Abstract

Title

Real World Evidence of the Effectiveness of Paritaprevir/r – Ombitasvir, ± Dasabuvir, ± Ribavirin in Patients with Chronic Hepatitis C -
An Observational Study in Poland (HCV RWE PMOS)

Keywords

Chronic hepatitis C (CHC), non-interventional study, paritaprevir/ritonavir, ombitasvir, dasabuvir, ribavirin, sustained virological response (SVR), Patient Reported Outcome (PRO), EQ-5D-5L, WPAI (Work Productivity and Activity Impairment)

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 Poland in a clinical practice patient population.

Methods

In this prospective, multi-center observational study a total of 394 adult patients chronically infected with HCV were enrolled by 17 centers in Poland.

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=394) had genotype 1b (88.6%), 31.7% were suffering from cirrhosis and 14.7% had transition to cirrhosis. More than half of the patients were treatment experienced (58.4%). The combination of paritaprevir/r plus ombitasvir plus dasabuvir without RBV for 12 weeks was prescribed to 58.1% and with RBV to 36.0% of the CP.

SVR12 was achieved in 96.7% of the CP overall and in 93.6% and 98.1% of patients with and without cirrhosis, respectively. There were only 2 virological failures reported, both cases were relapses (0.5%).

Treatment emergent serious adverse events were reported by 3.6% of the patients and 7 patients (1.8%) discontinued the ABBVIE REGIMEN early for safety reasons. Six patients died, none of these cases was deemed related to treatment (gastrointestinal haemorrhage, oesophageal varices haemorrhage, two hepatocellular carcinomas, one malignant lung neoplasm and one death with unknown cause), 4 of the patients died more than 30 days after EOT.

Discussion and Conclusion

Overall the present study provides evidence for the very high effectiveness - resembling results from pivotal trials - of the ABBVIE REGIMEN under real-world conditions in the Polish CHC population. Treatment was well tolerated, no new safety signals were detected during this study.