Short Communication

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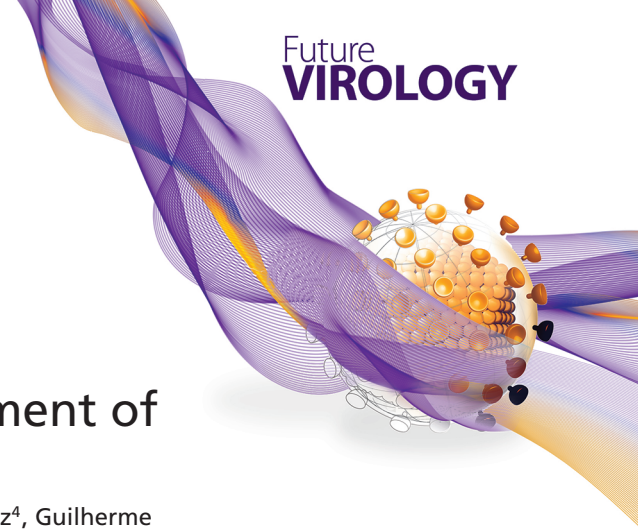

Real-world effectiveness of sofosbuvir/velpatasvir for the treatment of hepatitis C virus in prison settings

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Background: People in prison are at high risk of hepatitis C virus (HCV) infection and often have a history of injection drug use and mental health disorders. Simple test-and-treat regimens which require minimal monitoring are critical. **Methods:** This integrated real-world analysis evaluated the effectiveness of once daily sofosbuvir/velpatasvir (SOF/VEL) in 20 prison cohorts across Europe and Canada. The primary outcome was sustained virological response (SVR) in the effectiveness population (EP), defined as patients with a valid SVR status. Secondary outcomes were reasons for not achieving SVR, adherence and time between HCV RNA diagnosis and SOF/VEL treatment. **Results:** Overall, 526 people in prison were included with 98.9% SVR achieved in the EP (n = 442). Cure rates were not compromised by drug use or existence of mental health disorders. **Conclusion:** SOF/VEL for 12 weeks is highly successful in prison settings and enables the implementation of a simple treatment algorithm in line with guideline recommendations and test-and-treat strategies.

Plain language summary: Achievement of elimination of HCV as a major public health threat requires focus on vulnerable populations such as people in prison. The prison population is at high risk of HCV infection but their treatment is complicated by social issues such as mental health disorders and drug use. Simple and effective treatment regimens are required to increase access to treatment and improve cure rates. This real-world analysis across Europe and Canada analyzed data from 20 prison populations. HCV-infected individuals were treated with sofosbuvir/velpatasvir, a once daily treatment which requires minimal monitoring. This regimen achieved high cure rates in the prison population despite the existence of complicating social issues.

First draft submitted: 20 January 2022; Accepted for publication: 30 March 2022; Published online: 19 April 2022

Keywords: HCV elimination • hepatitis C • people in prison • real world • sofosbuvir/velpatasvir • sustained virological response

Chronic hepatitis C infection is a major global medical and public health issue affecting around 58 million people worldwide and is estimated to have resulted in approximately 290,000 deaths in 2019 [1]. The WHO has set a goal of eliminating viral hepatitis as a major public health threat by 2030 [2]. The achievement of this goal will provide huge individual, societal and economic benefits, but numerous challenges impact on the ability to meet this target, including those now presented by the COVID-19 pandemic. The impact of COVID-19 on healthcare systems worldwide has been reported to have resulted in a decrease in access to hepatitis C virus (HCV) testing and medications [3], increasing the pool of patients with active infection waiting for diagnosis and treatment. The resulting impact on HCV elimination may come at a high cost; it has been predicted that a 1-year delay in hepatitis elimination programs due to the COVID-19 pandemic has the potential to result in tens of thousands of additional liver cancers and deaths from HCV globally [4]. As vaccination programs for COVID-19 provide more coverage, it is important to re-focus HCV elimination efforts as soon as possible, including further simplification of the patient care cascade.

