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Circulatory Assistance: Basic Classification of Heart Assistance Methods and Devices

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This paper is focused on basic classification of mechanical circulatory assistance methods and devices regarding a way of their connection to the circulatory system (parallel, "in-series"), different manner of work (pulsatile, continuous-flow) or a goal of appliance (*bridge to recovery, bridge to transplant, Total Artificial Heart*). Also schematic layout of subjectively chosen assist devices are shown and discussed.
The paper does not pretend to give an exhaustive description of mechanical circulatory assistance but rather evidence, after some brief historical remarks, the substance of the circulatory support itself.

K e y w o r d s: mechanical heart assistance, coronary perfusion, heart support devices, diastolic augmentation, pulmonary stagnation

1. Introduction

In 1953 John Gibbon – the American surgeon famous for performing the first open heart surgery, applied for the first time a cardio-pulmonary bypass during a surgical operation and proved in this way the possibility of charging a heart-lung machine with the heart and lung function at least for some time. The next experiences evidenced anyway an insufficient post-operative work of the natural heart in many cases what required repeated switching on the heart-lung machine to keep the patient alive. On the other hand, long-lasting usage of the heart-lung machine occurred to be harmful for blood cells damage, caused mainly by oxygenators. It resulted in studies on heart assistance methods and devices not requiring oxygenators. Among the devices built up with this aim, quite a large group are mechanical assist devices.

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The mechanical circulatory support can be mainly used:
– in the case of heart infarction: to decrease cardiac effort by unloading the inefficient heart muscle during the *systole* and to improve its coronary perfusion in the *diastole* phase,
– in pre-operational states: to get time sufficient to make a diagnosis and to state suitable treatment procedure leading to hemodynamic parameters improvement,
– in post-operational states (e.g. after coronary bypasses, heart valves grafts) to enable disconnecting the patient from the cardio-pulmonary bypass,
– in the case of sudden (e.g. post-operational) break in heart action.

2. Mechanical Circulatory Assistance: Definition, Basic Role and Appliance

A simple definition of the mechanical circulatory assistance (MCA) can be given from strictly engineering point of view: in a case of heart failure one or both ventricles may become inable to transfer the energy to the load i.e. to the circulatory system, necessary for the organ perfusion. The role of the MCA is to deliver to the circulatory system the energy difference between demand of the system and the supply produced by the failing ventricle.

Of course, the problem is not only an engineering one – the role of the MCA is more complex and lies in our biological system. Its importance is greater or smaller in relation to the "clinical" aim of the assistance. The above simple consideration leads to the synthesis of main goals of the MCA.

Heart assistance methods and devices differ in a few ways – one of them is a goal of appliance:
- a ***bridge to recovery*** [1–3] when the heart inefficiency is reversible,
- a ***bridge to transplant*** [1, 4] when waiting for a donor's heart,
- a ***total artificial heart*** [4–6] in the end-stage failure of the heart when transplantation is not available.

Another way of division is a mode of the assist devices operation:
- pulsatile-flow assistance [7, 8],
- continuous-flow assistance [9],

and a way of the assist device connection to the cardiovascular system:
- "in-series" assistance [7],
- parallel assistance [1, 2].

Dependently on the measure of cardiac inefficiency and kind of the applied MCA, the extent of the surgical intervention invasiveness is bigger or smaller. It is evident that the way of the assist device insertion to the circulatory system (parallel or "in-series") and mode of flow generation can become extremely important for assistance.

In the case of reversible heart failure caused by cardiac ischaemia of different origin, a mechanical assist device can be used as a ***bridge to recovery***; the support in this case consists in inserting an additional pump to the circulatory system to restrain the ischaemic area extension, to unload the inefficient heart and to improve hemodynamic parameters of the system bringing about normal functioning of the whole organism. The energy transfer to the load is still fundamental but it has to be modulated taking into account need of creating the best conditions of the heart recovery. Then, beyond the relation between the MCA and the arterial load, other variables such as coronary perfusion should be considered.

