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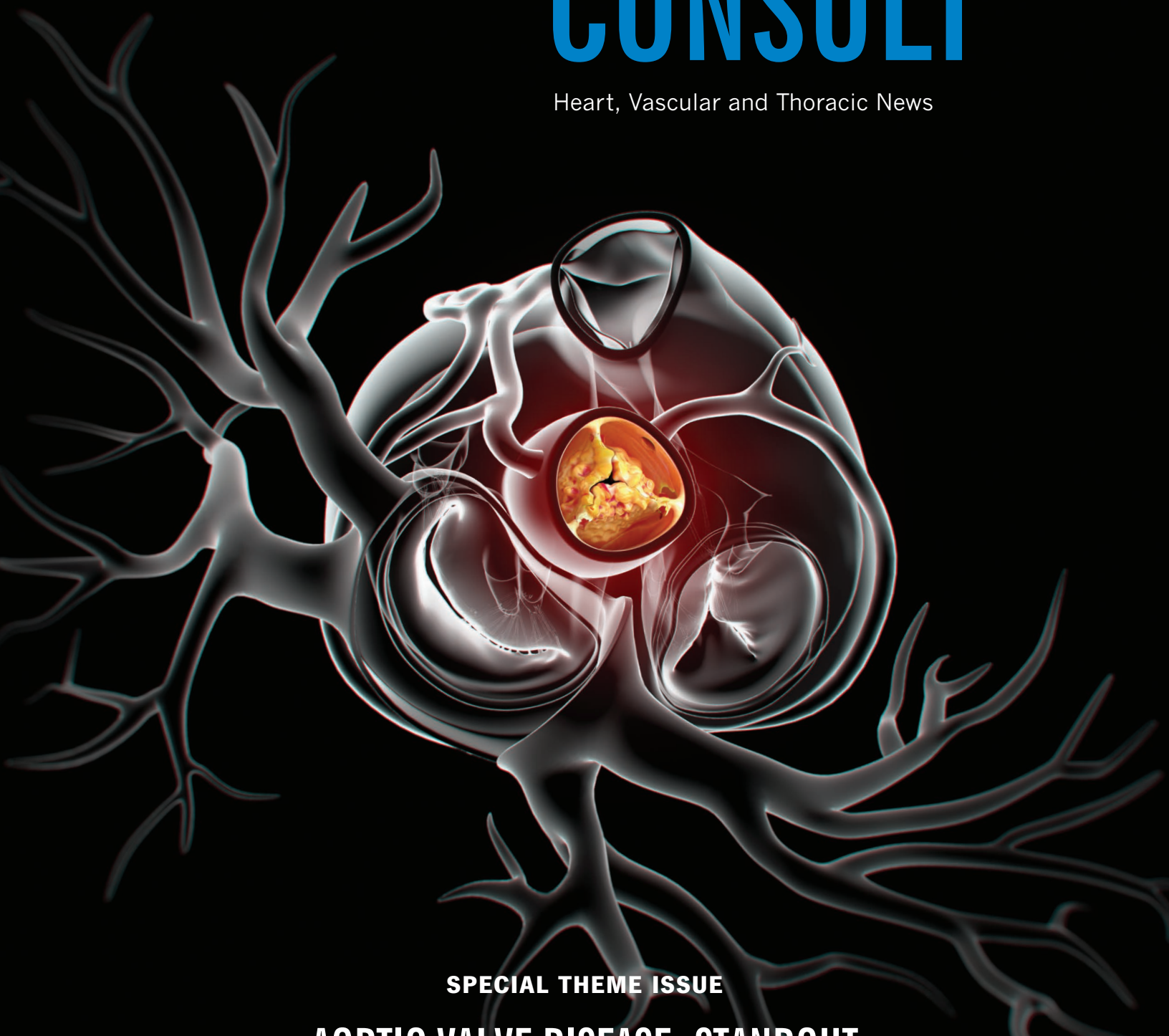

SPECIAL THEME ISSUE

AORTIC VALVE DISEASE: STANDOUT VOLUMES YIELD ADDED VALUE

DEAR COLLEAGUES,

As options for the care of aortic valve disease proliferate, judicious team-based management becomes more important than ever. Patients and providers today are privileged to be able to consider a range of aortic valve interventions across the lifespan that previous generations could only dream of.

This special theme issue of *Cardiac Consult* is intended as a guide to making the most of that range of options. The first four articles cover essentials of aortic stenosis management, from insights on patient evaluation to considerations for team-based lifetime management to fundamentals of follow-up after aortic valve replacement (AVR). We also discuss the relationship between volumes and quality for both surgical and transcatheter AVR.

The issue's final four articles address several more specialized areas, from management of bicuspid aortic valve disease to valve-sparing aortic root replacement and aortic valve repair, as well as AVR in the setting of multivalve surgery and in patients requiring preemptive mechanical circulatory support. All the articles feature perspectives from Cleveland Clinic surgeons and cardiologists with specialty interest and expertise in aortic valve disease.

We have developed this issue to raise awareness of the capabilities available to treat the most challenging cases of aortic valve disease and the deep experience underlying those capabilities. When you have a patient requiring the most advanced interventions for challenging aortic valve disease, we would be honored to partner with you in their care.

Respectfully,

Lars G. Svensson, MD, PhD
Chief, Cleveland Clinic Heart, Vascular and Thoracic Institute

ON THE COVER —
Illustration of a stenosed aortic valve in the context of the overall heart. Management of aortic stenosis is the focus of much of this theme issue on specialized care of aortic valve disease. The issue also touches on aortic regurgitation as well as aortic valve disease in the context of aortic dilatation, bicuspid valve anatomy and concomitant heart conditions.

Cleveland Clinic's Heart, Vascular and Thoracic Institute is nationally and internationally renowned as a leader in cardiovascular care. Its teams are dedicated to continuously improving upon their standard-setting clinical outcomes, unsurpassed volumes and experience, and rich legacy of innovation and research leadership.

Cardiac Consult is produced by Cleveland Clinic's Heart, Vascular and Thoracic Institute.

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EVALUATING PATIENTS FOR AORTIC STENOSIS INTERVENTION: NOT AS STRAIGHTFORWARD AS IT MAY SEEM

Optimally timed valve replacement depends on an expert approach to nuanced presentations

When the American College of Cardiology (ACC) and the American Heart Association (AHA) issued their latest guideline on the management of valvular heart disease four years ago, it reflected what was then relatively recent consensus on when and in whom aortic valve replacement (AVR) should be considered for treatment of valvular aortic stenosis (AS).

That consensus has only solidified in the subsequent years, but there remain important nuances in the evaluation of patients with AS that can be difficult for guidelines to elucidate.

"The evaluation and diagnosis of AS may be perceived as fairly straightforward, but it often gets complicated, especially when one factors in the question of exactly when to intervene," says Milind Desai, MD, MBA, Medical Director of Cleveland Clinic's Aorta Center and a cardiologist in its Valve Center.

Complexity behind the core recommendations

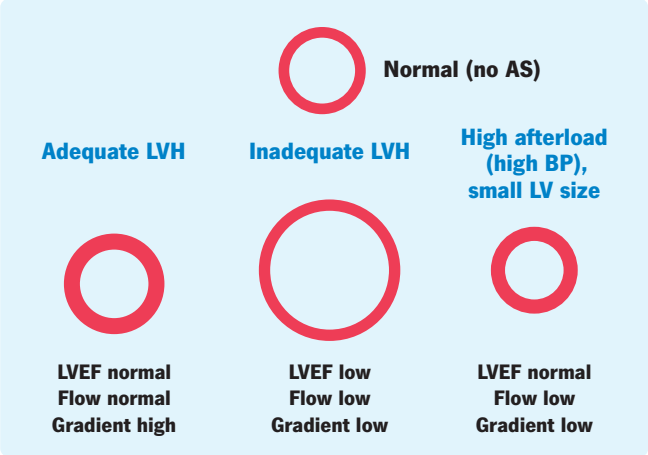
The ACC/AHA guideline (*Circulation*. 2021;143[5]:e35-e71) identifies four broad categories of indications for intervention for AS with AVR, whether surgical or transcatheter:

- Symptomatic severe AS
- Severe AS with left ventricular (LV) dysfunction
- Moderate AS when the patient is undergoing cardiac surgery for a separate condition
- Asymptomatic critical AS with a transvalvular mean pressure gradient ≥ 50 mm Hg

In real-world practice, however, these broad indications can quickly get clouded by discrepancies between AS severity and the patient's reported symptoms, between aortic valve area and mean pressure gradient, and between findings from different imaging modalities (Figure 1). "Patients often meet some criteria for severe AS but not all the criteria," notes Brian Griffin, MD, Head of Cleveland Clinic's Section of Cardiovascular Imaging and Medical Director of its Valve Center.

"About a quarter of patients with AS seen at Cleveland Clinic have normal LV function with a valve area and pressure gradients that are not fully in sync in terms of stenosis severity," Dr. Griffin continues. "In those cases we have to make a judgment whether or not it's true stenosis." He adds that another 5% of patients have low gradients, a severely reduced valve area and severely reduced LV function. "That amounts to about 30% of patients in whom disease classification and optimal management are difficult to figure out."

FIGURE 1 — Schematic illustrations contrasting a normal, stenosis-free aortic valve with a valve showing low-flow, low-gradient aortic stenosis (AS). These scenarios reveal why normal left ventricular ejection fraction (LVEF) does not always generate a high gradient in AS. "Adequate LVH" signifies an adequate degree of left ventricular hypertrophy (LVH) to maintain normal wall stress. "Inadequate LVH" signifies hypertrophy insufficient to normalize wall stress, leading to afterload mismatch and progressive dilatation of the left ventricle with reduced function. BP = blood pressure.



