



A Two-Year Outcome Evaluation of Government-Led Initiative to Upscale Hospital-based Hepatitis C Treatment Using a Standard Two-Drug Regimen in Malaysia

Huan-Keat Chan^{1,*}, Mohamed Azmi Hassali¹, Rosaida Md Said², Haniza Omar³, Noor Aliza Abd Mutalib⁴, Frederick Walter De Rozario⁵ and Muhammad Radzi Abu Hassan⁶

¹School of Pharmaceutical Sciences, Universiti Sains Malaysia, Gelugor, Malaysia

²Medical Department, Hospital Serdang, Kajang, Malaysia

³Medical Department, Hospital Selayang, Selayang, Malaysia

⁴Medical Department, Hospital Kuala Lumpur, Kuala Lumpur, Malaysia

⁵Medical Department, Hospital Umum Sarawak, Kuching, Malaysia

⁶Clinical Research Center, Hospital Sultanah Bahiyah, Alor Setar, Malaysia

*Corresponding author: Clinical Research Center, Sultanah Bahiyah Hospital, Kedah, Malaysia. Email: huankeati23@yahoo.com

Received 2021 January 24; Revised 2021 March 16; Accepted 2021 March 17.

Abstract

Background: Malaysia has been fully committed to the global endeavor to eliminate hepatitis C virus (HCV) infection by 2030. In early 2018, the Ministry of Health (MOH) embarked on a “one-size-fits-all strategy” by introducing generic versions of sofosbuvir and daclatasvir as the standard treatment for HCV infection in public hospitals nationwide.

Objectives: To evaluate the outcomes of such an initiative in multiple aspects, including the number and characteristics of patients treated, the extent of evidence-based drug use, the treatment completion status, individual responses to treatment, common side effects of treatment, and its economic implications.

Methods: The findings were generated from the data compiled by the MOH, capturing the information regarding the treatment provided to adult HCV-infected patients in 16 selected hospitals between April 2018 and March 2020, along with the drug costs incurred.

Results: A total of 1,797 patients were treated, nearly four times more than the patients receiving interferon-based treatment across the country in the preceding two years. Approximately one-third of them had liver cirrhosis, and the main HCV genotypes were 3 (46.9%) and 1a (20.0%). Dosing, treatment duration and the addition of ribavirin to the treatment generally agreed with the recommendations of the MOH. More than 90% of the patients completed the treatment course, and a sustained virologic response (SVR) rate of 95.4% (95% CI: 94.2, 96.7%) was recorded in those with a known treatment outcome (n = 1,163). The SVR achievement did not vary across HCV genotypes and cirrhosis status, but those ≥ 50 years of age (adjusted OR: 2.13; 95% CI: 1.16, 3.92) were more likely to fail the treatment. Side effects were rare. Anemia and fatigue caused treatment discontinuation in only 0.3% of the patients. The total drug expenditure reached US\$678,258.20, and the mean cost of a 12-week treatment course of sofosbuvir and daclatasvir (US\$235.16) was lower than the cost expected by the MOH (US\$300).

Conclusions: The findings demonstrate a high degree of real-world effectiveness, safety, and affordability of the standard treatment, suggesting that such a government-led initiative was reasonable and timely and could be extended to include more public health institutions.

Keywords: Health Care Costs, Hepatitis C, Liver Cirrhosis, Sustained Virologic Response, Treatment Outcome

1. Background

Hepatitis C virus (HCV) infection remains a global public health threat. Its chronic stage is commonly associated with potentially fatal complications, ranging from cirrhosis, liver failure to hepatocellular carcinoma (HCC) (1). Approximately 71 million individuals are currently living with HCV infection, and nearly 400,000 individuals died

from its complications in 2016 alone (2). In Malaysia, it is estimated that 1.9% of its population are infected with HCV (3), mainly of genotype 3 (61.9%) and 1 (35.9%) (4). Blood and blood product transfusion, intravenous drug use, incarceration, tattooing, body piercing and having multiple sexual partners are among the common risk factors of hepatitis C in the country (5).

The interferon-based regimen was once the backbone

of hepatitis C treatment, despite its relatively low post-treatment sustained virologic response (SVR) rate (40 - 50%) and unfavorable safety profile (6). Over the last decade, hepatitis C treatment reached an important milestone with the advent of all-oral direct-acting antivirals (DAAs). NS3/4A protease inhibitors, NS5A inhibitors and NS5B polymerase inhibitors, the three major classes of DAAs, have commonly been used in combination and promise a better treatment outcome as compared with the conventional treatment (7). They also demonstrate good tolerability in general, even in patients who are co-infected with human immunodeficiency virus (HIV) (8).

However, as the primary source of medical care for the Malaysian population, public hospitals have been under tremendous budgetary pressure to provide hepatitis C patients with no-cost treatment. Despite their improved effectiveness and safety profile, the use of DAAs was once limited in Malaysia, mainly attributable to their prohibitively high costs. A major change only took place in late 2017, the year in which Malaysia became the first country invoking the agreement on trade-related aspects of intellectual rights and issuing a compulsory license to a generic version of sofosbuvir (9). Such a decision was made after rounds of unsuccessful price negotiation with the patent-holder of sofosbuvir, which forms part of many recommended DAA regimens. Afterward, the generic version of sofosbuvir has widely been used together with daclatasvir, which is also available in the generic form in Malaysia, as the standard treatment for hepatitis C in public hospitals across the country (10).

The sofosbuvir-daclatasvir combination is one of the WHO-recommended pangenotypic DAA regimens for hepatitis C treatment (11). It was consistently shown to produce an SVR rate above 90% in non-cirrhotic and 80% in cirrhotic patients worldwide (12-32). It is noteworthy that some of these studies generated their findings from either a clinical trial or a structured treatment accessibility program (12-15). A few of them were undertaken in settings in which the sofosbuvir-daclatasvir combination only served as an option among many others (16-23), while the rest presented the data limited to specific populations, HCV genotypes and liver cirrhotic status (24-32).

Nevertheless, in a context like Malaysia, the effects of the “one-size-fits-all strategy” with the use of a fixed DAA regimen on all public health settings are still unclear. Although patented, high-priced alternatives are not widely available in Malaysia, the concern is raised about the performance of the generic forms of DAAs used on a large scale in hepatitis C treatment.

2. Objectives

Therefore, this study was designed to comprehensively evaluate the outcomes of such a government-led initiative in multiple aspects, including the number and characteristics of patients treated, the extent of evidence-based drug use, the treatment completion status, individual responses to treatment, common side effects of treatment, and its economic implications.

