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PREVALENCE OF TRANSFUSION TRANSMISSIBLE DISEASES BETWEEN MADINAH BLOOD BANK DONORS, SAUDI ARABIA

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Abstract

Objective: The possible risk of TTD caused by blood-borne pathogens is one of the most undesirable risks of blood transfusion worldwide. This study aimed to screen TTD carriage and prevalence in Madinah blood bank donors and to describe the dominant TTD in the study area within Al-Madinah city. The study also aimed to provide an examination over time of the prevalence of TTDs for three years 2020, 2021 and 2022, at Al-Madinah blood banks and compare validated results obtained from previous studies with our study results.

Methods: The testing method included screening serological tests for TTDs and confirmation assays according to each pathogen. The samples were collected and tested according to guidelines approved by the AABB, CBAHI and Saudi FDA. The study subjects were 104538 male and female volunteers and replacement donors aged 18 to 60 years who donated blood from 2020 to 2022 at five blood banks within Al-Madinah city. Donor samples were tested, abnormal TTDs results were further tested for confirmation, and all results were documented according to the following policy.

Results: A total of 104538 donors, 1061 donors giving abnormal serology results for at least one marker, had an overall carriage rate of 1.01%, and only 416 were confirmed by the approved confirmation method. Out of 1061 serology-positive donors, 334, 305, 214, 105 and 103 donors were positive for HBV, HCV, syphilis, HIV and HTLV infection, respectively.
HBV was the dominant TTDs marker, with an incidence rate of 31.47%, over other positively screened TTDs.

Keywords: Transfusion-Transmissible Diseases; Serology; Blood Donor; Blood Bank.

List of Abbreviations

TTDs	Transfusion-Transmissible Diseases
ELISA	Enzyme Linked Immunosorbent Assay
NAT	Nucleic Acid Tests
HIV	The Human Immunodeficiency Virus
HBV	Hepatitis B Virus
HbsAg	Hepatitis B Surface Antigen
anti-Hbc	Hepatitis B Core Protein Antibody
HCV	Hepatitis C Virus
HTLV	Human T-Lymphotropic Virus
TPHA	Treponema Pallidum Hemagglutination Test
BTS	Blood Transfusion Service
PRBCs	Packed Red Blood Cells
FFP	Fresh Frozen Plasma
PC	Platelet Concentrate
CRYO	Cryoprecipitate
CBAHI	Central Board for Accreditation of Healthcare Institutions
AABB	American Association of Blood Banks
WHO	World Health Organization
FDA	Food And Drug Authority

1. Introduction

1.1.Blood Transfusion Service in General

The Saudi Arabia Blood Transfusion Service (BTS) is a hospital-based blood banking system where blood banks control the whole service, including donor recruitment, blood unit screening for infective agents, component preparation, unit storage and the issue of components (packed red blood cells PRBCs, fresh frozen plasma FFP, platelet concentrate PC, and cryoprecipitate CRYO) for administration according to recipient needs **(World Health Organization, 2012)**.

1.2.Donation Status in Saudi Arabia

The previous source of blood and its derivatives used in Saudi Arabia was imported blood, which shifted dramatically to locally recruited blood donors. Currently, the source of donated blood is a mixture of involuntary donors (patient relatives, friends or workmates) and an increasing number of

voluntary unpaid donors. Voluntary donor sources are expanding rapidly through donor drives organized by many blood banks.

To meet the increase in clinical needs for safe blood and blood derivatives, continuous effort needs to be made.

The aim of blood transfusion services (BTS) is to collect blood from donors who are at low risk for any infectious agents that can be transmitted by blood or blood product transfusion and decrease donor adverse reactions that are likely to occur during blood donation. A strict process to assess the suitability of prospective donors is critical to provide the safety and sufficiency of the blood supply and protect the health of recipients and blood donors; however, guaranteeing that suitable blood donors are not deferred without need. The World Health Organization (WHO) issuing guidelines describe the effective roles of blood donor selection, which describes donor suitability for blood donation that has been established to assist blood transfusion services in countries and support national systems for the selection of blood donors **(World Health Organization, 2012; Heyredin et al., 2019).**

