

EuroValve April 26-27, 2018



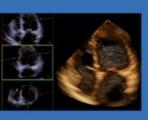




News FLASH

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Faculty disclosure

First name - last name

I disclose the following financial relationships:

Consultant for XYZ Company **Employee** of ABC Company Receive grant/research support from ACME Medical **Advisory board** of ACE Device Company Paid speaker for DRUG Company Major stockholder of ABC Company

OR I have **no financial relationships** to disclose.



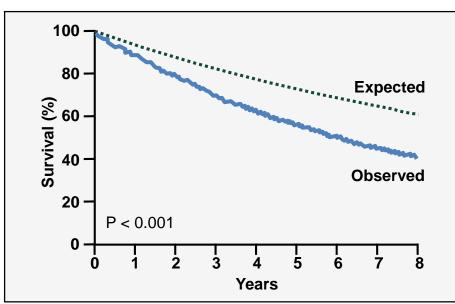
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The Burden of Valve Disease Increases

Prevalence

12%-12%-10%-Nitral valve disease ---- Aortic valve disease 8%-6%-4%-2%-0%-< 45 45-54 55-64 65-74 ≥ 75

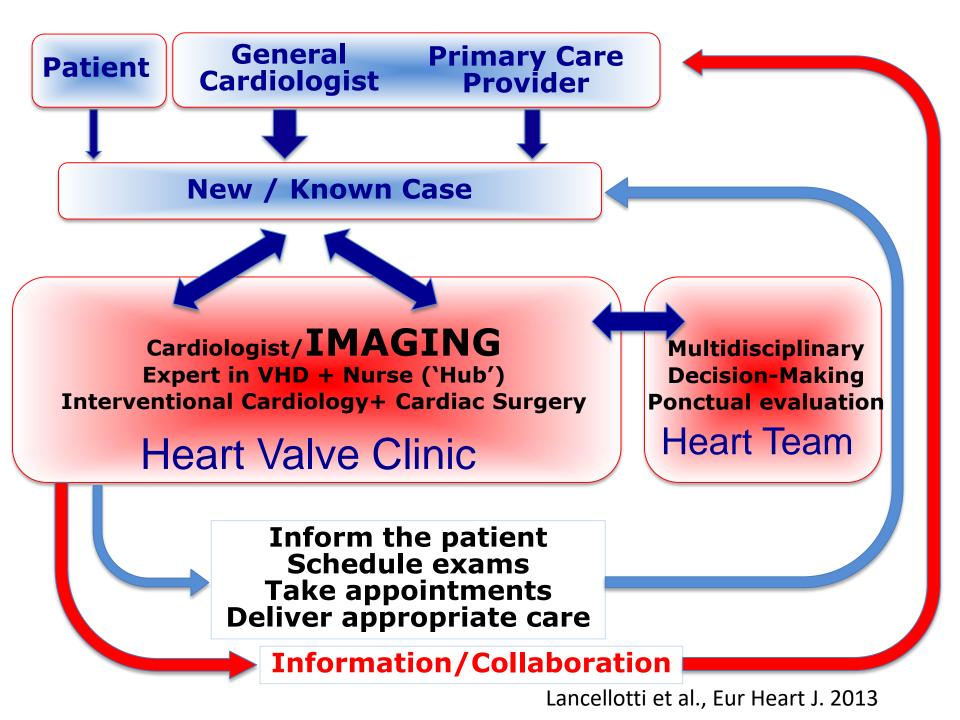
Survival



Nkomo. Lancet 2006;368:1005-1011

Many of these patients

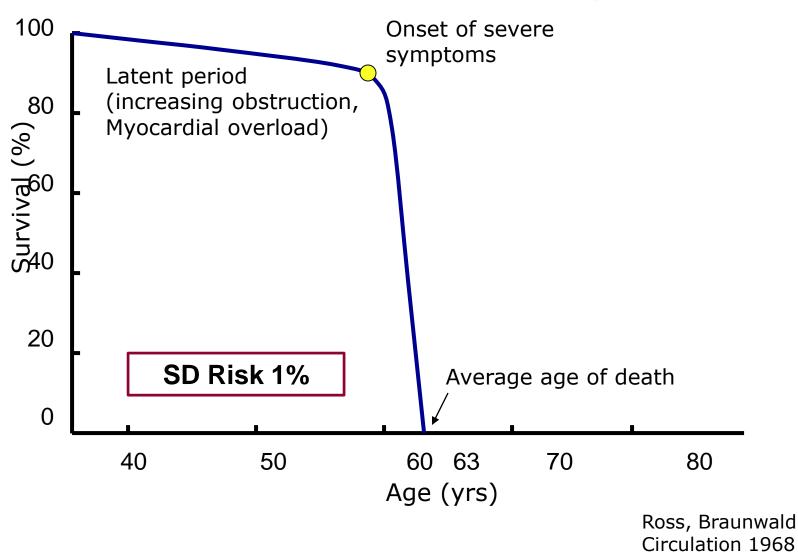
