Mechanical support of the circulation

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The recent development of modern direct techniques for coronary revascularization has made open heart surgery available to many critically ill patients. In an effort to deal with the increasing numbers of patients who require urgent open heart surgery and who have either many complicated patterns of coronary artery disease or valvular heart disease, or both, a spectrum of cardiac assist measures ranging from simple pharmacologic maneuvers to a variety of mechanical cardiac assist techniques have been developed. Temporary mechanical cardiac assist devices that use the principle of arterial counterpulsation have met with the most consistent clinical success.[1] It is the purpose of this paper to summarize our clinical experience with intraaortic balloon pumping (IABP) and the pulsatile assist device in patients requiring open heart surgery at the Columbia-Presbyterian Medical Center.

Intraaortic balloon pumping

IABP is the temporary mechanical cardiac assist technique of choice for the management of refractory intraoperative left ventricular power failure.[2, 3] Before the institution and use of IABP, left ventricular power failure and refractory ventricular tachyarrhythmias had been associated with a mortality of more than 90%.[1]

Our experience with IABP has been in conjunction with the System 80 and more recently System 82 (Datascope Corporation, Paramus, New Jersey) and the dual-chambered intraaortic balloon, both of which have been described.[1-4] The balloon is passed through the common femoral artery with the stronger pulse and is positioned just distal to the left subclavian artery. The balloon is passed through a 10-mm woven Dacron side arm graft, which is sutured to the common femoral artery. The balloon and catheter are then snared to permit perfusion of the distal extremity during the period of cardiac assistance. Since 1979 a percutaneous balloon has been available. Preoperative patients are given heparin, but postoperative patients are usually treated solely with aspirin given rectally. Additional details of patient management have been described.[1, 5] When practical, a Swan-Ganz thermodilution catheter (Edwards Laboratories, Irvine, California) is inserted in these patients for hemodynamic monitoring. In addition, an endocardial viability ratio (EVR) computer (Datascope Corporation), which enables the early detection of subendocardial ischemia and its continuous monitoring during support with counterpulsation, has been routinely employed.

Clinical experience

From February 1972 through February 1980, 140 patients required IABP of a group of 3400 adult patients who underwent open heart surgery at the Columbia-Presbyterian Medical Center. Twenty-one of these 140 patients were supported with a percutaneous balloon. The average age of these patients was 54 years (range, 15 to 75). Eighty-nine were men and 51 women. There were three groups of patients. The first group of 62 patients required preoperative IABP. These included patients in early cardiogenic shock (within the first 6 to 8 hours), high-risk patients for cardiac catheterization, patients with the acute mechanical complications of acute myocardial infarction (acute ventricular septal defect, acute mitral insufficiency), and patients with crescendo angina refractory to medical therapy. The second group of 52 patients required IABP for weaning from cardiopulmonary bypass. These patients usually suffered the intraoperative complications of either subendocardial ischemia or infarction or both or an intraoperative myocardial infarction. The third group included 26 patients who required balloon support in the recovery room, usually within the first 24 hours of surgery. These patients had the typical low cardiac output syndrome. Our entire experience with these 140 patients included 106 (76%) who could be weaned from IABP and 85 (61%) who were discharged from the hospital. In our present experience, the number in the medical group of intraaortic balloon patients is increasing, but the numbers in the intraoperative and postoperative groups are decreasing, probably as a result of the introduction of the pulsatile assist device to create pulsatile flow during open heart surgery and the routine use of cardioplegia.

Percutaneous intraaortic balloon pumping

A new single-chambered percutaneous intraaortic balloon, Percor, (Datascope Corporation) (*Fig. 1*) has been constructed around a central guidewire, enabling its insertion into the femoral artery through a 12F sheath, inserted by the conventional Seldinger technique.

