GENERAL GYNECOLOGY

Medical contraindications in women seeking combined hormonal contraception

Hanna Xu, MD; David L. Eisenberg, MD, MPH; Tessa Madden, MD, MPH; Gina M. Secura, PhD, MPH; Jeffrey F. Peipert, MD, PhD

OBJECTIVE: The objective of the study was to evaluate the prevalence of medical contraindications in a large group of women seeking combined hormonal contraception (CHC).

STUDY DESIGN: The Contraceptive CHOICE Project is a prospective cohort study designed to promote the use of long-acting reversible contraceptive methods to reduce unintended pregnancies in the St Louis region. During baseline enrollment, participants were asked about their desired methods of contraception and medical history. Potential medical contraindications were defined as self-reported history of hypertension, myocardial infarction, cerebral vascular accidents, migraines with aura, any migraine and age 35 years or older, smoking in women older than 35 years, venous thromboembolism, or liver disease. We reviewed all research charts of women with self-reported medical contraindications to verify all conditions. Binomial 95% confidence intervals (CIs) were calculated around percentages.

RESULTS: Between August 2007 and December 2009, 5087 women who enrolled in the CHOICE Project provided information about their medical history and 1010 women (19.9%) desired CHC at baseline. Seventy women (6.93%; 95% CI, 5.44—8.68%) were defined as having a potential medical contraindication to CHC at baseline. After chart review, only 24 of 1010 participants desiring CHC (2.38%; 95% CI, 1.53—3.52%) were found to have true medical contraindications to CHC including 17 with hypertension, 2 with migraines with aura, 2 with a history of venous thromboembolism, and 3 smokers aged 35 years or older.

CONCLUSION: The prevalence of medical contraindications to CHC was very low in this large sample of reproductive-aged women. This low prevalence supports provision of CHC without a prescription.

Key words: combined hormonal contraception, medical contraindications

Cite this article as: Xu H, Eisenberg DL, Madden T, et al. Medical contraindications in women seeking combined hormonal contraception. Am J Obstet Gynecol 2014;210:210.e1-5.

Women in the United States encounter barriers to hormonal contraception.[1] In the United States, women can obtain combined hormonal contraception (CHC) only through prescription whereas in some other countries (eg, China and India),[2] CHC is available over the counter.[3] Four of 5 ★EDITORS' CHOICE★ women born since 1945 have used combined oral contraceptives at some time in their lives.[3] CHC has several advantages including regular, cyclic bleeding, decreased blood loss, reduced risk of iron deficiency anemia, decreased dysmenorrhea, diminished premenstrual dysphoric disorder, and reduced risk of endometrial and ovarian cancer.[3,4] CHC provides women with safe and effective control of their fertility.[3]

However, CHC is not appropriate for every patient and there has been an

From the Division of Clinical Research, Department of Obstetrics and Gynecology, Washington University in St. Louis School of Medicine, St. Louis, MO.

Present address for Dr Xu: Department of Family Medicine, St. Margaret Hospital, University of Pittsburgh School of Medicine, Pittsburgh, PA.

Received July 5, 2013; revised Sept. 26, 2013; accepted Nov. 13, 2013.

This study was supported by an anonymous foundation and supported by a grant from the Doris Duke Charitable Foundation to Washington University in St. Louis School of Medicine to fund Clinical Research Fellow Hanna Xu and grant K23HD070979 from the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development. J.F.P. receives research funding from Bayer and Merck and serves on the advisory boards for Teva and Watson/Activis. T.M. receives research funding from Merck & Co, Inc and honorarium for serving on an advisory board for Bayer Healthcare Pharmaceuticals. D.L.E. receives research funding from Medicines360 and serves on their scientific advisory board.

The authors report no conflict of interest.

Presented at the Second Annual North American Forum on Family Planning, cosponsored by the Society of Family Planning and the Planned Parenthood Federation of America, Denver, CO, Oct. 27-29, 2012, and at the Annual Scientific Assembly of the American Academy of Family Physicians, Philadelphia, PA, Oct. 16-20, 2012.

Reprints: Jeffrey F. Peipert, MD, PhD, Campus Box 8219, Washington University in St. Louis School of Medicine, 4533 Clayton Ave., St. Louis, MO 6311. peipertj@wustl.edu.

