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# ADJUVANT THERAPY IN WOMEN UNDERGOING MAINTENANCE HEMODIALYSIS

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**Abstract**

The article presents the results of a study on the effectiveness of combined therapy with magnesium supplementation and phytoestrogens in women aged 45–55 years with climacteric syndrome (CS) undergoing maintenance hemodialysis (HD). It was demonstrated that this group of patients exhibited a pronounced deficiency of magnesium, calcium, and vitamin D3, along with a significant increase in parathyroid hormone levels and moderate hyperkalemia, which worsened after dialysis sessions. Standard therapy did not provide relief of CS symptoms or improve quality of life (QoL). The inclusion of a magnesium-containing preparation and a phytoestrogen in the treatment regimen for 90 days led to a significant increase in serum magnesium, calcium, and vitamin D3 levels, normalization of hormonal balance, reduction of parathyroid hormone, as well as a marked decrease in clinical manifestations of CS. These changes were accompanied by an improvement in QoL without adverse effects. The findings highlight the importance of correcting hypomagnesemia and the potential role of phytohormonal agents in the comprehensive management of women with CS undergoing HD.

**Keywords:** Maintenance hemodialysis, climacteric syndrome, magnesium, phytoestrogens, quality of life, macroelements, hormonal balance.

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# АДЪЮВАНТНАЯ ТЕРАПИЯ ЖЕНЩИН, ПОЛУЧАЮЩИХ ПРОГРАММНЫЙ ГЕМОДИАЛИЗ

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**Аннотация**:
В статье представлены результаты исследования эффективности комбинированного применения препарата магния и фитоэстрогена у женщин 45–55 лет с климактерическим синдромом (КС), находящихся на программном гемодиализе (ПГ). Показано, что у данной категории пациенток выявляется выраженный дефицит магния, кальция и витамина D3, а также значительное повышение уровня паратгормона и умеренная гиперкалиемия, усугубляющиеся после сеансов гемодиализа. Применение стандартной терапии не обеспечивало купирования проявлений КС и улучшения качества жизни (КЖ). Включение в терапию магнийсодержащего препарата и фитоэстрогена на протяжении 90 дней привело к достоверному повышению уровня магния, кальция, витамина D3, нормализации гормонального статуса, снижению паратгормона, а также выраженному уменьшению клинических проявлений КС. Это сопровождалось улучшением КЖ пациенток без побочных эффектов. Полученные данные подтверждают необходимость коррекции гипомагнемии и применения фитогормональных средств в комплексной терапии женщин с КС, находящихся на ПГ.

**Ключевые слова:** программный гемодиализ, климактерический синдром, магний, фитоэстрогены, качество жизни, макроэлементы, гормональный статус.

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In the process of improving the treatment tactics for patients receiving programmed hemodialysis (PH), the life expectancy of such patients has ceased to be the only criterion for the results of treatment. This indicator has been replaced by the problem of improving the quality of life (QOL), which includes the post-dialysis state with the psychological comfort of patients undergoing treatment. Therefore, when developing an adequate treatment program for long-term treatment of a patient, it is necessary to take into account many factors, including the state of the level of macroelements and the hormonal status of the patient. Currently, in patients receiving PH, the patterns of changes in such macroelements as potassium, calcium, iron, phosphorus have been well studied, but with regard to the dynamics of the magnesium level, especially in women in the fifth decade of life with the onset of the climacteric period with hormonal changes in the body, remained beyond the scope of detailed study. At the same time, some of them develop climacteric syndrome (CS), the manifestations of which often reduce QOL. Standardized basic therapy in the interdialysis period of patients with CS, unfortunately, does not lead to the relief of its manifestations with an increase in the quality of life in them, which dictates the need to search for new approaches to the correction of macronutrients and hormonal imbalance. According to modern recommendations, gynecologists prescribe hormone replacement therapy (HRT) to neutralize the negative manifestations of CS.

