Counterpulsation Devices for Myocardial Support

Slaughter MS, Sobieski M, Giridharan GA and Koenig SC

Division of Thoracic and Cardiovascular Surgery and Department of Bioengineering, University of Louisville, Louisville, KY

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Authors K. Franco and Dr. Vinod H. Thouram

Address Correspondence:

Mark S. Slaughter, MD
Division of Thoracic and Cardiovascular Surgery
University of Louisville
201 Abraham Flexner Way, Suite 1200
Louisville, KY 40202
Phone: 502-561-2180
E-mail: mark.slaughter@louisville.edu
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Congestive heart failure is one of the largest unsolved healthcare issues confronting medical professionals today. Affecting more than five million patients in the United States alone, with an annual cost of nearly 35 Billion dollars. Despite advances in medical therapy, many patients eventually deteriorate to the point where they require mechanical circulatory support. The earliest and most common form of mechanical circulatory support is counterpulsation therapy. Each year more than 160,000 patients worldwide receive counterpulsation therapy, often for cardiogenic shock or severe left ventricular dysfunction following acute myocardial infarction or heart surgery, with many thousands of lives saved each year (65% survival).  

Theory of operation:  
The objective of any counterpulsation technique is to use a mechanical device to increase aortic pressure during early native heart diastole to augment myocardial perfusion, and to decrease aortic pressure during early native heart systole to reduce ventricular workload and vascular afterload. There are many different types of counterpulsation devices in clinical use or in development that operate on this counterpulsation principle. To be effective, counterpulsation therapy requires precise timing and synchronization of the counterpulsation device to the native cardiac cycle, which may be accomplished by triggering device activation to the ECG or aortic pressure waveform. The ECG waveform (i.e. R-wave peak detection) can be used to determine the incipient onset of ventricular systole. The aortic pressure waveform may be used to monitor timing, placement, and efficacy of counterpulsation therapy by evaluating peak diastolic and end-diastolic pressure waveform landmarks (Figure 1). Finer adjustments in the counterpulsation device timings can be made manually to account for time delays in signal acquisition and to optimize therapy.  

For example, an IABP catheter positioned in the proximal descending aorta inflates a balloon with bursts of shuttle gas during native heart diastole pushing blood toward the heart and end organs, and deflates the balloon just prior to native heart systole reducing the proximal aortic pressure. Other counterpulsation devices achieve similar effects by displacing blood (Symphony) or squeezing the aorta (C-Pulse).  

Physiologic Benefits of Counterpulsation:  
Counterpulsation has many important clinical benefits for the heart, end organs and the peripheral circulation for patients with moderate myocardial dysfunction. Counterpulsation therapy increases the
diastolic aortic pressure by 30-70% improving end-organ perfusion and coronary perfusion\textsuperscript{1,8,9}. The ejection pressure of the native ventricle is diminished, reducing afterload and left ventricular external work\textsuperscript{1,3,10,11}. The peak systolic pressure is reduced by up to 15\%,\textsuperscript{1,3,10} while the end diastolic pressure is decreased by up to 30\%.\textsuperscript{1,3,10} Cardiac output and stroke volume have been found to increase by up to 20\%.\textsuperscript{8,12} Counterpulsation therapy also decreases the native heart rate by 10\%\textsuperscript{2} and may reduce the left ventricular end diastolic volume by 10-15\%.\textsuperscript{13} The hemodynamic benefits of counterpulsation support also translate into improved metabolic function and often assist in recovery of end organ function\textsuperscript{2}. Counterpulsation therapy improves the cardiac energy balance by increasing the oxygen supply to the myocardium through increased coronary perfusion\textsuperscript{14,15} and by reducing myocardial oxygen consumption through a decrease in afterload and left ventricular work\textsuperscript{2}. Counterpulsation therapy has been shown to augment cerebral, renal, mesenteric and pulmonary blood flows\textsuperscript{16-18}. Increases in urine output, decreases in lactic acidosis and enhancement of venous oxygen saturation have also been observed in patients\textsuperscript{2}, demonstrating improved end organ function. A summary of the hemodynamic and metabolic benefits of counterpulsation is listed in Table below.

