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REVIEW ARTICLE

# Investigating the Seroprevalence of HBV and HCV infection in Potential Donors: An6r tn e5r Study from Iranian Tissue Bank and Research Center (2014-2021)

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## ABSTRACT

**Background:** Hepatitis B virus (HBV) and hepatitis C virus (HCV) infections are major contributors to liver disease and hepatocellular carcinoma (HCC), affecting millions worldwide. Transmission routes and clinical outcomes vary between the two viruses, with both posing significant challenges in transplantation. Understanding the seroprevalence of HBV and HCV is crucial for effective pre-transplant screening and post-transplant management to prevent disease transmission and recurrence. The present study aimed to investigate the prevalence of HBV and HCV in potential donors referred to the Iranian Tissue Bank and Research Center (ITBRC).

**Methods:** The study population was potential donors referred to ITBRC between 2014 and 2021, including two groups: brain death donors and forensic donors referred from the Iranian Legal Medicine Organization. For HBV, HBsAg and HBsAb; and for HCV, HCV-Ab were detected by ELISA.

**Results:** A total of 3862 individuals were studied (32.4% female and 67.6% male), including 1349 (34.9%) brain death and 2513 (65.1%) circulatory death donors. Analysis showed 1.19 times higher rates of HCV infection in women than in men, but this was not statistically significant. Logistic regression showed no significant effects of donor type on HCV infection rates. For HBV, brain death subjects had over three times higher odds of HBsAg-positive tests compared to circulatory death (OR = 3.06, p-value < 0.05). Additionally, female cases had lower odds of an HBsAg-positive test compared to males (OR = 0.56). The odds of a positive HBsAg test in brain death cases were 2.7 times higher than in circulatory death, with 3.49% of cases being positive for HBsAg and HBsAb test results.

**Conclusion:** In conclusion, this retrospective study demonstrated a higher prevalence of HBV-positive tests in brain death donors compared to circulatory death donors, with female donors showing lower odds of HBsAg-positive tests compared to males.

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## Introduction

Hepatitis B virus (HBV) is a double-stranded DNA virus belonging to the *Hepadnaviridae* family. This virus is a common cause of liver inflammation, which can lead to Hepatocellular Carcinoma (HCC) [1, 2] It is estimated that 296 million people worldwide are living with chronic HBV [3]. Hepatitis C virus (HCV) is another virus responsible for liver cancer. This virus is a small enveloped RNA virus belonging to the *Flaviviridae* family [4]. A major serious complication of chronic hepatitis C is the development of cirrhosis [5]. HCV infection can affect individuals of all ages, but most acute cases of hepatitis C and the highest prevalence of anti-HCV antibodies are found in young adults [6]. It is estimated that there are approximately 100 million people worldwide with serological evidence of current or past HCV infection, causing about 700 000 deaths each year [7].

HBV and HCV viruses can be transmitted via parenteral, perinatal and sexual routes [8] HBV infection being more common than HCV, is mainly acquired by vertical transmission from an HBsAg+ mother or via horizontal transmission in childhood. In contrast, HCV is primarily transmitted parenterally in adulthood via intravenous drug abuse, and blood transfusion, but rarely through the placenta, breast-feeding, or sexual contact [9].

HBV and HCV carriers are at risk of developing cirrhosis and hepatocellular carcinoma (HCC) [10, 11]. Although transplantation is effective for treating decompensated cirrhosis and limited hepatocellular carcinoma associated with hepatitis C, recurrent infection leading to cirrhosis occurs in 10 to 25% of transplant recipients within 5 to 10 year of transplantation [12]. HBV has also posed a significant challenge within the field of transplantation over the past few decades [13]. HBV reactivation following organ transplantation, even in recipients with absent hepatitis B surface antigen at the time of transplantation can occur, and remains an important cause of morbidity and mortality [14].

Studying the seroprevalence of HBV and HCV in transplant recipients is important for pre-transplant screening, ensuring suitable organ allocation, and post-transplant management. It assists identifying infection in candidates, reducing the risk of transmission from infected donors, and tailoring care to prevent disease reactivation or progression.

Regarding the importance of this field, this study aimed to evaluate the HBV and HCV seroprevalence in potential donors referred to Iranian Tissue Bank and Research Center due to brain or circulatory death.

