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Venous and arterial thrombosis during oral contraceptive use in Libyan women

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Abstract: Birth control, known as contraception, can be defined as the use of medicines, devices, or surgery to prevent pregnancy. Hormonal contraceptive steroids are available mainly as oral preparations, although preparations for subcutaneous implantation and vaginal insertion have also been developed. There are two types of oral contraceptive pills: combined estrogen-progesterone and progesterone. The birth control pill is the most commonly prescribed form of contraception. Millions of women all over the world have used OCs for many years and Multiple prospective and case-control studies have shown that the currently available OCs are still associated with venous and arterial thrombosis, and that's what prompted us to do this study. OCs are a risk factor for myocardial infarction especially when there are other cardiovascular risk factors, such as, hypertension, diabetes, hypercholesterolemia, and obesity, and these risk factors increase with age. In addition, numerous alterations in blood proteins promote venous thrombosis, falling into one of three categories: increased procoagulants; decreased anticoagulants; and decreased fibrinolytics. A questionnaire was handed to patients (women aged 18 to 49) of gynecology clinics in the city of Misrata. The results showed that oral contraceptives are the most commonly used, and that contraceptives containing drospirenone plus ethenyl estradiol such as Yasmine are the most commonly used followed by levonorgestrel such as Microval. Most women used oral contraceptives under specialized medical supervision. However, many women who used oral contraceptives faced multiple side effects, most notably menstrual disorders. The results also showed that many women suffered from previous thrombo-vascular diseases, most notably CVDs and obstructive pulmonary diseases, which often appeared at an age of more than 30 years. Routine screening of all women for genetic risk factors before the prescription of an OC is not cost-effective. In addition, it would deprive a large number of women of the safest method of contraception.

Introduction

Delaying pregnancies in young girls who are at increased risk of health problems from early childbearing, are important health benefit of family planning [1-3]. About 214 million women of reproductive age in developing regions have an unmet need for contraception [4]. Most women use oral contraceptives (OCs) as a method for birth control and rarely use them for other reasons such as acne and dysmenorrhea [5]. Since the introduction of OCs, their use has been associated with an increased risk of venous and arterial thrombosis. The risk of venous thrombosis (VT) during low-dose OC use is a 3 to 6-fold increase compared with that of nonusers [1-3, 5]. Contraception is used to prevent pregnancy in different types; some are reversible, while others are permanent [6]. Although hormonal contraceptives and intrauterine contraception devices are effective at preventing

pregnancy, consistent and correct use of a condom reduces the risk for HIV infection and other STDs [7]. The most commonly prescribed pill is the combined hormonal pill with estrogen and progesterone [8, 9]. Less than one woman out of 100 will become pregnant in the first year of use [10]. Most women take OCPs to prevent pregnancy, but some use them for non-contraceptive reasons as menstrual-related disorders [11]. Strong epidemiologic evidence supports a 50.0% reduction in the risk of endometrial cancer among women who have used combined OCs. Combined OC decreases the risk of ovarian and colon cancer by about 25.0%; the longer the duration of use, the greater the risk reduction, and some formulations even have indications for the treatment of acne and hirsutism [10]. Progestogen negative feedback works at the hypothalamus to decrease the pulse frequency of the gonadotropin-releasing hormone [6]. The progestogen negative feedback and lack of estrogen positive feedback on LH secretion stop the mid-cycle LH surge with no follicle developed and no LH surge to release the follicle, thus, ovulation is prevented [10]. The mechanism of progesterone's ability to inhibit sperm from penetrating through the cervix and upper genital tract is by making the cervical mucous unfriendly [10, 11]. Any formulation of a combined (COC) pill can be used, but the monophasic pills are the easiest to manipulate [10]. It can be offered to women who have unprotected intercourse within 48 hours of initiating POP or missed a pill where backup contraception or abstinence was advised [12]. Women who have a pre-existing cardiovascular condition or who smoke should not use OCs. For the first six months, OC progestogens can impair glucose metabolism in healthy women, so, women with diabetes mellitus might need to increase insulin intake to regulate blood glucose levels within the desired range [13, 14]. OC pills can cause hypertension in healthy women and exacerbate hypertension in women with pre-existing hypertension. The use increases the risk of venous thrombotic events (VTE) during the first year of initiation. VTE risk increases with high ethinyl estradiol dose and 3rd and 4th generation progestin [6].

