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THE TRENDS OF TRANSFUSION TRANSMITTED INFECTION AMONG BLOOD DONORS IN A TERTIARY CARE MEDICAL COLLEGE FROM NORTH INDIA: A 7 YEAR RETROSPECTIVE STUDY

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ABSTRACT

BACKGROUND: Infectious disease transmission has always been a concern for blood bank professionals and for practising physicians who prescribe blood and blood components for their patients. The rate of Transfusion transmitted infections in donated blood is one of the main indicators of blood safety which has to be monitored precisely. This paper provides a thorough study of blood safety indicators. **AIM :**To study trends of transfusion transmitted infections (HIV, Hepatitis B Virus , Hepatitis C Virus , Syphilis and Malaria) among blood donors at a tertiary care Government medical college blood bank in north India in last 7 years. **MATERIALS &METHODS:** This study was conducted retrospectively over a period of 7 years (August 2013 –January 2020). A total of 29,262 blood donors who donated blood during this period were tested for HIV, HBV, HCV, Syphilis and Malaria. Comparative analysis was done to study trend of transfusion transmitted infection among these blood donors **RESULTS:** Out Of this 29262 blood unit tested a total of 86 cases of HIV, 840 cases of HBV, 163 cases of HCV ,4 cases of syphilis and 13 cases of malaria were identified. Among the blood donors 0.294 % were reactive to HIV, 2.87% were reactive to HBsAg, 0.557 % were reactive to HCV. Whereas 0.0136 % were found to be positive for syphilis and 0.044 % were positive for malaria.**CONCLUSION:** Comparing a retrospective data over a long period showed a linear trend in seroprevalance of HIV, HBsAg , HCV, Syphilis and malaria. The risk of transmission of these infections by blood transfusion remains high among first time donors. The results of the study reflect the prevalence of these infections in the healthy population and warrant measures like effective donor retention and education policy and newer testing modality such as nucleic acid testing (NAT) to detect infection early and prevent residual risk of transmission.

KEY WORDS : Blood Donor, HIV, hepatitis B virus, TTI, HBsAg, prevalence, incidence risk

INTRODUCTION:

Blood transfusion contributes to saving lives every day around the world, but it can also be a source of transmission of infectious agents, including HIV, HBV, HCV Syphilis and Malaria. Despite the necessity of blood components in certain medical circumstances, unhealthy blood components can cause serious risks for the patients or even endanger their lives.[1] although the performance of serological tests has been considerably improved in recent years; there remains a residual risk of transmission of viruses by blood transfusion. Blood presents a potential risk for the receivers of transfusions. The rate of transfusion transmitted infections in donated blood plays a key role as the main indicator of blood safety, which has to be monitored precisely. The biggest challenge in this regard is transfusion transmitted infections (TTIs), the most important of which are human immune deficiency virus (HIV) as well as hepatitis types B (HBV) and C (HCV) viruses which create a large burden for the healthcare system.[2,3]Every blood transfusion carries potential risk of transmitting transfusion transmitted disease (TTI) to the recipient. Screening of blood donors first started in 1947.[4] Today, India's blood transfusion program mandates the screening of HIV, hepatitis B virus (HBV), hepatitis C virus (HCV), malaria, and syphilis.[5] Estimated adult HIV prevalence in India is 0.2–0.3%;[6] and up to 40 million of 350 million hepatitis B chronic carriers worldwide are in India.[7] Hepatitis B surface antigen (HBsAg) prevalence varies from 1% to 13%, with an average of 4.7%[8] HCV carriers in India are around 12–13 million.[9]Given the significance of these infections and the ease with which they are transmitted through blood components, the blood transfusion services follows a set of standard operating procedure(SOPs) to identify infected blood donations and prevent their use.

These procedures include two main activities: selecting safe donors and performing screening tests in order to identify TTIs.[10] The selection process include interviewing each blood donors by a qualified interviewer. In case of any risk factors or any history of risky behaviour found in blood donor, blood donation from these donors were refused.[11,12]In the next step, donated blood is screened for TTIs. These tests investigate screening the HCV Ab , HBsAg and HIV (Ag/Ab) using the ELISA test and malaria by rapid card test method and syphilis by RPR method according to the standard operating procedure of blood bank SHKM Govt. medical college guidelines.[12] The screening method used to screen the donated blood needs to be improved over time based on new technologies of screening methods. For example, from ELISA to NAT can led to much more accurate and reliable test results and reduction in window period. In order to assess the effects of upgrading the mentioned screening methods, it is needed to develop a plan to analyze the situation of screening results, before and after this switching. The effectiveness of switching the methods of the TTIs screening system has to be analyzed.

