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10-YEAR EXPERIENCE IN ORTHOTOPIC HEART TRANSPLANTATION IN KUZBASS

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Background. Orthotopic heart transplantation (OHT) is the gold standard treatment for individuals with end-stage heart failure (HF), providing the best survival and quality of life. In Russia, the number of OHT procedures and transplantation of other organs have significantly increased in recent years. At the same time, there is lower perioperative mortality and higher survival in the post-OHT long-period. **Objective:** to analyze OHT outcomes in Kuzbass over a 10-year period. **Material and methods.** From January 2013 to December 2023, 72 OHTs (36.7% of those included on the heart transplant waiting list (HTWL) over a 10-year period) were performed at the Research Institute for Complex Issues of Cardiovascular Diseases. Recipient median age was 56 [50.5; 61.0] years, which included 61 men and 11 women. Among the etiologic causes of end-stage HF, ischemic cardiomyopathy was predominant in 65.3% (n = 47) of recipients, whereas dilated cardiomyopathy was present in 25% (n = 18) of recipients. Other cardiomyopathies accounted for 9.7% (n = 7). **Results.** A total of 196 patients with end-stage HF were included in the HTWL over a 10-year period; 74 (37.8%) of these did not live to get a transplant. The waitlist time was 173 days (5.77 months) – which is slightly longer than the average waiting time of 3.9 months for OHT according to data from European registries. Waitlist mortality was 19.6%. The 10-year average in-hospital mortality rates among patients after OHT were 16.7% and 1-year mortality was 15.3%. These rates are consistent with worldwide trends for this high-tech medical care. Cumulative survival at the end of 2023 was 51.4% (36 patients after OHT). Median length of stay in the hospital was 28 days, with 14 days spent in the intensive care unit. Donor heart anoxia time was 112 [85.25; 170.5] minutes, and cardiopulmonary bypass time was 145 [124; 169.5] minutes. Ten patients (13.9%) required extracorporeal membrane oxygenation, while 8.3% of cases required extracorporeal homeostasis correction. **Conclusion.** The 10 years of successful experience at the Research Institute for Complex Issues of Cardiovascular Diseases validates the need to develop the OHT program in Kuzbass as a gold standard for treating end-stage HF.

Keywords: heart transplantation, heart failure, organ donation.

Heart failure (HF) is a rapidly escalating global public health concern, currently affecting an estimated 64 million individuals worldwide. It remains associated with high rates of mortality and morbidity, as well as significantly diminished quality of life [1]. The prevalence of HF is expected to continue rising, largely due to the ageing population [1]. In the Russian Federation, data from the ERA-CHF study, a representative sample from the European part of the country, also highlight a marked increase in the prevalence of chronic heart failure (CHF) over the past 16 years, rising from 4.9% to 8.5%. Moreover, the absolute number of individuals diagnosed with CHF more than doubled during this period, increasing from 7.18 million to 12.35 million. The proportion of patients with severe CHF, classified as New York Heart Association (NYHA) functional classes (FC) III–IV, rose from 1.8% to 3.1%, corresponding to an increase from 1.76 million to 4.5 million individuals [2].

Despite advances in therapeutic strategies for HF, the proportion of patients progressing to end-stage heart failure (ESHF) continues to rise. According to large meta-analyses, nearly 10% of patients reach ESHF, defined by NYHA FC III–IV symptoms, despite receiving optimal medical therapy [3]. ESHF is associated with a high 1-year mortality, exceeding 50% following diagnosis [3]. For patients with severe HF, orthotopic heart transplantation (OHT) and left ventricular assist devices (LVADs) remain the most effective and widely recommended treatment options [3].

According to the World Health Organization's Global Observatory on Donation and Transplantation, organ transplantation is performed in 104 countries, encom-

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passing approximately 90% of the global population [4]. Recent data indicate that over 150,000 organ transplants are conducted annually worldwide, representing a 52% increase since 2010[1]. OHT continues to be the gold standard treatment for ESHF, offering the most favorable survival outcomes and quality of life improvements [5]. Over 6,000 heart transplants (HT) are performed globally each year, with a 1-year post-transplant survival rate of about 85% and a current median survival exceeding 12 years [6, 7].

Reports from the International Thoracic Organ Transplant Registry of the International Society for Heart and Lung Transplantation demonstrate both an upward trend in OHT procedures and concurrent improvements in postoperative outcomes over recent decades [8]. However, widespread implementation of HT programs remains constrained by factors such as donor organ shortages and the complexities of waiting list management in real-world clinical settings.

In recent years, Russia has seen a significant increase in the number of heart and other solid organ transplants. This trend has been accompanied by decreased perioperative mortality and higher long-term survival after HT [9, 10]. A notable milestone in the development of transplantology in the Russian Federation was achieved in Kuzbass, where the first HT procedure was successfully performed on January 31, 2013, under the leadership of Professor Leonid Barbarash, Fellow of the Russian Academy of Sciences and founder of the Kemerovo Cardiology Center. With active support from the Shumakov National Medical Research Center of Transplantology and Artificial Organs (Moscow), headed by Professor Sergey Gautier, also a Fellow of the Russian Academy of Sciences, Kemerovo became the first city in Russia with a population under 1 million to establish and implement a HT program.

Objective of the study: to analyze OHT outcomes in Kuzbass over a 10-year period.

MATERIAL AND METHODS

Within the framework of a registry-based study conducted at the Research Institute for Complex Issues of Cardiovascular Diseases (Kemerovo), data were collected and analyzed during both retrospective and prospective phases. The dataset included information from the heart transplant waiting list (HTWL) and the registry of OHT recipients. The study was conducted in accordance with Good Clinical Practice standards and the Declaration of Helsinki Principles. The study protocol was reviewed and approved by the joint local ethics committee of the Institute. The authors declare no conflicts of interest.

