

Original Article

SEROPREVALENCE OF HEPATITIS-C ANTIBODIES IN BLOOD DONORS

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ABSTRACT:

Objective: To assess the prevalence of anti HCV antibodies in blood donors.

Design: The retrospective sero-epidemiological data of the Institute of Haematology and Blood Transfusion Service, Punjab over a period of one year after starting HCV screening, was analysed to estimate the percentage prevalence.

Setting: The data was obtained regularly from the blood units established by this Institute at the public sector hospitals and retesting on initially reactive serum samples by EIA was done at the Institute.

Subjects: A total of 166183 directed first time donors or replacement blood donors aged 18-60 years who donated blood at these blood banks or at mobile sessions have been included in the study. All initially reactive donors who tested non-reactive on EIA were excluded from the study.

Main Outcome Measures: Assessment of prevalence of HCV in blood donors.

Results: 4.45% of the total donors initially tested reactive; of these 0.36 % were falsely reactive on initial screening. Further testing by EIA, indicated the correct prevalence of HCV in blood donors at 4.1%.

Conclusions: The blood transfusion service started screening for HCV in April 2000 and the prevalence of HCV, amongst the transfusion transmitted infections (TTIs) being screened for in the Punjab, is the highest. It is almost double the prevalence of HBV and several thousand times that of HIV. Meticulous and total screening coverage is needed to curtail impending catastrophe. With experience, the choice of testing methodology might have to be reviewed.

KEY WORDS: Blood safety; prevalence of HCV antibodies in blood donors.

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INTRODUCTION

Amongst the major causes of acute and chronic hepatitis, hepatitis C infection has an important place. It has now been recognized as the major etiologic agent of nonA-nonB hepatitis¹. Although, a great deal has been learnt about the epidemiology and transmissibility of HCV, the number of new cases still remains high². The prevalence of hepatitis C is approaching epidemic proportion with an estimated nearly 4.0 million people infected and 8000-10000 deaths annually in the United States alone³. Typically a benign disease, acute hepatitis C is rarely recognized. In the transfusion setting 70-80% of

HCV cases are anicteric and asymptomatic⁴. Fulminant disease is extremely uncommon. The significance of HCV infection therefore resides in its tendency to become persistent and induce chronic liver disease. At least 85% of patients with acute HCV infection become chronically infected⁵. It is also estimated that 20-30% of patients with chronic hepatitis C may develop liver cirrhosis⁶. An association with hepatocellular carcinoma has also been observed⁷. Consequently, HCV liver disease has now become the leading cause of liver transplantation in the US.

Presently, no vaccination is available and treatment with interferon apart from being expensive is effective in less than 20% of treated individuals⁸. HCV occurs primarily through direct percutaneous exposures, transfusion of contaminated blood products, parenteral drug abuse, accidental needle stick injuries in healthcare workers, and organs for transplant from infected donors⁹. These groups however account for only 50% of reported HCV cases. Whether HCV is transmitted efficiently or at all via sexual or household contact remains controversial. The higher prevalence amongst commercial sex workers and patients attending STD clinics may support the sexual route as a mode of transmission¹⁰. Vertical and familial transmission has occasionally been reported but major studies have failed to provide convincing evidence¹¹. A cross sectional study in Saudi Arabian children demonstrated an approximately equal prevalence (1%) as that found in adults¹². Varying prevalences have been reported ranging from 0.07% in England to 25% in Egypt. In general, significantly higher prevalence rates have been reported from Africa, the Middle East and Southeast Asia as compared to those from Europe, the United States or Australia².

HCV antibodies detectable in viremic blood donors co-relates well with infectivity. As transfusion is the major route of transmission, the screening of blood for HCV cannot be over emphasized. The screening for HCV in Punjab Blood Transfusion Service was started in April 2000. Over the period of one year, it has become evident that HCV infection in blood donors is

very high and overshadows the prevalence of HBV or HIV. As our donors are mostly first time healthy donors, the figures may also be utilised to estimate the prevalence of HCV in the healthy population in this age group (18-60 years).

