

When should we consider TAVI procedure in Korea ? *Interventionalist !*

Young-Hak Kim, MD, PhD

Cardiac Institute, University of Ulsan College of Medicine
Asan Medical Center, Seoul, Korea

Pyo-Won Park vs. Young-Hak Kim



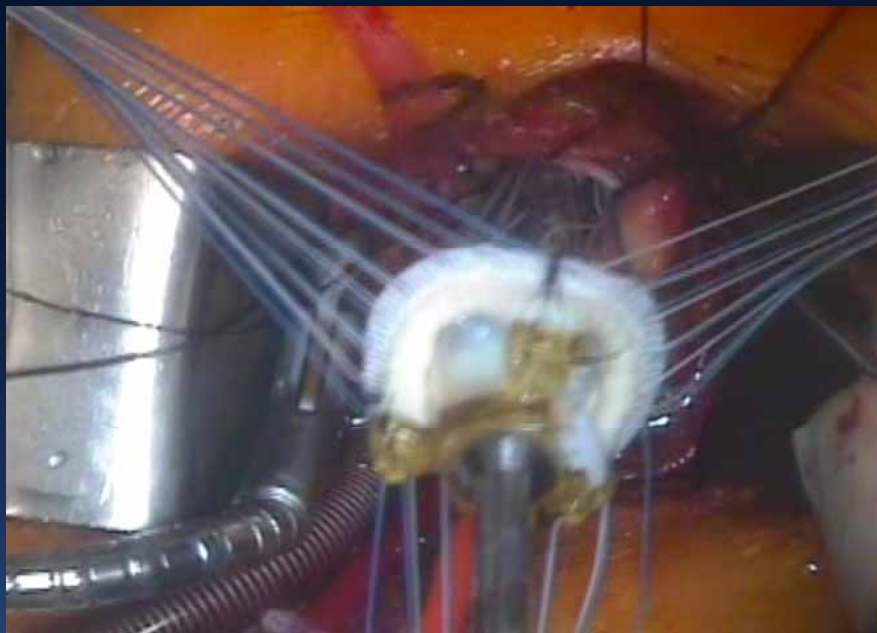
- President in the institute
- Very famous doctor in the country
- Cardiac surgery for ~ 30 yrs



- Just one of professors
- Known only in the family
- Interven. cardiology for ~ 15 yrs

Honorable but, hardly can be competed ...

Surgical AVR vs. TAVI



- Since 1967, 47 yrs old
- Numerous tissue and mechanical devices
- Widely applicable

- Since 2003, 9 yrs old
- Only two devices commercially available
- Selected indication

2011 FDA Panel Meeting

Vote for 3 major questions on Sapien

1. Is it safe ? **YES (7:3)**

2. Is it effective ? **YES (9:1)**

**3. Does the benefit outweigh
the risk ?** **YES (9:0)**

When should we consider TAVI in Korea ?

TAVI is nicely indicated for high-risk AS patients.

No doubt !

Issues remains debated.

Perspective based on Evidence

1. Appropriateness : Indications
2. Safety : Complications
3. Clinical efficacy : Longevity
4. Cost effectiveness : compared with surgical AVR

Very Selected Inclusion at Present

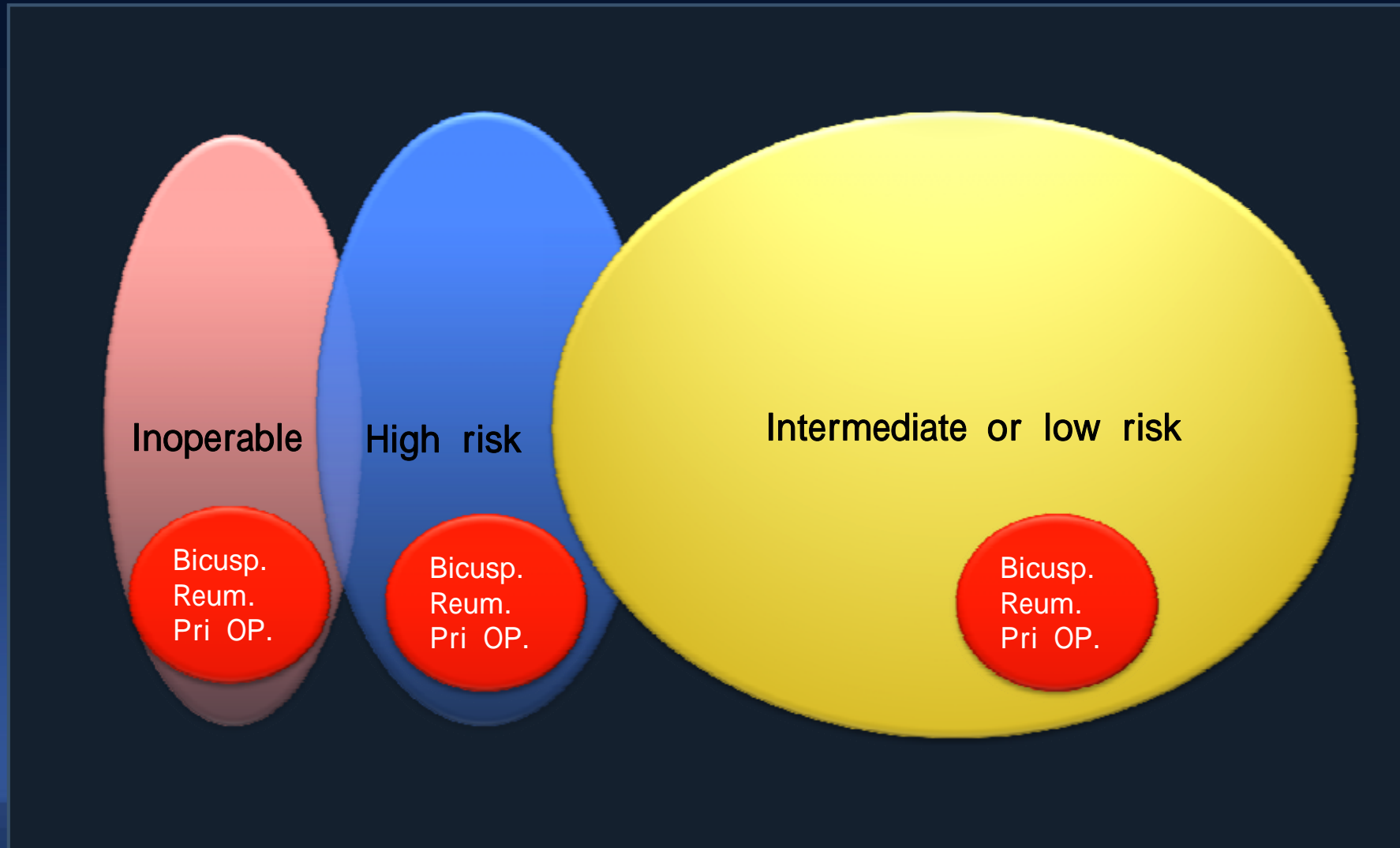
- **Inclusion**

- Severe symptomatic AS
- Very high surgical risk

- **Exclusion**

- AMI < 1 Mo
- Bicuspid or noncalcified AV
- AR > 3+
- PCI < 6 Mo
- Untreated severe CAD
- Other surgery
- EF < 20%
- Inability to antiplatelet
- Cr > 3.0mg/dL
- Annulus size < 18 or >25 mm
- Life expectancy < 12 Mo
- Aorta disease
- Active infection

Exclusion of Intermediate or Low Risk Patients



Current Indication

Identical Used in PARTNER-A and -B Trials

The NEW ENGLAND JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

OCTOBER 21, 2010

VOL. 363 NO. 17

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

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Raj R. Makkar, M.D., David L. Brown, M.D.,
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Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients

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Vinod H. Thourani, M.D., Paul Corso, M.D., Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D.,
Howard C. Herrmann, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D.,
and Stuart J. Pocock, Ph.D., for the PARTNER Trial Investigators*

Current indications are based on the ...
PARTNER-A RCT for High Risk

	<i>TAVR (N = 348)</i>	<i>AVR (N = 351)</i>	<i>p-value</i>
Age (yr)	83.6 ± 6.8	84.5 ± 6.4	0.07
Male sex - %	57.8	56.7	0.82
STS Score	11.8 ± 3.3	11.7 ± 3.5	0.61
Logistic EuroSCORE	29.3 ± 16.5	29.2 ± 15.6	0.93
NYHA			
II - %			
III or IV - %	94.3	94.0	
CAD - %	74.9	76.9	0.59
Previous MI - %	26.8	30.0	0.40
Prior CV Intervention - %	72.1	71.6	0.93
Prior CABG - %	42.6	44.2	0.70
Prior PCI - %	34.0	32.5	0.68
Prior BAV - %	13.4	10.2	0.24
Cerebrovascular disease - %	29.3	27.4	0.60

Relatively not-high risk patient in the practices...