Recipients enrolled in the study were diagnosed with end-stage CHF and met the established clinical criteria and indications for OHT, in accordance with the national guidelines of the Russian Federation. These criteria included: refractoriness to optimal pharmacological therapy with a predicted 1-year OHT-free survival <50%; left ventricular ejection fraction (LVEF) <20%; pulmonary artery occlusion pressure >20 mmHg; decreased peak oxygen consumption (VO_2 peak) <12 ml/kg/min in patients not receiving beta-blockers, or <14 ml/kg/min in those receiving the maximum tolerated dose. Additional indications comprised the presence of severe myocardial ischemia in patients with coronary artery disease for whom revascularization (via coronary artery bypass grafting or percutaneous coronary intervention) was not feasible; and recurrent, refractory, life-threatening arrhythmias unresponsive to electrophysiological interventions, including catheter ablation or implantation of an implantable cardioverter-defibrillator (ICD) [9, 11, 12].

The main contraindications to inclusion in the HTWL were [11, 12]:

- Elevated pulmonary vascular resistance >5 Wood units, unresponsive to inhaled vasodilators;
- Body mass index (BMI) greater >35 kg/m^2;
- Age over 80 years amidst comorbidities that increase perioperative risk and compromise long-term prognosis;
- Severe atherosclerosis of the carotid, cerebral, and/or peripheral arteries associated with organ or tissue ischemia for which surgical correction is not feasible;
- Pulmonary hypertension characterized by a transpulmonary gradient >15 mmHg or pulmonary vascular resistance >5 Wood units, refractory to pharmacologic therapy (e.g., nitric oxide, sildenafil) and/or mechanical circulatory support;
- Severe liver and/or kidney dysfunction;
- Autoimmune diseases, including systemic lupus erythematosus, sarcoidosis, or systemic amyloidosis.

Between January 2013 and December 2023, a total of 72 OHTs were performed at the Research Institute for Complex Issues of Cardiovascular Diseases, representing 36.7% of patients included in HTWL over the 10-year period. Recipient median age was 56 years [IQR: 50.5–61.0], with a predominance of males (n = 61, 84.7%) and 11 females (15.3%) (Table 1).

Ischemic cardiomyopathy was the leading etiology of ESHF) present in 47 recipients (65.3%), followed by dilated cardiomyopathy in 18 (25.0%), and other forms of cardiomyopathy in 7 (9.7%). The majority of patients exhibited a traditional cardiovascular risk profile: arterial hypertension (n = 51, 61.3%), hyperlipidemia (n = 40, 55.6%), prior coronary revascularization (n = 38, 52.8%), and cardiac arrhythmias. Among those with

[1] https://apps.who.int/gb/ebwha/pdf_files/WHA75/A75_41-ru.pdf.

arrhythmias, atrial fibrillation or atrial flutter was observed in 28 (38.9%), and ventricular arrhythmias in 43 (59.7%) patients.

ICDs were present in 24 patients (33.3%), and an additional 7 patients (9.7%) had ICDs with cardiac resynchronization therapy (CRT-D). Functional capacity, assessed using the 6-minute walk test, corresponded to NYHA FC III in 56 patients (77.8%) and IV in 16 patients (22.2%). All recipients were classified as United Network for Organ Sharing (UNOS) status 2 (urgency on the HTWL) at the time of transplantation.

Surgical technique was predominantly biatrial (n = 71, 98.6%), with only one case (1.4%) performed using the bicaval technique.

In-hospital and 1-year follow-up endpoints were assessed:

– In-hospital (transplanted heart arrhythmia and conduction disorders; graft rejection and dysfunction; infectious complications; bleeding; multiple organ dysfunction syndrome (MODS); kidney failure; acute stroke/transient ischemic attack (AS/TIA); myocardial infarction (MI); need for extracorporeal membrane oxygenation (ECMO); tacrolimus overdose; death),
– 1-year follow-up (transplanted heart arrhythmia and conduction disorders; graft rejection and dysfunction; infectious complications; bleeding; MODS; kidney failure; AS/TIA; MI; diabetes mellitus; oncologic diseases; chronic/acute kidney failure; need for ECMO; transplant coronary artery disease (TCAD); tacrolimus overdose; rehospitalizations; death).

Statistical processing was carried out using STATISTICA 10.0 software (StatSoft Inc., USA). To assess the conformity of data distribution to normal distribution, the Lilliefors test was employed. A p-value >0.05 indicated normal distribution of the variable. A symmetry test was used to support distributional assumptions.

For variables not meeting the normality criteria, data were presented as median (Me) along with lower and upper quartiles [LQ; UQ]. A p-value <0.05 was considered statistically significant. The Mann–Whitney U test was applied for comparisons between independent groups, while the Wilcoxon signed-rank test was used for dependent samples. Survival analysis was performed using the Kaplan–Meier method to estimate survival functions.

