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Short Registry of Terminal Forms of Chronic Heart Failure in the Samara Region

Aim	To study the clinical characteristics and prognosis of patients with functional class (FC) III–IV chronic heart failure (CHF) who meet the criteria for inclusion in the palliative care program.
Material and methods	A short registry of severe CHF forms was conducted at 60 outpatient and inpatient clinics in the Samara region for one month (16.05.2022–15.06.2022). The registry included patients with FC III–IV CHF who sought medical help during that period. Lethal outcomes were assessed at 90 days after the inclusion in the registry using the Mortality Information and Analytics system.
Results	591 patients (median age, 71.0 [64.0; 80.0] years were enrolled, including 339 (57.4%) men, of which 149 (24.1%) were of working age (under 65 years). The main cause of CHF was ischemic heart disease (64.5%). 229 (38.7%) patients had left ventricular ejection fraction <40%. During the past year, 513 (86.8%) patients had at least one hospitalization for decompensated CHF. 45.7% of patients had hydrothorax, and 11.3% of patients had ascites. Low systolic blood pressure was observed in more than 25% of patients; 14.2% required in-hospital inotropic support; and 9.1% received it on the outpatient basis. 4.2% of patients received outpatient oxygen support and 0.8% required the administration of narcotic analgesics. 12 (1.9%) patients were on the waiting list for heart transplantation. In this study, there was an inconsistency in the number of patients with ventricular tachycardia and/or left bundle branch block (LBBB) who were implanted with cardiac resynchronization therapy devices (CRTD) or an implantable cardioverter defibrillator (ICD), a total of 19 patients (11 patients with CRTD and 8 patients with ICD), while 58 (9.8%) patients had indications for CRTD/ICD implantation. Within 90 days from inclusion in the registry, 59 (10.0%) patients died. According to binary logistic regression analysis, the presence of LBBB, hydrothorax, the requirement for outpatient oxygen support, and a history of cardiac surgery were associated with a high risk of death.
Conclusion	Patients with severe forms of CHF require not only adequate drug therapy, but also dynamic clinical observation supplemented with palliative care aimed at improving the quality of life, including the ethical principles of shared decision-making and advance care planning to identify the priorities and goals of patients in relation to their care.

Keywords	Chronic heart failure; functional class III-IV heart failure; registry
For citations	Rubanenko O. A., Skripnik I. V., Matyukhina K. V., Rubanenko A. O., Davydkin I. L., Benyan A. S. et al. Short Registry of Terminal Forms of Chronic Heart Failure in the Samara Region. Kardiologiia. 2024;64(3):46–54. [Russian: Рубаненко О.А., Скрипник И.В., Матюхина К.В., Рубаненко А.О., Давыдкин И.Л., Бенян А.С. и др. Короткий регистр тяжелых форм хронической сердечной недостаточности в Самарской области. Кардиология. 2024;64(3):46–54].

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Introduction

The implementation of primary and secondary prevention, the establishment of a system of care for acute coronary syndrome, and the development of interventional cardiology and high-tech health care have led to a decrease in mortality from coronary artery disease (CAD) and an increase in life expectancy, which has contributed to an increase in the number of patients with chronic heart failure (CHF) [1, 2]. More than 10% of people over the age of 70 are thought to have CHF [3]. At the same time, the 5-year probability of death in some phenotypes of CHF reaches 80%, which determines a worse prognosis compared to various types of cancer [4].

The course of CHF is characterized by periodic exacerbations with the risk of decompensation, the need for intensification of therapy and the risk of death amidst the gradual deterioration of the patient's condition [5].

ISSN 0022-9040. Kardiologiia. 2024;64(3). DOI: 10.18087/cardio.2024.3.n2323

The establishment of a palliative care system is a priority task for patients with severe forms of CHF who have an end-stage disease that is actively progressing in the later years of their lives [4, 6, 7]. Assessing the clinical picture of the disease, understanding the current condition of patients with end-stage CHF in real time will allow the scope of specialized palliative care programs to be determined.

Objective

Study the clinical characteristics and prognosis of patients with class III–IV CHF who meet the criteria for inclusion in the palliative care program.

