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CARDIAC MUSCLE MODELING DURING TREATMENT WITH ALISKIREN IN PATIENTS WITH HEART FAILURE

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გულის კუნთის მოდელირება ალისკირენით მკურნალობის დროს გულის უკმარისობის მქონე პაციენტებში

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რეზიუმე

მიზანი. კვლევის მიზანს წარმოადგენდა გულის კუნთის მოდელირების შესწავლა ალისკირენით მკურნალობის დროს გულის უკმარისობის (HF) მქონე პაციენტებში.

მეთოდები. ალისკირენის მკურნალობის ეფექტების შესაფასებლად (დაკვირვების პერიოდი – 6 თვე) შემთხვევით შერჩეულ იქნა სხვადასხვა კლასის ქრონიკული გულის უკმარისობის მქონე 60 პაციენტი. ისინი შემთხვევითობის პრინციპით გადანაწილდნენ საკვლევ ჯგუფში. ალისკირენით (150 მგ) მკურნალობის ფონზე 55 პაციენტმა დაასრულა კვლევა.

შედეგები. თითქმის ყველა ექოკარდიოგრაფიულ პარამეტრისთვის არ დაფიქსირებულა მნიშვნელოვანი სარწმუნო ცვლილება. სარწმუნოდ შემცირდა მე-3 და მე-4 კლასის მიტრალური სარქვლის რეგურგიტაციით დაავადებულთა პროცენტული მაჩვენებელი; ასევე სარწმუნოდ შემცირდა მე-2 და მე-3 კლასის ტრიკუსპიდური სარქვლის რეგურგიტაციით დაავადებულთა პროცენტული მაჩვენებელი.

დასკვნა. HF პაციენტების 6-თვიანი ალისკირენით მკურნალობის ეფექტების შეფასებაზე დაყრდნობით შეიძლება დავასკვნათ, რომ ალისკირენმა აჩვენა უკეთესი შედეგები სარქვლოვანი რეგურგიტაციების შემცირების თვალსაზრისით, ვიდრე ექოკარდიოგრაფიული პარამეტრების გაუმჯობესების კუთხით. უფრო ძლიერი მტკიცებულებების მისაღებად აუცილებელია კვლევის გაგრძელება მტკიცებულებებზე დაფუძნებული შედეგებისა და დასკვნების მოწოდებისთვის.

Introduction. Heart failure (HF) became one of the main problems of medicine at the end of the 20th century and the beginning of the 21st century. The successful medicinal and surgical treatment of relatively common heart diseases has increased the proportion of the patients who live to a relatively old age at which the risk of the development of the heart failure is high. In the United States approximately 6.7 million people (age ≥ 20 years) were registered with a diagnosis of HF in 2017-2020, which is higher by 11.7% than the rate of 2015-2018 [1]. A comparative analysis of the 25-year periods of the Framingham Heart Study (1965-1989 vs. 1990-2014) showed that the residual lifetime risk at 50 years of age was increased by 6.1% in men, and by 3.7% - in women [2]. The HF prevalence is essentially related to age: 1.4% of the population aged 25-49 complain of HF, 2.9% - at the age of 50-59, 7.6% - at the age of 60-69, 12.7% - at the age of 70-79, and 16.1% - aged 80 and over [2-5]; at the same time the health-related quality of life also decreases [6].

It should be noted that the role of renin-angiotensin-aldosterone activation is central in the development of HF and left ventricular (LV) hypertrophy, which is the main risk factor for the development of HF and arterial hypertension [7,8]. In recent years the drug aliskiren has appeared which inhibits renin activity. Aliskiren is a direct renin inhibitor with the high specificity for the human renin. It is used to treat arterial hypertension. Luo Y and Chen Q [9] based on the results of a meta-analysis of 1973 patients from 5 randomized clinical trials, reported that the addition of aliskiren to conventional

therapy reliably reduced NT-proBNP levels and plasma renin activity, improving plasma renin concentrations in patients with HF. However, data about the treatment with aliskiren are very scarce, especially in terms of long-term studies. Zhao Q et al in their review article noted that there is strong evidence for the benefits of aliskiren in the treatment of essential hypertension, and that aliskiren can significantly lower blood pressure with adequate safety [10]. However, the authors also indicated that the effects on cardiovascular and renal outcomes are implausible.

