

IMMUNE RESPONSE TO HEPATITIS B VACCINATION IN HAEMODIALYSIS PATIENTS AND HEALTHY MEDICAL STAFF

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SYNOPSIS

The immune response of the medical staff of the Blood Services Centre (BSC), General Hospital, Kuala Lumpur (GHKL) and staff of the Haemodialysis Unit (HDU) and patients in HDU, was studied, after vaccination with Hevac Vaccine.

It was found that 100% (17/17) of the BSC Staff, 92.9% (13/14) of the HDU staff and 80.8% (21/26) of the HDU patients had developed antibodies to the hepatitis surface antigen (anti-HBs) after the third injection of the vaccine. None of the recipients of the vaccine was found to have hepatitis B surface antigen (HBsAg) detected in their blood at any time.

It is concluded that there is a high response rate to hepatitis B vaccination in staff of BSC and HDU. Patients on haemodialysis also showed a good response to the vaccination, with good anti-HBs titres after 3 injections of Hevac B vaccine.

INTRODUCTION

Hepatitis B is an endemic disease in many countries and is a major risk for people who have frequent contacts with human blood e.g. all medical staff members especially in haemodialysis units, blood banks and in laboratories (1). A very high level of HBsAg positivity is quite common in haemodialysis patients and in this the immune response is lower than in healthy people (2). Thus these individuals are prime candidates for hepatitis B prophylactics by active immunization. The present study was designed to follow the immune response of these staff and patients following vaccination.

MATERIALS AND METHODS

Vaccine

The hepatitis B vaccine used in this study was produced by the Institute Pasteur Production. The vaccine was made from purified, concentrated and inactivated HBsAg from healthy chronic carriers negative for HBeAg. Each dose of 1 ml contained 5 ug of HBsAg and was inoculated by the intramuscular route. Three doses of the above were given at monthly intervals.

Conditions of entry

To enter the study, each volunteer must be negative for the following B hepatitis markers namely HBsAg, anti-HBs and anti-HBc.

Condition of exclusion

Positivity of one of the HBV markers would be excluded.

As a result of the above criteria, 17 blood services centre (BSC) staff, 14 haemodialysis staff (HDU) and 26 patients from the HDU were given the vaccines as they were negative for the above markers. Ages of the staff from both the blood services centre and HDU were between 20-40 years while that of the HDU patients were between 14-52 years.

Clinical Test Protocol

The test protocol for this study is shown in Fig. 1. Each recipient was given three inoculations of 5 ug HBsAg at monthly intervals (total 15 ug). Blood sample was withdrawn immediately for tests prior to each inoculation. The tests done were HBsAg, anti-HBs and

anti-HBc, liver function tests and serum transaminases.

LABORATORY METHODS

All HBV markers were tested with commercial RIA reagents supplied by Abbott Laboratories: Austria II for HBsAg, Corab for anti-HBc and Ausab for anti-HBs. Radioactive counting was done on a Packard Auto-gamma Scintillation Spectrometer Model 5110. All serum transaminases and liver function tests were done by the Biochemistry Laboratory, General Hospital, Kuala Lumpur. Transaminase levels of 50 IU/L were considered raised.

HBV events (3)

- HBV events or infection was diagnosed when
- (1) two or more sequential blood specimens were positive for HBsAg followed by anti-HBc, or only one specimen was positive for HBsAg and subsequent specimens were positive for anti-HBc.
 - (2) HBsAg was absent but sequential specimens were positive for anti-HBc.

