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EFFICACY OF DAPAGLIFLOZIN IN THE TREATMENT OF PATIENTS WITH SIGNS OF CARDIO-RENAL-METABOLIC SYNDROME

Iryna O. Haman, Mariana M. Vasylechko, Oksana I. Kocherzhat, Bohdana R. Vatseba

Ivano-Frankivsk National Medical University of the Ministry of Health of Ukraine, Ivano-Frankivsk, Ukraine

Abstract

Introduction. The growing prevalence of cardio-renal-metabolic diseases underscores the importance of early diagnosis and the implementation of a comprehensive therapeutic approach.
Aim. To assess the clinical features and therapeutic efficacy of dapagliflozin in patients with cardio-renal-metabolic syndrome.
Materials and methods. The study enrolled 56 patients with chronic kidney disease (CKD). All participants underwent comprehensive clinical assessment, including echocardiography, biochemical blood test, measurement of glycated hemoglobin (HbA1c), N-terminal pro-B-type natriuretic peptide (NT-proBNP), urinary albumin-to-creatinine ratio, and estimated glomerular filtration rate. The patients were stratified into two groups: Group 1 comprised 30 patients with stage III CKD, while Group 2 included 26 patients with stage IV CKD. Dapagliflozin was incorporated into the treatment regimen.
Results. Clinical manifestations of cardio-renal-metabolic syndrome in the examined patients were characterized by the presence of heart failure (HF) with reduced left ventricular ejection fraction (LVEF), elevated NT-proBNP levels, as well as disturbances in carbohydrate metabolism, electrolyte homeostasis, and renal function. The addition of dapagliflozin to the standard therapeutic regimen resulted in an improvement in LVEF, a significant reduction in NT-proBNP levels by 31.7% ($p = 0.0028$) and 11.4% ($p = 0.012$) in Groups 1 and 2, respectively, in patients with HF and mildly reduced LVEF. Furthermore, a decrease in HbA1c was observed by 11.4% ($p = 0.041$) in patients with impaired glucose tolerance and by 14.8% ($p = 0.039$) in those with diabetic nephropathy. Under the influence of treatment, a significant reduction in the urinary albumin-to-creatinine ratio was noted in Group 1 by 26.7% ($p = 0.022$) and in Group 2 by 16.5% ($p = 0.047$), along with an increase in the estimated glomerular filtration rate by 21.7% ($p = 0.027$) and 11.3% ($p = 0.039$), respectively, predominantly in patients with HF and mildly reduced LVEF.
Conclusions. The use of dapagliflozin as part of combination therapy improves clinical outcomes in patients with cardio-renal-metabolic syndrome by enhancing myocardial contractility, optimizing electrolyte balance, and reducing albuminuria, while also increasing the estimated glomerular filtration rate, which provides cardio- and nephroprotection.

Keywords: **chronic kidney disease, heart failure, hypertension, diabetes mellitus, dapagliflozin**

INTRODUCTION

Cardio-renal-metabolic syndrome comprises a combination of cardiovascular disease, diabetes mellitus (DM), and chronic kidney disease (CKD), which are prevalent across populations in various countries and recognized as leading causes of mortality worldwide [1, 2]. According to the new ADA guidelines (2026) [1], one in nine individuals in the United States is affected by cardiovascular disease and type 2 DM (T2D) and dies from related complications. In Ukraine, over 1.2 million people have T2D, and the prevalence of CKD among these patients reaches 40% [2]. Over recent decades, mortality associated with CKD has doubled, primarily due to the asymptomatic course of the disease until its advanced stages [3]. Each of these conditions not only contributes to the development of the others but also exacerbates the clinical course and prognosis of this comorbid condition [4].

The development of cardio-renal-metabolic syndrome is associated with the excessive formation of

dysfunctional adipose tissue that secretes pro-inflammatory cytokines, which damage the arteries, heart, and kidney tissues. The inflammatory process leads to insulin resistance, the onset of diabetes mellitus, the progression of hypertension (HTN), and impaired renal function [5, 6].

Cardio-renal-metabolic diseases do not coexist independently but pathophysiologically potentiate one another, resulting in a poorer prognosis [7]. The coexistence of these conditions in a single patient requires a pathogenetically substantiated therapeutic approach at different stages of disease progression. Early diagnosis and screening, along with timely detection and treatment, may slow or prevent disease progression and reduce the risk of further complications [8].

