IMC Journal of Medical Science
January 2026; Vol. 20(1):007
DOI: https://doi.org/10.55010/imcjms.20.007

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Original Article

Seroprevalence of Hepatitis B surface antigen in a tertiary care setting in Maharashtra, India: clinical and public health impact.

Sabiha Tamboli[1*], Kananbala Yelikar[2]

[1]Department of Microbiology, ASPL'S CSMSS Medical College and Hospital, Limbejalgaon, Chatrapati Sambhajinagar, Maharashtra, India
[2]Dean, ASPL'S CSMSS Medical College and Hospital, Limbejalgaon, Chatrapati Sambhajinagar, Maharashtra, India

Abstract

Background and objectives: Hepatitis B virus (HBV) infection remains one of the most significant global health challenges, with an estimated 296 million chronically infected individuals worldwide. Hepatitis B surface antigen (HBsAg) detection is a cornerstone in the serological diagnosis of HBV, serving as a marker for both acute and chronic infection. Despite the availability of advanced diagnostic techniques such as enzyme-linked immunosorbent assay (ELISA) and chemiluminescent immunoassay (CLIA), rapid immunochromatographic tests (ICTs) are widely used in resource-limited healthcare settings for their affordability and simplicity. The present study aimed to determine the seroprevalence of HBsAg among patients attending a tertiary care hospital over six months, analyse the distribution of infection across age and gender and compare findings with other studies.

Materials and methods: A hospital-based cross-sectional study was conducted in the Department of Microbiology, from January 2025 to June 2025. A total of 3,200 serum samples were screened for HBsAg using rapid ICT kits. (Erba HBsAg Rapid test Manufacturer's name Transasia Biomedicals Ltd, Mumbai Maharashtra India). Data were analysed by age, gender, and monthly trends.

Results: Out of 3,200 samples screened, 53 tested positive, yielding an overall prevalence of 1.65%. The highest positivity was observed in patients >60 years (4.54%), followed by the 41-60 years age group (2.58%). No positive cases were detected among children <12 years. Prevalence was nearly equal among males (2.0%) and females (1.26%). Month-wise analysis showed a fluctuating trend, with the highest positivity in April (2.03%). The highest HBsAg rate was observed among suspected hepatitis cases 2.50%, followed by Preoperative screening 1.64%.

Conclusion: The study highlights a low prevalence of HBsAg in our hospital population, consistent with WHO's "low endemicity" category. The absence of infections in children reflects the success of childhood vaccination programs, while persistence in adults suggests the need for catch-up vaccination strategies. Comparisons with similar studies confirm declining HBV prevalence across India. Strengthened surveillance, improved diagnostic confirmation and targeted immunization remain critical for achieving HBV elimination goals.

***Correspondence**: *Sabiha Tamboli, Department of Microbiology, ASPL'S CSMSS Medical College and Hospital, Limbejalgaon, Chatrapati Sambhajinagar, Maharashtra, India. Email: sabihatamboli77@gmail.com.*

Introduction

Hepatitis B virus (HBV) infection continues to pose a global health burden, affecting both developed and developing nations. According to the World Health Organization (WHO), an estimated 296 million people were living with chronic HBV infection in 2022, resulting in nearly 820,000 deaths annually from cirrhosis and hepatocellular carcinoma (HCC) [1]. HBV is considered highly infectious, with transmission rates significantly higher than HIV and remains a major cause of preventable morbidity and mortality [2].

The epidemiology of HBV varies geographically. Based on HBsAg prevalence, WHO categorizes regions as low (<2%), intermediate (2–7%), and high (>8%) endemicity [3]. Countries in sub-Saharan Africa and East Asia report high prevalence, while Europe and North America fall into low prevalence zones. India represents an intermediate-endemic country, with earlier reports estimating an average prevalence of 2–8%, though significant difference exists among different states and communities [4,5]. Meta-analyses suggest that while rural and tribal populations exhibit higher prevalence, urban areas often show lower values due to improved healthcare access and immunization [6].

The introduction of hepatitis B vaccination has significantly altered prevalence rates globally. Nations such as Taiwan and South Korea have demonstrated remarkable declines in HBV prevalence following universal vaccination, with reductions to <1% among younger populations [7,8]. In India, the vaccine was introduced into the Universal Immunization Program (UIP) in 2002 in selected states and expanded nationally by 2011 [9]. Studies now indicate reduced prevalence in children and adolescents, though adult cohorts remain affected due to lack of vaccination during earlier decades [10].

