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Preoperative Intraaortic Balloon Pump for Off-Pump Coronary Arterial Revascularization

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Background. Prophylactic intraaortic balloon pump (IABP) support showed better outcomes in critical patients undergoing coronary revascularization compared with intraoperative or postoperative insertion. We conducted a prospective, randomized study to determine the optimal timing for preoperative IABP insertion in high-risk patients undergoing off-pump coronary artery revascularization.

Methods. The study enrolled 230 consecutive high-risk patients (having a logistic European System for Cardiac Operative Risk Evaluation score of ≥ 10) undergoing off-pump coronary artery revascularization. They were randomized for preoperative IABP starting at 2 hours (2T, $n = 115$) or 12 hours (12T, $n = 115$). Clinical, biochemical, and hemodynamic results, and the need for inotropic drug support, were markers of outcome and compared between groups.

Results. Hospital mortality in group 12T was reduced by 60%, but the difference between groups was not

statistically significant (hazard ratio, 0.4; 95% confidence interval, 0.1 to 1.5; $p = 0.1$). Twelve hours of preoperative IABP therapy reduced postoperative low output syndrome (hazard ratio, 0.4; 95% confidence interval, 0.1 to 0.9; $p = 0.03$) and biomarker leakage upper normal limit (hazard ratio, 0.3; 95% confidence interval, 0.1 to 0.7; $p = 0.001$). Postoperative left ventricular function was similar between the groups. Group 2T patients required higher inotropic support for a longer average duration and prolonged postoperative intensive care unit and hospital length of stay.

Conclusions. Twelve hours preoperative IABP therapy improved treatment efficacy. Postoperative morbidity was reduced, but hospital mortality rate was not affected. The IABP-related complication rate was low and not related to the length of treatment.

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The rapid development of invasive cardiology techniques has led to a changing pattern in the characteristics of patients referred for coronary artery bypass grafting (CABG). A larger proportion of patients coming for surgical intervention are older, have more extensive disease, present unstable angina, and poor left ventricular function, or a combination of these disorders. A number of experiences from randomized trials and cohort studies reported a proven advantage from the use of prophylactic preoperative intraaortic balloon pump (IABP) support in those high-risk patients [1–5].

However, several questions remain unanswered regarding the optimal timing for preoperative IABP insertion, which probably affects surgical outcome, intensive care unit (ICU) stay, and total hospital length of stay. The present randomized study was designed to determine the best timing for preoperative IABP treatment in hemodynamically stable high-risk patients undergoing off-pump CABG. A number of clinical, hemodynamic and biochemical findings were evaluated comparing two homogeneous groups of patients: one group received IABP

insertion 2 hours before induction of anesthesia and the other was supported by IABP for 12 hours before CABG.

Material and Methods

The protocol for this study was approved by the Ethics Committee of our institution and by the hospital's Institutional Review Board. Informed consent was obtained from each patient before enrolment in the study. The study was not supported by any external source of funding.

Patient Population and Study Design

This prospective randomized study was designed according to the Consolidated Standards of Reporting Trials statement. Between February 2005 and April 2011, 230 consecutive high-risk patients undergoing off-pump CABG and matching the study selection criteria were enrolled from a total of 3,009 patients undergoing off-pump CABG in the same period.

The definition of high-risk patients was based on the logistic European Risk Score System in Cardiac Operations (EuroSCORE) [6] and the cutoff of 10 points or higher was chosen on the basis of the available literature [6, 7]. The logistic EuroSCORE was calculated using the current online version (www.euroscore.org/calc.html).

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Left main stem stenosis exceeding 90%, left main stenosis exceeding 70%, and right coronary stenosis exceeding 70%, chronic occlusion of the 3 main coronary arteries, acute ongoing angina or myocardial ischemia with failed percutaneous coronary intervention were assigned to the model as a critical preoperative state.

Patients included in the study had generally severe coronary stenosis, such as left main stenosis exceeding 50% and right coronary stenosis, critical left main stenosis exceeding 70%, graft-dependent circulation in redo cases, chronic occlusion of the 3 main coronary trunks (left anterior descending, right and circumflex coronary arteries), stenosis exceeding 99% of the proximal left anterior descending coronary artery (before the first septal or diagonal branch), and proximal stenosis exceeding 99% of a dominant right coronary artery with remote branches for the posterior wall of the left ventricle. Preoperative cardiogenic shock, additional cardiac surgical procedures, and contraindications for an off-pump operation were absolute exclusion criteria. The study cohort was closely homogeneous for age, sex, clinical features, and severity of coronary artery disease (Table 1).

