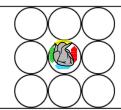


Session VI. Evidence-Based Medicine CornerII: Focus on TEVAR Complications

Stroke Risk after TAVR: Results from a large Meta-Analysis

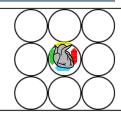
Raimund Erbel, Philpp Kahlert. Holger Eggebrecht
West-German Heart Center Essen, University Duisburg-Essen
Cardioangiological Center Bethanien (CCB), Frankfurt
Germany





I, Raimund Erbel, Essen, Germany have no conflict of interest for this presentation and the topic TAVR itself.

Aim of our Study



Meta-Analysis of risk of stroke in patients undergoing

TAVR as one of the major complication and threat

after PARTNER demonstrating the risk to be

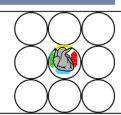
5.5 % and 8.3 % for TF TAVR and

2.4 % and 4.3 % for TA TAVR

at 30 days and 1 year

Eggebrecht H et al,

Methods



Research for: transcatheter, transfemoral, transapical, percutaneous, aortic, valve, implantation
English literature in MEDLINE database

Time window: January 1, 2004 to November 11, 2011

Stage analysis:

1. original articles selected after checking the abstracts

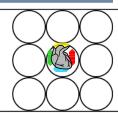
Exclusion: case reports, valve-in-valve TAVR, reviews 2. Full text version analysis for data extraction

For multiple reports, the most recent and complete data set selected

Eggebrecht H et al,



Methods



Research for: transcatheter, transfemoral, transapical, percutaneous, aortic, valve, implantation

English literature in MEDLINE database

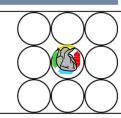
- Group 1: Medtronic/CoreValve
 - 2. TF Edwards Sapien
 - 3. TA Edwards Sapien

Definition: TIA reversible neurological deficit with duration < 24 h
Stroke not reversible neurological deficit
Procedural stroke/TIA defined as any event < 24 h after TAVI

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Results/ Demographics



728 citations be	etwenn January 1,	2004 and Novem	ber 11, 2011
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53 studies selected with 10,037 patients

Gender F	53.1 ±	7.6 %
Age	81.5 ±	1.8 years
Log Euro Score	24.8 ±	5.6 %
CV disease	19.0 ±	7.1 %
Previous stroke	114 +	6 1 %

Porcelain aorta $11.9 \pm 7.4 \%$ Atrial fibrillation $24.8 \pm 6.8 \%$

TF TAVR	66.5 ± 29.9 %
Transaxillary TAVI	$27 \pm 84\%$

TA TAVR $30.8 \pm 40.0 \%$ Medtronic CoreValve $41.8 \pm 42.8 \%$

Edwards Sapien 57.2 \pm 42.4 %

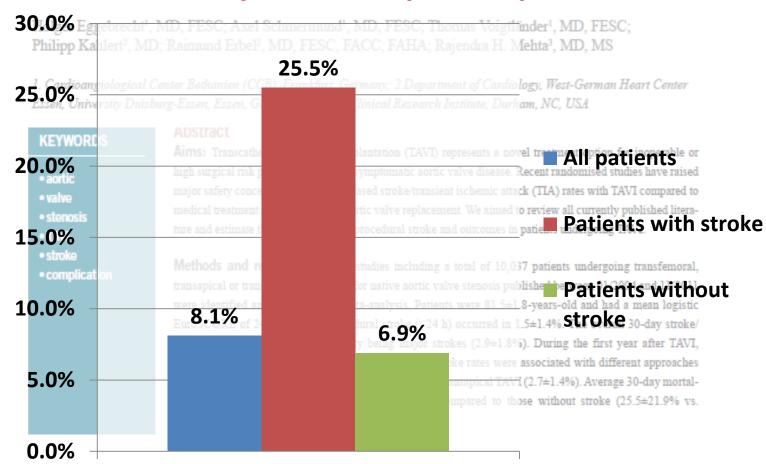
Eggebrecht H et al,

EuroIntervention 2012, 8: 129-138

CCD Cardioangiologisches

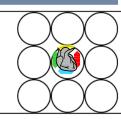


Risk of stroke after transcatheter aortic valve implantation (TAVI): a meta-analysis of 10,037 published patients