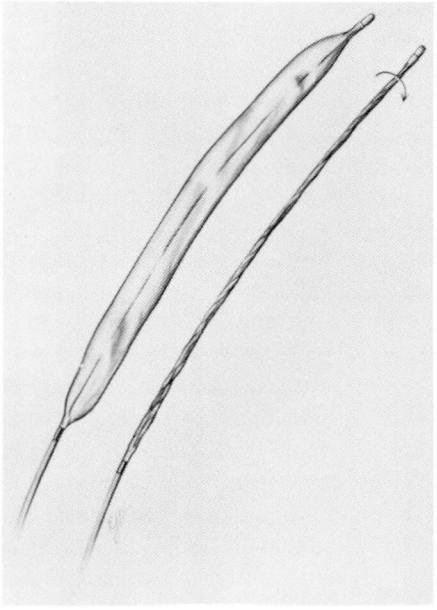

Figure. Intraaortic balloon furled for percutaneous insertion.

With the conventional surgical techniques, an experienced surgeon requires 30 to 45 minutes to insert the intraaortic balloon, and a second operative procedure is necessary for balloon removal. The percutaneous approach to IABP facilitates balloon insertion and removal, and permits the rapid institution of mechanical circulatory support. The availability of rapid percutaneous IABP has broadened clinical indications for IABP in our institution.[6]

Percutaneous IABP insertion has been performed in 21 patients (mean age, 57 years) with postinfarction angina (5), unstable angina (3), intraoperative myocardial infarction (2), postoperative cardiac arrest (3), acute myocardial infarction during coronary arteriography (3), postoperative left ventricular failure (2), terminal cardiomyopathy in cardiac transplant candidates (2), and cardiac arrest during cardiac catheterization (1). Percutaneous balloons could not be advanced into the aorta in two patients (10%) with severe bilateral aortoiliac occlusive disease. In all 21 assisted patients satisfactory circulatory support was achieved with percutaneous IABP, and 18 of the patients (86%) survived to be discharged from the hospital. Mean duration of IABP was 3.3 days.

Percutaneous IABP insertion generally required less than 5 minutes and was successfully performed in the cardiac catheterization laboratory, coronary care unit, operating room, and recovery room. Fluoroscopy was used for 15 IABP insertions. In six patients percutaneous IABP was successfully performed without fluoroscopy.

Following direct balloon removal, external pressure was applied for 30 minutes. No patient experienced groin hematoma, aortic dissection, compromised distal pulses, or late wound complications.

Cardiac transplantation for balloon dependent patients

Certain patients, who have acute cardiac failure superimposed on chronic end-stage heart disease and are dependent on IABP support, have been offered cardiac transplantation. Five such patients with acute cardiogenic shock received orthotopic cardiac allografts, and all patients could be weaned from IABP immediately after transplantation. All patients survived the operation, and four were discharged from the hospital fully active.[7]

Our experience suggests that cardiac transplantation is an effective method for treatment of certain patients with acute end-stage cardiac disease that requires temporary mechanical circulatory support with the IABP. Patients who are balloon-dependent can never-

theless be supported for several days to permit appropriate preparations of donors and recipients for cardiac transplantation.

Pulsatile cardiopulmonary bypass

The potential importance of pulsatile cardiopulmonary bypass has been recognized for several years by investigators in the field.[1, 8-20]

The advantages of pulsatile flow during clinical cardiopulmonary bypass include:

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 hepatocellular injury
8. Better myocardial perfusion (especially in the subendocardium)
9. Less elevation of coronary sinus lactate
10. Faster cooling and rewarming during cardiopulmonary bypass

Basically these categories suggest an improvement in both peripheral and organ perfusion. With specific reference to the heart, it is now clear that pulsatile flow results in better perfusion of the subendocardium during ventricular fibrillation,[21] even in the presence of a critical coronary stenosis.[22, 23] The reason that pulsatile cardiopulmonary bypass has not been used clinically on a routine basis has been a lack of simple technology to create the pulsations.

Evolution of pulsatile cardiopulmonary bypass

Even though the earliest heart-lung machines could create pulsatile flow, this feature was not used routinely because of excessive hemolysis.

