Kobalava Z.D.[1], Safarova A.F.[1,2], Gudieva H.M.[1], Lukina O.I.[1,2]
[1] Russian University of Peoples' Friendship, Moscow, Russia
[2] Vinogradov Municipal Clinical Hospital, Moscow, Russia

Risk Assessment of Adverse Outcomes in Symptomatic Patients With Arterial Hypertension and Chronic Heart Failure With Preserved Ejection Fraction Using THE HFA-PEFF Algorithm

Aim To study the incidence of heart failure (HF) in patients with arterial hypertension (AH), symptoms of HF, and left ventricular ejection fraction (LV EF) ≥50% using a novel, modified HFA-PEFF diagnostic algorithm and to evaluate the liver hydration status and density depending on the established HF profiles and the prognostic significance of this algorithm.

Material and Methods This study included 180 patients (median age, 72 years) with AH, symptoms of HF, and LV EF ≥50%. The incidence of chronic HF with preserved ejection fraction (CHFpEF) was studied with the stepwise, modified HFA-PEFF diagnostic algorithm, and long-term outcomes were assessed at 3, 6, and 12 months of follow-up. The hydration status was determined by a bioimpedance vector analysis, and the liver density was measured by indirect fibroelastometry. The following tests were performed for all patients: standard, general clinical and laboratory examination with evaluation of CH symptoms (including N-terminal pro-brain natriuretic peptide test); extended echocardiography with assessment of structural and functional parameters of the heart; a KCCQ questionnaire was used for evaluation of patients' condition and quality of life (QoL). Long-term outcomes were studied by phone calls at 3, 6, and 12 months following discharge from the hospital/visit (worsened QoL, repeated hospitalization for cardiovascular causes, cardiovascular death or all-cause death).

Results The following profiles were determined by the HFA-PEFF algorithm: with CHFpEF, with intermediate probability of HF, and without HF (58.9, 31.1, and 10%, respectively). The study showed that patients with CHFpEF compared to patients of the intermediate group and without HF, had higher levels of brain natriuretic peptide, more pronounced signs of congestion according to results of the bioimpedance vector analysis and a higher liver density according to results of indirect fibroelastometry of the liver, which allowed identification of a group of patients with a high probability of CHFpEF. The diagnosis of HF by HFA-PEFF had an adverse prognostic significance with respect of worsened QoL according to the KCCQ questionnaire, and of repeated admission for HF during a year.

Conclusion In AH patients with symptoms of HF and LV EF ≥50%, CHFpEF was detected with the HFA-PEFF algorithm in 58.9% of cases. Patients with AH and verified CHFpEF had a high incidence of hyperhydration and increased liver density. A diagnosis of CHFpEF by the HFA-PEFF algorithm had an adverse prognostic significance with respect of long-term outcomes.

Keywords Chronic heart failure; preserved ejection fraction; left ventricular diastolic function; arterial hypertension; HFA-PEFF algorithm

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Corresponding Author Lukina O.I. E-mail: 4579398@mail.ru

Introduction

The prevalence of heart failure (HF) continues to increase and is an enormous clinical and public health challenge. Chronic HF with preserved left ventricular ejection fraction (HFpEF) is a heterogeneous disease, that is patients with this disease have different clinical course and prognosis.

Chronic HFpEF results from a complex interaction of several risk factors (RFs) that cause organ dysfunction and lead to the emergence of corresponding clinical symptoms. For example, such RFs as the elderly age and the female sex are more common in chronic HFpEF than in chronic HF with reduced ejection fraction (HFrEF), which has been confirmed many times in epidemiological studies [1–4].

In the early stages, HF can be silent or have mild symptoms and signs [5, 6], which is why a number of criteria for determining HF are used in studies.

According to the Clinical Guideline on Chronic Heart Failure of the Ministry of Health of the Russian Federation, this diagnosis is currently established in the presence of the corresponding symptoms/signs of HF, changes in echocardiogram and elevated levels of brain natriuretic peptides (BNP) [7].

Many patients with chronic HFpEF have diastolic dysfunction only during exercise, thus, stress tests are important for the diagnosis of chronic HFpEF [8], including passive leg raise test as an alternative to diastolic stress echocardiography [9, 10].