Diagnosis of HBV infection relies on detection of specific viral antigens and antibodies. Hepatitis B surface antigen (HBsAg), which appears in the serum 1–10 weeks after exposure and indicates both acute and chronic infection. Chronic infection is defined as persistent HBsAg for >6 months [11]. Its detection is essential for blood donor screening, antenatal care, preoperative evaluation and hospital admissions. While enzyme-linked immunosorbent assay (ELISA) and chemiluminescent immunoassays (CLIA) remain the gold standard due to higher sensitivity and specificity, rapid immunochromatographic tests (ICTs) are extensively employed in resource-limited healthcare facilities [12]. Diagnostic accuracy varies: ELISA sensitivity 98-100% and specificity 99-100%; CLIA sensitivity /specificity 99-100%; ICT sensitivity 60-98% and specificity 90-99%. These tests provide quick results, are cost-effective and require minimal technical expertise, making them highly suitable for routine hospital-based screening.

In India, several studies have reported variable prevalence of HBsAg depending on geography, socioeconomic factors, vaccination coverage, and study population [13–15]. The present study was undertaken to estimate the prevalence of HBsAg among patients attending a tertiary care hospital over six months, to analyse the influence of age and gender, to observe monthly variations and to compare findings with other published studies.

Materials and methods

This was a prospective, hospital-based cross-sectional study conducted at CSMSS Medical College and Hospital, Limbejalgaon, Maharashtra, India, in the Department of Microbiology, over a six-month period from January 2025 to June 2025. The majority of patients attending this tertiary care hospital belong to lower and middle socio-economic strata from rural area.

Prior to initiation, the study protocol was reviewed and approved by the Institutional Ethics Committee (IEC). Confidentiality of patient information was strictly maintained and test results were reported only to treating physicians.

A total of 3,200 blood samples were collected from patients attending both outpatient and inpatient departments. Samples included those requested for preoperative screening, antenatal check-up, general medical evaluation and suspected cases of hepatitis. Hemolyzed and inadequate samples were excluded from the study. Vaccination history was not consistently available in medical records.

Serum samples were screened for HBsAg using a commercially available rapid immunochromatographic test (ICT) kit (Erba

HBsAg Rapid test Transasia Biomedicals Ltd, Mumbai Maharashtra India). Manufacturer's instructions were strictly followed. According to the manufacturer, sensitivity and specificity of the kit were 99.8% and 99.7%, respectively. Each test included built-in control lines and additional internal positive and negative controls were run periodically for quality assurance. Patients of all age groups and both genders tested for HBsAg. Repeat samples from the same patient within the study period were excluded.

Data were categorized by age, gender and month of collection. Results were expressed as frequencies and percentages.

Lack of ELISA/ CLIA confirmation is acknowledged as a limitation. Data were analysed using descriptive statistics and Chi-square testing, with $p<0.05$ considered statistically significant.

Results

Out of 3200 samples screened during the six-month period, 53 were positive for HBsAg, yielding an overall prevalence rate of 1.65%.

Table-1: *The distribution of HBsAg positivity across age groups*

Age group (years)	Total tested	Positive cases	Rate (%)
<12	420	0	0.00
13–20	610	5	0.82
21–40	1100	16	1.45
41–60	850	22	2.58
>60	220	10	4.54
Total	3200	53	1.65

Age association was statistically significant (p<0.05)

Table-2: *Gender-wise distribution of HBsAg positivity*

Gender	Total tested	Positive cases	Rate (%)
Male	1700	34	2.0
Female	1500	19	1.26
Total	3200	53	1.65

Difference was not statistically significant.

Table-3: *Month-wise distribution of HBsAg positivity*

Month (2025)	Samples tested	Positive cases	Rate (%)
January	500	5	1.0
February	520	4	0.77
March	530	7	1.32
April	540	11	2.03
May	550	6	1.09
June	560	8	1.43
Total	3200	53	1.65

Prevalence ranged 0.77% to 2,3%; overall 1.65%

Table-4: *The distribution of HBsAg positivity according to study group*

Study group	Total tested	Positive cases	Rate (%)
Preoperative screening	1100	18	1.64
Antenatal cases	900	14	1.55
General medical evaluation	800	11	1.37
Suspected hepatitis cases	400	10	2.50
Total	3200	53	1.65

Table-5: *Age and sex distribution of HBsAg positive cases according to study group*

Study group	Age Groups (years)	Male	Female	Total Positive
Preoperative screening (n=18)	13-20	2(11.1%)	0 (0%)	2(11.1%)
	21-40	1(5.6%)	0 (0%)	1(5.6%)
	41-60	7(38.9%)	1(5.6%)	8(44.4%)
	>60	3(16.7%)	3(16.7%)	6(33.3%)
	<12	0 (0%)	0 (0%)	0 (0%)
Antenatal cases(n=14)	21-40	0 (0%)	14(100%)	14(100%)
	Other age groups	0 (0%)	0 (0%)	0 (0%)
General medical evaluation (n=11)	13-20	2(18.2%)	0 (0%)	2(18.2%)
	21-40	0 (0%)	0 (0%)	0 (0%)
	41-60	7(63.6%)	0 (0%)	7(63.6%)
	>60	1(9.1%)	1(9.1%)	2(18.2%)
	<12	0 (0%)	0 (0%)	0 (0%)
Suspected hepatitis cases (n =10)	13-20	1(10%)	0 (0%)	1(10%)
	21-40	1(10%)	0 (0%)	1(10%)
	41-60	7 (70%)	0 (0%)	7 (70%)
	>60	2 (20%)	0 (0%)	2 (20%)
	<12	0 (0%)	0 (0%)	0 (0%)

Total positive cases = 53 (Male=34, Female=19)

Discussion

The present hospital-based cross-sectional study conducted over six months demonstrated an overall HBsAg prevalence of 1.65% among 3,200 patients. This prevalence places our study population within the low endemicity zone, as per WHO classification (<2%) [3].

