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TAVI in 2019: Appropriate Patient and Device Selection

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Disclosure Eberhard Grube, MD

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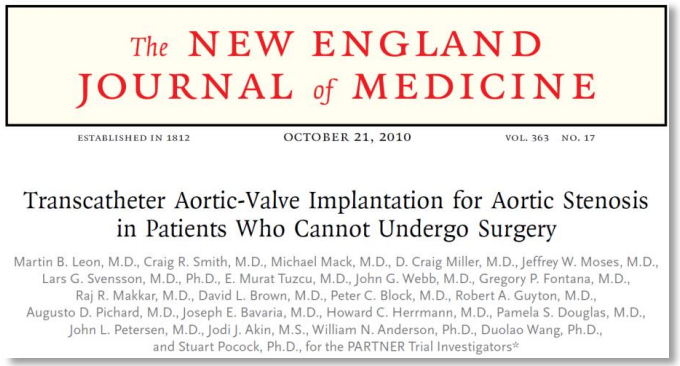
TAVI in 2019
Self-Expanding and Balloon-Expandable Clinical Trials

Clinical Trials with self-expanding and balloon-expandable TAVI devices have demonstrated excellent safety and device success in extreme, high, and intermediate surgical risk patients

Extreme Risk → **High Risk** → **Intermediate Risk**



The NEW ENGLAND JOURNAL of MEDICINE

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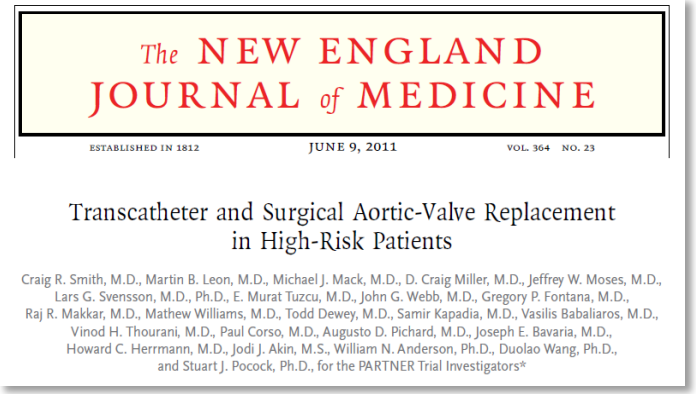
Transcatheter Aortic-Valve Implantation for Aortic Stenosis in Patients Who Cannot Undergo Surgery

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*



The NEW ENGLAND JOURNAL of MEDICINE

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Transcatheter and Surgical Aortic-Valve Replacement in High-Risk Patients

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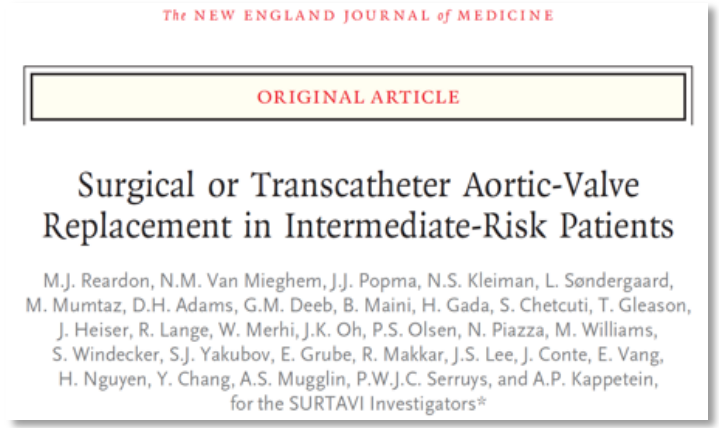
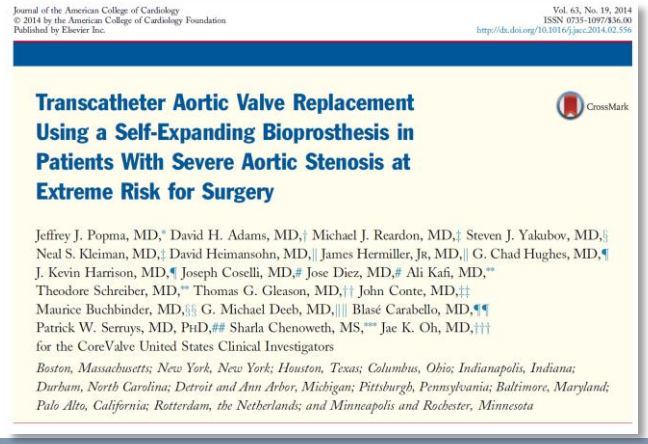


The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

M.J. Reardon, N.M. Van Mieghem, J.J. Popma, N.S. Kleiman, L. Søndergaard, M. Mumtaz, D.H. Adams, G.M. Deeb, B. Maini, H. Gada, S. Chetcuti, T. Gleason, J. Heiser, R. Lange, W. Merhi, J.K. Oh, P.S. Olsen, N. Piazza, M. Williams, S. Windecker, S.J. Yakubov, E. Grube, R. Makkar, J.S. Lee, J. Conte, E. Vang, H. Nguyen, Y. Chang, A.S. Mugglin, P.W.J.C. Serruys, and A.P. Kappetein, for the SURTAVI Investigators*



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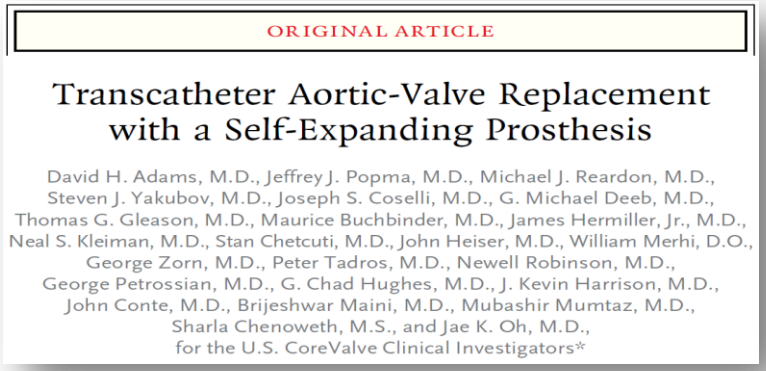
Transcatheter Aortic Valve Replacement Using a Self-Expanding Bioprosthesis in Patients With Severe Aortic Stenosis at Extreme Risk for Surgery

CrossMark

Jeffrey J. Popma, MD,* David H. Adams, MD,† Michael J. Reardon, MD,‡ Steven J. Yakubov, MD,§ Neal S. Kleiman, MD,‖ David Heimansohn, MD,‖ James Hermiller, Jr, MD,‖ G. Chad Hughes, MD,¶ J. Kevin Harrison, MD,¶ Joseph Coselli, MD,# Jose Diez, MD,# Ali Kafi, MD,** Theodore Schreiber, MD,** Thomas G. Gleason, MD,†† John Conte, MD,‡‡ Maurice Buchbinder, MD,§§ G. Michael Deeb, MD,‖‖ Blasé Carabello, MD,¶¶ Patrick W. Serruys, MD, PhD,## Sharla Chenoweth, MS,*** Jae K. Oh, MD,††† for the CoreValve United States Clinical Investigators

Boston, Massachusetts; New York, New York; Houston, Texas; Columbus, Ohio; Indianapolis, Indiana; Durham, North Carolina; Detroit and Ann Arbor, Michigan; Pittsburgh, Pennsylvania; Baltimore, Maryland; Palo Alto, California; Rotterdam, the Netherlands; and Minneapolis and Rochester, Minnesota



ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

David H. Adams, M.D., Jeffrey J. Popma, M.D., Michael J. Reardon, M.D., Steven J. Yakubov, M.D., Joseph S. Coselli, M.D., G. Michael Deeb, M.D., Thomas G. Gleason, M.D., Maurice Buchbinder, M.D., James Hermiller, Jr., M.D., Neal S. Kleiman, M.D., Stan Chetcuti, M.D., John Heiser, M.D., William Merhi, D.O., George Zorn, M.D., Peter Tadros, M.D., Newell Robinson, M.D., George Petrossian, M.D., G. Chad Hughes, M.D., J. Kevin Harrison, M.D., John Conte, M.D., Brijeshwar Maini, M.D., Mubashir Mumtaz, M.D., Sharla Chenoweth, M.S., and Jae K. Oh, M.D., for the U.S. CoreValve Clinical Investigators*

