Hepatitis C virus antibodies in patients with chronic liver disease: ELISA and RIBA HCV strip immunoblot assay results

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Abstract

In a study using the current first generation Ortho ELISA, a second generation Ortho ELISA, and the RIBA HCV strip immunoblot assay, all patients who were strongly positive for anti-hepatitis C virus (HCV) on ELISAs (OD₄₉₀>3) were reactive to RIBA for multiple bands. While all ELISA false positive samples had low or intermediate OD₄₉₀ values, RIBA confirmed HCV reactivity in 50% of the patients reactive to ELISA with a low suspicion of HCV infection, thus suggesting that RIBA HCV strip immunoblot assay will be most useful for patients who react weakly positive or intermediate to ELISA.

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Current assays for antibodies to hepatitis C virus (HCV) show both reactivity in liver diseases not thought to involve HCV and lack of reactivity in patients with presumed HCV infection. Newer assays use additional antigens to improve sensitivity and immunoblotting to improve specificity. We have screened patients with chronic liver diseases to discover the diagnostic utility of these assays.

Patients and methods

The study included 70 patients, with diagnosed chronic active non-A, non-B (NANB) hepatitis (n=43), autoimmune chronic active hepatitis (n=20), chronic hepatitis B (n=3) or other causes of liver disease (for example, primary biliary cirrhosis, n=4). The assays

were the current first generation Ortho ELISA (c-100-3), a second generation Ortho ELISA (c-100-3/c-200/c-22-3), and the RIBA HCV Strip Immunoblot Assay (RIBA HCV SIA).

Results

The results of ELISA and RIBA HCV SIA testing are shown in the Table. The rate of false positives was the same with either ELISA. All patients strongly positive with ELISAs (OD₄₉₀>3) were RIBA reactive for multiple bands, while all ELISA false positive samples had low or intermediate OD₄₉₀ values. Eight of 27 patients not thought to be infected with HCV were ELISA positive, and four were RIBA HCV SIA positive. Thus, RIBA HCV SIA confirmed HCV reactivity in half of ELISA reactive patients with low suspicion for HCV infection. Three of 43 NANB hepatitis patients had false negative first generation ELISAs because of poor reactivity to c-100-3. All three samples were reactive in the c-100-3/c200/c-22-3 ELISA, confirming the increased sensitivity of the multiple antigen ELISA.

Conclusion

This study confirms the high prevalence (77%) of anti-HCV antibodies in NANB hepatitis patients and the low prevalence (15%) of anti-HCV in patients with autoimmune hepatitis. RIBA HCV SIA confirmation will be most useful for patients with weakly positive or intermediate ELISA reactivity.

TABLE Results of ELISA and RIBA™ HCV Strip Immunoblot Assay (SIA) testing of patients with chronic hepatitis

					Discordant								
					c-100-3 ELISA				c-100-3/c-200/c-22-3 ELISA				
		ELISA positive		RIBA™ HCV SLA positive									
Diagnosis	before testing	n	c100-3	c100-3/c200/c22-3	E+/R-	E+/R-I	E-/R+	E-/R-I	E+/R-	E+/R-I	E-/R+	E-/R-I	
All patients		70	39/70	40/67	37/70	5	0	3	2*	5	0*	0	1*
NANB CAH		43	31/43	32/40	33/43	1	0	3	1	1	0	0	0
Autoimmune CAH		20	5/20	5/20	3/20	2	0	0	1	2	0	0	1
Chronic hepatitis B		3	1/3	1/3	0/3	1	0	0	0	1	0	0	0
Other (primary biliary cirrhosis, etc)		4	2/4	2/4	1/4	1	0	0	0	1	0	0	0

E+/R-: ELISA positive, RIBA HCV SIA negative; E-/R+: ELISA negative, RIBA HCV SIA positive; E+/R-I: ELISA positive, RIBA HCV SIA indeterminate; E-/R-I: ELISA negative, RIBA HCV SIA indeterminate; CAH: chronic active hepatitis.
*The other c-100-3 ELISA negative indeterminate was unavailable for testing in the c-100-3/c-200/c-22-3 ELISA.