



Clinical Outcomes Of TAVI Edwards, CoreValve... Which One?

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1st TAVI Summit 3rd September 2011

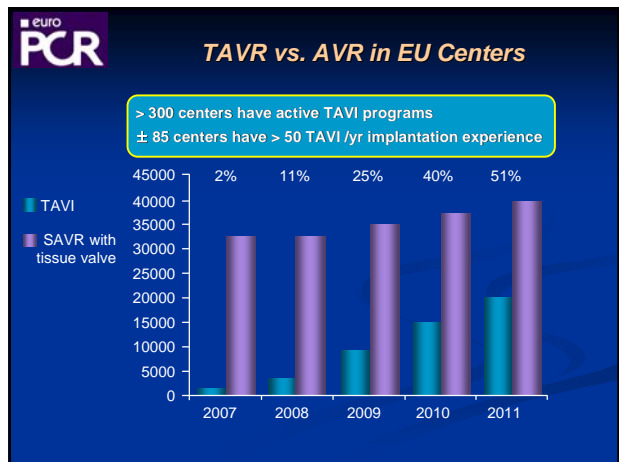
Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest /arrangement or affiliation with the organization(s) listed below

Affiliation/Financial Relationship	Company
Grant/ Research Support:	
Consulting Fees/Honoraria:	Edwards Lifesciences (consultant & proctor)
Major Stock Shareholder/Equity Interest:	
Royalty Income:	
Ownership/Founder:	
Salary:	
Intellectual Property Rights:	
Other Financial Benefit:	

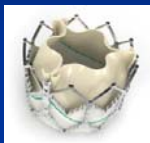
Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis First Human Case Description

Alain Cribier, MD; Helene Eltchaninoff, MD; Assaf Bash, PhD; Nicolas Borenstein, MD; Christophe Tron, MD; Fabrice Bauer, MD; Genevieve Derumesux, MD; Frederic Anselme, MD; François Laborde, MD; Martin B. Leon, MD



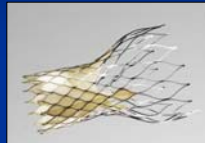
Current TAVI Devices

EDWARDS SAPIEN XT



- Balloon expandable
- Cobalt chromium stent
- Bovine pericardial leaflets
- Current sheath size – 16-18F
- Sizes: (20), 23, 26, 29

MEDTRONICS COREVALVE

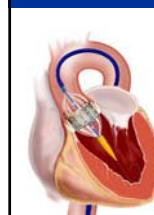


- Self-expanding
- Nitinol frame
- Porcine pericardial leaflets
- Current sheath size – 18F
- Sizes: (23), 26, 29, 31

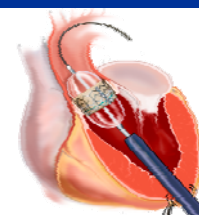
Current Most Widely Available TAVI Devices & Approaches

