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Assessment of Hepatic Biochemical Profile According to Anti-Hepatitis B Core IgM Reactivity in Apparently Healthy Blood Donors

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KEYWORDS
Alanine aminotransferase; Aspartate aminotransferase; Blood donors; Hepatitis B virus; Liver function tests..

ABSTRACT

Background & objectives: Hepatitis B virus (HBV) infection remains an important cause of transfusion-transmitted infections despite routine hepatitis B surface antigen (HBsAg) screening. Anti-hepatitis B core immunoglobulin M (anti-HBc IgM) is a marker of recent HBV infection and may be associated with subclinical hepatic injury. The present study aimed to evaluate the hepatic biochemical profile according to anti-HBc IgM reactivity among apparently healthy blood donors.

Methods: This hospital-based cross-sectional study included 115 apparently healthy voluntary and replacement blood donors recruited between December 2023 and March 2024. Donors were classified into anti-HBc IgM reactive (n=9) and non-reactive (n=106) groups based on serological status. Serum total bilirubin, aspartate aminotransferase, alanine aminotransferase, and alkaline phosphatase were estimated using an ERBA EM-200 automated clinical chemistry analyser. Comparisons between groups were performed using the independent Student's t-test.

Results: Anti-HBc IgM reactive donors demonstrated significantly higher mean serum total bilirubin (1.96±0.48 vs. 0.85±0.22 mg/dL), AST (68.77±11.92 vs. 32.45±8.56 U/L), ALT (74.33±14.85 vs. 34.90±9.14 U/L), and ALP (186.11±37.02 vs. 104.52±24.17 U/L) than non-reactive donors (all *P*<0.001). Elevated hepatic biochemical parameters were also more frequently observed among anti-HBc IgM reactive donors.

Cconclusions: Apparently healthy blood donors with anti-HBc IgM reactivity exhibited significant hepatic biochemical abnormalities compared with non-reactive donors, suggesting the presence of subclinical hepatic involvement despite the absence of clinical symptoms. Assessment of hepatic biochemical parameters may complement donor evaluation and improve understanding of early HBV-associated liver injury. Further multicentre studies with larger sample sizes and molecular confirmation are warranted.....

1. INTRODUCTION

Hepatitis B virus (HBV) infection remains a major global public health concern and a leading cause of chronic hepatitis,

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liver cirrhosis, and hepatocellular carcinoma[1,2]. Despite routine screening of donated blood for hepatitis B surface antigen (HBsAg), transfusion-transmitted HBV infection remains a concern because early or window-period infections may not be detected by conventional serological screening[3]. Ensuring the safety of donated blood therefore remains a

fundamental component of transfusion medicine. Apparently healthy blood donors may harbour subclinical hepatic abnormalities despite fulfilling standard donor eligibility criteria[4]. Hepatic biochemical markers, including aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase (ALP), and total bilirubin, are widely used to assess hepatocellular injury and liver function[5]. Evaluation of these parameters may provide valuable information on underlying hepatic alterations in asymptomatic individuals[6]. Immunoglobulin M antibody to hepatitis B core antigen (anti-HBc IgM) is a serological marker of recent HBV infection and may be detectable during the serological window period when HBsAg is absent[7]. Although several studies have investigated HBV serological markers among blood donors, limited evidence is available regarding hepatic biochemical alterations according to anti-HBc IgM reactivity, particularly among apparently healthy blood donors in the Indian population. Therefore, the present study aimed to evaluate the hepatic biochemical profile of apparently healthy blood donors and compare serum AST, ALT, ALP, and total bilirubin levels according to anti-HBc IgM reactivity.

2. MATERIAL AND METHODS

Study design and setting: This hospital-based cross-sectional study was conducted at the Blood Centre, Bright Star Hospital, Moradabad, Uttar Pradesh, India, between December 2023 and March 2024. The study was undertaken as part of the doctoral research programme of the College of Paramedical Sciences, Teerthanker Mahaveer University, Moradabad.

