Knowledge on adherence and safety of the oral contraceptive pill in Saudi women

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ABSTRACT

الأهداف: تقييم معرفة النساء السعوديات حول الالتزام بحبوب منع الحمل، وإتباع قواعد السلامة في أخذها بالاعتماد على معلوماتهن الأساسية.

الطريقة: أُجريت هذه الدراسة الاستطلاعية المقطعية في قسم صيدلية العيادات الخارجية، مستشفى الملك خالد الجامعي، الرياض، المملكة العربية السعودية وذلك خلال الفترة من أبريل إلى سبتمبر 2011م. لقد كانت المشاركات في الدراسة من النساء الأصحاء اللاتي تبلغ أعمارهن أو تتجاوز 18 عاماً، واللاتي وُصفت لهن حبوب منع الحمل المركبة في المستشفى. لقد قمنا باستعمال استبيان موثق، وقمنا أيضاً بمقابلة النساء وطرح الأسئلة عليهن من أجل تقييم مدى معرفتهن بقواعد الالتزام والسلامة أثناء تناول حبوب منع الحمل وذلك يشمل نسيان حبة، حدوث قيء أو إسهال.

النتائج: شملت الدراسة 460 مشاركة. ولقد عرف معظمهن (79%) بأن عليهن أخذ حبة إضافية في حال نسيان الحبة لأقل من 12 ساعة، ولكن عرف فقط 6.5% بأن عليهن استعمال وسيلة منع حمل إضافية لسبعة أيام في حال نسيانها لأكثر من 12 ساعة. ولقد أشار التحليل الانحداري اللوجستي بأن عدد سنوات استعمال حبوب منع الحمل، والمستوى التعليمي كانت من العوامل المؤدية لمعرفة أفضل لاستعمال حبوب منع الحمل. وكان قليل من النساء على علم بالتصرف الصحيح في حال حدوث إسهال لأكثر من 12 ساعة (10%)، أو قيء يستمر لساعتين (13.5%). وكان 30% فقط من النساء على علم بالآثار الجانبية للتدخين أثناء استعمال حبوب منع الحمل. ولقد كانت زيادة الوزن الأكثر شيوعاً من ضمن الآثار الجانبية الملاحظة من قبل المستخدمات (51%).

خاتمة: أظهرت هذه الدراسة بأن أغلبية النساء السعوديات اللاتي يستعملن حبوب منع الحمل لديهم معرفة محدودة لطريقة الاستعمال الصحيحة في حال نسيان الحبة، والقيء، والإسهال وتأثير التدخين أثناء استعمال حبوب منع الحمل.

Objectives: To assess knowledge regarding adherence and safety of oral contraceptive pills (OCP) in Saudi women.

Methods: We conducted a cross-sectional prospective study in an outpatient pharmacy at King Khalid University Hospital, Riyadh, Kingdom of Saudi Arabia from April to September 2011. Participants were healthy women aged ≥18 years with an OCP prescription for contraception. We used a validated questionnaire to assess their knowledge regarding adherence and safety of OCPs.

Results: Four hundred and sixty women participated. Most (79%) knew to take an extra pill if they missed one in less than 12 hours, but only 6.5% knew they also had to use extra protection for the next 7 days if it was more than 12 hours. Multiple logistic regression analyses indicated that years of contraceptive use and educational level are predictive factors of better knowledge regarding adherence. Few were aware of the action if they experienced diarrhea for more than 12 hours (10%) or vomiting within 2 hours (13.5%) of taking an OCP. Only 30% knew of the adverse effects of smoking while on OCPs. Weight gain (51%) was the most commonly reported side effect.

Conclusion: Most Saudi women taking OCPs have limited knowledge of its correct use regarding missing pills, vomiting and diarrhea, and poor awareness of the effects of smoking while using OCPs.

