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FIRST EXPERIENCE IN IMPLANTATION OF A MECHANICAL CIRCULATORY SUPPORT DEVICE BASED ON A DISK-TYPE PUMP: AN ACUTE EXPERIMENT

M.O. Zhulkov¹, A.M. Golovin², E.O. Golovina², A.S. Grenaderov³, A.V. Fomichev¹, S.A. Alsov¹, A.M. Chernyavsky¹

¹ National Medical Research Center, Novosibirsk, Russian Federation

² IMPULS-Project, Novosibirsk, Russian Federation

³ Institute of High Current Electronics, Tomsk, Russian Federation

Objective: to carry out the implantation of an artificial left ventricle of the heart based on a disk-type pump in an acute experiment on a large mammal (mini-pig). **Materials and methods.** To test the surgical technique of implantation and assess the biocompatibility of the apparatus for mechanical support of blood circulation based on a viscous friction pump, an acute experiment was conducted on an animal. A large mammal (mini-pig weighing 90 kg) was used as an experimental model. The implantation of the pump was performed extracorporeally according to the scheme “the apex of the left ventricle – the descending thoracic aorta”. During the experiment, invasive blood pressure, central venous pressure, cardiac arrhythmias, body temperature, blood gas composition, activated coagulation time were monitored. Under the control of transesophageal echocardiography, the pump operation mode was set with parameters – speed 2400–2600, productivity 4 ± 0.5 l/min, average IAD – 70–80 mm Hg. **Results.** In the course of the experiment, the fundamental possibility of using the developed disk-type pump as a device for supporting blood circulation was proved. For 4 hours, the pump provided adequate hemodynamic parameters with an average productivity of 4 ± 0.5 l/min and 2500 rpm. After 4 hours of operation of the pump in the conditions of inactivated heparin (AST – 114 sec), no blood clots were found between the pump disks. **Conclusion** The hemodynamics feature of the disk pump allows you to develop sufficient performance parameters to ensure adequate blood circulation. The mechanism of action of the “boundary layer” minimizes the risk of blood clots in the pump cavity. However, the topographic and anatomical features of the pig’s body do not allow experiments with a long observation period.

Keywords: heart failure, mechanical support of the heart, Tesla disk pump, left ventricular bypass system.

INTRODUCTION

Over the past decade, the use of circulatory assist devices in clinical practice has increased significantly [1]. According to the 25th report of the International Society for Heart and Lung Transplantation in 2008, every third heart transplant was performed in the second stage after implantation of the left ventricular assist device (LVAD) [2]. Already in 2014, however, half of the world’s heart transplants were performed against the background of previously implanted LVADs [3]. At the same time, in recent years, the need for LVAD has sharply increased with the growing number of the patients with implanted MCSs as the final method of treating end-stage CHF [4]. That is why domestic research in the development and implementation of circulatory support systems is the most relevant and highly demanded.

Earlier bench tests of the hemolytic properties of disk pumps have shown good outcomes, suggesting the basic possibility and high safety of implanting a living organism with a MCS based on a viscous friction pump [5].

MATERIALS AND METHODS

To test the surgical technique of implantation and preliminarily assess the biocompatibility of the viscous friction pump MCS, an acute animal experiment was performed. A large mammal (90 kg mini-pig) was used as an experimental model. The night before the experiment, the animal was deprived of food with unlimited access to water. The animal was premedicated in a vivarium with i.m. atropine / Zoletil solution dosaged for weight and height. With the animal asleep, the surgical site was prepared. The experiment was carried out under endotracheal anesthesia with sevoflurane and muscle relaxation (pipecuronium bromide).

During the experiment, invasive blood pressure (IBP) by catheterization of the right carotid artery, central venous pressure (CVP) by catheterization of the right jugular vein, cardiac arrhythmias (electrocardiography), body temperature, blood gas composition, and activated coagulation time (ACT) were monitored. To correct hy-

povolemic disorders, infusion therapy with crystalloid and colloid solutions was performed.

