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Evaluation the effect of oral contraceptive pills on coagulation profile in Sudanese women in Shendi -Sudan

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Abstract

The most side effects associated with hormonal contraceptive use is predisposition to higher risk of thromboembolic phenomena. Progestins have antiplasmin and antithrombin activity. Its increase platelet count and aggregability, thus predisposing to hypercoagulability. A descriptive cross-sectional study was conducted in Shendi - Sudan during the period from April to August 2018 to evaluate the effect of contraceptive pills on coagulation tests (Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and platelets count). A total of eighty women were selected as volunteers according to inclusion criteria and considered as case, and other forty women not taken these pills, were selected and considered as control group. Seven ml of fresh venous blood were collected after filling the questionnaire, about (4.5) ml of blood was drawn in trisodium citrate solution as anticoagulant and (2.5) ml was drawn in EDTA container to perform the platelet count by using hematology analyzer (Mindray bc-3000), citrated blood was centrifuged at 3000 round/min for 15 minutes for preparation of platelets poor plasma (PPP). The PPP were tested for the PT and APTT by using the coagulometer instrument (Clot).

The results revealed that the mean of APPT, PT and platelet count in test group was (33.4 seconds, (14.0) seconds and 519.000c/cmm) respectively, while in control group was (30.7 seconds, (13.4) seconds and 271.000c/cmm) respectively. Statistical analysis showed that there was significant variation in APTT value in test group when compared with control group with P value of (< 0.05), also there was no significant variations was noticed in PT and with P value of (> 0.05), and significant variation was observed in count of platelet with P. value (<0.005) which indicate the hypercoagulability, significant changes were noticed between age groups, type of oral contraceptives and duration of uses. This study concludes that OCP users had more tendency of hypercoagulability and therefore these women are at higher risk of thromboembolic effects.

Keywords: Contraceptive pills; Sudanese women; Prothrombin Time; PPP; Platelet count

1 Introduction

Contraception is the use of various devices, drug agents, sexual practices or surgical procedures to prevent conception or impregnation (pregnancy). This process help couples plan when they want to have a child. The first available preparation of hormonal contraceptives contained a high dose of the estrogen EE2 which was linked to increased risk

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of thrombosis. Estrogen containing contraceptives particularly at a reduced dose can led to an additional risk reduction of venous thrombosis. (1)

Hormonal contraceptives are often associated with different side effects including; nausea, headache, breast tenderness, weight gain, irregular bleeding, and mood changes (2)

Oral pills most frequently used are hormonal contraceptives and commonly can lead to increased blood pressure, blood clots, heart attack and stroke.(3, 4)

In Europe and North America studies have noted that estrogen /progestogen oral contraceptives can be associated with myocardial infarction, thromboembolism and stroke commonly among women over the age of (35 years) and smokers.(5)

The reduction of the estrogen dose from (>50 μg to 30 μg) can be associated with a significant decrease in the risk of venous thrombosis.(6)

The cause of differences in the coagulation and haemostatic status between women using oral hormonal contraceptives from widely different geographical areas is not clearly understood.

WHO recommended that studies should be conducted in different settings to bring about a clearer picture.(7).

The common drastic adverse effect that associated with oral hormonal contraceptive use is predisposition to higher risk of thromboembolic phenomena. Progestins have antiplasmin and antithrombin activity,It's use increase platelet count and aggregability, thus predisposing to hypercoagulability. (8).

Study which done by Naess IA and his colleagues in 2007, demonstrated an increased rate of thrombosis of 1-3 per 100,000 individuals per year.(9)

Epidemiologic studies were found a relationship between oral contraceptive use and altered level of coagulation factor, platelet changes and thromboembolic phenomenon. (10)

O.C.P users developed estate of hypercoagulability that was indicated by the significant elevation of plasma fibrinogen level, factor XII, vitamin K dependent clotting factors and total count of platelets which can lead to thromboembolic episodes.(11,12,13)

Venous thromboembolism including:-pulmonary and deep venous thrombosis is the most common serious cardiovascular event among women who use oral contraceptives.

Women who are taking pills have three to six time's greater risk of venous thromboembolism than women who don't use this contraceptive method and risk increase with age, obesity and recent surgery.

The pills may influence the effect on coagulation and fibrinolytic markers as well as on lipid metabolism. (12)

2 Material and methods

The study was conducted in Shendi - Sudan, during the period from April to August 2018, and aimed to evaluate the effects of oral contraceptive pills on some coagulation tests including Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and platelet count. A total of 120 women were participating in the study, (80) of them using oral contraceptive pills are considered as test group and remaining (40) which don't use oral contraceptive, as a control group). Participants with coagulation disorders, pregnancy and unused of oral contraceptive pills were excluded from the study. The consent of the selected individuals to the study was taken after being informed with all detailed objectives of the study and its health benefit in future. Data were collected using self-administered pre-coded questionnaire which was specifically designed to obtain information. Seven ml of venous blood was collected, (4.5) ml of blood mixed with trisodium citrate in ratio1:9, while remaining (2.5) ml were collected in EDTA. Platelet poor plasma was obtained by centrifuging the citrated blood for 15 minutes at 3000 rpm to estimate PT and APTT by using coagulometer, platelet count was performed from EDTA blood by using haematology analyzer(Mindray bc-3000).