The results of large-scale international studies (DAPA-HF, DAPA-CKD) have confirmed that treatment with sodium-glucose cotransporter-2 inhibitors (SGLT2i) reduces the composite risk of heart failure decompensation and cardiovascular death, while providing significant cardiorenal protection [9, 10]. Dapagliflozin provides simultaneous protection of target organs – the heart and kidneys – and reduces the risk of hospitalizations for HF and cardiovascular mortality, irrespective of glycemic status [9]. The cardio- and nephroprotective effects of dapagliflozin are manifested in improved left ventricular ejection fraction (LVEF) [9], reduced albuminuria [10], decreased intraglomerular pressure, and stabilization of glomerular filtration rate (GFR) [10], thereby effectively slowing disease progression and reducing the risk of end-stage renal failure.

Thus, the rising prevalence of cardio-renal-metabolic diseases, which are interrelated conditions associated with a high risk of mortality, underscores the need for early diagnosis and comprehensive treatment. Timely detection and treatment can slow their progression and reduce complications, while the use of SGLT2 inhibitors, with their proven multi-organ protective effects, provides effective cardioprotective and nephroprotective benefits, improving patients' quality of life and prognosis.

AIM

To evaluate the characteristics of dapagliflozin use in patients with cardio-renal-metabolic syndrome.

MATERIALS AND METHODS

A total of 56 patients with stage III-IV CKD were examined (26 men (46%) and 30 women (54%)), with a mean age of (62 ± 7.3) years. The average duration of the disease was (11±3) years. The main causes of CKD were diabetic and hypertensive nephropathy. CKD was diagnosed in accordance with the Clinical Guideline 00226, and treatment was conducted according to the unified protocol (2015) [11]. Patient examinations were conducted in accordance with standards established for patients with cardiological, endocrinological, and nephrological conditions.

A general clinical examination was performed, along with biochemical blood tests – measuring creatinine, urea, glucose, and potassium levels; determination of glycated hemoglobin (HbA1c) levels by chromatography, natriuretic peptide (NT-proBNP) levels by immunoassay, and the urine albumin-to-creatinine ratio; echocardiography (EchoCG); ultrasound examination of the kidneys and calculation of GFR using the CKD-EPI formula (mL/min/1.73 m²).

According to the 2024 Recommendations of the Ukrainian Association of Cardiology on the diagnosis, treatment, and prevention of Chronic Heart Failure and the 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure [12, 13], myocardial contractility and HF phenotyping were determined based on measurement of the left ventricular ejection fraction (LVEF), %: LVEF ≤40% – HF with reduced LVEF (HFrEF); LVEF 41-49% – HF with moderately reduced LVEF (HFmrLVEF); LVEF ≥50% and the presence of symptoms and signs of HF, supported by structural and/or functional changes in the heart along with elevated levels of natriuretic peptides – HF with preserved LVEF (HFpEF); baseline LVEF ≤40%, with a 10% increase on repeat measurement to >40% – HF with improved LVEF.

Depending on GFR levels and CKD stage, all patients were divided into groups: Group 1 consisted of 30 patients with stage III CKD, and Group 2 consisted of 26 patients with stage IV CKD. The control group comprised 15 healthy individuals.

The treatment regimen included angiotensin-converting enzyme inhibitors, calcium channel blockers, angiotensin II receptor blockers, diuretics, mineralocorticoid receptor antagonists, and oral glucose-lowering and metabolic agents. In addition, a sodium-glucose cotransporter-2 (SGLT2) inhibitor, dapagliflozin, was administered at a dose of 10 mg once daily. Patients with HFrEF received sacubitril/valsartan in titrated doses in addition to their treatment regimen.

The study was conducted over the course of a year, with quarterly monitoring of hemodynamic parameters, carbohydrate metabolism, and renal function.

Statistical analysis of the study results was performed using Microsoft Excel, employing methods of variational statistics and Student's paired t-test. Results were considered statistically significant at $p < 0.05$.

RESULTS

Among the examined patients, 30 (54%) were diagnosed with stage III CKD (eGFR <30-59mL/min) and 26 (46%) with stage IV CKD (eGFR <30-15 mL/min).

The main causes of CKD were diabetic nephropathy in 30 (53.6%) cases and hypertensive nephropathy in 26 (46.4%) cases. Anthropometric parameters were also analyzed. Among the examined patients, normal body weight according to body mass index (BMI) was observed in 21.4% of cases, while overweight and obesity were identified in 35.7% and 42.9% of cases, respectively.

