

Technical realization of the external counterpulsation equipment

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Modern cardiology, surgery and reanimation deal more widely with means replacing pump function of the diseased heart, partially or completely, temporary or constantly.

Methods of the temporal help to heart and replacements of its pumping ability with mechanical devices, are integrated into the concept “assist circulation”. The methods of an intraaortal balloon counterpulsation (IABP) and an external (non-invasive) counterpulsation (ECP) have a wide distribution.

The external counterpulsation – clinically proved effective method. It is widely used currently in our country and abroad. ECP is the alternative of an intraaortal counterpulsation and can be considered as a noninvasive and non-traumatic method.

During ECP procedure the cuffs are put on legs clasping accordingly calfs, lower and upper parts of thighs with capture of buttocks of the patient. This cuffs are pumped with air (up to 300 mm Hg) consequently from calfs to buttocks. The moments of the compression beginning are tuned so that the pressure wave of a blood superseded from the bottom extremities by arteries in a retrograde direction reaches an aorta during a diastole. The blowoff occurs before the beginning of a systole.

The method has received the greatest propagation after introduction in a clinical practice of such updating a method, as the enhanced external counterpulsation (EECP). It differs from ECP as so-called diastolic augmentation during procedure is achieved. After carrying out in the USA the successful large research at University Stony Brook, NY, and also multicenter clinical research (MUST-EECP) in the middle of 1990th years the method has spread widely in the USA and China.

The equipment for an external counterpulsation is not made in Russia, and currently any domestic researches and development in this area completed with the experimental sample are not known to authors. In this case, we have designed the equipment set of an external counterpulsation during 2004-2006. The machine is named «CARDIOPULSARtm» and now its

medical certification comes to finish. Also preparations for serial producing were made.

All currently known foreign devices use a source of compressed air, inflatable cuffs and pneumatic actuator devices for creation of a compression of the bottom extremities as a rule. The hydraulic drive is not applied now.

Our machine uses a electrocardiogram signal (ECG) for synchronization of a compression with cardiac cycle and a photoplethysmography (PPG) for observation over hemodynamic effects in the same manner as foreign ECP analogues.

Monitoring of the most important physiological parameters (an ECG, heart rate, SpO₂, the NIBP) for an objective estimation of a current patient condition, synchronization with cardiac cycle and parameters of influence control in real time are carried out by means of the specially developed software. Synchronization includes a problem of the ECG outline analysis in "real" time and definition of a QRS-complex with no more than tens milliseconds delay. The actuator part of machine constitutes the electropneumatical device with microcontroller connected to a personal computer. Influence is synchronized with phases of a cardiac cycle by means of the control commands sent from the personal computer to the microcontroller.

Essential difference from foreign analogues consists in the block diagram of pneumatic elements for creation of pressure pulses in compression cuffs. So we use immediate control of pressure in cuffs without preliminary setting desired pressure in intermediate receivers.

The high pressure of a compressed air source on an input of actuator elements allows us to use the valve with relatively small orifice. It allows us to use the standard industrial pneumatic valves in the scheme of the device. However, such decision demands the reliable scheme of protection.

In particular, we apply the scheme in which the compression channel is normally closed but the blowoff channel is normally opened. Such pneumatic scheme is most safe and dumps pressure in cuffs in supernumerary situations. We applied the scheme of protection against cuffs pressure excess above the safe level including the gauge of pressure, an electronic protection circuit and the valves with electric and electropneumatical control. Such decision is well-taken because the reliability, resource and speed of operation of modern valves of such type are not below than at mechanical passive elements. Besides such decision allows us to carry out monitoring of a situation on the personal computer that enables to provide a technical diagnostics.

The technical decision of the influencing unit is patented.

The equipment most important specifications:

1. Synchronization of pressure pulses with an cardiac cycle is carried by ECG. A choice of ECG leads used for synchronization is automatic.

2. A range of pressure in cuffs – $0 \div 360$ mm Hg

3. Rise/fall time of pressure pulses – no more than 150 msec.

4. Arbitrary (within the limits defined by cardiac cycle duration) setting of the compression pulse duration, and also of a delay between calfs, lower and upper parts of thighs compression pulses allows to arrange parameters of the time chart of influence for achievement of the maximal haemodynamic efficiency.

5. Some modes of exposure can be used: a continuous regimen (on every cardiac cycle), with the miss of one cycle of influence on 1, 2 or 3 cardiac cycle.

6. The software allows to visualize in real time all measured physiological signals and parameters, and also pressure in cuffs that allows the operator to adjust modes of exposure and change them in real time by means of visual "control panel".

7. The set of cuffs of the different sizes, considering anthropometric features of the overwhelming majority of patients is designed.

8. The design of functional bed is developed providing convenience to patients of different body height and weight for long (1-2 hours) procedures.

Thus, the domestic equipment is developed for an assist circulation by a method of an external counterpulsation with functional, technical and ergonomic characteristics not worth than those of foreign analogues. It is confirmed by technical and medical tests for enough plenty of patients.

Work is supported by the grant of the Russian Federal Property Fund 06-07-89321a.