

Hepatitis B Vaccine in Saudi Children

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ABSTRACT

The aim of our study is to know the protective efficacy and immunogenicity of Engerix B (Recombinant Deoxyribonucleic acid-Yeast derived Hepatitis B vaccine). In 1987, 113 seronegative children were vaccinated intramuscularly in the quadriceps region with 1.0 ml of Engerix B. Serum samples were collected at month 1,2,7,12 and tested for Anti HBs levels. The seroconversion rates for HBs Antibodies were 28% at month 1, 79% at month 2, 94% at month 7 and 92% at month 12. No significant adverse reactions were noticed.

Hepatitis B virus (HBV), a common and occasionally fatal infectious agent, identified in 1967,¹ causes acute hepatitis and chronic liver disease. In 1971, an HBV vaccine¹ was proposed. A recombinant deoxyribonucleic acid (DNA) yeast derived hepatitis B vaccine (Engerix B) was prepared and introduced.² We, herein, report our experience with the yeast-derived vaccine (Engerix B) in 113 children. We studied the safety and the efficiency of the above mentioned vaccine.

METHODS

A total of 113 children were included in our vaccination study. All the 113 children were screened for HBV markers before the study. They were all HBs antigen, anti HBs and anti HBe negative. Their age ranged from 2 to 10 years, and the mean was 4.7 years. Fifty four were males and 59 females. They were all given 1 ml of Engerix B, intramuscularly in the quadriceps region on a zero, one and 6 months after the first dose of the vaccine. Serum samples were collected at months 1,2,7 and 12. All samples were tested for HBsAG and anti HBs.

In our study HBs Ag and anti HBs were done using radioimmuno assay (RIA). The kits [AUSRIA (R) for HBs

Ag and AUSAB (R) for anti HBs] were obtained from Abbott Laboratories Diagnostic Division, USA.

For side effects, the parents of the children in our study were asked to report to the paediatric emergency room (PER) whenever any side effect appeared within three days. The parents were supplied with sheets to be filled by the PER doctor. In the PER, the child underwent a complete physical examination to rule out other causes for the complication. Temperatures were taken by the thermometer rectally. The PER - filled sheets were collected, and analyzed by us.

RESULTS

Seroconversion means that the anti HBs level is more than 1u/litre.³ Seroconversion rates after the first and second vaccine doses were 28% and 79%, respectively. One month after the third dose, ie month 7 samples, 94% of the children had seroconversion. The mean antibody concentration is mentioned in table 1.

Table 1
The mean anti HBs concentrations after vaccination

Month	Mean Anti HBs Concentration
1	8 IU/l
2	41 IU/l
7	1034 IU/l
12	322 IU/l

As seen in that table the mean antibody concentration rise from 8 IU/l at month 1 to 1034 IU/liter at month 7. The mean antibody concentration decreased to 322IU/liter at 12.

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Sheets for post vaccination symptoms for 98 patients out of 113 were completed. The most common complication was mild erythema (9.8%) and fever (24 patients ie 21%). The reaction gets less with more vaccinations.

DISCUSSION

Viral hepatitis is a disease of major public health significance. In the United States of America, the incidence rate increased from 6.9/100,000 in 1978 to 11.5/100,000 in 1985.⁵ Because of life style, occupation or ethnicity, certain groups have a much higher risk of hepatitis B infection than the general population. These groups include health care workers, persons from areas in which HBV infection is endemic, homosexuals, heterosexual persons with multiple sex partners, intravenous drug users, household contacts of HBV carriers, children of carrier mothers and clients and staff of programs for the mentally handicapped.⁶ In Saudi Arabia, several studies in various areas of the Kingdom were conducted. Fathallah et al⁷ studied the prevalence of hepatitis B in Eastern Province of Saudi Arabia; of 24690 people, 2418 (9.8%) were found to be positive for HBsAg. Other studies showed that the prevalence rates varied from 6.31% to 10.6% in the general population.^{8,9} Reasons for these variations include differences in the sensitivity of the tests used to detect HBsAg, small population samples and variations related to age, sex and social backgrounds. For example, two independent studies from Jeddah reported prevalence rates of HBsAg positivity in the female population that ranged from 2.3% to 5.4%.^{9,10} Associated with this high level of HBsAg in Saudi Arabia is a high incidence of liver cirrhosis and primary liver cancer. Due to the high prevalence rate in Saudi Arabia, Hepatitis B vaccine was included in the routine vaccination of every child.

The study was focused to find out the effectiveness of this vaccine and its side effect ie. its safety. The side effects of only mild rash and fever which were self-limited proved

the safety of the vaccine. The effectiveness of the vaccine was proved by 2 parameters. First was the high percentage of conversion rate and the second, the high level of the HBs antibodies. The results regarding the percentage of converters and the antibody level were comparable to other studies.¹¹ In view of the results and the high incidence of hepatitis B in Saudi Arabia, we strongly recommend the routine vaccination of all children residing in Saudi Arabia.

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