

GARY

Deutsches Aortenklappenregister German Aortic Valve Registry



Deutsches
Aortenklappenregister

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One year results of more than 14,000 patients from the German Aortic Valve Registry

Friedrich-Wilhelm Mohr

Heart Center Leipzig, Germany



ACC 2013, San Francisco

- Nationwide complete survey of patients with aortic valve disease undergoing invasive procedures:
 - surgical (AVR), replacement/reconstruction
 - catheter-based (TAVI) transfemoral
 - catheter-based (TAVI) transapical
 - valvuloplasty.
- To evaluate catheter-based procedures in comparison to surgical aortic valve replacement.
- Develop criteria for an adequate patient selection of best treatment modality.

- Prospective, controlled, multicenter registry.
- All patients undergoing an invasive therapy for acquired aortic valve disease consecutively included.
- The only exclusion criterion: no informed consent.
- Follow-up: in-hospital, 30 days, 1, 3, 5 years

- Data management:

BQS – Institut für Qualität & Patientensicherheit.



- Sponsorship:

Investigator initiated study with unrestricted grant from:
Edwards, Medtronic, Jena Valve, Symetis, St Jude, Sorin

- Support:

German Cardiac Society (DGK)

German Society for Thoracic and Cardiovascular Surgery

German Heart Foundation

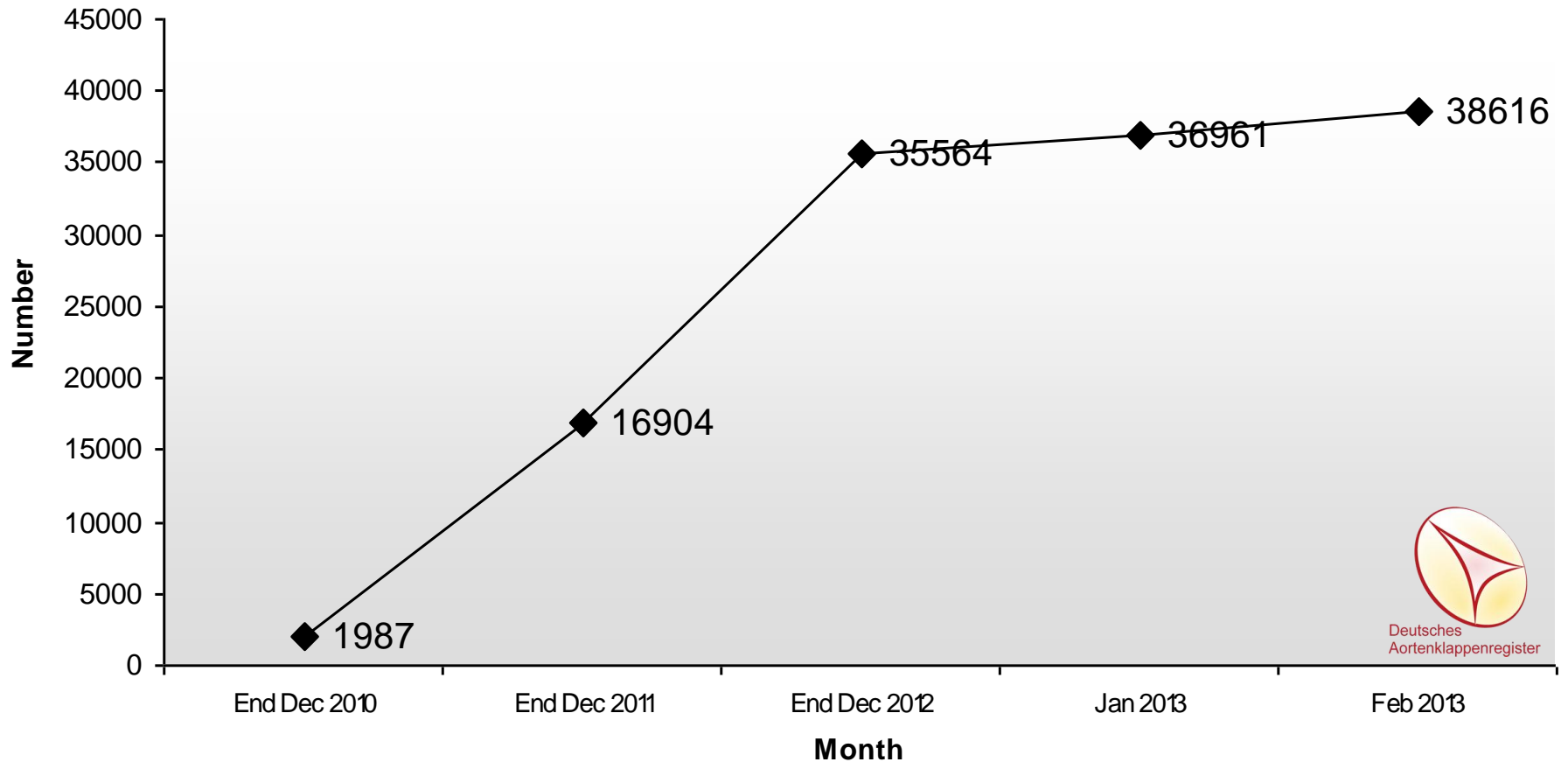
Patients with Written Consent

2010 until 02/2013



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Patients with Written Consent



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Inclusion from 01/01/2011 to 31/12/2011

53 cardiac surgery units

69 cardiology units

13.860 patients

6.523 surgical AVR
without CABG

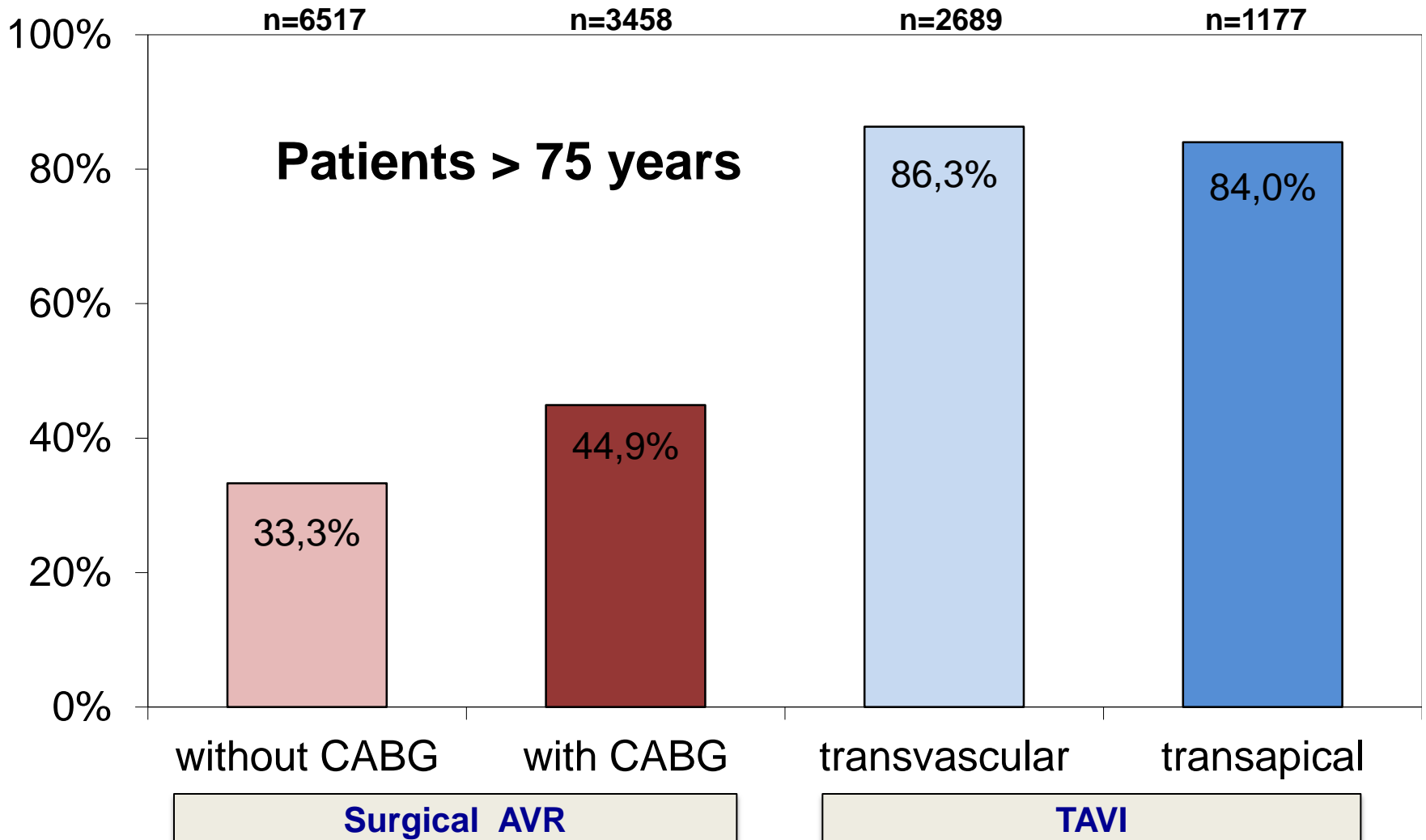
3.462 surgical
AVR with CABG

2.694 transvascular
TAVI

1.181 transapical
TAVI

	AVR without CABG	AVR with CABG	Transvasc. TAVI	Transapical TAVI
CAD	18.6	97.1	53.6	56.1
LV-EF <30%	3.1	5.1	9.3	7.5
A. fib.	15.9	15.0	28.9	29.5
Art. HT	79.5	86.1	86.4	90.0
Pulm. HT	10.8	11.1	39.8	23.4
COPD	10.0	12.2	19.8	20.5
IDDM	8.2	12.9	13.3	17.5

