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Evaluation of the effectiveness of the chronic heart failure therapy using the device cardiac contractility modulation according to the new non-invasive method of the myocardium work analysis

Aim To analyze echocardiographic parameters that reflect left ventricular (LV) myocardial contractility, using a novel method for evaluation of myocardial performance in patients with chronic heart failure (CHF) and atrial fibrillation (AF) during heart contractility modulation (HCM).

Material and Methods Standard echocardiographic parameters and indexes of myocardial strain and work were analyzed for 66 patients (52 men and 14 women; median age, 60 [54; 66] years). 36 patients had paroxysmal AF and 30 patients had permanent AF. All patients had CHF with a duration of 17 [4; 60] months; duration of AF was 12 [6; 36] months. At baseline, the left ventricular ejection fraction (LV EF) was 33 [27; 37] %.

Results After one year of HCM, LV EF significantly increased from 33 [27; 37] to 38 [33; 44] % (p=0.001). Also, there were improvements in the myocardial global longitudinal strain (from –6.00 [–8; –4] to –8 [–10; –6] %; p=0.001) and parameters of myocardial work, including the global work efficiency (from 74 [65; 79] to 80 [73; 87] mm Hg%; p=0.001), global constructive work (from 699 [516; 940] to 882 [714; 1242] mm Hg%; p=0.001), and global myocardial work index (from 460 [339; 723] to 668 [497; 943] mm Hg%; p=0.001). A segmentary analysis of LV work parameters showed positive changes in the myocardial constructive work in the area of the interventricular septal apical segment (at baseline, 844 [614; 1224]; after HCM, 1027 [800; 1520] mm Hg%; p=0.05) and the medium segment of the LV anteroseptal wall (at baseline, 593 [312; 1000]; after HCM, 877 [494; 1145] mm Hg%; p=0.05).

Conclusion This method for analysis of the myocardial work provides a more detailed examination of LV structural and functional remodeling and mechanisms for its effects on the LV contractile function in patients with CHF. This method is promising and merits further study in various clinical situations.

Keywords 2D-echocardiography; myocardial work; heart contractility modulation; chronic heart failure; atrial fibrillation

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As the most informative diagnostic technique in patients with chronic heart failure (CHF), echocardiography is indicated for all patients as a means of confirming this diagnosis [1]. The global left ventricular (LV) systolic function is estimated in all patients with CHF by calculating the left ventricular ejection fraction (LVEF) using the biplane method of disks (Simpson's rule). In cases of atrial fibrillation (AF), use of the mean value from multiple cycles is recommended. Use of the one-dimensional Teicholtz method for assessing LVEF or LV systolic function is not advised, especially in patients with local wall motion abnormalities. However, the method of evaluating LVEF has several drawbacks that sometimes prevent its use as the sole criterion for evaluating LV wall motion. The accuracy of measurements performed when calculating LVEF depends on many factors, such as imaging quality, the model of the ultrasound device and the expertise of the sonographer. Intra-operator and inter-operator discrepancies of up to 20% or more, which may occur when estimating LVEF, present challenges when assessing LV systolic function over time [2]. Various hemodynamics-related situations also arise when even an adequately calculated LVEF cannot be used as a marker of the patient's clinical condition. For example, patients with coronary artery disease (CAD) and severe mitral regurgitation may continue to have normal LVEF for a long time due to the increased preload in accordance with the Frank-Starling law. However, acute decompensation generally occurs at some point, along with an irreversible decrease in the LV systolic function. Latent LV systolic dysfunction observed in patients with CHF and normal LVEF occurs in the form of decreased indicators of the LV strain [3].

Although it has been recently shown that myocardial strain has a higher predictive value than LVEF, its use is limited by dependence on afterload, such as when blood pressure (BP) changes [4]. In the experimental studies carried out by Ky et al. [5], it was shown that global strains are not reliable markers of LV wall motion in the case of increased preload and afterload; the global myocardial work index (GWI) more accurately evaluates LV systolic function in various hemodynamic conditions since it is calculated based both on values of myocardial strain and pressure in the LV chamber.

The 2021 study carried out by Wang et al. [6] comprehensively evaluated the prognostic value of GWI for the first time. The researchers found a correlation between GWI and an increased risk of all-cause death and hospitalization for CHF. GWI had a higher prognostic value than both LVEF and myocardial strain.

Myocardial work is estimated based on measuring the energy expended by the myocardium when contracting. Since it is not easy to calculate the contraction force directly, the LV chamber pressure is used as an equivalent of the force overcome by the myocardium during contraction. Thus, the LV pressure-volume curve area comprises a regional performance indicator that reflects myocardial oxygen consumption [7].

