TAVR in 2015

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Michael E Jessen: Disclosures

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Quest Medical

Research Support:

Organ Transport System, Inc

Dallas CARDIOVASCULAR INNOVATIONS 2015

TAVR in 2015

- Results of a Pivotal Trial for Self-Expanding Transcatheter Valve in High-Risk Patients
- Results of a randomized trial comparing the Sapien and CoreValve devices (CHOICE Trial)
- Results of observational reports in low or intermediate risk patients with severe aortic stenosis. (OBSERVANT Study)

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TAVR in 2015

- Use of TAVR in anatomic situations outside of the current FDA approval guidelines:
  - Patients with bicuspid aortic valves
  - Patients with structural valve degeneration of a prior aortic bioprosthesis
- Results of TAVR in specific subsets of patients:
  - Patients with end-stage renal disease
  - Women
  - Patients with diabetes

- Transcatheter aortic valve replacement, or TAVR, has become increasingly used for the treatment of severe aortic stenosis.

- The procedure is principally used in high risk surgical patients or those deemed inoperable by a heart team of cardiologists and surgeons.

- The first device to receive FDA approval (November 2011) was the Edwards Sapien Device. Approval was in part based on the PARTNER Trial which found similar outcomes in high-risk patients treated with TAVR and open surgery.
- More recently, the results of a pivotal trial using the Medtronic CoreValve in high-risk surgical patients has been completed. This device received FDA approval in January 2014.

Original Article

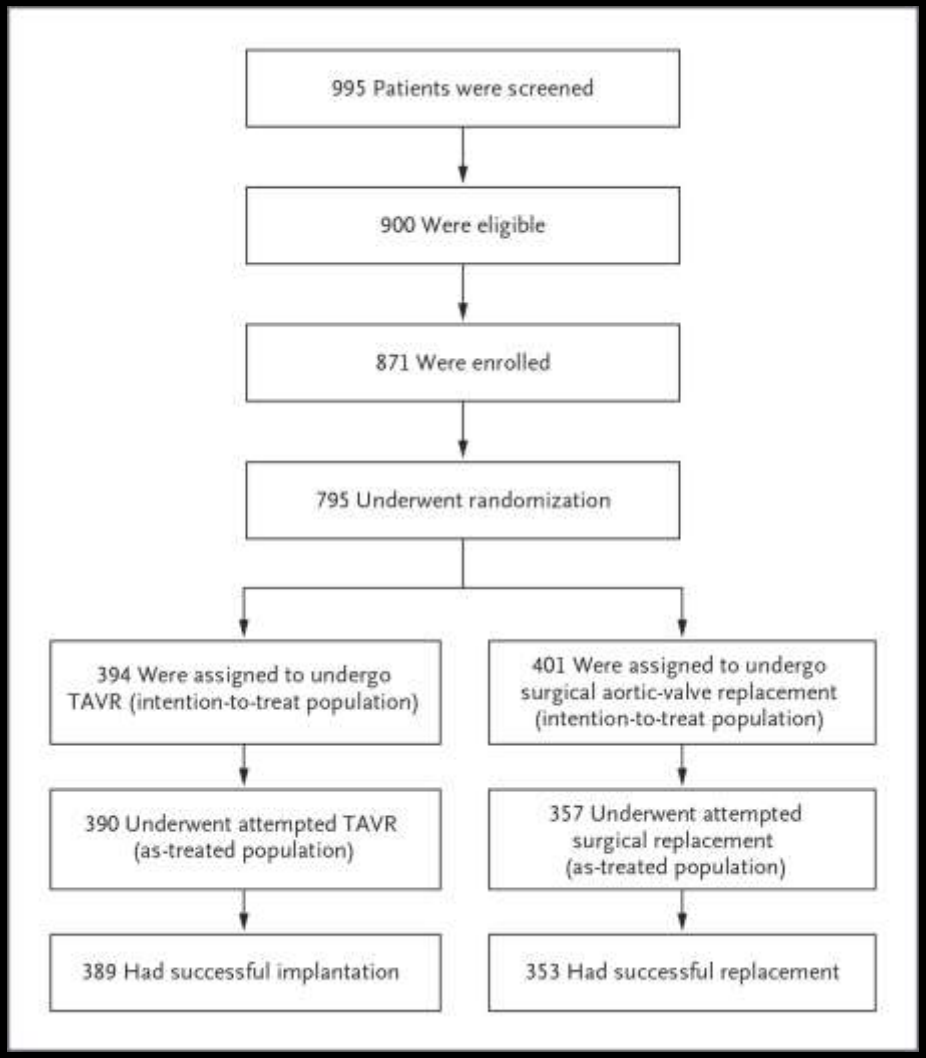
Transcatheter Aortic-Valve Replacement with a Self-Expanding Prosthesis

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., Jae K. Oh, M.D., for the U.S. CoreValve Clinical Investigators

N Engl J Med
Volume 370(19):1790-1798
May 8, 2014

The NEW ENGLAND JOURNAL of MEDICINE

Randomization and Analysis Populations.



Adams DH et al. N Engl J Med 2014;370:1790-1798

Procedural Outcomes at 30 Days and 1 Year in the As-Treated Population.

Table 2. Procedural Outcomes at 30 Days and 1 Year in the As-Treated Population.*

Outcome	30 Days			1 Year		
	TAVR Group (N=390)	Surgical Group (N=357)	P Value	TAVR Group (N=390)	Surgical Group (N=357)	P Value
	number (percent)			*number (percent)*		
Major vascular complication	23 (5.9)	6 (1.7)	0.003	24 (6.2)	7 (2.0)	0.004
Bleeding event†						
Life-threatening or disabling bleeding	53 (13.6)	125 (35.0)	<0.001	64 (16.6)	136 (38.4)	<0.001
Major bleeding	109 (28.1)	123 (34.5)	0.05	114 (29.5)	130 (36.7)	0.03
Acute kidney injury	23 (6.0)	54 (15.1)	<0.001	23 (6.0)	54 (15.1)	<0.001
Cardiogenic shock	9 (2.3)	11 (3.1)	0.51	9 (2.3)	11 (3.1)	0.51
Cardiac perforation	5 (1.3)	0	0.03	5 (1.3)	0	0.03
Permanent pacemaker implantation	76 (19.8)	25 (7.1)	<0.001	85 (22.3)	38 (11.3)	<0.001
New-onset or worsening atrial fibrillation	45 (11.7)	108 (30.5)	<0.001	60 (15.9)	115 (32.7)	<0.001

* All data are reported as Kaplan–Meier estimates at the specific time point and do not equal the number of patients with events divided by the total number of patients in each treatment group. The corresponding P values were calculated by the log-rank test for all data through 30 days or 1 year.

† Life-threatening or disabling bleeding was defined as fatal bleeding; bleeding in a critical area or organ (e.g., intracranial, intraspinal, intraocular, or pericardial) necessitating pericardiocentesis, or intramuscular bleeding with the compartment syndrome; bleeding causing hypovolemic shock or severe hypotension requiring vasopressors or surgery; bleeding associated with a drop in the hemoglobin level of 5 g per deciliter or more; or bleeding necessitating a transfusion of 4 units or more of whole blood or packed red cells. Major bleeding was defined as bleeding associated with a drop in the hemoglobin level of at least 3.0 g per deciliter or bleeding requiring transfusion of 2 or 3 units of whole-blood red cells; in addition, major bleeding was bleeding that did not meet the criteria of life-threatening or disabling bleeding.

