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International Journal of Toxicological and Pharmacological Research 2023; 13(6); 18-27

Original Research Article

Clinical Profile and Long-Term Follow-Up of Newly Diagnosed Hepatitis B Patients in Gujarat, India: A Retrospective Cohort Study

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Received: 18-03-2023 / Revised: 21-04-2023 / Accepted: 26-05-2023

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Conflict of interest: Nil

Abstract

Introduction: Hepatitis B Virus (HBV) is a significant public health concern in India, with a prevalence of intermediate endemicity and potential complications such as liver cirrhosis and primary liver cancer. However, there is a lack of data on the clinical and demographic profile of hepatitis B patients in Gujarat, India. This study aims to explore the clinical features, course, and outcomes of newly diagnosed viral hepatitis B in this patient population, contributing to improved management and outcomes.

Material and Methods: This retrospective cohort study was conducted at Pandit Dindayal Upadhyay Medical College and Civil Hospital, Rajkot, Gujarat, between July 2016 and July 2018. A total of 50 newly diagnosed hepatitis B cases were included in the study. Relevant demographic, clinical, and laboratory data were collected from medical records using a standardized data collection form. Descriptive statistics were used to analyze the data, including frequencies, proportions, means, and standard deviations. Ethical guidelines were followed, and patient confidentiality and privacy were maintained throughout the study.

Results: The study included 50 newly diagnosed cases of hepatitis B, with a male-to-female ratio of 2.13:1. The age distribution revealed cases across various age groups, with the highest percentage (38%) observed in individuals above 50 years. The majority of participants belonged to the lower socio-economic group (84%) and had diverse occupations, with the highest proportion being laborers (44%). Clinical presentations varied, with fever (52%) being the most commonly reported symptom. Objective findings showed manifestations such as hepatomegaly (38%), splenomegaly (8%), and ascites (28%). Laboratory analysis indicated normal total count (86%), normal differential count (86%), and normal hemoglobin levels (72%) in most cases. Liver function parameters, including AST and ALT levels, showed improvement over time. Bilirubin levels also decreased, indicating improved liver function. Positive outcomes were observed in serum albumin (96%) and serum protein (96%) levels, as well as prothrombin time (80%) at 6 months. HBsAg positivity decreased to 6% at 6 months and remained stable at 1 year.

Conclusion; The study highlights the diverse demographic characteristics, varied symptomatology, and potential risk factors associated with hepatitis B. Positive treatment responses, including improved liver function parameters and declining HBsAg positivity, demonstrate the effectiveness of management strategies. These findings contribute to a better

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understanding of viral hepatitis B and can guide efforts to enhance its management and outcomes in Gujarat, India.

Keywords: Clinical Profile, Hepatitis B, Outcomes.

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Introduction

Hepatitis B Virus (HBV) is a member of the hepadnaviridae family and primarily spreads through percutaneous or mucosal exposure to infected blood and other body fluids.[1] The prevalence of HBV infection in India is of intermediate endemicity, with nearly 4% of the population being chronic carriers.[2] In most cases, acute hepatitis caused by HBV is subclinical, and less than 1% of symptomatic cases progress to fulminant hepatitis.[3] HBV infection can lead to various consequences, manifesting as both acute and chronic stages, and posing potential complications such as liver cirrhosis and primary liver cancer.[4] The likelihood of transitioning to chronic infection is inversely correlated with the age at the time of infection, as perinatally infected infants have a high probability of becoming chronic carriers unless they receive vaccination immediately after birth.[2]

The prevalence of Hepatitis B in the general population in India varies significantly, with reported rates ranging from 0.1% to 11% according to the World Health Organization (WHO).[5] However, various studies on the epidemiology of hepatitis B India have reported HBsAg in seropositivity rates ranging from 2% to 4.7%.[6] This wide variation in prevalence can be attributed to diverse social. economic, and health factors across different regions of India. While there are numerous studies available on the prevalence of hepatitis B infections in both adult and pediatric populations, there is a paucity of data on the clinical and demographic profile of these patients, particularly in Gujarat, India.

This study focuses on 50 patients with newly diagnosed viral hepatitis B admitted

to Pandit Dindayal Upadhyaya Medical College and Civil Hospital in Rajkot, Gujarat, between July 2016 and July 2018. The study aims to investigate the clinical features, course, and outcomes of viral hepatitis B in this patient population. Additionally, the study aims to analyze the biochemical changes that occur during the course of the disease and assess the complications, recovery, and prognosis associated with viral hepatitis B. By addressing these objectives, the study aims to contribute to the understanding of viral hepatitis B and improve its management and outcomes in Gujarat, India.

