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Pharmacoepidemiological analysis of routine management of heart failure patients in the Russian Federation. Part I

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Aim. To assess the healthcare system costs for the management of patients with heart failure (HF) based on a retrospective analysis of primary medical documentation.

Material and methods. We performed the analysis of outpatient records of 1000 patients, followed up for 1 year by a general practitioner or cardiologist in ambulatory clinic in 7 Russian regions. The study included men and women over 18 years of age with an established class II-IV HF and at least one hospitalization due to acute decompensated HF within 12-month follow-up.

Results. The final analysis included 888 patients (men, 52,9%; women, 47,1%; mean age, 69 [61; 78] years). The preserved ejection fraction (EF) was detected in 47,86% of patients, mid-range — in 40,54%, reduced — in 11,6%. Only in 16% of patients, there was improved by 1 or more HF. Hypertension and coronary artery disease were predominant in etiology pattern of HF. Preserved EF was more often detected in women over 60 years of age, with HTN and obesity, as well as with HF with mid-range and reduced EF in men in the same age group. There was sufficient follow-up rate, but the extent examinations do not correspond to the recommended one. The prescription rate of renin-angiotensin-aldosterone system (RAAS) inhibitors corresponds to the recommended one, but there is a high frequency of prescribing angiotensin II receptor blockers (ARBs). The prescription rate of β-blockers and loop diuretics (mainly torasemide) increased in comparison with previous studies, while thiazide diuretics — decreased. In patients with reduced EF, the prescription rate of sacubitril/valsartan was only 14,7%, β-blockers — 83,3%, mineralocorticoid receptor antagonists (MCRA) — 72,5%. In patients with mid-range EF, there was a sharp decrease in prescription rate of RAAS inhibitors, β-blockers, MCRA.

Conclusion. The practical follow-up of patients with HF differs significantly from clinical guidelines. Due to inadequate pharmacotherapy, as well as insufficient noncompliance with the recommended extent of investigations, 1-year HF therapy does not lead to a pronounced improvement in the patients' class.

Keywords: pharmacoepidemiology, heart failure, left ventricular ejection fraction, functional class.

Relationships and Activities: none.

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Heart failure (HF) has a widespread prevalence and poor prognosis, which leads to a high burden on the healthcare system in any country in the world. The prevalence of HF in different Russian regions varies within 7-10% [1]. At the same time, in recent years, the proportion of patients with severe HF has increased most significantly. Thus, the number of patients with HF of any class increased 2 times (from 7,18 million to 14,92 million), and patients with severe HF (class III-IV) — 3,4 times (from 1,76 million to 6,0 million) [1]. In the Russian Federation, the mean annual mortality among patients with class I-IV HF is 6%, and among patients with severe HF — 12% [2], and this is despite the great progress achieved in the treatment of this disease [3]. Decompensated HF is the cause of every second case of hospitalization in the cardiology department [4]. In the Russian Federation, the main causes of HF are hypertension (HTN) and coronary artery disease (CAD) [5]. Approximately half of patients with HF have preserved ejection fraction (EF) (HFpEF). Its prevalence in relation to HF with reduced EF (HFrEF) continues to increase with a frequency of 1% per year [2]. With the isolation of another HF type (HF with mid-range ejection fraction (HFmrEF), 40-49%), attention to the prevalence of this category of patients, their management and prognosis has increased significantly [6].

Despite the obvious fact of HF burden for the healthcare system, data on the compliance of actual practice with clinical guidelines and accepted standards of patient management in Russia, the specifics of prescribed therapy, and the effect of treatment on disease outcomes are very limited [1, 7, 8].

Therefore, the aim of our study was to assess the healthcare system costs for the management of HF patients based on a retrospective analysis of primary medical documentation of patients under general and cardiology outpatient supervision.

In this work, the first part of the study results is presented, including the epidemiological characteristics of patients and the specifics of therapy. Pharmacoeconomic data on the management of patients with HF in Russia will be presented in the second part of the work.

Material and methods

The study used data obtained from the outpatient records of 1000 patients followed up for 1 year by a general practitioner or cardiologist in an outpatient clinic in 7 Russian regions.

Research centers: 9 in 7 cities of Russia (Volgograd, Yekaterinburg, Kazan, Moscow, Novosibirsk, Perm, Rostov-on-Don).

