METHODOLOGY

The Automyoneoventricle (AMNV) - New Horizons in the Surgical Treatment of Terminal Cardiac Failure (An Experimental Study)

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UDC 616.12-008.46-036.882-089:616.124.2/.3-089.844

Translated from *Byulleten' Eksperimental'noi Biologii i Meditsiny*, Vol. 117, № 3, pp. 321-324, March, 1994
Original article submitted December 29, 1993

An original myoneoventricle, with an additional active relaxing system which plays the role of a diastolic component, is used in experiments performed on dogs. The two broadest muscles of the back, stimulated by an original Russian-manufactured multiprogrammable stimulator, function as a mechanical pump. A marked improvement of the hemodynamic state of the animal is obtained during the work of the myoneoventricle in experiments.

Key Words: *dynamic cardiomyoplasty; automyoneoventricle*

Dissatisfaction with the performance of mechanical equipment for substitute and assisted blood circulation and the well-known problems associated with heart transplantation, along with the first favorable clinical trials of dynamic cardiomyoplasty (DCMP) [2,3,6,7,9,10], have called international attention to the problem of the use of dynamic automyosystems in the surgical treatment of terminal cardiac failure. The DCMP method has enormous potential for the creative specialist, offering new, sometimes unexpected solutions. Thus, initial studies using the skeletal-muscular automyoneoventricle (AMNV) [1,4,5,8,11,12] appeared as the result of developments in the field of automuscular contrapulsatory systems. The keen interest evinced in this trend is due to the logical solution regarding the energy source. A few reports of experimentally evaluated models of AMNV brought investigators close to the solution of some problems which had hindered their clinical use [1,4,5,11]. However, to date there is no truly effective method of producing AMNV. Such problems as the creation of an active relaxing component of the pump chamber and the high risk of thrombus formation on its inner surface remain unsolved. One of the difficulties lies in the cumbersomeness of the model, which makes the operation of forming and implanting the AMNV supertraumatic [6-8,12]. Still, the possibility of forming a heart neoventricle from an autogenic muscle inspires optimism in the case of surgical treatment of critical failure of the left ventricle. This primarily applies to the situation where a heart transplant is impossible for some reason and the patient is in need of constant assisted circulation. Intensive experimental research has been underway at the All-Russian

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0007-4888/94/0003-0326$12.50

Research Center of Cardiovascular Surgery since 1988 to study the possibilities of using skeletal muscle energy for the creation of systems of substitute and auxiliary neoventricles for the treatment of terminal heart failure. A fundamentally original AMNV construction has been devised. We have defined the AMNV system as an implanted biomechanical device for temporary support or substitution of the pumping function of the damaged heart using the contraction energy of the skeletal muscle tissue proper effected by special electrical pulses.

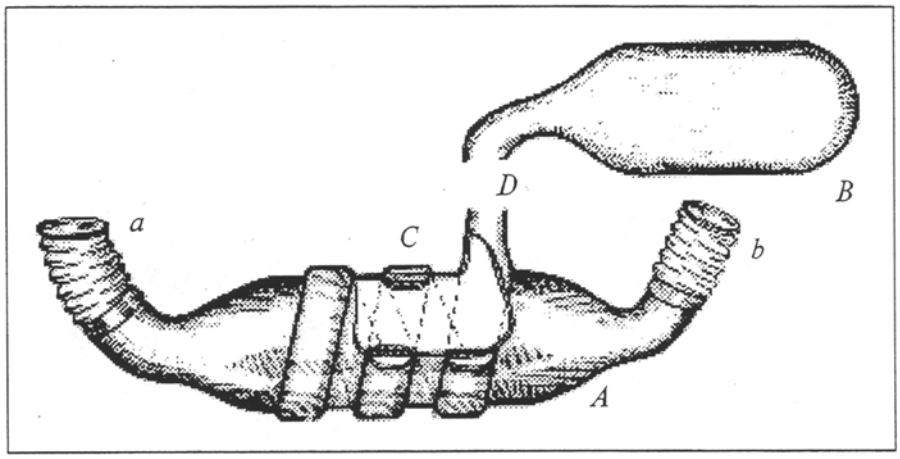

Fig. 1. Mechanical structure of the AMNV system. *A*) working pump chamber (WPC); *B*) working balloon of the AMNV active relaxing system (ARS); *C*) working coil cavity of ARS AMNV; *D*) connecting line of ARS; *a*) input part of AMNV system with mechanical valve; *b*) output part of AMNV system with mechanical valve.