Irreversible heart inefficiency is attended by necessity of appliance of a device able to take over entirely the pumping function of the natural heart for a period of time e.g. when expecting for a donor's heart to be transplanted (***bridge to transplant***) or for ever – to be used in end-stage heart failure patients for whom surgery or medical therapy is inadequate – such solution is called *a* ***total artificial heart***. Development of the ***total artificial heart*** was parallel to the MCA development and some technical solutions were adopted in both MCA and total artificial heart.

When the MCA plays a role of a ***bridge to transplant*** or long term implant, the energy transfer to the load is of a primary level importance to fulfill indispensable conditions of surviving.

3. Mechanical Heart Assistance Modes and Devices

Regarding a mode of flow generation, mechanical assist devices can be divided into two groups: continuous-flow devices and pulsatile-flow displacement pumps. In the continuous-flow pumps the energy transfer is established by velocity changes within the impeller vanes [9] while in the pulsatile-flow displacement pumps, the energy transfer to the fluid is connected with periodical changes of a working space [1]. In the case of larger flows and relatively small pressures, the continuous-flow pumps are more useful and, in contrast, at smaller flows and higher pressures, the pulsatile pumps occur to be better.

3.1. Continuous-flow and Pulsatile Assist Devices

Historically, the continuous-flow pumps were the forerunners in the MCA development [10]. One of the first devices of this kind – roller (peristaltic) pumps for over 50 years established in the clinical environment. Due to its relatively large dimensions and weight they can work only extrasomatically as heart-lung machines during surgical operations; it implies a whole set of the blood pump: the controller, actuator and supply unit to be placed out of the patient's body. The devices of such kind can be connected to the circulatory system using different modes of cannulation e.g. *apex – ascending aorta*, *left atrium – ascending aorta*, *apex – femoral artery*. Peristaltic

pumps are usually controlled manually when used to set the flow of blood to be transferred; during the assistance their volume is gradually decreased, according to the ECG signal and actual values of the hemodynamic parameters. Advantages of their usage: reliability, ease of management, low cost. Faults: large dimensions, short time of appliance (up to several hours only) due to hemolysis evoking. Roller pumps prevail on the European market of cardio-surgical extrasomatic circulation.

The next step was development of the rotary blood pumps (axial, radial, diagonal) that are characterized by smaller dimensions and invasiveness [11–13]. The rotary blood pumps, similarly to other continuous-flow pumps do not need any additional heart valves. The miniature axial flow pump developed at the Baylor School of Medicine (Houston, Texas) [14–16] being characterized by very small dimensions (68 mm length, 24 mm diameter) and weight only of 94 g has evidenced technical progress in the discussed area. The combination of two pumps of this kind can play a role of an artificial heart.

Advantages of the rotary pumps are: smaller hemolysis when compared with the roller pumps, small dimensions and filling volume, ability of appliance up to several days. The centrifugal (diagonal) pumps are gaining the American market of the cardio-pulmonary bypass. The main disadvantage of the rotary pumps is necessity of limiting their rotational speed because of stress and cavitation.

When an extrasomatic or implanted support of the circulatory system is needed for ***recovery***, a set of pulsatile-flow displacement assist devices usually associated with different type actuators: sac-type artificial ventricles (USA: Abiomed [5, 6, 8], Thoratec [17–19], Japan: Nippon-Zeon [20]), diaphragm artificial ventricles (Japan: Toyobo [21], Germany: Berlin Heart [22, 23]), intra-aortic balloons [24–31] or pusher-plate type units [4, 32] are available as a ***bridge to transplant*** or ***total artificial heart***.

3.2. Connection of the Mechanical Heart-assist Devices to the Circulatory System

Mechanical heart-assistance methods and devices, regarding the place of its connection to the circulatory system, can be divided into two groups:

1. "In-series" assistance:
   - Left Ventricular Assist Device (LVAD) – in *apical-aortic* connection.
   - Intra-Aortic Balloon Pump (IABP).
   - Para-aortic counterpulsation.
   - Rotary pumps.
   - External counterpulsation (EC) – a non-invasive method.
2. Parallel assistance:
   - Roller pumps.
   - Rotary (axial, radial, diagonal) pumps.
   - Left Ventricular Assist Device (LVAD) – in *atrio-aortic* connection.
   - Bi-Ventricular Assist Device (BVAD) – simultaneous assistance of the left and right ventricle.