30 day mortality

Results: Stroke/TIA



728 citations betwenn January 1, 2004 and November 11, 2011 53 studies selected with 10,037 patients

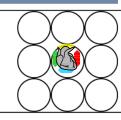
812 events

Procedural stroke < 24 h	1.5 ± 1.4 %
30 day stroke/TIA	$3.3 \pm 1.8 \%$
30 day major stroke	$2.9 \pm 1.8 \%$
30 day minor stroke/TIA	$1.0 \pm 1.3 \%$
30 day mortality	$8.1 \pm 3.9 \%$
30 day mortality in stroke pts	25.5 ± 21.9 %
30 day mortality no stroke	$6.9 \pm 4.2 \%$
6 months stroke	4.3 ± 1.6 %
12 months stroke	$5.2 \pm 3.4 \%$

Eggebrecht H et al ,



Results: Stroke/TIA: comparison of different valves

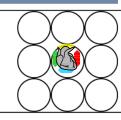


Me	dtronic CoreValve	Edwards Sapien
Patient/N	2733	1733
Age/years	81.1 ± 1.3	82.3 ± 2.6
Log EuroScore/%	22.1 ± 3.7	25.6 ± 4.2
Procedureal stroke < 24 h/%	$6 1.4 \pm 1.5$	2.1 ± 3.0
30 day stroke/TIA %	(3.1 ± 2.2)	4.2 ± 2.2
30 day major stroke/%	2.5 ± 1.8	3.0 ± 2.0
30 day minor stroke/TIA %	0.7 ± 1.4	1.7 ± 1.8
30 day overall mortality/%	6.4 ± 5.1	6.9 ± 3.8

Eggebrecht H et al,



Results: Stroke/TIA comparison of different routes



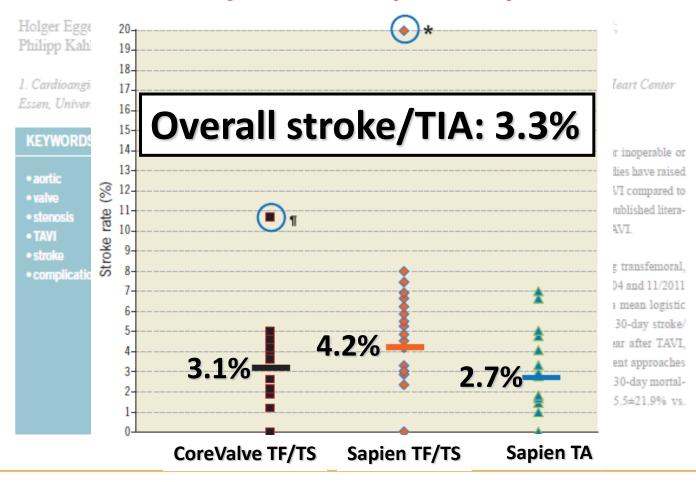
	Transfemoral	Transapical
	Edwards Sapien	Edwards Sapien
Patient/N	1733	1733
Age/years	82.3 ± 2.6	81.0 ± 1.6
Log EuroScore/%	25.6 ± 4.2	29.1 ± 7.5
Procedureal stroke < 24 h/	$^{\prime}\%$ 2.1 ± 3.0	0.7 ± 1.5
30 day stroke/TIA %	4.2 ± 2.2	2.7 ± 1.4
30 day major stroke/%	3.0 ± 2.0	2.5 ± 1.5
30 day minor stroke/TIA %	1.7 ± 1.8	0.8 ± 1.4
30 day overall mortality/%	6.9 ± 3.8	10.6 ± 4.2