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ORIGINAL ARTICLE

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

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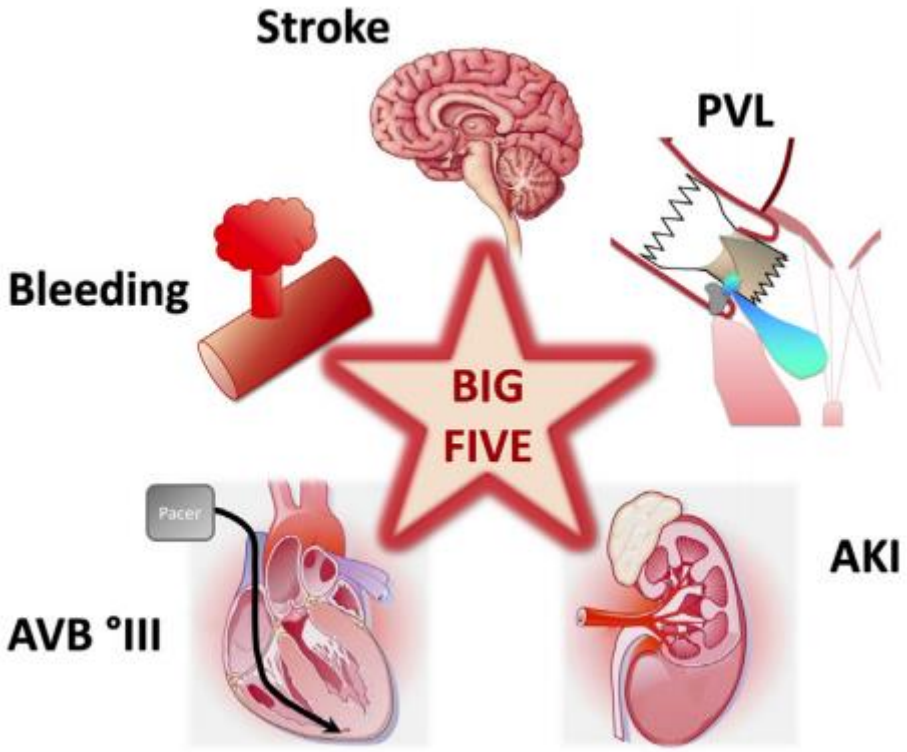
TAVI in 2019
Reducing Complications

Data from clinical trials and registries have demonstrated that device modifications, increased operator experience, better patient selection, and optimized pre-procedural planning have led to a substantial reduction in complications

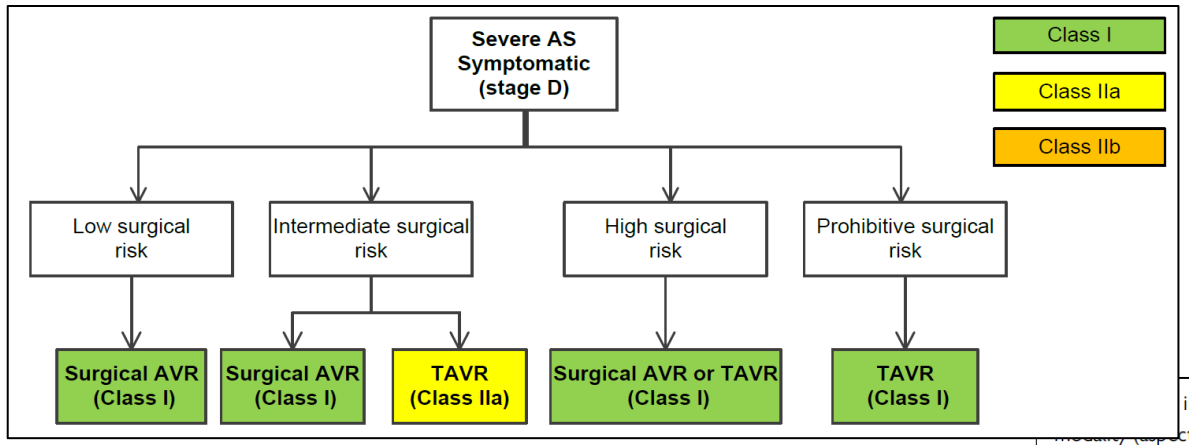
Rates of the “Big 5” complications (stroke, paravalvular leak (PVL), acute kidney injury, conduction abnormalities, and major vascular and bleeding complications) have been greatly reduced



Patient Selection
AHA/ACC and ESC/EACTS Guideline Recommendations

The AHA/ACC and ESC/EACTS Guidelines for the Management of Patients with Valvular Heart Disease were updated 2017 to reflect these results:

SAVR is recommended in patients at low-risk while TAVI is now a Class I indication for high-risk patients, with the choice left to the Heart Team for intermediate-risk patients based on individual patient characteristics



intervention must be based on careful individual evaluation of technical suitability and weighing of risks and benefits of each [illegible] (aspects to be considered are listed in *Table* 7). In addition, the local expertise and outcomes data for the given intervention must be taken into account.	I	C
SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II < 4% or logistic EuroSCORE I < 10%[d] and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).[93]	I	B
TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.[91,94]	I	B
In patients who are at increased surgical risk (STS or EuroSCORE II ≥ 4% or logistic EuroSCORE I ≥ 10%[d] or other risk factors not included in these scores such as frailty, porcelain aorta, sequelae of chest radiation), the decision between SAVR and TAVI should be made by the Heart Team according to the individual patient characteristics (see *Table* 7), with TAVI being favoured in elderly patients suitable for transfemoral access.[91,94–102]	I	B

Patient Selection
Intermediate- and High-Risk Patients

In addition to risk scores, the guidelines also provide ***clinical characteristics***, ***anatomical and technical aspects***, and ***cardiac conditions*** that can guide patients towards TAVI or SAVR.

	Favours TAVI	Favours SAVR
Clinical characteristics		
STS/EuroSCORE II <4% (logistic EuroSCORE I <10%)[a]		+
STS/EuroSCORE II ≥4% (logistic EuroSCORE I ≥10%)[a]	+	
Presence of severe comorbidity (not adequately reflected by scores)	+	
Age <75 years		+
Age ≥75 years	+	
Previous cardiac surgery	+	
Frailty[b]	+	
Restricted mobility and conditions that may affect the rehabilitation process after the procedure	+	
Suspicion of endocarditis		+

	Favours TAVI	Favours SAVR
Anatomical and technical aspects		
Favourable access for transfemoral TAVI	+	
Unfavourable access (any) for TAVI		+
Sequelae of chest radiation	+	
Porcelain aorta	+	
Presence of intact coronary bypass grafts at risk when sternotomy is performed	+	
Expected patient–prosthesis mismatch	+	
Severe chest deformation or scoliosis	+	
Short distance between coronary ostia and aortic valve annulus		+
Size of aortic valve annulus out of range for TAVI		+
Aortic root morphology unfavourable for TAVI		+
Valve morphology (bicuspid, degree of calcification, calcification pattern) unfavourable for TAVI		+
Presence of thrombi in aorta or LV		+

	Favours TAVI	Favours SAVR
Cardiac conditions in addition to aortic stenosis that require consideration for concomitant intervention		
Severe CAD requiring revascularization by CABG		+
Severe primary mitral valve disease, which could be treated surgically		+
Severe tricuspid valve disease		+
Aneurysm of the ascending aorta		+
Septal hypertrophy requiring myectomy		+

Patient Selection
Low Risk TAVI

Recently there has been a trend towards treating **younger, healthier patients at low surgical risk**

Results of two landmark trials investigating TAVI in low-risk patients were recently presented

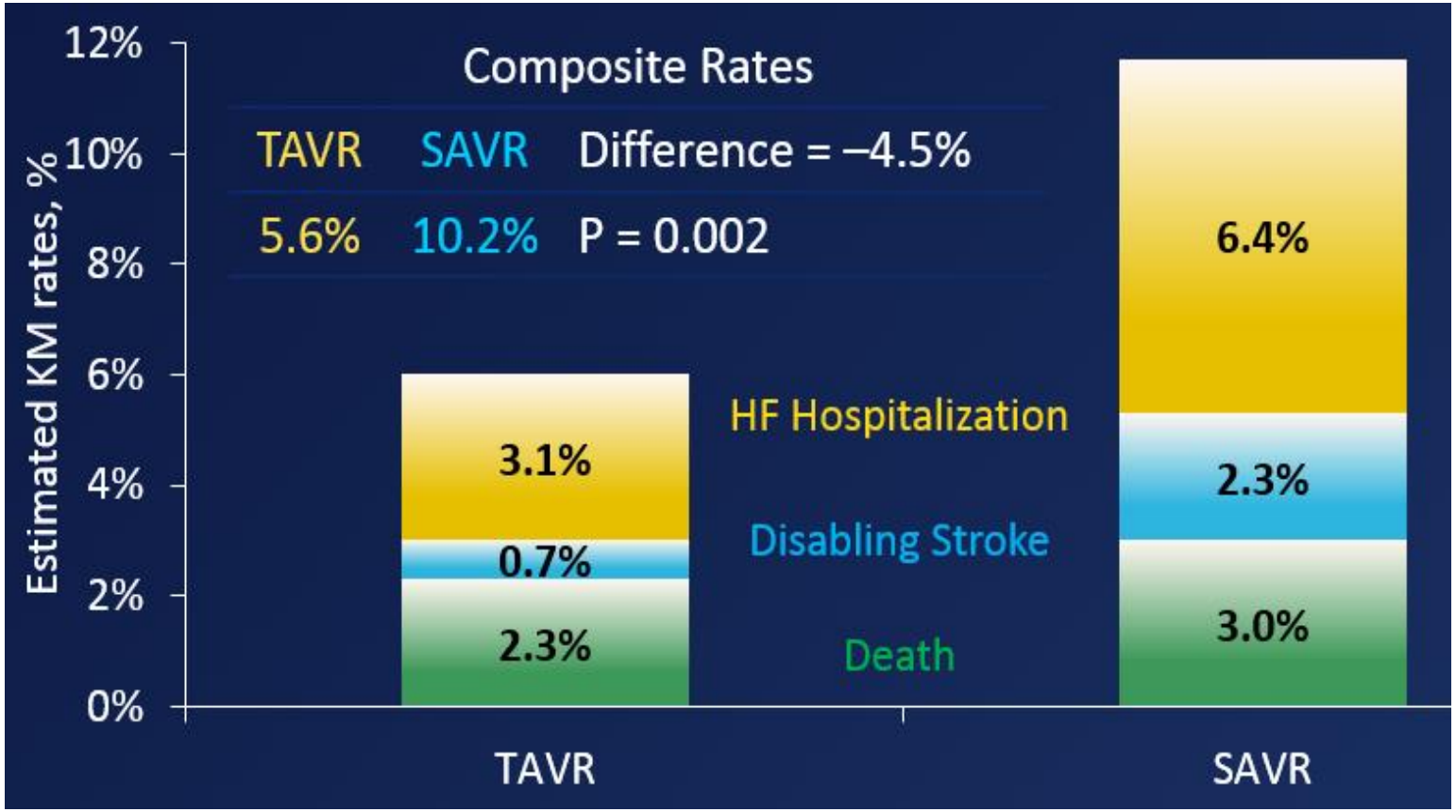
- The Medtronic Evolut Low Risk trial randomized patients at low surgical risk to TAVI with the Evolut platform or SAVR
- The Edwards PARTNER 3 trial randomized patients at low surgical risk to TAVI with Sapien 3 or SAVR

