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Results of one-year follow-up of patients with severe myocarditis associated with COVID-19 on glucocorticoid therapy

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The aim of the study – to investigate the effectiveness and safety of glucocorticoid therapy in patients with severe myocarditis associated with COVID-19.

Materials and methods. The results are based on data obtained from 72 patients with severe acute myocarditis (AM) and heart failure (HF) with reduced left ventricular ejection fraction (LVEF $\leq 40\%$). Patients were divided into two groups: the group 1 included 34 patients with AM, who had a documented history of coronavirus disease ≤ 3 months before the onset of clinical symptoms of AM; the group 2 consisted of 38 patients with AM, who had no history of coronavirus disease. All patients received optimal therapy for heart failure during all period of follow-up and immunosuppressive therapy with glucocorticoids (GKs) within first 6 months from the onset of AM. Patients underwent for echocardiography with speckle tracking and cardiac magnetic resonance (CMR). The studies were conducted three times: in the first month from the onset of clinical symptoms of myocarditis, after 6 months, and after 12 months of observation.

Results and discussion. After 6 months of follow-up, improvements in the structural and functional state of the heart were observed in both groups, with group 1 showing greater increases in LVEF and LGSS by 13.1 % and 22.2 %, respectively ($p < 0.05$). Additionally, group 1 exhibited a reduction in the number of LV segments affected by inflammatory changes and the total number of damaged segments by 28.4 % and 18.3 %, respectively, compared to group 2 ($p < 0.05-0.001$). After 12 months results of CMR demonstrated significantly less myocardial damage in group 1 compared to group 2: the total number of LV segments affected by inflammation and/or fibrosis was 39.0 % lower ($p < 0.001$). The most common complications of GKs therapy after 6 months were obesity (13.88 %) and leukocytosis (12.50 %), while hypokalemia occurred in 6.94 % of cases. Complications such as arterial hypertension, hyperglycemia, functional hypercortisolism, and myalgia were recorded in 4.16 % of cases. After 12 months, a significant reduction or complete resolution of GC-associated complications was observed in most patients: only 7 cases (9.72 %) of pathology associated with GC therapy were recorded.

Conclusions. In patients with acute severe myocarditis with a history of coronavirus disease, glucocorticoid therapy demonstrated greater efficacy in improving the structural and functional state of the heart after 6 months of follow-up compared to patients without a history of COVID-19. The use of glucocorticoids in patients with severe myocarditis was associated with the development of complications in more than a half of patients within the first 6 months of follow-up, while after 12 months, there was a significant reduction in their frequency or their complete regression. During the 12-month observation period, none of the patients developed diseases or pathological conditions associated with glucocorticoid use that required inpatient treatment.

Key words: acute myocarditis, COVID-19, glucocorticoids, cardiac magnetic resonance, complications.

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In recent years, the COVID-19 pandemic has become one of the main factors contributing to the increasing prevalence and severity of cardiovascular pathologies worldwide [2, 4]. Among cardiovascular diseases, the incidence of which has significantly increased during the coronavirus pandemic, myocardial damage occupies a leading position. Some international authors have reported that the detection rate of myocarditis during the active phase of the epidemic has increased several times during the active phase of the epidemic [3, 17].

It is now proven that the coronavirus itself is a relatively rare direct cause of myocarditis; in the structure of viral genomes detected in the myocardium during endomyocardial biopsy, its share did not exceed 5 % even during the pandemic [17]. However, COVID-19 has the ability to induce autoimmune inflammation with hyperproduction of pro-inflammatory cytokines, primarily interleukin 1- β (IL-1 β) and tumor necrosis factor- α (TNF- α), referred to in global literature as the «cytokine storm» [4, 6]. On the other hand, it is well known that the activation of autoimmune inflammation with hypersecretion of pro-inflammatory cytokines is one of the main mechanisms for the long-term persistence of inflammation in the myocardium [2, 3]. Thus, both coronavirus disease and myocarditis share common pathogenetic mechanisms of development and corresponding shared targets for pathogenetic therapy, primarily anti-inflammatory and immunosuppressive [1, 6, 13].

In recent years, immunosuppressive therapy, which includes glucocorticoids (GCs) alone or in combination with cytostatics, has been one of the main alternatives for treating both severe myocarditis and severe coronavirus disease [6, 13]. Despite the fact that the administration of GCs in patients with myocarditis associated with COVID-19 seems pathogenetically justified, the effectiveness and safety of such therapy remain insufficiently studied to this day.

