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An interdisciplinary debate initiated by the European Society of Cardiology Working Group on Valvular Heart Disease

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THE FIVE MOST IMPORTANT QUESTIONS ON TAVI: THE VALVE SPECIALISTS VIEW

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Abbreviations

STS	Society of Thoracic Surgery
AVR	aortic valve replacement
sAVR	surgical aortic valve replacement
TAVI	transcatheter aortic valve replacement
TF-AVI	transfemoral aortic valve implantation
TA-AVI	transapical aortic valve implantation
AV	aortic valve
AS	aortic stenosis
AR	aortic regurgitation
pAR	paraprosthetic aortic regurgitation
AVA	aortic valve area
CABG	coronary bypass grafting
ECHO	echocardiogram
3D-TEE	3D transoesophageal echocardiogram
CT	computer tomography
MV	mitral valve
sMVR	surgical mitral valve replacement
IDE	investigational device exemption

1. Which patients should have TAVI rather than surgery?

The only effective treatment for severe symptomatic severe AS is replacement with a prosthetic valve. The ideal valve replacement would be easy and safe to implant, have haemodynamics similar to a native normal valve, have low thrombogenicity and be durable for the lifetime of the patient. If TAVI meets all those criteria, it eventually will largely replace surgical sAVR. However, TAVI is an approach in evolution, with limited clinical trials evidence on long-term outcomes. sAVR is the current standard of care, so selection of patients for TAVI is based on comparison of the relative risks and benefits of these two approaches.

PROCEDURAL RISK AND OUTCOMES

Patient specific surgical risk can be estimated most accurately using the Society for Thoracic Surgery (STS) prediction model. In addition to the STS score, other clinical factors that impact surgical risk and outcomes, such as frailty, nutritional status, life expectancy and dementia, must be considered. In adults with severe symptomatic

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calcific AS and a prohibitive surgical risk, TAVI is associated with improved survival and quality of life compared to surgical AVR at one year (hazard ratio 0.55, 95% confidence interval [CI], 0.40 to 0.74; p<0.001), albeit with a higher risk of stroke and vascular complications.[1] In adults with a high surgical risk (>8%), one year survival is not inferior in patients treated with TAVI versus surgical AVR, with a similar improvement in clinical symptoms.[2] Lower risk populations have not been studied.

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ANATOMIC FACTORS

Anatomic factors that preclude or increase the risk of surgical AVR include a heavily calcified (porcelain) aorta, a history of mediastinal radiation and adhesions due to prior cardiac surgery. Anatomic factors that limit TAVI include an aortic annulus too small or too large for currently available prosthetic valves, coronary artery ostium too close to the aortic annulus and, for the transfemoral approach, access vessels too small for the transcatheter delivery system. TAVI has been studied only with calcified tri-leaflet valves; data for bicuspid valves and rheumatic disease is not available.

PROSTHETIC VALVES

TAVI and surgical bioprosthetic valves have similar haemodynamics. There is a high prevalence of paravalvular aortic regurgitation with TAVI but severity is usually mild and rarely requires therapy. There is concern that TAVI bioprostheses may be more thrombogenic than traditional valves, due to the stent supporting the valve tissue, so that antiplatelet therapy typically is prescribed after TAVI. Although data on intermediate outcomes is promising[3,4], the long-term durability of TAVI bioprosthetic valves is not known compared to the wealth of data on long-term outcomes with traditional bioprosthetic valves.

Conclusions

In adults with symptoms due to severe calcific stenosis of a tri-leaflet valve, an appropriate annulus size, acceptable distance between the annulus and coronary ostium, and large enough peripheral vessels (or candidacy for a transapical approach):

TAVI is appropriate when surgical risk is prohibitive and the patient has no other life-limiting comorbidities.

TAVI is a reasonable alternative to surgical AVR when surgical risk is high, taking patient preferences into consideration.

TAVI currently is not appropriate in lower risk patients, except in the context of a prospective randomised clinical trial, because long-term valve durability is not yet known. The potential role of TAVI in low-output low-gradient severe AS, with and without contractile reserve, also is unknown.

2. In which setting should TAVI be performed? What are the important prerequisites?

TAVI has progressively emerged as a technique of interventional cardiology which is now considered as a validated alternative to surgery in selected patients. The setting in which TAVI should be performed differs from other techniques of interventional cardiology by a number of features because of specificities, not only in the performance of the procedure, but also in patient screening and post-procedural management.

PATIENT SELECTION

The evaluation of the severity of aortic stenosis and of its consequences is well defined in guidelines. However, it should be performed by cardiologists who have a particular expertise in the management of valvular heart disease since the decision to perform TAVI or surgery or to deny any intervention relies on overall clinical judgment rather than on precise criteria. The involvement of geriatricians is of particular interest to assess the nutritional status, frailty and cognitive functions, which have an impact on the risk of interventions as well as spontaneous outcome[5,6]. The assessment of the feasibility of TAVI requires the presence of imaging specialists with a particular skill in the evaluation of the arterial tree using CT scan.

PERFORMANCE OF THE PROCEDURE

TAVI should be performed by appropriately trained interventionists who perform a sufficient number of procedures. The impact of the learning curve has also been shown with TAVI, immediate and midterm outcomes being better after the performance of 25 cases.[7]

At the beginning of experience, vascular surgical approach, transoesophageal monitoring and general anaesthesia were used in most cases of transfemoral TAVI. Technical improvements, in particular the reduction of introducer size and growing experience, tend to simplify TAVI procedures, which are now frequently performed using a pure percutaneous vascular approach under local anaesthesia and sedation. Anaesthesiologists are, however, still involved for optimising sedation protocols, planning the procedure and managing patients in poor haemodynamic conditions. Skilled echocardiographers should be part of the procedure in particular to quantitate and analyse the mechanisms of intra- or paraprosthetic aortic regurgitation and thus adapt the most appropriate intervention, e.g., additional balloon inflation or implantation of a second prosthesis. Cardiovascular surgeons should be promptly available on-site to manage vascular complications, and they obviously should be part of the procedure when a transapical or subclavian approach is used. Ideally, TAVI procedures should be performed in hybrid suites combining the asepsis requirements of an operating room and imaging facilities of a catheterisation laboratory.[8] Their diffusion is, however, limited because of financial considerations.

POST-PROCEDURAL CARE

Monitoring in intensive care units is required at least 24 hours after the procedure to allow for the diagnosis of deferred vascular lesions or conduction disturbances.

After the hospital period, follow-up modalities do not differ from those of other patients having undergone valvular intervention. Centres should have resources that are enabled for registries to be completed. For example, TAVI procedures are reimbursed in France

only if centres fill a registry for each patient and collect follow-up data up to five years.[9] Besides country-specific requirements, the completion of large registries is highly desirable to continue to assess the results of TAVI with extended follow-up.

