Original Article

Left ventricular ejection fraction is associated with intraoperative circulatory collapse during transcatheter aortic valve implantation

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Background: Intraoperative hemodynamic collapse during transcatheter aortic valve implantation (TAVI) is a devastating complication that requires mechanical support. In this study, we sought to analyze our early experience in using cardiopulmonary bypass (CPB) support to circumvent circulatory compromise during TAVI.

Methods: Between January 2018 and December 2020, 102 consecutive patients (54 males; mean age, 71.2±8.9 years) received TAVI at Tianjin Chest Hospital, and an emergency CPB device was used in 6 of these patients (5.9%). The clinical data of the CPB and no-CPB groups were analyzed to identify the factors associated with intraoperative hemodynamic collapse requiring CPB.

Results: All 6 patients who needed emergency CPB support were successfully weaned from the device. This group had a higher Society of Thoracic Surgeons Score [4.09 (2.02, 6.85) *vs.* 7.47 (5.07, 23.46); P=0.030], more patients with a left ventricular ejection fraction (LVEF) ≤30% [4 (66.7%) *vs.* 2 (2.1%); P=0.000], a larger right ventricle anteroposterior diameter [20.50 (19.75, 21.25) *vs.*19.00 (17.00, 20.00); P=0.016], and a higher degree of aortic regurgitation [4.50 (2.75, 5.00) *vs.* 2.00 (1.00, 4.00); P=0.018] compared to the no-CPB group. The CPB group also had a higher in-hospital mortality rate than did the no-CPB group (16.7% *vs.* 4.7%; P=0.026). Multivariable analysis determined that the presence of lower pre-TAVI LVEF was associated with intraoperative hemodynamic collapse.

Conclusions: Our results indicate that LVEF is an independent risk factor for requiring emergency CPB during the TAVI procedure. The need for emergency CPB support was associated with higher in-hospital mortality.

Keywords: Extracorporeal assisted cardiopulmonary resuscitation (ECPR); cardiopulmonary bypass (CPB); transcatheter aortic valve implantation (TAVI); left ventricular ejection fraction (LVEF); hemodynamic collapse

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Introduction

Since first being introduced by Cribier in 2002 (1), transcatheter aortic valve implantation (TAVI) has revolutionized the surgical treatment of aortic stenosis (AS). Most candidates for TAVI procedures are elderly patients who have high perioperative risks. These patients can easily deteriorate into a state of circulatory collapse, which is a devastating complication reported in 4–15.2% of these patients (2-5). Pulmonary hypertension, biventricular failure, transapical access, and cardiogenic shock due to hemodynamic collapse necessitating salvage mechanical support have all been reported in patients undergoing TAVI (6,7).

The emergency use of mechanical circulatory support (MCS) is technically feasible, safe, and effective, and guarantees adequate hemodynamic stability during TAVI (5,8-10). However, the available data have thus far failed to provide clear-cut guidelines regarding the indications for MCS, leaving the decision regarding its application to the consensus of the heart team (11,12). Unfortunately, experience on the use of emergency MCS in averting or correcting intraoperative circulatory collapse is quite limited (4). Therefore, there is a great need and interest for a detailed discussion on the salvage use of MCS. The current study aimed to analyze the emergency use of cardiopulmonary bypass (CPB) support during TAVI and to assess the related risk factors for intraoperative circulatory collapse during TAVI in a Chinese population. We present the following article in accordance with the STROBE reporting checklist (available at https://dx.doi.org/10.21037/atm-21-3446).

Methods

Participants

Clinical data of 102 consecutive patients who underwent the TAVI procedure in Tianjin Chest Hospital, China, between January 2018 and December 2020 were retrospectively collected. All procedures were completed using self-expanding transcatheter bioprostheses. Transfemoral TAVI was carried out in 90 patients (*Figure 1*), and the other 12 patients underwent transapical TAVI. Six patients required emergency CPB support for refractory circulatory collapse. All procedures in this study involving human participants were performed in accordance with the Declaration of Helsinki (as revised in 2013). This study was approved by the institutional review board of Tianjin Chest Hospital [approval no. IRB-SOP-016(F)-001-02]. Informed consent was taken from all the patients.

