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STUDY OF IMMUNE RESPONSE AFTER HEPATITIS B VACCINATION IN DOCTORS

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Abstract

Background: Aim of our study was to evaluate the immune response after hepatitis B vaccination and to determine the duration of protective levels of HBsAb titre in doctors. From our study we concluded that hepatitis-B vaccine gives protection for more than 10 years after primary vaccination and booster dose of Hepatitis-B vaccine is not required in immunocompetent persons after primary vaccination.

Method: In this study total 100 doctors of our institution were included who were vaccinated against hepatitis B. Data were obtained regarding age, sex, weight, height, BMI and duration of vaccination period. Doctors with no prior vaccination or incomplete vaccination or those who took booster vaccination were excluded from this study.

Results: The mean titre was observed to be higher in 30 to 34 years of age group (584.42±4.03.21) as compared to age group of less than 25 and greater than 40 years. Moreover, males were observed to have higher mean titre as compared to females. (411.64± 417.27 vs 333.66± 431.49) but not statistically significant. Similar with age and sex, duration of vaccination status was also not statistically significant. When we compared the duration of vaccination status with age group , mean titre was more in ≥30 years of age group as compared to <30 years (younger age groups) but statistically significant relation was observed only with the 1 month to <5 years of duration.

Conclusion: From our study we concluded that hepatitis-B vaccinegives protection for more than 10 years after primary vaccination and booster dose of Hepatitis-B vaccine is not required inimmuno-competent persons after primary vaccination.

Keywords: HbsAg titre , HepatitsB vaccine , seroprotection rate.

Introduction

Hepatitis B virus infectionis a general public health problem and more than 400 million males and females are chronically infected in India[1]. Infection due to Hepatitis B virus causes liver disease rangingfrom acute viral hepatitis to cirrhosis and hepatocellular carcinoma (HCC) [2].

Aim of primary prevention by vaccination is toprevent the hepatitis B virus infection[3].Doctors are highly susceptible to hepatitis B virus infection during surgical procedures and exposure to infectious body fluids[4,5]. Recombinant DNA Vaccine has been available since 1987[6] for intramuscular administration at 0,1,6 month to produce 85-90% sero-protection rate[7,8].

One to two months after the primary vaccination if the titre of HBsAb is >100 mIU/ml, it is considered to be an adequate response .If its between 10-100 mIU/ml, these are known as hypo-responders and the titre <10 mIU/ml, are non-responders. Thus, HBsAb titre >10mIU/ml is a marker of sustained immunity[9]. Seroprotection persists for 10-15 years so that booster vaccination may not be required[10] but booster dose are recommended only in certain circumstances such as patients on haemodialysis and immunocompromised persons (e.g., HIV-infected persons, haemopoietic stem-cell transplant recipients, and persons receiving chemotherapy). The need for booster doses should be assessed by annually testing HBsAb levels. A booster dose should be administered only when HBsAb levels are <10 mIU/mL.[11]

Material and Methods

It was a single centre observational study conducted on 100 doctors of Govt. Medical college, kota. They were also vaccinated against hepatitis B. Ethical clearance was obtained from the institutional ethical committee. Informed consent was obtained from doctors who volunteered to be a subject for this study. Data was obtained from Hepatitis B vaccinated doctors regarding age, sex, weight, height, BMI and duration of vaccination

period. Doctors with no vaccination history or incomplete vaccination or no booster vaccination were excluded from this study. We collected one intravenous blood sample (2.5 ml) with all aseptic precautions from all the vaccinated doctors who had been vaccinated for more than 10 years.

Blood samples were analyzed for Hepatitis B surface antibody (HBsAb) level by ELFA (Enzyme linked Fluorescent Assay) so as to determine the level of HBsAb levels in doctors. If HBsAb titre came out to be of low level, concerned doctor was informed and advised for booster vaccination so as to achieve protective HBsAb levels.

Statistical Analysis

Statistical analysis was performed with the SPSS, trial version 20 for Windows statistical software package (SPSS inc., Chicago, il, USA). The Categorical data were presented as numbers (percent) and were compared among groups using Chi square test. Group were compared for demographic data and were presented as mean and standard deviation and compared using student t-test . Relationship between variables in the patient group was assessed by using Pearson's correlation coefficient. Probability P value <0.05 was considered statistically significant.

