ISSN: 0975-833X

Available online at http://www.journalcra.com

International Journal of Current Research
Vol. 9, Issue, 05, pp.50010-50012, May, 2017

INTERNATIONAL JOURNAL OF CURRENT RESEARCH

RESEARCH ARTICLE

QUANTIFICATION OF ANTI-HBS IN VACCINATED HEALTHCARE WORKERS AT A TERTIARY CARE CENTER

***Kalyani Borde, Dr. Mythri, Dr. Jyoti S. Kabbin and Dr. Ambica, R.**

Bangalore Medical College and Research Institute, India

ARTICLE INFO

Article History:
Received 22nd February, 2017
Received in revised form
12th March, 2017
Accepted 16th April, 2017
Published online 19th May, 2017

Key words:

Hepatitis B vaccination,
Anti-HBs antibody,
Healthcare workers.

ABSTRACT

Introduction: Hepatitis B is the most common blood borne infection after occupational exposure in India. Awareness towards adult vaccination against hepatitis B is slowly rising amongst healthcare workers. However, it is well demonstrated that vaccine does not offer protection in 100% of recipients. It is important to seek out the vaccine non-responders as the post exposure management depends on the immune status of the vaccine recipient.
Objective: To check the immune response after hepatitis B vaccination and identify the non-responders.
Method: Healthcare workers were immunized with recombinant hepatitis B vaccine (GeneVac) according to the revised rapid schedule of 0-1-2. Antibody titers were checked after 6 weeks in HCWs who completed 3 doses of immunization. Blood samples for testing were collected and serum separated by centrifugation. Serum was stored at 4°C for no longer than 4 days. Anti-HBS quantitative ELISA (MBS, Italy) was used to measure the antibody titers. Serum samples from HCWs showing titers <10mIU/ml were retested after repeat vaccination.
Result: A total of 203 HCWs were tested for post-vaccination antibody titers. Of these, 39 samples showed titers below 10mIU/ml (19%). 15 out of 39 had undetectable levels. Repeat testing was done after administration of repeat vaccination in 20 HCWs – 14 of them seroconverted.
Conclusion: This study concludes that vaccination is not protective in 100% of recipients. As the HCWs are at an increased risk of exposure, it is advisable to check the immunity against hepatitis B, after finishing complete schedule of vaccination. In this way, non-responders can be identified to be revaccinated or relieved from high-risk areas.

Citation: Kalyani Borde, Dr. Mythri, Dr. Jyoti S. Kabbin and Dr. Ambica, R. 2017. "Quantification of Anti-HBs in vaccinated healthcare workers at a tertiary care center", *International Journal of Current Research*, 9, (05), 50010-50012.

INTRODUCTION

Hepatitis B virus (HBV) is a double stranded DNA virus belonging to the family *Hepadnaviridae* (Seeger, 2013). It causes a highly transmissible form of hepatitis which spreads by blood and body fluids. It is one of the hardiest viruses infecting humans, known to survive for up to 7 days on dry surfaces. It carries a definite risk for medical and paramedical professionals involved in direct patient care. Rates of serological conversion following an exposure by infected needle vary between 37%-62% (US, 2001). Most of the HCWs who get infected with HBV do not recall having a percutaneous infection. To complicate the matters further, there is a reluctance towards reporting the exposures due to various reasons; ignorance, fear of reprimand, not maintaining confidentiality being some of the few reasons only 54% of exposures get reported to authorities (US Public Health Service, 2001).

Corresponding author:* **Kalyani Borde,
Bangalore Medical College and Research Institute, India.

India is an endemic country for HBV with intermediate seroprevalence of hepatitis B surface antigen (HBsAg) - being 2-7% in general population (Ott, 2012). Hence, it is of utmost importance to protect HCWs, especially in India. Recombinant vaccines are available which use recombinant HBsAg to elicit protective anti-HBs antibody response. It is recommended that all HCWs be vaccinated. However, there are reports of non-response to usual vaccine regimen. Hence, this study was undertaken to assess the vaccine response in vaccinees.