In conclusion, despite technical improvements and growing experience, TAVI remains technically demanding and needs to be performed in centres comprising clinicians with expertise in valvular disease, imaging specialists, interventional cardiologists, surgeons and anaesthesiologists who are used to work in close cooperation. This justifies restricting the performance of TAVI to a limited number of high-volume centres combining on-site cardiology and cardiovascular surgery departments.

3. Which factors will govern short- and long-term prognosis in comparison with surgery?

Prognosis of patients receiving transcatheter aortic valves is influenced by the haemodynamic performance and the durability of the valve, by procedure related outcome and last but not least by overall patient comorbidity.

VALVE HAEMODYNAMICS AND DURABILITY

Good immediate and short-to-midterm haemodynamic results have confirmed the TAVI, both for the transfemoral and the transapical approaches[2]. These are reflected by a significant reduction in transvalvular gradients and increases in valve area that compare favourably with conventional aortic valve replacement. During an extended median follow-up period of 3.7 years, no cases of structural valvular deterioration, stent fracture, deformation or valve migration were reported (noting that survival rates in that study at three years were 61%)[10]. However, long-term data on the durability are still lacking and this needs to be considered in the decision-making process, in particular for patients with longer life expectancy. It remains to be tested, whether aortic regurgitation or non-circular stent-deployment have an impact on long-term valve durability.

While, the concept of a valve-in-valve implantation has been proposed, it is too early to routinely consider such an approach for potential future structural valve failure.

PROCEDURE RELATED OUTCOME

Experience has a major impact on early outcome and a significant improvement is observed after surmounting the early learning-curve[7]. Acute kidney injury, which occurs in approximately 12% of patients following TAVI, is associated with a greater than four-fold increase in the risk of postoperative mortality. Hypertension, chronic obstructive pulmonary disease, and blood transfusion are factors that are predictive of acute kidney injury[11]. Moderate to severe aortic regurgitation occurs in 12 to 17% of patients after TAVI[2,12]. It is associated with significantly higher rates of in-hospital death (15% vs. 7%), as well as higher rates of low cardiac output and respiratory failure[12].

New cerebral ischaemic lesions can be detected by diffusion-weighted magnetic resonance imaging in approximately 70% of patients after TAVI[13]. These lesions are usually multiple and dispersed in both hemispheres in a pattern suggesting cerebral embolisation, but are generally not associated with apparent neurological events or measurable impairment of neurocognitive function. The rate of major stroke is substantially higher than for conventional surgery with 3.8% as compared to 2.1%[2,13]. As demonstrated in the PARTNER trial, high-risk patients with severe aortic stenosis randomised to TAVI or surgical valve replacement have similar survival rates at one year (24.2% and 26.8%, respectively), although there are important differences in periprocedural risks with more frequent vascular complications in the TAVI group (11.0% vs. 3.2%, $p<0.001$) and more frequent major bleeding and new-onset atrial fibrillation with surgery[2]. It is important to recognise that it cannot be assumed that mortality for TAVI and conventional surgery will be necessarily comparable in patients at lower-risk.

EFFECT OF COMORBIDITY ON OUTCOME

Ultimately, survival of high-risk patients that are currently treated with TAVI is inherently limited by concomitant disease. One-year survival in the SOURCE registry (n=1038) was 76.1% (72.1% for transapical and 81.1% for transfemoral TAVI). Interestingly causes of death were mainly non-cardiac in 49.2% (cardiac in 25.1%, and unknown in 25.7%) with pulmonary complications (23.9%), renal failure (12.5%), cancer (11.4%) and stroke (10.2%) as the most frequent non-cardiac causes of death[14]. These data highlight the importance of associated comorbidities on long-term outcome after TAVI and the necessity to define patients who should preferably be managed conservatively.

4. What are the key determinants for successful individual patient management?

The fast growing use of TAVI now enables large series or registries to be available. Their findings are useful to identify important steps in patient management.

At the present time, the indication for TAVI is considered in patients with severe, symptomatic aortic stenosis who are at high-risk for surgical aortic valve replacement. The assessment of the severity of aortic stenosis should combine valve area and flow-dependent measurements and check for their consistency.[15] This is of importance in the elderly in particular, because discrepancies between valve area and gradient tend to be more frequent than in younger patients. The identification of patients who are at high risk for surgery is difficult. Risk scores contribute to decision-making, but the limitations of their predictive value underlines the need for a complete clinical assessment, taking into account comorbidities which are not included in risk scores.[16] It is also necessary to ensure that patient life expectancy and quality of life are not more compromised by comorbidities than by heart valve disease. Besides comorbidities, the overall assessment of functional capacity should include the use of validated indices of frailty to reduce subjectivity. When TAVI is considered, its feasibility and the choice of the approach are mainly based on imaging findings. The transfemoral approach is often the first-line choice when peripheral arteries are suitable.

Optimal patient management during the TAVI procedure depends mainly on the environment and the experience of the team. These features are detailed in question 2 "In which setting should TAVI be performed?". Although the current trend is to perform TAVI according to a less invasive environment, in particular with the use of a percutaneous approach under local anaesthesia and sedation, the individual benefit for the patient needs to be assessed by comparative series.

Consistent findings from large registries show that the most frequent complications are vascular complications when using the transfemoral route, pacemaker implantation when using the self-expandable prosthesis, residual aortic regurgitations and neurologic complications. Vascular complications and conduction disturbances are often easily managed provided they are diagnosed and treated promptly, and they generally do not impact midterm outcomes. At least moderate residual aortic regurgitation is encountered in 5 to 10% of patients and has been shown to have a negative impact on outcome.[17] Optimal prosthesis sizing still requires improvements in the interpretation of measurements obtained with echocardiography and CT scan.

Ischaemic neurologic events occur in 2 to 10% of patients and have become a concern, in particular because this was the main drawback of TAVI as compared with surgery in the PARTNER high-risk randomised trial.[2] The mechanism of embolism during or after TAVI is not obvious. It may be related to the migration of thrombi or calcium fragments from the aortic valve and these mechanisms raise the question of the usefulness of embolic protection devices. Another cause may be embolism due to atrial fibrillation which has recently been shown to occur in as much as a third of patients and to be related with the occurrence of stroke.[18] Early detection of atrial fibrillation after TAVI is thus needed to start anticoagulant therapy.

In conclusion, the heterogeneity of high-risk patients with aortic stenosis highlights the need for an individual approach of potential candidates to TAVI, thereby requiring a team approach at each stage of patient management.

5. What will be the world of percutaneous valve intervention look like in 2022?

Almost ten years after the first transcatheter aortic valve implantation (TAVI) by Dr. Alain Cribier in April 2002, more than 40,000 TAVI procedures have been performed worldwide. The considerable experience gained with TAVI has enabled the safety, efficacy, and midterm results to be assessed from large series. Now, what can expect as development for the next 10 years?