## Material and Methods

### *Study Population*

This retrospective study was conducted with approval of Tehran University of Medical Sciences ethics committee (IR.TUMS.SPH.REC.1402.329). The study population were potential organ/tissue donors referred to Iranian tissue bank and research center between 2014 and 2021. Demographic information of the patients including age, gender, and serological results of HBV and HCV were collected. Inclusion criteria involved the completeness of demographic information, including gender and age, along with the completion of serological test information for HCV and HBV. Both HBV and HCV initial screenings were performed using the ELISA kit (Dia.Pro, Italy), and confirmation of positive results was carried out using PCR.

### *Statistical Analysis*

In this study, collected data were entered and initially described in excel 2019, and analyzed by R programming language software. Frequency and percentage were calculated for categorical variables. Odds ratios were calculated and tested to compare subgroups. Logistic regression was applied to calculate adjusted odds ratio. Type I error considered 0.05.

## Results

A total of 3,862 donations were analyzed from 2014 to 2021. The annual number of donations ranged from 394 in 2021 (10.2%) to 616 in 2015 (16.0%). These donations comprised two categories: brain death donors (1,349; 34.9%) and circulatory death donors (2,513; 65.1%). The distribution of participants by year, gender, and type of case is summarized in (Table 1). Among the donors, 1,251 (32.4%) were female, and 2,611 (67.6%) were male.

Among brain death subjects, 956 (70.9%) were male; and 1655 (65.9%) subjects of forensic cases were male (Figure 1). In other words, 68.5% of females and 63.4% of males were brain death cases. As a result, the odds of being forensic case in female group was 1.26 times than in male group (OR= 1.26, p-value=0.003, 95% CI:(1.09, 1.45)).

Here, the data of HCV antibody was available for 3814 cases (48 were missing); in which, 44 (1.15%) cases had positive test results (e.g. 1.15% of them had hepatitis C antibody). The odds of hepatitis C infection in female were 1.19 times than in male (Table 2). However, this result was not significant at 0.05 type I error (p-value = 0.34). The odds of hepatitis C infection was the same in forensic and brain death cases (OR = 1.00, p-value = 0.53, 95% CI:(0.53, 1.87)). The simultaneous effect of gender and type of patient on HCV antibody was investigated using logistic regression. However, none of the effects in the model were significant (both p-values > 0.05).

(Table 3) demonstrates the results of HBV tests. The chance of having HBsAg in forensic subjects was

**Table 1.** Frequency and percentage by year, gender and type of subjects.

| Year | Total subjects | Gender | | Type of subject | |
|---|---|---|---|---|---|
| | | female | male | Brain death | Forensic |
| **2014** | 573 (14.8%) | 162 (28.3%) | 411 (71.7%) | - | 573 (100%) |
| **2015** | 616 (16.0%) | 240 (39.0%) | 376 (61.0%) | - | 616 (100%) |
| **2016** | 532 (13.8%) | 129 (24.2%) | 403 (75.8%) | - | 532 (100%) |
| **2017** | 413 (10.7%) | 157 (38.0%) | 256 (62.0%) | 89 (21.5%) | 324 (78.5%) |
| **2018** | 501 (13.0%) | 56 (11.2%) | 445 (88.8%) | 398 (79.4%) | 103 (20.6%) |
| **2019** | 421 (10.9%) | 147 (34.9%) | 274 (65.1%) | 421 (100%) | - |
| **2020** | 412 (10.7%) | 233 (56.6%) | 179 (43.4%) | 95 (23.1%) | 317 (76.9%) |
| **2021** | 394 (10.2%) | 127 (32.2%) | 267 (67.8%) | 346 (87.8%) | 48 (12.2%) |
| **Total** | 3862 (100%) | 1251 (32.4%) | 2611 (67.6%) | 1349 (34.9%) | 2513 (65.1%) |

Entries of the table are as follow: Frequency (percent)
For *gender* and *type of subject*, percent was calculated in each year (e.g. percent of row)

