

Head of German medicines body likens HRT to thalidomide

Jane Burgermeister *Vienna*

Doctors in Germany should drastically reduce the amount of hormone replacement therapy (HRT) that they prescribe to older women, a key commission has recommended.

Issuing its first guidelines on HRT to doctors in Germany, the country's Commission on the Safety of Medicines said that new international studies had shown that the risks of HRT clearly outweighed the benefits.

It recommended that doctors offer the treatment only to women with particularly severe menopausal symptoms. It also recommended that treatment be as short, and the doses as low, as possible.

Several recently published studies have shown that HRT significantly increases the risk of breast cancer. Also, the risk of venous thrombosis, heart attacks, and strokes increases as early as one year after treatment, according to the studies.

In the opinion of the commission, the new studies show that the risks of HRT far outstrip the benefits, which include lower rates of colon cancer and a reduction in the number of fractures.

Professor Bruno Müller-Oerlinghausen, the head of the commission, called HRT a "national

and international tragedy." Comparing it to thalidomide, a drug that caused thousands of babies to be born with birth defects in the 1950s, he said that the "naive and careless use of a medication that is perceived as natural and optimal" had caused many unnecessary deaths among women.

Professor Eberhard Greiser, of the Institute for Prevention Research in Bremen, said in an interview with the state health insurance press service that the use of hormone replacement therapy had resulted in 5000 extra cases of breast cancer in Germany every year and 2000 extra cases of cancer of the uterus (<http://212.227.33.34/bv/bundesvb/presse/tba/medizin/977632.html>).

The commission also launched a fierce attack on the pharmaceutical industry, suggesting that it had turned a "natural phase of life," the menopause, into a hormonal sickness that needed treatment.

Forty three per cent of all women aged 50-70 years in Germany take hormone preparations.

However, the number of prescriptions that doctors issue for hormone preparations has fallen

gynaecological cancers or the frequency of diagnostic procedures being performed to rule out cancer (*JAMA* 2003; 290:1739-48).

The WHI trial followed 16 600 postmenopausal women enrolled at 40 different US clinical centres who had not had a hysterectomy. The women were randomised to two groups, one of which received a placebo and the other a single tablet (0.625 mg/day) of conjugated equine oestrogens plus 2.5 mg a day of medroxyprogesterone acetate. Women who had had a hysterectomy were randomised to a parallel WHI trial of oestrogen alone.

The first trial was stopped early in 2002 because health risks, particularly of an increased risk of breast cancer, were found to outweigh the benefits of the



Breast cancer survivors turn to art for healing

Annabel Ferriman *BMJ*

These pictures are from an exhibition entitled *Beyond the Obvious*, which displays the work of artist Irene Lumley and 12 women who have either had breast cancer or are related to those with the disease.

It is funded by South Manchester Healthy Living Network, South Manchester University Hospitals NHS Trust, and the European Social Fund and has received support from the photographic printers GBM Digital Technologies.

The participants worked with Irene Lumley in a series of workshops using photography to explore the issues surrounding the effects of breast cancer, such as self image, femininity, relationships, physical transition, and family history.

Beyond the Obvious is at the North Gallery, Whitworth Art Gallery, Oxford Road, Manchester M15 6ER, from 8 to 23 October.

by 13% in the wake of the recent debate on the risks of the treatment, according to figures from the German state health insurance companies.

The women's health initia-

tive study showed that the long term use of HRT increased the risk of breast cancer by 26% but reduced the risk of a fracture by 34%. (*JAMA* 2003; 289:3243-53). □

HRT may increase risk of ovarian cancer

Scott Gottlieb *New York*

Treatment for postmenopausal symptoms with oestrogen plus progestogen therapy may increase a woman's risk of ovarian cancer and may also increase the number of endometrial biopsies that women need before cancer can be diagnosed.

Dr Garnet Anderson from the Fred Hutchinson Cancer Research Center in Seattle and colleagues used data from the recently completed women's health initiative (WHI) trial to determine whether hormone replacement was associated with

therapy. That study found a risk ratio of 1.26, or a 26% increase (38 v 30 per 10 000 person years) of breast cancer (*JAMA* 2002;288:321-33). The second trial, in women who had had a hysterectomy, is still ongoing and is expected to be completed in 2005.

In the new analysis by Dr Anderson, after 5.6 years of follow up, oestrogen plus progestogen reduced rates of endometrial cancer by 19% but increased rates of ovarian cancer by 58%. These differences were not significant, however. In total, 27 ovarian cancers were diagnosed per 100 000 women per year in women randomised to the placebo group. With oestrogen plus progestogen, this rate was increased to 42 cancers in 100 000 women per year.

No evidence of a difference

was found between treatment groups in the distribution of tumour anatomy, grade, or stage of disease at diagnosis. The authors concluded that the numbers of other gynaecological cancers were too small to make reliable conclusions.

Though combined hormones seem to have a slightly protective effect on endometrial cancer, this therapy does not completely prevent the disease, and the vaginal bleeding that commonly occurs with hormone replacement therapy required women to have additional monitoring. Women in the study randomised to continuous combined hormones were subjected to more endometrial biopsies and vaginal ultrasound scans and were more frequently found to have mild abnormalities in routine Pap tests. □