



Patient Selection for TAVI: The US Perspective

Charanjit S. Rihal MD MBA
Professor of Medicine
Chair, Division of
Cardiovascular Diseases

Mayo Clinic and Foundation
Rochester, MN, USA

Disclosures

- **Research: Edwards Lifesciences**

PARTNER: Why is it important?

- **Establishes unbiased evidence base to support FDA submission**
- **Provides real guidelines for clinical practice**
- **Opens doors to new investigations in aortic stenosis**
- **Provides more options for elderly patients**

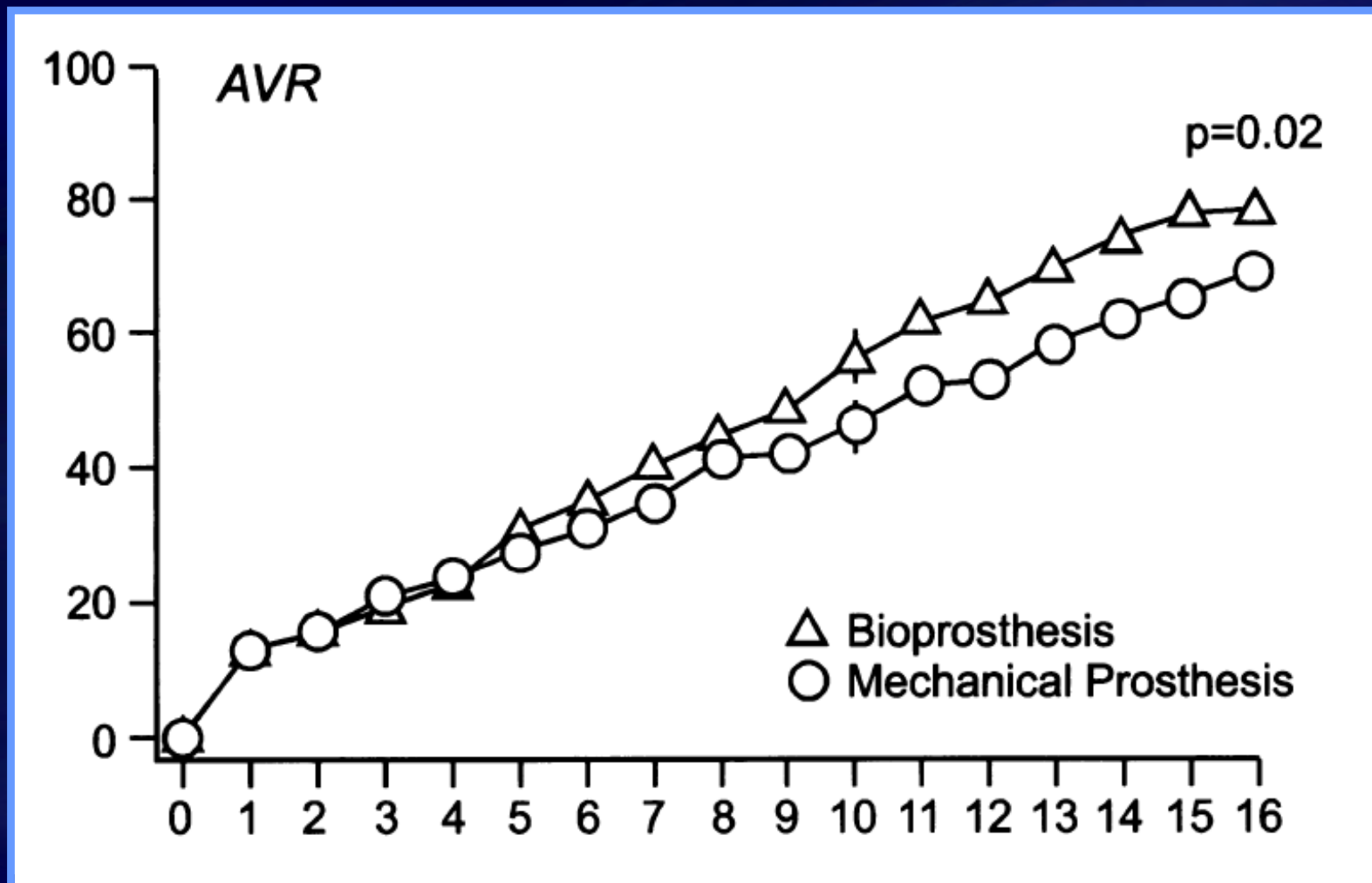
Choice of Valve Prosthesis in the Elderly

- What age is “Elderly”?
- 20 years older than I am?



All-Cause Mortality: AVR

VA Study 1977-82, N=575



Choice of Valve Prosthesis in the Elderly



Advantage

- Excellent durability

Risk

- Thromboembolism and hemorrhage

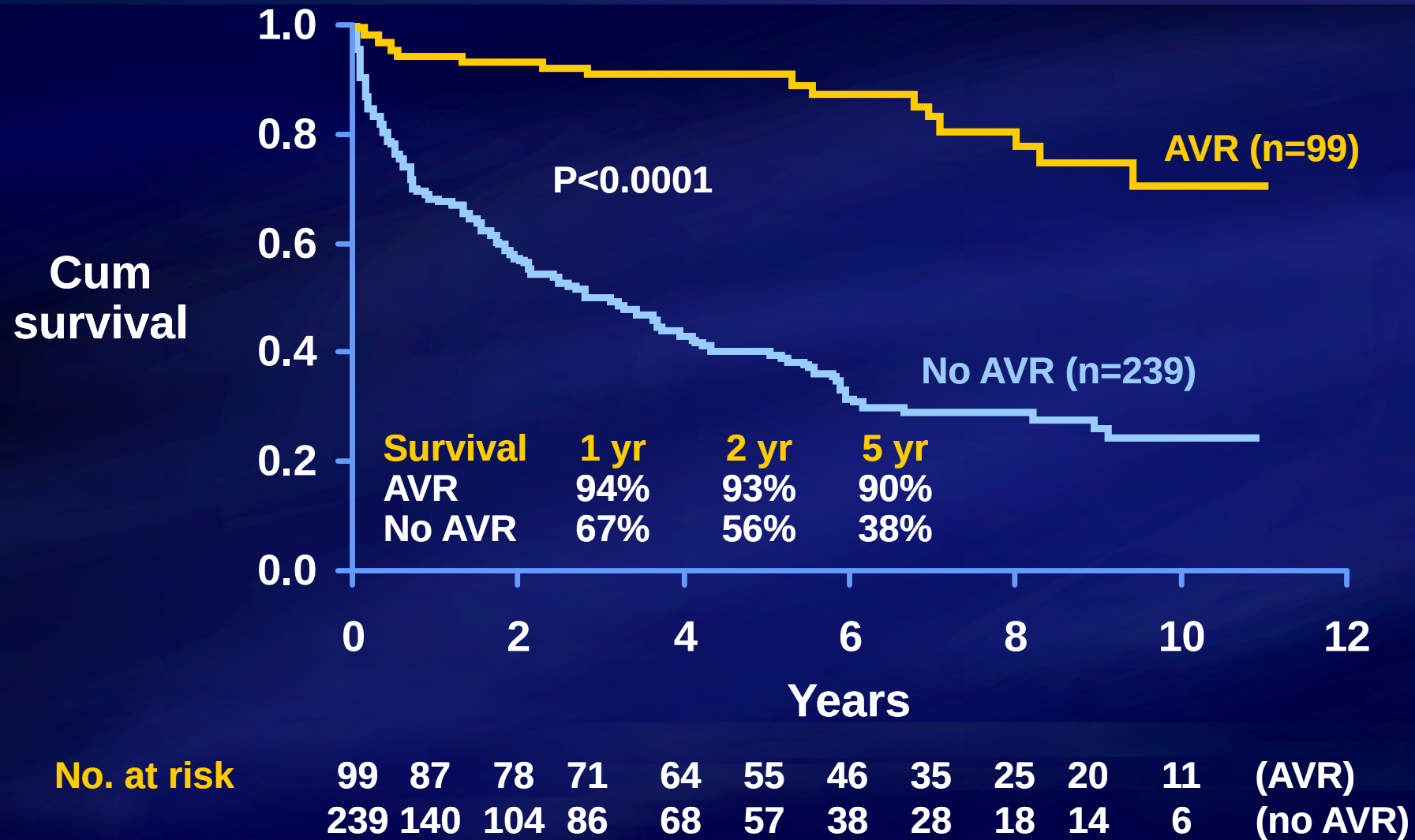
Advantage

- No anticoagulation

Risk

- Reoperation

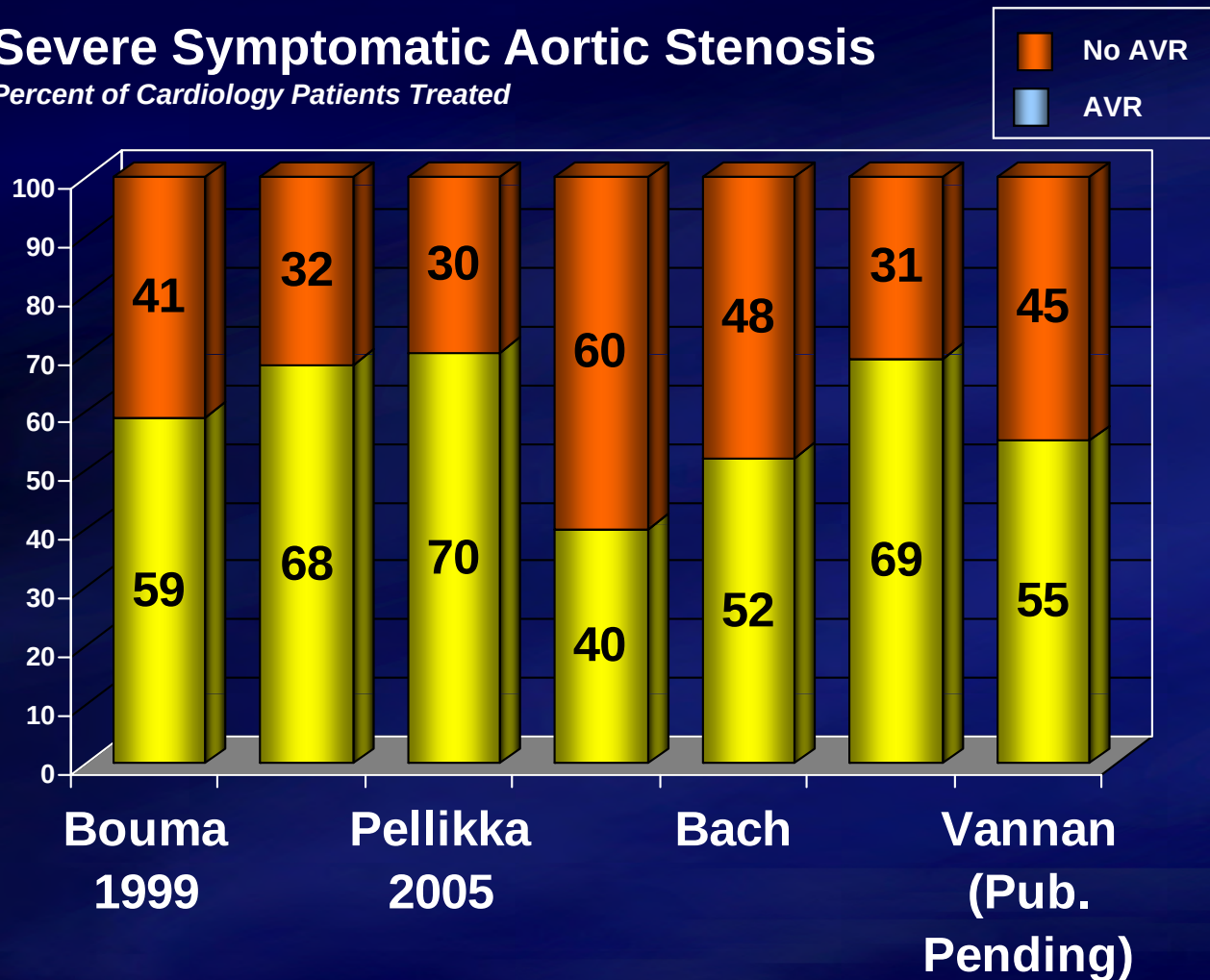
Kaplan-Meier Survival Curves Comparing Asymptomatic Severe Aortic Stenosis Patients with and without Aortic Valve Replacement



At least 30-40% Of Clinical Cardiologists' AS Patients Go Untreated

Severe Symptomatic Aortic Stenosis

Percent of Cardiology Patients Treated



**Under-treatment
especially
prevalent among
patients
managed by
Primary Care
physicians**

1. Bouma B J et al. To operate or not on elderly patients with aortic stenosis: the decision and its consequences. *Heart* 1999;82:143-148
2. Iung B et al. A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. *European Heart Journal* 2003;24:1231-1243 (*includes both Aortic Stenosis and Mitral Regurgitation patients)
3. Pellikka, Sarano et al. Outcome of 622 Adults with Asymptomatic, Hemodynamically Significant Aortic Stenosis During Prolonged Follow-Up. *Circulation* 2005
4. Charlson E et al. Decision-making and outcomes in severe symptomatic aortic stenosis. *J Heart Valve Dis* 2006;15:312-321



HOME

ARTICLES ▾

ISSUES ▾

SPECIALTIES & TOPICS ▾

FOR AUTHORS ▾

Keyword, Title, ...

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

Martin B. Leon, M.D., Craig R. Smith, M.D., Michael Mack, M.D., D. Craig Miller, M.D., Jeffrey W. Moses, M.D., Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D., Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela S. Douglas, M.D., John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D., and Stuart Pocock, Ph.D. for the PARTNER Trial Investigators

September 22, 2010 (10.1056/NEJMoa1008232)

Abstract

Article

References

BACKGROUND

Many patients with severe aortic stenosis and coexisting conditions are not candidates for surgical replacement of the aortic valve. Recently, transcatheter aortic-valve implantation (TAVI) has been suggested as a less invasive treatment for high-risk patients with aortic stenosis.

