Poster 44

HCV in the Australian primary care setting: Real-world effectiveness of 12 weeks of sofosbuvir/velpatasvir for the treatment of chronic hepatitis C

O'Loan J[1], Balcomb A[2], Baker D[3], Cooper M[4], Doyle J[5], Godfrey D[6], Kozminsky M[7], Poliness E[8], Mertens M[9], Myers L[10], Vanstraelen K[9], Watkinson S[8,11], Young M[1]

[1]Medico Clinic & Kombi Clinic, Brisbane, Australia, [2]The Prince Street Clinic, Orange, Australia, [3]East Sydney Doctors, Sydney, Australia [4]Lygon Court Medical Centre, Carlton, Australia, [5]Department of Infectious Diseases, The Alfred and Monash University, Melbourne, Australia, [6]Gilead Sciences, Melbourne, Australia, [7]Genesis Medical Centre, Brighton, Australia, [8]The Living Room, Melbourne, Australia, [9]Gilead Sciences, London, United Kingdom, [10]Harm Reduction WA, Perth, Australia, [11]Melbourne Health, Melbourne, Australia

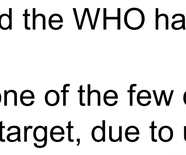
Gilead Sciences
Level 6, 417 St Kilda Road
Melbourne, Victoria 3004
Australia

Introduction

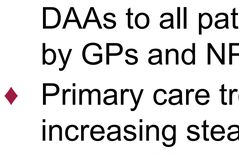
- An estimated 180,000 people are living with CHC in Australia, and the WHO has a goal to eliminate HCV by 2030[1,2]
- Australia is one of the few countries on track to achieve this target, due to unrestricted access of DAAs to all patients with CHC and treatment initiation by GPs and NPs, in addition to specialists[3]
- Primary care treatment of HCV in Australia has been increasing steadily since 2016 and now accounts for at least 39% of all DAA prescriptions[1]
- We need to optimise each part of the HCV cascade of care to simplify screening, diagnosis, treatment and follow-up
- Simplifying treatment is key to engaging marginalised patient populations
- The availability of pangenotypic regimens can provide HCPs around the world with the opportunity to simplify and facilitate treatment access
- SOF/VEL is a pangenotypic, panfibrotic, PI-free, single duration, single tablet regimen offering a simplified treatment option to address this goal
- 12 weeks of SOF/VEL is approved to treat most patients with CHC
- This integrated analysis of real-world data from 7 primary care clinics is the first to evaluate the efficacy of 12 weeks of SOF/VEL in patients with CHC regardless of genotype and fibrosis, and including those with compensated cirrhosis

Sofosbuvir/velpatasvir: A single tablet regimen[4]

SOF
Nucleotide polymerase inhibitor



Sofosbuvir (SOF)[5,6]
- Potent antiviral activity against HCV GT 1–6



VEL
NS5A inhibitor

Velpatasvir (VEL)[7,8]
- Highly effective in GT 1–6
- 2nd-generation NS5A inhibitor with improved resistance profile

SOF + VEL

SOF/VEL STR
- Once daily, single tablet, single duration (oral [400/100 mg])
- Taken with or without food

Objective

To evaluate the real-world effectiveness of SOF/VEL for 12 weeks as a simple treatment in a large heterogenous patient population in Australian primary care settings

Methods

- Retrospective data from 7 primary care clinics across Australia were included
- Patients were treated in primary care clinics (including GP clinics), homeless or Drug & Alcohol (D&A) clinics, NSP clinics, or outreach clinics
- Adults were treated according to local standards of care, with cirrhosis status determined by the treating HCP according to local clinical practice
- Data on 301 patients with or without compensated cirrhosis, who were treatment-naïve or treatment-experienced (i.e. pegIFN ± RBV ± PI* ± SOF) and who initiated 12 weeks of SOF/VEL treatment and with outcome data by July 2019 were included in the ITT population
- Patients with a history of decompensation, HCC, prior NS5A inhibitor exposure or addition of RBV were excluded
- SVR12 was assessed for patients who completed 12 weeks of SOF/VEL treatment and have virological outcome data by July 2019
- Patients with non-virological failures (LTFU, discontinuations, death†, still on treatment, and those who completed treatment but SVR yet to be determined) were excluded from the per protocol analyses

