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Experience of introducing a new form of organization of medical care for patients with heart failure in the Russian Federation

Aim	To present clinical characteristics of patients after hospitalization for acute decompensated heart failure (ADHF) and to analyze hemodynamic indexes and compliance with the treatment at two years depending on the conditions of outpatient follow-up.
Material and methods	The study included 942 patients with chronic heart failure (CHF) older than 18 years who had been hospitalized for ADHF. Based on patients' decisions, two groups were isolated: patients who continued the outpatient follow-up at the Center of CHF (CCHF) (group 1, n=510) and patients who continued the follow-up in outpatient multidisciplinary clinics (OMC) at their place of residence (group 2, n=432). The clinical portrait of patients was evaluated after ADHF, and hemodynamic parameters were evaluated on discharge from the hospital. Also, the patient compliance with the treatment was analyzed during two years of follow-up. Statistical analysis was performed with Statistica 7.0 for Windows.
Results	The leading causes for CHF included arterial hypertension, ischemic heart disease, atrial fibrillation, and type 2 diabetes mellitus. With the mean duration of hospitalization of 11 inpatient days, 88.1% and 88.4% of patients of groups 1 and 2 were discharged with complaints of shortness of breath; 62% and 70.4% complained of palpitations; and 73.6% and 71.8% complained of general weakness. On discharge from the hospital, the following obvious signs of congestion remained: peripheral edema in 54.3% and 57.9%; pulmonary rales in 28.8% and 32.4%; orthopnea in 21.4% and 26.2%; and cough in 16,5% and 15.5% of patients of groups 1 and 2, respectively. For the time of hospitalization, CHF patients did not achieve their targets of systolic BP (SBP), diastolic BP (DBP) and heart rate (HR). Patients of group 1 achieved the recommended values of SBP, DBP and HR already at one year of the follow-up at CCHF. Patients of group 2 had no significant changes in hemodynamic indexes. At one and two years of the follow-up, group 2 showed a considerable impairment of the compliance with the basis therapy for CHF compared to group 1.
Conclusions	During the short period of hospitalization (11 inpatient days), the patients retained pronounced symptoms of HF and clinical signs of congestion and did not achieve their hemodynamic targets. The patients who were followed up for a long time at CCHF were more compliant with the basis therapy, which resulted in improvement of hemodynamic indexes, compared to the patients who were managed in OMS at the place of residence.

Keywords	Hospital for treatment of heart failure; chronic heart failure; decompensated heart failure; rehospitalization; specialized medical care; seamless medical care; treatment of CHF, hemodynamics
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Introduction

Chronic heart failure (CHF) is a syndrome that forms at the end of the cardiovascular continuum and poses high risks of all-cause and cardiovascular death, especially in the case of decompensation [1]. The attainment of hemodynamic targets during treatment consistent with national clinical guidelines and prevention of acute decompensated heart failure (ADHF) can be a marker of effective therapy of CHF [2, 3].

All the CHF treatment objectives are attainable subject to satisfactory compliance with drug and non-drug treatments, which can be achieved through active outpatient monitoring of patients [4–7]. Successful treatment of a CHF patient requires high-level expertise in CHF from a physician or a cardiologist, since these patients are at very high risk of rapid changes in well-being and physical condition, hemodynamic parameters, reduced ability of self-care, physical activity that requires an immediate suitable response and changing

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drug therapy and treatment strategy [8–10]. However, CHF cannot be managed only by a physician or a cardiologist, because currently a CHF patient is polymorbid and has several diseases at the same time affecting the progression of CHF. Therefore, an idea emerged to create a specialized medical care system for this category of patients based on a multidisciplinary approach [11, 12].

On the one hand, the idea of creating specialized CHF clinics may seem far-fetched, since, in the Russian Federation, there is neither a system of statistical analysis of this syndrome, nor specialised training for physicians and nurses on CHF patient care. Nor is there nor seamless management of this category of patients, or strict continuity between hospitals and outpatient clinics. On the other hand, CHF treatment costs have increased substantially in recent years due to frequent rehospitalizations.

The increasing number of CHF patients is associated with increased life expectancy and effective treatment of acute cardiovascular diseases and diabetes mellitus. This has led to higher costs for the treatment of this syndrome at the level of the population, turning this purely medical problem into a financial, ethical, and state issue, since the treatment of CHF is not possible in the absence of state funding [13, 14].

The objective of the study was to present the clinical characteristics of CHF patients who had been hospitalized for ADHF and analyze hemodynamic parameters and treatment compliance within two years depending on the conditions of outpatient management.