The study included men and women over 18 years old with established class II-IV HF for at least 1 year. The inclusion criterion was the presence of at least one hospitalization (cardiology or therapy department) with acute decompensated HF within 12-month follow-up. All patients agreed to participate in the study and signed an informed consent. The starting point for 12-month period was any case of seeking medical help due to HF at the in- or outpatient stage in the period from January 01, 2018 to March 31, 2019.

Collection of primary data from a random sample. Demographic and clinical information, as well as data on investigations and pharmacotherapy were obtained from the primary medical documentation (outpatient records, discharge summary, UMIAS).

For a more detailed analysis, as well as for verifying and validating the data, a questionnaire was developed that includes, in addition to the information included in outpatient records, data on social status, disability and its cause, the source of payment for pharmacotherapy and rights for medicine assistance program.

Pharmacoepidemiological analysis was carried out in accordance with the international ATC/DDD methodology [9].

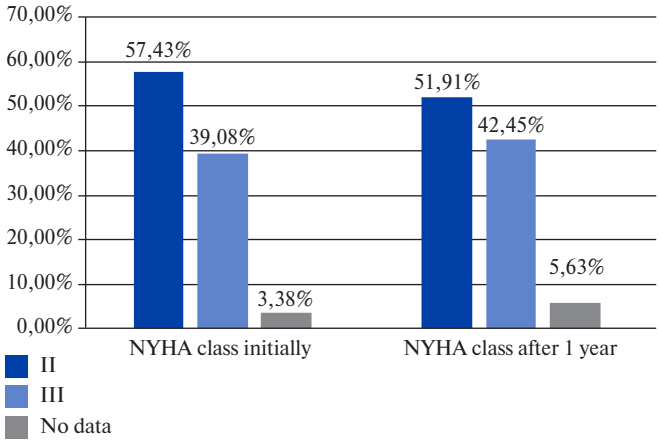

Figure 1. Distribution of patients by NYHA class.
Abbreviation: NYHA — New York Heart Association.

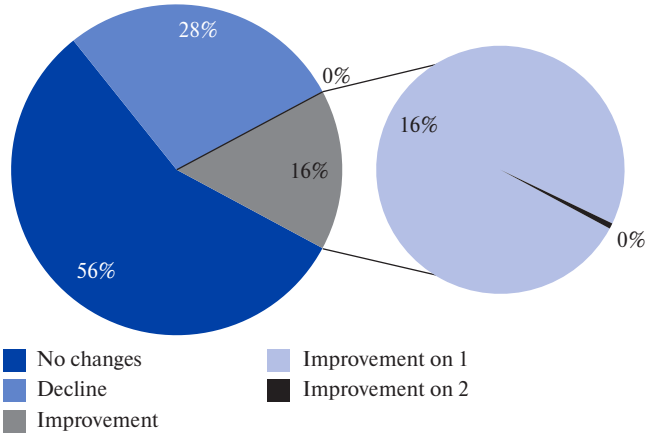

Figure 2. Changes in NYHA class in HF patients during follow-up.
Abbreviation: NYHA — New York Heart Association.

Table 1

Characteristics of the included patients

Parameter		Value	Sample (n)
Working-age patients, N (%)		181 (20,4%)	888
Patients included in medicine assistance program, N (%)		92 (10,4%)	888
Pensioners, N (%)		690 (78%)	888
Disability, N (%)	Total	311 (35%)	888
	Group I, N (%)	10 (3,2%)	311
	Group II, N (%)	192 (61,7%)	311
	Group III, N (%)	109 (35%)	311
Total number of working patients with HF		165 (18,6%)	888

Abbreviation: HF — heart failure.

Table 2

HF control parameters depending on the baseline LVEF

Parameter	Whole cohort, n=888		HFrEF LVEF <40%, n=103		HFmrEF LVEF ⩾40% ⩽49%, n=360		HFpEF LVEF ⩾50%, n=425	
	Baseline	After 1 year	Baseline	After 1 year	Baseline	After 1 year	Baseline	After 1 year
LVEF (%)	50,4±11,1	48,3±11,1	31,5±5,9	33,3±9,0	45,5±2,8	43,8±6,2	60,6±7,0	57,2±8,0
GFR (ml/min/1,73 m^2)	64,4±15,8	62,0±25,6	60,7±16,2	59,2±15,9	64,3±12,5	61,5±12,8	64,9±18,4	62,9±36,7
Weight (kg)	84,4±15,3	84,1±14,7	88,2±15,9	86,7±15	85,7±13,4	85,7±13,0	82,1±16,7	82,2±16,5
6 minute walk test, m	235,8±143,2	214,0±129,7	149,7±113,7	160,2±122,1	218,5±144,8	195,6±132,7	290,4±122,9	264,4±110,2
SBP, mm Hg	142,3±48,9	129,1±15,2	131,5±23,6	115,8±13,3	146,4±75,8	127,6±12,2	141,4±14,9	134,3±16,2
Heart rate, bpm	77,4±11,4	71,4±11,1	83,1±15,6	72±14,4	78,3±10,6	70,0±9,4	74,8±10,5	72,1±12,0

