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## News-Screen Menopause

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# News-Screen Menopause

## Androgentherapie in der Menopause

P. Frigo

### ■ Dehydroepiandrosterone for Women in the Peri- or Postmenopausal Phase

Scheffers CS, et al. *Cochrane Database Syst Rev* 2015; 1: CD 011066.

#### Abstract

**Background:** During menopause a decreasing ovarian follicular response generally causes a fluctuation and eventual decrease in estrogen levels. This can lead to the development of various perimenopausal and postmenopausal symptoms (for example hot flushes, night sweats, vaginal dryness). Dehydroepiandrosterone (DHEA) is one of the main precursors of androgens, which in turn are converted to testosterone and estrogens. It is possible that the administration of DHEA may increase estrogen and testosterone levels in peri- and postmenopausal women to alleviate their symptoms and improve general wellbeing and sexual function (for example libido, dyspareunia, satisfaction). Treatment with DHEA is controversial as there is uncertainty about its effectiveness and safety. This review should clearly outline the evidence for DHEA in the treatment of menopausal symptoms and evaluate its effectiveness and safety by combining the results of randomised controlled trials. **Objectives:** To assess the effectiveness and safety of administering DHEA to women with menopausal symptoms in the peri- or postmenopausal phase. **Search Methods:** The databases that we searched (3 June 2014) with no language restrictions applied were the Cochrane Menstrual Disorders and Subfertility Group Specialised Register, Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, PsycINFO, CINAHL and LILACS. We also searched conference abstracts and citation lists in the ISI Web of Knowledge. Ongoing trials were searched in the trials registers. Reference lists of retrieved articles were checked. **Selection Criteria:** We included randomised controlled trials comparing any dose and form of DHEA by any route of administration versus any other active intervention, placebo or no treatment for a minimal treatment duration of seven days in peri- and postmenopausal women. **Data Collection and Analysis:** Two authors independently extracted data after assessing eligibility for inclusion and quality of studies. Authors were contacted for additional information. **Main Results:** Twenty-eight trials with 1273 menopausal women were included in this review. Data could be extracted from 16 trials to conduct the meta-analysis. The overall quality of the studies was moderate to low with the majority of studies that were included in the meta-analysis having reasonable methodology. Compared to placebo, DHEA did not improve quality of life (standardised mean difference (SMD) 0.16, 95 % confidence interval (CI) -0.03 to 0.34,  $P = 0.10$ , 8 studies, 287 women (132 from parallel and 155 from crossover trials),  $I^2 = 0\%$ , moderate

quality evidence; one trial of the nine that reported on this outcome was removed in a sensitivity analysis as it was judged to be at high risk of bias). DHEA was found to be associated with androgenic side effects (mainly acne) (odds ratio (OR) 3.77, 95 % CI 1.36 to 10.4,  $P = 0.01$ , 5 studies, 376 women,  $I^2 = 10\%$ , moderate quality evidence) when compared to placebo. No associations were found with other adverse effects. It was unclear whether DHEA affected menopausal symptoms as the results from the trials were inconsistent and could not easily be pooled to provide an overall effect due to different types of measurement (for example continuous, dichotomous, change and end scores). DHEA was found to improve sexual function (SMD 0.31, 95 % CI 0.07 to 0.55,  $P = 0.01$ , 5 studies, 261 women (239 women from parallel trials and 22 women from crossover trials),  $I^2 = 0\%$ ; one trial judged to be at high risk of bias was removed during sensitivity analysis) compared to placebo. There was no difference in the acne associated with DHEA when comparing studies that used oral DHEA (OR 2.16, 95 % CI 0.47 to 9.96,  $P = 0.90$ , 3 studies, 136 women,  $I^2 = 5\%$ , very low quality evidence) to one study that used skin application of DHEA (OR 2.74, 95 % CI 0.10 to 74.87,  $P = 0.90$ , 1 study, 22 women, very low quality evidence). The effects did not differ for sexual function when studies using oral DHEA (SMD 0.11, 95 % CI -0.13 to 0.35,  $P = 0.36$ , 5 studies, 340 women,  $I^2 = 0\%$ ) were compared to a study using intravaginal DHEA (SMD 0.42, 95 % CI 0.03 to 0.81, 1 study, 218 women). Test for subgroup differences:  $Chi^2 = 1.77$ ,  $df = 1$  ( $P = 0.18$ ),  $I^2 = 43.4\%$ . Insufficient data were available to assess quality of life and menopausal symptoms for this comparison. There were insufficient data available to compare the effects of DHEA to hormone therapy (HT) for quality of life, menopausal symptoms, and adverse effects. No large differences in treatment effects were found for sexual function when comparing DHEA to HT (mean difference (MD) 1.26, 95 % CI -0.21 to 2.73,  $P = 0.09$ , 2 studies, 41 women,  $I^2 = 0\%$ ). **Authors' Conclusions:** There is no evidence that DHEA improves quality of life but there is some evidence that it is associated with androgenic side effects. There is uncertainty whether DHEA decreases menopausal symptoms, but DHEA may slightly improve sexual function compared with placebo.

