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Hepatitis C virus core antigen in the monitorization of interferon-free HCV therapies

Juan Manuel Sanchez Calvo*[1], Inmaculada Pavón Guerrero[2], Eva Torres Martos[1], Cristina Cepero Leon[2], Maria Jose Blanco Rodriguez[2], Jesus Francisco Sierra Sánchez[3], Juan Carlos Alados Arboledas[1]

[1]*Ags Norte de Cádiz. Hospital Sas de Jerez; Ugc Infectious Diseases and Microbiology*

[2]*Ags Norte de Cádiz. Hospital Sas de Jerez; Ugc Digestive Diseases*

[3]*Ags Norte de Cádiz. Hospital Sas de Jerez; Ugc Farmacia Hospitalaria*

Background: In recent years, there have been major changes in the management of HCV infection. The introduction of new high activity and interferon-free regimens has achieved sustained viral response rates in real life above 95%. The EASL guide 2016 introduces HCV core antigen (HCVAg) as a viral marker subrogated, similar to HCV RNA. The objective of the present study was to evaluate the behavior of this new marker in real life in order to simplify the virological follow-up of the patients treated with the new AADs.

Material/methods: We studied 253 patients who started HCV treatment the Health Management Area north of Cadiz during the year 2015, outside clinical trials. Viremia was studied by the quantification of HCV core antigen (Architect HCV core Antigen assay®Abbott) and by quantification of HCV RNA (Cobas AmpliprepTaqMan ®Roche), at baseline, week 1, 4 and 8/12 (end of treatment) and week 12 post treatment.

Results: One-third of patients was co-infected with HIV (31.6%) and 19.8% were women. The median age was 52 years (IQR 47-56). Genotype (GT) distribution was: GT1b 35.2%; GT1a 30.8%; (GT1a/b 3.2%); GT3 15.1%, GT4 14.6% and GT2 1.2%. The majority of patients had hepatic fibrosis stage F4 (58.9%) and F3 (28%). The main treatment regimens were Sofobuvir / Ledipasvir (28.5%), 3D (24.1%), Sofosbuvir / Daclatasvir (19%) and Sofosbuvir / Simeprevir (16.2%). A total of 95.3% patients

achieved sustained viral response at week 12 (SVR12). Viral kinetics of HCV-RNA and HCVAg were similar in both responder and non-responder patients. HCV-RNA levels at week 1 were lower in responders (R) (2.21 ± 0.83 log IU / ml) than in non-responders (NR) (2.85 ± 0.92 log IU / ml) ($p < 0.048$). When viremia was measured by HCVAg, differences between R and NR were detected at week 1 ($p < 0.043$) and week 4 ($p < 0.001$). The negative predictive value (NPV) of quantifiable virus levels at week 1 and 4, i.e. the proportion of patients with HCV RNA ≥15 IU / ml or AgHCV ≥ 3 fmol / l who did not reach SVR12, were calculated. NPV was very low: 20% and 13% for HCV-RNA and 16% and 29% for HCVAg. Conversely, NPV was very high (100%) at the end of treatment. All ten patients who did not show RVS12 were simultaneously detected by HCV-RNA and HCVAg.

Conclusions: 1. Virological follow-up of patients treated in HCV real-life with interferon-free regimens by quantification of HCV-RNA and HCVAg are comparable in kinetics and ability to detect response failure. 2.- Monitoring at weeks 1 and 4 are not useful in predicting therapeutic failure.