

**Contraindications to combined oral contraceptives among
over-the-counter and clinic pill users**

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Abstract

Objective: To compare the estimated proportion of contraindications to combined oral contraceptives (COCs) between women living in El Paso, Texas, obtaining COCs in US public clinics versus over the counter (OTC) in Mexican pharmacies.

Methods: We recruited a cohort of 501 El Paso resident women who obtained COCs over the counter (OTC) in Mexico and 514 women who obtained COCs from family planning clinics in El Paso. Based on self-report of WHO category 3 and 4 contraindications and interviewer-measured blood pressure, we estimated the proportion of contraindications and, using multivariable-adjusted logistic regression, identified possible predictors of contraindications.

Results: The estimated proportion of any category 3 or 4 contraindication was 18%. Relative contraindications (category 3) were more common among OTC users (13% vs 9% among clinic users, $p=0.006$). Absolute contraindications (category 4) were not different between the groups (5% for clinic users vs 7% for OTC users, $p=0.162$). Hypertension was the most prevalent contraindication (8%). After multivariable adjustment, OTC users had higher odds of being contraindicated compared to clinic users (OR 1.59, 95% CI: 1.11-2.29). Women age 35 years or older (OR 5.30, 95% CI: 3.59-7.81) and those with body mass index ≥ 30.0 kg/m² (OR 2.24, 95% CI: 1.40-3.56) also had higher odds of being contraindicated.

Conclusions: Relative COC contraindications are more common among OTC users in this setting. Research is needed to determine whether checklists can be used to accurately identify contraindications when women obtain COCs OTC. Progestin-only pills might be a better candidate for the first OTC product given their fewer contraindications.

Introduction

Combined oral contraceptives (COCs) are the most widely used method of family planning in the US (1). In the 50 years since COCs were first approved for sale, they have been demonstrated to be very safe (2). However, certain conditions are considered contraindications to COC use because they place the user at increased risk of complications such as myocardial infarction or stroke. The World Health Organization's (WHO) Medical Eligibility Criteria for Contraceptive Use lists contraindications to use, including hypertension, smoking over age 34 and migraine with aura, among others (3, 4).

Little research has evaluated the prevalence of contraindications in the general population. One study estimated that approximately 16% of US women of reproductive age had at least one contraindication to COC use, and these conditions were more prevalent among older women and those with public insurance or uninsured women (5). Another study from Texas found that 39% of reproductive aged women had at least one contraindication to COC use (6).

In recent years, there has been growing interest in the possibility of moving oral contraceptives over the counter, although some have expressed concern about whether women can accurately self-screen for contraindications without a clinician. Two studies in Mexico, where COCs are available without a prescription, found that the prevalence of contraindications was not significantly higher among those obtaining pills without a prescription compared to those who obtained the method from a clinician (7, 8). One study in the US found that women seeking contraception could accurately use a checklist to identify contraindications (9). In another study among the general population, women also were found to accurately self-screen for contraindications, although 6% thought they were eligible for use when they were truly contraindicated, largely due to unrecognized hypertension (6).

The objective of this study was to understand how well women self-screen for COC contraindications when they obtain this method over the counter in a real-life situation. We took advantage of a natural experiment where US women living along the Texas-Mexico border have the opportunity to obtain COCs in Mexican pharmacies without a prescription (10).

Materials and Methods

Between December 2006 and February 2008, bilingual (English/Spanish) female interviewers recruited El Paso resident oral contraceptive (OC) users into a study on women's access to OCs on the US-Mexico border. Women who were between age 18 and 44, reported receiving their last pack of OCs from either a family planning clinic in El Paso or over-the-counter at a pharmacy in Ciudad Juarez, Mexico, and were willing to complete a series of four interviews were eligible to participate. The target population for this study was 500 El Paso clinic users and 500 women who accessed OCs over-the-counter (OTC) at pharmacies in Mexico; at the end of enrollment, we recruited 532 clinic users and 514 OTC users. Interviewers recruited some of the clinic users from the major family planning providers in the El Paso area. The remaining proportion of the clinic user sample, as well as the entire OTC sample, was recruited using flyers, announcements, presentations at local community centers, as well as referrals from other participants. Our recruitment strategies reached women across the El Paso metropolitan area, with participants residing in 46 different zip codes; 16 of these zip codes each had 20 or more participants.

