SUPPLEMENT N°2 VOL. 62 2015

ELSEVIER

JOURNAL OF HEPATOLOGY

50th THE INTERNATIONAL LIVER CONGRESS™ 2015

Abstract Book

50th Annual Meeting of the European Association for the Study of the Liver
Vienna, Austria - April 22-26, 2015

EASL | JOURNAL OF HEPATOLOGY

However, data are scarce regarding universal use of the prophylactic antiviral agents or optimal duration of prophylaxis to date. In this study, we compared the frequency of hepatitis B reactivation between prophylactic group and non-prophylactic group in hematopoietic stem cell transplantation patients.

Methods: From January 2008 to December 2013, a total of 315 HBsAg-negative, anti-HBc positive patients were enrolled who receive autologous or allogenic stem cell transplantation. Patients were divided into prophylactic and non-prophylactic groups. The primary endpoint was the incidence of HBV reactivation, which was defined as a increase in HBV DNA 10 times than baseline or HBsAg-reverse seroconversion.

Results: The median age of patients was 49.7 years (range, 16–71), and 181 (57.5%) were male. Among the patients, 219 (69.5%) did not take prophylaxis, and 96 (30.5%) underwent prophylaxis as follows: 90 to telbivudine; 5 to entecavir; 1 to lamivudine, respectively. Of these, 12 patients developed HBV reactivation (prophylactic group, 4; non-prophylactic group, 8). The median time to reactivation was 20.5 months (range, 10.0–39.0) after the initiation of chemotherapy. All of the patients were successfully treated with telbivudine, entecavir or tenofovir, and none of them experienced liver-related death. The risk of reactivation was not different between prophylactic and non-prophylactic group ($P = 0.061$).

Conclusions: HBV reactivation in HBsAg-negative, anti-HBc positive patients undergoing hematopoietic stem cell transplantation is not rare. However, all cases were successfully treated with on-demand antiviral agents without serious liver problems, including hepatic failure and death. Antiviral prophylaxis against HBV reactivation was not effective, especially in the short-term duration (<12 months). Therefore, careful monitoring of HBV DNA and on-demand antiviral treatment would be safe and cost-effective rather than routine prophylaxis in these patients.

P0638
GLOBAL EPIDEMIOLOGY OF HEPATITIS DELTA: FIRST DATA FROM THE HEPATITIS DELTA INTERNATIONAL NETWORK

S. Hardtke[1,2], Z. Abbas[3], S. Hamid[3], E. Ceausu[4], G.N. Dalekos[5], G. Niro[6], G. Corti[7], L.M. Pinheiro Borzacov[8], R. Parana[9], N.K. Gatselis[5], A. Motoc[4], P. Ingiliz[10], M. Muche[11], A. Wranke[1], M. Wöbse[1], C. Yurdaydin[12], M.P. Manns[1,2], H. Wedemeyer[1,2], on behalf of The Hepatitis Delta International Network.

[1]Gastroenterology, Hepatology and Endocrinology, Hannover Medical School, [2]German Centre for Infection Research (DZIF), HepNet Study-House, Hannover, Germany; [3]Dep. of Medicine, Aga Khan University, Karachi, Pakistan; [4]Infectious Diseases, Victor Babes Clinical Hospital for Infectious and Tropical Diseases, Bucharest, Romania; [5]Department of Medicine and Research Laboratory of Internal Medicine, Medical School, University of Thessaly, Larissa, Greece; [6]Divisione di Gastroenterologia, Ospedale Generale Regionale "Casa Sollievo della Sofferenza", San Giovanni Rotondo, [7]Infectious and Tropical Disease Unit, University of Florence School of Medicine, Florence, Italy; [8]Centro de Pesquisa de Medicina Tropical de Rondônia, Bairro Lagoa, [9]Serviço de Gastroenterologia, Hospital Universitário Professor Edgard Santos, Universidade Federal da Bahia, Salvador, Brazil; [10]Infectiology, Medical Center for Infectious Diseases, [11]Gastroenterologie, Infektiologie und Rheumatologie, Charite, Berlin, Germany; [12]Medical Faculty, Ankara University, Ankara, Turkey

E-mail: hardtke.svenja@mh-hannover.de

Background and Aims: Hepatitis D virus (HDV) infection is the most severe form of chronic viral hepatitis associated with accelerated fibrosis progression and an increased risk for developing liver-related clinical complications. However, the clinical and virological presentation of hepatitis delta patients varies largely between different regions and countries. The Hepatitis Delta International Network (HDIN) was established in 2011 and granted with an EASL registry award in 2014.