Among the challenges faced are those associated with the successful engagement of vulnerable at-risk populations into and through the HCV care cascade. People in prison represent an important high-risk group for HCV infection [5–7]. They often bear a high burden of physical and psychological disorders compared with the general population, with a high incidence of high-risk behaviours such as injection drug use (IDU) [7,8] and mental health disorders [7–9]. It has been estimated that, of the 10.2 million people incarcerated worldwide on any given day in 2014, over 1.5 million (15.1%) had HCV infection [10]. Data from the USA suggest that a significant proportion of these cases are undiagnosed and more than 90% of prisoners are released untreated, contributing to HCV spread in the community [6]. However, prisons can provide an opportunity for HCV testing and treatment in high-risk, 'difficult-to-engage' groups, thus reducing the prevalence of HCV infection not only in incarcerated communities, but also in wider society [11]. To achieve this and bring individuals to a cure, there is a need for rapid diagnosis and prompt treatment initiation, and for the care cascade to be simplified and shortened as much as possible to overcome challenges such as 'loss to freedom' due to shorter prison sentences, or interruptions to care due to interprison transfers [12].

The European Association for the Study of the Liver (EASL) guidelines recommend the use of simplified HCV treatment algorithms to improve access to the care pathway, using pangenotypic direct-acting antivirals (DAAs) to obviate the need for pre-treatment genotyping/subtyping [5]. People in prison are one of the populations that are highlighted to particularly benefit from a simplified and streamlined care pathway to improve access to treatment [5]. Evidence for successful strategies using pangenotypic DAA regimens for people in prison is beginning to emerge [13–17].

Sofosbuvir/velpatasvir (SOF/VEL) is a pangenotypic, panfibrotic, protease inhibitor-free, single-tablet regimen that can be taken with or without food and used as a fixed 12-week treatment in all adult patients with chronic hepatitis C, with limited pre-treatment and on-treatment monitoring, as recommended by the EASL guidelines as part of the simplified treatment algorithm [5]. The safety and efficacy of SOF/VEL have been demonstrated in multiple clinical trials, with sustained virological response (SVR) rates of >95% across all HCV genotypes, in patients with or without compensated cirrhosis, irrespective of HIV status or previous treatment failure (with interferon, ribavirin or protease inhibitors) [18–21]. Similar findings have been reported outside the controlled settings of clinical trials in real-world cohort studies in a variety of clinical settings worldwide [22–27], including a large analysis of 5552 patients from 12 clinical practice cohorts, which showed high SVR rates in all patient subsets, including those with missing information for certain baseline characteristics [28].

The current integrated real-world analysis pooled data from 20 clinical cohorts in Canada and Europe to allow evaluation of the real-world effectiveness of SOF/VEL for 12 weeks without ribavirin in people in prison.

Materials & methods

Study design

This retrospective integrated analysis included patient-level data from 20 prison settings in Belgium, Canada, France, Italy, Portugal and Spain. People in prison infected with HCV genotype 1–6, with or without compensated cirrhosis and treated with the oral, once-daily, single-tablet regimen SOF/VEL 400/100 mg for 12 weeks without ribavirin as part of routine clinical practice were eligible for inclusion. Individuals could be treatment-naïve or previously treated with interferon-based therapy (pegylated interferon plus ribavirin with or without telaprevir,