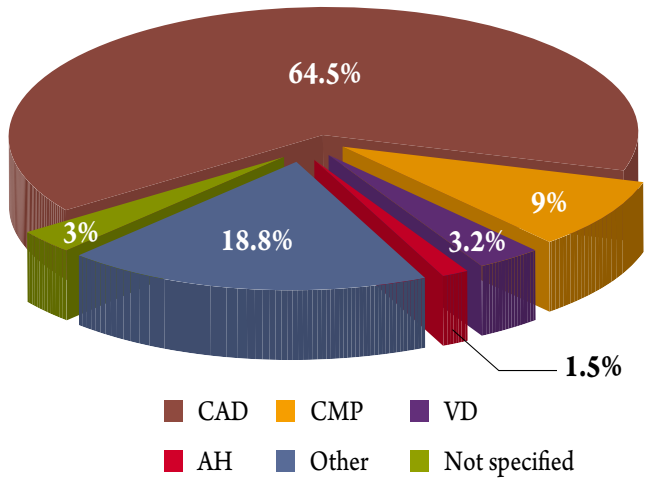
Material and Methods

Short registry study of severe forms of CHF was conducted in 60 outpatient and inpatient facilities of Samara region within 1 month (May 16, 2022 – June 15, 2022), lethal outcomes were evaluated in 90 days from the moment of patients' inclusion in the registry by means of information-analytical system «Mortality».

The study was conducted in accordance with the tenets of the Declaration of Helsinki. The protocol of the submitted registry was approved by the local ethics committee of the Samara Regional Clinical Cardiology Center.

Central illustration. Short Registry of Terminal Forms of Chronic Heart Failure in the Samara Region

591 patients	
• median age, years	71.0 (64.0; 80.0)
• men	339 (57.4%)
• of working age (under 65 years of age)	149 (24.1%)
• HCN III FC	491 (83.1%)
• FC was not specified	8 (1.4%)
• BLNPG in patients	108 (18.3%)
• VT in patients	55 (9.3%)
• AF in patients	125 (21.2%)



CHF severity criteria (n = 591)

Parameter	Value, n (%)
Hydrothorax	270 (45.7)
Ascites	67 (11.3)
Systolic blood pressure < 100 mm Hg	160 (27.1)
Inotropic support in the hospital	84 (14.2)
Need for inotropic support in the outpatient setting	54 (9.1)
Need to use oxygen in the outpatient setting	25 (4.2)
Need to use narcotic analgesics in the outpatient setting	5 (0.8)
Dialysis	23 (3.9)

After 90 days from the moment of inclusion in the registry, 59 (10.0%) patients died.

Characteristics of the association of independent predictors with the likelihood of death in patients with end-stage CHF

Predictor	Multivariate analysis	
	AOR (95 %CI)	p
LBBB	2.37; 1.27–4.45	0.007
Hydrothorax	1.86; 1.04–3.32	0.037
Need for oxygen support	4.0; 1.59–10.1	0.003
Previous heart surgery	0.47; 0.23–0.98	0.044

The registry was created on the basis of the extended criteria, which correspond to the Order of the Ministry of Health of the Russian Federation # 345n and the Order of the Ministry of Labor and Social Protection of the Russian Federation # 372n dated May 31, 2019 «On Approval of the Regulation on the Organization of Palliative Care, including the Procedure of Interaction between Medical Institutions, Social Service Organizations and Public Associations and Other Commercial Organizations Operating in the Field of Health Care». These criteria have been reviewed and refined in accordance with the objectives of the registry.