In 2012, Russell et al. [8] developed a method for the non-invasive estimation of LV chamber pressure based on an empiric normalized reference curve adjusted for the duration of isovolumic contraction and the ejection phase as the mitral and aortic valves open and close as shown by echocardiography. A strong correlation ($r = 0.99$) was found between pressure-strain curves using non-invasive and invasive measurements of LV pressure. The non-invasive pressure-strain curve area as shown by positron emission tomography was also well correlated with regional glucose metabolism in the myocardium ($r = 0.81$).

The main parameters of the LV myocardial performance include the following [9]: global work efficiency (GWE) is the ratio of constructive work to the sum of constructive and wasted work (GCW / [GCW + GWW], %); global constructive work (GCW) is the work to expulse blood from the ventricle in systole (mm Hg%); global wasted work (GWW) is the work performed by the myocardium, during which blood does not leave the LV chamber (mm Hg%); the global work index (GWI) describes all the work that the LV performs from closure to opening of the mitral valve considered as the pressure-strain curve area (mm Hg%).

Assessment of LV myocardial work is currently used to diagnose various pathologies, such as occurring in CAD, amyloidosis, hypertrophic, and dilated cardiomyopathy, in order to predict the response to cardiac resynchronization therapy (CRT) [10]. Studying the work of the myocardium in patients with CHF is also of interest, especially in relation to the determination of the efficacy of various treatments that contribute to reverse remodeling of the heart.

Cardiac contractility modulation (CCM), comprising a high-voltage stimulation in the absolute refractory period during myocardial depolarization, is currently used in patients with CHF. By normalizing the movement of ions in cardiomyocytes and producing a positive inotropic effect without increasing oxygen consumption, this represents a new treatment for patients with CHF [11].

Several large, randomized trials on CCM have been performed in recent years. The first randomized clinical trial (RCT) FIX–CHF-4 included 164 patients with CHF NYHA functional class (FC) II–III. The FIX-HF-5 II trial included 428 patients with CHF NYHA FC III-IV. Both studies showed a statistically significant increase in VO_{2peak} and improved quality of life indicators during CCM. A meta-analysis performed by Giallauria et al. [12] confirmed the positive effect of CCM on the clinical condition of patients and exercise tolerance.

It should be noted that echocardiographic parameters were studied in only one RCT (FIX–CHF-4), and only one parameter, namely LVEF, was considered when assessing the LV contractile function, which showed no significant positive trend. This is probably due to a short follow-up period (6 months) and limitations of the LVEF calculation method (low accuracy and reproducibility measurements) [13]. A few small studies assessed LV remodeling and wall motion parameters in more detail (based on LVEF assessment), but no studies conducted a detailed evaluation of the parameters of myocardial strain and work in patients who underwent CCM [14].

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Objective

To study in detail all parameters reflecting LV wall motion in patients with CHF and AF during CCM (LVEF, global strain, and LV myocardial performance) over a longer follow-up period (12 months).

Material and Methods

The study included 66 patients who underwent extended echocardiographic examination, which included a calculation of indicators of global longitudinal strain and LV myocardial work in addition to the more usual parameters. As well as undergoing complete laboratory and clinical examinations, including coronary angiography and magnetic resonance imaging if necessary, all patients fulfilled the following criteria [15]: documented CHF with reduced LVEF (20–40%); NYHA FC II or III for at least three months; the presence of permanent or paroxysmal AF; the best possible treatment of CHF following the current guideline; a stable condition for ≥1 month.

Exclusion Criteria were: a history of heart transplant or inclusion in a heart transplant waiting list; terminal stage of CHF; acute conditions that can adversely affect the safety or efficacy of treatment; reversible CHF; major surgery, trauma, cardiac complications, including acute myocardial infarction, acute coronary syndrome, percutaneous coronary intervention or heart surgery carried out within the previous three months; hemodynamically significant valvular disease having led to CHF; decompensated CHF; acute myocarditis; hypertrophic obstructive cardiomyopathy; angina FC IV or CHF NYHA FC IV; difficult vascular access; other diseases that generally limit life expectancy to 12 months.

CHF FC was determined using the NYHA classification based on 6-minute walk distance (6MWD) test results.

