Original article



Assessment of Females Awareness in Saudi Arabia about Long term use of COCP and Venous Thromboembolism Risk: A Cross Sectional Study

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Abstract

Background: Nowadays there are a lot of women using contraceptive oral combined pills for birth control and as we know VTE is one of the complications when it used for a long time, and here in this study our aim is to assess the awareness and knowledge of females who live in Saudi Arabia about COCP and its complications like VTE.

A cross-sectional observational study based on a questionnaire conducted among females who live in Saudi Arabia. Data collection was done by using online survey which contains questions about the age, education and contraception.

<u>Methods</u>: An observational cross-sectional study carried out during December 2020 in Saudi Arabia. We minimize our target population through inclusion criteria: 1- Female 2- Live in Saudi Arabia 3- Agree to participate. Sample size was 454 participants calculated by using survey system website through sample size calculator with Confidence Level 95% and margin of error 5%.

<u>Result</u>: A total of 454 patients completed the survey questionnaire. The results showed that the vast majority of the study participants aged 20 years or more. Moreover, more than 90% of the study participants were Saudi females. The average body weight is around 95 kg and height 164.2 cm. The results also indicated that two-third of the study participants attained university education level compared to 16.1% obtained secondary education. Additionally, 36.6% of the study participants worked as a housewife, 18.1% working in health field. Moreover, 40% of the respondents reside in the western regions, 34% live in eastern regions compared to the lowest percentage in South region 3.3%.

<u>Conclusion</u>: In summary, this study revealed that the internet was the main source of knowledge. Health care providers should perform their intended role in improving the female's awareness regarding family planning. The criteria for preferable contraceptive method are that it has few or no side effects, also it depends on how much effective and convenient it is. Educational programs may be warranted to minimize the fear of side effects and to enhance the general knowledge about contraception.

Keywords: Oral contraceptive, Awareness, Venous thromboembolism, Female

Introduction

COCP is a form of birth control used by millions of women due to high contraceptive effectiveness when it used correctly ^[1]. It is a hormone preparation medicine that contains both estragon and progestin and has both contraceptive and non-contraceptive purposes, such as relieving menstrual pain, for irregularity in menstrual cycle, fibroids, pimples, ovarian cancer, pain due to endometriosis and menstrual-related migraine. As often as COCP can be beneficial, it carries major risks, which include high likelihood of developing venous thromboembolism, myocardial infarction, stroke, breast and cervical malignancies ^[2]. It also cause several metabolic effects on lipid, carbohydrate, haemostatic parameters ^[1].

It is well evident that the use of COCP is associated with a high risk of venous thromboembolism, through blood clot formation in deep veins which is serious avoidable cause of mortality among women. DVT that commonly tends to occur in the legs can split off and goes into the pulmonary vasculature which can be life threatening ^[3].

The use of oral contraceptive pills (OCP) is taken into account as an appropriate practice worldwide, with so many women using OCPs internationally since its introduction in 1957. A research analysis released in 2017 reveals that out of 500 of the samples 389 (77.8%) used contraceptive pills and 111 (22 %) did not. The contraception awareness was 465(93 %) the majority were aware of it, but only 35 (7 %) were those who were not familiar with some form of contraception. Studies reported since 1990 showed that the third generation have a greater risk of contributing to the production of thrombosis compared with the second generation. In 2018, the rate of contraceptive use was 30.4%, according to the Saudi Household Health Survey. The use of combined hormonal contraception (CHCs) associated with an expanded hazard of venous thromboembolic events, including DVT and PE, and may be related with expanded hazards of ATEs, like acute MI and ischemic stroke [4] and also Increase tendency of bleeding and vascular trauma are common risks of VTE Among women^[3].

So many studies done to detect the relationship between combined oral contraceptives and VTE, some findings reported a higher relative risk of VTE among users of desogestrel, gestodene and drospirenone contraceptives compared to those with levonorgestrel ^[5]. And also latest research reveals that third generation of combined contraception with dense concentration of 17 α -ethynylestradiol associated with artrial and venous thromboembolism,^[6] while progesterone-only pill has lesser risk of venous thromboembolisms than other oral contraception regimens ^[7].

Studies also revealed the significant risk of VTE in current users of combined oral contraceptives compared to non-users,^[8] also pregnancy, postpartum periods and late menopause with multiparity are linked with an increase incidence of VTE in comparison to non pregnant state and menopause at usual age ^[9].

A study was done on clotting factors changes reveals that venous thromboembolism occur within first 90 days of using oral combined contraception ^[10]. women who's using oral combined contraception for days up to 6 months their d-dimer and factor VIII tests changed to be at risk of VTE,^[10] also there was elevation of liver enzyems ^[6]. The latest guide line of Swiss society of Gynecology and Obstetrics published in 2019 suggest that women whos in hazared to venous thromboembolism are should not use combined contraception ^[11].