The registry included patients with class III–IV CHF who sought outpatient care from an internist or cardiologist or were hospitalized in the cardiology or internal medicine departments of hospitals in Samara Region with decompensated CHF during the specified period. CHF could have been a manifestation of a previously established cardiovascular disease: CAD, post-infarction cardiosclerosis, congenital and acquired heart defects, cardiomyopathies, and others. In addition to class III–IV manifestations of CHF, the presence of at least one additional parameter was mandatory:

1) More than 1 hospitalization for CHF in the past 365 days;
2) History of or current therapy with inotropic drugs (dobutamine, dopamine, noradrenaline);
3) Left ventricular ejection fraction (LVEF) < 40%;
4) Systolic blood pressure (SBP) < 100 mm Hg;
5) Dialysis;
6) Presence of an implantable cardioverter defibrillator (ICD) / cardiac resynchronization therapy (CRT) device / pacemaker;
7) Untreated fluid retention and / or increasing need for diuretics;
8) Need to use narcotic analgesics in the outpatient setting due to recurring dyspnea and pain syndrome;
9) Waiting for a heart transplant;
10) Need to use oxygen in the outpatient setting.

Statistical processing of the data obtained was performed using IBM SPSS Statistics, version 26.0. Due to the non-normal distribution of the data, they were analyzed using non-parametric statistical methods. Quantitative variables were presented as medians (Me) and 25th and 75th percentiles, and qualitative variables were presented as absolute and relative frequencies (n (%)). A regression function (the most appropriate model) was developed, which made it possible to include the independent variables

Figure 1. Age distribution of patients included in the study

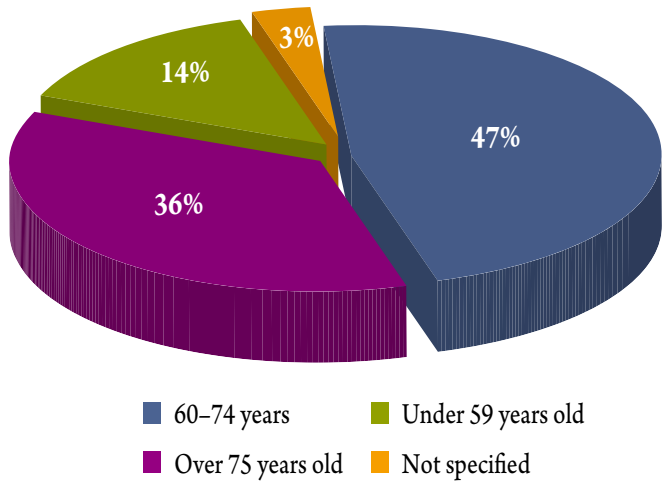
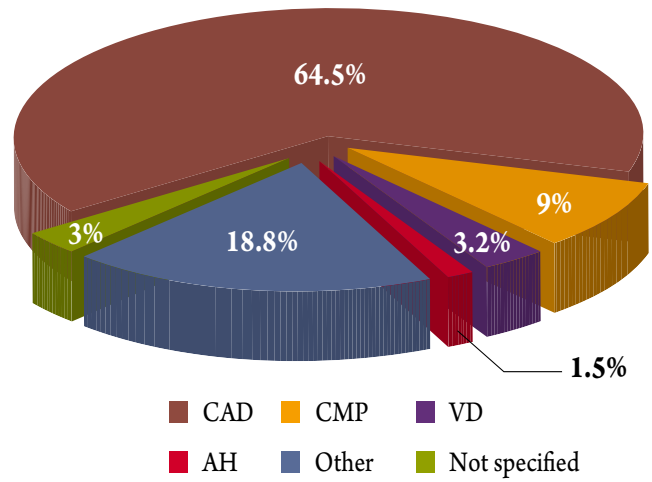
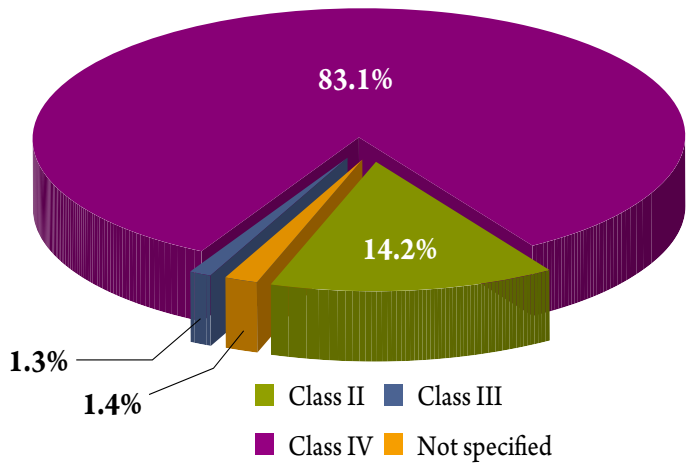


Figure 2. Structure of the principal diagnoses



CAD, coronary artery disease; CMP, cardiomyopathy; VP, valvular defect; AH, arterial hypertension.

