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Current Status on the Epidemiology of Hepatitis B Virus Infection in İstanbul

İstanbul'daki Hepatit B Virüsü Enfeksiyonunun Epidemiyolojisine İlişkin Mevcut Durum

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Abstract

Introduction: Despite the availability of safe and effective vaccines against Hepatitis B virus (HBV), the infection remains a significant global health issue. This study examined all serological markers of HBV at the largest hospital in İstanbul to identify hepatitis B cases and assess current seroprevalence.

Materials and Methods: Data from cases analyzed between May 2020 and October 2023 included the following parameters: hepatitis B surface antigen (HBsAg), hepatitis B e antigen (HBeAg), antibody to hepatitis B surface antigen (anti-HBs), antibody to hepatitis B e antigen (anti-HBe), IgM antibody to hepatitis B core antigen (anti-HBc IgM), and total antibody to hepatitis B core antigen (anti-HBc total), all measured using the Roche cobas e 801 analyzer.

Results: HBsAg positivity was detected in 2.11% of 467,163 patients. Among 39,046 children, the HBsAg positivity rate was 0.47%. The highest HBsAg positivity was observed in the 51-60 age group. Acute hepatitis B, indicated by anti-HBc IgM positivity, was identified in 0.41% of 17,293 patients. Among those who tested positive for HBsAg, 1.90% were also positive for HBeAg. Anti-HBs was positive in 46.27% of 294,631 patients overall and in 67.35% of 44,293 children. The highest anti-HBs positivity was observed in the <1 year and 1-5 year age groups. The lowest positivity rates for both HBsAg and anti-HBs were recorded in 2023.

Conclusion: With an HBsAg positivity rate of 2.11%, the region can be classified as having intermediate endemicity. This study aims to support seroprevalence assessments by providing updated data, contributing to efforts toward hepatitis B control goals.

Keywords: Hepatitis B virus, acute hepatitis B, hepatitis B vaccine, seroprevalence, İstanbul

Öz

Giriş: Hepatit B virüsü (HBV) için güvenli ve etkili aşılar mevcut olmasına rağmen, enfeksiyon küresel bir sağlık sorunu olmaya devam etmektedir. Bu çalışmada, İstanbul'un en büyük hastanesinde hepatit B vakalarını ve güncel seroprevalansı belirlemek amacıyla hepatit B virüsüne ait tüm serolojik parametreler incelenmiştir.

Gereç ve Yöntem: Mayıs 2020 ile Ekim 2023 tarihleri arasında analiz edilen vakalarda, hepatit B yüzey antijeni (HBsAg), hepatit B e antijeni (HBeAg), hepatit B yüzey antijenine karşı antikor (anti-HBs), hepatit B e antijenine karşı antikor (anti-HBe), hepatit B çekirdek antijenine karşı IgM tipi antikor (anti-HBc IgM) ve toplam hepatit B çekirdek antijenine karşı antikor (anti-HBc total) parametreleri, Roche Cobas e 801 cihazı kullanılarak değerlendirilmiştir.

Bulgular: Çalışmada, 467.163 hastanın %2,11'inde HBsAg(+) saptanmıştır. Otuz dokuz bin kırk altı çocukta HBsAg pozitiflik oranı %0,47 olarak bulunmuştur. En yüksek HBsAg oranı 51-60 yaş grubunda görülmüştür. On yedi bin iki yüz doksan üç hastanın %0,41'i anti-HBc IgM pozitif bulunmuş ve akut hepatit B olarak değerlendirilmiştir. HBsAg(+) hastaların %1,90'ında HBeAg testi pozitif çıkmıştır. İki yüz doksan dört bin altı yüz otuz bir hastanın %46,27'si anti-HBs pozitifti. Kırk dört bin iki yüz doksan üç çocuğun %67,35'i anti-HBs pozitifti. En yüksek anti-HBs pozitifliği <1 ve 1-5 yaş gruplarında saptanmıştır. HBsAg ve anti-HBs pozitifliği 2023 yılında en düşük seviyede bulunmuştur.

