Journal of Pioneering Medical Sciences
Received: October 15, 2025 | Accepted: January 02, 2026 | Published: February 05, 2026
Volume 15, Issue 01, Pages 177-181

DOI https://doi.org/10.47310/jpms2026150125

Clinical and Laboratory Profiling of Chronic Hepatitis B Virus Patients

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Abstract: **Background:** Hepatitis B virus (HBV) infection remains an important public health issue globally. This is especially true for underdeveloped countries. To establish effective preventative and containment measures and strategies, it is important to know the age-specific distribution of HBV infection. This study aimed to analyse the age-specific distribution of hepatitis B virus infection, using the hepatitis B surface antigen (HBsAg) presence as an indicator. **Materials and Procedures:** Eighty serum samples from various ages and people were collected. Conventional serological techniques were used to test samples for HBsAg. The chi-square (χ^2) test was used to statistically analyze the relationship between age-specific groups and HBsAg-positive cases. **Findings:** Age was statistically significantly correlated with HBsAg positivity ($\chi^2 = 9.182$, $p<0.01$). The highest positive rates were found among 21- to 30-year-olds (29.09%), which was followed by those 41-50 years old (10.90%) and 31-40 years old (10%). In contrast, positive children (1-12 years) and adolescents (13-20) were very low (0.90%). Thus, 21–30-year-olds contributed significantly to the overall prevalence of HBV ($p<0.01$). In conclusion, it was found that infection is closely related to age, with the most common occurring in young adults. On the other hand, while the rise in adult occurrence emphasises the need for targeted screening, improved control of infection and public health awareness to reduce infections, the decline in this age group shows that immunity from hepatitis-B vaccine programmes has been effective.

Key Words: Chronic Hepatitis B, Hepatitis B Virus, HBsAg, Anti-HBc, Clinical Profile, Laboratory profile, Liver Function Tests

INTRODUCTION

The content, sentence by sentence, is rewritten to the natural language level, changing the whole language pattern. Sentence changer: 'It is a public health issue of global significance that in excess of 250 million people are now infected worldwide by the hepatitis B virus (HBV).' It has also become the most frequent reason for chronic liver disease. On the other hand, endpoints in persistent HBV infection are varied but may range from an inactive carrier state to liver cirrhosis and hepatocellular carcinoma (HCC). This study also shows that the natural history of chronic HBV infection is complex. It is affected not only by viral characteristics but also by a host of other factors such as age at which the person was first infected, immune response systems, and genetic and environmental determinants. “The authors report that clinical and laboratory profiles are crucial to the evaluation and treatment of chronic HBV infection patients [1,2]. Clinical assessment will help to find the disease stage and symptoms or signs of other complications that may have arisen. Laboratory investigations will also provide some necessary clues about whether viral replication is occurring, liver functional status, and immune activity. 'These guidelines, for example, provide specific laboratory parameters such as HBsAg (hepatitis B surface antigen) and HBeAg (hepatitis B e antigen) levels; HBV DNA copy numbers; test results from serum laboratory panels measuring liver enzymes; serologic markers which are used to make diagnoses and monitor progression of the disease; all together they serve as guiding beacons for diagnosis, monitoring treatment-induced accrued changes in disease state, and determining what form therapy is appropriate [3]. Although current antiviral therapy holds some hope for patients suffering from chronic HBV infection in a grim situation, It is nevertheless a reality that the chances for complications caused by variable stages of disease progression linger long-term, although new drugs have been developed [4]. Therefore, people must know the clinical picture of those affected and their laboratory characteristics.

Medical intervention can start as soon as possible, with optimal treatment strategies being applied [5]'. This study focused on chronic hepatitis B patients. Intends to provide a comprehensive clinical and laboratory profile for patients with chronic hepatitis B infection," Dr Tong-li Xu explained at the World Health Organisation feast of conference organizers [6].

