Real-world effectiveness and cost per SVR of ledipasvir/sofosbuvir chronic hepatitis C treatment

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INTRODUCTION

• With the emergence of novel, highly effective, and safe therapies and the expected demand for them, the need for optimal resource allocation is high.

• Ledipasvir/Sofosbuvir (LDV/SOF) single tablet regimen (STR) is approved in Europe and the US for the treatment of chronic hepatitis C (CHC) patients.

• The cost per sustained viral response (SVR) is a measure which provides insights into the amount spent for the achievement of success in CHC therapy.

AIM

• This study aims to assess the safety, effectiveness, and cost per SVR associated with LDV/SOF therapy in clinical practice in Germany.

MATERIAL & METHODS

• The first CHC patients treated with LDV/SOF in a single centre (and for whom SVR after 12 weeks of follow-up (SVR12) could be available October 30th, 2015) were included in this analysis.

• Baseline characteristics, prior treatment history, safety, effectiveness and costs based on medication and medical interventions were investigated.

• HCV RNA was qualitatively measured by Roche COBAS® AmpliPrep/COBAS® TaqMan® with a cut-off of <12 IU/ml. Fibrosis was measured by FibroScan® with cut-off values for METAIVIR stage F3 or less of ≤12.3kPa.

• The analysis was performed using descriptive statistics.

Results

• 219 patients met the inclusion criteria for this analysis.

• 8w (50.2%), 12w (45.2%) or 24w (4.6%) treatment with LDV/SOF was initiated between 21/11/2014 and 01/06/2015.

• 21.5% of patients had ribavirin (R) added to the STR (78.7% of which F4).

• 68.5% of patients were treatment naïve; 24.2%, 6.9% and 0.5% had one, two and three previous therapies respectively.

• Evidence of non-adherence, assessed upon the discretion of the investigators and based on patient adherence to schedules / appointments, patient statements and congruence to the prescriptions was reported in 4.1% of patients.

• In patients with available outcome data, the SVR4 was 98% (n=188/191) and SVR12 was 97% (n=200/207).

• Seven F4 patients did not achieve SVR12; two of those were naïve; one was treated with 12w LDV/SOF+R and discontinued; one was on 24w LDV/SOF+R. Among the five treatment experienced patients, four were treated with 12w LDV/SOF+R and one was on 24w LDV/SOF+R.

• 7.3% (n=16) experienced grade 3 or 4 adverse events (AE) and 81.3% (n=133) were assessed as treatment-related; no AE led to discontinuation.

• 0.9% (n=2) of patients discontinued prematurely due to lack of adherence; SVR12 was unavailable for one of the patients and was not achieved by the second.

CONCLUSION

• This study suggests that as a result of a good tolerability profile, monitoring and AE related costs are minimal in LDV/SOF regimens.

DISCLOSURES

• P. Buggisch: Consultant: AbbVie, BMS, Gilead, Janssen, MSD, Novartis, Roche. Sponsored Lectures (National and International): AbbVie, BMS, Gilead, Janssen, MSD, Novartis, Roche, Siemens.

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