position paper

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2020 update of the Austrian Society of Cardiology (ÖKG) and the Austrian Society of Cardiac Surgery (ÖGHTG) on the position statement of the ÖKG and ÖGHTG for transcatheter aortic valve implantation 2011

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Summary This position statement is an update to the 2011 consensus statement of the Austrian Society of Cardiology (ÖKG) and the Austrian Society of Cardiac Surgery (ÖGTHG) for transfemoral transcatheter aortic valve implantation.
Due to a number of recently published studies, broadening of indications and recommendations of medical societies and our own national developments, the ÖKG and the ÖGHTG wish to combine the 2017 ESC/EACTS guidelines for the management of valvular heart disease with a national position paper and to focus on certain details for the application in Austria. Thus, this position statement serves as a supplement and further interpretation of the international guidelines.

Keywords Aortic stenosis · TAVI · Heart team · Perioperative risk · Interventional expertise

Abbreviations

AS	Aortic stenosis
AVA	Aortic valve area
BAV	Balloon valvuloplasty
CMR	Cardiac magnetic resonance imaging
EACTS	European Society of Cardiothoracic Surgery
ESC	European Society of Cardiology
ECMO	Extracorporeal membrane oxygenation
LV	Left ventricular
LVOT	Left ventricular outflow tract
MSCT	Multi-slice-computed-tomography
ÖGHTG	Austrian Society of Cardiac Surgery
ÖKG	Austrian Society of Cardiology
PCI	Percutaneous coronary intervention
TAVI	Transcatheter aortic valve implantation
SAVR	Surgical aortic valve replacement

Indications for TAVI

According to the ESC/EACTS guidelines [1] the indications for transcatheter aortic valve implantation (TAVI) following a heart team discussion are:

a) Symptomatic severe aortic stenosis (AS)

and:

b) Contraindication or increased risk for surgical aortic valve replacement (SAVR).

Comments on symptomatic severe AS

In older patients or patients with relevant comorbidities the clinical evaluation of typical AS-related symptoms (dyspnea, angina pectoris, syncope) may be difficult, thus an individual assessment is necessary:

- Medical history in older AS patients less sensitive: lack of cardiac symptoms due to restrictions because of extracardiac comorbidities; impaired medical history, for instance in patients with dementia, depressive disorders, impaired speech comprehension.
- Medical history in older AS patients less specific: overlap of symptoms due to comorbidities, such as pulmonary diseases, concomitant valvular heart diseases, systolic or diastolic heart failure, coronary artery disease, arrhythmia, anemia.

Low-gradient aortic stenosis

Some patients with aortic stenosis (AS) have a low-gradient AS defined as a small aortic valve area (AVA usually below 1.0 cm^2) but a low mean transvalvular gradient (below 40 mm Hg). This discrepancy may raise uncertainty regarding the actual severity of AS and may introduce error about the appropriate indication for aortic valve intervention. Additionally, patient's symptoms may result from left ventricular systolic dysfunction and could obscure the correct diagnosis. This condition is frequently caused by a low LV outflow state that may result from reduced left ventricular ejection fraction.

Classical low-flow, low-gradient (LF-LG) AS is defined as an AVA < 1.0 cm^2, a mean gradient < 40 mm Hg, and an LVEF < 50%. The low-flow state frequently results from LV systolic dysfunction, which may either be related to the presence of severe AS (LV afterload mismatch) or to the presence of coexisting cardiomyopathy.

Paradoxical LF-LG AS is defined as an AVA < 1.0 cm^2, indexed AVA < 0.6 cm^2/m^2, mean gradient < 40 mm Hg, LVEF ≥ 50%, and presence of low-flow (stroke volume index < 35 mL/m^2). The reduced stroke volume generally results from severe LV concentric hypertrophy with small LV cavity, which may be associated with impaired LV diastolic filling, and reduced LV systolic longitudinal shortening. The presence of a paradoxical low-flow, low-gradient AS pattern should raise the suspicion of cardiac amyloidosis, which is present in up to one third of those patients. Coexisting cardiac amyloidosis is associated with increased mortality, if severe AS is left untreated.

Normal-flow, low-gradient (NF-LG) AS is defined as an AVA < 1.0 cm^2, indexed AVA < 0.6 cm^2/m^2, mean gradient < 40 mm Hg, LVEF ≥ 50%, but normal flow, i.e. stroke volume index > 35 mL/m^2. Reduced aortic compliance combined with systolic hypertension may lead to a markedly decrease in transvalvular gradient and may result in a normal-flow LG pattern in patients with severe AS [1].

With all three categories of patients with low-gradient AS (classical low-flow, low-gradient, paradoxical low-flow, low-gradient, and normal-flow, low-gradient) the clinical decision making depends on accurate differentiation between true-severe AS (associated with a benefit from aortic valve intervention) and pseudo-severe AS (associated with no benefit from aortic valve intervention; usually managed conservatively).

Dobutamine stress echocardiography may be used to appropriately classify classical low-flow, low-gradient AS. Individuals with only modest increase in transvalvular flow during dobutamine stress echocardiography may not reach normal flow range. In such patients, uncertainty about stenosis severity may persist despite using dobutamine stress echocardiography. In such patients, it is useful to calculate the projected AVA at normal flow rate.

Calcium scoring of the aortic valve using computed tomography should be used for classification of patients with paradoxical low-flow, low-gradient and normal-flow, low-gradient AS.

