New ACC/AHA valve guidelines: aligning definitions of aortic stenosis severity with treatment recommendations

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This editorial is the first of many which will address key issues in new guidelines, providing a quick overview of major changes, comparing guidelines on the same topic from different professional societies and providing additional explanation of new concepts or controversial issues.

In the 2014 American College of Cardiology/American Heart Association (ACC/AHA) Guidelines for Management of Patients with Valvular Heart Disease, a new approach to writing and presenting guidelines has been implemented. First we started with the evidence, summarising the published data in 28 detailed evidence tables which can be found in the online supplement to the guidelines. Next, we focused on the specific recommendations, ensuring that the level of evidence, with the key references indicated, supported the strength of the recommendation, using the standard classification from class I to class III. The precise wording of each recommendation was extensively discussed by the committee and underwent rigorous external review. The text that accompanies each recommendation provides additional details and references to ensure clinicians have the information needed to follow these guidelines. Each recommendation is presented in a modular format with the recommendation, references, text and evidence tables linked to allow easy presentation of the information across digital platforms and to allow updating of individual recommendations in the future, without updating the entire document.

Several new concepts are introduced in these guidelines. We recommend a paradigm shift in the descriptions of the severity of valve disease with the introduction of disease stages, ranging from the patient-at-risk (stage A) to severe symptomatic disease (stage D). Valve disease stages are based on an integrative approach that includes patient symptoms, valve anatomy, valve haemodynamics and LV function. The example of aortic stenosis (AS) is shown in table 1. This patient centred approach to defining disease severity allows alignment of treatment recommendations with disease stages. It also allows inclusion of patients at risk of valve disease, for example patients with a bicuspid aortic valve, highlighting the need for appropriate follow-up and medical therapy across the full spectrum of clinical valve disease, rather than just focusing on end-stage disease. Breakpoints for definitions of severe disease were based on outcomes data showing that at the cut-off level there is either a poorer outcome in natural history studies or that intervention with this degree of disease improves symptoms or prolongs survival.

Evaluation of procedural risk in patients with valve disease being considered for transcatheter or surgical approaches is challenging because current risk scores, such as the STS-PROM or EuroSCORE, are based on all cardiac surgical procedures, not just valve disease. In addition, risks for surgery differ from risks for transcatheter procedures. Until more robust risk scores are available, we recommend consideration of patient frailty, major organ system compromise that is unlikely to be improved after the valve procedure, and procedure specific impediments (such as vascular access) in addition to the STS-PROM score. It also is recognised that valve interventions are likely to be futile in patients with a life expectancy less than 1 year or a low likelihood of a significant improvement in quality of life, even if the procedure is successful.

As in the 2012 European Society of Cardiology/European Association for Cardio-Thoracic Surgery (ESC/EACTS) guidelines, the 2014 ACC/AHA guidelines emphasise the importance of the heart valve team in the diagnosis and treatment of patients with valvular heart disease. As we develop more options for intervention for severe valve disease, decision making becomes more complex, requiring discussion among valve and imaging experts, cardiac surgeons and interventional cardiologists. Valve centres of excellence provide a structure for healthcare providers with expertise from multiple disciplines to offer all available options for diagnosis and management. These centres can also participate in outcome registries, ensure adherence to guidelines, promote quality improvement processes and publicly report mortality rates and procedural outcomes.

Now let us look more closely at the new guidelines for AS. The term ‘progressive AS’ (stage B) includes both mild and moderate valve obstruction, recognising that this degree of AS does not benefit from intervention, but periodic monitoring in needed because most patients will eventually progress to severe valve obstruction. In patients with severe AS, the most important distinction is between asymptomatic (stage C) and symptomatic (stage D) disease.

