JGH Open Open Access An open access journal of gastroenterology and hepatology

JGHF Journal of Gastroenterology and Hepatology Foundation

doi:10.1002/jgh3.12850

ORIGINAL ARTICLE

Real-world impact of a subsidy decision of sofosbuvir–velpatasvir for treatment of chronic hepatitis C on clinical practice and patient outcomes

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Key words
chronic hepatitis C, clinical practice, patient outcomes, real-world impact, sofosbuvir–velpatasvir.

Accepted for publication 18 November 2022.

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Declaration of conflict of interest: All the authors have no conflicts of interest to disclose.

Abstract

Background and Aim: Sofosbuvir–velpatasvir was recommended for subsidy to treat chronic hepatitis C in Singapore in 2018. We measured the impact of the subsidy decision on clinical practice and patient outcomes. Specifically, we looked at pre- and post-subsidy changes in the utilization and prescribing pattern of chronic hepatitis C treatment and the real-world clinical effectiveness.

Method: Utilization trends and prescribing patterns were assessed using aggregated drug utilization data from public hospitals' dispensing systems and clinical data from the national electronic health record database, respectively. An audit was conducted to evaluate sustained virological response rate 12 weeks post treatment (SVR12).

Results: Use of sofosbuvir–velpatasvir increased sharply since its subsidy listing and dropped subsequently, whereas the utilization of comparator drugs remained low. Prescribing rate of sofosbuvir–velpatasvir increased from 13.7% in the pre-subsidy period to 90.2% in the post-subsidy period; 39.1% of patients previously on pegylated interferon and ribavirin switched to sofosbuvir–velpatasvir following its subsidy listing. In the audit, 365 out of 375 patients (97.3% [95% confidence interval: 95.1–98.6%]) achieved SVR12.

Conclusion: The subsidy decision led to increased accessibility to patients and intended changes in clinical practice. Sofosbuvir–velpatasvir was also clinically effective in the real world. These findings augur well for the continued eradication of chronic hepatitis C infection in Singapore.

Introduction

Chronic hepatitis C (CHC) infection is a worldwide problem affecting up to 56.8 million individuals.[1] Subcutaneous pegylated interferon combined with oral ribavirin was the standard of care but both medications are fraught with significant adverse effects and suboptimal virus eradication rate.[2] The advent of direct-acting antivirals (DAAs) revolutionized the treatment for CHC, as DAAs constitute oral therapy with a high cure rate.[3] The DAA sofosbuvir–velpatasvir (SOF-VEL) is highly efficacious across all genotypes: that is, it is pangenotypic.[4,5] However, cost was an issue and widespread use of DAAs was limited to countries where they are covered by insurance or subsidized by the government.[6] The Ministry of Health (MOH), Singapore, began subsidizing SOF-VEL for the treatment of CHC on 1 October 2018, starting with the subsidy for genotype 1 and subsequently expanding to all genotypes from 2 January 2019. To date, there is scanty literature regarding the impact of subsidy of DAAs on the clinical practice of CHC treatment.

In Singapore, the main genotypes of hepatitis C virus (HCV) in the general population are 1 and 3.[7] The latter occurs mainly in persons who inject drugs (PWID) and have a history of incarceration.[7] To our knowledge, there is only one published study on the real-world experience of DAA in Singapore, but the study was limited to genotype 3 as the study cohort largely comprised PWID and the incarcerated population.[8]

Our objectives were to study the impact of the DAA subsidy decision by MOH on the clinical practice of CHC treatment and the real-world outcomes of DAA treatment of CHC in the general population of Singapore.

