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Sensitivity Comparison between Rapid Immuno-Chromatographic Device Test and ELISA in Detection and Sero-Prevalence of HBsAg and Anti-HCV antibodies in Apparently Healthy Blood Donors of Lahore, Pakistan

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***Abstract*—**Hepatitis B and hepatitis C are among the most significant hepatic infections all around the world that may lead to hepatocellular carcinoma. This study is first time performed at the blood transfussion centre of Omar hospital, Lahore. It aims to determine the sero-prevalence of these diseases by screening the apparently healthy blood donors who might be the carriers of HBV or HCV and pose a high risk in the transmission. It also aims the comparison between the sensitivity of two diagnostic tests; chromatographic immunoassay – one step test device and Enzyme Linked Immuno Sorbant Assay (ELISA). Blood serum of 855 apparently healthy blood donors was screened for Hepatitis B surface antigen (HBsAg) and for anti HCV antibodies. SPSS version 12.0 and X2 (Chi-square) test were used for statistical analysis. The sero-prevalence of HCV was 8.07% by the device method and by ELISA 9.12% and that of HBV was 5.6% by the device and 6.43% by ELISA. The unavailability of vaccination against HCV makes it more prevalent. Comparing the two diagnostic methods, ELISA proved to be more sensitive.

***Keywords*—**ELISA, Sensitivity comparison of diagnostic tests, seroprevalence of Hepatitis B and C

I. Introduction

Most of the diseases can be diagnosed using blood[1].A huge amount of blood is collected every year for various purposes [2] – [3]. The blood donors belong to many categories including the volunteer donors as well as professional ones [4]. Blood is considered one of the important causes of transmission of diseases including hepatitis B and Hepatitis C. Safe transfusion of blood is a matter of great concern among physicians as well as the patients nowadays [5] - [6]. It is possible to minimize the hazards of transfusion just by screening the donor selection properly before the blood is collected. It is found that the prevalence of diseases which are transmitted due to blood transfusion is lower in volunteer blood donors in comparison with the professional donors [3], [4].

Hepatitis B and C is mostly transmitted through the transfusion of unscreened blood and using unsterilized syringes and medical equipment repeatedly [7], [8]. Physicians and the concerned community should be encouraged to use the medical equipment which is sterilized properly and to screen the blood before transfusion. These behaviors should be promoted in order to decrease the rate of diseases spreading due to careless attitude involved in blood transfusion process [9].

Epidemiological studies are very important regarding prevention of any disease [3]. It is estimated by the World Health Organization that there are about 350 million chronic carriers of hepatitis B spreading in every continent in Asia, America, Europe, and Africa and about 170 million chronic carriers of hepatitis C all around the world. [7] - [10]. The number is increasing tremendously each year due to lack of awareness among various communities involved in blood transfusion method. It has been reviewed from the literature of last five years that the sero-prevalence of hepatitis B varies from 2% to 14% [11] and that of HCV varies from 0.7 % to 25 % among healthy blood donors in different parts of Pakistan [12].

This study was conducted to estimate the prevalence of both these liver diseases in apparently healthy blood donors of Lahore. Since there is a possibility of them being asymptomatic carriers of hepatitis, they need to be screened out. Lahore is a big city of Pakistan with tremendous diversity of population associated with various fields of life and social status. This retrospective study will give us the idea about the burden of disease in healthy looking general people living in different areas of Lahore. This data can be used to make important plans and policies for assuring safe blood. The two diagnostic techniques; a one step diagnostic kit and ELISA technique were used and the sensitivity comparison of both techniques was also studied.

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II. Materials And Method

A total of 855 healthy blood donors visiting Omar Hospital, Lahore were considered in the present study. They reported over the period of one year from January 2010 to February 2011. The consent from each donor was taken for this study in order to fulfill the ethical guidelines of research conducted on humans. Out of these 855 donors, 782 were males and 73 were females. Blood donors were selected on the strict basis of the standard operating procedures and their confidentiality was maintained as described by Blood Transfusion Services, Pakistan. The donors were screened for Hepatitis B and Hepatitis C using two diagnostic methods, i.e., one step immunochromatographic device method and ELISA technique. The ACON HBsAg , ONE step test device (Catalog Number: IHBsg-302) was used for screening of hepatitis B and ACON HCV, one step hepatitis C test device was used for screening of hepatitis C. The second method used was ELISA. For Hepatitis B, HBsAg ELISA test kit (Catalog Number: CLI- 22001, CARO Laboratories International) was used and for Hepatitis C, HCV ELISA kit (CARO Laboratories International) was used. SPSS version 12.0 was used for statistics of the study. The X2 (Chi-square) test was performed for qualitative variables to check the relationship of HBV and HCV infection. Percentages were calculated directly for HBV and HCV. P = 0.05 was used as the accepted significance level.