Women who agreed to participate in the study were asked to complete four interviews at three-month intervals: a face-to-face baseline interview, telephone interviews at three and six months following baseline, and a final face-to-face interview approximately nine months after

the baseline interview. Additionally, blood pressure, height and weight were measured at the final interview. Data collection was completed in December 2008, and 941 women completed the nine-month follow-up interview.

Interview data were collected using standardized questionnaires. At baseline, interviewers asked participants about basic sociodemographic information and their current OC use, including pill brand. Participants were also read a list of medical conditions, considered contraindications to COC use, and asked to report if they have ever had them. At each follow-up interview, participants were asked whether they had developed new medical conditions that would be considered contraindications to COC use; they were also asked to report their current contraceptive method. Due to the fact that a high proportion of participants reported migraine with aura at the baseline interview, during the final interview participants were asked a more detailed series of questions to better identify migraine with aura symptoms.

At the final interview, interviewers measured and recorded participants' blood pressure using an automated Omron HEM 705CP blood pressure monitor (Omron Healthcare, Inc., Bannockburn, IL). Interviewers underwent training in the proper measurement of blood pressure with these monitors. Blood pressure was measured twice, and the mean systolic and diastolic measurements recorded. In addition, participants' weight was measured using a Seca Clara 803 digital scale and their height measured using a Seca Road Rod 214 portable stadiometer (Seca Corporation, Hannover, MD). We calculated women's body mass index (BMI) using the measurement of participants' height and weight at the final interview. We used women's self-reported height and weight from the baseline interview to compute BMI for participants who were missing these data from the final interview (n=181); several participants (n=38) were missing both self-reported height and weight and final interview measurements. Participants

were categorized as normal weight ($<25.0 \text{ kg/m}^2$), overweight ($25.0 - 29.9 \text{ kg/m}^2$) and obese ($\geq 30.0 \text{ kg/m}^2$).

Participants were asked to report on WHO Medical Eligibility Criteria (MEC, 3rd edition) relative and absolute contraindications (category 3 and category 4 contraindications, respectively; Table 1) (3). The study was performed before the US MEC were released (11). All contraindications were based on participants' self-report from the baseline interview, with the exception of migraine with aura and hypertension; we assessed these two contraindications with composite measures from the baseline and final interviews. Women were considered contraindicated due to migraine headaches with aura symptoms if they met the following criteria: were using COCs at their final interview and reported migraine headaches (i.e. headaches on one side of the head with symptoms of nausea/vomiting and/or sensitivity to light and that interfere somewhat or a lot with normal activities) that were also accompanied by numbness, weakness and/or difficulty seeing (12). If they did not complete a final interview ($n=105$) or if they were not using COCs at the final interview ($n=145$), we used reported migraine headaches with numbness, weakness or difficulty seeing at baseline ($n=27$). We also assessed when these headaches began relative to current pill use, based on the reported date of starting COCs and the month and year the headaches began. In this analysis we did not include contraindications to continuing COCs according to the WHO MEC, such as the development of migraine without aura after starting COCs (reported by 5 clinic users and 1 OTC user).

Women's blood pressure was classified according to the WHO MEC based on the average of the two blood pressure measurements taken at their final interview. Women with category 3 contraindications also included those participants who completed a final interview, had a mean systolic blood pressure measurement less than 140 mm Hg or mean diastolic

measure less than 90 mm Hg, but who reported taking antihypertensive medication. Those who did not complete the final interview, did not have their blood pressure measured at the final interview (n=54), or who were not using OCs at the final interview were considered to have hypertension if they reported at baseline that they had hypertension or had high blood pressure when it was last measured (n=5).

