Percutaneous Aortic Valve Therapies- Update 2015

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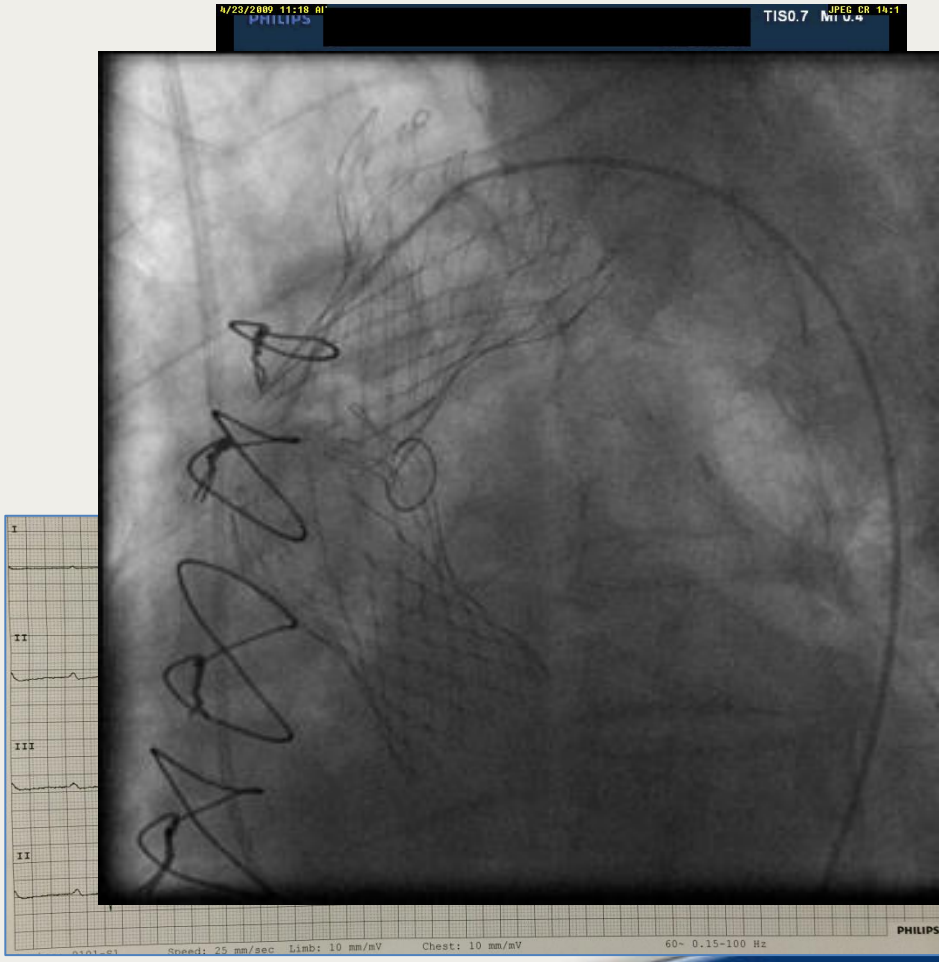
Goals of Percutaneous Valve Therapy

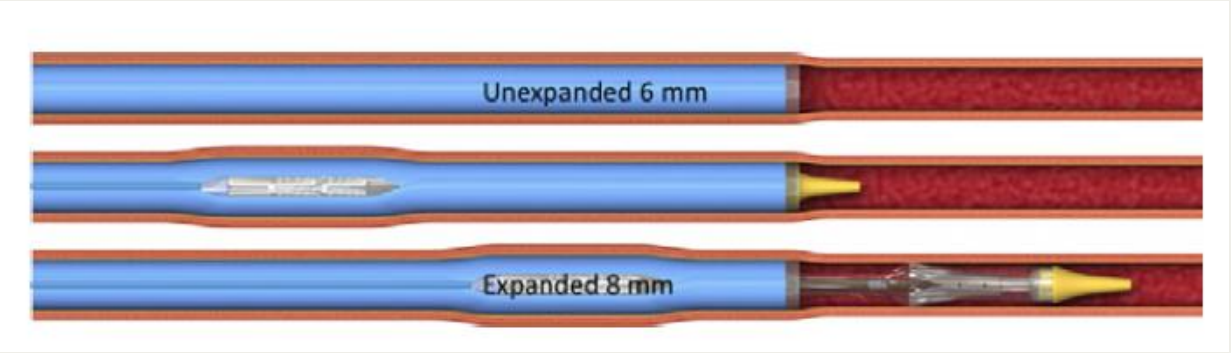
- No paravalvular leak
- Durable
- Safe
- Repositionable
- Low-Profile
  - Transfemoral access
- Prevents myocardial injury
  - Heart block
- Easy to Implant

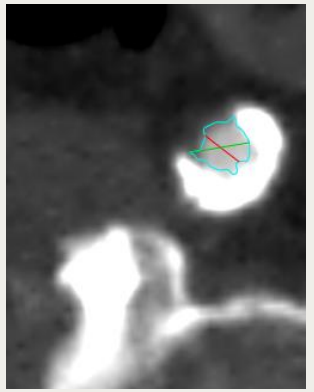


Edwards Balloon-Expandable Valves Characteristics

			
Frame	SAPIEN Stainless Steel	SAPIEN XT Cobalt Chromium	S3 Cobalt Chromium
Annulus range	18-25 mm	18-29 mm	17-29 mm
Sizes	23,26 mm	23, 26, 29 mm	20, 23, 26, 29 mm
Sheath Size (ID)	22, 24Fr	16, 18, 20 Fr	14, 16Fr
Vascular Complications (30D)	15.5%	9.5%	6.0%
Pacemaker (30D)	5.9 %	6.4%	13.3%
Stroke (30D)	3.0%	3.2%	2.7%
≥ Moderate AR	12.2%	4.1 %	3.4%

Edwards Balloon-Expandable Valves Access- XT





	Sheath ID	Sheath OD	Sheath OD Expanded	Minimum Vessel Diameter
23 mm	16Fr	6.7 mm	8.9 mm	6.0 mm
26 mm	18 Fr	7.2 mm	8.9 mm	6.5 mm
29 mm	20 Fr	8.0 mm	9.9 mm	7.0 mm

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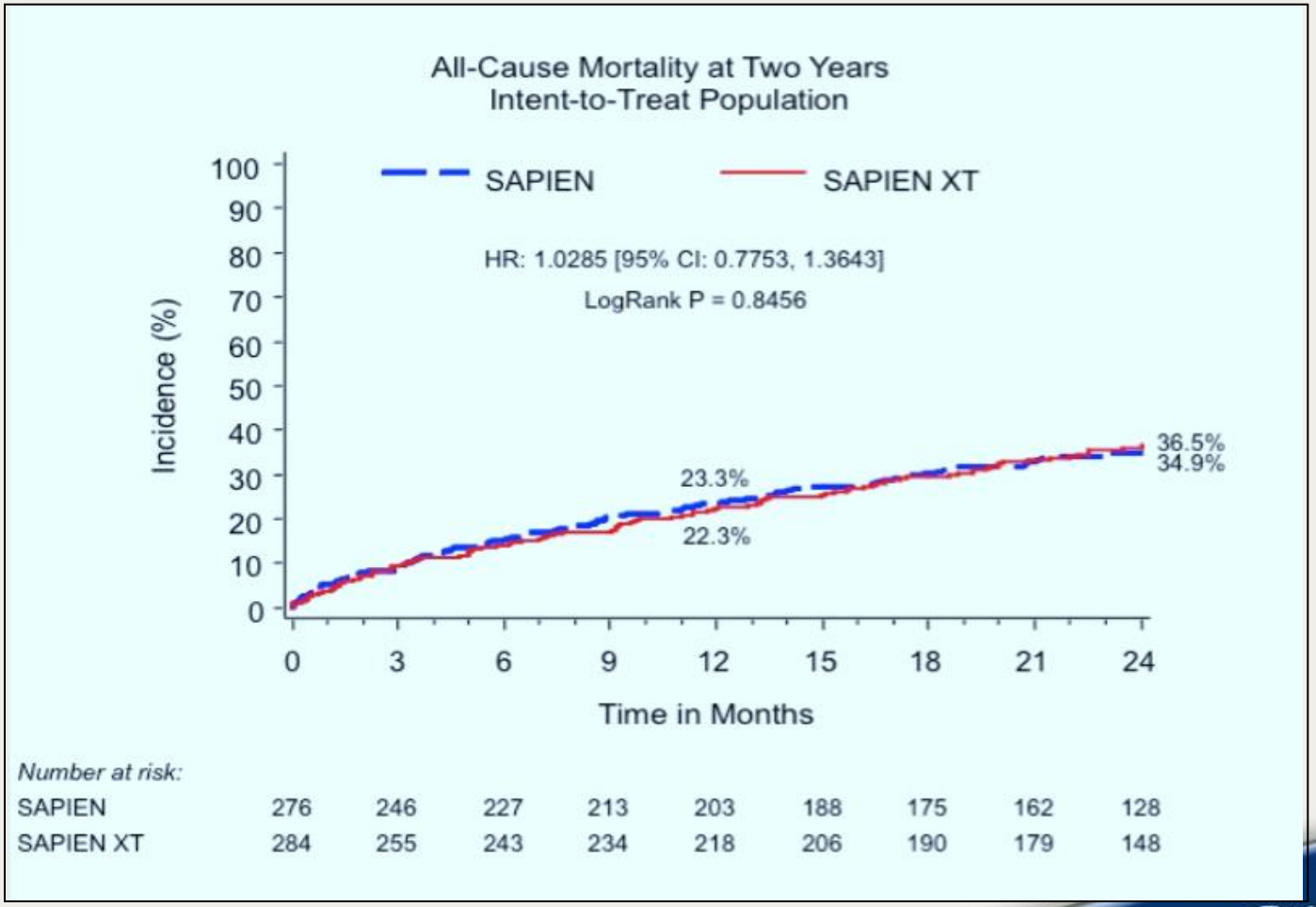
PARTNER II B
Sapien/Sapien XT Survival



