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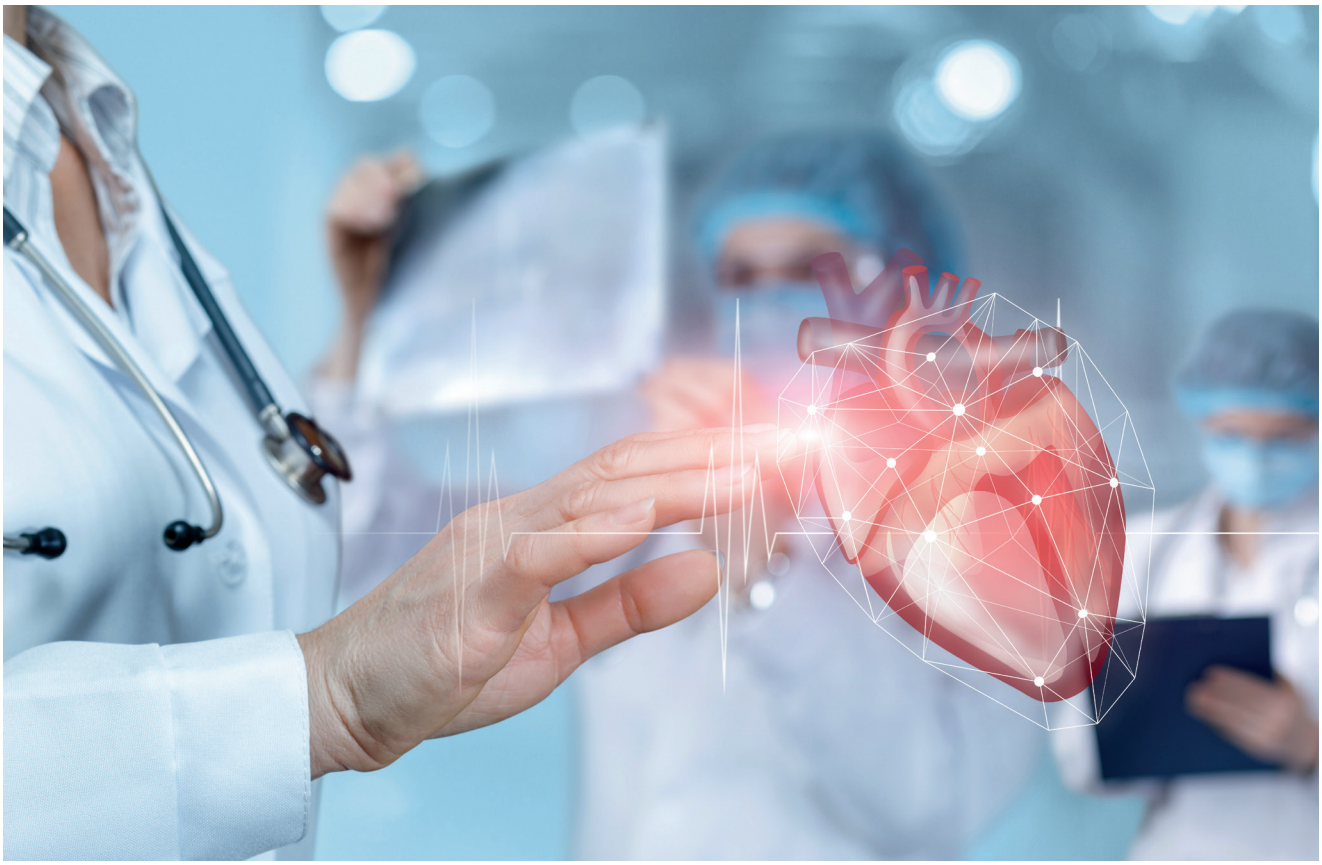
GUIDEBOOK

TAVI: Maximising benefits through contemporary innovations



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Foreword

Transcatheter aortic valve implantation (TAVI) has very much become an established part of the treatment landscape for severe aortic stenosis and is an alternative to conventional surgical aortic valve replacement, particularly in some patients for whom surgery is deemed inappropriate or who are at increased surgical risk.[1]

The trend is perhaps not surprising considering TAVI consumes fewer health care resources than surgical aortic valve replacement, mainly as a result of shorter hospital stays, less post-procedural rehabilitation, and fewer short- and long-term complications.[2]

The choice of valve is an important aspect of care and is guided partially by some patient characteristics, including age, frailty and comorbidities. Anatomical considerations are also taken into account, such as ease of access and amount of calcification. The valve characteristics are also important in determining choice. For example, self-expanding, lower-profile transcatheter aortic valves are steerable and can be easier to align.[3]

More recently, younger patients with severe aortic stenosis are being treated. For them, valve durability is a major consideration. The aim for these patients, in particular, is to be able to implant a valve with the longest possible durability or longevity to minimise the need for reintervention, which in itself is associated with a risk of complications. Long-term trial data are beginning to become available, and the signs are that bioprosthetic valve dysfunction – a composite of structural degeneration, non-structural degeneration, thrombosis and endocarditis – is typically lower with TAVI as compared with surgery, with some studies suggesting some differences between valve types.[4,5]

The management and care of heart valve transplant patients is best achieved through a multidisciplinary team, as recommended in guidelines. The concept of the heart team has developed to encompass the group of healthcare professionals responsible for patients from primary through to tertiary care.

The primary objective of the heart team is to ensure patients are offered the best possible individualised treatment. The way these teams work is constantly evolving to take account of different patient characteristics and presentation and also the newer ways of working in the health service, in particular the development of new technologies.[6]

Through a series of interviews conducted by *Hospital Healthcare Europe*, this resource brings together an eminent faculty of interventionalists and members of the multidisciplinary heart team from across the EU and UK to offer readers greater insight into aspects of the use of TAVI from their expert perspectives.

Key issues discussed include:

- The importance of valve selection and key clinical trial data
- Reducing length of stay after TAVI and improving efficiencies
- The importance of the team approach in TAVI success.

The resource will fully equip readers with insight into the benefits that TAVI offers for patients in terms of outcomes and long-term care, and the potential the technology has to improve the efficiency of use of health service resources and the resultant benefits.

