Vascular complications of intra-aortic balloon insertion in patients undergoing coronary revascularization: analysis of 911 cases

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Abstract

Objective: Intra-aortic balloon pump (IABP) is a well-accepted and widely used mechanical circulatory support in cardiac surgical practice. We evaluated the vascular complications of IABP and risk factors associated with the development of these complications in patients undergoing myocardial revascularization. Methods: Between January 1994 and December 2000, a total of 911 patients undergoing coronary artery bypass grafting received IABP. The preoperative risk factors, balloon-related variables and vascular complications were studied and analyzed. Univariate and multivariate analyses were performed to identify risk factors for the development of vascular complications. Results: Mean age of the patients was 59.2 ± 9.1 years and 10.5% of the patients were female. The incidence of diabetes and peripheral vascular disease was 41.1 and 8.5%, respectively. The mean Parsonnet score was 11.8 ± 4.6. IABP was inserted by percutaneous technique in 96.8% of patients. The duration of IABP therapy ranged from 20 h to 21 days (mean 3.8 days). Fifty-four (5.9%) patients developed major and 53 (5.8%) patients developed minor vascular complications. Ischaemia of the limb, requiring thromboembolectomy, developed in 25 (2.7%) patients. Patients who received IABP preoperatively had higher incidence of major vascular complications as compared to patients who received IABP in operating room before induction of anaesthesia. Multiple logistic regression analysis revealed age, triple vessel disease, indications of IABP therapy (unstable angina, cardiac arrhythmia and haemodynamic instability), left ventricular aneurysm surgery and use of balloon with sheath as independent risk factors for the development of vascular complications. Conclusions: IABP therapy is associated with certain vascular complications, which should always be kept in mind before insertion of a balloon. The use of a balloon without sheath and proper evaluation of peripheral circulation can help to minimize the development of vascular complications. © 2002 Elsevier Science B.V. All rights reserved.

Keywords: Intra-aortic balloon pump; Vascular complications; Coronary revascularization

1. Introduction

The intra-aortic balloon pump (IABP) which was introduced experimentally by Moulopoulos and associates in 1962 [1] and used clinically by Kantrowitz and associates in 1968 [2], is currently the most widely used mechanical circulatory support device in cardiac surgery. It has been shown to result in a more favourable myocardial supply/demand balance in the failing myocardium [3]. The indications for IABP have been increasing over the last three decades. The complications related to the use of IABP are frequent with a reported incidence of 8 to 18% [4–9]. IABP mortality has been reported to range from 0 to 2.6% [8,9].

Since the introduction of IABP therapy, there have been significant technical improvements in intra-aortic balloon (IAB) catheters, including the reduction in the size of the catheter. Most insertions are now done by percutaneous technique, either with a sheath or sheathless. In this study, we analysed vascular complications related to the insertion of IABP during cardiac surgery over a 7-year period.

2. Materials and methods

Patients who underwent coronary artery bypass grafting (CABG), with or without associated procedures, between January 1994 and December 2000 and received IABP therapy, were analysed. Patients who received IABP in the coronary care unit and did not undergo surgery were excluded from this study. A total of 911 patients received IABP therapy during this period. The data were entered prospectively into our database and analysed retrospectively.
2.1. Clinical variables

Clinical variables which were studied included age, sex, diabetes mellitus, hypertension, smoking (>10 cigarettes per day), peripheral vascular disease (PVD), preoperative serum creatinine, history of congestive heart failure, severity of coronary artery disease, left ventricular (LV) ejection fraction, redo surgery, mitral regurgitation, preoperative left ventricular end-diastolic pressure (LVEDP), preoperative pulmonary artery pressures, and type of surgery (elective, urgent, emergency).

The variables related to IABP which were studied included indications of IABP, time of IABP insertion (preoperative, preinduction, intraoperative or postoperative), technique of insertion (percutaneous, open femoral or trans-thoracic), volume of balloon used (40 or 34 cc), type of balloon used (sheathless or with sheath) and duration of IABP therapy.

