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Reinsertion Predictors of Intraaortic Balloon Pumps

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ABSTRACT

The reinsertion rate of intraaortic balloon pumps (IABP) has not been clearly reported. We evaluated the use of left-ventricular ejection fraction (LVEF), fractional shortening (FS), and cardiac index (CI) values to asses cardiac performance as weaning criteria for IABP in a prospective study performed in 100 patients who required IABP. Patients were randomly divided into 2 groups of 50 patients. In group 1, classical hemodynamic criteria were considered as weaning criteria of IABP. In this group, IABPs were removed when measurements of general hemodynamic criteria were established to be in normal ranges. In group 2, LVEF, FS, and CI values reflecting cardiac performance were used to monitor patients under IABP support, and IABPs were removed when LVEF, FS, and CI values reached >30%, >20%, and >2.4 L/min per m^2, respectively. Reinsertion of IABP was necessary in 13 patients in group 1 and in 9 patients in group 2 (P = .48). Vascular complications were the main cause of reinsertion of IABP in 7 and 9 patients in group 1 and group 2, respectively (P = .59). Nine patients died in group 1 and 2 in group 2 (P = .025). In group 1, death due to myocardial dysfunction occurred in 8 of 13 patients (62%) who had required reinsertion of IABP; 6 of these patients required reinsertion of IABP because of hemodynamic deterioration, whereas no patients in group 2 required reinsertion of IABP because of hemodynamic deterioration (P = .027). LVEF, FS, and CI values higher than 30% (P = .008), 20% (P = .005), and 2.4 L/min per m^2 (P = .013), respectively, showed good outcomes in regard to avoiding reinsertion of IABP, indicating that these measurements were significant predictors for reinsertion of IABP.

INTRODUCTION

Although the indications for and beneficial effects of intraaortic ballon pumps (IABP) are well described, the exact incidence of IABP reinsertion has not been reported. IABP reinsertion is generally required because of vascular complications (limb ischemia or bleeding), inappropriate insertion of the IABP catheter, or balloon rupture. In these circumstances the IABP can be reinserted via an alternative route. Catheter-related complications can necessitate earlier withdrawal of the IABP from patients who suffer low cardiac output syndrome. In addition, in intensive care units generally used hemodynamic criteria are not accurate for assessing patient condition, and IABP may be removed from patients that still need that support. Clinically, mean arterial pressure (MAP), adequate urine output, decreased pulmonary pressure, and improved general patient status are important criteria for determining the appropriate time to wean patients from IABP support. On the other hand, these parameters are not specific predictive criteria for determining the best time for IABP weaning. Therefore we evaluated some specific cardiac parameters (EF, FS, and CI) to identify reliable criteria for IABP weaning and thus decrease the IABP reinsertion rate.

MATERIALS AND METHODS

We performed a prospective study in 100 patients who required IABP at some time during the period from April to July 2005. The study received local research ethics committee approval, and written consent was obtained from all participating patients. Patients were randomly divided into 2 groups of 50 patients each according to a table of random digits [Tull 1973]. IABP weaning in group 1 patients was performed according to hemodynamic criteria such as mean arterial pressure, pulmonary pressure, and urine output and in group 2 patients according to left ventricular ejection fraction (LVEF), fractional shortening (FS), and cardiac index (CI) values of 30%, 20%, and 2.4 L/min per m^2, respectively. Transesophageal or transthoracic echocardiography was routinely performed before and after IABP insertion. LVEF and FS values were obtained by the same echocardiographer every day during the follow-up period. Patient characteristics are summarized in Table 1.

Intraaortic Balloon Pump

In 58 patients, IABP catheters were inserted perioperatively in the operating room because of low cardiac output syndrome after discontinuation of cardiopulmonary bypass. Inotropic drugs were administered in all patients. No patients were weaned from IABP until dopamine administration was tapered to 5 μg/kg per min. IABP weaning was performed gradually in all patients. First the frequency of counterpulsation was gradually decreased from 2:1 to 4:1, then balloon inflation volume was gradually decreased

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Table 1. Clinical Characteristics of the Study Patients*

Characteristics	Group 1 (n = 50)	Group 2 (n = 50)	*P*
Age	63.5 ± 12.8	63.2 ± 13.8	.93†
Sex, M/F	28/22	26/24	.69‡
Body surface area, m^2	1.73 ± 0.20	1.62 ± 0.14	.17†
Diabetes mellitus	22 (44)	28 (56)	.23‡
Hypertension	26 (52)	34 (68)	.10‡
Hypercholesterolemia	10 (20)	14 (28)	.35‡
Smoking history	26 (52)	18 (36)	.11‡
Alcohol abuse	14 (28)	10 (20)	.35‡
Carotid artery stenosis	4 (8)	4 (8)	1.00§
Prior cerebrovascular accident	4 (8)	6 (12)	.51‡
Preoperative serum creatinine, µmol/L	1.16 ± 0.21	1.13 ± 0.19	.87†
Preoperative NYHA class			
II	8 (16)	6 (12)	.56‡
III	36 (72)	38 (76)	.65‡
IV	6 (12)	6 (12)	1.00‡
LVEDP, mm Hg	11.3 ± 4.9 (10.2)	12.3 ± 4.3 (11.3)	.41¶
LMCA stenosis >50%	6 (12)	4 (8)	.51‡
IABP insertion			
Preoperative	2	4	.68§
Perioperative	32	26	.22‡
Postoperative	16	20	.41‡