Lastly, we also take a peek into the future to think about the 'new generation' and developments for the technology, the key factors in optimal TAVI valve design and how continued innovation and access to these newer valves will provide great value from both the physician and patient perspective.

We trust that readers will find the content of the book educational, enjoyable and deeply insightful.

References

1 Costa G et al. Trends in European TAVI practice. Current application of TAVI in Europe. Cardiac Interventions Today 2018; March-April.

2 Rosseel L et al. Contemporary European practice in transcatheter aortic valve implantation: results from the 2022 European TAVI Pathway Registry. Front Cardiovasc Med 2023;10:1227217.

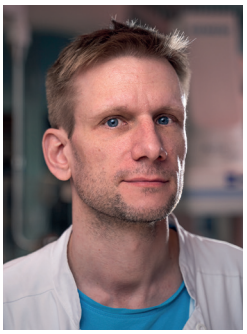
3 Tang GHL et al. Rationale, Definitions, Techniques, and Outcomes of Commissural Alignment in TAVR: From the ALIGN-TAVR Consortium. JACC Cardiovasc Interv 2022;15(15):1497–1518.

4 O'Hair D et al. Structural Valve Deterioration After Self-Expanding Transcatheter or Surgical Aortic Valve Implantation in Patients at Intermediate or High Risk. JAMA Cardiol 2023;8(2):111–9.

5 Jørgensen TH et al. Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement. Eur Heart J 2021;42(30):2912–9.

6 Archbold A et al. Getting the best from the Heart Team: guidance for cardiac multidisciplinary meetings. Heart 2022;108:e2.

TAVI valve selection: pivotal considerations and key evidence



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> The importance of valve durability cannot be overestimated and hopefully, the patient can be treated with one valve that will last the rest of their lifetime

As an introduction, could you very briefly talk us through the different types of valves that are available and their key design features?
The choice for patients with severe symptomatic aortic valve stenosis is between a surgical aortic valve or a transcatheter aortic valve. For transcatheter aortic valves, the choice is typically between a balloon-expandable or self-expanding transcatheter aortic valve.

What are the main factors to consider when selecting a valve?
First of all, the valve choice heavily depends on the baseline patient characteristics, including age and comorbidities. In terms of age and frailty, young patients – 50 years old, for example – who are fit and healthy are typically candidates for surgical intervention. On the other hand, frail young patients – aged 68 years, for example – are unlikely to be good surgical candidates.

When opting for a transcatheter aortic valve replacement – also called TAVI – the choice for a specific aortic valve type typically depends on the patient's aortic valve anatomy and/or vascular access. But this can also depend on other clinical variables.

Obviously, it is important to choose a transcatheter aortic valve system that can guarantee a safe procedure. Because of this reason, balloon-expandable aortic valves are typically excluded for patients with severe calcification at the aortic annulus, LVOT or sinotubular junction level.

Another important aspect to consider is which valve type will give you the best haemodynamic result. In particular, in small anatomies, the best haemodynamic result will be obtained by the use of a self-expanding aortic valve with a supra-annular leaflet position. Of course, it also speaks for itself that paravalvular regurgitation should be avoided by all means. And the valve choice may also have an impact on the risk of conduction disturbances and/or permanent pacemaker implantation. However, the implantation technique for the different valves has the greatest impact on this latter risk.

When treating patients with a longer life-expectancy, it is also important to consider a TAVI with commissural alignment and resulting in optimal haemodynamics.
This will be the best guarantee for long valve durability. Also, coronary access and the option to easily re-valve in the future may be important aspects, especially when treating the younger patient.

As the research and procedure evolve, what are we learning about long-term valve durability and why is improving durability an important focus?
In terms of evidence from clinical trials, real long-term durability data needs to be for a minimum of ten years. Ideally, it should be up to 10 to 15 years because most of these younger patients – around 65–70 years old – presenting with severe symptomatic aortic stenosis have, on average, a 12–15-year life expectancy. So, ideally, we want to implant a valve with a 10–15-year durability.

At the moment, we do not have 15-year valve durability on any transcatheter aortic valves as TAVI treatments only started less than 20 years ago, and the patients treated in the early days were older and high-risk patients who had multiple morbidities. Consequently, only 10% of these patients treated in the early days of TAVI are still alive at 10 years of follow-up, and it is not possible to extrapolate information on long-term durability from such a small cohort. That is why we are very dependent on trials that include low-risk patients; in other words, patients with lower comorbidity levels who typically have longer life expectancies.

The low-risk trials we have so far include studies such as the Evolut low-risk trial and the PARTNER 3 trial (please refer to Table 1 for a compendium of key TAVI clinical papers and trial data). They have, respectively, four- and five-year follow-up results, and for valve durability, the clear take-home message was that there was no sign of early degeneration or valve dysfunction in these transcatheter valves over this period.

Ten-year follow-up data from the NOTION trial shows that severe structural valve deterioration (SVD) is lower for TAVI (CoreValve – a self-expanding supra-annular leaflet position valve) compared with the surgical arm. Severe bioprosthetic valve dysfunction (BVD) was also significantly lower in the TAVI arm compared with the surgical arm. The rate of re-intervention for both TAVI and surgery is extremely low – there was only a 2–4% re-intervention rate in both arms at ten years, so that is very positive for both TAVI and surgery.

> When treating patients with a longer life expectancy, it is also important to consider a TAVI with commissural alignment and resulting in optimal haemodynamics

