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Changes in Pulmonary Hemodynamics Resulted From Long-Term Mechanical Heart Support

Aim	To study the dynamics of right ventricular function and pulmonary hemodynamics in patients with pulmonary hypertension during mechanical circulatory support of the heart.
Material and Methods	A retrospective analysis was performed for 25 implantations of left ventricular assist device performed in the Meshalkin National Medical Research Center from 2006 through 2021. Mechanical assist devices were implanted in 21 men and 4 women (median age, 37.5 [29; 48] years). All patients had severe, NYHA functional class III–IV chronic heart failure refractory to the optimal drug therapy. Invasive measurements showed that mean pulmonary arterial pressure (MPAP) was 50 [44.5; 60] mm Hg, transpulmonary pressure gradient (TPG) was 16 [14; 19] mm Hg, and calculated pulmonary vascular resistance was 5.4 [4.9; 9] Wood units, which is an absolute contraindication (TPG >15 mm Hg or pulmonary vascular resistance >5 Wood units) for heart transplantation (HT).
Results	Duration of left ventricular support was from 17 to 948 days. For 12 (48%) patients, the HT was performed at 180–948 days following the implantation of left ventricular assist device; 3 patients are presently waiting for HT; 10 patients died from various complications, 6 of them died during the hospital stage. Already during the early stage after the implantation of the mechanical assist device, pulmonary hemodynamics significantly improved. Thus, in one week, MPAP decreased from 50 [44.5; 60] mm Hg to 36 [33; 38] mm Hg (p=0.012) whereas pulmonary vascular resistance decreased from 5.4 [4.9; 9] to 2.9 [2.4; 3.6] Wood units (p=0.008). Follow-up showed further improvement of pulmonary hemodynamics; at 1 month, MPAP was 29 [27; 30] mm Hg and by the time of HT, MPAP was 2.0 [24.8; 26.3] mm Hg (p=0.01), i.e., reached a normal level, which made it possible to perform HT. Similar dynamics was observed for other variables that reflected pulmonary hemodynamics.
Conclusion	Mechanical support of the heart is able to alleviate manifestations of pulmonary hypertension in most patients with end-stage heart failure. It is necessary to develop an algorithm for identifying the category of patients with a high risk of progression of right ventricular failure.

Keywords	Mechanical support of the heart; heart failure; pulmonary hypertension
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Heart transplantation (HT) is the gold standard for patients with end-stage chronic heart failure (CHF) and allows increasing the survival of patients with CHF, exercise tolerance, and improves the patient's quality of life [1]. Significant shortage of donor organs is the main challenge in the field of organ transplantation [2, 3]. Critical organ shortage leads to a long wait for HT (an additional excuse is needed for patients on the waiting list), and subsequently to the progression and decompensation of CHF. Pulmonary hypertension (PH), defined as mean pulmonary artery pressure (mPAP) at rest >25 mm Hg, affects about 72% of patients with end-stage CHF [4, 5]. Secondary PH is reversible at initial stages but can gradually become irreversible due to the pulmonary vascular remodeling. The threshold between irreversible and reversible PH is still not clearly defined, and there is no agreement on the amount of time to reach theoretical irreversibility, and the most accurate parameters to determine this status. Pharmacological tests using pulmonary vasodilators are used to determine the reversibility of PH. It is well known that PH is a risk factor for death in the early and late periods after HT [6–10]. According to these results, patients with irreversible PH determined by the American Heart Association criteria [6] (mPAP > 25 mm Hg, pulmonary vascular resistance (PVR) > 2.5 Wood units and transpulmonary pressure gradient (TPG) > 12 mm Hg after pharmacological test), should be excluded from the waiting list for HT.

Due to the active introduction of various left ventricular assist devices (LVAD) into clinical practice as a bridge to transplantation, in conditions of donor organ shortage, there is an opinion about the favorable effect of

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such devices on pulmonary hemodynamics in patients with PH and high PVR [11–13]. In this case, mechanical circulatory support helps to wait for a donor heart and prepares the recipient for HT. However, few patients receive mechanical support, and the available data are highly inconsistent.

The Academician Meshalkin National Medical Research Center has experience in the clinical use of various LVADs (INCOR, AVK-N, Heart Mate 2, and Stream Cardio).

Objective

Study changes in the right ventricular (RV) function and indicators of pulmonary hemodynamics in patients with PH during mechanical circulatory support.

Material and Methods

A retrospective analysis of the results of 25 cases of LVAD implantation performed in the Academician Meshalkin National Medical Research Center from 2006 to 2021. LVADs were implanted in 21 male and 4 female patients with the median age of 37.5 [29; 48] years.

