Immunogenicity of 2.5 µg HBvax II in Thai preschool children

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B VIVATVKIN. Immunogenicity of 2.5 µg HBvax II in Thai preschool children. *Can J Gastroenterol* 1993;7(8):595-596. Mass immunization provides effective control of hepatitis B virus (HBV) infection and reduces the rise of hepatocellular carcinoma. Children have better immunological responses against hepatitis B vaccination than do adults. Thus, a study of one-quarter of the adult dose of HBvax II (recombinant hepatitis B vaccine) (2.5 µg) given to preschoolers was carried out. Sixty children in one Bangkok metropolitan day care were recruited and given three injections, each of 2.5 µg HBvax II injected intramuscularly at study start, and one and six months later. Seroconversion rates and geometric mean titres at six and eight months after the first injection were 98.3 and 100%, and 239.01 and 8604.5 mIU/mL, respectively. These results support a rational dosage of HBvax II for children.

Key Words: Immunogenicity, Recombinant vaccine, Hepatitis B

Immunogénicité de 2,5 g de HBvax II chez des enfants thaïlandais d'âge préscolaire

RÉSUMÉ : L'immunisation de masse procure une maîtrise efficace de l'infection au virus de l'hépatite B (HBV) et réduit l'élévation du taux de carcinomes hépatocellulaires. Les enfants manifestent une réponse immunologique meilleure que les adultes suite à la vaccination contre l'hépatite B. Une étude, portant sur le quart de la dose administrée chez l'adulte, soit 2,5 g, chez des enfants d'âge préscolaire a donc été effectuée. Soixante enfants d'une garderie de Bangkok ont été recrutés et ont reçu trois injections de 2,5 g chacune de HBvax II par voie intramusculaire, l'une au début de l'étude, les suivantes après un et six mois. Les taux de séroconversion et les titres des moyennes géométriques, six mois et huit mois après la première injection, ont été de 98,3 et de 100 %, et de 239,01 et 8604,5 mUI/mL respectivement. Ces résultats appuient l'emploi d'une posologie rationnelle de HBvax II chez les enfants.

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MASS IMMUNIZATION FOR HEPATITIS B virus (HBV) in the newborn aims to decrease the occurrence of HBV-related hepatocellular carcinoma in later life (1,2). To control horizontal transmission, mass immunization in children – especially preschoolers – is considered to be most effective.

The prevalence of HBV markers in Thailand increases abruptly after preschool age (3,4). The immunological responses in preschoolers are far better than in newborns and adults; thus, one-quarter of the adult quarter dose of HBvax II (2.5 µg) may be one germane recommendation (1,5), especially in a hyperendemic country, for the cost-benefit of mass immunization.

The presented study took place from November 1, 1988 to June 31, 1989 in the centre of metropolitan Bangkok, where there was equal distribution of Chinese-Thai and Thai children.

SUBJECTS AND METHODS

Sixty preschoolers in the Bangkok metropolitan day care were recruited in the study based on inclusion criteria of: negative for HBV markers by radioimmunoassay (Abbott Laboratories, Illinois); serum aspartate aminotransferase less than 50 U/L. After securing informed consent, preschoolers were given 2.5 µg HBvax II (Merck Sharp and Dohme batch G4453,

TABLE 1

Comparison of anti-hepatitis B surface antigen levels in preschoolers at six and eight months after first vaccination

	Six months	Eight months
Low responder (10 to 100 mIU/mL)	17.24%	2.33%
Moderate responder (100 to 1000 mIU/mL)	70.69%	2.33%
High responder (1000 to 150,000 mIU/mL)	12.07%	95.35%
Geometric mean titre (mIU/mL)	239.01	8604.05
Seroconversion rate	98.3%	100%

*After first vaccination

G4706) intramuscularly in the deltoid muscle at study start, and one and six months later. Blood was withdrawn at six and eight months for anti-hepatitis B surface antigen (HBs) levels.

Immediate side effects of injection, such as local tenderness, fever, nausea, vomiting and vertigo, were observed by the attending nurse. Seroconversion was defined as anti-HBs level more than 10 mIU/mL.

No immediate side effects were reported at the 'six month' injection. Blood from 59 children was analyzed (one child moved from the study location). The seroconversion rate was 98.3% and geometric mean titre (GMT) was 239.01 mIU/mL (range 15.5 to 2272). At eight months after the first injection, 43 children were

tested (the rest moved out of the study area); seroconversion was 100%, with a GMT of 8604.5 mIU/mL (range 45 to 128,972).

The immunological responses in these preschoolers were classified according to anti-HBs level: low responder (10 to 100 mIU/mL), moderate responder (100 to 1000 mIU/mL) and high responder (1000 to 150,000 mIU/mL). Two months after complete immunization (three injections), 95.35% of the subjects were in the high responder group, with appreciable GMT of 8604.05 mIU/mL (Table 1).

DISCUSSION

The determination of an anti-HBs level more than 10 mIU/mL is accepted as a protective level against HBV infec-

tion (6). Recent studies (7,8) claim that anti-pre S2 and anti-HBs may promote immunological clearance of HBV, but anti-HBs alone provides adequate protection. Antigenic determinants of S-antigen are classified into α , δ and γ , and correspond with antibody subtypes anti-HBs- α (which is determined as routine laboratory), anti-HBs- δ and anti-HBs- γ .

Laplanche (9,10) reported the correlation between level of anti-HBs and prediction for protection longevity, which established the concept that levels of higher anti-HBs provide longer immunity. From this study, the GMT level is 8604.05 mIU/mL which should provide more than adequate protection for at least 10 years.

Since January 1992, the Thai Ministry of Public Health implemented the hepatitis B vaccination in the 'Expanded program on immunization', starting with the newborn as the target. This schedule will cut off the vertical transmission and reduce the incidence of hepatoma in recipients. To control horizontal transmission, private sectors should react for mass immunization when the vaccine is available at an appropriate price.

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