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

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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].

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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.[1-3] The long-term consequences of chronic HBV infection include death from cirrhosis or primary hepatocellular carcinoma.[4]

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.[5]

Recently, routine vaccination of infants has been recommended as the most effective means of preventing chronic HBV infection worldwide.[6]

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 (anterolateral 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

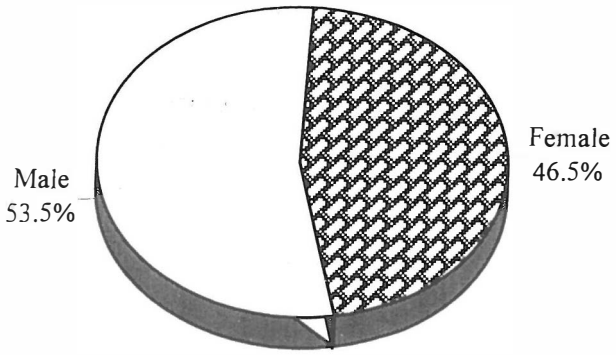

Fig. 1. Sex distribution in the study population.

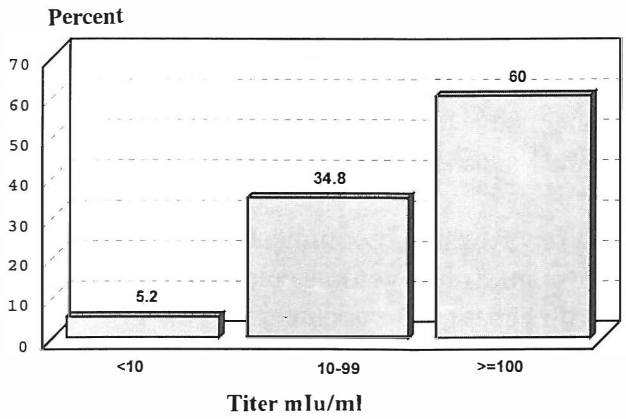

Fig. 2. Titer distribution in the study population.

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 > 10mIU/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]

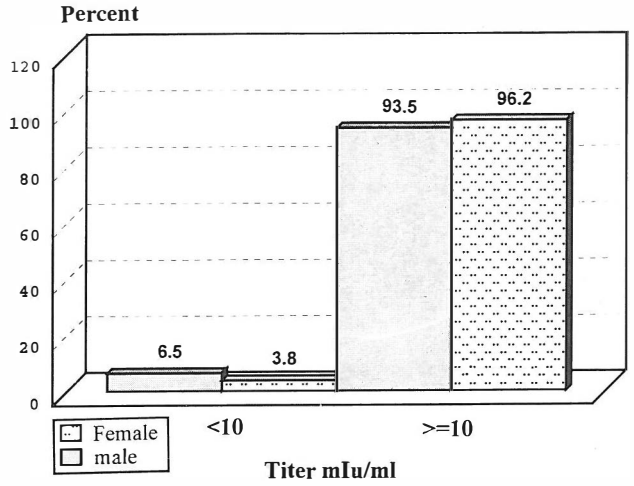

Fig. 3. Titer distribution in the study population according to breastfeeding status.

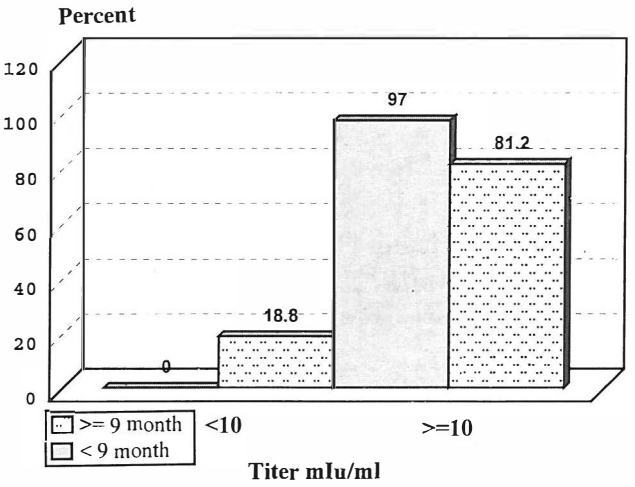

Fig. 4. Titer distribution in the study population according to sex.

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 2 kg 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,[3, 6, 9-13] our findings support that immunization is safe, immunogenic, and effective. Future research should clarify the need for further boosters.

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