

## Original Article

# Effectiveness of the intra-aortic balloon pump on emergency percutaneous coronary intervention for left anterior descending opening occlusion-induced acute myocardial infarction

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**Abstract:** Objective: This study aimed to investigate the usefulness of the intra-aortic balloon pump (IABP) in emergency percutaneous coronary intervention (PCI) for left anterior descending opening occlusion-induced acute myocardial infarction (LADOO-AMI). Methods: Among 240 patients with LADOO-AMI who underwent emergency PCI from January 2013 to January 2015, 120 patients assisted with an IABP were included in assisted with IABP group, and the other 120 patients without an IABP were included in without IABP group. The intraoperative and postoperative conditions were compared between the two groups. Results: The use of an IABP not only increased the success rate of emergency PCI, but also reduced the perioperative and postoperative 12-month adverse cardiac events ( $P < 0.05$ ). The cardiac function in the assisted with IABP group was significantly improved ( $P < 0.05$ ) compared with that in the without IABP group, while the renal function was not affected. Conclusions: The use of an IABP in emergency PCI for LADOO-AMI could significantly reduce perioperative adverse events, improve patients' cardiac function, and reduce the incidence of postoperative cardiovascular events, and eventually improve patients' prognosis.

**Keywords:** Angioplasty, transluminal, percutaneous coronary artery, intra-aortic balloon pump, left anterior descending opening

## Introduction

The left anterior descending branch of the coronary artery is a continuation of the left main coronary artery, and the main blood supply vessel to the left ventricle, interventricular septum, and heart apex. Its opening has multiple branches such as the circumflex artery and anterior septal branch, among others. The left anterior descending artery (LAD) opening is the key part of the entire arterial blood supply [1], and once occlusion occurs, it will seriously affect the blood supply to the left ventricle, interventricular septum, and heart apex, thus resulting in left ventricular dysfunction or myocardial infarction. Revascularization can be achieved rapidly with percutaneous coronary intervention (PCI). However, PCI without mechanical assistance [2] is prone to complications such as acute coronary occlusion, or no-reflow caused by blood clots entering the circumflex artery and anterior septal branch when

performing intra-PCI thrombus dissection [3, 4]. In particular, lesions at the LAD opening, which exhibits left-dominant distribution among coronary arteries and has larger blood supply areas, may easily induce a decrease in the intraoperative blood pressure and heart rate, nausea, arrhythmias, or acute left ventricular failure in severe cases, thereby increasing surgery-related risks and cardiovascular events after PCI, as well as affecting the patients' cardiac function and prognosis. So far, no effective measures have been identified to prevent this condition, and the treatment relies more on surgical proficiencies and manipulations.

The intra-aortic balloon pump (IABP) is a mechanical auxiliary support. Because it can increase the coronary perfusion pressure via increasing the aortic diastolic pressure, it can increase the coronary perfusion, and decrease regional myocardial ischemia, cardiac afterload, cardiac ejection resistance, and myocar-

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dial oxygen consumption, thereby increasing myocardial contractility and improving patients' cardiac function and prognosis. In 2013, the ACCF/AHA guidelines for the management of ST segment elevation myocardial infarction (STEMI) recommended the use of the IABP for STEMI-associated coronary syndrome (class IIa and level of evidence B) [5]. However, currently, the IABP is mainly applied as a preventive measure before cardiac catheterization or cardiovascular angiography in patients with cardiogenic shock, refractory angina, or myocardial infarction-induced unstable hemodynamics, or in patients with low cardiac output after cardiopulmonary bypass surgery. The IABP is not routinely applied in emergency PCI for left anterior descending opening occlusion (LADOO), and there is still controversy about whether this treatment protocol can reduce the perioperative mortality [6, 7].

In our center, the IABP has been used to assist in the treatment of proximal LAD lesions. We have achieved good results including a decrease in the incidence of perioperative adverse events and short-term mortality. To explore the possibility of routinely applying the IABP to treat emergency LADOO, to reduce the incidence of perioperative adverse events, and to improve patients' outcomes, this study aimed to investigate the usefulness of the IABP for the interventional treatment of emergency LADOO, and determine whether it can decrease the incidence of intraoperative complications and improve the prognosis of emergency PCI in LADOO-induced acute myocardial infarction (LADOO-AMI) patients. So far, there is no specific research on such lesions worldwide.

