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Research Article
Transfusion

Dual strategy testing with electrochemiluminescence and ELISA for sero-prevalence of transfusion transmitted viral infections in blood bank

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Introduction: Transfusion transmittable infections (TTI) continue to be a major threat to safe transfusion practices. Blood is one of the major sources of transmission of infectious diseases viz. human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), syphilis, malaria, and many other infections in India. **Methods:** The present study was designed to determine the seroprevalence of Transfusion Transmittable Infections viz., HIV, HCV, and HBV, Syphilis, malaria among the blood donors in blood bank from January 2013-December 2013. In the present study Sera samples were screened for hepatitis B surface antigen (HBsAg), antibodies to HCV, HIV using electrochemiluminescence and to syphilis using Rapid Plasma Reagin test (RPR), and to malaria by peripheral smear respectively. **Results:** Total 9,400 cases. Of which 51% were voluntary donors and 49% were replacement donors. The overall prevalence of HIV, HbsAg, and HCV were 0.35,1.86, and 0.22 respectively. All the markers tested there was increased prevalence of TTI among the replacement donors as compared to voluntary donors. **Conclusion:** The screening of blood and blood components by dual testing strategy using high sensitivity serological assay like enhanced chemiluminescence technology and NAT helps in detecting the potentially infectious blood units in all phases of infection, which aids in enhancing the safety of blood transfusion and reducing the potential risk of post-transfusion infection.

Keywords: Electrochemiluminescence, ELISA, Seroprevalence, Transfusion, Viral infections, Blood bank

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Introduction

Blood safety is major concern globally going by the increasing incidence of transfusion transmittable infections (TTIs). Safe transfusion of blood and blood components saves millions of lives, but unsafe transfusion practices put millions of people at risk of TTIs. Blood is one of the major sources of transmission of infectious diseases, viz. HIV, HBV, HCV, syphilis, and many other infections in India [1].

India has intermediate endemicity of hepatitis B with HBsAg prevalence of 2–10% among the study population. It has been estimated that up to 40 million people out of the 350 million people with hepatitis B chronic carriers worldwide arise in India. 2 HCV is a leading cause of chronic liver diseases, viz., hepatic fibrosis, cirrhosis, end-stage liver disease and hepatocellular carcinoma (HCC). In India, there are about 12–13 million HCV carriers and modeling data predict that the burden of disease could soon increase substantially [2,3]. Despite implementation of various screening assays for detection of TTIs, occasional cases of post-transfusion infections are common. Majority of these problems are due to prevalence of asymptomatic carriers in the society as well as due to blood donations during the window period of infections. The hazards of transfusion were minimized by proper selection of donors and screening for infectious diseases by a high sensitivity screening assay. World Health Organization (WHO) recommends an integrated strategy to improve blood transfusion safety by establishment of well-organized blood transfusion services; prioritization of blood donation from voluntary non-remunerated donors, screening of donated blood for atleast four major TTIs with quality assured system, rational use of blood and implementation of effective quality control systems [4].

Meticulous pre transfusion becomes mandatory so as to prevent life threatening diseases [5]. Unsafe blood transfusion leads to increased morbidity as well as mortality hampering human and economic growth [6]. A proper protocol for screening donor, effective counseling, screening tests, proper discarding techniques for reactive units ensure in the reduction of acquiring TTI [7]. Hence the present study was conducted to determine the seroprevalence of Transfusion Transmittable Infections viz., HIV, HCV, and HBV, Syphilis, malaria among the blood donors in blood bank.

Materials and Methods

The present study was designed to determine the seroprevalence of Transfusion Transmittable Infections viz., HIV, HCV, and HBV, Syphilis, malaria among the blood donors in blood bank from January 2013-December 2013.

Study setting: The present study was conducted among the blood donors in blood bank at JJMMC Davangere Hospital

Duration: This study was carried out among blood donors during January 2013 to December 2013.

Type of study: The present study was a hospital based cross sectional study.

Sampling method and sample size calculation: Universal sampling method was used where all the blood donors at JJMMC Davengere who fit in the inclusion criteria were selected.

Inclusion and exclusion criteria: All the blood donors in the age of 18-60 years, weight >45 kgs, heamoglobin >12.5gm% were included in the study. Professional donors were excluded in the study.

