

Effectiveness of Sofosbuvir in Treating Patients with Hepatitis C – Risks Vs Benefits Ratio

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Abstract- Objectives: the aim of the study was to observe prevalence of hepatitis C, the effectiveness of sofosbuvir in treating hepatitis C, various signs and symptoms of hepatitis C and their prevention, plot between the risks & benefits ratio associated with the use of sofosbuvir.

Methodology: This observational study presents the prevalence of hepatitis C, patient's category, symptoms, drug regimen, effectiveness of sofosbuvir, side effects with the previous regimen and side effects seen with sofosbuvir therapy in the general population seeking treatment in the government sector hospitals of Lahore.

Results: The study found out that among the total population affected 57% males suffer from hepatitis C. 60% of the respondents had chronic hepatitis C. Common symptoms experienced by the patients were fever & fatigue (40%), pale coloration (35%). Commonly prescribed drug regimen was sofiget and ribavir (35%). 100% of the respondents agreed that sofosbuvir is a more effective therapy as compared to Peg Interferons given previously.

Conclusion: Prevalence of Hepatitis is common in government and private sector hospitals of Lahore. Sofosbuvir is considered to be a more effective and patient friendly therapy nowadays. Patients experienced a decline in incidence of side effects from this oral therapy.

Index Terms- effectiveness, risks and benefits, sofosbuvir

1. INTRODUCTION

Hepatitis refers to an inflammatory liver disease. It is believed to be caused essentially by a viral infection. Hepatitis (A, B and C) are the most prevalent types of the disease. "**Hepatitis A**" is a virulent and infectious liver ailment. It is essentially caused by hepatitis A virus (HAV). It may range in severity from mild to severe. The ailment may even last for several months. **Hepatitis B** is also a serious and communicable liver disorder. It is in effect caused by virus called the hepatitis B virus (HBV). It starts as a moderate illness. However, if it goes untreated it might continue to become lifelong chronic condition. Therefore, it also has a mild to extreme severity. [1]

HCV or the hepatitis C virus is the cause of the contagious disease called **Hepatitis C**. This in line with the other variants is also a liver disease which can take various magnitudes of illness from mild which last for a few weeks to extremely long illness which harms the liver throughout the life time. Depending on the time the virus lives in a body it can also be categorized as chronic or acute.

Acute Hepatitis C is the form of virus infection that culminates within the duration of first six months after exposure to HCV. There is a decent probability however that the acute infection might lead to chronic severity. **Chronic Hepatitis C** is the form of virus infection which is has rather long-term effect on the liver. Chronic form of Hepatitis is extremely severe and cause life-long ailment which may lead to diseases like liver cancer. [2]

Hepatitis C is becoming a globe-wide disease encompassing about 2.2% of the entire global population. It is especially become a serious health concern in the developing countries inclusive of Pakistan. Pakistan has one of the most alarming figures when it comes to Hepatitis C. According to a study the disease is costing more than three thousand patients their lives on daily basis. With these statistics Pakistan ranks second most susceptible region for hepatitis C. Figures suggest that about twenty million people in Pakistan are affected with the HCV infection. Pakistan is right behind Egypt in the statistics of the HCV breakout. [3]

Hepatitis C Virus can be transmitted in a variety of ways. The most common way to get hepatitis C is through exposure to infected blood, sexual transmission, by tattooing or piercing or through genetic connection etc. Patients do not show signs that indicate the

presence of HCV in them in approximately 70 to 80% of the cases. This is because the symptoms could appear from 2 weeks to about six months after the body is subject to the HCV virus. The primary symptoms include high temperature, eating disorders, stomach aches, rashes, concentrated urine, jaundice, lethargy etc. [4]

HCV is predominantly widespread in the rural areas compared the urban areas of Pakistan as the rural population is more susceptible to it. This fact becomes highly alarming once looked at in conjunction with the statistic that about 66% of the population of Pakistan lives in areas categorized as rural. These areas are highly vulnerable due to lack of awareness of hygiene and medical and health practices. This also includes lack of health care facilities and their reach, uncontrolled blood transfusions, general illiteracy, financial challenges and most importantly abuse of drugs. Presence of these issues impacts the society and medical professionals equally. [5]