Abbreviations: SBP — systolic blood pressure, GFR — glomerular filtration rate, HFrEF — heart failure with reduced ejection fraction, HFmrEF — heart failure with mid-range ejection fraction, HFpEF — heart failure with preserved ejection fraction, LVEF — left ventricular ejection fraction, HR — heart rate.

Table 3

Number of investigations per patient year in patients with HF

Procedure	Mean ± Standard deviation	Median [95% CI, 0,25; 0,75]
ECG	1,87±1,27	2 [1; 2]
Echocardiography	0,84±0,61	1 [0; 1]
Chest X-ray	0,87±0,53	1 [1; 1]
NT-proBNP	0,02±0,19	0 [0; 0]
CBC	1,6±0,76	2 [1; 2]
Hemoglobin	1,61±0,76	2 [1; 2]
Potassium	1,25±0,79	1 [1; 2]
Sodium	1,23±0,81	1 [1; 2]
Creatinine	1,44±0,77	1 [1; 2]
GFR	1,2±0,87	1 [0; 2]
AST	1,41±0,75	1 [1; 2]
ALT	1,41±0,75	1 [1; 2]
Plasma glucose	1,59±1,95	1 [1; 2]
Clinical urine tests	1,19±0,65	1 [1; 2]
BBA	1,46±0,73	1 [1; 2]
6 minute walk test	It was initially performed in 65,3% of patients	

Abbreviations: ALT — alanine aminotransferase, AST — aspartate aminotransferase, CI — confidence interval, CBC — complete blood count, GFR — glomerular filtration rate, ECG — electrocardiography, NTproBNP — N-terminal pro-brain natriuretic peptide.

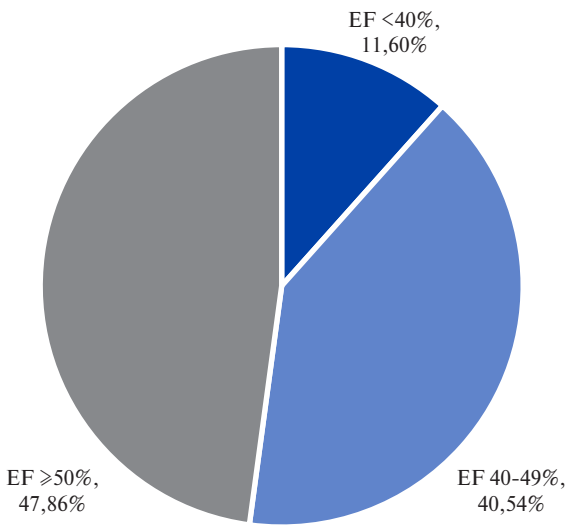

Figure 3. Distribution of patients by EF.
Abbreviation: EF — ejection fraction.

Statistical analysis. Statistical processing was carried out using STATISTICA 10.0, Stat Soft, Inc, and Microsoft Excel 2016. The normality of distribution in quantitative variables was tested using the Shapiro-Wilk, Kolmogorov-Smirnov, Cramer von Mises and Anderson-Darling tests.

Continuous quantitative data are presented as the mean and its standard deviation: M (SD). Non-normally distributed quantitative traits are presented as the median and its interquartile range: Me (25-75 percentiles). Dichotomous and ordinal qualitative data are presented as the number (n) and proportions (%).

