

Utility And Limitation Of Routine SGPT &HbsAg In Blood Donors

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Abstract:Background: After the introduction of blood banks and better storage techniques blood is more widely used in patients for various indications. In Pakistan more than 1.5 million pints of blood are collected each year. Hepatitis B and C virus infections are known to occur in the general population and due to their mode of transmission through blood and blood products, it has made safe blood transfusion difficult and screening of blood absolutely necessary. **Method:** In present study, total 2500 blood donors were screened for ALT estimation and HBsAg at Blood Bank, G.G. Hospital, Jamnagar. Results were tabulated in various observation tables and were compared and discussed with other workers study. **Result:** Out of 2500 blood donors, 2097 were replacement donors and 403 were voluntary donors, 2421 were male donors and 79 were female donors. Out of 2500 blood donors, 2415 were healthy donors and 85 were showing high level of ALT (> 45 KU/ml) or HBsAg positivity or both. Out of 2421 male donors, 34 donors (32 replacement + 02 voluntary) were having high level of SGPT, 30 donors (26 replacement + 04 voluntary) were having HBsAg positive and 18 donors (17 replacement + 01 voluntary) were having HBsAg positivity and high SGPT value. Out of 79 female donors, only 03 replacement female donors were having high SGPT and none of the female donor was HBsAg positive. Mean value of ALT was found to be 26.58+8.86.Male donors have higher level of ALT and also higher incidence of HBsAg than that of female blood donors.Replacement donors have higher level of ALT and also higher incidence of HBsAg than that of voluntary donors. 2.24% of 2500 donors had abnormal or high level of ALT (>45 KU/ml) 1.92% of 2500 donors were HBsAg positive. 0.72% of 2500 donors were HBsAg positive as well as having high ALT value (>45 KU/ml). **Conclusion:** Routine screening of ALT and HBsAgdefinetly decreases the incidence of post transfusion hepatitis.[Shah P et al NJIRM 2013; 4(1) : 92-97]

Key Words:HBsAg, ALT, ELISA, blood donors, blood transfusion

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Introduction: Despite that Hepatitis B is one of the most frequent infections associated with blood transfusion; it was the HIV epidemic that alerted the general public to the importance of serological tests in blood banks. Hepatitis B is a serious global public health problem. Worldwide two billion people have been infected with the hepatitis B virus (HBV) and more than 350 million have chronic, lifelong infections¹ (WHO, 2004). Based on the prevalence of HBV chronic carriers (individuals positive for hepatitis B surface antigen) amongst adults in the general population, countries are classified as having low endemicity<2%, intermediate endemicity 2 - 8% or high endemicity>8% of infection¹. Even with three effective vaccines available, hepatitis B remains a stubborn, unrelenting health problem, especially in Africa and other developing areas. The disease and its complications cause an estimated one million deaths globally each year. Studies in the Middle East showed that the prevalence of HbsAg ranged from 3% to 11% in Egypt. These groups of chronic carriers include apparently healthy adults, school

children, infants, pregnant women, blood donors and healthcare staff¹. The most common factors found to be associated with hepatitis infection and carrier status are the risk of prenatal transmission. Apart from the proven importance of the prenatal transmission, various studies found that maternal history of schistosomal infection was significantly associated with the prenatal transmission. Therefore, the objective of this study is to estimate the prevalence of virus B hepatic infection and to illustrate the various socio-economic, demographic and medical factors related to infection with HBV among apparently healthy individuals. It will be of interest to disclose the effect of the socioeconomic, behavioral and medical risk factors on the development of HBV infection among Egyptian blood donors. A better understanding of what contributes to the development of HBV infection will help in planning and implementing a national campaign for control of the infection all over the country.

Materials And Methods : This was a cross sectional study. The total number of blood donors tested was 2500 Subjects who were volunteers to donate blood G G Hospital Blood Bank, Jamnagar from January 2000 to April 2000. To be eligible to donate blood, a person must be in good health and must be between 18-60 years of age. Generally, donors must weigh at least 50 kg. All donors must pass general and medical examinations prior to donation. Exclusion criteria include: younger or older ages, past history of jaundice, HIV, hypotension, anemia and sever chronic diseases. Questionnaire was designed; it included personal data, family history, past history, and questions about the possible different ways of exposure to the virus (medical and behavior). Blood collected by venepuncture, serum or plasma may be used.