Due to insufficient researches realted to our topic, especially in Saudi Arabia and the fatal complications with long term use of COCP we aim through this study to optimize the awerness level in the society which inturn will aid to minimize serious consquences.

Methods

An observational cross-sectional study carried out during December 2020 in Saudi Arabia. We minimize our target population through inclusion criteria: 1- Female 2- Live in Saudi Arabia 3- Agree to participate. Sample size was 454 participants calculated by using survey system website through sample size calculator with Confidence Level 95% and margin of error 5%.Data collected through an online self-administered questionnaire designed as multiple choice questions was distributed randomly between participants. The questionnaire started with introduction about the investigators and consent. Followed by 21 questions divided into 2 parts: Demographic features including 8 questions: age, hight, weight, residency, nationality, number of children, job and qualification. The remaining 13 MCQs are about the general knowledge regarding COCP including source of information types, indications and complications. Data was Entered on computer using the "Microsoft office Excel Software" program (2016) for windows, after that data was transferred to the statistical package of social science software (SPSS) program, version 20 (IBM SPSS statistics for windows, version 20.0. Armonk, NY: IBM Corp.) to be statistically analysed.

Results

A total of 454 patients completed the survey questionnaire. The results showed that the vast majority of the study participants aged 20 years or more. Moreover, more than 90% of the study participants were Saudi females. The average body weight is around 95 kg and height 164.2 cm. The results also indicated that two-third of the study participants attained university education level compared to 16.1% obtained secondary education. Additionally, 36.6% of the study participants worked as a housewife, 18.1% working in health field. Moreover, 40% of the respondents reside in the western regions, 34.% live in eastern regions compared to the lowest percentage in South region 3.3%. Interestingly, 36.1 of study participants mentioned they did not have offspring, 41.6% had 1-3 children compared to 22% had 4 or more children. Table 1 presents the sociodemographic characteristics of the study participants.

 Table 1: Sociodemographic Characteristics of the Study

 Participants (n = 454)

Characteristics	Frequency	Percentage
Age	·	•
<20 years	14	3.1%
20-40 years	362	79.7%
>40 years	78	17.2%
Weight	95.03	13.52
Length	164.28	64.22
Nationality		
Saudi	415	91.4%
Non-Saudi	39	8.6%
Type of Employment		
Housewife	166	36.6%
Teacher	72	15.9%
Heath related field	82	18.1%
Manager	7	1.5%
Others	127	28.0%
Level of education	·	•
Primary	3	0.7%
Intermediate	7	1.5%
Secondary	73	16.1%
University	371	81.7%
Residence area in Sauc	li Arabia	
North Region	79	17.4%
South Region	15	3.3%
Eastern Region	156	34.4%
Middle Region	24	5.3%
Western Region	180	39.6%
Number of Children	·	•
No children	164	36.1%
1-3	189	41.6%
4-6	79	17.4%
>6	22	4.8%

Regarding the reason of using the contraceptive, it can be noted that 62.8% of the respondent used as the way to prevent pregnancy. 16.7% of the participants used contraception to regulate the menstrual cycle. Interestingly, 8.4% of the participants used oral contraception to treat acne. However, 4.6% of respondents were not informed about the reason for use contraception.

Regarding the information of the participants about the potential complication of using contraceptives, 28.9% of them indicated the headache is the most frequent complication. Also, 25.6% believed that DVT in the leg is another complication could be seen as a result of using the contraceptive. Additionally, 19.2% of the participants thought hypertension is another complication. However, 26.4% of respondents were not informed about the complication. Likewise, 67.2% expressed their notion that there is no relationship between contraceptive and blood disorder compared to 32.8% who asserted on the relationship between contraceptive and blood disorders.

Regarding the methods of contraception, 20.9% of the participants preferred to use intrauterine device with copper. 15.6% preferred The hormonal pills and 15.0% preferred male condoms. Additionally, 14.30% of the participants preferred natural abstinence.

7.3% of the participants preferred hormonal injection, 7.0% preferred contraceptive patch. However, the least preferred method is implanted contraception 1.8%. Table 2 presents the study participants responses on the selected items.

Item	Frequency	Percentage		
Why do you use contraceptive?				
Contraception	285	62.8%		
Treat acne	38	8.4%		
Regulating the menstrual	76	16.7%		
cycle				
I don't know	21	4.6%		
Others	34	7.5%		
Which of the following are the complications of birth				
control pills?				
DVT in the leg	116	25.6%		
Headache	131	28.9%		
Hypertension	87	19.2%		
I don't know	120	26.4%		
Did you know if there is a	relationship betwe	en the		
contraceptive pill and blood problems?				
Yes	149	32.8%		
No	305	67.2%		
From the following list choose the method of inhibitions that				
you have read or heard about (you can choose more than				
one answer)				
Hormonal pills	71	15.6%		
Male condom	68	15.0%		
The hormonal IUD	63	13.9%		
Hormonal injections	33	7.3%		
Natural abstinence	65	14.30%		
Contraceptive patch	32	7.0%		
Female condom	19	4.2%		
Implanted contraception	8	1.8%		
IUD with copper	95	20.9%		