all p<0.001



1 year follow-up: 13.860 patients

2011: 13.860 patients included

Follow-up: 13.595 patients → **98,1 %**

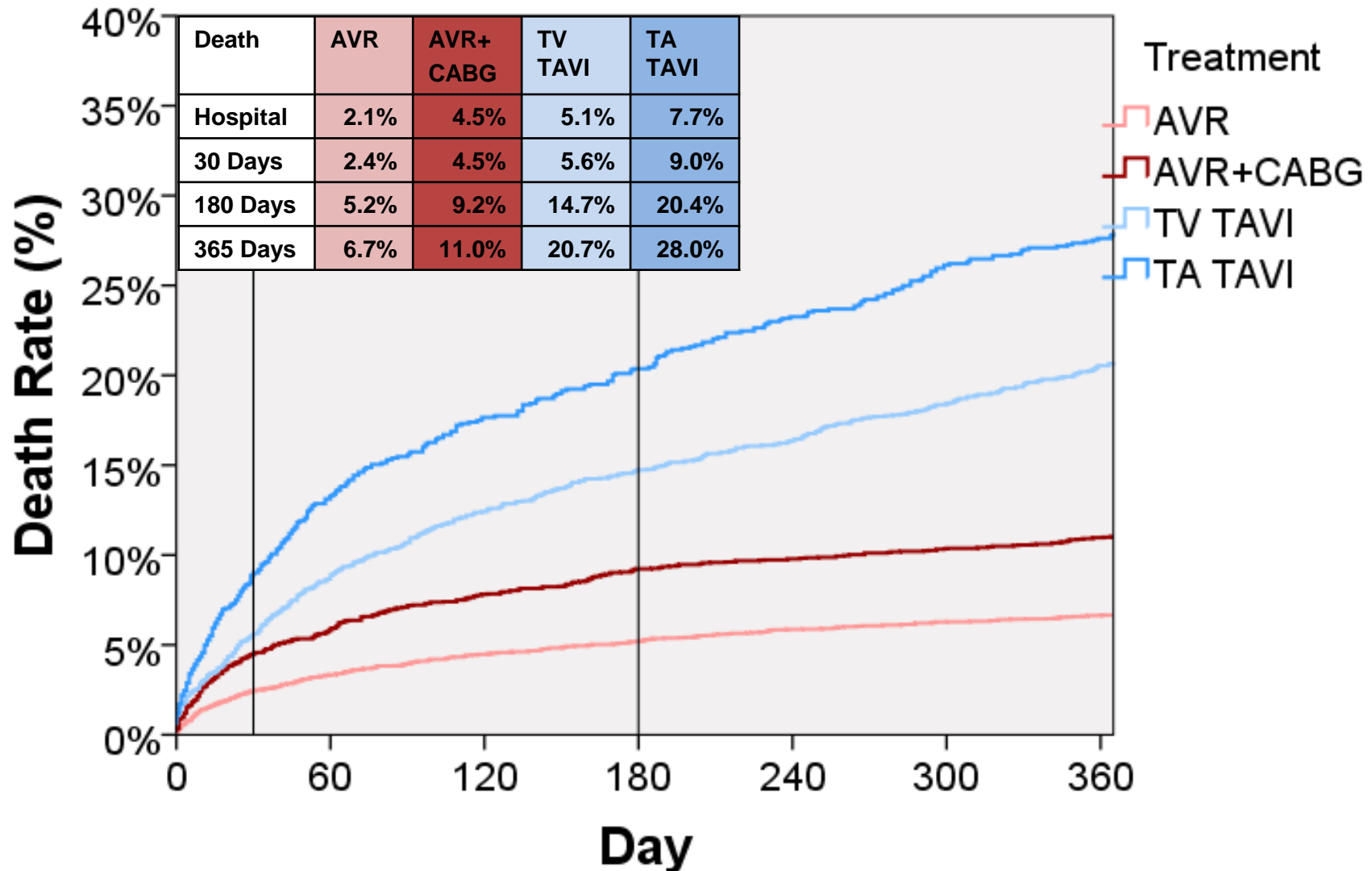
- direct follow-up: 89,5 %
- indirect follow-up: 8,6 %
(National population register)

Unknown: 1,9%

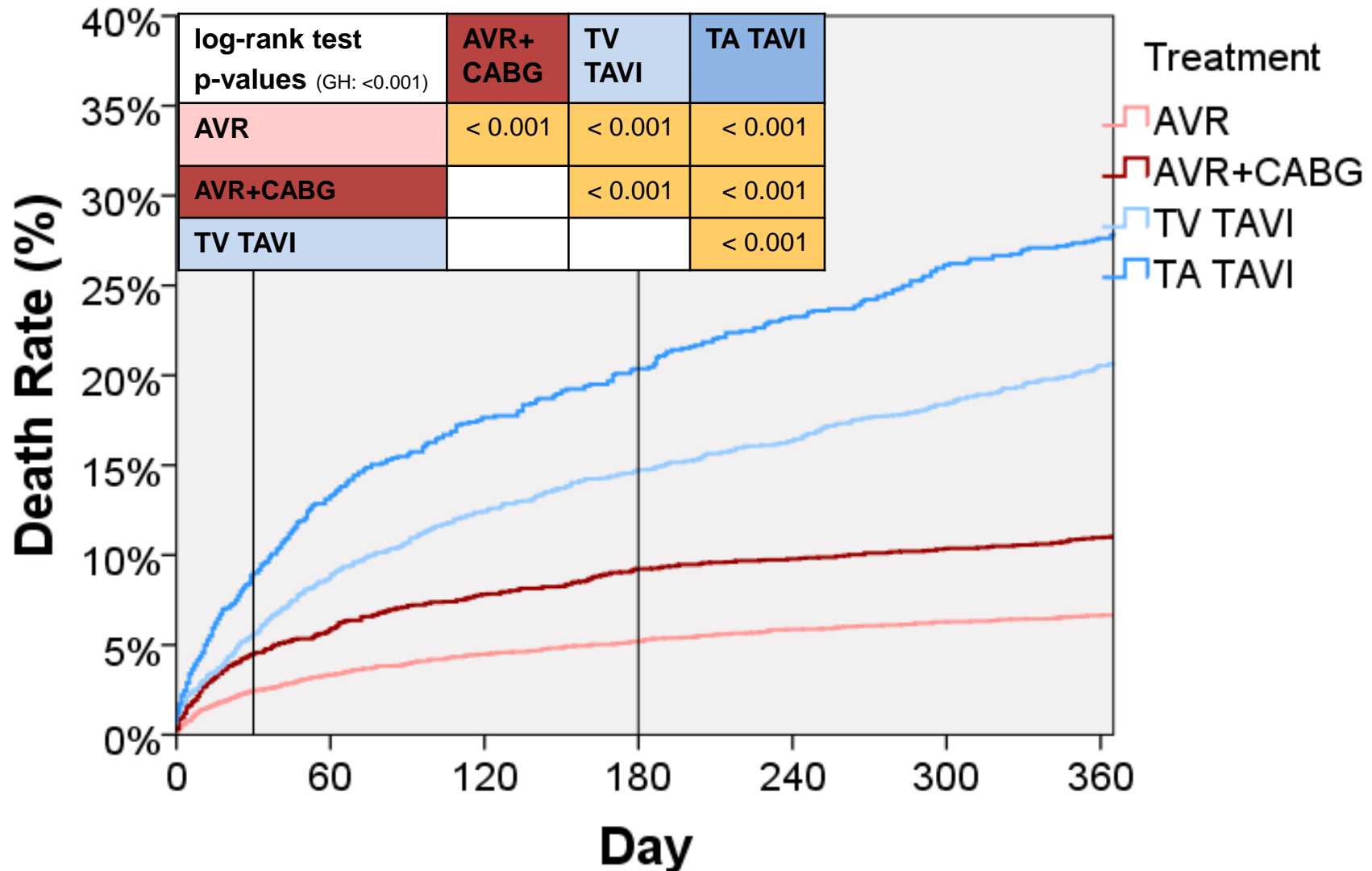
Kaplan-Meier mortality-rate by procedure



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Kaplan-Meier mortality-rate by procedure



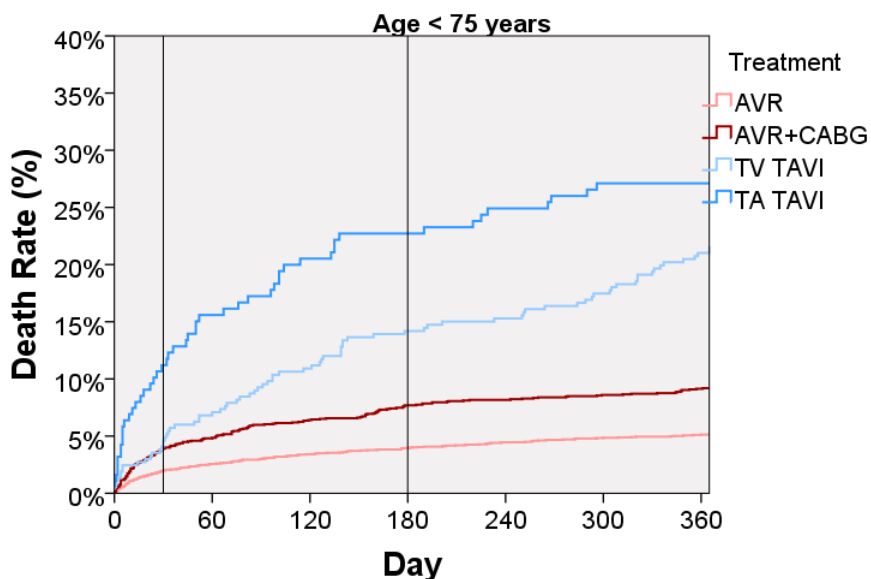
Kaplan-Meier mortality-rate by procedure