Dr. Desai says the most common nonstandard presentations include the following:

- Severe AS in the setting of heart failure with reduced ejection fraction (HFrEF), which may be accompanied by low gradients and appear to be mild or moderate AS unless the aortic valve area is measured very diligently
- Paradoxical severe AS, characterized by preserved ejection fraction, low gradients and low stroke volume index — suggestive of moderate AS despite actually being severe
- Pseudo-severe AS, where LV dysfunction suggests severe stenosis but careful valve measurements reveal mild to moderate disease

"Separating these presentations from standard severe AS can be daunting, and it has implications for appropriate timing of intervention," Dr. Desai observes.

A role for resourceful assessment

The challenge is overcome with various forms of additional testing beyond initial echocardiography. Often that means multimodality imaging, most often with the addition of CT. "Most of our patients nowadays undergo CT along with echo," Dr. Desai says. "If CT cannot be performed, MRI, transesophageal echo (Figure 2) or 3D echo can help us get a good handle on the valve area or identify something we might be missing on standard echo."

CT also is integral to another type of additional testing that can help define AS severity: calcium scoring of the aortic valve. "When necessary, we use CT scanning to assess the amount of calcium on the valve," Dr. Griffin explains. "Scoring is a bit different for women versus men, but in either sex the presence of a high calcium burden on the valve makes severe AS highly likely, even if the patient doesn't meet all the echo criteria. We do a lot of calcium scoring to make sure referrals for early intervention are appropriate."

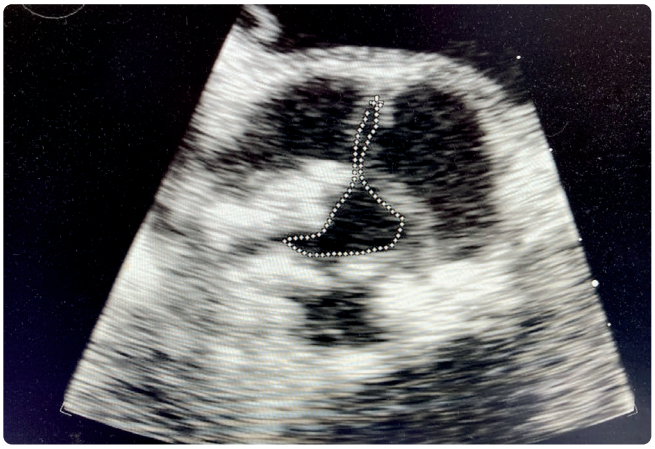
Exercise stress echocardiography can be another helpful indicator of increased risk from diminished functional capacity due to asymptomatic AS. Recognition of its role in this setting stems in part from a large Cleveland Clinic analysis showing improved survival following AVR in asymptomatic patients with AS undergoing stress echo (*Circ Cardiovasc Imaging.* 2016;9[7]:e004689). "We now use stress echo quite a bit when trying to decide the timing of intervention, especially when patients report no symptoms but we suspect their AS is getting worse based on other findings," Dr. Griffin says.

Biomarkers such as B-type natriuretic peptide (BNP) can also be useful in that context. "When a patient has severe AS but is asymptomatic, if their BNP level is two or three times normal, then valve replacement can and should be considered," Dr. Griffin notes.

"About a quarter of patients with [aortic stenosis] seen at Cleveland Clinic have normal LV function with a valve area and pressure gradients that are not fully in sync in terms of stenosis severity. In those cases we have to make a judgment whether or not it's true stenosis."

— BRIAN GRIFFIN, MD

FIGURE 2 — Severe aortic stenosis planimetry on transesophageal echocardiography.



The stakes of timely intervention

Indeed, Drs. Desai and Griffin say a resourceful, refined testing and evaluation strategy can make the biggest difference for patients who perceive themselves as asymptomatic. "We are not interested in sending patients for unnecessary procedures," Dr. Desai explains, "but when we have findings that strongly suggest severe AS despite the patient reporting no symptoms, our approach is to thoroughly assess whether the patient may in fact be able to benefit from intervention. That can be done with a stress test or strain imaging to confirm whether they are indeed asymptomatic or by calcium scoring, blood testing or additional imaging to make sure nothing is being missed."

The impetus for such thoroughness is the benefit that's been demonstrated from timely AVR. "Patients develop structural changes in their heart related to AS," Dr. Griffin says. "Resulting thickened muscle may regress after the valve is replaced, but it doesn't always regress completely to normal. That leaves patients at risk for a stiffer heart that's more likely to develop heart failure and other complications. Data show that earlier intervention in severe AS extends patients' survival and quality of life."

The benefits of early intervention are likely to be greatest at high-volume centers with very low rates of mortality and other complications, an observation made in the latest ACC/AHA guideline. "At a place like Cleveland Clinic, where procedural mortality rates for AVR are consistently 0.5% or less, the case for early intervention for AS is particularly compelling," Dr. Desai concludes.

Contact Dr. Griffin at 216.444.6812 and Dr. Desai at 216.445.5250.

TEAM-BASED MANAGEMENT OF AORTIC STENOSIS ACROSS THE LIFESPAN: IT'S ALL ABOUT OPTIONS

Age and other factors figure into the choice among SAVR, TAVR, Ross, Ozaki and more

Aortic valve replacement (AVR) has evolved into a treatment that can be offered as a range of options. Cardiac surgeons and interventional cardiologists performing AVR must have extensive expertise and experience to understand which option is the most appropriate for an individual patient. Skill in carrying out the procedure and diligence in follow-up are required to minimize complications.

At Cleveland Clinic, patients are advised about AVR by a multidisciplinary team consisting of a cardiovascular imaging specialist, an interventional cardiologist and a cardiac surgeon, sometimes with other clinicians as well. Additionally, specialized data coordinators assemble data on each patient to allow for ongoing assessment of outcomes.

Procedural mortality rates of 0% to 0.5% for surgical AVR (SAVR) and of 0.3% to 0.6% for transcatheter AVR (TAVR) in recent years validate this approach, says Samir Kapadia, MD, an interventional cardiologist who chairs Cleveland Clinic's Department of Cardiovascular Medicine. "These outcomes demonstrate that we are selecting patients appropriately for both procedures," he says.

Approaching treatment decisions as a team

Under Cleveland Clinic's group practice model, staff are not paid based on procedural volumes. This, together with the structure of its Heart, Vascular and Thoracic Institute integrating surgeons and cardiologists in shared spaces under unified leadership, aligns incentives in the interest of the patient rather than individual providers or specialties. Medical and surgical specialists have collaborated for decades to provide each patient with the optimal solution to their valve problem.

"We have improved our techniques for performing the Ross procedure since the 1990s. This potentially allows us to offer the Ross procedure to patients traditionally thought to be less ideal candidates for it."

— SHINYA UNAI, MD

"Our heart team is truly multidisciplinary," notes cardiac surgeon Faisal Bakaeen, MD. "It's not just the interventional cardiologist performing the TAVR or the surgeon performing the SAVR, but also the cardiologist who sees and follows the patient and the imaging specialist who provides us with precise measurements of the valve, root and annulus. This enables us to consider each patient as a unique case, discuss the pros and cons of SAVR and TAVR with them and recommend the ideal therapy for their individual needs. The patient then has the final say."

The role of case complexity

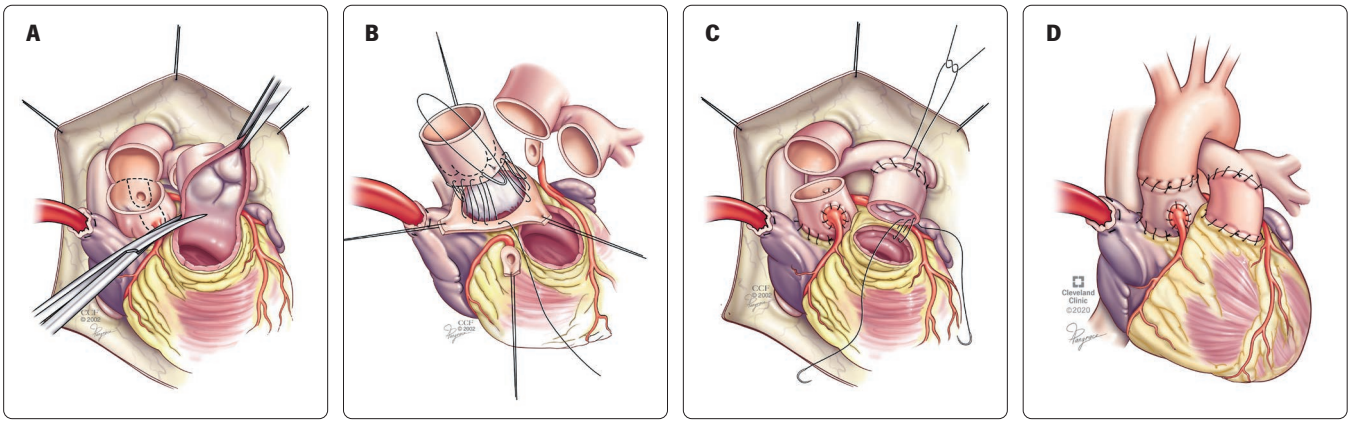
The breadth and depth of valve replacement expertise make the multidisciplinary team ideally suited for complex patients, many of whom have serious comorbid illnesses complicating their aortic valve stenosis, such as coronary artery disease (CAD). Experience enables the team to adjust their approach to maximize success.

"When a patient has extensive CAD involving the left anterior descending artery and multiple vessels, we lean toward open valve replacement and concomitant coronary artery bypass grafting," Dr. Bakaeen explains. "If a patient has a low burden of CAD or if unimportant vessels are affected and the patient is frail, we do TAVR and manage the CAD medically. In not-so-robust patients with significant affected arteries, we recommend TAVR and stenting. We believe the key is to be as comprehensive as possible in treatment options."

