

Table 3. Incidence of Adverse Reactions in Infants with Prior Reactions to DTP-OPV Vaccination in the Control and Treated Groups

Symptom	Placebo (%) n = 76	Acetaminophen (%) n = 62
Fever (>38.0 °C)	68.4	58.6
Fever (>39.0 °C)	10.5	11.2
Redness	13.1	9.2
Swelling	17.2	14.5
Pain	48.3	38.2
Fretfulness	60.3	55.2
Drowsiness	29.3	21.0
Vomiting	11.8	9.4
Anorexia	62.1	56.1
Crying	20.7	19.7

All results: *p* value > 0.1

48 hours post-vaccination were 30.9%, 31.3%, 20.5%, and 3.4%, respectively.

Incidence of Local Reactions

Rates of local reactions among the groups did not significantly differ, so the results for each age group are combined in Table 2. Redness (11.7% vs. 11.5%), and swelling (14.7% vs. 13.1%) over the injection site of the leg were also slightly less frequent after taking acetaminophen, but the differences were not statistically significant. Acetaminophen did not reduce the frequency of local reactions.

Incidence of Systemic Reactions

All rates of systemic reactions, including fretfulness, drowsiness, anorexia, vomiting, and crying, are listed in Table 2. Although the rates of occurrence reported were slightly lower in the treated group, there were no significant differences in rates of occurrence between the placebo and treated groups for fretfulness (51.8% vs. 51.3%), crying (16.8% vs. 15.2%), drowsiness (24.9% vs. 22.0%), anorexia (45.7% vs. 36.1%), or vomiting (8.5% vs. 6.0%).

Incidence of Adverse Reactions with Prior Reactions to DTP-P Vaccine

We collected data on infants who had had prior reactions to DTP-P vaccinations and compared the rates of

occurrence of adverse reactions, including fever, local reactions and systemic reactions. Although acetaminophen prophylaxis resulted in lower frequencies of adverse reactions in those infants, there were no significant differences among all adverse reactions between the control and treated subjects.

DISCUSSION

Immunization using the diphtheria, tetanus toxoids, and pertussis vaccine began nearly 40 years ago,⁴ and has been associated with a marked decline in morbidity and mortality related to pertussis, diphtheria, and tetanus. Although it is cost effective, the DTP vaccine has a high rate of adverse reactions, including fever, local reactions, fretfulness, crying, drowsiness, anorexia, vomiting⁵ and neurological sequelae.⁶ It has been reported that administration of the DTP vaccine causes severe permanent neurologic damage in approximately 1 of every 310,000 vaccinated individuals,⁷ and that seizures and hypotonic-hyporesponsive episodes without sequelae occur approximately once per 1,750 immunizations.⁶

Acetaminophen is one of the safest and most widely used analgesic/antipyretic agents for children and has been shown to be safer than acetylsalicylic acid in several studies.⁸⁻⁹ Since acetaminophen decreases both fever and pain,¹⁰ it seems logical that acetaminophen prophylaxis should alleviate the adverse reactions following DTP vaccination. We, however, found no significant prophylactic effects of acetaminophen on the adverse reactions.

The rates of febrile, systemic, and local reactions occurring in the placebo-treated infants in this study were slightly different from those of other reports.^{5, 11-14} Ipp and Gold¹ studied 519 infants who had received DTP vaccinations. The infants received 3 doses of acetaminophen (15 mg/kg per dose). Acetaminophen prophylaxis reduced only the adverse reactions after the primary series at 2, 4, and 6 months of age. Lewis and Cherry¹⁵ studied 282 vaccinated children who received 5 doses of acetaminophen (10 mg/kg per dose) for prophylaxis. The results only showed a decrease in the rate of fever. However, the first dose of study medicine in