

Study faults research linking hormone therapy to cancer

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A landmark investigation which found that hormone treatment for the menopause boosts the risk of breast cancer is riddled with flaws, a new study published on Monday alleges.

The so-called Million Women Study (MWS) unleashed headlines when it was first published in 2003.

Based on questionnaires returned by more than a million post-menopausal women in Britain, it said [hormone replacement therapy](#) (HRT) led to a rise in breast-cancer incidence.

Its estimate caused a wave of anxiety -- and much confusion -- among regulators and doctors and among women using HRT.

HRT uses the female hormones oestrogen or progestogen, sometimes combined, to ease [menopausal symptoms](#) such as hot flushes, loss of sex drive and [vaginal dryness](#).

Updates of the MWS have finetuned the perceived risk. The MWS website says there is an increased [cancer risk](#) of 30 percent in oestrogen-only treatment, and a twofold risk in oestrogen-progestogen therapy, compared with women who do not take these drugs.

The risk increases the longer a woman uses HRT, but drops to normal level within five years after stopping use, the MWS says.

But an assessment published on Monday in the Journal of [Family Planning](#) and [Reproductive Health](#) says the MWS's design has so many problems that a safe conclusion cannot be drawn.

"HRT may or may not increase the risk of breast cancer, but the MWS did not establish that it does," the paper says bluntly.

Among half a dozen points, the authors say cancers detected within a few months of the study's start would have already been present when the women were enrolled.

But these cases were not stripped out of the cancer count, it says.

The review also points to "detection bias" through the choice of participants.

The volunteers were taking part in a [breast screening](#) programme when they were invited to join the study.

They would thus have already known about [breast lumps](#) and suspect [lesions](#) that point to breast cancer. As a result, the MWS found a 40-percent higher incidence of breast cancer among its volunteers -- regardless of whether they used hormone therapy or not -- than in the population at large.

The paper also notes that breast cancers typically take many years to develop. It was thus "biologically implausible" that so many would have cropped up within a year or two of enrolment in the study, as the MWS maintained.

"The name 'Million Women Study' implies an authority beyond criticism or refutation," say the authors, led by Samuel Shapiro, a professor of public health at the University of Cape Town, South Africa.

"Yet the validity of any study is dependent on the quality of its design, execution, analysis and interpretation. Size alone does not guarantee that the findings are reliable."

In an email to AFP, the leaders of the MWS rebutted the criticism, saying that more than 20 studies had replicated its findings and a decline in the use of HRT had led to a fall in cases of breast cancer.

"Hormone-sensitive cancers are still three times as common in HRT users as in non-users or ex-users," said Richard Peto, a professor of statistics and epidemiology at Oxford University.

Independent commentator Anne Gombel, a French professor who is a member of the International Menopause Society, said a complex picture about breast cancer was emerging.

Breast density, alcohol and obesity, and not just HRT are now emerging as risk factors that should be taken into account, and not just HRT, said Gombel.

"HRT does not carry the same risk and benefit for each woman; some women will have increased risks, some will have only benefits, and this also applies to [breast cancer](#)."

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