PAKISTAN JOURNAL OF GASTROENTEROLOGY

Original Article

Effectiveness of Sofosbuvir-Based Therapy in Chronic Hepatitis C Patients: A Clinical Study from Abbottabad, KPK Pakistan

Saifullah Khan[1], Muhammad Idris[1]

1. *Abbott Lab & Blood Bank Abbottabad, KPK, Pakistan.*

Abstract:
Hepatitis C virus (HCV) infection is a significant public health issue in Pakistan. Direct-acting antivirals (DAAs), particularly Sofosbuvir-based regimens have demonstrated high efficacy in achieving sustained virologic response (SVR).
Objectives: The study aimed to evaluate the PCR outcomes before and after treatment with Sofosbuvir in chronic HCV Patients.
Methods: This observational study included 350 patients diagnosed with chronic HCV infection between July 2024 and September 2025. About 6ml venous blood sample was collected aseptically in 2 EDTA bottles from each patient and centrifuged at 5000 RPM for 3 minutes separated plasma was collected in 2 ml eppendorf tubes and samples were stored at -40 C. RNA extraction was carried out on stored samples by using Favorgen extraction kit and Sacace HCV Quant L Kit was used for amplification on CEPHEID smart cycler II PCR system. Positive patients were treated with Sofosbuvir-based regimens. HCV RNA PCR testing was conducted at the PCR Laboratory of Abbott Laboratories and the Blood Bank in Abbottabad, Pakistan. Virologic response was assessed at baseline, end of treatment and 12 weeks post-treatment (SVR12).
Results: Among 350 patients 190 were male and 160 were female age ranges from 16 years to 68 years. All the patients were put on Sofosbuvir 400 mg daily for 12 weeks. Out of 190 male patients 175 (92%) patients achieved SVR12 after treatment while 152 (95 %) female patients achieved SVR12 after 12 weeks.
Conclusion: Sofosbuvir-based therapy demonstrated high effectiveness in achieving viral clearance in the majority of patients. The study supports its continued use as a frontline treatment for chronic HCV in Pakistan.
Keywords: Hepatitis C, Sofosbuvir, HCV RNA PCR, SVR, DAAs

How to Cite this:
Khan S, Idris M**.** Effectiveness of Sofosbuvir-Based Therapy in Chronic Hepatitis C Patients: A Clinical Study from Abbottabad, KPK Pakistan**.** ***Pak J Gastro*****. 2026, 42(1), 864-868,**
DOI: https://doi.org/10.63521/pjg.42.1.2026.29

Corresponding Author: Saifullha Khan
Email: saifullahkha@gmail.com
Received: Oct 18, 2025
Accepted: March 27, 2026

Introduction:

The inflammation of liver tissue is referred to as hepatitis. Hepatitis is classified as a disease within the field of gastroenterology. This illness can arise from various causes, including viral infections, metabolic issues, alcohol consumption, bacteria and toxins. In some instances, autoimmune diseases can also trigger it. The primary contributors are alcohol consumption, with viral infections being the next most significant factor. The five key viruses that lead to hepatitis are hepatitis A, B, C, D, and E[1]. Chronic inflammation can lead to cirrhosis and liver cancer which is significant indicators for liver transplantation in advanced countries[2].The Hepatitis C virus (HCV) is a blood borne virus that

primarily affects the liver. It is a major global health concern because it can cause chronic hepatitis, which may lead to liver cirrhosis**,** liver failure, or hepatocellular carcinoma (liver cancer) if left untreated [3]. HCV belongs to family *Flaviviridae and Genus Hepacivirus with single*-stranded + sense RNA genome. Hepatitis C virus (HCV) is classified into 7 major genotypes (1 to 7) and over 80 subtypes (e.g., 1a, 1b, 3a), based on differences in the viral genome[4]. The HCV genome, which is a positive sense RNA strand is transcribed into a negative sense RNA strand which is then used to synthesize additional positive-strand copies of the genome. The positive-strand RNA genome serves as the initial template for producing a polyprotein that consists of both structural and non-structural proteins. The structural proteins consist of nucleocapsids and envelope proteins, E1 and E2. The non-structural proteins include the NS2-3 protease, NS3 serine protease, RNA helicase, and NS5B RNA polymerase[5]. Hepatitis C virus (HCV) infection impacts approximately 71 million people worldwide, with a high prevalence in low- and middle-income countries, including Pakistan [6]. Untreated chronic HCV can result in liver cirrhosis, hepatocellular carcinoma, and liver failure. Initially, the treatment alternatives for chronic hepatitis C encompassed both non-pegylated and pegylated interferons (Peg-IFN) along with ribavirin, which, over two decades, led to diminishing effectiveness and was often endured without success. Between 2001 and 2011, the typical therapy consisted of peg-IFN and ribavirin together, with the treatment length differing according to the HCV genotype. Typically, the rate of achieving a sustained virological response varied between 40% and 50% with 24 or 48 weeks of combination therapy for genotype 1. Among the subtypes, genotype 1a appears to have a slightly better response rate compared to genotype 1b [7].

