Original Article

Seroprevalence of transfusion-transmitted infections among blood donors in Makkah, Saudi Arabia

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Abstract

Introduction: Blood donation is vital for healthcare; however, transfusion-transmitted infections (TTIs) pose a serious risk. This study investigated the seroprevalence of TTIs among Saudi blood donors.

Methodology: This retrospective study included male blood donors aged ≥ 18 years who donated blood at Al-Noor Specialist Hospital in Makkah from January 2017 to December 2022. The blood units were screened for hepatitis B surface antigen (HBsAg) and core antibodies (HBc-IgG), hepatitis C antibodies (HCV-Abs), syphilis, HIV-1 antigen/antibody (HIV-1 Ag/Ab), human T-lymphotropic virus 1, 2 (HTLV-1/2), and malaria.

Results: There were 40,287 donors with an average age of 44.33 ± 18.12 years, and 62.3% (n = 25103) were Saudis. The overall rate of TTIs seropositivity was 7.4% (n = 2953); HBc-IgG (6.1%; n = 2473) was the most common, followed by HCV-Abs (0.4%; n = 177), and syphilis (0.34%; n = 136). All cases were negative for malaria, whilst HIV and HTLV positive donors were 0.06% (n = 24) and 0.13% (n = 52), respectively. Syphilis was more prevalent among non-Saudis (0.24%; n = 83) than among Saudis (0.1%; n = 53), whereas anti-HBc antibodies seropositivity was significantly higher among Saudi (3.4%; n = 1373) than non-Saudi donors (2.7%; n = 1100).

Conclusions: Hepatitis B virus was the most frequently detected bloodborne pathogen, followed by hepatitis C virus and syphilis. Hepatitis B virus was also more prevalent among Saudi donors, whilst expatriates had higher rates of syphilis. Additional prospective multicenter studies are needed to accurately determine the prevalence of TTIs in Saudi Arabia.

Key words: blood bank; hepatitis B virus; hepatitis C virus; syphilis; Saudi Arabia.

J Infect Dev Ctries 2024; 18(6):957-963. doi:10.3855/jidc.19559

(Received 14 November 2023 - Accepted 12 December 2023)

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Introduction

Although blood donation is crucial for healthcare systems, recipients are at risk of contracting transfusion-transmitted infections (TTIs), including hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), human Tlymphotropic virus 1, 2 (HTLV-1/2), and syphilis [1,2]. Diseases and death from TTIs have been documented by the World Health Organization (WHO) in recipients, as well as their close family members [3–5]. Hence, donors with known or suspected histories of transmissible infectious diseases are prohibited from donating blood [1,2]. Moreover, continuous monitoring of donated blood and its components is essential for infection control since many donors could have asymptomatic infection [6–8]. Mandatory serological screening tests for blood-borne pathogens include HBV surface antigen (HBsAg) and core antibody (anti-HBc), HCV antibody (anti-HCV), HIV antibodies (anti-HIV-1/-2), HTLV antibodies (anti-HTLV-1/2), syphilis, and malaria [9].

The average number of blood donations across the different geographical regions of the Kingdom of Saudi Arabia (KSA) is 300,000 per year, and the numbers have been steady during the last decade [10]. Moreover, a recent study in KSA reported a nationwide prevalence of TTIs as 8.7%, and HBV (6.4%) was the most common infection followed by HCV (0.4%) and syphilis (0.36%) [11]. However, reports related to the seroprevalence of TTIs in the blood banks from

Makkah city were scarce and included small numbers of donors [12–14]. Hence, this retrospective study measured the seroprevalence of TTIs in volunteer blood donors in Al-Noor Specialist Hospital in Makkah during the last six years (January 2017 to December 2022).

