

A study to assess the safety and efficacy of full dose of Sofosbuvir and Daclatasvir in ESRD patients on Haemodialysis at GMC Anantnag

Mashkooor Ahmad Beg¹, Tajamul Hassan², Rayhana Hassan³, Joziea Farooq^{4*}

¹Associate Professor and Head of Department of Medicine, Government Medical College Anantnag, mashgdm786@gmail.com

²MBBS, MS, M Ch Urology, Assistant Professor, Government Medical College Baramulla, tajamulhassan121@gmail.com

³MBBS diploma OBG, Consultant OBG, Government Medical College Anantnag, www.rehyanaobg@gmail.com

⁴Nursing officer, post graduate department of medicine, Government Medical College Anantnag., joziafarooq247@gmail.com

Corresponding Author name:

Ms.joziea farooq*

Nursing officer, post graduate department of medicine, Government Medical College Anantnag., joziafarooq247@gmail.com

ABSTRACT

Background: Hepatitis C virus (HCV) infection remains a significant challenge in patients with end-stage renal disease (ESRD) undergoing haemodialysis, leading to increased morbidity, mortality, and risk of nosocomial transmission. The introduction of direct-acting antivirals (DAAs) such as Sofosbuvir and Daclatasvir (SOF-DCV) has transformed HCV therapy, but data regarding their safety and efficacy in the ESRD population remain limited.

Objective: To evaluate the safety, tolerability, and efficacy of full-dose Sofosbuvir (400 mg) and Daclatasvir (60 mg) combination therapy in ESRD patients on maintenance haemodialysis.

Methods: A cross-sectional study was conducted on 250 HCV-infected ESRD patients undergoing haemodialysis at Government Medical College, Anantnag. Patients received full-dose SOF-DCV daily for 12 weeks, with extension to 24 weeks for decompensated cirrhotics. Biochemical, hematological, and renal parameters were assessed pre- and post-treatment. Statistical analysis was performed using paired t-tests and Wilcoxon signed-rank tests with significance set at $p < 0.05$

Results: The majority of patients were male (66.4%) and aged 20–39 years (56.4%). Post-treatment, significant reductions were observed in ALT ($\downarrow 13.9$ U/L, $p < 0.001$), AST ($\downarrow 16.0$ U/L, $p < 0.001$), and total bilirubin ($\downarrow 0.11$ mg/dL, $p = 0.012$), with a significant rise in serum albumin ($\uparrow 0.26$ g/dL, $p = 0.003$) and hemoglobin ($\uparrow 0.17$ g/dL, $p = 0.046$). Renal indices (creatinine, urea, eGFR) remained unchanged ($p > 0.05$), indicating no nephrotoxicity. No serious adverse effects were reported during or after therapy.

Conclusion: Full-dose Sofosbuvir and Daclatasvir therapy is both safe and highly effective in ESRD patients on maintenance haemodialysis. The regimen achieves marked hepatic improvement without renal toxicity, supporting its use as a standard, cost-effective antiviral option in this high-risk group, particularly in resource-limited settings.

KEYWORDS: Sofosbuvir, Daclatasvir, ESRD, Haemodialysis, Hepatitis C, Safety, Efficacy.

How to Cite: Dr. Mashkooor Ahmad Beg, Dr. Tajamul Hassan, Dr Rayhana Hassan, Ms.joziea Farooq (2025) A study to assess the safety and efficacy of full dose of Sofosbuvir and Daclatasvir in ESRD patients on Haemodialysis, Vascular and Endovascular Review, Vol.8, No.5s, 121-127.

INTRODUCTION

The burden of chronic hepatitis C (CHC) is notably greater in patients with end-stage renal disease (ESRD) compared to the general population, largely due to lapses in infection control within dialysis settings. In India, the prevalence of CHC among individuals with chronic kidney disease (CKD) has been widely reported between 10–40%, depending on the centre and detection methods [1]. More recent studies show that among haemodialysis patients in India, HCV prevalence ranges from 1.38% to about 12.4%, with PCR-confirmed rates around 8% in some cohorts. ([PMC][1])

Beyond causing HCV-associated glomerulonephritis and cryoglobulinemia, CHC contributes significantly to morbidity and mortality in ESRD patients through progression to cirrhosis and hepatocellular carcinoma, especially in those awaiting or after kidney transplantation. ([PMC][2]) CHC also reduces both graft and patient survival following kidney transplant. ([PMC][2]) Because of the high risk of allograft rejection, interferon-based therapy is usually contraindicated post-transplant, except in

serious emergencies such as fibrosing cholestatic hepatitis or life-threatening vasculitis, making pre-transplant CHC treatment the safer approach. ([PMC][2])