1.3 . Prospective Donor Assessment Before Donation

A current study reviewed the factors that affect the safety and supply of blood units. The most important factors are strict donor selection criteria and accurate blood unit testing for TTDs. Before donation education, the level of school education or health education in the general community about blood donation and donation obstacles that interfere with blood and blood product safety. Additionally, blood donor satisfaction with detailed information about donation time and location was found to be an important factor in adopting the altruistic attitude of blood donors. In general, some of the outcomes of these studies cannot be taken for granted to apply to our community because of cultural and social differences and variations in the standard of education, general health services and above all the economy **(Gader et al., 2011; Thakur et al., 2021).**

1.4. Role of Accreditation Organization in TTDs Control

Blood and blood component units used in the transfusion process as treatment are safe in general, but there is still some risk of infectious agents during transmission of the therapeutic unit from the donor to the recipient. Therefore, in the Kingdom of Saudi Arabia, the Saudi Food and Drug Authority (FDA) obligate tests for these infections in blood and blood products; screening blood donors for transmissible factors is critical in decreasing the hazards of TTDs. However, despite these tests, the majority of these infections are transmitted by blood and blood product transfusions. Thus, the harmless transfusion of blood and blood products is a main challenge in transfusion services. To ensure the safety of blood donations, strict actions are needed, such as strict donor selection criteria **(Babanejad et al., 2016; Dodd et al., 2016; Steele et al., 2020; Majid et al., 2020).**

1.5. Blood Unit Testing

Most donation centers screen for blood-borne agents (i.e., viruses, bacteria or parasites) with traditional serological investigations that depend on the detection of pathogen-specific antibodies or antigens. The most documented infectious causes are human immunodeficiency virus (HIV), hepatitis C virus (HCV), hepatitis B virus (HBV), syphilis infection caused by the bacterium Treponema pallidum and human T-lymphotropic virus (HTLV). Hence, the World Health Organization (WHO) mentions that all blood units collected must be screened for transfusion-transmissible diseases (TTDs) caused by these agents.

In Saudi Arabia, serological screening tests of all blood units for HIV, HBV, HCV, syphilis, HTLV and malaria, in addition to nucleic acid testing (NAT) for HIV, HBV and HCV infection, are mandatory by the force of the low (Saudi FDA) and accreditation requirements, such as CBAHI, AABB and CAP.

All blood donors undergo the clinical examination, which involves a donor interview with a licensed health care professional, with the full self-decision of assessing the donor clinical history and lifestyle to eliminate any chance of collecting blood from suspected donors with risk factors for transfusion-

transmissible diseases. The typical prevalence rate of TTDs in low- and middle-income countries is greater than that in high-income countries, most likely because of ineffective health services, hygiene behaviors, cultural social issues and limitations in screening test methods **(Sundaramoorthy et al., 2018).**

1.6.Transfusion-Transmissible Diseases (TTDs)

Incessant observation of transfusion-transmissible infection rates in blood donors and awareness of their profiles is the key to safe transfusion, as the number of blood units is directly related to the occurrence and prevalence rates of TTDs among blood donors. The TTDs rates were affected by the efficiency of clinical examination and laboratory screening tests. **(Pessoni et al., 2016)**

TTDs consist of infections that are spread from one to another by parenteral administration of infected blood or blood products. Many diseases are clustered under the classification of blood transfusion infections. These infections can cause acute or chronic disease or death. HIV, HCV and HBV are classified as serious risks to blood and blood product safety because of their lifetime incidence in the blood as carriers or in hidden states.

The incidence of TTDs between volunteer blood donors differs drastically worldwide. A study conducted in more than one center in Africa revealed that blood transfusions are responsible for 5–10% of documented HIV cases. The incidence of TTDs is still high in most countries of Africa and Asia, even with the restriction on blood transfusion safety submitted by the World Health Organization (WHO) and many other authorities to decrease the risk of TTDs. To decrease the risk associated with TTD exposure throughout blood or blood product transfusion, the WHO recommends obligatory screening of each blood donor for HIV, HCV, HBV, and syphilis. **(Alabdulmonem et al., 2020)**.