Methodology

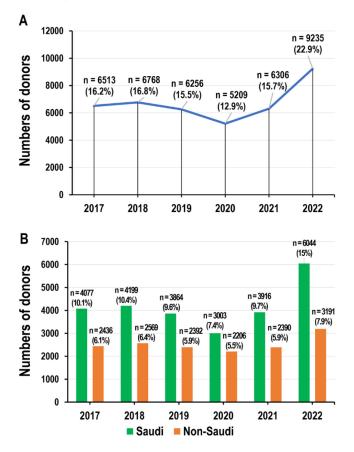
Ethical approval

This study was approved by the Ethics Committee Review Board of Umm Al-Qura university (HAPO-02-K-012-2022-01-1083) in Makkah.

Study design

This was a retrospective study covering the period from January 2017 to December 2022. The participants were males aged \geq 18 years who donated blood in the blood bank of Al-Noor Specialist Hospital in Makkah city, KSA. The blood units from all donors were screened for HBV, HCV, HIV, HTLV, syphilis and malaria using in vitro diagnostic (IVD)-approved serological tests (Supplementary Table 1). The serological results along with the demographic data of

Figure 1. Distribution of blood donors (numbers and percentage) during the study period (2017 to 2022). A. by year and B. by nationality.



the study participants were retrieved from the hospital's Health Information System (HIS).

Statistical analysis

Statistical Package for the Social Sciences (SPSS; NY, USA) version 25 was used for data analysis. Ordinal and non-continuous variables were analyzed by cross-tabulation with Chi square (χ^2) test to measure the frequency, and the results are expressed as numbers with percentages. Student's t-test or Mann-Whitney U test was used to compare between two groups according to data normality. The results of continuous data were presented as mean \pm standard deviation (SD). Statistical significance was considered when *p* value was < 0.05.

Results

General characteristics of blood donors

A total of 40,287 males donated blood from January 2017 to December 2022. The majority were Saudi citizens (62.3%; n = 25103), and the average age of donors was 44.3 ± 18.1 years. However, there was no significant difference between the mean age of the Saudi (44.1 ± 18.8 years) and non-Saudi (44.7 ± 16.8 years) donors. The lowest rate of donation was in 2020 (12.9%; n = 5209), whilst the highest was observed in 2022 (22.9%; n = 9235; Figure 1).

Seroprevalence of transfusion-transmitted infections (TTI)

The overall prevalence of TTI seropositive samples was 7.4% (n = 2,953), and the mean age of the positive donors (46.9 ± 18.1 years) was significantly higher than that of the negative donors (44.1 ± 17.9 years; p < 0.0001). Moreover, the highest rates of seropositivity were detected in 2018 and 2019 (1.5% for both), whereas the lowest frequency of positive TTIs was observed in 2020 (0.9%; Figure 2A). The overall rate of positive TTIs was also significantly lower among the Saudi (n = 1,625/25,103; 6.5%) than the non-Saudi donors (n = 1328/15184; 8.8%; p < 0.0001; Figure 2B). Furthermore, the mean of age of the positive non-Saudi donors (45.7 ± 16.7 years) was significantly lower than the positive Saudi donors (47.8 ± 18.1 years; p = 0.008). All donors were negative for malaria.

Hepatitis B virus

In general, 2,632 donors (6.5%) were positive for HBV with 159 cases (0.4%) positive for HBsAg and 2,473 cases (6.1%) positive for anti-HBc antibodies. Moreover, the positive HBV cases (48 ± 17.8 years) had significantly higher age than the negative donors (44.1 ± 18.1 years; p < 0.0001). While there was no difference

in the rate of positive HBsAg cases based on nationality, the frequency of positive cases for anti-HBc antibodies was markedly higher among the Saudi (3.4%; n = 1373) donors, compared with the non-Saudi donors (2.7%; n = 1100; Table 1). Moreover, the mean of age was higher among the Saudi (48.1 ± 18.6 years) than the non-Saudi (45.5 ± 16.6 years; p = 0.0002) positive cases for anti-HBc antibodies.

