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Combined hormonal contraception use in reproductive age women with contraindications to estrogen use

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Abstract

Background—The Centers for Disease Control's U.S. Medical Eligibility Criteria for Contraceptive Use recommends that combined hormonal contraceptives (i.e., birth control pills, contraceptive patch, vaginal ring) should be avoided in women with specific medical conditions due to increased risk of cardiovascular events associated with estrogen use. Whether women with category 3 (theoretical or proven risk usually outweigh the advantages) or category 4 (unacceptable health risk) contraindications are appropriately avoiding estrogen-containing combined hormonal contraceptives is unknown.

Objective—We describe the prevalence of combined hormonal contraceptive use among a sample of reproductive age women with medical contraindications to estrogen use. Our hypothesis was that women with category 3 and 4 contraindications would use estrogen-containing contraception less often than women without medical contraindications. We also explore whether inappropriate estrogen-containing contraceptive use is related to contraceptive provider characteristics.

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Study Design—Data are from the baseline survey of the MyNewOptions study, which included privately-insured women residing in Pennsylvania aged 18–40, who were sexually active and not intending pregnancy in the next year. Women were surveyed about their medical conditions, contraceptive use, and characteristics of their contraceptive provider. Women were considered to have a contraindication to combined hormonal contraceptives if they reported a category 3 or category 4 contraindication—hypertension, smokers over age 35, history of venous thromboembolism, diabetes with complications, coronary artery disease, systemic lupus erythematosus with antiphospholipid antibodies, breast cancer, or migraine headaches with aura. Chi-square tests for general association were used to compare combined hormonal contraceptives use, contraceptive health provider characteristics, and sociodemographic data in women with and without contraindications to estrogen use.

Results—The MyNewOptions baseline study sample included 987 adult women who were mostly young (46% were 18–25 years), white (94%), employed (70%), and married or cohabiting (54%). Thirteen percent (n=130) of the sample had a medical contraindication to estrogen-containing contraceptive use—migraine with aura (81%) was the most common contraindication, followed by smokers over age 35 (7%), hypertension (11%), history of venous thromboembolism (4%), and diabetes with complications (2%). High use of combined hormonal contraceptives was reported among the women with medical contraindications to estrogen at 39% (n=51). This was not statistically different from women without a medical contraindication (47%, p=0.1). Among the 130 women with a contraindication, whether they did or did not use an estrogen-containing contraceptive did not vary by education level, income, or weight category. With respect to their contraceptive prescribers, there were no differences in prescriber specialty, provider type, or clinic type comparing women using and not using an estrogen-containing contraceptive.

Conclusion—Among this study sample of reproductive age women, there was a high rate of combined hormonal contraceptive use in women with a medical contraindication to estrogen use. These women may be at increased risk for cardiovascular events. Processes need to be improved to ensure that women with medical contraindications to estrogen-containing contraception are being offered the safest and most effective methods, including long-acting reversible contraceptives, such as intrauterine devices and the contraceptive implant.

Keywords

combined hormonal contraception; medical contraindications

Introduction

Over 80% of women in the United States have ever used hormonal contraception.[1] Hormonal contraception includes estrogen-progesterone combined hormonal contraception (CHC), which can provide effective protection against pregnancy with many non-contraceptive health benefits[2] and can safely be used by most women. However, there are certain medical conditions that increase the risk of adverse events associated with CHC use, mostly related to cardiovascular complications. The prevalence of reproductive age women with medical contraindications to CHC has been reported at 2–16%.[3, 4]

The World Health Organization (WHO) Medical Eligibility Criteria for contraceptive use[5] and the adapted Center for Disease Control (CDC) Medical Eligibility Criteria for contraceptive use[6] provide evidence based guidelines for prescribing contraception to women with medical comorbidities. In the setting of various health conditions, these criteria classify CHC use as category 1 (no restrictions to method use), category 2 (advantages of method generally outweigh the theoretical or proven risks), category 3 (theoretical or proven risks usually outweigh the advantages for using the method), or category 4 (unacceptable health risk if the method is used). Previous studies report that 6–11% of current combined oral contraceptive users had at least one contraindication to CHC.[4, 7]

We describe the prevalence of CHC use among women with medical contraindications to estrogen use in a sample of reproductive age women. Our hypothesis was that women with category 3 or 4 contraindications to estrogen-containing contraception would be less likely to use CHC than women without a medical contraindication. We also explore whether inappropriate CHC use is related to contraceptive provider characteristics.