Participants provided written informed consent before completing the initial interview. If a participant reported contraindications to OC use during any of the interviews, or a mean systolic/diastolic blood pressure measurement of 140/90 mm Hg or greater was recorded at the final interview, she received a referral to a health care provider. Women received gift cards valued between \$10 and \$35 for each of the interviews they completed. This study was approved by the institutional review boards at the University of Texas at Austin and University of Texas at El Paso.

Questionnaire data were entered into an EpiData (EpiData Association, Odense, Denmark) database, and results were analyzed using Stata 10.0 (StataCorp LP, College Station, TX). Participants who were using progestin only pills (n=17), who did not report a pill brand (n=13) or were missing relevant sociodemographic information (n=1) were excluded from analysis; this resulted in a sample of 1,015 participants – 514 clinic and 501 OTC COC users.

Sociodemographic characteristics and the estimated proportion of contraindications to COC use were calculated for clinic and OTC users separately. The statistical significance of differences in proportions between these groups was determined using chi-square tests, and the Wilcoxon-Mann-Whitney test was used to compare medians. Crude and multivariable-adjusted logistic regression was used to model the association between having at least one category 3 or 4 contraindication and a woman's source of COCs (clinic versus OTC), age, parity, education,

country in which she was born and completed her last year of schooling, US health insurance coverage, and BMI. These variables were included to assess whether an association between contraindications and source of COCs was attributable to characteristics common among women who obtain their pills OTC in Mexico (10), correlates of access to health care, or identifiable risk factors for contraindications.

Based on our target of recruiting 500 clinic and 500 OTC users, a sample size that was based on another outcome, and a 28% prevalence of contraindications among current OC users in this population (13), assuming a two-tailed type-1 error of 5%, we had 80% statistical power to detect an absolute difference of 8 percentage points in the estimated proportion of contraindications between clinic and OTC users.

Results

Of the 1,015 El Paso resident COC users, 514 women had obtained their last pill pack prior to the baseline interview from a family planning clinic in El Paso, and 501 women had obtained their most recent pill pack over-the-counter at a pharmacy in Ciudad Juarez, Mexico. The characteristics of participants by source of COCs at baseline are presented in Table 2. OTC users were older than clinic users and less likely to be nulliparous and have a high school level education. They were also more likely to have been born in, and completed their last year of schooling in, Mexico. US health insurance coverage was low for both groups and less common among OTC users (11.0% compared to 23.9% of clinic users, $p < 0.001$). BMI was high among participants in this sample, with more than 60% of women in both groups in the overweight or obese categories. Finally, 18.8% of OTC users and 14.2% of clinic users reported being current smokers ($p = 0.047$).

Among all COC users, hypertension was the most common contraindication (7.7%), followed by smoking age 35 or over (4.9%) and migraine with aura (4.1%); for each of the remaining contraindications, less than 2% of participants reported that they had or currently have the condition. While the estimated proportion of contraindications was not significantly different for OTC and clinic users for the majority of the individual contraindications, OTC users were significantly more likely than clinic users to have category 3 hypertension or be 35 years and older and smoke (Table 3).

Category 3 contraindications were reported by 11.2% of all COC users in the sample, and category 4 contraindications were reported by 6.3%. The estimated proportion of category 3 and category 4 contraindications among OTC users was 13.4% and 7.4%, respectively, compared to 8.6% and 5.3% among clinic users. At least one category 3 or 4 contraindication was reported by 21.4% of OTC users and 13.8% of clinic users ($p=0.002$). While the estimated proportion of any category 3 contraindication was significantly different between the groups, the proportion of category 4 contraindications was not different.