Reardon et al., presented at ACC 2019; Leon et al., presented at ACC 2019

Patient Selection

Low Risk TAVI | Evolut Low Risk

Results from the randomized Evolut Low-Risk Trial demonstrated significantly less death, disabling stroke, or HF hospitalization out to 1 year compared to surgery



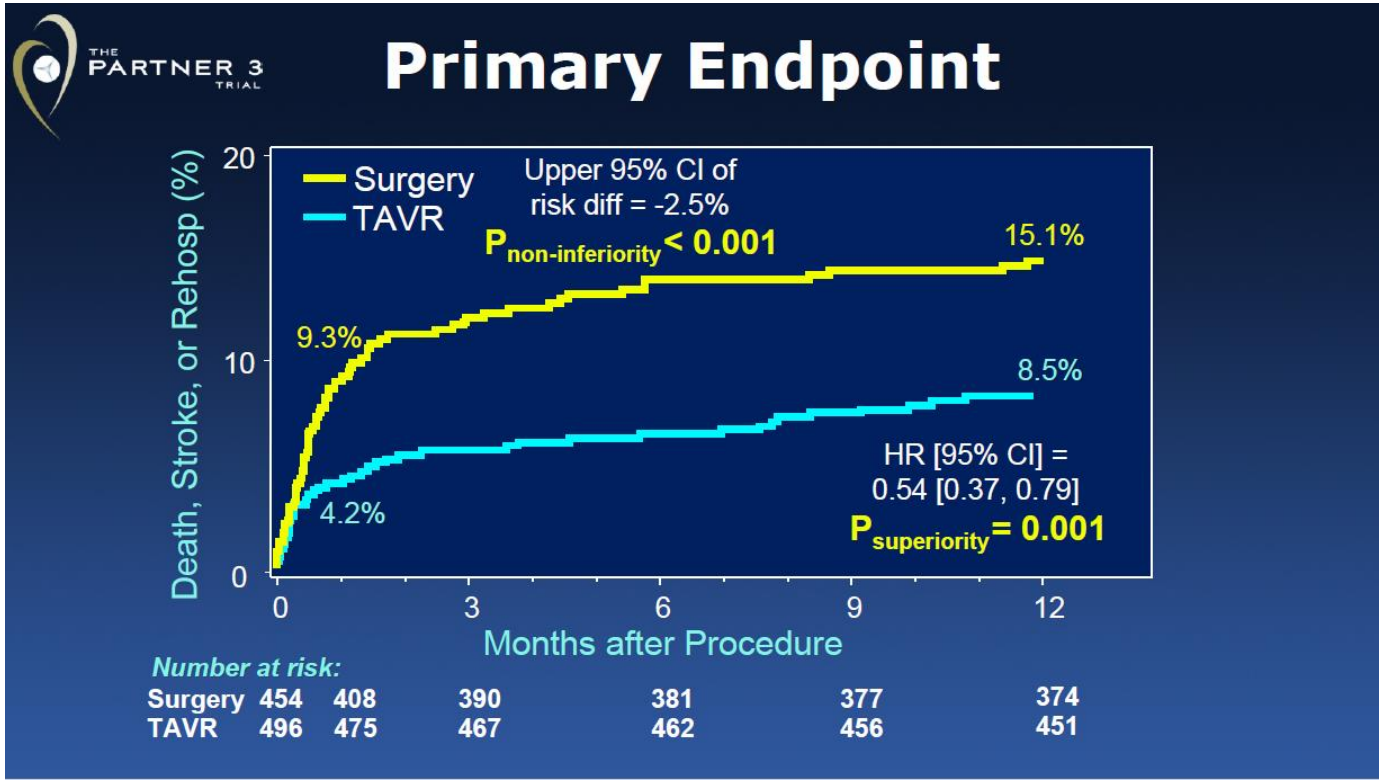
Patient Selection

Low Risk TAVI | PARTNER 3

The PARTNER 3 trial found TAVI with Sapien 3 had significantly less death, stroke, or rehospitalization out to 1 year.

The Evolut Low-Risk and PARTNER 3 data will likely drive an indication in 2019 for treating low surgical risk patients!

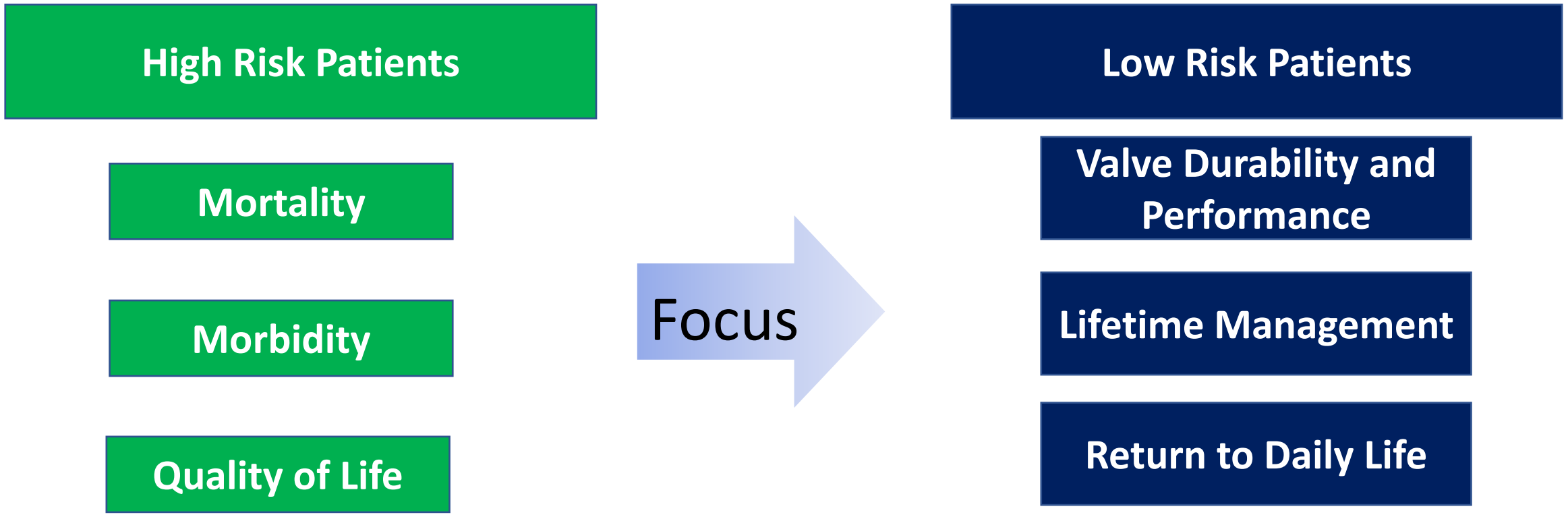
Age, rather than risk**, will be key in selecting patients for TAVI.**



Leon et al., presented at ACC 2019

Patient and Device Selection in 2019
Shift in Focus

Device selection in these younger patients will be driven by **valve durability** and **performance** of TAVI valves, **lifetime management** of patients, and **getting patients back to their daily lives faster**



Durability

TAVI valves must be durable to be a viable treatment option for younger, healthier patients. Although long-term durability data are limited, initial reports have been promising.

