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ORIGINAL ARTICLE

The Prevalence of Transfusion-Transmitted Infections and Nucleic Acid Testing Among Blood Donors in Makkah, Saudi Arabia

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SUMMARY

Background: **Despite saving a vast number of lives through blood transfusions, transfusion-transmitted infections (TTIs) still threaten the lives of people needing blood transfusion. Hence, screening blood donors and reviewing the prevalence of TTIs amongst blood donors might show the impact of these infections among our people. The aim of this study was to evaluate the prevalence rates of transfusion-transmitted infections among blood donors in Makkah as foundation for providing harmless blood transfusion in Makkah, Saudi Arabia.**

Methods: **A retrospective study was carried out at the Central Blood Bank in Makkah city, Saudi Arabia, from January 1, 2023, to December 31, 2023. A total of 13,706 samples were collected and screened for hepatitis B surface antigen (HBsAg), hepatitis B surface antibodies (HBsAbs), hepatitis B core antibodies (HBcAbs), antibodies to hepatitis C virus (anti-HCV), antibodies to HIV 1 and 2 (HIV I/II Ab), antibodies to HTLV 1 and 2 (HTLV I/II Ab), Malarial antibodies, and antibodies to VDRL.**

Results: **A total of 13,706 blood units were received and tested. Out of the total, 52% were non-Saudi donors and 47.9% were Saudi donors; 28.4% were aged 18 - 28 years, 42.8% were aged 29 - 39 years, 24.4% were aged 40 - 50 years, and 4.4% were aged 51 - 60 years. The majority was O+ blood group (42.7%), followed by A+ (26.2%), B+ (18.7%), AB+ (4.6%), O- (3.8%), A- (2.1%), B- (1.5%), and AB- (0.4%). While 42.6% of the blood units donated were from voluntary donors, 57.4% were donated by replacement donors. Sixty-one samples (0.4%) tested positive for HBsAg, 824 samples (6%) for HBcAb, 43 samples (0.3%) for HCV antibodies, 754 samples (5.5%) for HBsAb, and 44 samples (0.3%) for HIV I/II Ag/Ab combinations. Further, 44 samples (0.3%) were positive for HTLV I/II antibodies, 83 samples (0.6%) for VDRL antibodies, and only 3 samples (nearly 0%) for malaria antibodies. Forty-three samples (0.3%) were positive for NAT-HBV, 7 samples (0.1%) were positive for NAT-HCV, and 6 samples (0.1%) were positive for NAT-HIV. The analysis revealed a statistically significant and strong correlation between HBsAgs and NAT-HBV ($r = 0.819$, $p < 0.0001$). In contrast, while there was a statistically significant association between HBsAgs and HBcAbs, the correlation was weak ($r = 0.191$, $p < 0.0001$). Additionally, there was an association between HBsAbs and HBsAgs, but the Spearman correlation indicated a very weak relationship ($r = 0.042$, $p < 0.0001$).**

Conclusions: **Prevalence rates of transfusion-transmitted infections showed a steady decline in 2023, and these rates were much lower in Makkah than in other parts of the country or in neighboring countries. The importance of using NAT in the screening of blood donors was indicated in this study. These findings could contribute to improving the understanding of TTIs epidemiology and supporting health authorities in controlling blood-borne pathologies.**

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KEYWORDS

transfusion-transmitted infection, blood donor, nucleic acid testing, Saudi Arabia