All patients had severe CHF (NYHA FC III–IV) refractory to drug therapy. The cause of CHF was dilated cardiomyopathy and severe postinfarction CHF in 18 (72%) and 7 (28%), respectively. General characteristics of patients are provided in Table 1.

The preoperative examination included conventional clinical and biochemical analyses, electrocardiography, transthoracic echocardiography with measurement of left ventricular (LV) and RV parameters. Pulmonary artery pressure was measured directly, pulmonary hemodynamic parameters were assessed, and pharmacological test for PH reversibility was performed in all patients before LVAD implantation. Nitric oxide (NO) inhalation through a face mask was used as a pulmonary vasodilator. The test for PH reversibility was positive if PVR decreased to <2.5 Wood units and TPG was < 12 mm Hg.

LV failure and severe dilation of the left heart were the indications for LV mechanical support. Severe RV dysfunction with severe PH and severe multi-organ failure were absolute contraindications to this technique [3, 10].

The following baseline indicators of central hemodynamics were identified: left ventricular end-diastolic volume (LVEDV) 275 [229–339] mL; left ventricular end-systolic volume (LVESV) 228 [194.5–278.5] mL; LVEF 18 [14–19] %, preserved RV function, right ventricular fractional area change (RVFAC) 28 [25–40] % (see Table 1).

Invasive measurement of pulmonary hemodynamic parameters found mPAP 50 [44.5–60] mm Hg, TPG 16 [14–19] mm Hg, and estimated PVR 5.4 [4.9–9] Wood units (Table 2), which is an absolute contraindication (TPG >15 mm Hg or PVR > 5 Wood units) to HT [14]. During the PH reversibility test, only 5 (22%) patients had a decrease in PVR to an acceptable level (< 2.5 Wood units), and the others were found to have resistant PH.

Axial pumps were used in all cases analyzed: INCOR (n=12 (48%)); AVK-N (Russia; n=10 (40%)), Heart Mate 2 (n=1 (4%)), and a modification of AVK-N, Stream Cardio (Russia; n=2 (8%)). In all cases, the devices were implanted using the conventional technique, with the inflow graft anastomosis to the LV apex and the outflow graft anastomosed to the ascending aorta. The performance of the devices was estimated based on the technical characteristics of each specific model and the patient's anthropometrics (rotational speed of the impeller was 6000–8000 rpm with a flow rate of 3.5–5 L/min), with the correction of indicators relative to the opening of the aortic valve and the position of the interventricular septum, which were estimated using transesophageal echocardiography during the operation and using transthoracic echocardiography in the early postoperative period.

In the early postoperative period, all patients received direct anticoagulant heparin under the control of activated partial thromboplastin time (aPTT; 60–70 s), followed by the transition to indirect anticoagulant warfarin under the control of international normalized ratio (INR; 2.5–3.0) and antiplatelet agent acetylsalicylic acid 75–100 mg/day under the control of platelet aggregation (20–30%).

Drug therapy included the entire necessary list of drugs with target doses achieved, including a course of antibiotic therapy and drugs for the treatment of CHF: beta-blockers, angiotensin-converting enzyme inhibitors, cardiac

Table 1. Patient characteristics

Parameter	Value
Age, years	37.5 [29; 48]
Male	21 (84 %)
Female	4 (16 %)
Height, cm	175.5 [168; 177.8]
Weight, kg	80 [66; 83]
Body mass index, kg/m^2	25.5 [21.9; 29.7]
Body surface area, m^2	1.95 [1.95; 2.01]
Systolic BP, mm Hg	98 [95; 110]
Diastolic BP, mm Hg	67 [62; 71]
Mean pulmonary artery pressure, mm Hg	50 [44.5; 60]
Pulmonary vascular resistance, Wood units	5.4 [4.9; 9]
Cardiac index, L/min/m^2	1.72 [1.38; 1.99]
LVEDV, mL	275 [229; 339]
Left ventricular ejection fraction, %	18 [14; 19]
RVEDV, mL	60 [40; 74]
RVFAC, %	28 [25; 40]

BP, blood pressure; LVEDV, left ventricular end-diastolic volume; RVEDV, right ventricular end-diastolic volume; RVFAC, right ventricular fractional area change.

Table 2. Parameters of pulmonary hemodynamics before LVAD implantation

Parameter	Baseline (n = 25)	During NO inhalation (n = 25)
mPAP, mm Hg	46 [43; 49]	43 [36; 45]
TPG, mm Hg	16 [14; 19]	12 [6; 15]
PVR, Wood units	5.4 [4.8; 9]	3.3 [2.4; 3.5]

LVAD, left ventricular assist device; NO, nitric oxide; mPAP, mean pulmonary artery pressure; TPG, transpulmonary pressure gradient; PVR, pulmonary vascular resistance.

glycosides, mineralocorticoid receptor antagonists, diuretics, and antiarrhythmic drugs, if necessary [15].

