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Aortic and mitral structural interventions in the absence of cardiac surgery

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Traditionally, structural heart interventions have been performed at heart valve centres with on-site heart surgery to maximize expertise and deal with complications requiring emergent cardiac surgery (ECS). However, at present, only transcatheter aortic-valve implantation (TAVI) must be performed at centres with on-site heart surgery according to current guidelines, while mitral transcatheter edge-to-edge repair, or left appendage atrial occlusion could be performed also in centres without on-site cardiac surgery. Today, ageing of the population and improved results of TAVI have increased the need for such procedures posing strong pressure to traditional heart valve centres, prolonging waiting times for TAVI and increasing access disparities. Fortunately, TAVI procedures have a very low rate of complications, including those necessitating ECS, and observational data suggest that TAVI can be safely performed in centres without on-site cardiac surgery. However, guideline recommendations need randomized clinical trials like the TRanscatheter Aortic-Valve Implantation with or without on-site Cardiac Surgery (TRACS) trial to be updated. The TRACS trial randomizes high-risk symptomatic aortic stenosis patients to treatment by the same operators either at centres with or without on-site cardiac surgery and compares 1-year follow-up. Key issues for structural interventions, in particular TAVI, at centres without on-site surgery are shared indications through heart team evaluation, consistent experiences and competences of non-surgical centres, and strong networking with the Hub centre. The increasing demand for structural heart interventions highlights the need for innovative care models and the careful introduction of a 'Hub-and-Spoke' approach for high-volume heart valve networks could be a study option.

Introduction

Traditionally, structural heart interventions have been performed at heart valve centres with on-site heart surgery to maximize expertise and deal with complications requiring emergent cardiac surgery (ECS). However, at present, only transcatheter aortic-valve implantation (TAVI) must be performed at centres with on-site heart surgery according to current guidelines, while mitral transcatheter edge-to-edge repair (TEER), or left appendage atrial occlusion could be performed in centres without on-site cardiac surgery.[1] Today, ageing of the population and improved results of TAVI have increased the need for such procedures posing strong pressure on traditional heart valve centres, prolonging

waiting times to TAVI and increasing access disparities. Fortunately, advancements in structural interventions have significantly reduced complications requiring ECS, and observational data indicate that these procedures can be safely performed in centres without on-site cardiac surgery. Thus, we would focus on TAVI and TEER at centres without on-site surgery.

Aortic-valve intervention without on-site cardiac surgery

Transcatheter aortic-valve implantation has revolutionized the treatment of symptomatic severe aortic stenosis (AS), offering a less invasive alternative to surgical aortic-valve replacement. Landmark clinical trials have firmly established TAVI's safety and efficacy, demonstrating its effectiveness across a wide range of patient risk profiles, from prohibitive to low surgical risk. Both self-expanding and balloon-expanding prostheses have demonstrated favourable outcomes, which has led to the widespread adoption of TAVI in clinical practice.[2,3] As a result, international guidelines now recognize TAVI as a cornerstone therapeutic option for patients with AS, underscoring the pivotal role of a multidisciplinary heart team (HT) in determining patient suitability for the procedure.[1]

Over the past decade, TAVI use has expanded, leading to significant reductions in mortality rates among patients with AS. However, a substantial undertreatment remains, with data revealing that only ~60% of AS patients undergo valve replacement within 4 years of diagnosis.[4] Moreover, mortality risk increases with the progression of AS, emphasizing the importance of a timely intervention. Geographic and demographic disparities in TAVI utilization further exacerbate inequities in access to care, impacting outcomes. For example, the European Association of Percutaneous Cardiovascular Interventions has highlighted significant geographic disparities in TAVI access within Europe, particularly in the UK, where long waiting times and limited access are linked to higher mortality and poorer clinical outcomes.[5]