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Öz

Sonuç: Bölgemiz %2,11 HBsAg pozitiflik oranı ile orta düzey endemisite göstermektedir. Bu çalışmanın, hepatit B'nin mevcut seroprevalansını ortaya koyarak hepatit B kontrol hedeflerine ulaşılmasında seroprevalans değerlendirmelerine katkı sağlayacağına inanıyoruz.
Anahtar Kelimeler: Hepatit B virüsü, akut Hepatit B, Hepatit B aşısı, seroprevalans, İstanbul

Introduction

Although effective and safe vaccines exist for the Hepatitis B virus (HBV), the infection continues to represent a global health burden[1]. HBV remains a major public health issue, with approximately 296 million individuals chronically infected worldwide and 820,000 deaths reported in 2019[2]. The highest burden of HBV infection is observed in the World Health Organization (WHO) Western Pacific and African Regions[3]. The prevalence of HBV is assessed based on the serological presence of hepatitis B surface antigen (HBsAg) in the general population of a given geographic area. A prevalence of HBsAg of ≥8% is categorized as high endemicity, 5-7% as high-intermediate, 2-4% as low-intermediate, and <2% as low endemicity[4]. Türkiye is considered a intermediate endemic region for HBV, with HBsAg prevalence reaching between 2-8%. The national average HBsAg positivity rate is approximately 3.9%, corresponding to an estimated three million HBV-infected individuals[5,6].

HBV is a DNA virus with an envelope, classified under the genus *Orthohepadnavirus* within the *Hepadnaviridae* family[7]. There are 10 recognized HBV genotypes, labeled A through J[8]. The distribution of these genotypes differs by geographic region[2]. In Türkiye, genotype D is the most prevalent[9]. HBV infection can be either acute or chronic, presenting with a spectrum that includes asymptomatic cases, mild illness, or severe and fulminant hepatitis. The age at which infection occurs plays a critical role in the likelihood of developing chronic infection. Chronic infection develops in approximately 90% of newborns and infants who contract the virus, compared to less than 5% of individuals infected in adulthood[10].

Vaccination is the most effective strategy for preventing HBV infection. The first HBV vaccine was approved by the US Food and Drug Administration in 1981. In 1986, the original plasma-derived vaccine was replaced with a recombinant version[11]. In Türkiye, the HBV vaccine was first introduced in 1998 as part of the national Extended Immunization Program. Since 2006, it has been administered at 0, 1, and 6 months of age[12]. The WHO recommends giving the first dose of HBV to all newborns within 24 hours of birth, followed by two or three doses spaced at least 4 weeks apart. For individuals who complete the three-dose schedule, booster doses are typically unnecessary. The vaccine confers protection for at least 20 years and likely provides lifelong immunity[3]. Although effective and safe vaccines are available, HBV infection remains a global health challenge. Understanding the epidemiology of HBV is important from a public health perspective. This study aimed to identify hepatitis B cases and assess current seroprevalence by evaluating all serological markers of HBV at the largest hospital in İstanbul.

Materials and Methods

This retrospective study included patients aged 0-99 years who were tested for any of the following parameters: HBsAg, HBeAg, anti-HBs, anti-HBe, anti-HBc IgM, and anti-HBc total-in the Medical Virology Laboratory of our hospital between May 2020 and October 2023. Demographic data of the participants were retrieved from the hospital's electronic medical records. Ethical approval for the study was granted by the Institutional Review Board of Başakşehir Çam and Sakura City Hospital (approval number: 2023/585, dated: 27.11.2023).

The parameters HBsAg, HBeAg, anti-HBs, anti-HBe, anti-HBc IgM, and anti-HBc total were assessed using the commercial kits Elecsys HBsAg II, Elecsys anti-HBs II, Elecsys HBeAg, Elecsys anti-HBe, Elecsys anti-HBc IgM, and Elecsys anti-HBc II (Roche Diagnostics, Germany). These assays were performed using the electrochemiluminescence immunoassay method on the Roche cobas e 801 analyzer (Roche, Germany). Internal quality controls were implemented for each test.