Optimizer Smart CCM devices were implanted in 2018–2019. The CCM leads were delivered through a subclavian vein; two Ingevity active-fixation ventricular leads were located in the interventricular septum (IVS) area corresponding mainly to the apical and middle segments. Prior to CCM implantation and after 12 months of follow-up, all patients underwent transthoracic echocardiography using an expert-level ultrasound device and an M5S-D transducer (patient in the left lateral position; ECG synchronization; standard echocardiographic approaches in the B, M, PW, and CW modes; the analysis of the findings of myocardial tissue Doppler imaging (TDI) at the rate of more than 140–150 frames per second). Three cycles recorded during breath-holding in patients with sinus rhythm – and at least five cycles in patients with AF – were used to minimize the effect of rhythm variability in patients with permanent AF upon calculating the LV myocardial strain and work parameters. Blood pressure was measured according to the Korotkoff method during echocardiography in all patients. Based on these data, indicators of global longitudinal strain and times of valvular events (opening and closure of the aortic and mitral valves), the systolic pressure-strain curve was represented graphically, while the indicators of LV myocardial work were calculated.

LVEF was calculated in B-mode from the apical four- and two-chamber views using the method of disks (modified Simpson's rule). The digital records were saved for an autonomous analysis using EchoPac (version 6.1, GE Medical Health). Statistical data processing was carried out using SPSS Statistic 26 and Microsoft Excel 2010.

Following distribution normality analysis, descriptive statistics of continuous quantitative data are presented as the median and the 25th and 75th percentiles (Me [Q1; Q3]). Analytical processing of non-normally distributed quantitative data was performed using the Wilcoxon rank-sum test and Mann-Whitney U-test. The numerical value of probability (p) less than 0.05 (two-tailed significance test) demonstrated statistically significant differences.

Results

The general characteristics of patients are provided in Table 1. Of the 66 patients included in the study, 52 (79%) were male, while 14 (21%) were female; the median age was 60 [54; 66] years. Paroxysmal and permanent AF was established in 36 (55%) and 30 (45%) patients, respectively. At the time of inclusion, all patients had a diagnosis of CHF for more than three months; the total duration of the disease was 17 [4; 60] months; duration of AF was 12 [6; 36] months; baseline LVEF was 33 [27; 37]%.

Prior to the beginning of the study, the clinical condition of patients was compensated by the best possible treatment of CHF following the current guideline (angiotensin-converting enzyme (ACE) inhibitors – 42.5%; angiotensin II receptor blockers (ARBs) – 25%; angiotensin receptor-neprilysin inhibitors (ARNIs) – 32.5%; beta-blockers (BBs) – 100%; mineralocorticoid receptor antagonists (MCRAs) – 100%; loop diuretics – 100%). No significant corrections were made in the treatment during the follow-up period. Systolic blood pressure (SBP) was 112 [100; 120] mm Hg at baseline and 114 [102; 125] mm Hg in 12 months ($p>0.05$). There were also no significant changes in diastolic blood pressure (DBP): 75 [70; 79] mm Hg at baseline and 76 [71; 82] mm Hg in 12 months ($p>0.05$). The mean heart rate (HR) was 67 [60; 78] bpm at baseline and 70 [62; 79] bpm in 12 months ($p>0.05$). Body mass index (BMI) did not change significantly during the study.

During 12 months with CCM, an improvement was observed in exercise tolerance (6MWD increased from 340 [283; 384] to 361 [400; 447] m; $p<0.01$) and quality of life (the Minnesota score decrease from 33 [21; 52] to 29 [17; 38]; $p<0.05$). There was a trend to a decrease in the levels of N-terminal pro-brain natriuretic peptide (NT-proBNP) from 1056 [480; 2545] pg/mL to 906 [428; 2166] pg/mL ($p=0.07$).

The main echocardiographic parameters reflecting myocardial wall motion during CCM patients with CHF and AF are presented in Table 2. LVEF increased statistically significantly during CCM from 33 [27; 37]% to 38 [33; 44]% within 12 months ($p = 0.001$). Moreover, there was a significant improvement in myocardial global longitudinal strain (from –6.00 [–8; –4]% to –8 [–10; –6]%; $p = 0.001$). LVEF increased compared with the baseline value in 68% of patients; 8% of patients had decreased values in 12 months, while LVEF did not change in 24% of patients. There were no statistically significant changes in mitral regurgitation during the follow-up period.

A new technique for non-invasive estimation of LV wall motion, consisting in an analysis of myocardial function parameters in patients with CHF and AF, was applied for the first time in this study. All parameters of myocardial function were determined prior to CCM implantation and in 12 months following the start of treatment. The data are presented in Table 3.

During CCM, patients with CHF and AF had a statistically significant improvement in the global work (from 74 [65; 79] mm Hg% to 80 [73; 87] mm Hg%; $p = 0.001$) due to increased global constructive work (from 699 [516; 940] mm Hg% to 882 [714; 1242] mm Hg%; $p = 0.001$). Moreover, the global myocardial work index increased statistically significantly (from 460 [339; 723] mm Hg% to 668 [497; 943] mm Hg%; $p = 0.001$). Global wasted work did not change.

