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Main Principles Of Treatment For Chronic Heart Failure With Preserved Ejection Fraction

Umarova Zamira Fakhrievna

Associate Professor, Department of Faculty and Hospital Therapy, Nephrology and Hemodialysis No. 2, Tashkent State Medical University, Tashkent, Uzbekistan

Maksudova Malika Khamdamdjanovna

Associate Professor, Department of Faculty and Hospital Therapy, Nephrology and Hemodialysis No. 2, Tashkent State Medical University, Tashkent, Uzbekistan

Nadirova Yulduz Isomovna

Assistant, Department of Faculty and Hospital Therapy, Nephrology and Hemodialysis No. 2, Tashkent State Medical University, Tashkent, Uzbekistan

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Abstract: Chronic heart failure (CHF) is a pathophysiological syndrome that develops as a result of cardiovascular diseases or other etiological factors leading to impaired cardiac filling or emptying ability. It is accompanied by dysregulation of neurohormonal systems (renin-angiotensin-aldosterone, sympathetic-adrenal, kinin-kallikrein systems, and natriuretic peptides), resulting in vasoconstriction, fluid retention, and subsequent cardiac remodeling and multi-organ dysfunction. These changes cause an imbalance between tissue oxygen demand and supply, resulting in characteristic symptoms such as dyspnea, fatigue, reduced exercise tolerance, and edema.

Keywords: Dyspnea, fatigue, reduced exercise tolerance, and edema.

Introduction: The main etiological factors of CHF in the Russian Federation are arterial hypertension (95.5%), ischemic heart disease (69.7%), history of myocardial infarction or acute coronary syndrome (15.3%), and diabetes mellitus (15.9%). A combination of ischemic heart disease and hypertension is present in the majority of CHF patients.

The prevalence of CHF in different regions of Russia ranges between 7–10%. From 1998 to 2014, the proportion of patients with CHF of functional classes I–IV increased from 4.9% to 8.8%. Over 16 years, the total number of CHF patients doubled (from 7.18 million to 14.92 million), while the number of patients with severe CHF (III–IV functional class) increased 3.4 times (from 1.76 million to 6.0 million). The distribution by functional class was: I – 23%, II – 47%, III – 25%, and IV – 5%.

The average age of CHF patients increased from 64.0 ± 11.9 years (in 1998) to 69.9 ± 12.2 years (in 2014), with more than 65% being over 60 years old. The female-to-male ratio among CHF patients is approximately 3:1.

According to the ORACLE study (2010–2013), among 2,498 patients, 31% were rehospitalized within 30 days after discharge, 11% within 90 and 180 days, and 9.5% within 360 days. Hospital mortality was 9%, total mortality reached 13% at 30 days, 33% at 180 days, and 43% within one year.

CHF often presents not as a reduction in systolic function but rather as diastolic dysfunction. Asymptomatic left ventricular (LV) dysfunction is an important marker of impending heart failure. Approximately 40–60% of CHF patients exhibit diastolic dysfunction with preserved LV ejection fraction (LVEF). Early detection of asymptomatic LV dysfunction (LVEF <40%) enables timely treatment, slowing disease progression and improving survival. In 2014, the estimated national cost of inpatient care for CHF in the Russian Federation exceeded 520 billion rubles.

Main Principles of Treatment for CHF with Preserved Ejection Fraction (HFpEF)

The fundamental principles include strict blood pressure control, the use of diuretics, mineralocorticoid receptor antagonists, and management of comorbidities. Beta-blockers, ACE inhibitors, angiotensin II receptor blockers, phosphodiesterase inhibitors, digoxin, and nitrates have not shown positive effects on outcomes in HFpEF.Treatment of CHF with reduced ejection fraction (HFrEF) targets both causes and consequences of the disease and includes lifestyle modifications, pharmacotherapy, device therapy, cardiac rehabilitation, and patient education programs. Drugs proven to reduce symptoms and mortality include diuretics, beta-blockers, ACE inhibitors, angiotensin II receptor blockers, hydralazine combined with nitrates, digoxin, and aldosterone antagonists.