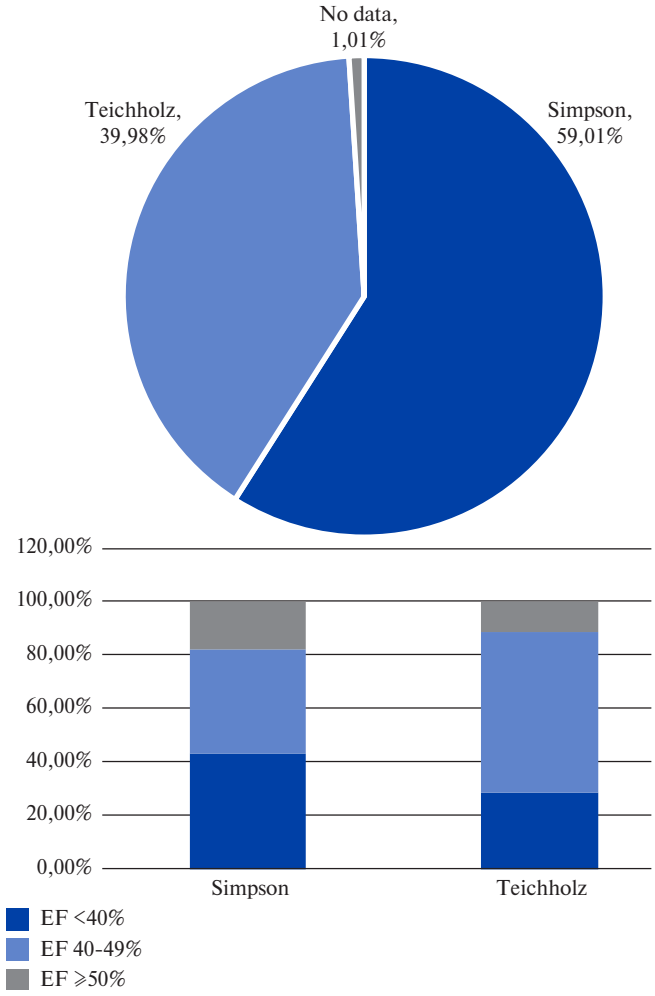

Figure 4. LVEF assessment technique and distribution of LVEF depending on the technique.
Abbreviation: EF — ejection fraction.

Results

Of the 1000 patients included in the study, 888 patients were included in the analysis. In 112 patients, the quality of primary medical documentation after filling out the questionnaire was insufficient for processing. Of the patients included, men accounted for 52,9%, while women — 47,1%. The mean age of patients was 69 years (95% confidence interval, 61-78 years); 24% of patients were of working age, and 35% of patients had persistent disability (Table 1).

Analysis of the patient distribution by NYHA classes showed that most of the patients at the start of follow-up and after 1 year had class II HF (Figure 1).

At the same time, in most cases, NYHA class did not change over 1 year of follow-up, and only in 16% of patients, as a result of therapy, it improved by 1 or more classes (Figure 2).

Most of the patients with HF, when included in the study, had preserved (47,86%) or mid-range ejection fraction (40,54%), while HFrEF was observed in 11,6% of cases (Figure 3).

It should be noted that, taking into account the clinical guidelines since 2016 [4, 6], the level of the N-terminal pro-brain natriuretic peptide (NT-proBNP) should be indicated in patients with HFpEF and HFmrEF. However, in actual clinical practice, NT-proBNP was determined only in 1% of patients. LVEF was more often determined by the Simpson method, which is consistent with modern guidelines [2], but the high frequency of using Teichholz method should be noted (Figure 4).

As shown in Figure 4, when determining LVEF by the Teichholz method, patients were more frequently assigned to the group with mid-range EF. In 15% of cases, patients with HFrEF were not detected when using this diagnostic method. This discrepancy is due to the fact that the Teichholz method is based on measuring linear dimensions, which can give inaccurate results, especially in patients with

