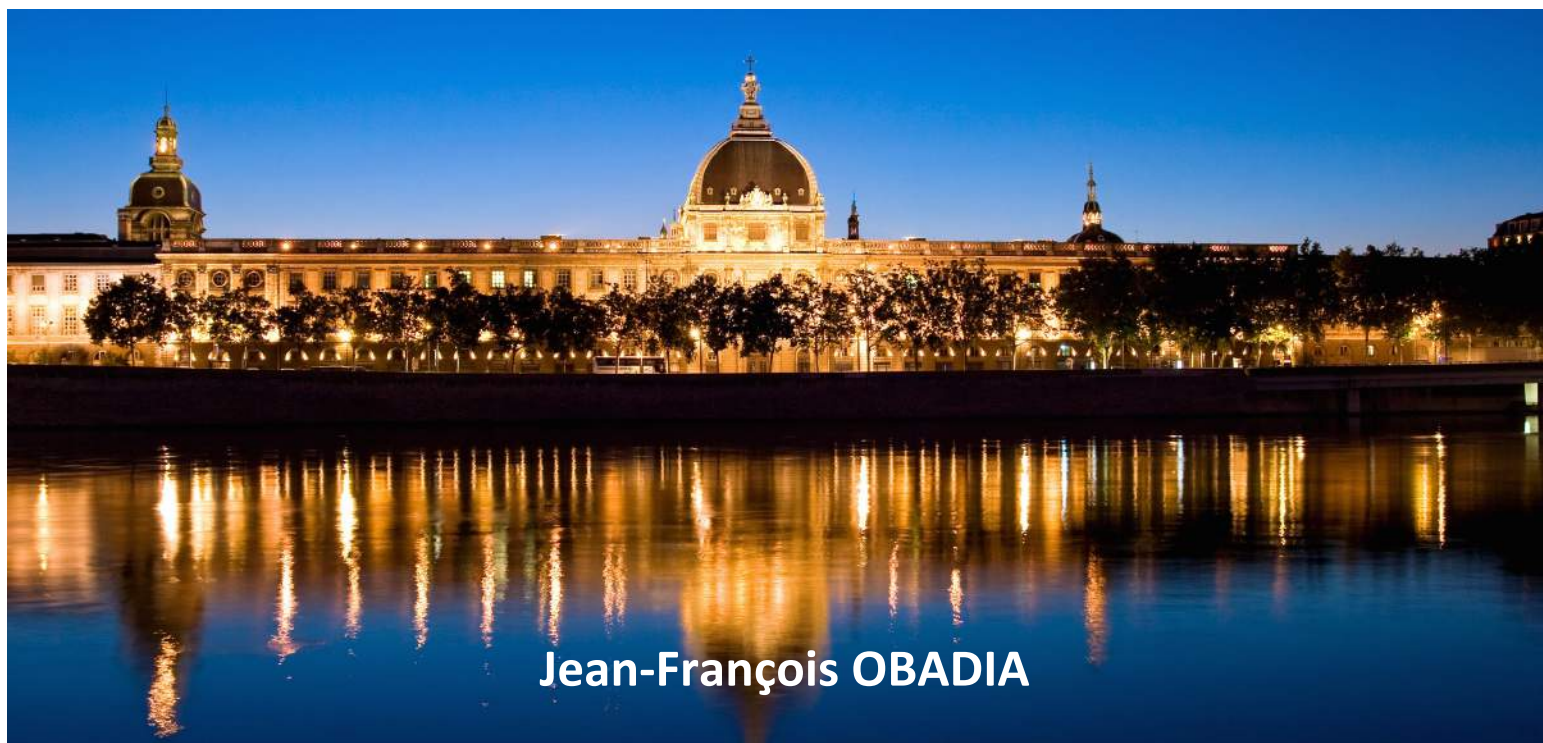




**Hospices
Civils de
Lyon**



V in V - TAVI : Is it a suitable alternative ?



Jean-François OBADIA

***Cardiothoracic and Vascular Surgery Department
Hôpital Louis Pradel
LYON - France***



Tables of the Law



Recommendations	Class ^a	Level ^b	Ref ^c
TAVI should only be undertaken with a multidisciplinary 'heart team' including cardiologists and cardiac surgeons and other specialists if necessary.	I	C	





JOURNAL OFFICIEL DE LA RÉPUBLIQUE FRANÇAISE

Décrets, arrêtés, circulaires

3 sept 2014

TEXTES GÉNÉRAUX

**MINISTÈRE DES AFFAIRES SOCIALES, DE LA SANTÉ
ET DES DROITS DES FEMMES**

INDICATION :

La prise en charge est assurée chez les **patients contre-indiqués à la chirurgie** ayant une sténose aortique sévère symptomatique. L'indication du remplacement valvulaire aortique doit être posée et la contre-indication à la chir. évaluée lors d'une **réunion multidisciplinaire** en prenant en compte les scores de risque opératoire (**Euroscore ≥ 20 % ou STS ≥ 10 %**) et les comorbidités. Cette réunion doit être assortie de la rédaction d'un **compte rendu** qui sera annexé au dossier médical du patient.

Le refus de la chirurgie de remplacement valvulaire aortique ne constitue pas une indication à la technique de remplacement valvulaire

aortique par voie transcutanée. Les patients ayant une espérance de vie inférieure à 1 an compte tenu de facteurs extracardiaques (comorbidités) ne sont pas éligibles à la technique (non-indication).

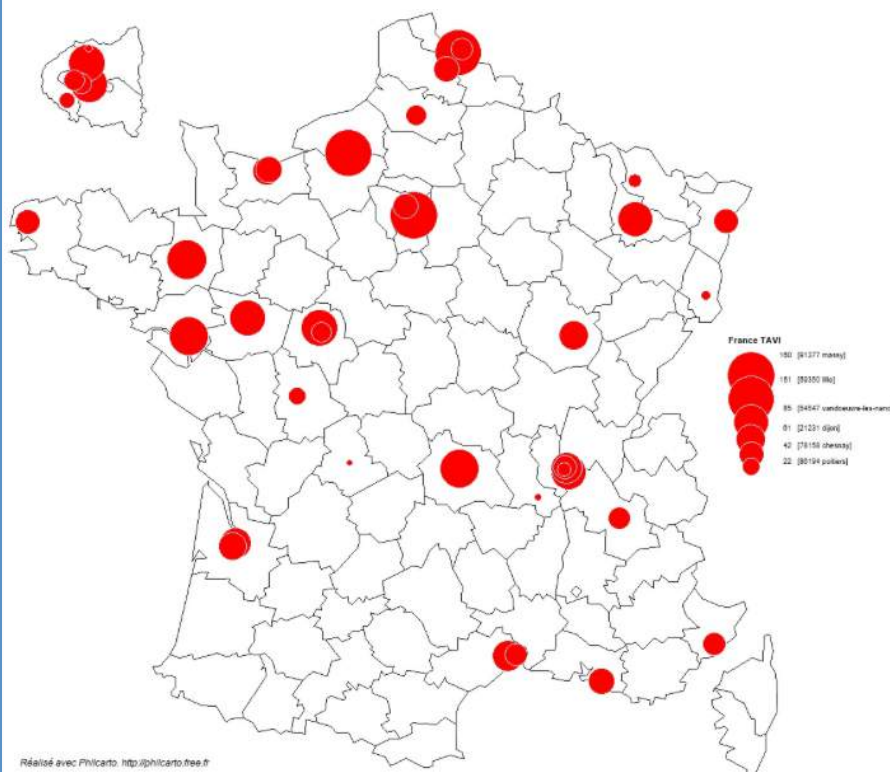
En France ?