Participant election criteria

All patients who were scheduled to undergo a TAVI procedure at our hospital and consented to participate were

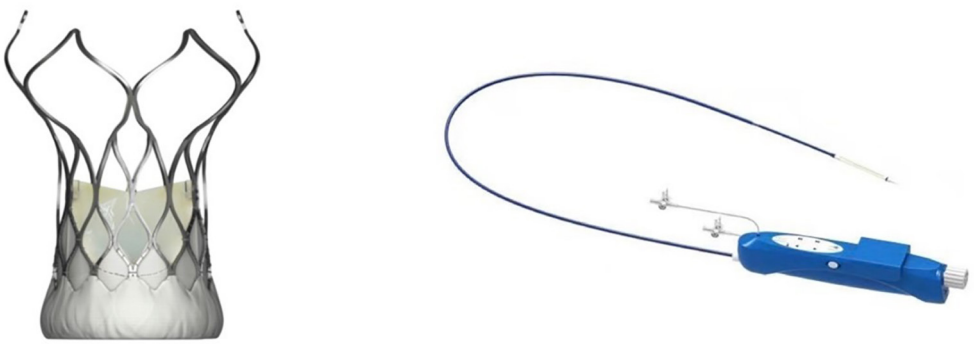

Figure 1 Product features of the VitaFlow Transcatheter Aortic Valve System. VitaFlow Transcatheter Aortic Valve System (VitaFlow) is a transfemoral (TF) valve made of trileaflet bovine pericardium in China. The system comprises a valve and a delivery system. VitaFlow uses bovine pericardium with patented anticalcification treatment as the leaflet material, which provides better durability. The "supra-annular" design preserves circularity and provides a large effective orifice area and low gradients. The frame of the VitaFlow valve has a hybrid density design, which delivers a balance of high radial force, space for the possible subsequent percutaneous coronary intervention, and the flexibility of the whole system. Additionally, the VitaFlow valve has an inner and outer polyethylene terephthalate skirt design, which can better fit the aortic root structure and reduce the paravalvular leakage. The motorized handle of the VitaFlow delivery system is easy to use, providing precise and stable positioning. There is also a manual, backup handle. The profile of the delivery system is 16F or 18F.

