

Varying Sensitivities and Specificities of Different HEV IgM Commercial Kits Can Lead to Erroneous Diagnosis of HEV Infection

Sook Yin Lui^{1*}, Siew Hoon Lim¹, Chai Teng Tan¹, Yee Leng Lee¹, Kwai Peng Chan¹

¹ Singapore General Hospital

Background/Objective

Hepatitis E virus (HEV) is the leading cause of enterically transmitted non-A hepatitis worldwide. In industrialized countries, HEV infection is considered rare, and is largely confined to travellers returning from endemic areas. However in recent years, there is increasing evidence suggesting that the prevalence of HEV infection in developed countries is more common than previously recognized.

Method

Several immunoassay kits have recently become commercially available for the detection of anti-HEV IgM. The use of a well-validated diagnostic kit is essential for the diagnosis and management of HEV infected patients. In this study, a total of 327 archived serum samples was analysed. To determine cross-reactivity, serum samples from the following groups of patients: HAV IgM positive, HBc IgM positive, HCV supplemental test positive, CMV IgM positive, HSV IgM positive and EBV IgM positive were tested. Interference from anti-nuclear factor (ANA) was determined using samples tested positive to ANA.

Result

Among the 3 commercial kits compared, there were 30 discrepant HEV IgM results. Of particular concern was the detection of HEV IgM in apparently healthy subjects and patients with clinical history and discharge diagnosis that suggest that their medical conditions were not or unlikely to be HEV related, while on the other hand, some HEV RNA positive cases were tested negative for HEV IgM.

The sensitivities and specificities of the HEV IgM kits ranged from 89.4-97.9 and 95.1-99.2%, respectively. Cross reactivities were observed in serum samples tested positive to HAV, CMV, and EBV. The kits also showed varying performance in terms of their intra- and inter-assay precisions.

Conclusion

In view of the varying sensitivities and specificities of different commercial kits, the HEV diagnostic results should be interpreted with caution and in relation to the clinical information of the patient.