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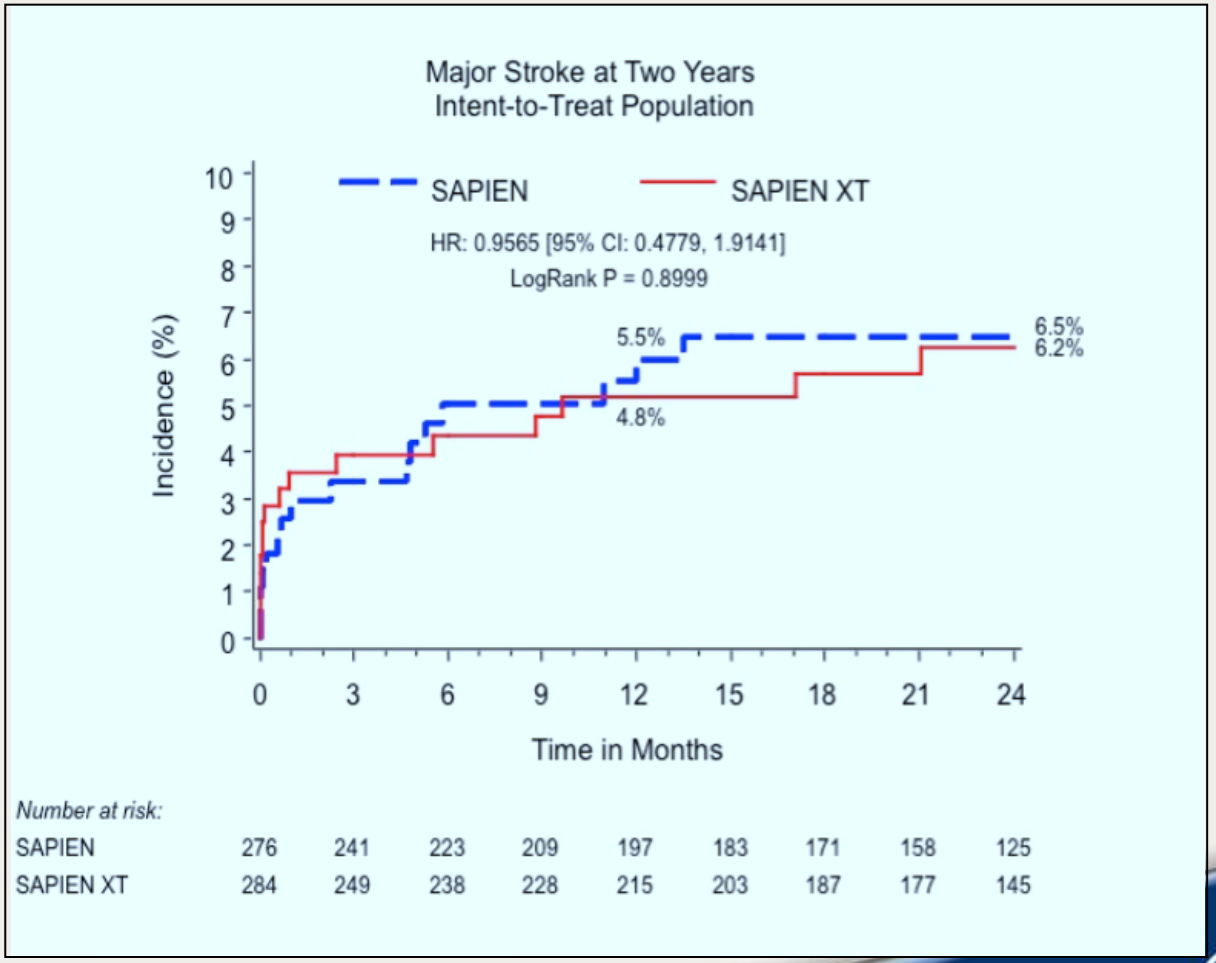
PARTNER II B
Sapien/Sapien XT Stroke



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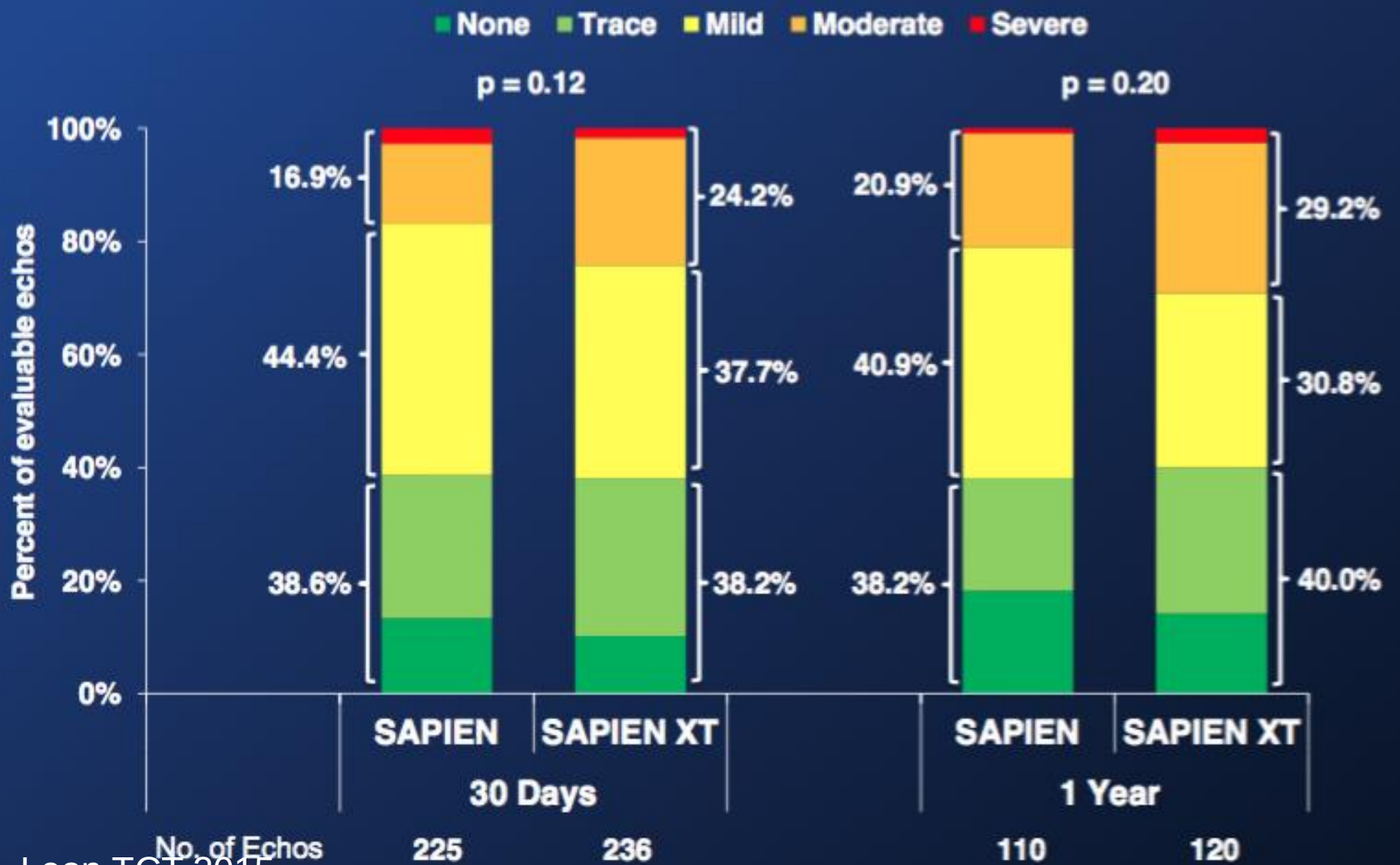
Paravalvular Aortic Regurgitation (AT, Valve Implant)



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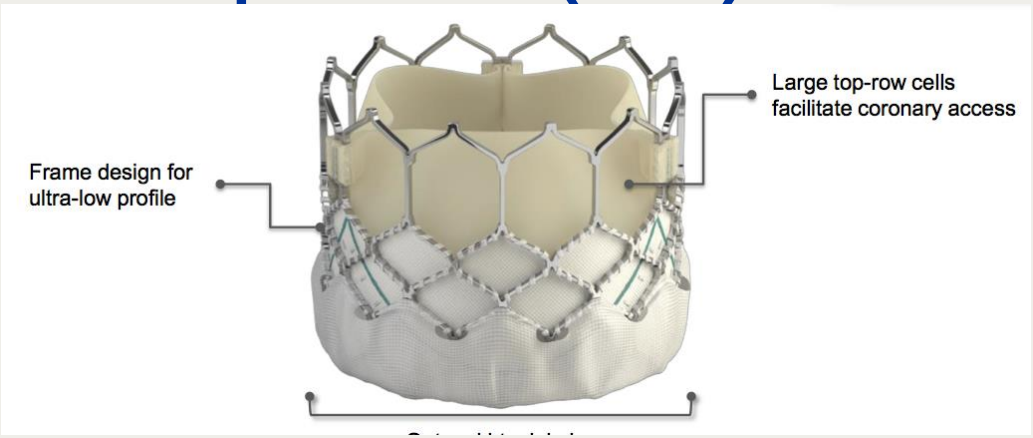
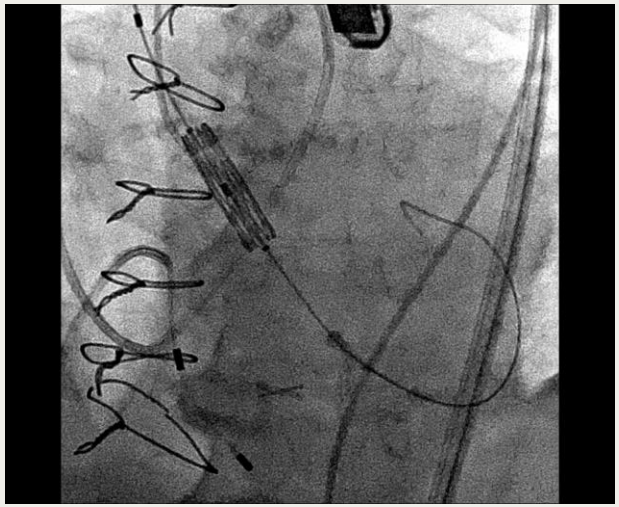
Balloon-Expandable Valves
Sapien 3 (S3)





	Sheath ID	Sheath OD	Sheath OD Expanded	Minimum Vessel Diameter
23 mm	14 Fr (4.6 mm)	6.0 mm	7.6 mm	5.5 mm
26 mm	14 Fr (4.6 mm)	6.0 mm	8.0 mm	5.5 mm
29 mm	16 Fr (5.3 mm)	6.7 mm	8.6 mm	6.0 mm

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Binder R et al. JACC Int. 2013;6:301-7

Edwards S3
Survival in Inoperable and HR

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Other Clinical Outcomes
S3 HR / INOP – 30 Days and 1 Year

THE PARTNER II TRIAL

N=364

Clinical Outcomes (%)	30 Days	1 Year
All-Cause Mortality	2.2	14.4
Cardiac Mortality	1.4	8.1
All Stroke	1.4	4.3
Disabling Stroke	0.9	2.4
Rehospitalization	8.0	17.1
New Permanent Pacemaker	13.3	16.9
Surgical AVR	0.2	0.6
Structural Valve Deterioration	0	0
Valve Thrombosis	0	0