Patients were divided into groups with ischemic CHF (n = 38) and non-ischemic CHF (n = 28) to analyze the effect of CCM on the echocardiographic parameters in CHF of various origins. The first group included patients with CAD, while the second group were patients with dilated cardiomyopathy and hypertension. The results of the assessment of changes in echocardiographic parameters of the ischemic CHF and non-ischemic CHF groups are presented in Table 4.

There were statistically significant improvements in all parameters of LV wall motion of interest in the general group of patients and the groups with different origins of CHF. A detailed analysis of echocardiographic parameters performed in the groups with paroxysmal and permanent AF to study

Table 1. General characteristics of the examined patients

Parameter	Value
Age, years	60 [54; 66]
Male / female,%	79/21
Ischemic/non-ischemic CHF	38 (57%)/28 (43%)
LVEF, %	33 [27; 37]
Paroxysmal / permanent AF	36 (55%)/30 (45%)
QRS, ms	112 [105; 120]

CHF, chronic heart failure;
LVEF, left ventricular ejection fraction; AF, atrial fibrillation.

Table 2. Changes in echocardiographic parameters during treatment (n = 66)

Parameter	Baseline	In 12 months	p
LVEF, %	33 [27; 37]	38 [33; 44]	< 0.01
LVEDV, mL	199 [169; 250]	190 [160; 225]	< 0.01
LVESV, mL	134 [106; 174]	120 [95; 150]	< 0.01
GLS, %	–6,00 [– 8; – 4]	–8 [– 10; – 6]	< 0.01

LVEF, left ventricular ejection fraction;
LVEDV, left ventricular end-diastolic volume; LVESV, left ventricular end-systolic volume; GLS, global longitudinal strain.

Table 3. Changes in parameters of myocardial function in patients with CHF during CCM

Parameter	Baseline	In 12 months	p	LV myocardial performance references [16]
GWE, %	74 [65; 79]	80 [73; 87]	< 0.01	96 (94–97)
GCW, mm Hg%	699 [516; 940]	882 [714; 1242]	< 0.01	2232 (1582–2881)
GWW, mm Hg%	200 [153; 280]	190 [128; 292]	> 0.05	78 (53–122)
GWI, mm Hg%	460 [339; 723]	668 [497; 943]	< 0.01	1896 (1292–2505)

CHF – chronic heart failure; CCM – cardiac contractility modulation; LV – left ventricle;
GWE – global work efficiency; GCW – global constructive work; GWW – global wasted work; GWI – global work index

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Table 4. Changes in echocardiographic parameters in ischemic and non-ischemic CHF during CCM

Parameter	Ischemic CHF (n = 38)			Non-ischemic CHF (n = 28)		
	baseline	in 12 months	p	baseline	in 12 months	p
LVEF, %	33 [27; 38]	37 [34; 42]	<0.01	33 [28; 37]	39 [31; 45]	<0.01
LVEDV, mL	252 [174; 214]	193 [165; 226]	<0.01	190 [152; 250]	182 [126; 222]	<0.05
LVESV, mL	135 [116; 182]	120 [95; 148]	<0.01	128 [100; 170]	119 [81; 150]	<0.05
GLS, %	–6 [– 4; – 9]	–8 [– 5; – 10]	<0.01	–6 [–4; –8]	–8 [– 7; – 10]	<0.05
GWE, %	71.5 [63; 78]	77 [70; 77]	<0.01	77 [67; 84]	82 [76; 88]	<0.01
GCW, mm Hg%	675 [485; 900]	978 [685; 1266]	<0.01	756 [540; 957]	869 [757; 1184]	<0.05
GWW, mm Hg%	206 [158; 258]	198 [142; 290]	>0.05	186 [124; 283]	159 [124; 297]	>0.05
GWI, mm Hg%	451 [332; 779]	668 [544; 871]	<0.01	525 [340; 694]	668 [544.5; 871]	<0.01

CHF – chronic heart failure; CCM – cardiac contractility modulation; LVEF – left ventricular ejection fraction; LVEDV – left ventricular end-diastolic volume; LVESV – left ventricular end-systolic volume; GLS – global longitudinal strain; GWE – global work efficiency; GCW – global constructive work; GWW – global wasted work; GWI – global work index.

LV wall motion during CCM in different forms of AF is presented in Table 5. There was a statistically significant improvement in all parameters of LV wall motion (LVEF, global longitudinal strain, LV myocardial work) in both groups of patients regardless of the type of AF.