3.2.1. "In-series" Assistance

Mechanical heart assist devices connected to the blood circulatory system of the patient "in-series" can be pulsatile or non-pulsatile ones.

The best known representative of the pulsatile-flow assist devices of this kind is an intra-aortic balloon pump (IABP) [7, 24–31]; it is widely used for temporary assistance in a variety of clinical situations such as the left ventricular failure induced by e.g. coronary stenosis, in patients with the cardiogenic shock due to acute myocardial infarction as well as in the case of massive pulmonary emboli. In the IABP, the role of the pump actuator plays a balloon generally inserted into the descending aorta through the femoral artery. The balloon connected to the drive unit by a catheter has been periodically filled with gas and emptied, according to the heart rate and *systole-to-diastole ratio* (S/D) of the patient. The goal of the IABP assistance is the heart muscle's recovery by its unloading – due to the systolic aortic pressure (p_{as}) decrease, and better perfusion, by the diastolic aortic pressure increase called *diastolic augmentation* (Fig. 1). The increased coronary flow attained in this way can give rise to the ventricular contractility increase finally resulting in improvement of the general hemodynamic conditions. The IABP assistance effectiveness depends on time delay of the balloon inflation and deflation initial moment in relation to the QRS complex of the patient's ECG, on the balloon shape, its emptying and filling

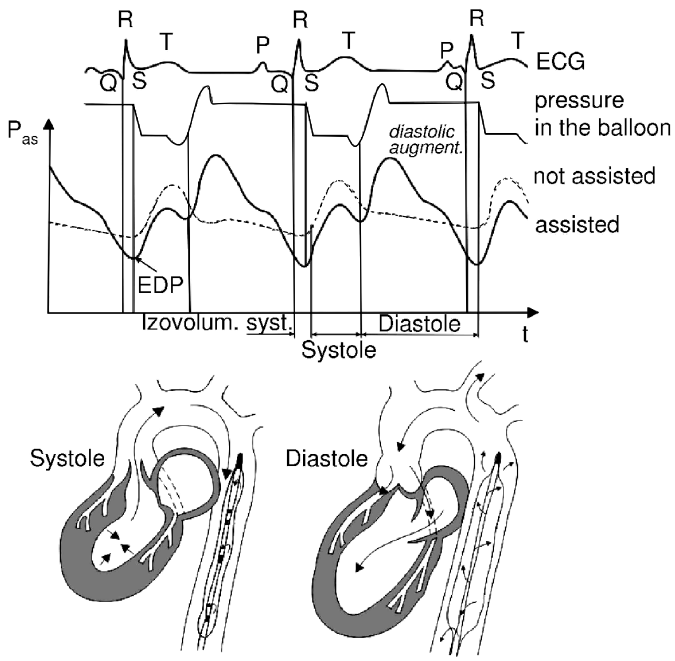

Fig. 1. IABP assistance. P_{as} – aortic pressure, EDP – end-diastolic pressure (from [33], reproduced by permission of Nova Science Publ.)

velocity, the balloon volume and position in the aorta as well as on a sort of gas filling the balloon; two kinds of gas soluble in blood helium and carbon dioxide are used to charge intra-aortic balloons.

Decrease of the systolic aortic pressure (p_{as}) and the end-diastolic pressure (EDP) as well as the *diastolic augmentation* are characteristic for the counterpulsation balloon assistance.

In the case of the bridge to transplant, transferring of blood volume from the inefficient native ventricle to the arterial system is available using an artificial ventricle (LVAD) working in apical "in-series" connection to the native heart; its work can be then asynchronous in relation to the ECG signal.

In the extreme conditions, the para-aortic counterpulsation is very suitable for mechanical assistance. This way of assistance is significantly more effective than the IABP thanks to a short, small-resistance connection of its membrane actuator to the ascending or abdominal aorta [34]. In clinical applications it shows excellent biocompatibility and promising hemodynamic effects. The high invasiveness of the device is its negative feature.

