

Lessons from European Registries

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Disclosure

Consultant / Proctor for Edwards Lifesciences

TAVI is a medical breakthrough

~ 80 000 valves implanted worldwide
(> 500 centers in Europe)
with two currently used devices



Balloon expandable
Edwards
(Sapien or XT)

In Europe

No randomized
comparison with AVR

No randomized
comparison of the
2 devices

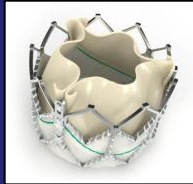
Multiple registries using
with each device
or the two devices



Self expanding
Medtronic
CoreValve

Several recent national or interventional registries allow a good overview of the current results of TAVI in the real life

European Registries



2 valves

FRANCE 2

34 centers

3933 consecutive pts

Belgium Registry

18 centers,

600 consecutive pts

UK Registry

26 centers

872 consecutive pts

German Registry

22 centers

833 consecutive pts

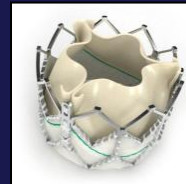


1 valve



SOURCE Registry

2307 pts Edw Sapien



SOURCE XT

(lower risk)

2681 pts



ADVANCE study

1015 Pts



Italian Registry

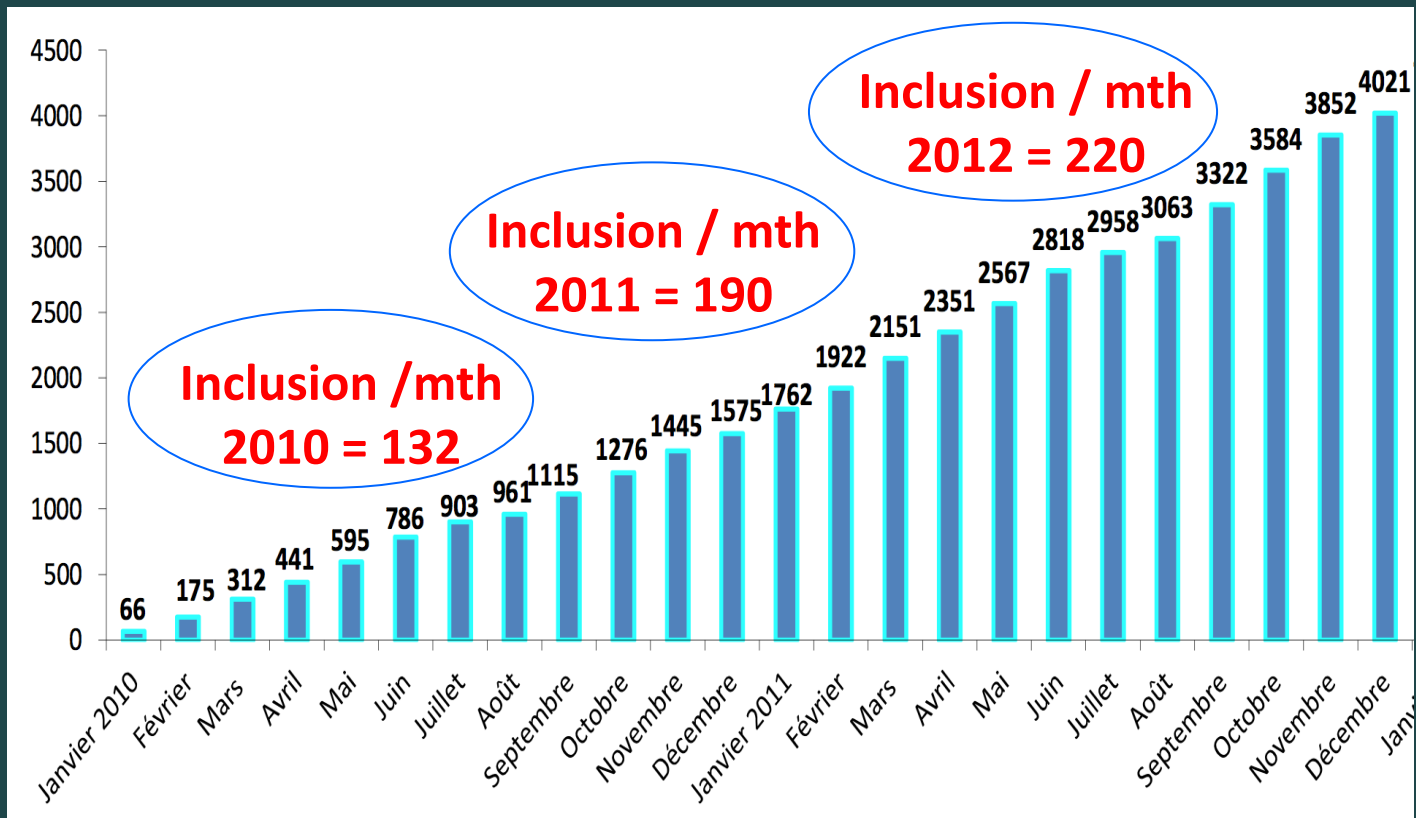
663 pts

Other national registries

FRANCE 2 Registry, *New Eng J of Medicine 2012*

33 centers, 5 587pts (06-2012)

A fast growing enrollment



FRANCE 2 Registry

Baseline Demographics and Risk Factors

Age, y	82.8 ±7
Female, %	49.5 %
Previous MI, %	16.2 %
CAD, %	47.9 %
Previous CABG, %	17.9%
PAD, %	20.4%
Previous Stroke, %	9.9%
Dialysis, %	2.6%
Previous AVR	1.7%