Figure 3. Functional class in patients with end-stage CHF



ISSN 0022-9040. Kardiologiia. 2024;64(3). DOI: 10.18087/cardio.2024.3.n2323

Table 1. CHF severity criteria (n = 591)

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Need to use oxygen in the outpatient setting	25 (4.2)
Need to use narcotic analgesics in the outpatient setting	5 (0.8)
Dialysis	23 (3.9)

CHF, chronic heart failure.

Table 2. Indications for CRT/ICD implantation in patients with severe CHF

Indication for implantation	Number of patients without implanted devices, n (%)	Implanted devices, n (%)
LBBB + LVEF < 40 %	37 (6.2)	CRT device – 3 (0.5) ICD – 3 (0.5) Not specified – 1 (0.2) Pacemaker – 2 (0.3)
LVEF < 40% + VT	12 (2.0)	CRT device – 1 (0.2) ICD – 1 (0.2) Not specified – 1 (0.2)
LVEF < 40% + VT + LBBB	9 (1.5)	ICD – 1 (0.2) CRT device – 1 (0.2) Pacemaker – 1 (0.2) Not specified – 1 (0.2)

LBBB, left bundle branch block; VT, ventricular tachycardia;
CRT, cardiac resynchronization therapy;
ICD, implantable cardioverter defibrillator.

as regressors from among the many possible variants of the regression equations. The calculated threshold of the P function at the cut-off point divided the patients into 2 groups according to the outcome (factor variable). Binary logistic regression analysis using univariate and multivariate models provided odds ratios for the indicators included in the model. ROC analysis was used to calculate the sensitivity and specificity of the indicators. Differences were considered statistically significant at $p < 0.05$ for two-tailed test value.

Results

Data from 618 patients were entered into the registry from May 16, 2022 to June 15, 2022, of which 27 patients were encountered in both the inpatient and outpatient phases. After excluding repeated matches, the final analysis included data from 591 patients, median age 71.0 (64.0; 80.0) years, 339 (57.4%) were male, of whom 149 (24.1%) were of Active working age (younger than 65 years). Figure 1 shows the age structure.

Despite the severity of the disease, only 133 (21.5%) patients had disability of various degrees (groups), mostly group II (15.6%).

The main cause of CHF development was CAD (64.5%), including myocardial infarction (MI), various types of cardiomyopathy (9%), valvular pathology, including acquired heart defects (3.2%), and arterial hypertension (1.5%). Other diseases accounted for 18.8% and included myocarditis, infective endocarditis, arrhythmias and conduction disorders, pulmonary embolism, congenital heart defects, cerebral vascular lesions, and chronic kidney disease (CKD). The principal diagnosis was unspecified in 18 (3.0%) patients (Figure 2). A total of 160 patients (25.9%) had a history of various types of cardiac surgery. A history of cancer was present in 46 (7.4%) patients.

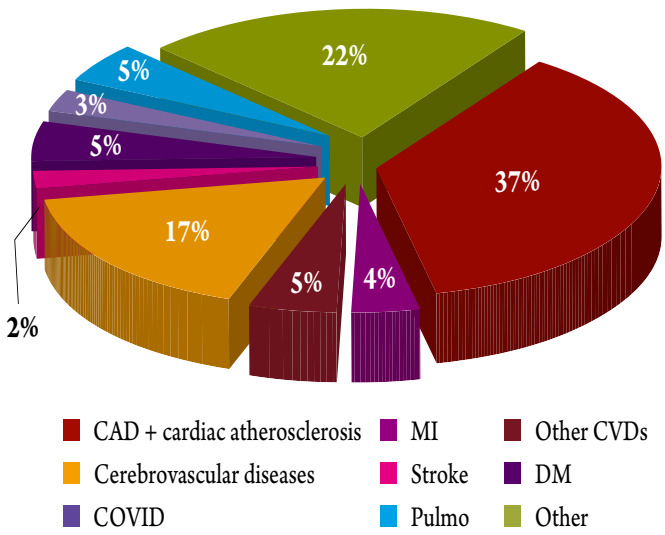
A total of 491 (83.1%) patients had class III CHF, and class of CHF was unspecified in 8 (1.4%) patients (Figure 3).

