Prognosis After the Implantation of an Intra-Aortic Balloon Pump in Cardiac Surgery Calculated With a New Score

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Background—Over the past decade, the use of a ventricular-assist device (VAD) in patients with postcardiotomy cardiogenic shock has resulted in hospital discharge rates of 25% to 40% and is improving. Nevertheless, indications for and timing of the implantation of a VAD in patients who have received an intra-aortic balloon pump (IABP) remain unclear.

Methods and Results—From July 1996 to March 2000, 391 patients with cardiac low-output syndrome who underwent open-heart surgery and had an IABP implanted were analyzed in a retrospective pilot study. The perioperative mortality was 34% (133 patients). Clinical parameters were analyzed 1 hour after IABP support began. Statistical multivariate analysis showed that patients with an adrenaline requirement higher than 0.5 μg·kg⁻¹·min⁻¹, a left atrial pressure >15 mm Hg, urine output <100 mL/h, and mixed venous saturation (SVO₂) <60% had poor outcomes. Using this data, we developed an IABP score (0 to 5 points) to predict survival early after IABP implantation in cardiac surgery. We evaluated our score by monitoring another 101 patients as a control group prospectively. Additionally, 210 patients who received coronary artery bypass grafting (CABG) exclusively were analyzed. All investigations confirmed the validity of the score.

Conclusions—The IABP score can predict survival early after IABP implantation. In patients with a high IABP score, implantation of a VAD should be considered. (Circulation. 2002;106[suppl I]:I-203-I-206.)

Key Words: heart failure ■ heart-assist device ■ cardiopulmonary bypass

Postcardiomyopathy cardiogenic shock occurs approximately 2% to 6% of patients who undergo open-heart surgery. Early implantation of an intra-aortic balloon pump (IABP) together with pharmacological support leads to the successful weaning from cardiopulmonary bypass of 70% to 90% of all patients, with hemodynamic recovery and successful explantation of the IABP in 60% to 70% of the patients. In those patients who are suffering from cardiac low-output syndrome despite IABP support, ventricular-assist devices (VADs) have been used to achieve circulatory recovery, with varying success and different intentions. Some patients were bridged to heart transplantation; others received a VAD as permanent replacement therapy. In our clinic, we have observed myocardial recovery of the failing heart in >30 patients with successful explantation of the assist devices as a third possibility. However, although worldwide activities in the field of mechanical circulatory assistance are increasing, the indication is not precisely defined, and there is far from a worldwide consensus. For this reason, we analyzed the hemodynamic parameters after IABP implantation to predict survival of the patients early after IABP support has started. Based on our own surgical experience, the hemodynamic parameters 1 hour after implantation were measured.

Methods
To identify selection criteria for patients with IABP support becoming candidates for the implantation of a VAD, we retrospectively analyzed 391 patients (3.4%) of 11,417 who were operated on with the heart-lung machine. These patients were all operated on at our clinic between July 1996 and March 2000. All patients studied had suffered from low-output syndrome with subsequent implantation of an IABP to separate them from heart-lung bypass. Patients in whom an IABP had been implanted preoperatively were excluded from this study. Statistical analysis of preoperative and perioperative parameters and hemodynamic data measured 1 hour after IABP implantation allowed prediction of survival and later successful explantation of the pump. The hemodynamic parameters were measured in the operating room by an experienced anesthesiologist. Preoperative status of the patients included hemodynamic parameters (eg, left ventricular ejection fraction [LVEF], left ventricular end-diastolic pressure, pulmonary artery pressures, and the need for pharmacological inotropic support) as well as patient demographics, such as duration of heart failure, history of myocardial infarction, or diagnosis of diabetes mellitus or hypertension. The transfusion trigger level was defined as a hemoglobin blood level of 8 g/dL to keep the level constant >8 g/dL also after IABP implantation. Mannitol/
TABLE 1. Operations

<table>
<thead>
<tr>
<th>Kind of operation</th>
<th>II n=391</th>
<th>% II</th>
<th>II n=101</th>
<th>% II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency operations</td>
<td>153</td>
<td>39</td>
<td>33</td>
<td>33</td>
</tr>
<tr>
<td>Elective operations</td>
<td>238</td>
<td>61</td>
<td>68</td>
<td>67</td>
</tr>
<tr>
<td>Coronary artery bypass grafting</td>
<td>306</td>
<td>78</td>
<td>78</td>
<td>77</td>
</tr>
<tr>
<td>Aortic valve replacement+CABG</td>
<td>42</td>
<td>11</td>
<td>12</td>
<td>12</td>
</tr>
<tr>
<td>Mitral valve repl./reconstr.:CABG</td>
<td>18</td>
<td>5</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>VSD closure after acute infarction</td>
<td>9</td>
<td>2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Aneureysmectomy+CABG</td>
<td>5</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Others</td>
<td>11</td>
<td>3</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