There is currently no strong evidence to suggest one valve type is more durable than another, with low rates of valve failure out to 5-8 years

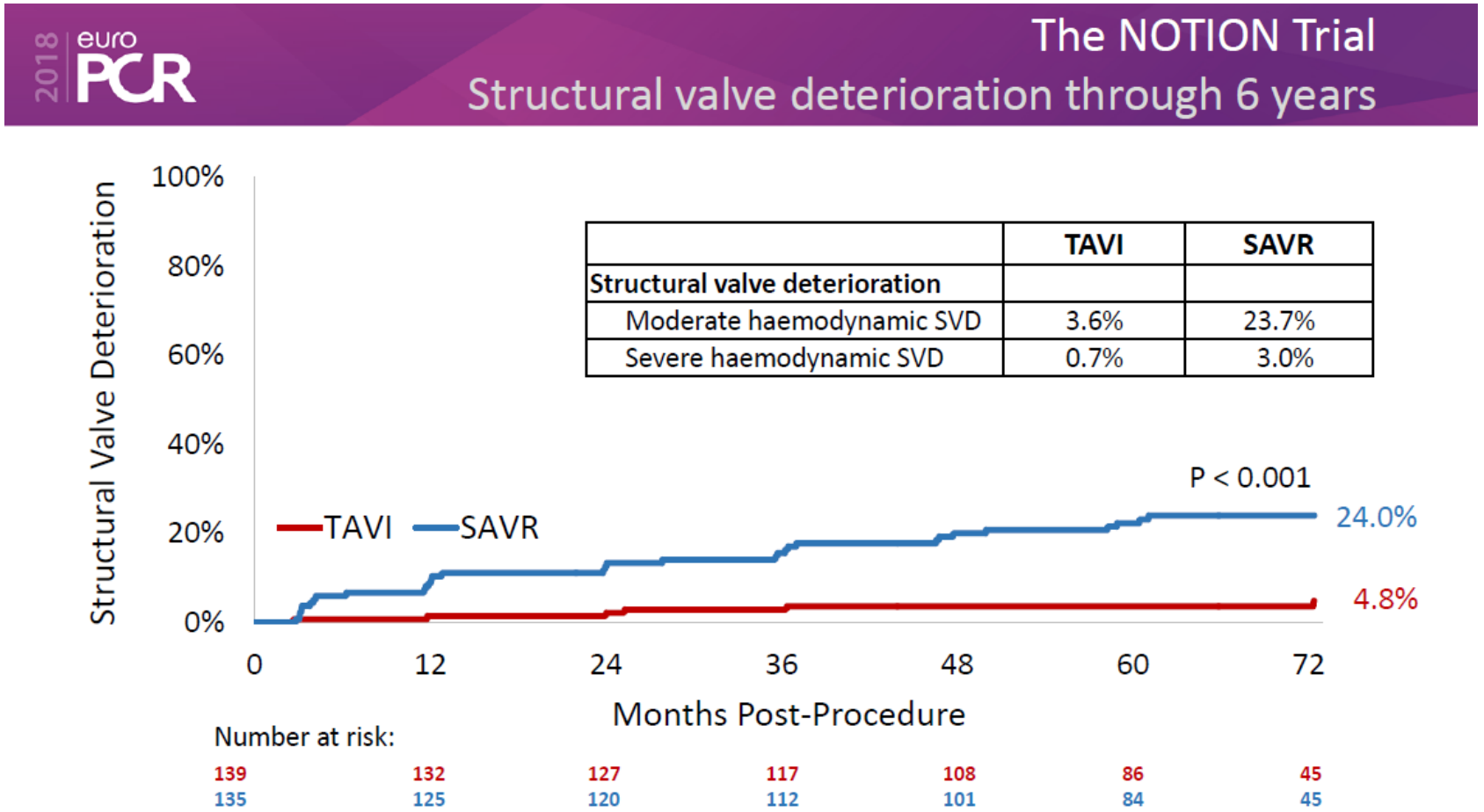
In the future, selecting devices with optimal durability will be critical in low risk patients

Study	N	Valve	Follow-up	Survival*	Severe SVD	BVF
COREVALVE US HR trial	391	SE 100%	5 years	44.7%	0.8%	-
FRANCE-2 Registry	4,201	BE 68%, SE 32%	5 years	39.2%	2.9%	-
NOTION trial	139	SE 100%	6 years	57.5%	0.7%	7.5%***
UK-TAVI Registry	241	BE 25%, SE 64%	6 years	-	0.4%	-
Deutsch et al.	300	BE 29%, SE 71%	7 years	23.2%	-**	3.7%
Sokoloff et al.	1,264	BE 84%, SE 16%	7 years	18.6%	4.2%	1.9%***
Eltchaninoff et al.	378	BE 100%	8 years	9.6%	3.2%	0.6%***
Barbanti et al.	288	BE 83%, SE 17%	8 years	29.8%	5.9%	4.5%***
Holy et al.	152	SE 100%	8 years	27.0%	0%	4.5%***
Antonazzo Panico, et al.	278	SE 100%	8 years	20.0%	3.6%	2.5%***

Capodanno et al., presented at CRT 2019; Gleason TG, et al., JACC 2018; Didier R et al., Circulation 2018; Eltchaninoff et al., EuroIntervention 2018; 14:264-71; Deutsch et al., EuroIntervention. 2018;14:41-9; Barbanti eet al. JAHA 2018 [Epub Ahead of print]; Holy et al., EuroIntervention. 2018;14:e390-e396; Sokoloff et al., Archives of Cardiovascular Diseases Supplements 2018; 10:220

Durability

The longest report of randomized data of TAVI vs. SAVR found that TAVI with self-expanding valves had significantly less hemodynamic structural valve deterioration than SAVR



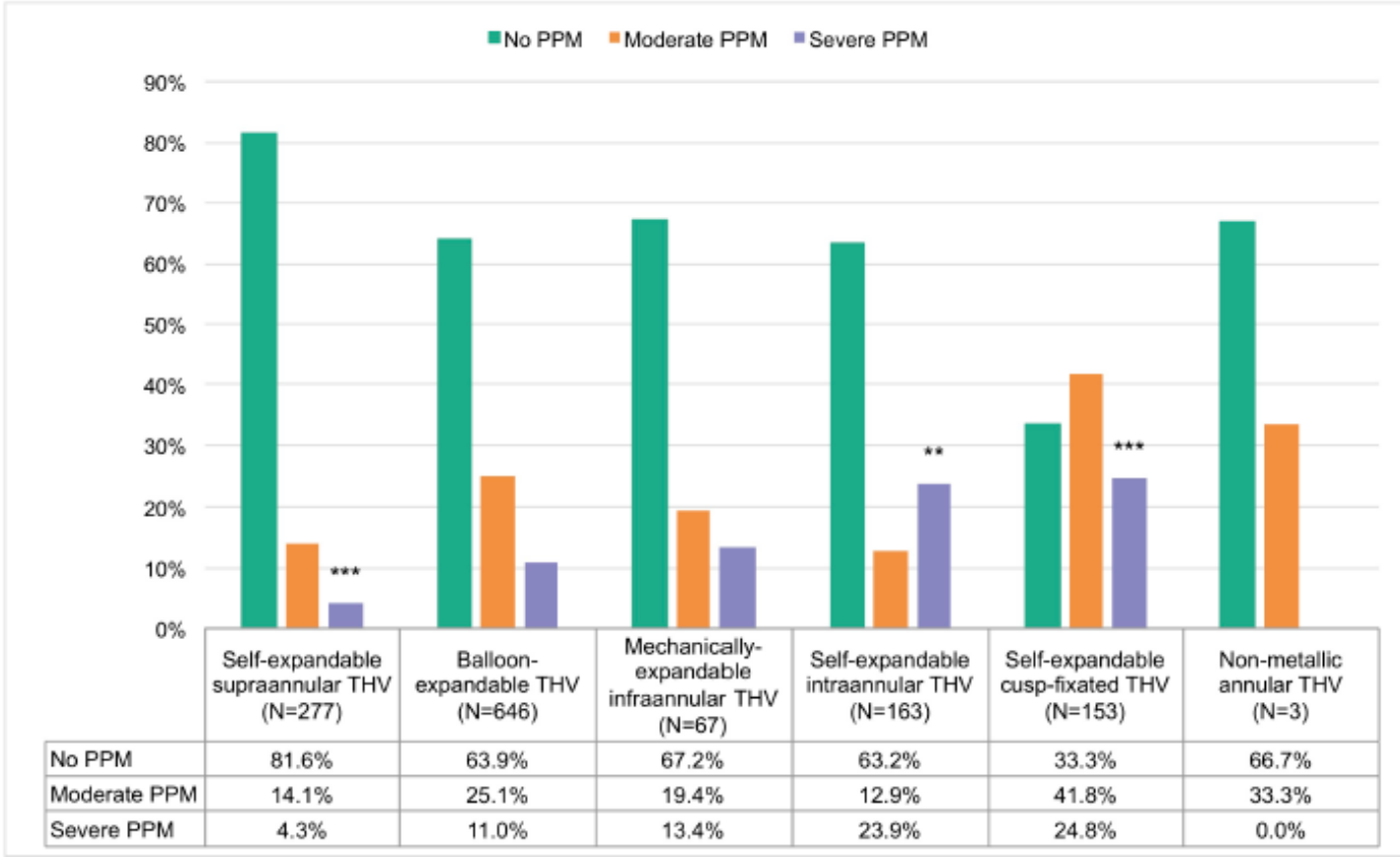
	TAVI	SAVR
Structural valve deterioration		
Moderate haemodynamic SVD	3.6%	23.7%
Severe haemodynamic SVD	0.7%	3.0%

Sondergaard et all., presented at EuroPCR 2018; Petrossian et al., presented at ACC 2018

Valve Performance
Prosthesis-Patient Mismatch

Prosthesis-patient mismatch (PPM) can be common after TAVI and is associated with increased rates of structural valve degeneration, mortality, rehospitalization and reduced quality of life

Recent reports suggested supra-annular TAVI valves have lower rates of PPM than intra-annular TAVI valves



	Self-expandable supraannular THV (N=277)	Balloon-expandable THV (N=646)	Mechanically-expandable infraannular THV (N=67)	Self-expandable intraannular THV (N=163)	Self-expandable cusp-fixated THV (N=153)	Non-metallic annular THV (N=3)
No PPM	81.6%	63.9%	67.2%	63.2%	33.3%	66.7%
Moderate PPM	14.1%	25.1%	19.4%	12.9%	41.8%	33.3%
Severe PPM	4.3%	11.0%	13.4%	23.9%	24.8%	0.0%

