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HEMODYNAMIC EVALUATION OF PULSATILE-FLOW GENERATING DEVICE IN LEFT VENTRICULAR ASSIST DEVICES

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Objective: to investigate the efficiency of a device that generates pulsatile flow during constant-speed axial-flow pump operation for use in left ventricular assist devices. **Materials and methods.** The pulsatile flow-generating device, hereinafter referred to as "pulsator", consists of a variable hydraulic resistance made in the form of a hull. A tube of elastic biocompatible material featuring an inner diameter of 11 mm is installed inside it. In the systolic phase of the left ventricle, due to systolic pressure, the elastic tube is fully opened, minimizing resistance to blood ejection. In the diastolic phase, due to suction action of the flow pump operating in constant revolutions, the elastic tube partially closes, creating additional hydraulic resistance to blood flow, which leads to reduced diastolic aortic pressure. Comparative assessment of axial-flow pump operation in pulsating and non-pulsating modes was carried out on a hydrodynamic stand that simulated the cardiovascular system. The following indices were calculated: arterial pressure pulsation (I_p), in-pump flow pulsation (ΔQ), energy equivalent pressure (EEP) and surplus hemodynamic energy (SHE). **Results.** When comparing axial-flow pump operation in pulsatile and continuous mode, arterial pressure pulsation index, in-pump pulsation index, and SHE index increased by 2.13 ± 0.2, 3.2 ± 0.2, and 2.7 ± 0.15 times, respectively, while EER index remained unchanged.

Keywords: heart failure, left ventricular assist devices, continuous flow, pulsatile flow, hydrodynamic stand, axial-flow pump.

INTRODUCTION

In clinical practice, continuous-flow circulatory assist devices have replaced pulsatile-flow circulatory assist devices, when applied as a bridge to transplantation and targeted therapy. This is due to a number of advantages of continuous-flow pumps (CFPs) over pulsatile-flow pumps (PFPs): they are placed inside the thoracic cavity, have small weight-and-size characteristics, better power consumption and performance characteristics. It promoted an increase in the number of various CFP models and their mass distribution, which led to an increase in these devices and considerable increase in survival rate among patients with end-stage heart failure (HF) [1–3]. However, when studying a large number of CFPs in conditions of long-term use, a number of complications, which were a consequence of low arterial pulsation, were revealed. These include gastrointestinal bleeding, arteriovenous malformation, aortic insufficiency, etc. [4–6].

In connection with the search for solutions to reduce complications, a number of works have shown the need to increase the level of pulsatile flow not only in extracorporeal systems, but also in implantable systems, including left and right ventricular assist devices (LVAD and RVAD) [7–9]. In the last decade, many researchers have mostly focused on developing flow pulse wave enhancement methods using the principle of electrocardiogram (ECG)-synchronized modulation of pump velocity [10–14]. The main disadvantage of this method is inertia of most circulatory assist pumps, which did not allow to obtain a given arterial pulsation especially when the heart rate (HR) was increased. Besides, there are still open questions related to the level of hemolysis in the blood in the CFP speed modulation mode [15].

To increase the level of pulsation in CFPs, we earlier proposed a method using parallel connection to the pump (input–output) of the recirculation channel [16–17]. In this case, the system operation was provided by a controlled electromechanical valve installed in the recirculation channel, which required relatively high power to close the recirculation channel in the systolic phase [18].

The present work shows a more efficient version of the device for enhancing pulsatile flow in CFPs, which has many potential advantages, the main one being realization of self-sustainable operation (without external control sources and heart rhythm signals) and formation of ECG-synchronized pulsatile flow and pressure.

MATERIALS AND METHODS

Pulsatile flow enhancement is based on connection to the CFP inlet line of the pulsator (Fig. 1) made in the form of a hull (1) with a tube of elastic biocompatible

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material (polyurethane) with inner diameter of 11 mm (2) installed inside it. An air cavity (4) is formed between the body (1) and the tube (2), which communicates with the atmosphere through the holes (3) in the hull (1) (Fig. 1, a).

The pulsator works in the following way: in systolic phase, due to left ventricular (LV) pressure and CFP work, the elastic tube opens fully, reducing pressure drop inside the elastic tube (2), and forming maximum flow and pressure amplitude.

