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Medical contraindications in women seeking combined hormonal contraception

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Abstract

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.

Keywords

combined hormonal contraception; medical contraindications

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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 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 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 Hg¹⁷ on the day of enrollment with history of hypertension (not during pregnancy).

Baseline demographic characteristics of study participants were described by means, SDs, frequencies, and percentages. For the comparison between participants desiring CHC vs those desiring LARC methods, a Student *t* test was used for continuous variables, and a χ^2 test was performed for categorical data. Binomial 95% confidence intervals (CIs) were calculated around percentages of participants with potential and true medical

contraindications. We used STATA 11 (StataCorp LP, College Station, TX) to perform the statistical analyses.

Results

Of the 5087 women included in this analysis, 1010 women (19.9%) desired CHC at baseline. The Table presents the baseline demographic and reproductive characteristics of participants desiring CHC compared with participants who desired LARC methods. Participants who desired CHC were younger, more likely to identify as white, have higher educational attainment, report being single, and have lower parity. Conversely, they were less likely to receive public assistance and be current smokers. The mean body mass index (BMI) of women desiring CHC was less than the mean BMI of women desiring LARC. There was no significant difference in Hispanic ethnicity between the CHC and LARC groups.

Seventy (6.93%; 95% CI, 5.44–8.68%) of 1010 participants desiring CHC were defined as having a potential medical contraindication to CHC at baseline. After reviewing the 70 research charts, only 24 of these participants (2.38%; 95% CI, 1.53–3.52%) were found to have confirmed medical contraindications to CHC including 17 with hypertension, 2 with migraines with aura, 2 with venous thromboembolism, and 3 smokers who were 35 years old or older.

Among the 46 participants who were evaluated as not having confirmed medical contraindications, 11 reported having hypertension during pregnancy and 8 reported a history of hypertension that had since resolved. Twenty participants reported a history of migraines with aura but upon further evaluation, did not meet the classification of true aura.¹⁸ Two participants who reported a history of migraine were 35 years old or older; one stated her migraines had resolved and the other was never diagnosed with migraine by a clinician. There were 4 women who reported history of venous thromboembolism: one participant was high risk for venous thromboembolism during pregnancy but did not actually have one; one reported blood clots were found in her placenta after delivery; one reported her doctor suspected clots in her arm that was subsequently ruled out after extensive testing; and one participant stated she had a thromboembolic event the year she was born, but this could not be validated and she had no subsequent events. Finally, one participant reported a history of cerebral vascular accident or transient ischemic attack at the age of 14 years that has resolved but could not provide any more information.

Comment

In this analysis, we estimated the prevalence of medical contraindications in a group of women seeking CHC. Of the 1010 women who desired CHC at baseline, only 24 participants (2%) had a confirmed medical contraindication to CHC. Although 70 participants self-reported a medical contraindication to CHCs, we determined that only 34% of these participants (and only 2.4% of women desiring CHC) had a confirmed contraindication to CHC after a chart review. Given that 2–4% of chronic NSAID users develop serious medical side effects,¹¹ we consider an occurrence of less than 5% to represent a low prevalence of medical contraindications. Therefore, in our study we observed a low prevalence of only 2% of participants who desired CHC but were found to have a potential medical contraindication.

The findings in this analysis add to the literature on medical contraindications in reproductive-aged women seeking CHC. In a 2006 cross-sectional study of 1330 women aged 20–51 years, Short-ridge and Miller¹⁹ found that 6% of current oral contraceptive method users reported at least 1 medical contraindication.¹⁹ Although this study was a large,

nationally representative sample of women in the United States, data did not include migraine with aura and venous thromboembolism.

Removing obstacles to effective contraception has the potential to reduce the epidemic of unintended pregnancy in the United States²⁰ and the resulting financial and human costs.²¹ A recent analysis of the CHOICE data found that CHC has a 20-fold increased risk of contraceptive failure compared with IUDs and subdermal implants.²² However, IUDs and implants are not acceptable or accessible for all women, and CHC remains an important contraceptive option.

