Clinical and hemodynamic criteria for use of the intra-aortic balloon pump in patients requiring cardiac surgery

In order to establish criteria for elective use of the intra-aortic balloon pump (IABP) in patients having cardiac surgery, we conducted a retrospective study of 43 patients who required counterpulsation, because of inability to be weaned from cardiopulmonary bypass, between May, 1972, and June, 1974. Patients in cardiogenic shock preoperatively were excluded. The 43 patients included 23 (Group A) who had severe preoperative left ventricular dysfunction with a mean cardiac index less than 1.8 L. per minute per square meter, ejection fraction less than 30 per cent, and end-diastolic pressure greater than 22 mm. Hg; 20 patients (Group B) had a combination of moderate cardiac dysfunction (cardiac index less than 2.2, ejection fraction less than 40, end-diastolic pressure less than 18) in the presence of acute infarction or severe aortic stenosis (gradient greater than 80 mm. Hg) with or without coronary disease. An inverse relationship was noted between survival and delay from completion of operation to the use of IABP. Thirty-two of 43 patients were weaned off bypass and were balloon assisted for 12 to 96 hours postoperatively: 25 patients were discharged (58 per cent). In Subgroup A, 14 of 23 (60 per cent) and, in Subgroup B, 9 of 20 (45 per cent) were long-term survivors. Based on these findings, 45 patients were operated upon between June, 1974, and December, 1975, with elective use of IABP and were assessed by serial hemodynamic studies. Sixteen had severe preoperative left ventricular dysfunction similar to Subgroup A and 29 had moderate dysfunction in combination with pathology similar to Subgroup B. Fifteen of these patients were hemodynamically unstable at time of arrival in the operating room; IABP was inserted under local anesthesia. Thirty-nine patients (87 per cent) were weaned off bypass and were hospital survivors. In Subgroup A, 13 of 16 (81 per cent) and, in Group B, 21 of 29 (72 per cent) were long-term survivors. Criteria for elective use of IABP in cardiac surgery should include severe preoperative left ventricular dysfunction or a combination of moderate dysfunction with coronary or valvular pathology. Elective IABP improves the survival with trivial iatrogenic morbidity.

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Cardiogenic shock owing to acute myocardial infarction has until recently been the major indication for use of counterpulsation with an intra-aortic balloon pump (IABP). Following the pioneering work of Buckley and Webb,² this modality has gained popularity as a method of treatment for left ventricular power failure.

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after cardiac surgery. Other reports in the literature have confirmed the beneficial effects of IABP in this setting.\(^3,4\)

In previous reports from this institution, we\(^5,6\) outlined the prognostic significance of preoperative hemodynamic studies on early and long-term survival of patients undergoing cardiac operations. The purpose of the present report is to analyze our data in patients in whom the IABP was used during two study periods. A group of 43 patients who required IABP because of difficulty in weaning from cardiopulmonary bypass were analyzed retrospectively. Subsequently, we analyzed prospectively a group of 45 patients operated upon utilizing the criteria developed from the previous retrospective study. From these analyses we describe criteria for recognition of patients prone to develop heart-pump failure at completion of open-heart surgery and propose elective use of IABP in this group in order to improve survival.

Patient material and methods

The clinical and hemodynamic data in a group of 88 patients requiring cardiac surgery (excluding cardiogenic shock) managed by IABP at Jackson Memorial and the Veterans Administration Hospitals, University of Miami School of Medicine, between May, 1972, and December, 1975, were analyzed. The data include two categories of patients who differ in time of IABP initiation:

**Group I.** Between May, 1972, and June, 1974, 47 patients developed heart-pump failure at the completion of various open-heart operations and required the use of IABP on an emergency basis. They were among a group of approximately 500 patients undergoing open-heart surgery for acquired cardiac disease. An IABP catheter could be inserted in 43 of these patients. In Table I criteria for utilization of this device in these patients are outlined. Prior to initiation of IABP in all these patients, cardiopulmonary bypass was continued at varying flow rates in order to maintain sufficient perfusion pressure and cardiac output while a left inguinal incision was made. A 30 or 40 c.c. balloon pump catheter (Datascope Corp., Paramus, N. J.) was inserted into the descending thoracic aorta via the left femoral artery. A 10 mm. woven Dacron graft was initially passed over the balloon catheter and—after placement of the catheter in a premeasured position to a level approximately 2 cm. below the angle of Louis—the graft was sutured to the femoral artery over a longitudinal arteriotomy. Flow through the left femoral artery was then re-established. IABP was initiated with the electrocardiogram or arterial blood pressure used as a trigger source. Various pharmacologic interventions were made simultaneously in order to maintain sufficient blood pressure and cardiac output in the course of weaning off bypass. Once successful weaning was accomplished and the patient transferred to the intensive care unit, circulatory assist was continued for a period varying between 12 and 96 hours at which time the patient was returned to the operating room and the balloon catheter removed under local anesthesia. As a pressor agent of choice, we utilized epinephrine in approximately 60 per cent of these patients and dopamine in the remaining patients. In roughly three quarters of the patients, a 1 to 2 mg. per minute infusion of lidocaine was administered to control ventricular dysrhythmia. While on IABP the patients received between 10 and 20 c.c. per hour of low molecular weight dextran (Rheomacrodex) for coagulation suppression. In all surviving patients, the heparin effect was neutralized with protamine sulfate in the operating room without problems.

