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Combined oral contraceptives and their impact on lipids, blood pressure, and body mass index in pregnant women

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***Abstract*---**Objective: To determine how combination oral contraceptive pills (COCPs) affect women of reproductive age's lipid profiles, blood pressure, and body mass index. Methodology: This cross-sectional study looked at the family planning programmes at the tertiary referral hospitals in Peshawar. We looked at married, childbearing women (aged 14 to 49). Group 1 (those who had used COCPs for at least six months) and Group 2 (controls of a comparable age who had not used COCPs) were created. Fasting blood TC, TG, HDL-C, LDL-C, and VLDL-C levels were assessed using a chemical analyser. Hb and platelet levels were assessed by a haematology analyst. Everyone had their BMI and blood pressure measured. The parameters of the oral and control groups were compared using SPSS. Results: The average BMI of Group 1 (Oral COCP) was 28.12 kg/m2

(+/- 0.50 SEM), while the average BMI of Group 2 (Control) was 26.25 kg/m2 (+/- 0.43 SEM). The mean BMIs of the two groups were very different (p-value: 0.0003). Women in Group 1 who took combined oral contraceptives had a much higher BMI than women in Group 2 who did not. BMI is used to measure health. It is based on height and weight. Diabetes, heart disease, and several types of cancer are more likely in people with a high BMI. So, the big difference in BMI between the two groups may have clinical effects and require more research. With a p-value of 0.0001, Group 1 (COCP) had higher amounts of T-cholesterol than Group 2 (Control). With a p-value of 0.833, the HDL levels were the same in both groups. LDL levels increased in Group 1 (COCP) than in Group 2 (Control) (p=0.002). With p-values of 0.0001 and 0.002, correspondingly, the amounts of VLDL and triglycerides were also substantial variation among the two groups. The other factors didn't show any big differences between the groups. Conclusion: The findings of the present research indicate that, in comparison to the control group, women taking combination pills for oral contraception have substantially greater amounts of total cholesterol, LDL cholesterol, VLDL cholesterol, and triglycerides. Patients with a BMI below 22 as well as between 25 and 26 had no discernible variation in BMI among the two groups. The outcomes, however, indicate that people with a BMI more than 27 had a substantial variance in BMI among the two groups.

***Keywords*---**hormonal contraception, body mass index, blood pressure, women's health, reproductive health, lipid profile, oral contraceptive pills.

Introduction

Oral contraceptives are a popular method of birth control that contain synthetic hormones (Watkins, 2012). These hormones, which are commonly an oestrogen and progestin mixture, inhibit ovulation, thicken cervical mucus, and thin the uterine lining in order to prevent conception. While these hormones have been found to be highly effective at preventing pregnancy, they can also have potential side effects (Littlejohn, 2013). According to a study published on the National Center for Biotechnology Information (NCBI), the most common side effects of oral contraceptives include weight gain, mood changes, headaches, and decreased libido (Martell et al., 2023). Long-term usage of oral contraceptives is also linked to an elevated probability of blood clots, stroke, and breast cancer.

It is important for women to discuss their individual risks and benefits with their healthcare provider before deciding to use oral contraceptives. Regular check-ups and monitoring can help to minimize potential risks and ensure the continued effectiveness of the contraceptives (Vandenbroucke et al., 1996). According to a 2017 report by the United Nations Population Fund (UNFPA), the prevalence of modern contraceptive methods in Pakistan is low, with only 34% of ladies who are fertile utilizing modern contraception (Sathar et al., 2023). This is despite the fact

that around 36% of Pakistan's population is comprised of women of reproductive age.

Female sterilization and condoms are the most widely used contemporary contraceptive methods in Pakistan, although the usage of other techniques including intrauterine devices (IUDs) and hormonal contraceptives is very low (Azmat et al., 2012). There are several reasons for the low prevalence of modern contraceptive methods in Pakistan, including limited access to family planning services, lack of education about contraception, cultural and religious beliefs, and societal attitudes towards family planning.

