

FROM THE CLINICAL EFFECTIVENESS UNIT (CEU)

The members' enquiry service: frequently asked questions

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Background

In the April 2003 issue of the *Journal of Family Planning and Reproductive Health Care* the Clinical Effectiveness Unit (CEU) presented an overview of the enquiry topics received by the Faculty's former clinical effectiveness team from September 2001 to August 2002. We also provided an illustrative response to the most frequently asked question from that time period, namely the impact of long-term depot medroxyprogesterone acetate (DMPA) on bone mineral density. In this issue, we present a further illustrative response.

Illustrative CEU response

Clinical question

Should women >70 kg in weight who use progestogen-only pills (POPs) take two pills per day to improve contraceptive efficacy?

Summary of response

A large cohort study investigated the relation between oral contraceptive (OC) failures and body weight. The Pearl index for POPs was 3.36 per 100 woman-years at ages 25–29 years and 0.28 per 100 women-years at ages 40–44 years. The failure rates for the POP and combined oral contraceptive (COC) were adjusted for age alone, and for age and parity in relation to body weight, height and body mass index (BMI). No association was found between failure rates and body weight, height or BMI. Although this study did not support the hypothesis that an increase in body weight correlates with increased contraceptive failure in women using either the COC or the POP, it may not have had sufficient power to either prove or disprove such a hypothesis.

The use of two POPs per day for women >70 kg in weight has been recommended on the basis of studies which have shown that obese women who use the levonorgestrel implant or the levonorgestrel-releasing vaginal ring have higher failure rates. Until more evidence becomes available, it would appear that the extra risk of adverse effects with two POPs per day is negligible and this two-pill regimen may be appropriate in young women. In women who already have decreased fertility, such as women aged over 45 years, there is no evidence to support the use of two POPs per day.

Evidence-based medicine question (which guided our literature search strategy)

Population: Women >70 kg in weight who use POPs.

Intervention: Two POPs per day.

Outcome: Contraceptive efficacy.

Information sources

The CEU searched the sources listed in Table 1 in developing this Member's Enquiry Response.

Evidence reviewed

MEDLINE and EMBASE from 1990 to 2002. A large cohort study investigated the effects of OC failures and body weight.¹ A total of 17 032 white, married women, who were using OCs, a diaphragm or an intrauterine device, were recruited from 17 family planning clinics in the UK between 1968 and 1974. The failure rates expressed as Pearl index for POPs were 3.36 per 100 woman-years at ages 25–29 years (95% CI 0.92–8.61) and 0.28 per 100 women-years at ages 40–44 years (95% CI 0.11–0.58). The failure rates for the POP and COC were adjusted for age alone, and for age and parity in relation to body weight, height and BMI. No association was found between failure rates and body weight, height or BMI. The overall failure rate, adjusted for age and parity, for women weighing <82 kg was 0.24 per 100 woman-years (95% CI 0.20–0.28). The overall failure rate for women weighing ≥82 kg, adjusted for age and parity, was 0.38 per 100 woman-years (95% CI 0.08–1.12). The study did not support the hypothesis that an increase in body weight is related to an increase in contraceptive failure in women using either the COC or the POP. However, this study may not have had sufficient power to prove or disprove the hypothesis.²

In another study, Kovacs et al.³ evaluated the use of the POP as a precoital contraceptive in 16 women whose husbands were known to be azoospermic. These women were randomised to receive one tablet of a POP, containing either levonorgestrel or norethisterone, 2–3 days prior to estimated ovulation. The quality and quantity of cervical mucus was then evaluated prior to taking the POP and 10–12 hours after it was taken. In four women sperm penetrability was completely prevented, while in the others there was reduction in sperm motility or cervical mucus pH. However, three obese women, who were >75 kg with a BMI >35, did not respond to the POP. The authors suggested that the metabolism of the POP might be influenced by excessive adipose tissue rendering it less effective.

Table 1 Sources used in developing the Member's Enquiry Response

Source searched	Information identified
Existing FFPRHC and RCOG guidance	No relevant information
National Guidelines Clearing House	No relevant information
WHO publications: <i>Improving access to quality care in family planning: medical eligibility criteria for contraceptive use</i> (2000) and <i>Selected practice recommendations for contraceptive use</i> (2002)	No relevant information
The Cochrane Library	No relevant information
MEDLINE and EMBASE from 1990 to 2002	See text

FFPRHC, Faculty of Family Planning and Reproductive Health Care; RCOG, Royal College of Obstetricians and Gynaecologists; WHO, World Health Organization.

Higher failure rates have been shown to occur in obese women using the levonorgestrel implant or levonorgestrel-releasing vaginal ring.^{4,5} The low systemic dose of levonorgestrel released by these contraceptives is comparable to that released daily by the POP. Pooled data for Norplant capsules identified a gross pregnancy rate, for women weighing ≥ 70 kg, of 1 per 100 users at 2 years of use. This increased to 4 per 100 users for this group during the third year of use. The 5-year cumulative pregnancy rate was then estimated to be above 7 per 100 users for these women. In contrast, the cumulative 5-year pregnancy rate for women weighing < 50 kg was 0.2 per 100 users.⁴

There is presently little direct evidence to support the hypothesis that women > 70 kg in weight have higher failure rates than women < 70 kg. However, no evidence was identified that taking two POPs per day was harmful and, until more evidence is available, women who are > 70 kg may be advised to use two POPs per day. It is unlikely that women weighing > 70 kg in whom fertility is inherently reduced, such as those aged over 45 years, would benefit from taking two POPs per day.

Disclaimer

The advice given in this Member's Enquiry Response has been prepared by the FFPRHC Clinical Effectiveness Unit team. It is based on a structured search and review of published evidence available at the date of preparation. The advice given here should be considered as guidance only. Adherence to it will not ensure a successful outcome in every case and it may not include all acceptable methods of care aimed at the same results. This response has been prepared as a service to FFPRHC members, but is not an official Faculty Guidance product; Faculty Guidance is produced by a different and lengthier process. It is not intended to be construed or to serve as a standard of medical care. Such standards are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge advances. Members are welcome to reproduce this Response by photocopying or other means, in order to share the information with colleagues.

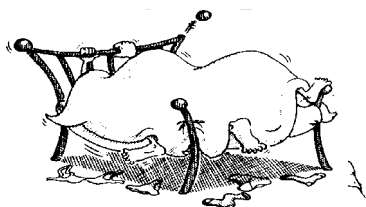
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