Ethical approval was obtained from the Faculty of Graduates Studies and Scientific Research, Shendi University. Verbal informed consent for participation was obtained from each participant before recruitment into the study.

Obtained Data were analyzed using SPSS computer program with a *P*-value less than or equal to 0.05 was considered significant.

3 Results

The results of study revealed that there was a significantly increase in APTT value and high Platelet count in test group when compared with control group as demonstrated in (Table 1).

Table 1 The mean of PT, APTT and platelet count among test and control group

Parameter	Group	Mean	P. value
PT/ seconds	Test	14.3	0.08
	Control	13.2	
APTT/ seconds	Test	32.1	0.003
	Control	29.7	
Platelet count ×109/L	Test	519	0.004
	Control	272	

Regarding the age of participant the results showed that there was significant variation in APTT and Platelet count with no effect on PT value as noted in (Table 2).

Table 2 The Mean of PT, APTT, and platelet count according to the age of the participants

Parameter	Age group / year	Mean	P. value
PT / seconds	≤30	14.0	0.35
	>30	13.6	
APTT/ seconds	≤30	36.2	0.05
	>30	33.5	
Platelet count ×109/L	≤30	535	0.04
	>30	291	

According the duration of contraceptives intake, the results revealed that was in significant variation in PT result and platelet count with significant variation in APTT result, as referred in (Table 3).

Table 3 The mean PT, APTT and platelet count according to duration of contraceptive intake

Parameter	Duration group/years	Mean	P. value
PT / seconds	5m-2y	13.8	0.92
	2y-5y	14.0	
APTT/ seconds	5m-2y	30.5	0.007
	2y-5y	35.4	
Platelet count ×109/L	5m-2y	316	0.65
	2y-5y	322	

Regarding the contraceptives type the results showed there were significant difference in the mean of PT,APTT and Platelet count result between usage of combined oral contraceptive (COC) and usage of progestin only pills (POP)mini pills), as demonstrated in (Table 4).

Table 4 Mean of PT, APTT and platelet count according to the type of oral contraceptive pills

Parameter	Type of contraceptives	Mean	P. value
PT / seconds	Combination	15.0	0.03
	Mini pills	14.1	
APTT/ seconds	Combination	36.2	0.01
	Mini pills	34.4	
Platelet count ×109/L	Combination	505	0.007
	Mini pills	290	

4 Discussion

This a descriptive cross-sectional study was conducted in Shendi -Sudan in the period from April to August 2018, and aimed to evaluate the effect of contraceptive pills on coagulation tests (Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT) and platelets count.

Regarding APTT, the statistical analysis showed that significant variation in the mean of APPT between test and control group with P.Value of (0.003). This results was similar to results of study which done by Mohieldin Elsayid and his colleagues.[14], Also there was significantly variation in Platelet count between test and control group with P.value of (0.004), while the PT value revealed no significant deference with P.value of (0.08), also this similar to results of study which done by Mohieldin Elsayid and colleagues.[14] Ahmed.J and Al-Husaynee [15] mentioned that there decrease in PT and APTT value, which not similar the results obtained by this study. Also the results of study which done by SawsanSalman and his colleagues [16] showed that there was no significant variation in PT and APTT.

Regarding to the age also there were significant difference in APTT and Platelet count with P.value of (0.05, 0.04) respectively, this result do not agreed to the results of study that done by Mohieldin Elsayid and colleagues. [14] Which notices that was no effect of age APTT. While PT values don't showed significant variation with P.value of (0.35), this result was similar to results of study done by Mohieldin Elsayid and colleagues. [14]Also this results was not similar the results of study which done by Sawsan Salman and his colleagues [16] which noted that there was no significant variation in APPT, while agreed regarding PT value.

Regarding the effect of contraceptives use duration on the mean of PT, APTT and platelet count results, statistical analysis revealed that there were insignificant difference in mean of PT and platelet count with P.value of (0.92, 0.65) respectively, while that there was significant difference in mean APTT result with P.value of (0.007). This results was not similar to the results of study which done by Sawsan Salman and his colleagues [16]

Also regarding the effect of contraceptives type on the mean of PT, APTT and platelet count), statistical analysis revealed that there were significant difference in PT, APTT and Platelet results between usage of combined oral contraceptive (COC) and usage of progestin only pills (POP)mini pills), with P.value of (0.03, 0.01 and 0.007) respectively. The results of PT and APTT were disagreeing with results of Mohieldin Elsayid and colleagues.[14] While the results of platelet count was similar to the results which noticed by Ahmed. J .Al-Husaynee and Muna A.Kashmooda. [15]