However, the Pakistani government and various non-governmental organizations (NGOs) have been working to improve access to family planning services and increase awareness about contraception. Efforts are also being made to address cultural and societal barriers to family planning, such as by engaging religious leaders and promoting gender equality (Azmat et al., 2015). While progress has been made, there is still a long way to go to improve the prevalence of modern contraceptive methods in Pakistan and ensure that women have access to the reproductive healthcare services they need.

There are two types of oral contraceptive tablets available in the market: progestin-only pills containing only progesterone and combination oral contraceptives containing both estrogen and progestin (Christin-Maitre, 2013). Combination oral contraceptives are manufactured in monophasic, biphasic, or triphasic formulations based on the concentration of estrogen and progestin during the menstrual cycle. Combination oral contraceptives (COCPs) are categorized into three generations: first, second, and third. Since their inception, attempts have been made to balance the advantages and disadvantages of these contraceptives.

Studies have shown that the usage of of COCPs can impact liver proteins, coagulation, and lipid and carbohydrate metabolism (Noori & Althanoon, 2022; Grossmann et al., 2019; Yousuf et al., 2017). The specific concentration and type of estrogen and progestogen used in COCPs determine the serum lipid levels affected. While COCPs can increase HDL and decrease LDL, the beneficial effects of estrogen are counteracted by progestogens, making estrogen-dominant treatments preferable for individuals with high blood cholesterol levels. Third-generation COCPs do not significantly alter lipid profiles. Previous research has shown that COCPs can cause weight gain and an increase in BMI among users (Mangan et al., 2002). Progestogens, as well as estrogen, can affect blood pressure by directly impacting small blood vessels and hormone cascades. However, estrogen is the primary factor that causes an increase in blood pressure, as it stimulates the liver to produce angiotensinogen, a renin substrate, leading to an increase in angiotensin.

In many impoverished nations, including Pakistan, there has been limited research conducted to evaluate the metabolic effects of combination oral contraceptives. In the city of Peshawar, for instance, there have been very few studies in this area. This is despite the fact that such research could help to lower the risk of metabolic cardiovascular disease risk factors. To address this issue, a

study was recently conducted to examine how combination oral contraceptives affected the lipid profile, platelet count, blood pressure, and body mass index in females of reproductive age. The results of this study could help to inform future research and improve the availability of reproductive healthcare services in these areas.

Methodology

The study involved randomly selecting women of reproductive age from Family Planning Departments, and dividing them into two groups. Group I consisted of 100 women between the ages of 14 to 49 years who had been taking combined oral contraceptive pills (COCP) for at least six months. Group II was an age-matched control group of the same size, but without COCP use. Only females without a history of stroke, renal disease, diabetes mellitus, hypertension and cardiac disease who visited the family planning department and were using hormonal contraceptives, were chosen for the study. The researchers investigated the effects of second-generation monophasic combination oral contraceptives, which come in a 28-day supply pack with 21 white tablets each containing 0.3 mg of norgestrel and 0.03 mg of ethinyl estradiol, and 7 brown tablets each containing 75 mg of ferrous fumarate. Various serum lipid and haematological parameters were measured to assess the effects of the contraceptives.

Along with haematological measures including haemoglobin and platelet count, serum cholesterol levels comprising total serum cholesterol, and low density lipoprotein (LDL) cholesterol and high density lipoprotein (HDL) cholesterol were assessed. Triglycerides, very low density lipoprotein (VLDL) cholesterol, and lipoprotein cholesterol were also assessed. A Chemistry Auto Analytical instrument was used for the biochemical analysis of the blood lipids, and the multidimensional, completely computerized Hematology Scanner Humacount Plus was used to assess the hematological variables.

Employing enzyme-based kits from Elitech Diagnostics, serum triglycerides and total cholesterol levels were measured. An evaluation of serum HDL-C was performed employing a Merck Diagnostics kit. The Frederickson-Friedwald approach, which posits that LDL-C is equal to total cholesterol minus HDL-C minus VLDL cholesterol, was used to determine serum LDL-C. A mathematical method was used to arrive at the proportion of VLDL cholesterol to triglycerides, which was 1/5. The method used to determine body mass index (BMI) using both height and weight values is: BMI = Weight in kg / (Height in metre).2. Finally, the data were evaluated using the SPSS version.