Material and methods

The prospective cohort study included 942 patients with CHF at the age of 18 years and older receiving inpatient care for ADHF. Two groups of patients were formed depending on their decision to continue outpatient management at a specialized CHF management center (CHFMC). Group 1 included patients who agreed to be followed up at the CHFMC, and Group 2 were patients who selected routine outpatient management in local outpatient clinics. At the CHFMC, patients were supervised by physicians and actively followed up by nurses by means of structured telephone surveys. Control cardiovascular examinations were scheduled depending on the severity of the patient's condition. These ranged from three days between visits to once every three months. If the condition deteriorated with decompensated CHF or other emergency pathologies, the patient was hospitalized. After discharge from hospital, patients who refused to be managed at the CHFMC continued supervision and treatment at the local outpatient clinics by a physician or a cardiologist. This group of patients reported on CHF symptoms, blood pressure (BP), heart rate (HR), treatment compliance and self-monitoring to the CHFMC nurses during structured telephone surveys at least once every three months. All patient responses were recorded and checked by a CHFMC cardiologist. When there was a need to clarify patient information (BP, HR, heart rhythm), this was requested from the outpatient record at the local outpatient clinic. Hemodynamic parameters were assessed for each patient against the reference values set in the national clinical guidelines: sinus HR less than 70 bpm, HR in atrial fibrillation (AF) less than 90 bpm, BP 120–139/80–89 mmHg [1]. Thus, patients in both groups were supervised and received CHF treatment.

In order to determine actual treatment compliance, the rate of using CHF-modifying agents (angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), beta-blockers (BBs), mineralocorticoid receptor antagonists (MRAs)) was analyzed in both patient groups. Sacubitril/valsartan (MRA) was not administered in any group at baseline, since it was approved in the Russian Federation only on March 25, 2016.

The study was conducted in accordance with the Declaration of Helsinki (revised by the World Medical Association in 2013). To be included in the study all patients signed an informed consent. This study was approved by the Ethics Committee of the Nizhny Novgorod Regional Medical Association (abstract of the minutes No. 94 dated 18.01.2016).

The statistical analysis was performed using the Statistica 7.0 software suite for Windows. Descriptive statistics are presented as the mean±standard deviation in the case of normal distribution of a quantitative trait, the median [1st quartile; 3rd quartile] in the case of the non-normal distribution of a quantitative trait, and the percentage in the case of a trait being estimated by a nominal or ordinal score. The Shapiro-Wilk criterion and a visual evaluation of the distribution histogram were used to test distribution consistency of the quantitative traits. The Student t-test was used to assess the statistical significance of the differences in the case of normal distribution, and the Mann–Whitney test was used in the case of non-normal distribution. The χ^2 or Fisher exact test was used to assess the statistical significance of the inter-group differences, if the trait was nominal or ordinal. Differences were statistically significant at $p<0.05$.

Results

Baseline clinical measurements, causes of CHF, and comorbidities in both study groups are given in Table 1. Arterial hypertension (AH), coronary artery disease (CAD), atrial fibrillation (AF), and diabetes mellitus (DM) type 2 were the main causes of CHF in patients with history of ADHF. A history of stroke, anemia, peripheral artery disease, cancer, and chronic kidney disease were common in both

Table 1. Baseline clinical parameters of patients

Parameter	Group 1, n=510	Group 2, n=432	p
Age, years	69.7±10.2	71.9±10.8	**0.002**
≥ 70 years old, % (n)	47.3 (241)	58.8 (254)	**<0.001**
Male/female, % (n)	42.5 (217)/57.5 (293)	41.4 (179)/58.6 (253)	0.7
Duration of hospitalization, bed-days	11.4±3.1	11.3±3.4	0.95
LVEF, %	53.7±11.7	54.4±10.7	0.3
HFpEF / HFmrEF / HFrEF, % (n)	68.8 (351)/17.9 (91)/13.3 (68)	73.1 (316)/17.6 (76)/9.3 (40)	0.1/0.9/0.05
6MWD, m	299.2±102.1	276.3±94.2	**<0.001**
CHF FC I / II / III / IV, % (n)	13.9 (71)/39 (199)/38.6 (197)/8.5 (43)	7.2 (31)/35.9 (155)/47 (203)/9.9 (43)	**<0.001**/0.3/**0.009**/0.4
SHOCS, score	3 [2; 4]	4 [2; 5]	**<0.001**
History of AH, % (n)	94.5 (482)	95.3 (412)	0.5
History of CAD, % (n)	81.4 (415)	82.4 (356)	0.7
History of MI, % (n)	27.3 (139)	25.9 (112)	0.6
History of revascularization, % (n)	9.4 (48)/3.3 (17)	4.9 (21)/1.6 (7)	**0.008**/0.1
PAD, % (n)	25.3 (129)	30.1 (130)	0.1
AHD, % (n)	40.2 (205)	28.5 (123)	**<0.001**
History of DM, % (n)	25.7 (131)	23.8 (103)	0.5
Obesity, % (n)	47 (240)	38.7 (167)	0.3
AF, % (n)	49.8 (254)	44.0 (190)	0.07
GFR (CKD EPI), mL/min/1.73 m^2	66.5±21.0	61.1±21.7	**<0.001**
GFR <60 mL/min/1.73 m^2, % (n)	35.5 (181)	40.5 (175)	0.1
History of CVA, % (n)	8.8 (45)	8.8 (38)	0.98
Anemia, % (n)	17.1 (87)	15.3 (66)	0.5
COPD, % (n)	15.7 (80)	10.4 (45)	**0.02**
BA, % (n)	5.1 (26)	2.5 (11)	**0.04**
Hospital-acquired pneumonia, % (n)	7.1 (36)	9.9 (43)	0.1
PUD, % (n)	9.4 (48)	4.9 (21)	**0.008**
Hystory of cancer, n (%)	7.5 (38)	6.5 (28)	0.6
Charlson comorbidity index, score	5 [4; 7]	5 [4; 7]	0.6