1.6.1.HIV and HCV

HIV and HCV studies in the U.S. and Europe have reported a significant decrease in HIV and HCV transmission through blood and blood products over the last three decades. In the 1980s, anti-HIV serological testing was started, followed a few years later by a similar method for HCV. (**Dodd et al., 2016; Steele et al., 2020).**

1.6.2.HBV

The risk of HBV infection has continuously decreased since the establishment of hepatitis B surface antigen (HBsAg) screening in the 1970s, and 300 million individuals infected with HBV worldwide have a considerable risk for TTDs infection. HBV surface antigen (HBsAg), the key screening test target, is routinely involved in donor screening tests. Some countries have also supplemented the HBV test (anti-Hbc), which is an antibody directed against the HBV core protein, to identify chronic virus in donors with low-level viremia who may not have detectable HBsAg levels. **(Sundaramoorthy et al., 2018; Alaidarous et al., 2018)**.

Currently, the remaining risk of HBV infection varies between 3.6 – 8.5 in the USA and Canada, 0.75 per million blood donations in Australia, 7.5 – 13.9 in Southern Europe up to 200 per million donations in Hong Kong, and 0.91 – 8.7 in Northern Europe, basically reflecting the global epidemiology of HBV. **(Bihl et al., 2007; Dodd et al., 2016; Steele et al., 2020)**

This study was conducted to define the incidence of TTDs among blood donors.

2.Aim of the study

Several new methods have currently been developed to decrease the risk of TTDs. However, screening suspected blood donors using serological and NAT tests is still the gold standard method. TTDs remain a prominent infection threat to blood transfusion safety with persistently increased mortality. Many studies have been conducted to identify the prevalence of TTDs and the epidemiology, evolution and administration of each TTDs agent, and as a contribution to these efforts, we conducted this study to differentiate between TTDs Agent from donors of Al-Madinah Al-Monawarah blood banks using serological-based assays, illustrating a diagram that shows the incidence of each

infectious agent among positive TTDs donors within the study region. Additionally, we provide an examination of the prevalence of TTDs in blood bank centers within the study region over time. Finally, the study aimed to provide the spreading pattern of TTDs in the study area, which could attract attention to epidemic TTDs agent and help to develop safe blood transfusion services.

3. Material and Methods

3.1 Study design

This cross-sectional retrospective study was conducted using blood bank donor TTDs results records from January 2020 until December 2022.

3.2 Data collection

The study collected data from five blood bank centers at the Madeina Regional Blood Bank (RBB), King Fahad Hospital Blood Bank (KFH), Maternity and Children Hospital Blood Bank (MCH), Yanbu General Hospital Blood Bank (YBB) and Prince Abdul Mohsen Hospital Blood Bank (ABB) during 2020, 2021 and 2022; the total number of donors was 104538 (n=104538). Qualified personnel carefully screened donor samples. The results of TTDs agents were validated by the medical director and head of the blood donor testing lab. However, each donor underwent physical examinations according to strict donor selection criteria provided by the American Association of Blood Banks (AABB) and Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI), and then the donor answered a donor questionnaire and signed forms. All donors were classified according to gender and donation type into I- volunteer donors and II- replacement donors, while paid donors were excluded. Paid donation is prohibited in Saudi Arabia. Additionally, basic information was registered for each donor: the donor's age, nationality, blood group and contact information.

3.3 Sample collection

For each donor, blood samples were collected from a blood bag pouch and divided into one EDTA sample and one plain sample in a vacutainer tube.

3.4 Processing

3.4.1 Serological testing

The donor samples were screened using the serological chemiluminescent method. Sample processing Serum samples were screened for HBsAgs, HBcAbs, anti-HCV, HIV Ag/Ab combinations, anti-HTLV and syphilis using an Architect i1000SR immunoassay analyzer (Abbott). The screening tests were performed according to the manufacturer's guidelines. Cutoff values ≥1.00 S/CO were reported as reactive results, and values equal to or less than 1.00 S/CO were reported as negative results. All reactive samples were retested in duplicate.

3.4.2 Confirmatory Test

Each sample was reactive for any TTDs Serological tests ware further processed for confirmatory testing according to each pathogen agent. Initial positive HIV and HTLV results were confirmed by Western blot analysis, and HBsAgs were confirmed by neutralization. HCV was confirmed by the RIBA technique, and syphilis was confirmed by TPHA or a chemiluminescent microparticle immunoassay technique. **(Alaidarous et al., 2018)**.

