

## UNDER WHAT CONDITIONS IS UTERINE MYOMA IN WOMEN OF REPRODUCTIVE AGE ASSOCIATED WITH THE USE OF COMBINED ORAL CONTRACEPTIVES?

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### RESUME

*Uterine myoma (UM) is a common benign tumor of smooth muscle cells of the myometrium, which is often associated with metabolic disorders. Hormonal contraceptives are used to control the duration and volume of menstrual bleeding in UM. At the same time, data on the relationship between the use of combined oral contraceptives (COCs) and uterine myoma are contradictory.*

**The aim.** To identify the relationship between uterine fibroids and the use of combined oral contraceptives in women of reproductive age, taking into account their ethnicity and the presence of metabolic disorders.

**Materials and methods.** The results of a re-analysis of a cross-sectional study conducted earlier in Eastern Siberia (2016–2019) are presented. A total of 1347 women of reproductive age ( $34.33 \pm 6.37$  years) were included in the study, of which 198 participants had uterine fibroids. The study methods included a questionnaire survey, general clinical and gynecological examinations, pelvic ultrasound, and statistical analysis.

**Results.** It was found that an increase in the likelihood of detecting uterine fibroids is associated with the use of COCs in the presence of metabolic syndrome and only in the Caucasian subpopulation (OR 3.287; 95% CI (1.490; 7.253)). The use of COCs is a factor associated with uterine fibroids in women with a BMI of more than  $30 \text{ kg/m}^2$ , due to the subpopulation of Caucasian ethnicity, for whom the likelihood of having uterine fibroids is 6 times higher when using COCs than when not using COCs (OR 6.253, 95% CI (1.857; 21.054)). For Caucasians, the association between COC use and uterine fibroids was also demonstrated in patients with a BMI of less than  $25 \text{ kg/m}^2$  (OR 2.521; 95% CI (1.255; 5.064)).

**Conclusion.** In women of reproductive age, the association between uterine fibroids and the use of combined oral contraceptives is observed in women of Caucasian ethnicity. The presence of metabolic disorders is a key co-factor in the association between uterine fibroids and the use of hormonal contraceptives.

**Keywords:** uterine fibroids, ethnicity, combined oral contraceptives, body mass index, and metabolic syndrome

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## ПРИ КАКИХ УСЛОВИЯХ МИОМА МАТКИ У ЖЕНЩИН РЕПРОДУКТИВНОГО ВОЗРАСТА АССОЦИИРОВАНА С ПРИЕМОМ КОМБИНИРОВАННЫХ ОРАЛЬНЫХ КОНТРАЦЕПТИВОВ?

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### РЕЗЮМЕ

*Миома матки (ММ) — распространенная доброкачественная опухоль из гладкомышечных клеток миометрия, которая часто ассоциирована с метаболическими нарушениями. Гормональные контрацептивы используются для контроля за длительностью и объемом менструальной кровопотери при ММ. В то же время, данные о взаимосвязи приёма комбинированных оральных контрацептивов (КОК) и миомы матки противоречивы.*

**Цель исследования.** Выявить связь миомы матки и приёма комбинированных оральных контрацептивов у женщин репродуктивного возраста с учетом этнической принадлежности и наличия метаболических нарушений.

**Материалы и методы.** Представлены результаты ре-анализа проведённого ранее в Восточной Сибири кросс-секционного исследования (2016–2019 г.). Всего в исследование было включено 1347 женщин репродуктивного возраста ( $34,33 \pm 6,37$  лет), из которых 198 участниц имели миому матки. Методы исследования: анкетный опрос, общеклиническое и гинекологическое исследование, УЗИ органов малого таза, статистические методы анализа.

**Результаты.** Установлено, что увеличение вероятности обнаружения миомы матки связано с приемом КОК при условии наличия метаболического синдрома и только в субпопуляции европеоидов (ОШ 3,287; 95% ДИ (1,490; 7,253)). Приём КОК является фактором, ассоциированным с миомой матки, у женщин с ИМТ более  $30 \text{ кг/м}^2$  за счет субпопуляции европеоидной этнической принадлежности, для которых вероятность наличия ММ при использовании КОК в 6 раз выше, чем без применения КОК (ОШ 6,253, 95% ДИ (1,857; 21,054)). Для женщин европеоидной этногруппы связь приема КОК и миомы матки продемонстрирована также при ИМТ менее  $25 \text{ кг/м}^2$  (ОШ 2,521; 95% ДИ (1,255; 5,064)).