LADOO-AMI involves a wide range of lesions, and has an extremely high morbidity and mortality [8]. Although emergency interventional therapy is one of the most effective treatment methods, however, it is associated with intra- and postoperative risks such as low blood pressure and high incidence of perioperative complications. We used the IABP in emergency interventional treatment for LADOO and observed whether it can reduce the incidence of perioperative complications and improve the prognosis in this setting.

### Subjects and methods

#### *Subjects*

A total of 240 patients with LADOO-AMI diagnosed by coronary angiography in Daqing

Oilfield General Hospital from January 2013 to January 2015 who underwent emergency PCI were enrolled in this study. Subjects with PCI and IABP contraindications, left main stem disease, and cardiogenic shock, were excluded. All the patients were informed about the treatment scheme before the surgery and randomly grouped using the random digital method to choose the patients for pre-PCI with IABP assistance. First, all the patients enrolled were numbered according to their operation sequences. Second, each patient was given a random number, and these random numbers were sorted by size for the final decision of whether the IABP should be applied. The patients with random numbers from 001 to 120 received IABP assistance and were included in the assisted with IABP group (120 cases). Those with random numbers from 121 to 240 did not receive IABP assistance and were included in the without IABP group (120 cases). This study was conducted in accordance with the declaration of Helsinki. This study was conducted with approval from the Ethics Committee of General Hospital of Daqing Oil Field. Written informed consent was obtained from all participants.

#### *Perioperative evaluation and surgical methods*

The following perioperative tests were performed: electrocardiogram (ECG), cardiac enzymes, myoglobin, troponin, coagulation, hepatitis B and C antibodies, syphilis antibody, and HIV antibody. After the informed consents for coronary angiography and PCI were signed preoperatively by the patients, the treatment method was selected according to the randomization principles and then communicated to the patient and families.

#### *IABP*

A 7F or 8F dual-lumen percutaneous aortic balloon catheter was selected, together with a 34- or 40-mL counterpulsation pump tube. The IABP Datascope97 and 98XT (Datascope, USA) were used. Before PCI, the patients were catheterized via the femoral artery to the descending aorta below the left subclavian artery level using the Seldinger technique. Then, the counterpulsation instrument was connected, the depth of the IABP catheter was adjusted, and the pipe was sutured. The arterial pressure or ECG-triggering 1:1 mode was used, together with 500 mL of saline containing 5000 U of heparin for the anticoagulation and the periodic

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pressure sensing catheter irrigation. The activated partial thromboplastin time was also monitored until it reached 1~1.5 times the reference value to maintain the patency of the catheter. After the surgery, each patient was closely monitored for hemodynamic improvements and IABP-related complications. The indications for withdrawing the IABP were as follows: reestablishment of cardiac function; good peri-tissue perfusion; stable mental state of the patient; without signs of heart failure; urine output > 30 mL/h; and discontinued use of vasopressors or use of a small dose of vasopressors, without malignant arrhythmia [9, 10]. Before the extubation, the counterpulsation ratio was reduced to 1:3 for 30 min, and the IABP could be withdrawn under the conditions of stable blood flow and stability of other cardiovascular and respiratory parameters. If necessary, the IABP assistance could be extended for a week or longer. The femoral puncture site was locally pressured for 20 min, followed by salt-bag compression for 6~8 h, and the bandage could be removed 24 h later if no subcutaneous hematoma appeared.

### *Coronary angiography*

An angiography instrument (Philips, Netherlands) was used, which included a cardiac catheter to percutaneously puncture the radial artery or lower limb femoral artery [11]. The catheter was then inserted into the ascending aorta, and the left or right coronary ostia was explored for insertion. The contrast agent was then injected for the coronary angiography.

### *PCI*

A stent (Firebird, Shanghai MicroPort Co. Ltd.) was implanted after the right radial artery was punctured and the coronary angiography was performed. A successful PCI was defined as the disappearance of postoperative stenosis and coronary TIMI flow grade  $\geq$  II [12].

