Eighth year evaluation and the therapeutic efficacy of two different regimens in naive children with chronic hepatitis B infection

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Background and Aim: The spectrum of chronic hepatitis B (CHB) infection in children ranges from asymptomatic carriage with minimal disease, to cirrhosis and risk of hepatocellular carcinoma in adulthood. Identifying those who will benefit from treatment is a challenge. Untreated infection may lead to natural seroconversion and reduced risk of further disease. Interferon-based therapies have limited efficacy in childhood.

The aim of the present study was to evaluate naïve children with CHB infection and to compare the therapeutic efficacy of two different regimens in patients with CHB infection who had been followed-up in the Department of Pediatric Infectious Diseases of Cukurova University Faculty of Medicine.

Patients and Methods: In this retrospective study, 227 naive children with chronic hepatitis B (CHB) infection who had been followed-up at the out-patient pediatric infectious disease clinics of Balcali Hospital from 2008 January to 2013 December were evaluated. These 227 children's demographic and clinical features; risk factors; biochemical, serological and virological feature were also evaluated.

Of the total 227 pediatric patients who had CHB infection, while 70 (30.8%) had spontaneous seroconversion, 157 (69.2%) did not have spontaneous seroconversion. Of the total 157 pediatric patients who had CHB infection, 49 (31.2%) were treated with two different treatment modalities, 108 (68.8%) had been followed-up with CHB infection.

Criteria for treatment of CHB infection included the presence of hepatitis B surface antigen (HBsAg) and elevated serum alanine amino transferase (ALT) for more than 6 months, along with distinctive necroinflammation in the liver.

A total of 49 children were prospectively allocated to two random treatment groups i.e. monotherapy and combination therapy. In the monotherapy groups; 25 patients in the first group (Group 1) received interferon-alpha (IFN-α) in a dose of 5 MU/m², subcutaneous injection, thrice/weekly alone for 6 months. In the combination groups; 24 patients in the second group (Group 2) received Lamuvudin (LAM) for 12 months (peroral, 4mg/kg per day dose, max.100 mg, daily) and IFN-α added to LAM for 6 months in a dose of 5 MU/m² (s.c., thrice/weekly).

Complete response was defined as HBe/antiHBe seroconversion, clearance of HBV DNA and normalization of ALT at the end of therapy. The presence of ALT normalization and HBV DNA clearance, but not anti-HBe seroconversion, was accepted as a partial response. Sustained response at 6 months of follow up after completion of treatment was defined using the same parameters. The complete follow-up period continued 6 months from at the end of the therapy.

All tests were done in the Laboratories of the Balcali Hospital of Cukurova University, Faculty of Medicine. Serum ALT was evaluated by using standart methods (upper limits of normal, 40 IU/L).

Viral markers were measured by using the macro ELISA method, (Cobas 601) Serum HBV DNA level was quantitatively assessed with a commercial PCR assay (real-time PCR, Cobas Taqman 48) (cut-off value, 20-170.000.000 copies HBV DNA / ml).

Statistical analysis was performed by SPSS software program (version 10.0). Comparisons between the groups were made with Mann-Whitney U test, Chi square test, Ficher's Exact test, Kruskal-Wallis test. A two-tailed P value < 0.05 was considered significant.