- do not receive a correct diagnosis
- do not have optimized care according to current guidelines



HeArt ValvE Clinic International Database (HAVEC Project)

Framework for the creation of large registries and the conduct of prospective studies

Severe Aortic Stenosis Natural History



Indication for AVR in AS

SEVERE STENOSIS

- + Symptoms
- + LVEF<50%

= AVR (Class I)

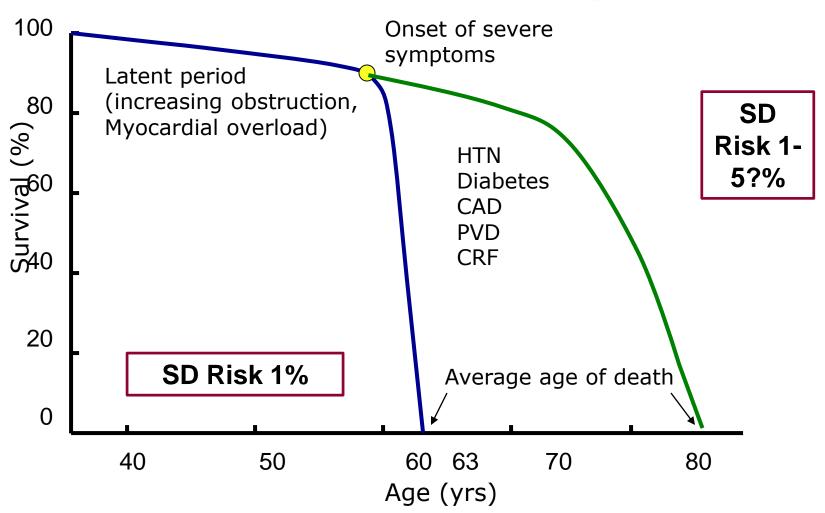
Asymptomatic pts.

- + Vel. > 5.5 m/s
- + High BNP
- + PHT

= AVR (Class IIa)

Baumgartner et al EHJ 2017 Nishimura, et al. JACC 2017

Severe Aortic Stenosis Natural History



Objective

Determine the natural history and outcome of moderate or severe AS in asymptomatic patients followed in a Heart Valve Clinic

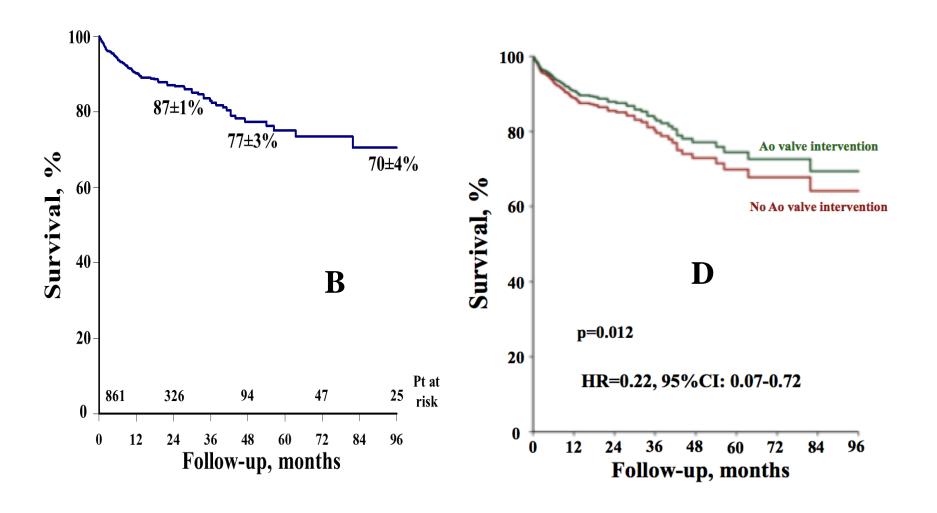
Number, follow-up duration, and clinical outcomes of patients according to participating center