Risk scores

L. Euroscore, %	21.8 ± 14
STS, %	14.1 ± 12

NYHA

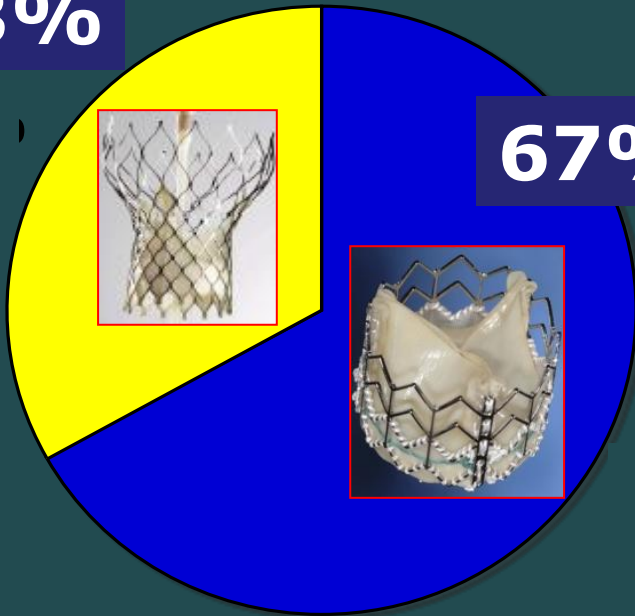
I - II	III - IV
24.6 %	75.4 %

FRANCE 2 Registry

Valves and approaches

Valves

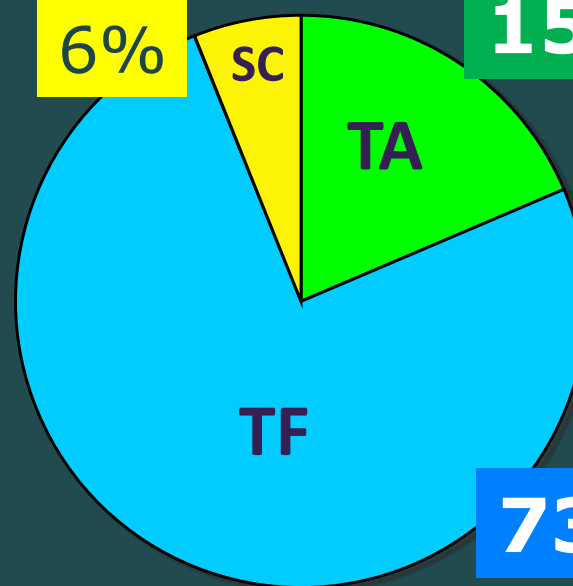
33%



67%

Approach

6%



15%

73%

Device success rate: 97.0% (3929/3933)

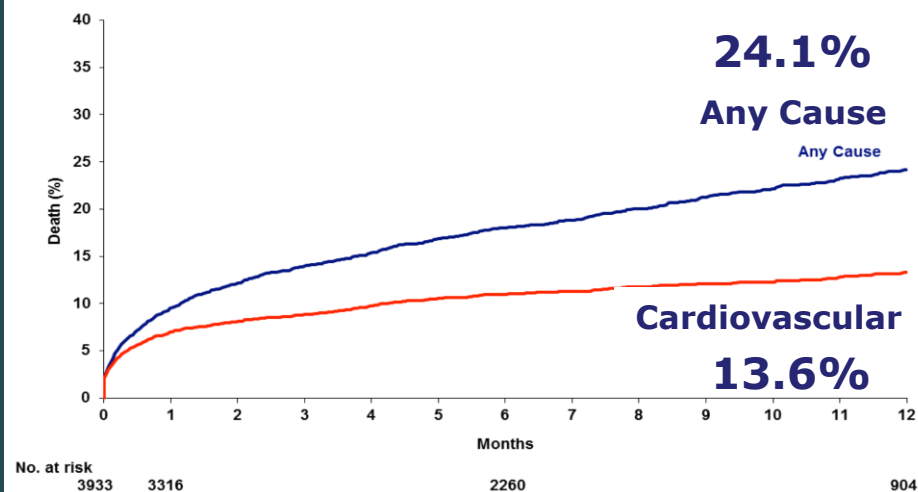
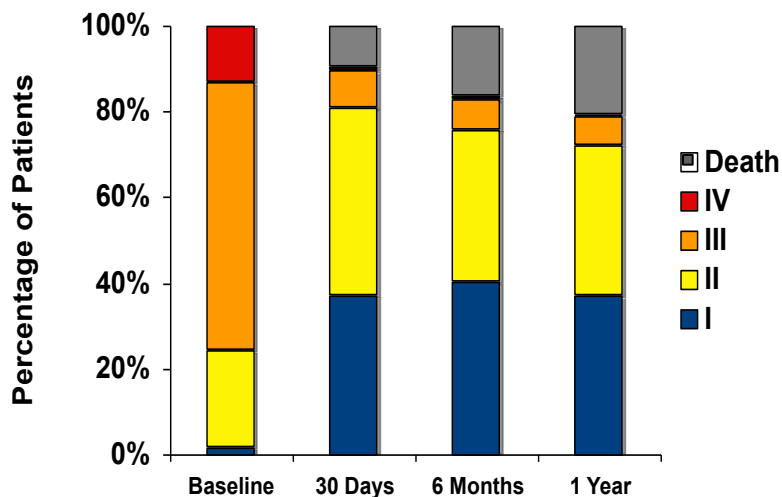
FRANCE 2 Registry

Clinical outcomes Major complications at 1 month

	Global N = 3933	Edwards N= 1634	CoreValve N=785
Vascular complications	11.8%	11.6%	12.2%
New Pacemaker	15.8	11.8%	24.0%
Bleeding(+tamponade)	17.7%	17.8%	17.5%
Stroke	4.6%	4.6%	4.7%

FRANCE 2 Registry

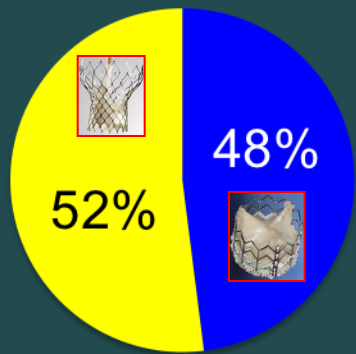
Clinical outcome: Symptoms and Mortality