* PI: telaprevir/boceprevir/simeprevir
† Not related to SOF/VEL

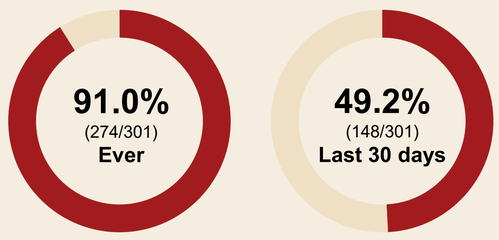
Results

Patient characteristics

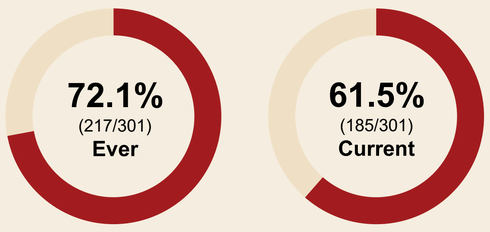
Characteristic – N (%)	ITT – N=301
Median age, years (range)	43 (19–67)
Male	208 (69.1)
Ethnicity:	
White	234 (77.7)
Aboriginal or TSI	32 (10.6)
Asian	21 (7.0)
Black	1 (0.3)
Other	13 (4.3)
Coinfection with	
HBV	3 (1.0)
Compensated cirrhosis	21 (7.0)
HCV GT:	
1	104 (34.6)
2	18 (6.0)
3	170 (56.5)
6	6 (2.0)
Mixed	3 (1.0)
Treatment-experienced*	7 (2.3)

* Included pegIFN ± RBV ± PI (telaprevir/boceprevir/simeprevir) ± SOF

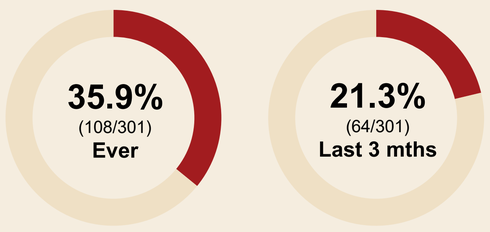
Proportion of patients reporting injecting drug use



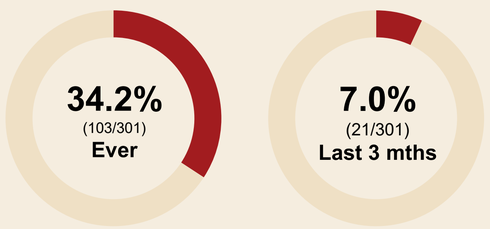
Proportion of patients reporting OST use



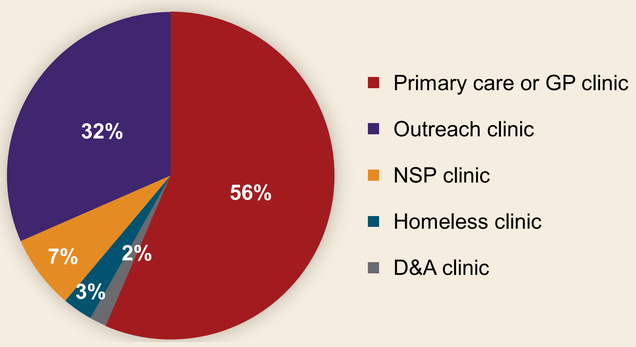
Proportion of patients reporting unstable housing



