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HBsAB Measurement after Hepatitis B Vaccination and Introduction of Non-Responder Persons

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Abstract: Hepatitis is a general term meaning inflammation of the liver and can be caused by a variety of different viruses such as hepatitis A, B, C, D and E. Infection with HBV occurs worldwide and the prevalence rate is different in various areas. HBV causes one million deaths per annum. Hepatitis B vaccines have been used for reducing prevalence in many countries. The aim of this research, is estimating efficacy of HBV Vaccine via HbsAb measurement in students who will be health-care workers in the future and presenting of non-responder persons. In this study, blood samples of 288 students, who were vaccinated compactly, 1-6 month after third vaccination, were collected. After serum preparation, HbsAb were estimated by ELISA method. The antibody titer greater than 10 IU seems to be protective after the injection of Hepatitis B vaccine .In the HbsAb negative persons, vaccination was repeated. The results show the presence of HbsAb more than 10 IU in 250 individuals. Therefore, the efficacy of vaccine in students is 86.8%. The average HbsAb production is 447.3 IU with 23.7 standard derivations. The lower limit was 0 and upper limit was 966 units. 25% of individuals have HbsAb less than 239, 25% of them 239-435, 25% of persons 435-653.7 and 25% of students more than 653-7 IU L^{-1}. Also, in the second vaccination, 30 people had HbsAb more than 10 IU L^{-1}. But 8 people (2.77%) were HbsAb negative or non-responder. The vaccine efficacy among students was same as that the other studies who reported 81-99%. In the mention of students who have HbsAb less than 10 IU L^{-1}, Its better, storage conditions and the method of injecting vaccine and efficiency of available vaccine in Iran were studied. Also, study of serologic markers of HBV (HbcAb, HbeAg and HBeAb) for negative people is recommended.

Key words: Hepatitis B, HBsAb, ELISA, vaccination, serum, injection

INTRODUCTION

Hepatitis B Virus (HBV) is a hepadnavirus which can cause systemic infection and hepatocellular damage in humans. Infection is acquired through contact with the blood of a person carrying HBV. The passive administration of anti-HBV surface Antigen (HBsAg) antibody protects against a subsequent infection and vaccination with HbsAg has proved an effective means of protection against HBV infection (Cristina *et al*., 1998).

Hepatitis B virus, one of several Hepatitis viruses, accounts for a large portion of the disease burden world-wide with almost 350 million chronic carriers of the disease (Goldsmith *et al*., 1989). HBV is the greatest threat of infe-ction for Healthcare Workers (HCW) (Luiz *et al*., 2005).

HBV infects the liver and causes a variety of complications, including cancer. There are three main modes of transmission: Through a mixing of blood products, through sexual contact and perinatally, from mother to fetus (Mahoney *et al*., 1999). Also the risk of contacting with hepatitis B by healthcare personnel is greater than that of the general adult population, among those who do not work in healthcare institutions (Luiz *et al*., 2005).

Mass vaccination against HBV has been implemented in Iran since 1993(Zali *et al*., 2005). Hepatitis B vaccine prevents hepatitis B disease and its serious complications like hepatocellular carcinoma (Mahoney *et al*., 1999). Therefore, this is the first anti-cancer vaccine. Medical, scientific and public health communities strongly suggest using hepatitis B vaccine as a safe and effective method to prevent disease and death. Scientific data show that hepatitis B vaccines are very safe for infants, children and adults (CDC, 1999).

The discovery of HBV vaccines and the results obtained from their introduction had a great importance for medical practice. Also providing immunity against

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HBV infection, these vaccines indirectly protect against hepatocarcinoma (CDC, 1999). During the last few years, the American Health Inspection Service has demonstrated a decrease in the incidence of hepatitis B in HCW, probably due to the use of vaccines and recommended safety measures. Current HBV vaccine is three doses over about 8 months (Beasley *et al*., 1988).

Although a very effective vaccine exists for HBV, researchers are constantly looking for new possibilities to increase its efficiency and to create new therapeutic vaccines.

Post-vaccination testing should be completed 1-2 months after the third vaccine dose for results to be meaningful. A protective antibody response is 10 or more milliinternational units (> = 10 mIUmL^{-1}).

The objectives of this study, were to determine efficacy of HBV Vaccine via HbsAb measurement in students who will be health-care workers in the future and presenting of non-responder persons and also comparison with other similar studies. This study provides insight into the potential for future studies in other parts of Iran and neighbor countries for prevention and remark the efficacy of HbsAb measurement for HCW, because in the most cases HbsAb was not examined. But after routine vaccination of infants, children, adolescents, or adults post-vaccination testing for adequate antibody response is not necessary (CDC, 1999).

MATERIALS AND METHODS

This cross sectional study, was done in Bonab city, located at a distance of 130 km from Tabriz (NorthWest of Iran) for 288 nursing and midwifery students(all female) who were vaccinated compactly from March 2005 to February 2006 (In the mention of students population and p = 0.05).

The blood transfusion record, previous STI and phlebotomy of these subjects were recorded. Then, 10 mL of venous blood was taken from each case. Blood samples were centrifuged and did tests for HBsAg, HBcAb and HbsAb, by Enzyme Immunoassay (EIA).The following materials were used in the study: The first Detection of HBsAg and HbsAb were done by Diaplus and the further confirmation test was performed by Diaporo. Instrument was provided by Awareness Company (USA). All testing was performed according to the protocols supplied by the manufacturers. All positive sera for HBsAg or HBcAb were tested again for these markers and also for HBeAg and HBeAb. Negative and positive controls were done for all tests and all of sera were rechecked. The histories of probable causes of infections were investigated.