MATERIALS AND METHODS

It was a prospective study for assessing vaccine response amongst vaccinated HCWs working in a super specialty tertiary care center in Bengaluru. Recombinant hepatitis B vaccine (GeneVac) was procured from Serum Institute of India. Rapid schedule of 0-1-2 was implemented for vaccination (http://www.cdsco.nic.in/writereaddata/ Serum% 20Institute%20Hep_B.pdf, Marsano, 1996). Informed consent was obtained from the study group. Antibody response was assessed after 4-8 weeks of the receipt of last dose of vaccine.

Venous blood samples were collected in plain tubes and transported to the laboratory. Serum was separated by centrifugation and anti-HBs quantitative ELISA (MBS, Italy) was performed according to the instruction manual. Data was analyzed categorically. HCWs having >10mIU/ml antibody titers were considered immune and <10mIU/ml were considered non-immune (Centers for Disease Control and Prevention, 2011). Non-immune HCWs were subjected to repeat vaccination (3 doses) and antibody titers (after 4-8 weeks of the last dose) were determined by the same ELISA method to look for seroconversion (Centers for Disease Control and Prevention, 2011).

RESULTS

Antibody response was assessed in 203 HCWs after vaccination. Of them, 82% were nursing staff, 10% were doctors, 6% were technicians and 2% were attenders [Figure 1]. 42(20%) were males while 161(80%) were females.

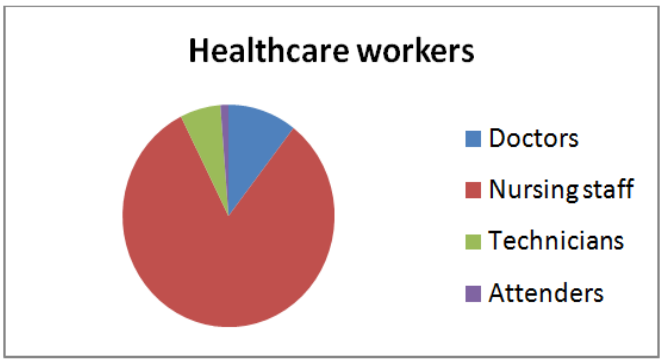

Figure 1. Distribution of Healthcare workers included in the study

39 (19%) HCWs were found to be non-immune, while remaining 164 (81%) had titers above or equal to 10mIU/ml [Figure 2]. 15 out of 39 non-immune HCWs had undetectable antibody titers. 11(28%) non-immune HCWs were males while 28(72%) were females [Figure 3]. However, 11 out of 42 males (26%)were non-responders as against 28 out of 161 females (17%). Mean age was 31.2 years. 12 HCWs were >40 years of age. 2(16%) of them were found to be non-immune. Response to repeat vaccination could be assessed in 20 HCWs. 14 (70%) out of 20 of the repeat vaccinees converted to titers above 10mIU/ml.

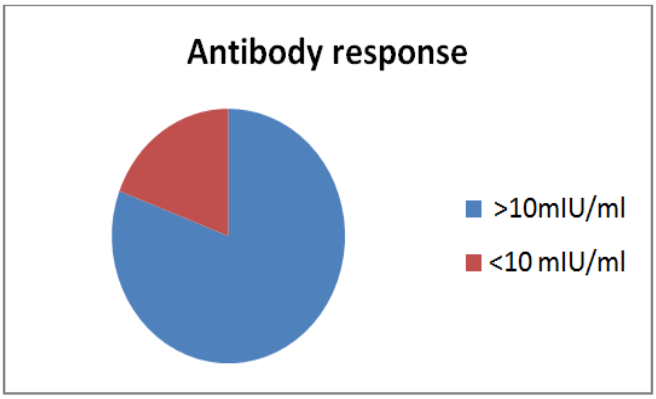

Figure 2. Antibody response amongst vaccinees after first vaccination series

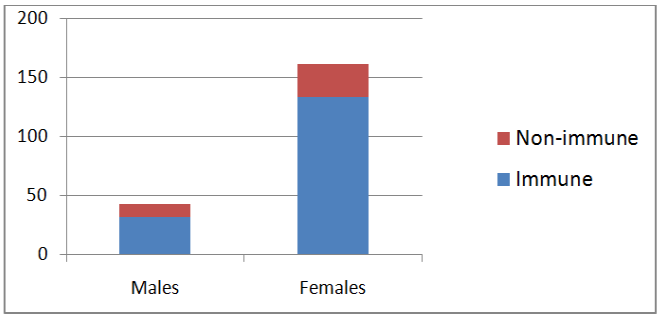

Figure 3. Distribution of immune and non-immune HCWs after first vaccination series