The study randomized 115 patients to preoperative IABP treatment during 2 hours before induction of anesthesia (group 2T) and 115 to preoperative IABP treatment during 12 hours before the operation (group 12T). Randomization was obtained on admission by means of a computer-generated algorithm and was fully blinded, without any account of clinical or demographic features.

Postoperative mortality and morbidity, as well as required in hospital or ICU stay, were registered for each of the group.

Hemodynamic variables (cardiac output and systemic vascular resistance indexed for body surface area, pulmonary capillary wedge pressure, left ventricular stroke work index, and mixed systemic venous oxymetry) were recorded in all patients through a Swan-Ganz Combo pulmonary artery catheter inserted just before IABP introduction and elaborated with a Vigilance CEDV monitor (Edwards Lifesciences, Irvine, CA). Hemodynamic variables were evaluated at any time during the IABP time counterpulsation but were registered before and after introduction of IABP, after anesthetic induction, just before the sternal closure, and every 2 hours after the operation until the IABP was removed.

Troponin I was evaluated before the operation and at 8, 12, 24, and 48 hours after, and then on every postoperative day until hospital discharge. Troponin I was assayed by means of a LIAISON kit (DiaSorin SpA, Saluggia, Italy). Upper normal limits were 0.08 ng/mL, defined as the 99th percentile of the value for the referenced controlled group with a total imprecision of less than 10%, according to Joint European Society of Cardiology/American College of Cardiology guidelines [8].

The amount of inotropic pharmacologic support required to maintain a cardiac index (CI) greater than $2 \text{ L} \cdot \text{min}^{-1} \cdot \text{m}^{-2}$ was monitored and used as a outcome marker.

Table 1. Main Demographic and Clinical Characteristics^a

Variable ^b	Group 12T (n = 115)	Group 2T (n = 115)	p Value
Age, years	65.5 ± 10.4 (43-81)	63.2 ± 11.7 (40-79)	0.1
Female sex	28 (24.3)	32 (27.8)	0.6
LVEF ≤ 0.35	62 (53.9)	59 (51.3)	0.7
LVEF	0.37 ± 0.06	0.38 ± 0.07	0.2
Myocardial infarction			
<90 days	55 (47.8)	58 (50.4)	0.7
>90 days	38 (33)	41 (32)	0.7
Chronic pulmonary disease	59 (51.3)	54 (46.9)	0.5
Extracardiac arterioplasty	21 (18.2)	28 (24.3)	0.3
Neurologic dysfunction	8 (6.9)	3 (2.6)	0.2
Previous cardiac operation	11 (9.5)	14 (12.1)	0.6
Creatinine > 20 μmol/L	18 (15.6)	13 (11.3)	0.4
Critical preoperative state	75 (65.2)	71 (61.7)	0.6
Unstable angina	71 (61.7)	74 (64.3)	0.7
EuroSCORE, logistic	15.8 ± 4.4 (11-22)	16.1 ± 4.5 (11-23)	0.6
Left main stenosis > 90%	22 (19.1)	20 (17.3)	0.8
Triple vessel disease	82 (71.3)	85 (73.9)	0.7
Failed recent PCI	4 (3.4)	2 (1.7)	0.6
Diabetes mellitus	37 (32.1)	48 (41.7)	0.1

^a Clinical and demographic variables were defined as used in the EuroSCORE.

^b Continuous values are expressed as mean ± standard deviation

(range) and categoric values as number (%).

EuroSCORE = European System for Cardiac Operative Risk Evaluation; LVEF = left ventricular ejection fraction; PCI = percutaneous coronary intervention; 2T = 2 hours of preoperative intraaortic balloon pump support; 12T = 12 hours of preoperative intraaortic balloon pump support.