Urgent surgery was defined as surgery performed within 24 h of angiography or referral by another centre. Emergency surgery was defined as surgery performed within a few hours of angiography or referral.

Peripheral vascular disease was defined as a history of intermittent claudication, diminished peripheral pulsations, or PVD demonstrated on Doppler ultrasound or angiography.

2.2. Technique of IABP insertion

IABP was inserted primarily by the percutaneous Seldinger technique. Open transfemoral technique was used only when the percutaneous technique failed. Intra-aortic balloon catheter used was a 9.5-F 40-ml or 36-ml balloon Percor STAT-DL catheter (Datascope Corp., Fairfield, NJ, USA). The console used was a Datascope pump (Datascope Corp., Rainbow, NJ, USA).

The position of the balloon was confirmed by chest X-ray in patients getting IABP outside theatre and by transoesophageal echocardiography in patients where the balloon was inserted in the operating theatre. The intra-aortic balloon pump was inserted through the thoracic aorta in the operating room when the patient had severe peripheral vascular disease or atherosclerotic disease of the lower aorta.

After 1996, all patients above the age of 60 years or with a history of PVD or clinical evidence of PVD, who required elective IABP insertion, underwent Doppler study of their peripheral circulation.

2.3. Post IABP protocol

All patients were heparinized after insertion of IABP. The anticoagulation was monitored by partial thromboplastin time, which was kept at twice the norm. The heparin was stopped approx. 0.5 h before the removal of the balloon.

The peripheral pulses were examined every hour after insertion of IABP. If the pulses were not palpable clinically or if there was any evidence of ischaemia, peripheral Doppler was performed. If the Doppler showed any obstruction to the flow in femoral artery, the balloon was removed and inserted into the other artery, if the patient still needed IABP therapy. The Doppler was repeated after removal of the balloon. If the Doppler showed any evidence of clot or obstruction to flow, the patient was taken to the operating theatre and an arterial procedure performed as required.

The vascular complications related to balloon therapy were grouped into two groups: major and minor. Major vascular complications included acute lower limb ischaemia requiring direct arterial intervention (thromboembolectomy, direct arterial repair and femorofemoral bypass), aortic or peripheral arterial perforation, aortic dissection, fasciotomy and amputation of limb. Minor complications included local haematoma, infection and ischaemia, which was reversed by removal of sheath or balloon.

2.4. Statistical analysis

All values are reported as mean ± standard deviation. The chi-square ($\chi^2$) test or Fisher’s exact test was applied for nominal measurements. Student’s t-test and one-way analysis of variance were used to assess differences between groups for statistical significance for continuous measurements. The null hypothesis was rejected when the $P$-value was less than 0.05. Multiple logistic regression analysis was used to determine the relationship between perioperative clinical variables and variables related to the balloon and development of vascular complications (major or minor). The variables in the predictors set were identified by a forward conditional process, such that the $P$-value associated with the introduction of additional variables was greater than 0.10. Those risk factors found to be significant were assigned logistic coefficients ($\beta$) and the predicted probability of vascular complications was calculated by the formula $P = (1 + eZ)^{-1}$, where $Z = \beta_0 + \beta_1X_1 + \beta_2X_2 + \ldots$, $\beta_0$ is the constant, $\beta_n$ are the logistic coefficients, and $X_n$ are the values of the predictor variables. The variables were coded according to the presence ($X = 1$) or absence ($X = 0$) of that variable. SPSS 10.0 software (SPSS Inc., Chicago, IL, USA) was used for statistical analysis.

3. Results

A total of 14 062 patients underwent CABG with or without associated procedures between January 1994 and December 2000. Out of these, 911 (6.48%) patients required IABP therapy. The clinical parameters of the patients are shown in Table 1. Only 10.5% patients were females. The incidence of PVD was 8.5%, and 41.1% of patients were diabetic. Mean Parsonnet score was 11.8 ± 4.6.

