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Mandatory Blood Donor Screening for Human T-Cell Lymphotropic Virus Type I and Type II in Saudi Arabia: Need for Review

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Abstract

Background

HTLV blood donor screening is recommended practice in high prevalence countries. However, although studies of HTLV seroprevalence in Saudi Arabia agree these viruses present limited threat in the country, serological screening of HTLV-I/-II in all prospective blood donor candidates is mandatory practice. Since the last publication of HTLV seroprevalence in Saudi Arabia 10 years ago, we review 2014-2015 data of 23,668 blood donors attending King Khalid University Hospital (KKUH) Riyadh, to determine whether this mandatory practice needs review.

Materials and methods

Serology screening was performed on the Abbott Architect system running the rHTLV assay. Repeat reactive results were confirmed by Western Blot analysis.

Results

This study revealed zero HTLV-I/-II seroprevalence amongst 23,668 donors over the study period.

Discussion

We further support Saudi Arabia as a HTLV non-endemic region, and review more cost-effective strategies to minimize HTLV risks as an alternative to mandatory blood donor screening.

Keywords: HTLV-I; HTLV-II; Saudi Arabia; Blood donors; Screening

Introduction

Human T-cell lymphotropic virus type I and type II (HTLV-I and HTLV-II), two closely related human type C retroviruses discovered in the late 1970s to early 1980s are associated with several neurologic disorders [1-3]. HTLV-I is the etiological agent of HTLV-I associated myelopathy (HAM), adult T-cell leukemia (ATL) and tropical spastic paraparesis (TSP) [4-5], whilst HTLV-II has been associated with HAM/TSP-like neurodegenerative diseases [6]. Transmission can occur sexually, parentally, via the sharing of contaminated needles among intravenous drug users (IVDU) and also via the transfusion of contaminated blood. Cases of transfusion transmitted HTLV infections have been documented since the 1980s [7-11]. Consequently, the World Health Organization (WHO) recommends screening blood donors for HTLV-I/II infections in high prevalence countries.

The Kingdom of Saudi Arabia is generally considered a HTLV non-endemic region since the seroprevalence of HTLV-I/II amongst the Saudi population has been reported to range from 0-0.046% [12-18]. Nevertheless, serological screening of HTLV-I/II in all prospective blood donor candidates is mandatory practice in Saudi Arabia. We present two years (2014-2015) blood donor serological screening data for HTLV-I/II at a tertiary care hospital in Central Saudi Arabia, to further support this region as non-endemic, and review more cost-effective HTLV prevention strategies to current mandatory screening practices.

Materials and Methods

Study design/subjects studied

This study comprised a retrospective analysis of HTLV seroprevalence amongst blood donors attending King Khalid University Hospital (KKUH) blood bank, Riyadh Saudi Arabia, between 1st January 2014 and 31st December 2015.

Serological screening

Serology screening was performed using the Architect system (Abbott Diagnostics, Wiesbaden, Germany), running the rHTLV-I/II assay for the qualitative detection of antibodies to HTLV-I and HTLV-II in human serum or plasma. Samples with a sample/cutoff ratio (S/CO) of ≥1.00 were initially considered reactive and were repeat tested in duplicate using the same assay. If both of the duplicate tests were negative, the donation was considered suitable for release into the clinical inventory. If one or both duplicates were still reactive, confirmatory testing was performed using a commercial Western Blot assay (Genelabs Diagnostics, Geneva, Switzerland) according to the manufacturer's instructions. A sample was considered HTLV-I seropositive if reactive to GAG (p19 with or without p24) and 2 ENV (GD21 and rgp 46-I) proteins and HTLV-II seropositive if reactive to GAG (p24 with or without p19) and 2 ENV (GD21 and rgp 46-II).

Results

During the study period, a total of 23,668 donors were screened for anti-HTLV-I/-II antibodies. The majority of donors screened were male (93.5%), volunteer donors (56.9%), of Saudi nationality (78.2%) (Table 1). Initial screening on the Architect system yielded 14 repeat reactive donations (Table 2). Confirmatory testing by Western Blot analysis revealed 14 negative results and 1 indeterminate result.

