Original Research Article

Sero-positivity of transfusion transmitted infections and reactive donors response to counselling among healthy blood donors

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ABSTRACT

Background: Human Blood is essential and life saving in certain medical and surgical conditions and considered as “liquid of life” as it is not replaced by any artificially prepared medicine, though there are tremendous advances in medical sciences. Though Safe blood practice is emphasised since many years, yet there are many side effects of blood transfusion, of which temporary and reversible are easily recognised and treated. Whereas others especially few transfusion transmitted infections which have long term morbidity and mortality needs attention. Recognising these dreaded transfusion transmitted infections in donated blood will help to procure safe blood and help to treat the reactive donors at the earliest. Indirectly reducing the prevalence of transfusion transmitted infections (TTIs) in the community. Tracing the reactive donors and initiating treatment at the earliest, which often would be a window period of transfusion transmitted disease, helps to formulate the strategy to curb the economic burden besides reducing morbidity and mortality.

Objective: 1) To know the seroprevalence of transfusion transmitted infection among healthy blood donors; 2) To study reactive donors response to counselling; 3) To suggest strategy to collect and issue safe blood with aim to reduce TTIs.

Materials and Methods: A retrospective study of 6.5 years done by review of blood donor registry maintained in blood bank from 2014 to June 2020. All the blood donors were clinically examined, and were asked fill up questionnaire and consent form as per standard guidelines. Mandatory screening tests suggested by WHO like for HIV, HBV, HCV and Syphilis were done and prevalence among both voluntary and replacement donors were calculated. Counselling for reactive donors done and they were directed to undergo advice and treatment by respective department concerned. SPSS software and MS excel sheet were used to analyze the data.

Results: Analysis of data revealed replacement blood donors outnumbered voluntary donors. TTIs were more common among replacement donors compared to voluntary. Most number of reactive donors were among men aged between 26 to 35 years. Prevalence of HIV, HBV, HCV, Syphilis and Malaria were 0.062%, 0.655%, 0.006%, 0.146% and 0.006% respectively in our study. Among reactive donors responders were 108(85.71%) as compared to non-responders 18(14.28%).

Conclusion: Following strict measures to select donor and to counsel donor before donation with appropriate privacy will help to decrease seroprevalence of Transfusion Transmitted Infections. Counselling reactive donors help to seek treatment at the earliest along with unnoticed ongoing blood donations by them. By knowing seroprevalence rate and response of reactive donors, Government and health administration should make and implement policy for safe blood collection and transfusion.

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1. Introduction

The theme for the Blood donor day 2020 is 'Safe Blood Saves Lives' which was promoted with the slogan 'Give blood and make the world a healthier place. Health is a human right; everyone in the world should have access to get safe blood as blood and its products play pivotal role in many medical and surgical emergencies. Transfusions of blood and blood products save millions of lives every year. The world needs enough safe blood for everyone in need.\(^1\)

Providing safe blood involves many fragmented procedures, collection from donor to correct labelling, maintaining cold chain, testing the blood for TTIs to proper cross matching, if not carried out properly would have grave risk which might endanger the blood recipient. Some of the risks are temporary and curable where as others have chronicity among which TTIs are of prime preventable causes. If proper selection of donor and testing is done TTIs can be reduced to great extent.\(^2,3\)

Out of many viral, bacterial and parasitic infections World Health Organisation (WHO) has made Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Syphilis detection as mandatory as these infections can cause chronic disease with possible serious consequences and present the greatest infection risk to recipients of transfusion. Foreseeing this to prevent the spread of TTIs through blood transfusion, Government of India has made mandatory to screen donated blood for HBV (since 1971), HIV (since 1989), HCV (since 2001)\(^4-6\) along with syphilis and malaria considering the endemicity of the diseases.

The transmission of HIV is by sexual, transplacental and blood born. The HIV seroprevalence in Indian scenario has been reported between 0.2. to 1%.\(^7-10\)

Likewise HBV is transmitted by percutaneous accidental puncture in healthcare workers, and also by sexual, transplacental and infected blood. Which can lead to chronic liver disease and Hepatocellular carcinoma in some. Percentage sero-positivity of HBV in an Indian study was shown to be 1.55% in 1996, which came down to 0.99% in 2002.\(^7\) Sero-prevalence of HBV in various other Indian studies has been shown to range between 1.86% to 4%.\(^11-14\)

HCV is transmitted primarily through blood exposure. In contrast to HBV, about 20-40% of HCV cases are acute while majority progress to chronic infection. The long-term significance of subsequent disease due to cirrhosis and Hepatocellular carcinoma is greater in HCV infected individuals than in those infected with HBV. An enzyme-linked immunoassay (EIA) is used for screening. Indian studies indicate that seroprevalence of HCV ranges between 0.4 and 1.09%.\(^7,13-15\)

Transfusion transmitted syphilis is not a major hazard of modern blood transfusion therapy. Treponema pallidum the bacterial agent causing syphilis survives for 5 days in blood stored at 4°C.\(^16\) Very rarely causes transfusion transmitted syphilis. Being a sexually transmitted disease, its presence points towards donor’s indulgence in "high risk" behaviour and consequent higher risk of exposure to infections like HIV and hepatitis.