[Full Text of Background...](#)

METHODS

We randomly assigned patients with severe aortic stenosis, whom surgeons considered not to be suitable candidates for surgery, to standard therapy (including balloon aortic valvuloplasty) or transfemoral transcatheter implantation of a balloon-expandable bovine pericardial valve. The primary end point was the rate of death from any cause.

[Full Text of Methods...](#)

RESULTS

A total of 358 patients with aortic stenosis who were not considered to be suitable candidates for surgery underwent randomization at 21 centers (17 in the United States). At 1 year, the rate of death from any cause (Kaplan–Meier analysis) was 30.7% with TAVI, as compared with 50.7% with standard therapy (hazard ratio with TAVI, 0.55; 95% confidence interval [CI], 0.40 to 0.74; $P<0.001$). The rate of the composite end point of death from any cause or repeat

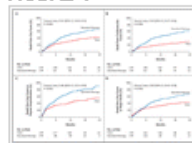
MEDIA IN THIS ARTICLE

Video



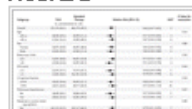
Two Videos Showing Fluoroscopy and Animation of the TAVI Procedure.

FIGURE 1



Time-to-Event Curves for the Primary End Point and Other Selected End Points.

FIGURE 2



PARTNER Cohort B

**Published on-line
Sept 23, 2010**

**Presented TCT
Sept 24, 2010**

**One of the most
important RCTs done
in the history of
cardiology**

Enrollment - Inoperable



n = 358 patients

21 Investigator Sites

17 USA, 3 Canada, 1 Germany

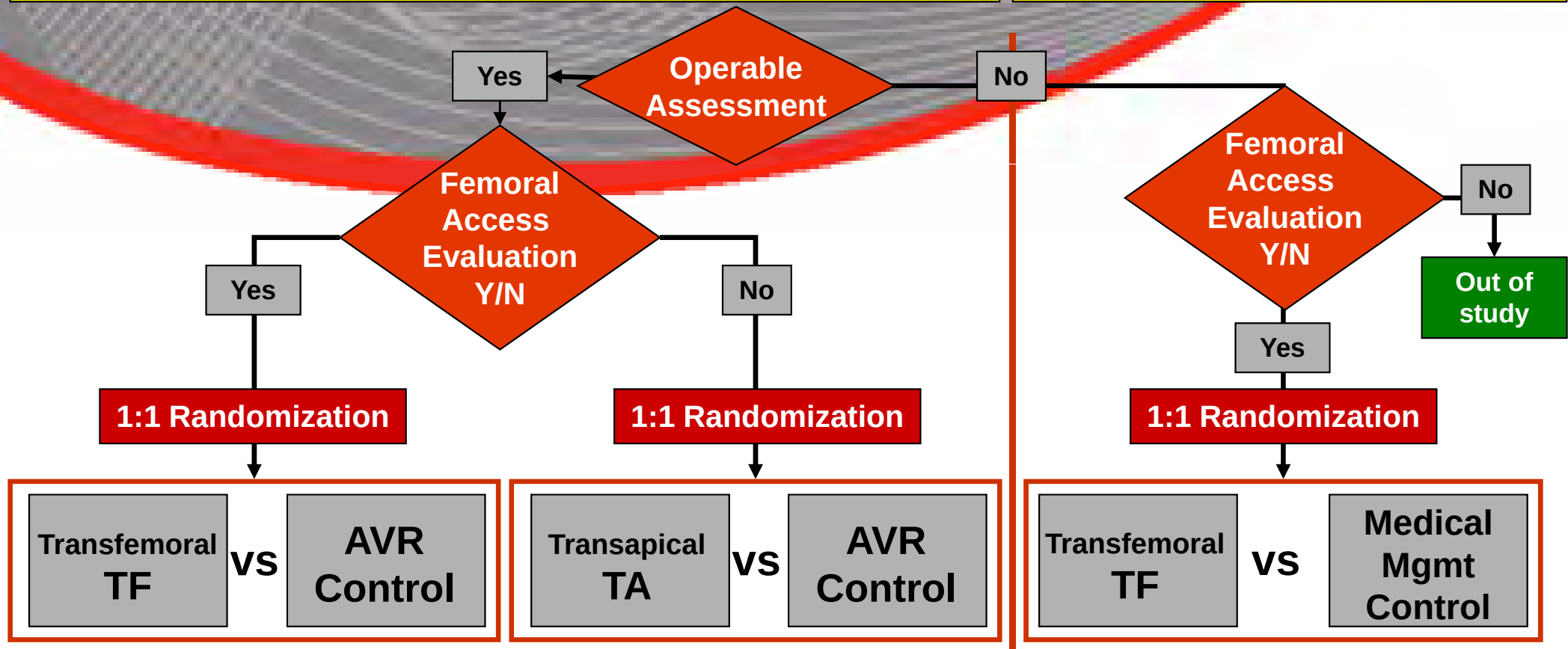
PARTNER Trial 2.0:

One Valve, Two delivery systems, TF & TA

Eligibility Met For High Risk
Symptomatic, Critical Calcific Aortic Stenosis

Surgical (Cohort A); N=690

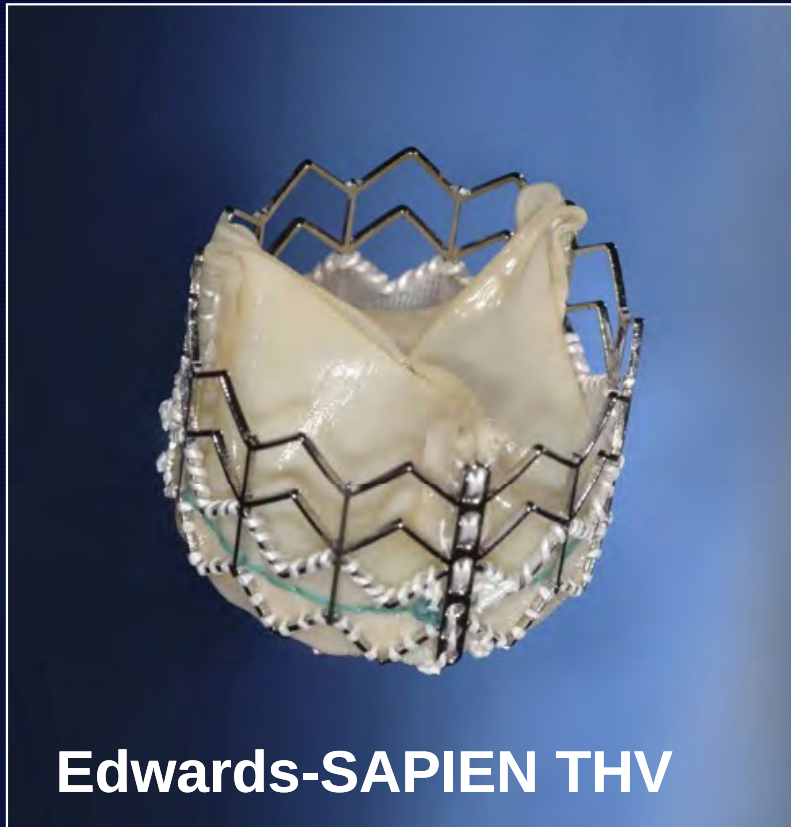
Medical Mgmt (Cohort B); N=350



Sub-group analyses:

- TA vs. control
- TF vs. control
- TF and TA vs. control (combined)

Study Devices



Edwards-SAPIEN THV

***23mm and 26mm
valve sizes***



Retroflex 1

***22F and 24F
sheath sizes***

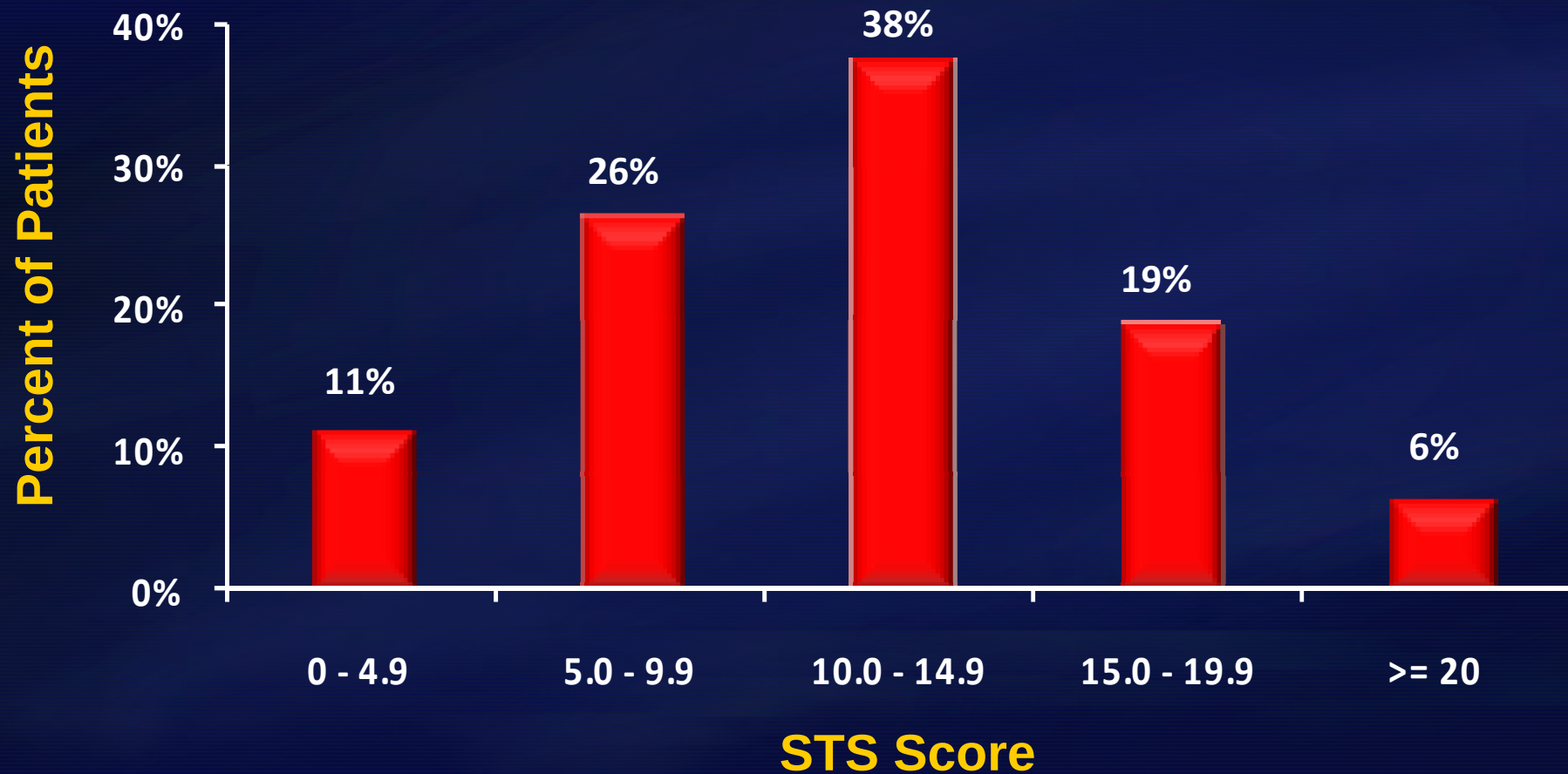
Patient Characteristics - 1

Characteristic	TAVI n=179	Standard Rx n=179	P value
Age - yr	83.1 ± 8.6	83.2 ± 8.3	0.95
Male sex (%)	45.8	46.9	0.92
STS Score	11.2 ± 5.8	12.1 ± 6.1	0.14
Logistic EuroSCORE	26.4 ± 17.2	30.4 ± 19.1	0.04
NYHA			
I or II (%)	7.8	6.1	0.68
III or IV (%)	92.2	93.9	0.68
CAD (%)	67.6	74.3	0.20
Prior MI (%)	18.6	26.4	0.10
Prior CABG (%)	37.4	45.6	0.17
Prior PCI (%)	30.5	24.8	0.31
Prior BAV (%)	16.2	24.4	0.09
CVD (%)	27.4	27.5	1.00