Methods

To measure the impact on clinical practice, we studied the pre- and post-subsidy utilization trends and prescribing pattern. Utilization trends of SOF-VEL and its comparator drugs (i.e. other non-subsidized DAAs, including asunaprevir, daclatasvir, elbasvir–grazoprevir, glecaprevir–pibrentasvir, ombitasvir–paritaprevir–ritonavi–dasabuvir, and sofosbuvir–ledipasvir, or treatments for CHC) were derived based on the aggregated non-indication-specific monthly drug utilization data extracted from all our public hospitals' dispensing systems. Drug

records with invalid data and those indicating sample, trial, or free drugs were excluded from computation of the overall volume. The utilization trends were presented in defined daily dose (DDD), which is the assumed average daily maintenance dose for a drug used for its main indication in adults as assigned by World Health Organization (WHO).[9] For the prescribing pattern, we studied the change in prescribing rate in public hospitals in the 1-year pre-subsidy period (i.e. October 2017 to September 2018) compared with the post-subsidy period (i.e. October 2018 to September 2019). Prescribing rate was defined as the proportion of patients who were newly prescribed with a particular CHC drug, out of all patients newly prescribed with any CHC treatment. We defined patients newly prescribed with CHC treatment as those with 1-year wash-out period (i.e. we excluded patients prescribed with any CHC treatment in the preceding 1 year). We also looked at treatment-switching, with the effect size calculated based on the number of patients previously on pegylated interferon and ribavirin who switched to the use of SOF-VEL with or without ribavirin in the post-subsidy period.

To evaluate the real-world efficacy of SOF-VEL in our general population, all patients who participated in the MOH's DAA subsidy scheme between 1 October 2018 and 31 March 2020 were audited for sustained virological response rate at 12 weeks post treatment (SVR12). Baseline data collected included demographics, fibrosis stage assessed by FibroScan (cirrhosis defined as ≥12.5 kPa), HCV genotype, viral load, renal status, intravenous drug usage, human immunodeficiency virus (HIV) status, hepatitis B co-infection, and past HCV treatment. The patients were then followed for 6 months following treatment initiation with SOF-VEL. HCV viral load was determined and reported by clinicians at 12 weeks post DAA treatment for the assessment of SVR12 using a prescribed form. Data were presented as frequency tables, and Fisher's exact test was used to test for significance in subgroup analyses. A two-tailed *P*-value of <0.05 was considered as significant.

As the intent was to audit the effect of SOF-VEL on clinical outcomes for the purpose of improving routine clinical care, institutional review board approval and patients' informed consent were not required in accordance with the local regulations.

Results

The overall utilization trends of SOF-VEL and its comparator drugs are shown in Figure 1. Specifically, the use of SOF-VEL increased sharply after its subsidy listing in October 2018. The absolute monthly growth in utilization volume increased 30-fold from 48 DDDs (95% confidence interval [CI]: 31–64) in the pre-subsidy period to 1442 DDDs (95% CI: 1130–1754) in the first 9 months post subsidy (i.e. October 2018 to June 2019) (Fig. 2). Subsequently, there was a monthly drop in utilization of 603 DDDs (95% CI: −1345 to 139).