Venous and arterial thrombosis during OC use thrombosis is a frequently occurring serious side effect of combined OCs. It has been known that OC use is associated with an increased risk of cardiovascular disease. The majority of women who use OCs remain free of thrombotic events, but in combination with other acquired risk factors and in women with genetic thrombophilic defects OC use will often trigger thrombosis [5, 15]. VT occurs as deep vein thrombosis (DVT) of the leg and pulmonary embolism (PE). Although some patients with DVT have symptoms indicative of PE, half of the patients have unequivocal evidence of asymptomatic PE [5]. Mortality is higher for PE than for DVT because the diagnosis can be easily missed in previously healthy women [15]. Relative risks for fatal PE associated with OC use were found to be the same for older formulations and currently available combined OCs [5]. The first case-control study on VT reported a threefold increased risk in OC users which was soon confirmed by other studies. Estrogens were found to be responsible for the increased risk of thrombosis but certain discrepancies in the data already suggested that the dose of estrogen could not be the factor related to the risk of thrombosis [5], estrogen can increase the levels of clotting factors within the blood. These factors make it easier to clot and increase risk of DVT and PE [16]. The risk of VT disappears within three months after stopping OCs; that is the risk is immediate, reversible and does not accumulate [15]. A strong association has been found between cerebral sinus thrombosis and OC use and in synergy with factor V_{Leiden} and prothrombin 20210A [16]. The increased risk for third-generation OCs compared with OCs was found for cerebral venous sinus thrombosis [17]. Hemorrhagic stroke is caused by an arterial rupture**,** and spasm or dissection of the blood vessels has been associated with endogenous and exogenous sex hormones [18-21]. Smoking is a risk factor for arterial cardiovascular disease in young women especially when there are other cardiovascular risk factors [22]. A study involved 1214 participant divided into two groups showed higher thrombotic risk in women with a body mass index (BMI) ≥30 who used OCPs vs women with a normal BMI who did not use OCPs [23]. As the absolute risk of myocardial infarction is highly age dependent, OCs will have the most impact in older women. Another study involving 4560 participants showed an increase risk when aged more than 30 years [24]. A study involved 3284

participants divided into three group showed OCs increased the risk of VT 5-fold, and the risk of VT was positively associated with COCs [25]. In contrast to the progress that has been made in understanding the genetic contributions to VT, much still remains to be studied on the genetic base of arterial thrombosis. A major complication in the study of gene-environment interaction for arterial disease is a chronic process of atherosclerosis compounded by an acute thrombotic event, in contrast to VT, which is due to acute clot formation. Consistent associations with arterial thrombotic disease have not been found [26]. Elevations of the procoagulant factors decrease of the anticoagulant factors protein S and antithrombin are consistent effects of OCs on the hemostatic system [27]. The underlying mechanisms are unknown, upon cessation coagulation parameters returned to normal within three months [28]. A study involving 62 women showed, F XII was significantly increased in the group that used COCs, which led to increased thrombotic risk [29].

Acquired Activated Protein C (APC) resistance is an impaired plasma anticoagulant response to APC *in vitro*, after the discovery of inherited poor anticoagulant response to APC resistance as a risk factor for familial VT, Factor V_{Leiden} is the most common cause of inherited APC. Acquired APC resistance without the presence of factor V_{Leiden} was recognized in OC users and is the major epidemiologic observations explaining the increased risk in OC users. Acquired APC resistance is best measured with an APC sensitivity assay based on the endogenous thrombin potential, in which coagulation is initiated through the extrinsic pathway, which proved to be sensitive to exogenous factors than the commonly used activated partial thromboplastin time-based test. Women who used third-generation OCs had almost the same degree of APC resistance as carriers of factor V_{Leiden} without OC use. Women with APC resistance related to factor V_{Leiden} are most susceptible to acquired APC resistance associated with OC use, probably due to a gene-environment interaction [29-31]. During OC use protein S and antithrombin levels decrease, women with inherited antithrombin deficiency developed VT during OC use or pregnancies earlier in life than women with inherited protein S deficiency. Antithrombin levels decrease more with gestodene-containing OCs than with levonorgestrel-containing contraceptives. In a randomized controlled trial free and total protein S from users of desogestrel-containing OCs were decreased more than from users of levonorgestrel-containing OCs. APC resistance is higher in COCs with levonorgestrel than those with desogestrel and may be affected by first-pass hepatic metabolism [30, 32]. Factors OCs induce changes in fibrinolytic parameters, but changes in the fibrinolytic system have not been associated with VT. High levels of TAFI have been found to be a mild risk factor for VT. Fibrinogen increases considerably during OC use, which may contribute to the increased cardiovascular risk, possibly in particular to the risk of arterial disease. The rise of fibrinogen was dependent on estrogen dose and smoking [33, 34]. Thus, as OC use is remarkably increased, this study aimed to investigate the association of OC use with an increased risk of venous and arterial thrombosis in Libya.

