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TAVI

INDICAÇÕES E RESULTADOS ATUAIS

Luiz Antonio Carvalho
10/06/2016

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Aortic Stenosis
Changing Epidemiology

Calcific Degenerative

© Elsevier 2005

Rheumatic

CDC PHIL #848

Bicuspid Valve

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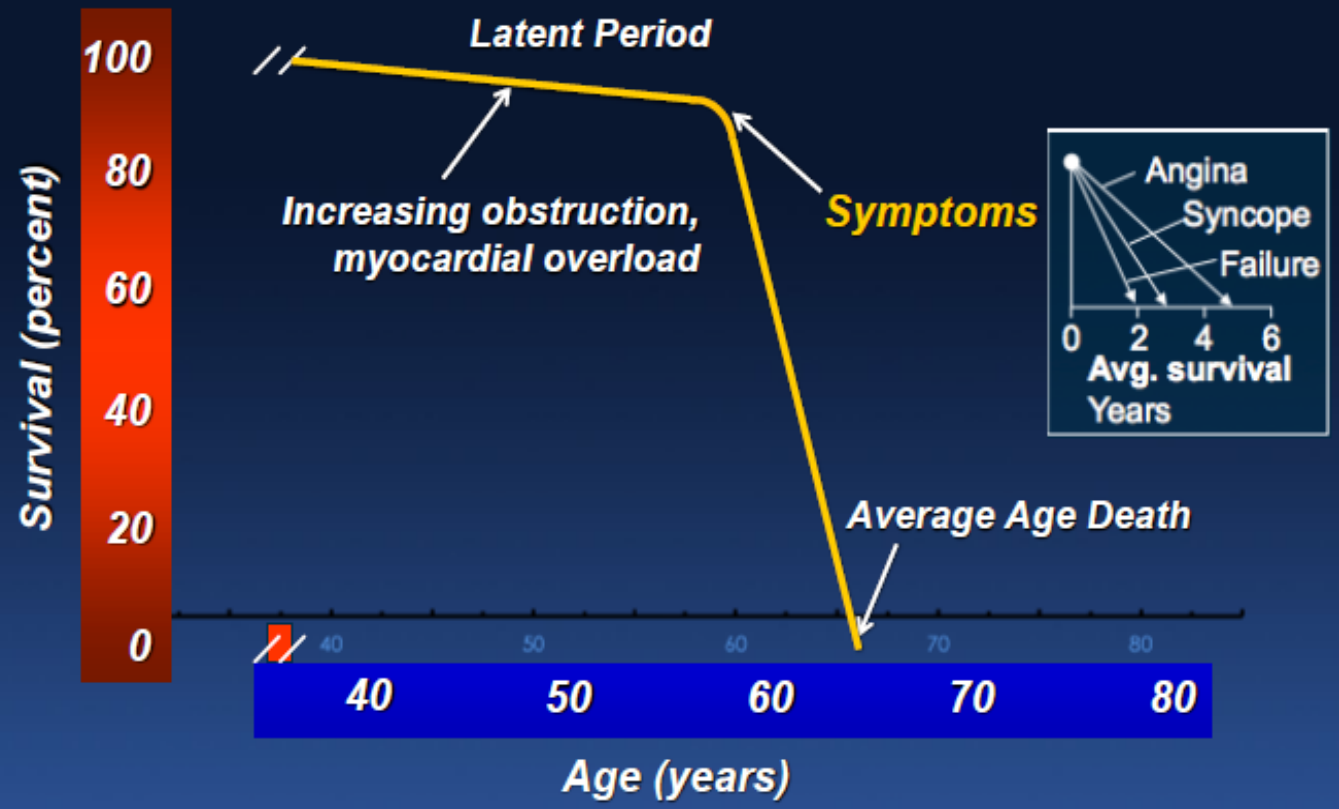
Natural History of Aortic Stenosis



from Ross and Braunwald, Circulation 1968;38:V-61

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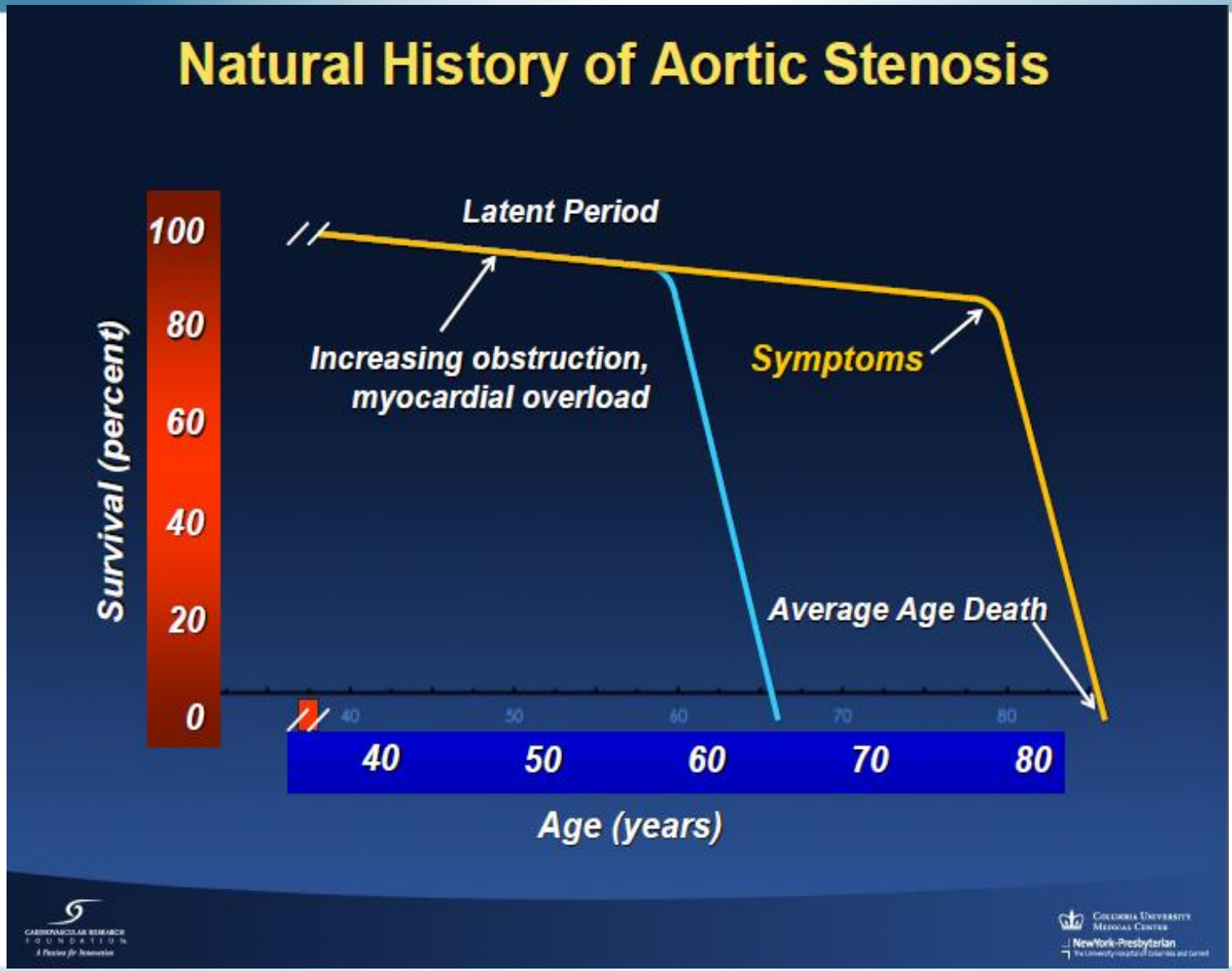
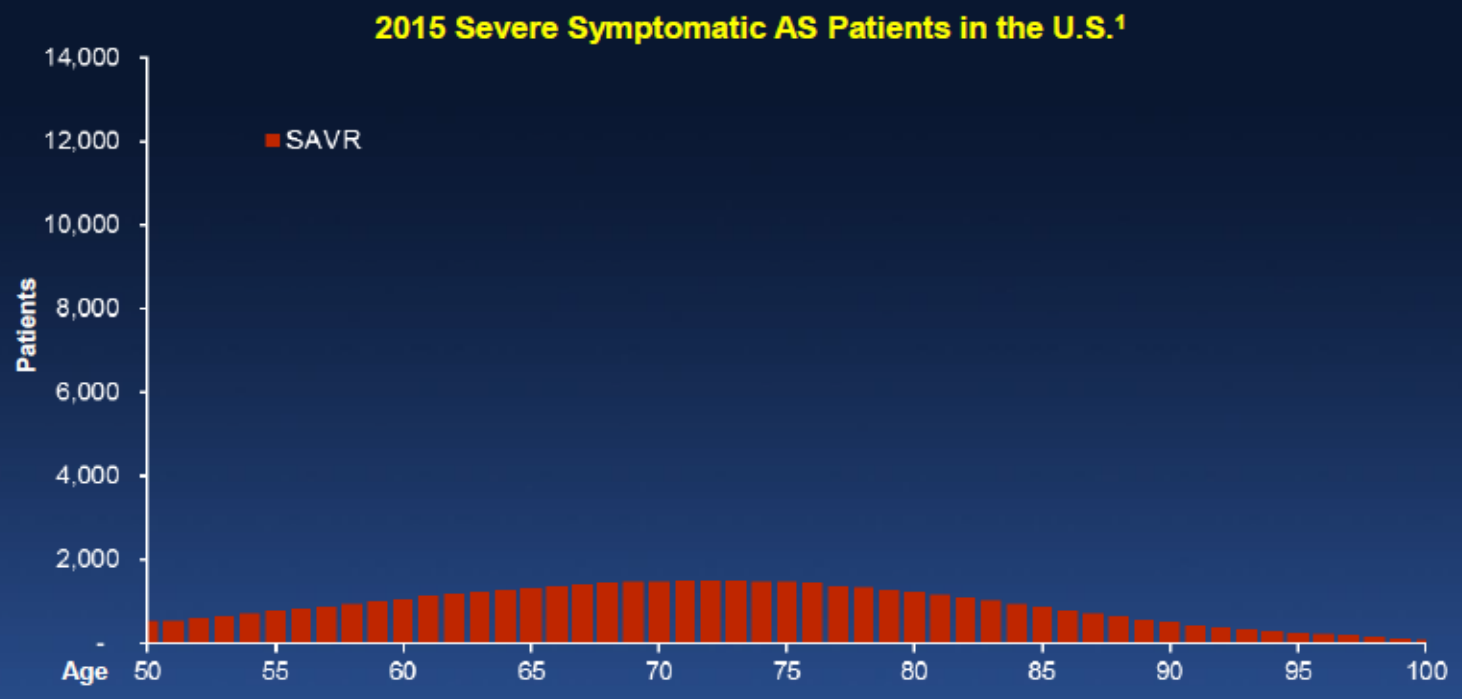
Natural History of Aortic Stenosis