Patients with low-flow, low-gradient true-severe AS have worse outcomes compared to patients with classical high-gradient AS following aortic valve intervention but they may have an important survival benefit compared to patients managed conservatively.

Importantly, patients with paradoxical LF-LG AS have worse outcomes compared with high-gradient AS, moderate AS, and NF-LG AS but have better prognosis when compared with classical LF-LG AS [1].

Asymptomatic aortic stenosis

In patients with asymptomatic severe aortic stenosis the ESC/EACTS guidelines [1] recommend additional criteria, such as exercise testing, progression of peak velocity in echocardiography, natriuretic peptides, pulmonary artery pressure, severity of AS calcification (on echocardiography, MSCT, potentially CMR) for decision making of indications for cardiac surgery.

The authors of this position statement postulate in analogy to patients with symptomatic aortic stenosis that those additional criteria are of clinical value for decision making in patients with inconclusive symptoms or comorbid conditions mimicking aortic stenosis, although there is no evidence and no statement on this issue in the ESC/EACTS guidelines [1].

There are not enough data for the efficacy of TAVI in patients with asymptomatic AS, but trials addressing this patient subgroup are ongoing (e.g. EARLY TAVR trial NCT03042104). According to the authors of this paper, TAVI in asymptomatic patients with AS may be indicated for timely referral to non-cardiac surgery such as urgent hip replacement or colorectal cancer resection.

Comments on the risk of SAVR

The ESC/EACTS guidelines [1] recommend:

> *In patients with increased operative risk (STS or Euro-SCORE II ≥ 4% or logistic Euro-SCORE I ≥ 10%) or other risk factors not included in these scores (such as porcelain aorta, sequelae of chest radiation, functional impairment, restricted mobility . . .) the decision between SAVR and TAVI should be made by the heart team according to individual patient characteristics, with TAVI being favored for older patients (≥ 75 years) with suitable transfemoral approach (class I-B).*

This recommendation includes two essential components of the individual therapeutic decision making:

a) The perioperative risk
b) The age and individual life expectancy

Perioperative risk

In clinical TAVI trials the perioperative risk is most often evaluated by surgical risk scores, with the STS score, the logistic EuroScore I and II being the most commonly used.

Although these scores are only of limited value for transcatheter interventions, they are still widely used due to a lack of appropriate alternative TAVI risk scores. The recommendation of the ESC/EACTS [1] to perform a TAVI procedure as an alternative to SAVR in patients with an STS or Euro-SCORE II ≥ 4% is based on the results of randomized controlled TAVI trials in intermediate risk patients (PARTNER 2A, SURTAVI). Those trials have shown superiority of transfemoral TAVI versus SAVR in the short-term and mid-term follow-up [2–4]. The 5-year data of the PARTNER 2 trial [5], however, showed no significant difference of the primary endpoint (mortality or severe stroke) between TAVI and SAVR (47.9% versus 43.4%, $p = 0.21$). A post hoc landmark analysis of this study, which excluded the endpoints of the first 24 months and which did not differentiate between the transfemoral and transapical approach, showed a lower incidence of the primary endpoint in the SAVR cohort. This may be related to the rate of paravalvular leaks using the SAPIEN XT (Edwards Lifesciences, Irvine, CA, USA) prosthesis or the different vascular access sites.

"LOW RISK" patients Recently, two randomized trials (PARTNER 3 [6] and Evolut Low Risk [7]) comparing TAVI and SAVR in patients with low surgical risk were published. In both studies the median STS score was 1.9%. The PARTNER 3 study included about 1000 patients and revealed a significant reduction in the combined primary endpoint (death, stroke or rehospitalization) after 1 year in favor of the TAVI cohort (8.5% vs. 15.1%). The Evolut Low Risk study showed non-inferiority of TAVI vs. SAVR concerning the combined primary endpoint (death or stroke 5.3% vs. 6.7%).

Limitations of these trials:

1. Certain relative common anatomic features were among the exclusion criteria (e.g. bicuspid aortic valve, severe calcification of the aortic root).
2. The surgical prostheses were older prostheses types (no rapid deployment prostheses).
3. Because of the short follow-up duration of 1–2 years no statement can be made concerning the durabil-

ity of the transcatheter valves, which is of importance for younger patients.
4. The pacemaker rate is higher after TAVI than SAVR (depending on the type of prosthesis).

Thus, there are concerns regarding a liberal expansion of TAVI indications to certain (younger < 75 years) low risk patients, which were underrepresented in the randomized trials.

Beyond the interdisciplinary decision process (heart team) the patient preferences will gain more and more importance if both methods (TAVI and SAVR) seem to be equally suited after detailed consultation by the cardiologist and the cardiac surgeon (that means shared decision making).

