STUDY ON THE EFFICACY OF RECOMBINANT HEPATITIS B VACCINE IN IRANIAN INFANTS

A. ZAMANI, M.D., H. SHAJARI, M.D., AND I. SEDIGHY, M.D.

From the Departments of Pediatrics and *Neonatology, School of Medicine, Tehran University of Medical Sciences, Tehran, I.R. Iran.

ABSTRACT

In order to determine the efficacy of recombinant hepatitis B vaccine in Iranian infants, we analyzed the efficacy of a recombinant hepatitis B vaccine in 115 infants aged 12-24 months born to HBsAg negative mothers who received three doses of HBV. Antibody to hepatitis B surface antigen (anti-HBs) was checked after the third dose of the vaccine. 94.8% of the infants had developed protective antibody levels. The vaccine was well-tolerated and no serious adverse effects were reported.

This study is in agreement with a WHO report which recommends that the easiest and most cost-effective strategy for the control and eventual eradication of HBV would be to immunize all newborns with hepatitis B vaccine only [World Health Organization report, 1984].

INTRODUCTION

The risk of chronic hepatitis B virus (HBV) infection is > 70% when mother-to-infant transmission of the virus occurs during the perinatal period. The long-term consequences of chronic HBV infection include death from cirrhosis or primary hepatocellular carcinoma.

In Iran, 3% of the population are carriers of the hepatitis B virus, and it is estimated that the majority of these individuals acquired their infection during the perinatal period.

Recently, routine vaccination of infants has been recommended as the most effective means of preventing chronic HBV infection worldwide.

We report the efficacy of the recombinant hepatitis B vaccine in Iranian infants.

PATIENTS AND METHODS

From 1997 to 1998, 115 infants born to HBsAg-negative mothers were entered to the Amir Kabir Hospital hepatitis B vaccination program and received 10 μg of recombinant HBV [Engerix-B] from Heber Biotec, S.A. Havana, Cuba.

The first two doses are given 1.5 months apart, and a booster dose is administered 9 months after the first. Conventionally, the vaccine is administered intramuscularly (antero-lateral thigh).

Eligible infants aged 12-24 months must not have a history of hepatitis B, immune deficiency or passive unoprophylaxis with hepatitis B immune globulin (HBIG).

Serum specimens were tested for antibody to HBsAg (anti-HBS) by RIA [Central Laboratory of the Blood Transfusion Organization of Iran].

Anti-HBs levels were expressed as sample ratio units (SRU) and concentrations were determined in milli-international units per milliliter.

Statistical analysis

Fisher's exact test was used as indicated for comparison of laboratory findings. A p value of less than 0.05 was considered to be statistically significant.

RESULTS

115 infants (62 boys, 53 girls, Fig.1) who ranged in age from 12 to 24 months with a mean age of 15.9 months had received three doses of hepatitis B vaccine at birth, 1.5, and
Efficacy of Hepatitis B Vaccine

MaJe

53.5%

Fig. 1. Sex distribution in the study population.

Percent

70 /

Fig. 2. Titer distribution in the study population.

Fig. 3. Titer distribution in the study population according to breastfeeding status.

Fig. 4. Titer distribution in the study population according to sex.

9 months of age (Amir Kabir Hospital).

After completing vaccination, the sero-conversion rate (anti-HBs: 1 - 10 mIU/mL) was 100% with a seroprotection rate (anti-HBs > 10 mIU/mL) of 94.8% (Fig. 2).

Data comparing immune response according to age, sex and birth weight showed no differences, but protective efficacy in girls (96.2%) was slightly more than boys (93.5%).

There was a significant correlation between seroprotection rate and breast feeding (p value = 0.03) (Fig. 3).

DISCUSSION

Hepatitis B is one of the most widely prevalent infections worldwide. Perinatal transmission is responsible for 35 - 40% of all new hepatitis B infections worldwide.2,7,8

There is no reliable treatment for hepatitis B disease, and the only easy intervention that prevents HBV infection is immunization.2,3,9

The vaccine is highly immunogenic, as seroconversion rates were found to be 100%, more than that seen in other studies, approximately 93% to 98%.10-12 A 92% - 98% seroprotection rate has been shown in different studies.13,14

In our study, seroprotective anti-HBs titers persisted in 94.8% of infants. Protective efficacy in girls (96.2%) was higher than in boys (93.5%) (Fig. 4).

Our research also indicated that breast feeding could significantly affect the antibody titers (p value = 0.03)

There were no statistically significant differences in protective efficacy between infants weighing <2000g or >2000g at birth. However, the American Academy of Pediatrics and the United States Public Health Service Immunization Practices Advisory Committee recommendations for hepatitis B immunization in premature infants weighing <2kg at birth born to hepatitis B surface antigen (HBsAg) negative mothers are to delay the initiation of vaccination until such infants reach 2kg or until 2 months of age.15,16 Similar to other studies, no subject dropped out due to a severe adverse reaction.6,9,11,17

This study supports current recommendations of the
American Academy of Pediatrics and the Centers for Disease Control and Prevention for hepatitis B immunization according to the Expanded Program of Immunization (EPI). As in previous controlled studies with this vaccine, our findings support that immunization is safe, immunogenic, and effective. Future research should clarify the need for further boosters.

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REFERENCES
