DOI 10.26724/2079-8334-2022-3-81-26-31
UDC 616.12-008.331.1-225.2:616.12-008.1-07

O.M. Bilovol, I.I. Knyazkova, V.O. Golovacheva, N.V. Kuzminova[1], V.O. Barbashova, D.V. Molodan, M.V. Bogun
Kharkiv National Medical University, Kharkiv
[1]Vinnytsia National Medical University named after M.I. Pirogov, Vinnytsia

EFFECT OF EPLERENONE ON SERUM LEVEL OF SOLUBLE GROWTH-STIMULATING RECEPTOR EXPRESSED BY GENE 2 IN PATIENTS WITH ARTERIAL HYPERTENSION

e-mail: sskripka72@gmail.com

The purpose of the work was to study the dynamics of diastolic function parameters, the content of the soluble growth-stimulating receptor expressed by gene 2 (sST2) and the N-terminal fragment of the brain natriuretic propeptide (NT-proBNP) in the blood of patients with hypertension, when eplerenone is added to antihypertensive therapy. In patients with stage 2 arterial hypertension, addition of eplerenone to antihypertensive therapy contributes to a more pronounced decrease of blood pressure measured by patients during self-monitoring; during daily monitoring compared to antihypertensive therapy. The inclusion of the selective aldosterone mineralocorticoid receptor antagonist eplerenone in the complex therapy of patients with stage 2 arterial hypertension has a pronounced positive effect on the structural and geometric indicators of the myocardium, parameters of the diastolic function of the left ventricle, as well as the content of sST2 and NT-proBNP in the blood serum, along with good tolerability.

Key words: hypertension, eplerenone, diastolic dysfunction, echocardiography, soluble growth-stimulating receptor expressed by gene 2, N-terminal fragment of brain natriuretic propeptide.

О.М. Біловол, І.І. Князькова, В.О. Головачова, Н.В. Кузьмінова, В.О. Барбашова, Д.В. Молодан, М.В. Богун

ВПЛИВ ЕПЛЕРЕНОНУ НА СИРОВАТКОВИЙ РІВЕНЬ СТИМУЛЮЮЧОГО ЧИННИКА ЗРОСТАННЯ, ЩО ЕКСПРЕСУЄТЬСЯ ГЕНОМ 2, У ПАЦІЄНТІВ З АРТЕРІАЛЬНОЮ ГІПЕРТЕНЗІЄЮ

Метою роботи було вивчити динаміку параметрів діастолічної, функції, вмісту розчинного рецептора стимулюючого чинник зростання, що експресується геном 2 (sST2) і N-термінального фрагмента мозкового натрійуретичного пропептида (NT-proBNP) в крові у пацієнтів з артеріальною гіпертензією при додаванні до антигіпертензивної терапії еплеренону. Встановлено, що у пацієнтів з артеріальною гіпертензією 2 ступеня додавання еплеренону до антигіпертензивної терапії сприяє більш вираженому зниженню артеріального тиску, виміряного пацієнтами при самоконтролі; при добовому моніторингу порівняно з антигіпертензивною терапією. Включення селективного антагоніста мінералокортикоїдних рецепторів альдостерону еплеренону в комплексну терапію хворих на артеріальну гіпертензію 2 ступеня надає виражений позитивний вплив на структурно-геометричні показники міокарда, параметри діастолічної функції лівого шлуночка, а також вміст sST2 і NT-proBNP в сироватці крові поряд з хорошою переносимістю.

Ключові слова: гіпертонічна хвороба, еплеренон, діастолічна дисфункція, розчинний рецептор стимулюючий чинник зростання, що експресується геном 2, N-термінальний фрагмент мозкового натрійуретичного пропептиду.

The work is a fragment of the research project "Development of methods for early diagnosis and drug prevention of fibrosing processes in patients with comorbid pathology (hypertension and type 2 diabetes mellitus) based on the assessment of cardiohemodynamics and renal function", state registration No. 0120U102062.

The therapeutic efficacy of the mineralocorticoid receptor antagonist (MCRA) eplerenone is preconditioned by favorable electrolyte changes, reduction of interstitial fibrosis, oxidative stress, improvement of endothelial function, reduction of platelet aggregation, activity of metalloproteinases and sympathoadrenal system [9]. It is important to mention that aldosterone binds not only to its specific receptors in the myocardium, macrophages, but also to fibroblasts. As a result of this interaction, the synthesis and accumulation of type III collagen increases, what contributes to the increase of stiffness of the myocardium, development of perivascular and interstitial fibrosis, remodeling of the myocardium and the arterial bed. Deterioration of the vasomotor reserve of coronary vessels, myocardial blood supply leads to the death of cardiomyocytes, accelerating the process of fibrosis, diastolic and systolic dysfunction [4].

