

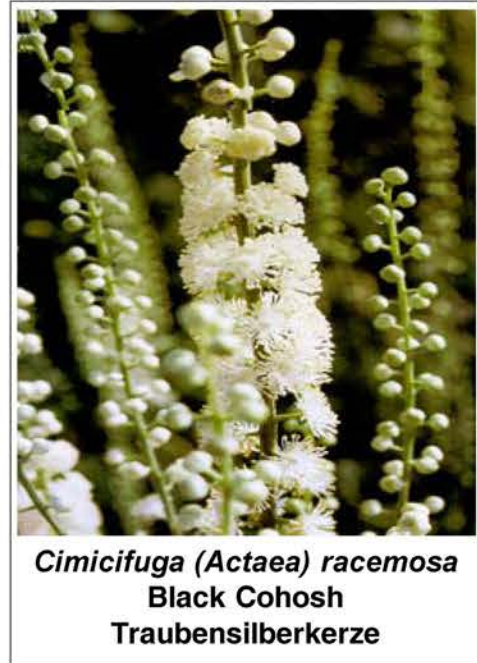
Key Point for Clinical Efficacy Evaluation of *Cimicifuga racemosa*

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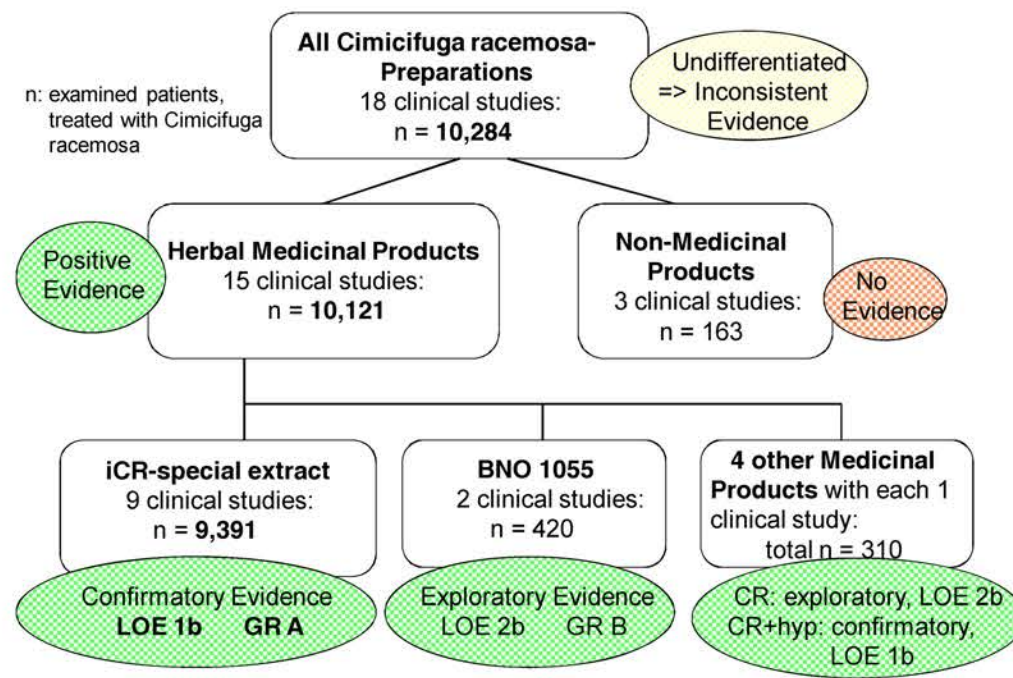
Introduction

Past reviews on *Cimicifuga racemosa* (CR, Black Cohosh) without differentiation between extracts (e.g. iCR = isopropanolic extract of CR), specifications as well as quality, regulatory status and indication complained of inconsistent efficacy. However, a recent review [1] and a meta-analysis [2] give a decisive criterion for consistency of evidence by considering such differentiations.

This poster summarizes the key facts and the most relevant conclusions of [1] and [2] and proposes perspectives for future research on medicinal products made from *Cimicifuga racemosa*.



