

# IMMUNOGENICITY OF HEPATITIS B VACCINE IN MEDICAL AND PARAMEDICAL PERSONNEL IN IRAN

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*Abstract* - Seroresponse to the full three - dose of the hepatitis B vaccine (Engerix-B) was studied in 138 medical and paramedical staff from Tehran. The vaccine was found to be highly immunogenic. Seroconversion rates, seroprotection rates and geometric mean titer were found to be 98.5%, 90% and 902.5 mIU/ml, respectively. This is the first report of sero-response in normal Iranian subjects to the hepatitis B vaccine.

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*Key Words:* Hepatitis B Vaccine, healthcare worker, seroconversion rate, seroprotection rate, immunogenicity

## INTRODUCTION

Hepatitis B virus infection is an occupational hazard for health care workers who have long-term or continuous exposure to human blood (1,2,3). Many of the infections caused by hepatitis B virus are subclinical and not associated with an easily identifiable source of infection (4). Because, prophylaxis with hepatitis B immunoglobulin after exposure has limited effectiveness (5), efforts have been directed at active immunization with hepatitis B vaccine before exposure (6).

Studies of hepatitis B vaccine in health care personnel and other high-risk groups indicate that the vaccine is, effective and immunogenic (7-8).

Iranian medical and paramedical personnel were immunized since 1370 (1991) (center for disease control, Department of health and human services, Tehran, Iran).

## MATERIALS AND METHODS

Hepatitis B Vaccine (Engerix - B) from Heber Biotec, S.A. Havana, Cuba was offered free to the medical and paramedical personnel working in Tehran University hospitals since 1370 (1991).

The vaccination programme was undertaken by the state. Without any prior screening for HBsAg, the vaccine was administered to the personnel.

The personnel had been vaccinated with three 20 - µg doses of hepatitis B vaccine intramuscularly in the deltoid region at 0, 1, and 6 months.

This study was performed in 1377 (98-99) at Amirkabir and Bahrami Hospitals. The eligible subjects were to have no history of hepatitis B or chronic liver disease, no serologic markers of past hepatitis B virus infection (antibody to hepatitis B core antigen, anti-HBc). Serum samples were obtained within 4 weeks of entry into the trial. 191 health care workers were screened, 162 were eligible (29 were anti - HBc positive and were excluded fig. 1. Twenty four previously received one or two doses of vaccine and were therefore had excluded; 138 cases ultimately entered the study.

### Laboratory methods

Levels of antibody to hepatitis B surface antigen (anti - HBs) were quantified by calculating estimated radioimmunoassay (RIA) units. To minimize interassay variation, anti - HBs levels were quantified by calculating estimated RIA units and multiplying by a dilution factor, as directed by the manufacturer. 40 estimated RIA units have been shown to be equivalent to approximately 10 mIU of anti - HBs (Miller WJ. Merck Sharp & Dohme Research laboratories, personal, 1981)

## RESULTS

138 employees (37 male, 101 female), who ranged in age from 19 to 65 years with a mean age of 38.8 years had received three doses of hepatitis B vaccine (55 in Amirkabir, 83 in Bahrami hospital).

The seroconversion rate for anti HBs was 98.5% (136 of 138) with seroprotection rate of 90% (124 of 138).

At the time of this study, geometric mean titers (GMT) of anti-HBs was 902.5 mIU/ mL.

Adults over 50 years of age responded less well than younger adults (Fig. 2) and GMTs in females are higher than those in males (Fig. 3.4). It was found that smoking significantly affected their antibody titer responses adversely (Fig. 5).

Figure 6 represents GMT in the different groups of personnel.

