Evaluation of the Effectiveness of Hepatitis B Vaccine, as a Preventive Measure, in Children, in Egypt, in Africa.

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Abstract: The prevalence of Hepatitis B virus (HBV) worldwide and in Egypt is considered one of the highest prevalence rates among viruses. Since 15 years, Vaccine against HBV was introduced, as an obligatory vaccine, in Egypt, to control the prevalence of HBV. The aim of this study is to evaluate the effectiveness of HBV vaccine as a preventive measure in infection, in children, comparing the prevalence of hepatitis B virus in vaccinated and unvaccinated children. A total number of 7500 blood samples were collected from children, below the age of 16, from different localities, in Egypt, either vaccinated (3700) or unvaccinated (3800). For full vaccination, children were vaccinated at 2, 4, 6 and 18 months age followed by booster doses annually up to age 6 years through intra muscular injection of RECOMBIVAX HB® Hepatitis B Vaccine (Recombinant). The samples were tested for the presence or absence of HBsAb and HBsAg using 4th generation ELISA technique. Comparing the results, a highly significant decrease in the incidence of HBV infection, in the vaccinated group was recorded indicating the effectiveness of the vaccine; it was 100% effective in four governorates (zero cases) and was effective in the rest governorates where only 1 out of 248, 1 out of 480 and 3 out of 670 were positive HBV. In contrast, a higher number of infected cases (up to 56 cases) were present in the unvaccinated control group.

Key words: Hepatitis B virus, Hepatitis B vaccine, Egypt.

INTRODUCTION

The prevalence of Hepatitis B virus (HBV) worldwide and in Egypt is considered one of the highest prevalence rates among viruses. Prevalence rates of 0.71%, 0.89% and 13.3% were reported in India, Middle East Asia and Turkey, respectively. (Sandesh K et al., 2006; Yakaryilmaz Fet al., 2006) In Egypt, the prevalence rates reported to be about 14.3–27.1% (el-Sayed NM et al., 1996; Hindy AM Met al., 1995). Since 15 years, Vaccine against HBV was introduced, as an obligatory vaccine, in Egypt, to control the prevalence of HBV.

Many countries all over the world made studies to measure the effectiveness of the hepatitis B vaccine and to measure the reduction rates in the HBV infection and/or hepatitis B surface antigen carriage. Two studies were performed in South America, one was in Colombia (a reduction of 60–75% in the prevalence of HBV infection and hepatitis B surface antigen carriage), (De la Hoz F et al., 2008) the second study was in South Brazil (The booster regimen was effective at reducing the percentage of non-responders.) (Petry A, Kupek EJ 2006)

Three studies in Asia, two in Taiwan and one in Mongolia, showed predominant disappearance rate and also a cost-saving primary preventive strategy and reduction in the rate of chronic carriage in the immunized generation. (Kao JT et al., 2009; Hung HF, Chen TH, 2009; Edstam JS, et al., 2002)

In Africa, Ivory Coast appears that HBV vaccine is highly effective, where it has already had a positive impact in reducing HBsAg carriage among children. (Magoni M et al., 2009)

In Europe, in Italy the findings indicate that a hepatitis B vaccine administered at birth in association with HBIG provides immediate and long-term protection against HBV in children. (Mele A et al. 2001) While in Netherlands the study showed that the incidence of HBV notifications in children born after the introduction of targeted childhood HBV vaccinations is lower compared to the incidence in children born before the start of this vaccination program. (Hontelez IA et al., 2009).

The aim of this study is to evaluate the effectiveness of HBV vaccine as a preventive measure in infection, in children, comparing the prevalence of hepatitis B virus of vaccinated and unvaccinated children.
MATERIALS AND METHODS

Blood samples: A total number of 7500 blood samples were collected from children, below the age of 16, from different localities, and classified into test fully vaccinated group (3700) or control unvaccinated group (3800). They were centrifuged for 3 minutes to separate blood cells from serum and the serum was examined for the presence of HBsAg and HBsAb in The Central Health Laboratories in The Ministry of Health in Egypt, using ELISA 4th generation method.

Vaccination: RECOMBIVAX HB® Hepatitis B Vaccine (Recombinant), a non-infectious subunit viral vaccine derived from hepatitis B surface antigen (HBsAg) produced in yeast cells. Intramuscular IM injection of 5 mcg/0.5 mL of the vaccine (HBsAg) at 2, 4, 6 and 18 months and annual booster doses within 5--6 years.

HBsAg kits: are the product of Dade Behring Enzygnost® HBsAg 5.0 with diagnostic specificity 99.83--99.88% and 100% sensitivity, according to the manufacturer.

HBsAb kits: are the product of ARCHITECT Anti-HBs Reagent Kits; a chemiluminescent microparticles (a two steps immunoassay for the quantitative determination of antibody to hepatitis B surface antigen –anti HBs- present in human serum and plasma, often used to monitor the success of hepatitis B vaccination), with overall specificity 99.67% and overall sensitivity 97.54%, according to the manufacturer.

Instruments: Washers, Photometers, Micro pipettes and ARCHITECT System.

Statistical method: Crosstab / Chi-Square test.

Results:
The overall effect was highly significant where a 10 fold decrease in HBV infection was recorded in the vaccinated group. However, the decrease in the infection rates varied in different governorates from 0--0.45% in test group while in the control group it was from 0.61--2.34%.

The vaccine was 100% effective in four governorates where there were no any infected persons recorded. While the effect was significant in the rest governorates where only 1 out of 248, 1 out of 480 and 3 out of 670 infected cases were recorded. In contrast, a higher number of infected cases (up to 56 cases) were present in the unvaccinated control group.

Discussion:
Many countries all over the world made studies to measure the effectiveness of the hepatitis B vaccine. A reduction in the prevalence of HBV infection and hepatitis B surface antigen carriage, predominant disappearance rate, cost-saving primary preventive strategy, reduction in the rate of chronic carriage in the immunized generation, long-term protection against HBV in children were reported in Colombia, South Brazil, Taiwan, Mongolia, Ivory Coast, and Netherlands.

To our knowledge, no local study was performed, in Egypt, to evaluate the effectiveness of Hepatitis B virus (HBV) vaccine. In the present study, the effectiveness of HBV vaccine was evaluated in two groups of children, of age below 16 years and from different localities. The samples taken were from seven different governorates in Egypt. A control group of 3800 unvaccinated children were compared to a test group of 3700 vaccinated candidates. The test group was fully vaccinated through intramuscular injection of 0.5 mL of RECOMBIVAX HB® Hepatitis B Vaccine (Recombinant) containing 5 mcg/0.5 mL of HBsAg at 2, 4, 6 and 18 months of age followed by booster doses given annually up to the age 5--6 years. The presence or absence of Hepatitis B surface antibody (HBsAb) and Hepatitis B surface antigens (HBsAg), in all blood samples, was carried out using ELISA technique. The Results obtained were analyzed and subjected to statistical analysis using Crosstab / Chi-Square.

Conclusion:
The vaccine was 100% effective in four governorates (zero cases) and was effective in the rest governorates where only 1 out of 248, 1 out of 480 and 3 out of 670 were positive HBV. In contrast, a higher number of infected cases (up to 56 cases) were present in the unvaccinated control group.

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