Original Article

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Impact of IDNAT on Blood Safety; A Retrospective Study on Prevalence of Infectious Markers and Their Trends amoung Blood Donors at a Tertiary Care Hospital

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Abstract

Introduction: Transfusion transmitted infections (TTI) are major risk factors for blood transfusion. To increase the blood safety IDNAT has been introduced along with compulsory donor screening tests in all NACO assisted blood banks by Government of Karnataka and KSAPS from Dec. 2011. To evaluate the safety benefits of introducing IDNAT and to estimate the seroprevalence of infectious markers TTI and their yearly trends among blood donors, a retrospective studywas conducted at Blood bank of Hassan Institute of Medical sciences, Hassan, Karnataka. *Materials and Methods*: Blood bank records were reviewed retrospectively from January 2013 to December 2016. Results of mandatory serological tests and NAT Yield cases were compared. Descriptive statistics were used to estimate the prevalence of TTI and to show their yearly trends for four consecutive years. *Result*: Total numbers of blood units collected during study period were 18,694. Voluntary donors were 69% and Replacement donors were 31%. Out of 176 infective cases detected 23 were serologically non reactive but NAT reactive giving a high NAT yield of 1 in 812 cases.Overall prevalence of TTI was 0.94% and seroprevalence of HIV (0.08%), HBV (0.80%), HCV (0.06%), Syphilis (0.01%). An increasing trend of HBV infection and decreasing trend of HIV, HCV were observed among blood donors in these four consecutive years. *Conclusion*: The present study population showedcomparatively low prevalence of Transfusion transmitted infection and it clearly indicated the benefits of IDNAT screening for the improvement of blood safety.

Keywords: IDNAT; Blood Safety; Blood Transfusion.

Introduction

Blood transfusion is an integral part of Health care system saving millions of lives every year. But transfusion transmitted infections (TTI) are the major risk factors associated with the blood transfusion. In developing country like India where there is high prevalence of HIV, hepatitis B and C, TTI pose a serious threat to transfusion recipient. To avoid such transmission NACO has made mandatory screening tests for Human Immuno Deficiency Virus (HIV), Hepatitis B Virus(HBV), Hepatitis C Virus (HCV), Syphilis and Malaria on all donated blood and any unit of whole blood or blood components that test positive should be discarded [1]. Still the blood is not entirely safe from TTI as there is always a risk of blood donation during window period, presence of occult blood infectionwhich are not detected by mandatory serological tests [2]. To increase the blood safety, Government of Karnataka, Department of Health and Family Welfare and Karnataka State AIDS prevention Society (KSAPS) has decided to introduce ID NAT (Individual Donor Nucleic Acid Testing) facility in all its NACO assisted Blood Banks in Karnatakastate. As a NACO assisted Blood bank ID NAT facility was implemented in our Institution Blood Bank from December 2011and henceblood samples from all donated blood units are sent to IDNAT laboratory at Blood bank of Bowring and Lady Curzon hospital

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which is the only authorized nodal agency to carry out Nucleic Acid Test.

ID NAT is a highly sensitive molecular technique which detects even low level of viral genomic material andthere by allows earlier detection of infection and reduces the window period when compared to serological screening methods which are based on seroconversion[3].

On this background we conducted a retrospective study toassess the safety benefits of implementing IDNAT. Objectives of our study were to estimate the seroprevalence of infectious markers among blood donors and to assess their yearly trends over a period of four years and to evaluate the impact of IDNAT on screening blood donation.

Materials and Methods

This is a retrospective study carried out at blood bank, Department of Pathology ,Hassan Institute of medical Sciences, Hassan , Karnataka . Blood bank records were reviewed retrospectively from January 2013 to December 2016. They were both Voluntary Donors (VD) and Replacement Donors (RD).The voluntary donations were obtained from walk in donors and in voluntary blood donation camps organized by different institutions, neighboring colleges, social and political organizations.

Donors are selected according to standard eligibility criteria for blood donation (4). Two blood samples; each of 2 ml was collected in labeled plain vial from donor tubing of blood bag. Samples are centrifuged at 3500 rpm for 5 minutes to obtain clear non hemolysedserum. One sample is screened in our blood bank for the presence of anti HIV1&2, anti HCV and HBs Ag by using semi automated 3rd generation ELISA and Syphilis is screened by using RPR (Rapid Plasma Reagin) test. Another sample is sent to NAT Laboratory in Bowring and Lady Curzon Hospital for IDNAT.

