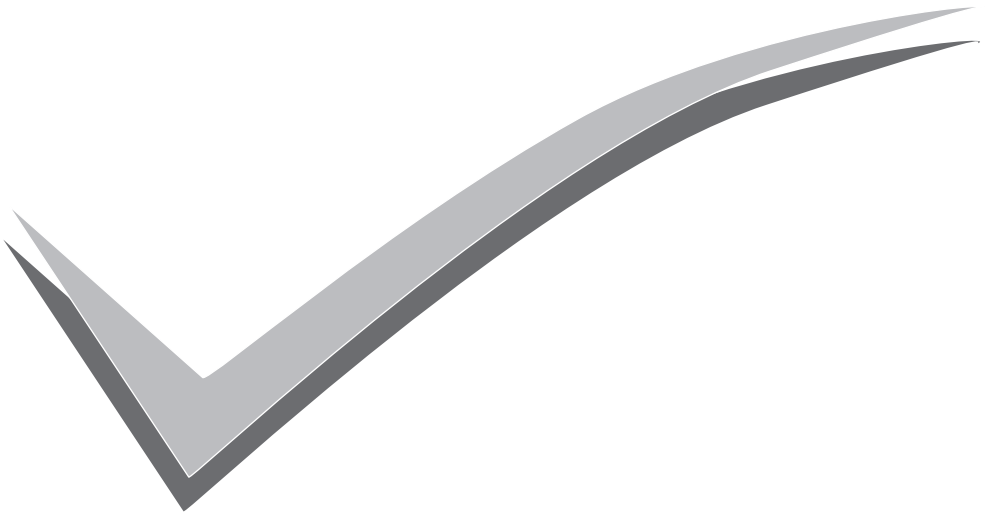
Performance Evaluations



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PREVALENCE OF TRANSFUSION TRANSMITTED DISEASES AMONG BLOOD DONORS AT A TERTIARY CARE TEACHING HOSPITAL IN INDIA

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Voluntary donors, Replacement donors, Blood transfusion, transfusion transmitted infection [TTI], Hepatitis B virus [HBV], Hepatitis C virus [HCV], Human immunodeficiency virus [HIV].

ABSTRACT

Aim of this study is conducted to evaluate the sero-prevalence of HBV, HCV, HIV, Syphlis and Malaria among blood donors in Bhopal along the duration of 3.5 years. All blood units received from replacement as well as voluntary blood donors were selected for the study at Chirayu medical college and Hospital associated blood bank , Bhopal, M.P., India during the period from February 2011toJuly 2014. Blood transfusion has become an essential part of treatment in number of medical or surgical emergencies. It is also true that blood transfusion is an important mode of transmission of infection to recipients. Present study was planned to know the prevalance of such infections among voluntary as well as replacement donors of this area. Screening of blood units was done by enzyme-linked immunosorbent assay (ELISA) method for HIV, syphilis, malaria and hepatitis B and C. HIV testing was done using third generation ELISA kits. Syphilis was tested by latex agglutination assay and malaria was tested by using ELISA method (for malaria antigen). Any sample found reactive was retested for confirmation. Seropositive units were discarded. All records were collected from blood bank records maintained as per Drugs and Cosmetic Act of India. A 3.5 year retrospective study carried out at blood bank of Chirayu medical college Bhopal Madhya Pradesh. Study includes record of 2842 voluntary and 6718 replacement donors attending blood bank from February 2011 to July 2014. Overall TTIs prevalence in voluntary and replacement donors was 2.81% and 4.15% respectively in our study. Seroprevalence of HIV, HBV, HCV, Syphilis and Malaria was found to be 0.07%, 0.35%, 0.10%, 0.35%and 0.00% in voluntary blood donors while 0.11%, 2.67%, 0.47%, 1.78% and 0.00% being the seroprevalence of HIV, HBV, HCV , syphilis and Malaria in replacement blood donors. It is clear from these data that seroprevalence of HIV, HBV, HCV and syphilis in replacement blood donors is higher than that in voluntary blood donors.The highest seroprevalence was found in age group of 18-30(2.06%). A noticeable numbers of replacement donors harbor HIV, HBV, HCV and Syphilis infections. So strict selection of donors and proper testing of donor's blood by using standard method is highly recommended to ensure safety for recipient. Efforts should be made to increase the number of voluntary donors and reduce replacement donations to a minimum.

INTRODUCTION

Blood transfusion is given for revival of life to critically ill patients as there is no genuine substitution of human blood [1]. Contaminated blood transfusion can transmit infectious diseases and can be fatal instead of saving life. The discovery of transfusion transmissible

infections (TTIs) has heralded a new era in blood transfusion practice worldwide with emphasis on two fundamental objectives, safety and protection of human life [2]. Measuring their severity, WHO has recommended pre-transfusion blood test for Human immunodeficiency virus (HIV), Hepatitis B virus (HBV), Hepatitis C Virus (HCV) and Syphilis as mandatory [3]. According to NACO guidelines, all mandatory tests should be carried out on donor's blood samples for HIV, HBV, HCV, syphilis and malaria. The whole blood or components from any unit that tests positive should be discarded [4]. Only continuous improvement and implementation of donor selection, sensitive screening tests and effective inactivation procedures can ensure the elimination, or at least reduction of the risk of acquiring TTIs [5]. For this NACO recommended 3rd or 4th generation ELISA HIV I & II test kits which are 100% sensitive should be preferred at blood banks for screening of donated blood [6]. Transfusion departments have always been a major portal to screen, monitor and control infections transmitted by blood transfusion. Blood transfusion departments not only screen TTIs but also give clue about the prevalence of these infections in healthy populations [7]. Evaluation of data on the prevalence of TTIs among blood donors permits an assessment of the accurate estimation of risk of TTIs which helps in the creation of long term strategies to improve public health and to prevent spreading of disease in local population [8].The aim of current study was to provide the detail epidemiological analysis of TTIs in blood donors of Bhopal district.

