DOI: 10.15825/1995-1191-2023-2-38-48

PERCUTANEOUS LEFT VENTRICULAR ASSIST DEVICE AS A SHORT-TERM MECHANICAL CIRCULATORY SUPPORT BEFORE HEART TRANSPLANTATION IN PATIENTS WITH HIGH PRE-TRANSPLANT PULMONARY HYPERTENSION (SERIES OF CLINICAL CASES)

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In certain categories of patients with end-stage heart failure (HF), short-term mechanical circulatory support (MSC) is successfully used as a mechanical "bridge" to heart transplantation (HTx). In predominantly left-ventricular (LV) dysfunction, the use of isolated coronary artery bypass, especially amidst high pulmonary hypertension (PH), seems to be a more physiological method of short-term MSC. **Objective:** to present the results of a series of clinical cases of the use of percutaneous left ventricular assist device (pLVAD) before HTx in potential recipients with predominantly LV dysfunction and concomitant high PH. **Materials and methods.** Three potential heart recipients with predominantly left-sided HF and high pre-transplant PH (pulmonary vascular resistance, PVR, 4.7–6.6 Wood units) who required MSC due to progression of hemodynamic disorders were included in the study. A standard venous extracorporeal membrane oxygenation (ECMO) cannula (26 F) was used for percutaneous left atrial-femoral artery (LA–FA) bypass. The cannula was passed from the transfemoral route through the interatrial septum into the left atrial cavity. A paracorporeal centrifugal pump provided blood injection through a standard arterial ECMO cannula (15 F). **Results.** pLVAD unloaded the left ventricle effectively (PCWP reduced from 27–32 to 15–20 mmHg), reduced pre-transplant PH (mean pulmonary artery pressure (mPAP) reduced from 45–53 to 28–33 mmHg) and improved systemic hemodynamics (cardiac index (CI) increased from 1.8–1.9 to 2.1–2.6 l/min/m^2 and mean arterial pressure (mAP) from 56–59 to 70–75 mmHg). All these created the prerequisites for subsequent successful HTx. Against the background of pLVAD, transpulmonary pressure gradient (TPG) decreased from 15–25 to 13–15 mmHg, and PVR decreased from 4.7–6.6 to 2.7–3.4 Wood units. pLVAD flow rate was 2.9–3.8 L/min or 1.38–1.83 L/min/m^2 at 4700–7100 rpm. pLVAD duration ranged from 4 (n = 1) to 7 (n = 2) days. All patients underwent successful HTx. **Conclusion.** pLVAD is a highly effective method of short-term MSC in potential recipients with predominantly LV dysfunction and concomitant high PH, leading to rapid regression of the dysfunction against the background of left ventricular unloading. This short-term MSC technique can be successfully realized using standard ECMO cannulas and centrifugal pumps of any modification, without requiring additional special equipment.

Keywords: heart transplantation, mechanical circulatory support, pulmonary hypertension.

INTRODUCTION

Despite the progress in development of technology and clinical application of implantable left ventricular assist device (LVAD) systems, short-term mechanical circulatory support (MSC) by mono-, biventricular or total cardiac bypass remains one of the options for assisted circulation, which is successfully used in certain categories of patients as a mechanical "bridge" to heart transplantation (HTx) [1, 2].

The leading method of short-term MSC before transplantation is venoarterial extracorporeal membrane oxygenation (VA-ECMO), which, regardless of the character of central hemodynamic disorder (biventricular, LV-predominant or RV-predominant acute heart failure (AHF) or decompensated heart failure (HF), provides simultaneous support of systemic circulation and pulmonary gas exchange [3]. However, in AHF or acute decompensated HF, VA-ECMO is a non-physiological method of MSC, whose use may be accompanied by aggravated LV systolic dysfunction, leading to LV overload and pulmonary edema [4].

