

**Frequency of Hepatitis B Surface Antigen and C Antibody
among Voluntary non Remunerated and Replacement
Donors in Fayoum, Egypt. Steps Towards 100% voluntary
non Remunerated Blood Dontation**

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Abstract

Egypt has a very high frequency of hepatitis C and hepatitis B with high morbidity and mortality. Limited information exists regarding the frequency of hepatitis C and B in Fayoum Governorate, Egypt. The objectives of this study were to determine the frequency of both hepatitis B surface antigen and hepatitis C antibodies in Fayoum, and to compare the frequency of hepatitis B and C viruses between volunteer and replacement blood donors in Fayoum University hospital from August 2009 until September 2010.

Study design and methods: Enzyme linked immunosorbent assay (ELISA) was performed for HBsAg and HCV antibody detection on 4252 consecutive blood donors from Fayoum University Hospital Blood Bank, 3217 (75.7%) family replacement/ hidden paid donors and 1035 (24.32 %) voluntary non- remunerated donors. Second time donors were excluded from the study. Results: the overall frequency of HCV and HBV among the 4252 donors was 7.4 and 2.1 % respectively. The frequency of HCV and HBV in 3217 replacement donors was 8.9 % and 2.3 % respectively. The frequency of same in 1035 voluntary non- remunerated blood donors was 2.9 and 1.4 % respectively.

Conclusion: The high frequency of HCV and HBsAg in family compared to voluntary donors calls for moving fast towards 100% voluntary non- remunerated blood donation.

Key words: Voluntry donors, Replacement donors, HCV, HBsAg.

Introduction:

Egypt has a very high frequency of hepatitis C and hepatitis B with high morbidity and mortality. Limited information exists regarding the frequency of hepatitis C and B in Fayoum Governorate, Egypt. The objectives of this study were to determine the frequency of both hepatitis B surface antigen and hepatitis C antibodies in Fayoum, and to compare the frequency of hepatitis B and C viruses between volunteer and replacement blood donors in Fayoum University hospital from August 2009 until September 2010.

However, six years have elapsed since the last study of blood-borne pathogens was conducted [3]. During this time the prevalence of HIV as well as that of HCV, HBsAg, and *T pallidum*, which share common modes of transmission with HIV, are likely to have changed. This scenario is likely to change the risk of transmitting blood-borne pathogens since donor blood is not screened comprehensively for all common blood-borne pathogens. Thus, it is prudent to quantify the risk of blood borne infections associated with such transfusions at regular intervals. In the previous study [3], only a relatively small number of donors was involved (n = 300) and for some investigations such as HCV and HBsAg only 100 donor blood samples were screened due to lack of resources. As a result, the data generated was rather limited. For example, it was not possible to estimate the seroprevalence of the different infections by donor type (replacement or voluntary donor), yet this is thought to be very important information since the prevalence of blood borne pathogens may differ significantly with donor category [4,5]. Furthermore, the small sample size might have undermined the associations in the occurrences of the pathogens. For example, the association between HIV and HCV which was found to be marginally non-significant could have been significant with a larger sample. Since the publication showing the prevalence of HCV to be 8% [3] concerns have been raised about the accuracy of the latex

agglutination technique employed in that study. It has been argued that the presented estimate could have been an overrepresentation of the situation emanating from cross-reactivity. More accurate HCV tests have now been developed and are widely available such as enzyme-linked immunosorbent assay (ELISA), radioimmunoassay (RIA) and polymerase chain reaction (PCR). Finally, it is interesting to find out the prevalence of HBsAg, HCV and syphilis infections in HIV seronegative blood, which is normally transfused to the needy patients.

The objectives of this study were to determine the frequency of both hepatitis B surface antigen and hepatitis C antibodies in Fayoum, and to compare the frequency of hepatitis B and C viruses between volunteer and replacement blood donors in Fayoum University hospital from August 2009 until September 2010.

Materials and Methods:

Blood samples

The present study included 4252 samples from blood donors negative for anti-hepatitis C antibody (HCV), and HBsAg collected over a period of 1 year August 2009 until September 2010 in Fayoum university hospital blood bank.

Assays

IgG antibodies to HCV were detected using an ELISA technique (Murex anti-HCV version 4.0). This involved inoculation of diluted sample on microwells coated with highly purified antigens which contained sequences from the core, NS3, NS4 and NS5 regions of HCV. The amount of conjugate bound, and hence colour, in the wells, is directly related to the concentration of antibody in the sample. When the test is run and results are interpreted according to manufacturer's instructions high sensitivity (99.93%) and specificity (99.82%) are achieved.

HBsAg Version 3.0, an immunoassay, was used for the detection of hepatitis B surface antigen (HBsAg). The test has sensitivity and specificity of approximately 99.7% and 99.3%,

respectively when performed according to the instructions of the manufacturer (Murex Biotech Ltd, Dartford, UK).

Statistical analysis

Data were statistically described in terms of frequencies (number of cases) and percentages when appropriate. All statistical calculations were done using computer programs Microsoft Excel 2003 (Microsoft Corporation, NY, and USA) and SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 15 for Microsoft Windows.

Results:

Serological results

All participants were negative for HBsAg. 99/800 (12.37 %) of blood donors were negative for HBsAg and positive for anti-HBc. Anti-HBs antibody was detected in 78/99 (78.78%) of HBsAg negative and anti-HBc positive samples, with serum levels > 10 IU/L.