Transfusion Transmitted Malaria (TTM) is one of the first recorded incidents of Transfusion transmitted infections (TTIs)\(^17\) its screening is mandatory in endemic areas. Though the incidence of malaria is less than 0.1%, incidental TTM is of a significant concern especially among vulnerable recipients like immuno-compromised individuals, elderly patients, children & pregnant women which can lead to fatal consequences.\(^18\) Plasmodium species are known to survive from 18-28 days with lower infectivity rate.\(^17,19\) Asymptomatic donors with low levels of parasitaemia goes undetectable even on microscopic examination.\(^20\) In recent years molecular methods like PCR provide increased sensitivity.\(^21,22\)

The blood banks apart from carrying out donation camps and motivating people to donate blood to meet the demands, have responsibility to inform reactive donors at the earliest to bring them to treatment channel. But it is not a universal procedure to communicate the positive test results to blood donors.\(^23\) In India, same was practiced until 2004 after which governing bodies made strategy to inform status of TTIs to reactive donors.\(^24\) This helped to inform donors about their seroreactive status and take necessary medical interventions at the earliest, possibly reducing morbidity and mortality due to TTIs, thus stressing on self-deferral for next blood donation.

2. Materials and Methods

2.1. Type of study

Retrospective non-experimental descriptive study.

2.2. Study period

From 2014 to June 2020 (six and half years)

2.3. Source of study

Blood bank registry, donor consent forms, registry maintained in counselling centre at blood bank and ART centre.

2.4. Study design

After selection of blood donors as per inclusion and exclusion criteria for age, weight, addictions, pregnancy and other medical illness. Donor was subjected to detailed clinical examination. Vitals were checked and the eligible donors were asked to fill blood donor consent and questionnaire form as formulated by governing agency in India,\(^25\) which also included questionnaire about high risk

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behaviour and symptoms and signs of disease which would mandatorily screened in donated blood and opinion was sought if they wish to be informed telephonically if their blood found to be seroreactive for TTIs.

2.5. Screening methods

Mandatory testing done for all collected units of blood by

1. Human immunodeficiency virus (HIV 1 and 2), Hepatitis B (HBV) and Hepatitis C (HCV) by 4th generation Enzyme-Linked Immunosorbent Assay (ELISA)(Biorad Monalisa)
2. Malaria by rapid pan antigen test kit (Tulips), thick and thin smear if required and
3. Syphilis by Rapid Plasma Reagin (RPR) antibody test.

If the screened blood was reactive for TTIs it was discarded as per SOP of blood bank, donors were informed telephonically and were termed as responders if they turned up to blood bank, where their blood was retested when they came for one-to-one counselling with keeping privacy during counselling. They were referred to ICTC at ART centre if they were reactive for HIV, and to physician if HBV, HCV, Syphilis or Malaria was detected. Reactive donors were termed non-responders if they were untraceable even after 3 repeated telephone calls, each call made after a gap of 1 week and one postal communication to just inform they have abnormal test report and at each step confidentiality was maintained. The data collected was analysed by using Microsoft excel sheet and statistical package for social sciences (SPSS) software. Chi square test was applied as test of significance.

3. Results

The study included 14,350 participants over six and half year out of which 8296 (57.81%) were replacement blood donors(RBD) where blood was collected at blood bank, whereas 6054 (42.18%) were voluntary blood donors (VBD) where blood was collected at blood camps. In the present study, Sero-positivity for TTIs was found consistent from 2014 to 2020 and it was found to be statistically significant (P < 0.05). Yearly distribution of blood donors are shown in Table 1. The overall prevalence of HIV, HBV, HCV, Syphilis and Malaria was found to be 0.062%, 0.655%, 0.006%, 0.146% and 0.006% respectively as shown in Table 2. Mixed infection was not seen any of the donors. The highest percentage of prevalence was observed for HBV, followed by syphilis, HIV and HCV in decreasing order (p<0.05). Malaria had similar prevalence as HCV. The Hepatitis B had shown a static phase over the years where as syphilis and HIV has increased over years HCV was seen in the year 2016-17 and malaria was seen in year 2017-18.