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The oral contraceptive pill (OCP) provides very effective reversible contraception, and has an excellent overall safety and tolerability profile.[1] It is the most widely used contraceptive method.[2,3] In the United States one million unintended pregnancies are associated annually with OCP misuse or discontinuation.[4] Worldwide, 338 million unintended pregnancies have resulted in nearly 700,000 maternal deaths between 1995 and 2000.[5] Unintended pregnancies can have serious negative consequences on infant health and can burden the individual and family, both psychologically and financially.[6,7] Knowledge of OCPs is inter-connected with contraceptive behaviour.[8] A study conducted in Denmark[9] on 120 women taking oral contraceptives assessed their knowledge of side effects and their compliance with taking OCPs using a structured interview. The results showed that there was a significant negative correlation between social status and the scoring of information and a significant positive correlation between age and information scoring. It is evident that poor knowledge of oral contraceptive therapy can lead to poor compliance, premature discontinuation of OCP, and unintended pregnancy. The objectives of our study were to assess knowledge of safety and adherence with OCPs in Saudi women, to determine the demographic factors associated with knowledge and to find out the most commonly reported side effects of OCPs. Limited data are available regarding knowledge on compliance with OCPs in the Saudi population. Hence, identifying the knowledge deficit is important, as there is a need for better education and patient counseling to improve OCP compliance and reduce unintended pregnancy.

Methods. We conducted a cross-sectional prospective study for 6 months April to September 2011 in the hospital outpatient pharmacy, following approval by the Institutional Review Board (IRB). King Khalid University Hospital is a tertiary care hospital in Riyadh, Saudi Arabia with a capacity of 1,000 inpatient beds and the pharmacy processes an average 3,000 prescriptions daily. The 18-item questionnaire used in this study was derived from information in the package insert of YASMIN® (3 mg of drospirenone/0.03 mg of ethinyl estradiol, Bayer, Berlin, Germany), and other combined OCPs (COCP). Questions were closed-ended and covered patient demographic data including age, educational level, occupation, number of children, patient history regarding oral contraceptives, and knowledge of their correct use. In addition, common side effects experienced with oral contraceptive use were assessed (**Appendix 1**). The questionnaire was validated in a crossover pilot study conducted in 20 females who were currently using a COCP. The women self-completed the questionnaire on 2 separate occasions, 2 weeks apart. A two-week interval period was chosen to avoid duplication of their first responses. For internal consistency of the knowledge on all questions of the pilot study, Cronbach's alpha, a coefficient of reliability, was calculated. The mean for Cronbach's alpha was 0.786 (range 0.757 - 0.803) with good reliability.

All healthy women aged 18 years and above presenting to the outpatient pharmacy with a COCP prescription for family planning (contraception) were invited to participate in the study, and a verbal consent was obtained. Individuals who were prescribed oral contraceptives for indications other than contraception (for example, dysmenorrhea, irregular cycle, acne, and so forth) or who had taken OCPs for less than, or equal to 6 months were excluded. Two pharmacists obtained verbal consent prior to interviewing the women and explained the study objectives, administered the questions and recorded the answers. The same 2 pharmacists were involved throughout the study in order to achieve uniformity. All patients were interviewed privately in a designated counseling area.

Descriptive statistics with counts and percentages were used to illustrate the results of the survey. To evaluate the multivariate association of knowledge on compliance with demographic characteristics, multiple logistic regression analysis was used, and odds ratios (OR) and 95% confidence intervals (95% CI) were calculated. Chi-square tests were used to detect whether there was any association between demographic characteristics and side effects. The Spearman rank correlation coefficient was used to detect any relationships among demographic background, for instance education level, number of years of oral contraceptive use, and number of children. Statistical analyses were conducted using the Statistical Package for Social Science software (SPSS Inc., Chicago, IL, USA), version 18.0.

Results. The survey population consisted of 460 women taking COCPs who were interviewed over a 6-month period between April and September 2011. The demographic characteristics of the population

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*The full text including Appendix is available in PDF format on Saudi Medical Journal website (www.smj.org.sa)

Table 1 - Demographic characteristics of women on the oral contraceptive pill (n=460).