**Заключение.** В репродуктивном возрасте ассоциация миомы матки и приёма КОК характерна для женщин европеоидной этнической принадлежности. Основным вмешивающимся фактором для реализации потенциала роста миомы матки с применением гормональных контрацептивов является наличие метаболических нарушений.

**Ключевые слова:** миома матки, этническая принадлежность, комбинированные оральные контрацептивы, индекс массы тела, метаболический синдром

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Uterine myoma (uterine leiomyoma, uterine fibroid) is a benign tumor that originates from the muscular layer of the uterus (myometrium) [1]. According to population studies, its prevalence reaches 14.7 % [2]. Risk factors for developing UM include certain ethnicities, older age, menstrual and reproductive history, and the presence of metabolic disorders [3]. The main symptoms reported by patients with uterine myoma include menstrual cycle disorders, in particular, abnormal uterine bleeding [4]. To reduce menstrual blood loss and duration, obstetrician-gynecologists often prescribe hormonal contraceptive methods for women who are not trying to conceive [1, 5, 6, 7]. At the same time, the impact of modern low- and micro-dose COCs on the size and number of myomatous nodes, as well as their growth, is still a subject of debate [8, 9]. Therefore, it has been established that when triphasic COCs are used in patients with interstitial uterine myomatous nodes, there is a significant reduction in the size of these nodes after 12 months. In contrast, previously healthy women of reproductive age who do not use COCs are more likely to be diagnosed with uterine myoma for the first time compared to healthy women who are taking these medications [7]. In their review, Krzyżanowski J. et al. concluded that further studies are needed to confirm the potential protective role of COCs with regard to the risk of uterine myoma [8]. Other researchers believe that COCs do not diminish uterine fibroid volume or uterine size. Moreover, they have minimal effects on other fibroid-related symptoms, making their use for fibroid treatment limited [9]. In contrast, our study demonstrated association between the use of COCs and the development of uterine fibroids [3]. The heterogeneity of the data available may be attributed to the multifactorial nature of uterine fibroids. When interpreting associations between these fibroids and COCs use, it is essential to consider the potential impact of metabolic disorders and ethnic background.

## THE AIM OF THE STUDY

To identify the relationship between uterine fibroids and the use of combined oral contraceptives in women of reproductive age, taking into account their ethnicity and the presence of metabolic disorders.

## MATERIALS AND METHODS

The article presents the results of a re-analysis of data collected between 2016 and 2019 as part of a cross-sectional epidemiological study [3]. Women residing in Irkutsk, Bokhan (Irkutsk Region), and Ulan-Ude (Republic of Buryatia), who were undergoing annual health check-ups at their workplaces, were invited to take part in the study.

**Inclusion criteria:** reproductive age (18–44 years inclusive) and informed consent to participate

in the study. The study excluded women who were currently pregnant or breastfeeding, those who had undergone bilateral hysterectomy and/or appendages, endometrial ablation, and/or uterine artery embolization, or who refused to participate in the study. A total of 1,347 women (mean age  $34.33 \pm 6.37$  years) were enrolled in the study. The ethnic distribution was as follows: 867 (64.37 %) were Caucasian, 361 (26.80 %) were Asian, and 119 (8.83 %) were mixed Caucasian-Asian participants. The main characteristics of the study population are presented in Table 1.

One hundred ninety-eight out of 1,347 study participants had uterine fibroids. No significant differences in the composition of the contraceptives used were found between the groups of women with and without uterine fibroids who were taking COCs (Table 2).

The study methods included a questionnaire, general medical examination, anthropometric assessment (including body mass index (BMI) calculation), blood pressure measurement, gynecological examination, and pelvic ultrasound using the Mindray M7 (MINDRAY, China) transvaginal (5.0–8.0 MHz) and transabdominal (2.5–5.0 MHz) transducers.