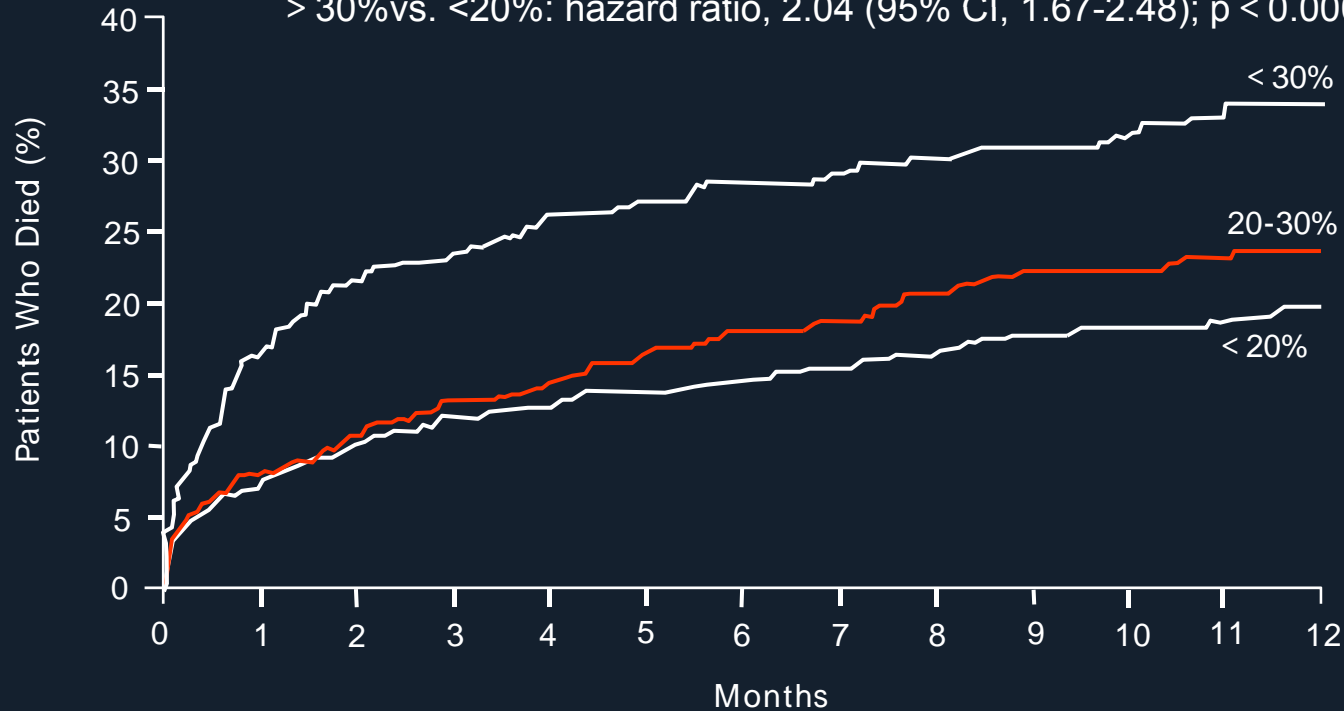
FRANCE-2 Registry

Characteristic	SAPIEN (N=2107)	CoreValve (N=1043)	Partner-A high risk
Age, yr	82.9±7.2	82.3±7.2	83.6±6.8
Male sex %	46.6	60.0	57.8
STS score %	15.6±12.4	14.2±11.2	11.8±3.3
Logistic EuroSCORE %	22.2±14.3	21.3±14.3	29.3±16.5
NYHA class or %	75.5	76.1	94.3
Clinical history %			
CAD	48.7	46.2	74.9
Previous MI	17.0	15.4	26.8
Previous CABG	18.2	18.3	42.6
Cerebrovascular disease	10.0	9.9	29.3
PVD	21.8	18.6	43.0
COPD	25.3	26.2	43.4
Renal dialysis	2.3	3.1	
Atrial fibrillation	25.2	29.6	40.8
Permanent pacemaker	13.5	15.5	20.0
Pulmonary hypertension	19.8	19.2	42.4

FRANCE-2 Registry

Mortality according to EuroSCORE

20-30% vs. < 20%: hazard ratio, 1.19 (95% CI, 0.95-1.49); P=0.13
 > 30% vs. < 20%: hazard ratio, 2.04 (95% CI, 1.67-2.48); p < 0.0001



No. at Risk

< 20%	1686	1301	636	208
20-30%	749	582	300	113
> 30%	717	518	269	81

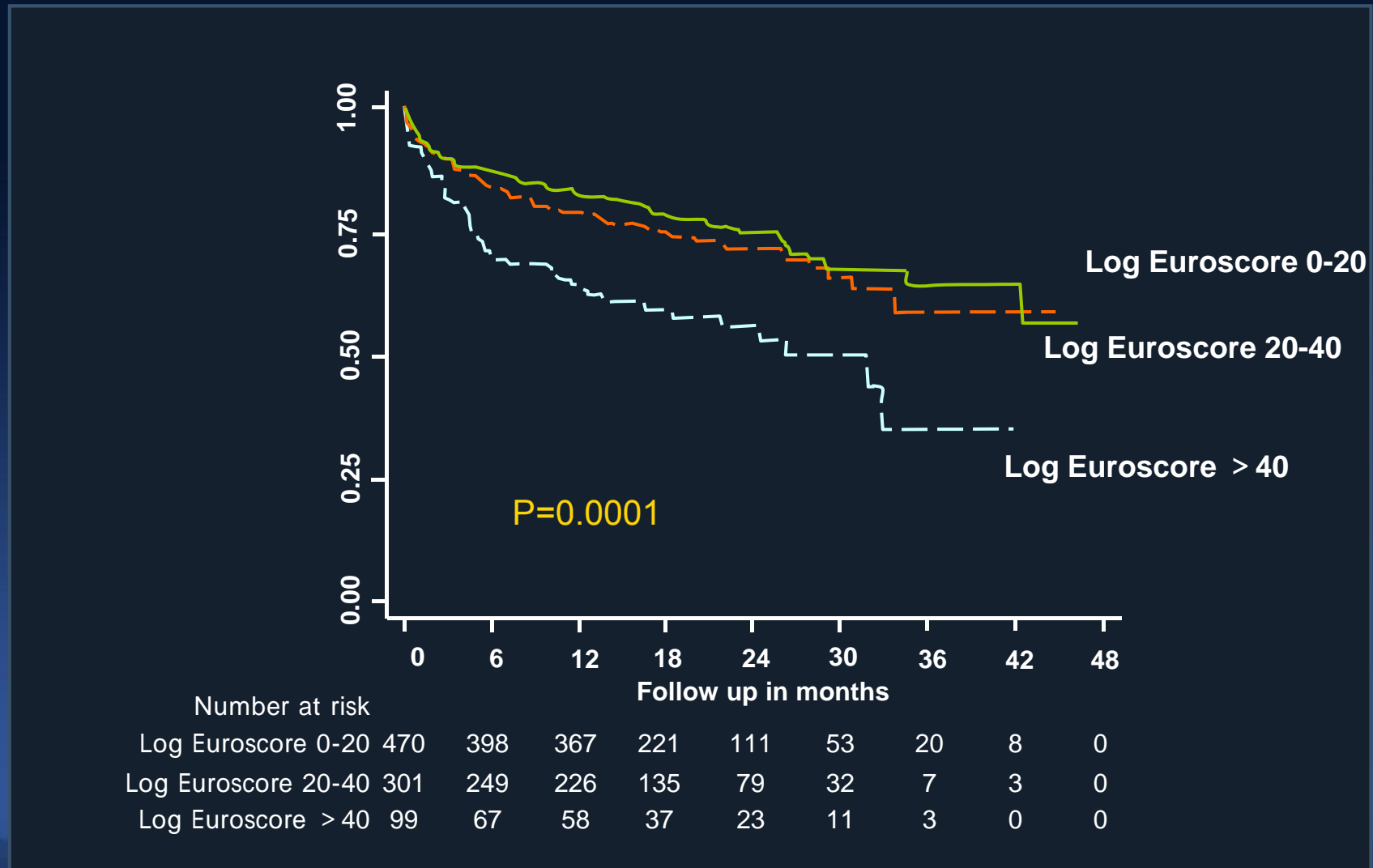
UK.TAVI Registry

Lower Risk Compared with PARTNER (EuroSCORE, 29.3)

Variables	Transfemoral Route (n = 599)	Other Routes (n= 271)	P Value
Male	51.9	53.5	0.66
Age, yrs	81.7 ± 7.4	82.3 ± 6.6	0.32
AV peak gradient	82.1 ± 27.8	77.9 ± 25.7	0.05
Logistic EuroSCORE	17.1 (11.0-25.5)	21.4 (14.4-33.6)	< 0.001
LVEF ≥50%	64.0	63.8	
LVEF 30%-49%	28.0	26.9	0.85
LVEF > 30%	8.0	9.3	
NYHA functional class /	26.1	16.0	
NYHA functional class /	79.9	84.0	0.001
Coronary disease	43.4	57.1	< 0.001
Any previous cardiac Surgery	27.3	37.1	0.004
PVD	19.5	48.7	< 0.001
Diabetes mellitus	23.0	22.2	0.79
COPD	27.5	31.2	0.28
Creatinine > 200mmol/l	5.4	9.4	0.03