3. Methods

3.1. Study Design

This was a nationwide retrospective cohort study complemented by a drug cost analysis. The clinical data were obtained from 16 public hospitals selected by the National Gastroenterology and Hepatology Services (NGHS) Committee of the Ministry of Health (MOH). Each of the 14 states of Malaysia was represented by at least one hospital, which had been actively offering no-cost DAA-based treatment to hepatitis C patients since the second quarter of 2018. They were either secondary or tertiary hospitals, staffed with at least one gastroenterologist or physician each. The drug cost data was collected from the Pharmaceutical Services Program, which acquired DAAs for all the 16 hospitals under central contracts. The study was granted with the registration number (NMRR-20-481-54147) by the National Medical Research Register and approved by the Medical Research Ethics Committee of the MOH.

3.2. Clinical Data Collection

The data were collected from April to June 2020. A gastroenterologist or physician from each hospital was assigned by the NGHS Committee to retrieve and verify the data from medical records of all the hepatitis C patients treated with sofosbuvir and daclatasvir from 1 April 2018 and 31 March 2020. Patients were eligible if they were (1) above 18 years of age; (2) had their diagnosis confirmed by either the HCV core antigen or ribonucleic acid (RNA) test; and (3) received treatment with an 8- or 12-week course of sofosbuvir and daclatasvir, with or without ribavirin.

The information gathered for each patient ranged from (1) their baseline characteristics, including age, gender, ethnicity, and their history of exposure to risk factors of HCV infection; (2) their comorbidities, including HIV infection, hepatitis B virus infection, and chronic kidney disease (defined as an estimated glomerular filtration rate < 60 mL/min/1.73m² lasting for > 3 months); (3) their HCV infection history, including the HCV genotype, and their experience with interferon-based treatment; (4) the presence and the Child-Turcotte-Pugh (CTP) classification

of liver cirrhosis; (5) their treatment history, including the date of treatment initiation, dose, the treatment duration, the use of ribavirin, and the treatment completion status (self-reported by patients during clinic visits, cross-checked with prescription-refill records or patient diary); (6) the treatment outcomes, including the achievement of an SVR (defined as an HCV RNA level < 15 IU/mL 12 weeks after the treatment completion), and the presence of common side effects (as listed in the clinical practice guidelines of the MOH and studied side effects, including headache, fatigue, nausea, diarrhea, and anemia) (33).

3.3. Clinical Data Assessment

The number of patients receiving treatment over the two-year period was tallied, and the distribution of their demographic and clinical characteristics was studied. The assessment of the extent of evidence-based drug use was performed according to the clinical practice guidelines of the MOH (33). It was recommended by the MOH that sofosbuvir and daclatasvir be used for 12 or 24 weeks at a fixed, once-daily dose of 400 mg and 60 mg, respectively. Dose adjustment was only required for daclatasvir in HCV/HIV co-infected patients treated with antivirals potentially causing drug-drug interactions (30 mg for CYP3A4 inhibitors and 90 mg for CYP3A4 inducers). The use of ribavirin as an adjunct to the two-drug combination could be considered for (1) genotype-3 HCV infection complicated with liver cirrhosis; and (2) genotype-1a HCV infection in interferon-experienced patients. The recommended daily doses for ribavirin were, respectively, 1,200 mg and 1,000 mg for a bodyweight above and below 75 kg.

The treatment completion status up until 31st of March 2020 was summarized as (1) complete treatment with the SVR test result; (2) complete treatment pending the SVR test or test result; (3) ongoing treatment (within the prescribed treatment duration); and (4) incomplete treatment. The reasons for incomplete treatment were further classified into (1) loss to follow-up during the treatment period; (2) discontinuation due to disease advancement (HCC, liver failure, hepatitis-related complications, or exacerbation of other chronic conditions); (3) discontinuation due to intolerable side effects; and (4) death during the treatment period.

The SVR rate was used as the measure for individual responses to treatment. It represented the proportion of patients achieving an SVR to those who had known treatment outcomes. In this regard, the known treatment outcomes included achieving an SVR; failure to achieve an SVR; and premature treatment discontinuation due to intolerable side effects, disease advancement or death. Those whose SVR test results were unavailable or treatment was still ongoing as at 31st of March 2020, along with those who

were lost to follow-up during the treatment period, were excluded from the treatment outcome analysis. In addition to the overall SVR rate and the factors associated with the treatment failure, the SVR rates for all the patient subgroups were also presented. In addition, the rates of common side effects of the treatment, along with the rates of side effects causing the treatment discontinuation, were determined.

3.4. Statistical Analysis

The clinical data were managed and analyzed by using the SPSS for Windows version 21.0 (IBM, New York). The findings were mainly summarized as frequencies and percentages. The SVR rates were presented as percentages and 95% confidence intervals (CIs). The factors associated with the failure to achieve an SVR were further explored by using the simple and backward stepwise multiple logistic regression analyses, with the findings expressed as odds ratios (ORs) and 95% CIs. The final model was tested for the interactions and multicollinearity between variables, as well as for its fitness using the Hosmer-Lemeshow goodness-of-fit test, the overall correctly classified percentages and the area under the receiver operating characteristic (ROC) curve. The significant level of all the statistical tests was fixed at 0.05.

3.5. Drug Cost Analysis

The mean unit costs (per tablet) of three drugs (sofosbuvir, daclatasvir and ribavirin) were calculated by dividing their total acquisition costs by the number of tablets acquired within the two-year period. The expenditure on each drug was estimated by multiplying their mean unit costs (per tablet) with the number of patients and treatment duration. In addition to the total drug expenditure, the average cost of a 12-week course of treatment of sofosbuvir and daclatasvir (with and without ribavirin) was computed. The findings were presented in US\$, with the conversion performed based on the mean exchange rate in 2019 (US\$ 1= MYR 4.14).

4. Results

4.1. Number and Characteristics of the Patients

A total of 1,797 hepatitis patients were treated with sofosbuvir and daclatasvir over a two-year period. The number of patients receiving the treatment ranged from 11 to 271 across the hospitals. They were mainly male (74.1%), below 50 years of age (51.4%) and of Malay ethnicity (60.2%). Approximately 4 in every 10 of them had a history of intravenous drug use, and nearly 10% of them were co-infected with HIV. The most common HCV genotype was 3 (46.9%),

followed by 1a (20.0%), 1b (8.7%) and 2 (2.4%). However, the HCV genotype in approximately one-fifth of them was untested. More than one-third of them had liver cirrhosis, mainly of CTP class A (31.4%). Only 9.1% of them were interferon-experienced (Table 1).

4.2. Extent of Evidence-based Drug Use

It was found that the drugs were generally used in line with the recommendations of the MOH. All of the patients were found to have received both DAAs at the right dose. This included 122 (6.8%) HCV/HIV co-infected patients for whom dose adjustment was required; 112 received daclatasvir at 90 mg and 10 at 30 mg daily. The treatment was extended to 24 weeks in 24.0% of the patients, more than 80% of whom had genotype-3 HCV infection complicated with liver cirrhosis. Ribavirin was used in slightly more than one-fifth of the patients, particularly those who had genotype-3 HCV infection complicated with liver cirrhosis (76.7%); and those who had genotype-1a HCV infection and were interferon-experienced (7.8%) (Table 1).

