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for the specific needs of our patients.*

FEBRUARY 2013

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PRESCRIPTION COMPOUNDING FOR

**OBSTETRICS &
GYNECOLOGY**

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MENOPAUSAL HORMONAL SYMPTOM CONTROL

The following clinical study found significant differences among women treated with conventional HRT and BHRT (compounded transdermal hormone therapy) "Compounded Transdermal Hormone Therapy and Effects on Hemostatic and Immunologic Factors in Peri- and Post-Menopausal Women" (*Circulation*. 2008;118:S_1139-S_1140).

Researchers at the University of Texas Health Science Center, in Tyler, found promising 1-year safety and efficacy results in 75 peri- and postmenopausal women who received individually formulated hormone-replacement therapy applied as a cream to the skin.

"The 1-year findings are pretty encouraging," lead author Kenna Stephenson, MD, told *Medscape Psychiatry*. "We thought compounded transdermal hormones would relieve menopausal symptoms, but we didn't anticipate that they would also have a favorable effect on inflammatory, hemostatic, and cardiometabolic pathways."

In the United States, about 15 million women are currently peri- or postmenopausal and, as such, have an increased risk for cardiovascular disease, said Dr. Stephenson. Since the Women's Health Initiative study showed an increased risk for breast cancer, stroke, and dementia with conventional hormone therapy, more women have been seeking alternative treatments for menopausal symptoms, such as hot flashes, night sweats, disrupted sleep, and irritability. "We've seen an increase in the use of compounded transdermal hormone therapies among this population, but the safety and efficacy of these formulations have not been studied," she said.

To evaluate the hemostatic and anti-inflammatory effects of a compounded transdermal hormone-replacement therapy, the researchers recruited 150 peri- and postmenopausal women, aged 30 to 70 years. Half were assigned to usual care and the rest were assigned to the compounded cream. Usual care was defined as conventional hormone therapy of conjugated equine estrogens and medroxyprogesterone. The transdermal hormonal therapy consisted of plant-derived estrogen, progesterone, and sometimes testosterone and dehydroepiandrosterone (DHEA). Subjects in the transdermal-cream group were prescribed individualized therapy on the basis of their hormone levels. The women applied the cream to the skin once or twice daily to receive the target dose.

At 12 months, the subjects who received the study treatment had:

- Significant decreases in depression and anxiety, as assessed by the Hamilton Depression Scale and the Hamilton Anxiety Scale
- Significant improvements in quality of life and menopausal symptoms, such as hot flashes and night sweats, as assessed by the Greene Climacteric Scale
- No harmful hemostatic effects, as indicated by significant decreases in fibrinogen and factor VII, and no significant changes in factor VIII or plasminogen activator inhibitor type I
- No harmful anti-inflammatory effects, as shown by significant decreases in C-reactive protein (CRP), and no significant changes in interleukin-6
- Beneficial cardiometabolic effects, as shown by significant decreases in systolic blood pressure, pulse pressure, fasting glucose, and fasting triglycerides.

"All hormones are not equal, and all hormone preparations are not equal," said Dr. Stephenson. "There are distinctly different risks and effects on inflammatory and thrombotic factors and cardiovascular biomarkers." In this study, CRP and triglycerides decreased in women who received transdermal plant-derived compound hormones, whereas other studies have shown increased CRP and triglycerides in women receiving conventional equine and synthetic hormone therapy, she added. However, "larger clinical trials are needed to determine whether this therapy is a good alternative to conventional hormone-replacement therapy," she said.

We have the ability to compound transdermal hormones (BHRT) to meet the unique needs of each one of your patients. We would be happy to discuss specific medical cases with you, and provide assistance in treating those patients that you deem appropriate for BHRT.

ATROPHIC VAGINITIS

The following clinical study finds that intravaginal administration of a combination estriol and progesterone agent to women with atrophic vaginitis may represent a safe and effective alternative to systemic hormone replacement - "Efficacy and safety of vaginal estriol and progesterone in postmenopausal women with atrophic vaginitis" ([Menopause](#). 2009 Apr 22).

ABSTRACT

OBJECTIVE: The aim of this study was to assess the efficacy and safety of intravaginal estriol and progesterone on atrophic vaginitis in postmenopausal women.

