HEPATITIS C VIRUS CORE ANTIGEN: A SIMPLIFIED TREATMENT MONITORING TOOL AMONG THOSE WITH RECENT HCV INFECTION, INCLUDING FOR POST-TREATMENT RELAPSE.

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Background: Simplified, affordable diagnostic tools are essential to facilitate global access to hepatitis C virus (HCV) treatment. This study evaluated the clinical performance of HCV core antigen (HCVcAg) detection as an alternative to RNA testing in plasma to monitor HCV treatment efficacy in recent infection.

Methods: Participants with recent HCV infection (duration of infection ≤12months) who completed 6 weeks of sofosbuvir+ribavirin in DARE-C II were assessed at week 1, 2, 3, 4, end of treatment (ETR) and post-treatment week 4, week 12 and week 24. HCV RNA and HCVcAg were quantified by AmpliPrep/COBAS Taqman assay (Roche) and ARCHITECT HCV Ag (Abbott Diagnostics). The sensitivity and specificity of HCVcAg assay (>3fmol/L) were calculated for quantifiable HCV RNA (>15IU/mL).

Results: 124 longitudinal samples in 18 treated participants were available for HCV RNA and HCVcAg testing, including baseline (n=18), ETR (n=16), post-treatment week 12 (n=18). Overall, HCVcAg demonstrated a sensitivity of 74.1% (95% CI 60.7-84.4) and a specificity of 98.5% (95% CI 90.7-99.9) compared with HCV RNA. At pre-treatment, HCVcAg was detected in 89% samples, demonstrating a sensitivity of 88.9% (95% CI 63.9-98.1). Two baseline HCVcAg non-reactive samples had quantifiable HCV RNA at 33 and 150IU/mL. At ETR, RNA and HCVcAg were detected in 13% and 6% samples, respectively (sensitivity 50%, 95% CI 2.7-97.3; specificity 100%, 95% CI 73.2-100%). At post-treatment week 12, RNA and HCVcAg were detected in 72% and 61% samples, respectively (sensitivity 84.6%, 95% CI 53.7-97.3; specificity 100%, 95% CI 46.3-100% CI). Two post-treatment week 12 non-reactive HCVcAg results had quantifiable HCV RNA at 50 and 2533IU/mL.

Conclusion: This study demonstrates core antigen provides high specificity when compared with HCV RNA. The potential clinical utility of HCV core antigen requires further evaluation, particularly in the context of low HCV RNA levels.

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