In diastolic phase, when LV pressure and CFP suction action decrease, pressure inside elastic tube (2) decreases, resulting in partial closure of elastic tube and an increase in hydraulic resistance to flow from the LV to the CFP, which leads to a decrease in arterial diastolic pressure. Thus, an ECG-synchronized pulsatile flow and pressure (co-pulsation mode) is formed at the CFP outlet.

At the first stage of the research, we assessed the efficiency of the pulsator on a hydrodynamic stand (HS) when connecting an axial pump in the left ventricular assist mode of the heart. The design of the HS used was previously described in Buchnev A.S. et al. [16]. Fig. 2 shows the general view of the HS, which consists of an axial-flow CFP (1) – a portable auxiliary circulatory assist device (AVK-N, Russia), pulsator (2) installed in the inlet line (3) of the CFP. A Medos 80 mL pulsatile pump (Medos, Germany) with pneumatic drive SINUS-IS (MZEMA, Russia) was used as the LV heart simulator (5). CFP outlet (4) was connected to the aorta, designed as a reservoir with an air cushion (6) associated with systemic peripheral resistance (10) and venous reservoir

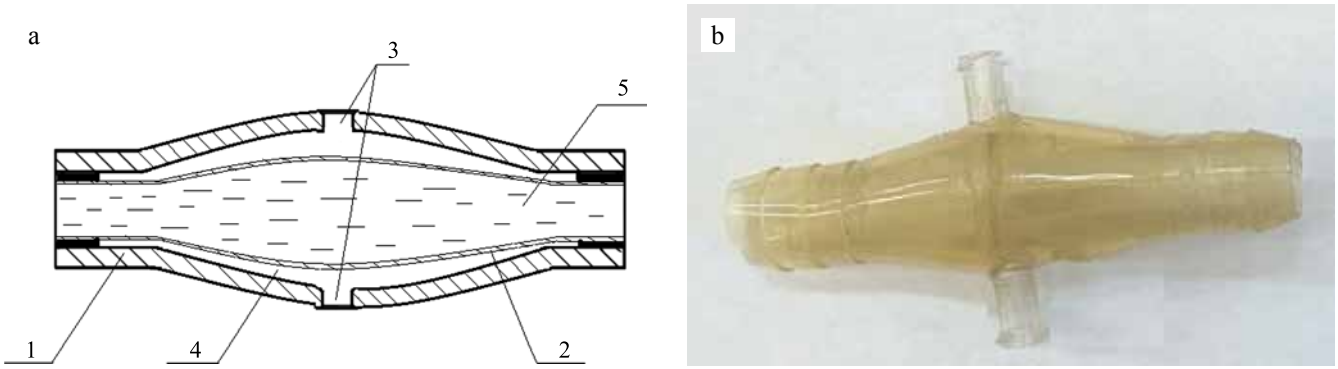

Fig. 1. a, schematic diagram of pulsator (1, hull; 2, elastic tube; 3, holes; 4, air cavity; 5, flow path); b, external view of pulsator