UK.TAVI Registry

Survival According to EuroSCORE

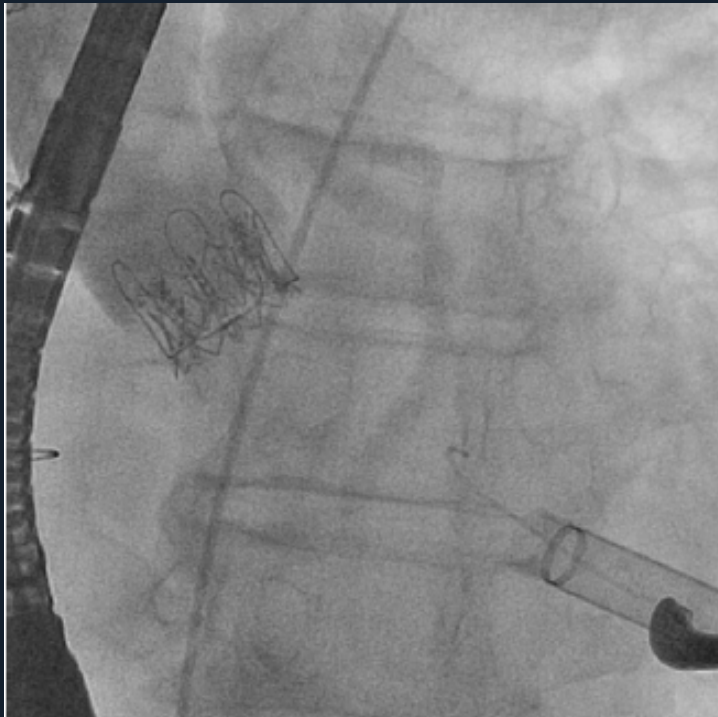


OBSERVANT Registry

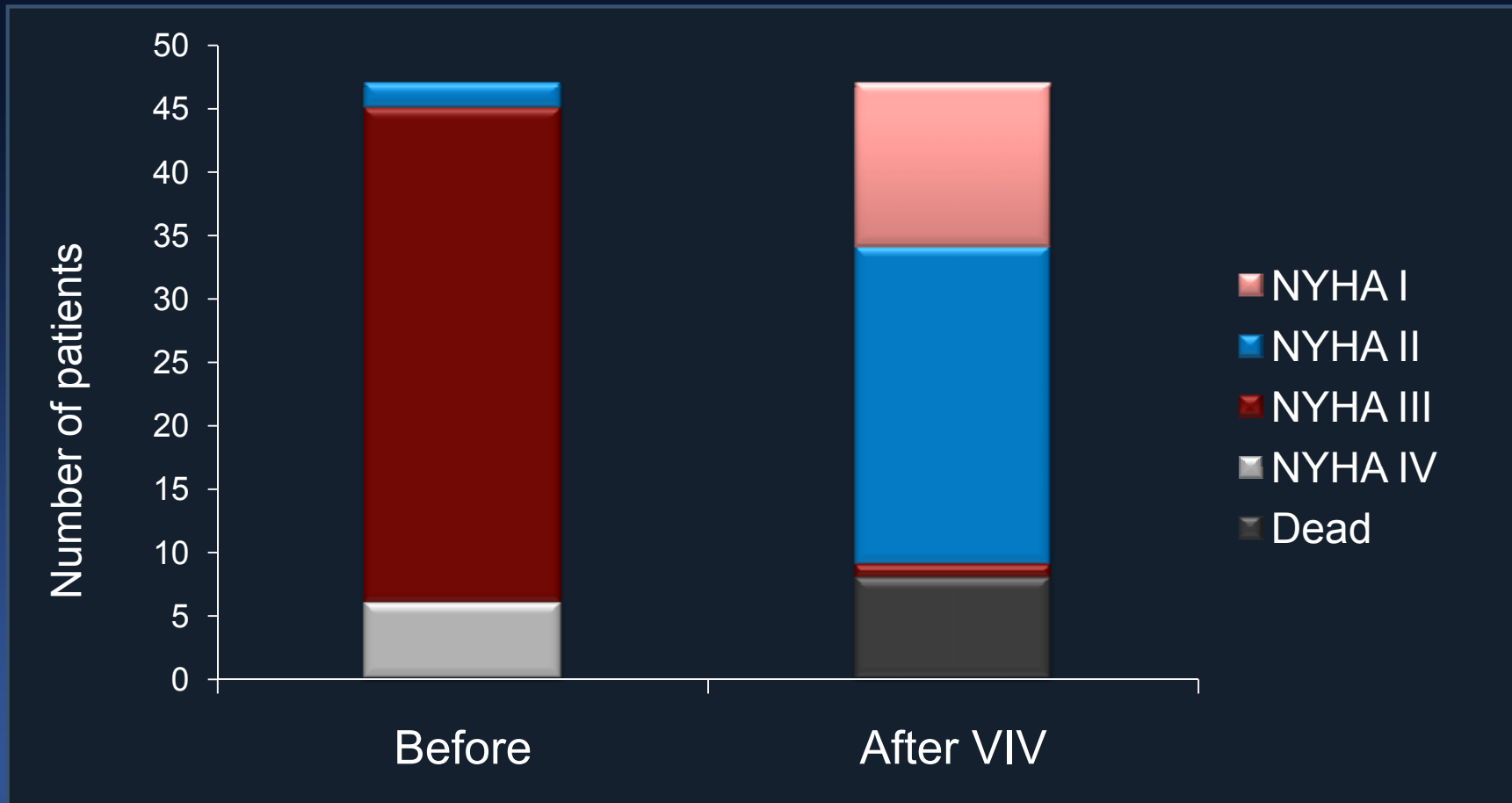
Propensity-Matched Intermediate Risk (EuroSCORE of 9%)

	SAVR N = 133	TAVI N = 133	P value
Mean gradient after the procedure (mm Hg)	13.6±8.6	10.8±6.4	0.0008
Residual AR			0.000
Moderate	1 (0.8)	7 (5.3)	
Severe	2 (1.5)	1 (0.8)	
Cardiac tamponade	2 (1.5)	3 (2.3)	0.632
Permanent A-V Block	1 (0.8)	16 (12.0)	0.000
MI	1 (0.8)	1 (0.8)	1.000
Major vascular damage	0 (0.0)	7 (5.3)	0.007
Stroke	2 (1.5)	0 (0.0)	0.156
Transfusions	66 (49.6)	48 (36.1)	0.026
Wound infection	0 (0.0)	5 (3.8)	0.145
Hospital stay (days)	8.8±5.5	8.1±5.1	0.271
Procedural mortality			
In-hospital	4 (3.1)	3 (2.3)	0.687
30 days	5 (3.8)	5 (3.8)	1.000

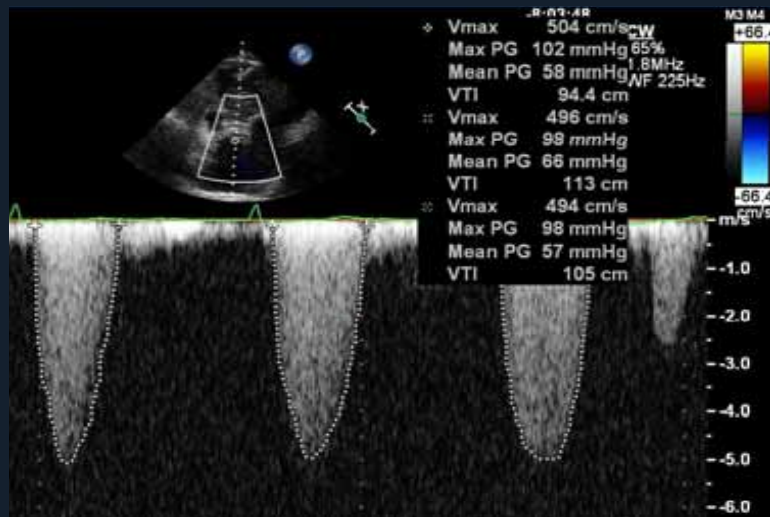
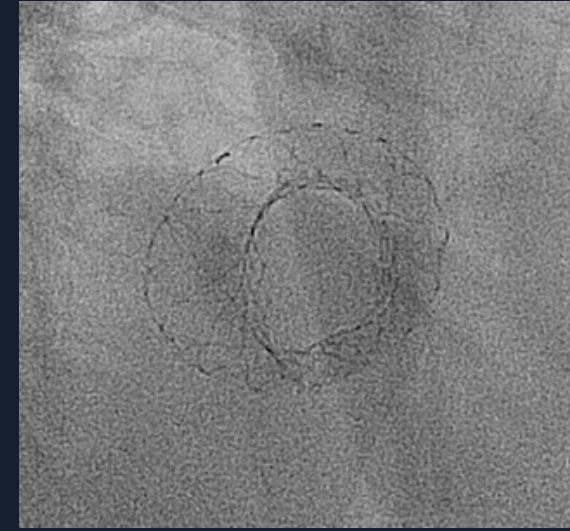
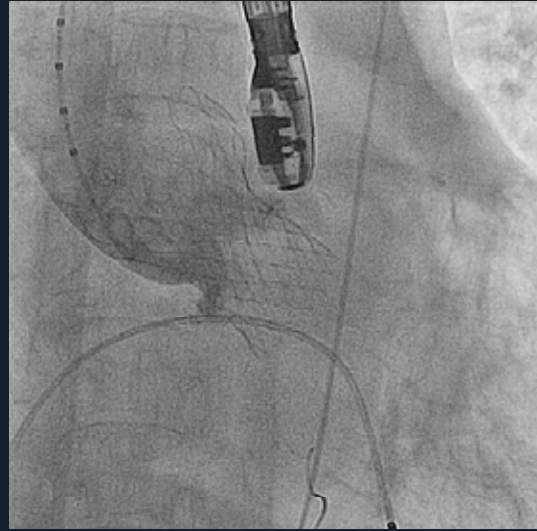
TAVI for Degenerative Bioprosthetic Valve Valve in Valve



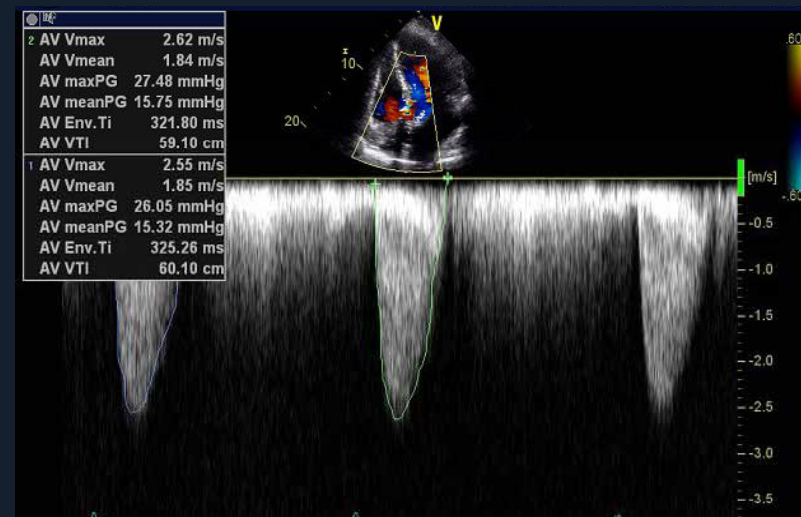
Improvement in Functional Status Valve in Valve (N=47)



TAVI for **Biscupid AV** in AMC



Pre-TAVI Vmax= 5.0m/s



Post-TAVI (9-mo) Vmax= 2.6m/s
Mild paravalvular leakage

Clinical Outcomes in a TAVI Registry For Bicuspoid AV

	Bicuspid	Non-bicuspid	P
Patient number	21	208	
Device success	21 (100%)	193 (92.8%)	0.23
30-day mortality	1 (4.8%)	17 (8.2%)	0.49
30-day combined safety point	3 (14.3%)	28 (13.5%)	0.56
ICU stay, days	4.5 ± 3.6	4.1 ± 4.2	0.70
Hospital stay, days	8.5 ± 3.6	11.0 ± 6.2	0.08

Indications are being revised with evidence over time ...