The indications and timing of balloon insertion are shown in Tables 2 and 3. Three hundred and sixty-two patients (39.7%) had IABP preoperatively before going for surgery (group I). These patients had unstable angina, haemodynamic instability, cardiac failure, arrhythmias or evolving myocardial infarction. In 379 (41.6%) patients, the balloon was inserted before induction of anaesthesia (group II) due to...
to poor ventricular function with high pulmonary artery (PA) pressures, critical coronary anatomy, ECG changes of ischaemia or a combination of these factors. In 161 (17.7%) patients, the balloon was inserted intraoperatively (group III), either due to difficulty in coming off cardiopulmonary bypass (CPB) or the patient not maintaining normal haemodynamics with inotropes. Four (0.4%) patients had very severe protamine reaction with hypotension and raised PA pressures. The IABP was required to stabilize the patients. The IABP was required postoperatively (group IV) in 9 (1%) patients only.

Percutaneous Seldinger technique was the commonest technique used for insertion of IABP. It was successful in 882 (96.8%) patients. In 24 (2.63%) patients, femoral artery was exposed to insert the balloon because percutaneous technique was not successful. This usually happened in patients who were in cardiogenic shock and femoral pulsation was not palpable or in the operating room when the patient was haemodynamically unstable. The balloon was inserted through the thoracic aorta in 5 (0.55%) patients. In these patients the peripheral vessels and lower aorta had severe atherosclerosis. These patients had to be taken to the operating theatre to remove the balloon.

The size of the balloon was decided by the body size of the patient. We preferred 34-cc balloon in short-stature patients and females. Before 1996, we were inserting IAB catheters with a sheath, while after that most catheters were inserted sheathless.

The duration of IABP therapy varied from 20 h to 21 days. In 71 (7.8%) patients, the balloon was removed within 24 h. The majority of patients (53.7%) required the balloon between 1 and 3 days. In 82 (9.2%) patients IABP therapy was required for more than 1 week. The mean duration of IABP therapy was 3.8 days.

3.1. Operative data

The operative procedures performed in the patients are shown in Table 4.

The mean number of grafts was 3.4 ± 1.3 per patient. The
mean cardiopulmonary bypass time was 92.4 ± 26.8, 81.2 ± 20.4, 102.34 ± 28.6, and 96.6 ± 24.4 min in groups I, II, III and IV, respectively. The CPB time was significantly less in group II patients as compared to group I and group III patients (P < 0.001).

The aortic cross-clamp time was 48.4 ± 8.2, 47.6 ± 6.8, 48.8 ± 9.4 and 47.9 ± 7.2 min in groups I, II, III and IV, respectively. There was no significant difference in the aortic cross-clamp time in the four groups.

3.2. Mortality

The overall hospital mortality was 5.6% (53/911 patients). Two (0.22%) patients died of IABP-related complications. The hospital mortality in different groups was 6.6% (24/368) in group I, 5.3% (20/379) in group II, 2.5% (4/161) in group III and 33.3% (3/9) in group IV. The hospital mortality in group I was higher than in group II and group III patients (P = 0.033). The mortality in patients who received IABP before surgery (groups I and II) was also not significantly different from the mortality in group III patients, (P = 0.115) but the mortality in groups I and II was significantly less than in group IV (P = 0.015).

Table 5 shows the preoperative risk score and postoperative outcome of different groups of patients.