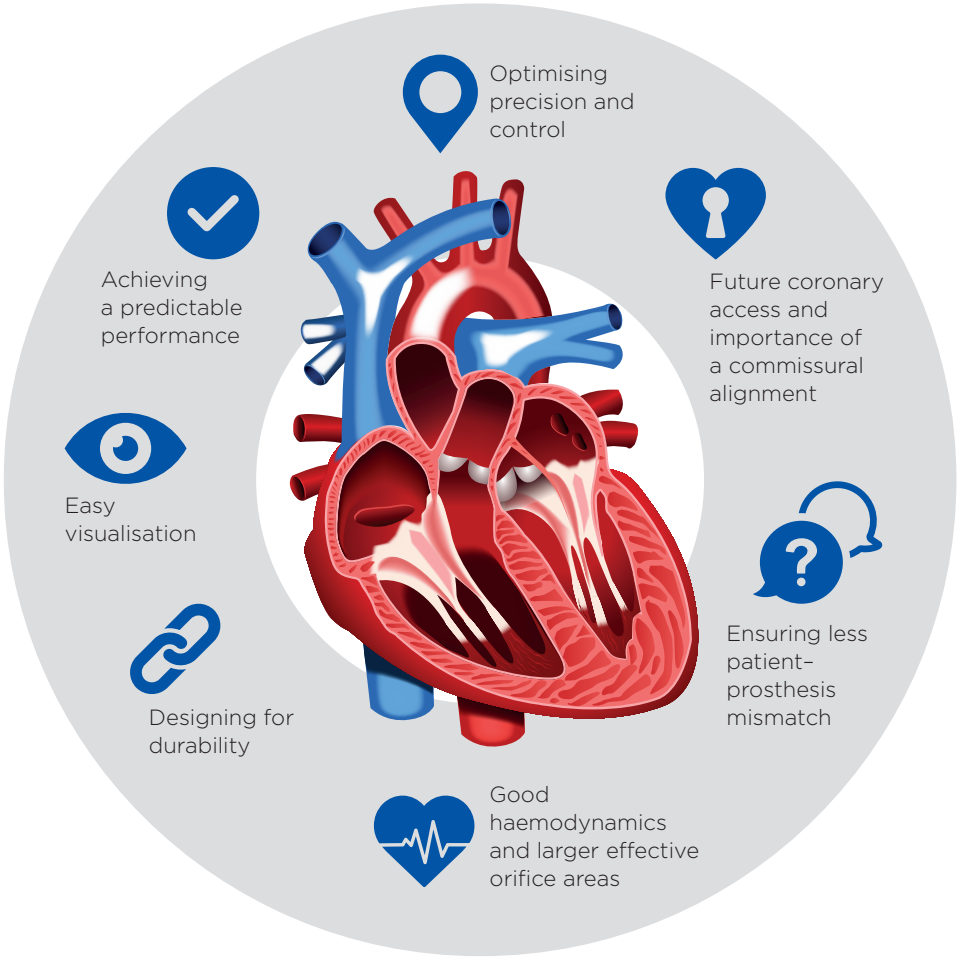
Why are low-risk/young patient populations so important when talking about durability?
The aim is to implant one valve that provides a lifelong solution. But beyond durability, we also must consider options to safely and effectively re-valve and preserve coronary access, which may be a challenge in case of such a re-valving scenario – this applies to both surgical valves and TAVI.

In conclusion, how do you see the field progressing? Where should the research go and what next steps are needed?
There are many areas to explore! Indications for TAVI have been expanding to younger patients and patients with longer life expectancies. That usually also means that more aortic stenosis patients are presenting with a bicuspid aortic valve instead of a classical tricuspid aortic valve. We don't have any data on how TAVI valves perform long-term in bicuspid valves. So, there is a question about whether TAVI is suitable for all patients with a bicuspid valve or perhaps a subgroup of these patients with some specific characteristics. And perhaps some TAVI valves are more suitable than others.

Quality of life is another area needing further research. Outcomes should perhaps not only focus on procedural outcomes and avoiding re-intervention but also other aspects, such as improving the patient's exercise capacity, may become increasingly important when treating younger and more active patients.

It can be difficult for the patient to grasp the complexities of the procedure and the intricacies of valve selection. Generally, patients themselves are not so worried about the long term – they usually just want to feel better and to be able to return home safely and quickly. They want good procedural outcomes without complications, such as stroke or bleeding. However, the importance of valve durability cannot be overestimated and hopefully, the patient can be treated with one valve that will last for the rest of their lifetime.

FIGURE 1
Optimising TAVI valve design



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Key points
- TAVI has revolutionised the treatment of patients with severe, symptomatic aortic stenosis.
- TAVI has become the default therapy for severe aortic stenosis patients ≥ 75 years of age regardless of their surgical risk.
- There are differences in valve performance between different transcatheter aortic valve platforms.
- Ideally, the transcatheter aortic valve used will outlive the patient.
- More evidence is needed on long-term valve durability in younger and, in particular, bicuspid aortic stenosis patients.

TABLE 1

Compendium of key clinical trials

Study	Population	Primary endpoint	Key results for valve durability/ performance
PARTNER-3 – 5-year data Mack MJ et al. PARTNER 3 Investigators. Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years. N Engl J Med 2023;389(21):1949–60.	n=1000: 503 TAVR, 497 surgery	Composite of death, stroke, or rehospitalisation related to the valve, the procedure, or heart failure	Haemodynamic performance of the valve, assessed by valve gradient (mean ±SD): 12.8±6.5mmHg TAVR group; 11.7±5.6mmHg surgery group
Evolut Low Risk 4-year Forrest JK et al. Evolut Low Risk Trial Investigators. 4-Year Outcomes of Patients With Aortic Stenosis in the Evolut Low Risk Trial. J Am Coll Cardiol 2023;82(22):2163–5.	n=1414: 730 TAVR; 684 surgery	All-cause mortality or disabling stroke	Mean valve gradient 9.1mmHg TAVR; 12.1mmHg surgery (p<0.001) at 3 years
Pooled CoreValve/Evolut 5 year O'Hair D et al. Structural Valve Deterioration After Self-Expanding Transcatheter or Surgical Aortic Valve Implantation in Patients at Intermediate or High Risk. JAMA Cardiol 2023;8(2):111–9.	Post hoc analysis, pooled data from the CoreValve US High Risk Pivotal (n=615) and SURTAVI (n=1484) RCTs; CoreValve Extreme Risk Pivotal trial (n=485) and CoreValve Continued Access Study (n=2178) 2099 RCT patients, (1128 TAVI; 971 surgery) and 2663 non-RCT patients who received TAVI were included	Severe structural valve deterioration through 5 years from RCTs. Defined as (1) increase in mean gradient of ≥10mmHg from discharge or at 30 days to last echocardiography with a final mean gradient of ≥20mmHg or (2) new-onset moderate or severe intraprosthetic aortic regurgitation or an increase of 1 grade or more	Cumulative incidence of SVD (treating death as a competing risk): TAVI, 2.20%; surgery, 4.38%; HR, 0.46; 95% CI, 0.27–0.78; p=0.004)
Meta-analysis SAVR vs. TAVI Ahmad Y et al. Transcatheter versus surgical aortic valve replacement in lower-risk and higher-risk patients: a meta-analysis of randomized trials. Eur Heart J 2023;44(10):836–52.	n=8698 from 8 RCTs	Death, strokes, and the composite of death or disabling stroke, occurring at 1 year (early) or after 1 year (later)	At one year, risk of death lower after TAVI vs SAVR (RR 0.67; 95% CI 0.47 to 0.96, p=0.031), as was death or disabling stroke (RR 0.68; 95% CI 0.50 to 0.92, p=0.014). After one year, in lower risk patients, no significant differences in main outcomes
NOTION – 10-year follow-up data Thyregod HGH et al. Ten-year outcomes after transcatheter or surgical aortic valve implantation in severe aortic valve stenosis: Results from the NOTION trial. Eur Heart J 2024;00:1–9.	n=280: 139 TAVI; 135 surgery	Composite primary endpoint of all-cause mortality, stroke or MI after one year.	No difference in all-cause mortality between the two groups (64% in the SAVR arm at 10 years, compared with 62.7% in the TAVI group); composite rate of all-cause mortality, stroke and MI was 65.5% for both groups