DEVICES

It is likely that catheter size will continue to decrease, thereby expanding the feasibility of the transfemoral access and contributing to a decrease in the frequency of vascular complications. A number of new devices are currently under investigation. Certain prostheses can be repositioned and/or retrievable, which may simplify and improve the safety of the procedure. However, it remains clear that the reduction of the size of the devices has intrinsic limitations and that the use of new devices will require specific training. In addition, new devices should be evaluated in comparison with existing devices, using the standardised VARC criteria.[19]

IMAGING

Echocardiography and CT scan play a key role in patient selection in measuring the aortic annulus size, assessing the overall morphology of the arterial tree and measuring arterial diameters. Imaging techniques are already accurate and reliable. However, it will be necessary to better delineate the respective contributions in echocardiography and CT scans in the measurements of aortic annulus size, given its implications in prosthesis sizing.[20] The assessment of the severity and distribution of valve calcification is also of potential interest to avoid uneven deployment of the prosthesis. An important potential impact of these improvements is to reduce the frequency of paraprosthetic regurgitations.

PATIENT SELECTION

Besides technical improvements, there is no doubt that the real challenge will continue to be patient selection and the respective indications of surgical aortic valve replacement and TAVI in the treatment of aortic stenosis.

The number of TAVI cases has increased from 609 cases in 2007 to 12,000 in 2010 in Europe and the percentage of TAVI among all interventions for aortic stenosis has increased from 1.2 to 20% during the same period. Even if restricting the use of TAVI to patients who have contra-indications or are at high risk for surgery, it is likely that the number of TAVI procedure will continue to increase because of patient ageing and the strong increase in the prevalence of aortic stenosis after the age of 80.[21]

The other key issue is the extension of indications towards patients who are at lower risk for aortic valve replacement. This trend is already present and certain patients are pushing to be treated by TAVI rather than aortic valve replacement, as shown by the 13% patient decision rate as a reason to perform a TAVI in the German registry.[22] This underlines the need for randomised trials specifically designed to compare surgery and TAVI in intermediate risk patients, such as the SURTAVI trial.

In the light of the experience gained over the last 10 years, it is likely that technical improvements will continue to contribute to improve the feasibility and decrease the rate of complications. The number of TAVI procedures will increase, but the indication should be validated by randomised trials as it has already been done for high-risk patients to avoid uncontrolled dissemination.

Commentary from the Surgeons

It must be a result of the long-standing cooperation between heart valve specialists and cardiac surgeons, that both see sAVR as the gold standard treatment for patients with severe AS. TAVI is accepted as a complementally treatment option for patients high-risk for cardiac surgery. However, we would like to use this opportunity to comment on some specific issues raised, which from our point-of-view, need clarification.

In procedural risks and outcomes, our colleagues mention that high-risk in the PARTNER-US trial (Cohort A) was defined as 30-day mortality >8%. However, patients were included in Cohort A if their expected mortality for sAVR was 10-15%, and thus much higher, estimated by an interventional cardiologist and a cardiac surgeon. An STS score of around 10 was used as a guideline to identify adequate patients[2].

They recommend that patient preference for TAVI/sAVR should be taken into consideration. Given the current evidence for TAVI, we strongly believe that the decision about the treatment approach should rather be based on scientific evidence and the assessment by a multidisciplinary Heart Team.

We are concerned by the view that patient selection, and even the procedure itself, should be "performed by the interventionist" with a particular interest in AV disease. Not to mention cardiac surgeons in this context is in great contrast to the interventionists' and our view, and we feel that it does not adequately conform with the idea of a multidisciplinary Heart Team as recommended by professional societies[8,23]. Surgeons are recognised in that they should be "involved and be part of the procedure in transapical and trans-subclavian TAVI", however, in these two procedures surgeons are the primary investigators.

In terms of procedural outcomes, we agree that stroke is an area of concern after TAVI. However, in their comparison with sAVR, an incidence for stroke after "conventional surgery" of 2.1% is quoted. We would like to clarify that this stroke rate is only observed in higher-risk patients, and is much lower in low-/median-risk cohorts[24].

Vascular complications after TF-AVI are quoted as a complication, but it is mentioned that due to new treatment strategies they do not affect 1-year outcome. This is in contrast to 1-year results from the SOURCE registry, which indicate that mortality is significantly higher in patients affected by this complication[14].

Given these challenges with TAVI, and additional issues such as paravalvular leakage and durability of THVs, we are surprised to read that valve specialists see TAVI being performed in low-risk patients in the near future. The German experience quoted, where 13% of patients underwent TAVI purely because of their personal preference, should not be seen as a positive example in this context.

In summary, we strongly believe that TAVI should be performed only in high-risk patients in whom scientific evidence has been obtained. This will not only be to the advantage of patients, but will also enable us to handle tightening resources in a responsible manner during economically challenging times.

Commentary from the Interventionalists

This group of experts in the field of valvular heart disease demonstrate the importance of the participation of dedicated specialists in the management of high-risk patients with aortic stenosis, as well as in governing the decision-making process in daily clinical practice to complement the skills of interventional cardiologists and cardiac surgeons.

Their answers reinforce the importance of patient selection, careful assessment of valve anatomy, pathophysiology and suitability for TAVI. The role of clinical cardiologists and imaging specialists in precise diagnosis and determination of the best decision for each individual patient is also underlined. Their call for further randomised trials before uncontrolled dissemination of TAVI to lower-risk cohorts is of course appropriate, not only for patients but for the sustained evolution of the procedure.

The concordance of responses in this series indicates that the era of the Heart Team in determining the best management of high-risk patients with aortic stenosis has truly arrived –not just as an ideal concept, but as an essential ingredient of day-to-day clinical practice.

THE FIVE MOST IMPORTANT QUESTIONS ON TAVI: THE SURGEONS' VIEW

Manuel J Antunes, MD, PhD, DSc; Pieter Kappetein, MD, PhD; Ruediger Lange, MD, PhD; Olaf Wendler, MD, PhD, FRCS

1. Which patients should have TAVI rather than surgery?

There is consensus in that TAVI is currently seen as a treatment option in patients with symptomatic severe AS who are inoperable or high-risk for sAVR. However, as risk scores such as EuroSCORE or STS score do not accurately predict outcome after sAVR[25] a multidisciplinary Heart Team of interventional and non-interventional cardiologists, cardiac surgeons, anaesthetists and imaging specialists is recommended to estimate surgical risk of individual patients. In the PARTNER-US trial mortality of sAVR was estimated by the involved interventional cardiologist and cardiac surgeon and a STS score of ≥10 was seen as a guideline to identify potential patients. Patients were classified as inoperable if expected mortality from sAVR was >50% (Cohort B) and high-risk if mortality was ≥15% (Cohort A)[1,2].

Results from Cohort B (intervention using TF-AVI randomised against standard medical treatment) demonstrate that inoperable patients have a maximum benefit from TAVI with one-year mortality being significantly lower in TAVI (30.7%) compared to medical treatment (50.7%) and one saved life with every fifth patient treated using TAVI[2].

