Epidemiology of Hepatitis C Virus Infection in Dialysis Units: First-versus Second-Generation Assays

C.		Vitale ^a
A.		Tricerri ^a
M.		Marangell ^a
G.M.		Vacha ^a
G.		Giorcelli ^a
C.		Marini ^b
G.		Molinaro ^b
D.		Cosseddu ^a
F.		Linari ^a

^aNephrology Division and ^bCentral Analysis Laboratory, Mauriziano Umberto I Hospital, Torino, Italy

Dr. Corrado Vitale, Divisione di Nefrologia e Dialisi, Ospedale Mauriziano Umberto I, Largo Turati, 62, I-10128 Torino (Italy)

Dear Sir,

Hepatitis C virus (HCV) is nowadays responsible for most of the infectious hepatitis in dialysis units [1]. The data of 38 reports on 8,668 patients on regular dialysis treatment, published between 1989 and 1991, gave a mean of 20.7% HCV seroprevalence [2, 3]. New 2nd-generation anti-HCV assays (EIAs) became available in 1991 and proved more sensitive than the older ones [4].

No data have been published as yet concerning 2nd-generation EIA HCV seroprevalence in dialysis units.

In September 1991, we made a survey of HCV seroprevalence in all 20 Dialysis Centers in Piedmont. Seventeen of them were already using 2nd-generation EIA: 567/1,757 patients (32.3%) were anti-HCV positive. In the remnant Centers, where a 1st-generation EIA was being used, 57/273 patients (20.9%) were anti-HCV positive. Then, we examined the impact of the higher sensitivity of the new test on these results.

Serum samples from 103 patients (59 males) on RDT for 68 ± 58 months (range 2-260) were simultaneously assessed for anti-HCV by means of both a 1st-generation EIA (EIA-HCV Abbott) and a 2nd-generation EIA (Hepatitis C rDNA-Antigen, Abbott). In addition, a 2nd-generation immunoblotting test (RIBA HCV Test System, Chiron Ortho) was used to confirm the 2nd-generation-EIA-positive values: samples which reacted with 2 or more HCV antigens were considered to be positive, and those with only one antigen were taken as indeterminate. The latter were re-evaluated 6 months later. The number of blood units transfused was accurately determined for each patient. Alanine aminotrans-ferase determinations (performed bimonthly) had been available for the previous 67 ± 40 months.

The results of the simultaneous determinations of anti-HCV by means of 1st- and 2nd-generation EIAs are listed in table 1-

RIBA confirmation results are reported, too. The 1st-generation EIA showed 28 (27.2%) of the 103 patients tested were positive, whereas a 2nd-generation EIA revealed 48 positive cases (46.6%). The positive results of the 1st-generation EIA were confirmed by the 2nd-generation EIA. When the 48 positive 2nd-generation EIAs were assayed by 2nd-generation RIBA, 34 (70.8%) were found to be positive, none were negative and 14 (29.2%) were indeterminate. Six months later, 7 indeterminate RIBAs (50%) became positive. The 2nd-generation EIA was positive for 44 of 88 (50%) transfused versus 4 of 15 (27%) nontransfused patients ($\chi^2 = 2.8$, $p = 0.094$). However, among the transfused subjects, the EIA-positive group had received a high number of blood transfusions and had been on RDT for a longer time than the EIA-negative one (table 2). Among nontransfused patients, the 2nd-generation-EIA-positive patients had

Table 1. Simultaneous determinations of anti-HCV by 1st- and 2nd-generation EIA

Table 2. Comparison of 2nd-generation-EIA-positive and negative patient

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been on dialysis longer than the negative ones (33 ± 6 vs. 15 ± 11 , $p = 0.03$).

Five patients who had shared the same dialysis timetable for about 3 years were all positive according to the 2nd-generation EIA, whereas only 3 of them were positive according to the 1st-generation EIA. Three of those 5 patients had never been transfused.

Our data confirm that RDT can be a specific, independent risk factor for HCV infection. The 1st-generation EIA greatly underestimates the prevalence of HCV infection in dialysis units. Because it can be foreseen that 50% of indeterminate RIBA cases will become positive within few months, patients showing indeterminate RIBA values should be considered as positive for HCV infection.

Unless such methodological problems are taken into account, comparison between the preliminary and the updated reports in the literature will give a misleading picture of the spread of HCV infection.

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Marini/Molinaro/Cosseddu/Linari