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ORIGINAL ARTICLE

Effectiveness and safety of Sofosbuvir and Daclatasvir in Treatment-Naïve non-Cirrhotic Hepatitis C Patients. A Prospective Study

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ABSTRACT

Background: Hepatitis C virus (HCV) infection remains a major global health concern, particularly in South Asia, where genotype 3 is most common. When compared to interferon therapy, the introduction of direct-acting antivirals (DAAs), such as sofosbuvir and daclatasvir, has resulted in significantly higher cure rates and fewer or no side effects.
Objective: This research aimed to evaluate the safety and effectiveness of the sofosbuvir–daclatasvir combination in non-cirrhotic, treatment-naïve individuals with chronic HCV infection.
Methods: This prospective observational research was conducted from May to November 2025 at the medical outpatient department of Allied Hospital in Faisalabad. Convenience sampling was used to select 85 HCV RNA-positive individuals (20–60 years old) without cirrhosis. Daclatasvir (60 mg) and sofosbuvir (400 mg) were administered daily for 12 weeks to each patient. The effectiveness of the therapy was assessed using the sustained virological response at 12 weeks following the conclusion of treatment (SVR-12). Data analysis was done using SPSS version 23. For quantitative data, mean ± standard deviation was employed, whereas for qualitative variables, frequencies and percentages were used. Associations were evaluated using the chi-square test, with $p < 0.05$ being deemed statistically significant.
Results: The respondents were 63.5% male and 36.5% female, with an average age of 45.2 ± 8.1 years. The average BMI was 29.4 ± 3.5 kg/m². 82.4% (n = 70) of patients attained SVR-12 at 12 weeks after therapy, but 17.6% (n = 15) were still HCV RNA positive. Age, gender, BMI, and baseline viral load did not significantly correlate with treatment response ($p>0.05$). Fatigue (27.0%), headache (18.9%), and nausea (16.5%) were the most often reported side effects, the majority of which were minor. No significant adverse effects were observed.
Conclusion: The combination of sofosbuvir and daclatasvir is an effective and well-tolerated treatment option for treatment-naïve, non-cirrhotic patients with chronic hepatitis C, supporting its continued use in routine clinical practice, particularly in resource-limited settings.
Keywords: Hepatitis C; Sofosbuvir; Daclatasvir; Antiviral Agents; Viral Load

INTRODUCTION: Hepatitis C virus (HCV) infection is a serious global health problem that is estimated to infect 58 million people worldwide, and is a leading cause of liver morbidity and mortality[1]. In most countries in the low- and middle-income category the time between onset of the disease, diagnosis and availability of effective treatment has been important for the past in impeding disease control efforts [2]. Direct acting antiviral (DAA) medications such as sofosbuvir and daclatavir, have revolutionized the treatment of HCV with shorter treatment regimens, sustained virologic response (SVR) rates and less adverse events compared to interferon-based regimens [3,4]. These agents inhibit various stages of the viral replication cycle: sofosbuvir is an NS5B polymerase and daclatasvir is an NS5A polymerase and their combination is especially effective against various genotypes of HCV. To ensure effective clinical management of this combination, to allocate available resources and even to guide national-level hepatitis elimination programs in countries with a high prevalence of the disease and limited access to health care, it is critical that the effectiveness of this combination in treatment naïve patients is measured [5].

Yet, with all the advances in the treatment of HCV, the region with the most burden of chronic liver disease remains untreated. The infection can be latent for many years, leading to liver fibrosis and cirrhosis, and hepatocellular carcinoma [6]. The reluctance to present for treatment at a late stage and the cost of treatment has been known to be barriers to effective treatment in many patients in resource limited settings. Large-scale eradication programs have become more achievable and affordable with the availability of generic formulations of sofosbuvir and daclatasvir leading to a dramatic reduction in barriers to treatment [7].