The statistically significant intergroup differences are highlighted in bold. SBP, systolic blood pressure; DBP, diastolic blood pressure; LVEF, left ventricular ejection fraction; HFpEF, heart failure with preserved left ventricular ejection fraction; HFmrEF, heart failure with mid-range left ventricular ejection fraction; HFrEF, heart failure with reduced left ventricular ejection fraction; 6MWD, 6-minute walk distance; SHOCS, Symptomatic Hospital and Outpatient Clinical Score; AH, arterial hypertension; CAD, coronary artery disease; MI, myocardial infarction; PAD, peripheral artery disease; AHD, acquired heart disease; DM, diabetes mellitus; AF, atrial fibrillation; GFR, glomerular filtration rate; CVA, cerebrovascular accident; COPD, chronic obstructive pulmonary disease; BA, bronchial asthma; PUD, peptic ulcer disease.

groups. In Group 2, the mean baseline glomerular filtration rate (GFR) was lower, although the percentages of patients with GFR <60 mL/min/1.73 m^2 did not differ between the groups.

Both groups included more female patients. In Group 2, the patients were older and had different clinical severity. The baseline 6-minute walk distance was shorter in Group 2 than in Group 1. This was consistent with the baseline distribution of the Symptomatic Hospital and Outpatient Clinical Score (SHOCS, V.Y. Mareev modification) and CHF functional class (FC). Group 2 included more patients with CHF FC III than Group 1. However, the mean duration of the index hospital stay for ADHF did not differ and was about 11 bed-days in both groups (Table 1).

The main symptoms and signs of HF at the inclusion in the follow-up program were recorded at the end of the index hospital treatment of ADHF, i.e., at the discharge from hospital (Table 2).

With a mean duration of hospital stay of 11 bed-days in both groups, almost every patient still had clinical manifestations of HF (dyspnea, palpitations, asthenia, and fatigue) at hospital discharge. In Group 2, patients were more likely to report palpitations, which may be due to their baseline clinical severity. There were severe clinical signs of congestion at the discharge: peripheral edema in

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Table 2. Baseline clinical symptoms and signs of heart failure

Parameter	Group 1, n=510	Group 2, n=432	p
Dyspnea, % (n)	88.1 (449)	88.4 (382)	0.9
Fatigue, asthenia, % (n)	73.6 (375)	71.8 (310)	0.5
Palpitations, % (n)	62.0 (316)	70.4 (304)	**0.007**
Peripheral edema, % (n)	54.3 (277)	57.9 (250)	0.3
Any weight gain within 4 weeks before, % (n)	25.3 (129)	28.2 (122)	0.3
Orthopnea, % (n)	21.4 (109)	26.2 (113)	0.08
Cough, % (n)	16.5 (84)	15.5 (67)	0.7
Pulmonary rales, % (n)	28.8 (147)	32.4 (140)	0.2
Chest effusion, % (n)	4.5 (23)	5.8 (25)	0.4
Pericardial effusion, % (n)	7.5 (38)	9.0 (39)	0.4
Ascites, % (n)	1.0 (5)	1.9 (8)	0.3
Anasarca, % (n)	2.2 (11)	3.5 (15)	0.2
Liver enlargement, % (n)	2.9 (15)	4.6 (20)	0.2
Swollen cervical veins, % (n)	4.5 (23)	3.2 (14)	0.3

The statistically significant intergroup differences are highlighted in bold.

Table 3. Changes in blood pressure and heart rate in Groups 1 and 2 after one and two follow-up years

