Clinical application of intra-aortic balloon pump in patients with cardiogenic shock during the perioperative period of cardiac surgery

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Abstract. Intra-aortic balloon pumps (IABP) have saved many patients with cardiogenic shock during the perioperative period of cardiac surgery. However, the ideal insertion timing is controversial. In the present study, we aimed to optimize the insertion timing, in order to increase the survival rate of the patients. A total of 197 patients with cardiogenic shock during the perioperative period of cardiac surgery and implemented IABP from January 2011 to October 2015 were selected for the study. Patients were divided into five groups on the basis of application timing of IABP: 0-60, 61-120, 121-180, 181-240 and >240 min. The 30-day mortality, application rate of continuous renal replacement therapy (CRRT), duration of mechanical ventilation, duration of hospital stay and hospitalization charges were analyzed in the above groups. The risk factors related to mortality and the occurrence of IABP complications were also analyzed. The mortality in the 0-60, 61-120, 121-180, 181-240 and >240 min groups were 42.17, 36.6, 77.3, 72.7 and 79.3%, respectively. Earlier IABP insertion resulted in less patients receiving CRRT from acute renal failure and less daily hospitalization charges. However, the IABP application timing had no effect on indexes such as hospitalization duration, duration of mechanical ventilation and total hospitalization charges. Multifactor logistic regression analysis indicated that the independent risk factors of death in patients with cardiogenic shock during cardiac surgery were related to IABP support timing and vasoactive-inotropic score (VIS) before balloon insertion. In the first 120 min of cardiogenic shock during the perioperative period of cardiac surgery, IABP application decreased 30-day mortality. Mortality was related with VIS score of patients, which can be used to predict the prognosis of patients with cardiogenic shock.

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Key words: cardiac surgery, cardiogenic shock, intra-aortic balloon pump, timing, vasoactive-inotropic score

Introduction

Although improvements of cardiac surgical procedures and perioperative management have significantly decreased patient mortality during cardiac surgery, cardiogenic shock remains the main reason for perioperative death (1,2). Cardiogenic shock progresses rapidly with mortality rates as high as 40-80%, because of a decrease in cardiac output, peripheral tissue hypoperfusion and microcirculation disturbance, resulting in fatal systemic inflammatory response syndrome (SIRS) and multiple organ dysfunction syndrome (MODS) (3-7). Therefore, basic and clinical research on cardiogenic shock has been a research hotspot in the field of cardiovascular medicine (8). Following the principles of improving oxygen supply and reducing oxygen consumption, the treatment goal of cardiogenic shock is to maintain hemodynamic stability, prevent systemic damage from low perfusion, and gain the opportunity for etiological treatment (9). However, when both drug and support means cannot reverse the trend of

deterioration, mechanical assist devices (MADs) remain the only option for patients. Presently, MADs include the intra-aortic balloon pump (IABP), extracorporeal membrane oxygenation (ECMO) and ventricular assist device (VAD) (10,11). Among which, the IABP is the most frequently used and has saved countless patients with advanced heart disease over the past 50 years (12). Theoretically, IABP can improve diastolic perfusion pressure, coronary blood flow and myocardial oxygen supply. It can also reduce left ventricular afterload, reduce ventricular work, reduce oxygen consumption, and promote heart function recovery. However, since 2012, a large number of clinical trials demonstrated that IABP cannot reduce cardiogenic shock 30-day mortality of patients with acute myocardial infarction (13). Whether IABP can reduce the mortality of patients with cardiogenic shock during the perioperative period of cardiac surgery remains to be determined. There is no accurate timing for IABP application in these patients. In the present study, patients with perioperative cardiogenic shock from cardiac surgery were followed. The influence of different IABP treatment timings and different severe degrees of cardiogenic shock were observed for patient prognosis and mortality.

Patients and methods

Patients. According to the diagnostic and exclusion criteria of the IABP SHOCK-II clinical trial, a total of 197 patients were included in this study. All patients experienced cardiogenic shock during the perioperative period of cardiac surgery and accepted IABP treatment from January 2011 to October 2015, when admitted to the Second Affiliated Hospital of Harbin Medical University.