In addition to the main inclusion criterion – the presence of class III–IV CHF – we used 10 additional criteria as previously defined. Meanwhile, 148 (25%) patients had 2 of 10 criteria, 92 (15.6%) patients had 3 criteria, 52 (8.8%) patients had 4 criteria, 9 (1.5%) patients had 5 criteria, 3 (0.5%) patients had 6 criteria, and 2 (0.3%) patients had 7 criteria.

LVEF < 40% was observed in 229 (38.7%) of the patients. Blood oxygen saturation (SpO2) was determined in 75 (12.7%) patients and was 97 (96; 97) %.

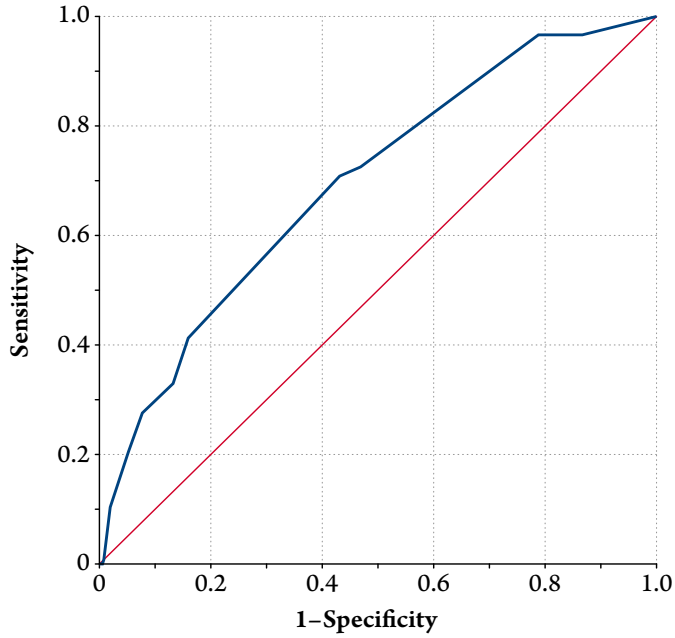
In the past year, 513 (86.8%) patients had at least one hospitalization for decompensated CHF. There were 129 (21.8%) patients with two hospitalizations,

Figure 4. Causes of death



Pulmo, pulmonary pneumonia; Others, interstitial lung diseases.

Figure 5. ROC curve for the prognosis of fatal outcome



32 (5.4%) patients with three hospitalizations, and 22 (3.7%) patients with four or more hospitalizations.

Parameters indicating the severity of the course of CHF, including the criteria of the palliative phase of the disease, specified in the orders of the Ministry of Health of Russia, are presented in Table 1.

Hydrothorax was present in 45.7% of the patients and 11.3% of the patients had ascites. More than 25% of patients had persistently low SBP, 14.2% of patients required in-hospital inotropic support, and 9.1% of patients received inotropic support in the outpatient setting. Outpatient oxygen support was used in 4.2% of patients, and 0.8% of patients required narcotic analgesics.

Left bundle branch block (LBBB) was observed in 108 (18.3%) patients. A history of or current ventricular tachycardia (VT) during hospitalization was reported in 55 (9.3%) patients, and 125 (21.2%) patients had various forms of atrial fibrillation.

Permanent pacemakers were previously implanted in 58 (9.8%) patients, only 8 (1.4%) patients had an ICD, 11 (1.9%) patients had a CRT device, and another 2 patients were awaiting CRT/ICD implantation. The type of device implanted was not specified in 16 (2.7%) patients.