On seeing pattern of sex distribution, very higher percentage of males constituting 98% were noted in both voluntary and replacement blood donors. Females accounted for around 2% in both the donor groups. Seropositive status (TTIs) outnumbered in male donors compared to their female counterparts. Prevalence of Seropositive status (TTIs)was more common in Replacement blood donors compared to voluntary and also, being more common in the age group between 26 to 35 years.

Among the seropositive (126) cases contacted, 108 responded to call, reported to blood bank for one-to-counselling and for repeat test sample, of which 7 cases were sent to ART associated ICTC for further follow up and treatment. Whereas HBV (80), HCV (1), Syphilis (19) and Malaria (1) positive cases were referred to physician for follow up and treatment. Responders’ percentage was maximum in malaria, HCV, Syphilis; HBV followed by HIV in decreasing order probably due to stigma attached to HIV and AIDS or may be self-awareness to seek treatment on their own at ART centre.

There were 18 non responders of which 2 in HIV, 14 in HBV, 19 in syphilis, 1 each in HCV and Malaria were noted. Most common among various reasons for not responding to phone call was wrong phone number and address other various reasons are depicted in Figure 1.

4. Discussion

Need for blood transfusion has increased over the years due to advances in treating disease, improved techniques in separation of components of blood and molecular diagnosis of TTIs which has made blood as safe form of medication however it should be judiciously used, as most of the TTIs are missed in window period, and is one of the most dreaded complications of blood transfusion. The prevalence of TTIs might vary with different regions of same country as many socio-cultural practises influence in maintaining pool of such disease in the community. There is a risk of 1 to 2 per 1000 recipients, to receive contaminated blood with viral,
Table 1: Showing year wise distribution of Random Blood donors (RBD) and Voluntary Blood Donors (VBD).

| Year       | RBD | VBD | Total |
|------------|-----|-----|-------|
| 2014-15    | 450 | 760 | 1210  |
| 2015-16    | 1004| 663 | 1667  |
| 2016-17    | 1647| 823 | 2470  |
| 2017-18    | 1635| 885 | 2520  |
| 2018-19    | 1548| 1380| 2928  |
| 2019-20    | 2012| 1543| 3555  |
| Total      | 8296| 6054| 14350 |
| Percentage | 57.81%| 42.18%| 100% |

Table 2: Showing year wise distribution of Transfusion Transmitted Diseases (TTIs) or seropositive status

| Year       | HIV1&2 | HBV | HCV | Syphilis | Malaria | Combined |
|------------|--------|-----|-----|----------|---------|----------|
| 2014-15    | 1      | 12  | 0   | 0        | 0       | 0        |
| 2015-16    | 1      | 15  | 0   | 0        | 0       | 0        |
| 2016-17    | 1      | 17  | 1   | 3        | 0       | 0        |
| 2017-18    | 2      | 13  | 0   | 3        | 1       | 0        |
| 2018-19    | 1      | 21  | 0   | 0        | 0       | 0        |
| 2019-20    | 3      | 16  | 0   | 0        | 0       | 0        |
| Total      | 9      | 94  | 1   | 21       | 1       | 0        |
| Percentage | 0.062% | 0.655% | 0.006% | 0.146% | 0.006% | 0        |

Table 3: Showing Age, Sex, Type of donor wise distribution of serorective status (TTIs)

| Character | Donors | HIV1&2 | HBV | HCV | Syphilis | Malaria |
|-----------|--------|--------|-----|-----|----------|---------|
| Sex       | Male-14063(98%) | 8      | 90  | 1   | 20       | 1       |
|           | Females-297(2%) | 1      | 4   | 0   | 1        | 0       |
| Donors    | Replacement | 8      | 88  | 1   | 16       | 1       |
|           | Voluntary   | 1      | 6   | 0   | 5        | 0       |
| Age       | 26-35      | 5      | 85  | 0   | 12       | 0       |
|           | 36-45      | 2      | 5   | 1   | 3        | 0       |
|           | Above 46   | 0      | 0   | 0   | 0        | 0       |

Table 4: Showing contacted responders with percentage and non-responders

| Donors     | HIV 1&2 | HBV | HCV | Syphilis | Malaria | Total |
|------------|---------|-----|-----|----------|---------|-------|
| Contacted  | 9       | 94  | 1   | 21       | 1       | 126   |
| Non responders | 2       | 14  | 0   | 2        | 0       | 18    |
| Percentage of non responders | 22.22% | 14.89% | 0% | 9.52% | 0% | 14.28% |
| Responders | 7       | 80  | 1   | 19       | 1       | 108   |
| Percentage of responders | 77.77% | 85.10% | 100% | 90.47% | 100% | 85.71% |

With every unit of blood, there is 1% chance of transfusion associated problems including TTIs. With the picture of prevalence is also quite different in developing nations when compared to developed ones as socio economic reforms have reduced TTIs burden in developed nations. In the last two decades, the scientific community has given much attention to the prevention of TTIs. To address these issues, novel non-serology-based approaches such as viral nucleic acid testing (NAT) have been established. However, blood components with very low viral load can even escape detection by NAT and cannot completely prevent transmission.