EDWARDS SAPIEN THV

Transfemoral

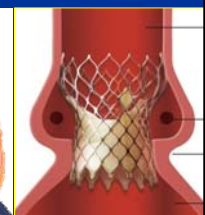


Transapical



MEDTRONICS COREVALVE

Transfemoral
Tran-subclavian



New TAVI Systems - Transfemoral

- Direct Flow
- Sadra
- AorTx
- HLT
- EndoTech
- ABPS PercValve

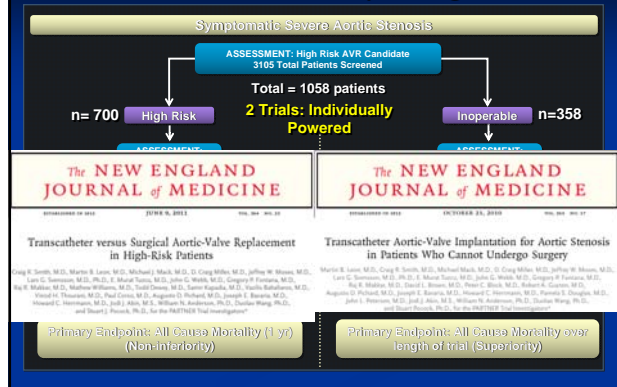


CONTEMPORARY CLINICAL OUTCOMES OF TAVI

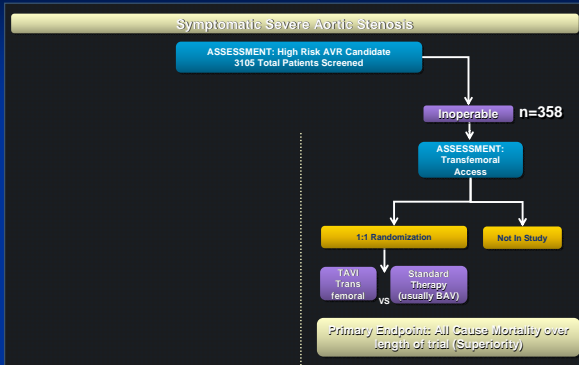
Data Source

- Randomized controlled trial – PARTNER
- Country /Region specific registries
 - Single centre
 - Multi-centres

PARTNER Study Design



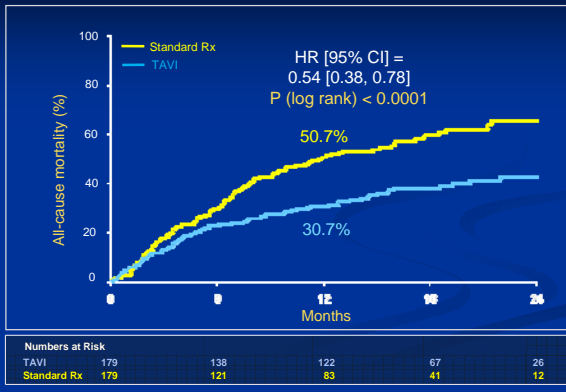
PARTNER Cohort B



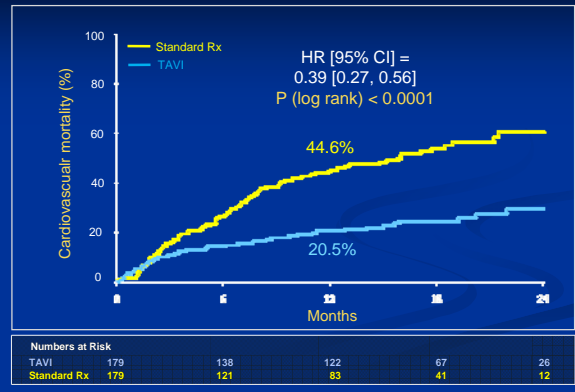
Patient Characteristics - 1

Characteristic	TAVI n=179	Standard Rx n=179	P value
Age - yr	83.1 ± 8.6	83.2 ± 8.3	0.95
Male sex (%)	45.8	46.9	0.92
STS Score	11.2 ± 5.8	12.1 ± 6.1	0.14
Logistic EuroSCORE	26.4 ± 17.2	30.4 ± 19.1	0.04
NYHA			
I or II (%)	7.8	6.1	0.68
III or IV (%)	92.2	93.9	0.68
CAD (%)	67.6	74.3	0.20
Prior MI (%)	18.6	26.4	0.10
Prior CABG (%)	37.4	45.6	0.17
Prior PCI (%)	30.5	24.8	0.31
Prior BAV (%)	16.2	24.4	0.09
CVD (%)	27.4	27.5	1.00