A scoring algorithm HFA-PEFF was proposed to improve the diagnosis of chronic HFpEF. It involves rating structural and functional changes in the heart and NP depending on the presence of atrial fibrillation (AF) [11], which is highly specific to establish (93%) and highly sensitive (99%) to exclude chronic HFpEF in patients with dyspnea [12]. Its prognostic value for all-cause death was also shown in patients of this category [13]. This algorithm was the basis of the current guidelines on the diagnosis of chronic HFpEF [14].

Objective

Investigate the incidence of HF in patients with arterial hypertension (AH), who have HF symptoms and LVEF ≥ 50% using new modified diagnostic algorithm HFA-PEFF. Assess the hydration status and stiffness of the liver depending on the established HF profiles, and the prognostic value of HFA-PEFF algorithm.

Material and Methods

The study included 180 patients with high-risk AH without the documented clinical diagnosis of HF at the age of > 60 years and/or ≥55 years in the presence of concomitant diseases (obesity (54%), AF (35%), diabetes mellitus (39%), chronic kidney disease (60%)); symptoms of HF; LVEF ≥ 50%. The median age was 72 years, female patients prevailed (54%); 29 (16%) patients had a history of myocardial infarction. The median level of the N-terminal pro-brain natriuretic peptide (NT-proBNP) was 121 pg/mL.

The study was conducted following the Declaration of Helsinki. At admission, all patients signed the informed consent approved by the local ethics committee.

All patients underwent standard clinical examinations and laboratory tests, HF symptoms were assessed (Table 1). The Kansas questionnaire for patients with cardiomyopathy (KCCQ) was used to assess the condition and quality of life (QoL) of patients, the functional status and the total clinical score, which was used as a clinically significant endpoint «deterioration» [15, 16].

According to the HFA-PEFF algorithm, the diagnosis of CHF was carried out in several stages: Step 1 – pre-test assessment (includes clinical manifestations of HF, comorbidities/RFs, electrocardiography, standard echocardiographic protocol, NP levels, 6 minute walk distance test); Step 2 (Table 2, adapted from [11]) extended echocardiogram with the assessment of the structural and functional parameters of the heart, including LV global longitudinal strain (GLS). Chronic HFpEF is unlikely if the total score is < 2, the diagnosis is confirmed if the score is ≥5. Patients with an intermediate likelihood (2–4) underwent diastolic stress echocardiography with passive leg raise test and a non-invasive assessment of pulmonary arterial wedge pressure (PAWP) using a modified algorithm (Step 3).

Echocardiographic assessment of PAWP was performed using tissue Doppler and the Nagueh equation:

$$PAWP = 1.91 + (1.24 + E/e'),$$

where E is the peak early diastolic LV filling velocity and e' is the peak early diastolic mitral annular velocity. Elevated PAWP ≥ 15 mm Hg at rest and ≥25 mm Hg during exercise is an indirect indicator of increased pressure in the left heart [17].

Table 1. Hemodynamic parameters and HF symptoms (n=180)

Parameter	Value
Systolic blood pressure, mm Hg (M ± SD)	142 ± 17.1
Diastolic blood pressure, mm Hg (M ± SD)	84 ± 10.3
Heart rate, bpm (M ± SD)	76 ± 11.3
Dyspnea during exercise, n (%)	
• Mild	131 (72.8)
• Moderate	36 (20)
• Severe	13 (7.2)
Leg swelling, n (%)	65 (36.1)
6 minute walk distance, m (Me [Q1; Q3])	330 [263; 400]
HF NYHA functional class, n (%)	
I	33 (18.3)
II	88 (48.9)
III	59 (32.8)
Functional status according to KCCQ, score (Me [Q1; Q3])	25 [19; 33]
KCCQ Clinical Summary Score (Me [Q1; Q3])	51 [39; 70]

KCCQ, Kansas City Cardiomyopathy Questionnaire.

