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P0775 Hepatitis C virus core antigen: utility in diagnosis, monitoring and detection of treatment failure

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Background: HCV core antigen (HCV-cAg) is a marker of HCV replication; it represents an alternative to HCV-RNA (VL). The aim of the study was to evaluate the clinical utility of HCV-cAg to diagnose active HCV infection, treatment follow-up and detection of sustained virological response (RVS) or failure with direct acting antiviral (DAA).

Materials/methods: We performed a prospective study (01/09/2016-31/12/2017) in Complejo Hospitalario de Navarra, Spain. Samples from patients (new diagnosis, under treatment patient and failure to DAA) were tested for HCV-cAg and VL. In monitoring group, we collected samples at baseline, after 4 weeks of treatment, at end of treatment and 12-weeks after the end of treatment. HCV-cAg was determined by Architect core antigen assay® (Abbot Diagnostics, Wiesbaden, Germany) and HCV-RNA quantification by Cobas 6800 (Roche Diagnostics, Mannheim, Germany).

Results: A total of 303 samples from 124 patients were analyzed. Correlation between HCV-Ag and HCV-RNA was excellent (R^2=0.932). ROC analysis showed 3 fmol/L as optimal cut-off value with an AUC (95%) of 0.987 (0.972-1.000). Sensitivity and specificity of HCV-cAg were 97% and 95% respectively. The relationship between the results obtained by both techniques is displayed in the table.

		Total (n=303)	**Screening (n=40)**	**Failure (n=14)**	**Treatment (n=70)**				
					Baseline	4 weeks	End treatment	12 weeks Post-ttm	
		VL	VL	VL	VL	VL	VL	VL	
		N[1]	P[2]	N[1]	P[2]	N[1]	P[2]	N[1]	P[2]
HCV-cAg	N[3]	166	4	2	1	0	0	0	0
	Indet[4]	5	2	0	1	0	0	0	0
	P[5]	3	123	0	36	0	14	0	69

[1]Negative ≤15UI/mL; [2]Positive >15 UI/mL, [3] Negative <3fmol/L,[4] Indeterminate ≥3-10fmol/L,[5] Positive ≥10fmol/L.

The majority of discordant samples corresponded to treatment monitoring group. Four false negatives of HCV-cAg had VL<726 UI/mL (20.1-726 UI/mL). HCV-cAg indeterminate results should be confirmed with a second HCV-Ag determination and/or HCV-RNA.

Conclusions: HCV-Ag assay is useful to diagnose viremic patients, monitoring and detection of RVS or treatment failure to DAA.