

Acute disseminated encephalomyelitis following vaccination. Epidemiological evaluation based on passive adverse events reporting systems

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Acute disseminated encephalomyelitis (ADEM) is an immune mediated inflammatory disorder of the central nervous system (CNS), which commonly occurs after one month from antigenic challenge in children (Tenembaum, 2007). ADEM occurring post vaccination is instead a rare event (5% of all cases) and systematic information on it is unavailable.

The main objective of this study was to evaluate epidemiological features of post vaccine ADEM considering data from VAERS database for domestic and non-domestic adverse event following immunisation (AEFI). AEFI databases were searched to identify post vaccine ADEM cases. Further cases from our pharmacovigilance centre were also included in the analysis.

Database search retrieved 236 cases of ADEM following immunization. For each patient one or more vaccines were suspected to be the causal agent of ADEM, resulting in 353 suspect vaccines. 70% of the cases were classified as 'probable', 'possible' or 'unlikely', while only 15% were found to be 'unrelated' or 'unclassifiable'. Half of the patients had less than 18 years and a male predominance was observed. The time interval from immunisation to ADEM onset was 2-30 days in 61% of the cases, while 37 patients (19%) developed ADEM after one month. Mean number of reports per year between 2005 and 2012 was 40 ± 21.7 with a general increase until 2009. Diphtheria, Pertussis, Tetanus, Polio, and Haemophilus Influenzae type b (DTaP+IPV+HiB) were the most frequently suspected vaccines (21%). Since 2010, the frequency of ADEM reporting per year has decreased mainly due to a reduction of reports associated with HPV and DTaP+IPV+HiB vaccines. This diminishing trend is in contrast with data regarding vaccine coverage and could be caused by a lower interest within this AEFI, which is a known cause of under-reporting. In the 0-5 years age group, the most commonly involved vaccines were the DTaP+IPV+HiB (30%) and MMRV+MMR+MEA (16%) groups. Vaccines from HPV(2&4) and MEN+MNQ groups were the most frequently suspected causes of ADEM in 6-17 years age group while seasonal flu vaccine was the most frequently suspected cause of ADEM after 18 years.

Post vaccine ADEM may occur at any age with a distribution more consistent with general vaccine exposure during lifetime than within a specific age group. Our findings do not support the belief that ADEM following vaccination is more common in child and highlight the aetiological role of different vaccines during lifetime.

Tenembaum S (2007). Neurology. 17. S23-36