The discussed para-aortic counterpulsation does not need additional heart valves.

The increased diastolic pressure in the aorta followed by the *diastolic augmentation* and improvement of the general heart condition can be also achieved by a kind of pulsatile non-invasive assistance. It consists in compression of a vascular bed in the process of enhanced external counterpulsation (EC) [35–39] by multi-chambered cuffs put mainly on lower extremities of the patient (Fig. 2).

Good effect of the external counterpulsation is best attained when compression is sequentially performed, starting from the lowest part of the legs (Fig. 3); its general goal is to create blood stream wave opposite to that from the heart, bringing about earlier discussed *diastolic augmentation*.

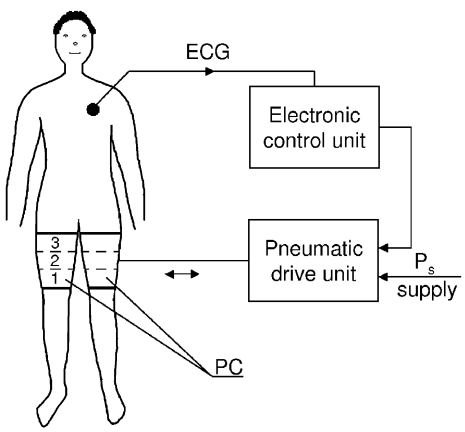

Fig. 2. Assist device for external counterpulsation. P_s – supply pressure, PC – three-chambered pneumatic cuffs

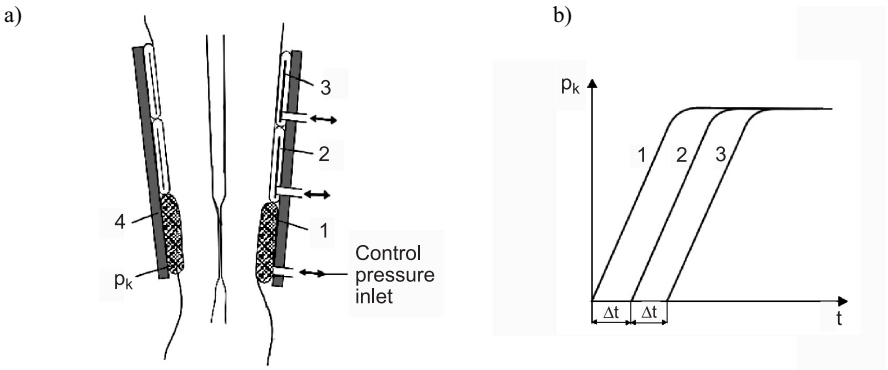

Fig. 3. Sequential external assistance – a) 1, 2, 3 – pneumatic cuffs chambers, 4 – cuff's housing, P_k – air pressure inside the chambers b) pressure (P_k) time courses in particular chambers (1, 2, 3) during sequential compression, delayed in time by Δt

Much smaller effectiveness of the external counterpulsation, reaching 30 percent of the IABP assistance effectiveness, is the cost of non-invasive support performance of the circulatory assistance.

3.2.2. Parallel Assistance

In the case of the pulmonary blood stagnation, usually caused by the left ventricular inefficiency, the parallel assistance using the left ventricular assist device (LVAD) can be applied to discharge it. Independently of the structure of the assist device pumping unit [20, 21, 32], the role of such assistance is to shift a volume of blood from the left atrium to the aorta by the created bypass of the left ventricle (Fig. 4). In the discussed assist device playing a role of a ***bridge to recovery*** its artificial ventricle only partially takes the pumping function of the native ventricle over [1, 3]. The LVAD action in that case should be synchronous with the ECG signal of the patient and carried out on the principle of counterpulsation; owing to such kind of assistance, harmful stagnation of blood in the pulmonary circulation can be discharged bringing about the arterial pulmonary pressure and the left atrial pressure drop along with significant increase in the left ventricular and systemic arterial pressure and in the total cardiac output as well.

