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Emergency bailout surgery saves lives in high-risk patients with complications after TAVR

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Running title:

Emergency surgery in TAVR

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Abstract

Introduction: With the expanding the indication for transcatheter aortic valve implantation (TAVR), the value of access to on-site emergency heart surgery at performing centers needs to be assessed.

Aims: To evaluate postoperative mortality after surgical rescue post-TAVR, in a population at high surgical risk.

Methods: Retrospective analysis of a cohort of patients included in the France-TAVI registry who had undergone TAVR with the latest generation valves between January 2017 and February 2020.

Results: Among the 968 patients undergoing TAVR, 6 patients (0.62 %) were identified as candidates for surgery: 3 in the peri-operative context and 3 during hospitalization . Four subjects were managed in a salvage situation, two due to tamponade, one due to aortic dissection and one due to aortic annulus rupture. One patient died of a delayed aortic annulus rupture and one patient presented a right coronary occlusion which was medically treated. All patients who underwent emergency surgery were discharged alive from the hospital.

Conclusions: In TAVR patients initially contraindicated for surgery, emergency bailout surgery could be performed successfully with all patients discharged alive. Access to on-site heart surgery represents a life-saving resource for TAVR centers.

Key words : Transcatheter Aortic Valve Replacement (TAVR), Transcatheter Aortic Valve Implantation (TAVI) cardiac surgical procedure, aortic stenosis.

List of abbreviations :

- EKG: electrocardiogram
- LVEF: left ventricle ejection fraction
- MACE: major adverse cardiac event
- NYHA: New York heart association
- VARC: Valve Academic Research Consortium
- TAVR: transcatheter aortic valve replacement

Introduction

Transcatheter aortic valve implantation (TAVR) is an established technique for the treatment of symptomatic aortic stenosis in patients with intermediate to high surgical risk. The indications have expanded recently, to include patients at low surgical risk¹. This expansion implies a need to consider all potential complications of the procedure in order correctly to assess eligibility and risk profile. Surgical conversion during TAVR is rare², ranging from 0.76% to 1.17% in the latest European and US registries, but with an estimated mortality rate of 50% at 30 days^{3,4}. These reports evaluated cohorts managed between 2011 and 2016. The main complications requiring emergency cardiac surgery were left ventricular perforation or rupture with the guidewire (in-hospital mortality 51%), annulus rupture (in-hospital mortality 62%), prosthesis migration (in-hospital mortality 22%) or aortic dissection (in-hospital mortality 52%)³. Surgical procedures that can be performed without extracorporeal circulation are associated with an in-hospital mortality of 40%, rising to 55% if extracorporeal circulation is required⁴.

The extension of TAVR procedures to centers without cardiac surgery is debated, with some publications⁵ reporting similar results in centers with or without on-site surgery.

The aim of the present analysis was to assess the prevalence of surgical bailout during TAVR, as well as outcomes during long-term follow-up of high-risk patients experiencing serious TAVR complications requiring emergency cardiac surgery.

Methods

Study population

All patients undergoing TAVR at the University Hospital of Clermont-Ferrand between Jan 2nd, 2017 and Feb 28th, 2020 were included in this study. The indications for TAVR were reviewed by the Heart Team ⁶. All patients provided written informed consent to collecting and processing their data within the framework of the FRANCE-TAVR registry (NCT01777828).

Data collection

The FRANCE-TAVI database is administered by the French Society of Cardiology (SFC) and accessed through a dedicated web-based interface. For the current analysis, collected data included clinical characteristics of patients, indication for TAVR, procedural data, type of valve implanted and procedural complications as well as early complications. In particular, valve migration, embolization, vascular complications and bleeding, as well as VARC endpoints (Valve Academic Research Consortium 2 criteria) ⁷ were recorded. For surgically managed complications, we also recorded the surgical procedure performed, the duration of hospitalization and post-operative care.