<table>
<thead>
<tr>
<th>Hemodynamic</th>
<th>Metabolic</th>
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<tbody>
<tr>
<td>Heart Rate\textsuperscript{2}</td>
<td>↓ 0-10%</td>
</tr>
<tr>
<td>Cardiac Output\textsuperscript{8,12}</td>
<td>↑ 0-20%</td>
</tr>
<tr>
<td>Left Ventricular Peak Systolic Pressure\textsuperscript{1,10}</td>
<td>↓ 5-15%</td>
</tr>
<tr>
<td>Left Ventricular End-Diastolic Pressure\textsuperscript{1,10}</td>
<td>↓ 5-30%</td>
</tr>
<tr>
<td>Left Ventricular End-Diastolic Volume\textsuperscript{10}</td>
<td>↓ 10-15%</td>
</tr>
<tr>
<td>Left Ventricular External Work\textsuperscript{1,2,10}</td>
<td>↓ 30-70%</td>
</tr>
<tr>
<td>Aortic Diastolic Pressure\textsuperscript{1,8}</td>
<td>↑ 0-100%</td>
</tr>
<tr>
<td>Coronary Perfusion\textsuperscript{14,15}</td>
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Summary of acute hemodynamic and metabolic benefits of counterpulsation in patients.

Counterpulsation therapy has been shown to be most effective in patients when their systolic aortic pressures are between 40-70 mmHg\textsuperscript{19}, native heart rates between 80-110 bpm\textsuperscript{20,21}, and with high arterial stiffness\textsuperscript{22-24}. The optimal performance level is achieved when the counterpulsation volume (e.g. IABP balloon displacement volume) equals the stroke volume of the native left ventricle\textsuperscript{25,26}. Counterpulsation is also more effective when the device is positioned closest to the aortic valve, but device placement in the descending aorta (IABP), around the ascending aorta (C-Pulse) or axillarley artery (Symphony) has become the standard of care as these locations avoid the risks of obstruction or embolization to the aortic arch vessels.

**Counterpulsation device**

*Extracorporeal Counterpulsation Devices*: Extracorporeal counterpulsation therapy is non-invasive and can be provided by Enhanced External Counterpulsation (ECP). ECP is performed by inflating and deflating pneumatic stockings (cuffs) placed on the surface of a patients lower extremities. The most common configuration involves three cuffs placed on each leg (on the calf, the lower thighs, and the upper thighs or buttocks). The cuffs are timed to inflate and deflate by triggering to the individual's ECG landmarks (i.e. R-wave detection). During the inflation period of the cycle, the calf cuffs inflate first, then the lower thigh cuffs and finally the upper thigh cuffs while during deflation the order is reversed. Inflation is controlled by a pressure monitor, and the cuffs are inflated to approximately 300 mmHg. The ECP regimen commonly performed in the US is a total of 35 one-hour sessions (one session a day, five days a week for 7 weeks). ECP has been shown to relieve angina, improve exercise tolerance, decrease the degree of ischemia in a cardiac stress test, and improve cardiac
output in patients with heart failure\textsuperscript{27-31}. ECP is indicated for patients with symptoms of ischemic cardiomyopathy who are not amenable to percutaneous coronary intervention or coronary artery bypass graft surgery. Contraindications of ECP include severe peripheral vascular disease, aortic insufficiency, atrial fibrillation, significant left main coronary artery disease, overt congestive heart failure, uncontrolled hypertension, phlebitis, deep vein thrombosis, stasis ulcers, and bleeding diathesis. The ECP therapy does not require surgical implantation or anticoagulation regimen.

The Enhanced external counterpulsation device is a series of pneumatically actuated cuffs placed on the patient’s lower extremities. The inflation and deflation of these cuffs are timed and sequenced to reduce afterload and increase cardiac output.

\textbf{Percutaneous Counterpulsation devices:} The hemodynamic and metabolic benefits of counterpulsation therapy in patients with acute and chronic cardiac dysfunction has led to the emergence of IABP as the single most effective and widely used circulatory assist device. There is clinical evidence that demonstrates counterpulsation can be effective in supporting patients with chronic congestive heart failure (CHF). IABP has been used in patients awaiting transplant and in patients undergoing coronary artery bypass surgery\textsuperscript{32}. The IABP is a cylindrical polyethylene balloon that sits in the aorta, approximately 2 centimeters (0.8 in) from the left subclavian artery. The IABP is inflated and deflated by shuttling helium. Placement of an IABP simply requires percutaneous access to the femoral artery using a modified Seldinger’s technique. However, the location of an IABP catheter (descending thoracic aorta) and biocompatibility issues limit the application of IABP to short durations (typically less than 14 days)\textsuperscript{33,34}. When IABP support was attempted for a prolonged period (>20 days), the frequency of vascular complications, infections and bleeding were significantly higher\textsuperscript{34,35}. Furthermore, in its current form, a balloon device mounted on a catheter is advanced from the femoral artery into the descending aorta, and requires a patient to remain supine for the duration of therapy. Timing of the IABP is critical—the IABP has to be significantly and rapidly deflated (~100 ms) before the onset of ventricular ejection to ensure that the balloon does not obstruct aortic flow\textsuperscript{36}. This rapid deflation causes brief retrograde cerebral, myocardial and systemic flows limiting the positive hemodynamic and metabolic benefits of IABP counterpulsation. Recent advances in IABP technology include smaller balloon catheter sizes, sheathless insertion technique and fiber-optic pressure sensors. The variable sizes enable the clinician to better match balloon size to the internal diameter of the aorta and height of the individual patient. The modified insertion technique (sheathless) and the removal of a fluid filled pressure sensor (fiber-optic) both improved distal limb perfusion by reducing the IABP catheter outer diameter lumen.

