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O.M. Bilovol, I.I. Kniazkova, V.M. Mishchenko[1], A.V Zhadan, N.V. Kuzminova[2], A.V. Starenky, M.V. Bogun
Kharkiv National Medical University, Kharkiv
[1]Institute of Neurology,Psychiatry and Narcology of the National Academy of Medical Sciences of Ukraine, Kharkiv
[2]Vinnytsia Pirogov Memorial National Medical University, Vinnytsya

EFFECT OF ANTI-HYPERTENSIVE THERAPY ON ARTERIAL WALL STIFFNESS IN PATIENTS WITH HYPERTENSION AND OBESITY

e-mail: sskripka72@gmail.com

The purpose of the study was to conduct a comparative analysis of the effect of 3-month therapy with a fixed combination of lisinopril dihydrate and amlodipine besylate on the clinical status, indicators of the daily profile of blood pressure, central aortic pressure and vascular stiffness, as well as the structural and functional state of the heart in patients with arterial hypertension with obesity and without it. 60 patients (average age 56.7±2.1 years) with stage 2 arterial hypertension were examined, 34 of which were diagnosed with Class 1 obesity (group 1) and 26 patients (group 2) without obesity who did not take regular antihypertensive therapy. After registration of baseline data, a fixed combination of lisinopril dihydrate and amlodipine besylate 10–20/5–10 mg/day was prescribed to the patients of both groups for 3 months. The control group consisted of 20 practically healthy people. After therapy, a significant improvement was found not only in the office systolic and diastolic blood pressure levels, but also in the daily profile of peripheral blood pressure and central blood pressure in both groups of patients. It was also established that the pulse wave propagation speed decreased by (1.0±0.2 m/s; $p<0.01$) in group 1 and by (1.5±0.2 m/s; $p<0.01$) in group 2. A significant decrease in the left ventricular myocardial mass index was found in both groups of patients. An increase in the E/A ratio was established by 33.3 % ($p<0.001$) in group 1 and by 26.3 % ($p<0.01$) in the patients of group 2. Thus, the long-term use of a fixed combination of lisinopril dihydrate and amlodipine besylate in arterial hypertension patients with obesity and without it, allows to control blood pressure effectively according to office measurement and daily blood pressure monitoring, has a positive effect on daily blood pressure profiles and indicators of arterial stiffness, as well as structural and functional parameters and status of diastolic function of the left ventricle, along with good tolerability of therapy.

Key words: hypertension, obesity, central aortic pressure, elastic properties of arteries, echocardiography, fixed combination of lisinopril dihydrate and amlodipine besylate.

О.М. Біловол, І.І. Князькова, В.М. Міщенко, А.В. Жадан, Н.В. Кузьмінова, А.В. Старенький, М.В. Богун

