TAVI For Low Gradient Severe AS

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial Interest /arrangement or affiliation with the organization(s) listed below

Affiliation/Financial Relationship	Company
Grant/ Research Support:	
Consulting Fees/Honoraria:	**Edwards Lifesciences (consultant & proctor)**
Major Stock Shareholder/Equity Interest:	
Royalty Income:	
Ownership/Founder:	
Salary:	
Intellectual Property Rights:	
Other Financial Benefit:	

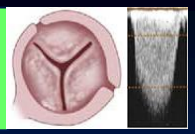
Severity of Aortic Stenosis

	MILD	MODERATE	SEVERE
MEAN GRADIENT	<25mmHg	25-40mmHg	>40mmHg
ESTIMATED VALVE AREA	>1.5cm^2	1.0-1.5cm^2	<1.0cm^2
ECHO DOPPLER JET VELOCITY	<3.0m/sec	3.0-4.0m/sec	>4.0m/sec

- Estimated valve area (EOA) is a function derived from measurement of gradient and flow
- Low gradient in severe aortic stenosis can result from low flow / cardiac output
- Dobutamine stress test (echo or catheterization) plays a central role in decision making for intervention and prognosis

Adapted from Pibarot, P. JACC 2012;60:1845-53

ΔP <40mmHg
EOA <1cm^2



EF <40%

EF >50%

Dobutamine Stress Echo / Cath

↑SV >20%

↑SV <20%

Flow Reserve

ΔP >35-40mmHg
EOA <1-1.2cm^2

ΔP >35-40mmHg
EOA <1-1.2cm^2

True Severe AS
Low Gradient Low
EF with Reserve

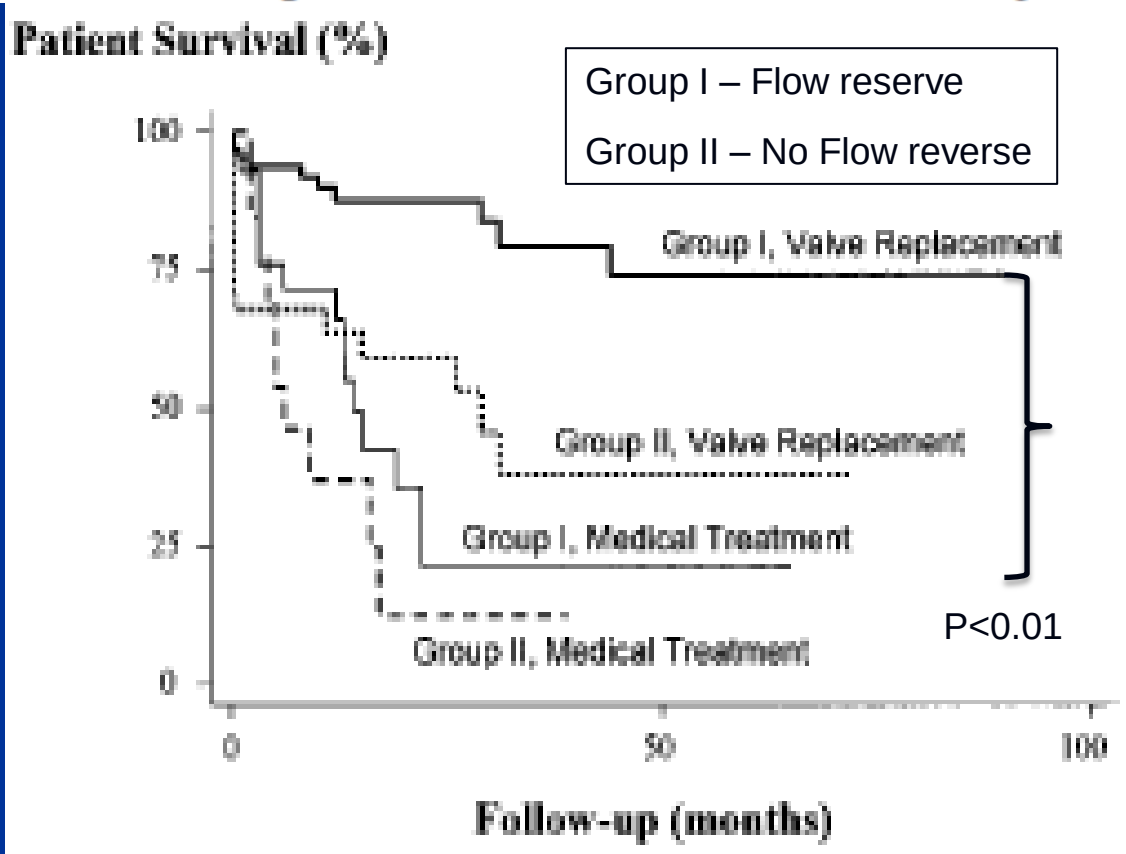
Low Flow Low Gradient AS with Cardiac Reserve

- Definition
  - Grad <40mmHg + EOA <1cm^2 + SV <35ml/m^2 (usu EF <40%)
  - DSE – SV improved >20%; EOA <1-1.2cm^2; Assoc mean PG elevation
- Associated with high incidence of CAD
- Associated with high operative mortality compared to high gradient severe AS
- Aortic valve replacement significantly improves survival compared to medical therapy

Low-Gradient Aortic Stenosis

Operative Risk Stratification and Predictors for Long-Term Outcome: A Multicenter Study Using Dobutamine Stress Hemodynamics

Jean-Luc Monin, MD; Jean-Paul Quéré, MD; Mehran Monchi, MD; Hélène Petit, MD; Serge Baleynaud, MD; Christophe Chauvel, MD; Camélia Pop, MD; Patrick Ohlmann, MD; Claude Lelguen, MD; Patrick Dehant, MD; Christophe Tribouilloy, MD, PhD; Pascal Guéret, MD



Kaplan-Meier survival estimates by group and treatment.

- 136 patient with low gradient severe AS
- 92 with flow reserve (Group I)
- 44 no flow reserve (Group II)

<u>Amongst Group I</u>

- AVR associated with significantly improved survival

- Operative mortalty – 5%
- Predictors of operative mortality – Mean PG <20mmHG
- Predictors of long term mortality – Prosthesis-patient mismatch

Low Flow Low Gradient AS with Cardiac Reserve

- Definition
  - Grad <40mmHg + EOA <1cm^2 + SV <35ml/m^2 (usu EF <40%)
  - DSE – SV improved >20%; EOA <1-1.2cm^2; Assoc mean PG elevation
- Associated with high incidence of CAD
- Associated with high operative mortality compared to high gradient severe AS
- Aortic valve replacement significantly improves survival compared to medical therapy
- Should be considered for AVR
  - ?Role of TAVR given high operative risk
  - ?Role of BAV as bridge to improve LV function

Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

AVR should be considered in symptomatic patients with severe AS, low flow, low gradient with reduced EF, and evidence of flow reserve.[f]

AVR is indicated in asymptomatic patients with severe AS and systolic LV dysfunction (LVEF <50%) not due to another		
AVR should be considered in asymptomatic patients with severe AS and abnormal exercise test showing fall in blood pressure below baseline.	IIa	C
AVR should be considered in patients with moderate AS[d] undergoing CABG, surgery of the ascending aorta or another valve.	IIa	C
AVR should be considered in symptomatic patients with low flow, low gradient (<40 mmHg) AS with normal EF only after careful confirmation of severe AS.[e]	IIa	C
AVR should be considered in symptomatic patients with severe AS, low flow, low gradient with reduced EF, and evidence of flow reserve.[f]	IIa	C
AVR should be considered in asymptomatic patients, with normal EF and none of the above mentioned exercise test abnormalities, if the surgical risk is low, and one or more of the following findings is present: • Very severe AS defined by a peak transvalvular velocity >5.5 m/s or, • Severe valve calcification and a rate of peak transvalvular velocity progression ≥0.3 m/s per year.	IIa	C
AVR may be considered in symptomatic patients with severe AS low flow, low gradient, and LV dysfunction without flow reserve.[f]	IIb	C
AVR may be considered in asymptomatic patients with severe AS, normal EF and none of the above mentioned exercise test abnormalities, if surgical risk is low, and one or more of the following findings is present: • Markedly elevated natriuretic peptide levels confirmed by repeated measurements and without other explanations • Increase of mean pressure gradient with exercise by >20 mmHg • Excessive LV hypertrophy in the absence of hypertension.	IIb	C

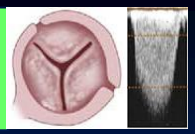
2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines

Rick A. Nishimura, Catherine M. Otto, Robert O. Bonow, Blase A. Carabello, John P. Erwin III, Robert A. Guyton, Patrick T. O'Gara, Carlos E. Ruiz, Nikolaos J. Skubas, Paul Sorajja, Thoralf M. Sundt III and James D. Thomas

AVR is recommended for symptomatic patients with severe high-gradient AS who have symptoms by history or on exercise testing (stage D1)	I	B
AVR is reasonable in symptomatic patients with low-flow/low-gradient severe AS with reduced LVEF (stage D2) with a low-dose dobutamine stress study that shows an aortic velocity ≥4.0 m/s (or mean pressure gradient ≥40 mm Hg) with a valve area ≤1.0 cm² at any dobutamine dose		
AVR is reasonable in asymptomatic patients (stage C1) with severe AS and decreased exercise tolerance or an exercise fall in BP	IIa	B
AVR is reasonable in symptomatic patients with low-flow/low-gradient severe AS with reduced LVEF (stage D2) with a low-dose dobutamine stress study that shows an aortic velocity ≥4.0 m/s (or mean pressure gradient ≥40 mm Hg) with a valve area ≤1.0 cm² at any dobutamine dose	IIa	B
AVR is reasonable in symptomatic patients who have low-flow/low-gradient severe AS (stage D3) who are normotensive and have an LVEF ≥50% if clinical, hemodynamic, and anatomic data support valve obstruction as the most likely cause of symptoms	IIa	C
AVR is reasonable for patients with moderate AS (stage B) (aortic velocity 3.0–3.9 m/s) who are undergoing other cardiac surgery	IIa	C
AVR may be considered for asymptomatic patients with severe AS (stage C1) and rapid disease progression and low surgical risk	IIb	C

Adapted from Pibarot, P. JACC 2012;60:1845-53

ΔP <40mmHg
EOA <1cm^2



EF <40%

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Dobutamine Stress Echo / Cath

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Flow Reserve

ΔP >35-40mmHg
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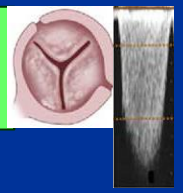


ΔP <35-40mmHg
EOA >1-1.2cm^2

True Severe AS
Low Gradient Low
EF with Reserve

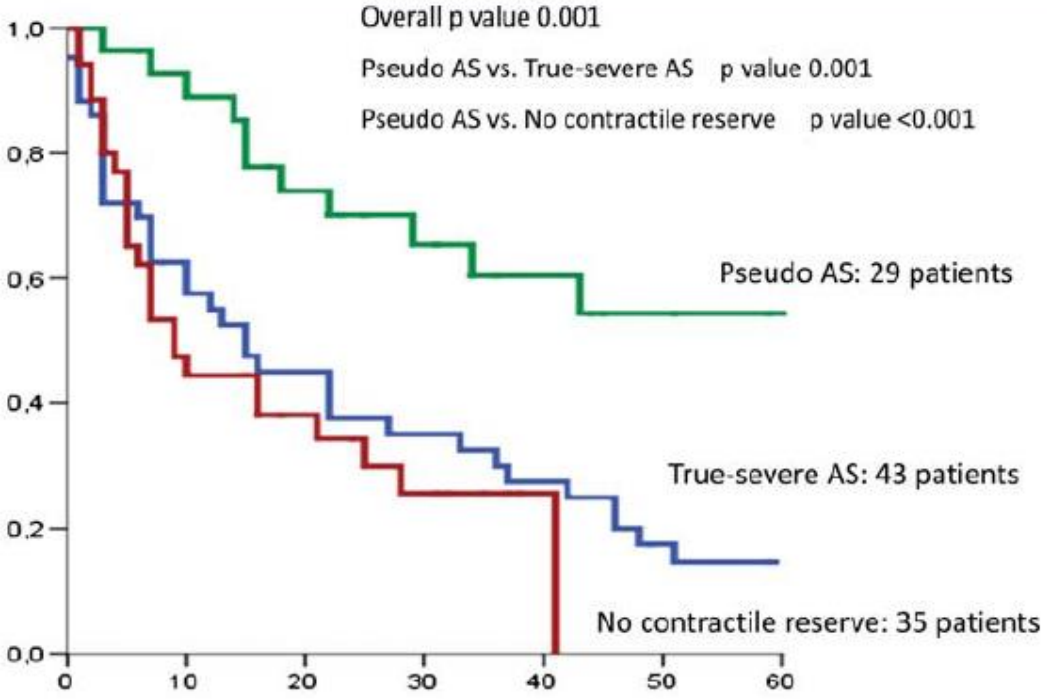
Pseudo-Severe AS

Pseudo-Severe Aortic Stenosis

- Definition
  - Grad <40mmHg + EOA <1cm^2 + SV <35ml/m^2 (usu EF <40%)
  - DSE – EOA >1-1.2cm^2; Disproportionate low mean PG elevation
- Feature of cardiomyopathy with moderate aortic stenosis
- Secondary to myopathic ventricle to generate sufficient force to open aortic valve
- Treatment mainly targeting cardiomyopathy
- Controversy regarding benefit of AVR

Outcomes of pseudo-severe aortic stenosis under conservative treatment

Emilie Fougères[1], Christophe Tribouilloy[2], Mehran Monchi[3], Hélène Petit-Eisenmann[4], Serge Baleynaud[5], Agnès Pasquet[6], Christophe Chauvel[7], Damien Metz[8], Catherine Adams[9], Dan Rusinaru[2], Pascal Guéret[1] and Jean-Luc Monin[1]*



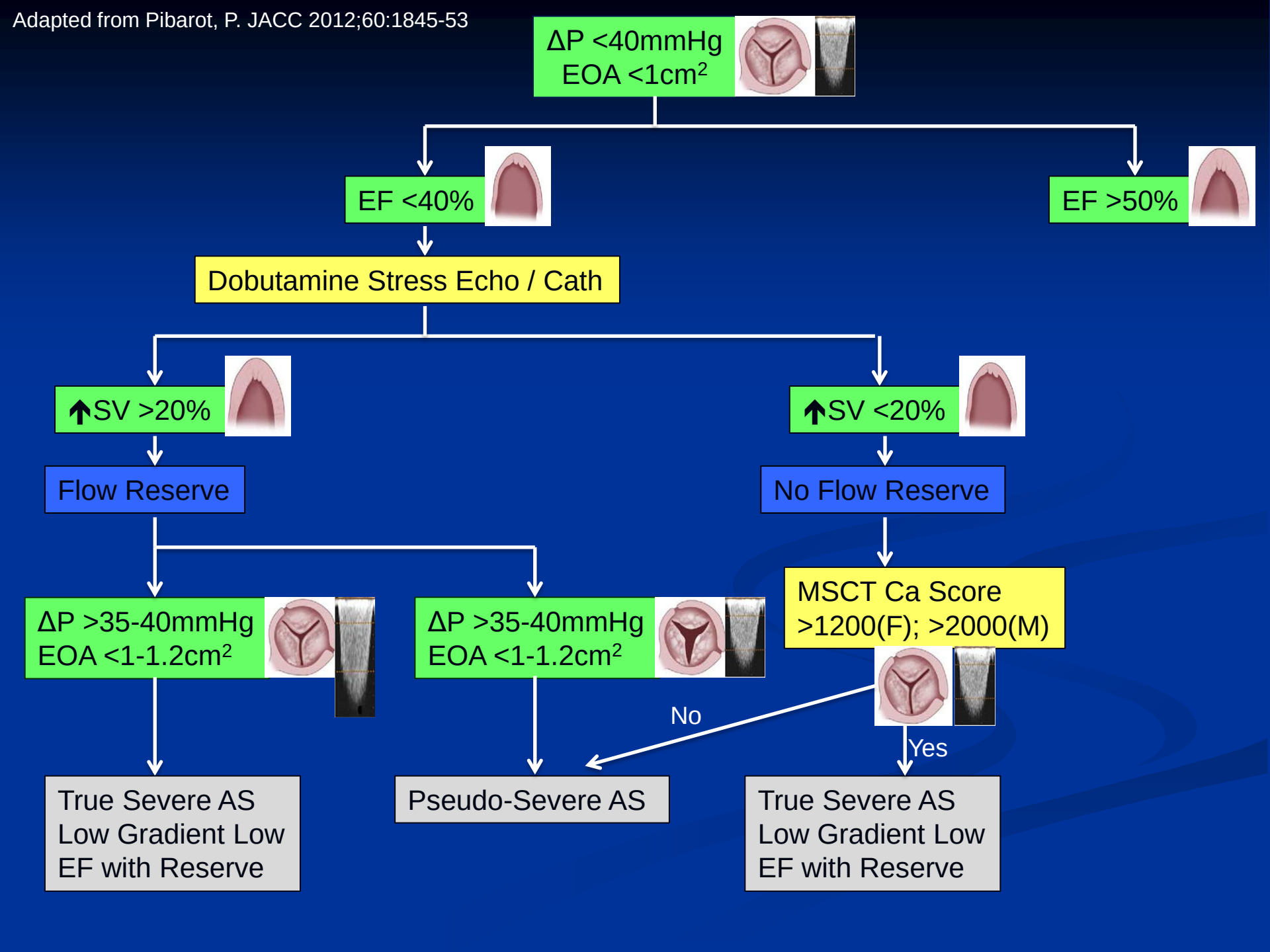
Patients at risk

True-severe AS	43	24	18	14	11	6	4
Pseudo AS	29	25	19	14	10	7	5
No contractile reserve	35	15	10	6	1	0	0

