Comparison of seroprevalence of transfusion transmissible infections between voluntary and replacement donors at a tertiary care center

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Abstract

Introduction: Transfusion transmissible infections (TTI) are a major threat for the recipients of blood and blood products. Voluntary blood donations (VBD) are considered safe to Replacement blood donations (RBD). Our main of the study is to find out the seroprevalence of TTI in our area and also to find out whether there is a significant difference in seroprevalence of TTI between VBD and RBD.

Materials and Methods: It is a retrospective, cross sectional study carried out in the regional blood bank of a tertiary care centre. Records of total 33341 blood donations carried out in a period of 6 years (January 2012 to December 2017) were studied for calculating the seroprevalence of HIV, HBsAg, HCV and Syphilis. Comparison of seroprevalence between VBD and RBD was done.

Results: Predominant donor population was male (91.86%). 91.63% donations were VBD and 8.37% donations were RBD. Most common type of TTI was HBsAg (85.9%) followed by HIV (6.72%), HCV (4.98%) and Syphilis (2.38%) respectively. The difference in seroprevalence of TTI between VBD and RBD was statistically significant (p value <0.05).

Conclusion: There is seen statistically significant difference in seroprevalence of TTI between VBD and RBD suggesting RBD are at more risk for transmitting TTI than VBD. Hence we recommend regular, non-remunerated, voluntary blood donations for assuring better safety and quality of blood and blood products.

Keywords: Seroprevalence, Transfusion transmissible infections, Voluntary blood donations, Replacement blood donations.

Introduction

History of first blood transfusion dates back in 1930.1 Blood transfusion is one of the important modes of treatment in certain diseases like haemolytic anaemia, severe anaemia, major trauma, surgeries. But it is associated with small but definite risk of transfusion transmitted infections (TTIs).2,3 Hence there is the need to screen the blood for the potential risk for TTIs. Transfusion transmissible infections include HIV, HBV, HCV and Syphilis. Transfusion transmissible infections can cause a major threat to all the recipients of blood and blood products. TTI is also a threat to all the health care workers. According to WHO estimates, each year, three million healthcare workers experience percutaneous exposures to blood pathogens in the world. Of these, two millions are exposed to HBV.4 Each unit of blood carries 1% chance of transfusion associated problems including TTI.5

Screening of blood donor started in the year 1947.6 In India, Screening of HIV, HBV, HCV, Malaria and Syphilis is made mandatory for each and every blood bank.7

Selection of blood donors plays important role in the quality and safety of blood and blood products. Regular, healthy, voluntary, non remunerated donors are considered as safe donors as compared to replacement donors. Voluntary blood donors (VBD) are the one who gives blood voluntarily without any incentive for the cause either in the form of money or any kin which could be considered as a substitute of money.8 Replacement blood donors (RBD) donates blood as replacement for blood units to be supplied for their relative or known patient. As RBD donate blood for interest of their patient it might not be of as safe and of good quality as that of VBD. It is a observed fact that the risk of TTI is much lower in blood collected from low risk population.9 Hence nowadays RBD is not recommended in the blood banks as safe transfusion of blood and blood products is a cornerstone of an effective high quality health care system.10

As blood donors are selected from the healthy population in the community with proper predonation counselling and questionnaire, blood transfusion services not only screen the blood donor but also give a clue about the rate of prevalence of TTD in asymptomatic healthy young adult. It can give us a reliable tool for statistical estimation of these infections in the general population as discussed by Attaullah et al.11 This statistics can be used to for formulation of long term strategies for prevention and control of spreading the disease in general population.

Objective

As compared to voluntary blood donors replacement blood donors are under pressure for urgent blood donation for their patient. Our aim of the present study is to find out the seroprevalence of TTIs in our area and also to find out whether there is any difference in seroprevalence of TTIs between voluntary and replacement donors.

Materials and Methods

It is a retrospective cross sectional study, carried out in the regional blood bank of tertiary care centre. Data was obtained by studying all the registration books of blood donors in the blood bank from year 2012 to 2017.
Aim of the Study
To determine the seroprevalence of healthy blood donors and to compare the seroprevalence of TTIs between Voluntary and Replacement donors.

