



INTERNATIONAL MENOPAUSE SOCIETY

THE SOCIETY FOR THE STUDY OF ALL ASPECTS OF THE CLIMACTERIC IN MEN AND WOMEN

Press Statement

ISSUED ON BEHALF OF THE INTERNATIONAL MENOPAUSE SOCIETY BY

David Sturdee, *President*

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The effects of tibolone in older postmenopausal women

The recent report from the LIFT study¹, a large, randomized, controlled trial of the hormone replacement therapy (HRT) tibolone in older postmenopausal women with osteoporosis, provides some good news and some bad news.

The primary aim of the study was to confirm that tibolone reduces the risk of osteoporotic vertebral fracture. The secondary aims were to evaluate the effects of tibolone on the risks of non-vertebral fractures, breast cancer, deep vein thrombosis and cardiovascular disease over 3–5 years of study.

There was a significant reduction in the risk of vertebral fractures, with 70 cases in the treated group compared with 126 cases per 1000 person-years in the placebo group. The absolute reduction was greatest in women with a previous fracture (20.8/1000 person-years (per year)) compared to those who had not had such a fracture (4.6/1000 person-years). There was also a significant reduction (68%) in the risk of invasive breast cancer at 6 cases versus 19 cases/1000 person-years and a reduction of colon cancer (69%) at 4 versus 13/1000 person-years. These very worthwhile benefits have to be considered against an increased risk of stroke at 28 versus 13/1000 person-years, which was the reason for stopping the study earlier than planned at 3 years. However, this risk was much greater in women aged over 70 years, who represented 40% of the study population, who had 3.1 extra cases with stroke/1000 person-years compared to 1.8 extra cases in those aged 60–69 years.

Executive Director: Mrs Jean Wright
PO Box 687, Wray, Lancaster LA2 8WY, UK
Tel: +44 15242 21190 Fax: +44 15242 22596
e-mail: jwright.ims@btopenworld.com

This study has shown that:

- Tibolone reduces the risk of osteoporotic fractures similar to other treatments such as HRT, bisphosphonates and raloxifene
- Tibolone *reduces* the risk of invasive breast cancer similar to raloxifene and tamoxifen
- The only significant adverse effect was an increased risk of stroke which was greatest in women over the age of 70 years
- Tibolone should be used with caution in elderly women, where the potential benefit/risk ratio may be less than for younger women below the age of 70 years
- The age at which hormone therapy is given is critical, as was also shown in the Women's Health Initiative (WHI) studies with the effects of conventional HRT
- The dose of tibolone in this study (1.25 mg) was half what is generally available and widely used, so the implications for women using the 2.5 mg preparation are not clear, but the risk of stroke may be greater.

Dr David Sturdee, President of the International Menopause Society, said:

This study confirms that tibolone reduces the risk of osteoporotic fractures and also reduces the incidence of invasive breast cancer. But in older women, or women with an increased risk of stroke, alternative treatments should be considered. As all the major studies over the last few years have shown, HRT is not a 'one-size fits all' solution, and the age at initiation of treatment is critical. For every woman, therapy needs to be individualized in consultation with her medical adviser, depending on her age and the indications.

Reference

1. Cummings SR, Ettinger B, Delmas PD, *et al.* for the LIFT Trial investigators. The effects of tibolone in older postmenopausal women. *N Engl J Med* 2008;359:697–708