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Blood donors – The life saviour, as per Kuppuswamy's socio economic scale –who are safest?

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Abstract---Evaluation of TTI (transfusion transmitted infections) are essential for assessing the safety of blood supply and monitoring the efficacy of currently employed screening procedures. Objective: To assess the prevalence of HBV, HCV and HIV among replacement donors and voluntary donor in association with the Kuppuswamy's socioeconomic status. Material and Methods: A retrospective analysis of total 10569 blood donors from Jan2014 to Sep 2015 was conducted at a blood bank in a tertiary care hospital in North India, Teerthanker Mahaveer Medical college and research centre. Donor with hemoglobin (Hb) less than 12.5gm% or known seropositive for TTI were deferred and excluded from the study group. The hemoglobin level was measured by copper sulphate method, samples were screened for: a) HIV-1 and p antigen ELISA kits from Mitra & Co. Ltd, for anti HIV I and II 4th generation Microlisa- HIV Ag and Ab. b) HBsAg- Hepalisac) anti HCV d) Malaria Age) Syphilis. Observation: The prevalence of HBV and HCV was noted to be higher among replacement donors as compared to voluntary donors, while in HIV, the prevalence was noted only in voluntary donors. Total 10,569 blood donors were grouped as per the KSESS, maximum donors in lower middle class III-5789. Maximum TTI positive for voluntary as well as replacement donors were found in class IV i.e. Upper lower class. Maximum seropositivity of HBV and HCV was found in

replacement donors maximum of those were in class IV but for HIV maximum seropositivity was found in voluntary donors in class V. It was also found that there was no voluntary donor in class V instead only replacement donors were found. Conclusion: Our study concluded following two important issues, One, the prevalence of TTI among Voluntary and Replacement donors of different Kuppuswamy's Socio Economic Status Scale, where prevalence of TTI was found more in class IV i.e. Upper Lower Class in both voluntary and replacement donors. No Voluntary donors were found in V class i.e. Lower Class. And second, the highest donation was noted in replacement donors in lower class (IV+V), which are also supposed to be the unaware or paid donors!

Keywords--Replacement donors, Voluntary donors, TTI- Transfusion Transmitted Infections.

Introduction

Blood donation is a major concern to the society as donated blood is lifesaving for individuals who need it. Blood is scarce. *There is shortage of active blood donors to meet the need of increased blood demand. One of the biggest challenges to blood safety particularly in accessing safe and adequate quantities of essential blood component is to enable a wide range of critical care procedure to be carried out in hospitals.* Donated blood can be a saviour for persons who have lost large amounts of blood because of serious accidents, new medical and surgical procedure, civil conflicts and military wars as well as for severely anemic patients because of serious hemolytic diseases or treatment such as cancer therapy. Therefore *accessibility of blood is a critical concern to the society.*

Globally, *higher rate of transfusion transmitted infections (TTI) have been documented among paid donors*^{1,2}. Therefore attempts have been implied to reduce it across the world. The World Health Organization and the council of Europe recommended that blood and blood components should only be collected from voluntary, unpaid repeat donors who can assist in managing blood demand and supply a schedule for transfusion smoothly³. Screening TTI is also essential for blood transfusion safety and for protecting human life⁴. Blood transfusion is a life saving procedure but can cause acute and delayed complications. These complications can be mild or life threatening, therefore meticulous pre transfusion testing and screening for TTI are mandatory⁵. All these transfusion transmitted infections cause prolonged viremia and carrier or be in latent state. These infections also cause fatal, chronic and life threatening disorders.

The TTI's include Human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), syphilis and malaria. To reduce risk of TTI, careful selection of donors is needed so that the blood is safe and is not collected from the people who are likely to be carriers of infectious agents. Evaluation of TTI are essential for assessing the safety of blood supply and monitoring the efficacy of currently employed screening procedures⁶. Poor health infrastructure, lack of health awareness camps, unhygienic life standards and failure to implement

strict norms of screening result in increasing prevalence and incidence of these infections in the population.

Material and Method

A retrospective analysis of total 10569 blood donors from Jan2014 to Sep 2015 was conducted at a blood bank in a tertiary care hospital in North India, Teerthanker Mahaveer Medical college & Research centre. All the potential blood donors were requested to fill questionnaire prepared as per NACO guidelines for donor eligibility. The questionnaire also included information about socio economic status of donor. Donor with hemoglobin (Hb) less than 12.5gm% or known seropositive for TTI were deferred and excluded from the study group. Informed consent was taken from all donors before blood donation.