### *Preoperative and postoperative medications*

All the patients were administered 180 mg of ticagrelor (AstraZeneca, UK) [13], 300 mg of aspirin (Bayer, Germany), and 80 mg of Lipitor (Pfizer, USA) orally immediately before the coronary angiography. Patients with a large thrombus were administered an intravenous bolus of a platelet glycoprotein IIb/IIIa inhibitor (Grand-

Pharma Co. Ltd., China) as a loading dose, according to their body weight (kg), followed by intravenous infusion for the maintenance dose. Low molecular weight heparin was applied after the surgery [14], and the need of a platelet membrane IIb/IIIa receptor antagonist was determined by the surgeons based on the lesion conditions. Postoperatively, patients were to receive 100 mg of aspirin once daily for the long term (over their lifetime in the absence of any contraindication), together with 90 mg of ticagrelor twice a day for at least 12 months, as well as other cardiovascular drugs.

### *Observation indexes*

The incidences of intraoperative complications were evaluated, including coronary artery spasm, no-reflow, acute coronary occlusion, and branch or adjacent vascular occlusion. Other function indicators were evaluated before discharge, including heart rate, systolic blood pressure, urine output, serum creatinine, serum brain natriuretic peptide, left ventricular end diastolic diameter (LVED), and left ventricular ejection fraction (LVEF). The incidences of cardiovascular events during hospitalization were evaluated, including myocardial infarction, CGBA, acute (within 24 h) or subacute (within 1 month) thrombosis, pulmonary edema, ventricular fibrillation, and cardiac mortality. The postoperative left ventricular systolic function was evaluated by the LVED and LVEF at 1, 6, and 12 months. The incidences of cardiovascular events after discharge were evaluated, including angina, recurrent myocardial infarction, target vessel revascularization, subacute/late thrombosis, re-hospitalization for heart failure, and cardiac mortality.

In summary, the incidence of intraoperative complications, functional parameters before discharge, the incidence of cardiovascular events during hospitalization, the postoperative left ventricular systolic function, and the incidence of cardiovascular events after discharge, IABP-related complications, and hospitalization costs were evaluated.

### *Statistical methods*

The t test and  $\chi^2$  test were used to compare the observation indexes between the two groups. SPSS 17.0 (SPSS Inc, Chicago, Illinois, USA) was used for the statistical analysis.

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**Table 1.** Comparison of baseline information between assisted with IABP group and without IABP group

Item	Assisted with IABP group (n = 120)	without IABP group (n = 120)	t/ $\chi^2$	P
Age	61.35 ± 8.78 years	62.02 ± 7.98 years	0.619	0.537
M/F	74/46	71/49	0.157	0.709
Smoking ratio	261.73 ± 22.39	257.95 ± 24.61	1.245	0.215
SBP	135.18 ± 28.33	138.32 ± 24.57	0.917	0.360
DBP	61.39 ± 11.36	62.08 ± 12.21	0.453	0.651
Hypertension	45	42	0.162	0.706
Hyperglycemia	30	31	0.022	0.896
Hyperlipidemia	47	45	0.071	0.805
Previous MI history	28	30	0.091	0.767
Previous CI history	40	37	0.172	0.699
Diseased branch (es) single/dual/triple	53/56/11	54/57/9	0.218	0.897
Killip's classification I/II/III	111/8/1	110/10/0	0.057	0.830
D-B time	185.54 ± 44.36 min	187.72 ± 40.11 min	0.399	0.690

**Table 2.** Comparison of intraoperative complications between assisted with IABP group and without IABP group

Group n	Assisted with IABP group (n = 120)	without IABP group (n = 120)	$\chi^2$	P
Coronary artery spasm (%)	2 (1.67)	6 (5.00)	0.164	0.295
No-reflow (%)	2 (1.67)	9 (7.50)	4.669	0.032
Acute coronary occlusion (%)	2 (1.67)	6 (5.00)	0.164	0.295
Branch or adjacent vascular occlusion (%)	5 (4.17)	14 (11.67)	4.630	0.033

### Results

#### *Baseline characteristics*

There were no significant differences in the male/female proportion, age, New York Heart Association classification (Killip's classification), and D-B time between the two groups (all,  $P > 0.05$ ; **Table 1**).