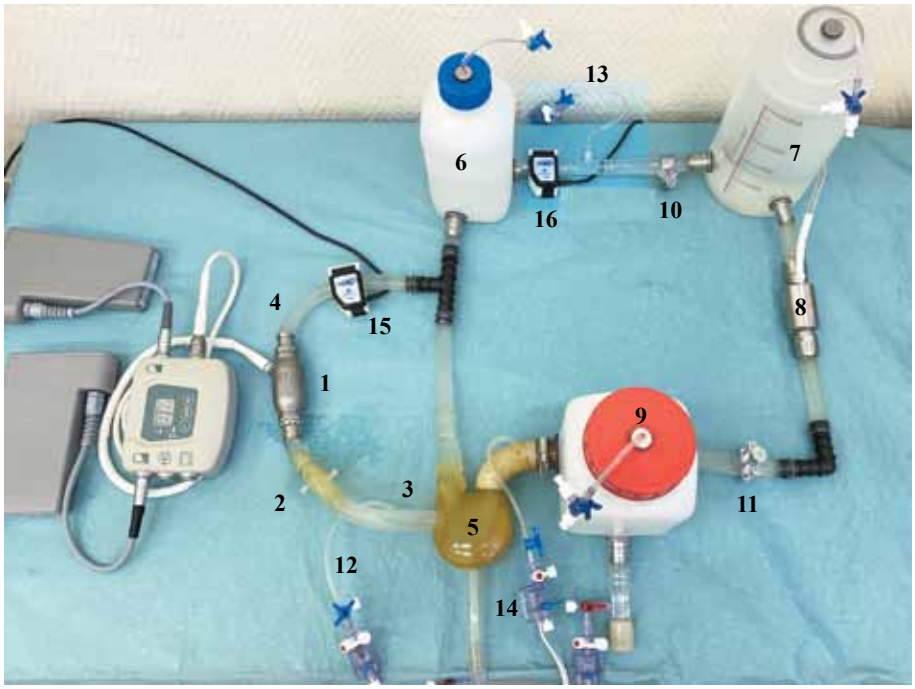

Fig. 2. Hydrodynamic stand: 1, non-pulsatile flow pump (AVK-N); 2, pulsator; 3, inlet cannula; 4, outlet cannula; 5, artificial heart ventricles; 6, aortic reservoir; 7, venous reservoir; 8, non-pulsatile flow pump (VISH); 9, left atrium; 10, systemic hydraulic resistance; 11, pulmonary resistance; 12–14, pressure sensors; 15, 16, flow sensors

(7). As the right ventricle of the heart, a mockup sample of implantable axial-flow pump VISH (Russia) was used (8). The flow in the pump and aorta was measured using ultrasonic flowmeter T402 (Transonic Systems Inc., USA) (15, 16). Pressures in LV, aorta, and left atrium were measured using pressure transducers (Edwards Life, USA) (12–14). We preliminarily simulated normal conditions on hydrodynamic stand, which were set by changes in LV pneumatic pressure, parameters of aortic capacity, systemic and pulmonary resistance in accordance with the Pantalos et al. guidelines [19], systemic flow was 5.0 ± 0.2 L/min, arterial pressure 118/81 ± 5 mm Hg. To record hemodynamic parameters, we used the multi-channel module Angioton (Biosoft-M, Russia) with recording on a personal computer in Pumpax program (Biosoft-M, Russia).

Heart failure mode was set by changes in LV cardiac pressure and systemic peripheral resistance without changes in aortic capacity. The following parameters were set: mean aortic flow 2.7 ± 0.3 L/min and aortic pressure 80/55 ± 5 mm Hg. When CFP was turned on, the pressure in the artificial ventricle was set at 60 ± 5 mm Hg (Frank-Starling Law). After that, continuous-flow and pulsatile-flow pump operation modes were started.

The aortic pulsation obtained during the experiments was analyzed based on the pulsatility index (Ip) calculated by the formula:

$$I_p = (P_{ao(max)} - P_{ao(min)}) / P_{ao(avr)}, \quad (1)$$

where $P_{ao(max)}$ is arterial systolic pressure, $P_{ao(min)}$ is arterial diastolic pressure and $P_{ao(avr)}$ is mean arterial pressure.

Surplus hemodynamic energy (SHE) was calculated using the Shepard equation [20]:

$$SHE(ergs/cm^3) = 1332 \times (EEP - P_{ao(avr)}), \quad (2)$$

where the energy equivalent pressure (EEP) was calculated by the formula:

$$EEP(mmHg) = \int_{t1}^{t2} fp\,dt \,/ \int_{t1}^{t2} f\,dt, \quad (3)$$

where f(t) is the aortic flow time curve for a fixed period of time, p(t) is the aortic pressure time curve for the same time period.

STUDY RESULTS

Fig. 3 shows the hemodynamic parameters taken on a HS in simulations of physiological norm (a) and heart failure (b). In the norm, systemic flow rate was 5.0 ± 0.2 L/min and blood pressure 118/81 ± 5 mm Hg. In HF, systemic flow rate was reduced to 2.7 ± 0.2 L/min and blood pressure to 80/55 ± 5 mm Hg.

Fig. 4 (a, b) shows hydrodynamic parameters when the pump is operating in continuous (n = 9200 rpm) and pulsatile modes (n = 10,000 rpm). At the same time,