MATERIAL AND METHODS

Study Design

This was a retrospective study conducted from August 2013 to January 2020 in the department of Blood Transfusion Shaheed Hasan Khan Mewati Government Medical College Nalhar, a tertiary care hospital from North India. All technical support was provided by the staff posted for the blood collection.

Data Collection

This study used the data registered in donor register who came for the blood donation either in blood bank or at voluntary blood donation camp. The data include the number of donors and the number of identified infections between the years 2013(August) and 2020 (January). For this study, blood donations and donor information collected included years of collection, sex, age, status of donor (first time or repeated), collection site (fixed or mobile collection), and results (positive or negative) of serological tests for

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HIV, HBV, HCV, syphilis and malaria. A repeat donor was defined as a donor who had donated blood at least twice during the study period.

Serological tests

Screening tests

HIV, HBV, and HCV serological tests were performed according to an algorithm defined by the NACO. Initially, all blood donation were tested with fourth generation ELISA to detect anti-HIV1and HIV2 antibodies and antigen P24 of HIV, surface-antigen HBs of HBV, and anti-HCV antibodies, respectively.

Confirmatory strategies

Due to limited resources, positive samples were not confirmed by reference tests, such as Western blot, for HIV or nucleic acid testing. Nevertheless, the algorithm applied by the NACO defined confirmatory strategies. For HIV, initial reactive samples were retested in duplicate using the same kit. Negative results in duplicate were considered negative. In cases of positive reaction, a parallel algorithm sampling two rapid diagnostic tests (RDTs), a screening test and an HIV1 and HIV2 discriminant test was applied. Positive samples in both RDTs were considered positive. Discordant samples in both RDTs(rapid diagnostic tests) or between RDT and ELISA were considered indeterminate.

For HBV and HCV, initial reactive samples were retested using Alere Determine HBsAg and SD Bioline HCV (Standard Diagnostics, Yongin, South Korea), respectively. Positive samples in both tests were considered positive, and discordant samples in both tests were considered indeterminate. Blood units detected positive or indeterminate for one TTI were discarded. Donors with indeterminate results were invited for a control test 3 months later.

For Syphilis and Malaria if sample gives positive test on rapid card of different make is considered positive.

STATISTICAL (DATA) ANALYSIS

The statistical analysis was carried out using statistical package for social sciences (SPSS Inc, Chicago, IL,US;version 15.0 for Windows).Scores were presented as percent age. Qualitative or categorical variables (eg age and sex were described as frequencies and proportions.Kruskal-Wallis test was applied to find if difference/variance exists between scores. Then Mann-Whitney test was applied to check this for statistical significance. Comparison for first time donors and repeat donors was done using Mann-Whitney U-test. Proportions were compared using chi-square or Fisher's exact test as applicable. All statistical tests were two sided and was performed at a significance level of 0.05.

RESULT

Descriptive Analysis

Between the period August 2013 and January 2020, a total of 29,262 units of blood was collected (overall, about 66% of donors are first time donors, and the remaining 34% had donated blood more than once before, this ratio that has been almost constant in recent years) in SHKM GMC Nalhar.(Refer Table-1) Out Of this 29262 blood unit tested a total of 86 cases of HIV, 840 cases of HBV, 163 cases of HCV ,4 cases of syphilis and 13 cases of malaria were identified. Among the blood donors 0.294 % were reactive to HIV, 2.87% were reactive to HBsAg, 0.557 % were reactive to HCV. Whereas 0.0136 % were found to be positive for syphilis and 0.044 % were positive for malaria. (Refer Table-2)

The period prevalence (7 years) of these infections was found to be 29, 287, 56, 1 and 4 cases per 10,000 donations for HIV, HBV, HCV, syphilis and malaria respectively. The largest number of infections were identified in the middle years of the study (2014 to 2017) while the number of infections was lowest in the year 2013. Among these infections, HBV had the highest prevalence (Refer Table 1).