Making a thorough assessment

When a patient presents with aortic stenosis or other aortic valve disease, the first step is to thoroughly assess their condition. Cleveland Clinic goes beyond conducting a hemodynamic assessment with echocardiography to assessing anatomy and function with CT or MRI. "These assessments are not commonly done elsewhere, but we feel they are very important," Dr. Kapadia notes.

FIGURE 1 — Key steps in the Ross procedure. (A) The pulmonary valve is harvested, and the diseased aortic valve is removed. (B) The pulmonary valve autograft is implanted to replace the aortic valve. (C) The coronary artery is reimplanted to the autograft, and a pulmonary valve homograft is implanted. (D) Completion of the procedure.



The imaging studies help determine if the valve is bicuspid or tricuspid and if calcifications are present. The team considers annulus size, health of the aorta and coronary arteries, degree of left ventricular function, and presence of atrial fibrillation, fibrosis, scarring or pulmonary hypertension. "All of these can be the result of aortic stenosis or may occur in addition to stenosis," Dr. Kapadia says.

Lifetime management and the role of age

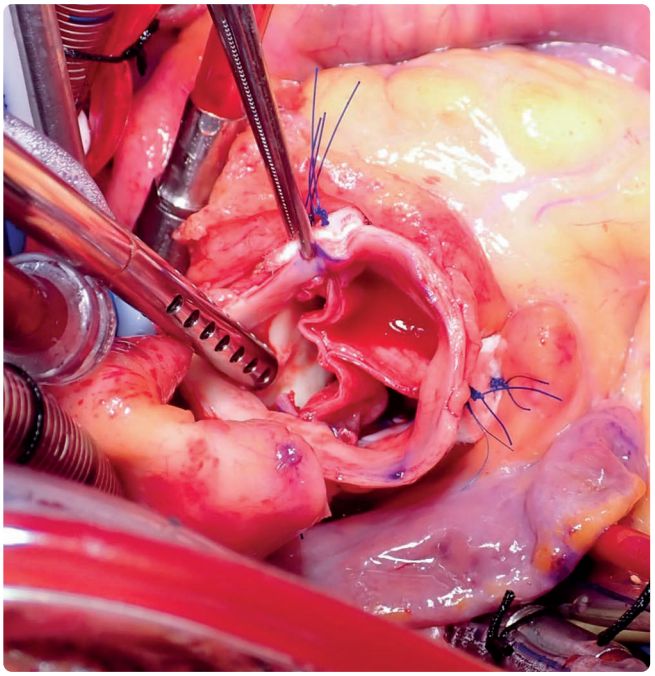
The optimal approach to AVR for an individual is based on the life expectancy of the patient and the durability of the valve.

Options for younger patients. Patients with aortic stenosis in their 20s through 50s have many different options, depending on their anatomy, lifestyle and other cardiac conditions and comorbidities. SAVR with a bioprosthetic valve or SAVR with a mechanical valve are the most commonly offered options. Each has its drawbacks, however: Bioprosthetic valves have limited durability in younger patients, whereas mechanical valves last longer than bioprosthetic valves but require lifelong anticoagulation and can be associated with complications such as bleeding and stroke.

A better option for patients in their teens to age 30 is often the Ross procedure, says cardiac surgeon Shinya Unai, MD. During a Ross procedure, the aortic valve is replaced with the patient's own pulmonary valve, and the pulmonary valve is replaced with a donor homograft (Figure 1). Anticoagulation is not required. "The Ross procedure has shown excellent durability and valve performance in young patients," Dr. Unai notes, "although it carries a risk of reintervention on two valves rather than one."

"A Ross procedure should last 20 to 30 years or more if a perfect technical result is achieved in the operating room," adds cardiac surgeon Marijan Koprivanac, MD.

FIGURE 2 — Photo of a completed Ozaki procedure.



"We have improved our techniques for performing the Ross procedure since the 1990s," says Dr. Unai, who frequently adds procedural steps to further support the autograft. These include annuloplasty to support the annulus, wrapping the entire autograft with native aortic root tissue and replacing a short area of ascending aorta to stabilize the distal autograft. "This potentially allows us to offer the Ross procedure to patients traditionally thought to be less ideal candidates for it," he explains.

"The last intervention in life should be TAVR, because you want to avoid operating on patients when they are elderly. Another consideration is to plan for one valve-in-valve procedure in the future and ideally avoid two valve-in-valve procedures, which would result in three valves being present in the aortic position."

— SAMIR KAPADIA, MD

Patients who are on multiple antihypertensive medications may not be ideal candidates for the Ross procedure. "Blood pressure must be controlled well, because the pulmonary valve is not accustomed to high pressures," Dr. Unai notes.

An alternative option in young patients is the Ozaki procedure. In this operation, the leaflets of the aortic valve are removed, after which new leaflets are fashioned from glutaraldehyde-treated pericardium and sewn onto the annulus (Figure 2). Benefits of the Ozaki procedure are that it does not require anticoagulation and provides a larger valve opening compared with the opening provided by prosthetic valves.

"When I see young patients, I discuss both the Ross and Ozaki procedures as options," says Dr. Unai, who has performed one of the highest volumes of Ozaki procedures in the U.S. "My team is always prepared to do both procedures. Intraoperatively, if we find that the patient's pulmonary valve is not suitable for the Ross procedure, the Ozaki procedure may be a better option. Alternatively, when the aortic root anatomy is not suitable for the Ozaki procedure, we can convert to a Ross procedure."

Although some centers may offer the Ross procedure beyond age 60, Dr. Unai says the risks are not justified in this population.

"The Ross is technically complex," Dr. Koprivanac adds. "We can do it safely — we have had no operative deaths with either the Ross or the Ozaki — but we need to use our judgment. We cannot compromise a patient's health." He notes that minimally invasive SAVR with a biologic valve may sometimes be more appropriate, as it carries a very low risk of reoperation, equivalent to a first operation at Cleveland Clinic, and also can be a good platform for valve-in-valve TAVR in the future when the valve degenerates.

Options at age 60 and beyond. Healthy, active patients in their 60s or early 70s should undergo SAVR, the surgeons say. If CT shows a small root or annulus, it should be enlarged. If the patient is tall or large, a larger valve is needed, even if the aortic root size is normal. "The valve must be sized relative to body size or patient-prosthesis mismatch is likely to occur," Dr. Koprivanac explains. "Otherwise, the patient's symptoms will not resolve and the valve will fail over time more quickly. Enlarging the root or annulus will set the patient up better for a future TAVR if needed."

"The last intervention in life should be TAVR, because you want to avoid operating on patients when they are elderly," Dr. Kapadia says. "Another consideration is to plan for one valve-in-valve procedure in the future and ideally avoid two valve-in-valve procedures, which would result in three valves being present in the aortic position." Anatomy of the aortic root, the patient's life expectancy and the choice of prosthesis all help guide the best strategy for future therapies.

Biologic surgical and transcatheter valves are expected to last 10 to 15 years. At age 75, TAVR can be offered if another TAVR valve can be placed inside it if the patient reaches age 85. If the patient is healthy and a large surgical valve can be placed at age 75 for future TAVR in a surgical valve, this can be an optimal strategy also. "Anatomy, comorbidities, opinions of our surgical and interventional experts, and patient preferences guide us to decide the optimal strategy," Dr. Kapadia says.

In their mid-70s or 80s, patients can undergo a TAVR-in-SAVR procedure and expect results comparable to a first-time TAVR. "The long-term durability of TAVR-in-TAVR is still uncertain, but patients who have SAVR first, followed by TAVR, do well," Dr. Koprivanac says.

The contemporary standard of care for SAVR is partial sternotomy ("J" incision) or mini-thoracotomy. Recovery is two to five days in the hospital, and patients return to normal activity more swiftly than with classic open sternotomy.

"Patients in their 80s who are physically strong and have good muscle mass are at low risk from SAVR and tend to do well after surgery, which often can be done with a minimally invasive approach," Dr. Koprivanac says. "We present all options, with their pros and cons, to patients and their families. The final choice, if both options will yield similar results and safety, is the patient's."

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Contact Dr. Kapadia at 216.444.6735, Dr. Bakaeen at 216.444.0355, Dr. Unai at 216.445.5902 and Dr. Koprivanac at 216.444.2035.

WHY APPROPRIATE FOLLOW-UP IS KEY TO SUCCESSFUL AORTIC VALVE REPLACEMENT

Ideal protocols feature frequent monitoring, high-quality imaging and an inclusive team approach

Frequent monitoring to enable early identification and treatment of potential abnormalities is key to the long-term success of aortic valve replacement (AVR), whether surgical (SAVR) or transcatheter (TAVR), say Cleveland Clinic heart valve specialists.

"As a large referral center for valvular heart disease, we see a substantial number of patients who develop valvular stenosis, valvular regurgitation or paravalvular regurgitation soon after SAVR or TAVR," says Amar Krishnaswamy, MD, Section Head of Invasive and Interventional Cardiology. "If any of these conditions is left unaddressed until the patient develops symptoms that would prompt testing, it could result in irrecoverable cardiac damage."

The foundational role of echo

Because the risks of early complications are similar in patients undergoing TAVR or SAVR, the follow-up protocol at Cleveland Clinic is essentially the same for both.

Echocardiography is the primary modality used for routine follow-up. It allows for visualization of the valve and assessment of blood flow through the valve.

The first echocardiogram is performed during SAVR or TAVR. A second echocardiogram may be performed on the day of or day following TAVR or two to three days after SAVR; this second echo serves as the patient's new "baseline" study.

