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Contraindications to progestin-only oral contraceptive pills among reproductive-aged women

Kari White[a], Joseph E. Potter[b], Kristine Hopkins[b], Leticia Fernández[c], Jon Amastae[d], Daniel Grossman[e,*]

[a]Health Care Organization and Policy, University of Alabama at Birmingham, Birmingham, AL 35294, USA
[b]Population Research Center, University of Texas at Austin, Austin, TX 78712, USA
[c]Department of Family Medicine, University of Pretoria, Pretoria 0084, South Africa
[d]College of Health Sciences and Department of Languages and Linguistics, University of Texas at El Paso, El Paso, TX 79968, USA
[e]Ibis Reproductive Health, Oakland, CA 94612, USA

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Abstract

Background: Progestin-only oral contraceptive pills (POPs) have fewer contraindications to use compared to combined pills. However, the overall prevalence of contraindications to POPs among reproductive-aged women has not been assessed.
Study Design: We collected information on contraindications to POPs in two studies: (1) the Self-Screening Study, a sample of 1267 reproductive-aged women in the general population in El Paso, TX, and (2) the Prospective Study of OC Users, a sample of current oral contraceptive (OC) users who obtained their pills in El Paso clinics (n=532) or over the counter (OTC) in Mexican pharmacies (n=514). In the Self-Screening Study, we also compared women's self-assessment of contraindications using a checklist to a clinician's evaluation.
Results: Only 1.6% of women in the Self-Screening Study were identified as having at least one contraindication to POPs. The sensitivity of the checklist for identifying women with at least one contraindication was 75.0% [95% confidence interval (CI): 50.6%–90.4%], and the specificity was 99.4% (95% CI: 98.8%–99.7%). In total, 0.6% of women in the Prospective Study of OC Users reported having any contraindication to POPs. There were no significant differences between clinic and OTC users.
Conclusion: The prevalence of contraindications to POPs was very low in these samples. POPs may be the best choice for the first OTC oral contraceptive in the United States.

Keywords: Oral contraceptives; Contraindications; Self-screening; Over-the-counter status

1. Introduction

Oral contraceptive pills (OCs) are the most common method of contraception in the United States (US) [1]. Although the relative safety of this method has been well established and some have advocated for making OCs available over the counter (OTC) [2,3], women interested in starting or continuing with this method must still obtain a prescription from a health care provider in the US. One of the justifications for maintaining the prescription-only status is that, during their clinician visit, women are screened for health conditions such as hypertension and diabetes, which may increase their risk of myocardial infarction, stroke or other complications while taking OCs [4]. However, these rare complications are associated with the use of combined oral contraceptives (COCs) and not progestin-only pills (POPs) [5].

According to the US Medical Eligibility Criteria (MEC), many more conditions are considered relative (category 3) and absolute (category 4) contraindications to COCs compared to POPs [6]. For example, hypertension, migraine headache with aura, and smoking among women 35 years and older — conditions with the highest prevalence in studies of reproductive-aged women — are not considered contraindications to POPs [6–9].

In addition, conditions that are contraindications to POPs, such as past or current breast cancer, cirrhosis and use of anticonvulsants, have been found to be relatively uncommon in several studies examining the prevalence of OC contraindications among reproductive-aged women in the US. Using

* Corresponding author. Tel.: +1 510 986 8941; fax: +1 510 986 8960.
E-mail address: dgrossman@ibisreproductivehealth.org (D. Grossman).

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data from the National Health and Nutrition Examination Survey (NHANES), Shortridge and Miller [7] found that less than 2% of women reported having breast, cervical or uterine cancer or current liver disease. Although some contraindications were broadly defined in this study and data on others were not available in the NHANES, several other studies also found that the prevalence of individual contraindicated conditions was low — less than 1% among both women in the general population and women seeking reproductive health services [8–10]. However, none of these studies reported on the overall prevalence of having any POP contraindication.