Material And Methods

This retrospective cohort study aimed to investigate the clinical profile and longterm follow-up of newly diagnosed hepatitis B patients in India. The present study, comprising 50 cases of newly diagnosed hepatitis B, was conducted at Pandit Dindayal Upadhyay Medical College and Civil Hospital, located in Rajkot, Gujarat. The study period spanned from July 2016 to July 2018.

Sample Selection: The selection criteria for the study included 50 newly diagnosed cases of jaundice with a positive hepatitis B surface antigen (HBsAg). Patients of all age groups, above 12 years, who met this criterion were included in the study. However, cases below 12 years of age, patients with a past history of alcoholism, patients with a past history of hepatotoxic drug use, and patients with a history suggestive of surgical jaundice were excluded from the study. These exclusion criteria were applied to ensure a focused study population and to minimize confounding factors that could impact the assessment of the clinical profile and longterm outcomes of newly diagnosed hepatitis B patients in India

Data Collection: Relevant demographic, clinical, and laboratory data were extracted from the medical records using a standardized data collection form. The data included patient demographics, presenting symptoms, laboratory investigations (such as liver function tests, viral load, and serological markers), imaging findings, treatment modalities, and follow-up information. The data collection process ensured adherence to patient confidentiality and privacy guidelines. Detailed medical histories were obtained, and if any associated systemic disorders were present, they were documented using a standardized case record forms.

Data Analysis:

Descriptive statistics, such as frequencies, proportions, means, and standard deviations, were used to summarize the collected data. The level P < 0.05 was considered as the cutoff value or significance. The clinical profile, including incidence, clinical features, and course of hepatitis B, was analyzed. Additionally, biochemical changes during the course of the disease, complications, recovery, and prognosis were assessed.

Ethical Considerations:

This study was conducted in accordance with ethical guidelines and obtained approval from the ethical review board of Pandit Dindayal Upadhyay Medical College and Civil Hospital, Rajkot. Patient confidentiality and privacy were maintained throughout the study, and all data were anonymized and securely stored.

Results

The study included a total of 50 newly diagnosed cases of hepatitis B, with a distribution of both age and sex. Among the participants, 68% were male, while 32% were female, resulting in a male-to-female ratio of 2.13:1. The age distribution revealed that 14% of the cases were in the 13-20 years age group, 22% were in the 21-30 years age group, 12% fell into the 31-40 years age range, and another 14% were in the 41-50 years category. Notably, the highest percentage of cases, accounting for 38%, was observed in individuals above 50 years of age. These findings highlight that hepatitis B can affect individuals of various age groups and both genders, with a slightly higher prevalence in males.

The socio-economic status of the study participants revealed that 84% belonged to the lower socio-economic group, while 16% were classified as middle class. In terms of occupation, the majority of cases laborers (44%), followed were bv housewives (30%) and students (12%). Among the participants, 30% resided in rural areas, while 70% lived in urban regions. These findings demonstrate the socio-economic diverse backgrounds, occupations, and regional distribution of individuals newly diagnosed with hepatitis B in the study population.

The past history of the study participants revealed various factors that could potentially contribute to their hepatitis B diagnosis. Within the past six months, 24% of cases had a history of blood transfusion or injections. Additionally, 18% reported a previous episode of jaundice, while 6% had engaged in multiple sexual partners. A smaller proportion (4%) had a history of previous hospitalization, and 10% had undergone surgical procedures. No cases reported intravenous (IV) drug abuse. Furthermore, 4% of participants had a family history of liver disease. These findings provide insight into the potential risk factors and medical background of the participants. highlighting the diverse factors associated with the diagnosis of hepatitis B. (Figure 1)



Figure 1: Past History and Risk Factors in HBV Diagnosis

The clinical presentations of the study participants with newly diagnosed hepatitis B were diverse, indicating a range of symptoms and manifestations. The most commonly reported symptom was fever, observed in 52% of cases. Other prevalent symptoms included nausea (28%), vomiting (32%), loss of appetite (42%), abdominal pain (40%), yellow urine (30%), and yellow sclera (26%). Itching, joint pain, edema feet, and distended abdomen were reported in 22-38% of cases. Bleeding from any site was observed in 12% of cases, while altered consciousness was reported in 4% of cases. Interestingly, a proportion of participants (24%) were asymptomatic. These findings underscore the varied clinical presentations of hepatitis B and highlight the importance of considering the diverse symptomatology associated with the disease.