Promising results have been demonstrated with the supramolecular complex sacubitril/valsartan (Entresto®)—the first representative of a new class of angiotensin receptor–neprilysin inhibitors (ARNIs)—for treating HFrEF.SGLT2 inhibitors (gliflozins) represent a class of antidiabetic agents that reduce blood glucose levels by inhibiting renal glucose reabsorption through sodium-glucose cotransporter type 2 (SGLT2) inhibition. These compounds are derivatives of phlorizin (discovered in 1835 from apple tree bark), which induced glycosuria ("phlorizin diabetes") through SGLT inhibition in renal tubules and intestinal mucosa.A major advantage of gliflozins is the low risk of hypoglycemia due to compensatory SGLT1 activation when blood glucose levels fall below the transport threshold. Additionally, they lower glycated hemoglobin (HbA1c), promote weight loss, improve lipid profiles and uric acid levels, and reduce blood pressure.

Beyond glucose lowering, SGLT2 inhibitors protect against chronic kidney disease by reducing glomerular hyperfiltration, oxygen demand, and albuminuria, thereby decreasing cardiovascular events in type 2 diabetes mellitus patients. Clinical trials have shown that empagliflozin, dapagliflozin, canagliflozin, and ertugliflozin improve cardiovascular and renal outcomes, reducing overall mortality in type 2 diabetes. Long-acting agents such as ipragliflozin and dapagliflozin have shown the strongest antihyperglycemic effects in preclinical models.

The TRANSITION Study and Sacubitril/Valsartan (Entresto®)

The TRANSITION trial demonstrated that Entresto® can be safely prescribed to both in-hospital and outpatient CHF patients early after stabilization. Approximately 83% of CHF patients are hospitalized at least once for acute decompensation, and within 30 days, one in four is rehospitalized, while nearly 10% die.Presented at the European Society of Cardiology Congress (Munich, Germany), TRANSITION showed that sacubitril/valsartan was safe for early use in a broad range of stabilized HFrEF patients. Participants included both treatment-naïve and previously treated individuals.Half of CHF patients have reduced ejection fraction, making optimized therapy crucial to prevent recurrent decompensation or death. However, physicians often hesitate to initiate new therapy post-hospitalization due to patient vulnerability.

Professor Rolf Wachter (University Hospital of Leipzig, Germany) stated: "In the weeks following acute decompensated heart failure, patients remain highly vulnerable and face a significant risk of rehospitalization and death. The PARADIGM-HF trial demonstrated that sacubitril/valsartan significantly reduces hospitalizations and mortality. The TRANSITION study confirms that early initiation after acute episodes is safe and effective."

In TRANSITION, patients were randomized to receive sacubitril/valsartan either before discharge or shortly after discharge. By week 10, more than 86% had been continuously treated for at least 2 weeks, and about half reached the target dose (200 mg twice daily). The incidence of adverse events and treatment discontinuation was similar in both groups.

Dr. Shriram Aradhye, Global Medical Director at Novartis Pharma, commented: "The TRANSITION results confirm that Entresto®—the new standard in heart failure therapy—can be safely initiated in recently hospitalized patients. Hospitalization offers a crucial opportunity to optimize heart failure management and improve prognosis, reducing mortality, rehospitalization, and healthcare costs."

Entresto® has been available in the Russian Federation since early 2017. The PARADIGM-HF phase III double-blind clinical trial, involving 8,442 patients across 47 countries (including 800 from Russia), compared Entresto® with enalapril in patients with HFrEF (LVEF <40%, NYHA II–IV).

The study demonstrated Entresto®'s superiority over enalapril across all primary endpoints:

- 20% reduction in cardiovascular death due to heart failure progression;

- 20% reduction in sudden cardiac death;

- 16% reduction in all-cause mortality;

- 20% reduction in first hospitalization due to worsening heart failure;

- 34% reduction in emergency medical service calls

related to heart failure exacerbation.

Patients treated with Entresto® lived significantly longer than those receiving enalapril.

Indication:

Chronic heart failure (NYHA class II–IV) with systolic dysfunction to reduce cardiovascular mortality and heart failure hospitalizations.

“CHF remains one of the most pressing healthcare problems due to its high prevalence and poor prognosis. The introduction of Entresto® marks a new era in the management of heart failure, offering millions of patients an opportunity to live longer and enjoy better quality of life.” — Krishnan Ramanathan, Director of Scientific Affairs, Novartis Pharma Russia.

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