ORIGINAL ARTICLE

Prevalence of Hepatitis C Virus Antibodies in Blood Donors in Malaysia

G. Duraisamy, FRCPA
H. Zuridah, BSc
M.Y. Ariffin
Blood Services Centre, Hospital, Kuala Lumpur

Summary

Hepatitis C virus (HCV) is the chief aetiologic agent for the parenterally transmitted Non-A, Non-B (NANB) hepatitis. This preliminary study was done to determine the prevalence of anti-HCV in the blood donor population. Blood from 3,540 donors who donated blood to the Blood Services Centre, Hospital, Kuala Lumpur, from 25th August 1991 to 13th January 1992, was tested for anti-HCV using both the Ortho and Abbott 2nd Generation ELISA test kits. ELISA positive specimens were repeated twice but no confirmatory test was done. There were 53 out of 3,540 (1.49%) blood donors who were repeatedly reactive to anti-HCV by ELISA. We plan to do further tests to confirm the results, using RIBA-2 or Abbott Neutralising test. Twenty eight out of 1,713 (1.63%) Malays, 22 out of 1,373 (1.60%) Chinese and 2 out of 393 (0.50%) Indians had antibodies to HCV. There was no significant difference in prevalence in the different age groups. The majority of donors tested were males (3,511 out of 3,540) of which 53 (1.50%) were anti-HCV positive. Only 29 females were tested and all were negative. To determine infectivity of the anti-HCV positive cases we would like to introduce testing for RNA by polymerate chain reaction (PCR). Screening all donated blood for anti-HCV will decrease, but not totally eliminate, post-transfusion hepatitis.

Key words: Blood donors, hepatitis C.

Introduction

Hepatitis C virus is the chief aetiologic agent for parenterally transmitted Non-A, Non-B (NANB) hepatitis. HCV infection is usually not severe and is often asymptomatic. Chronic hepatitis develops in at least 50% of those infected and at least 10% will die of associated complications in spite of the improvements in the quality of blood donor pools and testing of donated blood for Hepatitis B and anti-HIV. In the northern European population, the overall frequency of HCV antibody (anti-HCV) seropositivity is 0.5% to 1.5%[1,2] and in Taiwan the prevalence of anti-HCV amongst the blood donors is 2.0%[3]. In 1989, Japan started screening all blood donors for anti-HCV, using the 1st generation test kits, as Hepatitis C is a major cause of liver disease and hepatic cancer in that country. Antibody to Hepatitis C virus was found in about 75% of post-transfusion acute NANB hepatitis patients in Japan[4].

Clinical studies on the prevalence of anti-HCV in the blood donor population in Malaysia have not been reported and this study was done to determine its prevalence.

Method

This study included random samples collected from volunteer blood donors who donated to the Blood Services Centre, Hospital, Kuala Lumpur, between 25th August 1991 and 13th January 1992. Three

thousand five hundred and forty blood donors were screened for anti-HCV, using licensed Enzyme-Linked Immunosorbent Assay (Ortho HCV ELISA test System 2nd Generation and Abbott HCV EIA 2nd Generation). The Ortho HCV ELISA test system had 3 HCV antigens — namely the recombinant c22-3 structural (core) protein, c200 non-structural protein and an HCV derived recombinant polypeptide c100-3. In the Abbott HCV EIA 2nd Generation test, the same c100-3 antigen was employed along with a capsid (c22) protein and a non-structural (C33c) protein.

The presence or absence of antibody to HCV is determined in both the kits in relation to the mean absorbance of the cut-off control. Samples with absorbance readings less than the cut-off control were considered negative while those in excess of but within 10% of the cut-off control were considered 'indeterminates' and samples with absorbance values of more than 10% of the cut-off control were considered reactive.

Repeat ELISA tests were done with the other test kit, i.e., if the test was positive with the Ortho test, it was repeated with the Abbott kit and vice-versa, to verify positivity. According to information supplied by the manufacturers, the sensitivity in the Abbott test kit, defined using acute Non-A, Non-B cases, was 55.64% to 81.62% (95% CI). Using chronic Non-A, Non-B cases, the sensitivity of the assay was 94.04% to 100.0% (CI). Using the Ortho HCV ELISA test system, the sensitivity was 98.3% and the specificity was 99.8%.

Confirmation by Recombinant Immunoblot Assay (Chiron RIBA 2) and Abbott Neutralisation Test were not done. Hepatitis C virus genomic RNA detection by PCR or more specific tests to show Hepatitis C virus viraemia infectivity were also not done.

Table I
Prevalence of anti-HCV in blood donors

Ethnic group	No of positive/total screened	(% positive)
Malay	28/1,713	(1.63%)
Chinese	22/1,373	(1.60%)
Indian	2/393	(0.50%)
Others	1/61	(1.63%)
Total	53/3,540	(1.49%)

x^2=2.93; df=3; p=0.40.