Samples with a cutoff index ≥1.0 were interpreted as positive for HBsAg. Those with a cutoff index between ≥0.90 and <1.0 were classified as borderline, while samples with a cutoff index <0.90 were considered negative. For the anti-HBs test, a result was deemed positive if the cutoff index was ≥10 IU/L. A cutoff index ≥1.0 was used to define positivity for both anti-HBc IgM and HBeAg tests. For the anti-HBc total and anti-HBe tests, samples with a cutoff index ≤1.0 were considered positive. Based on Türkiye's national vaccination schedule, age groups for evaluating HBsAg and anti-HBs parameters were defined as <1, 1-5, 6-17, 18-30, 31-40, 41-50, 51-60, and ≥60 years.

Individuals with positive anti-HBc and anti-HBs but negative HBsAg results were classified as immune due to past infection. Patients positive for anti-HBs but negative for both anti-HBc and HBsAg were considered immune due to vaccination (serological evidence of immunization). Individuals negative for all serological markers were categorized as susceptible to HBV

infection. Cases with negative HBsAg and anti-HBs but positive anti-HBc total were identified as having isolated anti-HBc.

Statistical Analysis

Statistical analyses were conducted using SPSS version 22.0. The normality of variable distributions was assessed through visual methods (histograms and probability plots) and the Kolmogorov-Smirnov test. Comparisons of quantitative variables were performed using the Mann-Whitney U test, while qualitative variables were evaluated with the Pearson chi-squared test. The strength and significance of relationships between variables were determined using Spearman's rank correlation coefficient. A p-value of less than 0.05 was considered indicative of statistical significance.

Results

This study included a total of 480,620 individuals, of whom 6.54% were foreign nationals, and analyzed 675,503 samples for hepatitis B serology. The average age of participants was 37.93±19.18 years, with females comprising 49.99%. The mean age of foreign nationals (29.83±16.38) was significantly lower than that of Turkish citizens (38.50±19.23) (p<0.001).

HBsAg positivity was detected in 2.11% (n=9873) of the 467,163 patients tested (Table 1, Figure 1). Ninety-one cases (0.019%) were classified as borderline for HBsAg and excluded from further analysis. The mean age of HBsAg-positive patients was 47.41±16.04, with males having significantly higher values (p<0.001). Among 39,046 children (aged 0-18) tested for HBsAg, the positivity rate was 0.47%, which was significantly lower than in adults (p<0.001). The highest HBsAg positivity was found in the 51-60 age group (p<0.001) (Figure 2). There was no significant difference in HBsAg positivity between Turkish citizens and foreign nationals (p=0.190). The rate of HBsAg positivity in 2023 was lower compared to previous years (p<0.001). The yearly distribution of HBsAg positivity is detailed in Table 1.

Among 17,293 patients tested for anti-HBc IgM, 0.41% (n=70) were positive and diagnosed with acute hepatitis B. The mean age of these 70 patients was 45.09±12.91, and 64.29% (n=45) were male. All patients diagnosed with acute hepatitis B had positive HBsAg results. The HBeAg test was positive in 1.90% (n=188) of the HBsAg-positive patients. Anti-HBe positivity was found in 1.28% (n=5.964) of the 467,163 patients included in the study. Figure 1 shows the flowchart of the included cases and their serological results.

Out of 294,631 patients tested for anti-HBs, 46.27% were positive (Table 1, Figure 1). The mean age of anti-HBs-positive patients was 33.30±22.52 and the anti-HBs positivity rate was slightly but significantly higher in males (47.24%) than in females (45.47%, p<0.001). Among 44,293 children tested for anti-HBs, the positivity rate was 67.35%, which was significantly higher than in adults (p<0.001) (Table 1). The highest anti-HBs positivity was observed in the <1 and 1-5 age groups (p<0.001) (Figure 2). The anti-HBs positivity rate was higher in Turkish citizens compared to foreign nationals (p<0.001). Anti-HBs positivity was lower in 2023 than in previous years (p<0.001).