- As long as the device safety is approved, we need to test its effectiveness in a wider population.
- We need to open protocol that allows wide flexibility within a defined framework, through to a tightly specified protocol that has been determined by consensus with experts.

Upper Limit of *Age* in Korea ?

The screenshot shows the Chosun Media website with the following content:

- Header: ChosunMedia THE CHOSUNILBO english.chosun.com. Navigation: HOME, NEWS, PEOPLE, HOT ISSUE, INSIDE KOREA, VIDEO CLIPS.
- Date: September 6, 2012. Weather: Incheon 24.5 °C.
- Left sidebar: NEWS (National, Politics, Business, Sci-Tech, Sports, Arts & Entertainment, World, Opinion, Tip of the Day), PEOPLE, HOT ISSUE, INSIDE KOREA (City Life, Events, Travel, Korea 101), VIDEO CLIPS, PHOTOS, LATEST NEWS, RSS.
- Main article: "Life Expectancy for Korean Women 6th Longest in the World".
 - Text: "Korean women can now expect to live 83.8 years, the sixth longest among the 32 OECD member countries. But life expectancy for Korean men is only 20th on the list."
 - Text: "According to analysis of OECD health data by the OECD/Korea Policy Centre on Tuesday, Korean women's life expectancy surged 13 notches in 2009, up from 19th place in 2003, when it stood at 80.8 years."
 - Text: "Japanese people live the longest, followed by Spaniards, Swiss, French and Australians. Canada and Italy did not submit data."
 - Text: "Compared to 53.7 years in 1960, the life expectancy of Korean women rose the fastest in the OECD. The gap with Japanese women shrank from 16.5 years to a mere 2.6 years in 2009."
 - Text: "Although cancer rates among Korean women rose, the death rate has fallen and many people take care of their health through exercise, said Prof. Lee Sun-hee of Ewha Womans University's College of Medicine. Korea also has a much higher proportion of people who see doctors when they have health problems than in other countries, she added."
 - Text: "Meanwhile, the life expectancy of Korean men is 76.8 years, and 3.1 years shorter than that of Swiss men, who live longest. The gap in life expectancy between Korean men and women is seven years, higher than the OECD average of 5.6"

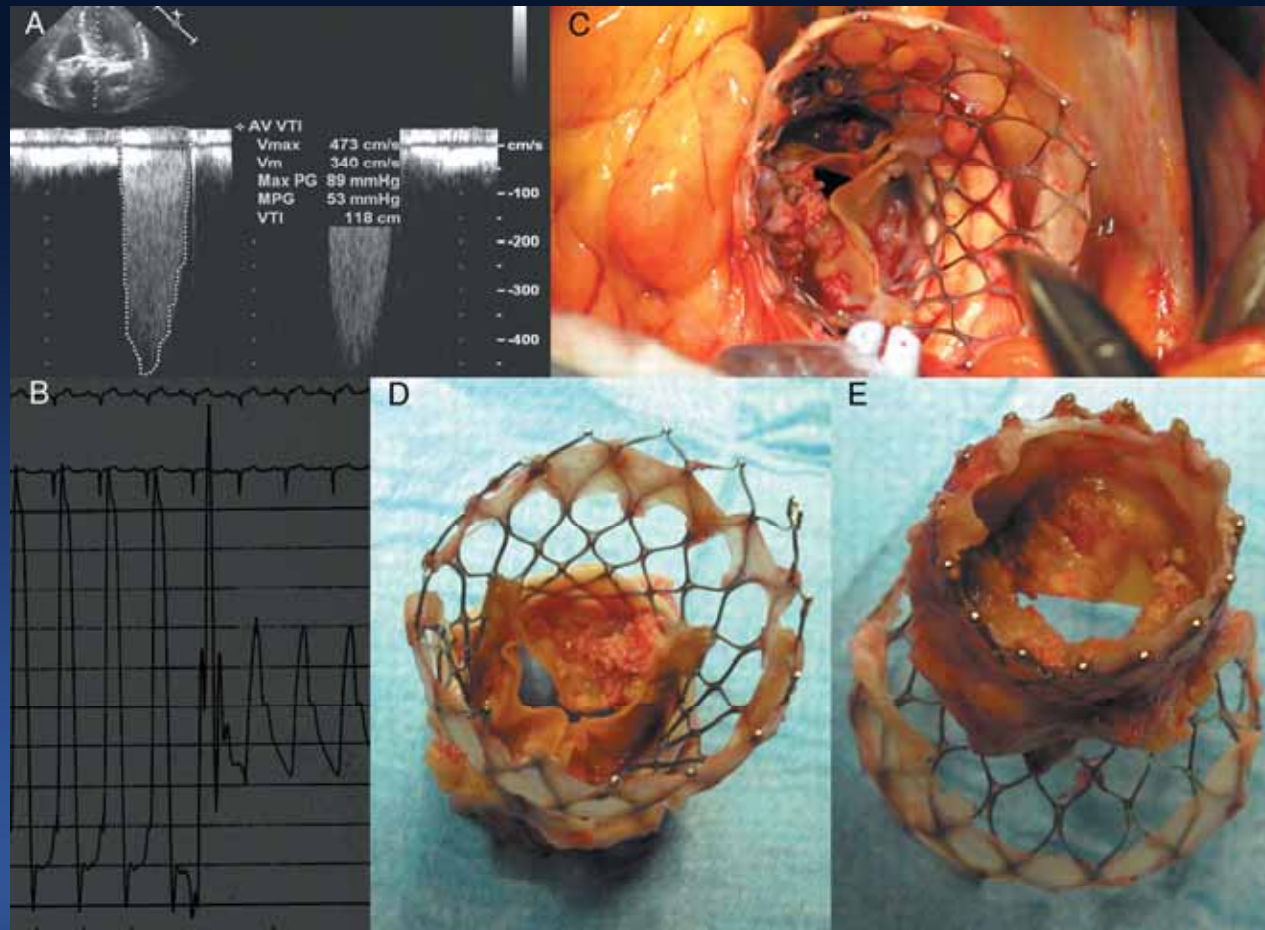
- Mean life in Korea
 - F: 83.8 yrs
 - M: 76.8 yrs
- Rank of expected life
 - Japan, Spain, Swiss, French, Australia, and Korea...



Lower Limit of *Age* in Korea ?

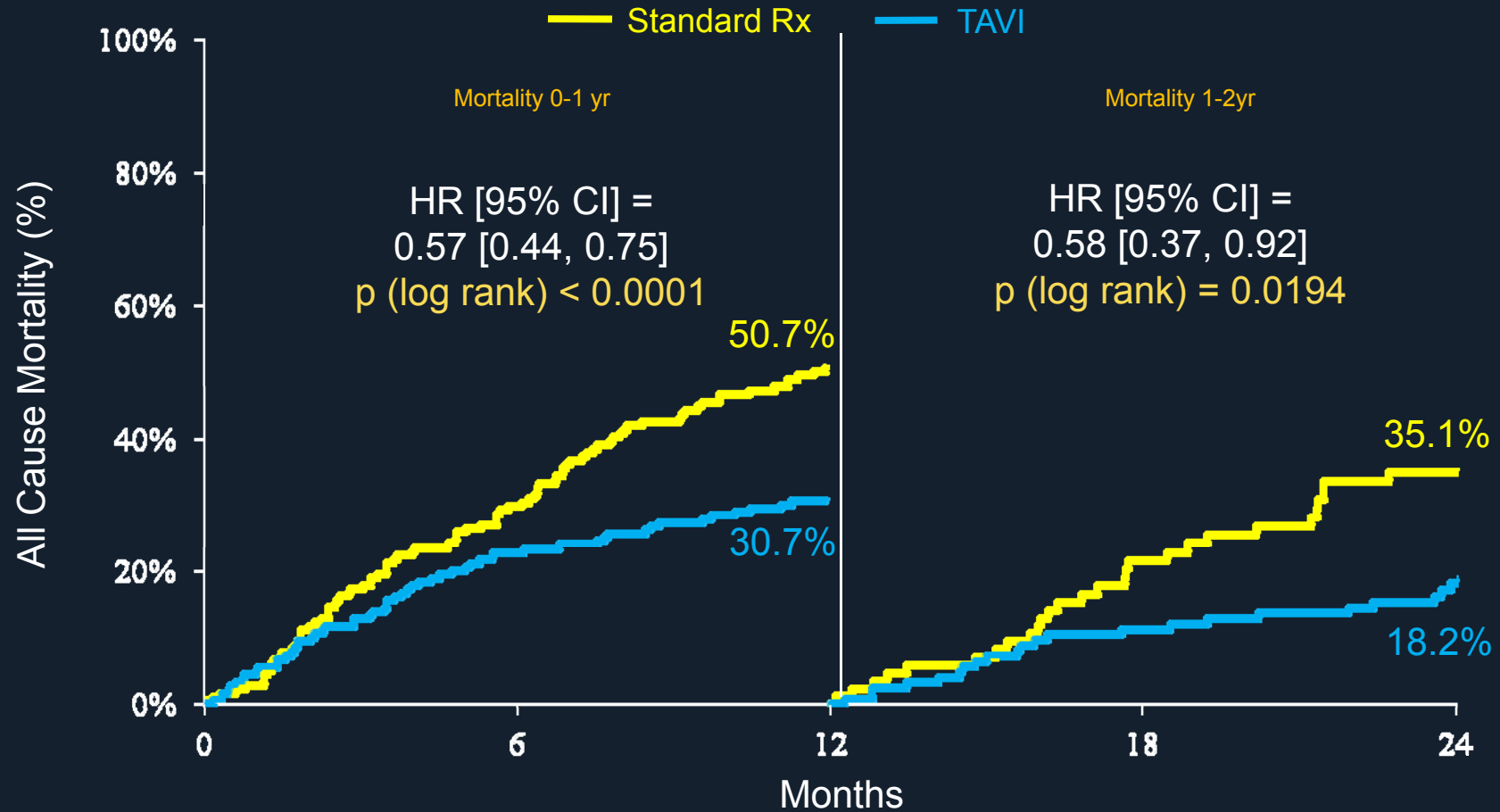
Early degeneration of Core valve after 5 years