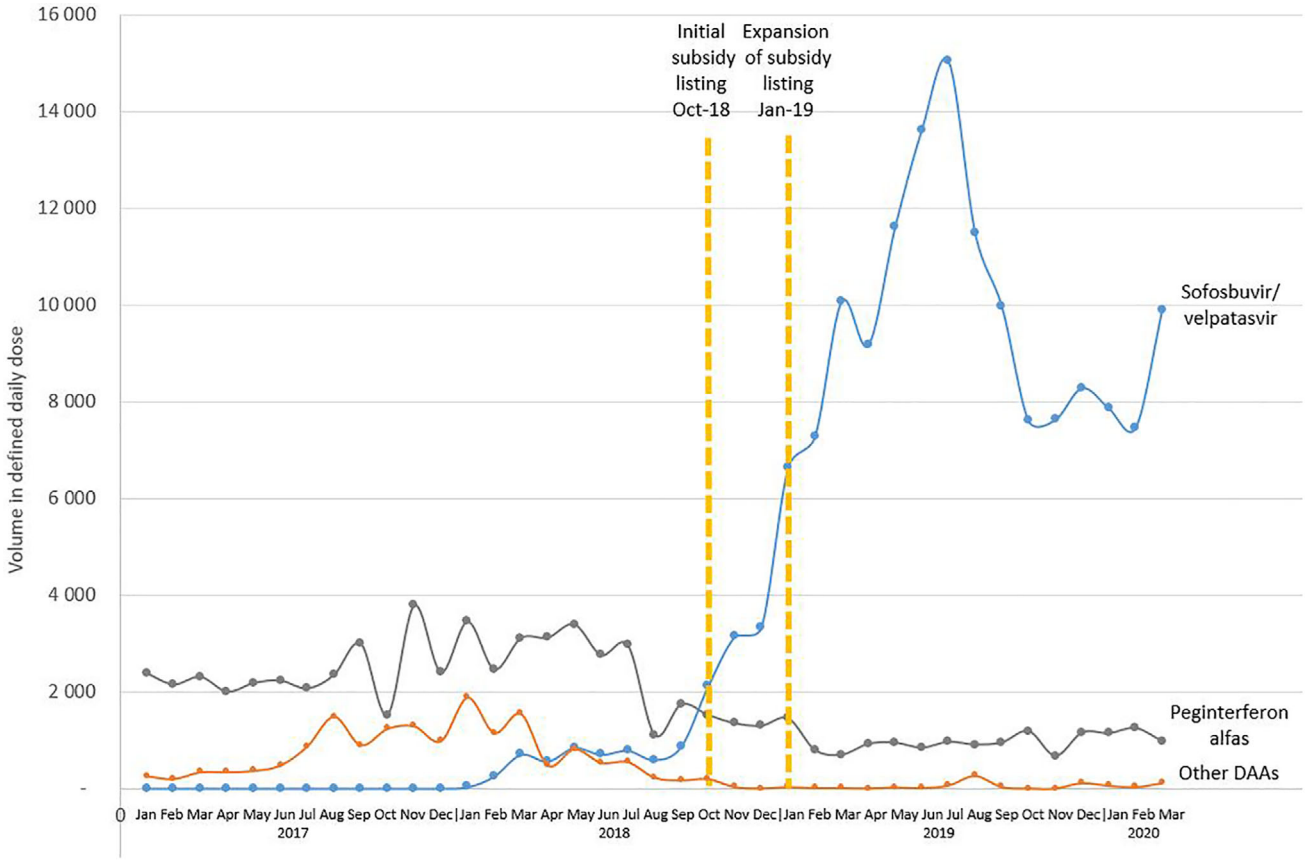

Figure 1 Overall utilization trends of sofosbuvir–velpatasvir, nonsubsidized direct-acting antivirals, and pegylated interferon-α.