Endpoints

The main objective was to determine the rate and outcomes of peri-procedural surgically managed complications. We also assessed all-cause hospital mortality, procedural complications, occurrence of ischemic stroke, cerebral stroke, myocardial

stroke, need for pacemaker implantation, and the MACE composite end point for the entire cohort.

Statistical analysis

Data are presented as frequencies and associated percentages for categorical variables and as mean \pm standard deviation or median and interquartile range for continuous variables. The assumption of normality (Gaussian distribution) was analyzed using the Shapiro-Wilk test. All statistical analyses were performed with R software (R Core Team (2021). R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria.)

Results

A total of 968 patients underwent TAVR between January 2, 2017, and February 28, 2020 and were included in the study cohort. Two-thirds of implanted valves were self-expandable: Corevalve Evolut in 517 cases (55.4%) and Acurate neo in 64 (6.9%), with the balloon-expandable Sapien 3 used in 352 patients (37.7%). The majority of the cohort (592 patients; 89.7%) had been evaluated by a gerontologist prior to TAVR. The main indications for TAVR are shown in table 1 together with preoperative clinical and echocardiographic characteristics. The main indication the procedure was frailty (660 patients). The mean age of the cohort was 80 years, with preserved LV systolic function (mean LVEF 58%). Patients were symptomatic in NYHA class III in 51% of cases and presenting with severe aortic stenosis (mean gradient 44.4 mmHg).

The procedural characteristics are listed in table 2. The incidence of peri-procedural complications is shown in table 3. Three peri-procedural complications were identified: one ring rupture diagnosed during the procedure, one tamponade, both of which were operated on immediately, and one occlusion of a small right coronary artery, treated conservatively. Three in-hospital complications were one dissection and one tamponade distally from the implant site, both of which were successfully operated on, as well as one suspected ring rupture which led to death before any surgery.

Four of the complications required emergency surgery and are described in detail below.

Peri-procedural complications:

Case report 1

A 79-year-old female patient who underwent implantation of Medtronic 26 mm Corevalve Evolut Pro with a right femoral approach presented tamponade due to a perforation of the tip of the left ventricle (image 1) by the Lunderquist ® guidewire (Cook medical). This guidewire was used due to tortuosity. Immediate percutaneous drainage was performed in the cath lab to restore correct hemodynamics. However, due to persistent pericardial effusion despite heparin antagonism, it was decided to carry out surgical management. Through sternotomy performed in the cath lab, we directly repaired the left ventricular apex wound with stitches without the need for a patch or extracorporeal circulation. The patient was transferred to the intensive care unit and to the conventional hospital ward on day 10. A pacemaker was implanted on day 18 post TAVR because of complete atrioventricular block. No adverse events have been reported so far at 6 months follow-up.

Case report 2

A 84-year-old patient whose TAVR was delayed, presented left heart decompensation. The heart team agreed on the indication for TAVR but noted severe and eccentric exuberant calcifications of the aortic valve (image 3). The approach and crossing of the aortic valve was complex. After pre-dilation, a 23mm Edwards Sapien 3 prosthesis was implanted. The implantation was performed without difficulty but a cardiogenic shock occurred. Aortography confirmed the annular rupture (image 4) and the patient was transferred urgently to cardiac surgery. Approximately 300 cc of recent intrapericardial thrombus was removed. Under extracorporeal circulation, the Sapiens prosthetic valve was explanted, as well as the massively calcified native valve. During this procedure we discovered a wound in the native left coronary annulus and a significant calcification of the valve. After treating the native annulus

with a pericardial patch, a surgical aortic valve replacement with 23mm Carpentier Edwards magna Ease prosthesis was performed. The post-operative course was uncomplicated, allowing the patient to be discharged on day 7 to the convalescent center.

