

Sutureless AVR vs TAVI

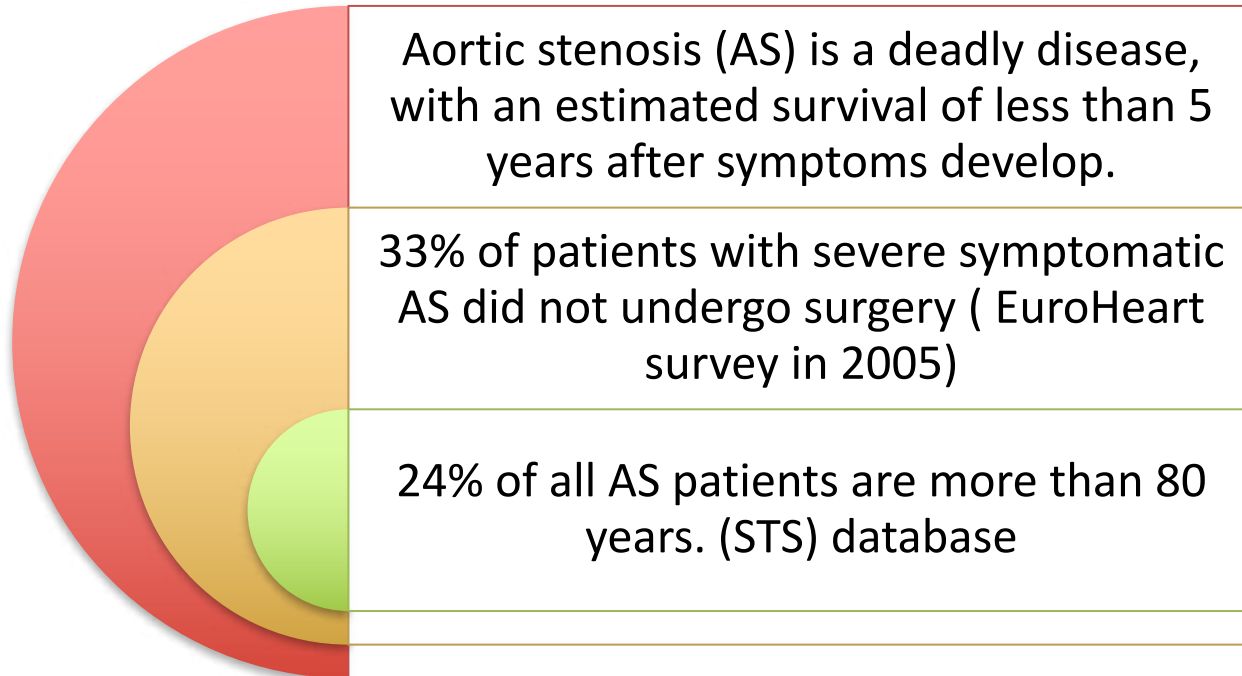
Alireza A. Ghavidel MD

Professor of Cardiac Surgery

Rajaie Cardiovascular Medical & Research center

Tehran , November 2017

CHALLENGE



SOLUTION

SU AVR

TAVI



Figure 2. Subcutaneous aortic valves: (A) Perceval (Zorn), (B) TriTilt (Medtronic), and (C) Trifly (Edwards) (Color version of figure is available online at <http://www.semanticscholar.org>.)

ADVANTAGES

www.shutterstock.com · 524414218

SUAVR

Reduction of operation time

Simplifies the procedure

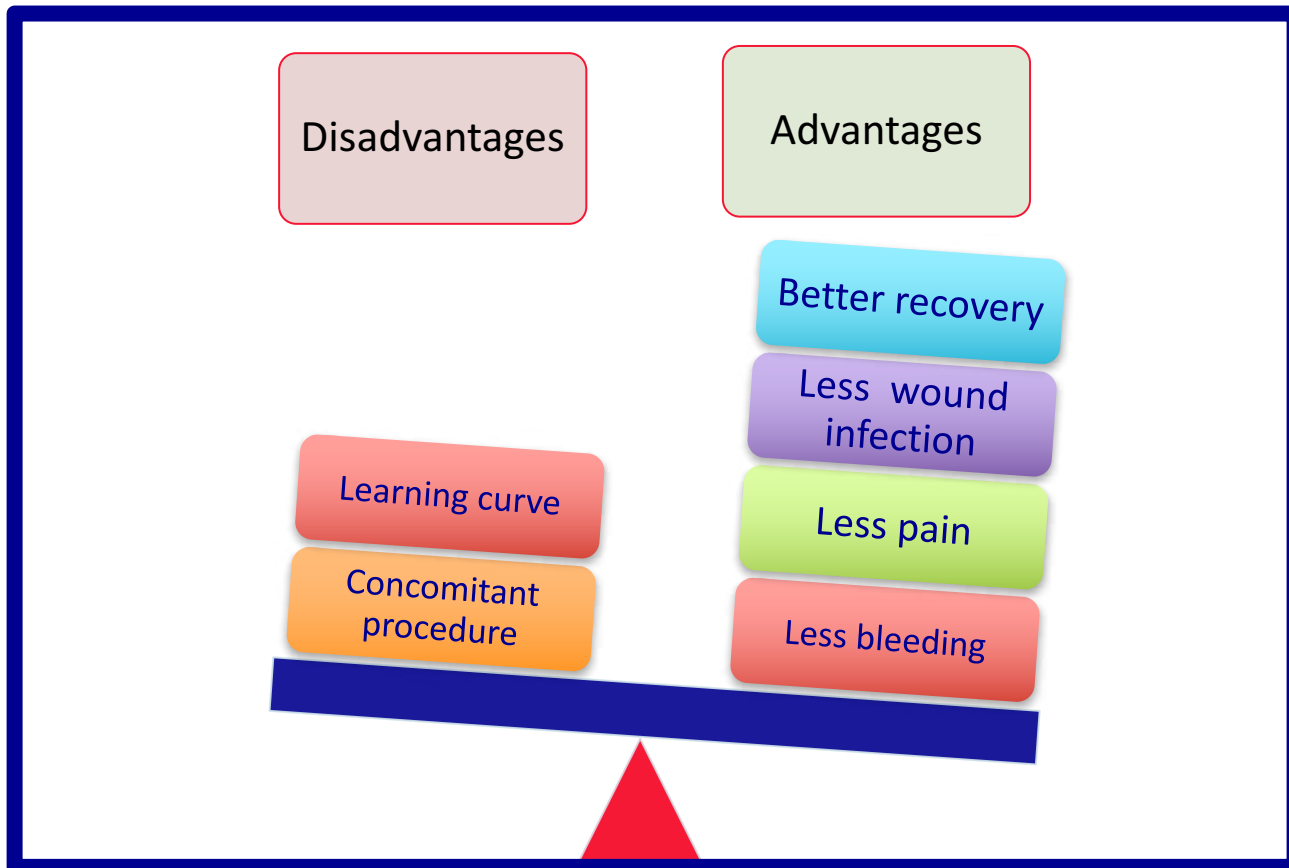
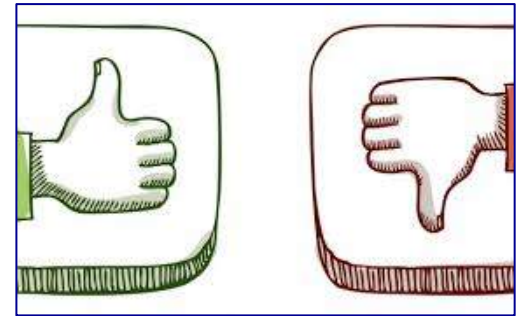
Replacement vs implantation