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Table 2. Modified HFA-PEFF algorithm

Step 2. Major and minor criteria for the diagnosis of HF

Parameter	Major criteria (2 points)	Minor criteria (1 point)
Functional parameters	e' sept < 7 cm/s or e' lat < 10 cm/s < 75 years; e' sept < 5 cm/s or e' lat < 7 cm/s ≥ 75 years, or E/e' mean ≥ 15 or TR > 2.8 m/s (PASP > 35 mm Hg)	E/e' mean: 9–14 or GLS < 16%
Structural parameters	LAVI >34 mL/m² (SR), LAVI >40 mL/m² (AF) or LVMI ≥149 g/m² in male patients and ≥ 122 g/m² in female patients and RWT > 0.42	LAVI 29–34 mL/m² (SR), LAVI 34–30 mL/m² (AF) or LVMI ≥115 g/m² in male patients and ≥ 95 g/m² in female patients/RWT > 0.42 and LVWTd ≥12 mm
NT-proBNP (SR)	> 220 pg/mL	125–220 pg/mL
NT-proBNP (AF)	> 660 pg/mL	375–660 pg/mL

Step 3. Functional tests

• HFA-PEFF algorithm; • Diastolic stress test; • Invasive assessment of PAWP	• Modified algorithm; • Diastolic stress test with passive leg raise; • Non-invasive echocardiographic assessment of PAWP

TR, tricuspid regurgitation; PASP, pulmonary artery systolic pressure, GLS, global longitudinal strain; LAVI, left atrial volume index; SR, sinus rhythm; AF, atrial fibrillation, LVMI, left ventricular mass index; RWT, relative wall thickness; LVWTd, diastolic left ventricular wall thickness; PAWP, pulmonary artery wedge pressure.

Bioimpedance vector analysis (BIVA) was performed on an ABC-01 analyzer to assess the hydration status. Active resistance R and reactance Xc were evaluated using the standard method. R and Xc were adjusted to height.

Fibroelastometry was performed on a FibroScan 502 Touch device to assess liver stiffness (kPa). In the Metavir score system, liver stiffness corresponds to the following stages of fibrosis: F0: ≤ 5.8 kPa, F1: 5.9–7.2 kPa, F2: 7.3–9.5 kPa, F3: 9.6–12.5 kPa, F4: > 12.5 kPa [18].

Long-term outcomes were assessed by telephone surveys in 3, 6, and 12 months after the discharge/visit. Worsening of QoL (changes in Clinical Summary Score (CSS) according to KCCQ); repeated hospitalizations for cardiovascular causes; death from cardiovascular diseases or all-cause death were used as the endpoints.

Statistica v.8.0 (Statsoft) and SPSS v.22.0 were used for the statistical processing of data. The Kolmogorov-Smirnov test and Shapiro-Wilk test were applied to determine the type of distribution. Normally distributed quantitative variables were described as the arithmetic means () and standard deviations (M±SD), and asymmetrically distributed quantitative variables were presented as the medians and interquartile ranges (Me [Q1; Q3]). The significance of the intergroup differences in quantitative variables was assessed using the Mann-Whitney U-test, and the Student's t-test in the case of normal distribution. The categorical variables were expressed as the absolute values (n) and percentages (%). The relationship between the two traits was evaluated by Spearman's correlation. A multivariate logistic regression model was used to evaluate the influence of factors and the prognostic significance of the diagnosis of chronic HFpEF on the risk of deterioration or re-hospitalization for HF by various algorithms. The quality of the constructed models was analyzed by sensitivity and specificity of the test and by constructing the ROC curves. Area Under Curve (AUC) was calculated to determine a numerical value of the clinical significance of the test. The larger the area under the curve, the better is the quality of the model. The probability of survival was assessed using Kaplan-Meier survival curves, and log-rank comparisons. The differences were statistically significant with $p<0.05$.

Results

Step 1 of the HFA-PEFF diagnostic algorithm included a pre-test evaluation. In step 2, chronic HFpEF was confirmed by major and minor criteria in 42.2% of patients. HF was unlikely in 10% of patients. The intermediate group consisted of 47.8% of patients who were subjected according to the algorithm to passive leg raise test in step 3 of the modified algorithm (Figure 1).

Criteria for elevated LV end-diastolic pressure during exercise were shown in 23 of 86 patients. Thus, the use of non-invasive assessment of PAWP and diastolic stress test allowed establishing HF additionally in 30 (16.7%) patients.

The total number of patients with chronic HFpEF verified by HFA-PEFF was 106 (58.9%), and 18 (10%) patients did not have HFpEF. The remaining 56 (31.1%) patients in the intermediate likelihood group require further examination (invasive assessment of PAWP). 26.7% of patients did not have minor diagnostic criteria, 1.7% of patients had a total score of 3 for minor criteria in all domains and no major criteria (Table 3).