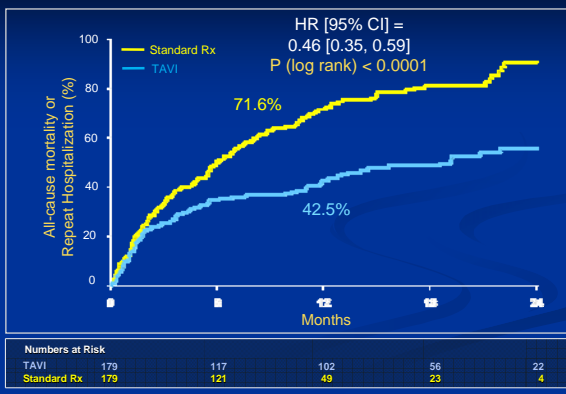
PARTNER Cohort B – All Cause Mortality



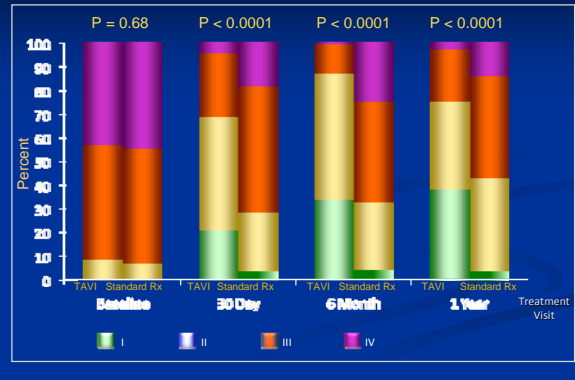
PARTNER Cohort B - CV Mortality



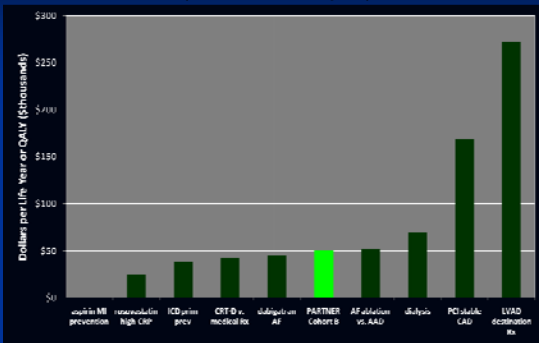
PARTNER Cohort B – Mortality or Rehospitalization



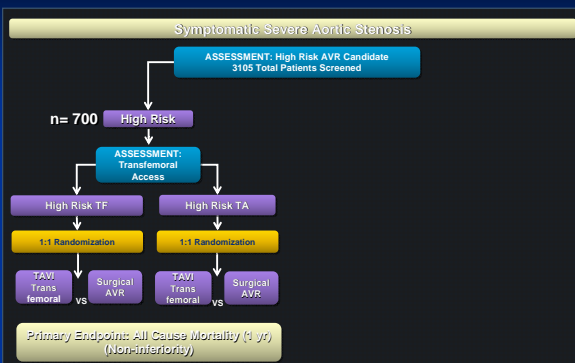
PARTNER Cohort B – NYHA Functional Class Survivors



PARTNER Cohort B – Cost Effectiveness (In Press NEJM)



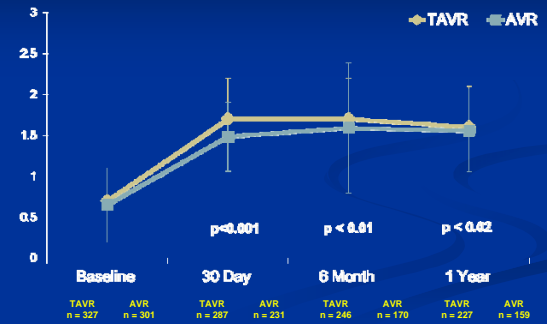
PARTNER Cohort A



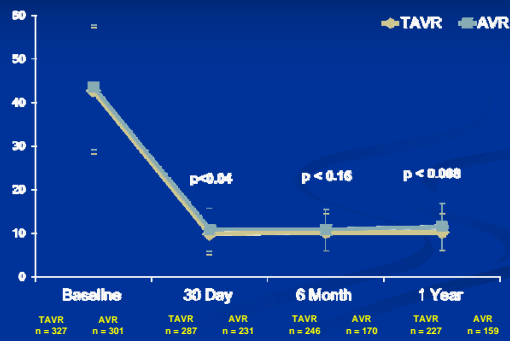
Patient Characteristics (1)

Characteristic	TAVR (N = 348)	AVR (N = 351)	p-value
Age (yr)	83.6 ± 6.8	84.5 ± 6.4	0.07
Male sex - %	57.8	56.7	0.82
STS Score	11.8 ± 3.3	11.7 ± 3.5	0.61
Logistic EuroSCORE	29.3 ± 16.5	29.2 ± 15.6	0.93
NYHA II - %	5.7	6.0	0.79
III or IV - %	94.3	94.0	
CAD - %	74.9	76.9	0.59
Previous MI - %	26.8	30.0	0.40
Prior CV Intervention - %	72.1	71.6	0.93
Prior CABG - %	42.6	44.2	0.70
Prior PCI - %	34.0	32.5	0.68
Prior BAV - %	13.4	10.2	0.24
Cerebrovascular disease - %	29.3	27.4	0.60