Less CPB time and AOX

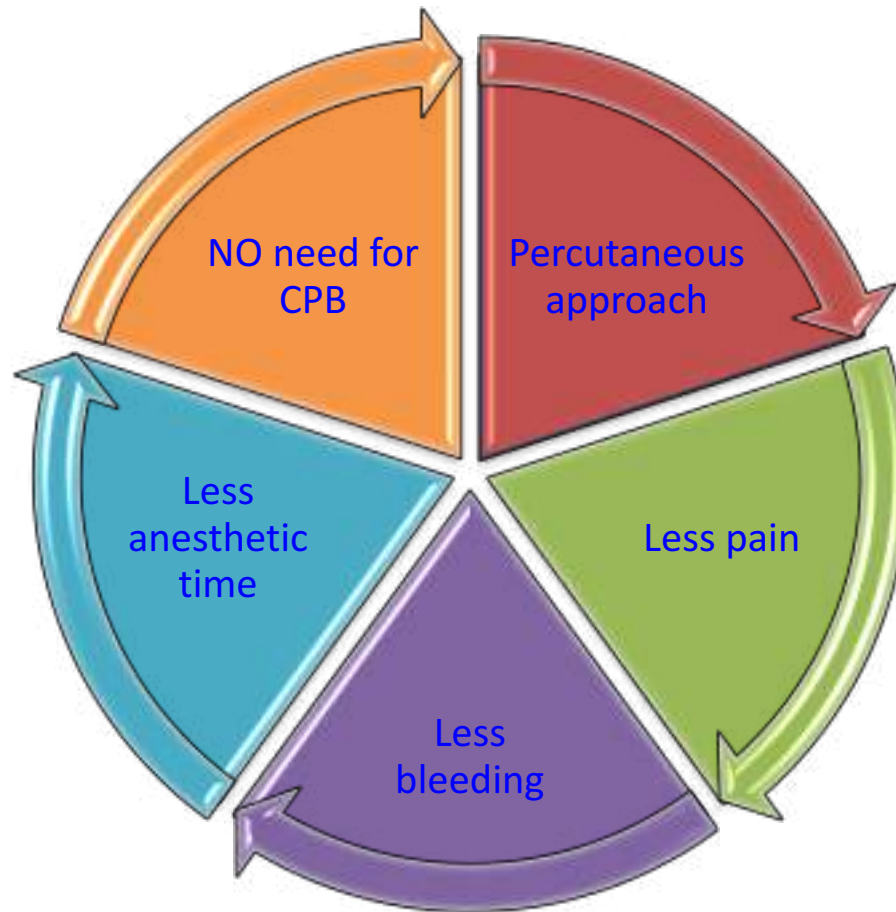
Easier Mini-AVR

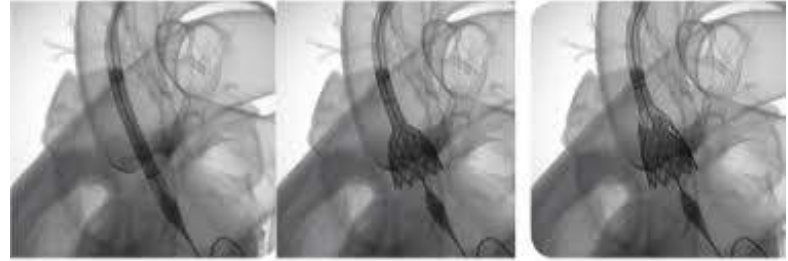
Good EOA

Mini AVR



TAVI



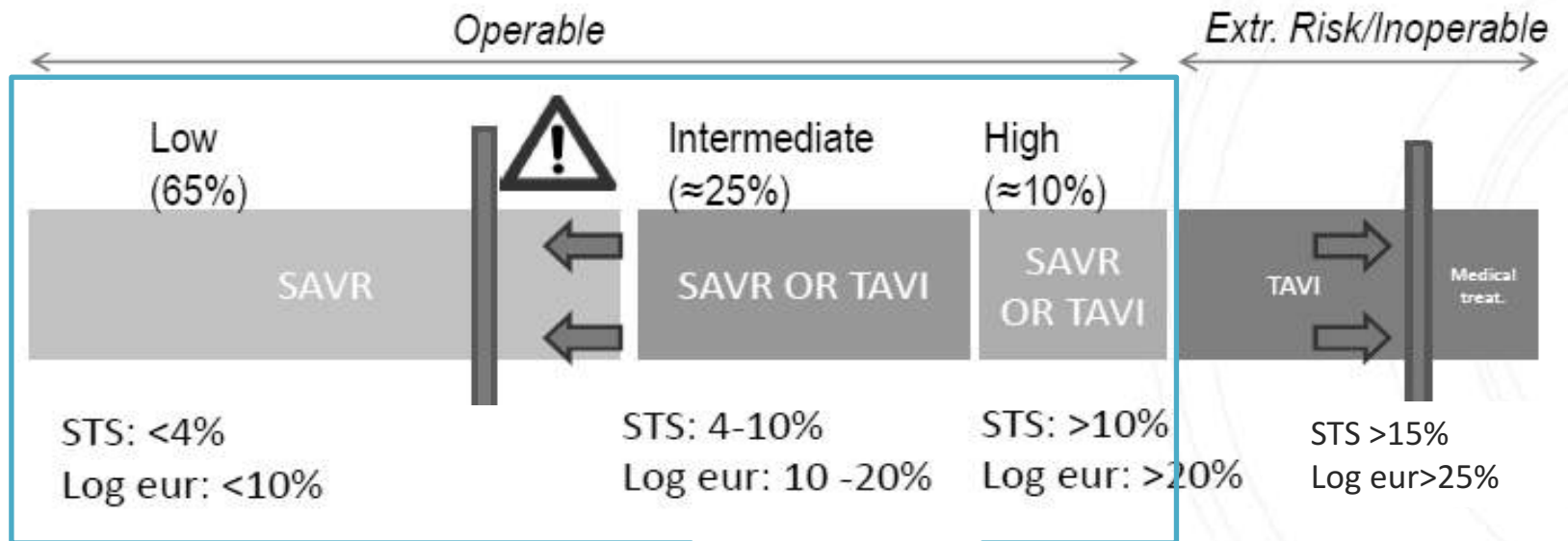


calcific native
valve is not
excised

AVB & PVL

Increased
Mortality or
Morbidity

Sutureless as alternative to conventional valves for all operable pts



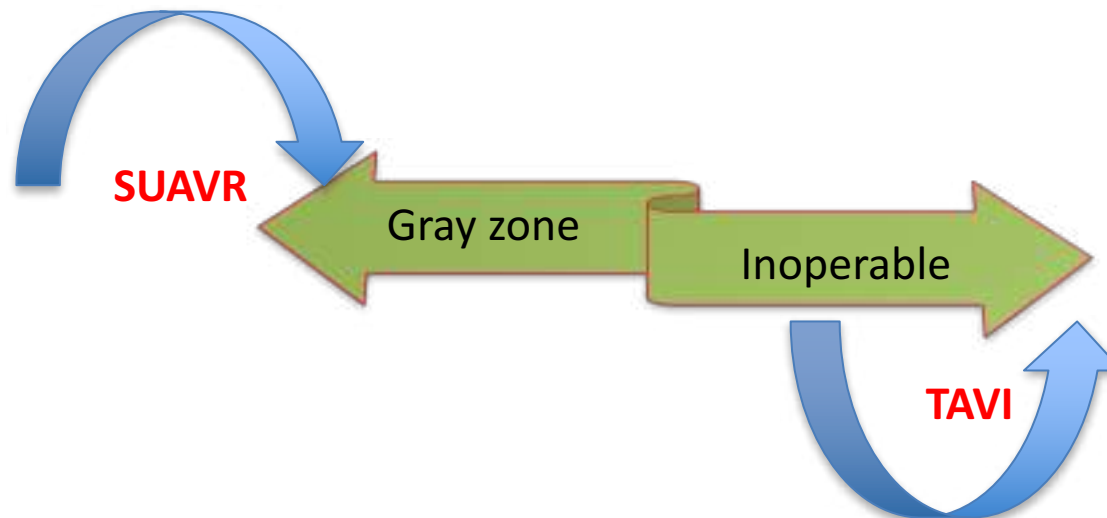
SU AVR

Sutureless aortic valve replacement as an alternative treatment for patients belonging to the “gray zone” between transcatheter aortic valve implantation and conventional surgery: A propensity-matched, multicenter analysis

Augusto D’Onofrio, MD,^a Antonio Messina, MD,^b Roberto Lorusso, MD,^c Ottavio R. Alfieri, MD,^d Melissa Fusari, MD,^c Paolo Rubino, MD,^f Mauro Rinaldi, MD,^e Roberto Di Bartolomeo, MD,^h Mattia Glauber, MD,ⁱ Giovanni Troise, MD,^b and Gino Gerosa, MD^a

The Journal of Thoracic and Cardiovascular Surgery • November 2012

No significant differences in hospital mortality, severe postoperative complications, and transprosthetic gradients between groups.



postprocedural paravalvular leak was identified as an independent predictor of late mortality after TAVI (hazard ratio, 3.79).²²

TABLE 3. Postoperative outcomes after TA-TAVI and SU-AVR

Variable	TA-TAVI (n = 38)	SU-AVR (n = 38)	P Value
Hospital mortality, n (%)	2 (5.3)	0 (0)	.49
ARF requiring CVVH, n (%)	1 (2.6)	2 (5.3)	1.00
AMI, n (%)	0 (0)	0 (0)	1.00
Stroke, n (%)	0 (0)	0 (0)	1.00
Bleeding (life-threatening/disabling, major), n (%)	2 (5.3)	1 (2.6)	1.00
PPM implantation, n (%)	2 (5.3)	2 (5.3)	1.00
Mean transaortic gradient, mm Hg	10.25 ± 5.03	10.95 ± 3.72	.59
AR at discharge (at least mild), n (%)	17 (44.7)	6 (15.8)	.001
LVEF at discharge, % (IQR)	60 (55-60)	60 (54-65)	.75
New-onset atrial fibrillation, n (%)	7 (18.4)	16 (42.1)	.04
Orotracheal intubation time, hours (IQR)	4 (0-5)	5.5 (4-8)	.21

TA-TAVI, Transapical aortic valve implantation; SU-AVR, sutureless aortic valve replacement; ARF, acute renal failure; CVVH, continuous venovenous hemofiltration; AMI, acute myocardial infarction; PPM, permanent pacemaker; AR, aortic regurgitation; LVEF, left ventricular ejection fraction; IQR, interquartile range.

Paravalvular leakage
New onset AFib

Sutureless replacement versus transcatheter valve implantation in aortic valve stenosis: A propensity-matched analysis of 2 strategies in high-risk patients

Giuseppe Santarpino, MD,^a Steffen Pfeiffer, MD,^a Jürgen Jessl, MD,^b Angelo Maria Dell'Aquila, MD,^c Francesco Pollari, MD,^a Matthias Pauschinger, MD,^b and Theodor Fischlein, MD^a

The Journal of Thoracic and Cardiovascular Surgery c February 2014

Combining the advantage of standard diseased valve removal with shorter procedural times, minimally invasive sutureless aortic valve replacement may be the first-line treatment for high-risk patients considered in the “gray zone” between TAVI and conventional surgery.

Variable	AVR (n = 37)	(n = 37)	value
In-hospital mortality	0	3 (8.1%)	.24
ARF requiring CVVH	0	2 (5.4%)	.25
Stroke	2 (5.4%)	2 (5.4%)	>.999
Permanent PM implantation	4 (10.8%)	1 (2.7%)	.18
Mean transaortic gradient (mm Hg)	13.3 ± 3.9	14.2 ± 5.8	.564
AR at discharge (at least mild)	0	5 (13.5%)	.027



Worse survival after transcatheter aortic valve implantation than surgical aortic valve replacement: A meta-analysis of observational studies with a propensity-score analysis☆

Hisato Takagi *, Takuya Umemoto, for the ALICE (All-Literature Investigation of Cardiovascular Evidence) Group

Department of Cardiovascular Surgery, Shizuoka Medical Center, Shizuoka, Japan

International Journal of Cardiology 220 (2016) 320–327

4 RCTs including a total of approximately 1800 patients

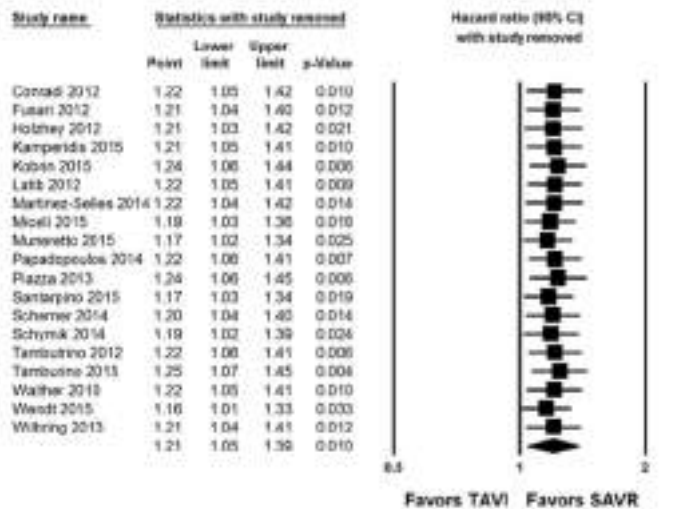
19 observational comparative studies, a total of more than 6000 patients,

All cause mortality

All cause mortality

19 observational comparative studies, a total of more than 6000 patients,

4 RCTs including a total of approximately 1800 patients



TAVI is likely to be associated with a **21% increase in the hazard** of follow-up all-cause mortality relative to SAVR.

The mean of 3-year survival rates was 71.3% after TAVI and 77.9% after SAVR.

Original article

Sutureless aortic valve replacement may improve early mortality compared with transcatheter aortic valve implantation: A meta-analysis of comparative studies



Hisato Takagi (MD, PhD)*, Takuya Umemoto (MD, PhD) for the ALICE (All-Literature Investigation of Cardiovascular Evidence) Group

Journal of Cardiology 67 (2016) 504–512

7

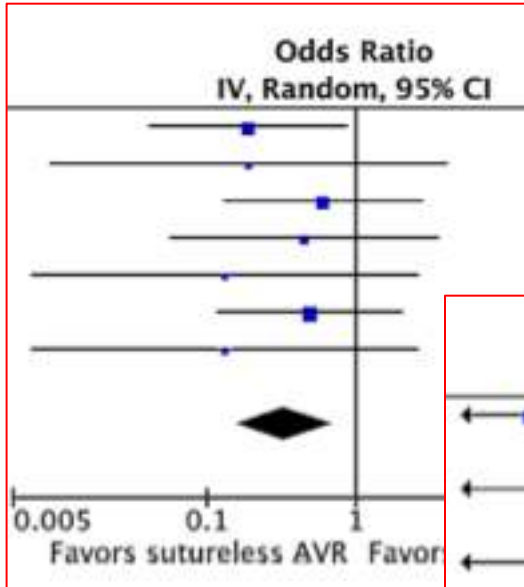
Observational
study, around
1000 patients

Primary End point: Early mortality

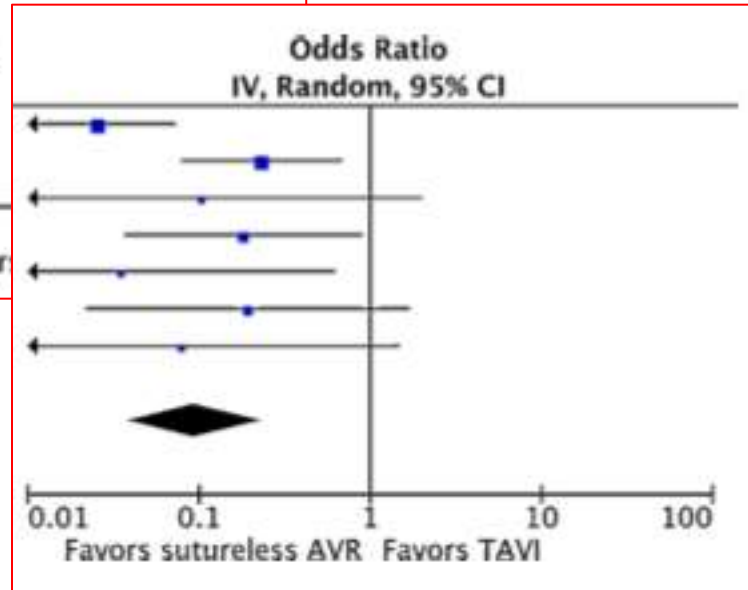
Secondary endpoints:

- CHB
- PVL
- AKI
- Bleeding

Early Mortality



2.5% versus 7.3%; odds ratio (OR), 0.33; 95% CI p= 0.003



3.5% versus 33.2%; OR, 0.09; 95% CI, p<0.00001

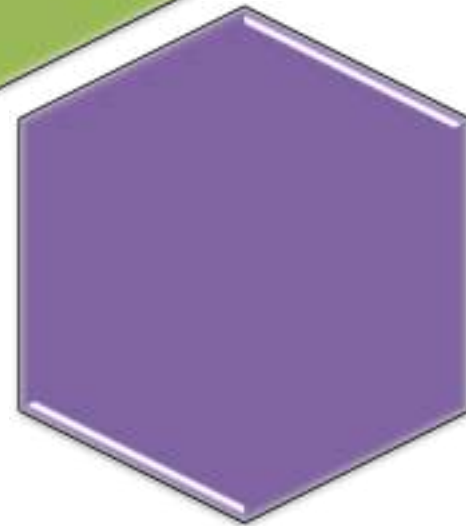
P.V Leakage

SUAVR vs TAVI

No
differences
in other
outcomes

Less
early
mortality

Less
PVL



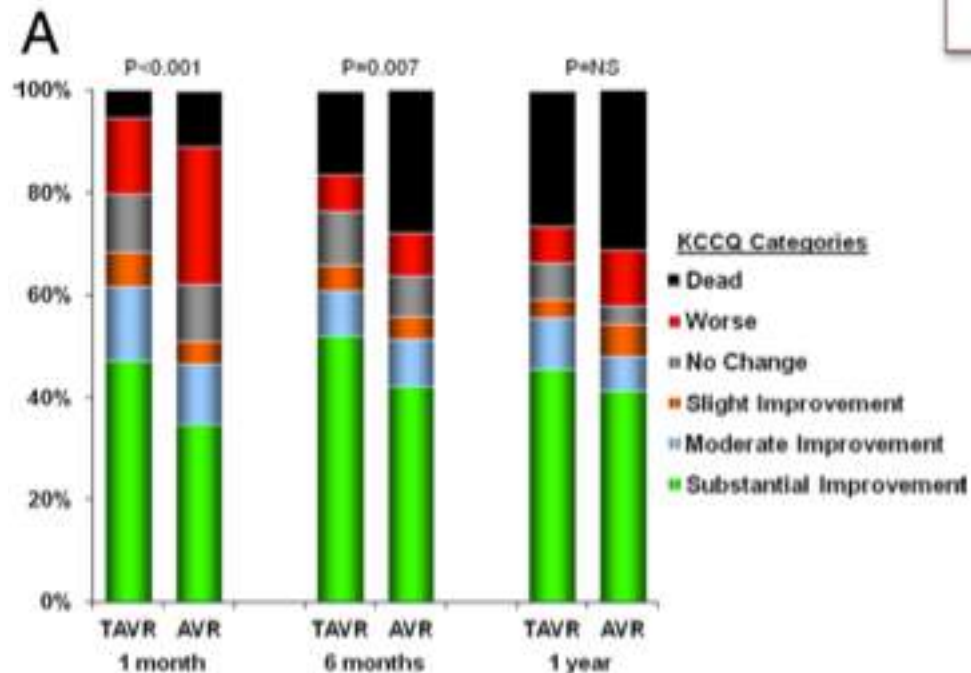
Health-Related Quality of Life After Transcatheter or Surgical Aortic Valve Replacement in High-Risk Patients With Severe Aortic Stenosis

Results From the PARTNER
(Placement of AoRTic TraNscathetER Valve) Trial (Cohort A)

Matthew R. Reynolds, MD, MSc,* Elizabeth A. Magnuson, ScD,† Kaijun Wang, PhD,†
Vinod H. Thourani, MD,‡ Mathew Williams, MD,§ Alan Zajarias, MD,|| Charanjit S. Rihal, MD,¶
David L. Brown, MD,# Craig R. Smith, MD,§ Martin B. Leon, MD,§ David J. Cohen, MD, MSc,†
on behalf of the PARTNER Trial Investigators

*Boston, Massachusetts; Kansas City and St. Louis, Missouri; Atlanta, Georgia; New York, New York;
Rochester, Minnesota; and Dallas, Texas*

JACC Vol. 60, No. 6, 2012
August 7, 2012:548-58





Correction of severe AS either by TAVR or AVR leads to very great improvement in patient-reported symptoms, functional status, and QOL over the first year of follow-up



The more rapid recovery from TAVR via the TF approach is associated with short-term benefits in health status, which may be important from the patient's perspective.



Tf approach had no evidence of health status benefits either in the short or medium term

Direct and adjusted indirect comparisons of perioperative mortality after sutureless or rapid-deployment aortic valve replacement versus transcatheter aortic valve implantation

Hisato Takagi ^{a,*}, Tomo Ando ^{b,1}, Takuya Umemoto ^a,
for the ALICE (All-Literature Investigation of Cardiovascular Evidence) Group


International Journal of Cardiology 228 (2017) 327–334

Tavi: Sapien XT,3
Corevalve
SL-AVR: Perceval,
Intuity, Enable

Logistic euroSCORE:
SL AVR: 12
TAVI 18

6 RCT, 30 observational study
>15000 patients

Paravalvular leakage



PVL prevalence was **significantly lower**
after SL-AVR than after TAVI

(3.5% versus 33.2%; OR, 0.09; 95% CI, 0.04 to 0.23; p < 0.00001).

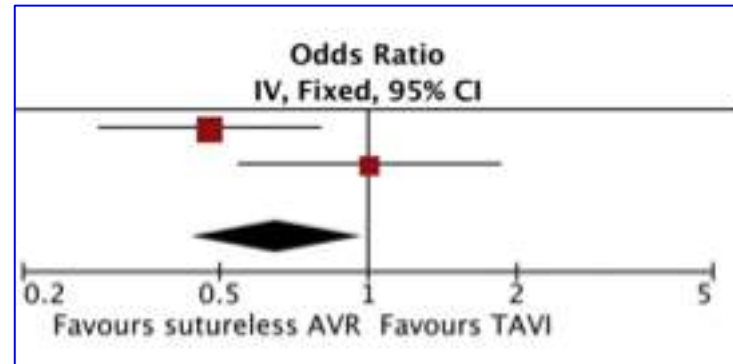
Moderate or severe PVL **occurs commonly** after TAVI

(11.7%; 95% CI, 9.6% to 14.1%)

Can predict perioperative and follow-up all-cause
mortality

30 days Mortality

Significantly
lower in SL-AVR
than TAVI



No significant
difference
between C-AVR
& TAVI

Transcatheter aortic valve implantation (TAVI) versus sutureless aortic valve replacement (SUAVR) for aortic stenosis: a systematic review and meta-analysis of matched studies

Nelson Wang¹, Yi-Chin Tsai², Natasha Niles², Vakhtang Tchanchaleishvili³, Marco Di Eusanio⁴, Tristan D. Yan², Kevin Phan^{1,2}

J Thorac Dis 2016;8(11):3283-3293

Compared to TAVI, SUAVR had a lower incidence of paravalvular leak

(OR =0.06; 95% CI: 0.03–0.12, P<0.01).

There was no difference in perioperative mortality, however

SUAVR patients had significantly better survival rates at 1 (OR =2.40; 95% CI: 1.40–4.11, P<0.01) and 2 years (OR =4.62; 95% CI: 2.62–8.12, P<0.01).

Two-Year Outcomes in Patients With Severe Aortic Valve Stenosis Randomized to Transcatheter Versus Surgical Aortic Valve Replacement

The All-Comers Nordic Aortic Valve Intervention Randomized Clinical Trial

Lars Søndergaard, MD, DMSc; Daniel Andreas Steinbrüchel, MD, DMSc;

(*Circ Cardiovasc Interv.* 2016;9:e003665. DOI: 10.1161/CIRCINTERVENTIONS.115.)

