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Immune Response against Hepatitis B Virus after Vaccination among Low Birth Weight and Preterm Newborns: A Retrospective Cohort Study in Magelang District Central Java

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ABSTRACT

Introduction: Hepatitis B virus (HBV) infection is a major cause of morbidity and mortality in the world. Over 2 billion people are infected with HBV and 378 million are carriers. The mortality rate is approximately 1-2 million and over 4 millions acute clinical cases are documented each year. The prevalence of HBV infection in Indonesia is 3-20%. Vertical and horizontal transmission in newborn and children occurs in 25-45%. Near 25-50% of children are infected before 5 years. The most effective approach to reduce the burden of HBV infection is mass vaccination of newborns and children.

Objectives: To determine immune response against HBV after HBV vaccine among low birth weight (LBW) and preterm newborns after HBV vaccination, and factors related to the immune response i.e. gender and weight gain in the first 6 months of life.

Methods: During May-July 2012, 106 infants aged 13-15 months were recruited after HBV vaccination. They were completed 4 doses of HBV basic vaccination in 0, 2, 3, and 4 months of life. Sera were examined for anti-HBs antibody titers using ELISA.

Results: A total of 98 subjects (92.5%) completed the study. Immune response of LBW subjects were positive in 89.7%, newborns were 95.9%. The Relative Risk (RR) were 2.5 CI (0.50 to 12.2) p=0.2178. Gender was not related to immune response RR 0.6 CI (0.15 to 2.69) p=0.6996. Gestational age associated with immune response RR 8 CI (1.05 to 63.9) p=0.0399. The first 6 months weight was not related to immune response RR 3.6 CI (0.73 to 17.7) p=0.1178. Logistic regression analysis showed LBW was not correlated with the immune response OR 1 CI (0.16 to 7.17) p=0.929. Gestational age correlated with immune response OR 9 CI (1.05 to 79.3) p=0.044 and the first 6 months of weight was not correlated with immune response OR 3.7 CI (0.65 to 21.1) p=0.138.

Conclusion: Immune response against HBV after vaccination was similar between LBW and NBW. Immune response was correlated with gestational age.

Keywords: Hepatitis B vaccine, immune response, LBW and preterm.
INTISARI


Tujuan: Penelitian ini bertujuan untuk mengetahui respon imun terhadap HBV pasca vaksinasi diantara bayi berat lahir rendah (BBLR) dan bayi lahir kurang bulan. Serta untuk mengetahui faktor yang berhubungan dengan respon imun seperti jenis kelamin dan pertumbuhan berat badan pada enam bulan pertama.

Metode: Selama bulan Mei-Juli 2012 telah dilakukan penelitian pada 106 anak usia 13-15 bulan yang telah divaksinasi HBV empat kali pada usia 0, 2, 3, dan 4 bulan. Serum diambil dan dilakukan pengukuran titer anti-HBs antibody dengan metode ELISA.

Hasil: Sebanyak 98 subjek (92,5%) menyelesaikan studi. Respon imun BBLR (89,7%) bersama dengan NBW (95,9%) RR 2,5 CI (0,50 12,2) p = 0,2178. Jenis kelamin tidak berhubungan dengan respon imun RR 0,6 CI (0,15 to 2,69) p=0,6996. Usia kehamilan berhubungan dengan respon imun RR 8 CI (1,05 to 63,9) p=0,0399. Berat bayi enam bulan pertama tidak berhubungan dengan respon imun RR 3,6 CI (0,73 - 17,7) p=0,1178. Analisis regresi logistic menunjukkan bahwa BBLR tidak berhubungan dengan respon imun OR 1 CI (0,16 - 7,17) p=0,929. Usia kehamilan berhubungan dengan respon imun OR 9 CI (1,05 - 79,3) p=0,044; dan berat bayi pada enam bulan pertama tidak berhubungan dengan respon imun OR 3,7 CI (0,65 - 21,1) p=0,138.

