Thesis Title	Comparison of the Detection of Hepatitis C Viral RNA by Polymerase Chain Reaction and the Detection of Antibody to HCV by Enzyme Immunoassay in Healthy Blood Donors
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ABSTRACT

Hepatitis C virus (HCV) is the major cause of posttransfusion hepatitis. The virus is transmitted by transfusion of blood and blood products. The screening of HCV infection in blood donors is necessary to eliminate the viral transmission. Currently, the assay for antibodies to HCV using enzyme immunoassay (EIA) is the most commonly used method in blood donor screening. Several assays are commercially available from various manufacturers.

The objectives of this study were to compare the effectiveness of five commercial anti-HCV EIA using a panel of Thai healthy blood donors with or without antibodies to HCV, and to compare the results of anti-HCV detection with the detection of HCV RNA using multiplex nested reverse transcription polymerase chain reaction (nested RT-PCR).

During September 14, 1993 to May 13, 1994, a total of 13,622 volunteer blood donors at Siriraj Hospital were tested for antibodies to HCV using one of the five available EIAs : Abbott HCV EIA, Abbott Diagnostics (USA); HCV ELISA, Diagnostic Biotechnology (Singapore); Microcheck HCV test, Syntron Bioresearch (USA); UBI HCV EIA, Organon Teknika (USA); and Murex anti-HCV, Murex Diagnostics (England). Of those, 162 donors were tested positive (1.2%). The prevalence of anti-HCV antibodies was 1.4% and 0.9% in first-time donors and repeated donors, respectively. One hundred and two anti-HCV positive samples were randomly selected for further assays. These samples were tested using all five assays; 64 of 102 (62.7%) samples gave concordant results. The sensitivity of Abbott HCV EIA, HCV ELISA, Microcheck HCV test, UBI HCV EIA, and Murex anti-HCV were 98.68, 92.10, 88.15, 100, 100 percent, respectively, whereas the specificity were 96.15, 92.30, 76.92, 23.07, 80.76, respectively.

There was a significant correlation between the presence of anti-HCV antibodies and liver cell dysfunction as determined by serum alanine aminotransferase level (ALT) ($p<0.005$).

HCV RNA was detected in 70 (68.6%) of those 102 samples. The detection rate of HCV RNA was similar among donors tested positive with each of the five EIAs. Importantly, 2 (0.58%) of 342 donors initially tested negative for anti-HCV antibodies, were subsequently found to be positive in EIA from other manufacturers different from one used for initial screening. The other two (0.58%) anti-HCV negative donors were found to have HCV RNA as detected by nested RT-PCR. This is alarming and indicates that further improvements of the assays for anti-HCV antibodies are necessary, to reduce the false negative rate and to make blood transfusion safer.