NOTION trial 2

280 patients
Core valve vs
SAVR

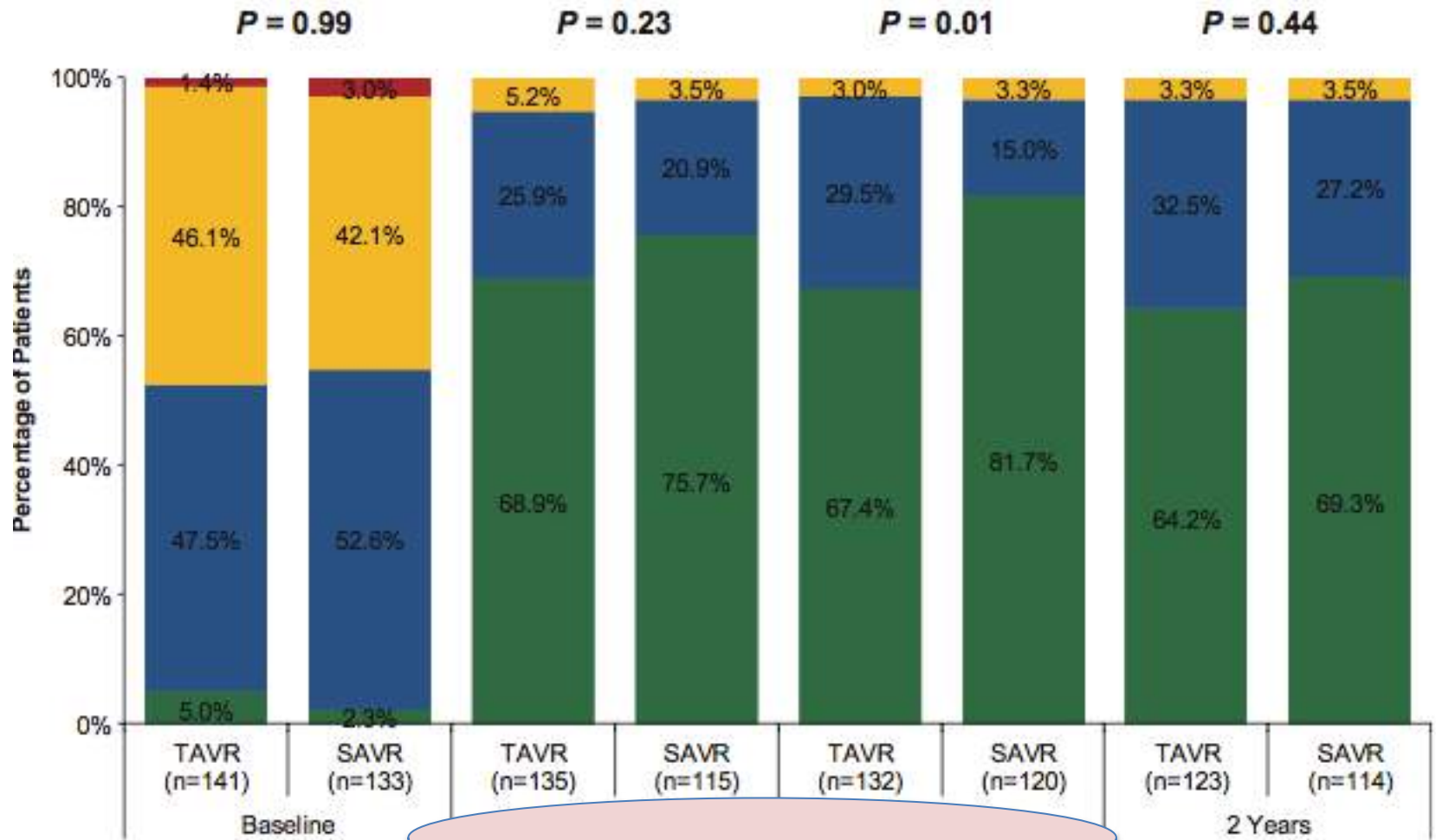
No difference in
All cause
mortality

Clinical Outcomes at 2 Years in the As-Treated Population

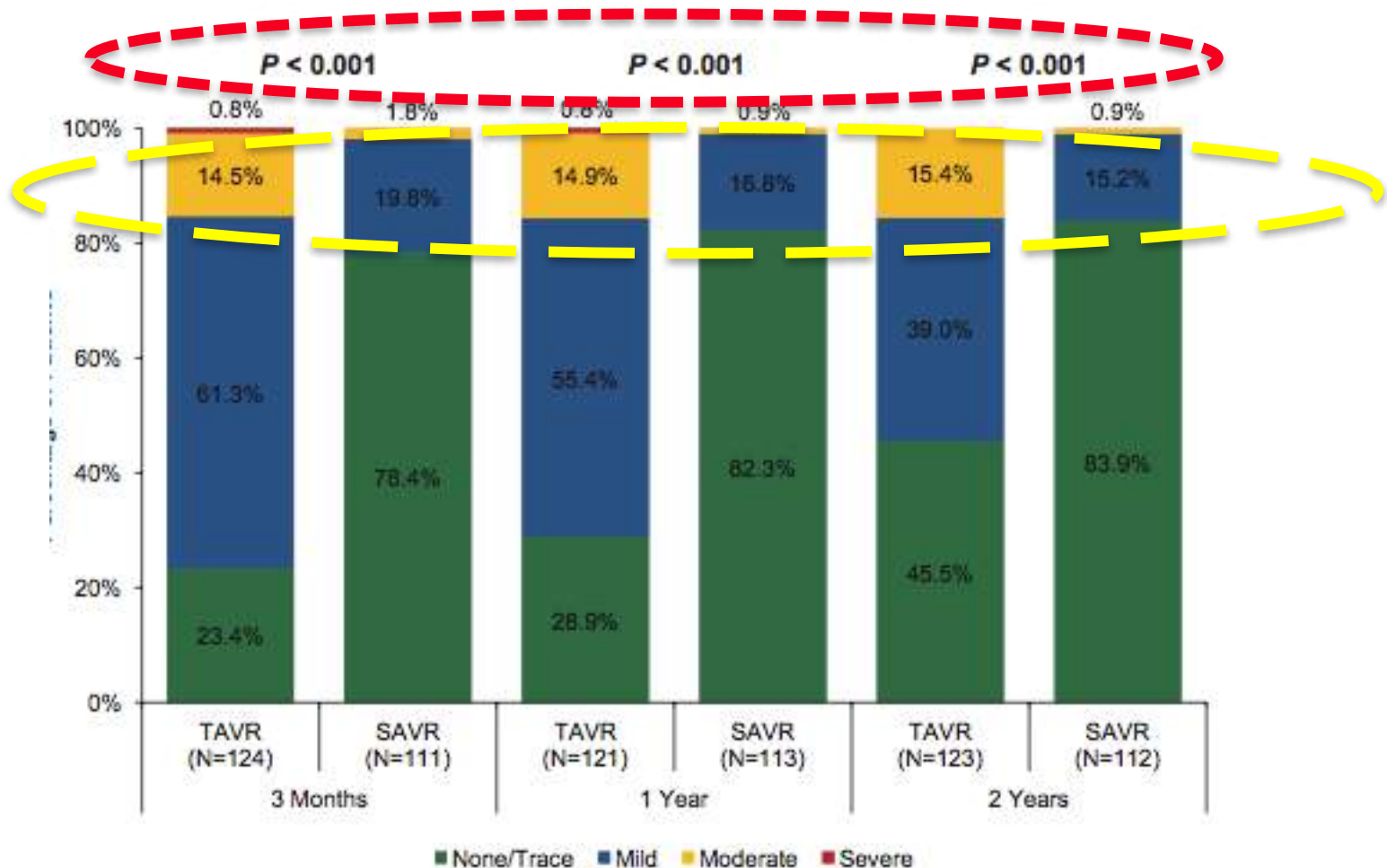
Characteristic	No. of Patients With Events (%)*		
	Transcatheter	Surgical	PValue
All-cause death	11 (8.0)	13 (9.8)	0.54
Cardiovascular death	9 (6.5)	12 (9.1)	0.40
Neurological events	13 (9.7)	10 (7.8)	0.67
Stroke	5 (3.6)	7 (5.4)	0.46
Transient ischemic attack	8 (6.0)	4 (3.3)	0.30
New-onset or worsening atrial fibrillation	32 (22.7)	80 (60.2)	<0.001
Permanent pacemaker implantation	55 (41.3)	5 (4.2)	<0.001

PPM

A-fib

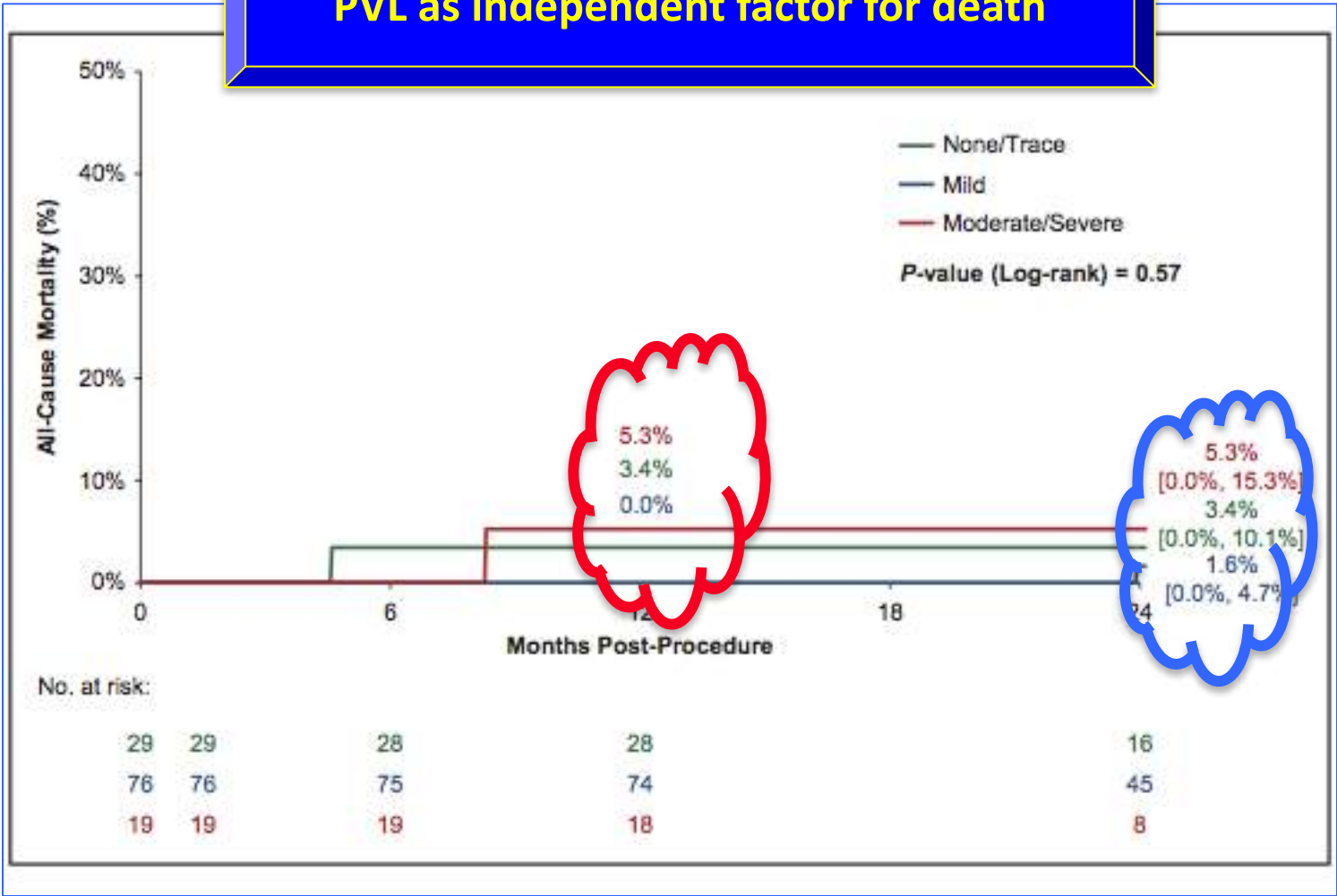


NYHA



Paravalvular leakage

PVL as independent factor for death



Two-Year Outcomes in Patients With Severe Aortic Valve Stenosis Randomized to Transcatheter Versus Surgical Aortic Valve Replacement

The All-Comers Nordic Aortic Valve Intervention Randomized Clinical Trial

Lars Søndergaard, MD, DMSc; Daniel Andreas Steinbrüchel, MD, DMSc; Nikolaj Ihlemann, MD, PhD; Henrik Nissen, MD, PhD; Bo Juel Kjeldsen, MD, PhD; Petur Petursson, MD, PhD; Anh Thuc Ngo, MD, PhD; Niels Thue Olsen, MD, PhD; Yanping Chang, MS; Olaf Walter Franzen, MD; Thomas Engstrøm, MD, DMSc; Peter Clemmensen, MD, DMSc; Peter Skov Olsen, MD, DMSc; Hans Gustav Hørsted Thyregod, MD

Conclusions—Two-year results from the NOTION trial demonstrate the continuing **safety and effectiveness of TAVR** in lower-risk patients. Longer-term data are needed to verify the durability of this procedure in this patient population.

Surgeons Predicted ... (ROM) (<4% versus ≥4%), there was no statistically significant difference for TAVR and SAVR groups ... composite outcome for low-risk (14.7%, 95% confidence interval, 8.3–21.2 versus 16.8%; 95% confidence interval, 9.7–23.8; $P=0.58$) or intermediate-risk patients (21.1% versus 27.1%; $P=0.59$).

Conclusions—Two-year results from the NOTION trial demonstrate the continuing safety and effectiveness of TAVR in lower-risk patients. Longer-term data are needed to verify the durability of this procedure in this patient population.

Clinical Trial Registration—URL: <http://www.clinicaltrials.gov>. Unique identifier: NCT01057173.

(*Circ Cardiovasc Interv.* 2016;9:e003665. DOI: 10.1161/CIRCINTERVENTIONS.115.003665.)