#### Relevanz für die Praxis

In dieser Arbeit wurden insgesamt 1273 menopausale Patientinnen aus Vergleichsstudien mit DHEA gegen Placebo oder einer anderen Therapie zusammengefasst und ausgewertet: Es zeigte sich, dass sich die Lebensqualität durch DHEA nicht erhöhte, allerdings war eine leichte Abnahme der klimakterischen Beschwerden beobachtbar. Die Hauptwirkung (placebo-kontrolliert) von DHEA lag in einer Verbesserung der Sexualität. Die beschriebene Nebenwirkung war eine klassische aller Androgene: unreine Haut, sprich Akne. In der Praxis wird

DHEA zumeist im Anti-Aging-Bereich eingesetzt; es scheint, dass der Einsatz bei z. B. Libidoverlust und anderen Sexualproblemen, die mit einem niedrigen Androgenspiegel vergesellschaftet sind, gerechtfertigt ist.

### ■ To Be or Not to Be in Sexual Desire: The Androgen Dilemma

Nappi RE. *Climacteric* 2015; 18: 672–4.

#### Abstract

The androgen milieu and sexual desire in women seem to be tightly linked because they both decline with age. However, we are still missing a cut-off plasma level for androgens (total testosterone, free testosterone) or androgen precursors (androstenedione, dehydroepiandrosterone (DHEA) and DHEA sulfate (DHEAS)) to diagnose androgen deficiency in clinical practice. Apart from the complex multidimensional nature of sexual desire across the reproductive lifespan, the correlation between measurements of testosterone and specific signs and symptoms has been difficult because, according to guidelines, most available assays are unreliable at baseline and under hormonal treatments. Recent data obtained with accurate methods based on mass spectrometry to measure total testosterone levels found a significant positive association with sexual desire, arousal and masturbation in midlife US women across the menopausal transition. Even in a European cohort of healthy women aged 19–65 years, sexual desire, measured with a validated questionnaire, correlated overall with free testosterone and androstenedione measured with mass spectrometry. Collectively, these data support the therapeutic use of testosterone for low desire and sexual dysfunction in those clinical conditions in which androgen deficiency may be accurately diagnosed.

#### Relevanz für die Praxis

In dieser Studie wird besonders auf die Bedeutung des Testosterons bei verringerter Libido bzw. anderen Sexualstörungen hingewiesen. Der Autor beruft sich auf Studien, die eine negative Korrelation von Testosteron und Sexualfunktion zeigen. Eine Lokaltherapie mit testosteronhaltigen Cremes kann empfohlen werden. Systemische Testosterontherapien für die Frau, wie das kurzzeitig am Markt erhältliche Testosteronpflaster Intrinsa, das leider vom Markt genommen wurde, sind nur in Ausnahmefällen indiziert.

### ■ Dry Eye in Postmenopausal Women: A Hormonal Disorder

Sriprasert I, et al. *Menopause* 2015 [Epub ahead of print].

