

Intra-aortic Balloon Pump Support in Patients with Acute Myocardial Infarction with Ventricular Septal Rupture

Running title: IABP support in AMI with VSR

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Abstract

Background: An intra-aortic balloon pump (IABP) is the most frequently used device as a bridge to surgical repair in cases of myocardial infarction. However, robust evidence of IABP support for patients with postinfarction ventricular septal rupture (VSR) is still lacking. We aimed to investigate the impacts of intra-aortic balloon pump (IABP) support on 30-day outcomes in patients with acute myocardial infarction (AMI) complicated VSR.

Methods: Retrospective data of patients with VSR after AMI at Fuwai Hospital between April 2002 and August 2020 were analyzed. Patients were initially stratified into 2 groups according to IABP implantation. The 30-day all-cause mortality of patients with or without IABP treatment was analyzed and compared.

Results: A total of 92 patients (mean age of 67.8 ± 8.3 years; 46.7% male) were included, and 59 underwent IABP implantation. Patients with IABP treatment were younger and more often male and had a higher BMI level and lower mean blood pressure at the onset of VSR than those without IABP treatment. At 30 days, all-cause death occurred in 21 patients in the IABP group (35.59%) and 31 patients in the group without IABP (93.94%). After adjustment for age, sex, left atrial diameter, left ventricular diameter, perforation diameter and ventricular aneurysm, IABP support was found to be an independent protective predictor of 30-day all-cause mortality (hazards ratio: 0.22; 95% confidence interval: 0.12 to 0.42; $p < 0.001$).

Conclusions: IABP support is associated with lower 30-day mortality in patients with VSR after AMI. Patients with postinfarction VSR with hemodynamic instability or cardiogenic shock could receive IABP treatment as a bridge to surgical repair.

Key words Intra-aortic balloon pump, ventricular septal rupture, acute myocardial infarction

1 INTRODUCTION

Ventricular septal rupture is an uncommon but catastrophic complication of acute myocardial infarction (AMI). Despite the use of reperfusion therapy, mortality in the acute phase of ventricular septal rupture (VSR) remains high [1]. The best timing and modality for VSR operation remain debated, with better results reported for delayed surgery. Mechanical circulatory support (MCS) strategies now offer new possibilities to achieve hemodynamic stabilization even in more critical patients, allowing a delayed operation and, possibly, contributing to improved survival [2]. An intra-aortic balloon pump (IABP) is the most frequently used device as a bridge to surgical repair and is recommended by the guidelines (class IIa, level C) in cases of mechanical complications of myocardial infarction [3]. The presence of a cardiogenic shock (CS) and hemodynamical instability substantially worsen the prognosis [2]. MCS is demonstrated to be an effective therapeutic option that can improve clinical outcomes [4]. However, robust evidence of IABP support for patients with postinfarction VSR and CS is still lacking. The present study aimed to determine the impacts of IABP support on 30-day outcomes in patients with AMI complicated with VSR.