In the crude logistic regression model, OTC users had significantly higher odds of having at least one category 3 or 4 contraindication to COC use compared to clinic users (OR 1.69, 95% CI: 1.22-2.36). Results were similar after multivariable adjustment (Table 4). In addition, women between ages 35 and 44 were significantly more likely to be contraindicated relative to younger women, and those born and educated in Mexico were less likely to be contraindicated compared to women born and educated in the US. Women with a BMI ≥ 30 kg/m² also had significantly higher odds of having a category 3 or 4 contraindication (OR 2.24, 95% CI: 1.40-3.56). Parity, education, and US health insurance coverage were not significantly associated with being contraindicated to COC use.

Discussion

We found a surprisingly high proportion of women in this population contraindicated to COCs, a finding we previously reported in El Paso (6). In addition to being obese, this population has limited access to health maintenance screening, which might contribute to the high prevalence of contraindications (6). Nineteen percent of women who had obtained pills from a clinic had a category 3 or 4 contraindication, suggesting that clinician screening is not perfect in this setting. It is also possible that in these cases, clinicians weighed the risks and benefits of all contraceptive options and determined that COCs were the best option. Alternatively, some contraindications, such as hypertension, might have developed after a woman was initially screened by her prescribing clinician. A study using data from the National Health and Nutrition Examination Survey found that approximately 6% of OC users in the US were contraindicated, although not all contraindications were identifiable in the database (5).

The estimated proportion of contraindications was significantly higher among women obtaining COCs in Mexico without a prescription compared to clinic users. These results are contrary to the findings reported in studies of Mexican women that found no difference in contraindications between those who obtained pills from a clinician or at a pharmacy (7, 8). It may be that some women in El Paso who were denied pills at a clinic because of a contraindication later obtained the method at a pharmacy in Mexico, possibly because it was the most effective contraceptive they could easily obtain. We are currently exploring this through additional in-depth interviews with hypertensive women in this sample.

In the multivariable-adjusted analysis, we found that in addition to obtaining pills OTC in Mexico, older age and obesity were the strongest predictors associated with having a category 3 or 4 contraindication. Although $BMI \geq 30 \text{ kg/m}^2$ itself is not a contraindication to COCs, obese

women are at risk of contraindicated comorbidities such as hypertension, hypercholesterolemia and diabetes (3, 4, 11, 14). In settings where COCs are available without a prescription and blood pressure measurement is not easily accessible, BMI could be used as a proxy measure of contraindicated status. Future research should examine the accuracy and feasibility of a simple self-screening tool including BMI, as well as a more detailed checklist (6), in this context.

Our findings raise the question of whether the criteria for contraindications might be too strict. In this setting where access to other forms of contraception, such as depot medroxyprogesterone acetate, IUDs, implants and sterilization is limited, contraindicated women have few options. Given that unintended pregnancy also conveys risk among contraindicated women, using COCs may be the lesser evil for some women. The majority of studies that identified hypertension as a risk factor for myocardial infarction and stroke while on COCs were case-control studies and relied on participant report of hypertension rather than measured blood pressure prior to taking pills (15, 16). Even the few prospective cohort studies of COC users did not report the blood pressure measurements of women labeled hypertensive who developed complications (17, 18). Given the rising prevalence of blood pressure $\geq 140/90$ mm Hg in recent years (19), as well as the association between obesity and hypertension, it might be worth reconsidering the blood pressure cut-off for the category 3 contraindication.

Our study has several limitations. We used a convenience sample of COC users, which may have introduced bias; however it is important to note that no other sampling technique was possible with OTC users. Women selected their source of COCs, and there may be important differences in the two populations that were not controlled for here. It is also likely that we overestimated the proportion of women with hypertension, since some participants might have had “white coat” hypertension, and blood pressure was measured on a single day. Screening for

contraindications was not performed by a licensed clinician and was more like self-screening. This may have introduced some measurement error, although the self-screening questions had been previously validated and found to correlate well with a clinician's assessment (6). The diagnosis of migraine with aura is particularly difficult with a small number of screening questions. In addition, since we collected data for this study, both the WHO and US MEC added several category 3 and 4 contraindications, such as a history of malabsorptive bariatric surgery or use of drugs like ritonavir-boosted protease inhibitors (4, 11). We do not know how common these contraindications are in this population, although we suspect they are rare. Finally, our findings are from one specific population and may not be reflective of what would happen if COCs were made available OTC throughout the US.

