нервової системи і відновленню вегетативного балансу згідно даних тимчасових показників ВРС, а також суттєва позитивна динаміка ситуативної та особистої тривожності. Таким чином, включення ЕМС у комплексну терапію лікування чоловіків молодого віку з АГ і клінічними ознаками вегетативної дисфункції позитивно впливає на клінічну симптоматику, сприяє відновленню вегетативного балансу і корекції психоемоційного стану.

Ключові слова: артеріальна гіпертензія у молодих, вегетативна дисфункція, варіабельність ритму серця, тривога, етилметилгідроксипіридина сукцинат.

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системы и восстановление вегетативного баланса по данным временных показателей ВРС, а также существенная положительная динамика ситуативной и личной тревожности. Таким образом, включение ЭМС в комплексную терапию лечения мужчин молодого возраста с АГ и клиническими признаками вегетативной дисфункции положительно влияет на клиническую симптоматику, способствует восстановлению вегетативного баланса и коррекции психоэмоционального состояния.

Ключевые слова: артериальная гипертензия у молодых, вегетативная дисфункция. вариабельность сердечного ритма, тревога, этилметилгидроксипиридина сукцинат.

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TREATMENT OF HEART FAILURE IN PATIENTS WITH DIABETES MELLITUS

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The purpose of the work was to study the effect of fixed combination of meldonium dihydrate and γ-butyrobetaine dihydrate (MD+γ-BD) on clinical, hemodynamic and glucometabolic parameters, as well as indicators of oxidant-antioxidant status in patients (pts) with heart failure (HF) and type 2 diabetes mellitus (DM). The total of 62 patients with HF and DM were examined. After registration of the baseline data, baseline therapy was prescribed to all patients, 30 of them (group 1) obtained an additional fixed combination of MD+γ-BD 2 capsules three times a day for 3 months and 32 patients were included in the comparison group (group 2). After treatment in group 1, the increase of the distance walked was determined according to the 6-minute walk test by 31.2% versus 12.7% in group 2 ($p < 0.05$). There was an increase in left ventricular (LV) ejection fraction by 4.5% in group 1 versus 1.9% in group 2 ($p < 0.05$). Positive changes in glucometabolic parameters were observed. A decrease of the activity of lipid peroxidation processes according to the level of malondialdehyde (Δ-22.3% in patients of group 1 versus Δ-11.2% in group 2, $p < 0.05$) and an increase in the activity of erythrocyte superoxide dismutase (respectively Δ29.5% vs. 8.1%, $p < 0.05$) were found. Thus, an addition of a fixed combination of MD+γ-BD in the complex therapy of pts with HF and type 2 DM improves clinical symptoms in patients, has a positive effect on the structural and functional parameters of the left ventricle, glucometabolic parameters and imbalance of the oxidant-antioxidant system by increasing the activity of intracellular antioxidant enzymes.

Key words: heart failure, type 2 diabetes mellitus, structural and functional changes of the left ventricle, lipid peroxidation, fixed combination of meldonium dihydrate and γ-butyrobetaine dihydrate.

The work is a fragment of the research project "Optimization of diagnosis and treatment of comorbid pathology (hypertension and type 2 diabetes mellitus) based on the assessment of cardiohemodynamics, metabolism and pharmacogenetic analysis", state registration No.0116U004983.

Heart failure (HF) is a rapidly growing disease of the clinical cardiology in many countries [2]. Despite significant advances in the study of pathogenesis, clinical findings and treatment, this pathology remains widespread with dismal course and prognosis. Patients with HF of ischemic etiology are characterized by the involvement of target organs, behind which lie hypoxia processes caused by impaired macro- and microcirculation [4].

Type 2 diabetes mellitus (DM) is also a rapidly growing medical and social problem in all industrially developed countries. It is particularly disturbing that the prevalence and incidence of type 2 DM in recent years have tendency to increase in young age groups [12]. More than 50% of patients with type 2 DM do not even suspect that they have this disease because it can be asymptomatic for many years [3]. The presence of type 2 DM in patients contributes to the formation of additional hemodynamic and metabolic damage to the heart and the blood stream [6].

Predictably poor and even fatal effect of DM on the prognosis of HF have been established in numerous clinical studies; diabetes mellitus was not only associated with an increase in mortality but was also recognized as an independent predictor in HF patients [10, 13]. The problem of optimization and individualization of pharmacotherapeutic approaches in this category of patients is extremely urgent. Therefore, it is important to optimize the treatment of patients with HF in combination with type 2 DM, taking into account clinical features found in this category of patients.