MATERIALS AND METHODS

The study was conducted at Chirayu Medical college and Hospital associated blood bank, Bhopal. Tests were routinely done on every blood unit.The Medical officer first fill up a registration form which carried all the information of donor like personal details, demographic details, occupation details and medical history regarding risk factor like history of previous surgery, hospitalization, blood transfusion,. The donors were then screened by a doctor according to blood donor selection criteria and guideline from drug and cosmetic act NACO [9,10] and blood donors who were unfit to donate blood according to standard blood donors selection criteria (As per the Drugs and Cosmetics Act,1999) [11] were excluded. Hemoglobin estimation was performed. This screening procedure was very helpful to exclude the professional donors. The total number of 9560 donors were considered medically fit and accepted for blood donation during the study period. On completion of blood donation, the units were screened for the five commonest TTIs namely HIV I & II, HBV, HCV**,** syphilis and malaria. The blood samples were collected from voluntary as well as replacement blood donors. All sera were initially tested for Hepatitis B Surface antigen (HbsAg), anti-HIV antibody, anti-HCVantibody, syphilis and malaria by enzyme linked immuno-sorbent assay (ELISA) test using a commercial kit by Tulip diagnostic Qualisa Microwell enzyme immunoassay third generation. Internal positive and negative controls along with external control which is known positive sample is tested while performing the ELISA. The data were recorded on specially formed proforma then tabulated and analyzed.

RESULTS

In the present study out of 9560 Voluntary and replacement donors, 9187(96.09%) were male and 373(3.90%) female which shows predominance of male. The most common age group of donors was found to be 18-30 years (54.87%) followed by age group of 31-40 years (30.92), 41-50 years (11.98%), and 51-60 years (2.23%) as shown in Table 1. The overall prevalence of HBV, HCV, Syphilis and HIV among Voluntary and replacement donors in the study area is 3.75%. The HBV prevalence is (190 cases) 1.987%, Syphilis (130 cases) 1.359%, HCV (35 cases) 0.366% and HIV (10 cases) 0.104% in overall 9560 donors. No donor was found to be positive for Malaria. Highest prevalence of transfusion transmitted infections was within age group 18-30 years (2.06%) followed by 31-40years (1.16%), 41-50 years (0.45%) and 51-60 years (0.08%). shown n Table 2.

Table 1. Age wise distribution of total donors from 18 years to 60 years

Age group in years	Cases (%)
18-30	5246 (54.87%)
31-40	2956 (30.92%)
41-50	1145 (11.98%)
46-60	213 (02.23%)
Total	9560 (100%)

Table 2. Age wise distribution of infected cases of HIV, HBSAg, HCV and Syphilis

Age group in years	Total number of donor	HIV	HBSAg	HCV	Syphilis	Malaria	Total infected	%
18-30	5246	05	121	19	52	00	197	2.06%
31-40	2956	05	54	11	45	00	115	1.16%
41-50	1145	-	11	04	30	00	45	0.45%
51-60	213	-	04	01	03	00	08	0.08%
Total	**9560**	10	190	35	130	00	365	

Table 3. TTI Prevalence in India

Comparison of TTIs prevalence rate in different parts of India					
Place	**HIV%**	**HBV %**	**HCV%**	**Syphilis%**	**Reference (**12-19**)**
Bangalore, Karnataka	0.44	1.86	1.02	1.6	Srikrishna A et al (1999) ,11
Ludhiana	0.084	0.66	1.09	0.85	Gupta N. et al (2004) 12
Delhi	0.56	2.23	0.66	-----	Pahuja S etal (2007) 8
Lucknow (UP)	0.23	1.96	0.85	0.01	Chandra T et al (2009) 10
Southern Haryana	0.3	1.7	1.0	0.9	Arora D et al (2010)7
West Bengal	0.28	1.46	0.31	0.72	Bhattacharya P et al (2007)
Jhalawar, Rajesthan	0.02	2.56	Nil	0.20	Diwan R et al (2012) 22
Ahmedabad, Gujrat	0.16	0.98	0.11	0.23	Shah N et al (2013)
Present study (2014)	0.104	1.987	0.366	1.359	

DISCUSSION

With every unit of blood, there is 1% chance of transfusion associated problems including TTIs. The risk of TTI has declined dramatically in high income nations over the past two decades, but the same may not hold good for the developing countries. The national policy for blood transfusion services in our country is of recent origin and the transfusion services are hospital based and fragmented. Voluntary donors (VD) are motivated blood donors who donate blood at regular intervals and replacement donors (RD) are usually one time blood donors who donate blood only when a relative or a friend is in need of blood.

Various studies in India about the seroprevalence of HCV have shown data ranging from the lowest (nil) in the study by Diwan R et al in 2012 to the higher one of 1.09% (Gupta et al, 2004). A significantly lower prevalence of 0.366% has been noted in our study. Sexually transmitted infections are wide spread in developing countries and constitute a major public health problem. The antibodies detected for syphilis shows reactivity of 1.359% in our study which is lower as compared to Srikrishna A et al but higher than other studies in India as shown in table 3. There has been a significant difference between seropositivity amongst voluntary and replacement blood donors. HIV prevalence was found to be lower in our study as compared to others except Diwan R et al and Gupta N et al as shown in table 3. HBV prevalence was found to be lower than Pahuja S et al and Diwan R et al.

The current practice of selection of voluntary donors over replacement donors to meet with the need for blood in a hospital coupled with more numbers of voluntary donor drives in the community as well as availability of better testing reagents (particularly for HIV and HCV infections) is sure to lower down the threats of transmitting TTIs to patients via transfusion of blood and blood products. As is apparent from the results of present study the results of which are comparable to other studies in India. Voluntary blood donors have significantly lower rates of prevalence for markers of TTIs as compared to replacement blood donors. Awareness of general population about voluntary regular blood donation should be created, to minimize the chances of spreading of transfusion transmitted infections. Replacement donors carry a relatively higher risk of transfusion transmitted infections due to chances of missing professional donors during donor screening procedures. Hence blood from replacement donors should be accepted only in cases of dire emergencies when transfusion of blood or blood products would be lifesaving. As is apparent form the results of present study, higher incidence of transfusion transmissible infections have been observed among replacement donors compared to voluntary donors.