Age: < 75 years; >= 75 years



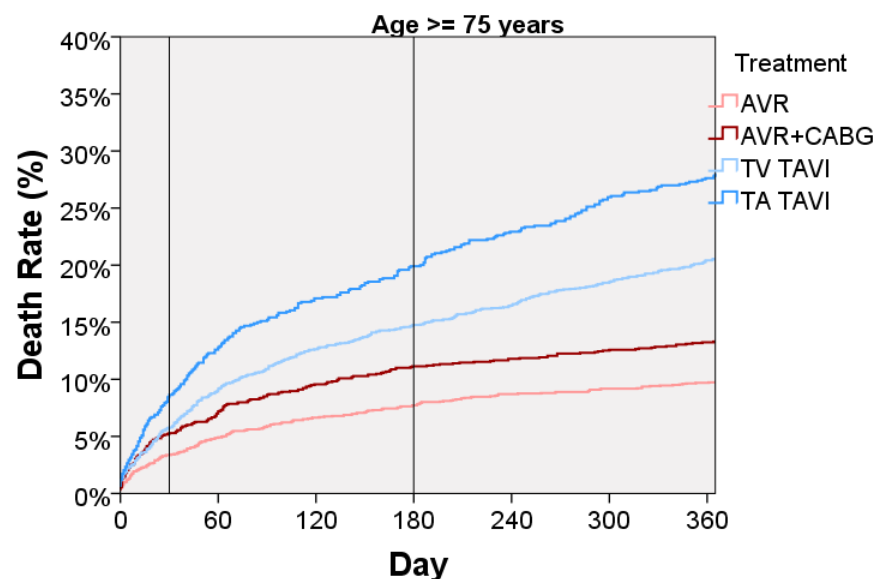
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Age: < 75 years



No. at Risk	Day 0	Day 30	Day 180	Day 365
AVR	4349	4251	4112	4050
AVR +CABG	1905	1823	1725	1697
TV TAVI	368	352	314	289
TA TAVI	188	165	141	133

Age: >= 75 years



No. at Risk	Day 0	Day 30	Day 180	Day 365
AVR	2168	2089	1971	1925
AVR +CABG	1553	1467	1351	1316
TV TAVI	2321	2176	1918	1781
TA TAVI	989	896	768	687

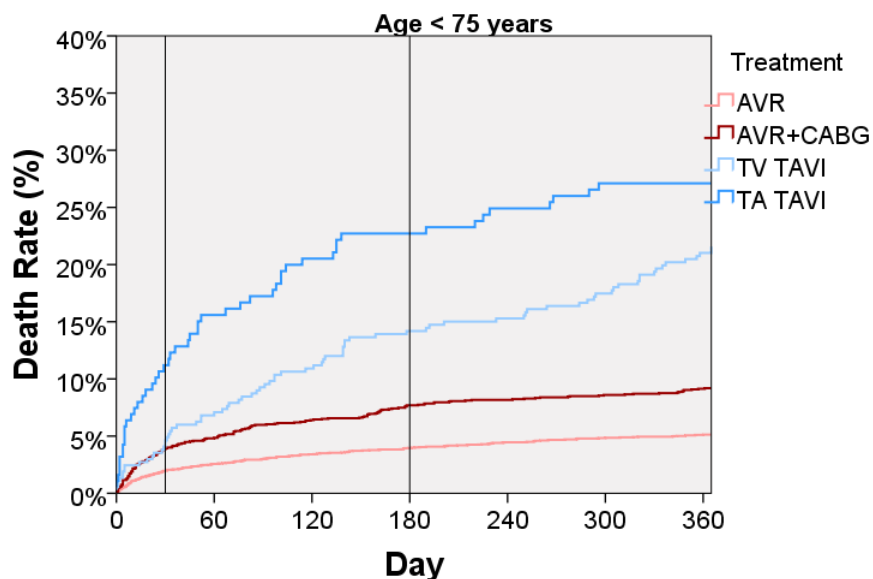
Kaplan-Meier mortality-rate by procedure

Age: < 75 years; >= 75 years



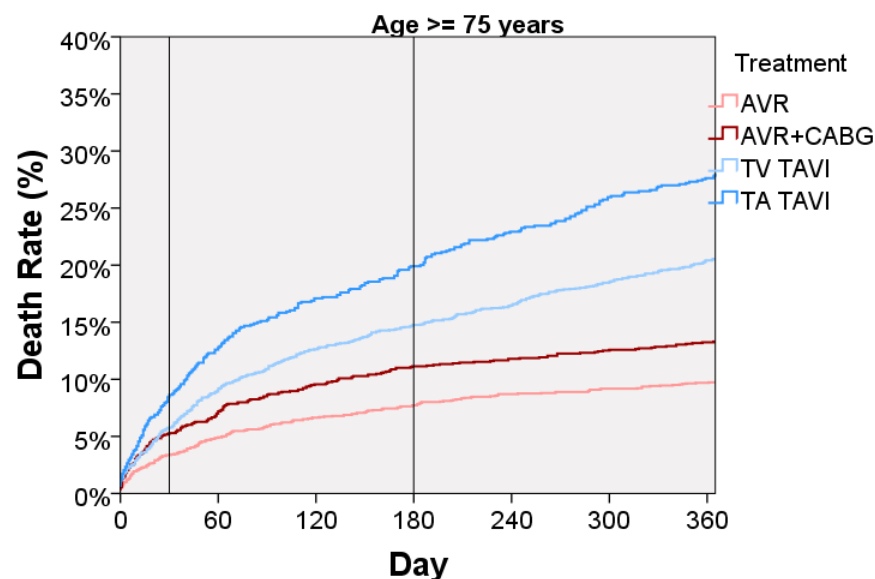
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Age: < 75 years



Death	AVR	AVR+C ABG	TV TAVI	TA TAVI
30 Days	2.0%	3.9%	4.6%	11.2%
180 Days	4.0%	7.7%	14.2%	22.7%
365 Days	5.1%	9.2%	21.6%	27.1%

Age: >= 75 years



Death	AVR	AVR+C ABG	TV TAVI	TA TAVI
30 Days	3.4%	5.3%	5.8%	8.6%
180 Days	7.7%	11.1%	14.8%	19.9%
365 Days	9.7%	13.3%	20.5%	28.0%

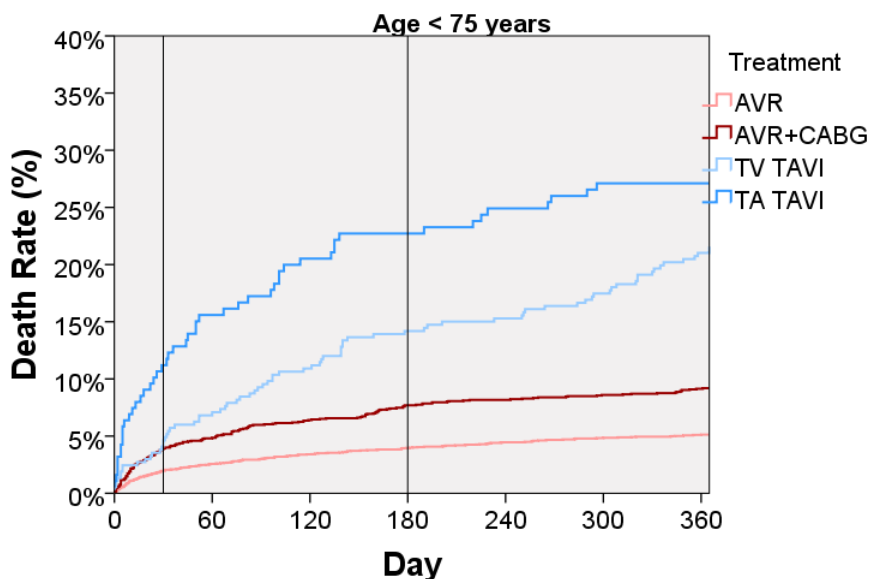
Kaplan-Meier mortality-rate by procedure

Age: < 75 years; >= 75 years



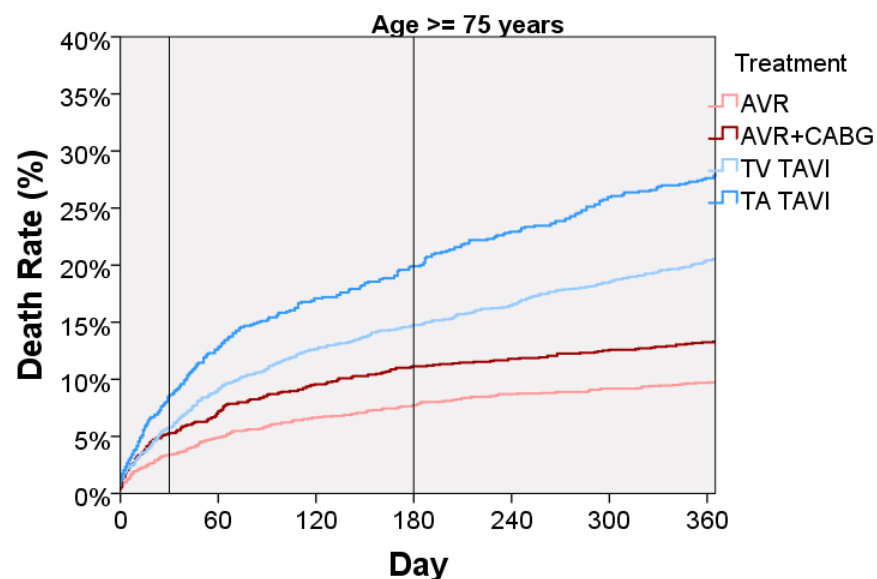
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Age: < 75 years



log-rank test p-values (GH: <0.001)	AVR+C ABG	TV TAVI	TA TAVI
AVR	< 0.001	< 0.001	< 0.001
AVR+CABG		< 0.001	< 0.001
TV TAVI			0.081