The majority of the 391 patients received coronary artery bypass grafting (CABG). More than one-third of all operations were performed in an emergency situation. The control group is comparable to the primary investigated group.

glucose and furosemide were given during and after cardiopulmonary bypass (CPB) to improve diuresis. Statistical analysis was performed using SPSS 7.5 for Windows. Group comparisons were performed with Student’s t test (parametric data) or the χ² test (categorical data). Parameters were first analyzed in a univariate logistic regression. In a second step, all prognostic factors were included in a multivariate logistic regression model, and backward elimination (selection level 0.01) was used to identify prediction parameters. Based on the coefficients of the multivariate analysis, an IABP score formula was determined. All patients were scored using this formula.

To assess how well the score could discriminate between patients who died or did not die within the first 30 days after operation, the area under the receiver operation characteristic (ROC) curve was evaluated for the developmental data set as well as for the validation data set.

A second cohort of 101 patients was examined as controls from April 2000 to March 2001 to evaluate the new score. All patients were scored during surgery prospectively. The CPB technique was similar to the technique that was used in the initially investigated study group.

The heart operations performed in both study groups are listed in Table 1. Finally, we analyzed all of the patients who had received coronary bypass grafting similar to the technique that was used in the initially investigated group. The CPB technique was evaluated for the developmental data set as well as for the validation data set.

TABLE 2. Results of Univariate Analysis

<table>
<thead>
<tr>
<th>Parameter</th>
<th>OPM (%)</th>
<th>Odds Ratio</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age &gt;70 years</td>
<td>44</td>
<td>2</td>
<td>0.0016</td>
</tr>
<tr>
<td>Ejection fraction &lt;25%</td>
<td>40</td>
<td>1.7</td>
<td>0.018</td>
</tr>
<tr>
<td>Emergency surgery</td>
<td>45</td>
<td>2.2</td>
<td>0.0004</td>
</tr>
<tr>
<td>Non-CABG procedure</td>
<td>59</td>
<td>3.8</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>No use of ITA in CABG</td>
<td>28</td>
<td>1.1</td>
<td>0.62</td>
</tr>
<tr>
<td>Aortic cross-clamp time &gt;90 min</td>
<td>67</td>
<td>4.4</td>
<td>0.0001</td>
</tr>
<tr>
<td>Diuresis &lt;100 ml/h</td>
<td>55</td>
<td>4.4</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Adrenaline dose &gt;0.5 μg/kg/BW/min</td>
<td>83</td>
<td>14.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Enoximone use</td>
<td>55</td>
<td>7.1</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>CI &lt;2 l/min/sqm</td>
<td>64</td>
<td>4.5</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>LAP &gt;15 mm Hg</td>
<td>77</td>
<td>7.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>MAP &lt;60 mm Hg</td>
<td>61</td>
<td>3.3</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Diastolic PAP &gt;20 mm Hg</td>
<td>44</td>
<td>1.9</td>
<td>0.003</td>
</tr>
<tr>
<td>SVO₂ &lt;60%</td>
<td>54</td>
<td>3.1</td>
<td>0.0016</td>
</tr>
</tbody>
</table>

Univariate analysis showed a high number of significant parameters to predict death despite IABP implantation: CABG indicates coronary artery bypass grafting; ITA, internal thoracic artery; BW, body weight; CI, cardiac index; LAP, left atrial pressure; MAP, mean arterial pressure; PAP, pulmonary artery pressure; and SVO₂, mixed venous saturation.

The indications for IABP implantation included the following: left atrial pressure (LAP) increased by >15 mm Hg, cardiac index decreased to <2 L·min⁻¹·m⁻², and mean systolic arterial pressure <90 mm Hg despite adrenaline support (>0.2 μg·kg⁻¹·min⁻¹) after being weaned from the heart-lung machine.