However, to date, society remains wary of hormone therapy, especially in women on PG. An alternative to hormone therapy are herbal preparations with an estrogenic effect. At the same time, a detailed study of such phytoestrogens from the standpoint of evidence-based medicine has intensified only recently (F.T. Khalimova, I.D. Karomatova, B.I. Isoeva, 2023; O.V. Filippova, 2020), but without covering the issue of the effectiveness of their use in dialysis patients. Also, for the effectiveness of stopping the manifestations of CS and improving the quality of life of women receiving PG, attention should be paid to the state of the magnesium level.

As is known, this macroelement is involved in many biochemical processes with the activation of many enzymes, influence on the processes of cell division, transmembrane transport of ions, etc. The important role of this macroelement in

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the regulation of the functions of the cardiovascular system and nervous systems has been convincingly proven (A. Z. Khashukoeva, S. A. Khlynova, Z. Z. Khashukoeva, L. A. Karelina), which are targets in the development of CS. In addition, at the end of the last century, H.E. Meema et al. proved that hypomagnesemia in the terminal stage of CKD in the absence of replenishment of its level contributes to the development of arterial calcification of arteries and an increase in cardiovascular mortality in patients with CKD stage V, and normalization of the magnesium level can slow down this process. From this perspective, the development of hypomagnesemia, in addition to other electrolyte disturbances in women in the 45-55 age group, can largely explain the development of symptoms characteristic of CS.

The need to correct hypomagnesemia is especially relevant in situations in women with CS receiving PG, since such procedures themselves lead to hypomagnesemia with aggravation of metabolic imbalance against the background of constant not only somatic, but also mental stress, which aggravates the decline in their quality of life. In connection with the above, the aim of our study was to study the effect of treatment with a phytoestrogen in combination with a magnesium preparation on the quality of life of women with CS receiving PG. Patients and methods. The study included 58 women aged 45-55 years, on average 48.3 ± 4.8 years (main group - MG) with clinically established presence of CKD stage V with impaired water excretion function of the kidneys, who are on PG in the Republican Specialized Scientific and Practical Center of Nephrology and Kidney Transplantation. The duration of stay on PGD ranged from 3 to 8 years and in the overwhelming majority of cases was 5-6 years. The causes of CKD development were chronic glomerulonephritis (42 patients) and chronic pyelonephritis (16 patients). The control group (CG) included 20 women of comparable age without any cardiovascular, diarrheal, endocrine or renal diseases, who were in the CP. Patients with CKD stage V received programmed hemodialysis 3 times a week for an average of 4 hours on the "Dialog" devices of the company BBraun (Germany) using dialyzers "Low Flux Series Hallon Fiber Dialyzers" of the company "Shadono Weigao Blood Purification Products Co. Ltd." (PRC). During the procedure, a certified standard dialysis solution was

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used, vascular access was in the form of a native arteriovenous fistula. Considering that the women of the MG were in the CP, for an objective assessment of their QOL, the level of which may be associated not only with the underlying disease and GD, but also with pronounced manifestations of menopause, they were examined by a gynecologist, who established the presence of CM. To assess the degree of decrease in QOL associated with manifestations of CM, a modified Kupperman questionnaire was used (https://pineamin.ru/indeks-kuppermana-shkala-grina.html). According to the questionnaire, based on the sum of points scored, 4 degrees of QOL impairment are distinguished in relation to CM: no climacteric syndrome (0-11 points), mild climacteric syndrome (12-34 points), moderate climacteric syndrome (35-58 points), severe climacteric syndrome (59 points and above). The composition of macroelements (magnesium, calcium, potassium) in the blood serum was studied by atomic absorption spectrophotometry on the Analyst-400 device (Perk in Elmer Inc.). The level of hormones in the blood serum was determined on the Mindray MR-96A device by OSIYO MEDIKA using the enzyme immunoassay (ELISA). The control points of the study were the first - before the start of the next PG procedure, the second - 30th day of observation, the third point - 90th day of observation.