Several additional factors, not adequately reflected by the classical risk scores, are associated with a higher perioperative risk and would therefore favor a TAVI procedure according to the ESC/EACTS guidelines [1]:

- Other severe comorbidities (e.g. liver disease, such as liver cirrhosis with an elevated Child score)
- Age ≥ 75 years (see Section *Age of the patient and individual life expectancy vs. durability of the prosthesis*)
- Previous cardiac surgery (especially intact bypass grafts)
- Frailty (see below)
- Restricted mobility and limited potential of postinterventional cardiac rehabilitation
- Technical and anatomical aspects (see below)

There are other criteria which would favor SAVR:

- Age < 75 years (see Section *Age of the patient and individual life expectancy vs. durability of the prosthesis*)
- Endocarditis
- Short distance between coronary ostium and annular plane
- Unfavorable size of the aortic annulus for TAVI
- Unfavorable aortic root for TAVI
- Unfavorable valve morphology (e.g. bicuspid aortic valve, severe calcification, calcification protruding into the LVOT)
- Thrombi in the left ventricle or in the aorta
- Cardiac comorbidities requiring a concomitant procedure:
  - Severe coronary artery disease requiring an aortocoronary bypass surgery.
  - Primary mitral valve pathology with severe valve dysfunction.
  - Tricuspid valve pathology with severe valve dysfunction.
  - Aneurysm of the ascending aorta.
  - Septal hypertrophy requiring myectomy.

Comments to the above criteria:

Concerning frailty The frailty of a patient is, in addition to comorbidities and age, a substantial determinant for prognosis. In recent years, different medical specialties (cardiology, surgery, oncology, neurology, orthopedics, rheumatology, geriatrics) have suggested a huge number of scoring systems in order to objectivize and quantitate the frailty of a patient [8]. Among them some can only provide simple and fast rough estimates, whereas others provide time-consuming and well-differentiated assessments. Some of those scores are more appropriate for population-based studies, others more for clinical questions. Thus so far, none of those frailty scores have been sufficiently validated for clinical decision making.

The results of ongoing studies will show if frailty scores could be used as independent predictors and supporting therapeutic decisions. The objective should be an international uniform scoring system validated for a multidisciplinary, clinical approach.

Concerning technical and anatomical aspects When considering SAVR or TAVI technical and anatomical aspects have to be taken into account. Thus, in patients with previous thoracic radiation therapy with higher radiation dose (when using low or moderate doses no relevant adhesions are expected), in patients with porcelain aorta or previous cardiac surgery—especially when intact bypass grafts would be at risk by another sternotomy—a transfemoral TAVI should be preferred given that the transfemoral approach is favorable. In the prohibitive risk cohort of the PARTNER trial a porcelain aorta was the most common cause for technical inoperability in 46% of the patients [9].

Concerning cardiac comorbidities:

- Coronary artery disease and aortic stenosis often are present at the same time [10]. The prevalence of coronary artery disease in older patients with severe aortic stenosis is around 60% [11]. Data showed that in patients with both diseases a concomitant aortocoronary bypass surgery and SAVR reduced the risk for perioperative myocardial infarction and the following long-term mortality [12]. On the other hand some other data showed that in TAVI patients PCI can be performed effectively and safely [13]. As those data are not prospectively randomized, the present ESC/EACTS guidelines [1] recommend PCI of only hemodynamically relevant proximal stenoses (class IIa recommendation).
- 2–33% of potential TAVI patients also suffer from moderate to severe mitral regurgitation (around 20% in the PARTNER trials [14, 15], in France II 21% ≥grade 2, 2% ≥grade 3 [16]). On average the rate of degenerative mitral regurgitation is 47% (n = 1248 patients) [17]. Recently published trials (GARY registry [18], and a meta-analysis [19]) showed that a moderate to severe mitral regurgitation is a negative prognostic factor for short-term and mid-term survival [17]. It is nevertheless im-

portant to know that a degenerative mitral regurgitation (= an intrinsic mitral valve pathology) will not significantly change after TAVI. Therefore, in those patients as well as in patients with severe tricuspid regurgitation, open-heart surgery should be the preferred method if possible.

Age of the patient and individual life expectancy vs. durability of the prosthesis

According to the ESC/EACTS guidelines [1] age ≥ 75 years is one of the criteria for preferring TAVI. This cut-off is due to several aspects:

- Less evidence for TAVI in patients < 70 years
- The perioperative risk correlating with age
- Other anatomical circumstances in younger patients (higher rate of bicuspid valves)
- The limited durability of bioprosthetic valves

Durability of TAVI prostheses In the meantime the Partner 3 trial [6] and the Evolut low risk trial [7] have shown good evidence for performing TAVI in patients at the age of 70–75 years. Nevertheless, one has to weigh the limited durability of bioprostheses against the individual life expectancy of the patient. According to the ESC/EACTS guidelines [1] a cut-off of 60 years is the most important trigger to select a bioprosthetic or a mechanical aortic valve. Recent studies have shown a tendency of better long-term results with mechanical aortic prostheses in patients between 50–70 years of age compared to bioprostheses [20]; however, the absence of oral anticoagulation is associated with lower bleeding rates [21]. The evidence-based recommendation for an age cut-off for transcatheter aortic valve prostheses—especially for TAVI devices of the third generation—can at the earliest be expected in 5 or rather 10 years. The TAVI trials which included patients with intermediate and high-risk patients, such as PARTNER 2A, SURTAVI, PARTNER 1A, and CoreValve High Risk [2–4, 22, 23], are of no help in this question because the mean age of the included patients was beyond 80 years, in the low-risk NOTION trial about 79 years [24, 25]. In PARTNER 3 [6] and Evolut Low Risk [7] the mean age was 73 years and 74 years, respectively. Long-term data of these and other studies (e.g. NOTION 2: inclusion criteria age ≤ 75 years) will provide more evidence, but will not be available before 2025. On the other hand the first available long-term results up to 10 years after TAVI (mainly from registries, low patient numbers, TAVI devices of the first generations with in part only echocardiographic endpoints) provided no concerns regarding earlier degeneration or shorter durability compared to surgical bioprostheses. Similar results were also shown in the recently published 6-year durability data from the NOTION trial [26]. Here the overall rate of structural valve deterioration (definition: mean aortic valve gradient ≥ 20 mm Hg or increase ≥ 10 mm Hg or new or increasing valvular regurgitation >grade 1) was higher with surgical valves compared to TAVI prostheses, whereas there was no significant difference in bioprosthetic valve failure (definition: prosthesis-dependent mortality, aortic valve reintervention, hemodynamically severe valve degeneration) [26]. The 5-year results of the PARTNER 2 trial [5] though showed a higher rate of valve-related reinterventions in the TAVI-cohort compared to SAVR (3.2% vs. 0.8%, hazard ratio (HR) 3.28; confidence interval (CI) 1.32–8.13). Long-term observations of the commonly used prostheses will show if this result is due to the implanted second generation device or due to procedural issues.