Our study conducted blood bank associated with district hospital which mainly caters village population included 14,350 blood donors over six and half year. Of which Voluntary blood donors (VBD) were motivated blood donors who donated blood at regular intervals and replacement blood donors (RBD) were usually one time blood donors who donated blood only when a relative or friend is in need of blood.$ Present study had 8269 (57%) replacement blood donors (RBD) who were more compared to voluntary blood donors(VBD) 6054(42.18%). Which was
Table 5: Showing comparison of present study’s seroprevalence of TTIs with studies done in different regions or states of country (India)

| Study                          | Year        | Region          | HIV  | HBV  | HCV  | Syphilis |
|-------------------------------|-------------|-----------------|------|------|------|----------|
| Sulhyan Kalpana et al         | 2013-2017   | Maharashtra     | 0.24 | 1.15 | 0.11 | 0.00     |
| NACO                          | 2015        | Maharashtra     | 0.19 | 1.09 | 0.28 | 0.04     |
| Patil AS et al                | 2008-2014   | Maharashtra     | 0.40 | 1.14 | 0.37 | 0.11     |
| Jaseen Hassan M et al         | 2012-2015   | New Delhi       | 0.33 | 1.70 | 0.74 | 0.16     |
| Makroo et al                  | 2005-2013   | New Delhi       | 0.24 | 1.18 | 0.50 | 0.008    |
| Sastry JM et al               | 2008-2013   | Maharashtra     | 0.28 | 1.23 | 0.41 | 0.008    |
| Ahmed Z et al                 | 2008-2011   | Karnataka       | 0.10 | 0.50 | 0.008| 0.007    |
| Karmakar PR et al             | 2008-2011   | West Bengal     | 0.60 | 1.40 | 0.59 | 0.23     |
| Ramole Archana et al          | 2007-2016   | Madhya Pradesh  | 0.11 | 2.17 | 0.22 | 0.002    |
| Gupta R et al                 | 2003-2008   | New Delhi       | 0.35 | 1.66 | 0.65 | 2.80     |
| Bhawani Y et al               | 2010        | Andhra Pradesh  | 0.39 | 1.41 | 0.84 | 0.08     |
| Garg P et al                  | 2018        | Haryana         | 0.13 | 0.94 | 1.26 | 0.61     |
| Adhikari et al                | 2010        | Sikkim          | 0.32 | 0.78 | 0.27 | 0.27     |
| Sirajunnisa Begum et al       | 2014        | Pondicherry     | 0.06 | 2.1  | 0.15 | 0.4      |
| Anjali et al                  | 2012        | Kerala          | 0.60 | 1.50 | 0.40 | 0.10     |
| Das DK et al                  | 2009-2010   | Kolka           | 0.32 | 1.55 | 0.35 | -        |
| Present study                 | 2014 -2020 June | Karnataka     | 0.062| 0.655| 0.006| 0.146    |

Table 6: Showing seroprevalence of TTIs in different countries of different continents

| Study           | Year | Country       | HIV  | HBV  | HCV  | Syphilis |
|-----------------|------|---------------|------|------|------|----------|
| Nagalo et al    | 2011 | Koudougou     | 2.21 | 14.96| 8.69 | 3.96     |
| Valerian DM et al | 2018 | Tanzania      | 13.3 | 29.6 | 7.5  | 9.3      |
| Tafuri et al    | 2010 | Italy         | 1.5  | 8.3  | 4.5  | 1.5      |
| Tessema et al   | 2010 | Ethiopia      | 3.8  | 4.7  | 0.7  | 1.3      |
| Stokx et al     | 2011 | Mozambique    | 8.5  | 10.6 | 1.2  | -        |
| Khedmat et al   | 2007 | Iran          | 0.003| 0.487| 0.093| 0.005    |
| Ahmad M U et al | 2009 | Bangladesh    | 0.008| 1.39 | 0.024| -        |
| Shrestha et al  | 2009 | Nepal         | 0.12 | 0.47 | 0.64 | 0.48     |
| Zheng X et al   | 2015 | China         | 0.15 | 0.51 | 0.25 | -        |
| Zameer M et al  | 2017 | Pakistan      | 0.11 | 1.59 | 3.85 | 2.08     |
| Present study   | 2014 | India         | 0.062| 0.655| 0.006| 0.146    |