One of the primary mechanisms of sacubitril/valsartan is to increase the circulatory and myocardial nitric oxide bioavailability, leading to an increase of a cyclic guanosine monophosphate (cGMP) and an activation of protein kinase G. The final effect is a reduction of a systemic oxidative stress, apoptosis, and hypertrophy accompanied by antiplatelet and antithrombotic effects [11]. In chronic patients, the earliest effect was observed in the EVALUATE-HF study: a significant reduction of the left ventricular end-systolic and end-diastolic volumes (LVESV and LVEDV), left atrial volume index (LAVI) and E/e' ratio compared with enalapril was observed in 12 weeks [12]. Another prospective study with the blind echocardiographic analysis demonstrated improvements in the systolic and diastolic functions after 4 months of ACEI/ARB II replacement with sacubitril/valsartan in patients with a chronic HF with a preserved ejection fraction (HFpEF) who were previously optimally treated [13].

Based on the mentioned above, the aim of the study was to study the dynamics of the development of heart muscle modeling during the treatment with aliskiren in the HF patients within months after the initiation.

Methods. This study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [14]. The cross-sectional observational study design has been chosen to assess the treatment effects of aliskiren. All procedures performed in the study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study protocol and a draft consent agreement for participation in the study were approved by the Ethics Committee of the Institutional Review Board of Tbilisi State Medical University (#5-2020/82; October 28, 2020). Written informed consent was obtained from all individual participants included in the study. We de-identified the patients' details so that they may not be identified in any way.

Inclusion criteria were diagnosed HF, and obtained informed consent. Exclusion criteria were chronic kidney disease, liver failure, hyperkalemia, hypotension episodes in anamnesis, and refusal to participate in the study at any stage.

Study groups. To achieve the aim of the study, after obtaining the informed consent, 60 randomly selected patients with chronic HF of different classes were randomly assigned to study group; 5 patients were excluded from the study because of not coming to the intermediate visits. 55 patients selected in the study group (mean age - 66.7 ± 9.6 years, 39 males/16 females) and assigned to the treatment with aliskiren (150 mg) finished the study.

Study tools. The instrumental examinations and laboratory tests provided by the study protocol were performed at the beginning of the study (baseline) and at 2 points after the initiation of the treatment - after every 3 months.

All patients at all points underwent echocardiographic studies, during which the parameters of the left ventricle (end-systolic-diameter - LVESD and volume - LVESV, end-diastolic-diameter - LVEDD and volume - LVEDV, ejection fraction-EF), left atrial parameters (diameter-LAD and volume - LAV) and valvular pathologies (mitral valve regurgitation - MVR, aortic valve regurgitation - AVR, tricuspid valve regurgitation - TR) have been measured and assessed.

Blood pressure (BP), pulse, saturation, respiratory rate, carbohydrate metabolism parameters (fasting glycemia - FPG, fasting C-peptide - FCP, HbA1C, HOMA-indexes), lipid metabolism parameters (total cholesterol, triglycerides, HDL-cholesterol, LDL-cholesterol, VLDL-cholesterol), blood renin, creatinine, electrolytes (potassium, calcium, sodium, chlorine) were also measured at all stages of the patient's examinations. The natriuretic peptide NT-proBNP and PAPS was also measured. The obtained baseline characteristics of the study group are given in Table 1.