Prolonged waiting times continue to be a critical concern, often leading to clinical deterioration and preventable deaths. In Canada, early TAVI programmes reported waitlist event rates ranging from 10–14%, with more recent data confirming that delays still contribute to significant adverse events, including heart failure hospitalizations and deaths. Despite ongoing efforts to streamline care pathways and improve procedural efficiency, the increasing demand for TAVI—driven by expanding indications—continues to outstrip the capacity of centres with on-site cardiac surgery.[6]

Advances in transcatheter aortic-valve implantation procedures and complications could limit the need for emergent cardiac surgery

The evolution of TAVI techniques has markedly improved both procedural safety and clinical outcomes. Nevertheless, complications can still occur, typically involving vascular access, bleeding, or the need for permanent pacemaker implantation. Although the incidence of severe complications has decreased with operator experience and technological progress, rare but significant events—such as valve migration, coronary obstruction, or annular rupture—can still arise, sometimes requiring ECS.

The frequency of complications necessitating ECS has notably decreased. For example, a U.S. nationwide study found that fewer than 0.5% of TAVI procedures required ECS.[7] Similarly, data from the Leipzig Heart Centre indicated a decline in ECS-related complications from 3.5% in the early years of TAVI to <0.5% more recently. Importantly, outcomes following ECS are highly variable: low- to intermediate-risk patients generally have favourable results, while high-risk patients often experience poor survival rates, even after ECS.[8]

Several factors have contributed to TAVI's improved safety profile. Enhanced pre-procedural planning, including routine computed tomography (CT) imaging and thorough HT assessments, allows for precise patient and prosthesis selection. Innovations such as echo-guided vascular access, the use of local anaesthesia, and advances in valve design have further reduced such procedural risks.

The Heart Team's Pivotal Role in selecting patients for the procedure

A cornerstone of TAVI's success is the management of the TAVI pathway through a multidisciplinary HT. This team, typically comprising interventional and clinical cardiologists, cardiac surgeons, imaging specialists, anaesthesiologists, and other relevant experts, plays a pivotal role.[1] A key member of the HT is the cardiac surgeon, whose expertise is critical in evaluating patient risk and selecting the optimal treatment strategy. Despite the increasing safety of TAVI procedures, there are instances where surgical intervention remains necessary. The cardiac surgeon also plays an essential role in managing emergent complications, which may require ECS. The HT's assessment starts with a detailed evaluation of each patient's clinical condition, encompassing factors such as frailty, comorbidities, and overall life expectancy to exclude futility. The HT's input is essential for identifying patients who will benefit most from TAVI, but it moves further to procedural planning and risk assessment of potential complications. Beyond ensuring appropriate patient selection, the HT is responsible for devising a personalized treatment plan for each patient. This approach includes a thorough evaluation of imaging results, such as CT scans, and selection of the most appropriate valve type and size. Through this collaborative decision-making process, the HT ensures optimal patient outcomes, minimizing complications and maximizing procedural success.

Characteristics required for transcatheter aortic-valve implantation centres

For centres willing to participate in a TAVI programme or other structural interventions, especially within the evolving framework of procedures performed in facilities without on-site cardiac surgery, certain criteria are essential. International guidelines have traditionally advocated for performing TAVI only in centres with immediate access to cardiac surgery, driven by concerns over potential complications that may require ECS.[1]

However, recent advancements in imaging, device technology, and procedural techniques have significantly reduced the occurrence of complications necessitating surgical backup. Observational studies suggest that, with appropriate patient selection and close collaboration between experienced operators and surgical centres, TAVI can be safely performed in facilities without on-site cardiac surgery.[9-13]

Key features of centres offering TAVI without on-site cardiac surgery include the following:

- Experienced operators: TAVI should be performed by interventional cardiologists with substantial expertise and a proven caseload in valve implantation acquired in centres with on-site cardiac surgery.
- Multidisciplinary HT: The centre must have access to a skilled multidisciplinary HT, including experienced cardiologists and heart surgeons, and there should be active critical pathways with cardiac surgeons of the Hub heart valve centres to deal with procedural complications requiring ECS.
- Advanced imaging and pre-procedural planning: Utilization of advanced imaging techniques, such as CT angiography and careful procedural planning, are critical for accurate patient management and prosthesis selection.
- Strong and formal collaborative agreements with the heart valve centre: Centres without on-site surgery must establish formal arrangements with Hub centres to share indications and ensure timely access to surgical intervention when necessary.