MATERIALS AND METHODS

Study Population:

Over one year period from April 2000 to March 2001, 166183 healthy blood donors aged 18-60 years were tested for anti HCV antibody at the blood banks of the teaching hospitals affiliated with the Institute of Haematology & Blood Transfusion Service, Punjab. Data was analysed at the Institute for prevalence of HCV among blood donors. The predominant donor pool consists of first time directed donors as there are very few repeat donors; our data, therefore also reflects the prevalence in the population at large in this age group.

Anti HCV testing algorithm

Initial screening for HCV was done on Gold labelled antibody-antigen (Ab/Ag) complex binding rapid test device for HCV (IgG) manufactured by LaboCompact GmbH. This is a type of solid phase immunoassay (SPIAs) through recombinant HCV poly protein encoded by genes for both structural nucleocapsid and non-structural proteins are detected by membrane chromatography with in built positive control¹³.

All initially reactive serum samples were retested using enzyme immunoassays (EIA) supplied by Human Diagnostics Germany. EIA kits detect IgG or IgM antibodies to a number of different viruses. Most commonly non-competitive EIA is used. In this method, the viral antigen is adhered on a solid phase usually microwell plates and is utilised to capture free viral-specific antibodies from a clinical specimen. Any unbound serum antibody is then washed away before the addition of an enzyme labelled antihuman detector antibody. After incubation and washing, a chromogenic substrate usually Horseradish peroxidase or alkaline phosphatase is added. Antigen antibody

complexes together with the enzyme labelled second antibody hydrolyse the colorless substrate to bring about a color change. The intensity of the color generated is proportional to the amount of viral specific antibody in the specimen. The results are measured in a spectrophotometer and compared with a set of positive and negative controls.¹⁴ All false positive initially reactive cases were excluded from the study.

RESULTS

Out of 166183 blood donors screened over a period of one year, 7398(4.45%) tested initially reactive on rapid test employing immunochromatography. On retesting by EIA for confirmation, only 6797 tested repeatedly reactive. 601(0.36%) of initially reactive blood donors were either cross reactive or falsely positive. The corrected prevalence is estimated to be 4.1%.

DISCUSSION

We have identified the highest prevalence of HCV in the TTIs being screened for in the service (4.1%). This is almost double that of HBV (2.21%) and many thousand times that of HIV (0.001%). The prevalence of HCV in blood donors in Punjab, Pakistan is much higher to that seen in other countries. The prevalence amongst blood donors is 0.15% in Zimbabwe¹⁵, 0.4% in Malaysia¹⁶ and 0.9% in Argentina¹⁷.

A major implication of our work is borne out of the fact that the prevalence of HCV in our study indirectly reflects prevalence in the general healthy population in the society in the relevant age group as most of our donors (99%) were first time directed or replacement donors. This suggest that causative risk factors in the transmission of HCV in our social set up need to be identified and contained if an HCV epidemic is to be prevented. Some such measures maybe a check on infectious waste disposal, reuse of disposable syringes by unscrupulous persons, awareness of risk in health care workers, needle sharing by intravenous drug abusers, reuse of blades by barbers, improperly

sterilized instruments used by dentists, midwives and those performing circumcisions especially in rural settings, haemodialysis practices, ear piercing by trinket shops and perhaps sexual transmission.

The proportion of blood donors that we found to be falsely positive/unconfirmed reactive (0.36%) is not as high as was initially thought or reported¹⁸. Studies have demonstrated apart from either host specific or test specific factors, influenza vaccination has contributed to these unconfirmed reactivity¹⁹. Although due to false positivity, blood safety might not be compromised, with time the adequacy of blood supply may be affected due to donor dropouts. There has been a longstanding concern about testing methodology to be adopted for HCV. As more experience is gained, the HCV testing algorithm and choice of test may have to be modified.

CONCLUSIONS

The results of our study permit us to draw the following conclusions:

1. The prevalence of HCV in the blood donors is very high (4.1%).
2. Our figures also reflect indirectly on the prevalence of HCV in the general population.
3. A larger sectional study is called for to identify other causes of spread of HCV.
4. With time the screening methodology for HCV needs to be reviewed.