ВПЛИВ АНТИГІПЕРТЕНЗИВНОЇ ТЕРАПІЇ НА ЖОРСТКІСТЬ АРТЕРІАЛЬНОЇ СТІНКИ У ПАЦІЄНТІВ З ГІПЕРТОНІЧНОЮ ХВОРОБОЮ ТА ОЖИРІННЯМ

Метою дослідження було провести порівняльний аналіз впливу 3-місячної терапії фіксованою комбінацією лізиноприлу дигідрату та амлодипіну бесілату на клінічний статус, показники добового профілю артеріального тиску, центрального аортального тиску і жорсткості судин, а також структурно-функціональний стан серця у хворих на артеріальну гіпертензію з ожирінням та без нього. Обстежено 60 пацієнтів (середній вік 56,7±2,1 років) з артеріальною гіпертензією 2 ступеня, з яких у 34 визначено ожиріння I ступеня (1 група) і 26 пацієнтів (2 група) без ожиріння, які не приймали регулярну антигіпертензивну терапію. Після реєстрації вихідних даних пацієнтам обох груп призначалась фіксована комбінація лізиноприлу дигідрату та амлодипіну бесілату 10–20/5–10 мг/добу протягом 3 місяців. Контрольну групу склали 20 практично здорових осіб. Після проведеного лікування встановлено достовірне покращення не тільки рівнів офісного систолічного і діастолічного артеріального тиску, а й добового профілю периферичного артеріального тиску та центрального аортального тиску в обох групах пацієнтів. Встановлено зниження швидкості поширення пульсової хвилі на (1,0±0,2 м/с; $p<0,01$) в 1 групі та на (1,5±0,2 м/с; $p<0,01$) у пацієнтів 2 групи. Встановлено збільшення співвідношення E/A на 33,3 % ($p<0,001$) в 1 групі та на 26,3 % ($p<0,01$) у пацієнтів 2 групи. Таким чином, тривале використання фіксованої комбінації лізиноприлу дигідрату та амлодипіну бесілату у пацієнтів з артеріальною гіпертензією з ожирінням та без нього дозволяє ефективно контролювати артеріальний тиск за даними офісного вимірювання та добового моніторингу артеріального тиску, позитивно впливає на добові профілі артеріального тиску та показники артеріальної ригідності, а також структурно-функціональні параметри та стан діастолічної функції лівого шлуночка, поряд з хорошою переносимістю терапії.

Ключові слова: гіпертонічна хвороба, ожиріння, центральний аортальний тиск, пружньо-еластичні властивості артерій, ехокардіографія, фіксована комбінація лізиноприлу дигідрату та амлодипіну бесілату.

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Arterial hypertension (AH) is one of the most common cardiovascular diseases and is considered to be a leading and independent risk factor for other cardiovascular, cerebrovascular and renal diseases [1,2]. In the European guidelines for AH diagnosis (2018), it was stated that the vascular wall is one of the target organs, and increase in its stiffness is closely related to a high risk of development of cardiovascular complications, therefore its function should be evaluated in real clinical practice [8].

Overweight and obesity have reached pandemic proportions, leading to increased incidence of type 2 diabetes, metabolic syndrome, and hypertension. All these diseases play an important role in the process of vascular aging and contribute to the rise in cardiovascular morbidity and mortality. Obesity, characterized by an increase in body mass index (BMI) ≥30 kg/m², is an independent predictor of cardiovascular diseases, while weight loss is associated with a reduction in obesity-related cardiovascular risk factors [5].

In clinical practice, various methods of AH treatment in obese people are used. However, at present, there are no universally accepted methods of treatment for this population of patients that can effectively reduce the progression of arterial stiffness and high cardiovascular risk associated with obesity. Therefore, expanding the arsenal of highly effective and safe methods of treatment of the patients with AH and obesity, aimed at increasing the effectiveness of therapy of such patients along with enhancing the stiffness of the vascular wall and elastic properties of vessels, remains a relevant challenge in practical medicine.

The purpose of the study was to perform a comparative analysis of the effect of 3-month therapy with a fixed combination of lisinopril dihydrate and amlodipine besylate on the clinical status, indicators of daily BP profile, central aortic pressure and vascular stiffness, as well as the structural and functional state of the heart in patients with arterial hypertension with and without obesity.

Materials and methods. The study was conducted in accordance with the standards of good clinical practice and principles of the Declaration of Helsinki. The study included 60 patients (40 males and 20 females), aged 45-60 years (mean age 56.7±2.1 years) with stage 2 AH. Among them, 34 were diagnosed with class 1 obesity (group 1) and 26 patients (group 2) without obesity, which were not receiving regular antihypertensive therapy. The groups of patients were compared according to age, gender, duration, grade and stage of AH.

The control group consisted of 20 practically healthy individuals (9 females and 11 males, mean age 55.8±2.5 years).

All examined persons signed an informed consent to participate in the study.

The standard method of patient examination included clinical and laboratory-instrumental investigations in accordance with the recommendations of the European Society of AH/European Society of Cardiology (ESH/ESC) in 2019.