Patient Characteristics - 2

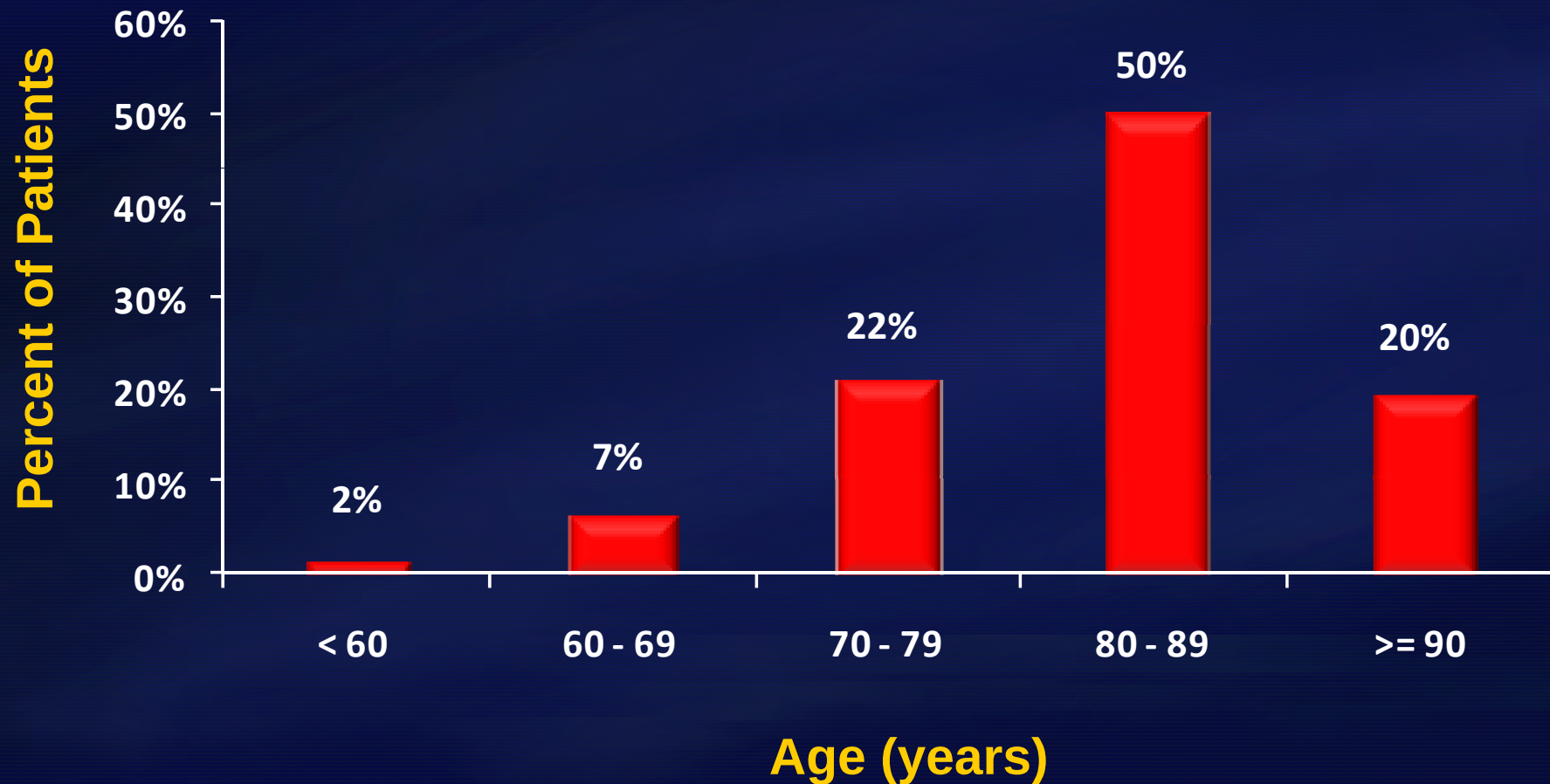
Characteristic	TAVI n=179	Standard Rx n=179	P value
PVD (%)	30.3	25.1	0.29
COPD			
Any (%)	41.3	52.5	0.04
O2 dependent (%)	21.2	25.7	0.38
Creatinine >2mg/dL (%)	5.6	9.6	0.23
Atrial fibrillation (%)	32.9	48.8	0.04
Perm pacemaker (%)	22.9	19.5	0.49
Pulmonary HTN (%)	42.4	43.8	0.90
Frailty (%)	18.1	28.0	0.09
Porcelain aorta (%)	19.0	11.2	0.05
Chest wall radiation (%)	8.9	8.4	1.00
Chest wall deformity (%)	8.4	5.0	0.29

