ORIGINAL ARTICLE

Hepatitis B Virus (HBV) Immunity Status of Laboratory Staff Working at a Tertiary Care Hospital in Lahore: An Interventional Study

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ABSTRACT

Background and Objective: Hepatitis B virus (HBV) infection is one of the common chronic viral infections worldwide. The World Health Organization (WHO) had estimated that only a minority are aware of their status and still a fraction of the diagnosed cases were receiving treatment for their ailment. Theaverageburden of disease in Pakistan is about 3.3%. The incidence may appear lower among the healthcare workers (HCWs) as compared to blood donors, but HCWs are at increased risk to acquire the HBV infection and the risk is even greater for laboratory personnel. This risk can be minimized by offering them the vaccination.

Methods: Blood samples from all categories of staff in the laboratory were tested for hepatitis B Surface Antibodies (HBsAb). Those foundnon-immune were offered recombinant hepatitis B vaccine by intramuscular (I/M) injections. The results were tabulated by entering age/sex of the laboratory staff with HBsAb level. Blood was drawn 4 weeks after completion of 3 doses vaccination course in 6 months. Repeat HBsAb levels were determined in this initially non-immune group. All results were analyzed using SPSS version 21.

Results: Out of 96 staff members, 30were found to be immune on first testing. Remaining 66 non-immune staff were offered complete course (3 doses) of HBV Vaccine. Five staff members were lost to follow up during the course of vaccination, two of them refused vaccination and two were non-responders. The rest 57 became immune after three doses of vaccination.

Conclusion: It is recommended that a national policy be adopted for HBsAb screening and offer of vaccination, to non-immune HCWs.

KEYWORDS: Hepatitis B virus, HBsAb, HBV vaccination, Health care workers.

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INTRODUCTION

Hepatitis B is a chronic viral infection occurring worldwide. World Health Organization (WHO) had estimated that 257 million people were living with and about 0.9 million died of chronic hepatitis B virus (HBV) infection in 2015. Only ~10.5% of the chronically infected were aware of their status and a minority (~16%) of the diagnosed cases were receiving treatment for their ailment. WHO places Pakistan in the Eastern Mediterranean region where the average burden of disease is about 3.3%.[1] The prevalence of chronic HBV infection in Pakistan varies from 0.8 – 5.8% among adult healthy blood donors. However, the incidence in certain high-risk groups varies from 4% to 22%.[2] A recent publication from Pakistan has shown that there are actually fewer cases of HBV among the healthcare workers (HCWs) in different areas of Pakistan than in blood donors.[3] The non-immune HCWs have an increased risk to acquire the HBV infection as they are exposed to the blood and other body fluids of the patients during the discharge of their duties. This risk is even more in case of laboratory personnel. Fortunately, an effective vaccine for HBV was marketed as early as 1981.[4] HBV infection is one of the most common viral infections transmitted to the laboratory personnel.[5]

Among the three common blood borne viral infections which include HBV, hepatitis C virus (HCV) and human immunodeficiency virus (HIV); onlyHBV infection can be prevented by vaccination. The HCWs especially laboratory personnel need to minimize the risk of acquiring HBV infection during the course of their duties. In clinical laboratories, the International Organization for Standardization (ISO) 15189 standards require that the immunity level of the staff be known and documented.[6] To fulfil the requirements of this standard, all categories of staff working in the Pathology Department at Shalamar Medical and Dental College were subjected to detection of immunity level against HBV infection. The obtained results were interesting and authors decided to document so that it may further help to formulate local, provincial and/or national policy guidelines. This is especially important as most of the laboratories may not realize the significance of this measure and their staff remains vulnerable to acquire a disease that is easily preventable through vaccination.

METHODS

This descriptive study was carried out in Pathology Department at Shalamar Medical and Dental Collegeafter theInstitutional Review Board approval, vide letter No.SMDC/IRB/05-07/106. After appropriate written consent, blood samples from 96 staff and faculty members were drawn. The level of hepatitis B surface antibodies (HBsAb) was determined using "MAGLUMI 1000" Chemiluminescence Immunoassay (CLIA) System. The tests were performed as per manufacturer's recommendations. Those found to be non-immune having HBsAb level ≤ 9.9 mIU/mL, were offered 3 doses of recombinant hepatitis B vaccine containing 20 µg/mL recombinant hepatitis B surface antigen (HBsAg) adsorbed onto aluminum hydroxide. Three doses schedule as recommended by Advisory Committee on Immunization Practices (ACIP)was followed (first dose day 0, second dose day 30 and third dose on day 180).[7] Deep intramuscular injections were given in the left or right deltoid muscle. The results were tabulated. Different parameters entered were age/sex of the laboratory staff with HBsAb level. Blood was drawn 4 weeks after the third dose and HBsAb levels were repeated using the same instrument.

STATISTICAL ANALYSIS

Results of repeat samples were entered in the table and the data was analyzed using statistical package for the social sciences (SPSS) version 21. Chi-Sqaure test was applied to check the level of significance between two different variables and P-values were calculated using SPSS version 21.