There was effect of age and type of contraceptive on coagulation profile. Regarding this study, it concludes that OCP users had more tendency of hypercoagulability and therefore these women are at higher risk of thromboembolic

5 Conclusion

The results concluded that the usage of contraceptive pills (COC & POP) show significantly variation in the APTT result when compare with control, no significant changes occurred in PT. On the other hand, significant increase in platelet count result. These findings were a sign of hypercoagulable state

Regarding to the results of the study the women that used Oral Contraceptive Pills had more tendency of hypercoagulability and therefore these women are at high risk of thromboembolic effects when compared with the women not used the pills.

We advise to use safe contraceptive method to reduce the risk of oral contraceptive pills.

Compliance with ethical standards

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Disclosure of conflict of interest

Authors declaring no competing interests.

Statement of ethical approval

Ethical approval was obtained from the *ethical committee of* Faculty of Graduates Studies and Scientific Research, Shendi University.

Statement of informed consent

Procedure of blood sampling was explained to participants. All participants were informed about the research objectives and procedures during the interview period. Verbal informed consent for participation was obtained from all participant include in the study.

References

[1] Levi M, Middeldorp S, Büller HR. Oral contraceptives and hormonal replacement therapy cause an imbalance in coagulation and fibrinolysis which may explain the increased risk of venous thromboembolism.

[2] Lidegaard O, Løkkegaard E, Svendsen AL, Agger C. Hormonal contraception and risk of venous thromboembolism: national follow-up study. Bmj. 2009 Aug 13; 339.

[3] Bonnar J. Coagulation effects of oral contraception. American journal of obstetrics and gynecology. 1987 Oct 1; 157(4):1042-8.

[4] Van Hylckama Vlieg A, Middeldorp S. Hormone therapies and venous thromboembolism. Journal of Thrombosis and Haemostasis. 2011 Feb; 9(2):257-66.

[5] Kunz F, Pechlaner C, Tabarelli M, Solder E, Zwierzina WD. Influence of oral contraceptives on coagulation tests in native blood and plasma. American journal of obstetrics and gynecology. 1990 Jul 1; 163(1):417-20.

[6] Van Hylckama Vlieg A, Helmerhorst FM, Vandenbroucke JP, Doggen CJ, Rosendaal FR. The venous thrombotic risk of oral contraceptives, effects of oestrogen dose and progestogen type: results of the MEGA case-control study. Bmj. 2009 Aug 13; 339.

[7] Afsar NA, Barakzai Q, Adil SN. Effect of a 'Progestin Only'Contraceptive On Platelet Aggregation In A Pakistani Set Of Population. Journal of Ayub Medical College Abbottabad. 2005; 17(3).

[8] Reid R, Leyland N, Wolfman W, Allaire C, Awadalla A, Best C, Dunn S, Lemyre M, Marcoux V, Menard C, Potestio F. Oral contraceptives and the risk of venous thromboembolism: An update: No. 252, December 2010. International Journal of Gynecology & Obstetrics. 2011 Mar; 112(3):252-6.

[9] Næss IA, Christiansen SC, Romundstad P, Cannegieter SC, Rosendaal FR, Hammerstrøm J. Incidence and mortality of venous thrombosis: a population-based study. Journal of thrombosis and haemostasis. 2007 Apr; 5(4):692-9.

[10] Toni .N.F. (1995).The pills Abrotifacaient of contraceptive, journal of the national catholic physican 5-10:-850.

[11] Burkman RT, Collins JA, Shulman LP, Williams JK. Current perspectives on oral contraceptive use. American journal of obstetrics and gynecology. 2001 Aug 1; 185(2):S4-12.

[12] Burkman, R, Schlesselman, ZiemanM, (2004). Safety concerns &health benefits associated with oral contraceptive .22:25. Volume 190, Issue 4, Supplement, Pages S5-S22

[13] Hoffbrand, A. V, Paul A.H.Moss (2016). Essential Haematology. Seventh Edition. Wiley Blackwell.

[14] Elsayid M, Elbasheer MA, Elgari MM, Elfaki TE. The Effect of Contraceptive Pills on Coagulation Tests among Sudanese Women in Khartoum State-Sudan. International Journal of Science and Research. 2015; 5(10):773-7.

[15] A Kashmoola M, J AL-Husaynee A. Effect of combined oral contraceptive pills on some haemostatic parameters. Annals of the College of Medicine, Mosul. 2007 Dec 28; 33(1):66-9.

[16] Salman ST, Hussein AA, Saadi RK. Effect of Combined Oral Contraception on Coagulation Profiles in Women Attending Fertility Control Clinic in Baqubah City-Iraq. Journal of the Faculty of Medicine Baghdad. 2018 Apr 1; 60(1):47-51.