Preparing the pump for implantation

On a sterile table, $\frac{1}{2}$ -inch lines were fixed to the pump inlet and outlet. Then the pump was filled with saline at low speed (500–1000 rpm), carefully removing air emboli (Fig. 1).

Main stage of implantation

The animal was placed in right lateral decubitus. Anterolateral thoracotomy was performed in the VI intercostal space from the left with partial subperiosteal resection of the 6th rib. The LVAD lines were passed through the formed subcutaneous canals paravertebrally. After systemic heparinization (3 mg/kg) and lateral compression of the thoracic aorta, an end-to-side anastomosis was formed between the 12 mm Dacron vascular graft and the descending thoracic aorta with 5/0 thread. The outflow line was connected to the pump outlet. The inflow cannula was implanted on the beating heart through the avascular zone of the left ventricular apex. The inflow line was connected to the corresponding pump connection. Under the control of transesophageal echocardiography, the pump operation mode was set at 2,400–2,600 rpm, 4 ± 0.5 l/min flow rate, 70–80 mm Hg average IBP (Fig. 2).



Fig. 1. Stage of preparation (refueling) of the pump

Initial bench tests of the hemolytic properties of the disc pump with human blood have shown a low level of hemolysis [4].

Besides finalizing the surgical technique of implanting a disk-type pump MCS, the experiment was aimed at investigating the thrombogenicity of the inner surface of the pump and its moving parts. For this, the pump was operated in tough conditions. In 30 minutes

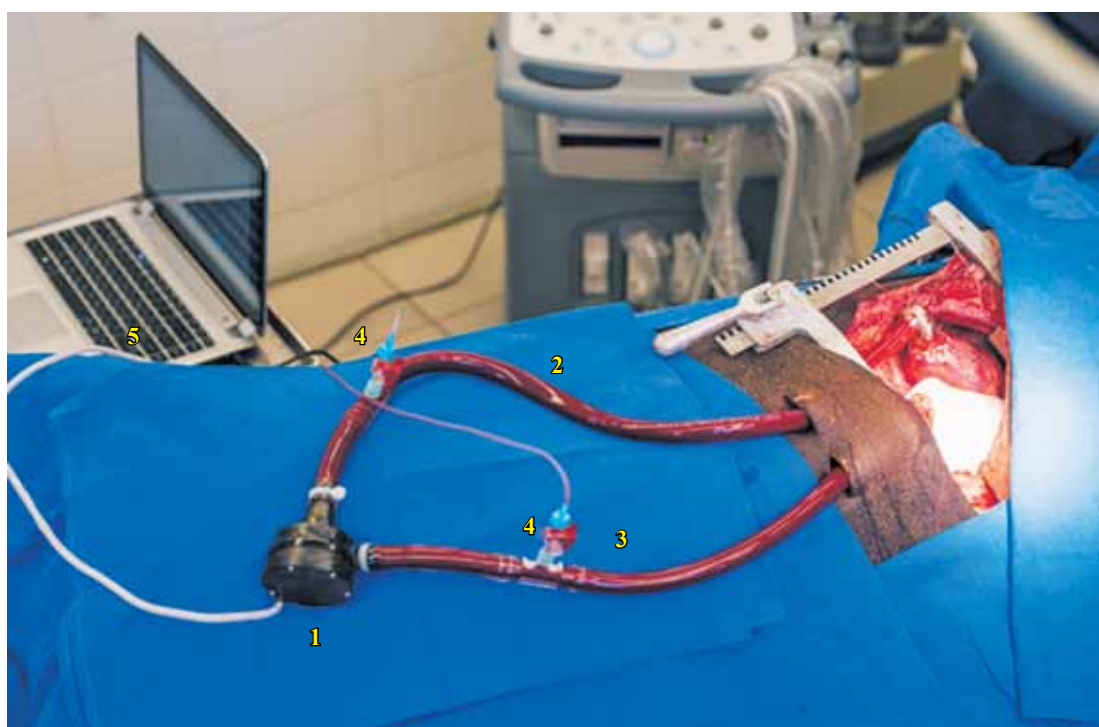


Fig. 2. General view of the wound and the working LVAD: 1 – pump; 2 – supply line; 3 – outlet line; 4 – port for measuring pressure; 5 – control unit

