV) for the treatment of chronic hepatitis C (CHC) has been shown to be safe and effective in randomized controlled clinical trials with strict inclusion and exclusion criteria under well controlled conditions.

The rationale for this observational study was to determine how the efficacy and safety of the ABBVIE REGIMEN as demonstrated in pivotal trials translates into real world everyday clinical settings when used according to local label in the Netherlands in a clinical practice patient population.

Methods

In this prospective, multi-center observational study a total of 51 adult patients chronically infected with hepatitis C virus (HCV) were enrolled by 9 centers in the Netherlands.

Patients were receiving the interferon-free ABBVIE REGIMEN ± RBV at the discretion of the physician in accordance with local clinical practice and label.

The primary objective was effectiveness as evidenced by sustained virological response 12 weeks after the end of treatment (SVR12).

Results

The majority of the core population (CP, N=48) had genotype 1b (70.8%) followed by genotype 1a (18.8%) and genotype 4 (10.4%); 12.5% were suffering from cirrhosis and 8.3% had transition to cirrhosis. Only 22.9% of the patients were treatment experienced. The combination of paritaprevir/r plus ombitasvir plus dasabuvir without RBV was prescribed to 70.8% of the CP whereas 20.8% received this combination with RBV and 8.3% took paritaprevir/r plus ombitasvir with RBV. The planned treatment duration was 12 weeks for all patients.

SVR12 was achieved in 89.6% of the CP (95% CI: [77.8, 95.5], N=48) and in 91.5% of the core population with sufficient follow-up data regarding SVR12 (CPSFU12) (95% CI: [80.1, 96.6], N=47). For genotypes 1a and 4 SVR12 in the CP (which is identical with the CPSFU12) was 100%. For genotype 1b the respective response rates were 85.3% (n/N=29/34) and 87.9% (n/N=29/33). In patients without cirrhosis SVR12 was achieved in 90.5% (n/N=38/42) of the CP and in 92.7% (n/N=38/41) of the CPSFU12, in patients with cirrhosis response was 83.3% (n/N=5/6) in both populations. There were 3 virological failures reported, all cases were relapses among genotype 1b infected patients without cirrhosis.

Treatment emergent adverse events (AEs) were reported by 64.0% of the patients and serious AEs by two patients (4.0%). One patient died more than half a year after treatment end due to acute myocardial infarction. Two patients (4.0%) discontinued the ABBVIE REGIMEN for safety reasons and one of the patients receiving RBV discontinued RBV early.

Conclusion

Overall the 3DUTCH study provides evidence for the effectiveness of the ABBVIE REGIMEN under real world conditions in the Dutch CHC population. Treatment was well tolerated, no new safety signals were detected during this study. Since the study population was small with 51 patients, results have to be interpreted with caution.

Marketing Authorisation Holder(s)

AbbVie B.V.

Wegalaan 9

2132 JD Hoofddorp

The Netherlands

Names and Affiliations of Principal Investigators

