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Research Article

Safety Profile Of Hepatitis B Vaccination.

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Abstract

Introduction: Hepatitis B poses a significant health problem worldwide. Hepatitis B vaccine as a part of universal immunization, is both cost-effective and efficacious with minimal side effects. The reported side effects of the Hepatitis B vaccine include soreness, redness, or swelling at the injection site, headache, fatigue, and a low-grade fever. These are typically mild and resolve within a couple of days. A severe allergic reaction (anaphylaxis) is very rare but possible, with symptoms like hives, swelling, and difficulty breathing occurring shortly after vaccination.
Aim of Study: To determine adverse effects associated with hepatitis B vaccination.
Materials & Methods: It was prospective study conducted at Department of Medical Gastroenterology, Post Graduate Institute of Medical Sciences (PGIMS), Rohtak, over a period of five years from 1st October, 2020 to 30th September, 2025. In total, only those five thousand people who got fully vaccinated against hepatitis B by three doses of 20 microgram (1 ml) at 0,1- and 6-months interval, were included in the study. Out of total five thousand participant in study group Out of these five thousand study groups who were hepatitis B negative, 1200 were health care workers, 1000 were HCV patients and 2800 were family members of Hepatitis B patients. Every participant was asked for any kind of adverse side effect, after each dose of HBV vaccination. All participants were above 14 years of age and none was HBV positive.
Results: Out of total five thousand participant in study group, 1200 were health care workers, 1000 were HCV patients and 2800 were family members of Hepatitis B patients. All were given three doses
Conclusion: Hepatitis B vaccination is devoid of any serious adverse side effects and wherever indicated, complete course should be given on priority.

Keywords: Hepatitis B virus; Hepatitis B Vaccination, Myalgias, Fever, Allergic reaction, Close contact.

INTRODUCTION

Hepatitis B poses a significant health problem worldwide [1]. The majority of patients are from the eastern part of the world, including China, Taiwan, and Southeast Asian countries such as India [1-3]. There have been no large population-based studies from the Indian subcontinent since the publication of the first consensus statements in 2018 [4]. Therefore, most of the available data is based on retrospective data analysis, blood bank donor data, and antenatal screening for viral hepatitis. Earlier studies reported the HBsAg carrier rate in India to be around 4%, placing India in the intermediate range of Hepatitis B prevalence, resulting in a total of 36 million carriers [2]. Among the estimated 400 million HBsAg carriers worldwide, it was believed that India contributed 9% of the total pool of hepatitis B to the world [1,3]. HBV infection is a major cause for causing chronic hepatitis, cirrhosis, and hepatocellular carcinoma. Hepatitis B vaccine recombinant is used to prevent infection by the hepatitis B virus. The vaccine works by causing human body to produce its own antibodies against the disease. Hepatitis B vaccine recombinant is made without any human blood or blood products or any other substances of human origin. Thus, it cannot lead to iatrogenic transmission of HBV or the human immunodeficiency virus (HIV). Immunization against hepatitis B disease is recommended for all newborn babies, infants, children, and adolescents up to 19 years of age. It is also recommended for adults who live in areas that have a high rate of hepatitis B disease or who may be at increased risk of infection from hepatitis B virus. These adults include: Males who have sex with males, including those with HIV infection, sexually active persons with multiple partners, health care workers, employees in medical facilities, patients and staff of live-in facilities and daycare programs for the developmentally disabled, morticians and embalmers, police and fire department personnel, and military personnel

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[5]. Other high-risk groups include chronic kidney disease patients (including on dialysis), Chronic liver disease, chronic heart failure, patients of blood clotting disorders who receive transfusions of clotting-factor concentrates, household and sexual contacts of HBV carriers intravenous drug abusers and prison inmates. The adverse effects reported with hepatitis B vaccination are less but variations have been reported in previous studies and meta-analysis. Hence, present study was conducted to determine the adverse effects associated with hepatitis B vaccination.

AIM OF STUDY

To determine adverse effects associated with hepatitis B vaccination.

MATERIAL AND METHODS

It was prospective study conducted at Department of Medical Gastroenterology, Post Graduate Institute of Medical Sciences (PGIMS), Rohtak, over a period of five years from 1st October, 2020 to 30th September, 2025. In total, only those five thousand people who got fully vaccinated against hepatitis B by three doses of 20 microgram (1 ml) at 0,1- and 6-months interval, were included in the study. Out of these five thousand study groups who were hepatitis B negative, 1200 were health care workers, 1000 were HCV patients and 2800 were family members of Hepatitis B patients. Every participant was asked for any kind of adverse side effect, after each dose of HBV vaccination. All participants were above 14 years of age and none was HBV positive.

Statistical Analysis

All the data was entered in Microsoft Excel and was analysed using SPSS 15.0 version.

OBSERVATIONS & RESULTS

Over a period of five years, five thousand people who got fully vaccinated against hepatitis B by three doses of 20 microgram (1 ml) at 0,1- and 6-months interval, were included in the study. Out of these five thousand, 1200 (24%) were health care workers, 1000 (20%) were HCV patients and 2800 (56%) were family members of Hepatitis B patients. In study group of five thousand, there was male predominance i.e. 3620 (72.40%) in comparison of female i.e. 1380 (27.60%). Out of five thousand participants, only 12 (0.24%) developed mild, transitory adverse effects. The rest 4988 (99.76%) The most common side effect associated was soreness at injection site (41.66%), followed by myalgia (33.34%) and fever (25%).

Table 1. Showing Distribution of Participants Vaccinated for HBV in Study Group.