Observational experiences with transcatheter aortic-valve implantation in centres without on-site cardiac surgery

Initial studies evaluating TAVI procedures in centres without on-site cardiac surgery, based on observational data, suggest favourable procedural and clinical outcomes. In 2014, Eggebrecht *et al.* compared 1254 patients treated at 27 German hospitals with on-site cardiac surgery to 178 patients at 8 hospitals lacking such facilities. All patients received first-generation valves between 2009 and 2010. The study revealed no significant differences in major complications or 30-day mortality between the two groups.[9] Gafoor *et al.*[10] reported 100% technical success in 97 high-risk AS patients treated at a Frankfurt centre with a visiting surgical team.

The AQUA registry, which tracks inpatient TAVI procedures in Germany, analysed 17 919 patients in 2016. Although patients in hospitals without on-site surgery were older and had higher predicted risks, their in-hospital mortality and conversion rates were similar to those in centres with on-site surgery.[11] Additionally, a review of data from the Austrian TAVI registry by Egger *et al.*[12] found no significant differences in mortality rates between patients treated at centres with and without on-site cardiac surgery after adjusting for confounders.

A Spanish study involving 384 patients at centres with no on-site surgery but with nearby surgical backup also demonstrated high technical success and relatively low mortality, further supporting the safety of TAVI in these settings.[13] Thus, data from Austria, Germany, and Spain suggest that while patients treated in centres without on-site surgery tend to have higher-risk profiles, adjusted analyses show comparable short- and long-term mortality rates to those treated at centres with on-site cardiac surgery. Meta-analysis of these studies found no significant differences in short-term mortality (5%) or cerebrovascular events (2%) between patients treated at centres with or without on-site cardiac surgery[13] (*Table 1*).

Applying the Hub-and-Spoke Network model to transcatheter aortic-valve implantation

The growing demand for TAVI underscores the need to reassess existing organizational models. Since improving patients' flow at heart valve center could be an issue in several instances, introducing the Hub-and-Spoke model, where patients are managed at different centres according to grading of complexity and resource availability, could be an interesting study option to deal with the increasing demand for TAVI and the longer waiting times. In this model, TAVI are performed at centres with cardiac surgery on-site (Hub centres) or at centres without on-site cardiac surgery (Spoke centres) according to patients' complexity and centre capabilities. This strategy offers mutual benefits for both patients and healthcare systems.

- Enhanced access to TAVI: by permitting Spoke centres to perform TAVI on carefully selected patients, the overall volume of TAVI increases, reducing waiting times and disparities of care.
- Optimal patient allocation: patients deemed inoperable or at high surgical risk in the case of ECS could be treated at Spoke centres, while those with lower procedural risk or with complex anatomies could be managed at Hub centres. This approach improves patient's flow.
- Resource optimization: Hub centres can concentrate on high-complexity or low-risk cases, where in case of complications ECS is a valuable option, thus optimizing procedural capacity and bed availability for other advanced interventions, reducing congestion, and enhancing resource distribution throughout the healthcare system.

Thus, expanding TAVI availability to centres without on-site cardiac surgery could help reduce care disparities and shorten waiting times, ultimately improving patient outcomes.

