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Compliance on Antiviral Treatment for Hepatitis B

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Abstract:

Introduction:

Hepatitis B virus (HBV) remains to be an important cause of liver related morbidity and mortality all over the world. India is a moderately endemic country for chronic hepatitis B (CHB) infection. Hepatitis B surface antigen (HbsAg) positivity in Indian population varies from 2 %-8% in different parts of country with an average of 4%. based on the result of an epidemiological study.

Aims and objectives:

To determine the compliance among Hepatitis B patients who were treated with Tablet Tenofovir 300 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 ten years and nine months from 01.01.2011 to 30.09.2021. Out of five thousand and six hundred patients of Chronic hepatitis B who reported in department in above duration, 1000 patients were started on treatment with tablet tenofovir 300 mg on daily basis. Out of these fifty patients expired, thus were excluded from final analysis. Hence, compliance was determined in the remaining 950 patients.

Results:

Out of 950 patients, 100 patients (10.53%) stopped treatment on their own leading to compliance rate of 89.47% which is good in view of prolonged course of treatment for hepatitis B.

Key Words: hepatitis b virus; tenofovir; compliance; cirrhosis; dyspepsia.

Introduction:

Approximately one third of the world's population has serological evidence of past or present infection with the hepatitis B virus (HBV). An estimated 350-400 million people are surface HBV antigen (HBsAg) carriers [1,2] .Thus,HBV infection is one of the most important infectious diseases worldwide. India is facing major burnt of this deadly disease and has 40 million HBV carriers i.e. 10–15% share of total pool of HBV carriers of the world. In India, 100,000 patients die due to HBV infection. The average estimated carrier rate of hepatitis B virus (HBV) in India is 4 %. Wide variations in social, economic, and health factors in different regions may explain variations in carrier rates from one part of the country to another. Most of India's carrier pool is established in early childhood, predominantly by horizontal spread due to crowded living conditions and poor hygiene. Acute and sub-acute liver failure are common complications of viral hepatitis in India and HBV is reckoned to be the aetiological agent in 42% and 45% of adult cases, respectively. HBV is reported to be responsible for 70 % of cases of chronic hepatitis and 80% of cases of cirrhosis of the liver. About 60% of patients with hepatocellular carcinoma are HBV marker positive. The progression rate from acute to chronic HBV infection decreases with age. It is approximately 90% for an infection acquired perinatally, and is as low as 5% for adults [3,4]. In all the cases of chronic hepatitis B (HBV) infection,15–40% will develop cirrhosis, liver failure and hepatocellular carcinoma [5,8]. The incidence of new infections has decreased in most developed countries, most likely due to the implementation of vaccination strategies [9]. Hepatitis B being a major public health problem in India has been included in National Viral Hepatitis Control Program but there is lacunae of large scale studies on hepatitis B in India which are essential for developing future preventive and treatment strategies, to curb the menace of this deadly disease. Hence, in light of above explained ground situation, our study was done.

Aims and Objectives:

To determine the compliance among hepatitis B patients who were treated with tablet tenofovir 300 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 ten years and nine months from 01.01.2011 to 30.09.2021. Out of five thousand and six hundred patients of hepatitis B who reported in department in above duration, 1000 patients who fulfilled the criterion for treatment were started on tablet tenofovir 300 mg or Entecavir 0.5 mg or 1 mg. Out of these fifty patients expired, thus were excluded from final analysis. Hence, compliance was determined in the remaining 950 patients who regularly took treatment for 6 months to 7 years duration with mean of 2.5 years. Out of these 950 patients, 50 patients were of Acute hepatitis B and rest were of Chronic hepatitis B. The patients of acute hepatitis B were started on treatment only if their serum bilirubin was more than 10 mg% or there was upward trend, even after diagnosis of acute hepatitis B, of serum bilirubin and International normalized ratio (INR) of above 1.5. The patients of chronic hepatitis B were started on treatment if they had cirrhosis on ultra-sonogram of abdomen or Fibroscan score was above 8.2 or serum transaminases were twice upper limit of normal with raised HBV DNA quantitative levels i.e. > 20,000 I.U./ml in HbeAg positive or > 2,000 I.U./ml in HbeAg negative patients.

Statistical Analysis:

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

Observation & Results:

Out of nine hundred and fifty patients of Chronic hepatitis B who were started on treatment with tenofovir 300 mg, males were predominant i.e. 618 (65.05%) while females were only 332 (34.95%). Majority of patients belonged to poor socio-economic status and had rural background i.e. 646 patients (68%). The maximum number of patients belonged to 40-70 yrs of age group i.e. 600 (63.15%) with lesser representation from extreme of age group. Out of this pool of 950 patients, 100 (10.53%) left treatment in between on their own, predominantly due to long duration of treatment and in lesser number of cases, in view of side effects and. Out of this pool of non-compliant hundred patients, seventy eight (78%) were males and twenty two (22%) were females, eighty (80%) were cirrhotic and twenty (20%) were non-cirrhotic. In this non-compliant group of hundred patients, six hundred (63.15%) were above 40 yrs of age and three hundred and fifty (36.85%) were below 40 yrs of age group.