Data from clinical studies show that eplerenone, both in monotherapy and in combination with other antihypertensive drugs, effectively controls blood pressure (BP) levels in patients with arterial hypertension (AH) [3].

It has been established that early administration of MCRA is especially important for the patients with chronic heart failure (CHF), who have suffered from a myocardial infarction, because MCRA have a

proven ability to slow down remodeling of the left ventricular (LV) myocardium [5]. At the same time, not without interest is to study the effectiveness of the therapy with addition of eplerenone for early and subclinical changes in the structural and functional condition of the heart. This approach is fundamentally important from a practical point of view, as it opens up new opportunities in the search for ways of personalized therapy and slowing down the progression of damage to target organs and cardiovascular complications in patients with AH.

The purpose of the study was to assess the dynamics of diastolic parameters, function, content of the soluble growth-stimulating receptor expressed by gene 2 (sST2) and the N-terminal fragment of brain natriuretic propeptide (NT-proBNP) in the blood of patients with the addition of eplerenone to antihypertensive therapy.

Materials and methods. The study included 64 patients (43 males and 21 females, aged 45–54 years (mean age 51.3±1.5 years) with stage II grade 2 hypertension, who hadn't undergone regular antihypertensive therapy. All patients were examined in accordance with the recommendations of the European Society of hypertension and the European Society of Cardiology (ESH/ESC, 2019). All respondents signed an informed consent to participate in the study.

Pregnant women were not included in the study; patients with resistant and symptomatic AH; with chronic heart failure (CHF); chronic kidney failure, rhythm and conduction disorders, rheumatic heart disease, cancer disease, thyroid disease, diabetes, as well as the patients who were expected to have a high probability of the study protocol violation. Daily monitoring of blood pressure (DMBP) was performed using the equipment "ABPM-02" (Meditech, Hungary).

The evaluation of the structural and functional parameters of the heart was performed with the device "GE Medical Systems" (Germany) with a Doppler sensor which allowed working in M- and B-modes, as well as having an energy Doppler sensor that made it possible to determine LV diastolic function in a pulse-wave mode. To characterize the systolic function of the heart, the LV ejection fraction (EF) was determined according to Simpson (normal >50 %). According to echocardiography, LV systolic function was preserved in all patients.

LV myocardial mass (LVMM) and LVMM index (LVMMI) were calculated according to the recommendations of ASE (2016). To evaluate the LV diastolic function, the following echocardiographic indicators were studied: left atrial volume index (LAVI), peak early diastolic blood flow on the mitral valve (E), peak late diastolic blood flow on the mitral valve (A), their E/A ratio, movement velocity of the mitral valve annulus to early diastole (e') in the septal and lateral parts, average E/e' ratio, peak regurgitation velocity on the tricuspid valve (TV), deceleration time of early diastolic blood flow (DT), isovolumic relaxation time (IVRT) [11, 12].

The concentration of the soluble growth-stimulating receptor expressed by gene 2 (sST2, Critical Diagnostics, USA) and the N-terminal fragment of brain natriuretic propeptide (NT-proBNP) were measured in blood serum with the help of enzyme immunoassay kits (Biomedica Slovakia, Slovakia).

After registration of baseline data, eplerenone medication ("Epletor", "Borshchagivskyi CPP", Ukraine) in a dose of 25-50 mg for 3 months in addition to the basic antihypertensive therapy (combination of lisinopril and amlodipine in medium therapeutic doses) was prescribed to 34 patients (group 1). Group 2 consisted of 30 people whom only basic therapy for hypertension was prescribed to. Patients in both groups also received statins, antiplatelet therapy. The mentioned groups of patients were comparable in terms of age and sex. The control group consisted of 20 practically healthy persons (9 females and 11 males, average age 51.1±1.3 years).

All patients successfully completed the study according to the protocol. Clinical examination and measurement of potassium content in blood serum were performed after 4 and 12 weeks of treatment. Side effects and undesirable phenomena were not registered during this period.

Mathematical computer processing of the research results was performed 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. Differences were considered reliable at the level of statistical significance $p<0.05$. The method of correlation analysis with the calculation of Pearson (normal distribution) and Spearman (non-normal distribution) correlation coefficients was used to assess the relationships between the indicators.