Patients without chronic HFpEF did not have elevated NT-proBNP, the median was 35 [28; 51,25] pg/mL, NT-proBNP was elevated in 7.1% and 80% of the intermediate group patients and patients with chronic HFpEF, respectively. The median level of NT-proBNP was 239 [133; 460] pg/mL in patients with chronic HFpEF.

The hydration status was estimated based on the BIVA data and liver stiffness was assessed using indirect fibroelastometry given the established HF profiles (Figure 2).

Patients with chronic HFpEF were significantly more likely to have more severe signs of subclinical stagnation (BIVA) and increased liver stiffness. There are associations between liver stiffness and significant stagnation according to BIVA as well as between liver stiffness, tricuspid regurgitation, and elevated PASP (Table 4).

The liver stiffness depending on the diagnosis of HF is shown in Figure 3.

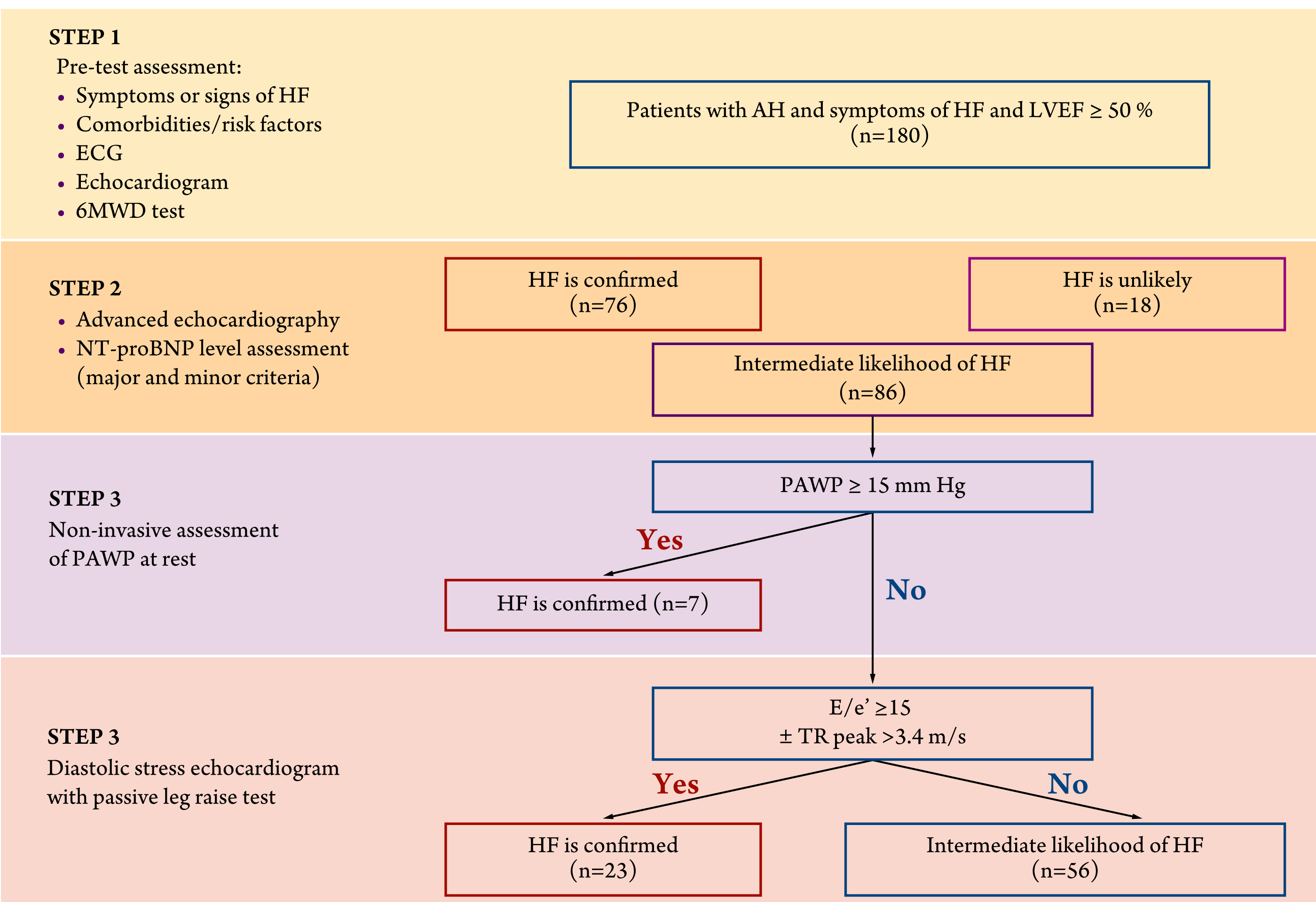
The long-term prognostic value of the diagnostic step-by-step algorithm was evaluated within 12 months.

