

Comparative assessment of the effectiveness of personalized treatment strategies for patients with chronic heart failure of ischemic origin with concomitant type 2 diabetes mellitus and obesity



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Objective — to conduct a comparative assessment of the effectiveness of personalized treatment strategies for patients with chronic heart failure of ischemic origin with concomitant type 2 diabetes mellitus and obesity.

Materials and methods. The study involved 75 patients with chronic heart failure due to coronary artery disease with concomitant type 2 diabetes mellitus and obesity. The average age of patients was 63.44 ± 2.06 years. For a comparative analysis of the various modulators of neurohormonal vasoconstrictor systems effectiveness, the examined patients with heart failure were divided into 2 groups, depending on the proposed therapy (a combination of valsartan and sacubitril ($n = 39$) or valsartan alone ($n = 36$)).

Results. All groups showed a decrease in galectin-3, nesfatin-1 and N-terminal fragment of pro-B-type natriuretic peptide serum levels, improvement in chronic heart failure functional class, increase in left ventricle ejection fraction, decrease in insulin resistance, positive changes in the lipid profile, and improvement in quality of life. A comparative analysis of two treatment strategies showed that in the 1st group, which received a combination of valsartan and sacubitril, significantly lower levels of galectin-3, nesfatin-1, and N-terminal fragment of pro-B-type natriuretic peptide and a higher level of catestatin were observed, as well as positive changes in the morpho-functional state of the myocardium compared to the 2nd group, which received only valsartan.

Conclusions. The obtained results confirm the benefits of the combination of neprilysin inhibitor and angiotensin II receptor blocker in the treatment of chronic heart failure, especially in patients with comorbidities such as coronary artery disease, type 2 diabetes mellitus, and obesity.

Keywords:

chronic heart failure, coronary artery disease, type 2 diabetes mellitus, obesity, personalized treatment.

Chronic heart failure (CHF) remains one of the leading causes of morbidity and mortality worldwide. Its prevalence is steadily increasing, especially among the elderly, largely due to the increasing number of patients with comorbid conditions. Coronary artery disease (CAD), type 2 diabetes mellitus (T2DM), and obesity are potent risk factors for the development and progression of CHF, and their combination significantly complicates the clinical course of the disease, worsens patients' quality of life, and increases the need for healthcare resources [4, 10].

Traditional approaches to the treatment of CHF, while effective, often do not take into account the individual characteristics of each patient, especially in the presence of such complex comorbidity. The pharmacokinetics and pharmacodynamics of drugs can change under the influence of obesity and T2DM,

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and the response to therapy can vary from person to person [5, 13]. In addition, the presence of comorbid metabolic pathology increases the risk of adverse drug interactions and side effects, requiring careful selection of drugs and their dosages [6, 8].

Personalized medicine opens up new perspectives in the treatment of CHF. As well as the use of genomic, proteomic, and metabolomic studies, the analysis of clinical data and patient lifestyle allows the development of individualized strategies for prevention, diagnosis, and treatment [11]. In CHF of ischemic origin with concomitant T2DM and obesity, a personalized approach may include, for example, genetic testing to determine individual predisposition to the development of the disease and predict response to therapy, monitoring of glycemia using continuous glucose monitoring systems, individual selection of physical activity taking into account functional status and the presence of comorbidities, as well as psychological support aimed at improving adherence to treatment and lifestyle modification [12].

It should be noted that the study is in line with the UN Sustainable Development Goal (SDG) No. 3 «Good Health and Well-being», as it focuses on the optimization and personalization of CHF treatment methods, which in turn can help to reduce morbidity and mortality from cardiovascular complications and improve the overall prognosis for patients. Similarly SDG No. 3 focuses on assessing the impact of treatment on patients' quality of life, which is an important aspect of well-being [3].

In this article we consider the possibilities and prospects of using personalized drug treatment strategies in patients with CHF of ischemic origin with concomitant T2DM and obesity.

Objective – to conduct a comparative assessment of the effectiveness of personalized treatment strategies for patients with chronic heart failure of ischemic origin with concomitant type 2 diabetes mellitus and obesity.

Materials and methods

The study involved 75 patients with CHF against the background of CAD with concomitant T2DM and obesity who were hospitalized in the cardiology department of the City Clinical Hospital No 27 in Kharkiv. All study subjects in the groups were comparable in age and sex. The average age of patients with CAD combined with T2DM and obesity was 63.44 ± 2.06 years.

