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Trend in Seroprevalence of Hepatitis B Virus Infection Among Blood Donors In A Tertiary Care Teaching Hospital In Tirupati

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Abstract

Introduction: *Hepatitis B virus (HBV) is a member of hepadna virus family – a DNA virus which is transmitted percutaneously (intravenous drug abuse / blood transfusion), perinatally and sexually. Transfusion associated Hepatitis B virus (TAHBV) is one of the major transfusion transmitted infections (TTI) in India and has high incidence in patients receiving multiple blood transfusions.*

Material and Method: *This study was carried out in a tertiary care teaching hospital. Retrospective analysis of donor profiles for a period of six years was analysed to assess the distribution of seropositive cases in relation to age, sex, and trend. The analysis was performed by enzyme linked immunosorbent assay (ELISA).*

Results: *A total of 43839 blood units were screened amongst which 775 (1.76%) were positive for Hepatitis-B. There were 754 (1.71%) males and 21 (0.04%) females. Replacement donors showed more seropositivity compared to voluntary donors. Seropositivity was common in young donors.*

Conclusion: *In the present study, there is gradual decline in prevalence of HBV from 2012 to 2017 which can be attributed to effective pre donation counseling of donors, encouragement of voluntary donation and increasing awareness in society etc. Advanced techniques of screening, immunization, health education to high risk groups ensures better blood transfusion services.*

Key Words: *Donor, ELISA, Hepatitis – B, Replacement donor, Voluntary donor*

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I Introduction

Hepatitis B virus is a significant cause of acute and chronic liver disease worldwide. HBV is a member of hepadna virus family a DNA virus that can be transmitted percutaneous (intravenous drug abuse / blood transfusion), perinatally and sexually [1]. The process of transferring blood or blood products from one individual to another is – Blood transfusion. This process can lead to transfer of infectious agents between individuals and is termed as Transfusion transmitted infections (TTI). Globally, the most notable TTI are Human immunodeficiency virus (HIV), HBV, Hepatitis C virus (HCV) due to their high prevalence rates [2]. Transfusion associated HBV (TAHBV) infection was and is one of the major TTI in India. Even though screening of hepatitis B surface antigen is mandatory by enzyme linked immunosorbent assay (ELISA), there is still a higher prevalence of TAHBV in patients who received multiple blood transfusions [3]. The risk of transmission of hepatitis through transfusion of blood and blood products has been known since 1950 [4,5]. There is approximately 30% of world's population having serological evidence of either current or past infection with HBV [3]. The assessment of the quality of donor selection and safety of the blood supply can be estimated by monitoring the prevalence of the serologic markers of infection and disease through screening tests [6]. Some blood donors who were negative for surface antigen are found positive for core antibody and are reported to have transmitted acute hepatitis infection [7]. In spite of remarkable efforts and meticulous screening procedures, the chance of transmission of HBV still exists from apparently healthy blood donors. This scenario can be due to failure of screening tests to detect HBV during window period or might be due to occult HBV infections [8]. The residual transmission risk of HBV through transfusion is still increasing. Thus, evaluation of data on prevalence of HBV, among blood donors will throw some light on occurrence of infections among blood donor population and will also allow blood banks to assure safe blood transfusions.

The present study was preferred in order to evaluate the prevalence and demographic trends of HBV in recent past six years from 2012 to 2017 among blood donors who were bled at Model Blood Bank, S.V.R.R. Government General Hospital, Tirupati.

II Material And Method

The current study unfolds the impact of seroprevalence of HBV in blood transfusion services. The study was conducted by retrospective review of the donor profiles over a period of six years (January 2012 to December 2017) at Model Blood Bank, S.V.R.R. Government General Hospital, Tirupati. A thorough check was performed for 43839 units of blood collected from replacement and voluntary donors. Only the healthy donors were selected after careful examination using personal questionnaire including general health related inquiry and any specific history physical examination – body weight; temperature; clinical examination – general examination, pulse and blood pressure and Hemoglobin estimation. The questionnaire was also included with past history of illness to be notified and TTI related etiological affiliations if any. The family and friends or relatives of the recipient were categorized as replacement donors and people who donate blood without expecting anything in return and are non-remunerated are classified as voluntary donors.

The donated blood units were serologically analyzed by ELISA using second generation Erba Lisa Sen HBsAg kit with reported sensitivity of 100% and specificity of 99.9% as per the manual / pack insert supplied by the manufacturer.

All blood units tested positive were analyzed once again using a rapid test kit which is based on the principle of one step immunoassay.

Blood units which showed positive / reactive results in both the tests were considered to be true positive and included in calculations. There were as such, no contradictory results.