Hemodynamic monitoring included left atrial, central venous, and arterial pressure in all patients. Coronary blood flow was measured with an electromagnetic probe (Statham) in all coronary bypass grafts (Fig. 1). During attempts to wean from cardiopulmonary bypass, the left ventricular pressure was measured directly by a large-bore needle inserted in the left ventricular drain. In the intensive care unit, a Swan-Ganz catheter was used in all these patients; serial

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**Table I. Criteria for IABP after cardiac operation**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Inability to wean patient from bypass within 30 minutes</td>
<td></td>
</tr>
<tr>
<td>2. Low cardiac output with hypotension and LVEDP (or LAP) &gt; 20 mm. Hg after trial of pharmacologic inotropic and afterload reduction therapy</td>
<td></td>
</tr>
<tr>
<td>3. Persistent pressor dependence</td>
<td></td>
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<tr>
<td>4. Tachyarrhythmias of ischemic origin unresponsive to usual measures</td>
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</tr>
</tbody>
</table>

**Legend:** LVEDP, Left ventricular end-diastolic pressure; LAP, Left atrial pressure.

**Table II. Criteria for elective use of IABP**

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Severe left ventricular dysfunction (CI &lt; 1.8, EF &lt; 30%, Edp &gt; 22)</td>
<td></td>
</tr>
<tr>
<td>2. Presence of moderate left ventricular dysfunction (CI &lt; 2.2, EF &lt; 40%, Edp &gt; 18) in patients with:</td>
<td></td>
</tr>
<tr>
<td>A. Severe aortic stenosis (gradient &gt; 80 mm. Hg)</td>
<td></td>
</tr>
<tr>
<td>B. Acute myocardial infarction or its complications</td>
<td></td>
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<tr>
<td>C. Intermediate coronary syndrome (especially due to LMC)</td>
<td></td>
</tr>
<tr>
<td>D. Valvular heart disease and coronary obstruction</td>
<td></td>
</tr>
</tbody>
</table>

**Legend:** CI, Cardiac index in liters per minute per square meter. EF, Ejection fraction. Edp, End-diastolic pressure of left ventricle in millimeters of mercury. LMC, Left main coronary stenosis.
thermodilution cardiac output determinations were used to assess cardiac function, efficacy of IABP, and as a guide for discontinuing counterpulsation.

Analysis of the clinical presentation and cardiac pathological condition for which these patients were operated upon and the preoperative hemodynamic data was conducted retrospectively. The preoperative cardiac hemodynamics and electrocardiograms were obtained by methods similar to those used in Group II patients.

**Group II.** Prospectively, based upon data obtained in Group I, we evaluated all patients undergoing cardiac surgery between June, 1974, and December, 1975, and compared them to Group I patients as possible candidates for elective utilization of IABP. Of 350 adult patients undergoing cardiac surgery, 45 met the criteria and IABP was used electively in the course of cardiac surgery. Table II outlines criteria used for selection of these patients.

All these patients underwent preoperative cardiac catheterization by means of methods published previously. Cardiac output was measured by the Fick principle; left ventricular volumes and ejection fraction were calculated from the angiographic studies. Left ventricular end-diastolic pressure was measured directly prior to angiographic studies. The extent of cardiac hypertrophy and dilatation was assessed from the preoperative electrocardiograms and cardiac silhouette size on plain chest x ray films in the posteroanterior view.

All patients in this group had an angiographic evaluation of the aorta and iliac arteries in the course of cardiac catheterization to assess the feasibility of introduction of IABP catheter and aid in selection of the site for insertion. The IABP catheter was successfully inserted in all these patients; the technique of insertion was similar to that in Group I. In 15 patients the catheter was inserted under local anesthesia because of clinical deterioration upon arrival in the operating room. In others IABP was initiated after induction. In all Group II patients IABP was continued during cardiopulmonary bypass, producing pulsatile flow. Synchronous counterpulsation was continued during weaning from cardiopulmonary bypass and thereafter until arrival in the surgical intensive care unit. Hemodynamic evaluation for weaning from IABP was then employed. In 25 patients a Swan-Ganz catheter was inserted in the operating room prior to induction or immediately thereafter. Serial cardiac output studies were conducted in 20 patients in order to maintain satisfactory cardiac output in the course of anesthesia and to assess the efficacy of IABP. Pulmonary capillary wedge pressure was used as a guide for volume replacement and maintenance of optimal left ventricular filling pressure.

Standard methods of cardiopulmonary bypass with hypothermic perfusion (28° C.) were utilized in all patients with a bubble oxygenator. Ischemic cardiac arrest was used at short intervals in patients undergoing coronary bypass surgery. In patients with aortic valve replacement, left coronary perfusion was utilized in

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**Fig. 1.** Double aorta-coronary bypass graft in a 53-year-old man. An example of data obtained intraoperatively in patients receiving IABP. In this figure, coronary graft flow is shown on the top and left ventricular pressure (VP) and its rate of rise (dp/dt) below. LAD, Left anterior descending coronary artery.
intermittent fashion. Saphenous vein bypass grafts were used in all but two patients undergoing coronary bypass surgery. Postoperative management in these patients was similar to that in Group I. IABP was discontinued after hemodynamic assessment when measurement of pulmonary capillary wedge pressure and cardiac output showed no significant improvement in these parameters with counterpulsation. Weaning from IABP was carried out by decreasing the ratio of assisted beats from 1:1 to 1:2 and finally to 1:3 at intervals of 6 to 12 hours. The IABP was left in place in the unactivated state for a few hours prior to final removal.

Follow-up. The two groups of patients were followed by one of the members of the Division of Thoracic Surgery or Cardiology. Follow-up varied from 4 months to 4 years with a mean of 14 months. Follow-up data were available for all patients.

Results

Group I survival. There were 43 patients in Group I. Counterpulsation was used for periods varying from 12 hours to 4 days postoperatively. Of these, 32 patients were weaned from cardiopulmonary bypass. Seven of these patients died 3 to 7 days after the operation. Twenty-five patients (58 per cent) were discharged. Two of these patients (5 per cent) have subsequently died, for an overall late (longer than 4 months) survival rate of 53 per cent (Fig. 2).

Relation of cardiac pathology to operative survival. As shown in Table III, the pathological condition for which these patients were operated upon consisted of valvular heart disease, coronary artery disease, or a combination of these two conditions. There were 11 patients with valvular heart disease—in 9, due to aortic valve disease. Seven others had associated valvular heart disease and coronary disease, of whom 6 had aortic stenosis. Operative survival among patients with isolated aortic or mitral valve disease in this group was 50 per cent (4 of 8), with patients having double valve disease and those having valvular and coronary artery disease showing slightly better results (Table III). All these patients had electrocardiographic voltage criteria for left ventricular hypertrophy and—in the group with aortic valve disease—the gradient across the aortic valve exceeded 80 mm. Hg (Table IV).

