Incidence and outcomes of emergent cardiac surgery during transfemoral transcatheter aortic valve implantation (TAVI): insights from the European Registry on Emergent Cardiac Surgery during TAVI (EuRECS-TAVI)

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Key words: TAVI; TAVR; complications; conversion; surgery; death

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Abstract

Aims: Disastrous complications continue to occur during transcatheter aortic valve implantation (TAVI) ultimately requiring emergent cardiac surgery (ECS). Risks and outcomes of patients needing ECS during or immediately after TAVI are still underreported.

Methods and results: Incidence, risk factors, management and outcomes of patients requiring ECS during transfemoral (TF)-TAVI were analysed from a contemporary real-world multicenter registry. Between 2013 and 2016, 28,515 patients underwent TF-TAVI in 80 centres. Of these, 216 patients (0.8%) required ECS secondary to TAVI complications (age 82.4±6.3 years, 67.5% females, logEuroSCORE: 17.1%, STS-score 5.8%). The risk of ECS declined from 2013 (1.1%) to 2014 (0.7%) but remained stable since, while annual TF-TAVI numbers more than doubled. Leading causes for ECS were left ventricular perforation by the guidewire (28.3%) and annular rupture (21.2%). Procedural mortality of TF-TAVI needing ECS was 34.6%, in-hospital mortality was 46.0%. In-hospital mortality was highest in case of annular rupture (62%). Independent predictors of in-hospital mortality following ECS were age > 85 years (hazard ratio (HR) 1.87, 95%CI [1.02-3.45], p=0.044), annular rupture (HR 1.96, [0.94-4.10], p=0.060), and immediate ECS (HR 3.12, [1.07-9.11], p=0.037). One-year survival of the 114 patients surviving the in-hospital period was only 40.4%.

Conclusion: Despite increasing annual numbers of TF-TAVI, the need for ECS remains stable around 0.7%. Complications such as LV perforation or annular rupture prompted immediate ECS in 80% of cases. Half of the patients could be salvaged by ECS – nevertheless, one-year all-cause mortality was high even in those TF-TAVI-ECS patients surviving the in-hospital period.

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Key words: TAVI, transcatheter aortic valve implantation, complications, surgery, bail-out.

Introduction

Severe complications that cannot be managed by catheter-based interventional approach but require emergent cardiac surgery (ECS) are the major concern when performing percutaneous cardiac interventions. Transcatheter aortic valve implantation (TAVI) uses large-bore catheters and stiff guidewires in fragile patients with severely calcified aortic valve stenosis. Earlier studies have reported on the risk for disastrous complications during TAVI, exceeding the spectrum and severity of that observed during percutaneous coronary interventions (PCI) [1, 2]. With the rapid technological development and refinements of TAVI devices, better pre-procedural imaging and increasing operators' experience, TAVI has evolved to a safer procedure than in the early days [3]. The risk of severe complications has constantly declined over recent years [4]. Nevertheless, complications that are often catastrophic such as annular rupture or aortic dissection ultimately requiring ECS continue to occur [2, 5, 6]. The incidence, risk factors and short- and longer-term outcomes of TAVI patients undergoing ECS are not known.

It was the aim of the present **Eu**ropean **R**egistry on **E**mergent **C**ardiac **S**urgery during **TAVI** (EuRECS-TAVI) to study the incidence, patient profiles and outcomes of ECS during TAVI in a contemporary real-world multicenter setting with additional focus on post-discharge outcomes.

Methods

Registry design. The **Eu**ropean **R**egistry on **E**mergent **C**ardiac **S**urgery during **TAVI** (EuRECS-TAVI) is an investigator-initiated independent multicenter observational registry conducted by a group of investigators from Europe, Israel and New Zealand. The registry was restricted to transfemoral (TF)-TAVI procedures only. In a first survey part, participants were asked for the annual number of TF-TAVI procedures performed from 2013 to 2016 and – if any – the annual number of patients needing ECS requiring full sternotomy. Next, details were obtained from those TF-TAVR patients that underwent ECS using dedicated case report forms – thereby collecting data about the onset of complication(s), baseline patient and procedural characteristics, the immediate postoperative course and longer-term clinical outcomes.

Definitions. Emergent cardiac surgery was defined according to the Valve Academic Research Consortium-2 (VARC-2) Consensus document as any conversion to open sternotomy during the TAVI procedure secondary to procedure-related complications [7]. All cardiac surgical procedures performed beyond the first 48 hours of TAVI were excluded. Immediate procedural mortality was defined according to VARC-2 as death <72 hours post-procedure.

