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*Original Article*

# Seroprevalence of transfusion transmissible infections among blood donors by chemiluminescent assay in a tertiary care centre

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## Abstract

Introduction: Blood transfusion is a life saving measure, but also carries risk of transfusion transmitted infections (TTIs). In spite of improved donor screening, risk of transmission of TTIs still remains a major concern. Stringent screening of blood not only ensures safe supply of blood and blood products, but also gives us an idea about prevalence of TTIs among general population.

Methodology: Blood donors (voluntary and replacement), fulfilling national and regional blood bank criteria, attended our blood bank, during Jan 2015-Dec 2016 (included). Retrospective data analysis was performed by a structured database. After obtaining informed consent, venous blood was collected and analysed for HBsAg, anti-HCV and Anti-HIV1&2 (Chemiluminescent assay -OrthoVitrosECi/ECiQ), Malaria (ICT–pf/pan-Alere) and Syphilis (RPR-Labcare Dignotics).

Results: A total of 9027 donors were screened; Males and females were 99.23% and 0.76% respectively with the mean age of 27.4 ± 2years (19-58years). Voluntary donors were 68.7%; replacement donors 31.3%. Voluntary donation increased by 3% in 2016 (69.7%) vs 2015 (67.1%). TTI prevalence was 1.12% (102/9027). Surprisingly prevalence was higher among voluntary donors, females and 21-30 years. Seroprevalence of HBV (0.42%), HIV (0.13%), and Malaria (0.01%), in our region was relatively inferior than other parts of country. Nonetheless, HCV (0.56%) infections were on the rise. No syphilis case was reported. Low seropositivity rate is believed to be attributed to improved counselling of blood donors, adherence to standard donor selection criteria and rational use of blood.

Conclusion: Even though low prevalence, effective control strategies including stringent screening, implementation of more sensitive tests and health education are urgently needed to prevent those TTIs.

**Key words:** TTIs; seroprevalence; blood donors: chemiluminescent assay.

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## Introduction

Transfusion of blood and its components is one of the most essential lifesaving procedure in the integrated part of health care delivery system. Nevertheless, the risk of blood transfusion transmitted infections (TTIs) poses a serious public health problem if proper screening of donated blood is not done. Globally, prevalent TTIs are mainly caused by Human immunodeficiency virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), *Treponemapallidum* and Malaria parasite which may be present in the blood being transfused [1]. Despite improved donor screening, factors such as the window period, asymptomatic carriers, concealing of medical history by paid blood donors and emergence of newer transmissible pathogens, pose a serious challenge to blood safety [2].

Various studies have reported high prevalence of HIV, HBV, HCV and syphilis, which has worsened the problem of blood safety worldwide [2-4]. Thus, continuous monitoring of TTIs among the donor is vital for risk assessment, and to minimize disease transmission, optimize donor recruitment strategies, and also to know the prevalence of these diseases among blood donors, which reflects the apparent as well as hidden load of these infections in the general population, since blood donors are usually healthy members of the society [5-7].

It is mandatory to screen all donated blood units, for five transfusion transmitted diseases, namely human immunodeficiency virus (HIV), hepatitis B and C, syphilis and malaria to monitor the magnitude of TTIs [3,4,6,8]. However, there is less published data on the burden of major TTIs in our study area using most

sensitive techniques like chemiluminescent assay (CLIA).

## Methodology

The study was carried out in Velammal Medical College Hospital and Research Institute (VMCH&RI) after obtaining Institute Ethical Committee clearance (IEC Ref NO VMCIEC/25/2017). Our study analysis included all the blood donors (voluntary and replacement) who fulfilled the national and regional blood bank criteria, and attended our VMCH&RI tertiary care blood bank, during the period of Jan 2015 - Dec 2016 spanning over a period of 2 years. Retrospective analysis was carried out by using data collected by a questionnaire regarding age, sex, number of previous donations, type of donation (replacement/ voluntary) /medical or surgical illness /history of previous blood transfusion /known case of tubercolosis /diabetes mellitus /heart disease /jaundice /asthmaand personal habits, antibiotic intake, etc. Blood donors who did not meet the inclusion criteria (< 18 or > 65 years, history of long-term medication use, surgical or medical illness and unwillingness to give oral informed consent were excluded based on questionnaire. Vital signs and weight were recorded. The donors who donated blood repeatedly was counted only once. Baseline complete blood count (CBC) was performed to exclude any donors with anaemia (< 12.5 g/dL) or thrombocytopenia and also inspection was carried out for any marks of drug abuse or skin lesion at the veni-puncture site as a routine practice.

