Transcatheter Aortic Valve Replacement: Will TAVR replace Surgical AVR?

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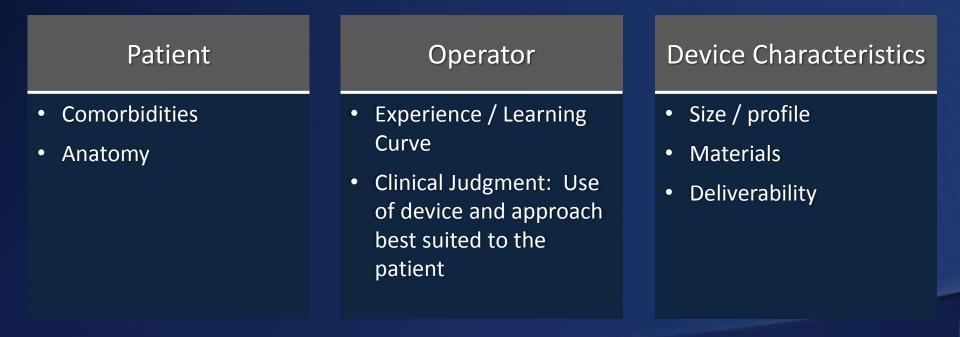
Medtronic, CoreValve: C, SB, AB, OF Direct Flow: C, SB, AB Mitralign: AB, SB, E Boston Scientific: C, SB, AB Cordis: AB Abbott Vascular: AB Valtech: E, SB, In Seal Medical: SB, E Claret: SB Keystone, SB

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TAVI Patients Risk | Background

- TAVI is typically indicated for patients <u>at high or extreme surgical</u> <u>risk</u>, and the clinical evidence has consistently demonstrated good outcomes for these patients.
- TAVI outcomes, though, are driven by multiple factors. A change in any one may alter the course for an individual TAVI patient.



Intermediate Surgical Risk | Background

 Contemporary clinical practice is evolving such that patients at lower surgical risk are being treated by TAVI.

MINI-FOCUS ON TAVI

CLINICAL RESEARCH

A 3-Center Comparison of 1-Year Mortality Outcomes Between Transcatheter Aortic Valve Implantation and Surgical Aortic Valve Replacement on the Basis of Propensity Score Matching Among Intermediate-Risk Surgical Patients

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STRUCTURAL HEART DISEASE

Acute and Late Outcomes of Transcatheter Aortic Valve Implantation (TAVI) for the Treatment of Severe Symptomatic Aortic Stenosis in Patients at High- and Low-Surgical Risk

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Improvements in Transcatheter Aortic Valve Implantation Outcomes in Lower Surgical Risk Patients

A Glimpse Into the Future

Ruediger Lange, MD, PHD, Sabine Bleiziffer, MD, Domenico Mazzitelli, MD, Yacine Elhmidi, MD, Anke Opitz, MD, Marcus Krane, MD, Marcus-Andre Deutsch, MD, Hendrik Ruge, MD, Gernot Brockmann, MD, Bernhard Voss, MD, Christian Schreiber, MD, Peter Tassani, MD, PHD, Nicolo Piazza, MD, PHD

Munich, Germany

Clinical outcomes of patients with estimated low or intermediate surgical risk undergoing transcatheter aortic valve implantation

Peter Wenaweser¹[†]*, Stefan Stortecky¹[†], Sarah Schwander¹, Dik Heg², Christoph Huber³, Thomas Pilgrim¹, Steffen Gloekler¹, Crochan J. O'Sullivan¹, Bernhard Meier¹, Peter Jüni², Thierry Carrel³, and Stephan Windecker^{1,2}

Transcatheter vs surgical aortic valve replacement in intermediate-surgical-risk patients with aortic stenosis: A propensity score–matched case-control study

