ARCHITECT HEPATITIS C VIRUS (HCV) CORE ANTIGEN TEST: A HCV RNA SCREENING ALTERNATIVE IN END-STAGE RENAL DISEASE (ESRD) AND HEMODIALYSIS PATIENTS?

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INTRODUCTION AND AIMS: HCV screening using Anti-HCV Antibody (Ab) is recommended to ESRD and chronic hemodialysis (HD) patients. There is a window period between acute infection and antibody production that may be more prolonged in those patients due to the immunodeficiency state. Furthermore, the Anti-HCV Ab test does not differentiate the concurrent infection from the resolved past one, that is why a more reliable and cost-effective screening test is needed. Direct viral detection such as polymerase chain reaction (PCR) and nucleic acid amplification technology are expensive, have a high technical skill requirement and long incubation time limitations for mass screening. ARCHITECT HCV Antigen (Ag) assay is a Chemiluminescent Microparticle Immunoassay for the quantitative determination of core Ag of the HCV in human serum and plasma. In some studies, it demonstrated a specificity of ≥ 99.5% and a sensitivity of < 3.00 fmol/L. Our aim was screening HCV infection in ESRD and HD patients from a hospital hemodialysis unit using ARCHITECT HCV Ag assay.

METHODS: Retrospective study of patients screened by anti-HCV Ab and ARCHITECT HCV Ag assay. Those with one or both positive results were submitted to real time PCR for determination of the virus and viral load quantification. Data collected comprised demographic information, renal disease etiology and viral status. Statistical analysis was made using SPSS version 23 for Mac OS X.

RESULTS: Among 77 patients, 67.5% (n=52) were males, median age was 72.7±4.1 years, 87% (n=67) were on HD and 9.1% (n=7) had a positive Anti-HCV Ab. Only 2 (2.6%) patients had the HCV core Ag positive. Cohen’s k test was run to determine if there was agreement between HCV RNA and HCV core Ag assays on 7 individuals with positive Anti-HCV Ab. The two tests had a perfect measurement agreement (Kappa 1, p<0.008). The 2 patients with positive HCV core Ag test were also positive for HCV RNA. Considering real time PCR for HCV RNA as the gold standard for HCV infection determination in this patient population, there were no false negatives or false positives and sensitivity and specificity were 100% for this sample.

CONCLUSIONS: Hepatitis C infection rate in HD units may be related to the infection’s prevalence in the general population of each region. In Portugal, the prevalence is 13.8/100000 inhabitants. The rate of HCV infection among HD patients was null. We think that HCV core Ag testing could be used as a sensitive method for HCV infection screening in this group of patients based on its accuracy, simplicity and low expense.