Statistical analysis. The study results were statistically analyzed using SPSS 22.0 software (IBM Corp., Armonk, NY, USA). Continuous variables are expressed as mean ± standard deviation (SD), cheked for normality by Kolmogorov-Smirnov Z-test and differences were assessed by analysis of variance (within the groups – paired t-test, between groups - independent t-test and Fisher's exact test). Categorical variables were compared using the chi-square test or Fisher's exact test. Pearson's coefficient (r) was used to evaluate the correlation between the parameters. P-values of <0.05 were considered as statistically significant.

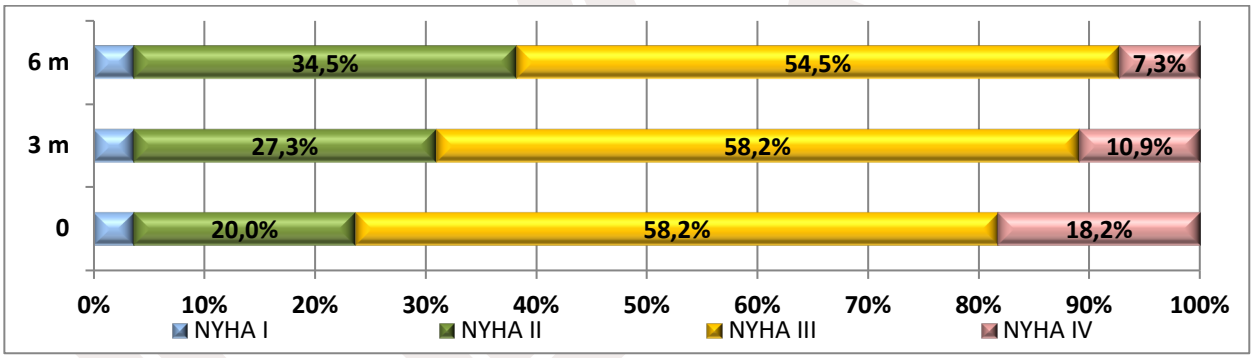
Table 1. The obtained baseline characteristics of the study group

Parameter	Group 1 (n=55) Mean±SD or n= (%)
Age, years	66.7 ± 9.6
Gender (Male/Fenale)	39 (70.9%) / 16 (29.1%)
Family status (Married/Widow)	39 (70.9%) / 16 (29.1%)
Education (Middle/High School)	22 (40.0%) / 33 (60.0%)
Employment (No/Yes)	13 (23.6%) / 42 (76.4%)
HF class	
NYHA I	2 (3.6%)
NYHA II	11 (20.0%)
NYHA III	32 (58.2%)
NYHA IV	10 (18.2%)
LVESD, mm	63.3 ± 5.2
LVEDD, mm	56.7 ± 7.3
LVESV, ml	193.3 ± 60.0
LVEDV, ml	130.4 ± 55.5
EF, %	34.6 ± 6.5
Valvular pathologies	
MVR	55 (100.0%)
AVR	22 (40.0%)
TVR	18 (32.7%)
BP, mmHg	
Systolic	122.2 ± 10.4
Diastolic	66.0 ± 6.8
Pulse, bpm	75.8 ± 12.3
Saturation, %	91.3 ± 2.3
Brearth Rate, bpm	21.7 ± 1.3
Carbohydrate Metabolism	
FPG, mg/dl	98.2 ± 16.6
FCP, ng/ml	1.0 ± 0.3
HBA1C, %	5.9 ± 0.9
HOMA-B,%	150.9 ± 58.3
HOMA-S, %	47.1 ± 12.8
HOMA-IR	2.3 ± 0.6
Lipid Metabolism	

Total cholesterol, mg/dl	205.3 ± 30.5
Triglycerides, ng/ml	154.7 ± 29.4
HDL- cholesterol, mg/dl	42.4 ± 5.0
LDL- cholesterol, mg/dl	132.0 ± 29.4
VLDL- cholesterol, mg/dl	30.9 ± 5.9
Renin, ng/ml/hr	11.3 ± 7.9
Creatinine, mmol/L	77.2 ± 5.3
NT-proBNP, pg/ml	158.5 ± 49.1
PAPS, mmHg	32.2 ± 15.0
Electrolytes, mmol/L	
K	4.0 ± 0.2
Ca	1.1 ± 0.1
Na	137.3 ± 4.5