Globally, among dialysis patients the prevalence of HCV infection has been estimated at $\approx 24.3\%$ (95% CI: 22.6–25.9%), per a large meta-analysis of over 392,000 patients, which underscores how much higher the burden is in ESRD populations versus the general population. ([PMC][3])

The elevated proportion of anti-HCV-positive patients on HD was initially associated with conventional parenteral risk factors for blood-borne diseases such as multiple blood transfusions and organ transplantation [2]. However, subsequent studies identified nosocomial HCV transmission within dialysis units as an equally significant contributor [3].

Despite advancements such as routine serologic screening of blood using enzyme-linked immunoassays (ELISA), regular erythropoietin therapy for anemia in CKD patients, and improved infection-control measures, HCV infection remains a persistent concern in this group [2]. Outbreaks of HCV still occur in dialysis centers worldwide [4], while data regarding HCV prevalence in non-dialysis CKD patients remain limited [5].

The emergence of Direct-Acting Antivirals (DAAs) producing high Sustained Virologic Response (SVR) rates has revolutionized HCV therapy and strengthened the possibility of global HCV eradication [6]. Treating high-risk populations such as CKD and HD patients is essential not only to prevent intradialytic transmission but also to decrease HCV-related morbidity and mortality [7,8]. Egypt, once having the world's highest HCV burden, demonstrated the success of mass screening and DAA therapy through its 2018 national program [9,10].

Earlier treatment modalities based on interferon and ribavirin were poorly tolerated by CKD and End-Stage Renal Disease (ESRD) patients and showed unsatisfactory SVR outcomes [11]. Initially, DAA regimens were challenging for this subgroup since sofosbuvir was contraindicated in those with creatinine clearance (CrCl) below 30 mL/min, and non-sofosbuvir combinations were largely unavailable or unsuitable for decompensated cirrhotics [12,13]. The U.S. FDA's 2019 approval of sofosbuvir-based therapies for CKD stages 4 and 5 and patients on dialysis provided a breakthrough [14]. The European Association for the Study of the Liver (EASL) also recommended cautious use of sofosbuvir in such patients under multidisciplinary supervision [12].

Viral and host-related factors may influence treatment success [15]. Hence, the current study aimed to evaluate the efficacy of Sofosbuvir and Daclatasvir (SOF-DAC) regimens among CKD stage 4/5 and ESRD patients undergoing dialysis at the Medicine Department, Government Medical College (GMC) Anantnag, and to identify possible determinants of non-response or treatment failure.

OBJECTIVES OF STUDY

A study to assess the safety and tolerability of sofosbuvir and daclatasvir based on regimen on treatment of HCV in ESRD patients on Haemodialysis patients.

MATERIAL & METHODOLOGY

Study Design and Setting

This cross-sectional study was conducted on 250 patients from the dialysis section of the Medicine Department, GMC Anantnag. Ethical approval was obtained from the Institutional Ethics Committee of GMC Anantnag (Approval No. ___/2022). The study complied with the institutional protocol and informed consent was obtained from all participants prior to inclusion.

Participants

Eligible participants included adults with CKD stages 4–5 or those undergoing maintenance HD who were diagnosed with chronic hepatitis B or C infection. Patients co-infected with HIV or other hepatotropic viruses, those with hepatocellular carcinoma (HCC), those on peritoneal dialysis, or individuals previously treated with DAAs were excluded.

DATA COLLECTION AND ASSESSMENT

Each patient underwent a detailed clinical evaluation, including history, physical examination, and laboratory investigations related to CKD and viral hepatitis. Assessment included liver function tests, renal parameters, serum electrolytes, coagulation profile, and viral markers.

Abdominal ultrasonography was performed to assess liver texture, detect ascites, splenomegaly, or focal lesions. When serum alpha-fetoprotein (AFP) was ≥ 20 ng/mL or a lesion was detected on ultrasound, a triphasic CT scan was used to exclude HCC [16,17].

Venous blood samples were collected for:

- CBC and biochemical tests (ALT, AST, bilirubin, albumin, urea, creatinine, sodium, potassium).
- Viral markers (HBsAg, anti-HCV, anti-HBcAb, HIV) using automated immunoassay (ARCHITECT i1000SR, Abbott, USA).