Distribution of STS Scores

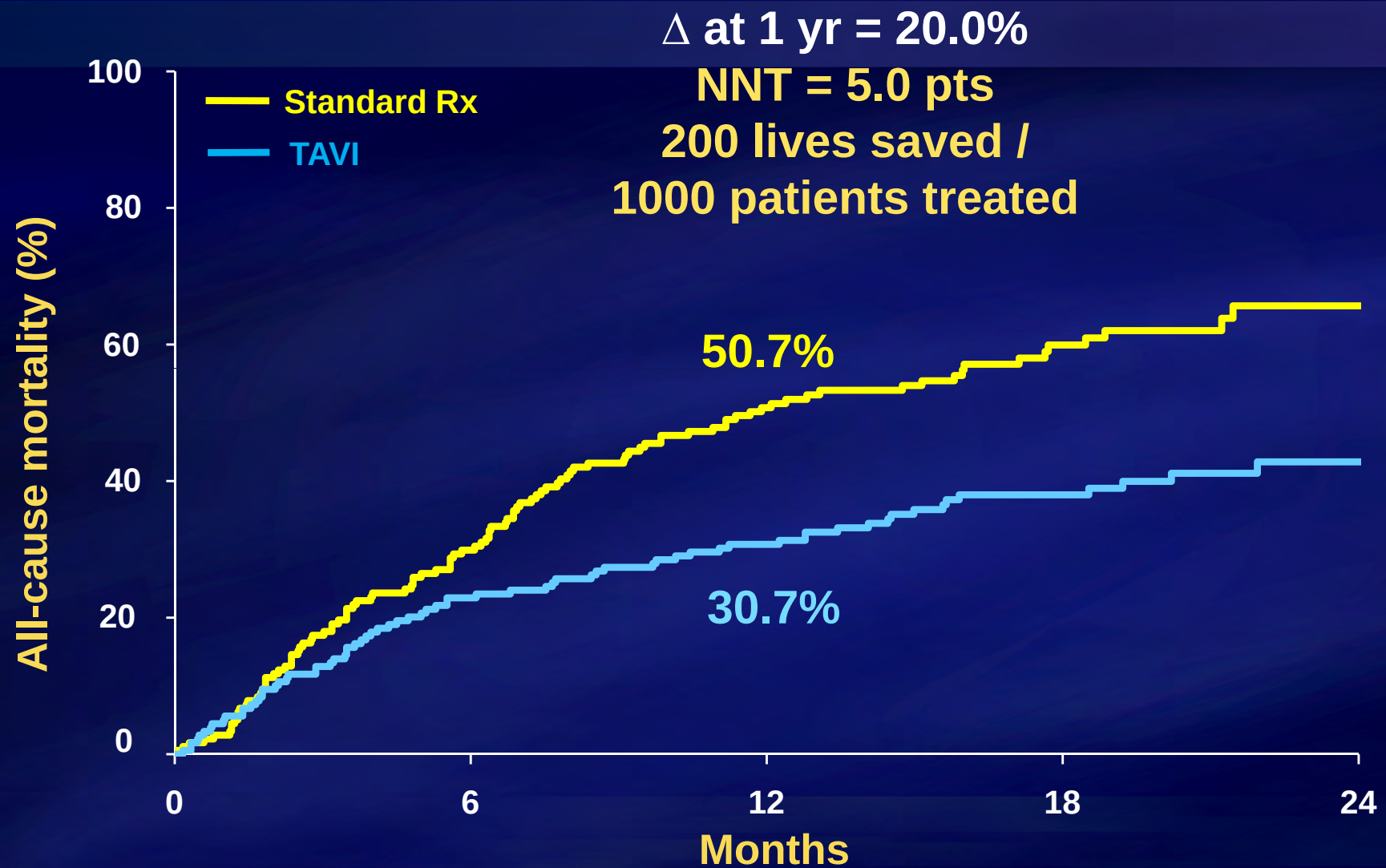


Distribution of Patient Age

70% of patients ≥ 80 years old



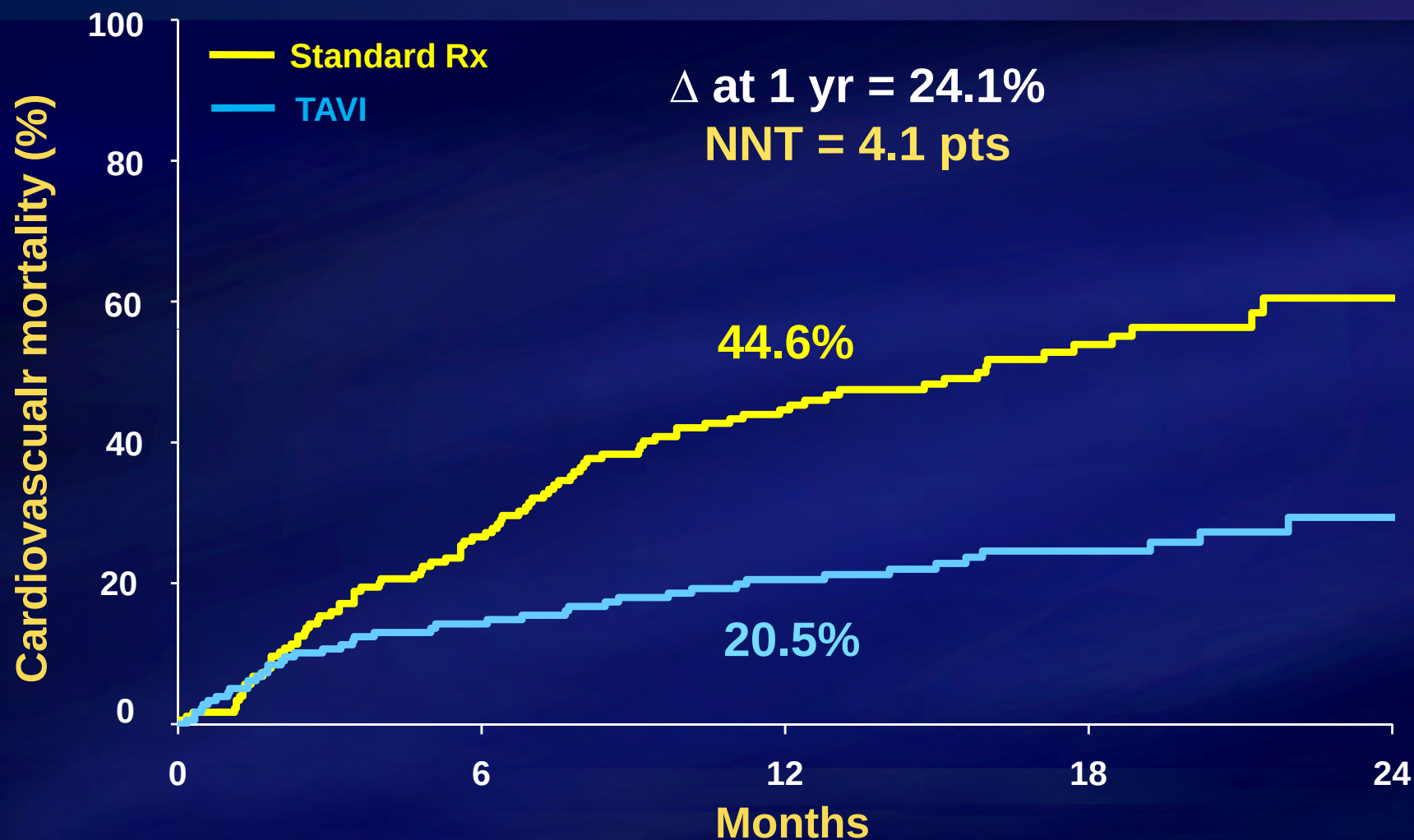
All Cause Mortality



Numbers at Risk

TAVI	179	138	122	67	26
Standard Rx	179	121	83	41	12

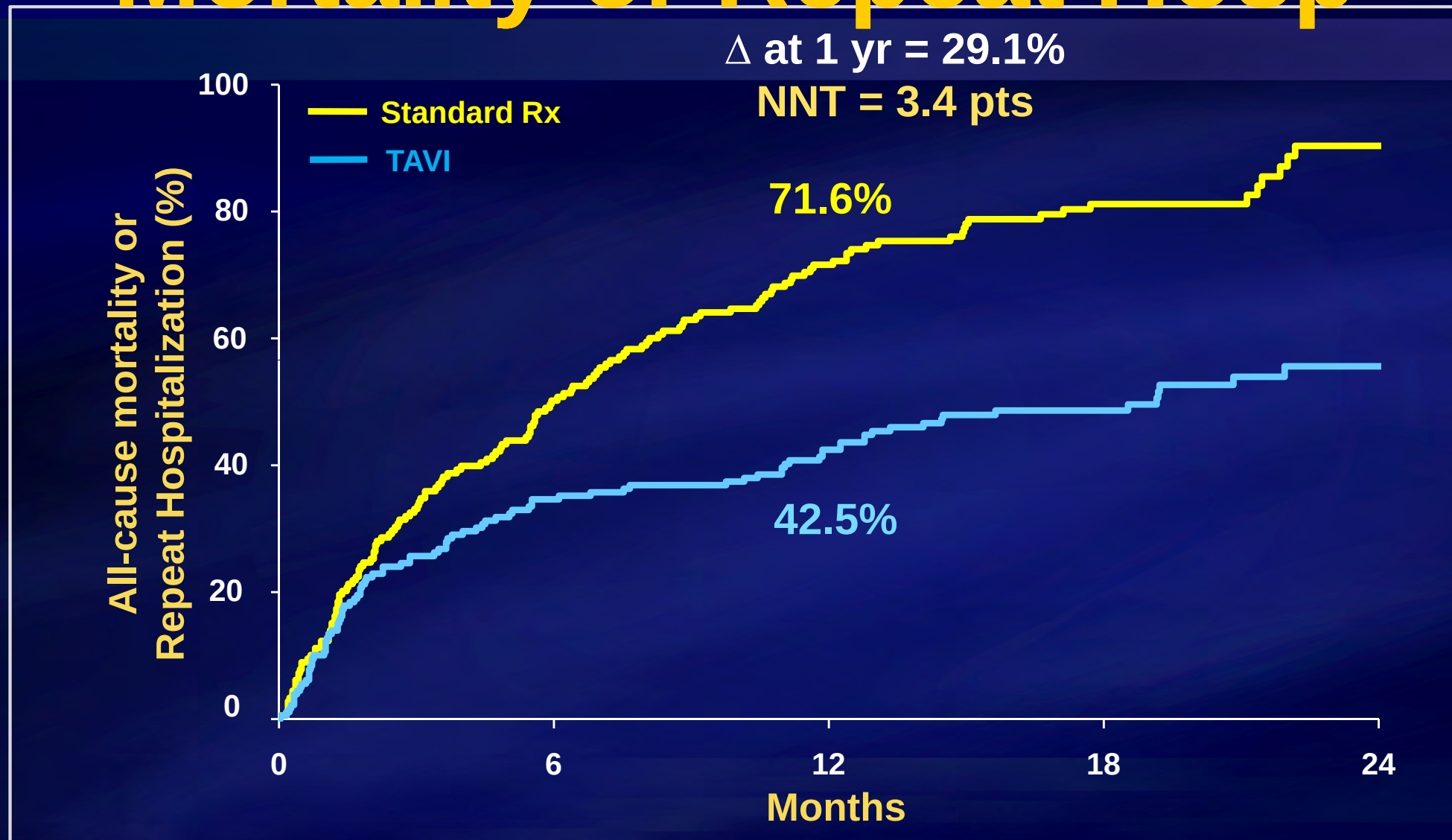
Cardiovascular Mortality



Numbers at Risk

TAVI	179	138	122	67	26
Standard Rx	179	121	83	41	12

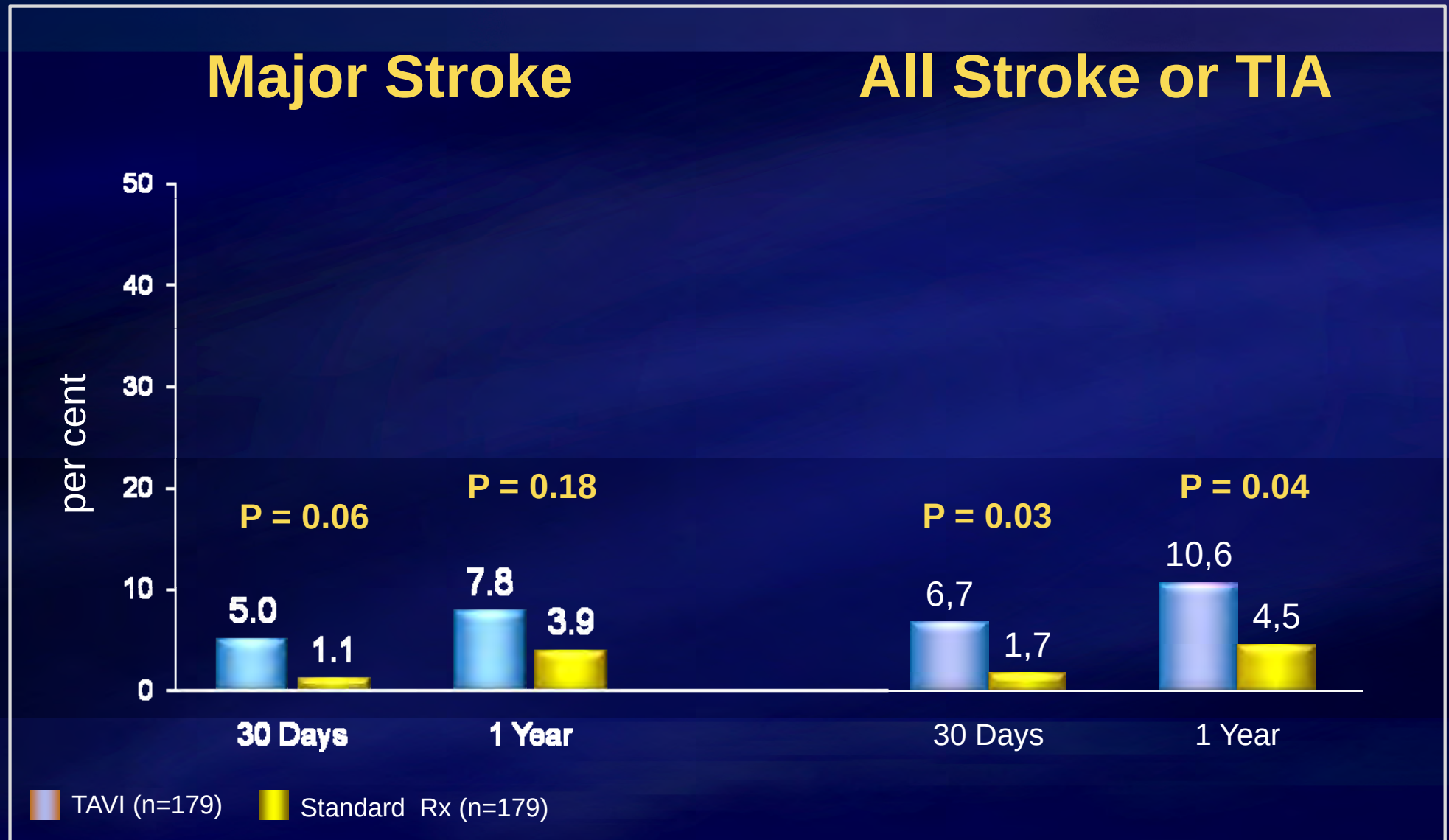
Mortality or Repeat Hosp



Numbers at Risk

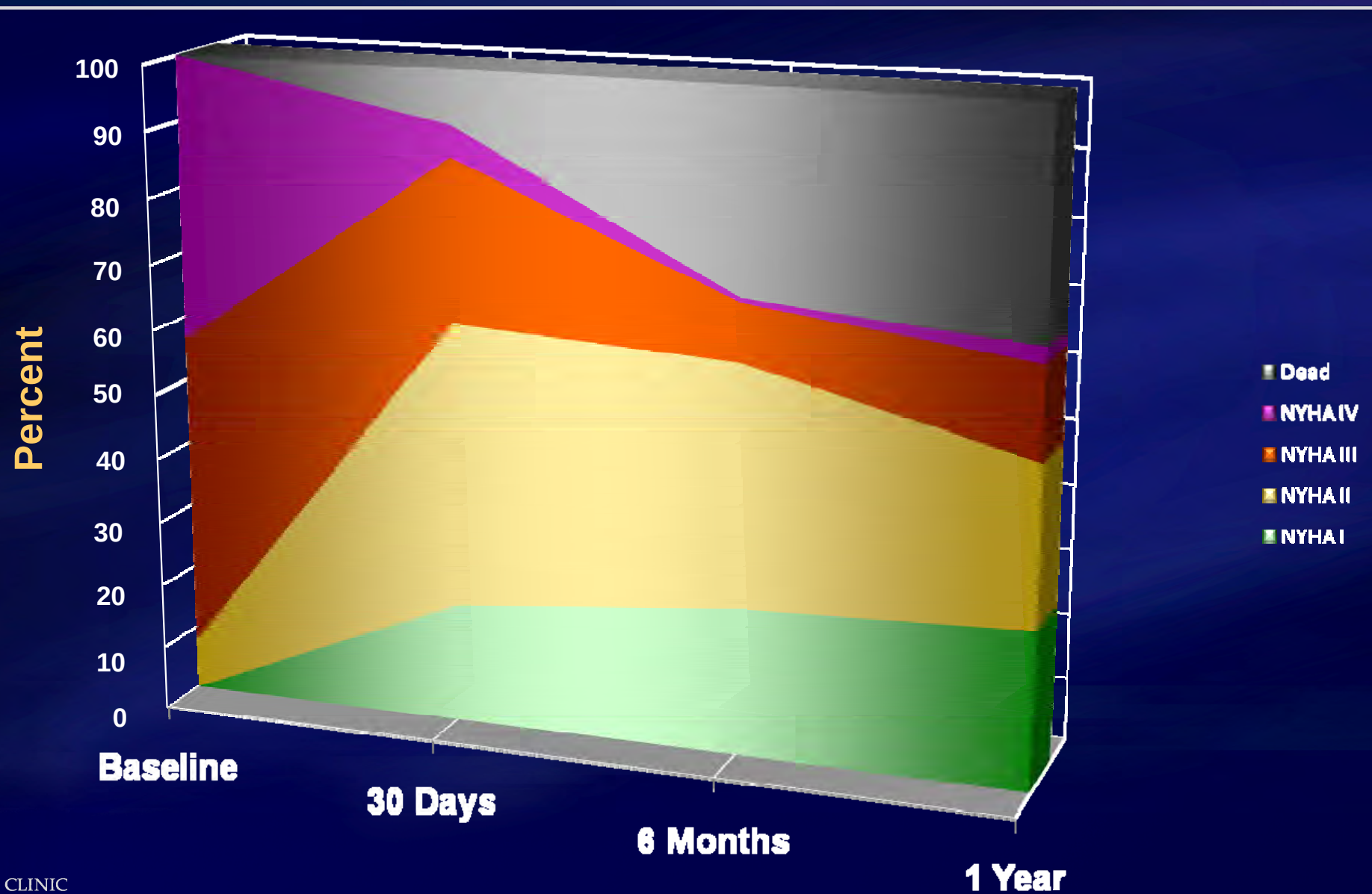
TAVI	179	117	102	56	22
Standard Rx	179	121	49	23	4

Periprocedural Stroke Remains an Issue



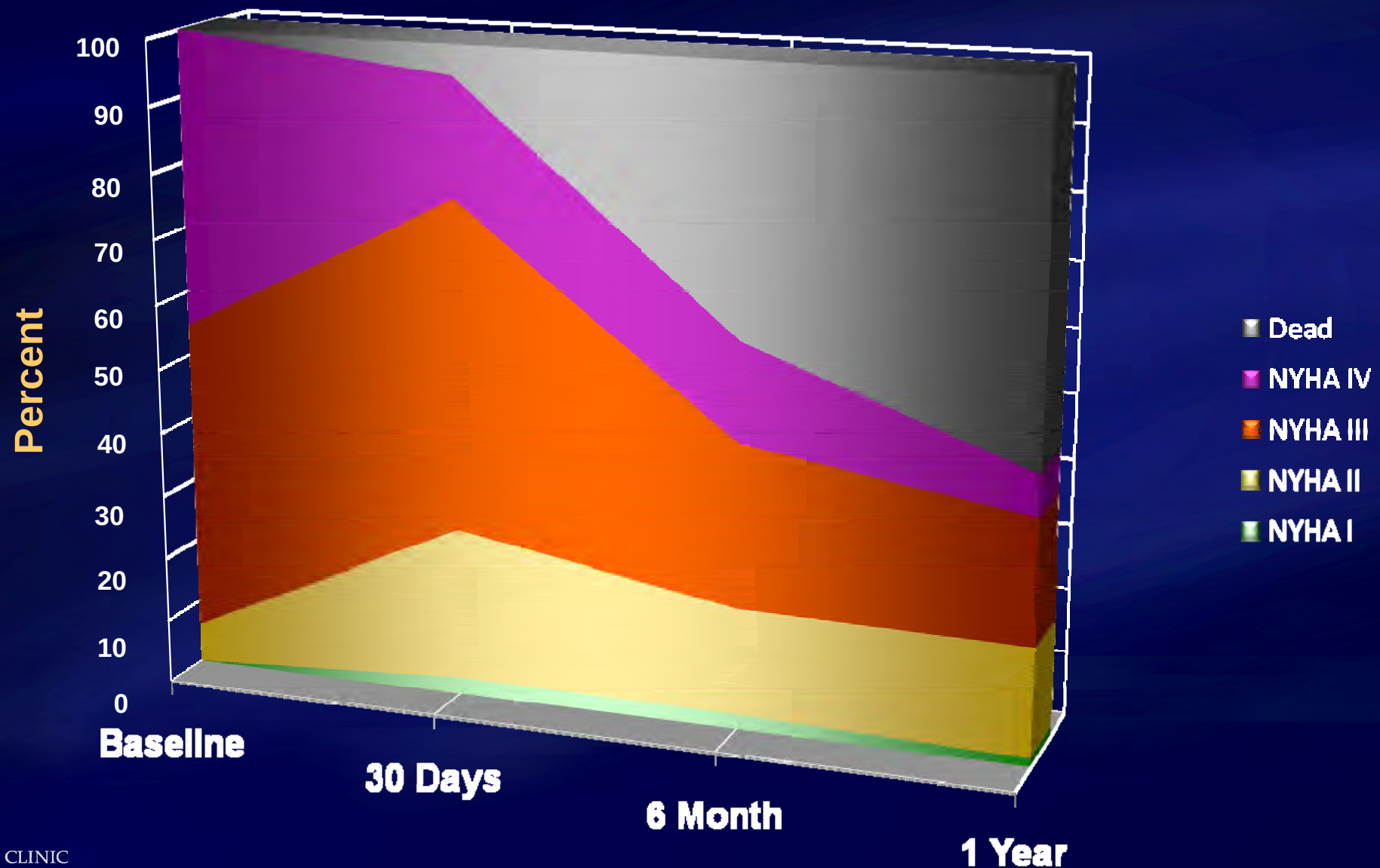
NYHA Class Over Time

TAVI (all patients)