Age: >= 75 years

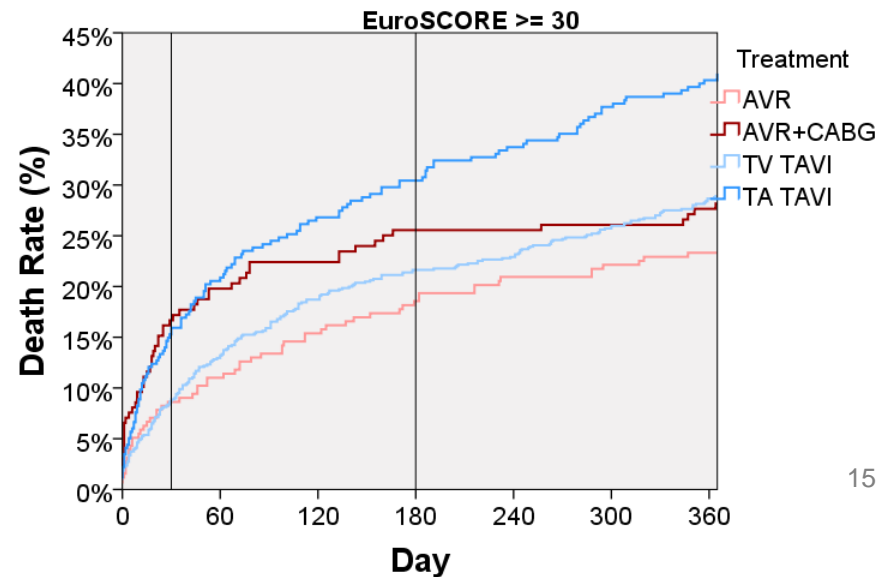
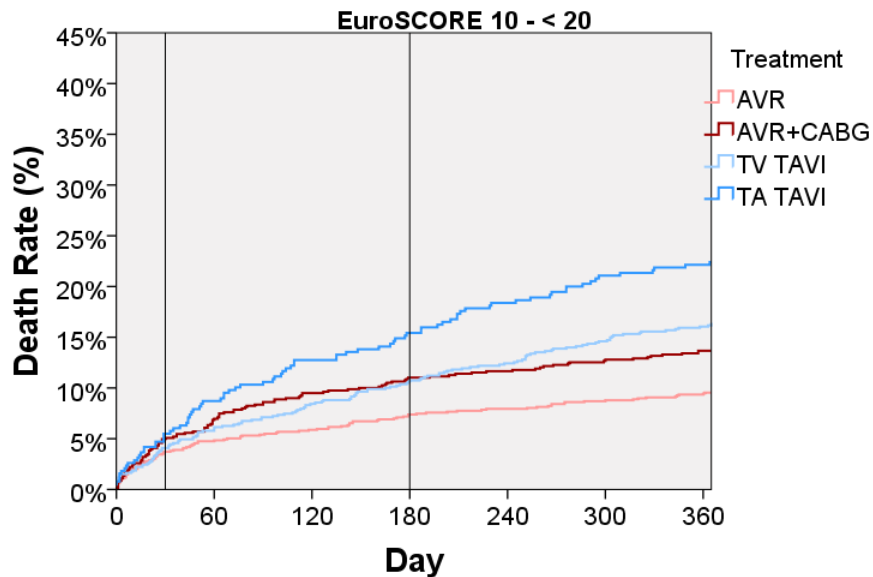
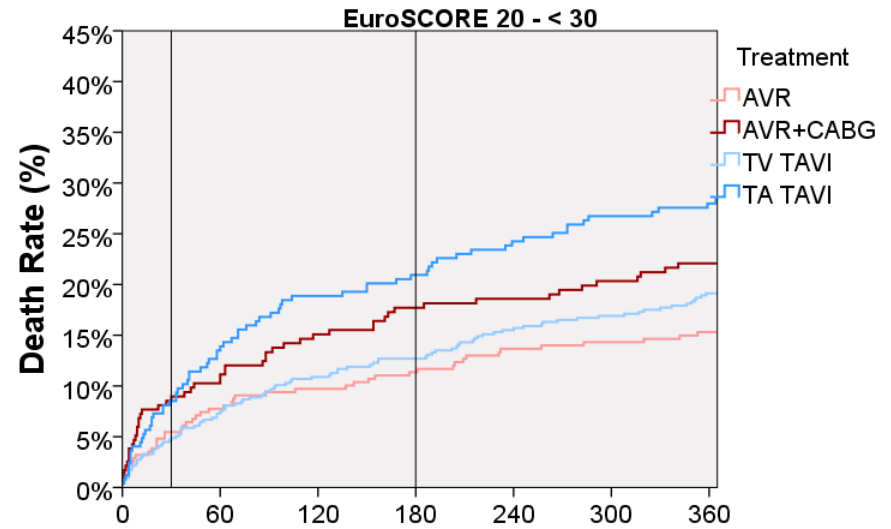
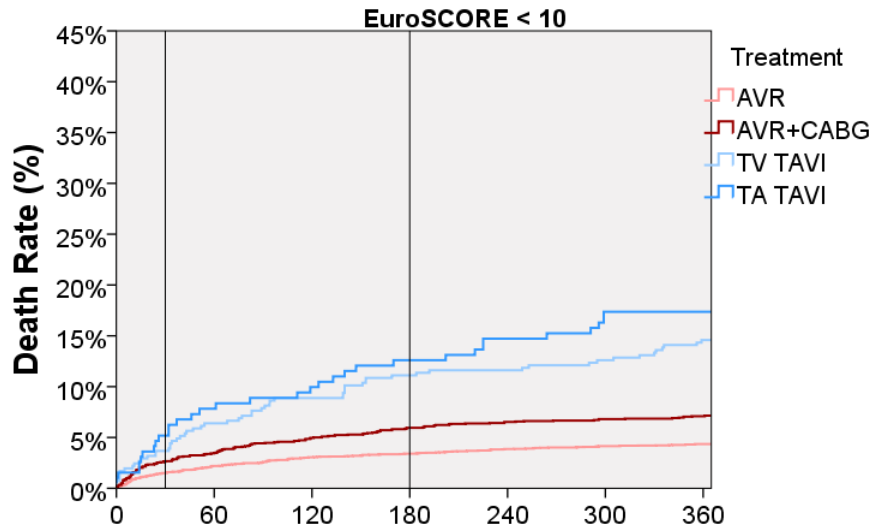


log-rank test p-values (GH: <0.001)	AVR+C ABG	TV TAVI	TA TAVI
AVR	0.001	< 0.001	< 0.001
AVR+CABG		< 0.001	< 0.001
TV TAVI			< 0.001

Kaplan-Meier mortality by procedure EuroSCORE



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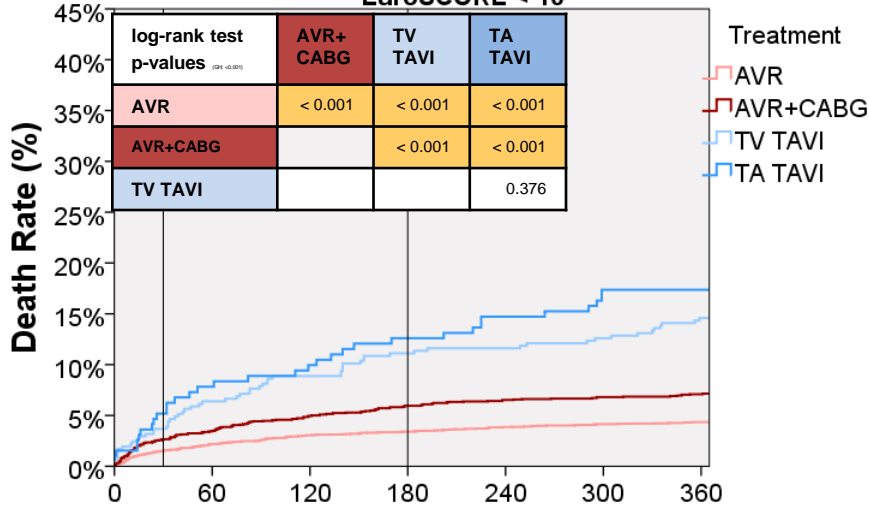