Results of ELISA andNAT are compiled and blood units which are found to be reactive by any of the tests were segregated and kept in separate quarantine area till they were sent for disposal using biohazard label

Results

During the study period of four years, total numbers of 18,694 blood units were collected from apparently healthy donors. Of these voluntary donors were 12,893 (69%), and 5813(31%) were replacement donors (Figure 1). Age group of donors was ranging between 18-45 yrs with mean age of 28 yrs. Male and Female proportion is 94.5: 4.5 (Figure 2). Total numbers of seropositive cases for transfusion transmitted cases were 176 (0.94%). Details of seropositive cases were given in Table 1.

Results of IDNAT in comparison with serological tests are given in Table 2. Out of 176 seropositive cases, NAT yield (Serologically negative/ NAT positive) was 23(1 in 812). NAT yield for HIV was 01; HBV was 20 and HCV was 02.

To see the trend of Transfusion transmitted infections we have divided the study group into GroupA(donors of year 2013 -2014) and Group B(donors of year 2015- 2016). Seroprevalence of TTI among Group A and Group B are described in Table 3 and Table 4 respectively.

Table 1: Details of seropositive casesDDedddddeta

TTI	No. of seropositive donors	Seropositivity rate	males	Females	Voluntary	Replacement
HIV	16	0.08%	15	1	3	13
HBSAg	145	0.80%	141	4	76	70
HCV	13	0.06%	10	3	6	7
VDRL	2	0.01%	2	0	0	2
MP	0	0%	0	0	0	0
Total	176	0.94%	168	8	85	92

Table 2: Results of IDNAT in comparison with serological tests

YEAR	Number of sample tested	Seropositive/NAT positive cases	Seronegative/NAT positive(NAT yield)	Seropositive /NAT negative cases
2013	4503	40	7	0
2014	4558	35	3	0
2015	4912	39	10	0
2016	4721	39	3	0
TOTAL	18694	176	23	0

Table 3: Seroprevalence in 2013-14

TTI	Group A(2013-2014) Seropositivity Rate	No. of Units
HIV	0.12%	11
HBsAg	0.69%	63
HCV	0.09%	9
SYPHILIS	0.02%	2
MALARIA	0%	0

Table 4: Seroprevalence in 2015-16

TTI	Group B(2015-2016) Seropositivity Rate	No. of units
HIV	0.05%	5
HBsAg	0.85%	82
HCV	0.04%	4
SYPHILIS	0.00%	0
MALARIA	0%	0

When study group A & B were compared, increasing trends was seen in seroprevalence of HBV (from 0.69% to 0.80%), whereas decreasing trends seen in HIV(0.12% to 0.05%), HCV(from 0.09% to 0.04%) and Syphilis (from 0.02% to 0%). Overall seroprevalence rate of TTI also showed a decreasing trend (from 0.94% to 0.90%). Trend charts of individual TTI are displayed in Figure 4.