INTRODUCTION

Blood transfusion is a crucial and life-saving system in current medicine; though, it remains a possible way of transmission of transfusion-transmitted infections (TTIs) including HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), syphilis, and many other infections [1-3]. Based on WHO reports in 2018, the prevalence of HIV, HBV, HCV, and syphilis infections among blood donations composed internationally differs from 0.003% to 1.08%, 0.03% to 3.70%, 0.02% to 1.03%, and 0.05% to 0.90%, respectively, with lesser prevalence in high-income states [4]. Hence, TTIs were measured to be chief dangers for the blood recipients and a principal distress for the public health experts [5]. Consequently, the WHO endorses that all blood donations are to be tested for these infectious pathologies [4]. Currently, screening of the donated blood for TTIs is obligatory and conducted habitually in the transfusion medicine centers. Providing safe blood needs improved quality blood transfusion facilities and qualified organization along with suitably skilled workers [6]. Prevention of TTIs in low-income and middle-income nations is a huge task due to the inadequate funds and deficiency of accessibility. In Saudi Arabia, although regulations are implemented on the obligatory screening of TTIs, transmission of infections still tracks. This might be because of a deficiency in the sensitivity of screening tests to identify the infection in the window period. Therefore, comprehensive surveillance and following control of TTIs among the blood donors is vital to guarantee blood security. Similarly, revising the registers of blood donors for screening procedures is essential for calculation of the protection of the blood supply. Around an average of 325,847 whole blood pints are yearly gathered from 128 governmental blood banks disseminated among the country's 13 provinces [7]. Appreciations to recognized quality blood screening procedures and the worldwide and local residual danger of transfusion-transmitted infections (TTIs) have been declined over time [8]. Though, a number of tasks have been documented by the National Transformation Plan (NTP) of Vision 2030, comprising people growth, increased economic load, and unpredictable statistical reports succumbed by the fragmented management of MOH's healthcare institutions [9,10]. Despite the significance of the learning TTI epidemiology in Makkah, existing data on TTI prevalence are inadequate. Major limitations of these studies are that they were done locally with smaller sample numbers and dedicated on particular hepatitis seromarkers. This study was conducted to signify the existence of HBV, HCV, HIV, HTLV, Malaria, and syphilis infections in the blood donors from January 2023 to December 2023. Therefore, this study not only gives efficient statistics on the prevalence of TTIs, it is also extra comprehensive given the bigger sample size and it displaying the drift of these infections in the study period.

MATERIALS AND METHODS

This was a retrospective 1-year study of consecutive blood donors` records covering the period from January 1, 2023, to December 31, 2023. The study was conducted at the Central Blood Bank of Makkah city, Saudi Arabia. Data was taken from pre-established data collection sheets including age, nationality, blood group type, donation type, hepatitis B surface antigen (HBsAg), hepatitis B surface antibodies (HBsAbs), hepatitis B core antibodies (HBcAbs), antibodies to hepatitis C virus (anti-HCV), antibodies to HIV 1 and 2 (HIV I/II Ab), antibodies to HTLV 1 and 2 (HTLV I/II Ab), Malarial antibodies, and antibodies to VDRL. Statistical analysis was carried out using SPSS (Statistical Package for Social Science; IBM Corp., Armonk, NY, USA), version 22, software. A p-value ≤ 0.05 was considered statistically significant. Descriptive statistics include the frequency, percentage, mean, and standard deviation. The normality of the data was checked through the Shapiro-Wilk test, and p-values greater than 0.05 confirm the normality of the data.

RESULTS

A total of 13,706 blood units were received and tested at the Central Blood Bank in Makkah, Saudi Arabia, from January 2023 to December 2023. Table 1 outlines the descriptive statistics for these samples. Out of the total, 7,135 (52%) were non-Saudi donors and 6,571 (47.9%) were Saudi donors. The donors' ages ranged from 18 to 60 years: 3,889 (28.4%) were aged 18 - 28 years, 5,870 (42.8%) were aged 29 - 39 years, 3,338 (24.4%) were aged 40 - 50 years, and 609 (4.4%) were aged 51 - 60 years. The majority of the blood samples were from the O+ blood group (5,857 or 42.7%), followed by the A+ blood group (3,586 or 26.2%), B+ donors (2,562 or 18.7%), AB+ donors (628 or 4.6%), O- donors (518 or 3.8%), A- donors (293 or 2.1%), B- donors (204 or 1.5%), and AB- donors (58 or 0.4%). Additionally, 7,870 (57.4%) of the blood units were donated by replacement donors, while 5,836 (42.6%) were

Table 1. The sociodemographic characteristics of the blood donors.

Characteristics		Number of units	Percentages
Nationality	Saudi	6,571	47.9%
	Non-Saudi	7,135	52.1%
Age (years)	18-28	3,889	28.4%
	29-39	5,870	42.8%
	40-50	3,338	24.4%
	51-60	609	4.4%
Blood type (ABO Rh)	A+	3,586	26.2%
	A-	293	2.1%
	AB+	628	4.6%
	AB-	58	0.4%
	B+	2,562	18.7%
	B-	204	1.5%
	O+	5,857	42.7%
	O-	518	3.8%
Donation type	Volunteer	5,836	42.6%
	Replacement	7,870	57.4%

Table 2. The prevalence of infectious serological markers in the blood units.