Modified colorimetric method of Mohan and Cook was used for estimation of SGPT. HbsAg was carried out by immunoassay kit for the qualitative test of Hepatitis B Surface Antigen. ELISA HBsAg ULTRA assay is a one step enzyme immunoassay used routinely in blood banks and based on the principle of the sandwich type using monoclonal antibodies and polyclonal antibodies selected for their ability to bind with HBsAg. The presence of HBsAg allows the enzyme to bind to the solid phase. The enzyme action produces a colour which is measured with a photometer.

Statistical analysis: All donors data were tabulated and processed using the SPSS (v.12) software packages, comparison between risk factors was done using student t- test. P value was considered significant if < 0.05 .

Result: The present study was carried at blood Bank, G.G.Hospital, Jamnagar. Two thousand five hundred blood donors who donated blood were tested for ALT and HbsAg. Total no. of blood donors were 2500. Out of these, 2421 donors were male and 79 donors were female. Out of 2421 male donors, 2072 were replacement and only 349 were voluntary. And out of 2500 donors, 2097 were replacement donors and 403 were voluntary donors.

Out of 2097 replacement donors, 2072 were male and only 25 donors were female. While out of 403 voluntary donors, 349 were male and 54 were female donors.

There were 55 donors with high SGPT (>45 KU/ml) Among these, 49 were replacement male donors, 03 were replacement female donors and 03 were voluntary male. But none of the voluntary female shows high SGPT. 48 donors were HBsAg positive and all were male. Out of these 48 donors, 30 donors (26 replacement and 04 voluntary) were show only HBsAg positivity, While 18 donors (17 replacement and 01 voluntary) were show HBsAg positivity as well as high SGPT (> 45 KU/ml). All female donors were healthy.

Total donors were 2500. Out of these, 2097 were replacement donors and 403 were voluntary donors, while 2421 were male donors and 79 were female. Out of 2500 donors, 2415 were healthy donors (2339 male and 76 female) and out of 2339 healthy donors, 2019 were replacement and 396 were voluntary. 34 male donors (32 replacement and 02 voluntary) were having high level of SGPT (> 45 KU/ml) and only 03 replacement female were having high SGPT and 30 male (26 replacement and 04 voluntary) donors were HBsAg positive but none of the female showed HBsAg positivity, while 18 male donors (17 replacement and 01 voluntary) were having HBsAg positivity as well as high SGPT (> 45 KU/ml)

The level of ALT ranges between 8-90 KU/ml in studied 2500 cases. Mean and + SD VALUES are 26.58 and 8.86 a respectively. Out of 2500 donors, 55 donors were having more than 45 KU/ml of serum ALT. Level of ALT Ranges between 6-90 KU/ml in studied 2097 replacement donors. Mean and + SD values are 28.25 and 7.96 respectively.

Out of 2097 replacement donors, 52 donors were having more than 45 KU/ml of ALT. ALT level among voluntary donors range between 8 – 60 KU/ml. Mean and + SD values are 18 and 8.45 respectively. Out of 403 voluntary donors, only 03 donors were having ALT Level more than 45

KU/ml.. ALT level in male donors range between 10 – 90 KU/ml. Mean and + SD values are 26.79 and 8.72 respectively. Out of 2421 male donors, only 52 donors were having more than 45 KU/ml of ALT.

ALT level among female donors range between 8 – 55 KU/ml. Mean and + SD values are 20 and 8.412.22 respectively. Out of 79 female donors, only 03 donors were having ALT Level more than 45 KU/ml. Comparison between replacement and voluntary donors for ALT Estimation, 'Z' value and 'P' value were 22.80 and < 0.0001 respectively. < 0.0001 'p' value suggest that the result were extremely significant.. comparison between male and female donors for ALT Estimation. 'Z' value was 4.77 and 'P' value was < 0.01 . < 0.01 'P' Value suggest that the result was highly significant.