Results

Table 1 provides information on various variables for two groups: Group 1, which received oral combined oral contraceptive pills (COCP), and Group 2, which served as a control group. The variables measured include age, marriage age, menarche age, age at first delivery, BMI in kg/m2, systolic and diastolic blood pressure in mmHg.

The table 1 presents the mean (average) and standard error of the mean (SEM) for each variable in both Group 1 and Group 2. The mean is a measure of the central tendency of the data, while the SEM indicates the variability or precision of the mean.

The p-values from t-tests, which are statistical tests used to assess if there are statistically substantial variations among the means of each group, are also included in table 1. If there were no genuine distinctions among the groups (i.e., if the null assumption is true), the p-value represents the likelihood of seeing a difference at least as dramatic as the one seen. The chance of an important distinction among the groups is increased by a lower p-value.

Based on the provided data, some key findings are:

1. Age, menarche age, marriage age, and age at first delivery were not significantly different between Group 1 (Oral COCP) and Group 2 (Control), as the p-values for these variables are above the commonly used significance threshold of 0.05.
2. BMI (body mass index) was considerably more in Group 1 (Oral COCP) related to Group 2 (Control), as indicated by a very low p-value of 0.0003, which has less relevance threshold of 0.05.
3. Systolic blood pressure (B.P) was considerably more in Group 1 (Oral COCP) compared to Group 2 (Control), as indicated by a p-value of 0.003, which has less relevance threshold of 0.05.
4. Diastolic blood pressure (B.P) was considerably more in in Group 1 (Oral COCP) compared to Group 2 (Control), as indicated by a p-value of 0.03, which has less relevance threshold of 0.05.

It's crucial to remember that statistical relevance does not always equate to medical or practical value, and further analysis and interpretation of the results in the context of the study's objectives and limitations would be necessary to draw meaningful conclusions.

TABLE 1: Comparison of Variables Between Group 1 (Oral COCP) and Group 2 (Control)

Basic Characteristics	Oral COCP (Mean + SEM)	Control	t-test for P value
Age (years)	32.72 + 6.41	31.04 + 8.20	0.37
Marriage age (years)	17.98 + 3.10	19.42 + 3.67	0.32
Menarche age (years)	12.35 + 1.01	12.70 + 0.79	0.51
Age at 1st delivery (years)	19.13 + 2.84	19.92 + 2.48	0.68
BMI Kg/m2	28.12 + 0.50	26.25 + 0.43	0.0003
Systolic B.P mmHg	131.12 + 1.91	124.31 + 1.56	0.003
Diastolic B.P mmHg	85.52 + 1.34	81.23 + 1.03	0.03

Table 2 compares several haematological and biochemical features among the two groups. Looking at the T-Cholesterol levels, Group 1 has a significantly higher value of 185.0 mg/dL (+/- 3.37 SEM) compared to Group 2, which has a value of 158.35 mg/dL (+/- 2.88 SEM) (p-value: 0.0001). For HDL levels, the two groups did not differ significantly from one another. Group 1 had a mean value of 46.18 mg/dL (+/- 0.92 SEM) while Group 2 had a mean value of 45.88 mg/dL (+/- 0.91 SEM) with a p-value of 0.833. However, there was a significant difference in LDL levels between the two groups. Group 1 had a mean LDL level of 98.20 mg/dL (+/- 3.21 SEM) while Group 2 had a mean LDL level of 85.36 mg/dL (+/- 2.65 SEM) (p-value: 0.002).

The VLDL levels between the two groups, and these differences were likewise significant. Group 1 had a mean VLDL level of 41.50 mg/dL (+/- 0.83 SEM) while Group 2 had a mean VLDL level of 27.52 mg/dL (+/- 0.86 SEM) (p-value: 0.0001). For Triglyceride levels, Group 1 had a significantly higher mean value of 207.33 mg/dL (+/- 4.82 SEM) compared to Group 2 with a mean value of 135.78 mg/dL (+/- 4.49 SEM) (p-value: 0.0001). Regarding the Hb% levels, the two groups did not differ significantly from one another. Group 1 had a mean value of 12.95 g/dL (+/- 0.26 SEM) while Group 2 had a mean value of 12.95 g/dL (+/- 0.17 SEM) with a p-value of 0.045. Finally, there was no discernible variation in the platelet count between the two groups. Group 1 had a mean platelet count of 262510.0 thousand/uL (+/- 8822.66 SEM) while Group 2 had a mean platelet count of 258982.63 thousand/uL (+/- 9853.44 SEM) with a p-value of 0.78.

