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New designs for counterpulsation devices

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Counterpulsation is an intervention used to restore the Windkessel effect of the aorta in the setting of hemodynamic compromise by increasing aortic pressure during early diastole that augments coronary and distal end organ perfusion as well as decreasing aortic pressure during early systole thus reducing ventricular afterload and workload. It was firstly introduced by Moulopoulos et al. (1) 40 years ago and was trialed as method for support of acute ischemic heart failure. This technique is now widely used in cardiac intensive care for stabilizing patients after cardiac surgery and myocardial infarction and in patients with acute heart failure under consideration of transplantation or use of another mechanical device.

The timing of the counterpulsation is critical for its effectiveness. Early counterpulsation action during diastole causes premature closure of aortic valve, reduced stroke volume and cardiac output (CO), and increased left ventricular end systole volume; late counterpulsation decreases perfusion and volume to coronary arteries; late withdrawal increases ventricular afterload and myocardial oxygen consumption and decreases CO.

Currently, there are a number of different types of aortic counterpulsation devices have been developed. Intra-aortic balloon pumping (IABP) is a cylindrical polyethylene balloon that is placed in the descending aorta through the femoral artery and inflated during diastole and deflated during systole by shuttling helium. It is triggered by the electrocardiogram and the systemic arterial pressure waveform. However, due to the location of the IABP balloon aorta and access through femoral artery, IABP can only be used for short durations (2).

Patients need to be immobilized and require anticoagulation. Given the limitations of IABP and the proven benefits of the counterpulsation technique, new counterpulsation devices are being developed aiming to be used for a longer period. The para-aortic counterpulsation device (PACD) is a pneumatically driven device with a polyurethane chamber being the main part of counterpulsation and a moveable diaphragm separating the chamber into the blood space and the air space. The chamber has a valveless orifice connected to the ascending or descending aorta through a Dacron vascular graft. Compared to IABP, PACD can provide larger counterpulsation volumes, has superior hemodynamic effect and fewer vascular complications (3-5). However, PACD requires thoracotomy for implantation and may cause depression of the thoracic organs. Similarly, the Kantrowitz CardioVAD are implantable long-term aortic counterpulsation devices designed to replace portions of the descending aorta with a patch that could inflate and displace blood in the descending aorta and provide chronic mechanical assistance (6-8). Initial human test has revealed the ability of the device to be used intermittently without anticoagulation and significant hemodynamic and functional improvement in end-stage patients (6). However, all the devices above cannot avoid the direct contact with blood.

C-Pulse system (Sunshine Heart Inc.) is an extra-aortic balloon counterpulsation device using an inflatable cuff around the ascending aorta (9). It includes a nonblood-contacting implantable cuff, a sensing lead and an extracorporeal controller/drive unit (9). It has been shown that extra-aortic counterpulsation device has comparable hemodynamic effects of standard IABP (10). C-Pulse does not require anticoagulation. The "thumb print" deflection by the C-pulse cuff on the aortic wall no mechanical injury to the endothelium and no alteration of aortic wall structures, hence has less risk of possible thromboembolic complications (11). However, device or drive-line infection remains the most common adverse event in the C-Pulse device. In patients with cardiac assist device implantation, 10-40 % of the patients suffer from device-related infections (12, 13) and 30-40 % of deaths are related to serious infections (14, 15). To avoid the need for an external drive-line, a total implantable extra-aortic counterpulsation device was

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developed using shape memory alloy fibres as an actuator. The contraction and relaxation of fibres is controlled by Joule heating with an electric current supply timed by a special control unit (16). Preliminary results in a systemic mock circulatory system revealed that the device significantly increased peak diastolic pressure and mean flow. Meanwhile, a new ferromagnetic silicone cuff has also been used in an extra-aortic counterpulsation device (17). The driving force is generated by an external magnetic field, which leads to contraction of a soft magnetic aortic cuff. However, its effectiveness still need further investigations.

In addition, either IABP or C-pulse require sophisticated pumping control based on a real-time electrocardiogram or pressure analysis, and their efficacy may be reduced in case of arrhythmias, where the device cannot precisely synchronize the action of the external pump with the heart (18). Therefore, a "passive" counterpulsation device was under development aiming to transfer the energy during systole to the pressure during diastole without a time-controlled operation and reduce the cost of instruments. A "passive" counterpulsating device comprising an intravascular balloon connected to an adjustable external reservoir. Preliminary studies showed the inflation and deflation of the balloon lead to progressive improvements in the characteristics of the aortic pressure curve in terms of reduction in the maximum systolic value and slower diastolic decay (19, 20). However, the key issue of such "passive" counterpulsation devices is the generation of the driving force, which can be stored and released at the optimal time during diastolic phase. The origin of this force is the contraction of the heart. To store and transfer this energy, the heart faces the resistance generated by the "media" served as the reservoir. This resistance could be quite deliberating in patients with severe heart failure. In addition, the "passive" extra-aortic device does not seem to be a novel idea. For instance, an elastic aortic warp has been developed to be a potential non-pharmacological treatment of age-related aortic stiffness, aiming to restore the Windkessel effect of the stiffened aorta. By optimizing the reduction of aortic diameter and material stiffness, the elastic aortic warp was expected to lower systolic pressure, improving ventricular ejection while it will increase diastolic pressure, improving myocardial blood flow (21). Although the elastic aortic warp significantly lowered aortic stiffness, there were no significant alterations in the hemodynamic values (22).

The aortic warp application and the reduction in radius nevertheless increase the resistance during systole. The main drawback of current elastic aortic warp is the early recoil during diastole, which results in premature closure of aortic valve and reduced stroke volume. As the development of new materials and device designs, an effective "passive" extra-aortic device could be promising, particularly in patients with preserved ejection fraction heart failure where aortic stiffening and low coronary perfusion are key features.

Currently there is a need for a fully implantable counterpulsation device simple and safe, with a straightforward implant procedure, with long-term efficacy and benefits for patients; it must be embraced by clinicians and applicable for majority of patients.

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