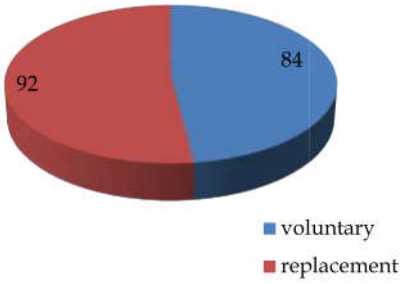

Fig. 1: Donors Type distribution

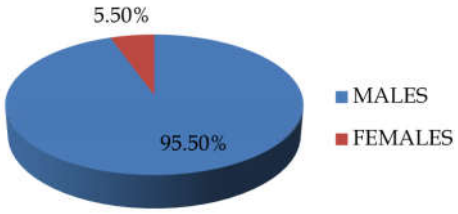

Fig. 2: Sex distribution

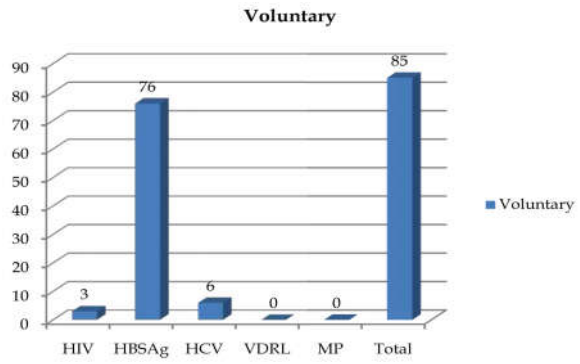

Fig. 3: Distribution of TTI among voluntary seropositive cases

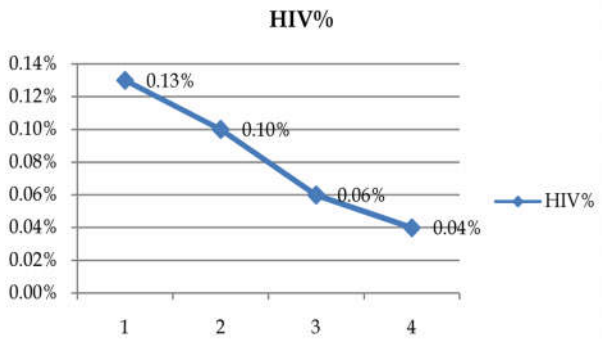

Fig. 4.1: Yearly Trends of seroprevalence of HIV

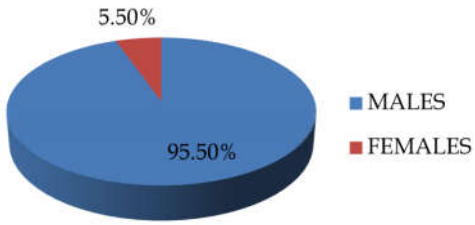

Fig. 4.2: Yearly trends of Hepatitis B seroprevalence

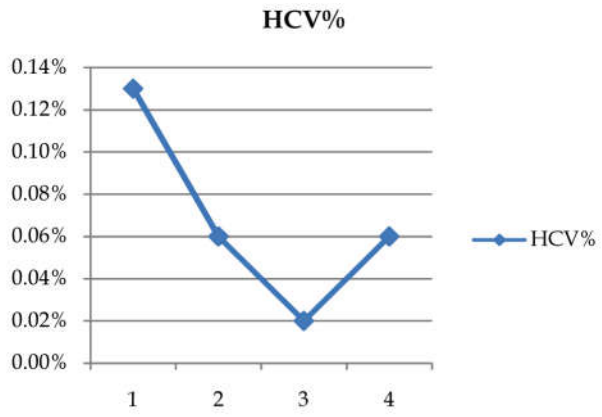

Fig. 4.3: Yearly trends of seroprevalence of HCV

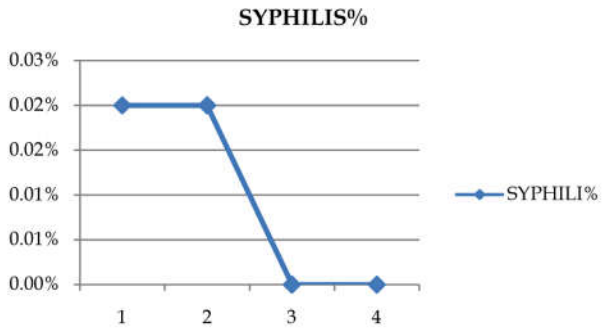

Fig. 4.4: Yearly trends of seroprevalence of Syphilis

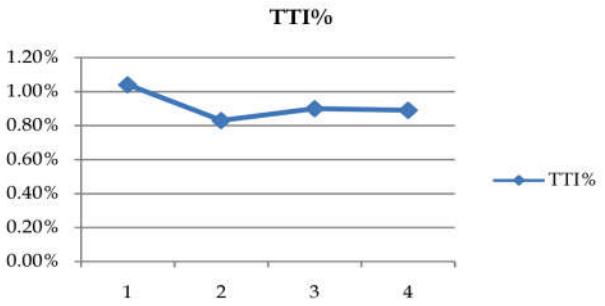

Fig. 4.5: Yearly trends of seroprevalence of overall TTI

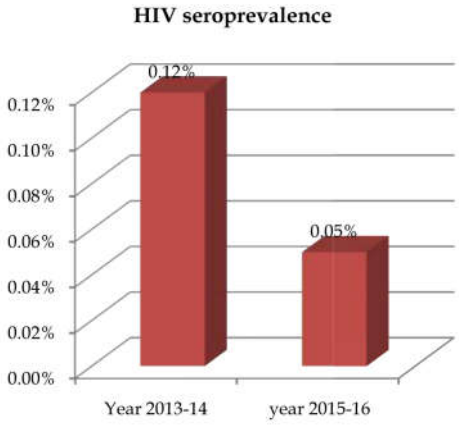

Fig. 5.1: Comparison of HIV prevalence between Gp.A (2013-14) and GP.B(2015-16)