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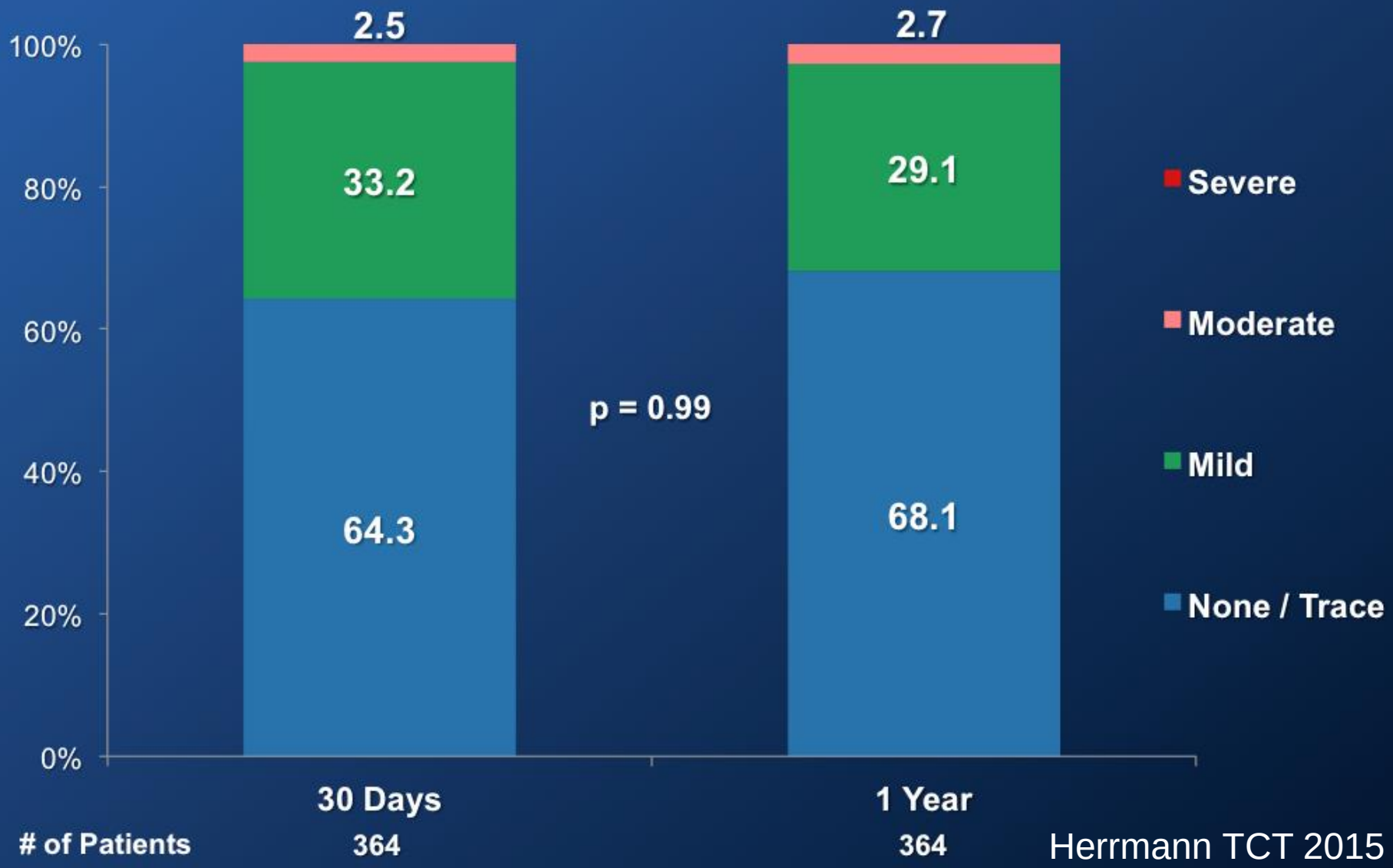
Paravalvular Regurgitation
Paired Analysis

THE PARTNER II TRIAL

S3 Inoperable and High Risk



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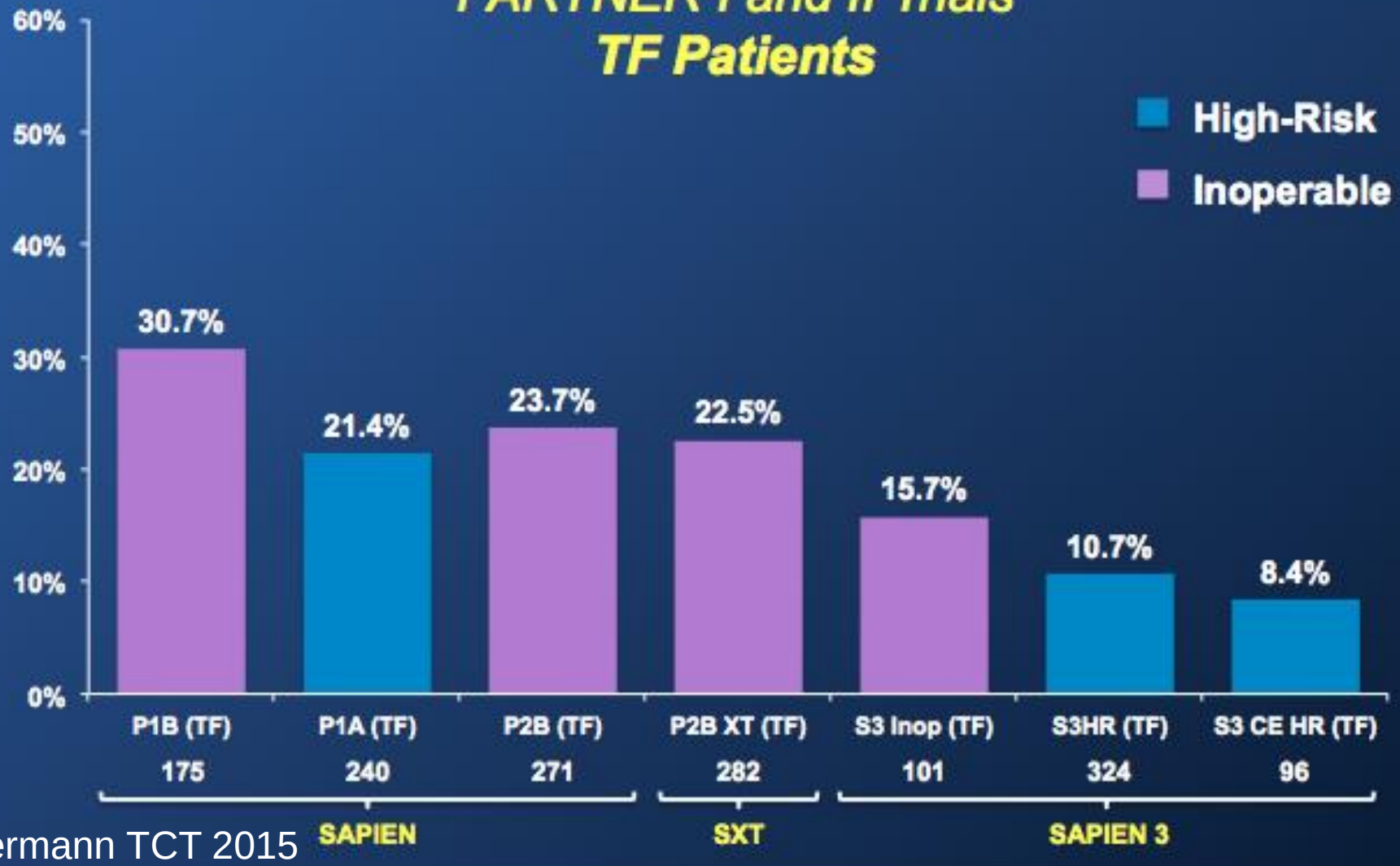
All-Cause Mortality at 1 Year

Edwards SAPIEN Valves (As Treated Patients)

THE PARTNER II TRIAL



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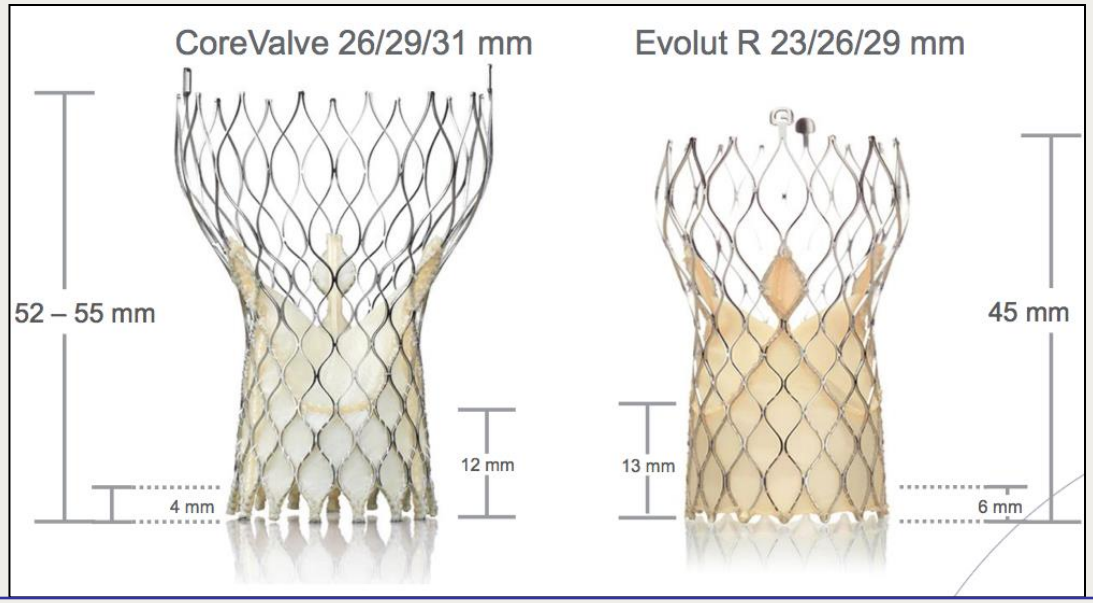
Self-Expanding Medtronic CoreValve Series



Annulus Range	18-29 mm	18-26 mm
Perimeter	56.5 - 91.1 mm	56.5 – 84.8 mm
Sheath Size (ID)	18Fr	14Fr
Access	TF, SC, TAo	TF, SC, TAo
Pacemaker rate	26.1%	11%