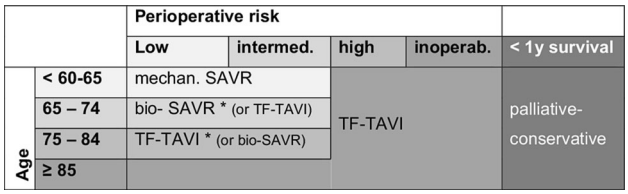

Fig. 1 Choice of SAVR versus TAVI according to patient's age and risk. *SAVR* Surgical Aortic Valve Replacement, *TF-TAVI* Transfemoral Transcatheter Aortic Valve Implantation, *weak recommendation. (Modified from [28])

In summary, there is currently no evidence that TAVI prostheses should not last as long as surgical bioprostheses. Data from long-term follow-up of low-risk trials are required to answer this scientific question.

But also another aspect concerning the life expectancy of the patient is mentioned in the ESC/EACTS guidelines [1]: if life expectancy of the patient due to comorbidities is expected to be less than 1 year (despite valve replacement), then both TAVI and SAVR should be withheld. The same applies if it is unlikely that life expectancy or quality of life will improve after valve replacement; however, the estimation of prognosis of the patient is rather difficult. An analysis of the PARTNER 1B trial [27] showed a survival benefit after TAVI only for patients with an STS score for mortality < 15%, but not for patients with an STS score for mortality ≥ 15%. In the latter group the rate of frail or "frail elderly" patients was extremely high, thus underscoring the importance of physical patient assessment before performing an intervention.

Based on a recent review [28] a therapeutic algorithm has been suggested differentiating according to perioperative risk and age [29], which in our opinion could be of additional use complementing the ESC/EACTS guidelines. But the recent results of the PARTNER 3 and the Evolut Low Risk trial [6, 7] are not yet included in Fig. 1.

Comments on valve selection

In the majority of cases, a balloon-expandable or a self-expandable valve prosthesis can be used with high efficacy.

However, in some patients the device selection for TAVI has to be individualized.

Patients with severe LVOT calcifications may benefit from self-expandable valves. Additionally, patients with small aortic annuli may benefit from the superior hemodynamic results associated with a self-expandable valve with a supra-annular design. The risk of ostial coronary occlusion may also influence valve selection (e.g. retrievable valves).

If the risk of conduction disturbances is deemed to be high, a balloon-expandable device or some novel self-expandable devices may be associated with a lower rate of pacemaker implantations.

Institutional requirements for TAVI procedures

TAVI procedures worldwide are being performed under various heterogeneous conditions due to regional and institutional differing historic developments. The ESC and EACTS provide rather general recommendations concerning the requirements of an institution for performing TAVI procedures ("heart valve center", „heart team"—see below). These recommendations are based on expert consensus and strong scientific evidence is lacking. Especially the interface between interventional cardiology and cardiac surgery in respect to the facility (OR, cath-lab ...), apparative and staff cooperation differs from center to center and is source of international controversy.

Procedural requirements

Indication of treatment in the heart team and local expertise

The updated ESC/EACTS guidelines for valvular heart disease [1] recommend a heart team decision for indication of aortic valve replacement in patients with severe aortic stenosis. The heart team requires the presence of at least one interventional cardiologist experienced in TAVI procedures and one cardiac surgeon experienced in valvular heart disease/heart valve procedures, whereas an imaging specialist, anesthesiologist, intensive care specialist, geriatrician, heart failure specialist will be involved if necessary. The heart team meetings should be scheduled on a regular basis and not only if required, and there should exist a structured protocol. The expertise of the heart team must not be limited to patients with aortic stenosis. As there are often additional valvular heart diseases the heart team must have experience in evaluation and treatment of other valvular heart diseases including their complications.