Materials and methods

A total of 410 questionnaire papers were handed to the participants (women aged 18 to 49) of Gynecology clinics in the city of Misrata, Libya during 2024 in order to determine the proportion of use of OCS, different types used, their side effects and their association with thrombosis cases. The questionnaire contained nine questions. An ethical approval was obtained from the University of Misrata, UoM-2024.

Results

In **Figure 1**, 157 answers were collected and the results were as follows: *Have you ever used a contraceptive* showed that 71.7% of entries used a contraceptive, versus 28.3% of females who did not use a contraceptive. *If your previous answer is yes, what type of contraceptive is used* showed that pills OCs are the most commonly used contraceptives (49.0%), followed by condoms, and injections (both at 10.0%).

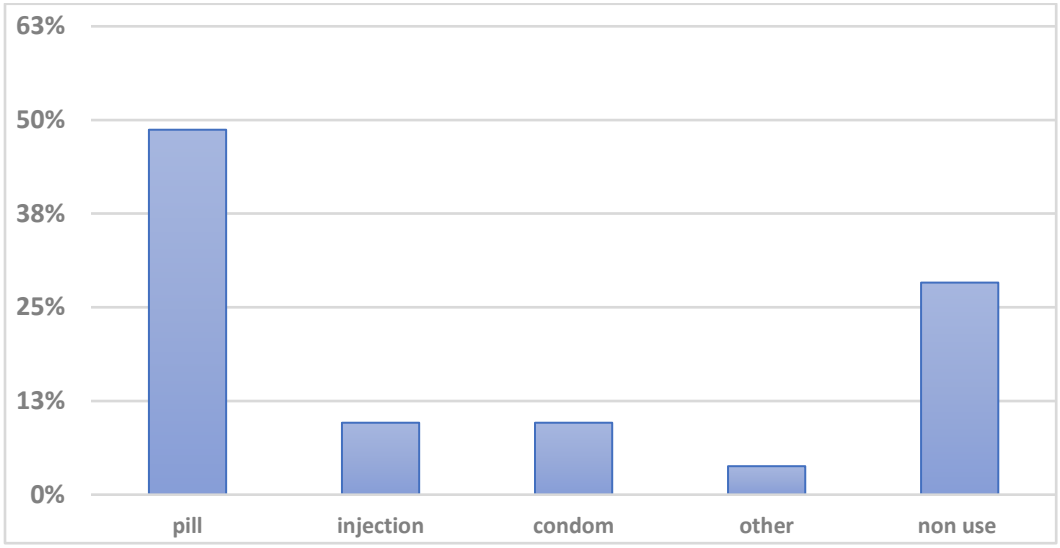

Figure 1: The type of contraceptive used

In **Figure 2**, *If you use an oral contraceptive, which of the following formulations has been used* drosperinone plus ethenyl estradiol was the most commonly used (42.0%), followed by levonorgestrel-containing drugs such as Microval (19.3%), then cyproterone-ethenyl-estradiol-containing drugs such as Diane (12.9%). Finally, norethisterone-containing drugs such as Primolut N are the least used (9.7%).

