DIAGNOSIS AND FOLLOW–UP OF HCV INFECTION IN HEMODIALYSIS PATIENTS AND RENAL TRANSPLANT RECIPIENTS: HCV CORE ANTIGEN AND IGM ANTI–HCV

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INTRODUCTION

Hepatitis C Virus (HCV) infection has a great impact on the prognosis of patients affected by end-stage renal disease. The prevalence of HCV infection in hemodialysis (HD) patients is still significantly higher than the one observed in general population. In this group, the infection bears a strong effect on both mortality and morbidity [***1***]. Similar considerations can be made for renal transplant (RTx) recipients: in addition to an increased mortality risk due to progressive liver damage, cardiovascular disease, infections and neoplasms, HCV infection is a negative prognostic marker of graft function and survival. Indeed, infected RTx patients have a higher relative risk for post-transplant glomerulonephritis and chronic allograft nephropathy [***2***]. To date, laboratory confirmation of HCV infection is based on two different principles: immuno-enzymatic assays (EIA), which can be considered as a screening test that identifies anti-HCV antibodies in the patients serum, and molecular biology techniques, based on viral RNA quantification, which are employed as confirmatory and follow-up assays [***3***]. The latter methods are considered as the gold standard due to their high accuracy, but they are burdened by some negative aspects, such as the high cost, the elevated turnaround time, and the need for dedicated personnel and spaces.

STUDY AIMS

The primary aim of the study was to determine the accuracy of two EIA for the quantification of HCV core antigen (HCVAg ARCHITECT®) and IgM anti-HCV (DIA.PRO HCV IgM), employed as a confirmatory test in two cohorts of HCV-positive patients (HD and RTx). Additionally, we studied the correlation between the results from these two assays and the gold standard for HCV diagnosis (HCV-RNA).

MATERIALS AND METHODS

We analyzed 32 serum samples from HD patients (Group A) from three different hemodialysis facilities, and 11 samples from RTx recipients (Group B) which tested positive at the commonly employed screening test (anti-HCV EIA). We compared the obtained results with a standardized molecular biology method, a real-time PCR (COBAS® TaqMan® HCV Test, v2.0).

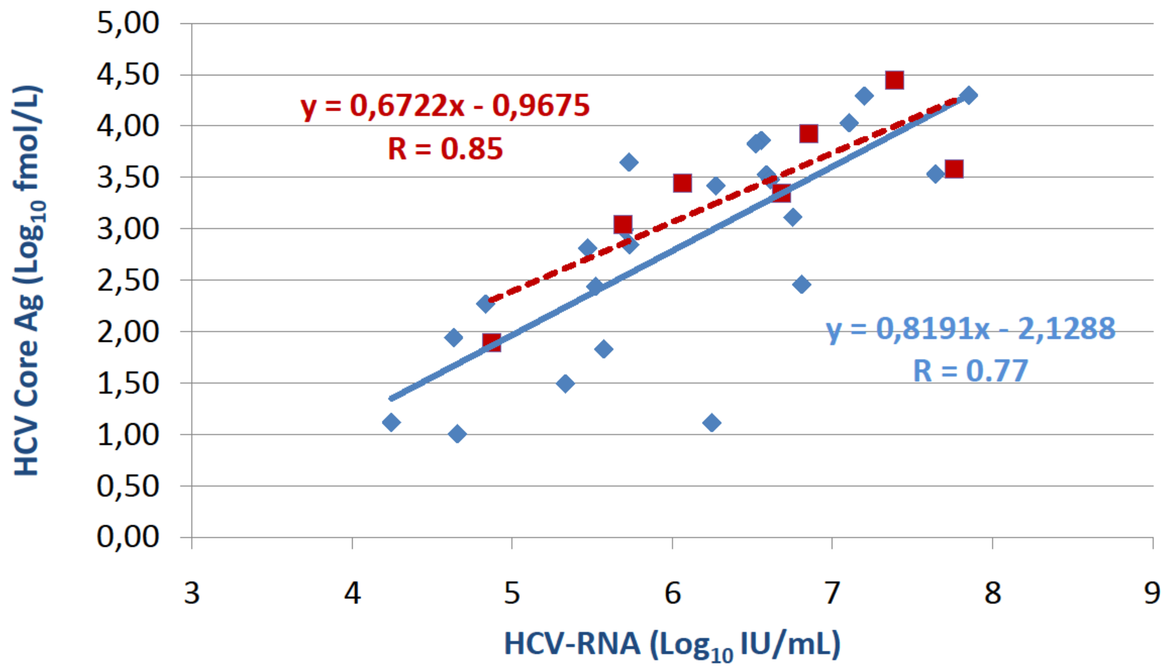

FIGURE 1 – Correlation between HCVcAg and HCV-RNA in the two groups (**red**: RTx, **blue**: HD)