Several subsequent pump consoles have been capable of pulsation and counterpulsation, but the ability to combine both features has generally been unsuccessful, and either the complexity or the hemolysis generated by the equipment precluded long-term or routine use.[12, 19, 23-26]

Berger et al,[27] Maddoux et al,[28] and Pappas et al[29] first called attention to the use of IABP to create clinical pulsatile cardiopulmonary bypass. They observed that when medical patients were taken to the operating room on IABP, the balloon could, in a simple fashion, create pulsatile cardiopulmonary bypass with no blood trauma. The data of Maddoux et al[28] and Pappas et al[29] suggest that pulsatile cardiopulmonary bypass improves myocardial metabolism and function, and results in less hepatocellular injury (postoperative serum glutamic oxaloacetic transaminase levels). In addition, there was better overall tissue perfusion (total lactic dehydrogenase), a lower incidence of perioperative myocardial infarctions, and possible improvement in late myocardial function was suggested. Renal failure was rare postoperatively in contrast to a study of Abel et al,[30] who found that 27% of their patients had mild to severe renal failure, which correlated with the duration of the operation.

Although use of the balloon is associated with low morbidity,[1, 4] its use cannot be justified for the routine creation of pulsatile cardiopulmonary bypass, because there may be a significant risk associated with peripheral balloon insertion.[31]

In an effort to broaden the applicability of the principles of intraaortic balloon pumping, a new pulsatile assist device (PAD) was developed,[1, 32-35] which is employed *externally* in the cardiopulmonary bypass circuit, and which

in all respects simulates the action of an intraoperative intraaortic balloon.

The PAD (Datascope Corporation) is a plastic disposable device designed to be inserted in the arterial line during cardiopulmonary bypass. The device can be used with either aortic or femoral artery perfusion. It consists of a flexible, valveless polyurethane balloon with 3/8-inch ends through which the arterial blood flows. The balloon is contained within a rigid plastic housing connected via an air hose to a standard System 80 or 82 IABP. More recently a compact System 42 has been developed specifically for pulsatile flow. As soon as the arterial perfusion cannula is inserted, before bypass is instituted, a tubing clamp is placed between the roller pump and the PAD, to maximize its central hemodynamic efficacy, and arterioarterial counterpulsation can be instituted. When cardiopulmonary bypass begins, the clamp is removed, and the PAD is pulsed synchronously with the ECG in diastole to create pulsatile cardiopulmonary bypass. During ventricular fibrillation or aortic cross-clamping, an internal trigger of 80 beats/min is used. Each time the heart is defibrillated, synchronous electrocardiograph-triggered pulsatile bypass is resumed. While weaning the patient from bypass, the PAD is again used as a counterpulsator, and when bypass is terminated, counterpulsation can continue until protamine is administered. While counterpulsating after bypass, the tubing clamp is again placed between the roller pump and the PAD. This clamp can be removed intermittently as blood is returned in increments from the heart-lung machine. Counterpulsation is continuous, as this blood is reinfused, and weaning from the PAD can be accomplished in a manner similar to IABP.[5]

Aside from its pneumatic connection to the PAD in the sterile operative field, the only other mandatory input to the System 42 or 80 console for PAD use is the electrocardiogram. Pressure acquisition is optional but is necessary for PAD counterpulsation timing. The PAD and air hose are kept sterile in the operative field, so that the PAD can be as close to the arterial tree as possible to maximize its effectiveness as a counterpulsator. In addition, this position facilitates excision of the PAD in the event of a device failure.

Clinical experience with PAD

After its initial evaluation in the laboratory, the clinical PAD was used beginning November 4, 1975.[36] One thousand adult patients, primarily from the group with impaired left ventricular function, who underwent elective open heart surgery at the Columbia-Presbyterian Medical Center, have been assisted intraoperatively with the PAD. There were 735 men and 265 women. The average age was 59 years (range, 18 to 82). Five hundred nineteen patients underwent coronary artery bypass alone, 341 valve replacement alone, 12 ventricular aneurysm alone, 105 combined coronaries and valves, and 23 combined coronaries and ventricular aneurysms.