To establish the diagnosis and assess the condition of patients, mandatory diagnostic methods were used in accordance with the Order of the Ministry of Health of Ukraine No. 2857 dated December 23, 2021, «On approval of the Unified Clinical Protocol of primary, secondary (specialized), and tertiary

(highly specialized) medical care for Stable Ischemic Heart Disease». The diagnosis of CAD included electrocardiography, echocardiography, and, if indicated, coronary angiography. Verification of T2DM involved measurement of blood glucose and insulin levels, assessment of glycated hemoglobin (HbA1c), and calculation of the HOMAinsulin resistance index. The diagnosis of obesity was established based on the body mass index (BMI), calculated as weight in kilograms divided by height in meters squared (kg/m^2). According to WHO criteria, obesity was defined as $\text{BMI} \geq 30 \text{ kg}/\text{m}^2$, while overweight was defined as $\text{BMI} 25.0\text{--}29.9 \text{ kg}/\text{m}^2$. In addition, waist circumference was assessed as a marker of abdominal obesity, with threshold values of $> 102 \text{ cm}$ for men and $> 88 \text{ cm}$ for women. The evaluation of chronic heart failure (CHF) was performed according to the clinical criteria of the New York Heart Association (NYHA), determination of N-terminal fragment of pro-B-type natriuretic peptide (NT-proBNP) levels, and echocardiography.

For a comparative analysis of the effectiveness of various modulators of neurohormonal vasoconstrictor systems, the examined patients suffering from CHF were divided into 2 groups, depending on the proposed therapy. As a result of randomization, 39 people were included in the 1st group, who received angiotensin II receptor blockers and neprilysin inhibitor (combination of valsartan and sacubitril) at a dose of 50–100 mg twice a day; 36 people were included in the 2nd group, who received angiotensin II receptor blocker (valsartan) at a daily dose of 80–320 mg.

In addition, all patients, regardless of the group, received a standardized treatment complex: furosemide 60–100 mg per day, intravenously for severe fluid retention, eplerenone at a dose of 25–50 mg per day, acetylsalicylic acid at a dose of 100 mg per day, rosuvastatin at a dose of 20 mg per day, dapagliflozin at a dose of 10 mg per day. Diuretic doses were adjusted depending on the patient's clinical response (body weight changes, severity of edema); eplerenone titration was performed with monitoring of potassium and creatinine levels to prevent side effects; dapagliflozin, acetylsalicylic acid, and rosuvastatin were administered at fixed doses according to current clinical guidelines and were not titrated unless combination with another drug was required to achieve target values. If it was impossible to achieve target levels of low-density lipoprotein cholesterol, a combination of rosuvastatin with ezetimibe 10 mg once a day was prescribed under the control of lipidogram and liver transaminases during the treatment. Glucose-lowering therapy was carried out according to individually selected regimens in compliance with an endocrinologist with the addition of metformin.

15 people of the first group (1.3%) and 13 people of the second group (1.2%) had complications in the form of atrial fibrillation, and taking into account the risk of thromboembolic (CHA₂DS₂-VASc) and hemorrhagic complications (HAS-BLED), rivaroxaban 20 mg was additionally administered to the therapy (according to the current Unified Clinical Protocol of primary, secondary (specialized), and tertiary (highly specialized) medical care «Atrial Fibrillation», Order of the Ministry of Health of Ukraine No. 597 dated June 15, 2016).

It should be noted that only after reaching the state of euvolemia 7–8 days after the start of treatment, one of the β -blockers was prescribed in addition to the standardized complex. The dose of β -blockers was chosen individually, by titration, starting from 1/8 of the average therapeutic dose. Bisoprolol: the initial dose was 1.25 mg once a day after meals, with an increase of 1.25 mg every 2 weeks, the target dose was 5 mg. With satisfactory tolerability of bisoprolol, a further increase in the dose to 10 mg – the level recommended by the working group of the European Society of Cardiology (2024) – was allowed.