74 yrs / Male



All Cause Mortality of Edward Valve

Landmark Analysis of PARTNER 2 Yr

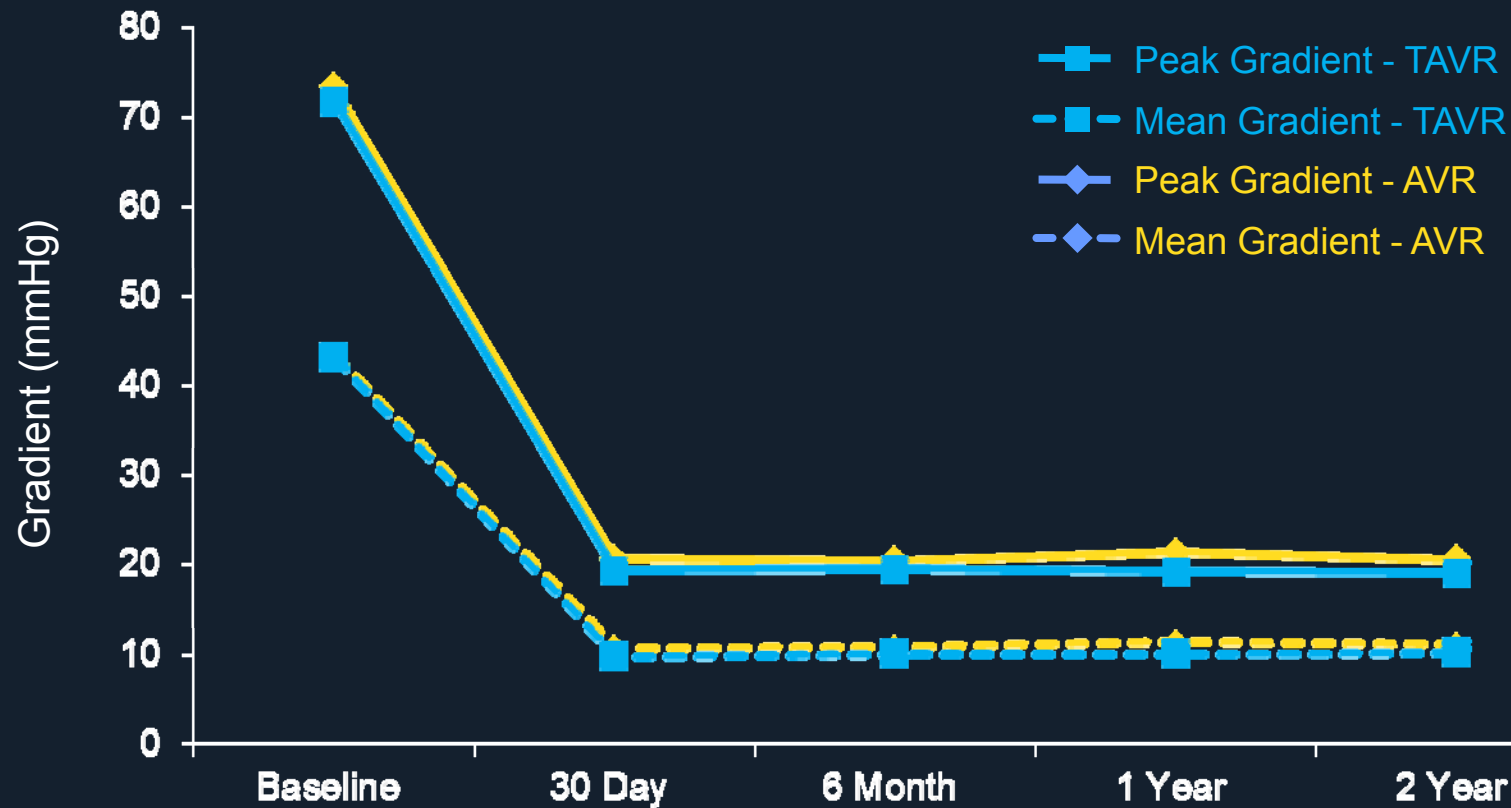


Numbers at Risk

TAVI	179	138	124	110	83
Standard Rx	179	121	85	62	42

Pressure Gradient of Edward Valve

PARTNER 2 Yr

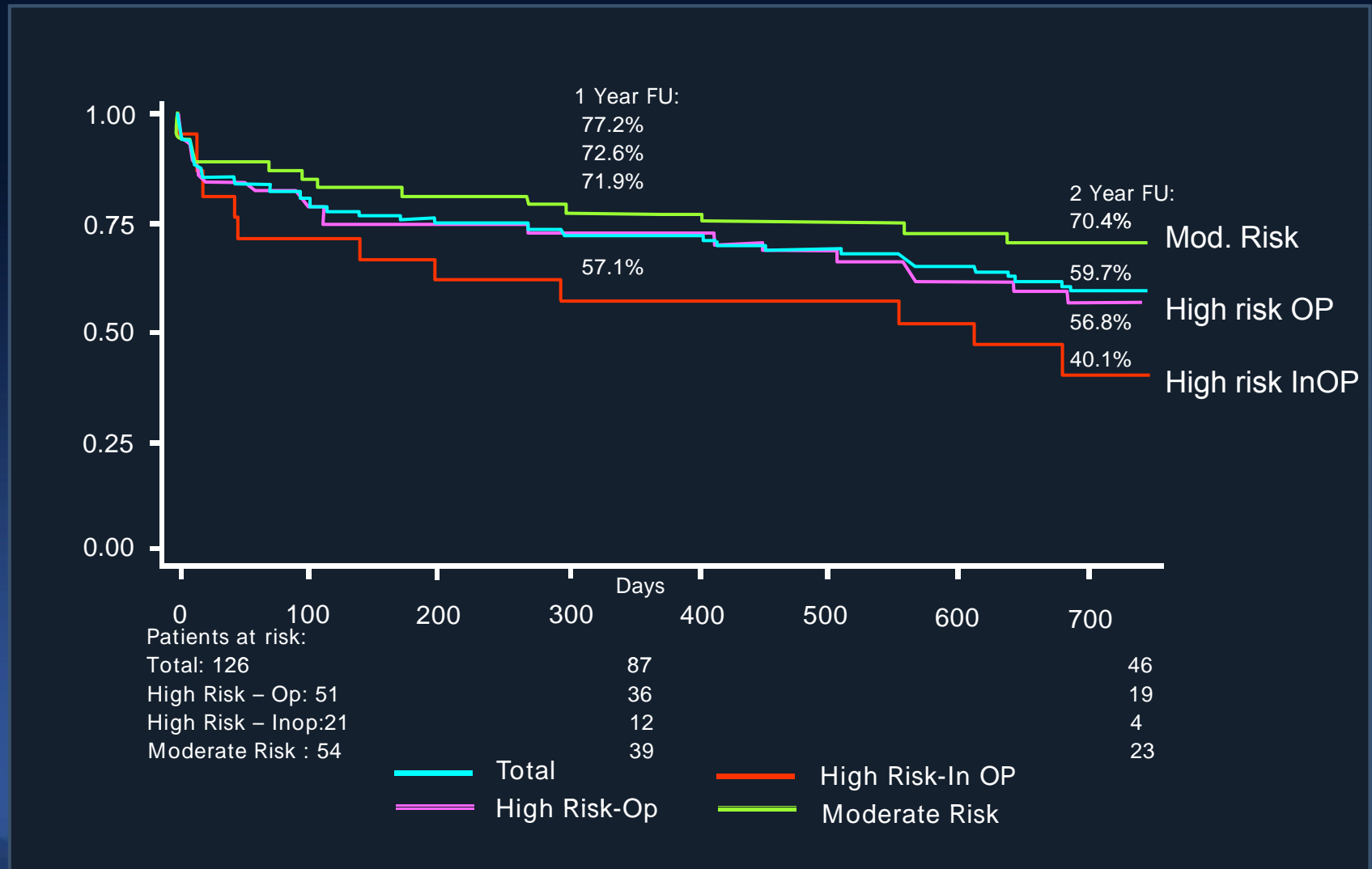


Numbers at Risk

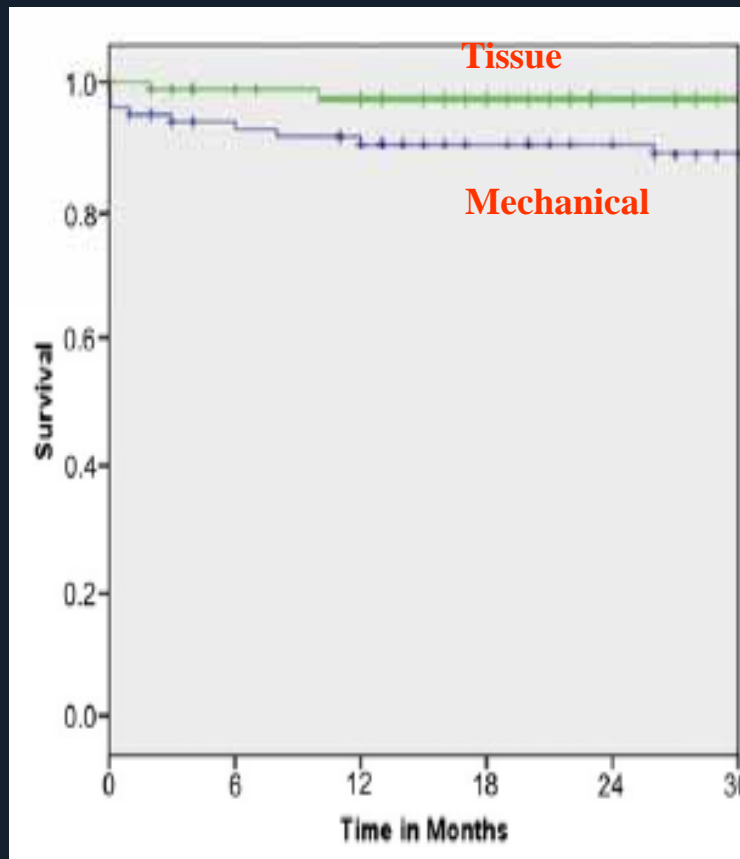
TAVI	307	275	233	218	144
AVR	295	228	168	155	112