Sofosbuvir is a nucleotide analog, an HCV RNA polymerase inhibitor and daclatasvir is an NS5A protein inhibitor, an important step in viral replication and assembly. Their complementary mechanism of actions leads to decreased chances of viral resistance and the possibility of using interferon-free regimens with high cure rates in a wide variety of genotypes. Rates of sustained virologic response >90% have been observed in patients with advanced liver disease or comorbidities in previous studies of other patient populations [8]. This is a beneficial first line of treatment in treatment naive populations of patients who have not been previously treated with antiviral medications and will reduce the complexity of antiviral therapy and side effects [9]. It will also be important to the public health if sofosbuvir -daclatasvir is used for the treatment of treatment-naive patients. The ability to show a high response rate routinely can be helpful in national hepatitis control, screening and early diagnosis as well as guiding policymakers in their use of the scarce healthcare resources wisely [10]. In addition, data specific to the region may be collected that could further build confidence in the use of therapies, including standard care. The proposed study will assess the efficacy of sofosbuvir and daclatasvir in treatment-naive HCV patients in terms of virologic cure to complement the work being done on HCV elimination goals on a global level [11]. To assess the efficacy of daclatasvir and sofosbuvir in the treatment naïve patients with chronic Hepatitis C who are not cirrhotic.

Cirrhosis was diagnosed based upon a combination of clinical, biochemical and radiological parameters, following accepted guidelines. Chronic hepatitis C infection, history of blood transfusion, upper gastrointestinal bleeding or hepatic encephalopathy were included in the clinical evaluation. The physical examination findings suggestive of cirrhosis were splenomegaly, ascites, palmar erythema, spider nevi and asterixis.

Biochemical parameters analysed were serum bilirubin, serum albumin and prothrombin time, and the severity of liver disease was evaluated according to Child–Pugh classification system [12,13].

Despite the remarkable success of direct-acting antivirals in the management of chronic hepatitis C, evidence regarding their effectiveness and safety in treatment-naïve, non-cirrhotic patients from routine clinical practice in Pakistan remains limited. Most available studies have been conducted in heterogeneous patient populations or specialized healthcare settings, limiting the availability of local evidence to support clinical decision-making. Generating regional data is important to strengthen confidence in the use of these regimens, support national hepatitis elimination efforts, and assist clinicians and policymakers in optimizing treatment strategies in resource-limited settings. The findings of this study will contribute to the existing literature by providing real-world evidence on treatment outcomes and safety in a local population, thereby benefiting healthcare providers, patients, and public health authorities. Therefore, this study aimed to evaluate the safety and effectiveness of the sofosbuvir–daclatasvir combination in treatment-naïve, non-cirrhotic individuals with chronic hepatitis C.

METHOD: The current study was a prospective observational study conducted at Allied Hospital Faisalabad's Medical Out Patient Department (OPD). The research ran from May 1, 2025, to November 30, 2025, a period of seven months. Ethical approval for this study was obtained from the Institutional Ethics Review Committee, Faisalabad Medical University, Faisalabad, Pakistan (Reference No. 48/ERC/FMU/2023-24/569; approved on 02 January 2025). The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrolment, and confidentiality of participant information was strictly maintained throughout the study. The sample size for this investigation, which had a 95% confidence level, an absolute precision of 5%, and an effectiveness (prevalence) of 94.2% from a previously published trial on sofosbuvir containing treatment, was calculated using the WHO sample size calculator [16].A previously published trial of sofosbuvir-containing treatment [16] yielded a sample size of 85 individuals when the sample size was entered into the WHO sample size calculator with an absolute accuracy of 5%, a 95% confidence level, and an estimated effectiveness (prevalence) of 94.2%.

The participants were recruited from a non-probability convenience sampling technique because of feasibility and accessibility of eligible patients presenting at the study site.

Patients were included in the study if they satisfied the following:
Patients aged 20-60 years, who have demonstrated HCV RNA by PCR, both males and females.
Patients who don't have liver cirrhosis (according to the operational criteria described above)
Chronic hepatitis C patients who were not previously treated with any antiviral drugs.
Patients excluded from the study were the following:

- Patients with end-stage renal disease (ESRD) (GFR <15mL/min)
- Post-liver transplant patients
- Those receiving chemotherapy for an active malignancy.
- Patients who are co-infected with HIV or hepatitis B