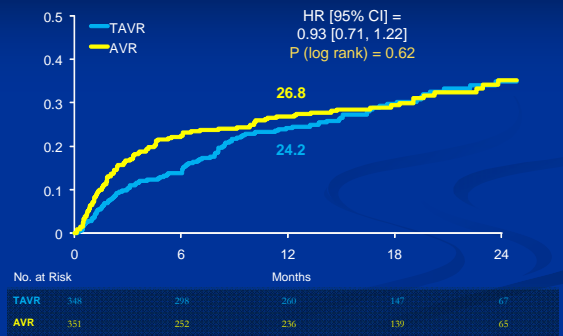
PARTNER Cohort A Better Haemodynamics with TAVI



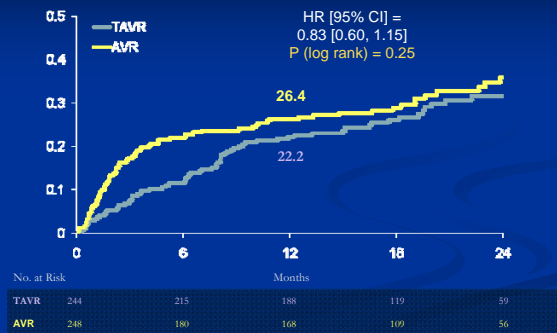
PARTNER Cohort A Better Haemodynamics with TAVI



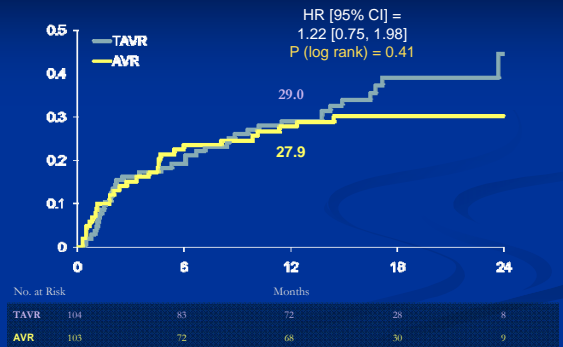
PARTNER Cohort A – All Cause Mortality



PARTNER Cohort A – All Cause Mortality Transfemoral Cohort



PARTNER Cohort A – All Cause Mortality Transapical Cohort



PARTNER Cohort A – All Cause Mortality

All-Cause Mortality at 30 Days

	All Patients no. of patients (%)			TF Patients no. of patients (%)			TA Patients no. of patients (%)		
	TAVR	AVR	p-value	TAVR	AVR	p-value	TAVR	AVR	p-value
ITT	12 (3.4)	22 (6.5)	0.07	8 (3.3)	15 (6.2)	0.13	4 (3.8)	7 (7.0)	0.32
AT	18 (5.2)	25 (8.0)	0.15	9 (3.7)	18 (8.2)	0.05	9 (8.7)	7 (7.6)	0.79

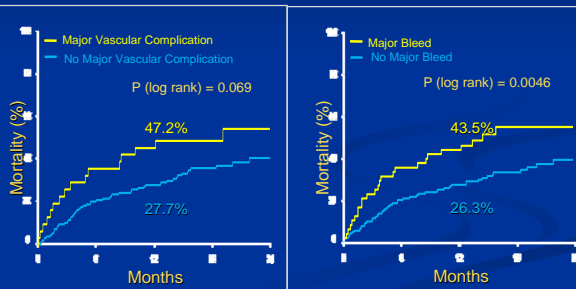
All-Cause Mortality at 1 Year

	All Patients no. of patients (%)			TF Patients no. of patients (%)			TA Patients no. of patients (%)		
	TAVR	AVR	p-value	TAVR	AVR	p-value	TAVR	AVR	p-value
ITT	84 (24.2)	89 (26.8)	0.44	54 (22.2)	62 (26.4)	0.29	30 (29.0)	27 (27.9)	0.85
AT	81 (23.7)	78 (25.2)	0.64	51 (21.3)	55 (25.2)	0.33	30 (29.1)	23 (25.3)	0.55