5. Results

5.1. General features of the study population

This study comprised a total of 104538 donors, the majority of whom were Saudi national, and males and females donated blood voluntarily and replacement from Madinah city. The 104538 donors under study were selected from January 2020 until December 2022. Out of 104538 donors, 54360 were volunteer donors (52%), and the remaining 50178 were replacement donors (48%). Male donors were dominant (98%) compared with female donors (2%).

5.2. Characterization of tested samples

TTDs positive samples were grouped according to donation type, donor gender, type of infectious pathogen test result, initial screening and confirmation test results. A total of 1061 samples were positive for at least one of TTDs pathogen from the initial screening test. The remaining 103477 samples were negative for all tested TTDs (HIV, HBV, HCV, HTLV and syphilis).

Table I: Prevalence of positive Screened and Confirmed among Blood Donors

	Donor	Screened positive (donor)	%	Confirmed positive (donor)	%
All years	104538	1061	1.01	416	39.20
2020	29823	294	0.98	129	43.87
2021	39873	408	1.02	152	37.25
2022	34842	359	1.03	135	37.60

All samples in the study were examined using serological methods. The serology markers of TTDs used were HBsAg, HCV Ab, HIV Ag/Ab, syphilis and HTLV. The results indicated that there were fewer confirmed positive results than screened results. Out of 334 donors positive for HBV from the screening serology test, only 276 donors were confirmed positive by neutralization, and out of 305 donors positive for HCV from the screening serology test, only 66 donors were confirmed positive by RIBA. The initial syphilis screening test showed that 214 donors were positive, while only 55 donors were confirmed. Finally, HIV and HTLV screening tests showed the same pattern; out of 105 and 103 positive screening serology tests, respectively, only 13 and 6 donors were positive by confirmation test WB, respectively.

5.3. Prevalence of TTDs among total blood donors

The prevalence of potential positivity for at least one pathogen of TTDs was 1061 donors (1%) in serology tests of all blood bank donors. The total confirmed positive results for at least one TTDs pathogen were 416 donors (39%) out of the total initial positive screening test results.

5.4. Prevalence of each pathogen among confirmed positive TTDs blood donors

The prevalence of pathogens showed a high incidence of HBV (66.34%) among positive TTDs, and 276 donors were positive out of 416 confirmed positive TTDs. HCV prevalence was (15.86%) among positive confirmed TTDs, and 66 donors were positive out of 416 confirmed positive TTDs. Then, syphilis became third in prevalence (13.22%) among confirmed positive TTDs, and 55 donors were positive out of 416 confirmed positive TTDs. Finally, HIV and HTLV prevalence were (3.12% and 1.44%), respectively, among positive TTDs, and 13 and 6 donors were positive out of confirmed positive TTDs, respectively.

Table II: Prevalence of TTDs among Blood Donors

TTD	Screened positive (donor)	Percentage out of total screened positive TTDs (%)	Confirmed positive (donor)	Percentage out of total confirmed positive TTDs (%)
HBV				
All years	334	31.47	276	66.34
2020	95	32.31	81	62.79
2021	116	28.43	97	63.81
2022	123	34.26	98	72.59
HCV				
All years	305	28.74	66	15.86
2020	79	26.87	19	14.72
2021	117	28.67	24	15.78
2022	109	30.36	23	17.03
Syphilis				
All years	214	20.16	55	13.22

2020	69	23.46	23	17.82
2021	88	21.56	27	17.76
2022	57	15.87	5	3.70
HIV				
All years	105	9.89	13	3.12
2020	31	10.54	4	3.10
2021	44	10.78	3	1.97
2022	30	8.35	6	4.44
HTLV				
All years	103	9.70	6	1.44
2020	20	6.80	2	1.55
2021	43	10.53	1	0.65
2022	40	11.14	3	2.22

6.Discussion

Blood-borne infections are caused by many pathogens, some of which are epidemic in selected countries, while others are rare pathogens.

