Original Article

Evaluation of Lipid Profile among Combined Oral Contraceptive Pill Users Attending Two Tertiary Level Hospitals in Bangladesh

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Abstract:

Background: Contraceptives are devices or techniques used to prevent pregnancy. In Bangladesh combined oral contraceptives are most commonly used birth control measures which contain two hormonal components either oestrogen and progesterone or only progesterone. However, it is known that the combination of different substances in contraceptives may have different effects on lipid profile. **Objectives:** The objective of the study was to evaluate the lipid profile among combined oral contraceptive pill users attending two tertiary level hospitals of Bangladesh. **Methods:** This cross-sectional analytical study was carried out in the family planning clinic of Dhaka Medical College Hospital (DMCH), Dhaka and Shaheed Tajuddin Ahmad Medical College Hospital (STAMCH), Gazipur, Dhaka during July 2022 to June 2023. A total of 94 female participants of 18 to 45 years of age were included in this study by consecutive considered as test group and rest 47 participants who did not use any hormonal contraceptives for last 36 months considered as control group. After taking informed written consent, 5 ml of fasting blood sample was collected for measurement of lipid profile of study participants. Then comparison of laboratory parameters with test group of the COCP users and control group was done. **Result:** There was a statistically significant ($p<0.05$) difference in the laboratory parameters (mean TC levels, TG levels, HDL-C levels, LDL-C levels) between the test group and the control group. In mean TC and LDL-C levels showed a significant ($p<0.05$) increase in the test group compared to the control group. In case of the mean TG and HDL-C levels, significant ($p<0.05$) rise was also observed in the test group compared to the control group. Overall serum lipid levels increased significantly ($p<0.05$) in the test group when compared with the control group. **Conclusion:** COCP use significantly increases serum lipid levels in females of reproductive age compared to the control group.

Key words: Combined oral contraceptives pills, lipid profile.

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Introduction:

Contraception is the act of preventing pregnancy and this can be a device, a medication, a procedure or a behaviour. The aim of contraception is to provide maximum comfort with minimum cost and side effects. To control unintended pregnancies various contraceptive methods are used[1,2]. Hormonal contraceptives include combined oral contraceptives pills (COCPs) (estrogen and progesterone), Progesterone only pills (POPs), Depot medroxyprogesterone acetate injection (DMPA) three monthly injection, Norethisterone-enanthate (NET-EN) two monthly injection, subdermal contraceptive implants and progesterone releasing intrauterine contraceptive devices (IUCDs)[3]. Wide spread use of hormonal contraceptive can affect various biochemical and metabolic risk factors. Metabolic risk factors include obesity, hypertension, type 2 diabetes mellitus and dyslipidemia[4,5]. In Bangladesh combined oral contraceptives are most common birth control measures and about 30% couples use oral contraceptive pills[6,7]. Combined oral contraceptives have been shown to alter lipid profile and produce different patterns of dyslipidaemia. Dyslipidaemia can be genetic in origin, but a variety of secondary factors including life style, other medical conditions and use of certain medication can exacerbate dyslipidemia[8].

In developing countries, dyslipidemia is a common public health problem. It is a condition which occurs due to abnormalities in the plasma lipids such as elevated plasma cholesterol TC, LDL-C, TG reduced HDL-C levels which

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occurs singly or in combination. The prevalence of dyslipidemia is higher among groups with higher educational level, higher income, subjects with family history of obesity, diabetes, hypertension, poor nutritional habit, and poor working condition and is increased with parity[9]. The effect of oral contraceptives on lipid levels depends on type and dose of estrogen and progesteron component, duration of use and route of administration and also to the androgenicity of the progesterone[10]. COCPs produce effect on lipid profile through the genomic pathway, involves estrogen receptor alterations affect hepatic apolipoprotein up-regulation. It has been suggested that oral contraceptives might exert their metabolic effects related to the synthesis and or turnover of lipids and lipoproteins, including total cholesterol (TC), triglycerides (TG), high-density lipoproteins (HDL), and low-density lipoproteins (LDL)[11].