INTERMEDIATE RISK PATIENTS

The NEW ENGLAND JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

APRIL 28, 2016

VOL. 374 NO. 17

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

Partner 2 trial

2032 intermediate-risk patients with severe aortic stenosis, at 57
centers,

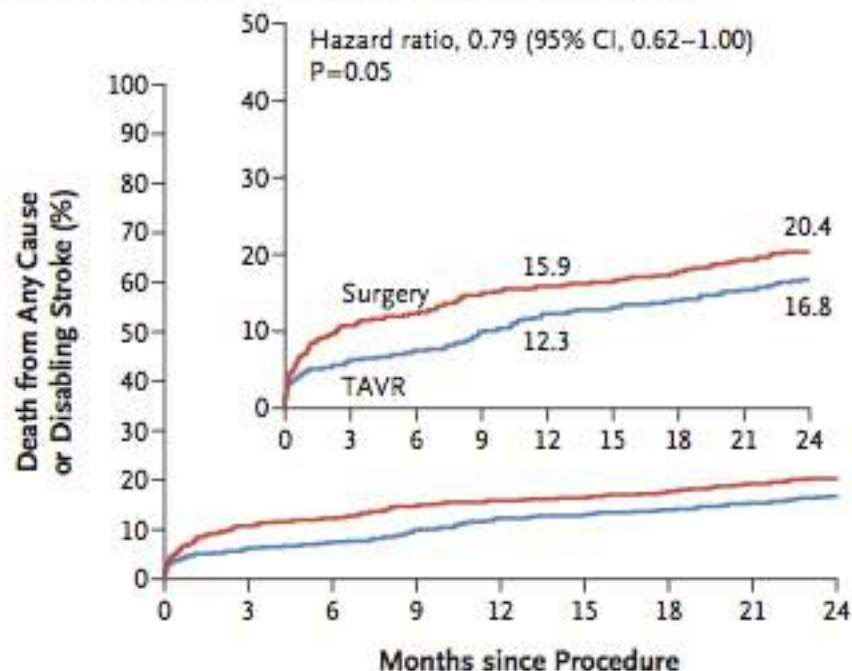
The primary end point was death from any cause or disabling stroke at 2
years.

Table 1. Characteristics of the Patients at Baseline.*

Characteristic	TAVR (N = 1011)	Surgery (N = 1021)
Age — yr	81.5±6.7	81.7±6.7
Male sex — no. (%)	548 (54.2)	560 (54.8)
Body-mass index†	28.6±6.2	28.3±6.2
STS risk score‡	5.8±2.1	5.8±1.9
NYHA class III or IV — no./total no. (%)	782/1011 (77.3)	776/1020 (76.1)
Coronary artery disease — no. (%)	700 (69.2)	679 (66.5)
Previous myocardial infarction — no. (%)	185 (18.3)	179 (17.5)
Previous CABG — no. (%)	239 (23.6)	261 (25.6)
Previous PCI — no. (%)	274 (27.1)	282 (27.6)
Previous balloon aortic valvuloplasty — no. (%)	51 (5.0)	50 (4.9)
Cerebral vascular disease — no. (%)	325 (32.1)	317 (31.0)
Peripheral vascular disease — no. (%)	282 (27.9)	336 (32.9)
Diabetes mellitus — no. (%)	381 (37.7)	349 (34.2)
COPD — no. (%)		

Previous CABG — no.**239 (23.6)****261 (25.6)**

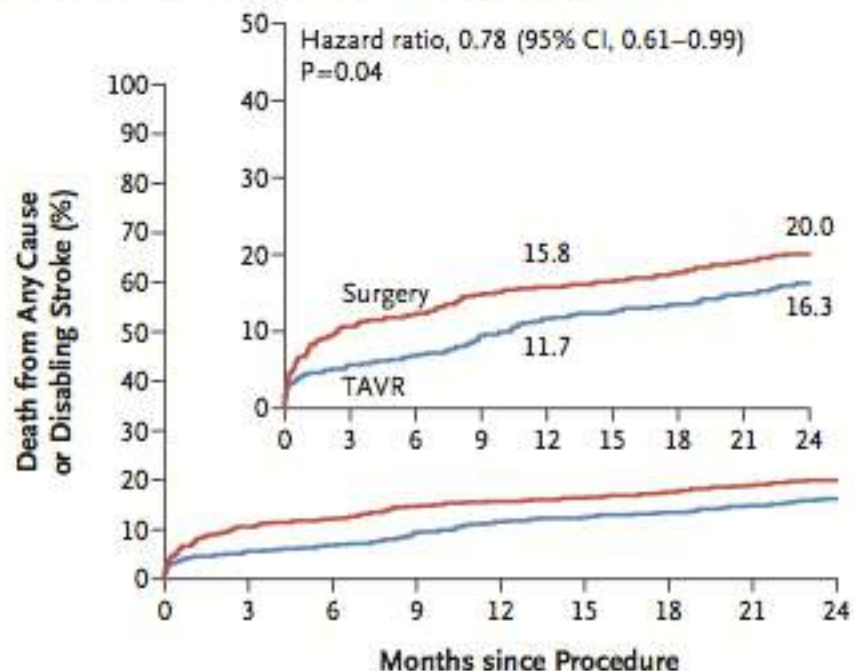
C Transfemoral-Access Cohort, Intention-to-Treat Analysis



No. at Risk

TAVR	775	718	709	685	663	652	644	634	612
Surgery	775	643	628	604	595	577	569	557	538

D Transfemoral-Access Cohort, As-Treated Analysis



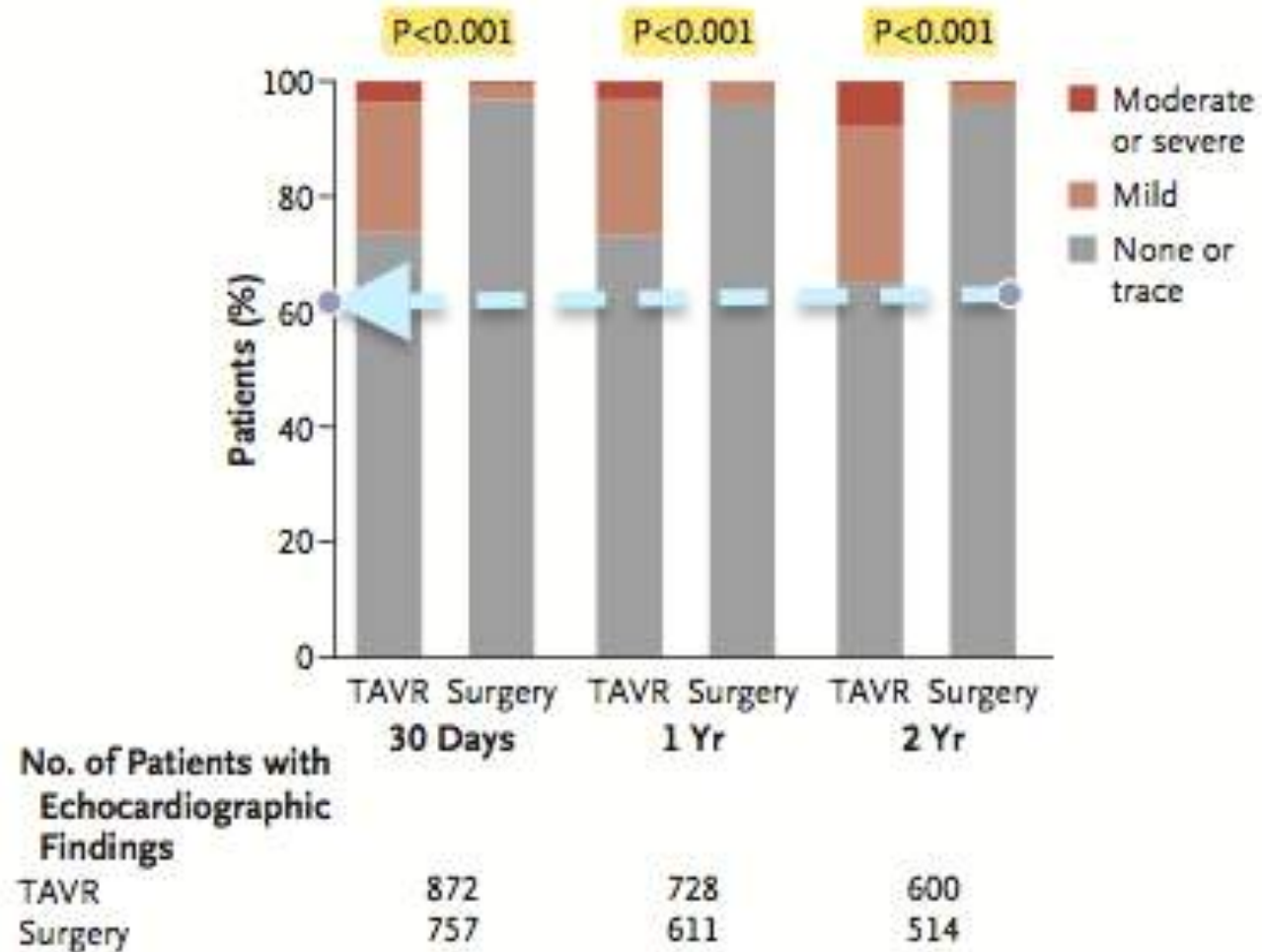
No. at Risk

TAVR	762	717	708	685	663	652	644	634	612
Surgery	722	636	624	600	591	573	565	555	537

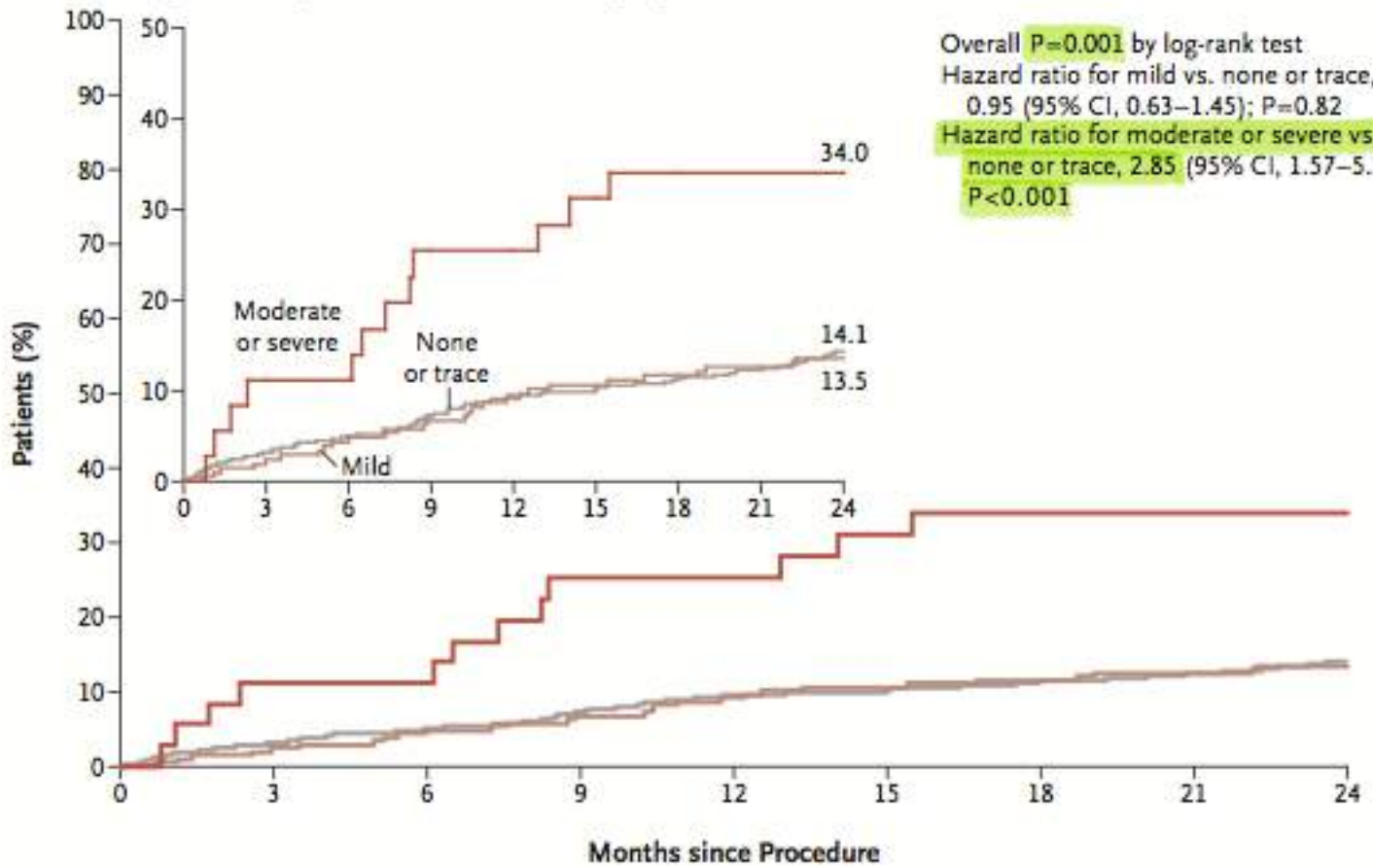
Figure 1. Time-to-Event Curves for the Primary Composite End Point.

