

Determine the Adverse Outcomes of Direct Antiviral Therapy in Patients with Hepatitis C Infection

MAHESH KUMAR WADHWA¹, DAUD GHILZAI², ALI HYDER MUGHERI³, SANIA⁴, KAMRAN ALI MEMON⁵, JAVERIYA MARIAM⁶

¹Assistant Professor, ³Professor, Department of Gastroenterology, Chandka Medical College, Shaheed Mohtarma Benazir Bhutto Medical University, Larkana

²Assistant Professor, Department of Gastroenterology, Bolan Medical College, Quetta

⁴Assistant Professor, Department of Obstetrics & Gynaecology, Pir Abdul Qadir Shah Jeelani Institute of Medical Sciences, Gambat

⁵Postgraduate Student, TB Hospital, Khairpur Mir's

⁶Postgraduate Student, Department of Medicine, Khairpur Medical College, Khairpur Mir's

Correspondence to: Mahesh Kumar Wadhwa, Email: drmahesh32@gmail.com, Cell: 0333-4972131

ABSTRACT

Objective: To determine the outcome of direct antiviral therapy in patients with hepatitis C infection.

Study Design: Prospective study

Place and Duration of Study: Department of Gastroenterology, Chandka Medical College, Larkana from 1st July 2021 to 30th June 2022.

Methodology: Two hundred hepatitis C patients after obtaining their informed consent were enrolled. Each patient was analyzed for phenotype and genotype of hepatitis C infection through polymerase chain reaction (PCR). The stage of cirrhosis was confirmed through the available of definition of liver biopsy interpretation. Non-invasive tests were also conducted for confirming the fibrotic stage. These tests included APRI, FIB-4 as well as transient-elastography. The patients selected for participation were between age group of 35-65years after taking informed written consent. The sustained viral response assessment was conducted through determining a 12-week viral load after the initiation of treatment of direct acting antivirals as per the available protocols through hepatic association.

Results: The mean age of the patients were 57±9.5 years with majority being males such as 60%. The majority of the cases were having genotype 3 followed by genotype 1. Within the total cases the adverse outcomes were noticed in 5% of the cases

Conclusion: These drug regimens show effectiveness in low income countries and proved to be safe Sofosbuvir-based drug choice for hepatitis C treatment.

Keywords: Genotyping, Antiviral drugs, Regimens, Prevalence, Efficacy

INTRODUCTION

Hepatitis C infection is one of the most common epidemics of the world with more than 7 billion people affected around the globe. Its frequency has been reported with varying rates in western and eastern part of the world. In developed countries the reported frequency of hepatitis C infection has been reported as around 3%.¹⁻⁵ Whereas, there are some countries where the prevalence is much lower as 0.7% of that of hepatitis C infection.⁶ In Pakistan the prevalence of hepatitis C infection is reported as 8.64% in all of its provinces which is much higher than reported in other parts of the world.⁷

Hepatitis C is reported as the major reason of end stage hepatic disease with high transplantation rates.⁸ World health Organization has initiated health policies for elimination of the hepatitis C infection by the year 2030.⁹ There have been efforts in various countries for accomplishing this task. In this context the use of direct acting antivirals (DAA) with or without the use of ribavirin has been started in various countries.⁶

The regimen of sofosbuvir based therapies in combination with ribavirin as well as delectasvir has been proposed for genotype 1, 3 and for genotype 4.¹⁰ The regimen has proven good result in some countries with an induced sustained viral response rate (SVR) as 85-90%.^{11,12} The present study was designed to evaluate the outcomes of DAA in hepatitis C infected patients as for proper assessment of their health related efficacy and management.

MATERIALS AND METHODS

This prospective study which was performed on hepatitis C infected patients was enrolled. A total of 200 patients were selected based on their genotype, clinical history and cirrhosis as well. Each patient was analyzed for phenotype and genotype of hepatitis C infection through polymerase chain reaction (PCR). The stage of cirrhosis was confirmed through the available of definition of liver biopsy interpretation. Non-invasive tests were also conducted for confirming the fibrotic stage. These tests included APRI, FIB-4 as well as transient-elastography. All the radiological, endoscopic as well as lab based findings were properly evaluated. Patient sample size was determined through WHO based

calculator using 80% power of test and 95% confidence of interval where prevalence of hepatitis C infection in Pakistan as 8.4%. All the demographic details of the patients were entered in a well-structured questionnaire. Patients with other hepatic diseases except hepatitis C infection were excluded from the study. The patient selected for participation was between age group of 35-65years after their informed consent gain. The SVR assessment was conducted through determining a 12-week viral load after the initiation of treatment of DAA as per the available protocols through hepatic association. The PCR limit for the detection of SVR was around 15IU/ml. The patients having SVR 12 were kept optional for SVR24. Outcomes of DAA treatment were also documented. Data was analyzed using SPSS version 26.0