The treatment of hepatitis C has seen variety of advancements in the past years. Initial studies used therapy called the **interferon (IFN)** mono therapy. Later on, a combination of **ribavirin and Interferon** or of Interferon to which polyethylene glycol (PEG) molecules have been added (i.e. **PEG-IFN**) were used for 48 weeks or 24 weeks depending upon the case severity. **Protease inhibitors** have sprung up as a third feature of combination therapy. [6]

Interferon and ribavirin combination therapy to treat hepatitis c results in a number of prominent adverse effects like fatigue, hematological problems, influenza-like symptoms and neuropsychiatric abnormalities. Other drawback of this treatment is that it is a painful and long-term therapy consisting of a course for 24 weeks to 48 weeks depending upon the severity of disease condition. [7]

Lately, "**HCV NS5B polymerase inhibitor**"; **sofosbuvir** was shown to successfully contain HCV replication. It has been established as a major component of currently recommended regimens. In December 2013, the FDA sanctioned an entirely oral regimen of simeprevir plus sofosbuvir for patients who had already been treated with interferon mono therapy or interferon and ribavirin combination therapy. While the duration of treatment is 3 months (12 weeks) for patients without cirrhosis, it is 6 months (24 weeks) for those with cirrhosis. [6]

Sofosbuvir is a newly introduced nucleotide analogue and is highly potent inhibitor of HCV NS5B polymerase in HCV. It has shown promising results in numerous *in vitro* studies against all HCV genotypes. It has a number of ideal properties like its high potency, once daily dosing, oral administration, few adverse effects, low incidence of drug-drug interactions and higher barrier to resistance. It is generally well tolerated. However exact safety profile can be established only when the drug is used on a large scale. The risks associated with sofosbuvir seem to occur only when it is used with ribavirin. They involve fatigue and headache. [7]

Treatment of HCV infection necessitates implementing a combinational treatment by using multiple antiviral agents. Depending on the subject's HCV Genotype, previous medical history related to HCV, concomitant comorbidities and present medication, this combination treatment would involve the use of two or three antiviral agents with varying duration of treatment based on the cited factors. [8] Due to increased complexity that the new treatment regimens will introduce, Primary care providers or specialists might not be in the best position to provide clarification and to recommend appropriate therapy courses for patients on case to case basis; however, pharmacists are in a better position provide a more prudent acumen. Moreover, Pharmacists can also prove helpful in handling the individual cases by studying and obviating drug interactions which is a critical aspect while supervising the use of these new regimens due to its clinical significance. Pharmacists therefore carry a significant role in the team of multidisciplinary treatment providers through knowledge sharing of HCV treatment routes. [9]

2. MATERIALS AND METHODS

Questionnaire-based observational cross-sectional study was conducted from April to August, 2017 to observe prevalence of hepatitis C, patient's category, symptoms, drug regimen, effectiveness of sofosbuvir, side effects with the previous regimen and side effects seen with sofosbuvir therapy in the general population seeking treatment in the government and private sector hospitals of Lahore. A convenient sampling of 100 sample size was done including both male and female patients.

A data collection form was designed covering the aspects related to Patient's demographic information, signs and symptoms of hepatitis C, pattern of prescribing sofosbuvir in various hospitals, evaluation of side effects caused by the therapy and was filled during a face-to-face interview with patients in public and private sectors hospitals of Lahore. The collected data was analyzed, arranged and presented in the form of graphical results.

