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 METAVIR 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.

RESULTS

Table 1. Baseline characteristics

Characteristics	Total cohort (n=219)
Age, Median (Range)	54 (22 - 79)
Males, n (%)	117 (53)
Caucasians, n (%)	218 (100)
Genotype, n (%)	
1a	117 (53)
1b	77 (35)
3	15 (7)
4	10 (5)
Liver disease stage, (%)	
F0	84 (38)
F1	38 (17)
F2	28 (13)
F3	22 (10)
F4	47 (22)
Baseline HCV RNA (log10 IU/ml) Median (Q1-3; min-max)	5.99 (5.44 – 6.28; 1.04 – 6.87)
Bilirubin (mg/dL) Median (Q1-3;min-max)	0.5 (0.4 - 0.8; 0.2 – 4.1)
Albumin (g/L) Median (Q1-3;min-max)	37.9 (36.1 – 40.0; 0.0 – 48.3)
Haemoglobin (g/dL) Median (Q1-3;min-max)	14.4 (13.5 - 15.4; 9.5 – 18.4)
Neutrophils (ANC/mm³) Median (Q1-3;min-max)	3.3 (2.6 – 4.7; 1.0 – 11.8)
Platelets (10⁹/L) Median (Q1-3;min-max)	213 (165 - 256; 4 - 890)
Previous treatment status	
Naïve, n (%)	150 (68)
Experienced, n (%)	69 (32)
Presence of co-infection, n (%)	14 (6)
HIV, n (%)	11 (5)
HBV, n (%)	3 (1)
At least one co-morbidity, n (%)	192 (93)

- 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=13) 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.

Figure 1. LDV/SOF regimens distribution

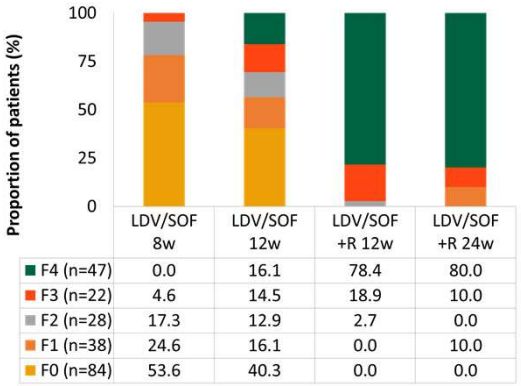


Figure 2. Effectiveness results

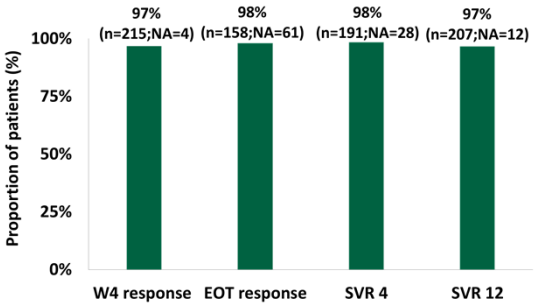
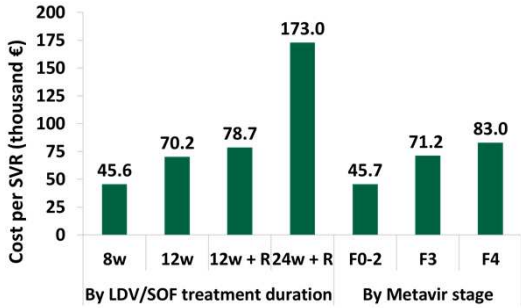


Table 2. Safety

Adverse events, n (%)	Total cohort (n=219)
Any AEs (Grades 3 & 4)	16
AEs 'probably' related to treatment	11
AEs 'possibly' related to treatment	2
AEs 'probably' related to SOF	2
Cephalaria	1
Nausea	1
AEs 'possibly' related to SOF	1
Headache	1
RBV-related AEs	11
AEs leading to discontinuation	0

Figure 3. Median cost per SVR



- The median cost per SVR12 was €51,480 (PP like approach).
- 71% of naïve patients and 64% of non-cirrhotic (NC) patients were on 8w duration; median cost per SVR12 was 81% lower in NC (€45,938) than in F4 patients and 61% lower in naïve (€46,273) versus TE patients.
- Total treatment costs were €11,541,996; 0.5% of costs were non-therapy costs, including physician visits, laboratory testing and management of AEs.

CONCLUSION

- This study suggests that as a result of a good tolerability profile, monitoring and AE related costs are minimal in LDV/SOF regimens.
- This study also suggests that, when the 8w regimen is used, the cost per SVR is significantly lower in naïve and NC when compared to TE and cirrhotic patients, indicating an economic benefit of early treatment and the selection of highly effective and well tolerated therapies.

DISCLOSURES

- **P. Buggisch:** Consultant: AbbVie, BMS, Gilead, Janssen, MSD, Novartis, Roche. Sponsored Lectures (National and International): Abbott, BMS, Gilead, Janssen, MSD, Merz, Novartis, Roche. Other: Clinical studies: AbbVie, BMS, Gilead, Janssen, MSD, Novartis, Roche, Siemens.
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