At baseline, all patients underwent physical examination, pulmonary hemodynamic parameters were studied 1 ыweek after LVAD implantation and after a month being on mechanical support and immediately before HT.

Statistical analysis of the data obtained was performed using SPSS version 23.0. The categorical data are expressed as the absolute and relative values (n (%)) or the medians and the interquartile ranges (Me [25th percentile; 75th percentile]). The Wilcoxon non-parametric test was used to assess the significance of differences between pulmonary hemodynamics before mechanical support and with LVAD implanted. Differences were considered statistically significant at $p<0.05$.

Results

Most patients had no complications after associated with the implantation of LVADs.

RV function was assessed over time using transthoracic echocardiography (changes in RVFAC). One patient (4%) developed acute right ventricular failure (RVF) during the LVAD implantation procedure, which required emergency venoarterial extracorporeal membrane oxygenation; the pumping function of the RV was restored in 4 days, and additional mechanical support was discontinued. In the early postoperative period, 3 (12%) patients had RVF progression, which required prolonged inotropic support with dobutamine and infusion of drugs to reduce PCR (sildenafil).

In 5 cases, re-sternotomy hemostasis was performed due to accelerated drainage.

Subsequently, all patients with mechanical support showed a significant improvement in central hemodynamics during hospital stay: LVEDV decreased from 275 [229; 339] mL to 148 [127; 180] ml ($p = 0.0023$); LVESV – from 228 [194.5; 278.5] mL to 157 [140; 199] mL ($p=0.013$), and RV wall motion improved: RVFAC increased from 28 [25; 40] % to 36 [35; 38] % ($p=0.034$), which was mainly due to LV and pulmonary circulation unload [3] (Table 3).

The duration of left ventricular circulation support ranged from 17 to 948 days. Twelve patients (52%) underwent HT on day 180–948 after LVAD implantation; 3 patients are waiting for HT; 10 patients died of various complications (6 of whom died in hospital): 5 patient died of severe ischemic cerebrovascular accidents; 2 patients died due to from hemorrhagic stroke, 1 patient died of progressive RVF associated with atrial fibrillation; another death occurred during chronic septic process, one case was a technical malfunction of the LVAD, and patient died during the device replacement.

Significant improvements in pulmonary hemodynamics were observed early after the LVAD implantation. After 1 week, mPAP decreased from 50 [44.5; 60] mm Hg to 36 [33; 38] mm Hg ($p=0.012$) and PVR decreased from 5.4 [4.9; 9] to 2.9 [2.4; 3.6] Wood units ($p=0.008$). During the follow-up, further improvements in pulmonary hemodynamics were revealed: mPAP was 29 [27; 30] mm Hg in 1 month and 25.0 [24.75; 26.25] mm Hg by the time of HT ($p=0.01$), i.e., was normal. Similar changes were observed for other indicators of pulmonary hemodynamics (Figure 1).

There was a considerable improvement in the patients' clinical state, including the regression of CHF symptoms and the gradual restoration of liver and kidney function, in addition to a significant improvement in the parameters of central and pulmonary hemodynamics during mechanical circulatory support.

Discussion

According to various authors, 72% of patients with long-term left ventricular insufficiency develop PH and RVF [16]. At the early stage, PH develops from pulmonary vasoconstriction accompanied by arterial wall remodeling, which is characterized by medial hypertrophy and intimal fibrosis. Pathophysiological mechanisms include endothelial dysfunction, increased production of thromboxane-A2 and endothelin-1, and decreased availability of nitric oxide and prostacyclin. The activity of serine elastase causes the deposition of glycoprotein and smooth muscle cell hypertrophy and hyperplasia. Pulmonary venous congestion is often associated with a reactive increase in pulmonary circulation resistance, which results is increased TPG.

Drug therapy is not able to significantly improve the condition of the pulmonary vessels in these patients. PH that does not respond to vasodilators is a contraindication to orthotopic HT. This is due to an extremely high risk of developing RVF and high mortality [6, 9, 10, 16].