A segmental analysis of the parameters of LV myocardial work was performed in the group of patients without local wall motion impairments (n = 20) for more detailed estimation of changes in the contractile function. Positive trends of the LV myocardial constructive work were found in the apical segment of the IVS (844 [614; 1224] mm Hg% at baseline; 1027 [800; 1520] mm Hg% after CCM; p = 0.05) and the middle segment of the anterior septal wall of the LV (593 [312; 1000] mm Hg% at baseline; 877 [494; 1145] mm Hg% after CCM; p = 0.05). No statistically significant differences were found in other regions.

The results of the analysis of the intra-operator reproducibility and inter-operator reproducibility of the ultrasound findings (n = 20) are shown in Table 6.

Figure 1 shows clinical examples of the pressure-strain curves and normal indicators of the myocardial work.

In healthy people, the fairly regular pressure-strain curve has a sufficient area under the curve, which corresponds to the global work index. The curve flattens in CHF along with a decrease in its area and the global work index. Some cardiomyocytes perform the wasted work, i.e., contract in diastole and relax in systole, in the normal and pathological setting. When a cardiovascular disease develops, the number of inefficient cardiomyocytes increases, resulting in higher global wasted work (GWW) and lower global constructive work (GCW) – and, thus, global work efficiency (GWE).

Figure 2 shows clinical examples of the pressure-strain curves and indicators of the myocardial work in CHF before and after CCM.

Patients with dilated cardiomyopathy and CHF FC II had a more than twofold increase in the global work index (from 207 mm Hg% to 509 mm Hg%),

Table 5. Changes in echocardiographic parameters in paroxysmal and permanent AF during CCM

Parameter	Paroxysmal AF (n = 36)			Permanent AF (n = 30)		
	baseline	in 12 months	p	baseline	in 12 months	p
LVEF, %	35 [27; 38]	38 [34; 44]	<0.01	31 [27; 36]	37 [30; 45]	<0.01
LVEDV, mL	197 [160; 254]	180 [164; 226]	<0.01	198 [173; 250]	193 [133; 221]	<0.05
LVESV, mL	133 [105; 165]	119 [95; 132]	<0.01	134 [111; 189]	131 [84; 151]	<0.01
GLS, %	–7 [– 5; – 9]	–8 [–7; –10]	<0.05	–5 [–4; –7]	–8 [–6; –9]	<0.01
GWE, %	76 [66; 80]	79 [72; 82]	<0.05	71 [63; 78]	84 [75; 89]	<0.01
GCW, mm Hg%	846 [539; 1072]	881 [734; 1286]	<0.01	573 [463; 775]	884 [712; 1145]	<0.01
GWW, mm Hg%	206 [132; 284]	198 [164; 301]	>0.05	186 [155; 270]	140 [113; 231]	>0.05
GWI, mm Hg%	584 [402; 817]	692 [565; 969]	<0.01	366 [301; 556]	630 [415; 907]	<0.01

AF – atrial fibrillation; CCM – cardiac contractility modulation; LVEF – left ventricular ejection fraction; LVEDV – left ventricular end-diastolic volume; LVESV – left ventricular end-systolic volume; GLS – global longitudinal strain; GWE – global work efficiency; GCW – global constructive work; GWW – global wasted work; GWI – global work index.

Table 6. Correlation analysis of the reproducibility of the LV wall motion parameters

Parameter	Reproducibility		p
	intra-operator	inter-operator	
LVEF, %	0.91	0.88	< 0.05
GLS, %	0.92	0.9	< 0.05
GWI, mm Hg%	0.95	0.91	< 0.05

LV – left ventricle; LVEF – left ventricular ejection fraction (Simpson); GLS – global longitudinal strain; GWI – global work index.

an increase in the work efficiency 75% to 89% due to increased constructive work (from 380 mm Hg% to 588 mm Hg%) and decreased wasted work (from 86 mm Hg to 50 mm Hg) during CCM. Among the standard parameters of interest, there was an increase in LVEF from 17–18% to 23–24% and an improvement in the LV deformity from 4% to 7%.

Discussion

The published results of the studies on CCM showed that clinical parameters improved and LVEF increased in patients with CHF and sinus rhythm during the treatment [17]. Several small trials were carried out to study CCM in patients with CHF and AF [18]. At the same time, no detailed assessment of echocardiographic parameters performed in patients before and after CCM implantation is given in the known randomized controlled clinical trials and registries. To date, only a handful of small-scale studies have been completed in which the parameters of myocardial function in patients with CHF were examined [19]; moreover, there are no data on myocardial function in patients with CHF during CCM. Thus, the parameters of the LV myocardial performance were studied in patients with CHF and AF for the first time.