Results

Of the 3,540 blood donors screened, 53 (1.49%) were repeatedly reactive for anti-HCV by ELISA. The results did not show any significant difference in prevalence in the various ethnic groups (Table I).

The results did not show any significant difference in the anti-HCV prevalence rates in the different age groups (Table II).

Most of the blood donors were males. Of the 3,511 males tested, 53 (1.49%) were positive. Only 29 females were tested and all were negative.

Discussion

The seroprevalence was 1.49% in the blood donor population screened. This high prevalence needs further investigation. There were 15 'indeterminates' who were not included as positive. If included, the percentage of overall reactive would have been 1.92%.

Table II
Distribution of anti-HCV by age

Age group (years)	No of positive/total screened	(% positive)
18 - 19	2/342	(0.58%)
20 - 24	20/1,426	(1.40%)
25 - 29	7/734	(0.95%)
30 - 34	9/395	(2.28%)
35 - 39	8/444	(1.80%)
>40	7/199	(3.52%)
Total	53/3,540	(1.50%)

x^2=10.9; df=5; p=0.0532.

Donors whose HCV antibody results were strongly reactive (sample optical density/cut-off optical density >2) were likely to be RIBA-2 positive and to have elevated alanine aminotransferase (ALT) levels. These donors may have more risk factors for HCV than those donors with weakly reactive HCV ELISA results. The seropositive donor population will be studied for these factors in future.

Some of the anti-HCV positive results may have been false positives, as the tests for the detection of anti-HCV have a substantial false positive rate even when using the 2nd generation kits and repeating the test on either Ortho or Abbott kits. This screening is not specific and only a proportion of the anti-HCV ELISA positive blood sample appear to transmit HCV[6].

As we did not perform any confirmatory tests, the true positive rate is not known. The ELISA anti-HCV test kits that were used were not sensitive or specific for ongoing HCV infection. The PCR assay for anti-HCV RNA is more specific but it is not yet available for use in this centre.

Blood donors' histories need to be studied in order to look for risk factors in these patients. It is important to note that when 100 intravenous drug users (IDU) were screened, 97% were found to be anti-HCV positive (unpublished data, Blood Services Centre, HKL). Although the Blood Services Centre takes great pains to ensure that donors are voluntary and that high risk behaviour blood donors are excluded, some of these anti-HCV positive blood donors may have been previously exposed to such risks like intravenous drug abuse.

The blood donors have to be interviewed to get a history of intravenous drug use and other risk factors like acupuncture, multiple sexual contacts, tattooing, ear piercing and blood transfusions. The North London Blood Transfusion Centre found that most of their anti-HCV positive blood donors had a history of intravenous drug abuse, while a few gave a history of previous blood transfusions, sex with multiple partners, sex with a drug user, tattooing or ear piercing[7].

Blood and blood products infectious for HCV will be substantially diminished, but not totally eliminated, if all donated blood is screened for anti-HCV. The infectious virus can coexist with HCV antibody. The relation between the antibody and the virus load and the period of infectivity before antibody is detected (infectious units that are seronegative) will give a false impression of non-infectivity. These tests have a limited value as they probably detect only 85% of infectious units.

Acknowledgement

We would like to express our thanks to the Director , Ministry of Health, Malaysia, and the Director, Hospital, Kuala Lumpur, for giving us the permission to publish this article. We are also thankful to all the staff of the Hepatitis/AIDS Lab, Blood Services Centre, HKL, for all the work rendered to make this work possible (M.H. Ariff, C.S. Kek and K. Selvarani).

References

1. Gowans E. Hepatitis C Virus. Virus Information Exchange Newsletter 1991;8 : 106-10.
2. Lin CK *et al.* A study of Hepatitis C Virus Antibodies and Serum Alanine Transferase in Blood Donors in the Hong Kong Chinese. Vox Sang 1992;62 : 98-101.
3. Ebeling F. Post-transfusion Hepatitis C in Finland. Finnish Red Cross Blood Transfusion Service and Third Department of Medicine, University of Helsinki, Finland, 1991. PhD Dissertation.
4. Anonymous: Report on Symposium Tokyo in Japan - 1989. Nature 1989;342 : 467.
5. Van der Poel, Reesink HW, Schaosberg W *et al.* Infectivity of Blood Seropositivity for Hepatitis C Antibody. Lancet 1990;335 : 558-600.
6. Watson K. Hepatitis C Infection in Australia. Modern Medicine of Australia 1991;July : 18-31.
7. Maclennan S *et al.* Screening Blood Donations for HCV. Lancet 1992;339 : 131-2.