According to echocardiography data (Table 1), in patients in Group 1, LVEF value corresponded to HFmrEF in 63.3% of cases – (46.32 ± 2.03) (p = 0.0022) and in 11 (36.7%) cases – to HFrEF (38.07 ± 1.24) (p = 0.039). In Group 2, the LVEF value corresponded to HFmrEF in 10 (38.5%) cases – (43.74 ± 1.77) (p = 0.033) and to HFrEF in 16 (61.5%) cases – (35.84 ± 1.08) (p = 0.019).

An increase in the level of natriuretic peptides in the blood is a marker of cardiac injury and the development of HF. In Group 1 patients with HFmrEF, a statistically significant 3.9-fold increase in NT-proBNP levels was observed (p = 0.035), and in those with HFrEF – a 5.3-fold increase (p = 0.016); in Group 2 patients with HFmrEF – a 6.4-fold increase in NT-proBNP levels (p = 0.012), and in the subgroup with HFrEF – an 8.9-fold increase (p = 0.009), respectively, compared to the control group's value of (104.23 ± 6.74) pg/mL.

Table 1

Left Ventricular Ejection Fraction (LVEF) and NT-proBNP Levels in Patients with Cardio-Renal-Metabolic Syndrome Undergoing Treatment (M ± m)

Parameter	Control Group (n=15)	Group 1 (n=30)		Group 2 (n=26)	
		HFmrEF (n=19)	HFrEF (n=11)	HFmrEF (n=10)	HFrEF (n=16)
EF, %	58,94± 4,18	before treatment			
		46,32±2,03*	38,07±1,24*	43,74±1,77*	35,84±1,08*
		after one year			
		48,52±3,78**	39,84±2,21**	45,22±2,04**	37,52±3,50**
NT-proBNP, pg/mL	104,23± 6,74	before treatment			
		404,74±8,26*	553,54±7,42*	674,33±17,12*	934,48±25,23*
		after one year			
		276,45±11,30**	430,11±14,87**	597,28±12,52**	879,22±19,47

Notes 1. * (p < 0.05) – statistically significant difference compared with the control group;
2. ** (p < 0.05) – statistically significant difference compared with baseline (before treatment).

Glycated hemoglobin allows assessment of the average blood glucose level over a period of 2-3 months prior to examination. The HbA1c level in 14 (53.8%) cases of patients with hypertensive nephropathy was 40.8% higher (p = 0.0013) compared to the control group – (4.24 ± 0.73)%, while in patients with diabetic nephropathy it corresponded to impaired glucose tolerance – it was greater than 6.5% and was twice (p = 0.024) the level in the control group.

The progression of CKD is associated with disturbances in mineral metabolism, particularly electrolyte imbalances. Certain changes in serum potassium levels were observed in the patients studied (Table 2). Specifically, in Group 1, normal potassium levels (3.5-5.2 mmol/L) were found in 18 (60%) cases, and hyperkalemia (5.6-6.5 mmol/L) in 12 (40%) cases; in Group 2, these values were observed in 10 (38.5%) and 16 (61.5%) cases, respectively, predominantly in patients with HFrEF; control group – (4.12 ± 0.14) mmol/L. Electrolyte imbalance is an aggravating factor in the multimorbid course of CKD with hypertension and diabetes. The prevalence of hyperkalemia can be considered a predictor of mortality in patients with end-stage CKD.

Table 2

Indicators of Electrolyte Balance and Renal Function in Patients with Cardio-Renal-Metabolic Syndrome under Treatment (M ± m)

Parameter	Control group (n=15)	Group 1 (n=30)	Group 2 (n=26)
Potassium, mmol/L	4,12±0,14	before treatment	
		5,61±0,82*	6,41±0,57*
		after one year	
		5,02±0,48**	5,29±0,46**
Urinary albumin-to-creatinine ratio (ACR), mg/g	15,24±3,48	before treatment	
		202,55±26,41*	507,84±33,35*
		after one year	
		148,42±17,54**	424,27±21,82**
eGFR, mL/min/1.73 m²	96,22±2,14	before treatment	
		48,64±9,37*	22,94±6,28*
		after one year	
		59,21±6,18**	25,53±4,19

Notes 1. * (p<0.05) – statistically significant difference compared with the control group;
2. ** (p<0.05) – statistically significant difference compared with baseline (before treatment).

Assessment of renal status in all patients revealed structural changes of the renal parenchyma according to ultrasound findings, as well as functional impairments. Specifically, in Group 1 patients with stage III CKD, the urinary albumin-to-creatinine ratio (ACR) increased 13.3-fold ($p = 0.0006$), while in Group 2 it increased 33.3-fold compared with the control group (15.24 ± 3.48 mg/g; $p = 0.0002$). In Group 2 patients with stage IV CKD and HFrEF, the ACR was 2.5 times higher ($p = 0.0003$) compared with Group 1. The estimated glomerular filtration rate (eGFR) in Group 1 was reduced twofold ($p = 0.0009$), while in Group 2 it was reduced 4.2-fold compared with the control group (96.22 ± 2.14 mL/min/1.73 m²; $p = 0.0005$).