Sample Collection

The hemoglobin level was measured by copper sulphate method, after which we bleed the donor who have Hb>12.5 gm%. Few milliliters of each donor's blood was dispensed in two small clean test tubes (one tube with EDTA and another , a plain tube) for mandatory screening of the TTI and hemogram, which was done using the automated cell counter. Serum samples were screened for:

- a) HIV-1 and p antigen ELISA kits from 3 Mitra& Co. ltd and for anti HIV I and II 4th generation Microlisa-HIV Ag and Ab.
- b) HBsAg- Hepalisa
- c) anti HCV:- HCV Microlisa, third generation ELIS test kits, with increased sensitivity and specificity having a combination of structural and nonstructural HCV antigens i.e. Core,E1, E2, NS3, NS4 and NS5 were used.
- d) For Malaria Ag: Malaria Ag P.F./Pan SD BIOLINE rapid test kits from SD Bio Standard Diagnostic Private Ltd.
- e) Syphilis: Ultra rapid test strips from con Biotech Co Ltd.

Validation of ELISA was done according to the acceptance criteria laid down by the manufacturer. All reactive samples were tested again before labeling as sero-positive and then discarded according to the guidelines.

Result

Data received was tabulated and statistical evaluation was performed. It was observed that among the total blood donors 10569, most of them were of replacement donors. Percentage wise distribution of TTI in positive donors of Voluntary donors category and replacement donors during study period , it was observed maximum blood donors belonged to upper lower class i.e. IV class (voluntary donors=40 and replacement donors=208) The difference were significantly more in replacement donors as compared to the voluntary donors in III,IV& V Class.

Total 10569 blood donors were grouped as per the KSESS as follows in UPPER CLASS I-484, in UPPER MIDDLE class II-1552, in lower middle class III -

5789, in upper lower class IV -2261, in lower class V- 483. Each class are further grouped in voluntary and replacement donor as shown in Table.

Table 1
Distribution of Voluntary donors and replacement donors in total bleed(10569)

KSESS	Number of bleeds (10569)	Voluntary Bleed(6757)	Percentage(by no of bleeds 10,569)	Replacement Donors(3812)	Percentage(by no of bleeds 10,569)	P Value LS
I	484	1	0.009	0	0	0.772NS
II	1552	13	0.12	9	0.085	0.802NS
III	5789	22	0.20	75	0.70	<0.001S
IV	2261	40	0.37	208	1.96	<0.001S
V	483	0	0	34	0.32	<0.001S

Table 2
Distribution of total donors in relation to replacement and voluntary donors

KSESS	Number of bleeds(10569)	Voluntary Bleed(6757)	Percentage	Replacement Donors(3812)	Percentage	P Value LS
I	484	250	2.4	234	2.2	<0.001S
II	1552	1355	12.9	197	1.9	<0.001S
III	5789	4000	37.8	1789	17.0	<0.001S
IV	2261	1002	9.4	1259	11.9	<0.001S
V	483	150	1.4	333	3.2	<0.001S
P Value LS	Chi-square = 1070.020 with 4 degrees of freedom; P < 0.001S					

In percentage wise distribution of transfusion transmitted infection positive donors , among voluntary donors and replacement donors, during study period it was observed that maximum blood donors were belonged to lower middle class III(V.D.-4000 or 37.8% and R.D. -1789 or 17% out of 5789 donations)

Table 3
% wise distribution of Voluntary Donors and replacement donors in specific KSESS

KSESS	Number of bleeds (10569)	Positive cases of TTI in each class from total bleed	Percentage of TTI positive in total bleed	Voluntary donor positive in each class	Replacement donors TTI positive in each class	Replacement Donors TTI positive percentage (3812)	Voluntary donor positive percentage (6757)	P Value LS
I	484	01	0.21	01	0	0	0.01	0.772NS
II	1552	22	1.42	13	9	0.24	0.19	0.802NS
III	5789	97	1.68	22	75	1.97	0.33	<0.001S
IV	2261	248	10.97	40	208	5.46	0.59	<0.001S
V	483	34	7.04	0	34	0.89	0.00	<0.001S
P Value LS	443.968 with 4 df; P = 0.000			Chi-square = 37.537 with 4 degrees of freedom; P = 0.000				

Maximum TTI positive for voluntary donors was found in class IV > class III > class II > class I > Class V.