RESULTS

Anti-HBs response in anti-HBs negative recipients after HB vaccine administration is shown in Fig 2. 35% (6/17) of the BSC, 21.4% (3/14) of the HDU staff and 27% (7/26) of HDU patients were positive for the antibody one month after the first dose was given while 100% (17/17) of BSC, 93% (13/14) of HDU staff and 80% (21/26) of HDU patients were anti-HBs positive three months after the first dose (one month after the third dose was given). Six months later the response was 100% (17/17), 93% (13/14) and 85% (22/26) for the BSC staff, HDU staff

Fig. 1

CLINICAL TEST PROTOCOL

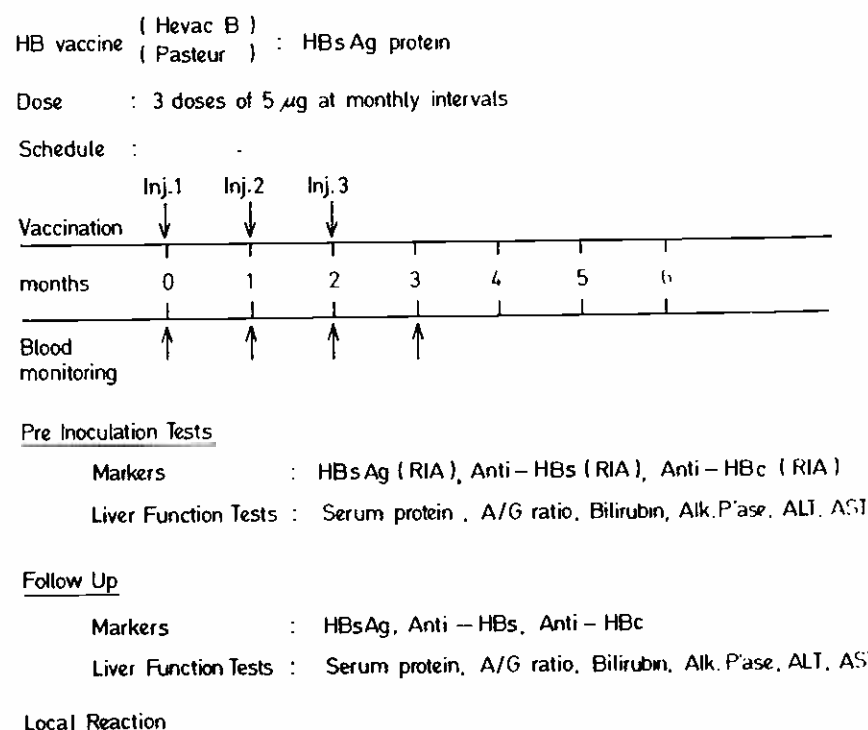


Fig. 2

ANTI HBs RESPONSE IN ANTI HBs NEGATIVE RECIPIENTS AFTER HB VACCINE ADMINISTRATION

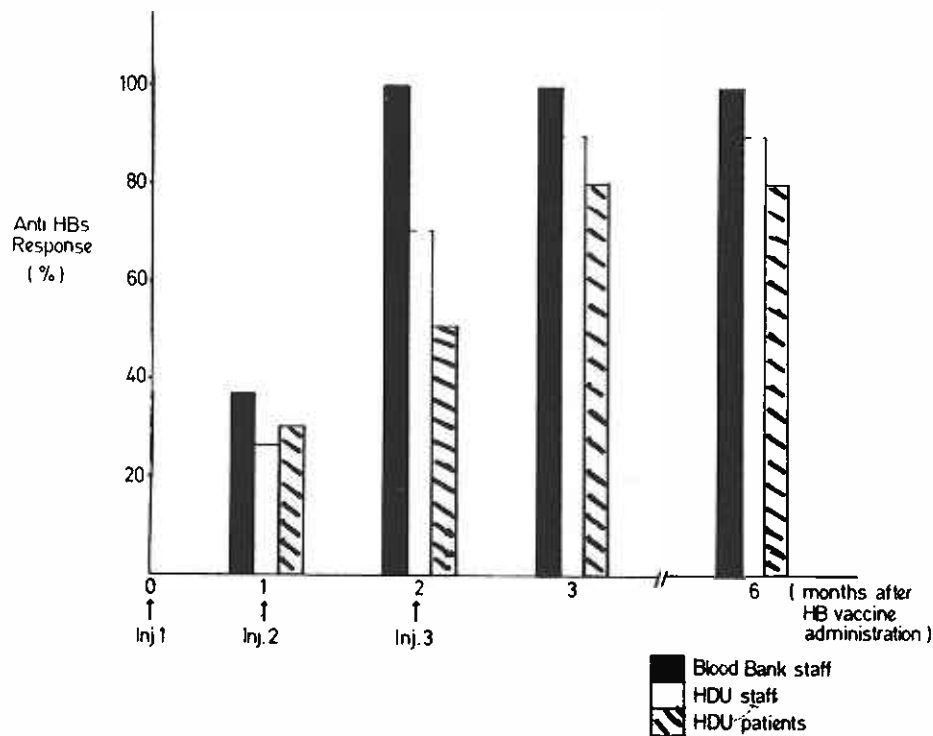


Table 1

Presence of HBsAg, Anti HBc and changes in liver enzymes in recipients after HB vaccine administration.

Category	HBsAg	Anti HBc	ALT	AST
Blood Bank Staff	0 / 17	2 / 17 (11.8%)	6 / 17 (35%)	3 / 17 (18%)
HDU Staff	0 / 14	3 / 14 (21.4%)	6 / 14 (43%)	1 / 14 (7%)
HDU Patients	0 / 26	6 / 26 (23.1%)	15 / 26 (58%)	5 / 26 (19%)

and HDU patients respectively.

The presence of HBsAg, anti-HBc and changes in liver enzymes in the recipients are shown in Table 1. None of the recipient had HBsAg in their blood at any one time. Anti-HBc was detected in 11.8% (2/17), 21.4% (3/14) and 23.1% (6/26) of BSC staff, HDU staff and HDU patients respectively.

35% (6/17) of BSC staff, 43% (6/14) of HDU staff and 58% (15/26) of HDU patients had raised ALT (alanine aminotransaminase) while 18% (3/17), 7% (1/14) and 19% (5/26) of BSC staff, HDU staff and HDU patients respectively had raised AST (aspartate aminotransaminase). The raised enzyme levels were observed after the first dose, second dose or the third dose was given i.e. there was no correlation between the raised enzyme levels and the period of inoculation. ALT levels were still raised in three BSC staff (two of these had raised

AST as well), one HDU staff and two HDU patients after the sixth month.

