



# What Saudi Arabian Women Believe about Oral Contraceptives and the Effect of Counselling

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### Essay

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**Abbreviations:** OCP: Oral Contraceptive Pill.

## Introduction

Contraception is one of the major health concerns of women in developing countries, and it prevent pregnancy by interfering with the normal process of ovulation, fertilization or implantation. Recently, with improved health care facilities and health care education, women in Saudi Arabia have been practicing the newer methods of contraception [1]. The oral contraceptive pill (OCP) provides very effective reversible contraception, and has an excellent overall safety and tolerability profile [2]. It is the most widely used contraceptive method [3,4]. In Saudi Arabia 73.6% of the women younger than 34 years old were using different methods of contraception and OCP was the first choice in preventing pregnancies [1]. Women around the world share a common mythology about alleged ill effects of OCP [5]. This mythology, which dates back decades [6], is perpetuated by gossip, rumours and illogic. The misinformation transcends continents [7,8] and is shared by highly educated women as well as by illiterate women<sup>9</sup>. This mythology is the most common reason why women quit taking OCP. Several studies have showed that at last half of OCP users discontinue the pill within the first year because of fears, side effects, and lack of Knowledge [10,11].

Published literature on the efficacy of the contraceptive counselling and education seems to reflect a significant gap between what providers think they offer and what consumers appear to receive [12]. An audit of family planning users in Scotland revealed a 30% discrepancy between

the number of women whom clinicians thought they had appropriately counselled and the number of patients who actually understood the teaching [13]. Oakley estimated that up to one third of women require more individualized counselling in effective use of OCP [14]. Getting the good news out about the many benefit of OCP will enable more women to take advantage of their positive health effects and may help increase the compliance [15]. Proper education and counselling on correct OCP use is needed to improve women knowledge to safeguard their health and limit unintended pregnancies [16]. Reduction of unintended pregnancy leads to avoid the abortion which is illegal in Saudi Arabia only with a very narrow exception. An abortion is only legal if the abortion will save the woman's life or if the pregnancy gravely endangers the woman's physical or mental health. The fetus must be less than four months old, and if longer, requires a panel of approved specialists to declare that the pregnancy will result in the death of the woman. Any approved abortion requires consent from three physicians as well as the patient and her husband or guardian [17-23].

The survey was designed to assess what Saudi women know about the risks, benefits and side effects of the OCP, and whether the level of knowledge was affected by the health care provider counselling.

## Materials and Methods

A cross sectional prospective study was conducted for six months in different gynecology clinics (private and governmental) in Riyadh area (the capital of Saudi Arabia). A published survey was used in this study (ref). The questionnaire has been translated from English to Arabic and then back translated from Arabic to English by two bilingual experts.

In the first part of the survey patient's demographics and history of OCPs use were covered. Questions were closed-ended and patient demographics include Nationality and age. Patient history regarding oral contraception was covered by four questions that include: duration of use, other contraception methods, reasons of non-use of OCPs, and who advise you to use OCPs. The questionnaire was validated in a crossover pilot study conducted in 20 females who were using OCPs. The women self-completed the questionnaire on two separate occasions, two weeks apart. A two-week interval period was chosen to avoid duplication of their first response. For internal consistency of the knowledge on all questions of the pilot study, Cronbach's alpha, a coefficient of reliability, was calculated 0.90 (range  $\alpha > 0.90$ ) with excellent reliability.

Women were instructed to report whether or not they had discussed separate issues about OCP use with their healthcare provider in the second part of the survey [12]. Issues are heavy bleeding, acne, missing a pill, drug interaction, missing a period, leg oedema, headache, sudden or irregular bleeding, nausea, breast pain, weight gain and future pregnancy. For each issue, respondents were asked to choose the most appropriate response from four choices, to a hypothetical situation. Five and seven responses were assigned to missing a period and feeling nauseous, respectively. Optimal responses were defined as those answers that would result in an appropriate use of physician intervention, while continuing to prevent pregnancy and ensure patient safety. Survey questions were later categorized as non-contraceptive benefits, potential problems, side effects and myths.