Study population: A total of 115 apparently healthy voluntary and replacement blood donors attending the blood centre during the study period were consecutively enrolled after obtaining written informed consent. Based on anti-hepatitis B core immunoglobulin M (anti-HBc IgM) antibody status determined during routine serological screening, donors were classified into anti-HBc IgM reactive (n = 9) and non-reactive (n = 106) groups. Hepatic biochemical parameters were subsequently evaluated and compared between the two groups.

Sample collection: Approximately 5 mL of venous blood was collected aseptically from each donor during routine blood donation. Blood samples were allowed to clot, and serum was separated by centrifugation at 3000 rpm for 10 min. The separated serum was immediately used for the estimation of hepatic biochemical parameters.

Biochemical analysis: Serum total bilirubin, AST, ALT, and ALP were measured using an automated clinical chemistry analyzer (ERBA EM-200, Transasia Bio-Medicals Ltd., Mumbai, India) with commercially available reagent kits according to the manufacturer's instructions.

Statistical analysis: Data were analysed using IBM SPSS Statistics version XX (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD), whereas categorical variables were presented as frequencies and percentages. Differences in biochemical parameters between anti-HBc IgM reactive and non-reactive donors were assessed using the independent Student's *t*-test. A two-tailed *P* value <0.05 was considered statistically significant.

3. RESULT

Demographic Characteristics of Study Participant

A total of 115 apparently healthy blood donors was included in the study. The mean age of the participants was 33.20 ± 7.03 years. Of the total donors, 112 (97.4%) were male and 3 (2.6%) were female, indicating a marked predominance of male donors (Figure 1).

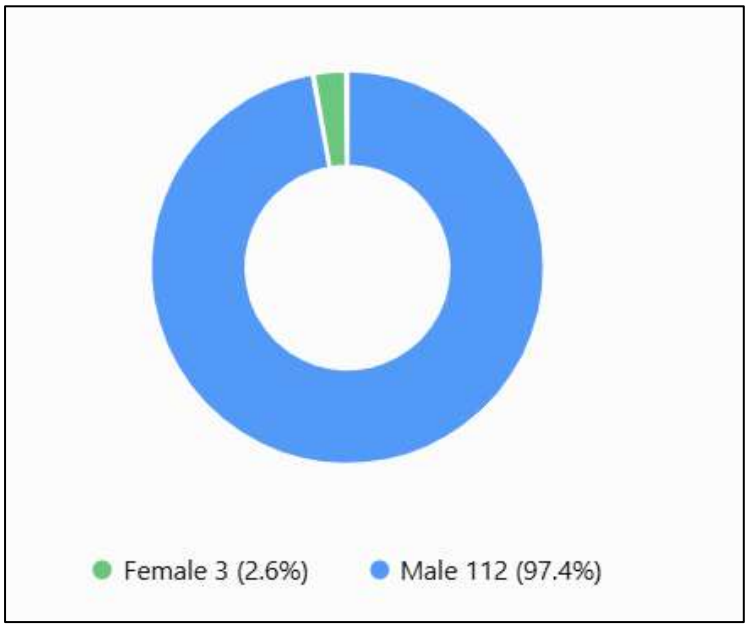

Figure 1. Gender Distribution of Study Participants.

Elevated hepatic biochemical parameters by anti-HBc IgM reactivity

Elevated total bilirubin was observed in 12 (11.3%) anti-HBc IgM non-reactive donors and 8 (88.9%) reactive donors. Elevated ALP was detected in 30 (28.3%) non-reactive and 7 (77.8%) reactive donors. Similarly, elevated AST and ALT were observed in 31 (29.2%) and 29 (27.4%) non-reactive donors, respectively, compared with 7 (77.8%) reactive donors for both parameters (Figure 2).