Table 1: Year wise Blood collection 2013 (August) – 2020 (January)

Year	First time Blood Donor			Repeat Blood Donor			Total	P-Value
	Male	Female	Total	Male	Female	Total		
2020 (January)	240	06	246	199	05	204	450	<.05
2019	3757	139	3896	2369	59	2428	6324	
2018	3846	48	3894	1923	25	1948	5842	
2017	3499	86	3585	1656	19	1675	5260	
2016	2307	48	2355	1632	30	1662	4017	
2015	2101	109	2210	1425	5	1430	3640	
2014	2047	151	2198	578	0	578	2776	
2013 (August-December)	917	36	953	0	0	0	953	
	18714	623	19337	9782	143	9925	2926	

Table 2: Year wise and total prevalence of transfusion Transmitted infections (TTIs)

TTIs ↓ YEAR→	2013	2014	2015	2016	2017	2018	2019	2020 (Jan)	Total (out of n=29,262 Donation)	% Prevalance	P-Value
HIV (ELISA)	2	20	11	7	12	9	25	0	86	0.294	
HBsAg (ELISA)	20	95	94	106	167	160	189	9	840	2.87	
HCV (ELISA)	4	46	18	10	22	25	38	0	163	0.557	<.05
SYPHILIS (RPR)	0	1	1	2	0	0	0	0	4	0.0136	
MALARIA (RAPID CARD)	0	4	3	1	4	0	0	1	13	0.0444	

Table 3: Prevalence of TTI among different blood groups

Blood Group	Total Number of Blood unit	TTI Prevalance					Total no & %		P-Value
		HIV	HBsAg	HCV	Syphilis	Malaria	Total	%	
A	6433	19	183	32	01	01	236	3.66	<.05
B	11465	44	439	79	02	09	573	4.99	
AB	2833	02	14	14	0	01	31	1.09	
O	8531	21	204	38	01	02	266	3.11	
Total	29262	86	840	163	4	13	1106	3.78	

Table 4: Prevalence of different blood groups during 2013 (August) – 2020 (January)

Blood group	2013	2014	2015	2016	2017	2018	2019	2020 (January)	Total	% of Total	P-Value
A	217	601	807	916	1103	1327	1364	98	6433	21.98	<.05
B	358	1098	1375	1556	2103	2215	2584	176	11465	39.19	
AB	85	241	408	383	509	581	582	44	2833	9.67	
O	293	836	1050	1162	1545	1719	1794	132	8531	29.16	
	953	2776	3640	4017	5260	5842	6324	450	29262	100	

Table 5 : Distribution of Rh (positive) and Rh (negative)

Blood Group	Total Blood unit collected	%	P-Value
Rh (positive)	26903	91.94	<.05
Rh(negative)	2359	8.06	
Total	29262	100%	

Table 6: Comparative % prevalence among different region of India with present study

Region	Place	HIV (%)	HBsAg (%)	HCV (%)	Syphilis (%)	Malaria (%)	P-Value	Author and Year
Present Study	South Haryana	0.294	2.87	0.556	0.0136	0.0444	<.05	Shailesh et el 2013-2020
North India	Delhi	0.56	2.23	0.66	--	--	<.05	*

	Ludhiana Punjab	0.08	0.66	1.09	0.85	--		Gupta et el 2001-2003[17]
	Etawah UP	0.19	2.63	0.34	--	--		Dayal S 2006-20112[6]
	Lucknow UP	0.23	1.96	0.85	0.01	--		Chandra et el 2001-2006[27]
	Bikaner Rajasthan	0.10	1.60	0.18	0.89	0.04		Devraj et el2001-2003[28]
Central India	Bhanpura MP	0.51	2.90	0.57	0.23	--	<.05	Sawke et el2006-2008[29]
South India	Karnataka	0.44	1.86	1.02	1.6	--		*
	Vikrabad AP	0.39	1.41	0.84	0.08	--		Bhawani et el 2004-2009[30]
West India	Maharastra	0.07	1.09	0.74	0.07	--		*
East India	West Bengal	0.28	1.46	0.31	0.72	--		*

Table7: Basic characteristics of the population under study

Parameter	n= 29262	%	P -Value
Sex			
Male	28,496	97.38	<.05
Female	766	2.62	
Age-Group(Years)			
<20	2126	7.26	<.05
20-29	15,834	54.11	
30-39	7,891	26.96	
40-49	3134	10,71	
50-59	243	0.83	
60-65	34	0.11	
Donor Type			
First Time	19337	66.08	<.05
Repeat	9925	33.92	

