

International Journal of Recent Scientific Research

International Journal of Recent Scientific Research Vol. 6, Issue, 8, pp.5901-5904, August, 2015

RESEARCH ARTICLE

SEROPOSITIVITY OF TRANSFUSION TRANSMISSIBLE HBV INFECTIONS AMONG VOLUNTARY AND REPLACEMENT DONORS

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ARTICLE INFO

ISSN: 0976-3031

Article History:

Received 2nd, July, 2015 Received in revised form 10th, July, 2015 Accepted 4th, August, 2015 Published online 28th, August, 2015

Key words:

Mobile genetic elements, IRAP-PCR, polymorphic information content (PIC), gene pool "standard" of breed.

ABSTRACT

Introduction: Blood transfusion is liquid organ transplantation. Many infectious diseases are likely to be transmitted by blood transfusion. Transfusion transmissible infectious agents are among the greatest threats to blood safety for recipient. According to NACO guidelines, all mandatory tests should be carried out and whole blood or components from any unit that tests positive should be discarded.

Voluntary non-remunerated blood donation is the source of the safest blood supply to the transfusion service. In the Indian setup where voluntary donations are fewer and poorly structured, safety of blood could still compromised.

Hence this study was undertaken to find out the to find and compare seroprevelence of HBsAg transfusion transmissible infection among voluntary and replacement blood donors and know demographic profile of donors with respect to age and sex.

Materials And Methods: The study was done in Blood bank of S.N Medical College, Bagalkot from July 2012 to June 2013. The blood units were collected from voluntary and replacement donors.

Sample collection: Two ml of blood sample was collected in labeled pilot tube at the time of collection of blood from donor tubing of blood bag the sample was further centrifuged at 3500 rpm for 5 minutes to obtain clear non hemolyzed serum. The samples were tested for HBV. Any donor meeting all criteria's for eligibility of blood donation as mentioned in SOP, Blood Bank, S. N .Medical College, Bagalkot. Any donor not fulfilling the criteria was excluded.

Screening Test for Hepatitis B was done by HEPACARD and confirmed by HEPAELISA.

Results: A total number of 8187 donor's blood units were screened. Replacement donors constituted 91.13% and remaining 8.7% were voluntary donors. The donor's age ranged between 18-60 years with majority (73.96%) in the range of 18-35 years. 97.39% donors were males and female donors constituted only 2.61%. The seroprevelence of HBsAg was 2.90% in total donors. The seroprevelence in replacement donors (3.17%) was more than voluntary donors (0.14%). Out of the 238 HBsAg positive donors 237 were males

Conclusion: The risk of TTI cannot be eliminated completely even after mandatory testing of blood units because of risk associated with donations during window period. With advent of nucleic acid amplification techniques (NAT) western countries have decreased the risk of TTI to a major extent.

Our study showed that the seroprevelence of HBV was more in replacement donors compared to voluntary donors. These results—suggest that voluntary blood donor's services are needed. There should be an establishment of nationally coordinated blood transfusion services

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INTRODUCTION

Blood transfusion is liquid organ transplantation. Many infectious diseases are likely to be transmitted by blood transfusion. Transfusion transmissible infectious agents are among the greatest threats to blood safety for recipient. ²

The safe blood transfusion begins with a healthy donor in the transfusion chain including the careful consideration of donor eligibility criteria, adherence to rigorous rules during donation, processing and storage, the optimal implementation of available resources.³ Preventing transmission of these

infectious diseases through blood transfusion presents one of the greatest challenges of transfusion medicine.²

According to NACO guidelines, all mandatory tests should be carried out on donor's blood samples for human immunodeficiency virus (HIV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), syphilis and malaria. The whole blood or components from any unit that tests positive should be discarded. Voluntary non-remunerated blood donation is the source of the safest blood supply to the transfusion service. In the Indian setup where voluntary donations are fewer and poorly structured, safety of blood could still compromised. 4

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Infectious agents that pose a serious threat to transfusion recipients are those that persist in the circulation of asymptomatic individuals who are healthy enough to be blood donors.^{3,4}

Hence this study is undertaken to find out the to find and compare seroprevelence of HBsAg transfusion transmissible infection among voluntary and replacement blood donors and know demographic profile of donors with respect to age and sex.

MATERIALS AND METHODS

The study was done in Blood bank of S.N Medical College, Bagalkot from July 2012 to June 2013. The blood bank has an average annual collection of 8000 units of blood from healthy blood donors. The blood units were collected from voluntary and replacement donors.