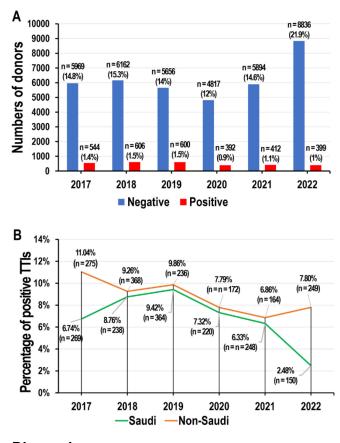
Hepatitis C virus

Serology test for HCV was positive in 0.4% (n = 177) of donors, and the mean of age was comparable between the negative (44.3 \pm 18.1 years) and positive (43.8 \pm 18.0 years) cases. Additionally, there was no statistical difference in the frequencies of positive cases according to nationality (Table 1).

HIV, HTLV, and syphilis

Overall, the numbers of seropositive donors were 24 (0.06%) for HIV, 52 (0.13%) for HTLV, and 136 (0.34%) for syphilis. Moreover, the mean age was similar among the negative and positive cases for HIV $(44.3 \pm 18.1 \text{ years vs. } 43.9 \pm 20.7 \text{ years, respectively})$ and HTLV (44.3 \pm 18.1 years vs. 48.3 \pm 18.2 years, respectively), whereas the donors positive for syphilis were significantly older $(47.6 \pm 17.9 \text{ years})$ than the negative cases (44.3 \pm 18.1 years; p = 0.03). Although there was no statistically significant difference in the frequencies of HIV and HTLV positive cases based on nationality, the rates of syphilis were significantly higher among the non-Saudi (0.24%; n = 83) relative to the Saudi donors (0.1%; n = 53; p < 0.0001; Table 1). However, the mean age was comparable between the Saudi (47.6 \pm 20.2 years) and non-Saudi (47.6 \pm 16.4 years) positive syphilis cases.

Figure 2. Annual numbers and percentage of seropositive cases for transfusion-transmitted infections (TTI) during the study period (2017 and 2022) **A.** by year and **B.** by nationality.



Discussion

This retrospective single-center study measured the seroprevalence of TTIs between 2017 and 2022 in Makkah city. The rate of blood donation declined substantially during the year 2020, which could be related to the lockdown during the coronavirus disease 2019 (COVID-19) pandemic [15–17]. Conversely, the

Table 1. Frequencies of TTI seropositivity in Saudi and non-Saudi blood donors.

		Saudi donors (n = 25103; 62.3%)	Non-Saudi donors (n = 15184; 37.7%)	<i>p</i> value	
mean \pm SD of age (Years)	Negative	43.8 ± 18.8	44.7 ± 16.8	0.008	
	Positive	47.8 ± 18.1	45.7 ± 16.7		
HBsAg (n = 159; 0.4%)	Negative	25010 (62.1%)	15118 (37.5%)	0.3	
	Positive	93 (0.2%)	66 (0.2%)		
HBcAb (n = 2473; 6.1%)	Negative	23730 (58.9%)	14084 (35%)	< 0.0001	
	Positive	1373 (3.4%)	1100 (2.7%)		
HCV-Ab (n = 177; 0.4%)	Negative	25005 (62.1%)	15105 (37.5%)	0.00	
	Positive	98 (0.2%)	79 (0.2%)	0.08	
HIV-Ab (n = 24; 0.06%)	Negative	25088 (62.26%)	15175 (37.68%)	0.0	
	Positive	15 (0.04%)	9 (0.02%)	0.9	
HTLV-Ab (n = 52; 0.13%)	Negative	25074 (62.23%)	15161 (37.64%)	0.2	
	Positive	29 (0.07%)	23 (0.06%)	0.3	
Syphilis (n = 136; 0.34%)	Negative	25050 (62.14%)	15101 (37.5%)	< 0.0001	
	Positive	53 (0.1%)	83 (0.24%)		

HBc-IgG: hepatitis B core antibodies; HBsAg: hepatitis B surface antigen; HCV-Ab: hepatitis C antibodies; HIV-Ab: HIV antibodies; HTLV-Ab: human T-lymphotropic virus antibodies; TTI: Transfusion transmitted infection.

number of blood donors in Saudi Arabia surged by 50% in 2022, which may be attributed to the implementation of numerous national blood donation campaigns by the Saudi Ministry of Health following the COVID-19 pandemic [18].