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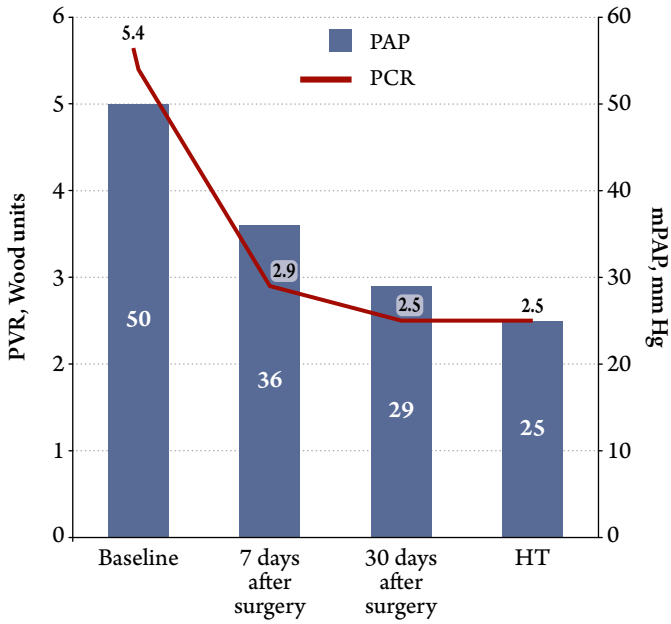
Table 3. Changes in the parameters of central hemodynamics during LVAD support

Parameter	Baseline	LVAD (1 week)	LVAD (1 month)
LVEDV, mL	275 [229; 339]	148 [127; 180]*	130 [115; 149]*
LVEF, %	18 [14; 19]	23 [20; 31]*	24 [20.5; 32.5]*
RVEDV, mL	60 [40; 74]	60 [39; 74]*	46 [44.5; 72.5]*
RVFAC, %	28 [25; 40]	36 [35; 38]*	37.5 [34; 44]*

*, p<0.05 versus baseline. LVAD, left ventricular assist device; LVEDV, left ventricular end-diastolic volume; LVEF, left ventricular ejection fraction; RVEDV, right ventricular end-diastolic volume; RVFAC, right ventricular fractional area change.

Figure 1. Changes in pulmonary hemodynamics during mechanical circulatory support



HT, heart transplant; mPAP, mean pulmonary artery pressure; PVR, pulmonary vascular resistance; PCR, pulmonary circulation resistance.

The reversibility of RVF due to LVAD implantation remains controversial and is widely discussed in the literature [13]. It was shown that 15–44% of patients develop, after LVAD implantation, severe RV dysfunction that often leads to death [8, 16]. In other papers, it was, on the contrary, convincingly shown that fixed PH and RVF were reversible during long-term mechanical circulatory support\[17, 18].

Several studies searched for selection criteria for patients with LVAD for the prevention of RVF [18–20], some papers report a decrease in PH during the LVAD support [15–25].

Usually, PH is considered a criterion for the development of RVF after LVAD implantation [21], and the decision on mechanical support, according to different authors, was based on the RV geometry [22]; this algorithm allowed reducing the risk of RVF progression to less than 10%. The influence of support modes, continuous or pulsatile flow on the reversibility of PH was not revealed [12, 17]. Although continuous flow devices typically discharge LV less than pulsatile flow devices, the reduction in pulmonary artery pressure is likely to depend on whether the device can decrease intracardiac pressure rather than the reduction in LV dimensions.

According to Mikus et al. [24], a significant decrease in the severity of PH during mechanical LVAD support was achieved within 6 months, and 70.37% of patients received a donor heart. Thus, LVAD support contributes significantly to the accessibility of HT for patients with severe PH.

Our observation confirms the research data that demonstrate the reversibility of PH accompanying end-stage CHF, when chronic mechanical support is used, despite possible LVAD-associated complications and taking into consideration 10–30% mortality after LVAD implantation reported in the literature [11, 19]. According to our data, RVFAC increased from 28 [25; 40] % to 36 [35; 38] % and mPAP decreased from 50 [44.5; 60] mm Hg to 29 [27; 30] mm Hg 1 month after LVAD implantation.

Normalization of intracardiac hemodynamics eliminates systemic circulatory disorders and improves pulmonary hemodynamics, which in some cases leads to the elimination of PH, and inoperable patients are returned to the waiting list for HT [7]. In 4 cases, patients had baseline mPAP > 50 mm Hg and PVR > 5 Wood units, which is a contraindication to HT. In 3 months after LVAD implantation, all patients had mPAP < 35 mm Hg, and they underwent successful HT. The logical conclusion of this retrospective analysis would be a large, multicenter, randomized, controlled, comparative study evaluating the best possible drug therapy and LVAD implantation. This would allow identifying the category of patients with the most likely favorable changes in pulmonary circulation during mechanical circulatory support and determining the exact risk factors for the progression of RVF and other adverse outcomes after the left ventricular assist device implantation.

Conclusion

Mechanical circulatory support can reduce the symptoms of pulmonary hypertension in most patients with end-stage heart failure. It is necessary to develop an algorithm for identifying patients with high risk of right ventricular failure progression.

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