

VALVULAR CALCIUM

The Importance of Calcium in Aortic Stenosis to Inform Shared Decision-Making Discussions

By Megan Coylewright, MD, MPH, FACC, FSCAI

As the heart team is focusing on the lifetime management of aortic valve disease and decision-making in younger patients with aortic stenosis (AS), considerations about calcium management are as important as ever.

Calcification of the aortic valve as it applies to treatment of severe symptomatic AS with aortic valve replacement is an important topic for interventional cardiologists and cardiac surgeons when engaging in shared decision-making about treatment options with patients and their families. Today, we are in an era when transcatheter aortic valve replacement (TAVR) is open to patients of all surgical risk groups. To be clear, “surgical risk” refers to the 30-day risk of dying after a surgical operation. This risk framing has not focused on the risk of TAVR itself, which is often driven by patient anatomy and, largely, calcification. In addition, “low risk” as the term is currently deployed does not equate to patient longevity, which is a critical component of decision-making between TAVR and surgical aortic valve replacement (SAVR) with bioprosthetic valves given limited durability.

There are now multiple treatment options open to patients with severe symptomatic AS. For older patients (aged ≥ 65 years), this is primarily a choice between TAVR or SAVR with use of a bioprosthetic valve. For younger patients, the choices include TAVR or SAVR, with surgery encompassing many more choices, with differing durability (eg, bioprosthetic valves, mechanical valves, Ross procedure, aortic valve repair).

CALCIUM CONSIDERATIONS FOR AORTIC VALVES

Significance in Decision-Making

Given the risks inherent to TAVR, the presence of aortic valve calcium does inform the treatment decision, which

involves placing a valve within the calcium as opposed to a surgical procedure in which the calcium is removed.

We quantify calcium through cardiac imaging.¹ This includes not just in the aortic valve and its annulus, but also in the left ventricular outflow tract (LVOT) or aorta itself. Patients are sometimes sent to the procedural portion of the heart team in clinic (ie, interventional cardiologist and cardiac surgeon) without CT data, which can make shared decision-making regarding harms and benefits of options challenging. At this stage in decision-making, patients may have met with their referring providers (a key part of the heart team) and had a preliminary discussion around the options. At times, referring clinicians may be focused on providing reassurance to worried patients by stressing that TAVR will be a likely, or even preferred, option. In addition, patients have often done their own research and are hopeful for a minimally invasive approach with a quick recovery, without a nuanced understanding of the potential harms and downsides.

It is preferred, to the extent possible, that patients and families come to the heart team clinic ready to learn more about their personalized harm and benefit summary and prepared to discuss their goals for any valve replacement, to lead to an informed shared decision-making process. Clinicians and their clinical staff continue to work to incorporate best practices in shared decision-making, including use of validated decision aids, to assist in this process. The degree of calcium in and around the valve remains a critical piece of information in this discussion regarding options.

Ultimately, it is nearly impossible to determine the potential harms and benefits of the procedural options without quantifying the calcium via CT.

Location of Calcium

The location of calcification in aortic valve disease remains a critical piece of information. Calcium exists in the valve leaflets themselves, leading to immobility of the aortic valve and elevation of gradients; reduction of valve area; and symptoms of dyspnea, chest pain, dizziness or syncope, and even sudden cardiac death. There is also calcium in the annulus, LVOT, and aorta.

Potential Complications

The complications of severe calcification include paravalvular leak (or inability of the transcatheter valve to seal around nodules of calcium in the annulus), excessive pacemaker risk due to disturbance of the conduction system, incomplete expansion of the transcatheter valve leading to pinwheeling of the leaflets, and, perhaps, early degeneration or elevated gradients. More rare is risk of annular rupture, which could lead to procedural mortality.

Calcium and “Low-Risk” Patients

It is important to note that the trials we commonly reference when thinking about AVR outcomes did not include patients with severe calcium. For example, the PARTNER 3 and EVOLUT Low-Risk trials of low-surgical-risk patients (ie, those with a lower risk of dying at 30 days following a surgery) excluded patients with severe aortic valve calcium. While severe calcium can significantly increase the risk of TAVR, this may be lower risk with a surgical approach. Indeed, valvular calcification is not one of the variables used to determine STS risk other than *porcelain aorta*. It was felt by the cardiology and cardiac surgery communities that for patients in whom there was equipoise (ie, they were candidates for the randomized trial), it had to mean the heart team felt TAVR and SAVR would be safe and effective for them. This is not the case for severe calcification of the aortic valve or LVOT.

Recently there has been controversy around the role of TAVR in younger patients. An abstract presented at the Society of Thoracic Surgeons annual meeting this past year used a cutoff of < 60 years of age, based on the assumption that there is a corollary between young age and longevity.² A bioprosthetic valve for severe AS will at some point degenerate, requiring a second procedure likely between 12 and 20 years. SAVR is recommended over TAVR, with SAVR including mechanical valves, Ross procedures, and bioprosthetic valves.³

For most patients aged <65 years who are healthy other than severe AS, the goal is for one sternotomy. It is important that patients, families, and referring clinicians are aware of the options of a Ross procedure (using the patient's native pulmonic valve in the aortic position,

and a homograft in the pulmonic position) or a mechanical aortic valve. In contrast, there are many patients aged < 65 years whose valvular heart disease occurs in the context of multiple comorbid conditions, which limits their life expectancy to the extent that the durability of a bioprosthetic valve is less of a factor in decision-making. This is where the guidelines highlight the role of life expectancy in framing the choices for patients—and not just age alone. In this case, the choice is between bioprosthetic valves: TAVR versus SAVR. The prevalence of bicuspid aortic valve disease is much higher in younger patients than in those aged > 65 years, such that more than one-quarter of patients undergoing surgery for aortic valve disease have bicuspid morphology, and bicuspid aortic valve stenosis is associated with severe calcification or more aggressive, earlier presence of calcification.