When any respondents selected multiple answers, or failed to indicate whether or not they had received counselling the response was deleted from the analysis. These omissions resulted in variable sample sizes.

A decoy question about dry mouth was inserted to test response validity. Dry mouth is not associated with OCP and healthcare providers would not provide advice on this fictitious side effect.

Four questions had a different format in the third and last part of the survey. "Yes" or "No" responses were recorded for being smoker or not and the effect of smoking on OCP risk.

The two final questions about the magnitude of the risk of uterine, ovarian and breast cancers were added. Simple, non-comparative response rates were calculated for these categories.

## Results

A sample of 430 women was approached over six months period where 70.6% (304) of them were Saudi and 63.5% of them have used OCPs. The commonest 38.8% (253) age range of respondents was 21-35 years. Around 32% (88) of women were new OCPs users, while experienced and long standing users were 33.3% (92) and 34.8% (96), respectively as shown in (Table 1).

Characteristics	N	(%)
Nationality		
Saudi	304	71
Non-saudi	126	29
Age ( years)		
18-20	36	8.4
21-30	127	30
31-35	126	29
36-40	72	17
41-50	4.6	11
> 50	23	5.3
Years of Contraception Taken		
Less than 1 (new users)	88	32
1-5 (experienced users)	92	33
Long-term users		
06-Oct	56	20
Oct-20	25	9.1
More than 20	15	5.4

**Table 1:** Demographic characteristics of women who responded to the questionnaire.

The reason provided by majority of women who did not use OCPs (36.5%, NO) was OCP's side effects (37%, no) while husband and family advice of not using OCPs have been chosen by 18.8% (n) of the respondents and 45% (n) chosen no specific reason. The natural family planning method was reported by the majority (59.9%, n) of women who did not use OCPs, followed by intrauterine device (25.7%, n), and (14.5%) using different hormonal methods including: vaginal ring, implant, and patch. More than half of the respondents (53.6%) reported having discussed the risk, benefits and side effects of the pill with their physician, followed by friends (20.7%), family members (19.9%), and pharmacist (5.8%).

The proportions of respondents who reported being counseled on particular issue are shown in (Table 2).

Topics	%
<b>Non-Contraceptive Benefits</b>	
Decrease menstrual blood loss(less dysmenorrhea)	53.10%
Frequency of acne	30.90%
<b>Potential Problems</b>	
Missed taking two or more pills	50.90%
Co-medication	43.30%
Missed periods	49.10%
Pain or swelling in leg	42.50%
Headaches	50.90%
<b>Side Effects</b>	
Breakthrough bleeding	47.60%
Nausea	47.30%
Breast tenderness	41.50%
<b>Myth</b>	
Weight gain	51.60%
Decreased fertility	54.20%

**Table2:** Percentage of respondents who reported being counselled on a particular topic.

A comparison of optimal response rates between those who reported being counselled and those who reported not being counselled, is provided in (Table 3). Counselling made

a significant impact on selection of the optimal response for 2 of the 12 questions ( $p < 0.005$ ).

Optimal response(s)	Yes	No	% differences	P-value
<b>Non-contraceptive benefits</b>				
The pill should make my periods:	53.10%	46.90%		
Lighter & less painful	43.20%	56.80%	-12.6	0.092
If I get acne on the pill, I will	30.90%	69.90%		
Keep taking pill & not call my doctor	20.60%	79.40%	-58.8	<0.005
<b>Potential Problem</b>				
If I forgot to take two or more tablet , I will:	50.90%	49.10%		
Use another form of birth control that month	39.70%	60.30%	-20.6	0.115
Take other drugs at the same time with the pill	43.30%	56.70%		
Sometimes a problem	49.10%	50.90%	-1.8	0.821
If I don't have period after I finish taking my first package of pills, I will	49.10%	50.90%		
Start next package and call my doctor.	54.40%	45.60%	8.8	0.467
If I get pain or swelling in my leg, I well:	42.50%	57.50%		
Call my doctor or go to hospital	51.20%	48.80%	2.4	0.823
If I notice headache, I will:	50.90%	49.10%		
Take a painkiller and call my doctor	54.70%	45.30%	9.4	0.388
<b>Side effect</b>				

