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Accuracy of Self-Screening for Contraindications to Combined Oral Contraceptive Use

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Abstract

Objective—To estimate how well a convenience sample of women from the general population could self-screen for contraindications to combined oral contraceptives using a medical checklist.

Methods—Women 18-49 years old (N=1,271) were recruited at two shopping malls and a flea market in El Paso, Texas, and asked first whether they thought pills were medically safe for them. They then used a checklist to determine the presence of level 3 or 4 contraindications to combined oral contraceptives according to the World Health Organization Medical Eligibility Criteria. Women were then interviewed by a blinded nurse practitioner who also measured blood pressure.

Results—The sensitivity of the unaided self-screen to detect true contraindications was 56.2% (95% CI: 51.7%-60.6%) and specificity 57.6% (54.0%-61.1%). The sensitivity of the checklist to detect true contraindications was 83.2% (79.5%-86.3%) and specificity 88.8% (86.3%- 90.9%). Using the checklist, 6.6% (5.2%-8.0%) of women incorrectly thought they were eligible for use when, in fact, they were contraindicated, largely due to unrecognized hypertension. Seven percent (5.4%-8.2%) of women incorrectly thought they were contraindicated when they truly were not, primarily due to misclassification of migraine headaches. In regression analysis, younger women, more educated women and Spanish-speakers were significantly more likely to correctly self-screen ($p<0.05$).

Conclusion—Self-screening for contraindications to oral contraceptives using a medical checklist is relatively accurate. Unaided screening is inaccurate and reflects common misperceptions about the safety of oral contraceptives. Over-the-counter provision of this method would likely be safe, especially for younger women and if independent blood pressure screening were encouraged.

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Précis Self-screening for contraindications to oral contraceptives using a medical checklist is accurate, especially for younger women with a low prevalence of contraindications.

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INTRODUCTION

Evidence from the 2002 National Survey of Family Growth suggests that contraceptive use among women at risk of unintended pregnancy has declined in recent years.¹ Limited access may contribute to contraceptive non-use, and the prescription requirement for hormonal methods may further deter initiation and continuation.² The public health benefits of over-the-counter access to oral contraceptives have been debated for years,³ and a recent study demonstrated the acceptability and feasibility of pharmacist-provision of hormonal methods.⁴

One criterion for determining whether combined oral contraceptives could be safely provided over the counter is demonstrating that women can screen themselves for medical contraindications to use. In two studies from Mexico, where oral contraceptives are easily available over-the-counter, women who obtained their pills over-the-counter at pharmacies had similar risk profiles to women who received pills from clinics.^{5,6} Zavala et al. found that women who obtained pills from a community-based distribution program had similar health profiles and prevalence of risk factors compared to those who obtained their pills from other locations, such as pharmacies.⁵ These findings indicate that women who had not consulted with a clinician were just as well-screened as those women who had received a formal medical evaluation. Another study used data from the Mexican National Health Survey and compared the health profiles and contraindications to oral contraceptive use among women obtaining pills from pharmacies and those who received pills from a public or private clinic.⁶ Although women who obtained pills from clinics had a lower prevalence of contraindications to pill use than those who purchased their pills directly from pharmacies, the differences between these groups were not statistically significant. Furthermore, the authors' analysis from the Mexican National Survey of Reproductive Health showed that the majority of women (69.2%) who currently purchased oral contraceptives at pharmacies had begun use under medical supervision through a private doctor or public clinic.⁶

In a recent study from Washington state, Shotorbani et al. demonstrated that women's responses to a medical eligibility checklist for hormonal contraceptives was just as accurate as a provider's formal evaluation.⁷ In an item-by-item analysis, agreement ranged from 84% to 100% between a woman's self-assessment and the provider's assessment of whether she had a given contraindication. Furthermore, the authors showed that where women and providers disagreed, women were more likely to report contraindications than were providers. Of note, less than 5% of the women in this study were judged to be contraindicated to hormonal contraceptive use.⁷

Although these studies demonstrate the general effectiveness of women to screen themselves for contraindications to oral contraceptive use, the populations studied were restricted to women already using hormonal contraception or accessing family planning services. Therefore, it is possible that women who had already screened themselves out of oral contraceptive use were not included. In this study, we surveyed both oral contraceptive users and non-users to reduce the possibility of selection bias.

