Review of clinical experience with estradiol in combined oral contraceptives

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Previous attempts to replace ethinylestradiol (EE) with 17beta-estradiol (E2) in combined oral contraceptives (COCs) have proved unsatisfactory in terms of bleeding outcomes. A review of previous studies of E2-based COCs has shown that, despite good ovulation inhibition, bleeding irregularities affected up to 100% of women, often resulting in high rates of discontinuation (up to 42%). Suggested reasons for the bleeding irregularities observed with these predominantly monophasic estradiol-progestin preparations included suboptimal doses of E2 and an inappropriate estrogen/progestin ratio. The progestin used in the investigated formulations (e.g., norethisterone acetate, desogestrel and cyproterone acetate) may also have affected the overall bleeding profile. More recent studies of a multiphasic COC containing estradiol valerate (E2V) and dienogest (DNG) indicate efficient ovulation inhibition and acceptable cycle control. In a randomized, double-blind trial that compared E2V/DNG with a monophasic COC comprising EE/levonorgestrel (LNG), the occurrence of scheduled withdrawal bleeding per cycle with E2V/DNG and EE/LNG was 77.7-83.2% and 89.5-93.8%, respectively. The intensity and duration of withdrawal bleeding was reduced with E2V/DNG. The incidence of intracyclic bleeding was similar with E2V/DNG (10.5-18.6%) and EE/LNG (9.9-17.1%). This review shows that after several unsatisfactory attempts to develop E2-based COCs, more recent studies employing endometrial-focused progestins, e.g., DNG, and multiphasic dosing regimens appear to be a promising approach for an E2-based COC that provides efficient ovulation inhibition and acceptable cycle control.
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