We carried out detailed analysis of the parameters of LV wall motion and the processes of volumetric LV remodeling in patients with CHF during CCM. A new technique was used to estimate the contractile function, which represents an examination of LV myocardial work with higher sensitivity and reproducibility than those determining LVEF and indicators of LV myocardial strain due to less dependency on subjective criteria, imaging and afterload [5].

The LV systolic function improved according to all echocardiographic parameters reflecting LV wall motion, i.e., LVEF, myocardial strain and work.

When patients were divided into groups depending on the origin of CHF and type of AF, an improvement

Figure 1. Normal pressure-strain curve

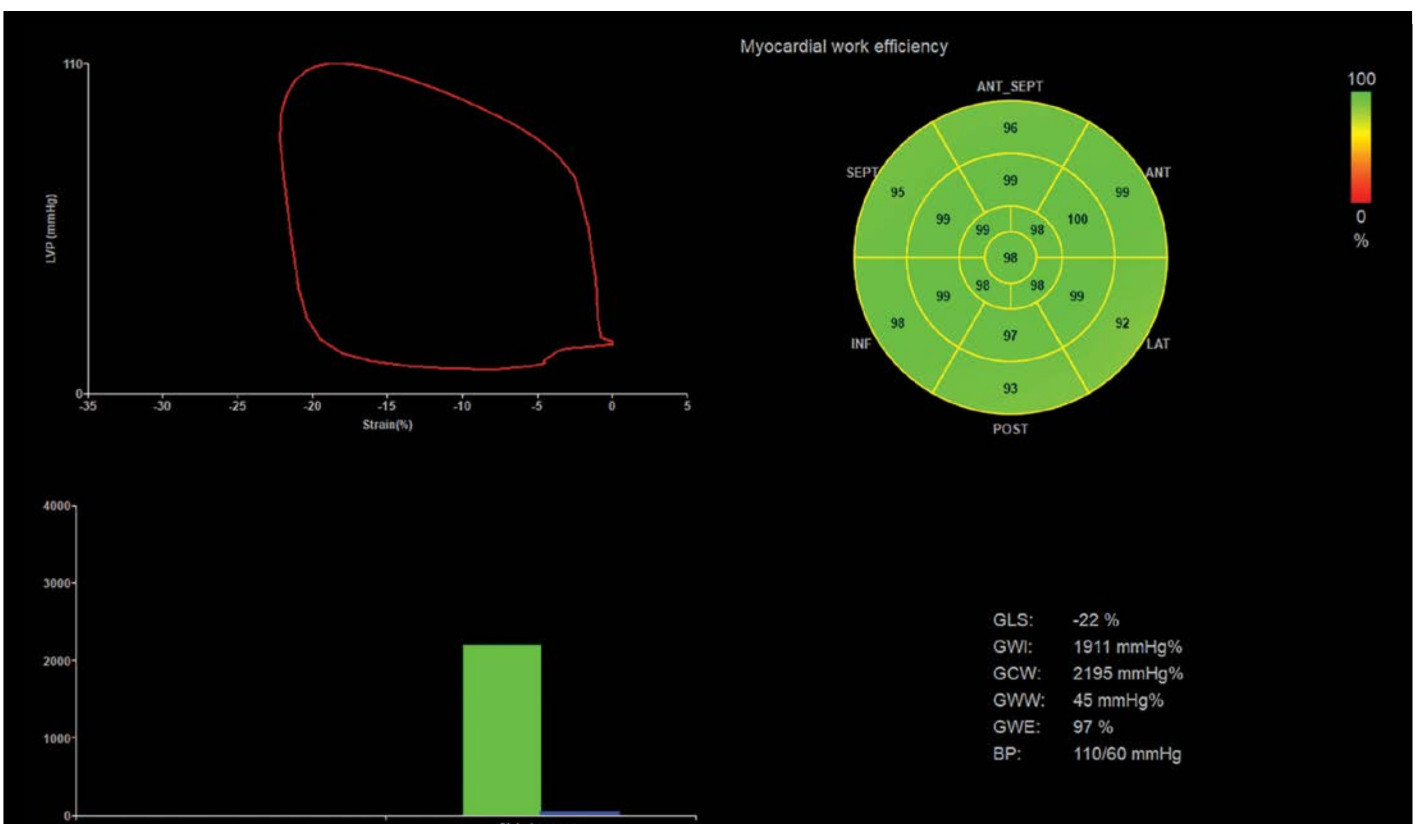

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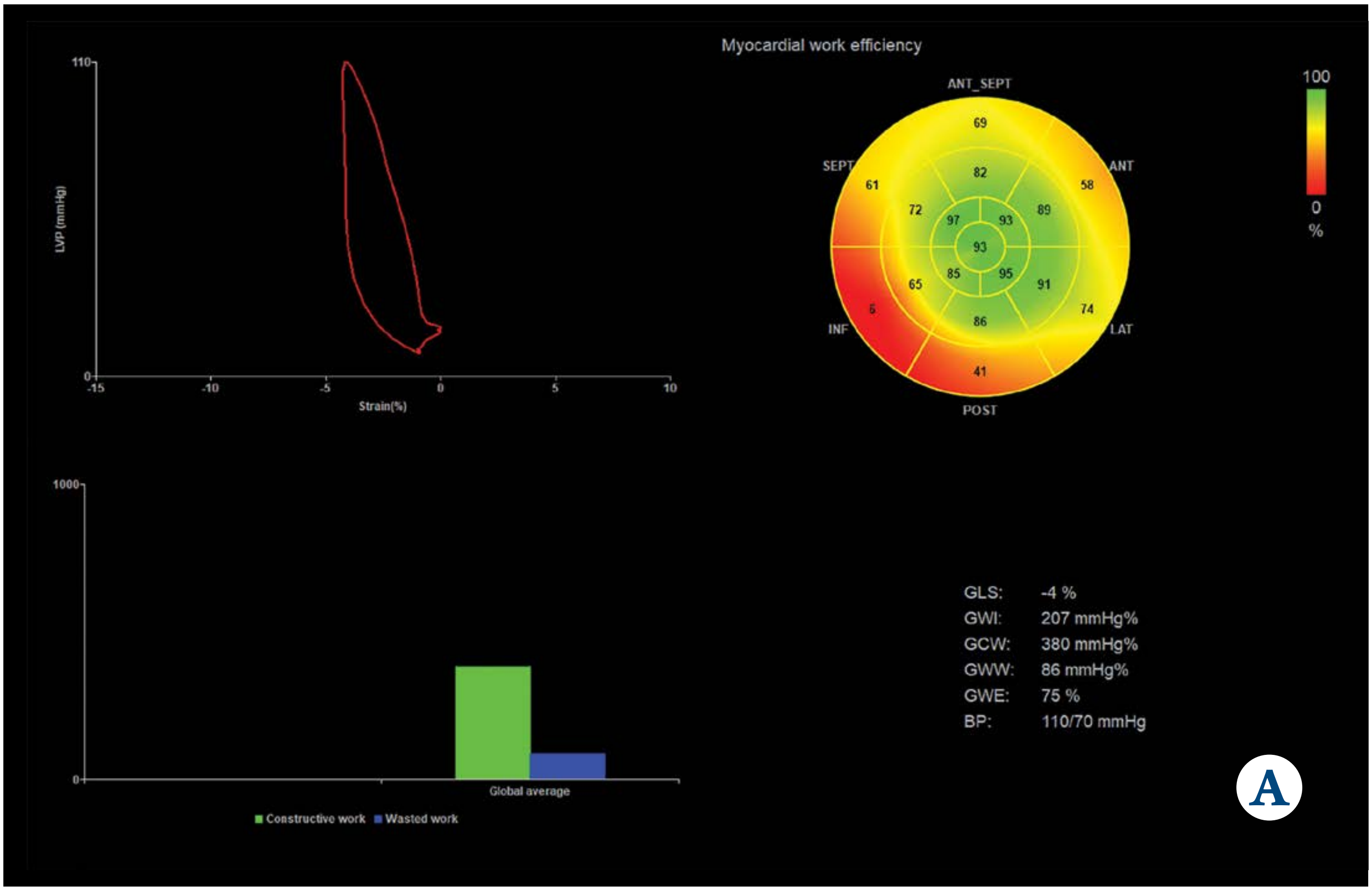