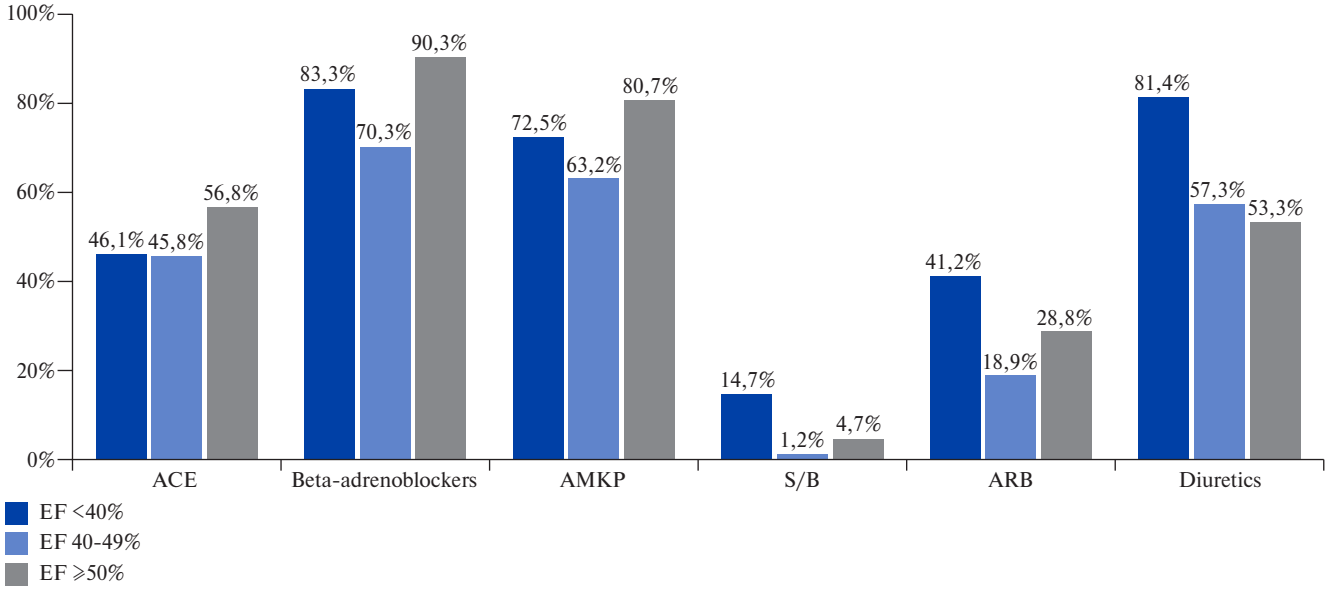

Figure 5. Compliance of the prescribed therapy with clinical guidelines.
Abbreviations: AMKR — mineralocorticoid receptor antagonists, ACE — angiotensin-converting enzyme, ARB — angiotensin II receptor blockers, S/B — sacubitril/valsartan, EF — ejection fraction.