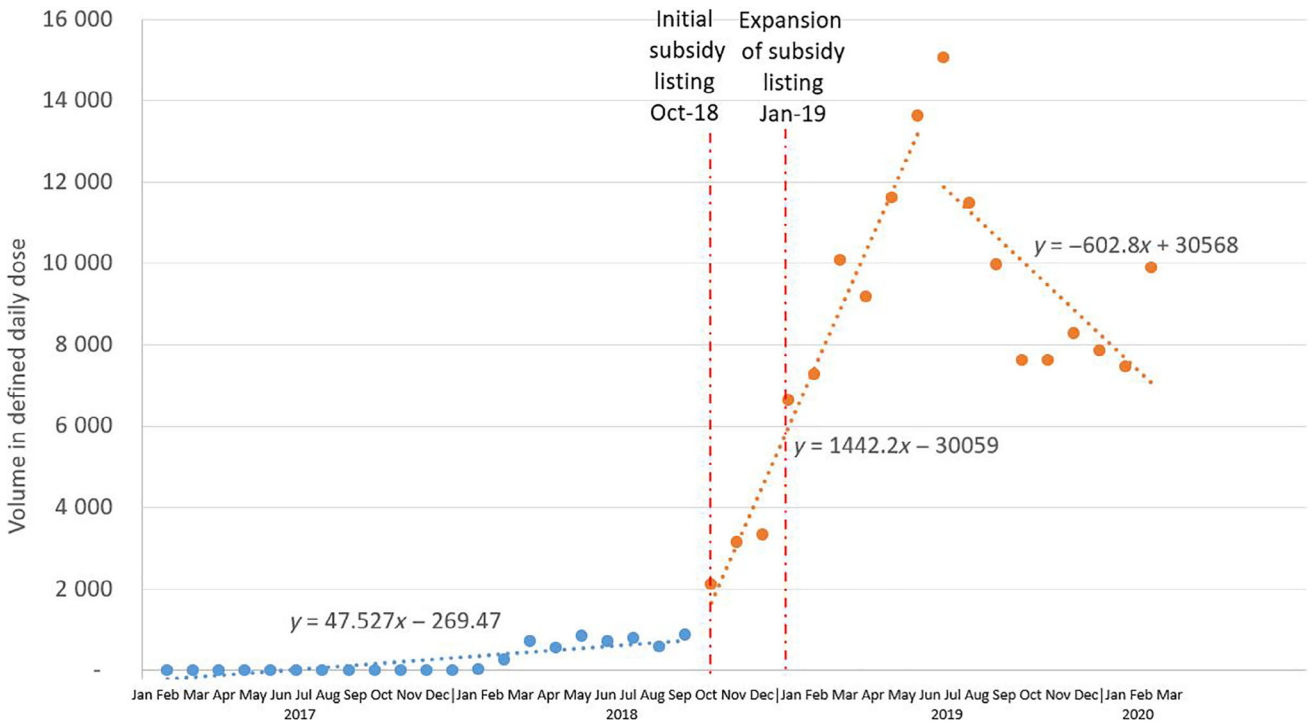

Figure 2 Utilization trends of sofosbuvir–velpatasvir before and after subsidy implementation.

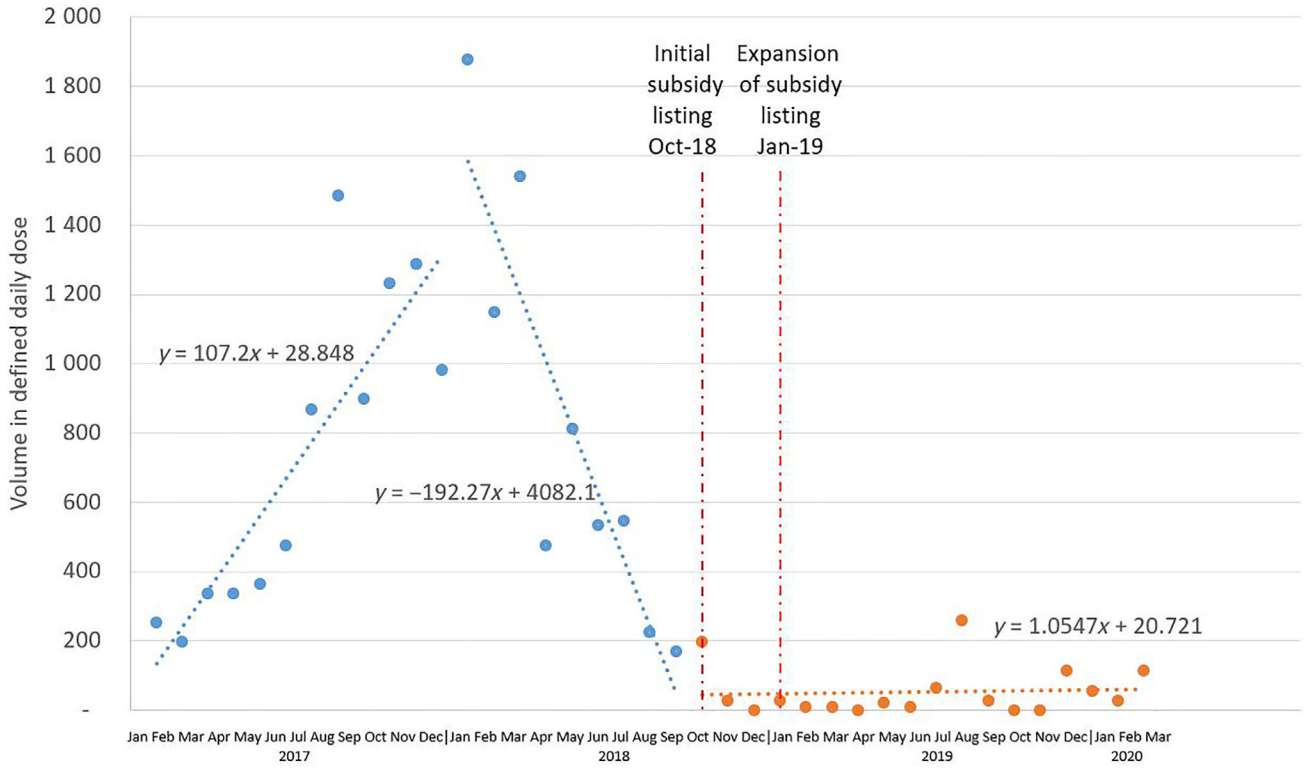

Figure 3 Utilization trends of nonsubsidized direct-acting antivirals before and after implementation of subsidy for sofosbuvir–velpatasvir.

