DTaP-HepB-IPV Can Be Given With Hb, PCV-7

BY DIANA MAHONEY
New England Bureau

RotaTeq® (Rotavirus, Live, Oral, Pentavalent)

BRIEF SUMMARY OF PRESCRIBING INFORMATION

CONTRAINdications

Contraindicated in patients with a history of severe allergic reaction, such as anaphylaxis, to any component of the vaccine. DTaP-HepB-IPV is indicated for the prevention of rotavirus disease in infants and young children 6 weeks of age through 11 months of age. The vaccine should not be given to infants who have previously received RotaTeq®.

PRECAUTIONS

Children with severe immune defects, including agammaglobulinemia, asplenia, or congenital dysgammaglobulinemia should not receive DTaP-HepB-IPV. The effects of DTaP-HepB-IPV in children with mild immune defects or immune deficiencies are not known. Immunocompromised Patients: No safety or efficacy data are available for the treatment of children who are immunocompromised. Children with immunodeficiency conditions, including those with cell-mediated defects, or those with severe combined immunodeficiency (SCID) are at increased risk of viral vector or vaccine virus infection and should not be vaccinated with DTaP-HepB-IPV.

Immunizations in Infants and Young Children: Infantile Hemangiomas: Children with infantile hemangiomas should not receive DTaP-HepB-IPV. It is not known whether this vaccine will increase the risk of hypoglycemia in infants with this condition. Transient Febrile Reaction: DTaP-HepB-IPV may be given with other vaccines without regard to the order of administration.

Soluble Adverse Events:

Diarrhea: The most common adverse event was diarrhea, which was observed at similar rates in vaccine (N=6,138) and placebo (N=5,573) recipients (42.6% vs. 42.8%). The incidence of severe diarrhea was 0.1% (10/6,138) in vaccine recipients and 0.0% (1/5,573) in placebo recipients. The most common treatment-related diarrhea was mild and resolved spontaneously. The incidence of diarrhea was higher in vaccine recipients on the first day of life with a peak incidence of 5.4% on the first day and 3.4% on the second day. Diarrhea rates in placebo recipients were 5.3% and 3.5% on the first and second days, respectively. The incidence of diarrheal episodes attributable to rotavirus infection was estimated to be 0.1% (6/6,138) in vaccine recipients and 0.0% (1/5,573) in placebo recipients. The incidence of rotavirus disease was 0.1% (6/6,138) in vaccine recipients and 0.0% (1/5,573) in placebo recipients.

Intussusception:

Intussusception was the only serious adverse event that occurred at a significant rate in vaccine recipients, 0.08% (5/6,138) in vaccine recipients and 0.00% (0/5,573) in placebo recipients. There have been no reported cases of intussusception in recipients of DTaP-HepB-IPV. Intussusception occurs in all age groups, but is more common in infants 2 to 6 months of age and most often seen within 8 weeks after the first dose of a rotavirus vaccine. Intussusception is usually detected on abdominal radiographs and the diagnosis is confirmed by barium enema or contrasted enema. The infant can usually be treated with a single dose of oral fluid and may return to normal bowel function in 2 to 3 days with no lasting sequelae. Intussusception is a recognized adverse reaction of DTaP-HepB-IPV.

Immunologic:

The immunogenicity of DTaP-HepB-IPV was at least as good as that achieved with separate vaccines. DR. PICHICHERO

Chlamydia Screening Guidelines Close to Agreement

Updated U.S. Preventive Services Task Force guidelines on chlamydia infection detection recommend screening all sexually active, nonpregnant women aged 24 years and younger, as well as older women at increased risk for disease. While there were many significantly higher rates of fever observed in the overall population, there were no significant differences in rates of fever at a fever of 38.5°F (102.0°C) or higher, and the fevers were short in duration, the authors said. Additionally, while the rates of irritability and some symptoms were similar, there was no clear difference in the rates of symptoms for which parents sought medical advice, they said.

Immunogenicity of the combination vaccine was at least as good as that achieved with separate vaccines.

DTaP-HepB-IPV was at least as good as that achieved with separate vaccines.