The clinical indications for use for IABP therapy are: Cardiogenic shock, reversible intracardial mechanical defects complicating infarction (acute mitral regurgitation and septal perforation), unstable angina pectoris, post-cardiotomy failure, perioperative injury to myocardial tissue, perioperative use for high-risk patients such as those with unstable angina with stenosis greater than 70% of main coronary artery, in ventricular dysfunction with an ejection fraction less than 35%, percutaneous
coronary angioplasty, high risk coronary artery bypass graft surgery and thrombolytic therapy of acute myocardial infarction. Absolute contraindications for IABP therapy are: severe aortic valve insufficiency, aortic dissection, and severe aorto-iliac occlusive disease. Further relative contraindications are prosthetic vascular aortic grafts, aortic aneurysm, and aortofemoral grafts. The IABP therapy requires surgical implantation (percutaneous or direct vision) with an anticoagulation regimen of Heparin (low-dose, ACT 180 -200 or PTT 1.5 times control) \(^1,4,14,36,37\).

**Implantable Counterpulsation devices:** Given the proven benefits of short-term counterpulsation therapy, it is not surprising that a number of new chronic heart assist devices are being developed to enable patients to receive long-term counterpulsation therapy (LVAD Technologies, Sunshine Medical, SCR). All of these devices offer the advantages of counterpulsation therapy (reduced ventricular work and improved systemic and coronary artery perfusion) on a chronic basis as well as offer an implantation system that is less invasive than current ventricular assist devices.

**LVAD Technologies (Detroit, MI):** The Cardioplus system (currently in clinical trial) is designed to provide permanent mechanical circulatory support to moderate to severe HF patients who still have some cardiac function, but who are unlikely to qualify for heart transplantation due to co-morbidities. The electrically powered, pneumatically driven Cardioplus system is designed for chronic support therapy. The Cardioplus system consists of the Cardioplus aortic blood pump, the company’s ViaDerm percutaneous access device (PAD), and a wearable or mobile drive unit with controls that weighs less than 5 lbs. The aortic blood pump is an inflatable, aavalvular bladder made of textured polyurethane, which serves as the blood-device interface and is designed to encourage the formation of a non-thrombogenic pseudointima over its intra-aortic surface. Approximately 6.5 inches in length and weighing less than an ounce, the pump is surgically implanted in the patient’s descending thoracic aorta (by excising a portion of the lateral aspect of the aortic vessel and suturing the device in its place). When inflated, the pump bladder displaces approximately 60cc of blood without occluding the aorta, which approximates the stroke volume of a normal heart. The Cardioplus system is an “on-off” device that the patient may disconnect from the external power source for minutes or hours and then reconnect when he/she wishes. Patients implanted with the Cardioplus have been reported to have major improvements in exercise capacity that were immediate and sustained\(^7,38,39\).
Implantation of this device requires a full thoracotomy and the use of cardiopulmonary bypass (CPB), which may increase the risk of morbidity and mortality. The Cardioplus requires surgical implantation (sternotomy, aortotomy and use of CPB) with an anticoagulation regimen of Heparin (low-dose, ACT 180 - 200 or PTT 1.5 times control) in the immediate postoperative period, which transitions to chronic Warfarin (INR 2.0 – 3.0).

The Cardioplus is an inflatable patch surgically implanted by an aortotomy via a sternotomy. The patch inflates during ventricular diastole and deflated during ventricular systole (left), providing counterpulsation support by a wearable pneumatic driver (right) that can be turned ‘off or on’ by the patient.