CONCLUSION

The major concern in transfusion services today is increased seropositivity among replacement donors for HCV, HIV, HBV and syphilis. A noticeable number of replacement donors harbor HIV, HBV, HCV, Malaria and Syphilis infections. So strict selection of donors and proper testing of donor's blood by using standard method is highly recommended to ensure safety for recipient. With the advent of nucleic acid amplification techniques (NAT), western countries have decreased the risk of TTIs to a major extent. But the cost-effectiveness of NAT is poor. The NAT has added benefits but its high financial cost is of concern, especially in underdeveloped countries like India. Apart from NAT for donor screening, other factors such as public awareness, vigilance of errors, educational and motivational programs is sure to help in decreasing the infections. Efforts should be made to increase the number of voluntary donors and reduce replacement donations to a minimum. Motivation of potential local blood donor population would help in effective implementing of voluntary blood donation program in the community.

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Original Articles

Prevention of Post-Transfusion Hepatitis by Screening of Antibody to Hepatitis B Core Antigen in Healthy Blood Donors.

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Abstract. ***Background:*** **Transfusion-associated hepatitis B viral infection continues to be a major problem in India even after adoption of mandatory screening for HBsAg by ELISA method. The high incidence of TAHBV is reported in patients receiving multiple transfusions.**
Objective: **To study the seroprevalence of hepatitis B core antibody among healthy voluntary blood donors**
Subjects and Methods: **The study was conducted in the department of Transfusion Medicine of a tertiary care referral hospital. A total of 12,232 volunteers after passing through the stringent criteria were selected for blood donation. Donor samples were tested for all mandatory transfusion transmissible infections and anti HBc IgM (Monolisa HBc IgM PLUS:BIO-RAD, France). Reactive results were confirmed by repeat testing in duplicate. Donor data was analyzed using SPSS software and Chi-square test was used to calculate the significance of difference between the groups.**
Results: **A total of 12,232 healthy voluntary blood donors were recruited. Majority (93.4%) were males. Median age of donor population was 26 years (range: 18-60 years). Eighty six (0.7%) were positive for HBsAg, which comes under "low prevalence (<2%) zone" as per WHO. On screening for HBcAg Ig M, 15 (0.1%) were found to be positive and none were HBsAg reactive. There was no significance of difference in the mean age between reactive and non-reactive donors.**
Conclusion: **Evaluating the usefulness of anti-HBc screening is critical. Anti HBcAg IgM screening may be included in routine screening of donors as it is an indicator of occult HBV during window period. The cost and the unnecessary wastage of the blood units when they are positive for anti HBsAg along with the core antibody need to be studied.**

Introduction. The risk reduction strategies for transfusion transmissible infections are adopted at various stages in transfusion centers. It includes the detailed donor interview, review of the donor history, careful medical selection of the blood donors, maintenance of donor deferral register, elimination of cash payment to donors, and using of sensitive serological tests in the laboratory. Transfusion-associated hepatitis B viral infection (TAHBV) continues to be a major problem in developing countries, even after the adoption of mandatory screening for HBsAg by ELISA method. The high incidence of transfusion associated hepatitis B virus is reported in patients receiving multiple transfusion like thalassemia and hemato-oncology patients. This is mainly because of the blood from the donors with 'occult' HBV infection (OBI). This condition is defined as viral DNA without detectable HBsAg observed after the initial period of primary infection and most of the time accompanied by the presence of anti-HBc. Thus the absence of HBsAg in the blood of apparently healthy individuals may not be sufficient to ensure the lack of circulating HBV. and blood containing anti-hepatitis B core antibody (anti-HBc) without detectable presence of HBsAg might be infectious. However implimentation of nucleic acid testing (NAT) reduces the risk of residual infection it may not be economically feasible at every blood bank in our country. In this context we studied the seroprevalence of hepatitis B core antibody (Ig M) among blood donors at our center. We have also studied the effect of core antibody testing on discard rate of blood. This is the first study of seroprevalence of hepatitis B core antibody in South Indian blood donors.

Subjects and Methods. The study was conducted in the department of Transfusion Medicine of a tertiary care referral hospital situated at the costal part of Karnataka State (Udupi district, India). A total of 12,232 volunteers were selected after passing through the stringent criteria for blood donation.[1] The family members, friends or relatives of the patients were categorized as replacement donors. People who donate blood without expecting any favor in return were classified as voluntary blood donors. Donors with history of jaundice, hepatitis and high risk behavior were deferred. All the donors were counseled and informed about the tests carried out on the collected blood units. The blood samples were tested for all mandatory transfusion transmissible infections like HIV(Genscreen ULTRA, HIV Ag-Ab. BIO-RAD, France), HCV(SP NANBASE General Biologicals Corp. Taiwan), HBV(MonalisaTM HBsAg ULTRA, BIO-RAD, France), Syphilis (RPR, BIO-RAD, France) & Malaria (Qualisa Malaria, Qualpro Diagnostics, Tulip Group. Goa, India) by ELISA, Rapid Plasma Reagin testing and thick smear examinations respectively. In addition to these tests, ELISA for anti HBc IgM (Monolisa HBc IgM PLUS:BIO-RAD, France) was done. The sensitivity anti HBc IgM assay is 98.5% with analytical sensitivity of 50U/ml and specificity is 99.9% as mentioned in the product insert provided in the kit. ELISA for all the 4 markers (HIV, HCV, HBsAg, anti HBc IGM) were done simultaneously using a 4 plate automated ELISA equipment (EVOLIS by Bio RAD). Reactive results were confirmed by repeating the test in duplicate. On confirming the results, as per our departmental standard operating protocol we inform the donor confidentially. Donor demographic data was obtained and compared between reactive and non-reactive groups. Data was analyzed using SPSS software and Chi-square test was used to calculate the significance of difference between the groups.

