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Is there a need to phase out replacement blood donors by voluntary blood donors in hospital based blood transfusion services?

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Abstract:

BACKGROUND: Providing safe blood for transfusion is a responsibility of every blood bank. Screening for transfusion-transmissible infections (TTI) is one of the ways to ensure safety of blood and its products. Prevalence of TTI varies in different countries. It is low in developed countries whereas it is higher in developing countries.

AIMS AND OBJECTIVES: This study was carried out to assess percentage of blood collected from the first-time voluntary blood donors (VBD) and family/replacement donors (RD) and to assess safety of RD by comparing seroprevalence of TTI among voluntary and RD.

MATERIALS AND METHODS: Over 1 year, donors were studied for the type of donation (voluntary or replacement) made at our blood bank. All donors were screened for human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), syphilis, and malaria. Comparison of the prevalence of TTI among voluntary and RD was done by entering data into Microsoft Excel 2007 software and using Chi-square tests.

RESULTS: Out of total 850 first-time donors, voluntary donors were 109 (12.82%) and RD were 741 (87.18%). Overall seroprevalence of HIV, HBV, HCV, syphilis, and malaria was 0, 23 (2.70%), 12 (1.41%), 7 (0.82%), and 0, respectively. Prevalence of TTI among voluntary donors was very low. All donors were seronegative HIV and malaria. Prevalence of HBV, HCV, and syphilis was higher in RD.

CONCLUSION: Data highlight that RD contributed major source of blood supply in hospital-based blood transfusion services and the prevalence of TTI was higher among them in comparison to first-time voluntary donors. Thus, efforts should be made to increase the number of VBD.

Keywords:

Hepatitis B virus, hepatitis C virus, human immunodeficiency virus, India, replacement donors, voluntary blood donors

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Introduction

Blood transfusion services form an integral part of any health-care system and it is responsibility of each nation to ensure adequate supply of safe blood for transfusion. Every blood transfusion has a risk of transmitting blood-borne infections to its recipient. By studying overall prevalence of transfusion-transmissible infections (TTI) among donors, safety of blood and blood

products can be accessed. According to the World health organization (WHO) report, risk of transmitting TTI was found to be higher in countries which are dependent on family/replacement or paid donors.^[1] The WHO developed a plan of action with a vision to achieve 100% voluntary nonremunerated blood donation throughout the world to reduce the risk of TTIs and provide adequate safe blood for transfusion.^[2]

Recently studies from Africa, where replacement donors (RD) form a major

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source of blood supply (75%–80%), found that RD can be considered as good alternative to altruistic/community blood donors in low-income group countries since cost of collecting blood from RD is cheaper and also blood collected from RD showed no significant difference in the prevalence of human immunodeficiency virus (HIV) and hepatitis as compared to voluntary donors.^[3,4] In Brazil, voluntary donors showed higher prevalence of HIV as compared to RD.^[5] As opposed to developed countries, risk of TTI among first-time voluntary donors in developing nations was found to be same or higher as compared to RD.^[5,6]

In India, National Blood Policy has been formed which focuses on phasing out RD and to achieve 100% voluntary blood donation.^[7] In 2008, India reported increase in the number of voluntary donors from 3.6 million in 2007 to 4.6 million in a report submitted to the WHO for global data on blood safety.^[8] Various studies from different parts of India indicate that many blood banks are still dependent on RD to maintain adequate stock.^[9-12] This indicates that in India implementation of national blood policy is not uniform since blood transfusion services are mainly hospital based and highly decentralized.

In India, it is mandatory to screen donors for HIV 1 and 2, hepatitis B virus (HBV), hepatitis C virus (HCV), syphilis, and malaria, as per the guidelines of the ministry of health and family welfare, under the Drug and Cosmetic Act 1945.^[13]

The present study was carried out with aims to assess percentage of blood collected from first-time voluntary and RD and to analyze safety of RD by comparing the prevalence of transfusion-transmissible infectious disease markers among first-time voluntary and RD.

Materials and Methods

This was a prospective cohort study conducted over 1 year from January 2016 to December 2016, in the blood bank, Department of Pathology, Private Tertiary Care Hospital and Medical College, Uttar Pradesh, North India. This study was approved by hospital's Ethical Committee. All first-time apparently healthy donors above 18 years and below 60 years of age, who fulfilled donor selection criteria, were included in the study. Paid/professional donors were identified and excluded from the study. This study was conducted at a private institution, so voluntary donation was done only at blood bank since in India, private institutes are not allowed to organize community-based camps.