Visit/Group	SBP, mm Hg	DBP, mm Hg	HR, bpm	HR in SR, bpm	HR in paroxysmal and persistent AF, bpm	HR in permanent AF, bpm
Group 1 by follow-up periods						
Baseline	135±24	77±12	76±16	74±17	73±15	83±18
12 months	129±18	75±10	73±14	71±12	70±12	81±16
$p_{baseline/12\ months}$	**<0.001**	**0.009**	**0.002**	**0.002**	0.07	0.2
2 years	130±20	76±11	73±14	69±12	69±11	82±17
$p_{baseline/24\ months}$	**0.02**	0.2	**0.01**	**<0.001**	**0.04**	0.6
$p_{12\ months/24\ months}$	0.4	0.4	0.98	0.2	0.7	0.7
Group 2 by follow-up periods						
Baseline	137±25	79±13	78±17	76±14	77±15	85±22
12 months	134±24	78±13	77±15	75±14	74±14	84±16
$p_{baseline/12\ months}$	0.056	0.5	0.4	0.7	0.1	0.7
2 years	135±24	78±13	79±15	76±14	78±15	85±15
$p_{baseline/24\ months}$	0.2	0.8	0.7	0.8	0.6	0.99
$p_{12\ months/24\ months}$	0.6	0.8	0.2	0.5	0.1	0.7
Group 1 versus Group 2 by follow-up periods						
Group 1 baseline	135±24	77±12	76±16	74±17	73±15	83±18
Group 2 baseline	137±25	79±13	78±17	76±14	77±15	85±22
p	0.2	0.1	0.1	0.4	0.05	0.4
Group 1, 12 months	129±18	75±10	73±14	71±12	70±12	81±16
Group 1, 24 months	134±24	78±13	77±15	75±14	74±14	84±16
p	**0.005**	**0.004**	**0.003**	**0.002**	**0.03**	0.08
Group 2, 12 months	130±20	76±11	73±14	69±12	69±11	82±17
Group 2, 24 months	135±24	78±13	79±15	76±14	78±15	85±15
p	**0.03**	**0.04**	**<0.001**	**<0.001**	**<0.001**	0.09

The statistically significant intergroup differences are highlighted in bold.
SBP, systolic blood pressure; DBP, diastolic blood pressure; SR, sinus rhythm; AF, atrial fibrillation.

more than half of patients in both groups; pulmonary rales in every third patient; orthopnea in every fifth patient; and coughing in every sixth patient with recent history of ADHF. Less often, patients had severe manifestations of stagnation at the discharge from hospital, such as chest and pericardial effusion, ascites, anasarca, liver enlargement, swollen cervical veins (Table 2).

Baseline hemodynamic parameters and their changes after 12 and 24 months of follow-up were analyzed (Table 3). During their hospital stay, patients with HF did not attain target levels of systolic blood pressure (SBP), diastolic blood pressure (DBP), and HR before being discharged from hospital.

Sinus rhythm (SR) in Groups 1 and 2 was detected in 50.2 and 56% of patients, respectively (p = 0.07). Paroxysmal or persistent AF was diagnosed in 22.8% of patients in Group 1 and 21.2% of patients in Group 2 (p = 0.6). Permanent AF wsa determined in 27 and 22.8% of patients respectively (p = 0.14). In Group 1, patients attained recommended levels of SBP, DBP in 12 months and were stable by the end of the second year of follow-up. In Group 1, the recommended HR levels in SR, persistent or paroxysmal forms of AF, were attained by the end of the second year of follow-up. In Group 2, patients did not have significant changes in hemodynamic parameters, which is particularly the case for HR. Thus, outpatient management of patients after ADHF in the local outpatient clinics proved ineffective in terms of controlling hemodynamic parameters.

We evaluated real-life compliance of patients with the use of CHF-modifying agents at 12 and 24 months of outpatient management (Table 4). Based on the history collection and analysis of data collected by means of a structured telephone survey, drugs administered by patients for a long time following their physician's orders were identified.

More patients in Group 1 (93.5%) in total received the first component of neurohumoral blockade (ACE inhibitor or ARB or ARNI) compared to Group 2 (45.4%), p<0.001 after 24 months of the follow-up. In Group 1, ARNI was introduced between the first and second year of treatment, and the differences in drug therapy became statistically significant immediately by the end of the second year of follow-up (7% of patients). Patients in Group 2 showed poor compliance with long-term use of ACE inhibitors or ARBs in the first place, and ARNIs were less frequently prescribed as part of outpatient treatment in this group. Real-life compliance with BBs after 12 and 24 months of the follow-up in Group 1 increased. This differed from Group 2, although they were recommended in both groups at the discharge from hospital with roughly the same frequency. After 12 and 24 months of follow-up, the frequency of MRA use decreased in Group 1. This was due to the discontinuation of this group of drugs in a part of stable patients. In Group 2, the actual use of MRAs decreased significantly and was lower than in Group 1 after 24 months of the follow-up.

Discussion

The main causes of HF in patients hospitalized with ADHF are AH, CAD, AF, and type 2 DM. In our study, the comorbidity of CHF patients hospitalized due to ADHF was high, which could influence the duration of HF and the patient's choice to continue outpatient management at a local outpatient clinic.