In LV-dominant dysfunction, the use of isolated coronary artery bypass in LV dysfunction seems to be a more physiological method of short-term MSC [5]. As one of

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the short-term MSC options for this type of cardiac pumping disorder, a percutaneous LV assist system called the TandemHeart percutaneous left ventricular assist device (CardiacAssist, Inc; Pittsburgh, USA), providing drainage of blood from the left atrium (LA) using a specially designed cannula, passed through the femoral vein and interatrial septum into the LA cavity, and subsequent injection with an external centrifugal pump through an arterial cannula into the femoral artery, was developed and introduced into clinical practice [6]. The effectiveness of TandemHeart in AHF/acute decompensated HF of various genesis has been demonstrated; it has been shown to be used as a method of pre-transplant MSC in HTx [7]. Besides, the use of percutaneous LVAD (pLVAD) seems to be more reasonable in potential recipients with high pre-transplant pulmonary hypertension (PH). This allows to estimate its degree of regression against volumetric unloading of the left heart and to make a choice between expediency of urgent HTx or long-term MSC using implantable LVAD [8].

We have developed an alternative approach to pLVAD implementation, using standard venous and arterial ECMO cannulas and a centrifugal pump as a short-term MSC method in potential cardiac recipients. This may increase the availability of this assisted circulation method.

The aim of the study was to present the results of our own series of clinical observations of the use of pLVAD as a method of pre-transplant MSC in potential heart recipients with LV-dominant dysfunction and accompanying high pulmonary hypertension (PH).

MATERIALS AND METHODS

The pLVAD program as a method of short-term pre-transplant MSC in potential cardiac recipients began in 2022, representing 2.9% of all cases of short-term pre-HTx MSC in a given year (3 of 103). Short-term MSC was used in 103 (48.6%) of the 212 HTx performed in 2022.

Clinical, hemodynamic, and echocardiographic manifestations of LV-dominant dysfunction associated with high pre-transplant PH were considered indications for this pre-transplant MSC method (Table 1).

The study included 3 patients (all men); the main parameters of their clinical, laboratory and instrumental examination before pLVAD implantation are presented in Table 2.

The pLVAD was implanted under intubation anesthesia in an operating room equipped with a fluoroscopic unit. Transesophageal echocardiography was also used to control atrial septal puncture (ASP) and positioning of the venous ECMO cannula tip in the left atrial lumen. LA cannulation was performed from percutaneous transfemoral venous access similarly to the previously described proprietary LA drainage technique for left atrial (LA) unloading (decompression) during peripheral VA-ECMO [9, 10]. The difference was in passing a larger diameter venous ECMO cannula into the LA cavity through the ASP (a 26 F venous ECMO cannula was used in all cases). The main pLVAD insertion stages were:

1. Anesthesia induction and tracheal intubation.
2. Pulmonary artery catheterization (Swan–Ganz thermodilution catheter).
3. Insertion of transesophageal echocardiography probe
4. Right or left femoral artery puncture and catheterization (creating a guaranteed vascular access) to facilitate subsequent insertion of peripheral arterial ECMO cannula.
5. Femoral artery puncture and catheterization (single-lumen catheter, diameter 14 G) on the side of subsequent cannulation with an arterial ECMO cannula to ensure guaranteed lower limb perfusion (mandatory condition).
6. Right femoral vein puncture and passing through its lumen in ascending direction with a long transseptal Endrys steel needle for LA puncture, including a curved external needle (diameter 17 G, length 75 cm) and an internal needle (diameter 19 G) with a curved elongated tip 22 G.
7. Image-guided LA transseptal puncture with fluoroscopic and echocardiographic imaging (Fig. 1).
8. Insertion of a transseptal catheter (8.5 F in diameter) into the LA cavity (see Fig. 1).
9. Insertion of super stiff guidewire (Amplatz Super Stiff J-tip guidewire 260 cm) into the LA cavity and further into one of the pulmonary veins through a transseptal catheter (see Fig. 2).

Table 1

Indications for pLVAD as a method of mechanical circulatory support before heart transplantation

SBP <90 mmHg
mAP <60 mmHg
rAP <14 mmHg
PCWP >25 mmHg
CI <2.0 L/min/m^2
VIS >5
rAP/PCWP <0.8
TAPSE >1.8 см
TPG >12 mmHg
PVR >3.5 Woods unit
No left atrial thrombus
No stenosing atherosclerosis (over 25%) of lower limb arteries

Note: SBP, systolic blood pressure; mAP, mean arterial pressure; RAP, right atrial pressure; PCWP, pulmonary capillary wedge pressure; CI, cardiac index; VIS, vasoactive inotropic score; TAPSE, tricuspid annular plane systolic excursion; TPG, transpulmonary pressure gradient; PVR, pulmonary vascular resistance.