Characteristic	Total number (%)
Male	22130 (93.5)
Female	1538 (6.5)
Saudi	18508 (78.2)
Non-Saudi	5160 (21.8)
Volunteer	13467(56.9)
Replacement	10201 (43.1)

Table 1: Demographics of blood donors attending KKUH blood bank between 2014 and 2015.

Year	Number of blood units screened	Repeat seroreactive	Western Blot analysis
2014	12,496	8 (0.06)	8 negative
2015	11,172	6 (0.005)	5 negative, 1 indeterminate
Total	23,668	14 (0.065)	14

Table 2: HTLV –I/-II seroprevalence amongst blood donors attending KKUH between 2014 and 2015.

Discussion

HTLV-I has a global distribution with highest prevalence rates in Japan, the Caribbean and in parts of South America and Africa [4,19]. However, HTLV-II has endemic foci in the Indian subcontinent, and North/South America [20,21]. To date, all reports of HTLV-I/II seroprevalence in Saudi Arabia have been very low. Murphy [22] estimates Saudi Arabia's HTVL-I/II seroprevalence as 0.000028 based on 7 studies reporting HTLV screening results between 1997 and 2005.

In non-endemic areas, HTLV risks are primarily associated with travel or residence history in endemic countries. Other high risk factors include country of birth, parental ethnicity, sexual contact with individuals from HTLV endemic areas and/or at-risk household contacts [23]. The Saudi Arabian workforce currently comprises a significant proportion of expatriate workers originating from HTLV endemic regions, e.g. the Indian subcontinent. This may have been the initial justification for implementation of the mandatory screening of HTLV-I/-II in blood donors in Saudi Arabia. However, blood donor screening policies should be primarily based on local epidemiological evidence, which in this case do not indicate a significant HTLV threat.

Our study revealed zero HTLV seroprevalence amongst 23,668 blood donor attending KKUH Riyadh between 2014 and 2015. This is in agreement with a previous study performed in the same hospital investigating HTLV infection in 24,173 blood donors over a 3 year period (January 2000-December 2002) which also reported zero HTLV infections [14]. Both studies highlight the limited threat of HTLV-I/-II infections to the safety of the blood supply in this region. Additionally, other studies investigating blood donor screening outcomes in Saudi Arabia have also shown that the majority of voluntary donors are from the native Saudi population and report a very low seroprevalence, supporting the country as a non-endemic region for HTLV infections [12-18]. We therefore question the cost-effectiveness of continued universal HTLV-I/-II screening of all blood donors in a low-prevalence country.

An alternative HTLV screening strategy proposed by Arif and Ramia [13] was to screen only the expatriate blood donor population. Kawashti et al. [17] also proposed HTLV screening of pooled sera instead of individual serum screening. However, a more pragmatic and still cost-effective strategy would be to implement stringent donor selection guidelines to identify donors with possible risk factors for HTLV and to selectively screen only at-risk donors, whilst deferring individuals with particularly high-risks of HTLV infection. Additionally, educating prospective donors on risk exposure for HTLV would encourage more open disclosure of infective risk factors, and encourage self-deferral of high risk donors. Such prevention strategies would be applicable to all transfusion transmissible infections, not just HTLV.

Conclusions

In conclusion, based on the collective reported frequencies of HTLV infections in Saudi Arabia, the current mandatory screening of all blood donors is neither justified nor cost-effective. We encourage the policy makers in the Saudi Ministry of Health to shift focus of HTLV prevention strategies to implementing selective screening of only at-risk blood donors and expanding donor education campaigns.

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Author contributions

HM and EA designed the study, HM and AFA collected the data, HM, AFA, AS, FMA, AHA and DM performed the analysis, interpretation and wrote the manuscript.

Disclosure of conflicts of interests

None to declare.

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