After receiving these medications in combination for 24 weeks the percentages of sustained virologic response for genotypes 2 and 3 ranged from 60 to 80%. Despite the fact that peg-IFN was more acceptable than the non-pegylated varieties, many patients had peg-IFN intolerance, and ribavirin frequently caused hemolytic anemia and other negative effects. Additionally difficult are worries regarding ribavirin's teratogenicity, which makes patient care more difficult[8,9]. Ribavirin has minimal effects on HCV RNA levels, but it can lower ALT levels [10]. Gradual enhancements in the rate of lasting virological response are facilitated by primary protease inhibitors, direct-acting antivirals, boceprevir and telaprevir in that sequence. The introduction of direct-acting antivirals (DAAs) has transformed HCV treatment, with Sofosbuvir being one of the most widely used agents. It is well tolerated, highly effective, and has enabled high sustained virologic response (SVR) rates across different genotypes [10]. Polymerase chain reaction (PCR) testing for HCV RNA is the gold standard for assessing viral load and treatment efficacy [11]. In this study, we aimed to evaluate the real-world effectiveness of Sofosbuvir-based therapy in chronic HCV patients by analysing pre- and post-treatment PCR results conducted at local diagnostic facilities in Abbottabad, Pakistan.

Objectives:

The purpose of the current study was to assess the effectiveness of Sofosbuvir + Ribavirin in patients with chronic HCV infection, with a focus on the effectiveness of Sofosbuvir therapy, non-responders and treatment-naive suspected patients in Abbottabad, Pakistan.

Materials and Methods

Study Population:

This prospective observational study was conducted at Abbott Lab Abbottabad, Pakistan from July 2024 and September 2025. A total of 350 patients diagnosed with chronic hepatitis C, aged 16–68 years, were enrolled consecutively during the study period, of whom 190 were male and 160 were female. Patients meeting the inclusion criteria and without exclusion conditions such as decompensated liver failure or severe comorbidities were included. Written informed consent was obtained from all participants prior to enrolment.

Treatment Protocol:

All patients received direct-acting antiviral therapy in combination with weight-based ribavirin. Ribavirin was administered orally at 1000 mg/day for patients weighing less than 75 kg and 1200 mg/day for those weighing 75 kg or more, divided into two doses. In patients with decompensated

cirrhosis, ribavirin was initiated at 600 mg/day and adjusted according to tolerance, hemoglobin levels and renal function.

Ethical statement:

This study is a retrospective analysis of routine clinical laboratory data. All samples were processed as part of standard diagnostic procedures. To protect patient privacy, all data were fully anonymized before analysis. Because this research involved pre-existing, de-identified diagnostic data and did not involve any intervention or contact with patients, formal ethical approval was deemed exempt by the laboratory administration with local institutional guidelines.

Exclusion Criteria:
Co-infection with HBV or HIV, Decompensated liver disease, Pregnant or lactating women and Incomplete treatment or lost to follow-up.

Sample collection:
A 6 ml venous blood was collected in EDTA bottles aseptically from all patients after labelling centrifuged at 7000 RPM for 3 minutes separated plasma was collected in 2 ml sterile eppendorf tubes and stored at -40 C.

Polymerase Chain Reaction:
Baseline HCV RNA PCR was performed before treatment initiation. HCV RNA was obtained from preserved samples utilizing the Favorgen extraction kit, amplification was carried out using Sacace HCV Real TM Quant L kit and Cepheid Smart Cycler II PCR system. The viral loads of all the samples were recorded. PCR tests were carried out using standardized protocols at the PCR Lab of Abbott Lab and the Blood Bank Abbottabad.