2010 → 1551 TAVI → EuroSCORE 23 %

2011 → 1640 TAVI → EuroSCORE 21 %

Mortality = 9,7 % DMS = 11 j

15.8% opted to undergo TAVI rather than conventional surgery



2013	3707	%
< 10%	521	23.9
10 à 19%	815	37.4
20 à 29 %	469	21.5
≥ 30 %	376	17.2

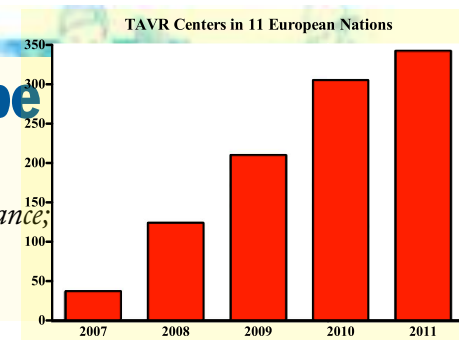
	n	%
Contre indication technique à la chirurgie	394	16.8
Haut risque opératoire	1289	55.1
Fragilité*	546	23.3
Autre	112	4.8

DMS 11 j
Mortality 6,6 %

Transcatheter Aortic Valve Replacement in Europe

Adoption Trends and Factors Influencing Device Utilization

Montreal, Canada; Galway, Ireland; Rotterdam, the Netherlands; Bern and Basel, Switzerland; Massy, France; Milan, Italy; London and Belfast, United Kingdom; Copenhagen, Denmark; Wilrijk, Belgium; Lisbon, Portugal; Madrid, Spain; and Munich, Germany *JACC Vol. 62, No. 3, 2013*



INTRO

Context

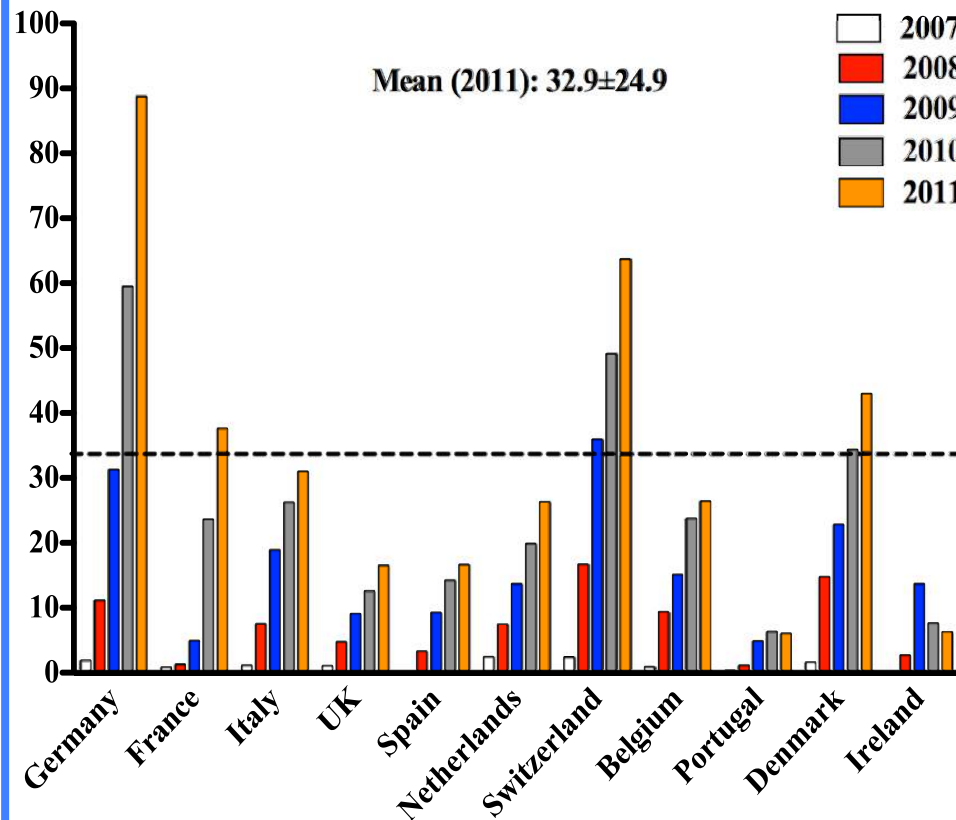
Technic

Results

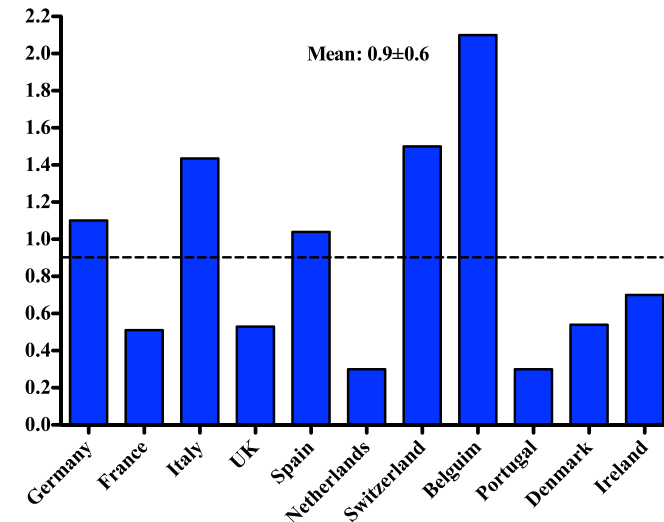
Conclusion

11 Europ. Countries → 350 centers (2007-2011)

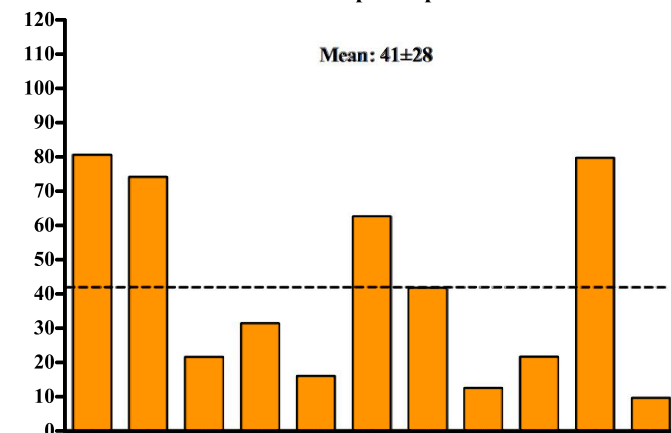
TAVR Implants per Million: 2007-2011



TAVR Centers per Million: 2011



Mean Number of TAVR Implants per Center: 2011



5

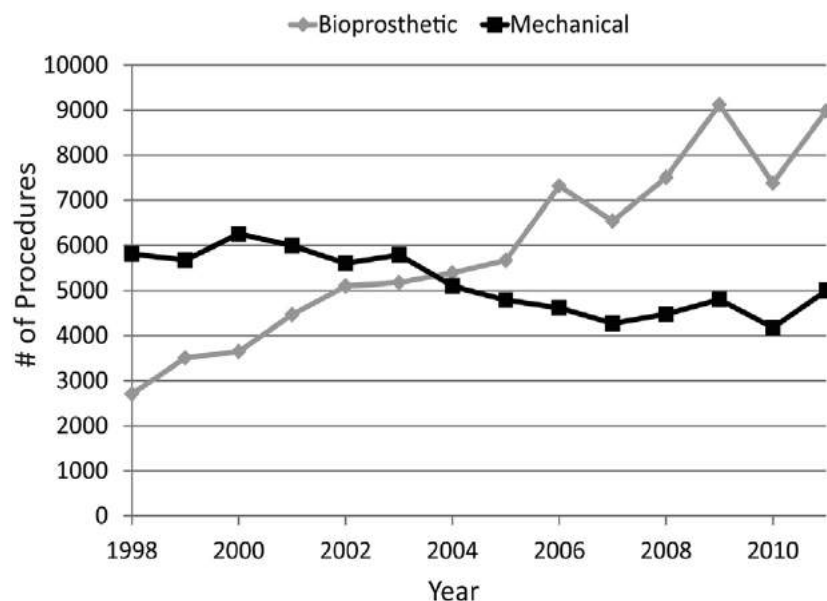


National trends in utilization and in-hospital outcomes of mechanical versus bioprosthetic aortic valve replacements

Abby J. Isaacs, MS,^a Jeffrey Shuhaiber, MD,^b Arash Salemi, MD,^c O. Wayne Isom, MD,^c and Art Sedrakyan, MD, PhD^a