Seven hundred seventy-six of these patients were New York Heart Association Class III or IV or had ejection fractions of <0.3 or LVEDP >18 mm Hg on their preoperative catheterization.

All bypasses were carried out with the Bentley Temptrol Q200 (Bentley Laboratories, Irvine, California) disposable bubble oxygenator (more recently the Spiraflo) with the use of a clear fluid prime. Moderate hypothermia was routinely employed. Our clinical experience has been primarily with ascending aor-

tic perfusion utilizing a No. 24 Bardic (U.S. Catheter Corporation, Glens Falls, New York) arterial perfusion catheter with a short arterial inlet.

Our technique of coronary bypass surgery with the PAD is as follows: counterpulsation with the PAD is begun as soon as the aortic (or femoral) artery cannula is inserted. If a long-tipped arterial perfusion cannula is employed, it is directed distally at the beginning of the operation. However, while weaning the patient from bypass at the conclusion of the operation, the cannula tip can be pointed toward the aortic valve, as this direction will maximize the counterpulsation effect from the PAD. As the venous cannulas are being inserted, the console is turned to 1:2, since atrial arrhythmias are frequent at this point. One or more vein grafts can be sutured to the ascending aorta while the patient is being counterpulsed 1:1 even before bypass is instituted. Whenever a partial occlusion clamp or an aortic cross-clamp is applied to or removed from the ascending aorta, the PAD is always momentarily switched off. When bypass commences, the PAD is turned off for a few minutes until total bypass is established. Cardioplegia is now routinely employed.

The PAD functioned as a hemodynamically effective arterial counterpulsator before and after cardiopulmonary bypass. During bypass, pulse pressures of 40 to 50 mm Hg were readily obtained without altering our usual average mean arterial perfusion pressures of 80 to 90 mm Hg. There were no device-related complications. During bypass, the urinary outputs of the PAD patients were more than twice the values seen in control patients (9.18 ± 0.68 cc/min vs 3.90 ± 0.35 cc/min). In addition, intraoperative coronary graft blood flow determinations (Carolina Medical Electronics, King, North Carolina) in coronary patients off and on the PAD revealed an increase in coronary graft blood flow of 21.4% with the pulsatile bypass.

Hemolysis studies were performed in both the PAD patients and in a control series. No significant difference was noted. Nine hundred ninety-three (99.3%) patients could be weaned from cardiopulmonary bypass with the pulsatile assist device, but six required conversion to IABP (five survived). Seven postoperative patients also required IABP, and five of these survived. The incidence of perioperative myocardial infarction was only 15 patients (1.5%). There were nine other (0.9%) hospital deaths within 4 weeks.

Discussion

Although intraaortic balloon pumping has been employed experimentally for the past 19 years and clinically for the past 12 years, only recently have clinical data become available to evaluate its use in a variety of clinical settings. Initially, it was felt that the use of IABP 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.

The most successful use of IABP to date has been as an adjunct to the preoperative, intraoperative, and postoperative support of patients undergoing open heart surgery.[3] It is now possible to stabilize the condition of critically ill individuals, subject them to cardiac catheterization safely, and bring them to the operating room in a more stable condition. Patients with hepatic and renal failure secondary to the cardiac lesion can be improved with the use of IABP before surgery. Also, high-risk pa-

tients and those with critical coronary artery lesions can undergo induction of anesthesia relatively safely with intraaortic balloon support until cardiopulmonary bypass can be established. The results in our intraoperative patients demonstrate the success of IABP in its role of weaning patients from cardiopulmonary bypass who have incurred subendocardial ischemia or infarction during the procedure, and in supporting them in the postoperative period.

An analysis of the data obtained in patients assisted with unidirectional IABP in conjunction with open heart surgery at Columbia-Presbyterian Medical Center has led to two groups of criteria for employing intraoperative IABP.[3]

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

Additional criteria include the following: (1) recurrent ventricular tachyarrhythmias, and (2) evidence of significant ischemia.