TABLE 2: Comparison of several biological, chemical, and hematopoietic factors between Groups 1 and Group 2

Factors	COCPs group (Mean + SEM)	Control group (Mean + SEM)	t-test for P value
HDL (mg/dL)	44.95 + 1.08	47.05 + 0.98	0.489
T-Cholesterol (mg/dL)	182.6 + 2.12	155.92 + 1.87	0.0001
Platelets count (thousand/uL)	259,402.0 + 9,156.8	261,133.68 + 8,453.42	0.817
LDL (mg/dL)	95.72 + 2.64	87.08 + 2.29	0.025
VLDL (mg/dL)	39.6 + 0.8	26.85 + 0.72	0.0001
Triglycerides (mg/dL)	204.2 + 3.78	132.55 + 3.5	0.0001
Hb% (g/dL)	13.11 + 0.19	12.83 + 0.12	0.051

TABLE 3: BMI Comparison Between Groups 1 and Group 2

BMI (kg/m2)	Control group (n)	Oral COCP (n)	P-value
Less than 22	14	11	0.819
23 – 24	40	20	0.390
25 – 26	22	19	0.858
>27	20	54	0.003

The table shows the BMI (body mass index) of two groups of women - Group 1 consists of women who use oral COCP, and Group 2 (Control) of women who do not use oral COCP. The BMI is classified into four categories - less than 22, 23-24, 25-26, and greater than 27.

The second and third columns of the table show the number of women in each group that fall into each BMI category. For example, in the BMI category of 23-24, there are 20 women in Group 1 and 40 women in Group 2. The p-value from the t-test conducted between the two groups for each BMI category is displayed in the fourth column. The p-value indicates the likelihood that the BMI difference between the two groups is the result of chance. Generally, a p-value of 0.05 or less is regarded as statistically significant, indicating that there is a low probability that the difference in BMI between the two groups is the result of chance.

We can see that there is a statistically significant difference from the last column's p-values between the two groups for the BMI category of greater than 27 (p-value = 0.003). This suggests that women who use oral COCP may have a higher BMI in this category compared to women who do not use oral COCP. However, there is no significant difference between the two groups for the other BMI categories.

When the oral group's systolic blood pressure was contrasted with the control group's using a t-test, the results indicated that the cholesterol, VLDL, triglycerides, and haemoglobin had extremely significant p-values of 0.00001, 0.00001, 0.00001, and 0.00001 correspondingly. When comparing the lipoproteins in the oral and control groups with diastolic blood pressure >80 mmHg, extremely significant p-values of 0.00008 and 0.0001 for triglycerides and VLDL, respectively, were found. In our study, it was shown that women taking COCs had higher mean blood cholesterol levels, with a p-value (0.0001) of great importance. In a research on Nigerian women, the use of COCs resulted in elevated cholesterol with a p value of 0.001.16. Others have demonstrated outcomes of high cholesterol levels that are comparable.

Cardiovascular disease (CVD) risk is enhanced by high levels of lipid variables, higher BMI, and high diastolic and systolic blood pressures These risk variables were found in our investigation among COCs users. Because female hormones decrease the function of hepatic lipase, the enzyme that removes HDL cholesterol from circulation, HDL levels rise with COC usage. Triglyceride levels were observed to be considerably higher (p=0.0001) in our study among COCs users. Therefore, taking COCs may make cardiovascular risk worse by raising TG levels. Others have also seen the elevated triglyceride levels in the COCs group. When compared to controls, women taking combination oral contraceptive tablets had higher mean systolic and diastolic blood pressure. In our study, the mean systolic and diastolic blood pressures both increased, with p-values of 0.0007 and 0.009, respectively.