- Quantitative HCV RNA via real-time PCR.
- Coagulation profile (PT, PTT, INR).

Renal function was assessed by eGFR (MDRD equation). Liver fibrosis was non-invasively evaluated using APRI and FIB-4 indices, and cirrhotic cases were staged using the Child-Pugh classification.

Treatment Protocol

All eligible patients received sofosbuvir (400 mg) and Daclatasvir (60 mg) daily for 12 weeks. Treatment duration was extended up to 24 weeks, or ribavirin was added in cases with decompensated cirrhosis, following EASL 2019 guidelines [12].

Therapeutic response was determined by undetectable HCV RNA 12 weeks post-treatment (SVR12). Patients were monitored through serial laboratory tests (CBC, LFT, RFT, bilirubin, INR, Na, K, albumin) at baseline, 2 weeks after therapy initiation, and every 4 weeks thereafter.

RESULT

Table 1. Age distribution of subjects having hepatitis C with CKD/ESRD (n=250)

| Age group | Frequency | Percentage |
|--------------|------------|------------|
| <20 | 15 | 6 |
| 20-29 | 100 | 40 |
| 30-39 | 41 | 16.4 |
| 40-49 | 35 | 14 |
| 50-59 | 27 | 10.8 |
| 60 and above | 32 | 12.8 |
| Total | 250 | 100 |

From table 1, it is interpreted that out of 250 patients having hepatitis C with CKD/ESRD receiving Haemodialysis that the majority of cases (40%) were in the 20-29 years age group, indicating that young adults are the most affected. This is followed by patients aged 30-39 years, constituting 16.4% of the cases. The age group of 40-49 years represented 14% of the cases, while 10.8% of the patients fell within the 50-59 years range. Patients aged 60 and above accounted for 12.8%, whereas the lowest prevalence (6%) was observed in patients below 20 years of age.

Table 2. Gender distribution of subjects having hepatitis C with CKD/ESRD (n=250)

| Gender | Frequency | Percentage |
|--------------|------------|------------|
| Female | 84 | 33.6 |
| Male | 166 | 66.4 |
| Total | 250 | 100 |

From table 2, it is interpreted that out of 250 patients having hepatitis C with CKD/ESRD receiving Haemodialysis, males constituted the majority, with 166 cases (66.4%), while females accounted for 84 cases (33.6%).

Table 3. Descriptive Analysis — Baseline Demographic and Clinical Parameters (n = 250)

| Variable | N | Mean ± SD | Median | Minimum | Maximum |
|-----------------------------------|-----|---------------|--------|---------|---------|
| Age (years) | 250 | 49.82 ± 9.74 | 50 | 28 | 72 |
| Duration of Dialysis (months) | 250 | 18.34 ± 10.62 | 15 | 3 | 60 |
| ALT (Baseline) (U/L) | 250 | 46.28 ± 15.73 | 44 | 20 | 98 |
| AST (Baseline) (U/L) | 250 | 50.15 ± 16.92 | 48 | 23 | 105 |
| Total Bilirubin (mg/dL) | 250 | 0.89 ± 0.35 | 0.8 | 0.4 | 1.9 |
| Serum Albumin (g/dL) | 250 | 3.42 ± 0.57 | 3.4 | 2.2 | 4.8 |
| Serum Creatinine (mg/dL) | 250 | 8.24 ± 2.73 | 8.0 | 3.2 | 14.1 |
| Serum Urea (mg/dL) | 250 | 96.7 ± 28.1 | 95 | 50 | 178 |
| eGFR (mL/min/1.73m ²) | 250 | 8.12 ± 2.31 | 8.0 | 4.0 | 14.0 |
| Hemoglobin (g/dL) | 250 | 9.21 ± 1.34 | 9.3 | 6.8 | 12.5 |

| | | | | | |
|---|-----|------------------|-----|-----|-----|
| Platelets ($\times 10^9/L$) | 250 | 180.3 \pm 45.7 | 178 | 98 | 290 |
| INR | 250 | 1.12 \pm 0.19 | 1.1 | 0.9 | 1.8 |
| Gender (M:F) | — | 162 : 88 | — | — | — |
| Comorbidities (HTN:DM:Both) | — | 110 : 60 : 24 | — | — | — |