Kaplan-Meier mortality by procedure EuroSCORE

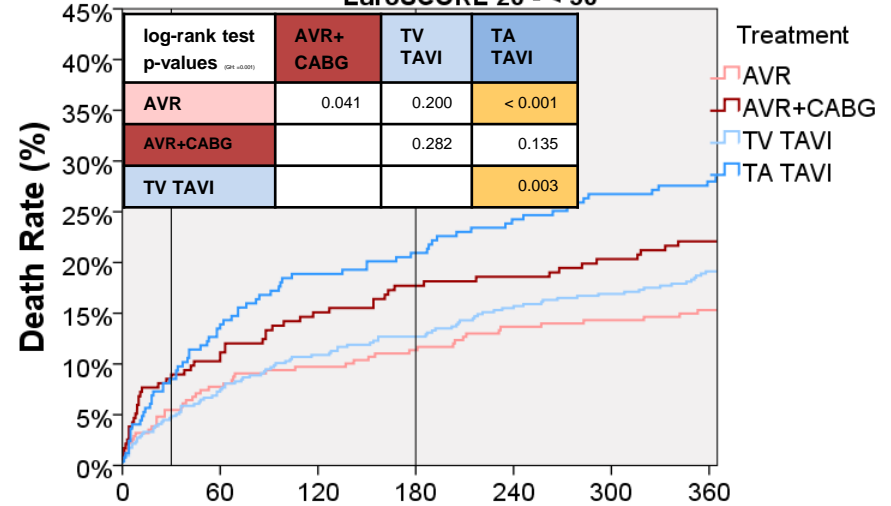


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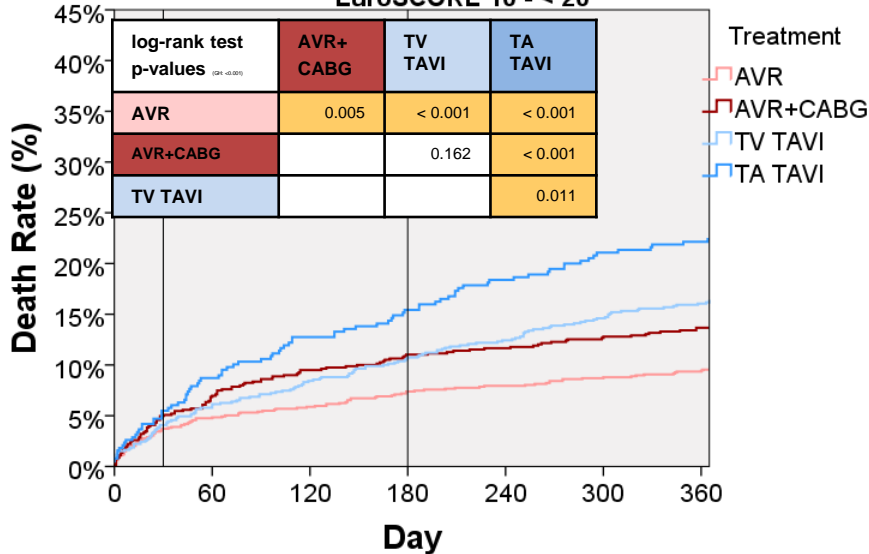
EuroSCORE < 10



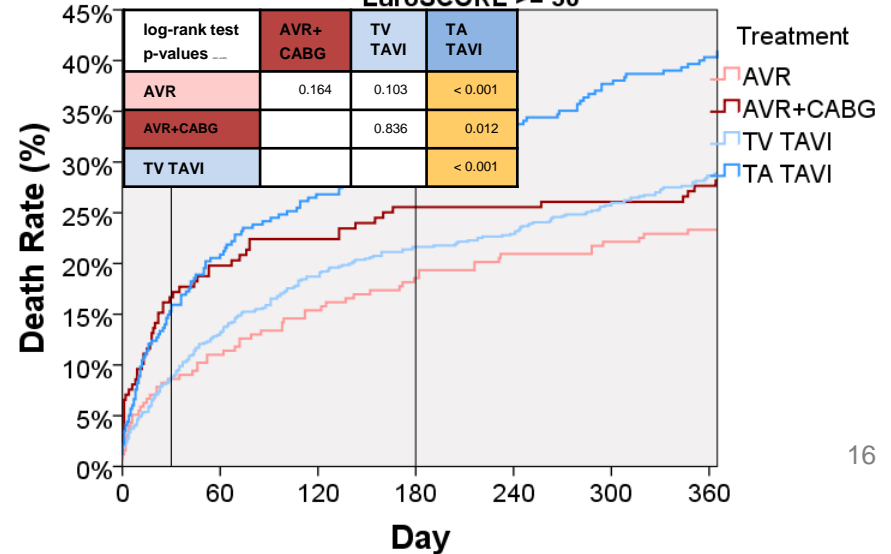
EuroSCORE 20 - < 30



EuroSCORE 10 - < 20



EuroSCORE >= 30



Kaplan-Meier mortality by procedure

German AV-Score (AKL-Score)



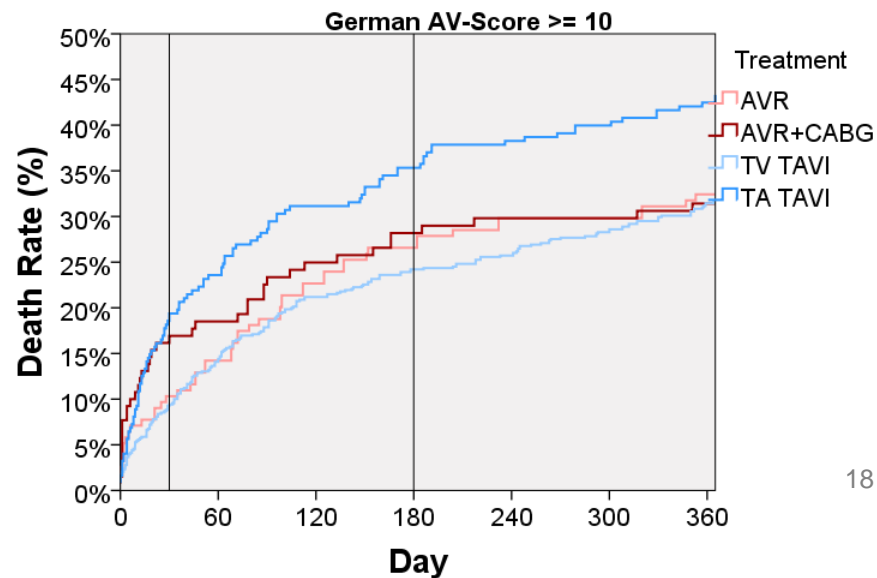
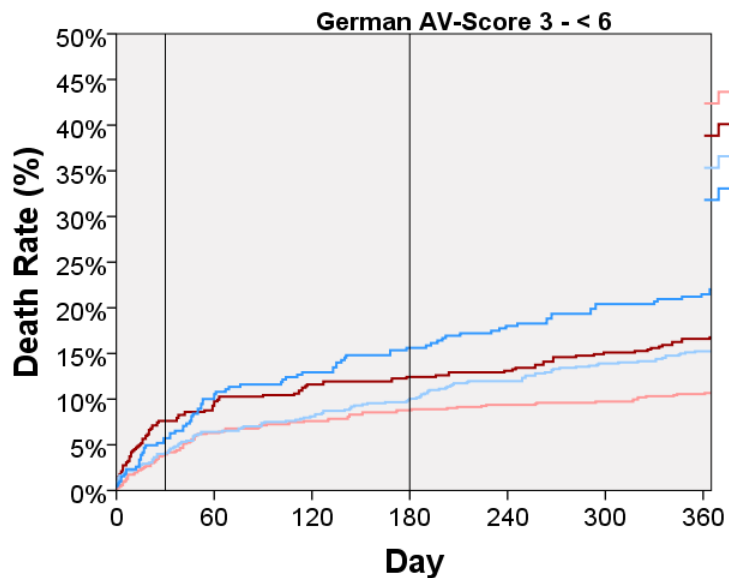
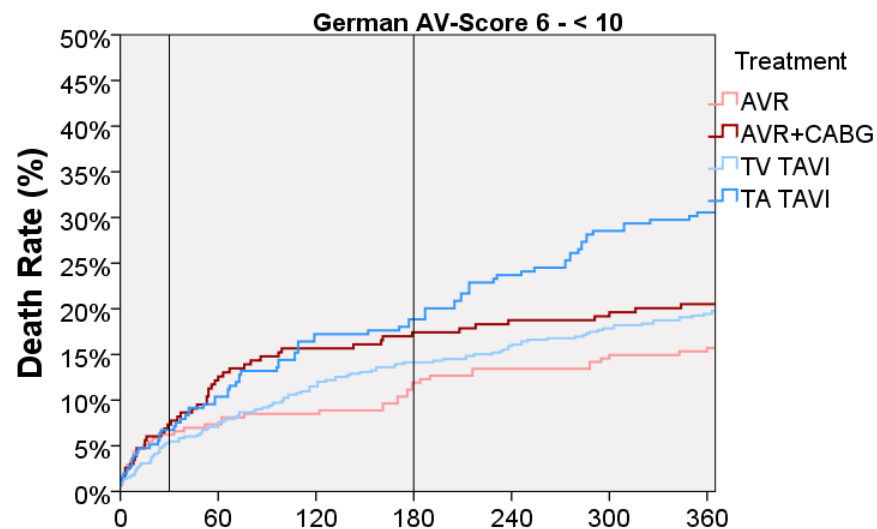
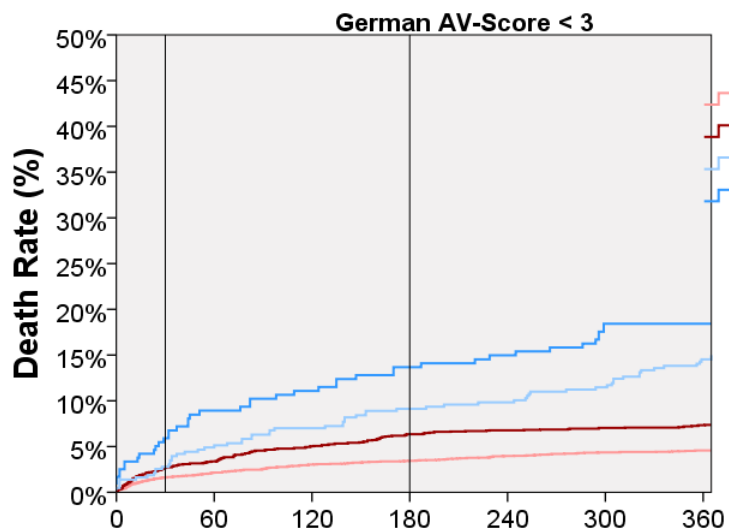
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German AV-Score (AKL-Score)