In-hospital complications

Case report 3

A 80-year-old female patient with pre-implantation EKG in sinus rhythm and isolated complete right bundle branch block underwent by left femoral access the implantation of 26mm Edwards Sapiens 3 valve. She displayed complete atrioventricular block during the procedure which required an systolic pacing lead for approximately 6 hours. Despite the initial recovery, it was necessary to re-implant the pacing lead 2 days postoperatively due to numerous episodes of paroxysmal complete atrioventricular block. After 24 hours of temporary cardiac pacing, a tamponade with profound hemodynamic instability occurred and required emergency surgical treatment. The echocardiography confirmed thrombotic pericardial effusion causing compression of the right atrium and ventricle. The operation was carried out through sternotomy revealed and hematoma on the lower surface of the right ventricle. This was surgically evacuated without any evidence of a perforation. The patient was discharged 14 days later and no adverse events have been reported over 4 years follow-up.

Case report 4

A 81-year-old female patient received a Medtronic 26 mm Evolut Pro valve via right femoral access, but the implantation procedure was complicated by embolization into the ascending aorta during removal of the EnVeo Pro device after the delivery. A second Evolut Pro valve implantation was attempted through the first prosthesis. This second valve had difficulty passing through the first valve and was accompanied by mobilization of the first valve towards the aortic root. It was then decided to stabilize the first Evolut valve with a lasso (left femoral route) to facilitate the crossing and limit the risk of mobilization. However, the second valve could not progress through the first valve due to an unfavorable approach angle. Finally, a 23mm Edwards Sapien 3 prosthesis was implanted in a normal position through the first Corevalve utilizing the torque provided by the flexion system of the delivery device. The angiographic result at the end of the procedure was satisfactory with the Edwards prosthesis in normal position, not leaking, transvalvular gradient of 13mmHg and the Evolut R prosthesis in the ascending aorta above the sinuses of Valsalva. The patient experienced sudden chest pain postoperatively on day 3, and echocardiographic examination revealed a circumferential pericardial effusion. A CT scan was performed which revealed a type A aortic dissection between the two prostheses (image 2). The patient was immediately taken into surgery for an ascending aortic replacement in moderate hypothermia. The postoperative course was uncomplicated and the patient was discharged 13 days after TAVR implantation and 10 days after cardiac surgery. She is still being followed-up 2 years later.

Discussion

In this single-center TAVR cohort, we found a very low rate of peri procedural or intra-hospital complications requiring surgical management (0.62% of cases). Nevertheless, when surgery is necessary, the survival rate seems to be excellent, which is in contrast to other reports ^{3,4}. The issue of extending TAVR to centers without on-site cardiac surgery therefore remains topical in 2022.

The rate of TAVR procedures with complications requiring surgical management was 0.62% in our local cohort, a rate comparable to what was reported by Popma and Mack ^{8,9}, although some studies report higher incidences ¹⁰. The Pineda cohort of more than 47,000 patients, from the American Registry of Cardiac Surgery and Cardiology Societies, reports an incidence of conversions of 1%, and this rate decreased over time ⁴. The second largest cohort, from the European registry, shows similar results and a remarkable stability of complications throughout the inclusion period, which can be explained by the experience acquired by the teams ³. Valve embolization seems to be the most important complication leading to cardiac surgery ². This was not the case in our local series, where tamponade was the primary reason for seeking surgical bailout as described by Liang ¹¹

Emergency surgery for TAVR complications has a high reported mortality rate (between 25% and 35% at 1 month) ^{10,11} but as the procedure represents a rescue situation, the rate is not prohibitive. In addition, the majority of patients analyzed in these studies were patients considered to be at high surgical risk. TAVR was initially indicated in patients who were contraindicated to surgery. This contraindication is well characterized by surgical risk scores used. Unfortunately, the choice between conventional surgery and TAVR can not be fully informed by these risk scores, which

are based on major organ dysfunction and frailty. Indeed, current surgical risks scores correlate poorly with the outcome from TAVR.