The effectiveness of blood testing is a major concern regarding the safety of blood and blood product transfusions. The prevalence of TTDs leads to mortality and morbidities related to infectious agents, especially HBV, HCV, HTLV and HIV pathogens. These TTDs are major issues in whole healthcare systems worldwide, including Saudi Arabia. Therefore, TTD testing is critical for evaluating blood and blood product transfusion risks.

Several studies were conducted to underline the prevalence of TTDs among the donor and population in the KSA. However, most of these studies focused on the general population and not on donors. On the other hand, only a limited number of previous studies were conducted to highlight the comprehensive prevalence of TTDs. In particular, carriage among donors in Madinah city.

There is a literature gap about the healthcare burdens of transfusion-transmitted HBV, HIV and HCV in Saudi Arabia, which needs to be applied in additional research **(Elbjeirami et al., 2015)**.

It is quite known that the results of prevalence studies vary considerably between different studies. Such difficulty in comparing the prevalence rates of possible TTD pathogens among diverse studies is related to numerous factors, such as age, geographical area, sampling site and technique, status of the immune system and socioeconomic conditions. In contrast to numerous studies that focused on blood-borne pathogens in the community, not blood donors, who usually have the highest prevalence of blood-borne pathogens because of donor selection criteria and donor deferral policy, this study paid more attention to the donors that have come for blood donation. Saudi and non-Saudi, male and female, volunteers and replacement donors were involved in this study.

6.1 Prevalence of TTDs

In this study, the general prevalence of a positive screening test for TTDs was 1.01%, which is lower than that reported from Qatar in 2017 (2.67%) **(Aabdien et al., 2020)** and higher than that reported in Saudi Arabia in 2018 (0.7%) **(Majid et al., 2020)**.

In our study, a large percentage of donors had a positive test for HBV (0.31%), less than the results of studies from eastern Saudi Arabia (3.24%) **(Alzahrani et al., 2019)** and Nigeria (10.1%) **(Akinbami et al., 2012)**, most likely reflecting the effects of hepatitis B vaccination and the hemovigilance system, such as the national donor history database (HESN).

Over standard HBV antigen tests, it was found that 334 (0.31%) samples were positive for HBsAgs, 305 (0.29%) samples reacted to HCV antibodies, and 214 (0.20%) samples reacted to syphilis. Moreover, 105 (0.10%) samples reacted to HIV antibodies and/or antigens, and 103 (0.09%) samples were positive for HTLV.

Several studies were conducted in various regions in Saudi Arabia, a study by Sarah et al. **(El Beltagy et al., 2008)** that was conducted in the Hail region; (8.6%) of samples were positive for HBV, (7.2%)

reacted to HCV antibodies, 2.2% reacted to HTLV antibodies and 4.7% reacted to HIV antibodies. Moreover, 1.7% of the samples were positive for syphilis **(Sarah et al., 2016).** However, similar to our study's results. A study by Bamaga et al. in Taif found that (0.33%) of samples reacted to HBsAgs **(Bamaga et al., 2009)**. A significantly higher reactivity (6.11%) to HBsAgs was reported in a paper from a study in Jeddah **(Redwan et al., 2012)**. However, studies in Jazan and Tabuk had findings similar to this study; 3.8% of samples reacted to HBV **(Abdullah et al., 2013; El Beltagy et al., 2008)**. The lowest rates of HBV reactivity were found by studies in Taif and Makkah; the percentages were 0.33% and 0.66%, respectively **(Elbjeirami et al., 2015; Bamaga et al., 2009)**. These findings were consistent with the present study.

Additionally, similar to the present study, a high HCV prevalence (0.83%) was found in a study in Dammam **(Abdullah et al., 2013)**. Moreover, an HCV prevalence of 0.44% was reported by a study in Makkah. Additionally, a prevalence of 0.4% was reported by a study in Riyadh, and a prevalence of 0.41% was reported by a study in Jazan **(Abdullah et al., 2013; Abdo et al., 2012; Abdullah et al., 2013)**.

In fact, the present literature found a very low incidence rate of HIV in Saudi Arabia, and these reports were reinforced by the present study's results. Few studies have compared HIV prevalence in different Saudi Arabian regions. However, 0.15% of samples in a study in Taif had HIV reactivity, and 0.07% of samples in a study in Makkah had HIV reactivity **(Elbjeirami et al., 2015; Bamaga et al., 2009)**. The results were significantly higher for a study in Dammam, in which 0.29% of samples had HIV seropositivity. These findings, as well as the present study's findings, suggest a low rate of HIV seropositivity in Saudi Arabia.