10. Sequential dilatation of the puncture hole in the ASP using dilators from venous ECMO cannulas of increasing diameter (18, 20, 22, 24 and 26 F).
11. Insertion of venous ECMO cannula through the ASP into the LA cavity (Fig. 3).
12. Insertion of arterial ECMO cannula into the femoral artery (15 F diameter).
13. Connecting the venous and arterial ECMO cannula to the LVAD paracorporeal circuit lines (Fig. 4).
14. Initiation of percutaneous paracorporeal LVAD.

Table 2

Data of clinical, laboratory and instrumental examination of potential heart recipients before pLVAD implantation (n = 3)

Patient	Parameter									
	Sex	Age (years)	Height (cm)	Weight (kg)	Body surface (m^2)	HF (stages)	NYHA	AF	VIS	Waiting list (days)
1	M	41	176	60	1.75	2B	4	No	12	7
2	M	40	184	87	2.11	2B	4	Yes	6	4
3	M	57	182	86	2.10	2B	4	No	8	15
Patient	Parameter									
	LA (cm)	LA (mL)	RV (cm)	LVEDV (mL)	LVEF (%)	MV (regurgitation grade)	TV (regurgitation grade)	TAPSE (cm)	HR	mAP (mmHg)
1	4.7	85	2.6	179	18	3.0	1.5	2.3	105	59
2	6.4	165	3.4	374	16	3.0	2.0	1.9	94	56
3	5.3	112	3.2	228	19	3.0	2.0	2.2	110	57
Patient	Parameter									
	rAP (mmHg)	PASP (mmHg)	PCWP (mmHg)	PCWP (mmHg)	CI, L/min/m^2	TPG (mmHg)	PVR (Woods unit)	pHv	BEv (mmHg)	Lactate (mmol/l)
1	8	69	53	32	1.9	21	6.4	7.38	–2.8	2.1
2	10	74	54	29	1.8	25	6.6	7.37	–0.4	1.9
3	11	62	45	27	1.8	18	4.7	7.44	1.6	2.4
Patient	Parameter									
	PvO_2 (mmHg)	SvO_2, %	Na (mmol/L)	Urea (mmol/L)	Creatinine (μmol/L)	Total bilirubin (μmol/L)	ALT (units/L)	AST (units/L)	Total protein (g/L)	INR
1	35.7	66.6	128	3.6	40.3	25.5	6.6	12.9	67.2	1.31
2	39.0	72.0	131	9.7	39.8	52.1	17.3	28.7	58.7	1.33
3	27.0	54.3	142	11.2	84.1	144.6	38.6	117.7	57.6	1.31

Note: HF, heart failure class according to Strazhesko–Vasilenko; NYHA, New York Heart Association (NYHA) functional class; AF, atrial fibrillation; VIS, vasoactive inotropic score; LA, left atrium; RV, right ventricle; LVEDV, left ventricular end-diastolic volume; LVEF, left ventricular ejection fraction; MV, mitral valve; TV, tricuspid valve; TAPSE, tricuspid annular plane systolic excursion; HR, heart rate; mAP, mean arterial pressure; RAP, right atrial pressure; PASP, pulmonary artery systolic pressure; mPAP, mean pulmonary artery pressure; PCWP, pulmonary capillary wedge pressure; CI, cardiac index; TPG, transpulmonary pressure gradient; PVR, pulmonary vascular resistance; ALT, alanine transaminase; AST, aspartate transaminase, INR, international normalized ratio.