J Thorac Cardiovasc Surg 2015;149:1262-9

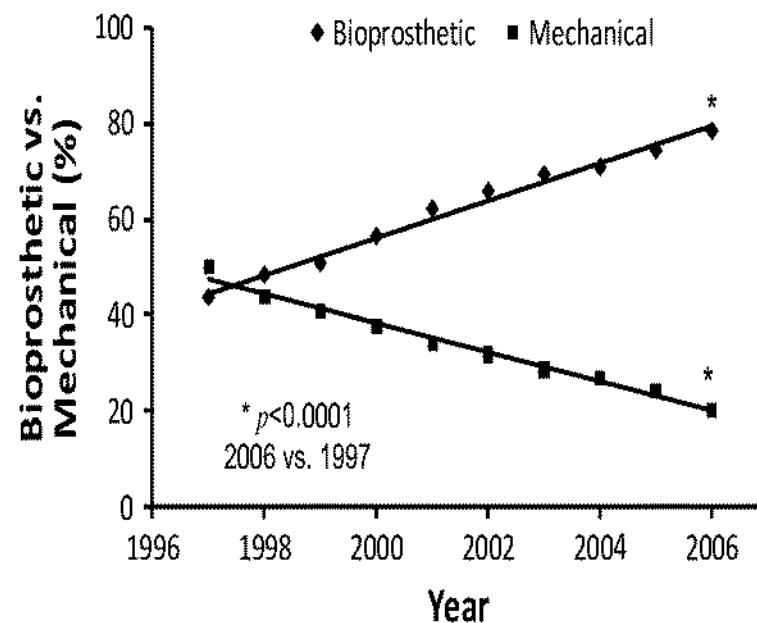
NIS



Isolated aortic valve replacement in North America comprising 108,687 patients in 10 years: Changes in risks, valve types, and outcomes in the Society of Thoracic Surgeons National Database

J Thorac Cardiovasc Surg 2009;137:82-90

STS





Freedom from SVD – Hancock II

980 pts (mean age 65.0 yrs) – undergoing AVR+MVR using the **Hancock II** valve between 1982-1994 @ Toronto General Hospital, Toronto, Canada

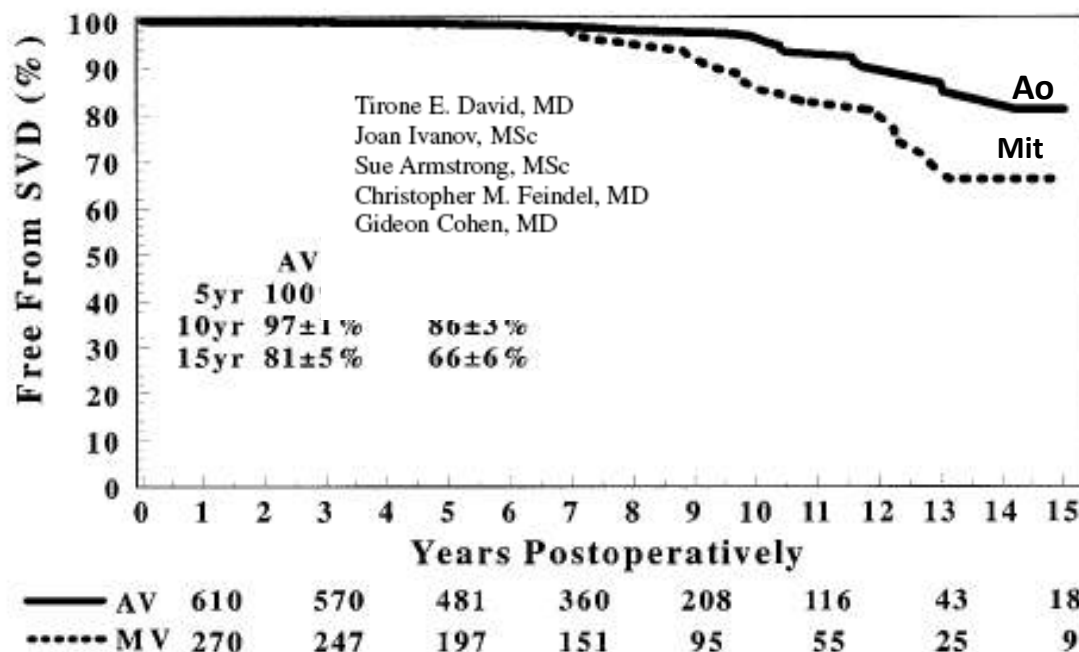
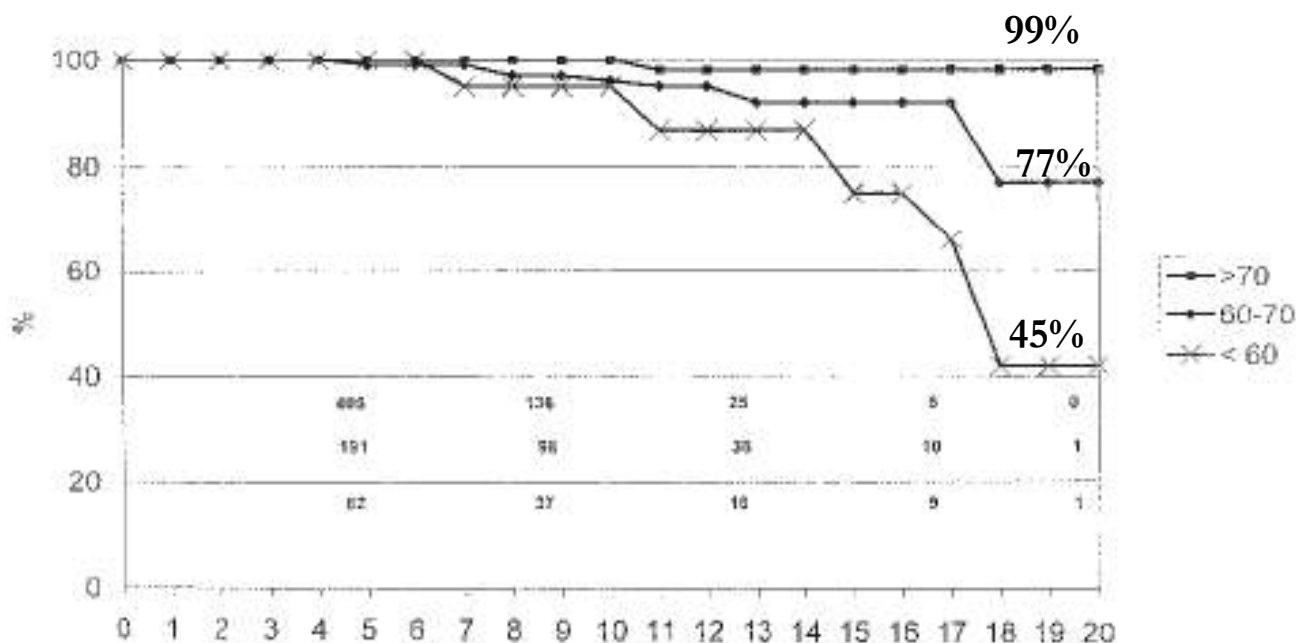


Fig 2. Actuarial (Kaplan-Meier) freedom from SVD. AV, Aortic valve; MV, mitral valve.



