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# Transcatheter aortic valve implantation without on-site cardiac surgery

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**Transcatheter aortic valve implantation without on-site cardiac surgery**

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## Resumo

**Introdução**: Atualmente já foram realizadas mais de 400.000 TAVI e o número continua a crescer a uma taxa de 40% ao ano. É recomendado que a TAVI esteja limitada a hospitais com cirurgia cardíaca institucional (iOSCS), acabando por restringir a sua expansão e aplicação. Com os avanços tecnológicos e um aumento esperado na demanda de TAVI, criou-se um forte debate sobre se a TAVI pode ser realizada sem suporte de uma equipa de cirurgia cardíaca no hospital.

**Objetivos**: Comparar as diferenças na TAVI entre hospitais com e sem iOSCS e identificar os fatores que afetam as taxas de conversão cirúrgica de emergência (ECS) e mortalidade pós-ECS.

**Métodos**: Foi realizada uma pesquisa na literatura entre 1 e 15 de outubro de 2021 usando a PUBMED e SCOPOS para identificar artigos relevantes. Os termos de pesquisa usaram os vocabulários controlados pelo MEDLINE e EMBASE.

**Resultados**: Um total de 17 estudos foram incluídos nesta revisão, com um total de 19.377 pacientes submetidos a TAVI em 100 centros com iOSCS, e um total de 2.281 pacientes em 44 centros sem iOSCS. Não houve diferenças estatisticamente significativas no sucesso do procedimento, taxas de mortalidade, taxa de ECS ou mortalidade a 30 dias após ECS comparando centros com e sem iOSCS. As causas da ECS foram avaliadas em 921 casos. As causas mais frequentes foram rutura ou perfuração cardíaca em 231 casos (25,1%), migração valvular em 190 (20,6%), rutura anular em 153 (16,4%), dissecção de aorta em 77 (8,4%), oclusão coronária em 63 (6,8%) e tamponamento em 29 (3,1%). Num total de 52.732 pacientes, a ECS foi necessária em 1.279 casos (0,8%), valor que na literatura varia de 0,4% a 3,9%. As taxas de mortalidade pós-ECS em 30 dias variaram entre 35% e 61,9%.

**Conclusão**: Não houve diferenças estatisticamente significativas entre os centros com e sem iOSCS nos parâmetros avaliados, além disso, houve uma tendência decrescente nas complicações com risco de vida com necessidade de ECS, que é inferior a 1%, e nos casos de necessidade de ECS os índices de moralidade permanecem muito altos. Portanto, o foco deve estar no controlo e mitigação dos fatores que contribuem para a ECS. Além disso, o efeito do tempo de espera para a intervenção por TAVI foi associado ao aumento das taxas de internamentos e óbitos. Tendo em conta estes dados e o aumento esperado da demanda para TAVI, devemos considerar o atual modelo de intervenção coronária percutânea sem iOSCS para a TAVI.

**Palavras-chave**: Substituição da válvula aórtica transcateter, Estenose Válvula Aórtica, Cirurgia Cardíaca, Prótese valvular cardíaca, Cardiologia Intervenção.

## Abstract

**Introduction**: TAVI has already been performed in over 400,000 patients worldwide and its implantation keeps growing at a rate of 40% annually. Nowadays, TAVI is restricted to hospitals with institutional on-site cardiac surgery (iOSCS). Nonetheless, technological advances and an expected increase on TAVI demand has created a strong debate about whether TAVI should be performed without on-site cardiac surgery support.

**Aims**: We seek to provide some insight on the possibility of performing TAVI without iOSCS by comparing outcomes between hospitals with and without iOSCS and by identifying the factors affecting the ECS and post-ECS mortality rates.

**Methods**: A literature search was performed between 1st-15th of October 2021 using PUBMED and SCOPOS to identify relevant articles. Search terms used the MEDLINE and EMBASE controlled vocabularies.

**Results**: A total of 17 studies were included in this review, with a total of 19,377 patients submitted to TAVI on 100 centres with iOSCS and a total of 2,281 patients submitted to TAVI in 44 centres without iOSCS. There were no statistically significant differences in procedural success, mortality rates, ECS rate or 30-day mortality after ECS comparing centres with and without iOSCS. ECS causes were evaluated in 921 cases. Most frequent causes were cardiac rupture or perforation in 231 (25.1%) cases, valve migration in 190 (20.6%), annular rupture in 153 (16.4%), aortic dissection in 77 (8.4%), coronary occlusion/STEMI in 63 (6.8%) and tamponade in 29 (3.1%). In a total of 52,732 patients reviewed, we estimated that ECS was needed in 1,279 cases (0.8%), with values described in the literature ranging between 0.4% and 3.9%. The post- ECS 30 day mortality rates varied between 35% and 61.9%.

**Conclusion**: There were no differences between with and without iOSCS centres in the evaluated parameters. Moreover, there was an overall decreasing tendency on life-threatening complications requiring ECS, which is below 1%, and in case of ECS need the mortality rates remain very high. Therefore, it seems that the focus should be on controlling and mitigating the factors contributing for ECS. Furthermore, it must also be noted that the effect of the waiting time to TAVI was associated with increased hospitalization rates and deaths. Taking all into consideration, we conclude that the current model of percutaneous coronary intervention without iOSCS should be considered for TAVI.

**Keywords**: Transcatheter Aortic Valve Replacement, Aortic Valve Stenosis, Cardiac Surgical Procedures, Heart Valve Prosthesis, Interventional cardiology.

## Abbreviation List

AQUA - German aortic valve replacement quality assurance registry

AS - Aortic valve stenosis

ASA score - American Society of Anesthesiology

CATH - Catheterization laboratory

CS - Cardiac surgery

ECS - Emergency cardiac surgery

ESC - European Society of Cardiology

iOSCS – Institutional on-site cardiac surgery

MDHT - Multidisciplinary heart team

OR - Operating room

PCI - Percutaneous Coronary Intervention

QOL - Quality of life

RCT - Randomized controlled trials

SAVR - Surgical aortic valve replacement

STS/ACC TVT Registry - Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry

TAVI - Transcatheter aortic valve implantation

TF - Transfemoral

TA - Transapical

VARC-2 - Valve Academic Research Consortium criteria

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## Introduction

The transcatheter aortic valve implantation (TAVI) has been introduced in 2002 by Cribier *et al*.[1,2] Since then, it became the main option for the treatment of severe aortic valve stenosis (AS) in patients that could not be submitted to traditional surgical aortic valve replacement (SAVR). In recent years, with the advance in technology and increased operator experience performing TAVI, the procedure has evolved into a promising and less invasive alternative treatment comparing to SAVR, with equivalent or even superior outcomes.[2] TAVI has already been performed in over 400,000 patients worldwide and implantations keep growing at a rate of 40% annually.[3]

Recently concluded and ongoing randomized controlled trials (RCT) have been demonstrating the safety and efficacy of TAVI - first in inoperable, and then in high-risk and intermediate, and lately on low-risk patients with symptomatic severe aortic stenosis.[2,4] Nowadays, TAVI can be considered the best approach in patients suitable for transfemoral (TF) access at increased/intermediate surgical risk (STS or EuroSCORE II ≥4% or logistic EuroSCORE I ≥ 10% or other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest irradiation).[4]

With the increasing indications for TAVI, and considering that the estimated prevalence of AS in more developed countries is about 4.5% corresponding to an estimated 16.1 million people aged ≥60 years, there are ≈1.9 million patients eligible for SAVR and 1.0 million patients eligible for TAVI.[5] Besides that, the burden of AS is expected to double within the next 50 years.[6] Moreover, the intervention needs to be fast because once the stenosis is severe, symptoms of dyspnoea, angina and syncope follow. Quality of life (QOL) declines and the prognosis is poor, with 50% of patients dead within 2 years of symptom onset and a mortality rate at 5 years of 97%.[7]

The guidelines define that the decision between TAVI and SAVR should be made exclusively by an experienced multidisciplinary heart team (MDHT), consisting of a cardiac surgeon, a cardiologist, an anaesthesiologist and, if necessary, a radiologist.[8,9] Moreover, the assessment of a patient's diagnostics and physical independence/frailty is a prerequisite and determines the perioperative risk and optimal treatment options. Once the patient is selected for TAVI, there are multiple minimally invasive access paths, including the transfemoral (TF), transapical (TA), transsubclavian, transcaval or the direct aortic approach, which can also be considered. In addition, there are numerous transcatheter aortic devices that specifically address the patient's anatomy and the interventional cardiologist's skills.[10]

Despite the MDHT, the 2021 Valvular Heart Disease Guidelines of the European Society of Cardiology (ESC) mandate that TAVI should be restricted to hospitals with both cardiology and cardiac surgery (CS) departments on-site (class IC recommendation).(8,11) This requirement is based on the need for a close cooperation between the heart team members for optimal patient selection, intervention, handling of complications, and pre- as well as postprocedural care. Besides that, the institutional on-site cardiac surgery (iOSCS) team could be required for prompt management of potential severe complications during or after TAVI, ultimately requiring emergency cardiac surgery (ECS).(8,11–13) Nonetheless, the risk of severe intraprocedural complications and procedural mortality has been constantly declining.(14) Thus, the need of ECS for complications during TAVI is currently lowering.(15)

The technological advances and an expected increase on TAVI demand has created a strong debate about whether on-site cardiac surgical support is mandatory at all or if a surgical team in the vicinity is sufficient to cover for complications during and after TAVI.(16) Thus, opening the door for performing TAVI not only in surgical centres, but also in any interventional unit, reducing the costs, having more proximity to the patient and shorter waiting lists.(16–18) During the past decade, there have been a few authors trying to clarify this question. There are two main reasons to justify the necessity of iOSCS: i) the MDHT approach to select the patients undergoing TAVI or SAVR(16) and ii) the management of complications during or after TAVI needing emergent cardiac surgery.(8)

In this review, we purpose to bring insight on the possibility of performing TAVI without iOSCS. To do this we want to: (1) compare the outcomes between hospitals with and without iOSCS; (2) evaluate the incidence of ECS during TAVI; (3) identify the factors contributing to the increase or reduction of the ECS incidence, and (4) study the impact of ECS on mortality rates.

