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RESEARCH ARTICLE

ASSESSMENT OF WOMEN 'KNOWLEDGE REGARDING COMPLIANCE AND SAFETY OF ORAL CONTRACEPTIVE PILLS.

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Key words:-

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Abstract

Background:- Most of Saudi women are using OCPs as a method of contraception. Failure rates of less than one percent have been reported among women who use OCPs effectively, with rates as high as nine percent in those who do not use pills consistently or correctly.

Objectives:- to study the compliance with as well as knowledge regarding OCP among women attending King Faisal armed forces hospital at Khamis Mushait and Family and community department clinics at Ahad Rufaidah.

Subjects and methods:- Cross-sectional study design was carried out among married Saudi women, aged over 18 years attending King Faisal armed forces hospital at Khamis Mushait and Family and community department clinics at Ahad Rufaidah, Southern Region, Saudi Arabia during November, 2016 and using OCPs for a period of more than 6 months. Simple random technique was applied to select all eligible women to complete a questionnaire to assess their Knowledge on adherence and safety of the oral contraceptive pill. A self-administered Arabic-questionnaire will be used for collection of data.

Results:- Three hundreds women participated in the study. The age of 45.3% of them ranged between 30 and 39 years. Slightly less than half of them (47.3%) had Bachelor degree or above whereas 6.7% were less than intermediate school educated. About two-thirds of the participants (65%) understood that they needed to take an extra pill if they forgot to take one in less than 12 hours. However, only 14% 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. Majority of the participants were unaware of the correct action to take if they had experienced diarrhea for more than 12 hours (93.7%), or vomited within 2 hours of taking an OCP (88.7%). Less than one-fifth of the participants could recognize that smoking affects contraceptive use. However, majority of them (81.7%) have read the package insert inside OCPs packages. Overall, sufficient knowledge was reported among 22.7% of women. The commonest reported OCPs side effects were weight gain (56%), nausea (36.3%), tender breast (35.7%), and facial acne pimples and body hair (26.7%). Abnormal vaginal bleeding was significantly associated with years of OCPs use

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as it was more reported among those used OCPs for less than one year compared with longer duration, $p=0.031$.

Conclusion:- Majority of Saudi women using OCPs have insufficient knowledge of its correct use regarding missing pills, diarrhea and vomiting, and poor awareness of the impacts of smoking while using OCPs. Proper counseling and counseling on correct use of OCPs are recommended to raise their knowledge to limit unintended pregnancies and consequently improve their health.

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Introduction:-

Oral contraceptive pills (OCPs) are the most widely used method of contraception worldwide because of their accessibility and reversibility.¹ Unfortunately, their efficacy is limited by problems related to compliance with prescribed regimens, which is in turn related to knowledge about correct usage and the occurrence of adverse events.²

Most oral contraceptives (the pill) contain a combination of female hormones, estrogen and progestin. This combination reduces the risk of pregnancy by preventing ovulation, keeping the mucus in the cervix thick and impenetrable to sperm and keeping the lining of the uterus thin.³

Failure rates of less than one percent have been reported among women who use OCPs effectively, with rates as high as nine percent in those who do not use pills consistently or correctly.^{4,5}

Most of Saudi women are using OCPs as a method of contraception.⁶ In the United States, eleven million women in the age group 15-44 years used contraceptive pills.⁷ However, one million unintended pregnancies are associated annually with misuse or discontinuation of OCP.⁸ International studies suggest that up to 47% of women do not fully compliant with OCP with 22% missing two or more OCPs per cycle.⁹

Unintended pregnancy is an important public health issue in both developed and developing countries because of its negative association with social and health outcomes for both mothers and children.¹⁰

Missing or forgetting to take the OCP is reported as one of the main reasons for seeking emergency contraception.¹¹ In women that rely on OCP for contraception. Poor compliance with OCP may therefore be a primary cause of unintended pregnancy in those that rely on this method of contraception, which is an important concern for public health.¹²

Possible side effects of the OCPs are nausea, breast tenderness, bloating, and mood changes, which typically improve within two to three months without treatment.¹³ Additionally, breakthrough bleeding or spotting is particularly common during the first few months of taking oral contraceptives. This almost always resolves without any treatment within two to three months. Forgetting a pill can also cause breakthrough bleeding.¹⁴

This study aimed to study the compliance with as well as knowledge regarding OCP among women attending King Faisal armed forces hospital at Khamis Mushait and Family and community department clinics at Ahad Rufaidah.

