

Comparative Sensitivity of HCV Antibody Versus Qualitative RNA in Screening for HCV in HIV-infected Patients

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Abstract

Background: Discordant results of anti-Hepatitis C virus (HCV) antibody (Ab) and Hepatitis C RNA (HCV Ab -, HCV RNA +) have been reported in individuals co-infected with HIV and HCV, mainly in cohorts of patients infected via the parenteral route. Our objective was to determine if these findings could be duplicated in a pt. population more representative of the HIV epidemic in the United States. **Methods:** HIV-infected patients in our clinic were prospectively evaluated for their demographics, risk factors, anti-HCV Ab (Abbott), COBAS AMPLICOR HCV Qualitative RNA (Roche), Amplicor HIV-1 Monitor (Roche) and CD4 counts. Genotyping was performed on all confirmed HCV RNA positive samples. **Results:** A total of 221 patients (82% male, mean age 43 years) were enrolled. HIV/HCV risk factors included: men who have sex with men (MSM) 62%, heterosexual sex 22%, IVDU 9%, and history of transfusion 3%. The mean and median CD4 count were 544 and 500 cells/mm³ respectively. The median nadir CD4 count was 233 cells/mm³, with a nadir to baseline of 48 mos. The mean and median viral load were 187 and 15910 copies/ml respectively. HCV Ab was confirmed positive in 35/221 (16%) patients 27/35 (77%) of HCV Ab+ patients, had HCV viremia. HCV genotypes were: 1A (56%), 1B (24%), 2A (4%), 2B (4%), 4 (4%) and 2A/2B (8%). There were no discordant results of HCV Ab vs HCV RNA testing. **Conclusions:** In a cohort of HIV-infected patients representative of the epidemic in the United States, the HCV Ab is a reliable screening test for the presence of HCV infection.

Study Objectives

To determine the sensitivity of the currently recommended HCV antibody screening test compared with HCV RNA detection in a patient population representative of the HIV epidemic in the United States

Background

- Morbidity and mortality from chronic liver disease in HIV/HCV co-infected individuals has become an issue of great importance
- HCV disease progression is accelerated in HIV co-infected patients, hence the need to identify and possibly treat patients with HIV/HCV infection
- Current HCV screening recommendations involve anti-HCV antibody testing
- In HIV-infected individuals, loss of antibody to chronic viral infections, including HCV, and impaired antibody production and detection have been reported
- Discordant results of anti-Hepatitis C virus (HCV) antibody (Ab) and Hepatitis C RNA (HCV Ab-, HCV RNA +) have been reported in co-infected individuals, mainly in those infected via the parenteral route

Methods

- Prospective study of HIV-infected patients in a University HIV Clinic
- Patients were enrolled between 1/01 and 10/01
- Data collected via subject interview and medical record review
 - Data collected included age, sex, previous HCV screening results, HIV/HCV risk factors and most recent and nadir CD4 cell count
- A single blood sample of 10 ml was obtained from each study participant
- All blood samples were processed through Rush Medical Laboratories
- Plasma was analyzed for anti-HCV with a second-generation antibody kit (Abbott Laboratories, Abbott Park, IL) and Qualitative HCV RNA with HCV COBAS AMPLICOR test (Roche Diagnostic Systems, Indianapolis, IN)
- Plasma quantitative HIV-1 RNA PCR (Roche Amplicor HIV-1 Monitor UltraSensitive Method) was performed on all samples
- Samples that yielded a result of HCV Ab + and HCV RNA negative were retested in duplicate by both methods and by an HCV-RIBA 3rd generation assay (Chiron Corporation, Emeryville, CA) and an HCV 3rd generation enzyme immunoassay (Ortho Diagnostic Systems, Raritan, NJ)
- HCV genotyping (LiPA HCV Assay, Ortho Diagnostic Systems) of all confirmed HCV RNA positive samples was performed

Demographics

Characteristic	N=221
Age (mean, yrs)	43
Gender (no. [%])	
Male	181 (82)
Female	40 (18)
Race (no. [%])	
African-American	80 (36)
White	113 (51)
Hispanic	24 (11)
HIV/HCV Risk Factors (no. [%])	
IVDU	18 (8)
MSM	143 (65)
Heterosexual	49 (22)
Other	9 (5)
CD4 cell count (cells/mm ³) (no. [%])	
0-49	11 (5)
50-199	23 (11)
200-499	76 (35)
>500	106 (49)
Median Nadir CD4 cell count (cells/mm ³)	233
Previous HCV Ab+ (no. [%])	29 (18)

Results

- 221 patients were enrolled
- HCV Ab was confirmed positive in 16% of pts
- 77% of HCV Ab+ pts had HCV viremia as evidenced by Qualitative HCV RNA
- There were no discordant results of HCV Ab vs HCV RNA testing

Results

HCV Ab+ (no. [%])	35 (16)
HCV RNA+ (no. [%])	27 (12)
HCV Ab-/HCV RNA+	0
Genotype	
1A	14 (56)
1B	6 (24)
2A	1 (4)
2B	1 (4)
2A/2C	2 (8)
4	1 (4)

HCV Ab+ and Risk Factors

Risk Factor	No. (%)
IVDU	20 (57)
MSM	10 (29)
Heterosexual	2 (6)
Other	
Needlestick	1 (3)
Transfusion	1 (3)
Intranasal Cocaine	1 (3)

Conclusions

In a cohort of HIV-infected patients representative of the epidemic in the United States, the HCV Ab is a reliable screening test for the presence of HCV infection

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