Intra-aortic balloon pumping in the management of patients with coronary artery disease

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At approximately the same time the first saphenous vein bypass grafts were being done in Cleveland, the clinical application of intra-aortic balloon pumping was initiated by Dr. Kantrowitz. The research efforts had been started by Moulopoulos and Kolff many years before. Rapidly following the first clinical application in 1967, other groups including the Massachusetts group initiated their efforts with the management of patients in cardiac failure with intra-aortic balloon assist. The early assumption was that the reduction of work during systole and the increase in diastolic pressure in the aortic root during diastole would greatly benefit patients with coronary artery disease. The premise for this benefit was that the marked increase in diastolic pressure would enhance coronary flow and in some circumstances increase the collateral flow to the ischemic areas related to myocardial failure.

Our early efforts focused on the application of intra-aortic balloon assist in patients who were in cardiogenic shock secondary to acute myocardial infarction. This was the same group of patients that Kantrowitz had selected for his early efforts with intra-aortic balloon. In the majority of patients the response was immedi-

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ate. More than 75% showed marked hemodynamic improvement. Survival, however, in these patients depended upon many factors: (1) the duration of their cardiogenic shock secondary to the acute myocardial infarct; (2) the status of their cardiac compensation prior to their most recent infarct; and (3) a relative amount of ischemic muscle as opposed to necrotic muscle that was present at the time balloon assist was initiated in the patient.

At the same time as the development of coronary artery surgery with saphenous vein bypass grafts and the application of intra-aortic balloon assist, there was in the United States a concomitant evaluation and definition of what was cardiogenic shock secondary to acute myocardial infarction. This study was carried out as a cooperative effort in the Myocardial Infarct Research Units throughout the United States. With the definition of this state hemodynamically as being a low output state, association with a cardiac index of less than 2 L/m/M^2, poor compliance of the left ventricle as shown by a left atrial or wedge pressure of 18 mm or greater, and a moderate hypotensive state. It was determined that the mortality associated with this condition was nearly 100%. When intra-aortic balloon assist was applied to this group of patients, survival was about 15%.

The study of patients who failed to respond adequately to intra-aortic balloon assist showed that they were balloon dependent. That is, if the balloon assist system were shut off, the patients would go back into failure and their low output state would recur. In detailed study of these patients, it was found that there was a marked injury of the left ventricular

myocardium at the time of intra-aortic balloon assist initiation. In light of these facts, Dr. Mundth was the first to apply the two new developing techniques in one patient. This was reported in 1971. Detailed studies of many patients who failed to respond to intra-aortic balloon assist were useful in determining what group of patients could have the greatest potential of improving with surgery when balloon dependence was evident. Patients with mechanical complications such as mitral regurgitation and ventricular septal rupture, particularly of the anterior septum, were good candidates for surgical correction. However, it was also evident that a large number of patients who had no mechanical defects, but ischemic muscle alone, were good candidates for revascularization. In these patients, the greatest improvement with revascularization occurred if the area of acute infarction and ischemia was perfused by a vessel that was collateralized on angiogram. If patients had large areas of noncollateralized muscle, the assumption could be made that the muscle in that area was infarcted rather than simply ischemic. In our series, all patients who did not have a resection of muscle or repair of ventricular septal defect and had revascularization alone to such areas of muscle as the dominant cause of their shock did not survive. Review of the present status of patients has shown that of 145 patients admitted to the hospital in cardiogenic shock, 21 were improved by balloon assist alone. Many of these patients early in our experience went home, and the coronary disease recurred. Now these patients are considered candidates for revascularization at an early inter-

val. The other 104 patients were determined to be balloon-dependent; 36 of these were not amenable to a surgical approach anatomically, 8 refused operation, and the other 60 were operated on. Of this group 33 survived.

Thus, from our early efforts of the 36% to 38% surgical success in patients in cardiogenic shock, we can now by a process of selection find those patients who have approximately a 60% chance of long-term survival after surgical correction.