Subjects and methods:-

Cross-sectional study design was carried out among married Saudi women, aged over 18 years attending King Faisal armed forces hospital at Khamis Mushait and Family and community department clinics at Ahad Rufaidah, Southern Region, Saudi Arabia during November, 2016 and using OCPs for a period of more than 6 months.

The sample size was calculated according to Bartlett et al. (2001)¹⁵ Thus minimal sample size was 278 women. At selected clinics in King Faisal armed forces hospital at Khamis Mushait and Family and community department clinics at Ahad Rufaidah. Simple random technique was applied to select all eligible women to complete a questionnaire to assess their Knowledge on adherence and safety of the oral contraceptive pill. Women who used

oral contraceptive for indication other than contraception (dysmenorrhea, irregular cycles, acne) and those who had taken OCPs for less than or equal to 6 months were excluded.

A self-administered Arabic-questionnaire was used for collection of data. It has been previously used in another Saudi study.¹⁶ It has 18 items. They 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.

Approval from the Research and Ethics Committee at King Khalid University in Abha was obtained. The researcher took permission also from the participant women after explaining the purpose of the study to all of them. A verbal consent was obtained from each participant prior to study conduction.

Data were entered to a personal computer and will be analyzed by using Statistical Package for the Social sciences (SPSS) program version 23. Regarding knowledge questions, a score of "1" was assigned to correct answer whereas a score of "0" was assigned to wrong answers. Total knowledge score and percentages were computed. Those scored 50% and over were considered as having "sufficient knowledge" whereas those scored below 50% were considered as having "insufficient knowledge". Chi-square test was used for the association between categorical variables. A p-value of less than 0.05 was adopted for statistical significance.

Results:-

Three hundred women participated in the study. Table 1 presents their demographic characteristics. The age of 45.3% of them ranged between 30 and 39 years. Slightly less than half of them (47.3%) had Bachelor degree or above whereas 6.7% were less than intermediate school educated. Almost two thirds of them (63.4%) were housewives. Number of children exceeded 4 among 26.7% of them and 22.3% reported taking of OCPs for at least four years.

Table 1:- Demographic characteristics of the participants (n=300).

		Frequency	Percentage
Age (years)	< 30	101	33.7
	30-39	136	45.3
	≥ 40	63	21.0
Educational level	<Intermediate school	20	6.7
	Intermediate school	34	11.3
	High school	80	26.7
	Diploma	24	8.0
	Bachelor and above	142	47.3
Occupation	Student	16	5.3
	Housewife	190	63.4
	Employed; Health care professional	7	2.3
	Employed; others	87	29.0
Number of children	None	7	2.3
	1-2	116	38.7
	3-4	97	32.3
	> 4	80	26.7
Years of contraceptive taken	< 1 year	35	11.7
	1 year	77	25.7
	2 years	47	15.7
	3 years	74	24.7
	≥4 years	67	22.3

Table 2 summarizes the knowledge of the correct utilization of the OCPs was evaluated by the responses to 6 questions. About two-thirds of the participants (65%) understood that they needed to take an extra pill if they forgot to take one in less than 12 hours. However, only 14% were aware that they needed to take an extra pill and use extra protection for

Table 2:- Responses of the participants to knowledge questions about the proper oral contraceptives use.

Questions	Correct responses	No. (%)
If you forgot to take your pill less than 12 hours ago, what do you do?	Take it as soon as you remember, even if that meant taking 2 pills in the same day.	195 (65.0)
If you forgot to take your pill more than 12 hours ago, what do you do?	Take it as soon as you as you remember, even if that meant taking 2 pills in the same day plus use extra protection for the next 7 days.	42 (14.0)
If you vomit within 2 hours of taking the tablet, what do you do?	Take an extra pill.	34 (11.3)
If you have diarrhoea for more than 12 hours after the pill was taken, what should you do?	Take another tablet once diarrhea is resolved plus Use other method of protection for the next 7 days.	19 (6.3)
Do you think smoking affects contraceptive use?	Yes	55 (18.3)
Have you read the package insert?	Yes	245 (81.7)

