Editorial:
Preservation of Ischemic Myocardium with Intraaortic Balloon Pumping: Modern Therapeutic Intervention or Primum Non Nocere?

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IN THE CURRENT ISSUE Leinbach et al. report their experiences with intraaortic balloon pumping (IABP) used in attempts to limit acute myocardial injury.\(^1\) Eleven patients seen within 6 hours of acute myocardial infarction had neither shock nor pulmonary edema; the indication for mechanical circulatory assistance was not hemodynamic collapse, but rather evidence of persistent severe ischemia as manifested by continuing substernal chest pain and ST segment elevation in the precordial electrocardiographic leads. The authors believe their results suggest "both exciting possibilities and exasperating limitations." Five patients appeared to respond favorably, with rapid resolution of chest pain and ST segment elevation after beginning IABP. Development of new electrocardiographic Q waves was modest, left ventricular ejection fractions following circulatory assistance were normal, and all patients have survived for a substantial time following discharge, without subsequent coronary events or angina.

In contrast, six other patients had apparently less salutary responses. In this group there was no immediate resolution of ST segment elevation, more prominent precordial Q waves were either present beforehand or developed in spite of IABP, peak creatine kinase (CK) values were much higher, and ejection fractions were all abnormal with prominent disorders of ventricular regional contraction. Subsequent follow-up was much more ominous: Two patients died within a year from coronary events, two have angina, and one is symptomatic from poor left ventricular function.

The authors note that the patients who seemed to respond to IABP had single focal stenoses of the left anterior descending (LAD) coronary artery but some residual patency of the vessel in every case. In contrast, all but one of the "poor responders" had total occlusion of the LAD with generally poor collaterals to the occluded vessel. The authors conclude that early IABP reverses acute myocardial injury, although apparently only in those patients who have less than total occlusion of the LAD coronary artery.

That IABP should reduce myocardial injury seems reasonable, if not conclusively proven in man. In the experimental model of anterior wall infarction in the dog that Maroko and coworkers have refined to near-classic status over the past several years, IABP reduced the area of myocardial ischemia as defined by epicardial ST segment mapping.\(^2\) Although controversy still rages over the value of precordial ST segment mapping, Maroko's direct epicardial recordings have been correlated with myocardial CK depletion, histologic and electron microscopic observations, regional myocardial blood flow, and a number of other indices of myocardial injury.\(^3\) Other investigators have reported increases in myocardial nutrient flow,\(^4\) protection against the development of left ventricular failure,\(^5\) and variable effects on myocardial oxygen consumption and coronary blood flow\(^6-8\) in experimental animals with and without shock treated with IABP. Thus, the value of intraaortic counterpulsation in limiting myocardial ischemia in the experimental situation seems fairly well-established.

In man, IABP has been most widely used in patients with either cardiogenic shock after acute myocardial infarction or left ventricular failure after cardiac surgery. The physiologic effects of balloon counterpulsation are favorable in man, at least while mechanical assistance is in progress. Systolic impedance ("afterload") is decreased, diastolic aortic pressure is increased, cardiac output rises, left ventricular size decreases and myocardial metabolism improves in most patients.\(^9-10\) With these favorable physiologic effects, clinical results have been cautiously optimistic.

In cardiogenic shock, only a relatively small number, perhaps 20\% of those pumped, respond well enough to be weaned from mechanical circulatory assistance and recover without further incident. Most patients with shock improve temporarily during IABP but remain balloon-dependent. Early weaning from the balloon is usually attempted within 24-48 hours; if unsuccessful, coronary angiography and, if feasible, emergency cardiac surgery are often done. Some additional patients with shock can be salvaged by this combination of IABP plus cardiac surgery.\(^11\) Table 1 summarizes results of IABP for cardiogenic shock at several institutions.\(^9-15\)

For profound left ventricular failure after cardiac surgery, IABP is widely used in operating and recovery rooms. The mechanical assist device is anecdotally credited by many surgical teams with facilitating the discontinuation of cardiopulmonary bypass in some patients who otherwise cannot be
TABLE 1. Results of Intraaortic Balloon Pumping (IABP)