*Values are expressed as mean ± SD (median), n, or n (%). IABP indicates intraaortic balloon pump, LMCA, left main coronary artery; LVEDP, left ventricular end-diastolic pressure, LVEF, left ventricular ejection fraction; NYHA: New York Heart Association.

†Independent sample *t*-test.

‡χ^2 Test.

§Fisher exact test.

¶Mann-Whitney U test.

from 40 mL to 25 mL. In both patient groups, each step of the balloon removal procedure lasted for 3 h. LVEF, FS, and CI values were measured at the end of the last step.

Exclusion Criteria

Patients with an LVEF fraction less than 25%; previous valvular, vascular, or left ventricular aneurysm surgery; severe chronic obstructive pulmonary disease; renal impairment (creatinine >3 mg/dL); or permanent atrial fibrillation were excluded from the study. Patients with low LVEF (<25%) during the preoperative period were excluded from this study because even with long-term IABP support their cardiac performance in the postoperative period would not prominently increase [Lorusso 2001].

Anesthesia

The finger-pulse oximeter, 5-lead electrocardiogram was connected to the patients to identify both the isoelectric line and J point. All hemodynamic data were continuously acquired using an electronic data acquisition device. Venous and radial artery lines were inserted into the left antebrachial region. Pulmonary artery catheterization (Swan-Ganz catheter) via the right internal jugular vein was performed with local anesthesia and light intravenous sedation as required. All patients received oxygen at 6 L/min via a face-mask. Carbon monoxide, left ventricle end-diastolic volume, and venous oxygen saturation were monitored continuously. Cardiac output was measured in the preoperative period and other variables were calculated. Cardiac output was routinely measured during IABP support. Swan-Ganz catheters were not routinely removed unless catheter-induced ventricular arrhythmias were detected. While these measurements were performed, catheters to monitor cardiac output were kept in place. If the patient could not be extubated during the postoperative period, LVEF was measured by transthoracic echocardiography after the patient was mildly sedated with midozolam.

Statistical Analysis

Results are expressed as the mean ± SD, numbers, and percentages. The differences between groups were tested for significance by independent-samples *t*-test, paired *t*-test, Mann-Whitney U test, and χ^2 test, as appropriate. Differences were considered significant for *P* smaller than .05. Data for both groups were combined and variables were subjected to statistical analysis as predictors of IABP reinsertion.

RESULTS

Operative Period

Table 2 shows a comparison of the intraoperative and postoperative variables in both groups. There were no significant differences in the average number of distal anastomoses performed in group 1 and group 2 (Table 2). The internal thoracic artery was used as a conduit for the left anterior descending artery in all patients. The saphenous vein, the second most commonly used graft, was used for 46 patients (92%) in group 1 and 48 patients (96%) in group 2. The radial artery was chosen as another graft for 16 patients in both groups. The mean cardiopulmonary bypass time was similar in both groups (98.9 ± 27.6 vs 97.9 ± 28.8; $P = .90$). Cross-clamp time was also similar in both groups ($P = .82$) (Table 2).

Postoperative Period

Hemodynamic parameters such arterial pressure, cardiac rhythm, arterial oxygen saturation, arterial blood gases, and required use of inotropic agents were monitored in all patients (Hewlett- Packard CMS 2000). IABP catheters were successfully removed after 49.4 ± 7.3 and 83.2 ± 9.1 h in group 1 and group 2, respectively ($P < .001$). In group 2, the IABP was routinely removed when patient values were: LVEF >30%, FS >20%, CI >2.4 L/min per m^2. In group 1 and group 2 patients, respectively, average values for EF were 26.4% ± 2.7% and 32.1% ± 3.4% ($P < .001$) and for CI were 2.24 ± 0.24 and 2.56 ± 0.29 L/min per m^2 ($P < .001$). There were also statistically significant differences in FS. Average FS values were 19.1% ± 2.1% and 22.9 ± 2.5% ($P < .001$) in group 1 and 2, respectively. Vascular complications related to IAB catheters were seen in 30 patients. IABP was removed and reinserted via the contralateral femoral artery in 7 patients in group 1 and 9 patients in group 2. In each group,