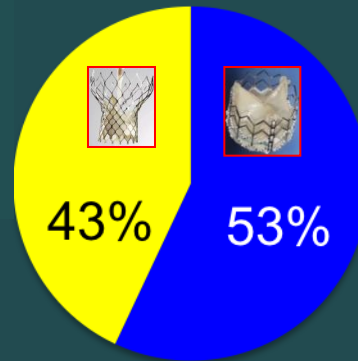
	30-day		6-month		12-month	
Global	367	9.5 %	640	18 %	762	24.1 %
CV	269	7.0 %	389	11 %	430	13.6 %

European Registries: valves / approaches

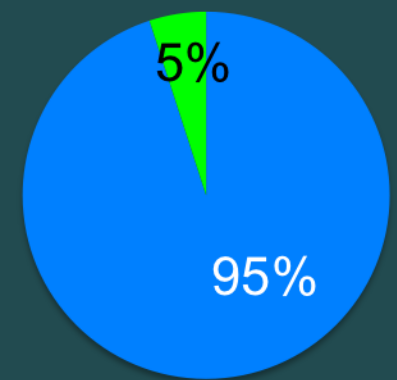
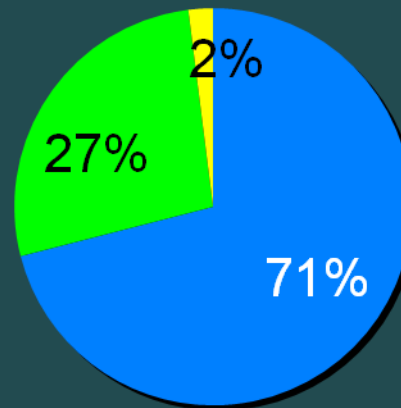
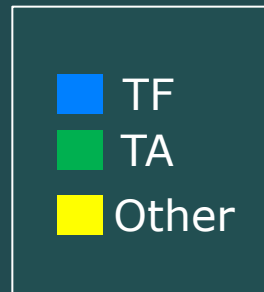
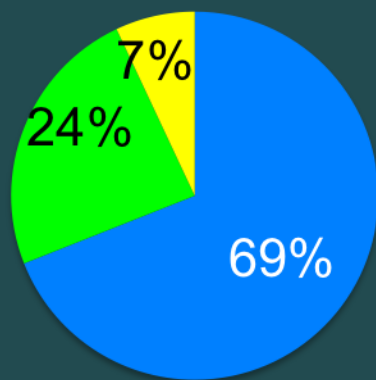
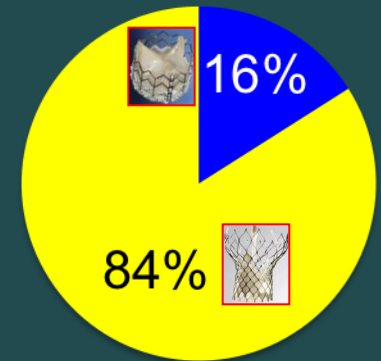
U.K.TAVI



Belgian TAVI



German TAVI



European Registries: 2 valves

Demographics and results

	French	UK	Belgium	German
Age (yr)	83±6	83±7	83±6	81±6
LVEF (%)	55±14	>50: 64%	53±15	52±15
Log Euroscore (%)	22±14	22±6	26±16	21±13
Procedure success (%)	97	99	98	98.7
New Pacemaker (%)	15.8	6E / 26CV	14	39
Stroke (%)	4.6	4.5	5	2.8
1-month survival (%)	90	93	92	88
1-year survival (%)	76	80.3		

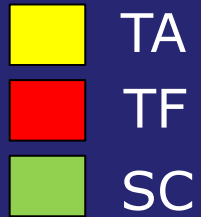
SOURCE and SOURCE XT registries TCT 2012

-Edwards-

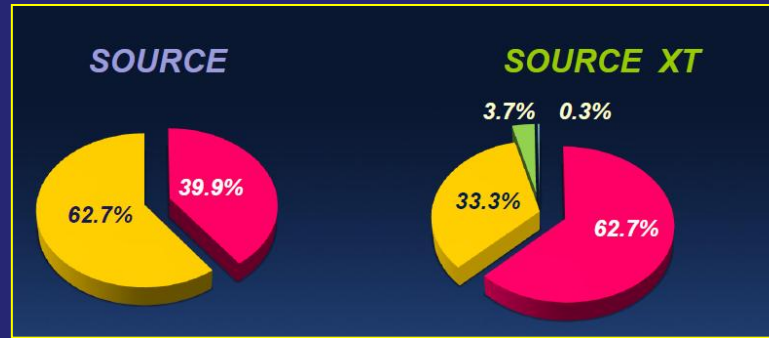
	SOURCE		SOURCE XT
	Cohort 1 N=1038	Cohort 2 N=1269	XT N=2681
	Nov 07- Jan 09	Feb 09 – Dec 09	Dec 10 – Jun 11
THV	SAPIEN		SAPIEN XT
TF Del. Sys.	Retroflex		Novaflex
TA Del. Sys.	Ascendra		Ascendra 2
STS, %	12.7 ± 9.6	8.4 ± 7.0	P<0.0001
Euroscore, %	26.0 ± 15.2	20.5 ± 12.6	p<0.0001