4.3. Status of Treatment Completion

Up until the end of March 2020, slightly over 90% of the patients had completed their treatment, most of whom had undergone the SVR test and the results were available (63.7%). Incomplete treatment was reported for 98 (5.5%) patients, primarily resulting from the loss to follow-up (4.4%). The premature treatment discontinuation in the rest was mainly caused by death (0.5%), followed by intolerable side effects (0.3%) and disease advancement (0.3%) (Figure 1).

4.4. Individual Responses to Treatment

Of the 1,163 patients with known treatment outcomes, 1,110 patients achieved an SVR. This yielded an overall SVR rate of 95.4% (95% CI: 94.2, 96.7%). The SVR achievement did not vary across HCV genotypes and the liver cirrhosis status of patients. The treatment duration, the use of ribavirin, and the previous exposure to interferon were also shown to have no effect on the SVR achievement (Table 2). However, treatment failure more likely occurred in the patients who were above 50 years of age (adjusted OR: 2.13; 95% CI: 1.16, 3.92) or had a history of tattooing (adjusted OR: 4.77; 95% CI: 1.85, 12.32) (Table 3).

4.5. Common Side Effects

Only 0.9% of the patients experienced the common side effects of the treatment. The most frequently reported side effects were anemia (0.6%), followed by fatigue (0.2%) and headache (0.1%). Premature treatment discontinuation due to intolerable side effects only took place in three patients with anemia (0.2%) and two patients with fatigue (0.1%) (Table 4).

4.6. Drug Expenditure

The drug expenditure added up to US\$678,258.20 (US\$377.44 per patient on average). Daclatasvir composed the largest portion of the expenditure (US\$308,523.88; 45.5%), followed by sofosbuvir (US\$225,225.91; 33.2%) and ribavirin (US\$114,508.41; 21.3%). The addition of ribavirin was found to increase the mean cost of a 12-week treatment course of sofosbuvir and daclatasvir by 45.2% (US\$429.13 versus US\$235.16).

5. Discussion

While Malaysia positioned HCV infection as a public health threat and applied compulsory licensing as a policy tool to enhance the accessibility of hepatitis C treatment, this study signifies that the MOH's decision to use a fixed regimen is comprised of two generic DAAs as a "one-size-fits-all strategy" for the entire country that is arguably reasonable and timely. Even though the pairing of sofosbuvir and daclatasvir would no longer be recommended as the first-line option for hepatitis C treatment (34), it was still shown to be highly efficacious and yet safe in the real world. From the economic standpoint, this study also points to the sustainability of such a strategy, showing that the mean cost of a 12-week treatment course of the two drugs (US\$235.16) had been kept below the cost expected by the MOH (US\$300) since their first use.

Most likely attributable to the guidance provided through the clinical practice guidelines (33) and continuous learning via various platforms, it is found that the 16 selected hospitals in this study all managed to practice evidence-based drug use in general. The combined use of sofosbuvir and daclatasvir, with or without ribavirin, recorded an overall SVR rate above 95%. This is consistent with the findings of most previous studies, including some undertaken in a controlled environment (13, 16-18, 20, 23, 25, 27, 29). Aside from producing similar outcomes across HCV genotypes and the liver cirrhosis status of patients, the treatment also yielded a comparable SVR rate for the harder-to-treat genotype-3 HCV infection. This strengthens the confidence of the MOH to treat more advanced hepatitis C cases and extend the existing practice to include more health institutions going forward. More importantly, this study could also help dispel the doubts about the efficacy of generic DAAs among both health professionals and the public.

Furthermore, the side effects of the treatment were found to be rare, and if present, were tolerable most of time. Anemia, which was most likely induced by ribavirin (33, 35), emerged as the most frequently reported side effect. Apart from its safety profile, this study raises the con-

Table 1. Characteristics of Patients and Treatment Regimens Used, 2018 - 2019 (n = 1,797)

Characteristics	No. (%)
Gender	
Male	1,331 (74.1)
Female	466 (25.9)
Age (y)	
< 50	923 (51.4)
≥ 50	874 (48.6)
Ethnicity	
Malay	1,081 (60.2)
Chinese	457 (25.4)
Indian	94 (5.2)
Others	165 (9.2)
History of exposure to HCV risk factors ^a	
Intravenous drug use	731 (40.7)
Invasive medical procedures/blood transfusion	327 (18.2)
Sexual contact	245 (13.6)
Tattooing	85 (4.7)
Hemodialysis	9 (0.05)
Body piercing	13 (0.07)
Presence of HBV infection	43 (2.4)
Presence of HIV infection	165 (9.2)
Presence of CKD	26 (1.4)
History of interferon-based treatment	163 (9.1%)
Genotype of HCV	
1a	359 (20.0)
1b	157 (8.7)
2	43 (2.4)
3	842 (46.9)
4	4 (0.2)
6	4 (0.4)
Untested	388 (21.6)
Presence of liver cirrhosis	
No	1,149 (64.0)
CTP class A (score 5 - 6)	565 (31.4)
CTP class B (score 7 - 9)	79 (4.4)
CTP class C (score 10 - 15)	4 (0.2)
Treatment duration of SOF/DAC	
12 weeks	1,365 (76.0)
24 weeks	432 (24.0) ^b
Use of ribavirin together with SOF/DAC	410 (22.8) ^c

Abbreviations: CKD, chronic kidney disease; CTP, Child-Turcotte-Pugh; DAC, daclatasvir; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; SOF, sofosbuvir.