Additionally, the ESC/EACTS guidelines [1] request that TAVI procedures being performed only in heart valve centers. The reason for this recommendation is the qualitative better treatment in centers of excellence, where there is a concentration of these procedures. Relevant for this are the in Fig. 2 listed requirements, especially:

- a higher case load with more specializing in complex multivalvular heart diseases resulting in faster

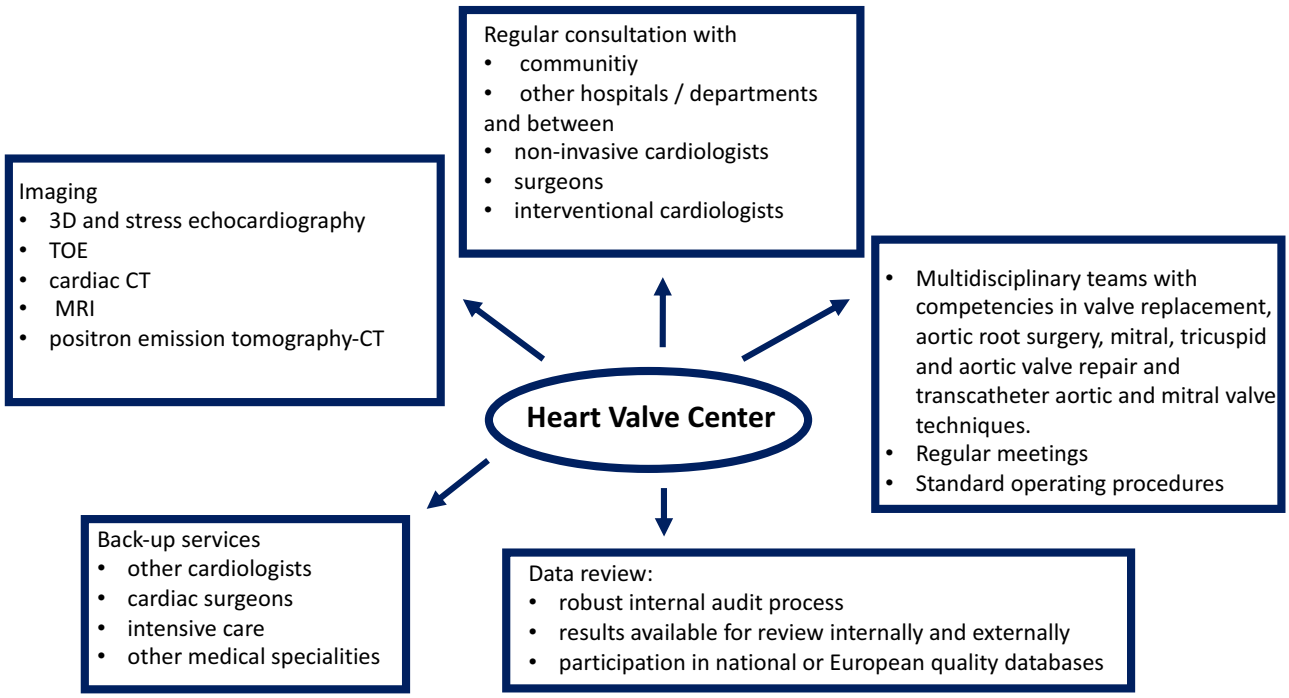

Fig. 2 Recommendation of the ESC/EACTS [1] for requirements of a heart valve center. *3D* three-dimensional, *TOE* transoesophageal echocardiography, *CT* computed tomography, *MRI* magnetic resonance imaging. (Modified from [1])

allocation and treatment avoiding irreversible damage or events to the patient.
- a continuous education with a structured and focused educational program and mentoring.
- and clinical and scientific interest in participating in national (and international) registries and studies.

Required interventional expertise: A transfemoral TAVI should be performed by an experienced interventionalist, who has appropriate expertise due to a fundamental education and a continuous practice to perform the procedure in good controlled quality. On the part of the ÖGHTG special criteria are being prepared in cooperation with the ÖKG. Concerning the interventional experience for a transcatheter aortic valve implantation the experts of this consensus paper consider the following conditions necessary based on the guidelines of the German Society of Cardiology 2016:

- at least 5 years expertise in percutaneous coronary interventions including acute PCI, left main PCI or more specifically percutaneous interventions for coronary obstructions—refers to cardiologists.
- Interventional expertise has to include catheterization of the right heart and safe placement of pacemaker leads.
- At least 5 years expertise in managing potential complications (surgical valve replacement, pericardial tamponade, annular rupture, implantation of cardiovascular assist devices, vascular complications)—refers to cardiac surgeons.
- Basic training in cardiovascular intensive care medicine including ECMO implantation.
- Expertise in management of large-bore percutaneous access, closure devices and experience in treatment of local vascular complications.
- At least 12 months experience in treatment of structural heart diseases especially TAVI.
- Certificate of training for the TAVI prostheses according to the company's requirements.
- At least 25 transfemoral TAVI procedures per year as first operator and at least 50 TAVI procedures per year as a heart valve center.

Required volume/case load: Concerning volume/outcome relationship a 2017 published study by Carroll et al. [30] showed that the relatively lowest complications rate can be achieved in the upper quartile with a cumulative case load >138 probably in accordance with the underlying operator's expertise. Other registry data show similar results starting with a cumulative case load ≥226 [31]. A recent publication from the USA with more than 100,000 TAVI procedures (from 2015 to 2017) showed up to a case load of 150 TAVI per year (top quartile) a persistent volume-outcome relationship [32]. But the authors emphasize that those numbers reflect the present situation in the USA (with a relatively short TAVI history) and they predict that with increasing expertise of the operators and more technical improvements and the expansion of the indication to lower risk patients the curve will more and more flatten [32]. As shown in the huge German registry (German Quality Assurance Registry on Aortic Valve Replacement—AQUA) [33], there is a wide range concerning the in-hospital mortality in low-volume centers. There are indeed low-volume centers with excellent results and an in-hospital mortality of 0%. Accordingly, data from the OCEAN TAVI registry [34] show that in a low-volume or in a center starting with TAVI outcome may be as good as in a high volume center, given that at least in the beginning there is a proctorship. The following aspects are responsible for minimizing complications rates, especially in low-volume centers:

- Regular support by an experienced proctor
- Precise planning of the procedure and avoidance of certain riskier constellations (e.g. severe calcification in the LVOT, excessive oversizing of the implanted valve).