And Maximum TTI positive for replacement donors was found in Class IV > Class III > Class V > Class II > class I. and these observations were statistically significant ($P < 0.001S$)

The overall cumulative sero-prevalence was noted to be highest for HCV, followed by HBV and HIV, no sero-prevalence of syphilis and malaria were detected. The prevalence of HBV and HCV was noted to be higher among replacement donors compared to voluntary donor, while in HIV, the higher prevalence was noted in voluntary donors in comparison to replacements

Maximum seropositivity of HBV and HCV was found in replacement donors in each class and maximum in class IV and maximum seropositivity for HIV was found in voluntary donors in class IV and in class III as depicted in table 4 and 5.

Table 4
% wise distribution of TTI in Voluntary donors

KSESS	Total positive	HBV	Percentage	HCV	Percentage	HIV	Percentage
I	484	1	0.2	0	0	0	0
II	1552	6	0.38	7	0.45	0	0
III	5789	11	0.19	10	0.17	1	0.017
IV	2261	17	0.75	22	0.97	1	0.044
V	483	0	0	0	0	0	0
P Value LS		17.596 with 4 degrees of freedom; $P = 0.001S$		32.368 with 4 degrees of freedom; $P < 0.001S$		1.250 with 4 degrees of freedom; $P = 0.870NS$	

Table 5
% wise distribution of TTI in replacement donors

KSESS	Total positive	HBV	Percentage	HCV	Percentage	HIV	Percentage
I	484	0	0	0	0	0	0
II	1552	4	0.25	12	0.77	0	0
III	5789	38	0.65	48	0.82	0	0
IV	2261	91	4.0	138	6.1	1	0.044
V	483	14	2.89	20	4.1	0	0
P Value LS		166.496 with 4 degrees of freedom; $P < 0.001S$		259.652 with 4 degrees of freedom; $P < 0.001S$		3.675 with 4 degrees of freedom; $P = 0.452NS$	

Overall seropositivity of HBV, HCV and HIV was found to be 0.75, 0.95 and 0.044 respectively in voluntary donors and 4.0, 6.1 and 0.044 respectively in replacement donors among total donations. Maximum TTI was found for HCV donation in both voluntary donors and replacement donors. VDRL and Malaria positivity was not found in any of the class.

It is also found that maximum donors positive for HBV, HCV and HIV belongs to Class IV (i.e Upper Lower Class), in both voluntary and replacement donations.

It is also found that there is no voluntary donor in class V but only replacement donors are found in V i.e. Lower Class.

Discussion

Blood transfusion is a significant route of transmission of infectious diseases like HBV, HCV and HIV. These diseases are of great concern because they can cause fatal acute and chronic life threatening disorders, risks may be reduced by the vigorous screening of donors and donated blood. Prevalence of HBV, HCV and HIV among the healthy blood donors or the replacement donors reflect the disease prevalence in the community⁷. Due to limitation in current blood screening practices in developing countries, donation by such individual is a potential threat to recipient⁸.

“A WHO report states that the viral dose of HIV transmission through blood is so large that one HIV positive transfusion leads to death on an average after 2 years in children and after 3-5 years in adults”⁹. Blood donation collected in latent period of infection may be infection despite of negative antibody test¹⁰.

In our study, out of 10569 blood donors, 63.9% (6757) were voluntary donors and 36% (3812) were replacement donors which is similar to the study done by Dr. Shah, et.al¹¹

However, in a study by Makroo, et. Al¹² and arora, et.al¹³ replacement donors constitute the largest group of blood donors in India, similar findings were reported by other studies^{14,15}. In a study of Shah et al, seroprevalence of HIV, HBV, syphilis and HCV were found to be 0.15%, 0.9%, 0.2% and 0.1% respectively. Overall seroprevalence was more in replacement blood donors than that in voluntary blood donors¹¹.

In a study in Haryana by arora, et.al, sero prevalence of HIV, HBV, HCV and syphilis was 0.3%, 1.7%, 1.0% and 0.9% respectively. No voluntary donor was found to be HIV positive. The seroprevalence of hepatitis and syphilis were most in replacement donors as compared to voluntary donors¹³. A study by Singh, et.al showed the prevalence of HBV and anti HCV was 1.8% and 0.5% respectively. 83.6% were replacement donors. The prevalence of HBV and HCV antibody ranged between 1.7-2.2% and 0.25%-0.9% respectively, among the donors¹⁴.

