Effects of hormone therapy on health related quality of life in postmenopausal women with CAD differed according to presence of menopausal symptoms


QUESTION: Does hormone therapy (HT) improve health related quality of life (HRQL) in postmenopausal women with coronary artery disease (CAD)?

Design
Randomised (allocation concealed)*, blinded [patients, clinicians, and outcome assessors]* placebo controlled trial with follow up to 3 years.

Setting
Outpatient and community settings in 20 clinical centres in the US.

Patients
2763 postmenopausal women <80 years of age (mean age 67 y) with documented CAD (previous myocardial infarction [MI], >50% luminal narrowing of a major vessel on angiography, or a previous coronary revascularisation procedure). Exclusion criteria were MI or revascularisation procedure in the previous 6 months, previous hysterectomy, contraindications to HT, HT in the previous 3 months, or life threatening illness. 2762 (99.9%) were included in the analysis; 2246 (81%) had HRQL data for all time points (baseline, 4 mo, 1 y, and 3 y).

Intervention
1380 women were allocated to HT (0.625 mg of conjugated equine estrogens and 2.5 mg of medroxyprogesterone acetate [Prempro, Wyeth Ayerst, Radnor, PA]), and 1383 were allocated to placebo.

Main outcome measures
HRQL questionnaires assessing physical function (Duke Activity Status Index), energy/fatigue (4 item RAND scale), mental health (RAND Mental Health Inventory), and depressive symptoms (8 item scale by Burnam et al).

Main results
Analysis was by intention to treat. At 3 years, scores for physical function, energy/fatigue, and depressive symptoms over 3 years, but did not differ from those who received placebo for physical function or energy/fatigue (table). Women with no flushing (n=2925) who received HT, however, had greater declines in physical function and energy/fatigue, but did not differ for mental health (table).

Subgroup analysis based on presence of flushing symptoms at baseline showed that women with flushing (n=434) who received HT had improved mental health and depressive symptoms over 3 years, but did not differ from those who received placebo for physical function or energy/fatigue (table). Women with no flushing (n=2925) who received HT, however, had greater declines in physical function and energy/fatigue, but did not differ for mental health or depressive symptoms from those who received placebo.

Conclusions
In postmenopausal women with coronary artery disease, hormone therapy reduced physical function and energy but improved depressive symptoms overall. Hormone therapy improved emotional quality of life in women with flushing symptoms, but reduced physical quality of life in women with no flushing symptoms.

A modified version of this abstract appears in Evidence-Based Medicine and Evidence-Based Mental Health

Hormone therapy v placebo for postmenopausal women with coronary artery disease

<table>
<thead>
<tr>
<th>Outcomes at 3 years</th>
<th>Mean change in scores (hormone therapy v placebo, p value)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All patients</td>
</tr>
<tr>
<td>Physical function</td>
<td>–4.4 v –3.1†</td>
</tr>
<tr>
<td>Energy/fatigue</td>
<td>–4.6 v –3.0†</td>
</tr>
<tr>
<td>Mental health</td>
<td>–0.2 v –0.9†</td>
</tr>
<tr>
<td>Depressive symptoms</td>
<td>No data available†</td>
</tr>
</tbody>
</table>

†p Values not reported.

COMMENTS
The issues surrounding HT have been conflicting and fraught with controversy for many years. Unfortunately, recent research has done little to clarify these issues for healthcare providers and patients. The aim of the study by Hlatky et al was to investigate quality of life issues in older, postmenopausal women using combined oestrogen and progestogen therapy as secondary prevention for CAD. The results are consistent with earlier studies in which depressive symptoms were improved with HT in older, postmenopausal women.1, 2

It is important to note that these study findings are highly specific and therefore should not be generalised to different age groups or patient populations. Study participants were older women with known or advanced heart disease only. Positive conclusions regarding HRQL were limited to women who had previously had postmenopausal symptoms of flushing.

The results are relevant to women’s healthcare nurses and geriatric nurses working to educate patients about the risks and benefits of HT. Specifically, advanced practitioners who are able to prescribe HT can use these data when making decisions about which patients are appropriate candidates for treatment. The findings support the use of HT for mental health outcomes in postmenopausal women who have symptoms such as flushing. The effect of HT on the physical dimension of quality of life was generally negative. The results do not provide advanced practitioners with assistance when considering the prescription of HT for younger patients approaching menopause. Additional quality of life issues in menopause such as insomnia, sexual satisfaction, concentration, memory, and mood were not addressed in this study.

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