The TRACS trial: a new paradigm for transcatheter aortic-valve implantation

The TRACS (TRanscatheter Aortic-Valve Implantation with or without on-site Cardiac Surgery) trial is a prospective, randomized, multicentre trial designed to evaluate the safety and efficacy of TAVI performed in centres without on-site cardiac surgery as compared with those performed by the same operators in centres with surgical backup.[14] Eligible patients must have symptomatic severe AS and be considered high or prohibitive surgical risks, with an STS PROM score above 8% or other risk factors. Patients unsuitable for transfemoral TAVI or with non-cardiac comorbidities precluding 1-year survival will be excluded. After evaluation, patients will be randomized 2:1 to either the experimental group (TAVI without on-site surgery as soon as possible) or to the control group (TAVI with on-site

Table 1 Summary of studies on transcatheter aortic-valve implantation procedures performed at centres without on-site cardiac surgery

Reference	Study period (year)	Country	Patients in CWCS (number)	Patients in CWOCS (number)	Meta-analysis results[14]
Eggebrecht *et al.*[9]	2009–10	Germany	1254	178	**CWOCS:**
Gafoor *et al.*[10]	2005–12	Germany		97	• In-hospital/30 days all-cause death: 5%
AQUA registry[11]	2013–14	Germany	16 587	1332	• Cerebrovascular events: 2%
Egger *et al.*[12]	2011–16	Austria	1532	290	**CWCS vs. CWOCS:**
Roa Garrido *et al.*[13]	2015–17	Spain		384	• All-cause death: OR = 0.84; 95% CI 0.57–1.25
					• Cerebrovascular events: OR = 0.96; 95% CI 0.58–1.57.

CWCS, centre witch cardiac surgery on-site; CWOCS, centre without cardiac surgery on-site.

surgery, according to the waiting list). The primary endpoint is a composite of 1-year rate of all-cause death, stroke, and cardiovascular readmissions. Secondary endpoints will focus on the safety of TAVI in centres without on-site surgery, particularly monitoring complications that may require ECS.

The TRACS trial will offer important insights into performing TAVI in centres without on-site surgery, and it would explore if networking according to a Hub-and-Spoke model could help to meet growing demand while maintaining high-quality care.

Mitral valve intervention without on-site cardiac surgery

Introduction

Mitral transcatheter edge-to-edge repair has gained prominence as an option for patients at high surgical risk as it replicates the edge-to-edge surgical procedure. Procedural technique is quite standardized and the risk of complications requiring ECS is trivial. Therefore, current guidelines on the one hand underscore the importance of HT evaluations before TEER, but on the other hand, they do not mention if this procedure should be performed exclusively in centres with on-site cardiac surgery or even without.[1]

No comparative studies to date compare the outcomes of mitral TEER in centres with vs. without on-site cardiac surgery. This lack of evidence leaves the feasibility and safety of TEER at non-surgical programmes underexplored.

Insights from the MitraSwiss registry provide valuable real-world data. This registry, encompassing 1212 procedures, includes one centre without on-site cardiac surgery—the Kantonsspital Aarau—which has successfully performed mitral TEER procedures within the registry framework. Surgical conversion risk within the first-month post-procedure was minimal: 1.3% for degenerative mitral regurgitation and 0.5% for functional mitral regurgitation.[15] In Italy, data from GISE (Italian Society of Interventional Cardiology) show that ~1561 MitraClip procedures are performed annually, reflecting a high demand for this therapy and the need to explore optimal models of care delivery. At present, several programmes at centres without on-site surgery are underway.

Organizational considerations

The organizational framework for delivering mitral TEER plays a crucial role in ensuring patient outcomes. While guidelines propose networking between community care, spoke, and hub centres, this often devolves into a hierarchical structure. In such systems, hubs perform the interventions, sometimes they do even complete the preliminary work-up for the procedure, and after a short follow-up, they frequently return patients to community care, undermining the continuity of care.

A peer-based network model, emphasizing collaboration and shared expertise, is essential to address the growing demand for structural heart interventions, like TEER. Similarly to the TAVI pathway, essential components for establishing a TEER pathway in hospitals without on-site heart surgery include the following:

- Presence of certified operators and dedicated echocardiographers with substantial experience, gained through close collaboration with the heart valve hub centre.
- Experienced anaesthesiologists skilled in managing interventional procedures in high-risk cardiac patients.
- A well-structured HT to assess surgical ineligibility and determine the current candidacy for TEER.