Table 4. The frequency of using disease-modifying drugs in Groups 1 and 2 at baseline and after 24 months of the follow-up

Drug	Group	Baseline	12 months	2 years	$p_{baseline/12\ months}$; $p_{baseline/24\ months}$
ACE inhibitors, %	1	64.5	73.4	69.2	**0.02**; 0.1
	2	63.3	32.1	29.8	**<0.001; <0.001**
	p	0.95	**<0.001**	**<0.001**	–
ARBs, %	1	19.8	20.2	17.3	0.9; 0.3
	2	22.8	17.8	14.9	0.07; **0.002**
	p	0.2	0.4	0.2	–
ARNI, %	1	0	2.1	7.0	NA; NA; $p_{1roA/2roA}$**<0.001**
	2	0	0.3	0.7	NA; NA; $p_{1roA/2roA}$=0.5
	p	NA	**0.02**	**<0.001**	–
BB, %	1	77.4	89.8	84.3	**<0.001; 0.006**
	2	82.2	72.7	74.1	**0.001; 0.03**
	p	0.06	**<0.001**	**<0.001**	–
MRA, %	1	78.4	69.1	58.7	**<0.001; <0.001**
	2	79.8	65.9	43.2	**<0.001; <0.001**
	p	0.6	0.3	**<0.001**	–

The statistically significant intergroup differences are highlighted in bold. NA, not applicable;
ACE, angiotensin-converting enzyme; ARB, angiotensin II receptor blocker; ARNI, angiotensin receptor-neprilysin inhibitor; BB, beta-blocker; MRA, mineralocorticoid receptor antagonist.

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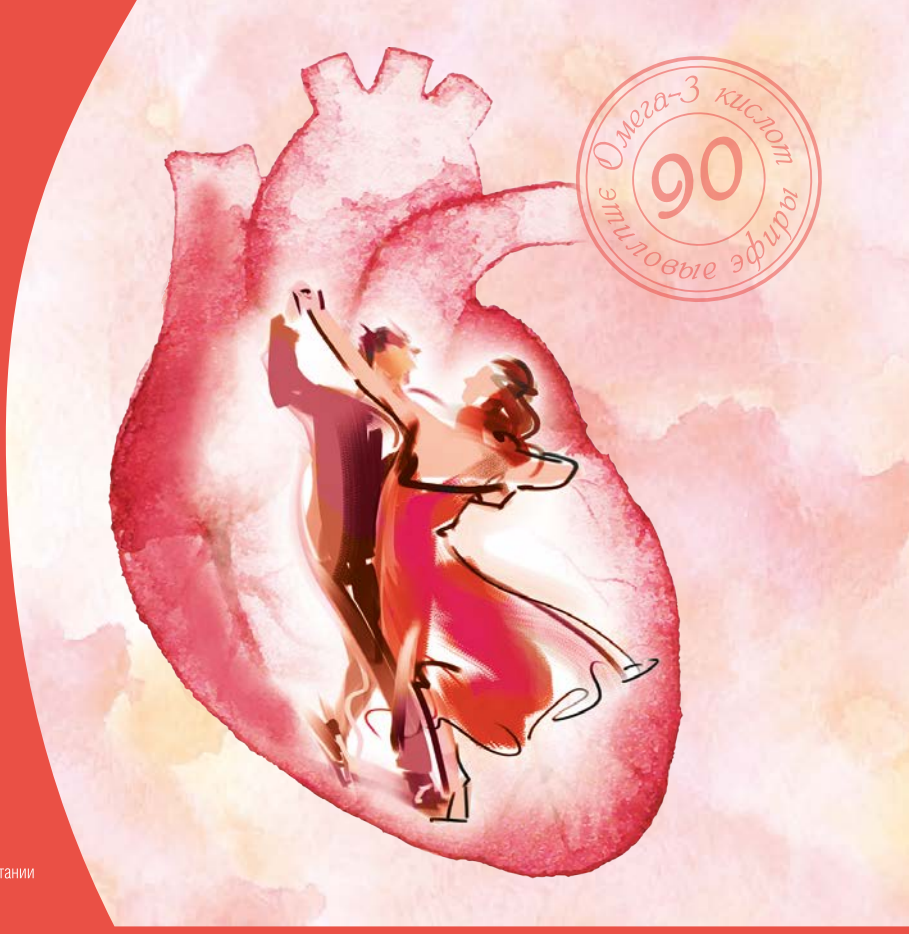
Abbott

- Способствует восстановлению клеток сердца*, 1, 2
- Снижает риск внезапной сердечной смерти на 45%*, 3
- Хорошо переносится при длительной терапии*, 4, 5

* У пациентов после инфаркта миокарда (в составе комбинированной терапии): в сочетании со статинами, антиагрегантными средствами, бета-адреноблокаторами, ингибиторами ангиотензинпревращающего фермента (АПФ).



