

Comparative Immunogenicity of Two Recombinant Hepatitis B Vaccines Given to Infants

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Three hundred healthy infants vaccinated with 10µg dose of recombinant hepatitis B Smith Kline vaccine at 2, 4 & 6 months of age were randomly enrolled in the study. Blood samples were taken at 9 and 18 months of age, sera were tested for HBs Ag, antibody to hepatitis B core antigen and quantitatively for antibody to hepatitis B surface antigen (anti-HBs) using commercial enzyme immunoassay kits. The results were compared with that of our previous studies using a 2.5 µg dose of recombinant hepatitis B Merck Sharp vaccine using three different dosing schedules (2, 4, 6 M, 0, 2, 6 M and 2.4, 9 M) Smith Kline vaccine gave 98.3% seroprotection rate, 95.2% of infants had good or excellent response with geometric mean anti HBs titers equal to 352.4 mIU/ml. At 18 months, the seroprotection dropped to 96% good or excellent response was found in 78% and the geometric mean anti HBs titers was 98.2 mIU/ml. The seroprotection rate and the anti HBs geometric mean titers in infants vaccinated with the Smith Kline vaccine were significantly higher than those vaccinated with the Merck Sharp vaccine in two schedules (2, 4, 6 and 0, 2, 6 M) and they were similar for schedule 2, 4, 9 M at 9 months, at 18 months, the drop in the anti HBS titers was significantly greater with all Merck Sharp vaccine schedules.

Selective hepatitis B vaccination strategies have failed to adequately control HBV infection or their sequelae. Several advisory groups have recommended that the only practical means to interrupt HBV transmission is to vaccinate all individuals before their exposure through routine immunization. Also, there is a particular need to protect infants because of their predilection to develop chronic HBV infection.

Consequently, the Centers for Disease Control and Prevention, Advisory Committee for immunization practices, the American Academy of Pediatrics and the World Health Organization expanded program of immunization (EPI) have recommended the integration of hepatitis B vaccine into the EPI in areas where HBV infection is endemic and morbidity is high⁽¹⁻⁵⁾ Based on this, the Egyptian Ministry of Health & population (MOH) began in July 1993 to

include the recombinant hepatitis B vaccine in the EPI for Egyptian infants. In an effort to maximize compliance, a pediatric dose 2.5 µg of recombivax, HB (Merck) was given at 2,4,6,M of age along with diphtheria, tetanus and pertussis (DPT) vaccinations. The immunogenicity of this vaccine using three dosing schedules was studied in a previous work⁽⁶⁻⁷⁾. We observed a direct correlation between the peak anti HBS titers achieved after the third dose and those measured at 18 Months of age however the percentage in the excellent and good response categories decreased significantly. Since Egypt shifted after 1994 to the use of Smith Kline Beecham vaccine (10 µg/dose) in its EPI.

Our objective was to compare the immunogenicity of these two vaccines particularly the response remaining at 18 M.