Table 1

Recipient characteristics

Indicator		Result
Age, years Me [LQ;UQ]		56 [50.5; 61.0]
Men, n (%)		61 (84.7)
Women, n (%)		11 (14.3)
HTWL time, days		140 [48.0; 339.8]
UNOS-2, n (%)		72 (100)
Genesis of heart failure		
ICM, n (%)		47 (65.3)
DCM, n (%)		18 (25.0)
Other CMs, n (%)		7 (9.7)
Medical history and risk factors		
CHF FC, n (%)	FC III	56 (77.8)
	FC IV	16 (22.2)
AH, n (%)		51 (61.3)
Afib-AF, n (%)		28 (38.9)
VA, n (%)		43 (59.7)
Heart block, n (%)		21 (29.2)
PM, n (%)		5 (6.9)
ICD, n (%)		24 (33.3)
CRT-D, n (%)		9 (12.5)
PCI, n (%)		27 (37.5)
CABG, n (%)		11 (15.3)
DM/CI, n (%)		13 (18.1)
Hyperlipidemia/dyslipidemia, n (%)		40 (55.6)
CKD C3a/C3b, n (%)		14 (19.4)
AS, n (%)		8 (11.1)
COPD/BA, n (%)		5 (6.9)
Smoking, n (%)		8 (11.1)
BMI, kg/m^2 Me [LQ;UQ]		26.4 [22.7; 29.1]

Note: HTWL, heart transplant waiting list; UNOS, United Network for Organ Sharing; ICM, ischemic cardiomyopathy; DCM, dilated cardiomyopathy; CMs, cardiomyopathies; FC, functional class; CHF, chronic heart failure; AH, arterial hypertension; Afib, atrial fibrillation; AF, atrial flutter; VA, ventricular arrhythmia; PM, pacemaker; ICD, implantable cardioverter-defibrillators; CRT-D, cardiac resynchronization therapy with defibrillator; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; DM, diabetes mellitus; CI, carbohydrate intolerance; CKD, chronic kidney disease; AS, acute stroke; COPD, chronic obstructive pulmonary disease; BA, bronchial asthma; BMI, body mass index.

RESULTS OF THE STUDY

Over the 10-year observation period, there was a consistent increase in the number of OHT performed in Kuzbass. In 2023, a record-high number of procedures was achieved, with 13 OHTs conducted, including 2 performed as single-step interventions (Fig. 1).

HTWL included an average of 29.6 patients per year (range: 21–44 patients) (Fig. 2). Between January 2013 and December 2023, a total of 196 ESHF patients were listed for OHT. Of these, 74 patients (37.8%) died before undergoing transplantation. The average waitlist duration was 173 days (5.77 months), which slightly exceeds the mean waiting time reported in European registries (3.9 months) [13].

Overall HTWL mortality was 19.6%, with the lowest annual mortality observed in 2014 (6.7%) and 2023 (7.5%), and the highest in 2019 (43.3%) and 2020 (37.5%). The elevated mortality rates during 2019–2020 were attributed to the COVID-19 pandemic, particularly among patients with ESHF. Polynomial trend analysis revealed a decline in waitlist mortality from 2021 onward, alongside improved survival to transplantation. This trend is likely associated with introduction of novel

therapeutic agents, such as angiotensin receptor–neprilysin inhibitors (ARNIs) and sodium-glucose cotransporter 2 inhibitors (SGLT2i), in the management of HF patients with reduced ejection fraction (HFrEF).

Over the 10-year period, in-hospital mortality following OHT was 16.7%, and 1-year mortality was 15.3%. These outcomes are consistent with global benchmarks for this type of high-complexity intervention [16, 17]. As of the end of 2023, cumulative survival stood at 51.4%, with 36 OHT recipients still alive.

Median hospital stay post-transplant was 28 days, including a median intensive care unit (ICU) stay of 14 days (Table 2). During the operative and perioperative phases, the median ischemic time of the donor heart (an-