## Methods

Literature search was done between the 1st and 15th of October 2021, using PUBMED and SCOPOS, to identify relevant articles. Search terms used the controlled vocabularies of MEDLINE and EMBASE alone or in combination with text words including “transcatheter aortic valve implantation”, “transcatheter aortic valve replacement”, “TAVI”, “TAVR”, “registry”, “Emergent cardiac surgery”, “Bailout cardiac surgery” and “on-site cardiac surgery”. References from the selected studies were manually searched to identify any other potentially suitable publications. The articles reviewed were time limited from 1st January 2010 to 1st October 2021 as a date of publication. A multistage assessment was used to determine if the articles would qualify for the analysis, as demonstrated in Figure *1*. In addition, all reports were automatically searched to find duplicates. Initially, only titles and abstracts were screened for publication type and we included in our study Randomized Clinical Trials, comparative studies, observational studies, and database registry reports and excluded review articles, case reports, letters and comments, articles comparing TAVI and SAVR, discussions about TAVI indications, and society guideline or consensus. Next, the full text versions of the selected articles were reviewed for data extraction. It were only included full articles in English, Spanish, and Portuguese. Article's evaluation and review was performed by one operator. Multiple reports of same databases were refined to only including the data with most information. The articles were then separated in 2 groups. The first one including only articles comparing outcomes between centres with iOSCS and without iOSCS or only data from no iOSCS centres (Table I), and the second one including the data from ECS conversion rates and ECS causes, as well as mortality outcomes (Table II and Table III).

We also calculated the total ECS rate of the studies included in this work Table IV using the total number of patients and the ECS data. Moreover, we calculated the incidence of causes leading to ECS on the articles who reported the causes (Table II).

## Results

As shown in Figure *1*, a comprehensive literature search identified 365 citations published between 1st January 2010 to 1st October 2021. After the duplicate's removal, 165 citations were eligible. During title and abstract screening, 108 studies were excluded due to irrelevant data (articles without TAVI references, comparison between TAVI and SAVR, TAVI complications, different TAVI outcomes, management of patients and complications during TAVI…). After full text review, it were excluded 39 articles - 16 because of the publication type, 9 study design, 5 language, 14 due to the lack of outcomes defined as ECS rates or mortality rates, 3 wrong patient population and 1 due to repeated patient data. A total of 17 studies were included in this review. In our first category, it were included 5 articles (data summarized in Table I) and in our second category, it were included 12 articles (data presented in Table II and Table III).

On Table I are presented the main results from our first category regarding the comparison between the TAVI outcomes from centres with and without iOSCS. On this dataset, a total of 19,377 patients were submitted to TAVI on 100 centres with iOSCS and a total of 2,281 patients were submitted to TAVI in 44 centres without iOSCS. Eggebrecht *et al*, used a case control analysis using only n=555 from either group(15) and Egger *et al*, used propensity scoring analysis using the same reasons as above, and used a n=290 from either group(13).

One study in particular, Eggebrecht *et al* in 2014, analysed the data from 1,432 patients enrolled in the German TAVI registry from 27 hospitals between January 2009 and June 2010. The patients were categorized in 2 groups. Group 1 - the patients from hospitals with iOSCS (n=19) and group 2 without iOSCS (n=8). In group 2 hospitals, 5 centres performed TAVI with a visiting heart surgery team (n=49) and 3 centres performed TAVI on the heart surgery team hospital (n=129). The annual average number of TAVI in group 1 was 44, and group 2 was 15. In all patients it was used the MDHT approach. Patients in group 2 were older, similarly symptomatic, and had similar risk profiles with respect to log EuroSCORE and American Society of Anesthesiology (ASA) score. The success rate according VARC criteria were similar and above 95% (98% group 1 vs 95% group 2). The ECS incidence was 20 in 1,253 (1.6%) in group 1, and 4 in 178 (2.2%) in group 2. Moreover, 3 out of 4 conversions in group 2 were in transapical TAVI in external surgical hospitals and a single case, 1 in 49, was observed during in-house TF TAVI. In group 1, the 30 day mortality rate in ECS patients was 45% and in group 2 it was 50%. Overall, 30 day and 1 year mortality were similar in both study groups, group 1: 8.3% and 20.4% vs. group 2: 6.2% and 17.4%. In conclusion, no statistically significant differences were obtained between centres with and without iOSCS regarding all the factors explored.[19] Again, in 2016, Eggebrecht *et al* made a new comparison between hospitals with and without iOSCS. In this study, it was used the data from the prospective German aortic valve replacement quality assurance registry (AQUA) collected between January 1st, 2013 and December 31st, 2014. The hospitals performing TAVI were divided in 2 groups, those with cardiology and cardiac surgery departments and those with cardiology but without cardiac surgery departments. In the hospitals without iOSCS, the MDHT was completed with visiting external cardiac surgical teams. In this study only TF TAVI patients were selected. In total, it were admitted 17,919 patients and 1,332 of these were treated in hospitals without iOSCS. Among hospitals without iOSCS only 6 departments in 2013 (32%) and 3 (14%) in 2014 performed >50 TAVI annually. In hospitals with iOSCS, the proportion of sites doing >50 TAVI was 74% in 2013 and 83% in 2014 (p<0.001 vs without iOSCS hospitals). The logistic EuroSCORE I was higher on hospitals without iOSCS: 23.2+15.8 vs 21.0+15.4%, (p<0.001). Significantly fewer low-risk (logEuroSCORE <10%) and more high-risk patients (logEuroSCORE >30%) underwent TAVI at non-CS hospitals (p< 0.001). Despite the mentioned above, the rate of intraprocedural complications was higher in the hospitals with iOSCS, 11.0% vs 8.4% (p=0.004). The intraprocedural complications likely to benefit from ECS (device malpositioning; device embolization, annular rupture, aortic dissection, coronary obstruction, and/or pericardial tamponade) were equivalent: 3.9% in hospitals with iOSCS and 3.4% in hospitals without iOSCS (p=*NS*). ECS was used more often in hospitals with iOSCS, 0.7% vs 0.3% (p=*NS*) although not having statistical significance. The rate of new permanent pacemaker implantation was higher in hospitals without iOSCS 19.8 vs 15.8% (p<0.001). In-hospital mortality of patients with complications likely to benefit from ECS was similar at hospitals without iOSCS and with iOSCS, 37.0% vs 33.7% (p=*NS*). In-hospital mortality of patients needing ECS for intraprocedural complications was 50% in hospitals without iOSCS and 62.5% in hospitals with iOSCS (p= *NS*). Because the differences between groups on patient characteristics the authors made a matched-paired analysis including n=555 patients and concluded that the only difference was the incidence of aortic regurgitation grade 2 or higher was larger in the no iOSCS hospitals group, 2.7% vs 1.1% (p=0.047).[15]

Another identical study was done by Egger *et al* in 2018 using the data from the prospective multicentre Austrian TAVI registry between 2011 and 2016. In this study were included 1,822 patients in the final analysis. 290 were treated in 3 hospitals without iOSCS and 1,532 were treated in 6 hospitals with iOSCS. In both groups every patient was discussed in MDHT and during TAVI it was present a team capable of ECS. There were significant differences between both groups. For instance, the logistic EuroSCORE surgical risk was significantly higher in no-iOSCS centres, 20.9% vs 14.2%. To overcome this patient differences, the authors decided to do a propensity matching analysis between all 290 patients from without iOSCS group and 290 patients from with iOSCS group and the procedural survival was 98.6% in both groups and the 30-day survival was not statistically significant between groups 93.1% in without iOSCS vs 93.8% in iOSCS group (p= *NS*). The only statistically significative differences were that the pacemaker implantation and prolongated hospital stay in no-iOSCS hospitals (>14 days) were higher 32.2% vs 19.0% (p<0.001) and 26.0 vs 14.5 (p<0.001), respectively.[13]