Donors were divided into following categories:

1. Voluntary blood donors (VBD): Nonremunerated donors who donated blood on his/her free will

without expecting anything in return either in form of cash or kind. They were further subdivided into following two categories:

- Repeat VBD: VBD who donated blood more than once at our blood bank
 - First-time VBD: VBD who donated blood for the first time at our blood bank. Only first-time VBD were included in the study.
2. RD: Apparently healthy donors who were either friends or relatives of the patients and donated blood as per the requirement of their patients without being paid either in cash or kind.

All donors were screened for five transfusion-transmissible infectious agents - HIV, HBV, HCV, syphilis, and malaria by collecting plasma from the pilot tube attached to the blood bag.

ELISA test was applied for detecting anti-HIV-1 and HIV-2, hepatitis B surface antigen (HBsAg), and anti-HCV using the following kits supplied by J Mitra and Co. Pvt. Ltd.:

1. HEPALISA: A third-generation microwell ELISA test used for detecting HBsAg
2. MICROLISA-HIV: Microwell ELISA test based on indirect ELISA, used for detecting antibodies against envelope antigens gp41, C-terminus of gp120 for HIV-1 and gp36 for HIV-2
3. HCV MICROELISA: A third-generation microwell ELISA test detects antibodies against HCV (anti-HCVs) using combination of antigen with the sequence of both HCV structural and nonstructural antigen, that is, CORE, E1, E2, NS3, NS4, and NS5.

All procedures were carried out as per the guidelines provided by the manufacturer. Known positive and negative controls were run with each test.

Repeat test was performed for all the positive samples using same ELISA test kits. Samples that were positive on repeat testing were labeled as positive for respective TTI and were placed separately under discarded blood units.

Screening for syphilis was done using syphilis rapid card test supplied by Beacon diagnostic Pvt Ltd., It detects TP antibody (IgA, IgM, and IgG) using immune chromatography principle.

Test for malaria was done by malascan plus rapid card test supplied by Zephyr biomedical. It is based on the principle of immunochromatography. It detects the presence of Pan malaria specific pLDH as well as Plasmodium falciparum specific histidine-rich protein (Pf. HRP-2).

Blood bags that were positive for any of the five TTI were properly discarded.

Statistical analysis

Data entry and analysis were carried out using Microsoft Excel Spreadsheet (version 2007) and seroprevalence of HIV, HBsAg, HCV, and Syphilis was derived. Prevalence of TTIs among replacement and voluntary donors was compared using Chi-square test.

Results

During the study period of 1 year, from January 2016 to December 2016, data were collected from total 850 apparently healthy VBD and RD (VBD: 109 [12.82%], RD: 741 [87.18%]). A total number of VBD was significantly lower as compared to RD ($P = 0.0001$).

Number of male donors in both categories of VBD and RD was significantly higher than the female donors [Table 1].

A total number of 42 (4.94%) donors were tested positive for TTI. Overall prevalence of HIV, HBV, HCV, syphilis, and malaria was zero, 23 (2.70%), 12 (1.41%), 7 (0.82%), and 0, respectively. HBV was most prevalent TTI.

On comparing the prevalence of TTI among VBD and RD, prevalence of HBV in RD was found to be significantly higher than VBD ($P = 0.0021$). Prevalence of HCV and syphilis was also higher in RD than VBD, but P value could not be derived [Table 2].

On comparing the prevalence of TTI among male and female donors it was found that prevalence of HBV and HCV was higher among male donors while the prevalence of syphilis was higher in female donors. As number of female donors and prevalence of TTI in them was very low, P value was not calculated [Table 3].

Table 1: Sex-wise distribution of voluntary blood donors and replacement donors

VBD (n=109)			RD (n=741)		
Male, n (%)	Female, n (%)	P	Male, n (%)	Female, n (%)	P
79 (72.48)	30 (27.52)	0.0001	721 (97.30)	20 (2.70)	0.0006

VBD = Voluntary blood donors, RD = Replacement donors

Table 2: Comparison of prevalence of transfusion-transmissible infections among voluntary blood donors and replacement donors

TTI	VBD (n=109), n (%)	RD (n=741), n (%)	P
HIV	0	0	NA
HBV	1 (0.91)	22 (2.97)	0.0021
HCV	0	12 (1.62)	NA
VDRL	0	7 (0.94)	NA
Malaria	0	0	NA

TTI = Transfusion-transmissible infections, VBD = Voluntary blood donors, RD = Replacement donors, HIV = Human immunodeficiency virus, HBV = Hepatitis B virus, HCV = Hepatitis C virus, VDRL = Venereal disease research laboratory, NA = Not available