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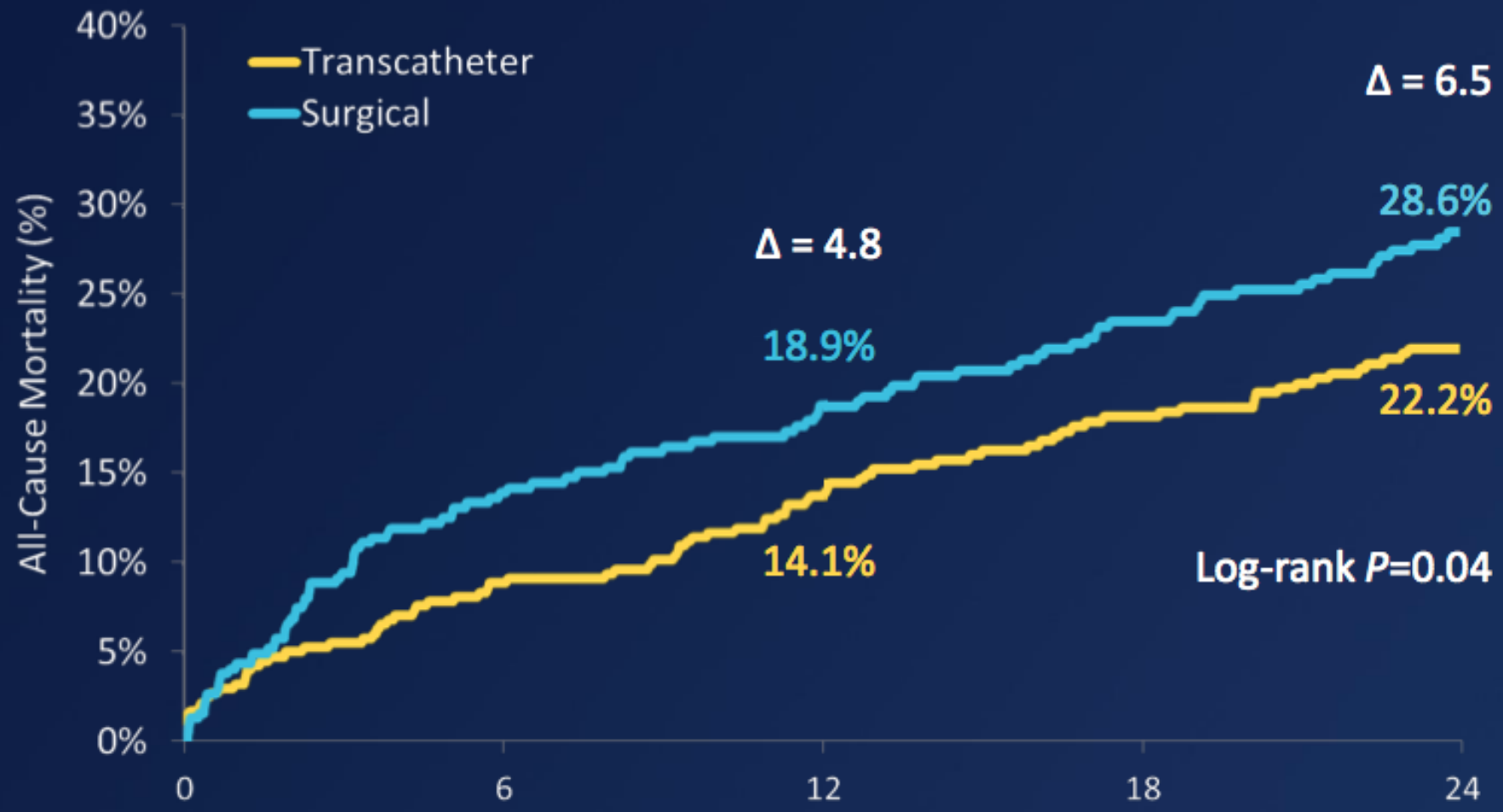
All-Cause Mortality



No. at Risk					
Transcatheter	391	378	354	334	219
Surgical	359	343	304	282	191

Other Clinical Endpoints

Events*	1 Month			1 Year			2 Years		
	TAVR	SAVR	*P*	TAVR	SAVR	*P*	TAVR	SAVR	*P*
Vascular complications (major)	6.2	1.7	0.002	6.4	2.0	0.003	7.1	2.0	0.001
Pacemaker implant	20.0	7.1	<0.001	22.5	11.6	<0.001	25.8	12.8	<0.001
Bleeding (life threatening or disabling)	13.6	35.1	<0.001	16.5	38.4	<0.001	18.1	39.6	<0.001
New onset or worsening atrial fibrillation	11.7	31.0	<0.001	16.4	33.2	<0.001	19.5	34.9	<0.001
Acute kidney injury	6.2	15.1	<0.001	6.2	15.1	<0.001	6.2	15.1	<0.001

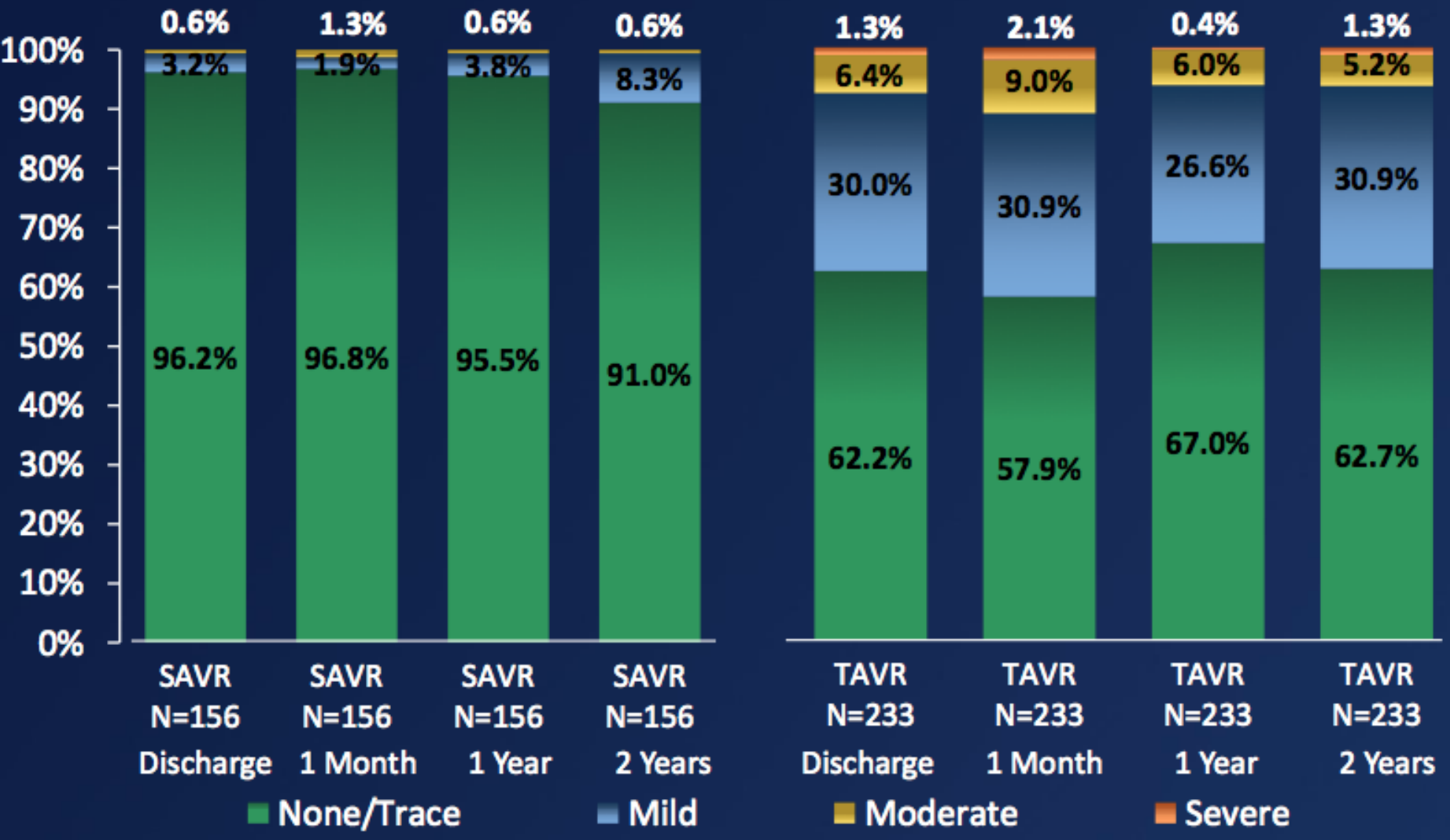
* Percentages reported are Kaplan-Meier estimates and log-rank *P* values

Echocardiographic Findings

TAVR had significantly better valve performance over SAVR at all follow-up visits (*P*<0.001)

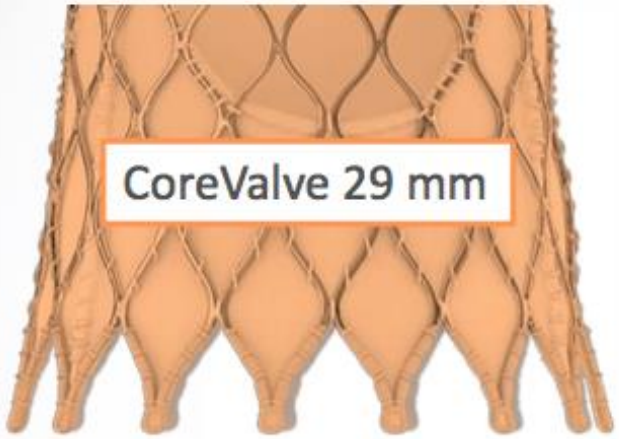
M Reardon TCT 2015

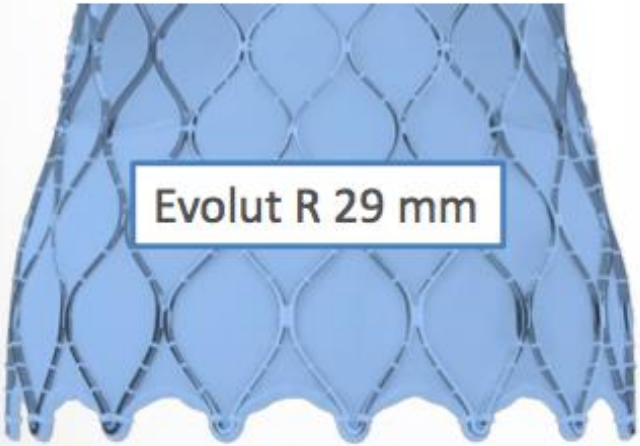
Paravalvular Regurgitation (Paired)



There was significantly lower PVL with SAVR over TAVR at each time point ($P<0.001$)

Self-Expanding Evolut-R





1. Optimized Oversizing
   - Larger and more consistent inflow diameter
2. More Consistent Radial Force
   - Promotes anchoring and sealing
3. Extended Sealing Skirt
   - 13 mm sealing skirt
   - Scalloped design for enhanced sealing