Kaplan-Meier mortality by procedure German AV-Score (AKL-Score)



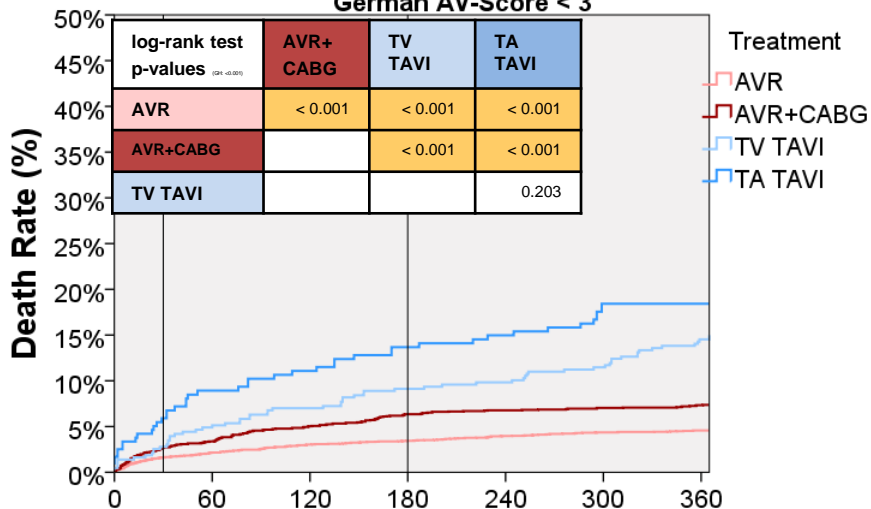
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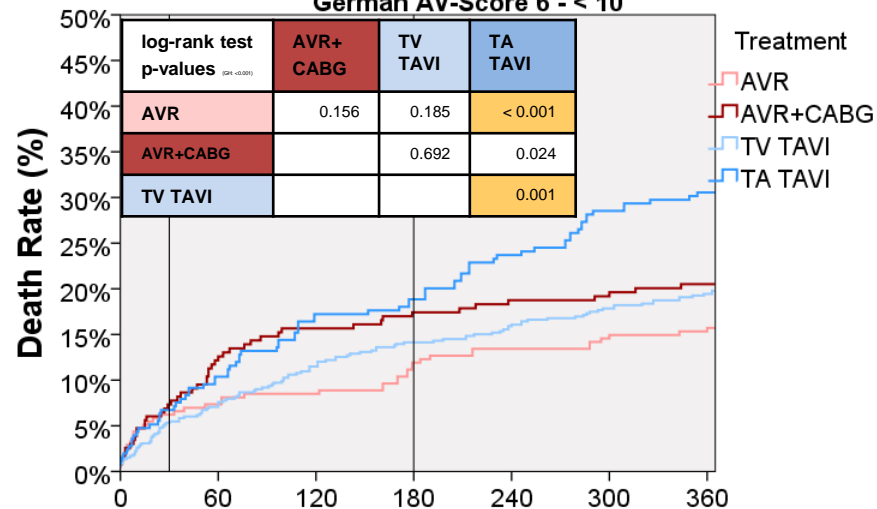
Kaplan-Meier mortality by procedure German AV-Score (AKL-Score)



