

Left Ventricular Assist Devices in the Management of End-Stage Heart Failure

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Abstract. Heart failure (HF) is a disease from which 12% of patients with NYHA FC III-IV die every year in the world. In Russia, this figure is about 612 thousand patients. This article discusses effective technologies for the treatment of patients with end-stage heart failure: orthotopic heart transplantation and a mechanical VAD device that partially or completely replaces heart function. Opportunities and prospects for improving the use of VAD are estimated.

Keywords: VAD, left ventricular assist device, LVAD, mechanical circulatory support, heart failure, heart transplantation,

Heart failure is a major worldwide health problem. Annual mortality from chronic heart failure (CHF), even under treatment in a specialized hospital, reaches 12% among patients with NYHA FC III-IV [1]. In Russia, up to 612 thousand patients die from CHF every year. Despite the significant achievements of modern pharmacology, in a number of cases, it is impossible to avoid the decompensation of heart failure and the development of its terminal stage. Such situations require an increase in the doses of taken drugs, but even with their help at this stage of the disease, it is not possible to achieve compensation for blood circulation. For such cases, new treatment technologies have been developed: orthotopic heart transplantation (OHT) or mechanical circulatory support using a left ventricular assist device (VAD). Both methods are better for the prognosis and quality of patient's life [2,3,4].

Orthotopic heart transplantation is a transplantation, in which the native heart is removed and replaced by the donor organ in the same anatomic position as the original heart. About 4000 heart transplantations are performed annually in the world [5] (the overwhelming majority of interventions take place in Europe and North America [6]). In Russia, over the past years, there has been a significant increase in the number of heart and other organs transplants. However, there are still many unresolved ethical and legislative problems, as well as the complexity of the optimal transplant selection, its engraftment/rejection, etc.

In patients who are not suitable for transplantation or who do not have an available organ donation, the method of mechanical circulatory support using a left ventricular assist device (VAD)

can be successfully applied. For the first time in 1966, American cardiac surgeon Michael Ellis DeBakey successfully used a ventricular assist device for post-cardiotomy heart function support [7, 8]. Since then, there has been a continuous process of miniaturization of implantable heart support devices. And the first implantable VAD device – HeartMate II – was placed in 1991 [9]. Its internal parts were developed based on the experience of existing components of the Hemopump – an implantable axial pump with a catheter, which was first used in clinical practice in 1988 [10]. The input and output bearing units are made of silicon carbide, which has high hardness and thermal conductivity, in the form of a ball pair. The design this bearing unit allows it to work on dry friction, i.e. blood does not enter the ball pair [11]. Further in 2001, the FDA approved the first implantable VAD using as a bridge to transplantation (bridge therapy), referred to as HeartMate XVE [12].

The outcomes turned out to be promising, therefore, the question arose about the applicability of the method in patients who are not suitable for surgical interventions. This hypothesis was tested in the prospective multicenter REMATCH study. It compared the results of HeartMate XVE implantation with the results of optimal drug treatment in patients who were not considered candidates for heart transplantation [13]. In patients on VAD, the survival rate after 1 year increased by 50%. Due to such effective indicators, VAD was approved as a form of definitive treatment in 2003. [14]. Current indications for left ventricular support device (LVAD) implantation as a definitive treatment include patients (1) with NYHA Class 4 heart failure, (2) with optimal drug therapy within 6 of the last 9 months, (3) with life expectancy exceeding 2 years, (4) who are not candidates for a heart transplant.

The left ventricular assist device (LVAD) therapy was revolutionary, but restricted by device failure at 18 months. This was due to the limited functioning life of the bearings, as well as the intake and exhaust valves [15]. In this regard, significant changes were required in the design of the device. The first human implant of VAD MicroMed DeBakey Noon with continuous blood flow in a man was performed in Germany in 1998. [16]. There have been two types of works (first in vitro and then in vivo) that demonstrated the preservation of cerebral, renal and visceral perfusion during VAD implantation with continuous flow [17, 18]. These test results made it possible to discard previously existing concerns about the incompatibility of human physiology with the absence of pulsation.

Advantages of modern VAD include (1) a short period of hospital stay (1-3 days), (2) lack of preventive prescription of antibacterial drugs, (3) a low level of pain intensity in the postoperative period, (4) short period of rehabilitation, (5) no need for bandaging and special therapy after surgery since there are no postoperative sutures.