#### *General conditions*

The PCI success rate in the assisted with IABP group was 98.33%, while that in the without IABP group was 92.50% ( $\chi^2 = 4.669$ ,  $P = 0.032$ ). The average duration of hospital stay in the assisted with IABP group was  $5.38 \pm 3.35$  days, and that of the without IABP group was  $5.06 \pm 4.03$  days. The average duration of IABP assistance was  $42.36 \pm 10.85$  h. Four patients in the assisted with IABP group presented subcutaneous ecchymosis at the femoral artery puncture site, and in one case, IABP assistance was prematurely terminated because of throm-

bocytopenia. The intraoperative use of the IABP in emergency PCI for LADOO-AMI not only reduces the incidence of perioperative adverse events but also further improves the perioperative and postoperative cardiac function, as well as the recovery of cardiac function.

#### *Comparison of intraoperative complications*

The assisted with IABP group had no no-reflow phenomenon. The incidence of branch or adjacent vascular occlusion in the assisted with IABP group was significantly lower than that in the without IABP group ( $P < 0.05$ ; **Table 2**).

#### *Comparison of functional parameters between the two groups before discharge*

The heart rate, systolic blood pressure, serum creatinine, and serum brain natriuretic peptide during hospitalization were averaged using the values detected immediately and 24-h after the surgery. The urine output was defined as the volume of urine excreted during the first 24

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**Table 3.** Comparison of functional parameters and hospitalization costs between assisted with IABP group and without IABP group during hospitalization

Group n	Assisted with IABP group (n = 120)	without IABP group (n = 120)	t	P
HR (beats/min)	76.26 ± 14.92	91.06 ± 18.20	6.889	0.000
SBP (mmHg)	132.45 ± 24.56	102.46 ± 19.84	10.405	0.000
SCr (umol/L)	135.67 ± 26.59	112.23 ± 21.47	7.513	0.000
Urine (ml/d)	1576.18 ± 307.55	1021.56 ± 217.31	16.134	0.000
BNP (pg/ml)	1040.85 ± 168.17	1701.95 ± 258.42	23.488	0.000
LV (mm)	51.36 ± 6.75	51.95 ± 6.27	0.702	0.484
LVEF (%)	50.63 ± 7.82	48.37 ± 9.31	2.036	0.043

**Table 4.** Comparison of cardiovascular events between assisted with IABP group and without IABP group during hospitalization

Item	Assisted with IABP group (n = 120)	without IABP group (n = 120)	χ <sup>2</sup>	P
Cardiovascular events	11 (9.17)	28 (23.33)	8.848	0.005
Re-CI	1 (0.83)	3 (2.50)	0.254	0.640
CABG	0 (0)	1 (0.83)	-	0.500
Acute/subacutethrombosis	2 (1.67)	5 (4.17)	0.589	0.460
pneumonema	3 (2.50)	10 (8.33)	3.985	0.047
Ventricular fibrillation	3 (2.50)	5 (4.17)	0.129	0.729
Cardiogenic death	2 (1.67)	4 (3.33)	0.171	0.699

hours after the operation. The LVED and LVEF values measured 24-hr after the surgery and before discharge were averaged. The between-group comparison of the above indexes showed statistically significant differences ( $P < 0.05$ ; **Table 3**).

### *Comparison of cardiovascular events during hospitalization*

The total incidence of cardiovascular events and pulmonary edema in the assisted with IABP group during hospitalization was significantly lower than that in the without IABP group ( $P < 0.05$ ; **Table 4**).

### *General conditions during postoperative follow-up*

All the patients were followed up for 12 months after discharge. After excluding 6 patients who died during hospitalization, the mean follow-up time was  $11.78 \pm 0.69$  months. In total, 118 patients in the assisted with IABP group and 116 patients in the without IABP group were follow-up.

### *Comparison of postoperative left ventricular systolic function*

The postoperative 1-month LVED value was significantly lower and the postoperative 1-month LVEF value was significantly higher in the assisted with IABP group than the without IABP group (both,  $P < 0.05$ ). There were no significant between-group differences in 6- and 12-month LVED and LVEF values after the surgery ( $P > 0.05$ ; **Table 5**).

### *Comparison of cardiovascular adverse events during follow-up*

The overall incidence of cardiovascular events and chest pain in the assisted with IABP group during the follow-up was significantly lower than that in the without IABP group ( $P < 0.05$ ; **Table 6**).

