
A case-control study of serious autoimmune adverse events following hepatitis B immunization.

Geier DA, Geier MR.

Source

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Abstract

Hepatitis B infection is one of the most important causes of acute and chronic liver disease. During the 1980s, genetically engineered hepatitis B vaccines (HBVs) were introduced in the United States. A large-series of serious autoimmune conditions have been reported following HBVs, despite the fact that HBVs have been reported to be "generally well-tolerated." A case-control epidemiological study was conducted to evaluate serious autoimmune adverse events prospectively reported to the vaccine adverse events reporting system (VAERS) database following HBVs, in comparison to an age, sex, and vaccine year matched unexposed tetanus-containing vaccine (TCV) group for conditions that have been previously identified on an a priori basis from case-reports. Adults receiving HBV had significantly increased odds ratios (OR) for multiple sclerosis (OR = 5.2, p < 0.0003, 95% Confidence Interval (CI) = 1.9 - 20), optic neuritis (OR = 14, p < 0.0002, 95% CI = 2.3 - 560), vasculitis (OR = 2.6, p < 0.04, 95% CI = 1.03 - 8.7), arthritis (OR = 2.01, p < 0.0003, 95% CI = 1.3 - 3.1), alopecia (OR = 7.2, p < 0.0001, 95% CI = 3.2 - 20), lupus erythematosus (OR = 9.1, p < 0.0001, 95% CI = 2.3 - 76), rheumatoid arthritis (OR = 18, p < 0.0001, 95% CI = 3.1 - 740), and thrombocytopenia (OR = 2.3, p < 0.04, 95% CI = 1.02 - 6.2) in comparison to the TCV group. Minimal confounding or systematic error was observed. Despite the negative findings of the present study regarding the rare serious adverse effects of HBVs, it is clear that HBV does, indeed, offer significant benefits, but it is also clear that chances of exposure to hepatitis B virus in adults is largely life-style dependent. Adults should make an informed consent decision, weighing the risks and benefits of HBV, as to whether or not to be immunized.

Multiple sclerosis and hepatitis B vaccination: adding the credibility of molecular biology to an unusual level of clinical and epidemiological evidence.

Comenge Y, Girard M.

Source

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Abstract

In spite of a huge number of reports of severe hazards after injection of hepatitis B vaccine (HBV), the issue is regularly raised that no mechanism is available for the development of central demyelinating disorders such as multiple sclerosis (MS). A number of convergent facts, however, suggests that the manufacturing process could introduce HBV polymerase as a contaminant, and then trigger an auto-immune process against myelin in some vaccinated subjects. Of great significance, this hypothesis is likely to give the missing link to account for the considerable body of clinical and epidemiological evidence documenting that, for a drug used with a preventive purpose, HBV has an unusual potential to induce central neurological disorders amongst others unwanted side-effects.


Concurrent HLA-related response factors mediate recombinant hepatitis B vaccine major adverse events.

Miller JD, Whitehair LH.

Source

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Abstract

Recombinant hepatitis B (HB) vaccines have successfully reduced infection, cirrhosis and carcinoma, but questions have endured about causality of serious adverse events following vaccination. After an event in a pediatric patient an investigation reviewed HLA vaccine response effects and analyzed genetics in reported cases. There are apparent common causal immune mechanisms among reported adverse events. HLA class II alleles/haplotypes linked to HB vaccine cellular/non-response and Crohn's disease can create conditions that actively/passively amplify, respectively, all or other components of the immune response to the HB vaccine. Presence of the HLA class I allele A2 can result in heavy cytotoxic T-cell activation and vaccine/self-peptide presentation to immune cells. If HLA autoimmune susceptibility alleles/haplotypes are present that control other immune response components, the probability is elevated that these will activate cross-reactive immune cells; the cells, their inflammatory secretions and/or auto-antibodies may initiate adverse events reflecting those susceptibilities. Probable DRB1 amplifying alleles are noted. High-resolution DNA typing and results analysis are described to test the hypothesis in known HB vaccine adverse event patients. Possible practical applications stemming from hypothesis validation are described.

Send to:

Autoimmune hazards of hepatitis B vaccine.

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Source
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Abstract

According to Hippocratic tradition, the safety level of a preventive medicine must be very high, as it is aimed at protecting people against diseases that they may not contract. This paper points out that information on the safety of hepatitis B vaccine (HBV) is biased as compared to classical requirements of evidence-based medicine (EBM), as exemplified by a documented selectivity in the presentation or even publication of available clinical or epidemiological data. Then, a review is made of data suggesting that HBV (hepatitis B vaccine) is remarkable by the frequency, the
severity and the variety of its complications, some of them probably related to a mechanism of molecular mimicry leading to demyelinating diseases, and the others reproducing the spectrum of non-hepatic manifestations of natural hepatitis B. To be explained, this unusual spectrum of toxicity requires additional investigations based upon complete release of available data.


