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Clinical impact ratings GP/FP/Primary care ★★★★★☆☆☆☆ Gynaecology ★★★★★☆☆☆☆

In women with climacteric complaints, does a fixed combination of black cohosh (Cimicifuga racemosa) and St John’s wort (Hypericum perforatum) extracts reduce symptoms?

METHODS

Design: randomised controlled trial (RCT).

Allocation: concealed. *

Blinding: blinded (patients, healthcare providers, data collectors, outcome assessors, data analysts, and data safety committee). *

Follow up period: 16 weeks.

Setting: a clinic in Berlin, Germany.

Patients: 301 women who were 45-60 years of age (mean age 52 y) and had climacteric symptoms for ≥3 months, a Menopause Rating Scale score ≥0.4 on ≥3 items, a Hamilton Depression Rating Scale Total score of 15–23 points, and a score ≥2 on the Hamilton Depression Rating Scale Item 1. Exclusion criteria included any treatment to alleviate climacteric symptoms in the previous 12 weeks; use of chemical or plant-based antiepileptics, psychopaths, or psychosomatics in the previous 12 weeks; psychological or psychiatric therapy; bilateral oophorectomy; severe disease; abnormal thyroid stimulating hormone concentration; and high risk of suicide.

Intervention: fixed combination of black cohosh extract (1 mg triterpene glycosides) and St John’s wort (0.25 mg total hypericin) extracts (n = 150) or placebo (n = 150). Patients took 2 tablets twice daily during weeks 1–8 and 1 tablet twice daily during weeks 9–16.

Outcomes: decrease in overall Menopause Rating Scale score. Secondary outcomes included the Hamilton Depression Rating Scale total score. Patient follow up: 97% (intention to treat analysis).

*See glossary. Information provided by author.

MAIN RESULTS

At 16 weeks, women who received black cohosh and St John’s wort extracts had greater improvement than women who received placebo in climacteric and depressive symptom scores (table).

CONCLUSION

In women with climacteric complaints, black cohosh and St John’s wort extracts reduced climacteric and depressive symptoms.

Commentary

The evidence on St John’s wort’s and depressive symptoms is much larger than that on black cohosh and vasomotor symptoms and generally supports its use for mild to moderate depressive symptoms; however, the data are inconsistent for major depression. A 2003 review on black cohosh reported that 3 of 4 RCTs showed no benefit for black cohosh. Although 1 placebo controlled trial found black cohosh to be effective, it did not find oestrogen to be effective, which calls into question its validity. Since 2003, 2 new placebo controlled RCTs have shown a benefit for black cohosh.

The study by Uebelhack et al showed that a combination of black cohosh and St John’s wort relieved climacteric and related depressive symptoms. It is unclear how much each extract contributed to the overall effect and whether a combination is necessary to achieve it. Previous studies have shown that black cohosh and St John’s wort improved Menopause Rating Scale scores. It would have been useful to have 4 groups for comparison: black cohosh, St John’s wort, the combination of black cohosh and St John’s wort, and placebo.

Many perimenopausal and postmenopausal women use herbal extracts for their climacteric complaints. The study medication is approved by several European Health authorities. While this study provides more evidence for the use of black cohosh and St John’s wort in this population, there are still substantial barriers for prescribing them in our routine clinical practice. Since manufacturers of herbal compounds are not subjected to the same regulations as pharmaceutical companies, the quality of herbal extracts available on the market varies, and contaminants are common. Of more concern is the lack of data on long term safety and herb-drug and herb-herb interactions. A 2002 review in N Engl J Med identified 16 commonly used drugs that interact with St John’s wort. More long term methodologically sound studies are urgently required to address these issues.

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