Parameters		Number of units	Percentages
HBsAgs	Non-reactive	13,645	99.6%
	Reactive	61	0.4%
HBcAbs	Non-reactive	12,882	94%
	Reactive	824	6%
HCV Ab	Non-reactive	13,663	99.7%
	Reactive	43	0.3%
HBsAbs	Non-reactive	12,952	94.5%
	Reactive	754	5.5%
HIV I/II Ag/Ab	Non-reactive	13,662	99.7%
	Reactive	44	0.3%

Table 3. The seroprevalence of other infectious markers.

Parameters		Number of units	Percentages
HTLV I/II antibodies	Non-reactive	13,662	99.7%
	Reactive	44	0.3%
VDRL antibodies	Non-reactive	13,623	99.4%
	Reactive	83	0.6%
Malaria antibodies	Non-reactive	13,703	100%
	Reactive	3	0%

Table 4. The prevalence of HBV DNA, HCV RNA, and HIV RNA markers.

Parameters		Number of units	Percentages
NAT-HBV	Non-reactive	13,663	99.7%
	Reactive	43	0.3%
NAT-HCV	Non-reactive	13,699	99.9%
	Reactive	7	0.1%
NAT-HIV	Non-reactive	13,700	99.9%
	Reactive	6	0.1%

Table 5. The correlations between HBsAgs and NAT-HBV, HBsAbs, and HBcAbs.

Parameters		HBsAgs					
		Number of negative units	Percentage	Number of positive units	Percentage	p	Spearman correlation
NAT-HBV	Non-reactive	13,644	99.5%	19	0.1%	0.0001	0.819
	Reactive	1	0%	42	0.3%		
HBcAbs	Non-reactive	12,866	93.9%	16	0.1%	0.0001	0.191
	Reactive	779	5.7%	45	0.3%		
HBsAbs	Non-reactive	12,903	94.1%	49	0.4%	0.0001	0.042
	Reactive	742	5.4%	12	0.1%		

from voluntary donors.

Table 2 presents the prevalence of infectious serological markers in the blood units. The testing revealed the following results: 61 samples (0.4%) tested positive for HBsAg, 824 samples (6%) for HBcAb, 43 samples (0.3%) for HCV antibodies, 754 samples (5.5%) for HBsAb, and 44 samples (0.3%) for HIV I/II Ag/Ab combinations.

Moreover, other seroprevalence tests, as seen in Table 3, showed that 44 samples (0.3%) were positive for HTLV I/II antibodies, 83 samples (0.6%) for VDRL antibodies, and only 3 samples (nearly 0%) for malaria antibodies.

Furthermore, nucleic acid testing (NAT), shown in Table 4, detected 43 samples (0.3%) positive for NAT-HBV, 7 samples (0.1%) positive for NAT-HCV, and 6 samples (0.1%) positive for NAT-HIV.

Table 5 presents the associations and correlations between HBsAgs and NAT-HBV, HBcAbs, and HBsAbs. The analysis revealed a statistically significant and strong correlation between HBsAgs and NAT-HBV ($r = 0.819$, $p < 0.0001$). In contrast, while there was a statistically significant association between HBsAgs and HBcAbs, the correlation was weak ($r = 0.191$, $p < 0.0001$). Additionally, there was an association between HBsAbs and HBsAgs, but the Spearman correlation indicated a very weak relationship ($r = 0.042$, $p < 0.0001$).