A third echocardiogram is performed in the two- to three-month follow-up window. Its primary purpose is to identify any increase in valve gradients or development of valvular regurgitation — and, if either is present, to determine the location and severity.

"Often these problems are small, but sometimes they are more than mild," notes L. Leonardo Rodriguez, MD, a staff cardiologist in the Section of Cardiovascular Imaging. "However, they are easily detected early on and easy to follow over time."

"Changes in gradients can be somewhat subtle, even remaining in the normal range," Dr. Krishnaswamy adds. "For tissue valves, an early increase in gradients could be associated with thrombosis. We compare this two- to three-month follow-up study to the postprocedure baseline study to see whether we are prompted to look further with CT imaging."

When CT may be added

If a tissue valve appears abnormal on echocardiography during the first few months or couple of years after implantation, a CT scan may be obtained. CT is the gold standard for diagnosing premature leaflet calcification and hypoattenuated leaflet thickening/thrombosis (HALT) (Figure 1), both of which can impair valve function.

"With a high-quality CT scan, you can see a thin film of thrombosis on the base of the leaflet," Dr. Rodriguez notes. "Sometimes you can actually visualize restricted motion of the leaflets."

"Whether HALT should be treated is decided on a case-by-case basis and may entail the use of anticoagulants," says Dr. Krishnaswamy. "When patients are not good candidates for anticoagulation, we may choose to observe them and repeat the echo a few months later. In half of patients, HALT resolves spontaneously. If their next echo is normal, we then recommend monitoring with annual echocardiography." What is not known is whether HALT may cause stroke or later calcification of the valve leaflets.

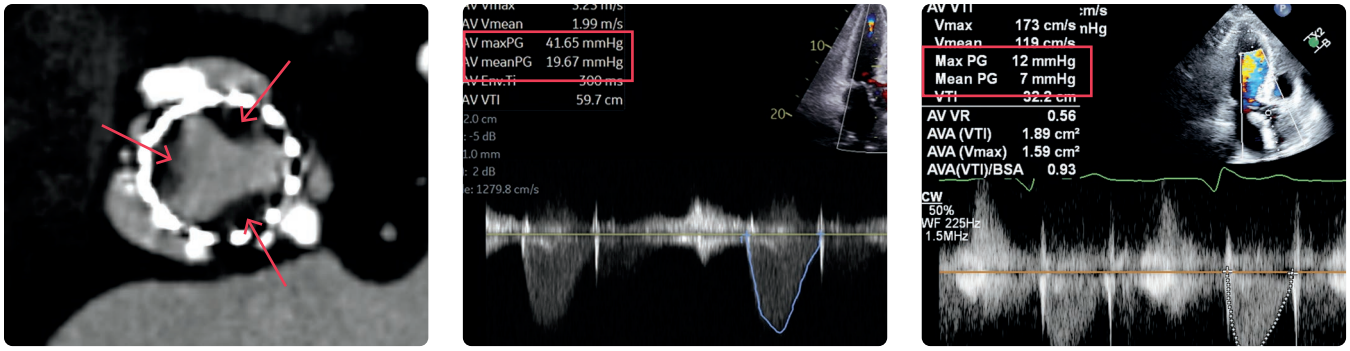
For patients who present with fever or other symptoms suggestive of endocarditis, or when new leakage of the valve is detected that could be "paravalvular" (Figure 2), a transesophageal echocardiogram may be necessary. Paravalvular leakage is usually due to failure of one or more sutures holding the valve in place or to incomplete TAVR valve deployment.

Long-term follow-up

After TAVR or SAVR, Cleveland Clinic valve specialists follow patients with yearly echocardiograms. "It's important to maintain vigilant surveillance because many younger patients may outlive their valve and require another valve replacement," Dr. Krishnaswamy says.

"Changes in tissue valves are often subtle and gradual, but a minority of patients experience rapid deterioration for unknown reasons," Dr. Rodriguez adds. "It's good to know the trajectory of these changes early on. Follow-up of mechanical valves is recommended based on symptoms. However, these valves also

FIGURE 1 — Hypoattenuated leaflet thickening/thrombosis (HALT) of a TAVR valve. CT image (left panel) shows thrombus (arrows) on the leaflets with resulting high echocardiographic gradients (middle panel) that resolved after anticoagulation (right panel).



may develop complications over time. That is why it is so helpful to have historical imaging."

A model of shared follow-up

At Cleveland Clinic, the care of patients with valvular heart disease is handled by a multidisciplinary team of experts.

"We have a number of caregivers in different specialties who collaborate in the management of these patients," says Marijan Koprivanac, MD, a cardiothoracic surgeon whose specialty interests include aortic valve disease. "We surgeons care for SAVR patients while they are in the hospital, but they are followed longitudinally by a cardiologist, who will call on us if needed."

The patient's local provider is also included in the care team. "We never see the care we provide as exclusionary," Dr. Krishnaswamy says. "We do our best to communicate our findings and our treatments to the referring provider. We like to see patients follow up with referring physicians seven to 10 days after discharge, and our nurse practitioners schedule their appointments. We are all one team."

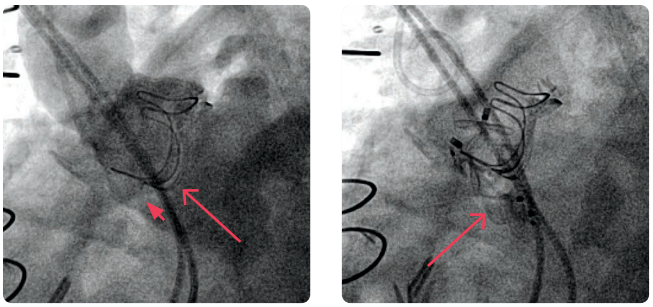
Many patients who live locally return to Cleveland Clinic yearly for follow-up. When travel isn't feasible, telephone or video visits may be arranged.

When patients have complex or unresolved issues, arrangements may be made for them to alternate every six months between seeing their Cleveland Clinic cardiologist and seeing their local provider.

Quality imaging is paramount

The role and extent of local follow-up is determined in large part by the availability of quality echocardiography studies. "The quality of imaging is paramount, as some of the valve abnormalities are important if they are detected or missed," Dr. Rodriguez explains.

FIGURE 2 — Paravalvular leak of a SAVR valve and its subsequent treatment. Space (arrowhead in left panel) between the valve (arrow in left panel) and the cardiac tissue is filled using special plug devices (arrow in right panel) via a catheter-based procedure.



CT scanning is generally less variable, but a scanner without cardiac gated software will be suboptimal.

Cleveland Clinic's electronic medical record system prompts physicians to schedule patients for a return visit one year after their current visit and conduct necessary testing if desired. This minimizes chances of patients being lost to follow-up.

Nevertheless, it is incumbent on patients to keep these appointments with their local provider or at Cleveland Clinic. "We rely on patients to be aware of what their follow-up should be," Dr. Krishnaswamy notes. "This is why it's important for referring physicians to have conversations with their patients about the need for appropriate follow-up. Our team approach with local physicians extends to the patient as well."

Contact Dr. Krishnaswamy at 216.636.2824, Dr. Rodriguez at 216.445.2149 and Dr. Koprivanac at 216.444.2035.

HOW AND WHY VOLUMES MATTER IN AORTIC VALVE REPLACEMENT

Experience and strength in both SAVR and TAVR make for the best patient options and outcomes

For decades it has been recognized that higher volumes correlate with reduced operative mortality and complications in surgical aortic valve replacement (SAVR).[1] This observation has been confirmed in more recent years, and a similar correlation has been seen with transcatheter aortic valve replacement (TAVR).[2,3]

The general association between procedural volumes and positive outcomes is hardly new and is somewhat intuitive, yet the implications are not always fully appreciated.

The numbers at a glance

For instance, the TVT Registry of the Society of Thoracic Surgeons (STS) and the American College of Cardiology shows that 100,501 commercial TAVR procedures were completed across 838 sites in the U.S. in 2023, for an average of 120 procedures annually per site. Since large centers perform many hundreds of TAVRs per year (Cleveland Clinic performs about 700), many sites are performing far less than 100 TAVRs per year to yield the overall average of 120. Some average little more than one per week, which can make it difficult for multiple operators to maintain optimal volumes and for the overall care team to develop expertise in the nuances of post-TAVR management.

The same phenomenon is also at play for isolated SAVR procedures, whose nationwide total of 18,792 in 2023 (according to the STS National Database™) was far below the 100,000-plus TAVR procedures that year. This suggests an average of about 18 isolated SAVR procedures annually per STS cardiac surgery site in the U.S., with an even lower average count per individual cardiac surgeon.

In contrast, Cleveland Clinic performs among the highest annual volumes of SAVR and TAVR in the world. In fact, even as isolated SAVR volumes have declined markedly nationwide in recent years with the growth of TAVR (down more than 37% from a peak of 30,171 in 2015, according to the STS National Database), Cleveland Clinic's isolated SAVR volumes have increased in the past several years (Table 1). As Tables 1 and 2 reflect, these high SAVR and TAVR volumes have been associated with procedural mortality rates at least two to five times lower than expected rates or national benchmarks, along with TAVR complication rates similarly reduced from national benchmarks.

Notably, in view of the complexity of patients referred to Cleveland Clinic, the total number of aortic valve procedures is approximately 2,800 annually when one includes SAVR done in combination with coronary artery bypass, aortic surgery and double/triple-valve operations.