Twenty-five patients in Group I were operated upon for coronary artery disease or its complications. Ten patients had left main coronary lesion with significant disease of the right coronary artery (6 patients) or intermediate coronary syndrome. This syndrome is defined in our institution as the presence of accelerated angina pectoris or angina at rest in association with electrocardiographic ST-T changes. Five patients in Group I had coronary bypass grafts for early acute myocardial infarction, and 6 patients had surgery for complications of coronary artery disease late after acute myocardial infarction. The latter subgroup of patients were not in cardiogenic shock and were being operated upon at an interval of 3 to 4 weeks after development of these complications. These complications consisted of left ventricular aneurysm (2 patients), rupture of papillary muscle (2 patients), and ventricular septal defect (2 patients). The survival results for the subgroups of patients with coronary disease or its complications are detailed in Table III. Over-all, 14 of the 25 patients (56 per cent) in this subgroup survived the operation.

Relation of operative survival to preoperative cardiac function. All patients in Group I were in New York Heart Association Class III or IV before surgery. Their preoperative hemodynamic studies from the cardiac catheterization laboratory were analyzed retrospectively. Two groups of patients were identified:

1. Subgroup A included 23 patients who had severe preoperative left ventricular dysfunction with a cardiac index of $1.57 \pm 0.51$ L. per minute per square meter (mean \pm S.D.), left ventricular end-diastolic pressure of $26.1 \pm 6.8$ mm. Hg, ejection fraction of $22 \pm 7$ per cent, and left ventricular end-diastolic volume of $152 \pm 40$ ml. (Table IV). The mean aortic valve gra-
Table III. Relation of operative survival to cardiac pathology in 88 patients (patient No./survival)

<table>
<thead>
<tr>
<th></th>
<th>Aortic</th>
<th>Mitral</th>
<th>Double</th>
<th>And CABG</th>
<th>LM + R</th>
<th>AMI</th>
<th>LM + ICS</th>
<th>Comp CAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group I (n = 43) Subgroup A</td>
<td>2/1</td>
<td>2/1</td>
<td>1/0</td>
<td>3/3</td>
<td>1/0</td>
<td>3/2</td>
<td>5/4</td>
<td>6/4</td>
</tr>
<tr>
<td>Group I (n = 43) Subgroup B</td>
<td>4/2</td>
<td>-</td>
<td>2/2</td>
<td>4/2</td>
<td>5/2</td>
<td>2/1</td>
<td>3/1</td>
<td>-</td>
</tr>
<tr>
<td>Group II (n = 45) Subgroup A</td>
<td>2/2</td>
<td>-</td>
<td>2/2</td>
<td>-</td>
<td>2/2</td>
<td>4/3</td>
<td>6/6</td>
<td>-</td>
</tr>
<tr>
<td>Group II (n = 45) Subgroup B</td>
<td>2/2</td>
<td>-</td>
<td>1/1</td>
<td>4/3</td>
<td>6/5</td>
<td>7/6</td>
<td>7/6</td>
<td>2/2</td>
</tr>
</tbody>
</table>


Table IV. Preoperative hemodynamic data in 88 patients

<table>
<thead>
<tr>
<th></th>
<th>CI (L/min./sq. M.)</th>
<th>Edp (mm. Hg)</th>
<th>EF (%)</th>
<th>EDV (ml.)</th>
<th>Gradient (mm. Hg)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
<td>B</td>
<td>A</td>
<td>B</td>
<td>A</td>
</tr>
<tr>
<td>Group I Mean</td>
<td>1.57</td>
<td>2.20*</td>
<td>26.1</td>
<td>20.2†</td>
<td>22</td>
</tr>
<tr>
<td>±S.D.</td>
<td>0.51</td>
<td>0.38</td>
<td>6.8</td>
<td>6.1</td>
<td>7</td>
</tr>
<tr>
<td>Group II Mean</td>
<td>1.88</td>
<td>2.20*</td>
<td>22</td>
<td>18.7†</td>
<td>24</td>
</tr>
<tr>
<td>±S.D.</td>
<td>0.69</td>
<td>0.45</td>
<td>7</td>
<td>5.6</td>
<td>9</td>
</tr>
</tbody>
</table>

Legend: Preoperative hemodynamic data in Groups I and II patients. Patient categorization is similar to that explained for Table III; abbreviations for hemodynamic parameters are similar to those in Table II. EDV, End-diastolic volume of left ventricle. Gradient relates to systolic pressure difference between the left ventricle and the ascending aorta.

*P Value A vs. B < 0.025.
†P Value A vs. B < 0.05.

Relation of cardiopulmonary bypass time to operative survival. There were no statistically significant differences in the initial bypass time comparing patients in Hemodynamic Subgroup A with patients in Hemodynamic Subgroup B. The mean bypass time was 135 minutes for both groups ranging between 80 and 240 minutes. The average time lapse to balloon assist in these patients was 99 minutes, ranging between 30 and 240 minutes. There was an inverse relationship between delay time from completion of cardiac procedure to utilization of IABP and eventual survival. Survival was 70 per cent when delay time was one-half hour, 50 per cent with delay of one hour, and 10 per cent after 2 hours’ delay prior to initiation of IABP. The delay time obviously extended the length of cardiopulmonary bypass, and consequently the over-all bypass time in these patients was longer than for most patients in dient measured in 5 of these 23 patients who had aortic stenosis was 93 ± 25 ml. Among 23 patients in Subgroup A, 15 (65 per cent) survived the operation and 14 (60 per cent) were long-term survivors (Fig. 2).