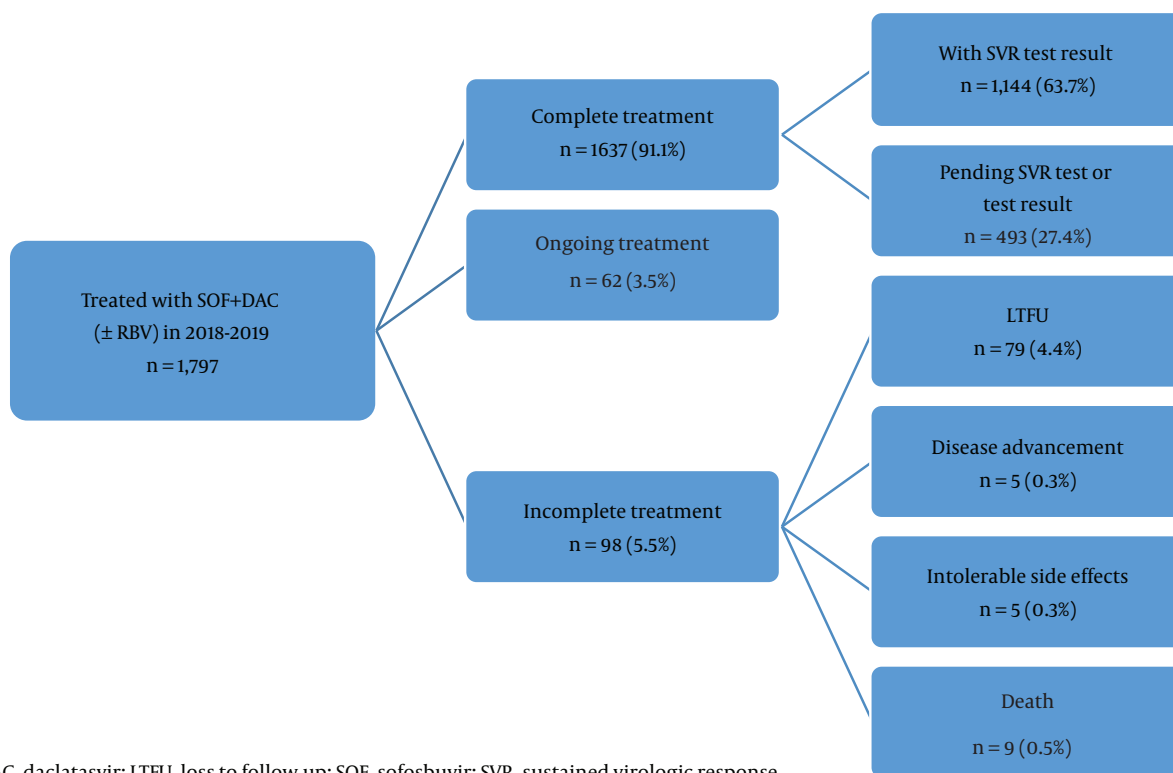
^a A patient could be linked to more than one risk factor.

^b Mainly used for genotype-3 HCV infection complicated with liver cirrhosis (n = 352; 81.5%).

^c Mainly used for genotype-3 HCV infection complicated with liver cirrhosis (n = 314; 76.6%) and genotype-1a HCV infection in interferon-experienced patients (n = 32; 7.8%).

cern about the increase in cost by nearly 50% when ribavirin was added to a 12-week treatment course of sofosbuvir and daclatasvir. Although the three-drug combination has primarily been used for genotype-3 HCV infection complicated with liver cirrhosis in Malaysia, this study also sug-

gests that the presence of ribavirin would not significantly improve the treatment outcome. Nevertheless, as a more detailed analysis is not feasible in this study due to a relatively small number of patients in this subgroup, more studies are required to corroborate the findings. Given



DAC, daclatasvir; LTFU, loss to follow-up; SOF, sofosbuvir; SVR, sustained virologic response.

Figure 1. Status of treatment completion up until 31st of March 2020 (n = 1,797)

Table 3. Factors Independently Associated with the Treatment Failure, Multiple Logistic Regression (n = 1,163)

Variables	Adjusted OR (95% CI) ^a	P-Value
Age (y)		
< 50	1	-
≥ 50	2.13 (1.16, 3.92)	0.015
Tattooing		
No	1	-
Yes	4.77 (1.85, 12.32)	0.001

Abbreviations: CI, confidence interval; HCV, hepatitis C virus; HIV, human immunodeficiency virus; OR, odds ratio.

^a Backward stepwise multiple logistic regression analysis was performed. Multicollinearity and interaction between variables were checked and not found. The Hosmer-Lemeshow goodness-of-fit test (P = 0.958), the overall correctly classified percentage (95.4%) and the area under the receiver operating characteristic curve (62.3%) were used to confirm the model fitness.

Table 4. Common Side Effects Reported During the Treatment Period (n = 1,197)^a

Side Effects	Number of Patients	Number of Patients Whose Treatment Was Discontinued
Anemia	11 (0.6)	3 (0.2)
Fatigue	4 (0.2)	2 (0.1)
Headache	2 (0.1)	0 (0.0)

^a Values are expressed as No. (%).

that the WHO also does not specifically recommend the addition of ribavirin to the sofosbuvir-daclatasvir regimen in any conditions (11), the MOH is looking at the possibility of

revising the clinical practice guidelines and further simplifying the treatment for hepatitis C.

It is also encouraging to note that the total number of

patients receiving DAA-based treatment at the 16 selected hospitals alone reached 1,797 over the span of two years, nearly four times more than the patients recorded by the MOH to have received treatment with interferon and ribavirin across the country between January 2016 and March 2018. However, there were no significant changes in the expenditure on viral hepatitis detected over the last few years, this implies that the expansion of treatment coverage is achievable by using the existing strategy without elevating the budgetary pressure. The substantial growth of the number of patients treated could also be ascribed to the collaborations between the MOH and civil society organizations, in particular the Drugs for Neglected Diseases initiative (DNDi), the Foundation for Innovative New Diagnostics (FIND) and the Malaysian AIDS Council (MAC), in upscaling the community-based screening for hepatitis C and subsequently linking the patients to hospitals for pharmacological treatment.

As much as the MOH is motivated by the positive findings of this study, it is worth highlighting that not all hepatitis C patients have access to hospital care. Aiming at the global goal to diagnose at least 90% of the HCV-infected individuals and initiate treatment in at least 80% of those who are eligible (36), Malaysia is currently pushing for decentralized hepatitis C management (10). Although public healthcare (PHC) centers in Malaysia generally have limitations with respect to their laboratory facilities and budgets, this study also suggests that ascertaining the genotype of HCV, particularly in non-cirrhotic patients, did not necessarily result in a better treatment outcome. The decision to omit the HCV genotyping at the stage of treatment initiation was arguably acceptable, given that the test results were only essential to guide the use of ribavirin in cases complicated with liver cirrhosis (33). Adopting such a practice in PHC centers can potentially streamline the treatment algorithms and avert unnecessary delay in treatment.

Although most patients were found to have completed their treatment, loss to follow-up was still reported for approximately 5% of them. In addition to expanding the treatment coverage in hepatitis C patients, the MOH, therefore, seek to reduce preventable treatment default. Additionally, this study shows that approximately 4 in every 10 hepatitis C patients treated with DAAs in Malaysia were PWID, who are also known to commonly have multiple encounters with police and the criminal justice system (37). Thus, it is timely for the MOH to forge a partnership with the Ministry of Home Affairs (MHA) in order to ensure the continuity of treatment among the PWID who are imprisoned or followed up at drug rehabilitation centers.

This study also relates the treatment failure in hepatitis C patients to their age and history of tattooing. Regard-

less of the conflicting conclusions drawn by the previous studies about the link between age and SVR achievement, it is a widely held view that a prolonged duration of HCV infection is likely to increase the risk of hepatitis-related complications and compromise the effectiveness of treatment (38, 39). As tattooing remains a cultural practice in certain areas and one of the key risk factors of hepatitis C in Malaysia (5), the suboptimal responses to treatment in tattooed patients were likely to be associated with their continuous exposure to unsafe practice during the treatment period. Nonetheless, further investigations into the reasons behind the aforementioned relationships are warranted.