- 107 patients with low gradient severe AS who were Rx medically
- Pseudosevere AS had best outcome, and matches a propensity-adjusted control group of severe LV dysfunction without valve disease

Fougeres, E., Eur Heart J. 2012;33:2426-33

Adapted from Pibarot, P. JACC 2012;60:1845-53



Low Flow Low Gradient AS with No Flow Reserve

- Accounts for 30-40% low flow low gradient AS
- Typically associated with multivessel CAD
- Poor prognosis without aortic valve replacement
- High operative risk for SAVR– 20-33%
- However in survivors of SAVR – outcome superior to medical therapy

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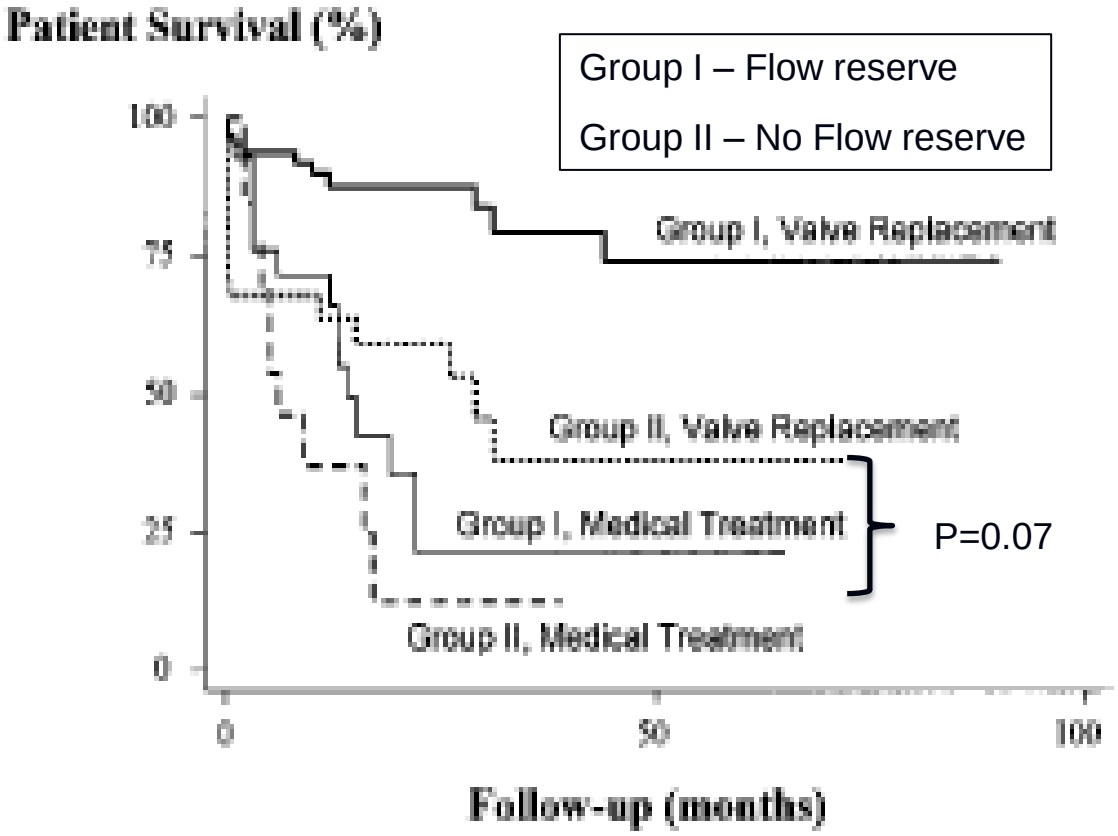

Kaplan-Meier survival estimates by group and treatment.

- 136 patient with low gradient severe AS Rx SAVR
- 92 with flow reserve (Group I)
- 44 no flow reserve (Group II)

<u>Amongst Group II</u>

- AVR associated with trend to improved survival

- Operative mortalty – 32%

CME

Outcome After Aortic Valve Replacement for Low-Flow/Low-Gradient Aortic Stenosis Without Contractile Reserve on Dobutamine Stress Echocardiography

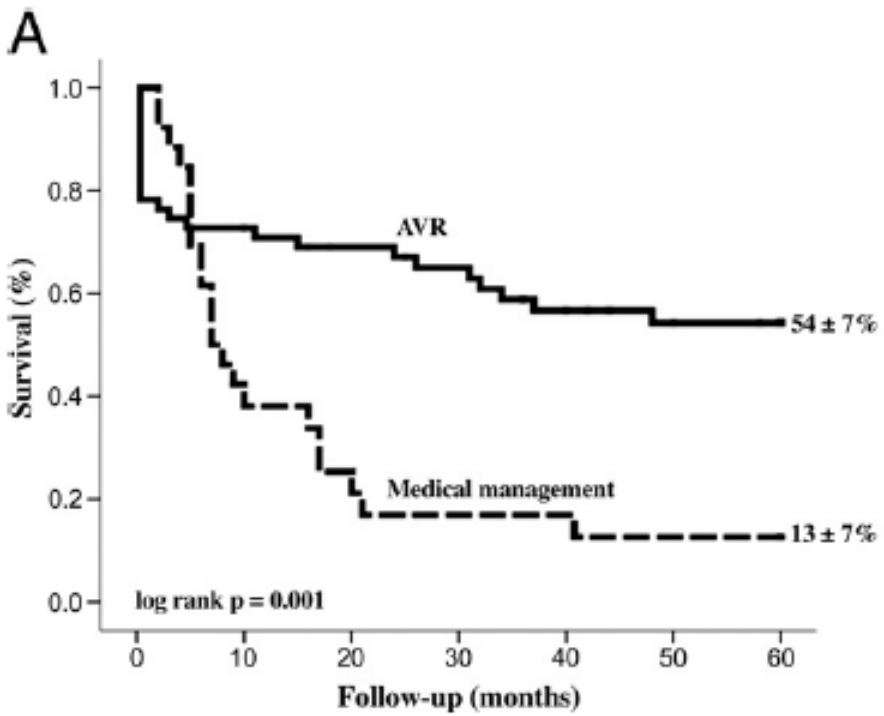

Figure 4 Prognostic Impact of AVR in LF/LGAS Patients Without

81 patients with Low Gradient Low EF Severe AS without Flow Reserve

- Operative Mortality 22%
- Predictors of operative mortality
  - Mean PG <20mmHg
  - CAD
- Significant improvement in survival compared to medical Rx

Tribouilloy, C., J Am Coll Cardiol. 2009;53:1865-73

Low Flow Low Gradient AS with No Flow Reserve

- Accounts for 30-40% low flow low gradient AS
- Typically associated with multivessel CAD
- Poor prognosis without aortic valve replacement
- High operative risk for SAVR– 20-33%
- However in survivors of SAVR – outcome superior to medical therapy
- Consider high risk AVR
  - ?Role of TAVR
  - ?Role of bridging BAV

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AVR is indicated in asymptomatic patients with severe AS and abnormal exercise test showing symptoms on exercise clearly related to AS.	I	C
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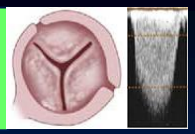

EF <40%

EF >50%

Dobutamine Stress Echo / Cath

↑SV >20%

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Confirm Severe AS

Flow Reserve

No Flow Reserve

ΔP >35-40mmHg
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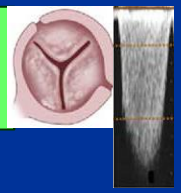
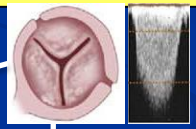