Sinus of Valsalva Height (Mean)	≥ 15 mm	≥ 15 mm	≥ 15 mm

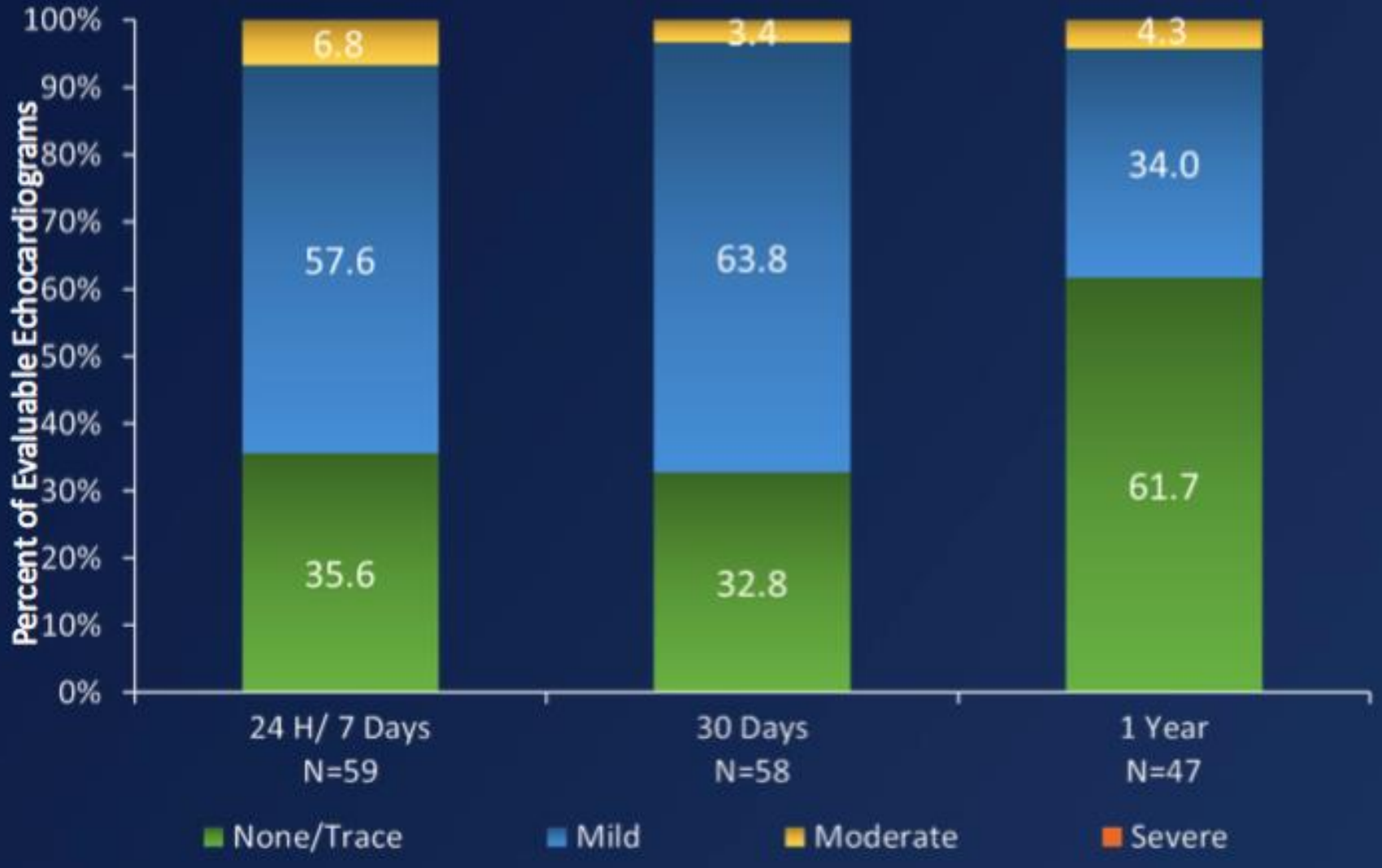
Evolut-R: 1 Year Clinical Events

Event, K-M rates – % (no. of patients)	30 Days N = 60	1 Year N = 60
Major vascular complications	8.3 (5)	8.3 (5)
Life-threatening or disabling bleeding	5.0 (3)	10.2 (6)*
Embolization or migration	0.0 (0)	0.0 (0)
Endocarditis	0.0 (0)	0.0 (0)
Coronary obstruction	0.0 (0)	0.0 (0)
Annular rupture	0.0 (0)	0.0 (0)
Valve thrombosis	0.0 (0)	0.0 (0)
Pacemaker†	11.7 (7)	15.2 (9)

*All events after 30 days due to GI bleeding.
†7 at 30 days due to 3rd degree AV block pacing indication; 1 due to AF and slow ventricular response at 6 months; 1 due to symptomatic junctional rhythm at 1 year.

Manoharan G TCT 2015

Evolut-R: 1 Year Paravalvular Regurgitation



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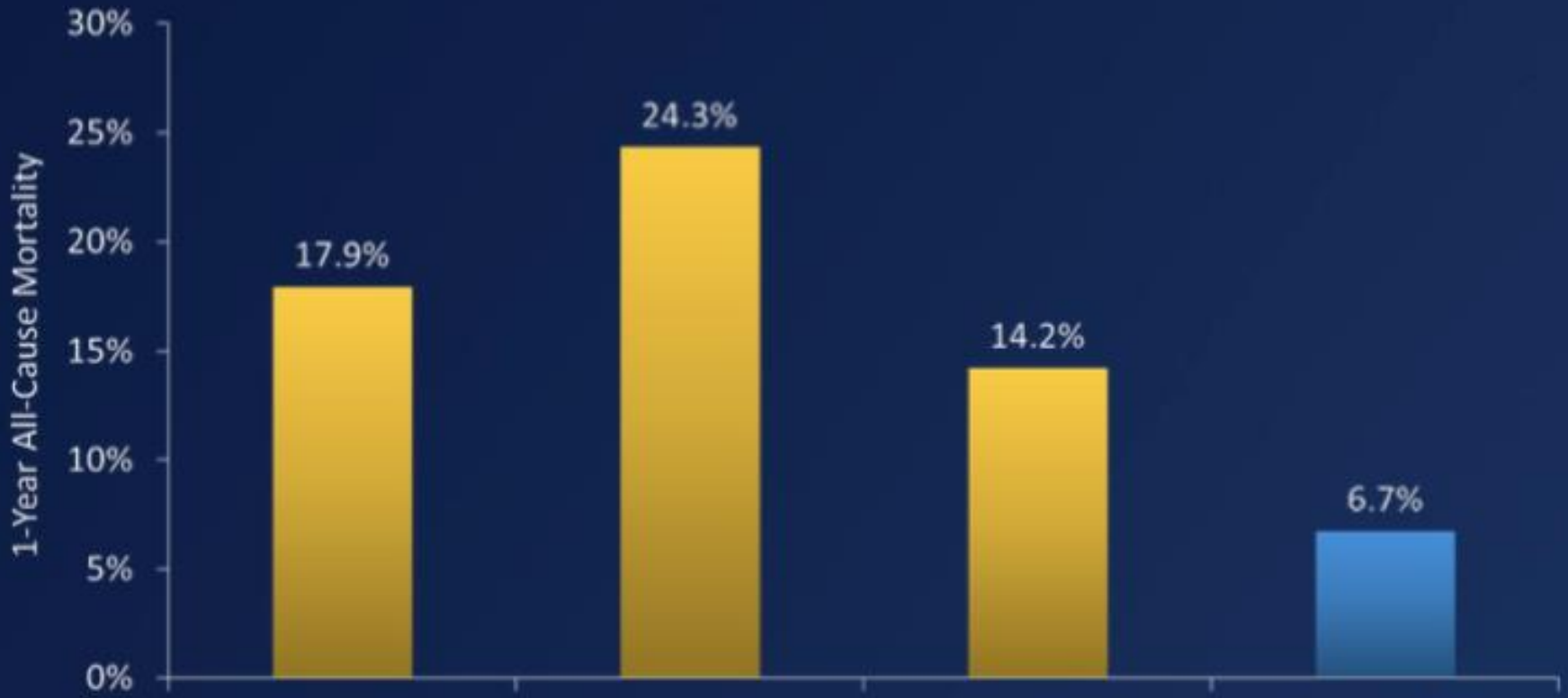
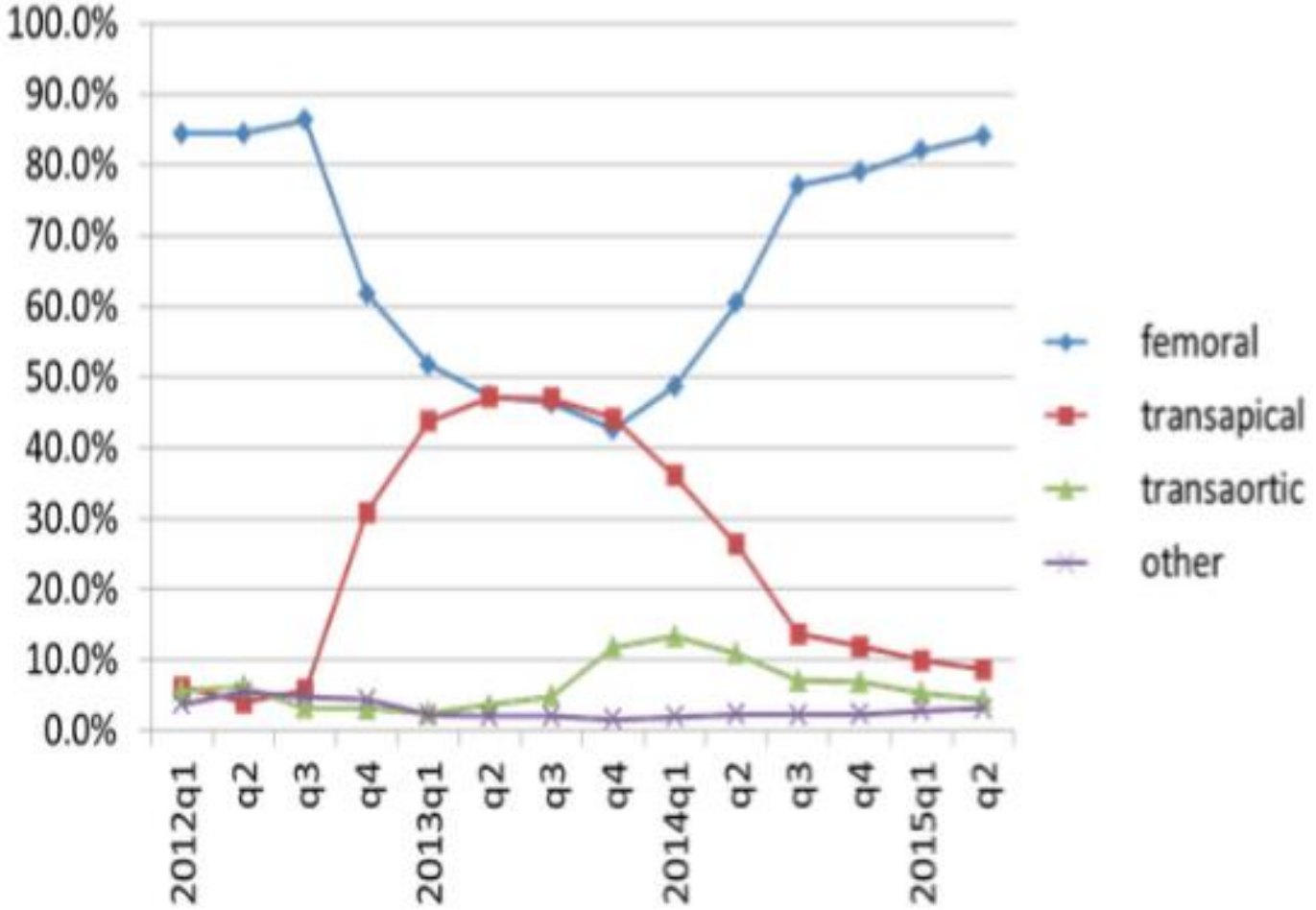
CoreValve: 1 Year All-Cause Mortality