There is growing evidence that women can accurately screen themselves for most health conditions that would contraindicate them for OC use. For example, women attending family planning clinics in Washington completed a self-assessment of 20 health conditions that would pose a risk to OC use, and the accuracy of this assessment was then compared to their providers' separate evaluation of these same conditions [10]. Patient–provider agreement was ≥90% on 17 of these items. In another study conducted in Texas, researchers also found a high level of agreement between contraindications identified through providers' assessment and those women reported in a self-administered checklist [8]. Disagreement between women and providers on eligibility for OC use was largely due to misclassification of migraine headaches and unrecognized hypertension, conditions that would not impact women's eligibility for POP use.

The purpose of this analysis was to provide a more focused examination of the prevalence of contraindications to POPs. Specifically, we assess the prevalence of individual POP contraindications as well as the overall prevalence of having any POP contraindication in a convenience sample of reproductive-aged women and in a sample of current OC users — including those who have the option to obtain OCs over the counter in a real-life setting. We also examine how well women's self-assessment of these contraindications compares to that of a health care provider.

2. Materials and methods

For this analysis, we use data from the Border Contraceptive Access Study (BCAS), which examined OC use along the US–Mexico border. The study design, sample size justification and characteristics of women participating in the two substudies of BCAS have been published previously [8,9,11]; we briefly describe the relevant methods here. In the first BCAS substudy (the Self-Screening Study), bilingual (English/Spanish) female interviewers recruited a convenience sample of 1271 women between the ages of 18 and 49 years at shopping malls and a flea market in El Paso, TX, from May to July 2006. Eligible women were given a checklist of contraindications to OC use, which was based on the WHO MEC and a previously validated instrument [10], and asked to mark whether they had any of the conditions listed. After completing the checklist, women were screened for these same conditions by a nurse practitioner who was not aware of the participants' self-screening assessment. If the nurse practitioner was unsure or felt that a woman needed further evaluation regarding a specific condition, she was classified as contraindicated. The questions used in each of these assessments are presented in Table 1. Women provided verbal consent to participate in the study and received a US$ 5–US$ 10 gift card to use at the shopping mall or flea market following completion of the interview.

In the second BCAS substudy (the Prospective Study of OC Users), we recruited 1046 El Paso resident women between the ages of 18 and 44 years who obtained their OCs either at US family planning clinics (n=532) or OTC from pharmacies in Mexico (n=514). In the baseline interview, which was conducted between December 2006 and February 2008, bilingual (English/Spanish) female interviewers read participants a list of medical conditions considered contraindications to OC use and asked women to report if they currently have or ever had the conditions. We assessed category 3 and category 4 contraindications according to the WHO MEC third edition, as the US MEC had not yet been released [6,9,12]. This substudy did not include screening by a clinician. Women who reported any contraindication to OCs were referred to a health care provider. We also asked women to report the specific brand of pill they were using and provided a pictorial guide to assist them in identifying their brand. Prior to completing the baseline interview, women provided written informed consent; they also received a US$ 20 gift card for their participation. Both substudies were approved by the Institutional Review Boards at the University of Texas at Austin and University of Texas–El Paso.

In our analysis of both substudies, we focus on just those conditions that are considered category 3 or 4 contraindications to initiation of POPs: history of or current breast cancer, liver disease (i.e., severe cirrhosis) or liver tumors (hepatocellular adenoma or hepatoma), and use of medications to treat seizures or tuberculosis (i.e., phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine or rifampicin). We did not ask women about whether they had systemic lupus erythematosus (SLE) with positive or unknown antiphospholipid antibodies, had malabsorptive bariatric surgery or

Table 1
Assessment of contraindications to POPs in the Self-Screening Study

Self-assessment	Provider screening
Do you take medicine for seizures or tuberculosis (TB)?	Do you take any of the following medications currently: rifampicin (Rifampin) or anticonvulsants such as phenytoin (Dilantin), carbamazepine (Tegretol), barbiturates, primidone (Myidone or Mysoline), topiramate (Topamax) or oxcarbazepine (Trileptal)?
Do you have liver disease or have you had liver cancer?	Do you currently have liver disease (active viral hepatitis or cirrhosis) or have you had liver cancer in the past?
Have you had breast cancer?	Do you currently have breast cancer or have you had breast cancer in the past?