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Original Research Article

Seropositivity and trends of transfusion transmitted infections among blood donors at blood center of tertiary care hospital of Marathwada region, Maharashtra, India

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ABSTRACT

Background: Blood transfusion is a life-saving intervention that has an essential role in patient management within health care system. The establishment of systems to ensure that all donated blood screened for transfusion -transmissible infections is a core component of every national blood programme. Testing for TTI's before blood transfusion is crucial for safety of recipients. with each unit of blood, there is 1% chance of transfusion associated problems including TTI. The aim of this 5-year retrospective study was to analyze the trend of transfusion transmitted infections among blood donors to evaluate the seroprevalence of HIV, HBV, HCV, syphilis and malaria.
Methods: A retrospective study was done at the blood center over a period of 5 years from January 2020 to December 2024 in healthy donors aged between 18-65 years. TTIs were performed using ELISA for HIV, HBV, HCV and HBsAg, peripheral blood smear for malaria and RPR (Rapid Plasma Reagin) for syphilis.
Results: Out of total 64603 healthy voluntary donors, prevalence of HIV, HBV, HCV, syphilis and malaria was (14) 0.021%, (257) 0.397%, (38) 0.058%, (12) 0.018% and 0 % respectively in our study.
Conclusions: Implementation of strict donor selection criteria along with proper counselling of donors can help to decrease seroprevalence rate of transfusion transmitted diseases. Also, the prevalence rate can be useful for government and health administrative services to implement better policy for safe blood collection and transfusion.

Keywords: Transfusion transmitted infections, Seropositivity, Human immunodeficiency virus, Hepatitis B virus, Hepatitis C virus, Syphilis, Malaria

INTRODUCTION

Blood transfusion is a life-saving intervention. Millions of lives are saved every year globally through this procedure. However, it can be a source of Transfusion transmissible infection (TTIs), posing a potential threat to the recipient.[1] Various infections agents such as bacteria, viruses and parasites can be transmitted via blood transfusion. As donors can transmit infectious diseases during their asymptomatic phase, such infection can contribute to a large pool of infection in society.[2] Therefore, Testing for TTIs before blood transfusion is crucial for the safety of recipients. Currently, there are more sensitive methods existing to detect markers of TTI. However, false negative results persist due to the prevalence of asymptomatic carriers in society, donors donating blood in the window period, viral strains with high genetic variability and technical errors. Hence, prevention of TTI remain one of the greatest obstacles in transfusion medicine to deal with.[3] According to the Ministry of health and family welfare (Government of India) under the Drugs and Cosmetics Act, 1945 (Amendments 2020), all blood donors are to be

screened against five major infections: HIV (1 and 2), HBV, HCV syphilis and malaria.[4] HIV, HBV and HCV are of high concern because of prolonged viraemia and long latency period. They can lead to chronic and life-threating disorders.[5] 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%.[6-9] 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. Sero-prevalence of HBV in various other Indian studies has been shown to range between 1.86% to 4%.[10-13] HCV is transmitted primarily through blood exposure. Indian studies indicate that seroprevalence of HCV ranges between 0.4 and 1.09%.[6,12-14]

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 4ºC. Very rarely causes transfusion transmitted syphilis.[15] 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 and pregnant women which can lead to fatal consequences.[16] Evaluation of TTI is important for estimating the safety of blood supply and in the surveillance of the efficiency of currently employed screening procedures. Thus, the study was undertaken to evaluate the overall seroprevalence and assess trends of TTI for a period of 5 years.

METHODS

Study design

A retrospective study was conducted in tertiary care hospital blood centre among blood donors who donated blood between January 2020 and December 2024. The blood centre is located in the Chattrapati Sambhajinagar of Maharashtra, where donors from all over Marathwada region donates blood through various blood donation camps. Institutional clearance was obtained from the ethical committee of the hospital.

Study population

Inclusion criteria

The study population included all blood donors who had donated blood in our blood centre from January 2020 to December 2024. A total of 64603 blood donors records were reviewed and included in the current study. The donor population comprised 100% voluntary donors.

Exclusion criteria

For blood donation were age <18 years and >65 years, weight <45kg, current history of medication, recent blood transfusion, any infection, anaemia and recent history of any surgical procedure.

Study procedure

Blood donor forms were used as a source of information. Healthy blood donors were screened by trained medical officers with detailed history and physical examination according to the standard operating procedures of the blood Centre as per the guidelines for blood donor selection and referral. Blood was collected from apparently healthy individuals after detailed history, physical examination and written consent. Under aseptic precautions, 2 ml blood was collected in plain tube and serum was separated for serological analysis. Peripheral blood smears were prepared and stained by field stain for malaria screening.