Data collection procedure: In the present study Sera samples were screened for hepatitis B surface antigen (HBsAg), antibodies to HCV, HIV using electro-chemiluminescence and to *syphilis* using Rapid Plasma Reagin test (RPR), and to malaria by peripheral smear respectively. All samples were screened for HIV, HBsAg, HCV, syphilis and malaria.

A detailed history and clinical examination was obtained from the blood donors followed by screening for HIV, HBV and HCV infections using electrochemiluminescence and ELISA. Sera samples were screened for hepatitis (HBsAg) surface antigen, antibodies to HCV, HIV using electrochemilu-minescence to syphilis using Rapid Plasma Reagin test (RPR) and to malaria by peripheral smear examination respectively. All the samples for HIV, HBsAg, and HCV were done using a electrochemiluscence and reactive samples confirmed by third generation enzyme-linked immunosorbent assays.

Serological screening for HIV, HBV, and HCV infections: All serum samples were screened for the presence of anti HIV 1 and 2 antibody, anti HCV antibody, anti HBcore antibody, and HBsAg using enhanced chemiluminescence technology in VITROS® ECiQ system, following manufacturer's instructions.

Screening for anti HBs antibody: In the present study, some of the serum samples that showed anti HBcore antibody alone reactive were tested for the presence of anti HBs antibody using VITROS® Anti HBs Antibody–quantitative assay based on enhanced chemiluminescence technology in VITROS® ECiQ system.

Data analysis: After Data collection data entry was done in excel sheet. The data was analyzed using IBM-SPSS 18 version. Qualitative data was analysed using frequency and percentage table. Whereas association among various parameters was done using Chi square test and P value <0.05 was considered as statistically significant.

Ethical consideration: Ethical clearance was obtained from institutional ethical committed and informed written and verbal consent was obtained from the participants.

Results

During the study period from January 2013 to December 2013 a total of 9400 individuals donated blood at JJMMC Davangere. Out of which majority were male 8836 (94%) as compared to females 564(6%). Majority of the donors were in the age group of 26- 35 years (48%). Followed by those in the age group of 19-25 years (28%). Majority of the donors were replacement donors 4800 (51%) followed by voluntary donors 4600(49%). All samples were screened for HIV, HBsAg, HCV, syphilis and malaria. The overall prevalence of HIV 33 (0.35%), HbsAg 175 (1.86%), and, HCV 21 (0.22). No blood donor tested showed positivity for malarial parasite and syphilis. Majority were voluntary donors with male preponderance (89%). In all the markers tested there was increased prevalence of TTI among the replacement donors as compared to voluntary donors. 229 (2.4%) donors had infection of each HIV, HbsAg, and HCV. Multiple infections were seen among 0.21% of the replacement donors. 20 (0.21%) donors had infection of both HbsAg and HCV. enhancing the safety of blood transfusion and reducing the potential risk of post-transfusion.

Table 1: Number of donors with the various transmissible infections.

Month	Number of donors per month	Number of HIV positive cases	Number of HbsAg positive cases	Number of HCV positive cases
January	742	4	19	0
February	756	2	15	2
March	868	6	18	2
April	744	2	12	2
May	838	5	11	2
June	670	4	15	1
July	593	2	13	0
August	630	3	19	0
September	1148	2	17	5
October	921	1	16	4
November	777	2	10	3
December	713	0	10	1
Total	9400	33	175	21

Discussion

Technological advancements have led to the development of more sensitive methods to detect various infectious disease markers, e.g. viral specific antigens, antibodies and nucleic acids in order to enhance the safety of blood transfusion. However, early detection of infection remains elusive goal due to the existing problem of "Window period," false negative results due to the limitation in the screening assays, genetic modifications in viral strains, and laboratory errors.

This study was undertaken to study the prevalence of infectious disease markers in the donor population attended in the blood bank in the tertiary care hospital based on dual testing strategy. Since ours is a hospital-based blood bank, majority of the blood units are collected from the replacement donors and voluntary donors. Since the transfusion transmittable diseases screening was carried out for transfusion safety, WHO [8] and NACO [9] testing strategy 1 were followed to maximize safety of the blood for transfusion and minimize the prevalence of TTI.