In therapeutic practice, 3- (2,2,2-trimethylhydrazinium) propionate dihydrate (meldonium dihydrate) has been widely used, the action of which is to optimize intracellular mitochondrial energy

metabolism, to reduce cell oxygen demand by shifting energy metabolism to oxidation of fatty acids to the dominating utilization of glucose. Antioxidant properties of meldonium have been established, which are able to influence the manifestations of insulin resistance and lipid metabolism [9].

Gamma-butyrobetaine dihydrate affects the induction of biosynthesis of nitric oxide (NO), protects cells from the toxic effects of free radicals, normalizes oxidative homeostasis at the cellular level, has a positive effect on endothelial function, inhibits aggregation and adhesion of thrombocytes, neutrophil adhesion to the endothelium, migration of monocytes [11].

The purpose of the work was to study the effect of fixed combination of meldonium dihydrate and γ-butyrobetaine dihydrate on the clinical, hemodynamic and glucometabolic parameters, as well as the indicators of oxidant-antioxidant status in patients with HF and type 2 DM.

Materials and methods. We examined 62 patients (18 women and 44 men, mean age 60.3 ± 1.6 years) with HF stage II A, NYHA class II and III of ischemic etiology and type 2 DM (moderate severity, subcompensation stage). The diagnosis of HF was established in accordance with the recommendations of the European Society of Cardiology for the diagnosis and treatment of acute and chronic heart failure (ESC, 2016), as well as the Ukrainian Association of Cardiology for the diagnosis and treatment of chronic heart failure (2017). Diagnosis of type 2 DM was established according to the general recommendations of the European Association for the Study of Diabetes (EASD, 2013).

All examined patients underwent general clinical examination, physical examination, anthropometric measurements, measurements of office blood pressure (BP), heart rate (HR), 6-minute walk test (6MWT), general blood test and urinalysis, biochemical analysis of blood with determination of glucose concentration in fasting blood serum (FBS), levels of glycosylated hemoglobin (HbA1c) in whole blood, insulin, lipid profile indices. Insulin resistance was evaluated by the NOMA-IR index. The content of malondialdehyde (MDA) was determined by reaction with thiobarbituric acid (TBA), which at high temperature (100 ° C) in acid medium proceeds with the formation of the stained trimethyl complex. The activity of superoxide dismutase (SOD) was determined by the level of enzyme inhibition of reduction of nitrotetrazolium blue with the participation of reduced nicotinamide adenine dinucleotide (NADH) and phenazin metasulfate.

Structural and functional parameters of the heart were accessed by echocardiography using the diagnostic system "GE Medical Systems" (Germany) by a phased array transducer with a modulated frequency of 2.25-3 MHz in M- and B-modes in accordance with the recommendations of the American Society of Echocardiography (ASE, 2016). The study included an assessment of the linear dimensions of the heart cavities (anterior-posterior size of the left atrium, end-systolic and end-diastolic dimensions of the left ventricle (ESD and EDD LV)), thickness of the interventricular septum and posterior wall of the LV. The mass of the left ventricular (MLV) (by the formula Devereux R.B. et al.) and the MLV index (IMLV) were calculated relative to the body surface and the LV systolic function was evaluated.

After registration of baseline data, basic therapy for HF (Lisinopril, Carvedilol, Eplerenone in individually selected dosages) and a fixed combination of meldonium dihydrate and γ-butyrobetaine dihydrate ("Kapikor", Olainfarm, Latvia) 2 capsules three times a day for 3 months were administered to 30 patients of the main group (group 1). The comparison group (group 2) consisted of 32 patients whom basic HF therapy was administered. Patients in both groups also received antiplatelet therapy (metformin + gliclazide), statins, antiplatelet therapy. These groups of patients were comparable by age, sex, disease severity, main clinical and hemodynamic parameters, as well as the administered doses of standard therapy for HF. The second study was performed after 3 months of treatment. Side and undesirable effects during this period have not been reported.

The mathematical computer processing of the results of the study was carried out using the software package "Statistica 8.0" (StatSoft Inc, USA). Mean value (M), variance, standard deviation, median (m), probability and significance level (p) were calculated. Differences were considered significant at the level of statistical significance $p < 0.05$. To evaluate the relationship between the indicators the method of correlation analysis with the calculation of the Pearson correlation coefficients (at normal distribution) and Spearman correlation coefficients (at the distribution different from normal) was used.