Other study, performed by Garrido *et al* in 2019, analysed data from 10 Spanish centres without iOSCS, across 5 regions, from a Multicentre Registry from Spain between May 2010 and May 2018. In all the cases it was involved a MDHT in the decision-making process with a consulting cardiac surgeon from a reference hospital and used a visiting on-site model during surgery. The average surgical risk of the population was moderated, as calculated by the Logistic EuroSCORE (14.3 +/- 5.3). The population was characterized by advanced age, high prevalence of frailty and most patients were deemed non-operable; a few have refused the surgery. TAVI was successfully performed in 371 patients (96.6%). ECS was needed in 1 case (0.3%), due to ventricular perforation and cardiac tamponade, with good outcome after surgery. During the procedure 3 patients died. The 30 day mortality was 6.1% (23 cases).[16] Another report from a single centre from Frankfurt, Germany, Gaffor *et al* analysed the data from their hospital records regarding all patients undergoing TAVI with a transarterial approach between 2005 and October 2012 with a visiting on-site surgical team. During this period 97 patients underwent TAVI with a mean log EuroSCORE of 21.6 ± 14.4 surgical risk and reported a case of cardiopulmonary resuscitation, tamponade in 2.1% of cases and a vascular complication rate of 16.5%. All complications were treated conservatively (12 out 16) or percutaneously (4 out 16). No procedural mortality was reported. Additionally, the authors report that the learning curve cases were included in this study. The 30-day mortality was 3.1%.[20]

**- Emergent Cardiac surgery (ECS) results**

For a better understanding of the primary necessity of on-site cardiac surgery team to address de ECS, we decided to investigate the more up to date ECS rates, the causes that can lead to ECS and the outcomes after ECS regarding mortality. Therefore, on Table II are displayed a total of 8 articles and it was calculated the incidence of the more prevalent causes of ECS. In total, it were evaluated 84,572 patients of whom 921 were submitted to ECS. The most frequent causes were cardiac rupture or perforation in 231 (25.1%) of the cases, followed by valve migration on 190 (20.6%), annular rupture on 153 (16.4%), aortic dissection in 77 (8.4%), coronary occlusion/STEMI on 63 (6.8%). The lowest cases were from tamponade 29 (3.1%) where 15 were counted as tamponade and tamponade after cardiac/ventricular perforation. A total of 163 (17.7%) were attributed to other less prevalent causes. On Table III were included 5 articles that reported only the number of patients and the ECS rates including a total of 68,160 patients, where 358 needed ECS. Using the data from Table II and Table III we calculated for a total 152,732 patients that ECS was needed in 1,279 cases, representing 0.8% of the cases, as represented on Table IV, ranging from a minimum of 0.4% to a maximum of 3.9%. From the data available, we searched for the values of 30 day mortality rates after ECS. These values were highly variable, ranging from a minimum of 35%[21,22] to a maximum of 61.9%.[10] It is worth to note that some authors instead of reporting 30 day mortality used in-hospital mortality rates.

We observed that the ECS rates have changed over time with a tendency to decline significantly across most of the studies. For instance, data analysis from larger multicentre studies as FRANCE 2 and FRANCE TAVI registries show that the device implantation success increased from 95.4% to 97.9% and the conversion to surgery rate decreased from 1.3% in 2010 to 0.45% in 2015 ($p<0.001$).[23] Moreover, data from the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry (STS/ACC TVT Registry) concluded that the incidence of ECS decreased significantly from 2011 with 1.25% to 1.04% in 2015 ($p=0.0088$).[24] In EuRECS-TAVI (European Registry on Emergent Cardiac Surgery during TAVI, an investigator-initiated independent multicentre observational registry conducted by a group of investigators from Europe, Israel, and New Zealand) the proportion of patients undergoing ECS decreased from 1.07% in 2013 to 0.70% in 2014, and this ECS rate remained stable at 0.68% and 0.73% during 2015 and 2016, respectively. In a more detailed analysis of this study, the ECS need at different centres varied between 0% and 6.7%, and 25 centres that performed 3,821 TF-TAVI procedures (13.3% of the total) reported no cases of ECS.[25] Single centre studies have shown the same tendencies, being that Fei Li *et al* had an ECS decrease from 11.8% in 2015 and reduced to 2.6% in 2019[21] and Arsalan *et al* had a decrease from 6% in 2011 to 1% in 2016.[26]

Some authors tried to identify patient related causes that could justify the reduction in ECS. From France registries, Auffret *et al* identified a significant Logistic EuroSCORE reduction in the patients submitted to TAVI from 23.2+/-14.7% in 2010 to 16.7 +/- 11.6% in 2015 ($p<0.001$).[23] Pineda *et al*, went a step further and identified as independent predictors of ECS female sex, hemoglobin, left ventricular ejection fraction, cardiogenic shock or use of a left ventricular assist device, salvage procedures (ECS, valve-in-valve procedure, pericardiocentesis…), and nonfemoral access site.[24] Lastly, Arsalan *et al* did not identified any patient-related factor for ECS as the clinical history and demographics of patients requiring conversion were very similar to those not requiring.[26]

However, when authors tried to identify causes related to TAVI procedure that could impact in decreasing ECS they concluded that in France registries the transfemoral approach increased from 75.2% to 83.0% ($p<0.001$). Another important factor was the need of transoesophageal echocardiogram and general anaesthesia that reduced from 64.1% to 26.7% and 70.3% to 47.2%, respectively. Additionally, it was identified a decrease from 72.1% to 54.8% of TAVI performed on the catheterization laboratory.[23] Although, another study concluded that there was no difference between ECS need in catheterization laboratory vs operating room with 0.4% vs 0.5% (p=*NS*), respectively, and a similar 30-day mortality in ECS patients, 43.3% vs 49.7% (p=*NS*) was found. Moreover, in high-risk surgical patients, the ECS was less likely in catheterization laboratory vs operating room, 0.2% vs 0.4% ($p = 0.04$).[27] Other studies pointed the non TF access routes as a factor for more ECS.[10,22,24] A single centre experience concludes that ECS was needed in 1.6% of TF-TAVI and 2.3% in TA-TAVI.[10] It is important to note that some of the authors stated the inclusion of the learning curves on the results.[10,21]

The post-ECS mortality-rates were very high when compared to a TAVI without ECS. As stated by Pineda *et al,* the all-cause in-hospital mortality was significantly higher in patients who required ECS, 49.64% vs 3.52% ($p <0.0001$). At 30 days, all-cause mortality was 50.0% vs 4.98% ($p < 0.0001$) [24]. In this study, predictors or differences between authors in the fatalities rates after ECS were not identified.

## Discussion

**- The outcomes of performing TAVI in centres with and without iOSCS**

Taking into consideration our literature research, summarized in Table I, we found no statistically significant differences on the outcomes in procedure success, 30 day mortality rates, ECS rate and mortality rates after ECS, when comparing centres with or without iOSCS. Moreover, the procedure success in every study was always above 95%. When we compare the 30-day mortality rate, we can see that the ECS need and the global mortality rates, as well as the post-ECS mortality rates were approximately the same, without statically significant differences. [13,15,16,19,20]

When comparing the mortality rates, Table I, we can clearly see that it is much higher when ECS is needed, going from a maximum of 8.3% on TAVI to a maximum of 50%[19] after ECS, but interestingly there is no differences in mortality between the ECS performed at hospitals with or without iOSCS[15,19]. This fact highlights the importance of focusing on strategies to reduce ECS cases, which will be further discussed in a section below.

Noteworthy, on all the centres without iOSCS the decision making was always based on a MDHT approach. Moreover, a cardiac surgery team was present during the TAVI using two different approaches: having a visiting heart surgery team[13,15,16,19,20] or performing TAVI in the heart surgery team hospital[19]. However, there is no available data regarding if it is possible to perform TAVI without the presence of a surgical cardiac team using other approaches, such as having an on-call surgery team from another hospital in the proximity in case of need. In addition, the establishment of rescue protocols in case of emergency catastrophic events during TAVI including cardiopulmonary resuscitation, femoro-femoral cardiopulmonary bypass and hemodynamic stabilization before definitive intervention could be enough to stabilize and transport a patient who needs cardiac surgery team support.

To the best of our knowledge, Eggebrecht *et al* published the only study comparing hospitals with and without iOSCS where patients were submitted to TF-TAVI or TA-TAVI. Regarding this case, 3 out of 4 ECS performed without iOSCS were when TA-TAVI was used on external hospital visits and only 1 of 4 was with TF-TAVI[19] , which clearly shows the impact of the technique used on ECS cases.