PARTNER Cohort A - Outcomes

Outcome	30 Days			1 Year		
	TAVR (N = 348)	AVR (N = 351)	p-value	TAVR (N = 348)	AVR (N = 351)	p-value
Vascular complications						
All – no. (%)	59 (17.0)	13 (3.8)	<0.01	62 (18.0)	16 (4.8)	<0.01
Major – no. (%)	38 (11.0)	11 (3.2)	<0.01	39 (11.3)	12 (3.5)	<0.01
Major bleeding – no. (%)	32 (9.3)	67 (19.5)	<0.01	49 (14.7)	85 (25.7)	<0.01
Endocarditis – no. (%)	0 (0.0)	1 (0.3)	0.32	2 (0.6)	3 (1.0)	0.63
New AF – no. (%)	30 (8.6)	56 (16.0)	<0.01	42 (12.1)	60 (17.1)	0.07
New PM – no. (%)	13 (3.8)	12 (3.6)	0.89	19 (5.7)	16 (5.0)	0.68

Vascular Complications and Bleeding Predicts Mortality



PARTNER Cohort A - Outcomes

Outcome	30 Days			1 Year		
	TAVR (N = 348)	AVR (N = 351)	p-value	TAVR (N = 348)	AVR (N = 351)	p-value
All Stroke or TIA – no. (%)	19 (5.5)	8 (2.4)	0.04	27 (8.3)	13 (4.3)	0.04
TIA – no. (%)	3 (0.9)	1 (0.3)	0.33	7 (2.3)	4 (1.5)	0.47
All Stroke – no. (%)	16 (4.6)	8 (2.4)	0.12	20 (6.0)	10 (3.2)	0.08
Major Stroke – no. (%)	13 (3.8)	7 (2.1)	0.20	17 (5.1)	8 (2.4)	0.07
Minor Stroke – no. (%)	3 (0.9)	1 (0.3)	0.34	3 (0.9)	2 (0.7)	0.84
Death/maj stroke – no. (%)	24 (6.9)	28 (8.2)	0.52	92 (26.5)	93 (28.0)	0.68

Stroke and TAVI

Editorial Response to PARTNER A

EDITORIALS



Transcatheter Aortic-Valve Implantation — At What Price?

Hartzell V. Schaff, M.D.

In 2000, Bonhoeffer et al. described transvenous placement of a pulmonary-valve prosthesis and speculated that similar technology might be used in other cardiac valves, including the aortic position.¹ Two years later, the first transcatheter in-

patients who are eligible for transfemoral insertion and may decrease vascular injury.

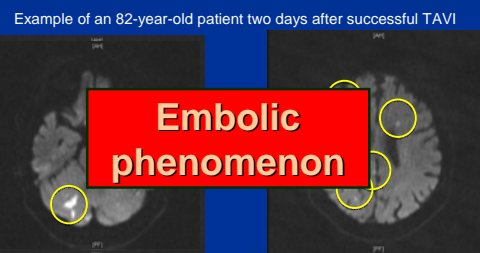
But the increased risk of stroke associated with transcatheter replacement, as compared with surgical replacement, is a special concern. Smith

Diffusion-Weighted MRI Study

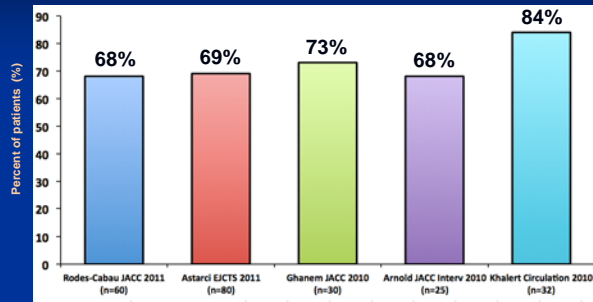
Philipp Kahlert, MD
West German Heart Center Essen

