

SAFETY AND EFFICACY OF BLACK COHOSH (*CIMICIFUGA RACEMOSA*) DURING PREGNANCY AND LACTATION

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ABSTRACT

Background

There is a lack of basic knowledge on the part of both clinicians and patients as to the indications for use and safety of herbal medicines in pregnancy and lactation. This is one article in a series that systematically reviews the evidence for commonly used herbs during pregnancy and lactation.

Objectives

To systematically review the literature for evidence on the use, safety, and pharmacology of black cohosh focusing on issues pertaining to pregnancy and lactation.

Methods

We searched 7 electronic databases and compiled data according to the grade of evidence found.

Results

Black cohosh, alone or in combination with other medicinal herbs as “mother’s cordial”, has a long traditional use and is frequently used by midwives as a uterine stimulant and labour-inducing aid. Low-level evidence based on theory and expert opinion shows the following concerns with respect to black cohosh use during pregnancy: 1) labour-inducing effects, 2) hormonal effects, 3) emmenagogue properties and, 4) anovulatory effects. During lactation, there is low-level evidence from theoretical and expert opinion of black cohosh having hormonal properties.

Conclusions

Black cohosh should be used with caution during pregnancy, particularly during the first trimester where its purported labour-inducing effects could be of concern, and during lactation. Black cohosh should undergo rigorous high quality human studies to determine its safety in pregnancy and lactation.

Key Words: *Black Cohosh, cimicifuga racemosa, pregnancy, lactation, breastfeeding, systematic review*

Black cohosh, latin names: *Actaea racemosa* and *Cimicifuga racemosa*, is a perennial plant member of the buttercup family that is native to North America. Black cohosh was originally used by Native American peoples in the treatment of many conditions, including gynaecologic disorders and musculoskeletal complaints.¹ The most widely used and best-studied commercial formulation available

in the United States is Remifemin, a standardised extract of the rhizome. Numerous other brands of black cohosh are available, but not all are standardised extracts. Black cohosh should not be confused with the herb blue cohosh (*Caulophyllum thalictroides*), that is also used for gynaecologic disorders and has a much greater potential for toxicity.² The principal modern use of black

cohosh relies on its purported efficacy in the treatment of menopausal symptoms, primarily hot flashes, sleep disturbances, and depression.³ Its therapeutic activity has been attributed to claims that the herb has estrogenic properties. These claims, however, have been disputed.^{4,6} Black cohosh has also been used to treat dysmenorrhoea as recommended by the German Commission E.

There does not appear to be any indications of therapeutic or supportive use of this herb during pregnancy. Of concern however, is that the herb does have a reputation as being used traditionally as an herbal abortifacient. In addition, midwives have used black cohosh during labour for induction.^{7,8} As black cohosh is often taken by women, and due to the potential for its use during pregnancy, a systematic review of the literature on the efficacy of black cohosh for a number of indications as well as for its safety during pregnancy and lactation was undertaken.

METHODS

The following databases were searched from inception to June 2005: AMED, CINAHL, Cochrane CENTRAL, Cochrane Library, MedLine, Natural Database, and Natural Standard. The common name and Latin name of the herb were used as keywords along with “pregnancy”, “lactation”, and “breastfeeding”. In the case of a well-known active constituent of the herb, this term was also used in the search for its safety during pregnancy and lactation.

The Complete German Commission E Monographs by the American Botanical Council were also searched. Each relevant journal article was collected and referenced in a database. The nature of the findings and the grade of evidence were then abstracted and compiled in a final report. The grades of evidence for indications were evaluated as displayed in Table 1. We rated evidence of harm as displayed in Table 2.

RESULTS

Synonyms/ Common names / Related substances⁹:

Baneberry, black snakeroot, bugbane, bugwort, cimicifuga, macrotys, phytoestrogen, rattle root, rattle snakeroot, rattle top, rattlesnake root, rattleweed, snakeroot, squaw root, squawroot.

Indications for Use

	Grade
Menopausal symptoms ¹¹⁻¹³	B1
Arthritis pain (with white willow bark, sarsaparilla, poplar bark, and guaiacum resin) ¹⁴	B2
Induction of labour ⁸	E

Safety of Consumption during Pregnancy

	Grade
Induces labour ⁸	4
Hormonal effect (potentially estrogenic and/or anti-estrogenic) ¹⁵	4
Emmenagogue (especially in first trimester) ¹⁰	4
Anovulatory effects ¹⁶	4

A survey of midwives in the United States found that 45% of midwives use black cohosh to induce labour.⁸ Black cohosh is part of a combination of herbal medicines that have been traditionally used in the third trimester to prepare a woman for delivery; this preparation is called “mother’s cordial” or “partus preparatus”. In addition to black cohosh, mother’s cordial contains: squaw vine (*Mitchella ripens*), raspberry (*Rubus idaeus*), blue cohosh (*Caulophyllum thalictroides*), and false unicorn (*Chamaelirium luteum*).