RESULTS

The HCVAg ARCHITECT® immunoassay, used as a confirmatory test for the infection, showed a good sensitivity (100%) in both groups of patients, while the specificity was estimated to be 87.5% and 66.7% in Group A and Group B respectively. The DIA.PRO HCV IgM immunoassay showed a lower concordance with the viremia, with a sensitivity of 100% and 85.7%, and a specificity of 75% and 50% in the two groups respectively [***Table 1***]. Owing to the high sensitivity of both assays in Group A, we considered as positive only the samples which tested reactive for both tests: in HD patients the accuracy of this combined test reached 100%. We also found a strong correlation of the HCV core antigen and the HCV-RNA levels in both Group A (R = 0.77) and Group B (R = 0.85) [***Figure 1***]. The HCV-RNA/HCVcAg ratio was higher at higher levels of viremia, even though the difference was only borderline-significant [***Figure 2***].

CONCLUSIONS

Both of the assays showed a good accuracy as confirmatory tests for HCV infection. In particular, HCVAg ARCHITECT® proved to be a reliable marker of viral replication, with an extremely good correlation with the viremia in both of the studied cohorts. Therefore, these assays could be a useful complementary tool to the gold-standard diagnostics for HCV infection.

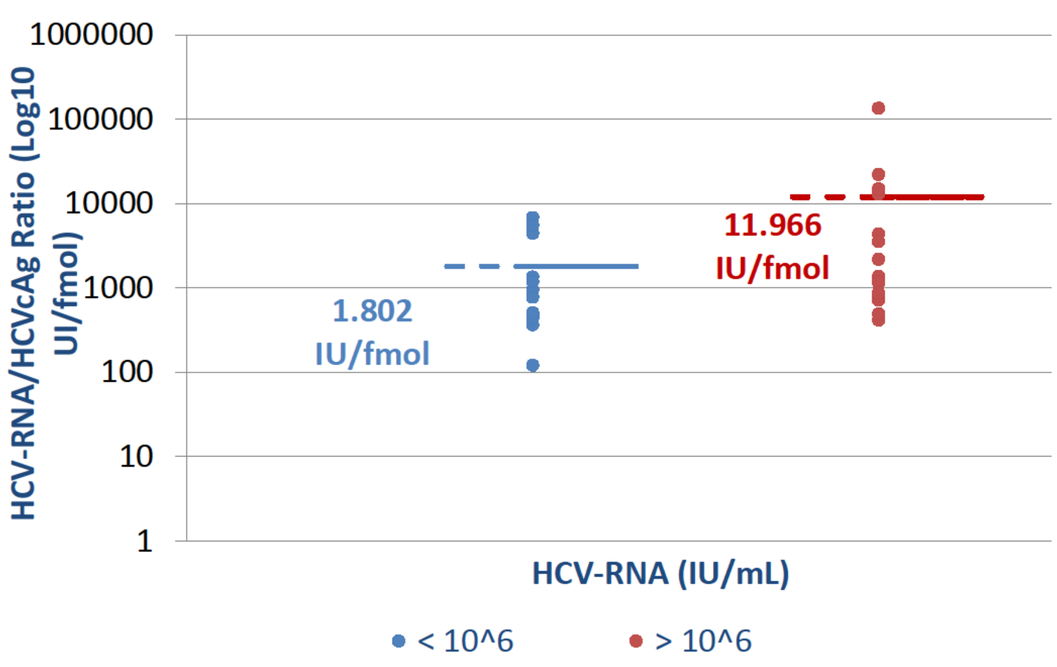

FIGURE 2 – HCV-RNA/HCVcAg ratio. A cut-off value of 10^6 UI/mL was chosen as the threshold for high and low viremia.

	HCVcAg	IgM anti-HCV	Combined
Sensitivity	100% / 100%	100% / 85.7%	100% / 85.7%
Specificity	87.5% / 66.7%	75% / 50%	100% / 66.7%
Positive PV	95.8% / 87.5%	92% / 75%	100% / 85.7%
Negative PV	100% / 100%	100% / 66.7%	100% / 66.7%

TABLE 1 – Sensitivity, Specifictity, Positive and Negative Predictive Values of the assays in the two cohorts of patients (Group A / Group B).

REFERENCES - [***1***] Fabrizi F et al, The impact of hepatitis C virus infection on survival in dialysis patients: meta-analysis of observational studies. *J Viral Hepat*, 2007;14:697-703. [***2***] Scott DR et al, Adverse impact of hepatitis C virus infection on renal replacement therapy and renal transplant patients in Australia and New Zealand. *Transplantation*, 2010;90:1165-71. [***3***] KDIGO clinical practice guidelines for the prevention, diagnosis, evaluation, and treatment of hepatitis C in chronic kidney disease. *Kidney Int Suppl*, 2008;S1-991

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M) Dialysis. M7) Pathophysiology and clinical studies in CKD 5D patients.
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