Presence of cardiac surgery in the TAVI center/TAVI in centers without cardiac surgery on site

Concerning cardiac surgery on site the recent ESC/EACTS guidelines [1] provide a class I C recommendation (Fig. 3). In the light of patient safety this recommendation is reasonable and important and has been extensively discussed within the ESC.

The following points can be made:

- The conversion rate to open heart surgery in TAVI patients is around 0.4–1% and thus generally low [35, 36], such as the rate of annular ruptures one of the most feared complications (0.9–1.2% [37]). Due to technical improvements of the TAVI devices the prevalence of coronary obstructions needing intervention is even rarer (GARY registry [38]/PARTNER 3 [6]). In the PARTNER 3 trial the risk of annular rupture was only 0.2% [6].
- The highly fatal complication of annular rupture is more prevalent in certain risk constellations, which potentially can be avoided (e.g. by implanting self-expanding devices or preferring a surgical valve replacement in patients with severe LVOT calcification, by avoidance of excessive oversizing of the implanted valve).
- Moreover, the complication rate in general has decreased because of available flexible devices with lower profile and better guide wires as well as the availability of repositionable or retrievable self-expanding prostheses; additionally, vascular complications also are decreasing because of lower device profiles and improved closure devices.
- German and Austrian registry data of several thousand patients prove that the TAVI complication rate in centers without cardiac surgery on site is similar to those in centers with cardiac surgery on site

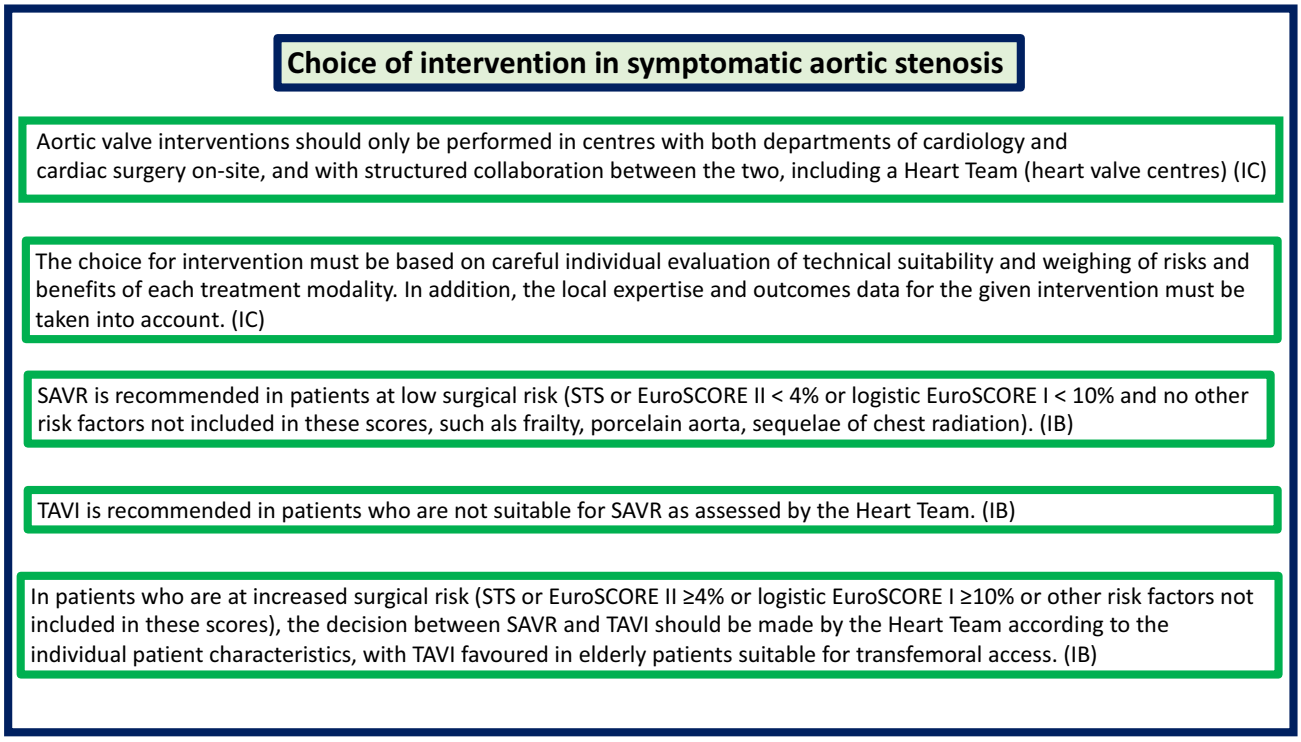

Fig. 3 Choice of intervention in symptomatic aortic stenosis according to the ESC/EACTS guidelines [1]. *IC* Class I recommendation and level of evidence C, *IB* class I recommendation and level of evidence B, *SAVR* surgical aortic valve replacement, *STS* Society of Thoracic Surgeons, *TAVI* transcatheter aortic valve implantation. (Modified from [1])

(AQUA registry from Germany [35] and our own Austrian registry data [39]).