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REFERENCES

1. McCaughan GW, McGuinness PH, Bishop GA, Painter DMF, Lien AS, Tulloch R, Wylie BR, Archer GT. Clinical assessment and incidence of hepatitis C RNA in 50 consecutive RIBA positive volunteer blood donors. *Med J Aust* 1992; 157:231-33.

2. Lenette EH, Smith TF. Laboratory Diagnosis of viral infections. Third Edition, Marcel Decker, New York 1999: Chapter 22: 449-457.
3. National Institute of Health Consensus development Conference Panel statement: management of Hepatitis C. *Hepatology* 1997;26(suppl 1) 2S-10S.
4. Farci P, Alter HJ, Shimoda A, Govindarajan S, et al. Hepatitis C virus-associated fulminant hepatic failure. *N Engl J Med* 1996; 335:631-34.
5. Barrera JM, Bruguera M, Ercilla MG et al. Persistent hepatitis C viremia after acute self-limiting posttransfusion hepatitis C. *Hepatology* 1995;21: 639-44.
6. Yano M, Kumada H, Kage M, et al. The long-term pathological evolution of chronic hepatitis C. *Hepatology* 1996; 23: 1334-1340.
7. Bruix J, Barrera JM, Calvet X et al. Prevalence of antibodies to Hepatitis C in Spanish patients with hepatocellular carcinoma and hepatic cirrhosis. *Lancet* 1989; 2:1004-1006.
8. Zein NN, Rakela J, Krawitt EL et al. Hepatitis C virus genotypes in the United States: epidemiology, pathogenicity, and response to interferon therapy. Collaborative Study Group. *Ann Intern Med* 1996; 125: 634-39.
9. Aach RD, Stevens CE, Hollinger FB, et al. Hepatitis C virus infection in post-transfusion hepatitis: an analysis with first and second generation assays. *N Engl J Med* 1991; 325:1325-1329.
10. Corona R, Prignano G, Mele A et al. Heterosexual and homosexual transmission of hepatitis C virus: relation with Hepatitis B and human immunodeficiency virus type 1. *Epidemiol Infect* 1991; 107:667-72.
11. Paccagnini S, Principi N, Massironi E et al. Perinatal transmission and manifestation of Hepatitis C virus infection in a high risk population. *Pediatr Infect Dis J* 1995; 14: 195-199.
12. Al-Faleh FZ, Ayoola EA, Al-Jaffry M et al. Prevalence of antibody to hepatitis C virus among Saudi Arabian children: a community-based study. *Hepatology* 1991; 14: 215-18.
13. Kassler WJ, Haley C, Jones WK et al. Performance of a rapid, on site human immunodeficiency virus antibody assay in a public health setting. *J Clin Microbiol* 1995; 33: 2899-2902.
14. Carpenter AB. Enzyme-linked immunoassays. In Rose NR, Conway de Marcario E, Folds JD, Lane EC, Nakamura RM, eds *Manual of Clinical Laboratory Immunology*. 5th ed Washington DC: ASM Press, 1997: 39-48.
15. Safe blood and blood Products. Costing Blood Transfusion Services. Case Study Zimbabwe;1998: WHO/BLS/98.8, 54-63.
16. Annual Report 1995. Blood Transfusion Services information System, Unit Sistem Maklumat Dan Dokumentasi, Kementerian Kesihatan Malaysia, Appendix 4, Mei 1996.
17. Schmunis A, Zicker F, Segura EL, Del Pozo AE. Transfusion transmitted infectious diseases in Argentina 1995 through 1997. *Transfusion* 2000;40:1048-1053.
18. Buffington J, Shapiro CN, Holman RC et al. Multiple unconfirmed-reactive screening tests for viral antibodies among blood donors. *Transfusion* 1994; 34: 5, 371-375.
19. Mackenzie WR, Davis JP, Peterson DE, Hibbard AJ et al. Multiple false positive serologic tests for HIV, HTLV-1 and hepatitis C following influenza vaccination. *JAMA* 1992; 268:1015-7.