Results. A total of 12232 healthy blood donors who have passed the stringent donor selection criteria were recruited for this study over a period of one year (2009-2010). Among them 8865 (72.47%) were voluntary blood donors and 3367 (27.52%) were replacement blood donors. A majority (11403, 93.2%) of them were males. Median age of donor population was 26 years (range:18-60 years). Eighty six blood donors (0.7%) were positive for HBsAg. On screening for anti-HBc (IgM), 15 (0.12%) samples gave reactive results and all of them were negative for HBsAg. Anti-HBc (IgM) reactivity was 0.03% among voluntary blood donors and, 0.35% in replacement donors (**Table 1**) and seroprevalence was significantly higher among replacement donors than the voluntary ones. Among 15 core antibody reactive donors only one was a female donor. Seroprevalence among male donors was 0.12% (14/11403) and among female donors was 0.11% (1/892), there was no significant difference between the two groups. On analyzing the occupation of the blood donors who were reactive for core antibody, 33% were students, 26% were businessmen and 40% as servicemen (2), electricians (2), driver (1) and barber (1). A decreasing trend of core antibody reactivity was observed with the increasing age of the donors. Seroprevalence of core IgM antibody was high in young donors with the age of <20 years and it is the lowest in donors between 31 to 40 yrs of age (**Figure 1**).

Sample to cut-off ratio of OD values ranged from 1.00 to 8.69 (<1.5: in 8 cases, 1.5 – 2.5: In 3 cases, > 2.5: In 3 cases). Cost analysis showed an addition of Rs.100/- per test when core antibody testing was done in addition to the other mandatory infection screening

Table 1. Hepatitis B Core antibody reactivity among different types of blood donors.

Blood donors	Anti HBc (IgM)		p-value
	Reactive	Nonreactive	
Voluntary	3	8862	
Replacement	12	3355	0.000
Male	14	11389	
Female	1	828	0.730

tests. Discard rate of blood was 0.88% per year due to HBV infection (HBsAg); with the addition of core antibody testing (IgM) discarding rate of increased to 0.97% per year.

Discussion. Post transfusion hepatitis is common even after practicing the stringent donor selection criteria and screening the blood for HBsAg. This is because a considerable number of HBV infected donors remained undiagnosed, if only HBsAg is used for screening. We have studied the seroprevalence of hepatitis B core antibody among the donor population of costal Karnataka, southern part of India. Knowing the seroprevalence rate of the core antibody will provide an idea about the usefulness of the implementation of routine core antibody testing for blood donor screening purpose. In the present study we have used the kits detecting only Ig M type of antibody. The prevalence rate of core antibody is found to be 0.12% in the present study.

HBV DNA was detected in 3.3% to 30% of the blood donors those who are negative for hepatitis B surface antigen (HbsAg) and hepatitis B surface antibody (HBsAb) but positive for anti-HBc .[2,3] As shown in various studies the prevalence of anti HBc antibody among blood donors varies from 0.12% to 19% (**Table 2**). The seroprevalence rate of anti HBc IgM in the south Indian population is not available and the present study shows a low prevalence rate in this part of country. Most of the studies from India and other countries showing high seroprevalence of core antibody have used kits with total anti HBc. A donor with a positive anti HBc-IgG indicates either a past infection or a carrier state. Anti-HBc IgG may remain positive for life in an affected individual although the individual has protective levels of anti-HBs and therefore, this does not necessarily mean that blood of such a donor is infectious. However unless we do sensitive NAT we can't confirm the presence or absence of the virus in such donor. Unlike IgG subtype anti-HBc IgM is a marker of recent hepatitis B infection.

Our finding of significantly higher seroprevalence of core antibody among replacement donors supported the national policies aiming towards 100% voluntary blood donation. Study done by Asim et al showed a difference in the seroprevalence of core antibody between male and female donors (19.3% Vs 18%) but as in our study the difference was statistically not significant.[5] We have observed an alarmingly high rate of core antibody positivity among younger population (with age <20 years) in contrary to the study done by Seo et al, which showed increasing prevalence of core antibody with the increasing age of the donor population.[7] Thirty three percent of reactive donors in our study were students. Higher rate prevalence among younger population shows the need for effective implementation of preventive measures, such as

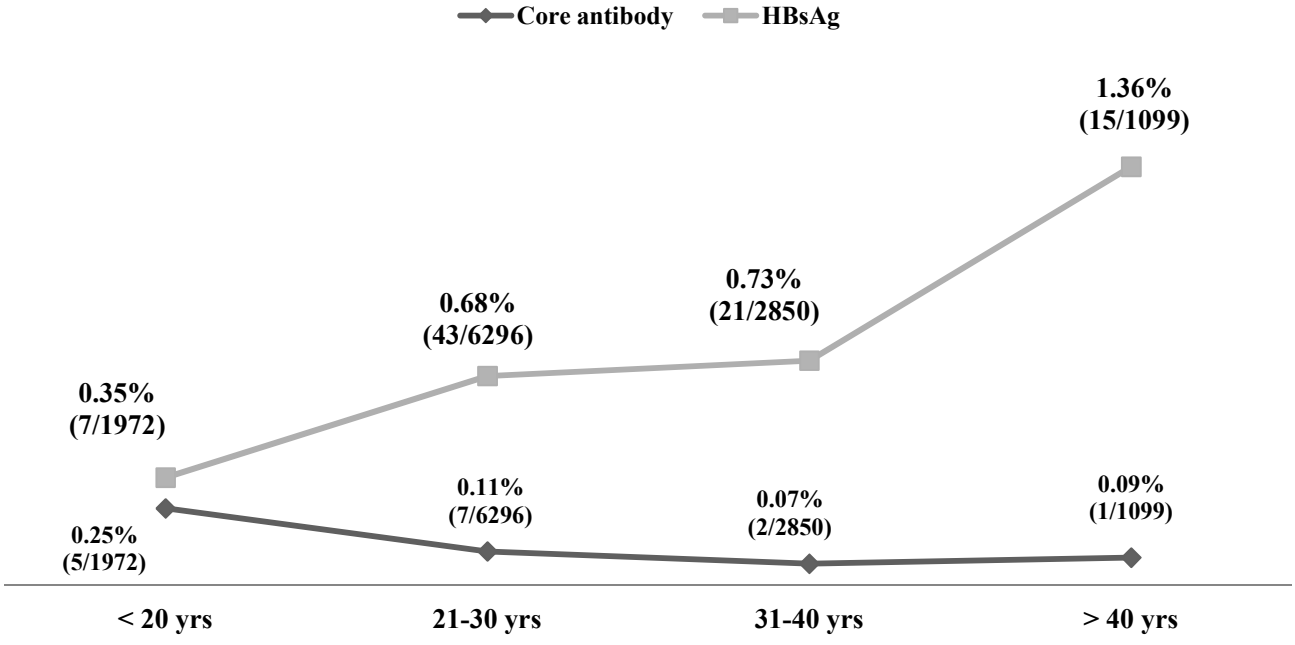

Figure 1. Seroprevalence of Hepatitis B Core antibody and HBsAg in different age groups of blood donors.