Adams DH et al. N Engl J Med 2014;370:1790-1798

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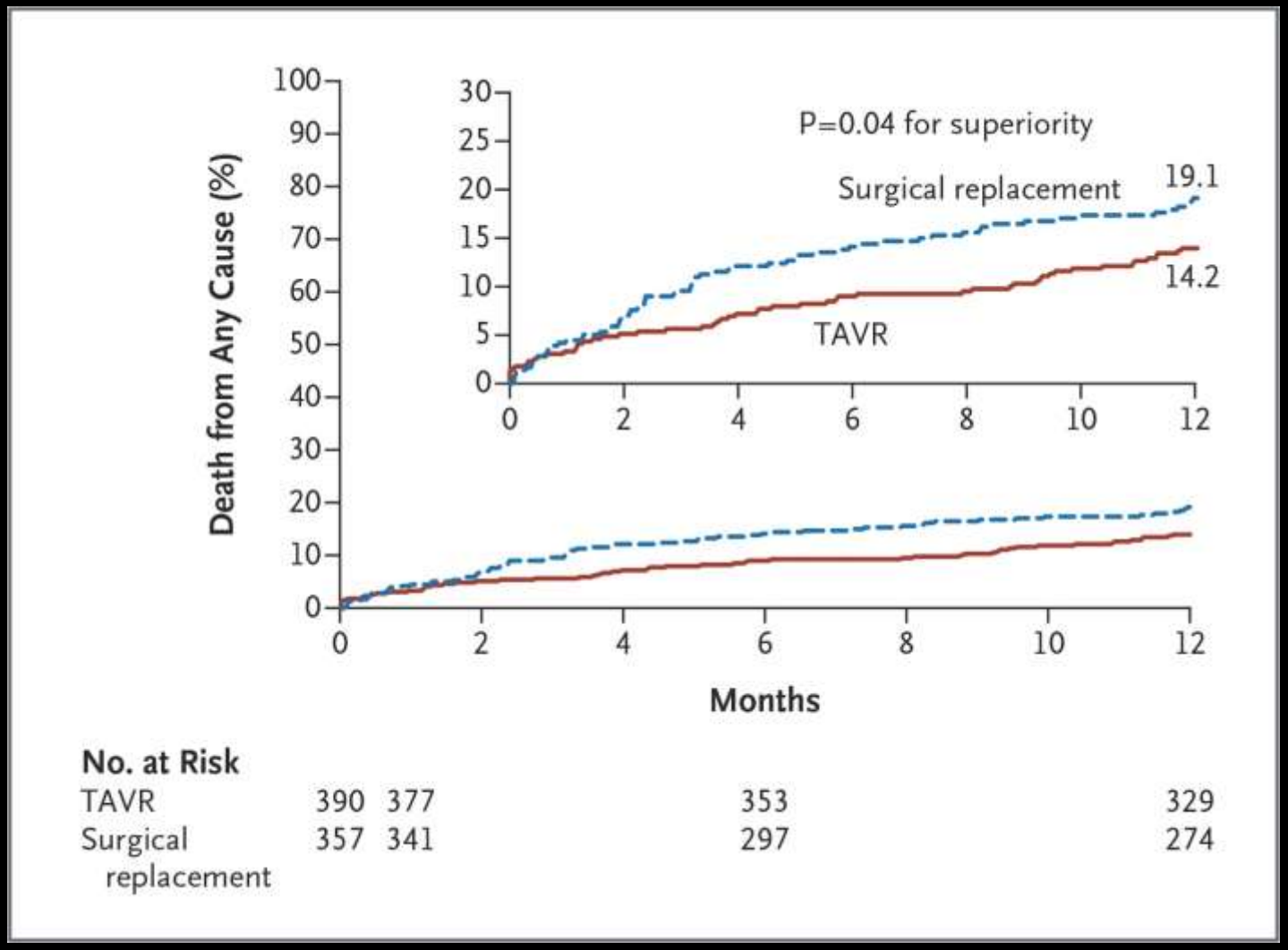
Kaplan–Meier Cumulative Frequency of Death from Any Cause.



Adams DH et al. N Engl J Med 2014;370:1790-1798

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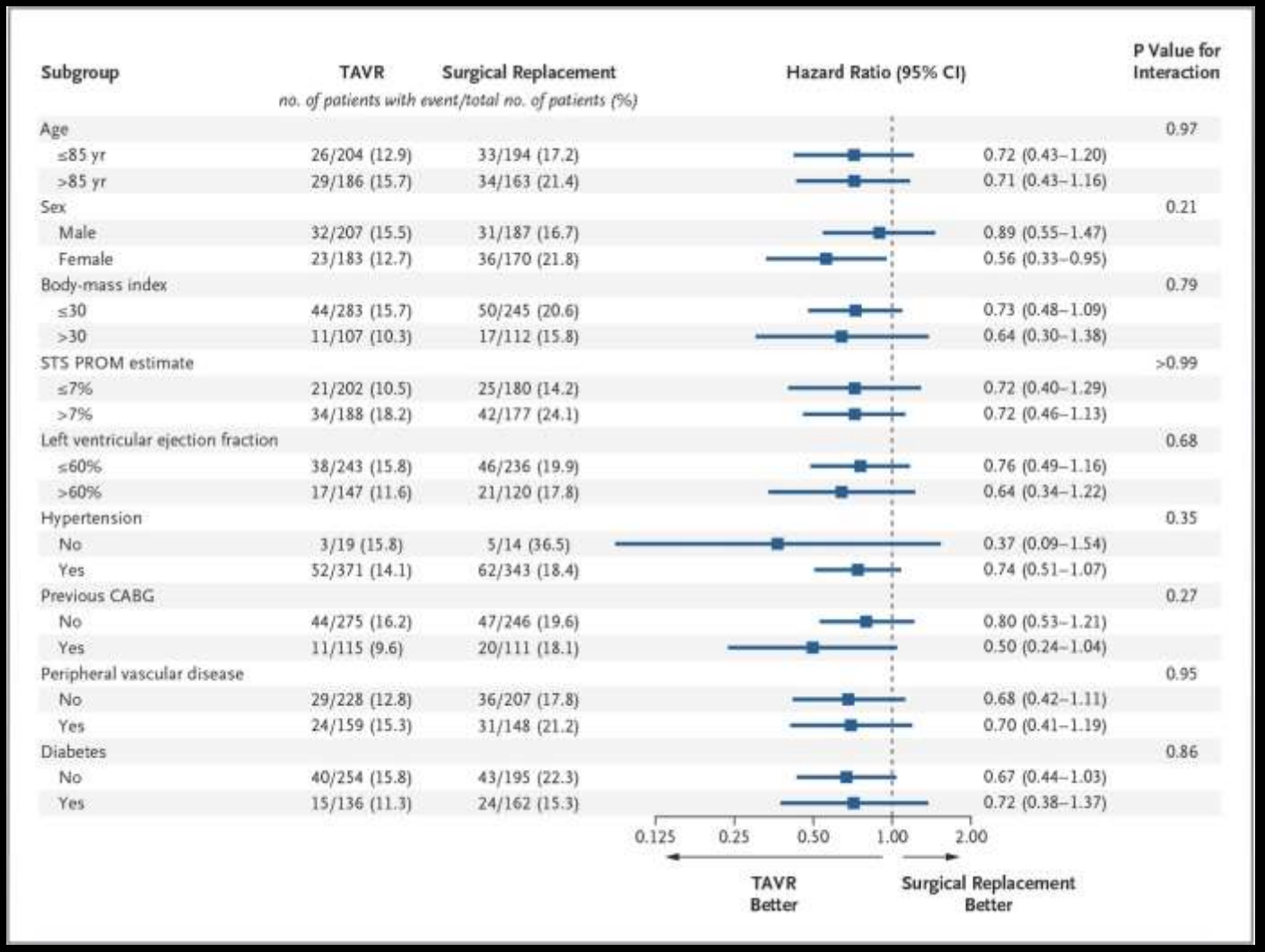
Subgroup Analysis for the Rate of Death from Any Cause at 1 Year.