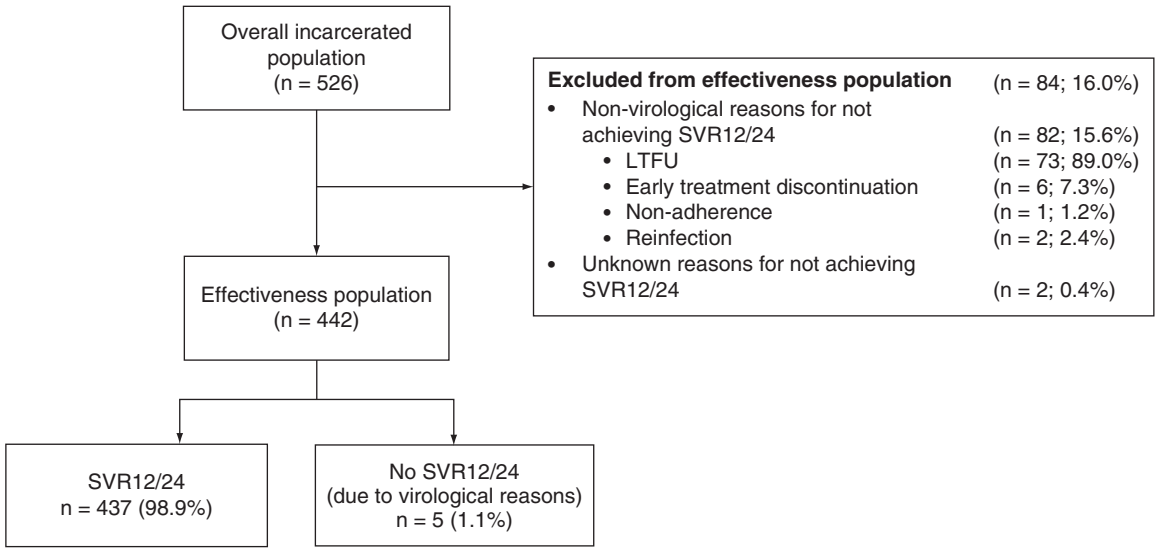

Figure 1. Flowchart and response of patients included in this real-world effectiveness analysis. Overall population includes all patients, including those with a virological, non-virological or unknown reason for not achieving SVR12/24. The effectiveness population includes patients with a valid SVR status, excluding patients who did not achieve SVR because of non-virological or unknown reasons.
LTFU: Lost to follow-up; SVR12/24: Sustained virological response 12/24 weeks after the end of treatment.

boceprevir or simeprevir). Individuals who received SOF/VEL for more than 12 weeks or received ribavirin as part of the treatment regimen, those with current or prior decompensated cirrhosis or hepatocellular carcinoma, and patients who had previously failed an NS5A-containing DAA treatment were excluded. Patients were managed and treated according to local guidelines and standard of care.

Outcomes

Effectiveness was assessed in two populations. The overall population (OP) comprised all patients, including those with a virological, non-virological or unknown reason for not achieving SVR at 12- or 24-weeks post-treatment. The effectiveness population (EP) comprised patients with a valid SVR status, excluding patients who did not achieve SVR because of non-virological or unknown reasons. Non-virological reasons for not achieving SVR were defined as early treatment discontinuation, non-adherence where associated with a lack of SVR assessment, reinfection, loss to follow-up (LTFU), death before SVR assessment and consent withdrawal. Virological reasons for not achieving SVR were defined as virological breakthrough/non-response, relapse or virological failure without availability of further details. Patients who did not achieve SVR, without information available about a virological or non-virological reason for not achieving SVR, were classified under 'unknown reason'.

The primary outcome was SVR in the EP overall and stratified by HCV genotype, fibrosis stage, IDU, presence of mental health disorders and antipsychotic drug use. Secondary outcomes were reasons for not achieving SVR, adherence, and time between most recent HCV RNA diagnosis and SOF/VEL treatment start. Adherence was assessed by the treating physician, according to the proportion of pills taken (patients were categorized with an adherence level of $\geq$90%, <90%, $\geq$80% or <80%).

Statistical analyses

Descriptive characteristics were presented as the number (n) and percentage of patients (%) for the categorical variables. Continuous variables were summarized as mean (standard deviation [SD]) or median (interquartile range). Statistical analysis was performed using R version 3.5.2.

Results

A total of 526 HCV-positive individuals from 20 cohorts who were treated with SOF/VEL for 12 weeks were included in this real-world pooled analysis (OP). Patients who did not achieve SVR due to non-virological (n = 82) or unknown reasons (n = 2) were excluded from the EP (n = 442). A summary of patient disposition is shown in

Figure 1 and patient baseline characteristics are shown in Table 1. In the OP, over half of patients with mental health disorders (53.4%; 62/116) were receiving treatment with antipsychotics, predominantly quetiapine (n = 35). In patients with mental health disorders, 74.1% (86/116) had a history of IDU and 16.4% (19/116) were active injecting drug users.