Materials and Methods

This analysis was performed using the baseline survey data from the MyNewOptions study, an ongoing randomized controlled trial to test an online reproductive life planning intervention for assisting privately-insured adult women with personalized contraceptive decision-making (ClinicalTrials.gov Identifier: NCT02100124). The sample included 987 female Highmark Health members in Pennsylvania between the ages of 18 and 40. Women were eligible for the study if they were sexually active, not intending pregnancy in the next 12 months, not surgically sterilized or with a partner who was surgically sterilized, had Internet access and a valid email address. Participants then completed a baseline survey that ascertained baseline demographics, current method of contraception, and their medical comorbidities. Randomization and online intervention occurred after completion of the baseline survey. Additional details regarding the study protocol have been published elsewhere.[8] This study was approved by the Penn State Hershey Institutional Review Board under IRB protocol No. 44583EP with informed consent obtained online.

Contraceptive Method

The survey measured current contraceptive method by asking women to indicate the method of contraception used within the last month. If more than one choice was selected, participants were then asked “which method do you consider to be your primary method?” The outcome measure is current use of a CHC, which was defined as combined birth control pills (containing both estrogen and progestin), the contraceptive patch, and the vaginal ring. For women using birth control pills, the survey response choice was “birth control pills,” and did not specify combined pills or progestin-only pills. To make this distinction, pharmacy claims data were obtained from Highmark Health and used to determine whether the most recent pharmacy claim prior to the woman’s baseline survey was for combined or progestin-only oral contraceptive. All other contraceptives were considered non-estrogen contraception, which included male and female condoms, the medroxyprogesterone acetate injectable, intrauterine devices (IUD), diaphragm, cervical cap, contraceptive foam, jelly,

cream or suppository, the sponge, contraceptive implant, rhythm or natural family planning, withdrawal, and no method of contraception.

Medical Contraindications to CHC

We identified study participants with the following category 3 (theoretical or proven risk usually outweigh the advantages) and category 4 (unacceptable health risk) contraindications to CHC, according to the CDC Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use[6]: 1) hypertension (category 3 if adequately controlled or category 4 if poorly controlled), 2) smokers over the age of 35 (category 3 if <15 cigarettes/day or category 4 if ≥15 cigarettes/day), 3) history of venous thromboembolism (VTE) (category 3 if lower risk for recurrent VTE or category 4 if higher risk for recurrent VTE), 4) diabetes with complications (category 3 if microvascular complications or category 4 if vascular disease or diabetes >20 years), 5) coronary artery disease (category 4), 6) systemic lupus erythematosus with antiphospholipid antibodies (category 4), 7) breast cancer (category 3 if previous breast cancer with no evidence of disease for 5 years or category 4 for current breast cancer), and 8) migraine with aura (category 4). Health conditions were determined by a series of questions asking, “Has a doctor, nurse, or other health professional EVER told you that you had or have any of the following?” Smoking was assessed by asking “Do you now smoke cigarettes every day, some days, or not at all?” In several cases, our survey tool was unable to distinguish category 3 from category 4 contraindications. For example, women over the age of 35 who smoked every day were considered to have a contraindication, but we were unable to specify whether it was category 3 or 4 because the number of cigarettes smoked per day was not ascertained. Of note, not all 18 category 3 and 4 health conditions were ascertained by the survey, so if women in the sample had other category 3 and 4 contraindications (severe liver cirrhosis, gallbladder disease, liver tumors, peripartum cardiomyopathy, organ transplant, thrombogenic mutations, and valvular heart disease) they may have been misclassified.

Contraceptive Provider Characteristics

Contraceptive provider characteristics were determined by a series of questions where the respondent was asked about “the most recent health care visit where you received any contraceptive or women’s health care services.” The clinic type (private office versus other clinic), specialty (Obstetrics and Gynecology versus other specialties), and provider type (physician versus non-physician provider) where the contraceptive or women’s health care services occurred were recorded.

Statistical Analysis

All variables were summarized with frequencies and percentages for categorical variables or with means, medians, and standard deviations for continuous variables prior to any analysis. Chi-square tests for general association, with Fisher exact tests substituted as needed, were used to compare CHC use, contraceptive health provider characteristics, and sociodemographics between women with and without contraindications to estrogen. This same approach was then applied to only the subgroup of 130 women with contraindications to CHC making bivariate comparisons of health provider characteristics and

sociodemographics between women with CHC use and women without CHC use. All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC).