The overall prevalence of reactivity for TTIs among our study participants was 7.4% and most cases were expatriate, which is aligned with many recent nationwide and regional studies from Saudi Arabia that underscored the necessity for continuous screening of blood to effectively prevent transmission of bloodborne pathogens [1,11,14]. Our data also revealed that HBV was the most common pathogen among the donors, with 0.4% and 6.1% positivity for HBsAg and anti-HBc antibodies, respectively. Furthermore, the rates of infections were significantly higher among Saudi donors. Indeed, HBV poses a substantial global health challenge, and its prevalence in KSA declined from 8.3% in 1988 [19] to 1.3–3.2% in recent years [20], which can be plausibly attributed to the mandatory vaccination program implemented by the Saudi health authorities [20,21]. Despite this, many reports have indicated that HBV was the most frequently detected infection in blood banks from the different Saudi provinces [1,7,22,23]. The present study, in alignment with earlier research, highlights the compelling need for intensified HBV screening and vaccination interventions to achieve the goal of complete viral eradication within the Saudi population [1,7,20,22,23].

Blood transfusion is the main mode of HCV transmission, and the virus is highly prevalent in the Middle East region [24-26]. Several phylogenetic studies in the KSA have shown that blood units imported during the 1980s were a major cause for spreading HCV among the Saudi population [25]. However, a limited number of studies measured the prevalence of HCV antibodies among blood donors in Saudi Arabia. In general, the reported frequencies of HCV in the different regions of the Kingdom range between 1.7% to 5.7% [24-26], whereas the incidence among blood donors was between 78.4 and 202 cases per 100,000 population [27-29]. The initial study by Al-Mofarreh et al. was conducted in Riyadh city during 1991 and included 580 donors; the overall rate of seropositivity was 2.2% and included 1.2% Saudi and 4.5% non-Saudi infected donors [30]. Another study from the same region included 10,646 blood units from Saudi (43%) and non-Saudi (53%) donors and also reported an overall HCV positivity rate of 1.01%, with equal frequencies of positivity among non-Saudi and Saudi donors [31]. A later study from Jeddah also showed positive HCV antibodies in 4.2% Saudi and

6.9% non-Saudi donors [32]. More recent reports have indicated a sharp decline in HCV seropositivity among Saudi and non-Saudi donors, with an overall prevalence ranging between 0.04% and 2% in the different studies [1,33–36].

Our data revealed an overall prevalence of 0.4% HCV positive cases by serology, and there was no significant difference in the rates of positive cases between Saudi and non-Saudi donors. Moreover, the mean age of the positive and negative cases was similar. The present findings agree with many recent studies from the different regions of Saudi Arabia, and further confirm the previously reported substantial declines in the prevalence of HCV in blood donors [1,33-36]. A possible explanation for the consistent declines in the rates of seropositive HCV could be related to the stringent system applied by the Saudi health authorities for screening expatriates before travelling to the KSA, as well as premarital screening programs [37-39]. Nonetheless, additional prospective studies are needed to measure the prevalence of HCV among populations requiring chronic transfusion and hemodialysis.