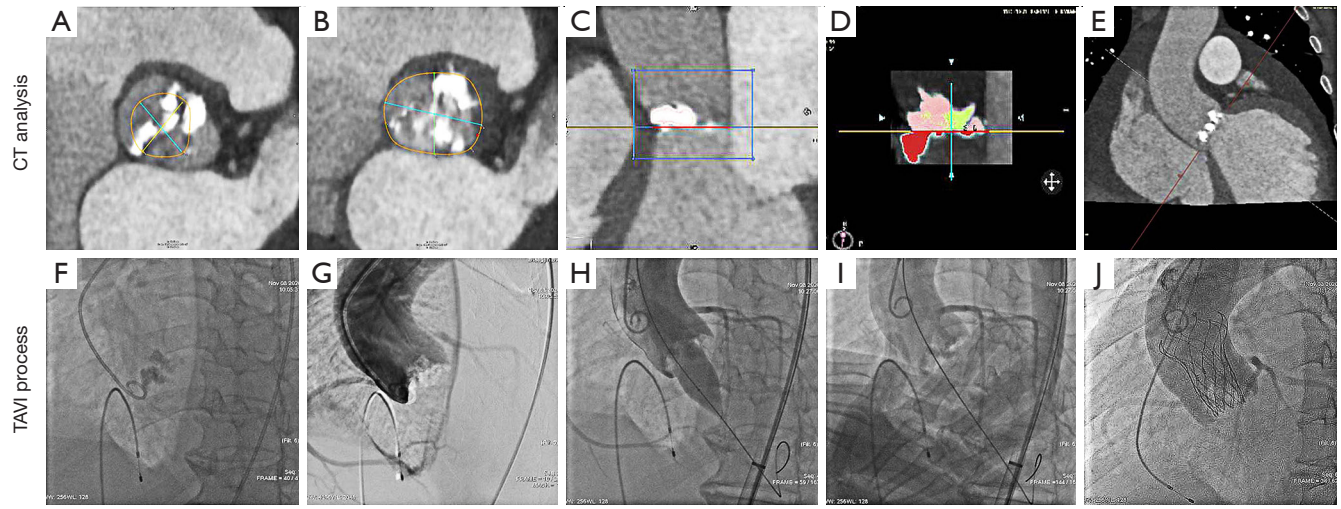

Figure 2 Cardiopulmonary bypass support to circumvent circulatory compromise during the transcatheter aortic valve implantation (TAVI) procedure. A 49-year-old male, whom surgeons considered not to be a suitable candidate for surgery, underwent TAVI with emergency intraoperative cardiopulmonary bypass (CPB) support. He presented with orthopnea and massive pleural effusion. Transthoracic echocardiography indicated severely calcified bicuspid aortic valve stenosis, moderate aortic regurgitation, and moderate to severe mitral regurgitation with a pulmonary arterial systolic pressure of 50 mmHg. Transesophageal echocardiography showed a mean aortic valve gradient of 55 mmHg, a maximum transaortic velocity of 4.5 m/s, and a left ventricular ejection fraction of 28%. The patient suffered from a hemodynamic collapse as a result of ventricular fibrillation after balloon predilation. The images show the patient's aortic root measurement and the entire TAVI procedure. (A) Supra-annular narrowing of the bicuspid valve at 6 mm above the basal ring. (B) The level of the basal ring: the minimum diameter was 28.62 mm, the max diameter was 37.82 mm, and the area was 9.11 cm^2. (C) Calcium volume of calcification volume (calcification detection was set at 850 Hounsfield units): the aortic valve region calcium was 1,116.0 mm^3. (D) The first bicuspid cusp was 797.5 mm^2, and the second bicuspid cusp was 318.4 mm^2. (E) Aortic angulation. (F) The pigtail catheter located at the base of the coronary sinus. (G) Aortic root angiography. (H) Recalcitrant ventricular fibrillation occurred after aortic predilation with a 20-mm balloon. (I) Cardiopulmonary resuscitation and femoral arteriovenous intubation were initiated immediately. The valve release assisted by CPB proceeded as follows: suspension of extracorporeal assistance, exsanguination, release, restart of CPB, and defibrillation. The prosthetic valve localization was indicated by calcified plaques of the native valve. (J) Both coronaries were patent, and no perivalvular leak was detected. The patient was weaned from CPB after 61 minutes of support. After the procedure, transesophageal echocardiography indicated that the mean transvalvular gradient was 10 mmHg, the maximum transaortic velocity was 2 m/s, and the effective orifice area was 1.9 cm^2. (Self-expandable valve: #24 VitaFlow, MicroPort, Shanghai, China).

eligible for inclusion in the study. Patients who died or who were converted to open surgery with complications, patients with incomplete clinical data, and patients who did not consent to participate in the study were excluded from the analysis.

Perioperative management

All patients received transthoracic echocardiography, and multislice computed tomography (MSCT) measurements were used to assess the anatomy of the aortic root and select the surgical approach, in line with the current guidelines (2). Curved multiplanar reconstruction analyses were used for annular and aortic valve dimension descriptions (software: CVI 42, version 5.12.1 Circle Cardiovascular Imaging, Calgary, AB, Canada; *Figure 2*). The multidisciplinary surgical team held a routine preoperative discussion with each patient to identify, avert, and plan for the handling of any potential complications. Procedures were monitored with transesophageal echocardiography, fluoroscopy, and angiography. Doppler examination was performed to evaluate the severity of paravalvular leakage, and valve regurgitation was classified as none/trace, mild, moderate, or severe, as previously described (2).

A hybrid operating suite with standby CPB was used for all TAVI procedures. The routine TAVI operative

procedure and management strategy adopted were described in our previous study (13). After administration of general anesthesia, we performed a routine puncture of the femoral artery and vein. In general, for patients whose complicated circulatory compromise occurred before the valve intervention could be performed, cardiopulmonary resuscitation, external defibrillation, and adjustment of medication were applied. If cardiopulmonary resuscitation proved unsuccessful after 2 rounds, then cannulation was performed. In the event of circulatory failure occurring during valve release, the first option was to release the valve and then perform cardiopulmonary resuscitation.