The mathematical computer processing of the results of the study was made using the software package "Statistica 8.0" (StatSoft Inc, USA). Mean value (M), variance, standard deviation, median (m), probability and significance level (p) were calculated. Differences were considered significant at the level of statistical significance $p < 0.05$. To evaluate the relationship between the indicators the method of correlation analysis with the calculation of the Pearson correlation coefficients (at normal distribution) and Spearman correlation coefficients (at the distribution different from normal) was used.

Results of the study and their discussion. Reduction of HF class (NYHA) was found in patients of group 1 by 12.5% (from 2.4 ± 0.5 to 2.1 ± 0.3) compared to group 2, where this index remained practically unchanged (2.4 ± 0.5 at baseline and 2.3 ± 0.3 after 3 months of treatment). In addition, according to 6MWT after treatment, the distance traveled increased significantly in patients in group 1 by 31.2% versus 12.7% in group 2 ($p<0.05$).

Analysis of the structural and functional parameters of the heart after the course of treatment showed that no significant changes in the end-diastolic and end-systolic dimensions of the left ventricle (LV) occurred (table 1). An increase in the LV ejection fraction by 4.5% in the group of patients, in addition to baseline therapy, receiving a fixed combination of meldonium dihydrate and γ-butyrobetaine dihydrate, versus 1.9% in the comparison group ($p<0.05$). The tendency to decrease the LV myocardial mass index (LVMI) was determined by 6.2% in patients of group 1 and 2.0% in the comparison group.

Table 1

Changes in biochemical parameters in the course of treatment of patients with CHF and type 2 DM (M ± m)

Indicators	Group 1 (n = 30)		Group 2 (n = 32)	
	Before treatment	After treatment	Before treatment	After treatment
EDD, cm	5.42±0.05	5.37±0.05	5.47±0.08	5.46±0.07
ESD, cm	3.92±0.04	3.67±0.04	3.90±0.06	3.75±0.06
EF LV, %	47.0±0.4	49.1±0.3*	46±0.6	46.9±0.5
IMLV, g/m^2	147.16±6.62	138.04±4.23	149.14±7.74	146.13±4.19

Note: * - significance of differences in comparison to the original data.

There was an improvement in carbohydrate metabolism indices, a decrease in the insulin resistance index HOMA ($p>0.05$) and lipidograms, but significant changes were found between the groups only for triglyceride levels (Δ -15.1% vs. Δ -3.9%, p <0, 05, respectively). Previous studies have also mentioned the positive effect of meldonium on lipid metabolism in patients with type 2 DM [8]. Analysis of the effect of treatment on lipid peroxidation (LPO) and antioxidant status (table 2) showed that in group 1 there was a significant decrease of MDA by -22.3% ($p<0.05$), indicating a decrease in free- radical processes. Determination of SOD content was used as indicators of antioxidant protection, which, being a key enzyme of antioxidant protection, interrupts the chain of free radical processes at the beginning of its origin. An increase in SOD activity by 29.5% ($p<0.05$) was observed, which indicates activation of antioxidant protection of the body. In group 2, the dynamics of LPO and antioxidant protection were significant, but much ($p<0.05$) lower than in the main group: reduction of MDA by -11.2% and increase in SOD activity by 8.1%, $p < 0.05$).

Table 2

Change of lipid peroxidation (LPO) and antioxidant status during therapy

Indicator	Group	Baseline data	After treatment
MDA, mmol/l	1 (n = 30)	7.70±0.20	5.98±0.18*
	2 (n = 32)	7.52±0.21	6.68±0.15*
SOD erythr., %	1 (n = 30)	37.0±1.3	47.9±1.1
	2 (n = 32)	37.3±1.1	40.32±1.0*

Note: * - significance of differences compared to baseline data ($p<0.05$).

The combination of HF with type 2 DM is accompanied by the development of hypoxia as a universal pathological process associated with an injury of target organs in case of comorbid pathology and the development of mitochondrial oxidative phosphorylation disorders in any cell. In this case, the violation of oxidative processes with insufficient antioxidant protection system contributes to the development of oxidative stress. Disruption of mitochondrial oxidation leads to the suppression of conjugated phosphorylation and causes a progressive deficit of ATP, a universal energy source. A promising trend in the treatment of HF is cytoprotective therapy aimed at improvement of the efficiency of myocardium by optimization of the synthesis of adenosine triphosphate in cardiomyocyte mitochondria with lower oxygen consumption [7].

Clinical studies [5] have shown the efficacy and safety of therapy with the addition of meldonium in the treatment of HF. It has been noted that meldonium cytoprotector, which inhibits β - fatty acid oxidation and activates glucose oxidation (aerobic glycolysis) in ischemic myocardium, contributes to the improvement of tissue microcirculation [1].