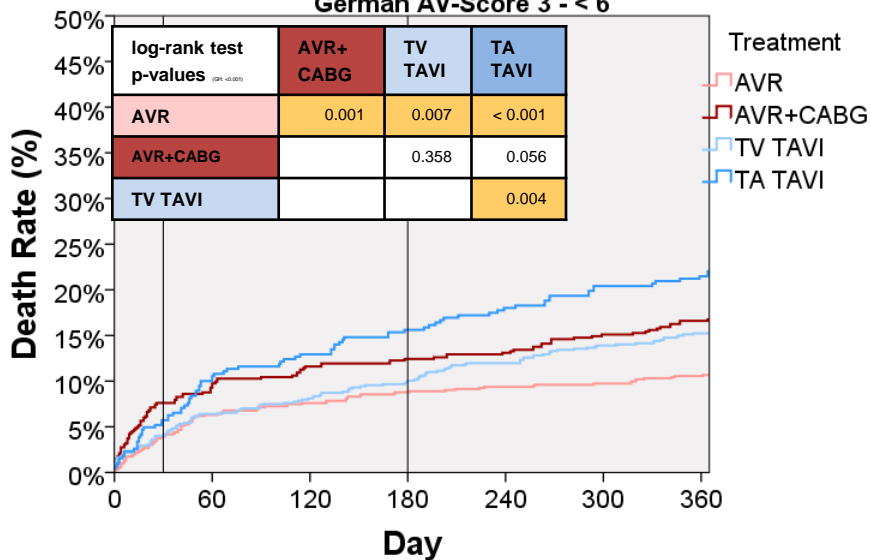
German AV-Score < 3



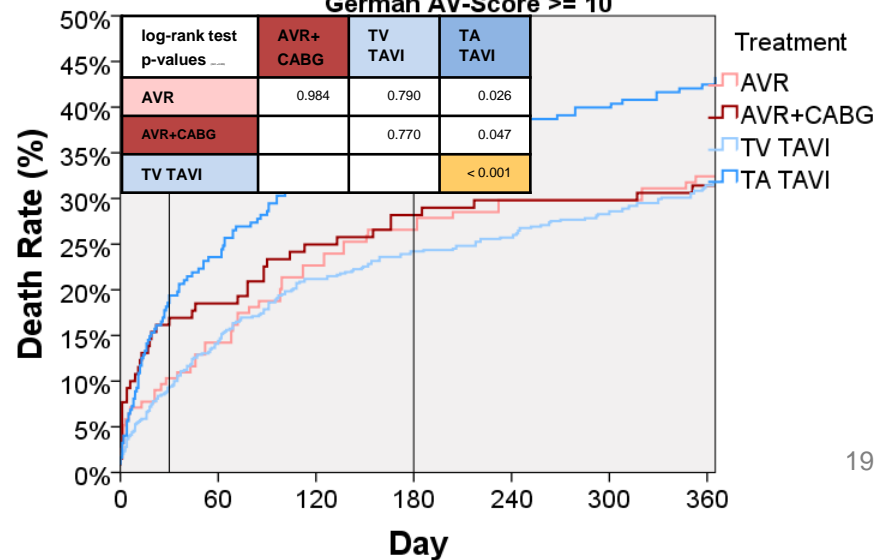
German AV-Score 6 - < 10



German AV-Score 3 - < 6



German AV-Score >= 10

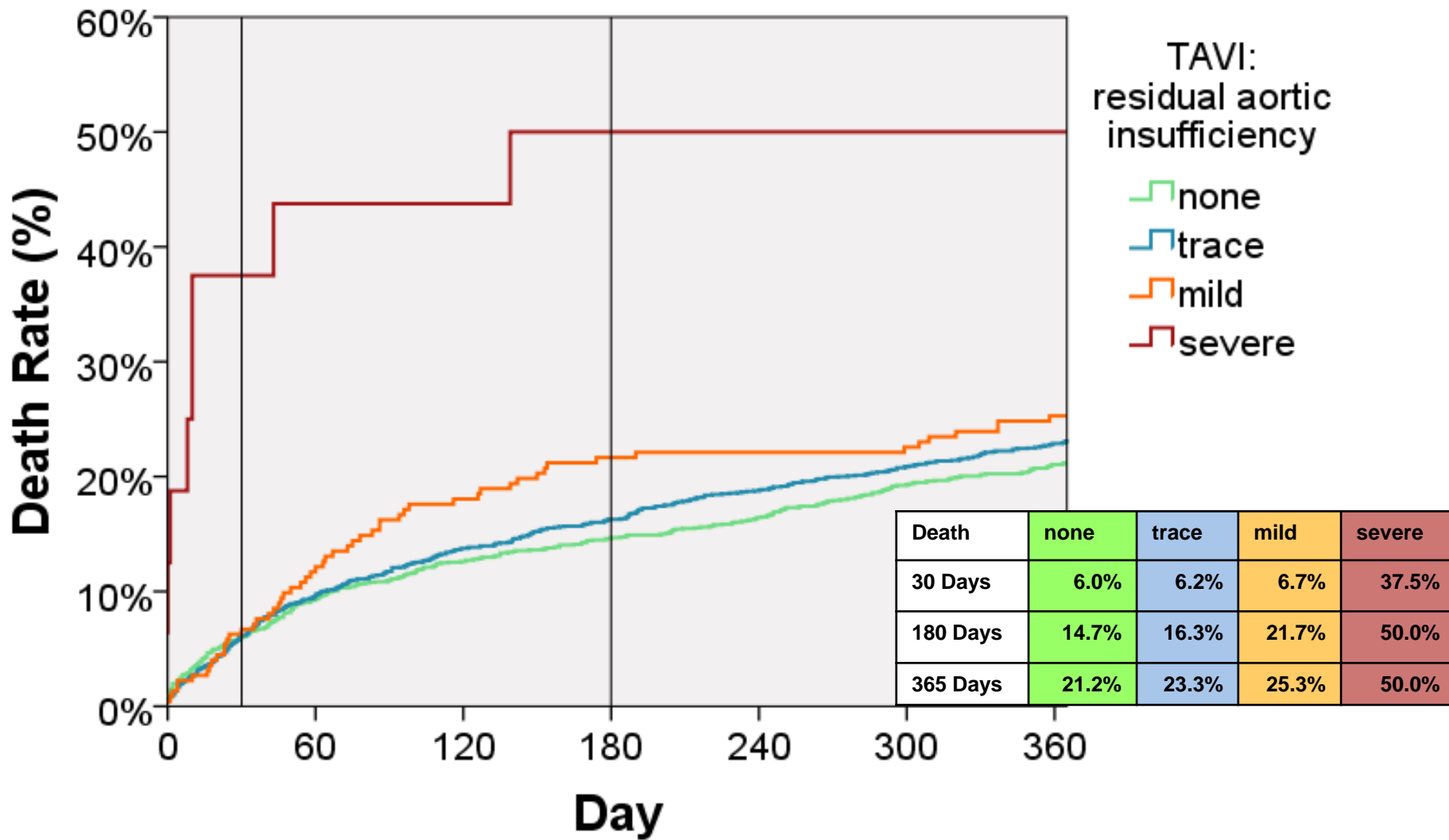


Kaplan-Meier mortality

TAVI: residual aortic insufficiency

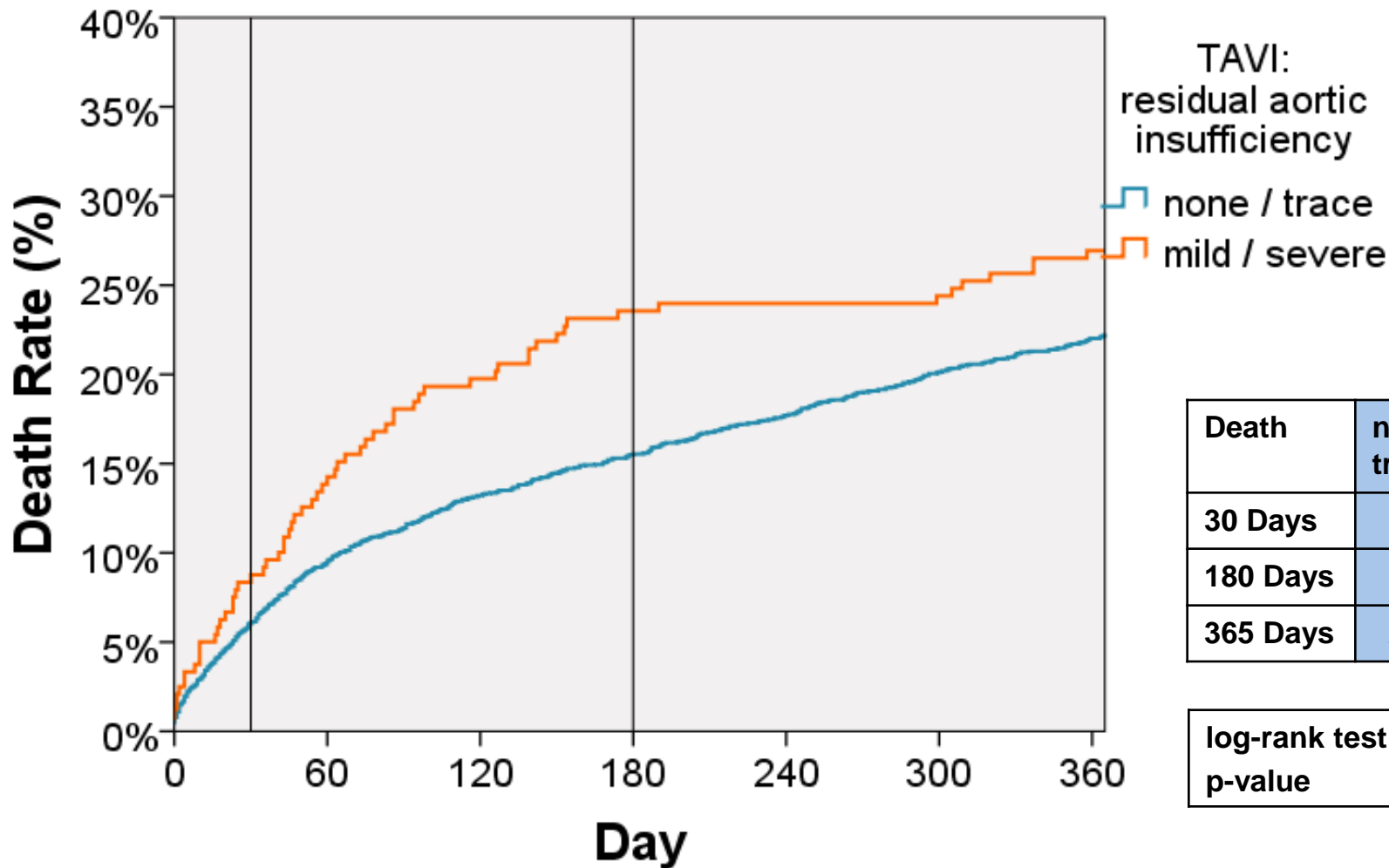


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Kaplan-Meier mortality

TAVI: residual aortic insufficiency

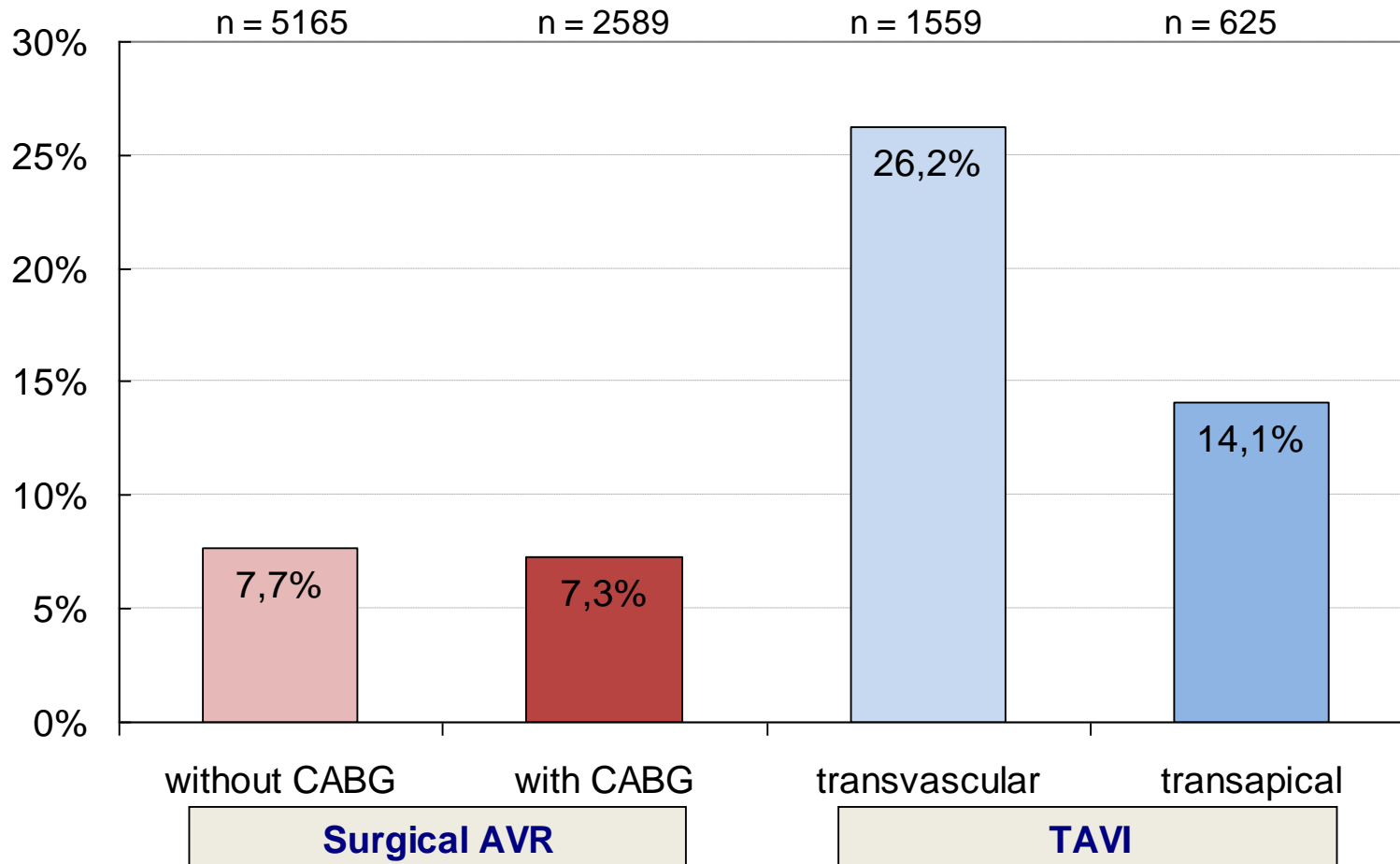


1-year follow-up: interviewed patients

New Pacemaker



1-year follow-up: interviewed patients New Pacemaker

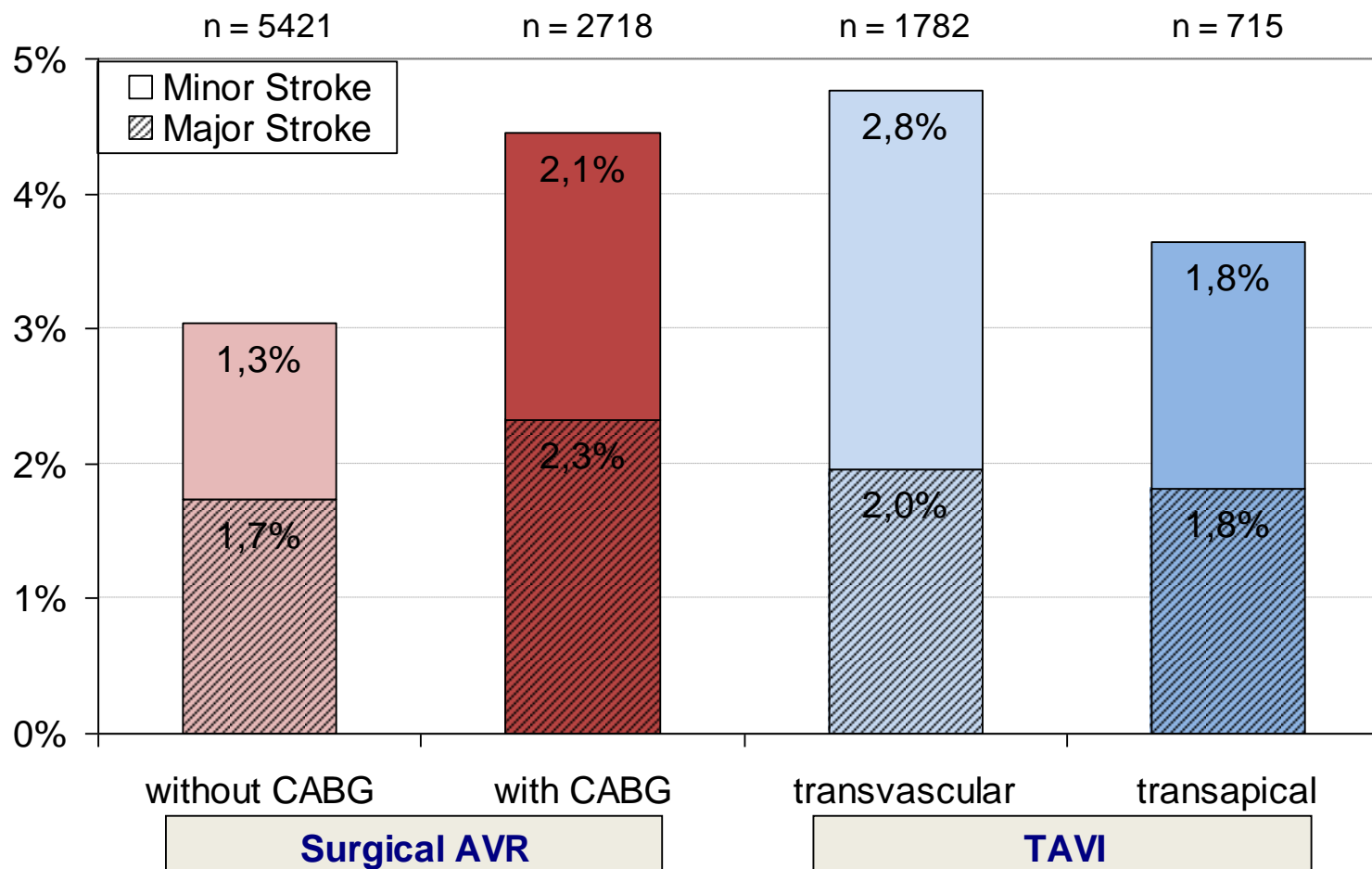


1-year follow-up: interviewed patients

Stroke



1-year follow-up: interviewed patients Stroke



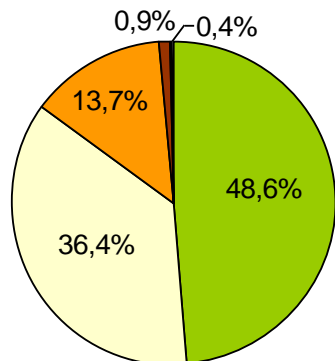
1-year follow-up: interviewed patients

NYHA-classification

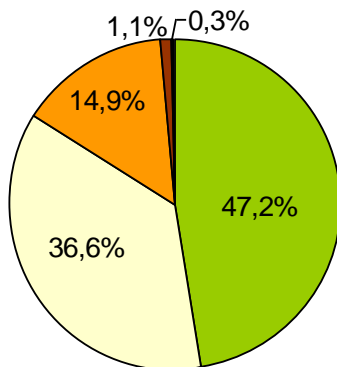


72 to 85 % in NYHA I or II

Surgical AVR

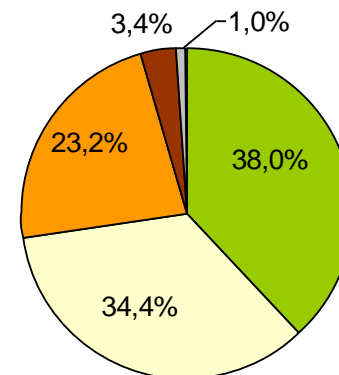


without CABG

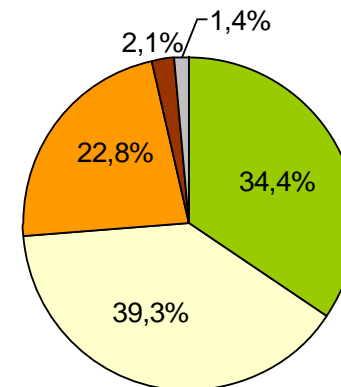


with CABG

TAVI



transvascular



transapical

1-year follow-up: interviewed patients

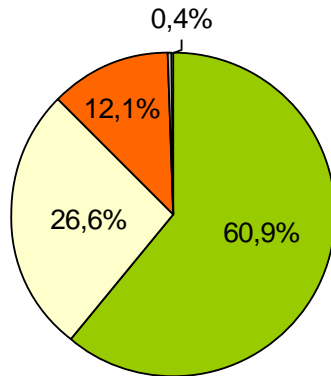
Current state of health vs. state of health before procedure



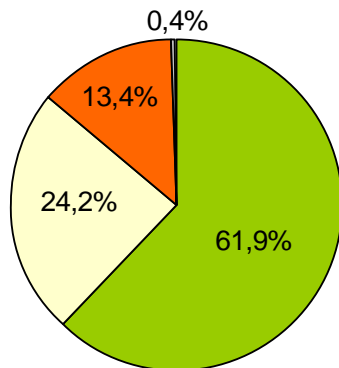
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~ 60 % better than before

Surgical AVR