Eggebrecht H et al,

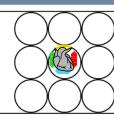




Risk of stroke after transcatheter aortic valve implantation (TAVI): a meta-analysis of 10,037 published patients



Results: Stroke/TIA: comparison of different regions

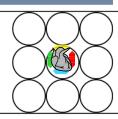


	USA/Canada	Europe
Patient/N	1.677	8.360
Valve type	Edwards	Edwards/MCV 50/50
Age/years	82.6 ± 1.7	81.2 ± 1.7
Log EuroScore/%	28.4 ± 4.3	24.3 ± 5.7
Procedureal stroke < 24 h/%	1.1 ± 0.8	1.7 ± 1.6
30 day stroke/TIA %	4.7 ± 1.9	3.1 ± 1.7
30 day major stroke/%	3.8 ± 2.0	2.6 ± 1.7
30 day minor stroke/TIA %	1.8 ± 1.5	0.7 ± 1.2
30 day overall mortality/%	8.1 ± 3.7	8.1 ± 4.0

Eggebrecht H et al,



Limitations of the Study

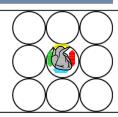


- no focus on stroke during the procedure
- minor strokes underestimated as 87 % of all strokes were major strokes
- no standardized definition of neurologic events according to the VARC criteria
- lack of control groups managed medically or by AVR
- nearly only historical controls

Eggebrecht H et al,

CCB Cardioangiologisches Centrum Bethanien

Conclusion

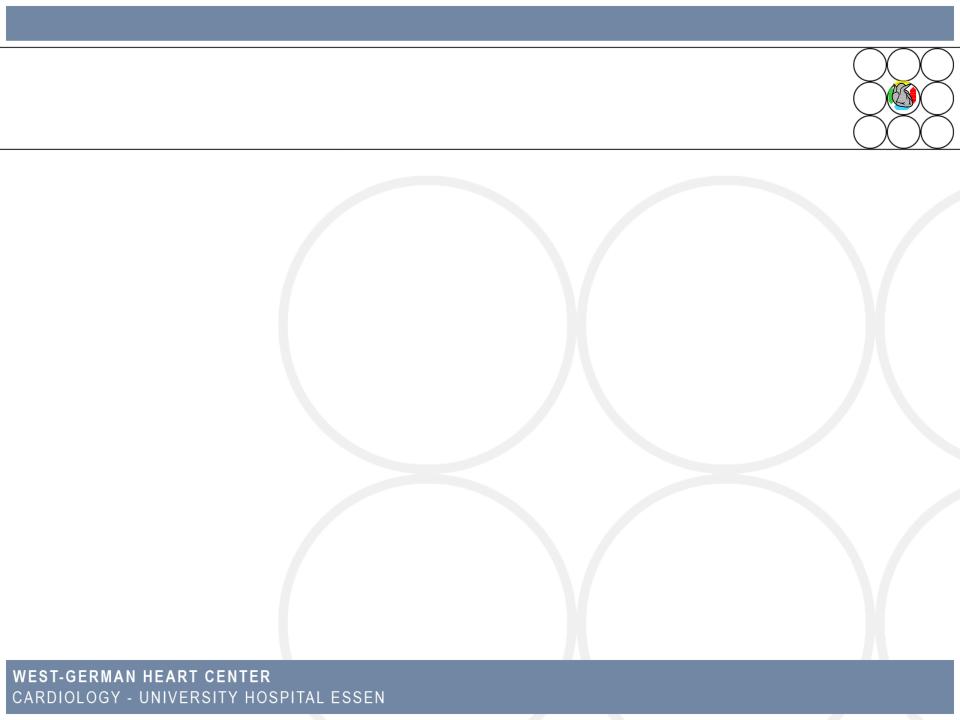


- in 10.037 patients reveiving TAVR stroke risk 3.3 \pm 1.8 %
- 1-year rate remains low with 5.2 \pm 3.4 %
- 6/7 strokes are major rather than minor meaning disability
- 50 % persistent neurological problems
- TA Edwards lowest event rate
- TF Medtronic/CoreValve lower rate than TF Edwards Sapien
- Corresponding PARTNER B medical therapy 1.7 % 30 day and 4.5 % 1-year stroke/TIA