We analyzed the indications for implanting the devices and the actual use (Table 2). Among 591 patients with severe CHF, a combination of three parameters (LBBB, LVEF < 40%, and VT) was present in 13 (2.2%) patients, two parameters (LVEF < 40% and VT) in 15 (2.5%) patients, and LBBB and LVEF < 40% in 45 (7.6%) patients. The under-utilization of

Table 3. Characteristics of the association of independent predictors with the likelihood of death in patients with end-stage CHF

Predictor	Univariate analysis		Multivariate analysis	
	COR (95 %CI)	p	AOR (95 %CI)	p
LBBB	2.15; 1.18–3.92	0.012	2.37; 1.27–4.45	0.007
Hydrothorax	2.14; 1.23–3.73	0.007	1.86; 1.04–3.32	0.037
Need for oxygen support	4.84; 1.99–11.77	0.001	4.0; 1.59–10.1	0.003
Previous heart surgery	0.51; 0.25–1.04	0.063	0.47; 0.23–0.98	0.044

LBBB, left bundle branch block; COR, crude odds ratio; CI, confidence interval; AOR, adjusted odds ratio.

ISSN 0022-9040. Kardiologiia. 2024;64(3). DOI: 10.18087/cardio.2024.3.n2323

the opportunities offered by high-tech medical care must be mentioned. In addition, pacemakers without resynchronization and/or defibrillation function were implanted in 3 (0.5%) patients requiring CRT/ICD implantation.

There are 12 (1.9%) patients on the waiting list for a heart transplant.

Fifty-nine (10.0%) patients died 90 days after inclusion in the registry. The structure of causes of death is shown in Figure 4. Overall, circulatory diseases accounted for 65%, with acute forms – IM and cerebral stroke – accounting for only 4% (2 patients) and 2% (1 patient), respectively.

Binary logistic regression analysis was used to identify predictors of fatal outcome. The resulting regression model was statistically significant ($p < 0.001$). Based on the value of the Nagelkerke R squared, 8.9% of the variance in the probability of death is determined by the factors included in the model. The prognostic parameters that determined the risk of fatal outcome were the presence of LBBB, hydrothorax, and the need for oxygen support in the outpatient setting. Previous cardiac surgery was inversely associated with the likelihood of death. Table 3 summarizes the characteristics of the association of predictors with the likelihood of death in patients with end-stage CHF.

The area under the ROC curve corresponding to the relationship between mortality prediction and the value of the logistic regression function was 0.695 ± 0.036 (95% confidence interval (CI) 0.624–0.765) (Figure 5). This indicates the average quality of the developed model and the need to further evaluate the parameters of each patient included in the study to re-evaluate the developed model.

The threshold value of the P function at the cut-off point was 0.09314. Function values equal to or greater than this value predicted a fatal outcome. Model sensitivity and specificity were 70.7% and 56.9%, respectively.

Discussion

CHF is a chronic, progressive, and ultimately fatal disease. The results of our registry are comparable to those of large trials [8–11]. The median age of our patients was 71 years, and CAD, including a history of MI, was the most common condition leading to the development of heart failure. At the same time, according to data from three epidemiological studies conducted in the Russian Federation (EPOCH-CHF, EPOCH-Hospital-CHF, and EPOCH-Decompensation-CHF), the prevalence of CHF increased significantly over 16 years – from 4.9% in 1998 to 10.2% in 2014. At the same time, the number of patients with class III–IV CHF increased even more, from 1.2% in 1998 to 4.1% in 2014. This was also associated with a significant increase in the mean age of patients from 64 years in 1998 to 70 years in 2014, as well as an increase in the contribution of CAD and a history of MI as an etiologic cause of the development and progression of CHF [8–11].

It should also be noted that despite the severity of the disease, according to our data, disability was registered in 21.5% of patients and 5 patients were recognized as palliative (more than 50% of CHF in the structure of palliative patients abroad) [12]. According to the World Health Organization, the majority of adults in need of palliative care have cardiovascular diseases (38.5%), which exceeds the number of patients with cancer (34%) [13]. However, no more than 5% of CHF patients in the general population receive specialized palliative care [14]. Analysis of data from 40 Russian Federation regions showed that palliative care for patients with class III–IV CHF is provided in only 16 regions, 2 regions are developing a program of care for this patient population, and 22 regions do not have any palliative care programs [15].