The purpose of this study was to estimate the accuracy of a woman's self-assessment regarding whether she was contraindicated to oral contraceptive use among a convenience sample in the general population. The self-assessment was first performed unaided and then repeated using a simple medical screening checklist. The gold standard to which these assessments were compared was an assessment by a nurse practitioner.

MATERIALS AND METHODS

This study was part of the Border Contraceptive Access Study, a five-year project examining oral contraceptive use along the U.S.-Mexico border. Between May and July 2006, bilingual (English/Spanish) female interviewers approached women in two shopping malls and an outdoor flea market in El Paso, Texas, and invited them to participate in the study. Women between 18 and 49 years of age and able to complete the interview in English or Spanish were eligible to participate. Information on refusal to participate was not collected, but study staff reported that very few women declined to participate in the survey.

Interviewers asked women about basic sociodemographic information as well as about their current contraceptive use. Women who were not current hormonal contraceptive users were asked if they thought the pill would be an appropriate birth control choice given their medical history and regardless of their intent to use this method. We assumed that hormonal users would consider pill use safe for them and therefore did not ask them the question.

Next, all women were given a checklist of medical contraindications to combined oral contraceptive use and were asked to check whether they had one or more of these conditions. The checklist was based on the World Health Organization (WHO) Medical Eligibility Criteria for relative and absolute contraindications to combined oral contraceptives (category 3 and 4 contraindications)⁸ and was based on an instrument that had been previously validated.⁷ We did not include conditions that are considered category 2 contraindications, as the WHO states that in situations with limited clinical judgment it is reasonable to use the method when an individual has such a contraindication. The questions included in the checklist are listed in the box.

Immediately after completing the questionnaire, women were screened by a nurse practitioner, blinded to the woman's responses in the interview. One of five female nurse practitioners evaluated each woman who completed a questionnaire. The clinician's screening instrument included, in addition to background demographic information, a medical history that focused on WHO category 3 and 4 contraindications. The nurse practitioner also measured and recorded the respondent's blood pressure either manually or using an automated Omron HEM-705CP blood pressure monitor (Omron Healthcare, Inc., Bannockburn, Illinois). Blood pressure was measured twice, and the mean systolic and mean diastolic measurements were recorded. Based on this information, the nurse practitioner determined if the respondent was contraindicated to oral contraceptive use or not. If the provider felt that additional tests or evaluation were necessary before prescribing pills, the respondent was classified as contraindicated.

For their participation, women received a \$5-\$10 gift card valid for use at the shopping center or flea market. The study was approved by the Institutional Review Boards of the University of Texas at Austin and the University of Texas at El Paso. We obtained verbal informed consent from all participants.

Questionnaire data were entered into a Microsoft Access (Seattle, Washington) database and analyzed using Stata version 9.2 (College Station, Texas). Univariable descriptive statistics were generated to characterize the study participants and to describe the overall distribution of responses. We used the point-estimate and 95% confidence interval (CI) to measure the sensitivity, specificity, and positive and negative predictive values of the self-assessments (with and without the contraindication checklist). 95% confidence intervals for the sensitivity and specificity measurements were calculated according to the efficient-score method.⁹ The McNemar chi-square test was used to assess whether participants were equally likely to incorrectly self-report a contraindication as to incorrectly self-report eligibility for pill use. We used logistic regression to model the outcome variable of interest (participant—provider

agreement) and to estimate agreement among subgroups defined by age, language preference, education, parity and contraceptive use.

Based on data from the 1998 National Health Interview Survey, we estimated that approximately 15% of women of reproductive age in the general population are contraindicated for oral contraceptive use.¹⁰ For this study, we sought to estimate if 1% of the population or more might falsely believe that oral contraceptives are appropriate for them when in fact they are medically contraindicated. We determined that a sample size of 1,200 would give us 95% confidence interval of this measurement of +/- 0.6%.

