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Low-Dose Ethinylestradiol/ Levonorgestrel

A Viewpoint by Andrew M. Kaunitz

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Oral contraceptives, which were first used clinically some 45 years ago, represent some of the best studied medications prescribed today. These agents are safe for most reproductive age women. Low-dose ethinylestradiol/levonorgestrel 20μg/100μg has been used clinically for over 5 years.

Although use of combination (estrogen progestogen) oral contraceptive increases the risk of venous thromboembolic disease, thrombotic events are rare among reproductive age women, whether or not they use oral contraceptives. Furthermore, the increased risk of thrombosis associated with oral contraceptive use is less than that associated with pregnancy. In contrast to the beliefs of many, extensive epidemiological data provides reassurance that use of oral contraceptives does not increase the risk of breast cancer.

In addition to allowing women to determine the occurrence and timing of pregnancy, use of oral contraceptives is associated with important noncontraceptive benefits. These include more predictable and lighter bleeding, shorter bleeding episodes, less menstrual pain, treatment of acne, and prevention of ovarian and endometrial cancers.

Annual oral contraceptive failure (pregnancy) rates of ≈1% are observed in clinical trials. By contrast, during typical use, annual failure rates approximate 8%, reflecting inconsistent adherence to the daily pill-taking regimen required for high contraceptive efficacy. Users may attribute the occurrence of headaches and weight gain to oral contraceptives. By contrast, randomised, placebo-controlled trials (including two trials of low-dose ethinylestradiol/levonorgestrel 20μg/100μg described by Coney et al.[1]) have clarified that headache and weight gain occur as commonly with placebo as with low-dose oral contraceptives. The most common adverse effects caused by oral contraceptives are unscheduled (intermenstrual) spotting and bleeding.

Intermenstrual spotting and bleeding is common during the initial cycles of ethinylestradiol/levonorgestrel 20μg/100μg use. In fact, the high rates of intermenstrual spotting and bleeding may represent the chief downside of use of oral contraceptive formulations involving very low doses of estrogen (20μg). By contrast, a positive attribute of very low-dose estrogen oral contraceptive formulations is that such agents may cause less nausea and breast tenderness than higher estrogen oral contraceptive formulations. Failure rates are similar with oral contraceptives formulated with estrogen doses of 20μg or 30–35μg. Epidemiological data have not suggested that oral contraceptives formulated with estrogen 20μg are safer than those formulated with estrogen 30–35μg.

Newer hormonal contraceptives including injections, a transdermal patch, a vaginal ring, and progestogen-releasing intrauterine devices and implants have expanded the choices for women. Nonetheless, the convenience, reassuring safety profile and important noncontraceptive benefits of modern oral contraceptives mean that, for the foreseeable future, they will remain an important contraceptive option for women worldwide. ▲

Reference

1. Coney P, Washenik K, Langley RGB, et al. Weight change and adverse event incidence with a low-dose oral contraceptive: two randomized, placebo-controlled trials. Contraception 2001 Jun; 63: 297-302