The impact of a monophasic continuous estro-progestogenic treatment on Latin American menopausal women


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Abstract

Objective: The present study was undertaken to assess the impact, effectiveness and safety of a monophasic hormone replacement treatment (HRT) for continuous use with regards to the clinical effects, bleeding patterns and lipid profile of menopausal women in four Latin American countries. Design: Three hundred and six postmenopausal women with natural menopause and uterus present were recruited. This was a multicentre prospective, clinical trial; the participating countries were Brazil (BR), Colombia (CO), Mexico (MX) and Argentina (AR). The study period was 12 months. The HRT regime was formulated in tablets containing 2 mg estradiol E₂ and 1 mg norethisterone acetate (NETA); one visit every 3 months was solicited. Methods: HRT was given as one tablet every day without interruption for 1 year. Climacteric complaints, side-effects, reason for discontinuation, bleeding patterns, lipid profile at baseline and 12 months of treatment were documented. Results: There were no significant differences between the four populations on clinical measurements. Thirty-four women discontinued, 13 for bleeding problems. The five most common side-effects were mastalgia, bleeding problems, headache, pelvic pain and nausea. 44.8% of women experienced scanty vaginal bleeding during the first 3 months of therapy. Ninety seven percent of women had amenorrhea at the end of the study in MX, BR and AR, and 100% in CO. Body weight was constant during the study, and no correlation was found between body weight and total days with bleeding. The Kupperman index score was used to evaluate the climacteric complaints, and the score decreased from a mean of 25.4 to 5.1 at 12-months visit. Total cholesterol levels were significantly reduced in BR and CO (P < 0.05) between baseline and the final sample; serum triglycerides remained unchanged, HDL-cholesterol was significantly increased in MX (P < 0.05), and LDL-cholesterol was significantly reduced in CO (P < 0.05).

The results of this 1-year study emphasize that a continuous combined HRT regimen with 2 mg E2/1 mg NETA is an attractive alternative for postmenopausal women who are at least 1 year after their menopause and optimally 2 years after their menopause.

Although the combination of 2 mg E2 with 1 mg NETA in a continuous combined therapy scheme has been in use in the Nordic countries for over a decade and in Latin America for the last 6 years, there have been no previous published reports on its effectivity in Latin American women. This publication reports the experience in a group of 306 Latin American women, and it is the first Latin American publication with this formulation.
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Keywords
Hormone replacement treatment; estradiol; Norethisterone acetate; Kupperman index

Corresponding author. Tel.: +52 817 717 6282; fax: +52 817 717 6282.
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