Prospective merge of gathered institutional databases of 10 Heart Valve Clinics

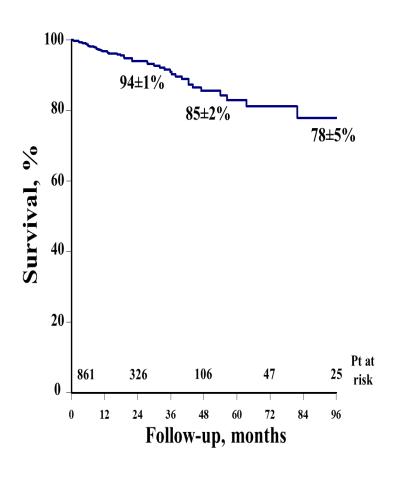
Center ID	Patients number, N= 1375 (%)	Follow-up (median), months	Cardiovascular related deaths (%)	Aortic valve intervention (%)
CN1	118 (8.6)	17.7±8.8 (19)	6 (5)	33.9
CN2	90 (6.5)	19.5±11.2 (17)	9 (10)	41.1
CN3	146 (10.6)	18.5±14.6 (17)	9 (6)	52.6
CN4	210 (15.3)	28.5±13.1 (27)	6 (2.9)	29.5
CN5	138 (10)	25.9±17.6 (23)	12 (8.6)	58.9
CN6	93 (6.7)	18.6±15.6 (17)	5 (5.4)	30.1
CN7	139 (10.1)	15.8±8.5 (13)	6 (4.3)	29.7
CN8	101 (7.3)	27.7±26.4 (12)	4 (3.9)	29.7
CN9	98 (7.1)	21±20.2 (12.5)	5 (5.1)	41.8
CN10	242 (17.6)	15.8±13.5 (12)	18 (7.3)	44.8

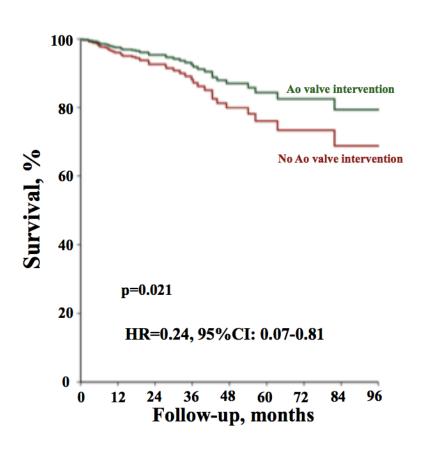
<1 cm² in 861, 542 (39.4%) AVR, 155 (11%) death, follow-up 27±24 months, crude rate of sudden death 0.72%

Kaplan–Meier analyses of overall survival and according to aortic valve intervention in patients severe AS



Kaplan-Meier analyses of cardiac-related mortality and according to aortic valve intervention in patients severe AS





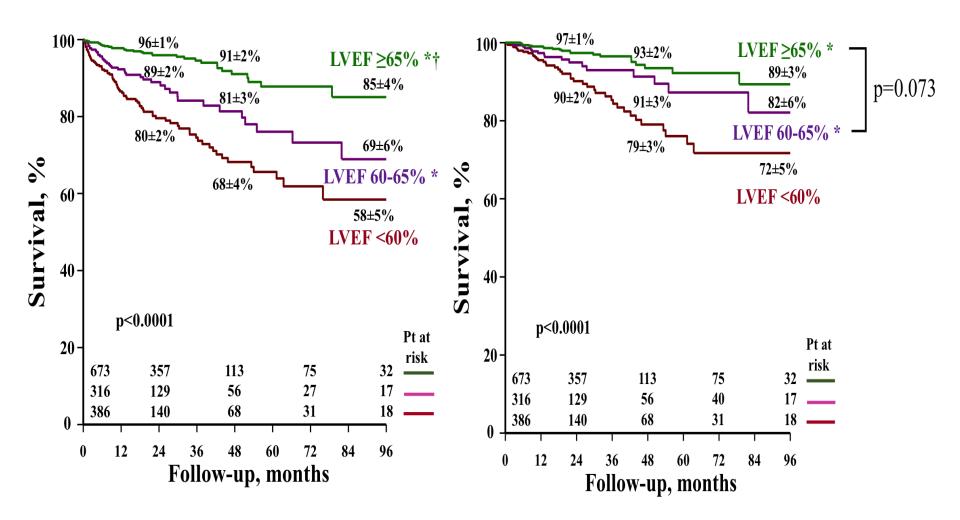
Multivariable predictors of mortality in patients with severe AS