CHC is much safer for a woman's health than are pregnancy and delivery.³ A study published by Grossman et al²³ concluded that a self-screening tool can be relatively accurate in identifying women who have contraindications to combined oral contraceptives. Our findings contribute to the body of literature supporting that eligibility for CHC can be determined by a simple, detailed history and blood pressure measurement. Women not currently using contraception can initiate these methods without a prescription or clinical visit. In a 2011 nationally representative survey, 62.2% of women were strongly or somewhat in favor of oral contraceptive pills being available over-the-counter.²⁴

Some individuals may be worried that women might abuse hormonal contraceptive methods or adolescents will be more likely to become sexually active if CHC is available without a prescription.⁷ Studies in the United States and Europe have shown that increased access to emergency contraception does not result in increased sexual activity or decreased condom use among adolescents.²⁵ Additionally, the improved use of contraception has resulted in a 77% decline in the pregnancy rate for teenagers in the United States aged 15-17 years.^{26,27}

Our study has a number of strengths. The CHOICE Project is a large prospective cohort study of women who desired CHC at baseline. The participants represent a diverse group of women in terms of race, marital status, and socioeconomic status that strengthens the generalizability of our findings. Limitations of this study include a convenience (nonrandom) sample and inclusion criteria that participants must initiate a new contraceptive method. Participants' self-reported medical contraindications were not supplemented by medical records from participants' medical providers. Also because the mean age of women enrolled in the CHOICE Project was less than 26 years, we cannot estimate the prevalence of medical contraindications to CHC in older women. Although our definitions for medical contraindications to CHC do not precisely match those in the CDC Medical Eligibility Criteria,¹⁰ the definitions used in this study are based on the 2004 WHO Medical Eligibility Criteria and ACOG clinical management guidelines.^{15,16}

In conclusion, the prevalence of medical contraindications to CHC was very low in this sample of reproductive-aged women. We believe the observed low prevalence supports the provision of CHC without a prescription.

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TABLE

Baseline characteristics of participants who desired CHC compared with LARC methods

Characteristic	Desire CHC (n = 1010)	Desire LARC (n = 3399)	P value
Age, mean (SD)	23.7 (4.6)	25.7 (6.0)	< .01
BMI mean (SD)	26.2 (6.5)	28.1 (7.2)	< .01
Participants aged 35 y, n (%)	32 (3.2)	340 (10.0)	< .01
BMI (kg/m ²), n (%)			< .01
<18.5	37 (3.8)	81 (2.4)	
18.5-24.9	483 (49.3)	1252 (37.6)	
25-29.9	230 (23.5)	907 (27.3)	
30	230 (23.5)	1088 (32.7)	
Race, n (%)			< .01
Black	408 (40.4)	1657 (48.8)	
White	508 (50.4)	1481 (43.6)	
Others	93 (9.2)	261 (7.7)	
Hispanic ethnicity, n (%)	48 (4.8)	176 (5.2)	.59
Marital status, n (%)			< .01
Never married	738 (73.0)	1922 (56.6)	
Not married but living with partner	151 (15.0)	760 (22.4)	
Married	91 (9.0)	467 (13.8)	
Divorced/separated/widowed	30 (3.0)	246 (7.3)	
Education, n (%)			< .01
High school or less	255 (25.3)	1300 (38.3)	
Some college	471 (46.6)	1405 (41.3)	
College or higher	284 (28.1)	693 (20.4)	
Insurance, n (%)			.52
No	435 (43.8)	1441 (42.7)	
Yes	558 (56.2)	1937 (57.3)	
Monthly income, n (%)			< .01
None	153 (16.0)	611 (18.3)	

Characteristic	Desire CHC (n = 1010)	Desire LARC (n = 3399)	P value
\$1-800	353 (36.8)	1032 (30.9)	
\$801-1600	260 (27.1)	1005 (30.1)	
\$1601	193 (20.1)	689 (20.7)	
Receives any form of public assistance, ^a n (%)			< .01
No	808 (80.1)	2052 (60.5)	
Yes	201 (19.9)	1342 (39.5)	
Parity, n (%)			< .01
0	718 (71.1)	1291 (38.0)	
1	184 (18.2)	920 (27.1)	
2	79 (7.8)	719 (21.1)	
3	29 (2.9)	469 (13.8)	
Current smoker, n (%)			< .01
No	789 (78.3)	2465 (72.8)	
Yes	219 (21.7)	921 (27.2)	

BMI, body mass index; CHC, combined hormonal contraception; LARC, long-acting reversible contraceptive.

^aCurrently receives food stamps, Women, Infant, and Children (WIC), welfare, or unemployment.