Martin Thomas, MD

SOURCE and SOURCE XT registries TCT 2012

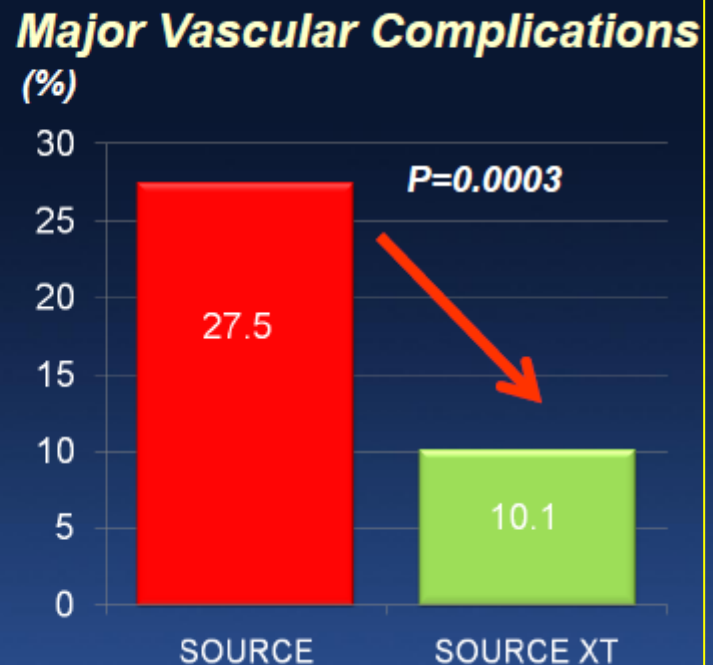
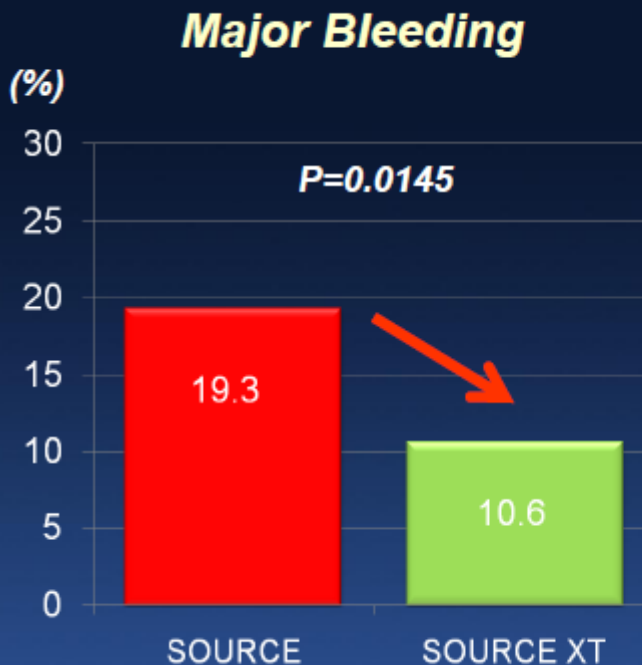