2. Subgroup B included 20 patients who had moderate left ventricular dysfunction preoperatively with a cardiac index of 2.20 ± 0.38 L. per minute per square meter (mean ± S.D.), end-diastolic pressure of 20.2 ± 6.1 mm. Hg, ejection fraction of 35 ± 7 per cent, and end-diastolic volume of 119 ± 32 ml. The mean aortic gradient in 3 of these patients with aortic valve disease was less than 60 mm. Hg. As shown in Table IV, the mean values for each hemodynamic parameter comparing Subgroup B with Subgroup A patients showed significant differences. Of 20 patients in Subgroup B, 10 survived the operation and 9 of them (45 per cent) were long-term survivors (Fig. 2).
Group II. There were no survivors in this group if the balloon pump was not used more than 3 hours after completion of the initial operation.

**Group II survival.** There were 45 patients in whom—based on the criteria established from the previous retrospective study (Group I, Table II)—IABP was used electively. Fifteen of these patients were hemodynamically unstable at the time of arrival in the operating room. This condition exhibited itself in 12 patients as continued anginal pain with mild hypotension (systolic blood pressure < 90 mm. Hg) or in patients with valvular heart disease in the form of hypotension (systolic blood pressure < 80 mm. Hg) with tachycardia (heart rate > 120 beats per minute). Three other patients with coronary artery disease had hypertension (systolic blood pressure > 160 mm. Hg) with tachycardia. All these patients were considered to be unstable hemodynamically, and IABP was inserted with the use of local anesthesia prior to induction of general anesthesia. Two of these 15 patients eventually could not be weaned from cardiopulmonary bypass owing to severe left ventricular failure postoperatively.

Thirty-nine of 45 patients (86 per cent) in Group II survived the operation. The six operative deaths were in 3 patients operated upon with acute infarction, one patient with aortic stenosis and coronary disease, one patient with left main and right coronary disease, and one patient with left main disease and intermediate coronary syndrome. Two of these patients were hemodynamically unstable on arrival to the operating room and were hypotensive with little response to infusion of epinephrine. Cause of death in these patients was severe left heart failure owing to hemorrhagic infarction of the left ventricle. In Group II 34 patients (76 per cent) were long-term survivors (Fig. 3). Comparing these results with those for Group I shows the difference to be statistically significant (p < 0.01).

**Relation of cardiac pathology to operative survival.** As shown in Table III, the number of patients in Group II with valvular heart disease was similar to that in Group I.

In Group II, 34 patients were operated upon for coronary artery disease or its complications. Compared with Group I, Group II included a considerably larger number of patients with intermediate coronary syndrome or acute myocardial infarction. The reason for this was better diagnosis of acute myocardial infarction in recent years by use of myocardial isotope scanning preoperatively. Twenty-nine of these 34 patients survived operation. In Group I, 7 of 14 patients (50 per cent) with left main coronary lesion survived coronary bypass surgery as compared with 19 of 21 patients (90 per cent) in Group II (p < 0.02). Similarly, of the patients operated upon in early stages of acute myocardial infarction (less than 6 hours) in Group II, 8 of 11 (72 per cent) survived as compared with 3 of 5 patients (60 per cent) in Group I (Table III).

**Relation of operative survival to preoperative cardiac function.** Preoperative hemodynamic data formed a basis for selection of patients in Group II (elective use of IABP). Similar to Group I, patients in Group II were divided into two hemodynamic subgroups, A and B. Subgroup A included 16 patients who had a preoperative cardiac index of 1.88 ± 0.69 L. per minute per square meter, end-diastolic pressure of 22 ± 7 mm. Hg, ejection fraction of 24 ± 9 per cent, and end-diastolic volume of 127 ± 45 ml. The aortic valve gradient in the 4 patients in this group with aortic stenosis was 83 ± 27 mm. Hg (Table IV). Comparison of preoperative hemodynamic data in these patients with patients in Group I (Subgroup A) showed no statistically significant difference for any of the parameters. These patients were also in New York Heart Association Class III or IV with a distribution similar to that of patients in Group I. Of 16 patients in this subgroup, 15 (93 per cent) survived the operation and were discharged. Thirteen of these (81 per cent) were long-term survivors (Fig. 3). Subgroup B included 29 patients who had a preoperative cardiac index of 2.20 ± 0.45 L. per minute per square meter, end-diastolic pressure of 18.7 ± 5.6 mm. Hg, ejection fraction of 35 ± 4 per
Table V. Hemodynamic effects of IABP in 35 patients having cardiac surgery

<table>
<thead>
<tr>
<th>CI</th>
<th>Edp</th>
<th>Diastolic pressure</th>
<th>Coronary graft flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>Before</td>
<td>Before</td>
<td>Before</td>
</tr>
<tr>
<td>1.3</td>
<td>24</td>
<td>55</td>
<td>120</td>
</tr>
<tr>
<td>After</td>
<td>After</td>
<td>After</td>
<td></td>
</tr>
<tr>
<td>1.8*</td>
<td>18*</td>
<td>110*</td>
<td></td>
</tr>
</tbody>
</table>

Mean values 1.3 1.8* 24 18* 55 110* 120 128
Average Δ ↑30% ↑20% ↑100% ↑5%

Legend: Mean values for hemodynamic data before initiation of IABP and within three hours after diastolic augmentation. Abbreviations are similar to those in Table II.

*p < 0.01.

Hemodynamic effects of IABP

In most patients, especially those who survived operation, IABP produced significant hemodynamic improvement. In patients with elective IABP (Group II), regardless of the level of blood pressure, IABP produced a 100 per cent increase in diastolic radial artery pressure, with a 20 to 30 per cent decrease in systolic pressure and presystolic pressure. During cardiopulmonary bypass, IABP increased the perfusion pressure by 20 to 30 mm. Hg from its mean value, producing pulsatile flow characteristics. In the post-bypass period, IABP in most Group I and II patients effectively decreased the left atrial pressure and increased the diastolic radial artery pressure (p < 0.01). In patients undergoing coronary bypass surgery, IABP produced a minimal increase in coronary graft flow. Over-all effects of IABP on hemodynamics in 35 patients are summarized in Table V. Although the range of change for each parameter varied considerably in various patients, there were no statistically significant differences between those patients with valvular heart disease and those with coronary artery disease. The hemodynamic changes with IABP after patient transfer to the intensive care unit were more pronounced, especially in patients with coronary artery disease.