Body mass index (BMI) was calculated according to the formula:

BMI = body weight (kg)/height (m²).

According to the WHO classification (1997), the following ranges were considered: normal body weight with BMI of 18–24.9; presence of excessive weight with BMI of 25–29.9 and obesity of Class 1 and 2 with BMI of 30–34.9; BMI – 35-39.9 kg/m². According to the same guideline, the presence of abdominal obesity was diagnosed when the waist circumference (WC) for males was more than 94 cm, and for females more than 80 cm. BMI in the patients of groups 1 and 2 was 32.0 (30.1; 34.6) kg/m² and 26.7 (25.1, 29.8) kg/m², respectively ($p<0.001$)). WC in patients of groups 1 and 2 was 106 (103; 111) cm and 92.5 (80.5; 96.7) cm ($p<0.05$)). Ratio WC/HV (hip volume) ≥0.9 CU was found in 26 patients of group 1 and in 7 patients of group 2.

Patients with resistant and symptomatic AH; with chronic heart failure; chronic kidney failure, rhythm and conduction disorders, rheumatic heart disease, obesity of class II-III, thyroid gland diseases, diabetes, as well as the patients who were expected to have a high probability of violation of the research protocol, were not included in the study.

Daily monitoring of blood pressure (DMBP) was carried out using the device "ABPM-02" (Meditech, Hungary). The following were evaluated: average values of SBP, DBP, pulse pressure (PP), $BP_{av.}$ per day (24 hours), day and night, variability of BP indicators during the day and night, time index (TI) of hypertension – % of measurements of SBP ≥140 and DBP ≥90 mm Hg in the period of wakefulness; and respectively, ≥120 and ≥70 mm Hg. during sleep [10]. The severity of the biphasic BP day-night rhythm was assessed by the diurnal index (DI), which was calculated according to the formula:

DI = 100% x (BPd – BPn)/BPd,

where BPd is the average BP in the period of wakefulness; BPn – anaverage BP during sleep.

Four groups of patients were distinguished according to the value of DI:

– dipper (DI – 10–20 %) – optimal nocturnal BP reduction;

– non-dipper (DI – 0–10 %) – insufficient nighttime BP decrease;

– night-picker (DI<0) – persistent increase in night BP;

– over-dipper (DI>20) – excessive BP nocturnal decrease.

Indicators of central aortic pressure and arterial stiffness were studied by the method of applanation tonometry on the device SphygmoCor-PVx, AtCor Medical Pty Ltd, Australia) at indoor air temperature

of 21–22°C, with a patient lying down, after a 10-minute rest. In order to calibrate BP, this indicator was measured on the brachial artery using the Korotkoff method. With the help of an applanation sensor, the pulse wave on the radial artery was captured, and the pulse wave in the ascending part of the aorta was determined by the method of inverted transfer function. The program automatically calculated the levels of SBP, DBP and PP in the aorta and main characteristics of the central pulse wave (aortic augmentation pressure (AP), amplitudes of systolic peaks P1, P2, index of increment – augmentation index (AIx = TP/PT P2/P1), including normalized to HR 75 bpm (AIx @HR 75), reflected wave appearance time (Tr), PP amplification, aortic pulse wave velocity (PWV).

The structural and functional parameters of the heart were determined by the method of echocardiography using the diagnostic system GE Medical Systems (Germany) with a phased sensor having 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). LV myocardial mass (LVMM) and LVMI index (LVMMI) were calculated according to the recommendations of ASE (2016). According to the recommendations of the European Society of Cardiology in 2018, 95 g/m² and 115 g/m² were used for females and males, respectively, as the threshold values when reaching or exceeding the presence of LVH. Types of LV remodeling (eccentric LVH, concentric LVH, concentric remodeling) were determined according to the recommendations of ASE (2016).