- The patient population with severe aortic stenosis is complex although the indication of different risk populations is changing. Accordingly, decisions will be taken on available treatment opportunities, device selection and influence of comorbidities. An interdisciplinary setting with broad expertise is required to minimize the risk of the procedure and to recognize and treat potential complications quickly.
- The close collaboration between cardiology and cardiac surgery on site is not only of benefit for patient safety reasons but also allows the treatment of patients with certain risk constellations and ensures a regular exchange of experiences and increase in knowledge for both disciplines.

Thus, there are data showing that TAVI can be performed with similar outcome whether there is a cardiac surgery on site or not and that TAVI can be performed in centers without cardiac surgery on site with similar safety and outcome for the patient. Nevertheless, in this case patients with certain risk constellations should be rejected or referred to a heart valve center. Basically, the authors of this document also believe that TAVI procedures should only be performed in centers with cardiac surgery on site. But if there is a shortage of TAVI treatment in a certain area which cannot be resolved by increasing the number of TAVI procedures in centers with cardiac surgery on site, alternative solutions will have to be discussed. Two possible solutions may be proposed: increasing the capacity of TAVI procedures in the already available specialized centers or introducing TAVI in centers having expertise in interventional cardiology. Many arguments support the increase of capacities in specialized centers. Apart from the complex treatment of complications in the perioperative setting, the expertise in postoperative treatment in the intensive care unit is another important point. Rather than increasing the number of TAVI centers the primary objective should be the adherence to high quality standards and the increase of capacity in the established TAVI centers.

Infrastructure and personal requirements, peri-interventional monitoring

Infrastructure and personal requirements

Concerning infrastructure and interventional material and instruments the essential repertoire for interventional cardiology must be available in the room.

For transcatheter aortic valve implantation X-ray technology including adequate radiation protection for the whole staff is a necessary prerequisite. Transfemoral TAVI procedures can also be performed in specialized hybrid operating rooms. In case of complications requiring an immediate cardiac surgery, this can be performed immediately in the hybrid operating room without any further delay. But the

abovementioned studies concerning TAVI in centers with or without cardiac surgery on site also show that it is not mandatory to perform TAVI procedures in hybrid operating rooms, because the rate of complications of transfemoral procedures requiring heart-lung machine is very low, and the most common complications are rather vascular than cardiothoracic (see also Section *Presence of cardiac surgery in the TAVI center/TAVI in centers without cardiac surgery on site*). Of course, the surgical treatment of vascular complications in a hybrid operating room is preferred. Nevertheless, there has been no difference in safety or efficacy in performing TAVI in a hybrid operating room or a cath lab [40–42]. The analysis of the FRANCE II registry of more than 12,000 TAVI patients has shown no benefit of performing TAVI in a hybrid operating room compared to the cath lab [42]. But this registry showed a considerable increase in procedures performed in a hybrid operating room—from 33–41% of all procedures [42]. A small study by Babaliaros from 2014 [40] confirmed a statistically identical outcome for TAVI procedures in a cath lab and in a hybrid operating room. Thus, a transfemoral TAVI can be performed either in a cath lab or in a hybrid operating room.

There are the following requirements for performing a transfemoral TAVI in a hybrid operating room:

- Image quality of the X-ray in the hybrid operating room as good as in the cath lab. Performing transapical/transaortic or transfemoral aortic valve interventions in a cardiac operating room using a conventional C-arm X-ray is viewed critically by the authors of this document, although so far there are no data on this issue.
- Adequate radiation protection.
- Availability of cath lab and PCI materials (catheters, balloons, stents, snares, guide wires) for the treatment of vascular and coronary complications.
- Collaboration protocol between cardiology and cardiothoracic surgery and accorded role assignment (especially for complications).

The use of transesophageal echocardiography (TOE) is not mandatory any more, as the procedure can be performed without TOE with the same quality, the duration of the procedure shortens and the need of conscious sedation is less. A transthoracic echocardiography (TTE) with good image quality and evaluation not only of complications (e.g. pericardial effusion) but also of the performance of the implanted valve (e.g. paravalvular leak) must be available.

The devices for pacing of transient pacemaker electrodes or for programming of implanted pacemakers of the patient (programming devices) must be available during the procedure all the time.

Mechanical assist devices (especially ECMO or heart-lung machine) must be available in the hospital all the time (immediate use in case of complications, elective use in certain indications). In the ideal setting those devices should be available in the cath lab/operating room during the procedure.

Comments on implantation technique

Basically, the transcatheter aortic valve implantation has to be performed according to the published standards and product instructions of the implanted device.