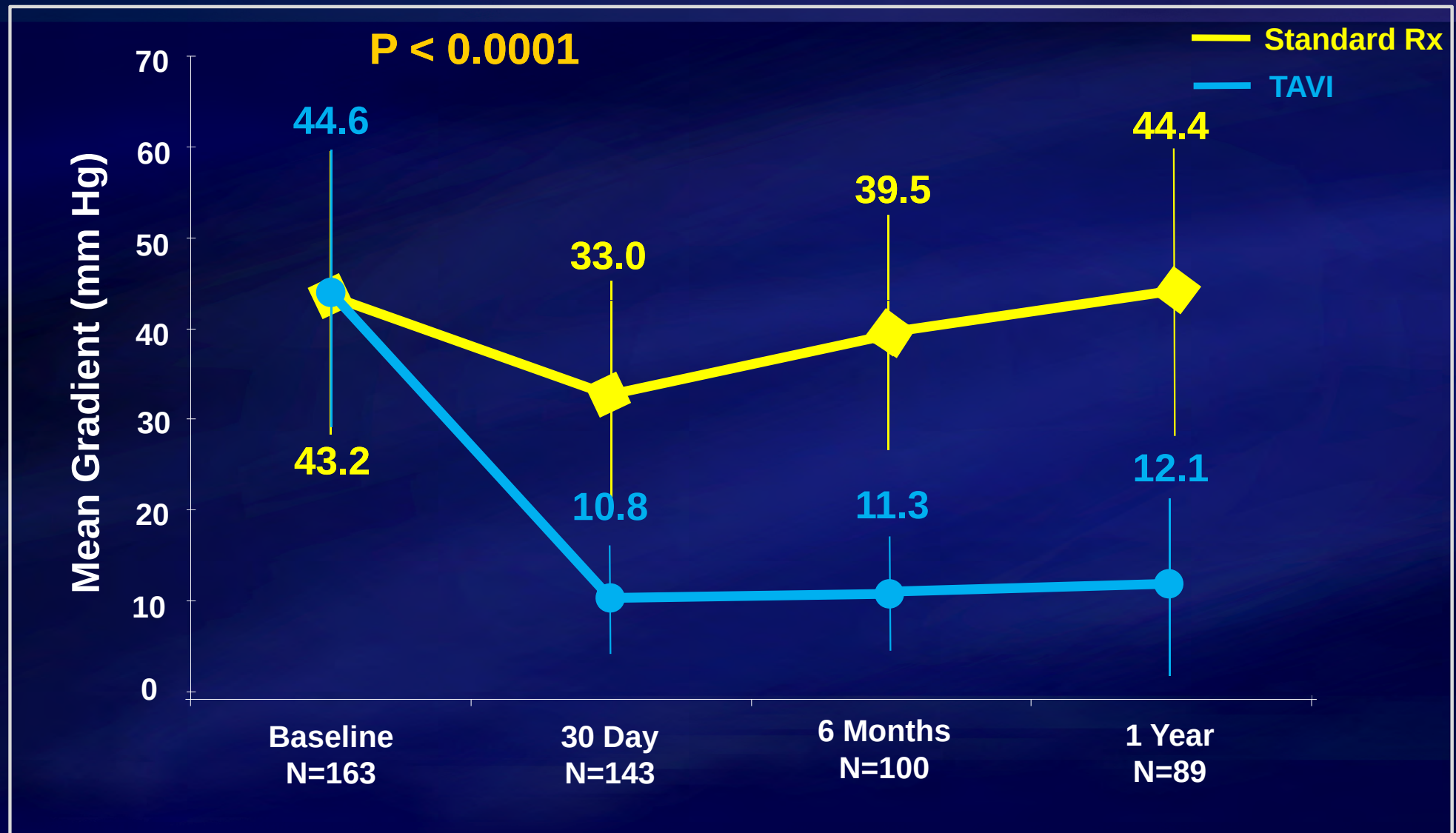


NYHA Class Over Time

Standard Rx (all patients)

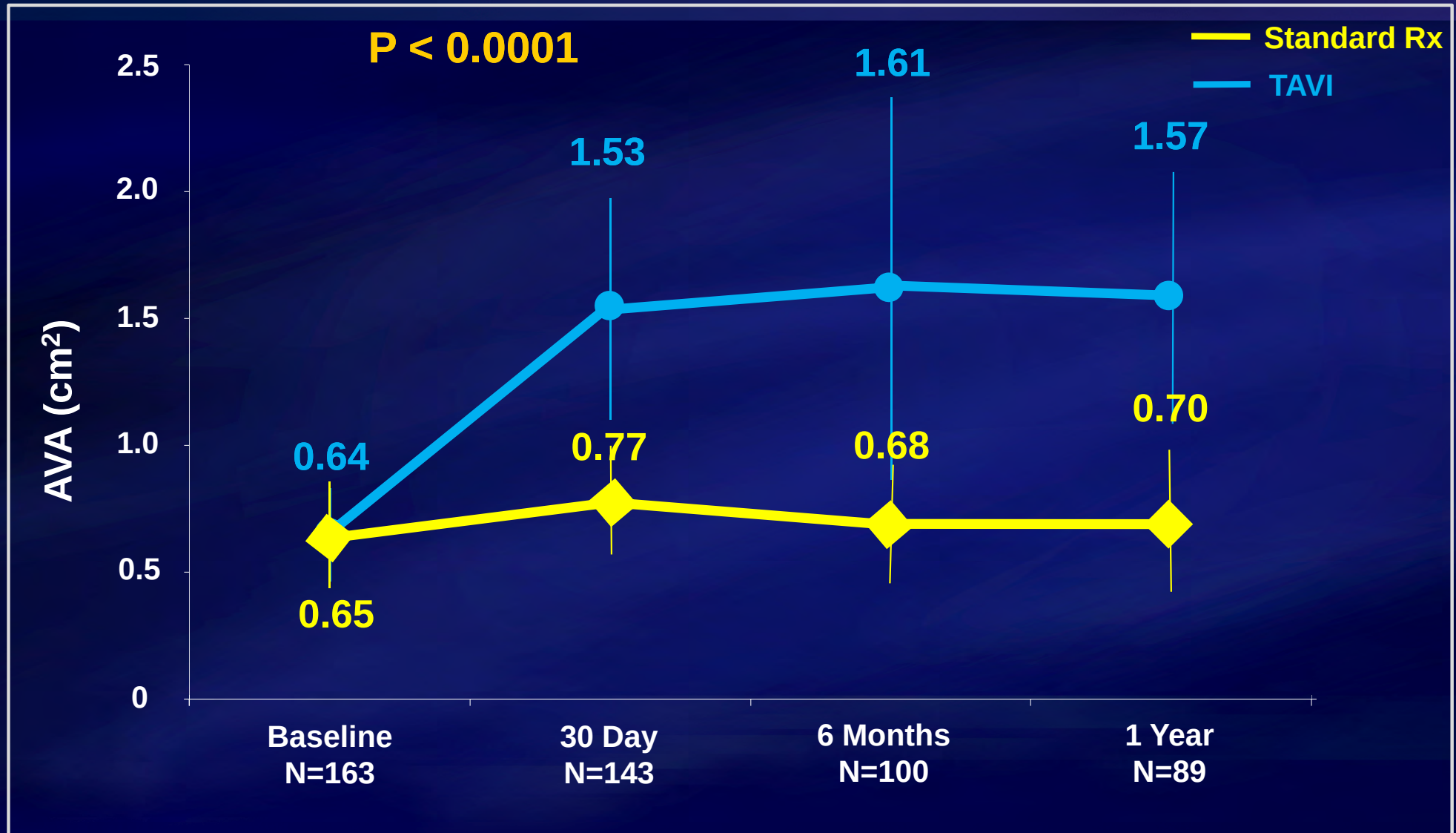


Mean Gradients Over Time



 Error bars = ± 1 Std Dev

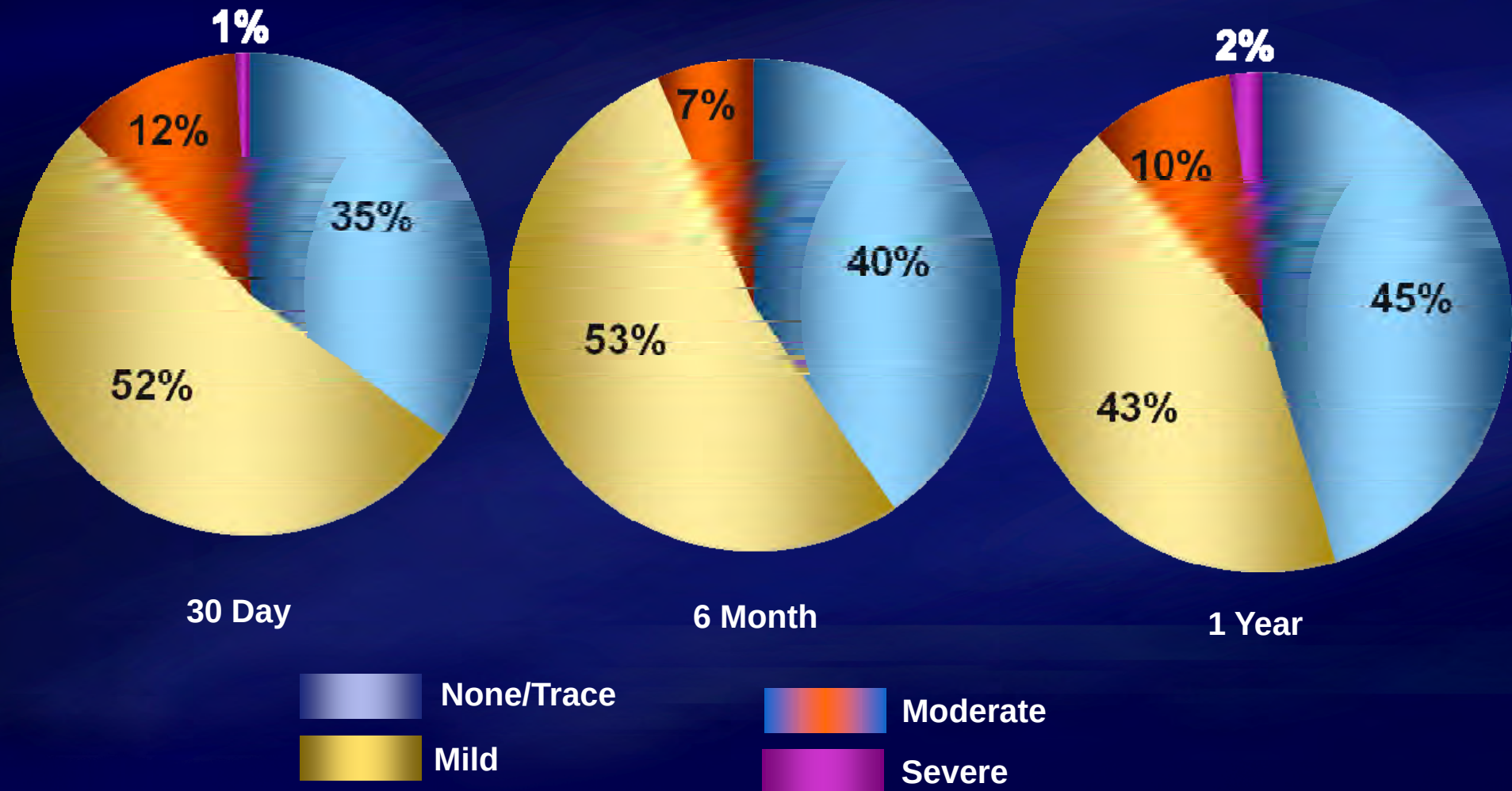
Aortic Valve Areas Over Time



 Error bars = ± 1 Std Dev

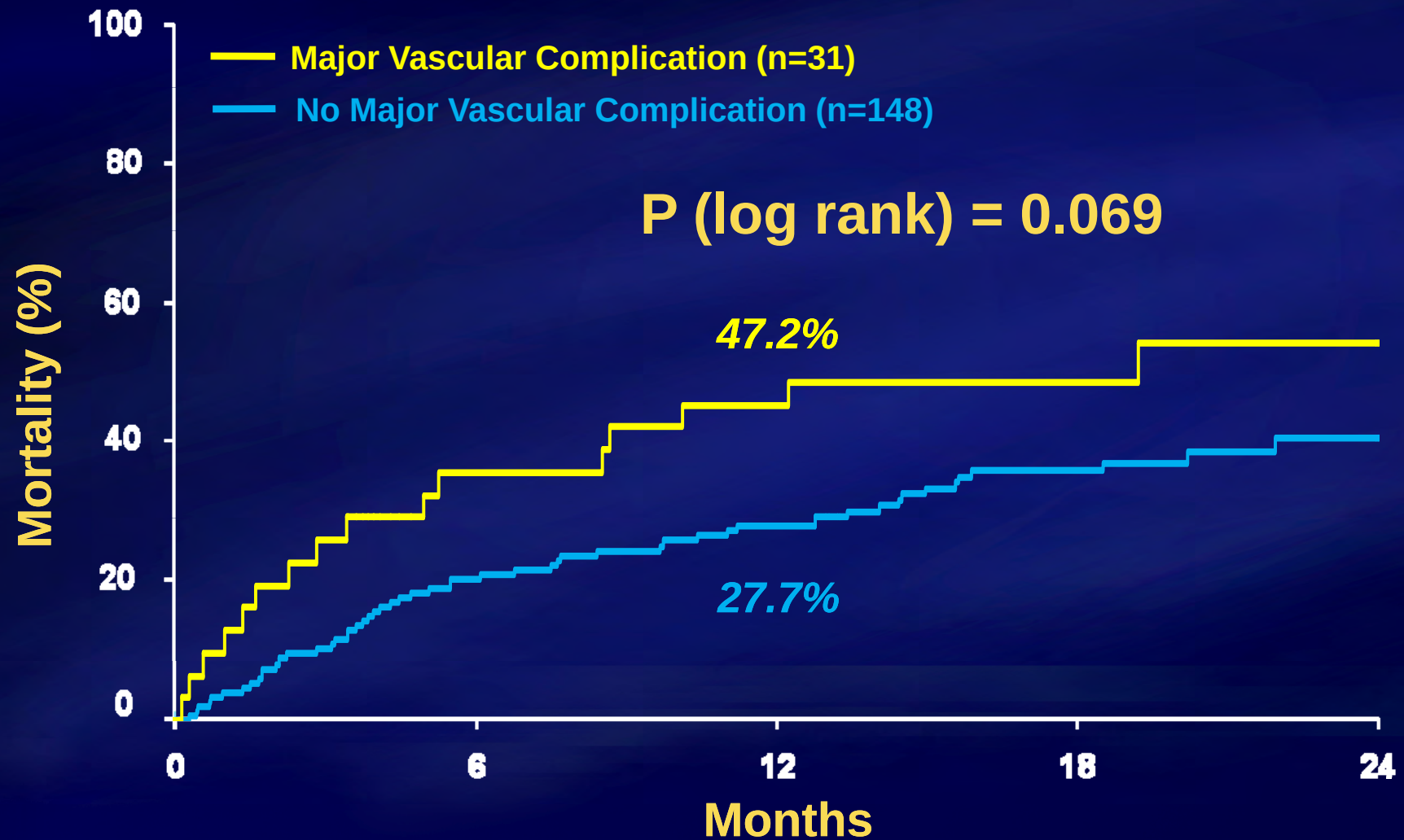
Paravalvular Regurgitation is an Issue

No changes over time



Mortality vs. Major Vasc Complications

TAVI patients



Patient Selection for TAVI

- Prohibitive surgical risk
- Anatomic contraindications to surgery
- High risk surgical candidates (pending PARTNER Cohort A)
- Patients currently receiving bioprosthetic valves
- Low to medium surgical risk (future studies)
- Valve in valve
- Asymptomatic severe AS
- Patient preference

