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EMPAGLIFLOZIN MITIGATES CHEMOTHERAPY-INDUCED CARDIOTOXICITY AND ENDOTHELIAL DYSFUNCTION IN BREAST CANCER PATIENTS

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Empagliflozin has recently been suggested as a potential cardioprotective agent for breast cancer patients undergoing chemotherapy, a treatment known for its cardiotoxic effects. This study evaluated the effects of empagliflozin on diastolic function and endothelial health in breast cancer patients without prior cardiovascular disease. Sixty-six female patients were divided into two groups: one receiving empagliflozin during chemotherapy, and a control group. The study found that patients treated with empagliflozin exhibited significantly better preservation of diastolic function, as evidenced by smaller declines in the E/A ratio, E/e' ratio, and left ventricular ejection fraction. Additionally, endothelial function, measured by flow-mediated dilation, was less impaired in the empagliflozin group. These results suggest that empagliflozin may effectively mitigate the cardiotoxic and endothelial adverse effects of chemotherapy, offering a novel approach to protecting cardiovascular health in breast cancer patients.

Key words: breast cancer, cardiotoxicity, chemotherapy, cardioprotection, endothelial dysfunction, empagliflozin, side effects of chemotherapeutic drugs.

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ЕМПАГЛІФЛОЗИН ЗМЕНШУЄ КАРДІОТОКСИЧНІСТЬ, СПРИЧИНЕНУ ХІМІОТЕРАПІЄЮ, ТА ЕНДОТЕЛІАЛЬНУ ДИСФУНКЦІЮ У ХВОРИХ НА РАК МОЛОЧНОЇ ЗАЛОЗИ

Емпагліфлозин нещодавно був запропонований як потенційний кардіопротекторний засіб для пацієнтів з раком молочної залози, які проходять хіміотерапію, що відома своїми кардіотоксичними ефектами. У цьому дослідженні було оцінено вплив емпагліфлозину на діастолічну функцію та здоров'я ендотелію у пацієнток із раком молочної залози без попередніх серцево-судинних захворювань. Шістдесят шість жінок було розділено на дві групи: одну, яка отримувала емпагліфлозин під час хіміотерапії, і контрольну групу. Дослідження показало, що пацієнтки, які отримували емпагліфлозин, мали значно краще збереження діастолічної функції, що проявлялося меншим зниженням співвідношення E/A, E/e' та фракції викиду лівого шлуночка. Крім того, функція ендотелію, виміряна за допомогою дилатації, опосередкованої потоком, була менш порушена у групі, яка отримувала емпагліфлозин. Ці результати свідчать про те, що емпагліфлозин може ефективно пом'якшувати кардіотоксичні та ендотеліальні побічні ефекти хіміотерапії, пропонуючи новий підхід до захисту серцево-судинної системи у пацієнток з раком молочної залози.

Ключові слова: рак молочної залози, кардіотоксичність, хіміотерапія, кардіопротекція, ендотеліальна дисфункція, емпагліфлозин, побічна дія хіміотерапевтичних препаратів.

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Breast cancer remains the most common malignancy among women worldwide, with millions of new cases diagnosed each year [7]. Advances in treatment, particularly chemotherapy, have significantly improved survival rates, but these gains are often accompanied by adverse effects that can compromise long-term health. Among these, cardiotoxicity has emerged as a major concern, especially as more patients live longer after successful cancer treatment [2, 5]. The spectrum of cardiotoxicity associated with chemotherapy ranges from asymptomatic changes in cardiac function to severe heart failure. Notably, the impact of chemotherapy on diastolic function and endothelial health has garnered increasing attention, particularly in patients without pre-existing cardiovascular disease [6].

Chemotherapy-induced cardiotoxicity, particularly diastolic dysfunction, represents a critical area of concern in breast cancer survivors. Diastolic dysfunction, characterized by impaired relaxation and abnormal filling of the left ventricle, is a subtle yet significant indicator of potential heart failure. Studies have shown that anthracyclines and other chemotherapeutic agents can lead to alterations in diastolic function, even in patients with no prior cardiovascular disease dysfunction may progress to symptomatic heart failure if not identified and managed early [4].