Results

Table 1: Descriptive Statistics of the variables

Variable	
Age (Years)mean ±SD (Range)	31.78±7.42(21 to 57)
Female : Male	15:85
duration of vaccination	6.94±4.96(0 to 17)
1 months to 5 years	46
titre	399.94±418.15 (0.35 to 1000) Median (154.35)
>5 years to <10 year	17
≥10 years	37
BMI(kg/Mt^2)	24.32±3.37 (17.51 to 36.42)

All 100 doctors involved in the study were in the age group of 21- 57 years. The mean age of the doctors was 37.78 ± 7.42 years. Out of 100 participants 85 were male and 15 females. Majority of them were in the age group of 25 to 29 years. Only 13 individuals belonged to age more than 40 years. Duration of vaccination in maximum doctors was 1month-5 years. Moreover,mean BMI in the study group was 24.32 ± 3.37.

Table 2: Association of Anti Hbs Titre (mIu/mL) with the various variables

Anti Hbs Titre (mIu/mL)				
	N	Mean	SD	P Value
Total	100	399.94	418.15	
Age Groups				
<25	10	421.02	425.87	0.065NS
25 to 29	36	296.65	401.47	
30 to 34	26	584.42	403.21	
35 to 39	15	277.20	394.05	
>40	13	442.44	435.45	
Sex				
F	15	333.66	431.49	0.5NS
M	85	411.64	417.27	
1 months to 5 years	46	459.80	430.63	0.09NS
5 years to <10 year	17	402.76	472.90	
≥10 years	37	324.23	373.04	
1 months to 5 years				
<30	26	321.16	386.74	0.01S
>=30	20	640.03	426.51	
>5 years to <10 year				
<30	9	351.11	487.02	0.64NS
>=30	8	460.86	482.5	
≥10 years				
<30	11	307.22	418.06	0.86NS
>=30	26	331.43	360.97	
BMI(Kg/m2)				
18.5 to 22.9(Normal)	35	426.39	418.35	0.98NS
23 to 24.9(overweight)	26	376.19	418.32	
25 to 29.9(obesity 1)	34	389.32	439.4	
30 to34.9(Obesity ll)	4	447.46	425.25	
>35 (Morbid obesity)	1	263.11		

Table 3: Correlation between Antibody titre with duration of vaccination status and anthropometric variables

Correlations						
		Age	Weight	Height	BMI	duration of vaccination
titre	Pearson Correlation	.075	-.048	-.016	-.047	-.210*
	Sig. (2-tailed)	.456	.637	.873	.642	.036
	N	100	100	100	100	100

*. Correlation is significant at the 0.05 level (2-tailed).

No significant correlation was observed between Antibody titres with anthropometric variables except with duration of vaccination status. Significant negative poor correlation exist with duration of vaccination (r=-210,P=0.036S)

No significant Association of Anti Hbs titre (mIu/mL) was observed with the various variables like age groups, sex ; although the mean titre was observed to be higher in 30 to 34 years of age group(584.42±4.03.21) as compared to less than 25 years and more than 40 years of age groups. Males were observed to have higher mean titre as compared to females. (411.64± 417.27 vs 333.66± 431.49) but not statistically significant. Similar with age and sex, duration of vaccination status was also not statistically significant.

When we compared the duration of vaccination status with age group , mean titre was more in ≥30 years of age group as compared to <30 years (younger age groups) but statistically significant relation was observed only with the 1 month - 5 years of duration of vaccination . Body mass index also had no statistically significant impact on antibody titre.

Discussion

Hepatitis B is the most infectious out of three important HBV, HCV and HIV Infection. Hepatitis B vaccination induces protective level of antibody after complete course of vaccination.

The Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), and American College of Obstetricians and Gynecologists (ACOG) recommend this vaccine. Increased risk of HBVinfection includes following people- Healthcare workers, sexually active people, intravenous drug users,people with end stage renal disease,staff and residents of institutions, sex partners of people with chronic HBV infection, travelers to regions with high or intermediate rates of HBV infection.[11]

Seroconversion rate of Hepatitis B vaccine is about 85-90%.[12].A k Jain et al found seroconversion rate of 98.45%. Our study was carried out in doctors and seoconversion rate from our study was 92.45%. Similar studies have been done in past in infants, adolescents, medical professionals, public safety personnel and homosexuals. In our study the serologic immune status of vaccinated doctors was assessed.