111 (13%) patients died, including 53 (6.1%) from cardiovascular causes (46 heart failure, 7 sudden death)

Continuous Variables	All-cause mortality			CV mortality		
Continuous Variables	HR	95% CI	p	HR	95% CI	p
Age, per 1 year	1.02	0.99-1.04	0.066	•••		
Systolic BP, per mmHg	1.02	1.01-1.03	<0.0001	•••		
Diabetes	1.40	0.88-2.22	0.161	2.23	1.18-4.19	0.013
Dyslipidemia	0.42	0.28-0.65	<0.0001			
Chronic obstructive pulmonary disease	2.04	1.09-3.84	0.027			
Peak aortic velocity, per 0.1 m/s	1.04	1.01-1.07	0.003	1.11	1.07-1.16	<0.0001
LV ejection fraction, pear 1%	0.92	0.89-0.95	<0.0001	0.94	0.90-0.98	0.006
Aortic valve replacement*	0.49	0.23-1.03	0.06	0.34	0.15-0.77	0.010

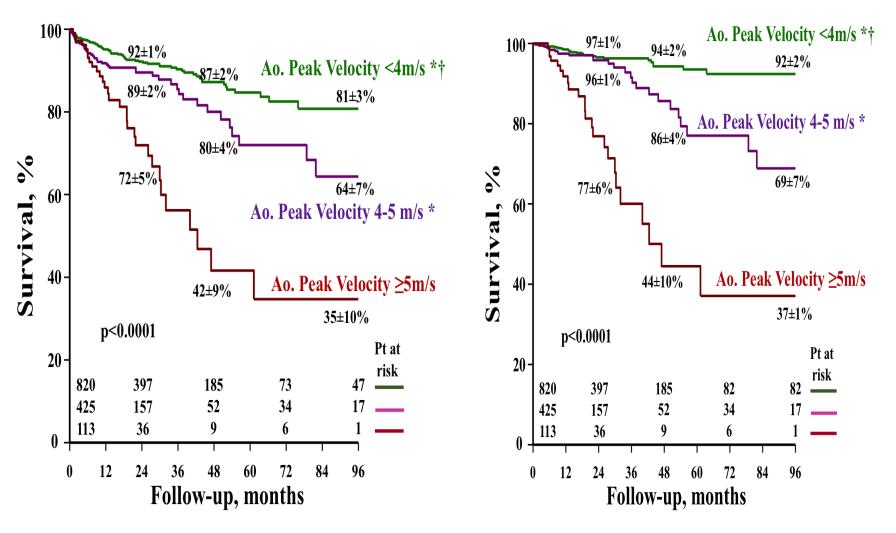
388 (45%) AVR (surgical AVR in 310), triggered by a recommendation's class I indication in 366 cases (94%), a class IIa indication in 18 (4.6%), and a class IIb in 4 (1.0%)

Kaplan-Meier analyses of overall survival and cardiovascularrelated mortality in patients with severe AS as a function of LVEF