Total Vaccinated against HBV	Family Members of HBV Patient	Health Care Workers	Hepatitis C Patients
5000	2800 (56%)	1200 (24%)	1000 (20%)

Table 2. Showing Sex Distribution of Participants Vaccinated for HBV in Study Group

Total Vaccinated against HBV	Males	Females
5000	3620 (72.40%)	1380 (27.60%)

Table 3. Showing Distribution among Participants who Developed Adverse Effects

Total Vaccinated against HBV	Developed Adverse Effects	No Adverse Effects
5000	12 (0.24%)	4988 (99.76%)

Table 4. Showing Distribution of Adverse Effects in Participants Vaccinated for HBV

Total Who Developed Adverse effects after HBV Vaccination	Soreness at Injection site	Myalgia	Fever
12	5 (41.66%)	4 (33.34%)	3 (25%)

DISCUSSION

WHO recommends universal hepatitis B vaccination for all infants, with the first dose given as soon as possible after birth [6]. Hepatitis B vaccine was universalized nationwide in India in 2011. The UIP schedule recommends hepatitis B birth dose to all infants within 24 hours, followed by three doses at 6, 10 and 14 weeks to complete the schedule. The hepatitis-B birth dose coverage among the total live births was 45% in 2015 and 60% in 2016. The National Viral hepatitis control program (NVHCP) strongly recommends about mandatory vaccination of health care workers and high-risk groups. In our department due to implementation of Jeevan Rekha Project & NVHCP through which there is provision of total free treatment including viral load and other routine tests, drugs, endoscopy, fibroscan, indoor admission in wards etc. Moreover, as a well-planned

policy, hepatitis B & C patients are given consultation and treatment on daily basis without any waiting period. There is lot of thrust on counselling which includes testing especially of the spouses and family members of HCV patients and HBV vaccination. This team effort has led to good social bonding with the patients who developed full faith in the treating team. This familial bonding led to overcome the hurdle of illiteracy and rural background in majority of patients who were treated for HCV and HBV. Thus, we were able to convince majority of patients and their close contacts for HBV vaccination. Moreover, our institute is a tertiary care center, hence has a big team of 8000 health care workers, thus we had opportunity under NVHCP for free HBV vaccination and thus determining of any side effects associated with it. The common side effects of hepatitis B vaccination include difficulty in moving, general feeling of discomfort or illness, headache, joint pain, muscle aches, cramps, pains, or stiffness, pain or tenderness at the injection site, swollen joints. The less common one is fever or redness or swelling at the injection site. The rare side effects include chest pain or discomfort, inability to move the arms and legs, nausea, pain or discomfort in the arms, jaw, back, or neck, sudden numbness and weakness in the arms and legs, sweating and vomiting, encephalitis, encephalopathy, migraine, multiple sclerosis, neuritis, neuropathy including hypoesthesia, Guillain-Barre syndrome and Bell's palsy, optic neuritis, paralysis, paresis, seizures, syncope, transverse myelitis, vertigo, demyelinating disease of the central nervous system, exacerbation of multiple sclerosis. Currently, most of the research on adverse effects focuses on the safety observation of newly used vaccines and there are few long-term studies on adverse effects of the hepatitis B vaccine [7-10]. Gong etal showed that from 2011 to 2023, a total of 157 cases of adverse effects of hepatitis B vaccine were reported in the surveillance system, and 894,574 doses of hepatitis B vaccine were administered during the same period, with a reporting rate of 17.55/100,000 doses [11]. The main symptoms of adverse events for vaccine product-related reactions were fever, redness and swelling, rash, and induration. Fever is the most commonly reported vaccine product-related adverse reaction following hepatitis B vaccination. This is part of the body's immune response, a useful mechanism that promotes cell, blood vessel, and metabolic defense mobilization, kills viruses, and activates immunity, but it turns into a "disease" above a certain temperature [12]. Because the aluminium adjuvants in the hepatitis B vaccines can increase local inflammatory responses and immune system responses [13], redness swelling, and induration at the recipient's injection site are also common. But it may also have to do with the method of administration. The hepatitis B vaccine is not fully shaken before injection, and the large particles contained in the vaccine are slowly absorbed, leading to a local reaction. In addition, shorter needles or shallow injections increase the risk of vaccine-related local reactions. It is recommended to strengthen the training of vaccinators, standardize the operation of vaccination, and reduce the occurrence of local reactions. In terms of the time interval between vaccination and the occurrence of vaccine product-related reactions, the vast majority of reactions occurred within 3 days. Our study group, the adverse effects reported were minimal, transitory and of very less degree, in alignment with most of previous studies and meta-analysis. In 5000 participants, total 15,000 doses of HBV vaccine were given. The adverse effects noted were temporary soreness at injection site, myalgia or low-grade fever, all of them lasted for one or two days. There were no serious adverse effects pertaining to neurological, cardio-vascular, respiratory system or anaphylactic reactions. Hence, it re confirms that hepatitis B vaccine is totally safe, even in pregnancy, as some family members in our study group were pregnant. This study will allay the fears about adverse events associated with HBV vaccination in mind of health care workers, patients & their family members and high -risk group people.

CONCLUSION

Hepatitis B vaccination is devoid of any serious adverse side effects and wherever indicated, complete course should be given on priority. The breaking of myths associated with HBV vaccination should be broken in society at large should be done by health professionals and recipients of HBV vaccination.

Limitation of Study

The study pool in previous studies and meta-analysis was large in comparison of our study group; hence more larger studies are required for exact determination of adverse effects associated with HBV vaccination.

Conflict of Interest

The authors declare that there was no conflict of interest and no funding was taken from any source to conduct this research.

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