TAVR Device Selection

Hemodynamic Current State/Prosthesis-Patient-Mismatch (PPM)

- Hahn et al., collected discharge and 30 day echos from 5 clinical trials:
- ***The authors provided EOA's for both self- and balloon- expanding valves in a given anular size.***
- ***Self expandable supraanular Valves performed well in patients with small annuli***
- If confirmed, this may be helpful in the Future for pre-procedural decision making and avoidance of PPM

Evolut R Hemodynamic Reference Values

Quintiles	≤22.3 mm	>22.3 to ≤23.2 mm
Evolut R		
EOA, cm²	1.66 ± 0.42 (53)	1.82 ± 0.43 (38)
EOAi, cm²/m²	0.99 ± 0.27 (53)	1.09 ± 0.26 (38)
Mean gradient, mm Hg	7.94 ± 3.10 (58)	6.91 ± 2.58 (43)
DVI	0.61 ± 0.11 (57)	0.61 ± 0.14 (41)

Sapien 3 Hemodynamic Reference Values

	248 to 384 mm² (n = 189)	385 to 439 mm² (n = 191)
EOA, cm²	1.41 ± 0.27	1.58 ± 0.33
EOAi, cm²/m²	0.80 ± 0.16	0.86 ± 0.19
Mean gradient, mm Hg	13.96 ± 5.28	11.94 ± 4.82
DVI	0.43 ± 0.1	0.44 ± 0.1

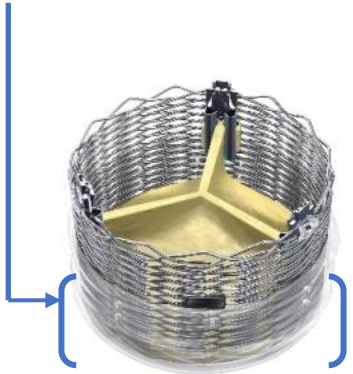
[1]Hahn et al., JACC Cardiovasc Imaging. 2018 Jun 8

Valve Performance
Paravalvular Leak

Moderate and severe paravalvular leak (PVL) are nearly non-existent with modern day TAVI devices. However, mild PVL still occurs frequently

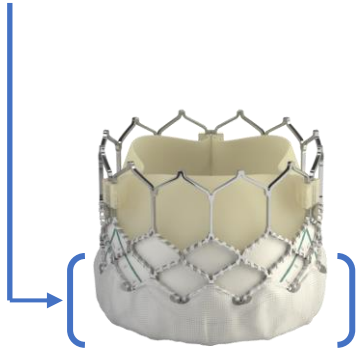
Mild PVL may become an issue in patients with longer life expectancies. Initial reports suggest that mild PVL is not associated with worse outcomes after TAVI, but more research is needed to determine if mild PVL will progress or impact clinical outcomes in long-term data

Adaptive Seal



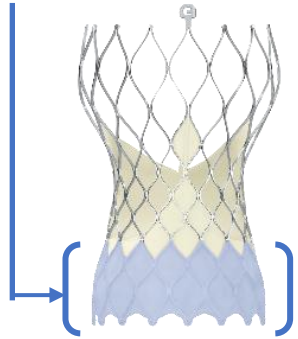
Lotus

Outer Sealing Skirt



Sapien 3

Outer Sealing Wrap



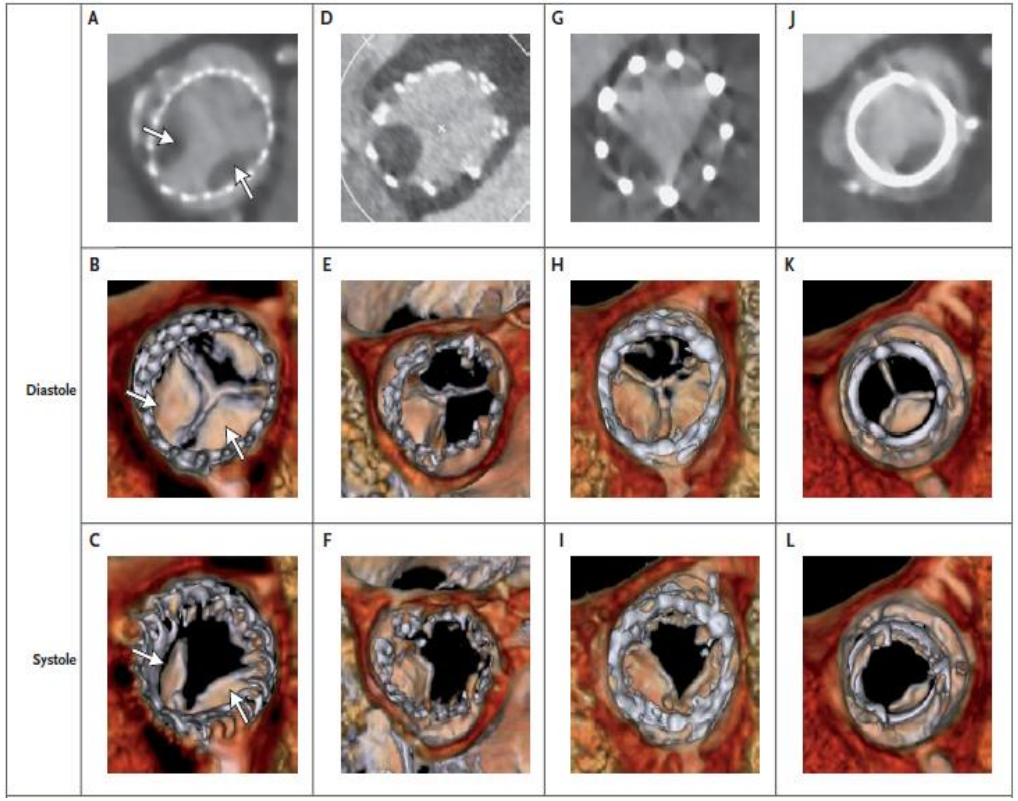
Evolut PRO

[1]Webb, et. al. *J Am Coll Cardiol Intv* 2015; 8: 1797-806; [2]Popma, et al., *J Am Coll Cardiol* 2014; 63: 1972-81; [3]Adams, et al., *N Engl J Med* 2014; 370: 1790-8; [4]Linke, et. al. presented at PCR London Valves 2015; [5]Williams, et al., presented at ACC 2016; [6]Kodali, et al., *Eur Heart J* 2016; doi:10.1093/eurheartj/ehw112; [7]Manoharan, et al., *J Am Coll Cardiol Intv* 2015; 8: 1359-67; [8]Lefevre, et al., *J Am Coll Cardiol Intv* 2016; 9: 68-75; [9]Meredith, et al., presented at PCR London Valves 2014; [10]Forrest et al., presented at ACC

Valve Performance
Thrombosis

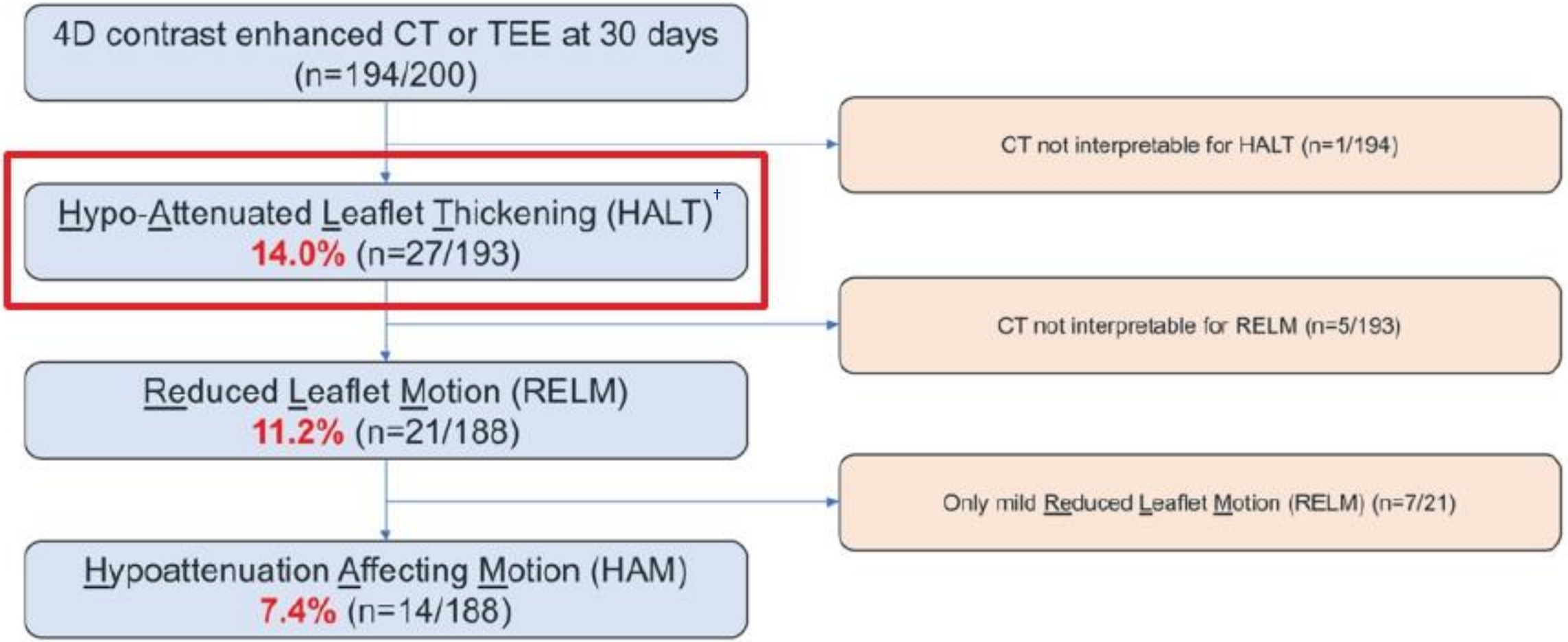
Thrombosis after TAVI can impact clinical outcomes and reduce valve durability. Small studies suggest thrombosis may be common in certain TAVI valves.