Sample collection: Two ml of blood sample was collected in labeled pilot tube at the time of collection of blood from donor tubing of blood bag the sample was further centrifuged at 3500 rpm for 5 minutes to obtain clear non hemolyzed serum. The samples were tested for HBV.

Inclusion Criteria

Any donor meeting all criteria's for eligibility of blood donation as mentioned in SOP, Blood Bank, S. N .Medical College, Bagalkot .

Exclusion Criteria

- Any donor not meeting all criteria's for eligibility of blood donation
- Any eligible donor having any kind of reaction during the blood donation procedure will be excluded from the studies.
- 3. Any defects found in the sample collected (Bag leakage, improper maintenance of cold chain during transportation, preservation defects, temperature defects, any undesirable physical and biochemical changes in stored blood).
- 4. Screening Test for Hepatitis B was done by HEPACARD and confirmed by HEPAELISA.

RESULTS

During the study period total 8187 donors blood units were screened for HBsAg. The donor age ranged from 18-60 yrs, majority (73.96%) in the age group of 18-35 yrs. Out of the 8187 blood donors, 7461 (91.13%) were replacement donors and remaining 726 (8.87%) were voluntary donors as shown in table 1.

Table No.1 Showing Type of blood donors

Type of donor	No. of screened blood units	Percentage
Voluntary	726	8.87%
Replacement	7461	91.13%
Total	8187	100%

Out of the total 8187 donors, males constituted 7974 (97.39%) and only 213 (2.61%) donors were females. Maximum donors were between the age group of 18-35 years constituting 73.96% as depicted in table 2

Table No 2 Age distribution of blood donors

Age in years	No. of donors	Percentage
18-25	2845	34.75%
26-35	3235	39.50%
36-45	1482	18.10%
46 and above	625	7.70%
Total		100%

Out of the total 8187 screened blood units 288 units were seropositive for transfusion transmissible infections (TTI), giving prevalence rate of 3.51% out of this 286 were replacement donors and remaining 2 were voluntary donors – table 3.

Table No.3 Seroprevelence of TTI 1in total donors

Total No. donors	No. of positive donors	Serporositivity (%)
No. of positive donors	288	3.51
No. of negative donors	7899	

Seroprevelence of HBs Ag in blood donors

Out of the total 8187 blood donors 238 (2.90%) were positive for HBsAg. Out of 238 positive donors, 237 were replacement donors and only one voluntary donor. The seroprevelence of HBs Ag in total donors was 2.90% as depicted in table 4.

Table No.4Seroprevalence of HBsAg in total donors

Total Donors	No. of positive	Seroprevelence
8187	238	2.90%

The seroprevelence of HBsAg among voluntary donors and replacement donors was 0.14% and 3.17% respectively. However the difference was statistically not significant as depicted in table 5

Table No 5 seroprevelence of HBsAg in different donor categories.

Donor category	No of screened blood units	No. of seropositive units	Percentage
Voluntary	726	1	0.137%
Replacement	7461	237	3.17%
Total	8187	238	2.90%

Age Distribution: out of the 238 HBsAg positive donors majority (187) were in the age group of 18-35 years as shown in table 6.

Table No 6 Age wise distribution of HBsAg positive donors

Age range (yrs)	No. of Positives	Percentage
18-25	79	33.20%
26-35	108	45.40%
36-45	45	18.90%
46 and above	6	2.50%
Total	238	100%

Out of the 238 seropositive donors for HBsAg, 237 were males and female donor

Marital status in HBsAg positive donors

Out of the 238, HBsAg positive donors 174 were married and remaining 64 were unmarried.

Geographical distribution: out of the total 238 positive HBsAg cases 132 (55.5%) were from urban area and remaining 106 (44.5%) were from rural area.

DISCUSSION

Over the past decades the risk of transfusion transmissible infections (TTI) has declined dramatically due to the advent of CLIA, NAT and fourth generation ELISA techniques, Strict FDA rules and increased public awareness.. But same may not hold good for the developing countries.⁵ The National Policy for Blood Transfusion Services in our country is of recent origin and the transfusion services are hospital based and fragmented.²

The donor's age ranged from 18-60 yrs. Similar age range was observed in other studies - table 7. In our study 97.39% donors were males while only 2.61% donors were females. This could be explained on the basis that Indian women have a very high incidence of anemia, especially in the child bearing age and hence are likely to face disqualification while being screened for blood donation.

In the present study replacement donors, constituting 91.13% and only 8.87% were voluntary donors. This is comparable to study done by Kakkar *et al* (94.7%)⁴, Srikrisna *et al* (98.5%)¹ and Singh *et al* (84.5%)⁶.

In contrast predominance of voluntary donors was noted by Bhattacharya *et al* (94.6%)⁷ and Pallavi *et al* (64.78%)⁸.

