Male gender, genotype 3, previous alcohol use, increased BMI, and diabetes are factors independently correlated to advanced HCV chronic liver disease in Italy: data from PITER (Piattaforma Italiana per lo Studio della Terapia dei Epatiti viRali) cohort study

INTRODUCTION

Italy has one of the highest prevalence rates of HCV infection in Europe, and a peculiar epidemiologic situation. In Italy, HCV infection is the leading cause of cirrhosis, HCC, and liver-related death. In order to evaluate factors associated with the severity of liver disease in Italian patients in care, data derived from the PITER HCV cohort study were analysed. PITER is a structured network that benefits from an integrated collaboration involving Italy’s National Institute of Public Health (Istituto Superiore di Sanità), the Italian Society for the Study of the Liver (AISF), the Italian Society for Infectious Diseases (SIMIT) and their affiliated clinical centres. The main goal of PITER is to evaluate the expected impact of DAs on the natural course of infection and on long-term morbidity and mortality in a real-life setting.

Aim

To evaluate the peculiarities, if any, of chronic liver disease in Italy, baseline and prospectively.

To evaluate factors correlating with liver disease severity in a sample which is representative of patients in care in Italy

MATERIAL & METHODS

To date 7600 patients in care in more than 80 Italian Clinical Centers are enrolled in the PITER HCV cohort study. The infomatic platform contains detailed clinical and therapeutic informations of these patients. The enrolled patients will be followed for 5 to 10 years, independently if they will be undergone an anti-HCV antiviral therapy.

Analysing baseline data of enrolled patients in the Informatum Platform so far the relationship between severe fibrosis stage/cirrhosis and sociodemographic characteristics, HCV RNA genotype, alcohol, body mass index (BMI), ALT, AST, GGt, platelets, diabetes, cardiovascular, neurological/pysiatric, autoimmune/reumatological and neoplastic diseases were evaluated by univariate and logistic regression statistical models. The regression model’s goodness of fit (calibration and sensitivity) was also estimated.

RESULTS

Framework of data collection in the different eCRFs

This analysis included 6831 patients enrolled as by June 2015.

The mean age of the enrolled patients is 59±11 years; 3797 males) on clinical care. HCV genotype 1b (58%) and genotype 2 (15%) are significantly prevalent in older ages (older than 59 years) compared to genotypes 3 (10%) and 4 (7%), which are prevalent in younger ages. F4/cirrhosis stage was present in 2579 (38%) patients. It increased by age as expected, although significantly prevalent in older ages (3797 males) on clinical care. HCV genotype 1b (58%) and genotype 2 (15%) are

CONCLUSION

Male gender, genotype 3, previous alcohol use and diabetes are factors independently associated with advanced liver disease in this large cohort of Italian patients. Diabetes is an independent factor significantly associated with cirrhosis also in patients younger than 50 years of age. PITER cohort study, through its prospective design, will provide a continuous update of the epidemiology of HCV chronic liver disease considering patients in care that will be continuously enrolled certain periods each year and patients that will be treated with antiviral therapies.

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REFERENCES


2.Piter Collaborating Group available on www.iss.it/piter

DISCLOSURES

Nothing to disclose

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Authorization and ethics

The study was carried out in accordance to the ethical principles for medical research with human subjects described in the American Medical Association’s Code of Ethics, the Helsinki Declaration, and the local ethics committee regulations.