TABLE 1. Cleveland Clinic Isolated SAVR Volumes and Operative Mortality

	Number of Operations	Observed Mortality	STS Expected Mortality*
2021	360	0.3%	1.5%
2022	405	0.0%	1.3%
2023	419	0.5%	1.4%
Total	1,184	0.25%	1.4%

* Per the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database

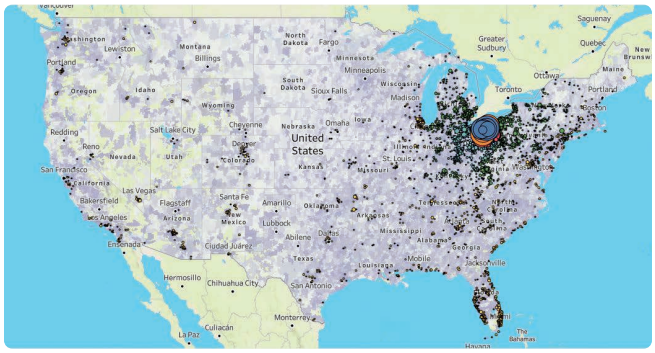
TABLE 2. Cleveland Clinic TAVR Volumes and Procedural Outcomes

	2021	2022	2023	Total for 2018-2023	2023 TVT National Benchmark (50th percentile)
Number of procedures	652	628	699	3,862	—
Mortality	0.6%	0.6%	0.3%	0.4%	0.7%
Stroke	0.4%	0.6%	0.3%	0.5%	0.9%
AR ≥ grade 2	0.4%	0.5%	0.3%	0.4%	0.0%
New PPM	2.9%	3.5%	4.0%	3.2%	6.1%

AR = aortic regurgitation; PPM = permanent pacemaker; TVT = Transcatheter Valve Therapy Registry

"Cleveland Clinic manages more patients with aortic stenosis than any other center," says Samir Kapadia, MD, Chair of Cardiovascular Medicine. "This is despite not being located in one of the most densely populated parts of the country. Our long-standing reputation for leadership and excellent outcomes in aortic valve care consistently draws patients from all corners of the U.S. (as reflected in the Figure) and all over the world."

FIGURE — Each black dot on the map depicts a patient who came to Cleveland Clinic for aortic valve care in 2022 or 2023, collectively representing a broad geographic draw.



Three key reasons for volume's role in AVR quality

Dr. Kapadia identifies three broad reasons why volume looms so large in the quality of aortic valve replacement (AVR) care.

Experience. "Experience matters not just for the technical skills of the surgeon or the proceduralist," Dr. Kapadia says. "It also has implications for how the whole care team manages the patient, such as when complications arise. It's essential for optimal diagnosis of aortic stenosis and determining the best timing of intervention. Our cardiologists have cared for so many patients with aortic stenosis that they have deep expertise in the use of multimodality imaging in this setting and how to factor other conditions, such as hypertrophic cardiomyopathy or cardiac amyloidosis, into treatment strategies."

Experience is particularly important for patients who have other cardiac conditions in addition to aortic stenosis. "Many of our patients requiring AVR have coronary disease, mitral valve disease and other heart conditions that need to be addressed at the same time," says cardiothoracic surgeon Lars Svensson, MD, PhD, Chief of Cleveland Clinic's Heart, Vascular and Thoracic Institute. "For instance, we perform nearly 200 combined SAVR and CABG operations each year, not to mention multivalve operations and SAVR combined with aortic surgery. These patients particularly benefit when they are managed by teams who perform these complex procedures often."

Dr. Svensson notes that failure to address concomitant heart conditions at the time of AVR is increasingly a problem with the recent growth of TAVR. "In addition to cases of failed TAVR, we see growing numbers of patients who come to us fairly soon after having TAVR elsewhere," he says, "because they have progression of other heart disease that was present at the time of their TAVR, such as coronary disease or other valve disease."

Options. High-volume heart valve programs are also best equipped to offer patients the most appropriate option for management of their particular case of aortic stenosis and any related conditions. "High-volume programs tend to have the most valve types available for both SAVR and TAVR and the most experience in using all of them," Dr. Kapadia says. "This allows us to precisely match valves to patients' anatomic needs. A high-volume program like ours is also able to offer true lifetime management of aortic valve disease, including options such as the Ross and Ozaki procedures, homografts, aortic valve repair and reimplantation, aortic root replacement and annular enlargement, valve-in-valve procedures, TAVR valve explantation, the BASILICA procedure and more."

Absence of procedural bias. Centers that have disproportionate experience with either TAVR or SAVR can tend to steer patients to the option they are most experienced and comfortable with rather than what is best for the patient's individual situation. "When a program has deep experience with both procedures, this is not a concern," Dr. Kapadia notes.

In fact, an analysis of a large Medicare database from a few years ago found that hospitals' total SAVR volumes were correlated with TAVR outcomes, with higher 30-day and one-year TAVR mortality seen at low-volume SAVR hospitals.[4]

"Just as having an experienced TAVR program improves SAVR outcomes by treating the highest surgical risk patients, the converse is also true that better SAVR makes for better TAVR," Dr. Svensson wrote in an editorial he co-authored to accompany the study.[5] "The two procedures are inextricably intertwined as part of a comprehensive disease management program for the management of aortic stenosis."

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BICUSPID AORTIC VALVE DISEASE: MULTIFACETED CHALLENGES DEMAND VERSATILE MANAGEMENT

Multidisciplinary teams can deliver good short- and long-term outcomes, Cleveland Clinic experience shows

In most cases, a bicuspid aortic valve (BAV) can be surgically treated very safely and effectively — with or without root replacement — even for severe regurgitation with aortic dilatation and aneurysm. In fact, most patients with severe regurgitation can have a successful repair. Surgeon experience is critical to success in these complex operations, as is careful assessment to determine patient candidacy and operative strategy.

"For the past 40 years, Cleveland Clinic surgeons have pioneered BAV repair techniques for patients with BAV regurgitation, gaining considerable expertise and longitudinal data on patient outcomes," says Xiaoying Lou, MD, a Cleveland Clinic cardiothoracic surgeon with specialty interests in the aorta and aortic valve. "In the current era, repair can be just as good as replacement: Our 10-year survival rate for elective BAV repair is 95%, with a 0.7% combined incidence of operative mortality and stroke."

BAV-related issues arise early

A BAV occurs in about 1% to 2% of the population and may be associated with an inherited connective tissue disorder. Many of these patients develop valvular regurgitation that requires intervention. Patients with a BAV are prone to progressive problems — including aortic regurgitation, stenosis and aneurysms — starting decades earlier than for patients with a tricuspid aortic valve. In Cleveland Clinic's experience, more than one-third develop aortic enlargement.

When possible, experienced surgeons prefer to perform repair over replacement for younger patients with a tricuspid aortic valve and a dilated root, to avoid prosthetic valve complications and lifelong anticoagulation therapy. However, BAV repair poses additional challenges that many surgeons are reluctant to take on, especially in centers where BAVs are not encountered often.

For aortic stenosis in patients with a BAV, the strategy is generally to surgically replace the valve, except in specific circumstances where the valve is also regurgitant and the leaflets are of sufficient quality to enable repair. Dr. Lou considers transcatheter aortic valve replacement (TAVR) in the setting of BAV only for older patients who are unable to undergo surgery due to comorbidity, as bicuspid anatomy is not conducive to good placement of the TAVR valve and the risk of stroke and paravalvular leak is higher.

"We don't offer TAVR even for a medium-risk patient with a BAV," she says. "If the valves are calcified, as they often are, the patient might end up with a worse leak and poor options for a future fix."

Strategy considerations for BAV regurgitation

"Aortic regurgitation is a difficult valve lesion to assess, because it is easy to underestimate the severity of the leak and its impact on left ventricular function," says Brian Griffin, MD, Medical Director of Cleveland Clinic's Valve Center. "Imaging plays a large role in preoperative assessment, as it provides important clues for determining timing of intervention, which is especially critical for asymptomatic patients."

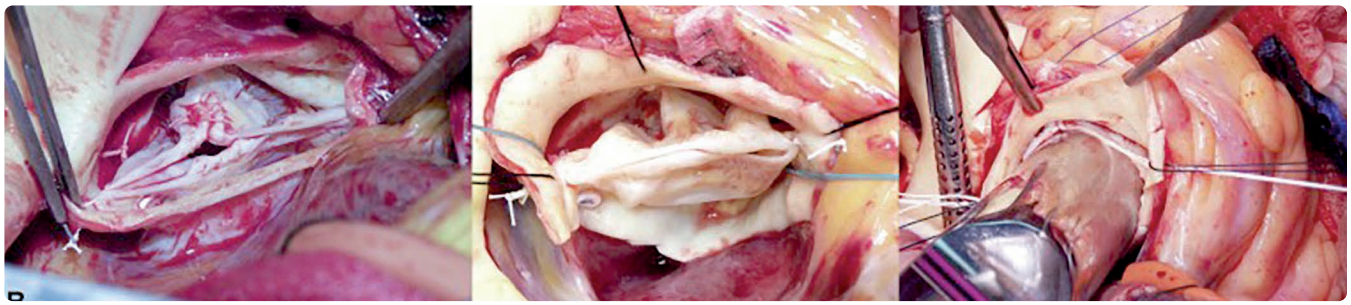
He adds that unlike for the mitral valve, intervention on the aortic valve is unlikely to last a lifetime in younger patients such as those with a BAV, so delaying it until really needed can be beneficial. On the other hand, if one waits until the left ventricle has become enlarged and function is compromised, it may not improve after an intervention. Another consideration is that for women, intervention generally should be undertaken earlier than guidelines often indicate, as women's hearts tend to be smaller than men's and appear to have greater difficulty handling an aortic valve leak.