Serological analysis

Screening of all blood donors sample for HIV, HBsAg, HCV, malaria and syphilis was done.

HIV, HBsAg and HCV test were done by enzyme-linked immunosorbent assay (ELISA) method. For the detection of antibodies to HIV ½ and P24 antigen, 4th generation Qualisa and Merilisa TM-HIV Ag and Ab kits (Qualpro Diagnostics) were used. For the detection of Hepatitis B Surface Antigen (HBsAg), 3rd and 4th generation Qualpro HBsAg enzyme-linked immunosorbent assay kits were used. For the detection of antibodies to HCV 3rd generation Qualpro enzyme-linked immunosorbent assay kits were used. For Syphilis diagnosis, rapid plasma regain ultima test kits (BEACON) were used.

Peripheral blood smears were prepared and stained by field stain for malaria screening. Tests on donor blood were carried out according to the manufacturer's instructions with positive and negative controls. Blood samples were tested and reactive sera were confirmed by repeat testing using another kit manufactured by the different company. Internal and external quality controls were carried out as per protocol. Confidentiality of reports was maintained as per the standard guidelines. Seropositive donors underwent further counselling by the counsellor. The Sero reactive blood bag units were discarded in accordance with Biomedical Waste Management regulations. Information regarding age, seropositivity, type of donation and frequency of donation was extracted from blood Centre records. The data collected was analysed by using Microsoft excel sheet and the results were evaluated

RESULTS

Out of total 64603 blood donors from the general population who donated blood over five years of period, 321 were Sero reactive. Out of 321 Sero reactive donors, 14 donors were reactive for HIV, 257 donors were reactive for HBV, 38 donors were reactive for HCV and 12 donors were reactive for syphilis. The seroprevalence rate during

this period was 0.50%. the total seroprevalence of TTI in the years 2020-2024 was 0.50%. All the seropositive donors in our study are males. The seroprevalence rate during this period for HIV, HBV, HCV, syphilis and malaria found to be (14) 0.021%, (257) 0.397%, (38) 0.058%, (12) 0.018% and 0 (0) % respectively in our study.

Table 1: Sex wise distribution of blood donors.

Year	Male	Female	Total
2020	11619	106	11725
2021	11868	140	12008
2022	14002	164	14166
2023	12969	240	13209
2024	13234	261	13495
Total	63692	911	64603

Table 2: Year and type of infection wise distribution

Year	HIV	HBV	HCV	Syphilis	Malaria
2020	02	62	04	2	0
2021	03	39	07	3	0
2022	01	45	10	3	0
2023	02	27	05	2	0
2024	06	84	12	2	0
Total	14	257	38	12	0

Table 3: Total seroprevalence in 5-year duration.

Year	Number of donors	Number of seropositive donors	Seropositivity
2020	11725	70	0.59%
2021	12008	52	0.43%
2022	14166	59	0.41%
2023	13209	36	0.27%
2024	13495	104	0.77%
Total	64603	321	0.49%

DISCUSSION

Blood is an expensive human resource and it should be prescribed justifiably and appropriately due to its scarcity. Prescribing recommendations should be based on national guidelines on the clinical usage of blood, taking into account the patient's needs, minimum cost and wastage, optimum safety and efficacy.[17] 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.[18] 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. With every unit of blood, there is 1% chance of transfusion associated problems including TTIs.[19,20] It is the duty of every healthcare organization to provide safe blood transfusion services, since transfusion transmissible infectious diseases carry long-term consequences for the recipients.[21]

The aim of this study was to determine the seroprevalence of HIV, HBV, HCV, malaria and syphilis among healthy blood donors in Indian population. Comparison of data with similar studies conducted in India is also done. All the donors in the present study were voluntary unpaid donors (100%). Most of the donors in our study were males comprising 98.58% with females forming mere 1.41% of total donor population. All the seropositive donors in our study are males. Similar trend was noted in the study by Natasha et al where 97.6% of donors were male and 2% were female, as well as in the study done in Ethiopia Somali Region by Mohammed and Bekele where 98.7% of donors were male and 1.3% were female.[21,22]

The reasons for less number of female donors in our study could be because of traditional patriarchal society of India, less awareness, low education levels, and increased deferral rate among female donors, due to most of females being anemic and underweight. However, it was also noted that from 2020 to 2024, there is gradual increase in the number of female donors (Table 1). This may be due to increasing awareness and improved education status of females. Overall seroprevalence among donors was 0.49%. which is slightly lower than other studies by Anjali et al, Arora et al, Natasha et al, Mohammed and Bekele, Pallavi et al, Pahuja et al and Matee et al.[20-26] The lower rate of seroprevalence of 321(0.49%) in our study is due to better donor awareness, better hygiene practices, and stringent donor selection criteria followed at our blood center. The seroprevalence rate during this period for HIV, HBV, HCV, Syphilis and Malaria found to be (14) 0.021%, (257) 0.397%, (38) 0.058%, (12) 0.018% and 0 (0) % respectively in our study. Incidence of hepatic viruses was found to be higher than HIV in our study population.

