

# Efficacy of Combination Therapy Sofosbuvir, Daclatasvir and Ribavirin in Patients of Hepatitis C

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## ABSTRACT

**Aim:** To determine the effectiveness of antiviral drugs such as sofosbuvir, daclatasvir and ribavirin in hepatitis C patients and frequency of complications associated to antiviral therapy.

**Study Design:** Prospective study.

**Place and Duration:** This study was conducted at the department of Gastroenterology and General Medicine AK CMH / Sheikh Khalifa bin Zaid Al Nahyan Hospital Rawalakot Azad Kashmir for one year duration from 5th July 2020 to 5th July 2021.

**Methodology:** 150 patients of both genders presented with hepatitis C were included. Patient's ages were ranging from 25 to 70 years. After taking informed consent from all the patients, detailed medical history including age, sex, residence and education were recorded. Quantitative PCR test was obtained before starting the antiviral therapy, kit method was used. Treatment response was examined after completion of therapy. All the statistical data was analyzed by SPSS 24.0.

**Results:** 88 (58.67%) patients were males while 62 (41.33%) patients were females. Mean age of patients was  $48.52 \pm 9.38$  years. At the end of treatment, 132 (88%) patients were cured and 15 (10%) patients were not cured, 3 (2%) patients had lost to follow-up. Complications associated to therapy were noted as anemia, ascites, hepatic encephalopathy and liver cirrhosis in 40 (26.67%), 20 (13.33%), 7 (4.67%) and 6 (4%) patients respectively.

**Conclusion:** Combination antiviral therapy with Sofosbuvir, daclatasvir and ribavirin shows better results in patients with Hepatitis C with 88% cure rate. Anemia was the most frequent complication found at end of therapy.

**Keywords:** Hepatitis C, Sofosbuvir, Daclatasvir, Ribavirin

## INTRODUCTION

Hepatitis C is the most common viral infection in the world. Chronic liver failure is caused by HCV, which is the most common cause of the disease [1-3]. Around 170 million individuals worldwide are infected with this disease, and the fatality rate associated with Hepatitis C is far too high, according to a WHO research. Hepatitis C is the leading cause of liver disease in the United States [4]. Pakistan has the highest fatality rate for hepatitis C compared to Western countries, and hepatitis C is the most common virus in Pakistan. This malignant illness has a prevalence of between 5 and 8 percent. Pakistan is the second most populous country in the world in terms of the prevalence of HCV infection [5-6].

Hepatitis C treatment with antiviral drugs/therapy is quite effective in more than half of the patients; however the exact rate of sustained viral response relies on viral, host, and adherence factors. It is possible, however, that poor antiviral therapy results can have an impact on treatment adherence and the percentage of patients who are not fully recovered. A patient's quality of life may be impacted by the side effects associated with antiviral therapy [7]. Hepatitis C is the most common cause of liver cirrhosis in developing countries, and the disease is most common in those countries. Tobacco use, heavy alcohol intake, and polluted water are all to blame [8].

Antiviral therapy is widely used in health care facilities, and the results were better. The cured response

rate ranges from 80% to 95%. Mortality is, however, influenced by severity and other factors [9-10].

Antiviral therapy efficacy and the occurrence of complication linked with antiviral therapy were the primary goals of this research.

## MATERIALS AND METHODS

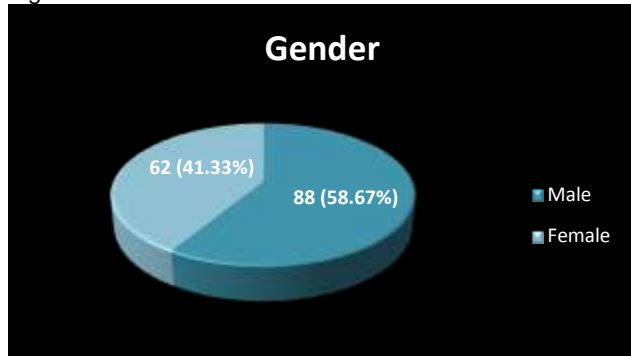
This study was conducted at the department of Gastroenterology and General Medicine AK CMH / Sheikh Khalifa bin Zaid Al Nahyan Hospital Rawalakot Azad Kashmir for one year duration from 5th July 2020 to 5th July 2021. Patients with Hepatitis C of both sexes were enrolled in this study, which had 150 participants total. The ages of the patients ranged from 25 to 70 years old. After obtaining informed consent from all of the patients, a full medical history was taken down, including age, gender, place of residence, and educational background. Patients with various blood illnesses, as well as those who were infected with HBV or E, were excluded from the study.

Antiviral medications such as Sofosbuvir 400mg, Daclatasvir 60mg, and Ribavirin 400mg were prescribed to the patients to begin treatment. The results of the quantitative PCR test were acquired prior to the start of antiviral medication. The Kit technique was used to diagnose all of the patients. After the course of treatment was completed, the response to the treatment was evaluated. The study looked on the complications linked with antiviral therapy. All the statistical data was analyzed by SPSS 24.0.