Results of the study and their discussion. After 3 months of treatment, patients in both groups achieved target blood pressure (BP) levels. Patients of both groups noticed an improvement in the quality of life, reduction of headaches, BP normalization and increase in tolerance to everyday physical load.

A more pronounced decrease of BP was found in group 1 in comparison to the patients of group 2 (table 1).

Table 1

Indices of central hemodynamics and morpho-functional state of the heart in the study groups

Indexr		Control (n=20)	Group 1 (n=34)	Group 2 (n=30)
HR, bmp	Baseline	71.1±2.1	72.6±3.7	71.2±3.6
	In 3 months		74.5±3.4	74.2±3.1
SBP[11], mmHg	Baseline	117.1±3.8	159.2±3.6	159.7±3.7
	In 3 months		119.8±3.4***	127.1±3.5***
DBP[1], mmHg	Baseline	72.7±4.2	101.8±3.8	102.1±3.7
	In 3 months		77.9±3.2***	83.7±3.3***
LV ESD, cm	Baseline	3.14±0.05	3.56±0.07	3.55±0.07
	In 3 months		3.23±0.06**	3.38±0.06
LV EDD, cm	Baseline	4.76±0.12	4.91±0.09	4.92 ±0.09
	In 3 months		4.60±0.08**	4.76±0.07
LVEF, %	Baseline	67.5±0.31	65.4±0.35	65.6±0.35
	In 3 months		67.1±0.33*	66.1±0.31
LVMMI, g/m²	Baseline	96.5±3.5	135±3.8	136±3.7
	In 3 months		124±1.7	130±2.3
LAVI, ml/m²	Baseline	28.8±0.18	32.6±0.15*	32.5±0.18*
	In 3 months			
LAVi, ml/min²	Baseline	22.5±3.1	36.8±4.3	35.38±4.5
	In 3 months			
E/A, cm/s	Baseline	1.28±0.02	0.90±0.06	0.90±0.07
	In 3 months		1.2±0.05**	1.0±0.06
E/e´	Baseline	6.50±0.82	9.81±0.81	9.80±0.73
	In 3 months		6.75±0.72*	9.75±0.71

Notes: * – reliability in comparison with the original data; * – p <0.05; ** – p <0.01; *** – p <0.001; 1 – systolic BP (SBP) and diastolic BP (DBP) measured during visit

The level of office SBP decreased by 24.7 % in group 1 and by 20.4 % in group 2 (all p<0.001 compared to baseline values; in comparison between groups p<0.05) and "office" DBP – by 23.5 % and 18.0 %, respectively (p<0.05 compared to initial values).

According to home BP self-monitoring in group 1, a more pronounced decrease in BP was found compared to group 2 according to the indicators of average systolic and average diastolic BP (fig. 1).

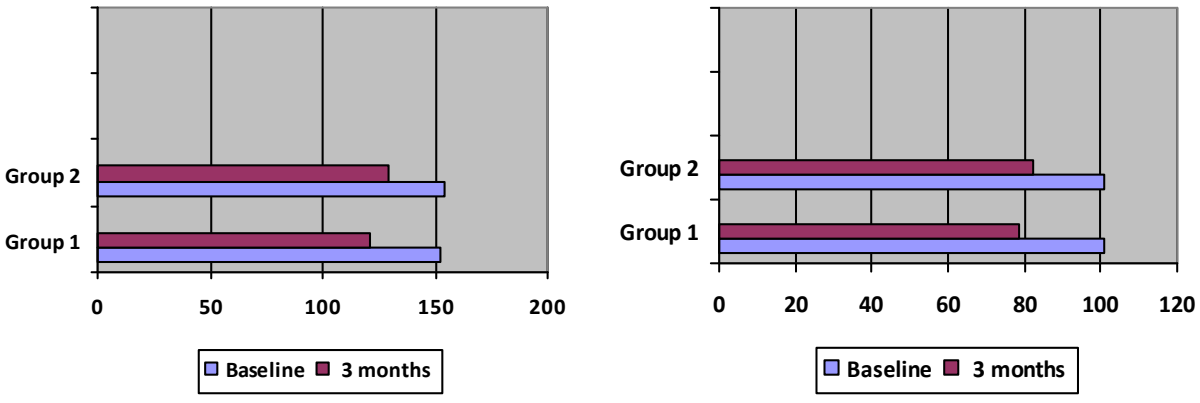

Fig.1. Dynamics of SBP (A) and DBP (B) after the treatment in the examined groups of patients according to home self-monitoring data.