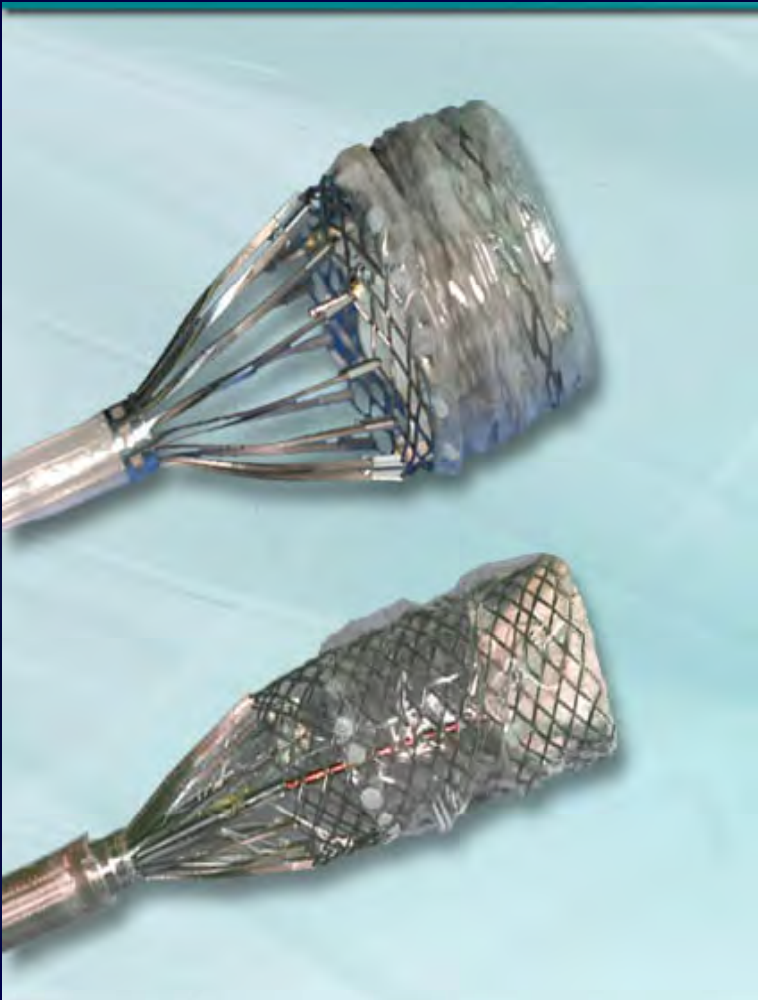
Clinical Implications

- *Balloon-expandable TAVI should be the new standard of care for patients with aortic stenosis who are not suitable candidates for surgery*
- Next generation devices (e.g. SAPIEN XT) may help to reduce the frequency of procedure-related complications in the future.
- The ultimate value of TAVI will depend on careful assessment of bioprosthetic valve durability, which will mandate obligatory long-term clinical and echocardiography FU of all TAVI patients.

Corevalve



Sadra Lotus Valve



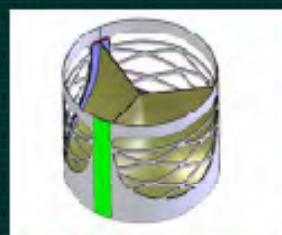
The Lotus Valve is designed to be:

- ▶ Self-centering for optimal placement
 - ▶ Leaflets begin to work as it is expanded
 - ▶ Actively shortened and locked to its final height – increasing radial force
- ▶ Re-elongated, *retrieved and repositioned* at any time prior to final release
- ▶ Removable if needed, providing control
- ▶ Adaptive Seal™ is designed to adapt to natural contours to prevent or minimize leaks

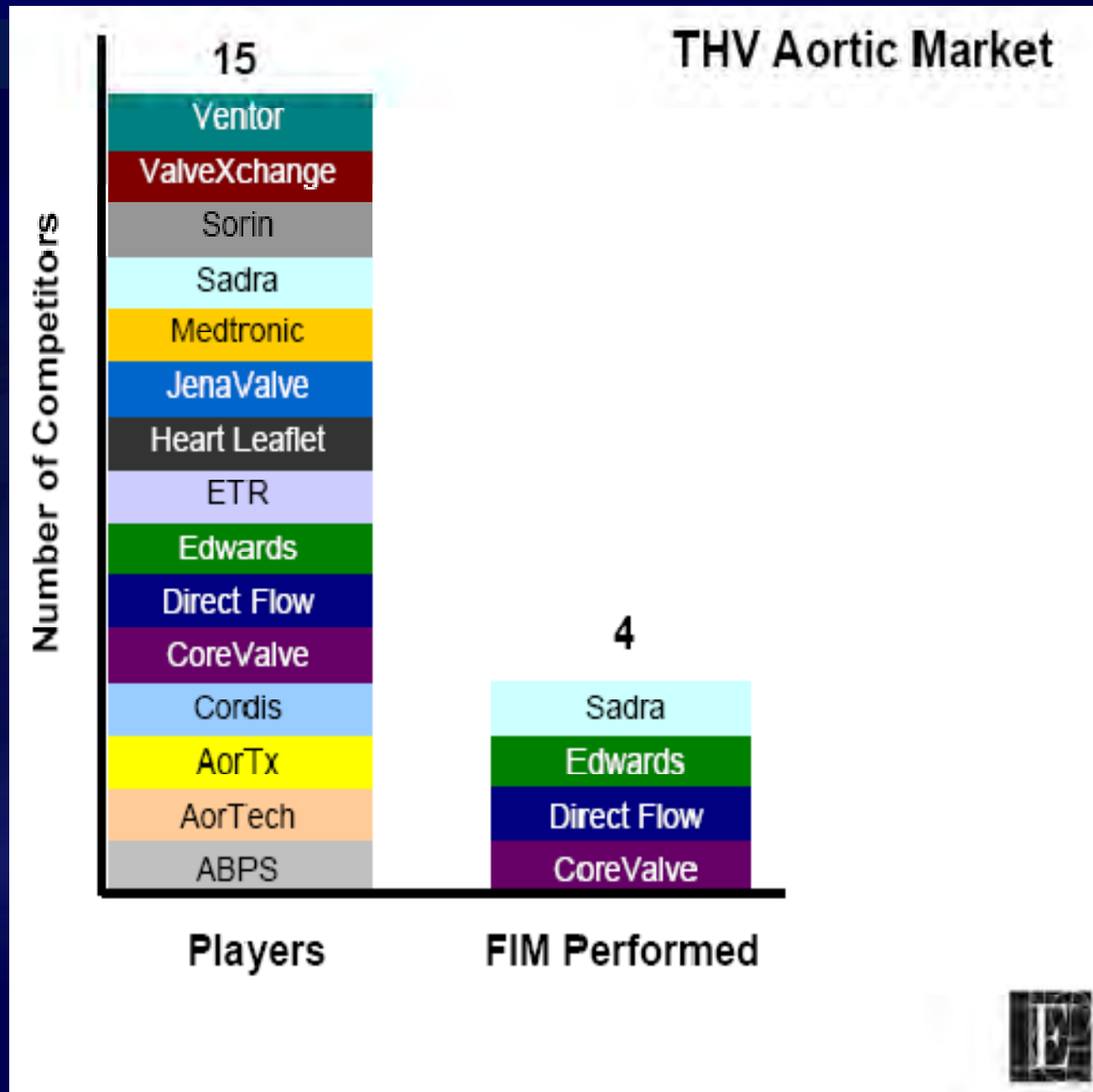
Future Designs....

- **Other stent-valve designs**

- Bonhoeffer (bovine jugular vein)
- AorTech
- Paniagua (EndoTech)
- 3F (apical)
- Palmaz-Bailey (nanotech-nitinol)
- Direct Flow
- AorTx
- Sadra Lotus valve



4 of 15 have done Human Implants



84 year old

Symptoms

- CCS class – no angina
- NYHA - 4

Cohort = B

Comorbidities

- Porcelain aorta
- CABG 1997
- Hypertension
- Stroke 4-5yrs ago
- PPM 2001 CHB
- PCI BMS 1/6/10
- Acute renal failure
- AV fistula post PCI (right side)

Hemodynamics

Echocardiogram

- EF - 59%
- Mean grad – 71
- AVA – 0.55
- AR – trivial
- RVSP – 45
- Annulus – 20

Catheterization

- Outside study (11/2009)
- No hemodynamic data obtained
- Study not repeated due to ARF

Cohort = B

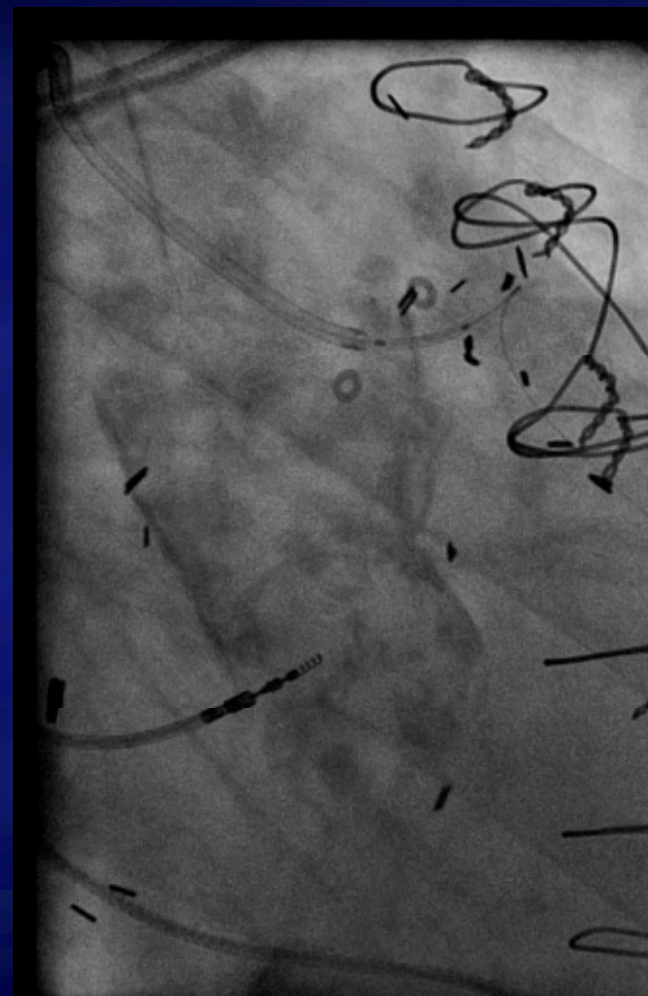
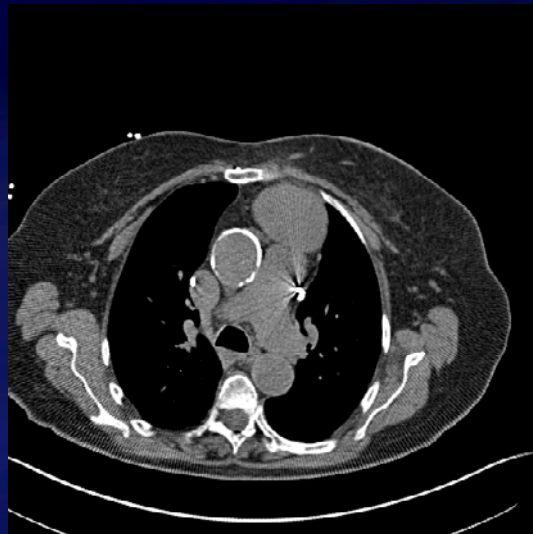
STS Score Points

- Wt 85.2 kg, Ht 156.8 cm
- Creatinine 1.0 (acute renal failure 11/2009))
- Hypertension
- Cerebrovascular disease – CVA
- Previous CABG
- Previous PCI > 6 hours
- CHF class 4
- Diseased vessels 3
- EF 59%
- AI trivial, MI mild, TI severe
- First reop elective