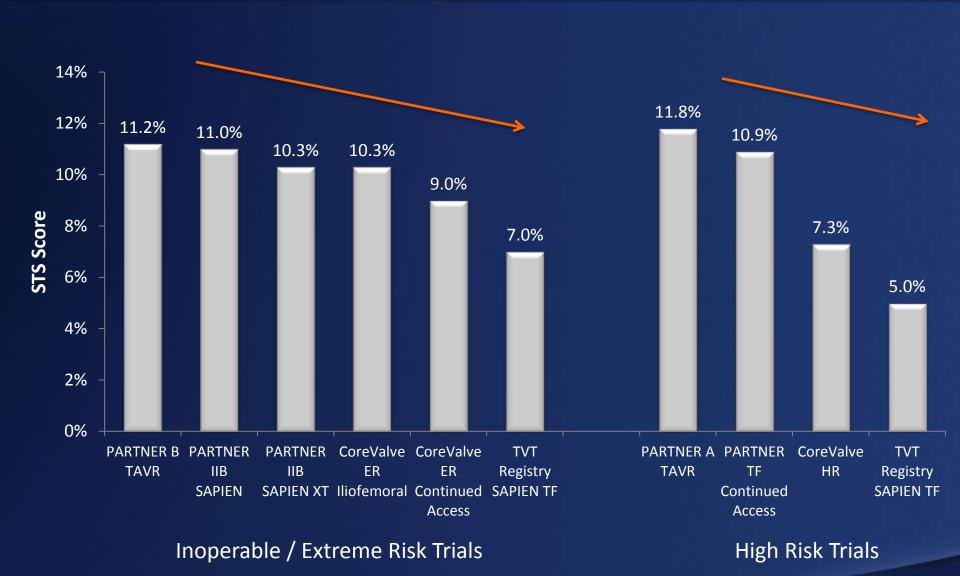
Azeem Latib, MB ChB, ^{a,b,f} Francesco Maisano, MD, ^{c,f} Letizia Bertoldi, MD, ^b Andrea Giacomini, MD, ^c Joanne Shannon, MD, ^a Micaela Cioni, MD, ^c Alfonso Ielasi, MD, ^b Filippo Figini, MD, ^{a,b} Kensuke Tagaki, MD, ^a Annalisa Franco, MD, ^d Remo Daniel Covello, MD, ^d Antonio Grimaldi, MD, ^d Pietro Spagnolo, MD, ^e Gill Louise Buchannan, MD, ^b Mauro Carlino, MD, ^b Alaide Chieffo, MD, ^b Matteo Montorfano, MD, ^b Ortavio Alferi, MD, ^c and Antonio Colombo, MD ^{a,b} Milan, Italy

Transcatheter aortic valve implantation versus surgical aortic valve replacement for severe aortic stenosis: Results from an intermediate risk propensity-matched population of the Italian OBSERVANT study

Paola D'Errigo^{*}, Marco Barbanti ^{b.c.*}, Marco Ranucci^d, Francesco Onorati^e, Remo Daniel Covello[†], Stefano Rosato^{*}, Corrado Tamburino^{b.c.}, Francesco Santini^e, Gennaro Santoro^{*}, Fulvia Seccareccia^{*} and on behalf of the OBSERVANT Research Group

¹Wenaweser, et al., *Eur Heart J* 2013; 34: 1894-905; ²Lange, et al., *J Am Coll Cardiol* 2012; 59: 280-7; ³Piazza, et al., *J Am Coll Cardiol Intv* 2013; 6: 443-51; ⁴D'Errigo, et al., *Int J Cardiol* 2013: 167: 1945-62; epub; ⁵Latib, et al., *Am Heart J* 2012; 164: 910-7; Schymik, et al., *J Interv Cardiol* 2012; 25: 364-74

Intermediate Surgical Risk | Evolution in Patient Selection



Intermediate Surgical Risk | TAVI Outcomes

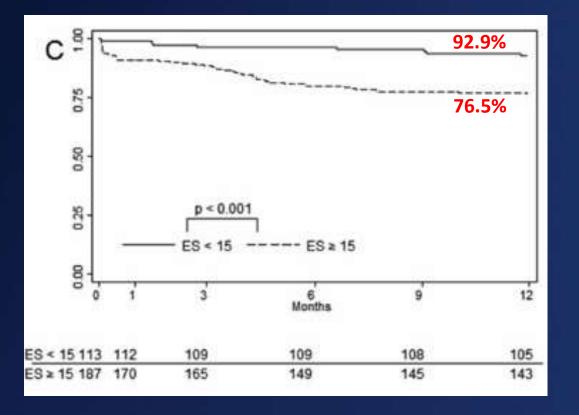
- Two European centers have directly compared TAVI outcomes of patients at lower- and higher-risk within their centers.
- Clinical outcomes were generally <u>favorable</u> for the patients at lower risk^{1,2}.