Table 2. Comparison of Seroprevalence of Anti HBc from various studies.

Place	Seroprevalence of Anti HBc	Year [Reference]
Costal Karnataka (India)	0.12%	2010 [present study]
Chandigarh (India)	8.4%	2006 [4]
New Delhi (India)	18.9%	2006 [5]
New Delhi (India)	0.43% (IgM) 15.9% (total)	2007[6]
Korea	13.5%	2008[7]
Pakistan	19.15%	2005 [8]
Iran	6.55%	2002 [9]
Italy	4.85%	2005 [10]
Turkey	15%	2006 [11]
Germany	1.52%	2002 [12]
Egypt	7.8%	2010 [13]

prenatal testing of HBsAg in pregnant women and vaccination program. As per Indian Academy of Pediatrics, current immunization schedule for hepatitis B vaccination is, first dose at birth, second dose at 6 weeks and third dose at 6 months of age. The Hepatitis B Project was initiated in India in the year 2002 with support of Global Fund for vaccines and immunization.[14] In addition to these measures, inclusion of educative sessions on health and hygiene may be helpful in creating awareness among younger population.

Screening of blood units for core antibody adds to the cost, but definitely useful in reducing the residual risk of post transfusion hepatitis. The false reactive results is another disadvantage of highly sensitive assays and in the present study we could not do the complete HBV panel. That is a limitation of our study. A study done in North India using IgM alone showed a little higher seroprevalence of 0.43% than the present study.[6] However the core antibody reactivity rate was too high (15.9%) when they used kits containing both IgG and IgM. It may not be practical for any blood bank to discard such a huge amount of blood units. And in majority of blood banks in developing countries NAT may not be feasible. As mentioned by Allain et al HBV NAT is a multi-step process and each of the steps is necessary and complementary of the preceding one. Information provided by the serological markers is important to determine whether the donor is truly infected or not. The key marker at this step is anti-HBc. In an area with low HBV infection prevalence, the association of anti HBc with HBV DNA is strongly suggestive of an established infection. Whereas in high endemic areas, the value of the information is limited since a majority of the population of blood donation age carries anti HBc.[15] Therefore, the role of anti-HBc in detecting blood donors with occult hepatitis B infection need to be considered separately in various countries.[16] Occult hepatitis B infection has a major impact on transfusion safety. The standard test for detection of occult infection is the amplification of HBV DNA. However, the serological assay for the long lasting antibody response to the highly immunogenic HBV core antigen represents a qualified candidate as a surrogate for DNA amplification.[16] Although HBs Ag seroprevalence rate in our study is <2% , which comes under the low prevalence area as per WHO guidelines, the implementation of core antibody testing becomes important step towards continual improvement in blood safety.

Conclusion. Evaluating the usefulness of anti-HBc screening is critical. Anti HBcAg IgM screening may be included in routine screening of donors as it is an indicator of recent HBV infection and is the marker which is helpful in detection of HBV infection in HBsAg window period. Costal Karnataka is a low prevalence area (<2%) for hepatitis B infection. In such areas the blood discarding rate due to core antibody is not high when the kits with Ig M antibody alone is used. The cost and the unnecessary wastage of the blood units when they are positive for anti HBsAg along with the core antibody need to be studied. Analysis of cost-effectiveness will be helpful in making a policy decision for the implementation of routine screening for hepatitis B core antibody.

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Original article:

Retrospective study of the five-Year Prevalence and Trends of transfusion transmitted infections (TTIs) among blood donors at a charitable hospital blood bank in Pune, India.

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Abstract:

Introduction: Transfusion Transmitted Infections (TTIs) remain important measures of healthcare delivery systems and need to be kept in check. The present study was planned to assess the prevalence of TTIs among the donor population of the blood bank of a tertiary care hospital and compare them with rates from other studies of blood donors across India. Follow up of TTIs positive donors was also examined. A retrospective analysis of TTIs among blood donors at the Blood Bank of a charitable tertiary care hospital and teaching medical school in Pune, India.

Methods and Material: Data on TTIs were examined on a total of 13,078 blood units collected from voluntary donors for five years between Aug 2008 and Aug 2013. Screening for TTIs underwent changes from second to fourth generation kits during the five years. The follow up of all donors and further care of those who were TTI positive was also examined.

Results: Overall sero-prevalence of HIV, HBV, HCV, Syphilis and malaria were 0.28%, 0.41%, 1.23 %, 0.1% and nil respectively; 205 donors were TTI positive; 36 for HIV, 161 for HBV, 44 for HCV and one for VDRL.. From Jan-Aug 2013, 14/ 22 (63.6%) TTI positive donors returned for follow up care.

Conclusions: Sero-prevalence of TTIs prevents potentially infectious blood from being transmitted. The system to increase follow up and care of TTI positive donors should be strengthened.

Key-words: Seroprevalence, blood donors, transfusion transmittable infections

Introduction:

Screening of blood donors first started in 1947 (1). Today, India's blood transfusion program mandates the screening of HIV, HBV, HCV, malaria and syphilis (2). The prevalence of TTIs in voluntary non-remunerated blood donors is lower than among family/replacement (3, 4, 5) & paid donors (6, 7, 8). Therefore, TTI risk is reduced if collected from low-risk populations (9). Estimated adult HIV prevalence in India is 0.2-0.3 %(10)**;** and up to 40 million of 350 million hepatitis B chronic carriers worldwide are in India (11). HBsAg prevalence varies from 1-13%, with an average of 4.7% (12)**.** HCV carriers in India are around 12–13 million

(13). With this background the present study was planned to assess the prevalence of TTI markers among the donor population of the blood bank of a tertiary care and teaching hospital, since it was set up in 2008 and to see if these rates were comparable with rates from some other studies of blood donors in India .