ОМАКОР ДЕЛО ЖИЗНИ

ДЛЯ ВТОРИЧНОЙ ПРОФИЛАКТИКИ ПОСЛЕ ИНФАРКТА МИОКАРДА*, 6

Омакор. Регистрационный номер: ЛС-000559. **Международное непатентованное или группировочное наименование:** Омега-3 кислот этиловые эфиры 90. **Лекарственная форма:** капсулы, 1000 мг. **Фармакологические свойства*.** Полиненасыщенные жирные кислоты класса омега-3 – эйкозапентаеновая кислота (ЭПК) и докозагексаеновая кислота (ДГК) – относятся к незаменимым (эссенциальным) жирным кислотам (НЭЖК). Результаты клинического исследования GISSI-Prevenzione, полученные за 3,5 года наблюдений, показали существенное снижение относительного риска смертности от всех причин, нефатального инфаркта миокарда и нефатального инсульта на 15 % ([2–26] p = 0,0226) у пациентов после недавно перенесенного инфаркта миокарда, принимавших препарат Омакор по 1 г в сутки. Дополнительно, относительный риск смерти по причине сердечно-сосудистой патологии, нефатального инфаркта миокарда и нефатального инсульта снижался на 20 % ([5–32] p = 0,0082). Результаты клинического исследования GISSI-Heart Failure, в котором пациенты с хронической сердечной недостаточностью получали препарат Омакор по 1 г в сутки в среднем в течение 3,9 лет, показали снижение относительного риска смертности от всех причин на 9 % (p = 0,041), снижение относительного риска смертности от всех причин и госпитализации по причине сердечно-сосудистых патологий на 8 % (p = 0,009), снижение относительного риска первичной госпитализации по причине желудочковых аритмий на 28 % (p = 0,013). **Показания к применению.** Гипертриглицеридемия: эндогенная гипертриглицеридемия IV типа по классификации Фредериксона (в монотерапии) в качестве дополнения к гиполипидемической диете при ее недостаточной эффективности; эндогенная гипертриглицеридемия IIb или III типа по классификации Фредериксона в комбинации с ингибиторами ГМГ-КоА редуктазы (статинами), когда концентрация триглицеридов недостаточно контролируется приемом статинов. Вторичная профилактика после инфаркта миокарда (в составе комбинированной терапии): в сочетании со статинами, антиагрегантными средствами, бета-адреноблокаторами, ингибиторами ангиотензинпревращающего фермента (АПФ). Противопоказания. Повышенная чувствительность к действующему веществу, сое, арахису или любому из вспомогательных веществ, входящих в состав препарата. Возраст до 18 лет (эффективность и безопасность не установлены). **Беременность и период грудного вскармливания.** Омакор не следует применять у пациентов с экзогенной гипертриглицеридемией (гиперхиломикронемией I типа). **С осторожностью.** Установленная гиперчувствительность или аллергия на рыбу; возраст старше 70 лет; нарушения функции печени; одновременный прием с пероральными антикоагулянтами; геморрагический диатез; пациенты с высоким риском кровотечений (вследствие тяжелой травмы, хирургической операции); вторичная эндогенная гипертриглицеридемия (особенно при неконтролируемом сахарном диабете). Применение при беременности и в период грудного вскармливания*. Назначать Омакор беременным следует с осторожностью, только после тщательной оценки соотношения риска и пользы, когда польза для матери превышает потенциальный риск для плода. Препарат не должен применяться в период грудного вскармливания. **Способ применения и дозы*.** Внутрь, независимо от приема пищи. Во избежание развития возможных нежелательных явлений со стороны желудочно-кишечного тракта (ЖКТ) препарат Омакор может приниматься во время приема пищи. Гипертриглицеридемия. Начальная доза составляет 2 капсулы в сутки. В случае отсутствия терапевтического эффекта возможно увеличение дозы до максимальной суточной дозы – 4 капсулы. Вторичная профилактика инфаркта миокарда. Рекомендуется принимать по 1 капсуле в сутки. **Побочное действие*.** Желудочно-кишечные расстройства (в том числе вздутие живота, боль в животе, запор, диарея, диспепсия, метеоризм, отрыжка, гастроэзофагеальная рефлюксная болезнь, тошнота или рвота). Перечень всех побочных действий представлен в инструкции по медицинскому применению. Передозировка. Особые указания отсутствуют. Должна быть проведена симптоматическая терапия. **Взаимодействие с другими лекарственными средствами*.** При одновременном применении препарата Омакор с пероральными антикоагулянтами или другими препаратами, влияющими на систему гемостаза (например, ацетилсалициловая кислота или НПВП), наблюдалось увеличение времени свертывания крови. При этом геморрагических осложнений не наблюдалось. Ацетилсалициловая кислота: пациенты должны быть проинформированы о возможном увеличении времени свертывания крови. Совместное применение препарата Омакор с варфарином не приводило к каким-либо геморрагическим осложнениям. Однако необходим контроль соотношения протромбинового времени/международного нормализованного отношения (ПТВ/МНО) при совместном применении препарата Омакор с другими препаратами, влияющими на соотношение ПТВ/МНО, или после прекращения терапии препаратом Омакор. **Особые указания*.** Омакор должен применяться с осторожностью у пациентов с установленной гиперчувствительностью или аллергией на рыбу. В связи с умеренным увеличением времени свертывания крови (при приеме в высокой дозе, т.е. 4 капсулы в сутки) требуется наблюдение за пациентами, имеющими нарушения со стороны свертывающей системы крови или получающими антикоагулянтную терапию или другие препараты, влияющие на систему гемостаза (например, ацетилсалициловую кислоту или НПВП); при необходимости, доза антикоагулянта должна быть скорректирована. Необходимо учитывать увеличение времени свертывания крови у пациентов с высоким риском развития кровотечения. При терапии препаратом Омакор снижается уровень образования тромбоксана А2. Существенного влияния на уровень других факторов свертывания крови не наблюдалось. У некоторых пациентов наблюдалось небольшое, но достоверное повышение активности АСТ и АЛТ (в пределах нормы), при этом отсутствуют данные, указывающие на повышенный риск приема препарата Омакор пациентами с нарушением функции печени. Необходим контроль активности АСТ и АЛТ у пациентов с любыми признаками нарушения функции печени (в частности, при приеме в высокой дозе, т.е. 4 капсулы в сутки). Опыт применения препарата для лечения экзогенной гипертриглицеридемии (гиперхиломикронемии типа 1) отсутствует. Опыт применения препарата при вторичной эндогенной гипертриглицеридемии ограничен (особенно при неконтролируемом сахарном диабете).**Влияние на способность управлять транспортными средствами, механизмами*.** Ожидается, что препарат не оказывает или оказывает несущественное влияние на способность управлять транспортными средствами и работать с механизмами. Условия хранения. Хранить при температуре не выше 25 °С. Не замораживать. Хранить в недоступном для детей месте! Условия отпуска. Отпускают по рецепту. *Полная информация представлена в инструкции по медицинскому применению. СИП от 27.09.2019 на основании ИМП от 29.08.2019.