<table>
<thead>
<tr>
<th></th>
<th>Total patients given IABP</th>
<th>Weaned off IABP</th>
<th>Hospital discharge without surgery</th>
<th>IABP dependent</th>
<th>Operated on</th>
<th>Hospital discharge with surgery</th>
<th>1-year survival</th>
<th>3-year survival</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scheidt et al.9</td>
<td>87</td>
<td>35</td>
<td>15 (17%)</td>
<td>52</td>
<td></td>
<td></td>
<td>8/15</td>
<td></td>
</tr>
<tr>
<td>Leinbach et al.11</td>
<td>80</td>
<td>12</td>
<td>10 (13%)</td>
<td>68</td>
<td>24</td>
<td>9 (11%)</td>
<td>0/10 medical</td>
<td>10/13 surgical</td>
</tr>
<tr>
<td>Wajszczuk et al.126</td>
<td>58</td>
<td>12</td>
<td>12 (21%)</td>
<td></td>
<td></td>
<td></td>
<td>7/12</td>
<td></td>
</tr>
<tr>
<td>Baron et al.13</td>
<td>46</td>
<td></td>
<td>11 (24%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Willerson et al.14</td>
<td>23</td>
<td>9</td>
<td>1 (4%)</td>
<td>14</td>
<td>4</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Roche pool14†</td>
<td>442</td>
<td></td>
<td>(24%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Some of these patients were also included in the report of Scheidt et al.9
†This data pool is raw data, collected by questionnaire under uncontrolled, non-research conditions. Survival data given as very rough estimate only.

weaned from bypass at the conclusion of the surgical procedure. In patients with hemodynamic decompensation in the immediate postoperative period, IABP is often viewed as helpful in the critical 24-48 hours immediately after surgery. Several reports from surgical teams have appeared, generally favorable, but admittedly uncontrolled.16-19 Refractory pre- and post-infarction angina20 and refractory ventricular arrhythmias14 have also been successfully treated with the intraaortic balloon pump.

The experimental and clinical foundation for the role of IABP in controlling myocardial injury has thus been firmly laid, and the results of Leinbach et al. in their initial series of patients seem encouraging. How widely, then, should this therapy now be used?

First, some sobering general comments about results to date with IABP. Although the results cited above might seem favorable, it is important to note that there is no reported treatment series with a randomized (or any other) control group. Further, there is a potential bias in the medical literature that may be quite significant. It seems likely that those institutions with favorable results using IABP will be motivated to report their data, and it is further likely that manuscripts with positive rather than negative results will be accepted for publication. Many thousands of patients have received IABP for various indications in the past decade (one estimate is 5,000 per year recently, calculated from the number of balloon catheters sold in 197621), yet the results of only a fraction of these have appeared in the medical literature. Nothing approaching a national registry, a large cooperative clinical trial, or even a single randomized study from one institution exists to give us any confidence that we know the true efficacy of IABP for ischemic shock, postoperative ventricular failure or any other indication. The current series of Leinbach et al. is, of course, in the nature of a pilot study. Thus, the very small number of patients and the absence of controls should not be taken as a criticism. It seems premature to conclude — and the authors do not — that we know the true role of IABP in limiting acute myocardial injury, either. By all indications, the "poor responders" in Leinbach's series appear to have sustained larger infarcts than the "good responders," but possibly the decreased myocardial necrosis is the cause of the favorable outcome with balloon pumping rather than the effect of IABP as a therapeutic modality.

Another sobering question is raised by the classic dictum, *primum non nocere*. There are complications of IABP (table 2) in several large series of patients.10, 11, 14, 15, 16, 19, 20, 22, 24 The complication rates are acceptable in the shock patient whose mortality without IABP is exceedingly high, but the same morbidity might not be acceptable in the patient with acute myocardial infarction without shock, whose expected mortality is 6% without cardiac failure or 17% with mild-to-moderate congestive failure.25

Table 2 is, however, seriously misleading in two ways. First, a higher complication rate would be expected in critically ill patients with shock compared with patients with acute myocardial infarction but little or no hemodynamic decompensation. In particular, ischemic complications of the leg, not frequent in shock patients, undoubtedly are caused by a combination of low peripheral flow due to decreased cardiac output, as well as the obstruction and/or trauma to the peripheral artery associated with insertion of the balloon. In patients with reasonably normal cardiac output, the incidence of leg ischemia should be much reduced, and indeed, in two large series from the Massachusetts General Hospital there was only one such complication.11, 20

On the other hand, table 2 presents results from large institutions, where physicians and surgeons have had a great deal of experience in dealing with the balloon and its potential complications. Should IABP be extended indiscriminately to large numbers of patients elsewhere, especially institutions where the procedure would be performed infrequently, almost certainly the complication rate would be far above the irreducible minimum where experienced teams have constant practice in maintaining proficiency. Given
Table 2. Complications of Intra-Aortic Balloon Pumping