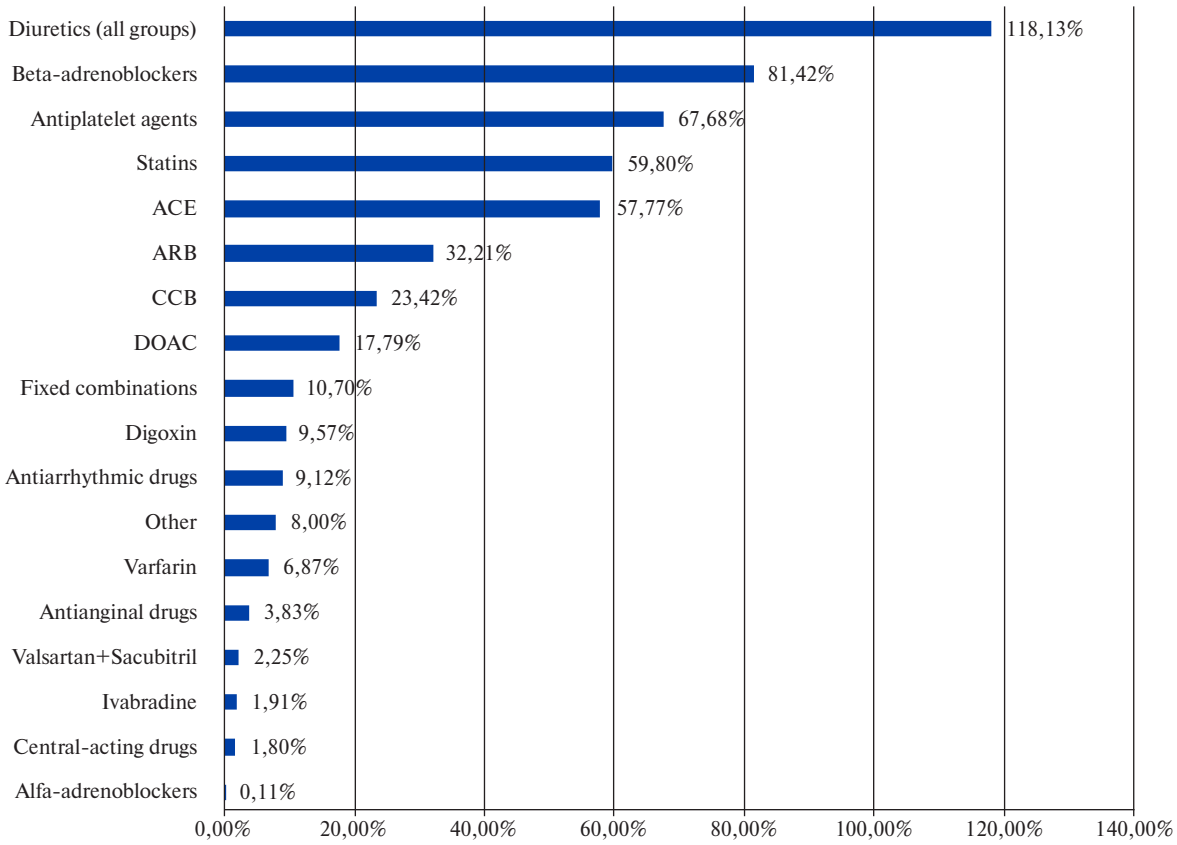

Figure 6. Distribution of prescribed therapy.
Abbreviations: ACE — angiotensin-converting enzyme inhibitors, ARB — angiotensin II receptor blockers, CCB — calcium channel blockers, DOAC — direct oral anticoagulants.

impaired local LV contractility. Therefore, this method is currently not recommended for clinical use [2].

In the majority of patients, there were data on comorbidities in the outpatient records. As for the etiology of HF, HTN and CAD prevailed — 94%

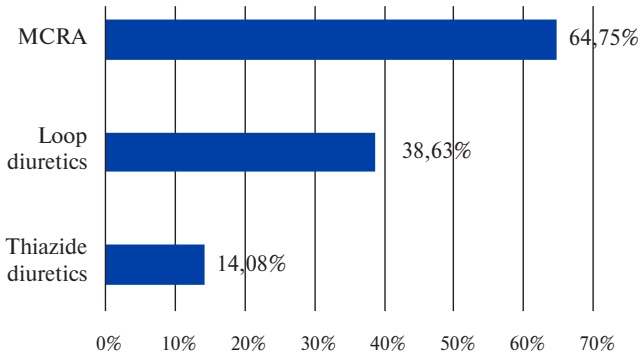

Figure 7. Distribution of diuretic prescriptions.
Abbreviation: MCRA — mineralocorticoid receptor antagonists.

and 75%, respectively. Their combination was found in 67% of patients. Valvular heart disease occurred in 0,6% of cases, dilated cardiomyopathy (DCM) — in 3,5%, type 2 diabetes — in 28,5%, atrial fibrillation, in most cases permanent one — in 38,7%.

Among patients with HFpEF, women over 60 years old, with a combination of HTN and obesity, were more common, and HF with mid-range and reduced EF was more common in men in the same age group.

The mean values of HF control at baseline and after 1 year are presented in Table 2.

As for diagnostic investigation rates, a pronounced discrepancy was found between the re-

Table 4

Therapy in patients with HF by INN

Groupe	INN	Total number of subscriptions	% total number of subscriptions	% receiving patients (total/in INN group)
ACE inhibitors		**513**	**11,51%**	**57,77%**
Captopril	7			1,4%
Lisinopril	60			11,7%
Perindopril	164			32,0%
Ramipril	20			3,9%
Fosinopril	23			4,5%
Enalapril	239			46,6%
ARB		**286**	**6,42%**	**32,21%**
Azilsartan	13			4,5%
Valsartan	66			23,1%
Candesartan	14			4,9%
Losartan	187			65,4%
Telmisartan	6			2,1%
β-blockers		**723**	**16,22%**	**81,42%**
Atenolol	2			0,3%
Bisoprolol	454			62,8%
Carvedilol	36			5,0%
Metoprolol	155			21,4%
Nebivolol	76			10,5%
α-blockers, Doxazosin	**1**	**1**	**0,02%**	**0,11%**
Centrally-acting drugs, Moxonidine	**16**	**16**	**0,36%**	**1,80%**
Diuretics, total		**984**	**22,08%**	**110,81%**
CAI, Acetazolamide	6			0,6%
Thiazide diuretics		125	2,80%	14,08%
Hydrochlorothiazide	45			36%
Indapamide	80			64%
Loop diuretics		343	7,70%	38,63%
Torasemide	300			87,46%
Furosemide	43			12,54%
MCRA		575	12,90%	64,75%
Spironolactone	416			72,35%
Eplerenone	159			27,65%