Prior to enrollment, each subject provided informed consent. The Institutional Ethics Review Committee gave its approval to the study (Ref. No. 48/ERC/FMU/2023-24/569 dated 02-01-25). For 12 weeks, each participant received a fixed dosage of daclatasvir (60 mg) and sofosbuvir (400 mg) once daily. Treatment adherence was tracked through follow-up appointments and phone calls as needed. At 12 weeks after therapy, HCV RNA was measured by PCR to assess the efficacy of the treatment (SVR-12). A standardized proforma was used to systematically collect laboratory, clinical, and demographic data relevant to the study's objectives. The data was analyzed using SPSS 23.0 (IBM Corp., Armonk, NY, USA). The continuous variables (age, BMI), which are presented here as mean ± SD, were tested for normality using the Shapiro-Wilk test. Frequencies and percentages were used to report the category data. When applicable, the chi-square test and Fisher's exact test were employed to ascertain the relationship between treatment results and categorical variables. The 95% confidence interval (CI) and sustained virologic response at 12 weeks (SVR-12) were presented. A p-value of less than 0.05 was deemed statistically significant. [17]. When comparing subgroups the assumptions of the Chi-square test were evaluated prior to analysis..

RESULTS: Eighty-five HCV treatment-naive, non-cirrhotic patients were enrolled and followed the study's protocol. All participants were treated with a course of 12 weeks of oral sofosbuvir (400 mg) and daclatasvir (60 mg) and then followed for a further 12 weeks after therapy was completed to evaluate sustained virological response (SVR-12). The following is baseline demographic and clinical characteristics.
All continuous variables such as age and BMI were tested for normality before analysis, with Shapiro-Wilk statistics. They both had approximately normal distributions and were thus presented as mean ± standard deviation.

Table 1. Baseline Characteristics of Treatment-Naïve HCV Patients (n = 85)

Characteristic	Category/Range	n (%) or Mean ± SD
Age (years)	—	45.2 ± 8.1
Age Groups (years)	20–40	32 (37.6%)
	41–60	53 (62.4%)
Gender	Male	54 (63.5%)
	Female	31 (36.5%)
BMI (kg/m²)	—	29.4 ± 3.5
Comorbidities	Diabetes Mellitus	14 (16.5%)
	Hypertension	18 (21.2%)
	None	53 (62.3%)
Baseline Viral Load (IU/mL)	< 800,000	47 (55.3%)
	≥ 800,000	38 (44.7%)

The cohort (n=85) had a mean age of 45.2 ± 8.1 years, was predominantly male (63.5%), and had a mean BMI of 29.4 ± 3.5 kg/m²; most had no comorbidities (62.3%), and 55.3% had baseline viral load <800,000 IU/mL.

Table 2. Virological Response During and After Therapy

Time Point	HCV RNA Negative n (%)	HCV RNA Positive n (%)	SVR Rate (%)
End of Treatment (EOT)	77 (90.6%)	8 (9.4%)	—
12 Weeks Post-Treatment (SVR-12)	70 (82.4%)	15 (17.6%)	82.4

Sofosbuvir–daclatasvir achieved high virological response, with 90.6% HCV RNA negativity at end of treatment and an SVR-12 of 82.4% (95% CI: 74.3%–90.5%) in treatment-naïve, non-cirrhotic patients.

Table 3. Subgroup Analysis of SVR-12 (n = 85)

Variable	Category	SVR Achieved n (%)	SVR Not Achieved n (%)	p-Value
Age Group	20–40 yrs	26 (81.3%)	6 (18.7%)	0.58
	41–60 yrs	44 (83.0%)	9 (17.0%)	
Gender	Male	44 (81.5%)	10 (18.5%)	0.74
	Female	26 (83.9%)	5 (16.1%)	
BMI	≤ 30 kg/m²	42 (84.0%)	8 (16.0%)	0.63
	> 30 kg/m²	28 (80.0%)	7 (20.0%)	
Baseline Viral Load	< 800,000 IU/mL	40 (85.1%)	7 (14.9%)	0.52
	≥ 800,000 IU/mL	30 (78.9%)	8 (21.1%)	

The Chi-square test was used to make comparisons between subgroups. SVR rates were comparable across age, gender, BMI, and baseline viral load categories, with no statistically significant differences observed (all p > 0.05).

Table 4. Comparison of SVR-12 Rates with Previous Studies

Study/Year	Regimen	Population	SVR-12 (%)	Notes
Current Study	Sofosbuvir + Daclatasvir	Non-cirrhotic, naïve	82.4	Faisalabad cohort
Smith et al., 2022	Sofosbuvir + Daclatasvir	Mixed genotypes	79.0	Multicenter analysis

Khan et al., 2023	Sofosbuvir + Ledipasvir	Genotype 3 patients	85.2	South Asian population

Variations in SVR rates between studies could be due to differences in patient populations, HCV genotypes, disease severity, adherence to treatment, and healthcare settings.