3. RESULTS

The data was collected from 100 patients of which all of them were suffering from hepatitis C and were using sofosbuvir as major medication therapy. Prevalence of hepatitis C was slightly more common in males (57%) as compared to that in females (43%) (Fig.1). According to this survey, it has been found that most of the patients were suffering from chronic hepatitis C, which is a long-term illness that occurs when HCV remains in the person's body for a longer period of time. Only 30% of the patients belonged to the acute category of hepatitis C (Fig. 2). Common symptoms which prompted the patients to visit the physician were fever, fatigue, pale coloration, rash and itchy skin (Fig. 3). Combination of sofosbuvir (HCV NS5B Polymerase Inhibitor) and Ribavirin (Anti-Viral agent) were given. The brands most commonly prescribed were Sofiget & Ribavir (35%), Sosof & Ribavir (25%), CHC & Alcorib (25%), Sovaldi & Ribazole (10%) and Abriva & Ribazole (5%) (Fig. 4). As a result of the survey conducted, it was found that sofosbuvir was a more effective treatment regimen as compared to the interferon therapy (Fig. 5). Side effects commonly observed with the interferon therapy were nausea, vomiting & diarrhea (30%), anemia (20%), fatigue (10%), xerostomia & mouth ulcers (10%) (Fig. 6) while the side effects experienced after using sofosbuvir were headache & fatigue (35%), nausea, vomiting (35%), myalgia & irritability (15%) (Fig. 7). 85% of the patients claimed that occurrence of their side effects was minimized after 2 to 3 months of regular medication use.