Table 1. HBsAg and Anti-HBs positivity rates by demographic factors and year

		HBsAg				Anti-HBs		
	Total, n	**Positive, n (%)**	**Negative, n (%)**	**p-value**	**Total, n**	**Positive, n (%)**	**Negative, n (%)**	**p[1]**
Number	467163	9873 (2.11)	457290 (97.87)		294631	136317 (46.27)	158314 (53.73)	
Age, mean		47.41±16.04	38.34±18.81			33.30±22.52	42.92±19.24	
Sex				<0.001				<0.001
Male	233156	5568 (2.39)	227588 (97.61)		132676	62674 (47.24)	70002 (52.76)	
Female	234007	4305 (1.84)	229702 (98.16)		161955	73643 (45.47)	88312 (54.53)	
Child	39046	185 (0.47)	38861 (99.53)	<0.001	44293	29832 (67.35)	14461 (32.65)	<0.001
Adult	428117	9688 (2.26)	418429 (97.74)		250338	106485 (42.54)	143853 (57.46)	
Nationality								
Turkish	436418	9231 (2.12)	427187 (97.88)	0.190	276519	129240 (46.74)	147279 (53.26)	<0.001
Foreigner	30745	642 (2.09)	30103 (97.91)		18112	7077 (39.07)	11035 (60.93)	
Years								
2020	35057	1111 (3.17)	33946 (96.83)	<0.001	22287	10421 (46.76)	11866 (53.24)	<0.001
2021	112341	2792 (2.49)	109549 (97.51)		75673	35758 (47.25)	39915 (52.75)	
2022	157566	3077 (1.95)	154489 (98.05)		95598	44692 (46.75)	50906 (53.25)	
2023	162199	2893 (1.78)	159306 (98.22)		101073	45446 (44.96)	55627 (55.04)	

[1]p-values <0.05 were considered statistically significant, HBsAg: Hepatitis B surface antigen