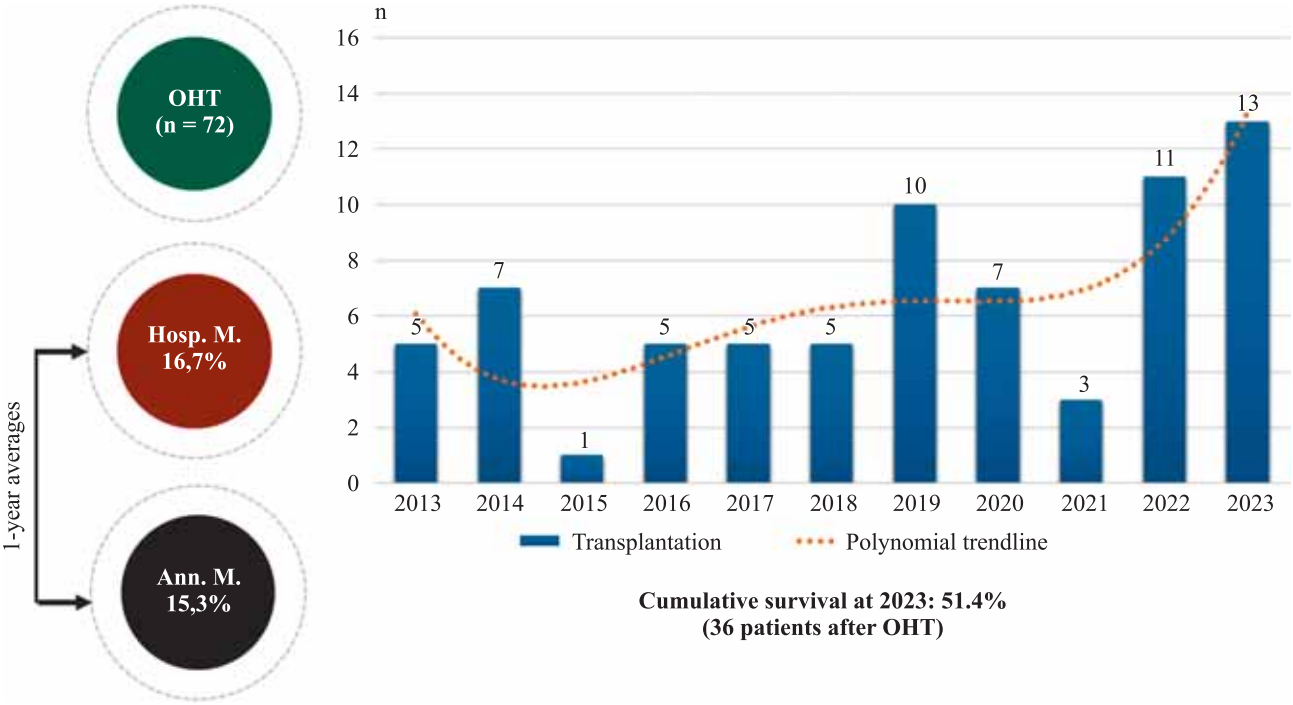

Fig. 1. Average survival between 2013 and 2023. OHT, orthotopic heart transplant; Hosp. M., hospital mortality; Ann. M., annual mortality

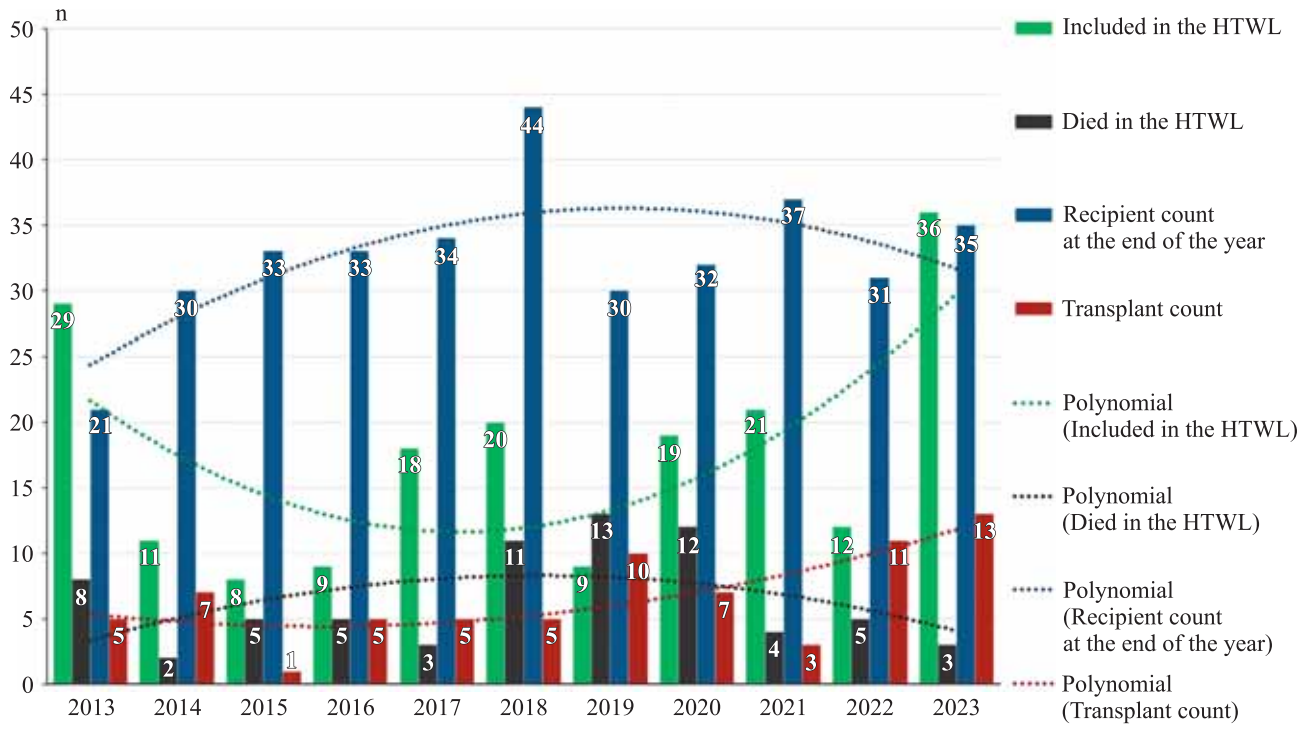

Fig. 2. Trends in the number of HTWL patients between 2013 and 2023

Table 2

Operative and perioperative indicators of heart transplantation

Indicator	Result
CPB time, min	145 [124; 169.5]
Donor heart anoxia time, min	112 [85.25; 170.5]
Surgery time, min	283 [247; 330]
Length of stay in the intensive care unit, day	14 [9; 28]
Hospitalization, day	28 [23; 36]
Need for PM, n (%)	37 (51.4)
ECMO use, n (%)	10 (13.9)
Extracorporeal correction of homeostasis, n (%)	6 (8.3)

Note: CPB, cardiopulmonary bypass; PM, pacemaker; ECMO, extracorporeal membrane oxygenation.

oxia) was 112 minutes [85.25; 170.5], while the median duration of cardiopulmonary bypass was 145 minutes [124; 169.5].

ECMO was required in 10 patients (13.9%), and 8.3% of cases required additional extracorporeal therapies.

Among the non-fatal complications during hospitalization, heart arrhythmias and conduction disorders (such as atrial fibrillation, ventricular extrasystole, and His bundle branch block) were the most prevalent, along with MODS, typically observed in patients experiencing cellular rejection or graft dysfunction (Fig. 3).

At the 1-year follow-up, 48 patients remained under observation, while 24 patients had passed away (including those who died during the hospitalization phase). Consequently, the analysis of therapy at the 1-year stage was based on the 48 surviving patients (Table 3). Notably, all patients showed high adherence to their prescribed specific therapy.