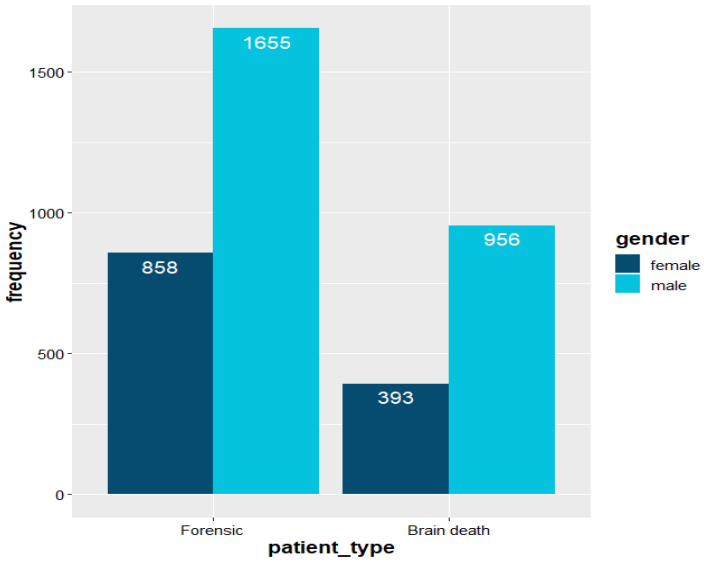


**Fig. 1.** Bar plot for type of patient and gender.

**Table 2**. HCV antibody by gender and type of patient (n=3814).

| | | total | positive | negative | OR (p-value) | 95% CI for OR | |
|---|---|---|---|---|---|---|---|
| | | | | | | lower | Upper |
| **Gender** | Female | 1236 | 16 (0.013) | 1220 (0.987) | 1.19 (0.340) | 0.64 | 2.21 |
| | Male | 2578 | 28 (0.011) | 2550 (0.989) | | | |
| **Type** | Circulatory death | 2512 | 29 (0.011) | 2483 (0.989) | 1.00 (0.399) | 0.53 | 1.87 |
| | Brain Death | 1302 | 15 (0.011) | 1287 (0.989) | | | |

*Significant level was considered 0.05. CI: confidence interval

3 times higher than in brain death cases (OR = 3.06, 95% CI: (1.61, 5.83), p-value <0.05). The odds of having positive HBsAg test results were significantly lower in female cases than in male (OR = 0.56, 95% CI: (0.42, 0.76)); the odds of positive HBsAg in males was 1.8 times than in females. The chance of having HBsAg in brain death cases was about 2.7 times more than in forensic (95% CI: (1.95, 3.73), p-value<0.001). 3814 out of 3862 cases had data about HBV antibody and antigen. 133 out of 3814 valid cases had HBsAb

(3.49%) and simultaneously had positive HBS-Ag test results.

## Discussion

The present study provided an insight into the distribution of positive cases over the years, between genders and various types of subjects. Brain death cases accounted for 34.9% of the total, while circulatory death cases constituted 65.1%. Furthermore, gender disparities were observed within these categories, with a higher prevalence of males in both brain death and forensic cases. Regarding HCV infection, the odds ratio suggested a slightly higher chances among female cases, although this finding did not reach statistical significance. Interestingly, no significant differences were observed between brain death and circulatory death cases concerning HCV infection. Similarly, the logistic regression model did not reveal any significant effects of gender or type of patient on HCV antibody presence. In contrast, for HBV, significant differences emerged. Brain death subjects exhibited over three-time higher odds of having HBsAg compared to circulatory death, with a statistically significant odds ratio. Additionally, females showed a significantly lower odds of having HBsAg compared to males. Similar trends were observed for HBsAb, with brain death cases again showing significantly higher odds compared to circulatory death cases, and females exhibiting significantly lower odds compared to males.