The focus of this study was on contraindications to COCs among current users. However, women's assessment of the risks of the pill can also be overestimated, creating a self-imposed barrier to use (13). More efforts are needed to educate women about both the contraindications to this method, as well as the safety and non-contraceptive benefits of COCs.

Regarding the possibility of over-the-counter access to OCs in the US, our findings present something of a cautionary tale. While the evidence is clear that women can accurately self-screen for contraindications using simple checklists (6, 9), if they are not given such tools, as was the case here, some women will miss contraindications. It may be that the population that chooses the OTC option lacks access to medical screening and may be at higher risk of contraindications to begin with. However, this study is somewhat reassuring in that at least absolute contraindications are not more common in among women obtaining COCs over the counter. An actual use study of OTC provision of COCs is needed to demonstrate whether self-screening for contraindications using a checklist on the label is accurate and whether women

would actually use it. The checklist could be combined with a blood pressure assessment using an automatic kiosk on site. Alternatively, progestin-only pills might be a better candidate for the first OTC oral contraceptive, given the much fewer—and rarer—contraindications for this method.

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Table 1. Medical conditions classified as category 3 and category 4 contraindications to initiation of combined oral contraceptive use according to the World Health Organization Medical Eligibility Criteria (3rd edition) and assessment of contraindications in the Border Contraceptive Access Study¹

World Health Organization Medical Eligibility Criteria	Border Contraceptive Access Study Assessment
Category 3 Contraindications	
Postpartum < 21 days and not breastfeeding	Date of last delivery
Breastfeeding ≥ 6 weeks to < 6 months postpartum ²	Are you currently breastfeeding? Date of last delivery
Age 35 or older and smokes 0-14 cigarettes per day	Do you smoke? How many cigarettes do you smoke a day?
Adequately controlled hypertension, elevated blood pressure readings (140-159/90-99 mm Hg), or history of hypertension without blood pressure assessment	Blood pressure reading <140/90 mm Hg and Do you take medicine for high blood pressure? Blood pressure reading 140-159/90-99 mm Hg Do you have high blood pressure? ³
Medically treated or current gall bladder disease	Do you currently have gall bladder disease?
Known hyperlipidemias ⁴	Are you currently taking medication for high cholesterol?
Diabetes for more than 20 years or with nephropathy, retinopathy, neuropathy, or other vascular disease ⁵	Do you have diabetes? If yes, do you have problems with your kidneys, eyes or nerves related to diabetes? Have you been told that you have problems with your arteries or veins related to your diabetes? Have you had diabetes for more than 20 years?
Use of anticonvulsant medications (phenytoin, carbamazepine, barbiturates, primidone, topiramate, or oxcarbazepine) or rifampicin therapy	Do you suffer from seizures (epilepsy) or Tuberculosis (TB)? If so, are you taking any of the following medications: rifampicin, phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine?
Migraine headaches without aura and age 35 or older	Do you have migraine headaches? If so, when you get these headaches do you have any of these associated symptoms: numbness, weakness, difficulty seeing, nausea or vomiting, sensitivity to light? Are your headaches usually on one side or both sides? When you get one of these headaches, does it interfere with your normal activities a little, somewhat or a lot?