Complications

The 4 patients in whom the IABP catheter could not be inserted eventually died. Among 25 patients in Group I who survived operation, all required large doses of vasopressor therapy for 24 to 48 hours after operation. Two patients developed inguinal infection and lymphorrhagia. The hospital stays for these 2 patients were 21 and 24 days. Group I patients had an average stay of 18 days. Hospital stay was increased in this group because of renal failure in 5 patients, requiring hemodialysis in 3 patients and pulmonary complications in 2 patients.

Between June, 1974, and December, 1975, when the protocol for elective use of IABP was in effect, the need for IABP on an emergency basis for heart failure after cardiac surgery occurred on only two occasions. In each of these cases, the bypass time was prolonged because of technical problems or bleeding. These complications eventually led to heart failure and the need for IABP. IABP was utilized in both these patients: they survived the operation. These patients were not included in either Group I or Group II because it was felt that the intraoperative technical problems caused their postoperative heart failure.

Among 39 patients in Group II who survived the operation, only 2 required vasopressor therapy for 12 to 24 hours and none developed inguinal infection. The average hospital stay in this group was 12 days. Two patients developed mild azotemia but none required hemodialysis.

Prophylactic antibiotics were administered to all patients according to our routine of the past 6 years. All patients received 1 Gm. of sodium cephalothin (Keflin, Eli Lilly and Company, Indianapolis, Ind.), intravenously prior to skin incision and 1 Gm. intravenously
every 4 hours thereafter for 2 days. If oral medications could be given, the antibiotic regimen was changed to cephalexin (Keflex, Eli Lilly and Company, Indianapolis, Ind.), 2 Gm. per day for an additional 2 days; otherwise, cephalothin was continued intravenously for a total of 4 days.

Discussion

In two previous communications, we related the preoperative cardiac performance to operative and late survival. As shown in Fig. 4, it was possible to separate the survivors from nonsurvivors when preoperative ejection fraction and cardiac index were related to mortality rate in 68 patients with valvular heart disease. Patients who survived operation had a mean cardiac index greater than 2.2 L. per minute per square meter, and a mean ejection fraction greater than 40 per cent. Preoperative values below these figures were associated with a high operative and late mortality rate. Analysis of these data in graphic form demonstrated a hyperbolic relationship between mortality and preoperative ejection fraction as well as cardiac index, since operative mortality rate increased as the values of these parameters decreased. The steep portion of this survival curve was at values of cardiac index less than 2.2 and ejection fraction less than 40 per cent. As seen in Fig. 4, some patients with an ejection fraction greater than 40 per cent died early or late postoperatively. This discrepancy (not seen with cardiac index) is explained by the fact that these patients had regurgitant valvular heart disease, in which afterload is low and therefore ejection fraction showed falsely high values. In these patients, cardiac index was a better indicator of performance of the left ventricle. After valve replacement in such patients, afterload is physiologically increased and ejection fraction may decrease or remain unchanged. These results confirm the findings of Litwak, Najafi, Appelbaum, and their associates. Such discrepancy is rarely seen in patients with coronary artery disease, in which end-diastolic pressure and ejection fraction are good indicators of the extent of left ventricular failure and are related directly to operative results. For these reasons we have considered the three parameters of ejection fraction, car-
diac index, and end-diastolic pressure in recognizing our high-risk patients. With the use of counterpulsation, as shown by Buckley and extensively reviewed by Weber, it is possible to improve left ventricular performance by increasing the diastolic blood pressure and by decreasing afterload and left ventricular filling pressure. In this study the hemodynamic effects of IABP were similar to previous reports with the observation that patients who eventually survived the operation showed a better response to counterpulsation.

We have emphasized the careful evaluation of preoperative cardiac function and pathology for which the patients are being operated upon as a guide for patient selection for elective IABP. We have reached this conclusion by observing a large number of patients with moderate-to-severe cardiac dysfunction who developed postoperative complications. We have outlined high-risk pathological conditions such as aortic stenosis with a gradient greater than 80 mm. Hg, severe aortic stenosis and coronary obstruction, left main lesion with right coronary disease or intermediate coronary syndrome, presence of acute myocardial infarction, and complications of acute infarction. All these conditions affect myocardial oxygen demand or supply. Presence of this type of pathological condition, as an indication for IABP, has also been outlined by Goldman and Bregman. In the absence of cardiac dysfunction, however, we believe these patients should be operated upon without IABP. Good results are to be expected.

In reporting our experience with 88 patients we divided our cases into two categories. IABP was initially used only as an emergency procedure when difficulty in weaning a patient from cardiopulmonary bypass was encountered. Subsequently, when criteria for identifying high-risk patients were established, these criteria were used to select patients for elective use of IABP. When IABP was used as an emergency procedure, there were difficulties with insertion of the catheter and—because of prolongation of the cardiopulmonary bypass time in the course of decision-making—multiple other complications such as cardiac, renal, and pulmonary failure were precipitated. There was an increasing need for vasopressor therapy and, most importantly, only one of every 2 patients was a long-term survivor after a prolonged hospital stay. On the contrary, for patients in whom the IABP was used electively, there was a shorter total bypass time, a shorter hospital stay, lesser need for pressor agents, and fewer postoperative complications. Most importantly, more than 75 per cent of these patients were long-term survivors. Preoperative evaluation of the aorto-iliac arteries in the course of cardiac catheterization contributed, we believe, to selection of the best IABP insertion site and a decrease in problems with insertion of the balloon catheter. With elective IABP, the survival results were better than 75 per cent despite comparable cardiac dysfunction and pathological condition. Similarly, patients with left main coronary disease and acute infarction benefited from elective IABP with survival rates of 90 and 72 per cent, respectively, as compared with 50 and 60 per cent with emergency IABP.