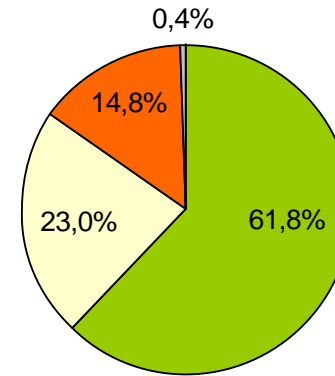


without CABG

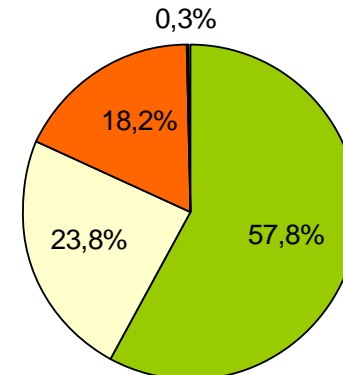


with CABG

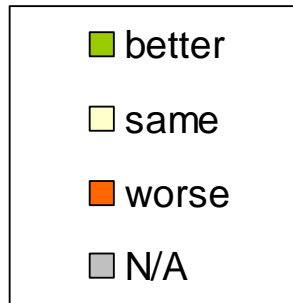
TAVI



transvascular



transapical



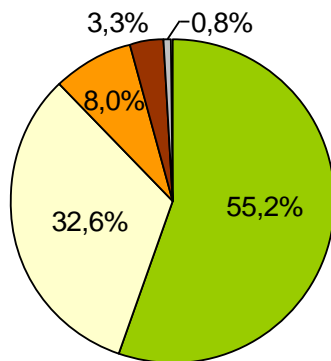
1-year follow-up: interviewed patients

Patient satisfaction 1 year after intervention

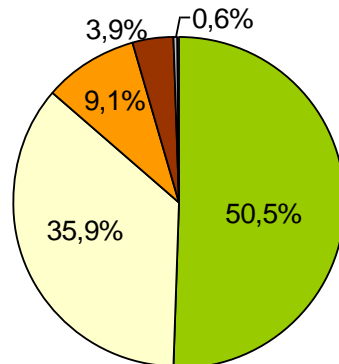


93 – 96 % satisfied with procedure

Surgical AVR

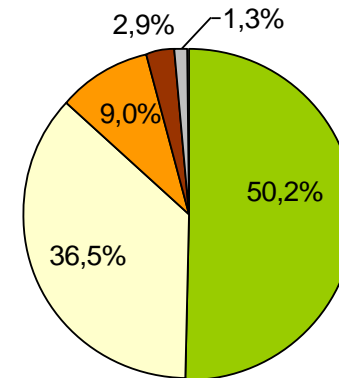


without CABG

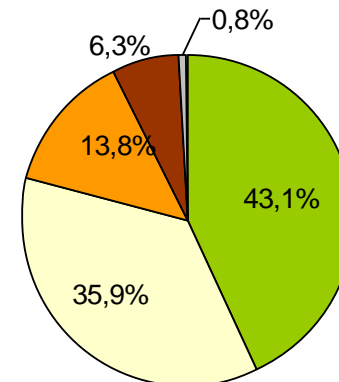


with CABG

TAVI



transvascular



transapical



Conclusion



- First large scale registry on *comparing* surgical & catheter based procedures with 1 year follow-up.
- New AV score good predictor for early outcome
- Continuous increase in mortality after hospital discharge, predominately in high risk groups.
- In low and intermediate risk groups, surgical AVR groups (without CABG) have better outcome than TAVI
- In highest risk groups, TAVI and conventional surgery have equal outcome.

Conclusion

- Mortality equal (TA-TAVI) or better (TV-TAVI) than PARTNER A.
- Good one year clinical outcome (QoL) and high patient satisfaction across all groups.

Limitations:

- Voluntary participation of centers
- The AV risk score is derived predominately from patients with SAVR, a separate risk score for TAVI is under development