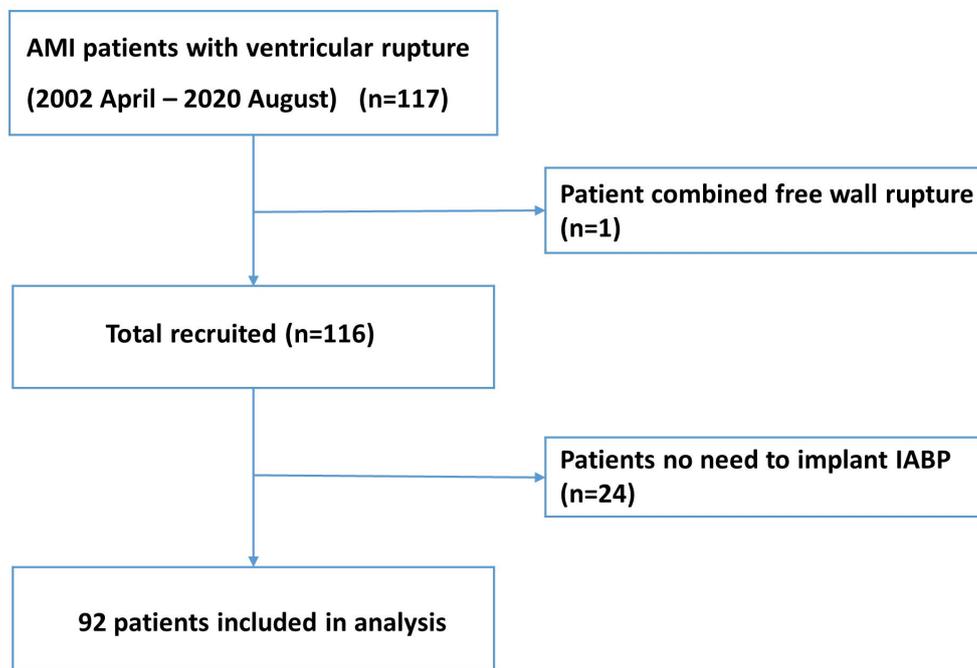
2 METHODS

2.1 Study populations

The inclusion criteria were consecutive patients admitted to the cardiac care unit (CCU) of Fuwai Hospital for AMI between April 2002 and August 2020 who had echocardiography-demonstrated evidence of VSR and were recommended for IABP support according to the 2023 European Society of Cardiology guidelines [3]. Those with hemodynamic instability and signs of hypoperfusion, such as cool, clammy skin, oliguria, or altered sensorium, were indicated for IABP support to maintain systolic blood pressure >90 mmHg. The onset of recorded vital signs was used to determine

the clinical hemodynamics for each patient. One patient with free wall rupture and 24 patients without an indication for IABP implantation due to stable hemodynamics were excluded. Clinical characteristics, echocardiographic features and surgical repair of VSR were recorded. This retrospective study protocol was approved by the Ethics Committee of FuWai hospital, approval number 2021-1422, and conducted in accordance with the principles contained within the Declaration of Helsinki. Patients were initially stratified into 2 groups according to IABP treatment. The study flowchart is available in Figure 1.

Figure 1. Flowchart of patient selection



2.2 Definitions

AMI was defined as clinical evidence of acute myocardial ischemia and with detection of a rise and/or fall of cardiac troponin values with at least one value above the 99th percentile upper range limit (URL) with electrocardiogram evidence of > 2 mm ST-segment elevation in the precordial leads or > 1 mm ST-segment elevation in the limb leads [5]. All patients underwent echocardiographic confirmation of VSR by transthoracic methods during hospital admission. A diagnosis of VSR was defined as

a disruption in the ventricular septum with evidence of left-to-right shunt by color Doppler. Left ventricular ejection fraction (LVEF) was calculated using the biplane Simpson's method.

2.3 IABP

IABP was implanted via the femoral artery. A 7 or 7.5 F balloon catheter (30- or 40-ml balloon depending on the height and weight of patients; Arrow, Datascope Corp, USA) was placed in the descending aorta and connected to a Datascope pump (Datascope, Oakland, N.J., USA). The balloon size was selected based on the patient's height (30, 40, or 50 cc). The correct position of the balloon catheter was identified by chest X-ray. All IABPs were inserted by a cardiologist experienced with the percutaneous insertion technique.

2.4 Endpoints

30-day mortality (all-cause death) after VSR diagnosis in patients with or without IABP treatment was analyzed and compared.

2.5 Statistical analysis

Continuous variables were summarized as the mean plus/minus the standard deviation (SD). Categorical variables were expressed as percentages. Student's t-test was used for the comparison of continuous variables or rank sum tests when necessary. To compare categorical variables, the chi-square test was used. To determine predictors of 30-day mortality, univariate logistic regression was performed on these baseline variables. Multivariate logistic regression was used to assess the impact of the selected parameters on IABP usage in VSR patients. Factors that were associated with IABP use in the multivariate model as well as other factors known to be associated with death were selected to enter the model in a stepwise fashion to adjust the influence of IABP on 30-day mortality. The results are presented as odds ratios (ORs) and 95% confidence intervals (CIs). Interaction analyses, including LVEF, renal

function, and their potential interactions with confounders, were performed to evaluate their relationship with IABP use and mortality. Follow-up mortality was analyzed using the Kaplan-Meier method. A 2-sided p-value <0.05 was considered significant. For all the calculations, SAS version 9.4 (SAS Institute, Cary, North Carolina) was used.

