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Original Research Article

The Study of Sero-Reactive Donor Demography, Notification and Counselling In Blood Centre Associated with Tertiary Care Hospital in South Gujarat

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Abstract

Introduction: While blood transfusion is a lifesaving intervention, prevalence of various Transfusion-Transmissible Infections (TTIs) in healthy donors leads to risk of TTIs in patients as well as in family/friends and community. If the blood centres make appropriate changes in donor demographic data collection parameters and do proper donor counselling to increase donor awareness for TTIs, it can lead reduction in prevalence of TTIs in patients.

Aim: The study aimed to estimate the prevalence of sero reactivity, to determine various demography related factors, to compare sero-reactivity rate in voluntary non remunerated blood donors (VNRBD) vs family/replacement donors, to estimate response rate of the notified sero-reactive donors for counselling and to determine reasons for non-notified and non-responded donors and to reframe donor notification and counselling formats and dialogue if required.

Materials and Methods: This Prospective observational study was carried at Blood centre attached to the Immuno Haematology & Blood Transfusion (IHBT) department of Government Medical College of South Gujarat from February 2023 to February 2024.All donors demographic and TTI details were entered in excel sheet with the segregation of sero-reactive status as well as other outcome parameters entered and descriptive Stastical analysis was done and evaluated with appropriate tabulations and graphical presentations. The statistical analysis in the form of Chi-squared test was done to find out any relationship between two parameters under study. The null hypothesis was rejected if two tailed P value was <0.05 with 95% confidence interval.

Results: Out of total 10991 units collection for the present study period, 174(01.58%) were sero-reactive which included 73 were syphilis reactive, 59 were reactive for HBV, 38 were HCV reactive, 06 were HIV reactive and 03 were malaria positive. Out of 174 sero-reactive donors, 06 donors had indeterminate results, so these 06 donors were not included in the list of donor notification. From these 168 sero-reactive donors, 123(73.21%) were able to get notified about their TTIs status and 45(26.79%) were non-notified because of various reasons. From those who got notified, only 79(64.23%) were responded to the blood center for further counseling and referral and 44(35.77%) donors never responded. Donors who responded to the blood center or got notified about their TTI status gave various reactions towards the news. Majority donor 61(49.59%) accepted the fact while 13(10.57%) donors got stressed, 17(13.82%) donors got shocked by the news and 11(08.94%) donors denied the fact.

Conclusions: Donor demographic details should be carefully collected, and addition of some other parameters should be considered. Finally, modification in approach to donor notification should be done so that maximum number of donors gets notified and respond.

Keywords: Sero Reactive, Notification, Blood Donors, Counseling.

Introduction

Blood transfusion is a life-saving intervention and millions of lives are saved each year globally through this procedure. [1] Although blood transfusion plays an important role in the supportive care of medical, surgical and paediatrics patients, unsafe transfusion practices also put millions of people at risk of TTIs. [2] According to the World Health Organization (WHO), safe blood is a

universal right, which indicates blood that will not cause any harm to the recipient, like hepatitis, malaria, Human immunodeficiency virus (HIV) or syphilis. [3] The WHO also recommends that, at least, all donated blood should be fully screened for Hepatitis B virus (HBV), Hepatitis C virus (HCV), HIV and syphilis. [4]

In developing countries, one of the sources of HCV, HBV, and HIV infections is transfusion of blood and blood products from unscreened or inadequately screened blood donors. TTIs were estimated for HIV, 1 in 493,000; for HCV, 1 in 103,000; and for HBV, 1 in 63,000. [5] The risk for acquiring TTIs is even higher in multiple-transfused patients. The study conducted by Mittal et al, [6] stated that 12.5% multiple-transfused patients were infected with TTIs. In India, as per Drugs and Cosmetics Act, 1945 amended from time to time, all blood donations are to be screened for HIV I and II, HBsAg, HCV, syphilis, and malaria. [7] 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), and HCV (since 2001). [8,9,10] However the risk of TTI still persists if the donation is done during window period of the disease.

Donor notification and counselling play a vital role in both blood safety and comprehensive donor care. This process informs donors about their status of TTI, modes of transmission of such infections, and helps prevent secondary transmission of these infections in the community.

