

New designs for counterpulsation devices

Shutan Liao^{1,2}

¹Rural Clinical School, University of New South Wales, Sydney, New South Wales, Australia

²The First Affiliated Hospital of Sun Yat-sen University, Guangzhou, China

Key words: cardiac assist device, counterpulsation, device

(Heart Vessels and Transplantation 2018; 2: doi: 10.24969/hvt.2017.49)

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).

Address for Correspondence: Shutan Liao, Rural Clinical School, Faculty of Medicine, University of New South Wales, Sydney, NSW 2052, Australia Email: shutan.liao@unsw.edu.au

Heart Vessels and Transplantation Copyright© 2018 All rights reserved

Received: 04.03.2018 Accepted: 10.03.2018

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 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.

Peer-review: Internal and external

Conflicts of interest: There are no conflicts of interest.

Authorship: S.L.

Acknowledgements and funding: Shutan Liao is funded under an NHMRC Development Grant

References

1. Mouloupoulos SD, Topaz S, Kolff WJ. Diastolic balloon pumping (with carbon dioxide) in the aorta--a mechanical assistance to the failing circulation. *Am Heart J* 1962; 63: 669-75. PubMed PMID: 14476645.
2. Freed PS, Wasfie T, Zado B, Kantrowitz A. Intraaortic balloon pumping for prolonged circulatory support. *The Am J Cardiol* 1988; 61: 554-7. PubMed PMID: 3344678.
3. Shi C, Zhou DD, Liu G, Zhang L, Meng JJ, Geng Y, et al. The left ventricular assist effect and biocompatibility study of a novel para-aortic counterpulsation device. *Eur Rev Med Pharm Sci* 2015; 19: 1859-65. PubMed PMID: 26044232.
4. Zhang JM, Liu XC, Liu ZG, Zhao L, Yang L, Liu TW, et al. Comparison of effects of extra-thoracic paraaortic counterpulsation to intraaortic balloon pump on circulatory support in acute heart failure. *J Cardiothorac Surg* 2015; 10: 173. doi: 10.1186/s13019-015-0349-z. PubMed PMID: 26602754; PubMed Central PMCID: PMC4659167.
5. Nanas JN, Lolos CT, Charitos CE, Nanas SN, Margari ZJ, Agapitos EV, et al. A valveless high stroke volume counterpulsation device restores hemodynamics in patients with congestive heart failure and intractable cardiogenic shock awaiting heart transplantation. *J Thorac Cardiovasc Surg* 1996; 111: 55-61. PubMed PMID: 8551789.
6. Jeevanandam V, Jayakar D, Anderson AS, Martin S, Piccione W, Jr., Heroux AL, et al. Circulatory assistance with a permanent implantable IABP: initial human experience. *Circulation* 2002; 106 (12 Suppl 1): I183-8. PubMed PMID: 12354730.
7. Koenig SC, Spence PA, Pantalos GM, Dowling RD, Litwak KN. Development and early testing of a simple subcutaneous counterpulsation device. *ASAIO J (American Society for Artificial Internal Organs: 1992)* 2006; 52: 362-7. doi: 10.1097/01.mat.0000227729.70008.66. PubMed PMID: 16883113; PubMed Central PMCID: PMC2828048.
8. Giridharan GA, Pantalos GM, Litwak KN, Spence PA, Koenig SC. Predicted hemodynamic benefits of counterpulsation therapy using a superficial surgical approach. *ASAIO J (American Society for Artificial Internal Organs : 1992)* 2006; 52: 39-46. doi: 10.1097/01.mat.0000196522.29376.96. PubMed PMID: 16436889; PubMed Central PMCID: PMC2849754.
9. Sales VL, McCarthy PM. Understanding the C-pulse device and its potential to treat heart failure. *Curr Heart Fail Rep.* 2010; 7: 27-34. doi: 10.1007/s11897-010-0007-7. PubMed PMID: 20425494.
10. Davies AN, Peters WS, Su T, Sullivan CE, Perkidides T, Milsom FP, et al. Extra-ascending aortic versus intra-descending aortic balloon counterpulsation-effect on coronary artery blood flow. *Heart Lung Circ* 2005; 14: 178-86. doi: 10.1016/j.hlc.2005.03.018. PubMed PMID: 16352274.
11. Cheng A, Monreal G, William ML, Sobieski M, 2nd, Slaughter MS. Extended extra-aortic counterpulsation with the C-Pulse device does not alter aortic wall structure. *ASAIO J (American Society for Artificial Internal Organs : 1992)* 2014; 60: e5-7. doi: 10.1097/mat.000000000000131. PubMed PMID: 25158886.