Dr. Griffin co-authored a paper in *JACC: Cardiovascular Imaging* (2018;11[10]:1499-1513) outlining Cleveland Clinic's strategy for determining whether a patient with chronic asymptomatic aortic regurgitation should be considered for surgery. Severity of aortic regurgitation and left ventricular function are the primary initial considerations, including in patients with BAV. Patients with aortic regurgitation should be monitored with echocardiography to track changes in left ventricular size and volume. Every one to two years, stress echocardiography should be done to objectively assess functional capacity. If results are unclear, MRI can provide quantitative measures of ventricular size and aortic regurgitation severity.

"We use multiple imaging modalities if needed, particularly in patients with a bicuspid valve, but there is no textbook answer in determining optimal timing for intervention," Dr. Griffin explains. "Experience is critical."

Once surgery is decided on, issues surrounding replacement versus repair become paramount. The choice is based on patient

BELOW — Intraoperative photographs of BAV repairs using Cabrol sutures, plication stitches and figure-of-8 sutures. Note the suture placement near the leaflet edge and the use of a Hegar dilator to ensure that stenosis is not created. Reprinted under the CC BY-NC-ND license from Svensson LG, "The art of aortic valve repair," *JTCVS Techniques.* 2021;7:121-125. ©2021 The Authors.



age (repair is especially advantageous for younger patients) and preoperative and intraoperative clinical findings. Replacement is needed for patients with moderate to severe aortic stenosis.

Patients with a preoperative aortic root or ascending aorta diameter of more than 4.5 cm, or who have an aortic area-to-height ratio of more than 10, are candidates for replacement of the ascending aorta in addition to valve repair or replacement.

Intraoperative assessment guides intervention

Systematic intraoperative assessment of commissures, leaflets, annulus, sinuses and sinutubular junction (CLASS) helps determine strategy and techniques. For patients with heavy calcification or major perforations of valve leaflets, replacement is recommended.

Dr. Lou emphasizes the imperative to ensure that results are optimal — with good function and no leakage, as determined visually and with intraoperative echocardiography — before closing the incision.

Outcomes of BAV repair

A study comparing Cleveland Clinic patients who underwent aortic root replacement with those who had either BAV reimplantation (n = 92) or tricuspid aortic valve reimplantation (n = 515) from 2002 to 2017 found similar short-term and five-year outcomes among 71 matched pairs (*J Thorac Cardiovasc Surg*. 2022;163[1]:51-63). However, higher gradients, less ventricular reverse remodeling and more aortic valve reoperations in the BAV group indicated a need for continued surveillance in such patients.

Another Cleveland Clinic study analyzed more than two decades of data (1998-2020) from patients who underwent BAV repair with (n = 419) or without (n = 421) ascending aorta replacement (*J Thorac Cardiovasc Surg.* 2023;166[6]:1561-1571). Between-group comparisons were made among 97 patient pairs after propensity score matching.

At 10 years, across the overall cohort, survival was 95% after BAV repair with aorta replacement and 96% after BAV repair alone, and rates of freedom from reoperation were 79% and 75%, respectively.

Among the matched pairs, severe aortic regurgitation developed within 10 years in 9.1% of patients undergoing BAV repair alone and 11% of those with BAV repair plus aorta replacement (P = .33). Among other findings:

- Aortic valve mean gradient increased over time, especially in patients who had BAV repair alone.
- Late reoperation in both groups was most often related to intrinsic cusp pathology.
- A very small minority of patients developed valve dysfunction over time related to progressive aortic root dilatation; this appeared to be independent of whether ascending aorta replacement was performed with BAV repair.

Dr. Lou notes that an important focus of the study was to determine the importance of replacing the ascending aorta with a tube graft for the sole purpose of stabilizing the sinutubular junction (STJ). BAV is often seen with ascending aortic aneurysms leading to STJ effacement, disrupting optimal commissural alignment and resulting in aortic regurgitation. However, comparison of the matched pairs revealed that stabilization of the STJ with ascending aorta replacement at the time of BAV repair had minimal effect on long-term repair durability. The authors concluded that STJ stabilization should not be undertaken solely for that purpose.

Collaborative decision making is essential

Both Drs. Lou and Griffin emphasize that with the number of considerations surrounding surgery for BAV disease, decisions are best made with the input of the full heart care team. "We all need to be on the same page regarding what a patient needs and what can realistically be accomplished," Dr. Lou says.

"A patient's lifestyle, hopes and expectations are also critically important," Dr. Griffin adds. "There's no single recipe for a correct solution in these complex situations."

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VALVE-SPARING AORTIC ROOT REPLACEMENT: A FEASIBLE, DURABLE OPTION FOR REGURGITATION WITH AORTIC DILATATION

In experienced hands, up to 95% of patients can be free of reoperation at 15 years

Patients who require aorta surgery for a dilated aorta or aortic root often have some degree of aortic valve regurgitation as well. At Cleveland Clinic, these patients frequently are offered aortic valve repair in combination with aortic root replacement with valve reimplantation, also known as valve-sparing aortic root replacement.

"Not all cardiovascular providers recognize how often the aortic valve can be repaired with really good results at a highly experienced center," says cardiothoracic surgeon Lars Svensson, MD, PhD, Chief, Cleveland Clinic Heart, Vascular and Thoracic Institute. "And the best results are achieved when repair is done with a reimplantation operation, which can achieve rates of freedom from reoperation over 10 to 15 years comparable to those with mitral valve repair. We currently perform concurrent aortic valve repairs in about 20% to 25% of our reimplantation operations."

Who's a candidate?

"We most often perform valve-sparing root replacement in patients who have no more than mild or moderate aortic regurgitation with an aneurysmal root," notes Milind Desai, MD, MBA, Medical Director of Cleveland Clinic's Aorta Center and a cardiologist in its Valve Center. "A small amount of calcium can be surgically removed from the valve if present, but the valve typically needs to be free of advanced stenosis or significant regurgitation to qualify for repair. These are generally younger patients in whom we want greater durability than a bioprosthesis can deliver without the lifelong anticoagulation required with a mechanical valve."

Procedure essentials

The reimplantation operation (Figure) involves mobilizing the aortic valve, putting pledgets in the left ventricular outflow tract (LVOT), placing the valve inside a tube graft to replace the aortic root, sewing the graft into position and hooking it to the coronary arteries. Dr. Svensson performs the operation using modifications he made to the David reimplantation method more than 20 years ago, with the goal of improved durability. Essential features of his modified technique include:

- Reducing the annulus size according to patient size, based on sex and body surface area
- Use of pledgets in the LVOT to reduce the risk of sutures pulling through
- Creating neosinuses to preserve the aortic valve, eliminate valve regurgitation and prevent aortic stenosis

The reimplantation operation makes repair — and thus preservation of the native valve — possible in more patients, especially those with more severe regurgitation, Dr. Svensson says. "Using the reimplantation operation in patients with severe aortic regurgitation without a particularly large root gives me much more control in repairing the valve leaflets, providing a leg up in preserving three-leaflet valves," he explains.

In fact, he adds, in recent years Cleveland Clinic has increasingly used the reimplantation operation for leaking valves in patients with small aortic roots, i.e., < 4.5 cm. Enough experience has been accumulated in this small-root population that Dr. Svensson and colleagues have completed a study (not yet published) showing good results in these patients in terms of operative success, survival and freedom from reoperation. "Very few people are doing these procedures in patients with such small roots, so we hope to provide some insight and guidance," he notes.

What about bicuspid valves?

Dr. Svensson adds that bicuspid aortic valves require slightly different techniques than those used for trileaflet valves, but the same principles apply to both valve types in this setting.

"I tell patients with trileaflet valves that there's a 95% chance we can preserve their native valve, particularly if their root is enlarged," he says. "For patients with a bicuspid valve, the chance is about 80%. Although that's still good, it's lower because bicuspid valves are more likely to have severe calcification that cannot be seen on echocardiography but is apparent during surgery, which means the valve needs replacing."

Precise imaging is imperative

The importance of detecting significant valve calcification or holes in valve leaflets makes highly precise imaging imperative in these patients, whether they have trileaflet or bicuspid valves.

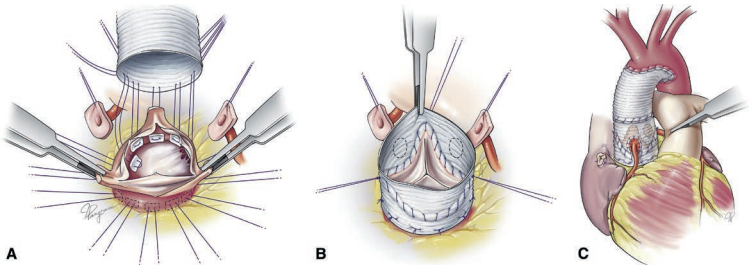

FIGURE — Key steps in the modified valve-sparing aortic root replacement procedure. (A) The aortic valve is mobilized so the entire annulus can be housed within the tube graft. Valve sutures are passed from inside the ventricular outflow tract and through the polyester tube graft. (B) The sutures are tied down around a Hegar dilator appropriate to the patient's body surface area, and the valve is sewn into position within the graft. (C) The coronary artery ostia buttons, buttressed by felt, are attached to the side of the graft. Reprinted from the *Journal of Thoracic and Cardiovascular Surgery* (2022;163:51-63), Mokashi et al., ©2020, with permission from the American Association for Thoracic Surgery.

"In most of these patients we obtain a gated contrast CT scan to get precise measurements of the root of the annulus and where the coronary arteries lie," Dr. Desai says. "We also obtain echocardiograms and, in some cases, transesophageal echocardiograms to ensure there is no significant calcification of the valve and that the leakage is not so significant as to rule out repair.

"The timing of most valve-sparing root replacements is driven by concern about aortic root aneurysm," Dr. Desai continues. "So the imaging-based valve assessment needs to be precise enough to determine whether the valve's condition, in terms of leakage severity and stenosis, allows for repair rather than replacement within that timetable driven by the root disease."

