HEPATITIS C VIRUS CORE ANTIGEN AND DRIED BLOOD SPOTS AS SIMPLIFIED HEPATITIS C VIRUS DIAGNOSTIC TOOLS

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Background: Simplified, affordable diagnostic tools are urgently required to scale up hepatitis C virus (HCV) treatment. This study evaluated the diagnostic performance of HCV core antigen (HCVcAg) detection in plasma and dried blood spot (DBS) samples.

Methods: Paired plasma and venous DBS samples were prepared from remnant diagnostic samples. Plasma HCV RNA was quantified by AmpliPrep/COBAS Taqman (Roche). HCVcAg were measured by ARCHITECT HCV Ag (Abbott Diagnostics). The agreement between both assays was assessed by Bland-Altman Bias plot (conversion factor, 1fmol/L = 500IU/mL). The sensitivity and specificity for the HCVcAg assay (>3fmol/L) at a threshold of HCV RNA>1000IU/mL were calculated for both plasma and DBS.

Results: Of 120 paired samples tested, 25 had non-quantifiable HCV RNA and 95 quantifiable HCV RNA. The median HCV RNA level in plasma was 5.8 log IU/mL (IQR: 5.2, 6.4). The median HCVcAg level for plasma and DBS was 2.7 log fmol/L (IQR: 2.0, 3.3) and 1.6 log fmol/L (IQR: 1.0, 2.1), respectively. The Bland-Altman bias (95% limits of agreement) for plasma and DBS was 0.37 fmol/L (-0.81, 1.55) with mean difference (95%CI) of 0.37 fmol/L (0.24-0.49) and 1.598 fmol/L (0.32, 2.87) with mean difference (95%CI) of 1.60 fmol/L (1.46-1.74), respectively. Of 4 samples < 1000IU/mL (range 27 to 220IU/mL) in plasma, 0 were reactive for HCVcAg in both plasma and DBS. One HCV RNA negative sample was HCVcAg reactive (7.5fmol/L) in DBS and negative in plasma. For diagnosing HCV RNA>1000IU/mL, the sensitivity of HCVcAg in plasma and DBS was 96.7% (95%CI 89.9-99.1%) and 91.0% (95%CI 83.2-95.5%), respectively. The specificity of HCVcAg in plasma and DBS was 100% (95%CI 85.9-100%) and 96.7% (95%CI 80.9-99.8%), respectively.

Conclusion: These data indicates HCVcAg in plasma and DBS may be suitable for HCV surveillance and diagnosis of chronic HCV, particularly in lower and middle-income or high prevalence countries.

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