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Digitized assessment of mammographic breast density – Effects c

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Digitized assessment of mammographic breast density--effects of continuous combined hormone therapy, tibolone and black cohosh compared to placebo.

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Abstract

OBJECTIVES: To determine the **effects** of **continuous combined hormone therapy**, **tibolone**, **black cohosh**, and **placebo** on **digitized mammographic breast density** in postmenopausal women.

STUDY DESIGN: A prospective, double-blind, **placebo**-controlled study of 154 postmenopausal women randomized to estradiol 2 mg/norethisterone acetate 1 mg (E2/NETA), **tibolone** 2.5 mg or **placebo** and a prospective, open, uncontrolled drug safety study, of which 65 postmenopausal women were treated with **black cohosh**. Mammograms, at baseline and after six months of treatment, were previously classified according to visual quantification scales.

MAIN OUTCOME MEASURES: Reanalysis of assessable mammograms by **digitized** quantification of **breast density**.

RESULTS: Treatment groups were comparable at baseline. During treatment, both E2/NETA and **tibolone** significantly increased **breast density** (mean increase 14.3%, $p < 0.001$ and 2.3%, $p < 0.001$, respectively), while **black cohosh** and **placebo** did not. Twenty-four out of the 43 women on E2/NETA had an increase in **density** exceeding 10% and 6 women had an increase of 30% or more. In the **tibolone** group, only one woman had an increase in **density** of more than 10%. The difference in increase in **breast density** between E2/NETA on the one hand and **tibolone**, **black cohosh** and **placebo** on the other was highly significant ($p < 0.0001$).

CONCLUSIONS: **Digitized mammographic breast density** is a highly sensitive method confirming significant increase in **density** by standard E2/NETA treatment and to a lesser extent by **tibolone**, whereas **black cohosh** does not influence **mammographic breast density** during six months treatment. **Digitized assessment** also yields data on individual variation and small increases left undetectable by visual classification.

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