The aim of the study was to investigate the effectiveness and safety of glucocorticoid therapy in patients with severe myocarditis associated with COVID-19.

MATERIALS AND METHODS

The results of the study are based on data obtained from 72 patients with severe acute myocarditis (AM) and heart failure (HF) with reduced left ventricular ejection fraction (LVEF \leq 40 %), who underwent inpatient treatment in the Department of Non-Coronary Heart Diseases, Rheumatology, and Therapy at the National Scientific Center «M.D. Strazhesko Institute of Cardiology, Clinical and Regenerative Medicine» of NAMS of Ukraine from September 2021 to December 2023. The diagnosis of myocarditis was established

based on the Guidelines for the Diagnosis and Treatment of Myocarditis of the All-Ukrainian Association of Cardiologists of Ukraine [9, 10].

The patients were divided into two groups: the group 1 included 34 patients with AM with a mean age of (35.7 \pm 2.6) years, who had a documented history of coronavirus disease \leq 3 months before the onset of clinical symptoms of AM; the group 2 consisted of 38 patients with AM with a mean age of (35.1 \pm 2.5) years, who had no history of coronavirus disease and had negative laboratory test on COVID-19 persistence.

Before the study, all patients signed informed consent forms for the processing of personal data in accordance with the Order of the Ministry of Health of Ukraine No. 110 dated 14.02.2012 «On Approving the Forms of Primary Accounting Documentation and Instructions for Their Completion Used in Healthcare Institutions Regardless of Ownership and Subordination». Data processing was conducted in compliance with the requirements of the Law of Ukraine «On Personal Data Protection».

To determine the functional class (FC) of HF according to NYHA criteria, a six-minute walk test (6MWT) was performed.

Transthoracic echocardiography (EchoCG) was performed on the Aplio Artida SSH-880 CV ultrasound diagnostic system by Toshiba Medical System Corporation (Japan). In the two-dimensional mode, during systole and diastole, end-diastolic volume (EDV) and end-systolic volume (ESV) of the left ventricle (LV) were calculated. LVEF was assessed using the biplane disk method by Simpson [12]. The EDV of the LV was related to the body surface area to obtain the indexed indicator (EDVi). Using the speckle-tracking (ST) method, longitudinal global systolic strain (LGSS) and circumferential global systolic strain (CGSS) were assessed [12]. The analysis of indicators was conducted using the Wall Motion Tracking software package. The results of ST EchoCG were presented in absolute values.

Cardiac magnetic resonance (CMR) imaging of the heart with gadolinium enhancement was performed on a «Toshiba Vantage Titan HSR 1.5 Tesla scanner» (Japan). Images of the heart in the T2 Black Blood Fsat, early T1 contrast, and delayed T1 contrast enhancement (LGE) modes were evaluated [7]. To assess the number of LV segments affected by inflammatory changes (IC) or fibrotic/necrotic changes, as evidenced by the presence of LGE, the modern concept of the 17-segment structure of the LV was used [5].

All patients received comparable doses of beta-adrenergic blockers, ACE inhibitors or the sacubitril/valsartan combination, sodium-glucose cotransporter 2 inhibitors, mineralocorticoid receptor antagonists, as well as diuretics, anticoagulants, and antiarrhythmics as indicated [15]. GCs were prescribed to all included

Table 1

Indicators of the structural and functional state of the heart in the study groups after 6 months of treatment

Indicator	Mean value (M±m)		p
	Group 1 (n=34)	Group 2 (n=38)	
Mean NYHA FC	II	II	–
6MWT, m	376.7±25.1	343.8±26.6	>0.05
LVEDVi, ml/ml	82.2±5.1	92.3±5.5	>0.05
LV EF, %	47.5±2.4	41.3±2.4	<0.05
LGSS, %	15.72±1.25	12.23±1.20	<0.05
CGSS, %	13.48±1.20	11.87±1.11	>0.05
Number of IC segments	2.45±0.21	3.42±0.27	<0.001
Number of LGE segments	2.46±0.20	2.60±0.24	>0.05
Total number of affected LV segments	4.91±0.39	6.02±0.44	<0.05

FC – functional class; 6MWT – six-minute walk test; LVEDVi – left ventricular end-diastolic volume index; LV EF – left ventricular ejection fraction; LGSS – longitudinal global systolic strain; CGSS – circumferential global systolic strain; IC – inflammatory changes; LGE – late gadolinium enhancement; LV – left ventricle.

patients for 6 months according to the scheme described by us earlier [9].

The studies were conducted three times: in the first month from the onset of clinical symptoms of myocarditis, after 6 months, and after 12 months of observation.