	В	ern ¹	Munich ²			
	Lower Risk (n=254)	Higher Risk (n=94)	Lower Risk (n=105)	Higher Risk (n=105)		
STS (%)	5.1 ± 1.4	13.3 ± 7.1	4.8 ± 2.6	7.13 ± 5.4		
Log EuroSCORE (%)	22.1 ± 11.9	35.1 ± 15.7	17.8 ± 12.0	25.44 ± 16.0		
30 Day Mortality (%)	3.9	14.9	3.8	11.4		
Total Vascular Complications (%)	17.7	20.3	14.7	28.6		
Stroke / TIA (%)	5.0	3.4	1	6.7		

¹Wenaweser, et al., Eur Heart J 2013; 34: 1894-905; ²Lange, et al., J Am Coll Cardiol 2012; 59: 280-7

Intermediate Surgical Risk | TAVI Outcomes

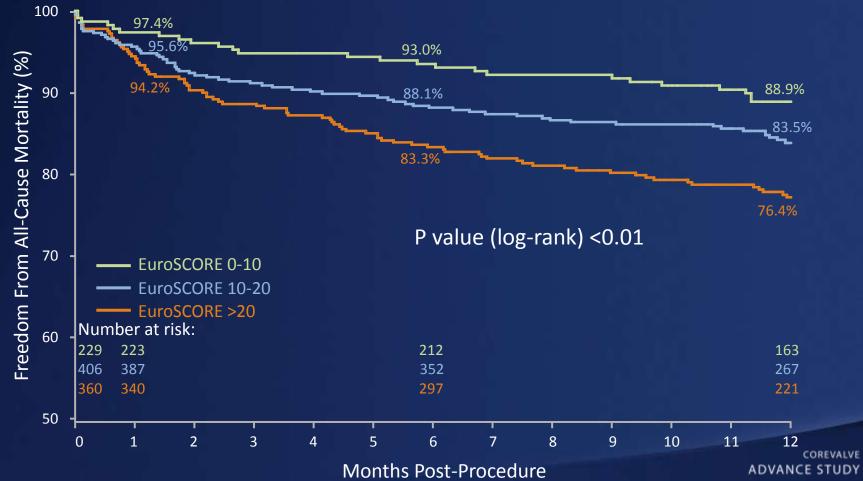
Schymik¹ demonstrated that for every 10-point increase in EuroSCORE the mortality risk increased within the first year by 67% (OR 1.67, 95% CI 1.34-2.08, P<0.0001)



Kaplan-Meier survival estimates EuroSCORE ≥15 vs EuroSCORE <15

Intermediate Surgical Risk | CoreValve Outcomes

The CoreValve ADVANCE Study demonstrated that decreased surgical risk score correlated with decreased mortality



¹Brecker, et al., presented at EuroPCR 2013

Intermediate Surgical Risk | Impact of Comorbidities

Many studies have shown that comorbidities add risk to TAVI. This may explain why patients at lower surgical risk have shown better outcomes compared to their higher risk counterparts.

Transcatheter Aortic Valve Implantation in Patients With "Porcelain" Aorta (from a Multicenter Real World Registry)

Ralf Zahn, MD²⁺⁺, Rudoff Schiele, MD⁴, Ulrich Gerckens, MD², Axel Linke, MD², Hove Sievert, MD², Philipp Kahlari, MD², Rainer Hambrecht, MD², Stefan Sack, MD⁴, Mohamed Abdel-Wahds, MD², Ellen Hoffmann, MD², and Jochen Senges, MD³, on behalf of the German Transcatheter Aseric Valve Interventions Registry Investigators

> The presence of severe atherms/motion of the ascending sorts, and its extreme form the "percella" sorts, is associated with a wome, clinical cutorese in patients undergoing samplest asortic value replacement. Percentaneous transcatchere and the value implementation (TAVI) for severe symptomatic astric seponds can ownersnee this problem 1,574 TAVI procedures were performed at 27 heapticals in 147 performant [85,76] with and 1,227 (98,295) sufficient a periodial assets. The mean reported providence of a porcelaim astria at the heaptical were $1.51\pm \pm 1.405$ (range 9% in 70%). Databetics meditims (66,55 w i) 2.2%, μ = 0.00018), choosic obstructive pointonary disease (65,55 w i) 2.2%, ρ < 0.00001), and peripherical astrick down of 2.47 w vol.20%, ρ < 0.0001) (set