RESULTS

A total of 1,271 women agreed to participate. Table 1 shows the demographic characteristics of the study participants according to their self-screening status using the checklist. The participants, on average, were in their early thirties, had completed 13 years of schooling and had between one and two children. The sample was overwhelmingly Latina, and the majority primarily spoke Spanish or were bilingual. Four out of five of the respondents lived in the US, and two-thirds completed their schooling in the US. In total, the nurse practitioners found that 39.3% (95% CI: 36.6%-42.0%) of respondents were medically contraindicated to oral contraceptive use. The prevalence of contraindications varied by age; among women age 18 to 34 (N=728) the contraindication prevalence was 31.3% (95% CI: 27.9%-34.7%), while it was 45.1% (95% CI: 39.9%-50.3%) among women age 35 to 44 (N=357) and 59.5% (95% CI: 52.3%-66.6%) among women 45 and older (N=185). No adverse events were observed during the study.

Table 2 shows the prevalence of each individual contraindication identified by the nurse practitioners. The most prevalent contraindications were migraine with aura (17.6%) and hypertension of 140/90 mmHg or greater (14.5%). Women's self-assessments of contraindications varied from 47.8% (95% CI: 45.1%-50.6%) for the initial self-screen (Table 3) to 39.5% (95% CI: 36.8%-42.2%) using the self-screening checklist (Table 4).

Regarding the accuracy of the initial screening question, 660 (52.2%) said the pill was medically safe for them, and 604 (47.8%) said it was unsafe or they were not sure. As shown in Table 3, this initial screening question demonstrated poor accuracy compared to the clinician screen. The overall sensitivity of the initial self-screen to detect a true contraindication was 56.0% (95% CI: 51.5%-60.4%), and the specificity was 57.6% (95% CI: 54.0%-61.1%). The positive predictive value of the initial self-screen was 46.2% (95% CI: 42.2%-50.3%), and the negative predictive value was 66.8% (95% CI: 63.1%-70.4%). The McNemar chi-square result indicates that respondents were significantly more likely to incorrectly assess themselves as contraindicated with the initial self-screen than to assess themselves eligible when they were not.

The accuracy of self-screening for contraindications using the medical checklist compared to the clinician screen is presented in Table 4. The sensitivity of the self-screening checklist to detect a true contraindication was 83.2% (95% CI: 79.5%-86.3%), and the specificity was 88.8% (95% CI: 86.3%-90.9%). The positive predictive value of self-screening using the checklist was 82.8% (95% CI: 79.2%-86.0%), and the negative predictive value was 89.0% (95% CI: 86.6%-91.1%). Eighty-six women (6.8%) using the checklist considered themselves contraindicated for pill use, when in fact the provider determined they were eligible. On the other hand, a similar number, 84 women (6.6%; 95% CI: 5.2%-8.0%), failed to identify a true medical contraindication using the checklist. According to the McNemar chi-square test, there was no significant difference between the proportion incorrectly self-reporting a contraindication using the checklist and the proportion incorrectly self-reporting eligibility for

pill use. Participants who did not understand a question on the medical checklist left it blank, and these responses were treated as missing values. Overall, self-screening or clinician-screening data were missing for three participants. Participants for whom data were missing were excluded from analyses requiring those responses.

Agreement between the respondent's self-screen and the clinician screen was 98% or higher for each of the individual contraindications except for two. In the case of hypertension, 9% of the respondents were found to be hypertensive (systolic blood pressure ≥ 140 mm Hg or diastolic blood pressure ≥ 90 mm Hg) and did not know this to be the case. With regard to migraine headaches, 6% of the respondents believed their condition made them ineligible to use the pill, but the nurse practitioner did not assess their migraine as one involving aura, which is the true contraindication.