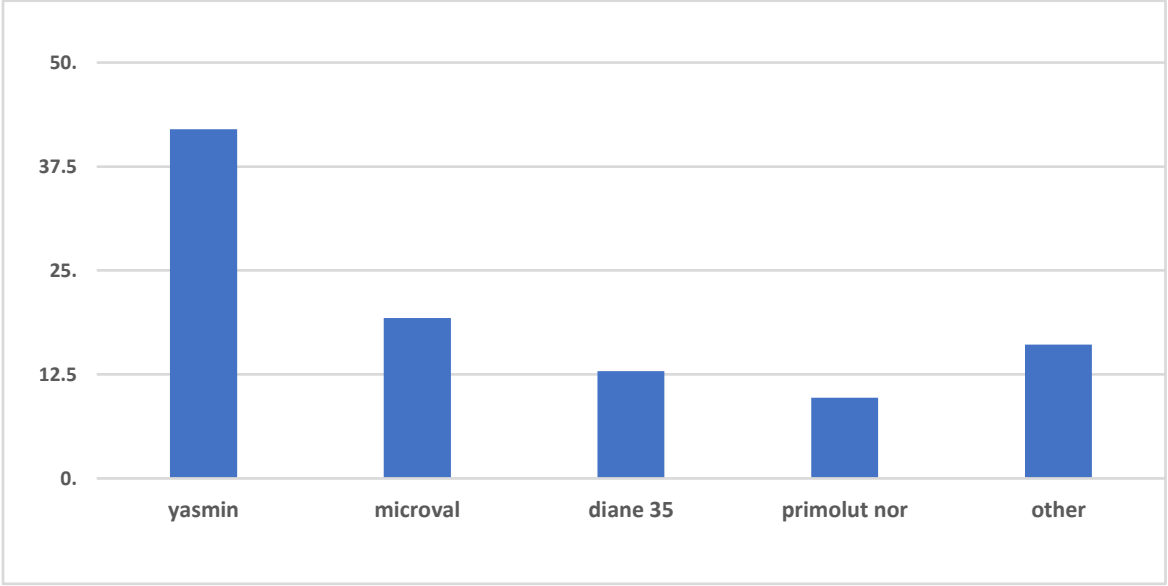

Figure 2: The type of oral contraceptive used

The findings of the following: *Was your use of oral contraceptives under specialized medical supervision?* Findings more than three quarters of the participants (78.0%) used OCs under specialized medical supervision, compared to 22.0% of those who used the contraceptive randomly and without consulting a specialist doctor. This indicates a high level of awareness among women about the need to take OCS under specialized medical supervision. *After taking an oral contraceptive, which of the following symptoms have you experienced?* **Figure 3** shows the results of the questionnaire showed that menstrual disorder is the most common side effect of COCs (38.6%), followed by abdominal cramping (17.3%), then headaches (13.4%), and nausea was the least common (11.5%).

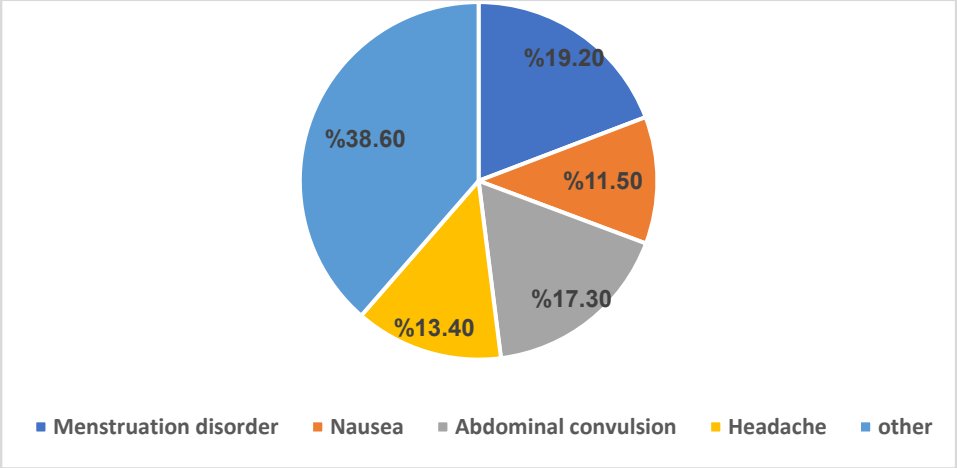

Figure 3: Side effects related to the use of oral contraceptives

Figure 4 shows the results of *Have you ever had one of the following diseases:* Cardiovascular disease, PE, the results showed that most participants did not suffer from any previous diseases. But about a quarter of participants suffered from cardiovascular disease or PE.