Surgical Procedure

All patients underwent off-pump CABG through a median sternotomy. Extensive arterial grafting and complete myocardial revascularization were preferred whenever possible. The left internal mammary artery was used in all patients, and the right internal mammary artery was the second-choice conduit when indicated. The radial artery was used as a Y-composite graft from the left or the right internal mammary artery to the diagonal artery or obtuse marginal coronary artery. The mandatory indication for radial artery use was critical stenosis ($\geq 85\%$ to 90%) and good size and quality of the target vessel. Saphenous veins were usually preferred for right coronary artery revascularization as an aortocoronary graft.

Suction devices to stabilize the target coronary artery and intracoronary shunts were routinely used. Graft flow was measured by means of a transit-time flowmeter in all cases at the end of the procedure. A standardized protocol was followed in the ICU.

IABP Support

The intraaortic balloon (Datascope Sensation 7F, 40 mL; Datascope Corp, Fairfield, NJ) was inserted percutaneously with sheathless technique and was connected to a Datascope CS300 console (Datascope Corp). Insertion through the best femoral artery was possible in all cases, and the correct placement was assessed by chest roentgenography. In 8 patients with severe peripheral vascular disease, the intraaortic balloon was inserted under fluoroscopic control.

Intraaortic balloon pump assistance was set at a 1:1 ratio in all patients. Heparin was systematically used for anticoagulation. After the operation, the IABP support was terminated once hemodynamic stability was restored: CI greater than $2.0 \text{ L} \cdot \text{min}^{-1} \cdot \text{m}^{-2}$ with only minimal inotropic support, and normal or nearly normal systemic vascular resistance. All IABP-related complications were recorded.

Definitions of Perioperative Data

Hospital mortality was defined as death occurring during hospitalization. Conversion to cardiopulmonary bypass was recorded as an unfavorable event. Postoperative acute myocardial infarction was diagnosed when the three different criteria indicated by the Joint European Society of Cardiology/American College of Cardiology guidelines were fulfilled [8].

Postoperative myocardial damage was defined as troponin I leakage exceeding the normal upper limit on two subsequent samples or maximal value exceeding three times the normal upper limits on one occasion without both electrocardiographic and echocardiographic modifications [9].

Postoperative renal failure was defined as an increase in serum creatinine value of greater than 2.5 mg/dL . Low-output syndrome (LOS) was diagnosed when CI decreased to less than $2.0 \text{ L} \cdot \text{min}^{-1} \cdot \text{m}^{-2}$, pulmonary capillary wedge pressure exceeded 15 mm

Hg, left ventricular stroke work index (LVSWI) decreased to less than $22 \text{ g} \cdot \text{m}^{-1} \cdot \text{m}^{-2}$, and results of mixed systemic venous oxymetry were less than 60% for at least 30 minutes after correction of all electrolyte or blood gas abnormalities and after preload optimization.

High dose inotropic support was defined when greater than $7 \mu\text{g} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$ of dopamine or dobutamine was given or any dose of adrenaline was added.

Statistical Analysis

The primary outcome for sample size calculation was hospital death after 12 hours of preoperative IABP support. On the assumption that a mean mortality rate of 6% in high-risk patients undergoing IABP support during the 1 to 2 hours before induction of anesthesia [10, 11], to detect an absolute reduction of hospital mortality of 20% after 12 hours of preoperative IABP support, at a 2-sided α level of 0.05 and 80% power, 226 patients for both sample were required. Therefore, 115 patients were enrolled in each group of study. Continuous variables are expressed as means \pm standard deviation and categorical data as percentages.

Comparisons of continuous variables between groups were performed with the Student *t* test for normally distributed values. The Mann-Whitney *U* test was used for variables not normally distributed (biomarker and hemodynamic values). Categorical variables were analyzed with the χ^2 or Fisher exact tests, when appropriate. The association between timing of IABP insertion and in-hospital mortality and morbidity was modelled using logistic regression and performed by calculating the hazard ratio (HR) with 95% confidential intervals (CI). Multiway analysis of variance with correction for serial measurements was performed for hemodynamic data and inotropic support evaluations. All variables with a value of $p < 0.05$ were considered significant. Statistical analysis was performed by SPSS 16.1 software (SPSS Inc, Chicago, IL).