PARTNER-US is currently the only randomised trial on treatment of patients considered high-risk for sAVR. Cohort A (with suitable femoral access: TF-AVI against sAVR, without suitable femoral access: TA-AVI against sAVR) results demonstrate that one-year mortality of TAVI (24.2%) is not significantly different from sAVR (26.8%)[3]. Sub-analysis of patients with suitable vascular access showed the same for one-year mortality in patients with TF-AVI against sAVR (22.2% vs. 26.4%, p=ns). Although one-year mortality in patients with unsuitable vascular access and therefore different spectrum of comorbidities was higher, there was, again, no significant difference noted between TA-AVI (29%) and sAVR (27.9%).

Surgical risk as a result of added comorbidities is only one way to determine suitability for sAVR. For identification of patients with potential benefit from TAVI, it is also important to recognise isolated conditions which by themselves can make sAVR extremely challenging. Data from large European registries are available and have been used to generate more insight in this patient cohort[14,26]. In general, technical/surgical challenges which increase peri-operative risk after sAVR are recognised in patients with chronic anterior chest wall defects, severe calcifications of the ascending aorta, and in patients post-CABG with internal thoracic arteries crossing the midline sternum. Immobilised patients or those with severe respiratory disease may also be unsuitable for sAVR due to their challenging postoperative recovery after sternotomy and cardiopulmonary bypass. These patients with isolated risk factors for sAVR build an additional cohort of patients where TAVI is accepted to be superior to sAVR.

TAVI is not suitable in patients with endocarditis and currently not recommended in patients with AR or bicuspid AV. However, there is growing evidence that it may develop into an alternative treatment option for patients with failing AV bioprostheses but midterm results remain to be seen. Most importantly, it needs to be noted that there is currently no evidence that TAVI is an appropriate treatment option in patients with low- or median-risk for sAVR.

2. In which setting should TAVI be performed? What are the important prerequisites?

TAVI should only be performed in institutions with an experience in AV surgery of the elderly. A Heart Team, led by interventional cardiologists and cardiac surgeons, should include cardiac imaging specialists, anaesthetists, non-interventional cardiologists, and nurse specialists. Their mixture of skills will enable the team to build patient care pathways in which patients will be assessed regarding cardiac and non-cardiac comorbidities, will have the most appropriate type of treatment jointly agreed upon and where, finally, various treatment options are delivered[8,23]. In this context, cardiac surgeons should be seen as the gatekeeper in the first instance, as they are most appropriate to identify patients with high-risk for sAVR. For the future of TAVI in general it is vital that patients who do not benefit from any invasive treatment are identified and directed towards non-invasive pathways.

As an initial step, heart valve clinics for patients who are high-risk for sAVR should be provided. Supported by strong ECHO services, they can also be used for follow-up and audit of outcomes[8,23]. Before the first implantation, the Heart Team should undergo a structured training program. Proctoring by experienced TAVI investigators/surgeons has been shown to reduce the learning curve. In addition, experience shows that Heart Teams who not only jointly decide on patient treatment, but also perform TAVIs as a joined team, irrespective of the mode of access used, increase their early experience and shorten their learning curve[8,23].

It is crucial that TAVI is only started in hospitals where additional supporting services such as interventional radiology and vascular surgery, but also intensive care and physiotherapy are available. This is of particular importance as vascular and renal complications as well as delayed patient mobilisation predict inferior outcome.

Currently most TAVI procedures are performed in catheter laboratories. Although outcomes are excellent, hybrid laboratories may be the places of choice for the future, as they are the cleaner environment and offer greatest flexibility for dealing with potential complications[8,23]. The majority of procedures are done under general anaesthesia. Some institutions have started to perform TF-AVI under conscious sedation. Although seen as an alternative in patients with severe impaired respiratory function, without intubation intra-procedural TEE is difficult to be used. However, imaging plays a vital role for exact sizing of aortic annulus and root, deployment of THVs and assessment of the final result. Most teams rely on a combination of fluoroscopy and ECHO, usually 3D-TEE, or/and multislice CT to identify appropriate THV sizes[27,28].

During the implantation, cardiac surgeons from the Heart Team should be present to strengthen the Heart Team approach, perform emergency cannulation if cardiopulmonary bypass is needed and for emergency surgery, if that has been agreed to be the bailout strategy. Early extubation in theatres or in the recovery unit are standard, followed by early mobilisation and improved pain management. Nevertheless, early discharge home will only be feasible, if support at home is organised in advance of the procedure.

In summary, key for a successful TAVI program is a Heart Team where all parties involved in the care and treatment of elderly patients with severe AS have equal rights and work closely together.

3. Which factors will significantly impact short- and long-term prognosis in comparison with surgery?

TAVI is currently indicated for high-risk patients with AS who cannot withstand open heart surgery. Although periprocedural mortality has been significantly improved after the initial experiences, a number of complications and concerns still question mid/long-term outcomes by comparison with sAVR. The most important perioperative complications are pAR and need for pacemaker implantation. However, coronary flow impairment due to partial obstruction of coronary ostias and vascular complications on the access site may also have long-term consequences. In addition, there remain concerns about the evolution of co-existing MR and the durability of THV prostheses.

Significant pAR after TAVI is common, and is associated with increased in-hospital mortality[12]. Regurgitation has been described in up to two-thirds of patients, being significant (moderate to severe) in approximately 15%[12]. The occurrence of significant pAR can be predicted by anatomical and procedural variables, such as the degree/symmetry of aortic calcification, angle of left ventricular outflow tract to ascending aorta, and the depth of the device in relation to the non-coronary cusp[29]. By contrast, significant AR is rare following sAVR (1-2%), but has also been associated with poor long-term outcome. Therefore, similar consequences on survival but also on the incidence of endocarditis, haemolysis and LV mass regression can logically be expected post-TAVI. Moderate/severe pAR after TAVI has been shown to be an independent predictor of mortality already at 1-year[12].

Pacemaker implantation has been required in approximately one-third of patients receiving the Medtronic CoreValve™ (Medtronic, Minneapolis, MN, USA), but is rarer with the Edwards SAPIEN™ (Edwards Lifesciences, Irvine, CA, USA). Its incidence with other devices is yet unknown. In either case, it is more common than after sAVR[30]. Besides the economic impact, pacemaker implantation is not innocuous and also has long-term consequences.

The influence of concomitant MR has been well studied in patients undergoing sAVR and increased late mortality reported in patients with significant residual MR[31]. Hence, MV intervention is recommended in patients with at least moderate concomitant MR who undergo sAVR. This experience can probably be transposed to the TAVI experience, and may explain why severe MR has already been reported as predictor of poor outcome after TAVI[32].

The final question is, whether durability of THVs is comparable to that of bioprostheses used in sAVR, which have an average freedom of structural failure of 12-15 years. So far, good durability of

THVs has been demonstrated up to four years, although some cases of structural failure have already been reported. Concerns about the durability are related to modifications of the pericardial tissues, behaviour of the supporting stents and the crimping of THVs inside the delivery catheter. Some of these may have been partially obviated in devices for TA-AVI, where everything is maximised to contribute to durability, because of the larger calibre permitted by this procedure.

