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The Effect of Using Combined Contraceptive Pills on Serum Lipid Profile among Females: A Hospital-Based Study at Thumbay Hospital, Ajman, UAE

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Abstract

Background: Globally, the use of contraception has been increased due to a serious problem facing the world which is population explosion. It has been suggested that the use of contraceptives is beneficial, but it has some side effects and metabolism impairment too. The most accepted and widely used birth control to avoid unintended pregnancy is Combined Oral Contraceptive Pills (COCPs).

Objective: To evaluate serum lipid profile level in females receiving COCPs at reproductive age. To assess association between the duration of the use of COCP with serum lipid profile.

Patients and methods: A case control study was conducted at Thumbay Hospital in Ajman, UAE. A total of 99 women were enrolled in the study. The participants were divided into two groups, (COCPs users, n=49) received monophasic COCP (Yasmin), which contains 3 mg prospirenone and 0.03 mg ethinyl estradiol and (Non-users, n=50) as a control.

Results: The results showed statistically significant differences among COCPs users compared with non-users. There was significant increase of Total Cholesterol (TC) (198.0 ± 33.0 mg/dl *vs*.176.7 ± 28.2 mg/dl; p=0.001), Triglyceride (TG) (112.4 ± 54.6 mg/dl *vs*.98.1 ± 54.4 mg/dl; p ≥ 0.05), High Density Lipoprotein (HDL-C) (60.1 ± 19.6 mg/dl *vs*.53.1 ± 13.7 mg/dl; p=0.04), BMI (28.4 ± 4.9 *vs*.28.0 ± 5.3 Kg/m2 ; p=0.55) was not significant.

According to duration of COCPs intake, there was statistically significant increase in Low Density Lipoprotein (LDL-C) (102.1 ± 31.8 mg/dl *vs*.123.9 ± 23.1 mg/dl; p=0.017).

Conclusion: Significantly elevated lipid profile and non-significant increase of BMI were recorded among COCPs users.

Keywords: Contraception • Population explosion • Beneficial • Birth control

Introduction

In a global manner, the use of contraception has been increased due to a serious problem facing the world which is population explosion. Many workers have suggested that the use of contraceptives is beneficial but also have some side effects too. Contraception method is used worldwide for over birth control [1]. Oral contraceptives were a major segregation in prevention of pregnancy and enhancing significant liberation of women. Based on composition, it is classified as combined (composed of estrogens and progestogens) and not combined (composed only of progestogens [2,3]. The most accepted type of birth control and widely used is Combined Oral Contraceptive Pills (COCPs) it has been introduced in 1960, Its use is on increasing by women in child bearing age all over the world, especially in the recent years when various organizations and government are encouraging it's use for spacing pregnancy in developing countries [4]. It is reported that COCPs can be classified into first-, second-, third- and fourth generation, according to the type of progestogen [5]. First-generation COCPs preparations combined high dose ethanol estradiol (>50 µg) and androgenic progestin are associated with adverse effects, such as strokes and thromboembolic events [6]. In addition, COCPs were found to be associated with cardiovascular risk factors that promote myocardial infarctions and deep venous thrombosis in its users [7]. To reduce these adverse effects, there is requirement for estrogen (<50 µg ethanol estradiol) with less androgenic progestin. The lowest doses of COCPs have estrogen in the range of 20-30 µg ,although these doses have less side effects, but still cardiovascular and thromboembolic effect not been eliminated [8,9]. Studies have shown that COCPs have effects on the metabolism of lipid and carbohydrate, liver proteins and coagulation and this effect depends upon the concentration of estrogen and the concentration and type of progestogens [10]. Studies have suggested that progestogens may also contribute to the raised blood pressure. Estrogens induce the hepatic production of renin substrate, angiotensinogen, with a subsequent increase in angiotensin [11]. Various studies have been conducted to evaluate the metabolic effect of COCPs for Cardio Vascular Diseases (CVD) and many researchers have notified the complexity and common side effects linked with the use of hormonal contraceptive pills [12-14], which comprise nausea and vomiting, headaches, breast tenderness, irregular bleeding, and weight gain. The wavy effects involve metabolism impairment, cardiovascular complications, and an increased risk of cancer and liver problems [12]. It has been suggested that some of these complications are a consequence of lipids disorders, a potential metabolic impairment effect of long-term use of some hormonal contraceptives [10]. Moreover, a study by Schueller and colleagues pointed that lipids disorders could arise from the hormones increasing the synthesis of apolipoprotein B-100 those there after increases the levels of Triglyceride (TG) and Low Density Lipoprotein (LDL-C) [13]. Several studies have demonstrated an increasing risk of CVD by increasing TG; on the other hand, other studies demonstrate no significant variation in serum TG, LDL-C, and Very Low-Density Lipoprotein (VLDL-C) in women