Simpulan: respon imun vaksin HBV setara antara BBLR dan bayi berat lahir cukup. Respon imun berhubungan dengan usia kehamilan.

Kata kunci: Vaksin HBV, respon imun, BBLR dan bayi lahir kurang bulan

INTRODUCTION

Hepatitis B Virus (HBV) infection was the main cause of morbidity and mortality. The transmissions of HBV have been become public health problem in the world. The vertical transmission from woman to infant was occurred at 24-45%, increasing the incidence of new infection of HBV in children.

The frequency of horizontal transmission was 79%. This was occurred amongst children, adolescent, adult. It was documented that 25-50% cases were new HBV infection involving children before their five year old. This condition become significant since the younger children get infection, the more probable to become chronic carrier1,2.

It was proposed that HBV vaccination decreases the morbidity and mortality at two third in 2015. American Academy of Pediatrics (AAP) recommended the HBV vaccination for the new born and premature babies or Low Birth Weight ≥ 000gr. The vaccination schedule is similar with the normal infant without respect to the status of HBs Ag of the mother3.

The incidence of LBW and premature babies has been increasing in the last 15 years. The newest advance of the caring for LBW and premature is important to be followed in order
to substantially increasing the survival\(^1\). The most effective approach to decrease the HBV infection and breaking the chain of transmission in their early life is by primary prevention through mass vaccination for the new born and children.

A national wide HBV vaccination programs was performed in Indonesia in 1997. One series of HBV vaccination able to gain optimal immune response at 95% in infant, children, adolescent and healthy adult\(^4\). Studies on immune response against HBV after vaccination was not conclusive reported that immune response against HBV was found lower in premature than the aterm infant\(^5\).

Other studies\(^6,7\) reported that, the premature and LBW infants have immune response that is comparable to the normal infants after hepatitis B vaccination with three doses in the different population.

Considering this inconclusive data, study to measure the immune response in LBW and normal infant and other factors that is influence the immune response is interesting.

**MATERIALS AND METHODS**

**Subjects:**

This was retrospective cohort study. Two parallel groups were observed in August to October 2013. Sampling was performed by cluster sampling in three area of Public Health Center with high incidence of LBW in Magelang District. This study had been approved by Research Ethic Committee of Faculty of Medicine, Universitas Gadjah Mada (MHREC). The subjects were consisted of 53 LBW infants and 53 normal birth weight (NBW) infants who have complete 4 series of the HBV vaccination at 0, 2, 3, and 4 months of their ages. The mothers, who their children was selected as subject, were invited to Public Health Center and Integrated Service Post. Informed consents were obtained from the mothers. Data were collected from medical records and child health cards.

**Anti-HBs antibody titer measurement**

Children were donate 1.5-2 \(\mu\)l of blood. Titer of anti-HBs antibody was measured by using ELISA method. The anti-HBs antibody titer was categorized as negative if their anti-HBs titer is less than 10 IU/L and positive if more than 10 IU/L.

**Statistical analysis**

the correlation between two variable were analyzed using fisher’s exact test and multivariable analysis by using logistic regression, with significance level \(p<0.05\), and confidence level at 95%.

**RESULTS AND DISCUSSIONS**

The study was performed at Salaman 1, Salaman 2 and Borobudur Primary Health Care. Table 1 summarized the variables which were studied among LBW and normal children.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Observation results</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HBs Titters</td>
<td>&lt;10 IU/L</td>
<td>7</td>
<td>7.2</td>
</tr>
<tr>
<td></td>
<td>≥10 IU/L</td>
<td>91</td>
<td>92.8</td>
</tr>
<tr>
<td>Sex</td>
<td>Male</td>
<td>53</td>
<td>54.1</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>45</td>
<td>45.9</td>
</tr>
<tr>
<td>Birth weight</td>
<td>LBW</td>
<td>49</td>
<td>50.0</td>
</tr>
<tr>
<td></td>
<td>NBW</td>
<td>49</td>
<td>50.0</td>
</tr>
<tr>
<td>Gestational age</td>
<td>&lt;37 weeks</td>
<td>42</td>
<td>43.0</td>
</tr>
<tr>
<td></td>
<td>≥37 weeks</td>
<td>56</td>
<td>57.0</td>
</tr>
<tr>
<td>Firts 6 month</td>
<td>Weight Decreased</td>
<td>40</td>
<td>40.8</td>
</tr>
<tr>
<td>weight</td>
<td>Weight Increased</td>
<td>58</td>
<td>59.2</td>
</tr>
</tbody>
</table>
Table 2. Relationship between birth weight, sex, gestational age and Weight the First 6 month weight and anti-HBs titers