The aim of the present investigation was to interpret the first experimental results of the study of the possible use of the original AMNV, with an assessment of its hemodynamic efficiency.

MATERIALS AND METHODS

Twenty-six acute experiments were performed on mongrel dogs weighing from 15 to 40 kg without observance of the chronobiological factor. All experiments were performed in keeping with generally accepted humane principles and international standards and guidelines issued by the Russian Ministry of Health and the Russian Academy of Medical Sciences pertaining to work with laboratory animals. The original AMNV with an additional relaxing system (Fig. 1) was used in the experiment. The device consists of two separate circuits, a working pump chamber (WPC), and an active relaxing system (ARS) made of elastic medical silicone with an internal finely dispersed covering of polyurethane preliminarily immobilized with heparin. WPC (*A*) is a hollow cylinder of 60 ml volume with an input part (*a*) R_1=16 mm in diameter and an output part (*b*) R_2=12 mm in diameter. The input and output parts of WPC contain mechanical low-profile valves ("Karboniks"). ARS consists of an elastic balloon (*B*) of 60 ml volume filled with physiological solution (with an initial pressure of 30 mm Hg) and connected by a main (*D*) with the working chamber of ARS. The latter (*C*) consists of three spiral coils of a special mainline tightly connected with the external wall of WPC. The ARS coil is h=12 mm in width, with a distance between coils of k=8 mm (pitch H=20 mm); the height of each coil in tension is z=6 mm. Multiprogrammable myostimulators created at the Moscow Institute of Engineering and Physics by Prof. I. A. Dubrovskii were used in the experiments. The experiments were performed under conditions of an experimental

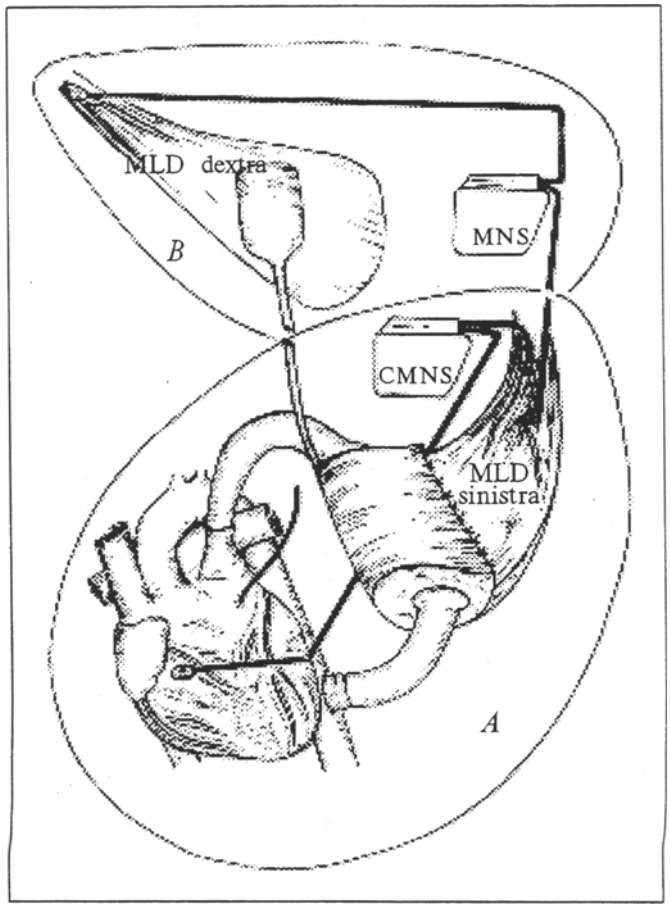

Fig. 2. Biomechanical system of AMNV. *A*) working pump system of AMNV: *MLD sinistra*: left *m. latissimus dorsi*; *CMNS*: R–dependent cardiomyostimulator; *B*) active relaxing system of AMNV: *MLD dextra*: right *m. latissimus dorsi*; *MNS*: system myostimulator.