Our findings are similar to several recent studies in India that have reported a declining trend in HBV prevalence. For instance, Chowdhury et al. [16] in West Bengal documented a prevalence of 1.2%, while Singh et al. [17] in Uttar Pradesh reported 1.5%. Similarly, a meta-analysis by Batham et al. [6] concluded that the pooled prevalence in India is approximately 1.5–2%. This indicates encouraging progress toward HBV elimination targets set for 2030.

In our study, prevalence was highest among individuals above 60 years (4.54%), whereas no positive cases were observed in children <12 years. The absence of infections among younger children likely reflects the impact of universal immunization programs introduced over the last two decades [9]. Similar age-related patterns have been reported in studies from Tamil Nadu [18] and Maharashtra [19], where vaccination was associated with significant reductions in paediatric prevalence. On the other hand, higher prevalence among older adults is attributable to infection acquired prior to the introduction of vaccination, as well as long-term persistence in chronically infected carriers.

We observed nearly equal prevalence among males (2.0%) and females (1.26%). While some studies

have reported a higher prevalence among males, possibly due to occupational exposure, risk behaviours or healthcare-seeking patterns [20] others have found no significant gender differences [21]. Our findings suggest that gender is not a major determinant in this population.

Within each study group, preoperative screening cases showed higher positivity among middle aged males (21-60 years). All antenatal positive cases belonged to 21-40 years age group, consistent with reproductive age profile. General medicine evaluation cases were distributed across adult age groups with higher positivity among male. Suspected hepatitis cases show higher positivity among males, particularly in the 21-60 years age group. No positive case was detected in children (<12 years). (Table-5)

A fluctuating monthly trend was observed, with the highest positivity recorded in April (2.03%). Such variations may be incidental or influenced by seasonal differences in hospital admissions, referral patterns and healthcare access. Similar fluctuations were noted by Ramesh et al. [22] in Karnataka.

Our prevalence (1.65%) is consistent with reports from several low-prevalence regions such as the United States (<1%) [23] and European countries (<2%) [24]. However, it remains far below the rates documented in sub-Saharan Africa and parts of Southeast Asia, where prevalence ranges from 5–10% [25]. This disparity emphasizes the need for region-specific public health strategies.

The absence of HBsAg positivity among children underscores the success of India's childhood vaccination strategy. Despite that, the persistence of infection among adults highlights the necessity of catch-up vaccination programs targeting unvaccinated adolescents and adults. Further, pregnant women remain a critical group for screening, given the risk of mother-to-child transmission [26].

When analyzed according to study groups, the highest HBsAg rate was observed among suspected hepatitis cases 2.50%, followed by preoperative screening 1.64% and antenatal cases 1.55%. General evaluation group showed the lowest rate 1.37%. highest positivity due to clinical presentation while lower rate in ANC is due to routine surveillance findings.

Although ICT kits are useful for rapid screening, they may lack the sensitivity and specificity of ELISA and CLIA [12]. False negatives can occur in cases of low antigenemia, while false positives may arise from cross-reactivity. Hence, confirmatory testing is recommended, particularly for blood donor screening and antenatal care.

The strength of this study lies in its sizeable sample size and detailed subgroup analysis. However, the reliance on ICT alone and the single-centre hospital-based nature limit generalizability. Future studies should incorporate confirmatory assays and molecular testing such as HBV DNA PCR for better accuracy.

Conclusion

The present study revealed a low prevalence (1.65%) of HBsAg among hospital patients in our region reflecting progress in HBV control measures. The results indicate significant progress in HBV control, particularly the absence of infection in children, reflecting the impact of vaccination programs. However, higher prevalence in older adults underscores the need for catch-up vaccination, routine screening and confirmatory testing to support HBV elimination goals. Rapid ICT-based screening remains valuable in resource-limited hospitals but should ideally be complemented by confirmatory methods. Sustained public health strategies, enhanced awareness, and universal vaccination are key to achieving WHO's target of eliminating viral hepatitis as a public health threat by 2030.

Source of funding

None

Conflict of interest

None of the authors has any conflict of interest

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Cite this article as:
Tamboli S, Yelikar K. Seroprevalence of Hepatitis B surface antigen in a tertiary care setting in Maharashtra, India: clinical and public health impact. *IMC J Med Sci.* 2026; 20(1):007.
DOI: https://doi.org/10.55010/imcjms.20.007.