Effectiveness

In the EP, SVR was achieved by 98.9% of patients (437/442), including 98.7% (379/384) of treatment-naïve and 100% (51/51) of treatment-experienced (DAA-naïve) patients. SVR was ≥98.5% across HCV genotypes (Figure 2A) and ≥95.4% across fibrosis stages (Figure 2B). SVR was ≥98% in patients with baseline characteristics historically considered complicating factors for HCV cure (Figure 2C), and 96.7% (29/30) in GT 3 patients with compensated cirrhosis. SVR rates were numerically similar between patients who received treatment soon after diagnosis and those in whom treatment was delayed: SVR was achieved by 97.7% (42/43) who received treatment within 1 day of diagnosis, 98.4% (60/61) of patients who received treatment within 7 days, 98.7% (236/239) of patients who received treatment within 90 days and 98.6% (145/147) of patients who received treatment more than 90 days after diagnosis. For patients with adherence information available in the EP, adherence was ≥90% in 99.3% (398/401); of these patients, all but one achieved SVR. The three patients with adherence <80% all achieved SVR.

Out of five patients who did not reach SVR due to a virological reason, three patients were documented as a non-response, two patients relapsed and for two patients no further details were provided.

Non-virological reasons for not achieving SVR

Non-virological reasons for not achieving SVR were cited for 82/526 individuals (15.6%); 73 (89%) lost to follow-up; six (7.3%) early discontinuation; one (1.2%) non-adherence; and reinfection in two (2.4%). Table 2 describes the baseline characteristics of patients who experienced a non-virological failure.

Discussion

In this large integrated real-world analysis, treatment with SOF/VEL resulted in high SVR rates in people in prison, including in those with unknown baseline characteristics (genotype and fibrosis) and those with characteristics historically considered to be complicating factors for HCV cure. SVR rates in this vulnerable population were in line with cure rates in more general populations in both clinical trials and real-world settings [19,20,28,29]. Only six individuals (1%) discontinued treatment with SOF/VEL early. Although the reasons for these discontinuations were not provided, the very low rate of discontinuations and high rates of adherence support the favorable safety and tolerability profile of SOF/VEL as shown previously in clinical trials and real-world settings [19,20,28].

High cure rates with SOF/VEL in this analysis were not impacted by the presence of active IDU, or the presence of mental health disorders, including those managed with antipsychotic drugs. These are characteristics that often challenge the successful treatment of HCV in people in prison, with HCV prevalence in prison being highly associated with IDU [30–32] and linked to risk behaviour such as sharing of injection equipment [8,33]. In this analysis, 13% of the OP were active injecting drug users, defined as drug use within 6 months prior to SOF/VEL treatment start. However, active IDU may have been under-reported by patients due to the legal implications of continued drug use in prison. High levels of psychiatric disorders, including serious mental illness such as psychosis and severe depression, are also consistently reported in the prison population [7,9] and have been associated with HCV infection [34]. These observations, together with the potential for high rates of polypharmacy in prison populations generally (e.g. due to older age and comorbidities, or opioid substitution therapy) [35,36], highlights the need for treatments with manageable DDI profiles. The lack of clinically significant interactions between most antipsychotic drugs and SOF/VEL [5] removes the need for dose adjustments or additional monitoring and supports the use of protease-inhibitor free regimens to enable simplified HCV treatment. The additional benefit of this regimen of being able to be taken with or without food eliminates the need to synchronize administration with prison meal schedules [37] and further simplifies HCV treatment.

Prisons provide important opportunities for identifying and treating HCV-positive individuals, particularly those who may find it difficult to access care in the wider community [11]. However, incarceration also provides multiple occasions for individuals to slip through the care cascade, both within the system (e.g. interprison transfers, short periods of incarceration in jails or remand centres, differing sentence length) or following release [38].