> > ARTICLE IN PRES

Effect of Body Mass Index on Short- and Long-term Outcomes After Transcatheter Aortic Valve Implantation

Robert M.A. van der Boon, MSc⁴, Alade Chieffo, MD², Nicolas Dunsomeil, MD², Didier Tchetche, MD⁴, Nicolas M. Van Mieghen, MD², Gill L. Buchanan, MBChB⁴, Olivier Vahdat, MD⁴, Bertrand Marcheix, MD, PhD², Dunick W. Seenuys, MD, PhD², Isun Fujadet, MD⁴, Antonio Colombo, MD, PhD², Didier Carrie, MD, PhD², Ron T. van Dombreg, PhD², and Peter P.T. de Jaegers, MD, PhD^{4+o}, on behalf of the PRAGMATIC-Plus Researchers



latter to the Editor

One year clinical outcomes in patients with severe aortic stenosis and left ventricular systolic dysfunction undergoing transcatheteter aortic valve implantation: Results from the Italian CoreValve Registry²⁷

Claudia Florina ^{4,*}, Marco Barbani ^{16,*}, Marco De Carla ⁴, Federico De Marco ⁴, Geneppe Tarantini ⁶, Irancesco Bedogni ⁶, Gennaro Jantoro ³, Anna Sonia Petronio ⁴, Gian Paolo Ussia ⁵, Diego Malfeo ⁴, Corrado Tamburino ^{16,*}, Federica Ettori ⁴

Transcatheter Aortic Valve Implantation in Patients With Severe Left Ventricular Dysfunction

Immediate and Mid-Term Results, A Multicenter Study

Chiara Fraccaro, MD; Rasha Al-Larnee, MA, MRCP; Giuseppe Tarantini, MD, PhD; Francesco Maisano, MD; Massimo Napodano, MD; Matteo Montorfano, MD; Anna Chiara Frigo, MSc; Sabino Iliceto, MD; Gino Gerosa, MD; Giambattista Isabella, MD; Antonio Colombo, MD

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Original Studies

Impact of Aortic Valve Calcification on the Outcome of Transcatheter Aortic Valve Implantation: Results from the Prospective Multicenter German TAVI Registry

Stephen Staatbach,¹¹ wu, Jernitler Fromin,² wu, Ulrich Gerckens,² wu, Garhard Schuler,² wu, Half Zohn,⁴ wu, Neliger Egyptinochi,³ au, Rainer Hambrecht,³ wu, Stellan Sack,³ au, Gert Richardt,⁴ wu, Marin Housek,⁴ Hauth et al.

Pulmonary hypertension is associated with worse early and late outcomes after aortic valve replacement: Implications for transcatheter aortic valve replacement

Eric E. Roselli, MD.⁹ Anas Abdel Arim, MD, MSc.⁹ Porty L, Houghtaling, MS.⁹ Wael A, Jaher, MD.⁹ and Engene H. Blackstone, MD¹⁴

Objectives Our relations were to interesting the periodence of patients hypertension (PHT) in patients being of the features fring at young of patients providents to the period of the terminal sector of terminal sector o

Heart Valve Disease

Outcomes of Patients With

Chronic Lung Disease and Severe Aortic Stenosis Treated With Transcatheter Versus Surgical Aortic Valve Replacement or

Standard Therapy

Insights From the PARTNER Trial (Placement of AoRTic TraNscatherER Value)

Impact of Diabetes Mellitus on Early and Midterm Outcomes After Transcatheter Aortic Valve Implantation (from a Multicenter Registry)

Federico Conton, MD*, Fabrino D'Assenzo, MD*, Francesco Gioslana, MD*, Stefano Salizzoni, MD*, Corrini: Tamburoni, MD*, Gasarype Transini, MD*, Printial Presitient, MD*, Marce Barbano, MD*, Valerio Granuelto, MD*, Marco Menuna, MD*, Mosilon Nopolaton, MD*, Marco L, Rossi, MD*, Michele La Torre, MD*, Gaetana Ferraro, MD*, Pierting Orneck, MD*, Paelo Sasenatella, MD*, Waleri Geneso Maria, MD*, Chara Coltad, MD*, Gaetappi Band-Scota, MD*, Datol Morti, MD*, Manirizo MD*, Anizo, MD*, Marco Riadki, MD*, Fierenzo Gaita, MD*, and Sebartano Maria, MD*, The Impact of Frailty Status on Survival After Transcatheter Aortic Valve Replacement in Older Adults With Severe Aortic Stenosis