Durable Effectiveness of Core Valve

2-Year Outcome of a Registry

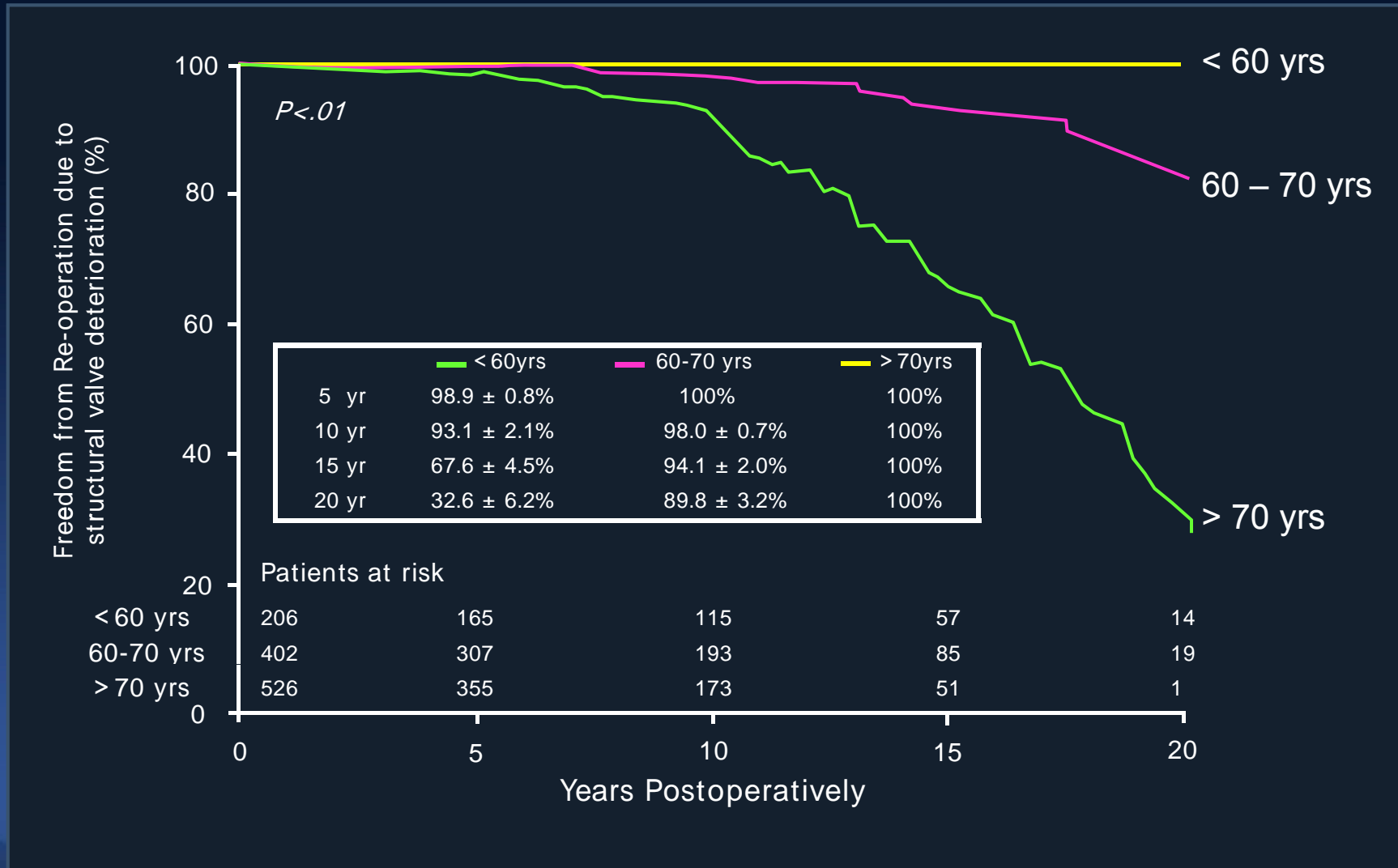


Biological vs. Mechanical Valve after Surgical AVR in Young (<60) Pts Propensity-Matched 103 pairs



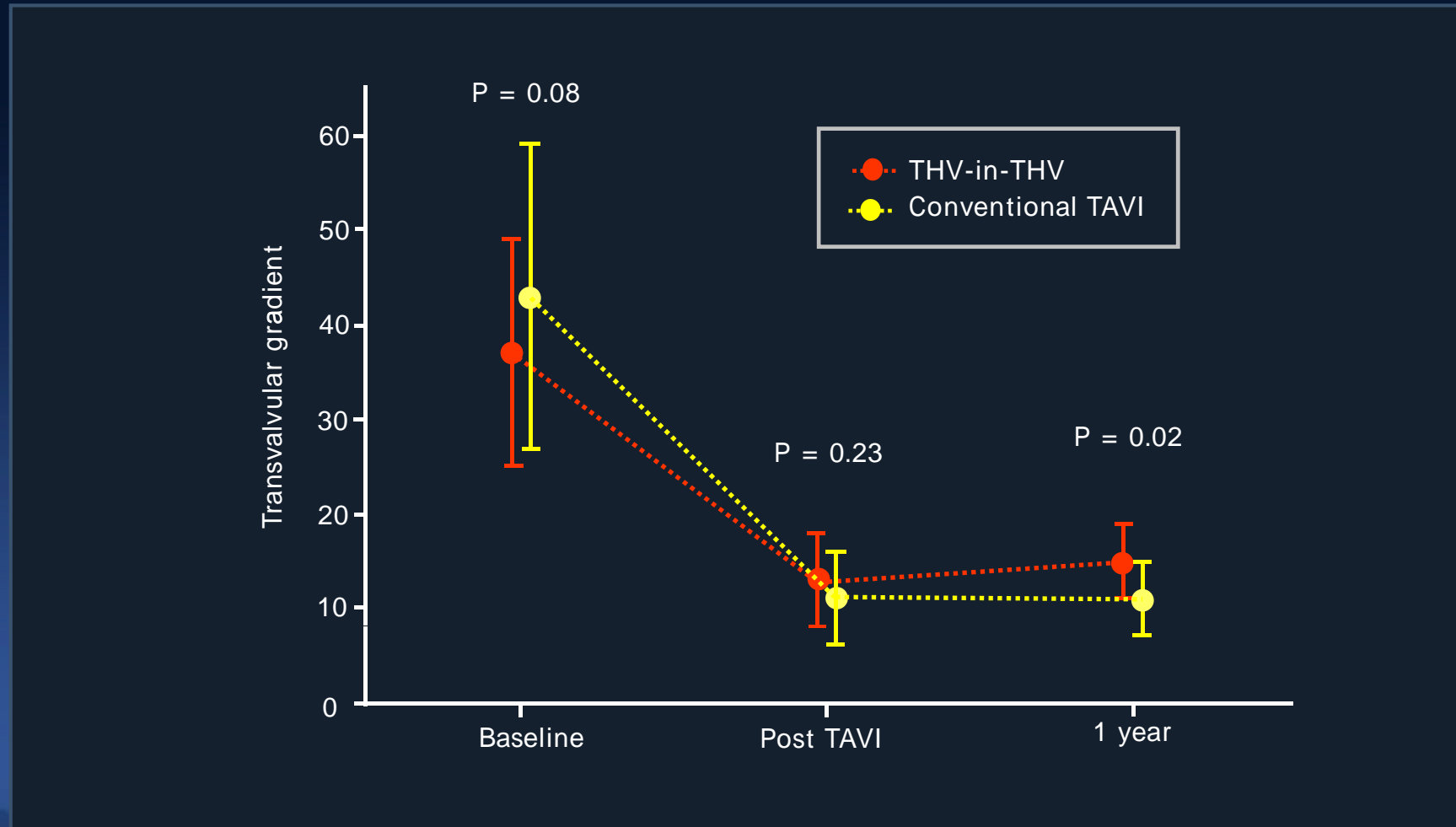
	Tissue	Mechanical	P
All-valve Cx	45.5%	48.4%	NS
Mortality	2%	9.7%	0.038
Re-OP	0	2%	NS
Mean Pr-gradient (mmHg)	11.2 ± 4.2	10.5 ± 6.0	0.05