According to Objective 4.16 of the Indian Action Plan for Blood Safety, donors are counselled about TTIs prior to donation and are offered the option of knowing their infective status provided they give consent to this. [11] Blood donors with reactive screening test results are requested to come for counselling and repeat testing either at a blood centre/an integrated counselling and testing centre (ICTC)11/national hepatitis control program OPD (NHCP) or sexually transmitted infections (STI) clinic. The importance of being aware of a reactive test result helps them to start early treatment and take preventive measures for self and others in family. [12]

Most blood centre discard blood that is TTI reactive but does not notify donors of their TTI status due to a lack of resources and trained counsellors. [13] Most of the reactive donors who are notified of their results either do not respond at all or do not follow-up. Some reactive donors continue to donate blood despite being notified about the infectious disease test results. [14] This study was undertaken to create awareness and to determine the response of blood donors after they were notified of their reactive status or to re-examine themselves as screening methods in the blood centres are more sensitive than specific. This helped in formulating strategies to inform donors about their seroreactivity status and take necessary medical interventions at the earliest before considering next blood donation and in spreading the importance of self-deferral. In the long term, this may help in creating a pool of safe repeat non-remunerated voluntary/family or replacement donors across the state.

Material and Method

This prospective observational study was based on all donations done in the Blood centre attached to the IHBT department of tertiary care hospital with Medical college of South Gujarat from February 2023 to February 2024. The filled donor forms which included the type of donation (voluntary/replacement), the donor's details, pre-donation questionnaire, counselling details and medical examination findings were analysed along with the TTI results. Only those blood donors who had given consent to be get informed of their serological screening status for TTIs, during pre-donation screening were contacted by the blood centre.

Five mandatory TTI screening tests for HIV 1 and 2, HCV, HBV, Syphilis, and malaria parasite were performed on adequate 05 ml plain and 03 ml EDTA blood collected in pilot tubes after donation of 10,199 donors who donated blood at camp site and in-house at blood center.

All Samples were screened for anti-HIV 1 & 2 antibodies & p24 antigen using 4th generation ELISA (Merilisa HIV Gen 4, Meril diagnostics pvt ltd), HBsAg for HBV (Merilisa HBsAg, Meril diagnostics pvt ltd) and anti HCV antibody for HCV (Merilisa HCV, Meril diagnostics pvt ltd) were tested using third-generation ELISA kits on fully automated ELISA system (Evolis, Biorad, USA) following the standard protocol for each according to the kit inserts. Syphilis test was done by Treponema Pallidum Hemagglutination test (TPHA) (Syphicheck, Tulip diagnosticspvt ltd) and malaria test was done using rapid kit (Falcivax, Viola diagnostics system). All samples with reactive results were repeated in duplicate before labelling as reactive. The donor samples that was reactive by both the testing, considered as confirmed reactive. However, the blood units collected from the donors who was reactive even once, considered as positive unit and components were discarded. The TTI results of all the donors were being maintained in the blood centre for 05 years as per regulatory guidelines. CUE (Confidential Unit Exclusion) donors, non-consented donors for their seroreactivity status were excluded from study. After confirming reactive result of the particular donor, the trained counsellor had contacted the donors (over telephone) by maintaining the confidentiality of the test result to avoid panic in

donors. Only primary information in the form of discrepancy about the results of tests was provided and donor was requested to come to the blood centre for counselling, recollection, and referral. In every case, the notifications over telephone were attempted three times. The donors who can be contacted over telephone were considered as notified donors. The donors who cannot be contacted even after third try of notification were considered as non-notified donors. For non-notified donors, try has been done for contacting the camp organizer considering possibility that organizer might be in contact with donor. In such cases, organizers were asked for only contact information of the donor without informing anything related to test result.

At the time of contacting the donor on phone, donor identity was reconfirmed by taking the donor demographic details with the details mentioned in the donor form. After donor confirmation, they were notified that the samples tested on the day of donation was showing discrepant results and to visit blood centre for counselling. Among the notified donors, those who visited the blood centre for counselling were considered as responders and others as non-responders.

When the donors came for counselling, their identity was verified again, and confidentiality was maintained at all the steps. They were informed that tests done at blood centre are screening tests and further confirmation and follow up are required. The HIV reactive responders upon communication were referred to the ICTC with a referral form for counselling and confirmatory testing, for HBsAg and HCV reactive donors were referred to NHCP OPD and syphilis reactive donors were referred to a sexually transmitted disease clinic (STI), whereas Malaria reactive donors were referred to a physician for further management.