Statistical evaluation

Data were tested for normality distribution with the Kolmogorov-Smirnov (K-S) test. Normally distributed data are presented as means ± standard deviations and were compared using the independent-samples *t* test. Data that did not show a normal distribution were summarized as means and interquartile ranges, and comparisons were conducted using the Mann-Whitney U test. Categorical data are presented as frequencies and percentages, and comparisons were made using the χ^2 or Fisher's exact test. Variables displaying a P<0.2 were included in a logistic regression model for multivariate analysis. Two-tailed tests were used, with a P value <0.05 being considered statistically significant. The SPSS version 22.0 software (IBM Corp., Armonk, NY, USA) was used for statistical analysis.

Results

Baseline characteristics

Intraoperative circulatory collapse occurred in 13 patients: CPB was used in 6 of these cases (46.2%), and cardiopulmonary resuscitation proved successful in 7 of these cases.

As shown in *Table 1*, demographic characteristics, including age, sex, and body mass index, were similar between patients who underwent CPB and those who did not. Both groups were similar in terms of comorbidities including hypertension, chronic obstructive pulmonary disease (COPD), diabetes, coronary artery disease, previous myocardial infarction, previous percutaneous coronary intervention (PCI), previous coronary artery bypass grafting (CABG), and bicuspid aortic valves. Atrial fibrillation was more prevalent in the CPB group. Notably, more patients in the CPB group underwent transapical TAVI than did those in the no-CPB group (50% *vs.* 9.4%; P=0.018).

Echocardiographic data

The echocardiographic data showed that the CPB group had a larger right ventricle diameter [20.50 (19.75, 21.25 *vs.* 19.00 (17.00, 20.00) mm; P=0.016], higher pulmonary artery systolic pressure [47.50 (41.25, 65.25) *vs.* 35.00 (30.00, 41.00) mmHg; P=0.017), a larger proportion of patients with LVEF ≤30% [4 (66.7%) *vs.* 2 (2.1%); P<0.001], and more moderate to severe aortic regurgitation [4.50 (2.75, 5.00) *vs.* 2.00 (1.00, 4.00); P=0.018] than did the no-CPB group. The left ventricular end-diastolic dimension in the CPB group was larger than that in the no-CPB group, but this discrepancy was not significantly significant [66.00 (60.50, 67.75) *vs.* 57.00 (50.00, 66.00); P=0.101]. The 2 groups were comparable regarding the maximum transaortic velocity, mean pressure gradient, aortic valve area, and degree of mitral regurgitation.

Reasons for using CPB

The characteristics of the patients that underwent emergency use of CPB are detailed in *Table 2*. Of these 6 cases, 3 patients collapsed after predilation [1 patient experienced a sudden drop in systolic blood pressure, while 2 cases had ventricular fibrillation (VF)], 2 patients experienced VF during valve release, and 1 patient experienced a sudden drop in systolic blood pressure after the passage of the guidewire through the native aortic valve. The mean duration of the CPB procedure was 68 minutes (range, 31–124 minutes) and all patients were successfully weaned from the CPB device after a short duration of support.

Outcomes and survival

Four (16.7%) in-hospital deaths occurred in the no-CPB group, compared with one (4.7%) such death in the CPB group (P=0.026). The length of stay in the intensive care unit (P=0.036) and overall length of hospital stay (P=0.026) in the CPB group were higher than those in the no-CPB group. There was no significant difference in the frequency of new pacemaker insertion (10.6% *vs.* 16.7%; P=0.359), mean postprocedural gradient (8.00 *vs.*10.00 mmHg; P=0.189), or incidence of peripheral arterial complications (3.1% *vs.* 16.7%; P=0.139) between the 2 groups (*Table 3*).