Despite a fairly large list of advantages, improvements to the existing VAD models are already planned. Further reduction of the pump size (creation of more miniature models), improvement of hemocompatibility and transdermal nutrition seems promising for improving the outcomes of surgery and survival after VAD implantation.

References

1. Мареев Ю.В., Герасимова В.В., Горюнова Т.В., Петрухина А.А., Даниелян М.О., Капанадзе Л.Г. и др. Факторы, определяющие прогноз при хронической сердечной недостаточности: роль ширины и морфологии комплекса QRS. *Журнал Сердечная Недостаточность*. 2012;13 (5):255–66. [Mareev Yu.V., Gerasimova V.V., Goriunova T.V., Petrukhina A.A., Danielian M.O., Kapanadze L.G. et al. Factors defining the prognosis in chronic heart failure: role of the QRS width and morphology. *Russian Heart Failure Journal*. 2012;13 (5):255–66.]
2. Yancy C.W., Jessup M., et al. ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2013; 128: e240-e327.
3. McMurray J.J., Adamopoulos S., Anker S.D. et al. ESC guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC. *Eur J Heart Fail*. 2012; 14 (8):803–869
4. Готье С.В., евченко А.О., Кормер А., Поццов В.Н., Саутгареев Р., Шумаков Д.В., Захаревич В.М. Три десятилетия трансплантации сердца в ФНЦ ТИО имени академика В.И. умакова: отдаленные результаты. *Вестник трансплантологии и искусственных органов*. 2015. Т. 15. № 2. С. 70-73.
5. Lund et al. The Registry of the International Society for Heart and Lung Transplantation: Thirty-second Official Adult Heart Transplantation Report—2015. *J Heart Lung Transplant* 2015; 34:1244–1254.
6. Национальные клинические рекомендации: трансплантация сердца и механическая поддержка кровообращения, 2016г.
7. Holub D.A., Hibbs C.W., Sturm J.T., et al. Clinical trials of the abdominal left ventricular assist device: progress report // *Cardiovasc. Dis*. 1979. Vol. 6 (3). P. 359–372.
8. A. McLarty. Mechanical circulatory support and the role of LVADs in heart failure therapy. *Clinical Medicine Insights. Cardiology*. 2015; Vol. 9 (S2): 1–5. doi: 10.4137/CMC.S19694
9. Gemmato CJ, Forrester MD, Myers TJ, Frazier OH, Cooley DA. Thirty-five years of mechanical circulatory support at the Texas Heart Institute: an updated overview. *Tex Heart Inst J*. 2005;32(2):168-177.
10. Francis D. Pagani, MD, PhD, James W. Long, et al. Improved Mechanical Reliability of the HeartMate XVE Left Ventricular Assist System
11. Г.П. Иткин, С.В. Селищев. Роторные насосы для искусственного и вспомогательного кровообращения. *Медицинская техника*. 2010. №6 (264).
12. J. Reiling, N. Butler, A. Simpson, et al. Assessment and Transplantation of Orphan Donor Livers: A Back to Base Approach to Normothermic Machine Perfusion. *Liver Transplantation*, 2018.
13. Rose E.A., Gelijns A.C., Moskowitz A.J., et al. Randomized Evaluation of Mechanical Assis-

tance for the Treatment of Congestive Heart Failure (REMATCH) Study Group. Long term use of an left ventricular assist device for end stage heart failure // *N. Engl. J. Med.* 2001. Vol. 345 (20). P. 1435–1443.

14. Centers for Medicare and Medicaid Services. Decision Memo for Ventricular Assist Devices as Destination Therapy (CAG-00119R). October 1, 2003. Available at: <http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=79>

15. Kalavrouziotis D., Tong M.Z., Starling R.C., et al. Percutaneous lead dysfunction in the HeartMate 2 left ventricular assist device // *Ann. Thorac. Surg*

16. Noon G.P., Loebe M. Current status of the MicroMed DeBakey noon ventricular assist device // *Tex. Heart Inst. J.* 2010. Vol. 37 (6). P. 652–623.

17. Miller L. Is pulsatile blood flow no longer essential? // *Circulation.* 2009. Vol. 120. P. 2313–2314.

18. Russell S.D., Rogers J.G., Milano C.A., et al. HeartMate II Clinical Investigators. Renal and hepatic function improve in acute heart failure patients during continuous flow support with the HeartMate 2 left ventricular assist device // *Circulation.* 2009. Vol. 120. P. 2352–2357.