More TA



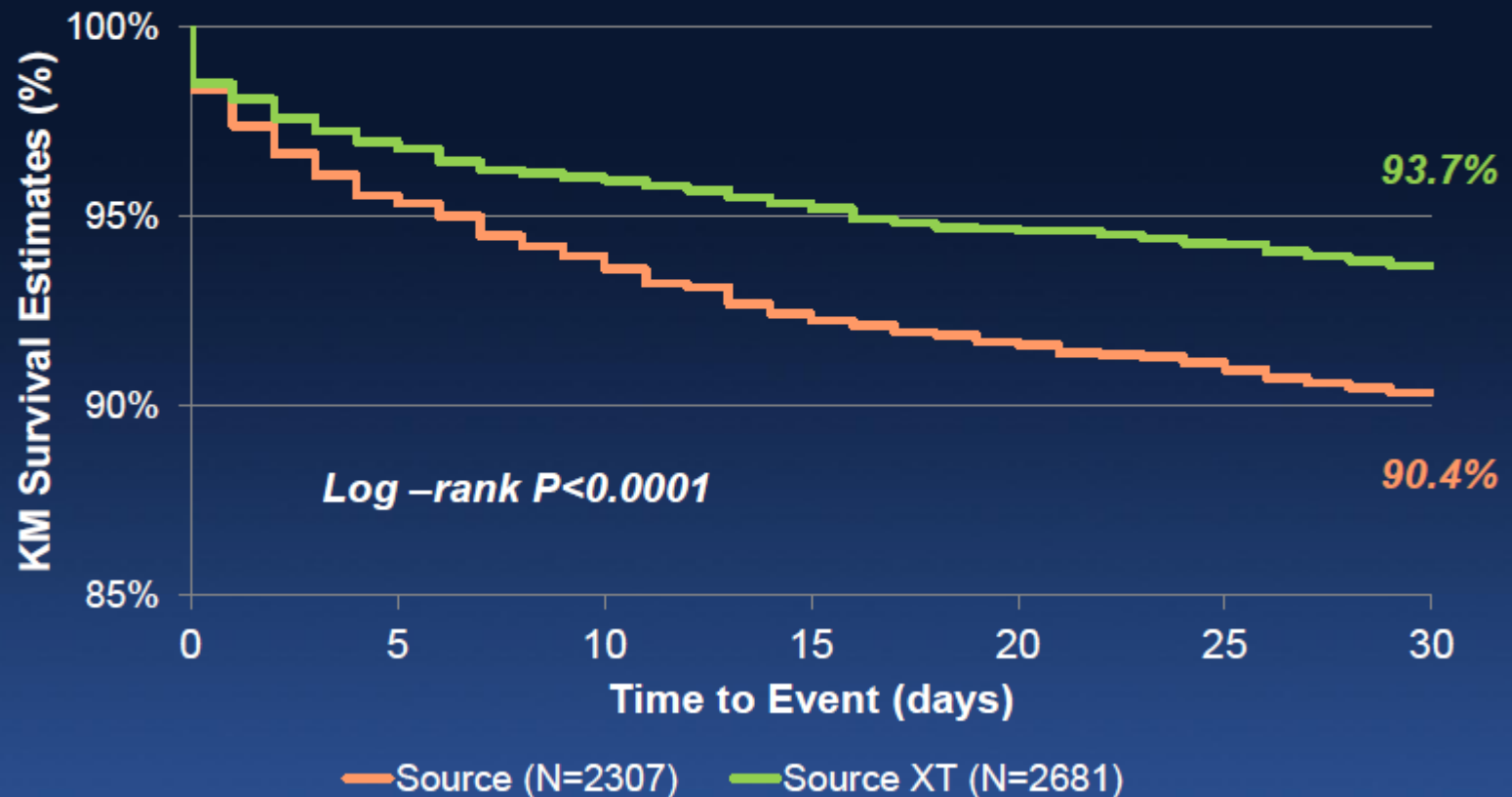
More TF

Mortality After Major Complications



SOURCE and SOURCE XT registries TCT 2012

Overall Mortality at 30 DAY



SOURCE and SOURCE XT registries TCT 2012

Clinical Outcomes at 30 Days

Characteristics	SOURCE N = 2307	SOURCE XT N = 2681	P Value
All-cause Mortality (%)	9.6	6.3	<0.0001
Cardiac mortality (%)	4.0	2.6	0.0072
Any Stroke (%)	4.7	2.2	<0.0001
Vascular Complication –Major (%)*	5.0	14.5	<0.0001
Major Bleeding (%) *	3.6	8.0	<0.0001
Ventricular Injury (%)	0.3	0.2	0.2453
MI (%)	0.7	0.6	0.7896
New pacemaker	7.2	9.5	0.0027

CoreValve ADVANCE Study TCT 2102

1015 Patients 03/2101 – 07/2011

44 centers, 12 Countries

Axel Linke, MD

Procedural results

Procedural Parameters	N=996	%
Successful vascular access, delivery & deployment of device & successful retrieval of the delivery system		97.8
Correct position of the device in the proper anatomical location		98.7
Mean aortic valve gradient < 20 mmHg		96.2
No severe AR requiring intervention		97.9
Only one valve implanted in the proper anatomical location		96.0

Major Complications; Valve Related	N=996	%
Annulus Rupture		0.0
Valve Embolization		0.3
Conversion to open AVR		0.1
Coronary Compromised		0.1