Statistical processing of the results obtained was carried out using Microsoft Excel 2010 (Microsoft Office, USA) and the statistical program STATISTICA 10.0 Portable (Statsoft, USA). The calculated quantitative indicators are presented as mean values and the standard error of the mean (M±m); for comparison of mean values in all groups, the Student's t-test was used. For all types of analysis, the critical level of statistical significance was $p < 0.05$.

RESULTS

Before the administration of GCs, both groups were comparable in terms of the severity of structural and functional heart abnormalities and the clinical manifestations of HF. According to the results of EchoCG and CMR during the initial examination, the LVEDVi and LVEF values, LGSS, CGSS, as well as the number of LV segments affected by inflammatory lesions and segments with LGE presence, did not differ significantly. The total volume of myocardial damage, as determined by CMR, was also comparable – (7.29±0.81) segments in group 1 and (7.08±0.74) segments in group 2 ($p > 0.05$). The groups did not differ in terms of the severity of clinical manifestations of HF:

the mean distance walked during the 6MWT was (249.1±19.6) meters in group 1 and (257.8±20.7) meters in group 2 ($p > 0.05$), which corresponded to NYHA class III.

After 6 months of follow-up, improvements in the structural and functional state of the heart were observed in both groups, with group 1 showing greater increases in LVEF and LGSS by 13.1 % and 22.2 %, respectively ($p < 0.05$) (Table 1). Additionally, group 1 exhibited a reduction in the number of LV segments affected by inflammatory changes and the total number of damaged segments by 28.4 % and 18.3 %, respectively, compared to group 2 ($p < 0.05–0.001$).

After 12 months of follow-up, the mean LVEF in group 1 had almost normalized, averaging (51.2±2.6) %, while the LGSS and CGSS values in group 1 were 17.9 % and 21.5 % higher, respectively, than those in group 2 ($p < 0.05$). The results of CMR demonstrated significantly less myocardial damage in group 1 compared to group 2: the total number of LV segments affected by inflammation and/or fibrosis was 39.0 % lower ($p < 0.001$) (Table 2). On this background, the results of the 6MWT were consistent: the distance covered by patients in group 1 was 17.4 % greater than that of patients in group 2 ($p < 0.05$), corresponding to NYHA class I, while in group 2, the mean FC remained at class II.

After completing the immunosuppressive therapy course, the frequency of complications potentially associated with GC administration was assessed after 6 months (Table 3). These complications were primarily recorded within the first 6 months of treatment and

Table 2
Indicators of the structural and functional state of the heart in the study groups after 12 months of treatment

Indicator	Mean value (M±m)		p
	Group 1 (n=34)	Group 2 (n=38)	
Mean NYHA FC	I	II	–
6MWT, m	459.7±34.2	379.1±32.7	<0.05
LVEDVi, ml/ml	76.9±4.8	83.7±5.2	>0.05
LV EF, %	51.2±2.6	46.3±2.5	>0.05
LGSS, %	17.31±1.32	14.23±1.28	<0.05
CGSS, %	15.84±1.35	12.45±1.27	<0.05
Number of IC segments	0.67±0.08	1.65±0.12	<0.001
Number of LGE segments	1.65±0.13	2.15±0.18	<0.01
Total number of affected LV segments	2.32±0.20	3.80±0.29	<0.001

FC – functional class; 6MWT – six-minute walk test; LVEDVi – left ventricular end-diastolic volume index; LV EF – left ventricular ejection fraction; LGSS – longitudinal global systolic strain; CGSS – circumferential global systolic strain; IC – inflammatory changes; LGE – late gadolinium enhancement; LV – left ventricle.

Table 3
Frequency of diseases and pathological conditions associated with GC therapy over 12 months of follow-up

Diseases and pathological conditions	Amount of patients (%) from all included	
	Persistence within first 6 months	Persistence after 12 months
Hypersensitivity reactions	2 (2.77 %)	–
Arterial hypertension	3 (4.16 %)	2 (2.77 %)
Obesity	10 (13.88 %)	5 (6.94 %)
Hypokaliemia	5 (6.94 %)	–
Leukocytosis	9 (12.50 %)	–
Hyperglycemia	3 (4.16 %)	–
Erosive lesions of the esophagus/stomach	2 (2.77 %)	–
Myalgia/Myopathy	3 (4.16 %)	–
Functional hypercortisolism	3 (4.16 %)	–

included a total of 40 cases (55.55 %). The most common complications were obesity (13.88 %) and leukocytosis (12.50 %), while hypokalemia occurred in 6.94 % of cases. Complications such as arterial hypertension, hyperglycemia, functional hypercortisolism, and myalgia were recorded in 4.16 % of cases. Additionally, it is noteworthy that 2 patients (2.77 %) developed erosive lesions of the esophagus/stomach. Patients with arterial hypertension were prescribed antihypertensive therapy in accordance with current recommendations, and patients with extracardiac

pathology were referred for consultations with specialized professionals.