Table 4. Continuation

Groupe	INN	Total number of subscriptions	% total number of subscriptions	% receiving patients (total/in INN group)
CCB		**208**	**4,67%**	**23,42%**
Amlodipine	190			91,35%
Verapamil*	1			0,48%
Diltiazem*	1			0,48%
Lercanidipine	10			4,81%
Nifedipine	6			2,88%
Statins		**531**	**11,91%**	**59,80%**
Atorvastatin	338			63,65%
Pitavastatin	1			0,19%
Rosuvastatin	173			32,58%
Simvastatin	19			3,58%
DOAC		**158**	**3,54%**	**17,79%**
Apixaban	44			27,85%
Dabigatran	35			22,15%
Rivaroxaban	79			50,00%
Warfarin		**61**	**1,37%**	**6,87%**
Antiarrhythmic agents		**81**	**1,82%**	**9,12%**
Amiodarone	60			74,07%
Sotalol	21			25,93%
Antianginal drugs		**34**	**0,76%**	**3,83%**
Isosorbide mono/dinitrate	31			91,18%
Molsidomin	1			2,94%
Nicorandil	2			5,88%
Ivabradin	**17**	**17**	**0,38%**	**1,91%**
Antiplatelet agents		**601**	**13,48%**	**67,68%**
Acetylsalicylic acid	502			83,53%
Clopidogrel	93			15,47%
Ticagrelor	6			1,00%
Digoxin		**85**	**1,91%**	**9,57%**

Note: * — in accordance with the indications.

Abbreviations: MCRA — mineralocorticoid receptor antagonists, ARB — angiotensin II receptor blockers, carbonic anhydrase inhibitors — CAI, CCB — calcium channel blockers, ACE — angiotensin-converting enzyme, INN — international non-proprietary name, DOAC — direct oral anticoagulants.

commended [2, 4] and the actual prevalence of their appointment and implementation (Table 3).

Analysis of follow-up monitoring of outpatients with HF revealed compliance with the clinical guidelines [2, 4]. The average number of outpatient visits per patient year to a primary care physician was 3,64±2,37 visits, to a cardiologist — 1,5±1,47 visits (in total — 5,14 outpatient visits per year). The number of visits to the cardiologist was directly related to the deterioration of a patient's condition and the increase in NYHA class of HF. The average hospitalization rate per patient year was 1,21, of which according to ICD I50 — 0,67 hospitalizations.

The analysis of therapy revealed its pronounced inconsistency with the current clinical guidelines [2, 4], both in the management of patients with HFrEF, as well as with HFpEF and HFmrEF (Figure 5).

A total of 888 patients with HF received 4457 prescriptions of the medication. The distribution of prescribed drug therapy is shown in Figure 6.

The distribution of diuretic prescriptions is shown in Figure 7.

The distribution of drugs by INN is shown in Table 4.

Discussion

Taking into account the steady aging of the population and the increase in the number of patients with

Table 5

Prescriprion rate of various drugs in the population of HF patients. Adapted from the study by I. V. Fomin (2016) with additions [1]

% of intake	1998 Nizhny Novgorod Oblast	2000 Nizhny Novgorod Oblast	EPOCHA 2002	EPOCHA-Hospit.	EPOCHA 2007	EPOCHA 2014	2020 Reznik E. V., et al. [18]	Current study
ACE inhibitors	24,3	33,5	53,2	78,9	64,9	69,3	63,7	57,77
ARB	0	0	0		1,9	16,5	4,8	32,21
β-blockers	15,3	20,0	20,3	58,7	30,5	43,3	90,9	81,42
Thiazide/loop diuretic	8,3/5,6	16,9/4,3	21,8/2,4	43,6/10,8	43,7/2,2	30,1/3,9	0/96,1	14,08/38,63
Glycosides	0	2,4	7,9	9,0	7,1	3,9	22,2	9,57
Spironolactone	0	0	1,3	11,4	2,3	11,0	79,7	64,75*
Antiplatelet agents	0	4,7	11,1	50,5	21,1	58,3	71,5	83,53
Anticoagulants	0	0	0,3	5,4	0,4	0,8	47,3	16,47
Lipid-lowering drugs	0	0	0	27,7	1,9	3,6	29,5	no data
CCB	5,0	4,7	14,9	24,7	14,9	18,5	no data	23,42
Antiarrhythmic agents	NA	0	0,7	2,4	0,4	0,8	no data	3,83
Nitrates	2,0	10,6	34,2	36,3	28,6	28,3	no data	9,12
Other	74,3	74,7	56,0	17,0	30,8	15,5	no data	no data

Note: * — including eplerenone.

Abbreviations: ARB — angiotensin II receptor blockers, CCB — calcium channel blockers, ACE — angiotensin-converting enzyme, NA — not available.