<table>
<thead>
<tr>
<th>Variable</th>
<th>Anti-HBs Titers</th>
<th>RR</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;10 IU/L</td>
<td>&gt;10 IU/L</td>
<td>Total</td>
<td></td>
</tr>
<tr>
<td>Birth weight</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LBW</td>
<td>5</td>
<td>44</td>
<td>49</td>
<td>2.5</td>
</tr>
<tr>
<td>NBW</td>
<td>2</td>
<td>47</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>91</td>
<td>98</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3</td>
<td>30</td>
<td>33</td>
<td>6.0</td>
</tr>
<tr>
<td>Female</td>
<td>4</td>
<td>41</td>
<td>45</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>91</td>
<td>98</td>
<td></td>
</tr>
<tr>
<td>Gestational age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;37 weeks</td>
<td>6</td>
<td>36</td>
<td>42</td>
<td>8.0</td>
</tr>
<tr>
<td>≥37 weeks</td>
<td>1</td>
<td>55</td>
<td>56</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>91</td>
<td>98</td>
<td></td>
</tr>
<tr>
<td>Weight first 6 months</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gain weight</td>
<td>5</td>
<td>44</td>
<td>49</td>
<td>3.6</td>
</tr>
<tr>
<td>Loss weight</td>
<td>2</td>
<td>47</td>
<td>49</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>91</td>
<td>98</td>
<td></td>
</tr>
</tbody>
</table>

Note: *: p<0.05

Table 2 showed the association analysis between birth weight, sex, gestational age and the first 6 month weight with anti-HBs titers. There was significant association between gestational ages and immune response (p<0.05).

Table 3 showed the significant positive correlation between the gestational age with the immune response p=0.044, OR=9.1 and 95% CI (1.05-79.3).

It was recommended by American Academy of Pediatrics that vaccination of HBV in the newborn particularly the premature > 2000 gram and LBW (with good clinical condition) with same vaccination schedule to the normal infant appropriate to the chronological age or vaccination schedule without respect to the status of HBsAg of the woman. It was reported that immune response against HBV between LBW infant <2500 gram normal birth weight infant e”2500 gram was comparable. The HBV vaccine showed effective and safe to prevent the newborn, children, and adult from the transmission of HBV. HBV vaccination with three dosages resulted in 90-99% newborn, children, adolescent and adult develop optimal immune response. It showed by the titer of anti-HBs ≥10 IU/L, and only 5-10% of the infant, health children, and adult who were vaccinated did not form optimal immune response.

Gestational age was one of parameter that might be used for assess immune response in premature infant. Table 2 described that gestational age <37 week contributed to 9 times
greater risk to have negative immune response compared to the gestational age ≥37 week. OR=9.1 and 95 CI 1.05-79.3; p value=0.044.

Previous study reported that premature infant had correlation to the decreasing of immunogenicity after the provision of 3 dosage of HBV vaccine and lower titer anti-HBs antibody compared to the aterm infant.10.5

CONCLUSION

The immune response against HBV of HBV vaccinated LBW infant was comparable to the normal infant. Immune response was correlated with gestational age.

REFERENCES


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\[\text{\ldots\ldots\ldots\ldots Weinstei & Swartz}^3\ \text{\ldots\ldots\ldots}\]

\[\text{\ldots\ldots\ldots\ldots conducted \ldots\ldots\ldots}\]

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