

Journal für

Gynäkologische Endokrinologie

Gynäkologie • Kontrazeption • Menopause • Reproduktionsmedizin

News-Screen Menopause: Pflanzliche Östrogene und deren Einsatz in der Menopause

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Journal für Gynäkologische Endokrinologie 2016; 10 (2)

(Ausgabe für Österreich), 17-19

Journal für Gynäkologische Endokrinologie 2016; 10 (2)

(Ausgabe für Schweiz), 18-20

**Offizielles Organ der Österreichischen
IVF-Gesellschaft**

**Offizielles Organ der Österreichischen
Menopause-Gesellschaft**

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Krause & Pachernegg GmbH · VERLAG für MEDIZIN und WIRTSCHAFT · A-3003 Gablitz

P. h. b. GZ072037636M · Verlagspostamt: 3002 Parkersdorf · Erscheinungsort: 3003 Gablitz

News-Screen Menopause

Pflanzliche Östrogene und deren Einsatz in der Menopause

P. Frigo

■ Efficacy of Phytoestrogens for Menopausal Symptoms: A Meta-Analysis and Systematic Review

Chen MN, et al. *Climacteric* 2015; 18: 260–9.

Abstract

Objective: To perform a meta-analysis examining the efficacy of phytoestrogens for the relief of menopausal symptoms. **Methods:** Medline, Cochrane, EMBASE, and Google Scholar databases were searched until September 30, 2013 using the following key words: vasomotor symptoms, menopausal symptoms, phytoestrogens, isoflavones, coumestrol, soy, red clover. Inclusion criteria were (1) randomized controlled trial (RCT), (2) perimenopausal or postmenopausal women experiencing menopausal symptoms, (3) intervention with an oral phytoestrogen. Outcome measures included Kupperman index (KI) changes, daily hot flush frequency, and the likelihood of side-effects. **Results:** Of 543 potentially relevant studies identified, 15 RCTs meeting the inclusion criteria were included. The mean age of the subjects ranged from 49 to 58.3 and 48 to 60.1 years, respectively, in the placebo and phytoestrogen groups. The number of participants ranged from 30 to 252, and the intervention periods ranged from 3 to 12 months. Meta-analysis of the seven studies that reported KI data indicated no significant treatment effect of phytoestrogen as compared to placebo (pooled mean difference = 6.44, $p = 0.110$). Meta-analysis of the ten studies that reported hot flush data indicated that phytoestrogens result in a significantly greater reduction in hot flush frequency compared to placebo (pooled mean difference = 0.89, $p < 0.005$). Meta-analysis of the five studies that reported side-effect data showed no significant difference between the two groups ($p = 0.175$). **Conclusion:** Phytoestrogens appear to reduce the frequency of hot flushes in menopausal women, without serious side-effects.

Relevanz für die Praxis

In dieser großen Metaanalyse wurde die Wirkung von pflanzlichen Östrogenen auf klimakterische Beschwerden untersucht; bei 10 placebokontrollierten Studien zeigte sich, dass sich Hitzewallungen durch Phytoöstrogene statistisch signifikant verbesserten. Weiters fiel auf, dass es keine signifikanten Nebenwirkungen bei Anwendung der Phytoöstrogene im Vergleich mit der Placebogruppe gab.

■ Phytoestrogens for Menopausal Vasomotor Symptoms

Lethaby A, et al. *Cochrane Database Syst Rev* 2013; 12: CD001395.

