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Original Article

Short- and Long-Term Outcome after Emergent Cardiac Surgery during Transcatheter Aortic Valve Implantation

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Objective: Our study aimed to evaluate short- and long-term outcomes of patients who required emergent conversion from transcatheter aortic valve implantation (TAVI) to open surgery. Besides, the reasons and procedural settings of emergent cardiac surgery (ECS) were also reported.

Methods: We retrospectively reviewed the patients who underwent TAVI in our institution between 2012 and 2019 and collected the clinical data of cases who converted from TAVI to bail-out surgery. Telephone and outpatient follow-ups were performed.

Results: Of 516 TAVI patients, 20 required ECS, and the bail-out surgery occurred less frequently with the increase in TAVI volume. The most common reason for conversion was left ventricular perforation (7/20, 35.0%). Thirty-day mortality was 35.0% in ECS patients. Kaplan–Meier survival curves showed that the cumulative survival rate was 65.0% at 1 year, 50.1% at 5 years in all ECS patients, and 77.1% at 5 years in patients who survived over 30 days after conversion.

Conclusion: Although the bail-out operation was performed immediately after TAVI abortion, ECS still associated with high 30-day mortality. The long-term survival benefit was seen in patients surviving from bail-out surgery. An experienced TAVI team is of crucial importance in avoiding ECS-related life-threatening complications and providing effective salvage surgery.

Keywords: bicuspid aortic valve, aortic stenosis, short-term follow-up, long-term follow-up

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Introduction

Transcatheter aortic valve implantation (TAVI) has emerged as a common alternative therapeutic option for patients with aortic stenosis who are suffering from intermediate-to-high operative risk[1)] and the long-term efficacy of this technology has been well established.[2,3)] TAVI procedure that is being a less invasive catheter-based procedure carries a potential risk of intraoperative complications such as transcatheter heart valve (THV) dislocation/embolization, aortic annular rupture, left ventricular (LV) perforation, etc. Emergent cardiac surgery (ECS), the timely conversion to sternotomy and necessary extracorporeal circulatory support, is an indispensable salvage measure to remediate these procedure-related life-threatening

events. In previous studies, the incidence, reasons, and short-term outcomes of ECS have been reported, and the emergency conversion from TAVI to open surgery associated with a high 30-day mortality ranging from 41.2% to 51.9%.[4–8] However, investigations into survival rate over long-term follow-up periods are still lacking in patients who survived from ECS.

In this study, follow-up was performed in patients who underwent emergent conversion from TAVI to open surgery to evaluate the short- and long-term outcomes. Besides, the reasons and procedural settings of ECS were also reported.

Materials and Methods

Study population

This research project was approved by the local medical ethical committee and all participating patients signed informed consent before TAVI. In the current analysis, we retrospectively reviewed the clinical data of patients who were treated with TAVI due to severe aortic stenosis or bioprosthetic valve failure between January 2012 and December 2019, which aimed to identify the individuals who underwent ECS[7] due to peri-interventional life-threatening complication. Of 516 TAVI patients within the institutional database, 20 cases who experienced ECS were identified and used for analysis. Follow-up information was obtained from telephone visits and outpatient clinical review until April 2020.

TAVI devices and ECS procedures

In converted patients, THVs were the SAPIEN-XT (Edwards Lifesciences, Irvine, CA, USA), the J-Valve (Jiecheng Medical Technologies, Suzhou, China), the Venus-A (Venus MedTech, Hangzhou, China), and the VitaFlow (MicroPort Scientific Corporation, Shanghai, China). Initial TAVI procedures were performed via transfemoral or transapical access. These implanted prosthetic valve systems and the procedures of THV implantation were described in the previous studies in detail.[9–13]

TAVI procedures were carried out under local/general anesthesia and guided by fluoroscopy and transesophageal echocardiography in a hybrid operating room. All patients were prepared and draped also for potential conversion to sternotomy. Cardiopulmonary bypass (CPB) was prepared routinely and placed on stand-by during the procedures. If peri-interventional complications occurred, the decision about whether to perform ECS was based on the consultation of our TAVI team that is composed of one cardiac surgeon, one interventional cardiologist, one anesthesiologist, and one imaging cardiologist. The use of CPB depends on the patient's hemodynamic status. If severe hypotension persisted, the emergency initiation of CPB will be indicated. The surgical exploration was performed to evaluate the necessity of heart/aortic surgery and the result reported to the TAVI team, who will make the final decisions.