RESULTS

The mean age of the patients were 57±9.5 years with majority being males such as 60%. Cirrhosis was observed in 46% of the cases with 94% of them having compensated cirrhosis. There were 12% transplant cases (Table 1). The majority of the cases were having genotype 3 followed by genotype 1. Genotype 1 and 4 were found with a least amount in the cases (Table 2).

Within the total cases the adverse outcomes were noticed in 5% of the cases with anemia being reported in 2.5% of the cases where as there was no cases reported with infections, depression or arrhythmias. One death was reported among DAA treatment cases (Table 3).

Table 1: Demographic details of the hepatitis C patients

Variable	No.	%
Gender		
Male	120	60.0
Female	80	40.0
Age (years)	57±9.5	
Body mass index (kg/m ²)	26±5.1	
Cirrhosis	92	46.0
Compensated cirrhosis	188	94.0
Decompensated cirrhosis	12	6.0
Treatment experienced	110	55.0
Transplant recipients	24	12.0
Co-infection	8	4.0
Chronic kidney disease	22	11.0

The SVR rate among all the cases was noticed as 95% with highest reported in the transplant recipients followed by the fibrosis, co infection and genotype 1 case (Fig. 1).

Table 2: Frequency of the various genotypes found in hepatitis C infection cases (n=200)

Genotypes (GT)	No.	%
GT1	44	22.0
GT2	4	2.0
GT3	150	75.0
GT4-6	2	1.0

Table 3: Adverse outcomes in patients on DAA

Outcome	No.	%
Total	10	5.0
Death	1	0.5
Anemia (Hb<10g/dL)	5	2.5
Decompensation	1	0.5
Organ insufficiency	1	0.5
Infections	-	-
Neoplasias	1	0.5
Bleeding	1	0.5
Depression	-	-
Arrhythmias	-	-

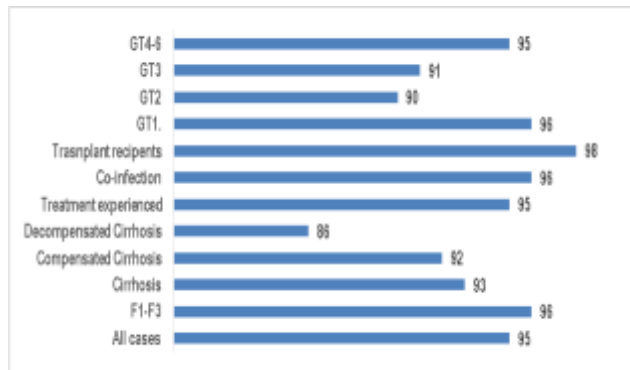


Fig. 1: Outcomes of the SVR in hepatitis C infection cases

DISCUSSION

The importance of conducting a prospective study in this context is due to the reason that there is a dire need of having a proper knowledge about the outcomes of the DAA treatment. Hepatitis C infection is a severe illness and requires a proper management on timely basis. In the current research the cases taken were within the age range of 35-65 years. Similar age group has also been taken in other research studies from various parts of the world which also reported on DAA treatment.¹³

The present study showed the majority of the cases having a genotype 3a as the most. In the worldwide 200 million cases of hepatitis were noticed. The annual death rate due to hepatitis infection has been reported as 3-7 million of the cases. There is a high risk of coinfections in various cases of hepatitis C infections. This co-infections majority includes hepatitis B also been having a clinical history of transferring through blood transfusions.¹⁴⁻¹⁶

The SVR reported in the current study were above 95% in all type of genotypes. The present study result showed similar findings as were observed in a Brazilian research on the hepatitis C infection patients. However, the SVR of the cirrhotic cases was slightly decreased than other cases.¹⁷ This was specifically noticed in the genotype 2. The reason behind this might be due to the decompensated cirrhosis. The regimen of the drug opted also had a positive role in SVR rate.¹⁸⁻²⁰

CONCLUSION

These drug regimens show effectiveness in low income countries and proved to be safe Sofosbuvir-based drug choice for hepatitis C treatment.

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