Our initial experience suggests that the vascular complications associated with conventional surgical intraaortic balloon insertion may be diminished by the percutaneous technique. Several studies have documented serious vascular or local wound complications in 5% to 30% of patients undergoing standard surgical intraaortic balloon insertion.[37,38] None of the patients in the present series experienced groin hematoma, aortic dissection, compromised distal pulses, or late wound complications after percutaneous IABP. Our experience indicates that complications may be minimized by adapting the percutaneous IABP method. This safe and rapid method for IABP insertion may justify earlier use of IABP in acute ischemic syndromes, including evolving acute myocardial infarctions and impending extension after acute infarction.

Percutaneous intraaortic balloons are available in the same size (40 cc) as conventional intraaortic balloons and provide the same hemodynamic augmentation. Inflation characteristics of the single-chambered percutaneous balloon are improved in comparison to the conventional single-chambered balloon because the inlet and outlet gas ports at the end of the balloon are larger, permitting more rapid inflation and deflation of the balloon. Another feature of the percutaneous balloon is that it can be used with any commercially available IABP console.

The technique for percutaneous IABP insertion is technically simple and can be performed by any physician experienced with catheter insertion into the femoral artery by the Seldinger method. Several technical details should be carefully observed. Neither the guidewire nor the balloon catheter should be forced into the artery if resistance is encountered. The balloon must be immersed in saline just before it is furled to facilitate unwrapping of the balloon after it is advanced into the descending thoracic aorta. The cannula and balloon catheter must be securely taped to the groin since accidental removal of the balloon catheter could cause serious hemorrhage. Although percutaneous IABP can be performed without the use of fluoroscopy, our ex-

perience indicates that a fluoroscope permits more precise positioning of the balloon in the aorta and obviates the risk of balloon occlusion of arterial branches.

Percutaneous IABP permits rapid and safe institution of intraaortic balloon support and may broaden the medical and surgical applications of IABP.

Our recent experience suggests that cardiac transplantation is an effective method for treatment of certain patients with acute end-stage cardiac disease that requires temporary mechanical circulatory support with the IABP.[7] Patients who are balloon-dependent can nevertheless be supported for several days to permit appropriate preparations of donors and recipients for cardiac transplantation.

The potential importance of pulsatile cardiopulmonary bypass has been recognized for many years, but although it appeared to have several physiologic advantages, it has not been routinely employed primarily due to a lack of simple atraumatic technology to produce the pulsations.

The PAD is the first clinical in-line device that produces atraumatic synchronized pulsatile cardiopulmonary bypass, and which can also function as an arterial counterpulsator. It is important that the routine of the surgical procedure is not significantly altered by the presence of the device.

Our experience with animals[36] has clearly documented the hemodynamic effectiveness of the PAD, which has been borne out in our initial clinical trials.[1, 33–35] In every respect PAD function is similar to an intraaortic balloon, without the need for additional surgery. Our clinical experience with the PAD has begun to confirm some of the reported advantages of pulsatile cardiopulmonary bypass. 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.[39] Of more interest is that during our initial clinical use of the PAD only six patients required intraoperative IABP. This is a marked reduction in the requirement for IABP at our institution.[1, 3]

It is concluded that the primary use for IABP is currently assistance of the open heart surgical patient. The criteria are now defined. It is our impression that the use of IABP in selected patients undergoing open heart surgery has improved survival of patients and has enabled us to operate on high-risk patients with greater confidence and with improved clinical results. The advent of the percutaneous intraaortic balloon will expand IABP even further in medical patients and in those with cardiac arrest. Also, use of the pulsatile assist device will extend the role of counterpulsation in open heart surgery on a routine basis. It is suggested from the data that the use of the PAD may obviate the need for prophylactic IABP in selected high-risk patients and that it will probably decrease both the incidence of perioperative myocardial infarctions and the need for postoperative IABP.

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