12. Gordon RJ, Weinberg AD, Pagani FD, Slaughter MS, Pappas PS, Naka Y, et al. Prospective, multicenter study of ventricular assist device infections. *Circulation* 2013; 127: 691-702. doi: 10.1161/circulationaha.112.128132. PubMed PMID: 23315371; PubMed Central PMCID: PMC3695607.
13. Nienaber JJ, Kusne S, Riaz T, Walker RC, Baddour LM, Wright AJ, et al. Clinical manifestations and management of left ventricular assist device-associated infections. *Clin Infect Dis* 2013; 57: 1438-48. doi: 10.1093/cid/cit536. PubMed PMID: 23943820; PubMed Central PMCID: PMC3805171.
14. Lietz K, Long JW, Kfoury AG, Slaughter MS, Silver MA, Milano CA, et al. Outcomes of left ventricular assist device implantation as destination therapy in the post-REMATCH era: implications for patient selection. *Circulation* 2007; 116: 497-505. doi: 10.1161/circulationaha.107.691972. PubMed PMID: 17638928.
15. Hayward CS, Peters WS, Merry AF, Ruygrok PN, Jansz P, O'Driscoll G, et al. Chronic extra-aortic balloon counterpulsation: first-in-human pilot study in end-stage heart failure. *J Heart Lung Transplant* 2010; 29: 1427-32. doi: 10.1016/j.healun.2010.06.014. PubMed PMID: 20817566.
16. Hashem MO, Yamada A, Tsuboko Y, Muira H, Homma D, Shiraishi Y, et al. Controlling methods of a newly developed extra aortic counter-pulsation device using shape memory alloy fibers. Conference proceedings: Annual International Conference of the IEEE Engineering in Medicine and Biology Society IEEE Engineering in Medicine and Biology Society Annual Conference. 2013; 2013: 2740-3. doi: 10.1109/embc.2013.6610107. PubMed PMID: 24110294.
17. Starck CT, Becker J, Fuhrer R, Sundermann S, Stark JW, Falk V. Concept and first experimental results of a new ferromagnetic assist device for extra-aortic counterpulsation. *Interact Cardiovasc Thorac Surg* 2014; 18: 13-6. doi: 10.1093/icvts/ivt416. PubMed PMID: 24061069; PubMed Central PMCID: PMC3867034.
18. Zannoli R, Corazza I, Branzi A. Mechanical simulator of the cardiovascular system. *Physica Med* 2009; 25: 94-100. doi: 10.1016/j.ejmp.2008.02.007. PubMed PMID: 18439864.
19. Zannoli R, Corazza I, Cremonesi A, Branzi A. A mechanical device for aortic compliance modulation: in vitro simulation of aortic dissection treatment. *J Biomechanics* 2007; 40: 3089-95. Epub 2007/05/08. doi: 10.1016/j.jbiomech.2007.03.021. PubMed PMID: 17482198.
20. Corazza I, Bianchini D, Marcelli E, Cercenelli L, Zannoli R. Passive aortic counterpulsation: biomechanical rationale and bench validation. *J Biomechanics* 2014; 47: 1618-25. doi: 10.1016/j.jbiomech.2014.03.001. PubMed PMID: 24679711.
21. Giudici F, Qian Y, O'Rourke M, Avolio A. Simulation of reduction of proximal aortic stiffness by an elastic wrap and effects on pulse pressure. Conference proceedings: Annual International Conference of the IEEE Engineering in Medicine and Biology Society IEEE Engineering in Medicine and Biology Society Annual Conference. 2012; 2012: 657-60. doi: 10.1109/embc.2012.6346017. PubMed PMID: 23365978.
22. Iliopoulos J. The aortic wrap procedure: a surgical method of treating age related aortic dilatation and stiffening [dissertation]. Sydney (NSW): University of New South Wales. 2006.