The next 7 days if they missed taking their OCP for more than 12 hours. Majority of the participants were unaware of the correct action to take if they had experienced diarrhea for more than 12 hours (93.7%), or vomited within 2 hours of taking an OCP (88.7%). Less than one-fifth of the participants could recognize that smoking affects contraceptive use. However, majority of them (81.7%) have read the package insert inside OCPs packages. Overall, sufficient knowledge was reported among 22.7% of women as illustrated in figure 1. None of the studied demographic factors (age, occupation, educational level, number of children and duration of OCPs use) was significantly associated with women's knowledge regarding proper OCPs use. Table 3

Table 3:- Factors associated with knowledge of proper oral contraceptives use among women.

	OCPs` knowledge		P-value
	Insufficient (n=232)	Sufficient (n=68)	
Age (years)			
< 30 (n=101)	78 (77.2)	23 (22.8)	0.497
30-39 (n=136)	102 (75.0)	34 (25.0)	
≥ 40 (n=63)	52 (82.5)	11 (17.5)	
Educational level			
<Intermediate school (n=20)	19 (95.0)	1 (5.0)	0.201
Intermediate school (n=34)	26 (76.5)	8 (23.5)	
High school (n=80)	61 (76.3)	19 (23.8)	
Diploma (n=24)	21 (87.5)	3 (12.5)	
Bachelor and above (n=142)	105 (73.9)	37 (26.1)	
Occupation			
Student (n=16)	11 (68.8)	5 (31.3)	0.665
Housewife (n=190)	150 (78.9)	40 (21.1)	
Employed; Health care professional (n=7)	6 (85.7)	1 (14.3)	
Employed; others (n=87)	65 (74.4)	22 (25.3)	
Number of children			
None (n=7)	5 (71.4)	2 (28.6)	0.986
1-2 (n=116)	90 (77.6)	26 (22.4)	
3-4 (n=97)	75 (77.3)	22 (22.7)	
> 4 (n=80)	62 (77.5)	18 (22.5)	
Years of contraceptive taken			
< 1 year (n=35)	23 (65.7)	12 (34.3)	0.376
1 year (n=77)	62 (80.5)	15 (19.5)	
2 years (n=47)	35 (74.5)	12 (25.5)	
3 years (n=74)	57 (77.0)	17 (23.0)	
≥4 years (n=67)	55 (82.1)	12 (17.9)	

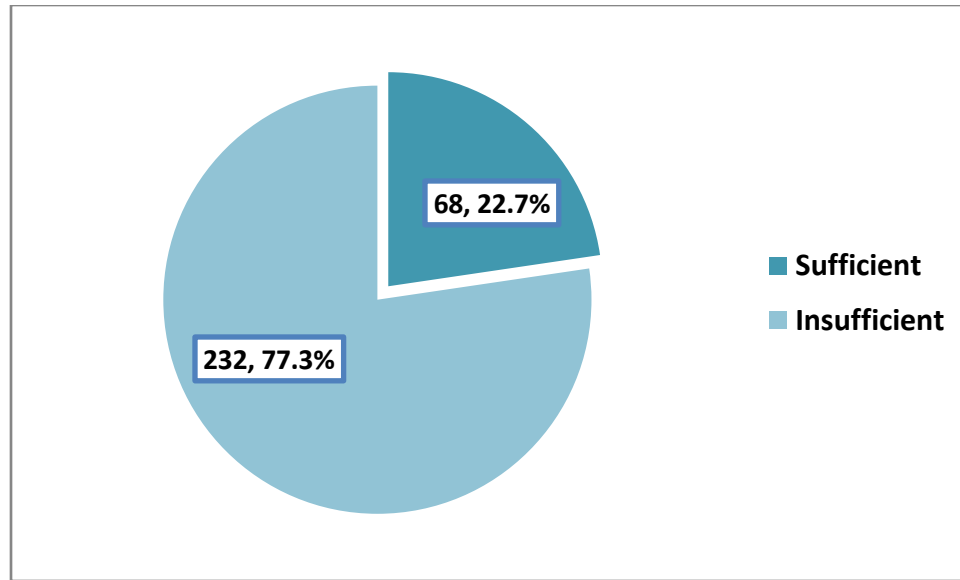


Figure 1:- Knowledge level of the participants about proper oral contraceptives use.