Results. The distribution of the patients in the study groups according to the NYHA class at all stages of the study is shown on Figure 1. As it is shown on Figure 1, the percentage of patients with NYHA class IV decreased from 18.2% at baseline to 7.3% after 6 months; the percentage of the patients with NYHA class III also started the decrease from baseline 58.2% to 54.5% after 6 months; the percentage of the patients with NYHA class II was increased at every study point and after 6 months it was 34.5%; the percentage of the patients with NYHA class I (3.3%) was unchanged at every study points.

Figure 1. The distribution of the patients in the study groups according to the NYHA class at all stages of the study (The distribution was statistically significant Chi2=29.16; p=0.004)



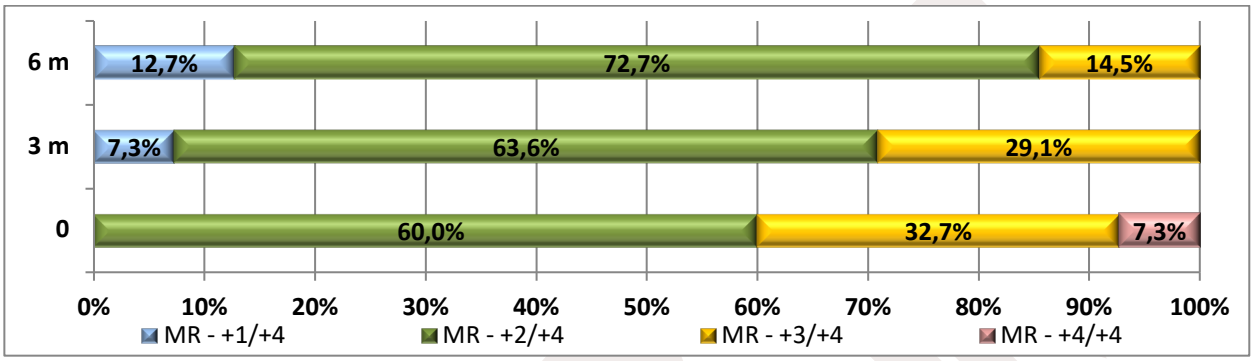
The changes of the echocardiographic parameters of the patients of the study group at all stages of the study is shown in Table 2. There were no significant changes in all echocardiographic parameters.

Table 2. The dynamics of the echocardiographic parameters of the patients at all stages of the study

	Baseline	After 6 months
	Mean (SD)	Mean (SD)
LVESV, ml	193.3 (60.0)	184.3 (40.2)
	t- test = 0.92, p=0.358	
LVEDV, ml	130.4 (55.5)	133.8 (36.2)
	t- test = 0.38, p=0.704	
LVESD, mm	63.3 (5.2)	62.3 (3.7)
	t- test = 1.16, p=0.248	
LVEDD, mm	56.7 (7.3)	56.8 (3.7)
	t- test = 0.09, p=0.928	
EF, %	34.6 (6.5)	36.1 (4.4)
	t- test = 1.42, p=0.159	