Results



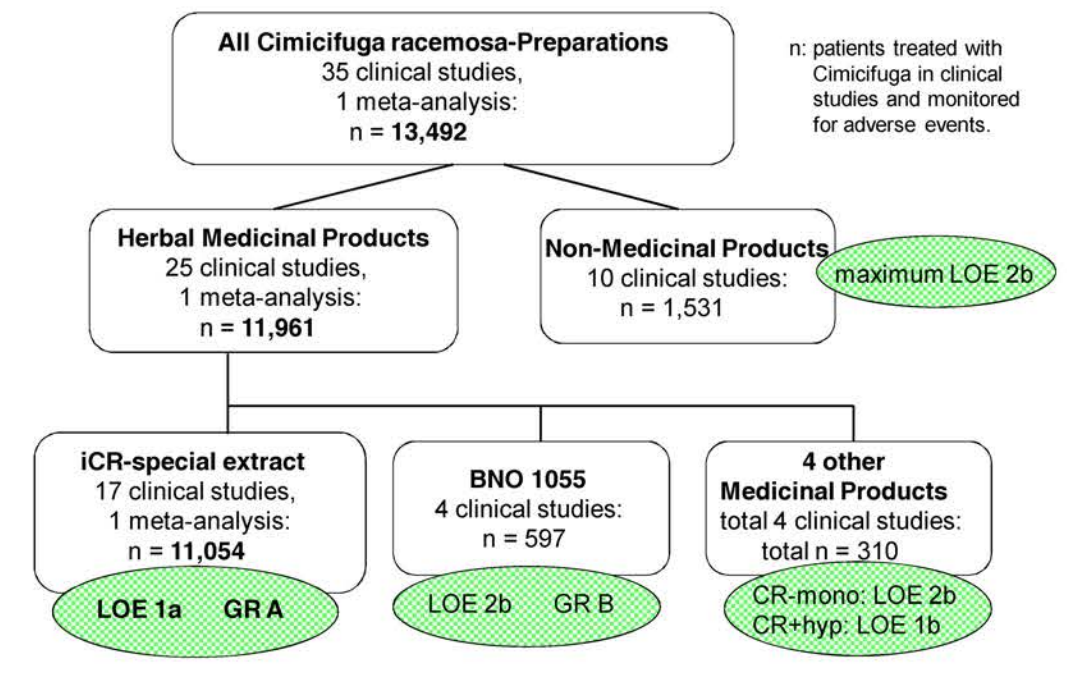
EFFICACY data on CR (2000 - 2012)

18 clinical studies investigated 10,284 patients treated with *Cimicifuga racemosa* against natural climacteric complaints. Thereof, 10,121 (98.5%) used a registered medicinal product, and 163 (1.5%) other *Cimicifuga* products [1].

Number of studies	Registered herbal medicinal product	
	Yes	No
Evidence for efficacy	15	1
	0	2

= 0.0008 (Chi²-test)

Evidence for EFFICACY clearly and significantly correlates with the regulatory status of the investigated herbal product [1].



SAFETY data on CR (2000 - 2012)

35 clinical studies investigated safety aspects in 13,492 patients treated with *Cimicifuga racemosa*. Thereof, 11,961 (88.6%) used registered medicinal products, and 1,531 (11.4%) used other *Cimicifuga* preparations [1].

Methods

Systematic Review

Beer and Neff [1] focused their systematic review on a rigorous literature search for clinical studies on the efficacy and safety of *Cimicifuga racemosa* for menopausal complaints. They searched scientific international and national databases such as MEDLINE, BIOSIS, EMBASE, EMBASE Alert, and PubMed and additionally their own library.

The identified studies were sorted by type of extract, regulatory status and indication. Based on this, specific assessments of the Oxford Levels of Evidence (LOE) and Grades of Recommendation (GR) were performed.