3 RESULTS

3.1 Baseline characteristics

A total of 92 patients with VSR after AMI between April 2002 and August 2020 in the CCU of Fuwai Hospital who met the inclusion criteria were included in the analysis. Baseline clinical characteristics are shown in Table 1. An IABP was used in 59 patients (64.1%). Compared with patients without IABP treatment, patients in the IABP group tended to be younger, were more likely to be current smokers and male, and had a higher body mass index (BMI) and lower mean blood pressure at the onset of VSR (all p<0.05). The characteristic distributions of other demographics and clinical comorbidities were balanced between the groups.

Table 1. Baseline demographic and clinical characteristics of the study participants

| Characteristics | All (n=92) | Patients with IABP (n=59) | Patients without IABP (n=33) | p Value |
|--|------------|---------------------------|------------------------------|---------|
| Mean age, yr | 67.8± 8.3 | 65.9 ± 7.8 | 71.2 ± 8.0 | 0.01 |
| Male | 43 (46.7%) | 33 (55.9%) | 10 (30.3%) | 0.02 |
| BMI, kg/m ² | 24.3± 3.3 | 25.2 ± 3.2 | 22.8 ± 3.1 | <0.001 |
| Time from infarction to the defect, days | 3.8± 3.8 | 3.8 ± 4.1 | 3.0 ± 3.1 | 0.56 |
| Emergency intervention | 12 (13.0%) | 8 (13.6%) | 4 (12.1%) | 0.84 |
| Current smoker | 44 (47.8%) | 33 (55.9%) | 11 (33.3%) | 0.04 |
| Hypertension | 56 (60.9%) | 33 (55.9%) | 23 (69.7%) | 0.19 |
| Diabetes mellitus | 24 (26.1%) | 12 (20.3%) | 12 (36.4%) | 0.09 |
| Prior stroke | 21 (22.8%) | 14 (23.7%) | 7 (21.2%) | 0.78 |

| | | | | |
|---|------------------|------------------|------------------|--------|
| Chronic renal insufficiency | 22 (23.9%) | 15 (25.4%) | 7 (21.2%) | 0.65 |
| Creatinine, $\mu\text{mol/L}$ | 135 \pm 58.8 | 137.1 \pm 66.7 | 130.7 \pm 39.4 | 0.62 |
| Mean blood pressure at the onset of VSR, mmHg | 73.4 \pm 10.8 | 70.4 \pm 9.4 | 78.9 \pm 11.1 | <0.001 |
| Heart rate at the onset of VSR, beats/min | 102.6 \pm 16.9 | 103.7 \pm 16.1 | 100.6 \pm 18.3 | 0.38 |
| Killip class IV | 86(93.5%) | 55(93.2%) | 31(93.9%) | 0.89 |
| Left atrial diameter, mm | 36.9 \pm 5.1 | 37.1 \pm 4.9 | 36.6 \pm 5.6 | 0.59 |
| Left ventricular diameter, mm | 51.6 \pm 5.8 | 52.2 \pm 5.8 | 50.5 \pm 5.7 | 0.19 |
| LVEF, % | 46.9 \pm 10.0 | 46.0 \pm 9.9 | 48.4 \pm 10.1 | 0.39 |
| Perforation size, mm | 13.7 \pm 6.1 | 14.8 \pm 6.5 | 11.8 \pm 4.7 | 0.03 |
| Combined ventricular aneurysm | 40 (43.5) | 29 (49.2%) | 11 (33.3%) | 0.14 |

Abbreviations: BMI, body mass index; LVEF, left ventricular ejection fraction.

3.2 Echocardiographic characteristics

Echocardiographic characteristics at the onset of VSR are presented in Table 1. The perforation size measured by transthoracic echocardiography was significantly larger in the IABP support group (14.8 \pm 6.5 vs. 11.8 \pm 4.7 mm, $p=0.03$). The diameter of the left atrium and left ventricle, level of LVEF and prevalence of combined ventricular aneurysm were not different between the two groups (all $p>0.05$).