3.3. Vascular complications

Fifty-four (5.9%) patients developed major vascular complications (Table 6). Ischaemia of lower limb, requiring thromboembolectomy, was the commonest vascular complication, occurring in 25 (2.7%) patients. Nine of these patients also required fasciotomy. Six other patients, who did not need any direct arterial surgery, required fasciotomy for compartment syndrome. Five patients required direct repair of the femoral artery, while four required saphenous vein femorofemoral bypass. In three patients there was dissection of the aorta. All three patients had preoperative IABP and complained of pain during insertion of guide wire. The balloon insertion was abandoned and a computed tomography scan confirmed aortic dissection. One of these patients died. One patient had perforation of the aorta. This patient also died. In two patients there was injury to the external iliac artery and one patient had injury to the common iliac artery. All three patients required surgical repair. Seven patients required amputation for ischaemia of the limb. Four of these patients required below-knee amputation and three required toe amputation. Five of these patients had severe PVD.

When we analysed the incidence of major vascular complications in different groups, the incidence in group I was not significantly different than in group II (P = 0.256). Similarly, the complication rate of groups I and II patients was not different from group III patients (P = 0.075). But the patients in group II had significantly less vascular complications than group III patients (P = 0.033). No patient in group IV developed any major complication.

Minor vascular complications developed in 53 (5.8%)
patients. Thirty-three (3.6%) patients developed ischaemia of the limb, which did not require any surgical intervention. In 13 of these patients, pulling the sheath out of the femoral artery relieved the ischaemia. In the remaining 20 patients, the ischaemia improved by removal of IABP. Localized haematoma developed in 12 patients and eight patients developed infection at the local site, requiring systemic antibiotics and local dressing of the wound. None of these patients required any surgical intervention. The incidence of minor complications in group II patients was significantly less than in groups I and III patients ($P < 0.001$) but there was no significant difference in the complication rate in groups I and II patients as compared to group III patients.

### 3.4. Risk factor analysis of vascular complications

Various preoperative and IABP-related factors were analysed for the development of vascular complications. The results of univariate analysis are shown in Table 7. Among the preoperative factors, age, sex, peripheral vascular disease and the severity of coronary artery disease were associated with the development of vascular complications. Patients who received IABP for unstable angina, left main coronary artery disease, cardiac arrhythmia and haemodynamic instability had a significantly higher incidence of vascular complications. Among balloon-related variables, use of sheath and duration of IABP therapy were significantly related to the development of vascular complications. Out of 356 patients, where the IAB catheter was inserted with a sheath, 61 (17.1%) had vascular complications while among 555 patients who received a sheathless balloon insertion, 41 (7.4%) developed vascular complications ($P < 0.001$).

Multiple logistic regression analysis of predictive variables was performed and the results are shown in Table 8. Use of sheath and unstable angina and cardiac arrhythmia as the indications of IABP therapy were found to be significantly related to the development of vascular complications. Age and severity of coronary artery disease were other risk factors, which were found to be significantly related to the development of vascular complications. PVD, presence of mitral regurgitation and inotropes, which were found to be significant risk factors on univariate analysis, were not found to be significant on multivariate analysis.

### 4. Discussion

IABP therapy has long been established as a valuable mechanical support for temporary ventricular assistance in the treatment of the failing heart [4,5,10]. Its main effects are reduction of ventricular afterload, improvement of diastolic coronary perfusion and enhancement of subendocardial perfusion [11]. Use of IABP is associated with certain complications, which can be categorized as peripheral ischaemia, infection, and haematological complications. The incidence of vascular complications reported in the literature ranges from 8.7 to 20% [7,12–14]. The risk factors that have been identified for the development of vascular complications include female sex, age, obesity, diabetes, hypertension, smoking, PVD and duration of IABP therapy [8,12–14].

The overall hospital mortality in our study was 5.6%. Two patients died due to IABP-related complications; one due to dissection of aorta and the other due to perforation of aorta. The balloon-related mortality has been reported to range from 0 [9] to 2.6% [8].