Morphology

Relevant to the discussion of calcium among younger patients with longevity is that bicuspid valves are far more prevalent in this group. Bicuspid valves, on average, are also more calcified than tricuspid valves, necessitating careful assessment with CT and acknowledging the limitations of transcatheter valves in some patients. Again, the CT to assess calcium severity and its distribution are critical for heart teams to be able to communicate personalized harm and benefit with the patients regarding the choices available.

While there are data on the efficacy of transcatheter solutions for bicuspid valves, most of this research is performed in the context of careful heart team assessment, and exclusion of patients with a significant calcium burden. Many referring clinicians ask the question of whether bicuspid valves do well with TAVR, and an important reminder is that many patients were excluded from the research focused on this question. Thus first, a heart team assessment of the calcium burden and location is essential in decision-making.

If choosing between TAVR or SAVR for patients aged < 65 years, one benefit to a surgical approach is the ability to remove the calcium to allow for complete expansion of the surgical prosthesis. Concerns specific to bicuspid valves with a transcatheter prosthesis, placed within the calcium, include paravalvular leak and incomplete expansion of the transcatheter valve, leading to early degeneration. This is true for all patients, but particularly for patients aged < 65 years for whom valve durability is a key focus.

THE ROLE OF CALCIUM IN SHARED DECISION-MAKING

What Is Shared Decision-Making?

Shared decision-making research has focused over the past 3 decades to understand how to breakdown clinical

trial results with patients and their families so they can make informed decisions that match with their values and preferences. Part of that research is using the STS/ACC TVT registry to understand the current practice patterns of heart teams regarding selection of TAVR versus SAVR.

Today, heart teams are challenged by their experience that patients come in “demanding” TAVR. Patient preference research in this area demonstrates that initial preferences that patients communicate are uninformed and that, after best practices in shared decision-making are deployed using validated decision aids, many patients end up switching their initial stated preferences.⁴ Further research in patient goals reinforce that a goal is not “to have a TAVR,” but instead to have complete information about the options, to reduce fear of heart failure, and for some patients, to avoid a second sternotomy or live longer.⁴ Focusing on getting to informed patient preferences that lead to patient-stated goals is the focus of shared decision-making approaches. And it is not possible for patients to have informed preferences without a discussion of potential harms and benefits based in large part on aortic valve calcium.

We are just beginning to understand the boundaries of transcatheter valve therapies in severe calcium, particularly as long-term data become more available. Importantly, the patients in the studies are those carefully selected by the heart team to have equipoise between TAVR and SAVR, indicating that prohibitive calcium was not present. It will be important for us to understand this further so we can align patient goals and preferences with the choices available.

Factors When Weighing TAVR and SAVR

There continues to be debate about the safety of transcatheter valves compared with surgical valves in patients who lack comorbid conditions and have either severe LVOT calcium or a bicuspid valve with severe calcium. However, ongoing research shows that many patients who present early (< 65 years of age) with severe AS and receive TAVR do have multiple comorbid conditions that have contributed to the early presentation, such as end-stage renal disease on dialysis or severe atherosclerotic disease leading to calcium burden in the coronary bed and peripheral vasculature.⁵

Many younger patients presenting with AS also have a history of severe congestive heart failure, which increases their surgical risk. The decision-making can become quite complex to balance not only the aspect of calcium but also their comorbid conditions. By removing the calcium, SAVR allows for a fully expanded valve to be placed, although surgical valves tend to be smaller than transcatheter valves. Still, there is no accepted evidence that a bal-

loon-expandable versus self-expanding valve functions better in a highly calcified aortic valve. It is important to note that when using a self-expanding platform in severe calcium, it may be that a balloon is needed as well. Although the nomenclature is a “self-expanding” valve, when the valve is severely calcified, there is often a need to predilate and sometimes postdilate with a balloon. It does become, in part, a balloon-expandable valve, albeit with a potentially smaller balloon than in a true balloon-expandable valve, and thus may carry greater risks. The three currently available platforms have skirts below the prosthetic valve leaflets and the seal is increasingly more effective in severe calcium, thus reducing our concerns about paravalvular leak, one of the key complications.

CONCLUSION

Overall, TAVR is a transformative technology that has increased access for treatment of severe AS for many. However, it is not safe and effective in all patients, with one of the primary limitations being the presence of severe calcification. Aortic valve calcium must be characterized and evaluated by a heart team prior to completion of a shared decision-making process with the patient, as this informs some of the key potential harms and benefits of the procedure. Best practices include using CT data on aortic valve calcium, and other critical testing to predict the heart team’s ability to meet patient goals with the therapeutic options that are available. While using best practices in communication with validated decision aids, the heart team can listen to and incorporate patients’ informed preferences to come to a true shared decision.⁴ ■

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Megan Coylewright, MD, MPH, FACC, FSCAI

Editor, ACC CardioSmart/Patient Voice Program
Chattanooga, Tennessee
coylewrightmd@gmail.com

Disclosures: Consultant to Alleviant, Boston Scientific Corporation, Edwards Lifesciences, Medtronic, and Occlutech.