Experimental grouping. Patients were divided into five groups on the basis of different application timing of IABP (time interval from cardiogenic shock to implementation of IABP): 0-60 min group (83 patients), 61-120 min group (41 patients), 121-180 min group (22 patients), 181-240 min group (22 patients) and >240 min group (29 patients). The highest vasoactive-inotropic score (VIS) of patients was calculated before the application of IABP, and they were divided into five groups according to VIS score: 0-10 group (25 patients), 11-20 group (62 patients), 21-30 group (60 patients), 31-40 group (23 patients) and >40 group (27 patients).

Experimental indexes. The leading index was 30-day mortality. The secondary indexes were mortality of patients in the different VIS-score groups, duration of mechanical ventilation, duration of ICU stay, duration of hospital stay, total hospitalization charges, daily hospitalization charges and the application rate of continuous renal replacement therapy (CRRT). The risk factors related to mortality and the occurrence of IABP complications were also analyzed.

Analysis of cause of death. Factors related to intervention: EuroSCORE, operation time, anesthesia time, IABP treatment timing, duration of IABP-support and the application of CRRT.

Factors related to drugs: The VIS score of patients before the application of IABP.

Table I. The distribution of type of surgery for IABP inserted cardiogenic shock patients.

Surgery	Case no.	Percent
CABG	108	54.82
CABG + other	24	12.187
Valve replacement	51	25.89
Pericardiectomy	8	4.06
Bentall	3	1.52
Congenital heart disease surgery	2	1.02
Atrial myxoma resection	1	0.51

IABP, intra-aortic balloon pump; CABG, coronary artery bypass grafting.

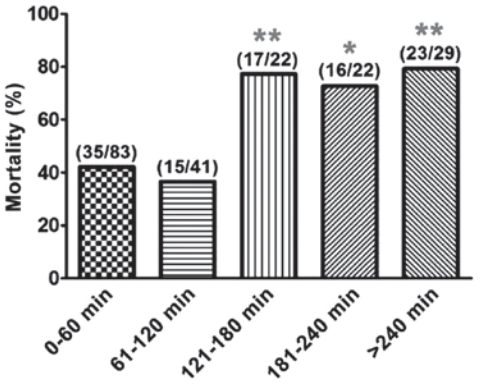

Figure 1. The mortality in different time intervals from cardiogenic shock to IABP. Compared with the former two groups, the latter three groups have higher rates of mortality. IABP, intra-aortic balloon pump. $^{*}P<0.05$, $^{**}P<0.01$.

The baseline characteristics of patients: Age, gender, smoking, drinking, diabetes mellitus (DM), hypertension, body mass index (BMI), lacunar infarction, cerebral infarction, percutaneous coronary intervention (PCI), stent implantation, unstable angina, preoperative cardiac function classification, preoperative ejection fraction (EF) value, preoperative interventricular septal thickness (IVST) and preoperative left ventricular posterior wall thickness (LVPWT).

The occurrence of IABP related complications: The occurrence of IABP complications were analyzed including thrombocytopenia; bleeding; lower limb ischemia; thrombosis and embolism; vascular injury; and mechanical complications, such as balloon burst and catheter fracture.

Statistical analysis. SAS software version 9.1.3 (SAS Institute, Cary, NC, USA) and GraphPad Prism 5.0 (GraphPad Software, Inc., La Jolla, CA, USA) computer data processing software were used. A χ^2 test was used to analyze enumeration data and ANOVA was applied for measurement data. Student's t-test was implemented for comparisons between two groups. For measurement data unsuitable for Student's t-test, a nonparametric test was used. Single factor and multifactor logistic regression analysis were applied for the analysis of risk factors for death.

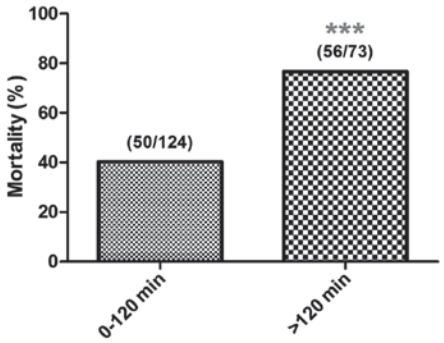

Figure 2. The comparison of primary outcome in the two groups. The mortality of the first group was significantly lower than the second group. ***P<0.001.