After one year of treatment, an improvement in left ventricular ejection fraction (LVEF), renal function parameters, patients' general condition, and a reduction in dyspnea were observed. Dapagliflozin was well tolerated, and no adverse events were reported. Regarding LVEF, in Group 1, among patients with HFmrEF, the parameter increased by 12.9% in 8 cases (42.1%) and reached the range of HFimpEF ($52.3 \pm 1.98\%$; $p = 0.046$). In the subgroup with HFrEF, LVEF increased by 10.5% in 3 cases (27.3%) ($p = 0.049$) and shifted to HFmrEF ($42.05 \pm 1.06\%$). In the remaining patients, LVEF showed a tendency toward improvement ($p = 0.063$). In Group 2 patients with HFrEF, LVEF demonstrated only a trend toward increase ($p = 0.059$). In the subgroup with HFrEF, LVEF increased by 14.6% in 3 cases (18.8%) ($p = 0.037$), corresponding to HFmrEF ($41.02 \pm 0.14\%$), while in the remaining patients it remained unchanged.

When assessing changes in NT-proBNP levels during treatment, variations were observed depending on left ventricular ejection fraction (LVEF). In patients in Group 1 with HFmrEF, NT-proBNP levels decreased by 31.7% ($p = 0.0028$), and in those with HFrEF – by 22.3% ($p = 0.0040$). In Group 2, patients with HFmrEF showed an 11.4% decrease in NT-proBNP levels ($p = 0.012$), while those with HFrEF showed only a trend toward a decrease in this parameter ($p = 0.061$).

Treatment with dapagliflozin contributed to an 11.4% reduction in HbA1c levels in patients with hypertensive nephropathy and impaired glucose tolerance ($p=0.041$), and in patients with diabetic nephropathy by 14.8% ($p = 0.039$), indicating its positive effect on the glycemic profile.

Under the influence of treatment, serum potassium levels in Group 1 patients decreased by 10.5% ($p = 0.046$), while in Group 2 patients they decreased by 17.4% ($p = 0.011$) compared with baseline values. This was interpreted as a reduction in the risk of adverse cardiac outcomes.

Assessment of renal functional parameters after one year of treatment demonstrated a reduction in the urinary albumin-to-creatinine ratio (ACR). Specifically, in Group 1, ACR decreased by 26.7% ($p = 0.0017$), while in Group 2 it decreased by 16.5% ($p = 0.0028$) compared with baseline values. At the same time, estimated glomerular filtration rate (eGFR) increased by 21.7% in Group 1 ($p = 0.0006$) and by 11.3% in Group 2 ($p = 0.008$), predominantly in patients with HFmrEF.

DISCUSSION

The combination of metabolic risk factors is closely associated with the risk of adverse cardiovascular and renal outcomes. In the examined patients with cardio-renal-metabolic syndrome, there are disturbances in cardiac hemodynamics with the development of HF and elevated levels of natriuretic peptides, as well as renal damage with reduced filtration capacity and albuminuria.

Our results confirm published data indicating that manifestations of cardio-renal-metabolic syndrome in patients with hypertension and T2D are associated with interrelated pathogenetic mechanisms and target-organ damage, which progressively worsens with disease progression [6]. One of the most important target organs frequently affected in arterial hypertension and type 2 diabetes mellitus is the kidneys, leading to the development and progression of CKD [2].

The modern treatment strategy for patients with cardio-renal-metabolic syndrome is aimed at systemic organ protection. According to multicenter studies, the sodium-glucose cotransporter 2 inhibitor (SGLT2 inhibitor) dapagliflozin plays a key role due to its multi-organ effects [10, 11]. Our study data demonstrate that the use of dapagliflozin contributes to an increase in left ventricular ejection fraction (LVEF) with a reduction in N-terminal pro-B-type natriuretic peptide levels and improved glycemic control, predominantly in patients with stage III CKD.

Thus, the sodium-glucose cotransporter 2 inhibitor (SGLT2 inhibitor) dapagliflozin is recommended for inclusion in the treatment regimen of patients with cardio-renal-metabolic syndrome not only as a glucose-lowering agent, but also as a cardio-renal protective therapy. The use of dapagliflozin in the comprehensive treatment of patients with cardio-renal-metabolic syndrome helps slow the progression of heart failure and end-stage renal disease and prevent the development of related complications.