Regarding OCPs` side effects, figure 2 shows that the commonest reported were weight gain (56%), nausea (36.3%), tender breast (35.7%), and facial acne pimples and body hair (26.7%).

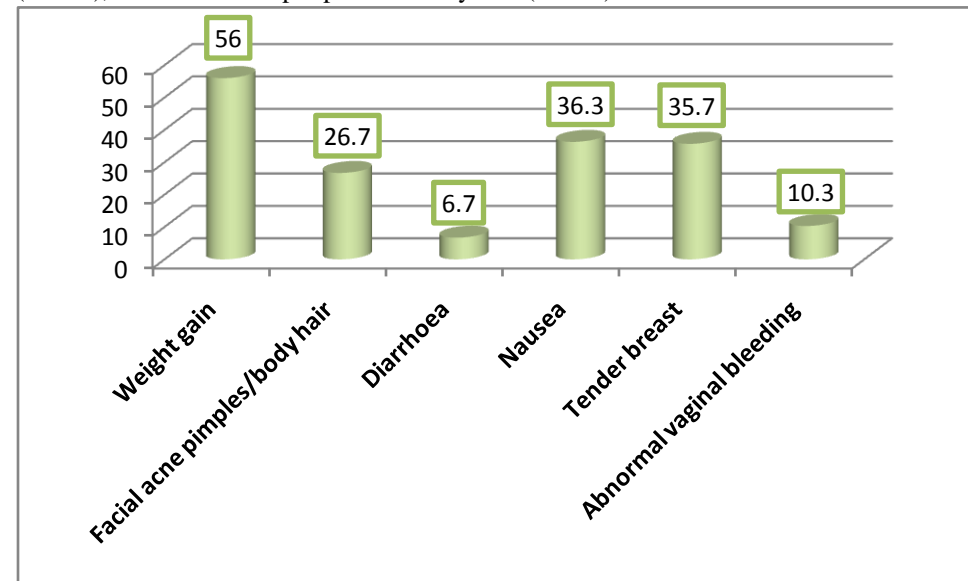


Figure 2:- Side effects of oral contraceptive pills

Studying the demographic factors associated with OCPs` side effects yielded only significant association between weight gain and woman`s age as 68.3% of those aged 40 or more years were more likely to report weight gain compared to those aged between 30 and 39 years (47.8%). The difference was statistically significant, $p=0.018$. Also, there was a significant impact of woman`s occupation on weight gain as 71.4% of health care professionals compared to 48.1% of house wives reported weight gain, $p=0.004$. Abnormal vaginal bleeding was significantly associated with years of OCPs use as it was more reported among those used OCPs for less than one year compared with longer duration, $p=0.031$. Other associations between demographic characteristics of women and OCPs side effects were not statistically significant. Table 4

Table 4:- Significant association between women`s demographic characteristics and oral contraceptive pills` side effects.

	Weight gain		P-value
	Yes (n=168)	No (n=132)	
Age (years)			
< 30 (n=101)	60 (59.4)	41 (40.6)	0.018
30-39 (n=136)	65 (47.8)	71 (52.2)	
≥ 40 (n=63)	43 (68.3)	20 (31.7)	
Occupation			
Student (n=16)	9 (56.3)	7 (43.8)	0.004
Housewife (n=190)	92 (48.4)	98 (51.6)	
Employed; Health care professional (n=7)	5 (71.4)	2 (28.6)	
Employed; others (n=87)	62 (71.3)	25 (28.7)	
	Abnormal vaginal bleeding		
	Yes (n=31)	No (n=269)	
Years of contraceptive taken			
< 1 year (n=35)	9 (25.7)	26 (74.3)	0.031
1 year (n=77)	6 (7.8)	71 (92.2)	
2 years (n=47)	3 (6.4)	44 (93.6)	
3 years (n=74)	6 (8.1)	68 (91.9)	
≥4 years (n=67)	7 (10.4)	60 (89.6)	