Freedom from SVD - Edwards

1,133 pts (mean age 72.6 yrs) – undergoing AVR using the **Perimount** valve between 1984-2003 @Trousseau Hospital, F. Rabelais University, Tours France



Actuarial freedom from structural valve failure

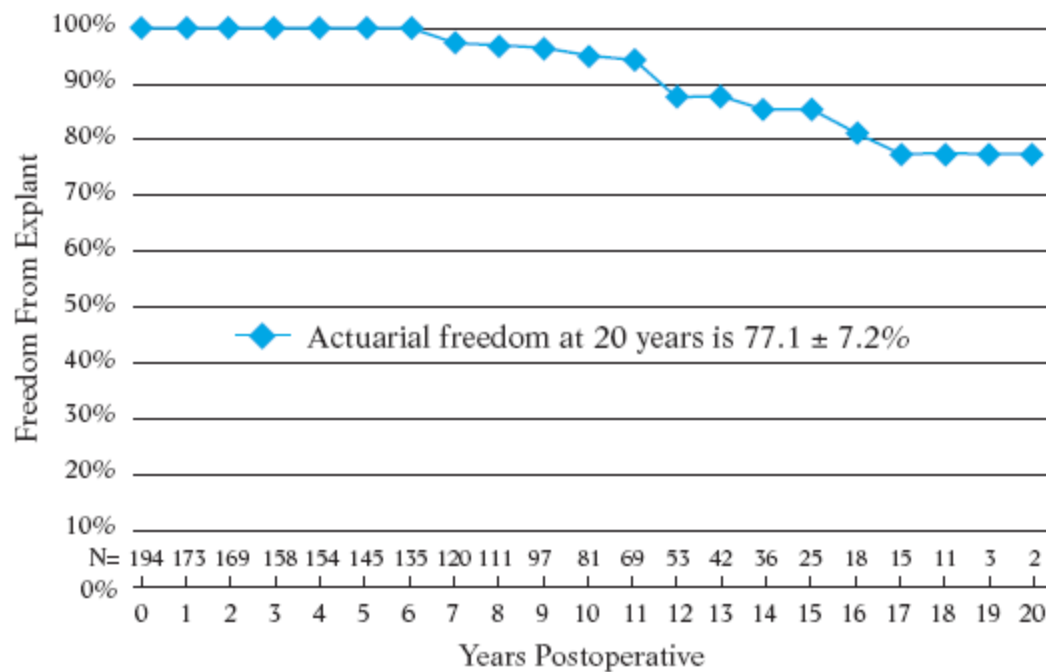
Aupart MR et al. J Heart Valve Dis 2006;768-75



Perimount Edwards

Figure 6: Freedom from Explant Due to SVD

Patients ≥ 60 Years

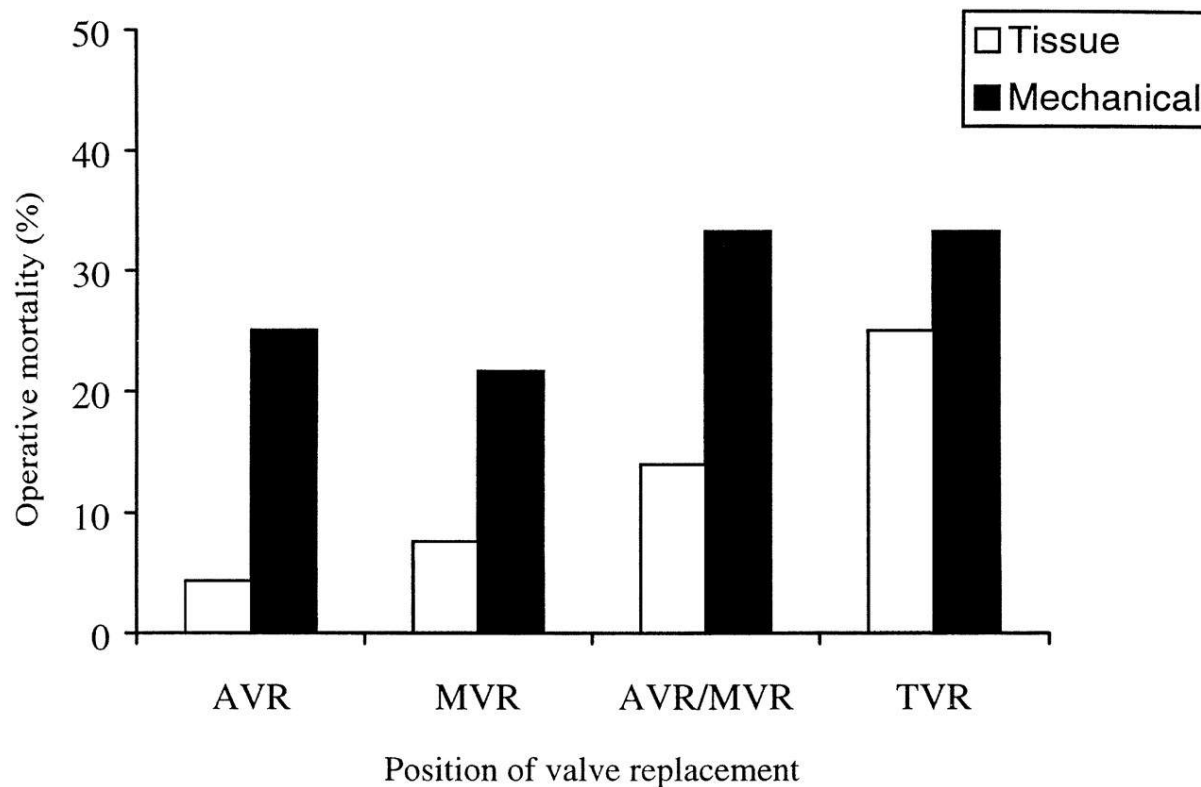


Edwards Lifesciences Perimount brochure 2007



Repeat Heart Valve Surgery

671 pts (mean age 54.7 yrs) – 1st repeat heart valve surgery between 1969-1998
@Royal Victoria Hospital, Belfast, Northern Ireland



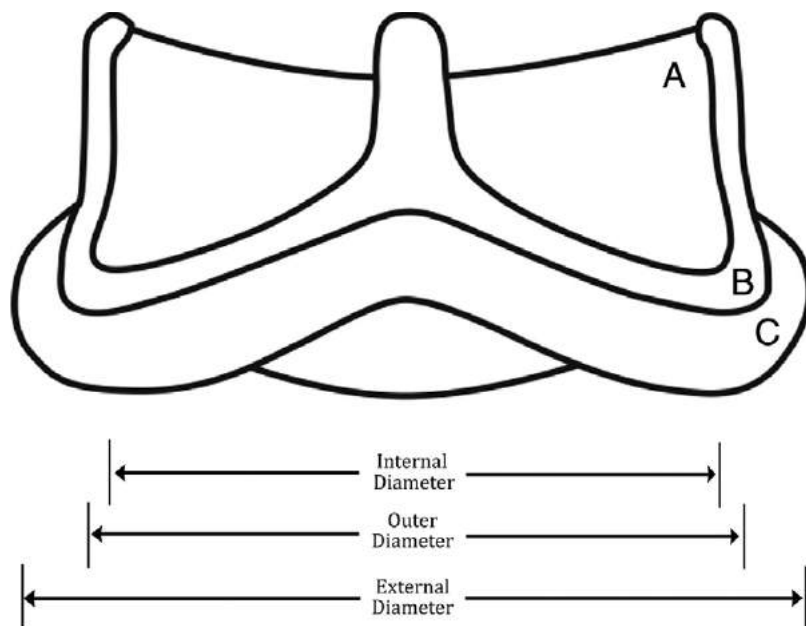
Jones J. M. et al.; J Thorac Cardiovasc Surg 2001;122:913-918



Transcatheter Valve-in-Valve Implantation for Failed Surgical Bioprosthetic Valves

J Am Coll Cardiol 2011;58:2196–209

Ronen Gurvitch, MBBS,*† Anson Cheung, MD,* Jian Ye, MD,* David A. Wood, MD,*
Alexander B. Willson, MBBS,* Stefan Toggweiler, MD,* Ronald Binder, MD,* John G. Webb, MD*
Vancouver, British Columbia, Canada; and Melbourne, Victoria, Australia



Stented
Stentless
Scalloped / Circular Ring
Low / High profile
Homograft
Valve sparing Surgery
Radio-opacity



Transcatheter Valve-in-Valve Implantation for Failed Surgical Bioprosthetic Valves

