FOCUS ON CONTRACEPTION

Continuous OC use to eliminate cyclic bleeding

Miller L, Hughes JP. Continuous combination oral contraceptive pills to eliminate withdrawal bleeding: a randomized trial. *Obstet Gynecol*. 2003;101:653-661.

OBJECTIVE To compare the bleeding profile of a traditional 28-day oral contraceptive (OC) cycle with continuous administration.

METHODS AND RESULTS Seventy-nine women were randomized to a 28-day regimen (21 active pills and a pill-free week) or continuous use of the same low-dose formulation (20 μg ethinyl estradiol/100 μg levonorgestrel) for 12 cycles. Women recorded the number of bleeding and spotting days, and a subset underwent pelvic ultrasound and endometrial biopsy in cycles 1 and 9.

During the first 3 cycles, 68% of continuous users experienced amenorrhea or infrequent bleeding; that rate increased to 88% during the last 3 cycles. Continuous users initially experienced a slight increase in spotting during cycle days 1 through 21, but it diminished over time and ultimately was less than that reported by cyclic users.

WHO MAY BE AFFECTED BY THESE FINDINGS? Women of reproductive age who wish to reduce monthly bleeding.

EXPERT COMMENTARY The notion that menstruation must occur each month in healthy, nonpregnant women using contraception is increasingly being questioned. One of the main factors contributing to this perception has been the packaging and labeling of OCs to induce monthly withdrawal bleeding.

Endometrium does not 'build up.' Monthly menstruation is not critical to OCs' mechanism of action. Nor does OC-induced amenorrhea lead to harmful "build-up" of the endometrium. Rather, extended OC use results in a thin, atrophic endometrium that is protective against hyperplasia and endometrial cancer.

Continuous use is well tolerated. This study showed continuous use to be well tolerated, with a low drop-out rate and little anxiety about pregnancy. Data also suggested a small improvement in compliance.

Comparable efficacy. Contraceptive efficacy with continuous OC use was comparable to a cyclic regimen. (In some cases, continuous use may even be superior, since follicular development can occur during the pill-free week.) As for safety, continuous users who underwent ultrasound and endometrial biopsy had no abnormal findings. Although long-term safety was not completely addressed in this study—as the authors acknowledge—the cumulative estrogen exposure with a daily 20-μg ethinyl estradiol OC over 1 year is less than that of a cyclic 30-μg formulation.

Other benefits. Many other health benefits occur with extended OC regimens. Besides its convenience, medically induced amenorrhea has been used successfully to treat dysmenorrhea, menorrhagia (particularly in women with anemia or bleeding diatheses), endometriosis-related pain, and menstruation-related headaches. In addition, some

special populations, such as female athletes, find amenorrhea particularly beneficial.[1]

What do women want? A number of studies suggest they don't necessarily want to menstruate monthly. For example, a Dutch survey found that 65% of women aged 25 to 34 preferred bleeding every 3 months or less and 31% favored no bleeding at all.[2] Another trial allowed participants to choose their own OC regimen; the median duration of continuous OC use was 9 weeks (maximum 104 weeks), and the median pill-free interval was 5 days.[3]

Advising patients. In offering my patients the option of extended OC use, I previously recommended scheduled withdrawal bleeds at 3- to 6-month intervals to avoid spotting. With this new evidence, however, I can offer patients even longer periods of amenorrhea. Moreover, a new 91-day extended OC formulation (Seasonale; *Barr Laboratories, Pomona, NY*) is under development and should be approved later this year.[4]

BOTTOM LINE Continuous use of a low-dose monophasic OC preparation for 1 year resulted in fewer bleeding days without a significant increase in overall spotting, compared with cyclic use of the same preparation. We can use this evidence to counsel patients about the benefits of continuous OC use and help them achieve menstrual "nirvana."[5]

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Cervical cap versus diaphragm: Efficacy and acceptability

Gallo MF, Grimes DA, Schulz KF. Cervical cap versus diaphragm for contraception. *Cochrane Database Syst Rev*. 2002;(4):CD003551.

OBJECTIVE To evaluate the efficacy, safety, discontinuation, and acceptability of the cervical cap in comparison with the diaphragm.