Study Population
It included all the blood donors who donated blood in six years i.e. from January 2012 to December 2017. It included donors donating blood in blood donation camps as well as voluntary and replacement donors donating blood in our blood bank. Replacement donors required during certain periods of year when voluntary donations in blood camps didn’t fulfil the requirements of blood in blood bank as the number of voluntary donations used to decrease during certain periods of year like summers due to hot climate in our area.

Age Group
All the blood donors were healthy with age group of 18-60yrs.

Weight
>45 kg in males and > 50 kg in females.

Haemoglobin
>12.5gm%

Serological Investigations
2ml of pilot sample was taken and plasma was separated. Plasma samples of all the donors were tested for Antibody to HIV type 1 and 2, HBsAg, Antibody to HCV using third generation ELISA kits – Merilisa HIV 1, 2, Merilisa HBsAg, Merilisa HCV respectively by Meril Diagnostics Pvt. Ltd. and Syphilis screening was done using RPR method. If ELISA showed positive result the sample was retested using another method of ELISA test using different principle. All the tests were done by trained personnel under the supervision of blood transfusion officer in well equipped TTD lab in the blood bank. Internal and external quality control was carried out with each run. Confidentiality of reports was maintained as per standard guidelines. Positive blood units were discarded according to the standard protocols of autoclaving and sent for incineration afterwards.

Consent
As the study used secondary data, informed consent was not sought from study participants.

Results

Table 1: Sex distribution of donors

| Year | Male | Female | Total |
|------|------|--------|-------|
| 2012 | 5133 | 571    | 5704  |
| 2013 | 4730 | 411    | 5141  |
| 2014 | 4810 | 357    | 5167  |
| 2015 | 5141 | 388    | 5529  |
| 2016 | 4937 | 488    | 5425  |
| 2017 | 5875 | 500    | 6375  |
| Total| 30626(91.86%) | 2715(8.14%) | 33341 |

Table 1 shows the sex distribution of donors. It is seen that majority (91.86%) donors are male.

Table 2: Distribution of blood units collected in each year

| Year | Voluntary Donors | Replacement Donors | Total |
|------|------------------|--------------------|-------|
| 2012 | 4762             | 942               | 5704  |
| 2013 | 4340             | 801               | 5141  |
| 2014 | 4139             | 1028              | 5167  |
| 2015 | 5510             | 19                | 5529  |
| 2016 | 5425             | 0                 | 5425  |
| 2017 | 6375             | 0                 | 6375  |
| Total| 30551(91.63%)   | 2790(8.37%)       | 33341 |

Table 2 shows the year wise distribution of blood units collected. From this table it is seen that, total 33341 donors donated blood in 6 year period. Out of them 30551(91.63%) were voluntary donors and 2790(8.37%) were replacement donors.

Table 3: Seroprevalence of TTI in each year

| Year | HIV | HBsAg | HCV | Syphilis | Total |
|------|-----|-------|-----|----------|-------|
| 2012 | 08  | 78    | 06  | 04       | 96    |
| 2013 | 05  | 70    | 02  | 02       | 79    |
| 2014 | 05  | 67    | 05  | 02       | 79    |
| 2015 | 05  | 65    | 01  | 00       | 71    |
| 2016 | 02  | 57    | 05  | 03       | 67    |
| 2017 | 06  | 60    | 04  | 00       | 70    |
| Total| 31(6.72%) | 396(85.9%) | 23(4.98%) | 11(2.38%) | 461 |

Table 3 shows the seroprevalence of TTI in each year.
It is seen that seroprevalence of HBsAg was most common (85.9%) while that of Syphilis was least common (2.38%).