The insets show the same data on an enlarged y axis. TAVR denotes transcatheter aortic-valve replacement.

B Paravalvular Aortic Regurgitation

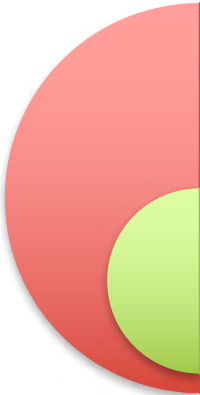


C Death from Any Cause, According to Severity of Paravalvular Aortic Regurgitation



No. at Risk

None or trace	701	678	664	647	628	621	612	605	585
Mild	210	204	199	194	188	184	182	180	175
Moderate or severe	36	32	32	26	26	24	22	22	21



Coronary revascularization was more commonly performed in the surgery group than TAVR (13.5% vs 3.9%)

The addition of either CABG or PCI to valve-replacement therapies had no deleterious effect on mortality or the rate of stroke.

Summary of Partner 2 trial

No difference in cardiac death and all cause mortality or CVA

AKI, post-op A-Fib, bleeding and stroke were more common in SAVR

26% redo in SAVR

Vs

24% protected TAVI

Paravalvular

leakage in TAVI

Moderate or severe PVL significantly increase the mortality

Re-intervention are more common in TAVI

MACCE

no difference

Bleeding complication was higher in SU-AVR

773 patients

No Randomized trial included

TAVI (394 patients, mean age, 80.8 ± 5.5 years, mean EuroSCORE II 5.6 ± 4.9 %)

In-hospital mortality

2.6 % after SU-AVR and 5.3 % after TAVI ($p = 0.057$)

PPM need

(17.3 vs. 9.8 %, $p = 0.003$)

Mild (44.0 vs. 2.1 %)

paravalvular regurgitation

moderate–severe

(14.1 vs. 0.3 %,

$p < 0.0001$)

Sutureless aortic valve replacement versus transcatheter aortic valve implantation: a meta-analysis of comparative matched studies using propensity score matching

Massimo Meco^{a,†}, Antonio Miceli^{b,c,†}, Andrea Montisci^{b,*,†}, Francesco Donatelli^{b,d}, Silvia Cirri^b, Matteo Ferrarini^b, Antonio Lio^b and Mattia Glauber^b

Interactive CardioVascular and Thoracic Surgery (2017) 1–8

Table 2: Patient preoperative characteristics

	Sutureless	TAVI	OR (95% CI)/(WMD)	P-value
Female gender (%)	48.25	48.25	0.93 (0.75 to 1.15)	0.48
Preoperative renal insufficiency (%)	10.5	10.5	0.88 (0.69 to 1.129)	0.29
Hypertension (%)	78.96	78.91	0.60 (0.46 to 0.78)	0.51
Redo (%)	1.7	1.7	0.54 (0.34 to 0.85)	0.13
Diabetes	10.5	10.5	0.99 (0.75 to 1.30)	0.94
CAD (%)	19.4	19.4	0.86 (0.58 to 1.26)	0.43
Extracardiac arteriopathy (%)	68.6	68.6	1.07 (0.82 to 1.4)	0.63
NYHA Class III-IV (%)	55.2 ± 8.6	55.2 ± 8.6	1 (0.78 to 1.28)	1
LVEF (%), mean ± SD	78.96 ± 4.6	78.91 ± 6	0.78 (-1.07 to 2.62)	0.41
Age (years), mean ± SD	15.45 ± 9	15.58 ± 8.1	-0.16 (-0.90 to 0.57)	0.66
EuroSCORE, mean ± SD			-0.36 (-1.11 to 0.40)	0.35



CAD: coronary artery disease; CI: confidence interval; LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; OR: odds ratio; TAVI: transcatheter aortic valve implantation; WMD: weighted mean difference.

Stroke

PVL

PPM need

Vascular complication

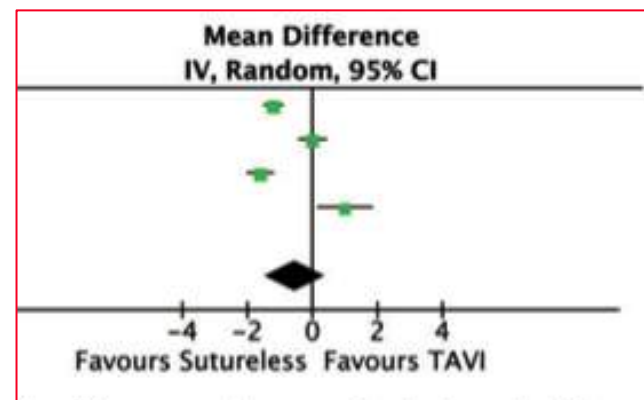
Higher rates in TAVI

Table 3: Postoperative data

	SU-AVR	TAVI	P-value
30-days mortality (%)	24/741 (3.23)	44/741 (5.93)	0.01
Postoperative stroke (%)	12/741 (1.61)	27/741 (3.64)	0.01
Postoperative aortic regurgitation (%)	21/731 (2.8)	133/731 (18.19)	0.001
Postoperative AKI (%)	35/527 (6.51)	37/527 (6.89)	0.8
Pacemaker implantation (%)	69/741 (9.31)	70/741 (9.44)	0.9
Transfused patients (%)	88/426 (20.6)	26/424 (6.1)	0.001
Vascular complications (%)	0/490 (0)	41/490 (8.36)	0.001

AKI: acute kidney injury.

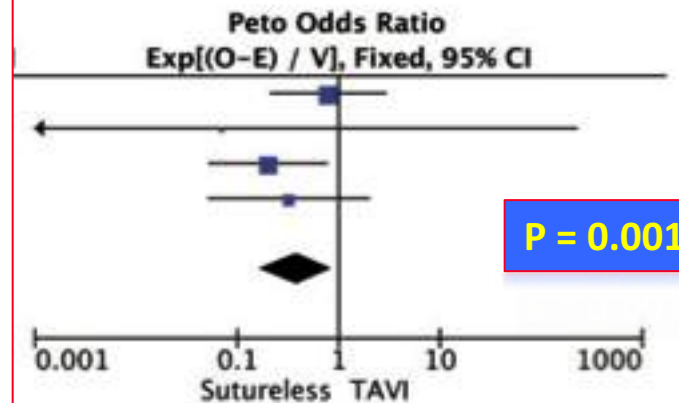
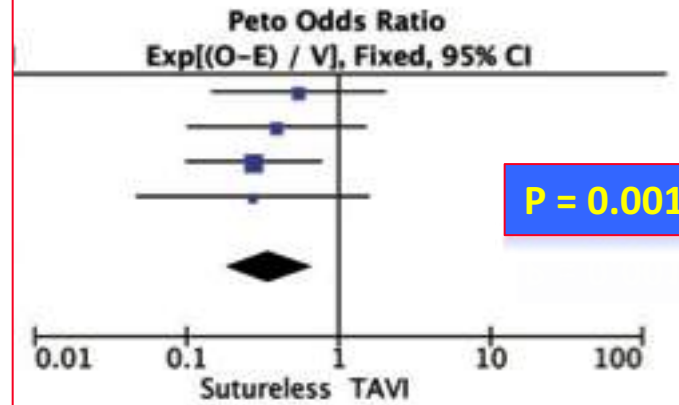
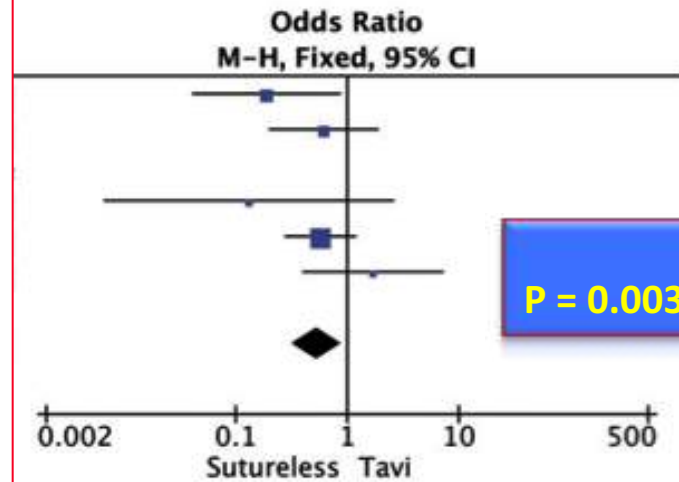
Similar ICU stay



In hospital death

1 yr Survival

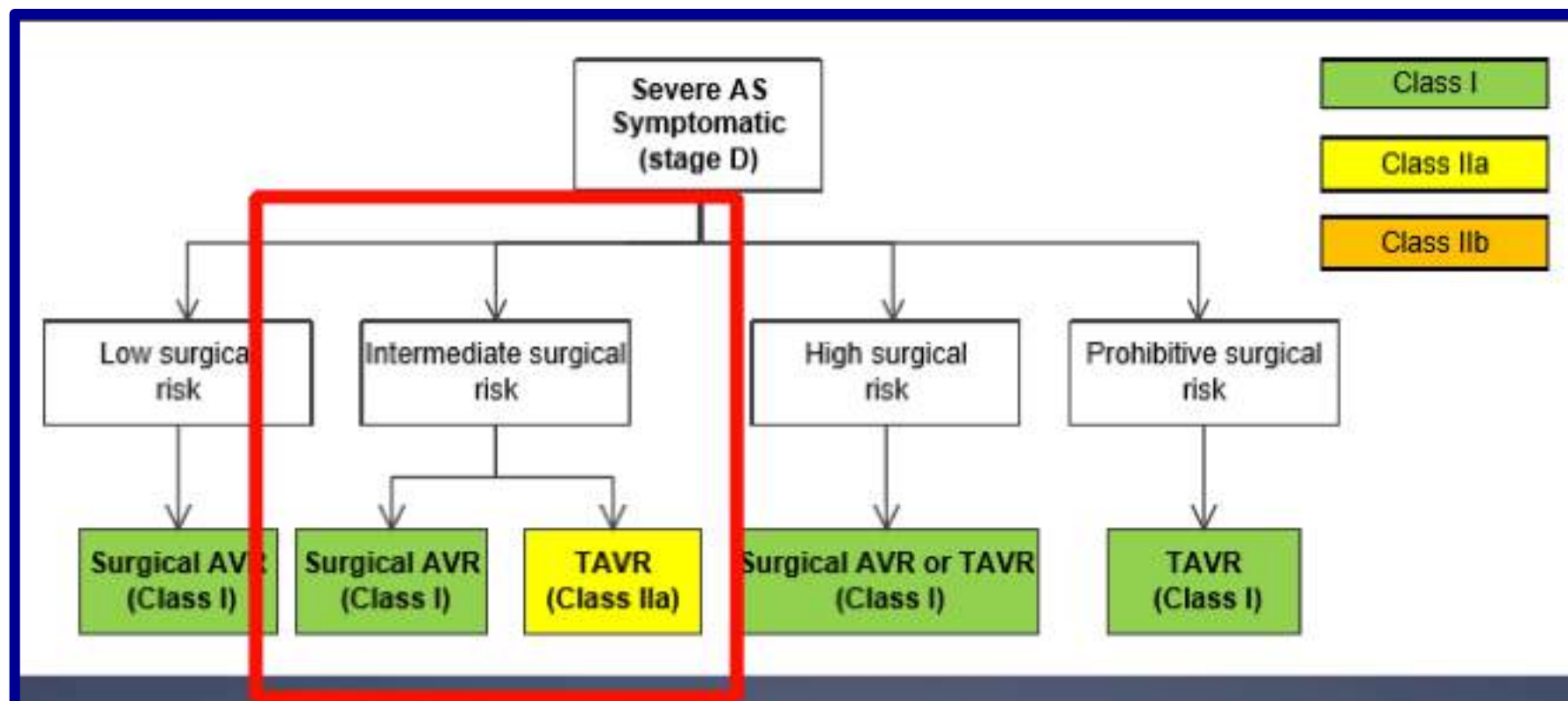
2 yr Survival



2017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

Developed in Collaboration With the American Association for Thoracic Surgery, American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons



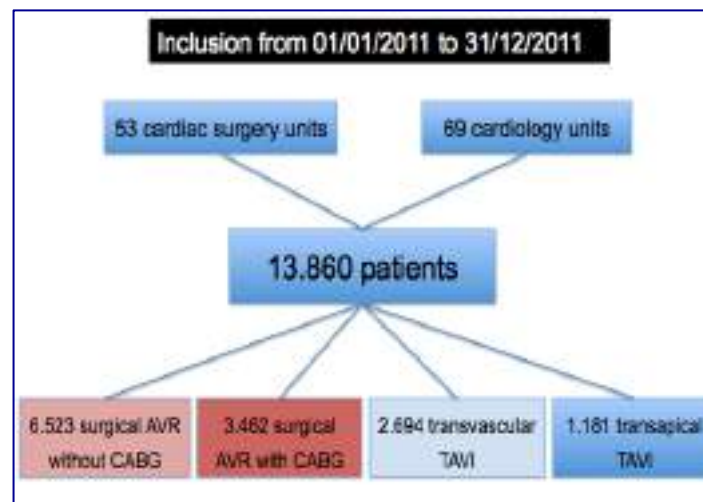
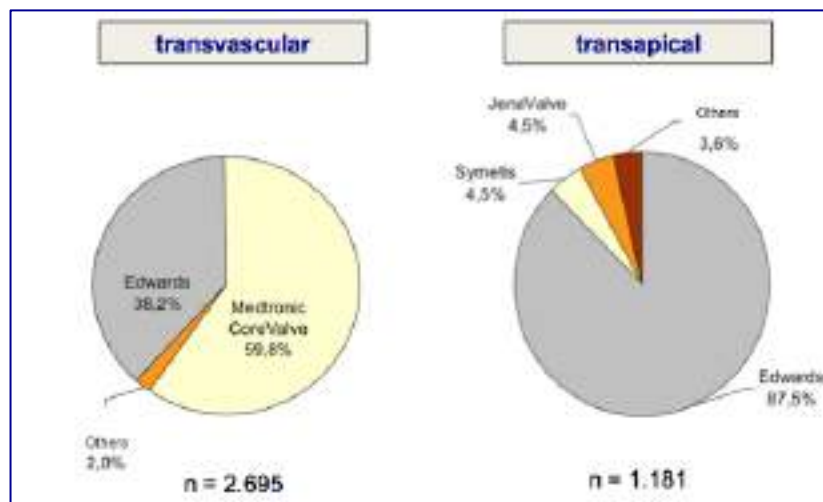
The German Aortic Valve Registry: 1-year results from 13 680 patients with aortic valve disease[†]

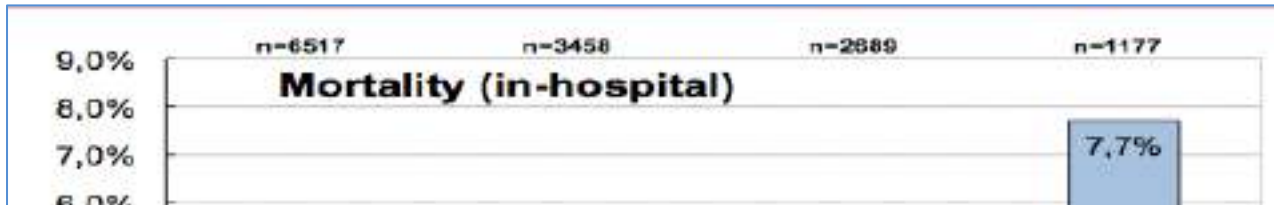
Friedrich W. Mohr^{a*}, David Holzhey^a, Helge Möllmann^a, Andreas Beckmann^a, Christof Veit^a, Hans Reiner Figulla^a, Jochen Cremer^a, Karl-Heinz Kuck^a, Rüdiger Lange^a, Ralf Zahn^a, Stefan Sack^a, Gerhard Schuler^a, Thomas Walther^a, Friedhelm Beyersdorf^a, Michael Böhm^a, Gerd Heusch^a, Anne-Kathrin Funkat^a, Thomas Meinertz^a, Till Neumann^a, Konstantinos Papoutsis^a, Steffen Schneider^a, Armin Welz^a and Christian W. Hamm^b, for the GARY Executive Board

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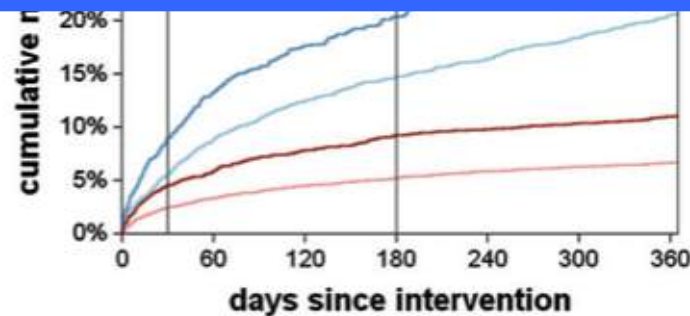
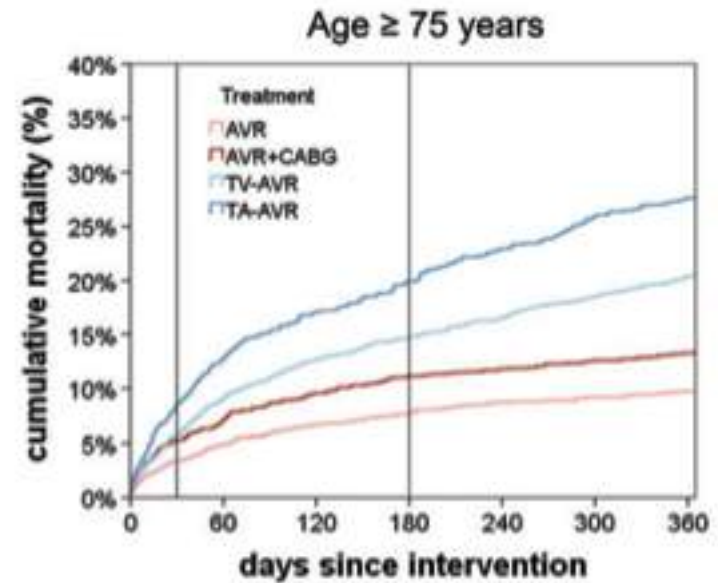
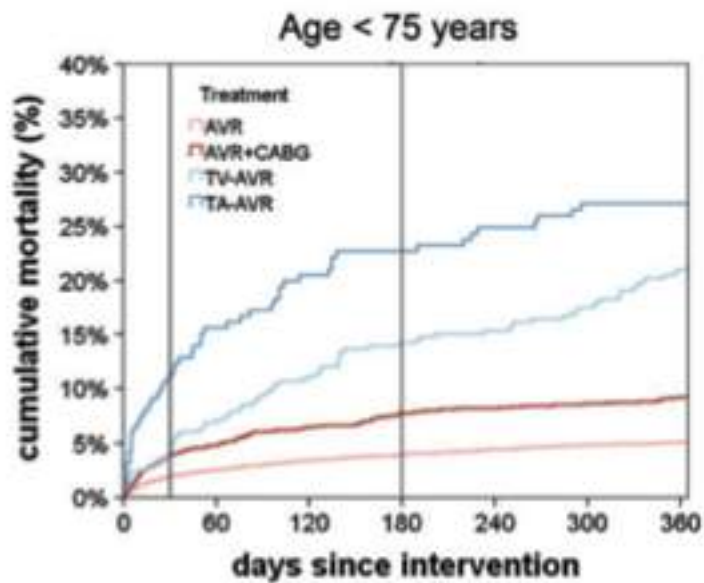
GARY

**Deutsches Aortenklappenregister
German Aortic Valve Registry**

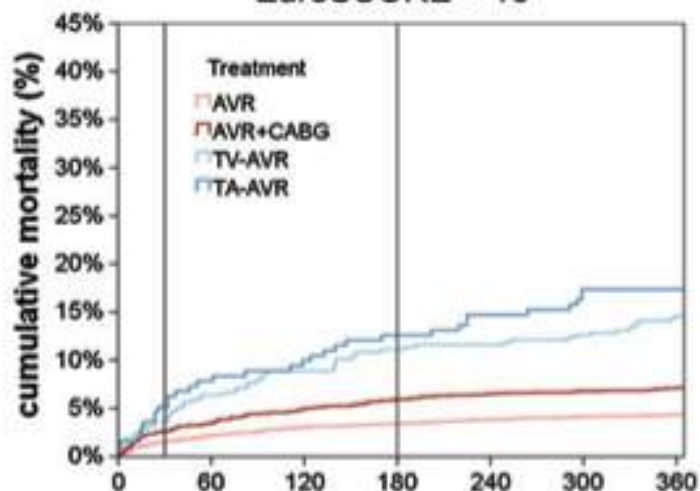




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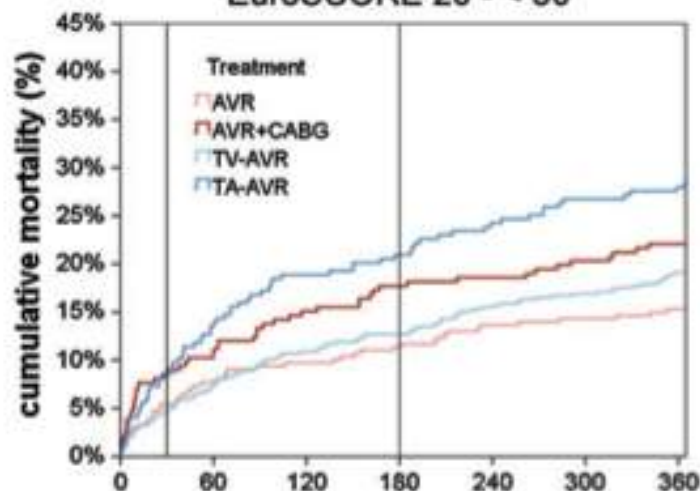
EuroSCORE < 10



days since intervention

# at Risk – day	0	30	180	365
AVR	4731	4648	4505	4452
AVR+CABG	2138	2075	1977	1951
TV-AVR	409	394	358	344
TA-AVR	194	182	165	154