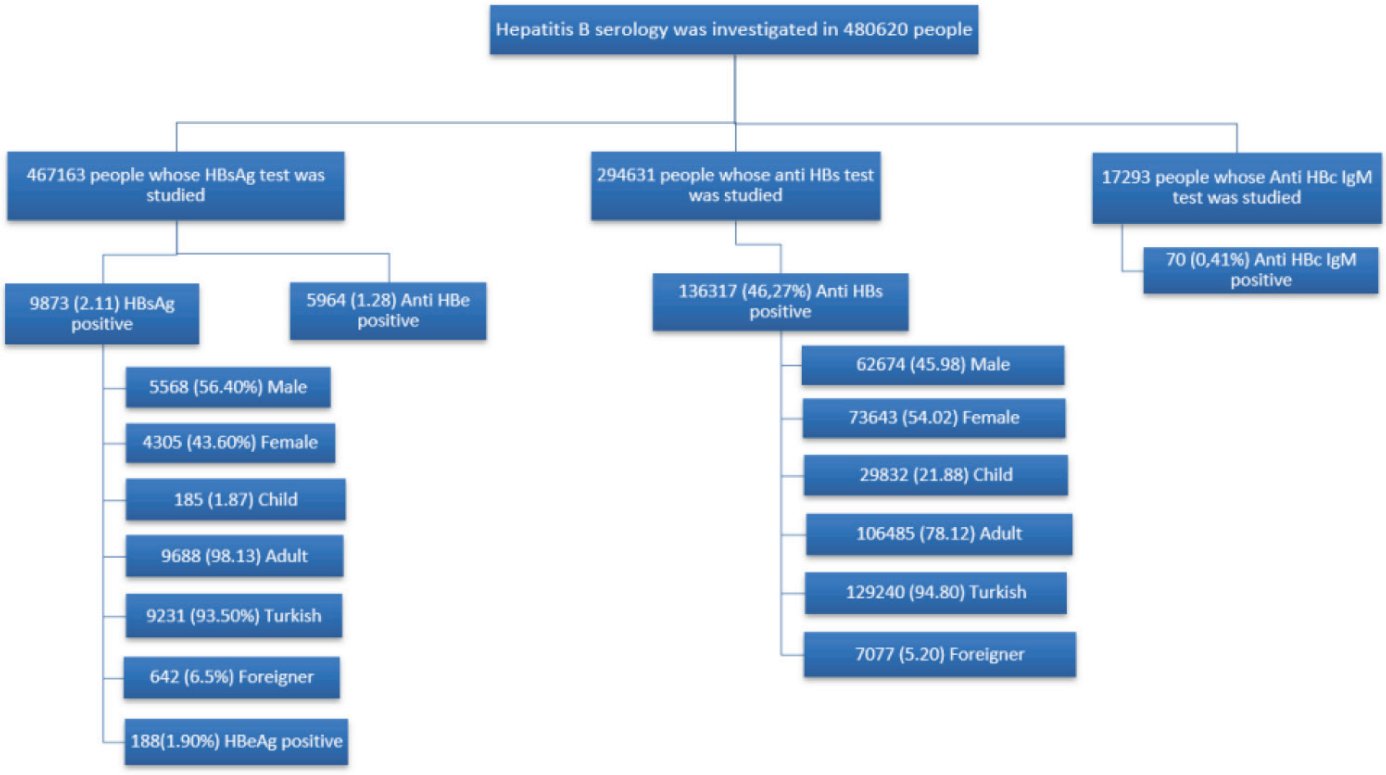

Figure 1. Flow chart and serological results of the people included in the study
HBsAg: Hepatitis B surface antigen, Anti-HBc IgM: IgM antibody to hepatitis B core antigen

The yearly distribution of anti-HBs positivity is presented in Table 1.

Immunity due to past infection was identified in 15.69% (4,688/29,874) of cases and was significantly higher among adults (p<0.001). The highest rate was seen in the >60 age group (p<0.001). Immunity from vaccination was observed in 25.10% (7,497/29,874) of cases. Isolated anti-HBc positivity was detected in 8.83% (2,639/29,874) of cases.

Discussion

Hepatitis B is among the most common infectious diseases worldwide. In our study, the prevalence of HBsAg positivity in the general population was 2.11%. A study from Northeast China reported an HBsAg positivity rate of 7.43%[13], while rates in Cameroon and South Africa were 5.08%[14] and 4.0%[15], respectively. Hepatitis B infection is endemic in many African countries, where HBsAg seroprevalence is higher compared to developed nations. This is linked to factors such as lower socioeconomic status, poor hygiene conditions, and limited education about infectious diseases in developing countries. Conversely, developed countries show lower prevalence rates. For instance, a study by Khetsuriani[16] found HBsAg prevalence rates of 0.3% in Germany and 0.2% in the Netherlands, which are significantly lower than those found in our study. This difference can be explained by established vaccination programs and better hygiene standards in developed countries. In Türkiye, a previous study reported an HBsAg positivity rate of 2.38%[17], aligning with our findings. The HBsAg prevalence of 2.11% found in our study indicates that Türkiye remains classified as a country with low to moderate endemicity (2-4%) according to WHO criteria. HBsAg positivity was 1.84% in females and 2.39% in males, with a significantly higher rate observed in males (p<0.001). In a study from Northeast China, HBsAg positivity was 5.80% in females and 8.94% in males[13]. In South Africa, the overall HBsAg positivity was 3.20%, with 4.80% in males. Both studies reported higher HBsAg positivity in males compared to females[15]. The prevalence of HBsAg was 0.47% in children and 2.09% among foreign nationals. HBsAg positivity was significantly higher in adults (p<0.001). There was no statistically significant difference between Turkish citizens and foreign nationals (p=0.190). The low prevalence of HBsAg in children (0.47%) is mainly attributed to the inclusion of HBV vaccine in the national childhood immunization program since 2006.

In our study, the mean age of HBsAg-positive patients was significantly higher (p<0.001). The highest HBsAg positivity was observed in the 51-60 age group (p<0.001). A study from

Northeast China reported the highest HBsAg prevalence in the 41-50 age group[13]. In Cameroon, the highest prevalence was found in the 17-31 age group, which differs from our findings[14]. In South Africa, the highest HBsAg prevalence was in the 40-44 age group[15]. A study conducted in Türkiye found the highest prevalence in the 25-44 age group[17]. The elevated HBsAg positivity in the older age group in Türkiye is thought to be related to the introduction of the hepatitis B vaccine in 2006. Therefore, individuals born before the vaccination program began may have been more susceptible to HBV infection and likely developed immunity through natural infection.