The indication for TAVR expanded to include patients at intermediate and low risk after the Partner3 trial ⁹ ,¹². This younger cohort, compared to our cohort, had particularly a low rate of complications but the report did not present data on the need for emergent conversion to cardiac surgery. Unfortunately, there are no data to date on surgical conversions of TAVR in intermediate- or low-risk patients. However, if surgical bailout is questionable for high-risk patients, with complex surgical and intensive care after surgery, this may not be true for intermediate-risk and low-risk patients. Although rare, these complications are extremely serious and require urgent surgical management.

The literature on the question of extending TAVR to non-surgical centers is growing. Eggebrecht compared intra and postprocedural TAVR complications according to the availability of on-site cardiac surgeons ⁵. Again, this work focused on an elderly and fragile population, not reflecting the new indications for TAVR. In addition, patient characteristics were profoundly different between surgical and nonsurgical centers. The comparison between centers with and without on-site cardiac surgery was carried out on the basis of procedures implemented for coronary angiography. However, implementing TAVR in non-surgical centers is different from performing coronary angiography because of the extreme emergency of an infarction which is not comparable to that of TAVR management and because of the different complications between these two procedures. Although operator experience plays a key role in the safety of TAVR procedures ^{13,14}, the expansion to younger

populations, at lower risk for surgical conversion, makes the possibility of immediate surgical recourse essential.

In addition, there are no data on the aftercare of patients who developed complications in centers without on-site cardiac surgery. However, a delay in surgical management of these younger and lower-risk patients could have a catastrophic impact. Recently, the University of Leipzig evaluated its large cohort of TAVR patients from 2006 to 2020¹⁵. The researchers reported an emergent conversion rate of around 1% over this period, consistent with what has been shown in other studies^(3,4). The incidence decreased with experienced and trained operators. The team also found a very good prognosis in low-risk and intermediate-risk patients (1 year survival rate at 87.5%) who required surgical bailout, and confirmed the need for on-site cardiac surgery.

To avoid these structural complications, we strongly emphasize the importance of procedure planning. The occurrence of dissections and ruptures of the implantation zone carry an associated mortality of up to 48-75%. It has been proposed that preoperative assessment should be meticulously prepared, searching for calcific deposits (image 3) in the LV outflow tract, for example¹⁶.

The present study is limited by the size of the single-center cohort who required salvage surgery. However, the data shed light on the need for careful selection of high-risk patients who are managed by TAVR as an essential prerequisite before the expansion to intermediate and low-risk groups. Furthermore, we recommend a preoperative multidisciplinary heart team meeting, to refine patient selection and the management of complications, in order to not delay possible emergent conversion to

surgery or the rapid provision of surgical bailout in patients not requiring heart surgery. This decision could rely on predictors such as risk scores including STS and Euroscore II.

Conclusion

In the present cohort, the peri procedural and in-hospital rates of patients who required surgical bailout was extremely rare, at 0.62%. Nevertheless, the severity of the complications fully justifies the performance of TAVR in surgical centers, guaranteeing prompt management of an adverse event. The safety of TAVR in intermediate- and low-risk patients depends on operator experience, organization of processes and the need to limit implantation time without sacrificing the management of complications requiring emergent surgery. The development of specific scores for low-risk patients is an important need , in order to better treat these severe complications in the future.

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Authors contribution :

NC : conception/design, data analysis/interpretation, drafting article, critical revision, approval of article, data collection

NDO : conception/design, data analysis/interpretation, drafting article, critical revision, approval of article, data collection

AI : analysis/interpretation, data collection

PM : drafting article, critical revision, approval of article

RE : drafting article, critical revision, approval of article

GC : drafting article, critical revision, approval of article

BP : drafting article, critical revision, approval of article, statistics

GS : conception/design, data analysis/interpretation, drafting article, critical revision,
approval of article, data collection

