Original Research Article

Prevalence of Non-responders among Medical Laboratory Technicians and Staff Nurses Evaluated for Anti Hepatitis B Surface Antigen Titre

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Abstract

Hepatitis B Infection is an occupational high risk factor. Immune response for vaccination was measured by Antibody to Hepatitis B surface antigen (anti HBs) levels. A course of Hep B vaccine yields a protective immune response (anti-HBs ≥ 10 mIU/mL) this study was designed to determine the anti HBs levels in Health Care Workers (HCWs) working as laboratory technician and staff nurses. The blood samples were collected from 546 HCWs, Anti HBs level was estimated using Chemi Luminescence Immuno Assay (CLIA) before and after 0,1,6 month of vaccination. Among 546 HCWs, before vaccination 83 HCWs was non-protected, after 0th dose of vaccination among 83 HCWs, 25 were again not protected. After administer two more doses, 4 were again non-protected. These 4 HCWs was termed as “Non Responders”, have confirmed the re vaccination history of complete dose with evidence and has remained to be non-protective after the two sets of complete vaccination course administered.

Keywords

Antibody to Hepatitis B surface antigen, Hepatitis B virus, Chemiluminescence Immuno Assay, Health care workers, Non responders, Hepatitis B Infection

Introduction

Hepatitis B infection (HBI) is a potentially life-threatening liver infection resulting from hepatitis B virus (HBV). Cirrhosis and liver cancer is the high risk for death and HBV also cause chronic infection (1). HBI is an occupational high risk infection for health care workers (HCWs) exposed to infected blood and contaminated needles and sharps (2). In 2015 World Health Organization (WHO) estimates, chronic HBV infection was residing in 257 million individuals confirmed by hepatitis B surface antigen (HBsAg positive), in the same year 887 thousand deaths were reported worldwide, commonly due to cirrhosis and hepatocellular carcinoma (3). In India, prevalence of general population was 1.1% to 12.2% were HBsAg positive, Average prevalence was estimated that 3% -
4%, due to chronic HBI approximately 40 million people were infected (4). Antibody to Hepatitis B surface antigen (anti-HBs) become a serological marker for both vaccine induced immunity and immunity because of infection. Protective immune response after vaccination as per CDC should be ≥10 mIU/mL (5). A hepatitis B vaccine “non-responder” refers to an individual who does not induce Anti Hbs even after took two complete course of vaccination (0, 1, 6 months) and those with acute or chronic HBI has been excluded (6).

The main objectives of the study assess the prevalence of HBV non-responders among technician and staff nurses by evaluating protective Anti HBs in a tertiary care hospital in Kancheepuram district (South India), in a period of about twelve months, from January 2019 to January 2020.

The results of the study can be used to analyses the protective and non-protective group of HCWs before and after vaccination and to track the non-responders after two complete set of vaccination.

**Materials and Methods**

This was a Cross-sectional study conducted on 546 HCWs who are in regular exposure to HBV infection. Institutional Ethics Committee has authorized this study (1520/IEC/2018 on 14.12.2018). The study group includes only Laboratory technicians and Staff nurses. Excluded groups were other HCWs other than staff nurses and laboratory technician and also excluding nursing students and short term internship individual in Laboratory. HCWs who had received blood component therapy like whole blood, plasma, immune globulin administration during the preceding months and immunosuppressed HCWs are also excluded. Previous vaccination status was obtained for all HCWs included in the study. Patient information sheet, consent form as been obtained duly signed by the HCWs participated in this study.A whole blood sample was collected with all aseptic precautions by a trained phlebotomist as per WHO guidelines(7) and allowed to clot and centrifuged to separate the serum. Anti-HBs titer was quantified in Chemiluminescense Immuno Assay (CLIA) method before and after 0, 1, 6 month vaccination. The Anti HBs titre of those showing > 10 mIU/ml, was eventually excluded from the study.

**Results and Discussion**

Anti-HBs were quantified using Chemiluminescence Immuno Assay (CLIA) and results were recorded. Out of 546 HCWs, number of males and female were 85 (15.6%), 461 (84.4%) respectively. Among the total 546 HCWs, nurses constituted of 439(80.4%) and technicians were 107 (19.6%) as shown in figure 1. All 546 HCWs serum was tested for anti-HBs, result shows 463 (84.8%) were Anti HBs protected, 83 (15.2%) were Anti HBs non-protected as shown in figure 2. As per the reference guidelines, those who having anti HBs ≥10 mIU/mL are termed as protected and those having < 10 mIU/mL are termed as non-protected.