Both Edwards and Medtronic are conducting CT sub-studies in their low-risk trials to better understand thrombosis after TAVI and SAVR



Makkar, et al., N Engl J Med. 2015 Nov 19;373(21):2015-247

Subclinical leaflet thrombosis*

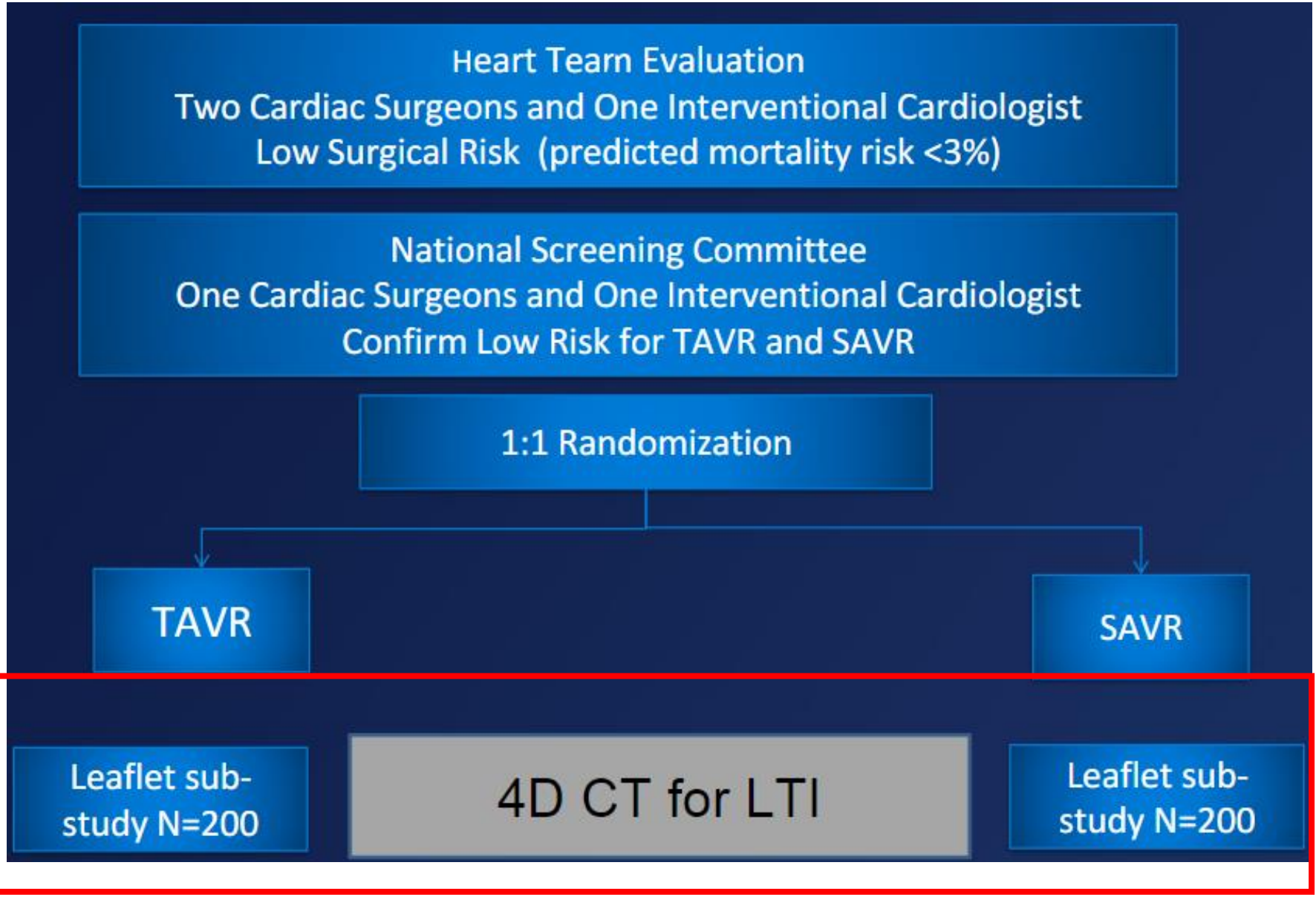


Lifetime Management

Ongoing Trials

The Medtronic Evolut R Low Risk trial and PARTNER 3 Low Risk trial both include leaflet CT sub-studies

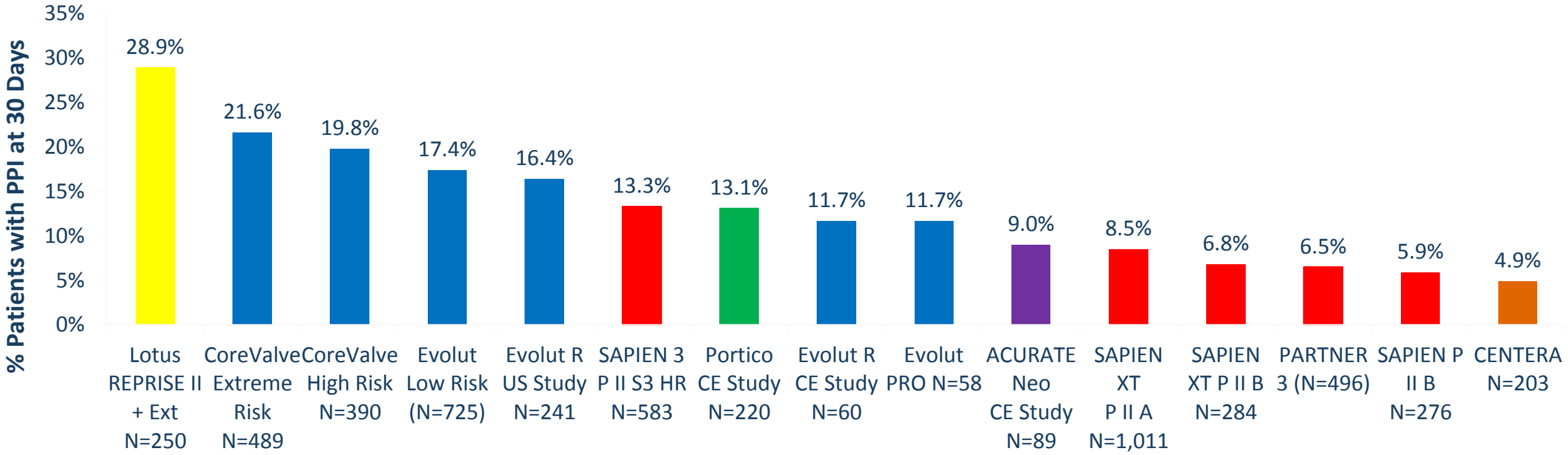
- **Results of the LTI sub-studies are expected in 2019**
- The robust, imaging data will be the first of its kind and will help answer many remaining questions on thrombosis after AVR



[1]Popma et al., presented at TVT 2018

Lifetime Management
Permanent Pacemaker Implantation

- New conduction abnormalities after TAVI have been associated with poor outcomes and increased risk of permanent pacemaker implantation. Choosing a valve that reduces the risk of new conduction abnormalities will be critical for the lifetime management of TAVI patients
- ***Studies have found that balloon-expandable valves have the lowest permanent pacemaker rates, and mechanically expanding the highest***