Definitions of ECS

ECS was defined as the cardiothoracic surgical intervention (with or without CPB) that was caused by acute TAVI complications requiring urgent repair of myocardial or aortic injury, aortic valve replacement, ascending aorta replacement, etc., within the first 24 hours after onset of initial TAVI procedure.[4] Surgical intervention for access-site complications (femoral artery or apex) were not included in this definition.

Statistical analysis

The normal distribution of continuous data was evaluated by Shapiro–Wilk test. Based on data normality or not, continuous variables were presented as the mean ± standard deviation or as median (interquartile range). Categorical variables were expressed as number (n) and percentage (%). Statistical analysis was performed using Fisher's exact test. Survival analyses were performed using Kaplan-Meier Analysis. All analyses used SPSS software, version 25 (IBM Inc., Armonk, NY, USA). Two-sided $p < 0.05$ was considered significant.

Results

The mean age of these patients was 74.40 ± 6.51 years, and 45.0% (n = 9) were males. Among them, the aortic valve was tricuspid in 11 individuals (55.0%), bicuspid in 9 individuals (45.0%). The mean Society of Thoracic Surgeons predicted risk of mortality score was 4.55%. The majority of the individuals (90.0%) had New York Heart Association (NYHA) functional class III/IV preoperatively. None of the patients underwent open heart surgery before TAVI procedure. One patient had atrial fibrillation and received anticoagulation therapy. Seven patients (35.0%) experienced prior stroke events. The baseline characteristics of ECS patients are shown in **Table 1** in detail.

Reasons for ECS

A total of 516 patients with AS or severely degenerated aortic valve bio-prostheses underwent TAVI during

Table 1 Baseline and procedural characteristics

Characteristics	Values
Baseline	
Age, years, mean ± SD	74.40 ± 6.51
Height, cm, mean ± SD	161.80 ± 9.49
Weight, kg, mean ± SD	58.95 ± 12.44
Male sex, n (%)	9 (45.0)
Hypertension, n (%)	12 (60.0)
Diabetes mellitus, n (%)	5 (25.0)
Atrial fibrillation, n (%)	1 (5.0)
Coronary artery disease, n (%)	11 (55.0)
Prior heart surgery, n (%)	0 (0)
Prior stroke, n (%)	7 (35.0)
STS Score, %, mean	4.55
Echo parameters, mean ± SD	
Mean pressure gradient, mm Hg	75.60 ± 22.01
Effective orifice area, cm^2	0.65 ± 0.32
Aortic annular diameter, mm	21.80 ± 2.07
LVEF, %	64.46 ± 6.21
TAV, n (%)	11 (55.0)
BAV, n (%)	9 (45.0)
NYHA functional class III/IV, n (%)	18 (90.0)
Usage rate of THVs (Total = 516)	
SAPIEN-XT	3.9%
J-Valve	8.9%
Venus-A	69.0%
VitaFlow	4.3%
Procedural settings	
Access, n (%)	
Transfemoral	17 (85.0)
Transapical	3 (15.0)
Pre-dilation, n (%)	20 (100.0)
Post-dilation, n (%)	4 (20.0)
Type of anesthesia used, n (%)	
General	9 (45.0)
Conversion to general	11 (55.0)
Fluoroscopy time, min, mean ± SD	27.40 ± 7.76
Contrast, ml, median(quartiles)	100.00 (80.00–147.50)
CPB, n (%)	14 (70.0)

