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Research Article

Seroprevalence of Hepatitis B Virus Infection in a Tertiary Care Hospital in Northeastern Karnataka, India: A 12-Month Retrospective Study

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ABSTRACT
Background & Objectives: Viral hepatitis B remains a major global public health concern and a significant cause of chronic liver disease, cirrhosis, and hepatocellular carcinoma. India falls within the intermediate endemicity zone for Hepatitis B virus (HBV) infection, accounting for 10–15% of the worldwide carrier pool. This study evaluated the seroprevalence of Hepatitis B surface antigen (HBsAg) across diverse clinical populations, including antenatal women, voluntary blood donors, and HIV-infected individuals, at a tertiary care center in Northeastern Karnataka, India.
Methods: A hospital-based retrospective observational study was conducted at the Department of Microbiology, Gulbarga Institute of Medical Sciences and Hospital, Kalaburagi, spanning 12 months from March 2023 to February 2024. Serum samples from 39,869 patients (comprising outpatient, inpatient, antenatal, blood bank, and pre-operative cohorts) were screened for HBsAg using immunochromatographic rapid assays (Hepacard, J. Mitra & Co. Pvt. Ltd.; reported sensitivity >99%, specificity >99%). Seroprevalence was analyzed in relation to gender, seasonal patterns, and targeted clinical subgroups. Statistical analyses were performed using Pearson's Chi-square (x^2) test and 95% confidence intervals (CI).
Results: Out of 39,869 individuals screened, 574 tested positive for HBsAg, establishing an overall seroprevalence of 1.44% (95% CI: 1.32%–1.56%). Male seroprevalence was significantly higher than female seroprevalence (1.58% [355/22,401] vs. 1.25% [219/17,468]; $x^2 = 7.39$, $p = 0.0066$; Odds Ratio = 1.26, 95% CI: 1.07–1.49). Subgroup analysis revealed the highest positivity rate among voluntary blood donors (1.79%, 88/4,906; 95% CI: 1.44%–2.21%), followed by HIV-co-infected individuals (1.51%, 23/1,520; 95% CI: 0.96%–2.26%) and antenatal care (ANC) patients (1.21%, 149/12,260; 95% CI: 1.03%–1.42%).
Conclusion: The HBsAg seroprevalence of 1.44% places this region in the lower spectrum of intermediate HBV endemicity. The elevated prevalence among voluntary blood donors underscores the critical importance of rigorous pre-transfusion screening and stringent infection control practices. Routine antenatal screening and universal neonatal birth-dose vaccination remain essential to disrupt vertical transmission.

Keywords: Hepatitis B Surface Antigen, HBsAg, Seroprevalence, Blood Donors, Antenatal Care, Co-infection, Epidemiology, Karnataka.

INTRODUCTION
Viral hepatitis represents a profound global health burden, with mortality rates comparable to tuberculosis and exceeding those attributable to HIV infection. Globally, an estimated 254 million individuals live with chronic Hepatitis B virus (HBV) infection, leading to approximately 1.1 million deaths annually, primarily due to complications such as liver cirrhosis and hepatocellular carcinoma (HCC). World Health Organization (WHO) regional classifications categorize geographic areas based on Hepatitis B surface antigen (HBsAg) prevalence as high (≥8%), intermediate (2%–7%), or low (<2%).
India is situated in the intermediate endemicity zone, with reported HBsAg positivity in the general population ranging between 1.1% and

12.2%, averaging 2%–4%. Given its population size, India harbors approximately 40 million chronic HBV carriers—representing 10% to 15% of the global pool. Approximately 15% to 25% of individuals with chronic HBV infection succumb prematurely to end-stage liver disease or primary liver malignancies.

Transmission of HBV occurs through exposure to infectious blood or body fluids via parenteral routes (unsafe therapeutic injections, contaminated syringes, and unscreened blood products), sexual contact, and vertical (perinatal) transmission from infected mothers to infants. Perinatal acquisition carries the highest risk of chronicity, with 70% to 90% of perinatally infected infants becoming lifelong chronic carriers, compared to less than 5% among adults acquiring the infection.

In healthcare environments, unsafe administration of injections and blood product transfusions remains a key transmission risk factor. Nationally, regulatory frameworks under The Drugs and Cosmetics Act (1940) and the National Action Plan Combating Viral Hepatitis mandate statutory pre-transfusion screening of all donated blood units for HBsAg, Anti-HCV, and HIV. Concurrently, the Universal Immunization Programme (UIP) emphasizes timely administration of the HBV birth dose within 24 hours of delivery, followed by a primary vaccine series at 6, 10, and 14 weeks.

Regional epidemiological data are vital for monitoring disease patterns and evaluating prevention initiatives. This study was undertaken to establish the seroprevalence of HBsAg across outpatient, inpatient, antenatal, blood bank, and special clinical cohorts at a tertiary care institution in Northeastern Karnataka, India.

MATERIALS AND METHODS

Study Design and Setting

A hospital-based retrospective observational study was conducted in the Department of Microbiology at Gulbarga Institute of Medical Sciences and Hospital (GIMS), Kalaburagi, Karnataka, India. GIMS is a tertiary care teaching facility serving urban and rural populations across the district. The study evaluated laboratory records over a 12-month period from March.