Abstract

Background: Vasomotor symptoms, such as hot flushes and night sweats, are very common during the menopausal transition. Hormone therapy has traditionally been used as a highly effective treatment, but concerns about increased risk of some chronic diseases have markedly increased the interest of women in alternative treatments. Some of the most popular of these treatments are foods or supplements enriched with phytoestrogens—plant-derived chemicals that have estrogenic action. **Objectives:** To assess the efficacy, safety and acceptability of food products, extracts and dietary supplements containing high levels of phytoestrogens when compared with no treatment, placebo or hormone therapy for the amelioration of vasomotor menopausal symptoms (such as hot flushes and night sweats) in perimenopausal and postmenopausal women. **Search Methods:** Searches targeted the following electronic databases: the Cochrane Menstrual Disorders and Subfertility Group Specialised Register of randomised trials (29 July 2013), the Cochrane Register of Controlled Trials (CENTRAL; 29 July 2013), MEDLINE (inception to 29 July 2013), EMBASE (inception to 29 July 2013), AMED (1985 to 29 July 2013), PsycINFO (inception to 29 July 2013) and CINAHL (inception to 29 July 2013). Attempts were made to access grey literature by sending letters to pharmaceutical companies and performing searches of ongoing trial registers. Reference lists of included trials were also searched. **Selection Criteria:** Studies were included if they were randomised, included perimenopausal or postmenopausal participants with vasomotor symptoms (hot flushes or night sweats), lasted at least 12 weeks and provided interventions such as foods or supplements with high levels of phytoestrogens (not combined with other herbal treatments). Trials that included women who had breast cancer or a history of breast cancer were excluded. **Data Collection and Analysis:** Selection of trials, extraction of data and assessment of quality were undertaken by at least two review authors. Most trials were too dissimilar for their results to be combined in a meta-analysis, so these findings are provided in narrative 'Summary of results' tables. Studies were grouped into broad categories: dietary soy, soy extracts, red clover extracts, genistein extracts and other types of phytoestrogens. Five trials used Promensil, a red clover extract; results of these trials were combined in a meta-analysis, and summary effect measures were calculated. **Main Results:** A total of 43 randomised controlled trials (4,364 participants) were included in this review. Very few trials provided data suitable for inclusion in a meta-analysis. Among the five trials that yielded data assessing the daily frequency of hot flushes suitable for pooling, no significant difference overall was noted in the incidence of hot flushes between participants taking Promensil (a red clover extract) and those given placebo (mean difference (MD) -0.93 , 95 % confidence in-

terval (CI) -1.95 to 0.10 , $I(2) = 31\%$). No evidence indicated a difference in percentage reduction in hot flushes in two trials between Promensil and placebo (MD 20.15 , 95% CI -12.08 to 52.38 , $I(2) = 82\%$). Four trials that were not combined in meta-analyses suggested that extracts with high (> 30 mg/d) levels of genistein consistently reduced the frequency of hot flushes. Individual results from the remaining trials were compared in broad subgroups such as dietary soy, soy extracts and other types of phytoestrogens that could not be combined. Some of these trials found that phytoestrogen treatments alleviated the frequency and severity of hot flushes and night sweats when compared with placebo, but many trials were small and were determined to be at high risk of bias. A strong placebo effect was noted in most trials, with a reduction in frequency ranging from 1% to 59% with placebo. No indication suggested that discrepant results were due to the amount of isoflavone in the active treatment arm, the severity of vasomotor symptoms or trial quality factors. Also, no evidence indicated that these treatments caused oestrogenic stimulation of the endometrium or the vagina or other adverse effects when used for up to two years. **Authors' Conclusions:** No conclusive evidence shows that phytoestrogen supplements effectively reduce the frequency or severity of hot flushes and night sweats in perimenopausal or postmenopausal women, although benefits derived from concentrates of genistein should be further investigated.

Relevanz für die Praxis

In dieser Metaanalyse zeigte sich vor allem ein Placeboeffekt, nur in 4 Studien konnte ein geringer Effekt der Phytoöstrogene beobachtet werden: Bei hohen Konzentrationen von Genistein scheint die Frequenz an Hitzewallungen und Nachtschweiß abzunehmen. Genistein ist vor allem in Soja und Rotklee enthalten. Ebenfalls beschreiben die Autoren die fehlenden Nebenwirkungen.

■ Protocol for Systematic Review and Meta-Analysis: Hop (*Humulus lupulus* L.) for Menopausal Vasomotor Symptoms

Abdi F, et al. *BMJ Open* 2016; 6: e010734.