After registration of baseline data, a fixed combination of lisinopril dihydrate and amlodipine besylate 10–20/5–10 mg/day (Combipril, Kyiv Vitamin Plant, Ukraine) were prescribed to the patients of both groups once a day. Adjustment of the drug dose was performed, if necessary, at the 2nd and 4th week. If necessary, indapamide was added at a dose of 2.5 mg/day. A follow-up examination was conducted after 3 months of treatment. Patients in both groups also received statins and antiplatelet therapy.

All patients successfully completed the study according to the protocol. Side effects and adverse events were not registered during this period.

Mathematical computer processing of the research results was carried out using the software package Statistica 9.0 (Statsoft Inc, USA). Mean value (M), variance, standard deviation, median (m), reliability and significance level (p) were calculated. For the analysis of variables, different from the Gaussian probability distribution, the median (Me) and interquartile range (IQR) indicators were calculated. Differences were considered reliable 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 Pearson correlation coefficients (with normal distribution) and Spearman correlation coefficients (with distribution that differs from the normal) was used.

Results of the study and their discussion. After the course of treatment, BP correction to target values was achieved in 100 % of patients. Indicators of BP levels according to office measurement and DMBP after 3 months of treatment in patients with AH combined with and without obesity are presented in Table 1.

Table 1

BP dynamics in obese and non-obese AH patients under the influence of antihypertensive therapy (M±SD)

Index	Group 1 (n=34)		Group 2 (n=26)	
	Before treatment	After treatment	Before treatment	After treatment
Sphygmomanometry:				
SBP, mm Hg	167.6±4.5	135.3±4.1***	165.8±4.6	129.3±4.3***
DBP, mm Hg	103.8±4.6	85.7±3.8***	101.6±4.3	82.2±3.7***
DMBP				
SBP24, mm Hg	160.8±4.6	125,5±4,3***	158.3±4.8	120.1±4.5***
DBP24, mm Hg	98.6±4.5	80,1±4,1**	95.6±4.7	75.1±4.0**
TI SBP day, %	55.7±3.5	28.5±2.3***	53.3±3.3	25.1±2.1***
TI DBP day, %	52.3±3.7	16.8±1.5***	50.8±3.6	15.1±1.5***
TI SBP night, %	53.9±3.8	27.1±2.5***	51.5±3.7	23.0±2.4***
TI DBP night, %	42.9±3.9	16.3±2.6***	41.3±3.8	15.1±2.5***

Notes: 1. * – reliability of differences in comparison with baseline data; 2. ** – $p<0.01$; 3. *** – $p<0.001$.

It was found that after the course of treatment, the levels of “office" SBP decreased by 19.3 % in group 1 and by 22.0 % in group 2 (all $p<0.001$ compared to baseline values; when comparing between groups $p>0.05$), and "office" DBP – by 17.4 % and 19.1 %, respectively ($p<0.001$ compared to baseline values).

Analysis of DMBP indicators after 3 months revealed a high antihypertensive effectiveness of the treatment in both groups of patients. A decrease in the levels of average daily SBP in group 1 by 21.9 %

(p<0.001) and average daily DBP by 18.8 % (p<0.01) and in group 2 by 24.1 % (p<0.001) and by 21.4 % (p<0.001) respectively).

After the treatment in all groups of patients, the indicators of pressure load of hypertension TI according to SBP and DBP decreased reliably in all time intervals, but did not exceed the norm, what indicates a stable 24-hour antihypertensive effect.

Analysis of the daily BP profile showed that in group 1, the number of "dippers" significantly increased from 5 (14.7 %) to 32 (94.1 %) (p<0.05), the number of "non-dippers" decreased from 21 (61.8 %) to 2 (5.9 %) (p<0.05). 8 (23.5 %) "night-picker" patients switched to the "dippers" group. Similar changes were observed in group 2: the number of "dippers" increased from 8 (30.8 %) to 24 (92.3 %) (p<0.05), the number of "non-dippers" decreased from 15 (57.7 %) to 2 (7.7 %) (p<0.05). From 3 (11.5 %) "night-picker" patients, all moved to the "dippers" group.