In summary one would hope that for TAVI, key lessons have been learned from previous sAVR experience in that one should not start calling for lowering the age limits of patients included before durability of THVs has been proven.

4. What are the key determinants for successful individual patient management?

A variety of different procedures are included under the term "TAVI". Having in common an image-guided placement of a crimped bioprosthetic valve, the approaches vary in terms of access used to insert the THV, from the commonly performed transfemoral and transapical routes to the newly developed approaches through the subclavian artery or ascending aorta[33]. There is also an increasing number of self-expandable and balloon-expandable THVs available for TAVI, with their individual characteristics. As the various access routes and THVs have their own strengths and weaknesses, key for success is a patient-centred individual decision-making process to identify the optimal treatment approach.

Vital information for this decision to be made comes from high quality cardiac imaging including ECHO, with 3D-TEE being the preferred technique, and multislice CT performed by experienced investigators[34]. This is of particular importance as we have learned from 3D-TEE and CT studies that the aortic annulus is not a round structure, something which is important for TAVI planning. Well equipped with this data and the results of peripheral vascular fluoroscopy, CT and clinical patient information, a multidisciplinary Heart Team is able to make individualised decisions on the optimal TAVI approach.

No randomised trials exist at this time comparing TA- versus TF-AVI. Similar outcomes have been reported in patients with comparable risk profile[3] and learning curves for TA-AVI have been reported to be low[35]. However, most institutions evaluate patients for a transfemoral approach in the first instance. If no peripheral vascular access can be achieved due to the size of the femoral arteries, tortuous vessels or severe atherosclerosis, patients are almost always suitable for TA-AVI. The trans-axillary and trans-aortic approaches are seen as alternatives in these patients, but have been used less frequently[3].

It is also common sense that patients with severe aortic atherosclerosis, particularly those who present with aortic aneurysms, intraluminal calcifications or thrombus formation may be best treated using TA-AVI. On the other hand, patients with severe respiratory disease may benefit from TAVI approaches that do not involve thoracic surgery at all, as postoperative chest pain can be avoided. There is also the view that in patients in whom upwards movement of the THV during deployment is a particular concern (e.g., after MV replacement or in presence of a bulky ventricular septum), TA-AVI guarantees more stability of the prosthesis during deployment and should be preferred.

A team trained for multiple skills can offer all TAVI procedures to the individual patient, being even able to switch from one to another, if needed, during the intervention. If the choice of the access site is not driven by availability or existing skills, decisions can be unbiased, which will improve procedural outcome. Successful individualised patient management mandates the intra-procedural provision of surgical and interventional equipment that adequately can be used by the multidisciplinary Heart Team in case intra-procedural complications occur[35,36].

In summary, the proposed setting of a multidisciplinary/skilled Heart Team is the cornerstone for a successful TAVI centre. It offers all treatment options for patients with AV disease and will individualise patient management, which is needed to optimise patient outcome.

5. How will the world of percutaneous valve intervention look in 2022?

Prosthetic valve markets, globally, are expected to grow 8.2%, between 2010 and 2017, to reach a value of over $2.5 billion. At the moment, growth of THVs for this period is estimated to reach a market value of $691 million[37]. Market growth is driven by demographic changes, product approvals, technology advancements and reimbursements. Regions such as Asia-Pacific, the Middle East, Africa and South America will see an economic growth in the coming years and will contribute to the demand of biologic valves and THV therapies. In addition, increased competition of various THV manufacturers will reduce the commercial price of THVs, and future devices will make single-handed implantation feasible. Both will improve the cost effectiveness of TAVI and facilitate its usage.

Current trials of TAVI include only patients with AS in the highest 10th percentile of risk[2]. If TAVI were to be expanded to lower-risk patients, results would have to compare favourably with those of sAVR. Techniques that remove calcified leaflets may allow for implantation of larger valves, symmetrical expansion of the frame, thereby increasing durability, and reducing paravalvular leakage and risk of stroke.

More experience will be gained with a "valve-in-valve" transcatheter approach to treat bioprosthetic degeneration, not only in the AV, but also other heart valve positions[38]. This option may decrease the age when one chooses for a biological instead of mechanical valve during open-heart surgery to as low as 50 to 55 years.

Implantation of THVs will be directed towards less invasive techniques. For TF-AVI this means that vascular complications have to be minimised. TA-AVI will become less invasive using apical closure devices. In the future, it might be even possible to perform complete percutaneous TA-AVI's. Nevertheless, it also remains to be seen how alternative access routes through the

ascending aorta or the subclavian artery will further develop. Improved imaging, device modification and usage of embolic protection devices will hopefully decrease vascular/access complications and risk of stroke in all access routes.

In contrast to TAVI, development of transcatheter techniques for MV treatment are more challenging, due to its anatomy. Current devices are unlikely to be ideal for the majority of patients, however, stent-based MV bioprostheses are currently being tested in animals and seem the more likely solution in patients where surgical MV repair is not feasible[39].

Training of interventional cardiologists and cardiac surgeons will need to include THV techniques and needs to be supported by interventional and surgical societies[23]. Over time, the number of sAVR's will decrease and training in surgical techniques will become more challenging. Patients who undergo sAVR in the future will also more often present with concomitant cardiac disease or present after failed TAVI, conditions which need technically more experienced surgeons.

In summary, THV techniques are still at an early stage of development, although implantation of more than 30,000 devices worldwide has helped establish the success of this procedure. More information on long-term results is needed to determine the real future evolution of these techniques.

Commentary from the Interventionalists

It is a great pleasure to comment on the manuscript of our surgical colleagues and important, as well, to highlight the similarity of our views. This doubtless reflects the increasing interdisciplinary teamwork involved in the evolution of TAVI into mainstream clinical practice.

For inoperable patients, TAVI is regarded as the treatment of choice by both groups. For operable but high-risk patients, we re-emphasise that mortality was non-inferior for TAVI versus surgery in the PARTNER trial, Cohort A. Both groups point out that risk scores are inadequate in isolation to determine the optimal therapy for a single patient, underline the importance of a team approach for decision-making and coordination of the treatment pathway, and call for caution with respect to premature expansion of the procedure to lower risk groups.

We also agree that the catheterisation laboratory provides the optimum environment for performance of TAVI procedures due to the key importance of optimal imaging facilities, with the availability of interdisciplinary teams should immediate conversion to open surgery or treatment of vascular complications be required. In the future, hybrid operating theatres may provide a superior setting.

With respect to factors influencing patient outcome, our surgical colleagues correctly stress the importance of concomitant mitral regurgitation. We agree that associated valve disease should be carefully investigated, and that research should aim to better identify patients in which mitral regurgitation will improve as a result of left ventricular remodelling after TAVI[40-42].

An important point for the future expansion of TAVI in differing health care systems will be the demonstration of cost effectiveness. Recent US data[43] suggest that the cost per quality adjusted life year was $2,000 less for transfemoral TAVI than for conventional surgical aortic valve replacement in high-risk patients. This is extremely unusual for an emerging technology, which is almost always superior but also more expensive. However, the cost per quality adjusted life year for transapical TAVI was approximately $10,000 more expensive than conventional surgery, principally as a result of the prolonged hospital stay in this group.

