Evaluation of hepatitis C virus core antigen testing using Elecsys hepatitis C virus Duo assay for screening and diagnosis of HCV in people in prisons

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Background:
The two-step procedure for HCV diagnosis (screening for antibodies and, if reactive, HCV-RNA testing) as well as the time, cost and technical skills needed for HCV-RNA assessment represent a bottleneck to the HCV cascade of care in the prison setting. HCV core antigen (HCVcAg) represents an alternative marker for confirming HCV infection. The aim of this study is to evaluate the HCVcAg component of Elecsys® HCV Duo assay for HCV screening, compared to the standard screening practice, in people living in prison (PLIP).

Methods:
The study was conducted in the largest prison in Greece (Athens, March-June 2024). Following written informed consent, participants were randomized into one of two screening groups. In Group 1 (standard testing), rapid anti-HCV testing was performed. If positive, blood sampling was performed for HCV-RNA determination. These participants were also tested with Elecsys® HCV Duo assay (anti-HCV and HCVcAg). In Group 2 (HCV Duo), blood sampling and testing with Elecsys® HCV Duo assay were performed. If positive, HCV-RNA was performed. HCVcAg sensitivity and specificity were evaluated using HCV-RNA as the reference method.

Results:
780 male inmates participated (Group 1: N = 507, Group 2: N = 273); 27.4% had history of injecting drug use. In total, 19.8% had reactive HCV antibodies; of those, 60.9% were HCV-RNA(+). HCVcAg sensitivity and specificity was 58% (95% CI: 46-69) and 96% (95% CI: 86-100), respectively. The mean (SD) $\log_{10}$ HCVRNA levels for the concordant [HCV-RNA(+)/HCVcAg(+)] and the discordant [HCV-RNA(+)/HCVcAg(-)] samples were 6.4 (0.8) and 5.0 (1.1), respectively. In total, 45 of 47 HCVcAg(+) individuals were also HCV-RNA(+) (HCVcAg positive predictive value: 96%).

Conclusion:
The implementation of HCVcAg could facilitate one-step hepatitis C diagnosis in populations at increased risk, such as PLIP, with reduced sensitivity compared to HCV-RNA (in particular when HCV-RNA levels are low) but high positive predictive value.

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