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Comparative Study of Clinical and Laboratory Parameters When Prescribing Complex Therapy to Postmenopausal Women with a History of PCOS

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ABSTRACT

A comparative study of clinical and laboratory parameters was conducted when prescribing complex therapy to postmenopausal women with a history of PCOS. Depending on the type of prescribed therapy, groups of patients with hyperglycemia and impaired glucose tolerance were formed, they underwent MHT in combination with drugs for the correction of insulin resistance. It was revealed that MGT in the composition with drospirenone, prescribed to women with menopausal complications with PCOS in the anamnesis, relieves menopausal disorders, has a favorable effect on the lipid profile, prevents the development of fatal complications of menopause. However, the addition of insulin sensitizers to complex therapy demonstrated significant significant differences in the levels of the studied parameters, which made it possible to achieve a significant increase in the effectiveness of the therapy.

KEYWORDS: *menopause, polycystic ovary syndrome, menopausal disorders, MHT, correction of insulin resistance*

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INTRODUCTION:

In recent years, considerable attention has been paid to metabolic disorders in postmenopausal women. Disorders of carbohydrate and lipid metabolism in combination with a physiological decrease in the hormonal function of the ovaries in menopausal women are considered an independent risk factor for the development of atherosclerosis, coronary heart disease, hypertension and hyperlipidemia [3,4]. The purpose of menopausal hormone therapy (MHT) in the correction of menopausal disorders is to prevent long-term complications of menopause. An important aspect in determining the indications and duration of MHT is, along with the advantages of the therapy used, the risk assessment for each woman.

The choice of a drug for MHT in patients with a history of PCOS and hyperandrogenism containing the progestogen drospirenone, which has an antiandrogenic effect, is more appropriate. In the conducted studies, it was proved that the progestogen drospirenone is metabolically neutral, does not affect glucose tolerance and insulin resistance [7,9].

The aim of this study is to compare the effectiveness of complex therapy of estrogen – progestogenic MHT and drugs that have a therapeutic effect on insulin resistance in postmenopausal patients with a history of PCOS.

MAIN BODY

Materials and methods of research. The criteria for including women in the study were: postmenopause, the presence of menopausal disorders, an indication of a history of polycystic ovary syndrome, the woman's consent to the examination. We studied the clinical manifestations of menopausal disorders in a group of women with a history of PCOS in the dynamics of treatment. The average age of the patients was 52.5±1.06 years. Before the start of

therapy, the examination included a consultation with a gynecologist with an assessment of individual and family history. Ultrasound examination of the pelvic organs, mammography, smear assessment for oncocytology, determination of blood sugar, blood lipid spectrum, hemostasiogram indicators and hormonal profile – follicle-stimulating hormone, estradiol, thyroid hormones, prolactin, total testosterone, globulin-binding sex hormone, electrocardiogram were performed. The key role of insulin resistance in the pathogenesis of PCOS is known, for many years such an insulin sensitizer as metformin was considered a possible therapeutic option for solving these problems. Recently, metformin has been used to treat patients with insulin resistance and hyperinsulinemia to improve ovarian function and increase the effectiveness of ovulation stimulation in women with infertility. It is known that metformin increases the affinity of receptors for insulin and stimulates the receptor and post-receptor stages of insulin signal transmission. Despite the fact that there is a significant positive experience of using metformin for several decades, numerous side effects of the drug do not allow using it for a long time. The most common side effects of metformin are gastrointestinal disorders, including a "metallic" taste in the mouth, decreased appetite, diarrhea, intestinal colic, metformin is more often associated with gastrointestinal side effects than most other drugs in this group. Long-term use of metformin may be associated with an increase in homocysteine levels and impaired absorption of vitamin B12, early detection and prevention of such conditions is recommended. The most severe side effect when using metformin is a high risk of developing lactic acidosis. It was also found that metformin reduces the level of thyroid-stimulating hormone in the blood of patients with hypothyroidism.