An adequate clinical response to titration doses of β -blockers was considered the absence of the following manifestations: decrease in systolic blood pressure below 90 mm Hg, heart rate less than 55 per minute, the appearance of shortness of breath at rest or its obvious increase with normal physical exertion, episodes of suffocation, orthopnea. If necessary, in patients with severe CHF, titration of β -blockers was carried out very slowly, with an increase in the intervals between successive titration steps. The results of the treatment were evaluated after 12 months.

Echocardiography was performed on an ultrasound machine RADMIR (Ultima PRO 30) (Kharkiv, Ukraine) in B-mode from parasternal and apical positions with a 2.5 MHz sensor. The level of catestatin, nesfatin-1, galectin-3, NT-pro-BNP in the serum of patients was determined by enzyme immunoassay on an analyzer Labline-90 (Austria) using commercial test systems.

A rigorous set of exclusion criteria was used to ensure group homogeneity and to avoid the influence of confounding factors on the results. Patients were excluded from the study if they had: acute and chronic infectious diseases in the exacerbation phase, newly diagnosed T2DM, autoimmune diseases and diffuse connective tissue diseases, acute inflammatory processes, diseases of the hypothalamus, pituitary gland, and thyroid gland, symptomatic arterial hypertension, heart valve pathologies, chronic obstructive pulmonary disease, liver cirrhosis, moderate to severe anemia, acute stroke, acute left

or right ventricular failure, oncological diseases, drug addiction, alcoholism, co-occurring mental disorders, vascular dementia or other memory impairments, inability to give informed consent, or if they refused to participate for any reason.

The research results were processed using the statistical package of the licensed program «Statistica® for Windows 6.0» (StatSoft Inc.). The obtained results are presented as the mean \pm standard deviation from the mean ($M \pm m$). Evaluation of differences between groups with a distribution close to normal was carried out using the Pearson criterion. Differences were considered statistically significant at $p < 0.05$.

This work was conducted as part of the research project of the Department of Internal Medicine No 2 and Clinical Immunology and Allergology named after Academician L. T. Malaya of Kharkiv National Medical University «Pathogenetic substantiation of clinical diagnostic, prognostic and therapeutic markers in patients with coronary artery disease under polymorbid conditions» (State Registration No 0123U100331; 2022–2025).

The studies were approved by the Biomedical Ethics Committee of KhNMU and conducted in accordance with the written consent of the participants and in accordance with the principles of bioethics set out in the Helsinki Declaration «Ethical Principles for Medical Research Involving Human Subjects» and the «Universal Declaration on Bioethics and Human Rights (UNESCO)».

Results and discussion

To evaluate the effectiveness of the proposed therapeutic approaches, a detailed analysis of the clinical, laboratory, and instrumental indicators dynamics was conducted. The results are systematized and presented in Table.

Analysis of treatment results in group 1, which received a combination of valsartan and sacubitril, demonstrated a marked positive trend in most of the parameters studied. Thus, the level of galectin-3 decreased by 50.17%, nesfatin-1 by 60.61%, and the level of catestatin, on the contrary, increased by 128.22% ($p < 0.05$). The NT-proBNP content decreased by 51.27% ($p < 0.05$), indicating a significant reduction in haemodynamic load on the ventricular walls. When analysing the morphological parameters of the heart, a decrease in left ventricle end-diastolic volume (LVEDV) by 12.29%, left ventricle end-systolic volume (LVESV) by 18.08% and left ventricle end-diastolic dimension (LVEDD) by 4.42% was observed, left ventricle ejection fraction (LVEF) increased by 48.30%, and the E/A ratio decreased by 4.84% ($p < 0.05$). This indicates an improvement in both systolic and diastolic left ventricle (LV) function and optimisation of

Table. Changes in studied parameters during the treatment of patients with comorbid CAD with manifestations of CHF, type 2 diabetes mellitus, and obesity, depending on the proposed treatment regimen