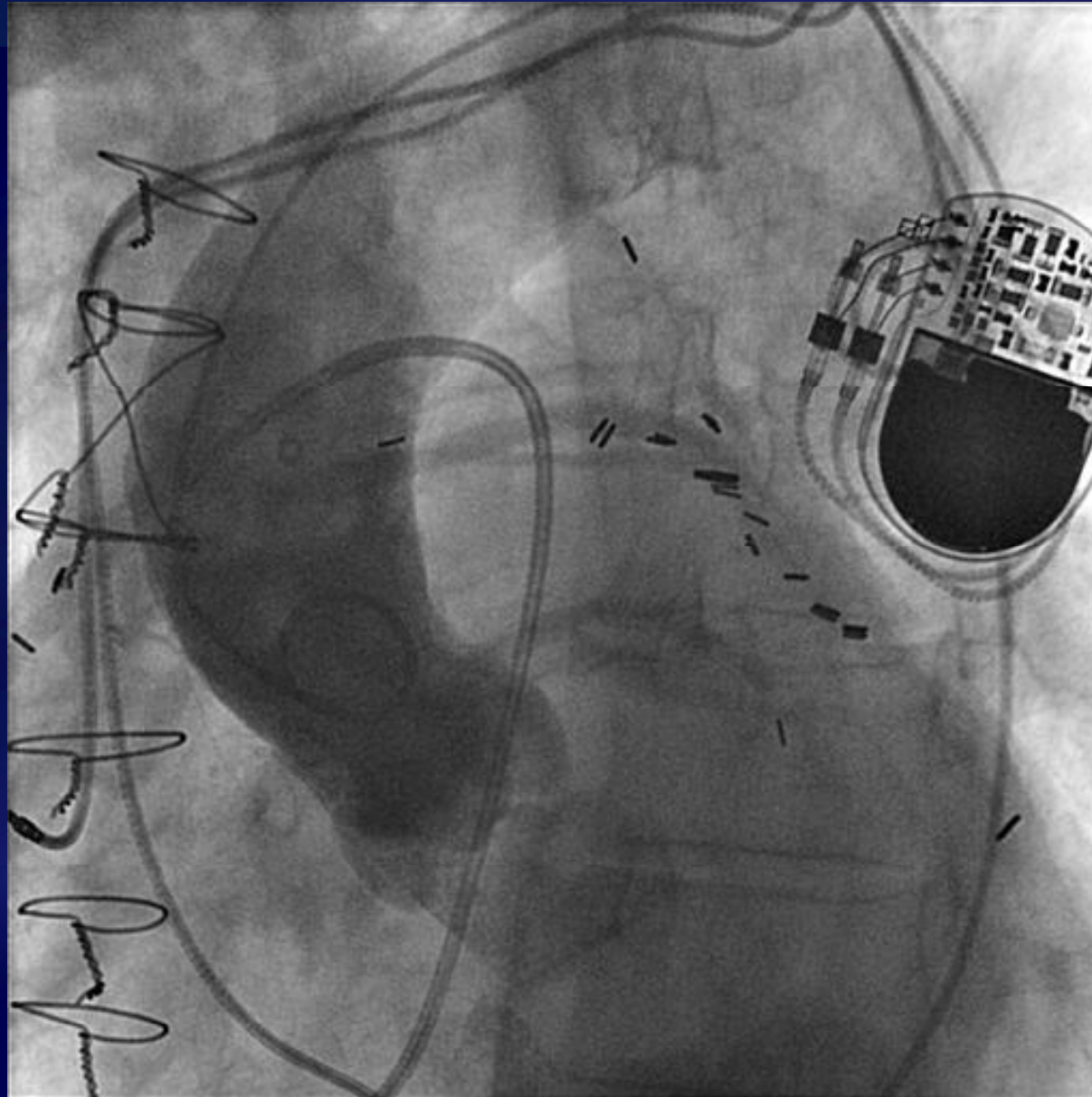
STS risk calculator

Procedure Name	Isolated AVRepl
Risk of Mortality	6.4%
Morbidity or Mortality	35.8%
Long Length of Stay	18.3%
Short Length of Stay	11.8%
Permanent Stroke	4.6%
Prolonged Ventilation	30.4%
DSW Infection	0.2%
Renal Failure	9.8%
Reoperation	10.8%

CT / fluoro asc ao.



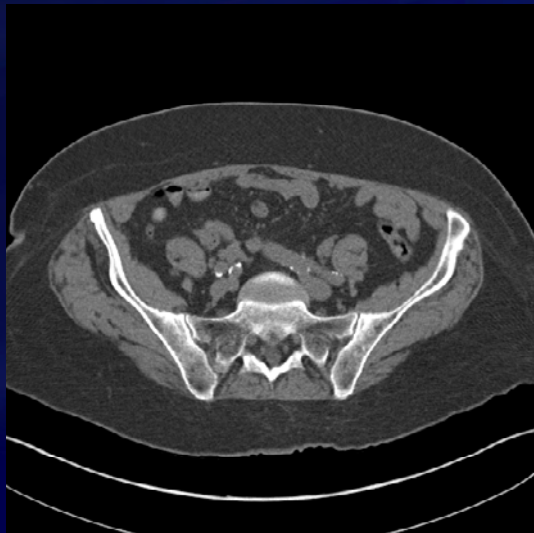
Invasive Aortogram



Non-contrast CT abdomen/pelvis



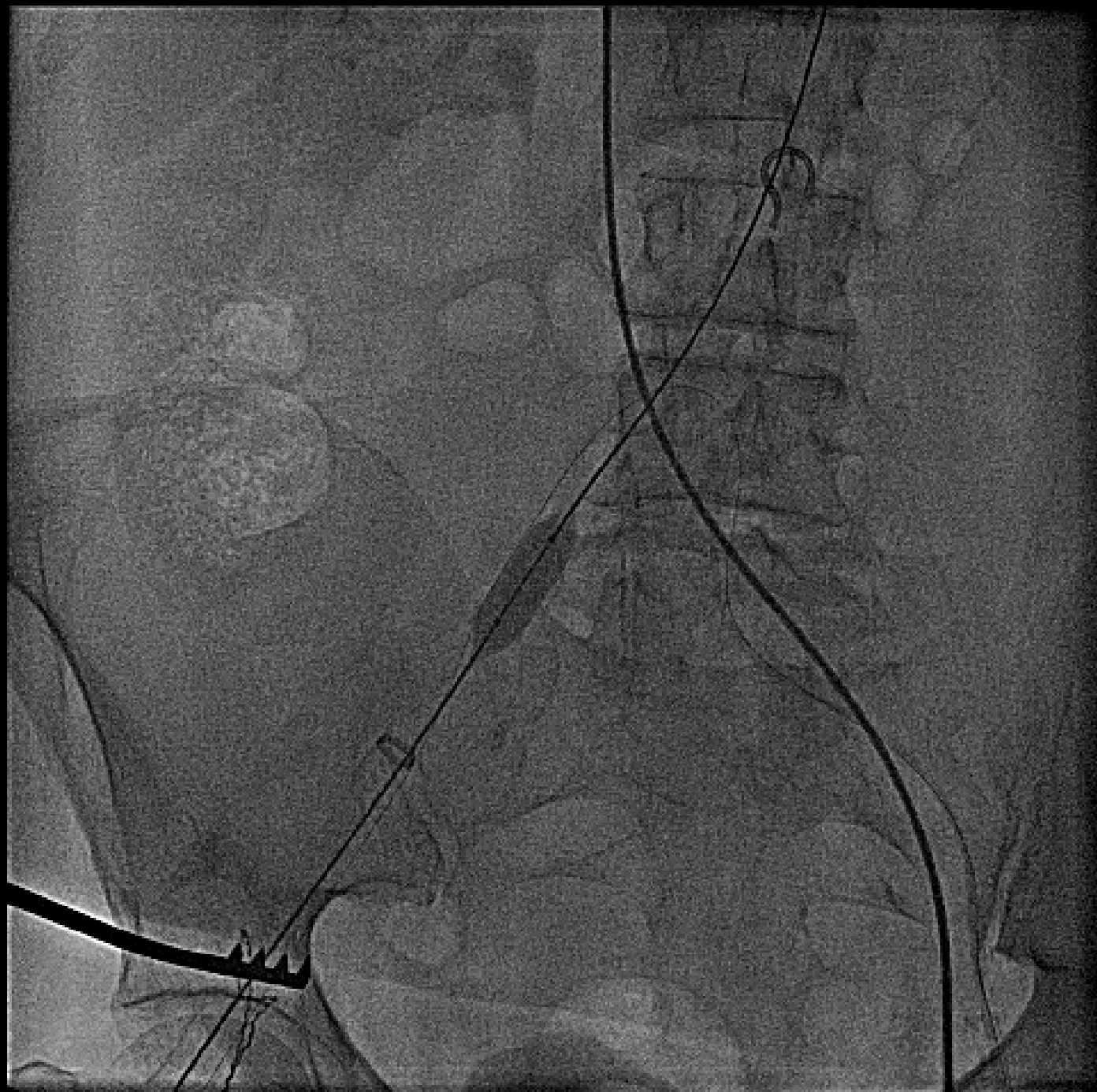
Measurements		
	Right	Left
CI	9X10	11X11
EI	8X10	9X10
CF	8X8	11X11