We used logistic regression models to assess the association between selected demographic characteristics (including age, education, language spoken at home, recruitment site, parity and contraceptive use) and respondents' incorrect self-assessment of one or more contraindications to pill use. The coefficients in these models indicate that women age 35 and older had significantly higher odds of incorrectly self-reporting that they were eligible for pill use compared to younger women ($p < 0.05$). Participants reporting Spanish as their primary language had lower odds of incorrectly reporting that they were eligible for pill use compared to English-speaking women ($p < 0.05$). In addition, women who had completed at least some college education had lower odds of incorrectly reporting that they were contraindicated to oral contraceptive use compared to those with less education ($p < 0.05$). Neither parity nor contraceptive use were significantly associated with the odds of either incorrectly reporting contraindications or incorrectly reporting pill eligibility. (Regression models not shown but available upon request).

DISCUSSION

In the population studied here, we found that 39.3% of women were contraindicated to oral contraceptives, a prevalence that seems surprisingly high. Shortridge and Miller examined the prevalence of contraindications to combined oral contraceptives in the US general population using data from the National Health and Nutrition Examination Survey (NHANES) and found that 16% of fecund women aged 10 to 51 were contraindicated to oral contraceptives.¹¹ Only nine contraindicated diseases were recorded in the NHANES dataset, and several prevalent conditions such as migraine with aura were not identifiable. The study from Washington found that among women presenting to a family planning clinic, 4.6% were contraindicated to hormonal contraceptive use.⁷ While it is certainly surprising that the prevalence of contraindications is ten-fold larger in our sample, there are important differences between our study and the report from Washington. Eighty-eight percent of the women in the Washington study were seeking hormonal contraception, and 90% were between the ages of 15 to 30.⁷ Our population was older, which increases the likelihood of being contraindicated to oral contraceptives, and a smaller proportion was using hormonal contraception, suggesting they were less likely to have been previously screened for contraindications. The prevalence of contraindications reported here is closer to that reported using data from a national health survey in Mexico,⁶ although, like the report based on the NHANES data, that study was not able to include migraine with aura as a contraindication.

A simple question asking a woman if she thought the pill was medically safe for her served as a poor screening test for being contraindicated to oral contraceptive use. Using a medical checklist of contraindications, women were more accurate in their self-assessments. One way to evaluate screening tests, known as Youden's J, involves adding the positive predictive and negative predictive values and subtracting one.¹² This value for the initial self-screening

question is 0.13, indicating poor accuracy that scarcely improves upon a coin toss, while it is 0.72 for screening using the medical checklist, indicating much better—although not perfect—accuracy. However, it is important to remember that a screening test's positive and negative predictive values are dependent on the prevalence of the condition in the population screened.¹³ The population studied here had a high prevalence of contraindications, and it may be that self-screening using the medical checklist would have lower positive and negative predictive values in a population with a lower prevalence of contraindications.

The main conditions that contributed to being contraindicated to oral contraceptives were hypertension, migraine with aura, and smoking over age 34. It is important to note that only the first condition is possibly unknowable to the woman. In the case of migraine with aura, we found that women were more likely to self-screen themselves out of oral contraceptive use, when in fact the nurse practitioner assessed that the respondent's headaches did not contraindicate pill use, a finding that has been reported previously.⁷

Some women were found to be better at self-screening than others. Younger women were better than older women, largely because older women were more likely to have unrecognized hypertension. More educated women were also found to be more accurate self-screeners. Interestingly, a study of data from Mexico found that women who obtained oral contraceptives over the counter were more educated than those who obtained pills from a clinic.⁶ Our findings that Spanish speakers were more accurate at self-screening also merits further investigation.

How accurate does self-screening need to be to be considered “good enough”? It is unlikely that any screening assessment for contraindications will be 100% sensitive and specific, and even clinician screening appears to be flawed. The study based on data from the NHANES survey found that 6% of current pill users in the US were actually contraindicated for use¹¹ even though the prescription requirement mandates clinician screening. Another study using mystery clients in Mexico found that few women seeking pills were appropriately screened for contraindications using evidence-based criteria.¹⁴ Although our study reports on a different population, our finding that 6.6% of women incorrectly thought they were appropriate for pill use when in fact they were contraindicated is remarkably similar to the proportion of pill users incorrectly screened by clinicians in the NHANES study.¹¹