Experience yields research insights

Over the past quarter century, Cleveland Clinic has accumulated the world's largest experience in valve-sparing aortic root replacements, enabling publication of some of the most extensive observational research on these procedures in the literature, which demonstrates excellent outcomes for patients.

For instance, a recent report of long-term outcomes in 491 adults undergoing elective modified aortic valve reimplantation found 95% freedom from aortic valve reintervention at 15 years (*J Thorac Cardiovasc Surg.* Epub 2024 Aug 22). There were no operative deaths, and survival at 15 years was 87%.

Another recent study in 756 patients with trileaflet valves undergoing modified reimplantation showed that the need for cusp repair at the time of reimplantation does not affect long-term hemodynamic or clinical outcomes (*JTCVS Open.* 2023;161:105-122). Across the cohort, 10-year freedom from reoperation was the same — 97% — regardless of whether patients underwent reimplantation with cusp repair or without it. "The need for cusp repair should not deter surgeons from performing a valve-sparing operation," Dr. Svensson and his Cleveland Clinic co-authors concluded.

In the two studies above, most patients had trileaflet aortic valves. The Cleveland Clinic experience has shown outcomes of valve-sparing root replacement with bicuspid valves to be comparable to those with trileaflet valves through five years; over longer follow-up, however, bicuspid valves have been associated with a somewhat higher rate of valve reoperations, requiring closer surveillance over time (*J Thorac Cardiovasc Surg.* 2022;163[1]:51-63). "At an experienced center, valve-sparing root replacement for aortic aneurysm can be an attractive option for appropriate patients with either a trileaflet or a bicuspid valve," Dr. Svensson says, "but bicuspid anatomy calls for extra vigilance in patient selection and long-term follow-up."

Importance of early referral, vigilant follow-up

Indeed, careful lifelong surveillance is essential in all cases of valve-sparing aortic root replacement, given the need for lifetime management of aortic disease. Its importance in this specific setting was highlighted by a Cleveland Clinic study of 756 patients with trileaflet valves who underwent valve-sparing root replacement (*J Thorac Cardiovasc Surg.* 2024;167[1]:101-111). The study found that although long-term survival was similar between patients who did and did not have residual aortic regurgitation at discharge, the risk of reoperation was significantly higher if residual regurgitation was present. "This underscores that complete elimination of regurgitation by a skilled surgeon is essential for long-term success," notes Dr. Svensson.

"This study also shows that it's critical to follow patients found to have residual regurgitation extra closely to ensure prompt recognition of any need for reoperation," adds Dr. Desai. "Moreover, this study's finding that the risk of residual regurgitation at discharge was associated with severity of preoperative regurgitation argues for early referral to an experienced center for valve-sparing root replacement. That appears to give patients the best chance of long-term regurgitation-free survival."

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AORTIC VALVE REPAIR FOR AORTIC REGURGITATION: A WELCOME OPTION IN EXPERIENCED HANDS

For many patients, repair is feasible, durable and preferred over replacement

At many heart centers, surgical valve replacement remains the standard of care for patients with significant valvular aortic regurgitation (AR), for whom no good transcatheter options exist. Over the past two decades or more, however, Cleveland Clinic has demonstrated that aortic valve *repair* is a safe, effective and durable option for many of these patients, particularly those younger than 65.

Repair holds a number of advantages over replacement in this setting:

- Avoidance of the risks of stroke and infection associated with valve replacement
- Freedom from the need for lifelong anticoagulation required with replacement with a mechanical valve
- The potential for greater valve durability relative to replacement with a bioprosthetic valve

"At Cleveland Clinic, we've performed over 3,500 aortic valve repairs to date," says cardiothoracic surgeon Lars Svensson, MD, PhD, Chief of Cleveland Clinic's Heart, Vascular and Thoracic Institute. While that includes many hundreds of valve-sparing aortic root replacements to address concurrent aortic disease (the focus of the preceding article), the majority of repairs involve solely the valve for treatment of AR. These are performed as minimally invasive keyhole operations.

"We've shown that, at experienced centers, valve repair is effective and durable for treating AR," Dr. Svensson says. "But only a small number of centers across the U.S. will attempt aortic valve repairs, as these procedures require a steady number of cases to maintain expertise and skills."

Success by the numbers

Dr. Svensson points to several Cleveland Clinic publications to underscore the effectiveness and durability of aortic valve repair.

A study of 1,009 patients who underwent aortic valve repair from 2001 to 2011 found 90% freedom from aortic valve reoperation and 83% survival at 10 years after repair (*Ann Thorac Surg.* 2018;105[3]:739-748). These repairs involved various techniques, including cusp repair with commissuroplasty in nearly half of cases as well as commissural figure-of-8 suspension sutures, debridement, free-margin plication or resection, and annulus repair with resuspension, root reimplantation or root remodeling.

This large series yielded at least two key insights:

- Repair durability is particularly strong for patients undergoing repair with annular support and those receiving commissural figure-of-8 suspension sutures.
- A comprehensive approach to all components of the aortic valve using the CLASS schema — for commissure, leaflet (cusps), annulus, sinus and sinutubular junction — is needed to ensure a durable repair.

While many patients in the above series had a trileaflet aortic valve, nearly comparable results can be achieved in patients with a bicuspid aortic valve (BAV). Dr. Svensson and colleagues reported long-term outcomes in 728 patients (mean age, 42 years) who underwent BAV repair at Cleveland Clinic from 1985 to 2011 (*Ann Thorac Surg.* 2014;97:1539-1548). Freedom from aortic valve reoperation at 10 years was 78%, and survival at 10 years was 94%. Hospital mortality was 0.41%.

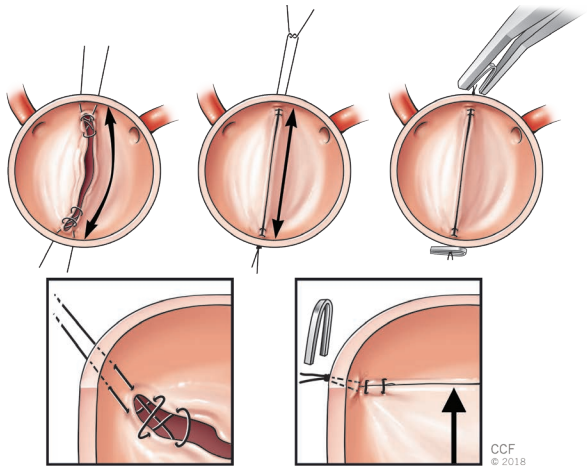
"This study period stretched over 26 years," Dr. Svensson observes. "Outcomes improved over time as we gained experience, learning how to better select patients for repair and choose which components of the operation to perform, and as we began to routinely employ the CLASS schema." Results improved to 91% freedom from reoperation at 10 years for isolated BAV repairs, he notes.

Technical innovations

One of the key lessons learned was the value of including a figure-of-8 hitch-up stitch among conventional BAV repair methods. "We now use this stitch at commissures in virtually all aortic valve repairs, whether BAV or trileaflet," says Dr. Svensson, who developed the technique. The rationale is to enhance repair durability by elevating the commissures to reinforce valve closure, as illustrated in the Figure.

A recent Cleveland Clinic study confirmed the safety of the stitch and the ability to use it for severe BAV regurgitation (*JTCVS Techniques.* 2024;24:27-40). That report compared early and later outcomes between two matched groups of 195 patients

FIGURE — Illustrations showing BAV repair with the figure-of-8 hitch-up stitch. This technique increases the area of apposition for the valve leaflets and elevates them to achieve more tension. The result is greater contact area and apposition, which may provide redundancy if the leaflets stretch over time.



each undergoing BAV repair — one group with conventional repair techniques alone (e.g., commissuroplasty and cusp plication) and the other with conventional techniques plus the figure-of-8 hitch-up stitch. Operative mortality in the figure-of-8 stitch group was low (0.3%), and 10-year freedom from reoperation was comparable to that in the conventional group (80% vs. 81%), as was 10-year survival (99.5% vs. 94.6%, respectively).

Another notable technique Cleveland Clinic surgeons occasionally use for aortic valve repair is known as the tailoring operation, in which the intercommissural angle is narrowed with a Cabrol stitch, after which the sinutubular junction is downsized. Figure-of-8 hitch-up stitches are often placed on top of the commissures as well, to increase the area of apposition. "We tend to use this in elderly patients, with excellent long-term freedom from reoperation," Dr. Svensson says.

Essential role of imaging

Beyond surgical expertise, optimal AR management demands well-informed vigilance in disease detection as well. "Patients with severe AR often remain asymptomatic for a very long time, yet a number of studies show that subclinical left ventricular myocardial dysfunction occurs early in the compensated stage with preserved left ventricular ejection fraction, before overt symptoms develop," says Milind Desai, MD, MBA, Medical Director of Cleveland Clinic's Aorta Center and a cardiologist in its Valve Center. "Recent years have seen recognition that patients can benefit from surgery at this stage."

To identify patients at this stage, Dr. Desai and his colleagues often rely on multimodality imaging that begins with transthoracic echocardiography. "A quality echo is absolutely needed," Dr. Desai says. "But often in patients with AR, the jet is eccentric, which can cause underestimation of the degree of AR. In many of those cases, we will add transesophageal echocardiography (TEE) or cardiac MRI, particularly when there is discrepancy between what we're seeing in terms of severity of valve regurgitation and size of the left ventricle. While TEE, including 3D TEE, is particularly helpful for recognizing the etiology and ascertaining the severity of AR, MRI can help quantify AR and, more importantly, provide a precise assessment of LV volumes and ejection fraction.