Figure 2: Clinical presentations of hepatitis B

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The objective findings in the study revealed additional clinical manifestations among the newly diagnosed hepatitis B patients. Yellow sclera was observed in 26% of cases, followed by pallor (20%) and skin changes (28%). Foeterhepaticus and lymphadenopathy were not reported in any cases. Hepatomegaly, indicating an enlarged liver, was observed in 38% of patients, while splenomegaly, indicating an enlarged spleen, was found in 8% of cases. Ascites, the accumulation of fluid in the abdominal cavity, was present in 28% of patients. Hemorrhage was reported in 12% of cases, and neurological signs were observed in 4% of cases. Notably, bradycardia was not reported, but tachycardia, an increased heart rate, was observed in 26% of cases. These objective findings provide valuable insights into the physical manifestations associated with hepatitis B infection, highlighting the importance of thorough clinical evaluations in diagnosing and managing the disease.

The evaluation of laboratory findings revealed important insights into the hematological profile of newly diagnosed hepatitis B patients. Most patients demonstrated a normal total count (86%), indicating a stable immune response, while a small proportion exhibited decreased (4%) or increased (10%) counts. The differential count showed a majority with normal distribution (86%), but some patients displayed granulocytosis (6%) or lymphocytosis (4%). No cases of eosinophilia or basophilia were observed. Leucopenia was present in a minority (4%). Hemoglobin estimation indicated that most patients had levels within the normal range (72%), while some showed mild (14%) or severe (6%) anemia. These findings provide valuable insights into the hematological status of hepatitis B patients,

contributing to a better understanding of their immune and overall health.

In the present study, out of 50 cases, approximately 60-70% of patients showed a 2-3 fold rise in AST and/or ALT levels upon admission, indicating liver dysfunction. However, on follow-up at 6 year, a significant months and 1 improvement was observed, with almost all patients showing normalization of S.AST and S.ALT levels. Similarly, the analysis of serum bilirubin levels revealed that the majority of cases (around 82%) had bilirubin levels in the range of 1.0-3.0 mg/dL on admission. Over time, there was a noticeable decline in the number of cases falling into higher bilirubin range categories (3.1-6.0 mg/dL and >9.0 mg/dL), indicating improved liver function. These findings suggest a positive trend in the management of hepatitis B, with both liver enzyme levels and bilirubin levels showing significant improvement over the course of the study.

In the study, positive outcomes were observed in the evaluation of serum albumin, serum protein, and prothrombin time/INR levels. (Table 1) The majority of cases (88%) had sufficient serum albumin levels upon admission, which remained stable at 96% during the 6-month and 1year follow-ups. Similarly, 84% of cases demonstrated adequate serum protein levels, increasing to 96% at both follow-up periods. Coagulation status showed improvement, with 50% of cases having normal prothrombin time on admission, reaching 80% at 6 months and 78% at 1 year. These findings indicate positive treatment response, restoration of protein homeostasis, and enhanced liver function and clotting ability among the study participants.

	On Admission	6 Months	1 Year
Serum Albumin			
< 3 g/dL	06 (12%)	02 (04%)	02 (04%)
\geq 3 g/dL	44 (88%)	48 (96%)	48 (96%)
Serum Protein			
< 6 g/dL	08 (16%)	02 (04%)	02 (04%)
$\geq 6 \text{ g/dL}$	42 (84%)	48 (96%)	48 (96%)
Prothrombin Time/INR			
< 15 seconds	25 (50%)	40 (80%)	39 (78%)
15-20 seconds	15 (30%)	07 (14%)	08 (16%)
20.1-25 seconds	04 (08%)	01 (02%)	02 (04%)
25.1-30 seconds	04 (08%)	02 (04%)	01 (02%)
> 30 seconds	02 (04%)	00 (00%)	00 (00%)

Table 1: Serum Albumin, Serum Protein, and Prothrombin Time/INR Levels

Initially, all cases (100%) tested positive for HBsAg upon admission. However, by the 6-month follow-up, only 6% of the cases remained positive. This positivity rate persisted at the 1-year mark. The majority of cases achieved HBsAg negativity, indicating a positive response to treatment and successful management of the hepatitis B infection. (Table 2)

Table 2: Seropositivity of HBsAg Over Time						
	On Admission	At 6 Months	At 1 Year			
Positive	50	3	3			
Negative	0	47	47			

Table 2: Sero	opositivity	of HBsAg	Over	Time
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The radiological findings in our study revealed hepatomegaly in 40% of cases on admission, decreasing to 38% at 6 months and 36% at 1 year. Splenomegaly was observed in 8% of cases consistently. Pericholecystic edema was present in 22% of cases initially but resolved by 6 months. Lymphadenopathy (LPD) increased from 4% to 6% at both follow-ups.(Figure 3) These findings demonstrate the evolving nature of radiological manifestations in hepatitis B patients.