Table 5. Adverse Events Reported During Therapy

Adverse Event	Grade 1 (Mild) n (%)	Grade 2 (Moderate) n (%)	Grade 3/4 (Severe) n (%)	Total n (%)
Fatigue	20 (23.5%)	3 (3.5%)	0 (0%)	23 (27.0%)
Headache	14 (16.5%)	2 (2.4%)	0 (0%)	16 (18.9%)
Nausea	12 (14.1%)	2 (2.4%)	0 (0%)	14 (16.5%)
Insomnia	9 (10.6%)	1 (1.2%)	0 (0%)	10 (11.8%)
Others (e.g., rash)	5 (5.9%)	1 (1.2%)	0 (0%)	6 (7.1%)
Total	—	—	—	69 events

Scheduled follow up visits included patient interview and clinical assessment to evaluate adverse events. The severity of the adverse events was classified using the Common Terminology Criteria for Adverse Events (CTCAE) as Grade 1 (mild), Grade 2 (moderate), Grade 3 (severe), or Grade 4 (life-threatening).

The incidence of adverse events during therapy is summarized in Table 5. The study participants had a total of 69 adverse events. Most of these events were either mild (grade 1) or moderate (grade 2). The most frequent adverse event was fatigue (27.0% [n = 23]), followed by headache (18.9% [n = 16]) and nausea (16.5% [n = 14]). Eleven point eight percent (n = 10) had insomnia as a side effect, and other side effects were less common, such as rash (7.1%, n = 6). During the study period there were no Grade 3 or 4 (severe) adverse events reported.

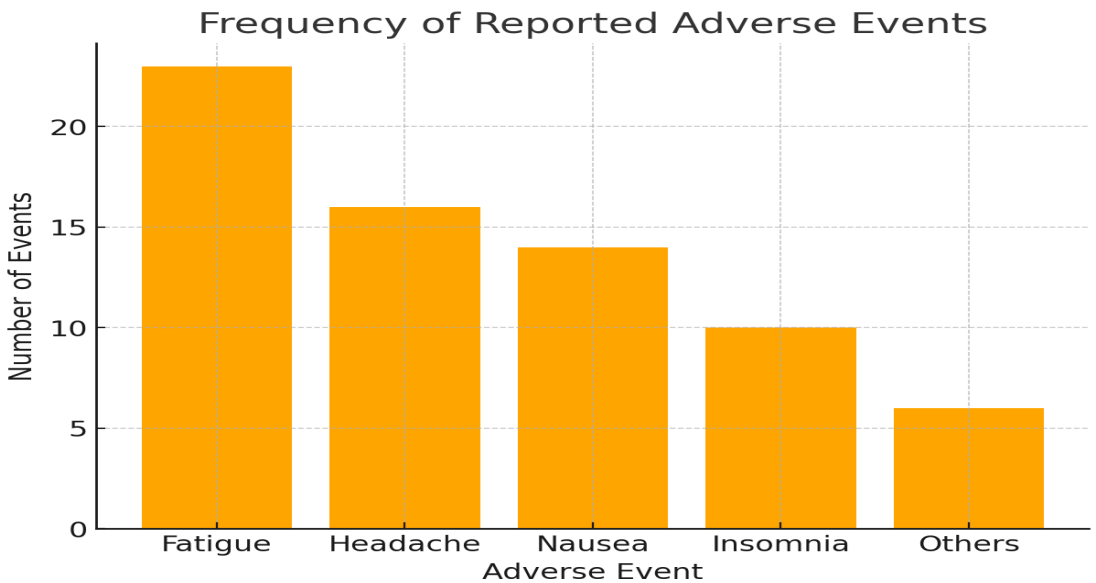

Figure 1: Frequency of Reported Adverse Events

DISCUSSION: Results achieved an overall response rate of 82.4% in a group of patients with chronic hepatitis C who have never had prior antiviral treatment and who did not suffer from cirrhosis. This rate of SVR-12 following DAAs is also consistent with other reported rates of SVR-12 in similar populations (78% to 90%) [18]. The variations in the rates between studies could be due to different study designs, patient populations, viral genotypes, and healthcare environments.