Abstract

Introduction: Menopause is a critical stage in every woman's life. It can cause a distressing time for women by creating various vasomotor symptoms (VMS). Phytoestrogens can potentially exert various favourable effects and alleviate VMS in postmenopausal women. The hop (*Humulus lupulus* L.) contains 8-prenylnaringenin (8-PN), the most potent phytoestrogen known to date. The hop is eight times stronger than any other herbal oestrogens. This study aims to conduct a comprehensive systematic review and a meta-analysis survey of the effects of hop in the management of VMS in postmenopausal women. **Methods:** Only randomised controlled clinical trials, with cluster randomisation and crossover, blinded and non-blinded designs, conducted be-

tween 2000 and 2015, will be included in this review. Quasi-experimental and observational studies as well as case reports will be excluded. The studies will be selected if their participants were aged 40–60 years, had elevated follicle-stimulating hormone (FSH) levels and/or menstrual irregularities, and experienced discomforting VMS (at least hot flushes or night sweats). The primary outcome will be the rate of response to treatment, such as changes in frequency and intensity of symptoms in the intervention and placebo groups. 'Hop', 'Humulus', 'menopause', 'vasomotor', 'hot flashes', 'phytoestrogen' and 'night sweats' will be used as search key words. Prior to their inclusion in the review, the selected papers will be assessed by two independent reviewers for methodological validity. Any disagreements will be resolved through a third reviewer. The risk of bias will be independently determined using the Cochrane Risk of Bias Tool. The quality of the papers will be assessed based on the CONSORT checklist. **Ethics and Dissemination:** Results will be disseminated through traditional academic literature. Dissemination of results will occur by peer-reviewed publications. The results of our project can help reproductive health researchers when evaluating the discomforts of research procedures described in study protocols or when designing a study. Information on experiences of menopausal women involved in previous studies may also help in future research. The expected dissemination actions are effective treatment in designing strategies that aim to develop women's health and healthcare providers when offering treatment for women with vasomotor symptoms.

Relevanz für die Praxis

Hopfen enthält 8-Prenylnaringenin (8-PN) und ist einer der stärksten Phytoöstrogene. Weitere Synonyme sind Flavaprenin oder Hopein. Seine Wirkungsweise ist sehr ähnlich dem Östradiol, wenn auch weniger potent (ER-alpha-Agonist).

In dieser Studie wird ein Protokoll für eine Metaanalyse vorgestellt, das sich mit dem Thema „response of treatment“, also Behandlungserfolg bei menopausalen Beschwerden und Phytoöstrogenen aus Hopfen auseinandersetzt.

■ Evaluation of the Biological Activity of *Opuntia ficus indica* as a Tissue- and Estrogen Receptor Subtype-Selective Modulator

An BH, et al. *Phytother Res* 2016 [Epub ahead of print].

Abstract

Phytoestrogens are selective estrogen receptor modulators (SERMs) with potential for use in hormone replacement therapy (HRT) to relieve peri/postmenopausal symptoms. This study was aimed at elucidating the molecular mechanisms underlying the SERM properties of the extract of Korean-grown *Opuntia ficus-indica* (KOFI). The KOFI extract induced estrogen response element (ERE)-driven

transcription in breast and endometrial cancer cell lines and the expression of endogenous estrogen-responsive genes in breast cancer cells. The flavonoid content of different KOFI preparations affected ERE-luciferase activities, implying that the flavonoid composition likely mediated the estrogenic activities in cells. Oral administration of KOFI decreased the weight gain and levels of both serum glucose and triglyceride in ovariectomized (OVX) rats. Finally, KOFI had an inhibitory effect on the 17 β -estradiol-induced proliferation of the endometrial epithelium in OVX rats. Our data demonstrate that KOFI exhibited SERM activity with no uterotrophic side effects. Therefore, KOFI alone or in combination with other botanical supplements, vitamins, or minerals may be an effective and safe alternative active ingredient to HRTs, for the management of postmenopausal symptoms.

Relevanz für die Praxis

Der Extrakt des Feigenkaktus scheint im Tierversuch als SERM positive Auswirkungen auf das Gewicht im Sinne eines Gewichtsverlustes zu haben und bei oraler Gabe erniedrigt es auch den Triglyceridspiegel. Bei ovariectomierten Ratten zeigt sich die SERM-Aktivität: Feigenkaktusextrakt (KOFI) inhibiert die Proliferation der Endometriumschleimhaut durch Östradiol. Ein interessanter Aspekt für zukünftige Therapien besonders im Bereich der Prävention.

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