**RESULTS**

Out of 150 patients, 88 (58.67%) patients were males while 62 (41.33%) patients were females. (Figure 1)

Figure No 1: Gender-wise distribution



Mean age of patients was 48.52±9.38 years. Mean BMI was 26.25±3.42 kg/m<sup>2</sup>. 100 (66.67%) patients had urban residency while 50 (33.33%) had rural residency. 52 (34.67) patients were literate while 98 (65.33%) were illiterate. (Table 1)

Table No 1: Baseline characteristics of all the patients

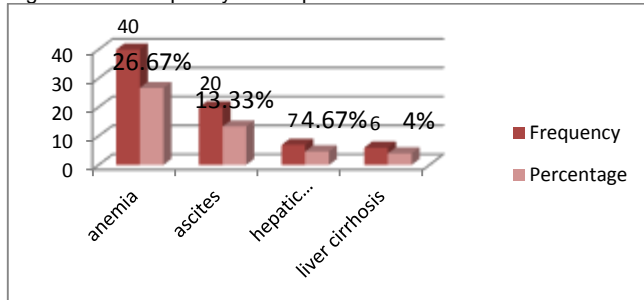
Characteristics	Frequency No.	%age
Mean Age (Years)	48.52±9.38	-
BMI (kg/m <sup>2</sup> )	26.25±3.42	-
Residence		
Urban	100	66.67
Rural	50	33.33
Education		
Literate	52	34.67
Illiterate	98	65.33

At the end of treatment, 132 (88%) patients were cured and 15 (10%) patients were not cured, 3 (2%) patients were lost to follow-up. Mortality found in 4/147 (2.67%) patients. (Table 2)

Table No 2: Outcomes of Antiviral Therapy

Variable	Frequency No.	%age
Response		
Cured	132	88
Sustained Antiviral response	15	10
Lost Follow-up	3	2
Mortality		
Yes	4	2.72
No	143	97.28

Figure No 2: Frequency of complications



Complications associated to therapy were noted as anemia, ascites, hepatic encephalopathy and liver cirrhosis in 40 (26.67%), 20 (13.33%), 7 (4.67%) and 6 (4%) patients respectively. (Figure 2)

**DISCUSSION**

Hepatitis C virus is the most common viral infection identified all over the world, and it affects both men and women. In the United States, HCV is the most common cause of chronic liver failure. With the introduction of direct acting antiviral medicines such as ribavirin, boceprevir, and telaprevir, the treatment of Hepatitis C Virus infection became moderate in the mild of 2011. Antiviral medications have a high rate of benefits, and the rate of cured patients is high when compared to the rate of non-cured patients [11-12]. A total of 150 confirmed cases of HCV infection were included in this investigation, with the majority of the cases (58.67 percent) being male. These findings are consistent with some other studies conducted to examine the effects of Antiviral Therapy in Hepatitis C infected patients, in which the male patient population rate was higher than the female patient population rate by 25 to 43 percent [13-14], indicating a similarity between the two studies.

The mean age of the participants in this study was 48.52 9.38 years. The mean body mass index (BMI) was 26.253.42 kg/m<sup>2</sup>. Patients from metropolitan areas constituted 66.67 percent of the total, while patients from rural areas constituted 33.33 percent. 52 (34.67%) of the patients were literate, while 98 (65.33 percent) were illiterate, according to the study. We discovered that the majority of patients were between the ages of 35 and 50 years, which may be attributed to the fact that the majority of patients drank alcohol and that the majority of patients were smokers, as well as their lack of knowledge about this malignant illness. A large number of research [15-17] have discovered the same risk factors for chronic liver failure.

For the purpose of initiating Antiviral Therapy, we performed a quantitative PCR test for the confirmed diagnosis of HCV in our study. We discovered that 132 (88 percent) of the patients were cured at the end of treatment, while 15 (10 percent) of the patients were not healed, and three (2 percent) patients were lost to follow-up. Mortality was discovered in 4 out of 147 patients (2.67 percent). These findings are consistent with the findings of the previous trial, in which 94 percent of the patients were cured [18].

In this study, we discovered that anaemia, ascites, hepatic encephalopathy, and liver cirrhosis were detected in 40 patients (26.67 percent), 20 patients (13.33 percent), 7 patients (4.67 percent), and 6 patients (4 percent) as a result of therapy. During the course of the therapy, four individuals with a sustained viral response died (2.67 percent). Anemia was shown to be the most common consequence linked with antiviral medication, according to our findings. In comparison to earlier studies undertaken to establish the efficacy of Antiviral Therapy in HCV infected patients, which found a prevalence of anaemia ranging from 18 to 30% [19-20], these findings are consistent.

Furthermore, due to the small number of patients participating in the current study, the results were insufficient. We should put in more effort to improve

treatment and raise awareness of this malignant condition among the general public.

## CONCLUSION

HCV infection is the most common cause of chronic liver failure, and the mortality rate associated with this condition is quite high throughout the world. This study concluded that individuals with Hepatitis C benefit from receiving combination antiviral medication that includes Sofosbuvir, daclatasvir, and ribavirin, as evidenced by an 88 percent cure rate. Anemia was the most common consequence found at the conclusion of treatment.

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