Parameter, unit of measurement	1st group (n=39)		2nd group (n=36)	
	Before treatment	After treatment	Before treatment	After treatment
Galectin-3, ng/ml	29.46 ± 1.83	14.68 ± 2.07*	33.21 ± 1.41	27.13 ± 1.64**
NT-proBNP, pg/ml	3257 ± 45	1587 ± 37*	3961 ± 42	2862 ± 35**
Nesfatin-1, ng/ml	0.36 ± 0.82	0.14 ± 0.53*	0.34 ± 0.78	0.20 ± 0.27**
Catestatin, ng/ml	1.63 ± 0.18	3.72 ± 0.41*	1.56 ± 0.23	2.02 ± 0.73**
Total CHF FC	3.13 ± 0.31	1.96 ± 0.07	3.27 ± 0.29	2.48 ± 0.03
Distance of the 6-minute walk test, m	181.3 ± 10.2	257.1 ± 7.3	178.1 ± 11.3	226.3 ± 8.2
Quality of life according to MLHFQ, scores	61.8 ± 2.4	37.3 ± 3.0*	63.9 ± 2.4	41.8 ± 3.4*
Total cholesterol, mmol/l	6.87 ± 0.19	4.89 ± 0.36	6.44 ± 0.20	4.96 ± 0.61
High-density lipoprotein cholesterol, mmol/l	1.06 ± 0.07	1.39 ± 0.16	1.09 ± 0.05	1.58 ± 0.25
Triglyceride, mmol/l	2.26 ± 0.04	1.32 ± 0.05	2.06 ± 0.04	1.37 ± 0.08
Low-density lipoprotein cholesterol, mmol/l	3.66 ± 0.29	2.16 ± 0.06	3.78 ± 0.45	2.13 ± 0.16
Very-low-density lipoprotein cholesterol, mmol/l	0.76 ± 0.31	0.42 ± 0.07	0.72 ± 0.42	0.41 ± 0.05
Atherogenic coefficient	3.41 ± 0.22	2.32 ± 0.04	3.69 ± 0.18	2.44 ± 0.08
Insulin, μU/ml	32.49 ± 2.44	18.32 ± 2.33*	36.52 ± 2.26	18.72 ± 2.41*
Glucose, mmol/l	7.18 ± 0.27	5.78 ± 0.21	7.29 ± 0.31	6.37 ± 0.33
HOMA index	10.46 ± 0.47	4.71 ± 0.58*	11.66 ± 0.51	4.91 ± 0.78*
HbA1c, %	8.57 ± 0.32	6.73 ± 0.37*	9.20 ± 0.28	6.98 ± 0.49*
LVEDD, cm	5.88 ± 0.44	5.62 ± 0.32*	5.86 ± 0.48	5.41 ± 0.36*
LVESD, cm	4.18 ± 0.22	3.84 ± 0.41	4.15 ± 0.19	3.89 ± 0.29
LVEDV, ml	152.1 ± 2.1	133.4 ± 2.3*	147.6 ± 2.1	162.3 ± 4.2**
LVESV, ml	89.6 ± 1.5	73.4 ± 1.6*	86.3 ± 1.1	90.2 ± 1.7**
E/A	1.24 ± 0.06	1.18 ± 0.06*	1.31 ± 0.04	0.89 ± 0.08**
LVEF, %	37.6 ± 2.4	55.7 ± 1.7*	38.7 ± 2.0	47.4 ± 1.4**

transmittal blood flow under the influence of treatment with the addition of a combination of sacubitril and valsartan. In terms of metabolic parameters, improved glycaemic control was noted: insulin levels decreased significantly by 43.61 %, glucose levels by 19.50 %, HbA1c levels decreased by 21.47 %, and the HOMA index decreased by 54.97 % ($p < 0.05$). Improvements in intracardiac haemodynamics translated into increased exercise tolerance: the 6-minute walk distance increased by 41.81 %, and the quality of life score on the Minnesota Living With Heart Failure Questionnaire (MLHFQ) questionnaire improved by 39.64 % ($p < 0.05$).

Analysis of treatment results in the second group with the addition of valsartan to standard therapy also revealed positive changes, but they were less

pronounced in terms of cardiovascular markers. Markers of inflammation and fibrosis, namely serum galectin-3, decreased by 18.31 %, and nesfatin-1 by 39.40 % ($p < 0.05$). At the same time, the level of catestatin showed a moderate increase of 29.49 %, and the content of NT-proBNP decreased by 27.75 % ($p < 0.05$). The structural and functional parameters of the heart also showed significant differences. Thus, LVEDV increased by 9.96 %, LVESV by 4.52 %, LVEDD by 9.96 %, and LVEF increased by 22.54 % ($p < 0.05$). A significant decrease in E/A by 32.06 % indicates a redistribution of diastolic filling, but without proper correction of volumetric parameters. Among the indicators of carbohydrate metabolism, it should be noted that insulin levels decreased by 48.74 %, glucose levels – by 12.62 %, HbA1c

levels – by 24.13 %, and the HOMA index – by 57.89 % ($p < 0.05$). In addition, the 6-minute walk distance increased by 27.06 %, and the MLHFQ quality of life index improved by 34.59 % ($p < 0.05$).