Some assist devices to be used for heart recovery or as a ***bridge to transplant*****,** available on the market, are extracorporeal, certain of them – implantable [1–5,19]. Further works on their miniaturization and reducing the weight have been carried on.

During the left ventricular assistance inefficiency of the right ventricle often reveals or appears [40]. In this case sometimes ***biventricular assistance*** (BVAD) can be relevant. Approximately 10 to 15 percent of all patients supported by the left ventricular assist devices require the right ventricular assistance as well [41].

Dependently on need, the biventricular support can be realized using two diaphragm LVAD and RVAD pumps [42–44], rotary pumps [45, 46] or mixed heart support systems e.g. a combination of the para-aortic left heart-assist pump connected to the aorta and the IABP with the intra aortic balloon inserted into the pulmonary artery [34].

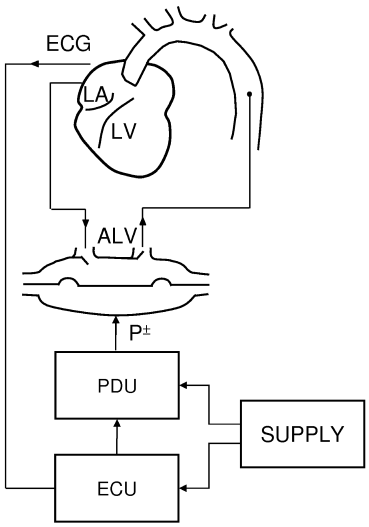

Fig. 4. Block diagram of the parallel ventricular assistance (LVAD): LA – left atrium, LV – left ventricle, ALV – artificial left ventricle, ECU – electronic control system, PDU – pneumatic drive unit, $P^{\pm}$ – control pressure (from [33], reproduced by permission of Nova Science Publ.)

3.3. Total Artificial Heart

Growing number of irreversible heart diseases is a source of rising demand for heart transplantation. The present shortage of organ donors, however, brings about heart transplantation to be offered only to a limited percentage of patients. For this reason, other alternatives in the surgical therapy for patients of end-stage heart failure called Total Artificial Hearts (TAH) have been developed in these days. According to the need of appliance two goals of the TAH can be distinguished: 1) to get a tool to keep the patient alive for a long period when waiting for a donor's heart to be transplanted, and 2) to built an artificial heart totally and entirely replacing the native heart of the patient; its role is to fulfill the essential functions of the heart and to enable the patient to live a quasi normal life for at least five years. In nowadays practice all effort of specialists and researchers has been oriented toward the first goal while the second one is still out of our abilities.

Clinical application of the TAH called Jarvik-7, probably the best known total artificial heart for permanent use in patients, took place in 1982 at the University

of Utah in a patient named Barney Clark who survived with the TAH for 112 days. The longest survival in the case of other five implantations of the Jarvik-7 performed during next years was 620 days. Later, surgeons at several US centers had applied the Jarvik-7 as a bridge to transplantation in more than 70 patients.

Subsequently, the Jarvik-7 name was changed to the Symbion TAH and the CardioWest TAH. Nowadays, the modern version of the Jarvik 7, known as SynCardia, originally used as a permanent replacement heart, currently is approved in selected US centers [47–49] as a bridge to human heart transplant for people dying from end-stage biventricular failure. It has been implanted in more than 800 people in this form. In March 2010, the 850th SynCardia temporary CardioWest™ TAH implant was applied in Moscow (Russia) to a 60-year-old female suffering from biventricular heart failure. In the paper [50], however, Leshnower et al. revealed that the discussed TAH was a more successful device in bridging patients to transplantation than in biventricular assistance.

In the United States in 1988 , research works on the new generation of implantable *total artificial heart* (TAH) systems started, followed by a few phases of their development characterized by Reul et al. in [4] and by Watson in [51]. Due to the definition of the total artificial heart designers, it should orthotopically replace both native ventricles and all cardiac valves; one of its aims is to eliminate all the problems characteristic for the bridge to transplant based on the LVAD or BVAD such as right ventricular failure [52] or valvular regurgitation. To speed the works on development of the TAHs free of pneumatic control systems risky for human health, the National Heart, Lung and Blood Institute opened in early nineties a competition for implantable electrically powered TAH designed for a five years usage. The program was to be realized in two phases: the first one, 1993–1996, devoted to completing the system design followed by the prototype performance, and the second (1997–2000) – to performing rigorous tests of the system's reliability and its biocompatibility, basing on animal's testing before the clinical use [53].