ΔP >35-40mmHg
EOA <1-1.2cm^2

MSCT Ca Score
>1200(F); >2000(M)



No

Yes

True Severe AS
Low Gradient Low
EF with Reserve

Pseudo-Severe AS

True Severe AS
Low Gradient Low
EF with Reserve

True Severe AS
Low Gradient
Normal EF

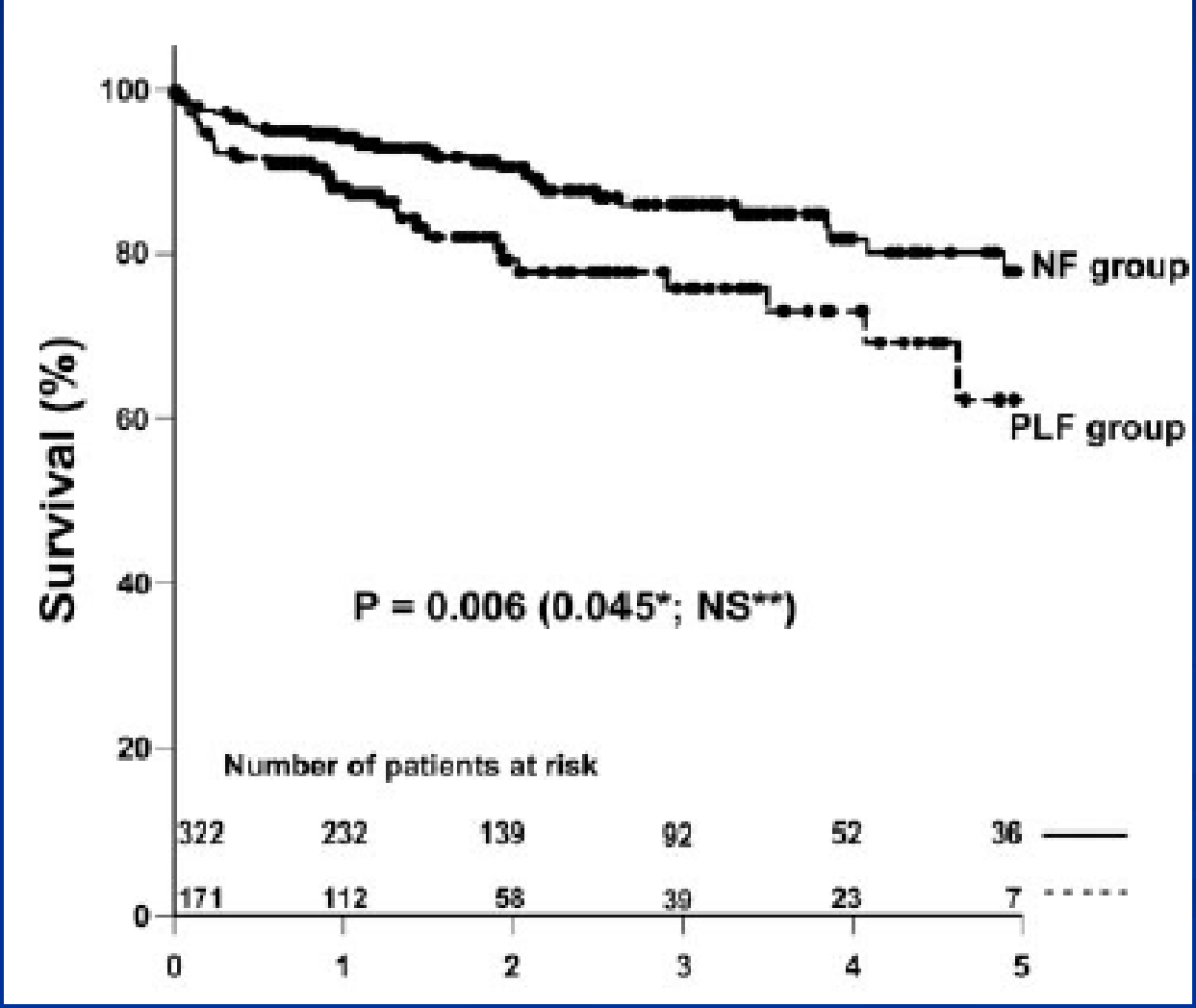
Low Gradient Normal EF Severe Aortic Stenosis

- AKA "Paradoxical low flow low gradient severe AS"
- Due to reduced intrinsic systolic function (ie. SV low) despite nornal EF – ie. Restrictive physiology
- Pathology associated with
  - Pronounced LV concentric remodelling / hypertrophy
  - Myocardial fibrosis
- Associated with – older age, female, systemic hypertension
- Worse prognosis than normal flow severe AS

Paradoxical Low-Flow, Low-Gradient Severe Aortic Stenosis Despite Preserved Ejection Fraction Is Associated With Higher Afterload and Reduced Survival

Zeineb Hachicha, Jean G. Dumesnil, Peter Bogaty and Philippe Pibarot

Circulation 2007;115;2856-2864; originally published online May 28, 2007;
DOI: 10.1161/CIRCULATIONAHA.106.668681



Low Gradient Normal EF Severe Aortic Stenosis

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- Due to reduced intrinsic systolic function (ie. SV low) despite nornal EF – ie. Restrictive physiology
- Pathology associated with
  - Pronounced LV concentric remodelling / hypertrophy
  - Myocardial fibrosis
- Associated with – older age, female, systemic hypertension
- Worse prognosis than normal flow severe AS
- Need to assess severity of AS carefully
  - Index to body size
  - Alternate hemodynamics – eg. Valvulo-arterial impedence
  - Corroborating imaging – eg. MSCT
- Survival improves with AVR

Impact of Aortic Valve Replacement on Outcome of Symptomatic Patients With Severe Aortic Stenosis With Low Gradient and Preserved Left Ventricular Ejection Fraction

Alper Ozkan, Rory Hachamovitch, Samir R. Kapadia, E. Murat Tuzcu and Thomas H. Marwick

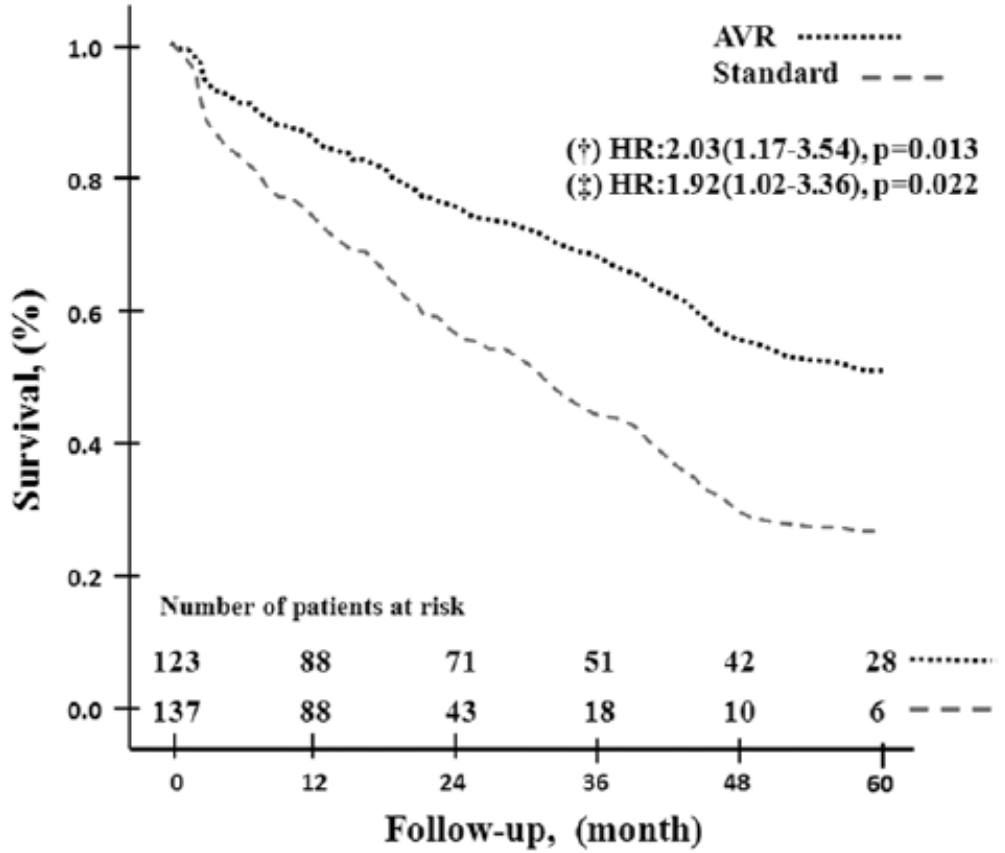

Figure 3. After adjustment for demographic variables (†) and a Society of Thoracic Surgeons score–based model (‡), aortic valve replacement (AVR) was found to be independently associated with better outcome (please see the text and Table 3 for models). HR indicates hazard ratio.