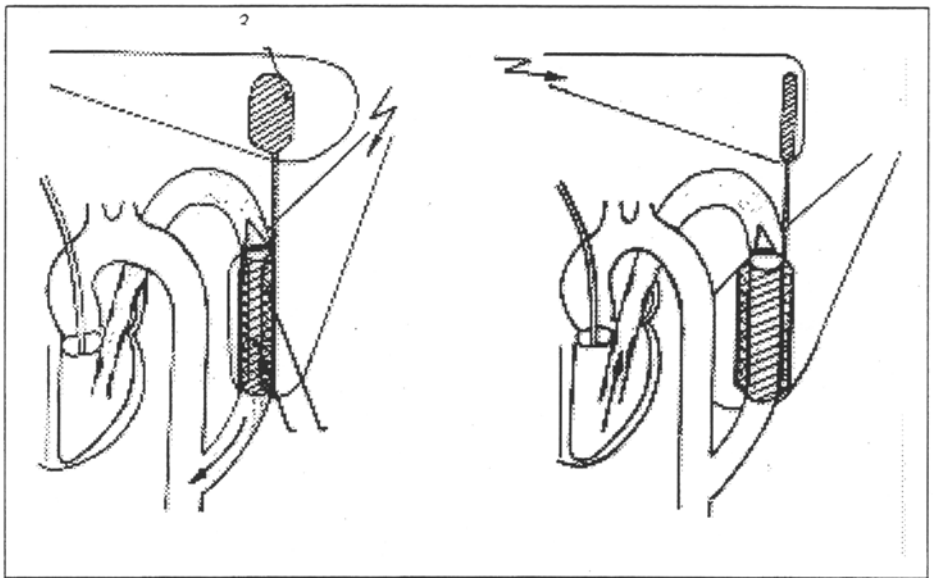

Fig. 3. Scheme of AMNV system functioning. *A*) AMNV systole (WPC is on); *B*) AMNV diastole (ARS is on). *1*) WPC of AMNV system; *2*) working cavity (ARS coil); *3*) working balloon of ARS; *4*) left MLD; *5*) right MLD; *6*) LVC.

operating room completely fitted out with the equipment necessary for performing operations and for the further study of the hemodynamic status of the animals. All hemodynamic parameters during and after the operation were monitored using a Mingograf-7 apparatus (Siemens Elema, Sweden) and a Statham-Gould, Inc. SP-2201 flowmeter (USA). Automatic artificial pulmonary ventilation was carried out during the whole operation using a Heyer respirator (Germany) that provides for inhalation anesthesia. During the operation anesthesia was performed according to a standard method analogous to that used in other operations with the use of automuscular tissue for dynamic replacement (without the use of myorelaxants [3]). The baseline hemodynamic parameters were recorded prior to the operation. The method of AMNV implantation is easy to carry out, but requires certain skills. The incision was made at the level of the right fourth intercostal space, and the lower margin of the right *m. latissimus dorsi* (MLD) was isolated (to make a bed for the working balloon of the relaxing system). The stimulative electrode was implanted in the region of the vascular-nerve bundle. The dog was turned on the left side. The left MLD was isolated, the stimulative electrode was implanted in the region of the vascular-nerve bundle, and a hole was made in the second intercostal space for the subsequent transference of the muscle to the thoracic cavity. After a left-side anterolateral thoracotomy has been performed through the sixth intercostal space, the compressed working balloon of the relaxing system was led on the inside through the thoracotomy hole in the right fifth intercostal space and placed in the prepared bed. A part of the descending aorta was parietally forced out and a distal anastomosis was created between the output line of AMNV and the descending part of the aorta. A Foley balloon catheter (capacity 30 ml) was inserted through the pursestring suture on the ascending aorta so that it was in the ring of the aortic valve and acted as an isolating element when the balloon was filled with fluid. The proximal AMNV cannula was implanted through the left atrium auricle and to lie in the left ventricle cavity (LVC). The system was wrapped up with the left MLD in the form of a loop. The pump chamber was filled with blood, after which left MLD stimulation was performed using an implanted stimulator (Fig. 2). After the beginning of stimulation of both muscles in a cardiosynchronized regime (600 msec of delay for the right muscle and a delay of 120 msec for the left) the Foley catheter balloon was filled, permitting LVC to be eliminated from the circulation. With the contraction of the left MLD in diastole, the blood from the working chamber is ejected by the pump system into the aorta and the fluid from the working chamber of the relaxing system is transported to the elastic balloon of the relaxing system. The right MLD is thereupon relaxed. In the phase of systole under the hydraulic pressure produced by the contraction of the right MLD and the relaxation of the left MLD the fluid from the elastic balloon of the relaxing system is transported to the working cavity of the relaxing system, the rise of pressure in the latter, due to its intimate connection with the wall of the working chamber, resulting in the extension of its walls. This brings into play the active (relaxing) component of AMNV functioning, which leads to the effective filling of the pump chamber with blood (Fig. 3). The given design of AMNV was thoroughly tested in the experiments on dogs.