Characteristics	n	(%)
Age (years)		
<20	6	(1.3)
20-29	178	(38.7)
30-39	190	(41.3)
≥40	86	(18.7)
Educational Level		
Middle school	58	(12.6)
High school	120	(26.1)
Diploma	50	(10.9)
Bachelor degree	214	(46.5)
Post graduate studies	16	(3.5)
Occupation		
Student	16	(3.5)
Housewife	291	(63.3)
Employed; healthcare professional	36	(7.8)
Employed; others	116	(25.2)
Number of children		
0	39	(8.5)
1 or 2	200	(43.5)
3 or 4	135	(29.3)
>4	86	(18.7)
Years of contraceptive taken		
<1 year	181	(39.3)
1 year	49	(10.7)
2 years	62	(13.5)
3 years	41	(8.9)
≥4 years	127	(27.6)

are shown in **Table 1**. The Spearman rank correlation coefficient showed a weak inverse relationship between education level and number of children (r=-0.293, p=0.0001), indicating that participants with a higher level of education had fewer children. There was a positive correlation between years of OCP use and the number of children (r=0.382, p<0.0001), with participants who had more children taking the OCP for a longer duration.

Knowledge of the correct use of the OCP was assessed by the responses to 6 questions (**Table 2**). Most participants (79.3%) understood that they needed to take an extra pill if they forgot to take one in less than 12 hours. However, only a few (6.5%) were aware that they needed to take an extra pill and use extra protection for the next 7 days if they missed taking their OCP for more than 12 hours. Most of the participants were unaware of the correct action to take if they had experienced diarrhea for more than 12 hours, or vomited within 2 hours of taking an OCP. Only 9.8% of the participants knew to take an extra pill in the case of vomiting, whereas 13.5% knew to take an extra pill and use extra protection for the next 7 days if diarrhea persisted.

Multiple logistic regression analyses of the demographic characteristics and knowledge on compliance with OCP use are summarized in **Table 3**. The results showed that a longer duration of contraceptive use, and higher education level are associated with a better knowledge of compliance pertaining to missing pills, and action to take if experiencing diarrhea or

Table 2 - Responses to compliance questions among oral contraceptive pill users.

Questions/responses	n	(%)
If you forgot to take your pill less than 12 hours ago, what do you do? N=460		
Did not know the correct action to take	95	(20.7)
Knew the correct action to take	365	(79.3)
If you forgot to take your pill more than 12 hours ago, what do you do? N=460		
Did not know the correct action to take	430	(93.5)
Knew the correct action to take	30	(6.5)
If you vomit within 2 hours of taking the tablet, what do you do? N=456		
Did not know the correct action to take	394	(86.4)
Knew the correct action to take	62	(13.5)
If you have diarrhoea for more than 12 hours after the pill was taken, what should you do? N=455		
Did not know the correct action to take	410	(90.1)
Knew the correct action to take	45	(9.8)
Do you think smoking affects contraceptive use? N=457		
Did not know that smoking affects oral contraceptive pill use	320	(69.6)
Knew that smoking affects oral contraceptive pill use	137	(29.8)
Have you read the package insert? N=458		
Yes	415	(90.2)
No	43	(9.3)

Table 3 - Multiple regression analyses of factors associated with correct knowledge or positive response on compliance among oral contraceptive pill users.