Table 1. Baseline demographics and clinical characteristics.

Characteristics	Overall population (n = 526)	Effectiveness population (n = 442)
Age, years, mean (SD)	44 (8.9)	44 (9.1)
Sex, male, n (%)	481 (91.4)	406 (91.9)
Fibrosis stage, n (%)		
F0–F2	343 (65.2)	287 (64.9)
F3	83 (15.8)	74 (16.7)
F4	78 (14.8)	65 (14.7)
Unknown	22 (4.2)	16 (3.6)
Treatment history, n (%)		
Treatment-naïve	446 (84.8)	384 (86.9)
Treatment-experienced (DAA-naïve)	59 (11.2)	51 (11.5)
Treatment history unknown	21 (4)	7 (1.6)
HCV, n (%)		
GT 1	227 (43.2)	194 (43.9)
GT 2	18 (3.4)	14 (3.2)
GT 3	236 (44.9)	201 (45.5)
GT 4–6	36 (6.8)	30 (6.8)
GT mixed/unknown	9 (1.7)	3 (0.7)
IDU, former or current, n (%)		
Yes	296 (56.3)	236 (53.4)
Active drug use, n (%)	70 (13.3)	53 (12.0)
No	44 (8.4)	37 (8.4)
Unknown	186 (35.4)	169 (38.2)
One or more mental health disorder, n (%)		
Yes	116 (22.1)	102 (23.1)
No	147 (27.9)	117 (26.5)
Unknown	263 (50.0)	223 (50.5)
Type of mental health disorder[†], n (%[‡])		
Anxiety	28 (24.1)	26 (25.5)
Depression	20 (17.2)	17 (16.7)
Mania or bipolar disorder	13 (11.2)	10 (9.8)
Cognitive or psychiatric disorder	55 (47.4)	47 (46.1)
Unknown	21 (18.1)	19 (18.6)
Use of one or more antipsychotic drugs, n (%)		
Yes	62 (11.8)	52 (11.8)
No	46 (8.7)	40 (9)
Unknown	418 (79.5)	350 (79.2)
Adherence[§]		
≥90%	463 (98.5)	398 (99.3)
<90%	7 (1.5)	3 (0.7)
≥80%	463 (98.5)	398 (99.3)
<80%	7 (1.5)	3 (0.7)
Time from HCV RNA diagnosis to SOF/VEL treatment, median days (interquartile range)	63 (25–154)	62 (25–154)
Time from HCV RNA diagnosis to SOF/VEL treatment, days, n (%)[¶]		
1	45 (10.1)	43 (11.1)
≤7	66 (14.8)	61 (15.8)
≤30	137 (30.7)	123 (31.9)
≤90	274 (61.4)	239 (61.9)
>90	172 (38.6)	147 (38.1)
Unknown	80 (15.2)	56 (12.7)

[†]Including patients for whom information on the specific mental health disorder was reported (OP: n = 95; EP: n = 83). Overlap between mental health disorders was possible.
[‡]Percentage calculated using number of patients with a mental health disorder as the denominator (OP: 116; EP: 102).
[§]Percentage calculated using number of patients with adherence information available as the denominator (OP: 470; EP: 401).
[¶]Percentage calculated using patients with time to treatment data available as the denominator (OP: 446; EP: 386).
DAA: Direct-acting antiviral; GT: Genotype; HCV: Hepatitis C virus; IDU: Injection drug use; SD: Standard deviation; SOF/VEL: Sofosbuvir/velpatasvir.