<table>
<thead>
<tr>
<th>Patients</th>
<th>Major complication rate, %</th>
<th>Reported complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cooperative Study*</td>
<td>96 16</td>
<td>13 leg ischemia resulting in 2 iliofemoral bypasses, 2 permanent neuropathies, 1 chronic arterial insufficiency, 1 subadventitial aortic hematoma, 1 balloon rupture, 1 renal embolus resulting in death</td>
</tr>
<tr>
<td>Massachusetts General Hospital:</td>
<td></td>
<td>cardiodenic shock</td>
</tr>
<tr>
<td>recurrent angina*</td>
<td>55 2</td>
<td>1 femoral artery trauma resulting in reconstructive surgery</td>
</tr>
<tr>
<td>Texas Southwestern Medical School*</td>
<td>27 0</td>
<td>none</td>
</tr>
<tr>
<td>The New York Hospital-Cornell Medical Center*</td>
<td>82 35</td>
<td>10 leg ischemia resulting in 2 patch angioplasties, 2 grafts, 1 fasciectomy, 1 chronic arterial insufficiency, 7 aortic dissections, all discovered incidentally, 1 requiring patch angioplasty, 1 performance of common iliac artery resulting in death, 7 wound infections, 2 resulting in septicemia, with 1 death, 3 lymphatic problems, 1 peripheral neuralgia</td>
</tr>
<tr>
<td>Beth Israel Medical Center, Newark*</td>
<td>36 36*</td>
<td>6 transient leg ischemia, all receiving femoro-femoral cross over grafts to continue IABPs, 4 arterial thrombosis, 2 resulting in thrombectomy, with 1 death, 3 local arterial injury or occlusion, 2 requiring reconstructive surgery with 1 persistent foot drop</td>
</tr>
<tr>
<td>Yale University School of Medicine*</td>
<td>287 4*</td>
<td>6 proven aortic dissection, 5 strongly suspected aortic dissection</td>
</tr>
<tr>
<td>Roche Data Pool*</td>
<td>386 11</td>
<td>14 distal thrombosis, 11 leg ischemia, 9 femoral artery thrombosis, 5 iatrogenic arterial damage, 2 infections, 1 thrombocytopenia</td>
</tr>
</tbody>
</table>

*Vascular complications only.

these two imponderables: less seriously ill patients than those assisted in the past, vs the possibility of widespread use by less than optimally experienced teams, it seems impossible to even guess at the ultimate complication rate of IABP were this therapy used for any significant fraction of the one million or so patients who suffer acute myocardial infarction every year in the United States.

Finally, there is the question of cost. Although the initial capital outlay for IABP is not great, surgeons and operating room fees for insertion and removal of the balloon, the probable need for more intensive hemodynamic monitoring and nursing care, and a possible major increase in coronary angiography, all will inevitably greatly increase the cost of hospitalization for acute myocardial infarction. If IABP truly reduces mortality, complications or disability resulting from myocardial infarction, the cost may be worthwhile.

The problem will then be to refine indications so as to select that subgroup of patients who will benefit most from IABP. Should the tentative conclusions of Leinbach et al. prove correct, potential noninvasive ways to identify those with partially obstructed but residually patent LAD coronary arteries might be lack of Q waves on the electrocardiogram, preserved motion, velocity or thickening of the interventricular septum on the echocardiogram, or preserved blood flow in the distribution of the LAD on thallium or other radionuclide scan.

How much is a life worth? What price per gram of salvaged myocardium? What cost per met of increased exercise tolerance? Unanswerable questions at present, but since this proposed therapy is complex and expensive, we do need to consider what else could be done with increasingly scarce medical resources. It is even possible that a noninvasive device that produces the physiologic changes of counterpulsation by exter-
nal compression of the lower extremities might be useful and less difficult or hazardous to use. A preliminary report has appeared claiming reduction in mortality and morbidity in patients with relatively uncomplicated acute myocardial infarction treated with early external counterpulsation.

We have a weighty responsibility to ensure that the scientific efficacy of mechanical circulatory assistance for limiting myocardial injury is firmly established before suggesting that its use become widespread. Current methods for quantifying myocardial injury, or change produced by this and other therapies, are not quite equal to the task. In the meantime, randomized clinical trials, which will probably have to be multi-institutional in order to accumulate sufficient patients within a reasonable time, are the most likely means of confirming or denying the usefulness of intra-aortic balloon pumping for preserving ischemic myocardium.

References

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Preservation of ischemic myocardium with intraaortic balloon pumping: modern therapeutic intervention or primum non nocere?

S Scheidt

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