The anti-HBc IgM test was positive in 0.41% (n=70) of the 17,293 patients tested, indicating acute hepatitis B. The HBeAg test was positive in 1.90% (n=188) of the HBsAg-positive patients. All acute hepatitis cases were HBeAg positive. In a North American study involving 2,018 individuals, 60 were diagnosed with acute hepatitis B, with a mean age of 41.6 (33.7-51.1), and 28.33% (n=17) were female, consistent with our findings. However, unlike our study, only 43 of these acute hepatitis B cases were HBeAg positive[18]. In a Polish study, the number of acute

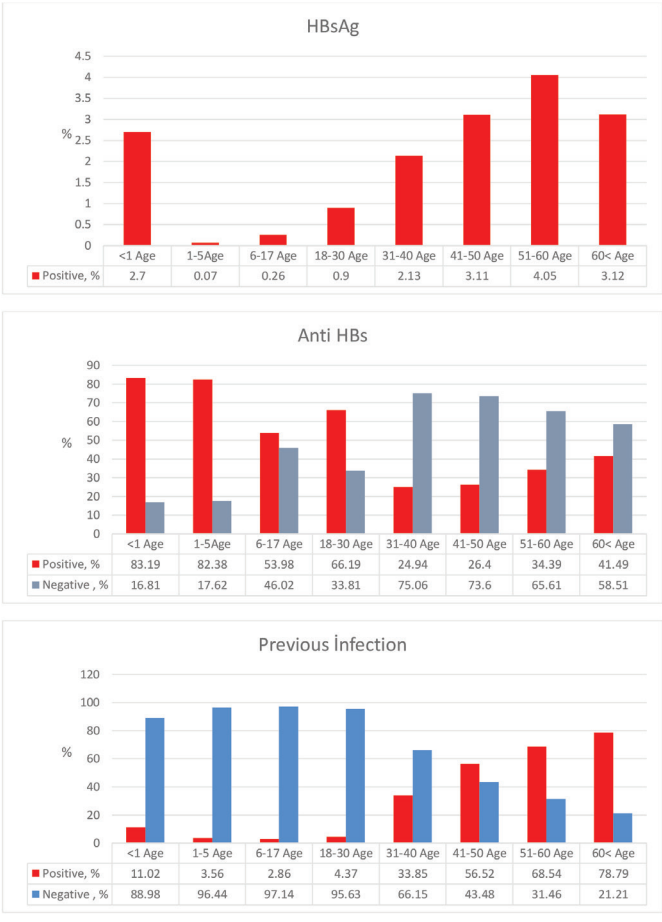

Figure 2. HBsAg, anti-HBs, and past infection positivity by age groups

HBsAg: Hepatitis B surface antigen

hepatitis B decreased from 649 in 2005 to 45 in 2019[19]. A study from Türkiye in 2013 reviewed acute hepatitis B notification rates between 1990 and 2012. The notification rate was 4.8 per 100,000 population in 1990, rising to 12.3 in 2005, then steadily declining to 3.9 and 3.6 per 100,000 in 2011 and 2012, respectively. In 1999, 64% of infants received three doses of the hepatitis B vaccine, and vaccination coverage increased to over 90% after 2006 following the implementation of the routine immunization program[20].

With the consistent implementation of vaccination programs in our country, along with improvements in socioeconomic conditions, better hygiene, and increased awareness about infectious diseases, we expect the number of cases to continue decreasing, eventually placing the country among those with low endemicity according to WHO classifications.

Among 294,631 patients tested for anti-HBs, 46.27% were positive. The mean age of anti-HBs-positive patients was 33.30±22.52 years. In a study from Northeast China involving 218,627 individuals, the prevalence of anti-HBs positivity was 46.88%, similar to our findings[13]. Another Chinese study reported an anti-HBs positivity rate of 44.75% among first-year university students between 2017 and 2019[21]. In a Turkish study of 309,037 individuals, the anti-HBs positivity rate was 55.38%[17]. Among 44,293 children tested for anti-HBs, 67.35% were positive, which was significantly higher than the rate observed in adults (p<0.001).