Factors	OR (95% CI)	*P*-value
Forgetting to take pill if less than 12 hour gap		
Age	0.7 (0.5-1.0)	0.055
Education level	1.1 (0.9-1.4)	0.071
Occupation	0.9 (0.7-1.1)	0.555
Number of children	1.2 (0.9-1.6)	0.257
Years of contraceptive use	1.2 (1.0-1.3)	0.013
Forgetting to take pill if more than 12 hour gap		
Age	1.1 (0.6-2.2)	0.964
Education level	2.1 (1.3-3.4)	0.002
Occupation	0.9 (0.7-1.5)	0.947
Number of children	0.7 (0.4-1.2)	0.172
Years of contraceptive use	0.9 (0.7-1.2)	0.631
Vomiting within 2 hours of taking		
Age	0.9 (0.5-1.4)	0.575
Education level	1.4 (1.0-1.8)	0.016
Occupation	0.9 (0.6-1.2)	0.854
Number of children	1.4 (0.9-2.2)	0.106
Years of contraceptive use	0.9 (0.8-1.1)	0.405
Diarrhoea for more than 12 hours after taking		
Age	0.8 (0.5-1.4)	0.511
Education level	1.4 (1.0-1.9)	0.041
Occupation	1.1 (0.8-1.6)	0.590
Number of children	1.6 (0.9-2.6)	0.052
Years of contraceptive use	0.8 (0.6-0.9)	0.022
Smoking affects contraceptive use		
Age	0.8 (0.6-1.2)	0.321
Education level	0.9 (0.8-1.2)	0.780
Occupation	0.9 (0.7-1.1)	0.238
Number of children	1.1 (0.8-1.5)	0.536
Years of contraceptive use	1.0 (0.9-1.2)	0.583
Read the package insert		
Age	1.3 (0.7-2.2)	0.389
Education level	0.8 (0.6-1.1)	0.143
Occupation	1.1 (0.7-1.6)	0.680
Number of children	1.2 (0.8-1.9)	0.360
Years of contraceptive use	0.8 (0.6-0.9)	0.013

OR - odds ratio, CI - confidence interval

vomiting.

Most oral contraceptive users in this study (90.2%) stated that they had read the package insert, and reading the package insert was strongly associated with years of contraceptive use. However, knowledge of the effect of smoking on OCP use was low with only 30% of participants aware of the adverse effect of smoking on contraceptive use. No association was found between knowledge of the effect of smoking on OCP use and any of the demographic characteristics.

Table 4 - Chi-square test of association between specific side effects and demographic characteristics.

Side effect/demographic characteristic	Side effect Yes	Side effect No	*P*-value*
	n (%)		
Weight gain			
Contraceptive use of <1 year	72 (43.0)	94 (57.0)	
Contraceptive use of >1 year	155 (57.0)	123 (43.0)	0.012
Weight gain			
<30 years	78 (44.0)	101 (56.0)	
>30 years	149 (56.0)	116 (44.0)	0.009
Abnormal vaginal bleeding			
<High school	14 (8.0)	157 (92.0)	
High school and higher education	43 (16.0)	228 (84.0)	0.019

*only significant results are reported

The most commonly reported side effects experienced with OCP use were weight gain or increased appetite (51% of the participants), nausea (27%), tender or sore breast (21%), facial acne pimples (13%), abnormal vaginal bleeding (12%), and diarrhea (3%). The results of the chi-square tests used to evaluate whether there was any association between demographic background and side effects are shown in **Table 4**. There was a significant association between reporting weight gain and duration of OCP use, with oral contraceptive users of more than a year more likely to complain of weight gain than those who had used it for less than one year. Associations between reporting weight gain and age above 30 years, and abnormal vaginal bleeding with high school and above education level were also evident.

Discussion. In this study, we investigate the knowledge of Saudi women regarding OCPs based on their demographic background. It showed that participants with a higher education level had fewer children. Women's access to education, health care, family planning, and employment are important factors influencing family size. Educated women are more likely to be aware of the social, community, and health services, including family planning services that are available and presumably, have more confidence in using them than less educated women. In addition, women with higher education have more opportunities outside the home, which reflects the tendency of these women to delay starting a family to pursue their career. Women who attain an advanced level of education are expected to enter the workforce before they marry or begin childbearing. They also tend to have high aspirations for their children and hence limit family size accordingly. This trend is evident in Middle Eastern countries.[10]

The finding that participants who had more children continued OCP for a longer duration may indicate that they had either completed their family or wanted to space out their children. There may also be some financial constraint influencing them to stay on the OCP for longer to avoid having more children.