CoreValve ADVANCE Study TCT 2102

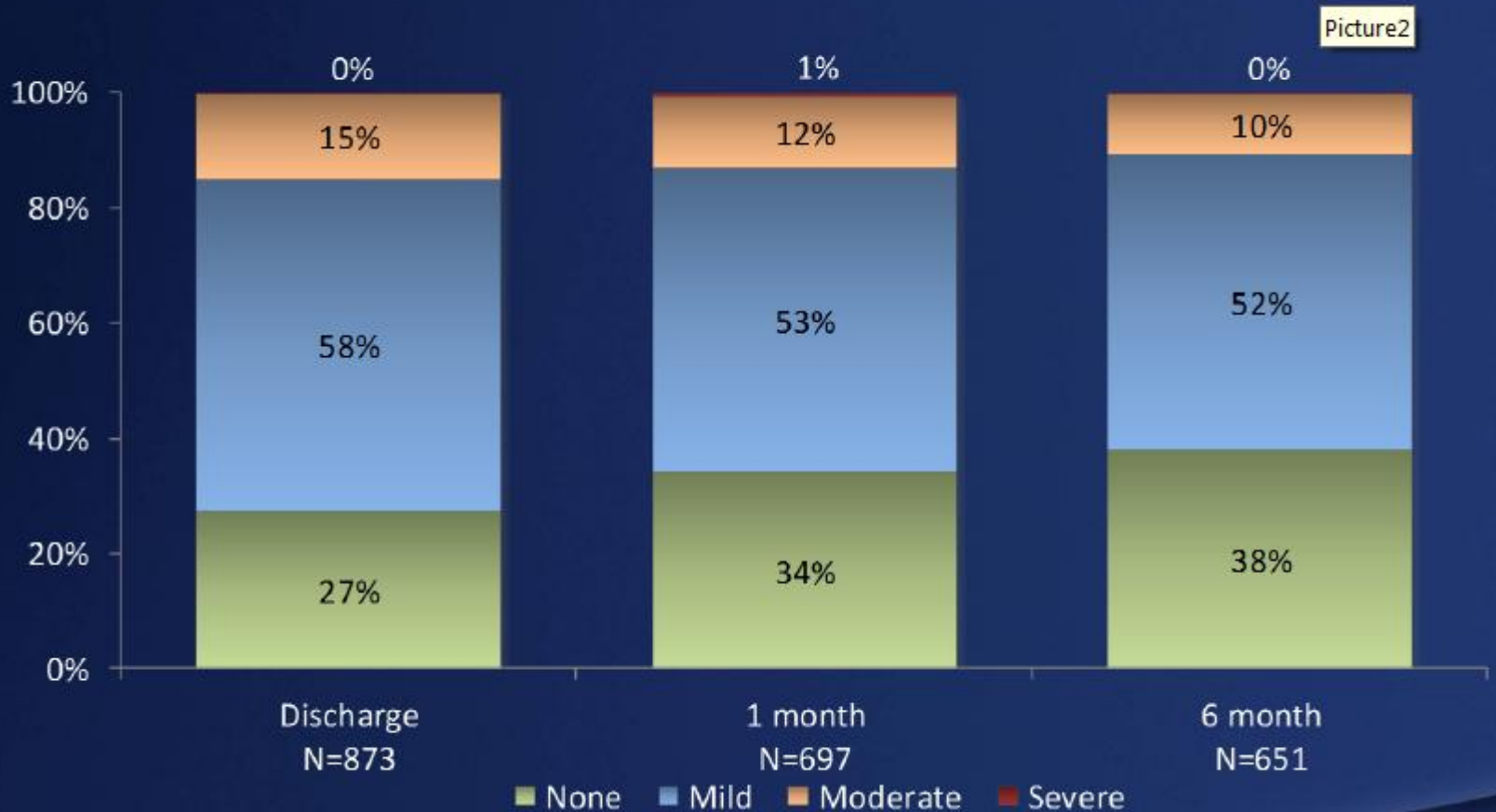
Outcomes at 30 Days

Primary Endpoint	N=996	Kaplan-Meier Estimates, %
MACCE		8.3
All-cause Mortality		4.5
Myocardial Infarctions		0.2
Emergent cardiac surgery or percutaneous re-intervention		1.7
Stroke		2.9
Additional VARC Endpoints	N=996	Kaplan-Meier Estimates, %
Cardiovascular Mortality		3.4
Major Bleeding		9.7
Life Threatening Bleeding		4.0
Major Vascular Complications		10.7
Acute Kidney Injury - Stage III		0.4
Additional Endpoint	N=996	Kaplan-Meier Estimates, %
New Pacemaker Implantation		26.3