Drug preparation for the dialysis procedure and treatment in the interdialysis period were carried out in accordance with the National Standard. According to this standard, traditional therapy of MG patients in the interdialysis period consisted of iron and erythropoietin preparations, calcium, B vitamins, hypotensive and diuretic agents. At the same time, patients of both groups did not previously receive magnesium-containing drugs and HRT. To justify the inclusion of a magnesium preparation and a phytoestrogen in the complex therapy of patients with CS undergoing PG, the women of the MG were divided into 2 subgroups. Patients of the MG I (38 women) received, in addition to the standard therapy, the magnesium preparation "Biolectra Magnesium Fortissimum" (containing 342 mg of light magnesium oxide and 670 mg of light magnesium carbonate, which corresponds to 365 mg of magnesium ions (15 mmol) in the form of effervescent tablets) 1 time in the morning after meals. Patients of the

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MG II (20 women) received, in addition to this magnesium preparation, HRT in the form of a phytoestrogen called "Monopouzessel", 1 drop 2 times a day during meals, which contains essential phospholipids and 40% soy isoflavone with an estrogen-like effect. The course of treatment was 90 days. No side effects from the additionally prescribed drugs were observed.

**Results and Discussion**

According to the results of the study of the modified Kupperman questionnaire, the level of QOL in all women of the MG ranged from 38 to 51 points and averaged 41.73 ± 5.3 points, which corresponds to moderate CC. At the same time, according to the National Guidelines, the appointment of HRT is required, however, the patients were not prescribed any therapy for CC before our study. The study of the macroelement composition of the blood, the level of vitamin D3, parathyroid and sex hormones in the examined patients of the MG demonstrated the following (see Table 1). The level of magnesium in the blood in the MG was sharply reduced and amounted to an average of 0.33 ± 0.024 mmol / l ($p < 0.001$), the calcium and vitamin D3 levels were also significantly reduced to 1.5 ± 0.04 mmol / l ($p < 0.003$) and to 9.1 ± 0.33 mIU / l ($p < 0.001$), respectively. In contrast, the concentration of potassium and parathyroid hormone in the serum of these patients was high, especially the latter. Thus, the potassium level was 4.5 ± 0.14 mmol / l ($p < 0.01$), parathyroid hormone - 833.46 ± 54.71 pg / ml ($p < 0.0004$), respectively. Hormonal imbalance in relation to sex hormones was manifested by a significantly reduced level of estradiol to 0.092±0.13 IU/l ($p<0.0001$) while maintaining the concentration of FSH and LH within their reference values (see Table 1).

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**Table 1 Content of macronutrients, vitamin D3, parathyroid hormone and sex hormones in women with CS who were on PG before treatment**

| Indicator | Norm | Indicators KG (N=20) | OG indicators (N=58) |
|---|---|---|---|
| **Mg (mmol/l)** | 0.8-1.00 | 0.67±0.08 P< 0.05 | 0.33±0.024 P< 0.01, P1< 0.05 |
| **Ca (mmol/l)** | 2.02-2.06 | 1.82±0.13 P< 0.05 | 1.48±0.20 P< 0.01 |
| **TO (mmol/l)** | 3.5-5.2 | 3.7±1.2 | 4.88±1.40 P< 0.05 |
| **Parathyroid hormone (pg/ml)** | 15.00-65.00 | 58.86±0.32 | 833±54.71 P< 0.0001 |
| **Vitamin D3 (ng/ml)** | 20.0-50.0 | 16.66±2.17 | 10.51±1.38 P< 0.01 |
| **FSH (Chalk)** | 10.0-150.0 | 43.65±9.27 | 75.91±2.51 |
| **LG (Chalk)** | 5.0-57.0 | 24.6±8.32 P< 0.05 | 37.6±7.84 P< 0.05 |
| **Estradiol (nmol/l)** | 0-0.23 | 0.13±0.025 | 0.092±0.0012 |