Table 1. Comparison of various studies for assessing antibody response to HBV vaccine

Study	Number of HCWs tested after 3 doses	Protected	Not protected
1. Chaudhari *et al*	146	88.4%	11.6%
2. Zeeshan *et al*	652	86%	14%
3. Chaturanga *et al*	342	90.1%	9.9%
4. Vijaya *et al*	268	72%	28%
5. Present study	203	81%	19%

DISCUSSION

This study aimed at immunizing HCWs working in a tertiary care hospital against hepatitis B virus and identifying the non-responders. HBV is highly infectious, being 100 times more likely to get transmitted by the needle prick injuries as compared to Human immunodeficiency virus (HIV) (Centers for Disease Control and Prevention, 2011). HCWs are at an increased risk of acquiring HBV infection due to its high infectivity and multiple exposures (Rosea, 1999; Talaat, 2003 and Kane, 1999). Hence, CDC has recommended HBV vaccination in all HCWs (Mahoney, 1997). In the U.S., Occupational Safety and Health Act (OSHA) has stated that the vaccine be made available at the employer's expense. In India, National Accreditation Board for Hospitals and Healthcare Providers (NABH) guidelines mention undertaking HBV vaccination of the hospital staff and booster doses if antibody response is found to be inadequate (Guidebook for pre-accreditation entry-level standards for small healthcare organizations, 2015). It has been established that the vaccines available currently do not offer protection to 100% recipients. Some individuals have been observed to remain chronically as non-responders. There are suggestions that this might be due to autosomal dominant inheritance (Egea, 1991). In this study, two variables of age and gender were studied which affect the vaccine reponse. 26% males were non-responders as against 17% females. This is in accordance with the findings of Zeeshan *et al*. (Zeeshan, 2007) and Wood *et al* (Wood, 1993). Both of these studies observed that males were almost twice as likely to be non-responders as females. 16% of HCWs >40 years of age were found to be non-responders whereas 20% of <40 year old HCWs were non-responders. However, this study did not take into account the other confounding factors such as obesity, smoking, site of injection, nutritional status or genetic factors. In the present study, 19% of the vaccine recipients were found to be non-responders which is similar to the findings of Zeeshan *et al*. (Zeeshan, 2007), but more than findings of Chaturanga *et al*. and Chaudhari *et al*. [Table 4]. 70% of the repeat vaccination recipients were found to be protected subsequently while remaining were chronic non-

responders. This is in accordance with the CDC report stating that the cumulative response rate after 3 revaccination doses reaches 69% amongst initial non-responders (Centers for Disease Control and Prevention, 2013). Non-responder is defined as an individual whose antibody titers remain <10mIU/ml after receiving ≥6 vaccine doses (Centers for Disease Control and Prevention, 2011). Vaccination with more than two series (6 doses) is not recommended. Knowledge of immune status of the HCW is important to protect the staff as well as the patient. Chronic non-responder needs to undergo further testing (anti-HBcAg, HBsAg, anti-HBeAg) to rule out active HBV infection. Furthermore, post-exposure management of non-responders differs from that of responders as the later class do not require passive immunization. HCWs shown to have >10mIU/ml anti-HBs antibodies need not take any post-exposure prophylaxis. Non-responders need to be administered HBIG (hepatitis B immunoglobulins) 0.06ml/kg, two doses one month apart (Centers for Disease Control and Prevention, 2013). In conclusion, we would like to stress upon the findings that the vaccine response can be variable and follow-up with antibody titers has to be done for high-risk individuals such as HCWs. This would help in ensuring safe work environment and proper post-exposure management. In a resource limited country like India, it is of utmost importance to seal the lapses in workplace safety for better patient care.

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