Sunshine Heart (Eden Prairie, MN): The C-Pulse (currently in clinical trial) is a mechanical, implantable, extra-aortic counterpulsation system. The system is designed to provide permanent, long-term, continuous or on-demand partial circulatory support for moderate to severe HF patients. The C-Pulse system includes a non-blood-contacting, ECG-gated, pneumatically driven, implantable cuff (consisting of a combination wrap and balloon); a sensing lead that transmits electrical signals from the heart to the controller; and an extracorporeal wearable battery-powered or mobile AC-powered controller/drive unit. During a short 15- to 20-minute implantation procedure (total operation time is approximately 60 to 90 minutes), the C-Pulse pneumatic polyurethane cuff is wrapped around the patient’s ascending aorta just above the heart (no aortic perforation is involved); the cuff is linked by an air tube to the controller/drive unit, which pumps air into the balloon, inflating and deflating in time with the heart’s filling and pumping cycle (the controller/drive unit is programmable, allowing adjustments in both inflation volume and the rate of inflation/deflation).

The C-Pulse is a pneumatically actuated cuff that is wrapped around the patient’s ascending aorta via a sternotomy. The cuff is inflated during ventricular diastole and deflated during ventricular systole to provide counterpulsation support (left). The cuff is connected to a wearable pneumatic driver via a driveline that exits the skin (right). The C-Pulse may be turned ‘off or on’ by the patient.
C-Pulse was reported to augment left coronary artery flow by 67%\textsuperscript{41,42}. The C-Pulse Heart assist system is designed to treat clinical symptoms associated with Class III and ambulatory Class IV heart failure. These symptoms normally include shortness of breath, dizziness, low blood pressure and fluid retention. Patients with Class III and ambulatory Class IV heart failure are typically unable to engage in normal activities, compromising their quality of life\textsuperscript{40}. Contraindications for the Sunshine heart include the presence of previous heart surgeries, significant vascular disease, aortic insufficiency, and presence of coronary artery bypass grafts. Further, placement of this device may significantly complicate further therapies such as LVAD placement or heart transplantation. The C-Pulse requires surgical implantation (sternotomy) but does not require anticoagulation (non-blood contacting)\textsuperscript{6}.

\textit{Abiomed (Danvers, MA) and SCR (Louisville, KY):} The Symphony device (currently in pre-clinical trials) is a 30-mL stroke volume polyurethane-lined pumping chamber, which is designed to fit comfortably in a pacemaker-like pocket on the right side of a patient\textsuperscript{43,44}. The pumping chamber is connected to the systemic circulation by a short ePTFE graft anastomosed to the right axillary artery using a simple surgical procedure. A percutaneous driveline runs from the pumping chamber, exits the skin near the costal margin, and connects to a small pneumatic external driver. During systole, the driver evacuates air from the pumping chamber, thus removing blood from the circulation and reducing cardiac work. During diastole, the Symphony ejects the blood into the circulation providing diastolic augmentation and improving coronary perfusion. The pneumatic driver weighs 2.2 kg and can be carried or worn on a patient’s belt. Symphony filling and ejection are triggered by the patient’s ECG, and timing is adjusted to maximize hemodynamic performance. Pre-clinical studies have shown equivalent or better hemodynamic and metabolic benefits compared to a 40-ml IABP\textsuperscript{43-47}. Patients with NYHA Class IIIB and IV heart failure with chronic angina or recovering from acute myocardial infarction (AMI) are indicated for this device. Contraindications are end-stage heart failure, aortic insufficiency, severe hypertension, infection, severe vascular disease, and small or obstructed axillary or brachiocephalic arteries. The Symphony requires surface surgical implantation (equivalent to ICD pocket and vascular anasomosis) with an anticoagulation regimen of initial Heparin (low-dose, ACT 180-200 or PTT 1.5 times control) in the immediate postoperative period which transitions to chronic Warfarin (INR 1.8 – 2.5) and antiplatelet therapy with Plavix.

The Symphony is implanted in the patient’s right side via a pacemaker-like pocket, anastomosed to the right axillary artery, and the driveline exits through the skin (left). The pump (center) fills during systole and empties during diastole through a valveless ePTFE cannula. The pump is actuated by a small, lightweight, pneumatic driver (right). (Pictures courtesy of SCR)

\textbf{Clinical Summary:}
Although there is a lot of interest and new developments with continuous flow technology, counterpulsation devices are still commonly used in everyday practice. One practical issue continues to be the role and clinical significance of a pulse or pulse pressure. It seems intuitive that end organ function would be better and more easily maintained by re-creating a pulse pressure similar to the native circulation. However, early clinical experience with continuous flow devices, which result in a markedly reduced or absent pulse pressure, demonstrates that end organ function is supported with diminished pulsatility physiology. As we gain new knowledge the role and purpose of a pulse wave will continue to be better defined. Until then, counterpulsation devices will continue to have a role and provide adequate support for appropriately selected patients.
References:


