Anti-HCV Reactivity in Dialysis Patients: Discrepancies between First and Second Generation Tests

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Table 1. Comparison between 1st- and 2nd-generation anti-HCV tests

Sir,

Current serological diagnosis of HCV infection includes either 1st- or 2nd-generation antibody tests. In dialysis patients, 1st-generation assays have shown a variable geographical anti-HCV prevalence [1,2] with an average of 15-25%.

We investigated the HCV prevalence of our dialysis population in two successive periods (T1 and T2).

At T1, from March 1990 to March 1991, we used 1st-generation screening one-antigen (C100-3) enzyme-linked immunosorbent assays (Ortho HCV ELISA and Abbott HCV EIA), with confirmatory Abbott neutralisation assay.

At T2, from May to August 1991, we used 2nd-generation tests: three-antigen (C100-3, C22-3, C33c) Ortho ELISA assay, Abbott EIA-2 and confirmatory four-antigen (C100-3, 5-1-1, C22-3, C33c) Chiron recombinant immunoblot assay (RIBA).

No patient received blood transfusions between T1 and T2. At T1, 52 HBsAg-negative hemodialysis patients (25 males and 27 females; median age 56 years, range 22-84) who had been on dialysis for 2-209 (median 50) months, were studied. 13 patients (25%) were anti-HCV C100-3 positive.

The prevalence was related to the duration of dialysis treatment ($p = 0.022$) and abnormal ALT (above 60 IU/l, normal range 10-40) on a 3-year retrospective analysis ($p = 0.009$) but was not related to age, sex, history of blood transfusions, HBcAb, CMV Ab, EBV Ab and surgical procedures.

Save 1 patient excluded because he had undergone kidney transplantation, all anti-HCV-positive patients were confirmed at T2 with 2nd-generation tests (table 1).

Also, 37 anti-HCV-negative patients were reexamined at T2. In ELISA-2, 27 patients (73%) were confirmed anti-HCV negative but 10 (27%) turned out positive.

IND = Indeterminate.

Only 6 of these 10 patients were positive with confirmatory RIBA-2 (16% of previously negative on 1st-generation) and another 4 being classified as indeterminate.

In conclusion, ELISA/EIA-2 confirmed only 80% of the 1st-generation screening assays (100% positive cases and 73% negative).

Reactivity was found in 10 patients previously negative, and 4 patients were RIBA-2 indeterminate.

Though we cannot determine how many cases of 'new' HCV infections arose between T1 and T2, we think that the higher specificity and sensibility of the 2nd-generation assays are due to the new C22-3 and C33c HCV markers lacking in the 1st-generation tests.

Although there is still lack of a single laboratory test that is entirely satisfactory, the new tests significantly cut the window between infection and detectable antibodies and show the best concordance between anti-

body reactivity and positivity on the polymerase chain reaction [3, 4].

Extensive use of the 2nd-generation assay tests will lead to a better, and unfortunately higher, rate of HCV antibody prevalence in patients on maintenance dialysis.

References

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