The poor knowledge displayed by our survey population regarding missing pills, vomiting, and diarrhea are a major concern. Lack of knowledge and awareness are potential causes of unintended pregnancy.[11] Each year more than 10 million women in the United States take the OCP to prevent pregnancy; 300,000 of those women become pregnant each year during a month in which they have been taking the pill.[12]

Interestingly, in our study, 90% of the participants stated that they had read the package insert so it appears that this information source is well accepted. However, despite reading the package insert, their knowledge on the correct use of OCP was still lacking. For most women, the OCP package insert, which explains their risks and benefits, side effects, and what to do when they have missed taking pills, is their sole source of information. Yet, these specific points of information in the inserts can be difficult to find and once found, hard to comprehend. The information varies between manufacturers, with the text of most package inserts written at a tenth to twelfth grade reading level, well above the sixth grade reading level usually recommended for health education materials by the Federal Drug Association.[13,14]

In light of this, there is a vital need to develop a unified, simpler, more understandable, and accurate patient package insert for inclusion in all packs of oral contraceptives. The simplified language will increase the consistency and clarity of information across oral contraceptive brands. In addition, providing patients with a simple booklet and reading material on proper use of OCP can enhance their knowledge of OCP use.[15] Besides written information, reinforcement of the key messages by verbal counseling from physicians, pharmacists, or nurses on OCP use is an excellent tactic to improve patient knowledge.[16,17]

Higher education and years of contraception use was associated with a better knowledge of compliance in our study. However, in the literature, patients of all educational levels have been shown to have limited knowledge regarding important issues in OCP use, such as their side effects, and what to do if they missed multiple pills.[18]

Smoking more than 15 cigarettes per day at age 35 or above while on the pill will increase the risk of stroke, and is considered an absolute contraindication.[19] Surprisingly, most participants in the study were unaware of the effect of smoking on the pill or its related complications. This issue is particularly relevant due to the increasing incidence of smoking in Saudi females.[20] It is important that patients are kept fully informed, and they should be advised that cigarette smoking increases the risk of serious side effects from oral contraceptives, including heart attacks, blood clots, and strokes. They should also be made aware that the risk is higher for women over 35 years of age and heavy smokers.

Several studies have showed that at least half of OCP users discontinue the pill within the first year because of fears, side effects, and lack of knowledge.[21,22] Twenty percent of the annual unintended pregnancies in the United States are linked to discontinuation of OCPs mainly because of its unpleasant side effects.[4] In our study, 51% reported weight gain as a side effect, although clinical trials have failed to establish any relationship between OCP use and weight gain.[23,24] The second most commonly reported side effect was nausea (21%), which is similar to other reports in the literature,[11] and usually improves with time.[25]

The main limitations of the study are that it was restricted to one center and that the survey population had a higher proportion of well-educated participants than expected. Hence, although our hospital treats all of the Saudi population around the Riyadh region, the survey population may not be fully representative of Saudi women using the OCP. The skewed distribution may be because educated women are more aware of the importance of family planning, and are more willing to use hormonal contraception. Another important limitation is that the number of missed pills per cycle was not assessed. The addition of questions covering self-reported compliance "frequency of missed pill per cycle over the last 6 months" is also recommended. Further purposeful sampling of those who completed education at an earlier stage is recommended in future evaluation studies.

In conclusion, the study demonstrated that most Saudi women taking the OCP have limited knowledge of its correct use regarding missing pills, vomiting, diarrhea and poor awareness of the effects of smoking with OCP use. Proper education and counseling on correct OCP use are needed to improve their knowledge to safeguard their health and limit unintended pregnancies. This can be accomplished by providing them with individual counseling, simplified package inserts, booklets, pamphlets, and educational videos in the waiting area.