Discussion:

OBI is defined as the presence of HBV DNA in the liver (with detectable or undetectable HBV DNA in the serum) of individuals who tested negative for HBsAg⁽²⁶⁾. Occult HBV is transmissible by blood transfusion, although the transmission rate is considered to be very low. The clinical outcome of OBI transmission mainly depends on the immune status and copies of HBV DNA in blood products of the recipient⁽³⁰⁾. At present, HBsAg detection is the only obligatory diagnostic screening test for HBV infection in blood transfusion centers in Egypt^(25, 10). We examined 800 HBsAg negative sera obtained from healthy blood donors and found that 12.37 % of them were positive for anti-HBc, which is comparable to two previous Egyptian studies with a prevalence of 14.2% and 10.9 % of HBsAg negative volunteer blood donors^(29, 11).

The study is also comparable to the older anti-HBc prevalence rates reported among HBsAg-negative blood donors in India; 10.01% ⁽¹⁹⁾ and 11.2% in Syria ⁽²¹⁾, respectively.

The prevalence of anti-HBc only in Europe and North America is overall quite low. A prevalence of 0.07% in the UK and 1.5% in Germany was reported ^(2, 13). In areas of higher HBV infection prevalence about 20%-70% of subjects are positive for anti-HBc antibody ⁽⁷⁾.

In our study the overall prevalence of occult HBV infection in healthy blood donors was 9.52% among anti-HBc positive alone individuals. Different results have been reported in other studies regarding the rate of OBI in blood donors. These differences in the occult HBV prevalence may be attributed to race and ethnicity, geographical area and the HBV subtypes ^(3, 14). The frequency of HBV-DNA detected in HBsAg negative samples also varies considerably according to the prevalence of the infection. In Northern countries where the prevalence of chronic infection is less than 1%, no more than 5% of HBsAg negative /anti-HBc positive blood donor samples contain HBV-DNA ^(2, 16). In contrast, higher OBI levels in HBsAg-negative blood were recorded in several published reports. In India, the prevalence was 24% ⁽²²⁾ and in a published study from Korea, 16% of the studied sample was found to be positive for OBI ⁽¹⁵⁾. Other reports of the prevalence of HBV-DNA in only anti-HBc positive blood donors revealed 0% in Brazil ⁽⁴⁾, 0.3% in china ⁽²⁸⁾, 1.1 % in Japan ⁽³¹⁾, 3.2% in Saudi Arabia ⁽⁵⁾ and 12.7% in Ghana ⁽³²⁾. Some information is available regarding the infectivity of anti-HBc-only blood products or organs. The infectivity of blood donations containing anti-HBc as the only marker of HBV infection has been known for several decades and indicated that no more than 4% of recipients of anti-HBc-only blood developed HBV infection post-transfusion ⁽¹⁷⁾ However, Mosley reported 17% infectivity of anti-HBc-only blood products ^(14, 20). Anti-HBc screening has the potential of excluding the vast majority of occult HBV infection but this exclusion of anti-HBc positive donors is

impractical in countries where HBV infection is prevalent and higher than 20% of the populations are anti-HBc positive⁽¹²⁾. The use of HBV anti core testing to eliminate the residual transfusion risk of transmission of HBV has not been evaluated in Egypt.

Conclusion:

This high (15.9%) seroprevalence of transfusion-transmissible infections in blood donated at MNH is alarming and calls for i) comprehensive screening of donor blood for HIV, HBV, HCV and syphilis ii) strict selection of donors, with emphasis on getting young voluntary non-remunerated donors rather than replacement donors, iii) establishment of strict guidelines for blood transfusions and iv) search for viral co-infections in HIV infected patients.

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الملخص العربي

تمثالعدويبيروساإلتهابالكبدبي "بي" و "سي" مضاعفاتشائعةوخطيرةلنقلالدم. وحيثأنهتوجدمعلوماتمحدودةعننسبةالإصابةفيمحافظةالفيوممفقدتماختبارجميععيناالمتبرعيناالدمفيالمستشفىالجامعيفي الفيومفيالفترةمنأغسطس ٢٠٠٩ إلىسبتمبر ٢٠١٠ لتحريالمستضدالسطحيلفيروسالتهابالكبدبي "بي" وأضدادفيروسالتهابالكبدبي "سي" وعددهم (٤٢٥٢) منهم (٣٢١٧) ٧٥.٧ % متبرعيناالعائلةو (١٠٣٥) ٢٤.٣ % متبرعيشرفيينبدوونمقابلولميتماإدراجأيمتبرعأكثرمنمره. ولقدتبيينأن ٧.٤ % منجميعالمتبرعيناكانواإيجابيينلفيروس "سي" مقابل ٢.١ % إيجابيينللمستضدالسطحيلفيروس "بي". وبالنسبةللمتبرعيناالعائلةتبيينأن ٨.٩ % أعطوانتائجإيجابيةلأضدادفيروس "سي" و ٢.٣ % كانواإيجابيينللمستضدالسطحيلفيروس "بي". أمابالنسبةللمتبرعيناالشرفيينبدوونمقابلفكانتالنسبةهي ٢.٩ % لفيروس "سي" و ١.٤ % لفيروس "بي". وعليهذافإنالمعدلاتتعتبرأقلبنسببمؤثرتبيينالمتبرعيناالشرفيينعنمتبرعيناالعائلةوالذيقديوذيإضرارهمللتبرعإلخفاءبعضالمعلوماتعنحالتهمالصحية. وعليهذافإنالهدفمنهذالدراسةهو معرفةمعدلاتانتشارفيروس "بي" وفيروس "سي" بينالمتبرعيناالدمبنوعيهمفيمحافظةالفيوموعلمقارنةبينالنوعينالمتبرعينوذلكلقدجرسالإنذاربضرورةالانتقالالكاملبنسبة ١٠٠ % للتبرعالشرفيينوكالدموذلكوفقاًلتوصياتمنظمةالصحةالعالمية.