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A Message from Cardiology Associates, LLC



Dear Colleagues,

Welcome to the September 2011 issue of our Cardiology Associates' Referring Physician Newsletter. This month's newsletter addresses treatment options for elderly patients with aortic stenosis (AS). While surgical intervention is often necessary treatment option for severe cases of AS, patients of advanced age may not be recommended for surgery due to its complications. New research in medical therapy and transcatheter intervention indicates that there are successful alternatives to traditional aortic valve surgery. Dr. John Kennedy elaborates on these AS treatment options in this month's column.

About the Author

Dr. John Kennedy practices general cardiology and has been in a member of Cardiology Associates for over 18 years. Dr. Kennedy is board-certified in Cardiology and Nuclear Cardiology, and he has a special interest in Cardiac Catheterization.

Dr. Kennedy has been the Director of the Non-invasive Vascular Lab at Anne Arundel Medical Center for the past 10 years, and he is the current Director of Cardiology Associates' Nuclear Cardiology Lab at our Annapolis location.

Dr. Kennedy is a member of the American College of Cardiology and a member of the American College of Nuclear Cardiology.

NEW DEVELOPMENTS IN AORTIC STENOSIS

Case Study: An active 76-year-old man with a history of aortic stenosis recently developed exertional angina. An echocardiogram revealed severe aortic stenosis with an aortic valve area of 0.8 cm². The left ventricle is mildly hypertrophied with normal systolic function. Given his symptomatic aortic stenosis, aortic valve surgery is planned. A coronary angiogram showed no flow limiting obstructions but there was evidence of calcification of the aorta. A CT scan of the chest revealed a severely calcified ascending aorta. The cardiothoracic surgeon declined to take the patient to surgery because of the high risk of stroke when cross-clamping the ascending aorta.

Degenerative aortic stenosis (AS) is a common valvular disease. The prevalence in individuals aged older than 75 years is 4.8%, and the incidence is steadily increasing as a result of the ageing population. Aortic stenosis progressed with age. Once a patient develops symptoms from aortic stenosis, the disease rapidly progresses. Without treatment, patients usually die within 2-3 years. However, due to significant comorbidities, elderly patients often are at high operative risk, and hence, are not suitable candidates for surgery. Approximately 30% of patients with symptomatic severe AS are thus not referred to surgery because of these comorbidities.

Lifestyle changes such as regular exercise and diet have not slowed the progression of AS. Smoking accelerates the progression of this disease.

What are the patient's options?

Two recent studies looked at medical therapy to slow the progression of AS and a third study explored a transcatheter approach to treating symptomatic Aortic stenosis.

Do statins slow the progression of Aortic Stenosis?

The **ASTRONOMER** trial (Aortic Stenosis Progression Observation: Measuring Effects of Rosuvastatin) was designed to see if statins might delay the progression of aortic stenosis. Two hundred sixty-nine patients with mild-to-moderate aortic stenosis were randomized to 40 mg of rosuvastatin vs placebo. At a median follow-up of 3.5 years, there was no significant difference between the 2 groups in the progression of severity of AS.ⁱ

Do Angiotensin Converting Enzymes or Angiotensin Receptor Blockers effect the prognosis of patients with AS?

A recent large retrospective study from Scotland suggested that Angiotensin Converting Enzymes/Angiotensin Receptor Blockers therapy is associated with improved survival and a lower risk of cardiovascular events in patients.ⁱⁱ ACEIs and ARBs have been considered relatively contraindicated in aortic stenosis because of vasodilation effects. The studied involved 2,117 patients with mean follow up of 4.2 years. There was a 22% lower risk of cardiovascular events in patients with mild to moderate AS and a 36% reduction in patients with severe AS.

The possible explanations for the benefit ACE/ARBs include:

- Favorable effects on the Renal Angiotensin system inhibition that effects LV remodeling.
- Possible reduction in atherosclerotic plaque.
- BP lowering effects (however in this study the BP in both groups were similar).

The outcome was similar to that of the HOPE trial in 2000 showing ramipril caused a 26% reduction in cardiovascular death.ⁱⁱⁱ

This study suggests that ACE/ARBs may be helpful in aortic stenosis. A randomized prospective study would be helpful confirm these findings.

Alternatives to Aortic Valve Surgery

- Balloon valvuloplasty may give temporarily relieve symptoms for a few months but restenosis occurs. The procedure does not extend life span.
- Surgical aortic valve replacement (SAVR) remains the standard treatment for symptomatic AS. Although minimally- invasive surgery has been used, usually sternal thoracotomy is standard. The patient is placed on heart-lung bypass machine, the old valve is removed and the new one is placed. However, due to significant comorbidities, elderly patients often are at high operative risk, and hence, are not suitable candidates for surgery

Transcatheter aortic valve implantation (TAVI)

Transcatheter aortic valve implantation is an investigational percutaneous procedure recently shown to be an appropriate alternative to standard medical care for select patients with severe symptomatic aortic stenosis who are not candidates for surgery and those who are at very high risk. With the TAVI approach, a prosthetic aortic valve can be inserted without the need for a thoracotomy. The valves are bioprosthetic are expandable.