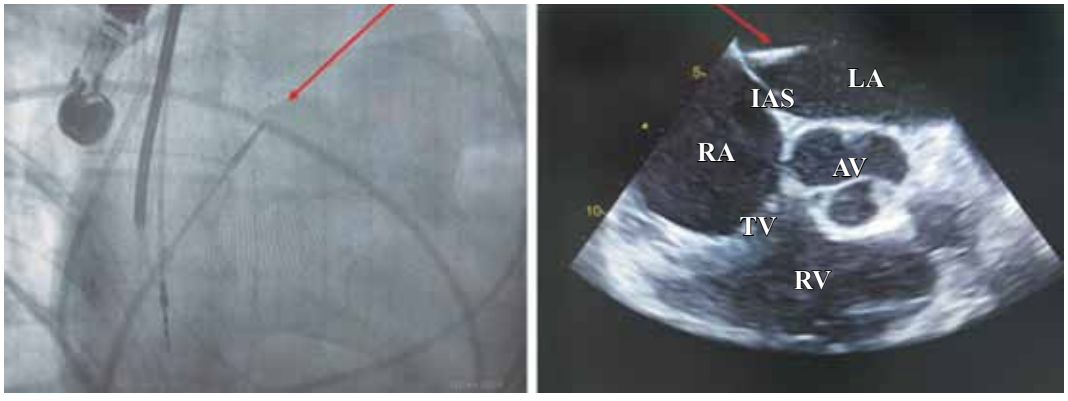

Fig. 1. Image-guided transseptal puncture for access to the left atrium and insertion of transseptal catheter (8.5 F diameter, indicated by red arrows) into its cavity using echocardiographic-fluoroscopic fusion imaging. AV, aortic valve; LA, left atrium; IAS, interatrial septum; RV, right ventricle; RA, right atrium, TV, tricuspid valve

Percutaneous LVAD was performed using Medos DeltaStream blood pump with a centrifugal pump (16 ml filling volume) (see Fig. 4).

Hypocoagulation was performed by continuous infusion of unfractionated heparin, maintaining the target level of activated clotting time at 140–160 sec.

Immediately before the start of cardiopulmonary bypass (CPB), during HTx surgery under transesophageal echocardiographic control, the venous ECMO cannula was brought down from the LA cavity to the level of the intrahepatic inferior vena cava, which corresponded to the 35–40 cm mark at the percutaneous entrance site. At this stage, blood was drained from left to right through the formed artificial defect in the ASP (Fig. 5). At all subsequent stages, including the CPB period and early postperfusion period, and taking into account the absence

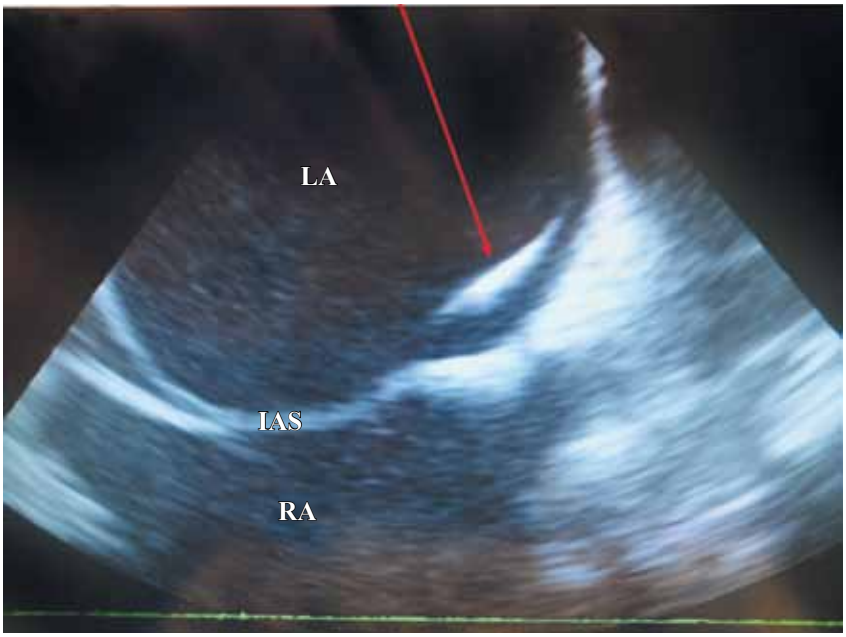

Fig. 2. Insertion of a super-stiff guidewire (Amplatz Super Stiff J-tip guidewire 260 cm, indicated by red arrow) into the left atrial cavity via transseptal catheter. LA, left atrium; IAS, interatrial septum; RA, right atrium