A Single-Center Experience

Chronic Obstructive Pulmonary Disease in Patients Undergoing Transcatheter Aortic Valve Implantation

Insights on Clinical Outcomes, Prognostic Markers, and Functional Status Changes

Mirhaul Mok, MBBS, "Lais Namhelis-Franco, MDA," Eric Darment, MDA, Marina Umma, MDA, Robert DeLarodelliere, MDA," David Doyle, MDA," Jacque Vilseoure, MDA, Mataria Cotta, MSA, "Hearinga B, Ribeiro, MDA," Baardo Allende, MDA," Joréme Laflanune, MSA, "Hage DeLarochelliere, MSA, Louis Laflanune, MSA, "Jurado Amuri-Santon, MDA," Philippe Pilanne, PriDA, "François Mahimi, MDA; Josep Rodes-Cahma, MDA"

Quebe City, Qselve, Canada

Disjectives This itsely usually to determine the effects of chronic obstructive pulmonary disease (CDPD on otheral options on patients undergoing transactives exofic valve implementation (TAW) and to determine the factors associated with works outcomes in COPD patients.

Background: No data exist on the factors determining poorer outcomes & CDFD patients undergoing TAM. Methods: A total of 310 convectable patients (2625), with CDFD1 who underware TAMI over totaled. Functional status near evaluated by New York Heart Association (NIPMAI Institutional class, Date Activity Status Index, and the 6-min wolk test (MINIC) at backing and a 6-m 12 months. The TAVI teatomeric was considered fable if the patient either died or did net improve in MINIA functional class as 6-months fable-view.

Heads Sarwin (rate at 1 year were 71erk in COPD patients and 84.5% in patients without COPD ($\mu=0.000$; COPD was an independent predictor of currolative manufact after TAM discord ratio 1.54 (P=50.00). Instrument in functional status was observed after TAM ($\mu<0.001$; for MTMA functional data, Dake Activity Status Index, and GMWT), but COPD patients and take to 1.51 ($\mu=50.001$). Instrument in the currol of the COPD patients and the currol of the currol of the currol of the currol of the cu

Impact of preoperative chronic kidney disease on short- and long-term outcomes after transcatheter aortic valve implantation: A Pooled-RotterdAm-Milano-Toulouse In Collaboration Plus (PRAGMATIC-Plus) initiative substudy

Skohn Duranveill, MC, ¹ Hohen N, A. van der Kosse, SSC, ² Höher Telescher, HC, ² Mahler Charlin, MD, ³ Nachen W, Wei Megleren, HO, ³ Horizonal Harchien, MD, PDD, ⁴ ell, ³ Linchanas, Michallo, ⁴ Woley Valadier, MD, ³ Patelsk W, Verreys, MD, PMA, ³ Jean Baidell, MS, ³ Janosto Golenskin, MD, ⁴MD, ³ Payer P, T. de Jangere, MD, PMR, ³ and Bilder Carlotti, MD, PD, ⁴ Tean Baidell, MS, ³ Janosto Golenskin, MD, ⁴Moler Charles MD, ⁴Miller, Hoff, ⁴ and Bilder Carlotti, MD, PD, ⁴ Tean Baidell, MS, ³ Janosto Golenskin, MD, ⁴Moler Charles MD, ⁴Miller, Hoff, ⁴