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Tables

Table 1: Baseline characteristics

		Cohort (n=968)
Age (years)		80 (\pm 5.5)
Median age (years)		83 (79 – 86)
Male		516 (53%)
BMI (kg/m ²)		27.2 (\pm 7.7)
Euroscore log		13.6 (\pm 8.3)
<i>Median (Q1Q3)</i>		11.3 (7.96-16.9)
<10		394 (40.7%)
10-19		390 (40.2%)
20-39		162 (16.7%)
>40		20 (2%)
NYHA class	III	498 (51%)
	IV	10 (1%)
Previous CABG		46 (4.8%)
Previous aortic surgery		21 (2.2%)
Arteritis		142 (15%)
Chronic pulmonary disease		93 (9.6%)
Stroke		101 (10.4%)
Poor mobility		33 (3.4%)
Pacemaker		90 (9.3%)
Diabetes mellitus		266 (27.5%)
Renal impairment		32 (3.3%)
Atrial fibrillation		237 (24.5%)
Pulmonary hypertension (mmHg)	31-60	492 (51%)
	>60	56 (5.8%)
LVEF (%)		57,7 (\pm 11)
Median		60 (52-65)
<50%		180 (18.6%)
Aortic mean gradient (mmHg)		44,4 (\pm 14.5)
Frailty according to geriatric evaluation(%)		660 (68%)

Calcified aorta (%)	2 (0.2%)
Technical surgical contra-indication (%)	24 (2.5%)
Prohibitive surgical operative risk (%)	79 (8.2%)
High risk (%)	177 (18.3%)
Intermediate risk (%)	4 (0.4%)
Other (%)	21 (2.2%)

Table 2 : Procedure characteristics

Procedure performed in cathlab (%)	961 (99%)
Local anesthesia (%)	768 (79.4%)
General anesthesia (%)	197 (20.4%)
Femoral approach (%)	765 (79%)
Subclavian approach (%)	195 (20%)
Trans-apical approach (%)	5 (0.5%)
Planned valvular predilation (%)	29 (3%)
Valve type used	
<i>Autoexpandable valve</i>	603 (62.3%)
<i>Balloon expandable valve</i>	175 (37.7%)
VARC success (%)	961 (99.4%)
Aortic leakage >2 (%)	9 (0.9%)
Contrast agent volume used (mL)	142 (\pm 41)
Fluoroscopy duration (min)	11.4 (\pm 5)
Mean postoperative gradient (mmHg)	8.2 (\pm 4.3)

Table 3

<i>Peri-procedural complications potentially requiring cardiac surgery:</i>	
Annular rupture (%)	1 (0.1%)
Coronary occlusion (%)	1 (0.1%)
Tamponade (%)	1 (0.1%)
<i>In hospital complications potentially requiring cardiac surgery:</i>	
Aortic dissection (%)	1 (0.1%)
Delayed annular rupture (%)	1 (0.1%)
Tamponade (%)	1 (0.1%)
Vascular complication (%)	47 (4.9%)
Complication requiring vascular or cardiac surgery	10 (1%)
Stroke (%)	19 (2%)
Atrial fibrillation (%)	1 (0.1%)
Pacemaker implantation (%)	193 (19.7%)
Need for dialysis (%)	2 (0.2%)
MACE (%)	44 (4.5%)
In hospital mortality (%)	9 (0.9%)

Figure legends

Figure 1 (case 2)

Case of left ventricle (yellow dotted line) perforation by the stiff wire which is kinked at the apex (white arrow)

Figure 2 (case 3)

Attempted implantation of a second Evolut valve through a first valve embolized in the ascending aorta and held by a lasso (A). Crossing of the Evolut valve with the Edwards delivery catheter system (B). Aortography reveals aortic hematoma (white arrow) between the Evolut valve and the Edwards valve (C) which is confirmed by CT imaging (D). CT imaging after rescue surgery (E) with 3D rendering (F).

Figure 3 (case 4)

CT data of the annulus rupture case confirming a 410mm² annulus area (A). CT imaging in Valsalva sinus revealing important leaflet calcifications with protruding calcification in left coronary sinus (yellow arrow) (B and C). Initial aortography (D) and localization of the calcification (yellow arrow) during balloon aortic valvuloplasty (E). Final angiography revealing annulus rupture with contrast product effusion (white arrow) (F).