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The age of patients included in the study suggests that ADHF is common in elderly patients with HF. In the ADHERE register, which included patients with ADHF, the hospitalized patients were older than outpatient patients (72.4±14 years), as indicated by this study. In the international OPTIMIZE-HF study, the mean age of hospitalized patients with CHF was even higher (73.1±14.2 years) [15, 16]. This data should be taken into account when planning outpatient follow-up after the discharge from hospital after ADHF, since older patients in Group 2 opted for the follow-up at the local outpatient clinics. At the time of the study, there was only one specialized center for CHF patients in the entire city, making it impossible for patients living far away to participate in the specialized follow-up program. Therefore, specialized care should be brought closer to patients and represented by a network of offices covering the entire region.

In previous studies, we have shown that age had no significant effect on the frequency of rehospitalizations, and patients were grouped by age, and age differences were taken into account in the analysis of mortality [17, 18].

In this study, patients had severe symptoms of CHF and evident signs of congestion at hospital discharge. This should be analyzed in terms of organizing the outpatient management of such patients. The following symptoms prevailed in patients after ADHF: dyspnea; palpitations; and asthenia. These symptoms are also the main ones in epidemiological studies [19]. The high prevalence of these symptoms and signs of congestion at hospital discharge suggests that it is impossible to achieve euvolemia in patients with ADHF during the mean hospital stay of 11 bed days. More than half of patients still had edema before hospital discharge, and every third patient had pulmonary rales, more frequently than in international practice [20]. For example, in the OPTIMIZE-HF study, 61.4% of patients with CHF complained of dyspnea at the admission to hospital. 64% of patients had pulmonary rales, and 64.6% had edema. Upon hospital discharge, 15.4 and 26,9% of patients had pulmonary rales and edema, respectively, which was less frequent than in the study groups of patients [16].

Obviously, all patients needed to continue active treatment of CHF, and doses of the main drug required titration at the outpatient stage immediately after hospital discharge. During this period, the titration of disease-modifying drugs only begins. Patients have a poor prognosis and a naturally high frequency of rehospitalizations in the absence of further routine outpatient management, which increases the burden on the health care system. This data confirms the urgent need for a seamless model of specialized management of patients after ADHF and complete continuity between the inpatient and outpatient stages.

It has been shown that patients did not achieve the target BP and HR values at hospital discharge. Therefore, it was impossible to achieve the best possible doses of the CHF-modifying drugs within 11 days in hospital.

During the two-year outpatient management period, the hemodynamic parameters in the CHFMC group changed, while the levels of SBP and DBP remained within the target values after 12 and 24 months of the follow-up. After 12 and 24 months of the follow-up, HR was lower in patients with sinus rhythm than in those with AF. No significant decrease in HR was reported in the CHFMC patients with permanent AF after 12 and 24 months of the follow-up.

No significant changes in SBP, DBP, and HR values were detected in patients followed up in the local outpatient clinics during any of the above follow-up periods. All the hemodynamic parameters analyzed were higher in patients of outpatient clinics than in the CHFMC patients, especially HR in patients with AF. This fact proves that doses of disease-modifying and HR-slowing drugs are not increased at the outpatient stage in patients followed up in the local outpatient clinics.

Treatment compliance in the study groups explains the differences in hemodynamic parameters during the follow-up. The CHFMC patients had better treatment compliance. In the local outpatient clinic group, compliance with the use of ACE inhibitors and BBs significantly decreased after 12 months of follow-up despite frequent rehospitalizations of these patients who should apparently have maintained an adequate level of compliance [17].