after reaching the calculated parameters, heparin was completely inactivated (ACT – 114 s). The pump has been working without interruptions for 4 hours with the absence of pulse peaks on sphygmogram (mean IBP 70–80 mm Hg), and blood gas parameters showed the adequacy of systemic perfusion. Every 30 minutes, blood was sampled to determine free hemoglobin level and gas composition (Table).

Table

Indicators of the main parameters of homeostasis during the experiment

Parameters	Time, min							
	30	60	90	120	150	180	210	240
IBP, mm Hg.	90	100	110	115	105	100	95	105
HR	76	86	83	78	80	86	89	85
SpO ₂ , %	98	97	98	97	95	98	98	98
Free Hb, mg/%	1.5	2.0	2.1	2.0	2.3	2.2	2.2	2.0
pH	7.4	7.5	7.4	7.4	7.4	7.4	7.4	7.5
cLac, mmol/l	2.0	2.5	3.0	2.0	3.5	2.0	3.0	3.0

After 4 hours, the animal was euthanized in accordance with the European Convention for the Protection of Vertebrate Animals used for Experimental and other Scientific Purposes (Strasbourg, March 18, 1986), and the pump was explanted. After dismantling the pump casing and visual assessment, a white, organized and tightly fixed thrombus was found on the rotor base; however, no blood clots were found between the discs suggesting a sufficiently high biocompatibility of the viscous friction pump with respect to the animal's cardiovascular system.

DISCUSSION

The first experiment on the implantation of a disk pump has resulted in the approved implantation protocol considering the topographic and anatomical features of the animal's body (mini-pig), thus promoting a series of future experiments to study the long-term operation of LVAD based on a viscous friction pump. The principal possibility of a disk-type pump to replace the function of

the left heart compartment has been proved. The results of blood biochemical and gas analysis confirm that the operating parameters of the pump (2,600 rpm, 4 ± 0.5 l/min productivity) allow for adequate perfusion support of the organism. At the first implantation of a disc pump as an LVAD in an acute experiment, the first assumptions were made about a high degree of biocompatibility of the coating of the inner surface of the pump housing and discs. After 4 hours of pump operation in inactivated heparin (ACT – 114 s), no blood clots were found between the pump discs. This allows us to assume the possibility of implementing the most sparing scheme of anticoagulant therapy after LVAD implantation based on a disk-type pump and significantly reduce the risk of serious adverse events.

The authors declare no conflict of interest.

REFERENCES

1. Halilulin TA i dr. Osobennosti implantacii sistemy podderzhki nasosnoj funktsii serdca AVK-N v kachestve "mosta" k transplantacii serdca. *Vestnik transplantologii i iskusstvennyh organov*. 2018; 20 (1): 13–22.
2. Nangia G, Borges K, Reddy KR. Use of HCV-infected organs in solid organ transplantation: An ethical challenge but plausible option. *Journal of viral hepatitis*. 2019.
3. Koloskova N.N. Terminal'naya serdechnaya nedostatochnost'. Otbor pacientov dlya postanovki v "list ozhidaniya" na transplantaciyu serdca / 14.01.05. – kardiologiya // 14.01.26. – serdechno-sosudistaya hirurgiya. M., 2011.
4. Lund LH et al. The registry of the International Society for Heart and Lung Transplantation: thirty-third adult heart transplantation report – 2016; focus theme: primary diagnostic indications for transplant. *The Journal of Heart and Lung Transplantation*. 2016; 35 (10): 1158–1169.
5. Medvedev AE et al. Implanted system of mechanical support of the disk-based heart pump viscous friction. *AIP Conference Proceedings*. AIP Publishing, 2018; 2027 (1): 030149.

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