Results

Characteristics of the study sample (n=987) are shown in Table 1. Of the total sample, 13.2% (n=130) of women had a contraindication to CHC. The most common contraindication was migraine with aura (n=105, 80.7%). Of the remaining 25 women with a contraindication, conditions included age ≥ 35 smokers (n=9, 6.9%), hypertension (n=14, 10.8%), history of venous thromboembolism (n=5, 3.9 %), and diabetes with complications (n=2, 1.5%). Five women had two medical conditions that were contraindications to CHC which included 2 patients with migraine with aura and hypertension, 2 smokers with hypertension, and 1 smoker with history of VTE. Results of the bivariate analysis comparing women with and without contraindications to CHC are summarized in Table 1. There were no statistically significant differences between women with and without contraindication to CHC with regards to race, education, income, or contraceptive provider characteristics. Women with contraindication to CHC were more likely to be overweight and obese compared with women without contraindications to CHC use (27.9% vs. 21.6% and 29.5% vs. 18.3% respectively, $p<0.001$). Mean age of women with contraindications was 28.85 ± 6.23 years and the mean age of women without contraindications was 26.88 ± 5.92 years. Only 12 (1.2%) women indicated Hispanic ethnicity.

Among the 130 women with a contraindication to CHC, 39.2% (n=51) were using CHC. This was not statistically different from women without a contraindication (47.0%, p=0.1). The bivariate analysis describing CHC use among the subset of women with contraindications to CHC (n=130) are summarized in Table 2. CHC use did not differ by education level, income, or weight category. There were also no differences in contraceptive provider specialty, provider type, or clinic type. CHC non-users were more likely to be non-white than CHC-users (12.7% vs. 2.0% p=0.049). Mean age of CHC users was 27.51 ± 6.02 years and non-users 29.71 ± 6.25 years. 21.6% (n=11) users and 27.9% (n=22) of non- users were ≥ 35 (p=0.422).

The largest group of women with contraindications to CHC were those with migraine with aura, therefore we performed a post-hoc analysis of just women with migraines to determine if women with and without aura had differences in contraceptive use. Of the total sample, 23.4% (n=231) reported that they suffered from migraine headaches, among whom 45.5% (n=105) reported experiencing aura, which was ascertained by the question, “Do you get migraine auras? Symptoms of migraine aura can include changes in your vision (blind spots, seeing flashing lights, or zigzag lines), feeling prickling skin, having difficulty speaking, or seeing things that aren’t there (hallucinations).” There was no statistically significant difference in CHC use between women with migraine with aura and those without (40.9% vs. 46.8%, p=0.371).

Comment

Among this study sample of privately insured reproductive age women, there was a high rate (39.2%) of CHC use among women with a medical contraindication to estrogen use. In fact, they were statistically no less likely to be using CHC than women without a medical contraindication to estrogen use. Almost half of women with migraine with aura, an "unacceptable health risk," were using CHC in our sample. Previous literature has shown lower rates of CHC use among women with contraindications compared to those without, although the association was no longer significant when controlling for sociodemographic characteristics.[3] Among CHC users, 11.23% had a contraindication to estrogen, similar to previously published data.[4, 7] There were no differences in contraceptive provider or clinic characteristic between those using CHC and those who were not.

The concerns about CHC use when contraindications are present center on cardiovascular risk. Although CHC has consistently been associated with an increased relative risk of venous thromboembolism,[9] the overall absolute risk remains low, especially compared to the risk associated with pregnancy. A recent Cochrane Review suggested there is no increased risk of arterial thrombosis including myocardial infarction or ischemic stroke, in average risk oral contraceptive users with estrogen formulations <50 μg.[10] However, for women with certain medical comorbidities, estrogen containing contraception, or CHC, increases their risk of these cardiovascular complications[2] and should be avoided. Our study was designed using the CDC Medical Eligibility Criteria, but there are women with increased cardiovascular risk due to multiple risk factors such as obese women who smoke or have migraines, for which this guideline is less clear. While not addressed in our study, this group would be of interest in future research. Processes need to be improved to ensure that women with medical contraindications are being offered the safest and most effective non-estrogen containing methods, including LARCs (long acting reversible contraceptives). LARCs, which include IUDs and the contraceptive implant, are the most effective reversible contraceptive methods currently available.

Reducing unintended pregnancy by increasing access to contraception has led to interest in over-the-counter oral contraception. While opponents have argued that requiring a prescription allows providers to assess women for contraindications to CHC, our study results suggest that the current process is not effectively helping women obtain the safest methods for their individual characteristics. Previous studies have shown women are able to accurately self-screen for contraindications to estrogen with a medical checklist.[11] In a recent survey of U.S women at risk for pregnancy, more than 60% of respondents were in favor of over-the counter access to OCPs, and almost one third of women not currently using contraception said they were likely to start using OCPs if available over-the-counter.[12]

The largest contraindication category in our study sample was migraine with aura, which is classified as a category 4, or "unacceptable health risk." In our study, almost half of women with migraines reported having migraines with aura, and almost half of women with migraine with aura were using CHC. Research has suggested that migraine headaches are associated with an increased risk of ischemic stroke,[13, 14, 15] with an increased risk in women with migraine with aura when compared to those with migraine without aura.