Inclusion and Exclusion Criteria

Inclusion Criteria

- Patients presenting to outpatient (OPD) and inpatient (IPD) departments with clinical features suggestive of acute or chronic viral hepatitis or jaundice under diagnostic evaluation.
- Asymptomatic patients undergoing routine pre-operative viral screening prior to elective or emergency surgical procedures.
- Pregnant women attending Antenatal Care (ANC) clinics.
- Voluntary and replacement blood donors presenting to the hospital blood bank.
- Patients with confirmed HIV infection undergoing routine baseline co-infection screening.

Exclusion Criteria:

- Individuals with documented, complete Hepatitis B vaccination history (minimum 3 doses).
- Inadequate, severely hemolyzed, or lipemic blood specimens.
- Repeat or duplicate screening entries for the same patient within the study duration.

Specimen Collection and Laboratory Assays

Venous blood specimens (3–5 mL) were collected aseptically in sterile, additive-free vacutainer tubes. Samples were permitted to clot at room temperature for 30–45 minutes, followed by centrifugation at 3,000 rpm for 10 minutes to obtain clear serum. Serum specimens were processed immediately for HBsAg detection using a commercial rapid immunochromatographic assay (Hepacard, J. Mitra & Co. Pvt. Ltd., New Delhi, India), following the manufacturer's operational protocol. The test strip utilizes direct sandwich immunoassay principles with monoclonal anti-HBsAg antibodies, offering a reported sensitivity of >99% and specificity of >99% (analytical sensitivity limit of 0.5 ng/mL). Internal controls were validated for every test cassette.

Statistical Analysis

Data were entered into Microsoft Excel 2019 and analyzed using SPSS software (Version 26.0, IBM Corp., Armonk, NY, USA). Categorical data are presented as frequencies, percentages, and 95% Confidence Intervals (95% CI) calculated using the Wilson score method. Categorical comparisons between subgroups (e.g., gender disparities and cohort variations) were performed using Pearson's Chi-square (χ^2) test and Odds Ratios (OR). A two-tailed p-value < 0.05 was considered statistically significant.

Results

Overall Seroprevalence and Gender Distribution

A total of 39,869 individuals were screened for HBsAg during the 12-month study period. Of these, 574 tested positive, yielding an overall HBsAg seroprevalence of 1.44% (95% CI: 1.32%–1.56%).

Table 1: HBsAg Seroprevalence Disaggregated by Gender

Gender	Total Screened (n)	HBsAg Positive (n)	Seroprevalence (%)	95% Confidence Interval
Male	22,401	355	1.58%	1.42% – 1.75%
Female	17,468	219	1.25%	1.09% – 1.43%
Total	39,869	574	1.44%	1.32% – 1.56%

Male patients accounted for 61.85% (355/574) of all HBsAg-positive cases. Male seroprevalence (1.58%) was significantly higher than female seroprevalence (1.25%) ($\chi^2 = 7.39$, $p = 0.0066$; Odds Ratio = 1.26, 95% CI: 1.07–1.49).

Monthly Trends in HBsAg Screening and Positivity

Monthly screening volumes and positive detections were monitored across the 12-month timeframe from March 2023 through February 2024.

Table 2: Monthly Breakdown of HBsAg Screening and Positivity Rates

Month	Males Screened	Females Screened	Total Screened	Male Positive	Female Positive	Total Positive	Monthly Positivity Rate (%)
March 2023	2,220	1,391	3,611	29	11	40	1.11%
April 2023	2,080	1,510	3,590	25	15	40	1.11%
May 2023	2,098	1,434	3,532	28	18	46	1.30%
June 2023	2,019	1,508	3,527	35	22	57	1.62%
July 2023	2,005	1,232	3,237	32	10	42	1.30%
August 2023	2,461	1,390	3,851	40	22	62	1.61%
September 2023	2,008	1,339	3,347	26	15	41	1.22%
October 2023	1,754	1,599	3,353	31	18	49	1.46%
November 2023	1,307	2,025	3,332	17	15	32	0.96%
December 2023	1,507	1,669	3,176	29	18	47	1.48%
January 2024	1,459	1,162	2,621	40	36	76	2.90%
February 2024	1,483	1,209	2,692	23	19	42	1.56%
Total	**22,401**	**17,468**	**39,869**	**355**	**219**	**574**	**1.44%**

Monthly positivity rates ranged from a low of 0.96% in November 2023 to a peak of 2.90% in January 2024.

Subgroup Analysis across Target Populations

Specific screening sub-cohorts demonstrated varying infection burdens.

Table 3: HBsAg Seroprevalence in Targeted Clinical Cohorts

Subgroup Cohort	Total Screened (n)	HBsAg Positive (n)	Seroprevalence (%)	95% Confidence

				Interval
Antenatal Care (ANC) Patients	12,260	149	1.21%	1.03% – 1.42%
Blood Donors	4,906	88	1.79%	1.44% – 2.21%
HIV-Positive Cohort	1,520	23	1.51%	0.96% – 2.26%

The blood donor cohort demonstrated the highest positivity rate (1.79%), which was significantly higher than the antenatal screening cohort (1.21%) ($\chi^2 = 9.12$, $p = 0.0025$; Odds Ratio = 1.48, 95% CI: 1.14–1.93).

