



Int J Pharm Compd. 2013 Jan-Feb;17(1):74-85.

The effects of compounded bioidentical transdermal hormone therapy on hemostatic, inflammatory, immune factors; cardiovascular biomarkers; quality-of-life measures; and health outcomes in perimenopausal and postmenopausal women.

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Abstract

Menopause impacts 25 million women world wide each year, and the World Health Organization estimates 1.2 billion women will be postmenopausal by 2030. Menopause has been associated with symptoms of hot flashes, night sweats, dysphoric mood, sleep disturbance, and conditions of cardiovascular disease, depression, osteoporosis, osteoarthritis, depression, dementia, and frailty. **Conventional hormone replacement therapy results in increased thrombotic events, and an increased risk of breast cancer and dementia as evidenced in large prospective clinical trials including Heart and Estrogen/Progestin Replacement Study I and the Women's Health Initiative. A possible mechanism for these adverse events is the unfavorable net effects of conjugated equine estrogens and medroxyprogesterone acetate on the hemostatic balance and inflammatory and immune factors.** Physiologic sex steroid therapy with transdermal delivery for peri/postmenopausal women may offer a different risk/benefit profile, yet long-term studies of this treatment model are lacking. **The objective of this study was to examine the long-term effects of compounded bioidentical transdermal sex steroid therapy including estriol, estradiol, progesterone, DHEA, and testosterone on cardiovascular biomarkers, hemostatic, inflammatory, immune signaling factors; quality-of-life measures; and health outcomes in peri/postmenopausal women within the context of a hormone restoration model of care.** A prospective, cohort, closed-label study received approval from the Human Subjects Committee. Recruitment from outpatient clinics at an academic medical center and the community at large resulted in three hundred women giving signed consent. Seventy-five women who met strict inclusion/exclusion criteria were enrolled. Baseline hormone evaluation was performed along with baseline experimental measures. Following this, **women received compounded transdermal bioidentical hormone therapy of BiEst (80%Estriol/20%Estradiol), and/or Progesterone for eight weeks to meet established physiologic reference ranges for the luteal phase in premenopausal women. The luteal phase hormone ratios were selected based on animal and epidemiologic studies demonstrating favorable outcomes related to traumatic, ischemic, or neuronal injury.** Follow-up testing was performed at eight weeks and adjustment to hormone regimens were made including addition of androgens of DHEA and Testosterone if indicated. Experimental subjects were monitored for 36 months. Baseline, 2-month, and annual values were obtained for: blood pressure, body mass index, fasting glucose, Homeostasis Metabolic Assessment of Insulin Resistance (HOMA-IR), fasting triglycerides, total Factor VII, Factor VIII, fibrinogen, Antithrombin III, Plasminogen Activator Inhibitor1(PAL-1), C-reactive protein (CRP), Interleukin-6 (IL-6), Matrix Metalloproteinase-9 (MMP-9), Tumor Necrosis Factor-alpha (TNF), Insulin-like Growth Factor (IGF-1), and sex steroid levels. Psychosocial measures included: Greene Climacteric Scale, Visual Analog Pain Scale, Hamilton Anxiety Scale, Hamilton Depression Scale, Holmes Rahe Stress Scale, Job Strain, and Home Strain. Health outcome measures included the number of prescribed medications used, number of co-morbidities, and endometrial thickness in postmenopausal women with intact uteri. Cardiovascular biomarkers, inflammatory factors, immune signaling factors, and health outcomes were favorably impacted, despite very high life stress, **aSubjects receiving compounded transdermal bioidentical hormone therapy showed significant favorable changes in: Greene Climacteric Scale scores, Hamilton Anxiety Scale, Hamilton Depression Scale, Visual Analog Pain Scale, fasting glucose, fasting triglycerides, MMP-9, C-reactive Protein, fibrinogen, Factor VII, Factor VIII, Insulin-Like Growth Factor 1, and health outcomes of co-morbidities and a number of prescribed medications. Antithrombin III levels were significantly decreased at 36 months. All other measures did not exhibit significant effects. Administration of compounded transdermal bioidentical hormone therapy in doses targeted to physiologic reference ranges administered in a daily dose significantly relieved menopausal symptoms in peri/postmenopausal women. nd home and work strain in study subjects. The therapy did not adversely alter the net prothrombotic potential, and there were no associated adverse events. This model of care warrants consideration as an effective and safe clinical therapy for peri/postmenopausal women especially in populations with**



high perceived stress and a history of stressful life events prior to, or during the menopausal transition.