According to DMBP data, a more pronounced decrease in average daily SBP (121.1±3.1 mmHg vs. baseline 150.9±3.6 mmHg, p<0.001) was found in group 1 and DBP (75.5±2.1 mmHg vs. baseline 101.3±3.5 mmHg, p<0.001) compared to group 1 (129.9±3.1 mmHg vs. baseline 151.3±3.9 mmHg, p<0.001 and 81.7±2.1 mmHg vs. baseline 101.5±3.8 mmHg, p<0.001, respectively) with a statistically significant difference between two groups of patients (p<0.05). There was no statistically significant difference in the remaining DMBP indices.

After the treatment, the analysis of structural and functional parameters of the heart allowed us to establish that there was a statistically significant decrease in LVMI by 8.1 % among the patients of group 1, vs 4.4 % among patients of group 2 (p<0.05). The percentage of people with LVH decreased by 14.7 % in group 1 (p<0.05) vs 3.3 % in group 2 (p>0.05) – p1-2<0.05 due to an increase in the number of people with concentric LV remodeling in both groups. This corresponded to a decrease in EDD by 6.3 % in group 1 (p<0.01) vs. 3.3 % in group 2 (p>0.05), a decrease in ESD by 9.3 % (p<0.01) vs 6.6 % (p>0.05), increase in LVEF by 2.6 % (p<0.05) vs 0.8 %, (p>0.05) respectively. Thus, a more pronounced positive time course

of the indicators of structural and geometric remodeling of the LV in patients of group 1 was discovered (table 1).

The dynamic analysis of the most sensitive parameters of LV diastolic function in the course of antihypertensive therapy with the addition of eplerenone is worth sharing, what indicates an improvement in LV relaxation and compliance (table 1). The positive effect of eplerenone on LV diastolic function takes attention. After the course of treatment, a significant increase in the E/A ratio by 33.3 % ($p<0.01$) and a significant decrease in the E/e ratio by 31.3 % ($p<0.05$) were found in patients of group 1. At the same time, in patients in group 2 the change of E/A and E/e did not differ reliably.

After the course of treatment, it was found that in group 1 the serum concentration of sST2 significantly decreased by 29.5 % ($p<0.05$) and was lower by 28.4 % ($p<0.05$) compared to group 2, in which this indicator actually did not change (34.2±2.8 ng/ml in baseline conditions and 33.1±2.1 ng/ml after treatment) (fig. 2).

At the same time, there was a decrease in NT-proBNP in patients of group 1 by 28.6 % ($p<0.01$), which was less by 25.3 % ($p<0.01$) compared to the data of group 2, where only a tendency to decrease of this indicator by 10.6 % ($p>0.05$) (fig. 3) was found.

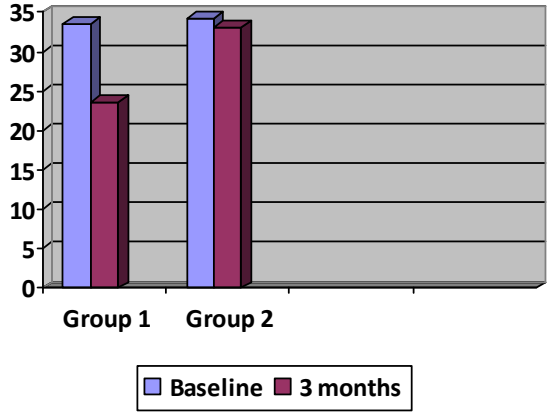

Fig.2 Dynamics of sST2 content in blood serum (ng/ml) during the treatment of AH patients of both groups.

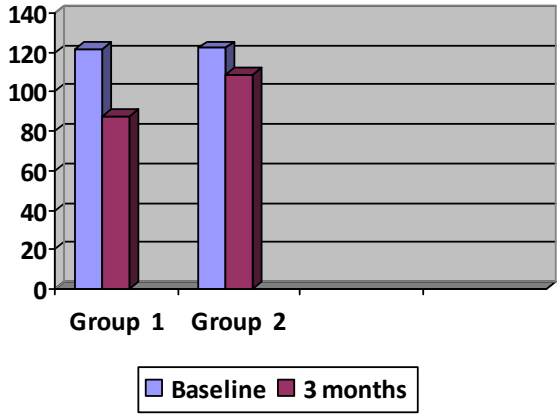

Fig. 3 Dynamics of NT-proBNP content in blood serum (pg/l) during the treatment of AH patients of both groups.