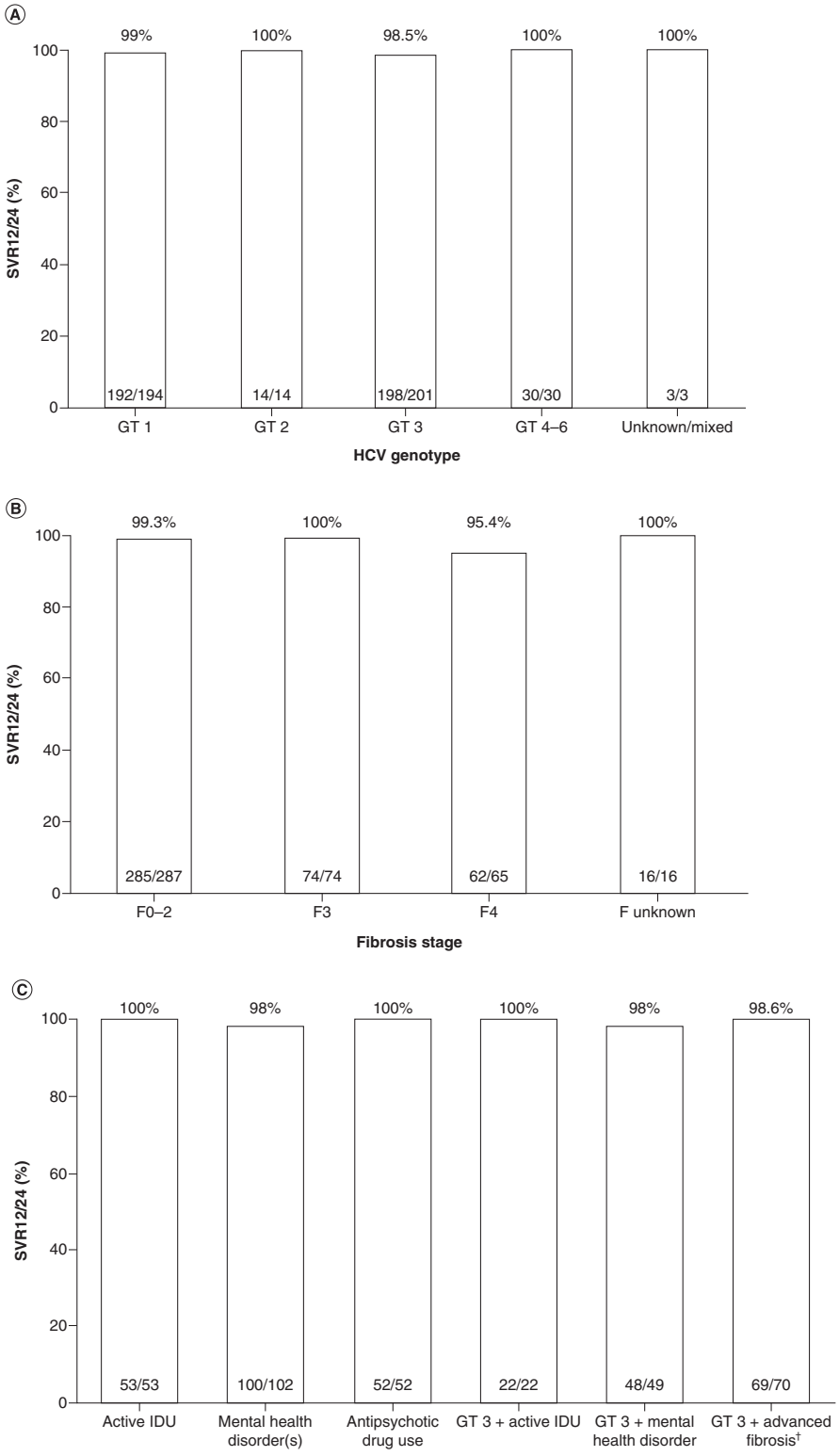

Figure 2. Sustained virological response stratified in the effectiveness population. Overall sustained virological response rates in the effectiveness population stratified by: **(A)** Genotype. **(B)** Fibrosis stage. **(C)** Complicating baseline characteristics.
†Advanced fibrosis is defined as F3/F4.
F: Fibrosis; GT: Genotype; HCV: Hepatitis C virus; IDU: Injection drug use; SVR12/24: Sustained virological response 12/24 weeks after the end of treatment.

Table 2. Baseline demographic characteristics of patients who did not achieve SVR12/24 due to non-virological reasons.