**Biochemical testing methods:** serum glucose and triglyceride levels were measured spectrophotometrically using commercially available BioSystems reagent kits on a BTS350 biochemical analyzer (Spain). Total cholesterol and HDL-C levels were also measured spectrophotometrically using the same commercial reagent kits and the same analyzer. These measurements were necessary for diagnosing metabolic syndrome. Metabolic syndrome was diagnosed in accordance with the NCEP ATP III criteria (Third Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults) criteria (2001) [10] in the presence of 3 out of 5 criteria: an increased waist circumference, increased fasting glucose levels, triglycerides levels  $\geq 1.7$  mmol/L ( $\geq 150$  mg/dL) or the use of medications to manage this condition, HDL cholesterol levels  $< 1.04$  mmol/L ( $< 50$  mg/dL), SBP  $\geq 130$  mmHg or DBP  $\geq 85$  mmHg or the treatment of previously diagnosed hypertension. Fasting plasma glucose was assessed using optimized criteria published in 2004, with values  $\geq 5.6$  mmol/l ( $\geq 100$  mg/dl) [11]. Waist circumference was measured according to the diagnostic criteria proposed by the International Diabetes Federation (2006) [12]. These criteria define a WC  $\geq 80$  cm as an indicator of metabolic syndrome, which is consistent with the consensus criteria established by the Russian Association of Cardiologists [13]. The characteristics of anthropometric measurements and the main parameters that characterize the presence or absence of metabolic syndrome in women with and without uterine fibroids are presented in Table 2.

The study was conducted in accordance with the ethical guidelines outlined in the World Medical Association's Declaration of Helsinki (1964, as amended in Brazil in October 2013), and the study protocol was approved

by the Biomedical Ethics Committee of the Scientific Center for Family Health and Human Reproduction Problems (protocol No. 2.1 dated February 24, 2016).

**Statistical Analysis**

The sample size calculation was carried out using the interactive software “PS: Power and Sample Size Calculation” version 3.1.2 (Vanderbilt University, USA, 2014). Data entry and storage was performed using the REDCap information system, hosted on the server of the Scientific Center for Family Health and Human Reproduction Problems [14]. Logistic regression models were employed in the study. The results of the analysis are presented

in the form of odds ratios (ORs) and 95% confidence intervals (CIs) for factors considered potentially significant relative to the hypotheses tested, and to assess their contribution to the risk/anti-risk process. Data analysis was conducted using statistical methods implemented in R, version 4.0.3 (R Core Team 2024).

**RESULTS**

As a result of a re-analysis of data from a previously conducted epidemiological study [2], it has been found

**TABLE 1**  
**AGE, ANTHROPOMETRIC PARAMETERS AND BLOOD PRESSURE OF WOMEN INCLUDED IN THE STUDY WITH AND WITHOUT UTERINE FIBROIDS**

Parameter	All women N = 1347	Women with uterine myoma N = 198	Women without uterine myoma N = 1149	p
	Mean±Std.Dev Median (Lower Q;Upper Q)			
Age, years	34.33 ± 6.37	38.95 ± 4.34	33.54 ± 6.32	<0.001*
Height, cm	163.09±6.00 163.00 (159.00; 167.00)	162.55±6.11 162.00 (159.00; 166.00)	163.19±5.98 163.20 (159.00; 167.00)	0.164*
Body weight, kg	68.42±15.13 65.90 (57.50; 76.20)	72.45±16.17 68.30 (61.20; 80.20)	67.72±14.84 64.90 (57.00; 75.45)	<0.001**
BMI, kg/m <sup>2</sup>	25.73±5.53 24.73 (21.55; 28.53)	27.43±5.96 26.27 (23.46; 30.36)	25.43±5.40 24.44 (21.36; 28.29)	<0.001**
BMI, kg/m <sup>2</sup> , n/N (%)				<0.001**
< 18.5	50/1345 (3.72)	3/197 (1.52)	47/1148 (4.09)	
≥ 18.5 and < 25	656/1345 (48.77)	75/197 (38.07)	581/1148 (50.61)	
≥ 25 and <30	375/1345(27.88)	63/197 (31.98)	312/1148 (27.18)	
≥ 30 and <35	165/1345(12.27)	30/197 (15.23)	135/1148 (11.76)	
≥ 35 and <40	69/1345(5.13)	16/197 (8.12)	53/1148 (4.62)	
≥ 40	30/1345(2.23)	10/197 (5.08)	20/1148 (1.74)	
Waist circumference, cm	78.29±12.85 76.00 (69.00; 85.00)	81.65±13.11 80.00 (72.00; 88.00)	77.73±12.73 76.00 (68.00; 85.00)	<0.001**
Systolic blood pressure, mmHg	122.65±13.86 122.00 (113.00; 130.00)	128.17±16.61 127.00 (118.00; 138.00)	121.69±13.11 121.00 (113.00; 129.00)	<0.001**
Diastolic blood pressure, mmHg	78.93±9.958 79.00 (72.00; 85.00)	82.39±10.75 82.00 (75.00; 88.00)	78.33±9.69 78.00 (71.00; 84.00)	<0.001**
Glucose >5.6, mmol/l	1093/1347 (81.14%)	163/198 (82.32%)	930/1149 (80.94%)	0.646
HDL <1.2, mmol/L	865/1347 (64.22%)	124/198 (62.63%)	741/1149 (64.49%)	0.613
TG ≥1.7, mmol/l	67/1347 (4.97%)	15/198 (7.58%)	52/1149 (4.53%)	0.068

Note. \* t-test, \*\* U-test, \*\*\* χ<sup>2</sup> test.