Subgroup	TAVR	Surgical Replacement	Hazard Ratio (95% CI)	P Value for Interaction
	no. of patients with event/total no. of patients (%)			
Age				0.97
≤85 yr	26/204 (12.9)	33/194 (17.2)	0.72 (0.43–1.20)	
>85 yr	29/186 (15.7)	34/163 (21.4)	0.71 (0.43–1.16)	
Sex				0.21
Male	32/207 (15.5)	31/187 (16.7)	0.89 (0.55–1.47)	
Female	23/183 (12.7)	36/170 (21.8)	0.56 (0.33–0.95)	
Body-mass index				0.79
≤30	44/283 (15.7)	50/245 (20.6)	0.73 (0.48–1.09)	
>30	11/107 (10.3)	17/112 (15.8)	0.64 (0.30–1.38)	
STS PROM estimate				>0.99
≤7%	21/202 (10.5)	25/180 (14.2)	0.72 (0.40–1.29)	
>7%	34/188 (18.2)	42/177 (24.1)	0.72 (0.46–1.13)	
Left ventricular ejection fraction				0.68
≤60%	38/243 (15.8)	46/236 (19.9)	0.76 (0.49–1.16)	
>60%	17/147 (11.6)	21/120 (17.8)	0.64 (0.34–1.22)	
Hypertension				0.35
No	3/19 (15.8)	5/14 (36.5)	0.37 (0.09–1.54)	
Yes	52/371 (14.1)	62/343 (18.4)	0.74 (0.51–1.07)	
Previous CABG				0.27
No	44/275 (16.2)	47/246 (19.6)	0.80 (0.53–1.21)	
Yes	11/115 (9.6)	20/111 (18.1)	0.50 (0.24–1.04)	
Peripheral vascular disease				0.95
No	29/228 (12.8)	36/207 (17.8)	0.68 (0.42–1.11)	
Yes	24/159 (15.3)	31/148 (21.2)	0.70 (0.41–1.19)	
Diabetes				0.86
No	40/254 (15.8)	43/195 (22.3)	0.67 (0.44–1.03)	
Yes	15/136 (11.3)	24/162 (15.3)	0.72 (0.38–1.37)	

Adams DH et al. N Engl J Med 2014;370:1790-1798

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Conclusions

- In patients with severe aortic stenosis who are at increased surgical risk, TAVR with a self-expanding transcatheter aortic-valve bioprosthesis was associated with a significantly higher rate of survival at 1 year than surgical aortic-valve replacement.

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- With two approved devices on the market, comparative trails have been initiated.
- One recent randomized trial comparing the Sapien device and the CoreValve (the CHOICE Trial) was reported in 2014 and randomized 241 patients to one of these devices.

Original Investigation

Comparison of Balloon-Expandable vs Self-expandable Valves in Patients Undergoing Transcatheter Aortic Valve Replacement

The CHOICE Randomized Clinical Trial

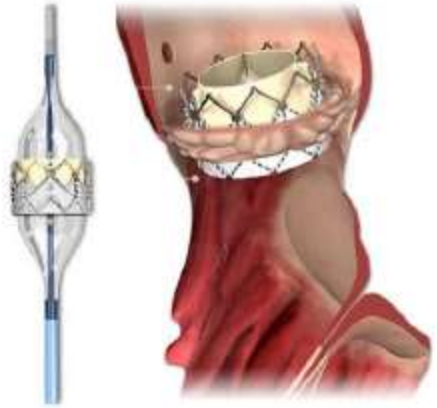
Mohamed Abdel-Wahab, MD; Julinda Mehilli, MD; Christian Frerker, MD; Franz-Josef Neumann, MD; Thomas Kurz, MD; Ralph Tölg, MD; Dirk Zachow, MD; Elena Guerra, MD; Steffen Massberg, MD; Ulrich Schäfer, MD; Mohamed El-Mawardy, MD; Gert Richardt, MD; for the CHOICE investigators

JAMA. 2014;311(15):1503-1514. doi:10.1001/jama.2014.3316
Published online March 30, 2014.

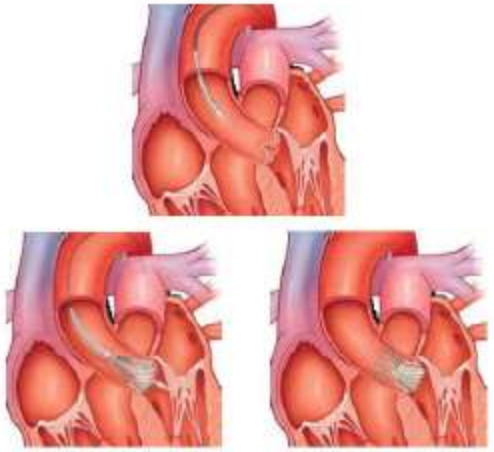
Background (II)

CHOICE

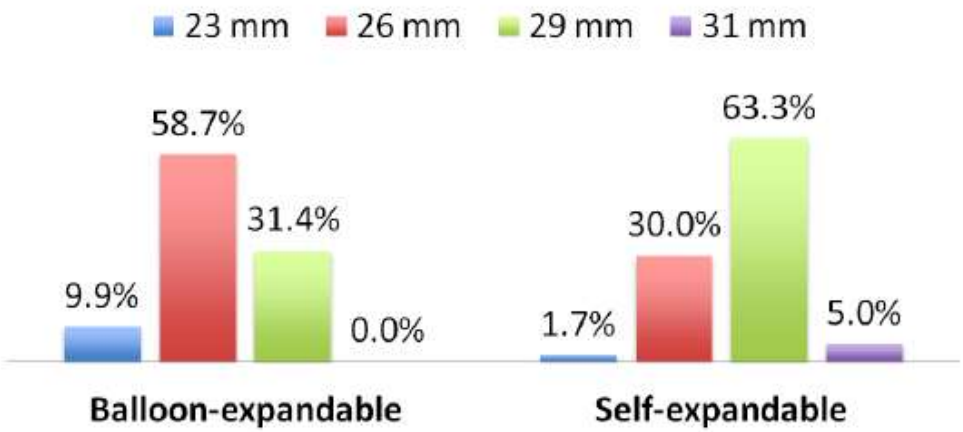
Balloon-expandable THV
Edwards Sapien XT
(Cobalt chromium stent frame, bovine pericardium)



Self-expandable THV
Medtronic CoreValve
(Nitinol stent frame, porcine pericardium)