Recent studies show that newer COCPs cause less upset in metabolic parameters. Various studies show that the extended use of estrogen associated with progesterone cannot be beneficial and may cause change in biochemical parameters which may lead to harmful event in body. These need to be confirmed in Bangladeshi women as diet, life style and BMI can affect pill induced changes. Therefore, considering the current doubts about the effect of combined oral contraceptives on the lipid in the body, the aim of this present study was to evaluate the possible changes on the lipid profile total cholesterol (TC), triglyceride (TG), high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C) in Bangladeshi women of reproductive age group taking combined oral contraceptive pills.

Methods:

This cross-sectional analytical study was conducted in the family planning clinic of Dhaka Medical College Hospital and Shaheed Tajuddin Ahmad Medical College Hospital, Gazipur after approval by Ethical Review Committee as well as permission from director of DMCH and STAMCH. Total 94 fasting blood samples were collected from participants after taking informed written consent. Sample size was calculated by using following formula.

$n = \frac{(z_\alpha + z_\beta)^2 \times (\sigma_1^2 + \sigma_2^2)}{(\mu_1 - \mu_2)^2}$. Here, n = sample size definite level of significance

$\mu_1 = 138.55$ (Mean of serum LDL level of non COCP users)

$\mu_2 = 188.82$ (Mean of serum LDL level of COCP users)

$\sigma_1 = 3.03$ (Standard deviation of non COCP users)

$\sigma_2 = 40.37$ (Standard deviation of COCP users)
(Khatun et al., 2020)

$z\alpha$ = Z value of standard normal distribution at 95% confidence level or 5% level of significance =1.96

$z\beta$ = Z value at 80% power =0.85

$$n = \frac{(1.96 + 0.85)^2 \times (3.03)^2 + (40.37)^2}{(138.55 - 188.82)^2}$$

n (number of study population) = $46.85 \approx 47$

Sample size 47 for each group.

They were chosen by consecutive sampling. All subjects were healthy 18-45 years, not taking hypolipidemic drug or any drugs affects lipid profile, non-lactating, and with no serious co-morbid diseases (thromboembolic disorder, hypertension, diabetes mellitus, stroke, chronic renal disease, chronic liver disease) and women with normal BMI range (18.5-24.9) kg/m^2.

Study groups:

Test Group: 47 participants, using COCPs, containing Ethinyl Estradiol and Desogestrel for 36 months.

Control Group: 47 participants (Not using any hormonal contraceptives last for 36 months)

With all aseptic precautions, 5ml of fasting blood sample were collected from participants with the help of sterile needle by venepuncture from the antecubital vein and kept in EDTAK3 (anticoagulant) containing test tube. Plasma was separated by centrifugation (3500 rmp for 10 minutes). Blood samples were analyzed by using automated analyzer by sysmex (XN-2000, Germany) and semi auto analyzer sysmex (XP-100), SIEMENS (IMMULITE 1000, USA), SELECTRA Netherlands, accurately programmed for analysis of serum lipid profile. Necessary data were collected according to the objectives of the study. Statistical analysis was carried out by using MS Excel and Statistical Package for Social Science (version 26.0).

Results:

This cross-sectional analytical study was conducted in the family planning clinic of Dhaka Medical College Hospital, Dhaka and Shaheed Tajuddin Ahmad Medical College Hospital, Gazipur during the period of July 2022 to June 2023. Total 94 female participants were enrolled in this study. The results were calculated by using different statistical tests. The findings are presented with tables and diagrams. In this current study, it was observed that the mean age for test group was 31.2 ± 7.0 years, and for control group was 30.4 ± 6.6 years. The range of age was from 18 to 45 years. In the present study, the mean Body Mass Index (BMI) values for test group and control group were observed to be 22.0 ± 1.9 kg/m² and 22.2 ± 1.8 kg/m² respectively. There was a statistically significant ($p<0.05$) difference in the mean total cholesterol levels and mean triglyceride levels between test group (P=0.001) and control group. Moreover, there was statistically significant ($p<0.05$) differences in HDL cholesterol levels between test group (P=0.001) and control group. There was a statistically significant ($p<0.05$)

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difference in LDL cholesterol levels between test group (P=0.001) and control group.