Pre-TAVI

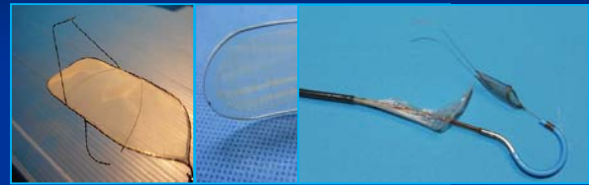
Post-TAVI



Diffusion Weighted MRI Silent Cerebral Insults after TAVI



Cerebral Embolic Protection Devices



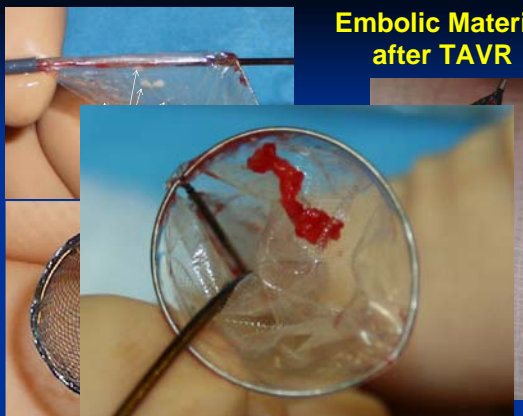
SHEF

Embrella

Claret

Deflectors and Filters

Embolic Material after TAVR



Published or Presented Contemporary Multicentre Registries

	Edwards	CoreValve	Dates	Completed
SOURCE-EU	2307	0	2007-2009	Yes
Canadian SAS	345	0	2005-2009	Yes
Italian	0	663	2007-2009	Yes
Belgian TAVR Registry	303	297	2008-2011	Yes
FRANCE I	166	78	2009	Yes
FRANCE II	1148	540	2010-present	No
Spanish	0	108	2007-2009	Yes
German TAVI Registry	109	588	2009	Yes
UK	412	460	2007-2009	Yes
ANZ CoreValve	0	346	2008-present	No
SOURCE ANZ	130	0	2008-2010	Yes

Weighted Meta-Analysis of Early and Late Clinical Outcomes after CoreValve TAVI in Seven National Registries

C.Ruiz et al. Presented at EuroPCR 2011

	Edwards	CoreValve	Dates	Completed
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Canadian SAS	345	0	2005-2009	Yes
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ANZ CoreValve	0	346	2008-present	No
SOURCE ANZ	130	0	2008-2010	Yes

TAVI – Contemporary Results

	PARTNE R B	PARTNE R A	SOURCE	Canadian	SOURCE ANZ	FRANCE 2	CoreValve Meta- analysis
N & Valve type	Edwards 179 TF	Edwards 244 TF 104 TA	Edwards 920 TF 1387 TA	Edwards 162 TF 177 TA	Edwards 130	Edwards -1145 CoreValve -540	2156 CoreValve
Age	83.1	83.6	80.1	81.8	82.8	82.5	81.6
Logistic EuroScore	26.4%	29.3%	26.1%	N/A	28.0%	22.6%	21.3%
30 day Mortality	5.0%	3.4%	9.5%	10.4%	7.7%	9.9%	6.6%
30 day Stroke	5.0%	5.5%	2.9%	2.3%	3.8%	3.8%	2.8%
1 year Mortality	30.7%	24.2%	23.5%	24%	N/A	24%	17.1%

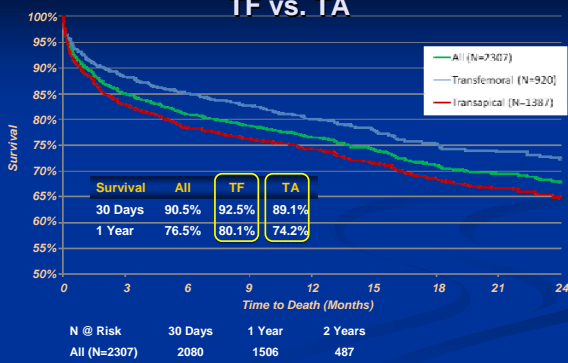
TAVI – Contemporary Results

	PARTNER B	PARTNER A	SOURCE	Canadian	SOURCE ANZ	FRANCE 2	Core-Valve Meta-analysis
N & Valve type	Edwards 179 TF	Edwards 244 TF 104 TA	Edwards 920 TF 1387 TA	Edwards 162 TF 177 TA	Edwards 130	Edwards -1145 CoreValve -540	2156 CoreValve
Vascular Cx	16.8%	11.0%	5.7%	13.0%	5.4%	12.5%	4.2%
Bleeding	16.2%	9.3%	3.3%	N/A	16.9%	18.4%	N/A
PPM	3.4%	3.8%	6.9%	4.9%	4.6%	12.4%	28.7%