Meta-analysis of Efficacy

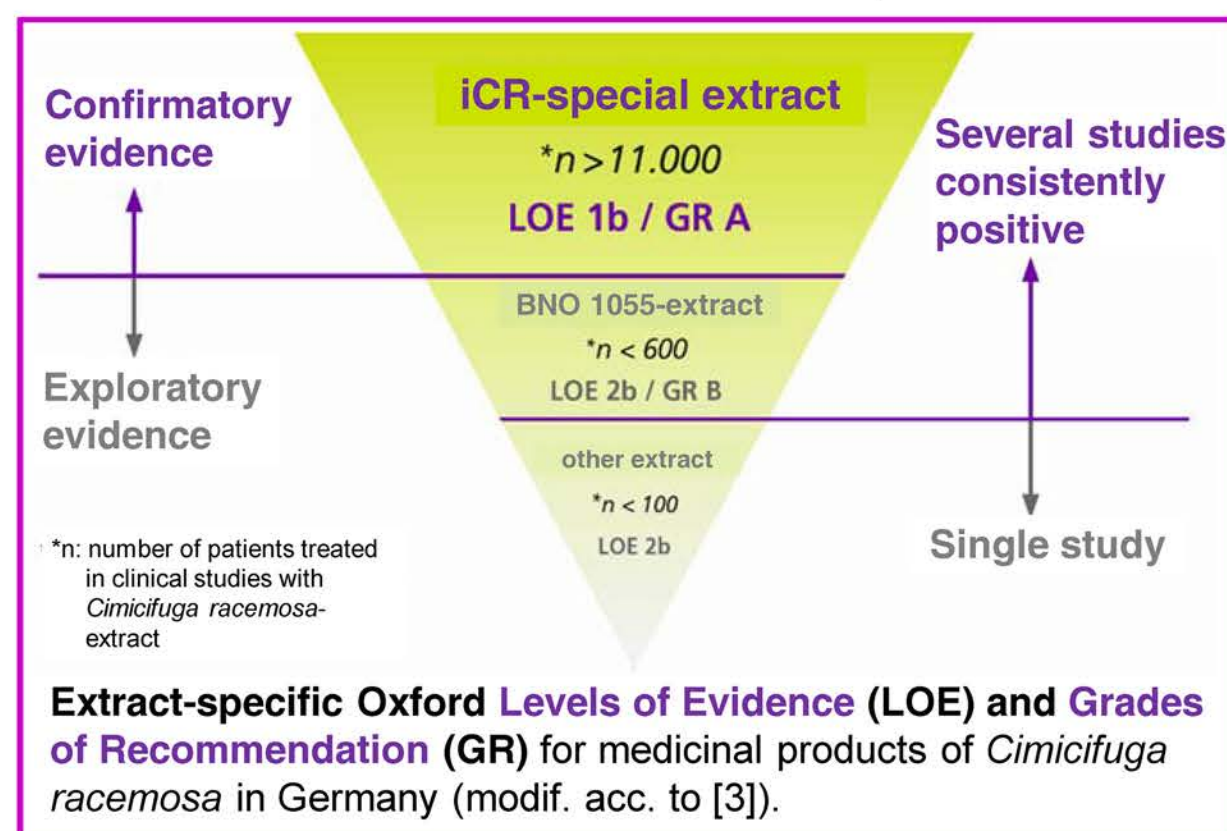
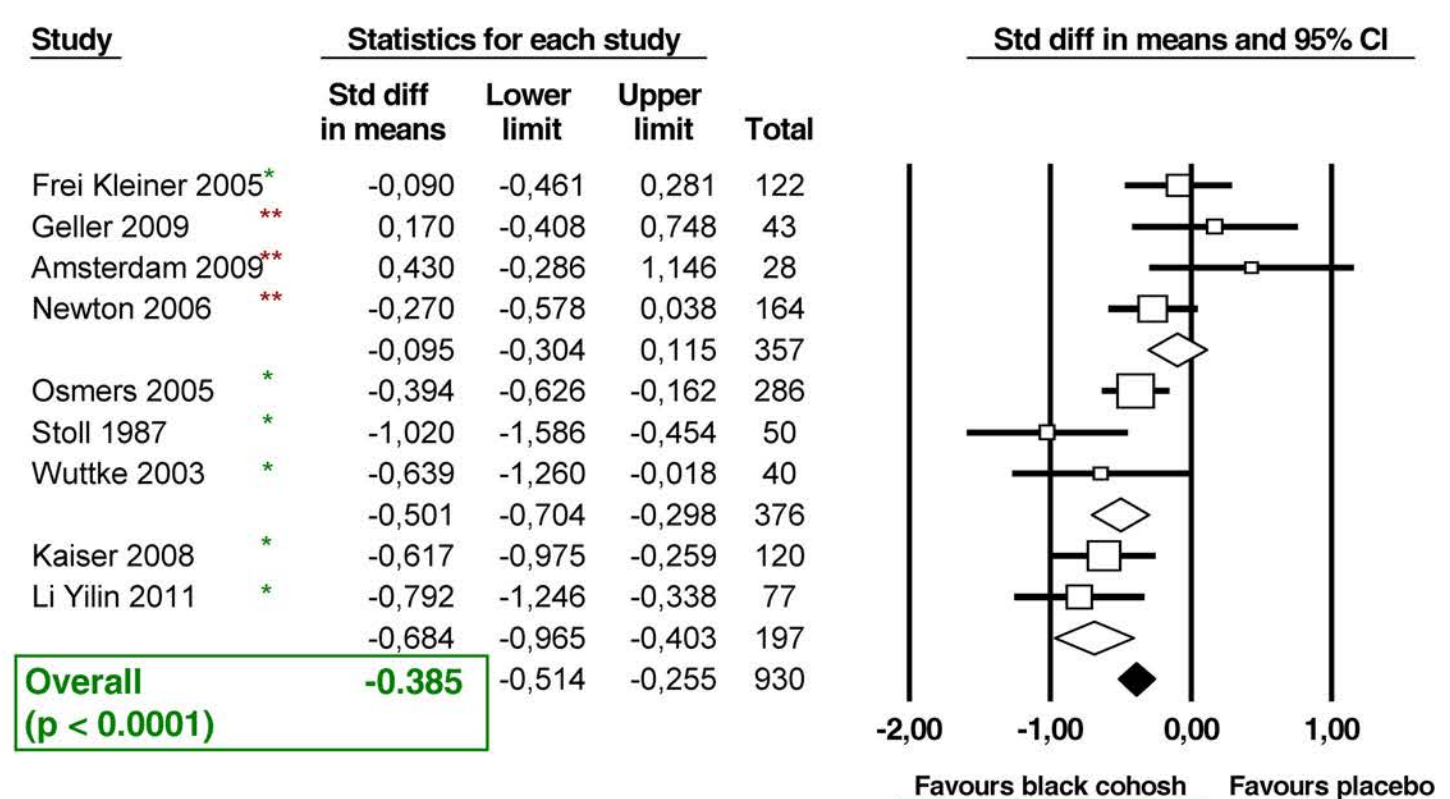
Another publication [2] assembled gynecological and biometrical experts including several principal investigators of recent controlled clinical studies with *Cimicifuga racemosa*. In contrast to a recent Australian review neglecting major evidence for beneficial effects of black cohosh, Beer et al. [2] defended the efficacy of CR-based herbal medicinal products by providing a proficient reconsideration and an accurate meta-analysis with all appropriate placebo-controlled clinical studies of *Cimicifuga racemosa* on natural climacteric complaints.