RESULTS

A total of 96 laboratory staff members,were tested. Twenty three were medically qualified doctors (

Table-1: Age Wise Primary Immunity Status.

Age Group (Total No)	*Frequency (Total 96)*	*Sex Distribution*		*Primary Immunity Status*			
				Immune		*Non-Immune*	
		Male	*Female*	*Male*	*Female*	*Male*	*Female*
20 – 29	41	36	05	06	02	30	05
30 – 39	34	23	11	03	07	20	04
40 – 49	11	11	00	05	00	06	00
50 – 59	04	01	03	00	03	01	00
≥ 60	06	04	02	03	01	01	01

Table-2: Age wise Post-Vaccination Immunity Status.

Age Group (Total No)	*Frequency (Total 96)*	*Previously Immune*		*Lost to Follow up*		*Immune due to Vaccination*		*Vaccination Refused*		*Non-Responder*
		Male	*Female*	*Male*	*Female*	*Male*	*Female*	*Male*	*Female*	
20 – 29	41	06	02	01	00	27	03	01	00	01 Male
30 – 39	34	03	07	03	00	17	03	00	00	01 Female
40 – 49	11	05	00	00	00	05	00	01	00	00
50 – 59	04	00	03	00	00	01	00	00	00	00
≥ 60	06	03	01	00	01	01	00	00	00	00

pathologists), one doctoral level scientist (molecular biologist), two technical managerial staff. The technical laboratory staff including support services staff were seventy. The maximum and minimum age of the staff members were recorderd as 65 and 20 years respectively. The mean was calculated as 33.79 ± 10.72 years. A total of 30 (31.25%) staff members were found to be immune (HBsAb ≥ 10 mIU/mL) after the first test. A total of 68.75% staff members were non-immune and were offered HBV Vaccine (Table-1). Five staff members had resigned (lost to follow up) after submitting thefirst blood sample and two of the staff members refused vaccination so the total number of non-immune staff members were calculated as fifty nine (Table-2].

A significant difference in the level of immunization (P= 0.01) was observed between the staff members of younger age group (20 – 40 years) than the relatively older age group (≥ 40 years). After the first test it was observerd that only 25% of the staff members of younger age group were immune while 55% of staff member who were 40 years and above were immune.

The results obtained indicated that there is a significant difference of immunity status between male and female staff members (P = 0.01). A total of 61.9% of female staff members were already immune to the HBV as compared to 22.6% male staff members.

After providing with the three doses vaccination series, the 87.9% of the 77.3% non-immune male staff members tested “immune”, 3.44% “refused the vaccination”, 6.90% were “lost to follow-up” and the status of 1.72% were “non-responders”. Out of the 38.09% of ‘non-immune’ female staff members, 75% were “immune” after the three doses vaccination series while the 12.5% of females were “lost to follow-up” and 12.5% were “nonresponders”.

After the three doses vaccination series, highly significant results of immunization were obtained (P=0.00) as out of total number of 59 staff members, who completed the three dose series, only 2 were non-responders and the rest 57 became immune and there were total 87 (90.62%) immune staff members.

DISCUSSION

The infectious diseases have always been a threat to the HCWs as they can infect the patients under their care and also get themselves infected during the course of their work. Luckily, a number of infectious diseases are preventable because effective vaccines are available. Many of these vaccines are now recommended for the HCWs if the immunity has waned over the years after childhood vaccination or nature of duties require them. In Pakistan, HBV vaccine is offered as part of Expanded Program for Immunization (EPI) program since 2002 and children born after that are expected to have received it.[8] Working in a clinical laboratory is an established risk factor for

the transmission of HBV infection for HCWs and the workforce in healthcare institutions older than 18 years needs screening for and vaccination against HBV if they are found non-immune.

The importance of circulating antibodies to Hepatitis B Surface Antigen was appreciated even before the discovery of the vaccination against HBV. Coppola et al.[9] showed that the intensity and duration of exposure to blood rather than patients was directly proportional to the prevalence of viral hepatitis infection among HCWs. The Occupational Safety and Health Administration (OSHA) mandated testing of Hepatitis B status of all HCW and vaccination of all susceptible individuals in 1992 (standard number 1910.1030). In 2010, the HBV vaccination coverage in the United States among HCWs ≥ 19 years old was 63.4%. Although it was well above the national levels (23%) but quite below the expected Healthy People goal of 90% coverage. Slight improvement (64.7%) was reported a few years laterbut still the increase was insignificant.[10] The situation in other developed countries was comparable. National Health Service (NHS) UK recommended vaccination for their employees doing exposure prone procedures (EPP) in 1993. In 2007, NHS issued the guidelines mandating that any HCW doing EPP will be required to be free from Tuberculosis, and blood borne viral infections including HBV infection.[11] Among the European countries, Germany had a coverage of ≥ 69.5% in HCW as compared to ~30% coverage for the general population.[12]Coverage in Italy had improved to 85.3% in 2006 vs. 64.5% reported in 1996.[13] The best results were reported in France where 91.7% had completed 3 dose series for HBV vaccine.[14] A Japanese study reported the presence of HBsAb among the HCWs in a tertiary care center in Tokyo to be in the range of 83.1%.[15] A recent survey conducted in China reported that 86% of all HCW had received at least one dose of HBV vaccine and 60% had completed 3 doses series.[16]