Intermediate Surgical Risk | TAVI vs. SAVR

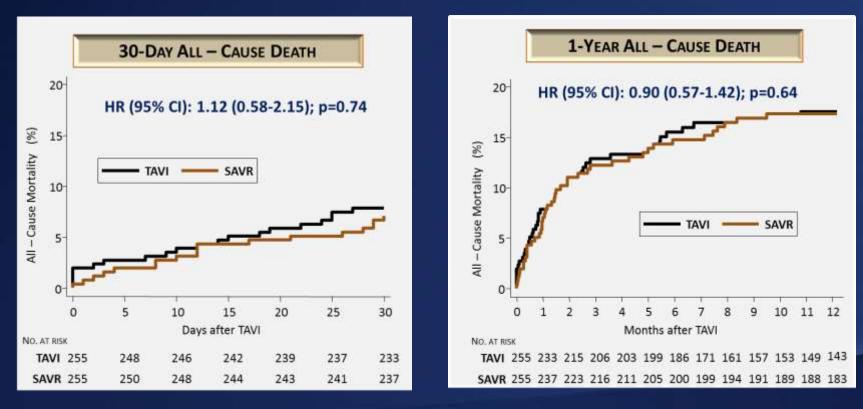
- Several studies have compared the effectiveness of TAVI and SAVR in propensity-matched patients at intermediate surgical risk^{1,2,3}.
- All studies showed similar mortality rates between TAVI and SAVR

	Piazza ¹		OBSERVANT ²		Latib ³				
	TAVI (n=255)	SAVR (n=255)	р	TAVI (n=133)	SAVR (n=133)	р	TAVI (n=111)	SAVR (n=111)	р
STS (%, mean)	3-8	3-8					4.6	4.6	
Log EuroSCORE (%, mean)	17.3	17.6		8.9	9.4		23.2	24.4	
30 Day Mortality (%)	7.8	7.1	0.74	3.8	3.8	1.000	1.8	1.8	1.00

¹Piazza, et al., J Am Coll Cardiol Intv 2013; 6: 443-51; ²D'Errigo, et al., Int J Cardiol 2013; 167: 1945-52; ³Latib, et al., Am Heart J 2012; 164: 910-7

Intermediate Surgical Risk | TAVI vs. SAVR

- Results of the Piazza study¹ showed that TAVI and SAVR result in *similar 30-day (7.8% vs. 7.1%, p=0.74) and 1-year mortality (16.5% vs. 16.9%, p=0.64).*
- Stratified analyses of 1-year all-cause mortality showed women to have a greater benefit from TAVI vs. SAVR compared to men (P for interaction = 0.027).



Intermediate Surgical Risk | TAVI vs. SAVR

 The Latib¹ study highlights that TAVI and SAVR patients experience similar mortality rates, but with a *different spectrum of procedural complications*.

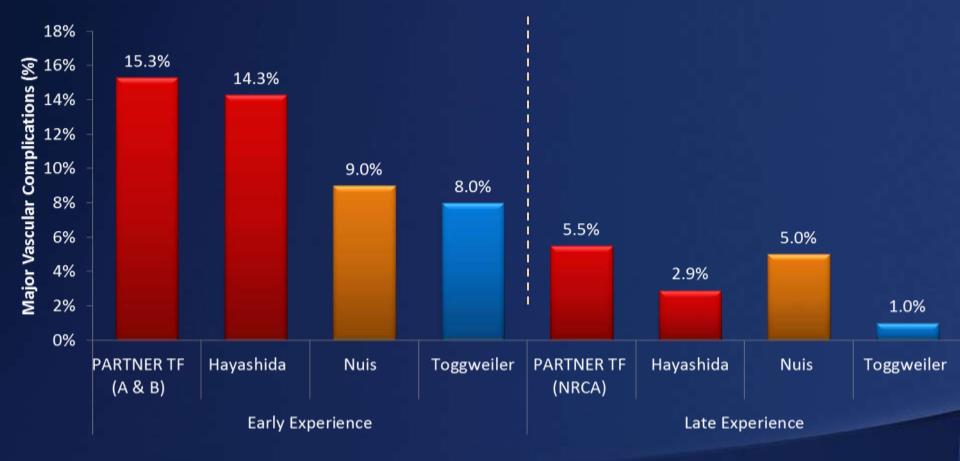
		Latib ¹	
	TF-TAVI (n=111)	SAVR (n=111)	р
Major Vascular Complications*	14.4	0	<0.001
Bleeding Complications*	66.7	82.9	0.005
Acute Kidney Injury	8.1	26.1	<0.001
Permanent Pacemaker Implant	11.7	2.7	0.009
30 Day Stroke / TIA (%)	3.6	8.1	0.08

* The Sapien device (22Fr / 24Fr delivery system) was used in 27% of the TF-TAVI patients in this study, which may contribute to higher complication rates than typically seen with contemporary devices.