STS (%)	6.4	10.3	7.3	7.0
Enrollment Period	Mar 2010–Jul 2011	Feb 2011–Aug 2012	Feb 2011–Sep 2012	Oct 2013–Jul 2014

[1]Linke, et al. , Eur Heart J 2014;35:2672-84; [2]Popma, et al., J Am Coll Cardiol 2014;63:1972-81; [3]Adams, et al., N Engl J Med 2014;370:1790-8.

Femoral Access
TVT Registry



The most dynamic element of TAVR that is tracked in TVT Registry.

Evolut and Sapien 3 will bring us to a plateau of TF access in >90%.

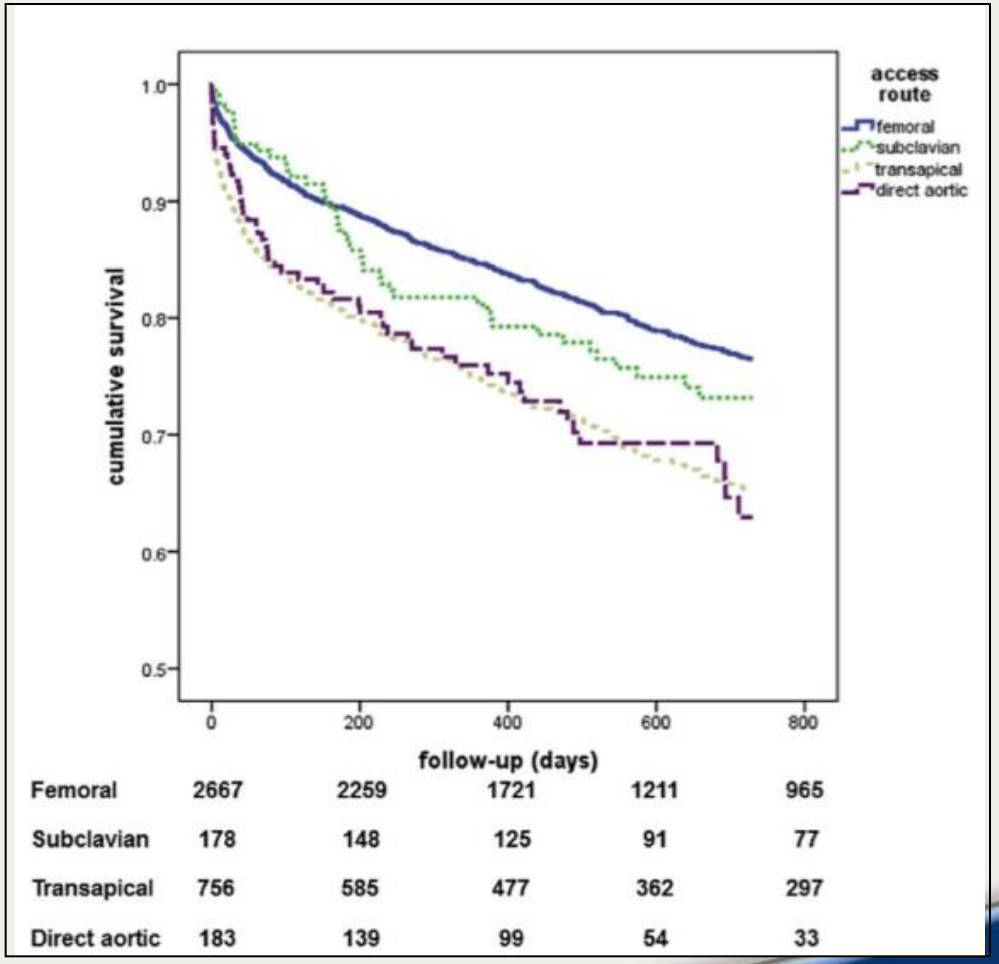
TF access now rarely requires cut-down

STS National Database
Using data to drive quality

NCDR
NATIONAL CARDIOVASCULAR DATA REGISTRY

Source: STS/ACC TVT Registry
37,553 patients as of 9-15

Alternative Access
UK Registry



Femoral	2667	2259	1721	1211	965
Subclavian	178	148	125	91	77
Transapical	756	585	477	362	297
Direct aortic	183	139	99	54	33

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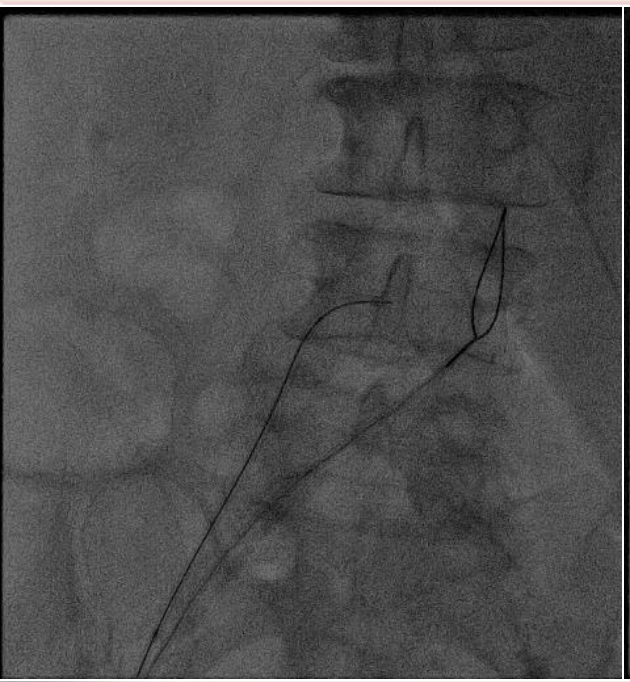
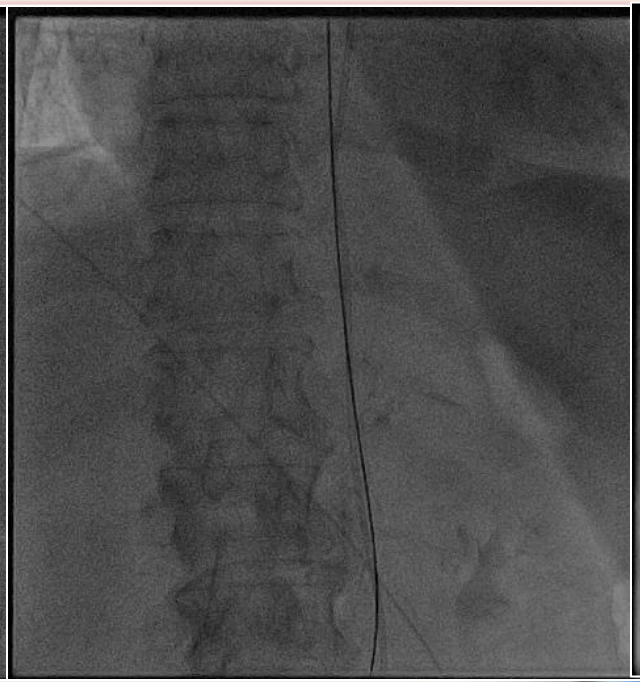
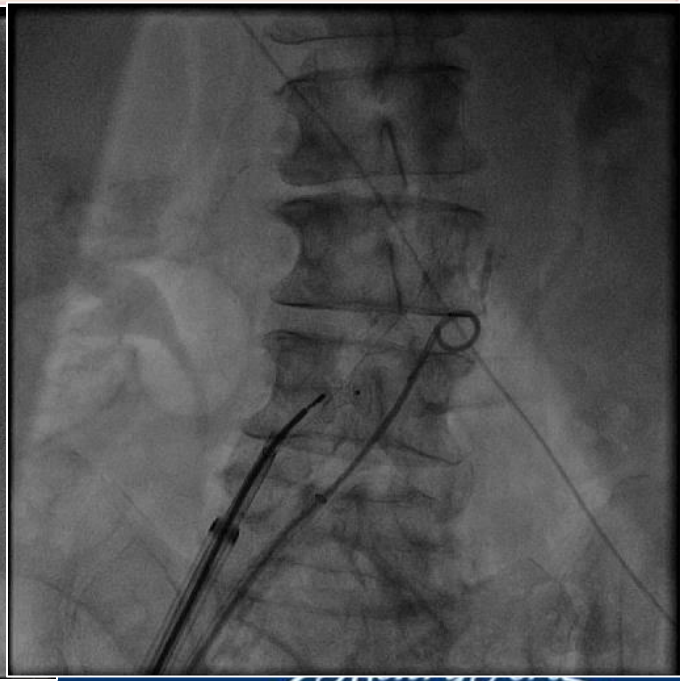
Caval-Aortic Access to Allow Transcatheter Aortic Valve Replacement in Otherwise Ineligible Patients

Initial Human Experience

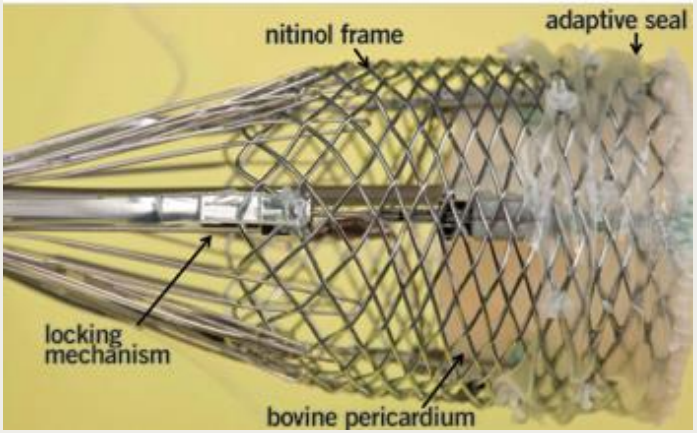
Adam B. Greenbaum, MD,* William W. O'Neill, MD,* Gaetano Paone, MD,†
Mayra E. Guerrero, MD,* Janet F. Wyman, DNP,* R. Lebron Cooper, MD,‡ Robert J. Lederman, MD§
Detroit, Michigan; and Bethesda, Maryland