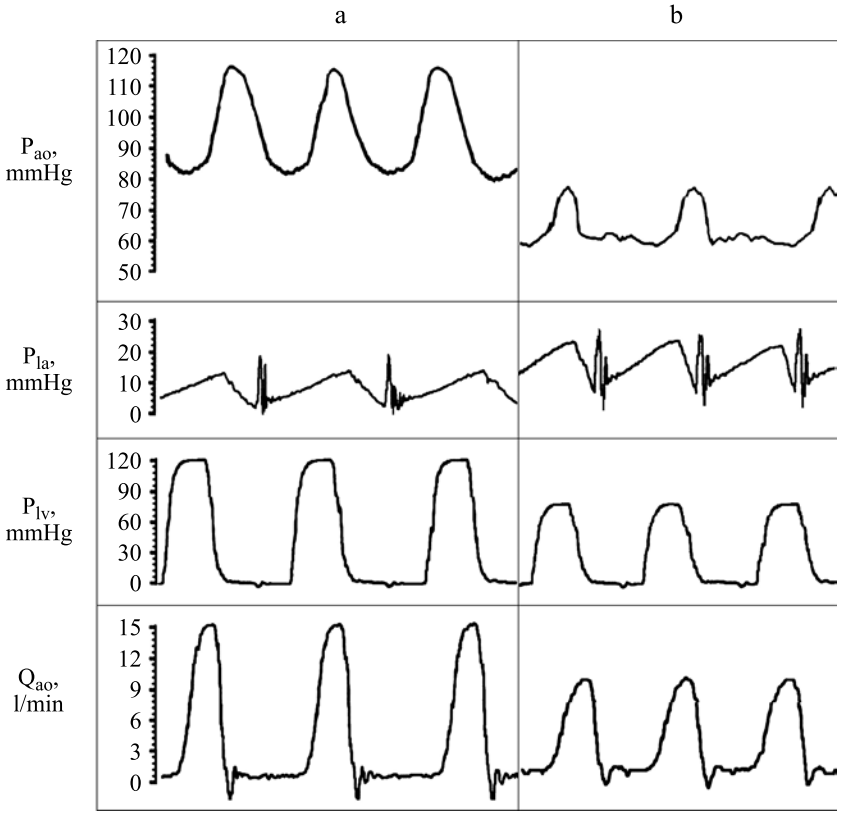

Fig. 3. Comparative results of hemodynamic parameters in norm (a) and in heart failure (b). (P_{ao}, arterial pressure; P_{la}, left atrial pressure; P_{lv}, left ventricular pressure; Q_{ao}, systemic blood flow)

pump speed during pulsator operation was increased to maintain mean arterial pressure and systemic flow rate at the same level as during continuous operation.

Hemodynamic parameters during CFP operation in continuous mode: systemic flow rate (5.0 ± 0.2 l/min), arterial pressure (95 ± 5 mm Hg), arterial pressure pulsation (14 ± 1 mm Hg) and in-pump flow pulsation 3.0 ± 0.2 l/min (Fig. 4, a). Hemodynamic parameters during CFP operation with pulsator: systemic mean flow rate 5.0 ± 0.2 l/min and mean arterial pressure 95 ± 5 mm Hg. At the same time, aortic pulsation increased to 30 ± 5 mm Hg, and in-pump flow pulsation was 9.5 ± 0.2 l/min (Fig. 4, b).

Table shows the comparative results of the main hydrodynamic indicators and the Ip, EEP and SHE indices for pump operation in continuous-flow and pulsatile-flow modes.

Thus, the Ip index during CFP operation with a pulsator increased 2-fold compared to the continuous mode,