It should be noted that despite the pronounced positive transformation of carbohydrate metabolism and the morpho-functional state of the myocardium, lipid metabolism indicators in both groups did not undergo statistically significant changes ($p > 0.05$). The absence of reliable dynamics of lipid markers against the background of both sacubitril/valsartan and valsartan monotherapy is explained by the specific mechanism of action of these drugs, aimed primarily at neurohumoral modulation (sodium-retaining peptide and renin-angiotensin-aldosterone systems) and improving tissue insulin sensitivity, rather than direct intervention in endogenous lipid synthesis or excretion. This emphasises the need for mandatory inclusion of potent hypolipidaemic support in the complex therapy of patients with ischaemic CHF, obesity and diabetes to correct dyslipidaemia as a fundamental factor in atherogenesis.

The next stage of the study was a comparative analysis of the clinical efficacy of two strategies of neurohumoral modulation in patients with ischaemic CAD against a background of T2DM and obesity. A comparison of treatment outcomes in both groups (see Table) allowed us to evaluate the advantages of using sacubitril/valsartan compared to standard therapy based on an angiotensin II receptor blocker. It was established that in the 1st group, the level of serum nesfatin-1 after treatment was 30 % lower than in the 2nd group ($p < 0.05$), which is due to the involvement of this indicator in the regulation of metabolism and cardiovascular effects, and the difference in levels may be related to the effect of sacubitril on neuroendocrine mechanisms.

The level of serum catestatin decreased significantly more in the 1st group during treatment – by 46 % ($p < 0.05$) compared to the 2nd group. Catestatin has anti-atherogenic and anti-inflammatory properties, and its greater reduction may be associated with the positive effect of combination therapy on endothelial function.

Also, in patients of the 1st group, a significantly lower level of NT-proBNP was found (by 45 %, $p < 0.05$), indicating a more significant effect of the neprilysin and valsartan combination on improving cardiac function and reducing the manifestations of heart failure.

Significant changes were observed in the morpho-functional state of the myocardium after treatment with the neprilysin and valsartan combination, namely, LVEDV was 22 % smaller ($p < 0.05$), and LVESV was 23 % smaller ($p < 0.05$) compared to the 2nd group. The E/A ratio significantly improved in

patients of the 1st group, where it was 32 % higher than in the 2nd group ($p < 0.05$). LVEF in the 1st group was 18 % higher compared to the 2nd group ($p < 0.05$). This indicates that combination therapy promotes positive cardiac remodeling and improves systolic and diastolic functions.

For other indicators, such as total NYHA functional class, 6-minute walk test distance, quality of life, lipid profile, carbohydrate metabolism parameters, and some other echocardiographic parameters, no statistically significant differences were found between the groups ($p > 0.05$).

The obtained data are consistent with the results of numerous studies that confirm the benefits of the neprilysin inhibitor and angiotensin II receptor blocker combination in the treatment of CHF, especially in patients with comorbidities such as CAD, T2DM, and obesity.

A significant lowering in NT-proBNP levels was noted, which aligns with numerous studies confirming that a reduction in NT-proBNP is an important marker of CHF treatment effectiveness. For example, in large clinical trials such as PARADIGM-HF, where sacubitril/valsartan demonstrated a considerable reduction in NT-proBNP levels compared to enalapril [1, 6, 8], it was shown that modern therapeutic approaches, including neprilysin inhibitors and beta-blockers, lead to substantive decrease in the level of this natriuretic peptide.

In our study, the serum galectin-3 level decrease was observed, which is a biomarker of inflammation and fibrosis in CHF, and its reduction is considered a positive trend. Similar results were obtained in studies where angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers [2] were used, indicating a degression in inflammatory processes in the myocardium.

