**Clinical Question**  How effective is paracetamol (acetaminophen) or non-steroidal anti-inflammatory drugs (NSAIDs), alone or combined, compared with placebo or no treatment in relieving pain in children with Acute otitis media (AOM)?

**Bottom Line**  Paracetamol and ibuprofen as monotherapies may be more effective than placebo in relieving pain at 48 hours (paracetamol versus placebo: proportion of children with pain 10% versus 25%; RR 0.38, 95% CI 0.17 to 0.85; NNTB 7; low-certainty evidence; ibuprofen versus placebo: proportion of children with pain 7% versus 25%; RR 0.28, 95% CI 0.11 to 0.70; NNTB 6; low-certainty evidence).

Adverse events occurred infrequently, and limited data were available for analysis. The evidence for the effects of paracetamol and ibuprofen, alone or combined, on adverse events is very uncertain.

This review did not draw any firm conclusions about the effectiveness of ibuprofen plus paracetamol versus paracetamol alone in relieving ear pain in children with AOM because of the very limited amount of data available for analysis.

**Caveat**  In some of the trials AOM was diagnosed either by the general practitioner or research nurse without further specification of diagnostic criteria applied.

**Context**  AOM is one of the most common childhood infectious diseases. Pain is the key symptom of AOM and central to children's and parents' experience of the illness. Because antibiotics provide only marginal benefits, analgesic treatment including paracetamol and NSAIDs is regarded as the cornerstone of AOM management.


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