This study had several limitations. The convenience sample used here was not representative of the general population, and the results may not be generalizeable to other populations. In particular, it is likely that the population from which this sample was drawn is less likely to undergo routine health maintenance screening and therefore more likely to have unrecognized hypertension. In addition, although we aimed to evaluate the accuracy of self-screening in the general population, our results cannot be extrapolated to a population seeking hormonal contraception, which likely is younger and has a lower prevalence of contraindications. Furthermore, several factors likely led to the over-diagnosis of contraindications. The nurse practitioners used a study instrument that forced them to evaluate for the presence of every category 3 or 4 contraindication, and this evaluation was likely much more rigorous than the typical evaluation of a woman seeking contraception in a clinic. In addition, a diagnosis of hypertension cannot be based on a single measurement, and at least some cases of elevated blood pressure may have been “white coat” hypertension. Finally, most of the nurse practitioners had minimal experience prescribing hormonal contraception and generally erred on requesting further evaluation (which led to a participant being categorized as contraindicated) if they were not confident that oral contraceptive use was safe for a given condition.

Overall, these findings suggest that women can, by and large, accurately self-screen for contraindications to pill use using a checklist of contraindications. Moreover, women who are

likely to seek contraception—especially younger women—are able to identify conditions that might make oral contraceptive use dangerous. If anything, self-screening may eliminate more people as appropriate candidates than clinician screening. In an over-the-counter environment, however, women who wanted to use the pill and find that they are contraindicated by self-screening would likely seek the counsel of a clinician rather than deciding definitively that the method is dangerous for them. It is also possible that a truly contraindicated woman who is very motivated to use oral contraceptives might ignore the results of her self-screening and use the method regardless, much as a woman might conceal elements of her medical history, such as smoking, from a clinician in order to obtain a prescription for pills. An actual use study of oral contraceptives provided in a simulated over-the-counter setting is needed to answer these remaining questions.

BOX

Participant Self-Screening Checklist for Medical Contraindications

1. Are you a smoker age 35 or older?
2. Do you think you might be pregnant?
3. Have you had a baby in the past 3 weeks?
4. Are you currently breastfeeding *and* your baby is less than 6 months old?
5. Do you have high blood pressure?
6. Have you had a heart attack or stroke?
7. Do you have heart disease?
8. Have you had a blood clot (thrombosis) in your lung or in your leg (NOT just varicose veins)?
9. Do you have diabetes?
10. Do you have migraine headaches?
11. Do you have liver disease or have you had liver cancer?
12. Do you have gall bladder disease?
13. Have you had breast cancer?
14. Do you take medicine for high cholesterol?
15. Do you take medicine for seizures or tuberculosis (TB)?

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Table 1Demographic Characteristics of Study Participants According to Self-Screening Status[§]

	Full sample (N=1,271)	Correctly self- screened (N=1,098)	Incorrectly self-reported...	
			contraindica- tion (N=86)	eligible for pill use (N=84)
Age, years				
Mean	32.6	32.4	31.6	35.3
Median	32.0	32.0	31.0	37.0
Race/Ethnicity				
Latina	92%	92%	88%	92%
African American	2%	2%	6%	2%
White	4%	4%	4%	6%
Other	2%	2%	2%	0%
Primary language used at home				
Spanish	52%	53%	45%	44%
English and Spanish, equally	12%	12%	15%	7%
English	36%	35%	40%	49%
Primary country of residence				
United States	81%	80%	83%	93%
US and Mexico, equally	1%	1%	1%	0%
Mexico	18%	19%	15%	7%
Other	1%	1%	1%	0%
Education, years				
Mean	13.2	13.2	12.9	13.5
Median	13.0	13.0	12.5	14.0
Parity				
Mean	1.5	1.5	1.4	1.5
Median	2.0	2.0	2.0	2.0
Current contraceptive use				
Sterilization	28%	28%	23%	32%
Oral contraceptive pills	15%	14%	21%	19%
Condoms	9%	9%	11%	10%
Injectors	3%	4%	1%	4%
IUD	3%	3%	1%	5%
Patch	1%	1%	4%	1%
Other barrier method	0%	0%	0%	1%
Spermicides (i.e. foam, film)	0%	0%	0%	0%
Vaginal ring	0%	0%	0%	0%
None: Not sexually active	18%	18%	15%	17%
None: Trying to get pregnant	8%	8%	5%	2%
None: Other reason	14%	14%	20%	10%