The major limitation of this study lies in the short observation period, and the disease progression of the patients following the SVR achievement, along with its economic implications, is unknown. As mounting evidence confirms the long-term effects of DAAs in reducing mortality and the risk of HCC (40), a comprehensive economic evaluation beyond drug costs is required to capture the actual impact of such a government-led initiative. Although Malaysia is moving toward a massive scale-up of hepatitis C treatment through decentralization and outreach programs, this study does not provide insight into how the existing strategy could work as well in other settings as it did in public hospitals. Such uncertainty leaves an important direction for future research.

5.1. Conclusion

This study reveals that in the following two years after generic versions of sofosbuvir and daclatasvir were introduced by the MOH, this two-drug combination had been used to treat nearly 1,800 hepatitis C patients in 16 public hospitals across Malaysia. More than 90% of the patients successfully completed the treatment course. While the drugs were generally used in accordance with the recommendations of the MOH, the treatment resulted in an SVR rate above 95%. Side effects of the treatment were rare and tolerable on most occasions. A standard 12-week treatment course of the two drugs was found to be accessible at an average cost below US\$300 throughout the two-year period. Overall, the treatment exhibited a high degree of effectiveness, safety and affordability, pointing to the timeliness of the “one-size-fits-all” strategy to combat hepatitis C in the country.

Acknowledgments

We would like to thank the director-general of Health, Malaysia, for his support throughout the conduct of this study and his permission to publish the findings. We

would also like to extend our gratitude to our partners, including the MHA, DNDi, FIND and MAC, for being part of the journey of pushing for hepatitis C agenda in Malaysia. We also appreciate all the assistance we received from the staff in the Ministry of Health, Malaysia.

Footnotes

Authors' Contribution: Study concept and design, H. K. C, M. A. H and M. R. A. H.; Data collection, R. M. S, H. O., N. A. A. M. and F. W. D. R.; Analysis and interpretation of data, H. K. C, M. A. H and M. R. A. H.; Drafting of the manuscript, C. H. K.; Critical revision of the manuscript for important intellectual content, R. M. S, H. O., N. A. A. M. and F. W. D. R.; Statistical analysis, C. H. K.

Conflict of Interests: The authors declare no conflict of interests.

Ethical Approval: The study was registered with the National Medical Research Register (NMRR-20-481-54147) and approved by the Medical Research Ethics Committee of the Ministry of Health Malaysia.

Funding/Support: This is a self-funded study.

