



The long-term efficacy, 13–23 years, of a plasma-derived hepatitis B vaccine in highly endemic areas in China



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ABSTRACT

Objective: To evaluate the long-term effectiveness of the plasma-derived hepatitis B vaccine that has been applied widely in five areas of China where HBV prevalence was highly endemic.

Method: A cross-sectional investigation was conducted in 2009 at five HBV surveillance sites around China. The target study subjects of 6772 were born between 1986 and 1996 and received plasma-derived HBV vaccine. Serum samples were collected to test for HBV markers using the microparticle enzyme immunoassay.

Results: The number of participants enrolled was 6772. The average hepatitis B surface antigen (HBsAg) prevalence was 2.01%. The birth dose group included 5052 children. In this group, the average positive rates of HBsAg and hepatitis B core antibody (anti-HBc) were 1.58% and 6.39%, respectively, and these values declined gradually from 1986 to 1996. The positive rates of anti-hepatitis B surface antibody (HBs) and the geometric mean concentration (GMC) of anti-HBs-positive subjects were 41.69% and 115.8 mIU/ml. **Conclusion:** The long-term effectiveness of the plasma-derived hepatitis B vaccine still provided protection 13–23 years after vaccination. It seems that a booster dose is not necessary. Enhancing the rate of the birth dose within 24 h is one of the most important measures to prevent and control HBV infection.

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1. Introduction

Hepatitis B virus (HBV) is a blood-borne and sexually transmitted virus [1,2]. HBV infection, which may progress to chronic hepatitis B, cirrhosis, and hepatocellular carcinoma, is a major public health problem in China. It was estimated in 1992 that hepatitis surface antigen (HBsAg) carriers accounted for about 9.8% of the population, and HBV infections caused about 300,000 deaths annually [3–5].

In China, hepatitis B vaccination became gradually widespread, as it is the most effective means to prevent a susceptible population from HBV infection. A blood-borne hepatitis B vaccine was used for newborns who were required to be vaccinated according to a 0,

1, and 6 month schedule since 1986. After 1997, a yeast-derived recombinant vaccine was widely used, whereas a Chinese hamster ovary (CHO) cell-derived vaccine was used in a small number of areas. From 2002, the yeast-derived hepatitis B vaccine was used in all areas [6,7]. Twenty years later, a nationwide hepatitis B investigation showed that in 2006, the HBsAg positive rate dropped to 6.2% in the whole population, and for children ≤14 years old, it dropped to about 2.08% [8].

In 1985, to survey the long-term effectiveness of the HBV immunization program, some surveillance sites were established in different endemic areas in China. Since 1986, every newborn infant has been vaccinated according to a 0, 1, and 6 months schedule regardless of the mothers' HBV infection status [6,7]. From 1986 to 1996, the plasma-derived HBV vaccine was used in five surveillance sites. Until 2009, it has been used for 13–23 years in these areas. However, the duration of protection of the hepatitis B vaccine remains incompletely understood [9]. To evaluate the long-term effectiveness of the HBV immunization program that has been applied widely in five areas where the HBV prevalence was highly endemic before universal hepatitis B vaccinations, we investigated the HBV infection status of children born from 1986 to 1996.

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2. Materials and methods

2.1. Ethics

The survey protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki and was approved by the China CDC Ethics Committee, and all study work was performed in accordance with national ethics regulations. Study participants were informed of the study purpose and of their right to keep information confidential. The written informed consent of adults and permission from the parents of minors were obtained before the interview and venous blood collection.

2.2. Field background

From 1985 to 1987, some surveillance sites, including Zhengding county, which is a rural area in Hebei province, Shanghai city, Longan county, which is in a remote rural area in Guangxi province, Xiangtan city in Hunan province, and Tongde county, which lies in a remote pastoral area in Qinghai province, were gradually established to survey the long-term efficacy of the HBV vaccine [10]. The five sites are located in north, east, south-west, central, and northwest China, respectively. In the economies and cultures, at that time, Shanghai was a developed city, and Zhengding and Xiangtan were developing areas, whereas Longan and Tongde were underdeveloped districts.

Before universal HBV vaccination, some cross-sectional investigations collected baseline data at these sites. The results showed that the five sites were all HBV-endemic areas. HBsAg prevalence rates of people who were 1–60 years old were 8.1% in Zhengding, 11.3% in Shanghai, 16.9% in Longan, 13.1% in Xiangtan, and 17.0% in Tongde. The HBsAg prevalence rates of those who were 1–25 years old were similar in every place [11–13]. In 1986, the first uniform recommendations for universal hepatitis B vaccination were made in these survey sites [11]. The local Center for Disease Control and Prevention (CDC) provided all neonates with free hepatitis B vaccines, but charged their parents for the injection service.