During the hospitalization phase, 100% of patients received specific immunosuppressive therapy. Statins and antiplatelet medications were consistently prescribed to all patients, both during the hospitalization period and at the 1-year follow-up. In the early postoperative period, 50% of patients required vasopressor medications, while 62.5% received inotropic agents. Selective cyclic guanosine monophosphate inhibitors were administered to 29.2% of patients during the hospitalization phase.

The use of loop diuretics decreased by the 1-year follow-up, with only 18.8% of patients requiring them (down from 76.4% during hospitalization). Similarly, the use of amiodarone decreased from 20.8% during hospitalization to 4.2% at the 1-year stage. While sodium-glucose cotransporter-2 (SGLT2) inhibitors were not used during the hospitalization phase, they were prescribed to one patient at the 1-year follow-up.

By 1 year, 5 patients (10.4%) had been switched to everolimus (a selective inhibitor of the mammalian target of rapamycin, mTOR), and 2 patients (4.2%) were receiving corticosteroid therapy.

At 1-year follow-up, the most common non-fatal complications were cellular graft rejection (26.7%) and graft dysfunction (21.7%). In addition, TCAD was identified in 15% of patients, while signs of MI were noted in 5% (Fig. 4). Importantly, the incidence of secondary infectious complications showed a significant decline compared to the hospital phase (8.2% *vs.* 16.5%, p = 0.023).

A detailed analysis of mortality patterns revealed that in 2015 and 2018, both in-hospital and 1-year mortality were zero. In the years 2017, 2019, and 2021, zero mortality was recorded exclusively during the in-hospital phase. Zero 1-year mortality following OHT was observed in 2016 and 2020 (Figs. 5 and 6). The highest in-hospital mortality rates over the 10-year period were recorded in 2016 (60%) and 2020 (43%), which were also associated with increased rates of non-fatal complications during these years (Figs. 3 and 5).

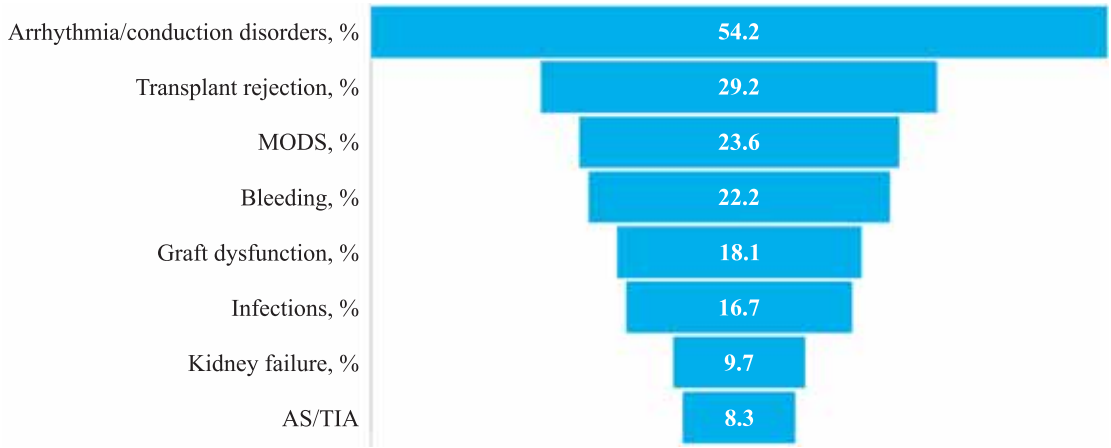

Fig. 3. Non-fatal complications during in-hospital follow-up. MODS, multiple organ dysfunction syndrome; AS, Acute stroke; TIA, transient ischemic attack

Trend analysis showed a consistent annual increase in the number of OHT procedures, accompanied by a rising trend in cumulative mortality (in-hospital + 1-year) (Fig. 6). In-hospital mortality trend remained relatively

Table 3

Therapy after OHT (hospital and 1-year stage)

Therapy (groups/drug)	In hospital (n = 72), n (%)	At 1-year stage (n = 48), n (%)
Specific therapy		
Induction of immunosuppression by an anti-interleukin-2 receptor antibody (basiliximab)	72 (100)	–
Calcineurin inhibitor (tacrolimus)	72 (100)	48 (100)
Mycophenolates	72 (100)	48 (100)
Selective mTOR serine-threonine kinase inhibitor (everolimus)	0 (0)	5 (10.4)
Corticosteroids	72 (100)	2 (4.2)
Antibacterials	72 (100)	27 (56.3)
Antifungals	32 (44.4)	26 (54.2)
Antivirals	72 (100)	26 (54.2)
Acetylsalicylic acid	72 (100)	48 (100)
Statins	72 (100)	48 (100)
RAAS inhibitors	37 (51.4)	26 (54.2)
Other therapy		
Vasopressors	36 (50)	0 (0)
Inotropes	45 (62.5)	
Selective inhibitor of cyclic guanosine monophosphate (cGMP)	21 (29.2)	0 (0)
UFH	34 (47.2)	0 (0)
Loop diuretics	55 (76.4)	9 (18.8)
Calcium channel blockers	7 (9.7)	4 (8.3)
Amiodarone	15 (20.8)	2 (4.2)
OAC	2 (2.8)	2 (4.2)
BB	0 (0)	2 (4.2)
ARNI	0 (0)	1 (2.1)
SGLT2i	0 (0)	1 (2.1)

Note: RAAS, renin-angiotensin-aldosterone system; cGMP, cyclic guanosine monophosphate; UFH, unfractionated heparin; OAC, oral anticoagulant; BB, beta blockers; ARNI, angiotensin receptor neprilysin inhibitor; SGLT2i, sodium-glucose co-transporter 2 inhibitor.