TABLE 2

## COMPOSITION OF COCs IN WOMEN WITH AND WITHOUT UTERINE FIBROIDS TAKING COCs

Types of COCs	All women taking COCs n/N, % N = 133	Women with uterine myoma taking COCs n/N, % N = 19	Women without uterine myoma taking COCs n/N, % N = 114	p
Estradiol hemihydrate + Nomegestrol acetate	1/133 (0.75%)	0/19 (0.00%)	1/114 (0.88%)	0.682
Estradiol valerate + Dienogest	2/133 (1.5%)	1/19 (5.26%)	1/114 (0.88%)	0.147
Ethinyl estradiol + Gestodene	32/133 (24.06%)	6/19 (31.58%)	26/114 (22.81%)	0.408
Ethinylestradiol + Desogestrel	30/133 (22.56%)	3/19 (15.79%)	27/114 (23.68%)	0.446
Ethinylestradiol + Drospiridone	24/133 (18.05%)	2/19 (10.53%)	22/114 (19.30%)	0.357
Ethinylestradiol + Dienogest	17/133 (12.78%)	3/19 (15.79%)	14/114 (12.28%)	0.671
Ethinylestradiol + Levonorgestrel	14/133 (10.53%)	1/19 (5.26%)	13/114 (11.40%)	0.419
Ethinylestradiol + Cyproterone acetate	5/133 (3.76%)	1/19 (5.26%)	4/114 (3.51%)	0.710
Ethinylestradiol + Chlormadinone acetate	3/133 (2.26%)	1/19 (5.26%)	2/114 (1.75%)	0.340
The composition of COCs is unknown	5/133 (3.76%)	1/19 (5.26%)	4/114 (3.51%)	0.710

that among the general population, the use of COCs is associated with uterine fibroids, particularly among individuals with a BMI  $\geq 30$  kg/m<sup>2</sup> (OR 4.795, 95% CI (1.997; 11.517)), mainly due to Caucasians with a BMI  $\geq 30$  kg/m<sup>2</sup>, for whom the risk of having UM when using COCs is 6 times higher than without using COCs (OR 6.253 95% CI (1.857; 21.054)). A feature of women of Caucasian ethnicity is the association of UM and the use of COCs even among women with a normal (less than 25 kg/m<sup>2</sup>) BMI (OR 2.521; 95% CI (1.255; 5.064)) (Fig. 1).

This study confirmed the previously reported association between UM and the presence of metabolic syndrome. When examining the association between UM and COC use, we found that this association was specific to women with MetS (OR 2.285; 95% CI (1.231; 4.242)), and was stronger in Caucasian women (OR 3.287; 95% CI (1.490; 7.253)) (Fig. 2).