DISCUSSION

The efficacy of blood screening is a major concern regarding the safety of blood transfusions. Incidences of TTIs lead to mortality and morbidities associated with infectious markers, especially HBV, HCV, HTLV, and HIV markers. These TTIs place major burdens on healthcare systems worldwide, including in Saudi Arabia. Thus, TTI screenings are crucial for assessing blood and blood product transfusion risks. Apart from this, there is a literature gap regarding the healthcare burdens of transfusion-transmitted HBV, HIV, and HCV in Saudi Arabia, which needs to be addressed. Studies were conducted in a number of places in Saudi Arabia, including a study in Mecca by Elbjeirami et al. [11], a study in Jeddah by Redwan et al. [12], a study in Taif by Bamaga et al. [13], a study in Riyadh by Abdo et al. [14], a study in Jazan by Abdullah [15], and a study in Dammam by Morsi [16]. However, these studies did not use common parameters, and none were large multicentric studies. The present study serologically examined the prevalence of HBV (using HBsAgs, HBcAbs, and HBsAbs), HIV, HTLV, HCV, syphilis, and malaria. In addition, it investigated the prevalence of HBV, HCV, and HIV in blood donors using NATs.

Moreover, 42.6% of the units came from voluntary donors and 57.4% of the units came from replacement donors. This was a higher percentage of replacement do-

nors than a study in the Jazan region had, which was 23.4% [15]. The most common blood type was O+ (42.7%) and the least common blood type was AB− (0.4%). Bashwari et al. conducted a study in the eastern region of Saudi Arabia and found similar distributions [17].

Generally, most blood donors are young people, below 30 years of age, as shown in many studies [18-20]. In this study, most of the blood donors were between 29 and 39 years old. According to the studies, the prevalence of TTIs among the blood donors in Iraq varied: HBV (0.7% - 3.5%), HCV (0.2% - 0.5%), and syphilis (0.26% - 1.1%) [20-22]. The present results showed that the seroprevalence of HBV, HCV, and syphilis were 0.4%, 0.3%, and 0.6%, respectively, which is within the ranges or less than the previous national studies. Furthermore, the current findings showed that the prevalence of TTIs was less than the prevalence reported by WHO in low-income countries, HBV 3.70, HCV 1.03, and syphilis 0.9%, but still higher than that reported prevalence in high-income countries, 0.03%, 0.02%, and 0.05%, respectively [4].

In addition, hepatitis B surface antigen is indicative of active infection, whereas HBV NAT is a marker of chronic infection. The prevalence of HBsAg was 0.4% in blood donors of this study, which is in agreement with the study of Alaidarous et al. (0.33%) [23] but is less than what has been reported in Tabouk with 0.5%, Aseer city of Southern province of Saudi Arabia with 1.2% [7], or in other countries of the region including Qatar, Jordan, Sudan, Egypt, Lebanon, Iran, and Pakistan [24-29]. As indicated in our study, screening blood donors for HBsAg alone is not adequate to exclude HBV from the blood supply, especially during the core window period. This may lead to post-transfusion hepatitis B in the recipient [30]. Therefore, screening for anti-HBc is significantly effective in reducing the occurrence of post-transfusion hepatitis B infection [31-33]. In Makkah, testing for anti-HBc has been implemented in the screening protocol for donated blood. Anti-HBc is indicative of chronic or resolved infection and our study showed that the rate for anti-HBc was 6%. This rate is higher than the reported ones from previous studies in Northern (0.9%), Central (1.2%), Eastern (1.1%), Western (0.8%), and Southern (1.8%) provinces of Saudi Arabia but lower than in the study of Alaidarous et al. (9.81%) [7,23]. The prevalence of HBsAbs was 5.5% in blood donors of this study, which is lower than in the study of Alaidarous et al. (7.8%) [23]. In our study, the prevalence of anti-HCV was 0.3%, which is consistent with the study done by Alsughayyir et al. in Central (0.3%) province of Saudi Arabia but higher than in Northern (0.02%), Eastern (0.02%), Western (0.02%), and Southern (0.1%) provinces of Saudi Arabia. In the current study, the prevalence of anti-HIV I/II was 0.3%, which is consistent with the study of Alaidarous et al. (0.2%) [23] but higher than in Northern (0.01%), Central (0.04%), Eastern (0.002%), Western (0.01%), and Southern (0.02%) provinces of Saudi Arabia in a study conducted by Alsughayyir et al. [7]. Similarly, the prevalence of anti-HTLV I/II was also 0.3%, which is in agreement with the study of Alaidarous et al. (0.2%) [23] but is higher than in Northern (0.003%), Central (0.1%), Eastern (0.01%), Western (0.002%), and Southern (0.01%) provinces of Saudi Arabia in a study conducted by Alsughayyir et al. [7]. This study found that the rate of syphilis among the blood donors throughout the study period was 0.6%, which is consistent with the study of Alaidarous et al. (0.5%) [23]. Yet, this rate is less than what was found in Iraq, including Karbala governate (0.76%) and Anbar province in the west of Iraq (1.09%), and in the Arab world and foreign countries including Sudan (6.6%), Pakistan (3.1%), and China (0.88%) [34-37]. However, this rate of syphilis is higher than the reported from a previous study in Northern (0.1%), Central (0.4%), and Southern (0.1%) provinces of Saudi Arabia [7]. This study also showed that the prevalence of anti-Malaria was almost 0%, which is consistent with the study of Alaidarous et al. (0%) [23] and Alsughayyir et al.'s study conducted in all provinces of Saudi Arabia [7].