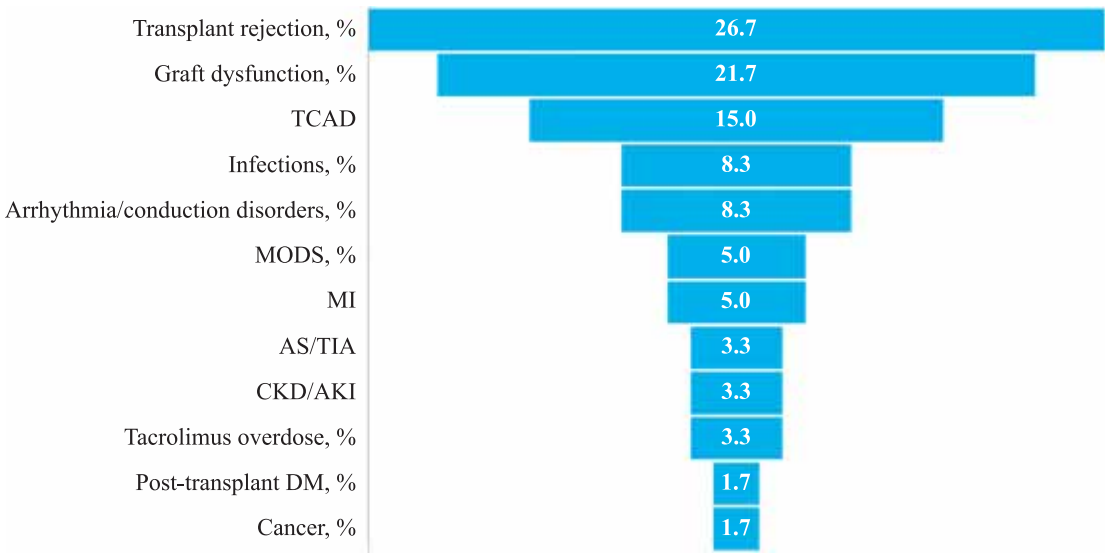

Fig. 4. Non-fatal complications during 1-year follow-up. TCAD, transplant coronary artery disease; MODS, multiple organ dysfunction syndrome; MI, myocardial infarction; AS, acute stroke; TIA, transient ischemic attack; CKD, chronic kidney disease; AKI, acute kidney injury, DM, diabetes mellitus

stable without significant fluctuations. According to Kaplan–Meier survival analysis, the median post-OHT survival among patients with more than 5 years of follow-up was 3.07 years [1.19; 6.09] (Fig. 7).