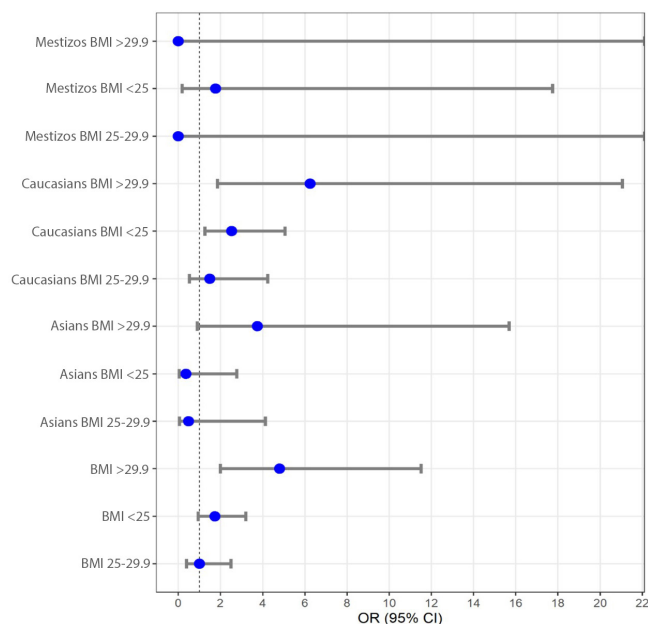
## DISCUSSION

This study investigated the relationship between uterine fibroids and COC use, depending on the presence or absence of metabolic disorders, among women from the main ethnic subgroups in Eastern Siberia. The study included women of reproductive age. A positive association was observed between the presence of uterine fibroids and the use of COCs among women with a BMI  $\geq 30$  kg/m<sup>2</sup>. According to one hypothesis regarding the development of uterine fibroids, estrogens play a primary role in their pathogenesis. Since adipose tissue serves as a depot for steroid hormones, primarily

estrogens, the risk of uterine fibroid development naturally increases in individuals with metabolic disorders such as overweight and obesity [15]. This likely explains the positive association observed between uterine fibroids and COC use among women with a BMI  $\geq 30$  kg/m<sup>2</sup>. Elevated BMI has previously been identified as potential risk factor for uterine fibroids [16], but this study is the first to demonstrate its role as a confounding factor in the association between COC use and MM. Further analysis revealed that this association is predominantly present in Caucasian women. Nevertheless, our data suggest that in Caucasian women, an association between MM and COC use can be observed even among women with a BMI below 25 kg/m<sup>2</sup>.

This study confirmed the previously reported association between MM and metabolic syndrome, which has been shown to occur even with in individuals with normal BMI values. Therefore, the possible role of MetS as a potential modifying factor in the association between MM and COC use was explored. Results showed that the association between MM and COC use is specific to women with MetS, particularly those of Caucasian ethnicity. Strengths of this study include a large sample size, lack of selection bias (non-hospital-based participants), and multi-ethnic composition of the participants. This study is the first to examine the association between uterine fibroids and COC use, while considering the participants' ethnic background and the presence or absence of common metabolic conditions.

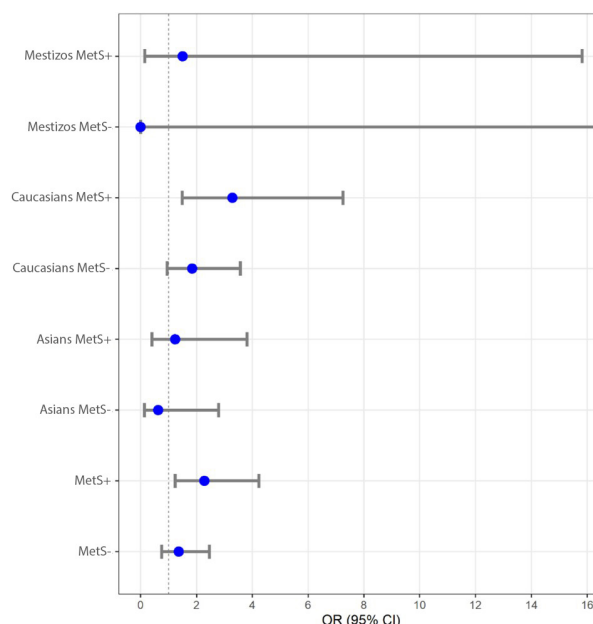
However, given that the study design did not involve long-term follow-up of patients, but rather a single, time-sensitive analysis, the data collected do not



Abbreviations: BMI – body mass index, OR – odds ratio, CI – confidence intervals.

**FIG. 1.**

Associations of MM with the use of COCs, depending on BMI, in the general population and in different ethnic groups



Abbreviations: MetS (metabolic syndrome), OR (odds ratio), CI (confidential intervals).

**FIG. 2.**

Associations between uterine fibroids and the use of COCs, depending on the presence of metabolic syndrome in the general population and in different ethnic groups

allow for drawing conclusions about causality when discussing the associations between COC use and the presence of uterine fibroids.

## CONCLUSION

Therefore, it has been determined that during the reproductive age, the correlation between uterine fibroids and COC use is primarily observed in Caucasian women. A significant contributing factor to the association between uterine fibroids and the hormonal contraceptive use is the presence of metabolic disorders. Large-scale prospective studies are needed to clarify the potential role of COCs in the development of uterine fibroids.

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2. No. 121022500180-6 titled "Pathophysiological Mechanisms and Genetic-Metabolic Predictors of Maintaining Reproductive Health and Longevity in Different Age, Gender, and Ethnic Groups".

## Conflicts of interest

No potential conflict of interest relevant to this article reported.

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