One of the main advantages of NATs is the reduction of HBV, HCV, and HIV transmissions due to reduced window periods [38]. However, as NATs are relatively new, little literature exists concerning the efficacy of NATs. Despite this, HBV DNA tests can contribute to safe blood strategies, especially for cases in which HBV cores react in immunoassays. NATs not only increase the safety of blood transfusions, but also decrease the amount of blood units discarded to an estimated of 9.8% because of an anti-HB core reactive status [15,39]. Current study revealed that 0.3% donors were positive for NAT-HBV in the current study, which is consistent with the study done by Alsughayyir et al. in Southern (0.3%) province of Saudi Arabia but higher than in Northern (0.003%), Eastern (0.1%), and Western (0.1%) regions and lesser than in the Central (1.9%) province of Saudi Arabia [7]. Similarly, 0.1% of the donors were positive for NAT-HCV in the current study, which is consistent with the study of Alsughayyir et al. in Central (0.1%) province of Saudi Arabia but higher than in Northern (0.01%), Eastern (0.01%), Western (0.01%) regions, and Southern (0.03%) provinces of Saudi Arabia [7]. Finally, 0.1% donors were positive for NAT-HIV in the current study, which is higher than in Northern (0.01%), Eastern (0.002%), Western (0.004%), Central (0.02%), and Southern (0.01%) provinces of Saudi Arabia [7].

Furthermore, the associations and correlations between HBsAgs and NAT-HBV, HBcAbs, and HBsAbs revealed a statistically significant and strong correlation between HBsAgs and NAT-HBV ($r = 0.819$, $p < 0.0001$). In contrast, while there was a statistically significant association between HBsAgs and HBcAbs, the correlation was weak ($r = 0.191$, $p < 0.0001$). Additionally, there was an association between HBsAbs and HBsAgs, but the Spearman correlation indicated a very weak relationship ($r = 0.042$, $p < 0.0001$). Another study found a

high correlation between HBsAgs and NATs. However, the studies also found weak correlations between HBc-Abs and NATs [40].

The value and importance of this study are based on a large-scale study covering a large sample size for a long period to examine the prevalence of seromarkers in blood donors in Makkah. The current findings will benefit to establishing a valued ground for evaluation in upcoming studies. Yet, there are some limitations worth stating. The main limitation of this study is that the data obtained may not reflect the actual prevalence in the whole society as it involved only blood donors. The second limitation is the lack of research and data of patients in association with risk factors as well as the outcome of donors with seropositive results due to unattainable history of blood donors. Despite the limitations mentioned above, this study still delivers a valuable conclusion that will help in improving the understanding of TTIs epidemiology and supporting health authorities in controlling blood borne diseases. Further nationwide studies are required to evaluate the circulation and the risk factors of these infections to develop effective and preventive strategies to protect our community from possible risks.

CONCLUSION

Prevalence rates of transfusion-transmitted infections showed a steady decline in 2023, and these rates were much lower in Makkah than in other parts of the country or in neighboring countries. The importance of using NAT in the screening of blood donors was indicated in this study. These findings could contribute to improving the understanding of TTIs epidemiology and supporting health authorities in controlling blood-borne pathologies.

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Ethical Approval:
The study was conducted in adherence to ethical standards and guidelines. All data used were anonymized and treated with confidentiality. The study protocol was reviewed and approved by the institutional review board at the Makkah Ministry of Health (reference number H-02-K-076-0424-1108).

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Declaration of Interest:
There are no conflicts of interest for all researchers.

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