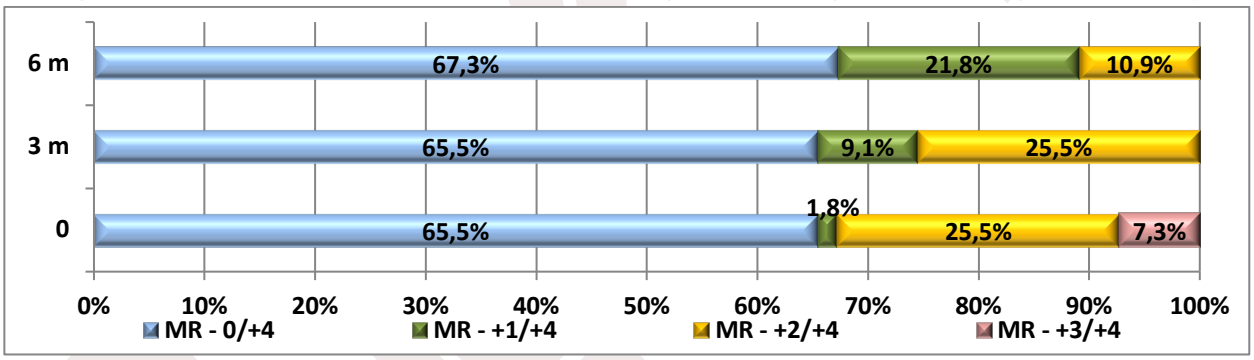
The distribution of the patients in the study group according to the degree of mitral valve regurgitation (MVR) at all stages of the study is shown on Figure 2. As it is shown on Figure 2, percentage values of the MVRs of 3rd and 4th grades were significantly decreased. The percentage value of the MVRs of 2nd grade was slightly increased. The distribution of the patients in the study groups according to the degree of Tricuspid valve regurgitation (TVR) at all stages of the study is shown on Figure 3. As it is shown on Figure 3, in the percentage values of the TVRs of 2nd and 3rd grades were significantly decreased. As a result of this reduction the percentage value of the TVRs of 1st grade was increased.

Figure 2. The distribution of the patients according to the MVR grades at all stages of the study



* The distribution was statistically significant (Chi2=62.22; p<0.001)

Figure 3. The distribution of the patients according to the TVR grades at all stages of the study



* The distribution was statistically significant (Chi2=54.56; p<0.001)

The values of the parameters of carbohydrate and lipid metabolism, renin, creatinine, NT-proBNP and electrolytes during the study in the group 1 are shown in Table 3; and in the group 2 are shown in Table 3.

Table 3. The study parameters during 6 months follow-up in the study group

Parameter	Baseline	3 Months	6 Months
	Mean (SD)	Mean (SD)	Mean (SD)
Systolic BP, mmHg.	122.5 (10.4)	122.6 (7.3)	121.1(8.0)
Diastolic BP, mmHg.	66.0 (6.8)	66.9 (5.2)	66.9 (5.5)
Pulse, bpm	75.8 (12.3)	75.7 (8.7)	77.1 (6.1)
Saturation, %	91.3 (2.3)	91.6 (2.0)	91.2 (3.8)
Breath Rate, bpm	21.7 (1.3)	22.1 (1.5)	22.4 (1.7)
FPG, mg/dl	98.2 (16.6)	97.0 (13.4)	100.2 (9.0)
HbA1C, %	5.9 (0.9)	5.9 (0.9)	6.1 (0.7)
FCP, nmol/l	1.0 (0.3)	1.0 (0.2)	0.9 (0.2)
HOMA-B, %	150.9 (58.3)	150.6 (48.2)	129.5 (27.6)*

HOMA-S,%	**47.1** (12.8)	**46.9** (9.7)	**48.5** (8.2)
HOMA-IR	**2.3** (0.6)	**2.2** (0.4)	**2.1** (0.4)
Renin, ng/ml/hr	**11.3** (7.9)	**10.9** (7.3)	**10.7** (6.8)
Creatinine, mmol/L	**77.2** (5.3)	**78.2** (4.8)	**81.6** (8.7)
Total Chol, mg/dl	**205.3** (30.5)	**201.3** (24.2)	**189.9** (26.9)*
Tg, mg/dl	**154.7** (29.4)	**154.1** (24.1)	**143.4** (26.6)*
HDL Chol, mg/dl	**42.4** (5.0)	**43.0** (3.7)	**45.2** (6.3)*
LDL Chol, mg/dl	**132.0** (29.4)	**127.5** (22.5)	**116.0** (26.4)*
VLDL Chol, mg/dl	**30.9** (5.9)	**30.8** (4.8)	**28.7** (5.3)*
PAPS, mmHg	**32.5** (15.4)	**31.2** (11.3)	**29.4** (7.9)
K, mmol/L	**4.0** (0.2)	**4.0** (0.2)	**3.9** (0.2)
Ca, mmol/L	**1.1** (0.1)	**1.1** (0.1)	**1.1** (0.1)
Na, mmol/L	**137.5** (4.5)	**135.0** (4.0)	**134.2** (3.0)
NT-proBNP, pg/ml	**158.5** (49.1)	**163.1** (38.8)	**156.5** (29.9)