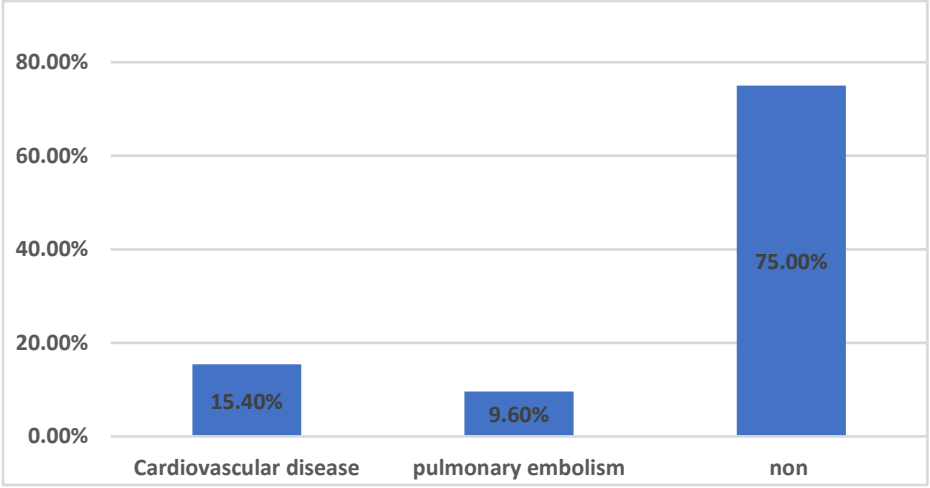

Figure 4: Previous cardiovascular disease or pulmonary embolism

How old were you when you had a previous illness: Although most females did not have a previous thrombotic disease, thrombotic disease often occurs in women older than 40 years (**Figure 5**).

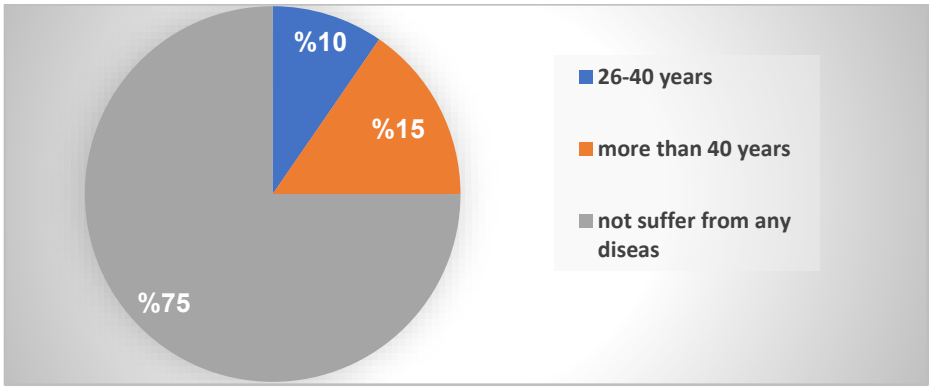

Figure 5: The age of the previous illness

If you have a previous illness, has your doctor changed the oral contraceptive? The results showed that the clinician often switches the OC used in case of previous thrombosis, or in case of some side effects (**Figure 6**).