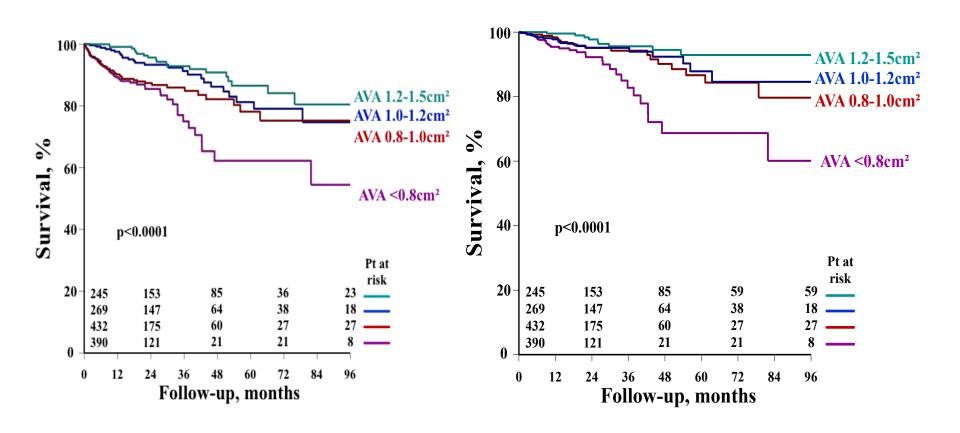
Above 60%, no EF threshold further determined survival

KM analyses of overall survival and cardiovascular-related mortality in patients with severe AS as a function of Peak Vel.



Above 5m/s, no AS severity threshold further determined survival

KM analyses of overall survival and cardiovascular-related mortality in patients with severe AS as a function of AVA



p value indicates AVA < 0.8 cm² versus others.

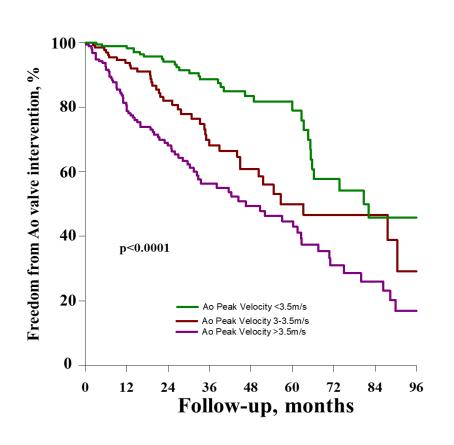
Multivariable analysis of all-cause mortality in the moderate aortic stenosis group

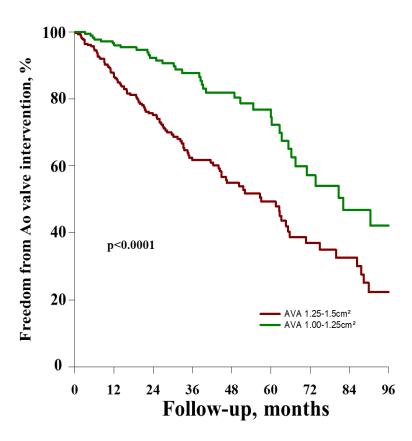
44 (13%,) patients died (27 cardiovascular causes including heart failure in 20, sudden death in 3)

Continuous	All-cause mortality		CV mortality			
Variables	HR	95% CI	p	HR	95% CI	p
Age, per 1 year	1.03	1.00- 1.06	0.034			
Body surface area, per m ²	0.22	0.03- 1.54	0.127	0.03	0.002-0.33	0.005
Dyslipidemia	0.37	0.18- 0.73	0.004	0.30	0.12-0.76	0.012
Peak aortic velocity, per 0.1 m/s	1.08	1.04- 1.13	<0.0001	1.15	1.09-1.21	<0.0001
LV ejection fraction, pear 1%	0.94	0.89- 1.00	0.054	0.90	0.83-0.97	0.009
Aortic valve replacement*	0.12	0.04- 0.40	0.001	0.05	0.01-0.39	0.004

154 (30%) AVR, 128 per class I indication, 22 per class IIa indication and 4 per class IIb indication)

Freedom from aortic valve intervention according to peak aortic velocity in patients with moderate AS





Conclusions

- In patients with asymptomatic aortic stenosis followed-up in Heart Valve Clinics, the risk of sudden death is low
- The rates of all-cause mortality compares favourably with those reported in previous series.
- Patients with peak Ao Vel. >5.0 m/s or LVEF <60% have markedly increased risk of all-cause and cardiovascular mortality even after AVR. These patients should be considered for prophylactic intervention.
- Closer and more frequent (every 6 to 12 months) clinical and echocardiographic follow-up might be implemented in patients with moderate AS and a peak aortic jet velocity ≥3.5 m/s or a LVEF <60%.