The observation regarding the dynamics of serum catestatin levels is interesting, as it was higher in patients who received the sacubitril/valsartan combination in the standard therapeutic regimen. The role of catestatin in the pathophysiology of CHF is still actively being studied, and there is data on its effect on endothelial function and inflammation [7]. Further research is needed to clarify the clinical significance of such an increase in catestatin in the context of the applied therapy.

The reduction in LVEDV and LVESV under the influence of combination therapy indicates positive cardiac remodeling. This is consistent with data from echocardiographic studies showing that sacubitril/valsartan promotes a decrease in left ventricular size and improvement in its geometry [9]. The increase in LVEF in the group receiving combination therapy is an important indicator of improved systolic heart function. Many studies confirm that

sacubitril/valsartan is more effective than traditional angiotensin-converting enzyme inhibitors or angiotensin II receptor blockers in increasing LVEF in patients with CHF.

Combination therapy with valsartan and sacubitril has significant advantages over valsartan monotherapy in patients with comorbid CAD, CHF, T2DM, and obesity. It contributes to reducing inflammation, decreasing cardiac load, positively influencing neuroendocrine mechanisms, improving cardiac function, and remodeling the myocardium.

Conclusions

The conducted evaluation of the effectiveness of two different chronic heart failure treatment regimens in patients with heart failure on the background of coronary artery disease, concomitant T2DM and obesity demonstrated that the use of

a combination of valsartan and sacubitril led to more significant changes: a decrease in serum galectin-3 levels (by 46 %, $p < 0.05$), serum nesfatin-1 levels (by 30 %, $p < 0.05$), and NT-proBNP levels (by 45 %, $p < 0.05$); an increase in serum catestatin levels (by 46 %, $p < 0.05$); and improvement in left ventricular systolic and diastolic functions, as well as a reduction in its chambers and dimensions. Thus, the combination of valsartan and sacubitril provides deeper neurohumoral modulation and better restoration of the structural and functional state of the myocardium in patients with comorbid coronary artery disease, T2DM and obesity.

Perspectives for further research. Conducting long-term follow-up of patients to assess long-term treatment outcomes, impact on survival, frequency of hospitalizations, and CHF progression.

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Порівняльна оцінка ефективності застосування персоніфікованих стратегій лікування хворих із хронічною серцевою недостатністю ішемічного генезу на тлі супутнього цукрового діабету 2 типу та ожиріння

Мета — провести порівняльну оцінку ефективності застосування персоналізованих стратегій лікування хворих із хронічною серцевою недостатністю ішемічного генезу на тлі супутнього цукрового діабету 2 типу та ожиріння.

Матеріали та методи. У дослідження було залучено 75 хворих на хронічну серцеву недостатність на тлі ішемічної хвороби серця з цукровим діабетом 2 типу та ожирінням. Середній вік пацієнтів — $(63,44 \pm 2,06)$ року. Для порівняльного аналізу ефективності модюляторів нейрогормональних вазоконстрикторних систем пацієнтів із серцевою недостатністю було розподілено на дві підгрупи залежно від запропонованої терапії (комбінація валсартану й сакубітрілу ($n = 39$) або лише валсартан ($n = 36$)).

Результати. У всіх групах зареєстровано зниження рівня сироваткового галектину-3, несфатину-1, N-термінального фрагмента попередника мозкового натрійуретичного пептиду, поліпшення функціонального класу хронічної серцевої недостатності, збільшення фракції викиду, зменшення інсулінорезистентності, позитивні зміни ліпідограми та поліпшення якості життя. Порівняльний аналіз двох схем лікування показав, що в підгрупі, яка отримувала комбінацію валсартану й сакубітрілу були значно нижчими рівні галектину-3, несфатину-1, N-термінального фрагмента попередника мозкового натрійуретичного пептиду і більший вміст катестатину, а також позитивні зміни морфофункціонального стану міокарда порівняно з підгрупою, яка отримувала лише валсартан.

Висновки. Отримані результати підтверджують переваги комбінації інгібітора неприлізину та блокатора рецепторів ангіотензину II у лікуванні хронічної серцевої недостатності, особливо в пацієнтів із супутніми захворюваннями, такими як ішемічна хвороба серця, цукровий діабет 2 типу та ожиріння.

Ключові слова: хронічна серцева недостатність, ішемічна хвороба серця, цукровий діабет 2 типу, ожиріння, персоніфіковане лікування.

ДЛЯ ЦИТУВАННЯ

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