More than the literature also showing that the prevalence of HTLV is limited in Saudi Arabia, Sarah et al. reported a prevalence of (2.2%) in the city of Hail, while our study had a rate of (0.09%) in Madinah. Moreover, Sarah et al. found that Hail had the lowest rate of syphilis (1.7%) **(El Beltagy et al., 2008)**.

6.2 Prevalence of HBV among Donors with TTDs

HBV disease is considered one of the greatest vital health problems in several countries of the world, exclusively those in Asia, the Middle East, and Africa. The rate of HBV infection has significantly decreased as a result of mass HBV vaccination programs. It was expected that there would be at least 400 million patients with HBV chronic infection universal in the year 2000, and the number has today increased beyond this limit.

In Saudi Arabia, approximately 60% had a clear mark of older exposure to HBV since 1988. Additionally, a high prevalence rate of HBV disease between children was documented in 1992; approximately 7% of well children younger than 10 years of age were HBsAg positive, and 20% were positive for at least one of the markers of HBV **(El Beltagy et al., 2008)**.

7.Conclusion

The public may be perfect in their trust that risk-free blood products are completely reachable in today's world. In fact, the threat of TTDs entering the blood supply is not stationary and may develop as new blood-borne pathogens appear or as old alterations in their epidemiological pattern **(Abdelaziz et al., 2020)**.

The aim of a safe and inexpensive blood supply that can come across growing worldwide demands may be reached by the optimization of every phase in the transfusion chain, including the strict and careful consideration of donor eligibility criteria, adherence to stringent standard rules during donation, appropriate component processing and storage, the optimal operation of available TTD screening tests, the use of proper pathogen inactivation systems and finally the attentiveness of reasonable physicians, who assess the requirement of each transfusion **(Alzahrani et al., 2019)**.

Laborers invested in providing the lowest potential TTD risk blood products need to be matched by the diligence of physicians managing the transfusions who need to report any undesirable adverse consequences of blood transfusions **(Hakami et al., 2021)**.

National hemovigilance systems linked to an international system are becoming essential elements of blood product safety and quality. Combined with the improvement and operation of sensitive and inexpensive recognition and inactivation approaches, these approaches make blood transfusion a safer form of treatment even in places where the risks up to the present time have to be considered significant **(Hanif et al., 2022)**.

In view of the results presented in this study, TTD-positive donors by serological methods among Madinah blood bank donor males and females were found to have the same local TTD rate **(Majid et al., 2020)**.

Inspection of the TTD pattern among TTD-positive donors by serological methods revealed that HBV infection was high. Such asymptomatic HBV carriers pose a potential threat to other blood recipients and require the development of essential approaches to reduce the carriage of such potential TTD pathogens. This can be done by constant monitoring and community screening of silent carriers to prevent the transmission of HBV infections and minimize the occurrence of TTD pathogens among blood donors.

In this retrospective study going over donated blood screened for TTDs among blood donors in Madinah, the rate of positive tests was low. None of the abnormal TTD results were analyzed for significant associations with age group, sex or nationality. The high percentage of study subjects with HBV infection indicates a need for more efforts to explain HBV prevalence in this study population **(Aabdien et al., 2020; Bobde et al., 2015; Ibrahim et al., 2014; Kurdi et al., 2014)**.

The overall results obtained in this study need to be considered with caution. This is because of the duration of the study time and because the participants were selected from different nationalities within the study area, all of which resided within the same city of Al-Madinah. Therefore, the call for a larger study that includes increasing the sample size and involving other cities and geographical regions within the country is needed to establish the findings. It would also help in properly identifying the dominant and city determinants that may predispose certain donors to carry more risk factors for TTDs.

Institutional Review Board Statement

Ethical approval for this study was obtained from General Directorate of Health affairs Institutional Review Board in Al-Madinah Al Munwarah, IRB log No:23-055. Donor privacy and data confidentiality were maintained according to the Helsinki declaration.

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