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Comparative evaluation of immunological response of Hepatitis B vaccines administered in pediatric patients

Dr. Rizwan Haider[1], Dr. Shobhakant Choudhry[2*]
[1, 2] Assistant Professor, Department of Pediatric, Darbhanga Medical College and Hospital, Laheriasarai, Darbhanga, Bihar, India
[*] Corresponding Author: Dr. Shobhakant Choudhry

Abstract
Hepatitis is inflammation of the liver tissue. Some people may have no symptoms whereas others develop yellow discoloration of the skin and whites of the eyes, poor appetite, vomiting, tiredness, abdominal pain, or diarrhoea.
The current retrospective study was planned in the Department of Paediatrics in Darbhanga Medical College and Hospital, Laheriasarai from Jan 2016 to Dec 2016. Total 80 Childs of age 1 to 12 months were enrolled in the present study. Cases having HBsAg positive mother, who had already received a hepatitis B vaccine, immunoglobulin or a blood product, and cases having an acute illness contraindicating routine immunization were excluded from the present study.
The main objective of this study is to evaluate the hepatitis B antibody response to a combination vaccine containing recombinant DNA hepatitis B vaccine along with DTwP or DTaP vaccine and a recombinant vaccine containing only S antigen and compare the two vaccines.
The present study demonstrates the immunological response to the two Hepatitis B vaccines with their antibody responses. Hence from the above findings it can be concluded that 0, 1, 6 schedule produces a higher antibody level than 0, 1, 2 schedule though both the schedules have good seroconversion and seroprotection rates with both the vaccines.

Keywords: immunological response, hepatitis B vaccine, combination vaccine, anti HB surface antibody response

Introduction
The hepatitis B vaccine is a safe and effective vaccine that is recommended for all infants at birth and for children up to 18 years. The hepatitis B vaccine is also recommended for adults living with diabetes and those at high risk for infection due to their jobs, lifestyle, living situations, or country of birth. Since everyone is at some risk, all adults should seriously consider getting the hepatitis B vaccine for a lifetime protection against a preventable chronic liver disease. The hepatitis B vaccine is also known as the first "anti-cancer" vaccine because it prevents hepatitis B, the leading cause of liver cancer worldwide.
Hepatitis B vaccine is produced by recombinant DNA technology, most commonly in yeast. The complete vaccination series consists of three doses of vaccine; the first two doses are usually given 1 month apart, with the third dose 1–12 months later. The WHO-recommended schedule for hepatitis B immunization of children consists of a dose within 24 hours of birth followed by a second and third dose of hepatitis containing vaccines at intervals of at least 4 weeks.
A complete series of immunization provides protection for at least 25 years and, according to current scientific evidence, probably for life. Boosters are not recommended for routine immunization programmes. Because of the prolonged incubation period of hepatitis B, some protection will be afforded to most travellers following the second dose given before travel. However, the final dose should always be given.
A combination vaccine that provides protection against both hepatitis A and hepatitis B should be considered for travellers who may be exposed to both organisms. This inactivated vaccine is administered as follows: day 0; 1 month; 6 months.
A rapid schedule of day 0, 1 month and 2 months with an additional dose at 12 months, and a very rapid schedule of day 0, day 7 and day 21 with a booster dose at 12 months, have been proposed by the vaccine manufacturer and approved by national regulatory authorities in some countries [1].
Approximately 5-15% of people who receive the vaccine are considered non-responders. This is especially important for health care workers, families living in households with people that have HBV, and others who may be at increased risk of exposure to HBV. A vaccine non-responder is someone that does not build up an adequate immune response after receiving two, 3-shot series of the HBV vaccine. In other words, they complete one series of the HBV vaccine, and follow it with a surface antibody test (HBsAb or Anti-HBs) 4-6 weeks following the last injection of the series. If the anti-HBs titre is not greater than 10IU/l, than the series is repeated, preferably with an HBV vaccine from a different manufacturer and the person is once again tested for immunity by testing for adequate anti-HBs.
Fortunately there are other options for those concerned with being an HBV vaccine non-responder. There is a higher concentration of the HBV vaccine recommended by the CDC that is used for patients undergoing dialysis, and for those that are immune suppressed. It is a 40µg/ml concentration. If it has been one year or less since one had completed the three-shot series of the regular concentration of the vaccine, one can try one intramuscular dose of 1.0 ml of the 40µg HBV vaccine. If it has been more than one year since one's last three shot series of the vaccine, one can repeat the entire three-shot series with the 40µg concentration of the vaccine. Follow up with an anti-HBs titre test 4 to 6 weeks following the last injection to ensure it is greater than 10 IU/l, and that you have adequate immunity.

If anyone continue to remain a non-responder, he can try a series of as many as five intra-dermal injections, given every two weeks, using the 40µg concentration of the HBV vaccine. Dose one consists of 0.10 ml of the 40µg/ml vaccine, followed by the same dose two 2-weeks later. At that time an anti-HBs titre test would be drawn to check for immunity. If there was not adequate immunity, a third-intra-dermal dose of the vaccine would be given two weeks later. Anti-HBs titres would be checked every two weeks and the patient would be given another intra-dermal injection up to a total of 5 intradermal injections of the 40µg concentration of the HBV vaccine. Don't forget to ensure that your anti-HBs titre is greater than 10IU/l [2].