If I Notice bleeding at a time other than my normal period, I will:	47.60%	52.40%		
Continue take the pill & not call the doctor	38.50%	61.50%	-23	0.405
If the pill make me nauseous, I will:	47.30%	52.70%		
OR Take the pill with food	40.60%	59.40%	-18.8	0.289
OR Take anti-nausea	43.90%	56.10%	-12.2	0.354
OR take the pill at different time of the day	42.30%	57.70%	-15.4	0.267
If I notice my breasts are painful, I will:	41.50%	58.50%		
Keep taking the pill & call my doctor	15.80%	84.20%	-68.4	<0.005
<b>Myth</b>				
While I am on the pill, I think my weight will :	51.60%	48.40%		
Stay the same	41.50%	58.50%	-17	0.172
If I take the pill, my fertility will :	54.20%	45.80%		
Not be affected	46.90%	53.10%	-6.2	0.54

**Table 3:** Effect of counselling on optimal response(s). It seems that there is error in reporting the percentage. In addition you need to report the actual numbers.

Optimal response were highly achieved (40%-60%) in dysmenorrhea, leg pain, fertility awareness, and drug interaction were answered. (30.9%) of respondents reported that they discussed with their health care provider what to do if they noticed acne while in the pill. Of those women who received counselling, (46.9%) they will continue taken the pill and they will call their doctor. Compared to (69%) of those not counselled on this issue ( $p<0.05$ ). Regarding compliance, (50.9%) of the women reported they were counselled, (37.5%) of them they will take the pill as soon as they remember while the proper answer is to use other contraception method during this month ( $p<0.05$ ).

(38.2%) women reported that they will do pregnancy test if they miss their period, (31.3%) they will stop taken the pill, (18.5%) they will start a new package and they will call their physician, while (4.4%) they will start a new package and they will not call the physician, and (7.6%) they don't know ( $p<0.05$ ).

Only (42.5%) of the respondents reported that they counselled by their health care provider what to do if they noticed pain or swelling in the leg while on the pill. (62.9%) of them they will go to the hospital, compared to (57.5%) of those not counselled on this issue. This 20% difference in optimal response rates was statistically significant ( $P<0.005$ ). Similarly, 51% reported being told of the effect of OCPs on headaches. 31% of this group gave the optimal answer (take pain killer and call the doctor) compared with only 57.5% of women who were not counselled. Overall 22% of the women would stop taking the pill if they had headaches ( $p<0.05$ ).

It was found that 47.6% of the women reported being told

what to do if they have break through bleeding, or bleeding at a time other than their normal period. Only 4.4% gave the optimal response (continue take the pill and not call the doctor) compared with only 52% who were not counselled. When we asked the women about nausea as a side effect of the pill 47% of them reported that they were speak with their health care provider about it, 56% who reported counselling they chose the optimal answer. Compared to 53% were not counselled about nausea.

Many women reported that they would contact their physician if they experience breast tenderness. While only 7% of them reported the optimal answer (keep taking the pill and not call the doctor) ( $p<0.05$ ). When asked of the effect of OCPs on weight, 23.6% correctly indicated they through their weight would stay the same; 54.2% thought it would increase, 10.5% thought it would decrease and 11.6% they didn't know ( $p<0.05$ ). About OCPs effect on fertility 54.2% of women reported that they discussed this issue with their healthcare provider 35 % of them said not be affected, while 28% of them thought infertility will be increased if they used the OCPs ( $p<0.05$ ).

The majority of women weren't asked by the individual providing counselling whether they smoked cigarettes or Hookah 73% and weren't told about the association risks of smoking 82%. The survey found that 32% of respondents indicated they talked about the side effect of dry mouth. The response to decay question that 3 in 10 might having been counselled I a particular area when, in fact, they were not.

With respect to the effect of OCPs on the risk of uterine cancer, 48.4 % of women indicated they weren't told; 10%

recalled being counselled correctly that the risk of this cancer was lower. The rest 17.8% told that no change, and 23.3% thought was higher. For the effect of breast cancer, 50.6% of the respondent indicated they don't know what they were told; 12.7 recalled being counselled correctly that the risk for breast cancer was un-change. The rest indicated they were told the risk for breast cancer was high 24.4% or lower 12 %.