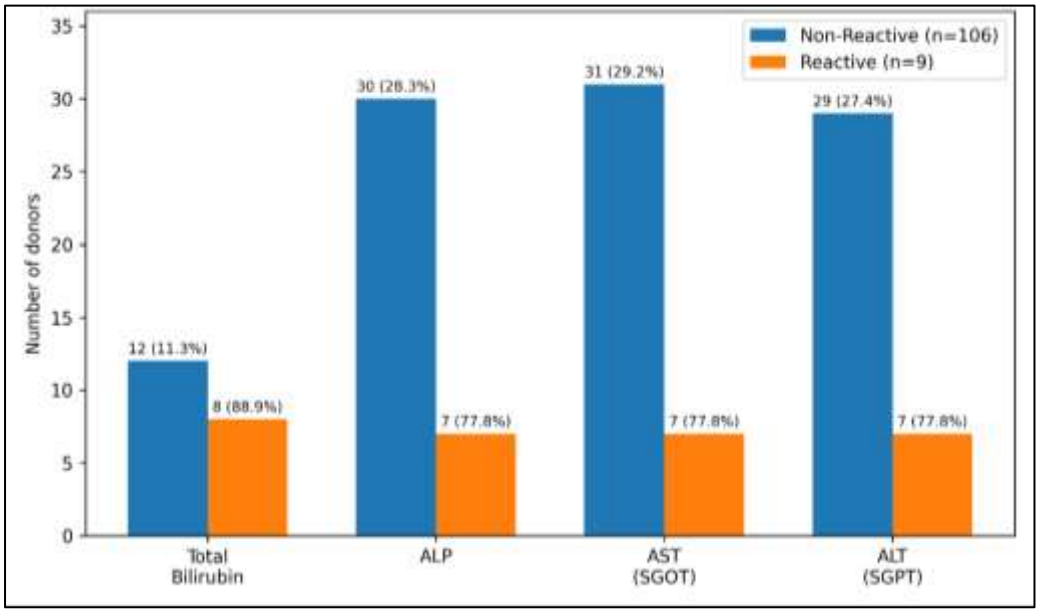

Figure 2. Elevated Hepatic Biochemical Parameters by Anti-HBc IgM Reactivity.

Comparison of hepatic biochemical parameters between anti-HBc IgM non-reactive and reactive blood donors

Serum hepatic biochemical parameters were significantly higher in anti-HBc IgM reactive blood donors than in non-reactive donors (Table 1). The mean total bilirubin level was 1.96 ± 0.48 mg/dL in the reactive group compared with 0.85 ± 0.22 mg/dL in the non-reactive group (t=7.82, P<0.001). Similarly, significantly higher mean levels of AST (68.77 ± 11.92 vs 32.45 ± 8.56 U/L), ALT (74.33 ± 14.85 vs 34.90 ± 9.14 U/L), and ALP (186.11 ± 37.02 vs 104.52 ± 24.17 U/L) were observed among anti-HBc IgM reactive donors (all P<0.001).

Table 1. Comparison of hepatic biochemical parameters between anti-HBc IgM non-reactive and reactive blood donors

Parameter	Non-Reactive (n = 106) Mean ± SD	Reactive (n = 9) Mean ± SD	*t*-value	*P* value
Total bilirubin (mg/dL)	0.85 ± 0.22	1.96 ± 0.48	7.82	<0.001
AST (SGOT) (U/L)	32.45 ± 8.56	68.77 ± 11.92	10.46	<0.001
ALT (SGPT) (U/L)	34.90 ± 9.14	74.33 ± 14.85	9.72	<0.001
ALP (U/L)	104.52 ± 24.17	186.11 ± 37.02	8.58	<0.001

Data are presented as mean ± standard deviation (SD). Comparisons between groups were performed using the independent Student's t-test. P<0.05 was considered statistically significant.