Treatment Regimen:
All patients were treated with antiviral therapy based on Sofosbuvir 400 mg daily plus Ribavirin for 12 weeks. Ribavirin was administered orally in a weight-based dosage 1000 mg per day for patients weighing less than 75 kg and 1200 mg per day for those weighing 75 kg or more divided into two doses. Follow-up PCR was performed at the end of treatment (EOT) and 12 weeks after completing treatment (SVR12).

Results:

A total of 350 patients with chronic Hepatitis C virus (HCV) infection were included in the study. Among them 190 (54.3%) were male and 160 (45.7%) were female with an age range of 16 to 68 years. All patients were treated with Sofosbuvir 400 mg once daily for 12 weeks along with Ribavirin. Out of 190 male patients, 175 (92.1%) achieved sustained virologic response at 12 weeks post-treatment (SVR12). Among the 160 female patients, 152 (95.0%) achieved SVR12. The overall SVR12 rate for the cohort was 93.4% (327 out of 350 patients). A chi-square test was performed to assess the association between gender and SVR12 achievement. The difference in SVR12 rates between male and female patients was not statistically significant ($\chi^2 = 0.89$, $p = 0.345$). Among 190 male patients 175 achieved SVR12 resulting in a 92.1% response rate with 15 not achieving SVR12. In contrast 160 female patients had a slightly higher response rate of 95.0% with 152 achieving SVR12 and 8 not achieving it. Overall, out of 350 total patients 327 achieved SVR12 yielding an overall rate of 93.4% with 6.96% not responding. The figure highlights a marginally higher SVR12 success rate among females compared to males Figure 1.

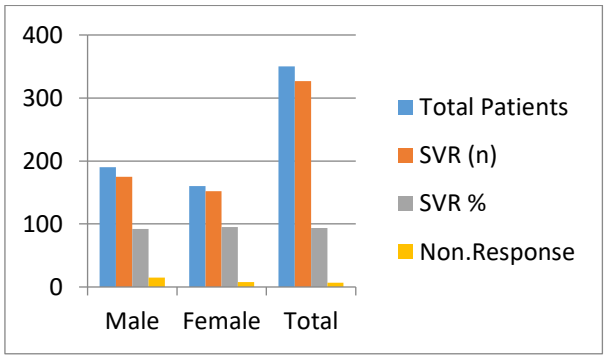

Figure1. End of therapy response of HCV patients treated with Sofosbuvir

Table1 SVR12 Achievement by Gender

Gender	Total Patients	SVR12 Achieved (n)	SVR12 Rate (%)
Male	190	175	92.1%
Female	160	152	95.0%
Total	350	327	93.4%

Outcomes for 350 patients assessed for Sustained Virologic Response at 12 weeks (SVR12), stratified by gender. Among male patients (n = 190), 175 (92.1%) achieved SVR12 while 15 (7.9%) did not. Among female patients (n = 160), 152 (95.0%) achieved SVR12, with only 8 (5.0%) failing to respond. Overall, the total SVR12 rate was 93.4% (327/350), with 6.6% (23 patients) not achieving response. The data suggest a slightly higher response rate among females. These findings may have implications for understanding gender-related differences in treatment efficacy.

Discussion: In rural and urban areas, the prevalence of HCV is extremely high. Nonetheless, it is important to take into account the socioeconomic aspect of the HCV epidemic in Pakistan. The true HCV burden in Pakistan is anticipated to be significantly larger because the majority of Pakistanis reside in these lagging areas with high HCV incidence [12]. The purpose of this study was to evaluate the effects of sofosbuvir treatment in patients with HCV. Our study aimed to promote awareness and motivate non-responders older than 40 to undergo treatment for HCV using direct-acting antiviral therapy, while practitioners should also take into account patients over 40 years of age who are challenging to treat.

In this study, we examined the effectiveness of sofosbuvir-based therapy in a cohort of 350 chronic Hepatitis C patients in Abbottabad, KPK, Pakistan. We observed an overall SVR12 (Sustained Virological Response at 12 weeks post-treatment) rate of **93.4%**, with male patients achieving 92.1% and female patients 95.0%. These results demonstrate very favorable outcomes, confirming that sofosbuvir-based regimens are highly effective in this setting.