An important finding in our study is that the late mortality rate of patients in Group I (emergency balloon pumping) was 5 per cent as compared with 13 per cent in Group II (elective balloon pumping). Considering all the Group I and II patients, these differences in late mortality rate were not significant. However, comparing Subgroup A and B patients from each of Groups I and II, the differences in late death were significant at p < 0.08 and p < 0.05, respectively. This indicates that, although we improved our operative results by using IABP as an elective procedure, we did not prevent late death in a number of these patients despite surgical correction. Since late deaths in Group I and Group II patients were similar in terms of the number of patients with valvular heart disease and coronary heart disease, we have concluded that these patients had end-stage cardiac disease and did not benefit from the operative procedure.

It is also important to note that, since application of the criteria for selection of patients for elective IABP, we have had only two occasions in which emergency IABP was required. Both these patients had technical problems which prolonged the cardiopulmonary bypass time and eventually led to development of heart-pump failure. We believe the criteria given in Table II for selection of patients for elective IABP can serve as a guide for preoperative recognition of high-risk cardiac surgical patients. In our experience, elective use of IABP was associated with improved early and late survival results and with trivial morbidity in patients meeting these criteria.

REFERENCES
3 Goldman, B. S., Gunstensen, J., Gilbert, B. W., Kelly, T. C., Scully, H., Williams, W. G., and Adelman, A.

Discussion

DR. FLOYD D. LOOP
Cleveland, Ohio

Dr. Bolooki and his colleagues have indicated previously that patient survival is improved by early use of the IABP. Their report today goes a step further by showing that intraoperative augmentation based electively on specific criteria for poor left ventricular function further diminishes mortality rate.

Our experience at The Cleveland Clinic Foundation with 28 consecutive patients who have undergone balloon support in a one-year period beginning in April, 1975, coincides very closely with the Group I patients presented by Dr. Bolooki. The augmentation was initiated because of refractory intraoperative left ventricular failure. Twenty-two devices were inserted late in the course of the operation, and in 6 cases the balloon was inserted after the patient had reached the intensive care unit. There were 16 survivors, or 57 per cent of this population, a figure almost identical to the series presented today. One point of difference is that our use of the balloon postoperatively represents a 1 per cent incidence of balloon usage compared to 10 per cent in their retrospective series.

The newer pulsatile assist device developed by Bregman that is interposed into the aortic perfusion cannula may even obviate the need for postoperative balloon support. As you know, the pulsatile pump produces diastolic augmentation from the ascending aorta. The pulsatile assist mimics the beating heart, and I wonder if this mechanism is one reason for the redistribution of myocardial perfusion during intraoperative pumping.

In the 12 deaths in our series, we noted renal failure in 7, and some of these patients apparently had good arterial perfusion without the use of vasopressors. Dr. Bolooki, do you or any of the other discussers have knowledge about pressure differentials above or below a unidirectional balloon and has your group performed renal blood flow studies during IABP augmentation?

DR. PETER A. PHILIPS
Bradbury, Calif.

Balloon augmentation in the preoperative and operative periods can help stabilize the condition of a precarious ill patient and minimize potentially lethal situations.

A new pulsatile unit, developed by Dr. Bregman, allows on-line arterial counterpulsation immediately prior to cardiopulmonary bypass and pulsatile flow during bypass. Both counterpulsation and pulsatile pumping effectively alter the Buckberg supply/demand ratio (endocardial viability ratio), that is diastolic pressure-time index/tension-time index or endocardial viability ratio.

As Buckberg has demonstrated, and as our clinical experience has verified, with a positive shift of this ratio toward
supply, myocardial blood flow becomes more evenly distributed across the myocardium.

Although the actual amount of coronary blood flow may not increase with augmentation or pulsatile flow, redistribution of this flow may be responsible for the better postoperative courses in these patients with balloon augmentation. Subendocardial ischemia and infarction is still the most common cause of low cardiac output after cardiopulmonary bypass; properly timed, balloon augmentation or pulsatile flow during bypass, as demonstrated by Dr. Habal, may afford better operative and postoperative myocardial protection and thereby avoid subendocardial embarrassment.

DR. DAVID BREDMAN
New York, N. Y.

I rise to compliment Dr. Bolooki and his colleagues for further establishing the preoperative criteria for IABP in the cardiac surgical patient with heart failure.

At the Columbia Presbyterian Medical Center, another approach to these challenging patients has been instituted.

A new simple pulsatile assist device (PAD) has been developed to convert roller pump flow to pulsatile flow. In addition the PAD can be used as an arterial counterpulsator before and after cardiopulmonary bypass (CPB). The PAD is inserted in the arterial line close to the aortic root. The device consists of a flexible, valveless balloon conduit through which the arterial return flows. The balloon is contained within a rigid plastic cylinder which is then connected to a standard intra-aortic balloon pump by a pneumatic hose.

Pulse pressures of 40 to 50 mm. Hg are readily obtained during total synchronous CPB. Free plasma hemoglobin values after bypass were in the usual range for these patients.

When the PAD is used as an arterial counterpulsator, there is a significant fall in systolic pressure (which represents unloading) and a large diastolic augmentation.

The PAD has been used in 50 patients undergoing open-heart surgery for coronary artery or valvular heart disease or both. Twenty-seven of these patients have had impaired ventricular function according to Dr. Bolooki's criteria, with a preponderance in his Subgroup A category. There was no mortality noted from the PAD, and it is of interest that only one patient incurred an acute intraoperative myocardial infarction. This patient was successfully treated with postoperative IABP. Myocardial blood flow increased 22 per cent with pulsatile CPB, and the urinary output of the patients with pulsatile bypass was one third higher than in a control group.

