JACC: ASIA VOL. 3, NO. 2, 2023


EDITORIAL COMMENT

# New Appropriate Use Criteria for Aortic Stenosis Patients*

Cheol Hyun Lee, MD, PhD

It has been more than 20 years since transcatheter aortic valve replacement (TAVR) was first introduced. According to the results of various randomized controlled trials, it is now considered in guidelines to be a preferred treatment for intermediate- and low-risk patients in addition to high-risk patients.[1,2] Moreover, previous reports indicated that the number of TAVR procedures performed, particularly among patients who were previously unable to undergo surgical aortic valve replacement (SAVR), is increasing because of the quick postprocedural recovery time, leading to an overall increase in the number of patients undergoing TAVR.[3] The decision-making process for surgical or interventional treatment always considers the risks and benefits. However, as TAVR technology and research rapidly advance, the risks decrease and the benefits improve.[4] Some previous studies reported the limits of the indications for severe aortic valve stenosis (AS) treatment,[5,6] but information about the optimal choice of treatment given an individual patient's circumstances is still lacking. Although it would be ideal to answer these questions through well-designed randomized controlled trials, patients with severe AS may still have unresolved issues, such as various comorbidities, low-flow, low-gradient AS, and patient frailty assessments, making it impossible to acquire adequate evidence through previous studies and guidelines. Therefore, it is recommended that treatment plans be derived through heart team discussions at each center in daily practice. However, specialists have knowledge of their own areas only, which can make it difficult to discuss other related areas.[7]

AS management requires a multidisciplinary approach with a team of experts working cooperatively to determine the best course of action for each patient. This is especially important in cases of severe AS, in which the risk of valve replacement must be balanced against the potential benefits of intervention or surgery. The development of appropriate use criteria (AUC) for the treatment of patients with severe AS is essential to assist physicians in making informed decisions regarding the best course of action for each patient, as demonstrated by the joint AUC published in 2017 by the American College of Cardiology Foundation and 10 other societies.[8] The recent updated publication in *JACC: Asia* by the OCEAN-SHD (Optimized Catheter Valvular Intervention Structural Heart Disease) investigators reports their consensus on AUC for the management of AS, providing valuable guidance for physicians in this field.[9] The investigators used a RAND-modified Delphi panel method to develop AUC for AS management. The panel of 11 experts consisted of physicians from various cardiovascular fields to ensure a balanced representation of expertise and prevent bias. The key factors and clinical scenarios were developed on the basis of a systematic literature review and feedback from an expert panel.

The panel found 3 factors that would make the intervention "rarely appropriate": 1) limited life expectancy; 2) frailty; and 3) pseudosevere AS on dobutamine stress echocardiography (DSE). They also identified 3 clinical scenarios in which TAVR would be "rarely appropriate": 1) patients with low surgical risk and high TAVR risk; 2) patients with severe primary mitral regurgitation or rheumatic mitral stenosis; and 3) patients with bicuspid aortic valves not suitable for TAVR. It is important to note that TAVR for patients older than 75 years of age was not considered "rarely appropriate." The panel also recommends that the decision to perform an intervention should be based

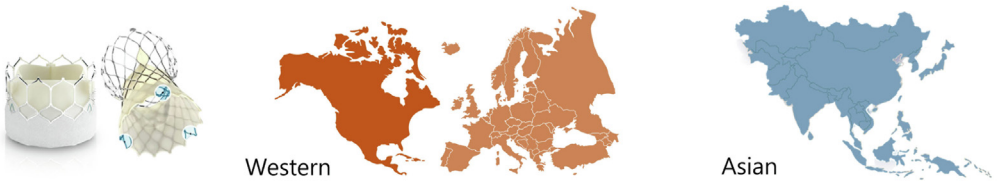
*Editorials published in *JACC: Asia* reflect the views of the authors and do not necessarily represent the views of *JACC: Asia* or the American College of Cardiology.

From the Division of Cardiology, Department of Internal Medicine, Keimyung University Dongsan Hospital, Daegu, Korea.

The author attests they are in compliance with human studies committees and animal welfare regulations of the author's institution and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

