

Transdermal Hormones Yield CV Benefits in Menopause

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NEW ORLEANS — Compounded transdermal hormone therapy relieves menopausal symptoms while improving cardiovascular risk factors and inflammatory and thrombotic biomarkers, according to a preliminary study.

“By replacing the hormone that’s deficient via transdermal dosing it may be possible to more closely mimic normal physiology and favorably impact cardiometabolic clinical biomarkers. Despite FDA concerns of dangers of compounded hormone use, our data suggest that transdermal compounded hormones may offer a safe and effective treatment for hormone-related symptoms when utilizing dosages targeting physiologic reference ranges and compounds, which meet USP standards for potency,” Dr. Kenna Stephenson, a family physician active in clinical research in women’s health at the University of Texas Health Science Center at Tyler, said at the annual scientific sessions of the American Heart Association.

Her study involves 150 women, mean age 51.9 years, with menopausal symptoms, who were randomized to usual care or individualized transdermal plant-derived estrogen, progesterone, testosterone, and dehydroandrostenidione therapy prepared by a compounding pharmacist.

After 12 months of follow-up, women on transdermal therapy showed significant reductions in triglycerides, blood pressure, fasting blood glucose, C-reactive protein, plasma fibrinogen, insulin-like growth factor-I, and factor VII along with significant symptomatic and quality of life improvements (see chart). The study will continue through 3 years of follow-up.

Ever since the Women’s Health Initiative linked oral hormone replacement therapy to increased risks of breast cancer and cardiovascular events, women with menopausal symptoms have expressed growing interest in alternative forms of hormonal therapy.

As in the ongoing study, Dr. Stephenson’s clinical practice is to take a history of hormone-related symptoms such

as hot flashes, night sweats, mood changes, sleep deprivation, and unexplained fatigue, measure the patient’s sex hormone levels, and then prescribe a low-dose transdermal hormone compounded specifically for her. Transdermal therapy avoids first-pass hepatic metabolism, thereby preventing buildup of atherogenic sex hormone metabolites, said Dr. Stephenson.

“What I see in clinical practice and my research studies is their biomarkers improve. They have adequate symptom relief, which is what’s most important to them. And once their symptoms are relieved they’re more likely to make positive nutritional and lifestyle changes: They feel like exercising; they feel like eating the way they’re supposed to,” she said.

Dr. Stephenson uses the university medical center’s compounding pharmacy. There are a growing number of such pharmacies as a result of increasing applications for compounded transdermal therapy in pain medicine, oncology, dermatology, and sports medicine, as well as hormone therapy. Physicians can locate a compounding pharmacist through the member registry maintained by the International Academy of Compounding Pharmacists (www.iacprx.org).

A home salivary specimen shipped to a CLIA-certified laboratory provides the most accurate way to assess a woman’s hormone status. “The reference ranges in serum testing for sex hormones are too broad,” Dr. Stephenson explained.

In January 2008, the Food and Drug Administration announced a new policy of restricted access to medications containing estriol that could have a negative impact on compounded transdermal hormone therapy for women, since prescribing physicians are required to fill out an Investigational New Drug application. Resolutions have been introduced in both the Senate (S.Con.Res. 88) and House of Representatives (H.Con. Res. 342) calling on the FDA to reverse this policy.

To watch a video interview with Dr. Stephenson, go to <http://www.youtube.com/familypracticenews>. ■

	Baseline	8 weeks	1 year
Blood pressure (mm Hg)	133/80	126/79	121/76
C-reactive protein (mg/mL)	6.2	5.8	3.9
Triglycerides (mg/dL)	175	154	120
Fasting blood glucose (mEq/L)	110	89	92
Fibrinogen (mg/mL)	4.6	4.4	4.0
Factor VII (mcg/mL)	1.1	1.1	0.9
Insulinlike growth factor-1 (ng/mL)	171	NA	151
Antithrombin (ng/mL)	341	341	329
Hamilton Depression score	6.6	4.9	5.0
Hamilton Anxiety score	9.6	7.0	6.5
Visual analog pain scale	1.5	1.2	0.9
Greene Climacteric Scale score	17.7	13.7	12.9

Note: Study comprised 150 women with menopausal symptoms.
Source: Dr. Stephenson