It is shown that replacement donors constitute the largest group of blood donors in India reflecting lack of awareness among the general population, the presence of misconceptions and fears associated with donating blood, the lack of health education and the indifference attitude of the health sector.

Table No 7 Percentage of voluntary and replacement donors in different studies.

Authors	Voluntary donors (%)	Replacement donors (%)
Srikrishna et al ¹	1.5%	98.5%
Kakkar et al ⁴	5.3%	94.7%
Singh et al ⁶	15.5%	84.5%
Bhattachary et al7	94.6%	5.4%
Pallavi et al ⁸	64.78%	35.22%
Present study	8.87	91.13%

Hepatitis B virus is the most important causative agent of transfusion associated hepatitis. India has been placed in the intermediate zone for prevalence of hepatitis B by WHO (2 - 7%)

In previous Indian studies by Srikrishna *et al* (1999)¹, Sonawane *et al* (2003)¹⁰ and Singh *et al* (2004)⁷ observed the seroprevelence of HBsAg among the blood donors was 1.86%, 4.07% and 1.8% respectively. They concluded that voluntary donors are comparatively safe donors table 8.

Bhattacharya *et al* (2007)⁷ observed a statistically significant increase in seroprevelence of HBsAg over a period of 2 years among the blood donors in Kolkata (Eastern India). The observed seroprevelence of HBsAg in 2005 was 1.66%.

In the present study out of the total 8187 screened blood units 238 were seropositive for HBsAg with 01 being voluntary donors and 237 being replacement donors, giving the seroprevelence of 0.137% and 2.90% among voluntary and replacement donors respectively. However the difference in seroprevelence among voluntary and replacement donors was statistically not significant.

Table No 8 Comparision of HBsAg seroprevelence among donors in different studies

Authors (yrs)	Voluntary	Replacement	Total
Garg et al (1998) ⁹	2.57%	3.52%	3.44%
Srikrishna et al ¹ (1999) ¹	-	-	1.86%
Sonawane <i>et al</i> (2003) ¹⁰	2.78%	4.84%	4.07%
Sharma <i>et al</i> (2004) ¹¹	0.9%	1.26%	1.08%
Gupta <i>et al</i> (2006) ⁷	0.77%	2.35%	1.86%
Sawake <i>et al</i> (2008) ¹¹	-	-	2.90%
Bhattacharya et al (2007) ⁷	-	-	1.66%
Singh <i>et al</i> (2009) ⁶	0.42%	0.65%	0.62%
Arora et al (2010) ¹²	-	-	1.70%
Farnandez et al $(2010)^{13}$	-	-	0.34%
Pallavi <i>et al</i> (2010) ⁸	-	-	1.27%
Present study			

The overall seroprevelence HBsAg in our study (2.90%) correlated well with those of Sawake *et al* $(2008)^{11}$ while seroprevelence in voluntary donors was 0.13%, is similar to those of Singh *et al* $(2009)^6$. The seroprevelence among replacement donors (3.17%) in our study correlates with that of Garg *et al* $(1998)^9$.

The difference in the seroprevelence of HBsAg among voluntary and replacement donors in the present study suggests, the need for the concrete and non remunerated voluntary blood donors base in India.

The seropositive HBsAg donors were given post test counseling and enquired about the past H/o of jaundice they were advised to undergo liver function tests and serology marker for HBeAg to know the status of their infectivity. They have been also advised about screening of their family members for HBsAg and immunization.

India is still in the intermediate prevalence zone for HBsAg (2-7%) and estimated to be a home to over 40 million HBsAg carriers, despite the fact that a safe and effective vaccine was available since 1982. This is because hepatitis B vaccination was not a part of our national immunization programme till recently.

CONCLUSION

The risk of TTI cannot be eliminated completely even after mandatory testing of blood units because of risk associated with donations during window period. With advent of nucleic acid amplification techniques (NAT) western countries have decreased the risk of TTI to a major extent.

Our study showed that the seroprevelence of HBV was more in replacement donors compared to voluntary donors. These results suggest that voluntary blood donors services are needed. There should be an establishment of nationally coordinated blood transfusion services

With the implementation of strict donor selection criteria, use of sensitive screening tests, and establishment of strict guidelines for blood transfusion, it may be possible to reduce the incidence of TTI in Indian scenario.

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How to cite this article:

Keshav.R.Kulkarni et al., Seropositivity Of Transfusion Transmissible Hbv Infections Among Voluntary And Replacement Donors. International Journal of Recent Scientific Research Vol. 6, Issue, 8, pp.5901-5904, August, 2015