All donors demographic and TTI details were entered in excel sheet with the segregation of sero-reactive status as well as other outcome parameters entered and descriptive statistical analysis was done and evaluated with appropriate tabulations and graphical presentations.

The statistical analysis in the form of chi square test was done to find out any relationship between two parameters under study. The null hypothesis was rejected if two tailed P value was <0.05 with 95% confidence interval. The statistical software used was that of online calculator of website https://www.openepi.com/ Menu/OE_Menu.htm.

Results

Out of 10991 blood units from donors, 174 (1.58%) donors found to be sero-reactive out of which 06 donors found out to be HIV reactive, 59 were HBsAg reactive, 38 were HCV reactive, 03 were positive for malaria parasite (MP) and 73 were syphilis positive which was the highest in number (73 out of 174). It was noticed that few donors were reactive for more than one infection, 04 (02.30%) donors were found out to be positive for more than one infection. During this study, 01 donor had co-infection in which donor was reactive for HIV, HBsAg and syphilis, where as another 03 donors were reactive for syphilis and HIV. Table 1 shows Sero reactive blood donors demography details.

Table 1: Sero Reactive Blood Donors Demography Details

Demography Details	Parameters	Total Numbers	Percentage
Age Group (Years)	18-30	72	40.22%
	31-50	90	50.28%
	51-60	15	08.38%
	61-65	02	01.12%
Gender	Male	173	99.43%
	Female	1	0.57%
Types of Blood Donor	Voluntary Non-Remunerated Blood Donors	133	76.43%
	Family/ replacement	41	23.56%
Donation Site	In House	42	24.14%
	Camp	132	75.86%
Education Status	Under graduate	91	52.30%
	Graduate	60	34.48%
	Post graduate	09	05.17%
	Uneducated	14	08.05%
Marital Status	Married	126	72.41%
	Unmarried	48	27.59%
Occupation	Job	95	54.60%
	Business	61	35.06%
	Students	14	08.05%
	Unemployed	04	02.29%

Table 2: Distribution of sero reactive donors for voluntary vs replacement donations.

	Voluntary	Family/Replacement	Total	P value 2-tail
Total donation	9435	1556	10,991	0.0003
Sero-reactive donors	133	41	174	
Percentage of seroreactive	01.45%	02.89%	01.58%	

From this data P value was significant, P=0.0003(<0.05).

The focus of the study was to identify proportion of 'Notified-Non notified and Responders Non responders.

Table 4: Distribution of notified and non-notified donors who were sero-reactive during the study period.

	Number (n)	Percentage (%)
Total sero-reactive donors	174	
Donors with indeterminate results (not included for further data analysis)	06	-
Total notified sero-reactive donors	123 (Out of 168)	73.21%
Total non-notified sero-reactive donors	45 (Out of 168)	26.79%

Out of 123 Notified Donors, 79 Donors Responders and 44 Donors are non-Responder.

Table 5: Distribution of responded and non-responded sero reactive donors out of total notified donors

	Number (n)	Percentage (%)
Total notified donors	123	
Total responded donors	79	64.23%
Total non-responded donors	44	35.77%

Table 3: Comparative demographic analysis for responders and non-responders

Variable	Responder/Non responder		Total	$\chi 2$	P Value
	Non-responder number	Responder number			
Gender					
Female	0	1	1	0.561	0.453
Male	44	78	122		
Voluntary/Replacement Donor					
Replacement	10	15	25	0.244	0.621
Voluntary	34	64	98		
Occupation					
Job	21	48	69	3.615	0.306
Business	17	26	43		
Students	5	3	8		
Unemployed	1	2	3		
Marital Status					
Married	30	59	89	0.597	0.439
Unmarried	14	20	34		
Education Status					
Under graduate	20	42	62	0.722	0.867
Graduate	18	28	46		
Post graduate	3	5	8		
Uneducated	3	4	7		

From above table, all variables are statistically not significant as P value is >0.05

Table 6: Reasons for non-notified sero-reactive donors

Reasons for non-notified	Number (n)	Percentage (%)
Phone not reachable/not picking up	33	73.33%
Switched off	5	11.11%
Wrong number	2	4.44%
Number not written	5	11.11%
Total	45	Total

Table 7: Reasons for non-responded sero-reactive donors

Reasons for non-responded	Number (n)	Percentage (%)
Will come some other day but has not visited	24	54.54%
Not willing to come	13	29.54%
Out of city/state/country	07	15.90%
Total	**44**	

On responding, reactions of the donors were recorded to know how donors were reacted to the information of sero reactive status given to them.