Table 4: Seroprevalence in voluntary and replacement donors

| Year | HIV | HBsAg | HCV | Syphilis |
|------|-----|-------|-----|----------|
|      | VD  | RD    | VD  | RD       | VD  | RD    | VD  | RD |
| 2012 | 06  | 02    | 74  | 04       | 05  | 01    | 04  | 00 |
| 2013 | 04  | 01    | 56  | 14       | 00  | 02    | 01  | 01 |
| 2014 | 04  | 01    | 43  | 24       | 02  | 03    | 02  | 00 |
| 2015 | 04  | 01    | 63  | 02       | 01  | 00    | 00  | 00 |
| 2016 | 02  | 00    | 57  | 00       | 05  | 00    | 03  | 00 |
| 2017 | 06  | 00    | 60  | 00       | 04  | 00    | 00  | 00 |
| Total| 26  | 05    | 353 | 43       | 17  | 06    | 10  | 01 |
| Total donors | 31(0.09%) | 396(1.19%) | 23(0.07%) | 11(0.03%) |

Table 4 shows the seroprevalence in voluntary and replacement donors. It shows that the total number of seropositive donors is more in voluntary donors as 91.63% donors are voluntary donors.
Table 5: Comparison of prevalence of seropositivity between VD and RD in year’s 2012 to 2015.

| Seropositive variable | VD| RD | Total |
|-----------------------|---|----|-------|
| HIV                   | 18 (0.1%) | 5 (0.2%) | 23 |
| HBsAg                 | 236 (1.3%) | 43 (1.5%) | 279 |
| HCV                   | 8 (0.04%) | 6 (0.2%) | 14 |
| Syphilis              | 7 (0.04%) | 1 (0.04%) | 8 |
| Study population(N)   | 18751 | 2790 | 324 |

Table 5 shows the prevalence of seropositivity between VD and RD in the years 2012-2015. As in years 2016 and 2017 there were no RD. So here, we have excluded those years. So Study population for comparison of TTIs between VBD and RBD is Voluntary donors- 18751 and Replacement donors- 2790.

Discussion

Out of total 33341 donors 461 showed seropositivity with any of 4 diseases. So overall seroprevalence for any of the 4 diseases is 1.38%.

Predominant population in this study is male (91.86%). This result is comparable with other studies by Anjali et al.¹³ Sushama et al.¹⁴ and Pallavi et al.⁵ This difference was mainly because female donors were less in number and many were not fitting in to weight and hemoglobin criteria for selection. Most common donors are voluntary donors (91.63%). This result is comparable to the study done by Dev Raj et al.¹⁵ The overall seroprevalence of HIV in our study is 0.09% which is comparable with the study done by Dev Raj et al.¹⁵ The overall seroprevalence of HBsAg in our study is 1.19% which is comparable with study done by Sushama et al.¹⁴ The overall seroprevalence of HCV in our study is 0.07% which is comparable with study done by Dev Raj et al.¹⁵ The seroprevalence of syphilis in our study is 0.03% which is low than all the other studies compared. The overall seroprevalence of all TTI was low compared to other studies by Yusuf et al.¹⁶ Sobia et al.¹¹ and Belete et al.¹⁷ The low seroprevalence of TTI in our study might be due majority of donors being voluntary donors as well as the study is done in a tertiary care centre academic institute where pretransfusion screening and history is taken by a trained medical officer or blood transfusion officer having experience. So strict criteria were applied for donor selection.

A similar study was done by Dev Raj et al.¹⁵ So we compared our findings with that study.

Table 6: Comparison of seroprevalence between VD and RD in our study verses study by Dev Raj et al

| Infection | Voluntary Blood donor | Replacement Blood donor |
|-----------|-----------------------|-------------------------|
|           | Our study             | Dev Raj et al.¹⁵         | Our study             | Dev Raj et al.¹⁵ |
| HIV       | 0.1%                  | 0.08%                   | 0.2%                  | 0.25%            |
| HBsAg     | 1.3%                  | 1.56%                   | 1.5%                  | 1.90%            |
| HCV       | 0.04%                 | 0.13%                   | 0.2%                  | 0.51%            |
| Syphilis  | 0.04%                 | 0.71%                   | 0.04%                 | 2.12%            |

Due to strict control over replacement donations, as according to NACO guidelines, there were no RD in year 2016 and 2017. So for the sake of comparison between VD and RD; we excluded donations in year 2016 and 2017. The comparison between VD and RD was done for 4 years period from 2012 to 2015. (Table 5). We found that there is difference in values i.e. seroprevalence in RD is high in HIV, HBV and HCV. There is no difference in values in Syphilis. So to know whether the difference is statistically significant, we applied chi square test. We found that the P value is <0.05. It indicates that the difference in seroprevalence is statistically significant, suggesting that replacement donors are having higher seropositivity than voluntary donors. A study by Dev Raj et al.¹⁵ also shows a statistically significant difference between VD and RD. Zero RD in last two years indicates that our blood bank is following strict guidelines given by NACO also it indicates improvement in the quality of blood and blood products and it insures high quality and safety of blood products.