3.3 Clinical outcomes

The overall 30-day mortality of AMI after VSR was 56.5%. Twenty-one patients in the IABP support group (35.59%) and 31 patients in the control group (93.94%) died (Table 2). Preoperative mortality in the IABP support group was lower (33.9% versus 90.9%). Univariate analysis demonstrated that IABP insertion was a protective factor for 30-day mortality in patients with VSR (HR 0.18, 95% CI 0.10–0.32, $p < 0.0001$), as shown in Table 3. Other factors, such as age, sex, left atrial diameter, left ventricular diameter, perforation size and ventricular aneurysm, were also significantly associated with 30-day mortality in univariate analysis (Table 3, Figure

2). The association between IABP treatment and 30-day mortality remained significant after adjusting for age and sex (HR 0.20, 95% CI 0.11–0.36, $p < 0.001$) (Table 4). After additionally controlling for age, sex, left atrial diameter, left ventricular diameter, perforation diameter and ventricular aneurysm, the association was still significant for IABP treatment (HR 0.22, 95% CI 0.12–0.42, $p < 0.001$) (Table 4). The Kaplan-Meier analysis in Figure 3 shows that death rates at 30 days were significantly lower in the IABP group than in the no-IABP group (35.6% versus 93.9%, $p < 0.001$).

Table 2. In-Hospital Management and Outcomes

| Characteristics | All (n=92) | Patients with IABP (n=59) | Patients without IABP (n=33) | p Value |
|--|------------|---------------------------|------------------------------|---------|
| Surgical repair | 30 (32.6) | 29 (49.2%) | 1 (3.0%) | <0.001 |
| Time from onset of the defect to surgery, days | 20.0 ± 9.1 | 20.6 ± 8.6 | 1.0 | <0.001 |
| Preoperative mortality | 50 (54.3) | 20 (33.9%) | 30 (90.9%) | <0.001 |
| 30-Day mortality from onset of defect | 52 (56.5) | 21 (35.6%) | 31 (93.9%) | <0.001 |

Table 3. Univariable Logistic Regression for 30-day mortality

| Characteristics | Statistics | Death | p value |
|------------------------|--------------|-------------------|---------|
| IABP | | | |
| No | 33 (35.87%) | 1 | |
| Yes | 59 (64.13%) | 0.18 (0.10, 0.32) | <0.0001 |
| Sex | | | |
| Male | 43 (46.74%) | 1 | |
| Female | 49 (53.26%) | 2.05 (1.16, 3.64) | 0.014 |
| Age | 67.77 ± 8.25 | 1.07 (1.03, 1.11) | 0.001 |
| Emergency intervention | | | |
| No | 80 (86.96%) | 1 | |
| Yes | 12 (13.04%) | 0.65 (0.26, 1.62) | 0.353 |

| | | | |
|--|----------------|-------------------|-------|
| Hypertension | | | |
| No | 36 (39.13%) | 1 | |
| Yes | 56 (60.87%) | 1.13 (0.64, 2.00) | 0.676 |
| Diabetes mellitus | | | |
| No | 68 (73.91%) | 1 | |
| Yes | 24 (26.09%) | 0.82 (0.43, 1.57) | 0.557 |
| Prior stroke | | | |
| No | 71 (77.17%) | 1 | |
| Yes | 21 (22.83%) | 0.89 (0.46, 1.73) | 0.732 |
| Chronic renal insufficiency | | | |
| No | 70 (76.09%) | 1 | |
| Yes | 22 (23.91%) | 1.71 (0.94, 3.08) | 0.076 |
| Current smoker | | | |
| No | 48 (52.17%) | 1 | |
| Yes | 44 (47.83%) | 0.69 (0.39, 1.19) | 0.179 |
| Mean blood pressure, mmHg | 73.41 ± 10.83 | 1.01 (0.98, 1.04) | 0.549 |
| Heart rate, beats/min | 102.57 ± 16.90 | 1.01 (1.00, 1.03) | 0.107 |
| Time from infarction to the defect, days | 3.52 ± 3.77 | 1.01 (0.94, 1.09) | 0.824 |
| BMI, kg/m ² | 24.34 ± 3.34 | 0.92 (0.84, 1.00) | 0.064 |
| Creatinine, µmol/L | 135.00 ± 58.83 | 1.00 (1.00, 1.01) | 0.252 |
| Left atrial diameter, mm | 36.94 ± 5.13 | 0.93 (0.87, 0.99) | 0.019 |
| Left ventricular diameter, mm | 51.61 ± 5.76 | 0.92 (0.87, 0.97) | 0.003 |
| EF, % | 46.88 ± 10.01 | 1.01 (0.98, 1.04) | 0.514 |
| Perforation size, mm | 13.73 ± 6.08 | 0.91 (0.86, 0.96) | 0.001 |
| Combined ventricular aneurysm | | | |
| No | 52 (56.52%) | 1 | |
| Yes | 40 (43.48%) | 0.38 (0.21, 0.69) | 0.002 |

Abbreviations: BMI, body mass index

Figure 2. Stratified analyses of the association between IABP insert and 30-day mortality according to baseline characteristics. Note: The p value for interaction represents the likelihood of interaction between the variable and IABP insert. Abbreviations: BMI, body mass index; LVEF, left ventricular ejection fraction.