Several studies in Iran have examined the prevalence of HBV and HCV infections among blood donors. Kafi-Abad et al. analyzed trends in blood-borne infections among 6,499,851 blood donations collected across Iranian blood transfusion centers from 2004 to 2007 [15]. Donors were categorized as regular (39%), lapsed (22%), or first-time (39%). The overall prevalence of HBV infection was 0.56%, with a significant decline from 0.73% in 2004 to 0.41% in 2007 ($p < 0.0000001$). Anti-HCV prevalence was 0.13% overall, with a modest increase from 0.13% in 2004 to 0.14% in 2005, followed by a gradual reduction to 0.12% in 2007 ($p = 0.04$). From 2006 to 2007, a detailed analysis of 2,435,393 donations revealed declining HBsAg prevalence across all donor types, with slightly higher rates in males and an age-related increase in both sexes. Anti-HCV prevalence decreased among repeat and lapsed donors but rose slightly in first-time donors. Female donors exhibited significantly lower rates of anti-HCV compared to males ($p < 0.0001$) [15]. In another study, Aghamohamadi et al. investigated the prevalence of HBV and HCV among blood donors in Semnan province between 2008 and 2011 [16]. Their study included a total of 124,704 donors, among whom 329 tested positive for hepatitis. Specifically, 297 cases were identified as HBV-positive, while 32 were HCV-positive. The overall prevalence rates of HBV and HCV among the donor population were 0.24% and 0.026%, respectively. Higher rates of HBsAg and HCVAb were observed among first-time donors, as well as male and married individuals [16]. Etminan et al. conducted a retrospective study to evaluate the prevalence of transfusion-transmitted infections and the characteristics of infected blood donors in Kerman Province, Iran, over a five-year period (March 2014 to February 2019) [17]. Among the total donors screened, confirmatory tests identified 500 cases of infection with one of the three blood-borne viruses: human immunodeficiency virus (HIV), HBV, or HCV. The prevalence rates, calculated with a 95% confidence interval, were 0.0006% for HIV, 0.1% for HBV, and 0.04% for HCV. A significant association was observed between infection prevalence and factors such as age, educational level ($P = 0.008$), and donation status ($P = 0.007$). However, no significant correlation was found between infection rates and gender or marital status ($P > 0.05$) [17]. In a separate retrospective cross-sectional study, the prevalence of HBV, HCV, and HIV was analyzed among 145,273 blood donors who visited the blood transfusion center in Ilam Province from 2007 to 2017 [18]. Screening for these infections was conducted using the ELISA method. The findings revealed that 249 donors tested positive for HBV, 66 for HCV, and 6 for HIV. Among the infected individuals, 202 were married, while 119 were single. The prevalence of all three infections was significantly higher in men compared to women ($P < 0.01$). Additionally, individuals over the age of 40 demonstrated a higher infection rate than those aged 20 to 40 years ($P < 0.01$) [18]. Another investigation

**Table 3.** HBsAg and HBsAb test results in different gender and donor types

| | | | total | positive | negative | OR (p-value) | 95% CI for OR | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | lower | Upper |
| **HBsAg (n=3814)** | Gender | Female | 1236 | 28 (0.023) | 1208 (0.977) | 1.25 (0.261) | 0.78 | 2.00 |
| | | Male | 2578 | 47 (0.018) | 2531 (0.982) | | | |
| | Type of patient | Forensic | 2513 | 64 (0.025) | 2449 (0.975) | 3.06 (0.001*) | 1.61 | 5.83 |
| | | Brain Death | 1301 | 11 (0.008) | 1290 (0.992) | | | |
| **HBsAb (n=3650)** | Gender | Female | 1245 | 58 (0.047) | 1187 (0.953) | 0.56 (<0.001*) | 0.42 | 0.76 |
| | | Male | 2605 | 208 (0.080) | 2397 (0.920) | | | |
| | Type of patient | Forensic | 2513 | 220 (0.088) | 2293 (0.912) | 2.69 (<0.001*) | 1.95 | 3.73 |
| | | Brain Death | 1337 | 46 (0.034) | 1291 (0.966) | | | |

*Significant level was considered 0.05. CI: confidence interval.

conducted in Fars Province, Iran, from 2006 to 2018, which assessed the prevalence and trends of HBV, HCV, and HIV among blood donors. Over this 13-year period, a total of 1,952,478 blood donations were screened for transfusion-transmitted infections [19]. The results revealed that 4,479 (0.229%) of the donations were positive for at least one of the infections: HBsAg, HCV antibodies, or HIV antigens/antibodies. Specifically, the seroprevalence rates were 0.137% for HBV (2,684 cases), 0.087% for HCV (1,703 cases), and 0.0047% for HIV (92 cases) [19].