*Study Design*

As a routine, after obtaining the informed consent from the donor, venous blood was collected from each blood donor. Proper sterilization and other precautions were taken during blood collection and collected blood units were stored in appropriate conditions. Serum was separated by centrifugation at a speed of 3500 revolutions per minute (rpm) for 5 minutes. Blood group for each blood donor was determined using blood group antisera: anti-A, anti-B, and anti-D for Rh factor. Each donor was tested for HBs Antigen (Ag) and anti-HCV and anti-HIV1&2 by enhanced chemiluminescent immunotechnique (Ortho Clinical Diagnostics- Vitros ECi/ ECiQ fully automated immunoassay system, Buckinghamshire, United Kingdom). Malaria test was carried out using rapid immune-chromatographic technique which will detect HRP-II Ag of *Plasmodium falciparum* and pLDH Ag of other Plasmodium species (Alere Trueline Medical Pvt Ltd, Gurgaon, Haryana, India) and Syphilis was tested by Rapid Plasma Reagin(RPR) assay (Labcare Dignotics, Gurgaon, Haryana, India). The tests were validated as per manufacturer's protocol.

*Statistics*

Data analysis was done using SPSS 16 version (IBM). Seroprevalence of TTIs between males and females; between replacement and voluntary donors was compared using chi-square test.

## Results

A total of 9027 donors were screened for TTIs during the study period; of these 8958 (99.23%) were males and 69 (0.76%) were females with the mean age of 27.4 ± 2 years (range from 19-58 yrs.). Voluntary blood donors were 68.7% (6200/9027) and 31.3% (2827/9027) were replacement donors (relatives/friends) (Table 1). Voluntary blood donation has increased about 3% in 2016 (69.7%) as compared to 2015 (67.1%).

Of all donations, 1.12% (102/9027) were reactive for TTIs in the screening assays. Prevalence of TTIs were significantly higher among voluntary donors than replacement donors (Table 2). Year-wise analysis

**Table 1.**Distribution of blood donors in study population year wise.

| Year | Voluntary | Replacement | Male | Female | Total |
|---|---|---|---|---|---|
| 2015 | 2302(67.1%) | 1133(32.9%) | 3394(98.8%) | 41(1.2%) | **3435** |
| 2016 | 3898(69.7%) | 1694(30.3%) | 5564(99.5%) | 28(0.5%) | **5592** |
| **Total** | **6200(68.7%)** | **2827(31.3%)** | **8958(99.23%)** | **69(0.76%)** | **9027** |

**Table 2.** Prevalence of TTIs among the voluntary and replacement blood donors.

| | TTIs Positive | TTIs Negative | Total |
|---|---|---|---|
| Voluntary blood donor | 89 | 6192 | 6200 |
| Replacement blood donor | 13 | 2814 | 2827 |

Chi-square statistic: 16.13; p value: 0.000059 (significant).

**Figure 1.** TTIs prevalence among voluntary and replacement donors year-wise.

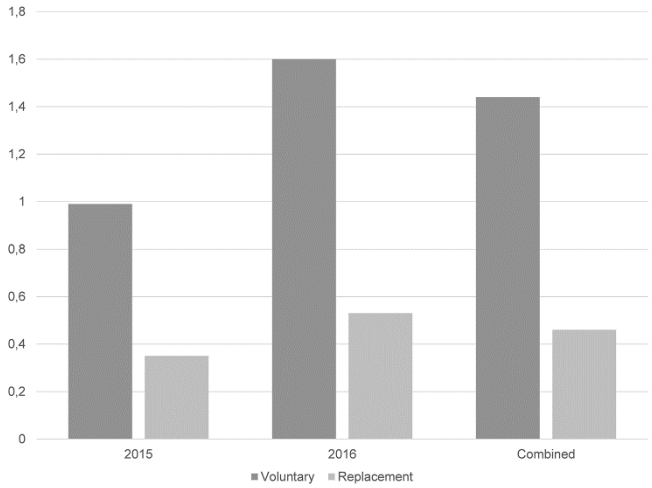
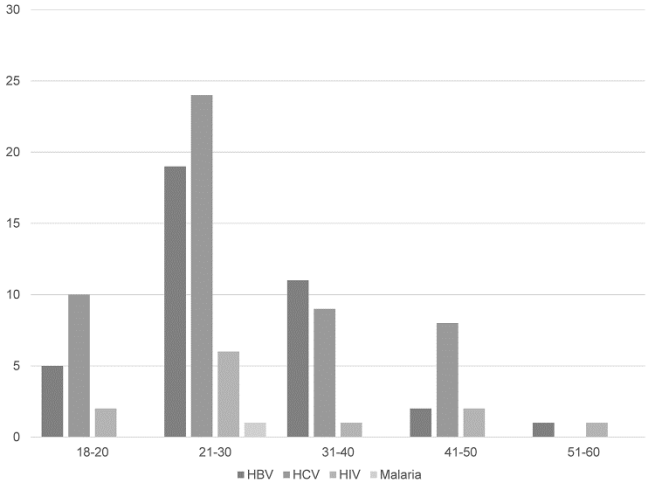



**Figure 2.** Age-wise distribution of reactive TTIs.




revealed prevalence of TTIs were increasing among both the donors (Figure 1).