References

- Khatun M, Ray RB. Mechanisms underlying hepatitis C virus-associated hepatic fibrosis. *Cells*. 2019;**8**(10). doi: [10.3390/cells8101249](https://doi.org/10.3390/cells8101249). [PubMed: [31615075](https://pubmed.ncbi.nlm.nih.gov/31615075/)]. [PubMed Central: [PMC6829586](https://pubmed.ncbi.nlm.nih.gov/PMC6829586/)].
- Shin EC, Han JW, Kang W, Kato T, Kim SJ, Zhong J, et al. The beginning of ending hepatitis C virus: A summary of the 26th international symposium on hepatitis C virus and related viruses. *Viruses*. 2020;**12**(3). doi: [10.3390/v12030302](https://doi.org/10.3390/v12030302). [PubMed: [32168867](https://pubmed.ncbi.nlm.nih.gov/32168867/)]. [PubMed Central: [PMC7150740](https://pubmed.ncbi.nlm.nih.gov/PMC7150740/)].
- Md Said R, Mohd Zain R, Chan HK, Soelar SA, Rusli N, Nasir NH, et al. Find the missing millions: Malaysia's experience with nationwide hepatitis C screening campaign in the general population. *J Viral Hepat*. 2020;**27**(6):638–43. doi: [10.1111/jvh.13267](https://doi.org/10.1111/jvh.13267). [PubMed: [31997563](https://pubmed.ncbi.nlm.nih.gov/31997563/)].
- Ho SH, Ng KP, Kaur H, Goh KL. Genotype 3 is the predominant hepatitis C genotype in a multi-ethnic Asian population in Malaysia. *Hepatobiliary Pancreat Dis Int*. 2015;**14**(3):281–6. doi: [10.1016/s1499-3872\(15\)60363-0](https://doi.org/10.1016/s1499-3872(15)60363-0). [PubMed: [26063029](https://pubmed.ncbi.nlm.nih.gov/26063029/)].
- Mohd Suan MA, Said SM, Lim PY, Azman AZF, Abu Hassan MR. Risk factors for hepatitis C infection among adult patients in Kedah state, Malaysia: A case-control study. *PLoS One*. 2019;**14**(10). e0224459. doi: [10.1371/journal.pone.0224459](https://doi.org/10.1371/journal.pone.0224459). [PubMed: [31661525](https://pubmed.ncbi.nlm.nih.gov/31661525/)]. [PubMed Central: [PMC6818779](https://pubmed.ncbi.nlm.nih.gov/PMC6818779/)].
- Palumbo E. Pegylated interferon and ribavirin treatment for hepatitis C virus infection. *Ther Adv Chronic Dis*. 2011;**2**(1):39–45. doi: [10.1177/20406622310384308](https://doi.org/10.1177/20406622310384308). [PubMed: [23251740](https://pubmed.ncbi.nlm.nih.gov/23251740/)]. [PubMed Central: [PMC3513870](https://pubmed.ncbi.nlm.nih.gov/PMC3513870/)].
- Feld JJ, Foster GR. Second generation direct-acting antivirals - Do we expect major improvements? *J Hepatol*. 2016;**65**(1 Suppl):S130–42. doi: [10.1016/j.jhep.2016.07.007](https://doi.org/10.1016/j.jhep.2016.07.007). [PubMed: [27641983](https://pubmed.ncbi.nlm.nih.gov/27641983/)].
- Gonzales Zamora JA. Adverse effects of direct acting antivirals in HIV/HCV coinfecting patients: A 4-year experience in Miami, Florida. *Diseases*. 2018;**6**(2). doi: [10.3390/diseases6020051](https://doi.org/10.3390/diseases6020051). [PubMed: [29921760](https://pubmed.ncbi.nlm.nih.gov/29921760/)]. [PubMed Central: [PMC6023459](https://pubmed.ncbi.nlm.nih.gov/PMC6023459/)].
- Douglass CH, Pedrana A, Lazarus JV, t Hoen EFM, Hammad R, Leite RB, et al. Pathways to ensure universal and affordable access to hepatitis C treatment. *BMC Med*. 2018;**16**(1):175. doi: [10.1186/s12916-018-1162-z](https://doi.org/10.1186/s12916-018-1162-z). [PubMed: [30296935](https://pubmed.ncbi.nlm.nih.gov/30296935/)]. [PubMed Central: [PMC6176525](https://pubmed.ncbi.nlm.nih.gov/PMC6176525/)].
- Hassan MRA, Chan HK. Comment on: "Projections of the healthcare costs and disease burden due to hepatitis C infection under different treatment policies in Malaysia, 2018-2040". *Appl Health Econ Health Policy*. 2020;**18**(1):139–40. doi: [10.1007/s40258-019-00543-x](https://doi.org/10.1007/s40258-019-00543-x). [PubMed: [31853748](https://pubmed.ncbi.nlm.nih.gov/31853748/)].
- World Health Organization. *Guidelines for the care and treatment of persons diagnosed with chronic hepatitis C virus infection*. Geneva, Switzerland: World Health Organization; 2018.
- Poordad F, Shiffman ML, Ghesquiere W, Wong A, Huhn GD, Wong F, et al. Daclatasvir and sofosbuvir with ribavirin for 24 weeks in chronic hepatitis C genotype-3-infected patients with cirrhosis: A Phase III study (ALLY-3C). *Antivir Ther*. 2019;**24**(1):35–44. doi: [10.3851/IMP3278](https://doi.org/10.3851/IMP3278). [PubMed: [30382942](https://pubmed.ncbi.nlm.nih.gov/30382942/)].
- Zhang M, O'Keefe D, Iwamoto M, Sann K, Kien A, Hang V, et al. High sustained viral response rate in patients with hepatitis C using generic sofosbuvir and daclatasvir in Phnom Penh, Cambodia. *J Viral Hepat*. 2020;**27**(9):886–95. doi: [10.1111/jvh.13311](https://doi.org/10.1111/jvh.13311). [PubMed: [32358826](https://pubmed.ncbi.nlm.nih.gov/32358826/)].
- Dhiman RK, Grover GS, Premkumar M, Taneja S, Duseja A, Arora S, et al. Decentralized care with generic direct-acting antivirals in the management of chronic hepatitis C in a public health care setting. *J Hepatol*. 2019;**71**(6):1076–85. doi: [10.1016/j.jhep.2019.07.006](https://doi.org/10.1016/j.jhep.2019.07.006). [PubMed: [31325468](https://pubmed.ncbi.nlm.nih.gov/31325468/)].
- Calvaruso V, Mazzarelli C, Milazzo L, Badia L, Pasulo L, Guaraldi G, et al. Daclatasvir-based regimens in HCV cirrhosis: Experience from the Italian early access program. *Sci Rep*. 2019;**9**(1):585. doi: [10.1038/s41598-018-36734-0](https://doi.org/10.1038/s41598-018-36734-0). [PubMed: [30679515](https://pubmed.ncbi.nlm.nih.gov/30679515/)]. [PubMed Central: [PMC6345835](https://pubmed.ncbi.nlm.nih.gov/PMC6345835/)].
- Mushtaq S, Mansoor A, Umar M, Khan A, Siddiqi S, Manzoor S. Direct-acting antiviral agents in the treatment of chronic hepatitis C-Real-life experience from clinical practices in Pakistan. *J Med Virol*. 2020;**92**(12):3475–87. doi: [10.1002/jmv.25745](https://doi.org/10.1002/jmv.25745). [PubMed: [32129507](https://pubmed.ncbi.nlm.nih.gov/32129507/)].
- Tsai WL, Wang CF, Cheng JS, Chen WC, Bair MJ, Lo CC. Sofosbuvir-based regimen for genotype 2 HCV infected patients in Taiwan: A real world experience. *PLoS One*. 2020;**15**(1). e0227424. doi: [10.1371/journal.pone.0227424](https://doi.org/10.1371/journal.pone.0227424). [PubMed: [31923251](https://pubmed.ncbi.nlm.nih.gov/31923251/)]. [PubMed Central: [PMC6953822](https://pubmed.ncbi.nlm.nih.gov/PMC6953822/)].
- Han Q, Fan X, Wang X, Wang Y, Deng H, Zhang X, et al. High sustained virologic response rates of sofosbuvir-based regimens in Chinese patients with HCV genotype 3a infection in a real-world setting. *Virol J*. 2019;**16**(1):74. doi: [10.1186/s12985-019-1184-y](https://doi.org/10.1186/s12985-019-1184-y). [PubMed: [31159813](https://pubmed.ncbi.nlm.nih.gov/31159813/)]. [PubMed Central: [PMC6547524](https://pubmed.ncbi.nlm.nih.gov/PMC6547524/)].
- Pariante A, Arpurt JP, Remy AJ, Rosa-Hezode I, Causse X, Heluwaert F, et al. Hepatitis C treatment with all-oral direct-acting antivirals: Effectiveness and tolerance in a multicenter, prospective, observational study from French general hospitals (APROVIE, ANGH). *Presse Med*. 2019;**48**(3 Pt 1):e101–10. doi: [10.1016/j.lpm.2018.06.019](https://doi.org/10.1016/j.lpm.2018.06.019). [PubMed: [30853287](https://pubmed.ncbi.nlm.nih.gov/30853287/)].
- Belperio PS, Shahoumian TA, Loomis TP, Mole LA, Backus LI. Real-world effectiveness of daclatasvir plus sofosbuvir and velpatasvir/sofosbuvir in hepatitis C genotype 2 and 3. *J Hepatol*. 2019;**70**(1):15–23. doi: [10.1016/j.jhep.2018.09.018](https://doi.org/10.1016/j.jhep.2018.09.018). [PubMed: [30266283](https://pubmed.ncbi.nlm.nih.gov/30266283/)].
- Hlaing NKT, Nangia G, Tun KT, Lin S, Maung MZ, Myint KT, et al. High sustained virologic response in genotypes 3 and 6 with generic NS5A inhibitor and sofosbuvir regimens in chronic HCV in Myanmar. *J Viral Hepat*. 2019;**26**(10):1186–99. doi: [10.1111/jvh.13133](https://doi.org/10.1111/jvh.13133). [PubMed: [31104344](https://pubmed.ncbi.nlm.nih.gov/31104344/)].
- Yang Y, Wu FP, Wang WJ, Shi JJ, Li YP, Zhang X, et al. Real life efficacy and safety of direct-acting antiviral therapy for treatment of patients infected with hepatitis C virus genotypes 1, 2 and 3 in northwest China. *World J Gastroenterol*. 2019;**25**(44):6551–60. doi: [10.3748/wjg.v25.i44.6551](https://doi.org/10.3748/wjg.v25.i44.6551). [PubMed: [31802834](https://pubmed.ncbi.nlm.nih.gov/31802834/)]. [PubMed Central: [PMC6886016](https://pubmed.ncbi.nlm.nih.gov/PMC6886016/)].