“Mechanical Expanding” Valve
Lotus Valve



- Neither self or balloon expandable
  - Mechanical expansion
- Repositionable
- Retrievable
- Adaptive Seal

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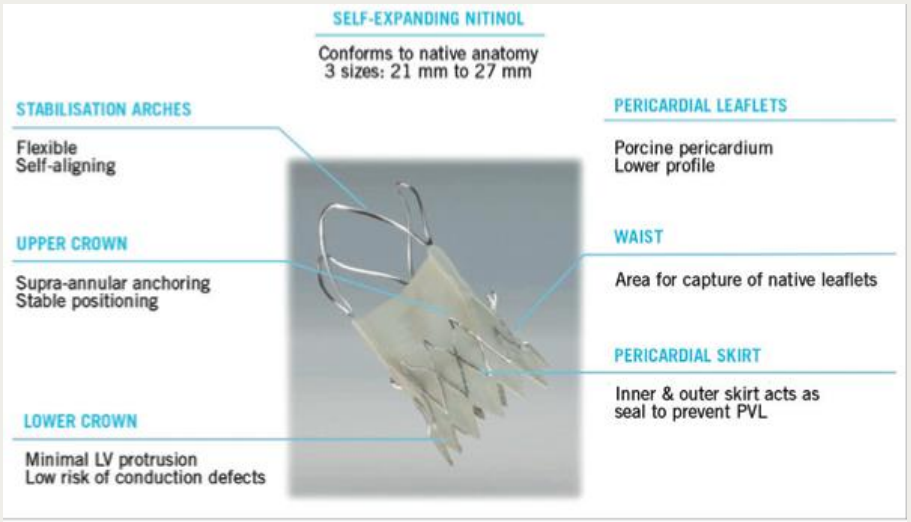
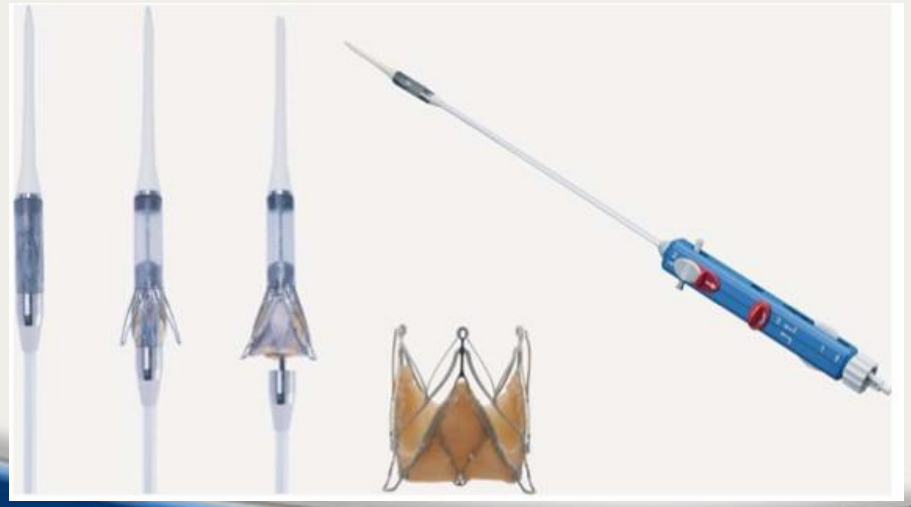
Merideth, I et al. EuroIntervention 2014;9: 1264-1270.

LOTUS 30 Day
RESPOND- Post-Market CE

All-cause mortality	1.9% (9/483)
Cardiovascular mortality	1.7% (8/483)
All stroke	3.9% (19/483)
Disabling stroke	2.7% (13/483)
Life-threatening or disabling bleeding	1.7% (8/483)
Myocardial infarction (>72h post-procedure)	0.2% (1/483)
Acute kidney injury (Stage 2 or 3)	1.7% (8/483)
Repeat procedure for valve-related dysfunction	0% (0/483)
Valve- or CHF-related repeat hospitalisation	0.8% (4/483)
Newly implanted permanent pacemaker	30.6% (148/483)
Pacemaker dependent at 30 days (site-reported)	36.5% (54/148)

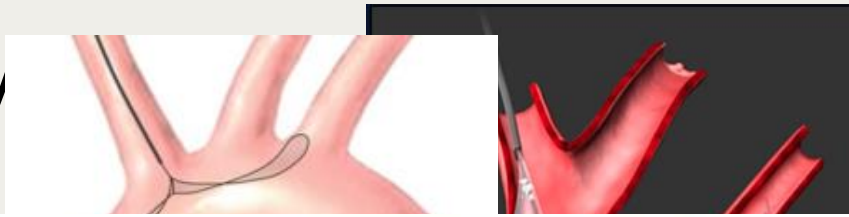
Other: Accurate, Jena, Direct Flow Innovare,Syntheon, Portico, VENUS A