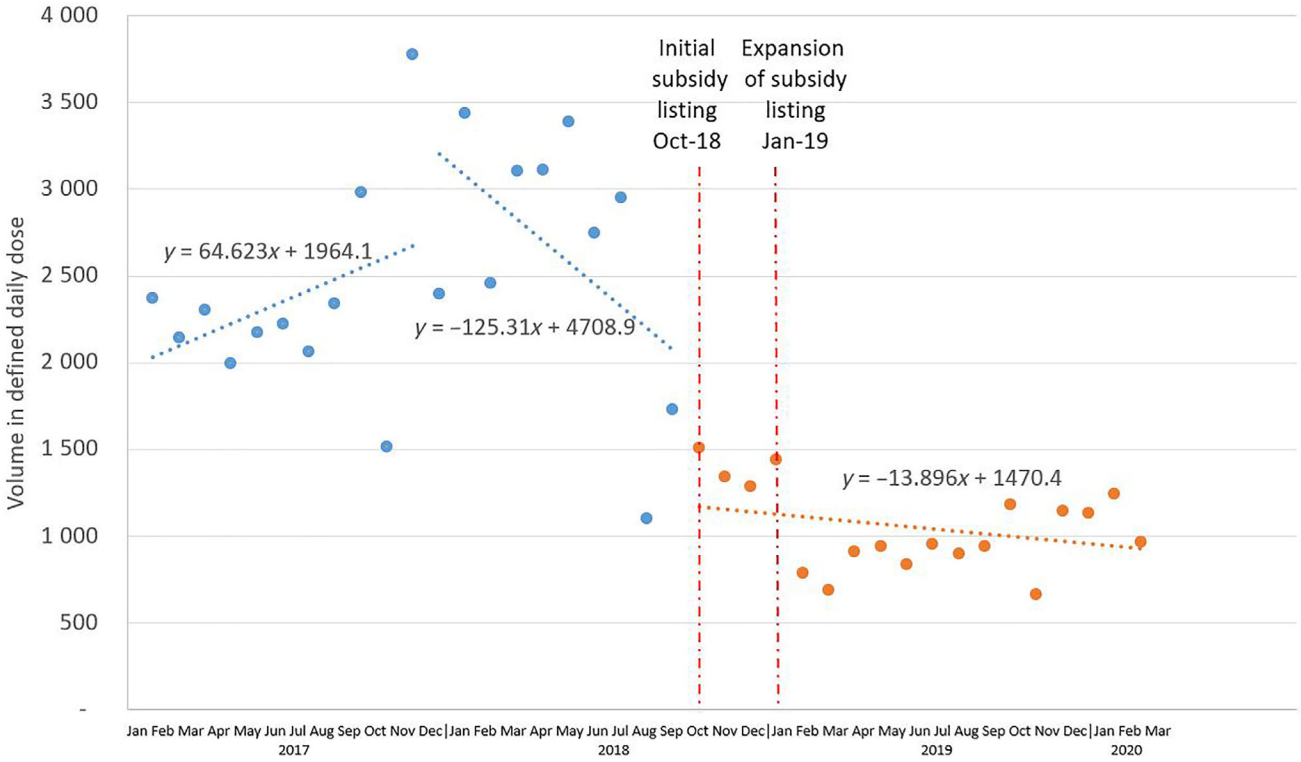

Figure 4 Utilization trends of pegylated interferon-α before and after implementation of subsidy for sofosbuvir–velpatasvir.