HBV, HCV and HIV all were more prevalent among females than males (Table 3). All TTI positive results were most commonly seen among the age group of 20-30 years (Figure 2).

Of the 102 positive TTIs, 38 (0.42%) were found to be the carriers of HBV (HBsAg), 51 (0.56%) were positive for anti-HCV antibodies, 12 (0.13%) were positive for anti-HIV antibodies and 1 (0.01%) had malaria *(Plasmodium falciparum)* (Table 4). On year-wise analysis, though seropositivity of overall TTIs were shown increasing; HCV showed the drastic increase of about 3 times of the 2015 prevalence with was statistically significant ($p$<0.05).

## Discussion

Blood transfusion is a life saving measure but, simultaneously, carries the risk of transmitting life threatening TTIs [9]. Each unit of blood have 1% chance of transfusion associated problems including TTIs. Even though risk of TTIs has declined drastically in developed countries over the past three decades, still it remains as a major threat in developing countries [7,10-12]. Stringent screening of blood not only ensures the safe supply of blood and blood products, but also

**Table 3.** Distribution of blood donors with TTIs according to the gender.

| | Male | Female | Total |
|---|---|---|---|
| HBV | 35 | 3 | 38 |
| HCV | 44 | 7 | 51 |
| HIV | 11 | 1 | 12 |
| Malaria | 1 | 0 | 1 |
| **Total** | **91/8958** | **11/69** | **102/9027** |

Chi-square statistic: 25.577; p value < 0.00001 (significant).

**Table 4.** HBV, HCV, HIV, malaria and syphilis prevalence among study population year wise.

| TTIs | 2015 | 2016 | Total |
|---|---|---|---|
| HBV (HBsAg) | 13(0.38%) | 25(0.45%) | **38(0.42%)** |
| HCV (anti-HCV) | 9(0.26%) | 42(0.75%) | **51(0.56%)** |
| HIV (anti -HIV 1&2) | 4(0.12%) | 8(0.14%) | **12(0.13%)** |
| Malaria (Pan/Pf) | 1(0.02%) | Nil | **1(0.01%)** |
| Syphilis (RPR) | Nil | Nil | **Nil** |
| **Total** | **27(0.79%)** | **75(1.34%)** | **102(1.12%)** |

gives us an idea about the prevalence of TTIs in healthy populations as discussed by Gharehbaghian *et al.*, [13] and Busch *et al.,* [14]. The prevalence rate of TTIs reported among the blood donors in India by various studies are the following: HBV = 0.24% to 12%, HIV = 0.084% to 3.87%, HCV = 0.0001% - 1.5%, malaria = 0.001% - 0.57% and syphilis = 0.0085% - 3% respectively [6,10,15-17].

In our study, voluntary donors were predominant, beingg 68.7% (6200/9027) and their contribution increased by 3% when compared to previous year. This is due to our motivation, guidance, and education of the younger generations and overall increased general public awareness of our population (Table 1).

In our study, TTIs prevalence was 1.12% (102/9027). Surprisingly, prevalence of TTIs were 3.5 times higher in voluntary blood donors (89/6200 = 1.44%) compared with replacement donors (13/2827 = 0.4%). This correlation was statistically significant: the $p$ value was < 0.5 (0.000059) (Table 2). This may be due to high proportion of voluntary donors enrolled in our study compared with other studies. Highly sensitive CLIA we used as a screening assay picks up positive signals at much earlier phase of disease, compared with other studies in which enzyme-linked immunosorbent assay (ELISA) was the screening tool. Among the voluntary donors, we could not specify common risk factor such as occupation, socio economic status and geographical background as our study population showed diverse group. However, further studies are required to analyse this contrasting findings. Year-wise prevalence of TTI among voluntary and replacement donors is on the raise as analysed in the data which reveals that in 2015 it was 0.99% and 0.35% which has increased to 1.6% and 0.53% respectively in 2016 (Figure 1). Though seropositivity of overall TTIs were shown increasing over years; HCV showed the drastic increase of about 3 times of the 2015 prevalence with was statistically significant ($p$ <0.05). So, monitoring the change of prevalence in TTIs is always essential to initiate appropriate preventive action.