Characteristics	Non-virological failures (n = 82)†
Sex, male, n (%)	73 (89)
Fibrosis stage, n (%)	
F0–F2	54 (65.9)
F3	9 (11)
F4	13 (15.9)
Unknown	6 (7.3)
Treatment history, n (%)	
Treatment naïve	60 (73.2)
Treatment experienced (DAA-naïve)	8 (9.8)
Treatment history unknown	14 (17.1)
HCV, n (%)	
GT 1	32 (39)
GT 2	4 (4.9)
GT 3	35 (42.7)
GT 4–6	5 (6.1)
GT mixed/unknown	6 (7.3)
IDU, former or current, n (%)	
Yes	59 (72)
Active drug use, n (%)	17 (20.7)
No	7 (8.5)
Unknown	16 (19.5)
One or more mental health disorder, n (%)	
Yes	14 (17.1)
No	29 (35.4)
Unknown	39 (47.6)
Use of one or more antipsychotic drugs, n (%)	
Yes	10 (12.2)
No	6 (7.3)
Unknown	66 (80.5)

†73 (89%) lost to follow-up; six (7.3%) early discontinuations; one (1.2%) non-adherence; two reinfections (2.4%).
DAA: Direct-acting antiviral; GT: Genotype; HCV: Hepatitis C virus; IDU: Injection drug use; SVR12/24: Sustained virological response 12/24 weeks after the end of treatment.

The number of patients who did not have an SVR assessment due to non-virological reasons was low and it remains difficult to predict patients likely to experience a non-virological failure, such as LTFU, as demonstrated in Table 2. The consistently high cure rates achieved with DAA regimens has led to recent guidelines questioning the need for SVR assessment [5] and, therefore, LTFU rates may be of less importance in the future when the focus is on achieving HCV elimination.

Nevertheless, the need remains to further improve the HCV care cascade within and beyond prisons [39,40]. Effective and well-tolerated DAA regimens, such as SOF/VEL, allow a simplified treatment algorithm and support prompt treatment initiation, which can help overcome historical barriers related to length of stay in prison or the need for multiple consultations in or outside the prison [6,12,38]. Interventions such as telemedicine, can further support simplification of the treatment cascade by facilitating access to specialist care outside of the prison [12,41]. Approximately 30% of patients in the EP had advanced fibrosis/cirrhosis (F3–4) highlighting the importance of implementing structures that facilitate HCC monitoring within and beyond the prison setting once SVR has been achieved.

A test-and-treat strategy is supported by the AASLD/ALEH/APASL/EASL joint call to action for viral hepatitis elimination [42]. The consistent SVRs achieved with SOF/VEL in the current analysis irrespective of time before initiating therapy, with 15% (66/446) of patients receiving treatment within 1 week of diagnosis and 10% (45/446) within 1 day of diagnosis in the OP, demonstrate the feasibility of a test-and-treat approach with SOF/VEL. Although information on time from incarceration to HCV diagnosis was not available this likely varied similar to

time from diagnosis to treatment start, due to different local regulations with regards to opt-out/opt-in screening and differences in implementation of the HCV care cascade. This reiterates the need for further action to simplify and shorten HCV care cascades in prisons.

Some limitations to the analysis are acknowledged. While there is variation in country approach to incarceration and HCV care pathways in these settings, given the high response rates there are unlikely to be differences in response depending on type of incarceration, although this cannot be proven. There is also a risk of selection bias in retrospective cohort studies. However, the characteristics of patients demonstrate a diverse population, which included characteristics previously considered 'difficult to treat' or 'difficult to cure', suggesting limited selection bias. Not all information was available for all patients since this is a real-world cohort with multiple sites using different protocols and recording strategies. However, high SVR rates were demonstrated in all patient subsets, including ≥97.6% in those with missing values for characteristics such as cirrhosis status, genotype subtype, IDU and mental health status. This supports the potential use of SOF/VEL in a simplified treatment algorithm with a minimal monitoring approach [5]. Because this is a real-world cohort, details on how fibrosis stage and reinfection/relapse were characterized were not consistently available for all patients. However, these outcomes were defined based on the reliable clinical expertise of healthcare professionals at each site.