Table-I: Mean value of total cholesterol levels of test group of COCP users and control group (n=94)

Total cholesterol	Test Group (n=47)		Control Group (n=47)		p value
	n	%	n	%	
Low Risk	23	48.9	41	87.2	
Borderline Risk	17	36.2	6	12.8	
High Risk	7	14.9	0	0.0	
Mean ± SD	198.2±40.4		160.2 ±34.4		0.001[s]
Range (min-max)	(92-325)		(94-230)		

s = significant

Table-II: Mean value of triglyceride levels of test group of COCP users and control group (n=94)

Triglyceride	Test Group (n=47)		Control Group (n=47)		p value
	n	%	n	%	
Low Risk	4	8.5	20	42.6	
Borderline Risk	43	91.5	27	57.4	
High Risk	0	0.0	0	0.0	
Mean ± SD	218.6±53.7		158.5±56.7		0.001[s]
Range (min-max)	(92-360)		(67-294)		

s = significant

Table-III: Mean value of HDL cholesterol levels of test group of COCP users and control group (n=94)

HDL cholesterol	Test Group (n=47)		Control Group (n=47)		p value
	n	%	N	%	
High Risk	3	6.4	10	21.3	
Low Risk	44	93.6	37	78.7	
Mean ± SD	62.1±13.5		47.9±8.9		0.001[s]
Range (min-max)	(35-94)		(26-65)		

s = significant

Table-IV: Mean value of LDL cholesterol levels of test group of COCP users and control group (n=94)

LDL cholesterol	Test Group (n=47)		Control Group (n=47)		p value
	n	%	n	%	
Low Risk	19	40.4	43	91.5	
Borderline Risk	19	40.4	1	2.1	
High Risk	9	19.2	3	6.4	
Mean ± SD	141.3±30.6		96.9±29.7		0.001[s]
Range (min-max)	(56-210)		(42-195)		

s = significant

Discussion:

In the present study, the mean Body Mass Index (BMI) values for the test group and the control group were observed to be 22.0 ± 1.9 kg/m² and 22.2±1.8 kg/m² respectively. The analysis showed no statistically significant (p>0.05) difference in BMI between two groups. In a separate study conducted by Ferdous et al., (2019), the mean BMI for the case group and control group were reported as 22.48±1.46 kg/m² and 22.27±1.48 kg/m² respectively. The statistical analysis revealed no significant (p>0.05) difference between these two groups. Similarly, a study was investigated the BMI of cases and controls and found their mean values to be 21.67±2.11 kg/m² and 21.63±2.11 kg/m², respectively. The statistical analysis in this study also showed no significant difference (p>0.05) between the two groups[12].

In this current study, the mean total cholesterol levels were observed in the test group (198.2 ± 40.4 mg/dl) and the control group (160.2 ± 34.4 mg/dl). Notably, the test group exhibited a higher mean total cholesterol level (198.2) then the control group (160.2). Statistical analysis indicated a significant (p<0.05) difference in mean total cholesterol levels, with the test group showing significantly higher values compared to the control group. These findings suggest that the prolonged use of COCPs is associated with elevated total cholesterol levels. These findings were consistent with a study which reported that the combined oral contraceptive user group had a significantly higher mean serum total cholesterol level (194.1 ±53.0 mg/dl) compared to the control group (177.9 ± 40.8 mg/dl)[13]. Other studies also reported significantly higher mean serum cholesterol levels in study groups (196.5 mg/dl and 246.03±48.10 mg/dl) compared to the control group (181.4 mg/dl and 156.50±2.26 mg/dl), respectively (p<0.05). The increased serum total cholesterol in contraceptive users may be attributed to impaired lipoprotein metabolism[14,15].

