The 12-month treatment with the oral contraceptive formulation containing dienogest (DNG) and estradiol valerate (E2V) shows beneficial effects on psychological symptoms: results from a prospective comparative study with a formulation containing ethinyl estradiol (EE) and drospirenone (DRSP)

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Summary

The COCs evolution has been obtained with new and different progestinic compounds associated with lower doses of EE (ethinylestradiol). The revolution in the COCs field is the introduction of estradiol valerate (E2V), ester of the natural estrogen, estradiol (E2) instead of EE. Dienogest (DNG) is the progestinic compound of the COC Klaira® associated with E2V in a multiphase formulation. DNG has a strong antiandrogenic action both on endometrial tissue and endometriosis implants (1). In addition, DNG has a strong antiandrogenic action without the mineralocorticoid and glucocorticoid action. In postmenopausal women, the addition of DNG to E2V demonstrated to increase the beneficial action of E2V on the activity of some neural centers, with a better improvement compared to E2V alone, on subjective sleep quality, somatic complaints and anxiety, vigilance, cognition and numerical memory (2).

Key words: dienogest, drospirenone, estradiol valerate, extracontraceptive benefits, psychological effects, contraception.

Introduction

Since the first “pill” the composition of the combined oral contraceptives (COCs) has been changed in order either to reduce side effects dependent on steroid compounds or to magnify extra-contraceptive benefits. This evolution has been obtained with new progestinic compounds, mainly with those with antiandrogenic and antimineralcorticoid properties, associated with lower doses of EE. The introduction of the natural estrogen, estradiol (E2), instead of EE represents the revolution in the COCs field.

The progestinic compound DNG combined with the natural estrogen, E2V, is an innovative multiple formulation contained in the COC manufactured by Bayer (Germany) and commercially called Klaira®. In comparison to EE, E2V has a lower action on liver protein induction (SHBG, angiotensinogen and coagulation proteins) without acting like EE on lipoproteins and on tryglicerides synthesis. Dienogest exerts an effective contraceptive action with a strong antiproliferative action both on endometrial tissue and endometriosis implants (1). In addition, DNG has a strong antiandrogenic action with the mineralocorticoid and glucocorticoid action. In postmenopausal women, the addition of DNG to E2V demonstrated to increase the beneficial action of E2V on the activity of some neural centers, with a better improvement compared to E2V alone, on subjective sleep quality, somatic complaints and anxiety, vigilance, cognition and numerical memory (2).
Beneficial effects of a 12-month treatment with the oral contraceptive formulation containing (DNG) and (E2V) or with a formulation containing (EE) and (DRSP)

Yaz® is the commercial name of a COC manufactured by Bayer (Germany) containing 20 mcg of EE and DRSP, a progestin compound characterized by antimineralocorticoid, antiandrogenic properties (3), associated with a central neural effect and beneficial impact on psychological symptoms (4).

In this prospective study we aimed to evaluate whether E2V/DNG is able to exert the same psychological effects of the formulations containing EE/DRSP.

Thirty seven women with inclusion and without exclusion criteria to COCs assumption, participated in the study: 23 of them were treated with E2V/DNG and 14 with EE/DRSP. Psychological changes were evaluated with the psychometric scale SCL90 before the COCs assumption, and at the first, the third, seventh and the twelfth cycle of treatments.

In comparison to basal values, the total global score of SCL90 was significantly reduced (p<0.001) during both treatments, showing a decrease from the first cycle with a continuous reduction up to the end of the study. No statistical differences between the treatments were calculated with the two way ANOVA analysis.

The similar psychological effects observed with these COCs, confirm that DNG and DRSP exert beneficial effects on central nervous system. Further studies are needed to evaluate whether similarly to the formulations with EE plus DRSP, E2V/DNG can also exert positive effect on body composition.

References