Conclusion

Treatment with SOF/VEL for 12 weeks is highly successful in the prison setting despite the complex nature and uncertainties of some patients. SOF/VEL offers a well-tolerated, simple treatment regimen with established effectiveness in a broad range of HCV patients and across varied settings with minimal monitoring requirements, allowing a simplified treatment algorithm in line with guideline recommendations [5], and potentially implementation of a test-and-treat strategy. This will help to reduce the prevalence of HCV infection not only in the prison environment, but also in the wider community, contributing to the WHO goal of eliminating viral hepatitis as a major public health threat by 2030.

Summary points

- People in prison are at high risk of hepatitis C virus (HCV) infection and the added burden of physical and mental health disorders often makes it difficult for them to engage in care.
- Prisons can provide an important opportunity to treat these high-risk individuals, who require rapid diagnosis followed by guideline-recommended simplified and effective treatments that require minimal monitoring.
- This integrated real-world analysis evaluated the effectiveness of a once-daily 12-week sofosbuvir/velpatasvir (SOF/VEL) regimen in 526 incarcerated individuals infected with HCV.
- In 442 patients with a valid sustained virological response (SVR) status, 98.9% achieved SVR.
- SVR was not affected by active injection drug use, mental health disorders, fibrosis stage or HCV genotype.
- SOF/VEL enables the implementation of simple treatment algorithms in line with guideline recommendations and test-and-treat strategies that are fundamental in the pursuit of the 2030 HCV elimination goal.

Acknowledgments

The authors would like to acknowledge L Barrett, S Borgia, A Martins, LE Morano and MG Retortillo for the contribution of patient data to the final data set analysed. Statistical support and data collection were facilitated by Gilead Sciences.

Financial & competing interests disclosure

S Rosati: grants from Gilead Sciences, Janssen Pharmaceuticals, Merck Sharp and Dohme and ViiV Healthcare. Sponsored lectures from Gilead Sciences. A Wong: grants and consultancy fees from AbbVie, Gilead Sciences and Merck Sharp and Dohme. Sponsored lectures from Gilead Sciences. V Di Marco: grants from Gilead Sciences, AbbVie, ViiV Healthcare, Takeda Pharmaceuticals and Janssen Pharmaceuticals. P Pérez-Hernandez: consultancy fees from Gilead Sciences. Sponsored lectures from AbbVie and Gilead Sciences. G Macedo: grants and sponsored lectures from AbbVie, Gilead Sciences and Merck Sharp and Dohme. Consultancy fees from Gilead Sciences and Merck Sharp and Dohme. C Brixko: Grants from AbbVie and Gilead Sciences. Consultancy fees and sponsored lectures from AbbVie, Gilead Sciences and Merck Sharp and Dohme. F Campanale: grants from AbbVie, Gilead Sciences, Merck Sharp and Dohme and ViiV Healthcare. V de Lédinghen: grants, consultancy fees and sponsored lectures from AbbVie and Gilead Sciences. E Teti: grants and consultancy fees from Gilead Sciences. A Mangia: Grants from Gilead Sciences, Intercept Pharmaceuticals and Merck Sharp and Dohme. Consultancy fees from Gilead Sciences and Merck Sharp and Dohme.

Sponsored lectures from Gilead Sciences. K Vanstraelen, C Hernández, M Mertens, I Ntalla and H Ramroth: employees and stock owners of Gilead Sciences, during the conduct of the study and outside of submitted work. E Jimenez: sponsored lectures from AbbVie and Gilead Sciences. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Medical writing assistance was provided by Anisha Desai from Elements Communications Ltd, funded by Gilead Sciences Ltd. Article processing charges were funded by Gilead Sciences Ltd.

Ethical conduct of research

This retrospective analysis was based on secondary use of data that were previously collected as part of routine clinical care and anonymized prior to analysis.

Supplementary data

An infographic accompanies this paper. To view or download this infographic in your browser please click here: www.futuremedicine.com/doi/suppl/10.2217/fvl-2022-0016

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