The highest anti-HBs positivity was found in the age group <1 to 5 years (p<0.001). In a study conducted in Italy among children aged 1-18 years, the prevalence of anti-HBs positivity was 59.4%, with the highest rate of 61.1% observed in the 16-18 age group[22]. The high rate of anti-HBs positivity among childhood in our country is likely due to the consistent implementation of childhood vaccination programs.

When total immunity was evaluated, vaccination-induced immunity accounted for 25.10% (7,497/29,874), while immunity from past infection accounted for 15.69% (4,688/29,874). Immunity from past infection was significantly higher in adults (p<0.001), with the highest rate seen in those >60 years of age (p<0.001). Although HBV infection is currently moderately endemic in our country, the rate of past infection remains considerable. However, we expect that the high prevalence of anti-HBs positivity will increase further in the coming years due to vaccination programs. The rate of anti-HBs positivity was lower among foreign nationals (39.07%) compared to Turkish citizens (p<0.001). This lower seroprevalence in foreigners may be related to the lack of or inadequate vaccination programs.

In our study, the prevalence of isolated anti-HBc positivity was found to be 8.83% (2,639/29,874). Isolated anti-HBc positivity

refers to the presence of anti-HBc alone without other hepatitis B serological markers. The frequency of isolated anti-HBc positivity varies from 0.1% to 20% across different populations. One study reported an average rate of 3-5% for isolated anti-HBc positivity in our country[23]. In the USA and Europe, this rate ranges between 1% and 4% of the population[24].

Isolated anti-HBc positivity can have multiple interpretations. It may represent a "false" positive caused by IgM-structured substances that disappear after treatment with reducing agents such as dithiothreitol, cysteine, or sodium metabisulfite, or it may result from diagnostic system errors (1-2%). It can also indicate acute infection during the window period when HBsAg has disappeared but anti-HBs has not yet developed; or chronic infection with HBsAg levels below the detection limit; or a humoral immune response defect to HBV antigens preventing the formation of other antibodies. Additionally, it may reflect the loss of anti-HBs over time or the inability to produce anti-HBs, especially in diabetic patients and those with kidney disease. Infections with viruses that share antigenic determinants with HBcAg (such as HCV) and, lastly, passive transfer of anti-HBc from mother to infant or through blood transfusion may occur[23].

Conclusion

Our region continues to show moderate endemicity for hepatitis B, with an HBsAg positivity rate of 2.11%. Therefore, the introduction of the anti-HBV vaccination program into the national immunization schedule in 2006 in our country is expected to prevent a worsening of the hepatitis B epidemiological situation in Türkiye from worsening, particularly by significantly reducing prevalence and incidence in the young population, which is the main target of vaccination efforts. Given the effectiveness of HBV vaccination in limiting the spread of the infection, it is expected that Türkiye will reach low endemicity for hepatitis B in the coming years. Measuring seroprevalence, preventing outbreaks, developing protective measures such as sanitation and hygiene, and especially implementing vaccination programs are important. By revealing the current status of hepatitis B in our region, we believe the results of this study will support efforts to improve vaccination coverage, implement regular population screening, and enhance HBV seroprevalence monitoring. These efforts will thereby aiding the achievement of hepatitis B control goals.

Study Limitations

This study has several limitations. First, because vaccination records were not available for the study population, it was not possible to assess vaccine failure or protection rates. Second, although the study was conducted in Istanbul, a cosmopolitan city, and at the largest city hospital, the findings may not be generalizable to the entire country.

Ethics

Ethics Committee Approval: Ethical approval for the study was granted by the Institutional Review Board of Başakşehir Çam and Sakura City Hospital (approval number: 2023/585, dated: 27.11.2023).

Informed Consent: Retrospective study.

Footnotes

Authorship Contributions

Concept: S.K., S.A., Design: M.K., S.K., S.A., Data Collection or Processing: M.K., Analysis or Interpretation: M.K., S.K., S.A., Literature Search: M.K., Writing: M.K.

Conflict of Interest: No conflict of interest was declared by the authors.

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