Forty-one point six percent of patients in our study received prophylactic balloon before induction of anaesthesia, due to one or more high-risk factors. The efficacy of preoperative IABP in high-risk patients, including patients

### Table 7

**Univariate analysis of risk factors for vascular complications**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Score</th>
<th>$P$-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>26.972</td>
<td>0.000</td>
</tr>
<tr>
<td>Sex</td>
<td>2.116</td>
<td>0.146</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>38.274</td>
<td>0.000</td>
</tr>
<tr>
<td>Mitral regurgitation</td>
<td>4.057</td>
<td>0.044</td>
</tr>
<tr>
<td>Triple vessel disease</td>
<td>5.693</td>
<td>0.017</td>
</tr>
<tr>
<td>Left ventricular aneurysm</td>
<td>4.647</td>
<td>0.031</td>
</tr>
<tr>
<td>Inotrope</td>
<td>4.601</td>
<td>0.032</td>
</tr>
<tr>
<td>Indication: unstable angina</td>
<td>15.003</td>
<td>0.000</td>
</tr>
<tr>
<td>Indication: left main stenosis</td>
<td>5.281</td>
<td>0.022</td>
</tr>
<tr>
<td>Indication: cardiac arrhythmia</td>
<td>39.253</td>
<td>0.000</td>
</tr>
<tr>
<td>Indication: haemodynamic instability</td>
<td>6.110</td>
<td>0.013</td>
</tr>
<tr>
<td>Duration of IABP</td>
<td>1.900</td>
<td>0.168</td>
</tr>
<tr>
<td>Sheath</td>
<td>20.725</td>
<td>0.000</td>
</tr>
</tbody>
</table>

### Table 8

**Multiple logistic regression analysis of the predictive variables**

<table>
<thead>
<tr>
<th>Variable</th>
<th>$\beta$</th>
<th>SE</th>
<th>Wald</th>
<th>$P$-value</th>
<th>Exp($\beta$)</th>
<th>95.0% CI for exp($\beta$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>0.050</td>
<td>0.015</td>
<td>11.706</td>
<td>0.001</td>
<td>1.051</td>
<td>1.022, 1.082</td>
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<tr>
<td>Triple vessel disease</td>
<td>1.467</td>
<td>0.579</td>
<td>6.421</td>
<td>0.011</td>
<td>4.337</td>
<td>1.394, 13.489</td>
</tr>
<tr>
<td>Left ventricular aneurysm</td>
<td>0.637</td>
<td>0.226</td>
<td>7.967</td>
<td>0.005</td>
<td>1.891</td>
<td>1.215, 2.944</td>
</tr>
<tr>
<td>Indication: unstable angina</td>
<td>1.496</td>
<td>0.273</td>
<td>29.968</td>
<td>0.000</td>
<td>4.462</td>
<td>2.612, 7.623</td>
</tr>
<tr>
<td>Indication: cardiac arrhythmia</td>
<td>2.982</td>
<td>0.480</td>
<td>38.560</td>
<td>0.000</td>
<td>19.734</td>
<td>7.699, 50.587</td>
</tr>
<tr>
<td>Indication: haemodynamic instability</td>
<td>1.132</td>
<td>0.264</td>
<td>18.426</td>
<td>0.000</td>
<td>3.103</td>
<td>1.850, 5.204</td>
</tr>
<tr>
<td>Sheath</td>
<td>1.182</td>
<td>0.240</td>
<td>24.327</td>
<td>0.000</td>
<td>3.260</td>
<td>2.038, 5.215</td>
</tr>
<tr>
<td>Constant</td>
<td>-8.300</td>
<td>1.071</td>
<td>60.104</td>
<td>0.000</td>
<td>0.000</td>
<td></td>
</tr>
</tbody>
</table>
with poor left ventricular function, redo surgery, left main stenosis and patients with unstable angina, has been shown by many studies [15–18]. In a retrospective study on preoperative use of IABP in patients with ejection fraction of 25% or less, Dietl et al. found that the mortality in patients who were operated on with IABP was 2.7% as compared to 11.9% mortality in patients who were operated on without IABP [15]. In a 27-year review of IABP use at Massachusetts General Hospital, the mortality in patients who received preoperative IABP was 13.6% as compared to patients who received intraoperative and postoperative IABPs, where the mortality was 35.7 and 35.9%, respectively [19].