Results

Baseline characteristics of patients. Between January 2011 and October 2015, 6,189 patients underwent open cardiac surgery in our center. Among them, 197 were enrolled in this study. The study included 130 males (65.99%) and 67 females (34.01%); mean age was 58.68±9.42 years, mean BMI was 24.614±3.86, mean duration of hospital stay was 34.83±19.11 days. IABP support time was 3-456 h (mean support time was 112.04±78.73 h). The vast majority of patients had cardiac function ranging from moderate to poor (two patients were New York Heart Association (NYHA) class II, 113 patients were NYHA class III and 82 patients were NYHA class IV. Mean operating time was 267.79±80.40 min, the average anesthesia time was 312.06±85.39 min. The overall hospital mortality of the entire cohort was 53.81%. Most patients accepted coronary artery bypass surgery in this study, followed by valve replacement (Table I).

The influence of IABP application timing on patient prognosis. The relationship between IABP application timing and 30-day mortality: Mortality was ~40% when IABP support began within 120 min from onset of shock. Mortality rates increased to over 70% when IABP support began after 120 min. Mortality rate was ~80% when IABP support began 240 min later (P<0.05, P<0.01 and P<0.001). According to the obvious trend of mortality, patients were divided into two groups based on different application timing, the 0-120 and >120 min groups. We found that compared with the >120 min group, IABP support beginning within 120 min from cardiogenic shock significantly reduced the 30-day mortality (40.3 and 76.7%, respectively; P<0.001) (Figs. 1 and 2).

Secondary indexes. Different IABP application timing had no effect on indexes such as hospitalization duration, duration of ICU stay, duration of invasive mechanical ventilation (through endotracheal intubation or tracheotomy), total hospitalization charges and daily hospitalization charges (P>0.05). The proportion of patients that received CRRT in the 0-60, 61-120, 121-180, 181-240 and >240 min groups were 15.66, 26.83, 31.82, 31.82 and 51.72%, respectively (Fig. 3). The increasing trend was statistically significant (P<0.001). These results demonstrated that, when timing of IABP application was later, tissue perfusion was worse which increased the likelihood of patients having severe renal insufficiency. The daily hospitalization charges in the 0-120 min group were lower than in the >120 min group by 1,300 yuan (P<0.01), while the invasive mechanical ventilation time, total mechanical ventilation time,