23. Charatcharoenwitthaya P, Wongpaitoon V, Komolmit P, Sukeepaisarnjaroen W, Tangkijvanich P, Piratvisuth T, et al. Real-world effectiveness and safety of sofosbuvir and nonstructural protein 5A inhibitors for chronic hepatitis C genotype 1, 2, 3, 4, or 6: a multicentre cohort study. *BMC Gastroenterol.* 2020;**20**(1):47. doi: [10.1186/s12876-020-01196-0](https://doi.org/10.1186/s12876-020-01196-0). [PubMed: [32138687](https://pubmed.ncbi.nlm.nih.gov/32138687/)]. [PubMed Central: [PMC7057522](https://pubmed.ncbi.nlm.nih.gov/PMC7057522/)].
24. Soria A, Fava M, Bernasconi DP, Lapadula G, Colella E, Valsecchi MG, et al. Comparison of three therapeutic regimens for genotype-3 hepatitis C virus infection in a large real-life multicentre cohort. *Liver Int.* 2020;**40**(4):769–77. doi: [10.1111/liv.14386](https://doi.org/10.1111/liv.14386). [PubMed: [31970845](https://pubmed.ncbi.nlm.nih.gov/31970845/)].
25. Lobato CMO, Codes L, Silva GF, Souza AFM, Coelho HSM, Pedrosa MLA, et al. Direct antiviral therapy for treatment of hepatitis C: A real-world study from Brazil. *Ann Hepatol.* 2019;**18**(6):849–54. doi: [10.1016/j.aohep.2019.08.001](https://doi.org/10.1016/j.aohep.2019.08.001). [PubMed: [31537509](https://pubmed.ncbi.nlm.nih.gov/31537509/)].
26. Lionetti R, Piccolo P, Lenci I, Siciliano M, Visco-Comandini U, De Santis A, et al. Daclatasvir, sofosbuvir with or without ribavirin for 24 weeks in hepatitis C genotype 3 cirrhosis: A real-life study. *Ann Hepatol.* 2019;**18**(3):434–8. doi: [10.1016/j.aohep.2018.09.005](https://doi.org/10.1016/j.aohep.2018.09.005). [PubMed: [31023614](https://pubmed.ncbi.nlm.nih.gov/31023614/)].
27. Cheng PN, Chiu YC, Chien SC, Chiu HC. Real-world effectiveness and safety of sofosbuvir plus daclatasvir with or without ribavirin for genotype 2 chronic hepatitis C in Taiwan. *J Formos Med Assoc.* 2019;**118**(5):907–13. doi: [10.1016/j.jfma.2018.09.016](https://doi.org/10.1016/j.jfma.2018.09.016). [PubMed: [30316677](https://pubmed.ncbi.nlm.nih.gov/30316677/)].
28. Butt Z, Shah SMA. Daclatasvir plus Sofosbuvir with or without ribavirin in patients with chronic Hepatitis C genotype 3a in Pakistani population - A real world experience. *Pak J Med Sci.* 2019;**35**(2):409–13. doi: [10.12669/pjms.35.2.637](https://doi.org/10.12669/pjms.35.2.637). [PubMed: [31086524](https://pubmed.ncbi.nlm.nih.gov/31086524/)]. [PubMed Central: [PMC6500802](https://pubmed.ncbi.nlm.nih.gov/PMC6500802/)].
29. Ridruejo E, Cheinquer H, Marciano S, Mendizabal M, Pinero F, Wolff FH, et al. B.A.R.C.O.S. (Brazilian Argentine Hepatitis C Collaborative Observational Study): Effectiveness and clinical outcomes of HCV treatment with daclatasvir and sofosbuvir with or without ribavirin. *J Viral Hepat.* 2019;**26**(10):1200–9. doi: [10.1111/jvh.13148](https://doi.org/10.1111/jvh.13148). [PubMed: [31141239](https://pubmed.ncbi.nlm.nih.gov/31141239/)].
30. Wu SH, Chu CJ, Su CW, Lin CC, Lee SD, Wang YJ, et al. Daclatasvir plus sofosbuvir, with or without ribavirin, is highly effective for all kinds of genotype-2 chronic hepatitis-C infection in Taiwan. *J Chin Med Assoc.* 2019;**82**(9):693–8. doi: [10.1097/JCMA.000000000000148](https://doi.org/10.1097/JCMA.000000000000148). [PubMed: [31356562](https://pubmed.ncbi.nlm.nih.gov/31356562/)].
31. Macken L, Gelson W, Priest M, Abouda G, Barclay S, Fraser A, et al. Efficacy of direct-acting antivirals: UK real-world data from a well-characterised predominantly cirrhotic HCV cohort. *J Med Virol.* 2019;**91**(11):1979–88. doi: [10.1002/jmv.25552](https://doi.org/10.1002/jmv.25552). [PubMed: [31329295](https://pubmed.ncbi.nlm.nih.gov/31329295/)].
32. Margusino-Framinan L, Cid-Silva P, Mena-de-Cea A, Rodriguez-Osorio I, Pernas-Souto B, Delgado-Blanco M, et al. Effectiveness and safety of daclatasvir/sofosbuvir with or without ribavirin in genotype 3 hepatitis C virus infected patients. Results in real clinical practice. *Rev Esp Quimioter.* 2019;**32**(2):137–44. [PubMed: [30761823](https://pubmed.ncbi.nlm.nih.gov/30761823/)]. [PubMed Central: [PMC6441991](https://pubmed.ncbi.nlm.nih.gov/PMC6441991/)].
33. Ministry of Health of Malaysia. [Clinical practice guidelines; management of chronic hepatitis C in adults]. Malaysia: Ministry of Health of Malaysia; 2021, [cited 20th Jan 2021]. Malay. Available from: <https://www.moh.gov.my/index.php?mid=5>.
34. European Association for the Study of the Liver. EASL recommendations on treatment of hepatitis C 2018. *J Hepatol.* 2018;**69**(2):461–511. doi: [10.1016/j.jhep.2018.03.026](https://doi.org/10.1016/j.jhep.2018.03.026). [PubMed: [29650333](https://pubmed.ncbi.nlm.nih.gov/29650333/)].
35. Wu LS, Jimmerson LC, MacBrayne CE, Kiser JJ, D'Argenio DZ. Modeling ribavirin-induced anemia in patients with chronic hepatitis C virus. *CPT Pharmacometrics Syst Pharmacol.* 2016;**5**(2):65–73. doi: [10.1002/psp4.12058](https://doi.org/10.1002/psp4.12058). [PubMed: [26933517](https://pubmed.ncbi.nlm.nih.gov/26933517/)]. [PubMed Central: [PMC4761234](https://pubmed.ncbi.nlm.nih.gov/PMC4761234/)].
36. Dore GJ, Martinello M, Alavi M, Grebely J. Global elimination of hepatitis C virus by 2030: Why not? *Nat Med.* 2020;**26**(2):157–60. doi: [10.1038/s41591-019-0706-x](https://doi.org/10.1038/s41591-019-0706-x). [PubMed: [32047317](https://pubmed.ncbi.nlm.nih.gov/32047317/)].
37. Strathdee SA, Beletsky L, Kerr T. HIV, drugs and the legal environment. *Int J Drug Policy.* 2015;**26**(Suppl 1):S27–32. doi: [10.1016/j.drugpo.2014.09.001](https://doi.org/10.1016/j.drugpo.2014.09.001). [PubMed: [25265900](https://pubmed.ncbi.nlm.nih.gov/25265900/)]. [PubMed Central: [PMC4346482](https://pubmed.ncbi.nlm.nih.gov/PMC4346482/)].
38. Reid M, Price JC, Tien PC. Hepatitis C virus infection in the older patient. *Infect Dis Clin North Am.* 2017;**31**(4):827–38. doi: [10.1016/j.idc.2017.07.014](https://doi.org/10.1016/j.idc.2017.07.014). [PubMed: [29079161](https://pubmed.ncbi.nlm.nih.gov/29079161/)]. [PubMed Central: [PMC5675560](https://pubmed.ncbi.nlm.nih.gov/PMC5675560/)].
39. Zoulim F, Liang TJ, Gerbes AL, Aghemo A, Deuffic-Burban S, Dusheiko G, et al. Hepatitis C virus treatment in the real world: Optimising treatment and access to therapies. *Gut.* 2015;**64**(11):1824–33. doi: [10.1136/gutjnl-2015-310421](https://doi.org/10.1136/gutjnl-2015-310421). [PubMed: [26449729](https://pubmed.ncbi.nlm.nih.gov/26449729/)]. [PubMed Central: [PMC5993679](https://pubmed.ncbi.nlm.nih.gov/PMC5993679/)].
40. Carrat F, Fontaine H, Dorival C, Simony M, Diallo A, Hezode C, et al. Clinical outcomes in patients with chronic hepatitis C after direct-acting antiviral treatment: A prospective cohort study. *Lancet.* 2019;**393**(10179):1453–64. doi: [10.1016/S0140-6736\(18\)32111-1](https://doi.org/10.1016/S0140-6736(18)32111-1). [PubMed: [30765123](https://pubmed.ncbi.nlm.nih.gov/30765123/)].