Results

Operative Data

A total of 687 conduits were implanted. A mean of 2.99 (range, 1 to 5) grafts were implanted per patient: 3.0 ± 1.2 in group 2T and 2.9 ± 1.5 in group 12T ($p = 0.2$). The overall index of completeness (number of grafts performed/number of grafts intended) was 0.92 . Mean procedural time necessary to construct all anastomoses was similar in both groups ($p = 0.8$). The left anterior descending artery was grafted in 227 patients (98.6%), the circumflex artery in 206 (89.5%), and the right coronary artery in 151 (65.6%). During the procedure, 34 patients (21 in group 2T and 13 in group 12T) were converted to cardiopulmonary bypass due to severe rhythm disturbances or hemodynamic instability, or both ($p = 0.1$). In those cases, revascularization was performed on the beating heart under cardiac assistance.

Hospital Mortality and Morbidity

Hospital mortality was 7.8% (10 patients) in group 2T and 4.3% (5 patients) in group 12T. Despite the apparent 60% reduction of hospital mortality deriving from preoperative 12-hour IABP support, this difference did not achieve statistical significance in our population of patients (HR, 0.4; 95% CI, 0.1 to 1.5; $p = 0.1$). The main causes of death were low cardiac output due to left ventricular failure in both groups. One patient in group 2T died of uncontrollable arrhythmias and 1 patient in group 12T died of multiorgan failure after pneumonia. Perioperative myocardial infarction occurred in 10 patients (8.6%) from group 2T and in 5 (4.3%) from group 12T ($p = 0.2$).

Mean preoperative values of troponin I were similar in the two groups. Postoperative biomarker leakage at the upper normal limit occurred in 92 patients (80%) from group 2T vs 69 (60%) from group 12T (Fig 1). Twelve hours of IABP treatment before CABG was associated with a 25% reduction in risk of troponin I leakage at the upper normal limit (HR, 0.3; 95% CI, 0.1 to 0.7; $p = 0.001$), although the greater risk factors the patients had, the higher the biomarker leakage.

No hemodynamic difference was observed between groups preoperatively. An initial significant reduction of CI and LVSWI was observed in group 2T compared with group 12T after the induction of anesthesia and in the early phase of the operation. A tendency to better cardiac indices was not registered in either group during the operation. The magnitude of postoperative CI and LVSWI maximal decline was not significant between groups. However, high doses of inotropic drugs were necessary in 25 patients (21.7%) of group 12T vs 42 patients (36.5%) of group 2T ($p = 0.02$) for a longer average duration (Table 2). Twelve hours of preoperative treatment with IABP was associated with a 30% reduction of patients who required high doses of inotropic support (HR, 0.4; 95% CI, 0.2 to 0.8; $p = 0.02$). CI and LVSWI declined to the lowest 4 hours postoperatively in each group. CI recovered to the preoperative level 34 ± 13 hours after CABG in group 2T and at 30 ± 11 hours in

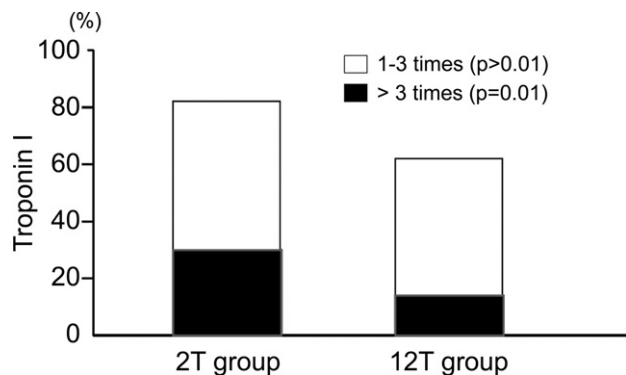


Fig 1. Cardiac marker elevations in patients who received 2 hours (group 2T) and 12 hours (group 12T) of preoperative intraaortic balloon pump assistance. Incidence of postoperative increase of troponin I was 1 to 3 times (white section) and >3 times (black section) above the upper normal limit.

Table 2. Doses of Inotropic Drugs

Drug	Group 12T (n = 115) No. (%)	Group 2T (n = 115) No. (%)	p Values
Dopa/DBT <7 $\mu\text{g} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$	90 (78.3)	73 (63.5)	0.02
Dopa/DBT >7 $\mu\text{g} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$	15 (13.1)	22 (19.2)	0.1
Dopa/DBT + adrenaline	10 (8.6)	20 (17.3)	0.03

DBT = Dobutamine; 2T = 2 hours of preoperative intraaortic balloon pump support; 12T = 12 hours of preoperative intraaortic balloon pump support.

group 12T ($p = 0.01$), whereas LVSWI recovered to the preoperative level 41 ± 18 hours after CABG in group 2T and at 36 ± 14 hours in group 12T ($p = 0.01$).