CONCLUSIONS

As comorbid conditions progress in patients with cardio-renal-metabolic syndrome, worsening structural and functional changes in the cardiovascular system and renal function have been observed. The use of dapagliflozin in combination therapy enhances the efficacy of treatment in patients with cardio-renal-metabolic syndrome by improving left ventricular

myocardial contractile function. The nephroprotective effect of dapagliflozin slows the progression of CKD by reducing albuminuria, increasing glomerular filtration rate, and improving the electrolyte profile in patients with cardio-renal-metabolic syndrome.

Prospects for further research. Further research should be directed toward an in-depth study of approaches for correcting markers of target-organ damage in patients with cardio-renal-metabolic syndrome for early detection and prevention of complications.

COMPLIANCE WITH ETHICAL REQUIREMENTS

The study was conducted in accordance with the ethical principles of the WMA Declaration of Helsinki and confidentiality standards. Before the study began, all participants received comprehensive information about the study objectives, methods, and potential risks, and provided informed consent.

FUNDING AND CONFLICT OF INTEREST

The study was conducted without external funding. The authors declare no conflict of interest.

AUTHOR CONTRIBUTIONS

Haman I. O.[A, B, C, D, F]

Vasylechko M. M.[A, B, E, F]

Kocherzhat O. I.[A, D, E]

Vatseba B. R.[D, E]

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Резюме

ЕФЕКТИВНІСТЬ ДАПАГЛІФЛОЗИНУ У ЛІКУВАННІ ХВОРИХ ІЗ ОЗНАКАМИ КАРДІО-РЕНО-МЕТАБОЛІЧНОГО СИНДРОМУ

Ірина О. Гаман, Мар'яна М. Василечко, Оксана І. Кочержат, Богдана Р. Вацеба

Івано-Франківський національний медичний університет Міністерства охорони здоров'я України, м. Івано-Франківськ, Україна

Вступ. Зростання поширеності кардіо-рено-метаболічних захворювань зумовлює необхідність проведення ранньої діагностики та комплексного підходу до лікування.
Мета. Оцінити особливості застосування дапагліфлозину у хворих із кардіо-рено-метаболічним синдромом.
Матеріали та методи. У дослідження включено 56 хворих на хронічну хворобу нирок (ХХН). Проведено загальноклінічне обстеження, ехокардіографію, біохімічне дослідження крові, визначення рівня глікованого гемоглобіну (HbA1c), натрійуретичного пептиду (NT-proBNP), співвідношення альбумін/креатинін сечі та швидкості клубочкової фільтрації. Хворих розподілено на групи: 1 група – 30 хворих із ХХН III стадії, 2 група – 26 хворих із ХХН IV стадії. До комплексу лікування включено препарат дапагліфлозин.
Результати. Прояви кардіо-рено-метаболічного синдрому в обстежених хворих характеризувалися розвитком серцевої недостатності (СН) зі зниженою фракцією викиду лівого шлуночка (ФВ ЛШ), зростанням рівня NT-proBNP, порушенням вуглеводного обміну, електролітного балансу, ниркової функції. Застосування дапагліфлозину сприяло покращенню показника ФВ ЛШ; зниженню рівня NT-proBNP на 31,7% (p = 0,0028) та 11,4% (p = 0,012) відповідно у 1 та 2 групах хворих із СН з помірно зниженою ФВ ЛШ; зниженню рівня HbA1c при порушеній толерантності до глюкози на 11,4% (p = 0,041) та на 14,8% (p = 0,039) – при діабетичній нефропатії. Під впливом лікування відмічалося зниження співвідношення альбумін/креатинін сечі у 1 групі – на 26,7% (p = 0,022), у 2 групі – на 16,5% (p = 0,047) та зростання швидкості клубочкової фільтрації у 1 групі на 21,7% (p = 0,027), у 2 групі – на 11,3% (p = 0,039), переважно у хворих із СН з помірно зниженою ФВ ЛШ.
Висновки. Використання в комплексній терапії дапагліфлозину підвищує ефективність лікування хворих із кардіо-рено-метаболічним синдромом завдяки покращенню скоротливої функції міокарда, електролітного профілю, зниженню рівня альбумінурії, зростанню швидкості клубочкової фільтрації, що забезпечує кардіо- та нефропротекцію.

Ключові слова: **хронічна хвороба нирок, серцева недостатність, артеріальна гіпертензія, цукровий діабет, дапагліфлозин**

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