

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

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Data di inizio studio (mese/anno)		February 1 st , 2008
Data presunta di termine studio (mese/anno)		January, 2012
Descrizione dell'attività svolta (max 400 parole)		
<p>The study was proposed by the three major hepato-gastroenterological Italian Associations (Associazione Italiana Gastroenterologi Ospedalieri (AIGO), Associazione Italiana Studio Fegato (AISF), Società Italiana Gastroenterologia (SIGE)) and by the Italian Association for Infectious Diseases (Società Italiana Malattie Infettive e Tropicali (SIMIT)), supervised by the Italian Institute of Health (Istituto Superiore di Sanità (ISS)) and financially supported by the Italian Drug Agency (Associazione Italiana per il Farmaco (AIFA)).</p> <p>Aim of our study was to assess the effectiveness of PEG-IFNs/Ribavirin in treatment naïve CHC patients in Italy.</p> <p>Independent observational multicenter study. All the 670 Italian clinical centers authorized to prescribe anti-viral treatment for CHC were invited to participate. One hundred and seventy nine centers applied (106 treating less than 50 pts/year (small centers) and 73 treating more than 50 pts/year (large centers). All the 106 small centers, expected to enroll 3,200 pts/year, were included, 32 of the 73 large centers, expected to enroll 7800 pts/year, were randomly included to achieve the same number of patients from large and small centers.</p> <p>All patients who had completed a PEG-IFN/Ribavirin course in the 18 months preceding (retrospective phase) or were prescribed therapy in the 18 months following (prospective phase) the start of the study (February 1st, 2008) were enrolled. There were no a priori inclusion and exclusion criteria</p> <p>Results: 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-IFNalpha-2b vs 444/1,212 (36.6%) treated with PEG-IFNalpha-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.</p> <p>Conclusions: the response to PEG-IFNs/Ribavirin in clinical practice is distinctly lower than in registration trials. SVR reduction was more pronounced among easy than difficult to treat genotypes.</p>		
Problematiche riscontrate e proposte di soluzione (max 200 parole)		
<p>The study has been published in DLD Dig Liver Dis. 2014 Sep;46(9):826-32.</p>		