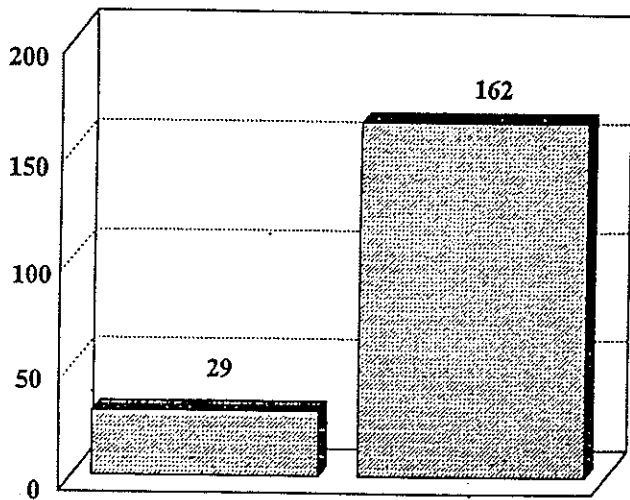


Fig. 1- Anti-HBC positive and negative subjects in the study

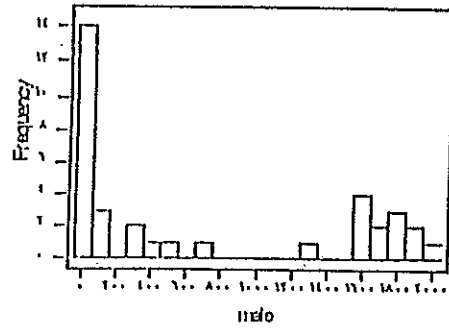


Fig. 3- GMT of anti-HBS in male

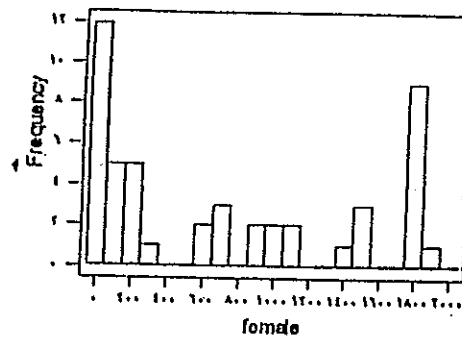


Fig. 4- GMT of anti-HBS in female

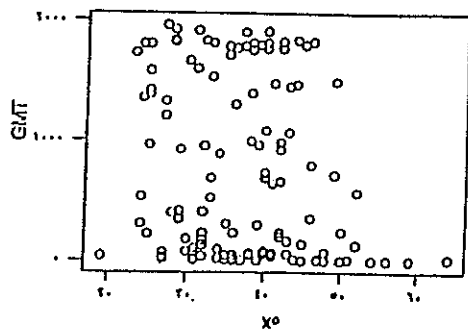


Fig. 2- The effect of age on GMT

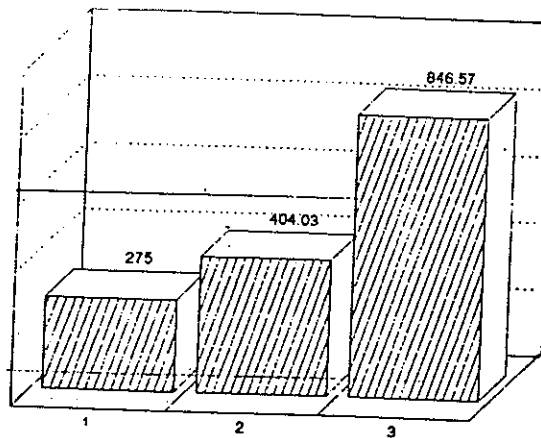


Fig. 5- The effect of smoking on GMT

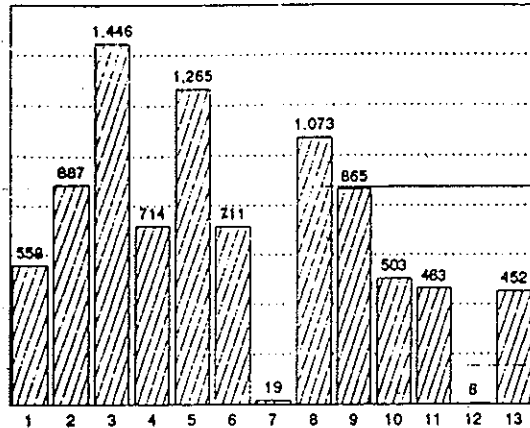


Fig. 6- GMT in the different groups of personnels.

## DISCUSSION

The recombinant DNA vaccine of hepatitis B has been shown to be highly immunogenic (9). The immunogenicity of vaccine is generally evaluated according to three parameters: seroconversion rate, seroprotection rates, and geometric mean anti - HBs antibody titers (GMT).

Seroconversion or seropositivity is defined as an increase in antibody titer (anti-HBs) from an undetectable amount to a level above the assay cut - off which is usually 1 mIU/ ML. Seroprotection was considered to have occurred if concentration of the anti-HBs antibody reached or exceeded 10 mIU/ml.

The GMT is calculated using the log - transformation of titers > 1 mIU/ml for anti-HBs and taking the anti-log of the mean of these transformed values (10).

The vaccine was highly immunogenic. Seroconversion rate was 98.5%: more than that seen in most studies, approximately 78% to 96.5% (11,12,13,14).

In two different reports, seroconversion rate were reported to be 100% (15-16).

81-100% seroprotection has been shown in different studies (17,18,19). In our study, seroprotective anti-HBs titers persisted in 90% of subjects (52% of subjects were vaccinated for 1-3 years, 31% for 3-5 years and 17% for > 5 years) mean GMT was 902.5 and higher in females than males.

These findings are similar to other studies in different parts of the world (20,21). We also confirmed that smoking could significantly affect the antibody titers(22). As in previous controlled studies (10,11,12,17,19), our findings support the high immunogenicity hepatitis B vaccine in medical and

paramedical personnel in Iran.

Failure to develop adequate antibodies may be related to freezing the vaccine or giving it in the buttock rather than the deltoid region.

A poor antibody response is seen in the aged and in the immunocompromised including HIV - positive persons.

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