The problem of compliance with CHF-modifying therapy is widely discussed in developed countries. According to the ESC-HF Pilot register, patients are admitted to hospital with ADHF administered CHF-modifying drug significantly less frequently than in ambulatory patients: 64.3% for ACE inhibitors/ARBs, 54.8% for BBs, and 33.9% for MRAs [21]. This data shows an increased risk of developing ADHF and hospitalization in the case of discontinuation of the Hf-modifying therapy, as we have shown in previous publications [17, 18].

The problem of poor compliance in patients followed up in the local outpatient clinics may be due not only to the clinical characteristics of patients (age, comorbidity, clinical severity) but also the compliance of physicians of the outpatient clinics with implementing clinical guidelines. According to the QUALIFY and MAHLER European studies, which studied the administration of the CHF-modifying drugs and loop diuretics, the patient outcomes depended on physicians' compliance with the guidelines [22, 23]. It is possible that in this study, patient compliance was influenced by the factors on both the patient's and physician's parts.

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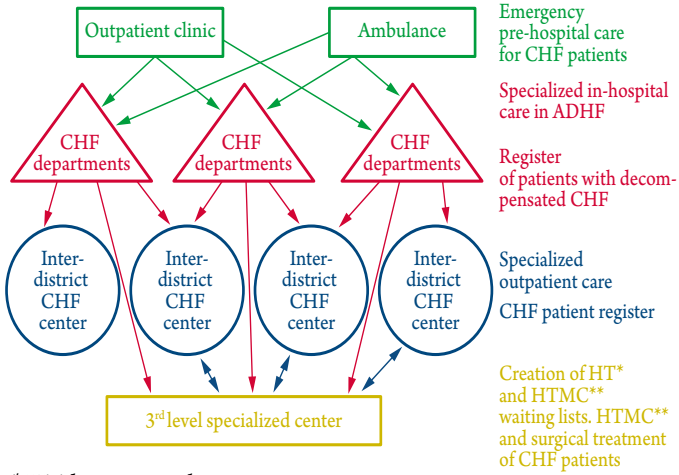
Figure 1. Structure of medical care for CHF patients in the Nizhny Novgorod Region



* HT, heart transplant.
** HTMC, high-tech medical care.

Findings

The modern portrait of a post-ADHF patient is characterized by high comorbidity, the predominance of AH, CAD, AF, and type 2 DM as the causes of CHF.

During a short period of hospitalization (11 bed days), patients continue to present with severe symptoms of CHF and clinical signs of congestion and fail to achieve the hemodynamic targets.

The long-term follow-up of patients after hospital treatment of ADHF at the specialized CHF management center is associated with effective hemodynamic monitoring, when compared to patients followed up at the local outpatient clinics.

Patients who were managed at the specialized CHF management center for a long time were more compliant with CHF-modifying drug therapy than those who were followed up at the local outpatient clinics.

Patients hospitalized for ADHF are at high risk of adverse outcomes and rehospitalizations and should thus be managed in the special care system for at least the first year after ADHF, in order to perform adequate titration of CHF-modifying agents and determine a management strategy.

Conclusion

The data obtained shows the benefits of managing patients at specialized CHF management centers.

According to the literature, seamless care by a multidisciplinary team in hospital and the outpatient follow-up in a clinical center in cooperation with nurses (assistants) with active telephone or telemedicine monitoring is the most feasible medical care system for patients with CHF [8, 11, 12, 24–32]. This will significantly reduce the risk of death in this category of patients.

We analyzed the impact of specialized medical care on CHF patient compliance with the use of the disease-modifying drugs on the example of the first Russian City Center of CHF Management in Nizhny Novgorod. It is evident that all sections of clinical guidelines on the management of patients with CHF can be performed under the conditions of specialized outpatient medical care for CHF patients, in order to attain the best possible compliance with the disease-modifying drug therapy. Despite the existence of modern and effective treatment of this disease, insufficient positive changes in the prognosis for patients with CHF were identified as due to high comorbidity of CHF patients, low mobility in elderly and clinically severe patients with CHF FC III-IV, and insufficient effectiveness of the primary care in the outpatient clinics in terms of maintaining treatment compliance.

Thus, approaches to CHF management need to be changed and a single three-level seamless system of specialized medical care for CHF patients needs to be formed at the population level along with the implementation of complete continuity between the inpatient and outpatient stages (Figure 1). The three-level system includes departments for CHF patients in hospitals providing emergency cardiac care; outpatient inter-district CHF management centers providing outpatient care and consultations to CHF patients and home nursing for low-mobile CHF patients; and a specialized 3rd level center providing high-tech and surgical medical care to CHF patients.

Limitations of the study

The data obtained should be interpreted to indicate that patients included in the trials may be more adherent to the treatment. The positive experience of the City CHF Management Center can be translated to other regions with the view to the regional context of providing medical care.

No conflict of interest is reported.

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