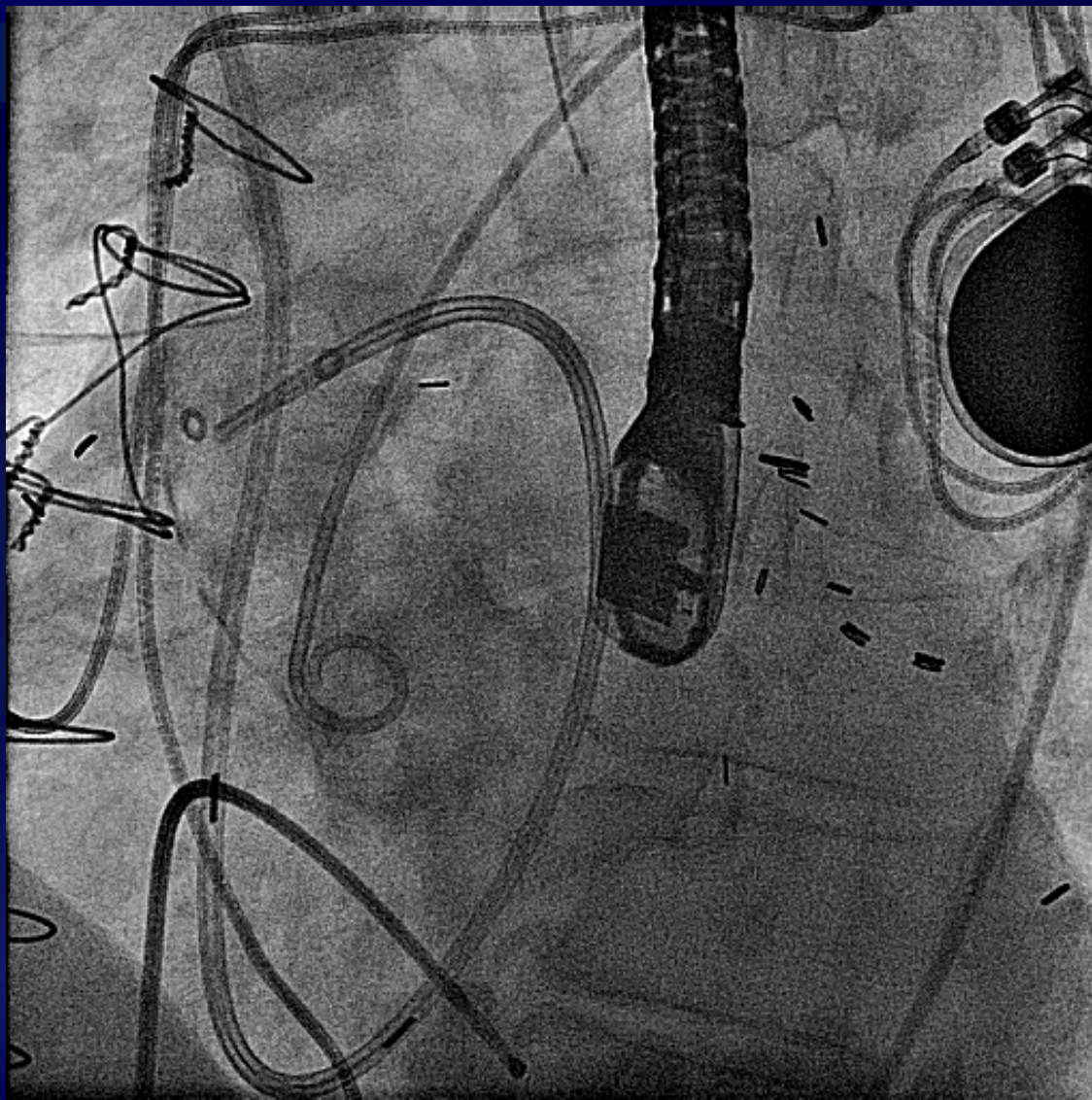


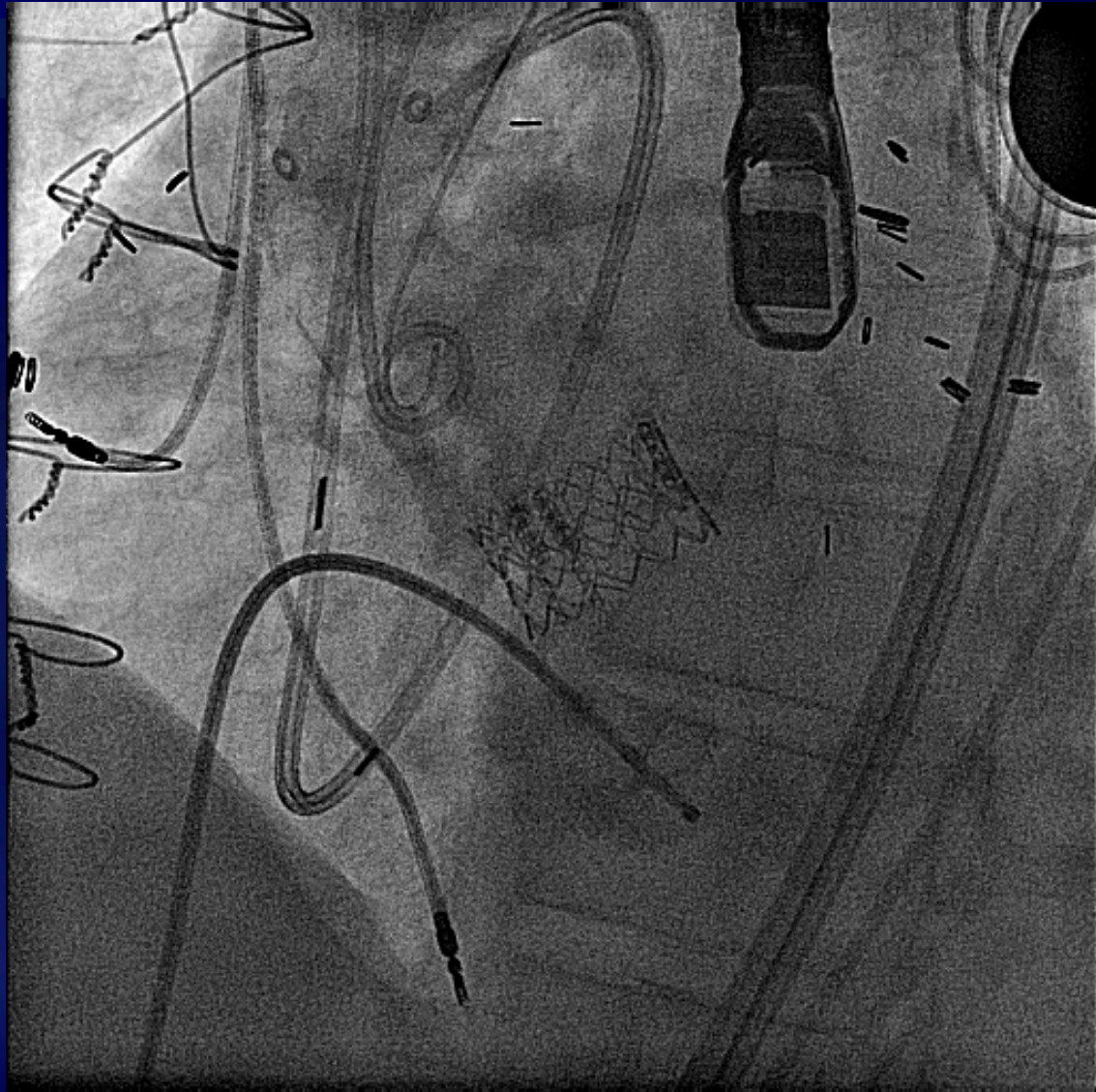
Invasive Aortogram aorta and Iliacs

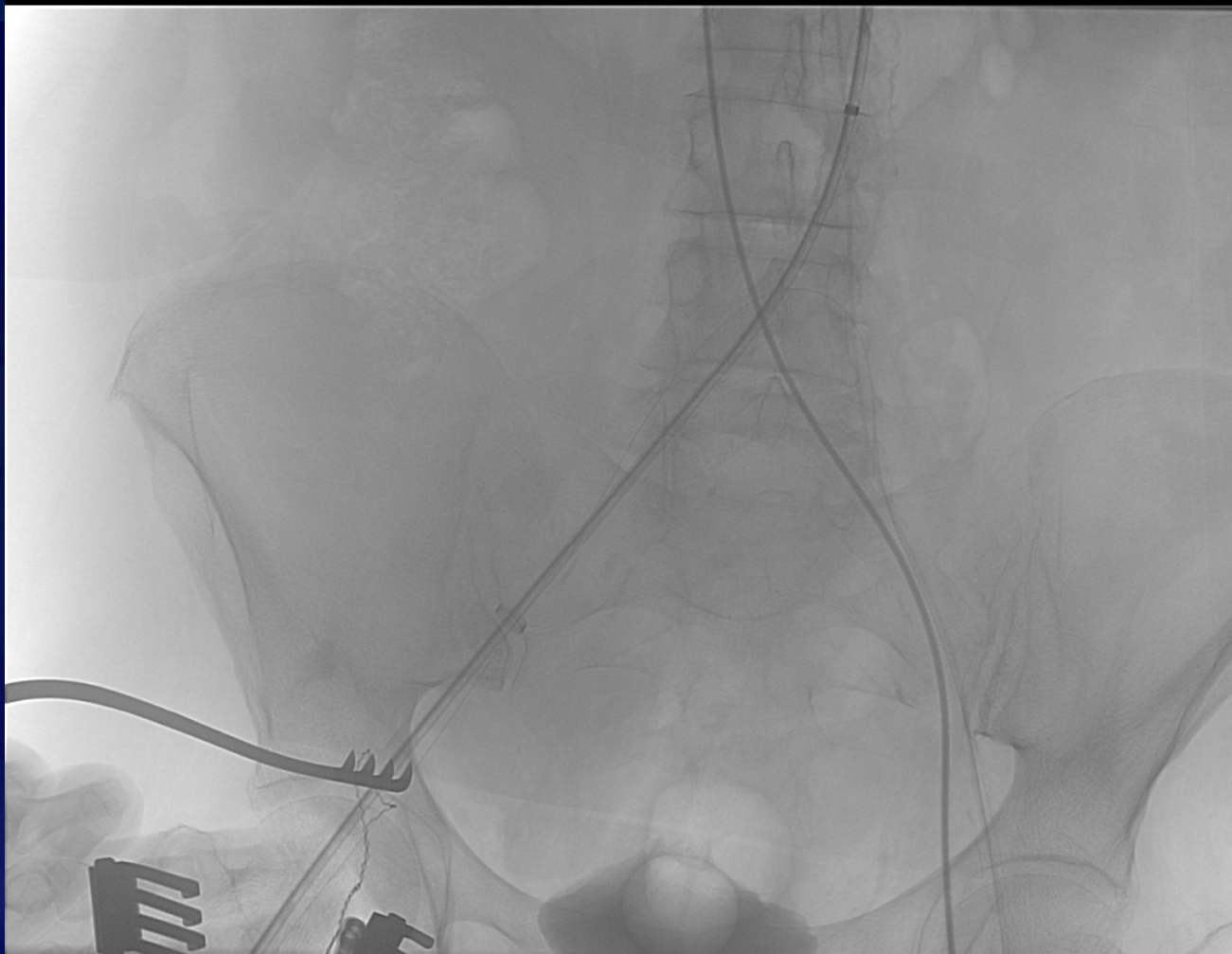




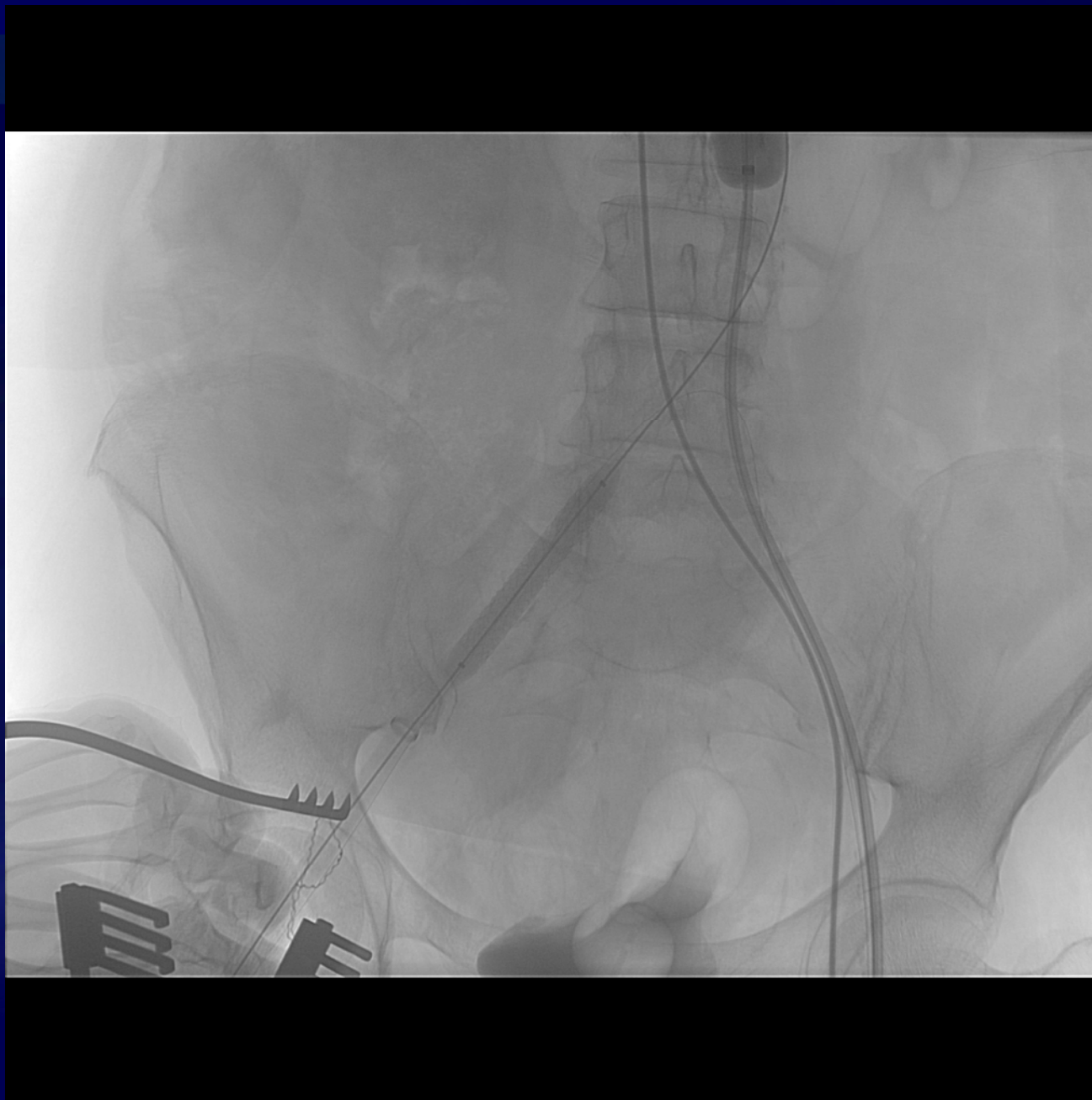


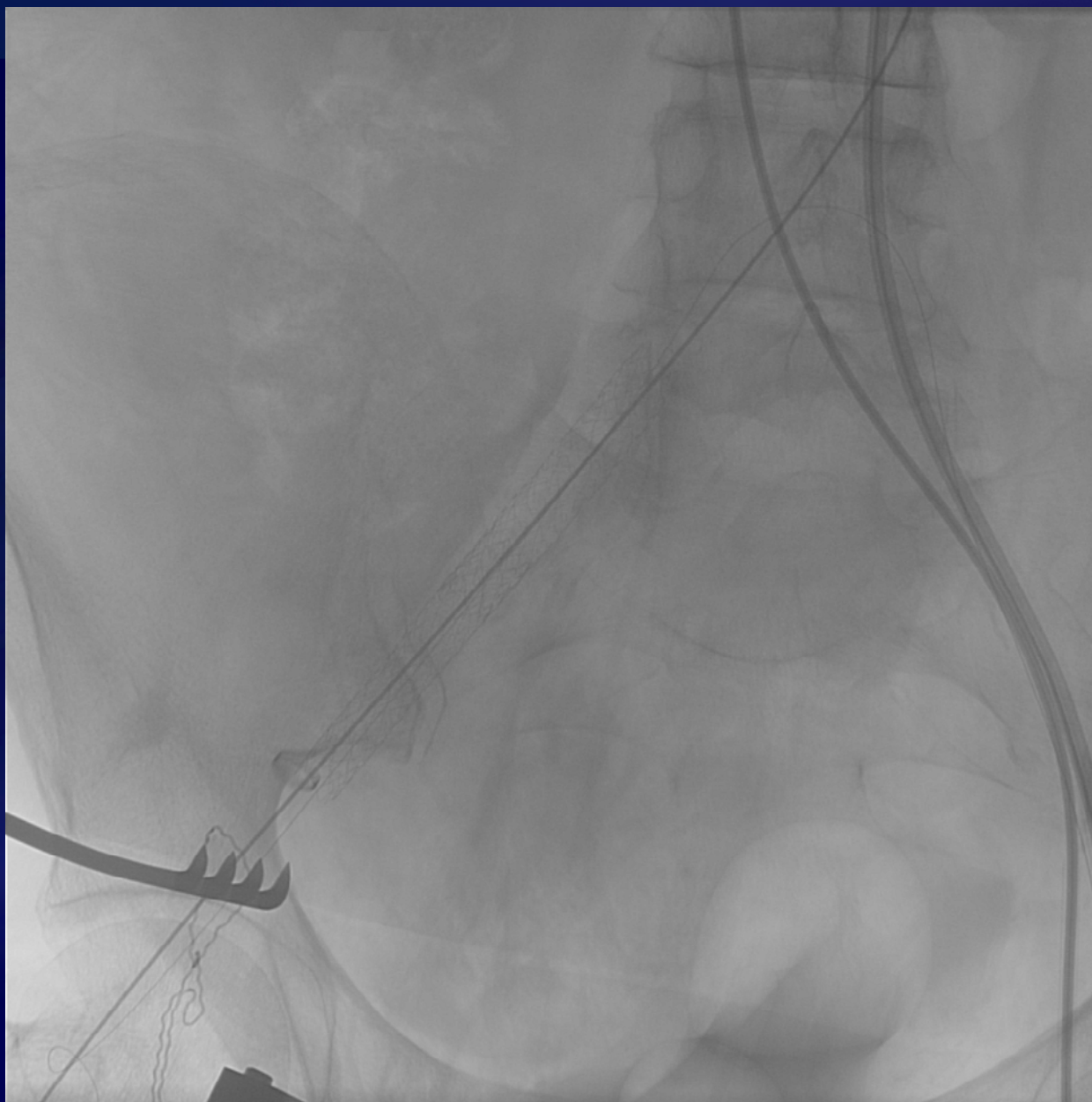












TAVI

- The future is bright but it should be treated with respect
- Data to guide clinical judgment
- Experience and learning curve is crucial
- New technologies needed for easy of delivery, stroke prevention and access management

