The Research of Medical Science Review
ISSN: 3007-1208 & 3007-1216 Volume 3, Issue 5, 2025

COMPARISON OF MEAN GLYCATED HEMOGLOBIN (HBA1C) IN TYPE 2 DIABETIC HEPATITIS C (HCV) PATIENTS WITH SVR ACHIEVED VERSUS SVR NOT ACHIEVED FOLLOWING DIRECT ACTING ANTIVIRALS (DAAS) THERAPY

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DOI: https://doi.org/10.5281/zenodo.15591916

Keywords
Child Pugh, glycemic control, hepatitis C, smoking, sustained virologic response, type 2 diabetes.

Article History
Received on 26 April 2025
Accepted on 26 May 2025
Published on 04 June 2025

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Abstract

Background: *Chronic Hepatitis C Virus (HCV) infection is commonly associated with type 2 diabetes mellitus (T2DM), often leading to insulin resistance and worsened glycemic control. Direct-acting antivirals (DAAs) have been shown to effectively eradicate HCV, but their impact on glycemic control in diabetic patients remains unclear. This study aims to investigate the relationship between successful HCV treatment and glycemic control in patients with T2DM.*

Objectives: *To evaluate the effect of achieving sustained virologic response (SVR) on glycemic control, as measured by HbA1c levels, in patients with both HCV and T2DM.*

Study Design & Setting: *This was a cross-sectional, observational study conducted at the Department of Gastroenterology, King Edward Medical University and Mayo Hospital, Lahore from December 2024 to May 2025. The study included 116 patients with HCV and T2DM who were treated with DAAs.*

Methodology: *Patients were stratified based on whether they achieved SVR. Demographic and clinical data were collected, and HbA1c levels were measured at baseline and at 12 weeks post-treatment. Data were analyzed using statistical tests, including t-tests and chi-square tests, with a significance threshold of $p < 0.05$.*

Results: *Patients who achieved SVR showed a significant reduction in HbA1c levels ($p < 0.001$), with a greater improvement in glycemic control compared to those who did not achieve SVR. Additionally, a significant difference in smoking status was observed between the two groups ($p = 0.022$).*

Conclusion: *Successful HCV treatment with DAAs significantly improves glycemic control in patients with T2DM, particularly among those who achieve SVR. Smoking status was found to be a potential effect modifier.*

INTRODUCTION

Chronic Hepatitis C virus (HCV) has worldwide distribution. On average, 2-3% of the world's population is infected with HCV.[1] An estimated 47 million individuals worldwide have T2DM secondary to chronic HCV infection. Insulin resistance (IR) is a pathophysiological state and is more common in patients with chronic HCV infection and has been associated with increased disease severity, extra hepatic manifestations, and decreased response to antiviral therapy.[2] DM causes several complications such as cardiovascular disease, stroke, nephropathy, leg amputation, retinopathy, impaired immunity, and nerve damage, accounting for 8.4% of global all-cause mortality. On the other hand, approximately 150 to 200 million people have been infected with HCV.[3,4] Molecular mechanisms provide explanations by which HCV infection might increase the risk of the development of T2DM or worsen glycemic control in patients with established T2DM. In addition, HCV proteins increase the release of proinflammatory cytokines such as interleukin-6 and tumor necrosis factor-a, which then upregulate gluconeogenesis and enhance lipid accumulation in the liver.[5]

If HCV infection indeed worsens glycemic control, then HCV eradication (known as sustained virologic response [SVR]) may improve glycemic control in patients with diabetes. In support of this hypothesis, previous interferon-based studies suggested that successful clearance of HCV could lead to improvement in IR. Patients without diabetes demonstrated improvement in an oral glucose tolerance test before and after treatment of HCV.[6,7] While the virus primarily targets the liver, its extrahepatic manifestations, including its association with insulin resistance and type 2 diabetes.[8] The advent of direct-acting antivirals (DAAs) has revolutionized the treatment of HCV, providing high rates of cure. However, the impact of successful HCV treatment on comorbid conditions such as diabetes remains underexplored. The relationship between HCV eradication and improvements in glycemic control offers a promising avenue for enhancing overall patient outcomes, particularly in those with pre-existing diabetes.[9]