BAV: bicuspid aortic valve; CPB: cardiopulmonary bypass; LVEF: left ventricular ejection function; NYHA: New York Heart Association; STS: Society of Thoracic Surgeons; TAV: tricuspid aortic valve; THV: transcatheter heart valve

the observation period. Among them, 20 (3.9%) patients underwent urgent conversion from TAVI to open surgery. There was a significant increase in TAVI volume per year in our institution. The incidence of ECS was highest (11.8%) in 2015. The conversion rate decreased with the increasing of TAVI experience (**Fig. 1**). Comparing with 2015, the incidence of ECS had a significant decrease in 2019 (2.6%, p = 0.032). The frequent complications mentioned was LV perforation (n = 7, 35.0%), THV embolization (n = 4, 20.0%), and aortic annular rupture (n = 4, 20.0%) (**Fig. 2**). Bicuspid aortic valve (BAV) is frequently

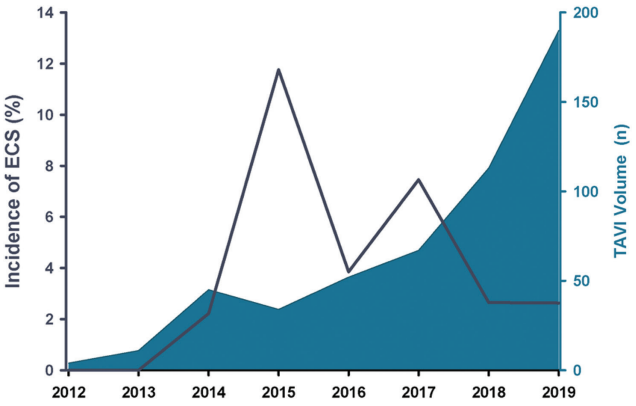

Fig. 1 The yearly volume of TAVI and the ECS rate during the study period. TAVI: transcatheter aortic valve implantation; ECS: emergent cardiac surgery

observed in the converted patients with LV perforation (71.4%).

Procedural settings

In converted patients, initial TAVI procedures were performed via transfemoral access in 17 cases (SAPIEN-XT, Venus-A and VitaFlow) and via transapical access in 3 cases (J-Valve). Stenotic valve pre-dilation was performed in all converted patients during the TAVI procedure, and four patients underwent post-dilation after THV implantation for the moderate paravalvular leak. General anesthesia was used for nine patients (45.0%) at the

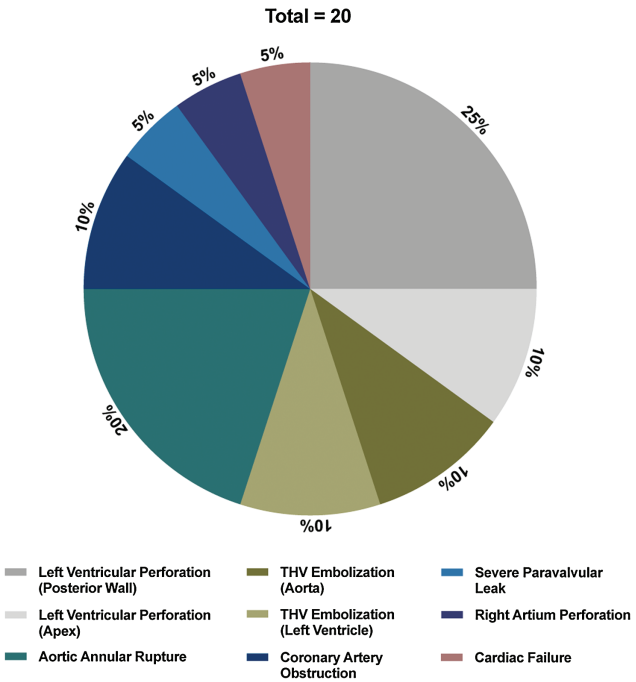

Fig. 2 Reasons for emergent cardiac surgery. THV: transcatheter heart valve

beginning of the initial TAVI procedure, and the local anesthesia was converted to general anesthesia in the remaining 11 patients (55.0%) before ECS performed. The mean time was 20.30 ± 5.66 minutes from the decision-making of ECS to sternotomy completed. CPB support was used in 14 patients to stabilize cardiac function.