Thus, mitral TEER without on-site cardiac surgery is feasible with appropriate expertise and infrastructure. The Swiss experience illustrates that such programmes can be effective and safe, provided they maintain rigorous standards and close ties with hub centres. As demand for mitral interventions grows, further research is critical to evaluate outcomes when TEER is performed in hospital without on-site surgery.

Conclusions

The evolution of transcatheter interventions for aortic and mitral valve diseases underscores the transformative impact of innovation and collaborative care models in modern cardiology. Transcatheter aortic-valve implantation has become a cornerstone therapy for AS, with emerging evidence evaluating its safety and efficacy even in centres without on-site cardiac surgery, provided appropriate expertise and infrastructure are in place. The Hub-and-Spoke model exemplifies efforts to decentralize care, reduce disparities, and meet growing

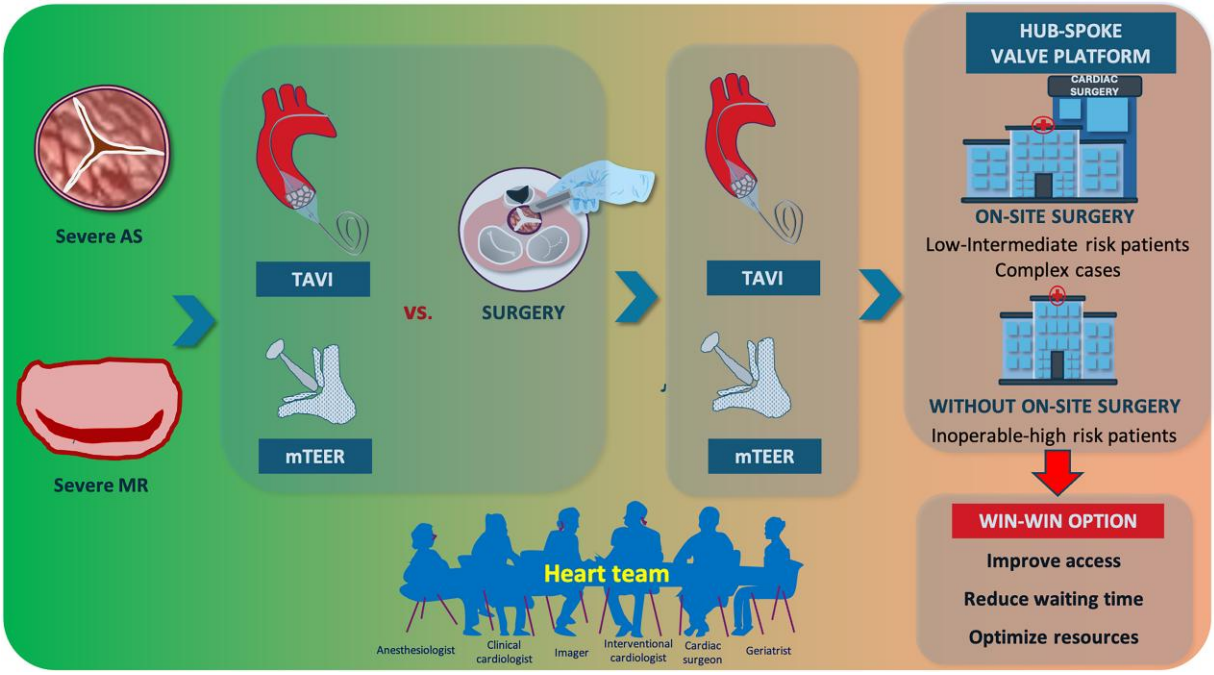

Figure 1 The Hub-and-Spoke Model for transcatheter aortic valve implantation and mitral transcatheter edge-to-edge repair. AS, aortic stenosis; MR, mitral regurgitation; mTEER, mitral transcatheter edge-to-edge repair; TAVI, transcatheter aortic valve implantation.

demand while maintaining high standards (*Figure 1*). However, rigorous research and robust organizational frameworks will remain critical to optimizing access, equity, and quality in heart valve care.

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