Figure 3: Radiological finding

Discussion

The present study, conducted at Civil Hospital, Rajkot, affiliated with Pandit Dindayal Upadhyay Medical College, Rajkot, between August 2016 and October 2018, aimed to explore the clinical profile and long-term follow-up of patients with newly diagnosed Hepatitis B. Hepatitis B is a complex viral infection known for its diverse clinical manifestations and potential complications. By analyzing the demographic characteristics, clinical presentations, laboratory findings, and radiological observations of the study participants, we gained insights into the clinical spectrum of Hepatitis B in this specific patient population. Understanding the clinical profile of Hepatitis B is crucial diagnosis, for accurate appropriate management, and effective prevention strategies.

In our study, the male-to-female ratio was found to be 2.33:1, with 35 out of 50 participants (70%) being male and 15 out of 50 participants (30%) being female. This ratio differs from the study conducted by Malewe Kolou et al.[7], which reported a male-to-female ratio of 1.38:1. In Kumar et al.[8] study, a total of 110 patients were enrolled, with 66 patients (60%) being male and 44 patients (40%) being female. Regarding the age distribution, our study revealed that among the different age groups, the highest percentage of cases was observed in the >50 years category (38%), followed by the 21-30 years group (22%), and the 13-20 years group (14%). These findings differ from the study conducted by Malewe Kolou et al.[7], where the highest percentage of cases was in the 31-40 years group (26.92%). In Kumar et al.[8]'s study, the maximum number of patients (65.45%) belonged to the younger age group of 15-45 years. Only 6 patients (5.5%) were aged over 65 years, and the mean age of the participants was 40.5±16.1 years. These comparisons highlight the variations in gender distribution and age groups among

different studies, emphasizing the need for further research to understand the demographic characteristics and epidemiology of hepatitis B in different populations.

In our study, we observed a higher proportion of participants from lower socioeconomic backgrounds (84%) compared to the study by Kumar et al.'s study, the majority of patients were married (55.5%) and had lower educational attainment. In Sivagamasundari et al.[9]'s study, patients with hepatitis B had a wide age range of 15 to 75 years. The majority (55.5%) were married, and 40% had completed their secondary education. Additionally, 47% of the patients belonged to the working class, and 69% had unknown sources of infection These variations in socioeconomic status, marital status. educational background, and occupation diverse demographic highlight the characteristics among different studies. Further research is needed to understand the potential associations between socioeconomic factors and the risk and management of hepatitis B in different populations. In our study, we found a small percentage (1.81%) of patients with a history of blood transfusion, while 69.09% had an unknown source of infection. In comparison, Kumar et al.[8]'s study reported a higher rate (24%) of blood transfusion or injection history. Shivagamasundari et al.[9]'s study revealed common modes of HBV transmission, such as blood transfusion and hemodialysis (17.7% each), risky injections (14.5%), and various other factors. These findings emphasize the diverse sources and modes of HBV infection observed in different studies.

Our study revealed diverse clinical presentations among participants newly diagnosed with hepatitis B. Fever (52%), nausea (28%), vomiting (32%), loss of appetite (42%), abdominal pain (40%), yellow urine (30%), and yellow sclera

(26%) were the most commonly reported symptoms. Itching, joint pain, edema feet, and distended abdomen were observed in 22-38% of cases. Bleeding occurred in 12% of cases, while altered consciousness was reported in 4% of cases. Notably, 24% of participants were asymptomatic. Comparing our study findings with other studies, Sudhamshu KC[10] reported that symptoms were present in almost all cases of acute hepatitis, with anorexia (100%), nausea (67%), jaundice (67%), dark urine (67%), myalgia (67%), and pain abdomen being the commonest symptoms in patients. Jabbar A and Pathan M[11] found that the commonest presenting symptom was yellowish discoloration of eyes and urine seen in 100% of cases, followed by fever seen in 87% of cases. In Kumar et al.[8]'s study, the majority of patients (69.1%) experienced abdominal discomfort symptoms, followed by fever (64.5%), fatigue (61.8%), jaundice (36.4%), and dark urine (31.8%). It was found that 72.7% (n=80) of cases were symptomatic, while 27.3% (n=30) were asymptomatic. Comparing the findings of our study with Shivagamasundari et al.[9], we observed that 38% of our study participants had hepatomegaly, while they reported a higher percentage of 55.5%. In Kumar et al.[8]'s 30.9% of the patients study, had hepatomegaly based on ultrasound findings. Joint pain, arthritis, and pruritus highlighted were as extrahepatic complications of hepatitis B. These comparisons highlight the similarities and variations in symptom prevalence among different studies, providing valuable insights into the clinical manifestations of hepatitis B.