Historically, Our Understanding of Aortic Stenosis Was Based on Surgical Experience



(1) Nkomo 2006, Ilvanainen 1996, Aronow 1991, Bach 2007, Freed 2010, Iung 2007, Pellikka 2005, Brown 2008, Thourani 2015,

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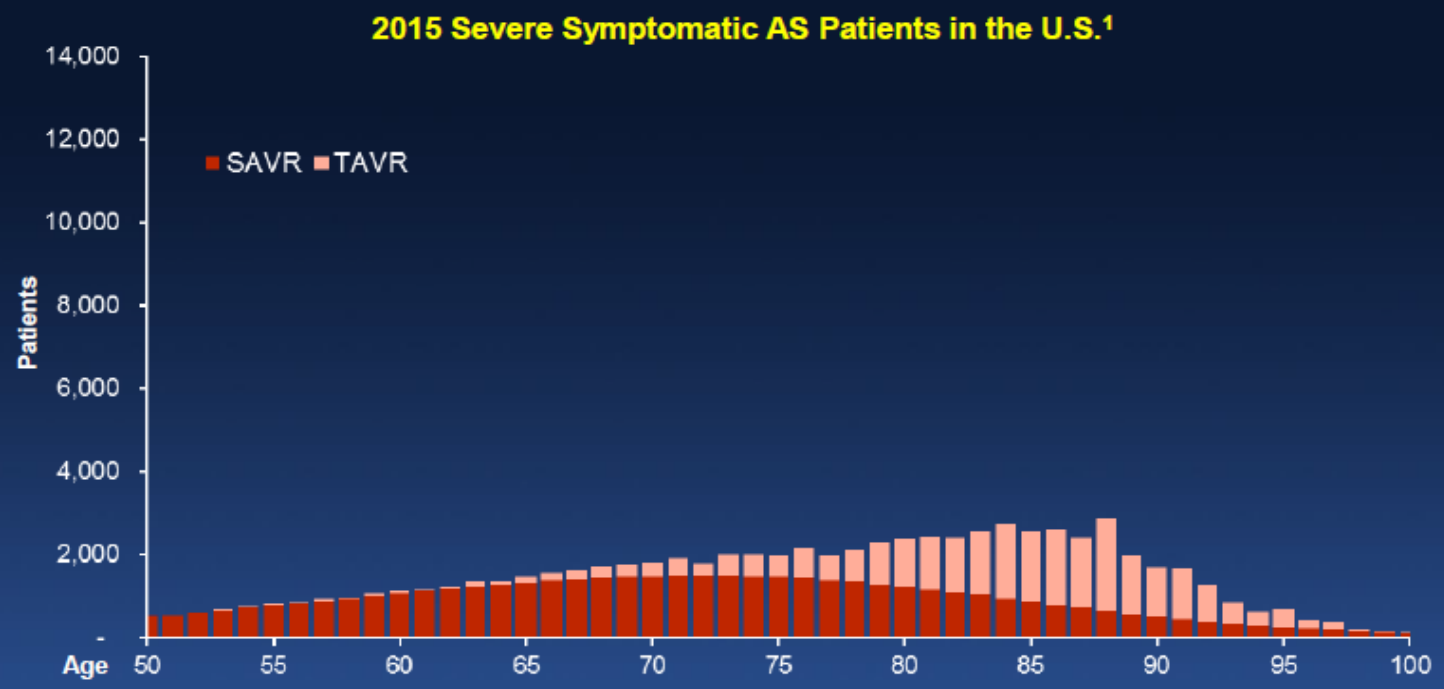
The TAVR Experience Has Changed Our Understanding of Aortic Stenosis



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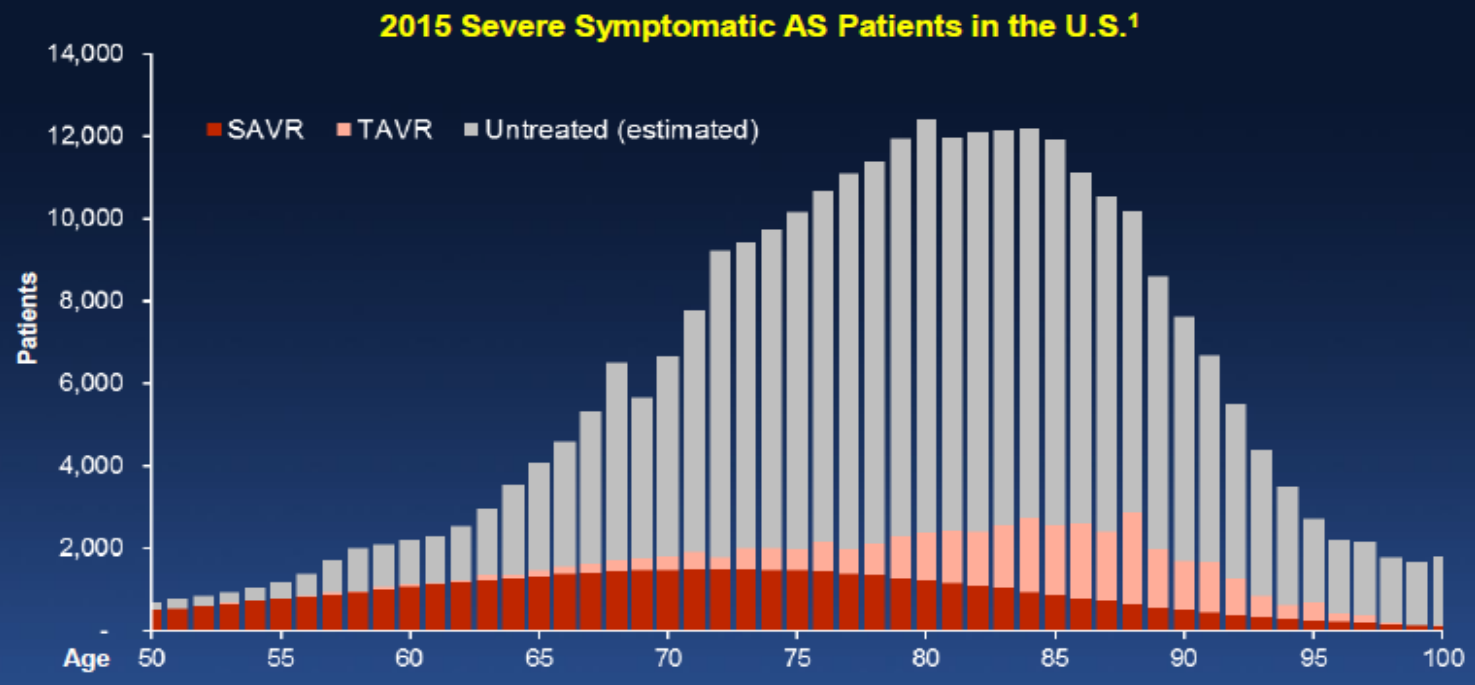
A Large Population of Severe Symptomatic AS Patients Remain Undiagnosed and Untreated



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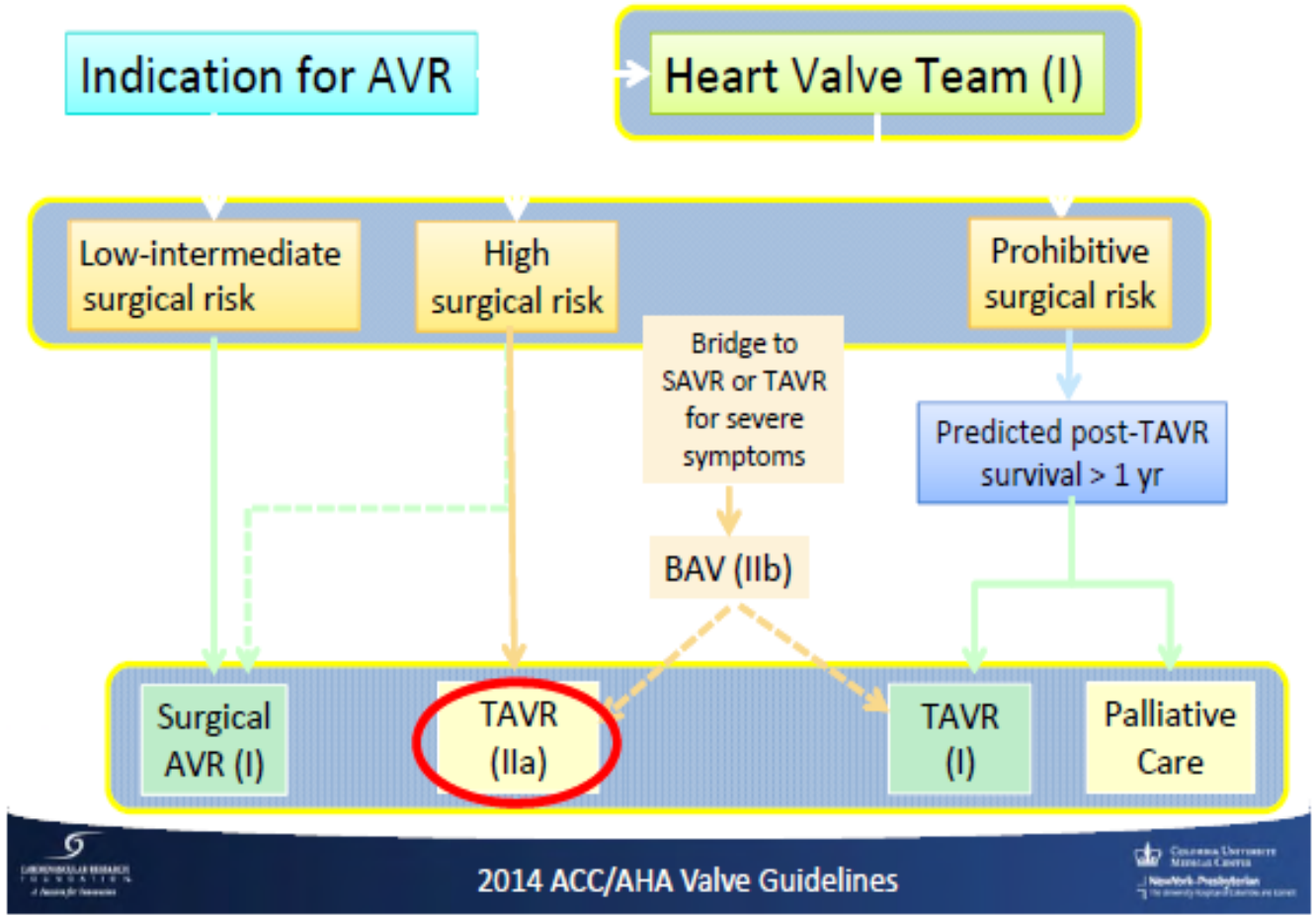
Following the Guidelines



