Timely Evaluation for Surgical Treatment of Aortic Valve Disease

Time is of the essence...

The pathology of aortic valve disease (AVD) typically develops over many years, and symptoms may not appear until the condition is severe. When symptoms develop, the rates of morbidity and mortality among patients are high.[1]

If AVD is left untreated or medically managed...

For aortic regurgitation (AR)[2,3]

25% of patients who have asymptomatic moderate-to-severe AR will die within 5 years after diagnosis, and **50%** will die within 10 years

25% of patients with symptomatic (NYHA class III/IV) moderately severe or severe AR will die within 1 year of diagnosis

For aortic stenosis (AS)[4]

56% of patients who have moderate AS and **67%** of those who have severe AS will die within 5 years of diagnosis

21% of patients who have moderate AS and **29%** of those who have severe AS will die within 1 year of diagnosis

---

2020 ACC/AHA Guideline recommendations for treatment of AVD[5]

- **Aortic regurgitation:** Surgical aortic valve replacement (SAVR) is recommended for the treatment of symptomatic severe aortic regurgitation and asymptomatic chronic severe AR with left ventricular (LV) systolic dysfunction
- **Aortic stenosis:** SAVR is recommended for patients who have symptomatic or asymptomatic severe AS with LV dysfunction and are <65 years of age or have a life expectancy >20 years

Proportion of patients with AVD in recent studies undergoing treatment after diagnosis

Only 26% of patients who have symptomatic severe AR received SAVR within 1 year of diagnosis[6]

Among patients who have symptomatic severe AS, only 31% received aortic valve replacement in the first year after diagnosis[7]

Among aortic valve replacement options, **SAVR** is the only guideline-directed treatment indicated to treat both **AS and AR.**

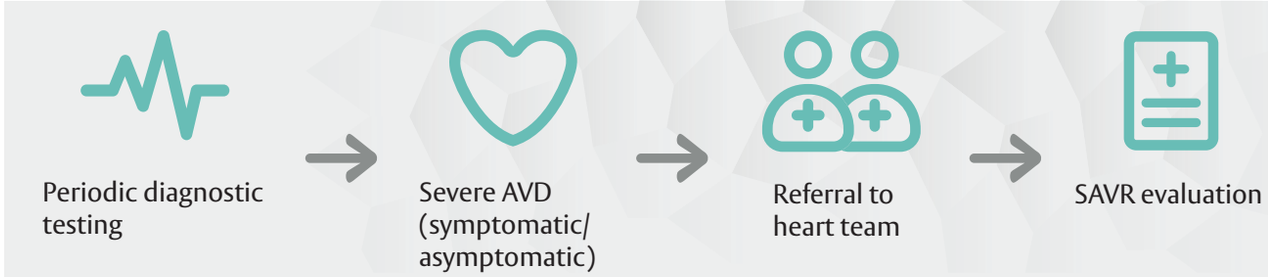
Edwards

Timely evaluation can lead to timely intervention for patients...

The current convention for treating asymptomatic severe AVD is to provide treatment once symptoms develop. However, advances in surgical techniques and aortic valve prostheses may help change this.[8]

Referral for SAVR

SAVR treatment is a class 1 indication (ie, is strongly recommended) for patients who have asymptomatic severe AR with LV systolic dysfunction and for patients who have asymptomatic severe AS. Guidelines suggest that postoperative outcomes are better when surgery is performed early or before the onset of symptoms.[5]



To move on to next step, patients must meet criteria recommended by ACC/AHA guidelines.

For additional information on surgical aortic valves:

- **www.yourtissuevalve.com**
- **www.edwards.com/inspiris**
- **www.edwards.com/inspiring**

Important Safety Information:

INSPIRIS RESILIA Aortic Valve

Indications: For use in replacement of native or prosthetic aortic heart valves.

Contraindications: There are no known contraindications with the use of the INSPIRIS RESILIA aortic valve.

Complications and Side Effects: Thromboembolism, valve thrombosis, hemorrhage, hemolysis, regurgitation, endocarditis, structural valve deterioration, nonstructural dysfunction, stenosis, arrhythmia, transient ischemic attack/stroke, congestive heart failure, myocardial infarction, any of which could lead to reoperation, explantation, permanent disability, and death.

Warnings: DO NOT ADJUST THE VALVE DIAMETER BY EXPANDING THE BAND PRIOR TO OR DURING IMPLANTATION OF THE SURGICAL VALVE. The expandable band is not designed to allow for compression or expansion during implantation of the surgical valve. This will cause damage to the valve and may result in aortic incompetence. DO NOT PERFORM STAND-ALONE BALLOON AORTIC VALVULOPLASTY PROCEDURES ON THIS VALVE FOR THE SIZES 19-25 mm as this may expand the valve causing aortic incompetence, coronary embolism or annular rupture. Valve-in-valve sizing in the INSPIRIS valve has only been tested with specific Edwards transcatheter heart valves. Use of other transcatheter valves may result in embolization of transcatheter devices anchored within or result in annular rupture.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a physician. See instructions for use for full prescribing information.

References

1. Wenn P, Zeltser R. Aortic valve disease. In: *StatPearls* [Internet]. Treasure Island (FL): StatPearls Publishing; 2021. Available at: https://www.ncbi.nlm.nih.gov/books/NBK542205/.
2. Griffin B. Valvular heart disease. In: Griffin BP, Callahan TD, Menon V, Wu WM, Cauthen CA, Dunn JM, editors. *Manual of Cardiovascular Medicine.* 4th ed. Vol 1. Philadelphia, PA: Lippincott Williams & Wilkins; 2013:238-355.
3. Dujardin KS, Enriquez-Sarano M, Schaff HV, Bailey KR, Seward JB, Tajik AJ. Mortality and morbidity of aortic regurgitation in clinical practice. Along-term follow-up study. *Circulation.* 1999;99:1851-1857.
4. Strange G, Stewart S, Celermajer D, et al. National Echocardiography Database of Australia contributing sites. Poor long-term survival in patients with moderate aortic stenosis. *J Am Coll Cardiol.* 2019;74(15):1851-1863.
5. 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(4):e25-e197.
6. Thourani VH, Brennan JM, Edelman JJ, et al. Treatment patterns, disparities, and management strategies impact clinical outcomes in patients with symptomatic severe aortic regurgitation. *Struct Heart.* 2021;5(6):608-618.
7. Matthew BJ, Leon MB, Sheridan P, et al. Racial differences in the use of aortic valve replacement for treatment of symptomatic severe aortic valve stenosis in the transcatheter aortic valve replacement era. *J Am Heart Assoc.* 2020;9(16):e015879.
8. Kang DH, Park SJ, Lee SA, et al. Early surgery or conservative care for asymptomatic aortic stenosis. *N Engl J Med.* 2020;382(2):111-119.

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com

Edwards