Material and Methods:

Retrospective data of blood collected at the hospital's blood bank from August 2008 – August 2013 were analyzed. The prevalence of TTIs was calculated and records of follow up data of all donors who tested positive for any of the TTIs was also examined. Different tests were used for screening for HIV, HBV, HBV and Malaria over the five years mostly for converting from third to fourth generation kits and are detailed below:

From 2008-09, HIV screening was done using Detect, Eliscan HIV, and Microlisa and from 2010-13, fourth generation ELISA as Enzydus, Wualisa and Genscreen HIV Ultra were used. Screening for HBs antigen used the following tests: EIAgen (Lenco Hellas, Greece), Eliscan (Ranbaxy) and Hepalisa (J Mitra &co), all third generation tests, were used from 2008-09. From 2010-11 initially Qualisa (Tulip group, India), a third generation test, followed later by Hepalisa Ultra (fourth generation) were used. From 2012-13, Monolisa (Biorad) and Hepalisa Ultra both fourth generation tests were used.

For screening for HCV, in 2008, the following screening assays were used: EIAgen Ab, Qualisa HCV (Tulip group, India), Microlisa - all third generation ELISA tests for HCV antibodies. EIAgen was replaced by Erbalisa (Transasia), a third generation test from 2009-10, which was replaced by Monolisa (Biorad) in 2011 and by GENEDIA HCV, a fourth generation EIA, in 2012-13.

Screening for malarial parasite was done using Leishmann (2008-10). From 2010-13, Pan Malaria Rapid and Qualisa ELISA (Tulip Group) were used.. And lastly, screening for syphilis, was done using RPR (Span) throughout the five years. This blood bank accepted voluntary donors only and so there were no replacement donors. NACO's guidelines were strictly followed for testing to ensure safe blood transfusion (1) and donors were informed about the tests for TTIs, consented and strongly encouraged to come back for their results and post test counselling. The publication of this study was approved by the Ethics Committee of the Institute.

Results:

All blood donations at the blood bank were voluntary and replacement donors were not accepted. Of 13,078 blood donors 12,715 (96.6%) were males and 363 (3.4%) were females. The mean age for males was 34 years (18-50 years) and 24 years (18-30 years) for females.

Blood was screened for HIV, HBV, HCV, malaria and syphilis, and the overall prevalence of sero-reactive samples over the five years are shown **(Fig. 1)**, while the yearly prevalence rates are shown in **(Fig. 2)**.

The overall sero-prevalence of HIV, HBV, and HCV, syphilis and malaria were found to be 0.28%, 1.23 %, 0.41%, 0.008 and 0% respectively **(Fig. 2).** Trend over the five years showed that HIV prevalence declined from 0.49 in 2009 to 0.22 in 2013. HBV prevalence progressively declined from 1.89% (n=899) in 2008 to 0.67% in 2013 (n= 1795). While the prevalence of HCV was 0.44% in 2008 and 2009 and fell to 0.33 in 2013, there were fluctuations in between with 0.28% in 2010 and 0.46% in 2011and 0.50% in 2012. There was one sample that was positive test for RPR for syphilis in 2008 (0.04%) and no malarial parasites were seen in the five years **(Fig. 3a-d).**

It was found that co-infections of TTIs among 13,078 samples tested in the five years were as follows: HIV and HBsAg were positive in three (0.023%) donors, HIV and HCV in one donor (0.008%) and HBsAg and HCV in one donor (0.008%). In all 205 (1.56%) donors tested positive for any TTI in the study period, of whom 36 donors tested positive for HIV, 161 for HBV, 44 for HCV and 1 for RPR. Further details of these individuals were not available for reporting.

Regarding post test counselling, the system for maintaining written records for follow up and counselling was initiated only from Jan 2013. Prior to this, there is no systematic documentation, but the bank reports that attempts were made to contact donors who had provided mobile phone numbers but were unsuccessful in many cases due to reasons such as phones being out of service or coverage area, changed numbers, unrecognizable receivers etc. However those who came for follow up were counselled and referred for treatment at the same hospital but no record. From Jan-Aug 2013, documented data shows that all 22 donors who were positive for any TTI were contacted by telephone. However only 14 (63.6%) came back for post test counselling. All 14 were referred to the department of Medicine at hospital for further care and treatment.

Figure 1: Overall prevalence of TTIs among blood donors at a hospital blood bank from Aug 2008 - Aug 2013

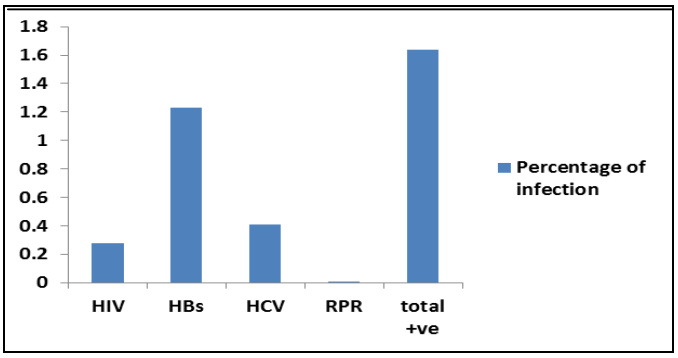


Figure 2: Yearly prevalence rate of TTIs in Blood Donors at a hospital blood bank from 2008-2013