A one year followup of chronic arthritis following rubella and hepatitis B vaccination based upon analysis of the Vaccine Adverse Events Reporting System (VAERS) database.

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Source
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Abstract

OBJECTIVES:

This analysis examined the incidence rate of chronic arthritis adverse reactions reported following adult rubella and hepatitis B vaccinations. In this analysis, etiologic mechanisms for chronic arthritis following adult rubella and hepatitis B vaccines were also explored.

METHODS:

The Vaccine Adverse Events Reporting System (VAERS) database was analyzed for the incidence rate of reported cases of chronic arthritis in comparison to Tetanus-diphtheria (Td) and tetanus toxoid adult vaccine control groups.

RESULTS:

Chronic arthritis adverse reactions following adult rubella vaccination were primarily reported in females (female/male ratio = 3.0), at about 45 years-old, and at a mean onset time of 10-11 days following vaccination. Chronic arthritis adverse reactions
following adult hepatitis B vaccination were also primarily reported in females (female/male ratio = 3.5), at about 33 years-old, and with a mean onset time of 16 days following vaccination. The incidence rates of chronic arthritis following adult rubella and adult hepatitis B vaccinations were statistically significantly increased, by chi 2 analysis, in comparison to the adult vaccine control groups. The attributable risk of chronic arthritis following adult rubella vaccine ranged from 32 to 53 and from 5.1 to 9.0 following adult hepatitis B vaccine in comparison to the adult vaccine control groups.

CONCLUSION:

This study revealed that adult rubella and adult hepatitis B vaccines were statistically associated with chronic arthritis which persisted for at least one year. The etiology for these adverse reactions may involve autoimmune mechanisms. Furthermore, potential biases in the reporting rates of adverse reactions to VAERS were not observed.


Vaccination and systemic lupus erythematosus: the bidirectional dilemmas.

Aron-Maor A, Shoenfeld Y.

Source

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Abstract

Vaccination has been perhaps the most important achievement in medicine of the last century. A hoard of infectious diseases that used to claim the lives of many, especially children, have been prevented and some even eradicated. However, it is possible that within this gift there is hidden a 'Trojan Horse'. During the last decade increasing numbers of reports regarding possible autoimmune side effects of vaccination, have been published. The existing data does not link the vaccines and the autoimmune phenomena observed in a causal relationship, nevertheless a temporal connection has been described. In this article we wish to address in particular the possible link between vaccines and systemic lupus erythematosus (SLE), namely two aspects of this inter-relationship: the occurrence of SLE following
vaccination and outcome of immunization of known SLE patients.


**Vaccination and autoimmunity- 'vaccinosis': a dangerous liaison?**

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**Source**

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**Abstract**

The question of a connection between vaccination and autoimmune illness (or phenomena) is surrounded by controversy. A heated debate is going on regarding the causality between vaccines, such as measles and anti-hepatitis B virus (HBV), and multiple sclerosis (MS). Brain antibodies as well as clinical symptoms have been found in patients vaccinated against those diseases. Other autoimmune illnesses have been associated with vaccinations. Tetanus toxoid, influenza vaccines, polio vaccine, and others, have been related to phenomena ranging from autoantibodies production to full-blown illness (such as rheumatoid arthritis (RA)). Conflicting data exists regarding also the connection between autism and vaccination with measles vaccine. So far only one controlled study of an experimental animal model has been published, in which the possible causal relation between vaccines and autoimmune findings has been examined: in healthy puppies immunized with a variety of commonly given vaccines, a variety of autoantibodies have been documented but no frank autoimmune illness was recorded. The findings could also represent a polyclonal activation (adjuvant reaction). The mechanism (or mechanisms) of autoimmune reactions following immunization has not yet been elucidated. One of the possibilities is molecular mimicry; when a structural similarity exists between some viral antigen (or other component of the vaccine) and a self-antigen. This similarity may be the trigger to the autoimmune reaction. Other possible mechanisms are discussed. Even though the data regarding the relation between vaccination and autoimmune disease is conflicting, it seems that some autoimmune phenomena are clearly related to immunization (e.g. Guillain-Barre syndrome). The issue of the risk of vaccination remains a philosophical one, since to date the advantages of this policy have not been refuted, while the risk for autoimmune disease has not been irrevocably proved. We discuss the pros and cons of this issue (although the temporal relationship (i.e. always 2-3 months following immunization) is impressive).
Rheumatology disorders developed after hepatitis B vaccination.