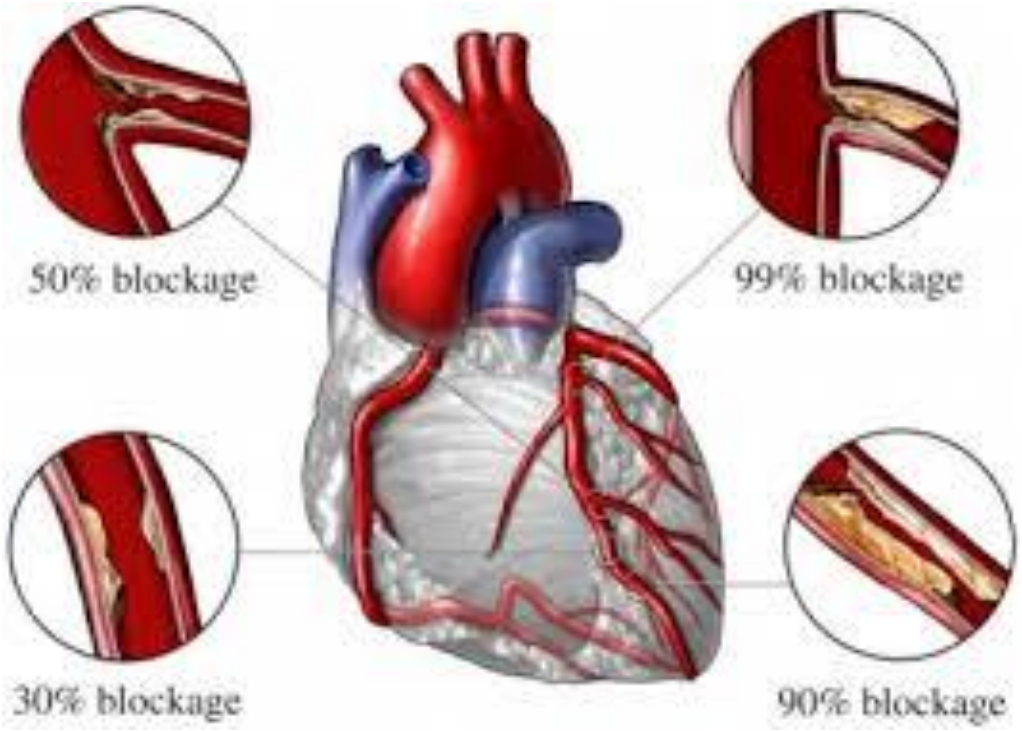


Webb, et. al. J Am Coll Cardiol Intv 2015; 8: 1797-806; Popma, et al., J Am Coll Cardiol 2014; 63: 1972-81; Adams, et al., N Engl J Med 2014; 370: 1790-8; Linke, et. al. presented at PCR London Valves 2015; Williams, et al., presented at ACC 2016; Abizaid, et al., presented at CRT 2015; Kodali, et al., Eur Heart J 2016; doi: 10.1093/eurheartj/ehw112; Leon, et al., N Engl J Med 2016 Apr 2 [E-pub ahead of print]; Manoharan, et al., J Am Coll Cardiol Intv 2015; 8: 1359-67; Lefevre, et al., J Am Coll Cardiol Intv 2016; 9: 68-75; Meredith, et al., presented at PCR London Valves 2014; Forrest et al., presented at TVT 2017; Tchetche, et al., presented at EuroPCR 2017

Lifetime Management

Coronary Artery Disease | PCI after TAVR

Preserving options for interventions beyond TAVR is critical for lifetime management of aortic stenosis patients especially as TAVR moves into younger patient populations.



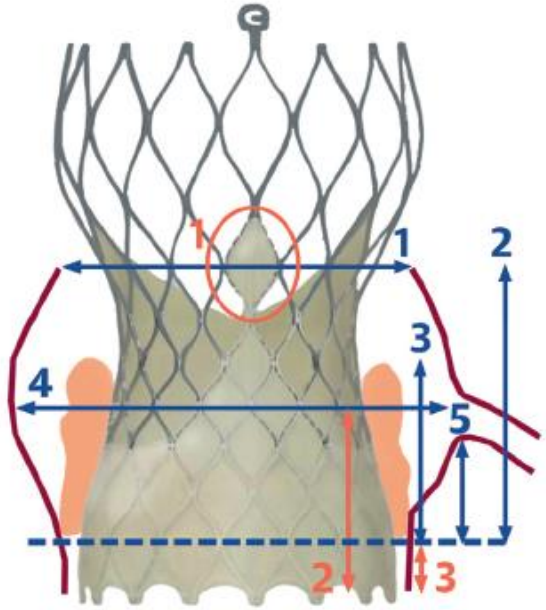
TAVR Device Selection

Post-TAVI PCI Current State

A recent review provided ***risk factors and guidelines for how to access the coronary arteries post-TAVI with CoreValve and Sapien***

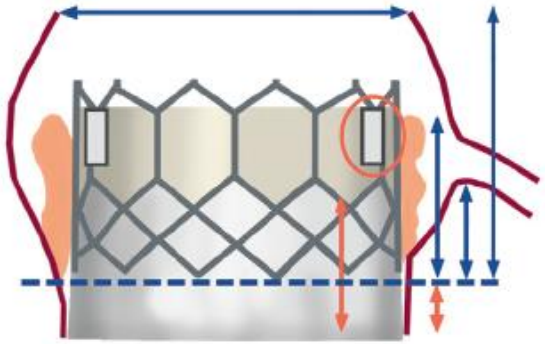
- The review suggested that post-TAVI PCI is a TAVI problem
- Patients with narrow sinuses, low coronaries, and small sinotubular junctions are at increased risk with all TAVI devices

Factors Impacting Coronary Access



Anatomical

1. Sinotubular junction dimensions
2. Sinus height
3. Leaflet length and bulkiness
4. Sinus of Valsalva width
5. Coronary height

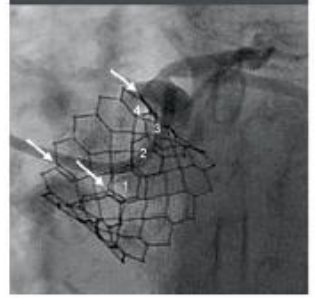


Device and Procedural

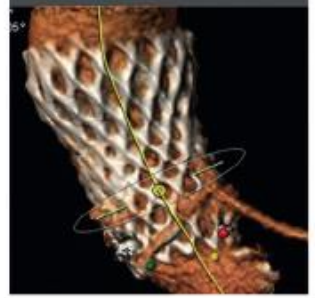
1. Commissural tab orientation
2. Sealing skirt height
3. Valve implant depth

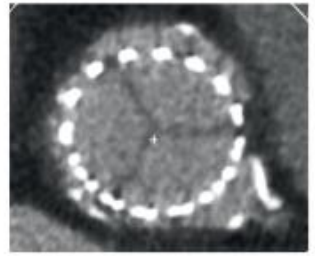
Imaging Evaluation

Fluoroscopy



MDCT





[1]Yudi, et al., *J Am Coll Cardiol* 2018; 71(12):1360–78

Lifetime Management

Coronary Artery Disease | PCI after TAVR

Today, studies have shown coronary access post-TAVR is possible in the majority of cases

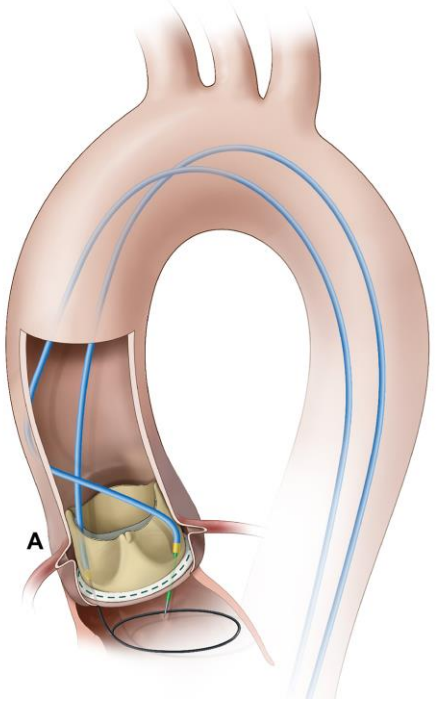
	Kerckhoff-Klinik	Segeberg Registry	UK Registry	TAVR-LM Registry
Incidence	**35 / 1,000 (3.5%)**	**17 / 296 (5.7%)**	**18 / 2,588 (0.7%)**	**9 / 6,405 (0.1%)**
ACS Indication	11.4%	37.5%	65%	78%
Time to Intervention Post-TAVI	233 ± 158 days	17.7 months (range: 1-72)	136 days (range: 1-1092)	368 days (IQR: 204-534)
Type of TAV Implanted			Not Reported	
CoreValve	29%	100%		44%
SAPIEN XT	54%			55%
JenaValve	3%			
Symetis	11%			
Portico	3%			
Procedural Success	74%	95.8%	Not Reported	100%

[1]Blumenstein, et al., *Clin Res Cardiol* 2015; 104:632-39; [2]Allali, et al., *Cardiovasc Revasc Med* 2016; epub ahead of print; [3]Snow, et al., *Int J Cardiol* 2015; 199:253-60;
[4]Chakravarty, et al., *J Am Coll Cardiol* 2016; 67:951-60

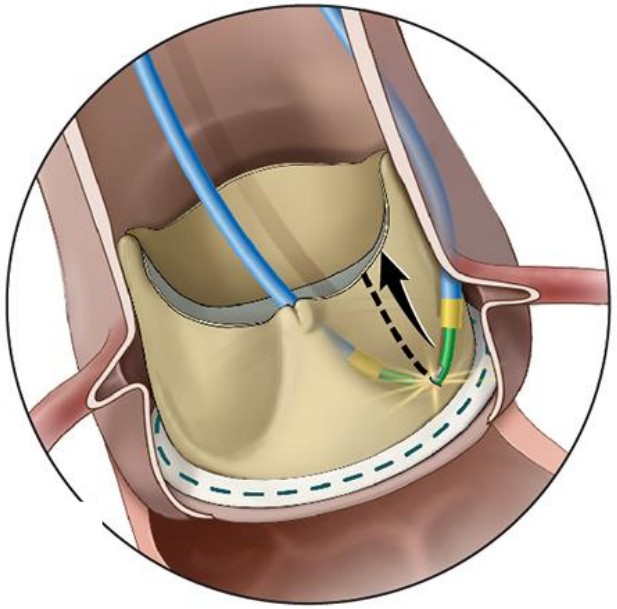
Lifetime Management

New Technique for Valve-in-Valve | BASILICA

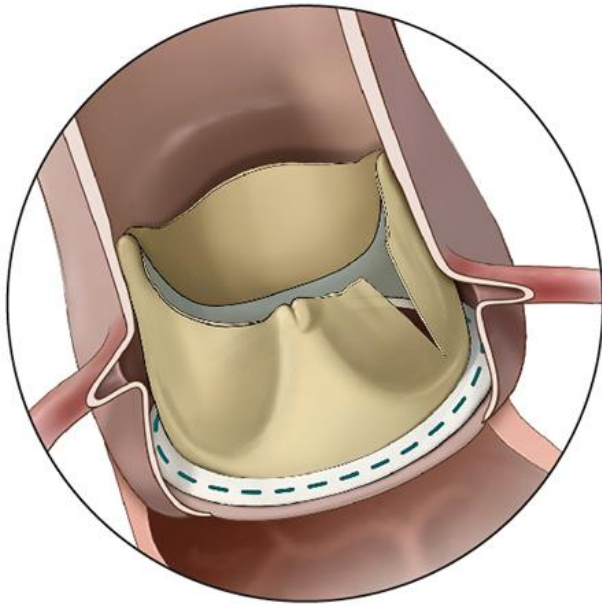
The BASILICA technique may help reduce coronary obstruction post valve-in-valve