Postoperative LOS occurred in 22 patients (19.1%) from group 2T vs 10 (8.8%) from group 12T. Twelve hours preoperative treatment with IABP was associated with a 54% reduction in risk of LOS (HR, 0.4; 95% CI, 0.1 to 0.9; $p = 0.03$). Most patients with postoperative LOS experienced renal failure as well as gastrointestinal and respiratory complications and required prolonged IABP assistance and ventilation support.

No major IABP-related complications were registered postoperatively, except for 3 group 12T patients with temporary limb ischemia that resolved completely after prompt IABP withdrawal. Three minor postoperative complications, consisting of bleeding at the balloon entry site that resolved with manual compression, were equally distributed between the groups. Mean postoperative IABP time was longer in group 2T (68 ± 26 vs 52 ± 21 hours; $p = 0.005$), as was mechanical ventilation time (12 ± 5 vs 10 ± 4 hours; $p < 0.001$), postoperative ICU (4.2 ± 1.7 vs 3.7 ± 1.1 days; $p = 0.01$), and hospital length of stay (13.1 ± 3.8 vs 11.4 ± 2.5 days; $p < 0.001$). Nonfatal postoperative complications were few and evenly distributed between the groups (Table 3). The effect of the

Table 3. Operative Results^a

Variable	Group 12T (n = 115)	Group 2T (n = 115)	p Value
Completeness index	0.90	0.92	1
Ventilation support, hours	10 ± 4	12 ± 5	<0.001
Postop IABP support, hours	52 ± 21	68 ± 26	0.005
Length of stay, days			
Intensive care unit	3.7 ± 1.1	4.2 ± 1.7	0.001
Hospital	11.4 ± 2.5	13.1 ± 3.8	<0.001
Reoperation for bleeding	2 (1.7)	3 (2.6)	0.5
Renal failure	3 (2.6)	5 (4.3)	0.3
IABP-related complication	4 (3.4)	2 (1.7)	0.3
Pneumonia	2 (1.7)	8 (6.9)	0.05

^a Continuous values are expressed as mean \pm standard deviation and categoric values as number (%).

IABP = intraaortic balloon pump; Postop = postoperative; 2T = 2 hours of preoperative IABP support; 12T = 12 hours of preoperative IABP support.

Table 4. Impact of Preoperative Intraaortic Balloon Pumping Length on Postoperative Main Morbidity and Mortality

Variable	Group 12T (n = 115) No. (%)	Group 2T (n = 115) No. (%)	HR (95% CI)	p Value
Hospital death	5 (4.3)	10 (7.8)	0.4 (0.1–1.5)	0.1
Myocardial damage	69 (60)	90 (80)	0.3 (0.1–0.7)	0.001
Low output syndrome	10 (8.8)	22 (19.1)	0.4 (0.1–0.9)	0.03
High inotrope doses	25 (21.7)	42 (36.5)	0.4 (0.2–0.8)	0.02
Myocardial infarction	5 (4.3)	10 (8.6)	0.4 (0.1–1.5)	0.2
Conversion to CPB	13 (11.3)	21 (18.2)	0.5 (0.2–1.2)	0.2

CI = confidence interval; CPB = cardiopulmonary bypass; HR = hazard ratio; 2T = 2 hours of preoperative intraaortic balloon pump support; 12T = 12 hours of preoperative intraaortic balloon pump support.

preoperative IABP treatment length on main morbidity and mortality is reported in Table 4.

Comment

Several clinical studies have reported worse outcome and high rates of complications in patients who required placement of emergency IABP support during intraoperative or postoperative critical hemodynamic decompensation [1, 4, 12]. Preoperative prophylactic IABP support has recently been suggested to have proven efficacy in significantly lowering hospital mortality and morbidity in high-risk coronary patients undergoing CABG [1–3, 10–13]. The Benchmark Registry and The Society of Thoracic Surgeons National Database report that preoperative IABP use is associated with reduced mortality of 8.8% and 9.5%, respectively, compared with 28.2% and 23.5%, respectively, with intraoperative IABP use [14]. These results have also been confirmed by a significant reduction in death in high-risk patients than that expected according to the logistic EuroSCORE.