Table 8: Reactions of responded sero-reactive donors.

Reactions	Number (n)	Percentage (%)
Accepted	61	49.59%
Confused	02	01.64%
Stressed	13	10.57%
Anxious	10	08.13%
Shocked	17	13.82%
Tensed	08	06.50%
Normal	01	00.81%
In denial	11	08.94%
Total	123	

Discussion:

Donor notification is an ethical duty and responsibility of the blood centre towards the donors. A thorough donor notification to sero-reactive donors can help in excluding them from the donor pool. It is essential for early clinical intervention to minimize the risk of disease transmission to close contacts. [15]

Out of 10991 units, 174 units (01.58%) were reactive test results for TTIs among which highest rate of 73 units with syphilis followed by 59 with HBsAg, 38 with HCV, 06 with HIV and 03 with malaria parasite. The prevalence of TTIs among Indian blood donors are reported to be ranging as follows; HBV-0.66% to 12%, HCV-0.5 to1.5%, HIV 0.08% to 3.87% and Syphilis 0.85% to 3.0%. [16, 17]

The study done by Bhutia & Das et al [18] in Sikkim had 01.7 % rate of TTIs in donated units. The study done by Mandal et al [19] also had similar rate of TTIs of 01.92 % in Haryana. The Present study's results were in accordance with both of these studies. The study by Omhare et al [20] had TTIs rate of 02.1% in Kanpur during the year of 2014-15. The study done by Nilam Patel et al. [21] had a TTIs rate of 2.08 % in donated units and this study was also having geographical similarity to the present study & it was conducted for the period of 04 years. These two studies had TTIs rate higher than the present study. The study in the region of West Bengal by the Adhikaryet al [22] had a TTIs rate of 0.42 % which was less as compare to the present study.

Out of those total collection total 174 donors were sero-reactive, it was observed that 70(40.23%) donors were from 18-30 age group, 87(50.00%) donors were from31-50 years age group, 15(08.62%) donors were from 51-60 age group and, 02(01.15%) donors were from 60-65 years age group. Here it was noticed that majority of the reactive donors were form the 31-to-50-year age group, it could have been due to the reason that majority of the donors in the study population were from the same age group, but when compared with the other studies it gave the conclusive evidence same as the present study Out of total collection, 174 donors were sero-reactive from which it was observed that 99.43% (173) donors were male and only 0.57% (01) donor was female, on further evaluation it was observed that out of total 10991 collection male to female ratio was 54:1 that was significantly high as total number of males during study period were 10791(98.18%) and female were only 200(01.82%) which was very less. So out of total female donors only 1 was reactive but the P value for this age distribution in current study was >0.05(0.22), so the findings suggesting that difference of seroreactivity between male and female was statistically insignificant.

Sstudies done by Kaur et al [23] (01.91% were sero-reactive donors among replacement donors vs 0.98 % sero reactive donors among voluntary donors) & Manjusha P Tambse et al [24] (01.97 % were sero-reactive donors among replacement donors vs 01.43 % sero reactive donors among voluntary donors) that proportion of the sero-reactive donors were found more in Family/Replacement donors than voluntary non-remunerated blood donors. In present study out of total voluntary donations, 133(01.40%) were sero-reactive and out of total replacement donations, 41(02.63%) donors were sero-reactive. It can be observed in present study and can be compared with the other studies that proportion of the sero reactivity with replacement donors was

higher than that of voluntary donors. In this study the p value was <0.05(0.0003) which was significant in stating that there were more sero reactivity found in replacement donors than voluntary donors.

It was observed in present study was marital status in the sero-reactive donors and it was noticed that majority 126(72.41%) of the sero-reactive donors were married and 48(27.59%) donors were unmarried. Compared with other studies Manish Raturi et al [25] showed similar results that total number of married were 88(68%) and un married were 41(32%) in the total number of sero-reactive donors. Whereas another study done by Kotwal et al [26] showed that number of sero-reactive married and un married donors were almost similar and rather unmarried donors were bit more than married in the reactive population at 247(53.23%) and 217(46.76%) respectively.