Table 3. Frequency of detection of major and minor criteria using the HFA-PEFF algorithm

Parameter	Number of patients	
	n	%
Assessment by major criteria:		
0	3	1.7
2	52	32
4	34	19
6	42	22
Assessment by minor criteria:		
0	48	26.7
1	110	61.1
2	19	10.6
3	3	1.7
Only minor criteria	32	17.8

During the follow-up period, 61 patients experienced deterioration of QoL (KCCQ), of whom 47 patients had HF and 14 patients did not have HF. 44 patients (34 patients with HF, 10 patients without HF) were rehospitalized for cardiovascular reasons, including 16 patients admitted for decompensated HF. 11 patients died, 2 of them due to cardiovascular causes.

Figure 1. HF status according to the modified HFA-PEFF algorithm



Т6МХ – тест с 6-минутной ходьбой; ДЗЛА – давление заклинивания легочной артерии.

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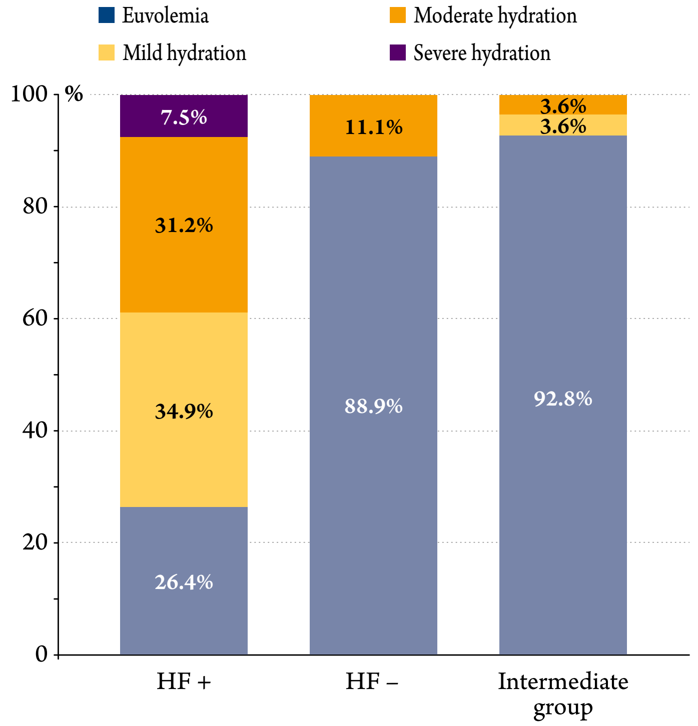
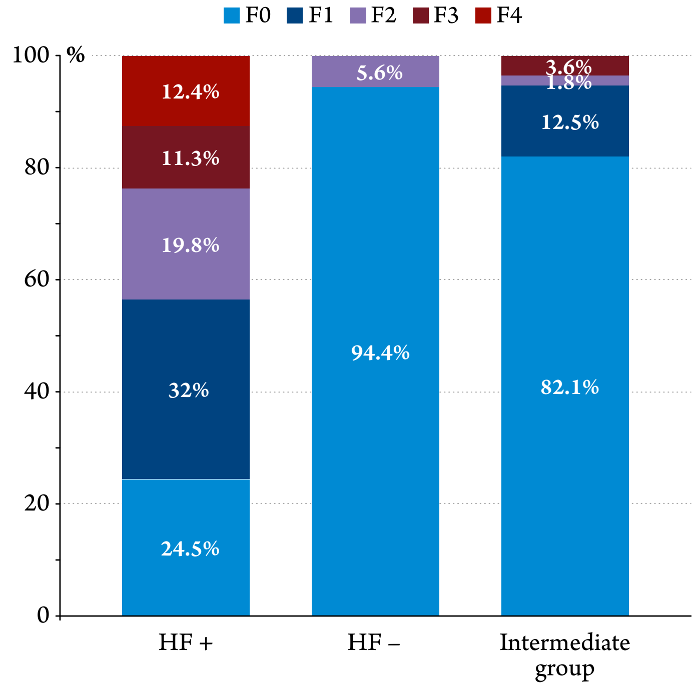
Figure 2. Hydration status according to BIVA depending on the HF diagnosis (p<0.05)



