PEG-Interferons for chronic hepatitis C in clinical practice: an independent study supported by the Italian Drug Agency

Background: data on the efficacy of PEG-IFNs/Ribavirin therapy of chronic hepatitis C (CHC) are mostly derived from treatment of selected patients enrolled in clinical trials. Limited information is available from routine clinical practice. Aim of our study was to assess the effectiveness of PEG-IFNs/Ribavirin in treatment naïve CHC patients in Italy.

Methods: independent observational multicenter study. Patients consecutively prescribed PEG-IFNs/Ribavirin in the 18 months preceding (retrospective) and in the 18 months following (prospective phase) the start of the study were enrolled. Patients' eligibility and therapeutic management were independently judged by each clinical center.

Findings: 4176 patients were enrolled: 2091 during the retrospective, 2,085 during the prospective phase. The final study population consisted of 2051 patients in the retrospective and 2073 in the prospective phase.
SVR was more frequent during the retrospective than the prospective phase (1,036/2,051 (50·5%) vs 800/2,073 (38·6%) P < 0.001). SVR was achieved by 325/954 (34·1%) genotype (G) 1&4 and 684/1,018 (67·2%) G2&3 patients during the retrospective and by 300/1,056 (28·4%) G1&4 (-5·7%) and 473/918 (51·5%) G2&3 (-15·7%) during the prospective phase. Age, gender, BMI, cirrhosis, viral genotype, viremia and low GGT were significantly associated with response during the prospective phase; these associations were also present in the retrospective phase except for age and BMI. PEG-IFN choice influenced SVR during the prospective phase: 355/852 patients (41·7%) treated with PEG-IFNalfa-2b vs 444/1,212 (36·6%) treated with PEG-IFNalfa-2a achieved an SVR (p = 0.021). At multivariate analysis G2&3 were significantly associated with higher SVR, cirrhosis and GGT > 2 times the normal limit with poorer response rates. After adjustment the effect of PEG-IFN type disappeared.
Interpretation: the response to PEG-IFNs/Ribavirin in clinical practice is distinctly lower that in registration trials. SVR reduction was more pronounced among easy than difficult to treat genotypes.
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