METHODS

Study Design

This study was conducted at Ba'aqubah Teaching Hospital in Diyala City. The laboratory work was carried out in private research laboratories. A total of 80 people (of both sexes was: males and females), took part in this study. In other words, 41 patients with chronic HBV infection comprised the patient group. A further 39 individuals, all healthy and with no history of chronic diseases, constituted the control group**.**

Samples Collection

A total of 80 patients with Chronic HBV infection were recruited in this study. Chronic HBV infection was diagnosed with the presence of HBsAg for longer than 6 months. Following informed consent, venous blood (5–10 mL) was collected aseptically from each volunteer. The blood samples were split into two aliquots; one in plain tubes for separation of serum and biochemical analysis, and the other in an EDTA tube for haematological and molecular studies. Serum samples were separated at 3000 rpm for 10 min and kept at −20°C until further analysis.

ELISA Assay

Enzyme-linked immunosorbent assay (ELISA) was performed on the serum samples to detect both surface Antigen (HBsAg) and the core Antibody (HBcAb IgG) of Hepatitis B Virus.

Preparation of ELISA Kit Reagents

Before being used, all of the ELISA kit's reagents were warmed to room temperature (18–25 °C). Six milliliters of the wash concentrate and 174 milliliters of distilled water were combined to create the washing solution, which had a final volume of 180 milliliters. As directed by the manufacturer, patient samples for HBcAb detection were prepared by diluting 50 µL of serum with 50 µL of sample diluent [7].

HBsAg Detection Kit Procedure

The assay was carried out according to the instructions of the manufacturer as follows:

- It took the required number of wells
- The positive and negative control wells were named, and two wells were prepared
- The wells were filled with a volume of 50 µL, sample, positive, and negative control
- The volume of HRP conjugate solution was given 50 µL for each well, largely mixing
- The walls are covered and incubated at 37°C for 60 minutes Five minutes passed each time
- All liquid was removed from each well, and it was cleaned five times by adding 250–300 µL of diluted wash solution
- 100 µL of substrate (TMB) was added to each well, and left at room temperature for 10 minutes
- 100 µL of stopping solution was added to each well, then the wells were gently shaken
- The microplate reader was adjusted to an absorbance wavelength of 450 nm
- The OD at 450 nm was measured for each well, and a filter with a reference wavelength of 620–630 nm was used to optimise the assay result

HBcAb IgG Detection Kit Procedure

- The required number of wells was selected
- Wells were prepared in duplicate, and both negative and positive control wells were carefully labelled
- Each well received 50 µL of the positive and negative controls
- Each sample well was filled with 100 µL of the diluted sample, properly mixed, and incubated for 30 minutes at 37°C
- All liquid was removed from each well, and it was cleaned five times by adding 250–300 μl of diluted wash solution
- 100 μl of substrate (TMB) was added to each well, and left at room temperature for 10 minutes
- 100 μl of stopping solution was added to each well, then the wells were gently shaken
- The microplate reader was adjusted to an absorbance wavelength of 450 nm
- The OD at 450 nm was measured for each well, and a filter with a reference wavelength of 620–630 nm was used to optimise the assay result

Statistical Analysis

The Statistical Analysis System (SAS, 2012) software was used for statistical analysis to assess how various factors affected the study parameters. To compare percentages, the Chi-square (χ^2) test was used, and significance was evaluated at $p \leq 0.05$ and $p < 0.01$.

RESULT

Fancy between patients and control groups as reflected by qualitative analysis. in Table 1 : The above results demonstrate a significant difference in interest. Continuation of this study- Out of 48 total patients, 41 (85.4%) had a positive result, while 7 (14.58) were negative. Meanwhile, none of the control volunteers (32/32; 100%) tested positive. Such was consistent for all five geographical areas under investigation; square analysis showed that this difference was highly significant ($\chi^2 = 13.98$, $p \leq 0.01$), and indicated a close relation between disease state and ELISA positivity.