When comparing the TAVI volume, we can see that most hospitals without iOSCS were low volume centres with less than 50 TAVI/year[15], which is usually associated with worst results. Thus, could be the cause of the only differences stated by the authors: higher pacemaker implantation, 32.2% vs 19.0% (p<0.001), higher prolongated hospital stay (>14 days) 26.0% vs 14.5% (p<0.001),[13] and higher incidence of aortic regurgitation grade 2 or higher, 2.7% vs 1.1% (p=0.047) in centres without iOSCS.[15] Another important result is the fact that the rate of potentially needing ECS complications was equivalent between hospitals with or without iOSCS, 3.9% vs 3.4% in hospitals without IOSCS (p=*NS*).[15] Nevertheless, several other factors can have an impact in the need for ECS during the TAVI procedure and are discussed below, as we attempt to shed some additional light on these risks to anticipate and mitigate them, and ultimately try to clarify whether TAVI can be performed without on-site cardiac surgery and under what pre-requisites.

**- The types of valves used and the ECS need**

Balloon-expandable valves can be associated with higher risk of annular rupture[25,28] leading to ECS compared to self-expanding and mechanically expandable valves (32.0% vs 15.4% vs 0%, p<0.001)[25], while the mechanically-expandable are associated with more aortic dissections.[25] In single centres studies, Arsalan *et al* identified the self-expandable valve as a predictor for ECS (odds ratio 0.38, 95% confidence interval 0.16–0.90; p = 0.03) possibly due to the fact that the implantation of these devices requires more wire manipulation, increasing the risk of ventricular perforation,[26] and, Liang *et al* had higher incidence of catastrophic events during TAVI when compared to balloon-expandable transcatheter heart valve, (6.5% vs 2.3%, p = 0.003). In this case, the authors refer that the differences could be caused by the less experience in using the self-expanding valve.[29]

Some authors, considering this data, tried to purpose new strategies to further diminish the complications rates from TAVI. Addressing the complication of cardiac perforation by the guidewire, Roy *et al* suggested in 2013 that the introduction of a dedicated pre-shaped TAVI guidewire would result in a lower incidence of this specific complication and thus may decrease the need for ECS in the future even further.[30] Nowadays, the standard guidewires are already pre-shaped. In order to reduce annular rupture, Kim *et al* reported an increasing trend towards less predilation of the native aortic valve and more use of undersized balloons, which may further contribute to a lower incidence of annular rupture.[31] In the analysis of EuReCS-TAVI registry performed by Eggebrecht *et al*, it is suggested an approach on choosing the valve type according to patient characteristics. For example, avoiding balloon-expandable valves in those patients with severe calcifications extending into the LV outflow tract or avoiding the mechanically expandable valves with a stiff delivery system in those patients at risk of aortic dissection. Although, this type of patient management would make mandatory the availability and experience to work with multiple valve types on the same centre.[25] Moreover, the use of multidetector computed tomography (CT) by the MDHT for aortic root assessment and, hence, a more accurate valve sizing in current practice and identification of patients with high-risk anatomy for serious complications can play an important role on selecting patients for sites without iOSCS.[32]

**- The impact of the procedure volume in TAVI outcomes**

The analysis of EuRECS-TAVI refers no difference on ECS incidence between low volume centres (<50 TAVI/year) and high volume centres (>50 TAVI/year), 0.75% vs 0.76% (p=*NS*) and the post ECS in-hospital mortality was also not significantly different, 53.1% vs 44.7% (p=*NS*).[25] In opposition, Isogai *et al* had different results using Nationwide Readmissions Database 2012–2017 from USA with data from 82,764 patients. The authors concluded that low volume centres (<50 TAVI/year) had an incidence of open heart surgery of 1.81%. Medium volume centres, 50-99 TAVI/year, had 0.92% incidence, the high volume centres, 100-199 TAVI/year, had 0.72% and the Very High volume centres, >200 TAVI/year, had only 0.49% (p<0.001).[33] Similar results were obtained in 2014 data from AQUA registry from Germany with 9,924 patients obtaining an inverse relationship between the mortality rates and procedural volume without a specific cut-off (p<0.001). Average in-hospital mortality was half in highest-volume centres performing ≥200 TF-TAVI procedures annually as compared to low-volume centres with <100 procedures and intermediate for those with TF-TAVI volumes of >100 and <200 procedures. [34]

Taking these results in consideration, centres with higher TAVI volume reduce proportionally the ECS need and should be taken in account as a major factor contributing to the ECS reduction, thus having better outcomes after TAVI.

**- The recent time trends in ECS**

In this study we show an ECS incidence that can be highly variable in the last decade. Starting with a publication from a single centre study from Griese *et al* having a rate of 4.9% ECS but using mostly an apical approach to TAVI. All the other groups used only, or in the majority of cases, the transfemoral approach that has shown better overall results and lower complication rate.[35] Moreover, another single centre study from Fei Li *et al* shows a high ECS rate of 3.9% and attributes this discrepancy to other studies because of different valve use, as 75% of ECS-patients used Venus-A prosthetic valve.[21] The other studies presented an incidence rate ranging from 2.1% to values as low as 0.4% on the STS/ACC TVT registry and RISPEVA registry, and 0.5% in the FRANCE TAVI (see Table III). In our analysis of the published works, we obtained a total ECS rate of 0.8%, as shown in Table IV. Earlier data from a meta-analysis performed by Eggebrecht et al comprising data from 2004 to 2011, had an ECS rate of 1.1% that was marginally higher among TA-TAVI, and the 30-day mortality rate in patients needing ECS was 67.1%.[35] When we compare this result to the data from

Table II, Table III and Table IV there is a tendency in the decrease of ECS need but the 30-day mortality after ECS is still very high, ranging from 35.0% to 62.0%.

With a more detailed year by year analysis we can see that studies like the EuRECS-TAVI show a decrease in ECS from 1.07% in 2013 to 0.73% in 2016[25]. France registers an ECS rate of 1.3% in 2010 to 0.45% in 2015[23], and according to the STS/ACC TVT Registry, the ECS decreased significantly from 2013 to 2014, 1.43%, to 1.04% between 2014 and 2015 [24]. Interestingly, another study based in the same database shows a major decrease from 2.66% in 2012 to only 0.49% in 2017, (p<0.001) and the in hospital mortality after open-heart surgery did not significantly changed, 26.0% vs 23.5% (p=*NS*).[33] In this line, Arsalan *et al* demonstrated that the ECS incidence decreased from 6% in 2011 to only 1% in 2016.[26] On contrary, the RISPEVA study shows a stable ECS need between 2013-2015 variating from 0% to a maximum of 0.8%.[36] Altogether, these works show that with the technology advance and operator experience, the ECS rate is still decreasing to date to values as low as 0.4%.

**- The ECS conversion causes**

Comparing our results regarding ECS causes (Table II) to a meta-analysis (n=88) with data from 2011-2014[35], we found that cardiac wall perforation and ventricular perforation accounted for most cases contributing to ECS in our study, being responsible for 24.3%; in the meta-analysis only 13.6% (n=12) of the cases resulted in ventricular/atrial wall perforation rate and tamponade.[35] Valve embolization occurred on 20.6% vs 41% (n=36) that accounted as the most frequent cause of ECS in the meta-analysis.[35] Annular rupture was the third most common cause corresponding to 16.4% vs 6.8% (n=6).[35] Aortic dissection happened on 8.4% vs 15.9% (n=14).[35] Coronary occlusion/STEMI occurred on 6.8% of our causes vs 5.7% (n=5).[35] As we can see there are major difference between the two groups analysed. Moreover, Auffret *et al* reported using FRANCE 2 and FRANCE TAVI registry the evolution of the complications potentially needing ECS between 2010-2015. The cardiac tamponade rates increased overtime from 1.6% to 1.9% (p=0.027), and the coronary obstruction with STEMI significantly reduced from 0.6% to 0.1% (p<0.001). Over the years, annulus rupture variated between 0.2% and 0.5% (p=*NS*), aortic dissection was between 0.2% and 0.6% (p=*NS*), valve migration was between 1.1% and 1.4% (p= *NS*).[23] In the end, the most common cause leading to ECS was cardiac tamponade, followed by valve migration, aortic dissection, annulus rupture and coronary obstruction with STEMI. Importantly, this data does not translate to ECS numbers since not all events lead to ECS, because a part of them can be managed using percutaneous or conservative techniques and other part are immediately fatal. In fact, a Lang *et al*, reported an incidence of 2.5% (n=51) periprocedural catastrophic events but only 0.6% ECS, as presented in Table II. A total of 37.3% (n=19) experienced cardiac perforation and tamponade but only 7 needed ECS, the other 12 were successfully managed with pericardiocentesis. Of the 19.6% (n=10) that had coronary obstruction, 8 of them could be managed conservatively using percutaneous coronary intervention (PCI) and only one patient did not improve and required a surgical coronary artery bypass graft (CABG). Another 19.6% (n=10) patients experienced acute left ventricular failure but none of them needed ECS. A percentage of 13.7% (n=7) experienced annular rupture and only 2 were submitted to ECS. The device embolization occurred in 9.8% of the cases (n=5) and 3 of them needed ECS to retrieve the valve. In total only 13 patients needed ECS, a total of 0.6% of the 2,102 patients. However, 41.2% (n=21) of the patients with catastrophic cardiac events required stabilization by ECMO in the immediate perioperative period. The in-hospital mortality for patients undergoing ECS was 54.5%.[29]

