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The 7 Things You Should Know About Hormones



A muddle of misinformation keeps clouding the debate over hormone-replacement therapy for women.

Last week, millions of women tuned into "The Oprah Winfrey Show" to hear actress Suzanne Somers sympathize with women suffering from what she called "The Seven Dwarfs of Menopause: Itchy, Bitchy, Sleepy, Sweaty, Bloated, Forgetful and All Dried Up." As she's done in her best-selling books, Ms. Somers, age 62, credited a custom-made blend of "bio-identical" hormones with maintaining her youthful zest and told viewers that the hormone debate boils down to a choice between "restoration versus deterioration."

There was little discussion of potential risks of HRT. The compounding pharmacies that make up such custom blends of hormones without oversight by the Food and Drug Administration often claim their products are so natural that they confer the benefits of hormone replacement (from restoring sleep, mood, memory and sexiness to protecting against osteoporosis) without the risks.

Millions of women abandoned menopause hormones after the big Women's Health Initiative trial was halted early in 2002 amid signs that they increased the risk of heart attack and stroke. A growing number of experts now believe that the women in the WHI -- average age 63 -- do not reflect the typical women entering menopause, and that the same risks may not apply to younger women.

Even so, women seeking safer alternatives have turned to "bio-identicals" -- a trend that worries mainstream medical groups. "Women who were afraid after the WHI, as were their doctors, are going to alternative approaches that have little or no scientific information behind them," says Margaret Weirman, a professor of medicine at the University of Colorado Denver and a spokeswoman for the Endocrine Society, a professional organization devoted to hormone research. "These women may be putting themselves at much higher levels of risk."

Amid all the confusion, here are seven things women should know about the HRT debate now:

1) 'Bio-identical' hormones are available in FDA-approved forms.

Though many experts dismiss "bio-identical" as a meaningless term, proponents use it to mean hormones with the same molecular structure as those that women's bodies make. The main one lost at menopause is estradiol, which affects functions throughout the female body, from skin to bones, hearts and brains. Chemically equivalent estradiol is

available in many FDA-approved pills, patches, creams and gels from traditional drug companies, generally made from the exact same plant sources that compounding pharmacies use. What's more, the FDA-approved varieties are covered by insurance, unlike compounded blends that can cost hundreds of dollars a month.

A growing number of doctors prescribe these estradiol-based products instead of Premarin, the estrogen made from horse urine that was used in the WHI. Many also prefer natural progesterone, available in FDA-approved Prometrium, to the synthetic form that was used in the WHI. But there is little evidence comparing one HRT variety against another.

2) Hormones from compounding pharmacies aren't safer than conventional HRT.

Compounded drugs don't carry warnings or list side effects on their labels, but that's because they are not made under FDA scrutiny. In fact, they can vary greatly in strength and potency and little is known about how they release active ingredients over time. "We don't know if it comes out in peaks and valleys or continuously," says Dr. Weirman. "Some people may be getting very high doses, and some people may be getting very little or none."

The International Academy of Compounding Pharmacists contends that its members perform a valuable service in making drugs and strengths that aren't commercially available, that they are providing women with freedom of choice in health-care decisions and that much of the criticism is coming from groups funded by makers of traditional HRT.

3) Don't trust saliva tests.

Some compounding pharmacies use saliva tests to monitor women's hormone levels and develop custom blends. But many experts say such tests (which can cost hundreds of dollars) are unreliable and lack uniform standards.

Blood tests are more accurate -- but monitoring how women feel is just as key. Many doctors believe that HRT should be used mainly to treat actual symptoms such as hot flashes, mood swings, sleep problems, foggy thinking and other symptoms, rather than arbitrary blood levels since individual ranges vary widely. FDA-approved estradiol products are available in a wide variety of strengths that can be tapered as a woman's symptoms change.

4) There's a critical window of time for starting HRT.

There's a growing consensus that the risks and benefits are different for younger and older women, and that for women who start HRT shortly after menopause, the benefits may outweigh the risks. Women in the WHI who were 20 years past menopause had a 71% higher risk of heart attack on estrogen and progesterone than those taking placebos, but women closer to menopause had an 11% lower risk of heart problems. One theory is that estrogen helps keep healthy blood vessels supple, but make atherosclerosis worse once it has set in.

Similarly, HRT seems to help preserve thinking ability when started just after menopause, but it may hasten the progression of pre-existing memory problems when started later in life, writes JoAnn E. Manson, a Harvard Medical School professor who was a lead investigator on both the WHI and the long-running Nurses' Health Study, in her new book, "Hot Flashes, Hormones and Your Health."

HRT was associated with a lower risk of fractures and colorectal cancer regardless of age. The WHI did not assess whether HRT improved quality-of-life issues such as mood, sleep and hot flashes. Women experiencing such symptoms were excluded from the study on the grounds that immediate effects might prompt some to guess whether they were in the control or placebo group.

5) The increased risk of breast cancer appears related to progesterone rather than estrogen.

Women taking both estrogen and progesterone in the WHI had eight more cases of breast cancer per 10,000 than the control group; women taking estrogen alone had six fewer cases. Women who still have a uterus need some

progesterone to guard against uterine cancer, but many doctors now try to give the lowest dose possible to prevent a build-up of uterine lining.

6) Estrogen applied to the skin, in patch, cream or gel form, may have a lower risk of blood clots and strokes than in pill form.

A large study in France published in the Lancet found that women taking estrogen in pill form were three times as likely to develop blood clots than non-users, while women using the estradiol patch had no increased risk. But more study is needed to determine this conclusively.

7) Stay tuned.

Several of these new theories are being tested in another trial called KEEPS (for Kronos Early Estrogen Prevention Study) that is comparing 720 newly menopausal women on oral Premarin, an estrogen patch or placebo. Investigators will monitor their arteries, as well as quality-of-life aspects like mood, fatigue, sleep, bone health and cognition.

In the meantime, women entering menopause should discuss all the risks and benefits with their doctors, as well as their symptoms, health and family history, and make an individual, informed decision.

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