#### Abstract

**Objective:** This review examines the etiology and pathophysiology of dry eye disease in postmenopausal women, and describes the steroid reproductive hormone influences that may contribute to its development. **Methods:** We have

reviewed the relevant studies on dry eye disease related to hormonal status and hormone therapy (HT) in both animal models and humans. **Results:** Although both low and high estrogen levels have been associated with symptoms of dry eye disease, low androgen levels are a more consistent factor in its etiology. Postmenopausal HT with estrogen or estrogen plus progestogen has shown a limited benefit for dry eye symptoms and may even result in progression of meibomian gland dysfunction, decreased tear film break up time, and tear flow reduction. However, systemic or local androgen treatment has shown promising results in improving dry eye symptoms. **Conclusions:** Because of the high incidence of dry eye among postmenopausal women that may be related to the hormonal treatment, we propose that a multidisciplinary approach should be considered between gynecologists and ophthalmologists in management of this disorder.

#### Relevanz für die Praxis

Das trockene Auge und die Therapie mit Östrogenen ist schon länger bekannt [1, 2]. Eine Therapie mit Androgenen ist ein interessanter neuer Aspekt, der sicher noch einiger Studien bedarf.

### ■ Androgen Therapy in Women: A Reappraisal: An Endocrine Society Clinical Practice Guideline

Wierman ME, et al. *J Clin Endocrinol Metab* 2014; 99: 3489–510.

#### Abstract

**Objective:** To update practice guidelines for the therapeutic use of androgens in women. **Participants:** A Task Force appointed by the Endocrine Society, American Congress of Obstetricians and Gynecologists (ACOG), American Society for Reproductive Medicine (ASRM), European Society of Endocrinology (ESE), and International Menopause Society (IMS) consisting of six experts, a methodologist, and a medical writer. **Evidence:** The Task Force commissioned two systematic reviews of published data and considered several other existing meta-analyses and trials. The GRADE methodology was used; the strength of a recommendation is indicated by a number “1” (strong recommendation, we recommend) or “2” (weak recommendation, we suggest). **Consensus Process:** Multiple e-mail communications and conference calls determined consensus. Committees of the Endocrine Society, ASRM, ACOG, ESE, and IMS reviewed and commented on the drafts of the guidelines. **Conclusions:** We continue to recommend against making a diagnosis of androgen deficiency syndrome in healthy women because there is a lack of a well-defined syndrome, and data correlating androgen levels with specific signs or symptoms are unavailable. We recommend against the general use of T for the following indications: infertility; sexual dysfunction other than hypoactive sexual desire disorder; cognitive, cardiovascular, metabolic, or bone health; or general well-being. We recommend against the routine

*use of dehydroepiandrosterone due to limited data concerning its effectiveness and safety in normal women or those with adrenal insufficiency. We recommend against the routine prescription of T or dehydroepiandrosterone for the treatment of women with low androgen levels due to hypopituitarism, adrenal insufficiency, surgical menopause, pharmacological glucocorticoid administration, or other conditions associated with low androgen levels because there are limited data supporting improvement in signs and symptoms with therapy and no long-term studies of risk. Evidence supports the short-term efficacy and safety of high physiological doses of T treatment of postmenopausal women with sexual dysfunction due to hypoactive sexual desire disorder. Importantly, endogenous T levels did not predict response to therapy. At present, physiological T preparations for use in women are not available in many countries including the United States, and long-term safety data are lacking. We recommend that any woman receiving T therapy be monitored for signs and symptoms of androgen excess. We outline areas for future research. Ongoing improvement in androgen assays will allow a redefinition of normal ranges across the lifespan; this may help to clarify the impact of varying concentrations of plasma androgens on the biology, physiology, and psychology in women and lead to indications for therapeutic interventions.*

### Relevanz für die Praxis

Das Konsensuspapier der Amerikanischen Gesellschaft, der Internationalen Menopausengesellschaft u.v.m. zeigt, dass die Androgentherapie der Frau wie auch die weibliche Andropause überhaupt erst am Beginn ihrer Erforschung steht. Selbst Normalwerte für die einzelnen Lebensphasen sind auch aufgrund zahlreicher unterschiedlicher Labormethoden nicht standardisiert. In diesem Statement wird die Testosterontherapie der Frau bei Libidoverlust angesprochen; diese sollte möglichst physiologisch und auch nur kurzzeitig sein, da Daten aus Langzeitstudien fehlen.

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2. Sator MO, Joura EA, Frigo P, et al. Hormone replacement therapy and intraocular pressure. Maturitas 1997; 28: 55–8.

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