Balloon-expandable TAVI valves included the Sapien XT and Sapien S3 valve (both Edwards Lifesciences, Irvine, CA, USA). Self-expandable TAVI valves included the CoreValve and CoreValve Evolut R (both Medtronic, Dublin, Ireland), Portico (Abbott, Santa Clara, CA, USA), ACURATE neo TF (Symetis, Ecublens, Switzerland), Direct Flow Medical Transcatheter Aortic Valve System (Direct Flow Medical Inc., Santa Rosa, CA, USA), JenaValve (JenaValve Technology Inc., Irvine, CA, USA), and Centera valves (Edwards Lifesciences, Irvine, CA, USA). The only mechanically expandable valve used in this study was the Lotus valve (Boston Scientific, Marlborough, MA, USA). Low-volume centers were defined as those performing < 50 TF-TAVI procedures per year while high-volume centers performed ≥ 50 TF-TAVIs annually.

Statistical analysis. Continuous variables are presented as mean ± standard deviation and/or median, as appropriate, and compared using the Student´s t-test including Levene´s test or ANOVA. Categorical variables are given as frequencies in percent and compared using either Fisher´s exact test or chi-square, as appropriate. The univariate Cox proportional regression hazard model was used to analyse the correlation between different variables and clinical outcome, i.e. in-hospital mortality in case of ECS during TF-TAVI. In order to prove an independent prognostic value of a variable, a multivariate Cox analysis was performed including those variables with a $p < 0.10$ in the univariate analysis. A p-value < 0.05 was considered statistically significant. Statistical analysis was performed using IBM SPSS Version 22.0.

Results

Eighty centers performing a total of 28,515 TF-TAVI procedures between 2013 and 2016 participated in this registry. During the study period, annual TF-TAVI numbers increased from 4,435 in 2013 to 9,896 in 2016. Of the 80 centres, 25 centres performing 3,821 TF-TAVI procedures (13.3% of total volume) reported no need for ECS in any patient; all but three centers had cardiac surgery departments on-site. Overall, 216 (0.8%) of the 28,515 patients underwent ECS secondary to TAVI complications. The proportion of patients needing ECS decreased from 1.1% in 2013 to 0.7% in 2014; this ECS rate remained stable at 0.7% for 2015 and 2016 (Figure 1).

Details were reported for 212 (98.1%) of the 216 patients undergoing ECS. Patients were 82.4 ± 6.3 years old and predominantly female (67.5%). Surgical risk scores were high with a mean logistic EuroSCORE of 17.1% and mean STS risk score of 5.8% (Table 1). The distribution of different valve types used in those TF-TAVI patients with need for ECS was similar to the distribution of valve types used in the total TF-TAVI population (Suppl. Figure 1).

ECS was performed for different TAVI complications with left ventricular (LV) perforation by the guide wire (28.3%) and annular rupture (21.2%) accounting for almost half of ECS cases. TAVI valve embolization/migration (12.7%), aortic dissection (11.8%), and other complications such as pacemaker perforation, coronary obstruction, pericardial tamponade or LV perforation by the delivery system were less frequent causes for ECS (Figure 2A). Temporal trends of the different types of complications necessitating ECS showed a stable incidence for most complications except for annular rupture, which markedly decreased over time (Figure 2B).

Most complications (>90%) occurred and manifested acutely during the TAVI procedure; only a minority (n=7, 3.3%) of complications leading to ECS became evident >24 hours after the procedure. Cardiac surgery was performed immediately in almost 80% of cases, usually directly on the TAVI table, either in the hybrid room or cath lab. Eighty-two (38.9%) patients were transferred to a surgical operating room. No patient was transferred to another hospital for ECS (Figure 3). In 42% of cases, the transcatheter heart valve (THV) was explanted and replaced by a surgical bioprosthesis.

Procedural mortality (< 72 hours) of ECS according to VARC-2 definition was 34.6% (73/211 patients). In-hospital mortality was 46% (97/211 patients, Figure 4A). Death usually occurred early

after ECS (5.5 ± 14.4 days, median 0 days) with half of the non-survivors (51/97, 52.0%) dying on the day of surgery. One-year survival of the 114 patients surviving the in-hospital period was 40.4 ± 4.9% (Figure 4A). In-hospital mortality rates were highest in case of ECS for annular rupture (62.2%) followed by coronary obstruction (54.5%), aortic dissection (52.0%), and LV guide wire perforation (50.8%) (Figure 4B).