Methods: The primary aim of the HDIN registry is to establish a large global data base of patients chronically infected with HDV to better define the course of hepatitis delta and response to antiviral therapy in the context of different HDV and HBV genotypes and diverse host genetic and environmental backgrounds. A structured eCRF optimized for hepatitis delta was implemented and 12 centers world-wide are participating. We here report data of the first 674 patients included until November 1st 2014.

Results: 85% of patients were HDV RNA positive, 75% HBeAg-negative and 37% had liver cirrhosis with 10.9% reporting an episode of previous hepatic decompensation. Patients were divided according to the country of birth into Eastern Mediterranean (EM, n = 152), Eastern Europe and Central Asia (EE/CA, n = 158), Central and Southern Europe (CE, n = 40), South Asian (SA, mainly Pakistan; n = 242) and Africa/South America (AF/SA, n = 50). The mean patient age differed largely between regions with patients from SA being more than 10 years younger than EE/CA and EM patients (SA mean age 35.9 years vs. EE/CA 47.0 years and EM 49.7 years) while CE patients were oldest with a median age of 54.1 years ($P < 0.001$). Gender distribution of patients included in the registry differed largely with patients being male ranging from 46.8% (EE) to 82.4% (CA). Previous antiviral therapy was reported for only 37% of patients (48–70% for European patients vs. 33.5% SA vs. Brazil 5%). Patients receiving polymerase inhibitors vary from 2.48% (SA) to 13.82% (EM) and different types of IFNa from 4% (AF/SA) to 22.15% (EE/CA). Liver cirrhosis was most frequent in CE and EM patients (47.5% and 52.63% vs. 28.93% SA, 31% EE/CA and 12% AF/SA).

Conclusions: The HDIN registry confirms the severity of chronic hepatitis delta but also highlights the diversity of patient characteristics in different regions world-wide – possibly requiring different management strategies. More detailed data on virological and clinical characteristics will be presented at the ILC.

P0639
TELBIVUDINE VERSUS TENOFOVIR-BASED TREATMENT OPTIMISATION STRATEGY IN HBeAg-NEGATIVE CHRONIC HEPATITIS B PATIENTS

Z. Krastev[1], I. Kotzev[2], M.K. Celen[3], D. McNeeley[4], K. Hamed[5].

[1]Clinic of Gastroenterology, University Hospital "Sv. Ivan Rilski", Sofia, [2]Clinic of Gastroenterology, University Hospital "Sv. Marina", Varna, Bulgaria; [3]Department of Infectious Diseases, Dicle University School of Medicine, Diyarbakir, Turkey; [4]Established Medicines Dev Franchise, [5]Global Medical Affairs, Novartis Pharmaceuticals Corporation, East Hanover, NJ, United States

E-mail: zahkrastev@gmail.com

Background and Aims: Chronic hepatitis B (CHB) is a common global health problem. Early virological response with antiviral treatment with telbivudine (LdT), particularly at week 24, is associated with better long-term treatment outcomes in CHB patients. This study evaluated the treatment outcomes of conditional intensification of LdT monotherapy with tenofovir (TDF) in HBeAg-negative CHB patients.

Methods: Patients were randomised (1:1) to receive LdT 600 mg q.d. or TDF 300 mg q.d. in this prospective, open-label study. After LdT or TDF monotherapy for 24 weeks, patients with HBV DNA ≥300 copies/mL received TDF/LdT add-on therapy until week 104, whereas those with <300 copies/mL continued monotherapy. The modified intent-to-treat (mITT) population comprised patients who did not discontinue before and had not received add-on therapy at week 24.

Results: Of the 241 randomised patients (LdT, 121; TDF, 120), 232 (LdT, 115; TDF, 117) were included in the mITT population. Overall, 80% and 89.7% of patients on LdT and TDF had early virological response (HBV DNA level <300 copies/mL) at week 24. In total, 92% and 95% of patients on LdT and TDF achieved HBV DNA