Table 1: The Percentage of Patients and Control Sample Results by ELISA

Groups	No.	Positive No. (%)	Negative No. (%)	Chi-Square (χ^2)
Patients	48	41 (85.4)	7 (14.58)	13.48 **
Control	32	0	32 (100.0)	15.00 **
Total	80	41 (51.52)	39 (48.75)	9.02 **
Chi-Square (χ^2)	--	13.98 **	13.98 **	--

**p≤0.01

Table 2: The Percentage of Patients and Control Sample Results in Relation to Gender

Gender	Positive No. (%)	Negative No. (%)	Total	Chi-Square (χ^2)
Males	25 (89.28)	3 (10. 7)	28	13.37 **
Females	16 (80. 0)	4 (40.0)	20	12.71 **
Total	41 (85.42)	7 (14.58)	48	13.48 **
Chi-Square (χ^2)	0.972 NS	0.972 NS	---	---

**p≤0.01, NS: Non-Significant

Table 3: The Percentage of Patients and Control Sample Results (Hbcab Igg Kit Result) in Relation to the Age Group of the Patients

Age group (year)	No. of samples	HBsAg Positive No. (%)	HBsAg Negative No. (%)	Chi-Square (χ^2)
1-12	4	1 (1.25)	3 (3.75)	0.319 NS
13-20	5	1 (1.25)	4 (5.00)	0.577 NS
21-30	21	15 (18.75)	6 (7.50)	7.41 **
31-40	25	13 (16.25)	12 (15.00)	0.403 NS
41-50	25	11 (13.75)	14 (17.50)	0.427 NS
Total	80	41 (51.25)	39 (48.75)	7.24 **
Chi-Square (χ^2)	---	9.182 **	5.027 *	---

*p≤0.05, **p≤0.01, NS: Non-Significant

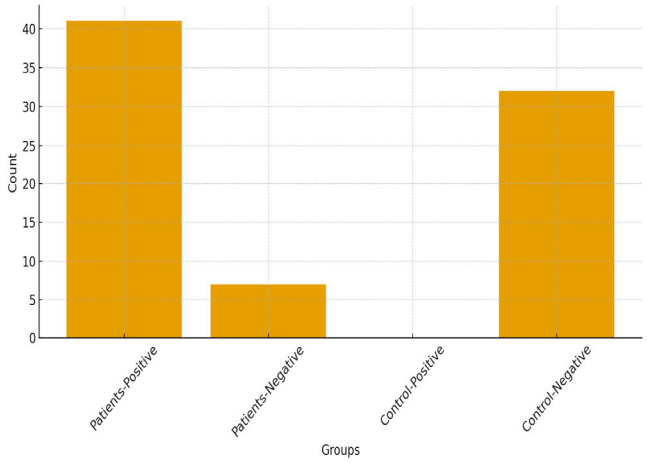

Figure 1: Distribution of Positive and Negative Cases

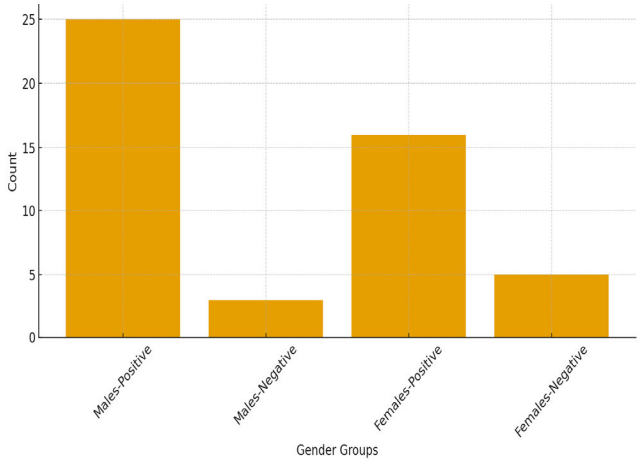

Figure 2: Distribution of Positive and Negative Cases by Gender

This is further evidence for the diagnostic validity and specificity of the ELISA method in distinguishing infected patients from healthy controls.