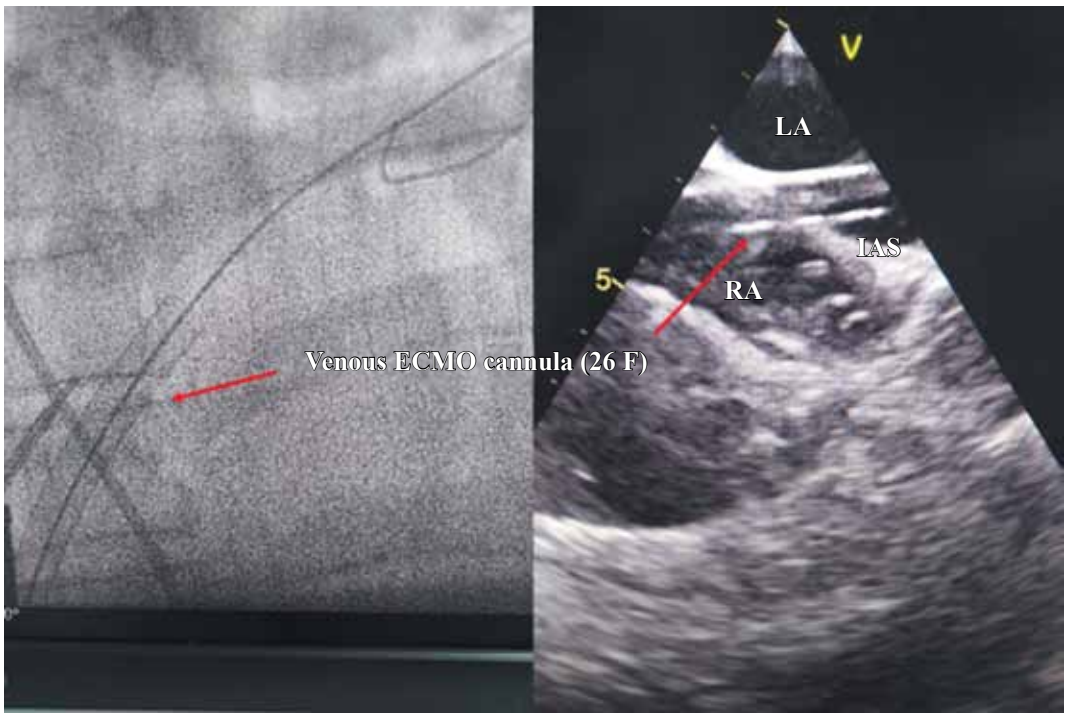

Fig. 3. Insertion of venous ECMO cannula (26 F) through the interatrial septum into the left atrial cavity. LA, left atrium; IAS, interatrial septum; RA, right atrium

of a membrane oxygenator in the circuit, extracorporeal blood flow was maintained at no more than 0.5 l/min to reduce admixture of venous blood pumped through the femoral arterial ECMO cannula into systemic circulation. In the case of severe heart graft dysfunction requiring post-transplant MSC, a membrane oxygenator was integrated into the extracorporeal circuit and thus switched to peripheral VA-ECMO. With a stable optimal cardiac graft function and no signs of delayed dysfunction of the transplanted heart, the venous and arterial ECMO cannulas were removed no earlier than 12 hours after the end of HTx surgery.

RESULTS

Uncomplicated LA puncture and cannulation was performed from percutaneous transfemoral venous access in all cases. Surgical intervention for percutaneous bypass lasted for 48 to 74 minutes. All patients were activated within 1 hour after the end of surgery and were on spontaneous breathing on oxygen therapy (4–6 l/min) until HTx. Percutaneous LVAD unloaded the left heart effectively (PCWP reduced from 27–32 to 15–20 mmHg), pre-transplant PH reduced (mPAP reduced from 45–53 to 28–33 mmHg) and systemic hemodynamics improved (CI increased from 1.8–1.9 to 2.1–2.6 l/min/m^2 and mAP from 56–59 to 70–75 mmHg), which set the stage for subsequent successful HTx (Table 3). Against the background of pLVAD, TPG decreased from 21 to 13 (patient 1), from 25 to 15 (patient 2), from 18 to 14 mmHg (patient 3), PVR from 6.4 to 2.9 (patient 1), 6.6 to 3.4 (patient 2), 4.7 to 2.7 Wood units (patient 3). The pLVAD flow rate was 2.9–3.8 L/min or 1.38–1.83 L/min/m^2 at 4700–7100 rpm. pLVAD lasted for 4 (n = 1) to 7 (n = 2) days.

