Review of the efficacy and tolerability of the diclofenac epolamine topical patch 1.3% in patients with acute pain due to soft tissue injuries

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CRD summary
The review concluded that diclofenac epolamine topical patch 1.3% significantly reduced pain in patients with soft tissue injuries and was well tolerated. Given the potential for bias in the review and the limitations of the small evidence base (such as uncertain quality and heterogeneity), the author's conclusions should be interpreted with caution.

Authors' objectives
To assess the efficacy and tolerability of the diclofenac epolamine topical patch 1.3% in the treatment of patients with acute pain due to soft tissue injuries.

Searching
MEDLINE, BIOSIS Previews, EMBASE and Derwent Drug File databases were searched between 1984 and October 2009 without language restrictions; search terms were reported. References of relevant articles were handsearched. The drug manufacturer was contacted for relevant post-marketing surveillance information and presentations from scientific meetings.

Study selection
Clinical studies that assessing the efficacy and/or tolerability of diclofenac epolamine topical patch 1.3% in patients with acute pain due to soft tissue injuries or localised periarticular disorders were eligible for inclusion. Studies of patients with other chronic medical conditions (with the exception of reports on tolerability) or that assessed other diclofenac topical formulations were excluded.

The included studies were of patients with humeroradial epicondylitis, ankle sprain, painful sports-related sprain, strain or contusion, periarticular/tendinous inflammation or pain due to minor soft tissue injury. Different inclusion and exclusion criteria were reported for each included study. Patients received diclofenac epolamine topical patch 1.3% once daily for seven days or twice daily for 14 days. Most controls received placebo plaster once daily for seven days or twice daily for 14 days. One study administered diclofenac diethylammonium (DDA) topical gel three times per day for 14 days. Spontaneous pain, pain on pressure, pain on movement, and summed pain scores were measured using visual analogue scales, verbal scales, and global assessments by physicians and patients. Median time to pain resolution was reported.

The author did not state how many reviewers screened studies for inclusion.

Assessment of study quality
The authors did not state that they assessed study validity. Details on study design (including randomisation and blinding) were reported.

Data extraction
Data were extracted from the original articles.

The author did not state how many reviewers performed the data extraction.

Methods of synthesis
Data were presented as a narrative synthesis and in tables.

Results of the review
Six randomised placebo-controlled trials (n=1,371), one randomised active-controlled trial (n=190) and one open-label
study (n=101) were included in the review, along with three additional reports on tolerability. Three of the placebo-controlled trials were double blind.

Diclofenac epolamine topical patch 1.3% was associated with improvements in acute pain associated with minor soft tissue injuries over seven to 14 days compared with placebo plaster and DDA topical gel. Spontaneous pain was reduced from baseline at seven days (visual analogue scale (VAS) score 26% to 88%) and at 14 days (VAS score 56% to 61%) (three studies) and resulted in significantly better pain relief on day seven (88% versus 74%, p<0.001, one study) and day 14 (56.5% versus 46.8%, p=0.001, one study) compared to placebo plaster and on day 14 compared to DDA topical gel (60.8% versus 40.8%, p<0.001, one study).

Median time to pain resolution was three days less with diclofenac patch compared to placebo (8.8 versus 12.4 days, p=0.009).

Adverse events were reported in five of the included studies. Incidence was low and equivalent for diclofenac patch and placebo. The most common adverse events were cutaneous application-site reactions (pruritus, rash and dermatitis) and gastrointestinal symptoms (nausea). Tolerability findings from the additional three reports were also reported.

**Authors' conclusions**

Diclofenac epolamine topical patch 1.3% significantly reduced pain in patients with soft tissue injuries and was well tolerated.

**CRD commentary**

The review question was clear and supported by broad inclusion criteria. The literature search was appropriate and did not include language restrictions, which reduced potential for language bias. The author noted that potentially relevant data may have been missed by the literature search. Data on study quality were limited and not formally assessed, so the quality of the included studies was unclear. The review process did not appear to have been performed in duplicate, so reviewer error and bias could not be ruled out. Given the heterogeneity among studies, a narrative synthesis was appropriate. The evidence base was small and follow up duration was limited. The author highlighted that two of the included studies did not use the recommended daily dose of the diclofenac patch, which may have underestimated the findings.

Potential for bias in the review and the limitations of the small evidence base mean the author's conclusions should be interpreted with caution.

**Implications of the review for practice and research**

**Practice:** The author stated that the evidence supported use of diclofenac epolamine topical patch 1.3% as an option for the topical management of pain in patients with minor soft tissue injuries.

**Research:** The author stated that future research should compare the efficacy and tolerability of topical versus oral analgesics.

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**Bibliographic details**

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.