CoreValve ADVANCE Study TCT 2102

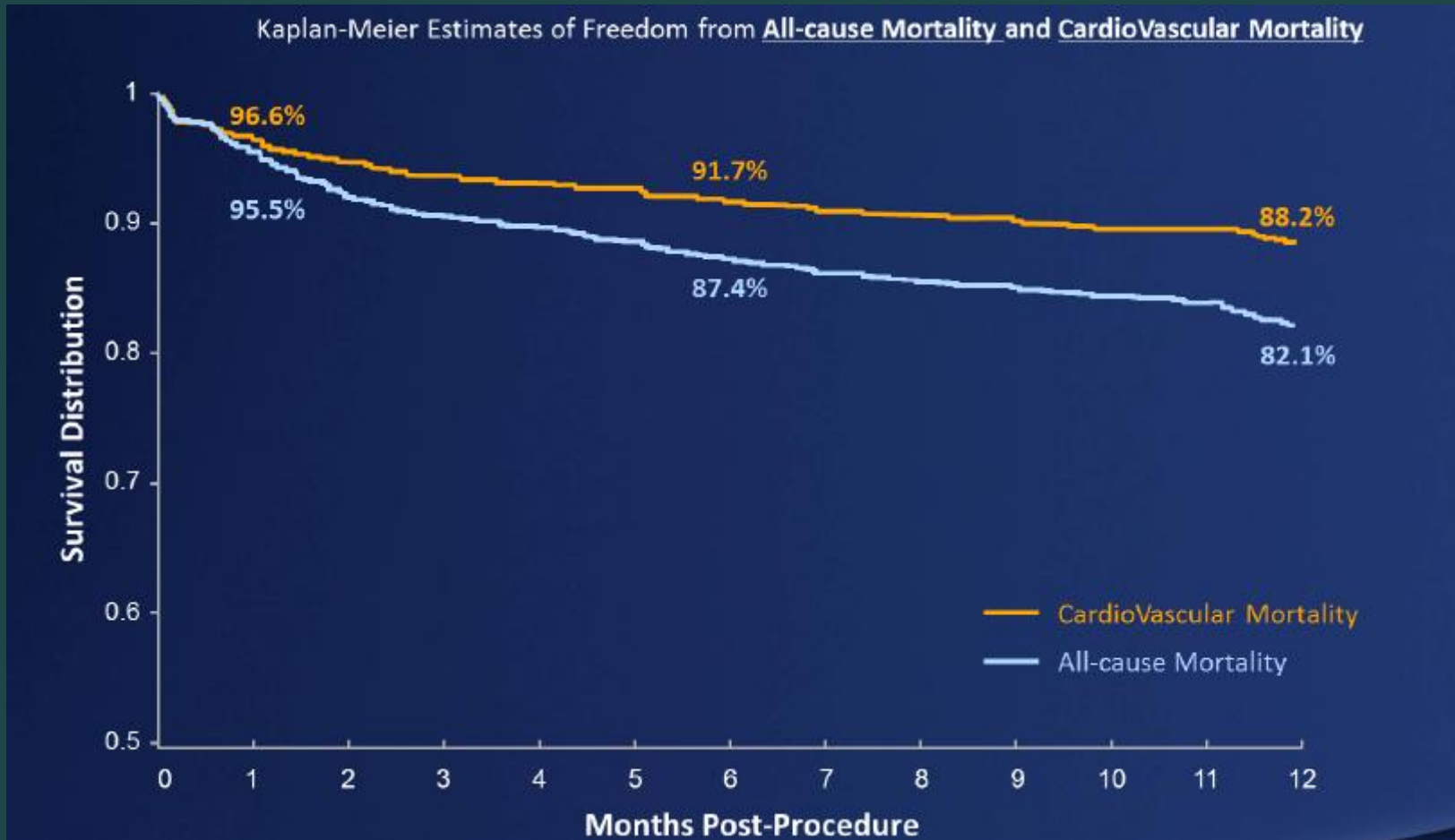
Paravalvular Leak

echo assessment



CoreValve ADVANCE Study TCT 2102

1 Year Survival

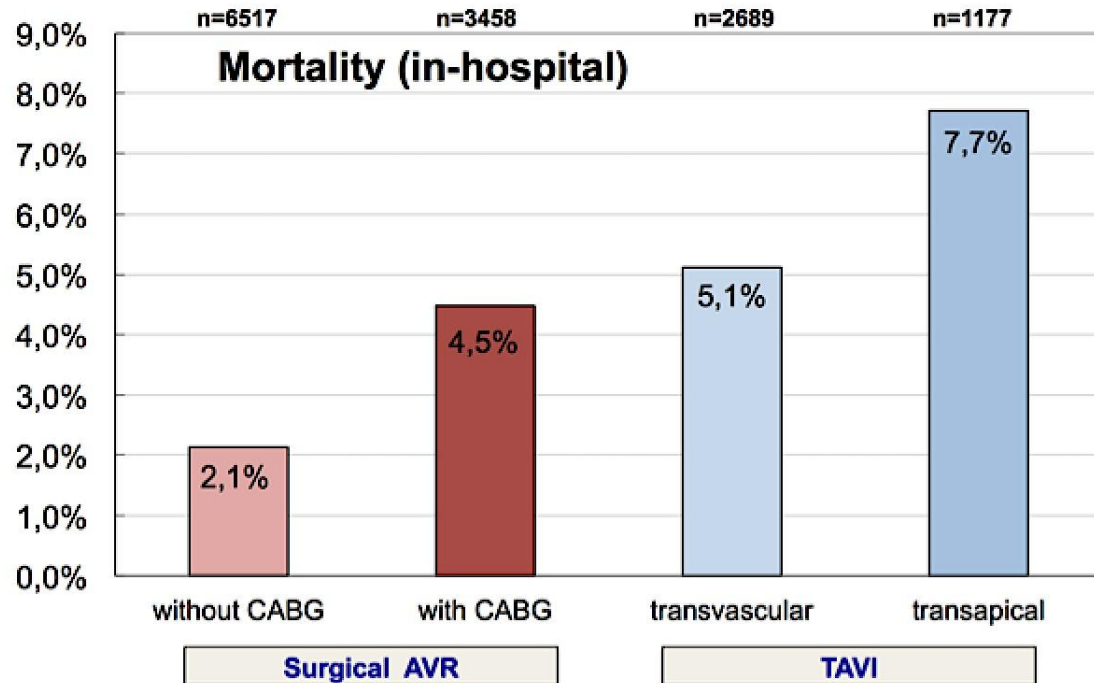
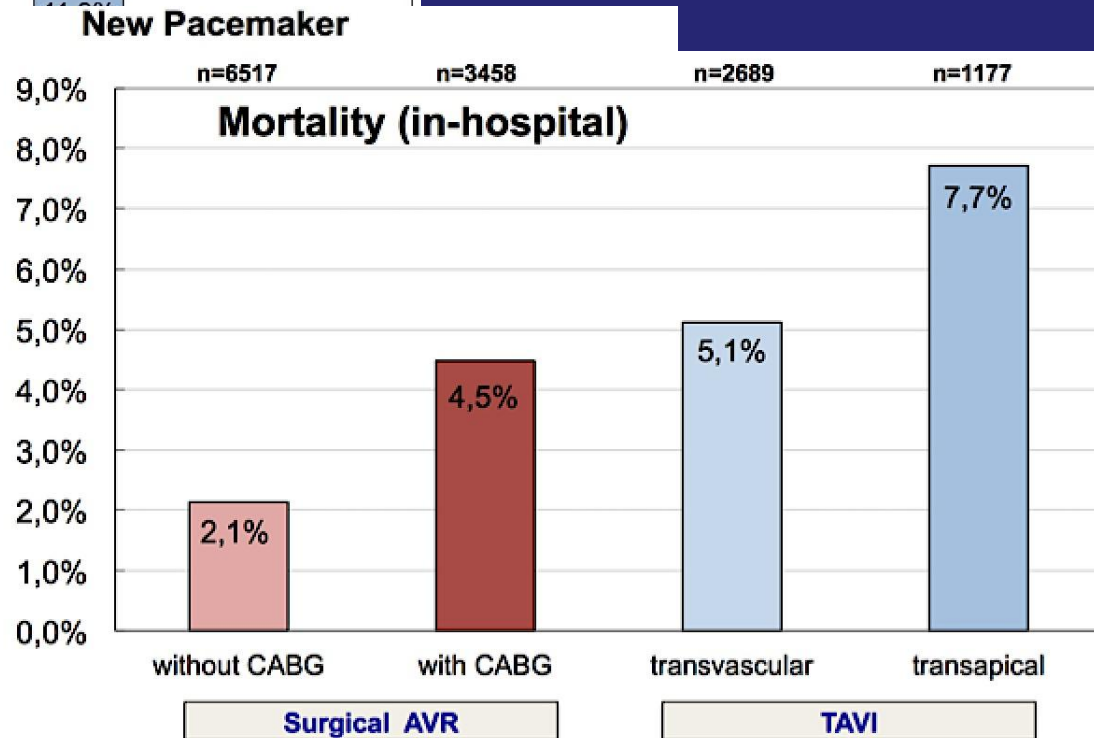
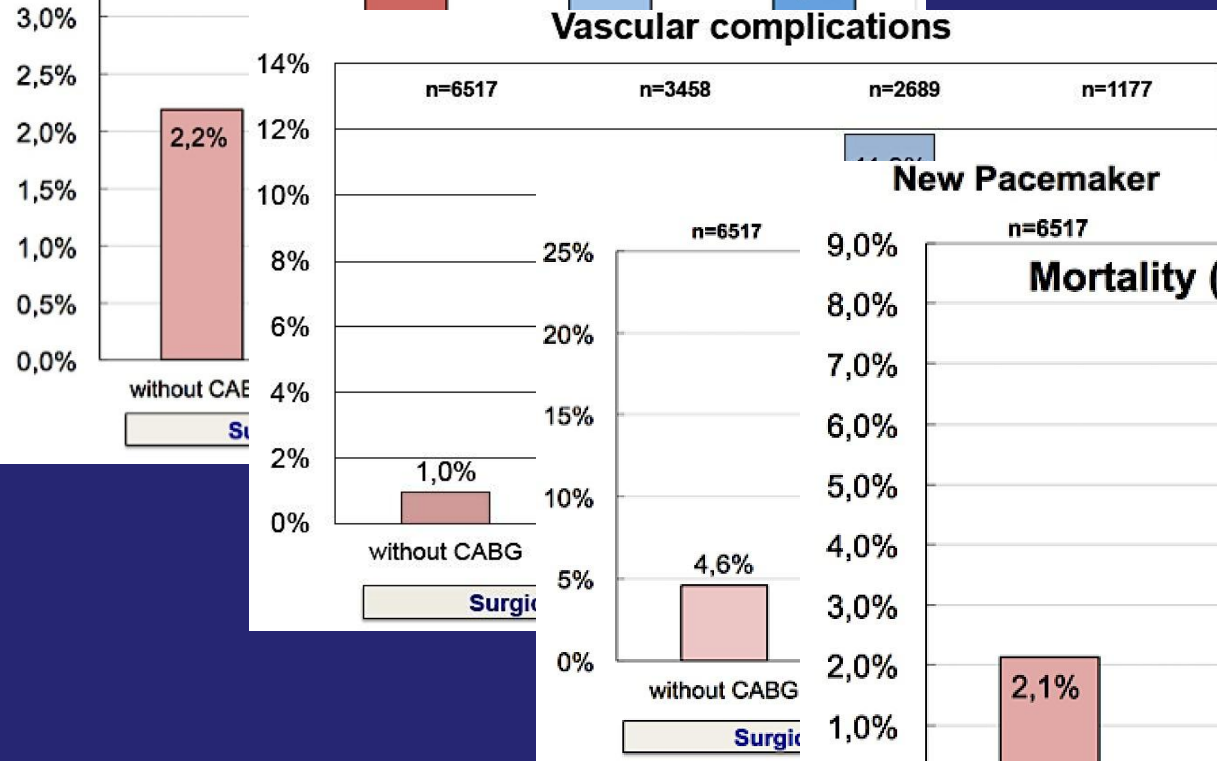
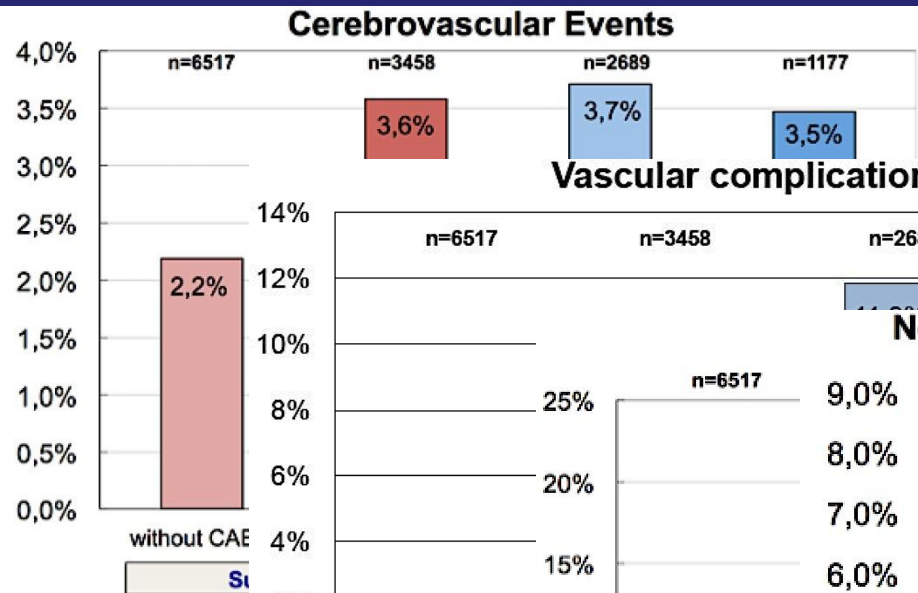