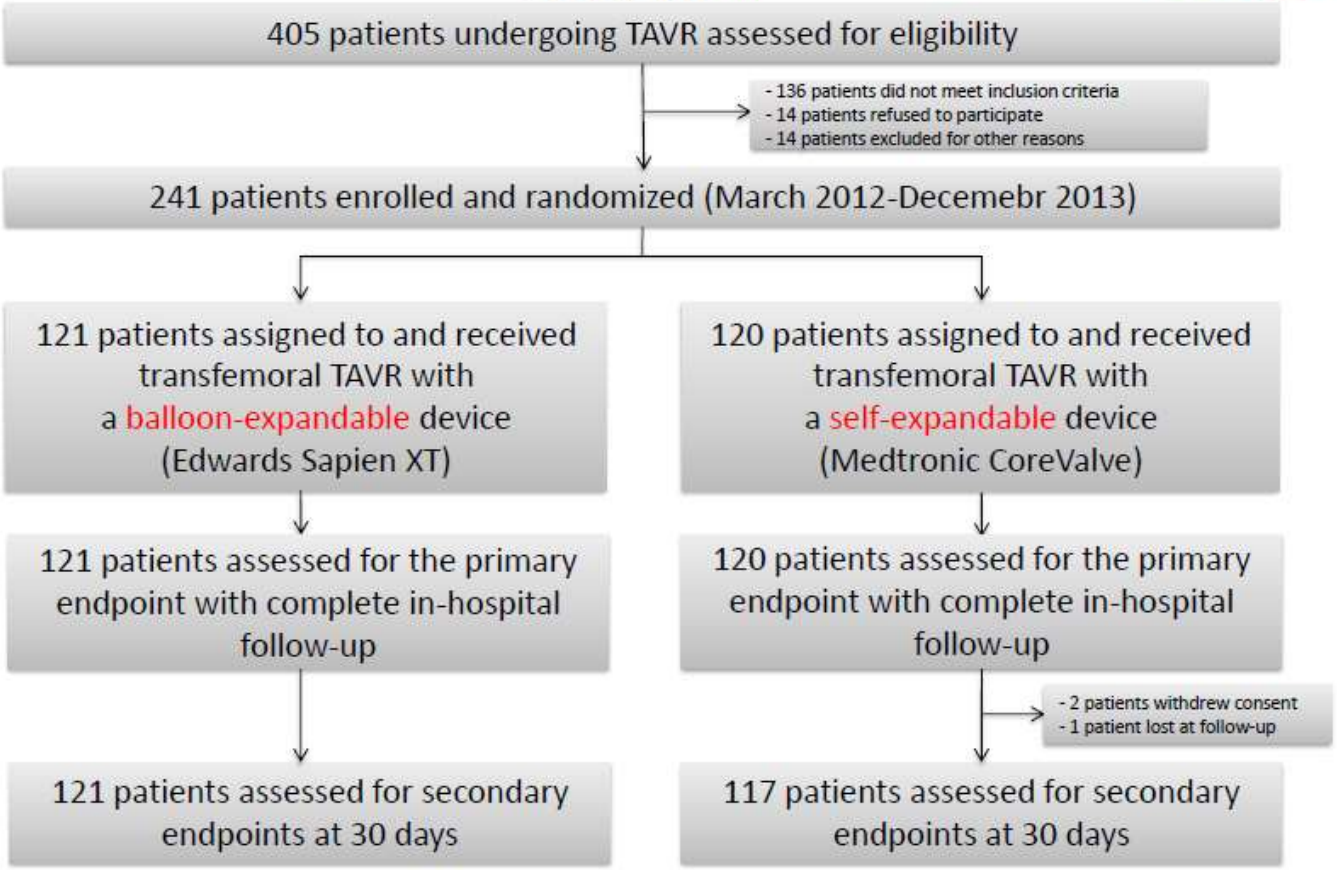
Procedural Factors: Valve Sizes



	Balloon-expandable	Self-expandable	p-value
Percent oversizing			
TEE diameter	12.8±5.4	17.7±5.9	<0.001
Mean MDCT diameter	9.6±5.6	15.8±4.5	<0.001
MDCT area	19.5±8.0	30.8±8.2	<0.001
MDCT perimeter	7.2±4.9	14.8±4.9	<0.001

Study Flow

CHOICE



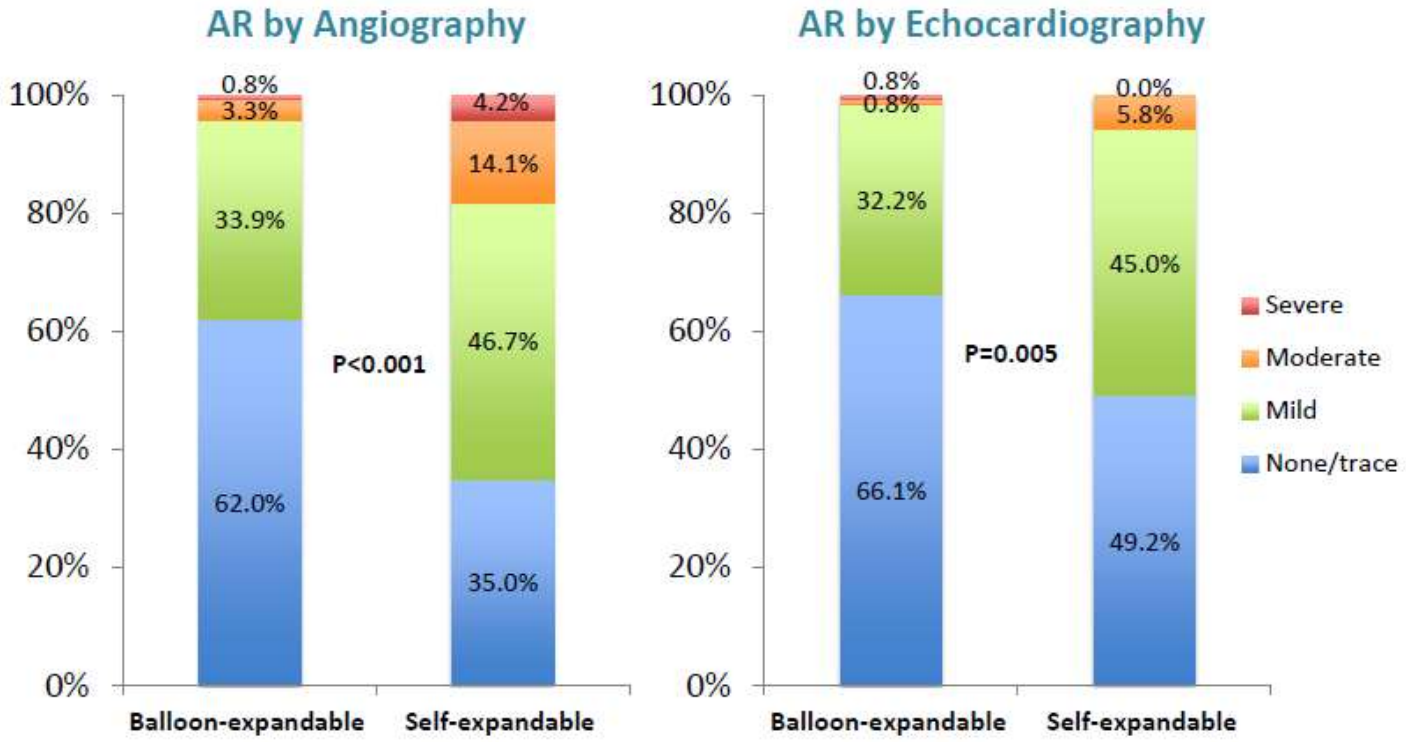
Procedural Details

CHOICE

	Balloon-expandable (n=121)	Self-expandable (n=120)	p-value
Balloon pre-dilatation	121/121 (100%)	106/120 (88.3%)	<0.001
AR after initial implantation			<0.001
none/trace	72/121 (59.5%)	31/120 (25.8%)	
mild	34/121 (28.1%)	38/120 (31.7%)	
moderate	10/121 (8.3%)	33/120 (27.5%)	
severe	5/121 (4.1%)	18/120 (15.0%)	
Maneuvres to improve AR			
balloon post-dilatation	24/121 (19.8%)	59/120 (49.2%)	<0.001
valve snaring	0/121 (0.0%)	2/120 (1.7%)	0.24
implantation of ≥ 2 valves	1/121 (0.8%)	7/120 (5.8%)	0.03
Coronary obstruction	2/121 (1.6%)	0/120 (0.0%)	0.49
Annular rupture	0/121 (0%)	0/120 (0%)	--
Left-to-right shunt	2/121 (1.6%)	2/120 (1.7%)	0.99
Depth of implantation (mm)	--	5.2±3.2	--
Procedural duration (min)	74.5±29.5	80.5±40.5	0.20
Contrast amount (ml)	208.6±71.4	223.1±98.2	0.19

Post-Procedural Aortic Regurgitation

CHOICE

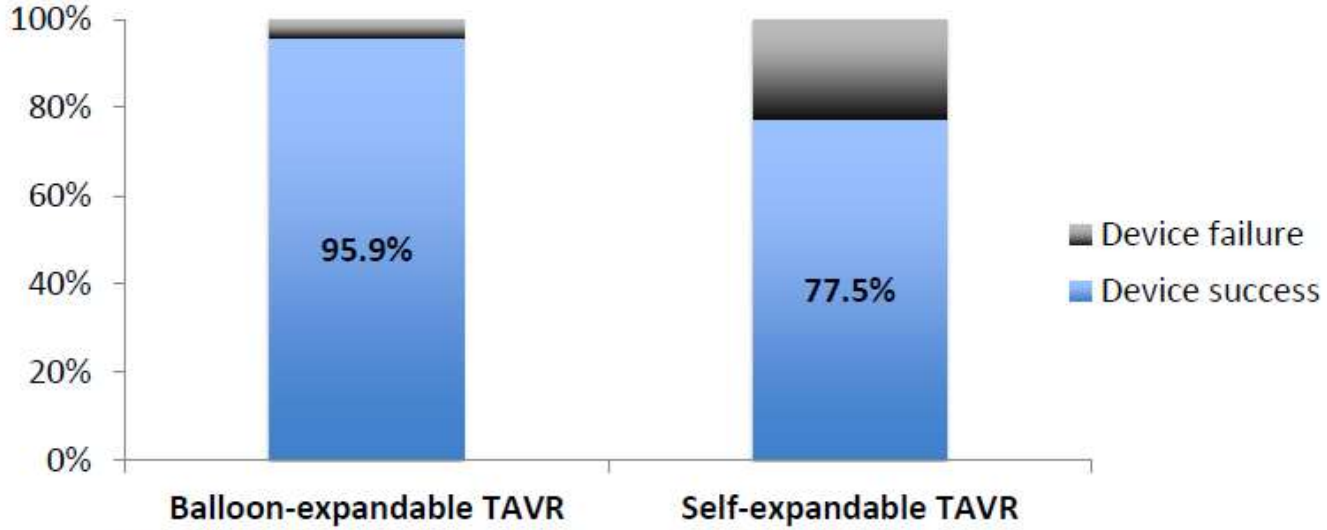


	Balloon-expandable (n=116)	Self-expandable (n=114)	p-value
Dimensionless AR Index	29.0±7.1	27.3±7.2	0.08