 Table 2: Study Participants Responses for Questions

Regarding the source of participant's information, it seems that one third of them relied on internet to obtain health information related to the contraception. 24.2% of the participants received the

information from reliable health person as care professionals.21.4% of respondents informed about the contraception from family or friends. The books and scientific research are cited as the least source of information about the contraceptive. This answer is consistent with the source of help as 44.1% of females received help from the physician, 14.5% of respondents received information from pharmacist. However, 11.8% obtained information from spouse and 15% from family.

Currently, 61.9% of the study sample did not use any method of contraception compared to 38.1% who used one method. The study participants preferred to use specific type of contraception as it has minimal or no side effect this is the most frequent answer (48.8%). Another frequent reason to use the contraceptive approach is that it is already known to prevent pregnancy (18.7%) followed by easy to be used (17.1%). However, the lowest percentage is that price is the cause to use the contraceptive method (3.3%).

Approximately, half of the study respondents had previous experience in using the contraceptive methods. The results showed that 49.8% of the study participants had no previous experience of using the birth control compared to 35.0% of females used contraceptive one time as well as 15.2% used the method frequently.

It should be noted that 51.55% of females have used the contraceptive without seeking physician prescription compared to the 48.5 of females who sought physician consultation.

Discussion

Our primary goal of this study was to estimate the awareness and knowledge of women who live in Saudi Arabia about combined oral contraceptive pills (COCP) and its complications. Studies have suggested that a lack of contraceptive knowledge is one factor that contributes to poor contraceptive behavior and the risk of unintended pregnancy among young women.

Our study showed that the most popularly known contraceptives were intrauterine devices with copper, followed by hormonal pills and male condoms. Similar to our results, a study conducted in Qatar showed that most women knew about oral contraceptives (OCs) (90.0%), followed by IUDs (89.1%) ^[12]. In addition, previous studies reported that most popularly

In clinical practice, many women report headache as an undesired side effect of hormonal contraception, which may lead to the cessation of the method ^[14]. A cross-sectional study at a family planning clinic in Brazil showed that the first episode of headache was related to COCP use in 8.5% of women with nonmigraine headache ^[15]. Our results also revealed that the headache is the most frequent side effect stated by the females. On the other hand, a multicenter observational study of 3679 first-time OCs users suffering from headache baseline reported improvements (57-71%) in their symptoms after using OCs for three cycles ^[16].

Studies have shown that COCP significantly increases the risk of venous thrombotic events (VTE) in women. About half of VTE events are unprovoked or occur during the use of OCs, postmenopausal estrogen, or with pregnancy, and the remaining events are considered provoked ^[17]. In our study, we found 25.6% believed that DVT is a complication that could be seen as a result of using the contraceptive. Moreover, a global survey of 7,233 adults showed only 57% of 800 Americans were aware of DVT ^[18]. Fear of complications was the most reported reason for not using contraception and the spread of incorrect information about contraception can play a significant role ^[19]. We found that 26.4% of respondents were not informed about the complications. Therefore, physicians should ensure that users are aware of the potential consequences of contraceptives.

The study indicated that the most preferred source of information about family planning was the internet, followed by health care professionals and family or friends. However, another study found that the majority of females would prefer health centers rather than the internet ^[20].

Contraceptive counselling provides education, dispels incorrect information, facilitates the determination of a method that will be successful for the individual, and helps patient engagement in healthcare decisions and life goals ^[21]. Bardaweel et al reported that 82.5 % of the participating women received consultation from the physician ^[22]. Conversely, We found in our study that only 48.5% of women were counselled by their physicians.

Many misconceptions, like fear of side effects and underestimating efficacy, prevented women from OCs use. In our study, most of the participants would prefer to use a method of contraception that has few or no side effects. In line with this, a study among Jordanian women revealed that the incidence of side effects was the main reason for OCs cessation and the utilization of alternative contraception methods ^[22].

The limitations to our study include the cross-sectional design and collection of data using an online self-administered questionnaire.

Conclusion

In summary, this study revealed that the internet was the main source of knowledge. Health care providers should perform their intended role in improving the females' awareness regarding family planning. The criteria for preferable contraceptive method are that it has few or no side effects or depend on how much effective and convenient it is. Educational programs are warranted to minimize the fear of side effects and to enhance the knowledge about COCP and birth control.

Ethics approval

This study was approved by the institutional review board at Qurayyat Health Affaires Registered with NCBE, Saudi Arabia, (reference: 057).

List of abbreviations

Oral Contraceptive Pills (OCP)

Venous Thromboembolism (VTE)

Conflicts of Interest

The authors have no conflicts of interest to declare.

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