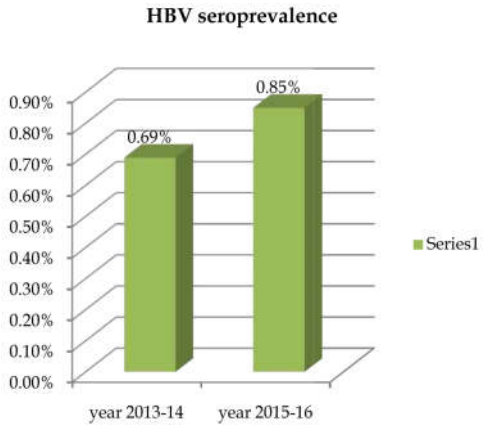

Fig. 5.2: Comparison of HBV seroprevalence between GpA(2013-14) and Gp.B (2015-16)

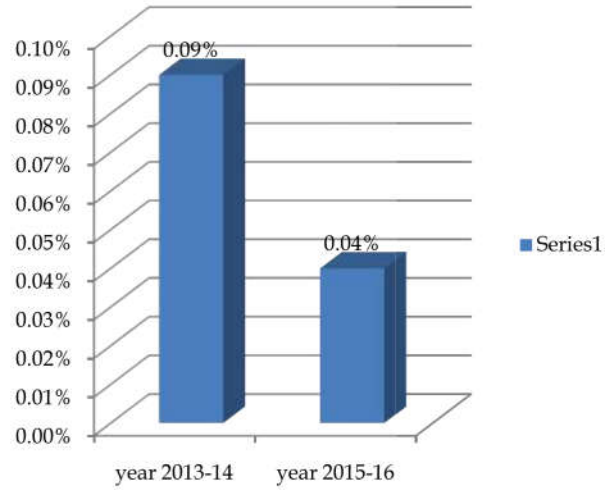

Fig. 5.3: Comparison of HCV seroprevalence between Gp.A(2013-14) and Gp B (2015-16)

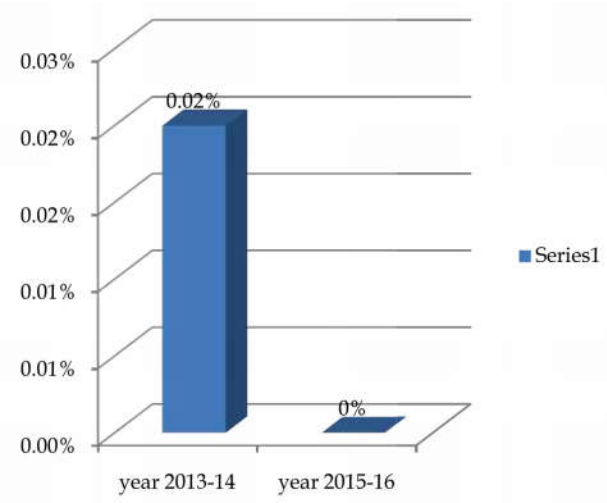

Fig. 5.4: Comparison of seroprevalence of Syphilis between GpA(2013-14) and Gp B(2015-16)

Discussion

Our study was aimed at analyzing two blood transfusion related issues- one was to estimate the seroprevalence of infectious markers of TTI and their yearly trends among blood donors for four consecutive years (2013-2016) and another aim was to assess the safety benefits of implementing IDNAT.

- In the present study; out of 18,694 samples tested 176 cases (0.94%) were positive for TTI. Out of them NAT yield (serologically non reactive but NAT reactive) was 23 (1 in 812) which is very high when compared to NAT yield rates from other blood banks in India that is 1 in 3182 [5], 1in 2972 [6] and 1 in 2622 [7]. But blood bank in Dayanand Medical College, Punjab showed higher NAT yield rate of 1 in 753 [8]. This high NAT yield rate

may be attributed to the fact that though we have 69% of Voluntary donation, majority of them being first time donors who may not be safer than the replacement donors. Replacement donors never declare their risk behavior or medical condition with the fear of rejection. There is a need for better predonationcounselingand chance for donors self exclusion to improve the blood safety.