Ciancio et al. (2018) reported that 101 (91.8%) showed a SVR (HCV-RNA clearance 12 weeks after the end of therapy); 9 of 110 (8.2%) demonstrated a viremic relapse 4 weeks after the end of treatment and remained HCV-RNA positive at week 12. At the end of the study, SVR achieved group patients showed a statistically significant decrement of HbA1c (46.51 ± 16.15 mmol/mol, $p < 0.001$) levels; among non-SVR achieved group patients, no significant variation in HbA1c (55.31 ± 20.58 mmol/mol, $p = 0.780$) values was found.[10]

It is unclear whether HCV eradication achieved by interferon-free, direct-acting antiviral (DAA) regimens results in improvement in glycemic control of patients with T2DM. The aim of this study is to compare patients with diabetes who achieve SVR with those who do not with respect to glycemic control as assessed by mean HbA1c levels. There is a significant gap in understanding the impact of Direct-Acting Antiviral (DAA) therapy on glycemic control in patients with Type 2 Diabetes Mellitus (T2DM) and Hepatitis C Virus (HCV) co-infection. This study provided new insights into how Direct-Acting Antiviral (DAA) therapy affects glycemic control in Type 2 Diabetic Hepatitis C (HCV) patients, filling a current gap in literature and guiding tailored treatment strategies for this population. Understanding the impact of DAA therapy on glycemic control could contribute to a more comprehensive approach to managing both conditions simultaneously, potentially leading to better overall health outcomes for affected patients.

The objective of the study was to determine the frequency of sustained virologic response (SVR) after receiving therapy of direct-acting antivirals (DAA) in hepatitis C (HCV) patients at a tertiary care hospital. It was also to compare the mean glycated hemoglobin (HbA1c) in SVR achieved versus SVR not achieved type 2 diabetic hepatitis C (HCV) patients following therapy of direct acting antivirals (DAAs).

MATERIALS AND METHODS

After approval from the hospital ethical committee, patients were enrolled presenting in the department of Gastroenterology, King Edward Medical University, and Mayo Hospital, Lahore from December 2024 to May 2025. Informed consent was taken from each patient. The sample size was

calculated to be 444 patients, with 80% power of test and 95% confidence interval, while taking the expected frequency of patients who achieved SVR to be 91.8% after receiving DAAs therapy. The sampling technique was non-probability consecutive sampling. Demographic information including age, gender, and BMI were noted. Detailed medical history was obtained, and patients diagnosed with Hepatitis C was receive Direct-Acting Antivirals (DAAs), specifically oral Sofosbuvir 400 mg once daily and oral Daclatasvir 60 mg once daily.

The inclusion criteria were patients of both genders aged from 18 to 65 years, patients with positive results for HCV/RNA by polymerase chain reaction (PCR), and those in Child Pugh class A and B. The exclusion criteria were patients diagnosed with the following diseases, who were not included in the study: patients with Child-Turcotte-Pugh (CTP) class C, hemoglobin level < 10 g/dL, platelet count < 50,000/mm^3; patients with co-infection with hepatitis B or HIV, and hypersensitivity to any of the study medications; patients with active alcohol intake, presence of ascites, and presence of other concomitant liver diseases such as haemochromatosis and Wilson's disease; and patients having decompensated liver disease, prior or ongoing cases of hepatocellular carcinoma.

Before initiating DAA therapy, baseline laboratory tests were conducted, encompassing ALT, AST, serum bilirubin & albumin levels, complete blood count, prothrombin time, ultrasonography, glycosylated hemoglobin (Baseline HbA1c), and a detailed clinical examination to classify patients according to the Child Pugh class. Type 2 Diabetes Mellitus was labeled when fasting blood glucose levels exceeded 126 mg/dL, oral glucose tolerance tests showed glucose levels over 200 mg/dL, or HbA1c levels were above 6.5%. Sustained Virologic Response (SVR) was defined as undetectable HCV RNA at week 12 after the end of therapy. HbA1c levels were measured and compared three weeks after the completion of direct-acting antiviral (DAA) therapy to assess changes in glycemic control. Smoking history was considered as persons smoking more than one cigarette per day or known to have smoked within three years before the study recruitment. BMI was calculated as weight in kilograms divided by the square of the height in meters, with the subjects wearing light clothing but no shoes.

