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[Intervention Review]

Diclofenac for acute pain in children

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ABSTRACT

Background

Diclofenac is commonly used for acute pain in children, but is not licensed for this indication in all age groups.

Objectives

- 1) Assess the efficacy of diclofenac for acute pain in children.
- 2) Assess the safety of diclofenac for short-term use in children.
- 3) Identify gaps in the evidence to direct future research.

Search methods

Seventeen databases indexing clinical trial reports were searched in February 2005 (with an update search as part of this first review in May 2008). A hand search of Paediatric Anaesthesia was undertaken and summaries obtained of adverse reaction reports from the UK Yellow Card Scheme and World Health Organization (WHO) Monitoring Centre. The reference lists of included studies were also searched.

Selection criteria

Any published report, in any language, involving the administration of diclofenac to a patient aged 18 years or younger for acute pain and detailing either monitoring of efficacy or safety.

Data collection and analysis

Two review authors independently assessed study quality and extracted the data. Authors were contacted where necessary. Review Manager version 5 was used for analysis.

Main results

- 1) Efficacy:** randomised controlled trials (RCTs) comparing diclofenac with placebo/any other treatment by using pain scores (assessed or reported), or need for rescue analgesia.
- 2) Safety:** any type of study seeking adverse events (regardless of cause). An adverse event was defined as any reported adverse or untoward happening to a patient being treated with diclofenac for acute pain.

Seven publications on diclofenac efficacy and 79 on safety (74 studies plus five case reports) were included in the final analysis. Compared with placebo/no treatment, diclofenac significantly reduced need for post-operative rescue analgesia (relative risk [RR] 0.6; number needed to treat to benefit [NNT] 3.6; 95% confidence interval [CI] 2.5 to 6.3).

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Compared with any other non-NSAID, patients receiving diclofenac suffered less nausea or vomiting, or both (RR 0.6; NNT 7.7 [5.3 to 14.3]). There appeared to be no increase in bleeding requiring surgical intervention in patients receiving diclofenac in the peri-operative period. Serious diclofenac adverse reactions occurred in fewer than 0.24% of children treated for acute pain. The types of serious adverse reactions were similar to those reported in adults.

Authors' conclusions

Diclofenac is an effective analgesic for perioperative acute pain in children. It causes similar types of serious adverse reactions in children as in adults, but these are rare. More research on optimum dosing and safety in asthmatic children is required.

PLAIN LANGUAGE SUMMARY

Diclofenac for pain relief in children

Diclofenac is commonly used for short-term pain relief in children, particularly around the time of surgery. There is good evidence that diclofenac is effective for pain relief in adults, and side effects such as stomach upset are well known. However, developmental differences mean that children may sometimes react differently to medicines than adults do. It is important to assess whether diclofenac is also effective in children, and to understand the type and frequency of adverse reactions that diclofenac causes in children. This review has found that, as with adults, diclofenac is effective for the relief of pain after an operation. If it is given at the time of an operation, it will halve the number of children needing extra pain relief. Diclofenac seems to be twice as effective as paracetamol (acetaminophen) for surgical pain, and this is also true for adults. Diclofenac appears to cause similar types of serious adverse reactions (such as bleeding of the stomach and allergic-type reactions), but these are rare and occur in fewer than 3 in 1000 children who take the drug. We had hoped to investigate whether diclofenac made children with asthma more wheezy, but there was not enough information for us to do this. The main conclusions of this review are that diclofenac is effective for relief of acute pain arising from operations in children, with a low risk of serious adverse reactions. Intramuscular injections of diclofenac should be avoided, due to risk of injection site problems. The main questions still to be answered are: What is the best dose to give and should diclofenac be avoided in children with asthma?