After conversion to sternotomy, eight (40.0%) patients underwent aortic valve replacement with or without ascending aorta replacement. In seven patients with LV perforation, the injury repaired successfully in four individuals. Two of these patients died as a result of hemodynamics collapse during ECS procedure, and one patient died of multi-organ failure 17 days after ECS. Gauze packing was used to control bleeding for four patients who suffered from aortic annular rupture following with delayed sternal closure. The treatment measures succeed in three patients, and one patient died intraoperatively due to circulatory failure. Percutaneous coronary intervention was attempted in two patients with completed right coronary ostial obstruction, but it failed. During the ECS procedure, they died as a result of cardiogenic shock. Besides, procedure-related death was recorded in one patient who underwent surgical aortic valve replacement due to severe paravalvular leak. The detailed information of procedural settings is shown in **Tables 1** and **2**.

Short- and long-term outcomes of ECS patients

Procedure-related death occurred in five patients, and among those patients who survived the procedure, two died within 30 days, leading to a 30-day mortality rate of 35.0%. The incidence of 30-day mortality did not gradually decrease with yearly increasing TAVI volume during the study period (**Fig. 3A**). **Figure 3B** depicts the Kaplan–Meier survival curves of patients who survived over 30 days after conversion, which revealed that the cumulative survival rate was 90.0% at 2-year follow-up and 77.1% at 5-year follow-up. Kaplan–Meier survival analyzes of all ECS patients revealed that the cumulative patient survival rate was 65.0% at 1 year and 50.1% at 5 years (**Fig. 3C**). In patients who survived over 30 days after ECS, 92.3% (12/13) were in NYHA functional class I/II at 6-month follow-up. No patients reported major adverse cardiovascular events during the follow-up period.

Discussion

Our study reported the causes, procedural settings, and outcomes of ECS that occurred during TAVI procedure. We found that a considerable proportion of TAVIs (3.9%) was complicated by life-threatening conditions requiring ECS. The most common reason resulting in the urgent conversion was LV perforation. Although on-site ECS (19 cases) was performed without time delay and the procedure was completed by experienced surgeons (>300 heart surgeries per year), urgent surgery was still associated with a 30-day mortality of 35.0%. However, it is reassuring that the outcome in long-term follow-up was satisfactory in patients who survived over 30 days after conversion. The cumulative survival rate of them was 77.1% at 5-year follow-up.

Leading causes of ECS are different among related researches.[5,7] In our study, the leading cause of ECS was LV perforation, followed by THV embolization and aortic annular rupture. However, a meta-analysis of 46 studies including 9251 TAVI patients reported that THV dislocation/embolization was the most common complication for ECS.[14] We noticed that different kinds of THVs were used among these studies, which may be one possible reason for this discrepancy. Medtronic CoreValve and Edwards SAPIEN were the most common THVs[4,5,7,14] used in TAVI. In our study, 75% of ECS-patients used Venus-A prosthetic valve that is a tri-leaflet valve composed of three porcine aortic valves integrated into a titanium-alloy self-expandable stent frame.[12] Every THV has its unique design of valve stent frame. The shape and the expanding patterns of THV stent frame may influence the structural stability of the conjugation site between prosthetic valve stent and stenotic valve margins. Structural destabilization of the junction area may cause prosthetic valve dislocation leading to acute life-threatening events thereby.

BAV is more often observed in patients with aortic stenosis who candidate for TAVI in China. In this study, 45.0% of converted patients had a BAV. BAV is shown as adjacent cusp fuse into a single large cusp resulting in two aortic cusps, which lead to the eccentric limited opening of the aortic valve, comparing with normal three cusps.[15] The degree of eccentricity was further aggravated with the progression of thickening and calcification of the valve tissue, which may increase the probability that stiff guidewire or catheter pierces the myocardium after passing through the native aortic valve leaflets leading to a relatively higher incidence of LV perforation in BAV patients. Hence, the prevalence of BAV may also be a possible reason for the difference in incidence rate and the types of intraoperative complications among these studies.