More number of transfusion transmitted infections were reported amongst the blood donors with blood group **"B"**,This may be due to more blood donors with B blood group donated blood.(Refer Table 3,4,5)

DISCUSSION

Blood transfusion services not only screen the blood donor but also give a clue about the rate of prevalence of TTI in asymptomatic healthy young adults. It can be considered as a reliable tool for statistical estimation of these infections in the general population as discussed by Gharehbaghian, Attaullah, et al.[13,14] The prevalence rate may be under or overestimate due to their different gender, age, area of residence, and other characteristics.[15,16] It can suggest to make strategies to identify, recruit, and retain VBD from low-risk population, as blood donors with high-risk group such as history of jaundice, injectable drug abuse, and multiple sexual partners have been screened out by donor questionnaire at our center and also in blood donation camps. Blood transfusion is an important preventable modality of spread of TTI. Accurate estimation of risk of TTIs is essential for monitoring of blood safety and efficacy of currently employed screening programs as discussed by NACO guidelines.[17] It has been found that prevalence of various TTI varies with different geographical regions.[14]

The results indicated that the prevalence of HBV (287 cases per 10,000 donations) was higher than that of HCV (56 cases per 10,000 donations) in donated bloods in the study period (7 years) while the prevalence of HIV (29 cases per 10,000 donations) was comparable to that in blood donors in most other countries. Other studies in India (HBV=1.77%, HIV=0.14% and HCV=0.04%), Colombia (HBV=0.12%, HCV=0.45% and HIV= 0.12%), Italy (HBV=0.01%) and Turkey (HBV=4.19% and HCV=0.38%) showed a higher prevalence of TTIs among blood donors compared to this study.[18-21]

A systematic review studies on the prevalence of HBV among the WHO member countries showed that the prevalence of HBV in Italy (2.52%), Colombia (2.3%) and Turkey (4%) is comparable to our present study (2.88%).[22]The prevalence of TTIs among blood donors in this study showed a decreasing trend between the years 2013 and 2020. The results of other studies on the prevalence trends of TTIs among blood donors of other study are similar to the results of our study and show a decreasing trend of TTIs .[1,23] This study showed that highest prevalence of TTIs was observed in the first-time donors which is similar to Iranian study.[24] It appears that as years go by, a larger ratio of donors is made up from repeat and regular blood donors. These people receive more education compared to first-time blood donors, which can explain a lower prevalence of TTIs among repeat donors.

When various other studies from different parts of India was compared it was found that percent prevalence of HIV was similar to other studies,though some studies reported less prevalence speciallystudy from Maharastra and Ludhiana Pujab.Percent prevalence of HBsAg were similar to the study done at Bhanpura MP (2.9%)All other studies had lower prevalence compared to present study. Study done in West Bengal and Etawah UP showed less prevalence of HCV than present study and all other studies showed higher prevalence for HCV compared to present study. Study done at Ludhiana Punjab (0.85%) ,Bikaner Rajasthan (0.89%),Karnataka (1.6%) West Bengal (0.72%),Bhanpura MP (0.23%) showed higher percent prevalence for syphilis compared to present study whereas study done at Lucknow and Vikrabad AP showed similar result for percent prevalence for HCV compared to present study. This study showed highest prevalence of malaria compared to other study.(Refer to Table 6)

When basic characteristics of the population under study was analysed it was found that maximum transfusion transmitted infections(TTIs)were reported among age group of 20-29 years. The reason for high reactivity of this group may be these group donate blood maximally.(Refer Table 7)

CONCLUSION

Voluntary donations are safer as compared to replacement ones and should be encouraged. Proper efforts in planned way should be made to increase the number of voluntary donors with a target of 100% and reduce replacement donations to a minimum. We have observed decreasing trend of HIV, HBsAg, HCV, syphilis and Malaria with a significant difference in repeat blood donor as compared to First time blood donor.

Transmission of TTIs during serologically negative window period is still a threat to blood safety. Therefore, strict selection of blood donors and comprehensive screening of donor's blood using standard and latest such as NAT (nucleic acid testing) methods are highly recommended to ensure the safety of blood for recipient. This trend suggests that for prevention of TTIs healthy VBD recruitment and safe VBD retention strategies should be strengthened at all levels in blood transfusion service so that first time blood donors may turn into repeat blood donor.

Disclosure

The authors have reported no conflicts of interest in this work.

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