Ultimately, patients will always opt for less invasive techniques in preference to conventional surgery as long as those involved in their medical care can prove that newer techniques are non-inferior with respect to robust clinical endpoints and impact on quality of life.

Commentary from the valve specialists

The surgeons' point-of-view on the indications for TAVI is consistent with the opinion of interventionists and valve specialists and restricts the discussion of TAVI to patients who are at high-risk for surgery. It is difficult to distinguish patients in whom surgery is contraindicated from those who are at high risk but considered as surgical candidates, as attested by the very close values of risks scores in the two cohorts A and B of the PARTNER trial (respectively 29 and 28% for the EuroSCORE and 12% in both cohorts for the STS score)[1,2]. This highlights the limitation of risk scores in high-risk patients and the importance of clinical judgment from a multidisciplinary team. Associated risk factors not included in risk scores, such as porcelain aorta, chest wall radiation, prior CABG with crossing grafts should be defined more accurately, and the results of TAVI should be specifically assessed in these subgroups.

There is also a consensus on the need for closely involving surgeons in the TAVI process. Surgeons should be available on-site to promptly manage procedural complications. They should be also part of decision-making regarding the most appropriate intervention because of their experience in assessing surgical risk, which cannot be reduced to the analysis of risk scores. Surgeons should be part of a multidisciplinary Heart Team in which all specialists should be appropriately trained and in centres where a sufficient number of procedures are performed.

The identification of prognostic factors deal mainly with post-procedural complications. There is no doubt that preventing early complications is an important goal. However, there is also a need for refining the identification of predictive factors of long-term outcome because midterm results of TAVI are still hampered by a high proportion of non-cardiac deaths[14]. The impact of comorbidities should be better ascertained to better identify the patients who are unlikely to derive a benefit from the procedure because their life expectancy or quality of life is more compromised by their comorbidities than by their heart valve disease.

A particular feature of individual patient management is the choice of the modalities of TAVI. There is a diversity of prostheses, approaches, imaging modalities for patient screening and monitor-

ing the procedure. Comparisons are often difficult because of the influence of confounding factors. It is likely that TAVI will become less invasive, thereby favouring the trans-arterial approach under sedation without monitoring by transoesophageal echocardiography[44]. However, it is necessary to ensure that the evolution towards less invasive procedures will not compromise the quality of the results. This highlights the need for a continuous evaluation of TAVI to appropriately assess the potential impact of technical changes.

Forecasts expect an important increase in the number of TAVI procedures within the next 10 years because of population ageing and the lack of validated prevention strategies. The use of "valve-in-valve" for deteriorated bioprostheses, of "valve-in-ring" after failed mitral valve repair, already expands the field of TAVI. However, an important increase will be achieved only if TAVI is performed in lower-risk patients, something which needs to be validated by appropriate randomised trials.

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THE FIVE MOST IMPORTANT QUESTIONS ON TAVI: THE INTERVENTIONISTS' VIEW

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1. Which patients should have TAVI rather than surgery?

Current evidence demonstrates that if two surgeons (and the patient) agree that medical factors preclude surgery for severe aortic stenosis, then clinical outcome after transcatheter aortic valve implantation (TAVI) is significantly better than a combination of balloon valvuloplasty and medical therapy[1,8]. These are, without doubt, high-risk patients. We also know that if two surgeons, a cardiologist (and the patient) agree that surgery for severe aortic stenosis is feasible, but that medical factors pose a high risk, then mortality one year after TAVI is equivalent to mortality after surgical aortic valve replacement[2]. No such data exist for intermediate or low-risk patients. However, discussion and deliberation are blurred by the difficulty in accurately determining risk for an individual patient, and, at which level of risk one technique may be considered superior to the other.

In conventional surgery, such decisions are determined by well-established clinical risk scores –no such scores exist for TAVI. Moreover, currently available risk scores for cardiac surgery (EuroSCORE, STS and Ambler scores) only provide a gross estimation of risk and cannot be used in isolation to estimate the exact operative mortality in an individual patient[16]. They should therefore be interpreted with caution and only used as part of an integrated approach, which incorporates other patient characteristics, the clinical contex and local outcome data. These issues are particularly relevant in the very elderly where mortality benefits are more difficult to demonstrate (and are arguably less important), and where early mobilisation, rapid recovery and freedom from symptoms with improved quality of life after a procedure may make the ultimate difference for the individual and their carers.

In this context, cost effectiveness of any newly available procedure becomes a crucial factor, even in developed countries with comprehensive health care systems. In inoperable patients with severe aortic stenosis, follow-up data at two years indicate that TAVI is cost-effective at a level comparable with other well accepted therapies.

Are there some patients with severe aortic stenosis who should not be treated at all? Clearly, despite the demonstrated efficacy of TAVI, high-risk (and expensive) interventions should not be offered to patients with short life expectancy or those whose general frailty will limit the overall benefits to quality of life.

Finally, who should determine the choice between TAVI, conventional surgery or medical therapy, and to what extent should the patient's preference play a role? Ultimately, the final decision remains the responsibility of all parties, and is usefully informed by the outcome of multidisciplinary team discussions. On the basis of the current data, there is no mandate to offer TAVI in lower risk patients purely in response to patient preference for a less invasive procedure – in these circumstances, honest and comprehensive discussion should aim to convince the patient that surgery is currently the best solution.

In summary, clinical risk scores in isolation remain insufficient to determine the best treatment option for an individual patient which should be based upon global appraisal and the judgement of a multidisciplinary team. For patients unsuitable for surgery, TAVI

is the best choice in most cases –without intervention, two-year mortality is 68%[1] although medical therapy alone remains appropriate in frail patients and those whose life expectancy is diminished for other reasons.

For high-risk surgical candidates, both TAVI and conventional valve surgery may be considered. No comparative data exist in lower risk groups, and surgery remains the established approach. Similarly, long-term follow-up data and information concerning the durability of current percutaneous devices are required before TAVI can be offered routinely to younger patients. Current data extend up to 46 months follow-up and demonstrates no early loss of valve function[17] though, like other bioprostheses, TAVI devices are likely to degenerate with time[45].

2. In which setting should TAVI be performed? What are the important prerequisites?

TAVI remains a complex procedure, but despite advances in the technique and greater operator experience has an attributable 30-day mortality of 6-10%.

First, we need to define the crucial prerequisites for best patient outcomes. The first factor is experience –there is a significant learning curve for TAVI[36] and previous data concerning percutaneous coronary procedures suggest that high volume operators and centres have significantly less complications than their low-volume counterparts (particularly for higher risk procedures)[46]. Although it remains unclear how much experience is sufficient, it appears reasonable that TAVI should currently be limited to centres with a procedural volume affording frequent and routine exposure for all team members (perhaps 40 procedures per annum). Furthermore, in the initial roll-out phase, procedures should be performed under the observation of experienced operators. Expertise should extend beyond the TAVI procedure itself to include the percutaneous management of peripheral vascular and access site complications. These are the most frequent complications associated with TAVI and associated with poor long-term outcome[14,23,36,47].

