

Efficacy of Sofosbuvir and Daclatasvir Combination Treatment in Haemodialysis Patients with Chronic Hepatitis C

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ABSTRACT

This study aimed to determine the effectiveness of the Sofosbuvir and Daclatasvir (SOF/DCV) combination treatment in haemodialysis patients with chronic hepatitis C virus (HCV). This prospective interventional study was conducted from October 2023 to April 2024. Sixty patients of either gender, aged 18 to 60 years, with chronic HCV infection who had been on haemodialysis for >3 months were included. All patients received a fixed dose of SOF/DCV. Sustained virologic response (SVR) was assessed three months after completion of therapy. The mean age of the patients was 45 ± 14.32 years, with 31 (51.7%) females and 29 (48.3%) males. SVR was achieved in all cases, indicating a 100% efficacy of SOF/DCV. Furthermore, no side effects were reported. Thus, combination of SOF/DCV is effective and safe for the treatment of HCV infection in haemodialysis patients.

Key Words: Chronic hepatitis C virus, Daclatasvir, Haemodialysis, Sofosbuvir.

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The incidence of hepatitis C virus (HCV) infection is nearly 2.5% globally, while it ranges from 6-11% in Pakistan. Globally, chronic kidney disease (CKD) has emerged as a major concern for community well-being. The prevalence of CKD is >10% worldwide, while in Pakistan it is 23.3%. Most patients progress to end-stage renal disease (ESRD), necessitating haemodialysis (HD) and transplantation. In Pakistan, the frequency of ESRD is estimated to be more than 100 new cases per million.¹

HCV in HD patients is an additional source of infection that not only raises contact risk for other patients and medical personnel but also results in liver and renal disease in individuals themselves, greatly raising the mortality rate. Therefore, HD patients with HCV infection must promptly receive antiviral medication. In the past, interferon- and ribavirin-containing regimens were the only options for treating HCV infection, but these treatments had lower cure rates and unfavourable and severe side effects. Direct-acting antivirals (DAAs), as indicated by international recommendations, have become the therapy of choice for chronic HCV due to their increased efficacy, minimal drug interactions, and excellent safety.²

Nevertheless, studies evaluating the use of DAAs in HD-dependent individuals infected with HCV are scarce in this part of the world. Therefore, the present study aimed to assess the efficacy of the DAA agents, Sofosbuvir and Daclatasvir (SOF/DCV), in the maintenance of HD patients with chronic HCV infection.

This prospective interventional study was carried out over six months from October 2023 to April 2024 at the Department of Nephrology, Liaquat University Hospital, Hyderabad, Pakistan. Before starting the study, ethical approval from the Ethical Review Committee of the hospital (Letter No. LUMHS/REC/-54) was sought. After obtaining informed consent, a total of 60 patients of either gender, aged from 18 to 60 years, with chronic HCV, who were on HD for >3 months, were included using a non-probability consecutive sampling technique. Hepatitis B-positive patients, HIV positive, cirrhotics, and treatment-experienced patients were excluded. Before the initiation of the treatment, all patients underwent complete blood count (CBC), liver function tests (LFTs), prothrombin time/international normalised ratio (PT/INR), alpha-fetoprotein (AFP) tests, abdominal ultrasound, and FibroScan. Blood samples were taken before HD on the same day. SOF (400 mg once daily) and DCV (60 mg once daily) were administered for 3 months as per the KIDGO guidelines. HCV RNA was checked by PCR at weeks 4 and 12 to document sustained virologic response (SVR). Data were entered in a pro-forma and then into SPSS version 26 for analysis. Quantitative variables were defined as mean ± standard deviation (SD), while qualitative variables were expressed as frequencies and percentages.

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Table I: Baseline data of the patients (n = 60).

Parameters	Results
Age (mean ± SD)	45 ± 14.32 years
Duration of dialysis (mean ± SD)	3 ± 0.36 hours
Frequency of dialysis per week	
• Once	4 (6.6%)
• Twice	42 (70%)
• Thrice	14 (23.3%)
Gender	
• Males	29 (48.3%)
• Females	31 (51.7%)
Causes of CKD	
• Kidney stones	2(3.3%)
• Bilateral small size kidneys	27 (45%)
• Diabetic kidney disease	12 (20%)
• Autosomal dominant polycystic kidney disease	5 (8.3%)
• Hypertension	8(13.3%)
• Diabetes and hypertension	2 (3.3%)
• Obstructive nephropathy	4 (6.7%)

CKD: Chronic kidney disease.

The mean age of patients was 45 ± 14.32 years. There were 29 (48.3%) males and 31 (51.7%) females. The mean duration of dialysis was 3 ± 0.36 hours. The most common cause of CKD was bilateral small kidneys, accounting for 27 cases (45%) followed by diabetic kidney disease in 12 cases (20%), hypertension in 8 (13.3%), autosomal dominant polycystic kidney disease (ADPKD) in 5 (8.3%), and obstructive nephropathy in 4 (6.7%). Kidney stones and coexisting diabetes with hypertension were observed in 2 (3.3%) patients. Most of the patients had HD twice a week, accounting for 42 (70%) cases (Table I).

All patients were evaluated for SVR at the 12th week post-treatment. All 60 (100%) cases achieved SVR, which shows 100% effectiveness of SOF/DCV combination therapy in chronic hepatitis C patients undergoing HD.

Limited data is available on HCV-infected patients with CKD on HD in Pakistan. Most available studies have evaluated the prevalence, risk factors, genotypes, and treatment outcomes with PEG-interferon rather than DAAs. Fewer data were available on treatment with DAAs in this group. This study attempted to investigate the efficacy of SOF/DCV combination therapy in Pakistani HD patients with chronic HCV infection and found SVR response in 100% of cases. The results of this study align with a meta-analysis that demonstrated 97% effectiveness of SOF-based regimens in individuals with advanced CKD.³ Ghanaat *et al.*³ found the combination of SOF/DCV effective in 97.5% of cases.⁴

Patients with HCV infection receiving continuous HD were prospectively enrolled by Cheema *et al.* and randomly allotted to two groups: Group 1 received 400 mg SOF and 60 mg DCV daily, whereas Group 2 received 400 mg SOF daily and 60 mg DCV three times a week for a period of 12 weeks. HCV viral load was evaluated at weeks 4 and 8, at the conclusion of treatment, and 3 months post-treatment. According to their findings, at the 12-week mark, every patient in both groups had an unnoticeable viral load. The authors concluded that daily administration of SOF and DCV,

two DAA medications, was very efficacious and tolerable for patients with HCV receiving maintenance HD.⁵

Lastly, an encouraging result of this study was that nearly all individuals with chronic HCV infection undergoing DAA therapy experienced no side effects during or after treatment. This finding validated previous research that demonstrated SOF-based therapy regimens are well-tolerated in ESRD patients.⁶

The combination of SOF/DCV showed significant efficacy and safety in HD-dependent individuals with chronic HCV infection. However, it is recommended that further studies, with a larger sample size and taking into account variable dosages of the same regimen, should be conducted to validate the findings of the current study. It is also recommended to search further SOF-based regimens in combination with other accessible alternatives.

ETHICAL APPROVAL:

The study was conducted after obtaining ethical approval from the hospital's Ethical Committee.

COMPETING INTEREST:

The authors declared no conflict of interest.

AUTHORS' CONTRIBUTION:

SM, PM: Study design, manuscript writing, data collection, and analysis.

JS: Data collection and manuscript drafting.

AY: Data collection and interpretation.

SR, NM: Data collection and analysis.

All authors approved the final version of the manuscript to be published.

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