Arsalan et al.[16] reported that the usage of a self-expandable device was a predictor for ECS attributing to

Table 2 Case descriptions

Patient number	TF/TA	Age	Gender	Valve Morpho-type	THVs	Cause for conversion	Time until sternotomy completed (min)	CPB	Days ICU	30-day death	Time until death
1	TF	67	Male	TAV	Venus-A	Coronary obstruction	19	YES	—	YES	8 hours
2	TF	80	Female	TAV	Venus-A	Right atrium perforation	40	NO	2	NO	—
3	TA	73	Female	BAV	J-Valve	THV embolization into LV	15	YES	15	NO	—
4	TF	78	Female	BAV	Venus-A	Aortic annular rupture	20	NO	—	YES	12 hours
5	TA	75	Female	TAV	J-Valve	THV embolization into TDA	11	YES	4	NO	—
6	TF	73	Female	BAV	Venus-A	Left ventricular perforation	18	YES	—	YES	4 hours
7	TF	78	Female	BAV	Venus-A	Aortic annular rupture	22	YES	9	NO	—
8	TF	58	Male	TAV	Venus-A	Left ventricular perforation	17	NO	3	NO	—
9	TF	84	Female	TAV	Venus-A	THV embolization into TAA	19	YES	15	NO	29 months
10	TF	80	Female	TAV	Venus-A	Left ventricular perforation	18	NO	17	YES	17 days
11	TF	72	Male	BAV	Venus-A	Cardiac failure	21	YES	15	NO	—
12	TA	81	Male	TAV	J-Valve	Aortic annular rupture	16	YES	36	NO	23 months
13	TF	71	Male	TAV	SAPI-EN-XT	THV embolization into LV	25	YES	6	NO	—
14	TF	84	Female	BAV	Venus-A	Left ventricular perforation	20	NO	18	NO	—
15	TF	75	Female	TAV	Venus-A	Severe aortic regurgitation	19	YES	15	YES	15 days
16	TF	77	Male	TAV	Venus-A	Aortic annular rupture	25	YES	10	NO	—
17	TF	64	Male	TAV	Venus-A	Coronary obstruction	20	YES	—	YES	1 hour
18	TF	76	Female	BAV	Venus-A	Left ventricular perforation	18	NO	2	NO	—
19	TF	72	Male	BAV	Venus-A	Left ventricular perforation	20	YES	6	NO	—
20	TF	70	Male	BAV	VitaFlow	Left ventricular perforation	23	YES	—	YES	7 hours

BAV: bicuspid aortic valve; CPB: cardiopulmonary bypass; ICU: intensive care unit; LV: left ventricular; TA: transapical; TAA: thoracic ascending aorta; TAV: tricuspid aortic valve; TDA: thoracic descending aorta; TF: transfemoral; THV: transcatheter heart valve

that the implantation of self-expandable devices requires more wire manipulation, increasing the risk of LV perforation. Shortening the time that the stiff guidewire is in LV during TAVI procedure could be an effective measure to minimize the risk for the LV perforation. Nielsen et al.[17] reported that no cases of LV perforation occurred in patients undergoing a modified TAVI that shorten the use of a stiff guidewire in left ventricle. Besides, pathophysiological factors that associate with LV perforation were also recognized in previous studies,[18] including a small LV cavity, a thin muscular wall, a hypercontractile state, and a narrow aorto-mitral angle. The detailed evaluation of preoperative images and meticulous handling of the guidewire/catheter is beneficial to perform TAVI safely and to reduce the occurrence of LV perforation.