* - significant compared to baseline value

As it is shown from the Table, BP data (both systolic and diastolic) did not change significantly. It should be noted here that there were very few episodes of hypotensions at all stages of the study. The pulse, saturation rate, breath rate did not change at any point. FPG, HbA1C, fasting C-peptide levels did not change significantly at all points of the study compared to the baseline value. The change of HOMA-B indice was significant at final point of the study.

Among the parameters of lipid metabolism, the mean level of total cholesterol, triglyceride, LDL-cholesterol was significantly reduced after 6 months, and HDL-cholesterol levels were significantly increased; blood renin and creatinine levels did not change significantly compared to the baseline one.

Discussion. To discuss the obtained results, attention should be paid to the several interesting findings. Aliskiren improved significantly the data of NYHA class of HF after 6 months of treatment. This was reported by Yenercag M and co-authors [16]. We could not find information on this effect of aliskiren either from ATMOSPHERE [17] or ASTRONAUT [18] studies.

New finding of the study refers to the regurgitations. This was noted by Martens and co-authors [13]. They concluded that sacubitril/valsartan reduced mitral valve regurgitation more than valsartan in the patients with secondary functional mitral valve regurgitation. According to the data of another study, the authors believed that angiotensin receptor-neprilysin inhibitor can be considered as an optimal medical therapy for patients with HF and functional myocardial valve regurgitation [15]. The analogous significant improvement in terms of regurgitations observed in the aliskiren monotherapy group in our study was not found in the literature.

For the left ventricular echocardiographic parameters, significant changes in the aliskiren group have not observed for almost all echocardiographic parameters.

Limitations. This study has several limitations, including the inherent limitations of the study design, the relatively small sample size, and the short follow-up. Moreover, the comorbidities that could have impact on the study parameters were not specified. Future studies on larger numbers of patients with longer follow-up and a comparative double-blind randomized design are required to address these limitations.

Conclusion. Based on the evaluation of the effects of 6-month treatment of the HF patients with Aliskiren, it may be concluded that Aliskiren showed better results in terms of reducing valvular regurgitations rather than improvement of echocardiographic parameters. To obtain more strong evidences, it is necessary to continue the study to provide the evidence-based results and conclusions.

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CARDIAC MUSCLE MODELING DURING TREATMENT WITH ALISKIREN IN PATIENTS WITH HEART FAILURE

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SUMMARY

Background and objectives. The aim of the study was to study the cardiac muscle modeling during treatment with aliskiren in patients with heart failure (HF).

Methods. To assess the treatment effects of aliskiren (follow-up period – 6 months) 60 randomly were selected patients with chronic HF of different classes. They were randomly assigned to the study groups. 55 patients treated with aliskiren (150 mg), and finished the study.

Results. Significant changes have not observed for almost all echocardiographic parameters. Percentage of the patients with mitral valve regurgitations of 3rd and 4th grades were significantly decreased; percentages of the patients with tricuspid valve regurgitations of 2nd and 3rd grades were also decreased significantly.

Conclusion. Based on the evaluation of the effects of 6-month treatment of the HF patients with Aliskiren, it may be concluded that Aliskiren showed better results in terms of reducing valvular regurgitations rather than improvement of echocardiographic parameters. To obtain more strong evidences, it is necessary to continue the study to provide the evidence-based results and conclusions.

Keywords: Aliskiren; Echocardiography; Heart Failure; Valvular regurgitations.