As well, it is proposed that, immunosuppression in solid organ transplant (SOT) recipients can create conditions for HBV to be reactivated using ccc DNA as a replication template, leading to the risk of progressive hepatitis, hepatic failure, and even death. Research by Yin et al. showed that in liver transplant recipients from donors with a history of resolved HBV infection, the probability of reactivation of the virus ranges from 4% to 58%. This amount depends on antiviral prophylaxis regimens and recipients' HBV serological status [20]. A multicenter US cohort study by Terrault et al. showed that in HCV-positive transplant recipients, donor age was significantly associated with, higher rates of graft loss, an increased risk of recurrent HCV cirrhosis, and reduced responsiveness to HCV treatment, and [21]. In addition, Gane et al. reported 1% and 4% risk of HBV recurrence at 1 and 5 years post-transplant, respectively in Austrailia and New Zealand [22]. In an investigation by Shah et al. 317 donor-recipient liver transplant pairs were grouped and monitored on the basis of their pretransplant HCV antibody status. The occurrence of anti-HCV positivity in recipients and the rate of seroconversion were 13.6% and 9.2%, respectively [23]. Moreover, research in blood donors demonstrated that the seroprevalence of HBV was higher in male, 3.64% (218 out 5983) compared to females, 0.43% (26 out 5983). Similarly, the seroprevalence of HCV in male was 1.5% (89/5983) while in females was 0.15% (9/5983). In this study, 88.2% (431/489) and 11.8% (58/489) had single and multiple infections, respectively. Among those with multiple infections, HBV-HCV infection rate was 25.9% [24]. In a study on dialysis patients, HBsAg (5.88% vs 0.31%) and HCV (9.24% vs 0.30%) rates were meaningfully higher among patients than donors (P = .001), while anti-HBc was greater among donors (4.60%) than patients (1.7%; P = .01) [25].

Evaluation of 5849 blood donors showed sero-positivity of HBS Ag and HCV, 1.7% and 1.0% respectively [26]. Furthermore, investigating 1633 kidney recipients showed that majority of patients (89.8%) displayed a negative hepatitis serology. The prevalence of HBV in this German population was 4.4% (n = 72), of HCV 5.8% (n = 94), and both HBV and HCV 0.3% (n = 5) [27]. In a study performed by Tiwari et al. among blood donors in regional blood transfusion services of Nepal, 47 donors were identified as a seropositive for HBV, representing a seroprevalence of 0.87% (47 out 5,351, 95% CI= 0.6- 1.2%). The prevalence of HBV was reported to be 0.96% (44 out 4,537) among male donors and 0.36% (3 out 814) in female donors. Also, the HCV seroprevalence was found 0.26%, with all detected cases occurring in males [28]. Additionally, Calderon et al. showed that in a 1-year, crosssectional seroprevalence study in patients with a history of multiple transfusions, the prevalence was 13.7% for HCV and 7% for HBV [29]. In a study conducted by E. Bae et al., serum samples of 217 HBsAg-negative patients before transplantation were evaluated for HBV DNA detection. As a result, HBV DNA was detected in 2.3% of HBsAg-negative patients (5 out of 217). In the anti-HCV antibody test, 13 patients (3.4%, 13/377) were positive. Among the 5 OBI patients, 1 had hepatitis B core antibodies (anti-HBc IgG) and 2 had hepatitis B surface antibodies (anti-HBs). None showed evidence of HCV co-infection, as tested for anti-HCV antibodies [30].

In 6827 consecutive blood donors tested for HBV and HCV, 647(9.48%) were HBsAg positive, 50(0.73%) were HCV positive [31]. Finally, in a study by Miro et al. where eighty-four HCV/HIV-coinfected and 252-matched HCV-monoinfected liver transplant recipients were included in a prospective multicenter study, 75 (30%) HCV monoinfected patients died, with a survival rate at 5 years of 54% (95% CI, 42–64) [32]. It is important to acknowledge that the comparison of findings across countries with significantly different rates, methods, and timeframes for HPV testing and vaccination programs may introduce variability that could affect the interpretation of results.

## Conclusion

In conclusion, this retrospective study demonstrated higher prevalence of HBV positive tests in brain death donors compared to the circulatory death, with female donor showing lower prevalence of HBsAg positive tests compared to male. However, HCV positivity did not show any significant difference across groups. These findings might provide an insight for clinicians and policymakers in devising strategies for prevention, screening, and management of viral hepatitis infections in transplant settings.

## Ethics approval and consent to participate

This research was approved by Tehran University of Medical Sciences ethics committee (IR.TUMS.SPH.REC.1402.329). Also, consent letter was provided for each patient.

## Consent to participate

informed consent for publication of identifiable information/ images journal was obtained from all study participants.

## Availability of data and materials
Data will be made available on reasonable request from corresponding author.

## Competing interests
None.

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## Clinical trial number
not applicable.

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