International Journal of Community Medicine and Public Health
Indernath S et al. Int J Community Med Public Health. 2023 Jan;10(1):250-253
http://www.ijcmph.com
pISSN 2394-6032 | eISSN 2394-6040

DOI: https://dx.doi.org/10.18203/2394-6040.ijcmph20223552

Original Research Article

A prospective study on the quantification of anti-HBs antibody titers of vaccinated health care workers in a tertiary care teaching hospital by using automated enzyme linked fluorescent assay

Sunil Indernath[1], Sudha K.[1], Shanmugavadivoo N.[1], Usha B.[1], Vinod Babu S.[2]*

[1]Department of Microbiology, Annapoorana Medical College and Hospitals, Salem, Tamil Nadu, India
[2]Department of Biochemistry, Saveetha Medical College, SIMATS, Chennai, Tamil Nadu, India

Received: 26 October 2022
Accepted: 02 December 2022

***Correspondence:**
Dr. Vinod Babu S.,
E-mail: drvinodbabu@gmail.com

ABSTRACT

Background: Hepatitis B virus (HBV) infection poses a major health problem among health care workers (HCWs). Globally, 350 million peoples have infected, and it was estimated by WHO. CDC has recommended HBV vaccination for all health care workers. The objective was to determine the anti-HBs antibodies titres among health care workers using automated enzyme linked fluorescent assay (ELFA).
Methods: This prospective study was conducted in department of microbiology, tertiary care hospital. The test samples have been collected from health care workers who have completed the course of vaccination. VIDAS anti-HBs total II (AHBS) assay was initiated according to the manufacturer's instructions.
Results: Out of 100 subjects, 62% showed positive for anti-HBs antibodies and the remaining 38% showed negative. Positivity of anti-HBs antibody titers ranges from 27 mIU/ml to 500 mIU/ml.
Conclusions: In the present study, 100 subjects have been selected based on the HBV vaccination with completion of three doses of vaccination. Presence of anti-HBs antibodies titers against the vaccination is fully immunized. The study was determined the vaccinated status of anti-HBs antibodies against the infection among clinicians, nurses and CRRIs and it has to be revealed at regular intervals of every 6 to 8 months.

Keywords: AHBS, Anti-HBs antibodies, Antibody titer, Health care workers, Hepatitis B virus, Vaccination

INTRODUCTION

Hepatitis B virus (HBV) infection poses a major issue among health care workers (HCWs). Globally, one third of the population have been infected with HBV and it was estimated by WHO worldwide.[1-3] Initiated the administration of hepatitis B vaccine to the health care professionals by the occupational safety and health administration (OSHA), who has been directly or indirectly exposed to the blood or other body fluids. The HBV vaccines should not be rescheduled when there is a delay of doses. Globally, move forward towards the elimination of hepatic viral infections which was indorsed at 69th World Health Assembly, approved by the "global health sector strategy to eliminate viral hepatitis by 2030".[4] Hepatitis B virus is a causative agent of hepatitis as well as chronic liver failure. Chronic infections arise in 5% of cases who become carriers and one quarter of these carriers which leads to hepatic cirrhosis and hepatocellular carcinoma.[4] Most of the developing countries like Bulgaria and India have major threat to HBV.[2-6] Since, CDC has recommended HBV vaccination for all HCWs from 1997. HBV vaccinated among healthcare workers varies from 67-79% in developed and 18-35% in developing countries.[6] WHO estimates that nearly 40% of hepatitis B and C infections from the occupational exposure and 2.5% of HIV infections among HCWs. In developing countries, it accounts nearly 90% of infection occurs through occupational exposure and it is quite high when compared to the developed countries.[7]

Anti-HBs is a defending antibody, it is a quantitative remains the determinants of immunity to HBV. Workers who have either partially or fully vaccinated will have still lack of anti HBs titres. HBsAg is tends to be a preventable disease and the infection was controlled by the immunization among health care workers.[5,7-9] Vaccination is highly mandated for doctors, nurses, paramedical as well as nursing students and staff. The titres can be evaluated in post vaccinated workers to confirm the protectivity before initiation of the risk. Populations who are non-responders to vaccination it remains prone to HBV infections. The current vaccination schedule is of three doses were followed at the intervals of 0-1-6 months intramuscularly.[7,10,11] But some subjects may not show a protective response even after completing the primary vaccination. The main aim of this study was to determine the anti-HBV antibodies among vaccinated health care workers (HCWs) using automated enzyme linked fluorescent assay (ELFA).