TABLE 1

Compendium of key clinical trials

Study	Population	Primary endpoint	Key results for valve durability/ performance
NOTION – 8-year follow-up data Jørgensen TH et al. Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement. Eur Heart J 2021;42(30):2912–9.	n=280; 145 TAVI; 145 surgery	Composite outcome of all-cause mortality, stroke, or MI	Cumulative incidence of SVD: TAVI 13.9%; SAVR 28.3% (p=0.0017) (HR 0.42, 95% CI 0.24–0.72)
Raschpichler M et al. Commissural Alignment After Balloon-Expandable Transcatheter Aortic Valve Replacement Is Associated With Improved Hemodynamic Outcomes. JACC Cardiovasc Interv 2022;15(11):1126–36.	n=324	Valve Academic Research Consortium-2 (VARC-2)-based early safety (excluding mortality) and the relative increase of the mean AV gradient between discharge and 30 days (ie >50% increase of mean AV gradient at 30 days resulting in an AV mean gradient at 30 days ≥10mmHg)	Relative mean AV gradient increase >50% more frequent in CMA patients (17.6% vs 8.3%; OR: 2.4; 95% CI: 1.1–5.7; p=0.04) Endpoint of early safety (excluding periprocedural mortality) met in 11 patients (3.8%); 9 had CMA (p=0.07). Reached significance in the subgroup of patients with sinus rhythm (OR: 0.16; 95% CI: 0.01–0.90; p=0.04)
Bieliauskas G et al. Patient-Specific Implantation Technique to Obtain Neo-Commissural Alignment With Self-Expanding Transcatheter Aortic Valves. JACC Cardiovasc Interv 2021;14(19):2097–108.	n=60 (20 assigned to each of three valves: Evolut R/PRO, Medtronic; ACURATE neo2, Boston Scientific; and Portico, Abbott)	THV implantation with ≤mild CMA, as assessed at post-TAVR cardiac CT	Optimal commissural alignment (<15 degrees) in 36/60 (60%) ≤mild CMA (<30 degrees) in 53/60 (88%) Severe CMA (>45 degrees) 2/60 (33.3%)
Fuchs A et al. Commissural Alignment of Bioprosthetic Aortic Valve and Native Aortic Valve Following Surgical and Transcatheter Aortic Valve Replacement and its Impact on Valvular Function and Coronary Filling. JACC Cardiovasc Interv 2018;11(17):1733–43.	n=240 (28 SAVR, 212 TAVR)	Not explicitly stated. Commissural alignment between native and prosthetic aortic valves defined as: aligned (angle deviation 0–15 degrees), mild CMA (angle deviation 15–30 degrees); moderate CMA (angle deviation 30–45 degrees); severe CMA (angle deviation 45–60 degrees)	27 (96%) SHVs aligned; 1 with mild CMA 47 (22%) THVs aligned; 53 (25%) mild CMA, 46 (22%) moderate CMA, 66 (31%) severe CMA Significantly higher rate of mild central aortic regurgitation in those THVs with moderate or greater CMA compared with those THV with mild or less CMA (7.8% vs. 1.1%; p=0.03).

CMA = commissural misalignment; CT = computed tomography; MI = myocardial infarction; SHVs = surgical heart valves; TAVR = transcatheter aortic valve replacement; THVs = transcatheter heart valves; SAVR = surgical aortic valve replacement; SVD = structural valve degeneration

Reducing LOS and improving efficiencies: what are the benefits?

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> Reducing LOS can also bring benefits such as reducing delays for patients by helping reduce waiting list time. That said, reducing LOS is not the primary goal of treatment. the priority is to provide high-quality, effective and safe care

We are delighted to speak with you today about reducing the length of stay after TAVI. Could you take us through the important general outcomes of improving hospital efficiencies?

With greater numbers of patients and a widening range of indications in the context of an ageing population with more comorbidities, improving efficiencies and reducing the length of stay is key. It is not only important to accommodate the increasing demand for transcatheter aortic valve implantation (TAVI) but is also important for patients themselves, particularly in terms of their autonomy. The less time patients spend in hospital, the less their autonomy is impaired.

Patient autonomy has an impact on the morale of the healthcare team too, because the more autonomous patients are, the less they rely on the team to help with everyday activities (such as using the bathroom). That is particularly significant at night when there are fewer staff on duty.

Reducing the length of stay (LOS) can also bring benefits such as reducing delays for patients by helping to reduce waiting list time. Every small gain helps and adds up – by the end of the year, more patients can then be treated.

How does TAVI itself impact the efficiency of an organisation and why is reducing LOS particularly beneficial for patients and HCPs after TAVI?

Apart from giving patients autonomy sooner, streamlining care is particularly beneficial for older patients who have habits they like to maintain, which is difficult while they are in hospital. Most patients want to be in their own homes rather than in hospital – so streamlining care and making it more efficient allows them to return home as soon as possible after their procedure.