- In our study, majority of NAT yield was for HBV (20 cases) .This is very significant finding , as there is increasing trend of Hepatitis infection in the population , there will increase number of donors in window period and Occult blood infection (OBI) which are not detected by mandatory HBsAg test. This finding supports the fact that HBs Ag screening alone is not sufficient to detect HBV in all phases of infection and in combination with IDNAT it can detect most of the potentially infectious donors [2].
- Due to concerted and active efforts, the prevalence of TTIs has come down significantly over the years. Overall the nationalseropositivity of transfusion transmitted infections among blood donors in the year 2016 is HIV (0.136%), HBV (0.93%), HCV (0.326%), Syphilis (0.182%) and Malaria (0.039%) [9]. However, there is a huge variation between States. Mythree et al reported low seroprevalence of TTI in south Indian donors when compared to North Indian studies [10]. NACO assessment showed seroprevalence of TTI in Karnataka HIV(0.12%), HBV(0.89%), HCV(0.18%), Syphilis (0.04%) and Malaria(0%) [9].

Our data is correlating with recent NACO statistics and showed significantly low prevalence rate of TTI when compared with other recent studies done in South India on serosurveillence of TTI. Comparison was shown in the Table 5.

Table 5: Comparison of Seroprevalenceof TTI among Blood donors in various studies

Year of study 2016	Place Present study Hassan ,KAR	TTI % 0.94%	HIV% 0.08%	HBV% 0.80%	HCV% 0.06%	Syphilis% 0.01%	Reference
2016	NACO,KAR		0.12%	0.89%	0.18%	0.04%	9
2015	A.P	1.85%	0.18%	1.58%	0.10%		11
2013	Bagalkot, KAR	3.15%	0.39%	2.90%			12,13,14
2011	Tamilnadu		0.19%	0.98%	0.22%	0.05%	10
2011	Bangalore,KAR		0.23%	0.53%	0.05%	0.05%	15
2009	coastal karnataka			0.62%			16
2008	Mysore,KAR		0.34%	1.16%	0.19%	0.29%	17
2002	Kerala		0.18%	1.26%	1.40%	0.22%	18

KAR- Karnataka

- To see the significance of yearly trends study group was divided into 2 groups, Group 'A' (2013-2014) and Group 'B'(2015-2016).
- Trends of Individual TTI were as follows: The seropositivity of HIV was 0.12% in Group A significantly decreased to 0.05% .This decreasing pattern is comparable with findings of studies done in Mysore [17], Bangalore [15] and Tamilnadu [10]. The prevalence of HIV in various parts of India is different; NACO surveillance (2016) showed an overall prevalence of 0.14% in India and 0.12% in Karnataka [9].
- Seropositivity of HBV in Group A was 0.69% which significantly increased to 0.85% in Group B. Similar increasing trends were also seen in seroprevalence of Hepatitis B infection in studies done at Bangalore [15] and Mysore [17], whereas study done in coastal Karnataka [16] showed low prevalence. HBV was more prevalent than HIV in our study. The focus was so far been on HIV and the problem of transfusion associated hepatitis that is greater in magnitude, has to be seriously addressed.
- The seropositivity of HCV in Group A was 0.09% and in Group B was 0.04%. This decreasing pattern is comparable with findings of similar studies done at Mysore and Bangalore [17,15].
- Syphilis showed low prevalence (0.02%) and decreasing trends (from 0.02% to 0%); no Malaria positive samples were found in the study period. This correlated with 2016 NACO prevalence rate for syphilis (0.04%) and Malaria (0%) among blood donors in Karnataka [9].

Conclusion

The present study in our institution showed low prevalence of Transfusion transmitted infections when compared to recent similar studies done in south India. On comparing retrospective data over 4 years

significantly increasing trend was seen in seroprevalence of HBV and decreasing trend was seen in seroprevalence of HIV, HCV and Syphilis. judicious use of blood and blood products are equally important measures to reduce transfusion transmitted infections.

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