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Nanotechnology in Hormone Replacement Therapy: Safe and Efficacy of Transdermal Estriol and Estradiol Nanoparticles after 5 Years Follow-Up Study

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***SUMMARY*. This study aimed to evaluate the safety and efficacy of a novel protocol of transdermal Hormone Replacement Therapy (HRT) based on a nanostructured formulation of Estriol (0.1 %) + Estradiol (0.25 %) restoring serum levels and relieving menopausal symptoms. We evaluated 122 women with mean age of 56.88 (± 6.27) as part a longitudinal prospective study on post-menopausal women with natural menopause, received in the right forearm a transdermal formulation of (EE) daily for 60 months. Clinical parameters including the degree of satisfaction with symptomatic relief, serum concentrations of estradiol, weight, blood pressure, and bilateral mammography BI-RADS were compared between the baseline and five years after treatment. New evidence regarding this HRT protocol was assessed. The transdermal nanoformulation estradiol improved clinical parameters. Satisfaction with treatment was 92 %. Serum concentrations of estradiol changed significantly after treatment ($p < 0.05$). Weight and systolic and diastolic blood pressures had no significant differences ($p > 0.05$) over the years. No vaginal bleeding was observed. Bilateral mammography assessment of the breasts following 60 months of HRT with bioidentical estradiol treatment found normal results in all women. This paper shows for the first time the effectiveness of a nanostructured transdermal formulation enhancer on the delivery of estradiol and estriol measured *in vivo* using Raman Confocal Spectroscopy. The Nanostructured formulation is safe and effective in reestablishing estradiol serum levels and relieving menopausal symptoms. The nanoformulation may serve as a good choice for hormone replacement therapy to protect against other post-menopausal symptoms.**

KEY WORDS: Hormone replacement therapy, Nanoparticles, Raman Spectroscopy, Menopause, Transdermal delivery.

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