About a third of the world population has been infected at one point in their lives, including 343 million who have chronic infections. Another 129 million new infections occurred in 2013. Over 750,000 people die of hepatitis B each year. About 300,000 of these are due to liver cancer. The disease is now only common in East Asia and sub-Saharan Africa where between 5 and 10% of adults are chronically infected. Rates in Europe and North America are less than 1%. It was originally known as "serum hepatitis". Research is looking to create foods that contain HBV vaccine. The disease may affect other great apes as well [3].

The main objective of this study is to evaluate the hepatitis B antibody response to a combination vaccine containing recombinant DNA hepatitis B vaccine along with DTwP or DTaP vaccine and a recombinant vaccine containing only S antigen and compare the two vaccines.

Methodology

The current retrospective study was planned in the Department of Paediatrics in Darbhanga Medical College and Hospital, Laheriasaria Jan 2016 to Dec 2016. Total 80 Childs of age 1 to 12 months were enrolled in the present study.

The approval of the institutional ethic committee had been taken before the study. All the patients were informed about nature of study and consent taken verbally. The aim and the objective of the study are conveyed to all patients.

Cases having HBsAg positive mother, who had already received a hepatitis B vaccine, immunoglobulin or a blood product, and cases having an acute illness contraindicating routine immunization were excluded from the present study.

Group I: received vaccine A, a combination vaccine containing recombinant HB DNA along with either DTwP or DTaP in 0.5 ml on a schedule of 6 10, 14 weeks schedule. The constituents of the combination vaccine were: diphtheria toxoid 20-30 Lf, tetanus toxoid 5-25 Lf with HB s antigen.

Group II: received vaccine B, a recombinant HB vaccine containing 10 µg of only S antigen in 0.5 ml given separately with. DTP on a schedule of 6, 10 and 14 weeks.

Group III: received recombinant HB vaccine on a schedule of 0, 6 and 14 weeks.

Group IV: received HB vaccine on a schedule of 0,1,6 months.

All the samples were analysed for HBsAg by ELISA method. The anti-HBsAg antibody was assayed using ELAgen Anti HBs Quantitative Kit. Protective antibody titre was taken as 10 micro gm/L of antibody to surface antigen. Vaccine A& B were administered with the recommended doses in the selected study populations.

Result & Discussion

The 20 patients were enrolled into each study group. The data was collected and presented as below.

Table 1: Group wise age and sex

Group	Age in month	Sex		Total child
		Male	Female	
Group I	1-4	12	8	20
Group II	1-4	10	10	20
Group III	0-4	15	5	20
Group IV	0-6	14	6	20

Table 2: Anti HB surface antibody Responses to Vaccine A (combination vaccine.) & B (HB vaccine given separately) in Different Patients.

Response	Nonresponder <1 IU/L	Seroconversion ≥1 IU/L	Seroprotection≥10 IU/L	Antibody Level≥100 IU/L
Group I	1	18	17	11
Group II	2	19	16	13
Group III	0	19	19	14
Group IV	1	18	17	14

In our study however, vaccine A(combination vaccine) containing only 3µg of antigen per dose and vaccine B containing 10 µg of the antigen per dose produced a similar geometric mean concentration of the antibody in spite of the difference in the doses in both the schedules. This could perhaps suggest that the presence of pre-S component in vaccine A enhances the

BMI might influence the level of vaccine response. The low response to vaccination of overweight on vaccine could be due to the main distribution of the vaccine in fat not in muscle. This could hinder absorption and enable denaturation of the vaccine antigen by enzymatic action [4]. Another possible interpretation is damaged proliferation and function of the antibody-secreting plasma cells.

The lower immunogenicity of hepatitis B vaccine was linked with smoking and male gender. In smokers, smoking can affect cells and humoral mediated immune responses in humans and animals. Nicotine restrains the antibody-forming cell response by damaging antigen-mediated pathway in T cells and intracellular calcium response. In addition, a high prevalence of HBV markers has been reported in alcoholics. Persistent alcohol intake could restrain immune responses especially in female [5]. But some studies also reported that difference was undetected between alcohol consumption and seroprotection of hepatitis B vaccination [6]. In this study, the in apparent association within alcoholic subgroup may result

from the small sample size and drinking is not common in females.

Aside from those factors, patients with concomitant disease usually have a complicated and inconstant status due to diverse pathogenesis. Although some researchers found no association between comorbidity and seroprotection [7], comorbidity may be a significant element decreasing the efficacy of hepatitis B vaccine from this analysis and others [8], which could bring immunity disturbance. However, the detailed mechanisms between the poor response to hepatitis B vaccine and adults suffering from concomitant disease are still incompletely understood.

Asians and non-Asians as study location may also play an important role in seroprotection efficiency of hepatitis B vaccine in adults. The percentage of nonresponders after hepatitis B vaccine remarkably varied in ethnic groups, which may result from the difference of environmental surroundings, the mutation rate and genetic variability, especially at the human leucocyte antigen (HLA) genetic region. However, it is also hard to accurately locate the variation affecting the HBV response in the HLA locus as a result of the long-range linkage disequilibrium in this area [9]. It needs further studies to explore.

Conclusion

The present study demonstrates the immunological response to the two Hepatitis B vaccines with their antibody responses. Hence from the above findings it can be concluded that 0, 1, 6 schedule produces a higher antibody level than 0, 1, 2 schedule though both the schedules have good seroconversion and seroprotection rates with both the vaccines.

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