Three groups: Nimbus Corporation (CA)/Cleveland Clinic Fundation (Ohio), Penn State Hershey Medical Center (Pennsylvania) and AbioMed Inc. (Massachusetts) received founds for that aim. After the first five years, the Cleveland program was closed. The other two continued their job.

As a result of the above mentioned competition, at present the most advanced ***total artificial heart*** seems to be the AbioCor developed by AbioMed (MA, USA) [5, 6, 8]. It is a permanent use device, fully implantable due to miniaturization (small dimensions, weight not exceeding 1000 g), biosensors, plastics and energy transfer. It runs on a rechargeable battery-electrical source of power. First clinical applications of the AbioCor were performed in 2001 in two end-stage heart failure patients who survived 151 and 512 days. In 2006, the FDA announced that the AbioCor could be implanted for humanitarian uses after its testing on 15 critically ill patients who are to receive a heart transplant (up to the 2004 far, the device has been implanted in 11 of a projected 15 patients). limitation of AbioCor at that moment was the size

reducing its applicability to 50% of the male population and its useful life limited to two years. Later, AbioMed has designed, in co-operation with Penn State, a smaller and much more stable artificial heart – AbioCor II; the TAH in that version should be implantable in much bigger amount of patients for its advanced miniaturization and a larger life span up to five years.

4. Discussion

First bad experience from early appliance of heart-lung machines during surgical operations (hemolysis) caused researchers to look for a new heart and lung support methods and devices not requiring oxygenators harmful for human blood and being suitable to be used for assistance of the inefficient organs. Among the devices built up to this aim quite a large group are mechanical assist devices.

One of the main goals of mechanical circulatory assistance (MCA) is delivering to the cardiovascular system the energy difference between its demand and supply to compensate a certain biological malfunction of the organism. Dependently on need, the MCA can be used in clinical practice as a ***bridge to recovery*** when the heart inefficiency is reversible and coming back to a pre-disease stage of human circulatory system is available, or as a ***bridge to transplant*** in not reversible stages, when waiting for a donor's heart. The present shortage of organ donors, however, brings about heart transplantation to be offered only to a limited percentage of patients. For this reason, other alternatives in the surgical therapy for patients of end-stage heart failure called Total Artificial Hearts (TAH) have been developed in these days. According to the need of appliance two goals of the TAH can be distinguished: 1) to get a tool to keep a patient alive for a long time period when waiting for a donor's heart to be transplanted, and 2) to replace the totally inefficient native heart of the patient by the artificial heart to fulfill the essential functions of the heart and to enable the patient to live a quasi normal life for at least five years. In nowadays practice all effort of specialists and researchers has been oriented toward the first goal while the state of the second one is still not satisfying.

The patient's heart condition as well as the type of his reversible heart disease impose the choice of the assist device to be used. For example, the IABP is widely used for assistance in the case of the left ventricular failure (e.g. induced by the coronary dysfunction) to unload the ventricle due to systolic aortic pressure decrease when the balloon inserted to the descending aorta deflates, and to enable better heart muscle perfusion by the *diastolic augmentation* when the balloon inflates. The IABP connected to the cardiovascular system in-series is the most often clinically used assist device for facility of its surgical appliance. In-series assistance can be also realized using an artificial ventricle (LVAD) working in the apical-arterial connection.

As opposed to the in-series assistance, the main goal of the parallel LVAD support is to discharge pulmonary stagnation by creating a kind of bypass of the

inefficient left ventricle to shift a volume of blood from the left atrium to the aorta bringing about the decrease of both the arterial pulmonary and left atrial pressure to the physiological level.

Mechanical heart assistance can be carried on using pulsatile and continuous-flow devices.

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