In parallel, endothelial dysfunction, a condition marked by impaired endothelium-dependent vasodilation, is increasingly recognized as a precursor to atherosclerosis and other cardiovascular diseases. The endothelium plays a vital role in vascular homeostasis, regulating blood flow, inflammation, and thrombosis. Chemotherapy, through its systemic effects, can disrupt endothelial function, leading to an increased risk of cardiovascular events. The impairment of flow-mediated dilation (FMD), a widely used

measure of endothelial function, has been documented in patients undergoing chemotherapy, correlating with future cardiovascular risk [1].

Recently empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor, was researched for a potential role in mitigating chemotherapy-induced cardiotoxicity. Originally developed for the management of type 2 diabetes, empagliflozin has demonstrated cardioprotective effects in various populations, including those without diabetes [3]. Empagliflozin is believed to exert through mechanisms such as improved myocardial energy metabolism, reduction of oxidative stress, and enhancement of endothelial function. Given these properties, empagliflozin may vel an approach to protecting the cardiovascular system during chemotherapy, particularly in preventing or attenuating diastolic dysfunction and endothelial impairment.

The purpose of the study was to evaluate the cardioprotective potential of empagliflozin in breast cancer patients undergoing chemotherapy.

Materials and methods. This prospective, comparative study was conducted at the Precarpathian Regional Oncological Center from January 2023 to May 2024, aimed at evaluating the impact of empagliflozin on diastolic function and endothelial health in breast cancer patients undergoing chemotherapy. A total of 66 female patients with breast cancer were included in the study, divided into two groups. Group 1 (n=35) received empagliflozin 10 mg daily during their chemotherapy regimen, while Group 2 (n=31) did not receive empagliflozin. Ethical approval was obtained from the institutional review board, and all participants provided written informed consent before enrollment.

Eligible patients were those diagnosed with breast cancer, scheduled to receive chemotherapy, and without any prior history of cardiovascular disease. Patients were divided into two groups: one group received empagliflozin 10 mg daily during their chemotherapy regimen, while the control group did not receive empagliflozin. Inclusion criteria were female patients aged 18–75 years, with a confirmed diagnosis of breast cancer, no prior history of cardiovascular disease, scheduled to undergo a chemotherapy regimen including anthracyclines or trastuzumab, and signed written informed consent. Exclusion criteria included pre-existing cardiovascular conditions (e.g., heart failure, ischemic heart disease), concurrent treatment with other SGLT2 inhibitors or medications with known cardioprotective effects, history of diabetes mellitus, severe renal impairment (eGFR<45 mL/min/1.73 m²), and non-compliance with follow-up protocols.

Patients were evaluated at two time points: before the initiation of chemotherapy and after the completion of the entire chemotherapy regimen. Echocardiographic assessments were performed using the Siemens NX3 Elite ultrasound system, and measurements of endothelial function were performed at both time points. The following echocardiographic parameters were assessed to evaluate diastolic function and left ventricular performance: E/A ratio (ratio of early (E) to late (A) ventricular filling velocities), E/e' ratio (ratio of early ventricular filling velocity (E) to early diastolic mitral annular velocity (e')), Left Atrial Volume Index (LAVI), Isovolumetric Relaxation Time (IVRT), Deceleration Time (Dec Time), and Left Ventricular Ejection Fraction (EF LV).

Table 1

The baseline characteristics of studied patients

Variable	EMPA (n=35)	Control (n=31)	p-value
Age, years	48.00 (43.00;52.00)	48.00 (44.00;53.50)	0.634
Sex - Female	35 (100 %)	31 (100 %)	1.000
BMI, kg/m^2	29.40 (26.55;31.66)	28.84 (25.95;30.44)	0.214
Normal weight	6 (17.1 %)	13 (41.9 %)	0.107
Overweight	17 (48.6 %)	8 (25.8 %)	
Grade 1 Obesity	10 (28.6 %)	7 (22.6 %)	
Grade 2 Obesity	0 (0.0 %)	3 (9.7 %)	
Grade 3 Obesity	2 (5.7 %)	0 (0.0 %)	
Doxorubicin dose, mg/m^2	247.82 (243.70;252.61)	246.39 (243.12;249.86)	0.389

Endothelial dysfunction was assessed using flow-mediated dilation (FMD) of the brachial artery, a non-invasive measure of endothelial health. The FMD procedure was performed in a temperature-controlled room after the patient had rested in a supine position for at least 10 minutes. A blood pressure cuff was placed around the forearm, just distal to the antecubital fossa, and inflated to 50 mmHg above systolic blood pressure for 5 minutes to occlude blood flow. Upon cuff release, reactive hyperemia occurs, leading to an increase in brachial artery diameter, which was measured using high-resolution ultrasound. The percentage increase in diameter from baseline is calculated to assess endothelial function.

Data were analyzed using the Statistical Package for the Social Sciences (SPSS). Categorical variables were compared using the chi-square test. Continuous variables were analyzed using the Mann-Whitney U test for non-parametric data. Logistic regression analysis was employed to identify factors

independently associated with changes in echocardiographic and endothelial function parameters. A p-value of less than 0.05 was considered statistically significant.

Results of the study and their discussion. The baseline characteristics of enrolled patients are presented in Table 1.

The median age of the patients in Group 1 was 48.00 years (43.00; 52.00), compared to 48.00 years (44.00; 53.50) in Group 2, with no statistically significant difference between the groups (p=0.634).

All patients in both groups were female (100 %), and there were no differences in gender distribution between the groups (p=1.000). The body mass index (BMI) of the patients in Group 1 had a median value of 29.40 (26.55; 31.66), while in Group 2, the median BMI was 28.84 (25.95; 30.44), with no significant difference observed between the groups (p=0.214). When examining the distribution of weight categories, Group 1 had 6 patients with normal weight, 17 overweight patients, and 12 patients with obesity (10 with Grade 1 Obesity and 2 with Grade 3 Obesity). In contrast, Group 2 had 13 patients with normal weight, 8 overweight patients, and 10 patients with obesity (7 with Grade 1 Obesity and 3 with Grade 2 Obesity). The differences in weight category distribution between the groups were not statistically significant (p=0.107). The cumulative dose of doxorubicin administered was comparable between the two groups, with a median dose of 247.82 mg/m² (243.70; 252.61) in Group 1 and 246.39 mg/m² (243.12; 249.86) in Group 2, and this difference was not statistically significant (p=0.389). The dynamic of echocardiographic parameters is presented in Table 2.

Table 2

Changes in echocardiographic parameters over time

Variable		EMPA (n=35)	Control (n=31)	p value
E/A Ratio	Pre-treatment	1.40 (1.29;1.56)	1.39 (1.27;1.50)	0.472
	Post-treatment	1.39 (1.22;1.50)	1.03 (0.89;1.16)	0.001
	Δ %, p	-6.10 %, p=0.108	-25.57 %, p<0.001	
E/e' Ratio	Pre-treatment	6.86 (6.00;7.91)	6.36 (6.06;7.10)	0.253
	Post-treatment	7.15 (6.58;8.03)	9.10 (8.28;9.99)	0.001
	Δ %, p	6.30 %, p=0.134	39.35 %, p<0.001	
IVRT (ms)	Pre-treatment	86.40 (83.39;90.75)	86.98 (82.81;95.04)	0.589
	Post-treatment	89.16 (83.03;96.27)	101.63 (93.80;111.47)	0.001
	Δ %, p	4.52 %, p=0.092	16.38 %, p<0.001	
Dec Time (ms)	Pre-treatment	177.02 (150.27;191.87)	178.40 (163.22;196.67)	0.368
	Post-treatment	188.22 (175.14;200.31)	195.39 (176.94;206.26)	0.208
	Δ %, p	8.65 %, p=0.007	8.36 %, p=0.043	
EF LV (%)	Pre-treatment	62.22 (58.53;65.20)	60.71 (57.30;63.89)	0.576
	Post-treatment	58.92 (57.36;60.78)	54.18 (52.91;57.00)	0.001
	Δ %, p	-4.22 %, p=0.002	-9.81 %, p<0.001	

The E/A ratio was comparable between the two groups before treatment, with a median of 1.40 (1.29; 1.56) in the EMPA group and 1.39 (1.27; 1.50) in the control group (p=0.472). However, after chemotherapy, the E/A ratio remained relatively stable in the EMPA group at 1.39 (1.22; 1.50) but showed a significant decline in the control group to 1.03 (0.89; 1.16), with a highly significant difference between the groups post-treatment (p<0.001). The percentage change in the EMPA group was -6.10 % (p=0.108), whereas the control group exhibited a much larger decrease of -25.57 % (p<0.001).

The E/e' ratio was also similar between the groups before treatment, with medians of 6.86 (6.00; 7.91) in the EMPA group and 6.36 (6.06; 7.10) in the control group (p=0.253). Post-treatment, the E/e' ratio increased modestly in the EMPA group to 7.15 (6.58; 8.03) with no significant within-group change (p=0.134), while the control group saw a significant increase to 9.10 (8.28; 9.99) (p<0.001). The difference between the groups after treatment was also significant (p<0.001), with percentage changes of 6.30 % in the EMPA group compared to 39.35 % in the control group.

IVRT was measured, and no significant difference was observed between the groups before treatment: 86.40 ms (83.39; 90.75) in the EMPA group versus 86.98 ms (82.81; 95.04) in the control group (p=0.589). Post-treatment, the IVRT increased slightly in the EMPA group to 89.16 ms (83.03; 96.27) (p=0.092), while the control group showed a significant increase to 101.63 ms (93.80; 111.47) (p<0.001). The difference between the groups after treatment was significant (p<0.001), with percentage changes of 4.52 % in the EMPA group compared to 16.38 % in the control group.

Dec Time was not significantly different between the groups at baseline: 177.02 ms (150.27; 191.87) in the EMPA group and 178.40 ms (163.22; 196.67) in the control group (p=0.368). Post-treatment, both groups showed an increase in Dec Time, with the EMPA group at 188.22 ms (175.14; 200.31) (p=0.007) and the control group at 195.39 ms (176.94; 206.26) (p=0.043). However, the difference between the groups after treatment was not statistically significant (p=0.208).

EF LV was similar between the groups before treatment: 62.22 % (58.53; 65.20) in the EMPA group and 60.71 % (57.30; 63.89) in the control group (p=0.576). After chemotherapy, EF LV declined in both groups, but the reduction was less pronounced in the EMPA group, which decreased to 58.92 % (57.36; 60.78) (p=0.002), compared to 54.18 % (52.91; 57.00) in the control group (p<0.001). The difference between the groups post-treatment was significant (p<0.001), with percentage changes of -4.22 % in the EMPA group versus -9.81 % in the control group.

Endothelial function showed no significant difference at baseline between the groups, with medians of 12.85 % (11.54; 14.05) in the EMPA group and 13.34 % (11.72; 14.00) in the control group (p=0.877). Post-treatment, FMD decreased in both groups, but the reduction was significantly less in the EMPA group, which had a median FMD of 10.94 % (9.60; 11.93) compared to 7.43 % (6.10; 9.23) in the control group (p<0.001). The percentage decrease in FMD was -15.87 % in the EMPA group (p<0.001) compared to -39.41 % in the control group (p<0.001), with a significant difference between the groups post-treatment (p<0.001) (fig. 1).

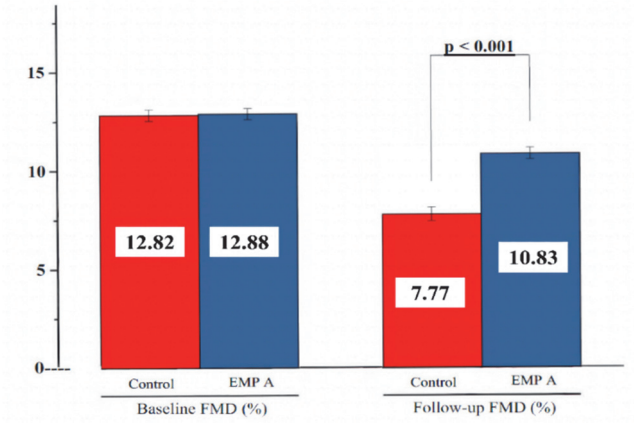

Fig. 1. Dynamic of endothelial function of studied patients.

The results of univariate regression analysis yielded the following. For the E/A ratio, the baseline measurement showed no significant association with group membership (OR=1.315, 95 % CI (0.289–3.052), p=0.336). However, at follow-up, the E/A ratio was significantly associated with the EMPA group, with an odds ratio of 1.972 (95 % CI (1.665–2.478), p<0.001). This indicates that patients in the EMPA group were more likely to have a higher E/A ratio after treatment, suggesting a protective effect of empagliflozin on diastolic function.

The E/e' ratio at baseline also showed no significant association with group membership (OR=1.293, 95 % CI (0.854–1.958), p=0.224). In contrast, at follow-up, the E/e' ratio was significantly inversely associated with being in the EMPA group (OR=0.251, 95 % CI (0.131–0.482), p<0.001). This suggests that patients in the EMPA group were less likely to have a high E/e' ratio after treatment, indicating a potential benefit of empagliflozin in maintaining better diastolic function.

IVRT at baseline was not significantly associated with group membership (OR=0.982, 95 % CI (0.927–1.04), p=0.543). However, at follow-up, the IVRT was significantly associated with the EMPA group (OR=0.905, 95 % CI (0.856–0.957), p<0.001), suggesting that patients in the EMPA group were less likely to have prolonged IVRT, reflecting better diastolic function.

Dec Time was not significantly associated with group membership at either baseline (OR=0.990, 95 % CI (0.971–1.008), p=0.276) or follow-up (OR=0.985, 95 % CI (0.963–1.008), p=0.19), indicating that Dec Time was not a strong predictor of group membership in this study.

EF LV was not significantly associated with group membership at baseline (OR=1.039, 95 % CI (0.939–1.149), p=0.462). However, at follow-up, EF LV was significantly associated with the EMPA group (OR=1.456, 95 % CI (1.200–1.768), p<0.001), suggesting that patients in the EMPA group were more likely to maintain higher ejection fractions post-treatment.

FMD at baseline showed no significant association with group membership (OR=1.022, 95 % CI (0.760–1.373), p=0.888). However, follow-up FMD was strongly associated with the EMPA group (OR=2.492, 95 % CI (1.622–3.829), p<0.001), indicating that patients in the EMPA group were significantly more likely to have higher FMD values, reflecting better endothelial function after chemotherapy.

The findings of this study provide significant insights into the potential cardioprotective and endothelial benefits of empagliflozin in breast cancer patients undergoing chemotherapy. Our results demonstrate that empagliflozin use was associated with more favorable outcomes in diastolic function and endothelial health compared to the control group, as evidenced by smaller declines in echocardiographic parameters and FMD after chemotherapy. These findings align with and extend the growing body of literature suggesting that empagliflozin may offer cardiovascular benefits beyond its glucose-lowering effects.

One of the key findings of this study was the preservation of the E/A ratio and a significantly smaller increase in the E/e' ratio in the empagliflozin group compared to the control group. These parameters are critical indicators of diastolic function, with the E/A ratio reflecting the relative contributions of passive and active filling of the left ventricle and the E/e' ratio providing insight into left ventricular filling pressures. Our

results are consistent with previous studies that have shown SGLT2 inhibitors can positively influence cardiac function. For example, Pabel S et al discussed the potential mechanisms by which empagliflozin may improve cardiac function, including enhanced myocardial energetics and reduced oxidative stress, which could contribute to the observed preservation of diastolic function [10].

The significant association between empagliflozin use and lower IVRT after chemotherapy further supports the cardioprotective role of this drug. IVRT is a measure of the time required for the left ventricle to relax and is a key parameter in assessing diastolic dysfunction. Our findings are in line with those reported by Packer et al, who noted that SGLT2 inhibitors may improve diastolic function by reducing myocardial stiffness and improving ventricular relaxation [11].

Furthermore, the preservation of EF LV in the empagliflozin group, as compared to the significant decline in the control group, underscores the potential of empagliflozin in mitigating chemotherapy-induced systolic dysfunction. Previous research has highlighted the impact of chemotherapy, particularly anthracyclines, on reducing EF, leading to an increased risk of heart failure. The observed protective effect of empagliflozin on EF is consistent with findings from large cardiovascular outcome trials, such as EMPA-REG OUTCOME, which demonstrated a reduction in heart failure hospitalization in patients treated with empagliflozin [6].

Endothelial function, assessed by FMD, also showed significant preservation in the empagliflozin group compared to the control group. Chemotherapy is known to impair endothelial function, which can contribute to long-term cardiovascular risks. The improvement in FMD observed in our study is in agreement with the work of Ganbaatar et al., who suggested that SGLT2 inhibitors might protect endothelial function through anti-inflammatory and anti-oxidative mechanisms [8]. This is particularly important in the context of cancer patients, as endothelial dysfunction is a precursor to atherosclerosis and other cardiovascular events. Our findings are also in line with previous research of metabolic treatment as a prophylaxis of chemotherapy induced injury [9].

Despite these promising findings, there are several limitations to our study. The sample size was relatively small, and the follow-up period was limited to the duration of chemotherapy. Long-term studies with larger cohorts are needed to confirm the durability of the cardioprotective effects of empagliflozin and to explore its impact on long-term cardiovascular outcomes in cancer patients. Additionally, while our study focused on breast cancer patients, further research is warranted to determine whether these benefits extend to other cancer populations receiving cardiotoxic chemotherapy.

Conclusion

Empagliflozin may offer significant cardioprotective and endothelial benefits for breast cancer patients undergoing chemotherapy, as demonstrated by its association with better preservation of diastolic function, systolic function, and overall endothelial health. The observed improvements in key cardiac parameters with empagliflozin highlight its potential to mitigate these effects, reducing the likelihood of chemotherapy-induced cardiotoxicity. These findings suggest that empagliflozin could serve not only as a metabolic agent but also as an integral part of a cardioprotective strategy, offering dual benefits in terms of both glucose regulation and heart health.

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CHANGES OF THE CARDIOVASCULAR SYSTEM STATE IN YOUNG MEN DEPENDING ON THEIR PSYCHOLOGICAL STATUS

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The purpose of the study was to establish the influence of the psycho-emotional state on clinical and hemodynamic parameters and the level of physical performance in young men. 82 young men (average age 28.4±5.2 years) without cardiovascular pathology and any somatic diseases in the anamnesis were examined. Depending on the psycho-emotional state, according to the anxiety questionnaire by Ch. D. Spielberg, the examined white men were divided into 2 groups: the main – with high anxiety – 43 people and the control – 39 people without violations of psycho-emotional status. It was established that young men without pathology of the cardiovascular system with a high level of anxiety according to the scale of Ch. D. Spielberg had reduced physical capacity according to the test with dosed physical load. It was determined that young men with reduced physical capacity and increased anxiety have a high prevalence of heart rhythm disorders according to daily ECG monitoring and signs of left ventricular diastolic dysfunction.

Key words: young people, psychoemotional disorders, daily monitoring of electrocardiography, dosed physical exercise test, diastolic function.

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ЗМІНИ СТАНУ СЕРЦЕВО-СУДИННОЇ СИСТЕМИ У МОЛОДИХ ЧОЛОВІКІВ В ЗАЛЕЖНОСТІ ВІД ЇХ ПСИХОЛОГІЧНОГО СТАТУСУ

Метою роботи було вивчити вплив психоемоційного стану на клініко-гемодинамічні показники і рівень фізичної працездатності у молодих чоловіків. Обстежено 82 молодих чоловіків (середній вік 28,4±5,2 роки) без серцево-судинної патології та будь-яких соматичних захворювань в анамнезі. В залежності від психоемоційного стану за даними опитувальника тривожності Ч.Д. Спілберга обстежені чоловіки біли розподілені на 2 групи: основна – з високою тривожністю – 43 особи і контрольна – 39 осіб без порушень психоемоційного статусу. Встановлено, що у чоловіків без патології серцево-судинної системи молодого віку з підвищеним рівнем тривожності за шкалою Ч.Д. Спілберга встановлено зниження фізичної працездатності за даними проби з дозованим фізичним навантаженням. Визначено, що у чоловіків молодого віку зі зниженою фізичною працездатністю та підвищеним рівнем тривожності виявляється висока поширеність порушень ритму серця за даними добового моніторування ЕКГ та відзначаються ознаки діастолічної дисфункції лівого шлуночка.

Ключові слова: особи молодого віку, психоемоційні порушення, добовий моніторинг електрокардіографії, проба з дозованим фізичним навантаженням, діастолічна функція.

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Because the prevalence of chronic stress and stressful conditions in today's world is increasing rapidly [12], the identification of stress as an independent risk factor for CVD and the development of new preventive strategies have become challenges for public health, and it needs urgent attention. Previous studies have shown a link between post-traumatic stress disorder and cardiovascular disease (for example, coronary heart disease, myocardial infarction and stroke), repeated cardiovascular events, as well as mortality from all causes with cardiovascular diseases [4, 14]. To reduce mortality from cardiovascular diseases, their timely diagnosis is extremely important [11]. One of the ways to solve many aspects of