III Results

A total of 43839 blood units were collected for a period of six years i.e., from January 2012 to December 2017. There were 40933 (93.37%) of male donors and 2906 (6.62%) of female donors. The male: female ratio obtained was 14.08:1. The total number of blood units collected with respect to gender is tabulated in Table No: 1.

TABLE 1: Total number of blood units collected – Gender wise distribution in respective years

Year	Male donors (%)	Female donors (%)	Total
2012	6924 (95.62)	314 (4.38)	7238
2013	6518 (95.71)	292 (4.23)	6810
2014	6629 (91.81)	591 (8.04)	7220
2015	7356 (92.62)	586 (7.37)	7942
2016	7251 (94.11)	453 (5.88)	7704
2017	6255 (90.32)	670 (9.67)	6925
Total	**40933 (93.37)**	**2906 (6.62)**	**43839**

Of the total collection 22329 (50.93%) units were from replacement donors and 21600 (49.27%) units were from voluntary donors. In this study 775 units were found to be positive for HBsAg with seroprevalence of 1.76%. This happens to be low risk prevalence as per WHO guidelines [9].

In present study, of the 775 positive cases 754 (97.29%) were male donors and amongst them 445 (57.41%) were replacement donors; 309 (39.87%) voluntary donors and 21 (2.70%) were female donors constituting 12 (1.54%) replacement donors and 9 (1.16%) voluntary donors. Therefore there were more of the replacement donors 457 (58.96%) showing HBsAg positivity compared to voluntary donors – 318 (41.03%) cases. The year wise trend in HBsAg positive cases with respect to gender distribution with replacement donor and voluntary donor stratification is tabulated in Table No:2.

The results as such show declining trend in prevalence in males but was inconsistent in female donors. The study revealed that, most of the HBsAg positive cases were amongst donors between 19-30 years of age accounting to 700 (90.32%) cases and the least were found in >50 years of age – 2 (0.25%) cases. The year wise trend and age related distribution of HBsAg positive cases is tabulated in Table No:3, which shows declining trend with respect to increase in age of donor and the same is observed in advancing time scale with decrease in seroprevalence from 2012 to 2017. The trend in seroprevalence as such decreased when compared to past years. Maximum numbers of cases were reported in 2012 (169/7238; 2.33%). But, seroprevalence was more in 2013 (168/6810; 2.46%). The observed seroprevalence was higher in replacement donors (457/22329; 2.04%) when

compared to voluntary donors (318/21600; 1.47%). Year wise trend and replacement versus voluntary donor distribution of HBsAg positive cases is tabulated in Table No: 4.

There is a slight increase in prevalence from 2012 to 2013; thereafter there is phenomenal decrease with 1.06% of prevalence in 2017. This was not found to be significant as the p value is <1%.

TABLE 2: Sex wise distribution of HBsAg positive donors – Replacement *versus* Voluntary donors in respective years

Year	Rep. D Male	Vol. D Male	Total Male (%)	Rep. D Female	Vol. D Female	Total Female (%)	Rep.D Total	Vol. D Total	Total HBsAg (+)
2012	98	63	161 (95.26)	6	2	8 (4.73)	104	65	169
2013	107	57	164 (97.61)	2	2	4 (2.38)	109	59	168
2014	67	58	125 (100)	-	-	-	67	58	125
2015	70	50	120 (96)	4	1	5 (4)	74	51	125
2016	65	46	111 (97.36)	0	3	3 (2.63)	65	49	114
2017	38	35	73 (98.64)	0	1	1 (1.35)	38	36	74
Total (%)	**445 (57.41)**	**309 (39.87)**	**754 (97.29)**	**12 (1.54)**	**9 (1.16)**	**21 (2.70)**	**457 (58.96)**	**318 (41.03)**	**775 (100)**
Total number of blood units collected from 2012 to 2017 – 43,839									
	Seroprevalence in Male donors – 1.71%			**Seroprevalence in Female donors – 0.04%**			**Total seroprevalence in donors – 1.76%**		
Rep. D – Replacement Donor ; Vol.D - Voluntary Donor									

IV Discussion

Hepatitis B infection continues to remain as a significant global health problem. More than 7.80,000 people die every year due to acute or chronic consequence of HBV infection [10-15]. India has one-fifth of world's population which in turn accounts for large proportion of the worldwide HBV burden. India harbors 10-15% of entire pool of HBV carriers of the world [16]. On these grounds the blood bands in India face numerous challenges to provide