Most of the studies have showed 90% reduction of the anti-HBs level within first 2years after that slower rate of decline was observed[13,14]. In the present study 100 mIU/L anti–HBs level was adequate antibody titre. Although most of the studies have reported 10 mIU/L as a minimum value for adequate anti –HBs level ,The US Public Health Service Advisory Committee On Immunization Practice (ACPI) recommendation issued in 1987 defined the protective level of anti HBs-Ab as greater than or equal to 10 mIU/ml, measured 1-2 months after completion of hepatitis b vaccine[15,16].An Indian study by Kunal Das showed that among seroprotected individuals there were 32.4% hyporesponders (HBsAb level 10 - 99 mIU/ml) and 52.9% were responders (anti HBsAb >100mIU/ml)[17]. There are some factors like gender,age,BMI and duration of vaccination which influence immune response. Brian J Mac Mohan have showed males had higher antibody level than females[18]. W.S Fang et al found that female children significantly higher antibody level than male children[19]. A study conducted by Mohd.Abdul in Bangladesh had protective level of anti HBs antibody in 85.88% males and 92.31% of females[20]. Our study showed that mean anti HBs antibody titre in male was higher than female. Most of the studies showed that antibody response decreases with age. R.John Looney found that antibody response was different between young and elderly group. In his study, all 35 out of 35 young adult developed protective titre as compared to only 19 elderly out of 45[21].

In this study no significant difference in mean antibody titre in different age groups was observed but mean titre was more in ≥30 years of age group as compared to <30 years (younger age groups) but significant relation was observed only with the 1month to <5 years of age. BMI showed no relation with the antibody titre in our study. Study by Kunal das et al', showed seroprotection (HBsAb >10mIU/ml) after primary vaccination in 85.3% volunteers of more than 40 years of age. Surg Cdr C N Choudhury et alfound that higher age at vaccination is a risk factor for low antibody titres[22].Few long term studies have reported that hepatitis B vaccine protects an individual for more than 15 years[23,24]. Regarding persistence of antibody level in different individuals, we have found antibody level decreases with time.

In our study mean Ab titer was 459.80mIU/ml between1month to 5 years after vaccination,402 mIU/ml in 5years to<10years and 324 mIU/ml after 10 years. Previous studies havesuggested that primary vaccination could provide protection for atleast 5-7 years[25,26].Shruthi Hegde et al. included 110 hepatitis B vaccinated dental students andmajority of dental students had desirable immune response to the HBV vaccine. Male gender and positive smoking history could have a low anti-HBs titre in subjects[27]. Sunita Tripathy et al. have reported that 88.236% protective levels of antibody within 5 years of vaccination and 85% had protective levels even after 10 years, there was no significant difference of mean antibody titre between male and female participants[28].

But subsequently it has been showed that protection may be at least 25 years due to long term immunity derived from immunological memory in theseindividuals and showed adequate response to primary Hepatitis b vaccination[29].Our study has showed that DNA recombinant vaccine maintains protective level of HBs Ab for more than 10 years. Gabbuti et al reported that booster dose may not be required in immunocompetent persons[30].

Conclusion

From our study we concluded that hepatitis-B vaccinegives protection for more than 10 years after primary vaccination and booster dose of Hepatitis-B vaccine is not required inimmuno-competent persons after primary vaccination. The present study shows males have higher

mean titre of HbsAb as compared to females .Similar to age, BMI and duration of vaccination status also have no statistically significant relation with antibody titre. Although on comparing duration of vaccination status with age group , mean titre was more in ≥30 years of age group as compared to <30 years (younger age groups) but statistically significant relation was observed only with the 1 month to <5 years of duration .

Limitation

Persistence of protective level of antibody against HBV infection was studied in different individuals for different post vaccination duration .It needs a long term continuous monitoring of same study group over 10-15 years for more accurate statistical results.

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