Primary Endpoint – Device Success

CHOICE

Relative risk 1.24, 95%CI 1.12-1.37, p<0.001



Causes of device failure	Balloon-expandable (n=121)	Self-expandable (n=120)
Unsuccessful vascular access, delivery and deployment	0/121 (0)	0/120 (0)
Incorrect position with implantation of more than one valve	1/121 (0.8)	7/120 (5.8)
Inadequate performance of the prosthetic heart valve		
- Aortic valve area < 1.2 cm^2 or mean aortic valve gradient > 20 mmHg	0/121 (0)	0/120 (0)
- Moderate or severe prosthetic valve regurgitation	5/121 (4.1)	22/120 (18.3)
Total (hierarchical)	5/121 (4.1)	27/120 (22.5)

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CHOICE Trial - Summary

- Cardiovascular mortality at 30 days was similar, bleeding and vascular complications were similar, and the combined safety endpoint was similar.
- However, the Sapien device was reported to have greater device success driven largely by a significantly lower frequency of residual more-than-mild aortic regurgitation. The need for permanent pacemaker implantation was also lower with the Sapien device.
- Further comparative trails are anticipated.

- Use of TAVR has been expanding into patient populations that are outside of the scope of the initial randomized trials. Multiple reports are now appearing of use of this technology in low or intermediate risk patients with severe aortic stenosis.
- Of these, the OBSERVANT study serves as an example.
- Results of other randomized trials of intermediate risk patients are in progress.

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journal homepage: www.elsevier.com/locate/ijcard

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 [a], Marco Barbanti [b,c,*], Marco Ranucci [d], Francesco Onorati [e], Remo Daniel Covello [f], Stefano Rosato [a], Corrado Tamburino [b,c], Francesco Santini [e], Gennaro Santoro [g], Fulvia Seccareccia [a] and on behalf of the OBSERVANT Research Group

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[g] Division of Cardiology, Careggi Hospital, Florence, Italy

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OBSERVANT Study

- **OBSERVANT is a cohort study that enrolled all patients admitted to multiple hospitals in Italy between December 2010 and June 2012 with a diagnosis of aortic-valve stenosis requiring (and eligible for) an intervention, either TAVR or SAVR.**
- **Excluded any patients undergoing concomitant CABG or PCI, transapical TAVR, or patients with porcelain aorta or hostile thorax.**
- **Patients treated with either of the two procedures were then propensity matched, leaving 650 patients undergoing isolated SAVR and 650 undergoing isolated transcatheter aortic-valve implantation (TAVI).**

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OBSERVANT Study

- **In the TAVI group, the analysis included primarily patients treated with the Sapien (Edwards Lifesciences) or CoreValve (Medtronic) devices.**
- **Importantly, patients in OBSERVANT were at markedly lower risk than those treated in the Sapien and CoreValve randomized trials that led to US regulatory approval of these devices.**
- **In PARTNER A and the CoreValve High-Risk study, mean logistic EuroScores were 29 and 19, respectively. In OBSERVANT, the mean EuroScore was 9.8.**

OBSERVANT Study

End point	SAVR (%)	TAVR (%)	p
Mortality	13.3	13.1	0.936
MACCE	17.6	17.1	0.831
Rehospitalization for cardiac causes*	21.4	20.3	0.672
Rehospitalization for heart failure*	17.6	17.2	0.911

<u>30 Day Results</u>:
Vascular complications and new pacemaker implantations were higher among the transcatheter-valve group,
Renal failure and blood transfusions were higher among the surgically treated patients.

<u>One Year Results</u>:
No differences between the two groups in mortality, major adverse cardiac and cerebrovascular events (MACCE), or rehospitalizations for cardiac causes, or for heart failure specifically.

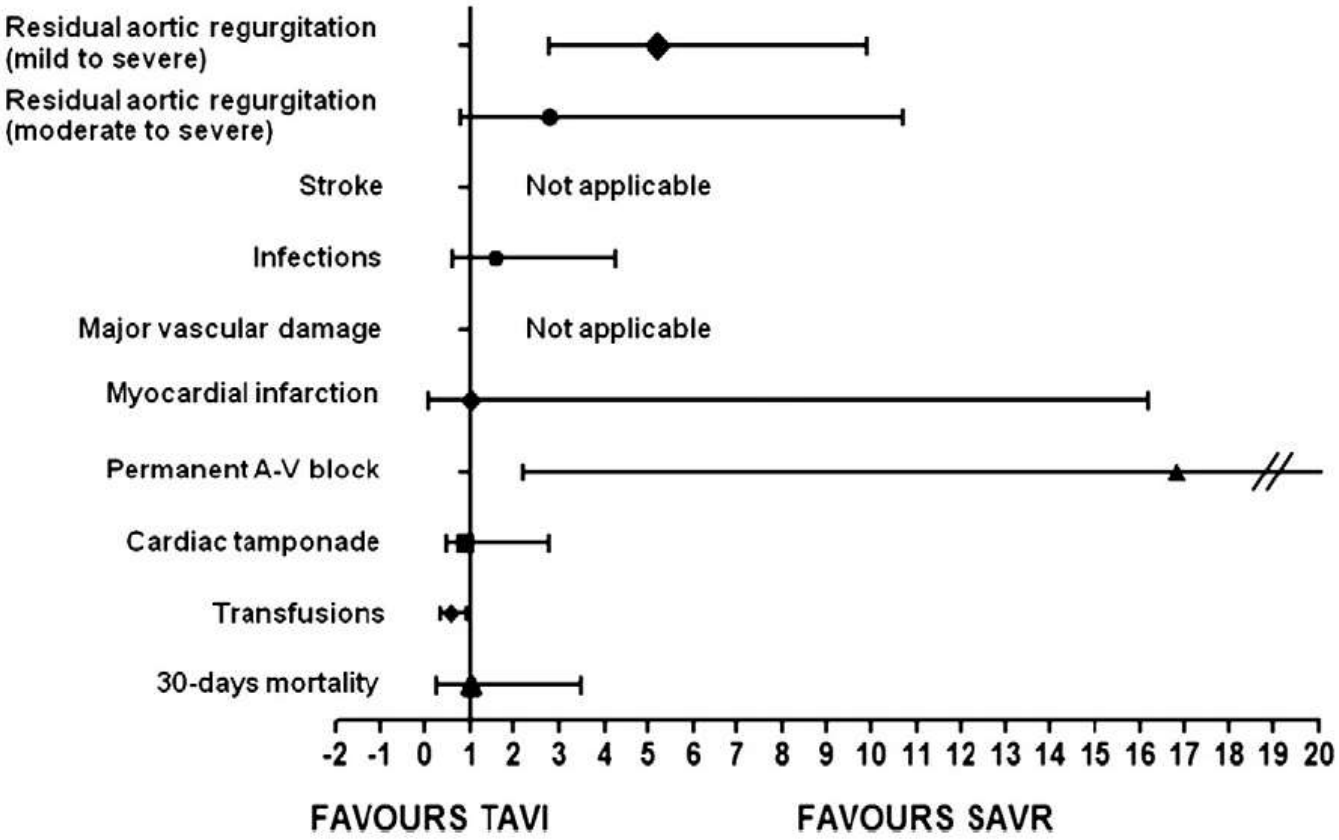

Fig. 1. Main outcomes in the matched population presented as relative risks and their 95% CI.

