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Prognostic value of FIB4 in HIV positive patients of the Icona cohort with or without HCV

C.Mussini[1], P. Lorenzini[2], A.De Luca[3], M. Puoti[4], M. Lichtner[5], G. Lapadula[6], S DI Giambenedetto[7], A Antinori[2], M.S. Mura[8], A. Cozzi-Lepri[9] and A. d'Arminio Monforte[10] for the Icona Foundation Study Group

1Clinic of Infectious Diseases, University of Modena and Reggio Emilia, Italy - 2 National Institute for Infectious Diseases L. Spallanzani, Rome, Italy – 3 University Division of Infectious Diseases, Siena University Hospital, Siena, Italy – 4 Clinic of Infectious Diseases, Maggiore Hospital, Milan, Italy -5 Clinic of Infectious Diseases, La Sapienza University, Rome, Italy - 6 Department of Infectious Diseases, San Gerardo Hospital, Monza, Italy - 7 Istituto di Clinica delle Malattie Infettive, Università Cattolica del Sacro Cuore, Roma -8 Clinica delle Malattie Infettive, Università di Sassari, 9 Department of Infection & Population Health Division of Population Health, Hampstead Campus, University College London, UK - 10 Clinic of Infectious Diseases, San Paolo Hospital, Milan, Italy

Background. Liver-related events represent a major cause of morbidity and mortality in HIV-infected individuals. FIB4 is a non-invasive serum fibrosis marker, which has been validated in HCV positive pts. We aimed at evaluating the FIB4 score as a predictor of major liver events and liver-related death in patients initiating cART.
Methods. All treatment-naive patients enrolled in ICONA were selected who: initiated cART, with a known HCV serology, were HBsAg neg, had an available FIB4 index at cART start and during follow up. FIB4 value>3.25 was used as a proxy for cirrhosis, a value<1.45 was considered as absence of cirrhosis, while for values between 1.45 and 3.25 cirrhosis status was considered undetermined. Major liver events were defined by: variceal/gastrointestinal bleeding, ascites, hepatic encephalopathy, jaundice with direct hyperbilirubinemia, hepatic-renal syndrome or hepatocellular carcinoma (HCC). Patients were followed-up until a major liver event or liver-related death; in those without events follow-up was censored at last clinical visit or at death for causes other than those liver-related. Incidence rates were calculated as number of major liver events or liver-related death divided by person year follow-up (PYFU). Multivariable Cox regression model was used to determine the association of FIB4 with the risk of major liver events or liverrelated death.
Results. 3475 subjects were selected, 73.3% males, 42.7% infected through heterosexual contacts, 16.6% with prior AIDS, 27.2% anti-HCV+ (92.1% of anti-HCV+ tested were HCV RNA+), median age was 39 years (IQR 33-45), CD4 260, HIV RNA 4.9 log. 65.9% had a FIB4<1.45, 26.4% 1.45-3.25 and 7.7% >3.25. Over a follow up of 18,662 PYFU, a total of 41 events were observed: 25 major liver events and 16 liver-related deaths.The incidence rate (IR) was 2.2 per 1,000 PYFU (95%CI 1.6-3.0). IR was higher in anti-HCV+ as compared to negatives (5.9 vs 0.5 per 1,000 PYFU). IR for subjects with baseline FIB4<1.45 (65.9%) was 0.5 (95%CI 0.2-1.1), FIB4=1.45-3.25 (26.4%) IR=3.1 (95%CI 1.8-5.1), FIB4>3.25 (7.7%) IR=14.6 (95% CI 9.4-22.6). Current CD4 (per 100 cells/μL higher HR 0.73, 95% CI 0.61-0.88), higher baseline FIB4 category (versus <1.45, FIB4 1.45-3.25 HR 5.08, 1.64-15.71; FIB4>3.25 HR 14.66, 4.64-46.32) and change from baseline FIB4 (+1 higher, HR 1.02, 1.01-1.04) were independently predictive of the hazard of major liver events/liver-related death, after adjusting for sex, mode of transmission, AIDS diagnosis, time from HIV diagnosis, HCV serostatus, current viral load, alcohol consumption, baseline glucose levels and calendar year of cART initiation.
Conclusions. The FIB4 score, at cART initiation and its modification after cART are risk factors for major liver events or liver-associated death independently of infection with HCV. FIB4 represents a candidate prognostic marker for monitoring patients on cART.