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Compliance on Directly Acting Oral Antiviral in HCV Patients

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Abstract

Introduction: Chronic hepatitis C is one of the most common cause all over the world for causing cirrhosis of liver and thus requiring liver transplantation as the definitive treatment which is beyond reach in most of patients in developing countries. The availability of oral directly acting antiviral for treatment in India since 2015 has changed the scenario due to its good compliance among the patients.

Aims and Objectives: To determine the compliance among patients who were treated with directly acting oral antiviral drugs for Hepatitis C (Sofosbuvir 400 mg, Daclastavir 60 mg, Velpatasvir 100 mg).

Materials & Methods: It was prospective study conducted at Department of Medical Gastroenterology, Post Graduate Institute of Medical Sciences (PGIMS), Rohtak, over a period of five years from 01.01.2016 to 31.12.2020. Out of four thousand patients of Chronic hepatitis C who reported in department in above five years duration, 570 patients pre therapy HCV RNA was not detected, hence they were not treated and were not part of the study. Out of the remaining 3430 patients, 130 patients went for alternative medications and hence were excluded from the study. The remaining 3300 confirmed patients of Chronic hepatitis C who were started on treatment with oral antiviral drugs were followed till they completed their treatment. Out of these 3300 patients,10 patients who were cirrhotic died during their course of treatment, hence in final analysis 3290 patients were included.

Results: Only ten patients out of total pool of 3290 left medicines due to side effects, thus high compliance rate of 99.69% was achieved.

Keywords: Hepatitis C virus; Oral antiviral drugs; Compliance; Side effects

Abbreviations: HCV: Hepatitis C Virus; DAA: Direct-Acting Antiviral; SVR: Sustained Virologic Response; HCC: Hepatocellular Carcinoma; IFN: Interferon; RBV: Ribavirin; DDI: Drug-Drug Interactions

Introduction

Hepatitis C virus (HCV) infection has effected over 71 million people worldwide [1] and proportion of cirrhosis in chronically infected patients is rising and projected to reach 44.9% by 2030 [2]. The wide availability of multiple pan-genotypic, oral, direct-acting antiviral (DAA) drugs has completely changed the scenario of HCV treatment. These DAA regimens are simple, safe, to be taken orally once a day, well-tolerated, highly effective with reported sustained virologic response (SVR) rates exceeding 95% in patients with compensated liver disease [3]. The SVR leads to improvement in HCV-related liver damage, leading to liver fibrosis regression, and a reduction in the incidence of hepatocellular carcinoma (HCC), thereby prolonging overall survival [4-7]. A recent community-based, non-randomized study showed that there were no differences in SVR rates when treatment was administered by nurse practitioners, primary care physicians or specialists. Nevertheless, SVR rates ranged from 75% to 100% among the providers, suggesting a wide variability in SVR rates that could be due to patient factors, clinic setting, or other hitherto unknown variables [8]. The availability of direct-acting antiviral (DAA) in India in December,2015, HCV therapy has been revolutionized because of being more effective, shorter duration of treatment, lesser side effects and can be used in those groups of patients for whom Interferon (IFN) therapy was contraindicated i.e. in decompensated cirrhosis or in presence of significant comorbidities. Though the side effects are less but they are not completely absent especially in patients with advanced liver disease in whom the usage of ribavirin (RBV) is still recommended [9-11]. Moreover, other important aspect is possibility of drug-drug interactions (DDI) because more patients with severe comorbidities are being treated due to overall good tolerability of DAA treatment [12-15].

Aims and Objectives

To determine the compliance among patients who were treated with directly acting oral antiviral drugs for Hepatitis C (Sofosbuvir 400 mg, Daclastavir 60 mg, Velpatasvir 100 mg).

Material and Methods

It was prospective study conducted at Department of Medical Gastroenterology, Post Graduate Institute of Medical Sciences (PGIMS), Rohtak, over a period of five years from 01.01.2016 to 31.12.2020. Out of six thousand patients of Chronic hepatitis C who reported in department in above five years duration, 570 patients pre therapy HCV RNA was not detected, hence they were not treated and were not part of the study. Out of the remaining 5430 patients, 130 patients went for alternative medications and hence were excluded from the study. The remaining 5300 confirmed patients of Chronic hepatitis C who were started on treatment with oral antiviral drugs were followed till they completed their treatment.

Statistical Analysis

All the data was entered in Microsoft Excel and was analysed using SPSS 15.0 version.