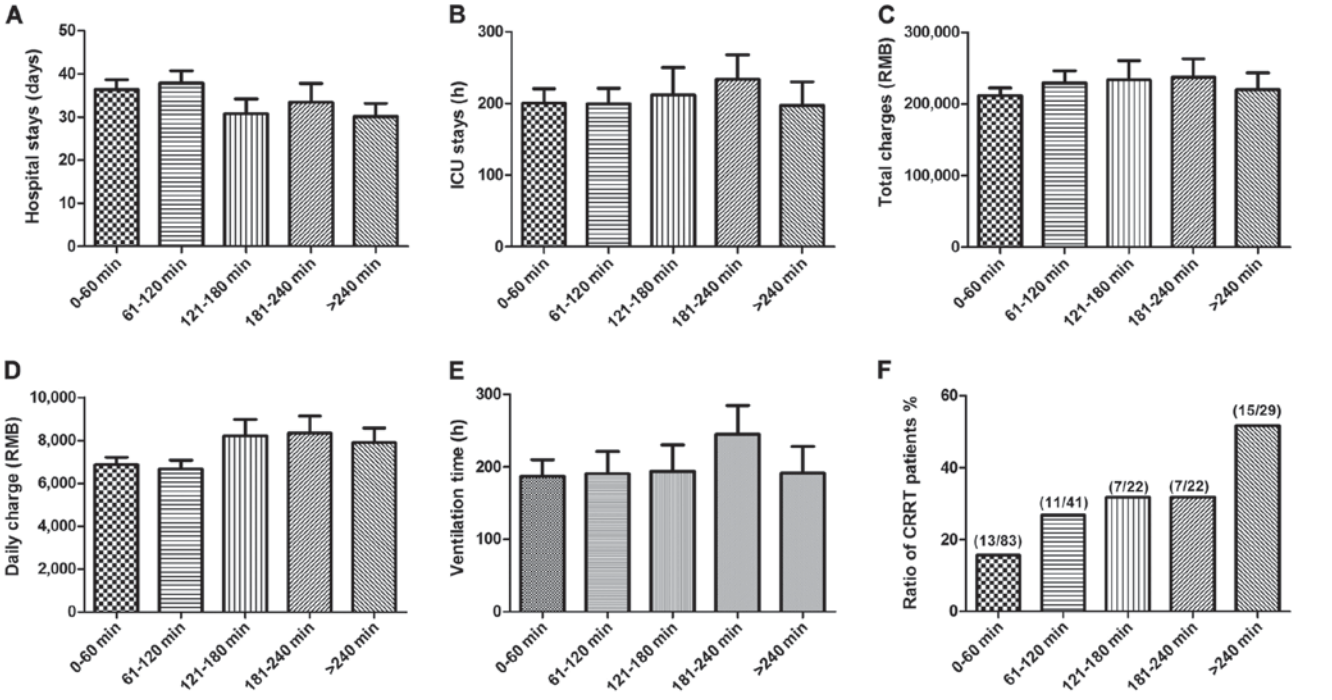

Figure 3. (A) Duration of hospital stay in patients of different time intervals from cardiogenic shock to IABP. (B) Duration of ICU stays of patients in different time intervals from cardiogenic shock to IABP. (C) The comparison of total hospitalization charges in different groups. (D) The comparison of daily hospitalization charges in different groups. (E) Invasive mechanical ventilation time in different time intervals from cardiogenic shock to IABP. (F) The ratio of patients receiving CRRT. IABP, intra-aortic balloon pump; CRRT, continuous renal replacement therapy.

Table II. The difference between secondary indexes.

Groups	0-120 min	>120 min	P-value
N	124	73	
Duration of hospital stay (days)	36.88 (19.84)	31.34 (17.37)	0.049
Duration of ICU stay (h)	200.14 (170.22)	212.78 (171.05)	0.616
Invasive mechanical ventilation time (h)	184.28 (197.19)	206.04 (180.89)	0.446
Total mechanical ventilation time (h)	222.27 (211.904)	231.34 (190.227)	0.763
Total hospitalization charges (yuan)	217741.67 (99665.91)	229460.59 (124098.73)	0.468
Daily hospitalization charges (yuan)	6799.13 (2942.2)	8127.4 (3583.77)	0.005

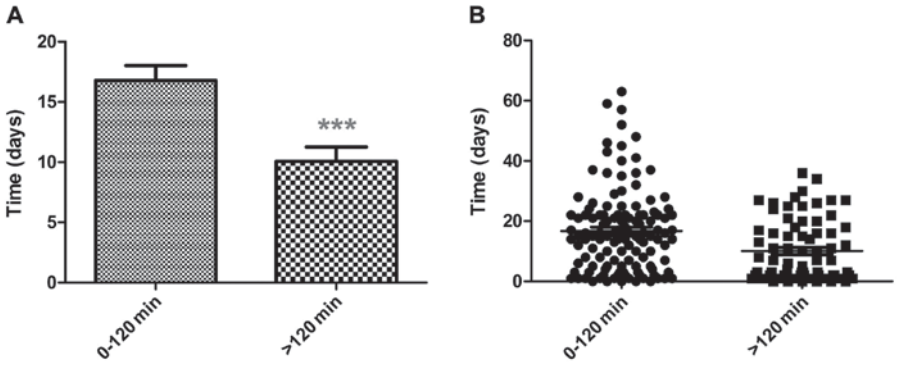

Figure 4. Temporal survival time of both groups. The group with earlier application showed longer survival time. ***P<0.001.

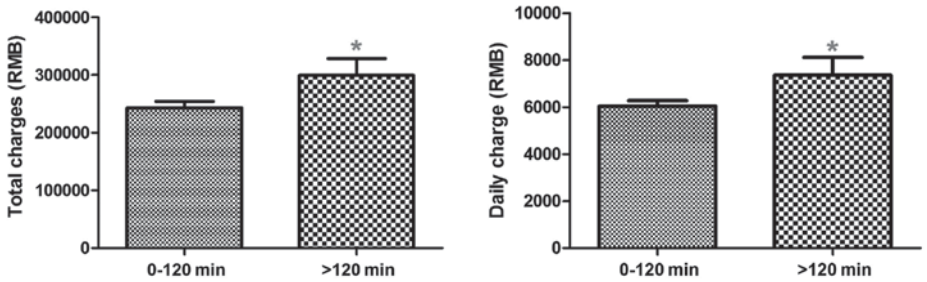

Figure 5. The comparison of total charges and daily charges in the two groups of surviving patients. There were no statistically significant differences. Both total charges and daily charges in the first group were less than the in the second group, and the differences were statistically significant. *P<0.05.

duration of hospital stay, duration of ICU stay and total hospitalization charges were not statistically different between the two groups (P>0.05) (Table II).