In a conference held in 2011 in the Hague Netherlands under the auspices of WHO, it was agreed that the workers' health is an integral part of general health and daily life, therefore, the health systems should facilitate local strategies to meet workers' health needs. Consequently, in moving towards universal coverage, those at greatest risk or having greatest needs should be included first.[17] The HCWs are at great risk of acquiring blood borne viral infections especially HBV and, as an effective vaccine is available for protection against it, they must be protected from getting infected with HBV. Even before its recommendation by the WHO, many countries had included vaccination against HBV as a pre-requisite for offering any jobs for individuals who will be performing EPP because cost-effectiveness of HBV vaccination had been established both as an infant (as part of the childhood vaccination) and/or later in life as catch-up vaccination.[18] A global review of studies done during 1994 to 2000 concluded that universal vaccination (UV) is cost-effective in very low and low endemicity countries. UV is also useful in medium and high endemicity countries; and in such areas even screening and catch-up vaccination is economically viable.[19] A more recent review concluded that UV against HBV is essential as International Agency on Research of Cancer (IARC) puts the HBV as a carcinogen and WHO estimates that HBV will be the third leading cause of death for infectious diseases in 2030 especially in the industrialized countries.[20] Another review published earlier clearly recommended UV for all infants in developing countries with intermediate or high endemicity for HBV infection.[21] Studies in neighboring countries show varied response in different health care facilities. In New Delhi, India a study similar to the current study showed that 58% of their laboratory workers had protective antibody.[22] A study in Iran reported a 78.6% of post-vaccination immunity in their Health care workers.[23] Only one study in Pakistan conducted at Agha Khan University (AKU) reported on pre and post vaccination immunity. This study reported that 14% of HCWs were non-responders, meaning there by that they remained negative for HBsAb six weeks post vaccination.[24]

Several studies have been conducted in Pakistan which were questionnaire based, focusing only on vaccination status. Although, these studies didn't document the immunity status by HBsAb estimation yet they did reflect the awareness on the part of HCWs regarding their HBV vaccination status. In Jinnah Hospital/Allama Iqbal Medical College Lahore, 60% of their HCWs were completely immunized.[25] Similarly, a study at another tertiary care hospital in Lahore reported 72% complete immunization of HCWs.[26] A study in

Peshawar gave 73% complete immunization.[27] Another study at AKU Hospital in Karachi stated that 86% of their HCWs were completely immunized, but this may be due to the fact that the HCWs are provided free of cost immunization against hepatitis B.[28]

The study results clearly show that the HCWs are willing to accept the vaccination to save themselves from the long term sequelae of HBV infection. This is also reflected in many other studies (referred to earlier) done elsewhere in the world. The uptake of HBV vaccine is much better in those countries/healthcare systems where the employees were offered vaccination as a requirement of their joining the work. Surprisingly, two laboratory staff refused vaccination. Presently in Pakistan, there is no regulatory requirement for documenting HBsAb levels for HCWs before joining hospital or for performing EPP. University of Health Sciences (UHS) Lahore recently published its guidelines for Infection Prevention & Control in public and private sector hospitals within its jurisdiction. These guidelines clearly recommend the documentation of HBV immunity status by testing for the presence of HBsAb and that it should be made part of the pre-employment screening of all HCWs.[29] The current study supports the view that fewer HCWs know their HBsAb level which is required for management of any untoward incident in the form of an exposure due to neddlestick injury or otherwise.

CONCLUSION

As the vaccination is offered as part of the EPI since 2002, it is only a matter of demonstrating the HBsAb by appropriate testing. This can be done by adopting a national policy and investing some resources for knowing the immunity status of HCWs after testing for HBsAb. In addition, HCWs should be counseled and motivated for behavior change, in cases of ignorance and negligence.As clearly shown in the current study and elsewhere, HCWs would not object to vaccination if offered free of cost. For HCWs performing EPP, stringent measures should be enforced so that they do not get infected as a result of their duties.

LIMITATIONS OF THE STUDY

The sample size is small as the study was done in one department of the hospital. The authors intend to not only expand it to the whole hospital but also make it multi-center, if the resources (financial and others) are available.

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CONFLICT OF INTEREST

None to declare.

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None to disclose.

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Author's Contribution

TN: Conception and design of data, drafting the article.
MRT: Conception of data, drafting the article.
AS: Analysis and interpretation of data.
MDI: Drafting the article.
MEN, ST: Acquisition and analysis of data.
ALL AUTHORS: Approval of the final version of the manuscript to be publsihed.