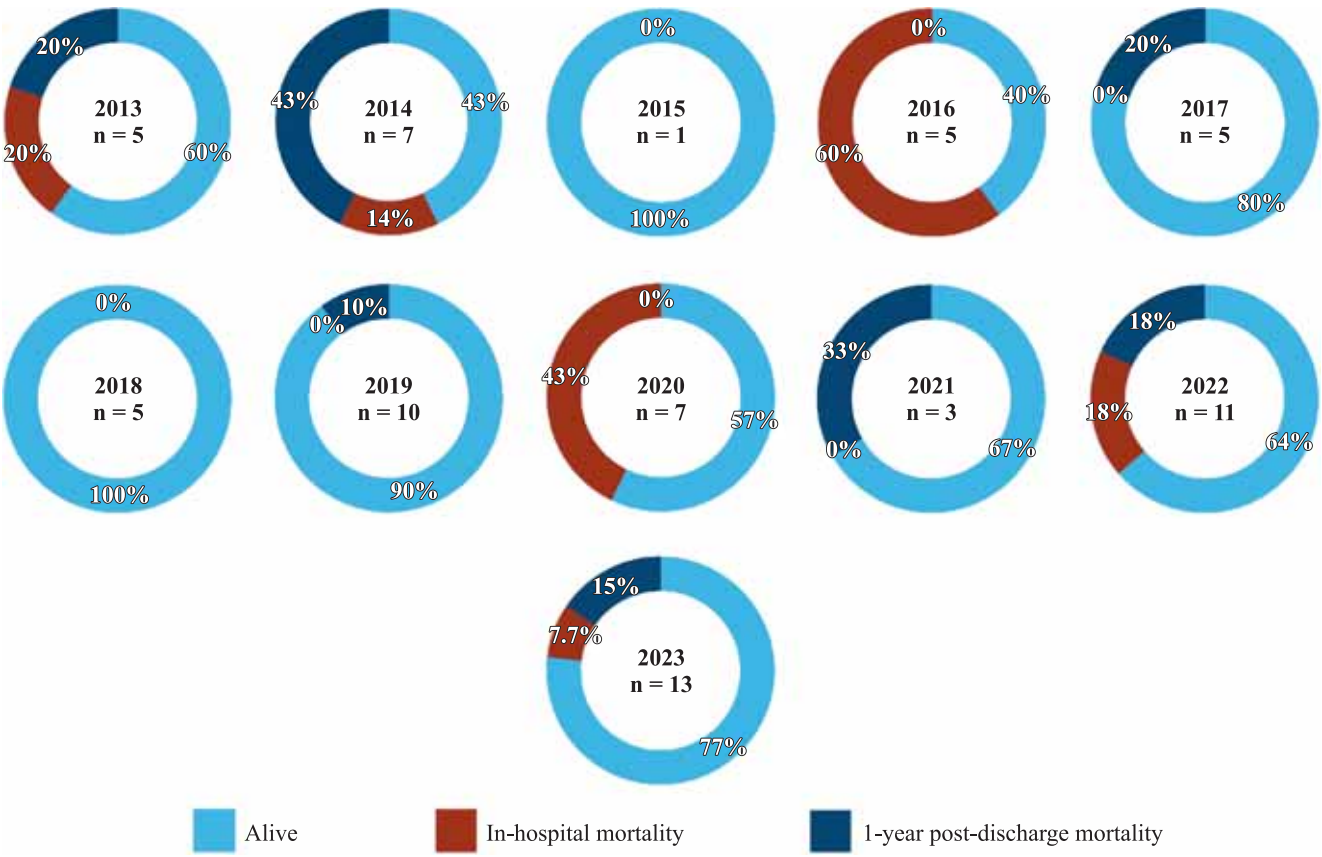

Fig. 5. Trends in 1-year patient mortality after heart transplantation in the period between 2013 and 2023

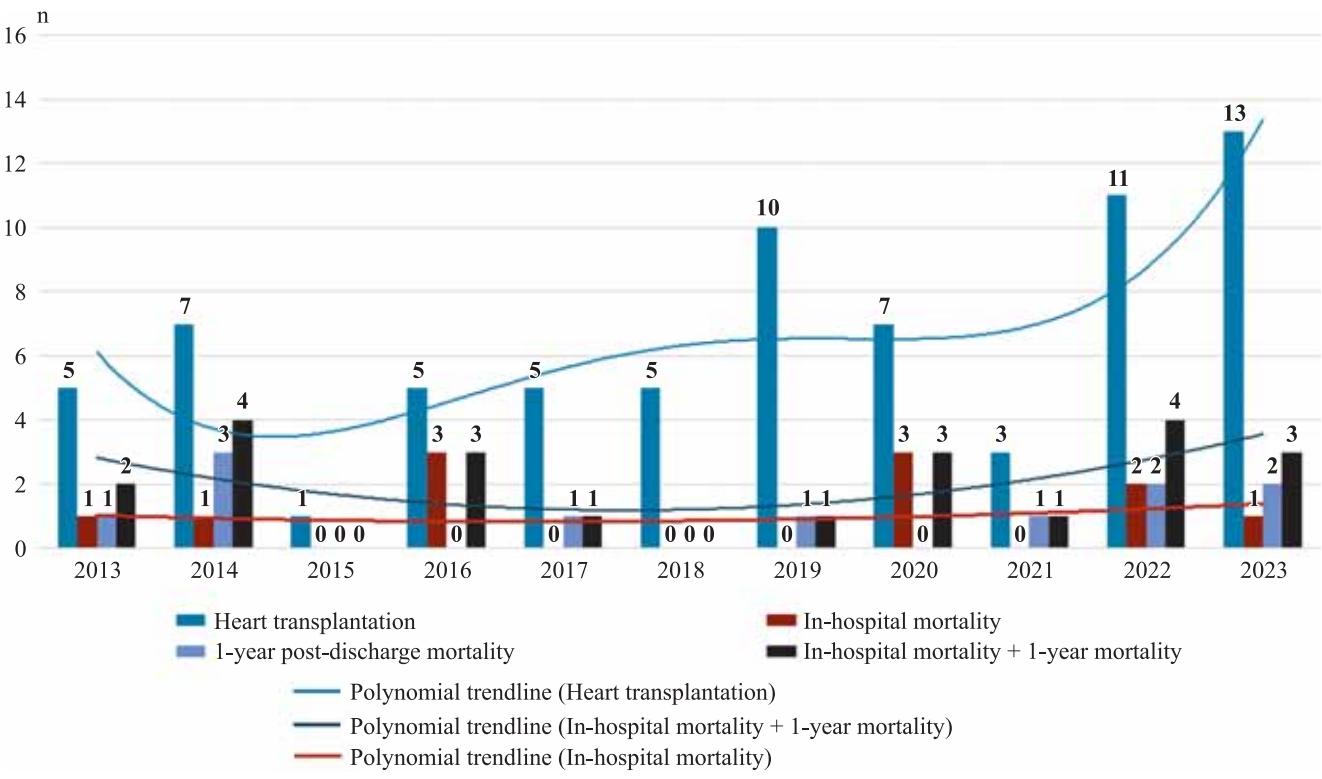

Fig. 6. Polynomial trend analysis of patient mortality after heart transplantation between 2013 and 2023