Aortic Stenosis: Choice of Surgical or Transcatheter Intervention

Recommendations	COR	LOE
Surgical AVR is recommended in patients who meet an indication for AVR (listed in Section 3.4) with low or intermediate surgical risk	I	A
For patients in whom TAVR or high-risk surgical AVR is being considered, members of a Heart Valve Team should collaborate closely to provide optimal patient care	I	C
TAVR is recommended in patients who meet an indication for AVR for AS who have a prohibitive surgical risk and a predicted post-TAVR survival >12 months	I	B

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Aortic Stenosis: Choice of Surgical or Transcatheter Intervention (cont.)

Recommendations	COR	LOE
TAVR is a reasonable alternative to surgical AVR for AS in patients who meet an indication for AVR and who have high surgical risk	IIa	B
Percutaneous aortic balloon dilation may be considered as a bridge to surgical or transcatheter AVR in severely symptomatic patients with severe AS	IIb	C
TAVR is not recommended in patients in whom the existing comorbidities would preclude the expected benefit from correction of AS	III: No Benefit	B

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The Heart Valve Team and Heart Valve Centers of Excellence

Recommendations	COR	LOE
Patients with severe VHD should be evaluated by a multidisciplinary Heart Valve Team when intervention is considered	I	C
Consultation with or referral to a Heart Valve Center of Excellence is reasonable when discussing treatment options for 1) asymptomatic patients with severe VHD, 2) patients who may benefit from valve repair versus valve replacement, or 3) patients with multiple comorbidities for whom valve intervention is considered	IIa	C

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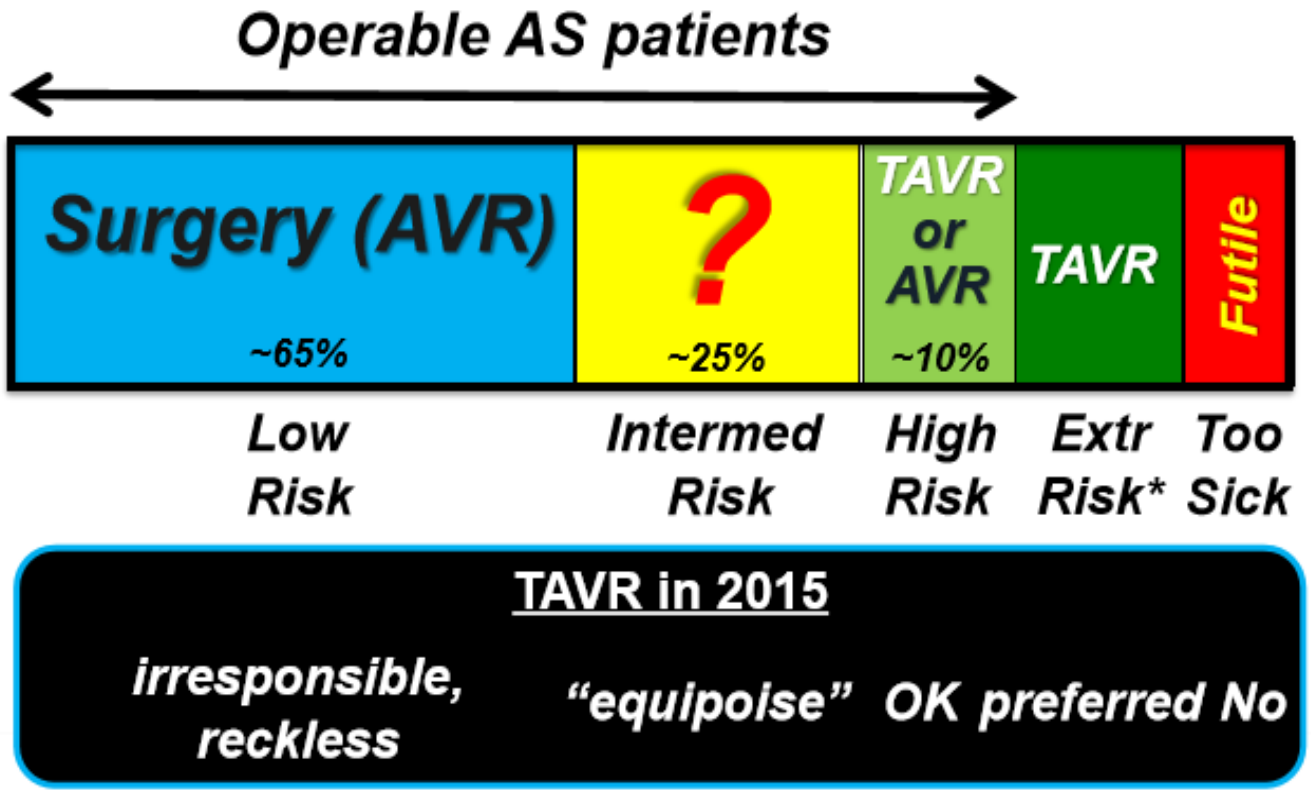
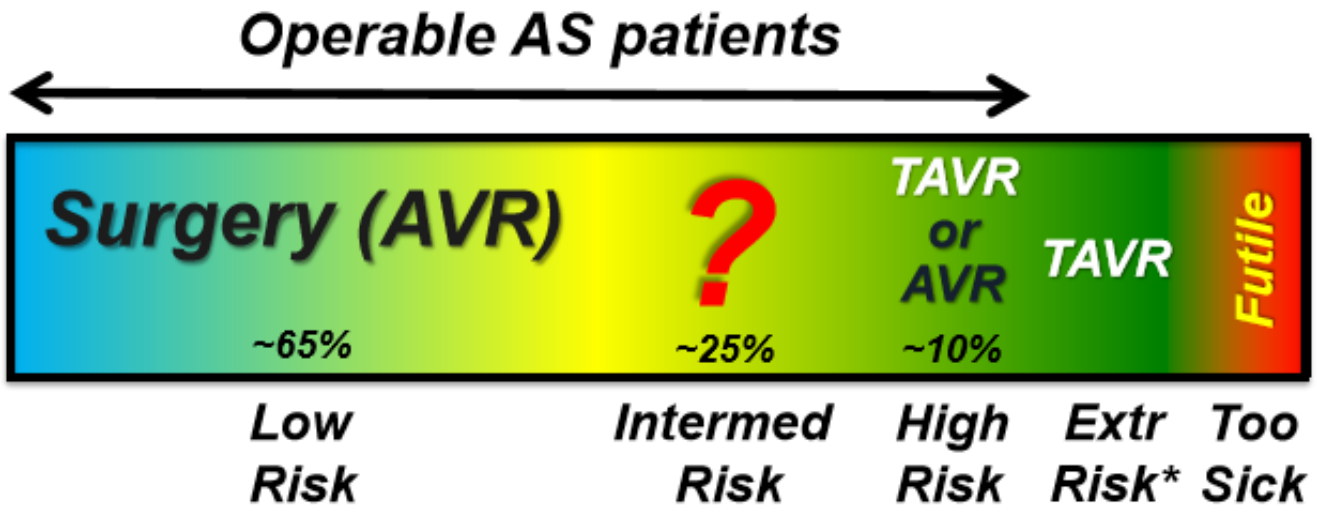
Role of the Heart Team
Assessing Risk



* Extreme risk = "inoperable"

Role of the Heart Team Assessing Risk



TAVR in 2015

irresponsible, reckless	"equipoise"	OK	preferred	No

* Extreme risk = "inoperable"

How do you define risk?