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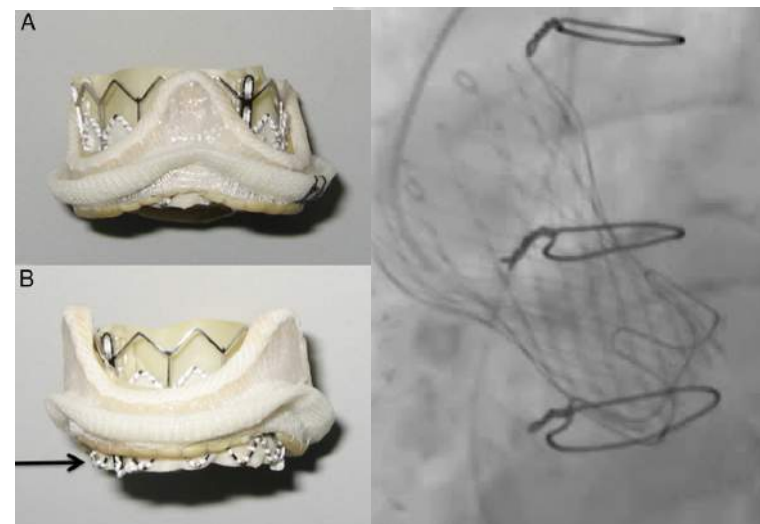
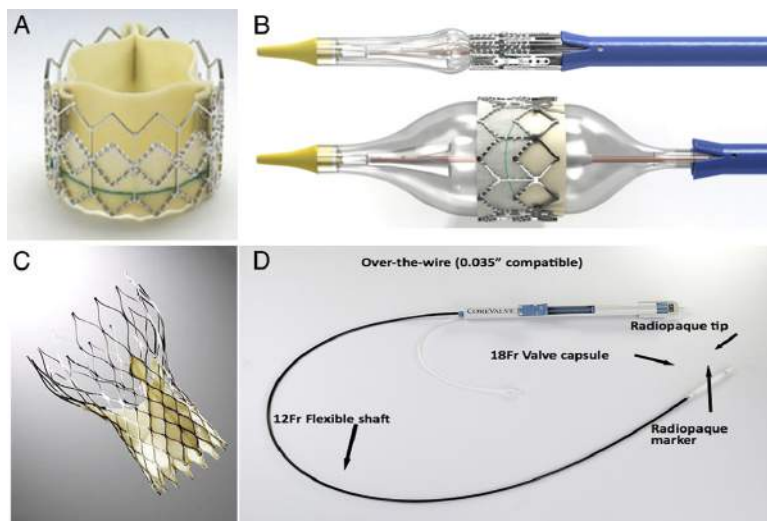


Causes of Bioprosthetic Failure :

Leaflet degeneration → Wear / Tear / Calcif

Leaflet destructions → IE

Non leaflet failure → Pannus / Thrombus / Para-valvular leaks





Mechanism of valve failure

Pannus

Thrombus

Calcification

AS

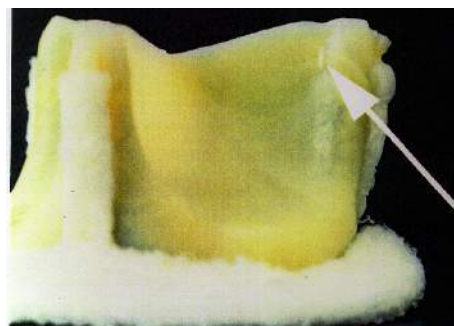
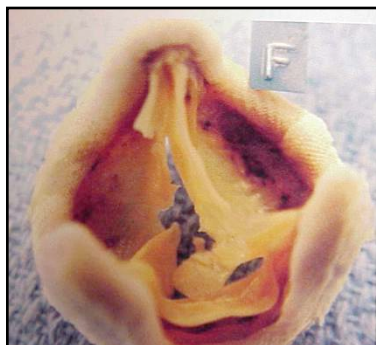


Wear & Tear (int.)

Wear & Tear (ext.)

Endocarditis

AR





Transcatheter Valve-in-Valve Implantation for Failed Surgical Bioprosthetic Valves

J Am Coll Cardiol 2011;58:2196–209

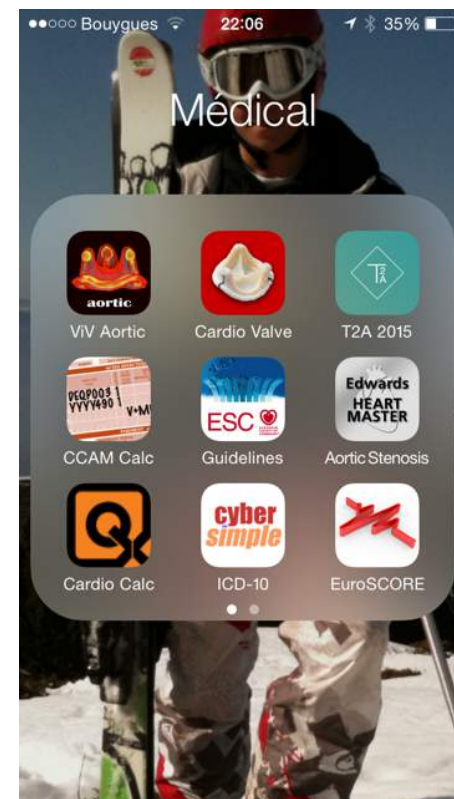
Ronen Gurvitch, MBBS,*† Anson Cheung, MD,* Jian Ye, MD,* David A. Wood, MD,*
Alexander B. Willson, MBBS,* Stefan Toggweiler, MD,* Ronald Binder, MD,* John G. Webb, MD*
Vancouver, British Columbia, Canada; and Melbourne, Victoria, Australia



Table 1

**Valve Dimensions for Selected 18- to 23-mm Stented Surgical Bioprostheses,
per Manufacturer Product Information**

Valve Label Size	Valve Type/Model (Manufacturer)	Sewing Ring External Diameter, mm	Stent Outer Diameter, mm	Stent Internal Diameter, mm
18	Soprano (Sorin Biomedica)	26	21	17.8
19	Magna (Edwards Lifesciences)	24	19	18
	Perimount (Edwards Lifesciences)	26	19	18
	Mosaic (Medtronic)	25	19	17.5
	Hancock Ultra (Medtronic)	24	19	17.5
	Hancock II (Medtronic)	N/A	N/A	N/A
	Mitroflow (Sorin Biomedica)	21	18.6	15.4
	Trifecta (St. Jude Medical)	24	19	N/a
	Epic/Bicor (St. Jude Medical)	N/A	N/A	N/A
	Epic Supra/Bicor Supra (St. Jude Medical)	N/A	N/A	N/A
20	Soprano (Sorin Biomedica)	28	23	19.8
21	Magna (Edwards Lifesciences)	26	21	20
	Perimount (Edwards Lifesciences)	29	21	20
	Mosaic/Hancock II (Medtronic)	27	21	18.5
	Hancock/Hancock Ultra (Medtronic)	26	21	18.5
	Mitroflow (Sorin Biomedica)	23	20.7	17.3
	Trifecta (St. Jude Medical)	26	21	N/A
	Epic/Bicor (St. Jude Medical)	N/A	21	19
	Epic Supra/Bicor Supra (St. Jude Medical)	N/A	21	21
22	Soprano (Sorin Biomedica)	30	25	21.7





Transcatheter Valve-in-Valve Implantation for Failed Surgical Bioprosthetic Valves

