Postmenopausal HRT and tibolone in relation to muscle strength and body composition

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CRD summary
This review concluded that hormone replacement therapy and tibolone increase muscle strength. Tibolone also increases lean body mass and total body fat content. The authors’ conclusions appear to be supported by the data presented, but their reliability is unclear given the poor reporting of the review methods and the lack of a validity assessment.

Authors' objectives
To assess the effects of hormone replacement therapy (HRT) and tibolone on body composition and muscle strength in postmenopausal women.

Searching
MEDLINE, PubMed, EMBASE and SUMSearch were searched without date limits; the search terms were reported. In addition, the reference lists of retrieved articles were screened for further studies.

Study selection
Randomised controlled trials (RCTs), cross-sectional studies and observational studies assessing the effects of HRT on muscle strength and body composition were eligible for inclusion; studies had to initially include at least 20 participants per study group. Seven studies assessed tibolone in comparison with HRT and/or placebo and other control groups. Four studies also included exercise alone or in addition to HRT or tibolone. The duration of follow-up varied from 6 months to 2 years in the muscle strength studies, and from 16 weeks to 5 years in the body composition studies. Body composition was determined using a variety of methods including dual-photon absorptiometry and dual-energy X-ray absorptiometry; intra-abdominal and subcutaneous fat was usually determined using bioelectrical impedance assessments. The age of the included participants ranged from 40 to 75 years, and both early and late menopausal women were included. One study also included premenopausal women and men.

The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not report that they assessed validity, although they did report whether studies were randomised, blinded and the proportion of participants that dropped out, where relevant.

Data extraction
The outcomes were recorded as either negative, no effect or positive. Where effects were positive, effect sizes and p-values were usually reported.

The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction.

Methods of synthesis
Study data were grouped according to outcome (body composition or muscle strength) and combined in a narrative, with accompanying data tables. Some differences between the studies were discussed in the review text and were evident from the data tables.

Results of the review
Twenty-eight studies (n=5,755) in total were included: 10 placebo-controlled RCTs, 7 RCTs, 4 cross-sectional studies, 2 prospective studies, 2 partly randomised cohort studies, an open-label study and 2 longitudinal studies (one randomised and one prospective).

Ten RCTs (of which eight were placebo-controlled) were double-blinded. Drop-out rates within individual treatment
and control groups ranged from 0 to 50%, where reported. Most of the study groups had drop-out rates below 20%, but 3 studies (one placebo-controlled RCT of muscle strength, one placebo-controlled RCT, and one partly randomised cohort of body composition) had one or more treatment groups with a drop-out rate of 40% or more.

Effects on muscle strength (6 RCTs and 5 observational studies).

Two double-blind, placebo-controlled RCTs, both of which included an exercise component, and one other RCT reported statistically significant positive effects of HRT on muscle strength (isometric back extensor muscle strength; knee extension and vertical jumping height). However, the 2 RCTs of exercise had high drop-out rates in the exercise groups, which confounded the data. In comparison, one placebo-controlled RCT and one other RCT found no effects of HRT. One cross-sectional study also reported positive effects for HRT, but another cross-sectional study and 2 prospective studies reported no effect of HRT on muscle strength. Further details of the studies were reported in the review.

One double-blind, placebo-controlled RCT reported a significant improvement in handgrip strength for tibolone in comparison with placebo in postmenopausal women, in addition to a positive effect on body mass index-adjusted isometric knee extension strength. One cross-sectional study also reported non significant positive effects on mean knee extensor strength for tibolone and oestrogen, in comparison with no HRT.

Effects on body composition (11 RCTs, one open-label controlled trial and 5 observational studies).

Five studies (one placebo-controlled RCT, one RCT, one prospective longitudinal study and 2 partly randomised cohort studies) reported that conventional HRT had a significant positive effect on body composition. However, 5 RCTs (3 double-blind, placebo-controlled RCTs, one placebo-controlled RCT and one RCT) failed to find any effect of HRT on body composition. One double-blind, placebo-controlled RCT, one RCT, one open-label controlled study and one randomised longitudinal study reported significant positive effects for tibolone on body composition. One cross-sectional study reported a negative effect for HRT. Further details were reported in the review.

Authors’ conclusions
HRT increases muscle strength. Tibolone increases muscle strength and lean body mass, whilst also significantly reducing the total body fat content. The effects of HRT on body composition are unclear.

CRD commentary
This review answered a clear review question using a broad range of study designs, but inclusion criteria for the participants were not clear and had to be assumed from the review title. A number of electronic databases were searched for published studies, but it is unclear whether there were specific attempts to locate unpublished data and whether any limitations were placed on the language of publication; it is therefore difficult to assess the risk of publication and language bias. The authors failed to report details of the review methods, which makes it difficult to assess the risk of reviewer error and bias. In addition, there was no report of a validity assessment being carried out, although important data relating to randomisation, blinding, drop-outs and follow-up were reported, which gives the reader some indication of the reliability of the results. Given the different study designs, patients, interventions and outcomes included in the review, the narrative synthesis is justified and the data were often discussed with respect to both heterogeneity and potential methodological flaws. Overall, the authors’ conclusions appear to be supported by the data presented, but it is difficult to assess the reliability of the data without further details of the review methods and the validity of the included studies.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that further research is required to confirm the effects of tibolone on muscle strength and to investigate its safety, particularly for use in patients with sarcopenia.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.