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on COCPs [15]. Several factors have made hormonal contraceptives users more susceptible to lipid disorder, such as age, obesity, lifestyle, and diseases such as diabetes mellitus [14,16-19]. Many of these factors are common in UAE. It has been reported that 24% of the females in UAE are obese [20]. Obesity is linked with alterations in lipid profile levels and the use of hormonal contraceptive makes the risk of lipid disorder worse [16,17]. It was notice that most of the studies regarding the effect of COCPs use on metabolic risk factors for development of CVD have directed mainly on the evaluation of the effect on serum lipid profile with little studies have reported on long term effect of COCPs[15]. However, this study was conducted to evaluate the effect of use of COCPs on serum lipid profile in women at reproductive age, as well as Body Mass Index (BMI) effect which related to the duration of the use of COCPs on lipid profile among users.

Materials and Methods

A case control study was conducted at Thumbay Teaching Hospital in Ajman, United Arab Emirates. Ethical approval was received from Gulf Medical University (GMU) Institution Research Board Committee. Data collection was done between 2014-2016. Women ≥ 15 years old who had accepted to participate in the study were recruited and written consent forms were obtained from all subjects included in the study. A total of 99 women were included in this study. The case control ratio fixed for the study is 1:1. Interview for all patients was done with the use of validated questionnaire, and then clinical examination was done for each patient enrolled in the study. The participants (n=99) were divided into two groups. The first group (COCPs users) includes 49 women received monophasic COCP (Yasmin), which contains 3 mg prospirenone and 0.03 mg ethyl estradiol. The second group (non-users) includes 50 women as a control. None of the subjects in the study was smoking or alcoholic or having previous history of CVD. Both groups apparently were looking healthy. Women having history of any disease which may affect the level of lipid profiles were excluded from the study. Specimen analysis was done at Thumbay Laboratory at gulf medical university, Ajman. Biochemical analysis of lipoproteins which include serum Total Cholesterol (TC), TG, HDL-C, was done enzymatically by using chemistry auto analyzer. Serum LDL-C was calculated by Frederickson-Fried Wald's formula according to which LDL-C=TC-HDL C–VLDL-C. VLD-C was calculated as 1/5 of TG.

The BMI was calculated from the measurement of weights and heights by using the following formula: BMI=Weight in Kg/Heights in meter^2.

The data was analyzed by using software Statistical Package for the Social Science (SPSS version 24). All the values were expressed as mean ± S.D. Independent sample z-test, and Two-way ANOVA followed by Tukey's post hoc analysis was used to compare control and subjects' groups. Significance was accepted at <0.05.

Results

The present study was a case control study, included 99 women (COCPs users, n=49 and non-users, n=50). Most of the participants were between the ages of 15-45 years. Data presented in this study was obtained from questionnaire and laboratory diagnosis of biochemical parameters TC, TG, HDL-C, LDL-C and VLDL-C in serum of two groups of participant's users and non-users.

Table 1 shows the mean value of lipid parameters between users and nonusers. All results are expressed in terms of mean ± S.D. Difference in means is statistically tested by independent Sample z-test. Mean Cholesterol and mean HDL differ significantly among COCPs users and non-users (p<0.05). Average TC and HDL-C levels are significantly higher among COCPs users compared to non-users.

Table 1. Lipid profiles among users and nonusers of COCPs.

Parameters	COC users n=49	Non-users n=50	p value
	Mean ± S.D	Mean ± S.D	
Age (Yr.)	33.7 ± 5.6	33.4 ± 6.3	0.83
BMI (Kg/m^2)	28.4 ± 4.9	28.0 ± 5.3	0.55
TC mg/dL	198.0 ± 33.0	176.7 ± 28.2	0.001
TG mg/dL	112.4 ±5 4.6	98.1 ± 54.4	0. 2
HDL-C mg/dL	60.1 ± 19.6	53.1 ± 13.7	0.04
LDL-C mg/dL	110.8 ± 30.8	105.3 ± 29.9	0.38
VLDL-C mg/dL	22.0 ± 11.3	18.9 ± 10.4	0.16

Table 2 shows that the mean LDL-C is significantly differing (mean LDL-C increases) according to the duration of COCPs intake (p<0.05). Using Pearson's chi square test of association, significant association was found between LDL and duration of COCP which indicates the impact of COCP intake on patients' LDL level. If duration of COCP intake is more than 1 year, approximately 5.7 times (Crude odds ratio-5.7, CI: 1.1-29.6, p value-0.02) more likely to be LD abnormal, though there is widen confidence interval.

Table 2. The effect of duration of COCPs intake on serum lipid and BMI in women.