Lathamani, et.al in their study found prevalence of HIV as 0.08%, HBV as 0.5%, HCV as 0.098% and syphilis as 0.09%¹⁶. Garg, et.al in their study found prevalence of HIV as 0.44%, HBV as 3.44%, HCV as 0.25% and syphilis as 0.22%¹⁷. Overall prevalence of HIV was in accordance with Mandal R et.al, U Geethakhshmi et.al, Dhruva G et.al, Sabhharwal R.E, et.al, anand V, Bhakta G, et.al studies which shows prevalence as 0.42%, 0.14%, 0.074%, 0.14% and 0.13% respectively and dissimilar to Raghwanti B et.al study with higher 0.31% prevalence.

In our study, Prevalence of positive transfusion transmitted infections in donors of specific Kuppaswamy's socio-economic status scale in respect of voluntary donors are:-

Class IV (0.37%) > class III (0.20%) > class II (0.12%) > class I (0.009%) > class V (0%).

Prevalence of positive transfusion transmitted infection in donors of specific Kuppuswamy's socio economic status scale in respect of replacement donors are:-

Class IV (1.96%) > class III (0.70%) > class V(0.32%)> class II (0.085%) > class I (0%).

Prevalence of infection in voluntary donors and replacement donors according to Kuppuswamy's socio economic status scale (class IV) are:-

- a) HBV is more in replacement donors (4%) than Voluntary donors (0.75%)
- b) HCV is more in replacement donors (6.1%) than voluntary donors (0.97%)
- c) HIV is common in voluntary donors than in replacement donors (0.044%)

In our study it is found that prevalence of HCV is more in both voluntary donors and replacement donors than other transfusion transmitted infection across the globe, infection caused by hepatitis C virus are a rising public health issue. HCV infections are caused mostly by contaminated blood exposure. It is observed that in many of the HIV infected patient's co-infection of HDV and HCV occur probably due to immunosuppression. Hence, donor selection is of paramount importance. Sero positivity of VDRL and malaria was not similar to variable results of other studies.

Scant positivity for syphilis has been documented in literature among healthy blood donors. Syphilis being a STD is the illness of much concern. The world health organization goal is for all countries to obtain all blood supplies from voluntary unpaid donors by 2020 in accordance with World Health assembly Resolution 2872, which was adopted in 1975. World Health Organisation and the International Federation of Red Cross and Red Crescent Societies has jointly developed a global framework for action to achieve 100% voluntary blood donation. It is designed to provide guidance and support to countries seeking to establish effective voluntary blood donor programmes, phase out family/replacement donations and eliminate paid donations¹⁸.

Prevention of TTI

- 1) Strategies have been extremely effective , but transmission of diseases still occurs, primarily because of the inability of the test to detect the disease in the "window" phase of their infection
- 2) High cost of screening test
- 3) Lack of funds and trained laboratory personnel
- 4) Genetically variant viruses.
- 5) Laboratory testing errors
- 6) Non- sero-converting immune silent or chronic carriers

Conclusion

Out of 10569 blood donors, 402 cases screened positive. Overall prevalence of TTI was 3.82%, *Voluntary donors forms the majority (63.9%) of our study that shows good awareness among the population. In our study prevalence of HBV, HCV, HIV in voluntary donors was 1.52%, 1.59%, 0.061% and in replacement donors was 7.79%, 11.79%, 0.044% respectively. Among transfusion transmitted infections HCV was more common in both voluntary and replacement donors.*

Our study concluded following two important issues,

One, the prevalence of TTI among Voluntary and Replacement donors of different Kuppuswamy's Socio Economic Status Scale, where *prevalence of TTI was found more in class IV i.e. Upper Lower Class in both voluntary and replacement donors. No Voluntary donors were found in V class i.e. Lower Class* And second, among the replacement and voluntary donors which category showed the highest donations and which should be considered the safest among the two.

So, the highest donation was noted by replacement donors in lower class (IV+V), which are also supposed to be the unaware or paid donors!

Hence, the maximum Donation was by Replacement donors and at the same time those with maximum TTI positivity in Lower Class of Kuppuswamy's socio economic status scale eventually forcing us to think over... -- Among Voluntary and Replacement Donors who are The Safest?-----The one who are Ignorant, unaware and selling the blood or the ones who Volunteer to lead an aware life and Save the Life of the needy Unconditionally !

Recommendations

- 1) To ensure the risk of infections non- remunerated repeat voluntary donor services need to be instituted.
- 2) The emphasis must also be laid on voluntary risk reduction, which will require increased awareness and change in the attitude of people.
- 3) Sterile aseptic precaution should be followed by medical staff while collecting and performing test.

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