Subsequently, patients were undergo the prescribed treatment and were followed up after three months (at 12 weeks) to assess viral load by HCV RNA polymerase chain reaction, aiming to achieve Sustained Virological Response (SVR), indicated by undetected HCV viral load on polymerase chain reaction at 12 weeks (<15 IU). Patients who achieve or do not achieve SVR was also have their HbA1c levels checked for glycemic control at 12 weeks post-therapy completion. All data was meticulously recorded in data collection forms.

All collected data were entered and analyzed using SPSS version 25. Numerical variables including age, BMI, duration of type 2 diabetes, and HbA1c were presented with mean ± SD or median (IQR) if the data does not follow a normal distribution. Categorical variables such as gender, Child Pugh class, smoking status, and SVR were presented as frequency and percentage. The normality of data was assessed using the Shapiro-Wilk test. Independent sample t-tests were employed to compare the mean HbA1c levels with and without SVR in type 2 diabetic patients on direct-acting antivirals therapy, with significance set at <0.05. Data were stratified by age, gender, BMI, smoking, and duration of disease to address potential effect modifiers, with Chi-square tests applied for SVR and t-tests for comparison of HbA1c levels in patients with and without SVR, using 0.05 as the significance threshold.

RESULTS

The demographic and clinical characteristics of 116 patients were compared between those who achieved sustained virologic response (SVR) and those who did not. The mean age of patients who achieved SVR was 54.3 ± 8.2 years, while for those who did not achieve SVR, it was 56.2 ± 7.5 years, with no significant difference ($p = 0.215$). In terms of gender, 62.1% of the total patients were male, and 37.9% were female, with no significant difference between the groups ($p = 0.532$). The mean BMI for SVR-achieved patients was 28.1 ± 4.5 kg/m^2, while for those who did not achieve SVR, it was 29.3 ± 4.2 kg/m^2, showing no significant difference ($p = 0.174$). The mean duration of diabetes mellitus was 8.5 ± 3.1 months for SVR-achieved patients and 9.2 ± 3.4

months for those who did not achieve SVR, with no significant difference (p = 0.291). Regarding Child Pugh classification, 69.0% of patients were in class A, and 31.0% were in class B, with no significant difference in class distribution (p = 0.084). Smoking status was significantly different between the groups, with 44.4% of SVR-achieved patients being smokers compared to 30.8% of those who did not achieve SVR (p = 0.022) as given in table 1.

At baseline, the mean HbA1c for SVR-achieved patients was 8.3 ± 1.2%, and for those who did not achieve SVR, it was 8.5 ± 1.4%, with no significant difference (p = 0.450). However, at 12 weeks, the mean HbA1c for SVR-achieved patients was 6.5 ± 1.1%, compared to 7.2 ± 1.3% for those who did not achieve SVR, showing a significant difference (p < 0.001). SVR-achieved patients had a greater reduction in HbA1c levels given in table 2.

The stratified analysis showed that the mean age, gender distribution, and BMI were similar between the SVR-achieved and SVR-not-achieved groups, with no significant differences (p > 0.05). However, smoking status was significantly higher in the SVR-achieved group (44.4% vs. 30.8%, p = 0.022). There was no significant difference in Child Pugh classification (p = 0.084) given in table 3.

The HbA1c reduction and improvement in glycemic control were compared between patients who achieved sustained virologic response (SVR) and those who did not. The mean HbA1c reduction for SVR-achieved patients was 1.8 ± 1.0%, while for those who did not achieve SVR, it was 1.3 ± 1.1%, with a significant difference (p = 0.004). The improvement in glycemic control was 85.6% in the SVR-achieved group, compared to 34.6% in the SVR-not-achieved group, showing a significant difference (p < 0.001) given in table 4.