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Vascular Approches

3) Carotid D/G

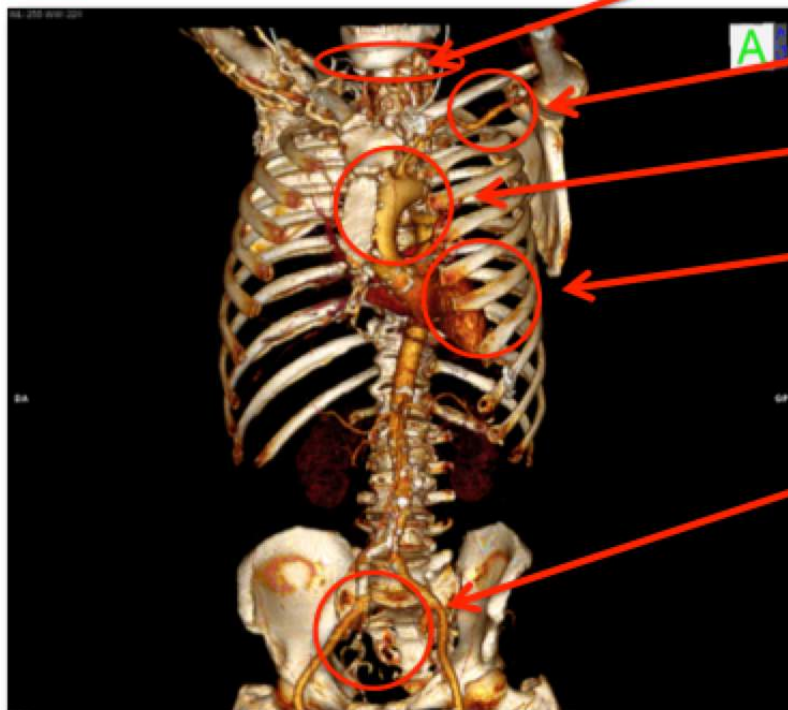


2) Sub-clavian / Axillary

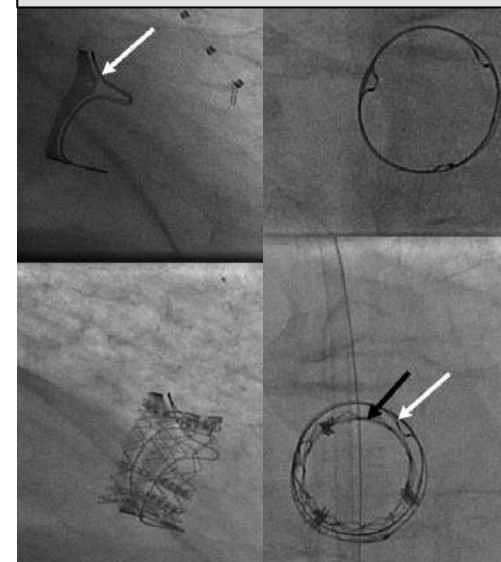
4) Direct transAo

5) transapical

1) Trans femoral
- per-cut.
- Surg
- Iliac I/E



No pre-dilatation





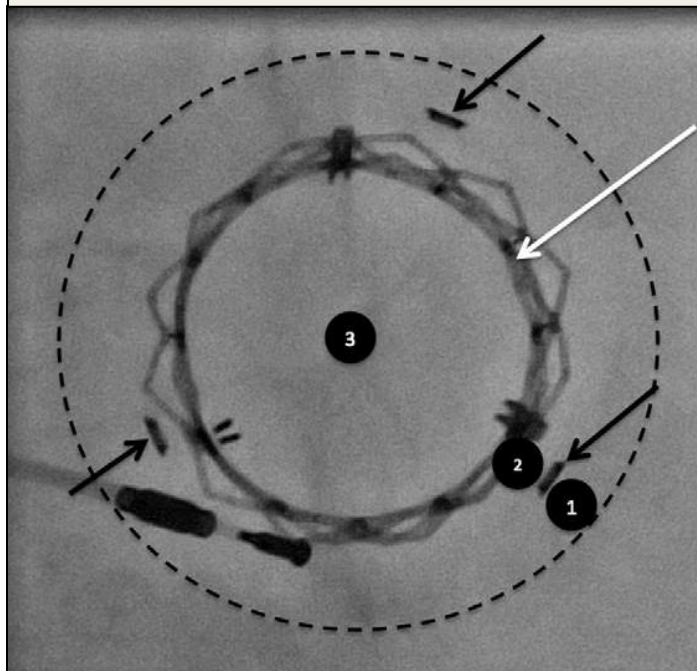
Transcatheter Valve-in-Valve Implantation for Failed Surgical Bioprosthetic Valves

J Am Coll Cardiol 2011;58:2196–209

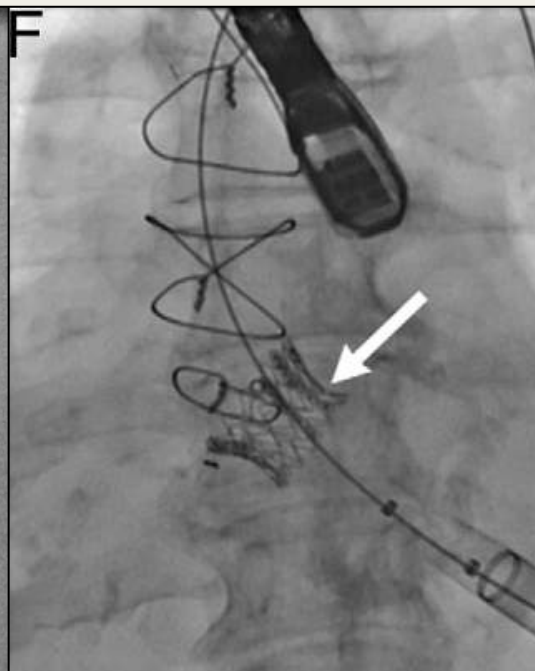
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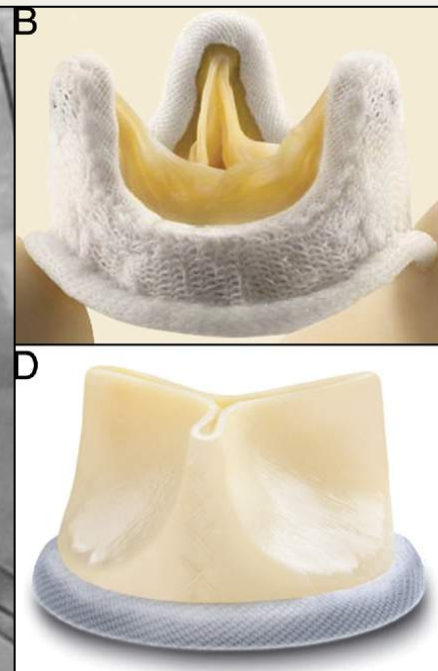
Para-Valvular leaks



Miss-match



Coronary



INTRO

The Valve-in-Valve Technique for Treatment of Aortic Bioprosthesis Malposition

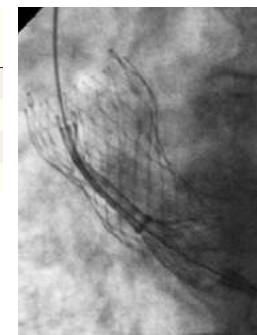
J Am Coll Cardiol 2011;57:1062–8

An Analysis of Incidence and 1-Year Clinical Outcomes From the Italian CoreValve Registry



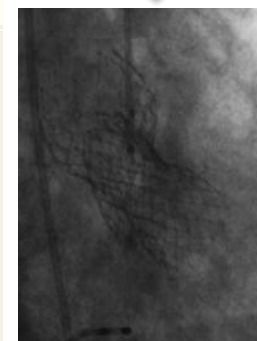
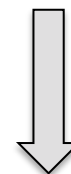
Context

	Overall Population (n = 663)	No VIV Group (n = 639)	VIV Group (n = 24)	p Value
Age, yrs	81.0 ± 7.3	81.0 ± 7.3	80.3 ± 6.2	0.656
Female	371 (56.0)	358 (56.0)	13 (54.1)	0.857
Diabetes mellitus	175 (26.4)	171 (26.7)	4 (16.6)	0.271
Coronary artery disease	320 (48.3)	306 (47.9)	14 (58.3)	0.315
NYHA functional class III and IV	434 (71.5)	415 (64.9)	19 (79.2)	0.486
Logistic EuroSCORE, %	23.0 ± 13.7	22.9 ± 13.7	23.6 ± 14.3	0.803
Baseline echocardiographic parameters				
Left ventricular ejection fraction, %	52.1 ± 25.5	52.2 ± 25.9	49.3 ± 15.1	0.581



