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The prevalence of transfusion-transmitted infections and nucleic acid testing among blood donors in Majmaah, Saudi Arabia

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ABSTRACT

Background: Few studies discussed the prevalence of TTIs in Saudi donor blood samples. Thus, this study investigated the prevalence of hepatitis B virus (HBV), hepatitis C virus (HCV), human immunodeficiency virus (HIV), human T-lymphotropic virus (HTLV), syphilis and malaria in such samples to determine the efficacy of conducting serological and NATs on blood donors at King Khalid General Hospital in Majmaah, Saudi Arabia.

Methods: A total of 3028 donated blood units were collected from August 2015 to March 2017. Serum samples were screened for hepatitis B surface antigens (HBsAgs), HBsAbs, total anti-core antibodies (HBcAbs), HCV antigens and HIV Ab/Ag combinations. Additionally, plasma was screened for syphilis (TPHA) and HTLV. Samples were also tested for malaria with rapid malaria antigen tests. Finally, NATs were performed for the simultaneous direct detection of HBV, HCV and HIV in each sample.

Results: Out of the 3028 blood samples, 10 (0.33%) reacted to HBsAgs; 12 (0.40%) reacted to HCV antigens; 4 (0.13%) reacted to HIV Ab/Ag combinations; 6 (0.20%) reacted to HTLV antibodies; 297 (9.81%) reacted to HBcAbs and 236 (7.80%) reacted to HBsAbs. Additionally, NATs showed that 14 (0.46%) reacted to NAT-HBV; 20 (0.66%) samples were reacted to NAT-HCV and 2 (0.07%) samples reacted to NAT-HIV. Finally, 16 (0.53%) were positive for syphilis. No samples were positive for malaria.

Conclusions: The results indicated that NATs are more effective than serology tests for detecting TTIs. Moreover, correlations between standard serology tests and NATs indicated that using NATs could improve test sensitivities and decrease residual risks of TTIs and ensure safe blood transfusions.

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Introduction

Blood and blood products are considered potentially hazardous materials, especially when they are infected with HBV, HCV, HIV types I and II (HIV I and II), HTLV, syphilis and malaria. Consequently, in Saudi Arabia, the Saudi Food and Drug Authority (FDA) mandates investigations for these infections in blood and blood products; screening blood donors for transmissible agents is crucial in reducing the risks of TTIs. However, despite these investigations, most of these infections are transmitted through blood transfusions [1]. Thus, the safe transfusion of blood and blood products is a major challenge in transfusion medicine. To improve the safety of blood donations, strict measures are enforced, such as strict selection criteria. Donors with clinical histories or theoretical risks of carrying any of the aforementioned infectious agents are excluded, and this is taken seriously [2]. To elucidate, the transmission of such infectious diseases is due to a prevalence of donors who are asymptomatic carriers of the diseases during the window periods of the infectious agents [3]. The majority of blood banks screen for blood-borne pathogens (i.e., viruses) with conventional serological tests that depend on the production of viral-specific antibodies [4]. Most studies reported that the transmission of HIV, HCV and HBV by blood and blood products declined remarkably over the last two decades as a result of the implementation of such testing methods, which are sensitive and can detect blood-borne infectious markers early and accurately [5]. However, serologic testing cannot detect all infectious agents in blood donations due to the window periods

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of infections, as well as occult (i.e., hidden) infections and other factors [3,4].

NATs for HCV, HIV and HBV are major advances in blood screening that can eliminate serologically false-negative blood units. Moreover, NATs significantly decrease the residual risks of pathogens. Finally, such tests have the advantage of reducing serological window periods; with NATs, the HBV period is reduced to less than 11 days, the HCV period is reduced to less than 2 days and the HIV period is reduced to less than 3 days [6,7]. Therefore, NATs should always be considered when establishing an effective and efficient program based on antibody/antigen testing. Indeed, in countries with high incidences of TTIs, donations positive for infectious agents that are not usually detected due to their window periods are often identifiable using NATs [8,9]. Thus, in countries with sufficient resources, NAT offers certain benefits when combined with standard antibody/antigen tests. However, although the risks of blood transfusion may decrease using NATs, the benefits such tests offer to populations must be balanced with the complexities and high costs of performing the tests. That is, the benefits of detecting infections agents early and preventing TTIs should be assessed in relation to other factors based on incidences or the prevalence of infections within a blood donor population [4]. The sensitivities of the serological screening methods that are used and the effectiveness of the blood-donor selection process [10–12] must also be considered. This study was initiated in order to determine the prevalence of TTIs screened in donated blood units. The study period was August 2015 to March 2017. Blood donated at King Khalid General Hospital in Majmaah, Saudi Arabia, was examined.