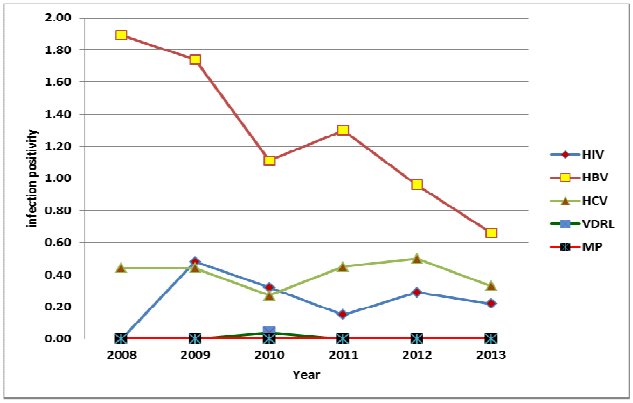


Fig 3: Trends of TTI prevalence among blood donors from 2008-13 at a hospital blood bank:

Fig 3a: Sero-prevalence of HIV

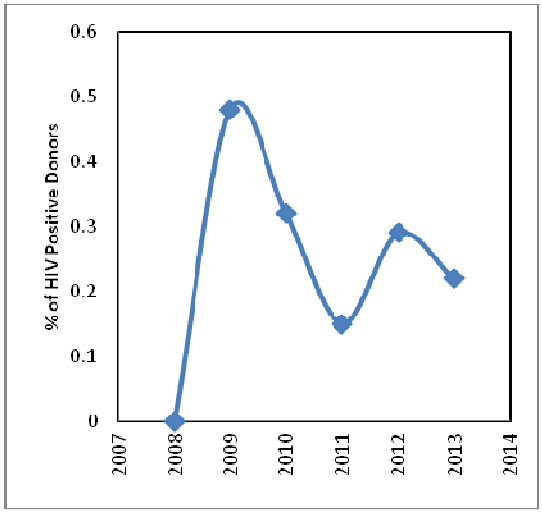


Fig 3b: Sero-prevalence of HBsAg

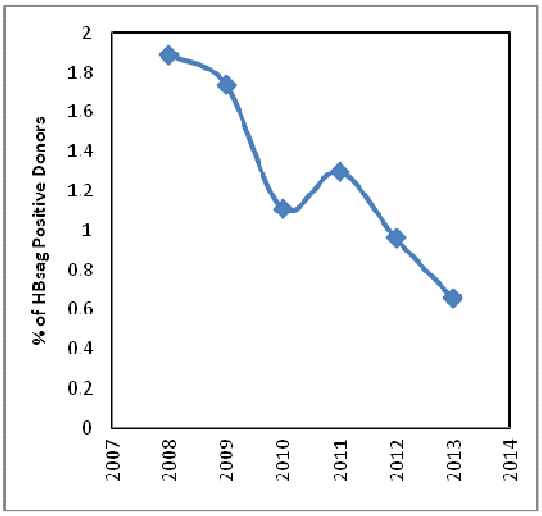


Fig 3c: Sero-prevalence of HCV

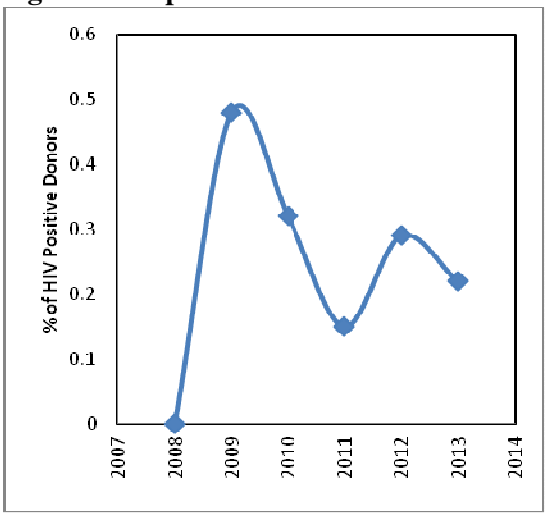
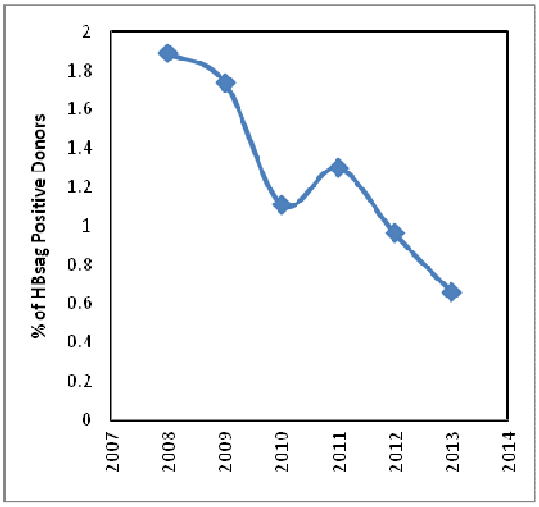


Fig 3d: Sero-prevalence of Syphilis



Discussion:

The HIV/AIDS pandemic has focused particular attention on the importance of preventing transfusion-transmitted infections (TTIs). Up to 3% of HIV infections worldwide are transmitted through the transfusion of contaminated blood and blood products. Many more recipients of blood products are infected by hepatitis B and C viruses, syphilis and other infectious agents, such as Chagas disease (14)

In 2009, an estimated 2.4 million people were living with HIV in India, which translates to a prevalence of 0.3% (15)**.** In our study, the overall sero-reactivity was 0.28% for HIV which correlates well with the national average. HIV prevalence in our study declined from 0.49 in 2009 to 0.22 in 2013. The reason for this is not clear but may perhaps be explained by the fact that third generation kits were used until 2009 and were changed to fourth generation kits from 2010 onwards.

HBsAg prevalence in our study showed a slightly declining trend in study period from Jan 2008-Aug 2013 from 1.89-0.93**,** while others studies in Karnataka (16, 17) reported HBsAg prevalence of 1.27 and 0.87.

