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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

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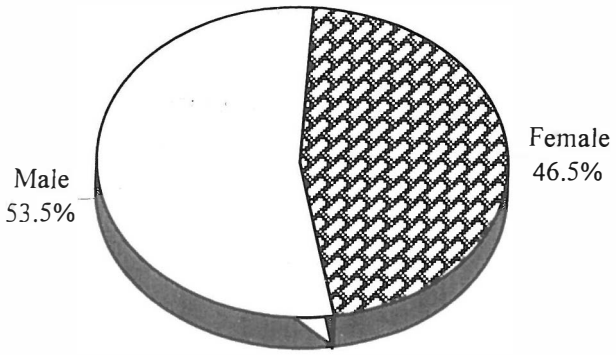


Fig. 1. Sex distribution in the study population.

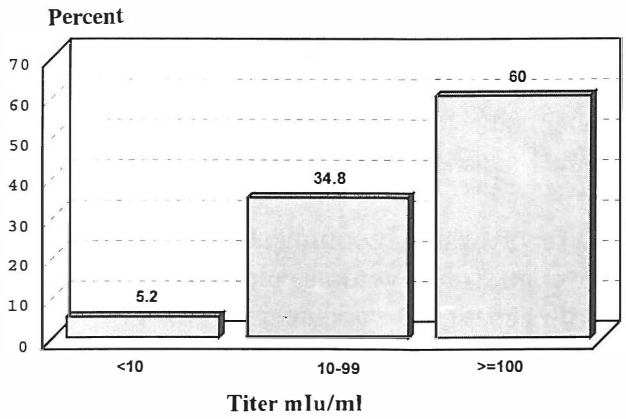


Fig. 2. Titer distribution in the study population.

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]

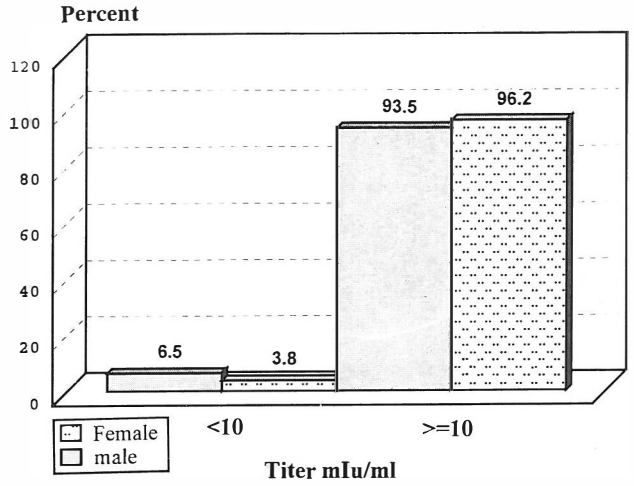


Fig. 3. Titer distribution in the study population according to breastfeeding status.

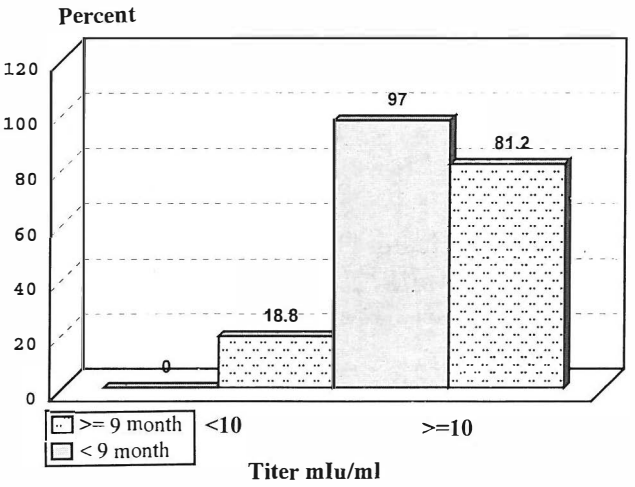


Fig. 4. Titer distribution in the study population according to sex.

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

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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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REFERENCES

1. Stevens CE, Toy PE, Tong MJ, et al: Perinatal hepatitis B virus transmission in the United States. Prevention by passive-active immunization. JAMA 253: 1740-5, 1985.
2. Andre FE, Zuckerman AJ: Protective efficacy of hepatitis B vaccine in neonates. Journal of Medical Virology 44: 144-151, 1994.
3. Xu ZY, Duan SC, Margolis HS, et al: Long-term efficacy of active post-exposure immunization of infants for prevention of hepatitis B virus infection. The Journal of Infectious Diseases 171: 54-60, 1995.
4. Beasley RP: Hepatitis B virus. The major etiology of hepatocellular carcinoma. Cancer 61: 1942-56, 1988.
5. Malek-Zadeh R, Khatibian M, Rezvan H: Viral hepatitis in the world and Iran. Epidemiology, diagnosis, therapy and prevention. Journal of the Medical Council of the Islamic Republic of Iran 4: 183-200, 1997.
6. Osterholm MT: Hepatitis B infection in Minnesota: a case for universal immunization. Pediatr Infect Dis J 17: 530-4, 1998.
7. Panda SK, Rajagopa LR, Rao VS, et al: Dynamics and impact of perinatal transmission of hepatitis B vaccine in infants. J Med Virol 35: 297, 1991.
8. Ghendon Y: Perinatal transmission of hepatitis B virus in high incidence countries. Journal of Virological Methods 17: 69-79, 1987.
9. Woodruff BA, Stevenson J, Yusnf H, Kwong SL, et al: Progress toward integrating hepatitis B vaccine in to routine infant immunization schedules in the United States, 1991 through 1994. Pediatrics 97: 798-803, 1996.
10. Lee SS, Lo YC, Young BW, Wong KH, et al: A reduced dose approach to hepatitis B vaccination for low-risk newborns and preschool children. Vaccine 13(4): 373-6, 1995.
11. Aspinall S, Kocks DJ: Immunogenicity of a low-cost hepatitis B vaccine in the South African Expanded Program on Immunization. S Afr Med J 88(1): 36-9, 1998.
12. Egemen A, Aksit S, Kurugol Z, et al: Low-dose intradermal versus intramuscular administration of recombinant hepatitis B vaccine: a comparison of immunogenicity in infants and preschool children. Vaccine 16(6): 1511-5, 1998.
13. Grzesiowski P, Ziolkowska H, Sobolewska-Wojeiechowska B, Sieniawska-M: Long-term efficacy of hepatitis B vaccine in children with chronic renal failure. Pediatr Pol 70(5): 401-5, 1995.
14. Arrstegui J, Dal Re R, Garrote E, et al: Assessment of the immunogenicity and reactogenicity of a quadrivalent diphtheria, tetanus, acellular pertussis and hepatitis B (DTPa-HBV) vaccine administered in a single injection with *Haemophilus influenzae* type b conjugate vaccine, to infants at 2, 4 and 6 months of age. Vaccine 16(20): 1976-81, 1998.
15. Losonsky GA, Wasserman SS, Stephens I, et al: Hepatitis B vaccination of premature infants: a reassessment of current recommendations for delayed immunization. Pediatrics 103(2): E14, 1999.
16. Khalak R, Pichichero ME, D'Angio CT: Three year follow-up of vaccine response in extremely preterm infants. Pediatrics 101(4 pt 1): 597-603, 1998.
17. Aristegui J, Muniz J, Perez Legorburu A, et al: Newborn universal immunization against hepatitis B. Vaccine 13(11): 973-7, 1995.

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