In the multivariate model, the presence of LVEF ≤30% was identified as an independent factor associated with the

Table 1 Baseline characteristics of patients who underwent TAVI with or without CPB support

Variable	TAVI with CPB support		P value
	No (n=96)	Yes (n=6)	
Age	72.56±9.01	71.33±7.97	0.984
Male	47 (52.9)	5 (83.3)	0.089
BMI, kg/m^2	24.31±4.16	23.07±2.66	0.475
STS score	4.09 (2.02, 6.85)	7.47 (5.07, 23.46)	0.030
Comorbidities			
Hypertension	49 (51.0)	4 (66.6)	1.000
COPD	16 (16.7)	1 (16.7)	1.000
Diabetes	25 (26.0)	2 (33.3)	1.000
Coronary artery disease	43 (45.8)	2 (33.3)	0.677
Previous myocardial infarction	11 (11.5)	0 (0.0)	1.000
Previous PCI	9 (9.4)	0 (0.0)	1.000
Previous CABG	5 (5.2)	0 (0.0)	1.000
Cerebral vascular disease	19 (19.8)	1 (16.7)	0.337
Peripheral vascular disease	11 (11.5)	1 (16.7)	0.583
Atrial fibrillation	19 (19.8)	4 (66.6)	0.034
NYHA III or IV	76 (79.2)	6 (100.0)	1.000
Porcelain aorta	10 (10.4)	1 (16.7)	0.820
Bicuspid aortic valve	35 (40.7)	2 (33.3)	1.000
Calcification volume (mm^3)	459.0 (204.8, 1,355.0)	476.0 (301.0, 1,022.6)	0.573
Glomerular filtration rate (mL/min/1.73 m^2)	62.93±25.75	55.81±15.60	0.507
NT-pro-BNP, pg/mL	1,911.00 (902.85, 5,755.25)	8,274.00 (2,268.50, 14,538.00)	0.081
Approach			
Transfemoral	87 (90.6)	3 (50.0)	
Transapical	9 (9.4)	3 (50.0)	0.018
Post-dilatation	10 (10.4)	1 (16.7)	0.283
Echocardiographic data			
LVEDD (mm)	57.00 (50.00, 66.00)	66.00 (60.50, 67.75)	0.101
RVD (mm)	19.00 (17.00, 20.00)	20.50 (19.75, 21.25)	0.016
Vmax (m/s)	4.68 (4.30, 5.49)	4.00 (3.61, 4.78)	0.075
Mean gradient (mmHg)	57.00 (46.50, 70.00)	43.00 (40.00, 71.50)	0.353
Aortic valve area (cm^2)	0.60 (0.49, 0.79)	0.59 (0.51, 0.80)	0.766
LVEF	53.00 (43.50, 60.00)	30.50 (29.50,36.75)	0.001
LVEF ≤30%	2 (2.1)	4 (66.7)	<0.001
Pulmonary artery systolic pressure (mmHg)	35.00 (30.00, 41.00)	47.50 (41.25, 65.25)	0.017
Aortic valve regurgitation	2.00 (1.00, 4.00)	4.50 (2.75, 5.00)	0.018
Mitral valve regurgitation	2.00 (2.00, 4.00)	3.50 (2.00, 4.00)	0.142

Values presented as mean ± SD, n (%), or median (IQR). TAVI, transcatheter aortic valve implantation; CPB, cardiopulmonary bypass; STS, Society of Thoracic Surgeons; COPD, chronic obstructive pulmonary disease; PCI, previous percutaneous transluminal coronary intervention; CABG, previous coronary artery bypass grafting; NYHA, New York Heart Association; NT-pro-BNP, N-terminal pro brain natriuretic peptide; Vmax (m/s), maximum aortic valve gradient; LVEDD, left ventricular-diastolic diameter; RVD, right ventricular diameter; LVEF%, percentage of left ventricular ejection fraction.