The patients underwent HTx from male donors 54 (patient 1), 40 (patient 2), and 46 (patient 3) years of age with ischemia time of 167, 150, and 160 minutes, respectively. Two patients (patient 1 and 2) did not show early cardiac graft dysfunction. Hence, the extracorporeal pre-transplant LVAD circuit was removed 5 and 7 hours after the end of the surgical intervention, respectively. The highest dopamine and adrenaline doses in the early posttransplant period in both patients were 6 μg/kg/min and 40 ng/kg/min, respectively. Patient 3 had hemodynamic and echocardiographic signs of biventricular cardiac graft dysfunction, which required posttransplant

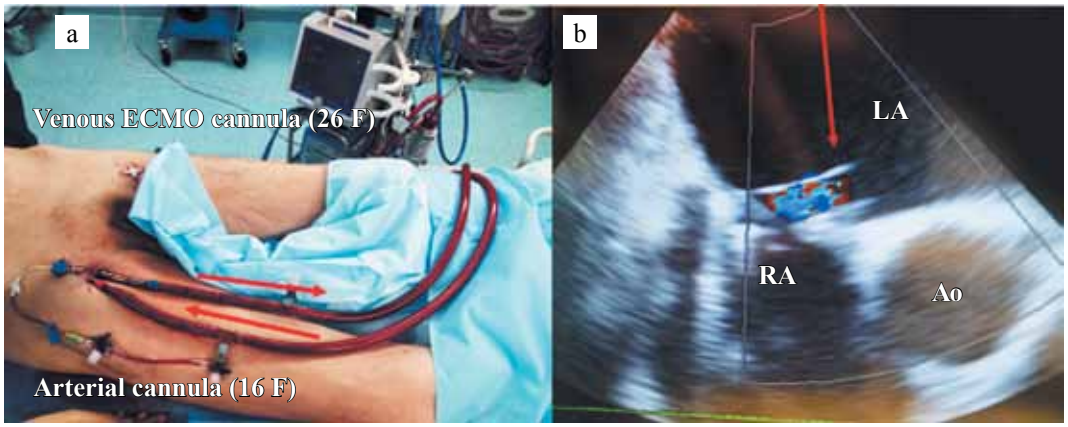

Fig. 4. Patient with pLVAD (a, red arrows indicate blood flow direction) and blood drainage from left atrium into venous ECMO cannula (26 F) (b, indicated by red arrow). Ao, aorta; LA, left atrium; RA, right atrium

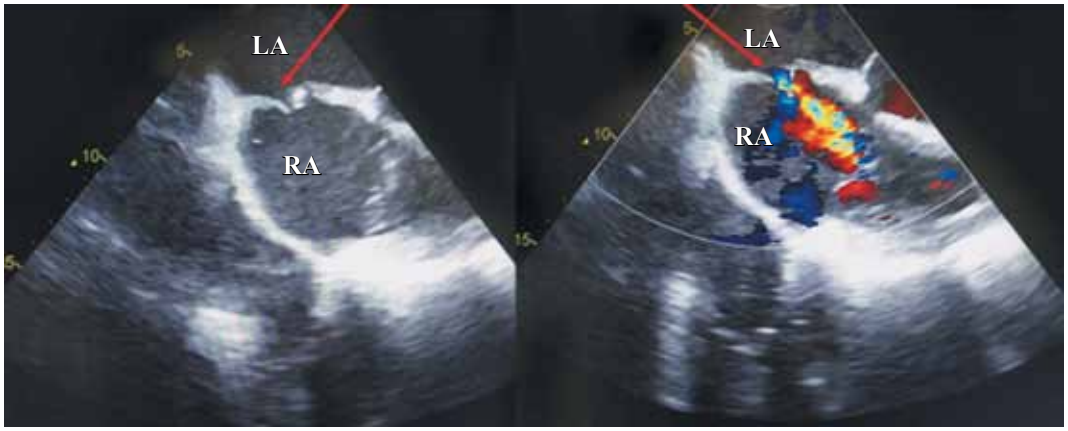

Fig. 5. Atrial septal defect (indicated by red arrows) formed after removal of drainage cannula from the left atrial cavity, with left-to-right blood shunt

MSC. A membrane oxygenator was integrated into the extracorporeal circuit of the pre-transplant LVAD, and it was transformed into a peripheral VA-ECMO, whose blood flow rate, centrifugal pump rpm and duration of application were 2.7 L/min, 6800 per min and 3 days, respectively. All patients survived and were discharged from the hospital. At the end of the follow-up period (December 31, 2022), all patients were alive. The follow-up period for the patients was 119 (patient 1), 90 (patient 2), and 35 (patient 3) days.