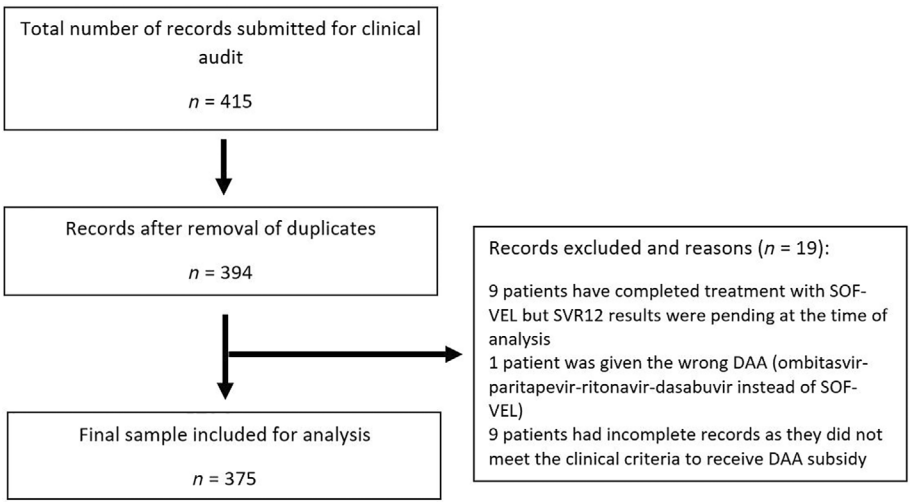

Figure 5 Enrolment flowchart for the clinical audit of sustained virological response rate 12 weeks post treatment.

In contrast, there was monthly growth in utilization volume of other nonsubsidized DAAs by 107 DDDs (95% CI: 52–162) in 2017 before a monthly drop in utilization of 192 DDDs (95% CI: −298 to −87) in 2018 before the subsidy listing of SOF-VEL. In the post-subsidy period, utilization of the other nonsubsidized DAAs remained low at less than 300 DDDs per month (Fig. 3). For pegylated interferon-α, either alone or in combination with ribavirin, the monthly utilization was slightly increasing by 65 DDDs (95% CI: −83 to 212) in 2017 before dropping from 2018 onwards. The absolute monthly drop in utilization was 125 DDDs (95% CI: −332 to 82) in 2018 before the subsidy listing of SOF-VEL, and 14 DDDs (95% CI: −41 to 14) in the post-subsidy period (Fig. 4).

A total of 293 and 1089 patients were newly prescribed with CHC treatment in the 1-year pre- and post-subsidy period, respectively. The prescribing rate of SOF-VEL increased from

Table 1 Rates of sustained virological response at 12 weeks post treatment (SVR12) for different subgroups

Parameter	Number of patients who achieved SVR12 (%)	Number of patients who did not achieve SVR12 (%)	Total number of patients	*P*-value
Genotype				
1	153 (98.7%)	2 (1.3%)	155	0.21
2	6 (85.7%)	1 (14.3%)	7	
3	189 (96.4%)	7 (3.6%)	196	
4	7 (100%)	0 (0%)	7	
6	2 (100%)	0 (0%)	2	
Missing	8 (100%)	0 (0%)	8	
Baseline hepatitis C viral load				
<5.9 log IU/mL	143 (98.6%)	2 (1.4%)	145	0.33
≥5.9 log IU/mL	221 (96.5%)	8 (3.5%)	229	
Missing	1 (100%)	0 (0%)	1	
Liver cirrhosis				
No	231 (98.3%)	4 (1.7%)	235	0.30
Yes	131 (96.3%)	5 (3.7%)	136	
Missing	3 (75.0%)	1 (25.0%)	4	
Chronic kidney disease				
No	321 (97.6%)	8 (2.4%)	329	0.35
Yes	44 (95.7%)	2 (4.3%)	46	
Human immunodeficiency virus positive				
No	335 (97.1%)	10 (2.9%)	345	1.00
Yes	30 (100%)	0 (0%)	30	
Hepatitis B co-infection				
No	353 (97.5%)	9 (2.5%)	362	0.30
Yes	12 (92.3%)	1 (7.7%)	13	
Persons who inject drugs				
Never	235 (97.1%)	7 (2.9%)	242	0.29
Former	64 (100%)	0 (0%)	64	
Current	66 (95.7%)	3 (4.3%)	69	
Previous hepatitis C treatment				
No	338 (97.1%)	10 (2.9%)	348	1.00
Yes	27 (100%)	0 (0%)	27	

13.7% in the pre-subsidy period to 90.2% in the post-subsidy period, and 39.1% of patients previously on pegylated interferon and ribavirin switched to SOF-VEL following its subsidy listing.