III. Results

Out of the 855 blood donors screened, 91.4% (782/855) were males and 8.53% (73/855) were females. Among them, 48 were found seropositive for HBV giving the seroprevalence of 5.6% (48/855) using the one step device method, whereas the ELISA technique shows 55 positive cases of HBV which turns out to be 6.43% (55/855) (Figure: 1)

Considering the total population size screened for anti HCV 69 donors were found positive by the device method, which gives the seroprevalence of 8.07% (69/855) whereas, ELISA analysis shows 78 donors positive for anti HCV and the seroprevalence turns out to be 9.12% (78/855). (Figure: 1)

Co-existence of HBsAg and HCV in healthy donors was also observed in this study. Out of 855 blood donors, 5 were found positive for both the diseases. This turns out to be 0.58% (5/855) using both the analytical methods. (Figure: 1)

The comparison of two analytical methods i.e., the one step device method and the Enzyme Linked Immunosorbent Assay (ELISA) was studied and the results proved that the ELISA technique is more sensitive and accurate as compared to the device method as shown in the figure1.

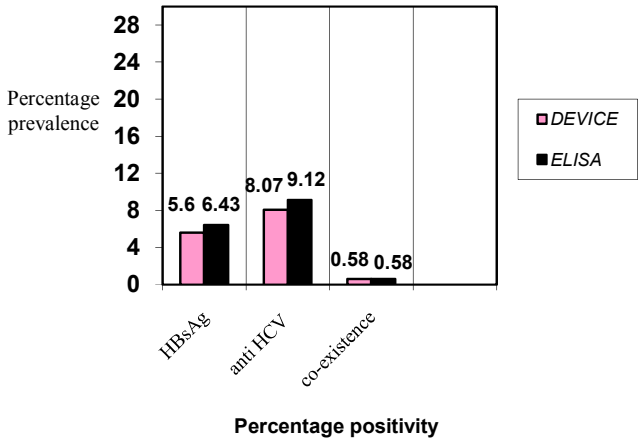

Fig. 1 The sero prevalence of HBV, HCV and their co-existence in apparently healthy blood donors and the comparison of one step device method and the ELISA method; 5.6% were positive for HBsAg by the device method whereas the ELISA gives 6.43% positive results. On the other hand, 8.07% were positive for anti HCV by the device whereas 9.13% were positive using ELISA technique.

IV. Discussion

An overall 6.43% prevalence of hepatitis B was recorded, which is similar to many other studies. The literature published during last few years gives the idea that the seroprevalence of HBV in Pakistan varies from 1.55 % to 7.53 % in healthy blood donors belonging to various parts of the country. The lowest value is reported from Abbotabad 1.55 % [16] and the highest value is reported from Bahawalpur 7.53% [13] - [14]. Chronic HBV infection is prevalent in South east Asia, China and Africa, where over 10% of the healthy blood donors were positive for HBV [15].

An overall 9.12% seroprevalence of Hepatitis C infection has been observed in this study. Different studies performed at different times in Pakistan shows the sero prevalence that varies from 0.7 % to 25 % [12]. A similar study performed in Islamabad shows a seroprevalence of 14% [2]. The lowest seroprevalence observed is 0.27% from Multan [17]. Similarly, the sero prevalence of HCV is also different all around the world. It is found about 6 % in Africa [16] , 1,5 % in Japan, 0.6 % in USA. 1.5% and 28% in Egypt [17].

Co-existence of HBsAg and anti HCV turned out to be 0.58% in the present study which is quite low. Another study was conducted in Republic of Yemen, where 7.7% co-existence was observed [18] and in India the co-existence was found to be 1.22%.

This study gives us the awareness about the alarming condition of viral hepatitis among the apparently healthy population and about the asymptomatic carriers of liver infections in Pakistan. Comparing the sero-prevalence of both the diseases, the above data clearly indicates that the seroprevalence of anti HCV is more as compared to HBsAg in healthy blood donors of Lahore. This is probably because of

the availability of vaccinations for HBV whereas, there is no vaccination developed for HCV so far. So, there is the need for healthy people to get their blood screened for HBV and HCV and they are advised to get it done using the ELISA technique which is found to be more accurate as compared to the one step device method. Moreover, the government should devise certain mass vaccination and general awareness programs in public to make them aware of these deadly liver infections and their mode of transmission in order to control the spread.

V. Conclusion

- This is the first study on seroprevalence of hepatitis B and Hepatitis C in apparently healthy blood donors at Omar hospital, Lahore.
- The comparison of two techniques; the device method and the ELISA method is also done in this study and the later is found to be more sensitive.
- This study gives us the idea that the viral hepatitis among the apparently healthy population refers to an alarming condition about the asymptomatic carriers of liver infections in Pakistan. So, there is the need for healthy people to get their blood screened for HBV and HCV and devise methods to control the spread of these liver infections.

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