Table 2 Characteristics of patients who received emergency CPB support during TAVI

Patients	Age	Sex	STS score	LVEF (%)	Approach	Reason for CPB	CPB duration (min)
1	81	M	36.45	30	Transapical	Sudden systolic blood pressure drop after predilation	61
2	72	M	2.68	29	Transfemoral	Blood pressure drop after passage of the guidewire	124
3	73	M	5.86	30	Transapical	VF after aortic balloon valvuloplasty (predilation)	31
4	75	M	6.43	42	Transapical	Refractory VF during the process of releasing	37
5	70	F	8.51	35	Transfemoral	Refractory VF during the process of releasing	115
6	57	M	19.11	28	Transfemoral	VF after aortic balloon valvuloplasty (predilation)	40

CPB, cardiopulmonary bypass; TAVI, transcatheter aortic valve implantation; LVEF%, percentage of left ventricular ejection fraction; VF, ventricular fibrillation.

Table 3 Outcomes of patients who underwent TAVI with or without CPB support

	Without CPB support	CPB support	P value
In-hospital mortality	4 (4.7)	1 (16.7)	0.026
Length of ICU stay (d)	2.00 (2.00, 3.00)	3.50 (2.00, 8.00)	0.036
Length of hospital stay (d)	7.00 (6.50, 9.00)	11.00 (8.00, 12.50)	0.026
Cost of hospitalization (RMB)	326.40 (276.40, 343.90)	360.20 (320.05, 404.05)	0.089
New pacemaker	2 (2.08)	1 (16.7)	0.109
Mean postoperative gradient (mmHg)	8.00 (5.00, 13.00)	10.00 (8.50, 12.00)	0.189
Peripheral arterial complication	3 (3.1)	1 (16.7)	0.139

Values presented as n (%) or median (IQR). TAVI, transcatheter aortic valve implantation; CPB, cardiopulmonary bypass; ICU, intensive care unit.

Table 4 Results of multivariate analysis

	Regression coefficient	P value	OR (95% CI)
Approach	–5.290	0.050	0.000–0.992
LVEF ≤30%	–7.889	0.017	0.000–0.240
LVEDD (mm)	–0.169	0.136	0.676–1.055
RVD (mm)	–0.680	0.054	1.020–3.818

OR, odds ratio; 95% CI, 95% confidence interval; LVEDD, left ventricular-diastolic diameter, LVEF, left ventricular ejection fraction; RVD, right ventricular diameter.

need for emergency CPB during TAVI [P=0.017; odds ratio (OR) :0.000–0.240; *Table 4*].

Discussion

There has been a drastic increase in the number of TAVI procedures in China since the first successful operation was reported in 2010. As attested to by the 2020 White Paper of China Structural Heart Disease (12), more than 6,000 operations have been successfully carried out across China using the technique. Over the past year alone, more than 3,500 TAVI procedures have been performed at more than 200 centers. Further, in addition to the Edwards SAPIEN valve (Edwards Lifesciences, Irvine, CA, USA), a balloon-expandable valve that is frequently used in Western countries (4), becoming the most popular device approved

by the National Medical Products Administration, three other domestically produced self-expandable prostheses (the VitaFlow Valve, J-Valve, and Venus A-valve) have played a central role in the expansion of TAVI in China. However, due to the severe calcification associated with the bicuspid valve, Chinese doctors still prefer and frequently use first-generation nonrecoverable TAVI valves. The collective experience of Chinese surgeons in the use of diverse valvular devices is still nascent and limited. Therefore, determining the clinical indications, implantation strategies, intraoperative emergency management, and valve durability for TAVI still requires further clarification. Our study highlights the fact that emergency CPB is still required and is needed at a higher frequency than that reported in previous studies. The previous study indicated low LVEF has been strongly associated with circulatory collapse requiring CPB support during TAVI (14,15). It is possible that patients with depressed LVEF have a severely compromised decompensation capacity, resulting in a poor tolerance to predilation balloon valvuloplasty and inherent rapid ventricular pacing.

Unbehaun *et al.* (16) and Schaefer *et al.* (10) found that patients with a very poor LVEF and an enlarged right ventricle were more likely to develop hemodynamic collapse, which was also observed in the present study. Other researchers have also reported that pulmonary hypertension, biventricular failure, transapical access, and cardiogenic shock are independent risk factors for requiring CPB during TAVI (4,6-8). However, our results indicated that influence of LVEF accounted for less than 30% among the factors associated with the need for CPB.