For example, looking at data for our hospital in Rennes for 2022, even though the number of days the ward where most TAVI patients are managed was available decreased by 9% due to scheduled closures, we treated 155 more patients than the previous year (amounting to a 6% increase). That was achieved through streamlining care, particularly outpatient care.

That said, reducing LOS is not the primary goal of treatment. The priority is to provide high-quality, effective and safe care. Shorter hospital stays are one of the consequences of achieving those objectives and achieving good procedural outcomes, rather than a priority in themselves.

As the procedure evolves, how do you feel that even greater efficiencies for TAVI could be achieved?

There is some discussion about whether it might be possible in future to achieve same-day discharge. In other words, patients are admitted, have their procedure, and are discharged all on the same day. That may become possible for certain patients, for example, those who already have a pacemaker implanted. The reason is that one of the issues we currently face with TAVI is the risk of conduction disturbances; where there is a risk of AV block, which may require permanent pacemaker implantation. Therefore, patients previously implanted with a permanent pacemaker may be natural candidates for same-day discharge..

To achieve same-day discharge, we also need to be very confident that there will not be any vascular complications on the access side (usually the femoral artery) once the patient has left hospital – and this could be a barrier to achieving same-day discharge.

We have come a long way in simplifying TAVI to the extent that it is a minimalist procedure. There is probably not much scope for improving the procedure itself much further with current devices. However, the widespread adoption of measures advocated by two recent studies – FAST-TAVI II and Benchmark – that allow for a shorter length of stay, should be a goal for the future. And that aim should probably be the priority for the next step in improving TAVI for all patients as it would be beneficial for the population as a whole because it would reduce waiting list time.

At our hospital, we typically discharge about 40% of TAVI patients the day after their procedure and around 30% two days following their procedure. These rates compare favourably with data from FAST-TAVI II.

How might enhanced education and staff training be beneficial to healthcare providers and patients alike? And what options do clinicians have to influence LOS after TAVI and what do the data tell us?

Educating the healthcare team is important in terms of logistics such as early mobilisation. Some members of the healthcare team who are not

Key points

- TAVI has emerged as the standard of care for the treatment of severe aortic valve stenosis in older adults through a series of randomised trials performed over the past 20 years.
- International guidelines reflect these data from the literature and have given TAVI a prominent role in the management of aortic stenosis. Consequently, indications are expanding.
- The increasing number of procedures performed annually worldwide put strain on healthcare systems in the context of bed shortages and limited physicians' and healthcare professionals' availabilities.
- Streamlining patients' procedural and post-procedural pathways by preventing complications and implementing logistical measures, such as educational resources and early mobilisation of TAVI recipients, is key to achieving shorter LOS, reduced waiting list times, and overall maximal efficiency.
- Two recent studies – FAST-TAVI II and the BENCHMARK registry – have tested and validated this hypothesis, paving the way for a widespread adoption of these simple measures.

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> In the FAST-TAVI II study, 60.3% and 56.3% of self-expandable and balloon-expandable valve recipients, respectively, were discharged within 3 days of the procedure in centres where these measures were implemented compared with 40.7% and 43.8% in centres not applying this protocol

familiar with a particular approach – allowing patients to walk the same day, four to six hours after their procedure, for example – might be reluctant to adopt the strategy. It seems to help if the operator is personally involved in implementing the measures alongside the ward staff – leading by example so to speak. Even so, it takes a lot of education for the doctors and the nursing staff in general.

Patients and their families also need education. They need information about TAVI itself, and what it involves, and they need to be reassured that it is a relatively straightforward procedure that is not debilitating. They need to understand that patients will feel better right away, as soon as the procedure is completed, and will be able to go home within a day or two after it has been done. The treating physician needs to communicate his/her confidence in the safety of TAVI and that the results will be good for patients. That way patients and their families can have full confidence in their treatment.

The nurse coordinator also plays an important role in educating patients and families and the process starts when the patients are first seen, up to a month or so before the procedure itself takes place. The nurse coordinator's involvement and availability for patients and their families is crucial and is a role that should be implemented in all centres.

In terms of data supporting early mobilisation and discharge of patients after TAVI, two main studies are expected to be published in the European Heart Journal – FAST-TAVI II (https://clinicaltrials.gov/study/NCT02956915) and an analysis of data from the Benchmark Registry. These will provide information to show that when streamlined patient care measures are implemented for TAVI, a greater proportion of patients can be discharged sooner while maintaining patient safety compared with patients not treated via the streamlined pathway.

Importantly, in the FAST-TAVI II study, 60.3% and 56.3% of self-expandable and balloon-expandable valve recipients, respectively, were discharged within 3 days of the procedure in centres where these measures were implemented compared with 40.7% and 43.8% in centres not applying this protocol. This result suggests a more prominent role of procedural and post-procedural protocol of care's excellence in reducing length of stay rather than the choice of valve.

In conclusion: how is research developing and what next steps are needed to further streamline the LOS and maximise efficiencies?

In terms of streamlining the procedure, the priority is to encourage widespread adoption of the measures used in FAST-TAVI II and the Benchmark Registry analysis. That will be important as demand for services grows and we treat greater numbers of patients in future, especially those with degenerated valves. These valves pose challenges in terms of coronary re-access and should be a priority area for research for the next few years.

Another current area of interest from a research perspective is how best to manage conduction disturbances, which can limit the adoption of early discharge, particularly where there is not a clear indication for a pacemaker to be implanted. Ambulatory ECG monitoring of patients using small devices that can be worn on the chest for a month or more can provide information that will inform what might be the best way to manage these events.

The devices might also provide an alternative to implanting a pacemaker, allowing patients to go home with the knowledge that they can be monitored for conduction disturbances remotely, and which might provide yet another way to streamline the TAVI care pathway.

These devices are currently being compared in randomised trials to other management strategies based on invasive electrophysiological studies performed during the index hospitalisation.

Lastly, we should bear in mind that TAVI is still a relatively recent therapy, the first-in-man procedure dating back to 2002. Thus, it has been an area of massive research and development by the industries involved for the past 20 years. We therefore cannot rule out further refinements in transcatheter heart valves and implantation device sthat might further streamline patients' care in the near future.