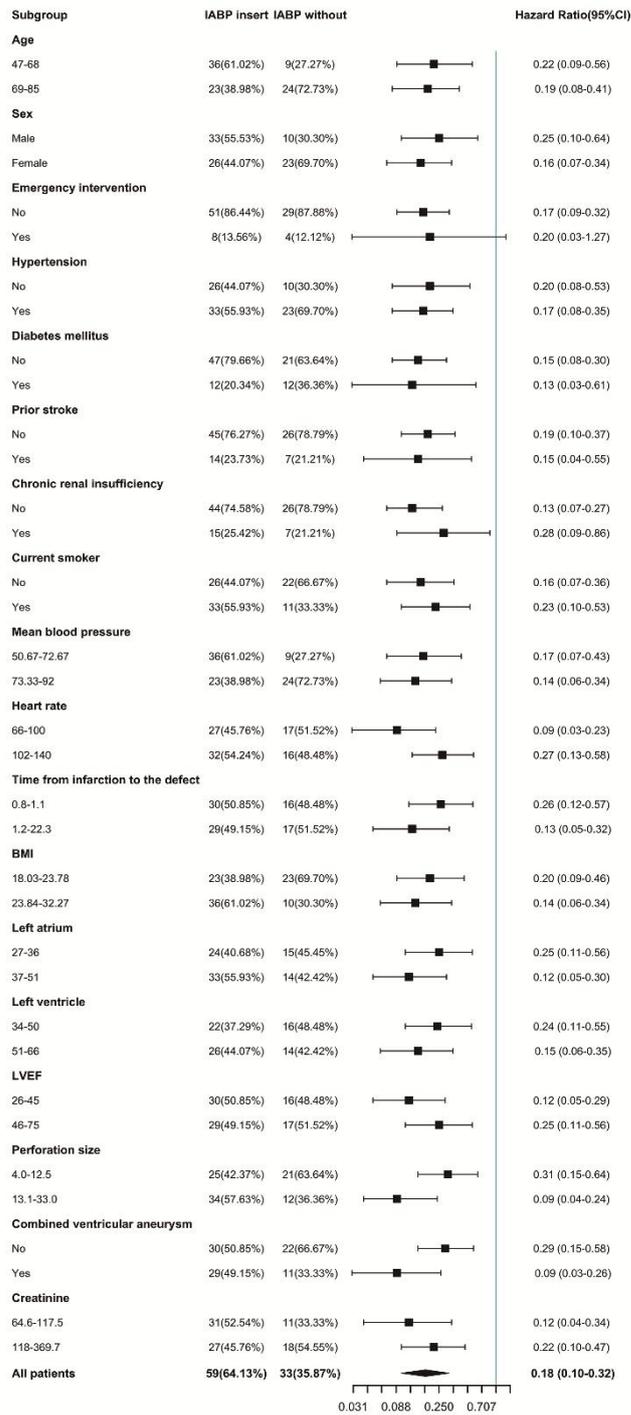


Table 4. Association between IABP and 30-day mortality in the multiple regression model

| Outcome | Unadjusted Model | | Model I | | Model II | |
|-------------|------------------|---------|-------------|---------|-------------|---------|
| | OR (95% CI) | p value | OR (95% CI) | p value | OR (95% CI) | p value |
| IABP | | | | | | |
| Without | Reference | | Reference | | Reference | |
| Insert | 0.18 (0.10, | <0.001 | 0.20 (0.11, | <0.001 | 0.22 (0.12, | <0.001 |

0.32)

0.36)