DISCUSSION

Despite the fact that according to ISHLT, over 50% of HTx are performed in patients with long-term pre-transplant MSC by implanted LVAD method, individual transplant centers, usually having a large annual volume of heart transplants, also adopt the practice of urgently performing them in patients with short-term MSC [11]. VA-ECMO remains the most commonly used short-term MSC before HTx with a predominant peripheral technique for its implementation [12]. VA-ECMO, simultaneously improving systemic blood flow and gas exchange, ensures survival to emergency HTx in most patients [13]. However, being a non-physiological method of MSC in patients with AHF or acute decompensated HF, which includes the majority of potential heart recipients, VA-ECMO can be accompanied by exacerbation of LV dysfunction, leading to left heart overload, pulmonary vascular congestion and pulmonary edema [14]. To resolve this pathological condition, various mechanical LV unloading methods have been proposed [15].

In potential cardiac recipients with LV-dominant failure (e.g., coronary heart disease), the use of isolated LVAD appears to be a more physiological and effective method of pre-transplant MSC. However, implementation of paracorporeal LVAD requires sternotomy with central cannulation of the left atrium or left ventricle and aorta. This increases the traumaticity not only of the LVAD, but also of subsequent HTx, which becomes a repeated surgical intervention with increased risk of peritransplant complications and death [17].

Table 3

Central hemodynamic parameters before and against the background of pLVAD (n = 3)

Parameter	Study phase	Patient 1	Patient 2	Patient 3
HR (mins)	Before LVAD	105	94	110
	Day 1 after LVAD	89	91	93
	Before HTx	84	90	88
mAP (mmHg)	Before LVAD	59	56	57
	Day 1 after LVAD	69	73	72
	Before HTx	70	71	75
rAP (mmHg)	Before LVAD	9	10	11
	Day 1 after LVAD	10	9	10
	Before HTx	8	8	9
PCWP (mmHg)	Before LVAD	53	54	45
	Day 1 after LVAD	40	38	32
	Before HTx	33	33	28
PCWP (mmHg)	Before LVAD	32	29	27
	Day 1 after LVAD	22	19	18
	Before HTx	20	18	15
CO (L/min)	Before LVAD	3.3	3.8	3.8
	Day 1 after LVAD	4.5	4.3	4.7
	Before HTx	4.5	4.4	4.9
CI, L/min/m^2	Before LVAD	1.9	1.8	1.8
	Day 1 after LVAD	2.6	2.0	2.2
	Before HTx	2.6	2.1	2.3
TPG (mmHg)	Before LVAD	21	25	18
	Day 1 after LVAD	18	19	14
	Before HTx	13	15	13
PVR (Woods unit)	Before LVAD	6.4	6.6	4.7
	Day 1 after LVAD	4.0	4.4	3.0
	Before HTx	2.9	3.4	2.7

Note: HR, heart rate; mAP, mean arterial pressure; RAP, right atrial pressure; mPAP, mean pulmonary artery pressure; PCWP, pulmonary capillary wedge pressure; CO, cardiac output; CI, cardiac index; TPG, transpulmonary pressure gradient; PVR, pulmonary vascular resistance.

The introduction into clinical practice of pLVAD technique implemented as TandemHeart pLVAD was aimed at increasing efficiency and reducing MSC traumaticity in patients with LV-dominant AHF or decompensated HF [17]. The method is based on LA transfemoral transvenous cannulation (21 F diameter) with a specially designed cannula with a beak-shaped, curved dilator to facilitate passage through the atrial septum. Arterial blood drained from the LA is pumped using a centrifugal pump through the femoral cannula (15 F diameter) into the systemic circulation [18]. LA cannulation is performed under fluoroscopic and echocardiographic control in an X-ray operating room. The pLVAD procedure lasts for 14 to 25 minutes [19].

