Clinical Experience with a New Pulsatile Cardiac Assist Device

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The development of modern techniques for revascularization surgery has resulted in many more critically ill patients undergoing open heart surgery. To deal with the increasing numbers of patients who require both urgent open heart surgery and who present with many complicated patterns of disease, a multitude of cardiac assist measures have been developed. Those temporary mechanical cardiac assist devices which employed the principle of counterpulsation and balloon pumping have met with the most consistent clinical success.\textsuperscript{1,2}

Prior to the institution and use of counterpulsation techniques in open heart surgery, left ventricular power failure and refractory ventricular arrhythmias had been associated with mortality after open heart surgery in excess of 90%.\textsuperscript{3,4} It is the purpose of this paper to discuss our clinical results with a new application of counterpulsation with pulsatile bypass as a routine adjunct in open heart surgery.

A new cardiac assist device, the pulsatile assist device (PAD) which was developed at the Columbia Presbyterian Medical Center, will be described.

Unidirectional Intra-Aortic Balloon Pumping

Intra-aortic balloon pumping (IABP) is currently the temporary mechanical cardiac assist technique of choice for the management of refractory left ventricular power failure. Our experience at the Columbia Presbyterian Medical Center is entirely with the unidirectional dual chambered intra-aortic balloon in conjunction with Datapace System 80.

The Datapace System 80\textsuperscript{*} (Figure 1), a mobile failsafe, battery operated, cardiac assist console was used to drive the intra-aortic balloon.\textsuperscript{5} Pumping was affected from the R wave of the electrocardiogram, which triggered de-
2. Schematic—Mechanism of action of unidirectional dual-chambered untra-aortic balloon (see text).

3. Schematic representation of clinical dual chambered IABP.

Inflation of the intra-aortic balloon followed by inflation during diastole; thus balloon inflation never coincided with ventricular systole. A unidirectional dual chambered intra-aortic balloon (30 or 35 cc) was used exclusively in these studies. (Figure 2)\(^6,7\) The balloon was a spherical distal chamber which inflates early in diastole and occludes the aorta. This is sequentially followed by the inflation of a narrower cylindrical proximal balloon, in the same diastolic interval, which pumps intra-aortic blood entirely toward the aortic root. Both chambers are completely deflated by an active vacuum just prior to ventricular ejection.

The balloon was passed through the common femoral artery of the extremity with the stronger pulse and was positioned just distal to the left subclavian artery. (Figure 3) A dacron side arm graft was sutured to the common femoral artery, and the graft and balloon catheter were snared so that the distal extremity
would be perfused during the period of cardiac assistance. In our pre-operative patients, intravenous aqueous heparin was administered in a dose of 5,000-7,500 units every four to six hours. In the intra and postoperative patients aspirin, given rectally (600 mg every four hours), was utilized as the sole “anticoagulant” in these patients. When the balloon was removed, a Fogarty catheter was passed proximally and distally, and then a 1 cm stump of the graft was oversewn and left as a patch graft. Additional details of the patient management have been previously described.

From February, 1972 to April, 1976, 981 adult patients underwent corrective open heart surgery at the Columbia Presbyterian Medical Center. Sixty-three patients received IABP; 55 (87%) could be weaned from IABP and 40 (63%) were discharged from the hospital.

The Pulsatile Assist Device (PAD)

Although the advantages of intraoperative counterpulsation with intra-aortic balloon pumping have been well documented (Table 1) it has, up until now, not been possible to routinely use counterpulsation in open heart surgery. Evidence from Berger and Pappas has clearly documented the advantages of pulsatile cardiopulmonary bypass when an intra-aortic balloon pump was used to create the pulsations.

A new pulsatile assist device (PAD) has been developed to convert in a simple fashion roller pump flow to pulsatile flow. (Figures 4 & 5) In addition, the PAD can be used as an arterial counterpulsator before and after cardiopulmonary bypass.

4. Schematic of Pulsatile Assist Device (PAD) in cardiopulmonary bypass circuit. Oxygenated blood flows through the valveless balloon with the PAD, and then into the aorta. The balloon pump pneumatically squeezes the PAD balloon to effect either synchronous counterpulsation or pulsatile cardiopulmonary bypass.

5. The clinical PAD—Displacement volume of the balloon is 80 cc.
ADVANTAGES OF PULSATILE FLOW

1. BETTER CAPILLARY PERFUSION
2. LESS METABOLIC ACIDOSIS
3. INCREASED OXYGEN CONSUMPTION
4. LOWER PERIPHERAL ARTERIAL RESISTANCE
5. BETTER RENAL PERFUSION
6. IMPROVED CEREBRAL PERFUSION
7. LESS HEPATOCYCLULAR INJURY
8. BETTER MYOCARDIAL PERFUSION (Especially in the subendocardium)
9. LESS ELEVATION OF CORONARY SINUS LACTATE

The PAD is inserted in the arterial line close to the aortic root. The device consists of a flexible valveless balloon through which the arterial blood flows. The balloon is contained within a rigid plastic housing which is connected to a standard intra-aortic balloon pump, thereby enabling the blood filled balloon to be squeezed.

The PAD was evaluated in twelve canine preparations. A cardiogenic shock model was induced with propranolol (3mg/kg). When used as a counterpulsation device (Figure 6) mean cardiac output increased 53% (range 25-95%), diastolic pressure increased 99% (range 33—165%), and systolic pressure decreased 12% (range 0-50%). During two hours of assist, plasma hemoglobin values range between 4 and 12 mgs.16

When the PAD was used in conjunction with a roller pump during two hours of total synchronous cardiopulmonary bypass, with an average pulse pressure of 40mmHg, hemolysis values ranged between 10.5 and 17.7 mgs (within the normal range for our laboratory).