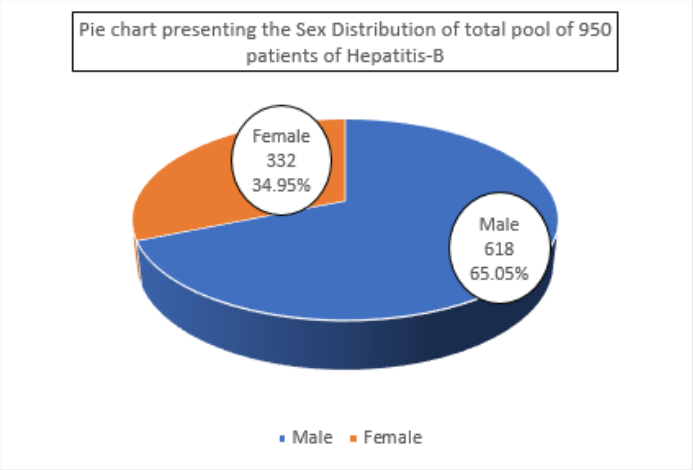

Figure 1: Showing Sex Distribution of Total Chronic Hepatitis B Patients

Total Number of Patients on Treatment	Males	Females	Rural Background	Urban Background	Compliant Patients	Non-Compliant Patients
950	618 (65.05%)	332 (34.95%)	646 (68%)	304 (32%)	850 (89.47%)	100 (10.53%)

Table 1: Showing Distribution Among Total Pool of Chronic Hepatitis B Patients

Total Number of Non-Compliant Patients	Males	Females	Cirrhotic	Non-Cirrhotic	Above 40 yrs of Age	Below 40 yrs of Age
100	78 (78%)	22 (22%)	80 (80%)	20 (20%)	600 (63.15%)	300 (36.85%)

Table 2: Showing Distribution Among Non Compliant Group of Chronic Hepatitis B Patients

Discussion:

In the present study the compliance rate of 89.47% was achieved and can be explained on basis of lesser side effects of drugs, availability of free treatment on daily basis, issuing of three month of therapy in one go, proper counselling of patients in starting and throughout the course of treatment by the treating team. The good effectivity of drug leading to early virological decline generates lot of confidence among the patients and paves the way for regular intake of drug and proper follow up. The oral antiviral tenofovir 300 mg has minimal side effects like dyspepsia, generalized weakness etc. that too only in 4% of patients and none of patients had any significant renal or bony side effects due to deranged renal function tests and serum calcium levels. In one Australian study, therapy was ceased in 12% of patients at the discretion of individual clinicians due to concern about renal (3%) and bone impairment. Tenofovir was self-ceased by 4% of patients due to non-specific adverse events. It was not possible to establish causality for these events; all possible renal events were mild and reversible with discontinuation [10]. No confirmed cases of

proximal tubular dysfunction were observed. 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 B patients are given consultation and treatment on daily basis without any waiting period. The other important decision taken was providing three-month course of treatment together to every patient and then to remain connected telephonically for making sure that patients are taking drugs regularly. The appointment of dedicated team which included Consultant, Peer view support, Pharmacist and data operator played a vital role in achieving this good 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. The 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 B. 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 the pool of hundred patients who left treatment in between, were contacted telephonically and reasons for discontinuing treatment were analyzed. Majority of patients i.e. 96 (96%) left the treatment due to prolonged course of treatment for years together, may be life long as cirrhotic were eighty percent (80%) in this pool. Only four patients (4%) left treatment in between due to side effects of the drug. The compliance on oral antiviral in hepatitis B patients is significantly much lesser than in hepatitis C patients as shown by Malhotra etal [11] because in latter there is shorter duration of treatment i.e. 12-24 weeks in comparison to hepatitis B which requires long treatment, may be lifelong in cirrhotic patients.

Conclusion:

In view of long duration of treatment for hepatitis B in majority of patients, especially in cirrhotic, there is need of proper and regular counselling of patients, uninterrupted supply of free drugs and good bonding between treating team and patients.

Limitation of Study:

In the present study, hundred patients who left treatment in between and were contacted telephonically to restart the treatment. The analysis of the percentage of patients who again got restarted on treatment is not included in this research.

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Conflict of Interest: The authors disclose that there is no conflict of interest.

Author Contribution:

Parveen Malhotra- Conceived, Designed and Formulated this retrospective analysis Vani Malhotra- Reviewed draft of paper Isha Pahuja & Ajay Chugh- Data Analysis Yogesh Sanwariya & Akshay- Data Collection

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