It is suggested that the PAD is a simple and reliable device, both for intraoperative arterio-arterial counterpulsation and for the creation of pulsatile CPB. The experimental work presented by Dr. Habal would suggest that pulsatile flow clearly has advantages in the fibrillating heart over standard roller pump flow. In selected high-risk patients, the PAD appears to be a reasonable alternative to the elective use of IABP. More significantly, use of the PAD may decrease both the incidence of intraoperative myocardial infarction and the need for postoperative IABP.

DR. JOHN W. KIRKLIN
Birmingham, Ala.

I too congratulate Dr. Bolooki and his colleagues for their very high survival rate in their prospective group in which intra-aortic balloon pulsation was used. However, our own experience makes us skeptical that such an apparently high incidence of the use of balloon pumping and such a complex protocol are truly necessary in patients undergoing aortic valve replacement with or without concomitant coronary artery bypass grafting and those undergoing coronary artery bypass grafting exclusive of the ones operated upon for cardiogenic shock from acute myocardial infarction.

To really resolve the controversy initially mentioned by the authors requires considerably more data than we have at the present time. To me, at least, the question is not the efficacy of intra-aortic balloon pulsation, for we are convinced that it is a powerful tool in many circumstances. The question really is whether the authors are using IABP in patients who might not truly require it or whether they are doing something in the operating room that makes IABP necessary more frequently than should be the case. The hemodynamic criteria used for their Subgroup B patients raise both of these questions. In our experience, patients with preoperative cardiac indices between 1.8 and 2.2 L. per minute per square meter, ejection fractions greater than 35 or 40 per cent, and left ventricular end-diastolic pressures between 18 and 25 mm. Hg have a high rate of survival without intra-aortic balloon pulsation.

We raise these questions because intra-aortic balloon pulsation and complicated intraoperative protocols have certain risks of their own. I would like to ask about some of the specific details of the operative procedure: the length of aortic cross-clamping, if this was used; whether or not an effort was made to prevent ventricular fibrillation during the operations, and the average length of cardiopulmonary bypass for these various procedures.

DR. ROQUE PIFARRE
Maywood, Ill.

I would like also to congratulate Dr. Bolooki on his excellent presentation and on his criteria for application of intra-aortic balloon counterpulsation. Our results are very similar to his, and our indications are not too different.

As can be seen in Table I, the three most common indications have been (1) low cardiac output syndrome after coronary or valvular surgery, (2) cardiogenic shock, and (3) prophylactic use of IABC in left main coronary artery disease, recurrent arrhythmia, and left ventricular failure owing to aneurysm, mitral regurgitation, or acute septal defect.

The worst result has been in the group with cardiogenic shock, with only 50 per cent of the patients surviving.

Since July of 1975, IABP has been used prophylactically in 45 patients. Of these, 34 patients had main left coronary artery diseases and 10 had left ventricular dysfunction. Only one patient with aortic stenosis had severe left ventricular dysfunction. Some patients had complex problems and there was only one death. Over-all survival was 136 (67 per cent) of 203 patients.
Table I

<table>
<thead>
<tr>
<th>Indication</th>
<th>Patients</th>
<th>Survivors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
</tr>
<tr>
<td>Intraop. LCOS*</td>
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<td>47</td>
</tr>
<tr>
<td>Prophylactic</td>
<td>45</td>
<td>44</td>
</tr>
<tr>
<td>Cardiogenic shock</td>
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<td>21</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>17</td>
<td>9</td>
</tr>
<tr>
<td>Accelerating angina</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Postinfarction pain</td>
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<td>6</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Totals</td>
<td>203</td>
<td>136</td>
</tr>
</tbody>
</table>

*Low cardiac output syndrome.

I agree with Dr. Kirklin that perhaps a balloon pump is being used too often, but I think that in some of these cases the patient's life has been saved by IABP. I believe this can be a useful tool if used when properly indicated.

**DR. HUGH E. SCULLY**
Toronto, Ontario, Canada

At the Toronto General Hospital, we strongly support the principle of preoperative diastolic counterpulsation in patients who have significant left ventricular dysfunction or who are hemodynamically very unstable preoperatively.

In a manner very similar to that presented in Dr. Bolooki's paper, it became clear to us that most patients undergoing coronary artery surgery or valve surgery or both, who required balloon support because of inability to be weaned from cardiopulmonary bypass, either had been unstable hemodynamically before the operation or had very significant left ventricular dysfunction. Our hemodynamic criteria for those who were selected electively among patients with unstable angina or vessel disease or both included ejection fractions of less than 40 per cent, cardiac indices of less than 2.0 L. per minute per square meter, end-diastolic pressures of greater than 25 mm. Hg, endocardial viability ratios of less than 0.7, or left main coronary lesions of 90 per cent or more anatomically, with significant right-sided disease as well.

The results with the postcardiotomy group and the unstable angina group of patients were similar to those described by Dr. Bolooki. I should point out that those who have survived are all functionally better by at least one New York Heart Association category than was the case preoperatively.

I noted in the presentation that 15 of the 22 patients who were supported electively had the balloon inserted with the use of local anesthesia. I would like to direct one question to Dr. Bolooki and his group. Have you compared the perioperative infarction rate in patients who were supported before and after induction of anesthesia relative to the time of the insertion of the balloon?

**DR. WILLARD M. DAGGETT**
Boston, Mass.

It is a pleasure to discuss this very careful analysis of the use of intra-aortic balloon pumping in patients who failed to wean from cardiopulmonary bypass versus a similar group of patients in whom balloon pumping was initiated electively prior to bypass. The similarity both as to function and pathologic condition of the two groups makes the results even more striking.

On the other hand, an examination of the preoperative cardiac function data of Group I, Subgroup A, patients versus Group II, Subgroup A, patients indicates that the latter group with a higher survival rate also had a higher cardiac index, higher ejection fraction, lower end-diastolic pressure, and lower end-diastolic volume. These facts suggest a hemodynamic basis for the improved survival in this group. I would like for Dr. Bolooki to address this question of differing hemodynamics.