Predictors of Mortality from TAVI Registries

- **SOURCE**
 - 1 Yr mortality in TF – Smoking, Renal failure, Logistic EuroScore, Carotid endarterectomy
 - 1 Yr mortality in TA – Logistic Euroscore, Renal failure, Liver disease
- **Canadian**
 - 30-day mortality – pulmonary hypertension, severe MR, need for periprocedural support
 - Late mortality – COPD, CKD, AF, Frailty
- **FRANCE 2**
 - 30-day mortality – Logistic euroscore, NYHA class

SOURCE - KM 1-year Survival TF vs. TA

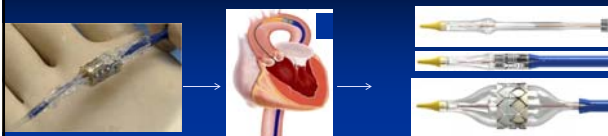


FRANCE 2 – Mortality by Access Route

Access Site

	TF Edwards	TF CoreValve	TA Edwards	SC CoreValve
30 day	7.8%	10.3%	11.5%	11.0%
6 month	13.2%	16.3%	20.2%	25.9%

Edwards Transfemoral Delivery System Refinement



RetroFlex 1 System

- Balloon-expandable transcatheter valve delivery
- Steerable catheter
- No nose-cone
- THV tends to migrate aortic on deployment
- 22-24F sheath

RetroFlex 3 System

- Balloon-expandable transcatheter valve delivery
- Steerable catheter
- Tapered distal end
- More accurate valve deployment (less aortic migration on deployment)
- 22-24F sheath

NovaFlex System

- Balloon-expandable transcatheter valve delivery
- Steerable catheter
- Tapered distal end
- More accurate valve deployment
- Valve crimped on shaft and aligned to balloon upon exit from sheath
- Combined with SAPIEN XT valve → 18-19F sheath

Reduction in size of sheath



Periprocedural and Short-term Outcomes of TAVI with Sapien XT vs. Edwards Sapien Valve

120 consecutive pts treated in Italy from November 2007 to April 2010.

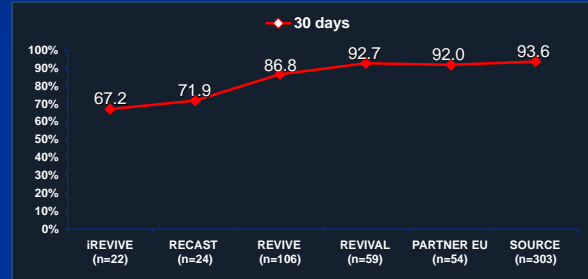
	Sapien (n = 66)	Sapien XT (n = 54)	P Value
Periprocedural Life-Threatening Bleeding	33.3%	11.1%	0.004
Periprocedural Major Bleeding	40.9%	35.2%	0.52
30-Day VARC Combined Safety Endpoint	45.5%	20.4%	0.004

VARC = Valve Academic Research Consortium

Conclusion: The newer XT valve is comparable to the Sapien but results in fewer major vascular events and may have broader clinical application.

Mussardo M, et al. *J Am Coll Cardiol Interv.* 2011;4:743-750.

Transfemoral TAVI with Edwards THV Survival at 1 month



EDWARDS VS COREVALVE WHICH ONE??

TAVI – Contemporary Results

	PARTNE R B	PARTNE R A	SOURCE	Canadian	SOURCE ANZ	FRANCE 2	Core-Valve Meta- analysis
N & Valve type	Edwards 179 TF	Edwards 244 TF 104 TA	Edwards 920 TF 1387 TA	Edwards 162 TF 177 TA	Edwards 130	Edwards -1145 Core-Valve -540	2156 Core-Valve
30 day Mortality	5.0%	3.4%	9.5%	10.4%	7.7%	9.9%	6.6%
30 day Stroke	5.0%	5.5%	2.9%	2.3%	3.8%	3.8%	2.8%
1 year Mortality	30.7%	24.2%	23.5%	24%	N/A	24%	17.1%
Vascular Cx	16.8%	11.0%	5.7%	13.0%	5.4%	12.5%	4.2%
Bleeding	16.2%	9.3%	3.3%	N/A	16.9%	18.4%	N/A
PPM	3.4%	3.8%	6.9%	4.9%	4.6%	12.4%	28.7%