Category 4 Contraindications

Breastfeeding < 6 weeks postpartum ⁶	Are you currently breastfeeding? Date of last delivery
Age 35 or older and smokes 15 cigarettes per day or more	Do you smoke? How many cigarettes do you smoke a day?
Elevated blood pressure reading (\geq 160/100 mm Hg)	Blood pressure reading \geq 160/100 mm Hg
History of or current deep vein thrombosis or pulmonary embolism	Have you had a blood clot in your lung or in your leg (not just varicose veins)?
Known thrombogenic mutations	Not applicable given recruitment setting
Major surgery with prolonged immobilization	Do you have heart disease? If so, what kind?
Current and history of ischemic heart disease and stroke	Have you had a heart attack or stroke?
Complicated valvular heart disease	See migraine headache questions under Category 3
Migraine headaches with aura	Do you currently have breast cancer or have you had breast cancer in the past?
Current breast cancer (history of breast cancer in the past without evidence of current disease is a category 3 contraindication)	Do you currently have liver disease (like hepatitis or cirrhosis) or have you had liver cancer in the past?
Viral hepatitis, severe cirrhosis, hepatocellular adenoma or malignant liver tumors	
COC-related cholestasis ⁷	

1. In the Border Contraceptive Access Study, all contraindications to COC use were assessed using participants' self-report, except for hypertension; hypertension was assessed using the average of two blood pressure measurements taken at the final interview.
2. In the US MEC, breastfeeding 1 month to < 6 months postpartum is a category 2 contraindication (11).
3. We used self-reported history of high blood pressure if no blood pressure measurement was available (n=2) or the participant was not using OCs at the final interview (n=3).
4. Known hyperlipidemias are listed as a category 2/3 contraindication, depending on the type, severity and presence of other cardiovascular risk factors (3, 4). We classified women taking medication for a hyperlipidemia as having a category 3 contraindication.
5. Diabetes of long duration or with vascular complications is listed as a category 3/4 contraindication, depending on the severity of the condition (3, 4). We classified women reporting this condition as having a category 3 contraindication.

6. In the US MEC, breastfeeding <1 month postpartum is a category 3 contraindication (11).
7. This is a category 3 contraindication (3, 4), but we were not able to separate the responses for this condition and other current liver disease.

Table 2. Characteristics of participants by source of COCs at baseline

	US Clinic (n=514)	OTC from Mexico (n=501)	χ^2 P-value ¹
	%	%	
Age			
18 – 34 years	77.6	64.3	<0.001
35 – 44 years	22.4	35.7	
Median age, years	28.0	31.0	<0.001
Parity			
0 live births	19.5	12.6	0.003
1 or more live births	80.5	87.4	
Education			
Less than High School	43.6	51.3	0.014
High School or more	56.4	48.7	
Nativity/Education			
Born and Educated in US	39.3	21.2	<0.001
Born in Mexico, Educated in US	32.5	35.7	
Born and Educated in Mexico	28.2	43.1	
US insurance coverage			
Has US health insurance	23.9	11.0	<0.001
No US health insurance	76.1	89.0	
Body Mass Index			
Normal weight (< 25.0 kg/m ²)	27.8	29.1	0.080
Overweight (25.0 – 29.9 kg/m ²)	32.3	37.3	
Obese (\geq 30.0 kg/m ²)	35.0	30.9	
Missing BMI	4.9	2.6	
Smoking			
Current smoker	14.2	18.8	0.047
Non-smoker	85.8	81.2	

1. The chi-squared test was used to determine the statistical significance of differences between clinic and OTC users for all characteristics, except median age for which the Wilcoxon-Mann-Whitney test was used.

Table 3. Frequencies of Contraindications to COC use by source of COCs at Baseline¹