A representation of positive and negative incidences by gender 2 is shown in the following table. With significant differences, percentages are also given along with the chi-square condition to decide if there is really any difference at all between women and men in their occasional disease rates: Negative exams: 25 were positive, and 3 (10.7%) were negative in our example. Positive exams: Females-16 (76%) positive, 5 negative (23%) Females-26 (89%) positive, 3 negative Males-23 (78%) positive, 6 negative in the left-hand column; Males-22 (88%) positive, 3 negative When we look at the chi-square value for gender differences (0.972), it is marked as non-significant (NS), implying that there are no statistically significant differences in male and female distribution with respect to this particular data-set's state of health Nevertheless, statistical analysis showed no significant differences (p≤0.01) between sexes in this study as seen from Table 2 (Figure 1).

In Table 3, the present study demonstrates a statistically significant association between age group and HBsAg seropositivity ($\chi^2 = 9.182$, $p<0.01$), indicating that hepatitis B virus (HBV) infection is not uniformly distributed across age categories. Out of the total 80 examined individuals, 41 (51.25%) were HBsAg positive, while 39 (48.75%) were negative, reflecting a relatively high burden of HBV infection in the studied population (Figure 2).

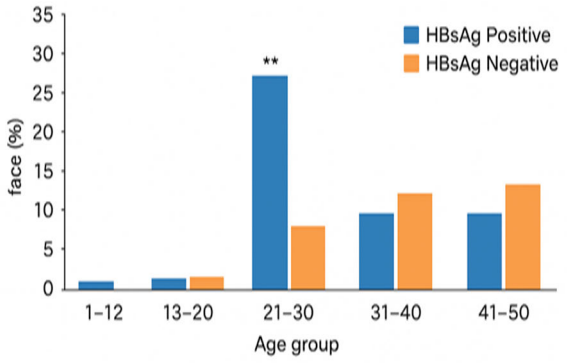

Figure 3: Distribution of HBsAg-Positive and HBsAg-Negative Cases by Age Groups

DISCUSSION

Table 4 shows a very strong separation between the patient group and controls by ELISA, and this pattern is exactly what you would expect when the "patients" are clinically suspected/known HBV cases and the controls are truly healthy/low-risk. Controls: 0/32 positive (100% negative) strongly supports high practical specificity in your setting and reduces concern about false-positive reactivity. Patients: 41 positives vs 7 negatives indicate ELISA is capturing most suspected cases. The reported $\chi^2 = 13.98$; $P \leq 0.01$ confirms a statistically significant association between disease status and ELISA positivity.

The "all controls negative" finding is consistent with Iraqi blood-donor and screening data showing generally low HBsAg prevalence in donor/healthy populations (often around the low-to-intermediate range depending on place/time and screening strategy) [8].

Recent Iraqi blood bank work also highlights why anti-HBc can be positive even when HBsAg is negative and why confirmatory nucleic acid testing may be used when "occult" HBV is suspected. In Iraqi clinical cohorts (patients rather than donors), studies commonly rely on ELISA markers (HBsAg, anti-HBc, HBeAg, etc.) for profiling, which aligns with your approach [9]. Internationally, ELISA/serology remains the frontline test for identifying HBV infection, and major guidelines emphasise that staging and treatment decisions should integrate serology with ALT, HBV DNA, HBeAg status, and fibrosis assessment [10]. So, ELISA has diagnostic utility for case–control discrimination, but a "negative" ELISA in symptomatic/suspected patients [11].

It provides a distribution of positive and negative cases for gender (male and female). Sample size percentages along with chi-squares are given so that you can see that the difference between the two is significant. Males: 25 (89.28%) males were positive, and 3 (10.7%) were negative. Females: 16 (76.19%) were positive, and 5 were negative (23.81%). Although not significant, when we look at the chi-square value for gender differences (0.972), this is marked as non-significant (NS), indicating there's no statistically significant difference in this particular dataset [12]. In this study, however, the data-analysis showed that there are no significant differences between genders ($p \leq 0.01$), as seen from Table 2.