After 12 months, a significant reduction or complete resolution of GC-associated complications was observed in most patients: only 7 cases (9.72 %) of comorbid pathology associated with GC therapy were recorded. This included obesity in 6.94 % of cases and arterial hypertension in 2.77 % of cases (Table 3). It is important to note that two patients who exhibited persistent arterial hypertension after 12 months of follow-up had a family history of this condition. Patients

with persistent obesity were provided with recommendations for its management.

Thus, GC therapy as an immunosuppressive treatment for myocarditis was associated with the development of a fairly wide spectrum of complications, including arterial hypertension, hypokalemia, erosive lesions of the gastrointestinal tract, and others. However, during the 12-month observation period, none of the patients developed conditions requiring inpatient treatment directly related to GC administration.

DISCUSSION

The results of the study demonstrated higher efficacy of GCs in patients with myocarditis who, within 3 months from the onset of AM symptoms, had a history of COVID-19 infection, compared to patients without COVID-19. Data obtained after 6 and 12 months showed a faster recovery of LV contractile function and a significant reduction in the volume of inflammatory LV damage in patients with COVID-19 in their medical history. The higher LVEF, LGSS, and CGSS values observed in group 1 compared to group 2 at 6 and 12 months of follow-up were directly related to the smaller number of LV segments affected by inflammation and the reduced overall damage volume according to CMR findings. Predictably, this was reflected in greater physical exercise tolerance in group 1 patients after 12 months of treatment.

A possible explanation for the greater efficacy of GCs in patients with AM and a history of COVID-19 is that myocarditis associated with coronavirus disease primarily develops via an autoimmune mechanism caused by lymphocyte auto-sensitization, macrophage and monocyte activation, and, consequently, the hypersecretion of pro-inflammatory cytokines [1, 2, 6]. Immune cells, such as lymphocytes, monocytes, and macrophages producing pro-inflammatory cytokines, including IL-1 β , IL-2, and TNF- α , represent the primary targets for the anti-inflammatory and immunosuppressive effects of GCs [14, 19]. The results of this study confirmed this hypothesis: a more substantial reduction in the volume of inflammatory damage to the LV in group 1 patients was observed as early as 6 months, with this effect persisting at 12 months. This contributed positively to reducing the overall volume of LV damage. As it is known, the evolution of the inflammatory process in the myocardium is characterized by the gradual transformation of inflammatory changes into fibrotic ones, which is indicated by the presence of LGE on CMR [8, 11, 16, 18]. The smaller number of LV segments showing LGE in group 1 patients after 12 months may be attributed to the more pronounced anti-inflammatory

effect of GCs, which significantly reduced the volume of inflammatory changes in the LV as early as 6 months. This was accompanied by better structural and functional parameters of the heart compared to group 2.

Analysis of the spectrum of complications associated with GC therapy allowed the identification of the frequency of typical side effects, such as obesity, leukocytosis, hypokalemia, hyperglycemia, erosive gastrointestinal lesions, and others, as described in the global literature [19, 20]. After discontinuation of GCs, the majority of GC-associated diseases and pathological conditions gradually regressed, which, considering the efficacy of GCs, argues in favor of their use, especially in patients with AM associated with a history of COVID-19 infection, strictly following modern recommendations and algorithms, and only in cases of severe myocarditis.

CONCLUSIONS

1. In patients with acute severe myocarditis with a history of coronavirus disease, glucocorticoid therapy demonstrated greater efficacy in improving the structural and functional state of the heart after 6 months of follow-up compared to patients without a history of COVID-19. This was evidenced by a 28.4 % lower number of left ventricle segments affected by the inflammatory process and an 18.3 % smaller total volume of left ventricle damage on cardiac magnetic resonance, accompanied by 13.1 % and 22.2 % higher values of left ventricular ejection fraction and longitudinal global systolic strain, respectively.