OBSERVANT Study

Study Limitations

- OBSERVANT included a subset of TAVR patients—those undergoing a transfemoral procedure, but not those treated via a different access route, potentially introducing some bias.
- Patients were not randomized
- No core lab analysis.

- Surgical valve replacement is the "gold standard" in intermediate- and low-risk patients, and ongoing randomized trials, including **PARTNER II A** and **SURTAVI** , will determine the future role of TAVI in these patients.
- Three reasons for not extending TAVR beyond high surgical-risk patients are the excellent outcomes with SAVR, the high cost of TAVR, and the lack of durability data.

- TAVR is also being used in anatomic situations that are outside of the current FDA approval guidelines.
- Several centers have now used TAVR successfully in patients with **bicuspid** aortic valves.
- As well, TAVR has been accomplished in patients with structural valve degeneration of a **prior aortic bioprosthesis** with increasing frequency.

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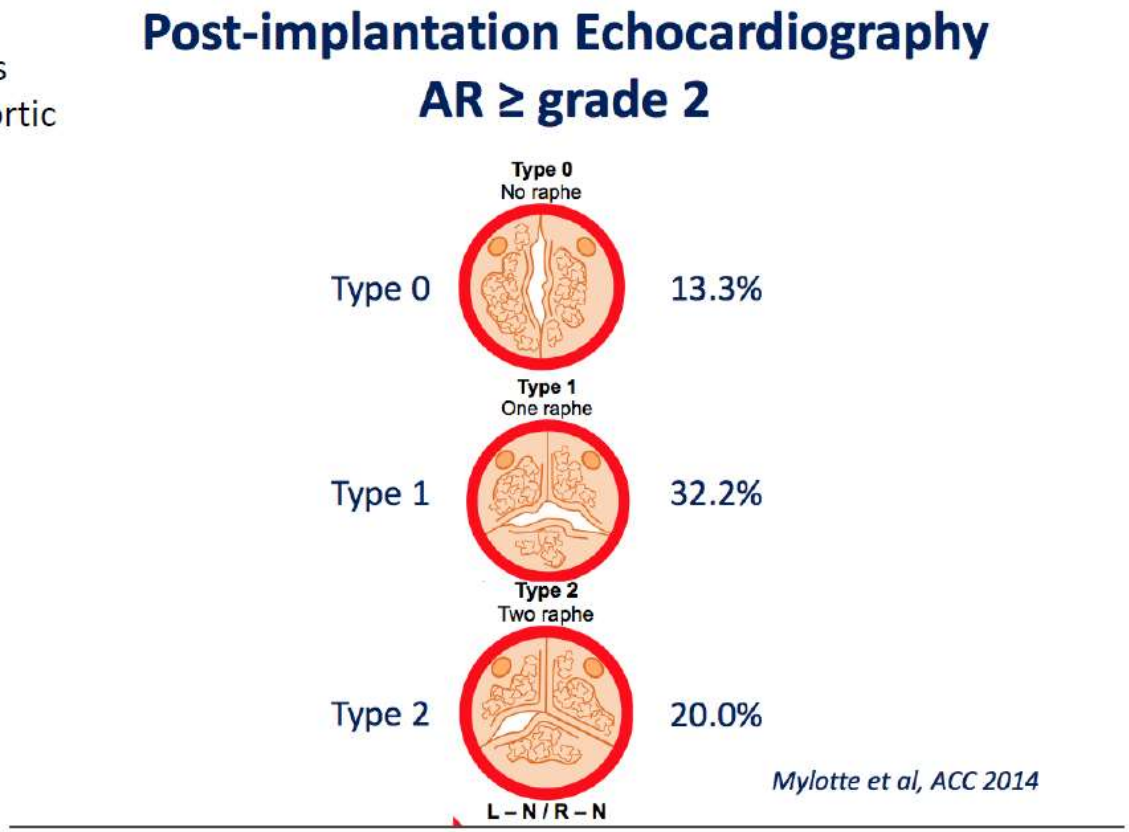
Transcatheter Aortic Valve Replacement in Bicuspid Aortic Valve Disease

Darren Mylotte, MB, MD,*† Thierry Lefevre, MD,‡ Lars Søndergaard, MD,§ Yusuke Watanabe, MD,‡ Thomas Modine, MD,‖ Danny Dvir, MD,¶ Johan Bosmans, MD,# Didier Tchetche, MD,** Ran Kornowski, MD,†† Jan-Malte Sinning, MD,‡‡ Pascal Thériault-Lauzier, PHD,† Crochan J. O'Sullivan, MB, MD,§§ Marco Barbanti, MD,‖‖ Nicolas Debry, MD,‖ Jean Buithieu, MD,† Pablo Codner, MD,†† Magdalena Dorfmeister, MD,¶¶ Giuseppe Martucci, MD,† Georg Nickenig, MD,‡‡ Peter Wenaweser, MD,§§ Corrado Tamburino, MD,‖‖ Eberhard Grube, MD,‡‡ John G. Webb, MD,¶ Stephan Windecker, MD,§§ Ruediger Lange, MD, PHD,¶¶ Nicolo Piazza, MD, PHD†¶¶

Bicuspid Aortic Valve

Paravalvular AR rates higher in bicuspid aortic valves



Bicuspid Aortic Valve

TABLE 6 Predictors of Aortic Regurgitation Grade ≥2

Characteristic	Univariate Analysis			Multivariate Analysis		
	Odds Ratio	95% CI	p Value	Odds Ratio	95% CI	p Value
Age	0.95	0.96-1.03	0.63			
Males	3.50	1.50-8.20	0.004	4.29	1.63-10.79	0.003
STS PROM	0.85	0.75-1.04	0.05	0.88	0.75-1.04	0.13
Mean aortic gradient	0.99	0.97-1.02	0.61			
Aortic valve area	3.20	0.34-29.86	0.31			
LV ejection fraction <40%	1.40	0.62-3.14	0.41			
Annulus size	0.93	0.82-1.04	0.20			
TAV size	1.10	0.92-1.31	0.31			
MSCT-based TAV sizing	0.23	0.10-0.51	<0.0001	0.19	0.08-0.45	<0.0001
Bicuspid type 1	2.14	0.82-5.56	0.11			
CoreValve	1.93	0.82-4.54	0.13			
Year of procedure	0.78	0.60-1.03	0.08			

Abbreviations as in Tables 1 and 5.