Discussion:-

The contraception use can have a positive influence on better child spacing, child care, improvement of health of children, and is considered as an effective preventive measure against maternal and child morbidity.¹⁷ In the current study, the knowledge of Saudi women regarding OCPs use was investigated. Overall, knowledge regarding missing pills, vomiting, and diarrhea among Saudi women in this study were insufficient. This finding is in accordance with other Saudi studies carried out in Riyadh¹⁶ Al-Khobar,¹⁸ and Qassim Region.¹⁹ In India, 11.2% of the study population were aware of contraception.²⁰ Other studies in Pakistan²¹ and in rural southern Nigeria²² revealed a higher value of awareness of contraception; 81% and 92.2% respectively. This insufficient knowledge and awareness could be potential causes of unintended pregnancy.²³ In the United States, each year more than ten million women intake the OCP to prevent pregnancy; three hundred thousands of those women become pregnant each year during a month in which they have been taking the pill.²⁴

In the current study, 81.7% of the Saudi women claimed that they had read the package insert so it appears that this information source is well accepted. However, despite reading the package inserts their knowledge on the proper OCPs use was mostly insufficient. The same has been reported in another Saudi study carried out in Riyadh.¹⁶ For most women, the OCP package insert is the sole source of information, which explains their risks and benefits, side effects, and what to do when they have missed taking pills. Yet, these specific points of information in the inserts might be difficult to find and understood. 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.²⁵

Therefore, we recommended developing a simpler, more understandable, an accurate and specific patient package insert for inclusion in all packs of oral contraceptives to increase the clarity of information across oral contraceptive brands. Also, providing patients with a simple booklet and reading material on proper use of OCP can enhance their knowledge of OCP use.²⁶ In addition to these, reinforcement of the key messages by verbal counseling from physicians, nurses or pharmacists on OCP use is a good way to improve patient knowledge.²⁷

The current study showed that although higher educated women had more sufficient knowledge regarding OCPs use compared to less educated women, however, this was not significant statistically. In a study carried out in South Africa, also education level of women was not significantly associated with proper OCPs use.²⁸ It had been

documented that educated women are more likely to be aware of the health services, including family planning services that are available, have more confidence in using them than less educated women.¹⁵ Additionally, more educated women have more work opportunities, which reflects their tendency to postpone starting a family to complete their career.¹⁵ In Middle East countries, including KSA, higher educated women tend to limit family size to have more time to take care of their children.²⁹

Years of contraception use was not significantly associated with a better knowledge of compliance in the present study contrary to what has been reported in another Saudi study where prolonged use of OCPs was associated with better knowledge.¹⁵

Smoking while on the pill of more than fifteen cigarettes per day at age 35 or above will increase the risk of stroke, and is considered a contraindication.³⁰ However, most participants in the present study couldn't recognize that smoking affects contraceptive use. This finding is of relative importance in Saudi Arabia due to the increasing incidence of smoking among females.³¹

Some studies have reported that at least half of OCPs' users discontinue the pill within the first year because of fears, side effects, and lack of knowledge.^{32, 33} Twenty percent of the annual unintended pregnancies in the United States are linked to discontinuation of OCPs mainly because of its unpleasant side effects.³⁴ In the current study, 56% reported weight gain as a side effect, although clinical trials have failed to establish a relationship between OCP use and weight gain.^{35, 36} The second most commonly reported side effect was nausea (36.3%), which is higher than those reported in the literature.³⁷ In addition, tender breast (35.7%), facial acne pimples and body hair (26.7%) were reported amongst OCPs' side effects in the present study. Quite similar findings have been documented in another Saudi study.¹⁶

Among limitations of the current study, it was limited to one institution, therefore, although our hospital treats all of the Saudi population in Khams Mushait, the study population may not be fully representative of Saudi women using the OCPs.

In conclusion, the study showed that most Saudi women taking the OCP have insufficient knowledge of its correct use regarding missing pills, vomiting, diarrhea and poor awareness of the effects of smoking with OCP use. Therefore, proper education and counseling on correct OCP use are recommended to improve their knowledge to protect their health and limit unintended pregnancies.

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