METHODS AND RESULTS Investigators searched the literature for randomized controlled trials comparing the cervical cap to the diaphragm. Two trials met inclusion criteria; both recruited sexually active women aged 18 to 40 years. The first trial randomized subjects to the Prentif Cavity Rim Cervical Cap (*Lamberts Ltd, Oxford, England*) or the Ortho diaphragm (*Ortho Pharmaceutical, Raritan, NJ*). The second compared the FemCap cervical cap (*FemCap Inc, Del Mar, Calif*) with the All-Flex diaphragm (*Ortho*). Outcomes were calculated as Peto odds ratios with 95% confidence intervals (CI), using total number of women as the denominator. Life-table and Kaplan-Meier cumulative rate ratios were also calculated for selected measures.

As a contraceptive, the Prentif Cap was comparable in efficacy to the diaphragm, but the FemCap was less effective than its comparison diaphragm.

The Prentif Cap had a higher proportion of class I to class III (older classification of Papanicolaou smears) cervical cytologic conversions at 3 months than the diaphragm, with an odds ratio of 2.3 (95% CI, 1.0-5.1); there were no differences in Pap smear results between groups in the FemCap trial. Prentif Cap users had a lower odds ratio of vaginal ulcerations or lacerations (0.3; 95% CI, 0.1-0.7) than diaphragm users, and FemCap users had a higher odds ratio of blood in the device on removal (2.3;

95% CI, 1.3-4.1). FemCap users also had a lower odds ratio of urinary tract infections than women using the diaphragm (0.6; 95% CI, 0.4-1.0).

EXPERT COMMENTARY Few women use the cervical cap as their primary contraceptive, although it has been available since the late 1980s. Concerns about efficacy, frequent office visits, and limited sexual spontaneity likely contribute to its relatively low popularity. Further, residency training programs tend to focus on hormonal contraception.

Unfortunately, despite its comprehensive and detailed database review, this meta-analysis is of limited value, since only 2 studies were deemed worthy of inclusion. Other concerns include:

- **Unacceptable dropout rates.** Only 34% of women assigned to the Prentif Cap completed the study. The FemCap group had a similar but slightly lower rate of discontinuation. These dropout rates contribute negatively to any predetermined significance.
- **Different follow up durations.** For the Prentif Cap, investigators calculated the cumulative life-table rate ratios of pregnancy in comparison with the diaphragm for periods ranging from 6 months to 2 years. (At 6 months, it was 1.3.) In the FemCap trial, the Kaplan-Meier 6-month cumulative pregnancy rate in comparison with the diaphragm was 1.7, but the FemCap's efficacy beyond that time was not established.
- **Incomparable groups for cytologic review.** As the authors discuss, the cervical cap has been implicated in the progression of cytologic abnormalities on Pap smears. Further, it does not protect women from sexually transmitted infections such as human papillomavirus, so the risk of developing subsequent cytologic abnormalities exists.

Because Prentif Cap users demonstrated a significantly higher rate of progression of cervical cytologic abnormalities, clinicians are encouraged to repeat cytologic evaluation after 3 months of use. We also recommend physicians use patient demographics such as sexual history and previous abnormal Pap reports to select appropriate patients for the cap.

Although the rate of cytologic conversions among FemCap users did not increase, only a small subset of women within the trial (n = 41) were sampled.

- **The difficulty of determining acceptability.** Accurate estimates of acceptability are difficult to formulate, although the high dropout rate in both trials suggests limited popularity. Interestingly, 31% of FemCap users experienced dislodgement of the device and a significant number had difficulty with removal, yet there was a lower dropout rate than among Prentif Cap users.

Although the Prentif Cap was at least as effective as the diaphragm in preventing pregnancy, more women using this cap discontinued use because of fears of conception. No randomized studies have compared the different brands of cervical caps.

BOTTOM LINE Both the diaphragm and cervical cap provide acceptable levels of birth control, but should be recommended primarily to women unable to utilize more effective methods and those who have infrequent intercourse. Frequent office visits may be required to ensure proper use, ascertain rates of discontinuation, and assess for Pap smear abnormalities. ■

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