2.05% of Replacement donors and 1.24% of voluntary donors were HBsAg positive. Overall incidence of HBsAg positivity in present study of 2500 donors was 1.92%. Thus higher incidence of HBsAg was found in replacement donors compared to that of voluntary donors. None of the female show HBsAg positivity.

52 of Replacement donors out of 2097 and only 3 voluntary donors out of 403 were having SGPT more than 45 KU/ml. Out of 55 donors with ALT Level more than 45 KU/ml, 18 donors (17 replacement + 01 voluntary) were having HBsAg positive result and rest of the HBsAg positive donors (26 replacement + 04 voluntary) were having normal ALT Level.

Discussion : In present study, we tested total 2500 blood donors who donated blood at Blood Bank, G.G. Hospital, Jamnagar. As shown in table No. 6, total 2421 donors were male and only 79 were female donors. Out of these 2421 male donors, 2072 were replacement donors and 349 were voluntary donors. Out of 79 female donors, 25 were replacement and 54 were voluntary donors. In short, numbers of replacement donors were more as compared to voluntary donors and also numbers of male donors were more as compared

to female donors. Incidence of SGPT in male donors compared to female donors.

Leclerq I et al² showed that ALT was significantly higher in male donors than in female donors. In present study, also the mean value of SGPT for male donors was 26.79 and for female was 20.0, which is highly significant. Incidence of SGPT in replacement donors compared to voluntary donors. In present study, mean value of SGPT in replacement donors was 28.25 and in voluntary donors was 18, which is extremely significant. Also higher level of SGPT (> 45 KU/ml) was found mainly in replacement donors.

Incidence of HBsAg positivity in male donors as compared to female donors. Incidence of HBsAg positivity in replacement donors as compared to voluntary donors

Fazadegan et al³ and Satoskar A et al⁵ showed that incidence of HBsAg positivity was significantly high among replacement donors than among voluntary donors. In present study, 2.05% of replacement donors and 1.24% of voluntary donors showed HBsAg positivity. Incidence of HBsAg positivity and high level of SGPT (> 45 KU/ml)

Giusti G et al⁴ showed that only 0.57% of the occasional donors were having both HBsAg positivity and elevated ALT. In present study 0.72% of the donors were having both HBsAg positivity and elevated ALT. Incidence of HBsAg positivity in relation to the age.

Jayprakash P A et al⁵ showed that the personal data of donors showed a higher rate of HBsAg among men than women and in the age group of 21 to 30 years than in other age groups. In present study, it is in the age group of 21 to 40 years than in other age groups which is quite comparable with above study.

It is evident that the results of the present study were comparable with the results of Caboud et al and Mohan and Cook, while the other workers

study show lower mean value as compared to present study.

Fazadegan H et al³, Jayprakash P A et al⁵, Maeda Y et al⁶ and Sandler S G et al⁷ have reported the mean values of males was higher than that of females. In the present study, as the numbers of female donors were very less compared to male donors. So it was not possible to correlate the incidence as per sex. It was found that only 3 female donors were having abnormal (> 45 KU/ml) ALT level and 52 male donors out of 2421 were having abnormal ALT Level.

As shown in observation table, mean level of male was 26.79 KU/ml which was higher than that of female donors in whom it was 20.0 KU/ml. In addition as shown in observation table no. 16 'P' value was < 0.01 was statistically highly significant.

Aach R. D et al⁸ found that 30% to 40 % of post transfusion Non-A, Non- B hepatitis can be prevented by rejection of the donors having abnormal ALT value. At present, it is difficult to established a cutoff level because there are variety of methods for determining absolute values. Many times it happened that blood donors accepted by one test were not accepted by another.

Leclerca I et al¹ Goncales Jr. F. L. et al⁹ and Lozano M et al¹⁰ showed that ALT level may be affected by certain factors e.g. sex, obesity, diabetes Melitus, Hypertriglyceridemia, Hypercholesterolemia and Hypothyroidism. So there are few limitations for the routine ALT screening of blood donors.