Table 2. Achievement of a Sustained Virologic Response and Factors Associated with Treatment Failure, Simple Logistic Regression (n = 1,163)

Factors	Number of Patients Achieving SVR	SVR Rate (95% CI)	Crude OR (95% CI)	P-Value
Overall	1,110/1,163	95.4 (94.2, 96.7)	-	-
Gender				
Male	795/838	94.9 (93.4, 96.4)	1.70 (0.85, 3.43)	0.136
Female	315/325	96.9 (95.0, 98.8)	1	-
Age (y)				
< 50	536/555	96.6 (95.1, 98.1)	1	-
≥ 50	574/608	94.4 (92.6, 96.2)	1.67 (0.94, 2.97)	0.079
Ethnicity				
Malay	676/702	96.3 (94.9, 97.7)	1	-
Chinese	289/309	93.5 (90.8, 96.3)	1.80 (0.99, 3.28)	0.055
Indian	54/58	93.1 (86.4, 99.8)	1.93 (0.65, 5.72)	0.238
Others	91/94	96.8 (93.2, 100.0)	0.86 (0.25, 2.89)	0.804
Intravenous drug use				
No	689/723	95.3 (93.8, 96.8)	1.09 (0.62, 1.94)	0.761
Yes	421/440	95.7 (93.8, 97.6)	1	-
Invasive medical procedures/blood transfusion				
No	884/931	95.0 (93.5, 96.4)	2.00 (0.85, 4.74)	0.114
Yes	226/232	97.4 (95.4, 99.5)	1	-
Sexual contact				
No	969/1,015	95.5 (94.2, 96.7)	1	-
Yes	141/148	95.3 (91.8, 98.7)	1.05 (0.46, 2.36)	0.914
Tattooing				
No	1,072/1,119	95.8 (94.6, 97.0)	1	-
Yes	38/44	86.4 (75.8, 96.9)	3.60 (1.45, 8.94)	0.006
Hemodialysis				
No	1,102/1,155	95.4 (94.2, 96.7)	-	-
Yes	8/8	100.0	-	-
Body piercing				
No	1,106/1,159	95.4 (94.2, 96.6)	-	-
Yes	4/4	100.0	-	-
Presence of HBV infection				
No	1,084/1,135	95.5 (94.3, 96.7)	1	-
Yes	26/28	92.9 (82.7, 100.0)	1.64 (0.38, 7.08)	0.511
Presence of HIV infection				
No	1,011/1,056	95.7 (94.5, 97.0)	1	-
Yes	99/107	92.5 (87.5, 97.6)	1.82 (0.83, 3.96)	0.134
Presence of CKD				
No	1,094/1,145	95.5 (94.3, 96.7)	1	-
Yes	16/18	88.9 (72.8, 100.0)	2.68 (0.60, 11.98)	0.196

History of interferon-based treatment				
No	987/1,034	95.5 (94.3, 96.7)	1	-
Yes	123/129	95.3 (91.7, 99.0)	1.02 (0.43, 2.45)	0.957
Genotype of HCV				
1a	267/279	95.7 (93.3, 98.1)	1	-
1b	118/122	96.7 (93.5, 99.9)	0.75 (0.24, 2.39)	0.631
2	21/22	95.5 (86.0, 100.0)	1.06 (0.13, 8.55)	0.957
3	530/561	94.5 (92.6, 96.4)	1.30 (0.66, 2.58)	0.449
Others ^a	174/179	97.2 (94.8, 99.6)	0.64 (0.22, 1.85)	0.408
Presence of liver cirrhosis				
No	725/746	97.2 (96.0, 98.4)	1.55 (0.89, 2.70)	0.120
Yes	388/398	97.5 (95.9, 99.0)	1	-
Treatment duration				
12 weeks	876/900	97.3 (96.3, 98.4)	1	-
24 weeks	237/244	97.1 (95.0, 99.2)	1.46 (0.79, 2.70)	0.226
Ribavirin use				
No	862/885	97.4 (96.4, 98.5)	1	-
Yes	251/259	96.9 (94.8, 99.0)	1.62 (0.90, 2.94)	0.109

Abbreviations: CKD, chronic kidney disease; CI, confidence interval; CTP, Child-Turcotte-Pugh; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; OR, odds ratio; SVR, sustained virologic response.

^a SVR rates were 100% (3/3) for genotype 4, 100% (2/2) for genotype 6, and 97.1% (169/174; 95%CI: 94.6%, 99.6%) for untested cases.