At univariate Cox analysis, age > 85 years, use of balloon-expandable THV, annular rupture and acute ECS were significantly associated with in-hospital mortality in case of ECS (Table 2). In-hospital mortality was significantly higher in patients with acute-onset complications as compared to patients with complications manifesting after TAVI (92/187 (49.2%) vs. 5/17 (20.8%) respectively; p=0.013). None of the 7 patients with complications manifesting beyond 24 hours died after ECS. In accordance, acute ECS was associated with higher mortality than "semi-elective" (sub-acute) surgery (53.9% vs. 15.9%; p<0.001). Multivariate Cox analysis revealed age > 85 years (hazard ratio (HR) 1.87, 95% CI [1.02-3.45]; p=0.044), annular rupture (HR 1.96, 95% CI 0.94-4.10]; p=0.060) and acute ECS (HR 3.12, 95% CI [1.07-9.11]; p=0.037) to be independent predictors of in-hospital mortality in case of ECS (Table 2). The majority of TF-TAVI patients needing ECS without any of these three factors were discharged alive (84.6%) (Suppl. Figure 2).

Different THV types and their risk for complications leading to ECS. LV perforation by the guidewire was reported in a similar range for all three different THV types. Annular rupture occurred more frequently with balloon-expandable THV as compared to self-expandable or mechanically-expandable THV (32.0% vs. 15.4% vs. 0%, p<0.001). Consequently, in case of complications necessitating ECS with a balloon-expandable THV, these complications more often manifested acutely, prompting more acute ECS and resulting in a higher in-hospital mortality. Aortic dissection occurred more frequently with mechanically expandable THV (Table 3).

Low-volume versus high-volume centers. Low-volume hospitals performed a median of 28 TF-TAVI procedures per year (range, 3-49) while high-volume centers performed a median of 116 TF-TAVIs annually (range, 50-475) (p<0.001). There was no difference between the two groups with regards to incidence of ECS (low-volume: 0.75% vs. high-volume: 0.76%; p=1.00) as well as in-hospital mortality (53.1% vs. 44.7%; p=0.49) (Suppl. Figure 3).

Discussion

To the best of our knowledge, this contemporary, observational, multicenter registry comprises the largest series of patients requiring ECS during TF-TAVI (n = 216). Based on data of more than 28,000 TF-TAVI procedures, it can be stated that the incidence of severe procedural complications requiring ECS varied between sites, but was low with 0.7%. Despite increasing annual numbers of TF-TAVI procedures, the need for ECS remained stable over the past three years. Complications necessitating ECS typically manifested acutely during the TF-TAVI procedure and prompted immediate open heart surgery in 80% of patients. One third of patients died within 72 hours of ECS and almost half of the patients during the index hospitalization. Patients with annular rupture were at the highest risk with an in-hospital mortality rate of 62%. At one-year follow-up, only 40% of patients surviving the in-hospital period were still alive.

In the early phase of this registry (2013), the risk of ECS was 1.1% and very comparable to that from previous analyses reporting ECS rates between 1.1% and 1.2% [8, 9]. The data reported in this contemporary study suggest that rates of ECS are declining, from 1.1% in 2013 to a stable rate of 0.7% for the period 2014 to 2016. This is also consistent with a previous report from the German Quality Assurance Registry on Aortic Valve Replacement (AQUA) showing a similar decline in the risk of intra-procedural complications as well as in the need for ECS during TAVI from 1.2% in 2012 to 0.6% in 2014 [4]. Experience with TAVI has significantly increased since the early days of TAVI and even since the start of this registry. In our analysis, annual numbers of TF-TAVI have more than doubled between 2013 and 2016, a trend similar to that observed in Germany and the United States [10, 11]. This gain in experience, along with better TAVI devices and improvements in pre-procedural imaging, may have accounted for the lower incidence of severe complications needing ECS observed in recent years. In addition, also the lower risk profile of the more recently treated patients may have contributed to this lower incidence of ECS during TF-TAVI [4, 12].