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Appendix 1 - Patients knowledge and compliance to oral contraceptives questionnaire

1. Patient age (العمر)

1 □ <20
2 □ 20-29
3 □ 30-39
4 □ ≥40

2. Educational Level (المستوى التعليمي)

1 □ Middle school (متوسط)
2 □ High school (ثانوية)
3 □ Diploma (دبلوم)
4 □ Bachelor (بكالوريوس)
5 □ Post graduate (Master, PhD,…etc) (دراسات عليا)

3. Occupation (الوظيفة)

1 □ Student (طالبة)
2 □ Housewife(ربة منزل)
3 □ Employed; Healthcare professional (موظفة في المجال الطبي)
4 □ Employed; others (أخرى)

4. Number of children (عدد الأطفال)

1 □ 0
2 □1-2
3 □ 3-4
4 □ >4

5. Years of contraceptive taken (مدة استعمال مانع الحمل)

1 □ < 1 year
2 □ 1year
3 □ 2 years
4 □ 3 years
5 □ ≥ 4 years

6. If you forgot to take your pill for less than 12 hrs ago, what do you do?(اذا نسيتي تناول الحبة لأقل من ١٢ ساعة)

1 □ Skip the missed pill and take that days pill as scheduled (الغي الحبة المنسية و اخذ الحبة المقررة لذلك اليوم)
2 □ Take it as soon as you remember, even if that meant taking 2 pills in the same day.
(أخذ الحبة المنسية عندما اتذكرها حتى لو أخذت حبتان في نفس اليوم)
3 □ Use extra protection (eg. condoms) for the next 7 days. (أستعمل موانع أخرى لمدة أسبوع)

7. If you forgot to take your pill for more than 12 hrs ago, what do you do (اذا نسيتي تناول الحبة لأكثر من ١٢ ساعة)

1 □ Skip the missed pill and take that days pill as scheduled (الغي الحبة المنسية و اخذ الحبة المقررة لذلك اليوم)
2 □ Take it as soon as you remember, even if that meant taking 2 pills in the same day.
(أخذ الحبة المنسية عندما اتذكرها حتى لو أخذت حبتان في نفس اليوم)
3 □ Take it as soon as you remember, even if that meant taking 2 pills in the same day PLUS use extra protection (eg. condoms) for the next 7 days. (أخذ الحبة المنسية عندما اتذكرها حتى لو أخذت حبتان في نفس اليوم و أستعمل موانع أخرى لمدة أسبوع)

8. If you vomit within 2 hrs of taking the tablet, what do you do? (اذا استفرغتي خلال ٢ ساعات من أخذ الحبة ماذا تفعلين)

1 □ Nothing (لاشي)
2 □ Take an extra pill (أخذ حبة إضافية)

9. If you have diarrhea for more than 12 hrs after the pill was taken, what should you do?
(اذا حصل لك اسهال لأكثر من ١٢ ساعة بعد أخذ الحبة ماذا تفعلين)

1 □ Nothing (لاشي)
2 □ Take another tablet once diarrhea is resolved (أخذ حبة اضافية عندما يتوقف الاسهال)
3 □ Take another tablet once diarrhea is resolved PLUS Use other method of protection (ex. condoms) for the next 7 days
(أخذ حبة إضافية عندما يتوقف الأسهال و استعمل موانع أخرى لمدة أسبوع)

10. Have you read the package insert? (هل قرأتي النشرة المرفقة)

1□ Yes
2□ No

Have you noticed any of the followings while using contraceptive pills (هل لاحظتي أي من العوارض التالية أثناء استعمال المانع)

11. Wight gain or increase appetite	□Yes	□No	(زيادة الوزن أو الشهية)
12. Facial acne pimples and body hair	□Yes	□No	(حبوب الشباب أو زيادة شعر الجسم)
13. Diarrhea	□Yes	□No	(اسهال)
14. Nausea	□Yes	□No	(غثيان)
15. Tender or sore breast	□Yes	□No	تغييرات في الثدي (ألم أو شد)
16. Abnormal vaginal bleeding	□Yes	□No	(نزيف مهبلي غير طبيعي)
17. Others ( )	□Yes	□No	(أخرى)

18. Do you think smoking affect the contraceptive use (هل تتوقعين أن التدخين يتعارض مع استعمال المانع)

1 □Yes
2 □No
3 □ I don't know