Also the prevalence of HBV was determined. Besides, these values were compared with the estimated prevalence of HBV infections in the normal population of Iran (1.7 %). The antibody titer greater than 10 IU seems to be protective after the injection of Hepatitis B vaccine. In the HbsAb negative persons, vaccination was repeated and after 6 months HbsAb was rechecked and Non-responders were determined.

Then, the results were analyzed by SPSS, version 13, software package and chi-square tests for categorical variables. P values less than 0.05 were considered statistically significant.

RESULTS AND DISCUSSION

The mean age of cases was 21.2 year (ranged from 22-24). Prevalence rate of Hepatitis B surface Antigen positive was 1.04 %. That was about 1.5 times less than other parts of Iran ($p<0.05$) (Alavian *et al*., 2002) because our cases were high risk persons. Two hundred and fifty people (86.8%) had HbsAb more than 10 mIU mL^{-1}. It seems to be no difference between the HBsAb positivity rates with Luiz *et al.* (2005) study. The mean range of Ab was 447.3 ± 8.7. The minimum was 0 and the maximum was 966 mIU mL^{-1}. 25% of individuals have HbsAb less than 239, 25% of them 239-435, 25% of persons 435-653.7 and 25% of students more than 653-7 IU L^{-1}. After second vaccination period, 30 people had HbsAb more than 10 mIU mL^{-1}, but 8 person had HbsAb negative and known real non-responder (2.77%).

Total 3 persons had positive HBsAg but all of them had negative HBcAb. Besides all of HBsAg positive cases had HbeAb positive and HBeAg negative. HbcAb was negative in all of people. Therefore, they had past infections. About risk factors, there was no evidence of previous hepatic disease, phlebotomy, the history of intravenous drug use or multiple sexual partnerships. But, all of positive cases had previous vaginal infections.

Health care workers are at particular risk of developing the infection. In a study, from Egypt combined HBsAg and HBsAb frequencies by occupational group were: Nonprofessional staff 60% dentists 32%, graduate nurses 33%, physicians 29% and student nurses 26% (Goldsmith *et al*., 1989). In a similar study performed on the health workers of the National Iranian Oil Company (NIOC), 23% had evidence of exposure to HBV and 1.8% had a positive HbsAg but there is no significant difference with our study ($p>0.05$). Also in that study, the laboratory personnel were found to be at higher risk than other health workers (Hamidi *et al*., 2000).

The prevalence of HBV and its patterns of transmission vary throughout regions of the world, with about 45% of the world's population living in areas of high endimicity, defined as areas where 8% of the population has a positive test for the HBsAg. Also, another 43% of the world's population lives in areas of moderate endimicity like Iran (i.e., 2-7% of the population is HbsAg positive). Only 12% of the world's population lives in areas of low endimicity (i.e., <2% of the population is HbsAg positive) (CDC, 1999).

Prenatal exposure is a well established risk factor for HBV infection (Ahmed *et al*., 1998). However, the role of the sexual route in the transmission of hepatitis B has remained controversial (Alavian *et al*., 2002). There are few studies carried out to evaluate these high risk groups in Iran. High risk factors for the development of HBV infection include intravenous drug abuse, male homosexuality, sexual promiscuity, vagrancy, alcoholism and/or immigration from hyper endemic regions.

It is estimated that over 35% of Iranians have been exposed to the HBV and about 3% are chronic carriers, ranging from 1.7% in Fars Province to over 5% in Sistan and Balouchestan (Malekzadeh *et al*., 1997). Our results was similar to fars but there was significant difference with Sistan ($p<0.05$), that can be related to hygienic conditions.

Some studies in neighbor countries showed high prevalence of HBV, HCV (Shamim *et al*., 2002). The other study demonstrated the presence of HBsAg in 934 patients (10.4%), (Dray *et al*., 2005). But in our study, the prevalence rate of Hepatitis B surface Antigen positive was 1.04% and had a significant difference with Dray x study ($p<0.05$). Vaccinated people in the first period were 86.8% and also similar to Jefferson *et al*. (2003) and Walter *et al*. (2001) but there was no significant correlation ($p>0.05$) between prevalence rate and educational course. None of persons remarked the history of previous diseases or using intravenous drugs. In the mention of HbeAb, HbeAg and HBcAb results, they had past infection. Risk factors, including bloody fights, tattoo, unprotected anal or vaginal sex, also may have been the cause of HBV infection.

Therefore, in the mention of results, it is necessary that HbsAb was examined for all Health care workers after vaccination.

CONCLUSION

Health care center is a source of viral transmission. There are many reports of HBV infections acquired through infected surgeons, dentists, nurses, the using equipment and needle stick injuries (Goldsmith *et al*., 1989). Some medical specialties are associated with greater risk of transmission of HBV: Dentistry, nurses, obstetrics and gynecology, general surgery, orthopedic surgery, neurosurgery, cardiology, gastroenterology and nephrology (Dray *et al*., 2005). Furthermore, household contacts of patients infected with HBV and high risk groups should also be vaccinated (Beasley, 1988).

It is better that all health care workers must be tested for HBV, HCV, HIV and other blood borne diseases. Also, the efficiency of vaccine kind and HbsAb must be determined for prevention of infections in the future because this study suggests that conditions exist for potential non-responders.

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