

Different hormone therapy formulations may pose different risks for heart attack and stroke

September 18 2013

Post-menopausal women whose doctors prescribe hormone replacement therapy for severe hot flashes and other menopause symptoms may want to consider taking low doses of Food and Drug Administration-approved bioidentical forms of estrogen or getting their hormones via a transdermal patch. A new observational study shows bioidentical hormones in transdermal patches may be associated with a lower risk of heart attack and FDA-approved products—not compounded hormones—may be associated with a slightly lower risk of stroke compared to synthetic hormones in pill form.

"If confirmed by future randomized trials, these findings may be significant because for the past decade, many women who experienced severe menopause symptoms opted not to use hormone therapy because of the reported increased risk of stroke and heart attacks," said Chrisandra Shufelt, MD, director of the Women's Hormone and Menopause Program at the Barbra Streisand Women's Heart Center in the Cedars-Sinai Heart Institute.

Shufelt said the study's findings are not conclusive and are based on observational follow-up, not a randomized clinical trial. Additionally, all types of hormone therapy had similar rates of total <u>cardiovascular</u> <u>outcomes</u> and all-cause mortality, the study showed. The similarities in results across formulations were greater than the differences.



Following a 2002 study by the Women's Health Initiative (WHI), a randomized clinical trial sponsored by the National Heart, Lung, and Blood Institute that tied hormone replacement therapy to an increased risk for heart disease and stroke, many women avoided hormone therapy altogether. The WHI trials examined only synthetically-derived hormones delivered in pill form.

Shufelt and a team of investigators at the Barbra Streisand Women's Heart Center, Harvard Medical School, and other WHI clinical centers reviewed the scientific data collected by the Women's Health Initiative on 93,000 post-menopausal women and tracked their use of hormone therapy, along with their health outcomes. Results have been published on the website of the medical journal *Menopause* and will appear in the March 2014 print edition.

"Today there are many hormone options in the form of pills, patches and creams, synthetic or bioidentical, low dose or higher dose, and we wanted to answer whether they all have the same risk. This study is important because it is the first of its kind to provide a head-to-head comparison of the different doses and delivery methods. We found low dose and the transdermal patch may carry less risk for some outcomes than traditional hormone therapy, but more research is needed," Shufelt said.

"Our analysis of the data shows that women taking oral estradiol, the bioidentical as opposed to synthetic form of estrogen, may have a trend toward a slightly lower risk of having a stroke. Also, taking estradiol through a patch on the skin was associated with a slightly lower risk of heart disease when we compared it to taking a synthetic hormone in pill form." But the numbers of women using these newer forms of hormone therapy were small.

The researchers concluded that the FDA-approved estradiol form of



estrogen, and the transdermal delivery of hormones, may not carry that same increased risk for heart attack and stroke seen with oral regimens, but stressed that the findings are inconclusive and must be confirmed by randomized trials.

Shufelt said that this study adds to a growing body of evidence suggesting that hormone therapy taken through a patch, in smaller doses, may have less adverse effects on a woman's <u>risk</u> for developing cardiovascular disease than traditional <u>hormone therapy</u>.

Provided by Cedars-Sinai Medical Center

Citation: Different hormone therapy formulations may pose different risks for heart attack and stroke (2013, September 18) retrieved 2 May 2024 from https://medicalxpress.com/news/2013-09-hormone-therapy-pose-heart.html

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