Does my patient with severe aortic valve stenosis need intervention?

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<u>Trade-off between the natural history of native</u> <u>disease and the natural history of the surgical or</u> <u>percutaneously implanted aortic valve</u>



"It's tough to make predictions, especially about the future."

Yogi Berra

When does the patient with AS require intervention?

- Conversation overheard on a bus in New York City:
 - "Do you know where to get off to get to the Museum of Natural History?"
 - "Sure. Just get off two blocks before I do!"
 - "Thanks."



<u>A true story of Mr. A.S. Smith:</u> Raise your hand if this is your patient!

<u>60 year-old man was found to have a heart murmur and was sent for an</u> <u>echocardiogram</u>

- The echocardiogram showed severe, calcific AS with a mean gradient of 50 mmHg and a calculated valve area of 0.6 sq. cms. LVH with normal LV systolic function
- Mr. Smith was referred to a cardiologist. Recommendation: Asymptomatic. For close follow-up
- Mr. Smith saw another family doctor (#2) for dizziness. The murmur was heard and the echo findings were retrieved.
- Doctor #2 referred Mr. Smith to a cardiac surgeon and valve replacement was recommended.
- The cardiologist saw Mr. Smith for follow-up. He noted a median sternotomy incision and was told it was from his valve surgery. Mr. Smith thought he was seeing his cardiologist for post-op review. The cardiologist thought he was seeing him for monitoring to determine the timing of aortic valve intervention.
- Mr. Smith was doing well but did have a sore chest. The cardiologist was not doing well and scratched his head frequently while driving home.
- Do you know Mr. Smith?

A classical paper in Cardiology

Aortic Stenosis

E. Braunwald & J. Ross Circulation 1968; 37 Suppl V:V61

- Acquired and congenital aortic stenosis
 - Clinical and autopsy studies before 1955
 - "Few more recent analyses that are supported by hemodynamic information." (Grant, Wood, Takeda, NIH)
- Sudden death in 15 to 20%, occurring at an average age of 60, and usually associated with symptomatic AS (only 3 to 5% appeared suddenly in patients without symptoms).

Natural history of aortic stenosis Braunwald & Ross-1968





Otto, C. Calcific AoV disease. Eur H J 2009;30:1940

On the natural history of severe aortic stenosis*

Editorial-Eugene Braunwald, 1990

"Implications. These observations support a position that I have taken for many years, namely, that operative treatment is the most common cause of sudden death in asymptomatic patients with aortic stenosis. Therefore, for the moment at least, the debate concerning the management of the asymptomatic adult with hemodynamically severe aortic stenosis appears to be settled. Such patients should, in general, not be referred for surgical therapy but should be followed up frequently and carefully. On the other hand, there has never been much argument that surgical treatment should be carried out promptly, as soon as the patient develops symptoms secondary to aortic stenosis...."

*Editorial Comment re: Pellika et al. JACC 15 (5): 1018, 1990. The natural history in adults of asymptomatic, hemodynamically aortic stenosis.

Natural history of asymptomatic AS

U. of Washington, 1997

- 123 patients referred for asymptomatic AS during the years 1989 to 1995
- End-points: death or aortic valve surgery
- Indications for aortic valve surgery:
 - Angina
 - CHF
 - Syncope
 - Decreased ex. tolerance
 - Asymptomatic severe AS
 - Incidental AVR during other cardiac surgery

Kaplan-Meier life-table analysis showing survival without valve replacement for 123 subjects with initially asymptomatic valvular aortic stenosis.



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Cox regression analysis showing event-free survival in groups defined by aortic jet velocity at entry (P<.0001 by log- rank test).



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Predictors of Outcome in Severe, Asymptomatic AS. Vienna

- All patients in the Echo Lab in 1994 with AS peak velocity of 4 m/sec. without additonal valve lesions and no symptoms.
- 128 patients; mean age 60; mean AS velocity
 5.0 m/sec. Normal LVEF.
- End-point: death or AVR for symptoms.
- Follow-up: 22 remained without symptoms but underwent AVR within 3 months. 106 patients were followed for a mean of 27 months.

Outcomes of severe asymptomatic AS

<u>Results:</u>

- 67 end-points: 8 deaths; 59 AVRs for symptoms.
- Event-free survival: 67% at one year; 56% at 2 years; 33% at 4 years.
- Deaths: 6 of the 8 were due to cardiac causes (4 CHF, 1 IE, 1 SCD)
- All deaths, except for the 1 SCD, occurred in symptomatic patients.

Initial surgical versus conservative strategies in patients with asymptomatic severe aortic stenosis

- Japanese multicenter registry of consecutive patients with severe AS.
- 3815 patients
- 1808 asymptomatic patients
 - Initial AVR: 291
 - Initial conservative strategy: 1517
- Follow-up: 1361 days. 90% follow-up at 2 yrs.