METHODS

This prospective study was conducted in the department of microbiology, tertiary care hospital during the period of February 2021 to August 2021. Ethical clearance was obtained from Institutional Human Ethical Committee (IHEC) and the subjects were selected from the HCWs of tertiary care teaching hospital. After getting written consent from the subjects, about 3 ml of blood specimens were collected and handled anonymously and the confidentiality was maintained among the HCWs.

Inclusion criteria

All the demographic, laboratory and clinical details have kept confidential, and the blood samples were collected from the clinicians, nursing staff, interns, postgraduates, technical and housekeeping staff who have completed HBsAg vaccination of three doses have more than six months of post vaccination period, were included in the study.

Exclusion criteria

Subjects with history of HBV infection, followed by diabetes mellitus, steroid therapy for prolonged period and chronic liver disease were excluded from the study.

The test assay VIDAS anti-HBs total II (AHBS) was performed according to the manufacturer's instructions.[5] Briefly, reagents were removed from the refrigerator and used immediately. One strip from AHBS and another from AHBS SPR for calibrator, control, samples to be tested. The calibrator was tested in duplicate, positive, negative control and samples were tested in single. About 200 µl of calibrator, controls and samples are mixed using vortex mixer and "AHBS" SPRs and "AHBS" strips were inserted into the instrument. Colour labels had been checked with the assay code on the reagent strips as well as on SPRs match and all the assay steps were performed automatically. After pipetting the vials have been reclosed and the instrument was operated with recommended temperature. All unused reagents were stored at 2-8°C. The assay was completed within 60 minutes and the used SPRs and reagent strips are discarded into the appropriate decant. The assay results were interpreted according to the kit instructions as directed by the WHO International standard of Immunoglobulin. Titre <8 was considered as negative followed by 8≥ titre <12 was equivocal and titre ≥12 was considered as positive. An equivocal result should be reconfirmed by the second sample.[5]

RESULTS

A total of 100 samples obtained from the doctors (n=50), Nursing staff (n=20) and CRRI (n=30) positivity and negativity for anti-HBs antibodies were presented in Table 1. Age ranged from 21 to 70 years old viz., clinicians (21 to 70 years), CRRI (20 to 22 years) and nursing staff (22 to 28 years). Mean age was calculated for female was 30.2±2.97 and male 27.5±2.75 with 95% of confidence interval. Out of 100 subjects, 62 (62%) with 37 male (59.6%) and 25 females (40.3%) were showed positive for anti-HBs antibodies and the remaining 38 (38%) showed negative in 24 males (63.1%) and 14 females (36.9%). Positivity of anti-HBs antibody titers ranges from 15 to 500 mIU/ml. Most of the clinicians, nursing staff and CRRIs had low titers ranges from 15 mIU/ml followed by 39 mIU/ml and 38 mIU/ml to the highest value of 500 mIU/ml each group respectively. Remaining negative cases were marked titer of 3 mIU/ml or less than that. None of the volunteers were positive for HBsAg rapid immunochromatographic card test.

Table 1: Demographic details on the positivity of anti-HBs antibodies among vaccinated health care workers.