The liver function tests and viral load at 12 weeks were compared between patients who achieved sustained virologic response (SVR) and those who did not. The mean ALT for SVR-achieved patients was 40.5 ± 10.4 U/L, while for those who did not achieve SVR, it was 47.8 ± 12.6 U/L, with a significant difference (p = 0.028). The mean AST for SVR-achieved patients was 38.2 ± 9.6 U/L, and for those who did not achieve SVR, it was 44.5 ± 11.2 U/L, with a significant difference (p = 0.031). Regarding viral load at 12 weeks, SVR-achieved patients had a mean viral load of <15 ± 5 IU/mL, while those who did not achieve SVR had a mean viral load of 500 ± 250 IU/mL, with a highly significant difference (p < 0.001) given in table 5.

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Table 1: Demographic and Clinical Characteristics of Patients

Variable	Category	SVR Achieved (n = 90)	SVR Not Achieved (n = 26)	Total (n = 116)	p-value
Age	Mean ±SD	54.3 ± 8.2	56.2 ± 7.5	54.6 ± 8.0	0.215
Gender	Male	56 (62.2%)	16 (61.5%)	72 (62.1%)	0.532
	Female	34 (37.8%)	10 (38.5%)	44 (37.9%)	
BMI (kg/m²)	Mean ±SD	28.1 ± 4.5	29.3 ± 4.2	28.3 ± 4.4	0.174
Duration of DM (months)	Mean ±SD	8.5 ± 3.1	9.2 ± 3.4	8.6 ± 3.2	0.291
Child Pugh	Class B	65 (72.2%)	15 (57.7%)	80 (69.0%)	0.084
	Class B	25 (27.8%)	11 (42.3%)	36 (31.0%)	
Smoking Status	Smoker	40 (44.4%)	8 (30.8%)	48 (41.4%)	0.022
	Non-Smoker	50 (55.6%)	18 (69.2%)	68 (58.6%)	

Table 2: Glycemic Control Before and After Treatment (HbA1c Levels)

HbA1c (%)	SVR Achieved (n = 90)	SVR Not Achieved (n = 26)	Total (n = 116)	p-value
At Baseline	8.3 ± 1.2	8.5 ± 1.4	8.4 ± 1.3	0.450
At 12 Weeks	6.5 ± 1.1	7.2 ± 1.3	6.7 ± 1.2	<0.001

Table 3: Stratified Analysis of SVR Achievement Based on Effect Modifiers

Variable	Category	SVR Achieved (n = 90)	SVR Not Achieved (n = 26)	p-value
Age (mean ± SD)	Mean ±SD	54.3 ± 8.2	56.2 ± 7.5	0.215

Gender	Male	56 (62.2%)	16 (61.5%)	0.532
	Female	34 (37.8%)	10 (38.5%)	
BMI (kg/m²)	Mean ±SD	28.1 ± 4.5	29.3 ± 4.2	0.174
Smoking Status	Smoker	40 (44.4%)	8 (30.8%)	0.022
	Non-Smoker	50 (55.6%)	18 (69.2%)	
Child Pugh	Class B	65 (72.2%)	15 (57.7%)	0.084
	Class B	25 (27.8%)	11 (42.3%)	

Table 4: HbA1c Reduction and Improvement in Glycemic Control Based on SVR Achievement

Variable	SVR Achieved (n = 90)	SVR Not Achieved (n = 26)	Total (n = 116)	p-value
HbA1c Reduction (%)	1.8 ± 1.0	1.3 ± 1.1	1.7 ± 1.0	0.004
Improvement in Glycemic Control (%)	85.6%	34.6%	72.4%	<0.001

Table 5: Liver Function Tests and Viral Load Stratified by SVR Achievement

Variable	SVR Achieved (n = 90)	SVR Not Achieved (n = 26)	Total (n = 116)	p-value
ALT (U/L)	40.5 ± 10.4	47.8 ± 12.6	42.2 ± 11.5	0.028
AST (U/L)	38.2 ± 9.6	44.5 ± 11.2	40.2 ± 10.3	0.031
Viral Load at 12 Weeks (IU/mL)	<15 ± 5	500 ± 250	100 ± 200	<0.001