Hancock Bioprosthetic Valve after AVR

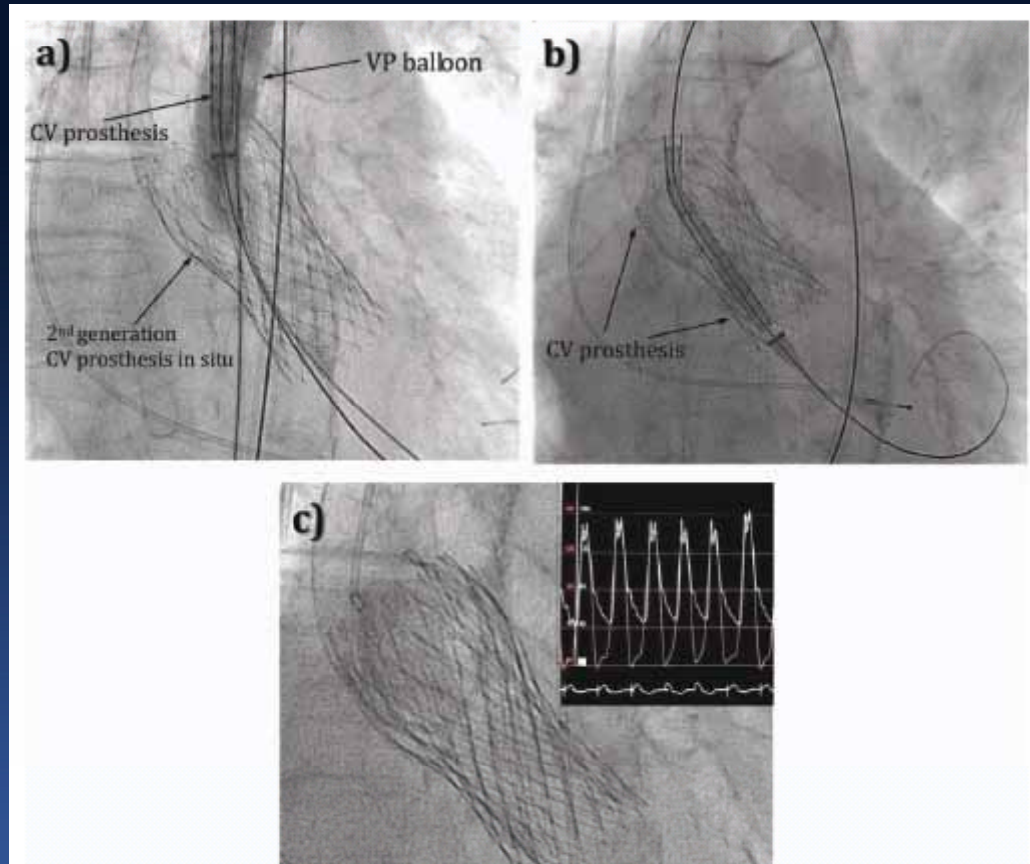


In case of TAVI failure

TAVI Valve in failed TAVI Valve



Repeated TAVI for Degenerative Core Valve



TAVI may be indicated for a wide range of ages ...

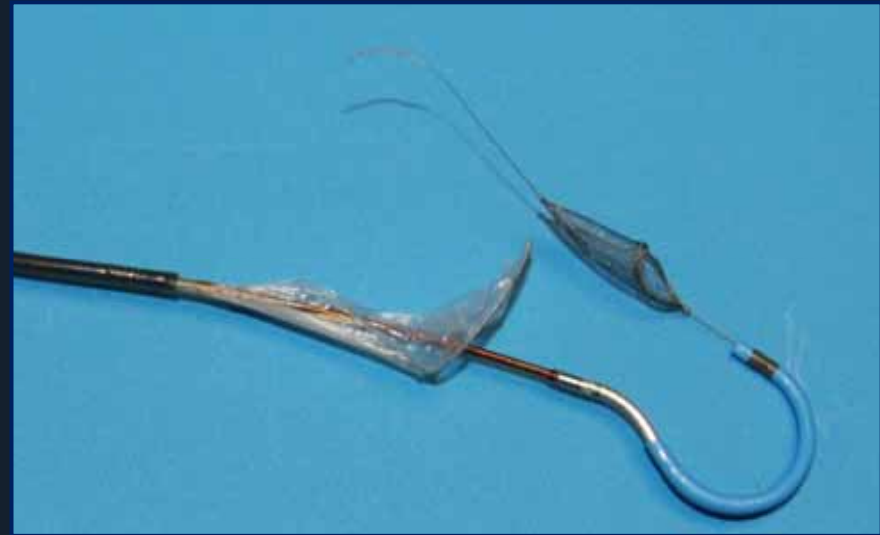
Major Complications

- Mortality
- Stroke
- Vascular complications
- Pacemaker
- Paravalvular regurgitation

Cerebral Embolic Protection Device



Embrella Embolic Deflector
Device



Claret Dual Filter Device

NovaFlex transfemoral delivery system



18 Fr and 19 Fr delivery systems
Minimum ilio-femoral diameter:
6mm

Flexible nose cone



Shorter, softer tip
New balloon processing for intra-aortic stent
mounting

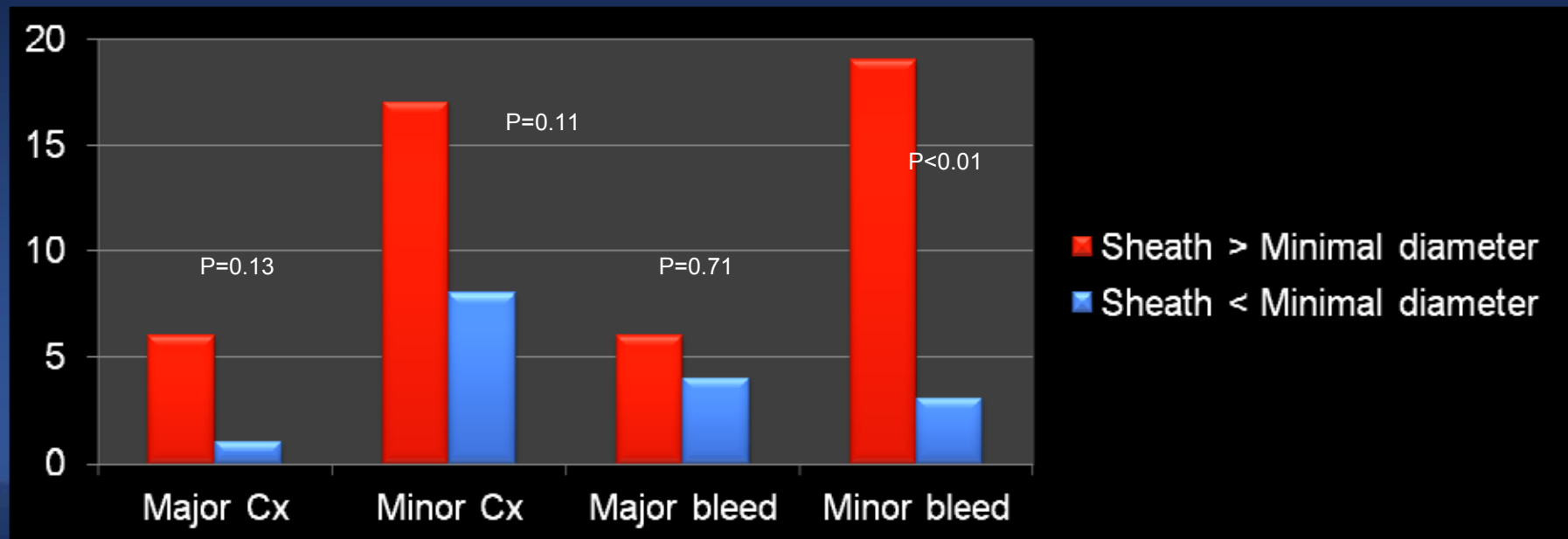


Expandable Sheath



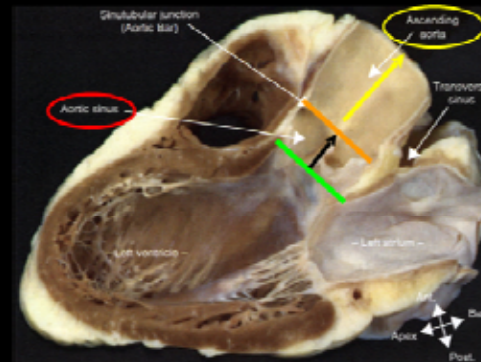
MDCT Parameters of Vascular Cx

Variable	No Cx (N=71)	Cx (N=11)	p
Minimal artery diameter (mm)	7.7 ± 1.1	7.0 ± 1.0	0.04
Minimal artery diameter < sheath external diameter	30 (42%)	9 (82%)	0.01
Moderate to severe calcification	12 (17%)	5 (46%)	0.03
Maximal tortuosity ≥ 45°	17 (24%)	1 (9%)	0.27