As stated above, there are techniques that can be used to handle percutaneously many complications leading to ECS. Valve malposition or migration to the aorta can be managed using more recent repositionable or recapturable valves or using valve-in-valve procedure. Cardiac tamponade caused by perforation and some localized ruptures can be managed by pericardiocentesis. Coronary occlusion can be managed initially by PCI instead of CABG in majority of the cases.[20,29,37] However, aortic and cardiac rupture do not have percutaneous repair alternatives.[20]

Another important discussion relates to ways to avoid such complications. To accomplish this objective, it were identified independent predictors of ECS: increased hemoglobin, increased left ventricular ejection fraction, emergent or salvage procedures[24], female sex[24,38] and nonfemoral access.[24,39,40] Nowadays, the technological advances have allowed the use of repositionable valves aiming to reduce the rate of valve migration and  new guidewires aiming to reduce the risk of perforation. Also, assessing the patient characteristics prior to TAVI can preview possible complications leading to ECS, as an example accounting the annular calcification on choosing the valve type or adapting the valve dilatation to the risk of annular rupture.[20,29,37] Moreover, as high surgical risk patients have poor prognosis in case of ECS, the most important aspect is the need for the conservative or percutaneous management of the complications once they previously were not eligible for SAVR.

More recent clinical trials, such as PARTNER 3 that comprises a total of 496 patients submitted to TAVI, reported only 1 case of annulus rupture (0.2%) that died during procedure, 1 case of coronary obstruction that survived (0.2%) and 1 ventricular perforation (0.2%) that died after ECMO withdrawn.[41] Thus, showing that there still exists room to improve the ECS rate with the development of new generation valves.

**- The waiting list impact**

Another question requiring to be addressed is if the need of iOSCS during TAVI has impact on the waiting list, limiting the accessibility of patients to the technique. Elbaz-Greener *et al* demonstrated that clinical events and waiting times had a relatively constant relationship with mortality and morbidity.[17]

Albassam *et al,* in a population-level retrospective cohort study, in Canada, identified between April first of 2012 and March twenty fist of 2018, 8,098 patients referred to treatment of symptomatic AS with TAVI, and concluded the mean and median waiting times were 87 and 59 days, respectively. Moreover, there was an increase in waiting times ($p<0.001$) throughout time. The TAVI waiting time mortality was 5.2% and the cumulative probability of heart failure hospitalization was 7.7%.[42] Moreover, another study in Ontario, Canada, has shown that between 2015 and 2016 at the median waiting time of 80 days the cumulative mortality rate on the waiting list was 2% and the cumulative probability of heart failure requiring hospitalization was as high as 12% and increased proportionally to increased waiting times.[17] Considering this data, the Canadian Cardiovascular Society benchmarked the waiting time to 2 weeks for a patient deteriorating and 12 weeks for stable elective patients.[43] In the United Kingdom, in 2019, the median waiting times from referral to TAVI among 23 centres of the NHS was 141 days – 20 weeks resulting in 299 deaths in patients waiting for TAVI.[18] In Portugal, a single-centre retrospective study conducted by Marques *et al* concluded that in 120 patients referred for aortic valve implementation by SAVR or TAVI, between 2014 and 2018, 13 patients (11%) were hospitalized due to heart failure and 7 (6%) died in a median time of 3 months between referral and the occurrence of heart failure or death.[44] In Spain, 300 patients with severe aortic stenosis were referred to TAVI or SAVR in January 2014 and, by the end of the year, 42 patients did not get treated. From this patients, 34 remained in the waiting list and 8 died, of which 4 died in the first 100 days.[45]

All these data show the importance of attempted intervention in these patients and implementation of guidelines for optimal waiting list times. Patient stratification according to risk factors can avoid unnecessary deaths and hospital admissions before intervention. Moreover, reducing waiting times by implementation of TAVI on centres without iOSCS can be an effective solution, as the probability of ECS conversion related complications can be much lower that the probability dying in the waiting list. For a better understanding of the waiting list impact, it would be important to determine the time between beginning of symptoms until diagnosis of AS and an evaluation of the impact of longer waiting times in TAVI outcomes, however, this is beyond the current scope of this work.

**- The costs associated with having a heart surgery team during procedure**

To our knowledge, Droppa *et al* were the only authors so far that evaluated the impact on TAVI clinical outcomes and costs of performing TAVI with a minimalist heart team, comprised of two interventional cardiologists, two cardiac catheterization laboratory nurses and echocardiography staff and a surgical team on call, or with an extended heart team that includes a full surgical team. In this single centre study in Germany, the authors concluded that using an extended heart team approach during TAVI did not result in statistically better clinical outcomes but resulted in an index hospitalization cost increase of +€1604 driven by expenditure on physicians (difference +€581, $p<0.001$), medical technicians (difference +€372; $p< 0.001$) and medical supplies (difference + €244; $p = 0.001$). In case of need, the surgical team could be available in 5 minutes and the interventional cardiologists could immediately implant extracorporeal life support.[46] The safety and successes of the procedure is utterly important, but the optimization of human and financial resources is relevant too and, in this case, this study not only shows that TAVI interventions can be done successfully without the presence of a surgical team during the procedure but that it can improve the resource management without negatively impacting the procedure outcomes.

**- The case of the percutaneous Coronary Intervention (PCI) without on-site cardiac surgery**

The discussion about performing a procedure in centres with or without cardiac surgery is not new. PCI faced the same discussion. Recent articles have shown that performing PCI without iOSCS was non-inferior to performing PCI with iOSCS. Moreover, recent meta-analysis studies have shown that PCI centres without on-site cardiac surgery backup can achieve similar results compared with centres with cardiac surgery in outcomes such as the rates of all-cause mortality, emergency surgery, and serious complications for both primary and nonprimary PCI.[47,48] Moreover, it was reported that the need for ECS could be as high as 2.4% and 1.5%, (p=*NS*) after primary PCI, and 0.8% and 0.5% (p=*NS*), respectively, for centres with and without on-site surgery, after nonprimary PCI. Moreover, the tendency of higher emergency surgery rates in centres with on-site surgical backup could reflect lower thresholds for emergency surgery in these centres.[48]

Comparing the data from PCI studies to the data from TAVI studies we can see that the rationale behind expanding PCI to centres without iOSCS, based on the principle that centres without iOSCS have non inferior outcomes to centres with iOSCS, could also be applied to TAVI as recent studies have also shown that the outcomes in TAVI are identical.[13,15,16,19,20] Moreover, in the case of the PCI, the ECS rate when the first RCT studies were performed was higher, 0.5-2.4%,[48] than nowadays ECS rates during TAVI, 0.8%. This data of observational and retrospective studies on TAVI could serve as a base for more accurate RCT studies to confirm if we could safely use TAVI on sites without iOSCS.

## Limitations

A comparison between different studies investigating conversion rates, causes and the outcome of these type of procedures is complicated due to heterogeneous definitions used by the different authors. One of the main issues is whether a sternotomy alone during the TAVI or if a surgery during the first postprocedural hours are included in the analysis or elective periprocedural conversions (e.g., access site problems). The ECS causes reported variated between authors, thus, it was necessary to join patients with cardiac perforation with ventricular perforation and other localizations of perforation in one group. Moreover, some authors separately reported tamponade cardiac, including the ones caused by perforation. A specific definition has recently been released in the second report from the Valve Academic Research Consortium (VARC-2) that can overcome these problems in the future.(49) Furthermore, the differences in surgical risk is another potentially bias source. High surgical risk TAVI patients are so old and fragile that, in case of a severe complication, they either would not want conversion to conventional surgery or that they would not survive it anyway reducing the number of ECS attempts. Also, the quality of cardiosurgical back-up and the frequency of attempting ECS were not always stated. The studies analysed are observational and/or based in national registries that are naturally subject of bias. Moreover, there is bias when analysing the total ECS rate and the total causes for ECS once we do not account for important factors such valve type and include different approaches in addiction to TF-TAVI.

## Conclusion

In this study we reviewed the outcomes from performing TAVI in sites without iOSCS, concluding that there is no significant differences in procedural success, nor increase in mortality rates. Likewise, no higher ECS need or 30-day mortality after ECS were found. Moreover, there is a decreasing tendency on life-threatening complications requiring ECS, which is below 1%, and in cases of ECS need the 30-day morality rates remain very high 34%-62%. Therefore, it seems that the main focus should be on controlling and mitigating the factors contributing for ECS, which as we described previously can be associated with more high volume centres, better technology and better anatomy assessment of patients by the MDHT. Furthermore, the effect of the waiting time between clinical referral to TAVI was associated to the observation of increased adverse outcomes, such as hospitalization rates and deaths, thus it should be explored and taken into consideration when limiting the places that could perform TAVI. This fact associated with the expected increase on indications for TAVI and with the rise in the incidence of aortic stenosis will require, in a near future, a higher TAVI availability. Thus, we propose that there should be a discussion on the possibility of implementation of an approach where the MDHT select the patients for intervention on sites without iOSCS accounting for the risk factors for complications requiring ECS. Additionally, centres whitout iOSCS should implement alternative strategies for ECS and, in cases where ECS is necessary, protocols to stabilize the patients until a transfer or arrival of a cardiac surgery team must be established. The main goal should be decreasing the waiting times and consequently the patient's morbidity and mortality rate when waiting for TAVI while optimizing the cost-effectiveness of TAVI. Still, the most important approach should be to find ways to further reduce the risk of complications, as well as management strategies in case of the occurrence of unexpected events, preferably using percutaneous or conservative techniques for high risk patients or stabilization techniques until a cardiac surgery arrives when ECS can not be avoided.