	US Clinic		OTC from Mexico		χ^2 p-value
	(n=514)		(n=501)		
	n	(%)	n	(%)	
Hypertension²					
Any hypertension ($\geq 140/90$ mm Hg)	29	(5.6)	49	(9.8)	0.013
Hypertension 140-159/90-99 mm Hg	23	(4.5)	42	(8.4)	0.036
Hypertension $\geq 160/100$ mm Hg	6	(1.2)	7	(1.4)	
Smoking and age 35 years or more					
Smokes < 15 cigarettes/day	16	(3.1)	32	(6.4)	0.017
Smokes ≥ 15 cigarettes/day	0	(0.0)	2	(0.4)	
Migraine headaches with aura³	21	(4.1)	21	(4.2)	0.932
Current gall bladder disease	5	(1.0)	8	(1.6)	0.377
High cholesterol on medication	2	(0.4)	3	(0.6)	0.633
Diabetes with complications⁴	2	(0.4)	1	(0.2)	0.578
Current liver disease or history of liver cancer	0	(0.0)	3	(0.6)	0.079
History of or current heart disease	1	(0.2)	1	(0.2)	0.986
Previous heart attack or stroke	0	(0.0)	2	(0.4)	0.152
History of thrombosis or pulmonary embolism	1	(0.2)	1	(0.2)	0.986
Current use of medications for TB or seizure⁵	1	(0.2)	1	(0.2)	0.986
History of or current breast cancer	0	(0.0)	1	(0.2)	0.311
Classification of assessed contraindications					
Any category 3 contraindication	44	(8.6)	70	(13.4)	0.006
Any category 4 contraindication	27	(5.3)	37	(7.4)	0.162
Any category 3 or 4 contraindication	71	(13.8)	107	(21.4)	0.002

1. Contraindications not reported here were not identified in this sample.

2. Women's blood pressure was categorized based on the average of two blood pressure measurements taken at the end of their final interview. Those who completed a final interview, had a blood pressure measurement < 140/90 mm Hg, but who reported taking medication for hypertension were categorized as having blood pressure between 140-159/90-99 mm Hg (n=13). Those women who did not complete a final interview, did not have their blood pressure measured at the final interview or who were not using OCs at the final interview and reported at

their baseline interview that they had hypertension or had high blood pressure when it was last measured were categorized as having blood pressure between 140-159/90-99 mm Hg (n=5).

3. Women who were using COCs at their final interview and who reported migraine headaches (i.e headaches on one side of the head with symptoms of nausea or vomiting and/or sensitivity to light and that interfere somewhat or a lot with normal activities) with numbness, weakness and/or difficulty seeing were classified as having migraine headaches with aura. Additionally, women who were not using COCs at the final interview or did not complete the final interview but reported migraine with aura symptoms at baseline were considered to have migraine with aura (n=27).

4. Women who reported diabetes-related problems with their kidneys, eyes, nerves, arteries, veins and/or who have suffered from diabetes for more than 20 years.

5. Medications include: rifampicin, phenytoin, carbamazepine, barbiturates, primidone, topiramate, and oxcarbazepine.

Table 4. Multivariable-adjusted Odds Ratios for any Category 3 or 4 Contraindications to COC use

	OR	(95% C.I.)	p-value
Source of COCs at Baseline			
US Clinic	1.00		
OTC from Mexico	1.59	(1.11-2.29)	0.012
Age Groups			
18 – 34 years	1.00		
35 – 44 years	5.30	(3.59-7.81)	<0.001
Parity			
0 live births	1.00		
1 or more live births	0.99	(0.53-1.84)	0.978
Education			
Less than High School	1.00		
High School or more	0.73	(0.49-1.08)	0.115
Nativity/Education			
Born and Educated in US	1.00		
Born in Mexico, Educated in US	0.69	(0.42-1.13)	0.130
Born and Educated in Mexico	0.55	(0.32-0.94)	0.029
US insurance coverage			
No US health insurance	1.00		
Has US health insurance	1.11	(0.67-1.84)	0.679
Body Mass Index			
Normal weight (< 25.0 kg/m ²)	1.00		
Overweight (25.0 – 29.9 kg/m ²)	1.03	(0.63-1.68)	0.918
Obese (≥ 30.0 kg/m ²)	2.24	(1.40-3.56)	0.001
Missing BMI	1.79	(0.66-4.90)	0.254

Abbreviations: OR – odds ratio; CI – confidence interval