TAVI Anatomical Criteria

VARIABLES	EDWARDS SAPIEN	CORE-VALVE
Iliac / Femoral Vessels	≥6mm for 23mm valve ≥6.5mm for 26mm valve No restriction for TA	≥6mm (7mm if diabetic) Subclavian ≥7mm for TS
Aortic annulus	18-21mm for 23mm valve 21-25mm for 26mm valve	20-23mm for 26mm valve 23-27mm for 29mm valve
Ascending aorta size	No restriction	≤40mm for 26mm valve ≤43mm for 29mm valve
Sinus height	≥14mm	>10mm, preferably ≥14mm
Bulky aortic valve calcium	NO	NO
LVH / Severe septal LVH	Preferably not (risk malposition)	Less issue, but officially not if ISW >1.7cm
STJ / Aortic root	>30mm	>30mm

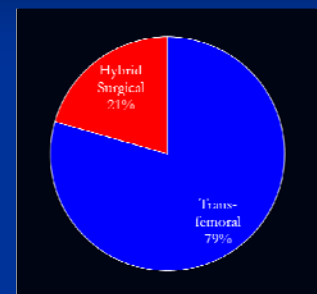
RPH Experience

N=74 cases

Edwards
-RF 1 & 3 – Feb 2009
-NF – Sept 2011

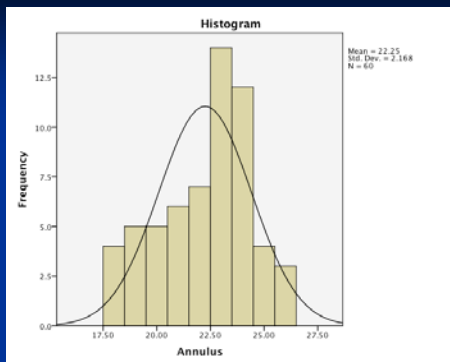
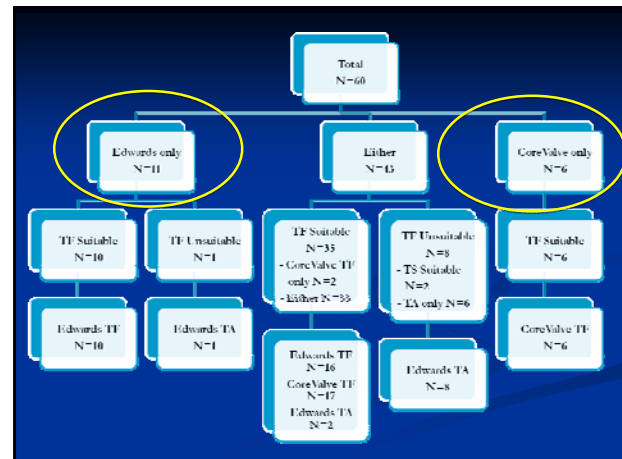
Core-Valve
-Aug 2009

Not yet had access to
-29mm Sapien XT
-31mm Core-Valve
-E-sheath
-(Direct aortic procedure)



Decision Making

- Annulus & ascending aorta
 - Annulus 18-20 or Ascending Ao >40-43 – Only Edwards
 - Annulus 25-27 – Only CoreValve
- Peripheral vessels
 - Femoral vessels <6mm – need to consider L-subclavian
 - If subclavian <7mm – direct aortic or transapical
- Other considerations
 - If LIMA – avoid transsubclavian
 - If CAD possibly needing PCI in future – Edwards
 - If existing heart block – Edwards
 - Severe LVH / septal bulge - CoreValve



Conclusion

- Untreated severe AS has extremely poor prognosis
 - Even if treated with balloon aortic valvuloplasty
- Compared to medical treatment, TAVI significantly improved outcome in severe aortic stenosis
 - ? Standard of care for inoperable severe AS
- Compared to surgical AVR in high risk patients, TAVI achieves non-inferior one year outcomes
 - At the potential cost of more CVA
- Current results from TAVI
 - 30-day mortality 6-10%
 - 1 year mortality 15-30%
 - 30-day CVA 3-5%

Conclusion

- Results should improve with
 - Improving technology – smaller sheath sizes
 - ? Lower risk patients treated – RCT undergoing (PARTNER II & SURTAVI)
- No difference in clinical outcomes between Edwards valve and CoreValve
 - Except PPM rate
- Both valves may serve complementary purposes to allow treatment of wider proportion of patients