Our own experience with balloon pumping parallels that of Dr. Bolooki and his group, and we have recently used the balloon earlier to control ischemic symptoms and signs rather than waiting to use the balloon for patients with established myocardial damage.

Based on experience over the past several years, we projected an increased use of the balloon in 1975. However, despite a 10 per cent increase in the number of operations, we used 137 balloons in 1975, rather than the 160 predicted. The decrement was in the group who had intraoperative, postbypass insertion. Like Dr. Spencer's group and others, we have paid particular attention to that dangerous time period starting with induction of anesthesia until cardiopulmonary bypass is initiated.

With the increased use of the Swan-Ganz balloon catheter, close monitoring of the electrocardiogram, and serial thermodilution measurements of cardiac index, we have been able to recognize acute ischemic events earlier and reverse these pharmacologically, events which we surely would not have detected with less sophisticated monitoring techniques.

It is for these reasons, we believe, that we used fewer balloons in 1975. As has been said before, the best treatment for cardiogenic shock is to prevent it.

**DR. WATTS R. WEBB**
Syracuse, N. Y.

Dr. Bolooki is to be congratulated for identifying this particularly high-risk group that has been aided by intra-aortic balloon pumping. In the initial group he salvaged about 50 per cent, and in the latter group he was able to salvage about 75 per cent.

Many factors play a role in this. First, the frequency with which one uses the intra-aortic balloon is dependent, obviously, on the patient clientele. In Dr. Bolooki's group, about 14 per cent had very severe left ventricle dysfunction. This is true in about 4 per cent of our patient group, and we correspondingly use the intra-aortic balloon only about one third as often as he does.

Much depends likewise on the degree of myocardial protection that one is able to provide. Certainly, we can do a much better job than was being done a few years ago. Only about 4 years ago several clinics, including our own, reported a 15 to 18 per cent intraoperative myocardial infarction rate as
judged by electrocardiographic changes, although very seldom was there clinical evidence of myocardial infarction.

At the moment, we have only a 4 per cent incidence of electrocardiographic changes, and none of the patients during the past year showed any clinical evidence of myocardial infarction.

Probably other factors probably play a role, along with prophylactic use of the intra-aortic balloon, to help explain Dr. Bolooki's good results.

Most of the time we similarly anticipate those patients who are going to have trouble. We have found, interestingly, that those who have unexpected postoperative problems have been in their 60's and 70's, the very elderly patients. Just exactly why, I am not sure.

In addition to the criteria that have been used, we along with Dr. Philips and Dr. Buckberg have found that the endocardial viability ratio is particularly helpful in selecting those patients who are beginning to get into trouble. One can anticipate this trouble and start using the intra-aortic balloon.

With the methods we now have of pre-, intra-, and postoperative support of the myocardium, it is no longer necessary to accept the concept that there has to be myocardial depression in the postoperative period. I think we can usually prevent it, and then treat it effectively in the infrequent occasions when it occurs.

DR. BLOOOKI (Closing)

I would like to thank all the discussers. They are all pioneers in this field, thus indicating the importance of this subject.

Dr. Loop indicated that he has used the balloon in about 1 per cent of his patients. I must say that approximately 25 per cent of our patients have severe left ventricular dysfunction preoperatively. We use the balloon pump in about 12 per cent of our patients. Our data were evaluated very carefully, and the hemodynamic groups as we have defined them are those of patients who are prone to develop postoperative left ventricular failure. In fact, for the past 2 months we tried not to use the balloon in some of those patients who, based on these criteria, should have been treated with the IABP. We got into trouble and ended up using the balloon pump on an emergency basis. Of course, I am talking about 4 years' experience with the balloon pump. Dr. Loop is talking about one year. I am sure that 3 to 4 years from now he will have used the balloon pump in more patients and perhaps will have new criteria for use of this modality. In answer to his question on differences in pressure above and below the balloon and decrease in renal flow, we have not noted significant differences. Renal flow if anything increases with balloon pumping unless the patient is in severe left ventricular failure and has very low cardiac output.

As Dr. Watts indicated, the balloon pump is an effective adjunct to cardiac surgery and it is used only based on the percentage of patients with a bad heart.

I agree with Dr. Philips that IABP redistributes the coronary blood flow, but the important point is that the IABP improves the cardiac output, with afterload reduction simultaneous with redistribution of coronary blood flow.

Dr. Bregman's device probably is the device of the future. However, I think the IABP is better because it helps the patient not only intraoperatively and postoperatively but also preoperatively, especially during induction.

The figures quoted by Drs. Scully and Pifarre actually are similar to ours, the only difference being that they use the balloon more often in patients with left main and extensive coronary lesions whereas we used it less on the basis of anatomic findings alone. This was mainly because we use hemodynamic criteria. I should indicate that the hemodynamic values must be from a reliable catheterization laboratory, since this is what we depend upon for patient selection.

In response to the question of incidence of operative infarction in relation to time IABP was used, it is our feeling that it was less in our elective group. The numbers are too small for us to draw a significant conclusion.

I thank Dr. Daggett for his important remarks. Certainly, it is their group that has brought this device into wide clinical use. As you noted, their numbers were almost ten times ours. They have a great deal of experience in this modality and we simply follow their criteria. In response to his question, in the manuscript details of statistical analysis of the two subgroup's A are given, and hemodynamically the two subgroups were similar. The speculation is that combination anatomic lesions associated with left ventricular dysfunction are as serious or worse than dysfunction with a single anatomic lesion.

Dr. Kirklin, has asked an important question. Our operative technique has been detailed in the manuscript. There were no unusual intraoperative complications. However, as seen from Fig. 4 in the text, we just have a higher number of patients with poor preoperative cardiac function. His group has recently published results for mitral valve disease and point out that patients with depressed preoperative cardiac function have a high mortality rate. Our elective use of the balloon pump is to decrease this type of mortality rate. Dr. Kirklin, however, sounds like Dr. Effler; that is perhaps because he has not as yet used the IABP. To that point, I am very sure if he tries it, he will like it!