RESULTS

The LVC myocardium was additionally damaged (with strict control of the myocardium state by ECG monitoring) by the administration of formalin after relative stabilization of the hemodynam-

ics, which generally already feels the impact from the implantation of the cannula. The hemodynamic indexes were recorded.

Stimulation of both MLD in a cardiosynchronizing regime (Fig. 4) was performed after obtaining the hemodynamic pattern of acute left ventricle failure accompanied by a lowering of PAM to 46.8±4.5 mm Hg with EDPLV 32.4±2.6 mm Hg, and a critical drop of the pump function indexes of the "left heart" was recorded (CO 1.74±0.03 liter/min, SV 8.6±1.1 ml/m², LVSWI 0.184±0.012 J/m², KLH 0.897±0.011 cm⁵/dyne/sec/m², NLH 0.28±0.02 W/m²). A marked improvement of hemodynamic indexes was noted, particularly in the first minutes of AMNV operation. A plateau of the hemodynamic pattern was maintained for half an hour of system operation, and the circulation generally tended to revert to normal indexes (10 min of AMNV functioning): the minimal pressure in the LVC dropped to 12.4 mm Hg, the pressure in the pulmonary artery dropped with the rise of PAM to 90.4±8.5 mm Hg, CO and SV rose to 3.42 liter/min and 25.3 ml/m², respectively, and the indexes K(N)LH and N(N)LH rose markedly by 270% and 87%, respectively (Fig. 4). N(L)VSP in the AMNV cavity attained 250 mm Hg and N(L)VEDP w3as 28.4 mm Hg for good diastolic relaxation (Fig. 4).

After one hour of AMNV operation, a steady relative deterioration of hemodynamic state was noted due to the fatigue of untrained muscles. But the main hemodynamic parameters, which reflect the competence of AMNV functioning during the maintenance of the hemodynamic state of animals, remained in the range of acceptable physiological values (Fig. 4). During the next 2-3 hours, and in some cases longer, the capacity for proper muscle contractions was successively recovered, restoring hemodynamic wellbeing, but there was no stable effect from further stimulation (Fig. 4). In view of this, it may be concluded that it is necessary to devise not only regimes of training stimulation of skeletal muscle, but also regimes of prolonged stable performance of a muscle in the AMNV system.

The findings attested to the marked hemodynamic efficiency of the use of AMNV in the treatment of terminal heart failure. The implanted AMNV model designed and tested experimentally may be used as a device for temporary maintenance or replacement of the pumping function of the damaged LVC.