The positive effect of preoperative insertion of IABP in high-risk patients is thought to be due to an improved myocardial oxygen supply/demand ratio and reduced ventricular wall stress before the operation in addition to diastolic augmentation and decreased afterload resulting in the redistribution of coronary blood flow toward the ischemic areas of the myocardium, and in the recovered energy depletion of myocardial cells [15]. As a consequence, preoperative prophylactic IABP assistance provides better hemodynamic stability in the crucial times for higher oxygen demand when the anesthesia is induced and the conduits are harvested, as well as when the heart is displaced in off-pump procedures [5, 16–18].

The optimal timing for preoperative insertion of IABP in high-risk patients undergoing CABG remains controversial, although the subject has been treated frequently in the past decade. The unanswered question about whether the surgical outcome is time-related to the length of prophylactic preoperative IABP treatment is still challenging. Preoperative balloon counterpulsation should be neither too long, in an effort to minimize the complications rate that seems time-dependent during IABP use, nor too short, leading to impaired metabolic and hemodynamic recovery.

The time-related results for preoperative insertion of the IABP on a randomized basis were investigated by Christenson and colleagues [11] in a cohort of high-risk patients who underwent CABG. They found no difference in outcome whether the IABP was inserted 2, 12, or 24 hours preoperatively, whereas results of intraoperative or postoperative IABP insertion were disappointing owing to an associated high mortality and complications rate [11]. Their study is the only randomized trial in the literature; unfortunately, it was underpowered to detect statistically significant differences among the groups. Hence, the results remain insufficiently robust enough to validate the prophylactic insertion of IABP only 2 hours before CABG in truly elective high-risk patients.

Our study was designed to define the optimal time for IABP insertion by comparative evaluation of two randomized groups of patients. Both study arms were homogeneous regarding the possible misleading factors for such a study. Demographic, clinical, and operative characteristics were similar between the groups as well as the index of completeness, as complete revascularization was the principal advantage of the cardiac operations and was essential in such cohort of high-risk patients.

Our results evidenced that preoperative IABP insertion 12 hours before operation did not carry a statistically significant survival advantage compared with 2 hours of preoperative treatment. However, longer prophylactic support with IABP resulted in a significant reduction of postoperative LOS rate, of assisted ventilation time, as well as hospital and ICU length of stay.

Preoperative IABP treatment resulted in similar postoperative cardiac function in both groups in maximal decline of CI and LWSWI. However, patients who experienced balloon insertion 2 hours before CABG required higher doses of inotropic drugs for a longer time and showed significantly higher biomarker leakage. It is clear, therefore, that 12 hours of preoperative IABP support provides good myocardial preservation, better hemodynamic stability and coronary perfusion, minimizes inotropic support, and reduces the incidence of LOS.

Intraaortic balloon pump insertion can occasionally be cumbersome or risky because of severe and diffuse atherosclerosis of the descending aorta and peripheral arteries, or even contraindicated because of abdominal

aortic aneurysms. The major disadvantages related to IABP use thus far were complications associated with its placement, mainly bleeding, vascular injury, and limb ischemia [19].

Despite the presence of peripheral vascular disease in more than 25% of the patients and regardless the period of preoperative IABP treatment, the overall incidence of IABP-related complication rate was low in this study (2.6%) compared with the Benchmark Registry (7.0%) [20]. Complications were all reversible, at most with discontinuation and removal of the balloon. The low incidence of IABP-related complications reported in this study was probably due to planned preoperative insertion as well as to smaller-caliber 7F catheters, sheathless placement techniques, and careful surveillance of patients focused on IABP-related complications. Furthermore, advances in IABP design, such as fiberoptic technology, reduction of need for repeated zeroing, and automatic trigger modes, have made handling of balloon pumps simpler, more accurate, and user-friendly.

In conclusion, 12-hour preoperative IABP treatment improved cardiac performance, reduced inotropic requirements, and shortened ICU and hospital length of stay significantly. A short preoperative IABP treatment seems to be a less attractive alternative because it was associated with higher morbidity and ICU and hospital stay. Preoperative insertion of IABP was safe and not associated with postoperative significant complications regardless, the counterpulsation time.

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