Hepatitis B vaccine and the risk of CNS inflammatory demyelination in childhood.

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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.

Comment in

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