Category	Positive (n=62)		Negative (n=38)	
	Male	Female	Male	Female
Clinicians (n=50)	18	13	11	8
Nursing staff (n=20)	5	9	1	5
CRRI (n=30)	14	3	12	1
Total	37 (59.6%)	25 (40.3%)	24 (63.1%)	14 (36.8%)

DISCUSSION

Hepatitis B virus infection causes a major health issue among health care professionals. Body fluids like blood and other fluid products are highly contagious and easily can transmit the infection to other persons.[11] Hence, this virus can transmit due to leakage of sample container or sharps. Globally, the WHO and other organizations made

a vaccination is mandatory for healthcare workers.[2] In the present study targets two hundred subjects mentioned at the age between 21 to 70 years old as per the inclusion criteria and the mean age was calculated for Female was 30.2±2.97 and male 27.5±2.75 with 95% of confidence interval. Similarly, the same study was conducted by Mall et al, in 2022 which the age ranges from 19 to 52 years only and the mean age was 27.29±0.568 years quite like this study. Duration of vaccination is highly recommended to track the immune status of the individuals against the HBsAg.[12-18] In one of the cohort studies, they estimated the antibody titres of HBsAg in post vaccination schedule and the titres were >100 mIU/ml in 85.0%, 10-100 mIU/ml in 11.0% and ≤10 mIU/ml in 3.5%.[19] The duration of antibody titres against the HBsAg was declined after vaccination was increased and the increasing age was associated with falling protective titres.[4] In the present study, 100 subjects have been selected based on the HBV vaccination with completion of three doses. A similar study was also observed in Dehradun and Kerala with the involvement of 84-86% of fully vaccinated and 14-16% were partially vaccinated.[1,10,20] Glampaolo et al recorded the prevalence of anti-HBs antibodies 21.83% in uncovered trainees who vaccinated at age of 12 years old and followed by 45.03% who vaccinated in neonatal age.[14] Age factor will not be able to determine the production of protective antibodies during post vaccination. Sharma et al, from Kerala, were estimated the protective levels of vaccination even after 5 years of duration but in this study, extremely limited to less than one year of duration and hence, it was 100% fully vaccinated for HBV.[1,21] Many of the studies have shown that the anti-HBs antibody titer correlates with the number of doses vaccinated, as well as with the subject age and gender either in elderly or at the age of 12 years.[22] In most of the prevalence studies from India, were recorded above 80% of HCWs were respondents to vaccination which ranges from 70% to 99.9%.[1,6] On estimation of anti-HBs antibodies, 9.7% had titer <10 mIU/ml and 90.3% with >10 mIU/ml, but in the present study, 62% with the titer of >12 mIU/ml were considered as responders and remaining 38% <8 mIU/ml were non-responders in which there was no sufficient protective antibodies have been noted.[11] Most of the physicians were responders to the protective antibodies when compared to the CRRIs and other hospital staff including nursing assistants. Although vaccines are carefully monitored and safe coverage appears to be significantly variable over time due to the decline status of the immunity.[14] Particularly in India, Batra et al was recorded that 49.6%, 46.1% and 4.3% HCWs have vaccinated, unvaccinated, and partially vaccinated, respectively. Among HCWs, 92.5% doctors had the highest vaccination rate, followed by medical students (62.4%), nursing staff (41.6%), technical staff (24.2%), administrative staff (12.1%), nursing students (8.5%), and grade IV/laundry staff (0%).[13] The present study was highly limited to the health care professionals who have been vaccinated in the tertiary teaching hospital and in future the study will be extended to the public to create awareness and the importance of viral hepatitis vaccination.

CONCLUSION

To conclude that the study was determined the presence of protective status of anti-HBs antibodies among clinicians, nurses and CRRIs in post vaccination. Anti-HBs antibody titers must be revealed at regular intervals of every 6 to 8 months.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Indernath S, Sudha K, Shanmugavadivoo N, Usha B, Babu VS. A prospective study on the quantification of anti-HBs antibody titers of vaccinated health care workers in a tertiary care teaching hospital by using automated enzyme linked fluorescent assay. Int J Community Med Public Health 2023;10:250-3.