BMI & lipid profiles	Duration of COCP intake				p value
	<=1 yr.		>1 yr.		
	Mean ± S.D	N	Mean ± S. D	N	
BMI(Kg/m^2)	27.7 ± 4.4	31	29.9 ± 5.7	17	NS
TC mg/dL	191.2 ± 34.1	31	210.3 ± 29.0	17	NS
TG mg/dL	116.2 ± 61.1	30	108.7 ± 42.3	17	NS
HDL-C mg/dL	58.2 ± 20.3	30	64.6 ± 18.2	17	NS
LDL-C mg/dL	102.1 ± 31.8	30	123.9 ± 23.1	17	<0.05 (p-=0.017)
VLDL-C mg/dL	23.1 ± 12.1	30	20.7 ± 9.8	17	NS

Table 3. Average lipid profile among COCPs users and non-users across different levels of BMI.

COCP		Cholesterol			p value	TG			p value
		Mean	Std. deviation	N		Mean	Std. deviation	N	
Nonuser	Normal (<25)	164.8	21.7	13	p>0.05 (NS)	89.5	60.8	13	p>0.05 (NS)
	Over wt. (25-29.9)	181.3	32.2	24		102.8	55.6	24	
	Obese (>=30)	180.2	24	13		97.9	48.2	13	
User	Normal (<25)	190.8	26.1	13		98.3	53.5	13	
	Over wt. (25-29.9)	200.3	38.5	19		108.3	57.3	18	
	Obese (>=30)	201	32.3	17		127.4	52.1	17	
	Total		33			112.4	54.6	48	
COCP		LDL			p value	VLDL			p value
		Mean	Std. deviation	N		Mean	Std. deviation	N	
Nonuser	Normal (<25)	93.5	19	12	p>0.05 (NS)	15.8	9.7	12	p>0.05 (NS)
	Over wt. (25-29.9)	109.9	35.4	24		20.2	11.1	24	
	Obese (>=30)	107.8	25.4	13		19.6	9.7	13	
User	Normal (<25)	96.3	25.5	13		19.7	10.7	13	
	Over wt. (25-29.9)	114.7	36.6	18		20.4	12.2	18	
	Obese (>=30)	117.7	25.1	17		25.5	10.5	17	
	Total	110.8	30.8	48		22	11.3	48	

Table 3 shows that the mean of TG, TC, LDL, and VLDL-C in user and nonuser of COCP is compared across BMI level and mean were found to be statistically significant for HDL (p<0.05).Though mean difference was not statistically significant in other parameters, mean levels were increasing for higher BMI levels among COCP users compared to non-users.

Discussion

Lipid and lipoproteins disorder in hormonal contraceptive users has been studied and reported significant changes in the lipid profile levels by various researchers [5,6,14,19]. These changes can be due to the lipogenic effect of estrogen hormone which increases liver lipogenesis and results in raising LDL-C and TG levels [20].

The Combined Oral Contraceptives Pills (COCPs) have been in use for long time with effectiveness, but it has metabolic effect on lipid metabolism due to estrogens and progestogens hormones. Evidence suggests that the individual composition of different COCPs, in terms of estrogens dose and progestogen type, also influences their respective effects on lipids and lipoproteins [15].

The estrogen increases HDL-C and decreases LDL-C and progestogen have opposite effect, so these effects taken into consideration by keeping a balance in the dosage of two hormones in COCPs.

In our study it was noted that the mean serum TC and HDL-C levels were significantly increased (p=0.001 and 0.05 respectively) among COCPs users. These findings are consistent with Halperin [17]. Who found that COCPs use was significantly associated with an increase in HDL-C (p=0.004). Also, these findings are in agreement with [21,22]. Studies which showed a significant increase in serum TC in subjects using COCPs as compared to control (p=0.002 and p=0.01 respectively).

Our findings also consistent who revealed that the mean levels ± SD of TC and TG were significantly higher among COCPs users (p=0.0001) compared to controls. At the same time, he stated that the mean values ± SD of HDL-C among COCPs users (44.08 ± 3.671 mg/dl) was not significant (p=0.822) compared to the controls (44.13 ± 4.22 mg/dl) [23].

On the contrary Okeke Udoka Stated that no significant change (p>0.05) in TC and HDL-C levels among COCPs users [18]. Similarly Abdurrahman stated that the effect of COCPs on cholesterol level was not significant, and the mean of cholesterol does not exceed the normal levels, but there is a significant decreased in the HDL-C level among COCPs users compared to control group, which is in agreement [24,25]. Study that showed a highly significant reduction in HDL-C level in the study group when compared with the control group [22]. Noted that HDL-C level was insignificantly decreased among COCPs users compared to controls.