The incidence of vascular complications in our study was 11.7% (107/911 patients). The patients who received IABP in the operating room before induction of anaesthesia (group II) had fewer vascular complications than patients who received IABP preoperatively in the intensive care unit or intraoperatively (groups I and III). The difference was more marked in the incidence of minor complications. This may be because these patients in group II received IABP under better-controlled conditions. As has been reported in other studies [7,20], lower limb ischaemia requiring thromboembolectomy was the most common complication in our study. Age was identified as a significant risk factor for the development of vascular complications. Sex, which was found to be a risk factor in some studies [8,12,13,21,22] was not a risk factor in our study, both on univariate and multivariate analysis.

The Benchmark registry included worldwide prospectively collected data from 203 hospitals on 16909 patients, who received IABP between June 1996 and August 2000 [22]. The registry reported overall IABP-related morbidity of 2.6% and IABP-related mortality of 0.05%. Female sex, old age and peripheral vascular disease were reported as independent predictors of a major complication.

Severity of coronary artery disease and left ventricular aneurysm surgery were found to be an independent risk factor. Many of these patients had unstable angina, haemodynamic instability and cardiac arrhythmias as the indications of IABP insertion, which were also found to be independent risk factors for vascular complications. These factors reflect the severity of cardiac dysfunction and depressed preoperative cardiac function. In a recent study by Cohen et al., who found PVD, female sex and body surface area as independent predictors of a major complication, cardiac index was also identified as an independent predictor of any or major complications [21]. Arafa et al. [20] found preoperative end-diastolic pressure to be an independent risk factor.

The use of a sheath for insertion of IAB catheter was an independent risk factor in our study. The ratio of the femoral artery size to the balloon size has been implicated as a causative factor in arterial occlusion. Use of a sheathless balloon can therefore be expected to be associated with fewer complications than balloons with a sheath. Tatar et al. [9] also found a significantly high incidence of vascular complications in patients who received IABP by conventional percutaneous insertion as compared to patients who received sheathless insertion of a balloon. Out of 67 patients who developed ischaemia of the limb in our study, removal of sheath from the femoral artery relieved ischaemia in 13 patients. Use of a small-diameter catheter should further reduce the incidence of vascular complications.

Peripheral vascular disease, which has been shown to be a significant risk factor in some studies [8,20,23] was found to be a risk factor on univariate analysis in our study, but logistic regression analysis did not find PVD an independent risk factor. We now perform peripheral Doppler study of all patients where IABP is used electively.

Some authors have stated a preference for the open technique of femoral insertion of the IABP because of an increased tendency of vascular complications to develop in patients who undergo percutaneous insertion [24]. This could be due to the additional percentage of the intra-arterial lumen that is occupied by the percutaneously placed intra-aortic balloon and its introducer sheath. We did not find the percutaneous technique to be a risk factor for vascular complications.

Diabetes, hypertension, smoking, timing of insertion, technique of insertion, use of inotropes and duration of therapy were not found to be significant risk factors in our study, though some studies have demonstrated diabetes, smoking and duration of IABP insertion as significant risk factors for the development of vascular complications [8,12,13,15,25]. In a study by Manord et al. [25], the incidence of IABP-related complications was 32% in patients with prolonged IABP support. The mean duration of IABP support in their study was 23.2 days. In our study, the mean duration of support was 3.8 days.

In conclusion, percutaneous insertion of IABP is successful in a majority of the patients requiring this support. Use of IABP is associated to an extent with morbidity. Insertion of IABP without a sheath and proper assessment of peripheral vasculature can help in minimizing vascular complications. In many patients, ischaemia can be relieved simply by removing the balloon. Some patients need direct arterial surgery to prevent limb loss.

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References