In our study the overall prevalence of HCV was 0.41% which correlates well with the study of Beenu Thakral *et al* (18) from Chandigarh that reported an overall HCV sero-positivity of 0.44 per cent (72/16,250)**.** However, Mukhopadhya (19) reported HCV prevalence in blood donors from different parts of India ranging from 0.5% to 1.85% and Meena *et al* (20) showed a significant increasing trend in the prevalence of HCV among blood donors from 0.18% in 2005 to 0.82% in 2009 and Unnikrishnan B et al (17) showed an HCV prevalence of 0.36. Similarly, two studies from Vellore and Chennai in Tamil Nadu (21, 22) reported a prevalence of 0.22% prevalence for HCV. From the studies referred to in the period 2004-2013, it appears that most studies in the north India (23-27) excepting the Chandigarh (18)and Delhi (28) studies of 2005 and 2013) report prevalence >0.5%, (0.65-1.18%)with the southern states of Tamil Nadu & Karnataka (excepting the Karnataka study of 1999(29)) report lower prevalence 0.06-0.36% (30, 16,17,22) while the eastern city of West Bengal (31) reported 0.31%, our own study which is in the western zone, is reporting 0.41% o HCV (**Table 1**). However Garg *et al* (32) from Jodhpur reported a higher prevalence of HBsAg of 2.57-3.53%.

Our study showed just one case that was reactive for Syphilis (0.008%) while the study by Pallavi P. *et al* (16) showed a positive rate of 0.28%. The prevalence of syphilis in India from 1999-2013 have shown a declining trend **(Table 1).** Only one study from Karnataka (30) reported 0.01% (1/9599) prevalence of malarial parasite.

Regarding co-infections, while there was no information regarding this in most of the above studies, our study showed HIV and HBsAg were positive in three (0.023%) donors, HIV and HCV in 1 donor (0.008%) and HBsAg and HCV in 1 donor (0.008%).

In general there is correlation is seen between the prevalence rates of all TTIs i.e. HIV, HBV, HCV, syphilis and malaria among blood donors in our study with some of the above reported studies from India from 2006-2012 **(Table 1).**

Data of follow up of donors at the blood bank started only from Jan 2013, and until August 2013, 63.6% (14/22) donors who positive for any of the TTIs came for follow up and were counselled and referred for further treatment to the Medicine Department. A study by Kaur G *et al* reported that only approximately 35% (60/172) donors found to be positive for any TTI, responded to letters and were counselled (33) and a response rate of 59.8%

(249/416) among reactive donors in a study in Uttarkhand by Agarwal N (34). The follow up of blood donors in our study is for a much shorter period and has to be reviewed over the coming years, while making systematic efforts to strengthen and increase follow up.Sero-prevalence of transmissible transfusion infections continues to be an important function of healthcare delivery systems which helps in preventing potentially infectious blood from being transmitted in all phases of infection. In addition, a system to increase follow up of donors who are found test positive for any of the TTIs should be strengthened so that they may be appropriately counselled and treated, if required.

Certain studies have used more sensitive such as PCR and NAT for HBV and HCV (23) that can uncover latent infections in the window period and may actually suggest underestimation of prevalence by currently used screening tests in our study. This implies that screening for TTIs needs to be upgraded across blood banks in India.

Conclusion: The prevalence of TTIs in our study correlate well with prevalence rates from some of the other studies on blood donors in India. HBV continues to be the most prevalent TTI. In India, HBV vaccine was initiated in Universal Immunization Program (UIP) in a phased manner since 2007 (35) and is currently widely available. This means that youth born before 2008, who have not been immunized for HBV, should receive the vaccine at their earliest point of contact with the healthcare system. This can also reduce the complications of its co-infection with HIV and HCV.

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Performance Evaluations

INTERNAL EVALUATION

QUALISA® MALARIA

ELISA for detection of Malaria antigen (pan PLDH)

Tulip Group

QUALPRO DIAGNOSTICS

Evaluation of Qualisa Malaria

Qualisa Malaria was evaluated against rapid Immunochromatography tests using **ParaTROL Pv Control**. The below mentioned data suggests that Qualisa Malaria is more Sensitive and Specific then Rapid Immunochromatography Test. **ParaTROL** is a set of lyophilized preparation of selected human whole blood sources parasitized with *P. falciparum, P. vivax* parasites and parasites negative whole blood. In this evaluation **ParaTROL Pv** was used and comparison was done between Pan band of Rapid Immunochromatographic tests and **Qualisa Malaria**.

ParaTROL PV Dilution	OptiMAL IT (Pan band)	SD-Bioline Malaia Pf/Pan (Pan band)	Advantage MALPAN (pLDH)	Qualisa Malaria Cutoff:0.137
Pv/ Neat	**Positive**	**Positive**	**Positive**	**2.595 (Positive)**
Pv/ 1:2	**Positive**	**Positive**	**Positive**	**2.467 (Positive)**
Pv/ 1:4	**Positive**	**Positive**	**Positive**	**2.390 (Positive)**
Pv/ 1:8	**Positive**	**Positive**	Negative	**2.062 (Positive)**
Pv/ 1:16	Negative	Negative	Negative	**1.527 (Positive)**
Pv/ 1:32	Negative	Negative	Negative	**0.965 (Positive)**
Pv/ 1:64	Negative	Negative	Negative	**0.516 (Positive)**
Pv/ 1:128	Negative	Negative	Negative	**0.206 (Positive)**
Pv/ 1:256	Negative	Negative	Negative	0.105 (Negative)

Qualisa Malaria comes with a unique **DHS^3 Technology**, where;

D is Dense; Proprietary blockers are used to coat optimally dense antigen / antibody on the micro well surface. Ensures high delectability of analyte particularly for low-titter samples

H is Homogenous; Due to proprietary technology, only analyte-specific antigen / antibody get coated forming a homogenous layer. Ensures correct protein folding to expose immunodominant epitopes. Confers high specificity.

S^3 is **Sensitive**, **Specific** and **Stable**.

Qualisa Malaria is comparatively highly Sensitive and Specific in comparison to Immunochromatographic tests. Below are some points which differentiate Qualisa Malaria from ICTs:

- Higher sensitivity because of longer incubation time between analyte and microwells.
- Higher Specificity, because of washing steps which removes unbound material.
- High S/CO: This means that for true positive samples, the signal to cut-off ratio is higher than other ELISA systems.

Data on file, Qualpro Diagnostics. January 25, 2014.

For Qualpro Diagnostics

Authorized Signatory

TÜV MANAGEMENT SERVICE ISO 9001

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