Table 2. Operative and Postoperative Characteristics of the Patients*

Characteristics	Group 1 (n = 50)	Group 2 (n = 50)	*P*
Vascular Complications	15	15	1.00†
Ischemic leg	7	9	.59†
Hematoma	8	8	1.00†
Bleeding	6	8	.56†
Mortality	9	2	.025†
IABP reinsertion	13	9	.48†
Mortality with IABP reinsertion	8/13 (62%)	2/9 (22%)	.09‡
IABP reinsertion because of			
Vascular Complications	7	9	.59†
Hemodynamic deterioration	6	0	.027‡
LVEF during IABP insertion, %	22.0 ± 2.3	22.8 ± 3.1	.14§
LVEF during IABP removal, %	26.4 ± 2.7	32.1 ± 3.4	<.001§
FS during IABP insertion, %	12.3 ± 1.2	12.6 ± 1.7	.46§
FS during IABP removal, %	19.1 ± 2.1	22.9 ± 2.5	<.001§
CI during IABP insertion	1.87 ± 0.20	1.91 ± 0.15	.19§
CI during IABP removal	2.24 ± 0.24	2.56 ± 0.29	<.001§
No. of distal anastomoses			
2	4 (8)	4 (8)	1.00†
3	8 (16)	8 (16)	1.00†
4	24 (48)	26 (52)	.69†
5	14 (28)	12 (24)	.65†
Conduit			
LIMA	50 (100)	50 (100)	1.00‡
SVG	46 (92)	48 (96)	.69‡
Radial artery	16 (32)	16(32)	1.00†
Cross-clamp time, min	69.4 ± 23.9 (69)	69.5 ± 19.9 (69) ()()()(71.5)	.82¶
CPB duration, min	98.9 ± 27.6 (99)	97.9 ± 28.8 (99)	.90¶
Duration of IABP use, h	49.4 ± 7.3	83.2 ± 9.1	<.001§
ICU stay, d	3.56 ± 2.43 (3)	3.64 ± 2.00 (3)	.026¶
Re-ICU, n	8	1	.031‡
Hospital stay, d	9.40 ± 2.34 (9)	8.58 ± 2.49 (8)	<.001¶

*Values are expressed as mean ± SD (median), n, or n (%). CI indicates cardiac index; CPB, cardiopulmonary bypass; FS: fractional shortening; IABP, intraaortic balloon pump; ICU, intensive care unit; LIMA, left internal mammary artery; LVEF, left ventricular ejection fraction; re-ICU: readmission to ICU because of hemodynamic deterioration; SVG, saphenous vein graft.

†χ^2 Test.

‡Fisher exact test.

§Independent sample *t*-test.

¶Mann-Whitney U test.

femoral artery embolectomy was required in 10 patients. Reinsertion was performed in 13 patients in group 1, 6 of whom required IABP because of hemodynamic deterioration. Nine patients in group 2 required reinsertion, all because of catheter-related vascular complications. The average intensive care unit stay was longer for group 2 than group 1 (3.56 ± 2.43 vs 3.64 ± 2.00 days, $P = .026$). Readmission to the intensive care unit was required for 8 patients in group 1 and for 1 patient in group 2 ($P = .031$), and hospital stays in group 2 were significantly shorter than in group 1 (8.58 ± 2.49 vs 9.40 ± 2.34 days; $P < .001$) (Table-2).

Mortality

No intraoperative mortality occurred in either group. Nine patients died in group 1 and 2 patients died in group 2 ($P = .025$). One patient in each group died because of myocardial failure without IABP removal. In both groups mortality rates were different in patients who required IABP reinsertion than in those who did not. The mortality rate in group 1 was higher than in group 2. Eight of 13 patients (62%) died from myocardial dysfunction in group 1, and 6 of those 8 required balloon reinsertion because of hemodynamic deterioration. Reinsertion was necessary for 9 patients in group 2, and 1 of these patients died because of hemodynamic instability.

Statistical Evaluation

Univariate analysis results indicated that preoperative LVEF ($P < .001$), postballoon LVEF >30% ($P < .001$), postballoon FS >20% ($P < .001$), postballoon CI >2.4 L/min per m^2 ($P = .001$), and vascular complications related to IAB catheters ($P < .001$) were predictors for reinsertion of IABP. Preoperative LVEF lost significance ($P = .089$) in the multivariate analyses, whereas multivariate analyses also proved the significance of postballoon LVEF >30% ($P = .008$), postballoon FS >20% ($P = .005$), postballoon CI >2.4 L/min per m^2 ($P = .013$), and vascular complications of IABP catheters ($P = .042$) as predictors of balloon reinsertion. In univariate analysis, preoperative LVEF, postoperative LVEF, postoperative FS, postoperative CI, vascular complications due to IABP insertion, and the presence of 3 distal anastomoses were found to have statistical significance. Although 27 patients in the study group had 3 distal anastomoses, this variable was excluded because of clinical insignificance, and the remaining 5 variables were used in multivariate analysis. In multivariate analyses, postoperative LVEF, postoperative FS, postoperative CI, and vascular complications due to IABP insertion were found to be independent predictors of IABP reinsertion, except that preoperative LVEF lost significance ($P = .089$) in multivariate analysis.