In earlier studies, valve embolisation/migration was the leading cause for ECS [6]. In the present analysis, this complication was responsible for only 10-15% of all TF-TAVI cases ending up with ECS. This finding can most likely be ascribed to the use of newer-generation and often repositionable

THVs in this contemporary study as well as to the higher experience among operators nowadays. It was somewhat surprising to find that LV guidewire perforation was in fact the leading cause for ECS in this contemporary multicenter registry. Almost 1/3 of patients underwent ECS for LV perforation by the guidewire, and the incidence of this complication remained stable over the past few years. The recent availability of dedicated pre-shaped TAVI guidewires will hopefully result in a lower incidence of this specific complication and thus decrease the need for ECS in the future [13]. Annular rupture was found to be the second leading cause for ECS. Fortunately, we noted a downward trend for annular rupture as a cause for ECS in this study from 2013 to 2016. This may, in part, be attributed to more routine use of high-resolution computed tomography (CT) and, hence, more accurate aortic annulus sizing in current practice. The presence of severe calcifications extending into the left ventricular outflow tract has been identified as a risk factor for annular rupture [14, 15]. In such patients, the risk for annular rupture can be mitigated by using self-expandable THVs instead of balloon-expandable THVs. Use of CT also allows for more accurate sizing, thereby avoiding the use of oversized balloons and/or valves [16-17]. Finally, there is an increasing trend towards less pre-dilatation of the native aortic valve and - if performed at all – more use of undersized balloons, which may further contribute to a lower incidence of annular rupture [18].

Our data further indicate that specific complications may be more frequent with some type of THV devices. Annular rupture was more frequently observed in patients treated with balloon-expandable THVs, whereas aortic dissection was more commonly seen when using mechanically expandable THVs. A THV choice tailored to the risk profile of the patient may further decrease the number of severe complications resulting in ECS – e.g. avoiding balloon-expandable THVs in those patients with severe calcifications extending into the left ventricular outflow tract or avoiding the mechanically expandable Lotus™ THV with a stiff delivery system in those patients at risk of aortic dissection (e.g. aortic aneurysm, coarctatio-like aortic arch in bicuspid aortic valves); however, this demands the knowledge and availability of multiple THV types in a center.

As reported earlier, mortality among TF-TAVI patients needing ECS was high, mainly reflecting the seriousness of the complication that mandated emergent ECS [19]. Nevertheless, more than half of the patients with disastrous TAVI complications could be salvaged by ECS. The observed in-

hospital mortality of 46% was almost identical to previous studies reporting 30-day mortality rates of 46% to 52% [6, 8, 9]. Mortality after ECS was higher among patients aged > 85 years and those with annular rupture and needing immediate ECS. In-hospital mortality in patients without these three characteristics was only 15.4%. In accordance to previous reports, we noted differences in in-hospital mortality rates depending on the underlying complication causing ECS. Patients with annular rupture had the highest mortality of 62%; this is in line with data from the European SOURCE registry and the German TAVI registry reporting 30-day mortality rates - in smaller number of patients - of 57% and 67%, respectively [6, 8]. Annular rupture continues to be the deadliest TAVI complications. Other complications such as coronary obstruction, aortic dissection, as well as LV perforation by the guidewire were also associated with high in-hospital mortality exceeding 50%. A better understanding and preparation to manage these kinds of complications [20] as well as less frequent use of general anaesthesia for TF-TAVI procedures may have the potential to further decrease mortality in these patients.

Clinical implications. Our analysis has several potential clinical implications. First, disastrous complications requiring ECS during TAVI are rare, occurring in <1% of patients in contemporary TAVI practice. Although half of the patients with such complications were salvaged by ECS, prevention of complications needing ECS remains the most important strategy for improving outcomes of TAVI patients. Improved pre-procedural imaging to identify patients at higher risk of specific complications and subsequent individual tailoring of the TAVI procedure may help to reduce fatal complications. The unexpected high rate of LV guidewire perforations can probably be reduced by using dedicated stiff guidewires with pre-shaped curves. Finally, vigilance for complications may allow earlier identification and result in a better management of these complications. Altogether, this extra knowledge should result in continuously improving outcomes in the near future.

Limitations. Despite being the largest series of TF-TAVR patients needing ECS, our registry is mainly limited by the (still) modest number of ECS patients as well as its observational, retrospective design. All data were self-reported by the centers/investigators without on-site data verification. This study only focused on mortality, other important outcomes such as quality of life and functional status were not investigated.

Conclusion. ECS during TAVI is a rare event that is needed in <1% of TF-TAVI patients. Complications necessitating ECS mainly comprised of LV guidewire perforation, annular rupture, valve embolisation/migration, and aortic dissection. Despite the high-risk profile of the patients, more than half of the patients could be salvaged by ECS. However, mortality varied with the type of complications with highest mortality seen in those patients with annular rupture. Overall, less than 25% of TF-TAVI patients undergoing ECS survived at one year, but survival was 40% among those discharged alive from the hospital. Prevention of severe complications should be the main focus in order to improve overall survival among patients undergoing TF-TAVI in the future.

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