To assess the effect of renal replacement therapy sessions on the level of macronutrients in the blood serum, we additionally conducted a one-time study of some laboratory parameters of MG patients after the next PG session. It was found that after the next hemodialysis, the concentration of calcium, and especially magnesium, in the blood had a clear tendency to decrease, but without a reliable difference between the content of these macronutrients before and after HD. Thus, dialysis patients were found to have a pronounced deficiency of magnesium, calcium and a significant deficiency of vitamin D3 with a simultaneous sharp decrease in estradiol levels. At the same time, the concentration of parathyroid hormone was very high in combination with

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moderate hyperkalemia. The studied similar parameters in the CG group of women in the CP did not reveal reliable differences from the reference values of the studied parameters, except for a slight decrease in magnesium levels to 0.67 ± 0.08 mmol / l ($P < 0.05$). At the second control point (on the 30th day of observation), the assessment of the severity of the manifestations of CS according to the questionnaire, in patients of OGI and OGII demonstrated some decrease in its subjective manifestations with an increase in the quality of life of patients in both groups, but without reliable differences in comparison with the initial scores and between the groups. The dynamics of laboratory parameters at the same time in both groups did not reveal any differences in comparison with their initial values before the start of treatment. When assessing the dynamics of the studied indicators at the end point (90 days), the following was established (see Table 2). The study of the questionnaire data and laboratory tests at the end point of the study (90 days of observation) revealed other patterns. Thus, the assessment of the severity of clinical manifestations of CS indicated a significant improvement in QOL in both groups with a clear advantage in patients of OGII

**Table 2 Content of macroelements, vitamin D3, parathyroid and sex hormones in women with cesarean section undergoing PG in the dynamics of differentiated treatment with magnesium and phytoestrogen**

| Indicator | Norm | Indicators KG (N=20) | OG indicators before treatment (N=58) | OG indicators after 90 days of treatment | |
|---|---|---|---|---|---|
| | | | | OG I (N=38) | OG II (N=20) |
| **Mg (mmol/l)** | 0.8-1.00 | 0.67±0.08<br>p< 0.05 | 0.33±0.024<br>P< 0.001 | 0.48±0.031<br>P< 0.01 | 0.59±0.0 25<br>P< 0.05 |
| **Ca (mmol/l)** | 2.02-2.06 | 1.82±0.13<br>P< 0.05 | 1.48±0.20<br>P< 0.001), p < .0.01 | 1.62±0.29<br>P< 0.05 | 1.81 ± 0.18<br>P<.0.01 |
| **TO (mmol/l)** | 3.5-5.2 | 3.7±1.2 | 4.88±1.40<br>P< 0.05 | 4.73±1.12 | 4.61±1.37 |
| **Parathyroid hormone (pg/ml)** | 15.00-65.00 | 58.86±0.32 | 833.23 ±54.71<br>P< 0.0001 | 457, 33±72.11<br>P< 0.003 | 398.64±48.22<br>P< 0.0001 |
| **Vitamin D3 (ng/ml)** | 20.0-50.0 | 16.66±2.17<br>P<0.05 | 10.51±1.38<br>P< 0.01 | 15.79±2.23<br>P<0.05 | 22.66±1.78<br>P<0.03 |
| **FSH (Chalk)** | 10.0-150.0 | 23.65±9.27 | 35.91±2.51 | 46.73±6.28<br>P< 0.05 | 72, 65±4.55<br>P< 0.001 |
| **LH (IU/L)** | 5.0-57.0 | 24.6±8.32 | 37.6±7.84 | 41, 27±4.33 | 15.25±2.51<br>P< 0.004 |
| **Estradiol (nmol/l)** | 0-0.23 | 0.13±0.025 | 0.092±0.0012 | 0.11±0.035<br>P<0.01<br>. | 0.18 ±0.019<br>P<0.01 |