Methods

Data collection

This study was carried out using the Blood Bank Laboratory of King Khalid General Hospital. Trained personnel carefully screened donors. However, the donors first underwent complete physical examinations, satisfactorily answered a donor questionnaire and signed forms, as per the guidelines of the Saudi FDA.

Professional and paid donors were excluded by examining each donor's history and conducting clinical examination; paid donors are illegal in Saudi Arabia. Then, basic information was obtained for each donor: the donor's age, sex, nationality, blood group and informed consent. Subsequently, for each donation, blood samples were obtained from a blood pouch and divided into two EDTA samples and one plain sample in a vacutainer. The samples were then screened using serological assays and NATs.

Sample processing

Serum samples were screened for HBsAgs, HBcAbs, HCV antibodies, HIV Ag/Ab combinations and HTLV antibodies using an Architect i1000SR immunoassay analyzer (Abbott). The tests were performed according to the manufacturer's instructions. For cutoff values, $\geq$1.00 was considered reactive and $\leq$1.00 was considered negative. All reactive samples were retested in duplicate. Additionally, donor plasma was screened for syphilis using a rapid RPR kit from Crescent, and all RPR positive samples were confirmed using a chemiluminescent microparticle immunoassay to detect *Treponema pallidum* (TP) antibodies in the serums and plasma. This was done with the i1000SR analyzer. A cutoff value of $\geq$1.0 was considered reactive. Finally, malaria antigens were screened for in each unit with an OptiMAL-IT test kit (Bio-Rad).

Quantitative and differentiation tests were conducted for HIV I, HIV II, HCV and HBV using a cobas TaqScreen MPX Test, version 2.0 (Roche molecular diagnostics), using a generic nucleic acid preparation technique. The machine was a quantitative multiplex–random access analyzer that was capable of the simultaneous direct detection and discrimination of HIV I group M RNA, HIV I group O RNA, HIV II RNA, HCV RNA and HBV DNA. All positive and negative results were valid based on a replication of a negative control (i.e., TS [−] C) and a replication of each positive control (i.e., HIV-1M [+] C; HIV-1 O [+] C; HIV-2 [+] C; HCV [+] C and HBV [+] C) processed with each batch.

Statistical analysis

Frequencies and cross-tabulations were used with donor prevalence to compare demographics related to standard serological and NAT tests. Chi-square and Spearman correlation tests were used to assess these comparisons. Statistical significance was denoted as a confidence interval (p) of $\leq$0.05.

Results

A total of 3028 blood units were received and tested at King Khalid General Hospital from August 2015 to March 2017. Descriptive statistics, variables and outcomes for these samples are shown in Table 1. All the parameters were statistically significant and clinically acceptable. It was found 2956 (97.6%) of the donors were male and 72 (2.4%) of the donors were female. A total of 2473 (81.7%) of the units came from volunteers, while 555 (18.3%) of the units came from replacement donors. Additionally, the donors' ages were as follows: 836 (27.6%) donors were 18–28 years old, 9722 (23.8%) donors were 29–39 years old, 605 (20%) donors were 40–50 years old and 123 (4.1%) donors were more than 61 years old. Moreover, the donors' blood groups were as follows: 203 (3.4%) donors were A−, 392 (12.9%) donors were A+, 35 (1.1%) donors were AB−, 124 (4.1%) donors were AB+, 50 (1.7%) donors were B−, 657 (21.7%) donors were B+, 415 (13.7%) donors were O− and 1252 (41.3%) donors were O+.

Seroprevalence tests found that 10 (0.33%) samples reacted to HBsAgs, 297 (9.81%) reacted to HBcAbs, 236 (7.80%) reacted to HBsAbs, 12 (0.40%) reacted to HCV antibodies and 4 (0.13%) reacted to HIV Ab/Ag combinations (Table 2). Moreover, other serology tests found that 6 (0.20%) samples reacted to HTLV antibodies, 16 (0.53%) samples reacted to TPHA and no samples reacted to malaria antigens (Table 3). Furthermore, NATs showed that 14 (0.46%) samples reacted to NAT-HBV, 20 (0.66%) samples reacted to NAT-HCV and 2 (0.07%) samples reacted to NAT-HIV, shown in Table 4.

Table 1
The sociodemographic characteristics of the blood donors.

Characteristic		Number of units	Percentage
Sex	Male	2956	97.6%
	Female	72	2.4%
Age (years)	18–28	836	27.6%
	29–39	722	23.8%
	40–50	742	24.5%
	51–60	605	20.0%
	>61	123	4.1%
Blood type (ABO Rh)	A−	103	3.4%
	A+	392	12.9%
	AB−	35	1.1%
	AB+	124	4.1%
	B−	50	1.7%
	B+	657	21.7%
	O−	415	13.7%
	O+	1252	41.3%
Donation type	Volunteer	2473	81.7%
	Replacement	555	18.3%

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