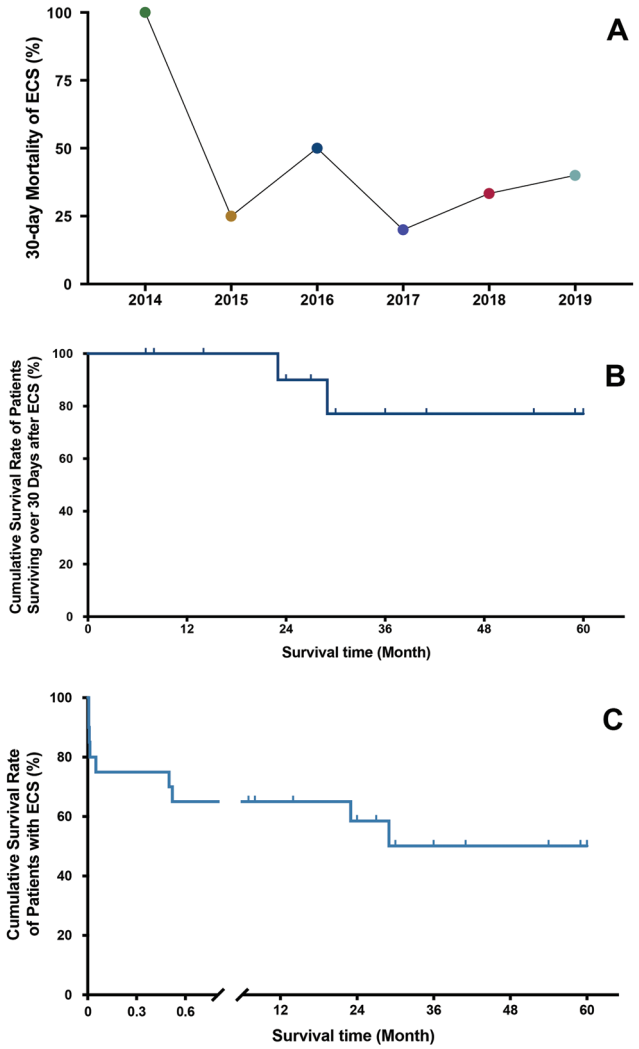

Fig. 3 30-day mortality of ECS per year during the study period (**A**); Kaplan–Meier survival curves for patients who survived over 30 days after ECS (**B**); and all patients with ECS (**C**). ECS: emergent cardiac surgery

We found that TAVI experience significantly influences the incidence of ECS during TAVI procedure. Previous studies[5,7] also reported that the rate of ECS was lower in the more recently treated patient cohorts compared with the earlier cohorts, which means that experienced high-volume TAVI centers could have a lower rate of ECS. Technical efficiency and proficiency in performing TAVI procedure are of crucial importance in the improvement of periprocedural outcomes. When the learning curve was completed, there will be a significantly increased success rate of THV implantation during TAVI procedure. It was reported that 25–50 cases were needed for one interventional cardiologist to overcome the learning curve.[19–22] In this study, we observed a significantly higher ECS rate in 2015, which may attribute to the use of a new device (J-Valve) in our institution. The ECS rate was 5.6% in the first multicenter study of J-Valve,[23] which is higher than the incidence of other THVs. In the multicenter study, the number of enrolled patients who had aortic stenosis in each center is no more than 30, which may be the reason that we got a higher ECS rate. When new centers start a new TAVI program, the excellent pre-clinical training and proctoring programs will be beneficial to decrease the incidence of ECS.

Considering relatively high 30-day morbidity of ECS, finding predictive factors may be helpful to prevent this life-threatening adverse event. However, complications requiring ECS showed to be unpredictable, and none of the predicators that have good repeatability was found in the previous studies.[4] The 30-day morbidity of ECS patients was not affected by TAVI experience. It may relate to underlying disease severity and the complexity of procedural complications. Life-threatening complications requiring ECS occur in ineluctable events surrounding TAVI, and the salvage operation should be an integral part of the logistic conditions during the TAVI procedure. These also emphasized that an experienced heart team appears to be of crucial importance to decrease the incidence of life-threatening complications and to increase the success rate of ECS with immediate access to surgical bail-out procedures.

Limitations

The present study was a single-center study with a relatively small sample size; therefore, a multi-center study with a larger number of patients and longer follow-up are warranted to confirm long-term outcomes of patients who underwent ECS. Further studies that aimed to analyze clinical outcomes of converted patients who were stratified by surgical risk may be more helpful in assessing the impact and efficacy of ECS.

Conclusion

Emergent conversion from TAVI to cardiac surgery occurred in about 3.9%, with LV perforation and THV embolization being the most common causes. The mortality of patients who underwent ECS during TAVI was as high as 35.0% within 30 days. However, the long-term survival benefit was seen in survived patients from this bail-out surgery. An experienced TAVI team could significantly decrease perioperative complications

associated with ECS and administer salvage regimens to remediate the life-threatening events.

Disclosure Statement

The authors declare that they have no conflict of interest.

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