Ozkan, A., Circulation. 2013;128:622-31

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TAVR ON LOW GRADIENT AS

Impact of Low Flow on the Outcome of High-Risk Patients Undergoing Transcatheter Aortic Valve Replacement

Florent Le Ven, MD,* Mélanie Freeman, MD,† John Webb, MD,† Marie-Annick Clavel, DVM, PHD,* Miriam Wheeler, MD,† Éric Dumont, MD,* Chris Thompson, MD,† Robert De Larochellière, MD,* Robert Moss, MD,† Daniel Doyle, MD,* Henrique B. Ribeiro, MD,* Marina Urena, MD,* Luis Nombela-Franco, MD,* Josep Rodés-Cabau, MD,* Philippe Pibarot, DVM, PHD*

Outcome of Transcatheter Aortic Valve Implantation in Patients With Low-Gradient Severe Aortic Stenosis and Preserved Left Ventricular Ejection Fraction

Simon Biner, MD*, Edo Yaakov Birati, MD, Yan Topilsky, MD, Arie Steinvil, MD, Eyal Ben Assa, MD, Ben Sadeh, MD, Yaron Arbel, MD, Amir Halkin, MD, Yigal Abramowitz, MD, Eran Leshem-Rubinow, MD, Shmuel Banai, MD, Gad Keren, MD, and Ariel Finkelstein, MD

Clinical outcomes of patients with low-flow, low-gradient, severe aortic stenosis and either preserved or reduced ejection fraction undergoing transcatheter aortic valve implantation

Crochan J. O'Sullivan[1,2], Stefan Stortecky[1], Dik Heg[3,4], Thomas Pilgrim[1], Nicola Hosek[1], Lutz Buellesfeld[1], Ahmed A. Khattab[1], Fabian Nietlispach[1], Aris Moschovitis[1], Thomas Zanchin[1], Bernhard Meier[1], Stephan Windecker[1,3], and Peter Wenaweser[1,2]*

Clinical Presentation and Outcomes after Transcatheter Aortic Valve Implantation in Patients with Low Flow/Low Gradient Severe Aortic Stenosis

Yacine Elhmidi,* MD, Nicolo Piazza, MD PhD, Markus Krane, MD, Marcus-André Deutsch, MD, Domenico Mazzitelli, MD, Rüdiger Lange, MD PhD, and Sabine Bleiziffer, MD

Predictors of Mortality and Outcomes of Therapy in Low-Flow Severe Aortic Stenosis: A Placement of Aortic Transcatheter Valves (PARTNER) Trial Analysis

Howard C. Herrmann, Philippe Pibarot, Irene Hueter, Zachary M. Gertz, William J. Stewart, Samir Kapadia, E. Murat Tuzcu, Vasilis Babaliaros, Vinod Thourani, Wilson Y. Szeto, Joseph E. Bavaria, Susheel Kodali, Rebecca T. Hahn, Mathew Williams, D. Craig Miller, Pamela S. Douglas and Martin B. Leon

TAVR in Low Gradient Low EF Severe AS

Study	N	Population	LVEF	Mean Gradient	Logistic EuroScore	1mth Mortality	1 Year Mortality
Le Ven.	90	SV<35ml/min/m^2, EF <50%%, Mean PG <40mmHg	32%	27	31.8%	12%	
O'Sullivan	60	Mean PG<40mmHg; EF<40%	29%	25.5	38.0%	6.6%	24.5%
Ehlmidi	38	SV<35ml/min/m^2, EF<50%, Mean PG <40mmHg		30.3	30.8%	7.8%	36.8%

Le Ven, F., J Am Coll Cardiol. 2013;62:782-8

O'Sullivan, C. J., Eur Heart J. 2013;34:3437-50

Elhmidi, Y., Catheter Cardiovasc Interv. 2014;84:283-90

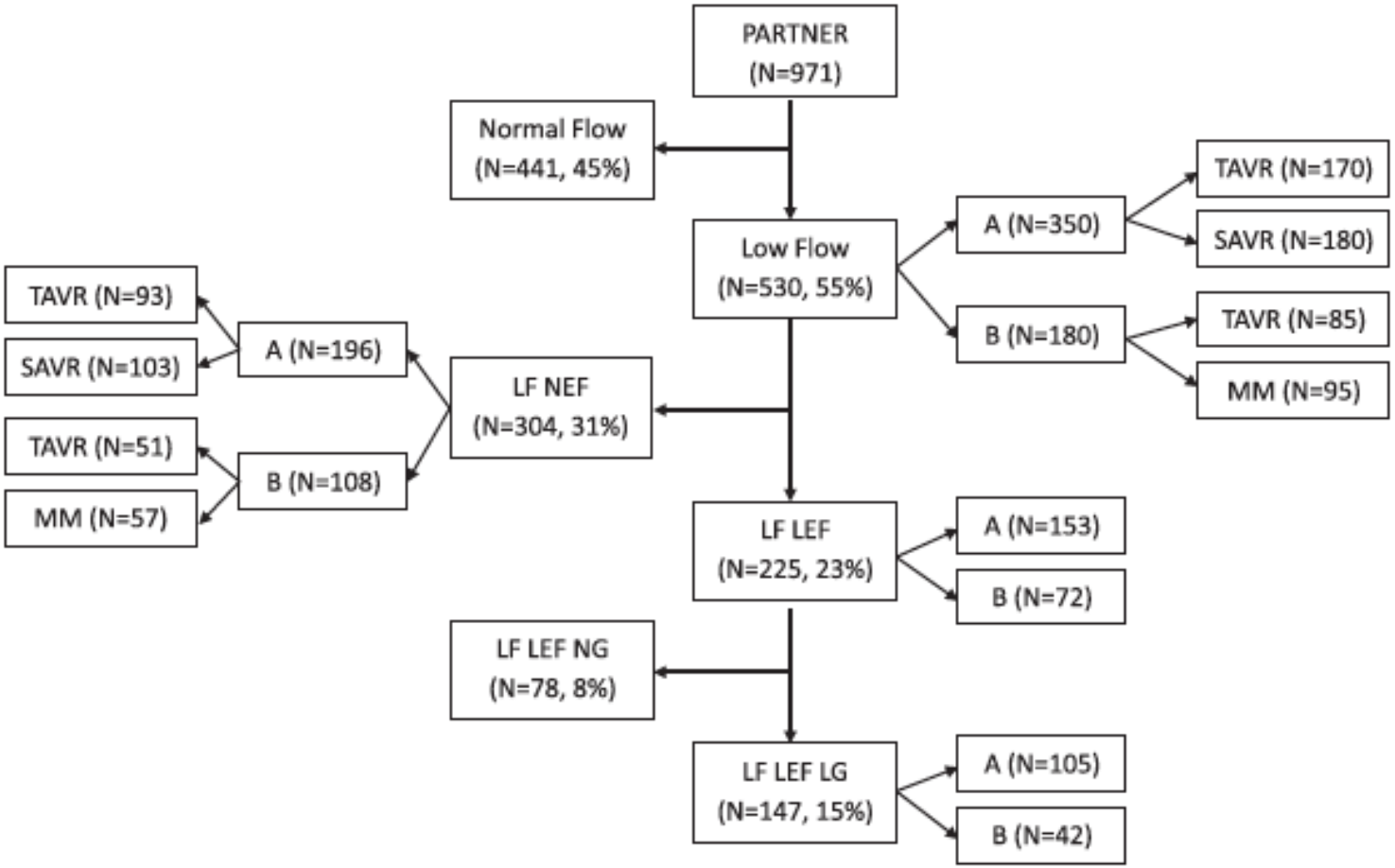
TAVR in Low Gradient Normal EF Severe AS