Valve-in-Valve

Original Investigation

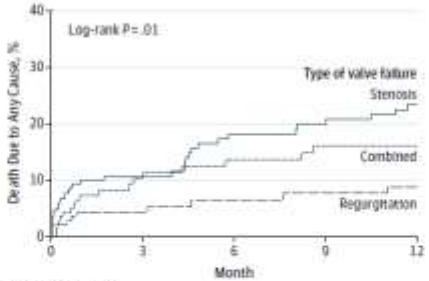
Transcatheter Aortic Valve Implantation in Failed Bioprosthetic Surgical Valves

Danny Dvir, MD; John G. Webb, MD; Sabine Bleiziffer, MD; Miralem Pasic, MD, PhD; Ron Waksman, MD; Susheel Kodali, MD; Marco Barbanti, MD; Azeem Latib, MD; Ulrich Schaefer, MD; Josep Rodés-Cabau, MD; Hendrik Treede, MD; Nicolo Piazza, MD, PhD; David Hildick-Smith, MD; Dominique Himbert, MD; Thomas Walther, MD; Christian Hengstenberg, MD; Henrik Nissen, MD, PhD; Raffi Bekeredjian, MD; Patrizia Presbitero, MD; Enrico Ferrari, MD; Amit Segev, MD; Arend de Weger, MD; Stephan Windecker, MD; Neil E. Moat, FRCS; Massimo Napodano, MD; Manuel Wilbring, MD; Alfredo G. Cerillo, MD; Stephen Brecker, MD; Didier Tchetche, MD; Thierry Lefèvre, MD; Federico De Marco, MD; Claudia Fiorina, MD; Anna Sonia Petronio, MD; Rui C. Teles, MD; Luca Testa, MD; Jean-Claude Laborde, MD; Martin B. Leon, MD; Ran Kornowski, MD; for the Valve-in-Valve International Data Registry Investigators

JAMA. 2014;312(2):162-170. doi:10.1001/jama.2014.7246

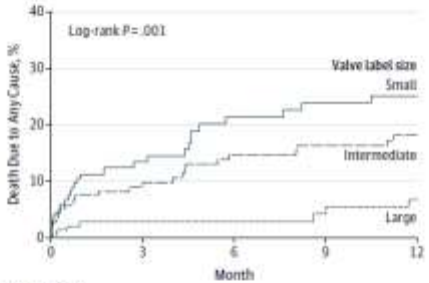
Figure 1. Time-to-Event Curves in Patients Undergoing Valve-in-Valve Procedures

A Mechanism of surgical valve failure



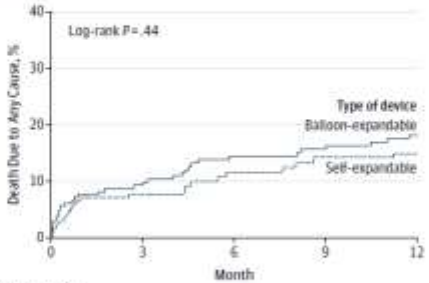
No. at risk by type of valve failure					
Stenosis	181	112	98	91	86
Regurgitation	139	92	84	78	76
Combined	139	85	76	68	66

B Surgical valve label size[a]



No. at risk by valve label size					
Small	133	81	68	61	57
Intermediate	176	116	103	95	92
Large	139	89	82	76	73

C Device used during valve-in-valve implantation



No. at risk by type of device					
Balloon-expandable	246	163	146	136	130
Self-expandable	213	126	112	101	98

[a] Surgical valve sizes were as follows: small, label size ≤21 mm; intermediate, >21 mm and <25 mm; and large, ≥25 mm. In 11 patients (2.4%), label size was unknown.

- Finally, the use of TAVR is being defined in subsets of patients to attempt to identify groups that may derive greater benefit from this technology.
- These data are derived from retrospective reviews of randomized trails or registry data and will need further study for confirmation

The Outcomes of Transcatheter Aortic Valve Replacement in Patients with End-stage Renal Disease: A Report from the STS/ACC TVT Registry

Michael Mack, J. Matthew Brennan, Sarah Milford-Beland, Dadi Dai, Ralph Brindis, John Carroll, Fred Edwards, Fred Grover, Sean O'Brien, Eric Peterson, John Rumsfeld, Dave Shahian, Vinod Thourani, E. Murat Tuczu, Alan Zajarias, David Holmes

For the TVT Registry

Patient Characteristics

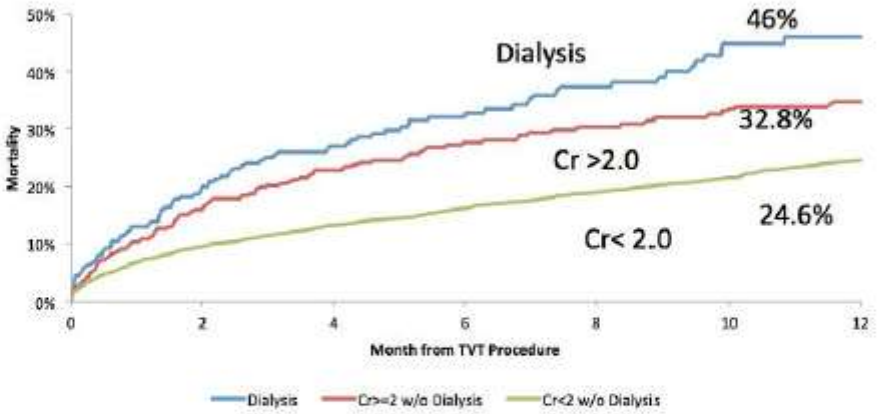
	No Dialysis N=11,749	Dialysis N=528	P value
Age Median (IQR)	84 (78,88)	**77** (69,84)	<.0001
Gender % Male	48.5 %	**58.3**	<.0001
Race % Black/African American	3.3%	**11.4**	<.0001
STS PROM (%) Median (IQR)	6.76 (4.51, 10.23)	**14.43** (9.50, 20.07)	<.0001

In Hospital Outcomes

	No Dialysis N=11,749	Dialysis N=528	P value
Mortality (%)	5.1	**8.9**	<.0001
Observed/Expected Mortality (O:E)	5.1/8.2 (0.62)	**8.9/16.2 (0.55)**	
Stroke (%)	2.1	**1.3**	.23
VARC Major Bleed (%)	3.2	**6.4**	<.0001
LOS (IQR) (Days)	6 (4,10)	**8 (5,13.5)**	<.0001

O:E calculated from STS PROM mean

Mortality



Mortality	Dialysis N=249	Cr>2	Cr<2	P value
30 Day (%)	**13.0**	10.4	6.8	<.001
6 Month (%)	**32.8**	27.6	16.3	
1 Year (%)	**46.0**	34.7	24.6	

One Year Outcomes
Dialysis vs. No Dialysis Patients

	Univariable HR	P value	Multivariable HR	P Value
Mortality	**2.22**	<.001	**1.81**	<.001
Stroke	**1.43**	.269	**1.24**	.578

ESRD
Second highest predictor of mortality (STS>15 highest)

- Patients with end-stage renal disease have significantly worse outcomes, particularly those on hemodialysis.

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Sex-Related Differences in Outcomes After Transcatheter or Surgical Aortic Valve Replacement in Patients With Severe Aortic Stenosis

Insights From the PARTNER Trial (Placement of Aortic Transcatheter Valve)

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New York, New York; Vancouver, British Columbia, Canada; Rochester, Minnesota; Kansas City, Missouri; Durham, North Carolina; Dallas, Texas; Cleveland, Ohio; Atlanta, Georgia; and Washington, DC