## Discussion

This study showed the knowledge of women in Riyadh city on OCPs regarding risks; benefits and side effects of the pill remain deficient in several key areas, which need to increase by counselling. The counselling process should be confined to the physician and the pharmacist to make sure that the information given to patients are correct; on the other hand the health care provider should have a feedback after the counselling to make sure patient well understand all the instructions given.

Discussion on particular issue related to the pill may have ranged from dogmatic and time constrained to evidence base and interactive [12].

In many cases, misinformation may have actually been transferred to patients. Misperception and ignorance is likely to be observed at a higher frequency among women who have either chosen not to use OCPs or to use other methods of contraception.

The appearance to be uncertainty among both patients and healthcare provider about the effect of the pill on weight. In one study 60% of the pill users who returned to their physician because of the side effects were concerned about weight gain [11]. Research evidence indicates weight gain attributed to the OCPs is misperception [17]. Rosenberg, et al. [11] weight women for four cycles of OCPs use and they found there was no weight gain over baseline. Over each pill cycle, a minor weight increase about 0.2 kg did occur, with a return to base line by the end of each cycle, suggestion that the effect might be related to fluid retention. A study in teenage women showed that OCPs are associated with less favourable blood lipid patterns, but not associated with weight gain or increased body fat [18]. Two randomized, controlled trials showed that low-dose OCPs are well tolerated and not associated with weight gain [19]. Al-shaikh, et al. [16] study said the most common side effect experienced with OCPs use were weight gain or increased appetite (51% of the participants). In our study, 54.2% of respondents thought their weight would increase on the pill. Interestingly, 23.6% women who reported discussing this issue indicated their weight would stay the same. Weight gain may be a myth that is actually propagated by some health care providers [12].

Women who are considering taking the OCPs are often concerned with their effects on cancer risk. Breast cancer is the main concern to patients, especially whom have a family history. In 1996, the Collaborative Group on Hormonal Factors in Breast Cancer brought together and reanalysed the worldwide epidemiological evidence on the relation between breast cancer risk and the use of combined oral contraceptives [20]. This reanalysis involved 54 studies and represented 53,297 women with breast cancer and 100,239 control patients. They concluded that there is a small increase in risk of having breast cancer diagnosed in OCPs users, and the risk disappears within 10 years of stopping OCPs. In absolute term, the risk is 0.5 excess cancer cases per 10,000 women for use at 16 to 19 and increases with age (e.g., 4.7 at age 25-29) the cancer detected are less advanced in OCPs users than in non-users and are therefore potentially more curable. A recent population-based, case control study has shown that among older women (35-64 years), current or former OCPs user is not associated with significantly increase in breast cancer [21].

The OCPs reduces the risks of developing both uterine and breast cancer by approximately 50% [22]. Around half of the respondents indicated that they did not know of the effect of OCPs use on breast, uterine or ovarian cancer. This suggests that women either are not retaining or are not receiving this important information with current counselling methods.

Rosenberg, et al. [11] said that 22% Off OCPs users called their health care provider at least once about pill-related side effects, 9% made at least one visit for this reason. There are few well-recognized major problems related to use, including thrombosis, headache and misses pills. Regarding thrombosis all OCPs users should be able to identify obvious warning signs and be given instructions to contact their physician or proceed to the hospital. Our data showed around 40% of the women who were counselled were aware of this risk and what they should do if they experience a painful, swollen leg. However, 30% of the users were unaware of what to do if they experienced worse than usual headaches. On the other hand, around 80% of the respondents were not told about the association risks of smoking.

In conclusion, the study demonstrated that most of the Saudi women using OCPs have incorrect believes about compliance, amenorrhoea, unusual bleeding, weight gain, breast cancer, ovarian cancer and poor awareness of the effect of smoking with OCPs. Providing Clear, evidence based information OCPs will enable women to take advantage of the pill's positive health benefits, and may result in fewer unnecessary health care provider contacts and unwanted pregnancies. We also need to explore other more efficient strategies with a broader perspective. These include audio-visual, social media and other possible counselling tools to

change the all incorrect believes.

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