[16, 17, 18] The association between ischemic stroke and migraine also appears stronger in younger women, particularly those under 34 to 45.[15, 16] Use of hormonal contraception, particularly estrogen containing, is independently associated with an increased risk of ischemic stroke.[19, 20] This risk increases with age, smoking, and other medical comorbidities that increase the risk of ischemic stroke.[21] Studies suggest there is an increased risk among migraine patients who are using CHC.[14, 17, 18, 22, 23] although the risk of ischemic stroke may be lower with low-dose estrogen preparations.[20, 22]

One limitation of our study is we were not able to distinguish whether some women had category 3 (theoretical or proven risk usually outweigh the advantages) or category 4 (unacceptable health risk) contraindications to CHC. For example, we ascertained if women had hypertension, but did not have information on how well it was controlled—adequately controlled hypertension is category 3 and poorly controlled hypertension is category 4. Similarly, we included women over age 35 who reported smoking every day, but do not know if they smoked <15 cigarettes/day (category 3) or if ≥15 cigarettes/day (category 4). Additionally, patients who reported smoking some days may influence prescribing patterns, which was not addressed in our study. The high use of CHC in women with contraindications could be a result of patient and provider acceptance of the increased associated risk with CHC in favor of the contraceptive and non-contraceptive benefits associated with CHC in women with category 3 contraindications. However, less than 20% of patients could potentially have had a category 3 contraindication; therefore most women with contraindications in our study were using CHC despite “unacceptable health risk”. Another possible explanation for the similar rates of CHC use could be lack of knowledge of contraindications to CHC by both the prescriber and the patient. Previous research has demonstrated over 30% of surveyed Obstetrician/Gynecologists and Family Physicians disagreed with a statement that “migraine with aura should not be prescribed” CHC.[24] The CDC and WHO rate this a category 4, and this was the largest group in our study at over 80%. This highlights the need for adequate provider education on appropriate patient selection for the varying contraceptive methods. The choice to use CHC when contraindicated could also be related to cost considerations. Although our study was conducted in a sample of privately insured women after the Affordable Care Act’s (ACA) contraceptive coverage mandate, we have previously reported that awareness of contraceptive coverage in this sample is low.[25] Another possible explanation for our negative finding is a result of type II error. A post-hoc power analysis results in only 38% power for a two-sided Chi-square test using a significance level of 0.05. However, our study still highlights a large number of women with contraindications to estrogen using CHC, who could potentially benefit from safer, more effective methods of contraception.

A limitation of our study is that we relied on self-report of medical comorbidities, and did not verify through medical records. Previous studies, however, have shown strong concordance between physician screening and patient reporting of medical comorbidities for contraindications to CHC, 90% or higher for many of the conditions we studied.[26] In our study, there were higher numbers of migraine with aura than in previous studies. This could also be a result of self-report of medical conditions, or selection bias of patients who chose to participate in our study. Previous research has suggested that patient report of migraine also has a high degree, >87%, of agreement with International Classification of Headache

Disorders based migraine classification[27], but there is limited data regarding the agreement of self-reported aura. Future research on this topic should include access to medical records to confirm the diagnosis. Our study was survey based, and although the risk of social desirability bias is minimized with anonymous electronic surveys, this could still influence patient reporting.

Many factors contribute to the decision on contraceptive method. The decision may be based on safety, efficacy, perceived pregnancy risk, desire for future pregnancy, and method.[28, 29, 30] The decision also depends on access, availability, and cost of a particular method.[31] The majority of women in our study were college graduates, over one third reported an income ≥$75,000, more than half were normal weight or underweight, and there were very few Hispanic women in the study. The decision to use CHC for these women may not be generalizable to all populations. However, expansion of contraceptive benefits through the ACA can provide the opportunity for women with contraindications to estrogen to choose a safer, more effective method without cost concerns. In our study, inappropriate CHC use was not related to contraceptive provider characteristics, suggesting contraceptive providers of all types and specialties can play a greater role in identifying contraceptive contraindications and offering safer alternatives.

