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# SEROLOGICAL CONVERSION AFTER HEPATITIS B VACCINATION IN EXPANDED IMMUNIZATION PROGRAMME

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## ABSTRACT

**Objective:** To observe the seroconversion rate after routine Hepatitis B immunization in pediatric infants. **Methods:** A prospective observational study was conducted in Department of Pediatrics, NSCB Medical College Jabalpur. 50 consecutive healthy infants were enrolled after taking informed consent from parents as per the inclusion criteria. The blood samples were collected from 40 full term infants after full hepatitis B immunization with 6, 10, 14 week schedule. The antibody (antiHBs) titer of ≥10 IU/L was considered to be protective against hepatitis B. The data was recorded, compiled and analyzed by using SPSS 20 and MS excel and appropriate statistical analysis was done. The critical level of significance was considered at P<<0.05. **Result:** Of the 40 babies analyzed in the study, 62.5% were males and 37.5% were females. 77.5 %( n=31) children were found to be protected against Hepatitis B. It was found that, 40% of the females were unprotected as compare to 12% males. **Conclusion:** The efficacy of Hepatitis B vaccination in national immunization program was found less than the desired response.

**KEYWORDS**: Hepatitis B, Vaccination, Seroconversion,

## INTRODUCTION

Human Hepatitis B viral infection is a major public health concern, because of the disease burden in some parts of the world, particularly Africa and Asia causing about 0.5 to 1.2 million deaths annually.[1] Hepatitis B disease severity usually differs from one individual to other and may also depend on the genotype of the infecting virus.[2] 80–90% infants (infected during the first year of life) and 30–50% of children (infected before the age of 6 years) are more prone to develop chronic hepatitis infections[3], as compare to incidence of chronic hepatitis of 1%-12% in older children and < 5% in teenagers or adults when they are infected. So, it is really important to prevent early childhood infection. Immunization with Hepatitis B vaccine (HBV) is the most effective means of preventing infection and its further consequences.[4]

Globally Hepatitis B vaccination has produced very convincing result in reducing disease burden.[5] As per WHO recommendations, most countries have included hepatitis B Vaccination in national expanded programme immunization (EPI) schedule. In Indian scenario Hepatitis B vaccine was included as a pilot project in immunization program in April 2002 and in national immunization schedule in 2009.

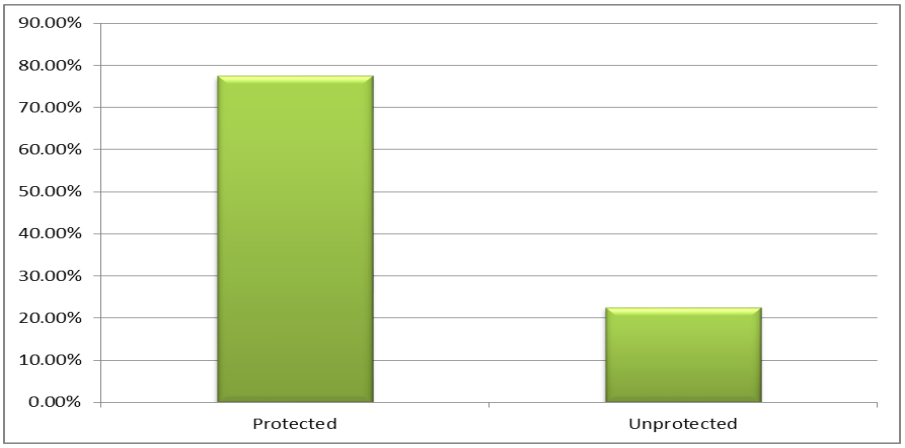
## METHODS

This prospective observational study was conducted in the tertiary care Government hospital, Department of Pediatrics, NSCB Medical College Jabalpur. 50 consecutive healthy infants (full term) attending the immunization OPD was included after taking inform consent from the parent. Infants were immunized at 6, 10, and 14 week of age with the 0.5 ml of hepatitis B vaccine injected at anterolateral aspect of thigh (I.M) as per National Immunization Programme. Those children who received birth dose of hepatitis vaccine and those who were born to mother with history of hepatitis B infection were excluded. Out of 50 subjects 10 babies were lost to follow up. Remaining 40 infants were followed upto 1 month after the last dose of vaccination and their blood sample was collected for antibody titer (antiHBs). antiHbS titer was tested using VRDL via MONOLISA Anti-HBs PLUS 192 test kit at Indian Council of Medical Research( ICMR), Jabalpur. A titer of ≥10 IU/L was considered to be protective against hepatitis B. All relevant information was entered in a predesigned data proforma sheet. All children had a baseline physical examination, including recording of anthropometric data such as weight, height and head circumference.

**Statistical Analysis:** Data was analyzed using SPSS version 20 and MS Excel. Descriptive statistics were used to describe the data, i.e. mean and standard deviation (SD) for quantitative variables, while frequency and percentages were used for qualitative. Quantitative variables were compared through independent samples'-test and qualitative variables were compared through the chi-square test between both the groups. A p-value <0.05 was considered as significant.