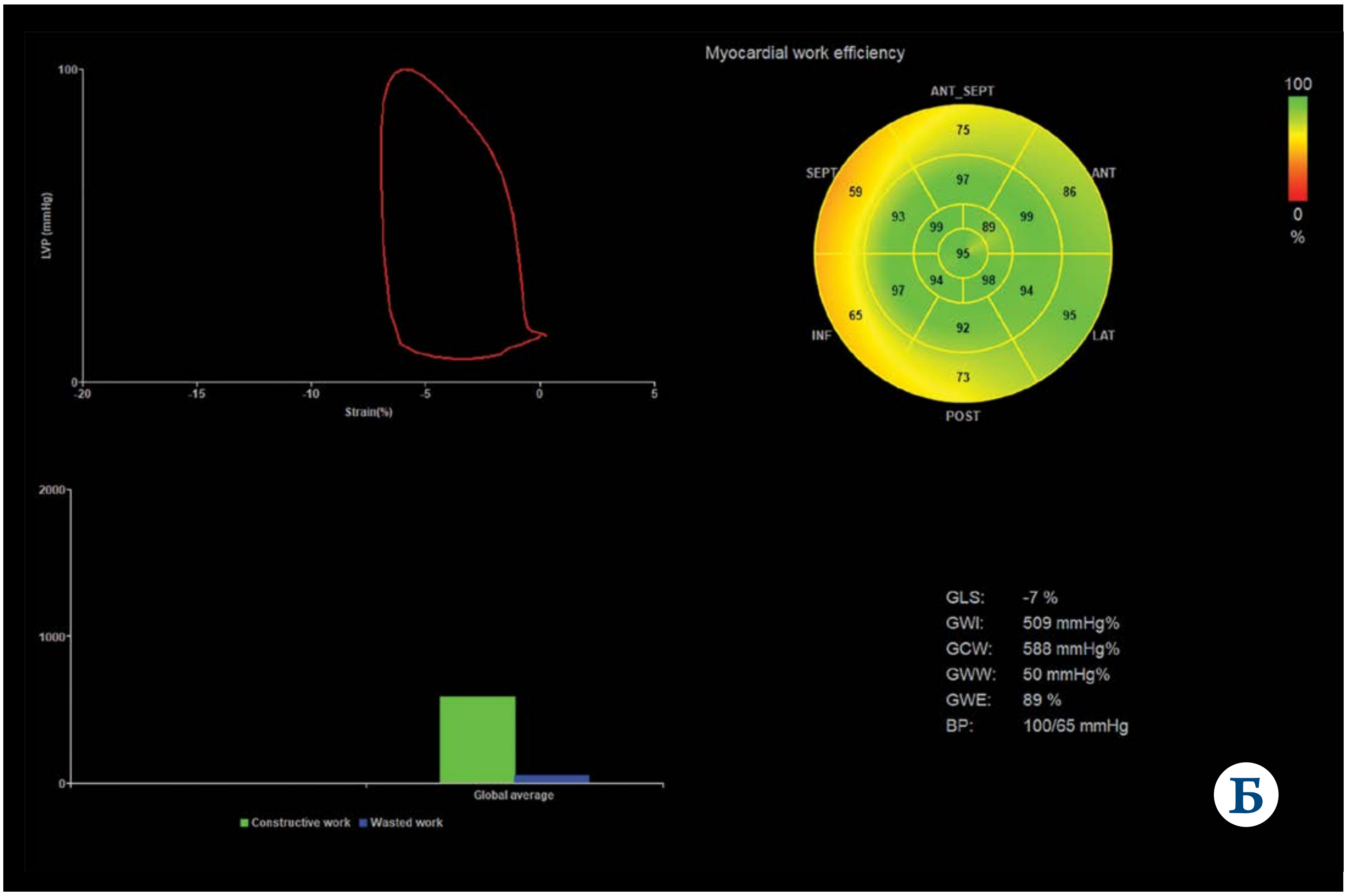
Figure 2. Pressure-strain curve in CHF at baseline (A) and during CCM (B)





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was also shown in all parameters of LV wall motion. Thus, CCM is shown to be beneficial for myocardial performance in paroxymal and permanent AF regardless of the origin of CHF.

The segmental analysis of the LV myocardial performance showed a statistically significant increase in the LV constructive work in the apical part of IVS and the middle part of the anterior septal wall of the LV, where ventricular leads are mainly placed. It is likely that the improvement of segmental parameters of the myocardial performance begins from the point of the lead fixation. However, this hypothesis requires separate and careful research.

Заключение

Cardiac contractility modulation improves exercise tolerance and quality of life in patients with chronic heart failure and atrial fibrillation. Echocardiography is shown to have a beneficial effect on the left ventricular wall motion, including the assessment of the myocardium work parameters, which are more reproducible and less dependent on afterload compared to the left ventricular ejection fraction and global longitudinal strain.

This new technique for myocardial function assessment allows processes of structural and functional left ventricular remodeling to be analyzed along with the mechanisms of influence on the left ventricular wall motion in patients with chronic heart failure during various treatments. This is a promising technique that requires further research in various clinical settings.

No conflict of interest is reported.

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