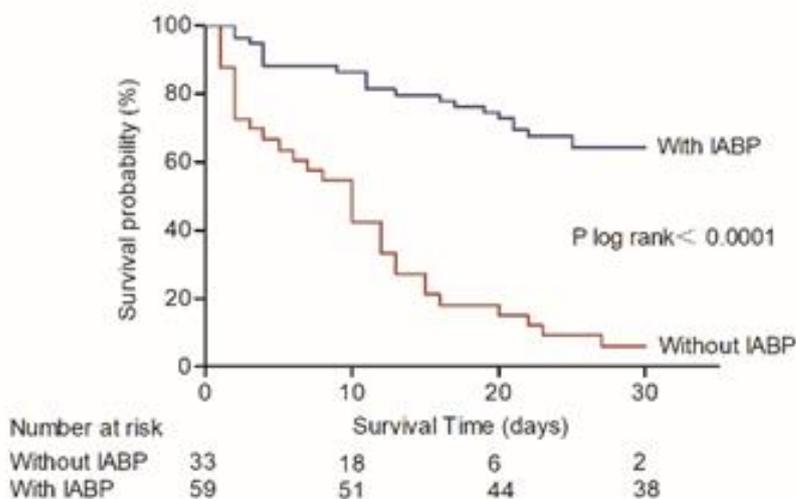
0.42)

Model I: Adjust for age and sex.

Model II: Adjust for age, sex, left atrial diameter, left ventricular diameter, perforation diameter, combination with ventricular aneurysm.

Abbreviations: OR, odds ratio; CI, confidence interval.

Figure 3. K-M curve in patients with and without IABP.



4 DISCUSSION

The most important findings of our analysis are as follows: 1) application of IABP is associated with a lower 30-day risk of death in patients with AMI complicated by VSR combined with hemodynamic instability or cardiogenic shock; and 2) application of IABP is related to more opportunities for surgical treatment.

Despite improvements in early diagnosis and management, mortality rates associated with post-myocardial infarction VSR have not changed significantly over time and are especially poor in the setting of coexistent CS [6,7]. The main cause of death in AMI patients with VSR is “pump failure”, which results in hemodynamic instability. Therefore, it is urgently necessary to improve the hemodynamic status of patients to

reduce early mortality. The advantage of IABP is represented by afterload reduction, which decreases LV wall stress, thereby facilitating contractility and increasing cardiac output, simultaneously reducing left-to-right shunting [8]. Despite representing the safest and most cost-efficient type of MCS, IABP support is often limited by insufficient hemodynamic support in more critical patients, especially in the presence of a large VSR or infarction as well as biventricular involvement [8]. With the rapid advancements in extracorporeal circulation technology, the survival rate of patients with AMI complicated by VSR has increased, especially when extracorporeal membrane oxygenation (ECMO) and IABP are used preoperatively [4].

Among percutaneous devices, IABP is often considered early in the treatment of CS because of its relatively low cost, ease of implantation procedures and low complication rates [9]. Preoperative IABP use has been demonstrated to effectively prevent complications in high-risk patients undergoing coronary artery bypass grafting (CABG) [10]. A retrospective analysis suggested that preserved LVEF was associated with better prognosis in the surgical management of VSR complicating AMI but not IABP implantation [11]. A total of 92 AMI with VSR patients with hemodynamic instability or CS were included in our study. Traditional medical treatment is not effective. IABP was used in 59 patients (64.1%). Compared with the control group, patients in the IABP group had lower 30-day mortality (35.59% vs. 93.94%). It is suggested that IABP is still a very effective treatment for VSR with unstable hemodynamics. These results supplement and are consistent with previous research [4,12].

Surgical management of VSR is the definitive treatment, but the optimal timing is unclear. Studies have shown that earlier surgical repair in VSR increases the risk of mortality because in the early phase after AMI, the infarcted myocardium is very fragile; it is very difficult to perform surgical repair, as it increases the risk of recurrent septal defects. A longer time is needed for the heart and different body systems to adapt to the hemodynamic results of the abrupt left-to-right shunt. It seems that the best time for the operation is after the maturation of VSR with scarring at the