DISCUSSION

IABP is routinely used in a wide range of serious cardiovascular conditions, ranging from hemodynamic stabilization in patients suffering from complications of acute myocardial infarction or cardiogenic shock to very high risk patients undergoing angioplasty or coronary artery bypass grafting. Extensive documentation exists for IABP regarding indications, clinical outcomes, patient hemodynamics, concomitant medications, complications, risk factors, and insertion techniques [Ferguson 2001]. The incidence of vascular complications of IABP is reported to be between 0.9% and 27.5%. Approximately 66.6% of patients need an alternative arterial line for reinsertion due to vascular complications after IABP insertion [Busch 1997, Ferguson 2001].

Several predictors for vascular complication related to IABP catheters have been reported. Tatar and colleagues [1993] found that the sheath of the catheter is a predictor of vascular complications. Other reported predictors are previous vascular disease (ankle arm index <0.8), female sex, catheter size, body surface area, obesity, and diabetes [Gottlieb 1984; Alderman 1987; Iverson 1987; Makhaul 1993; Gol 1994]. Funk [1989] and Patel [1985] found CI and vasopressors to be predictors of vascular complications.

Table 3. Univariate and Multivariate Logistic Regression Analyses of Effects of Various Variables on IABP Reinsertion*

	Univariate			Multivariate		
Variable	Crude OR	95% Confidence Interval	*P*	Adjusted OR	95% Confidence Interval	*P*
Preoperative LVEF	0.811	0.723-0.909	<.001	1.398	0.950-2.058	.089
Postoperative FS ≥20%	0.696	0.600-0.809	<.001	0.747	0.609-0.916	.005
Radial artery	0.390	0.120-1.263	.116			
3 Distal anastomoses	3.200	1.098-9.324	.033			
Perioperative MI	3.287	0.901-11.996	.072			
Postoperative CI ≥2.4 L/min/m^2	0.496	0.370-0.919	.001	0.456	0.323-0.946	.013
PAP	1.108	0.980-1.252	.102			
CVP	1.498	0.992-2.261	.054			
Vascular complication	19.500	6.073-62.615	<.001	19.562	1.112-344.093	.042
Postoperative LVEF ≥30%	0.758	0.673-0.852	<.001	0.830	0.722-0.953	.008
MAP	1.009	0.973-1.047	.620			
Age	0.988	0.954-1.023	.483			

*CI indicates cardiac index; CVP, central venous pressure; FS, fractional shortening; IABP, intraaortic balloon pump; LVEF, left ventricular ejection fraction; MAP, mean arterial pressure; MI: myocardial infarction; OR, odds ratio; PAP, pulmonary artery pressure.

Beneficial effects of IABP on hemodynamic parameters during cardiogenic shock are also well documented. In patients with cardiogenic shock, IABP can be expected to decrease systolic pressure approximately 20% and increase diastolic pressure approximately 30%. In such patients, IABP may decrease heart rate by <10%, decrease mean pulmonary capillary wedge pressure by 23%, and increase cardiac output by 20% [Kern 1999]. The permanence of the beneficial effects of IABP are difficult to predict despite gradual weaning, which can be done both by volume and frequency reduction. According to our experience and personal communications, hemodynamic deterioration develops just after IABP removal in 10% of patients, and in these circumstances readministration or increased dose increment of inotropic drugs was required for hemodynamic restoration, and 7% of these patients required reinsertion of IABP. Several published studies have investigated IABP weaning methods, which usually involve gradual reduction in both volume and assistance frequency, conducted according to hemodynamic parameters. The exact incidence of IABP reinsertion due to subsequent hemodynamic deterioration has not been reported. In our study, multivariate analyses confirmed that vascular complication and postoperative EF >30%, FS >20%, and CI >2.4 L/min per m^2 are predictors of IABP reinsertion. Thus to avoid IABP reinsertion, which has high mortality (62% in our study), IABP weaning should be performed not only according to hemodynamic parameters but also according to cardiac performance criteria.

Study Limitations

The present study is a unique comparison of hemodynamic and cardiac performance criteria for IABP removal in patients undergoing coronary artery bypass grafting. A limitation of our study was the relatively low number of cases (6 patients) who required IABP reinsertion because of hemodynamic deterioration. Studies with large numbers of patients are required to further investigate the predictors of reinsertion.

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