During the analysis of central aortic pressure indicators after the treatment, it was found that a statistically significant decrease in central SBP (cSBP) and DBP (cDBP) was observed in patients of both groups (Fig. 1). Thus, a decrease in cSBP groups 1 and 2 by 23.3 % (p<0.001) and 23.5 % (p<0.001) and cDBP by 19.1 % (p<0.01) and 20.5 % (p<0.01) respectively was found. After the treatment, a decrease in PWV was established by (1.0±0.2 m/s; p<0.01) in group 1 and by (1.5±0.2 m/s; p<0.01) in patients of group 2.

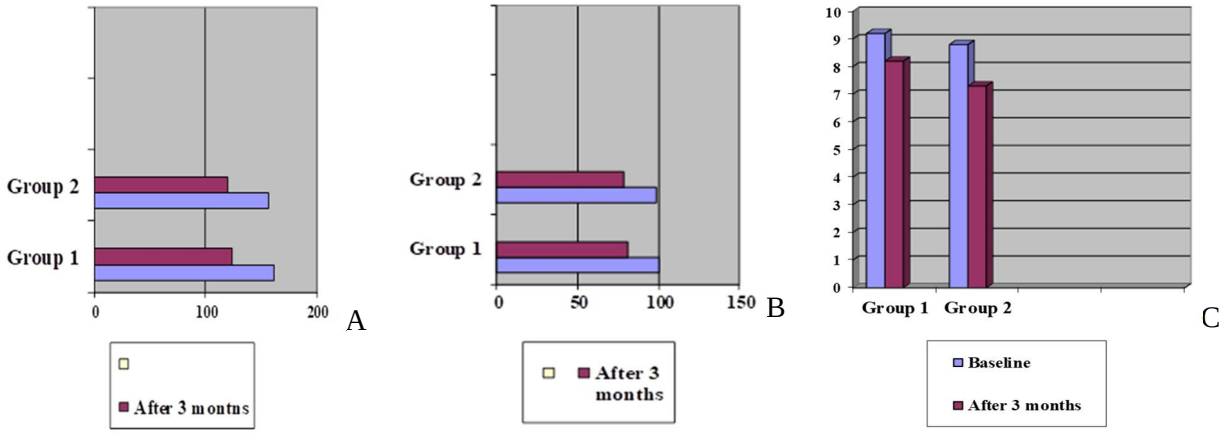

Fig.1 Dynamics of central SBP (A), central DBP (B) and pulse wave velocity (C) after the treatment in the examined groups of patients.

During analysis of the structural and functional parameters of the heart, a statistically significant decrease in LVMI by 7.3 % (p<0.05) in group 1 and by 6.9 % (p<0.05) in group 2 was found. The percentage of individuals with LVH decreased by 14.7 % in group 1 (p<0.05) versus 11.5 % in group 2 (p>0.05) due to an increase in the number of individuals with concentric LV remodeling in both groups.

After the treatment, positive dynamics of diastolic function indicators were found in both groups. Thus, an increase in the E/A ratio was established from 0.90±0.06 m/s to 1.2±0.05 (p<0.001) in group 1 and from 0.95±0.07 m/s to 1, 2±0.06 (p<0.01) in patients of group 2.

AH and obesity have been shown to be closely related, as abdominal obesity disrupts the endocrine and immune systems and carries a greater risk of developing insulin resistance, diabetes, AH, and cardiovascular diseases [7]. Moreover, obesity is recognized as a major risk factor for AH in both adults and children, regardless of race, ethnicity, and gender [3]. Thus, the prospective cohort study Nurse's Health Study and Framingham Heart Study [4] included 83,882 adult females who were observed for 16 years. It was found that increased BMI is associated with the development of AH, relative risk of AH development was 1.7 and 5.2 in females who gained 5–10 kg and >25 kg, respectively, and 40 % of new cases of AH were associated with overweight and obesity [4].