Technic

Procedural variables, min				
Procedure time	79.1 ± 33.6	78.0 ± 33.4	101.3 ± 30.8	0.001*
Fluoroscopy time	21.3 ± 13.3	20.6 ± 12.2	35.9 ± 25.5	<0.001*
Approach				0.306
Transfemoral	599 (90.3)	576 (90.1)	23 (90.4)	
Transsubclavian	64 (9.7)	63 (9.9)	1 (9.6)	
Device†				0.898
CRS 26 mm	394 (59.4)	379 (59.3)	15 (62.5)	
CRS 29 mm	269 (40.6)	260 (40.7)	9 (37.5)	
Ratio CRS diameter/aortic annulus‡	1.23 ± 0.1	1.23 ± 0.1	1.21 ± 0.9	0.397
Post dilation	68 (10.2)	56 (8.8)	12 (50)	<0.001*
Procedural success	650 (98.0)	626 (97.9)	24 (100)	0.616
Valve embolization	4 (0.6)	4 (0.6)	0 (0.0)	0.831
Death	6 (0.9)	6 (0.9)	0 (0.0)	0.801
Myocardial infarction	0 (0)	0 (0)	0 (0.0)	1.000
Stroke	8 (1.2)	8 (1.2)	0 (0.0)	0.743
Conversion to open heart surgery	5 (0.8)	5 (0.8)	0 (0.0)	0.831



Results

Conclusion

The Valve-in-Valve Technique for Treatment of Aortic Bioprosthesis Malposition

J Am Coll Cardiol 2011;57:1062–8

An Analysis of Incidence and 1-Year Clinical Outcomes From the Italian CoreValve Registry

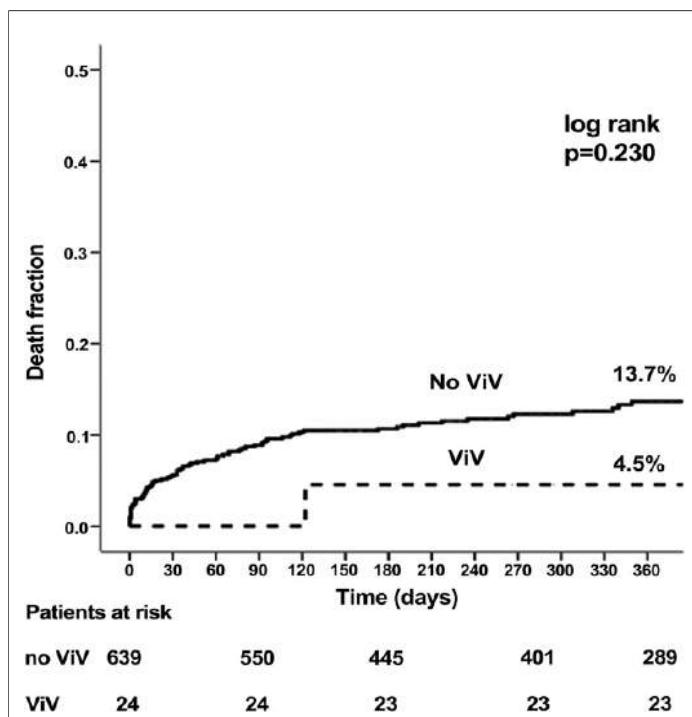


Figure 3 Time-to-Event Curves for the Mortality End Point

Event rates were calculated with the use of Kaplan-Meier methods and were compared with the use of the log-rank test. ViV = valve-in-valve.

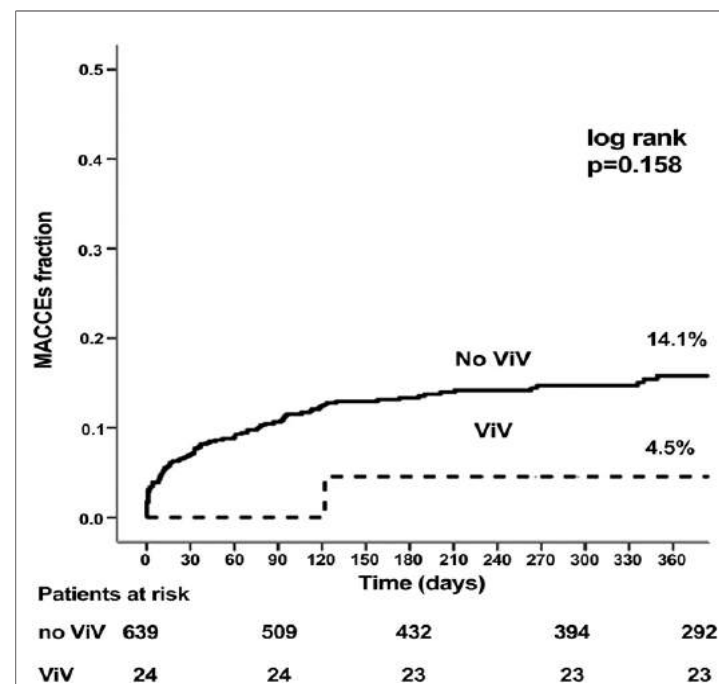


Figure 4 Time-to-Event Curves for MACCE

Event rates were calculated with the use of Kaplan-Meier methods and were compared with the use of the log-rank test. MACCE = major adverse cardiovascular and cerebrovascular events; ViV = valve-in-valve.



Transcatheter Aortic Valve Implantation in Failed Bioprosthetic Surgical Valves

JAMA. 2014;312(2):162-170

Danny Dvir, MD; John G. Webb, MD; Sabine Bleiziffer, MD; Miralem Pasic, MD, PhD; Ron Waksman, MD; Susheel Kodali, MD; Marco Barbanti, MD; Azeem Latib, MD; Ulrich Schaefer, MD; Josep Rodés-Cabau, MD; Hendrik Treede, MD; Nicolo Piazza, MD, PhD; David Hildick-Smith, MD; Dominique Himbert, MD; Thomas Walther, MD; Christian Hengstenberg, MD; Henrik Nissen, MD, PhD; Raffi Bekeredjian, MD; Patrizia Presbitero, MD; Enrico Ferrari, MD; Amit Segev, MD; Arend de Weger, MD; Stephan Windecker, MD; Neil E. Moat, FRCS; Massimo Napodano, MD; Manuel Wilbring, MD; Alfredo G. Cerillo, MD; Stephen Brecker, MD; Didier Tchetché, MD; Thierry Lefèvre, MD; Federico De Marco, MD; Claudia Fiorina, MD; Anna Sonia Petronio, MD; Rui C. Teles, MD; Luca Testa, MD; Jean-Claude Laborde, MD; Martin B. Leon, MD; Ran Kornowski, MD; for the Valve-in-Valve International Data Registry Investigators



The VIVID registry ➔ CoreValve + Edwards from 2007 to 2013

55 centers : Europe, North America, Australia, New Zealand, Middle East

Characteristics	Mechanism of Surgical Valve Failure					Device Used		
	All (n = 459)	Stenosis (n = 181)	Regurgitation (n = 139)	Combined (n = 139)	P Value	Self- Expandable (n = 213)	Balloon- Expandable (n = 246)	P Value
Age, mean (SD), y	77.6 (9.8)	78.8 (7.8)	77.1 (10.6)	76.6 (11.1)	.10	77.6 (10)	77.6 (9.7)	.95
Men, No. (%)	257 (56)	87 (48)	93 (66.9)	77 (55.4)	.002	113 (53.1)	144 (58.5)	.25
LogEuroSCORE, median (IQR), % ^b	29 (19.1-42.3)	29.8 (20-39.9)	25.7 (16-41.9)	30.3 (22.3-44.7)	.18	29 (18.6-38.7)	29 (19.3-44.2)	.48
STS score, median (IQR), % ^b	10 (6.2-16.1)	9.9 (6.1-13.9)	9.9 (5.8-15.6)	10.8 (7.1-18.4)	.33	11 (6.2-17.3)	9.3 (6.1-14.1)	.13
Left ventricular ejection fraction, mean (SD), %	50.3 (13.1)	51.7 (12.9)	49.0 (13.1)	49.7 (13.3)	.16	49.1 (13.4)	51.2 (12.8)	.08