Results

Of 391 patients who underwent implantation of an IABP for cardiac low-output syndrome, 133 (34%) died within the first 30 days after the operation. In 258 patients, the IABP was explanted successfully. The mortality rate in emergency cases was 44.7% (68 of 152 patients) and 27.2% (65 of 239 patients) in the elective cases. The most common mechanism of death was continued ventricular failure in 85.3% (58 of 68 patients). Of the patients in the emergency group, 3 suffered from predominant arrhythmia, and 7 (10.3%) developed sepsis followed by multiorgan failure. In the elective group, 60 (92.3%) of 65 patients died as a result of continued ventricular failure, 2 patients had severe arrhythmia, and 3 (4.6%) patients died after developing sepsis. The operative mortality relative to surgical procedure is shown in Table 1. Univariate analysis showed a high number of parameters to predict death despite IABP-implantation (see Table 2).

The multivariate logistic regression showed 4 parameters as statistically significant to predict survival or death 1 hour after IABP implantation in patients with low-output syndrome in cardiac surgery. The 4 parameters are the adrenaline requirements, urine output under maximum diuretic treatment, mixed venous saturation with a minimum hemoglobin blood level of 8 g/dL, and LAP (Table 3). All other periproactively and preoperatively analyzed parameters were not significant. From these 4 parameters, an IABP score was determined. The heart operations performed in both study groups are listed in Table 1. Finally, we analyzed all of the patients who had received coronary bypass grafting (CABG) (isolated) separately. There were no “off-pump” operations in this group of patients.

The average age of the initial investigated group of 391 patients was 66.3 years (SD=9.5). Two hundred sixty-two (67%) were male and 129 (33%) female. The average preoperative LVEF was 35.8% (SD=16.3). One hundred thirty-five (88.8%) patients from the emergency group went into surgery with an acute myocardial infarction documented by troponin blood levels >4.1 ng/mL.

The average age of the 101 patients in the control group was 65.8 years (SD=10.5). The average preoperative LVEF was 39.0% (SD=17.3). The clinical and demographic data of the control group were comparable to those of the initial group.

The multivariate logistic regression showed 4 parameters as statistically significant to predict survival or death 1 hour after IABP implantation in patients with low-output syndrome in cardiac surgery. The 4 parameters are the adrenaline requirements, urine output under maximum diuretic treatment, mixed venous saturation with a minimum hemoglobin blood level of 8 g/dL, and LAP (Table 3). All other periproactively and preoperatively analyzed parameters were not significant. From these 4 parameters, an IABP score was determined.

TABLE 3. Results of Multivariate Analysis

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Odds Ratio</th>
<th>Range (OR)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenaline dose &gt;0.5 μg/kg/BW/min</td>
<td>6.6</td>
<td>2.3–18.8</td>
<td>0.0005</td>
</tr>
<tr>
<td>Diuresis &lt;100 ml</td>
<td>2.5</td>
<td>1.2–5.4</td>
<td>0.026</td>
</tr>
<tr>
<td>SVO₂ &lt;60%</td>
<td>2.5</td>
<td>1.0–6.3</td>
<td>0.048</td>
</tr>
<tr>
<td>LAP &gt;15 mm Hg</td>
<td>3.0</td>
<td>1.1–8.5</td>
<td>0.036</td>
</tr>
</tbody>
</table>

Multivariate analysis showed 4 parameters as statistically significant for the prediction of survival or death 1 hour after IABP implantation in patients with cardiac low-output syndrome in cardiac surgery. All other parameters were not significant.
calculated to predict death or survival 1 hour after IABP implantation:

\[
\text{IABP score} = I(\text{adrenaline dose}) + I(\text{urine output}) + I(\text{SVO}_2) + I(\text{LAP})
\]

where \( I(X) \) denotes the indicator function, being equal to 1 if \( X \) holds and 0 otherwise; AD = adrenaline dose; UO = urine output/h; SVO\(_2\) = mixed venous saturation, and LAP as defined before (Table 4). The cutoff point of the adrenaline level was set arbitrarily in accordance with our personal experience. The calculation of the score should be as simple as possible. The multivariate regression showed an odds ratio of 6.6 (2.3 to 18.8) for an adrenaline dose \( \leq 0.5 \) \( \mu \text{g} \cdot \text{kg body weight}^{-1} \cdot \text{min}^{-1} \), of 2.5 (1.0 to 6.3) for an SVO\(_2\) \( < 60\% \), and of 3.0 (1.1 to 8.5) for LAP \( > 15 \) mm Hg. Because of the high odds ratio of the adrenaline dose, 2 points were awarded for this parameter in the formula.