HBV positivity in our study was less (0.39%) as compared to other similar studies both national and international. The less HBV positivity in our study is due to screening by latest methods: third and fourth generation HBsAg ELISA test kits with sensitivity and specificity of 98.6% as against second-generation kits which had high false positivity. To further decrease the incidence of posttransfusion HBV infection, it is necessary to find out the tests which detect the presence of hepatitis B during the window period. In this situation, nucleic acid testing (NAT) assay is very useful, which has considerably shortened the window period. However, the cost of this assay is high which makes it unaffordable for many centres. In spite of availability of a safe and effective vaccine, the seroprevalence of HBsAg in India is high. This is due to a long window period between initial HBV infection and the detection of HBsAg during which the virus is transmissible, the residual transmission risk of HBV

infection through a transfusion is higher.[27,28] HIV positivity was 0.03% in our study which is again low in comparison to other similar studies. This again could be due to the use of fourth-generation Qualisa and Merilisa HIV kits for the detection of HIVp24 antigen and antibodies to HIV-1 and HIV-2 at our center. The sensitivity and specificity of Qualisa & Merilisa were 100%. We also observed while comparing our study with other similar studies that initially, the seropositivity for HIV was high, but over the years, the incidence of HIV positivity among donors has decreased. This can be because of increased awareness among donors and use of more sensitive methods for screening. In the present study, none of the donors were found to be positive for malaria parasites. In studies conducted by Srikrishna A et al, Mendhe VV & Pallavi P et al, Prakash VB et al, Kaur G et al, Makroo RN et al, Shilpa Krishnakant Patel et al and Sethi B et al, no donors were positive for malarial parasites.[3,24,1,29-33]

Table 4: List of various studies showing seropositivity (in percentage) of blood donors.

Study	Publication year	Place of study	Total donors	HIV	HBsAg	HCV	Syphilis	Malaria
Kaur et al[31]	2010	Chandigarh, India	42439	0.60	1.70	0.80	0.70	00
Bhawani et al[34]	2010	Andhra Pradesh, India	8097	0.39	1.41	0.84	0.08	-
Leena et al[35]	2012	South India	6939	0.27	0.71	0.14	0.10	0.12
Sethi et al[33]	2014	Uttarakhand, India	7884	0.19	0.63	0.20	0.02	00
Mandal et al[36]	2015	Darjeeling, India	28364	0.42	1.24	0.62	0.65	0.004
Makroo et al[32]	2015	New Delhi, Indi	180477	0.24	1.18	0.43	0.23	00
Assessment of NACO supported blood banks-A Preliminary report 2016 (Gujarat)[37]	2016	Gujarat, India	606683	0.11	0.64	0.15	0.18	0.039
Sharma et al[6]	2018	Gujarat, India	13724	0.03	0.29	00	0.04	00
Naik et al[38]	2020	Andhra Pradesh, India	54937	0.23	1.82	0.31	0.04	0.01
Arif et al[39]	2021	Uttar Pradesh, India	36614	0.35	2.38	1.27	1.29	0.29
Cheema et al[27]	2022	Haryana, India	10797	0.03	0.49	0.50	0.05	0.009
Mendhe et al[29]	2023	Maharashtra, India	12193	0.09	0.7	0.106	0.04	00
Patel et al[1]	2024	Gujarat, India	20392	0.09	0.76	0.14	0.20	00
Present study	2026	Maharashtra, India	64603	0.021	0.397	0.058	0.018	00

CONCLUSION

In the present study, the Overall seroprevalence among donors was 0.49% over a period of 5 years. The seroprevalence rate during this period for HIV, HBV, HCV, Syphilis and Malaria found to be (14) 0.021%, (257) 0.397%, (38) 0.058%, (12) 0.018% and 0 (0) % respectively in our study.

The low incidence of TTI in this study is due to better awareness among general public, 100% voluntary blood donation and strict donor selection criteria followed at our blood center. We recommend Implementation of strict donor selection criteria, utilization of sensitive screening tests along with proper counselling of donors and judicious use of blood products can help to decrease seroprevalence rate of transfusion transmitted diseases.

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