A systematic review of the safety of black cohosh

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CRD summary
This review assessed the safety of medicinal extracts of black cohosh (Actaea racemosa). The authors' concluded that limited evidence available suggested that adverse events were rare, mild and reversible and that black cohosh, and in particular the product Remifemin, appeared to be a safe herbal medicine. The authors' recognised the limitations of the evidence and their conclusions appear justified.

Authors' objectives
To assess the safety of medicinal extracts of black cohosh (Actaea racemosa).

Searching
Seven electronic sources were searched; details of the databases, dates and search terms were given in the report. In addition, the reference lists of all located papers were checked and information was sought from the World Health Organization and national drug safety bodies. Sixteen manufacturers of black cohosh preparations were contacted for data held on file. Departmental files were also searched ((Department of Complementary Medicine, Peninsula Medical School, Universities of Exeter and Plymouth) and colleagues with an interest in herbal medicine were contacted. No language restrictions were imposed on the searches.

Study selection
Study designs of evaluations included in the review
All data from postmarketing surveillance studies, clinical trials, case reports, spontaneous reporting programmes and Phase I studies were included in the review.

Specific interventions included in the review
Papers needed to report information relating to the safety of black cohosh. Combination products and homeopathic preparations were excluded. The majority of the included clinical studies used Remifemin (Schaper and Brummer). The doses in the clinical studies ranged from 20 to 80 drops or from 2 to 6 tablets daily (dosage in mg not stated). Where stated, the treatment lasted from 20 days to 18 months.

Participants included in the review
All types of participant appeared to be eligible. The studies included participants with menopausal problems and those taking black cohosh for a variety of menstrual conditions.

Outcomes assessed in the review
All types of adverse events appeared to be eligible for the review.

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 authors stated that it was not possible to formally assess the validity of the evidence, but issues relating to the interpretation of the data were highlighted in the report. The authors did not state how many reviewers interpreted the data.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data.
Methods of synthesis
How were the studies combined?
The studies were combined in a narrative summary.

How were differences between studies investigated?
Differences between the studies were highlighted within the text of the report.

Results of the review
Twenty-two studies (2,474 participants) were accepted for inclusion in the review. There were 4 randomised controlled trials (285 participants), 1 equivalence trial (with 152 participants) 5 open trials (334 participants) of which one was placebo-controlled, 2 postmarketing surveillance trials (732 participants), 1 in vitro study (110 participants) and 9 case series (861 participants). In addition, drug surveillance reports revealed 62 case reports linked to black cohosh. A database of complaints logged from 1998 to 2001 revealed 5 reports of adverse events.

Although there were considerable data relating to the efficacy of black cohosh, in particular Remifemin, safety aspects have not been the focus. The available data suggested that adverse events were rare, mild and reversible, with gastrointestinal upsets and rashes being the most common events observed. The spontaneous reporting programmes contained a few serious adverse events, but cannot prove causality.

Authors' conclusions
The authors concluded that, although definitive evidence is not available as regards the risk of adverse events, black cohosh appears to be a safe herbal medicine.

CRD commentary
This review had broad inclusion criteria for the participants, interventions, study design and outcomes. A comprehensive range of sources was searched. Validity was not formally assessed, but issues relating to the interpretation of the data were addressed in the report. It was unclear whether more than one reviewer was involved throughout the review process, which can help minimise bias in the study selection, data extraction and interpretation processes. The authors recognised the limitations of the evidence, and discussed the problems of poor monitoring and reporting of safety data relating to herbal medicines. They also acknowledged that the vast majority of the adverse events concerned the product Remifemin and that these results may not be generalisable to other preparations of black cohosh. Within these limitations, their conclusions on the safety of black cohosh appear justified.

Implications of the review for practice and research
The authors did not state any implications for practice or further research.

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**Record Status**
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.