Observations & Results

Out of four thousand patients of Chronic hepatitis C who reported in department in above five years duration, 570 patients pre therapy HCV RNA was not detected, hence they were not treated and were not part of the study. Out of the remaining 3430 patients, 130 patients went for alternative medications and hence were excluded from the study. The remaining 3300 confirmed patients of Chronic hepatitis C who were started on treatment with oral antiviral drugs were followed till they completed their treatment. Out of these 3300 patients,10 patients who were cirrhotic died during their course of treatment, hence in final analysis 3290 patients were included. In this total pool of 3290 patients, there was male predominance i.e. 2270 (69%) while females were only 1020 (31%). Majority of patients belonged to poor socio-economic status and had rural background i.e. 2105 patients (64%). The maximum number of patients belonged to younger age group i.e. from 20-40 yrs of age group i.e. 1875 (57%) with minimal representation at extreme of age group. Out of the pool of 3290 patients, 3280 (99.69%) completed the treatment and only 10 patients (0.31%) left treatment in between due to side effects and starting on alternative medications. Out of this small pool of these non-compliant ten patients, eight (80%) were males and two (20%) were females, seven (70%) were cirrhotic and three (30%) were non-cirrhotic. In this non-compliant group of ten patients, eight (80%) were above 50 yrs of age and two (20%) were below 50 yrs of age group.

Discussion

In the present study the exceptional compliance rate of 99.69% was achieved and this can be attributed to multiple factors like lesser side effects of directly acting oral antiviral, availability of free treatment on daily basis, issuing of total therapy in the beginning of treatment, constant contact with patients throughout the course of treatment by the treating team. The availability of directly acting oral antiviral since 2015 in India has changed the scenario of treatment because earlier only option was 24-48 weeks treatment with Pegylated Interferon and Ribavarin which had multiple serious side effects ranging from infections, anaemia, alopecia, Psychiatric disturbances, weight loss etc, hence compliance rate was not as per expectation. The oral antiviral have temporary minimal side effects like dyspepsia, allergic reactions, generalized weakness, insomnia or excessive sleepiness, that too only in 6-7% of patients which is very less as compared to Pegylated Interferon and Ribavarin combination [15,16]. The other important reason for high compliance rate is due to implementation of Jeevan rekha Project & National Viral Hepatitis Control Program (NVHCP) through which there is provision of total free treatment including viral load and other routine tests, drugs, Endoscopy, Fibroscan, indoor admission in wards etc. Moreover, as a well-planned policy, hepatitis C patients are given consultation and treatment on daily basis without any waiting period. The other important decision taken was providing full course of twelve-week (84 days) treatment to every patient in the beginning of treatment and then to remain connected telephonically for making sure that patients are taking drugs regularly. It was learnt from previous experience with Pegylated Interferon and Ribavarin treatment, at that time ever week patients had to come for treatment but on multiple occasions they failed to report due to personal issues. The appointment of dedicated team which included Consultant, Peer view support, Pharmacist and data operator played a vital role in achieving this exemplary compliance rate. The concept was to provide all facility under one roof i.e., all four of them were available in one room on daily basis. The first interaction was with qualified consultant who analysed the patient clinically and all tests including viral load, routine tests, ultra-sonogram, Fibroscan and Endoscopy, if indicated was done on the same day. All the data was entered into government portal, peer view support used to do psychological and family counselling and pharmacist explained the patient and relatives about the dosages schedule, interaction, effects and side effects of drugs. This team effort lead to good social bonding with the patients who developed full faith in the treating team and telephonically connectivity during course of treatment was game changer because all apprehensions and fears were allayed round the clock during treatment. This familial bonding lead to overcome the hurdle of illiteracy and rural background in majority of patients who were treated for Chronic hepatitis C. Moreover, any patient who developed any kind of side effects and required admission, then it was done on priority on daily basis and there was no charge for any kind of treatment. Out of this small pool of ten patients who left treatment in between, eight (80%) were males and two (20%) were females, seven (70%) were cirrhotic and three (30%) were non-cirrhotic. In this non-compliant group of ten patients, eight (80%) were above 50 yrs of age and two (20%) were below 50 yrs of age group. As there

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was more predominance of males in overall pool of 3290 patients in study group and same has been reflected in the non-compliant group of ten patients. The important point is that noncompliance is seen more in patients in older age group and cirrhotic which can be due to other adverse clinical features associated with stage of disease and poor tolerability and other ailments in older age group. This group of ten patients was very small to be statistically significant for deriving any kind of conclusions on comparing with total pool of 3290 patients.

Conclusion

The approach of scientific rationale-based treatment, free and easy accessible availability of drugs and good bonding between treating team and patients can lead to exceptional compliance rate and ultimately higher sustained virological response.

Limitation of Study

The present study excluded patients in final analysis who went for treatment with alternative medications or who died during treatment, hence if these subsets of patients were also included then the compliance rate achieved would have decreased substantially. The number of non-compliant ten patients was very small for making statistically analysis.

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