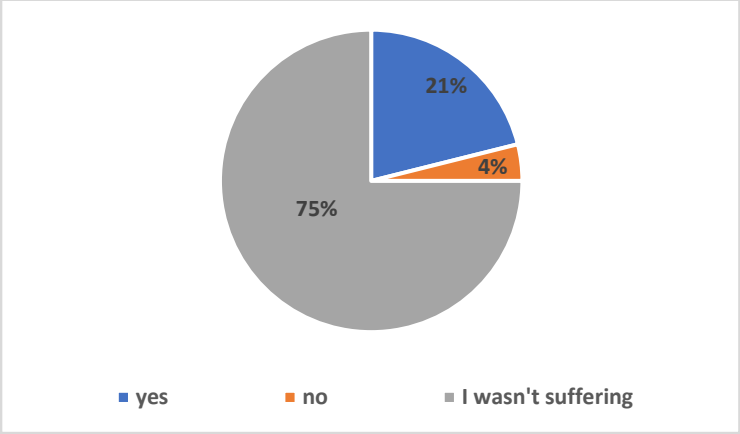

Figure 6: The response of the clinician to the reported illness

If you have any observations about oral contraceptives, please mention them: Observations varied as it emerged that there were females who suffered from the side effects of OCs whcih caused them to lose hair, become overweight, have poor eyesight, and experience stress. Conversely, it appeared that there were females who did not suffer any side effects and used contraceptives comfortably. The questionnaire directed at females showed that OCs are the most commonly used, and that contraceptives containing drospirenone plus ethenyl estradiol such as Yasmine are the most commonly used followed by levonorgestrel such as Microval. Most women used the OCs under specialized medical supervision. However, many women who used OCs faced multiple side effects, most notably abdominal cramping and menstrual disorders. The results also showed that many women suffered from previous vascular diseases, most notably CVDs and obstructive pulmonary diseases, which often appeared at an age of more than 40 years. When there are curd diseases, the physician often resorts to replacing the drugs which are often oral combined contraceptives.

Discussion

Oral contraceptives are the most commonly used and consist of several mono or composite formulations. But OCs possess many side effects that often reduce their use. OCs increase the incidence of thrombocytosis, this percentage increases if a woman has previous thrombocytopenia, so the physician may resort to replacing the type of OC. The use of contraceptives was common as this study shows 71.7% of entries used a contraceptive versus 28.3% of females who did not use a contraceptive, which correlates with the previous publications in this field. The findings were compatible with the previously published studies, which suggest that the most used type of contraception is OCs at 50.0%. There are several types of contraceptive pills that have been officially labeled because they have shown reliability in preventing conception from occurring, and among those OCs we found that COCs (brand name Yasmin) were the most commonly used at 42.0% [35]. The most commonly experienced symptoms or side effects of COCs were menstrual disorder (38.6%), followed by abdominal cramping (17.3%). 15.4% of the participants suffered from cardiovascular disease and around 9.7% PE. Other observations variable and included: loss of hair, overweight, poor eyesight and stress. On the other hand, it appeared that there were females who did not suffer any side effects and used contraceptives comfortably. Combined OCs containing ethinylestradiol and a progesterone are associated with an increased risk of VTE. This association is considered to be related to COC induced changes in coagulation, anticoagulation and fibrinolysis in a prothrombotic

direction, which alter the hemostatic balance. These changes have more impact in women who are already at increased risk of VTE, for instance because of pre-existing hereditary thrombophilia. The risk of VTE occurring with estrogen and third-generation progestins in combination preparations increases the extent of adverse hemostatic changes and the associated risk of thrombosis and thus should not be the first choice for new users. Routine screening of all women for genetic risk factors before prescription of an OC is not cost effective. In addition, it would deprive a large number of women of the safest method of contraception because a growing number of genetic risk factors for VT have been discovered. Moreover, it would prevent a small number of deaths due to PE. In patients with a previous VTE, myocardial infarction, stroke, or peripheral arterial occlusive disease, OCs should not be used except for women receiving anticoagulation therapy or having specific individual circumstances, since all monophasic combined OCs are equally effective for birth control, the safest brand should be chosen. Previous studies have shown that the relative risk of VT is elevated by OC use in young users and COCs and third-generation of progesterone led to higher risks of VT than second generation OC [36]. Among young women, VT is more common than arterial disease, formulations with low-dose ethinyl estradiol and a second-generation (levonorgestrel) progestagen should, therefore, be preferred to minimize the risk of VT. The effect of age should be taken into account, and conventional risk factors for cardiovascular disease should be identified in individual women before prescription of OCs. The risk of cardiovascular disease increases exponentially in older age, especially in combination with other risk factors [37]. Therefore, women over 35 years and women with a genetic defect should be informed about alternative methods of contraception before prescription of OCs and special attention should be given to conventional risk factors. OC use should not be discouraged in all women with familial thrombophilia, as the risk of an unplanned pregnancy brings an increased risk of thrombosis, which may be higher than that during OC use. It is most important to make these diagnostic work-up in case of complaints [38]. There is significant decrease in total protein and globulin levels in the women serum used pregestational agents in comparison with control group, because of the longtime using to pregestational agents cause a decrease in the total protein and reduction of some amino acid in plasma and globulin. There is increase in lipids levels in the women serum used pregestational agents in comparison with control group [39]. In general, contraceptives containing the progestins norethindrone, norgestrel, or levonorgestrel have the strongest androgenic effects and have the biggest potential to trigger hair loss [1]. Effectiveness of hormonal contraceptives may be related to metabolic changes in obesity or to greater BMI or body fat. Hormonal contraceptives include OCs, injectable, implants, hormonal intrauterine contraception (IUC), the transdermal patch, and the vaginal ring. Given the prevalence of overweight and obesity, the public health impact of any effect on contraceptive efficacy could be substantial [40-44].