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Table 1

Characteristics of reproductive age women with and without contraindications to CHC use

Characteristic	Total (N=987)	Women with contraindication to CHC (n=130)	Women without contraindication to CHC (n=857)	P-value[a]
Current CHC use				0.097
Yes	454 (46.0)	51 (39.2)	403 (47.0)	
No	533 (54.0)	79 (60.8)	454 (53.0)	
Non-white race				0.061
Yes	50 (5.1)	11 (8.5)	39 (4.6)	
No	931 (94.9)	119 (91.5)	812 (95.4)	
Education				0.803
HS grad or less	70 (7.1)	9 (7.0)	61 (7.1)	
Some college	318 (32.4)	45 (34.9)	273 (32.0)	
College grad	595 (60.5)	75 (58.1)	520 (60.9)	
Income				0.691
<$25,000	133 (13.9)	14 (10.9)	119 (14.4)	
$25,000–$49,999	243 (25.4)	32 (25.0)	211 (25.5)	
$50,000–$74,999	233 (24.4)	31 (24.2)	202 (24.4)	
≥$75,000	347 (36.3)	51 (39.8)	296 (35.8)	
Body Mass Index (kg/m^2)				**<0.001**
Underweight (<18.5)	27 (2.8)	5 (3.9)	22 (2.6)	
Normal (18.5–<25)	542 (55.1)	50 (38.8)	492 (57.6)	
Overweight (25–<30)	220 (22.4)	36 (27.9)	184 (21.6)	
Obese (≥30)	194 (19.7)	38 (29.5)	156 (18.3)	
Contraception managed by OB/Gyn				0.709
Yes	672 (82.0)	92 (80.7)	580 (82.2)	
No	148 (18.0)	22 (19.3)	126 (17.8)	
Contraception managed by physician				0.852
Yes	566 (71.0)	78 (70.3)	488 (71.1)	
No	231 (29.0)	33 (29.7)	198 (28.9)	
Contraception managed by private doctors office				0.278
Yes	826 (87.5)	114 (90.5)	712 (87.0)	
No	118 (12.5)	12 (9.5)	106 (13.0)	

[a] P-value from Chi-square test for general association, exact test used as needed

Table 2

Characteristics associated with CHC use among women with known contraindications to CHC use

Characteristic	Total (N=130)	CHC Users (N=51)	Non-CHC Users (N=79)	P-value[a]
Medical Comorbidity				
Migraine with aura	105 (80.7)	43 (84.3)	62 (79.5)	0.551
Age ≥ 35 smokers	9 (6.9)	2 (3.9)	7 (8.9)	0.321
Hypertension	14 (10.8)	3 (5.9)	11 (13.9)	0.149
Other[b]	7 (5.4)	3 (2.3)	4 (3.1)	1.000
Age				0.422
≥35 years	33 (25.4)	11 (21.6)	22 (27.9)	
<35 years	97 (74.6)	40 (80.4)	57 (72.15)	
Non-white race				**0.049**
Yes	11 (8.5)	1 (2.0)	10 (12.7)	
No	119 (91.5)	50 (98.0)	69 (87.3)	
Education				0.155
HS grad or less	9 (7.0)	1 (2.0)	8 (10.3)	
Some college	45 (34.9)	17 (33.3)	28 (35.9)	
College grad	75 (58.1)	33 (64.7)	42 (53.9)	
Income				0.470
<$25,000	14 (10.9)	6 (11.8)	8 (10.4)	
$25,000–$49,999	32 (25.0)	9 (17.7)	23 (29.9)	
$50,000–$74,999	31 (24.2)	13 (25.5)	18 (23.4)	
≥$75,000	51 (39.8)	23 (45.1)	28 (36.4)	
Body Mass Index (kg/m^2)				0.394
Underweight (<18.5)	5 (3.9)	3 (5.9)	2 (2.6)	
Normal (18.5–<25)	50 (38.8)	23 (45.1)	27 (34.6)	
Overweight (25–<30)	36 (27.9)	11 (21.6)	25 (32.1)	
Obese (≥30)	38 (29.5)	14 (27.5)	24 (30.8)	
Contraception managed by OB/Gyn				0.723
Yes	92 (80.7)	38 (79.2)	54 (81.8)	
No	22 (19.3)	10 (20.8)	12 (18.2)	
Contraception managed by physician				0.891
Yes	78 (70.3)	32 (69.6)	46 (70.8)	
No	33 (29.7)	14 (30.4)	19 (29.2)	
Contraception managed by private doctors office				0.358
Yes	114 (90.5)	48 (94.1)	66 (88.0)	

Characteristic	Total (N=130)	CHC Users (N=51)	Non-CHC Users (N=79)	P-value[a]
No	12 (9.5)	3 (5.9)	9 (12.0)	

[a] P-value from Chi-square test for general association, exact test used as needed

[b] Other includes history of venous thromboembolism, diabetes with complications. These groups were combined due to small numbers.