The importance of the team approach in TAVI success

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Kerry Pena BSN
Cardiac valve nurse specialist

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How did the concept of the 'Heart Team' in TAVI come about and what was the rationale behind establishing it?

DB The concept of the multidisciplinary team approach to patient care was pioneered in oncology, but within cardiovascular medicine TAVI led the way. In terms of TAVI, one of the factors that lay behind the heart team being pivotal was that when TAVI began, there was a clear sense that as a new non-invasive alternative to open-heart surgery, it needed to be done in collaboration with cardiac surgeons – they should be the 'gate-keepers' – determining who was not suitable for surgery and should be considered for TAVI. So, it was embedded from the beginning that no patient could have a TAVI unless they had been through a properly constituted heart team consultation with a cardiac surgeon as part of that team.

TAVI became routine in clinical practice from 2007–2008. In 2007, there were only three centres in the UK offering TAVI; by the end of 2008, there were around 15–20.

What is the primary objective of the Heart Team?

DB The primary objective of the heart team is to ensure patients are offered the best possible individualised treatment. For more complex cases, other specialists might also be included. For example, to consider frailty, a care of the elderly physician could be invited to join, or for issues around suitability for anaesthetic in surgical cases, then cardiac anaesthetists can be involved.

KP The success of the randomised controlled trials and the European Society for Cardiology working group position regarding the heart valve team emphasised the need for a more structured setup for the whole heart team, including cardiac surgeons, cardio-interventionalists, imaging doctors, geriatricians in some centres, and valve nurse specialists. The heart team's expertise has further developed due to the peer-to-peer discussions and collaborations. This collaborative learning, often supported by industries, made significant contributions that helped the heart team provide the most evidence-based practice tailored to a patient with heart valve disease.

Please tell us about the roles of the members of the Heart Team and the importance of the TAVI coordinator in the patient pathway

DB Most people would agree that a minimum requirement for a quorate team meeting would include a cardiac surgeon, an interventional cardiologist who performs the TAVI procedure, at least one imaging specialist, ideally a TAVI nurse specialist, and an administrator.

Input from a cardiac anaesthetist might be helpful for some patients. Care of the elderly physicians are not often required as other members of the valve team have developed expertise in assessing elderly patients and frailty effectively, especially the nurse specialists who are also skilled in assessing cognitive function. Occasionally referring hospitals from the district join us – probably online – usually to listen to the team, but sometimes they contribute.

KP The valve nurse specialist role has evolved through the years but the main role that has been consistent is coordinating the pathway for patients being referred for heart valve treatment. One significant role I have is being the main point of contact for patients and the link between all stakeholders involved in patient care. We have the administrative team who assists in collating information at the initial referral stage. It is very important to get this process right at the start so we can the provide the patient with the right treatment at the right time.

We also rely on our imaging team who have special interests in these group of patients. They understand the urgency in getting quality images to expedite the decision-making process and treatment for the patient.

A dedicated team during the procedure in the catheter lab makes things really flow smoothly. Therefore, our team ensures that the allied healthcare professionals are provided training and the education that the rest of the team receives.

DB Administrators also have a key role, particularly in coordinating patient lists.

How has the Heart Team evolved during the 20+ years of TAVI? What do you feel is needed next to continue to improve the effectiveness and ultimately patient outcomes?

DB One of the questions is whether it is necessary to discuss every patient in the heart team meeting. Although heart team meetings are hugely valuable, bringing together so many different people at the same time for every patient becomes quite challenging. So, there is some debate about

> Most people would agree that a minimum requirement for a quorate team meeting would include a cardiac surgeon, an interventional cardiologist, at least one imaging specialist, ideally a TAVI nurse specialist and an administrator

whether some patients could be reviewed in a more informal setting. For example, patients over the age of 80 years who will not need to be considered for open heart surgery could be discussed by a smaller group, perhaps involving a nurse specialist, an interventional cardiologist and an imaging specialist.

Another challenge is making sure patients are discussed rapidly enough. Again, smaller meetings for some patients could be helpful. The situation reflects the increase in the burden of acute cases, with patients who are hospitalised requiring urgent treatment.

There should ideally always be someone at the heart team meeting who knows the patient and video conferencing can facilitate that, especially for patients from other hospitals.

Patient involvement in team meetings might be something to be considered more widely in the future.

KP Electronic referrals, which are starting, would be more efficient than current arrangements. This would create a single point of referral, which could be via a link that opens a pro forma. All the information needed will be mandated by the pro forma, so referrals can be processed more efficiently. And I am hoping that would translate into outpatient referrals too.

It would also help if we could access information from district hospitals, such as blood results, investigations, etc, to avoid duplication.

How can you ensure that you get the best from the Heart Team, the MDT and the meetings? Is there any guidance to help achieve this and best practices?

DB One of the keys to an effective MDT is to have a named chairperson. Documentation is also very important. There needs to be an effective mechanism for documenting the MDT – including who was there, what was discussed and the outcomes.

Our heart team administrator records discussions with close input from clinicians in the meeting. Previously one of the consultants dictated a letter after the meeting, which produced an effective report, but sometimes there was a delay in documentation being distributed.

Formal guidance on heart team meetings does exist (Archbold A et al. Getting the best from the Heart Team: guidance for cardiac multidisciplinary meetings. Heart 2022;108:e2). However, local guideline-based agreements about some situations can help streamline meetings. For example, patients 75 years or older are most likely candidates for TAVI; those 74 years old or younger are more likely to have surgery. It is an evolving area and younger patients are being treated with TAVI, but it can help to avoid some >

> TAVI is more expensive than surgery even though it is less invasive; however, NHS England supports its use, including in lower-risk and intermediate-risk individuals, so more patients can be treated, particularly while the NHS is recovering from Covid-19

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Key points

- TAVI is now an established safe and effective treatment for the past two decades but the success of a patient's treatment relies heavily on the role of the heart team/ stakeholders.
- The primary goal of the Heart Team is to ensure the optimal treatment is offered to each individual patient.and should include an interventional cardiologist, cardiac surgeon, imaging cardiologist, valve nurse specialist, and an administrator.
- As TAVI volumes grow, some patients may not need to be discussed in the full Heart Team meeting if decision-making is straightforward. Agreed local guidelines should be used to define such patients.
- Continual review and optimisation of TAVI programmes should be practised to meet with the increasing demands and innovations for this treatment.
- The benefit of upskilling cardiac valve nurse specialists and/or other allied healthcare professionals in the team can bring a significant impact to the service.
- Collaboration with industry in providing support with training and education for the structural team is valuable in ensuring a thriving TAVI service.