AVR Surgical Risk Algorithms

- **Algorithms for estimating surgical risk generated from large patient databases**
- **Established risk algorithms**
  - **Society Thoracic Surgeons (STS): N=67,292 AVR**
    - *riskcalc.sts.org/*
  - **EuroSCORE (Additive, Log, EuroSCORE II): N=5595 Valve**
    - http://www.euroscore.org/calc.html
  - **Ambler Risk Score: N=32,839 Valve**
    - *http://www.ucl.ac.uk/stats/research/riskmodel*
- **In high-risk patients, STS most accurate, but tends to underestimate risk, while other models overestimate**

Rosenheck et al. European Heart Journal 2012;33:822-8

Risk Assessment Combining STS Risk Estimate, Frailty, Major Organ System Dysfunction, and Procedure-Specific Impediments

	Low Risk (must meet ALL criteria in this column)	Intermediate Risk (any 1 criteria in this column)	High Risk (any 1 criteria in this column)	Prohibitive Risk (any 1 criteria in this column)
STS PROM	<4% **AND**	4% to 8% **OR**	>8% **OR**	Predicted risk with surgery of death or major morbidity (all-cause) >50% at 1 y **OR**
Frailty	None **AND**	1 index (mild) **OR**	2 or more indices (moderate-to-severe) **OR**	
Major organ system compromise not to be improved postoperatively	None **AND**	1 organ system **OR**	No more than 2 organ systems **OR**	3 or more organ systems **OR**
Procedure-specific impediment	None	Possible procedure-specific impediment	Possible procedure-specific impediment	Severe procedure-specific impediment

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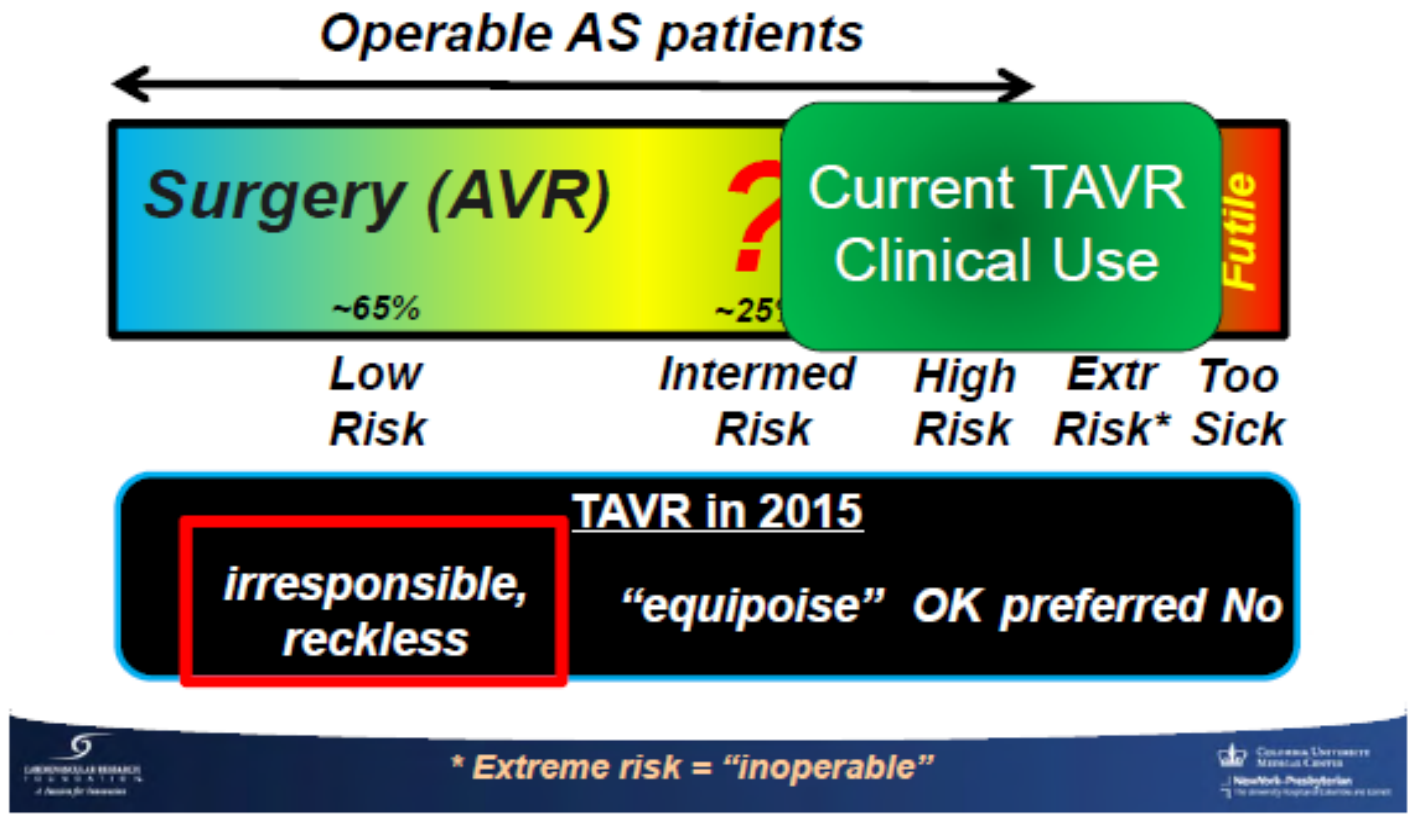
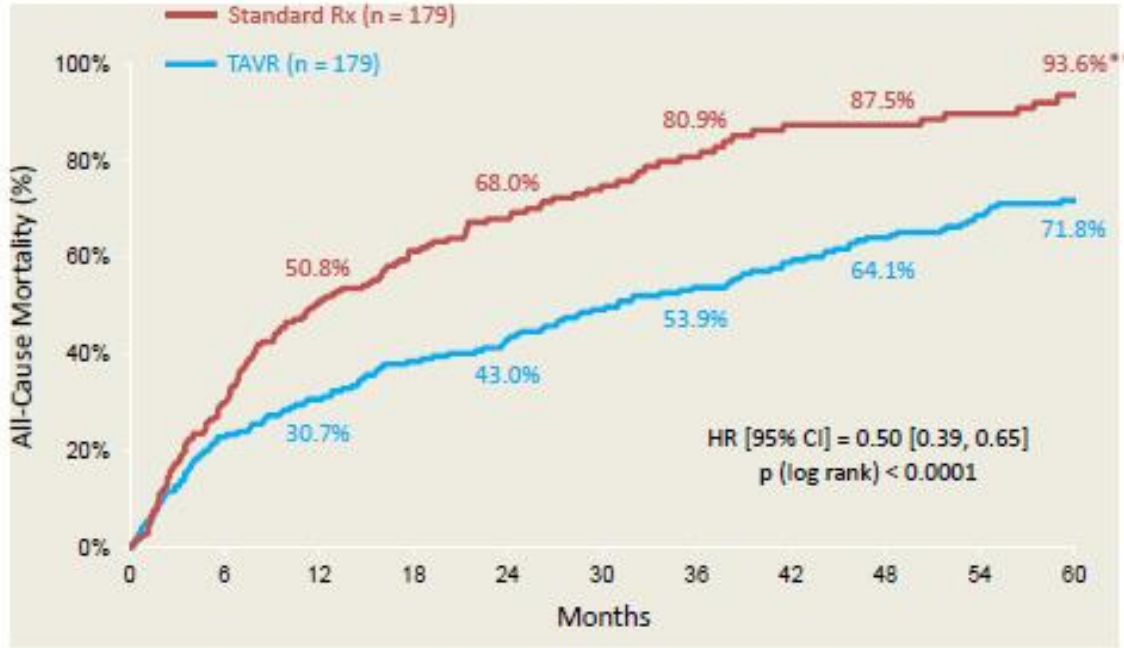
Role of the Heart Team
Assessing Risk



TAVR Improves Survival

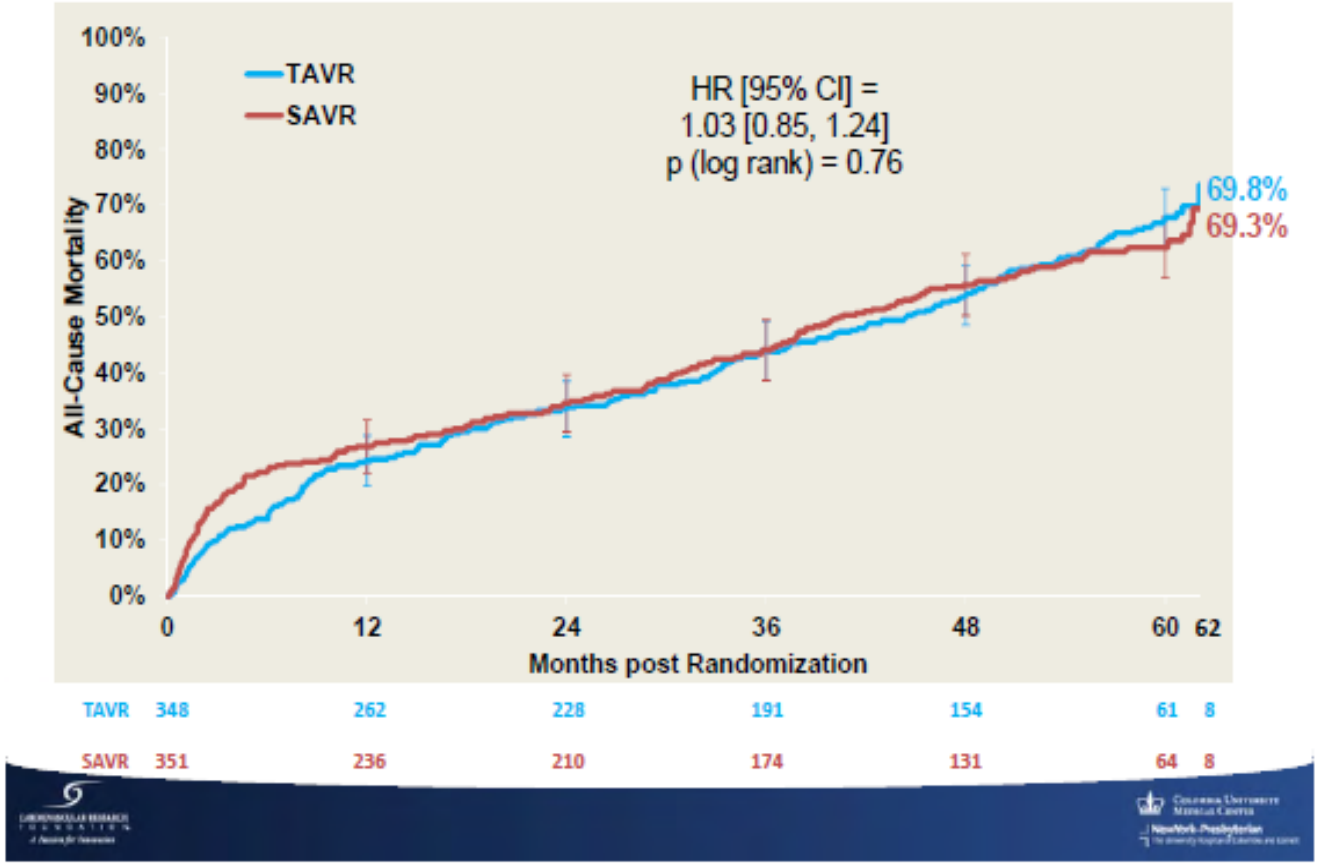
PARTNER Cohort B (TAVR vs Standard Therapy)