## Discussion

AMI is caused by acute coronary artery occlusion. LADOO-AMI has the highest risk of complications because of its larger blood supply areas, including the left ventricle, interventricular septum, and heart apex. Therefore, LADOO could seriously affect the blood supply to the above mentioned areas, and could seriously affect the function of the left ventricle. Currently, the most effective treatment recognized internationally is to open the culprit artery as early as possible. It has been reported that opening the coronary culprit artery within 30 min of the onset can effectively reduce the mortality by 8% [15], and can significantly improve patients' cardiac function and prognosis [16]. Direct PCI for timely revascularization is one of the most effective methods, and can significantly improve the patients' prognosis [17]. Such patients normally have severe illness, so the incidence of intraoperative and postoperative adverse events will be higher;

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**Table 5.** Comparison of LV and LVEF between assisted with IABP group and without IABP group 1-, 6-, and 12-month after the surgery

Group n	LV (mm) ( $\bar{x} \pm S$ )			LVEF (%) ( $\bar{x} \pm S$ )		
	1-month	6-month	12-month	1-month	6-month	12-month
Assisted with IABP group 118	51.38 ± 6.17	51.65 ± 6.05	51.77 ± 6.67	50.89 ± 6.23	50.64 ± 6.53	50.87 ± 6.42
without IABP group 116	52.98 ± 5.86	52.01 ± 7.13	52.02 ± 7.34	48.49 ± 7.25	50.46 ± 7.18	50.16 ± 6.95
t	2.033	0.422	0.276	2.717	0.203	0.822
P	0.043	0.674	0.783	0.007	0.839	0.412

**Table 6.** Comparison of cardiovascular adverse events during follow-up

Item	Assisted with IABP group n = 118 (%)	Without IABP group n = 116 (%)	$\chi^2$	P
Cardiovascular adverse events during follow-up	24 (20.33)	46 (39.66)	10.410	0.005
Chest pain	13 (11.02)	25 (21.55)	4.773	0.030
Re-CI	1 (0.85)	2 (1.72)	0.000	0.949
TVR	3 (2.54)	4 (3.45)	0.000	0.949
Subacute/delayed thrombosis	1 (0.85)	2 (1.72)	0.000	0.949
Heart failure-induced re-hospitalization	5 (4.24)	9 (7.76)	1.250	0.259
Cardiogenic death	1 (0.85)	4 (3.48)	0.853	0.384

The assisted with IABP group had 4 cases (3.33%) of death during hospitalization and follow-up, and the without IABP group had 8 cases (6.67%); the difference between assisted with IABP group and without IABP group was not statistically significant ( $\chi^2 = 1.404$ ,  $P = 0.241$ ).

particularly, patients with hemodynamic instability have a significantly increased mortality risk. During PCI, the thrombus could enter the circumflex artery and LAD and cause complications such as no-reflow or affect the circumflex artery blood flow. If no effective mechanical assistance is performed simultaneously, the surgical risks and postoperative cardiovascular adverse events could be significantly increased. The use of the IABP could help alleviate these issues [18], mainly by decreasing the mortality risk and improving the prognosis of high-risk patients when combined with a left ventricular assist device [19].

The IABP is a mechanical assist device. During IABP assistance a balloon is implanted into the aorta and its pressure change is used to produce "cavity" effects, thus effectively enhancing the aortic diastolic pressure and coronary perfusion pressure. The cardiac output can be increased by 10 to 20%. Meanwhile, the cardiac work and myocardial oxygen consumption can be reduced. The use of the IABP in the perioperative period of PCI in LADOO-AMI patients can improve their cardiac output and end-organ perfusion, reduce perioperative and postoperative cardiovascular adverse events at 12 months, and promote the recovery of cardiac

function. The latest European guidelines have proposed to downregulate the levels of IABP use in treating acute STEMI [20]. This study enrolled 240 patients with LADOO-AMI for direct PCI and IABP-assisted PCI. We expected that IABP assistance would reduce the surgical difficulties and risks in emergency PCI for LADOO-AMI, as well as reduce the intraoperative complications [21], and improve patients' prognosis. After our 3-year research and observation, our findings confirm that the use of the IABP in PCI for the treatment of LADOO-AMI patients can really improve the success rate of PCI, reduce intraoperative and postoperative complications and the incidence of cardiovascular adverse events during follow-up, and improve the patients' outcomes. The between-group comparison revealed that the assisted with IABP group exhibited obvious advantages such as a lower incidence of perioperative adverse events, improved postoperative LVEF, and a lower degree of left ventricular dilatation, and these benefits extended to 1 month after the surgery. These benefits are mainly related to the fact that IABP can increase the diastolic perfusion pressure, improve the coronary blood supply, reduce the left ventricular load, and reduce the myocardial oxygen demand [22].