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disagreements between surgeons and interventionists if the centre has locally agreed guidelines to act as a basis for decision making.

KP Team decisions should be communicated quickly to patients and those who need to action them. Patients also need to be kept up to date with information such as waiting times for procedures. At the same time as giving them information, we will assess patients over the phone. If there has been some progression in their symptoms we need to act quickly and prioritise them. Similarly, patients need to know to contact us if their symptoms worsen.

There will be times when demands start to outstrip capacity. That is when other ways of working that are perhaps more efficient need to be considered. The team recently implemented use of the MDT by discussing patients who are 'sitting on the fence' where decision is collectively made by our heart team whether the patient should have surgery or transcatheter heart valve treatment. Furthermore, international guidelines such as the ESC guideline helped the team streamline this process whereby clear-cut patients for surgery or TAVI can have technical discussions among the two subspecialties.

TAVI is more expensive than surgery, even though it is less invasive. However, NHS England supports its use, including in lower-risk and intermediate-risk individuals, so more patients can be treated, particularly while the NHS is recovering from Covid-19 (National Institute for Health and Care Excellence (NICE). Heart valve disease presenting in adults: investigation and management; www.nice.org.uk/guidance/ng208/resources/implementation-strategy-for-transcatheter-aortic-valve-implantation-10885926925). NICE guidelines on heart valve disease however somewhat controversially suggested TAVI was not cost-effective in low- or intermediate-risk patients (Transcatheter aortic valve implantation for aortic stenosis. Interventional procedures guidance [IPG586]; www.nice.org.uk/guidance/ipg586/chapter/2-Indications-and-current-treatments).

Please tell us about your role as the valve specialist nurse and what this entails. What is the the impact of your role and how does it fit with the larger team structure.

KP My main role is coordinating the care pathway: I am the initial touchpoint for referrals, and I triage referrals according to the protocol and criteria agreed by the heart team. I collect all the minimum data sets, including information from the heart team meeting and I will relay that information to patients.

Once the patient comes in for the procedure I will arrange a clinic, which is a nurse-led pre-assessment clinic where we ensure that patients are ready physically and psychologically for the procedure.

We follow up with patients to evaluate whether the treatment has been effective, whether we need to adjust medications and to schedule the next follow-up meeting or surveillance follow-up.

Coordinating the patients within the pathway appears to be an administrative task but requires clinical knowledge to ensure the patient is navigated efficiently through that journey. For instance, a patient who contacts the valve nurse due to deteriorating symptoms will be assessed remotely and will be advised whether to contact a general practitioner, to come to the valve nurse's clinic for an expedited assessment or attend the emergency department. With our expertise and experience, we can determine if the patient requires treatment urgently without asking the doctors.

Therefore, a major impact of my role is to free up consultants' time for the clinics and to provide a single point of access for the patients, which creates a positive experience for them.

I am also heavily involved in the planning and execution of service developments in our programme. For example, the single point of referral process which we have implemented in our service. This required collaboration between the subspecialties, administrative and referring clinicians. This project had its ups and downs but overall was beneficial to streamlining pathways for patients with aortic valve disease.

Why is it important to have access to the latest TAVI technologies?

Mohamed Abdel-Wahab MD
Head of the Structural Heart Disease Unit, Leipzig Heart Center Germany

Could you start by telling us about the recent innovations in TAVI procedures that are generating excitement in the field?
One of the most significant trends we're witnessing in the world of TAVI is the encouraging durability data we're seeing, particularly in the low-risk patient segment. In 2023, there was considerable excitement surrounding the latest results from the Partner 3 study and the Evolut Low Risk study. In addition, the publication of 10-year data from the NOTION study is extremely promising for the CoreValve™/Evolut™ platform (see the compendium of key clinical data on pages 6–7 for further details of the trials). These data demonstrated the durability and sustained efficacy of these valves over a significant period, which is crucial for reassuring both clinicians and patients about the long-term outcomes of TAVI procedures.

In addition to durability, what other aspects are becoming increasingly important in TAVI procedures?
One crucial aspect that's gaining prominence is the lifetime management of patients who undergo TAVI. As we continue to expand TAVI to younger populations, ensuring optimal valve performance over the patient's lifetime becomes paramount.

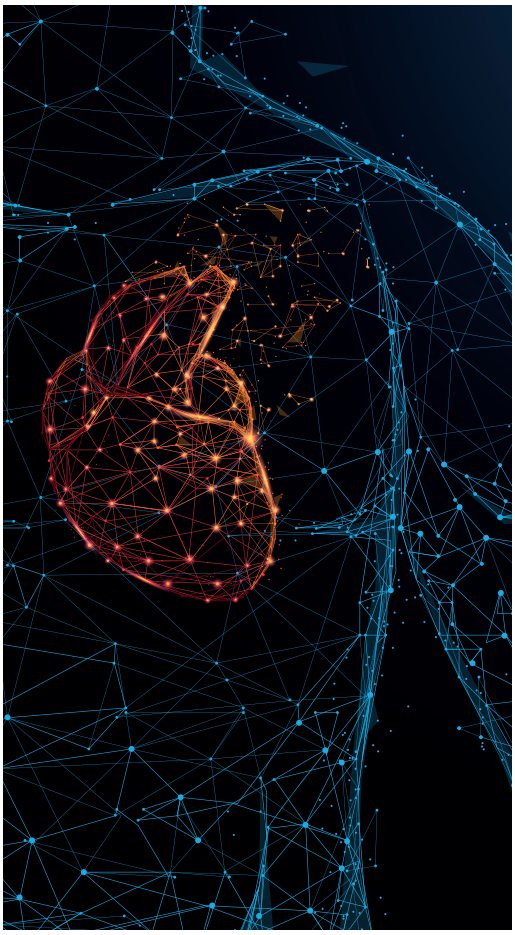
The latest generation of TAVI devices are designed with features that address these evolving needs. One notable advancement is in commissural alignment. Previously considered a trend, it's now recognised as a requirement, especially for valves implanted in younger patients.