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The number of points in these periods left on average 33.85±4.11 points for women in OGI and 28.72±6.33 points for women in OGI with a reliable intergroup difference (P<0.05), which corresponded to a mild degree of CS with an increase in QOL. When comparing the dynamics of laboratory parameters in the same periods in both groups, the following was revealed. The state of macronutrient metabolism was characterized by a significant increase in magnesium concentration in both groups with higher values in OGI: up to 0.48±0.031 mmol/l and up to 0.59±0.0 25 mmol/l, respectively, with reliable intergroup differences - p<0.05, which, however, did not reach the normal values of this macronutrient. The calcium concentration increased significantly in both groups compared to the initial values and was 1.62±0.29 mmol/l in OGI and up to 1.81±0.18 mmol/l in OG II, with a significant difference between the groups ($p < 0.05$). The vitamin D3 level also increased in all patients, while in OGI patients it was 15.79±2.23 ng/ml on the 90th day of observation, in OGII - 22.66±1.78 ng/ml with a significant intergroup difference ($p < 0.05$). The parathyroid hormone values indicated its sharp decrease in both groups: to 457, 33±72.11 (in OGl) and to 398, 64±48.22 (OGII) with a reliable difference in the groups (p<0.01), which, however, significantly exceeded its normal concentration. In addition, a clear inverse relationship was established between the content of parathyroid hormone and magnesium in the blood serum of the studied patients. At the same time, there was some decrease in the concentration of potassium without a reliable intergroup difference, but with a clear tendency towards its depression in OGII. With regard to the dynamics of sex hormones, a reliable significant increase in the FSH level was established compared with the initial data in patients with OGII, which amounted to 72.65±4.55 IU/l (p<0.001), in contrast to patients with OGI, in whom the same indicator amounted to 46.73±6.28 IU/l (p<0.05), with an intergroup difference (p<0.01). The concentration of other sex hormones in the dynamics of treatment fluctuated within the normal range, but with a significant decrease in LH values to 15.25 ± 2.51 IU / l compared with the initial data ($p < 0.003$) and compared with such OGI values (41.27 ± 4.33 IU / l, $p < 0.001$). The level of estradiol increased significantly to the same extent in both groups to 0.11 ± 0.035 nmol / l to 0.18 ±

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0.019 nmol / l. In addition, we have established a clear relationship between the content of magnesium and calcium in the blood of patients with CKD stage V. It was also found that magnesium replenishment in patients receiving PG leads to a more significant increase in calcium concentration.

At the same time, before prescribing the magnesium preparation to our patients, while they were receiving significant doses of vitamin D3 - 50,000 IU (1.250 mg) per week, the state of hypocalcemia nevertheless persisted.

Conclusion. Thus, for patients with CS receiving PG, one of the areas of therapy for maintaining and improving QOL is replenishment and maintenance of a stable level of magnesium. A course of adjuvant therapy consisting of the preparation Magia and phytoestrogen for three months led to the elimination of the imbalance in macronutrients and hormonal status with the relief of most manifestations of CS and an increase in the QOL of patients receiving PG.

**Conclusions**

1. In patients with KS receiving PG, a deficiency of the main essential macroelements (magnesium and calcium), as well as vitamin D3, with a simultaneous increase in the content of potassium and, especially, parathyroid hormone was revealed in the blood serum.

3. The next session of HD leads to an aggravation of the deficiency of magnesium and calcium in the blood in this category of patients.

4. Increasing the concentration of magnesium more effectively leads to the elimination of calcium and vitamin D3 deficiency and excess parathyroid hormone.

5. The inclusion of a magnesium preparation in combination with a phytoestrogen in interdialytic adjuvant therapy of patients with KS on PG largely eliminates the manifestations of KS and improves the quality of life of patients without side effects.

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