Similar to studies done by Singh et al, (82.4%), Sehgal PK, Garg Dinesh et al (87.75%), Singh et al, (84.43%), Pahuja et al, (99.48%) and Arora et al, (68.6%) 28 It is shown that replacement donors constitute the largest group of blood donors in India, reflecting the lack of awareness amongst the general population. In contrast to the studies done by Bhattacharya et al, and P. Pallavi et al, where voluntary blood donors outnumbered replacement blood donors.

Majority of donors 14063 (98%) were males compared to females 297(2%) which was similar to other studies like Rao and Annapurna et al, in Pune, Rose et al., in Vellore, Arora D et al, in Southern Haryana, Singh K et al., in Coastal Karnataka, Pahuja et al, in Delhi and Singh B et al, noting more than 90% of the male donors.

The study done by us on seroprevalence of Transfusion transmitted infections (TTIs) showed HIV, HBV, HCV, Syphilis and Malaria prevalence of 0.062%, 0.655%, 0.006%, 0.146% and 0.006% respectively which was similar to Ahmed Z et al a study conducted in Karnataka(India), NACO studies done in Maharashtra (India) and various other studies as shown in Table 5 done in different states or regions of India. It’s important to note that pool of blood donors carrying TTIs are part of community or region of particular part of country.

Among the seropositive donors (126) maximum pool of TTIs was seen in replacement blood donors (RBD) 114 (90.47%) as compared to voluntary blood donors (VBD) 12 (9.52%) which was similar to the studies done by Kakkar N et al, Singh K et al and Pahuja et al. 58,60,61
Similarly studies done in African subcontinent showed higher prevalence of TTI as seen in studies done by Nagalo et al in koudougou,48 Tessema et al. in Ethiopia51 and Stoks et al. in mozambique52 compared to Asian subcontinent countries as noted in Khedmat et al. in Iran53 Ahmad M U et al. in Bangladesh,54 Shrestha et al in Nepal,55 Zheng X et al. in China56 and Zameer M et al in Pakistan57 which is shown in Table 6.

Notification of a blood donor about the abnormal test results is a very sensitive and crucial aspect of post donation counselling as it has its psychological and social impacts.67 The basic principles of donor notification should involve providing information to the donor promptly, accurately, confidentially, and in a manner that alleviates anxiety and promotes understanding.68,69 Safe blood transfusion requires proper pre donation counselling and TTI screening along with post donation counselling and notification to the TTI reactive donors.70 In the study conducted seropositive cases (126) were contacted out of which 108 (85.71%) were responders which is similar to studies conducted by Tynell et al.88.00% lesser compared to Kotwal et al.98.20%67 other various studies comparison is shown in Table 7. Among seroreactive cases18 (14.28%) donors could not be contacted and informed about abnormal test results for their treatment and removing them from donation pool. Incomplete or incorrect demographic details provided by donors were the main reason behind it. May be One Time Password linked mobile number collection and verifying Identification Data card issued by government authority to issue benefits can be used to reduce non responders.

| Study name | Percentage of responded reactive donors |
|------------|----------------------------------------|
| Agarwal et al. | 59.80 |
| Kotwal et al.67 | 98.20 |
| Kaur et al. | 38.90 |
| Kleinman et al. | 42.00 |
| Tynell et al. | 88.00 |
| Present study | 85.71 |

5. Conclusion

Our study concluded that there are more number of middle aged male donors in society. Less number of female donors may be due to various medical and socio-cultural differences between sexes. Voluntary donations needs to be encouraged through various educational and mass, social as well by print-medias which indirectly help in procuring safe blood as it is noted that seroreactive donors are less among voluntary donor category with high awareness about self- deferral. Complete protocol adherence from Selection of donor to compatible testing and transfusing would reduce the TTIs in collected blood. Contacting Seroreactive donor by blood bank and referral to concerned department would help in initiating early treatment and reduce mortality and morbidity thus reducing economic burden to individual and Nation.

Reactive donors should be treatment free of cost or on discounted affordable rates with an incentive which would further enhance the follow-up compliance and response to notifications in developing countries like India. Government health authorities should be notified of the non-responders so that they could further contact and trace the blood donors.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare that there is no conflict of interest.

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