BIVA, bioimpedance vector analysis.

Figure 3. Liver stiffness according to fibroelastometry depending on the HF diagnosis (p<0.05)



F0 – F4 = liver stiffness in accordance with the stages of fibrosis.

A univariate Cox regression analysis was performed to evaluate the prognostic significance of the HFA-PEFF algorithm for deterioration of QoL. It was found that higher liver stiffness shown by fibroelastometry (p=0.014) and the diagnosis of HF according to HFA-PEFF (p=0.043) were associated with the risk of QoL deterioration.

An HFA-PEFF score of more than 4 is associated with a high risk of QoL deterioration within 12 months in this category of patients, with a sensitivity of 72% and specificity of 79% (Figure 4, A). The Kaplan-Meier curves of the cumulative probability of survival without the deterioration of QoL depending on the presence / absence of HF according to HFA-PEFF are shown in Figure 4, B.

A univariate Cox regression analysis was performed to evaluate the prognostic significance of the algorithm for repeated hospitalizations.

It was found that higher liver stiffness shown by fibroelastometry (p=0.001), the presence of diabetes mellitus (p=0.039), diagnosis of HF according to HFA-PEFF (p=0.031) were associated with the risk of repeated hospitalization. A HFA-PEFF score of more than 4 is associated with a higher risk of repeated hospitalization within 12 months in the studied patients, with a sensitivity of 77% and specificity of 81% (Figure 5, A). The Kaplan-Meier curves of the cumulative probability of survival without repeated hospitalizations depending on the presence / absence of HF according to HFA-PEFF are presented in Figure 5, B.

Discussion

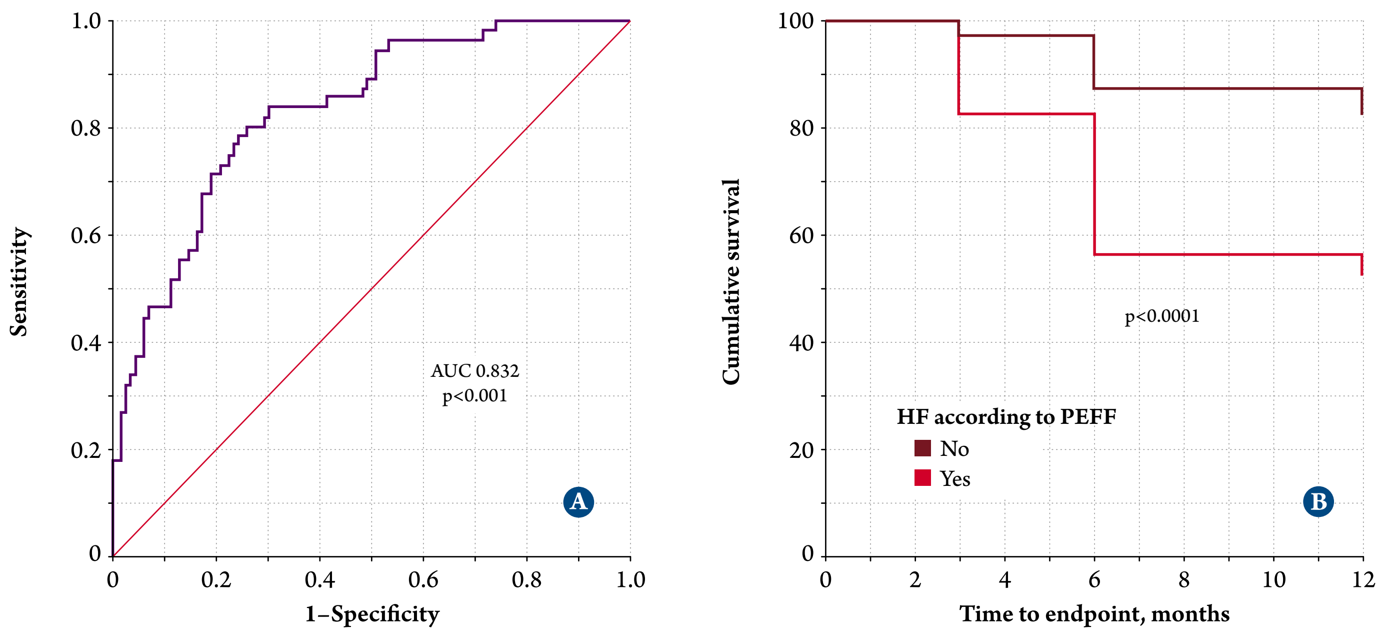
In our work, chronic HFpEF was detected using the modified HFA-PEFF algorithm in 58.9% of in patients with symptomatic AH and LVEF ≥50%. Diastolic stress echocardiography with passive leg raise