After its initial evaluation in the laboratory by clinical PAD was employed in 61 adult patients undergoing open heart surgery for coronary artery and or valvular heart disease. There were 46 males and 15 females in this group. Ten patients underwent isolated valve replacement, four patients underwent combined ventricular aneurysm resection with coronary artery revascularization, seven patients underwent com-

6. Effect of the PAD is an arterial counterpulsator
   EKG = electrocardiogram
   AoP = aortic pressure
   LVP = left ventricular pressure
   DA = diastolic augmentation

Note significant pressure (unloading) and large diastolic augmentation during the assist. Tracing speed 25 mm/sec.
7. Effect of the PAD to create synchronous pulsatile cardiopulmonary bypass.

EKG = electrocardiogram
AoP = aortic pressure

Note pulse pressure of 45 mmHg during bypass.

bined valve replacement and 40 patients underwent coronary revascularization alone. Thirty-three patients in this group were either New York Heart Association class III or IV, or had ejection fractions of less than 0.4. In the clinical setting the device functioned as a hemodynamically effective counterpulsator both before and after cardiopulmonary bypass. During cardiopulmonary bypass pulse pressures of 40-50 mmHg were readily obtained (Figure 7). Urinary outputs during cardiopulmonary bypass were increased with the PAD when compared to a control group (7.51 ± 1.22 cc per minute versus 4.53 ± .73 cc per minute). In addition, during cardiopulmonary bypass, coronary graft blood flow increased an average of 22.4% with the PAD, and after cardiopulmonary bypass, coronary blood flow increased an average of 27.7%. Free plasma hemoglobins after cardiopulmonary bypass were not elevated when compared to a control group.

Clinical Results With the PAD

In the group of 61 patients assisted with the PAD, all patients were successfully weaned from cardiopulmonary bypass with the PAD alone. In one patient it was necessary to insert an intra-aortic balloon postoperatively. This patient incurred an acute intraoperative myocardial infarction, the only patient who experienced such an infarction in the 61 patients. His postoperative course with intra-aortic balloon pumping was uneventful. In one additional patient who was successfully weaned from bypass with the PAD, postoperative intra-aortic balloon pumping became necessary. However, this patient had recently undergone resection of an abdominal aortic aneurysm with endarterectomies of both femoral arteries, and balloon insertion was not possible. One additional patient who was successfully operated upon in conjunction with the PAD, expired in the recovery room from an anaphylactic reaction to a drug.

Discussion

Although intra-aortic balloon pumping has been employed experimentally for the past sixteen years\textsuperscript{17} and clinically for the past eight years,\textsuperscript{18} only recently has
clinical data become available to evaluate its use in a variety of clinical settings. Initially, it was felt that intervention with intra-aortic balloon pumping in a patient with acute myocardial infarction and cardiogenic shock would lead to increased patient survival. However, although the shock syndrome is frequently reversed, the ultimate outcome has not been significantly altered.\textsuperscript{19}

The most successful use of intra-aortic balloon pumping to date has been as an adjunct to the pre, intra, and postoperative support of patients undergoing open heart surgery.\textsuperscript{1}

An analysis of the data obtained in patients assisted with unidirectional IABP in conjunction with open heart surgery at the Columbia Presbyterian Medical Center has led to two groups of criteria for employing intraoperative IABP.\textsuperscript{1}

The primary indications for intraoperative IABP as suggested by our data include any two of criteria 1 to 3, in conjunction with criteria 4, in patients in whom weaning from cardiopulmonary bypass has been attempted for one hour: (1) mean blood pressure 60 mmHg and falling; (2) cardiac index 1.8L per minute per square meter and falling; (3) left atrial pressure 25 mmHg and rising; and (4) requirement for high-dose inotropic support.

Additional criteria include the following: (1) recurrent ventricular tachyarrhythmias; (2) evidence of a significant intraoperative myocardial infarction; (3) subendocardial ischemia (EVR less than .8 at the conclusion of bypass) and (4) coronary graft blood flows less than 40 c.c. per minute (projected use).

The pulsatile assist device has added new dimension to the safety of cardiovascular surgery. It is now possible to utilize counterpulsation routinely and safely in open heart surgery with the PAD. The pulsatile assist device functions in every respect as an intraoperative intra-aortic balloon pump, without the need for additional surgery. It has been interesting to see that in our initial evaluation of the pulsatile assist device the advantages of pulsatile cardiopulmonary bypass are being supported and clarified. Certainly greater urinary output indirectly implies better renal perfusion. In addition, the increase in intraoperative myocardial blood flow would appear to offer greater protection to the myocardium during cardiopulmonary bypass. The extremely low incidence of perioperative myocardial infarctions in this series would attest to this fact. Of more interest is the fact that during our initial six month clinical utilization of the pulsatile assist device, only one patient required intraoperative intra-aortic balloon pumping. This is a marked reduction in the requirement for balloon pumping at our institution and suggests that the use of the pulsatile assist device will probably decrease the need for postoperative intra-aortic balloon pumping.

It is concluded that the primary use for intra-aortic balloon pumping is currently assistance of the open heart surgical patient.\textsuperscript{1, 20-27} The criteria are now defined. It is our impression that the use of intra-aortic balloon pumping in selected patients undergoing open heart surgery has lead to improved patient survival and has enabled us to operate upon high risk patients with greater confidence and with improved clinical results. More significantly, use of the pulsatile assist device will extend the role of counterpulsation in open heart surgery and will probably decrease the need for postoperative balloon pumping in these high risk patients.
REFERENCES