It should be mentioned that the level of potassium in blood serum remained within normal values (4.4±0.4 and 4.3±0.5 mmol/l in groups 1 and 2 respectively), which is consistent with previously performed studies.

It has been established that the progression of AH is accompanied by the development of target organ lesions, the most prognostically significant of which is LV hypertrophy, which leads to an increase in its stiffness and the development of myocardial dysfunction [6]. It is established that diastolic dysfunction (DD) has an independent prognostic value in cardiovascular diseases, despite the absence of LV dilatation and presence of the normal LV ejection fraction (EF) [14]. Clinical data indicate that the severity of DD, and not LVEF, correlates with the severity of CHF and is associated with the hardest patient survival for 2 years [10]. Instead, DD often stays undiagnosed.

Since in patients with AH, LV DD is one of the earliest and most common manifestations of myocardial dysfunction (especially at the stage of myocardial hypertrophy), BP normalization is one of the simplest and most effective ways to improve LV diastolic filling [6]. AH determines not only the type of heart remodeling during its long course due to overload of LV resistance and increase of its preload as a result neurohumoral changes, but also contributes to systemic low-intensity inflammation [10]. Therefore, the normalization of BP can lead to a decrease in the severity of preclinical LV DD. The administration of renin-angiotensin-aldosterone system (RAAS) blockers – ACE inhibitors and mineralocorticoid receptor blockers in AH patients is an independent predictor of improved prognosis [6]. Data on the effect of drug therapy on structural and functional LV diastolic parameters in AH patients with subclinical LV DD is confined.

The results of the study showed significant positive dynamics of both structural (decrease in LVMI) and functional indicators (in the form of an increase in LVEF and normalization of E/A and E/e´) in case of eplerenone administration within long-term complex pharmacotherapy of AH patients with preserved LVEF.

It is known that BNP and NT-proBNP enter the blood directly from the myocardium of the ventricles as a result of diastolic tension of the heart walls when it is overloaded with volume or pressure [6]. The concentration of BNP and NT-proBNP in the blood, as a rule, reflects the severity of the

hemodynamic stress of the ventricular myocardium and correlates with the tension of the myocardium of the left ventricle at the end of diastole.

As shown by fundamental studies [13], ST2 belongs to the family of interleukin-1 receptors and exists in two forms: bound to target cell membranes and soluble in blood plasma. The last form is defined as sST2 (soluble ST2).

It was established that ST2 is capable of binding to the inflammatory mediator interleukin-33 (IL-33) (the ligand of the ST2 receptor), forming IL-33/ST2 complex on the membrane of cardiomyocytes, which has an ability to protect heart cells in conditions of hypoxia, to resist the factors of their hypertrophy under the influence of angiotensin II, reduce the intensity of fibrosis of cardiomyocytes and reduce the production of natriuretic peptides [8].

The consequences of an effectively working IL-33/ST2 system include a significant reduction in the severity of myocardial dysfunction and dilatation, as well as inhibition or leveling of the processes of unfavorable ventricular remodeling in response to various damaging factors [1, 7].

According to a number of studies combined administration of sST2 and BNP/NT-proBNP is able to improve risk stratification and clinical management of patients, contributing to the determination of an optimal preventive treatment strategy [1, 8, 13].

Given the fact that sST2 is a marker of myocardial stress, fibrosis and remodeling of the heart, it can be considered as a potential pathophysiological mediator of myocardial fibrosis, including acute coronary syndromes. The obtained data indicate the possibility of adding eplerenone to the combination of an ACE inhibitor and a calcium antagonist due to its active effect on the RAAS to reduce the formation of myocardial fibrosis and myocardial stiffness.

According to modern clinical recommendations, the use of the NT-proBNP biomarker is a convenient non-invasive method of diagnosis of CHF presence, as well as the assessment of severity and effectiveness of treatment of these patients [2]. According to the data obtained in our study, determination of the sST2 level in combination with NT-proBNP provides additional information on the detection of subclinical forms of CHF, which can be used in the evaluation of therapy effectiveness.

Conclusion

1. In patients with stage 2 arterial hypertension, an addition of eplerenone to antihypertensive therapy contributes to a more pronounced decrease in blood pressure being measured by patients during self-monitoring; daily monitoring compared to antihypertensive therapy.

2. The inclusion of the selective antagonist of mineralocorticoid receptors eplerenone in the complex therapy of patients with stage 2 arterial hypertension has a pronounced positive effect on the structural and geometric indicators of the myocardium, the parameters of the diastolic function of the left ventricle, as well as the content of sST2 and NT-proBNP in the blood serum along with good tolerability.