Table 4. Associations between liver stiffness and hydration status, pulmonary artery pressure, and peak TR velocity

Parameter	Spearman's correlation coefficient	95 % CI	p
BIVA, R/h	–0.3167518	–0.4438745 — –0.1771310	< 0.0001
BIVA, Xc/h	–0.32678	–0.4528124 — –0.1879447	< 0.0001
PASP	0.2542336	0.1117276 — 0.3864939	0.0005
Peak TR velocity	0.2581699	0.1158858 — 0.3900716	0.0004

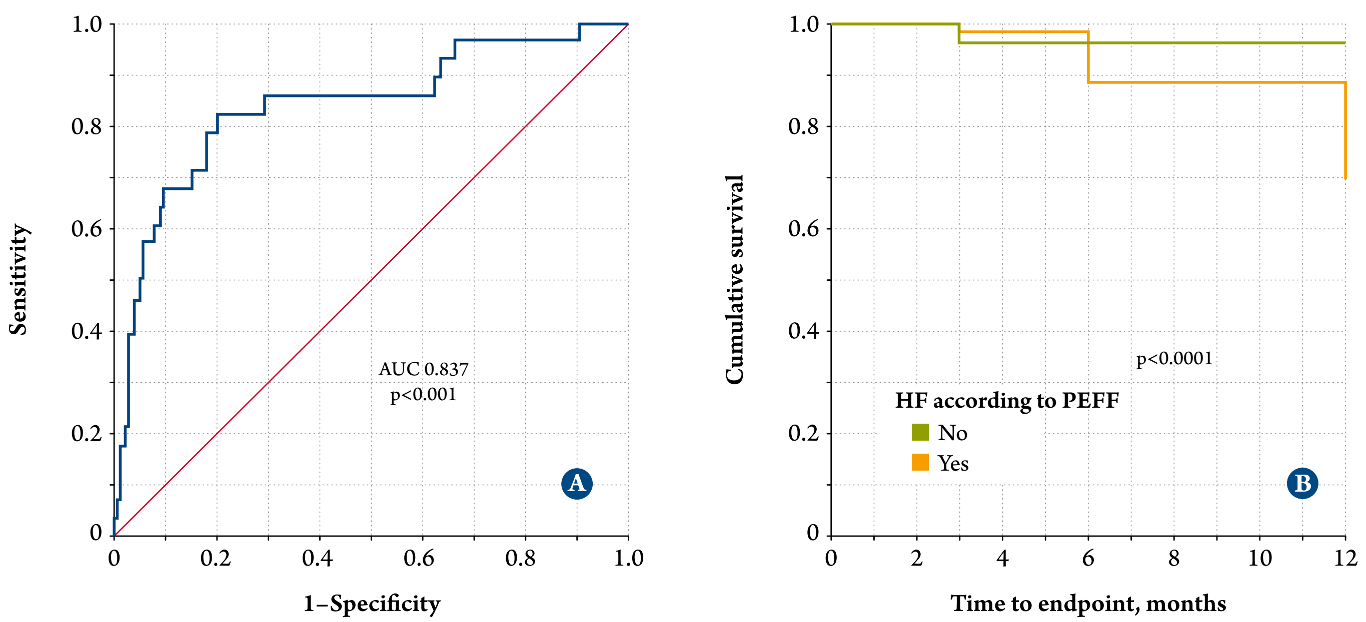
R/h, resistance/height; Xc/h, reactance/height; PASP, pulmonary artery systolic pressure; TR, tricuspid regurgitation; CI, confidence interval.