In this regard, the search for therapeutic alternatives is an urgent direction. One of the promising methods of correcting insulin resistance in recent years is the use of Myo-Inositol. The research results indicate that Myo-inositol affects the functioning of the reproductive system by stimulating the effects of gonadotropins. Myo-inositol is one of the varieties of inositol hexatomic alcohols. Inositol exists in nine possible stereoisomers, of which only one form is present in a living cell – myo-inositol. It is myo-inositol that acts as a transmitter of the signal for regulating intracellular calcium levels, a signal from the insulin receptor, participates in the breakdown of fats and lowering cholesterol levels in the blood, modulating the activity of neurotransmitters, etc.[10]. It is the participation of myo-inositol in such signaling cascades that explains its role in supporting metabolic (in particular, sugar metabolism) processes. PCOS is comorbid with insulin resistance and compensatory hyperinsulinemia. For complex therapy, we used the combined drug Inotir, which contains five active components, the interaction of which is synergistic: in addition to Myo-inositol, Inotir contains L-tyrosine, Selenium, Folic acid and chromium Picolinate. L-tyrosine is an important amino acid and acts as a precursor to many hormones (thyroxine, dopamine, epinephrine, norepinephrine). Tyrosine also increases the synthesis of sex hormone binding globulin. Selenium is necessary for the biosynthesis of a large number of selenoproteins involved in the metabolism of thyroid hormones with the help of selenium-dependent iodothyronine (type I, II and III), which controls hormonal homeostasis. Selenium is also an antioxidant and its activity is due to its ability to neutralize reactive oxygen species. Folic acid is responsible for cell growth and maintaining the integrity of DNA. Folic acid is necessary for the functioning of the immune, hematopoietic, cardiovascular systems and the synthesis of amino acids. Chromium picolinate contributes to the normalization of lipid and carbohydrate metabolism, reducing the risk of alimentary obesity and metabolic syndrome. Chromium is also a mineral that is involved in regulating the action of insulin. All components of Inotir act synergistically at different levels of development of insulin resistance and ovarian dysfunction.

Depending on the type of prescribed therapy, groups of patients with hyperglycemia and impaired glucose tolerance were formed, 86 women turned out to be such. Group 1 included 40 women who underwent combined treatment with Metformin at a dose of 850 mg/day in combination with MHT in a monophasic mode with drospirenone content. The 2nd group included 46 women. All women in this group received combined treatment with a drug containing inositol (Inotir) at a dose of 1000 mg/day in combination with MHT.

RESULTS AND DISCUSSION

The effect of the drug correction on the parameters of lipid metabolism is presented in Table 1.

Table 1 Results of the study of lipid metabolism in menopausal women with PCOS in the anamnesis in the dynamics of complex treatment

Studiedparameters	Initial data (n =174)	MHT + Metformin (n =40) Igroup	MHT + Myo-Inositol (n =46) II group
BMI, kg/m2	29,7±0,4	28,1±1,1	27,6±0,8*
Waist/hip circumference	1,1±0,0	1,0±0,01*	0,9±0,01*
Cholesterol, mmol/L	6,5 ± 0,1	5,9±0,2*	5,8±0,1*
Triglycerides, mmol/L	3,9±0,1	3,1±0,1*	3,0±0,1*
HC-HDL (mmol/L)	0,6±0,0	1,1±0,06*	1,2±0,01*
HC-LDL (mmol/L)	4,7±0,1	4,1±0,1*	4,0±0,1*
AI	3,9 ± 0,1	3,7±0,2*	3,4±0,1*

Note: * p< 0.05 compared to the original value.