** Only 1 standard Rx patient was alive at 5 years who didn't crossover to TAVR or had SAVR (out of protocol)

TAVR is Equivalent to Surgery

PARTNER Cohort A (TAVR vs. SAVR)

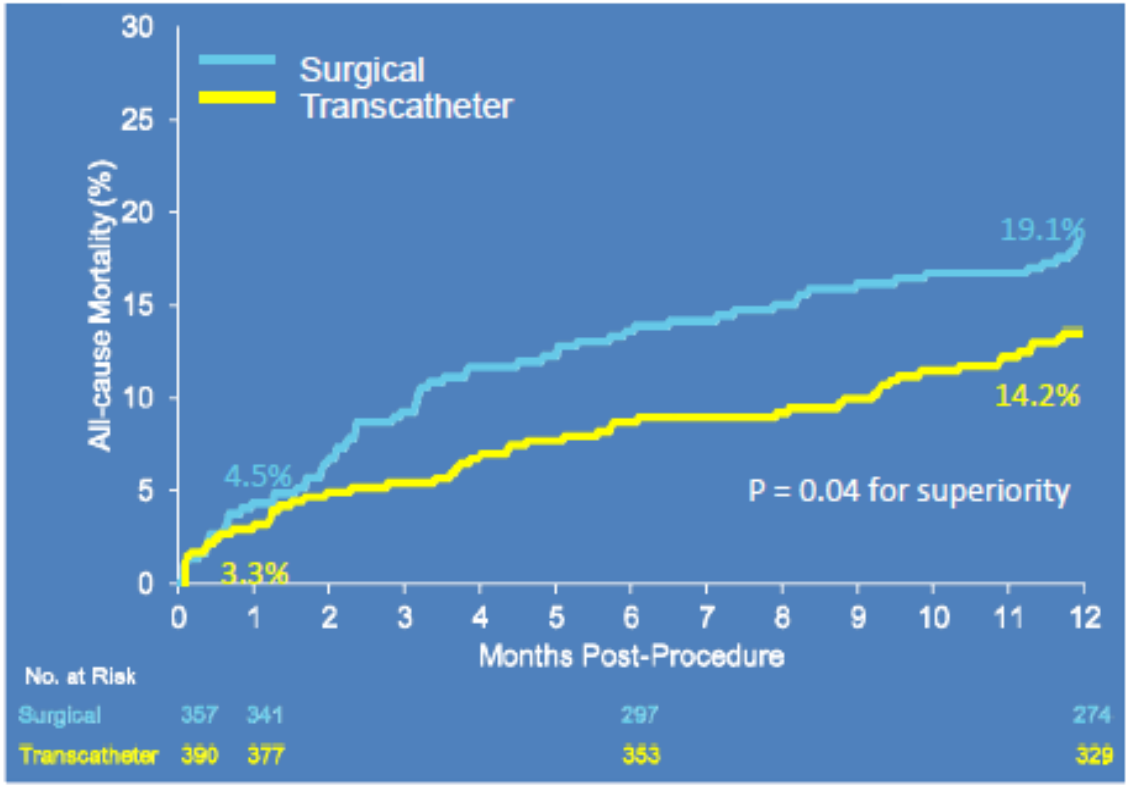


Key Facts About PARTNER Trial

1. Trial started in 2007 - <100 TAVRs done in US
2. Only 6 of the 25 sites had experience with TAVR before PARTNER trial
3. Outcomes of TAVR compared with SAVR in arguably the best surgical centers in the country
4. 22F and 24F devices for transfemoral approach (40% not eligible for TF)
5. Retroflex 1 device used for majority of cases

Is TAVR Superior to Surgery?

CoreValve US Pivotal High Risk Cohort



PARTNER 2A

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael J. Mack, M.D., Raj R. Makkar, M.D., Lars G. Svensson, M.D., Ph.D., Susheel K. Kodali, M.D., Vinod H. Thourani, M.D., E. Murat Tuzcu, M.D., D. Craig Miller, M.D., Howard C. Herrmann, M.D., Darshan Doshi, M.D., David J. Cohen, M.D., Augusto D. Pichard, M.D., Samir Kapadia, M.D., Todd Dewey, M.D., Vasilis Babaliaros, M.D., Wilson Y. Szeto, M.D., Mathew R. Williams, M.D., Dean Kereiakes, M.D., Alan Zajarias, M.D., Kevin L. Greason, M.D., Brian K. Whisenant, M.D., Robert W. Hodson, M.D., Jeffrey W. Moses, M.D., Alfredo Trento, M.D., David L. Brown, M.D., William F. Fearon, M.D., Philippe Pibarot, D.V.M., Ph.D., Rebecca T. Hahn, M.D., Wael A. Jaber, M.D., William N. Anderson, Ph.D., Maria C. Alu, M.M., and John G. Webb, M.D., for the PARTNER 2 Investigators*

PARTNER 2A

The NEW ENGLAND JOURNAL of MEDICINE

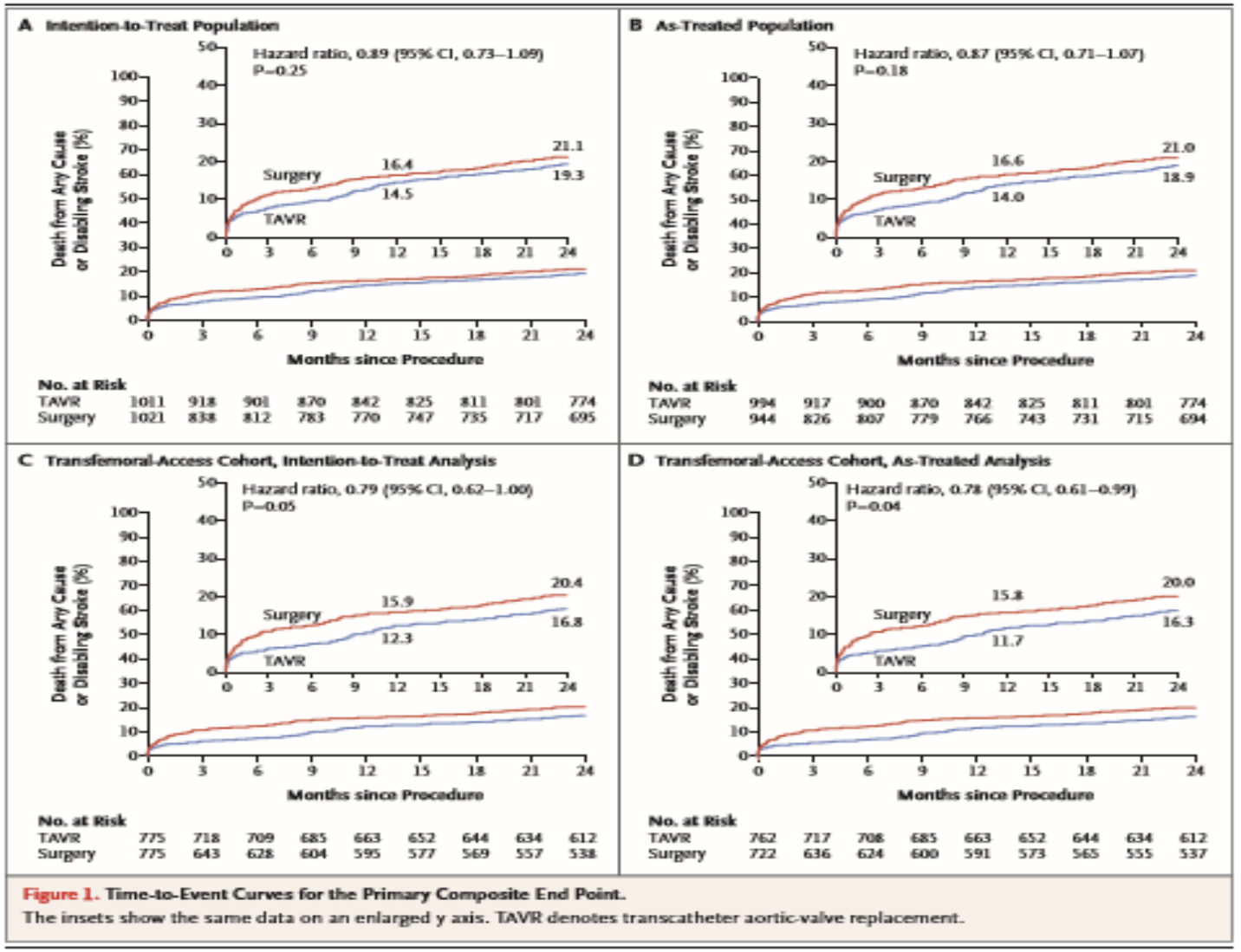


Figure 1. Time-to-Event Curves for the Primary Composite End Point.
The insets show the same data on an enlarged y axis. TAVR denotes transcatheter aortic-valve replacement.