Duration of hospital stay after IABP in the 0-120 and >120 min group. The duration of hospital stay after IABP in the 0-120 min group was 16.81 days, which was significantly higher than in the 120 min group (10.45 days) (Fig. 4). When patients accepted IABP treatment 120 min after occurrence of cardiogenic shock, the effect was unsatisfactory, and most patients died prematurely. According to the following formula: Total hospitalization charges = duration of hospital stay x daily hospitalization charges. Although the daily hospitalization cost of patients in the 120 min group was higher, premature death occurred after IABP, which shortened the duration of hospital stays. Therefore, the advantages of IABP are not reflected in economic indicators. By analyzing data of surviving patients, early IABP intervention reduced hospital charges (Fig. 5).

Analysis of the factors related to death

EuroSCORE. The EuroSCORE of all 197 patients in this study was 6.48±3.16 (1-17), there were no statistical differences between the 0-120 and >120 min groups (P>0.05). This suggested that the operative risks of patients in both groups were similar. Single logistic regression analysis indicated that mortality and EuroSCORE had no significant correlation (P>0.05) (Fig. 6).

The relationship between IABP application timing and VIS score. VIS score = dopamine dose (μg/kg·min) + dobutamine dose (μg/kg·min) + 100 x epinephrine dose (μg/kg·min) + 10 x milrinone (μg/kg·min) + 10,000 x vasopressin dose (U/kg·min) + 100 x norepinephrine dose (μg/kg·min) + 10 x phenylephrine dose (μg/kg·min) (18). VIS score reflects the dosage of vasoactive drugs and positive inotropic drugs. Higher score shows a higher level of critically ill patients. In this study, VIS score before IABP treatment

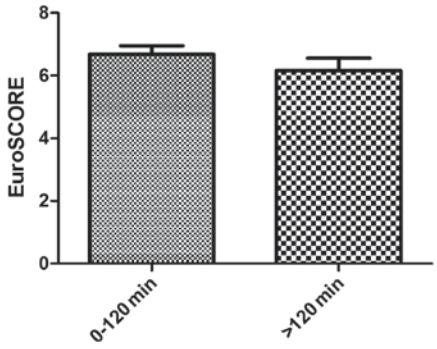

Figure 6. The comparison of EuroSCORE between two the groups.

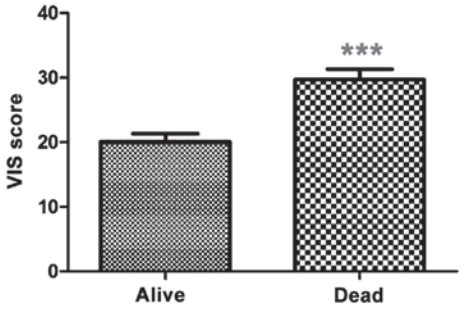

Figure 8. The comparison of VIS score between surviving patients and those that died. VIS, vasoactive-inotropic score. ***P<0.001.

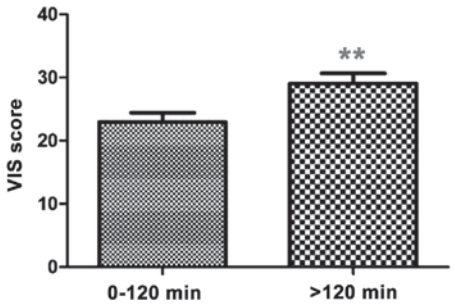

Figure 7. The comparison of VIS score between the 0-120 min group and the >120 min group. VIS, vasoactive-inotropic score. **P<0.01.

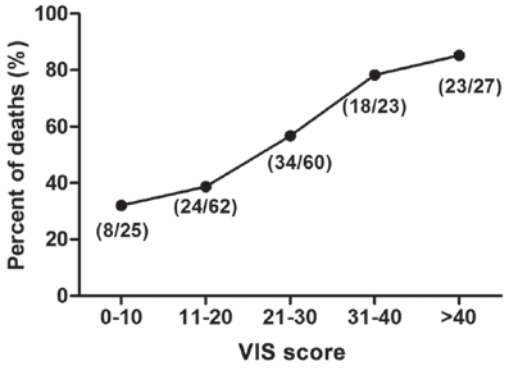

Figure 9. The mortality of patients with different VIS score. VIS, vasoactive-inotropic score.

was 25.42±15.80. By statistical analysis, we found that the VIS score in the 0-120 min group was significantly lower than in the >120 min group (P<0.01). Therefore, later IABP application was related to higher VIS score (Fig. 7). VIS score in surviving patients was also significantly lower than in patients who died (P<0.001) (Fig. 8).