edges of the defect [13]. If pharmacological therapy is not effective, an IABP should be used [14,15]. IABP support reduced 30-day mortality in patients with shock (61% vs. 100%, $p=0.04$). The benefit of IABP support in the shock cohort was driven mainly by a reduction in preoperative mortality (11% vs. 88%, $p < 0.001$) [12]. Transcatheter device closure has been alternatively proposed, but so far, procedural mortality has been as high as traditionally reported for surgical repair, suggesting that percutaneous treatment may be appropriate in selected cases when local expertise exists [16]. Hua Kun et al demonstrated that the overall in-hospital mortality was 47% and that the most common reason for death was refractory heart failure ($n=35$), suggesting that the early application of hemodynamic support would be particularly important for improving in-hospital outcomes [7]. According to previous studies, IABP can increase diastolic coronary and systemic blood flow, and it reduces afterload and myocardial work, which is supposed to protect LV function and prevent low cardiac output [17]. Experimental and clinical studies have indicated that IABP results in a hemodynamic benefit as a result of afterload reduction and diastolic augmentation with improvements in coronary perfusion [18]. Given the upfront surgical risk, bridging with temporary MCS is a reasonable option to consider for VSR and has been supported in the most recent European Society of Cardiology STEMI guidelines [19,20]. Preoperative IABP will increase cardiac output, decrease the left to right shunt, and improve coronary perfusion. Preoperative CS influenced early survival, indicating that improving the hemodynamic status of patients before surgery is crucial [21]. A combination of preoperative mechanical circulatory support and delayed surgery may improve the outcomes of patients with VSR, which is complicated by CS [22].

Perspectives

The presented analysis derives from an observational study and should be considered hypothesis-generating only. The obtained results support the routine use of IABP in

patients with VSR with signs of CS or the need for medical support to maintain hemodynamic stability. IABP insertion was associated with lower 30-day mortality. Surgery can reduce the preoperative mortality rate. On the other hand, as death can still occur with IABP, it is necessary to develop a risk scale that will help to choose patients who would benefit from additional support of the circulatory system. Such personalization of the therapeutic process can increase the effectiveness of applied devices and improve the prognosis in this difficult group of patients [23]. VSR represents a rare, but life-threatening condition, often associated with CS and characterized by a peculiar pathophysiology and hemodynamic profile. The best timing and modality for VSR operation remain debated, with better results reported for delayed surgery. MCS strategies now offer new possibilities to achieve hemodynamic stabilization even in more critical patients, allowing a delayed operation and, possibly, contributing to improved survival. Due to the low incidence of mechanical complications of myocardial infarction, limited use of delayed surgery treatment and therapy with MCS, the most important investigated studies include a small number of patients. Nevertheless, they emphasize the presence of certain trends [8].

Study limitations

This analysis is a single-center retrospective observational study and is thus limited by the particular patient population at this center. The study period was long, which may have limited the number of statistical variables. Moreover, we did not have data concerning the moment of IABP insertion (after insertion), and thus, this important aspect was not analyzed. The trial protocol allowed for the insertion of a ventricular assist device based on the investigator's clinical judgment and patient consent. It cannot be excluded that in some patients, IABP was not inserted due to an initially extremely poor clinical condition, or patients' own treatment expectations were not optimistic, or insufficient family support. The optimal duration of mechanical

circulatory support remains unknown. However, investigators seem to be balancing between stabilizing the patient and avoiding serious complications of IABP. Therefore, prospective collection of data from multiple centers is needed to verify the results of this study.

Conclusion

In this cohort of patients with AMI complicated with VSR, IABP support was associated with lower 30-day mortality. Patients with postinfarction VSR with hemodynamic instability or cardiogenic shock could receive IABP treatment as a bridge to surgical repair.

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Author contributions

X.-L. Luo carried out the studies, participated in data collection, performed the statistical analysis and drafted the manuscript under the supervision of J. Zhang and S.-B. Qiao. H.-B. Xu, J. Li, C. Guo, J.-S. Yuan, and Y. Ma participated in data collection and proofread the manuscript. All authors read and approved the final manuscript.

CONFLICT OF INTEREST

The authors declare no potential conflict of interests.

Research Data

The data used to support the findings of this study can be accessed by contacting the email addresses zhangjun_cv@sina.com (J. Z.) and dr_qiao@163.com (S. Q.).

Footnote

The authors are accountable for all aspects of the work, including ensuring that any questions related to the accuracy or integrity of any part of the work have been appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ethics Committee of T Fuwai Hospital (No. 2021-1422). Because of the retrospective nature of the research, the requirement for informed consent was waived.