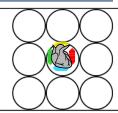
Thus, stroke/TIA are a severe complication and all efforts have to be addressed in order to reduce these disabiling events

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Conclusion



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VIEWPOINT

The Problem With Asymptomatic Cerebral Embolic Complications in Vascular Procedures

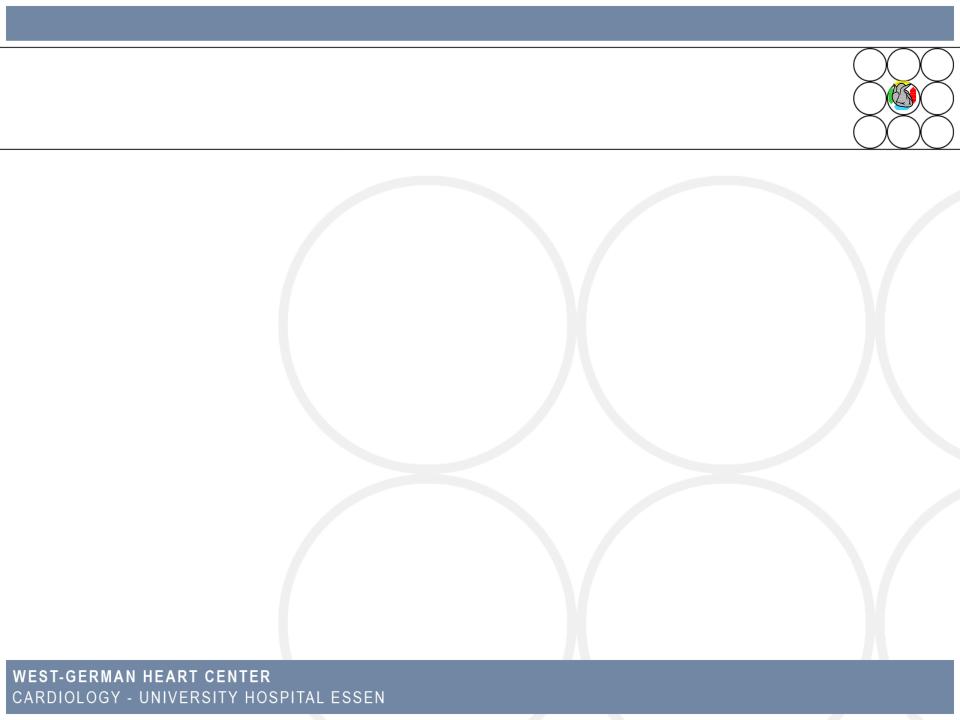
What If They Are Not Asymptomatic?

decline, and dementia related to these so-called silent infarcts. Literature reports of magnetic resonance imaging events lead to an estimate of as many as 600,000 patients with new brain injury each year in the United States alone. Given the magnitude of the numbers involved, the impact of accelerated cognitive loss and premature senescence in a vulnerable at-risk population could well be significant. (J Am Coll Cardiol 2012;xx:xxx)
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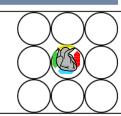
decline, and dementia related to these so-called silent interests. Literature reports of magnetic resonance imaging events lead to an estimate of as many as 600,000 patients with new brain injury each year in the United States alone. Given the magnitude of the numbers involved, the impact of accelerated cognitive loss and premature senescence in a vulnerable at-risk population could well be significant. (J Am Coll Cardiol 2012;xx:xxx)

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Methods



Research for: transcatheter, transfemoral, transapical, percutaneous, aortic, valve, implantation
English literature in MEDLINE database

Statistics

Individual rates for different studies and combination of these rates

into a weighted average

Weights defined as the proporation of available patients provided

in a specific study

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