HF [1], medical tariffs, and costs of drug therapy, the cost of managing patients with HF will progressively increase. Back in 2014, the burden of HF in Russia amounted to over 520 billion rubles and there was a significant increase in costs compared to 2008-2010 [10]. At the same time, in developed countries, the costs of treating HF patients amount to 1-2% of the total health care costs and up to 10% of the total spending on the therapy of cardiovascular diseases, of which 62-75% is spent on inpatient treatment [11, 12]. In addition, in the period from 2012 to 2030, costs are expected to increase by 127% [13]. Back in 2010, the healthcare reform in the United States identified the reduction in the number of HF-related readmissions as a key area to achieve a potential decrease in the cost of managing HF patients [14]. This makes important to study the HF in Russia to improve the management of such patients and meet the clinical guidelines [2], which will reduce the healthcare costs of treating patients and improve clinical outcomes.

In accordance with the aim of the paper, at the first stage, we analyzed the epidemiological characteristics of patients with class II-IV HF in actual clinical practice. The average age of studied HF patients reflected some stabilization and was 69 years (95% confidence interval, 61-78 years), after the growth in previous years: 64,0±11,9 (1998), 67,0±11,0 (2000), 68,3±11,7 (2007) and 69,9±12,2 (2014) [1]. The distribution by NYHA class also corresponded to the hospital stage of the EPOCH-CHF study [8] with a tendency to an increase in the number of patients with class III-IV HF, which are characterized by frequent readmissions [13].

The etiology of HF, demonstrated in our study, reflect the national trends [1]. The overwhelming majority of patients had comorbidities. HTN and CAD prevailed as the etiological cause of HF. Their combination was found in 67% of patients, which coincides with the available data [2]. Various heart defects occurred in 0,6% of cases, which reflects a tendency towards a decrease in the contribution of this factor to HF etiology [1]. DCM, on the contrary, was more common — in 3,5% of cases vs 0,8% in the hospital stage of the EPOCH-CHF study [15]. However, the prevalence of DCM as an etiology in our study correlates with the EuroHeart Survey data (Russian sample), where the prevalence of DCM as a cause of the disease in patients with class III-IV HF was 5% [16]. Type 2 diabetes (28,5%) and atrial fibrillation (38,7%) were also, as expected, identified as common comorbidities.

In our study, sex differences were shown — HFpEF was more often diagnosed in women over 60 years old with a combination of HTN and obesity, while HF with mid-range and reduced EF — in men in the same age group. Similar data were obtained by Dushina A. G. et al. (2019) in the in-depth examination of patients with HF depending on EF [17].

The analysis of follow-up monitoring of patients with HF showed that with a sufficient frequency of visits, the extent of diagnostic investigations, determined by clinical guidelines [2], is not observed in actual clinical practice. Thus, echocardiography and chest x-ray were performed at half the rate recommended. The six-minute walk test was initially performed in only 63% of patients, while NT-proBNP was measured in 10 patients (1%) from the cohort.

The analysis of drug therapy shows a lower prescription rate of angiotensin-converting enzyme inhibitors (mainly enalapril (47%) and perindopril (32%)) and, on the contrary, a higher prescription rate of angiotensin II receptor blockers in all patients with HF in comparison with previous studies, and also an increase in prescribing β-blockers. In addition, there is a pronounced increase in prescribing loop diuretics (mainly, torasemide) and a decrease — thiazide diuretics, which is associated both with an increase in the availability of torasemide in recent years, and with the characteristics of patients observed in large federal centers. The prescription rate of mineralocorticoid receptor antagonists (MCRA) also increased, with about a quarter of patients taking eplerenone (Table 5).

In patients with HFrEF, the prescription rate of sacubitril/valsartan is only 14,7%, β-blockers — 83,3%, MCRA — 72,5%. At the same time, the prevalence of prescribing renin-angiotensin-aldosterone system (RAAS) inhibitors generally corresponds to the recommended [2], but there is a high prescription rate of angiotensin II receptor blockers. As for patients with HFmrEF, there is a sharp decrease in the prescription rate of RAAS inhibitors, β-blockers, and mineralocorticoid receptor antagonists (MCRA).

It has been shown that the HF therapy received by patients for 1 year in actual clinical practice does not lead to a pronounced improvement in NYHA class.

Conclusion

The practical follow-up of patients with HF differs significantly from clinical guidelines:

- One-year HF therapy in actual clinical practice does not lead to a pronounced improvement in NYHA class;
- With a sufficient frequency of visits, the extent of diagnostic investigations, determined by clinical guidelines, is not observed in actual clinical practice.

Relationships and Activities: none.

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