The relationship between VIS score and mortality. According to the highest VIS score before IABP treatment, the patients were divided into five groups: 0-10, 11-20, 21-30, 31-40 and 40+ group and the mortality rates were 32.00, 38.71, 56.67, 78.26 and 85.19%, respectively. Mortality increased with VIS score (P<0.001) (Fig. 9). Early treatment of IABP may therefore delay or reverse the rise of VIS score, which may reduce the adverse effects of hypotension on perfusion of peripheral organs, and prevent the occurrence of MODS, thereby reducing patient mortality.

Analysis of risk factors. Single factor logistic regression analysis showed that the death of patients was related to the insertion timing of IABP (P<0.001) and the VIS score (P<0.001) before the insertion of IABP (Table Ⅲ). Multifactor logistic regression analysis indicated that the independent risk factors of death in patients with cardiogenic shock during cardiac surgery were related to the IABP insertion timing and VIS score before balloon insertion (Table IV). Furthermore, every 1 h delay of IABP application increased the patient's risk of death by 1.373. Every increase of VIS score by 10 points, increased the patient's risk of death by 1.047 (Table V). Mortality had no significant correlation with age, gender, smoking, drinking, DM, hypertension, BMI, lacunar infarction, cerebral infarction, PCI, stent implantation, unstable angina, preoperative cardiac function classification, preoperative EF value, preoperative IVST and preoperative IVPWT (P>0.05).

Complications. The main complications included thrombocytopenia, peripheral ischemia, thrombosis, embolism and vascular impairment. Two patients underwent thrombectomy (removal of thrombus) of the femoral artery, followed by remission of disease (Table V). There were no IABP complication related deaths in this study.

Discussion

For evaluation of any kind of treatment, two of the most important premises are treatment timing and indications on whether it is reasonable. This includes IABP. Regarding therapeutic effect of IABP, several studies over the past 50 years have shown that IABP is a means of assisting circulation, but it cannot solve primary heart problems. However, if the right patients for IABP treatment are chosen at the optimal time, they could be greatly benefitted because the mechanism and effect of IABP is certain (15). The IABP counterpulsation is key for patients with severe cardiac function after primary disease is resolved, which is sufficient to recover the function of stunned myocardium in the reversible stage (16). Because IABP improved tissue perfusion to avoid progression of SIRS and MODS, patients had a chance to recover during the most dangerous part of the perioperative phase. The application of IABP in cardiac surgery has increased (17), and the rate of

Table III. Risk factors associated with mortality.

Variables	B	WALD	P-value	OR	CI lower	CI upper
Gender						
M						
F	0.455	2.216	0.137	1.577	0.866	2.872
Age	0.011	0.563	0.453	1.012	0.982	1.042
Smoking						
N						
Y	-0.083	0.080	0.777	0.921	0.519	1.632
Drinking						
N						
Y	-0.257	0.588	0.443	0.774	0.401	1.491
DM						
N						
Y	-0.265	0.707	0.401	0.767	0.414	1.423
Hypertention						
N						
Y	0.129	0.204	0.652	1.138	0.649	1.994
BMI	0.016	0.172	0.678	1.016	0.941	1.098
Lacunar infarction						
N						
Y	0.333	0.733	0.392	1.395	0.651	2.991
Cerebral infarction						
N						
Y	0.877	2.571	0.109	2.404	0.823	7.025
Previous PCI						
N						
Y	-0.665	1.725	0.189	0.514	0.191	1.387
Cardiac function (NYHA class III-IV)						
N						
Y	0.107	0.136	0.713	1.113	0.629	1.969
CS-IABP (min)	0.007	17.733	0.000	1.007	1.004	1.010
CS_IABP(1) (0-60)	-0.105	0.053	0.817	0.900	0.368	2.200
CS_IABP(2) (61-120)	-0.299	0.384	0.535	0.742	0.289	1.907
CS_IABP(3) (121-180)	1.475	5.640	0.018	4.371	1.294	14.768
CS_IABP(4) (181-240)	1.232	4.263	0.039	3.429	1.064	11.043
CS_IABP(5) (240+)	1.595	7.547	0.006	4.929	1.579	15.380
CS_IABP (0-120)						
CS_IABP (120+)	1.584	22.775	0.000	4.875	2.544	9.345
VIS score	0.056	17.812	0.000	1.058	1.031	1.086
EF value	0.018	1.989	0.158	1.018	0.993	1.043
IVST	0.218	3.696	0.055	1.244	0.996	1.554
LVPWT	0.124	1.346	0.246	1.131	0.918	1.394