The presence of dyslipidemias in COCPs users has been reported by several other studies [14,16,21]. Found significant changes in the lipid profile levels among COCPs users reported that a significant increase in serum HDL-C level in COCPs users is mostly due to inhibition of hepatic lipase, the enzyme responsible for clearing HDL-cholesterol from the circulation by the hormone estrogen [26]. On the other hand yesmin stated that the progestin component of COCPs enhances hepatic lipase enzyme activity which increases the removal of HDL-C, hence decreasing the serum HDL-C levels [27].

The present study reported that there was a statistically insignificant increase in serum triglycerides in COCPs users as compared to control. Our results were in accordance with they revealed that oral estrogens and progestins in hormonal contraceptives have been shown to increase total cholesterol and triglycerides [22,28,29]. Also revealed in their study that the users of COCPs experienced significantly greater increases in levels of triglycerides and total cholesterol (p<0.001) [30]. Stated that COCPs induced increase in triglycerides is due to increased synthesis rather than decreased clearance.

Our study showed insignificantly increases in serum LDL-C and VLDL-C among COCPs users as compared to control. This finding is in line revealed that the mean levels ± SD of LDL-C and VLDL-C were significantly higher among COCPs users (p=0.0001, p<0.05 and p<0.001 respectively) compared to the control [18,23,29]. Our results are also consistent reported a statistically significant elevation in total cholesterol, HDL-C, LDL-C, and

triglycerides levels in COCPs users [31]. Similarly, the mean LDL-C and VLDL-C was significantly increased (p value 0.002 and 0.0001 respectively) [32]. On the other hand, no significant variations were found in serum triglyceride, LDL-C and VLDL-C in COCPs user [33].

Our findings showed statistically insignificant increase in LDL-C level among users compared to control which is inconsistent with [22]. Who reported that LDL-C was significantly decreased in COCPs users as compared to nonusers ($p<0.001$), which stated that these changes in the lipid profile levels can be attributed to the lipogenic effect of estrogen in which liver lipogenesis is increased and results in elevated levels of TG and LDL-C levels and also causes an increase in the synthesis of hepatic LDL-C receptors, resulting an increase in the removal of serum LDL-C and hence reduction in its levels. Our findings were in contrast with the results of who reported that there was non-significant effect of COCPs on LDL-C level [24]. Our study showed a significant increase in serum LDL-C with increased duration of COCPs intake ($p=0.017$) and highest in second year of use, this is in agreement with study which stated that an increase in LDL-C and VLDL-C was seen with duration of intake of oral pills, and in disagreement with which showed no significant correlation between period of using COCPs and effect in the lipid profile levels [34,24]. The present results showed the BMI in the women using COCPs was found to be insignificantly high when compared with control. Our results are consistent with the BMI in the women using COCPs was found to be significantly high ($p<0.0004$) when compared with control [32]. The current study revealed that when BMI increases, Lipid values also increase among COCPs users and showed that the mean HDL-C differs among normal, overweight, and obese category ($p<0.05$). This is in harmonization with the results from a systematic review by Halperin and colleagues, who reported that variation in average BMI of women, explained the heterogeneity found in HDL-C levels [17]. These changes can be attributed to BMI independently affecting lipid profile levels as reported by other studies [35,36], which indicate spotted a significant association between high BMI and the projection of lipids disorders.

Conclusion

In conclusion to this analysis, the study showed elevation in lipid profile among women using COCPs except for HDL-C which has a significant decrease according to increase duration of COCPs intake.

It is concluded that the use of combined oral contraceptives was linked with an undesirable lipid profile and BMI, which are considered metabolic risk factors for cardiovascular diseases development. Oral contraceptives were a major segregation in prevention of pregnancy and enhancing significant liberation of women. Based on composition, it is classified as combined (composed of estrogens and progestogens) and not combined (composed only of progestogens. The most accepted type of birth control and widely used is Combined Oral Contraceptive Pills (COCPs) it has been introduced in 1960, Its use is on increasing by women in child bearing age all over the world, especially in the recent years when various organizations and government are encouraging it's use for spacing pregnancy in developing countries.

Recommendation

Since lipid profile levels are not measured routinely in women using hormonal contraceptive in UAE and in order to prevent or at least reduce the risk of cardiovascular disease, women before starting COCP should be screened for lipid profile and followed up regularly while using contraceptives. Screening should particularly target women whose BMI is greater than 25 kg/m^2 for better management to decrease disease burden on the country.

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Limitation of the Study

Despite the highlights of the study, the methodology of sample size calculation may raise few concerns of generalization. Since it is a case control study, inclusion of adequate sample for a 1:3 case control ratio could not attain due to the challenges faced while collecting the data.

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