## Appendix

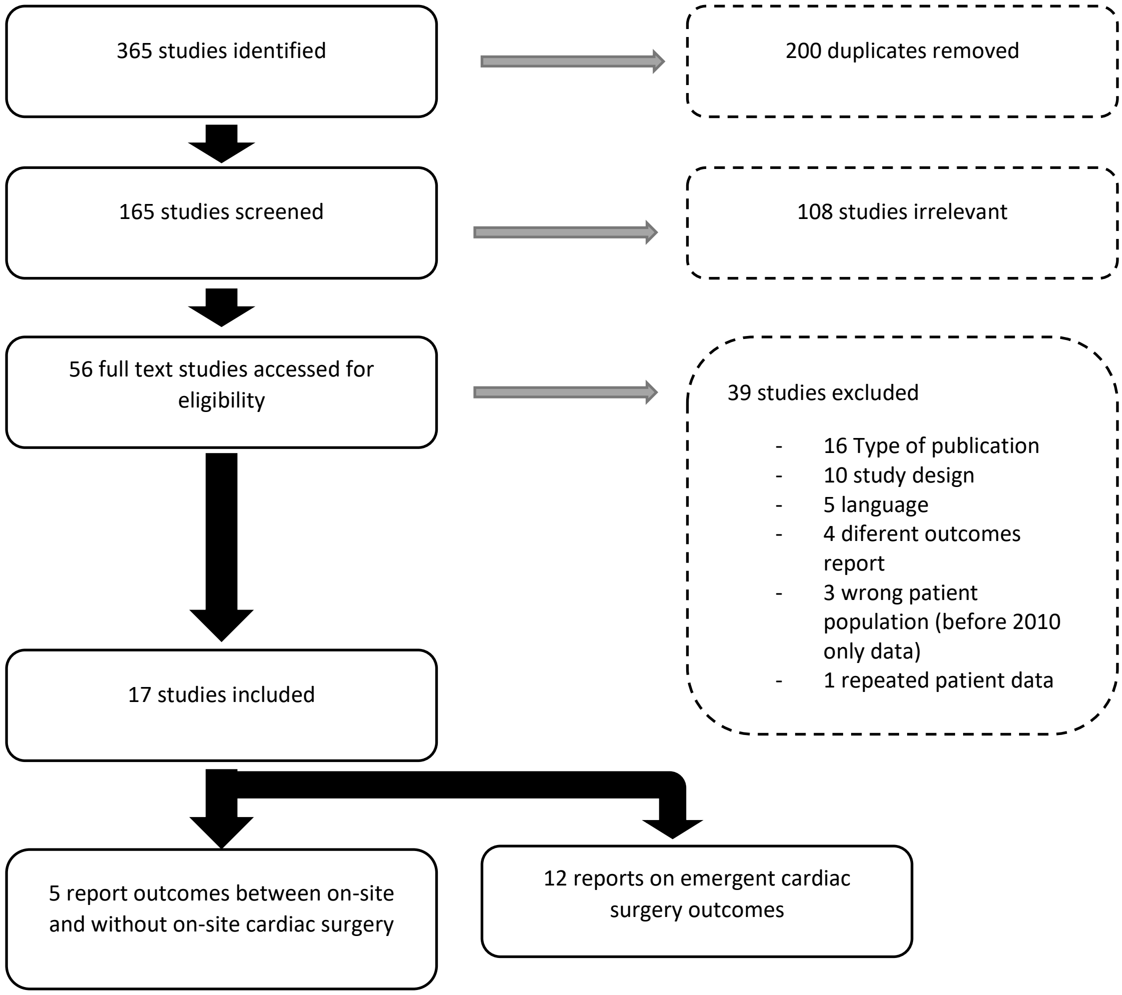


Figure 1 Strategy for data collection, categorization, and analysis.

Table I Summary of studies reporting TAVI in centres with and without on-site cardiac surgery. The articles included in this study were time limited from 1 January 2010 to 1 October 2021 as a date of publication.

| Study | Data Source | Type of facility | Patient Population | Access | Procedural Success % | 30 day mortality, % | ECS, % (n) | 30-day mortality post ECS % (n) | Logistic EuroSCORE (%) |
|---|---|---|---|---|---|---|---|---|---|
| Eggebrecht *et al*, 2014[19] | German TAVI registry 2009-2010 (n=1432) | With iOSCS | 19 sites-n=1258 | TF/TA | 98 | 8,3 | 1.6 (20) | 45 (9) | 21±14 |
| | | W/out iOSCS | 8 sites- n=178 | TF/TA | 95 | 6,2 | 2,2 (4) | 50 (2) | 20±11 |
| Gafoor *et al*, 2015[20] | Single center Frankfurt 2005-2012 | W/out iOSCS | n=97 | TF | 100 | 3,1 | 0 | ND | 21,6 +/- 14,4 |
| Eggebrecht *et al*, 2016[15] | AQUA, 2013-2014 N=17919 | With iOSCS | 75 sites n=16587 | TF | ND | 4,2 [1] | 0,7/ 0,9 [2] | 33,7 * | 21,0 +/- 15,4 |
| | | W/out iOSCS | 22 sites n=1332 | TF | ND | 3,8 [1] | 0,3 / 0,4 [2] | 37,0* | 23,2+/-15,8 |
| Egger *et al*, 2018[13] | Austrian TAVI registry,2011-2016 n=1822 | With iOSCS | 6 sites-n=1532 patients (n=290(1)) | TF | 98.6 | 6,2 [3] | ND | ND | 14.2 |
| | | W/out iOSCS | 3 sites-n=290 (15.9%) | TF | 96.9 | 6,9 [3] | ND | ND | 20.9 |
| Garrido *et al*, 2019[16] | Multicenter Registry Spain, 2010-2018 | W/out iOSCS | 10 sites-n=384 | TF | 96,6 | 6,1 | 0.3 (1) | 0 | 14.3 +/- 5.3 |

Notes: * In-hospital death for the composite of intraprocedural complications likely to benefit from ECS; [1] In Hospital death; [2] before/after case-control analysis n=555; [3] after propensity score matcing; W/out- without; TF: Transfemural access; TA: tranapical access; ND: No Data

Table II Summary of TAVI results from recent years, including ECS causes and 30-Day mortality after ECS. Only studies with data of publication between 1 January 2010 and 1 October 2021 are presented.

| Study Database, author | Year | Patients, n | ECS, % (n) | Valve Migration % (n) | Ventricular/ cardiac rupture % (n) | Annular rupture % (n) | Aortic dissection % (n) | Coronary oclusion % (n) | Tamponade % (n) | 30 Day mortality % |
|---|---|---|---|---|---|---|---|---|---|---|
| STS/ACC TVT registry [24] | 2011-2015 | 7,546 | 1.17 (558) | 22.3 (131) | 19.9 (117) | 14.2 (83) | 8.2 (48) | 6.1 (36) | ND | 50.0 |
| Single center, Fei Li *et al* [21] | 2012-2019 | 516 | 3.9 (20) | 20 (4) | 40 (8) | 20 (4) | 0 | 10 (2) | ND | 35 |
| EuRECS-TAVI, Eggbrecht *et al* [25] | 2013-2016 | TF=27,760/ TA=212 | 0.76 (212) | 12.7 (27) | 37.7 (80) | 21.2 (45) | 11.8 (25) | 5.2 (11) | 6.6 (by PM wire) + 2.8% (delivery system) (14) | 46,0 (in-Hospital mortality) |
| Single centre, P. Kiefer *et al* [10] | 2006-2013 | TF=1523/ TA=752 | TF-1.6 (25) TA-2.3 (17) | 26 (TF-7/TA-4) | 24 (TF-7/ TA-3) | 19 (TF-6/TA-2) | 7 (TF-0/TA-1) | 16 (TF-4/TA-4) | ND | 61,9 |
| Single centre, M. Arsalan *et al*[26] | 2011-2016 | TF/TA=1775 | 2.1 (32) | 28 (9) | (included in tamponade) | 16 (5) | 0 | 0 | 47 (15) | 44 |
| Single centre, Daniel P. Griese *et al*[22] | 2009-2012 | TF/TA=411 | 4.9 (20) | 0 | 25 (5) | 15 (3) | 5 (1) | 10 (2) | ND | 35 |
| German TAVI, Ralph Hein *et al*[49] | 2009-2011 | TF=1720/ TA=255 | 1.2 (24) TF- 1.0 (18) TA-2.4 (6) | 21 (5) | 17 (4) | 12.5 (3) | 8.3 (2) | 12.5 (3) | ND | 45.8 |
| Single centre. Yafen Liang *et al*[29] | 2015-2019 | TF-2041/ TA=61 | 0.6 (13) | 23.1 (3) | 53.8 (7) | 15.4 (2) | 0 | 7.7 (1) | Included in annular rupture and cardiac rupture | 54.5 (in-hospital mortality) |
| **Sum** | | **84,572** | **1.1 (921)** | **20.6 (190)** | **25,1 (246)** | **16.6 (153)** | **8.4 (77)** | **6.8 (63)** | **3.1 (29)** | |

Notes: TF: Transfemural access; TA: transapical access; ND: No Data; ECS: emergent cardiac surgery; ND: No Data.