Four-hundred and fifteen records of patients reported to have finished the 12-week course were submitted for the clinical audit of SVR12. After excluding duplicate records, patients who did not have SVR12 results at the time of analysis, and incomplete records, the final patient population comprised 375 patients who participated in the MOH's DAA subsidy scheme between 1 October 2018 and 31 March 2020 (Fig. 5). The median age was 56 years (interquartile range: 49–61) and males constituted 79.2% of the cohort. The two main ethnic groups were Chinese (46.1%) and Malay (43.5%).

Three-hundred and sixty-five (97.3%, 95% CI: 95.1–98.6%) out of the 375 patients had achieved SVR12. There was no patient with genotype 5. No significant differences were seen in the SVR12 rates for the rest of the different genotypes (*P*-value = 0.21). There was also no difference in the SVR12 rates between patients with high (≥5.9 log IU/mL) and low viral loads (*P*-value = 0.33). Similarly, the presence of liver cirrhosis (*P*-value = 0.30), chronic kidney disease (*P*-value = 0.35), co-infection with HIV (*P*-value = 1.00) or hepatitis B (*P*-value = 0.30), and past or current history of intravenous drug usage (*P*-value = 0.29) did not significantly adversely affect the SVR12 rates. Non-treatment-naïve patients also fared as well as treatment-naïve patients (*P*-value = 1.00). All these results are shown in Table 1.

Discussion

There are reports on how government's financial support for DAAs is instrumental in a country's success in its CHC treatment program,[6,10] but to our knowledge there is no published literature on the real-world impact of government subsidy of a DAA in changing the clinical practice of CHC treatment in the country. We have shown how our government's decision to subsidize a DAA for the treatment of CHC has changed real-world clinical practice. The use of SOF-VEL in the country increased 30-fold from an absolute monthly growth of 48 DDDs in utilization volume before the subsidy to 1442 DDDs after the subsidy. We also took the opportunity to conduct an audit of the efficacy of SOF-VEL, as to date there is no nationwide data on DAA treatment of CHC in Singapore. The audit showed that SOF-VEL is highly efficacious for the treatment of CHC (overall SVR12 of 97.3%), with SVR12 above 95% for all groups of patients except those with genotype 2 or with hepatitis B co-infection,

possibly confounded by the small sample size for these subgroups (7 and 13 patients, respectively).

Prior to the subsidy of SOF-VEL, pegylated interferon was already subsidized by the government. However, the treatment burden for patients receiving pegylated interferon and ribavirin was high. This was due to the long treatment duration (24–48 weeks), rigorous dosing requirements with interferon administration through subcutaneous injections and daily ribavirin tablets, and significant side effects. While DAAs were the preferred first-line treatment, most patients were treated with pegylated interferon and ribavirin because of cost concerns. Many patients with stable CHC liver disease were also warehoused in anticipation of government subsidy of DAA. This is seen in Figure 1 showing the use of nonsubsidized DAAs and pegylated interferon falling from early 2018 as the start of the subsidy for SOF-VEL neared.

The subsidy program started with genotype 1 on 1 October 2018 and subsequently expanded to all genotypes 3 months later on 2 January 2019. The surge in use of the subsidized pangenotypic SOF-VEL dropped 9 months after the initiation of the subsidy (Fig. 1). This can be explained by the fact that the backlog of patients with CHC had been treated and cleared by then. As patients with CHC are usually seen by the physicians every 6 months to monitor their liver status as well as surveillance for the development of hepatocellular carcinoma locally, it is conceivable that almost all the patients received their DAA treatment by 6 months after the start of the expanded subsidy for all genotypes, which is 9 months after the start of the whole subsidy program. Subsequently, the use of SOF-VEL depended mainly on newly diagnosed cases of CHC. As the prevalence of CHC in the general population of Singapore is very low at 0.05%, there are very few new cases of CHC.[7] The use of the other nonsubsidized DAAs continued to remain low after the start of the subsidy program because the subsidized DAA is pangenotypic with very few contraindications for its use.