The present study noted that number of female donors were comparatively less than male donors which is similar to studies carried in Pune. [10, 11, 12, 13]. The reason behind less female donors may be attributed to myths associated with blood donation among females. In the present study majority of the donors were males (94%) the findings are similar the study done by various authors in Africa, Libya, Nigeria etc. 96.3% [14, 15, 16, 17, 18].

The majority blood donors in the present study were in the age group of 26 to 35years (48%). This differs from the figures published by the World Health Organization (WHO) which reported that 45% of donors were aged 25 or less. In the present study finding revealed that a lot of awareness is required among the blood donors to decrease the gender and age gap [19]. In this study the overall prevalence of TTI among blood donors of JJMMC Davangere Blood bank was 1.86%. This was lower, in comparison from neighboring Eritrea 3.8% [20], study done by Manzoor et al. and was 9.9% [21], Yemen by Saghir et al. 2.35% [22], among blood donors in Kassala, eastern Sudan by Abdallah and Ali 3% [23], Tessema et al. 9.5% [24] by Baye et al. 6.2% [15]. Whereas it is similar to findings of TTI in Brunei Darussalam et al. 1.49% [19], the lower prevalence in the present case may be due to the increased awareness. In the present study, the overall seroreactivity based on enhanced chemiluminescence assay, was 0.35% for HIV and1.86% for HbsAg, 0.22% for HCV. In 2009, it was estimated that 2.4 million people were living with HIV in India, which equates to a prevalence of 0.3%.

Based on the seroprevalence study among blood donors by dual testing strategy using high sensitivity serological assay and NAT testing, the present study reveals serious concerns regarding the HIV, HBV, and HCV infections among the blood donors and the safety of the blood supply in our country. Considering the vast population of the country, even low prevalence amounts to large number of infected people. If high sensitivity serological assays are not used, the safety of the blood for transfusion may become a big concern. Stringent measures in donor screening including better donor recruitment, promoting voluntary blood donation, screening of blood and blood products using dual testing strategy with high sensitivity serological Assays like chemiluminescence and ELISA, inclusion of anti HB core antibody screening In blood donors and other infectious diseases markers would considerably improve the current screening procedure for blood donation and enhance the safety of the blood intended for transfusion. The present study was a cross sectional study the donors were not followed up due to time constraint. Hence more longitudinal studies are required among blood donors.

Conclusion

With the implementation of strict donor criteria and use of sensitive screening tests, it may be possible to reduce the incidence of TTI in the Indian scenario. HBV and HCV remain the greatest threats to blood safety in India. Strict selection and retention of voluntary, non-remunerated low-risk blood donors are recommended to improve blood safety in the regional blood transfusion centre. Based on the seroprevalence study of infectious diseases viz., HIV, HBV, and HCV, it can be concluded that screening of blood and blood components by testing strategy using high sensitivity serological assay like ELISA helps in detecting the potentially infectious blood units in all phases of infection, which aids in enhancing the safety of blood transfusion and reducing the potential risk of post-transfusion. It can be concluded that dual testing strategy using enhanced chemiluminescence technology and ELISA helps to detect potentially infectious blood units in all phases of infection, which in turn helps in enhancing the safety of the blood and blood components for transfusion.

What the study adds in the existing knowledge?

The present study showed that most of the donors were voluntary donors with male preponderance. In all the markers tested there was increased positivity rate amongst the replacement donors as compared to the voluntary donors. Based on these results non remunerated and repeat voluntary blood donor services are needed. There should be an establishment of a nationally coordinated blood transfusion services. All blood should be tested for compatibility and TTI's with reduction in unnecessary blood transfusion, thus ensuring safe blood supply to the recipients. With the implementation of strict donor selection criteria, use of sensitive screening tests and establishment of strict guidelines for blood transfusion it may be possible to reduce the incidence of TTI in the Indian

Scenario.

Author's contribution

Dr. Ravikanti was the Principal investigators who carried out the research under the guidance of **Dr. Sunitha B.R.**, **Dr. G. Vishwanath**, **Dr. Jagadeshwari. K.** Whereas **Dr. Siddaganga** prepared the manuscript. The final manuscripts has been read and approved by all the authors.

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