Study	N	Population	LVEF	Mean Gradient	Logistic EuroScore	1mth Mortality	1 Year Mortality
Le Ven.	86	SV<35ml/min/m^2, EF >50%, Mean PG <40mmHg	60%	31	18.4%	9%	
O'Sullivan	85	Mean PG<40mmHg; EF>50%	60%	31	19.7%	6.1%	20.5%
Biner	38	EF<50%, Mean PG <40mmHg	60%	32	29%	3.3%	2 year 43%

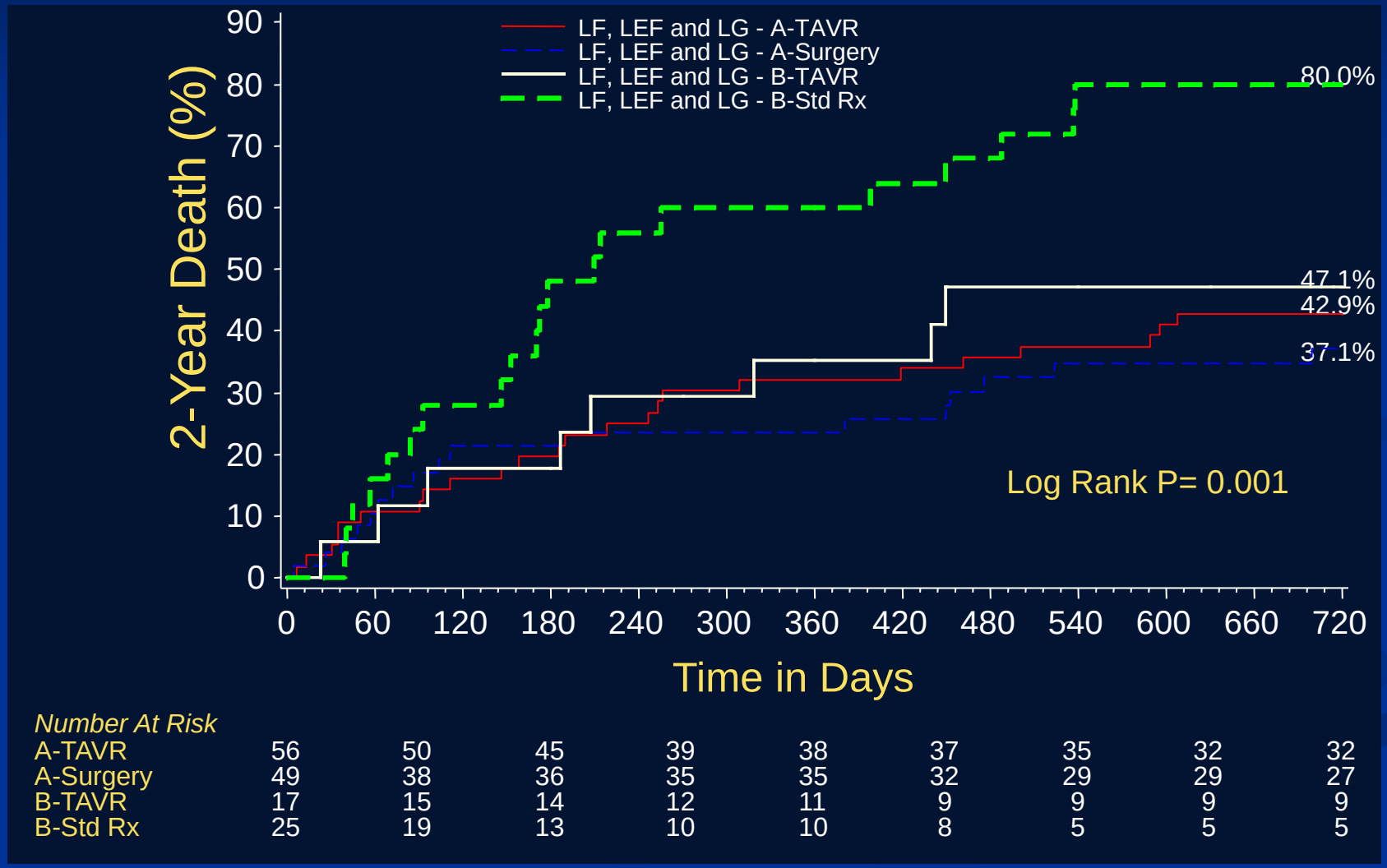
Le Ven, F., J Am Coll Cardiol. 2013;62:782-8
O'Sullivan, C. J., Eur Heart J. 2013;34:3437-50
Biner, S., Am J Cardiol. 2014;113:348-54

Predictors of Mortality and Outcomes of Therapy in Low-Flow Severe Aortic Stenosis

A Placement of Aortic Transcatheter Valves (PARTNER) Trial Analysis



PARTNER
Outcomes in Low Gradient Low EF



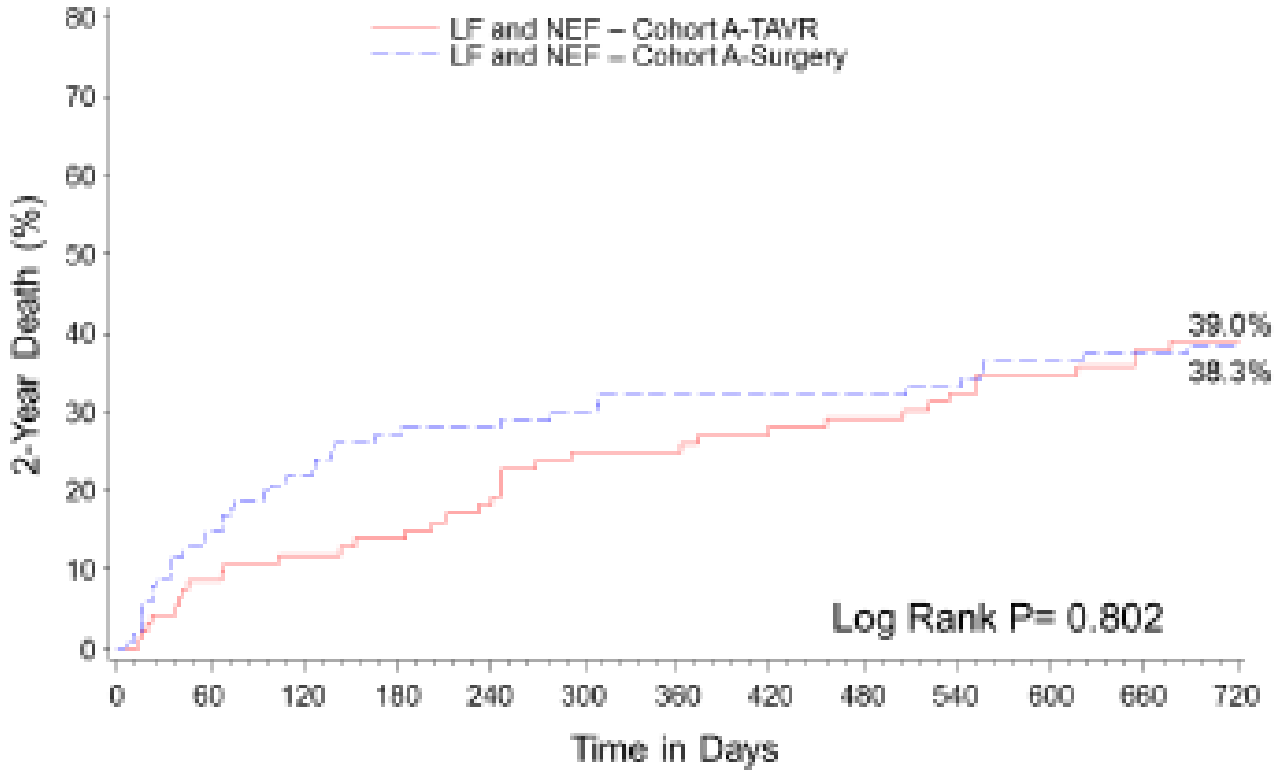
Number At Risk

A-TAVR	56	50	45	39	38	37	35	32	32
A-Surgery	49	38	36	35	35	32	29	29	27
B-TAVR	17	15	14	12	11	9	9	9	9
B-Std Rx	25	19	13	10	10	8	5	5	5

Herrmann, H. C., Circulation. 2013;127:2316-26

PARTNER
Outcomes in Low Gradient Normal EF

B.