According to the results, in group I of women who took combined treatment with Metformin in combination with MHT, BMI decreased from the initial indicator – 29.7±0.4 to 29.1±1.1, but the difference is unreliable. In group II of women, a significant decrease in BMI to 28.7±0.8 was noted against the background of complex administration of MHT and Myo-Inositol (Inotir). In the dynamics of treatment, statistically significant changes in the indicator W/HC in both groups, but more significant changes occurred in the second group of women. If before the start of therapy the initial indicator was at the level of 1.1±0.0, then measured after 24 weeks of therapy was 1.0±0.01 in group I and 0.9±0.01 in group II patients.A comparative analysis of lipid metabolism revealed the following. A more pronounced decrease in the level of total cholesterol in the blood serum was observed in group II of patients, where the indicator decreased from 6.5 ± 0.1 mmol/l to 5.8±0.1 mmol/l. In group I of women, there was also a significant decrease in TH – to 5.9±0.2 mmol/l, but it was less significant. A similar trend can be traced in the dynamics of a decrease in the level of TG. Thus, the triglyceride levels decreased in both study groups, but it was less significant – 3.1±0.1 mmol/l in group I, while in group II the TG level decreased to 3.0±0.1 mmol/l, which is significantly lower compared to the initial value of 3.9±0.1 mmol/l.The pronounced dynamics was revealed in the change in the LDL fraction, the decrease of which was significant in group II of women, where the indicator decreased from 4.7±0.1 mmol/l to 4.0±0.1 mmol/l. A significant increase in the level of HDL fraction was observed in both groups: initially 0.6±0.0 mmol/l, after 24 weeks of treatment – 1.1±0.06 mmol/l and 1.2±0.01 mmol/l. The dynamics of the level of the atherogenicity index during treatment revealed its statistically significant decrease in the groups of women receiving combined treatment. The atherogenicity index decreased to 3.8±0.2 in group I and 3.4±0.1 in group II, compared with the initial value of 8.3±0.2.

The effect of the drug correction on the indicators of carbohydrate metabolism was also studied (Table 2).

Table 2 Results of a study of carbohydrate metabolism in menopausal women with a history of PCOS in the dynamics of treatment

Studied parameters	Initial data (n =174)	MHT + Metformin (n =40) Igroup	MHT + Myo-Inositol (n =46) II group
Glucose (fasting), (mmol/L)	5,6 ± 0,1	5,4 ± 0,2**	5,1 ± 0,2 **
Glucose (after 2 h) (mmol/L)	7,1 ± 0,1	7,0 ± 0,2*	6,8 ± 0,2**
HbA_{1c} (%)	7,9 ± 0,1	6,8 ± 0,2*	5,9 ± 0,1**
Insulin (pmol/L)	11,9 ± 0,2	11,4 ± 0,4*	10,8 ± 0,4**
HOMA-IR	1,6 ± 0,0	1,5 ± 0,0**	1,4 ± 0,01**

Note: ** p<0.01, – * p< 0.05 compared to the original value.

In the dynamics of treatment, a decrease in all indicators of carbohydrate metabolism was noted after 24 weeks of treatment in group I. In group II, there was a significant decrease in fasting glucose values of 5.1 ± 0.2 mmol/l from the initial value of 5.6 ± 0.1 mmol/l and after 2 hours from the initial value of 7.1 ± 0.1 mmol/l to 6.8 ± 0.2 mmol/l (p<0.05).

There was also a significant decrease in the level of glycosylated hemoglobin (HbA1c) from the initial level of 7.9 ± 0.1% to 5.9 ± 0.1% (p<0.05) in this group. As for the insulin index, it also decreased from the initial level of 12.9 ± 0.3 pmol/l to 12.3 ± 0.4 pmol/l, but it is less significant. A significant significant difference is demonstrated by the insulin resistance index (HOMA-IR) in group II of treatment. After 24 weeks of therapy, HOMA-IR significantly decreased from 1.6 ± 0.01 to 1.4 ± 0.01.

CONCLUSIONS

Thus, the use of combined estrogen-progestogenic MHT drugs in postmenopausal women makes up for the physiological deficiency of estrogens, reduces the level of testosterone in the blood serum, leveling its adverse effect on atherogenicity indicators, improves the lipid spectrum.

It should be noted that MHT containing drospirenone, due to antiandrogenic and antimineralocorticoid effects, is a more preferable type of MGT in the correction of metabolic syndrome indicators in women with PCOS. However, the addition of the multicomponent drug Inotir with myo-inositol to complex therapy demonstrated significant significant differences in the levels of the studied parameters, which made it possible to achieve a significant increase in the effectiveness of the therapy.

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