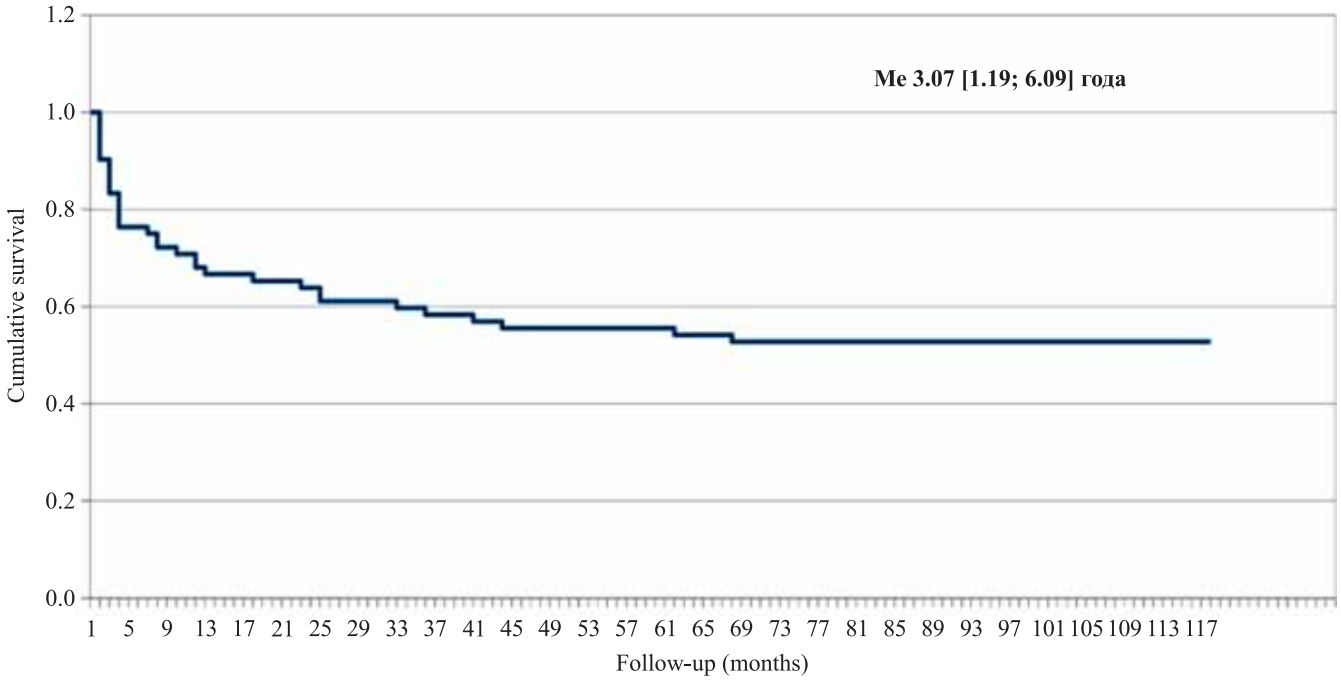

Fig. 7. Kaplan–Meier survival curve

DISCUSSION

Kuzbass is a major industrial region where circulatory system diseases (CSD) consistently rank as the leading cause of morbidity among the adult population, accounting for 20.6% of the total disease burden. According to data from Kemerovostat (a regional branch of the Federal State Statistics Service for Kemerovo Oblast), HF mortality in the region reached 532.7 per 100,000 population in 2023 – representing 38.2% of all deaths. However, this reflects an 18.8% decrease compared to 2022[2]. HF remains a prevalent and significant contributor to the CSD burden in Kuzbass, reaching critical levels in 2023 and highlighting the need for the widespread implementation of modern therapeutic and surgical interventions.

ESHF prevalence among HFrEF patients can reach up to 40%, making the evaluation for inclusion in HTWL a crucial consideration for this patient group [16, 17]. Globally, the HT rate in 2022 was about 1.5 transplants per million population[3], whereas in Russia, this figure stood slightly higher at 1.7 per million. Remarkably, Kuzbass recorded 5 HTs per million population in 2023, over 2.9 times the national average.

In 2023, 16 HT centers were operational across Russia, collectively performing 381 HTs – an increase of 73 procedures (+19.16%) compared to the previous year. From the beginning of 2004 through December 2023, a total of 3,275 OHT have been performed in the Russian Federation.[4]

The estimated need for OHT is typically calculated based on a benchmark of 10 HTs per million population annually. With a population of approximately 2.6 million in 2023, Kuzbass has a projected requirement for 25 OHT procedures per year. Despite a consistent influx of patients into HTWL and its regular updates, a persistent challenge remains the region's low donor activity. This is primarily attributed to factors such as the vast geographical size of Kuzbass and limited transportation accessibility, which in turn restricts the viability of donor organs due to prolonged heart anoxia time. The shortage of donors, coupled with a growing number of eligible candidates, continues to limit access to heart transplantation not only in many regions of the Russian Federation but globally as well [18–22].

According to global statistics, the highest mortality among OHT recipients is observed within the first 6 months post-transplant, with the hospital stay representing the most critical period [23]. In this context, survival outcomes at our center – 83.3% in-hospital survival, 84.7% 1-year survival, and 54.2% 5-year survival – are comparable to those reported by other prominent cardiac surgery centers across Russia. For instance, the Meshalkin National Medical Research Center in Novosibirsk documented an 82% in-hospital survival and 69% 5-year survival over a 10-year period encompassing 66 OHTs

[2] https://rustransplant.com/

[3] https://www.statista.com/

[4] Public Report, Sergey Gautier, December 2023; https://rustransplant.com/

[19]. Similarly, the Sklifosovsky Research Institute for Emergency Medicine in Moscow reported an 82% in-hospital survival from a cohort of 70 OHTs [20]. In Krasnodar, the Ochapovsky Regional Clinical Hospital achieved a 1-year survival of 83.1% based on 230 OHTs performed between 2010 and 2023 [21].

CONCLUSION

Modern pharmacological therapy, guided by current clinical guidelines, has significantly improved symptom control and survival rates in HF patients with preserved ejection fraction. However, the population of patients progressing to ESHF continues to grow. The successful outcomes achieved over a 10-year period at the Research Institute for Complex Issues of Cardiovascular Diseases highlight the necessity of further developing the HT program in Kuzbass, reinforcing its role as the gold standard for the treatment of ESHF. However, long-term success is contingent not only upon surgical expertise and institutional experience but also on comprehensive recipient preparation by a multidisciplinary team, effective organization of the donor network, and implementation of continuous, structured long-term follow-up for transplant recipients.

The authors declare no conflict of interest.

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