During this period of trial and evaluation in the shock patients, certain findings were noted. Marked ischemic changes that were evident on electrocardiogram could be seen to reverse. Patients with early infarction and severe ischemic changes had the most rapid improvement. Because of these findings we decided to apply the intra-aortic balloon assist technique to patients who were in cardiogenic shock secondary to injuries occurring in cardiopulmonary bypass. Our early efforts showed that of 26 patients studied, 11 were discharged from the hospital and 10 were long-term survivors. Further evaluation of these patients showed that survival was highest among patients who had early and acute electrocardiographic changes indicating ischemia. This was most common in patients with hypertrophied hearts, that is, patients undergoing coronary artery surgery who had a history of hypertension or patients undergoing aortic valve replacement. Patients who had marked deterioration of cardiac function before heart surgery, for example, long-standing mitral regurgitation and aortic regurgitation did not greatly improve in the long-term from intra-aortic balloon

assist. Transient improvement in cardiac output and in compliance with the ventricle could be accomplished, but balloon dependence persisted. As our experience increased, wider application of the balloon assist device was made and survival was higher. However, the application to end-stage disease does not seem reasonable unless some evidence of reversible ischemia can be accomplished.

Finally, a new area of application of balloon assist became evident as these two studies were carried out. Patients in cardiogenic shock from acute myocardial infarction often had a premonitory state during which they had severe pain or increasing angina. Patients who failed to come off bypass and required balloon assist for periods of time, particularly patients with coronary artery disease, frequently had preoperative periods of severe ischemia and transient electrocardiographic changes. Because of these findings it was decided that the use of an intra-aortic balloon device should be evaluated in patients entering the hospital with acute severe ischemia. These patients were selected after treatment had failed with bed rest, oxygen when indicated, morphine, heparin, beta blockade to the point of tolerance, and vasodilator therapy either with isosorbide dinitrate, or with intravenous nitroglycerin or nitroprusside. Patients who failed to respond to this program were then treated with intra-aortic balloon device. The first group of patients evaluated were those who had been admitted with a myocardial infarct, and within the first 10 days after that infarction showed evidence of extension, either in the perimeter of the infarct or in the contralateral wall. The balloon

device was inserted in all patients but one prior to cardiac catheterization; assist was carried out during surgery and for a short interval after surgery. The pattern of response was usually immediate, except in a few patients who still had some pain after the application of counterpulsation. At angiography these were the patients who had the most severe and extensive coronary artery disease. All of the patients became surgical candidates and underwent operation. Subsequently, a second group was studied. These were patients admitted with severe, unstable angina, and failed to respond to the medical program outlined. Infarction had not occurred, but seemed imminent. The balloon device was inserted, the patients were studied, and surgery was performed in all cases. Thus, in these two groups of patients the course of therapy was delineated. The overall mortality for the group was 4.5%, and in the survivors there were only two new Q waves for a very low perioperative infarction rate. Thus, a seemingly dangerous group of patients were treated successfully. The infarction rate was highest in patients who had had recent infarctions. In the others the mortality was close to that in elective surgical patients.

Finally, the balloon device has been applied to many patients as a preoperative group to make the induction of anesthesia safer, and the course of the operative management easier. Dr. Bregman in his discussion of the pulsatile assist device will delineate more of the intraoperative aspect. Our concern has been the management of the unstable patient during the induction of anesthesia, which

may be the most dangerous point for acute ischemia during the operation. Thus, the device in some cases has been inserted a few hours preoperatively under local anesthesia or even days prior to surgery to stabilize the tenuous patient. Once the patient has been appropriately stabilized, surgery can be carried out safely.

The dangers of the intra-aortic balloon device are mainly related to the vascular system. In patients with severe arteriosclerotic disease, perforation of the iliac or aortic wall can occur. In our experience this has only been a problem in shock patients when the catheter has been inserted with some force, knowing that this is the only way a satisfactory course of therapy can be carried out. With the introduction now of a wire-guided balloon, the chance of this occurring will be negated. Superficial and deep wound infections have occurred, but in our series no deaths have been related to the infection itself.

Summary

As we review the total experience of intra-aortic balloon pumping we cannot say that its growth has been as rapid as coronary artery surgery. The field of application is smaller, but we have been surprised to find that over the past 10 years intra-aortic balloon assist has been carried out in more than 35,000 patients. We think that the combination of coronary artery surgery and the use of the device has been additive and has made the application of the techniques developed here in Cleveland more easily applied to patients in more difficult circumstances.