Analysis on gender and TTIs showed HBV, HCV and HIV were more prevalent among females and was statistically significant ($p < 0.05$), which was discordant with the reports by Giri PA *et al.,* [16],Waheed Y *et al,.*[18], and Iqbal W *et al.*, [19]. This statistical significance could not be generalised due to disproportionate samples size between male and female donor in our study (Table 3).

Seroprevalence of HBV was 0.42%, which is in concordance with Patel PJ *et al.,* [20] from Gujarat, who also reported the prevalence of HBV was 0.38%. Various studies reported the variable results of prevalence from various places of India. Studies from South India reported the prevalence of 0.69% (Fatima A *et al.*) [21], 0.71% (Leena MS *et al.*) [22]0.98% (Manoharan Mythreyee *et al.*) [23], 1.67% (B. Suresh *et al.*) [24]; 1.66% in Eastern India [25], 1.7% from Northern [26], and as high as 3.44% in Western India [15].

Seroprevalence of HBsAg was relatively low in our study (0.42%) when compared to the reported rates in other parts of country. This may be due to safe and effective immunization against hepatitis B has been adopted in southern part of the country and also overall improved awareness among the general population.

Seroprevalence of HCV was found out to be 0.56%, which is in concordance with Suresh *et al.*, [24] from Tirupathi, who also reported the prevalence of HCV was 0.56%. Furthermore, previous reports from the western, eastern, and northern states of India revealed the HCV seroprevalence to be 0.29% [15], 0.35% [25], 1.5% [26], respectively. Lower prevalence of HCV was reported from Southern India by Mythreyee *et al.* (0.22%) as well as Ather Fatima *et al.*, (0.01%) [21,23]. Seroprevalence of HCV was relatively high in our study (0.56%) when compared with the reported rates in other parts of country. This may be due to the fact that we have used the most sensitive technique (CLIA) to identify the HCV infections and chance of asymptomatic carrier state of our population may be apparently high. Even though with increased awareness among the blood donors and stringent donor screening, the prevalence of HCV is increasing in our population, which also is evolving as a global public health problem; has to be addressed quickly.

Seroprevalence of HIV was found out to be 0.13%, which is in concordance with Mythreyee *et al.*, [23], who also reported the prevalence of HIV was 0.19%. Higher seroprevalence of 0.26%, 0.47%, 3.8% and 11.7% [3,15,27,28] have been reported by various studies. Lower seroprevalence of HIV (0.13%) in our study may be due to improved awareness among the general population as well as the donors.

Even though malaria was the first reported transfusion transmitted infection, seroprevalence of malaria was found out to be only 0.01% in our set up, which is in concordance with Tulika C *et al.,* [29], Sunderam S *et al.*, [30], and no positive syphilis case was reported during the study period. Overall TTIs were most common in the age group of 21-30 years (Figure 2) which is in concordance with B Suresh *et al.,* [24].

## Conclusion

Overall seroprevalence of HBV (0.42%), HIV (0.13%), and malaria (0.01%), in our geographical region was relatively less than that of other parts of the country. But HCV (0.56%) infections were on the rise. No syphilis case was reported during study period. This lower seropositivity is believed to be attributed to improved counseling of blood donors, adherence to standard donor selection criteria, and rationale use of blood. Safe blood transfusion is a need of hour for the recipients and the community as well. Even though low prevalence recorded in our study, effective control strategies including stringent screening of all blood donors, implementation of more sensitive tests such as nucleic acid amplification testing /chemiluminescent assay, public awareness programs, and institution of adequate public health measures are urgently needed to improve the prevention of those TTIs.

## Implications

Providing safe and adequate blood is supposed to be an integral part of every country's national health care policy. Continuous improvement and implementation of donor selection, sensitive screening tests will ensure the elimination, or at least reduction, of the risk of acquiring TTIs.

## Limitations

In our study, to diagnose HBV infections, we have used HBs Ag status only; not including the anti HBc IgM a useful parameter for analysing the occult hepatitis (HBV core mutant). So in future studies, both (HBsAg & anti HBc IgM) has to be included to know the exact prevalence of HBV.

As no previous data for the prevalence of TTIs in our study population was available; we have compared the 2015 and 2016 data. This study will point out for the future references.

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### Author's Contribution

RS, RA, VG has given the concepts and intellectual content; RS designed the study; RS, RA carried out the literature search; RS, SP, RT have collected and analysed the data; RS, RA, VG, JC carried out the statistical analysis; RS done the manuscript preparation; RA, VG, JC have done the manuscript editing; JC, RT, SP carried out the manuscript review; RS-Raja Sundaramurthy; RA-Ramesh Arunagiri; VG-Vithiya Ganesan; SP-Sethuammal Perumal; RT-Rajendran Tiruvannamalai; JC-Jhansi Charles.

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