In our study, it was found that in addition to basic therapy a fixed combination of meldonium dihydrate and γ-butyrobetaine dihydrate contributes to slowing of the progression of HF. Thus, more pronounced positive changes in clinical status and physical activity were observed during the therapy, which included a fixed combination of meldonium dihydrate and γ-butyrobetaine dihydrate.

Metabolic disorders during oxidative stress (activation of the polyol pathway, impaired free fatty acid metabolism, development of hypertriglyceridemia, endothelial dysfunction) lead to the occurrence of metabolic remodeling of the myocardium and impaired function of the left ventricle [1].

Therefore, additional administration of a fixed combination of meldonium dihydrate and γ-butyrobetaine dihydrate has a positive effect on both the oxidant and antioxidant systems, what is manifested in the inhibition of lipid peroxidation and activation of the compensatory processes that provide retention of free radicals to keep the normal level for metabolic processes in the cell.

Conclusion

Thus, 3-month therapy with fixed combination of meldonium dihydrate and γ-butyrobetaine dihydrate as a part of complex therapy of patients with chronic heart failure and type 2 DM improves clinical symptoms of patients, has a positive effect on the structural and functional parameters of left ventricle, glucometabolic parameters and imbalance of the oxidant-antioxidant system by increasing the activity of intracellular antioxidant enzymes.

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Реферати

ЛІКУВАННЯ ХРОНІЧНОЇ СЕРЦЕВОЇ НЕДОСТАТНОСТІ У ПАЦІЄНТІВ З ЦУКРОВИМ ДІАБЕТОМ 2-ГО ТИПУ

Біловол О.М., Князькова І.І., Богун М.В., Кузьмінова Н.В., Осовська Н.Ю.

Метою дослідження було вивчення впливу фіксованої комбінації мельдонію дигідрату та γ-бутиробетаїну дигідрату (МД+γ-БД) на клініко-гемодинамічні та глюкометаболічні параметри, а також показники оксидантно-антиоксидантнлого статусу у пацієнтів з хронічною серцевою недостатністю (ХСН) та цукровим діабетом (ЦД) 2 типу. Обстежено 62 хворих з ХСН та ЦД 2 типу. Після реєстрації вихідних даних усім пацієнтам призначали базисну терапію, з них 30 (1 група) додатково фіксовану комбінацію МД+γ-БД по 2 капсули тричі на добу протягом 3 місяців та 32 пацієнта увійшли у групу порівняння (2 група). Після лікування в 1 групі визначалось збільшення пройденої дистанції за даними теста 6-хвилинної ходьби на 31,2% і 1,9% ($p<0,05$) відповідно. Спостерігалось позитивні зміни глюкометаболічних показників. Відзначено зменшення активності процесів перекісного окислення ліпідів за рівнем малонового діальдегіду (Δ-22,3% у 1 групі, проти Δ-11,2% у 2 групі, $p<0,05$) і підвищення активності супероксиддисмутази еритроцитів (відповідно Δ29,5%

ЛЕЧЕНИЕ ХРОНИЧЕСКОЙ СЕРДЕЧНОЙ НЕДОСТАТОЧНОСТИ У ПАЦИЕНТОВ С САХАРНЫМ ДИАБЕТОМ 2-ГО ТИПА

Беловол А.Н., Князькова И.И., Богун М.В., Кузьминова Н.В., Осовская Н.Ю.

Целью исследования было изучение влияния фиксированной комбинации мельдония дигидрата и γ-бутиробетаина дигидрата (МД+γ-БД) на клинико-гемодинамические и глюкометаболические параметры, а также показатели оксидантно-антиоксидантнлого статуса у пациентов с хронической сердечной недостаточностью (ХСН) и сахарным диабетом (СД) 2-го типа. Обследовано 62 больных с ХСН и СД 2 типа. После регистрации исходных данных всем пациентам назначали базисную терапию, из них 30 (1 группа) дополнительно МД+γ-БД по 2 капсулы три раза в сутки в течение 3 месяцев, и 32 пациента составили группу сравнения (2 группа). После лечения отмечено увеличение пройденной дистанции по данным теста 6-минутной ходьбы на 31,2% в 1-й против 12,7% во 2 группе ($p<0,05$) и фракции выброса левого желудочка (ЛЖ) на 4,5% против 1,9% ($p<0,05$), соответственно. Наблюдалось положительные изменения глюкометаболических показателей, уменьшение уровня малонового диальдегида (в 1 группе Δ-22,3% против Δ-11,2% во 2 группе, $p<0,05$) и повышение активности супероксиддисмутазы эритроцитов (соответственно Δ29,5%

проти 8,1%, p<0,05). Таким чином, додавання МД+γ-БД до комплексної терапії пацієнтів з ХСН та ЦД 2 типу покращує клініко-гемодинамічні і глюкометаболічні показники та коригує дисбаланс оксидантно-антиоксидантної системи.