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The NOTION Trial

An All-comers Randomized Clinical Trial Comparing Transcatheter with Surgical Aortic Valve Replacement in Patients with Aortic Valve Stenosis

Lars Søndergaard

The Heart Center, Rigshospitalet, Copenhagen, Denmark

- on behalf of the NOTION Investigators

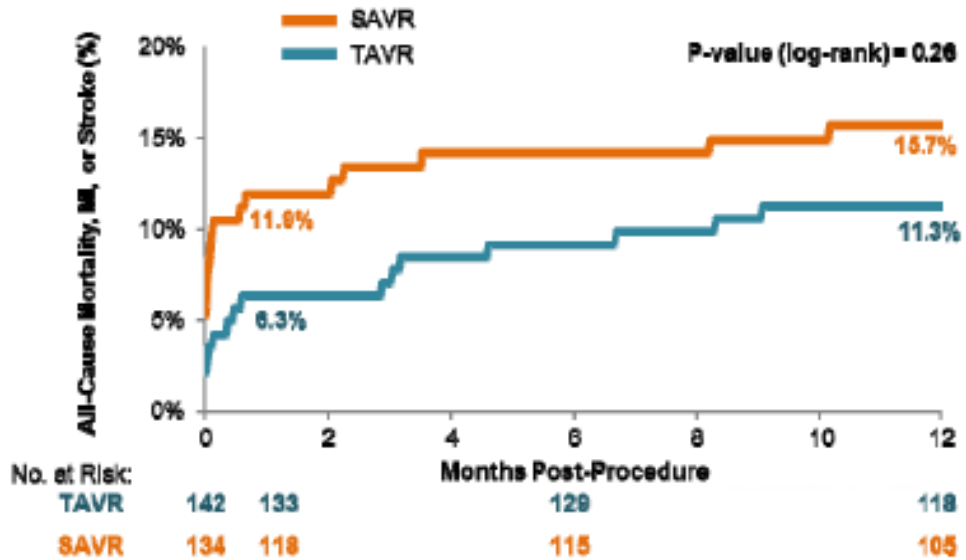
NOTION TRIAL

Baseline Characteristics

Characteristic, % or mean ± SD	TAVR n=145	SAVR n=135	p-value
Age (yrs)	79.2 ± 4.9	79.0 ± 4.7	0.71
Male	53.8	52.6	0.84
STS Score	2.9 ± 1.6	3.1 ± 1.7	0.30
STS Score < 4%	83.4	80.0	0.46
Logistic EuroSCORE I	8.4 ± 4.0	8.9 ± 5.5	0.38
NYHA class III or IV	48.6	45.5	0.61

Notion Trial (All-Comers TAVR vs SAVR)

Death from Any Cause, Stroke or Myocardial Infarction at 1 Year in As-Treated Population



Catheterization and Cardiovascular Interventions 85:E153–E162 (2015)

Outcomes and Predictors of Mortality After Transcatheter Aortic Valve Implantation: Results of the Brazilian Registry

Fábio S. de Brito Jr,[1*] MD, Luiz A. Carvalho,[2] MD, Rogério Sarmento-Leite,[3] MD, José A. Mangione,[4] MD, Pedro Lemos,[5] MD, Alexandre Siciliano,[6] MD, Paulo Caramori,[7] MD, Luiz São Thiago,[8] MD, Eberhard Grube,[9] MD, and Alexandre Abizaid,[1,10] MD, on behalf of the Brazilian TAVI Registry investigators

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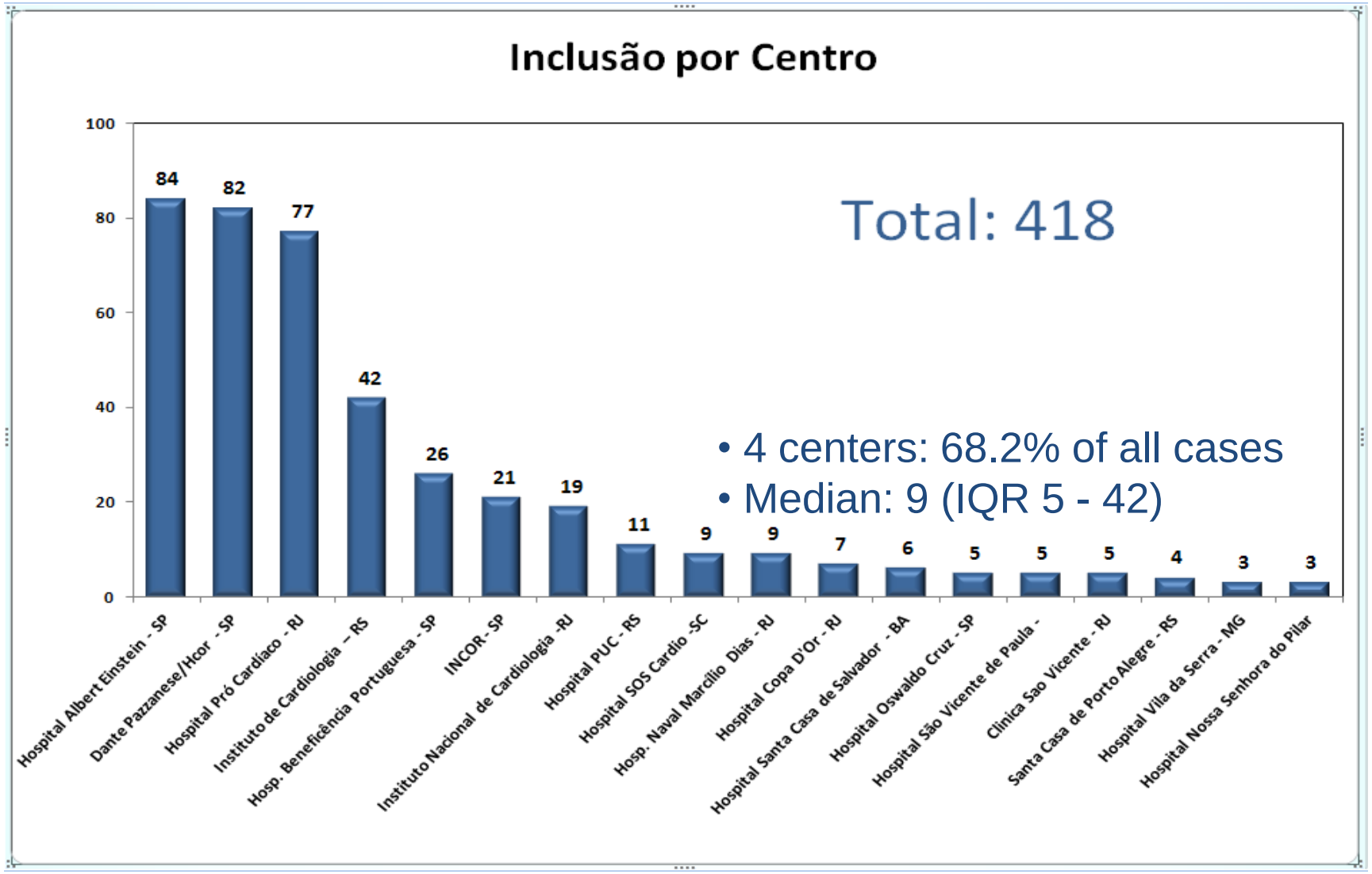
Brazilian TAVI Registry: Inclusion by center



Brazilian TAVI Registry

Baseline Characteristics

Characteristics	(n = 418)
Age, years	81.5 ± 7.7
Male, n (%)	200 (47.8 %)
Logistic EuroScore, %	20.2 ± 13.8
STS Score, %	14.2 ± 11.5
Congestive Heart Failure (NYHA)	
I or II, n (%)	70 (16.8 %)
III or IV, n (%)	348 (83.2 %)
Diabetes, n (%)	133 (31.8 %)
Renal Failure, n (%)*	313 (78.0 %)

* GFR<60ml/min

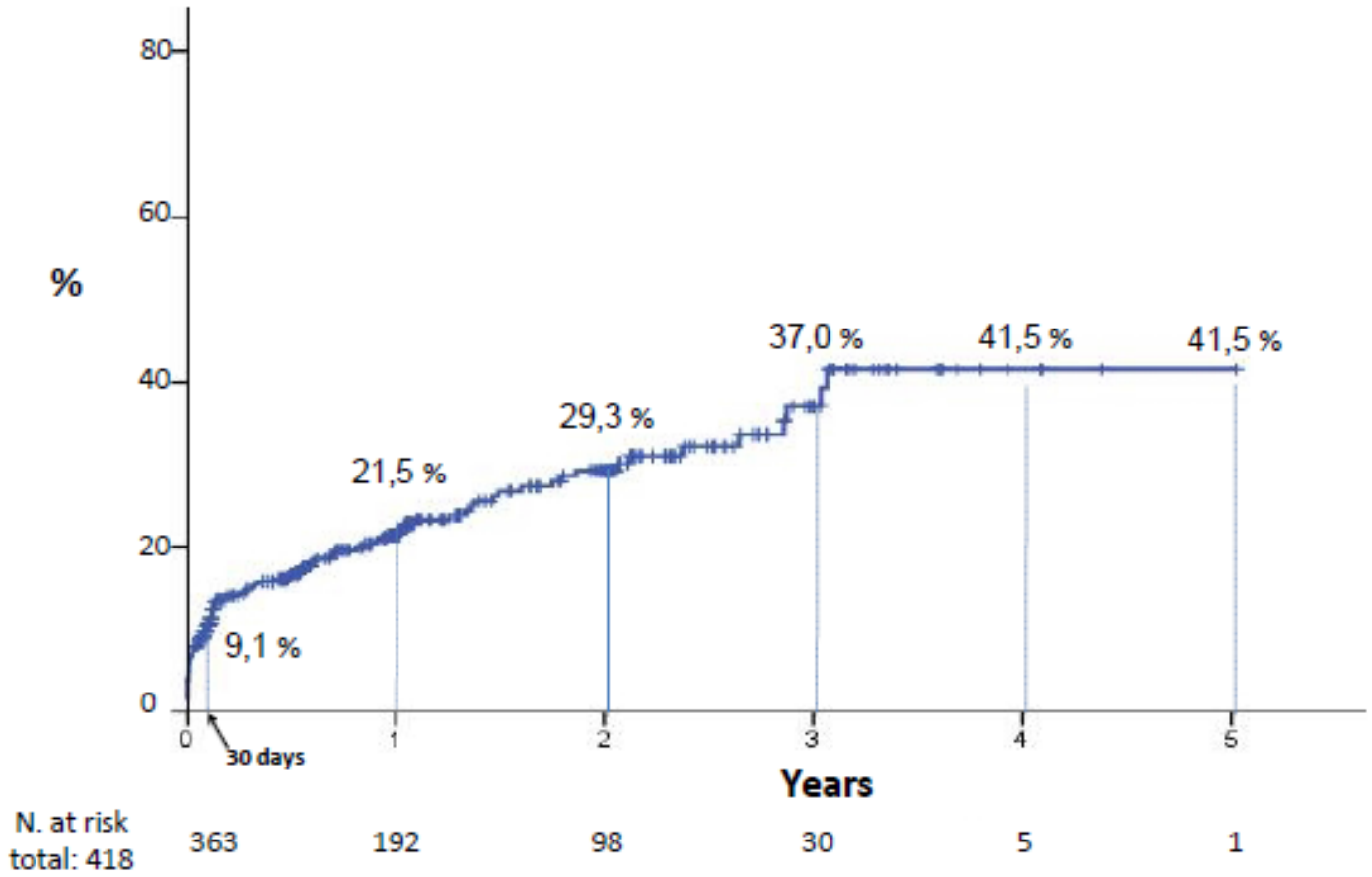
Brazilian TAVI Registry

Procedural Data

	(n = 418)
BAV, n (%)	255 (61%)
Valve-in-Valve, n (%)	13 (3.1%)
Prosthesis	
CoreValve	360 (86.1%)
Sapien XT	58 (13.9%)
Post dilatation, n (%)	146 (39.4%)
Device Success *	319 (76.3%)