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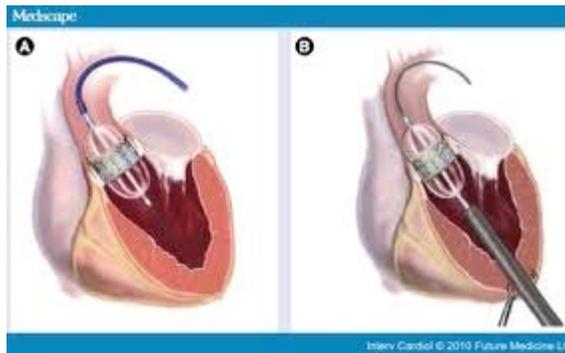


- Tri-leaflet bovine pericardial tissue treated with TheraFix Process

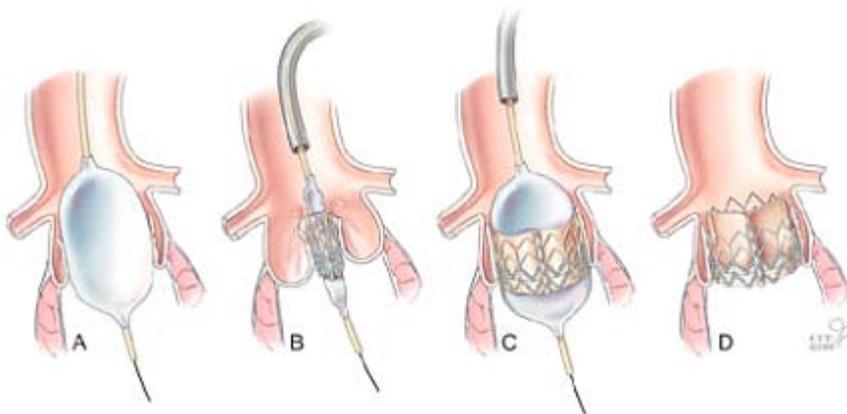


- Balloon expandable stainless steel stent for sutureless implantation

The TAVI procedure is performed in the catheterization lab. A catheter is placed in the femoral artery and guided across the aortic valve. For patients with severe peripheral vascular disease, surgeons and cardiologists use an approach through the left ventricular apex of the heart.



A balloon is inserted across the aortic valve and is inflated. A compressed tissue heart valve is placed on the balloon-mounted catheter. The catheter is positioned directly over the diseased aortic valve. Once in position, the balloon is inflated to secure the valve in place.



The [PARTNER](#) (Placement of Aortic Transcatheter Valves) trial enrolled patients with severe symptomatic aortic stenosis who were not candidates for surgery. The patients were randomly selected to receive either TAVI or standard medical care.

The trial is studying the valve in both operable high risk and inoperable patients with severe aortic stenosis. The trial indicated that this therapeutic option was viable for patients too sick to undergo traditional open-heart surgery. As compared to standard medical therapy, the new procedure, transcatheter aortic valve implantation significantly reduced mortality rates in the patients who received the new valve.

Among the inoperable patients who had TAVI, the procedure reduced their absolute risk of dying by 20%. TAVI has become a valuable, less-invasive treatment option for these high-risk individuals.

The mortality was determined to be 11.5% at 30 days. The overall 1-year survival was 80%. At 1 year, 68.5% of patients were living independently at home after the procedure. Thirty-day device success was high (91.5%).

Complications of Transcatheter Aortic Valve Implantation (TAVI) include: Life-threatening or disabling bleeding (episodes were observed in 8.5% of patients), major vascular complications (in 11.5% of patients), acute kidney injury was observed (in 6.2% of patients), new left bundle branch block, permanent pacemaker requirement and arrhythmia.

Although 60% of patients displayed complications, the complications did not seem to substantially influence outcome or prolonged hospital stay of patients following TAVI, as prompt and successful treatment is usually available.

In this elderly patient population, improvement of quality of life is important. TAVI was associated with a significant reduction in symptoms with an improved NYHA classification and a 6-minute walking test. The benefits were sustained over the follow-up period, as all patients who survived to 1 year were in NYHA class I or II.

Although this is an important randomized trial, the benefits over "standard therapy" group may, in part, be exaggerated due many patients in the standard group receiving aortic balloon valvuloplasty, which is an ineffective therapy abandoned several years ago.

The Partner Trial showed that transcatheter aortic valve implantation is a viable solution for inoperable aortic stenosis (which was formerly considered untreatable). Longterm data is still needed.

At the time of this column, The PARTNER trial is still an ongoing study. At the Washington Hospital Center they continue to randomize high surgical patients to standard open surgery vs TAVI. For inoperable patients, they are randomized to the transfemoral TAVI approach vs LV apical TAVI approach.

ⁱ Astronomer Trial

ⁱⁱ M. Nadiret al. Impact of Renin-Angiotensin System Blockade Therapy on Outcome in Aortic Stenosis. JACC 2011;58:570-6

ⁱⁱⁱ Mathew J et al. Circulation 2001;104:1615-21. Hope trial

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Our focus will be on real questions and issues that we encounter in our day-to-day medical practice. In fact, if there is a topic that is of particular interest to you (or a question that is related to any of our articles) please e-mail your inquiries to our Project Manager, Nazar Snihur at nsnihur@heartcapc.com. (Of course, we will not share your e-mail address outside of our offices.)

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