Comparison with Other Studies in Pakistan: Our overall SVR12 rate is consistent with other studies carried out in Pakistan using sofosbuvir in various combinations:

Sofosbuvir + Daclatasvir (SOF+DCV) in Karachi showed an SVR rate of **88.3%** among chronic, cirrhotic, and treatment-experienced patients [13].

In Abbottabad (Ayub Teaching Hospital), the combination of SOF + DCV in genotype 3 patients gave a SVR of **95.8%** [14].

In Lahore, a SOF + Velpatasvir (SOF+VELPA) study reported efficacy of ~94.03% [15].

Another study in Faisalabad with SOF + VELPA + Ribavirin achieved SVR in **98.29%** of patients [16].

Thus, our findings are broadly in line with the higher end of efficacy seen in recent DAA (direct-acting antiviral) trials in Pakistan.

Factors Influencing SVR Rates: From both our study and earlier reports, some factors seem to influence treatment response:

- **Gender**: We observed slightly higher SVR12 in females (95.0%) vs males (92.1%). This trend has been noted in other studies, albeit sometimes modestly and not always statistically significant. For example, in the "SOF for Genotype 3" study at Holy Family Hospital Rawalpindi, attainment of SVR was slightly more in females[18]. **Cirrhosis / Liver disease status**: Cirrhotic patients and those with more advanced liver disease often have somewhat lower response rates. Some studies report slightly reduced SVR in cirrhotics or in treatment experienced patients. Our study had good outcomes overall, suggesting that even among mixed populations, the regimens are robust.

Implications for Abbottabad / KPK Context:

- The high SVR12 rate (93.4%) suggests that sofosbuvir-based regimens are very effective in the local patient population in Abbottabad. This is important because the burden of Hepatitis C is high in Pakistan, and effective, tolerable regimens are critical to achieving national public health goals.
- Given similar efficacy among males and females, gender does not appear to be a major barrier, though monitoring and ensuring access across gender is still essential.
- Cost, adherence, access to diagnostics (viral load, genotype testing), and ensuring follow-up are likely important

considerations to sustain such high rates in real life.

Limitations:

- Our study is (presumably) observational, which may limit control over confounding variables (e.g. severity of liver disease, viral load, prior treatments).
- This study did not include baseline disease severity markers, such as ALT levels, fibrosis stage, cirrhosis status, or viral load categories, which may limit interpretation of treatment outcomes in relation to disease stage.
- This study did not include systematic assessment of end-of-treatment response beyond summary figures, nor were relapse, viral breakthrough, or long-term follow-up data collected. This limits the ability to assess sustained virologic response and long-term treatment effectiveness.
- Follow-up may have some dropout, and missing data (especially for those lost to follow up) could influence the SVR12 calculation.
- We may not have detailed data on adverse events in all patients, which is useful for assessing tolerability fully.

Future Directions:

- **Long-term outcomes**: While SVR12 is a good endpoint, follow up to SVR24, liver function improvement, fibrosis regression, incidence of hepatocellular carcinoma are needed.
- **Subgroup analyses**: Stratification by cirrhosis, baseline viral load, prior treatment experience to see where response is lower, so intervention can be tailored.
- **Real-world implementation**: Ensuring that these high rates seen in study settings can be replicated in community clinics and less resourced settings in KPK and other provinces.
- **Cost-effectiveness and access**: Work to reduce barriers to treatment (diagnostics, drug cost, patient education) to scale up therapy to more patients.

Conclusion: Our findings support that sofosbuvir-based regimens deliver high rates of virological response (SVR12) in chronic Hepatitis C patients in Abbottabad, comparable to other regions of Pakistan. This supports the use of these regimens for HCV elimination efforts in KPK. The high rates among both genders and overall suggest that with adequate resources, commitment, and monitoring, treatment goals are achievable.

Author's Contribution:

SA: Conceived and designed the study, involved in data collection, performed statistical analysis and writing the manuscript.
MA: Collected the data, critical review and preparation of manuscript.

All authors have read, approved the final manuscript and are responsible for the integrity of the study.

References:

1. KQ de Andrade, FA Moura, JM dos Santos, OR de Araujo, JC de Farias Santos, and MO Goulart, "Oxidative stress and inflammation in hepatic diseases: Therapeutic possibilities of N-acetylcysteine," Int. J. Mol. Sci., vol. 16, no. 12, pp. 30269-30289, 2015.