Discussion

The most effective way to reduce the prevalence of TTI is self-deferral by donors who find themselves ineligible to donate blood. It is hypothesized that family/RD may hide information related to their health condition or any high-risk behavior due to fear of letting down family members or pressure to save their patient's life, which increases the risk of TTI.^[14] Furthermore, it has been observed that in case of emergency patient's relatives may resort to unethical practice of obtaining blood from paid donors by posing them as friend or relatives which further increases the risk of TTI.^[15]

Percentage of voluntary and replacement donors

In North India, proportion of voluntary donors varies from 9.1% to 52.3%.^[16] In the present study, majority of donors were RD ($n = 741$, 87.18%) which is comparable to studies from North India by Awasthi *et al.*^[12] (85.19%) and Singh *et al.*^[17] (82.4%). Higher percentage of RD was also reported by a study from Central India by Yadav *et al.*^[10] (92%) and by Chatteraj *et al.*^[11] from Western India.

In contrast to our findings, a study from North India by Arya *et al.*^[18] reported that majority of the blood donors were voluntary donors (87%). Similar finding was also reported by studies from Western India by Patel *et al.*^[15] and Shah *et al.*^[19] as well as by Khamankar *et al.*^[20] from Central India.

Although our national blood policy aims at achieving 100% voluntary blood donation, still significantly large amount of blood is collected from RD in various parts of India. In India, up to November 2012, there were 2545 licensed blood banks out of which 1564 (61.5%) were private blood banks and the remaining 981 (38.5%) were government blood banks.^[21] Furthermore, in India, private institutions are not allowed to conduct voluntary blood donation camps outside the blood bank campus whereas government institutions can organize community-based voluntary blood donation camps. According to the strategic management information system data of National AIDS Control Organization in 2012–2013, percentages of voluntary donors were 73%, out of which majority of voluntary donations were done at community-based camps organized outside the blood banks.^[21]

The present study was conducted at blood bank of a private tertiary care hospital whereas Arya *et al.*,^[18] Patel *et al.*,^[15] and Shah *et al.*^[19] carried out their work at government-run blood bank. Arya *et al.*^[18] reported increase in a total number of voluntary donors during their study period due to increase in number of community-based camps. In community-based camps, people are motivated by number of social factors and

Table 3: Sex-wise distribution of transfusion-transmissible infections among voluntary blood donors and replacement donors

TTI	VBD (n=109)		RD (n=741)		Total (n=850)	
	Male (n=79), n (%)	Female (n=30), n (%)	Male (n=721), n (%)	Female (n=20), n (%)	Male (n=800), n (%)	Female (n=50), n (%)
HIV	0	0	0	0	0	0
HBV	1 (0.91)	0	22 (2.97)	0	23 (2.88)	0
HCV	0	0	12 (1.62)	0	13 (1.63)	0
VDRL	0	0	6 (0.81)	1 (5)	6 (0.75)	1 (2)
Malaria	0	0	0	0	0	0

TTI = Transfusion-transmissible infections, VBD = Voluntary blood donors, RD = Replacement donors, HIV = Human immunodeficiency virus, HBV = Hepatitis B virus, HCV = Hepatitis C virus, VDRL = Venereal disease research laboratory

feel more comfortable in familiar surroundings to donate blood.

Sex-wise distribution of donors

In the present study, number of male donors was significantly higher than female donors. Similar observation was reported by studies from different parts of India.^[9-10,18-20]

Whereas studies from developed countries reported that percentages of female donors were more than male donors.^[22,23] Studies have shown that though women are more motivated to be a voluntary donor, actual number of blood donation done by them is less. This can be explained by high deferral rate among women due to low hemoglobin.^[24,25]

Prevalence of human immunodeficiency virus, hepatitis B virus, hepatitis C virus, syphilis, and malaria among all donors

In the present study, HBV was found to be the most prevalent TTI with a prevalence rate of 2.7% which is comparable to other studies from North India by Awasthi *et al.*^[12] (1.82%), Arya *et al.*^[18] (1.60%), and Kaur *et al.*^[26] (1.7%) as well as studies from Central India by Yadav *et al.*^[10] (1.77%) and Khamankar *et al.*^[20] (3.2%). It is higher as compared to studies from Western India by Patel *et al.*^[15] (0.85%) and Shah *et al.*^[19] (0.97%).

In the present study, HIV seropositivity in all donors was zero. Very low prevalence of HIV among donors was reported by Awasthi *et al.*^[12] (0.1%) and Arya *et al.*^[18] (0.1%) from North India, by Yadav *et al.*^[10] (0.14%) from Central India, and Shah *et al.*^[19] (0.16%) from Western India. While Khamankar *et al.*^[20] from Central India reported higher prevalence rate of HIV (0.92%) among donors. In the present study, zero seropositivity of HIV among donors can be explained by strict donor selection criteria followed at our blood bank and paid/professional donors posing as RD were identified and excluded from the study.