The successful experience of using TandemHeart pLVAD as a highly effective short-term MSC before HTx as well as in severe cardiac transplant rejection has been demonstrated [7]. There is also accumulated experience of successful application of this short-term MSC technique in the treatment of patients with acute fulminant myocarditis of various etiology, myocardial infarction, as well as a method of preventive MSC during endovascular coronary interventions and transcatheter aortic valve replacement of high operational risk [20, 21]. TandemHeart pLVAD was used as a short-term MSC before implantation of long-term LVAD (bridge to bridge) systems [8].

Like any high-tech treatment method, short-term MSC realized using TandemHeart pLVAD has both advantages and disadvantages related to the risk of various complications. Transfemoral transvenous LA cannulation requires to be performed in the X-ray operating room conditions and by X-ray endovascular surgeons with extensive experience in transseptal LA puncture, considering the risk of aortic and atrial perforation. LA cannulation is associated with the risk of thrombosis at the LA cannula site, which increases the risk of cardioembolic complications [22]. If the drainage cannula depth into the LA cavity is insufficient, it can be dislocated into the right atrium, which will result in venous blood injection into systemic blood flow that will require either MSC termination or its transformation into VA-ECMO by integrating into the membrane oxygenator circuit [22]. In addition, there is a risk of lower limb ischemia due to cannulation of the return (arterial) cannula of the femoral artery. Possible complications include bleeding and purulent inflammation in the femoral cannulation site, arteriovenous fistula, femoral nerve damage, lymphocele, etc. [23]. The incidence of vascular complications with percutaneous LVAD ranges from 4.0 to 9.7 [24].

Introduction of transcatheter, minimally invasive LVAD techniques (e.g., Impella) has led to a reduction in the use of TandemHeart pLVAD [1]. However, the use of this MSC method seems still relevant in potential cardiac recipients with LV-dominant intracardiac hemodynamic disorders when implementing emergency HTx programs using short-term assisted circulation techniques.

Given the absence of a registered TandemHeart pLVAD in the Russian Federation, we assumed that this short-term MSC technique can be successfully implemented by using a standard venous ECMO cannula of the required size and design, which can be performed from transfemoral venous access through the right atrium and ASP into the LA cavity, provided there are radiological endovascular surgeons with experience in transseptal LA puncture. We have chosen the Medos venous ECMO cannula, which, unlike other counterparts, has no lateral drainage holes and will provide isolated drainage of arterial blood from the LA without admixture of venous blood from the right heart and inferior vena cava. In addition, one of the indications for pLVAD use was acute decompensated HF with LV-predominant intracardiac hemodynamics, requiring short-term MSC, and accompanied by high, borderline pre-transplant PH.

A series of presented clinical cases demonstrated the high hemodynamic efficiency and safety of this technique of pre-transplant short-term MSC by percutaneous paracorporeal LVAD. Application of this MSC method not only improved systemic hemodynamics, but also regressed PH to the level allowing to perform HTx by orthotopic technique effectively without development of severe right ventricular dysfunction of the heart transplant. In the absence of rapid PH regression, percutaneous LVAD can be used as an intermediate method of assisted circulation before implantation of a long-term LVAD (bridge-to-bridge) system [25]. If early dysfunction of the transplanted heart occurs, the pre-transplant LVAD circuit can be used for post-transplant VA-ECMO after integration of the membrane oxygenator. Our presented experience of short-term MSC by percutaneous LVAD can be used in the domestic medical practice not only as auxiliary circulation before HTx, but also in other clinical situations accompanied by critical LV dysfunction.

CONCLUSION

Percutaneous left ventricular assist device is a highly effective short-term MSC method in potential heart recipients with dominant LV dysfunction and concomitant high pulmonary hypertension, leading to rapid regression of the dysfunction against the background of LV unloading. Depending on the clinical situation, pLVAD can be considered a method of short-term MSC before urgent HTx or implantation of long-term MSC systems. This short-term MSC technique can be successfully implemented using standard ECMO cannulas for femoral transfemoral cannulation and centrifugal pump of any modification, without requiring additional special equipment.

The authors declare no conflict of interest.

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The article was submitted to the journal on 12.01.2023