Arterial stiffness results from several important morphological modifications of the arterial wall, including increased collagen deposition, reduction and fragmentation of elastin fibers, irreversible cross-links between glycation end products and collagen, vascular smooth muscle cell hypertrophy, and matrix calcification [11]. The gold standard for measurement of stiffness of the large arteries is the aortic pulse wave velocity (PWV), which has an independent prognostic value for all-cause mortality and cardiovascular diseases [9].

Many epidemiological and clinical studies evaluating arterial distensibility in obese individuals have shown that obesity, especially in its abdominal form, is associated with increased arterial stiffness [14]. In a high-fat, high-sucrose experimental mouse model, obesity developed before or concurrently with arterial stiffness, suggesting that arterial modifications are the consequence of obesity [12].

Expansion of the arsenal of highly effective and safe methods of treatment of AH patients with obesity and without it, aimed at increasing the effectiveness of treatment of such patients, along with

improvement of the stiffness of the vascular wall and the elastic properties of vessels, is an important task of practical medicine.

The regimen of antihypertensive therapy used had a favorable effect on the parameters of daily BP and cBP monitoring, leading to a statistically significant improvement in the main indices of central hemodynamics in patients with hypertension combined with obesity and without it. After the treatment, a significant improvement was found not only in the levels of office SBP and DBP, but also in the daily profile of peripheral BP and central BP in both groups of patients. A decrease in SBP and DBP TI during the day and at night indicates a decrease in the pressure load.

In recent years, there has been growing interest in the study of some cBP parameters in order to investigate their contribution to the pathogenetic mechanisms of cardiovascular continuum [6]. It has been proven that cBP has an independent prognostic value as a risk factor for the development of cardiovascular complications [13].

The fixed combination of lisinopril dihydrate and amlodipine besylate reliably and comparably improved the elasticity of large vessels, what was shown by the reduction of PWV in AH patients with and without obesity. A significant reduction in the stiffness of the vascular wall of arteries is probably preconditioned by the additional vasodilatory effect of amlodipine to the effect of lisinopril. Moreover, in both groups of patients, the percentage of people with PWV>10 m/s, which is a marker of asymptomatic vascular damage, significantly statistically decreased. Both groups showed high antihypertensive efficacy and good tolerability in AH patients with obesity and without it.

During the analysis of features of the functional state of the heart, the groups were compared by the value of LV ejection fraction, characterizing the systolic function of the heart, what gives reason to suggest a long-term preservation of this index in patients with AH, even in case of obesity. It was established that normal diastolic function was found in 32.3 % in group 1 and 15.4 % in group 2 ($p<0.05$). The frequency of detection of concentric LV hypertrophy was significantly higher in patients of the 1st group compared to the 2nd group. The results obtained may be related to chronic left atrial overload due to the increased circulating blood volume caused by obesity and LV diastolic dysfunction.

Against the background of 3-month antihypertensive therapy, a tendency to improve the structural condition of the heart was established. A significant decrease in LVMI and improvement in LV diastolic function were found in both groups of patients.

Thus, the long-term use of the fixed combination of lisinopril dihydrate and amlodipine besylate in AH patients with and without obesity allows to effectively control of BP according to office measurement and daily BP monitoring, has a positive effect on daily BP profiles and indicators of arterial stiffness, as well as structural and functional parameters and status of diastolic function of the left ventricle, along with good tolerability of the therapy.

Conclusions

1. In AH patients in combination with obesity and without it, 3-month therapy by a fixed combination of lisinopril dihydrate and amlodipine besylate contributed to the achievement of the target levels of office BP, statistically significant reduction in daily SBP and DBP, improvement in daily BP profiles and indices of vascular wall stiffness, what indicates a leading role of BP reduction in the improvement of the elastic properties of blood vessels.