Figure 4. Assessment of the deterioration of quality of life



A – the ROC-curve for HFA-PEFF of the deterioration of quality of life within 12 months; **B** – the Kaplan-Meier curves of cumulative probability of survival without the deterioration of quality of life depending on the presence/absence of HF according to HFA-PEFF.

Figure 5. Оценка риска повторных госпитализаций



A – the ROC-curve for HFA-PEFF of the repeated hospitalizations within 12 months; **B** – the Kaplan-Meier curves of cumulative probability of survival without repeated hospitalization depending on the presence/absence of HF according to HFA-PEFF.

test and non-invasive estimation of PAWP allowed additionally identifying HF in 12.8% of cases. Similar possibilities of an alternative stress test method were demonstrated in the early works [19, 20]. According to the invasive measurement methods, elevated PAWP was observed after a passive leg raise test in 41% of patients with normal PAWP levels at rest and correlated with the Doppler indicators of diastolic dysfunction [9]. This may be due to fibrosis and myocardial remodeling in patients with a long-term history of AH. Increased preload due to venous inflow from the legs leads to an increase in the LV filling pressure, which allows additionally identifying patients with chronic HFpEF.

Our study, fibroelastometry showed that 51% of patients had elevated liver stiffness values associated with an unfavorable prognosis in the studied patients for

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the deterioration of QoL and repeated hospitalizations within 12 months. Liver stiffness was shown to have an important prognostic value in the early studies, including in patients with CHF [21, 22].

Since hyperhydration is often difficult to diagnose in patients with chronic HFpEF, BIVA was performed to detect subclinical stagnation in our patients, which allowed detecting hyperhydration in 46.7% of cases. It should be noted that only 36.1% of patients had pastosity or edema of the legs. The findings determine the relevance of assessing subclinical stagnation and its prognostic significance using BIVA in patients with HF [23].

The diagnosis of HF made by the HFA-PEFF algorithm was associated in the studied patients with the deterioration of QoL according to the KCCQ questionnaire and the risk of repeated hospitalizations for HF within 12 months. The data obtained are consistent with the findings of the few foreign researches. The HFA-PEFF score of more than 5 was shown in the ARIC study to predict a higher risk of death and hospitalization within 5 years [24]. The prognostic value of the HFA-PEFF algorithm for all-cause death and repeated hospitalizations for decompensated HF was also shown in another paper [25].

Conclusion

Thus, the diagnosis of chronic heart failure with preserved ejection fraction is a significant issue in routine clinical practice that can lead to both overdiagnosis and underdiagnosis. A new diagnostic algorithm for chronic heart failure with preserved left ventricular ejection fraction (HFA-PEFF) takes into account all modern aspects of the diagnosis of chronic heart failure with preserved ejection fraction and involves a comprehensive step-by-step examination of patients. The proposed algorithm is easy-to-use and allows accurately assessing the presence of chronic heart failure with preserved left ventricular ejection fraction despite more time and efforts for the patient examination. In our study, the diagnosis of chronic heart failure with preserved ejection fraction in patients with symptomatic arterial hypertension was confirmed in 58.9% of cases and rejected in 10% of cases. The prevalence of hyperhydration was significantly higher according to bioimpedance vector analysis and liver stiffness values were also higher in patients with chronic heart failure with preserved ejection fraction compared with patients with intermediate probability and without heart failure. An unfavorable prognostic value was established for the diagnosis of chronic heart failure with preserved left ventricular ejection fraction according to the HFA-PEFF algorithm for the long-term outcomes.

Limitations

Technical limitations for invasive assessment of PAWP; passive leg raise test was used as a diastolic stress test to avoid unequal results due the fact that individual patients had conditions resulting in reduced exercise tolerance (detraining, musculoskeletal diseases, etc.); assessment of global systolic function was carried out only in patients with sinus rhythm (n=173); the prognostic significance of the algorithms for mortality was not presented due to a small number of events.

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