Currently, there are three main phenotypes of patients – those with preserved, mid-range and reduced LVEF. CHF with preserved LVEF has been shown to account for approximately 50% (25–70%) of all heart failure cases [3, 16]. An unexpected finding of our registry was that only 37% of patients with severe CHF (class III–IV) had LVEF < 40%.

Implantation and deactivation of cardiac resynchronization therapy devices in patients with advanced CHF is an important issue. On the one hand, these devices prevent the onset of life-threatening arrhythmias or manage them and synchronize cardiac function; on the other hand, keeping the devices active in patients with end-stage CHF leads to unwarranted pacing for the patient and the surrounding people [17].

In our study, the number of patients with VT and/or LBBB who received a CRT/ICD was different (a total of 19 patients – 11 patients with a CRT device and 8 patients with an ICD), with 58 (9.8%) patients having indications for CRT/ICD implantation. Another 3 (0.5%) patients who had indications for CRT/ICD implantation had a pacemaker without resynchronization and/or defibrillation function.

In our study, 87% of patients were hospitalized at least once due to decompensation of the underlying disease, and 183 (31.0%) patients had two or more

hospitalizations. Despite advances in the treatment of CHF, nearly 40% of patients die within one year of their initial hospitalization [18].

It should be noted that 59 (10.0%) patients included in our registry died after 3 months. We demonstrated that factors associated with mortality were the presence of LBBB, hydrothorax, the need for oxygen support in the outpatient setting, and a history of cardiac surgery. Our results differ from those of other authors who found an association of mortality risk with LVEF, brain natriuretic peptide levels, C-reactive protein, age 61–74 years and ≥ 75 years, and male sex [18]. Another factor contributing to the high risk of mortality in patients with CHF is the refusal of follow-up care in a specialized CHF center [19].

Patients with decompensated CHF experience debilitating physical and emotional symptoms, loss of independence and social role impairment – all of which dramatically affect quality of life. Physical symptoms in severe CHF, such as pain, are of great concern to patients and caregivers, but remain poorly understood and inadequately managed. Patients and their families are often faced with making decisions about risky and complex treatments (e.g., implantation of cardiac synchronization devices, heart transplantation) without adequate prognostic information, decision support, or advance treatment planning [20].

Traditionally, palliative care has been provided to patients with cancer, perhaps because the more predictable course of cancer makes it easier to identify needs and plan care for patients and their families. This approach explains the perception that palliative care is the domain of specialized services and is relevant only in the last weeks of a patient's life [20].

There are difficulties in providing palliative cardiology care due to lack of awareness among primary care physicians about the goals and objectives, procedures for admission to appropriate departments and centers, and lack of knowledge about the principles of palliative care.

Our registry provides evidence that the organization of care for patients with severe CHF is far from ideal in terms of oxygen therapy, inotropic support, and narcotic analgesic prescription, both in the inpatient and outpatient setting.

For a long time, palliative care and standard of care were mistakenly viewed as conflicting options, and palliative care was used only as a last resort when conventional management of CHF failed to stabilize the patient's condition [20]. A misconception has developed that palliative care is needed in the last days of a patient's life, whereas palliative care should be initiated at the onset of CHF. Given the unpredictable course of CHF, waiting for a trigger event to initiate palliative care should be recognized as unwarranted. The current situation shows that there are many areas for the integration of palliative care during the course of CHF.

Limitations

The study was conducted in a single region and included patients with end-stage CHF according to specific criteria developed for selection for palliative care.

We did not analyze the drug therapy administered and its adherence to clinical guidelines.

Conclusion

Patients with severe chronic heart failure require not only appropriate medical therapy, but also dynamic follow-up with the implementation of palliative care aimed at improving patients' quality of life, including the ethical principles of shared decision making and advance care planning to identify patients' priorities and goals for their care.

Funding

No funding was received for this study.

No conflict of interest is reported.

The article was received on 25/11/2022

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