M, male; F, female; N, no; Y, yes; DM, diabetes mellitus; BMI, body mass index; PCI, percutaneous coronary intervention; NYHA, New York Heart Association; IABP, intra-aortic balloon pump; VIS, vasoactive-inotropic score; EF, ejection fraction; IVST, interventricular septal thickness; LVPWT, left ventricular posterior wall thickness.

application of IABP in the cardiac surgery department of our hospital increased from 1.72% in 2011 to 4.78% in 2014.

At present, many clinical studies on cardiac surgery do not support the preventive application of IABP (19,20), and

Table IV. The independent predictors associated with mortality.

Variables	B	WALD	P-value	OR	CI lower	CI upper
CS IABP	0.317	9.953	0.002	1.373	1.127	1.671
VIS	0.045	12.515	0.000	1.047	1.020	1.073

IABP, intra-aortic balloon pump; VIS, vasoactive-inotropic score.

Table V. Complications.

Complication	Number	Percent
Thrombocytopenia (need platelet transfusion)	19	9.64
Ischemia or embolism	7	3.55
Vascular impairment	1	0.51
Severe bleeding	0	0

guidelines recommend IABP only as a means for circulation in patients with refractory cardiogenic shock. The present study did not adopt a preventive application strategy. Although all selected patients met the criteria for cardiogenic shock, there were differences in the severity of conditions. We adopted VIS score to assess the critical conditions of patients (18,21,22), and EuroSCORE to evaluate baseline status of patients (23,24). The results showed that the overall EuroSCORE in patients was 6.48±3.16 points (out of 17 points). Therefore, the patients in the study were high-risk. VIS score was initially used in newborns and infants after cardiac surgery but in recent years has gradually been used in adults and adolescents (25) during the perioperative period of cardiac surgery to evaluate degree of critical illness. Relative to the complexity of APACHE II, the calculation method of VIS score is simpler and quicker (26). We found that the mortality rate of patients was as high as 85.19% when VIS score was over 40 points, therefore we do not recommend IABP for patients with VIS score >40 and where cardiogenic shock occurred over 240 min, as the ideal recovery time was missed because of ischemic myocardium. Not only is the effect of IABP at this time not ideal, but may increase the risk of complications.

Unfortunately, the application of IABP within 120 min after cardiogenic shock did not reach the expected effect in economic benefits. Through further analysis, we found that many patients with premature death and survival time shortened because of starting IABP treatment 120 min after cardiogenic shock, missed the optimal timing of treatment. This offset the advantage of early IABP application which can save on total charges. Patient survival is however, the most important outcome, and length of hospital stay and hospital expenses cannot be compared with survival rate. Moreover, we found that IABP treatment 120 min after cardiogenic shock reduced the total and daily hospitalization charges of surviving patients. Without the interference of shorter survival time because of death, the evaluation of the advantages of IABP is more reasonable and saves on charges.

IABP support from 3-456 h (1-19 days), an average of 112.04±78.73 h in this study, was comparable with the results (24 h to 11 days) of most studies (27). Complications occurred only in a minority of patients (13.7%) as in other clinical studies (28-31), and there were no serious bleeding events related to IABP, or IABP complication related deaths. Therefore, IABP is relatively safe for patients with cardiac shock during the perioperative period of cardiac surgery. Because of the efficacy of IABP technology itself and its circulation support being very precise, focus should be placed on selecting the optimal timing in different patients, and how to improve the treatment effect of IABP. Assessing the patient's condition by VIS score alone is not sufficient and many factors should also be considered. For example, the area of myocardial infarction, cardiac function, organ function, effect of cardiac surgery and microcirculation. Damage to heart function because of large areas of infarction are irreversible regardless of drugs, intervention, circulatory assist devices and conventional surgery. Therefore, new evaluation systems which are more rapid, accurate and comprehensive are required, to help judge IABP intervention timing accurately and choose the appropriate patients, so as to improve the therapeutic effect of IABP, thereby improving the prognosis of patients with cardiogenic shock during the perioperative period of cardiac surgery.

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