* VARC criteria: a single prosthesis implanted in the correct position, with normal function, without moderate or severe AR and with a mean gradient < 20 mmHg

Brazilian TAVI Registry
All-Cause Mortality



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Brazilian TAVI Registry

Independent Predictors of All-Cause Mortality

Overall mortality	HR	CI (95%)		p
		Upper	Lower	
COPD	3.50	2.14	5.73	<0.001
TEE guidance	0.57	0.36	0.91	0.018
Moderate/ severe PVR	2.76	1.51	5.04	0.001
Stroke	2.71	1.30	5.66	0.008
Acute kidney injury	3.07	1.89	4.98	<0.001

Results of Cox proportional-hazards regression model

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Implante de Válvula Aórtica por Catéter: Resultados de 152 casos consecutivos Experiência do Hospital Pró Cardíaco

Implante de Válvula Aórtica por Cateter e Seus Fatores de Morbimortalidade em Experiência de 5 Anos no Brasil

Transcatheter Aortic Valve Implantation and Morbidity and Mortality-Related Factors: a 5-Year Experience in Brazil

André Luiz Silveira Souza[1,2], Constantino González Salgado[1,3], Ricardo Mourilhe-Rocha[1,3], Evandro Tinoco Mesquita[1,2], Luciana Cristina Lima Correia Lima[1], Nelson Durval Ferreira Gomes de Mattos[1], Arnaldo Rabischoffsky[1], Francisco Eduardo Sampaio Fagundes[1], Alexandre Siciliano Colafranceschi[1], Luiz Antonio Ferreira Carvalho[1]

Hospital Pró-Cardíaco[1]; Pós-graduação em Ciências Cardiovasculares – Universidade Federal Fluminense[2]; Pós-graduação em Ciências Médicas – Universidade do Estado do Rio de Janeiro[3], Rio de Janeiro, RJ – Brasil

André Luiz Silveira Souza e Constantino González Salgado tiveram igual participação na confecção deste artigo

Resumo

Fundamento: O implante de válvula aórtica por cateter tornou-se uma opção para pacientes com doença valvar aórtica de elevado risco cirúrgico.

Objetivo: Avaliar os resultados dos seguimentos intra-hospitalar e de até 1 ano do implante de válvula aórtica por cateter.

Métodos: Estudo de coorte prospectiva de casos de implante de válvula aórtica por cateter entre julho de 2009 e fevereiro de 2015. Análise de variáveis clínicas e do procedimento, correlacionando com mortalidade intra-hospitalar e de 1 ano.

Resultados: Foram submetidos ao implante 136 pacientes, com média de idade de 83 (80-87) anos, sendo 49% mulheres, 131 (96,3%) deles com estenose aórtica, um (0,7%) com insuficiência aórtica e quatro (2,9%) com disfunção de prótese. A classe funcional da NYHA foi III ou IV em 129 (94,8%) casos. A área valvar inicial foi 0,67 ± 0,17 cm² e o gradiente ventrículo esquerdo-aorta médio de 47,3 ± 18,2 mmHg, com STS de 9,3% (4,8%-22,3%). As próteses implantadas eram autoexpansíveis em 97% dos casos. A mortalidade peroperatória em 1,5% dos casos; em 30 dias em 5,9%; intra-hospitalar em 8,1%; e após 1 ano em 15,5% dos casos. A hemotransfusão (risco relativo de 54; p = 0,0003) e a hipertensão arterial pulmonar (risco relativo de 5,3; p = 0,036) foram preditoras de mortalidade hospitalar; e a proteína C-reativa pico (risco relativo de 1,8; p = 0,013) e a hemotransfusão (risco relativo de 8,3; p = 0,0009) de mortalidade em 1 ano. Aos 30 dias, 97% dos pacientes estavam em classe NYHA I/II e, em 1 ano, o número chegou a 96%.

Conclusão: O implante de válvula aórtica por cateter foi realizado com alto índice de sucesso e baixa mortalidade. A hemotransfusão associou-se com maior mortalidade hospitalar e de 1 ano. Proteína C-reativa pico se associou com a mortalidade de 1 ano. (Arq Bras Cardiol. 2016; 106(6):519-527)

Palavras-chave: Estenose da Valva Aórtica / cirurgia; Mortalidade; Implante de Prótese; Valvuloplastia com Balão; Estudos de Coortes.

Resultados - Dados demográficos

	n = 152
Idade (anos)	83,0 ± 7,3
Sexo Masculino	74 (48 %)
IMC	25,7 ± 5,1
Classe Funcional *NYHA*	
II	11 (7%)
III	87 (57%)
IV	54 (36%)
Área Valvar Aórtica (cm^2)	0,6 ± 0,2
Gradiente VE-Ao médio (Eco, mmHg)	50,8 ± 16,2
Euroscore I	24,1±15,3
Valvuloplastia aórtica por balão prévia	9 (6%)
Cirurgia cardíaca prévia	
RVM	36 (24%)
Prótese Mitral	3 (2%)
Prótese Aórtica	3 (2%)
FE VE <40% (ecocardiograma)	35 (23%)

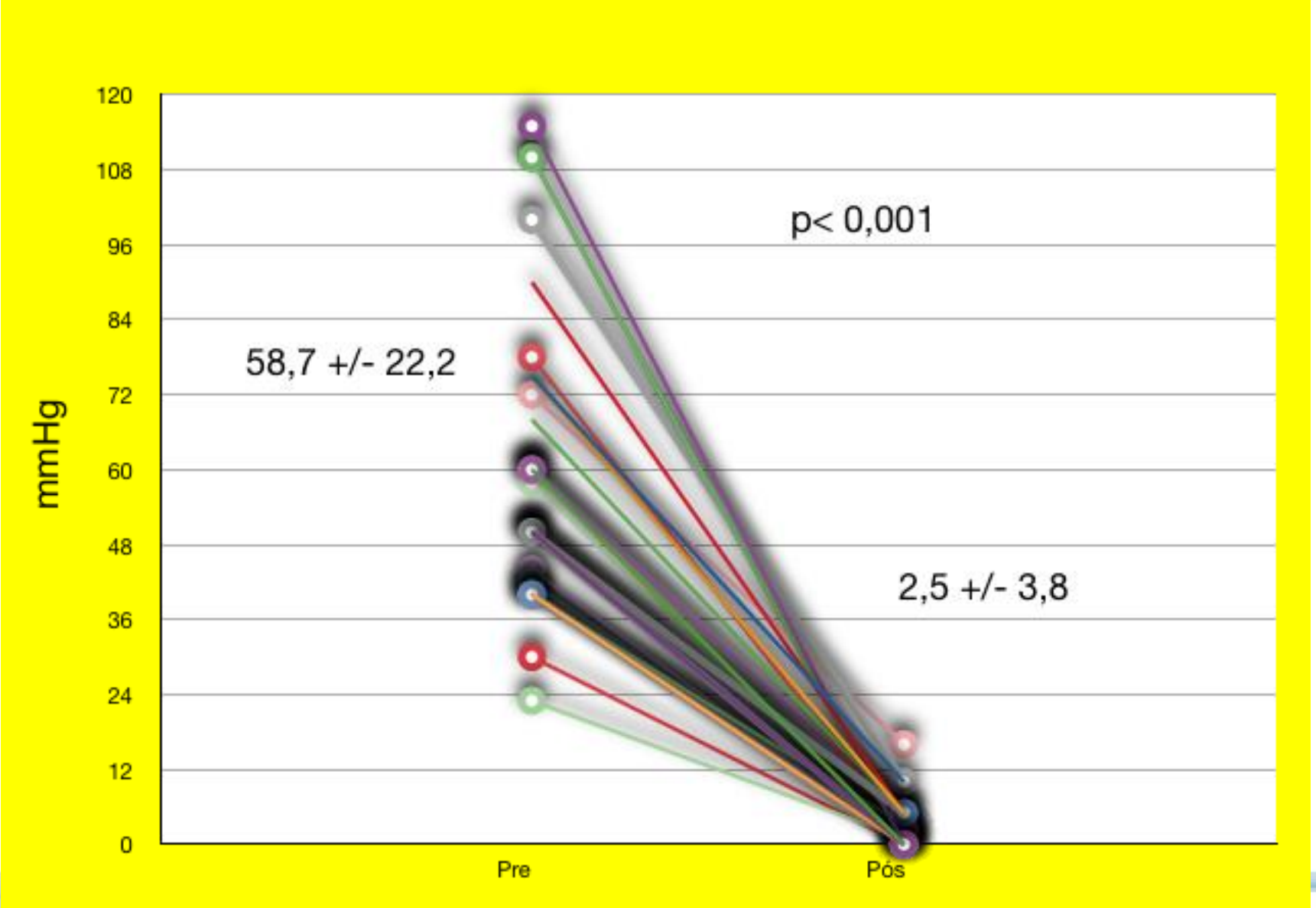
Resultados Comorbidades

	n = 152
Hipertensão Arterial Pulmonar	39 (25,6%)
Doença Respiratória Crônica	27 (17,7%)
Insuficiência Renal Crônica (Cl < 60)	79 (51,9%)
Doença Arterial Coronariana	83 (54,6%)
Doença Valvar Mitral	
Estenose Mitral (AVM <2,0 cm^2)	7 (4,6%)
Insuficiência Mitral (>2+/4)	12 (7,8%)
Prótese Mitral	3 (2,0%)
Ritmo cardíaco	
FA permanente	17 (11%)
Ritmo de marcapasso	21 (14%)