"Many of these patients will have aortopathy," he continues. "If we suspect aortopathy, a gated tomographic scan like contrast-enhanced CT or MRI is helpful to allow precise measurements. And CT is valuable for identifying significant calcification, which will rule out repair."

All about versatility

Once AR requiring intervention is confirmed, Dr. Desai becomes even more focused on determining whether the patient's anatomy is conducive to valve repair. "Every patient we refer for repair is told we will attempt repair but there's a chance the surgeon may have to replace the valve based on what's seen in the operative field," he says. "I advise patients younger than 45 or 50 to be prepared for the possibility of a mechanical valve unless we identify in advance a compelling reason to go with a bioprosthesis if repair isn't feasible."

In fact, Dr. Desai sees the nimbleness of his surgical colleagues as a leading asset for patients seeking the best solution for their AR at Cleveland Clinic. "Aortic valve repair is a sophisticated operation that should only be attempted by deeply experienced surgeons who have performed plenty of these repairs before," he says. "We have a highly competent group of surgeons who, even with their experience, are not just aortic valve repair specialists. They are highly versatile surgeons who can respond to the patient's valve anatomy in the moment and do whatever is needed to take the patient out of harm's way."

He adds that these surgeons are backed by highly experienced cardiologists "who have seen enough to be able to tell a patient, when necessary, 'Unfortunately, repair is not going to work here. Replacement will be a much better option, based on solid imaging evidence.' That's what we owe our patients."

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SPECIAL ISSUES IN HIGH-RISK AORTIC VALVE REPLACEMENT: MULTIVALVE SURGERY, EARLY DEVICE SUPPORT

Surgeons credit good outcomes to experience with complex cases and team approach

Surgical aortic valve replacement (SAVR) can be a major operation for any patient if compounded by factors such as reoperation, low ejection fraction and the concomitant need for other procedures, such as mitral valve repair/replacement or coronary artery bypass grafting.

"As a high-volume center with long experience handling complex cardiovascular cases, Cleveland Clinic is at the forefront of developing surgical techniques and management strategies for high-risk aortic valve replacement," says Edward Soltesz, MD, MPH, Surgical Director of Cleveland Clinic's Kaufman Center for Heart Failure Treatment and Recovery. "We are able to achieve excellent outcomes for many patients who are deemed too high risk for surgery, including SAVR, at other hospitals."

Cardiac Consult checked in with Dr. Soltesz and his Cleveland Clinic cardiothoracic surgery colleague Haytham Elgharably, MD, to explore two key areas relevant to more than a few SAVR cases: concomitant additional valve repair or replacement, and the use of preemptive microaxial temporary left ventricular assist device (LVAD) support for patients at high risk of postoperative cardiogenic shock.

Multivalve replacement/repair

Dr. Elgharably has developed a specialty interest in multivalve operations, either as initial surgery or in the reoperative setting, often resulting from a failed or mismatched aortic valve prosthesis. "These are technically demanding surgeries that can involve multiple components," Dr. Elgharably notes. He adds that the patient may have been operated on more than once previously, compounding the challenges.

"Whenever approaching a patient with low ejection fraction — or any patient about to undergo complex cardiac surgery — having a strategy in place to support the heart in the first few days after surgery is of utmost importance."

— EDWARD SOLTESZ, MD, MPH

Cleveland Clinic surgeons recently reported on over 2,300 reoperations involving replacement or repair of multiple heart valves from 2008 to 2022 (*J Thorac Cardiovasc Surg.* 2024;168[6]: 1632-1642), more than half of which included SAVR as a component. Outcomes included 3.9% hospital mortality and 4.2% operative mortality. Elective isolated multivalve reoperations — i.e., without additional procedures such as aorta surgery or coronary bypass — had lower mortality (1.6% hospital and 1.7% operative). Factors that raised risk included preoperative end-organ dysfunction and additional surgical components, especially coronary bypass.

"We need to tailor our surgical approach to each patient based on their cardiac pathology, clinical presentation and comorbidities," Dr. Elgharably says. "Yet regardless of the complexity of the operation, simply adding more time on the bypass machine increases risk, which must also be considered."

He nevertheless acknowledges the importance of addressing problems that are not likely to improve on their own after simply replacing the aortic valve, such as a leaky mitral valve or stenotic coronary arteries. He identifies the following as instances when complex multivalve surgery may be indicated:

- Extensive calcification involving the aortic valve, the mitral valve and the aortomitral curtain connecting them. For such cases, Dr. Elgharably employs a Commando approach (Figure), which involves extending the incision in the aorta into the roof of the left atrium and performing aggressive debridement. The curtain is replaced with a bovine pericardial patch. A video from Dr. Elgharably and colleagues illustrating the Commando operation is available at *mmcts.org/tutorial/1952*.
- Infection, which requires replacing both the aortic and mitral prosthetic valves to avoid recurrent infection, even if disease is evident in only a single valve. Double-valve endocarditis can present with invasive pathology that requires complex reconstruction, as described in a Cleveland Clinic report (*Ann Thorac Surg.* 2019;108[5]:1314-1323).
- Radiation heart disease, which typically involves scarring of both the aortic and mitral valves. Even if one of the valves has

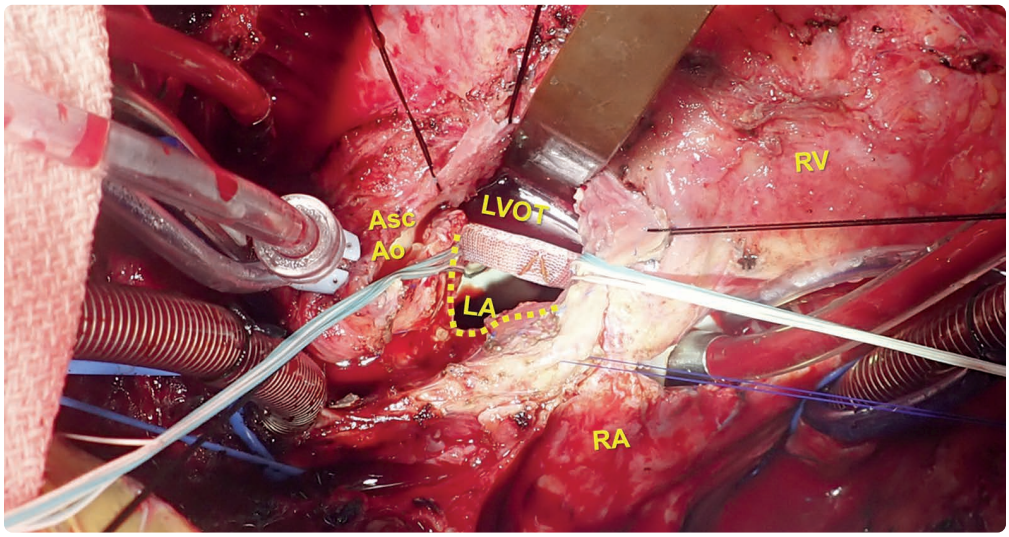

FIGURE — Operative photo showing a Commando exposure. Asc Ao = ascending aorta; LVOT = left ventricular outflow tract; LA = left atrium; RA = right atrium; RV = right ventricle.

only moderate disease, Dr. Elgharably urges replacing both valves, as the disease will likely progress, and a redo operation in patients with prior history of mediastinal radiation is very challenging.

- Right heart failure, which is seen in very high-risk patients who may present for multivalve reoperation with pulmonary hypertension, right ventricular dysfunction and chronic liver congestion. Careful patient selection is crucial for successful outcomes in this population, as illustrated by a recent Cleveland Clinic study showing operative mortality of 1.6% in a cohort of patients undergoing tricuspid valve surgery (*J Thorac Cardiovasc Surg.* 2023;166[3]:740-751).

"Many factors are critical to success in these complex cases," says Dr. Elgharably. "These include thorough preoperative assessment of the heart and proper sizing of the replacement valves, as well as preoperative evaluation of lung, liver and other organ status. Outcomes are optimized when a team of specialists can closely collaborate on determining strategy and patient management."

Preemptive pVAD device support

"Whenever approaching a patient with low ejection fraction — or any patient about to undergo complex cardiac surgery — having a strategy in place to support the heart in the first few days after surgery is of utmost importance," says Dr. Soltesz, who has published several papers with Cleveland Clinic colleagues on the preemptive use of a percutaneous ventricular assist device (pVAD) for high-risk patients undergoing cardiac surgery.

He notes that *preemptive* use of such support appears to be crucial. "Waiting for cardiogenic shock to develop and then reacting with pVAD insertion is associated with very high mortality," he says.

Dr. Soltesz is national co-principal investigator of the multicenter, prospective, single-arm IMPACT trial (NCT05529654), which is evaluating the preemptive use of pVAD support for cardiac surgery in patients with low ejection fraction. Results are expected in late 2025.

He adds that defining which patients are likely to develop postoperative cardiogenic shock — and would therefore most benefit from preemptive device placement — is an important area of ongoing research. A recent study in the *Journal of Thoracic and Cardiovascular Surgery* (2024;168[5]:1489-1499) examined Cleveland Clinic data and found that baseline predictors of postoperative cardiogenic shock differed between patients with ischemic cardiomyopathy (in whom right heart dysfunction, indicated by low pulmonary artery pulsatility index, was most important) and those with nonischemic cardiomyopathy (in whom greater cardiac decompensation was most important).

Dr. Soltesz emphasizes that for complex cardiac surgery, including SAVR in high-risk settings, engaging in a shared decision-making process with patients is essential. "We need to thoroughly discuss with the patient their goals and what can be expected from the various treatment strategies," he says. "Patients usually have strong opinions about the amount of risk they are willing to take on."

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