Lozano M et al¹⁰ showed that different cutoff values should be considered for male and female. In the same way Saraswat RV et al⁹ indicates the need to correct ALT value for BMI for blood donor screening instead of using actual ALT value. ALT screening is still considered a useful indicator of risk donors despite its nonspecificity and limited predictive value.¹¹

Aach R. D et al⁸ found that the attack for Non A, Non B hepatitis was 10% and the incidence of hepatitis was directly related to ALT level in blood donors and the attack rate was increase progressively, reaching 45% in recipient of units with an ALT of 60 KU/ml or greater.

Members of transfusion transmitted viruses study group present the best evidence of data that the blood donors with elevated serum ALT level have a significantly increased likelihood of transmitting Non A, Non B post transfusion hepatitis and one of the primary conclusion of their study is that 40 % of the Non A, Non B post transfusion hepatitis could have been prevented by discarding units with an ALT value > 45 KU/ml with loss of 3% of donors population.¹²

Different workers found that the incidence of abnormal ALT varies between 1-4% 89 In the present study, 2.2% of total 2500 blood donors screened, showed abnormal ALT value which is comparable with the result of other workers.

Aach R D et al⁸ found that irrespective of ALT level in donors blood, the source of blood is also important. In their study, the rate of post transfusion Non A, Non B hepatitis and hepatitis B was higher in those patients who received blood from commercial sources than those who received blood from voluntary donors.

In our blood bank, we don't encourage the professional donors, but many of the replacement donors are likely to be professional donors. In present study, 52 were replacement donors and only 03 voluntary donors were having abnormal ALT value (> 45 KU/ml). In addition, as shown in observation table No. 7 and 8, mean level of ALT was higher in replacement donors (28.25 KU/ml) than that of voluntary donors (18.0 KU/ml). 'P' value was < 0.0001 , was statistically extremely significant.

Abnormal ALT value with negative HBsAg in donors suggest the hepatic disorder and not necessarily the carrier of Non A, Non B hepatitis because not all the recipient who received blood

with abnormal ALT develop post transfusion Non A, Non B hepatitis¹³. This elevation in serum ALT value may be due to other factors as mentioned earlier or the negative HBsAg may be found if patient is in ' Window Period".^{14,15,16}. Negative result of HBsAg may be also due to limitation of routine EIA method.

Since the discovery of Australia antigen (HBsAg) by Blumberg in 1965, incidence of post transfusion hepatitis is increased in all over the world. The incidence of post transfusion hepatitis vary from 1 to 20% among this 90% cases of post transfusion hepatitis are of Non A, Non B type.⁸⁹ As mentioned earlier, serum ALT was elevated in various hepatic disorders such as (I) various type of hepatitis (II) hepatic carcinoma (III) cirrhosis of liver. (IV) obstructive jaundice (V) heart failure and (VI) myocardial infarction. So, demonstration of abnormal ALT in the serum of donors appears to be potentially important both in the study of hepatic disorder and in the prevention of post transfusion Non A, Non B hepatitis.¹⁷

Giusti G et al¹⁸ and Shanty S B et al¹⁹ showed that there is a geographic variation in prevalence of HBsAg. Giusti G et al⁸² showed that only 0.27% of the occasional donor showed both HBsAg positivity and elevated serum ALT level. In present study 0.72% of the donors showed both HBsAg positivity and elevated serum ALT level.

Lastly, detection of ALT in donors blood may provide a simple method for the recognition of apparently healthy but potentially infectious individuals. It is used as surrogate test for HCV where detection of HCV is not done routine as a donor screening test. Though the value of this method in screening blood donors for prevention of post transfusion hepatitis remain to be fairly established, it is work making an attempt in introducing this test as a routine procedure in institution like blood banks. Along with ALT level estimation more reliable, specific and sensitive test must be used for detection of HBsAg and if possible more advanced method with high specificity and sensitivity is used as mentioned earlier.

Conclusion: Number of the male donors were more than that of female donors. Number of replacement donors were more than that of voluntary. Male donors carry more chances of post transfusion hepatitis. Replacement donors carry more chances of post transfusion hepatitis. Absence of HBsAg in donors blood does not rule out of hepatic disorders. It is necessary to screen a blood donor for ALT level, especially where serum is not routinely tested for HCV infection. Routine screening of ALT and HBsAg definitely decreases the incidence of post transfusion hepatitis.

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