ISSN 2772-3747 https://doi.org/10.1016/j.jacasi.2023.02.003

**FIGURE 1** **Differences Among Regional AUC for Aortic Stenosis**




| | 2017 AUC - American College of Cardiology Foundation and 10 other societies | 2023 Japanese AUC - OCEAN-SHD investigators |
|---|---|---|
| Scenarios | 95 | 122 |
| Panels | 17 (anesthesiologists, cardiovascular surgeons, interventional, imaging, and general cardiologists) | 11 (cardiovascular surgeons, interventional, imaging, and heart failure cardiologist) |
| Discussion | Face to face meeting | Web based meeting |
| Frailty | Conventional frailty factor ≥3 (slow gait speed, weak handgrip, exhaustion, physical inactivity, and shrinking; 5 factors) | Clinical frailty score (CFS) ≥ 7 point (face to face assessment; 7 point- completely dependent for personal care) |
| Asymptomatic | No pulmonary hypertension | Including pulmonary hypertension (>60mmHg) |
| Comorbidities | STS-PROM score | TAVR / SAVR risk - High / Low |
| CAD | SYNTAX score, Disease Extent | PCI favor / CABG favor |
| Reduced EF, LFLG | DSE, Valve calcium | Symptom, DSE, Valve calcium |
| Bicuspid | SAVR risk, Aorta size | Age, TAVR favor / SAVR risk, Aorta size |
| Other VHD | Including TEER, PMBV option | No TEER, PMBV option |
| ViV TAVR (size ≤19mm) | Rarely appropriate except high SAVR risk | Appropriate except low SAVR risk and high TAVR risk |
| Non-cardiac surgery | Elective / Urgent / Symptom | Elective / Urgent / Symptom / Age - TAVR / SAVR |

A summary of the key differences between the 2017 Western and 2023 Asian appropriate use criteria (AUC) for aortic stenosis management. CABG = coronary artery bypass graft; CAD = coronary artery disease; CFS = clinical frailty score; DSE = dobutamine stress echocardiography; EF = ejection fraction; LFLG = low-flow, low-gradient; OCEAN-SHD = Optimized Catheter Valvular Intervention Structural Heart Disease; PCI = percutaneous coronary intervention; PMBV = percutaneous mitral balloon valvuloplasty; SAVR = surgical aortic valve replacement; STS-PROM = Society of Thoracic Surgeons Predicted Risk of Mortality; SYNTAX = Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery; TAVR = transcatheter aortic valve replacement; TEER = transcatheter edge-to-edge repair; VHD = valvular heart disease; ViV = valve-in-valve.

on a careful assessment of the risks and benefits, considering the patient's age, symptoms, SAVR and TAVR risk, coronary artery disease, other valve diseases, bicuspid aortic valve, and noncardiac surgery.

The major differences between the previous and present studies can be summarized as follows (**Figure 1**):

1. Patients' frailty evaluation is recommended to be assessed using the evidence-based clinical frailty score (CFS) for TAVR patients.[10]
2. Significant pulmonary hypertension (≥60 mm Hg) was included in the treatment decision for asymptomatic patients with AS.
3. In the treatment of low-flow, low-gradient AS with reduced ejection fraction, DSE, aortic valve calcium, and the presence or absence of symptoms were added to the treatment decision.
4. To determine the treatment modality for severe AS, the conventional STS-PROM (Society of Thoracic Surgeons Predicted Risk of Mortality) score has limitations and is simply divided into TAVR risk and SAVR risk.
5. Coronary artery disease was more clearly summarized as percutaneous coronary intervention or coronary artery bypass graft favor instead of SYNTAX (Synergy Between Percutaneous Coronary Intervention With Taxus and Cardiac Surgery) score or disease extent.
6. The treatment of aortic valves with other concomitant valves has not yet included interventional options such as transcatheter edge-to-edge repair, percutaneous mitral balloon valvuloplasty, and tricuspid intervention.
7. The treatment of bicuspid aortic valves is classified on the basis of surgical risk, ascending aorta size, and newly added factors such as age and TAVR favor.
8. In valve-in-valve TAVR, even for patients with previous small bioprostheses (≤19 mm), the appropriate rating has been adjusted upward in

cases of high surgical risk and older age, reflecting the latest trends.

9. The classification of treatment for severe AS before major noncardiac surgery was further divided on the basis of age and treatment modality.

To summarize the important points, the investigators emphasize, first, that CFS by careful face-to-face patient evaluation was identified as a useful marker for predicting late mortality in elderly patients after aortic valve treatment. Second, low-dose DSE is recommended to distinguish truly severe AS and pseudosevere AS in patients with low-flow, low-gradient AS. However, symptomatic patients may be considered for treatment, even if DSE demonstrates pseudosevere AS or DSE is not performed. Third, surgical risk, traditionally represented by the STS-PROM score, can help determine the intervention method; however, many factors that can affect the decision-making process for the treatment modality are not included in this score. Therefore, the investigators suggest that a patient's TAVR or SAVR risk should be assessed on a case-by-case basis before a heart team discussion.