In the current study, two groups were analysed for their mean HDL levels: the test group had 62.1 ± 13.5 mg/dl and the control group had 47.9 ± 8.9 mg/dl. There were statistically significant (p<0.05) differences in HDL cholesterol levels between two groups. Moreover, a significant (p<0.05) difference between the test group when compared with the control group. A study on serum HDL-C levels in COCPs groups finding a mean HDL-C (58.65 ±1.1 mg/dl) compared to non-users (48.17±0.54 mg/dl) which was similar to the finding of the present study[16]. Mustafa et. al.,[17] also found increased serum HDL-C level (45.94 ± 5.11 mg/dl) in the study groups compared to control groups (40.26 ±7.8 mg/dl).

In the current study, two groups were analysed for their mean LDL cholesterol levels: Test group had the highest mean of 141.3±30.6 mg/dl. Meanwhile, the control group showed a

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mean LDL cholesterol level of 96.9± 29.7 mg/dl. The comparison revealed significantly increased LDL cholesterol levels in the test group compared to the control group ($p<0.05$). Hamed conducted a study on serum LDL-C levels in a combined oral contraceptive group, finding a mean of 87.6±20.9 mg/dl. In the control group, the mean LDL-C level was 66.5±6.2 mg/dl, which was significantly higher in the combined oral contraceptive group ($p<0.05$). The study also highlighted that, oral contraceptives increased apolipoprotein B-100 synthesis, leading to elevated LDL-C levels. The rise in LDL-C levels in oral contraceptive users may be attributed to increased lipoprotein synthesis rather than impaired lipolytic catabolism, resulting in cholesterol accumulation and higher LDL-C levels[18]. Naz et al., found significantly higher mean levels of LDL-C (115.84±1.3 mg/dl) in the case group compared to the control (100.32±0.95 mg/dl)[16]. Faryal et al., also found significantly higher LDL-C level 123.1±14.6 mg/dl in the COCP groups compared to the control group 130.0±14.9 mg/dl. These results are closer to the findings of the current study[13]. In this study, the mean triglyceride levels in two groups were examined, and the results indicated that test group exhibited the highest average of 218.6 ± 53.7 mg/dl, followed by the control group with 158.5 ± 56.7 mg/dl. A statistically significant difference was observed in the triglyceride levels between the test group and the control group ($p<0.05$) indicating higher levels in the test group. In another study conducted by Hamed also examined the triglyceride levels in users of combined oral contraceptives and the control group. The mean serum triglyceride levels were 141.0±2 mg/dl and 95.3±15.1 mg/dl, respectively. Users of oral contraceptives showed significantly elevated triglyceride levels ($p<0.05$), suggesting a potential negative impact on cardiovascular risk due to increased triglycerides, potentially linked to VLDL production and transport[18]. Other studies conducted by Khatun et al., and Sultana et al.,[6, 19] also reported almost similar findings, with significantly higher serum triglyceride levels observed in oral contraceptive users 246.32±35.98 mg/dl and 190.30 ± 38.7 mg/dl compared to non-users 229.00 ± 24.52 mg/dl and 148.30±27.99 mg/dl respectively.

Conclusion:

The result of this study provides a general picture of lipid profile of women using COCPs visiting family planning clinic of DMCH & STAMCH compared to non-users. Women who received combined oral contraceptive pill containing 30 mcg ethinyl estradiol and 150 mcg desogestrel showed elevated levels of serum TC, TG, HDL-C, LDL-C.

Limitations:

There were some limitations in our study. The sample size was relatively small, and data was collected from only two centres of Bangladesh. This study may not reflect the exact picture of the whole country.

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