2. On the background of 3-month therapy with a fixed combination of lisinopril dihydrate and amlodipine besylate in AH patients with obesity and without it, a pronounced positive effect on the structural-geometric parameters and state of diastolic function of the left ventricle along with good tolerability, was observed.

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A.S. Herashchenko, S.V. Fedorov, M.V. Bielinskyi, N.M. Seredyuk, I.V. Kozlova
Ivano-Frankivsk National Medical University, Ivano-Frankivsk

PREDICTING HEART FAILURE IN PATIENTS WITH DIABETES MELLITUS: GALECTIN-3, SST2, AND CAROTID THICKNESS

e-mail: Herashchenko_An@ifnmu.edu.ua

Heart failure and Type 2 Diabetes Mellitus are two of the most common chronic conditions affecting adults worldwide. Soluble suppression of tumorigenicity 2 and galectin-3 are two biomarkers that have been studied extensively in recent years as predictors of risk of heart failure in patients with Type 2 Diabetes Mellitus. Carotid Intima Media Thickness is a well-established measure of arterial stiffness and vascular aging. We enrolled 154 patients with diabetes mellitus who presented to a private medical clinic: 83 patients in the diabetes mellitus with heart failure group and 71 patients in the diabetes mellitus–only group. We found that the diabetes mellitus with heart failure group had a significantly higher body mass index, mean Carotid Intima Media Thickness, and Galectin-3 compared to the diabetes mellitus group. However, there was no significant difference in age, gender composition, left ventricular ejection fraction, HbA1c, and soluble suppression of tumorigenicity 2 levels between the two groups.

Key words: heart failure, diabetes mellitus, galectin-3, low-grad inflammation, carotid intima media thickness

А.С. Геращенко, С.В. Федоров, М.В. Бєлінський, Н.М. Середюк, І.В. Козлова

ПРОГНОЗУВАННЯ СЕРЦЕВОЇ НЕДОСТАТНОСТІ У ХВОРИХ НА ЦУКРОВИЙ ДІАБЕТ: ГАЛЕКТИН-3, SST2 ТА ТОВЩИНА СОННОЇ АРТЕРІЇ

Серцева недостатність та цукровий діабет 2 типу є двома поширеними хронічними захворюваннями, що впливають на дорослих у всьому світі. Розчинна форма стимулюючого фактору росту 2 та галектин-3 – це два біомаркери, які активно досліджуються як показники ризику розвитку серцевої недостатності у пацієнтів з цукровим діабетом 2 типу. Товщина інтими сонної артерії є визнаним показником ступеня жорсткості артерій та старіння судин. У нашому дослідженні ми залучили 154 пацієнтів з цукровим діабетом, які звернулися до приватної медичної клініки: 83 пацієнтів із цукровим діабетом та серцевою недостатністю, і 71 пацієнтів з цукровим діабетом без серцевої недостатності. Ми виявили, що у групі пацієнтів з цукровим діабетом та серцевою недостатністю спостерігається значно вищий індекс маси тіла, середня товщина інтими сонної артерії та рівень галектину-3 у порівнянні з групою пацієнтів з цукровим діабетом без серцевої недостатності. Проте, між двома групами не було значних різниць у віці, статевому складі, відсотку викиду лівого шлуночка, рівнів HbA1c та розчинної форми стимулюючого фактору росту 2.

Ключові слова: серцева недостатність, цукровий діабет, галектин-3, запалення низького ступеня, товщина інтими сонних артерій

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Heart failure (HF) and Type 2 Diabetes Mellitus (T2DM) are two of the most common chronic conditions affecting adults worldwide. According to the World Health Organization, the prevalence of T2DM is estimated to have increased from 4.7 % in 1980 to 8.5 % in 2014, while the global burden of HF is enough to constitute it as an epidemic, that affects 64 million people [12, 14]. HF and T2DM are both