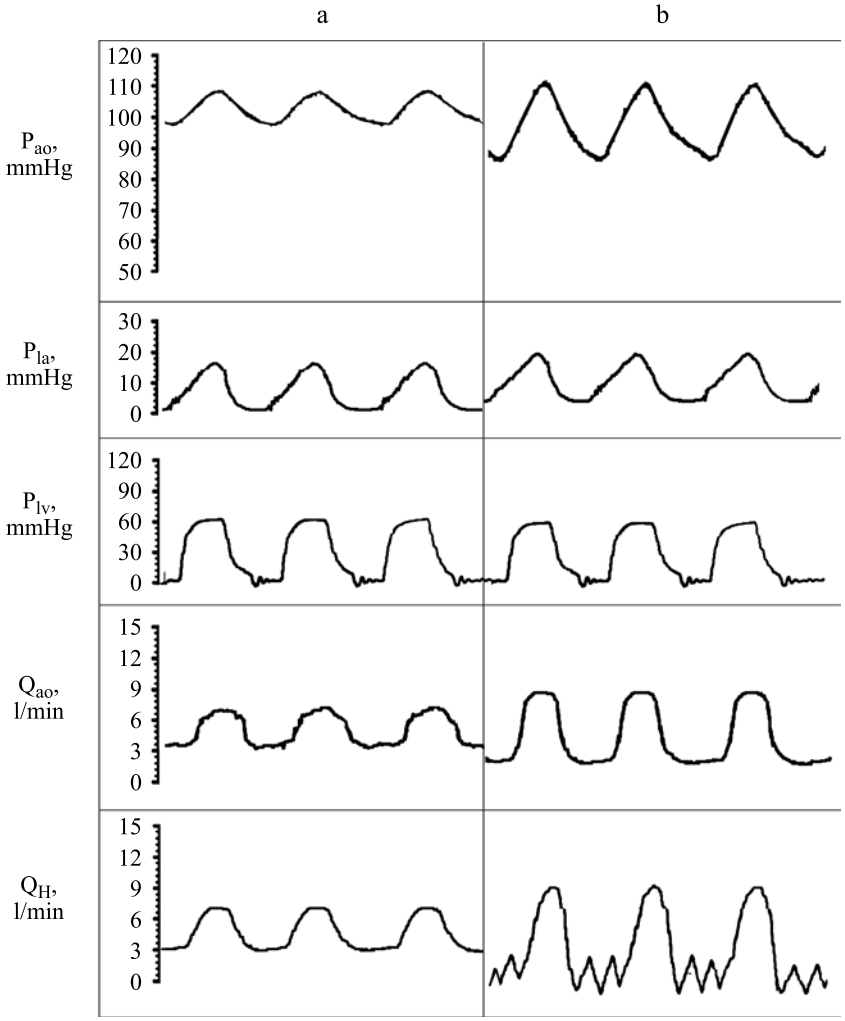

Fig. 4. Comparative results of hemodynamic parameters under conditions of continuous (a) and pulsatile (b) flows for left ventricular assist device (P_{ao}, arterial pressure; P_{la}, left atrial pressure; P_{lv}, left ventricular pressure; Q_{ao}, systemic blood flow; Q_H, flow through the AVK-N pump)

Table

Hemodynamic parameters of the CF-LVAD operating modes

	P_{ao} (mmHg)	Q_{ao} (l/min)	ΔQ_H (l/min)	I_p	EEP (mmHg)	SHE (ergs/cm^3)
Norm	118/81 (95)	20.2/0.2 (5.0)	–	0.38	99.44	5918
Heart failure	80/54 (65)	10.1/0.1 (2.7)	–	0.40	67.7	3596
Continuous mode	104/90 (95)	7.5/3.4 (4.9)	3.0	0.15	96.2	1599
Pulsatile mode	111/81 (95)	9.0/2.2 (5.1)	9.6	0.32	98.3	4393

P_{ao}, arterial pressure; Q_{ao}, aortic flow pulsation; ΔQ_H, pump flow pulsation; I_p, pulsatility index; EEP, energy equivalent pressure, SHE, surplus hemodynamic energy.

ΔQ increased 3.2-fold, the SHE index increased 2.7-fold, and the EER index remained unchanged.

DISCUSSION

The proposed method for increasing the flow pulsation level in CFP pumps is based on inclusion of a self-sustainable pulsator in the input line. The results of bench studies on a hydrodynamic stand showed the high efficiency of the method with simple design solutions in the implementation of this system. The pulsator works on a self-sufficiency basis without external energy control and feedback, closed on the electrical signals of the heart rate. With an increase in systemic blood flow against the background of CFP, rarefaction occurs in the left ventricle in the diastolic phase [21]. In this method, due to increased hydraulic resistance of the pulsator at the left ventricular outlet, rarefaction magnitude is significantly reduced. The pulsatile mode of the CFP in diastolic phase minimizes blood flow from the LV, which leads to more complete LV filling and according to Frank-Starling Law to subsequent more complete LV ejection. This device provides high flow pulsation, comparable with physiological parameters of blood circulation, which helps to reduce formation of stagnation zones and flow recirculation in CFP. This will help to reduce the chances of thrombosis both in the pump itself and in the inlet cannula of the circulatory assist system.

CONCLUSION

This paper demonstrates the first stage of the study of a pulsatile flow enhancement device, which can be considered as an effective method of increasing arterial pulsation in LVADs. Further studies will include optimization of the device dimensions for implanted auxiliary circulatory assist systems using a helium-filled compensation chamber. Comparative hemolysis studies of the device and optimization of the pulsator design for right ventricular bypass are envisaged. In the future, we consider the possibility of developing a pediatric system of pulsatile flow enhancement and biventricular bypass using this device, and application in extracorporeal membrane oxygenation systems.

The authors declare no conflict of interest.

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