Second, we need to consider whether all TAVI procedures should be performed in a surgical theatre or hybrid room rather than in a general catheterisation laboratory. Sterility is imperative and has to be guaranteed, wherever TAVI is performed. Although interventional cardiologists perform thousands of percutaneous procedures annually (even with large French size devices) under sterile conditions, the possible need for immediate conversion to open surgery during TAVI procedures makes a sterile environment mandatory. Currently, rates of conversion to emergency surgery are low (0-2%) with survival less than 10%[14,23,36,47].

Immediate surgical intervention may be required during transfemoral or trans-subclavian TAVI for closure of a myocardial perforation that cannot be treated with pericardiocentesis alone, and treatment of access site complications which are not amenable to endovascular repair. In both scenarios, surgery can be performed immediately and without need for cardiopulmonary bypass. Other complications, such as aortic dissection or device embolism are extremely rare and usually require more comprehensive preparation and stabilisation of the patient before surgery can be performed successful. In case of, e.g., aortic rupture, there is only little chance of a successful surgical intervention at all. The current reduction of mortality associated with TAVI is attributable to the increasing experience of the team, availability of optimal imaging techniques for precise positioning of the prosthesis and optimal endovascular management of vascular complications. These requirements are more readily met in a fully equipped catheterisation laboratory than in a surgical theatre. Procedures performed via the transapical or direct aortic route are readily performed in a surgical theatre provided optimal imaging resources exist. In these procedures, access site complications cannot be treated by catheter techniques and pericardiocentesis has little role as a lifesaving intervention[36]. In the future, hybrid operating rooms may be a good compromise for both groups of patients.

For the present time, the immediate availability of a cardiothoracic and/or vascular surgical team is key, together with access to a fully prepared bypass machine to allow a period of haemodynamic stability in the event of unexpected complications, and (according to local expertise and facilities) an interventionist with experience in the percutaneous management of vascular complications.

3. Which factors will significantly impact on short- and long-term prognosis in comparison with surgery?

Survival during the first year after TAVI is influenced by both cardiac and non-cardiac factors. Some of these relate to the pre-procedural global appraisal of an individual patient's risk and correspond with factors related to outcome after other surgical and percutaneous procedures. Comorbidities such as peripheral artery disease, left ventricular dysfunction, impaired renal function, and pulmonary hypertension, need to be carefully considered. However, recent data suggest that immediate and long-term outcome after TAVI does not differ between patients with normal and reduced ejection fraction, suggesting that TAVI should not be withheld in carefully selected patients with impaired left ventricular function[48].

Other factors associated with adverse short and long-term outcome include peri- and post-procedural complications, notably access site bleeding or infection, stroke and paraprosthetic aortic regurgitation. Stroke, although less frequent than bleeding and vascular complications[14,48], has multifactorial causation, and only 50% of events occur in immediate relation to the procedure itself. Diverse solutions are likely to be required, including the use of mechanical protection devices to prevent procedural stroke and optimised antiplatelet therapy to reduce the incidence of post-procedural and late (>30 days) events – it remains unclear whether later stroke events are related to the procedure, the antiplatelet or anticoagulation regimen, or other comorbidities[49]. Paraprosthetic aortic regurgitation may be due to imprecise valve sizing and positioning, as well as valve calcification or geometrical misshaping of

the annulus or aortic root[12]. Although usually mild, recent data demonstrate that moderate or severe paraprosthetic aortic regurgitation is associated with adverse outcome at long-term follow-up. Successful treatment by means of valve repositioning using snaring-devices, post-dilatation, device closure, and valve-in-valve implantation have all been reported, and newer generation valves are under development to minimise the frequency of this complication.

The need for permanent pacemaker implantation is a frequent complication of TAVI, particularly after implantation of self-expanding prostheses. New conduction disturbances requiring permanent pacing usually occur within the first seven days, and have an association with implant position[50].

4. What are the key determinants for successful individual patient management?

Each of the steps in a TAVI care pathway including assessment, patient selection, procedural techniques and post-procedural care should be conducted in a standard, yet individualised manner to ensure a high quality outcome for each individual patient. Though challenging, this goal can be achieved by the development of standard-operating procedures, the use of standard protocols and checklists to account for patient related factors wherever possible.

The most important factor in ensuring successful outcome for an individual patient is thorough assessment and case selection. This clearly requires a team approach with contribution from cardiologists, cardiac surgeons, imaging specialists, anaesthesiologists, and (ideally) physicians with expertise in the care and assessment of the elderly. A consensus decision should be reached for each individual patient regarding the necessity for any treatment at all and the choice of TAVI as the best treatment option. The decision-making process should be transparent, and include the input of the patient (and their carers), although expansion of the indications for TAVI to lower-risk cohorts in response to patient preference should be resisted until appropriate trial data are available.

Patients presenting acutely with haemodynamic compensation secondary to aortic stenosis should not undergo immediate TAVI since outcome in these patients is poor (as with emergency surgical aortic valve replacement). Balloon aortic valvuloplasty should be considered as an initial strategy, and may provide a bridge to TAVI at a later stage[51]. Balloon valvuloplasty may also be a very useful initial option in cases with poor left ventricular function or when there is doubt concerning the relative contributions of cardiac and respiratory disease to symptoms of dyspnoea. This differentiation is of particular importance, since many patients who die in the first year following TAVI do so as a result of background respiratory disease[17].

The second key step is adequate patient preparation including adequate hydration, avoidance of excess exposure to contrast media (particularly in the presence of renal impairment) and choice of the best access site[52]. The optimal mode of periprocedural imaging remains the source of debate. While some highly experienced operators perform successful procedures under deep conscious sedation using fluoroscopy without echocardiographic guidance[53] (allowing reduction in procedural time and overall cost, rapid mobility and a shorter hospital stay) others argue that periprocedural transoesophageal echocardiography is mandatory to allow precise positioning of the prosthesis, immediate post-implantation assessment and support in the event of unanticipated complications. There are no conclusive data to indicate that either strategy is superior, although most would concur that transoesophageal echocardiography should be available during the procedure if needed. Several newer imaging tools have been developed to support valve positioning, but further data are needed to evaluate their clinical advantage.

The optimal approach to the treatment of associated coronary artery disease is yet to be determined and is the subject of planned randomised trials. Both simultaneous and staged procedures are feasible and currently management should be determined on an individual case basis after assessment by the multidisciplinary team[54].

Finally, it should be re-emphasised that teamwork is mandatory and essential for the best management of TAVI patients. All team members (surgeons, interventionists, general cardiologists, anaesthesiologists, intensive care specialists, nurses and technicians) contributing to a TAVI programme need to cooperate and share their experience with a common goal to provide best individual patient care. Data collection, internal audit and quality control help rapidly overcome the learning curve and help to identify and negate negative trends.

