

Table 2. Incidence of Adverse Reactions in the Control and Treated Groups

Adverse reactions	Placebo (%)	Acetaminophen (%)	Chi-square
Fever			
38.0-39 °C	54.0	50.3	p > 0.1
39.1-40.0 °C	9.6	8.9	p > 0.1
Local reactions			
Redness	11.7	11.5	p > 0.1
Swelling	14.7	13.1	p > 0.1
Systemic reactions			
Fretfulness	51.8	51.3	p > 0.1
Crying	16.8	15.2	p > 0.1
Drowsiness	24.9	22.0	p > 0.1
Anorexia	45.7	36.1	p > 0.1
Vomiting	8.5	6.0	p > 0.1

as positive.

Each parent was given a questionnaire in which they were requested to record the rectal temperature and occurrence of local/systemic reactions within 48 hours after vaccination. Systemic reactions included drowsiness, fretfulness, vomiting, anorexia, and unusual crying. The parents completed the questionnaire and returned it 48 hours after recording the information in a preaddressed stamped envelope. We assessed and promoted compliance of the parents with the recommended schedule of administration of the study medications by telephone calls from their doctor that night and the next morning.

Statistics

Differences in frequency distributions of the individual adverse reactions in the control and treated subjects were analyzed using chi-squared or Fisher's exact test.

RESULTS

Characteristics of Subjects:

In total 514 infants were enrolled in this study. Questionnaires were returned from 412 parents (82%): 203 infants received a placebo, and 209 infants received acetaminophen (Table 1). There were approximately equal numbers of subjects in each age group who received a placebo or acetaminophen. Since there was no significant differences among age groups for all items

compared, the results are presented without age specificity.

Incidence of Fever

The frequency distributions of peak temperatures did not significantly differ among the groups, so the results for each age group are combined in Table 2. Although 59.2% of acetaminophen-treated infants developed a fever > 38 °C compared with 63.6% of those treated with a placebo, there were no significant differences between the 2 groups (Table 2).

The incidence of fever is shown in Fig. 1. The highest rates of fever (36.8%) occurred at 16 hours post-vaccination. The occurrence rates at 4, 6, 24, and

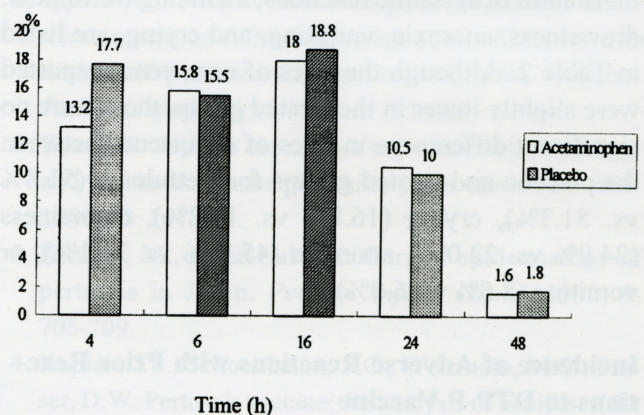


Fig. 1. Incidence of fever occurring at the 4, 6, 16, 24, and 48 hours after DTP-OPV vaccination.