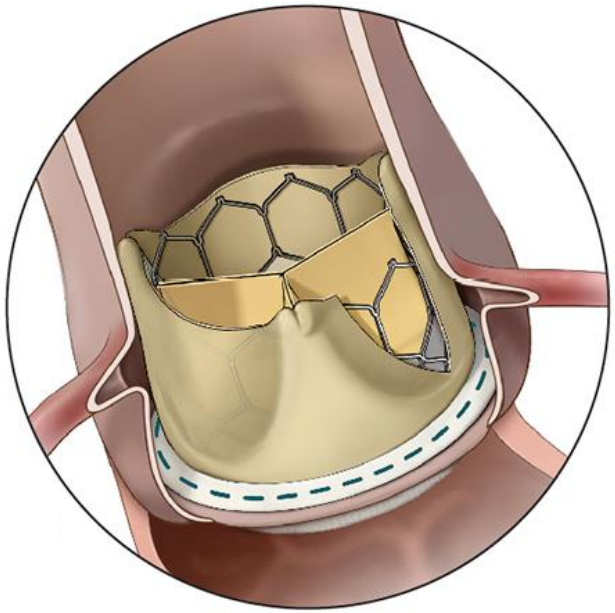
Leaflet wire traversal and snaring



Leaflet slicing



Sliced leaflet



Valve-in-Valve

[1]Dvir, presented at TCT 2017

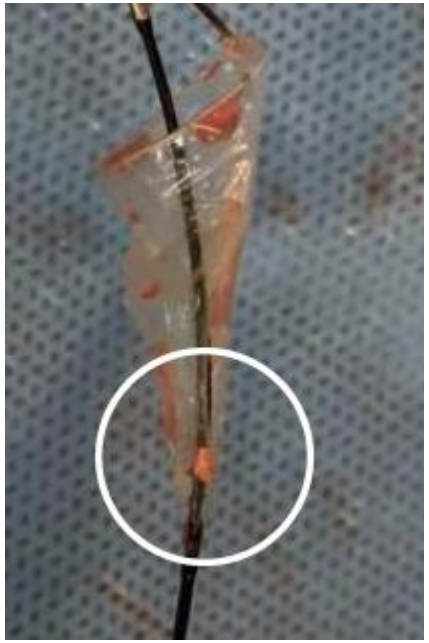
Lifetime Management
Neurocognitive Function

Stroke rates post-TAVI have been reduced to low single digits. However, recent data has suggested that ***embolic debris and silent cerebral lesions are common after TAVI***

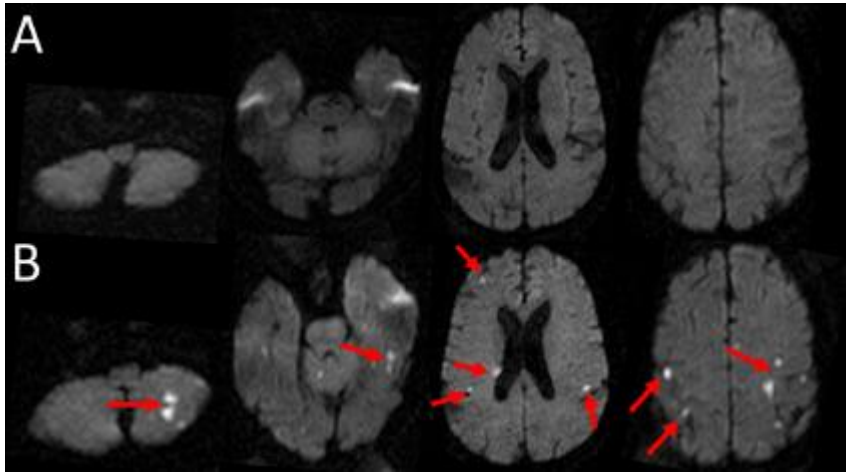
More research is needed to determine whether these “silent” events are associated with certain TAVI valve types. It may be more important to avoid these in low-risk patients where cognitive function will impact the lifetime management of patients

The use of cerebral embolic protection devices may help reduce rates of debris and lesions

Debris caught in embolic protection device



Diffusion-weighted MRI of the brain examining new silent cerebral lesions

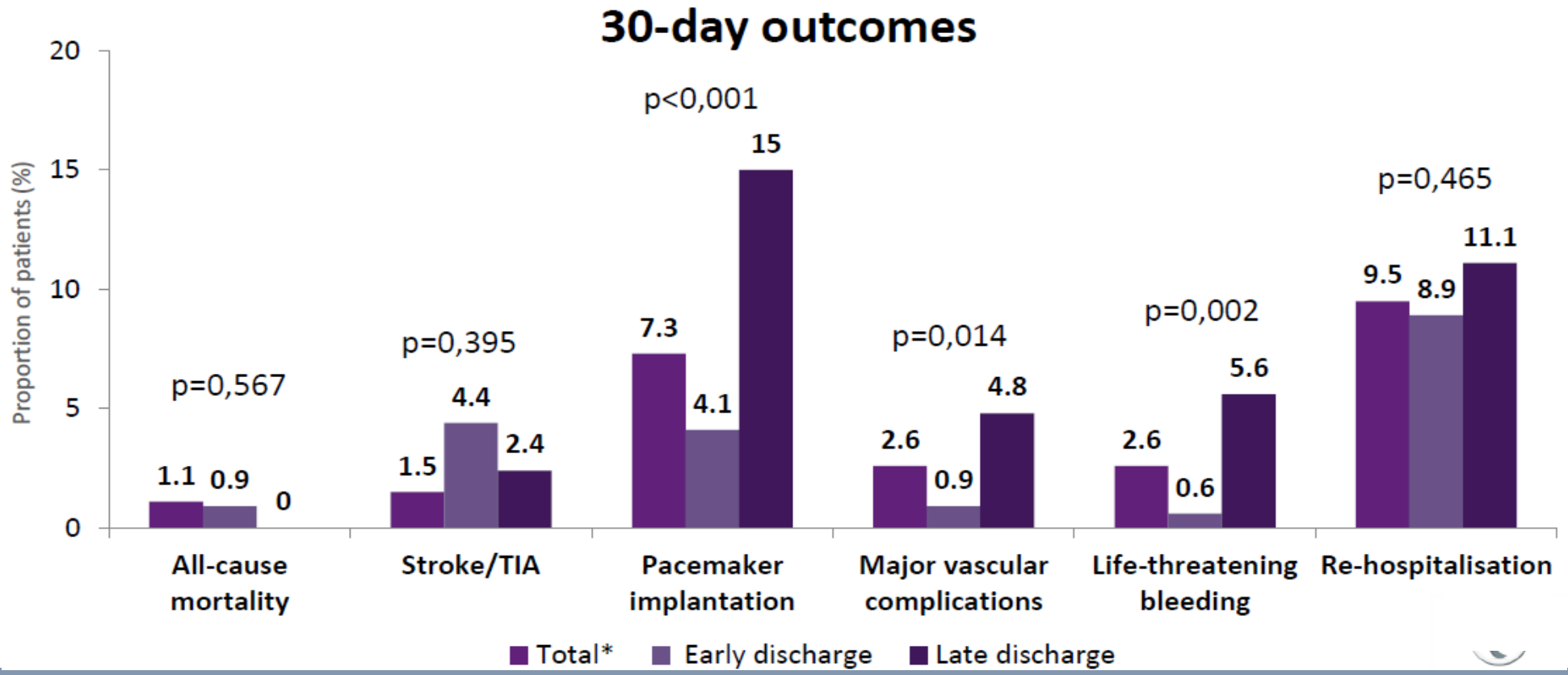


Ussia et al., presented at New York Transcather Valves 2018; Musa et al., BMJ Open. 2019 Jan 21;9(1):e022329

Patient and Device Selection
Returning Patients to Routine Daily Life

In low-risk patients who are still working and active, the ability to return to routine daily life will be important.

Early discharge has been demonstrated to be safe in the majority of TAVI patients. Complications such as pacemaker implantation, major vascular complications, and bleeding may limit early discharge



Conclusions

- TAVI has been proven safe and achieved excellent results in extreme, high, and intermediate risk patients
- With the recent success of randomized, low-risk trials, TAVI will likely be preferred over SAVR
- Patient selection in low-risk patients will likely be driven by age, anatomy, and if concomitant procedures are needed
- Patient and device selection will become increasingly important in younger, healthier patients
- Valve durability and performance, lifetime management, and getting patients back to routine daily life will drive TAVI device selection

Thanks for your attention!