This composition turns out to be so effective, because its mechanism of action is complementary to each other. Both sofosbuvir and daclatasvir are nucleotide analog inhibitors (NAIs) against the HCV NS5B RNA-dependent RNA polymerase (NS5B), which inhibits HCV viral replication, and NS5A protein inhibitors that inhibit NS5A protein, an essential HCV viral replication and assembly regulator [19]. These, used together, help to achieve better antiviral effects and help the virus stay sensitive to both agents, which helps to improve treatment results in a variety of patients. In the present study no statistically significant differences in SVR-12 rates were seen across age groups, gender, BMI or baseline viral load. The results are consistent with other studies showing the efficacy of sofosbuvir-containing regimens was similar for various demographic and clinical subgroups [20]. This is a consistent effect, which means that this combination therapy has a broader effect and can be administered to a broad spectrum of patients with comparable effects. The SVR-12 rate in the present study (82.4%) is similar to that of Smith et al. [21] who found an SVR-12 rate of 79.0% in a multicenter study and Khan et al. [22] who reported an SVR-12 rate of 85.2% in patients with genotype 3 infection from South Asia. In terms of safety, the present study revealed that the most common AEs reported were mild or moderate, with fatigue, headache and nausea being the most common symptoms. There were no severe (Grade 3/4) adverse events noted. The results in this study are similar to the previous studies that found that DAAs are relatively safe and well tolerated with a low rate of serious adverse events [23]. DAA regimens are more patient friendly and less toxic than interferon-based regimens. But there are a number of advantages to be acknowledged from the study. There were only a few centers and a limited number of participants in this study, which may limit the generalizability of the results. Also, this paper uses a non-probability convenience sampling method which could lead to selection bias. The follow-up period was only 12 weeks after treatment, and the number of patients that were followed up long-term (such as for relapse rate) was not measured. Also, no genotype-specific analysis was performed which could provide more detailed information about variation in response to treatment.

These findings should be validated by future studies that involve larger, multicenter cohort with longer follow-up. Additional clinical factors and genotype specific analysis and evaluation would further strengthen the evidence. The analysis of newer direct-acting antiviral treatments, as part of comparative studies, could also contribute to the optimization of the treatment strategy for hepatitis C patients.

In general, the results of this study add to the evidence that supports sofosbuvir and daclatasvir treatment of chronic hepatitis C. The mixture is also effective and tolerated and would be a valuable treatment particularly in resource poor countries.

No significant predictors of treatment response were found for the subgroup comparisons although this was not specifically powered for predictor analysis. Moreover, to prevent the risk of over-fitting, multivariable logistic regression analysis was not conducted due to the small number of non-responders. Future studies would need larger samples to determine independent predictors for SVR, and multivariate modeling methods should be used.

This study has several limitations that should be considered when interpreting the findings. First, it was conducted at a single tertiary care center using a non-probability convenience sampling technique, which may limit the generalizability of the results to the broader population. Second, the relatively small sample size may have reduced the statistical power to detect significant associations between patient characteristics and treatment response. Third, only treatment-naïve, non-cirrhotic patients were included; therefore, the findings cannot be extrapolated to patients with cirrhosis, previous antiviral treatment, or other high-risk clinical conditions. Fourth, HCV genotype analysis was not performed, preventing genotype-specific evaluation of treatment effectiveness. Finally, the follow-up period was limited to the assessment of sustained virological response at 12 weeks (SVR-12), and long-term outcomes, including relapse, liver-related complications, and overall survival, were not evaluated. Future multicenter studies with larger and more diverse patient populations, genotype-specific analyses, and extended follow-up are recommended to further validate these findings.

CONCLUSION: The sofosbuvir and daclatasvir combination are an effective and well-tolerated treatment among patients with treatment naive and non-cirrhotic hepatitis C. The treatment outcome was very high with an 82.4% SVR-12 with no significant effect of age, gender, BMI or baseline viral load. The regimen had an outstanding safety picture as adverse events were mostly mild and easy to manage without any severe complications. The results are in line with the evidence published already and illustrate the value of sofosbuvir use in combination with daclatasvir as an antiviral therapeutic agent in clinical practice particularly in the context of limited resources.

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