4. DISCUSSION

The present study evaluated the hepatic biochemical profile of apparently healthy blood donors according to anti-hepatitis B core immunoglobulin M (anti-HBc IgM) reactivity. Although all donors fulfilled standard eligibility criteria for blood donation and were clinically asymptomatic, anti-HBc IgM reactive donors demonstrated significantly higher serum total bilirubin, AST, ALT, and ALP levels than non-reactive donors. These findings suggest that recent HBV exposure, as indicated by anti-HBc IgM reactivity, may be associated with subclinical hepatic injury despite the absence of overt clinical manifestations. In the present study, the mean serum AST, ALT, ALP, and total bilirubin levels were significantly higher among anti-HBc IgM reactive donors (all P<0.001). Elevation of aminotransferases reflects hepatocellular injury resulting from hepatocyte membrane damage, whereas increased ALP and bilirubin may indicate associated cholestatic changes or impaired hepatic function **Iluz-Freundlich et al. (2020)**[8]. These biochemical abnormalities observed in apparently healthy donors emphasize that liver involvement may be present even in individuals who satisfy routine donor selection criteria **Marjani et al. (2016)**[9]**.** Our findings are consistent with the observations of **Makroo et al. (2012),** who evaluated anti-HBc-positive blood donors in India and reported that a proportion of anti-HBc-reactive donors exhibited elevated liver enzymes despite being HBsAg negative[10]. The authors suggested that biochemical abnormalities in these donors may represent underlying hepatic injury requiring further evaluation. The present findings also support the biological significance of anti-HBc IgM as a marker of recent HBV infection. Anti-HBc IgM may be detectable during the serological window period when HBsAg is no longer detectable, allowing identification of donors who might otherwise remain undetected by routine HBsAg screening alone **Kumar et al. (2007)**[11] studies have therefore highlighted the potential value of anti-HBc IgM testing in improving blood safety, particularly in regions with intermediate to high HBV endemicity. The significant elevation of AST and ALT observed in the present study is biologically plausible because these enzymes are released into the circulation following hepatocellular injury induced by viral infection and immune-mediated destruction of infected hepatocytes **Kew et al. (2000)**[12]**.** Likewise, increased ALP and total bilirubin may reflect early hepatic dysfunction accompanying acute or recent HBV infection **Kwo et al. (2026)**[5]. Although the biochemical abnormalities observed in the present study cannot independently establish active liver disease, they indicate ongoing hepatic involvement that warrants further clinical evaluation. The clinical implications of these findings are noteworthy. Blood donor screening in many centres primarily relies on HBsAg testing for HBV detection. However, donors with anti-HBc IgM reactivity may represent recent infections during the serological window period and may already exhibit biochemical evidence of hepatic injury despite being apparently healthy. The present study has certain limitations. It was conducted at a single centre with a relatively small number of anti-HBc IgM reactive donors. Molecular confirmation using HBV DNA testing and long-term clinical follow-up were not performed. Nevertheless, the study provides valuable preliminary evidence regarding hepatic biochemical alterations associated with anti-HBc IgM reactivity among apparently healthy blood donors and highlights the need for larger multicentre studies incorporating molecular assays to validate these findings.

5. CONCLUSION

The present study demonstrated that apparently healthy blood donors with anti-HBc IgM reactivity exhibited significantly higher serum levels of total bilirubin, AST, ALT, and ALP than non-reactive donors, indicating the presence of subclinical hepatic biochemical alterations despite the absence of clinical symptoms. These findings highlight the potential value of evaluating hepatic biochemical parameters alongside routine donor screening to identify individuals with recent HBV exposure and possible early liver involvement. Further large-scale, multicentre studies incorporating molecular assays such as HBV DNA testing are warranted to validate these findings and to better define their implications for blood donor screening and transfusion safety.

Declarations:

Ethics approval and consent to participate: Approved by the Institutional Ethics Committee, College of Paramedical Sciences, Teerthanker Mahaveer University, Moradabad, Uttar Pradesh, India (Ref. No. PM/ETHICAL/COPS/2023/024; dated 31 July 2023). Written informed consent was obtained from all participants before enrolment in the study.

Consent for publication: Not applicable.

Availability of data and materials: The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests: The authors declare that they have no competing interests.

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Authors' contributions: D.S. conceptualized and conducted the study, performed data analysis, and prepared the manuscript. N.K. supervised the study, critically reviewed the manuscript, and approved the final version.

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