Acknowledgement

We thank Professor Beer for permitting the use of his charts in our current poster.

References

- [1] Beer AM, Neff A. Differentiated Evaluation of Extract-Specific Evidence on *Cimicifuga racemosa*'s Efficacy and Safety for Climacteric Complaints. eCAM DOI: 10.1155/2013/860602.
- [2] Beer AM, Osmers R, Schnitker J, Bai W, Mück AO, Meden H: Efficacy of black cohosh medicines for treatment of menopausal symptoms. Gynecol Endocrinol 29 (2013):1022-5.
- [3] Beer AM: Lecture at the Annual Meeting of Deutsche Menopause Gesellschaft, Frankfurt/Germany, 15.11.2013



Research Forecast

Given the proven efficacy and well-established safety by decades of use in millions of women, the mode of action of *Cimicifuga racemosa* is of major interest for current and future research. Additionally, aspects such as bone protection, protraction of cancer recurrence, or dose increase for alleviating drug-induced menopausal complaints may be investigated.

Forest Plot on EFFICACY of black cohosh compared to placebo in Menopausal Symptom Scores.

Meta-analysis of all placebo-controlled clinical studies on different CR extracts showed a standardized mean difference of 0.385 favoring CR (p<0.0001) [2].
* Medicinal product ** non-medicinal product

Conclusions

A positive benefit-risk profile is limited to *Cimicifuga racemosa* medicinal products holding a marketing authorization for treating climacteric complaints.

Confirmatory Level 1-evidence leading to Grade of Recommendation A has been shown for and is limited to the isopropanolic *Cimicifuga racemosa* extract (iCR, in Remifemin® and Remifemin® plus).

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