Several pathogens are transmitted by blood transfusion; including HIV, HTLV, and syphilis; and they are routinely screened in all donated blood and its products in all blood bank facilities [40,41]. The first identified case of HIV infection in KSA was recorded in 1984 and the incidence has since increased and reached 3 cases per 10000 population in 2018 [42,43]. Although the serology study by El-Hazmi in 2004 failed to detect any positive HIV case in 24,173 blood donors from Riyadh city [44], others reported less than 0.2% seropositivity for HIV in tested blood units [1,14,45]. On the other hand, the first study regarding HTLV positive cases among blood donors from KSA was reported in 1991 and showed 0.01% reactive cases among non-Saudis only [46]. A later study then reported an overall prevalence of 0.0038% after screening over 100,000 blood units [47]. Similar rates (0.008%) were also reported by another study from Rivadh that included 34,541 donors in 1998 [48]. A more recent study from Jeddah also demonstrated an overall prevalence of 0.09% for HTLV among 107,419 donations over a period of 10 years, and the authors recommended to amend the policies that mandate screening for HTLV in Saudi blood banks [49]. Concurrently, another study from Qassim reported zero prevalence for HTLV in 4,590 blood donors in 2020 [8]. On the other hand, earlier studies from Hail [50], Al Khobar [51], and Majmaah [1] cities reported syphilis seropositivity of 0.8%, 0.45%, and 0.53% among blood donors, respectively. The present study agrees with many earlier reports from Saudi Arabia since it identified 0.06% HIV [1,14,45], 0.13% HTLV [8,46– 49], and 0.34% syphilis [1,50,51] positive cases. Collectively, our study and the earlier studies suggest that the possibility of HIV and HTLV infections among apparently healthy blood donors in KSA are extremely low. In contrast, infection with syphilis appears to be more common, especially among non-Saudi donors. However, more prospective multicenter studies from the different regions of KSA are needed to confirm our observation.

There are several drawbacks to our study. Firstly, the availability of socioeconomic data was restricted due to the retrospective nature and single-center design of the study. Moreover, the study exclusively included male donors, since the numbers of women donating blood in KSA is limited due to social and cultural constraints [52]. Hence, large prospective multicenter studies are needed to precisely determine the risk factors associated with TTIs in blood donors, as well as to confirm the results with nucleic acid amplification tests.

Conclusions

This was a large retrospective single-center study that included more than 40,000 blood donors from Makkah city. Despite the initial decline in blood donation rates during the COVID-19 pandemic, a substantial (50%) increase in the number of donors was observed in 2020, potentially attributable to the nationwide blood donation campaigns conducted by the Saudi health authorities. Moreover, HBV was the most frequently detected bloodborne pathogen followed by HCV and syphilis. HBV was more prevalent among Saudi donors, while the rate for syphilis was substantially higher among expatriates. In contrast, the frequencies of presence of HCV in Saudi and non-Saudi donors were equal. On the other hand, the seropositivity rates were markedly low for HIV, HTLV, and malaria. further Nevertheless. large-scale, prospective, multicenter studies are warranted to accurately determine the prevalence of TTIs in Saudi Arabia.

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Conflict of interests: No conflict of interests is declared.

Annex – Supplementary Items

Supplementary Table 1. Serological tests used for screening for hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), human T lymphotropic virus (HTLV), syphilis and malaria in all blood units.

	Serological tests			
	Target	Kit and manufacturer	Sensitivity and specificity	
HBV	Anti-HBV core (HBc) IgG antibodies HBV surface antigen (HBsAg)	Monolisa [™] HBs Ag ULTRA (BIORAD, Hercules, CA, USA)	100% Sensitivity and 99.9% Specificity	
HCV	Anti-HCV IgG antibodies	Monolisa [™] HCV Ag-Ab ULTRA (2 nd generation; BIORAD, Hercules, CA, USA)	100% Sensitivity and 99.9% Specificity	
HIV	Anti-HIV-1/2 IgG antibodies	Genscreen TM ULTRA HIV Ag-Ab (4 th generation; BIORAD, Hercules, CA, USA)	100% Sensitivity and 99.9% Specificity	
HTLV	Anti-HTLV-1/2 IgG antibodies	Architect rHTLV-I/II (Abbot, IL, USA)	100% Sensitivity and 99.5% Specificity	
Syphilis	Latex agglutination kit	VDRL (Spinreact, Girona, Spain)	100% Sensitivity and 100% Specificity	
Malaria	Malaria pf/pan antigen	Quick profile [™] (LumiQuick Diagnostics Inc., CA, USA)	100% Sensitivity and 100% Specificity	

HBV: hepatitis B virus; HCV: hepatitis C virus; HIV: human immunodeficiency virus; HTLV: human T-lymphotropic virus; HTLV-1/2: human T-lymphotropic virus 1: 2; HBc-IgG: hepatitis B core antibodies.