DISCUSSION

Chronic Hepatitis C Virus (HCV) infection has been associated with various comorbidities, including type 2 diabetes mellitus (T2DM), leading to significant complications. Insulin resistance is commonly observed in patients with chronic HCV, which worsens glycemic control and disease outcomes.[11,12] Direct-acting antivirals (DAAs) have emerged as a standard treatment for HCV, showing promise in eradicating the virus. However, their impact on glycemic control in T2DM patients remains under investigation.[13,14] This study aims to explore how successful HCV treatment affects glycemic control in diabetic patients. The findings could offer insights into improving diabetes management in HCV-infected individuals.

Our study aligns with several previous studies that have investigated the effects of HCV treatment on glycemic control in patients with type 2 diabetes mellitus (T2DM). Similar to the findings of Ciancio et al. (2018), who observed a significant reduction in HbA1c values in patients who achieved sustained virologic response (SVR), our study also found a significant improvement in glycemic control among patients who achieved SVR, with a mean reduction of 1.8 ± 1.0% (p = 0.004). Additionally, both studies reported that patients who did not achieve SVR showed minimal improvement in glycemic control, aligning with our results where HbA1c reduction was only 1.3 ± 1.1% in this group.[10]

Jang et al. (2024) found that 79% of patients in their study had a significant reduction in HbA1c after HCV treatment, with a greater percentage in the insulin group (82.75%) compared to the oral hypoglycemic group (75.7%). Our study also showed substantial improvement in glycemic control in the SVR-achieved group, with 85.6% of patients improving their glycemic control. Furthermore, we observed that smoking status was significantly higher in the SVR-achieved group, which supports the findings of Jang et al. (2024), who identified various factors, including diabetes and higher pretreatment HbA1c, as associated with significant HbA1c improvement.[15]

Hussein et al. (2020) similarly reported a significant reduction in HbA1c in patients after HCV treatment, and El Badry et al. (2020) found that 37.6% of patients had a significant improvement in HbA1c following DAAs therapy.[16,17] Our study supports the findings of Chen et al. (2024), which reported a significant reduction in HbA1c levels after

HCV treatment in patients with type 2 diabetes. Chen et al. observed a reduction from 8.05% to 7.19%, with an absolute mean decrease of 0.72%. Similarly, our study showed a significant HbA1c reduction of 1.8 ± 1.0% in patients who achieved SVR, reflecting improved glycemic control. Both studies highlight the extrahepatic benefits of HCV eradication, particularly in enhancing glycemic control in diabetic patients, with sustained improvements at follow-up.[18] Our findings reflect these results, with a significant reduction in HbA1c in the SVR group and minimal improvement in the non-SVR group. In contrast, Benetti et al. (2024) reported a significant reduction in HbA1c after SVR in patients with cirrhosis and genotype 3, suggesting that baseline characteristics may influence the response to HCV treatment.[19] However, our study did not find significant associations between baseline characteristics such as age or gender and glycemic control improvement, similar to the findings of Sarwar et al. (2022).[20]

The strengths of this study include its large sample size of 116 patients, allowing for robust analysis of glycemic control and SVR achievement. Stratification of data by key variables such as age, gender, and smoking status enhances the reliability of the findings. The use of HbA1c as a marker for glycemic control is a strong point due to its clinical relevance. However, the study's limitations include its observational nature, which may not account for all confounding variables. Additionally, the lack of long-term follow-up data prevents assessment of the sustained effects of DAAs on glycemic control. The generalizability of findings could also be affected by regional differences in patient characteristics.

CONCLUSION

The study indicates that HCV treatment with DAAs significantly improves glycemic control in patients with T2DM, particularly among those who achieve SVR. Smoking status was identified as a key factor influencing treatment outcomes. Future research should explore long-term effects and other potential predictors of glycemic improvement.

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