TABLE 3: Age wise distribution of HBsAg positive donors – in respective years

Year	Age group of the donors				
	19 – 30 yrs (%)	**31 – 40 yrs (%)**	**41 – 50 yrs (%)**	**>50 yrs (%)**	**Total (%)**
2012	158 (93.49)	11 (6.50)	-	-	169 (21.80)
2013	151 (89.88)	13 (7.73)	4 (2.38)	-	168 (21.67)
2014	115 (92)	8 (6.40)	2 (1.60)	-	125 (16.12)
2015	118 (94.4)	3 (2.40)	3 (2.40)	1 (0.8)	125 (16.12)
2016	100 (87.71)	10 (8.77)	3 (2.63)	1 (0.8)	114 (14.70)
2017	58 (78.37)	12 (16.21)	4 (5.40)	-	74 (9.54)
Total (%)	**700 (90.32)**	**57 (7.35)**	**16 (2.06)**	**2 (0.25)**	**775 (100)**

safe blood to the recipient who is of paramount importance and most significant responsibility of each and every blood bank. The overall prevalence of 1.76% was found in current study which was close to prevalence rate of previous studies carried out by Sri Krishna et al – 1.86% (1999) [17]; Chandra et al – 1.96% (2009) [18]; Arora et al – 1.70% (2010) [19] and Suresh et al – 2.48% (2015) [3]. In present study the prevalence of HBV amongst blood donors in our local area has declined from 2.33% to 1.06% from 2012 to 2017 respectively which is a similar finding in a study performed in middle east (Saudi Arabia) by Saleh(2012) [20]. The declining trend over six years in prevalence of HBsAg was also observed in a similar study carried out by Singh et al (2009) [6]. Increasing literacy in urban as well as rural areas and strict pre donation counseling assisted with quality donor selection criteria has profound impact in declining the trend of disease and infection. Awareness regarding the disease and safety precautions being followed by health care providers and general public also played a significant role.

In our study, the seroprevalence of HBsAg was significantly high in male donors (1.84%) as compared to female donors (0.7%), where as in similar studies conducted by Singh et al (2009) [6] and Bagiyalakshmi et

al (2017) [8], the prevalence was 0.61% in males; 0.29% in females and 0.65% in males; 0.25% in females respectively.

The present study also revealed that, majority of seropositive donors was in younger age group with highest seroprevalence rate in 19-30 years of age (1.59%). The findings correlated with other studies carried out by Baba et al (2000) [21]; Singh et al (2009) [6]; Quadri et al (2013) [22]; Remya et al (2014) [23] and Bagialakshmi et al (2017) [8]. In contrast to the above studies Rodenas et al (2006) [24] reported higher prevalence in donors older than 38 years.

The present study shows that, prevalence of HBsAg is higher amongst replacement donors (1.04%) and the same was found in other similar studies carried out by Singhvi et al (1990) [25]; Sonwane et al (2003) [26]; Gulia et al

TABLE 4: Trend in Seroprevalence of HBsAg in Replacement versus Voluntary donors

Year	Replacement Collection	Replacement HBsAg (+) (%)	Voluntary Collection	Voluntary HBsAg (+) (%)	Total Collection	Total HBsAg (+) (%)
2012	4132	104 (2.51)	3106	65 (2.09)	7238	169 (2.33)
2013	3472	109 (3.13)	3338	59 (1.70)	6180	168 (2.46)
2014	3420	67 (1.95)	3800	58 (1.52)	7220	125 (1.73)
2015	3860	74 (1.91)	4082	51 (1.24)	7942	125 (1.57)
2016	3795	65 (1.71)	3909	46 (1.25)	7704	114 (1.47)
2017	3650	38 (1.04)	3365	36 (1.06)	6925	74 (1.06)
Total (%)	**22329**	**457 (2.04)**	**21600**	**318 (1.47)**	**43839**	**775 (1.76)**

(2011) [27] and Suresh et al (2015) [3]. This problem can be taken care by careful elimination of commercial / professional donors and encouragement of voluntary donations.

V Conclusion

Hepatitis B still holds the place which needs a check for ensuring safe blood transfusion services. Eventhough, there is gradual decline in seroprevalence among replacement and voluntary donors, there is still need for effective donor education, simple and quality donor selection protocol framework by qualified personnel. In most of cases mere absence of HBsAg is not a sufficient platform to mark any blood unit as negative for HBsAg. The risk of TTIs can be minimized further by careful analysis of unequivocal test results with nucleic acid tests (NAT). Immunization in turn plays most efficient role at community level and is also an economical way of prevention of HBV infections. Immunization summed up with health education to high risk groups and health care professionals. Therefore, pre donation counseling, donor self exclusion, 100% voluntary donation and technical advancements in screening of blood units acts as foundation pillars in safe blood transfusion practices.

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