In fact, to evaluate the long-term effectiveness of the plasma-derived hepatitis B vaccine, which was administered from 1986 to 1996, the children in these sites had their blood tested for HBV markers every 3–5 years. All the basic information (sex, birth date, ethnicity, immunization history, etc.) and test results, including a month after every baby had finished their vaccinations on schedule, is kept at the National Hepatitis Laboratory, Chinese CDC.

2.3. Study population

The target population was people born between 1986 and 1996 in the five surveillance sites. They were immunized with three doses of the plasma-derived hepatitis B vaccine according to the routine vaccination schedule that was recommended for newborns in 1986. The first dose of the hepatitis B vaccine was required to be given within 24 h after birth at the hospitals or clinics where they were born, and the 2nd and 3rd doses were given at local community hospitals. The vaccines were manufactured by the Beijing Institute of Biological Products (Beijing, China), and the dosage was 10 µg/ml. No member of this target population received a booster immunization.

2.4. Sampling method and specimen collection

Subjects enrolled in our study were selected by multiple-stage random sampling. The primary sampling unit was the village, the secondary was the town. Sample size calculation was according to the HBV infection rate in the local areas. Approximately 30% of the population was sampled. The non-response rate was less

than 10%. If the child was selected as a study subject, researchers went to visit their parents at their home. There, they explained the research project to the subjects and their parents and asked them to take part in the survey. Then, researchers checked the child's immunization record booklet, asked questions about their birth and administrations of hepatitis B vaccine according to a questionnaire prepared beforehand, and took 3 ml of venous blood from every participating child. Basic information, including sex, birth date, ethnicity, place of birth, immunization history, etc., was entered into the study database and well documented. Serum was separated in county laboratories, transported, and stored at -20°C , initially at provincial laboratories, and subsequently at the National Hepatitis Laboratory, China CDC (Beijing). Once a child was found to have a HBsAg-positive serum sample, the researchers would refer to historical data that are kept at the National Hepatitis Laboratory, China CDC, to estimate whether the child was a newly infected person.

2.5. Laboratory detection

In the National Hepatitis Laboratory, Institute for Viral Disease Control and Prevention, China CDC, serum samples were tested for three HBV markers, HBsAg, anti-HBs, and anti-HBc. These markers were detected with Abbott microparticle enzyme immunoassay (MEIA) kits (AXSYM, Abbott, Chicago, IL, USA). When the S/N value of HBsAg was ≥ 2.0 , the CO/S value of anti-HBc was < 1.0 , and the value of anti-HBs was ≥ 10 mIU/ml, the marker was defined as positive respectively.

2.6. Statistical analysis

All data were entered into Access 2000 and analyzed using SAS software, version 9.13. The difference in the prevalence of HBV markers in different areas was determined by a chi-squared (χ^2)-test. The change in the prevalence of HBV markers in trend with the birth year was examined by a χ^2 trend test. p values < 0.05 were considered statistically significant. Geometric mean concentrations (GMCs) of anti-hepatitis B surface antibody (HBs) were calculated from values observed in anti-HBs-positive children (≥ 10 mIU/ml). The formula for vaccine protective efficacy was: protective rate of vaccine = (incidence of baseline group – incidence of vaccinated group)/incidence of baseline group $\times 100\%$.

3. Results

3.1. Sample collection

A total of 6772 subjects who were born from 1986 to 1996 were enrolled in the survey, and the neonate gender ratio was approximately 1:1 in all surveillance sites. There were 986 subjects from Zhengding, 2618 from Shanghai, 1587 from Longan, 1199 from Xiangtan, and 392 from Tongde. By checking the inoculation information of each subject, the researchers found that the birth dose of 5052 children had been administered within 24 h of their birth, while the first doses of the other 1720 subjects was received between 3 days and 30 days after birth.

3.2. Positive rates of HBsAg

The overall HBsAg average positive rate of the 6772 subjects was 2.01% (136/6772). The HBsAg average prevalence rates were 1.58% (80/5052) and 3.20% (55/1720) in the groups of children who were vaccinated with the birth dose within 24 h of their births and those who were inoculated after more than 24 h post-birth, respectively. There was a significant difference between the two groups ($\chi^2 = 17.111$, $p < 0.05$, Table 1).

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