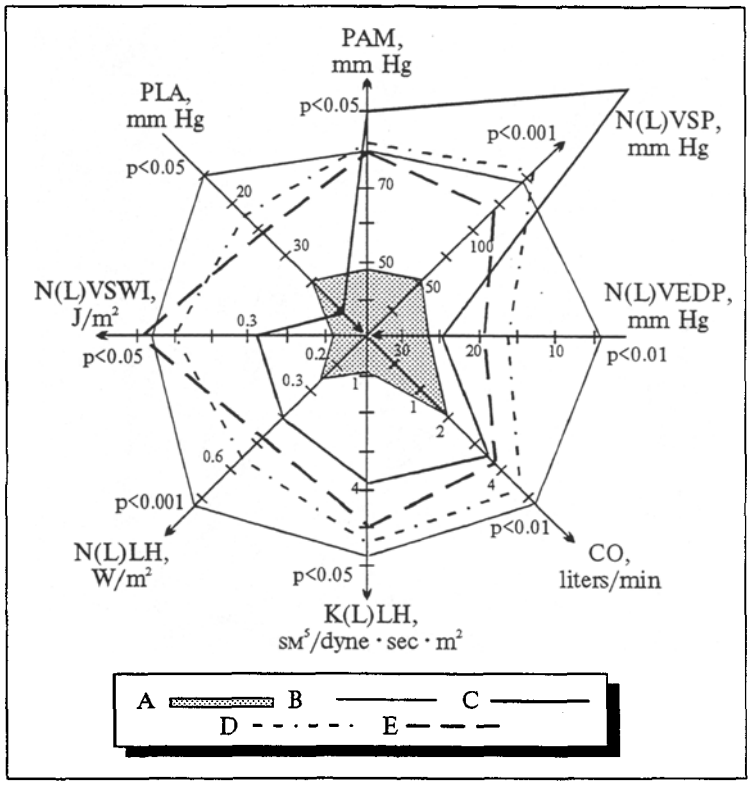

Fig. 4. Hemodynamic status of experimental animals in a model of critical left ventricle failure followed by hook-up to the greater circulation of the AMNV system. *A*) start ($n=26$); *B*) stage of creation of "left heart" failure ($n=26$); *C*) stage of 10-min functioning of AMNV system ($n=26$); *D*) stage of 60-min operation ($n=18$); *E*) stage of 180-min operation ($n=7$). *PAM*: mean arterial pressure; *PLA*: mean pressure in left atrium; *N(L)VSP*: maximum pressure in neoventricle cavity (at start in LV); *N(L)VEDP*: final diastolic pressure in neoventricle cavity (at start in LV); *CO*: minute volume; *K(N)LH*: pumping coefficient of "left heart"; *N(N)LH*: power of "left heart"; *N(L)VSWI*: index of "left heart" stroke volume.

However, prior to discussing the possible clinical uses of this method, some problems have to be solved, the main one being how to prepare automuscular tissue for prolonged work under electropulse stimulation. Moreover, there are a number of problems concerning the most advantageous and least traumatic mode of implantation of the muscle pump, as well as the problem of endothelialization of the inner AMNV walls.

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Engineering Methods for Monitoring the Proper Localization of Muscle and Cardial Electrodes during Cardiomyoplasty Operation

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UDC 616.127-089.844:615.84.03

Translated from *Byulleten' Eksperimental'noi Biologii i Meditsiny*, Vol. 117, № 3, pp. 325-328, March, 1994
Original article submitted June 9, 1993

Methods are elaborated for monitoring the localisation of muscle and cardiac electrodes during cardiomyoplasty operation. The necessary operation testing system is devised. The paper presents the results of the monitoring of 42 cardiomyoplasty operations with implantation of Stiminak-805 and EKS-445 electrostimulators.

Key Words: *cardiomyoplasty; localization of cardial and muscle electrodes; operation controlling system*

Cardiomyoplasty (CMP) is gaining growing acceptance both in Russia [2-4] and in the West [5]. To date more than 200 CMP operations have been performed [5], 40 of them in Russia. Specialists consider CMP potentially useful for 50,000 patients per year [8]. Lond-term reliable functioning of the muscle blood pump thus becomes of crucial importance.

This intricate problem is being solved by animal experiments, the creation of engineering devices for stimulation, patient selection, performance of the operation itself, and postoperative care of the patients. All these factors obviously affect the reliability of the muscle pump functioning. At the same time, the engineering accoutrements of CMP operations also play an essential albeit less evident role. This aspect of the reliability control is subject of the present study.

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From the technical point of view, a CMP operation is a process of creating a biotechnical system, consisting of a heart, a cardial (synchronizing) electrode, an implantable electrostimulator of the muscle blood pump (ESMBP), a muscle (stimulating) electrode, and muscle autograft (Fig. 1.) It is evident that failure of any element of this complex system renders its functioning impossible even in the case of irreproachable patient selection, operation, and postoperative treatment. Failure may evidently occure in both the technical (electrodes, ESMBP) and biological (heart, muscle) elements of the system.

It should be specified that neither clinical complication (suppurstions, necrosis, etc.) nor lethal outcomes which are not related to failure of the biotechnical system are considered here.

Analysis of the functioning of 52 biotechnical systems manufactured in Kaunas, Moscow, Tomsk, Kiev, and Delhi allow us to state that technical failures occur rather seldom. One electrode break-

0007-4888/94/0003-0330$12.50