The number of new patients prescribed with CHC treatment also increased substantially by almost fourfold from 293 in the pre-subsidy period to 1089 after subsidy listing of SOF-VEL, suggesting an increased linkage of CHC patients to treatment. The significant increase in prescribing rate of SOF-VEL after its subsidy listing and the observed treatment-switching from pegylated interferon and ribavirin to SOF-VEL in some patients also demonstrated the real-world impact of a subsidy decision for treatment of CHC on the ensuing clinical practice.

Our audit of 375 patients in the SOF-VEL subsidy program provided, for the first time, real-world data on the nationwide multicenter DAA treatment of CHC in Singapore. A previous report on the outcome of SOF-VEL treatment in Singapore was limited in scope, as it was confined to a single center's experience with mainly incarcerated patients afflicted with genotype 3 CHC.[8] Our results showed that SOF-VEL is highly efficacious with an overall SVR12 of 97.3%. No significant differences in SVR12 were observed between the different groups of patients (Table 1). Real-world data on SOF-VEL use in the Asian region, including mainland China,[11] Taiwan,[12] Japan,[13] Thailand,[14] Myanmar,[15] and India,[16] have shown similar findings. In addition, there are specific studies of SOF-VEL treatment showing excellent SVR12s across different genotypes, varying viral loads, in treatment-experienced patients, and in patients with cirrhosis.[4,5] SOF-VEL is also highly efficacious in patients with chronic kidney disease and in those with HIV coinfection.[17,18] Previous studies of SOF-VEL in former and current PWID have also showed excellent SVR12, as is the case with our study cohort.[19] While there is no known nationwide study on the overall SVR prior to the subsidy of SOF-VEL, the SVR data reported at one of the major public healthcare institutions obtained from genotype 3 CHC patients from 2014 to 2017, which was the pre-subsidy period of SOF-VEL, reported an overall SVR of 81.3% in a mix of patients predominantly treated with pegylated interferon and ribavirin regimen.[20] Using this as a proxy of the pre-subsidy SVR, it may be reasonable to infer that other than increased accessibility to patients, the subsidy of SOF-VEL has also led to higher overall SVR and hence reduced prevalence of CHC in Singapore.

Overall, the government subsidy of SOF-VEL has reduced the barrier to access to highly efficacious CHC treatment, as evidenced by the observed increased linkage to care and uptake in DAA treatment of patients with CHC. Increasing treatment and care is a necessary and important component of the cascade of care leading to the elimination of hepatitis C by 2030 as envisaged by the WHO.[21,22] It is fundamental to reducing disease burden and mortality due to CHC. Nonetheless, efforts in other strategies such as sufficient screening and testing, especially in high-risk populations, are also crucial to avail the full benefits of DAAs and achieve the WHO elimination targets. This is supported by both local[23] and overseas[24–26] modeling studies. In Singapore, new targeted initiatives have been launched to provide education, testing, and linkage to care services for high-risk patients such as former drug offenders.[27] It is with hope that these programs, together with the DAA subsidy, can drive the elimination of CHC as a public health threat.

There are some limitations in our study. As we captured data only from the public hospitals and the DAA subsidy program only covered patients seen in the public healthcare system, the findings may not be generalizable to patients seen in private healthcare facilities. However, this is ameliorated by the fact that majority (approximately 80%) of our local population uses the public healthcare system, so the data is still representative of the national situation. Another limitation is that we did not have longer term follow-up to enable the study of the long-term benefits of HCV treatment. Nevertheless, we have shown excellent HCV eradication rates, and there is no reason for our patients to differ from other published populations on the benefits of HCV eradication.

Conclusion

In summary, we have shown the real-world impact of a subsidy decision for the treatment of hepatitis C on clinical practice and patient outcomes. The high rate of adoption of DAA treatment and the excellent patient outcomes are very encouraging and augur well for the continued eradication of CHC in the country.

Acknowledgments

The authors would like to thank the public hospitals for sharing the data with us and Emeritus Professor Satvinder Singh Dhaliwal for the statistical advice.

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