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Стаття надійшла 28.08.2021 р.

DOI 10.26724/2079-8334-2022-3-81-31-34
UDC 612.017.3:616-079

A.Ye. Bogomolov, S.V. Zaikov[1], L.G. Kulyk, O.V. Plykanchuk
National Pirogov memorial medical university, Vinnytsya,
[1] Shupyk National Healthcare University of Ukraine, Kyiv

SAFETY AND CLINICAL EFFECTIVENESS OF BILASTINE IN THE TREATMENT OF ALLERGIC RHINITIS IN CHILDREN

e-mail: art.bogomolov@gmail.com

The purpose of the study was to evaluate the effectiveness and safety of bilastine in relieving symptoms in patients aged 6–12 years with allergic rhinitis. In this prospective, randomized study, 50 patients aged 6 to 12 years with newly diagnosed allergic rhinitis and confirmed sensitization to allergens of household or pollen group participated; 46 completed the course of treatment within 4 weeks. Patients received bilastine orally at a dose of 10 mg daily for 4 weeks. Before starting treatment, the average level of severity of eye and nasal symptoms was assessed using the total nasal symptom score questionnaire for 5 days, with further assessment in 7, 14 and 28 days after starting bilastine intake. In general, at the endpoint of monitoring after 4 weeks, the reduction in the severity of symptoms was 49.1 %. A total of 89.1 % of patients (n=41) who received bilastine at a dose of 10 mg had no adverse reactions during the study. All adverse reactions were classified as mild, with headache being the most common, reported in 2 (4.3 %) cases.

Key words: allergic rhinitis, children, symptomatic therapy, antihistamines, bilastine

А.Є. Богомолов, С.В. Зайков, Л.Г. Кулик, О.В. Пликанчук

БЕЗПЕЧНІСТЬ ТА КЛІНІЧНА ЕФЕКТИВНІСТЬ БІЛАСТИНУ У ЛІКУВАННІ АЛЕРГІЧНОГО РИНІТУ У ДІТЕЙ

Метою роботи було оцінити ефективність та безпеку біластину щодо полегшення симптомів у пацієнтів віком 6–12 років з алергічним ринітом. У цьому проспективному, рандомізованому дослідженні прийняли участь 50 пацієнтів віком від 6 до 12 років з вперше встановленим діагнозом алергічного риніту та підтвердженою сенсибілізацією до алергенів побутової або пилкової групи, з них повністю завершили курс лікування протягом 4 тижнів 46 осіб. Пацієнти отримували біластин перорально у дозі 10 мг 1 раз на добу протягом 4 тижнів. До початку прийому середній рівень вираженості очних та назальних симптомів був оцінений за опитувальником Total nasal symptom score протягом 5 днів, з подальшою оцінкою через 7, 14 та 28 днів після початку прийому біластину. Загалом у кінцевій точці моніторингу через 4 тижні зменшення вираженості симптомів становило 49,1 %. У цілому 89,1 % пацієнтів (n=41), які отримували біластин у дозі 10 мг, не мали побічних реакцій під час дослідження. Усі побічні реакції були класифіковані як легкі, а найпоширенішим був головний біль, зареєстрований у 2 (4,3 %) випадках.

Ключові слова: алергічний риніт, діти, симптоматична терапія, антигістамінні препарати, біластин

The work is a fragment of the research project "Effectiveness of modern methods of combined treatment (specific immunotherapy and pharmacotherapy) of allergic respiratory diseases", state registration No. 0116U003349.

Allergic rhinitis is defined as symptoms of sneezing, nasal pruritus, airflow obstruction, and mostly clear nasal discharge caused by IgE-mediated reactions against inhaled allergens [12].

Often, allergic diseases manifest quite early, although in early childhood sometimes the characterizing of the symptoms can be a problem. The International Study of Asthma and Allergy in Childhood (ISAAC) reported an approximately 10–20 % prevalence of childhood allergic rhinoconjunctivitis in most countries [6]. The prevalence of allergic rhinoconjunctivitis varies considerably between regions and countries, but worldwide it is reported to be 8.5 and 14.6 % at 6–7 and 13–14 years, respectively [10]. In Ukraine, allergic diseases in general and allergic rhinitis, in particular, continue to remain a significant socio-economic problem due to the high incidence rate, which continues to grow, the inconsistency of official statistical data with the real picture of prevalence, as well as often untimely diagnosis of these diseases and inadequate treatment of the relevant categories of patients. Optimization of