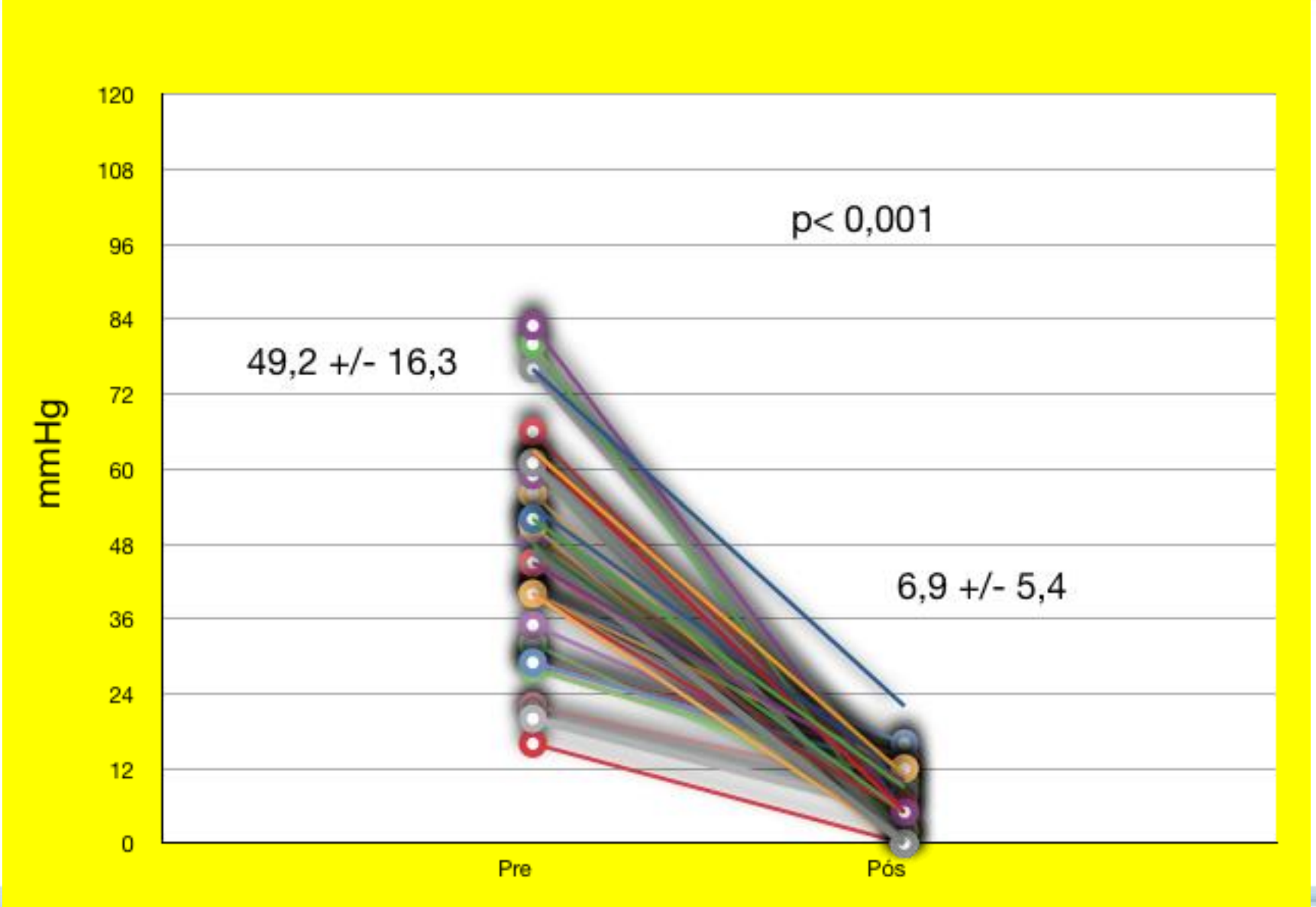
Resultados - Procedimento

	n = 152
Anestesia geral	134 (88%)
Contraste (ml)	143 +/- 35
ATC associada	13 (8,5%)
Acesso	
Femoral	142 (93%)
Subclávia Esquerda	9 (6%)
Transaórtico	1 (1%)
Implante direto (sem pre-dilatação)	25 (16,4%)
Tamanho da Prótese	
CoreValve 26 mm	65 (42,7%)
CoreValve 29 mm	76 (50%)
Corevalve 31 mm	11 (7,3%)

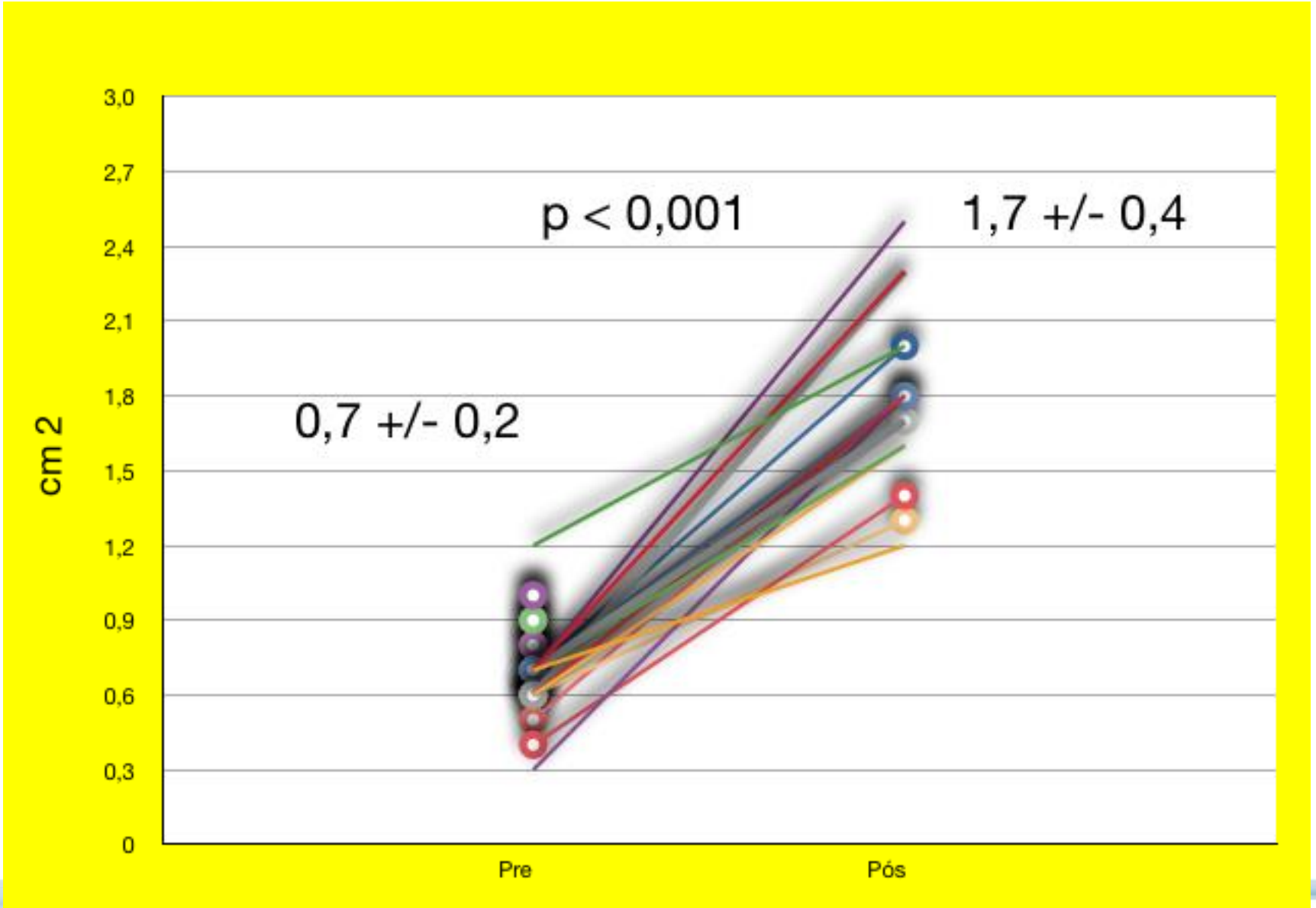
Gradiente Invasivo - (pico a pico)



Gradiente VE- Ao médio (ECO)



Area Valvar Aórtica (eco)



Resultados Imediatos

	n =152
Sucesso do Procedimento	**151 (99%)**
Sucesso do Dispositivo	**135 (88%)**
Complicações em Sala	
Óbito	**1 (0,6%)**
Insuficiência Aórtica >leve	**11 (7,2%)**
AVC	**2 (1,6%)**
Vasculares	**6 (3,9%)**
IAM	**0**
Marcapasso Definitivo	**35 /133(26%)**

Resultados de 30 dias

	n = 152
Óbito	8 (5,2%)
Complicações	
Cirurgia Cardíaca ou ECMO	2 (1,3%)
IAM	0
AVC	2 (1,3%)
Reintervenções	1 (0,6%)
Nefropatia com diálise	6 (3,9%)
Hemotransfusões	23 (15,1%)
Sangramento ameaçador à vida	7 (4,6%)

RESULTADOS

Registro	Morte 30 dias	Morte 1 ano
Canadá (n=339)	10,4%	24%
SOURCE (n=1038)	8,5%	24%
Europeu (n=646)	8,4%	-
Itália (n=663)	5,4%	15%
França (n=244)	12,7%	-
Alemanha (n=697)	12,4%	-
Bélgica (n=328)	11%	21%
Inglaterra (n=870)	7,1%	22%
PROCARDÍACO (N=100)	**5,2%**	**17,7%**

TAVR

Current Reality

- TAVR works!!!
- Patients (and physicians) want a less invasive therapy
- Risk/benefit thresholds vary with age

TAVR has been integrated into treatment algorithm and will continue to move into lower risk patient population

Rio2016