Comparing our findings to Kumar et al., they reported severe anemia in 16% of cases, thrombocytopenia in 10% of cases, and elevated total bilirubin levels in 66% of cases. In contrast, our study showed a noticeable improvement in hemoglobin levels, with most patients having levels within the normal range, and no cases of thrombocytopenia or elevated bilirubin levels.

In our study, we observed a significant improvement in liver enzyme levels, with almost all patients showing normalization of AST and ALT levels upon follow-up at 6 months and 1 year. Similarly, our analysis serum bilirubin levels indicated of improved liver function over time. Additionally, the majority of our cases had sufficient serum albumin levels (88%) and adequate serum protein levels (84%) upon admission, which remained stable during the follow-up periods. Coagulation status also improved, with 50% of cases having normal prothrombin time on admission, increasing to 80% at 6 months and 78% at 1 year. Comparing these findings to Kumar et al.[8], they reported that 19% of their cases had serum albumin levels below 3.5gm%, indicating chronic liver disease or hypoalbuminemia of other causes. They also found that 29% of cases had prolonged prothrombin time or coagulopathy, and 7.3% had elevated serum creatinine levels, possibly indicating hepatorenal syndrome or renal failure due to shock. Furthermore, in Sivgamasundari et al.'s study, they found that 38.7% of individuals had severe anemia, 24.2% had thrombocytopenia, and significant proportions had abnormal total bilirubin, alkaline phosphatase, serum albumin, prothrombin time, and serum creatinine levels. In comparison, our study demonstrated favorable outcomes in terms of serum albumin, serum protein, and prothrombin time levels, indicating improved liver function, protein synthesis, and coagulation status.

These differences in laboratory findings between our study, Sivagamasundari et al.[9] and Kumar et al[8]. highlight the heterogeneity and complexities of hepatitis B presentations and outcomes. Our study demonstrates positive trends in liver function, protein synthesis, and coagulation status, suggesting improved management and prognosis. However, the presence of chronic liver disease, coagulopathy, and renal complications in Kumar et al.'s findings emphasizes the diverse spectrum of disease severity and associated complications in hepatitis B patients. Individualized approaches to management and monitoring are crucial to address the specific needs and challenges posed by different patient populations.

The declining seropositivity rate observed in our study over a period of 1 year holds substantial significance. Initially, all patients included in our study tested positive for HBsAg, indicating an active hepatitis B infection. However, as the study progressed, a remarkable reduction was observed in the seropositive rate. By the 6month follow-up and continuing to the 1year mark, only 6% of the cases remained positive for HBsAg. This decrease in seropositivity highlights the efficacy of the treatment and management strategies implemented during the study period. It suggests that the interventions employed, antiviral therapy, lifestyle such as modifications, and regular monitoring, have been successful in suppressing viral replication and promoting disease control. The persistence of a low seropositive rate even after 1 year indicates the long-term effectiveness of the interventions in achieving viral suppression and possibly reducing the risk of transmission.

Conclusion

In conclusion, our study provides valuable insights into the clinical profile. demographic characteristics, and long-term follow-up of newly diagnosed hepatitis B patients. We observed variations in gender distribution, age groups, socioeconomic factors, and sources of infection among different studies, highlighting the need for understand further research to the epidemiology of hepatitis B in diverse populations. Clinical manifestations varied, with fever, abdominal pain, and jaundice being symptoms, common while hepatomegaly was frequently observed. Laboratory findings demonstrated improvements in liver enzyme levels,

bilirubin levels, serum albumin, serum protein, and coagulation status over time, indicating enhanced liver function and protein synthesis. The decline in seropositivity rate from 100% at baseline to 6% at the 6-month and 1-year follow-ups reflects the effectiveness of the implemented interventions in achieving viral suppression and successful disease management. These findings emphasize the importance early diagnosis. of comprehensive management strategies, and ongoing surveillance for the improved outcomes of hepatitis B patients. Further research is warranted to explore the diverse of hepatitis В aspects and tailor interventions based on individual patient needs.

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