2. S. Pascual, I. Herrera, and J. Irurzun, "New advances in hepatocellular carcinoma," World J. Hepatol., vol. 8, no. 9, pp. 421–438, 2016. doi: 10.4254/wjh.v8.i9.421.
3. World Health Organization. Hepatitis C. Geneva: World Health Organization; 2023 [cited 2025 Oct 10]. Available from: https://www.who.int/news-room/fact-sheets/detail/hepatitis-c

4. A. Petruzziello, S. Marigliano, G. Loquercio, A. Cozzolino, and C. Cacciapuoti, "Global epidemiology of hepatitis C virus infection: An up-date of the distribution and circulation of hepatitis C virus genotypes," World J. Gastroenterol., vol. 22, no. 34, pp. 7824–7840, 2016. doi: 10.3748/wjg.v22.i34.7824.
5. M. Umer and M. Iqbal, "Hepatitis C virus prevalence and genotype distribution in Pakistan: Comprehensive review of recent data," World J. Gastroenterol., vol. 22, no. 4, pp. 1684–1700, 2016.
6. World Health Organization, Global Hepatitis Report 2017. Geneva: World Health Organization, 2017. [Online]. Available: https://www.who.int/publications/i/item/9789241565455
7. M. Asato, B. Lagana, G. Antonelli, F. Dianzani, and L. Bonomo, "Long-term results of therapy with interferon-alpha for type II essential mixed cryoglobulinemia," Blood, vol. 78, no. 12, pp. 3142–3147, 1991.
8. F. Zoulim, T.J. Liang, A.L. Gerbes, A. Aghemo, S. Deuffic-Burban, G. Dusheiko, et al., "Hepatitis C virus treatment in the real world: optimising treatment and access to therapies," Gut, vol. 64, no. 11, pp. 1824–1833, 2015. doi: 10.1136/gutjnl-2014-308594.
9. T. Kanda, S. Nakamoto, M. Nakamura, X. Jiang, T. Miyamura, S. Wu, et al., "Direct-acting antiviral agents for the treatment of chronic hepatitis C virus infection," J. Clin. Transl. Hepatol., vol. 2, no. 1, pp. 1–6, 2014. doi: 10.14218/JCTH.2014.00002.
10. J.M. Pawlotsky, "Hepatitis C virus resistance to direct-acting antiviral drugs in interferon-free regimens," Gastroenterology, vol. 151, no. 1, 2016. doi: 10.1053/j.gastro.2016.04.039.
11. M.G. Ghany and T.R. Morgan, "Hepatitis C guidance 2023 update: AASLD-IDSA recommendations for testing, managing, and treating hepatitis C virus infection," Hepatology, vol. 78, no. 2, pp. 479–500, 2023. doi: 10.1002/hep.32173.
12. M. Umer and M. Iqbal, "Hepatitis C virus prevalence and genotype distribution in Pakistan: Comprehensive review of recent data," World J. Gastroenterol., vol. 22, no. 4, pp. 1684–1700, 2016. doi: 10.3748/wjg.v22.i4.1684.
13. N. Butt, A. Saleem, M.A. Khan, and A. Akbar, "Effectiveness of Sofosbuvir and Daclatasvir in treatment of Hepatitis C: An experience of tertiary care hospital in Karachi," Pakistan J. Med. Sci., vol. 37, no. 7, pp. 2014–2019, 2021. doi: 10.12669/pjms.37.7.3967.
14. Z. Ullah, S.Z. Khan, H. Lodhi, H. Khan, R. Hidayat, and M. Ahmed, "Efficacy of Sofosbuvir and Daclatasvir in achieving the end treatment response and sustained viral response in patients infected with Hepatitis C virus genotype 3," Pak. Armed Forces Med. J., vol. 72, no. 3, pp. 1074–1077, Jun. 2022.
15. W. Agha, G. Hassan, S. Hussain, and M.N. Aslam, "Effectiveness of Sofosbuvir and Velpatasvir combination in chronic Hepatitis C," Pakistan J. Med. Health Sci., vol. 16, no. 8, p. 790, 2022.
16. Ather HM, Shahid A, Usama M, Amir M, Mahmood A, Waheed U (2023). "Efficacy of Velpatasvir and Sofosbuvir Combination Therapy in Chronic HCV Patients." Annals of Punjab Medical College.;17(2):179 182.