Immunogenicity of 2.5 µg HBvax II in Thai preschool children

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B Vivatvakin. 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

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

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

*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 infection. Asian J Trop Med Public Health 1980;11:5882.

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REFERENCES