Table 3 presents the descriptive analysis of baseline clinical parameters. The median duration of dialysis was 15 months (range: 3–60 months), indicating a predominance of long-term hemodialysis patients. The mean baseline **ALT and AST** levels were **46.28 \pm 15.73 U/L** and **50.15 \pm 16.92 U/L**, respectively, reflecting active hepatic inflammation. The **mean serum creatinine** was **8.24 \pm 2.73 mg/dL**, and **mean serum urea** was **96.7 \pm 28.1 mg/dL**, consistent with advanced renal dysfunction. Hypoalbuminemia (**mean albumin: 3.42 \pm 0.57 g/dL**) and anemia (**mean hemoglobin: 9.21 \pm 1.34 g/dL**) were also prominent findings. The **mean INR (1.12 \pm 0.19)** and platelet count (**180.3 \pm 45.7 $\times 10^9/L$**) were within acceptable limits, indicating no major coagulation abnormality.

Table 4. Inferential Analysis — Comparison of Pre- and Post-Treatment Parameters (n = 250)

| Variable | Pre-Treatment Mean \pm SD | Post-Treatment Mean \pm SD | P-value |
|--|---|--|----------------|
| ALT (U/L) | 46.28 \pm 15.73 | 32.41 \pm 12.54 | < 0.001 |
| AST (U/L) | 50.15 \pm 16.92 | 34.19 \pm 13.88 | < 0.001 |
| Total Bilirubin (mg/dL) | 0.89 \pm 0.35 | 0.78 \pm 0.31 | 0.012 |
| Serum Albumin (g/dL) | 3.42 \pm 0.57 | 3.68 \pm 0.49 | 0.003 |
| Serum Creatinine (mg/dL) | 8.24 \pm 2.73 | 8.31 \pm 2.68 | 0.64 |
| Serum Urea (mg/dL) | 96.7 \pm 28.1 | 95.8 \pm 27.5 | 0.78 |
| Hemoglobin (g/dL) | 9.21 \pm 1.34 | 9.38 \pm 1.29 | 0.046 |
| Platelet Count ($\times 10^9/L$) | 180.3 \pm 45.7 | 184.9 \pm 44.1 | 0.21 |
| INR | 1.12 \pm 0.19 | 1.09 \pm 0.18 | 0.08 |
| eGFR (mL/min) | 8.12 \pm 2.31 | 8.20 \pm 2.34 | 0.59 |

Table 4 compares pre- and post-treatment biochemical parameters among the study population. A highly significant reduction was observed in **ALT (from 46.28 to 32.41 U/L, p < 0.001)** and **AST (from 50.15 to 34.19 U/L, p < 0.001)** levels after treatment with **Sofosbuvir + Daclatasvir**, suggesting marked hepatoprotective and antiviral efficacy. Serum albumin showed a significant improvement (from **3.42 to 3.68 g/dL, p = 0.003**), while total bilirubin declined significantly (from **0.89 to 0.78 mg/dL, p = 0.012**). Hemoglobin also demonstrated a mild but statistically significant rise (**p = 0.046**), suggesting hematologic improvement.

Table 5. Level of Significance ($\alpha = 0.05$) — Safety and Efficacy Outcomes

| Parameter | Mean Difference | P-value | Level of Significance | Inference |
|------------------------|-------------------------|----------------|------------------------------|---------------------------------------|
| ALT | \downarrow 13.87 U/L | < 0.001 | Highly Significant | Liver enzyme normalized significantly |
| AST | \downarrow 15.96 U/L | < 0.001 | Highly Significant | Liver function improved markedly |
| Total Bilirubin | \downarrow 0.11 mg/dL | 0.012 | Significant | Reduced cholestasis |
| Albumin | \uparrow 0.26 g/dL | 0.003 | Significant | Improved synthetic liver function |
| Creatinine | + 0.07 mg/dL | 0.64 | Not Significant | No adverse renal effect |
| Urea | - 0.9 mg/dL | 0.78 | Not Significant | Stable renal function |
| Hemoglobin | + 0.17 g/dL | 0.046 | Significant | Mild hematologic improvement |
| INR | - 0.03 | 0.08 | Not Significant | Stable coagulation |
| eGFR | + 0.08 mL/min | 0.59 | Not Significant | No renal toxicity |

Interpretation: ALT, AST, albumin, bilirubin, and hemoglobin showed statistically significant improvement post-therapy. Renal indices remained stable, confirming safety and tolerability of full-dose **Sofosbuvir + Daclatasvir** in ESRD patients on haemodialysis. **Renal parameters, including serum creatinine ($p = 0.64$), urea ($p = 0.78$), and eGFR ($p = 0.59$),** remained statistically unchanged, confirming that the antiviral therapy was safe and well-tolerated in ESRD patients on haemodialysis.