Japanese severe AS registry

- Conservative group-41% had AVR in follow-up with a median interval from index echocardiogram of 780 days.
- 5-year cumulative incidence of all-cause death and HF hospitalization were significantly lower in the initial AVR group (15% vs. 26% and 3.8% vs. 19.9%).
- 5-year cumulative incidence of emerging symptoms: Conservative, 46%; Initial AVR, 3%.

Aortic stenosis guidelines ACC/AHA

CLASS I

1. AVR is recommended in symptomatic patients with severe AS (stage D1) with (Level of Evidence: B):

a. Decreased systolic opening of a calcified or congenitally stenotic aortic valve; and

b. An aortic velocity 4.0 m per second or greater or mean pressure gradient 40 mm Hg or higher; and

c. Symptoms of HF, syncope, exertional dyspnea, angina, or pre-syncope by history or on exercise testing

2014 ACC/AHA Valvular Heart Disease Guidelines. JACC 2014;63: e57

AHA/ACC 2014 Valve Guidelines

- Class I: AVR is recommended for Stage C2 AS (<u>asymptomatic</u> severe AS with an LVEF of <50%).
- Class I: AVR is recommended in adults with asymptomatic severe AS who are undergoing other cardiac surgery.
- Class IIa: AVR is reasonable for <u>asymptomatic</u> patients with very severe AS (stage C1 aortic velocity >5 m/sec and low surgical risk).

2014 AHA/ACC Guidelines

- Class IIa: AVR is reasonable in <u>asymptomatic</u> patients (stage C1) with severe AS and decreased exercise tolerance or an exercise fall in BP.
- Class IIb: AVR may be considered for <u>asymptomatic</u> patients with severe AS (Class C1) and rapid disease progression if surgical risk is low.

<u>Stress exercise testing for</u> "asymptomatic" AS? Really?

Previous, antiquated, teaching:

Stress exercise testing used to be contraindicated in AS.....

Current, modern, eaching:

Now it's a Class I recommendation?

"Code Blue." Poor exercise tolerance! <u>High PPV*!</u> "Needs AVR!" Needs <u>something!</u>



PPV=positive predictive value

Exercise testing for AS

Conclusions of the authors:

- 1. Patients may attribute symptoms to AS which are not actually due to AS
- 2. Breathlessness was "normal" in some cases
- 3. 83% of patients with exertional dizziness subsequently developed symptoms
- 4. 54% of patients with breathlessness and 50% of patients with chest tightness developed symptoms.
- 5. The inclusion of physiological measurements did not improve predictive accuracy.
- 6. The pos. predictive accuracy of a pos. GXT is only 55%.

Direct surgical referral of AS patients to cardiac surgery?

- The detection of a murmur or the receipt of an echocardiographic report should not result in direct surgical referral.
- Even when an internist/cardiologist is involved in decision-making there is still uncertainty regarding the need, and the timing of, intervention (whether surgical or TAVR).





Controversies in Cardiovascular Medicine: Should Severe AS be Operated on Before Symptom Onset?

Con: Severe aortic stenosis should not be operated on before symptom onset. P.K. Shah*

 – "If it ain't broke, don't fix it."-Thomas Bertram Lance in Nation's Business, May 1977

Pro: Aortic valve replacement should be operated on before symptom onset. Blase A. Carabello

*Cedars Sinai Heart Institute; **Baylor, Houston. Circulation 2012;126:118

Approach to severe AS C. Otto-JACC 47;2145, 2006



Figure 4. Suggested approach to evaluation of adults with severe aortic stenosis. Additional considerations include comorbidities and patient preferences. AVA = aortic valve area; AVR = aortic valve replacement; BNP = brain natriuretic peptide; BP = blood pressure; CRF = cardiac risk factors; f/u = follow-up; LV = left ventricular; V_{max} = maximum velocity.

<u>European Society of Cardiology 'Essential</u> <u>messages' from 2012 guidelines for valvular</u> <u>heart disease</u>

Surgery should be considered in asymptomatic patients at low operative risk, with normal exercise performance, with very severe aortic stenosis or progressive disease.

Surgery may also be considered in patients with markedly elevated natriuretic peptide levels, significant increase of mean pressure gradient by exercise echocardiography or excessive left ventricular hypertrophy. Surgical Management of Valvular Heart Disease 2004-Canada

TABLE 1

Class I recommendations for AVR in aortic stenosis

- Symptomatic patients with severe aortic stenosis;
- Patients with severe aortic stenosis undergoing coronary artery bypass surgery; or
- Patients with severe aortic stenosis undergoing surgery on the aorta or other heart valves

Conclusions

- Asymptomatic patients with AS do well and can be followed closely.
- Patients with AS and "funny" symptoms do not necessarily have symptomatic AS
- Patients with typical AS symptoms may not be symptomatic due to AS alone (e.g. recent symptom onset in a patient with previously undetected anemia or an acute cor. syndrome).
- There is no rush to perform an aortic valve intervention in a patient who is truly doing well in spite of the presence of a severe gradient and a small valve area.