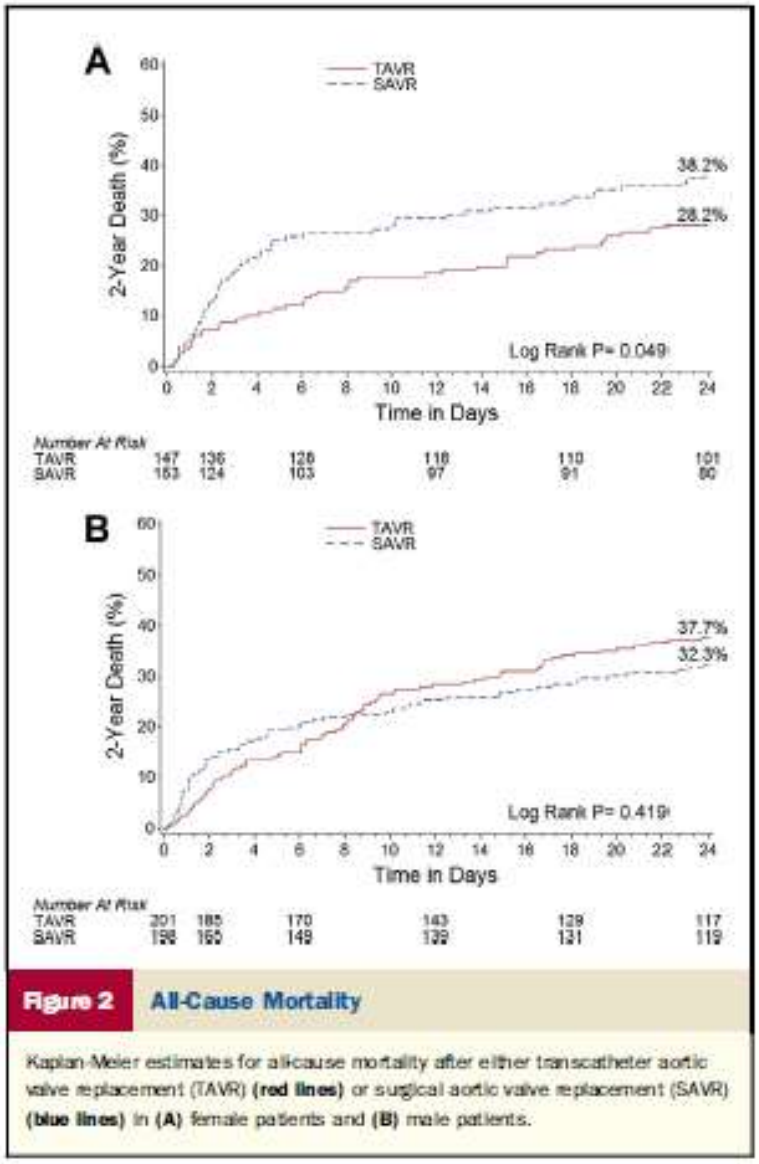

Figure 2 **All-Cause Mortality**

Kaplan-Meier estimates for all-cause mortality after either transcatheter aortic valve replacement (TAVR) **(red lines)** or surgical aortic valve replacement (SAVR) **(blue lines)** in **(A)** female patients and **(B)** male patients.

Women

Men

- Women at high risk for surgical AVR appear to derive a survival benefit with TAVR, a finding not seen in men.

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Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Diabetes and Severe Aortic Stenosis at High Risk for Surgery

An Analysis of the PARTNER Trial (Placement of Aortic Transcatheter Valve)

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St. Louis and Kansas City, Missouri; Quebec City, Quebec, Canada; Rochester, Minnesota; New York, New York; Atlanta, Georgia; Cleveland, Ohio; and Washington, DC

Patients with Diabetes

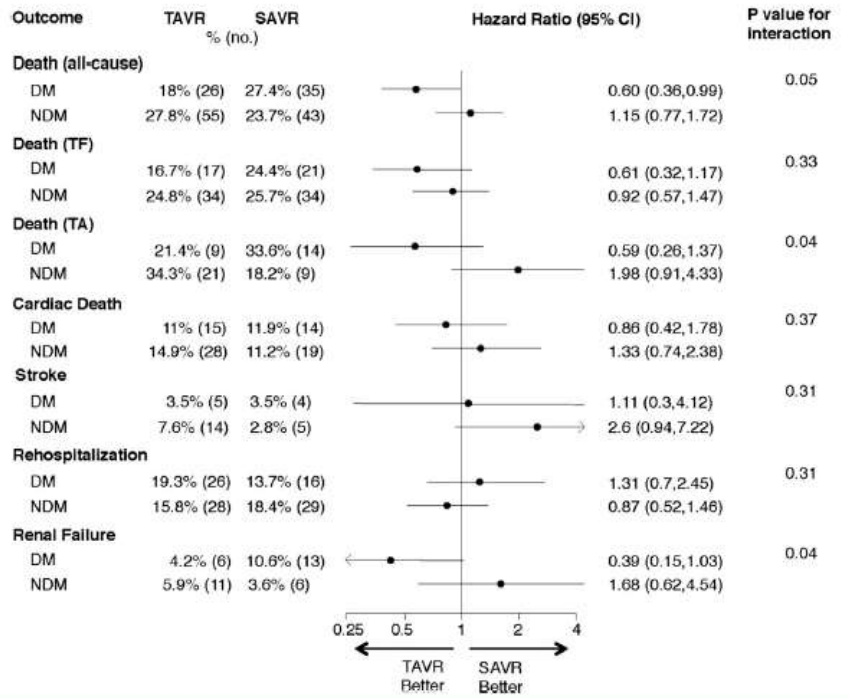

Figure 1 **Clinical Outcomes Stratified by Diabetes in the High-Risk Cohort of the PARTNER Trial**

Cox proportional hazards models were used to evaluate the hazard ratios for patients with diabetes mellitus (DM) and without diabetes mellitus (NDM) for the clinical outcomes shown and the interaction between diabetes status and treatment for each clinical outcome. CI = confidence interval; PARTNER = Placement of Aortic Transcatheter Valve; SAVR = surgical aortic valve replacement; TA = transapical; TAVR = transcatheter aortic valve replacement; TF = transfemoral.

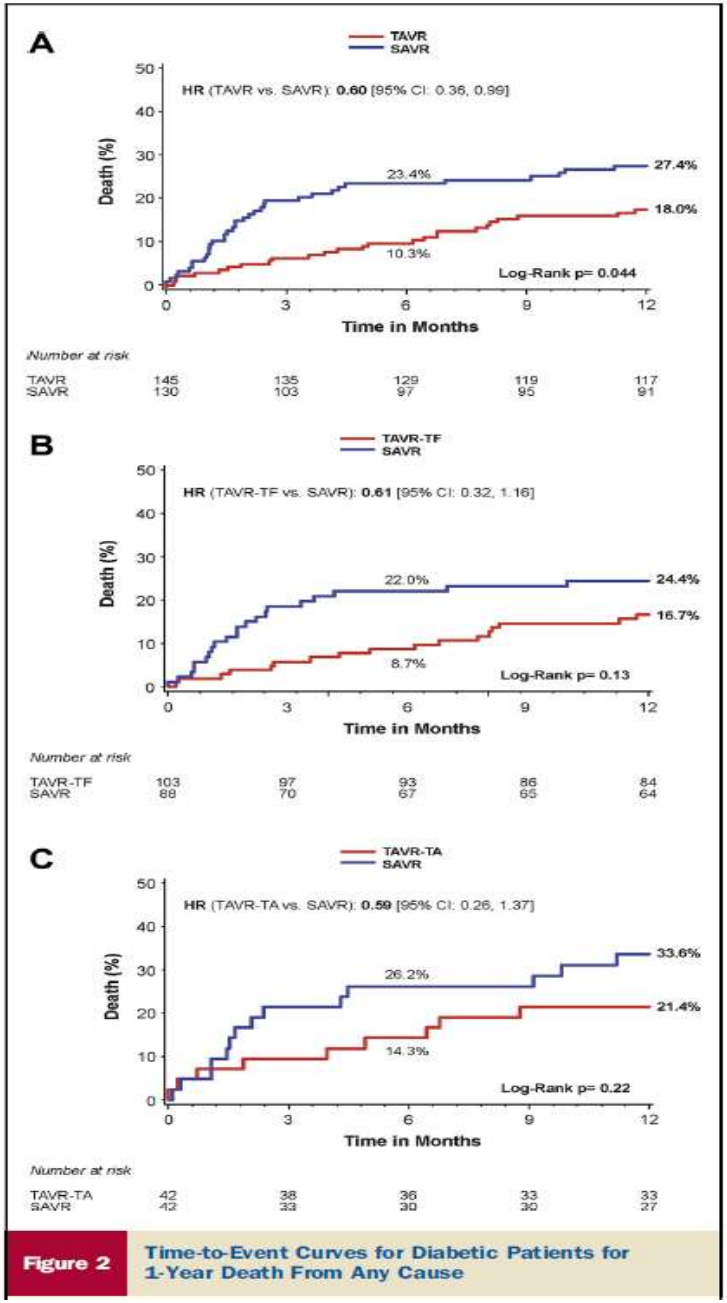

Figure 2 **Time-to-Event Curves for Diabetic Patients for 1-Year Death From Any Cause**

Summary

- TAVR is expanding rapidly in clinical use and is becoming the preferred treatment in some patients with the highest surgical risk.
- Use of TAVR is increasing in intermediate and lower risk patients with early results similar to surgical AVR
- Post-procedure AR is improving but has not been solved.
- Further studies are needed to identify anatomic subsets of patients that may benefit most from this technology

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