METHODS: Under a physician-sponsored Investigational New Drug application, 19 healthy postmenopausal women with atrophic vaginitis received vaginal suppositories containing estriol (1 mg) and progesterone (30 mg). The participants were instructed to insert one suppository intravaginally once daily for 2 weeks and thrice weekly for a total of 6 months. Vaginal pH, Vaginal Maturation Index, urinalysis, self-reported vaginal dryness, menopausal quality of life, and serum estriol and progesterone levels were measured at enrollment and after 3 and 6 months of suppository use. Endometrial biopsies were obtained at enrollment and at 6 months. After 2 weeks of therapy, 6 participants had serum estriol and progesterone measured.

RESULTS: The Vaginal Maturation Index, vaginal pH, and vaginal dryness rating improved significantly at 3 and 6 months compared with baseline. Menopausal quality of life scores improved significantly in all domains, with the sexual subscale showing the most improvement. There were no cases of endometrial hyperplasia after 6 months of suppository use. Serum preinsertion estriol at week 2 and months 3 and 6 were similar to baseline levels. Serum preinsertion progesterone increased but returned to baseline preinsertion levels at month 6, and preinsertion levels were significantly less at month 6 compared with month 3.

CONCLUSIONS: Intravaginal administration of a combination estriol and progesterone agent to women with atrophic vaginitis may represent a safe and effective alternative to systemic hormone replacement, although this study was not adequate to provide proof of efficacy given that it was uncontrolled. PMID: 19390463

We have the ability to compound estriol and progesterone together in several unique forms of delivery.

An example of how you might prescribe follows:

COMPOUNDED MEDICATION

Estriol 1mg / Progesterone 30mg

Vaginal Suppository

#30

Insert one suppository QD for 2 weeks,
then 3x per week for 6 months

VAGINAL LICHEN PLANUS

The following study concludes that intravaginal hydrocortisone suppositories are an effective treatment for vulvovaginal lichen planus - "Treatment of vulvovaginal lichen planus with vaginal hydrocortisone suppositories" (*Obstet Gynecol.* 2002 Aug;100(2):359-62).

ABSTRACT

OBJECTIVE: To estimate the effectiveness of vaginal hydrocortisone suppositories in the treatment of vulvovaginal lichen planus.

METHODS: A nonprobability sample of 60 patients diagnosed with vulvovaginal lichen planus were treated with intravaginal hydrocortisone 25-mg suppositories (1-1/2) twice a day. The dose was tapered to two times a week dosing after several months to maintain symptom-free disease. The participants' charts were reviewed and pretreatment symptoms and physical examination were compared to posttreatment symptoms and physical examination. Data were analyzed using McNemar chi(2).

RESULTS: The sample population included mostly white (86.7%) patients with a mean age of 58 years. Forty-three participants had complete data with follow-up subjectively and objectively after treatment. Most symptoms (eg, vulvar burning, pruritis, dyspareunia, vaginal discharge) were improved and the improvement was found to be statistically significant. Sexual activity was unchanged in the women. Additionally, most physical findings by examination (eg, erythema, erosions, vulvar and vaginal lesions) were improved and the improvement was found to be statistically significant. Vaginal stenosis did not significantly improve. Treatment was continued in 35 patients with a mean duration of 28.1 months. There was overall improvement in 81% subjectively and in 76.8% objectively.

CONCLUSION: Intravaginal hydrocortisone suppositories are an effective treatment for vulvovaginal lichen planus. PMID: 12151163

With our state of the art compounding lab and pharmaceutical knowledge and experience, we can compound hydrocortisone as a vaginal suppository.

An example of how you might prescribe follows:

COMPOUNDED MEDICATION

Hydrocortisone 37.5mg
Vaginal Suppository
#60
Insert 1 suppository vaginally BID

Prescriber Name _____

Prescriber Address _____

City _____ State _____ Zip _____

Phone _____ Fax _____

Date _____ Patient Name _____ DOB _____

Address _____ City/State/Zip _____ Phone _____

Patient will pick up at pharmacy Please ship to patient

Bill Insurance Plan: _____ ID# _____

All topical compound %s are per 1 ml or 1 gm unless otherwise noted

Menopausal Hormonal Symptom Control

We would be happy to discuss specific medical cases with you, and provide assistance in treating those patients that you deem appropriate for BHRT.

Atrophic Vaginitis

[] Estriol 1mg/Progesterone 30mg

Vaginal Suppository

Quantity #30

Directions: Insert 1 suppository QD for 2 weeks, then 3x per week for 6 months

Vaginal Lichen Planus

[] Hydrocortisone 37.5mg

Vaginal Suppository

Quantity #60

Directions: Insert 1 suppository vaginally BID

Directions

Prescriber's Signature _____ Refills: 1 2 3 4 5 6 7 8 9 10 11 12 NR

