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Immunization with recombinant hepatitis B vaccine in Japanese

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Introduction

Healthcare workers (HCW) are at high risk of acquiring hepatitis B virus (HBV) infection trough occupational exposure to blood or body fluids. Japanese Society for Infection Prevention and Control renewed the guideline of vaccination for HCW in 2014, however evidence of Japanese HCW was not enough[1-4]. Japanese summary basis of approval of recombinant HBV vaccine (Heptavax ®) showed that 95.0% (662/697) of Japanese HCW had anti-HBs titer >10mU/ml by intramuscular vaccination and 90.2% (776/860) by intradermal vaccination[5]. Universal vaccination in infants or children is not performed in Japan.

Purpose

This retrospective observation study was aimed to analyze the risk factors for failure to develop adequate levels of antibodies (anti-HBs titer >10mU/ml) in Japanese HCWs.

Methods

A total of 2,394 HCWs and medical students of Osaka Medical College were enrolled for study of a primary vaccine course (10 mg of recombinant HB vaccine injection at 0, 1, and 6 months). 1,225 persons were injected intramuscularly, and 1,169 persons were injected subcutaneously.
Second vaccine course was recommended to non-responders (anti-HBs titer <10mU/ml).
The protocol was approved by the independent ethics committee of Osaka Medical College.
P value of <0.05 was considered statistically significant.

Results

There was no significant difference in response rate between the intramuscular vaccination (91.8%, 1,124/1,225) and intradermal vaccination (91.8%, 1,074/1,169) (Figure 1).
The response rate to the primary vaccine course was 96.3% (660/685) among teens, 92.0% (1248/1356) among those in their twenties, 87.0% (134/154) among those in their thirties, and 83.8% (155/185) among those over 40 years of age (Figure 2). There was a significant difference in response rate ($p<0.05$) between those in their teens, twenties and thirties. There was a significant difference of response rate ($p<0.05$) between those in their teens and over forty, twenties and over forty, however there was no significant difference of response rate between those in their thirties and over forty.
The overall response rate to the second vaccination course was 87.3% (83/95) (Figure 3). The response rate to the second vaccination course was 88% (66/75) among twenties, 83% (10/12) among thirties, and 88% (7/8) over 40 years of age (Figure 4).
There was no significant difference in response rate to the second vaccination course between those in their twenties, thirties, and over forty.
The response rate to the second vaccination course for those with low titer (>1mU/ml) before the second vaccination course was 100% (32/32), and those with very low titer (<1mU/ml) was 89.5% (51/57) (Figure 5). The response rate to the second vaccination course for those with no titer (0mU/ml) was 80% (12/15) , and the response rate of those with no titer was significantly lower than the response rate for those who had a low titer (>1mU/ml).

Figure 1

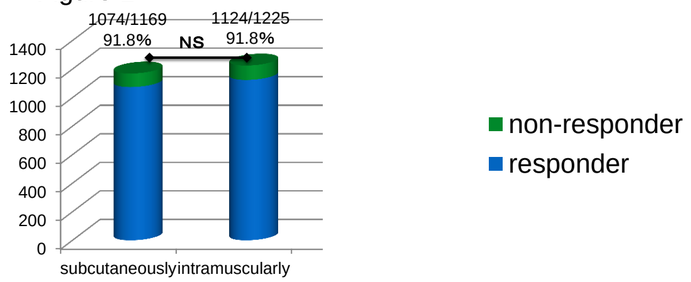


Figure 2

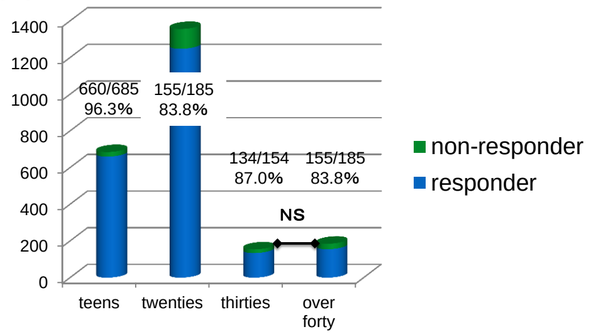


Figure 3

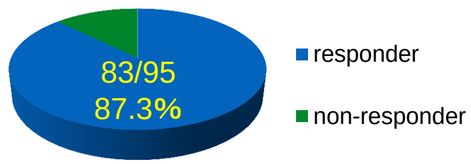


Figure 4

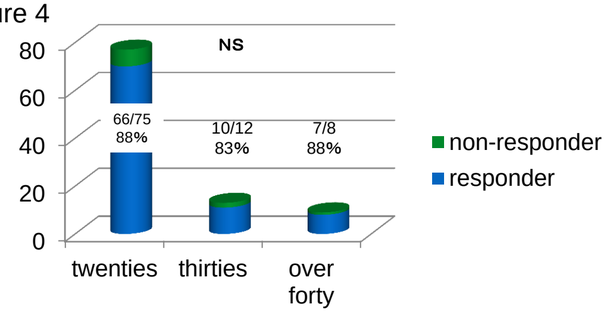
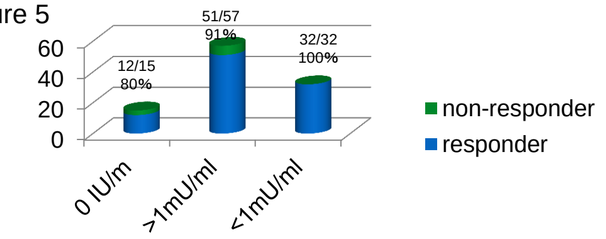


Figure 5



Discussuion

Aging was a risk factor for non-response in Japanese in a primary vaccination course, however aging was not a risk factor for non-response in second vaccination course. It was suggested that genetic non-responder may exist at certain proportion in all generation. The response rate to the second vaccination course for those with no titer (0mU/ml) was 80% (12/15), and the response rate of those with no titer was significantly lower than the response rate for those who had a low titer (>1mU/ml).

Conclusion

There was no significant difference between the response rates to the intramuscular and subcutaneous vaccinations, and aging was a risk factor for non-response in Japanese. An anti-HBs titer of 0mU/ml after a primary vaccination course may be a risk factor for non-response to a second vaccination course.

References

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Conflict of interest

Akira Ukimura received research funding from Pfizer Japan Inc.

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