The ability to achieve easy commissural alignment is essential for ensuring optimal valve function and longevity. With Evolut FX™, for example, radiopaque markers have been added above the inflow of the valve to both mark the location of each of the three commissures as well as assisting in implant depth assessment, features that will contribute to better outcomes.

What specific innovations do these new technologies offer?
The new technologies introduce several novel features that enhance flexibility and predictability during the implantation procedure. In addition to the use of radiopaque markers, innovations such as stability layers and redesigned capsule tips, for example, confer improvements to the delivery system catheters, all of which contribute to improved tracking, deliverability, and predictability during deployment. This expands the anatomical subset of treatable patients by including much more complex anatomies (such as those with tortuous access vessels or a horizontal aorta), all of which would have been difficult to treat with earlier-generation devices.

> Newer technologies introduce several novel features that enhance flexibility and predictability during the implantation procedure

In summary, these exciting developments and technological innovations are making an impact in shaping the future of transcatheter aortic valve implantation and improving patient outcomes.



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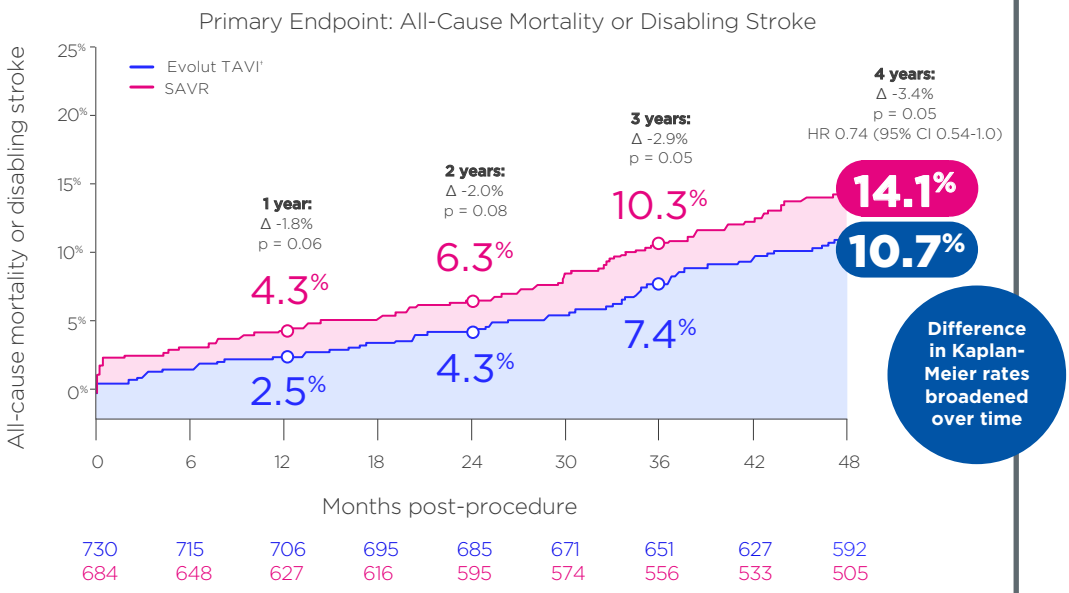
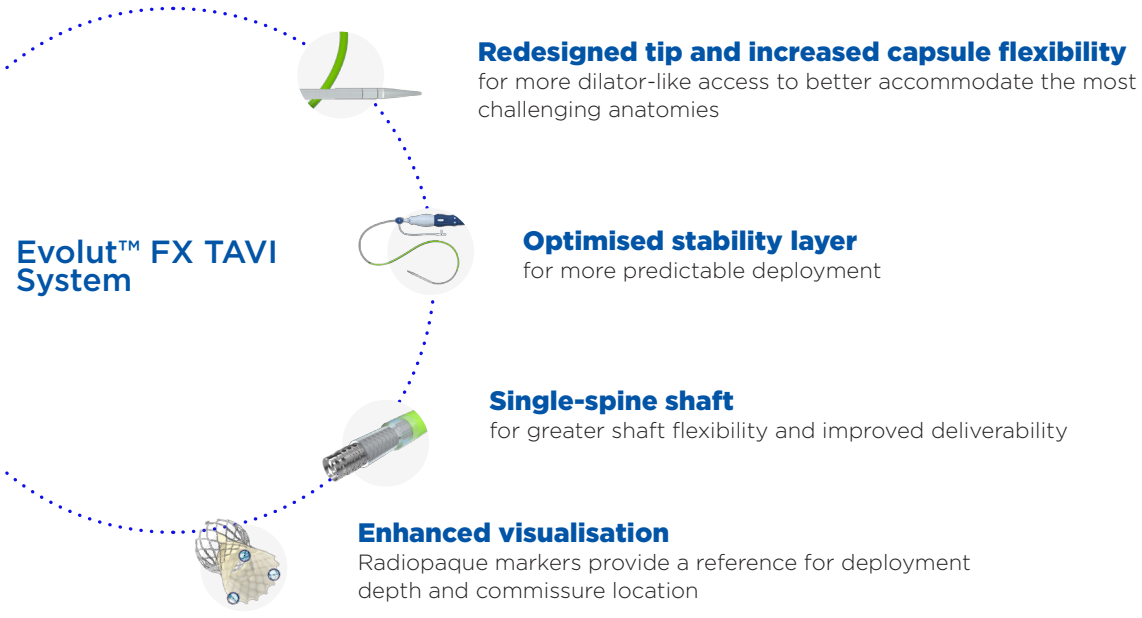
TAVI Corevalve™ Evolut™ platform evolution

Clinical implications from late-breaking evidence presented at TCT 2023

In younger low-risk patients, the Evolut™ platform had lower reported rates of death or disabling stroke (26%) compared with SAVR at 4 years.

Reardon M et al. Transcatheter Versus Surgical Aortic Valve Replacement in Aortic Stenosis Patients at Low Surgical Risk: 4-Year Outcomes from the Evolut Low Risk Trial. TCT 2023





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