Examining Diagnostic Discordance of Hepatitis C Virus Infection in Maintenance Hemodialysis Patient.

Kamyar Kalantar-Zadeh, MD PhD MPH; Eric S Daar, MD; Loren G. Miller, MD MPH

Harold Simmons Center for Kidney Disease Research and epidemiology, Division of Nephrology and Hypertension, and Division of Infectious Disease and HIV, Harbor-UCLA and Los Angeles Biomedical Research Institute; and David Geffen School of Medicine at UCLA, Torrance and Los Angeles, CA

Background

- Hepatitis C virus (HCV) infection is common in maintenance hemodialysis (MHD) patients and associated with poor clinical outcomes.
- Hence, reliable methods to detect HCV infection in MHD patents are crucial.
- We previously noted that HCV transcription-mediated amplification (TMA), a sensitive qualitative HCV RNA molecular test, may identify HCV-infected MHD patients not detected by antibody enzyme immunoassay (EIA).

Methods

- We examined HCV status using EIA and TMA in participants of the Nutrition and Inflammation Evaluation in Dialysis Patients (NIED) study (www.NIEDstudy.org).
- We used the 3rd generation EIA (Abbott 2.0) and TMA (Bayer Diagnostics). A quantitative HCV RNA test, bDNA (Bayers VERSANT HCV RNA 3.0 Assay) was also employed in all TMA+ patients.

Results

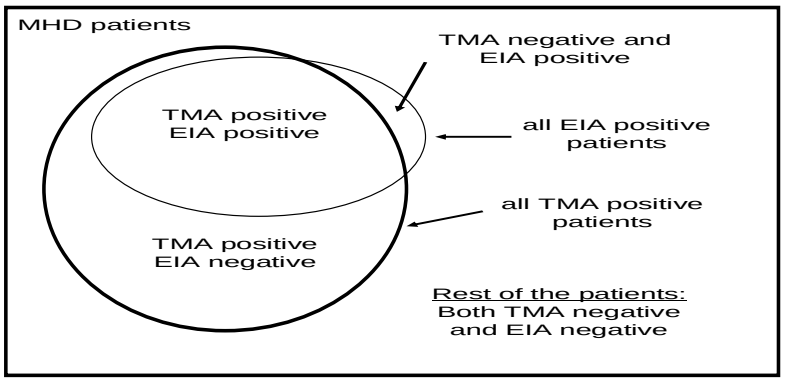
- Subjects included 329 MHD patients who were randomly selected from a pool of 1,450 MHD patients in 8 dialysis clinics.
- Mean (SD) age was 52.315.6 yrs and subjects were 54% diabetic, 48% women, 31% Black, 51% Hispanic and had undergone dialysis for a mean of 37 months.

Results

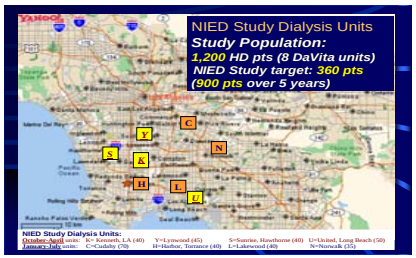
- HCV infection seroprevalence was 12% (n=39)
- 19 of these subjects were viremic by TMA.
- 14% of the seronegative subjects were TMA+.

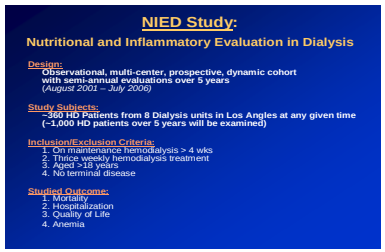
- bDNA was performed in 62 (out of 65) TMA+ patients with 27 having quantifiable viral loads (>3,200 copies (qc)/mL), ranging from 7,464 to 33,174,712 qc/mL, including 13/19 (68%) concordant TMA+/EIA+ and 14/46 (30%) discordant TMA+/EIA- patients.

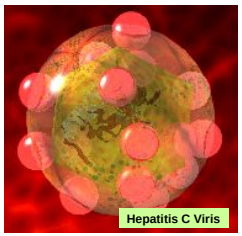
	TMA+	TMA-	
EIA+	19 (6%)	20 (6%)	39 (12%)
EIA-	46 (14%)	244 (74%)	290 (88%)
	65 (20%)	264 (80%)	329 (100%)

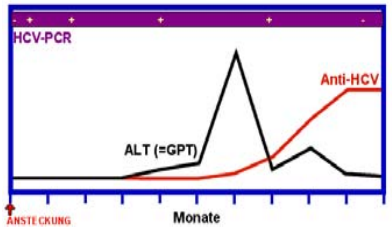


Nutritional and Inflammatory Evaluation in Dialysis patients (NIED) Study: 2001-2006









Conclusions

- Detectable HCV RNA by bDNA was more prevalent among those TMA+/EIA+ (68%) than TMA+/EIA- (30%).
- Although approximately 1/3 of TMA+/EIA- patients had supportive evidence of HCV infection via bDNA, further investigation is needed to define whether the remainder of the TMA+/EIA- patients, almost 10% of the cohort, have true HCV infection and if so the clinical relevance of these finding.

Acknowledgements

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Correspondence:
Kamyar Kalantar-Zadeh, MD, PhD, MPH
Associate Professor of Medicine and Pediatrics
Director of Off-Campus Dialysis Expansion Program and Epidemiology
UCLA David Geffen School of Medicine, Harbor-UCLA Medical Center
1124 W. Carson St., C-1 Annex, Box 406 , Torrance, CA 90502-2064
Tel: (310) 222-3891, Fax: (310) 782-1837, Cell: (310) 686-7908
Email Address: kamkal@ucla.edu
Website: www.NIEDstudy.org

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