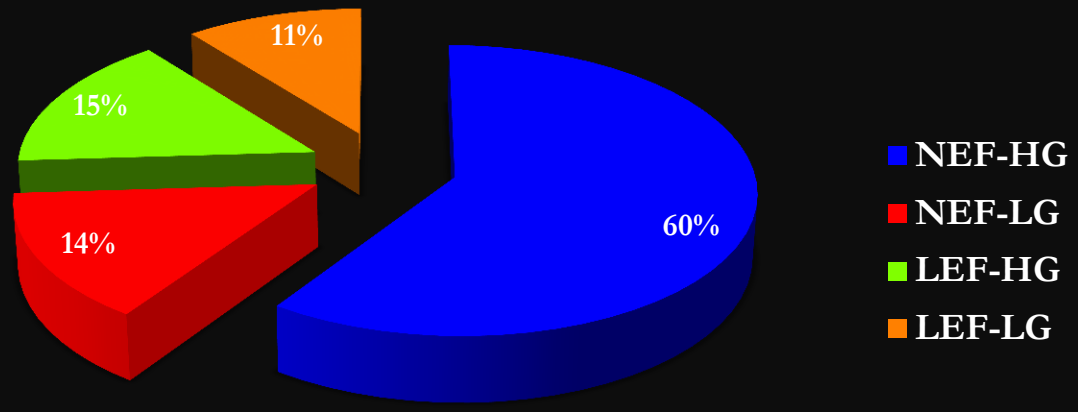
Number At Risk

A-TAVR	93	83	80	70	69	66	62	59	55
A-Surgery	103	80	71	69	66	66	65	61	60

Herrmann, H. C., Circulation. 2013;127:2316-26

When Does Baseline Left Ventricular Function Influence Survival Post Transcatheter Aortic Valve Implantation?

