HCV Ag core screening performance in mono-infected, HIV- and HBV-coinfected patients

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Introduction
Despite the shift occurring in HCV management thanks to the recent release of really efficient new oral antiviral drugs against HCV, it still remains some barriers to HCV treatment.

First of all, too few infected people are diagnosed: it is estimated that 90% of HCV-infected people are unaware of their infection1. In the low- and middle-income countries (LMIC), where 115 million of infected persons live, only 1% know their HCV status2.

Thus, although early detection of HCV infection is of great importance it still remains challenging because of the complexity of the present HCV chronic infection diagnosis procedure which combines anti-HCV antibody (HCV-Ab) and HCV-RNA measurement, two technics barely available in LMIC.

Quantifying HCV core antigen (cAg), a marker of HCV viral replication, as a one-step procedure, could shorten this diagnosis procedure.

Objective
Principal objective
To assess the performance of HCV core antigen quantification as a diagnostic tool for chronic hepatitis C in Africa.

Secondary objective
To assess the impact of the demographic variables (age, gender), the HCV genotype and the HIV or HBV infection on the cAg diagnostic performance.

Material and methods
Patients
1009 serum samples from the Pasteur Center of Cameroon in Yaoundé were included in the present study according to the following inclusion criteria:

• HCV positive samples:
  - HCV antibody (HCV Ab) positive serology
  - Quantifiable HCV RNA
  - HCV negative samples:
  - HCV Ab negative serology
  - OR undetectable HCV RNA
  - HIV status known
  - HBV status known

Laboratory methods
- cAg quantification: Abbott ARCHITECT HCV Ag Assay
- cAg quantification = 10 fmol/L; negative
- ≥ 10 fmol/L: positive
- 3 ≤ cAg < 10 fmol/L, < grey zone; retested twice
- HCV RNA quantification by quantitative rt-PCR: gold standard
- Anti-HCV Ab
- Anti-HIV Ab
- Ag HBs
- ELISA serologies

Statistical analysis
Categorical data were expressed as absolute frequencies and percentages. Categorical data were compared using Fisher’s exact test or chi-squared test. Quantitative data were compared using Student’s t-test or ANOVA, followed or not by Bonferroni correction. All statistical analyses were done using R software (v3.4.4, CRAN R Project). A receiver operating characteristic (ROC) curve was drawn using the “ROCR” package in R. The AUC was considered significant when p < 0.05. All tests were two-tailed. The significance level was set at 0.05.

Conclusions
- The cAg quantification assay displayed high specificity and sensitivity; in addition neither genotype nor HBV-infection influenced its discrimination capacity.
- HCV infection did not affect its overall performance but its specificity was lower in sera with this infection.
- This assay represents a reliable HCV diagnosis tool and, being less costly than viral load tests, could ease HCV screening, notably in resource-limited settings.

Table 2: Performance of the cAg quantification by infection group

Table 3: Performance of the cAg quantification by genotype among the mono-infected and uninfected sera group

Figure 3: ROC curves of the performance of cAg quantification for the diagnostic of chronic hepatitis C in HCV mono-infected and HCV uninfected, HIV-infected and HBV-infected patients

Acknowledgements and References
This work was supported by the ANRS. The authors disclose no conflicts of interest.


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CROI 2016, Boston, MA, USA
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