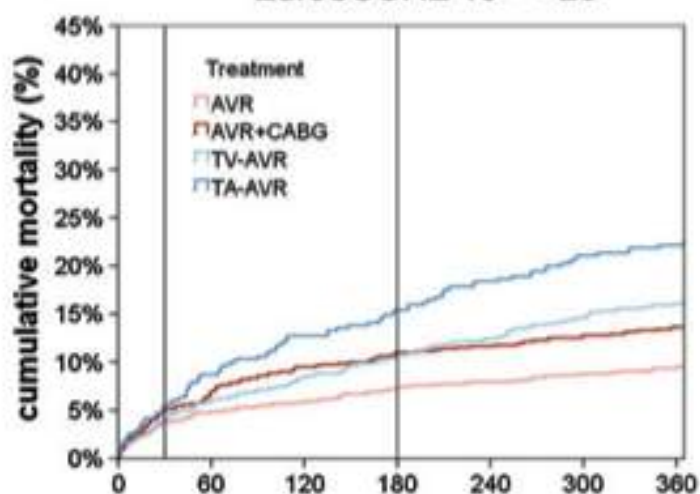
EuroSCORE 20 - < 30



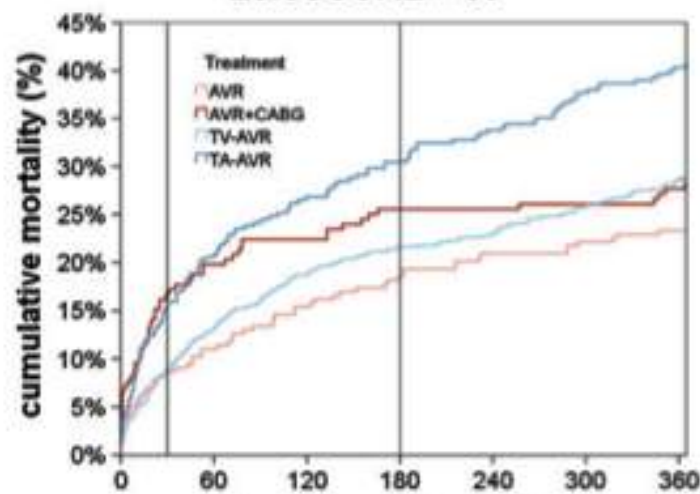
days since intervention

# at Risk – day	0	30	180	365
AVR	312	294	270	255
AVR+CABG	235	213	188	178
TV-AVR	514	488	435	402
TA-AVR	247	225	191	173

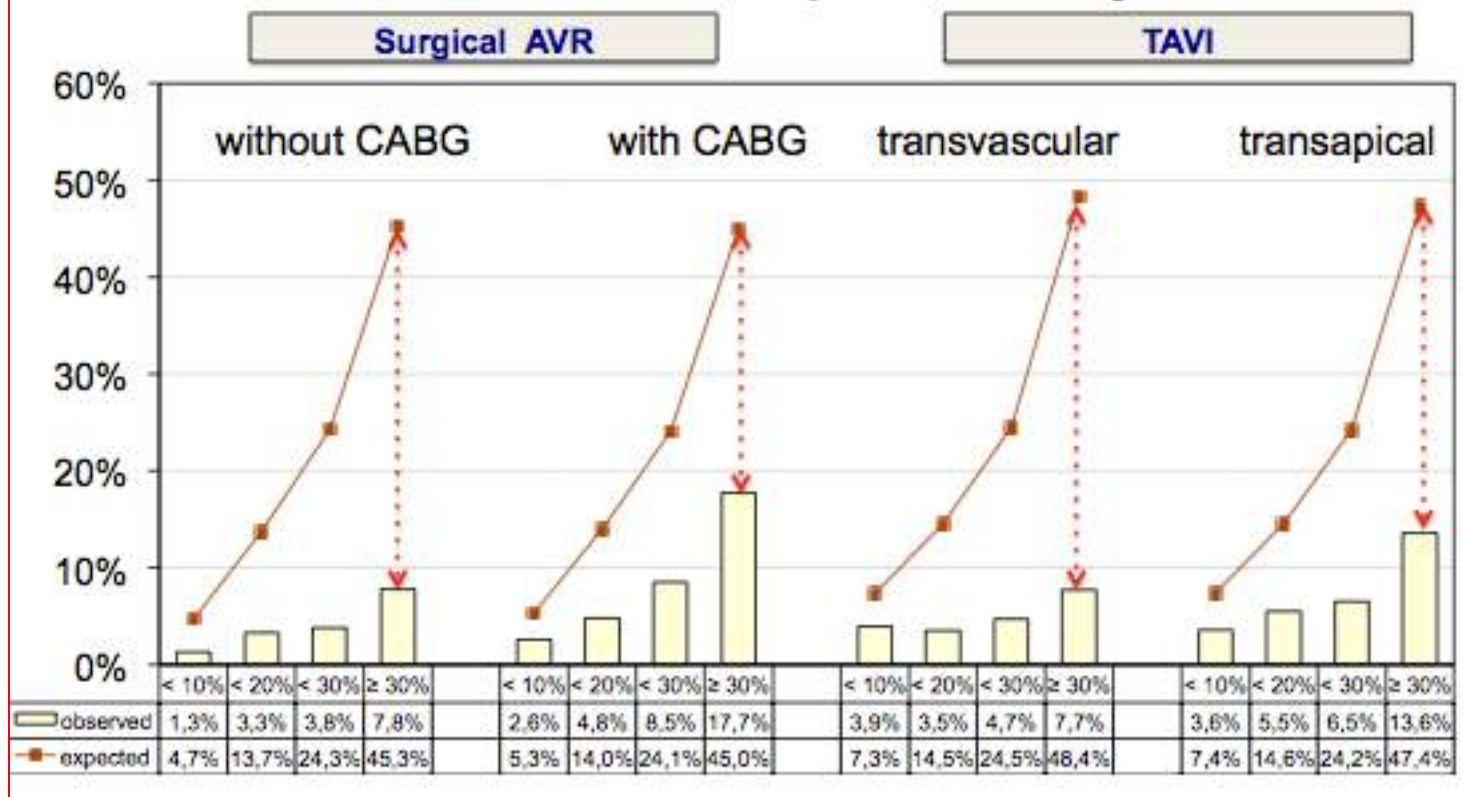
EuroSCORE 10 - < 20



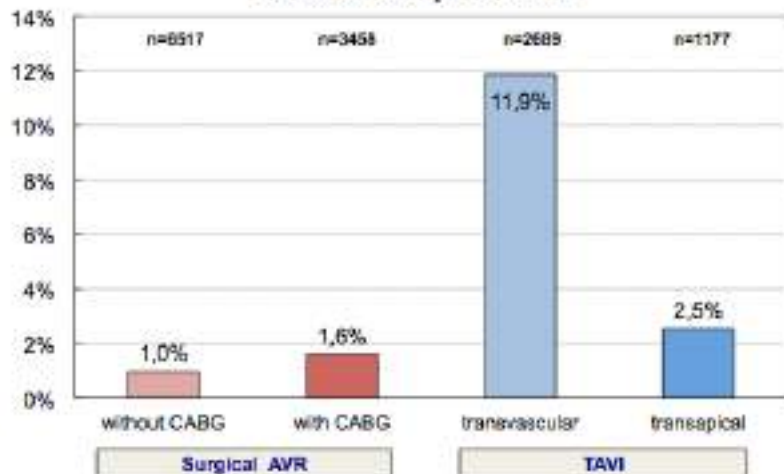
EuroSCORE ≥ 30



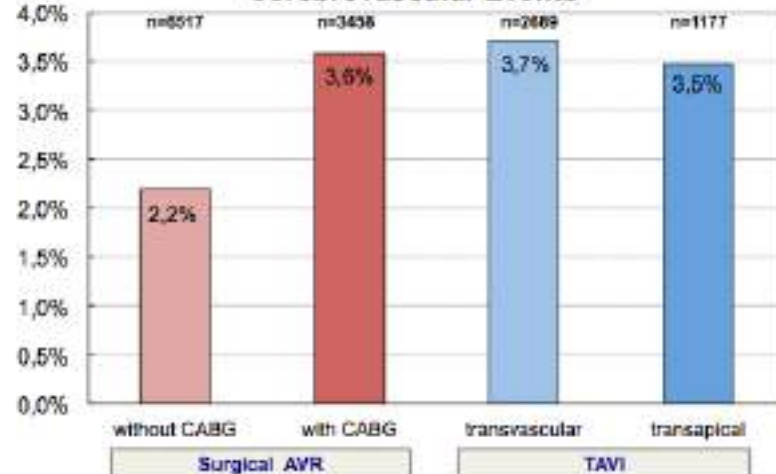
Euro-Score in-hospital mortality



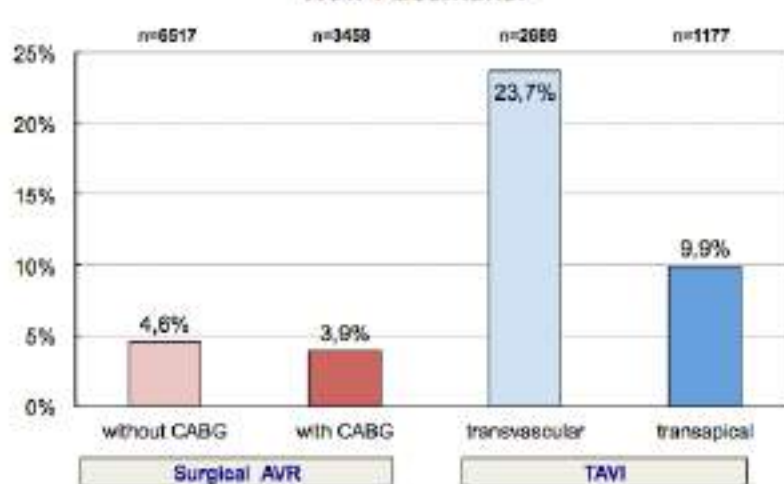
Vascular complications



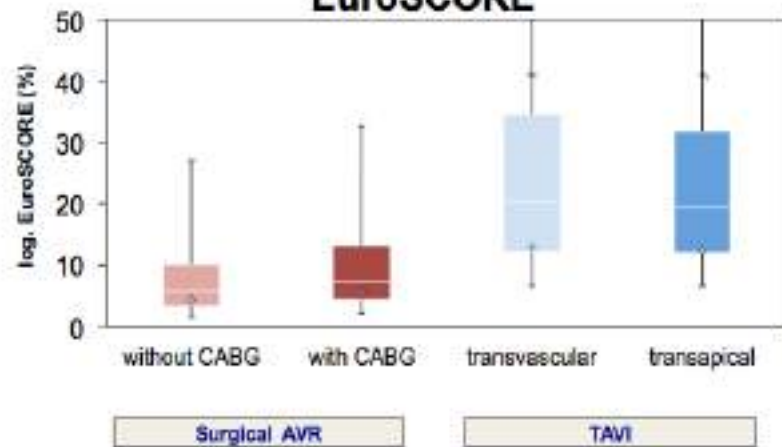
Cerebrovascular Events



New Pacemaker



EuroSCORE



GARY confirm in a large 'real-world', all-comer patient population that

Conventional surgery in operable patients yields excellent results in all risk groups.

TAVR is a good alternative for high-risk patients.

GARY confirm in a large 'real-world', all-comer patient population that

GARY

Conventional surgery in operable patients yields excellent results in all risk groups.

TAVR is a good alternative for high-risk patients.

TAVI



Expensive

Needs less anesthesia

Need for X-ray (radiation)

Indirect vision

Compressed valve tissue & Implantation

Higher incidence of paraleakage

Higher PPM needed

Less pain

Rapid recovery

SUAVR



Less expensive

Need for anesthesia

Need for CPB & AOX

Direct vision

Valve resection and replacement

Less Paravalvular leakage

Less PPM needed

In summary

SUAVR is superior in

Early and 2 years
mortality rates

Paravalvular leakage



The Major Concern?

Durability

Long term outcomes

The concern with PVL is probably temporary, as TAVI will continue to improve in valve designs

Performance of SUAVR is promising and evolving

Minimally invasive approaches continue to improve the patients outcome

Cardiac Surgeons must be engaged and learn the endovascular surgery

Respect to the current guideline and heart team approach



**BRIGHT
FUTURE**

Sutureless and Rapid deployment valves implantation techniques