In asymptomatic patients, the goal in calling AS ‘severe’ is to identify which patients are likely to become symptomatic soon, thus mandating close medical follow-up and patient education to ensure that early symptoms are reported promptly. Thus, severe asymptomatic AS is defined by a high aortic velocity (and gradient), not by valve area. Although valve area typically is reduced, the key feature is an aortic velocity of 4 m/s or higher (or mean gradient of 40 mm Hg or higher). This definition ensures that all patients with significant disease receive appropriate attention, although many will go several years before needing aortic valve replacement (AVR). Special subgroups of severe asymptomatic AS are those with LV systolic dysfunction who will benefit from AVR, and those with very severe AS in whom elective AVR is reasonable, given that symptom onset is imminent.

In the symptomatic patient with AS, the purpose of measuring valve haemodynamics is to ensure that AS is the cause of symptoms. In a symptomatic patient, a calcified aortic valve with a velocity of 4 m/s or higher confirms the diagnosis of severe AS, regardless of valve area. Typically, valve area is 1.0 cm² or less, but may be larger in patients with mixed stenosis and regurgitation and is expected to be smaller in smaller patients. Valve area calculations do become important in patients who have an immobile calcified

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CHOICE OF TYPE OF VALVE REPLACEMENT

Class I: Surgical AVR or TAVR is recommended

Surgical AVR in patients who meet an indication for AVR with low or intermediate surgical risk

Members of a heart valve team should collaborate to provide optimal patient care For patients in whom TAVR or high-risk surgical AVR is being considered

TAVR in patients who meet an indication for AVR for AS who have a prohibitive surgical risk and a predicted post-TAVR survival >12 months

Class IIa: TAVR is a reasonable alternative to surgical AVR

In patients who meet an indication for AVR for severe AS and who have high surgical risk

Class III: Percutaneous aortic balloon dilation may be considered

AS a bridge to surgical or transcatheter AVR in severely symptomatic patients with severe AS (or before urgent non-cardiac surgery in ESC/EACTS guidelines)

Class III: TAVR is not recommended

In patients in whom the existing co-morbidities would preclude the expected benefit from correction of AS


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TAVR in patients who meet an indication for AVR for AS who have a prohibitive surgical risk and a predicted post-TAVR survival >12 months

Class I: AVR is indicated in patients with

Severe high-gradient AS with symptoms by history (or on exercise testing)

Class II: AVR is reasonable in patients with

Asymptomatic very severe AS (aortic velocity ≥5 m/s) and low surgical risk

Asymptomatic severe AS with decreased exercise tolerance or an exercise fall in BP

Mod. AS: 2.0–2.9 m/s; <20 mm Hg

Mild AS: 2.0–2.9 m/s; <20 mm Hg

Class IIb: TAVR is not recommended

Class IIa: TAVR is a reasonable alternative to surgical AVR

Asymptomatic severe AS with normal EF

Resting AVA ≤1 cm² with aortic Vmax <4 m/s or mean ΔP <40 mm Hg

Indexed AVA ≤0.6 cm²/m² and Stroke volume index <35 mL/m²

Class III: AVR may be considered in patients with

Asymptomatic severe AS with rapid disease progression and low surgical risk

Valve anatomy

Ca++ Mobility

Haemodynamics

Key criteria

Additional measures

Left ventricular EF

Stage Description and symptoms

A At risk (asymptomatic)

B Progressive (asymptomatic)

C1 Asymptomatic severe AS with normal EF

C2 Asymptomatic severe AS with low EF

D1 Symptomatic severe high gradient AS

D2 Symptomatic severe low gradient AS with low EF

D3 Symptomatic severe low gradient AS with normal EF

<2

Mild AS: 2.0–2.9 m/s; <20 mm Hg

Mod. AS: 3.0–3.9 m/s; 20–39 mm Hg

Typically ≤1 cm² (or AVAi ≤0.6 cm²/m²)

Typically ≤1 cm² (or AVAi ≤0.6 cm²/m²)

Typically ≤1 cm² (or AVAi ≤0.6 cm²/m²)

<50%

<50%

Normal

<50%

Normal

Symptoms on exercise testing are LOE C in the ESC/EACTS guidelines.

†ESC/EACTS guidelines require evidence of flow reserve. ACC/AHA guidelines require an aortic velocity ≥4 m/s with a valve area ≤1 cm² at any flow rate.