- Complications that are higher in TAVI compared to SAVR include major vascular complications, paravalvular leak, and in some series, stroke.
- For TAVI to be favored over SAVR, these rates should decrease.
 - Evidence shows that these complication rates are decreasing as operators gain experience and technology improves.
- Improving the risk profile of the patients will also contribute to decreased complication rates.

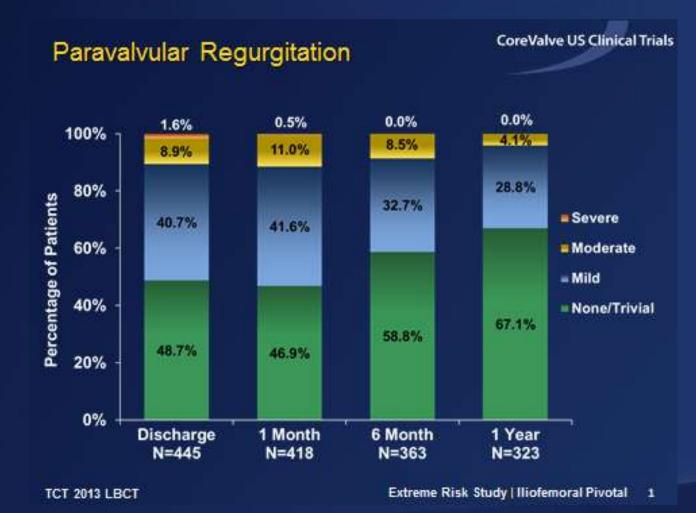
Major Vascular Complications | Effect of Experience

- Major vascular complication rate is strongly impacted by operator experience.
- We may expect to see these rates to continue to decrease with time.



Paravalvular Leak | Effect of Improved Imaging Techniques

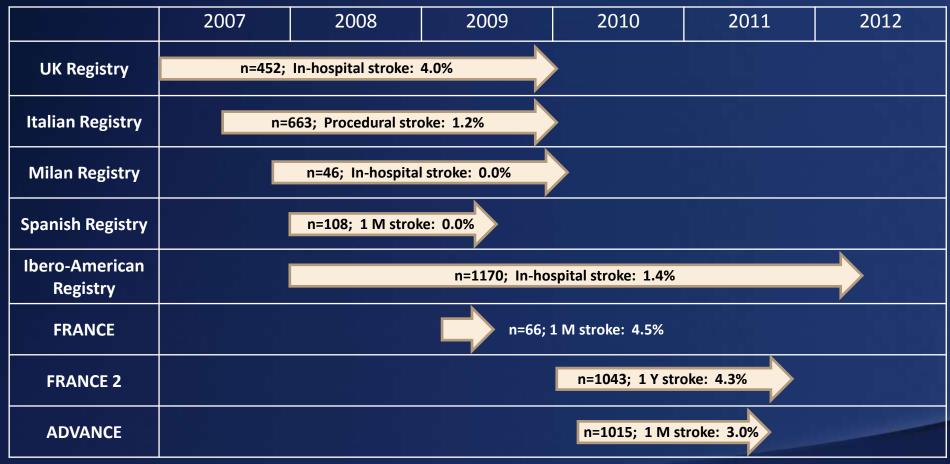
The CoreValve Extreme Risk Pivotal Trial showed low rates of PVL, which may be attributable to strict valve sizing criteria using MSCT.



¹Popma, et al., presented at TCT 2013

Stroke | Lower-Risk Patients May Have Fewer Strokes

Multicenter registry data on 4,563 patients indicate that CoreValve has a historically low stroke rate, staying below 4.5% for any given cohort. Patients with fewer comorbidities may experience less stroke after TAVI.



Arrows indicate implant period and the reported rate of total stroke for the CoreValve cohort

Intermediate Surgical Risk | Discussion

- In contemporary clinical practice, TAVI is being performed in patients at lower surgical risk.
- Studies which compare outcomes between higher-risk and lower-risk TAVI patients^{1,2} show that lower-risk patients have better outcomes.
- As TAVI technology continues to evolve and operators continue to gain experience, the risk to all patients is likely to continue to decline.
- Though we are seeing encouraging outcomes in lower-risk TAVI patients, modern randomized controlled trials are needed to confirm that TAVI is at least as good as SAVR in patients at intermediate surgical risk.