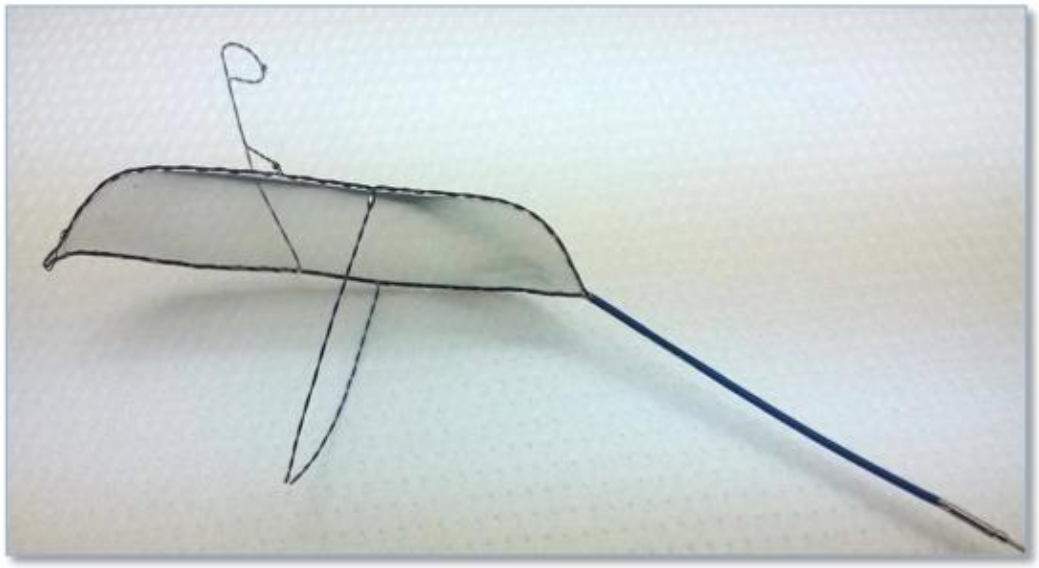


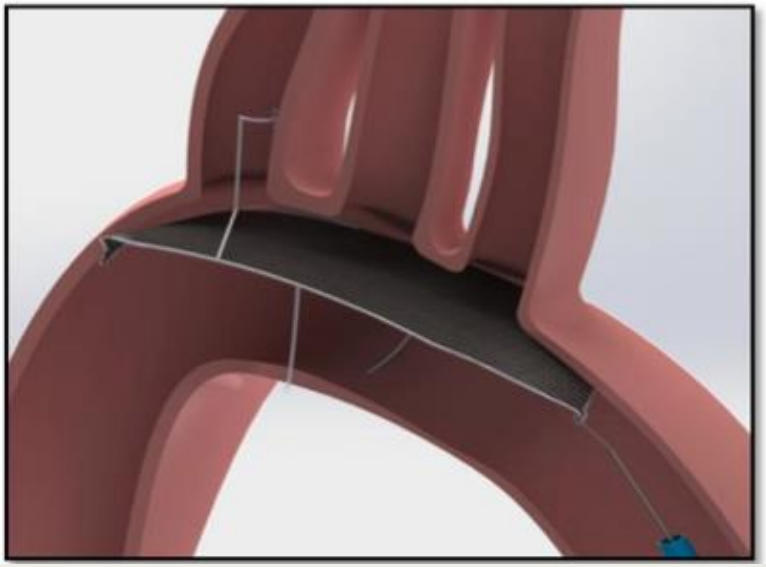


Stroke Prevention
Embolic Protection

- CLEAN-TAVI (Claret Dev
  - Randomized 100 patients







- Keystone TRIGUARD
  - Protects entire arch

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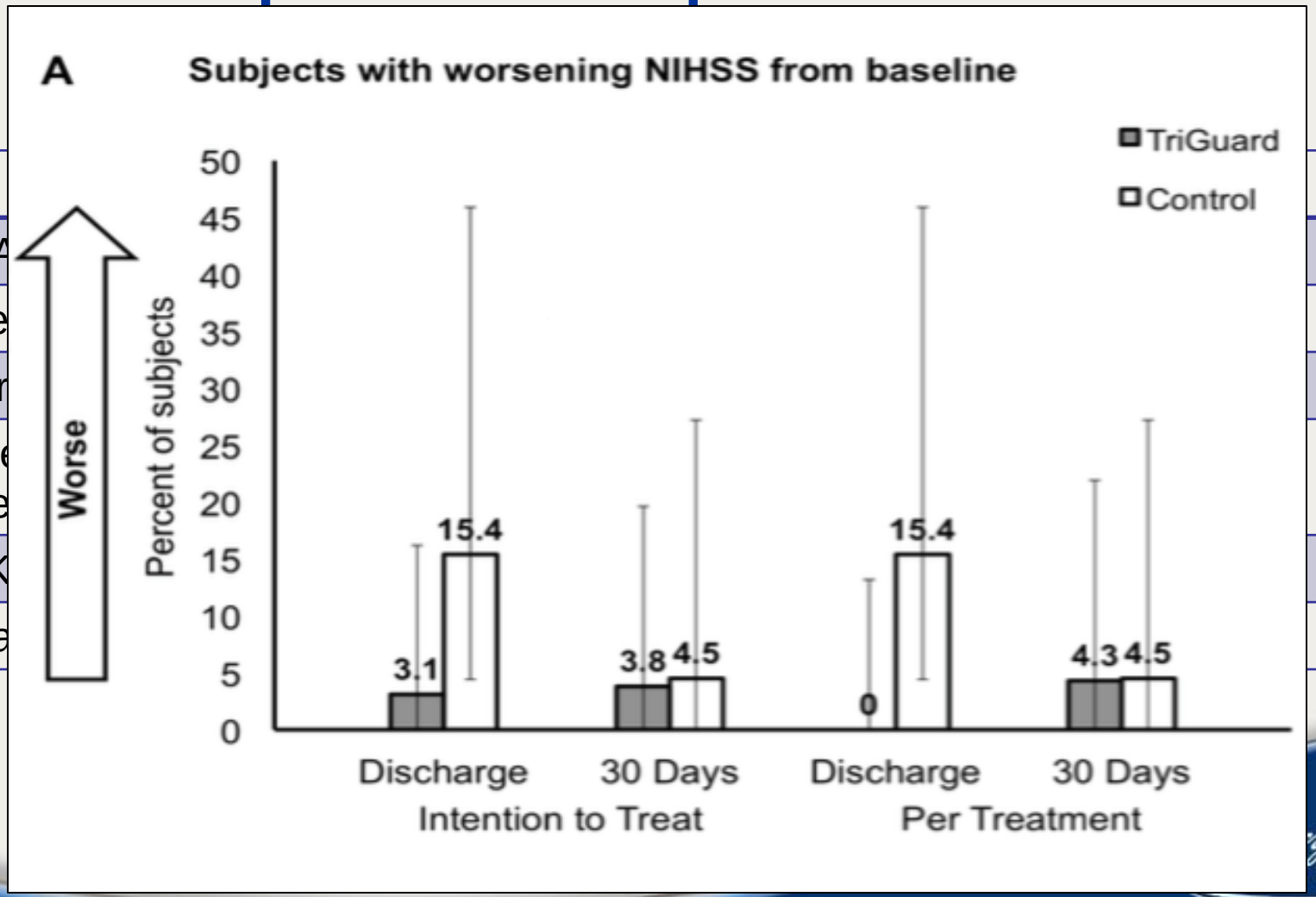
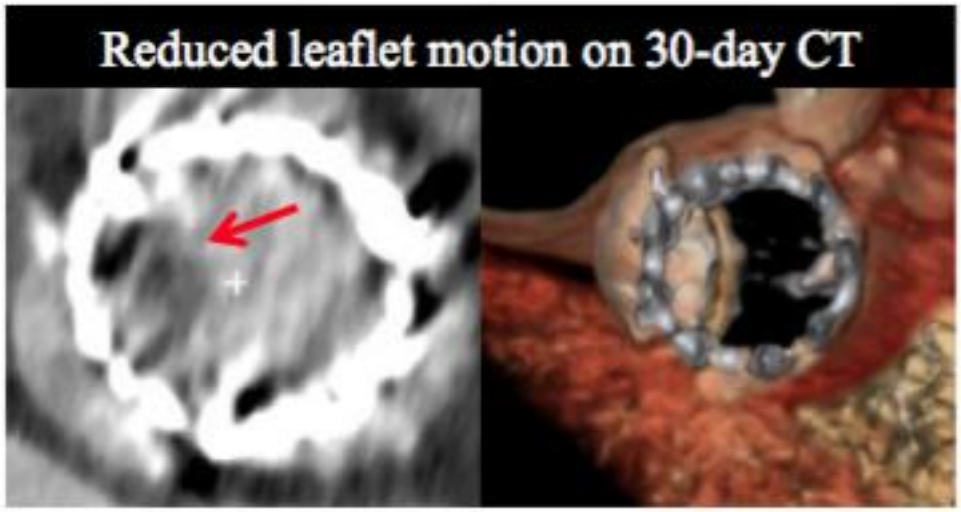
Samim M. et al. EuroPCR 2014 Kodali S et al. TCT 2015

DEFLECT III- KEYSTONE In-Hospital Complications

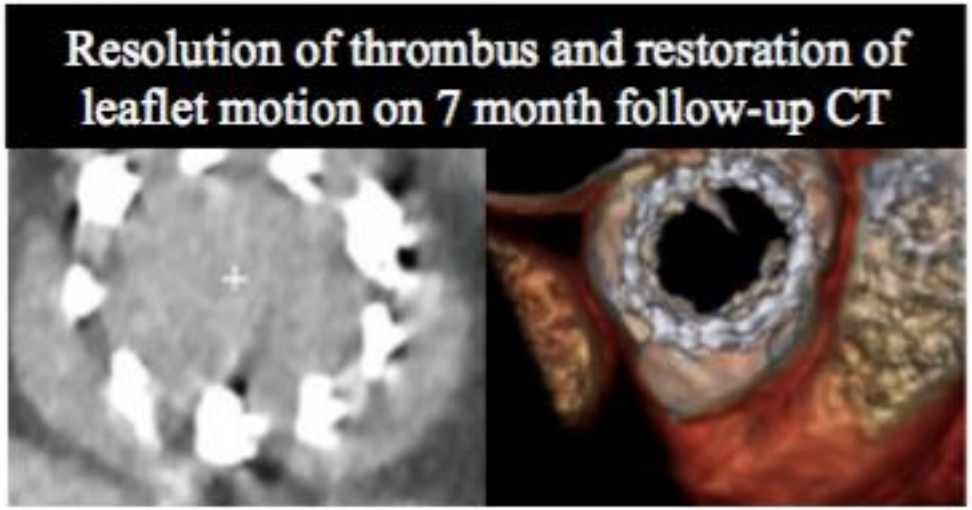


Lansky A TCT 2015

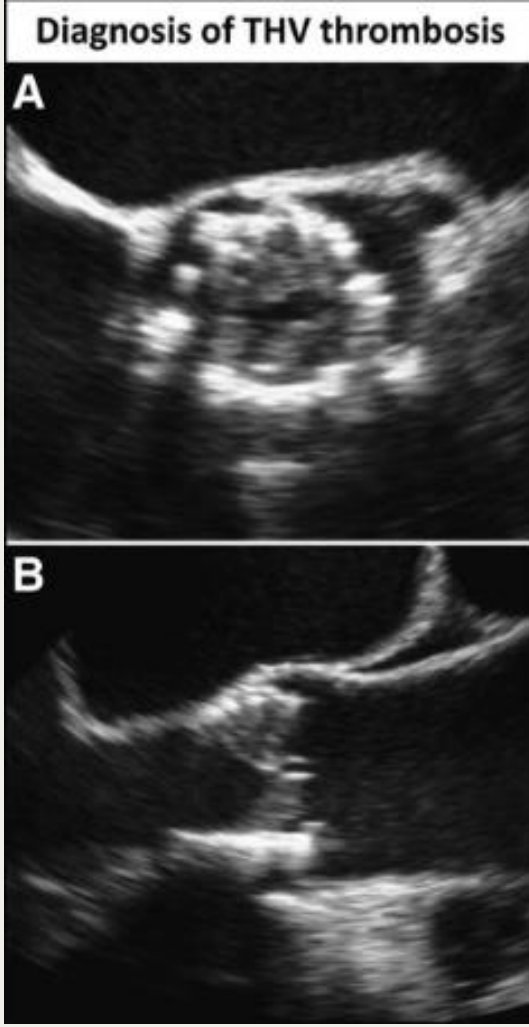
Anticoagulation was associated with resolution of thrombus and restoration of leaflet motion in 11 out of 11 patients



Patient was started on Warfarin



Median time to THV thrombosis, d	181 (IQR, 45–313; range, 3–735)
Incidence of THV thrombosis	26/4266 (0.61)
Edwards Sapien or Sapien XT	20/2813 (0.71)
Medtronic CoreValve	6/1453 (0.41)
Clinical presentation	
Dyspnea	17 (65.4)
No worsened symptoms	8 (30.8)
NSTEMI, acute heart failure	1 (3.8)
Echo findings at THV thrombosis	
LVEF, %	58.0±10.6
Mean aortic valve gradient, mm Hg	40.5±14.0
Mean aortic valve gradient <20 mm Hg*	2 (7.7)
Maximal aortic valve gradient, mm Hg	65.1±19.0
Worsened AR (to more than moderate) as compared with post procedure	2 (7.7)
Thrombus morphology	
Thickened leaflets or thrombotic apposition of leaflets	20 (76.9)
Thrombotic mass on leaflets	6 (23.1)



Latib A et al.
Circ Int. 2015

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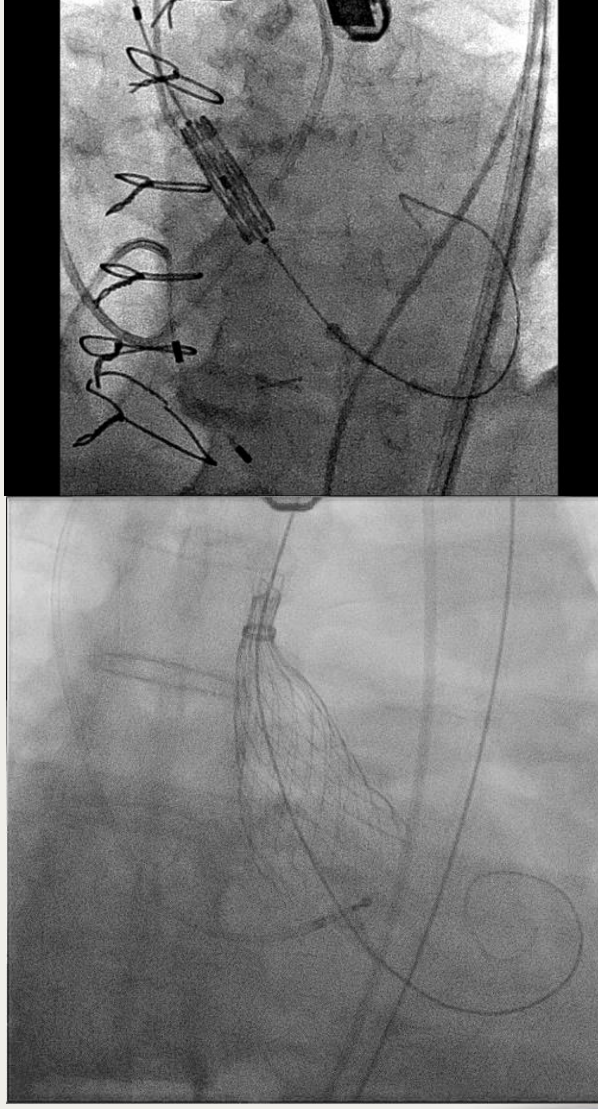
Iterative Advances TAVI

- TAVI in Intermediate Risk
  - PARTNER IIA-Randomized Data
  - S3 Prospective Data
  - OBSERVANT
  - European Registry Data
- Low Risk Study
- New THV's
- Lowering Complications
  - Stroke
  - Vascular Access
  - LOS
  - Pacing
- Sub-acute Valve Thrombosis



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