Out of total 174 sero-reactive donors, 06 donors had indeterminate results, so these 06 donors were not included in the list of donor notification. So, further data analysis was done for 168 donors. In present study, 168 reactive donors were subjected to notification (except for 6 donors as discussed above,) via telephonic medium.

A total of 45(26.78%) out of 168 donors, 45 remained not notified/unnotified during the study period. Here it was observed that majority of the donors were either not picking up the phone or their phone were out of network/not reachable. This can be due to majority of the population usually avoids answering to unknown phone number and it was also observed that many of the donors changed their phone numbers. 123(73.21%) donors were able to get notified during the study period by telephonic medium. Out of total notified that is 123 donors 79(64.23%) donors were responded either telephonically or in person, 44(35.77%) donors remained non-responded for various reasons. A study done by Kotwal et al, [26] which had study duration of a year, 15322 total units were collected out of which 03.03% donors were sero-reactive, from those reactive donors they were able to notify 49.4%, from those who got notified 98.2% donors were responded. Similarly, study done by Palai et al, [27] had study period from January 2022 to December 2022 (01 year) &in this duration total collection was 32700, after screening of the collected units, 02.22% donors were tested reactive for TTI markers. From those sero-reactive donors, 68.30%donors were able to get notified and from those notified 70.97% donors responded and visited blood center for further counselling. The notification rates were generally high, with most studies notifying over 60% of the sero-reactive donors. Patel et al [14] had highest notification rate (90.65%), followed by Mandal [19] et al (89.30%). In present study, notification rate was 73.21%.

In different studies, it shows that highest percentage of responded donors were from study done by Kotwal et al. [26] being 98.2%, whereas least percentage of responded donors were observed in study done by Sachdev et al. [28] being 21.6%. In present study responded rate was observed 64.23% of total notified donors It can be observed that studies done by Suman et al, [29] Mandal etal [19] and Agarwal et el [30] showed almost similar responded results of 70.3%, 59.8%, 59.8% in respectively.

In present study during study period total 44(26.78%) donors were non-notified. In majority of the donor's reason for non-notified observed was "Phone not reachable/Not picking up the phone" 18.96% (33) followed by "phone switched off" in 02.87% (05) donors, "number not written" in 02.87% (05) and "wrong information given" in 01.16% (02) donors. Palai et al [27] mentioned reasons for non-notifications phone not reachable: not picking up 24.79% (180):06.885(50) donors respectively for the total 31.68% (230) non-notified donors. Manish Raturi et al [25] and Kotwal et al [26] mentioned only one reason that wrong information given by donors during filling up the donor registration form, were 11.63% (15) and 50.64% (235) respectively.

In present study maximum non-responded donors gave reason that they will visit on some other day on their convenience 19.51% (24) but never responded, followed by 10.57% (13) donors were not willing to come to the blood center or the respective referral clinics. In such donor's majority of those donors gave reaction of denial and were not ready to accept, other proportion were giving reason of either being too busy or cannot visit due to work hours, 05.69% (07) donors gave reasons that they were either out of city/state or country and thus cannot visit at the moment.

During the study, various type of reactions were observed in donors such as 49.59% (61) Accepted, 13.82% (17) Shocked, 10.57% (13) Stressed, 08.94% (11) In denial, 08.13(10) anxious, 06.50% (08) Tensed, 01.64% (02) Confused and 00.81% (01) Normal. The trained and efficient counsellor is required to deal all these emotional reactions. The blood center must take help of effective information, Education and Communication (IEC) materials in a language understandable by the donor forthe abnormal test concerned for each donor along with the offering of competent physician reference if donor asks besides counselling him or her. [14]

Conclusion:

All the sero-reactive status of the donor should be checked thoroughly and if needed by various methods repeated testing via more sensitive and specific method preferably like Chemiluminescence

immunoassay **(**CLIA) or Nucleic Acid Amplification Test (NAT) to avoid false positive rates and to eliminate indeterminant results. Donor demographic details should be carefully collected and addition of some other parameters like taking alternative contact number, email address and social media address should be considered.

Finally, modification in approach to donor notification should be done so that maximum number of donors gets notified and respond.

Limitations:

Limitations of this study were,

- Un availability of more sensitive TTI screening tests like CLIA and NAT,
- Unable to separate 1st time donors and repeat donors,
- Unable to get follow up of all responded donors,
- Other means like door-to-door visit by grass root workers, electronic mail and posts for notification were not used.

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