The present study evaluated the association between age groups and hepatitis B surface antigen (HBsAg) seropositivity among the studied population. The results demonstrated a statistically significant association between age and HBsAg status ($\chi^2 = 9.182$, $P<0.01$), indicating that age is an important determinant in the epidemiology of hepatitis B virus (HBV) infection [13]. The χ^2 result indicates that, within your sampled patients, sex was not a strong independent determinant of ELISA positivity. In practice, this means the assay performs similarly across sexes and that the observed male–female difference could be due to sampling variation rather than a true biological difference. That indicate to "a higher proportion in males was observed, but the difference did not reach statistical significance" [14].

In Table 3 the highest prevalence of HBsAg positivity was observed in the 21–30 years age group (18.75%), followed by the 31–40 years (16.25%) and 41–50 years (13.75%) age groups. In contrast, markedly lower positivity rates were recorded among children aged 1–12 years (1.25%) and adolescents aged 13–20 years (1.25%). These findings suggest that young and middle-aged adults represent the most affected population, likely due to increased exposure to risk factors such as unsafe medical procedures, occupational exposure, blood transfusion, dental treatments, and behavioural factors [15].

This protective effect of early immunisation against hepatitis B has been observed in countries with a high prevalence of the disease [16].Our results are consistent with those of several Iraqi epidemiological studies. Al-Kubaisi et al. (2021) and Al-Dulaimi et al. [17,18]. reported that HBV infection is mainly found in Iraq among people aged 20-45 years, with a much lower incidence in children who have received vaccination. In the same way, results from Baghdad, Diyala and Basrah suggest that Iraq's highest carrier of HBV is the 21–40 age group – a result borne out by this work and those of other researchers [19].Also, Hussein et al. [20] found a statistically significant link between age and HBsAg positivity ($P<0.05$), which meant that it is of great importance for Iraq's population to consider their own role in the accumulation of hazards from healthcare and society during their adult life.

The same trends have been found in the Middle East, Asia and Africa. Iran, Egypt, Pakistan and China have given consistent testimony that HBV infection prevalence is higher among middle-aged young adults. By contrast, children show far lower rates due to the wider coverage achieved by vaccination programmes [21].In Iraq, the spread of HBV in adults has been put down to horizontal transmission alongside unsafe injections, and questions about who should be tested do not arise until relatively late in the infection. In particular, the World Health Organisation (WHO) has pointed out that in many countries where HBV is prevalent

Table 4: A Very Strong Separation between the Patient Group and Controls by Elisa

Age group (years)	HBsAg Positive (%)	HbsAg Negative (%)	Total
1–12	1 (1.25)	0 (0.00)	1 (1.25)
13–20	1 (1.25)	1 (1.25)	2(2.50)
21–30	15 (18.75)	2 (2.50)	17 (21.25)
31–40	13 (16.25)	2 (2.50)	15 (18.75)
41–50	11 (13.75)	2 (2.50)	13 (16.25)
Total	41 (51.25)	7 (8.75)	48 (60.0)

at an intermediate level, the adult population remains the major source of chronic HBV infection. This applies especially to Iraq [22].

CONCLUSIONS

In summary, these results are in line with recent literature indicating that ELISA offers strong sensitivity and specificity if under automation and with well-defined antigens. The statistically significant difference in patients from controls gives powerful support for the clinical relevance of the assay in this study group. The serological findings show a physiologically meaningful level of HBV burden among patients sampled and underscore the need for structured clinical–laboratory data. Iraq urgently needs work to add, along the lines of what WHO/EASL/AASLD says, HBV DNA, HBeAg, ALT and fibrosis staging. This would give a more rigorous risk calculation with clearer implications for treatment and surveillance.

Availability of Data and Materials

All data generated or analysed during this systematic review will be included in the published article and its supplementary information files.

Competing Interests

The authors declare that they have no competing interests.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

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