Hepatitis A Vaccine Found Safe for 12-Month-Olds

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The hepatitis A vaccine is immunogenic and generally well tolerated in healthy 12-month-old children and can be administered concomitantly with certain other vaccines, Dr. Fernando A. Guerra of the San Antonio Metropolitan Health District and his associates said.

"The immunogenicity and safety data collected in this study support the administration of hepatitis A vaccine as early as 12 months of age, regardless of initial hepatitis A serostatus, …concomitantly with measles, mumps, and rubella vaccine and poliovirus vaccines," wrote Dr. Guerra and his colleagues (Pediatr. Infect. Dis. J. 2006;25:912-9). "The study is insufficient to assess the immunogenicity of varicella vaccine and DTaP [diphtheria-tetanus-acellular pertussis] vaccine when administered concomitantly with hepatitis A vaccine."

In the open-label study, the researchers randomized 503 healthy 12-month-old children to receive hepatitis A vaccine with or without measles, mumps, and rubella (MMR) and varicella zoster virus (VZV) vaccines (with dose one) and diphtheria-tetanus-acellular pertussis (DTaP) vaccine (with dose two). Children in the concomitant vaccine group could have also optionally received oral or inactivated poliovirus vaccine with dose two.

The immunogenicity of the hepatitis A vaccine was acceptable in this young population. With observed seropositive rates of 98.3% and 100% after the first and second doses, respectively, the vaccine appeared as immunogenic in 12-month-old children as it is in children 2-3 years of age.

Geometric mean antibody titers were similar among the 40 initially seropositive children (6,207 mIU/mL) and the 259 initially seronegative children (6,810 mIU/mL), which suggested that the presence of maternal antibodies does not affect responses to the vaccine. However, the researchers noted that many factors, including the concentration of maternal antibodies at vaccination, could affect immunogenicity outcomes.

Concomitant administration of hepatitis A and MMR vaccines did not appear to affect seropositive rates or geometric mean titers to either vaccine in either combination. The seropositive rates were 95.5% for hepatitis A, 98.8% for measles, 99.6% for mumps, and 100% for rubella.

Although the concomitant administration of hepatitis A and DTaP vaccines yielded acceptable response rates to hepatitis A (100%), diphtheria (98.6%), tetanus (100%), and filamentous hemagglutinin (83.3%) , the response rate for pertussis toxoid (PT) was 76%, which is lower than the historical rate of 85%. The investigators hypothesized that early timing of the prevaccination blood draw resulted in higher preboost antibody titers, which could have prevented them from seeing an adequate increase for PT.

Study-related problems may have contributed to a failure to detect adequate responses to the VZV vaccine. Only 79% of children concomitantly immunized with hepatitis A and VZV vaccines developed antibody responses to VZV, a rate lower than the 90% historical rate.

Polio antibody response rates of 98%-100% were reported after 4 weeks in the 189 subjects who received both vaccinations. Antibody titers increased at least 30-fold after administration of the poliovirus vaccine booster dose at age 18 months.

The researchers reported two potentially vaccine-related serious clinical adverse events; both were febrile seizures that occurred 9 days after vaccination. One child had received hepatitis A, MMR, and varicella vaccines, whereas the other had received MMR and varicella vaccines. Neither child discontinued participation in the study.

The most common injection site adverse events reported in the first 4 days after the first hepatitis A vaccine dose were pain, tenderness, and soreness, which occurred in 1.3%-4.8% of children across the treatment groups. Between 2.7% and 6.2% of children in each group developed a temperature higher than 102 ° F within that period.

The most common systemic adverse events that were reported across treatment groups in the 42 days following the first dose of hepatitis A vaccine were fever (22%-25%), upper respiratory tract infection (8%-16%), and otitis media (6%-12%). About one-third of children with systemic adverse events were considered to have vaccine-related events.

Safety outcomes were similar after the second dose of hepatitis A vaccine. ■