Table III Summary of TAVI results from recent years (publication between 1 January 2010 and 1 October 2021) in studies only reporting ECS rate.

| Data Source, author | Year | Patients, n | ECS, % (n) | 30 Day mortality, % |
|---|---|---|---|---|
| FRANCE 2[23] | 01/2010-01/2012 | 4165 | 1.2 (50) | ND |
| FRANCE TAVI[23] | 01/2013-12/2015 | 12,804 | 0.5 (64) | ND |
| RISPEVA, A. Giordano *et al* [36] | 2013-2015 | 1157 | 0.4 (8) | ND |
| Single centre, Alessandra Laricchia *et al*[50] | 2007-2017 | 1348 | 1.2 (17) | 41.2 |
| STS/ACC TVT registry, Tom Nguyen *et al*[27] | 2015-2018 | CATH: 24343 | 0.4 (97) | 43.3 |
| | | OR: 24343 | 0.5 (122) | 49.7 |

Notes: ECS: Emergent surgery conversion; CATH: catheterization laboratory; OR: operating room; ND: No Data.

Table IV Determination of the total number of patients submitted to TAVI, from the studies presented in table II and III, as well as the total number of ECS conversion.

| | Patient n | ECS, n (%) |
|---|---|---|
| Table II | 84,572 | 921 (1.1%) |
| Table III | 68,160 | 358 (0.5%) |
| Sum | 152,732 | 1,279 (0.8%) |

## References


1. Cribier A. Development of transcatheter aortic valve implantation (TAVI): a 20-year odyssey. Arch Cardiovasc Dis. 2012 Mar;105(3):146–52.

2. Spears J, Al-Saiegh Y, Goldberg D, Manthey S, Goldberg S. TAVR: A Review of Current Practices and Considerations in Low-Risk Patients. J Interv Cardiol. 2020;2020:2582938.

3. Kourkoveli P, Spargias K, Hahalis G. TAVR in 2017-What we know? What to expect? J Geriatr Cardiol. 2018 Jan;15(1):55–60.

4. Ielasi A, Latib A, Tespili M, Donatelli F. Current results and remaining challenges of trans-catheter aortic valve replacement expansion in intermediate and low risk patients. IJC Heart and Vasculature. 2019.

5. De Sciscio P, Brubert J, De Sciscio M, Serrani M, Stasiak J, Moggridge GD, et al. Quantifying the Shift Toward Transcatheter Aortic Valve Replacement in Low-Risk Patients. Circ Cardiovasc Qual Outcomes [Internet]. 2017 Jun 1 [cited 2021 Oct 13];10(6). Available from: https://www.ahajournals.org/doi/abs/10.1161/CIRCOUTCOMES.116.003287

6. Iung B, Vahanian A. Degenerative calcific aortic stenosis: A natural history. Heart. 2012;98(4):iv7–13.

7. Généreux P, Stone GW, O'Gara PT, Marquis-Gravel G, Redfors B, Giustino G, et al. Natural History, Diagnostic Approaches, and Therapeutic Strategies for Patients with Asymptomatic Severe Aortic Stenosis. J Am Coll Cardiol. 2016;67(19):2263–88.

8. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S, Bauersachs J, et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease: Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). Eur J Cardio-Thoracic Surg [Internet]. 2021 Aug 28;60(4):727–800. Available from: https://doi.org/10.1093/ejcts/ezab389

9. Otto CM, Kumbhani DJ, Alexander KP, Calhoon JH, Desai MY, Kaul S, et al. 2017 ACC Expert Consensus Decision Pathway for Transcatheter Aortic Valve Replacement in the Management of Adults With Aortic Stenosis: A Report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. J Am Coll Cardiol. 2017;69(10):1313–46.

10. Kiefer P, Seeburger J, Noack T, Schröter T, Linke A, Schuler G, et al. The role of the heart team in complicated transcatheter aortic valve implantation: A 7-year single-centre experience. Eur J Cardio-thoracic Surg. 2014;47(6):1090–1096.

11. Vahanian A, Alfieri O, Andreotti F, Antunes MJ, Barón-Esquivias G, Baumgartner H, et al. Guidelines on the management of valvular heart disease (version 2012): The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). Eur J Cardio-Thoracic Surg [Internet]. 2012 Oct 1;42(4):S1–44. Available from: https://doi.org/10.1093/ejcts/ezs455

12. Cremer J, Heinemann MK, Mohr FW, Diegeler A, Beyersdorf F, Niehaus H, et al. Commentary of the German Society for Thoracic and Cardiovascular Surgery to the position paper of the German Cardiac Society - Quality criteria for the implementation of transcatheter aortic valve implantation (TAVI). Thoracic and Cardiovascular Surgeon. 2014.

13. Egger F, Zweiker D, Freynhofer MK, Löffler V, Rohla M, Geppert A, et al. Impact of On-Site Cardiac Surgery on Clinical Outcomes After Transfemoral Transcatheter Aortic Valve Replacement. JACC Cardiovasc Interv. 2018;11(21):2160–7.

14. Eggebrecht H, Mehta RH. Transcatheter aortic valve implantation (TAVI) in Germany 2008-2014: On its way to standard therapy for aortic valve stenosis in the elderly? EuroIntervention. 2016;11(9):1029–33.

15. Eggebrecht H, Bestehorn M, Haude M, Schmermund A, Bestehorn K, Voigtländer T, et al. Outcomes of transfemoral transcatheter aortic valve implantation at hospitals with and without on-site cardiac surgery department: insights from the prospective German aortic valve replacement quality assurance registry (AQUA) in 17 919 patients. Eur Heart J [Internet]. 2016 Jul 21;37(28):2240–8. Available from: https://doi.org/10.1093/eurheartj/ehw190

16. Roa Garrido J, Jimenez Mazuecos J, Sigismondi A, Cardenal-Piris R, Gallardo-López A, Vaquerizo B, et al. Transfemoral TAVR at Hospitals Without On-Site Cardiac Surgery Department in Spain: A Multicenter Registry. JACC Cardiovasc Interv. 2019;12(9):896–8.

17. Elbaz-Greener G, Masih S, Fang J, Ko DT, Lauck SB, Webb JG, et al. Temporal trends and clinical consequences of wait times for transcatheter aortic valve replacement: A population-based study. Circulation. 2018;138(5):483–93.

18. Ali N, Faour A, Rawlins J, Dawkins S, Appleby CE, Maccarthy P, et al. Valve for Life': Tackling the deficit in transcatheter treatment of heart valve disease in the UK. Open Hear. 2021;8:e001547.

19. Eggebrecht H, Mehta RH, Haude M, Sack S, Mudra H, Hein R, et al. Transcatheter aortic valve implantation (TAVI) by centres with and without an on-site cardiac surgery programme: preliminary experience from the German TAVI registry. EuroIntervention [Internet]. 2014 Sep;10(5):602–8. Available from: https://eurointervention.pcronline.com/article/transcatheter-aortic-valve-implantation-tavi-by-centres-with-and-without-an-on-site-cardiac-surgery-programme-preliminary-experience-from-the-german-tavi-registry

20. Gafoor S, Sirotina M, Doss M, Franke J, Piayda K, Lam S, et al. Safety of transcatheter aortic valve implantation in a hospital with visiting on-site cardiac surgery. J Interv Cardiol. 2015 Feb;28(1):76–81.

21. Li F, Wang X, Wang Y, Li X, Zhao S, Wu Y, et al. Short- and Long-Term Outcome after Emergent Cardiac Surgery during Transcatheter Aortic Valve Implantation. Ann Thorac Cardiovasc Surg Off J Assoc Thorac Cardiovasc Surg Asia. 2021 Apr;27(2):112–8.

22. Griese DP, Reents W, Kerber S, Diegeler A, Babin-Ebell J. Emergency cardiac surgery during transfemoral and transapical transcatheter aortic valve implantation: Incidence, reasons, management, and outcome of 411 patients from a single center. Catheter Cardiovasc Interv [Internet]. 2013 Nov 1;82(5):E726–33. Available from: https://doi.org/10.1002/ccd.25049

23. Auffret V, Lefevre T, Van Belle E, Eltchaninoff H, Iung B, Koning R, et al. Temporal Trends in Transcatheter Aortic Valve Replacement in France: FRANCE 2 to FRANCE TAVI. J Am Coll Cardiol. 2017 Jul 4;70(1):42–55.