Routine balloon valvuloplasty (BAV) procedure prior to valve implantation during TAVI is controversial taking into account potential complications (arterial emboli, annular rupture, risk while performing rapid pacing). Recently, a large controlled study concerning this topic has been published [43]: 2579 patients with and 3205 patients without BAV (direct-TAVI) of the FRANCE TAVI registry were compared retrospectively. The procedural success rate did not differ significantly, but in the direct-TAVI group there was a significant reduction of procedure time, contrast medium and radiation. Pericardial tamponade and moderate to severe aortic regurgitation occurred significantly less frequently in the direct-TAVI group. In the participating centers almost 49% of all procedures were already performed as direct-TAVI procedures at the end of 2015. In non-complex valvular situations this kind of standard procedure seems to be reasonable, especially if there are concerns with performing BAV (e.g. LV dysfunction, risk of arrhythmia). Randomized controlled trials investigating this topic are ongoing. Due to technical improvements of the delivery systems and in order to avoid BAV-associated complications most of the TAVI centers currently support the concept of direct-TAVI.

Cerebral protection devices during TAVI Cerebral protection devices were designed to reduce the risk of cerebrovascular events during and immediately after TAVI.

The Sentinel embolic protection device (Boston Scientific, Marlborough, MA, USA) is a dual filter device with 140 µm pores. The filters are placed into the brachiocephalic and left common carotid arteries. The Embrella Embolic Deflector (Edwards Lifesciences, Irvine, CA, USA) uses two heparin-coated membranes with 100 µm pores. This device is deployed in the aortic arch and covers the brachiocephalic and left common carotid arteries. The TriGuard embolic deflection device (Keystone Heart Ltd., Caesarea, Israel) is a nitinol-coated device with 250 µm pores and additionally covers the left subclavian artery.

For the Sentinel device, delivery and retrieval were reported to be successful in about 95%; however, because about one fifth of all cerebral lesions associated with TAVI occur in the posterior territories (brainstem and cerebellum), efficacy of this device may be limited.

Such devices can be used safely and may reduce cerebral embolisms detected by cerebral imaging; however, currently available data are insufficient to

determine their efficiency regarding improvement in clinical outcomes.

Valve-in-valve procedures Valve-in-valve transcatheter aortic valve interventions (ViV-TAVI) have emerged as an alternative to redo-surgery, in particular for high-risk and prohibitive-risk patients; however, technical challenges comprise a higher risk of prosthesis-patient mismatch and coronary ostial obstruction. Such risk depends on the type of the implanted surgical valve prosthesis. Novel techniques to overcome the risk of coronary ostial obstruction include methods like the Bioprosthetic Aortic Scallop Intentional Laceration to prevent Iatrogenic Coronary Artery obstruction (BASILICA) procedure. Additionally, bioprosthetic valve fracture (BVF) is as a novel technique to address the problem of prosthesis-patient mismatch.

In appropriate cases, redo-TAVI appears to be feasible. One of the major concerns is coronary access depending on the implanted and selected valve prosthesis. In the acute setting, paravalvular regurgitation is the most common indication for a redo-TAVI procedure. Some small series of comorbid patients undergoing redo-TAVI suggest high mortality rates.

Comments to alternative TAVI approaches

Current data strongly support the transfemoral TAVI approach as the first choice approach. In case of unsuitable transfemoral access other approaches (transapical, transaxillary, transcarotid, transcaval) may be evaluated and used depending on the anatomical situation and the team expertise.

Monitoring of vital parameters, conscious sedation, anesthesia

A transfemoral TAVI can be performed in local anesthesia with the patient conscious. Most of the time conscious sedation is applied in order to increase patient comfort. General anesthetics for performing a transfemoral TAVI are not routinely applied and necessary only under certain circumstances (e.g. combined procedure or surgical cut-down). For all procedures, especially in case of complications, the expertise for hemodynamic and respiratory management including intubation, mechanical ventilation and the essential equipment and drugs must be available on-site. This goes beyond the standard emergency equipment in a cath lab. Thus, a TAVI procedure must be supported by an intensive care specialist or an anesthesiologist.

Postinterventional monitoring

An (intensive care) monitoring for 24 h after the procedure is recommended in any case, whereby this may be in an intensive care unit, an intermediate care unit or a recovery room. The indication for maintaining the temporary pacemaker lead should be liberal, because especially in self-expanding prostheses AV-block may occur later on. But if the first 12-channel-ECG after TAVI shows a narrow QRS-complex and a normal PQ-time, the temporary pacemaker lead can quickly be removed [44].

Medical treatment post-TAVI

Balancing ischemic and bleeding complications remains the main challenge regarding antithrombotic treatment in patients after TAVI.

Current guidelines suggest oral anticoagulation in patients who have an indication for such treatment based on concomitant conditions such as atrial fibrillation. Additionally, in patients without an indication for oral anticoagulation, dual antiplatelet therapy is usually recommended; however, recent data suggest that a reduction in the intensity of antiplatelet treatment (aspirin only) may be associated with a reduction in bleeding events and improved outcome [45, 46].

Concluding remarks and future directions: Ongoing and recently published clinical trials and new [47, 48] and upcoming guidelines will influence current positions and recommendations and further updates of this position statement may be required periodically.

Summary

Transfemoral TAVI is an established method for the treatment for severe aortic stenosis. The indication for TAVI has to be verified in the heart team jointly by a cardiologist and a cardiac surgeon. For decision-making the age of the patient, the life expectancy, the anatomy of the thorax, the valvular apparatus and the vascular access, the perioperative risk, comorbidities and the patient's wishes have to be taken into consideration. A TAVI procedure should be performed by experienced interventionalists with appropriate expertise and practice in a heart valve center. The expanding indication for TAVI should be based on developing scientific evidence.

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