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AMI patients tend to release a high amount of catecholamine because of pain, stress, or other factors that cause sympathetic nervous overexcitement. This often leads to the transient increase of blood pressure and affects the assessment of their condition. Furthermore, intraoperative and postoperative hypotension may normally appear, which could seriously affect the patients' coronary perfusion and lead to re-coronary occlusion. In addition, patients with heavy thrombus load may be prone to slow blood flow, and if no effective perfusion pressure support is provided, acute in-stent thrombosis could occur and even threaten their lives in severe cases. The above situations will undoubtedly increase the perioperative risk of death. The active application of the IABP can speed up the coronary blood flow, effectively increase the infarct-related arterial perfusion, and increase the blood pressure and urine output to further stabilize the patients' hemodynamic indexes. IABP assistance can also reduce the microvascular thrombosis-related slow blood flow and no-flow ranges, thus further increasing the success rate of emergency PCI. In this study, the PCI success rate in the assisted with IABP group was 98.33%, and that in the without IABP group was 92.50%, and the difference between the two groups was statistically significant, indicating the obvious advantages of IABP-assisted PCI therapy. IABP can reduce the myocardial oxygen consumption while not affecting the cardiac ejection function, thus reducing the cardiac afterload and increasing the cardiac output and LVEF. This is especially beneficial in patients with cardiogenic shock. Our findings of a decreased incidence of adverse events in the assisted with IABP group are consistent with those of other international reports [23, 24]. It has been reported that IABP-assisted therapies could affect the renal perfusion and renal function to some extent [25]. However, this study did not find any association between IABP assistance and renal function by observing the urine output and renal functional indexes, and the between-group comparison was not statistically significant, indicating that IABP can further protect the renal function while improving the hemodynamic status and cardiac function. Although the cost of applying the IABP requires an additional 10,000 yuan, the overall cost is not high, and this treatment will not increase the patients' hospital stay. The bet-

ween-group comparison of costs showed no statistically significant difference. The reason for this may be that the patients' hemodynamic indexes, cardiorenal functions, and clinical symptoms can be recovered in a timely manner, thus, avoiding the costs related to increased hospital stay. The patients enrolled in this study were clinically followed-up for up to 12 months, and the results showed that the overall incidence of cardiovascular adverse events in the assisted with IABP group was significantly lower than that in the without IABP group, which is related to the timely recovery of the patients' cardiorenal functions. In addition, the comparison of the overall mortality 1 year after the surgery between the two groups showed a significantly decreasing trend in the assisted with IABP group, but this difference was not statistically significant. We consider that the reason for this finding may be the small sample size in this study. This finding is consistent with the expectation and similar to that reported in foreign studies [26, 27]. Previous studies agree with the concept that timely opening the culprit artery is critical, and the D-B time should be shortened much as possible, namely to reduce the total ischemic time, save the dying myocardial cells in a timely manner, improve the survival rate, and improve the prognosis [28]. In this study, the average D-B time was relatively longer than that in other studies, and it needs to be further improved. Currently, there is some delay in the STEMI rescue time in China [29], which is related to the current situation of the rescue centers in China. We believe that after specialized chest pain centers are well established, the D-B time can be significantly shortened, thereby improving the overall rescue success rate among emergency patients.

In conclusion, emergency PCI for LADOO-AMI should be assisted by the IABP in a timely manner, which can improve the surgical tolerance and results, decrease the incidence of perioperative adverse events while not affecting the renal function, decrease the cost of hospitalization and hospital stay, and improve the cardiac function and prognosis to a certain extent.

The present study has some limitations. Foreign studies reported that the intraoperative support of the IABP for AMI-PCI cannot reduce the long-term mortality [30] even though it has some beneficial effects on the patients' long-

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term survival [31]. Although this study showed that this method can reduce the short-term mortality, studies with a larger sample size are warranted to confirm whether this method can reduce the long-term mortality. Because the D-B time in our center did not reach the desired level, this could have affected the results of this study. Studies with a larger sample size and with a wider range of enrollment criteria are warranted to validate our findings.

### Disclosure of conflict of interest

None.

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