Prevalence of HCV in the present study was 1.41% which is higher as compared to other studies from different part of India which reported the prevalence of HCV varying

from 0.09% to 0.9%.^[10,15,18-20,26,27] Yadav *et al.*^[10] reported that wide variations of HCV seroprevalence reported by several studies from India might be due to variable sensitivity and specificity of different ELISA kits used for testing.

In the present study, prevalence of syphilis was 0.82% which is comparable to studies from North India by Arya *et al.*^[18] (0.89%) and Kaur *et al.*^[26] (0.7%) while it is higher as compared to studies by Awasthi *et al.*^[12] (0.13%) from North India, Patel *et al.*^[15] (0.25%) and Shah *et al.*^[19] (0.23%) from Western India, Khamankar *et al.*^[20] (0.44%) and Yadav *et al.*^[10] (0.04%) from Central India, and Pallavi *et al.*^[27] (0.28%) from South India.

In the present study, all donors were tested negative for malaria which is comparable to studies done by Yadav *et al.*^[10] and Pallavi *et al.*^[27] Studies from North India by Awasthi *et al.*^[12] and Arya *et al.*^[18] reported its prevalence to be 0.04% to 0.2%. Screening for malaria is easier as compared to other TTIs as donors easily give a history of suffering from malaria and self-defer, since there is no social taboo associated with it.

Comparison of prevalence of transfusion-transmissible infections among voluntary and replacement donors

In the present study, seropositivity for HIV among both voluntary and RD was zero. Makroo *et al.*^[9] found no significant difference in the prevalence HIV among voluntary and RD. Statistically significant higher prevalence of HIV among RD was reported by Arya *et al.*^[18] Patel *et al.*^[15] and Shah *et al.*^[19] While Khamankar *et al.*^[20] found higher prevalence of HIV among voluntary donors as compared to RD.

In the present study, prevalence of HBV among RD was significantly higher ($P = 0.0021$) as compared to voluntary donors. Similar finding was reported by Makroo *et al.*^[9] Patel *et al.*^[15] and Arya *et al.*^[18] Studies by Shah *et al.*^[19] and Pallavi *et al.*^[27] also reported increased seropositivity of HBV in RD but data on P value was not provided. While Khamankar *et al.*^[20] found higher prevalence of HBV among RD which was not statistically significant.

In the present study, prevalence of HCV and syphilis was higher in RD but *P* value could not be derived. Studies by Makroo *et al.*^[9] and Arya *et al.*^[18] reported statistically significant (*P* < 0.05) higher prevalence of HCV in RD, whereas Patel *et al.*^[15] reported higher prevalence of HCV among RD which was not statistically significant. Higher prevalence of HCV among RD was also reported by Khamankar *et al.*^[20] and Pallavi *et al.*^[27] but *P* value was not provided.

Studies by Makroo *et al.*,^[9] Patel *et al.*,^[15] and Arya *et al.*^[18] reported higher prevalence of syphilis among RD which was statistically significant (*P* < 0.05). Studies by Kaur *et al.*,^[26] Shah *et al.*,^[19] Khamankar *et al.*,^[20] and Pallavi *et al.*^[27] also reported higher prevalence of syphilis in RD but data on *P* value was not provided.

In the present study, all donors in both categories were negative for malaria. Similar finding was reported by Pallavi *et al.*^[27] In a study by Arya *et al.*,^[18] no statistically significant difference was found in the prevalence of malaria among voluntary and RD.

Studies from neighboring developing countries of Nepal, Bangladesh, and Pakistan also reported that RD forms a major source of blood supply and they found higher prevalence of TTI among RD.^[28-30]

Conclusion

Thus, in the present study, total number of RD was significantly higher and prevalence of HBV, HCV, and syphilis was among them was higher as compared to first-time voluntary donors. All donors were seronegative for HIV which is a unique finding in the present study. Major limitation of the present study was less number of data collected during the study period. In developing countries where blood transfusion services are mainly hospital based, onus of providing blood for transfusion falls on patients' relatives. To provide adequate safe blood for transfusion efforts are required on larger scale such as centralizing blood transfusion services and increasing number of community-based camps. Meanwhile, in hospital-based blood transfusion services where number of RD is significantly higher, efforts should be made to identify healthy RD and they should be motivated to become regular voluntary donors by providing proper donor education and counseling.

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Conflicts of interest

There are no conflicts of interest.

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