The investigators of the present publication provide valuable insight into AS management, and the updated AUC are an important step toward improving patient outcomes. These AUC provide practical guidance for physician decision making and will help each member of the heart team make decisions. Furthermore, as the investigators have extensive experience with the heart team approach for patients with AS in Asia, their opinions may be especially helpful in managing patients with AS in this region, considering the racial differences in TAVR. The present study avoided the use of numerical scores such as the STS-PROM score, SYNTAX score, and conventional frailty evaluation[11] and instead introduced a physician's intuitive evaluation of each case, such as TAVR or SAVR risk, percutaneous coronary intervention or coronary artery bypass graft, and CFS by face-to-face observation. Therefore, the AUC were simplified to improve readability and enhance the overall simplicity of the evaluation process, and the opinions of experts in each field were respected as much as possible. In addition, these simplified and more detailed scenarios have many advantages and can be particularly useful at large-volume centers, as they facilitate more effective heart team discussions than are currently possible. However, this advantage may be a disadvantage for general cardiologists who require help with decision making or for mid-volume centers with less experience. As TAVR becomes more widespread, the number of cases at mid-volume centers will also need to increase; however, this study may be difficult for heart teams at mid-volume center where AUC help is essential. The future direction of the present study is to regularly update the content on severe AS, which has been the subject of much recent research, to provide sufficient information for both experts and nonexperts and to add more detail on the crucial references and details that influenced the panelists' ratings for each scenario.

In summary, this study presents updated, risk-stratified AUC for individuals with AS that incorporate the latest advances in this field. This considers various factors and helps health care professionals determine the optimal course of treatment for these patients. It also serves as a valuable resource by providing information on trends in contemporary opinions from various experts on the management of AS.

## FUNDING SUPPORT AND AUTHOR DISCLOSURES

The author has reported that he has no relationships relevant to the contents of this paper to disclose.

**ADDRESS FOR CORRESPONDENCE:** Dr Cheol Hyun Lee, Division of Cardiology, Department of Internal Medicine, Keimyung University Dongsan Hospital, 1035 Dalgubeol-daero, Dalseo-gu, Daegu 42601, Republic of Korea. E-mail: movicbeat@gmail.com.

## REFERENCES

**1.** Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2021;77:e25–e197.

**2.** Vahanian A, Beyersdorf F, Praz F, et al. 2021 ESC/EACTS guidelines for the management of valvular heart disease. *Eur Heart J*. 2022;43:561–632.

**3.** Eggebrecht H, Mehta RH. Transcatheter aortic valve implantation (TAVI) in Germany 2008-2014: on its way to standard therapy for aortic valve stenosis in the elderly? *EuroIntervention*. 2016;11(9):1029–1033.

**4.** Mentias A, Saad M, Desai MY, et al. Temporal trends and clinical outcomes of transcatheter aortic valve replacement in nonagenarians. *J Am Heart Assoc*. 2019;8(21):e013685.

**5.** Attinger-Toller A, Ferrari E, Tueller D, et al. Age-related outcomes after transcatheter aortic valve replacement: insights from the SwissTAVI registry. *J Am Coll Cardiol Intv*. 2021;14(9):952–960.

**6.** Yamamoto M, Meguro K, Mouillet G, et al. Comparison of effectiveness and safety of transcatheter aortic valve implantation in patients aged ≥90 years versus <90 years. *Am J Cardiol*. 2012;110(8):1156–1163.

**7.** Archbold A, Akowuah E, Banning AP, et al. Getting the best from the Heart Team: guidance for cardiac multidisciplinary meetings. *Heart*. 2022;108(11):e2.

**8.** Bonow RO, Brown AS, Gillam LD, et al. ACC/AATS/AHA/ASE/EACTS/HVS/SCA/SCAI/SCCT/SCMR/STS 2017 appropriate use criteria for the treatment of patients with severe aortic stenosis: a report of the American College of Cardiology Appropriate Use Criteria Task Force, American Association for Thoracic Surgery, American Heart Association, American Society of Echocardiography, European Association for Cardio-Thoracic Surgery, Heart Valve Society, Society of Cardiovascular Anesthesiologists, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Computed Tomography, Society for Cardiovascular Magnetic Resonance, and Society of Thoracic Surgeons. *J Am Coll Cardiol*. 2017;70(20):2566–2598.

**9.** Inohara T, Tabata M, Isotani A, et al. Appropriate use criteria for the management of aortic stenosis: insight from the Japanese expert panel. *JACC: Asia*. 2023;3:255–267.

**10.** Shimura T, Yamamoto M, Kano S, et al. Impact of the clinical frailty scale on outcomes after transcatheter aortic valve replacement. *Circulation*. 2017;135(21):2013–2024.

**11.** Fried LP, Tangen CM, Walston J, et al. Frailty in older adults: evidence for a phenotype. *J Gerontol A Biol Sci Med Sci*. 2001;56(3):M146–M156.

**KEY WORDS** aortic stenosis, appropriate use criteria, indication, surgical aortic valve replacement, transcatheter aortic valve replacement