0002-9378/free • © 2014 Mosby, Inc. All rights reserved. • http://dx.doi.org/10.1016/j.ajog.2013.11.023

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increased awareness among the general public regarding the health risks associated with CHC use.[3] In 2010, the Centers for Disease Control and Prevention (CDC) published the Medical Eligibility Criteria for Contraceptive Use to provide guidance for the use of contraception in women and men with medical conditions.[5] Although there are multiple studies indicating that many women overestimate the risks associated with hormonal contraception,[6-8] many medical providers perceive hormonal contraceptive methods to be safe and require minimal screening for contraindications.[7]

Also, some studies have reported that the only truly essential information before providing CHC is medical history and blood pressure.[9] Many clinicians in the United States, however, still require patients to have pelvic examinations and cytological screening before prescribing CHC. The CDC just released an adaptation to the World Health Organization's Selected Practice Recommendations to provide additional guidance to ensure safe prescribing of contraception.[10]

Other over-the-counter medications also have risks for users. The US Food and Drug Administration estimates that 2-4% of chronic nonsteroidal antiinflammatory drug (NSAID) users will develop upper gastrointestinal bleeding, symptomatic ulcers, or intestinal perforation each year.[11] In addition, over-the-counter use of acetaminophen is associated with serious liver damage.[12]

The controversy regarding the safety of CHC has restricted efforts to provide CHC without a prescription. Even women who have access to regular health care report appointment delay as a significant impediment.[7] Access to CHC without a prescription could eliminate the obstacle of a mandatory clinical appointment to obtain prescriptions. This inconvenience may put women at risk of unintended pregnancies because of gaps in obtaining contraception.[7]

In December 2012, the American College of Obstetricians and Gynecologists (ACOG) released a Committee Opinion supporting over-the-counter access to oral contraceptive pills and concluded that women should self-screen for most medical contraindications.[13] The principal question remains: how many women have medical contraindications to CHC?

The purpose of this secondary analysis was to estimate the prevalence of self-reported medical contraindications to CHC among reproductive-aged women, which were subsequently confirmed by clinician assessment. Our hypothesis was that few women report medical contraindications to CHC and even fewer have confirmed medical contraindications to CHC after chart review.

Materials and Methods

We used data from the Contraceptive CHOICE Project (CHOICE) to estimate the prevalence of medical contraindications in a large group of women seeking CHC. CHOICE is a large prospective cohort study of 9256 women aged 14-45 years in the St Louis area designed to promote the use of long-acting reversible contraceptive (LARC) methods and reduce unintended pregnancies. The methods of this project have been fully described in a previous publication.[14] The CHOICE protocol was approved by the Washington University in St. Louis School of Medicine Human Research Protection Office, and participants provided informed written consent.

During baseline enrollment, participants were asked about their desired method of contraception, general health information, and medical history through a standard paper questionnaire. We defined desiring CHC as women who desired combined oral contraceptives, the contraceptive patch, or the contraceptive vaginal ring at baseline. Women desiring LARC were those who desired intrauterine devices (IUDs) or subdermal implants.

We recorded age, blood pressure, and number of years of smoking and number of cigarettes per day/week for each participant. Medical history was collected by trained study staff using a standard questionnaire to determine whether participants had any contraindications to CHC. Potential medical contraindications were defined as self-reported history of breast cancer, hypertension, myocardial infarction, transient ischemic attack, cerebral vascular accident (stroke), migraines with aura, any migraine and age 35 years or older, smoking in women aged 35 years or older, venous thromboembolism, or liver disease. This definition was based on the 2004 World Health Organization (WHO) Medical Eligibility Criteria for contraceptive use and the ACOG clinical management guidelines.[15,16] All method use was approved by a study clinician prior to initiation. All participants were provided with no-cost contraception.

Recruitment began in August 2007; participants enrolled before Jan. 1, 2010, were followed for 36 months, and women enrolled after this date were followed for 24 months. Between August 2007 and December 2009, 5090 participants enrolled in the CHOICE Project. This analysis includes 5087 participants who provided complete medical history information. Of the 5087 participants, 4409 participants either desired CHC or desired LARC during baseline enrollment.

At enrollment, the clinician reviewed information documented on the standard medical history form collected by study staff. The condition, year(s) of diagnosis, and current treatment were assessed. Potential medical contraindications that were reported were reviewed for accuracy by the clinician or study staff during the enrollment session.

For this analysis, we retrospectively reviewed all research charts of women with self-reported medical contraindications to verify all conditions. We defined confirmed medical contraindications as documented history of hypertension, myocardial infarction, cerebral vascular accident, transient ischemic attack, migraines with aura, any migraine and age 35 years or older, smoking and age 35 years or older, venous thromboembolism, or liver disease that required medical care or treatment, in accordance with WHO and ACOG.[15,16] We defined participants as having hypertension if they self-reported hypertension and documented medication use or if they had a systolic blood pressure greater than 139 mm Hg or diastolic blood pressure above 89 mm Hg[17] on the day of enrollment

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