[§] Data regarding the accuracy of self-screening were missing for 3 participants

Table 2
Clinicians' Assessment of Medical Contraindications (N=1,271)

Respondents' Contraindication	N	%
Smoker age 35 or older	55	4.3
Pregnant	47	3.7
Postpartum 3 weeks or less	1	0.1
Currently breastfeeding and infant less than 6 months old	12	0.9
Hypertension of 140/90 mmHg or greater	184	14.5
Hypertension of 160/100 mmHg or greater	86	6.8
History of stroke	6	0.5
History of heart disease including myocardial infarction	16	1.3
History of deep venous thrombosis or pulmonary embolism	15	1.2
Diabetes with vascular complications or for more than 20 years	10	0.8
Migraine with aura	224	17.6
Liver disease or liver cancer	5	0.4
Current gall bladder disease	11	0.9
History of breast cancer	4	0.3
Elevated cholesterol requiring medication	28	2.2
Currently taking contraindicated anticonvulsant or antibiotic	11	0.9
History of serious complication with hormonal contraceptive	30	2.4
Other medical condition considered to be possible contraindication	10	0.8
At least one contraindication	499	39.5

Table 3

Accuracy of Initial Self-Screening Compared to Provider Screening for Contraindications to Use of Oral Contraceptives

<i>Initial self-screen</i> ¹ N, % and (95% C.I.)		Provider		
		Contraindicated	Eligible for pill use	Total
Respondent	Contraindicated	279 22.1% (19.8-24.4%)	325 25.7% (23.3-28.1%)	604 47.8% (45.1-50.6%)
	Eligible for pill use	219 17.2% (15.1-19.3%)	441 34.9% (32.3-37.6%)	660 52.2% (49.4-54.9%)
	Total	498 39.4% (36.7-42.2%)	766 60.6% (57.9-63.3%)	N=1,264 100.0%
Sensitivity = 56.0%; 95% CI: (51.5-60.4%) Specificity = 57.6%; 95% CI: (54.0-61.1%) Positive predictive value = 46.2%, 95% CI: (42.2-50.3%) Negative predictive value = 66.8%, 95% CI: (63.1-70.4%) McNemar chi-square test=20.8, P=0.0				

¹ Initial self-screen refers to women's answer to the question whether the pill would be bad for their health. Hormonal contraceptive users were, by default, classified as deciding that they were eligible for pill use.

Table 4

Accuracy of Self-Screening Using Checklist Compared to Provider Screening for Contraindications to Use of Oral Contraceptives

<i>Self-screening checklist</i> ² N, % and (95% C.I.)		Provider		Total
		Contraindicated	Eligible for pill use	
Respondent	Contraindicated	415 32.7% (30.1-35.3%)	86 6.8% (5.4-8.2%)	501 39.5% (36.8-42.2%)
	Eligible for pill use	84 6.6% (5.2-8.0%)	683 53.9% (51.2-56.6%)	767 60.5% (57.8-63.2%)
	Total	499 39.3% (36.6-42.0%)	769 60.7% (58.0-63.4%)	N=1,268 100.0%
Sensitivity = 83.2%; 95% CI: (79.5-86.3%) Specificity = 88.8%; 95% CI: (86.3-90.9%) Positive predictive value = 82.8%, 95% CI: (79.2-86.0%) Negative predictive value = 89.0%, 95% CI: (86.6-91.1%) McNemar chi-square test=0.24, P=0.878				

² Self-screening checklist refers to women's yes/no answers to the medical checklist of possible contraindications to pill use. Women were classified as self-contraindicated if they checked "yes" to any of the itemson the list.