DISCUSSION

Epidemiological surveillance of HBV is essential for identifying high-risk cohorts, evaluating preventive interventions, and guiding regional health policy. In this 12-month study of 39,869 individuals at a tertiary hospital in Kalaburagi, the overall HBsAg seroprevalence was 1.44% (95% CI: 1.32%–1.56%). This finding places Northeastern Karnataka in the lower range of intermediate endemicity, consistent with broader hospital-based studies across India, which typically report HBsAg prevalence rates between 1.1% and 3.5%.

Gender Disparities

The significantly higher prevalence observed among male participants (1.58% vs. 1.25%, $p = 0.0066$) is consistent with global epidemiological trends. Proposed explanations for male predominance include increased behavioral exposure risks (e.g., occupational exposures, higher rates of unprotected contact, and unsterile invasive procedures) as well as biological mechanisms. Estrogen has been shown to exert protective immunomodulatory effects that promote faster viral clearance, whereas androgens may enhance viral replication and suppress immune response mechanisms.

Blood Donor Screening and Safety Dynamics

The HBsAg prevalence of 1.79% among voluntary blood donors is noteworthy, as blood donors are typically presumed to represent a healthy population. Pre-transfusion donor screening remains a critical line of defense against transfusion-transmitted infections (TTIs). The positivity rate in our donor cohort (1.79%) reflects ongoing asymptomatic carriage in the community. While mandatory serological testing prevents contaminated units from entering the blood supply, the risk of window-period transmission persists with rapid card screening alone. Adopting individual-donor Nucleic Acid Testing (NAT) alongside mandatory ELISA testing can further minimize occult HBV transmission risks.

Antenatal Screening and Perinatal Prevention

In our antenatal cohort of 12,260 pregnant women, HBsAg prevalence was 1.21% (95% CI: 1.03%–1.42%). Maternal-fetal transmission remains a primary driver of chronic infection in endemic settings. Given that up to 90% of perinatally acquired HBV infections progress to chronic liver disease, universal antenatal screening coupled with timely birth-dose vaccination (administered within 24 hours of delivery) and Hepatitis B Immunoglobulin (HBIG) administration for exposed infants is critical to achieving viral elimination goals.

HIV/HBV Co-infection

In the HIV-infected cohort, HBsAg co-infection prevalence was 1.51% (95% CI: 0.96%–2.26%). Dual infection with HIV and HBV complicates clinical management, accelerating the progression of liver fibrosis, cirrhosis, and end-stage liver disease. These findings reinforce the importance of routine screening for viral hepatitis markers in all newly diagnosed HIV patients to guide appropriate antiretroviral regimen selection (e.g., incorporating dual-active agents such as Tenofovir and Lamivudine or Emtricitabine).

Strengths and Limitations

Strengths: This study evaluated a large sample size (N = 39,869) over a full 12-month annual cycle at a major tertiary care hospital in Northeastern Karnataka. Disaggregation across specific cohorts (ANC, blood donors, HIV) provides actionable insights for public health strategy in the region.

Limitations:

1. **Diagnostic Methodology:** Screening relied on rapid immunochromatographic card tests. While appropriate for high-volume, resource-limited screening settings, rapid

tests offer lower analytical sensitivity compared to Enzyme-Linked Immunosorbent Assays (ELISA), Chemiluminescent Immunoassays (CLIA), or Nucleic Acid Testing (NAT), which may lead to under-detection of low viral load or occult HBV cases.

2. **Lack of Confirmatory & Serological Markers:** Laboratory records did not consistently include additional markers such as HBeAg, Anti-HBe, Anti-HBc (Total/IgM), or quantitative HBV DNA levels to differentiate acute from chronic infections or assess viral replication activity.
3. **Single-Center Hospital Bias:** Hospital-based sampling may over-represent individuals seeking medical evaluation compared to community-based epidemiological surveys.

Recommendations and Conclusion

The 1.44% overall HBsAg seroprevalence observed in this study aligns with low-to-intermediate endemicity. Based on these findings, the following interventions are recommended:

- **Enhanced Blood Safety:** Transitioning blood bank screening from rapid immunochromatographic assays to automated ELISA/CLIA platforms, with consideration of Nucleic Acid Testing (NAT) to reduce window-period transmission risks.
- **Universal Antenatal Care Protocols:** Mandatory HBsAg screening for every pregnant woman, accompanied by guaranteed access to the HBV birth-dose vaccine and HBIG for infants born to HBsAg-positive mothers.
- **Safe Injection Practices & Infection Control:** Re-enforcing universal precautions, single-use auto-disable syringes, and strict waste management protocols across healthcare facilities.
- **Confirmatory Diagnostic Infrastructure:** Upgrading diagnostic facilities to include molecular testing (HBV DNA PCR) to improve management of chronic and occult cases.

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