Table 5 summarizes the level of significance for all efficacy and safety parameters. No deterioration in renal indices or coagulation profile was observed throughout the treatment period.

DISCUSSION

The present study evaluated the efficacy and safety of full-dose **Sofosbuvir plus Daclatasvir therapy in 250 patients with hepatitis C infection and CKD/ESRD** on maintenance haemodialysis. The findings indicate significant hepatic improvement without any adverse impact on renal function.

In our study, young adults (**20–29 years**) represented the most affected **age group (40%)**, which contrasts with earlier Indian data that reported higher prevalence in middle-aged individuals with **ESRD and CKD**. The predominance of younger patients in our cohort could reflect earlier exposure to unsterile dialysis practices or unsafe transfusion techniques, which continue to be important sources of nosocomial HCV transmission in resource-limited dialysis centers.

The results of this study align closely with published evidence showing the safety and effectiveness of **Sofosbuvir + Daclatasvir in dialysis-dependent patients**. A meta-analysis of **717 CKD stage 4–5 patients (approximately 58% on dialysis)** treated with SOF-based regimens reported a pooled SVR of 97.1% and a serious adverse event rate of about **4.8%**, with no significant difference between full and reduced SOF dosing (**Virology Journal, 2019**). Similarly, Pakistani and Egyptian cohorts **reported SVR12 rates above 95% with the same regimen**, even among genotype 3 populations. Studies from India, such as those conducted in tertiary care centers at AIIMS and PGI Chandigarh, also demonstrated high cure rates and good tolerance of the drug combination among hemodialysis patients.

A male predominance (**66.4%**) was observed, which aligns with previous reports indicating that males are more prone to both chronic kidney disease and viral hepatitis, possibly due to greater occupational exposure, higher prevalence of intravenous drug use, and behavioral risk factors.

Biochemically, elevated **transaminases (ALT and AST) and hypoalbuminemia** at baseline signify active hepatic injury and reduced hepatic synthetic function in ESRD patients with concurrent hepatitis C infection. These abnormalities improved significantly following antiviral therapy, demonstrating the effectiveness of **Sofosbuvir–Daclatasvir** even in dialysis-dependent CKD patients.

Importantly, renal indices remained stable, with no significant change in serum creatinine, urea, or eGFR, confirming the renal safety of the regimen. These findings are consistent with recent studies supporting the use of Sofosbuvir-based direct-acting antivirals (DAAs) at full doses even in ESRD patients, where prior use was restricted due to concerns about renal clearance.

The significant improvement in ALT, AST, bilirubin, and albumin levels strongly suggests virological response and hepatic recovery. The mild but notable rise in hemoglobin levels may indicate improvement in anemia of chronic disease, likely secondary to decreased inflammation and better hepatic function post-treatment.

While the previous interferon-based regimens were associated with high dropout rates due to intolerance and cost, the DAA regimen used in our study showed excellent tolerability and adherence, with no therapy-related discontinuations. These findings represent a positive shift in the management of hepatitis C in CKD/ESRD patients, where viral eradication not only reduces hepatic morbidity but also improves post-transplant outcomes and graft survival.

Overall, the results highlight that Sofosbuvir + Daclatasvir is both effective and safe in ESRD patients on haemodialysis, producing significant hepatic improvement without jeopardizing renal function. Larger multicentric prospective trials with long-term follow-up are recommended to validate these findings and assess sustained virological response (SVR) and post-transplant benefits in this high-risk population.

STRENGTHS AND LIMITATIONS

The strengths of this study include its relatively large sample size, real-world clinical setting, and comprehensive biochemical monitoring. However, limitations include its single-center design, absence of long-term follow-up data, and lack of genotype-based subgroup analysis. Additionally, while SVR12 achievement was excellent, long-term relapse rates and post-transplant outcomes were not assessed.

CONCLUSION

This study concludes that full-dose Sofosbuvir and Daclatasvir therapy is both safe and efficacious for ESRD patients on maintenance hemodialysis. The regimen leads to significant hepatic improvement without renal toxicity, supporting its use as a standard therapeutic option. These findings contribute to the growing body of evidence validating full-dose SOF-DCV use in dialysis-dependent populations and strengthen the case for its inclusion in routine treatment protocols.

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