Source

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Abstract

OBJECTIVE:

To obtain an overview of rheumatic disorders occurring after hepatitis B vaccination.

METHODS:

A questionnaire was sent to rheumatology departments in nine French hospitals. Criteria for entry were rheumatic complaints of 1 week's duration or more, occurrence during the 2 months following hepatitis B vaccination, no previously diagnosed rheumatic disease and no other explanation for the complaints.

RESULTS:

Twenty-two patients were included. The observed disorders were as follows: rheumatoid arthritis for six patients; exacerbation of a previously non-diagnosed systemic lupus erythematosus for two; post-vaccinal arthritis for five; polyarthralgia-myalgia for four; suspected or biopsy-proved vasculitis for three; miscellaneous for two.

CONCLUSIONS:

Hepatitis B vaccine might be followed by various rheumatic conditions and might trigger the onset of underlying inflammatory or autoimmune rheumatic diseases. However, a causal relationship between hepatitis B vaccination and the observed rheumatic manifestations cannot be easily established. Further epidemiological studies are needed to establish whether hepatitis B vaccination is associated or not with an incidence of rheumatic disorders higher than normal.
Hepatitis B vaccine and the risk of CNS inflammatory demyelination in childhood.

Mikaeloff Y, Caridade G, Suissa S, Tardieu M.

Source

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Abstract

BACKGROUND:

The risk of CNS inflammatory demyelination associated with hepatitis B (HB) vaccine is debated, with studies reporting conflicting findings.

METHODS:

We conducted a population-based case-control study where the cases were children with a first episode of acute CNS inflammatory demyelination in France (1994-2003). Each case was matched on age, sex, and geographic location to up to 12 controls, randomly selected from the general population. Information on vaccinations was confirmed by a copy of the vaccination certificate. The odds ratios (ORs) of CNS inflammatory demyelination associated with HB vaccination were estimated using conditional logistic regression.

RESULTS:

The rates of HB vaccination in the 3 years before the index date were 24.4% for the 349 cases and 27.3% for their 2,941 matched controls. HB vaccination within this period was not associated with an increase in the rate of CNS inflammatory demyelination (adjusted OR, 0.74; 0.54-1.02), neither >3 years nor as a function of the number of injections or brand type. When the analysis was restricted to subjects compliant with vaccination, HB vaccine exposure >3 years before index date was associated with an increased trend (1.50; 0.93-2.43), essentially from the Engerix B vaccine (1.74; 1.03-2.95). The OR was particularly elevated for this brand in patients with confirmed multiple sclerosis (2.77; 1.23-6.24).

CONCLUSIONS:
Hepatitis B vaccination does not generally increase the risk of CNS inflammatory demyelination in childhood. However, the Engerix B vaccine appears to increase this risk, particularly for confirmed multiple sclerosis, in the longer term. Our results require confirmation in future studies.


**[Pharmacovigilance of hepatitis B vaccines].**

[Article in French]

Imbs JL, Decker N, Welsch M.

**Source**

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**Abstract**

Since the hepatitis B vaccine are on the market in France, until the end of 2002, 1211 observations of demyelinating disease of the central nervous system (1109 cases of which 895 multiple sclerosis) or peripheral (102 cases of which 49 Guillain Barre Syndrome), have been reported to the french network of pharmacovigilance and to the AFSSAPS. It is not possible to singularize these observations, neither from a clinical nor an epidemiological point of view. No risk factor has been detected. Only the chronology could suggest a causal relationship, the vaccine preceding the pathology in all the cases notified.


**Encephalitis after hepatitis B vaccination: recurrent disseminated encephalitis or MS?**


**Source**
Abstract

OBJECTIVE:

To describe clinical and MRI features of patients with a disease suggestive of CNS inflammation after hepatitis B vaccination.

METHODS:

Eight patients with confirmed CNS inflammation occurring less than 10 weeks after hepatitis B vaccination are described. They received follow-up clinically and on MRI for a mean period of 18 months.

RESULTS:

Clinical and MRI findings were compatible with acute disseminated encephalomyelitis. However, clinical follow-up, repeated MRI, or both showed the persistence of inflammatory activity, which makes this encephalitis more suggestive of MS than of acute disseminated encephalomyelitis.

CONCLUSION:

The persistent inflammatory activity observed clinically and on MRI in these patients is comparable with that usually observed in MS. Epidemiologic studies are currently testing the hypothesis of a triggering role of hepatitis B vaccination in CNS demyelination.

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