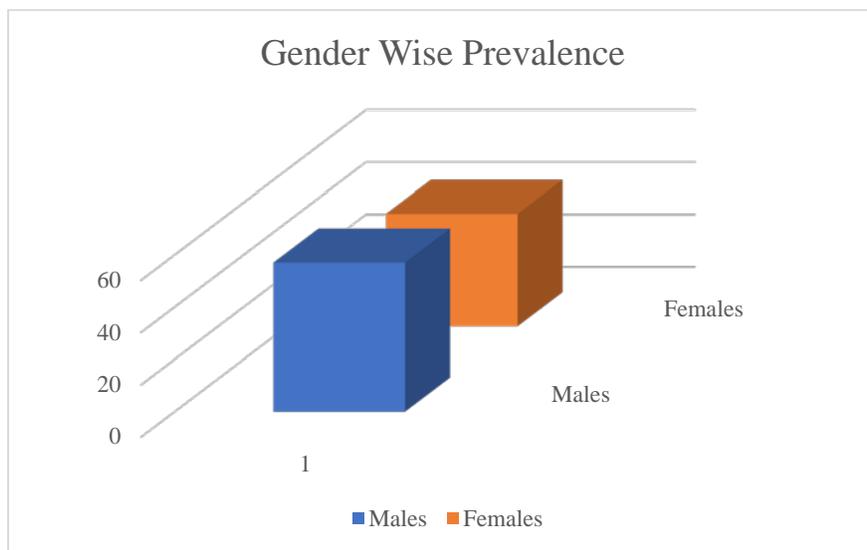


Figure 1: Prevalence of hepatitis C

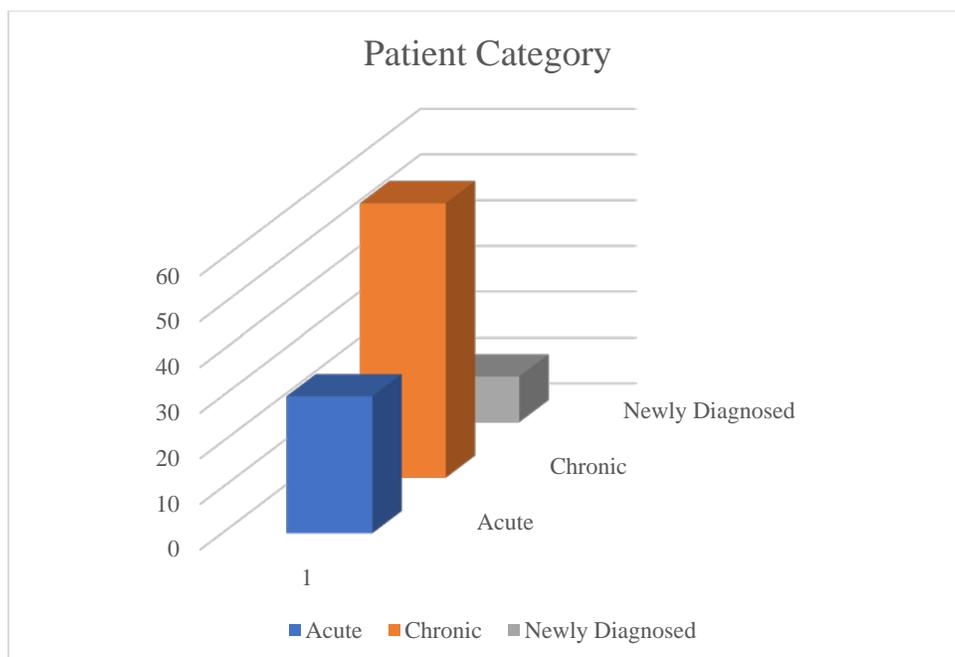


Figure 2: Patient Category

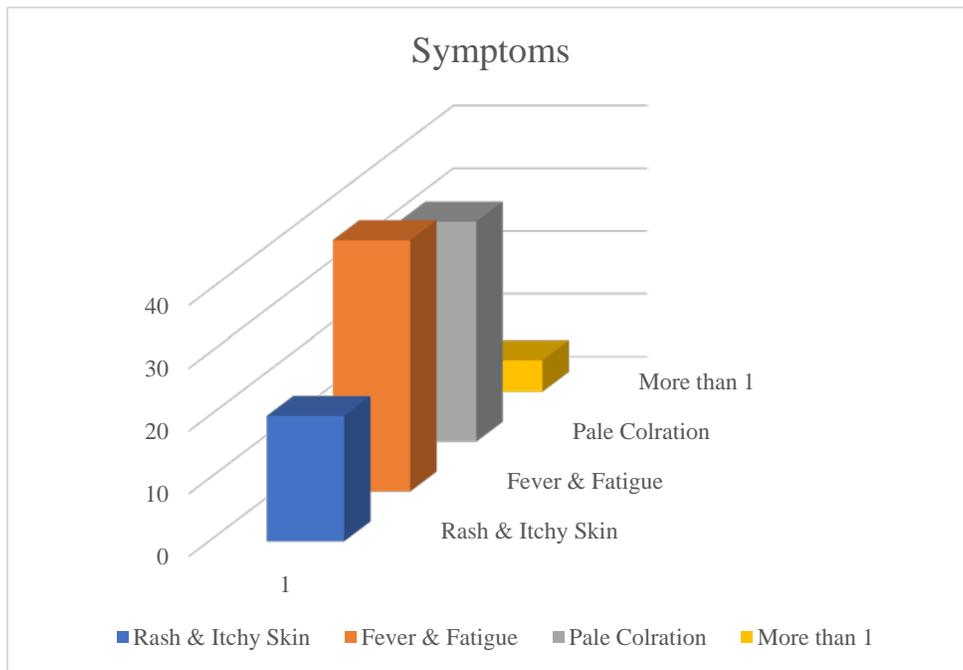


Figure 3: Symptoms

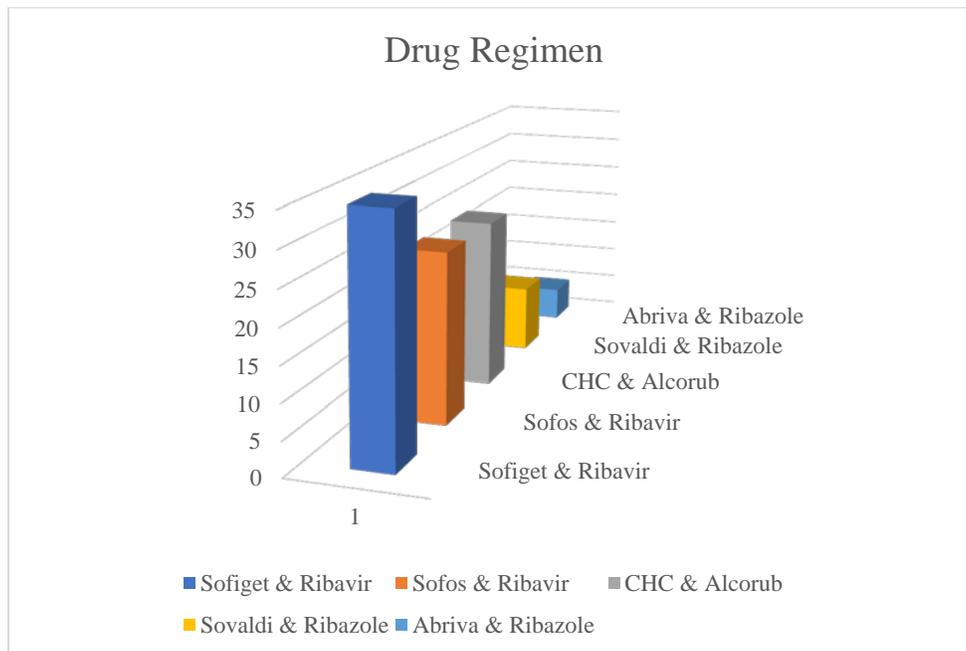


Figure 4: Drug Regimen

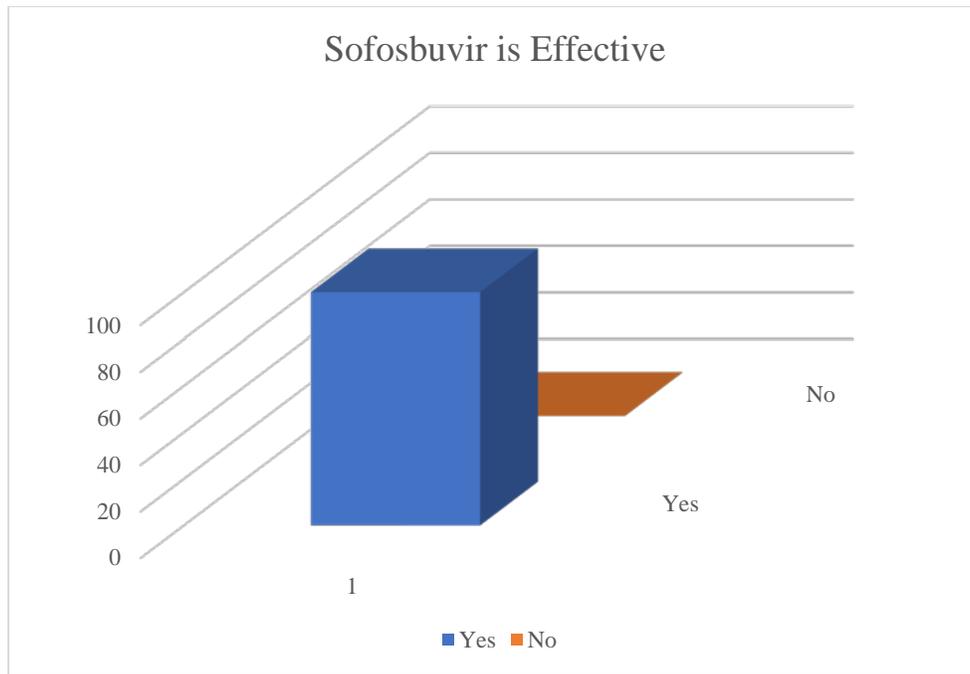


Figure 5: Effectiveness of Sofosbuvir

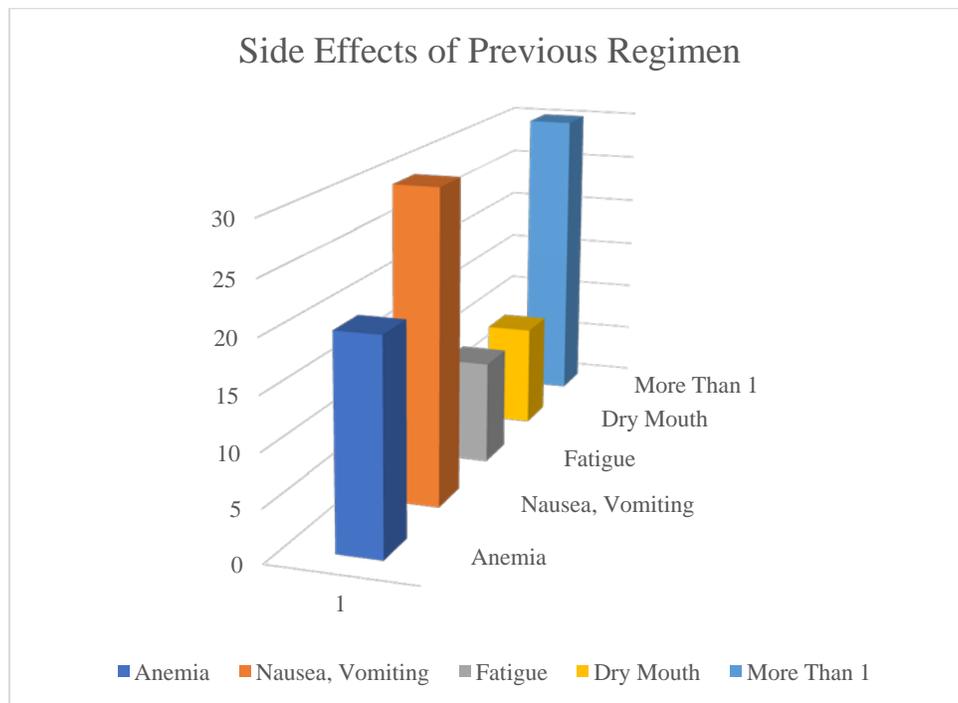


Figure 6: Side effects associated with previous regimen

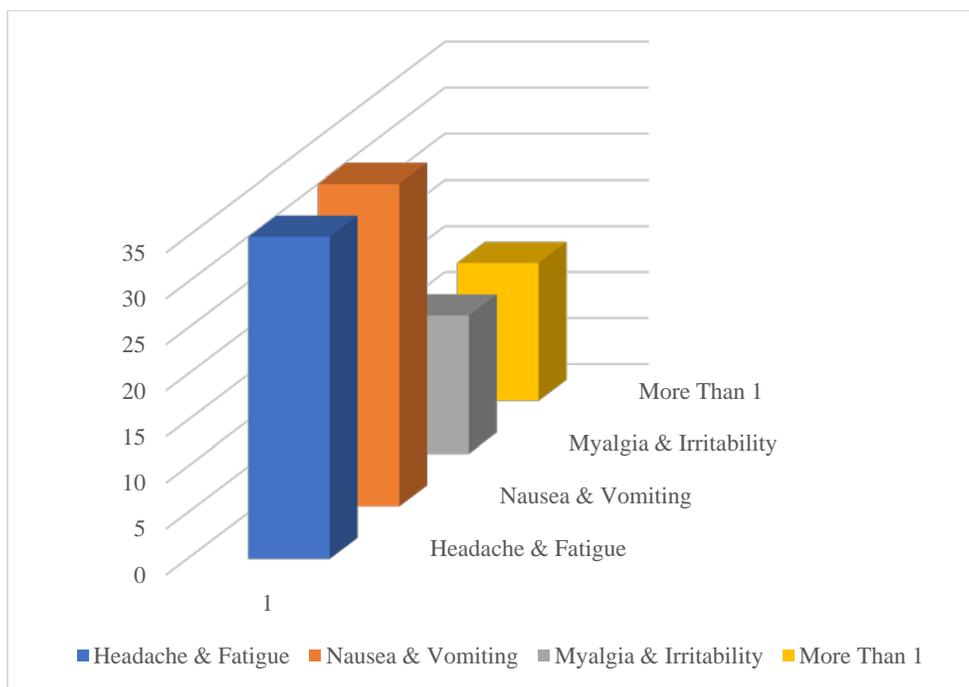


Figure 7: Side effects experienced after using sofosbuvir

4. CONCLUSION

Prevalence of hepatitis C was studied in various government and private sector hospitals of Lahore and it was concluded that hepatitis C is more common in males (57%) than that in females (43%). Common signs and symptoms that prompted the patients to visit the physician were fever & fatigue (40%), pale coloration (35%), rash & itchy skin (20%). Sofosbuvir and ribavirin oral therapy was a more effective treatment plan as compared to interferon injection therapy in terms of effectiveness as well economically. The incidence of side effects has also been decreased to an extent by the use of sofosbuvir. Patients claimed that their side effects presided after some time ranging from 2-4weeks of using sofosbuvir and this was a major reason for their adherence to therapy. Most of the patients were satisfied with the treatment regimen. Patients were properly counselled about the correct usage of medicines, precautionary measures and dietary instructions.

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