## OBSERVATION AND RESULT

Of the total 40 babies included in the study, 25( 62.5%) were males and15 (37.5%) were females. 31(77.5%) subjects among the study population were having antibody titer ≥ 10 IU/L, and was considered to be protective and 9(22.5%) were having antiHBs titer < 10 IU/L **[Graph 1, Table 1].** Out of the 25 male children, 22 (88%) shows anti HBs titer ≥ 10 IU/L and 3(12%) were unprotected, and out of 15 female children, 9(60%) were protected and 6(40%) were unprotected **[Table 1].**




**Graph1: Seroconversion status of study subjects after completed vaccination**

**Table 1: Gender wise protection status of the study subjects**

| Gender | Protection Status | | Total |
|---|---|---|---|
| | Protected | Unprotected | |
| **Male** | 22 (88%) | 3 (12%) | 25 |
| **Female** | 9 (60%) | 6 (40%) | 15 |
| **Total** | 31 (77.5%) | 9 (22.5%) | 40 |

## DISCUSSION

This study was a prospective longitudinal study conducted in the department of Pediatrics', NSCB medical collage Jabalpur. Out of 50 study subjects enrolled for the study, 10 were lost during follow up and the remaining 40 subjects completed follow up after vaccination. There were 25 male subjects and 15 female subjects who completed follow up which corresponds to 62.5% and 37.5% respectively. In a similar study conducted in Pakistan by **Mohammad afzal et al** to study the seroprotection after hepatitis B vaccination under expanded immunization programme ,out of the total 194 study group, 129 were male children and 65 were female, which corresponds to 66.4% male study subjects and 33.5% female study subjects.[6]

Total 40 infants completed vaccination under national immunization program and Anti HBs titer was tested after 1 month of last dose of hepatitis B vaccine. 31 (77.5%) subjects were having Anti HBs titer ≥10 IU/L and was considered to be protective and 9 (22.5%) were having Anti HBs titer <10 IU/L and was considered as unprotected. These results are better compare to a similar study conducted in Pakistan by **Mohammad afzal et al.** In this out of the total 194 subjects ,133 (68.5%) study group had anti HBs titre ≥ 10IU/L (considered as protective level) and 61 (31.5%) study group had anti HBs titre < 10 IU/L after hepatitis B vaccination under expanded immunization program.[6]

**Apuing Thomas et al** conducted a study to determine immune response of Ghanaian children to the hepatitis B antigen in the pentavalent (DPT-HB-Hib) vaccine. Out of 424 children who completed vaccination with the 6, 10, 14 week schedule, 340 children (80.18%) had anti HBs titer ≥ 10 IU/L ( protective level) and 84 children developed anti HBs titer < 10 IU/L which was (considered unprotected). The percentage of seroprotective status in this study was comparable with our study.**[7]**

In our study, out of the total 25 male children, 22 (88%) shows anti HBs titer ≥ 10 IU/L and 3(12%) had anti HBs titer <10 IU/L and out of 15 female infants 9 (60%) shows anti HBs titre ≥ 10 IU/L and 6 (40%) were having anti HBs titer <10 IU/l. In a similar study conducted in Pakistan by **Mohammad afzal et al,** out of the total 129 male infants 95 (73.6%) developed protective titre and 34 (26.4%) did not developed protective titer. Out of the total 65 female study group 38 (58.5%) developed protective titer and 27 (41.5%) did not developed protective titer.[6]

So in both the study the female protective seroconversion was less compared to the male protective seroconversion. Although female infants were less in the study but there is no plausible explanation for this observation found in literature.

In a study conducted by **Apuing Thomas et al** to determine the immune response of Ghanaian children to the hepatitis B antigen in the pentavalent (DPT-HB-Hib) vaccine ,the mean anti-HBs titers of the males was slightly higher (202.381mIU/ml) compared to the mean anti-HBs titre of females (188.641 mIU/ml). Though a number of studies have shown female seroconversion rate to be higher than male seroconversion rate, no reasons have yet been found as to why this difference in seroconversion is observed.[7]

Dosing schedule is an important factor in the development of an antibody response and titer levels. According to the Advisory Committee on Immunization Practices (ACIP) of America, there should be a minimum gap of 8 weeks between the second and third doses and at least 16 weeks between the first and third doses of the HB vaccination.**[8]** To minimize frequent visits and improve compliance, the dosing schedule has been negotiated in the EPI to 6, 10 and 14 weeks. Although some studies have shown this schedule to be effective, the geometric mean titers (GMT) of anti-HBs antibodies achieved was lower than that achieved by the standard WHO schedule.[9]

**Ajay Kumar Jain** from India has reported a study using an alternative schedule of 0, 6 weeks and 9 months. He has reported it to be comparable to the standard WHO schedule of 0, 1, 6 months in regards to seroprotection and GMT levels achieved.[10]

It has been reported that the 0 dose (birth dose) of the HB vaccine alone is 70% - 95% effective as post-exposure prophylaxis in preventing perinatal HBV transmission without giving HB immunoglobulins. This may also be a factor contributing to lower rates of seroprotection in our study as we included only those children who missed the birth dose. Possible causes for poor seroconversion are poor injection technique i.e. subcutaneous injection or indradermal injection, injection in gluteal region, poor measurement of dose. Poor vaccine due to faulty cold chain technique is also a reason for poor seroconversion since hepatitis B vaccine is damaged by freezing more rapidly than other vaccines

## CONCLUSION

The efficacy of Hepatitis B vaccine in government program was found less than the desired response.[5]

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