The management of patients with AS, especially those diagnosed as stage D2 and D3, is quite challenging (14,17). Approximately 1 in 3 of these patients die within 2 years (18). Drews *et al.* (8) reported that the prophylactic use of CPB may increase the safety of the TAVI procedure for patients who have severely reduced heart function. These researchers recommended that valvuloplasty and valve deployment be considered for short-term CPB support in patients with poor LVEF (10–20%) or decompensated right ventricular failure. Another retrospective study (5) found that the emergency use of MCS during TAVI in extremely high-risk groups of patients was associated with high mortality rates (30–46%). Taken together, the available data suggest that the primary use of CPB, rather than its secondary, emergency use, may provide superior results. There is, however, the possibility of selection bias in the sampled studies. Currently, evidence on the prophylactic use of MCS in critically ill patients undergoing TAVI procedures is limited. Moreover, the specific indications and optimal treatment for emergency implantation of CPB devices are usually determined by heart team consensus (11).

Additional indications for MCS noted in other studies include left ventricular or aortic annular rupture, aortic dissection, severe aortic regurgitation or paravalvular leak, and coronary occlusion (4,5,19). These life-threatening complications often lead to hemodynamic collapse, which requires expeditious use of CPB support to avert a disastrous outcome (20).

It is worth noting that not all forms of hemodynamic collapse require mechanical support. In our study, in addition to the 6 CPB recipients, 7 patients (53.8%, 7/13) who experienced circulatory collapse did not receive CPB support but recovered after receiving the comprehensive management mentioned above. Among them, 3 patients developed VF and a drop in blood pressure during or after rapid pacing for balloon predilation. During valve deployment, 1 and 2 patients suffered from VF and hypotension, respectively. While performing intraoperative CPB implantation during the management of circulatory collapse, we considered the following: (I) Refractory hypotension or persistent hemodynamic frequent occurred after high-dose vasopressor treatment before the operation. (II) During the valve deployment step, we first chose to release the valve without rapid pacing and then attempted cardiopulmonary resuscitation. (III) During the period before interposition of the valve device, a comprehensive rescue strategy was initiated via cardiopulmonary resuscitation, external defibrillation, and medication adjustment. The initial cannulation would only be started after 2 rounds of cardiopulmonary resuscitation had failed. (IV) In the event of circulatory collapse due to aortic root or left ventricular rupture, pericardial tamponade, or aortic dissection, CPB was immediately initiated. Particular attention should be paid to patients at high risk of rupture, especially those with an oversized valve, a heavily calcified annulus, or an annulus with an enhanced oval shape (21,22).

The choice of MCS device in the procedures was individualized not only based on the conditions of the patient, but also related to clinical setting, such as the urgency of the required support, the operator's experience, and hospital availability. Among patients with preoperative severe heart failure who needed long-term hemodynamic assistance after surgery, venous-arterial extracorporeal membrane oxygenation (VA-ECMO) was used. ECMO has the benefit of having fairly high availability and is thus

used in many centers. However, 1 study recorded a low success rate (56.5%) with ECMO, with 45.5% of cases requiring upgrading to CPB for open conversion (23). We used CPB, a well-established technique in our center, to manage all cases of refractory circulatory compromise, with a device success rate of 100%. Other studies have also used CPB for MCS (20), reporting mortality rates (9.6%) and complications (59.4%) comparable with those of ECMO (6,20,24). We acknowledge that there are limitations to the current study. First, our research has the associated weakness of all retrospective studies. Data were limited regarding the CPB group, as the procedure was only rarely applied. Second, the findings might have been affected by those TAVI procedures performed in the early experience of center. Nonetheless, our approach will inevitably improve through extensive practical training and accumulated local clinical experience.

Conclusions

LVEF was found to be an independent risk factor for emergency CPB implantation during the TAVI procedure. The need for emergency CPB support was associated with higher in-hospital mortality.

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Footnote

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional review board of Tianjin Chest Hospital [no. IRB-SOP-016(F)-001-02] and informed consent was obtained from all the patients.

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