GARY: German Registry

13 860 Pts, 122 centers

AVR: 9985 pts (EScore <10%) - **TAVI:** 3875 Pts (ESscore > 20%)

Transvascular
CoreValve: 60%
Transapical
Edwards: 87.5%



Pilot European Sentinel Registry

2011-12

4 571 pts-137 centres-10 European countries

Edwards 57% (n=2604) - CoreValve 47% (n=1943)

	BE	CZ	FR	DE	IL	IT	PL	SP	CH	GB
										
CENTRES	2	9	33	2	2	13	11	26	12	25
PATIENTS	20	141	2279	12	4	254	157	689	129	886
%	0.4	3.1	49.9	0.3	0.1	5.5	3.4	15.1	2.8	19.4

Pilot European Sentinel Registry

Procedural succes 96.5%

Outcomes at 30 Days

Outcome (%)	Femoral	Apical	Other	
Death (Total 7.4%)	5.9	12.8	9.7	<0.01
Stroke (Total 1.8%)	1.9	1.6	1.4	0.68
MI (Total 0.9%)	0.9	0.7	1.9	0.09
PM implantation	15.5	4.5	10.7	<0.01
Haemodialysis	1.2	2.4	3.6	<0.01
Transfusion(s)	15	20.8	22.9	<0.01
New onset AF	5.1	9	6.5	<0.01
Hosp. stay >10 days	22	43.8	39.5	<0.01

Pilot European Sentinel Registry

Outcomes: Valve comparison

	CoreValve	Sapien XT	
Death (Total 7.4%)	6.7	7.9	0.15
Surgical conversion	5.5	3.3	<0.01
Second valve implanted	3.7	1.4	<0.01
Haemodialysis/filtration	1.1	2.1	<0.01
PM implantation	23.4	6	<0.01
AR grade 2	9.9	6.1	<0.01
AR grade 3	2.3	0.6	<0.01

Conclusions

Lessons from the european registries

- **Increased use of TAVI in Europe**
- **Satisfactory results at 30 days and 1 year (mortality 20%)**
- **Homogeneous outcomes in the registries**
- **Improvement of results with updated devices**
- **Marked and durable symptomatic improvement**
- **Femoral approach in a vast majority of patients**
- **Higher mortality with TA than TF but sicker pts**
- **Higher PM implantation associated with CoreValve**