Out of 83 (15.2%) non-protected HCWs, in that 17 (3.10%) technicians and 66 (12.10%) staff nurses were < 10 mIU/mL. Out of 83 non protected HCWs, 19 (3.46%) had completed their course, 39 (7.14%) had incomplete vaccination, 23 (4.21%) HCWs don’t know their vaccination status and 2 (0.39%) were not vaccinated as shown in figure 3. After Administered 1st dose of Hep B Vaccine for 83 (15.2%) non-protected HCWs, 67 (12.25%) were participated for Anti HBs titre test remaining 16 (2.95%) were dropped out from the study since they left the job for which result shows 42 (7.69%) were protected and
25 (4.56%) were non-protected. After Administered 2nd and 3rd dose of Hep B Vaccine for 25 (4.56) non-protected HCWs again their Anti HBs titre was analyzed and that result shows 17 (3.10%) were protected, 4 (0.73%) were non-protected 4 (0.73%) has again dropped out of my study. Out of 4 (0.73%) non-protected HCWs, 1 (0.18%) was technicians and 3 (0.55%) were staff nurses.

The total sample size of the study as 546 Health care Workers and among which 19.6% were technicians and 80.4% were Staff Nurses. 546 HCWs included in the study we had 15.5% Male (10.2% technicians, 5.3% staff nurses) and 84.5% female (9.5% technicians, 75% staff nurses). This shows that in categories the percentage of female health care worker is employed more in nursing field, where as both male and female are employed equally as technicians. The number of HCW who had completed their course of vaccine was 3.46%, 7.14% had incomplete course, 4.21% did not know their vaccination status and 0.39% were not vaccinated. Both not vaccinated and didn’t know their vaccination status comes under incomplete vaccination that shows total of 64 (12.25%) HCWs After administered 1st and 6th month doses of Hep B vaccine for non-protected 25 (4.56%) HCWs, 0.73% HCWs were dropped their jobs, 3.10% HCWs were protected and 0.73% were non-protected.

The occupation based percentage of non-protected healthcare workers are 0.55% Staff nurses, 0.18% technician. As per the CDC guidelines, the individuals who remain to have lower Anti HBs titre even after two series of complete vaccination are to be termed as non-responders. All those 4 (0.73%) repeatedly non-protective category of health care workers in our study as termed as “Non-responders” have confirmed there vaccination history of complete dose with evidence and has remained to be non-protective after the second set complete vaccination course administered by us. This study shows that HCWs specifically technicians and nurses has non-responder of 0.73% in a tertiary care hospital of Tamilnadu, India.

As stated by Amaddah radia et al., (8), Health employees constitute a population of chance for being exposed and getting transmission of the Hepatitis B Virus (HBV). Hence, raising a group of worker's attention and introducing compulsory HBV vaccination for all health care workers is important. In our study to signify the importance of HBV the study had free vaccination, screening and analysis of the immune response with the support of our institution with its hospital infection control committee.

In this study, total of 546 health care workers were suggesting they want for proactive implementation of HBV vaccination program. Considering on the Increasing age, time period and overweight could have decreased the immunity for those who have been previously vaccinated and for those who had remained to be as non-responders shall be the factors, as referred in a study by Praveena reddy et al., (9). As per the results of our study, the constant low titer of individuals after repeating a booster vaccination and complete course of vaccination emphasizes the want for monitoring vaccination reputation amongst health care workers.

The study have proved that there a gradual decline in antibody titers as duration of post vaccination increased. The percentage of subjects who have been non-protected after five and 10 years after vaccination were 20% and 27% respectively.

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Figure 1. Occupation wise distribution of technicians and staff nurses (n=546)

Figure 2. Occupation wise distribution of healthcare care worker based on Anti-hbs titre (n=546)

Figure 3. Initial vaccination status of health care workers (n=83)
Pre Exposure evaluation for Health Care Workers

546 HCWs were measure for antibody to hepatitis B surface antigen (Anti-HBs)

83 HCWs has Anti-HBs (<10 mIU/mL).

463 HCWs has Anti-HBs (≥10 mIU/mL)

Administered 1 dose of Hep B Vaccine

16 HCWs were left their job

Post Vaccination Serological testing for 67 HCWs participants

25 HCWs
Anti-HBs (<10 mIU/mL)

42 HCWs
Anti-HBs (≥10 mIU/mL)

Administered 2 more doses of Hep B Vaccine, post vaccination serological test

4 HCWs were left their job

HCWs to receive hepatitis B evaluation for all exposures

4 HCWs
Anti-HBs (<10 mIU/mL)

17 HCWs
Anti-HBs (≥10 mIU/mL)

No action for Hepatitis B prophylaxis (regardless of Source HCWs hepatitis B surface antigen status)

Our study evidences that the HBV vaccine efficacy and immune response to a booster vaccine indicates an extended-lasting amnestic reaction in in those who has less or nil exposure to HBI. In Health care workers, Hep B vaccine as a full course of vaccination affords long-term protection against HBI and booster vaccination does not appear to be vital
in HCWs (10). As per the previous researchers suggestion Serological testing should be done after pre vaccination and post vaccination also to all Health Care Workers (11).

HCW who had been non-responsive in spite of repeating a complete course of vaccination had to research on their HLA allele in advance know if it is related to non-responsiveness to the vaccine (12).

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