In the validation group (101 patients), the mean adrenaline dose of patients who survived was 0.2 \( \pm 0.1 \) \( \mu \text{g} \cdot \text{kg body weight}^{-1} \cdot \text{min}^{-1} \), and 0.4 \( \pm 0.2 \) \( \mu \text{g} \cdot \text{kg body weight}^{-1} \cdot \text{min}^{-1} \) in those who did not survive (\( P = 0.001 \)). We also frequently used Perfan (enoximone), but we did not see any correlation between use of this drug and the possibility of 30-day survival for the patients.

The probability of survival dependent on the IABP score is shown in Figure 1. Patients who scored 5 points had no probability of surviving 30 days, whereas patients with a score of zero had a probability of 86%. The area under the ROC curve was 0.79 (0.72 to 0.86).

These findings were confirmed by the results of the control group. The probability of survival was 81% in patients with 0 points, 50% with 1 point, 36% with 2 points, 25% with 3 points, and 0% in patients with 4 or 5 points (see Figure 2). Discrimination by the ROC was 0.81 (0.72 to 0.90). This statistical analysis showed that the discrimination of the score was almost identical in both samples. The distribution of both study cohorts in the different score values was also statistically similar.

A group of 210 patients who had received CABG exclusively were scored additionally. The score was also valid for the probability of these patients surviving 30 days.

### Discussion

The results of circulatory support in the urgent setting of postcardiotomy cardiogenic shock have remained poor despite the use of numerous continuous centrifugal and pulsatile pneumatic devices. In a review of a combined registry experience of VADs for postcardiotomy shock, Pae and colleagues\(^9\) reported a 45% weaning rate and only a 24.6% discharge rate among 965 patients supported between 1985 and 1990. In this series, patients were supported for a mean of 4 days, and both pneumatic and centrifugal devices were used. A model-based odds ratio showed renal failure, biventricular failure, a neurological event, bleeding, and infection to be predictive of unsuccessful weaning from circulatory support. Since this article, similar results have been obtained with temporary mechanical assistance after postcardiotomy circulatory failure.\(^10,11\) Deciding when to place a patient on mechanical support is the key to success in our view. There is a fine balance between giving the patient the opportunity to respond to extensive medical therapy with and without IABP support and avoid a device and waiting too long so that end-organ failure progresses and they become a poor candidate for assist-device implantation. Not surprisingly, patients who have their device implanted in an elective setting enjoyed better survival than those in a more urgent scenario.\(^12\)

The goal of our studies is to be able to predict the success or failure of IABP support early, providing the option, in
those with low-output syndrome despite IABP support, of implanting a VAD before septicemia or multiorgan failure develops and the opportunity to “bridge” such a patient to heart transplantation is lost.

The IABP score developed here has been validated by an examination of a representative group of patients and has been proven by an analysis of a comparable control group. We have shown that the prognosis of patients who have an IABP implanted after cardiotomy can be calculated while they are still in the operating room. In patients with a high IABP score and poor survival prognosis, the implantation of an assist device should be considered. In our primary study group, there were 102 (26.1%) patients <60 years of age, of whom 23 died despite IABP support. Consequently, “bridging” to heart transplantation should be considered when the prediction of survival is low after IABP implantation and when the patient fulfills the requirements of a transplant recipient.13 However, we observed myocardial recovery in >30 patients in our clinic who underwent implantation of a VAD, with successful explantation.14 This may be another course of treatment in some circumstances.

As reported by other investigators, we observed that early recovery of the failing left ventricle predicts survival of the patient.15 ,16 Thus, it is not surprising that our measurements of hemodynamic parameters 1 hour after counterpulsation was started led to significant prognostic results.17 Patients with postcardiotomy low-output syndrome who have received CABG only have the best prognosis after IABP implantation.18 –20 In a group of 225 patients with coronary artery disease and severely impaired left ventricular function who were referred to our clinic as possible candidates for heart transplantation, CABG only was performed after the preoperative demonstration of “hibernating myocardium.”21 In the 46 patients in whom an IABP was implanted to wean them from heart-lung bypass, 16 patients died within 30 days, while 30 patients were discharged successfully from the hospital.

This study demonstrates that the success of IABP implantation in patients with cardiac low-output syndrome can be predicted 1 hour after implantation. The IABP score can assist the surgeon to change to a VAD when the IABP may not be successful. This would provide the option of heart transplantation or myocardial recovery on total left ventricular support.

References
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