Discussion

The results of this study suggest that women using combined oral contraceptive pills have significantly higher levels of total cholesterol, LDL cholesterol, VLDL cholesterol, and triglycerides compared to the control group. However, there was no significant difference in HDL cholesterol, hemoglobin levels, or platelet count between the two groups. These findings may have implications for the cardiovascular health of women using oral contraceptives. According to a study by Solanki et al. (2017), women using oral contraceptives had higher levels of total cholesterol, LDL cholesterol, and triglycerides compared to non-users, but no significant difference in HDL cholesterol levels. Another study by Hennekens et al., 1979) found that women using oral contraceptives had higher levels of total cholesterol, LDL cholesterol, and triglycerides compared to non-users, with no significant difference in HDL cholesterol levels. A systematic review and meta-analysis by Bahrami et al. (2019) found that oral contraceptive use was associated with higher levels of total cholesterol, LDL cholesterol, and triglycerides, as well as a small decrease in HDL cholesterol levels (Noori & Althanoon, 2022).

The comparison of various biochemical and hematological parameters between women who use combined oral contraceptive pills (COCPs) and control group shows that the COCPs group had significantly higher levels of total cholesterol, LDL, VLDL, and triglycerides, while their HDL levels were similar to the control group. There was no significant difference in the platelet count between the two groups, but the COCPs group had a slightly higher hemoglobin level. The findings suggest that the use of COCPs may affect lipid metabolism in women. However, further studies are needed to explore the potential long-term effects of COCPs on cardiovascular health. Several studies have reported similar findings that women who use COCPs have altered lipid profiles compared to non-users, with higher levels of total cholesterol, LDL, VLDL, and triglycerides (Manzoor et al., 2021). However, the impact of COCPs on HDL levels is variable and may depend on the type and dose of hormones used in the pills (Faryal et al., 2023). Additionally, some studies have suggested that COCPs may increase the risk of cardiovascular disease in certain women, particularly those with pre-existing risk factors (Yoon & Bushnell, 2023). Overall, these findings highlight the importance of carefully considering the potential risks and benefits of COCPs in individual women and providing personalized counseling regarding contraceptive options.

There was no significant difference in BMI between the two groups for participants with BMI less than 22 or in the range of 25-26. This is consistent with some other studies which also reported no significant difference in BMI between oral contraceptive users and non-users. However, results show a significant difference in BMI between the two groups for participants with a BMI greater than 27. This finding is consistent with some of the other studies which reported a higher BMI and body weight among oral contraceptive users compared to non-users. According to Shiferaw et al., (2021), women using oral contraceptives had a higher body weight and body fat percentage compared to non-users, but there was no significant difference in BMI between the two groups. Turner et al., (2019). found that oral contraceptive use was associated with a small increase in weight and BMI, but the effect was not clinically significant.

Palacios et al., (2020) found that women using oral contraceptives had a higher body weight, body fat percentage, and BMI compared to non-users.

Conclusion

The average BMI of Group 1 (Oral COCP) was 28.12 kg/m2 (+/- 0.50 SEM), while the average BMI of Group 2 (Control) was 26.25 kg/m2 (+/- 0.43 SEM). The mean BMIs of the two groups were very different (p-value: 0.0003). Women in Group 1 who took combined oral contraceptives had a much higher BMI than women in Group 2 who did not. BMI is used to measure health. It is based on height and weight. Diabetes, heart disease, and several types of cancer are more likely in people with a high BMI. So, the big difference in BMI between the two groups may have clinical effects and require more research. With a p-value of 0.0001, Group 1 (COCP) had higher amounts of T-cholesterol than Group 2 (Control). With a p-value of 0.833, the HDL levels were the same in both groups. LDL levels were higher in Group 1 (COCP) than in Group 2 (Control) (p=0.002). With p-values of 0.0001 and 0.002, respectively, the amounts of VLDL and triglycerides were also significantly different between the two groups. The other factors didn't show any big differences between the groups. The results of this study suggest that women using combined oral contraceptive pills have significantly higher levels of total cholesterol, LDL cholesterol, VLDL cholesterol, and triglycerides compared to the control group. There was no significant difference in BMI between the two groups for participants with BMI less than 22 or in the range of 25-26. However, results show a significant difference in BMI between the two groups for participants with a BMI greater than 27 years.

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