2. After 12 months of follow-up, in the group of patients with myocarditis and a history of coronavirus disease, the number of left ventricle segments with inflammatory changes or late gadolinium enhancement was 39.0 % lower compared to patients without a history of COVID-19. This was associated with normalization of the average left ventricular ejection fraction (51.4 %), 17.9 % and 21.5 % higher values of longitudinal global systolic strain and circumferential global systolic strain respectively and a lower functional class of heart failure based on the 6-minute walk test results.

3. The use of glucocorticoids in patients with severe myocarditis was associated with the development of complications in 55.55 % of patients within the first 6 months of follow-up, while after 12 months, there was a significant reduction in their frequency (down to 9.72 %) or their complete regression. Importantly, during the 12-month observation period, none of the patients developed diseases or pathological conditions associated with glucocorticoid use that required inpatient treatment.

The authors declare no conflict of interest.

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Результати 1-річного спостереження за хворими із тяжким перебігом міокардиту, асоційованим із COVID-19, на тлі застосування глюкокортикоїдної терапії

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Мета роботи – дослідити ефективність і безпечність призначення глюкокортикоїдів у хворих із тяжким перебігом міокардиту, асоційованим із COVID-19 інфекцією.

Матеріали і методи. Результати дослідження базуються на даних обстежень 72 хворих із тяжким перебігом гострого міокардиту (ГМ) і серцевою недостатністю (СН) зі зниженою фракцією викиду лівого шлуночка (ФВ ЛШ ≤ 40 %). Хворих розподілили на дві групи: 1-ша група – 34 хворих на ГМ, які мали в анамнезі документально підтверджену коронавірусну хворобу, перенесену в строки ≤ 3 місяців до початку клінічних симптомів ГМ; 2-га група – 38 хворих на ГМ, які не мали в анамнезі коронавірусної хвороби. Пацієнти отримували оптимальну медикаментозну терапію СН згідно із сучасними рекомендаціями протягом усього періоду спостереження та глюкокортикоїдну (ГК) терапію протягом перших 6 місяців від початку клінічних симптомів міокардиту. Всім пацієнтам проводили спекл-трекінг ехокардіографію та магнітно-резонансну томографію серця. Дослідження проводили тричі: в 1-й місяць від початку клінічних симптомів міокардиту, через 6 та 12 місяців спостереження.

Результати та обговорення. Через 6 місяців спостереження структурно-функціональний стан серця покращився в обох групах, при цьому в 1-й групі порівняно з 2-ю відзначали більші величини показників ФВ та поздовжньої глобальної систолічної деформації лівого шлуночка (ЛШ) на 13,1 та 22,2 % відповідно ($p < 0,05$). Також в 1-й групі кількість сегментів ЛШ, уражених запальними змінами, як і загальна кількість уражених сегментів, були на 28,4 та 18,3 % відповідно меншими порівняно з такими в 2-й групі ($p < 0,05-0,001$). Через 12 місяців результати магнітно-резонансної томографії засвідчили суттєво менший об'єм як запального, так і фібротичного ураження ЛШ в 1-й групі, при цьому загальна кількість уражених сегментів ЛШ була на 39,0 % меншою ($p < 0,001$) порівняно з 2-ю групою. Найчастіше ускладненнями терапії ГК були ожиріння (13,88 %) та лейкоцитоз (12,50 %), гіпокаліємія розвинулася в 6,94 % випадків. Ускладнення, такі як артеріальна гіпертензія, гіперглікемія, функціональний гіперкортицизм, міалгії реєстрували в 4,16 % випадків, також привертає увагу те, що у 2 (2,77 %) пацієнтів розвинулись ерозії стравоходу/шлунку. Через 12 місяців спостереження суттєво зменшилася частота ускладнень, асоційованих із лікуванням ГК – реєстрували тільки 7 (9,72 %) випадків такої патології.

Висновки. У хворих із ГМ із тяжким перебігом та коронавірусною хворобою в анамнезі порівняно з такими без COVID-19 призначення глюкокортикоїдів було ефективнішим щодо поліпшення структурно-функціонального стану серця через 6 місяців спостереження. Застосування глюкокортикоїдів у хворих із тяжким перебігом міокардиту асоціювалось із розвитком ускладнень у більше ніж половини хворих протягом перших 6 місяців спостереження, через 12 місяців відзначали суттєве зменшення їх частоти або їх повний регрес. При цьому в жодного з досліджуваних пацієнтів протягом 12 місяців спостереження не виникло захворювань і патологічних станів, пов'язаних із прийманням глюкокортикоїдів, що потребували стаціонарного лікування.

Ключові слова: гострий міокардит, COVID-19, глюкокортикоїди, магнітно-резонансна томографія серця, ускладнення.