Conclusion: Current available OCs increased markedly the thrombosis risk, the highest risk of venous thrombosis was found in high doses of estrogen. VT is a more common disease than arterial thrombosis, in the younger age groups, but arterial events are slightly more frequently lethal. The relative risk is about fourfold increased for venous and twofold increased for arterial thrombosis. The risk of VT in OC users is high in women with genetic risk factors for thrombosis, and the risk of arterial thrombosis is high in women with classical cardiovascular risk factors. VTE recurs in about a third of surviving patients within the next decade. The small but definite increased risk of venous and arterial thrombosis indicates that a history of a thrombotic event is a contraindication to using OCs and hormone replacement therapy. Although the absolute risk of a thrombotic event during OC use is low, the reduction of known risk factors for cardiovascular disease, in smoking and hypertension, should be stressed. All patients with a previous arterial thrombotic event should be monitored periodically for optimal management of conventional risk factors.

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الخثار الوريدي والشرياني أثناء استخدام موانع الحمل الفموية لدى النساء الليبيات

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الملخص: يمكن تعريف تنظيم النسل، أو منع الحمل، بأنه استخدام الأدوية أو الأجهزة أو الجراحة لمنع الحمل. تتوفر موانع الحمل الهرمونية بشكل رئيسي على هيئة أقراص فموية، على الرغم من تطوير مستحضرات للزرع تحت الجلد والإدخال المهبلي. يوجد نوعان من حبوب منع الحمل الفموية: حبوب الإستروجين والبروجسترون المركبة، وحبوب البروجسترون فقط. تُعد حبوب منع الحمل أكثر وسائل منع الحمل شيوعًا. استخدمت ملايين النساء حول العالم حبوب منع الحمل الفموية لسنوات عديدة، وقد أظهرت العديد من الدراسات المستقبلية ودراسات الحالات والشواهد أن حبوب منع الحمل الفموية المتوفرة حاليًا لا تزال مرتبطة بتجلط الأوردة والشرايين، وهذا ما دفعنا لإجراء هذه الدراسة. تُعد حبوب منع الحمل الفموية عامل خطر للإصابة باحتشاء عضلة القلب، خاصةً عند وجود عوامل خطر أخرى لأمراض القلب والأوعية الدموية، مثل ارتفاع ضغط الدم، وداء السكري، وارتفاع الكوليسترول، والسمنة، وتزداد هذه العوامل مع التقدم في السن. بالإضافة إلى ذلك، فإن العديد من التغيرات في بروتينات الدم تعزز تجلط الأوردة، وتندرج ضمن إحدى الفئات الثلاث التالية: زيادة عوامل التخثر؛ انخفاض مضادات التخثر؛ وانخفاض عوامل انحلال الفيبرين. تم توزيع استبيان على مريضات (نساء تتراوح أعمارهن بين 18 و49 عامًا) من عيادات أمراض النساء في مدينة مصراتة. أظهرت النتائج أن موانع الحمل الفموية هي الأكثر استخدامًا، وأن موانع الحمل التي تحتوي على دروسبيرينون بالإضافة إلى إيثينيل إستراديول مثل ياسمين هي الأكثر استخدامًا تليها الليفونورجستريل مثل ميكروفال. استخدمت معظم النساء موانع الحمل الفموية تحت إشراف طبي متخصص. ومع ذلك، واجهت العديد من النساء اللائي استخدمن موانع الحمل الفموية آثارًا جانبية متعددة، أبرزها اضطرابات الدورة الشهرية. أظهرت النتائج أيضًا أن العديد من النساء عانين من أمراض الأوعية الدموية الخثارية السابقة، وأبرزها أمراض القلب والأوعية الدموية وأمراض الانسداد الرئوي، والتي غالبًا ما تظهر في سن أكثر من 30 عامًا. الفحص الروتيني لجميع النساء بحثًا عن عوامل الخطر الوراثية قبل وصف موانع الحمل الفموية ليس فعالاً من حيث التكلفة. بالإضافة إلى ذلك، فإنه سيحرم عددًا كبيرًا من النساء من أكثر طرق منع الحمل أمانًا.