—The CoreValve Australia New Zealand Study —



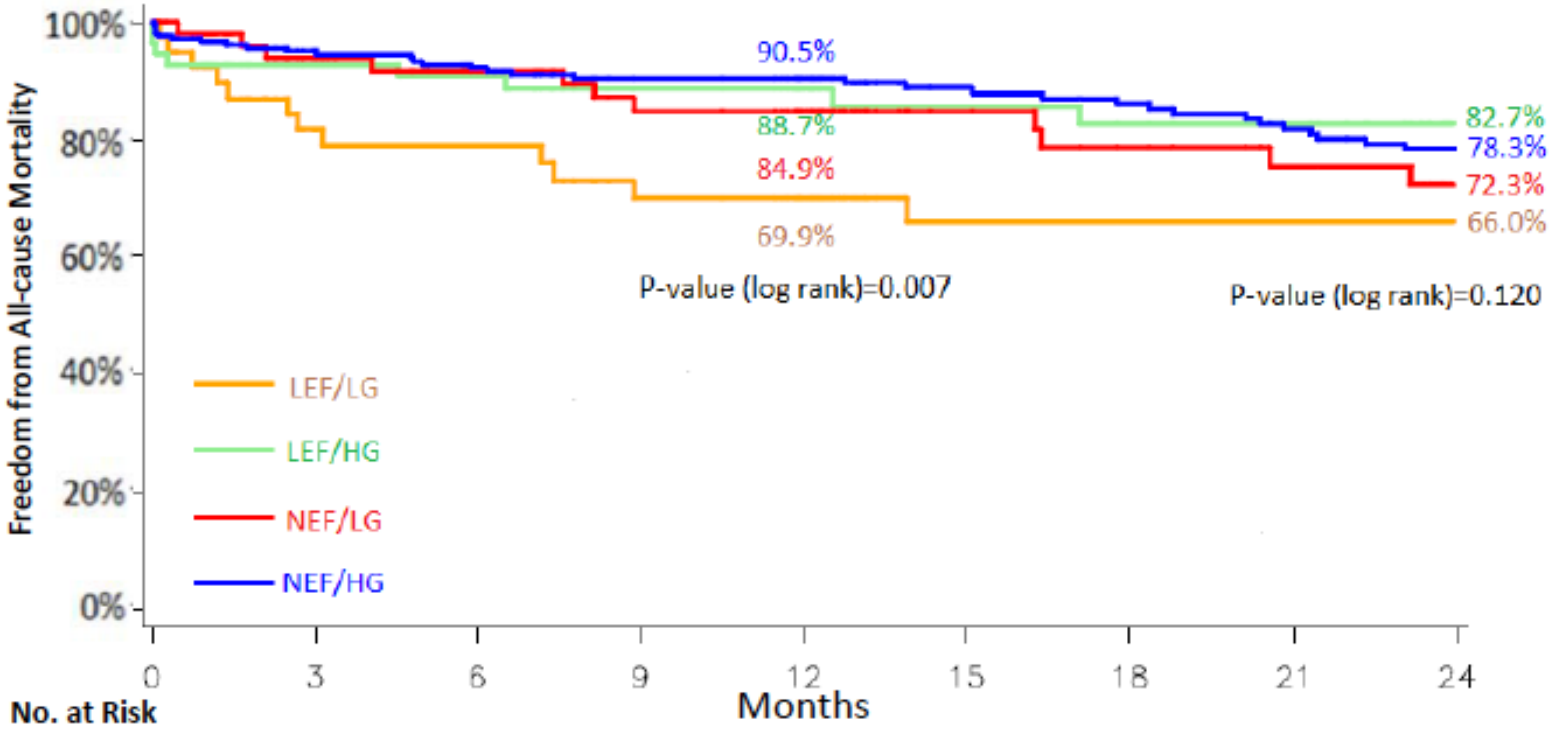
NEF-HG – EF>50%, Grad >40mmHg

NEF-LG – EF>50%, Grad <40mmHg

LEF-HG – EF<50%, Grad >40mmHg

LEF-LG – EF<50%, Grad <40mmHg

All Cause Mortality

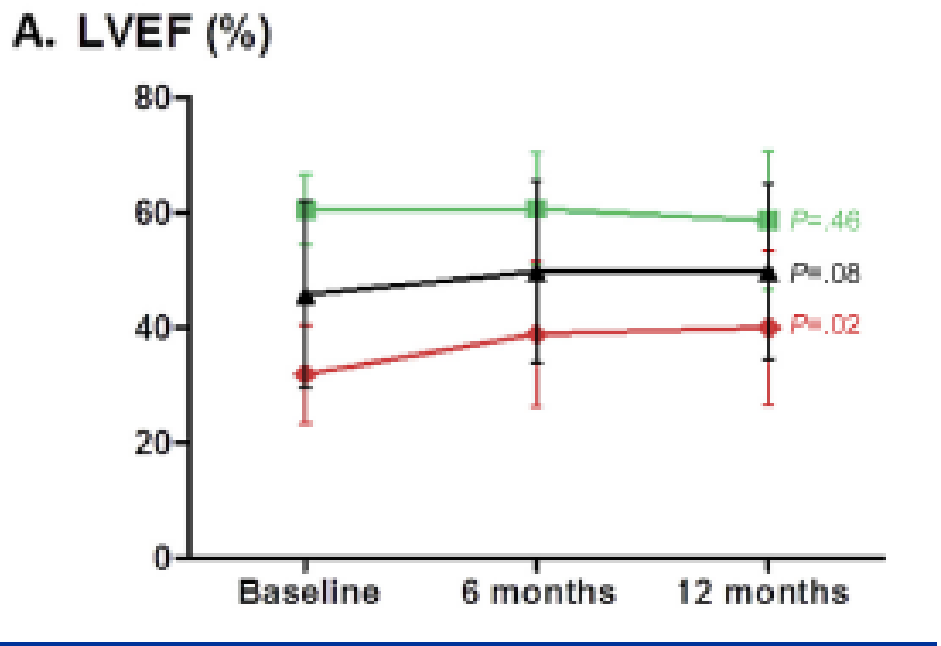


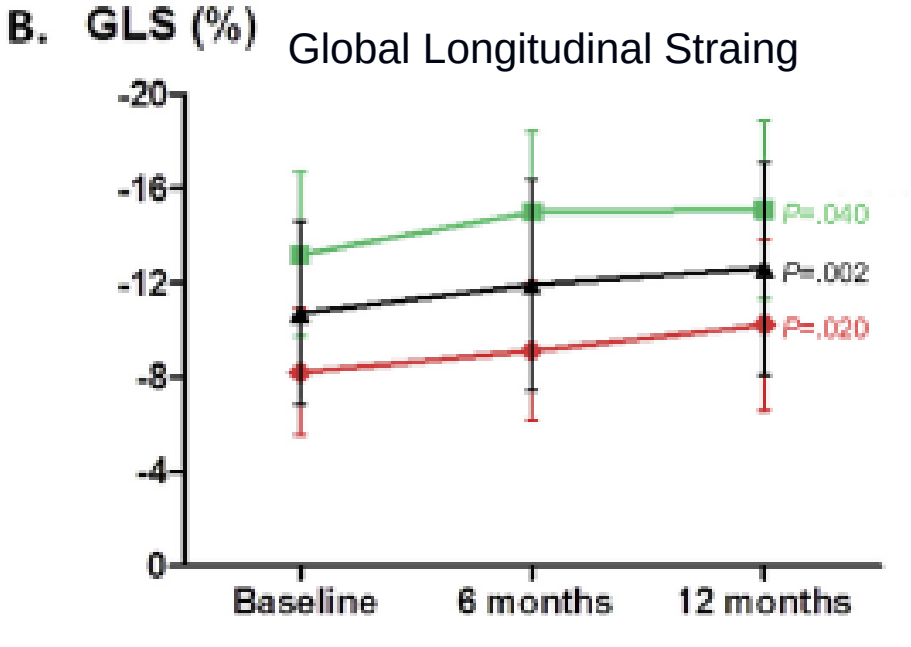
No. at Risk

Months	0	1	6	12	24
LEF/LG	39	36	27	21	11
LEF/HG	56	52	44	32	11
NEF/LG	53	49	41	34	19
NEF/HG	218	197	163	131	65

CoreValve Australia-New Zealand Study

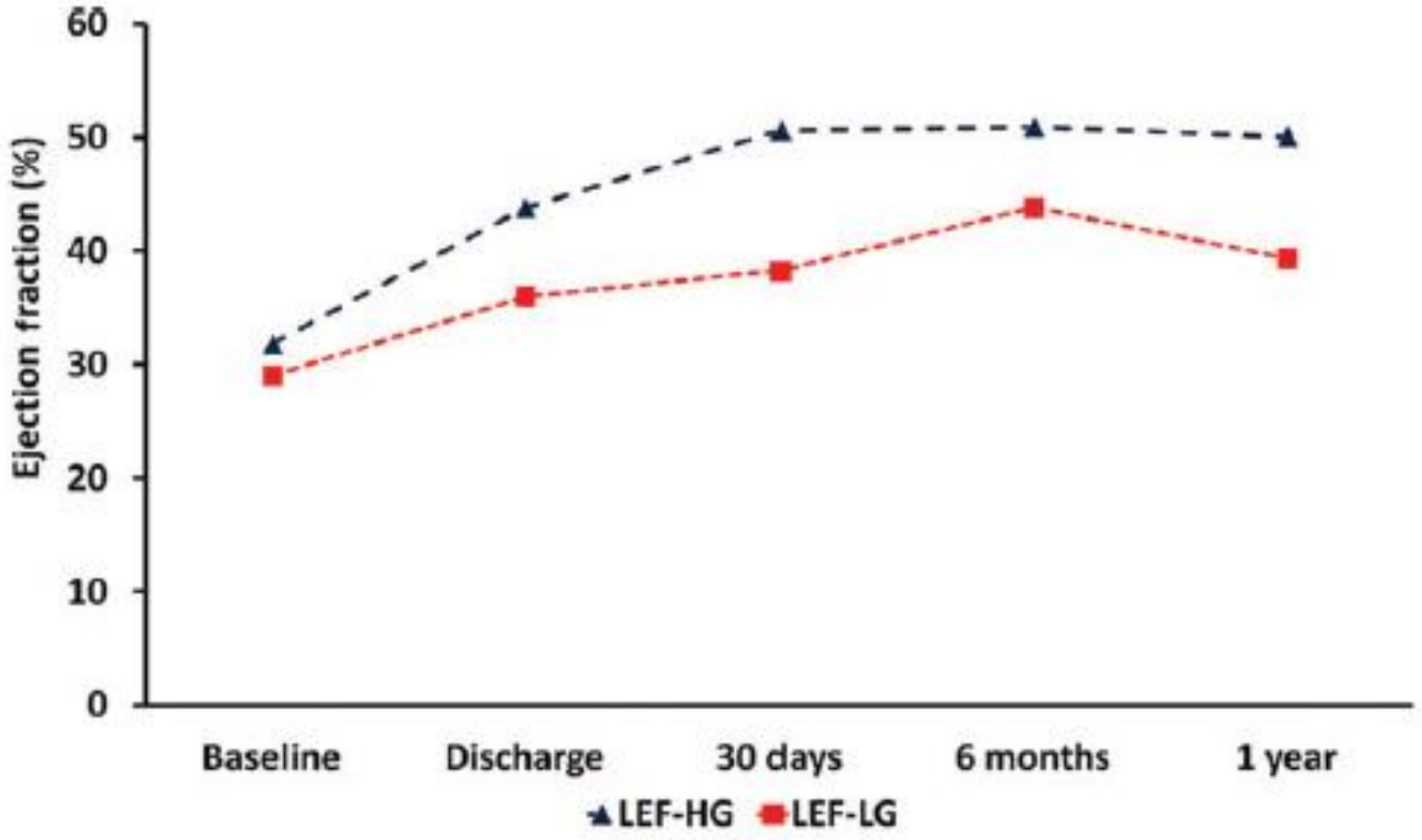
TAVR improves LV function in Low gradient AS





Kamperidis, J Am Soc Echocardiogr. 2014;27:817-25

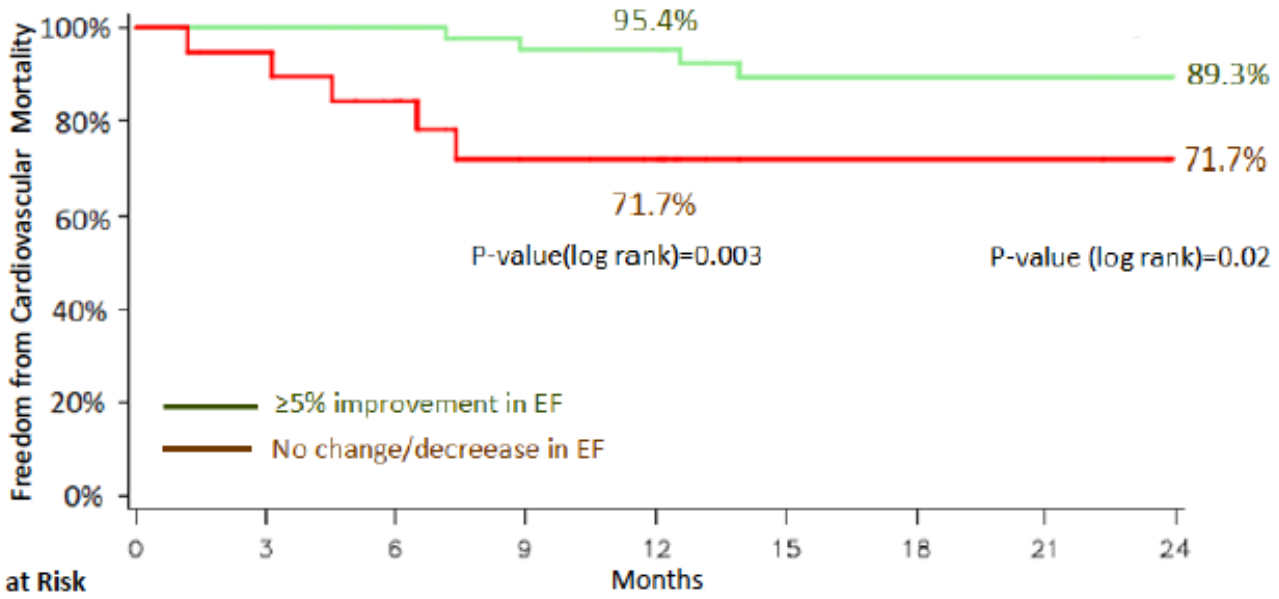
Clinical outcomes of patients with low-flow, low-gradient, severe aortic stenosis and either preserved or reduced ejection fraction undergoing transcatheter aortic valve implantation



Improvement in LV impacts on survival

euro PCR 2013

Impact on CV Survival of Improved EF after TAVI



No. at Risk

Months	0	1	6	12	24
Improved ≥ 5%*	53	53	48	33	15
No Change/ Decreased*	20	20	14	11	5

Conclusion / Final Comments

- Low gradient severe AS is a challenging subset of AS for both diagnosis and treatment
- Associated with worse outcomes than normal gradient/flow severe AS
- Aortic valve replacement improves survival
- But at the cost of high operative risk (5-35%)
- TAVR is an attractive option in face of high operative risk
  - Improves survival
  - Improves EF
- ?Role of BAV – as bridge and potential selection role