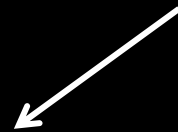
Better Anatomic Evaluation

Aortic Root



Sinotubular junction

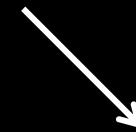
Basal attachment of AV leaflets



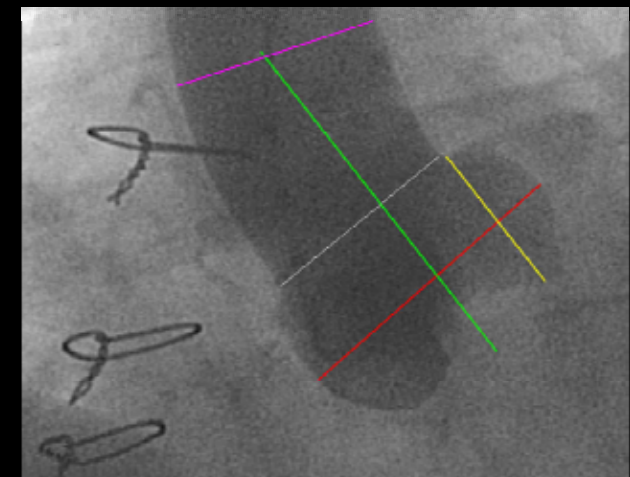
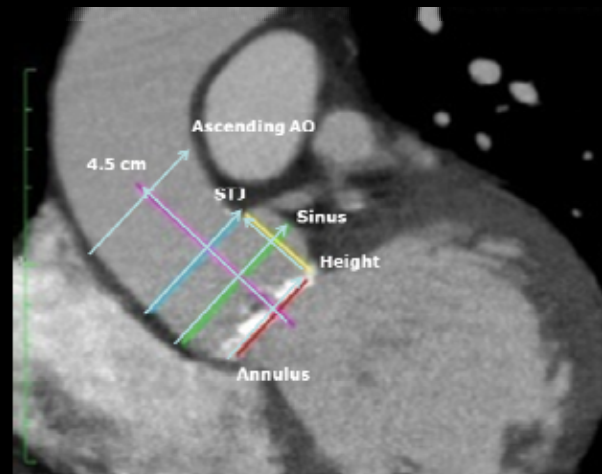
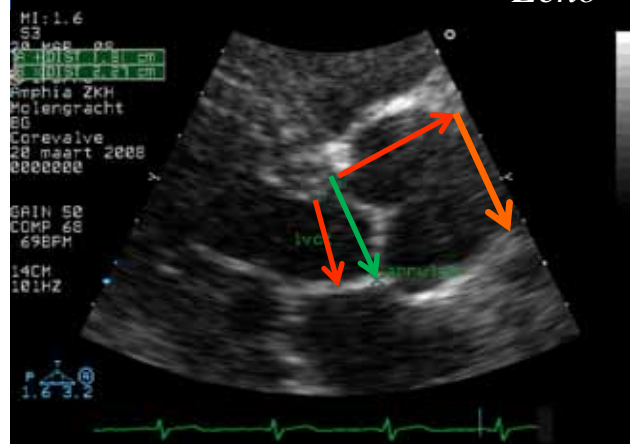
Echo



CT



Angio



ASAN FOUNDATION
ASAN
Medical Center

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About AMC Medical Service Education / Research

Service Flow Department & Subspecialties **Special Centers & Clinics** Find a Doctor Int'l Healthcare Center Appointments

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Medical Service > Special Centers & Clinics

BOOKMARK

Asan Heart Institute

List of Centers



-
- Invasive cardiology
 - Noninvasive cardiac imaging
 - Radiology
 - Cardiac surgery
 - Anesthesiology
 - Vascular surgery

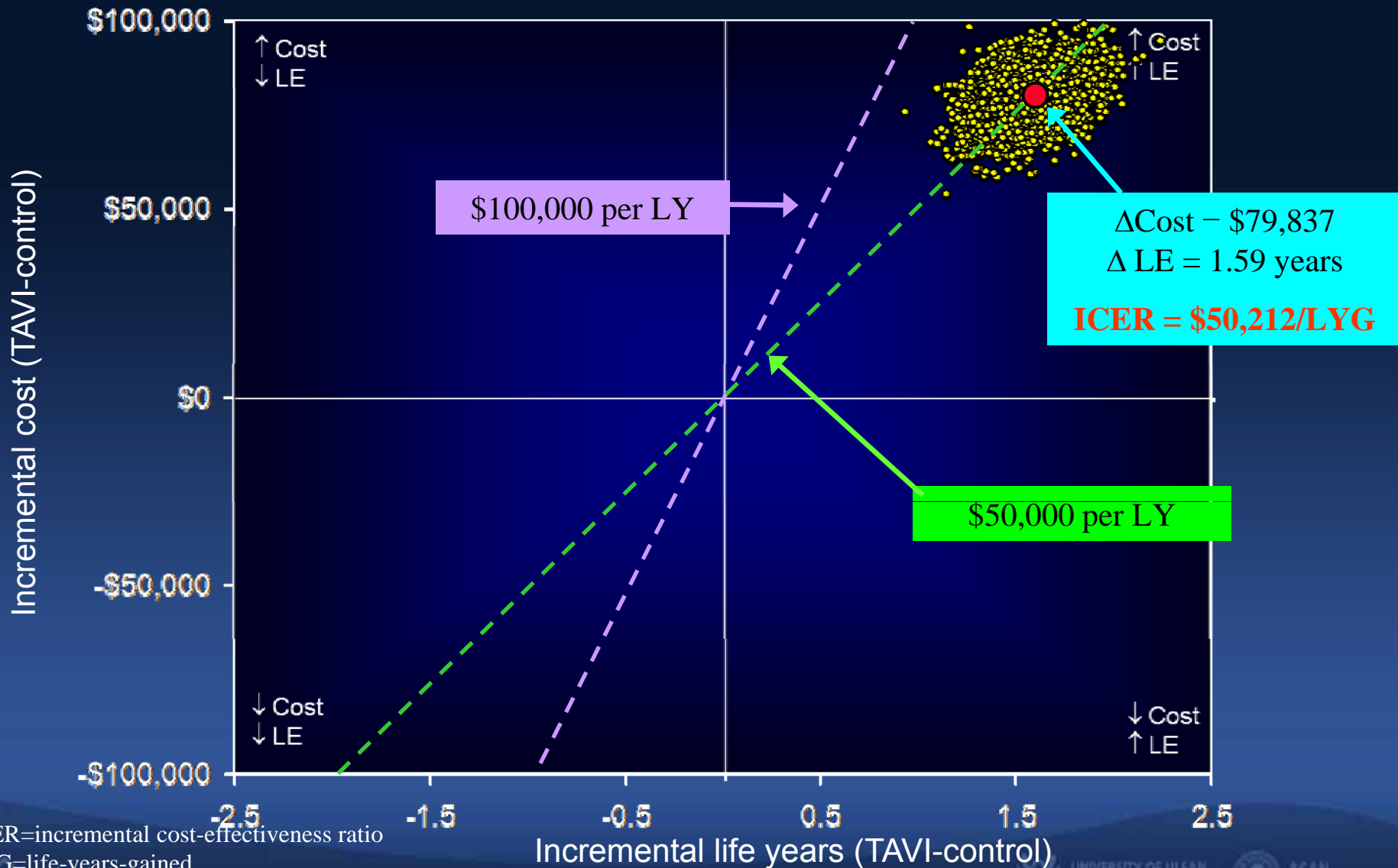
Cooperative Heart Team in AMC

TAVI Complications in AMC

Not common and more decreasing with New Devices

	RF I or III N=9	NovaFlex N=16
Procedural success	8 (88.9%)	16 (100%)
Mortality	0	0
Stroke	0	1 (6%)
Permanent pacemaker	0	0
Vascular complication		
Access site	1 (11.1%)	0
Iliac artery perforation	1 (11.1%)	0
Device embolization	2 (22.2%)	1 (6%)

Cost-Effectiveness of TAVR vs. Control Lifetime Results from PARTNER-B



ICER=incremental cost-effectiveness ratio
LYG=life-years-gained
LE=life expectancy

GDP vs. Cost-Effectiveness

Country	Per Capita GDP*	~ ICER Threshold (\$/QALY)†
Switzerland	\$67,000	\$100,000
Australia	\$55,000	\$82,000
France	\$41,000	\$61,000
UK	\$36,000	\$54,000
Korea	\$23,680	\$35,520
Poland	\$12,000	\$24,000
Brazil	\$11,000	\$22,000
Russia	\$10,000	\$20,000

But, limited generalizability in other countries and no analysis in PARTNER-A (with surgery)

Simple comparison of hospital cost in Korea

No consideration of physician fee

- **TAVI**

- Device : ₩ 30,000,000
- Procedure and admission : ₩ 5,000,000
- Total : approx. ₩ 35,000,000 (\$ 35,000)

- **Surgical AVR**

- Device : ₩ 2,900,000
- Procedural fee : ₩ 3,400,000
- Admission and others : ₩ 18,700,000
- Total : approx. ₩ 26,000,000 (\$ 26,000)

Cost-effectiveness of TAVI will improve ...

Deja vu of Debates

Dr. P. Teirstein

Dr. SJ Park



Narrow Ix vs. Wide Ix



*For LM PCI
in ACC 2005 in Orlando*

***7 years later,
LM PCI is globally indicated***