DISCUSSION

The aim of this trial was to compare the immune response induced by three vaccination schedules in haemodialysis patients and staff of both the haemodialysis unit and the blood services centre of the General Hospital, Kuala Lumpur.

As seen from the results, the response of both staff and patients was good, with 97% of the staff and 85% of patients developing anti-HBs six months after the first injection. The staff immune response was comparable to that reported by Crosnier et al (3) who, using a similar protocol and vaccines produced by the Institute Pasteur Production, found that 94% of the

vaccine recipients responded. However, the immune response of our haemodialysis patients is higher than that reported by the same group (4) who found that only 60% of the haemodialysis patients had responded to the vaccine. Stevens et al (2) and Desmyter et al (5) using a different protocol and dose concentration reported a response rate of 80% and 88% respectively.

It is interesting to note that the non-responders in the patients are all in the higher age group (above 30 years). This age effect on the response had also been reported by Crosnier et al (4).

From the results it appears that two of the BSC staff, three of the HDU staff and six of the HDU patients had an HBV event (3). There was no correlation between HBV events and serum transaminases. Some recipients had an HBV event without raised serum transaminases while others did not have an HBV event but had raised serum transaminases. Such an observation had been reported by Desmyter et al (5) who found that 12 of the 197 vaccine recipients had raised ALT levels not associated with an HBV event and not attributed to an extrahepatic cause.

From this study we found that the Institute Pasteur Production vaccine was effective in eliciting high antibody response in haemodialysis patients as well as in healthy medical staff.

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