ACC/AHA, 2014 American College of Cardiology and American Heart Association guidelines; AS, aortic stenosis; AVR, aortic valve replacement, either surgical or transcatheter; BP, blood pressure; BNP, brain natriuretic peptide; ESC/EACTS, 2012 European Society of Cardiology and European Association for Cardio-Thoracic Surgery guidelines. Level of Evidence (LOE) classified as A, B or C for each recommendation shown in parenthesis.

Adapted from Nishimura et al.1 and Vahanian et al.5

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AVA, aortic valve area; AVR, aortic valve replacement, either surgical or transcatheter; BP, blood pressure; BNP, brain natriuretic peptide; ESC/EACTS, 2012 European Society of Cardiology and European Association for Cardio-Thoracic Surgery guidelines.

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AVAi, valve area indexed for body surface area; BP, blood pressure; Ca++, calcification; EF, ejection fraction; Vmax, maximum transvalvular aortic velocity.

†Symptoms on exercise testing are LOE C in the ESC/EACTS guidelines.

Adapted from Nishimura et al.1
valve and symptoms that might be due to AS, but have only a modest increase in aortic velocity or transvalvular pressure gradient. As detailed in table 1, severe AS with a low gradient due to concurrent LV systolic dysfunction can be evaluated with dobutamine stress echocardiography. This test separates those with true severe AS, despite a low gradient, from those with only moderate AS with concurrent LV dysfunction. Diagnosis is more difficult in the patient with a small aortic valve area and a low-gradient and low stroke volume in the setting of a normal EF, most often seen in elderly women with a small hypertrophied LV. Many of these patients have concomitant hypertension, with serial obstruction to LV outflow by the narrowed valve and increased systemic vascular resistance. Concurrent hypertension can also affect measurement of AS severity. If severe AS remains a possibility after treatment of hypertension and symptoms persist, the patient should be referred to a heart valve centre for further evaluation.

This paradigm change in the classification of AS severity avoids concerns about whether individual components ‘match’ with each other. Of course pressure gradient/velocity and valve area are not always ‘concordant’; the point is that they measure different parameters of disease severity. One or the other may best characterise disease severity in an individual patient depending on transvalvular flow rate, body size, myocardial function, systemic vascular impedance and other cardiovascular perturbations. In addition, haemodynamics are only one descriptor of disease severity; clinical and anatomic descriptors are equally important.

Recommendations about intervention for severe AS are aligned with the stages of disease severity as shown in table 2. Importantly, recommendations for timing of intervention are separated from recommendations about the type of intervention. Overall, the ACC/AHA and ESC/EACTS guidelines are concordant, with only minor differences. Some of the levels of evidence increased from a C to B in the ACC/AHA guidelines as additional data has been published since 2012. Both guidelines recommend AVR for symptoms provoked by exercise testing, although the ACC/AHA guidelines group exercise testing and spontaneous symptoms whereas the ESC/EACTS guidelines consider symptoms on exercise testing separately. The definition of very severe AS is a velocity of 5.5 m/s or higher in the ESC/EACTS guidelines but only 5.0 m/s in the ACC/AHA guidelines, both with a class IIa indication for AVR. Also, the ACC guidelines have added the recommendation that transcatheter aortic valve replacement (TAVR) is not appropriate (class III recommendation) in patients with severe symptomatic AS who are unlikely to benefit from AVR due to co-morbidities, frailty or an expected longevity less than 1 year even if the procedure is successful.

In summary, the 2014 ACC/AHA recommendations for management of AS provide a new framework for thinking about disease severity and seek to align definitions of severity with recommendations for intervention. The importance of integration of clinical, anatomic, valvular and ventricular measures in defining disease severity is emphasised and the need for healthcare provider teams with expertise in all aspects of patient management is outlined. With continued improvements in both the TAVR procedure and in the valves themselves, we will continue to see a gradual shift from surgical to transcatheter valve implantation. However, until further data on valve durability are available, surgical AVR will remain the standard for treatment of severe symptomatic AS in patients with a low surgical risk.

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