24. Pineda AM, Harrison JK, Kleiman NS, Rihal CS, Kodali SK, Kirtane AJ, et al. Incidence and Outcomes of Surgical Bailout During TAVR: Insights From the STS/ACC TVT Registry. JACC Cardiovasc Interv [Internet]. 2019 Sep 23 [cited 2022 Jan 3];12(18):1751–64. Available from: https://pubmed.ncbi.nlm.nih.gov/31537276/

25. Eggebrecht H, Vaquerizo B, Moris C, Bossone E, Lämmer J, Czerny M, et al. 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). Eur Heart J. 2018;39(8):676–84.

26. Arsalan M, Kim WK, Van Linden A, Liebetrau C, Pollock BD, Filardo G, et al. Predictors and outcome of conversion to cardiac surgery during transcatheter aortic valve implantation. Eur J Cardio-thoracic Surg. 2018;54(2):267–272.

27. Nguyen TC, Keegan P, Nguyen S, Loyalka P, Kaneko T, Shah PB, et al. Balloon-expandable transcatheter aortic valve replacement outcomes by procedure location: Catheterization laboratory versus operating room. Cardiovasc Revascularization Med [Internet]. 2020;21(2):149–54. Available from: https://www.sciencedirect.com/science/article/pii/S1553838919302337

28. Barbanti M, Yang TH, Rodès Cabau J, Tamburino C, Wood DA, Jilaihawi H, et al. Anatomical and procedural features associated with aortic root rupture during balloon-expandable transcatheter aortic valve replacement. Circulation. 2013 Jul;128(3):244–53.

29. Liang Y, Dhoble A, Pakanati A, Zhao Y, Kork F, Ruan W, et al. Catastrophic Cardiac Events During Transcatheter Aortic Valve Replacement. Can J Cardiol. 2021 Oct;37(10):1522–9.

30. Roy DA, Laborde JC, Sharma R, Jahangiri M, Brecker SJD. First-in-man assessment of a dedicated guidewire for transcatheter aortic valve implantation. EuroIntervention J Eur Collab with Work Gr Interv Cardiol Eur Soc Cardiol. 2013 Jan;8(9):1019–25.

31. Kim WK, Praz F, Blumenstein J, Liebetrau C, Gaede L, Van Linden A, et al. Transfemoral aortic valve implantation of Edwards SAPIEN 3 without predilatation. Catheter Cardiovasc Interv Off J Soc Card Angiogr Interv. 2017 Jan;89(1):E38–43.

32. Hayashida K, Bouvier E, Lefèvre T, Hovasse T, Morice MC, Chevalier B, et al. Potential mechanism of annulus rupture during transcatheter aortic valve implantation. Catheter Cardiovasc Interv Off J Soc Card Angiogr Interv. 2013 Nov;82(5):E742-6.

33. Isogai T, Saad AM, Michihata N, Ahuja KR, Shekhar S, Abdelfattah OM, et al. Association of hospital procedural volume with incidence and outcomes of surgical bailout in patients undergoing transcatheter aortic valve replacement. Catheter Cardiovasc Interv [Internet]. 2022 Jan 1;99(1):160–8. Available from: https://doi.org/10.1002/ccd.29847

34. Bestehorn K, Eggebrecht H, Fleck E, Bestehorn M, Mehta RH, Kuck KH. Volume-outcome relationship with transfemoral transcatheter aortic valve implantation (TAVI): insights from the compulsory German Quality Assurance Registry on Aortic Valve Replacement (AQUA). EuroIntervention J Eur Collab with Work Gr Interv Cardiol Eur Soc Cardiol. 2017 Oct;13(8):914–20.

35. Eggebrecht H, Schmermund A, Kahlert P, Erbel R, Voigtländer T, Mehta RH. Emergent cardiac surgery during transcatheter aortic valve implantation (TAVI): a weighted meta-analysis of 9,251 patients from 46 studies. EuroIntervention J Eur Collab with Work Gr Interv Cardiol Eur Soc Cardiol. 2013 Jan;8(9):1072–80.

36. Giordano A, Corcione N, Biondi-Zoccai G, Berti S, Petronio AS, Pierli C, et al. Patterns and trends of transcatheter aortic valve implantation in Italy: insights from RISPEVA. J Cardiovasc Med (Hagerstown). 2017 Feb;18(2):96–102.

37. Laborde JC, Brecker SJD, Roy D, Jahangiri M. Complications at the time of transcatheter aortic valve implantation. Methodist Debakey Cardiovasc J. 2012;8(2):38–41.

38. Kodali S, Williams MR, Doshi D, Hahn RT, Humphries KH, Nkomo VT, et al. Sex-Specific Differences at Presentation and Outcomes Among Patients Undergoing Transcatheter Aortic Valve Replacement: A Cohort Study. Ann Intern Med. 2016 Mar;164(6):377–84.

39. Schymik G, Würth A, Bramlage P, Herbinger T, Heimeshoff M, Pilz L, et al. Long-term results of transapical versus transfemoral TAVI in a real world population of 1000 patients with severe symptomatic aortic stenosis. Circ Cardiovasc Interv. 2015 Jan;8(1).

40. Panchal HB, Ladia V, Amin P, Patel P, Veeranki SP, Albalbissi K, et al. A meta-analysis of mortality and major adverse cardiovascular and cerebrovascular events in patients undergoing transfemoral versus transapical transcatheter aortic valve implantation using edwards valve for severe aortic stenosis. Am J Cardiol. 2014 Dec;114(12):1882–90.

41. Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, et al. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. N Engl J Med. 2019 May;380(18):1695–705.

42. Albassam O, Henning KA, Qiu F, Cram P, Sheth TN, Ko DT, et al. Increasing Wait-Time Mortality for Severe Aortic Stenosis: A Population-Level Study of the Transition in Practice From Surgical Aortic Valve Replacement to Transcatheter Aortic Valve Replacement. Circ Cardiovasc Interv. 2020 Nov;13(11):e009297.

43. Asgar AW, Ouzounian M, Adams C, Afilalo J, Fremes S, Lauck S, et al. 2019 Canadian Cardiovascular Society Position Statement for Transcatheter Aortic Valve Implantation. Can J Cardiol. 2019 Nov;35(11):1437–48.

44. Marques A, Cale R, Cruz I, Joao I, Pereira A., Alegria S, et al. What is the risk of a patient with severe aortic stenosis while waiting for aortic valve intervention? Eur Heart J [Internet]. 2020 Nov 1;41(Supplement_2):ehaa946.1978. Available from: https://doi.org/10.1093/ehjci/ehaa946.1978

45. González Saldivar H, Vicent Alaminos L, Rodríguez-Pascual C, de la Morena G, Fernández-Golfín C, Amorós C, et al. Evolución de los pacientes con estenosis aórtica grave tras la indicación de intervención. Rev Española Cardiol [Internet]. 2019;72(5):392–7. Available from: https://www.sciencedirect.com/science/article/pii/S0300893218300976

46. Droppa M, Borst O, Katzenberger T, Krause R, Bramlage K, Bramlage P, et al. Clinical and economical impact of the presence of an extended heart team throughout the balloon-expandable transcatheter aortic valve implantation procedure. Clin Res Cardiol [Internet]. 2019;108(3):315–23. Available from: https://doi.org/10.1007/s00392-018-1359-3

47. Zia MI, Wijeysundera HC, Tu J V, Lee DS, Ko DT. Percutaneous Coronary Intervention With vs Without On-Site Cardiac Surgery Backup: A Systematic Review and Meta-analysis. Can J Cardiol [Internet]. 2011;27(5):664.e9-664.e16. Available from: https://www.sciencedirect.com/science/article/pii/S0828282X10000735

48. Lee JM, Hwang D, Park J, Kim KJ, Ahn C, Koo BK. Percutaneous Coronary Intervention at Centers With and Without On-Site Surgical Backup: An Updated Meta-Analysis of 23 Studies. Circulation. 2015 Aug;132(5):388–401.

49. Hein R, Abdel-Wahab M, Sievert H, Kuck KH, Voehringer M, Hambrecht R, et al. Outcome of patients after emergency conversion from transcatheter aortic valve implantation to surgery. EuroIntervention J Eur Collab with Work Gr Interv Cardiol Eur Soc Cardiol. 2013 Aug;9(4):446–51.

50. Laricchia A, Mangieri A, Latib A, Montorfano M, Tzanis G, Gallone G, et al. Temporal trends

in procedural death and need for urgent open surgery during transcatheter aortic valve replacement: A single, high-volume center 10-year experience. Int J Cardiol [Internet]. 2019;293:80–3. Available from: https://www.sciencedirect.com/science/article/pii/S0167527319316067

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