Ключові слова: хронічна серцева недостатність, цукровий діабет 2 типу, структурно-функціональні зміни лівого шлуночка, перекісне окислення ліпідів, фіксована комбінація мельдонію дигідрату та γ-бутиробетаїну дигідрату.

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против 8,1%, p <0,05). Таким образом, добавление МД+γ-БД в составе комплексной терапии пациентов с ХСН и СД 2 типа улучшает клинико-гемодинамические и глюкометаболические параметры и корригирует дисбаланс оксидантно-антиоксидантной системы.

Ключевые слова: хроническая сердечная недостаточность, сахарный диабет 2 типа, структурно-функциональные изменения левого желудочка, перекисное окисление липидов, фиксированная комбинация мельдония дигидрата и γ-бутиробетаина дигидрата.

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INFLUENCE OF EXCESSIVE NIGHTTIME ACTIVITY ON THE RISK OF ISCHEMIC CEREBRAL STROKE EVENT AND ITS COURSE FEATURES

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Clinical neurological and neuroimaging examination of 300 patients with ischemic stroke was performed. The control group included 40 patients without signs of acute cerebral stroke (men - 21, women - 19) aged 46 to 76 years (mean age being 62.6 ± 10.2 years). The data obtained confirmed that the important role of excessive nighttime activity (ENA) is characteristic of all groups of patients, but 100% correlation is observed in patients with nocturnal strokes. In patients with ENA there are two peaks of blood pressure increase: - 9:00 and 21:00. Patterns of blood pressure disorders at night were as follows: 68.4% (n = 13) - night peaker, 26.3% (n = 5) - non dipper, 5.2% (n = 1) - dipper subtype. Against the background of an optimized stroke prevention program, the incidence of recurrent ischemic strokes was by 2.09 times lower than in the control group within 2 years. The present study results show the importance of ENA for the diagnosis and pathogenesis of acute ischemic stroke.

Key words: stroke, excessive nighttime activity, onset time, stroke risk, prevention.

The study is a fragment of the research project "Development and improvement of diagnostic and therapeutic tactics in patients with acute diseases of the abdominal cavity complicated by peritonitis", state registration No. 0118U001029.

The problem of acute ischemic stroke remains one of the main issues in modern medicine, being one of the main causes of disability and mortality of people in Ukraine and in the world. The issue of ischemic stroke treatment, regardless of the economic status of the country, remains expensive, therefore, the world's organizations focus on the therapeutic strategy to combat ischemic stroke, precisely on the prevention of this disease [6].

Importance of the ischemic stroke prevention brings to the forefront identification and unifying the whole variety of risk factors for cerebral ischemia [1]. However, at this stage, researchers have only agreed concerning unmodified (age, gender, race, etc.) and "internal" modified risk factors for cerebrovascular catastrophe (arterial hypertension, hypercholesterolemia, diabetes, etc.) [1, 2]. As for the "external" risk factors, researchers have not yet come to a single conclusion, separately identifying only the factors of bad habits [3, 5].

One of the important predictors of cerebral ischemia, which, however, is poorly described in modern literature, remains excessive nighttime activity (ENA). Excessive nighttime activity is a habitual permanent deformation of the day regime (social risk groups are doctors, taxi drivers, night shift workers). This factor plays a significant social role in many people's lives and can seriously affect the incidence of cerebrovascular pathology in many groups of population [4]. Studies have already confirmed that excessive nighttime activity shows a pronounced association with cardiovascular disease [7], diabetes mellitus and cancer, but the question of the impact on patients with acute ischemic stroke remains understudied [9].

The purpose of the work was to determine the extent and nature of the excessive nighttime activity factor's influence on the incidence of ischemic stroke and to study the efficacy of ENA prevention in association with the recurrent ischemic strokes incidence.

Materials and methods. To achieve this purpose, we performed a clinical neurological and neuroimaging examination of 300 patients who had acute ischemic stroke (men - 196, women - 104) aged 42 to 84 years (mean age - 65.2 ± 8.7 years). The inclusion criteria for this study were: the patients' age from 40 to 85 years; ischemic stroke focus verified by MRI; consent of the patient or his legal representative.