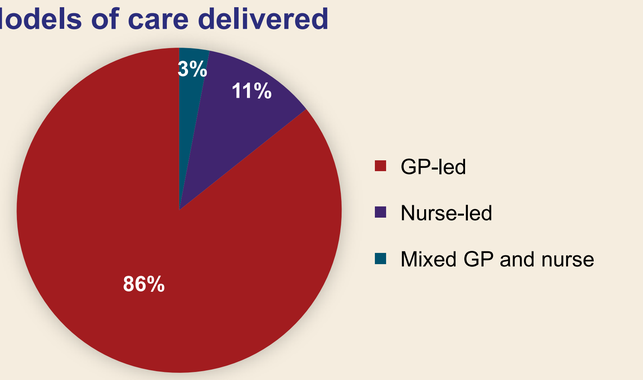
Proportion of patients reporting incarceration



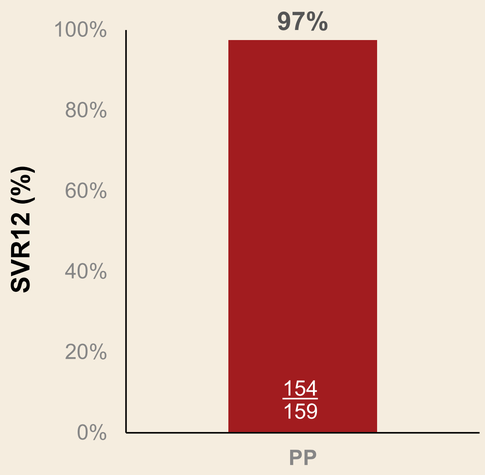
Types of clinics utilised



Models of care delivered



Overall SVR12 rate



VF*	N=5	% of VF
Relapse	2	40.0
Breakthrough/non-response	3	60.0

Non-VF†	N=142	% of NVF
LTFU	63	44.4
Completed treatment but SVR yet to be determined	50	35.2
Still on treatment	17	12.0
Discontinuations‡	10	7.0
Death§	2	1.4

* Included in the PP population. All patients were treatment-naïve and completed 12 weeks' treatment. 3 patients had GT 3, 1 each had GT 1 or 2. 3 patients were non-cirrhotic and 2 had compensated cirrhosis
† Not included in the PP population
‡ Included 3 patients who were non-adherent; 1 discontinued due to adverse event (unspecified), 1 discontinued due to hospitalisation from a motor vehicle accident, 5 discontinued due to unknown reasons
§ 1 resulted from injecting drug overdose, 1 from bacterial peritonitis. Both deaths were not related to SOF/VEL

Conclusion

- This is the largest real-world cohort treated with SOF/VEL in primary care settings
- 12 weeks of SOF/VEL treatment resulted in a 97% cure rate (per protocol) in this highly marginalised, diverse patient population in primary care settings
- This RWD is comparable to Phase 3 and other real-world studies with SOF/VEL[9–11]
- Lost to follow-up was the main reason for not achieving SVR12 (21% of the ITT population)
- Simplification of the HCV cascade of care is possible with SOF/VEL
- Strategies to help engage marginalised patients are urgently needed and further simplification of HCV management should be considered

Abbreviations

CHC, chronic hepatitis C; D&A, drugs and alcohol; DAA, direct-acting antiviral; GP, general practitioner; GT, genotype; HCC, hepatocellular carcinoma; HCP, healthcare professional; HCV, hepatitis C virus ITT, intent-to-treat; LTFU, lost to follow-up; NP, nurse practitioner; NSP, needle and syringe programme; PBS, Pharmaceutical Benefits Scheme; pegIFN, pegylated interferon; PI, protease inhibitor; PP, per protocol; OST, opioid substitution therapy; RBV, ribavirin; RWD, real-world data; SOF, sofosbuvir; SVR12, sustained virologic response at 12 weeks post-treatment; TSI, Torres Strait Islander; VEL, velpatasvir; VF, virological failure.

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