Devil's Claw (Harpagophytum procumbens) as a treatment for osteoarthritis: a review of efficacy and safety

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CRD summary

The authors concluded that there are insufficient high-quality trials to determine the safety and efficacy of Devil's Claw (Harpagophytum procumbens) in the treatment of osteoarthritis, and that definitive trials are needed. Given the methodological weaknesses in the included studies, the authors' cautious conclusions are warranted.

Authors' objectives

To assess the efficacy and safety of Devil's Claw (Harpagophytum procumbens) in the treatment of osteoarthritis (OA).

Searching

AMED (1985 to 2006), CINAHL (1982 to 2006), EMBASE (1980 to 2006), MEDLINE (1960 to 2006) and ISI Web of Science (1981 to 2006) were searched for articles in any language; the search terms were reported. Three monographs and citations were also checked. Serious adverse reactions reported to the Medicines and Healthcare Regulatory Agency were sought up to June 2003.

Study selection

Study designs of evaluations included in the review

The inclusion criteria for study designs were not clearly specified. Double-blind randomised controlled trials (RCTs) and observational studies were included.

Specific interventions included in the review

Studies of the herbal remedy Devil's Claw were eligible for inclusion. Included studies evaluated both the drug and extract at varying dosages; details of the dosage, harpagoside concentration and drug-to-extract ratio were reported. Treatment duration ranged from 3 weeks to 6 months. Comparator studies compared Devil's Claw with phenylbutazone, diacerhein or placebo.

Participants included in the review

Studies of participants with OA were eligible for inclusion. The authors stated that formal diagnostic criteria to confirm OA were not applied in all studies and some studies included patients with conditions other than OA.

Outcomes assessed in the review

The inclusion criteria for outcomes were not clearly specified. The outcome measures reported were pain severity (determined by either the Likert or visual analogue scales or the Hamberg Pain Adjective), concomitant medication use and change in symptoms (measured by disease-specific tools). Adverse events were also reported.

How were decisions on the relevance of primary studies made?

The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality

The methodological quality of the studies was assessed according to aspects of internal and external validity The former covered adequacy of treatment dosage and duration of treatment, description of randomisation, rate of drop-out, method of blinding and appropriateness of statistical analysis. The latter covered description of inclusion or exclusion criteria and baseline characteristics, number of trial centres and appropriateness of outcome measures. The findings of the validity assessment were discussed in detail in the text. The authors did not state how many reviewers performed the validity assessment.

Data extraction

The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. For observational studies, data on the percentage improvement in outcome were extracted. For comparator studies, data were extracted on the difference in outcome between the comparator groups. Data on the occurrence of adverse events were also extracted.

Methods of synthesis

How were the studies combined?

The results of the studies were combined in a narrative summary. In addition, each individual study was summarised in the text and tables, with the tables grouped by study design.

How were differences between studies investigated?

Differences between the studies were discussed in the text.

Results of the review

Fourteen studies (n=3,838) were included: 2 double-blind RCTs with comparator treatment (n=172), 4 double-blind RCTs with placebo control (n=285) and 8 observational studies (n=3,381).

The majority of the included studies had significant methodological weaknesses, to the extent that their conclusions could not be deemed valid.

Two RCTs were considered to be of higher methodological quality than the rest of the other studies. One showed that Devil's Claw was as effective as diacerhein (p=0.001) and had significantly fewer side-effects (p=0.042). However, a high drop-out rate (26%) and limitations in terms of inclusion criteria and outcome measures mean that these conclusions should still be treated with caution. The second RCT showed that Devil's Claw significantly reduced pain compared with placebo at both 30 days (p=0.018) and 60 days (p=0.012). This study was of sufficient methodological quality for its findings to be considered valid. No adverse events were reported: the sample size (n=89) was too small to reliably detect adverse effects.

Authors' conclusions

The methodological quality of the existing evidence is generally poor. The authors provided some evidence to indicate that Devil's Claw may be of potential therapeutic value in the treatment of OA. However, the poor quality of studies in this area precludes any clear conclusions about its efficacy.

CRD commentary

The review question was supported by the somewhat broad inclusion criteria for the intervention and participants only. Some of the included studies evaluated patients with conditions other than OA, which might affect the applicability of the findings. However, this is likely to be a limitation of the available evidence rather than the review itself. Several relevant sources were searched with no language restrictions, and unpublished safety data were sought from the UK competent authority. However, it is unclear whether the authors searched systematically for unpublished data on efficacy, therefore publication bias cannot be ruled out. It is not clear what methods were used in the study selection, validity assessment and data extraction procedures, which means that reviewer error and bias may have been introduced.

Appropriate criteria were used to assess both the internal and external validity of the included studies, the results of which were discussed thoroughly within the text and when considering the strength and reliability of the evidence presented. This discussion highlighted several methodological weaknesses affecting both the internal and external validity of the included studies. Given the heterogeneity of the included studies, the authors' decision to use a narrative synthesis was appropriate. In light of methodological limitations in the review and the generally poor quality of the included studies, the authors' cautious conclusions are appropriate.

Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that high-quality trials are needed to assess efficacy and optimum dosage. There is also a need to address inconsistencies in the quality of different preparations, and to address safety.

Bibliographic details

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