The most common infection in our study was HBV. Positivity for HBsAg indicates a carrier state or an active infection. HBV positive people are prone to develop chronic hepatitis, cirrhosis and hepatocellular carcinoma. HBV infection is most infectious among all TTIs. So even laboratory workers and health care workers are prone to get infection with HBV. The WHO has categorised endemicity with HBV in to three categories. Low endemicity (<2%), Intermediate endemicity (2-7%) and high endemicity (>8%). In India it ranges from intermediate to high endemicity. High endemicity is seen in countries like China, Korea and Melanesia. It is said that posttransfusion HBV infection rate is high as HBV circulates at very low and undetectable level for screening assays.⁴

HIV has a large window period (3 months). As according to WHO, HIV positive blood if transfused in its window period, viral dose of HIV through blood is so large that one HIV positive transfusion leads to death of an average after 2 years in children and 3-5 years in adults.⁵ Also there is high risk for the spouse of HIV positive patients as this is a sexually transmitted disease.

HCV is known for its spread through blood transfusion, practices like tattooing and needle prick injuries in intravenous drug abusers. The prevalence of HCV is quite low in our study, might be because of proper pretransfusion screening of donors as well as such types of practices are less in our region. Worldwide about 350 million people have chronic HBV infection; about 125 million people have infection with HCV. HBV and HCV if put together have world’s greatest infectious disease burden. So these diseases together are the main target for public health measures like prevention, early diagnosis and treatment.⁶

Syphilis is a venereal disease caused by spirochetes Treponema Pallidum. It is also associated with increased risk of HIV infection hence increasing the morbidity and mortality of the disease.

Though all the blood units are meticulously screened for TTI, the infection can be transmitted by seronegative blood unit as infection can be transmitted in the window...
period. Window period is the interval between potential exposure to infection by particular disease and the point when antibodies will be detectable in plasma and test will give an accurate result by commonly used screening tests. But the blood unit of donors in window period can transfuse the infection to the recipient. The possibility of transmission of the disease in window period can be minimized if blood is collected from low risk targeted general public. Also there are newer molecular tests like NAT (Nucleic Acid Amplification) where window period is lowered to large extent. The NAT system is capable of detecting more infectious donations than current tests because it detects viral genes by doing their amplification rather than finding viral antibodies and antigens. Detection of viral genes permits detection earlier in the infection since the appearance of antibodies requires time for the donor to develop an immune response and since detection of antigens requires time for a higher level of virus to appear in the blood stream. The only drawback of NAT testing is that it is not cost effective and cannot be used routinely for screening purposes in Government blood banks where sample load is high. So to lower the seroprevalence rate there should be stringent donor selection criteria, regular, voluntary, non remunerated donors should be promoted. Effective donor education and proper counselling of seropositive donors should be done so that they will not donate the blood in future.

In our study malaria screening is not done as in predonation interview and donor questionnaire was done which omitted the donor having history and symptoms of malaria.

Conclusion
This study showed the seroprevalence of TTI. The average seroprevalence of HIV, HBsAg, HCV and Syphilis in the study was 0.09%, 1.19%, 0.07% and 0.03% respectively which was lower than many other studies. There was seen a difference in seroprevalence between voluntary and replacement donors and difference was statistically significant. Hence we recommend regular, non remunerated, healthy, voluntary donations to ensure utmost safety and quality of blood and blood products. There is small but definite risk of disease transmission in window period. To minimize this risk proper donor selection through predonation interview and donor questionnaire should be done and use of more sensitive and advanced techniques like NAT testing should be encouraged.

Conflict of Interest: None.

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