5. How will the world of percutaneous valve intervention look in 2022?

We believe that TAVI will account for 80% of interventions for aortic stenosis in 2022 as a result of the less invasive nature of the procedure (which will eventually lead to a lower incidence of hospital complications), faster patient recovery and ultimate cost-effectiveness[54]. Valve-in-valve TAVI will become the solution for treatment of failing surgical bioprostheses[55-58]. Newer devices will help to resolve current issues, such as paravalvular aortic regurgitation and need for repositioning. Devices will be delivered through smaller access sheaths with improved closure devices and vascular access problems will be rare. The problem of periprocedural stroke will be reduced by mechanical protection devices and the incidence of post-procedural stroke will be reduced by improved valve design and leaflet construction, and by standardised, evidence-based antiplatelet therapy.

There will be standardised protocols for patient selection retaining the cooperation of cardiac surgeons, and TAVI will have paved the way for increasing interaction of multidisciplinary specialists.

Interventional cardiologists and cardiac surgeons will remain busy, and the multidisciplinary "Heart Team" will be at the centre of the decision making process for each individual patient.

Commentary from the surgeons

Although cardiologists and cardiac surgeons traditionally do not always agree on patients care, we were impressed by the conformity of our thoughts and the interventionists' view regarding the importance of a multidisciplinary Heart Team. This can obviously be seen as a result of the successful collaboration over recent years, and is in itself already one of the great achievements of THV treatment compared to the historical interactions on percutaneous coronary intervention.

A close collaboration between various specialties is not only key to patient selection, but of particular importance during the procedure itself to improve patient outcome. Therefore, both groups agree with recommendations by interventional/surgical societies that a consensus decision on the mode of treatment should be aimed for by multidisciplinary Heart Teams[8,23].

However, there are some points, which justify different views from our side.

We agree that current risk scores cannot adequately be used to predict outcome for TAVI, but one should also be cautious in using them to predict outcome after sAVR[25]. Recent trials have demonstrated that outcomes after sAVR are better than even those predicted by the best validated STS score[2]. Therefore, current scores should only be used as a guidance to assist Heart Teams identifying patients who are high-risk for sAVR. It remains to be seen how the modified EuroSCORE II will improve this situation.

A hybrid room has been cited by the interventionists as the optimal place for the procedure. Although we agree with this, it is worth noticing that so far the vast majority of TAVIs, even through transapical access, have been performed in catheter laboratories. However, cases of even late infection, particular endocarditis of the implanted THV, are rarely reported and results have been excellent[14].

Survival of TAVI patients in whom cardiopulmonary bypass was needed is quoted to be 10%. There is not much evidence published on the outcome of these patients, and the SOURCE registry[14] should not be used as a reference, as it does not contain this data. Cardiopulmonary bypass during TAVI can be used as a bail-out strategy if major complications occur, or as prophylactic in very high-risk patients (e.g., severe left ventricular failure), and hence survival needs to be seen in this context.

Concerning long-term prognosis and determinants for a successful TAVI procedure, we agree with our interventional colleagues that stroke, paravalvular leakage and pacemakers, particularly when using self-expandable devices, are of major concern if one discusses TAVI in low-/median-risk patients. The fact that there are no easy solutions available to resolve these issues, and given that 80% of surgical patients are of low-/median-risk (STS score <3), we were surprised to read that our colleagues estimate that by 2022, 80% of all procedures to treat AS will be performed using TAVI. We believe that this figure will be reached for high-risk patients, but we do not expect that use of TAVI will reach more than 50% of the total number of procedures, as long as it is used in a responsible manner.

Commentary from the valve specialists

Concerning the choice between TAVI and surgery, there is clear consensus that the current use of TAVI should be restricted to patients who are at high risk for surgery. We agree entirely that it is too early to extend the indications for TAVI towards patients at lower risk, not least because of the lack of information on the durability of current valve substitutes. Despite their limitations, only multivariate risk scores can assess the combined impact of age and comorbidity on overall operative risk.[16] However, they should be interpreted cautiously by an experienced multidisciplinary team.

The discussion concerning the optimal setting in which TAVI should be performed addresses two main issues: the need for a Heart Team and the best technical environment. We agree with the consensus for on-site surgery, firstly for optimal patient selection, secondly for joint participation in the procedure, and thirdly for the prompt and effective management of peri- or post-procedural complications. Hybrid operating rooms would be a welcome development, addressing the need for optimal sterile conditions and imaging though their cost remains a limiting factor and a further incentive for restricting performance of TAVI to a limited number of high-volume centres. The threshold of at least 40 procedures per year seems reasonable.

Unlike our colleagues whose principal focus may be on the procedure itself, the identification of prognostic factors is an important priority for physicians involved in patient follow-up.[59] Early specific complications of TAVI (including stroke, paraprosthetic aortic regurgitation and need for pacemaker implantation) may contribute to impaired outcome. Besides the assessment of long-term durability of the prostheses, appropriate strategies for predicting and preventing complications are a prerequisite before the extension of the indications for TAVI to lower risk cohorts.

The issues linked to the management of the individual patient highlight the difficulties in selecting the most appropriate therapy and is particularly relevant to valve specialists. There is no doubt that an individual approach is needed and that it should include detailed information for the patient and their family. However, we should take care that patient preference for TAVI does not dominate the clinical decision-making process, particularly if conventional surgery is a safe option. A recent statement on the application of non-surgical treatment in mitral regurgitation is also relevant in aortic stenosis, "…we need to be sure that we do not sacrifice proven long-term effectiveness for short-term issues, such as convenience, invasiveness, or reversible procedural complications."[60] Comparative series are still needed to guide the choice of approach, the modalities of anaesthesia or sedation and the most appropriate imaging techniques.

We agree with our interventional colleagues that an important increase in the number of TAVI procedures within the following 10 years is inevitable, not only because of an ageing population, but also an extension of the indications for TAVI. Further important increases also seem likely if high quality evidence supports the use of TAVI in lower-risk patients and substantial reduction in the cost of the devices enhances the already encouraging cost-effectiveness data.[61,62]

Conflict of interest

C. Naber reports speaker and research cooperation for Medtronic and study participation for Claret Medical and Sadra Medical. B. Pendegast reports speakers honoraria for Edwards LifeSciences. M. Thomas reports proctoring and consultancy for Edwards LifeSciences. A. Vahanian reports honoraria for Edwards LifeSciences, advisory board for Abbott and Valtech. B.Iung reports consultant for Abbott, Bayer, Boehringer Ingelhiem, Servier, Valtech and speaker's fees for Sanofi Aventis and Edwards LifeSciences. A.P. Kappetein reports steering committee member of SURTAVI trial which is supported by Medtronic. O. Wendler proctor for Edwards LifeSciences, former consultant for Edwards LifeSciences, JenaValve and Medtronic. R. Rosenhek, P. Tornos, C.M. Otto, M.J. Antunes, R. Lange report no conflict of interest to declare.

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