It is unclear if black cohosh has an estrogenic and/or an anti-estrogenic effect.¹⁵ Nonetheless, a review article recommended that black cohosh be avoided during pregnancy due to its potential hormonal effect.¹⁵

A herbal contraindication and drug interaction compendium reported that black cohosh was an emmenagogue and contraindicated during pregnancy, particularly in the first trimester.¹⁰ A review article on the potential value of plants as sources of anti-fertility agents reported that black cohosh had anovulatory effects *in vitro*.¹⁶

Safety of Consumption during Lactation

	Grade
Hormonal effect (potentially estrogenic/anti-estrogenic) ¹⁵	4

It is unclear if black cohosh has an estrogenic and/or an anti-estrogenic effect.¹⁵ Nonetheless, a review article recommended that black cohosh be avoided during lactation due to its potential hormonal effect.¹⁵

Parts Used

Roots, rhizome¹⁰

Constituents

- Triterpene glycosides (acetin, cimicifugoside, 27-deoxyacetin)¹⁰
- organic acids (isoferulic acid, cimicifugic acids) (A, B, E and F)
- fukinolic acid
- caffeic acid, salicylic acid^{9,10}
- cimicifugin¹⁰
- tannins¹⁰
- phytosterin⁹.

Pharmacology

In some studies, black cohosh constituents bind to estrogen receptors *in vitro* or have an estrogenic effect.¹⁷⁻²⁰ In other studies, black cohosh estrogenic or estrogen receptor-binding effects were not found.^{21,22} Black cohosh antagonizes the proliferation of cells induced by estradiol *in vitro*, thereby having anti-estrogenic activity.²³

Black cohosh decreases luteinizing hormone (LH) levels, but has no effect on follicular stimulating hormone (FSH) levels.¹⁹ Black cohosh inhibits the growth of human breast cancer cells *in vitro*.^{24,25} Black cohosh has anti-inflammatory effects.²⁶

Drug Interactions

- Docetaxel⁹
- Doxorubicin⁹.

DISCUSSION

There is strong scientific evidence for the use of black cohosh in the treatment of menopausal symptoms. In combination with other herbs, there is good evidence for the treatment of arthritis. During pregnancy, black cohosh has a long history of use for inducing labour; on its own or in combination with other medicinal herbs to make a formula referred to as “mothers cordial” or “partus preparatus”.

The level of evidence on the use of black cohosh during pregnancy is limited to theoretical evidence, a survey of midwives in the United States and to *in vitro* evidence. Although the quality of evidence is poor, there are concerns with black cohosh use during pregnancy, which can be summarized as:

1. labour-inducing effects,
2. hormonal effects,
3. emmenagogue properties, and
4. anovulatory effects.

Black cohosh should be used with caution during pregnancy, particularly during the first trimester where the labour-inducing properties of black cohosh could be of greatest harm to the fetus. Despite no reports of malformations in the scientific literature, black cohosh should be used with caution in the third trimester and at delivery when used as a labour-inducing aid, until further clinical research is conducted.

The level of evidence for using black cohosh during lactation is also poor. Black cohosh should be used with caution as *in vitro* evidence suggests estrogenic/anti-estrogenic properties.

Traditional and common use has indicated a risk of taking this herb during pregnancy, particularly during the first trimester, and during lactation. Clearly more rigorous and well-controlled research is needed in this area.

TABLE 1 Grades for evidence for efficacy

GRADE	EVIDENCE
A	VERY STRONG SCIENTIFIC EVIDENCE Statistically significant evidence of benefit from one or more systematic reviews/ meta-analysis.
B1	STRONG SCIENTIFIC EVIDENCE Statistically significant evidence of benefit from one or more properly conducted random control trials (RCTs).
B2	GOOD SCIENTIFIC EVIDENCE Statistically significant evidence of benefit from one or more RCTs. The RCTs, however, are either of small sample size OR have discrepancies in their methodologies.
C	FAIR SCIENTIFIC EVIDENCE Statistically significant evidence of benefit from one or more cohort studies OR outcome studies.
D	WEAK SCIENTIFIC EVIDENCE Evidence from case series.
E	INDIRECT AND/OR CLINICAL EVIDENCE Evidence from case reports OR expert opinion OR laboratory studies.
F	HISTORICAL OR TRADITIONAL EVIDENCE Historical or traditional use by medical professionals, herbalists, scientists, or aboriginal groups.

TABLE 2 Levels for evidence for harm

LEVEL	EVIDENCE
1a	STRONG SCIENTIFIC EVIDENCE Statistically significant evidence from one or more systematic reviews or RCTs.
1b	GOOD SCIENTIFIC EVIDENCE Statistically significant evidence from one or more cohort studies OR control study.
1c	WEAK SCIENTIFIC EVIDENCE Evidence from one or more case series.
2	VERY WEAK SCIENTIFIC EVIDENCE Evidence based on case reports.
3	IN VITRO SCIENTIFIC EVIDENCE Evidence based on scientific studies conducted on animals, insects or microorganisms OR laboratory studies on human cells.
4	INDIRECT EVIDENCE Evidence based on scientific theory OR expert opinion.
5	UNKNOWN No available information.

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