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Table 2. Surgical Valve Characteristics at the Time of Valve-in-Valve Procedure

Characteristics	All (n = 459)	Mechanism of Surgical Valve Failure				Device Used		
		Stenosis (n = 181)	Regurgitation (n = 139)	Combined (n = 139)	P Value	Self- Expandable (n = 213)	Balloon- Expandable (n = 246)	P Value
Time since last SAVR, median (IQR), y ^a	9 (6-12)	8 (5-11)	10(7-14)	10 (7-14)	.04	9 (7-13)	9 (6-12)	.08
Type, No. (%)					<.001			<.001
Stented	366 (79.7)	173 (95.6)	84 (60.4)	109 (78.4)		152 (71.4)	214 (87)	
Stentless	93 (20.3)	8 (4.4)	55 (29.6)	30 (21.6)		61 (28.6)	32 (13)	
Label size, No. (%)								
≤21 mm	133 (29)	67 (37)	29 (20.9)	37 (26.6)	.005	68 (31.9)	65 (26.4)	.19
>21 mm and <25 mm	176 (38.3)	74 (40.9)	43 (30.9)	59 (42.4)	.09	83 (39)	93 (37.8)	.80
≥25 mm	139 (30.3)	34 (18.8)	65 (46.8)	40 (28.8)	<.001	53 (24.9)	86 (35)	.02
Unknown	11 (2.4)	6 (3.3)	2 (1.4)	3 (2.2)	.54	9 (4.2)	2 (0.8)	.02

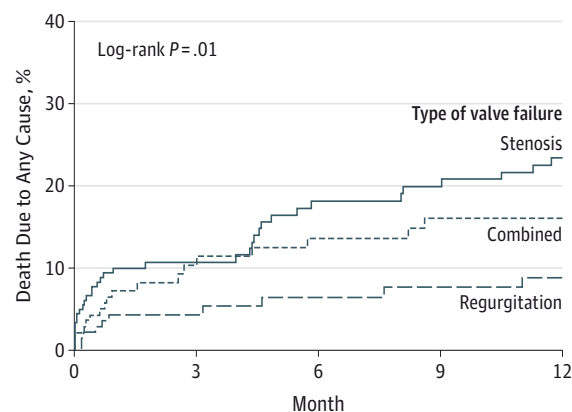


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JAMA. 2014;312(2):162-170

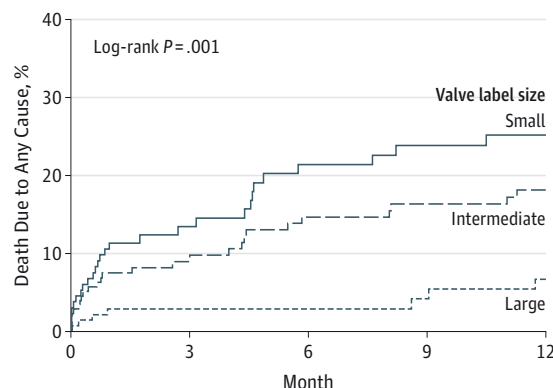


Danny Dvir, MD; John G. Webb, MD; Sabine Bleiziffer, MD; Miralem Pasic, MD, PhD; Ron Waksman, MD; Susheel Kodali, MD; Marco Barbanti, MD; Azeem Latib, MD; Ulrich Schaefer, MD; Josep Rodés-Cabau, MD; Hendrik Treede, MD; Nicolò Piazza, MD, PhD; David Hildick-Smith, MD; Dominique Himbert, MD; Thomas Walther, MD; Christian Hengstenberg, MD; Henrik Nissen, MD, PhD; Raffi Bekeredjian, MD; Patrizia Presbitero, MD; Enrico Ferrari, MD; Amit Segev, MD; Arend de Weger, MD; Stephan Windecker, MD; Neil E. Moat, FRCS; Massimo Napodano, MD; Manuel Wilbring, MD; Alfredo G. Cerillo, MD; Stephen Brecker, MD; Didier Tchetché, MD; Thierry Lefèvre, MD; Federico De Marco, MD; Claudia Fiorina, MD; Anna Sonia Petronio, MD; Rui C. Teles, MD; Luca Testa, MD; Jean-Claude Laborde, MD; Martin B. Leon, MD; Ran Kornowski, MD; for the Valve-in-Valve International Data Registry Investigators



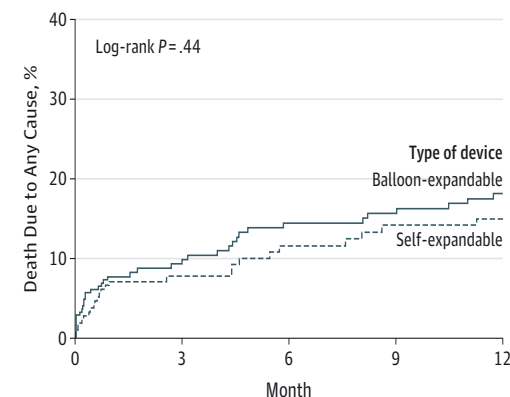
Type of valve failure

181	112	98	91	86
139	92	84	78	76
139	85	76	68	66



Valve label size

133	81	68	61	57
176	116	103	95	92
139	89	82	76	73



Type of device

246	163	146	136	130
213	126	112	101	98



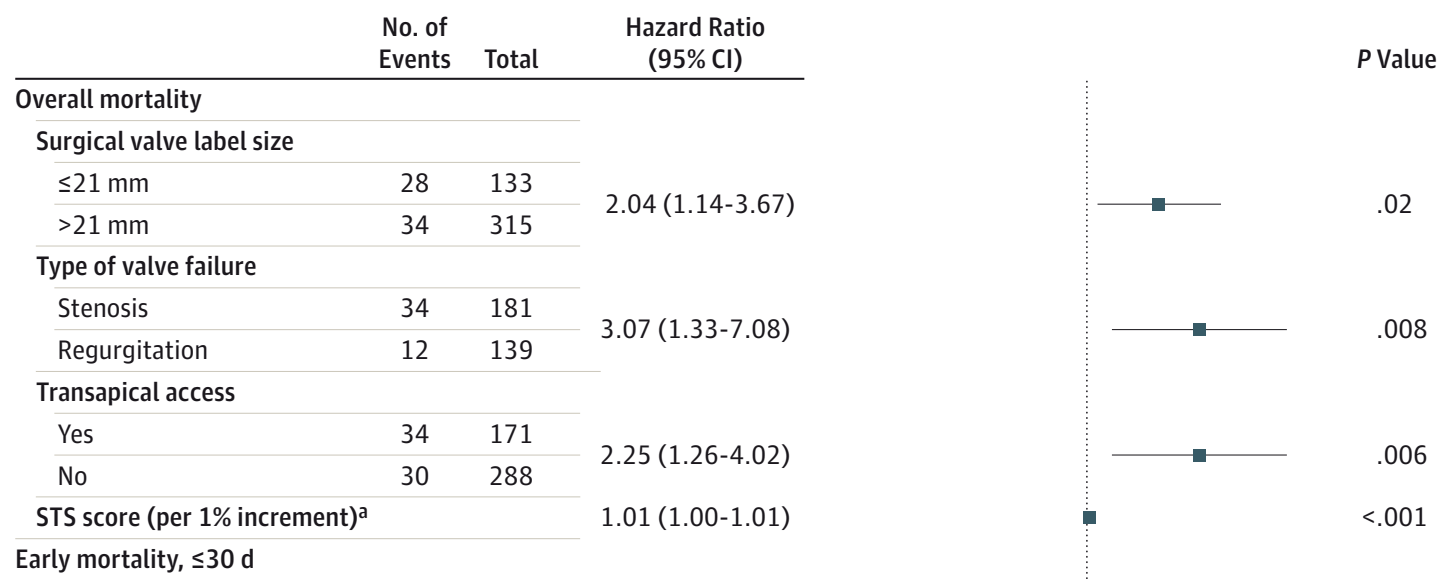
Transcatheter Aortic Valve Implantation in Failed Bioprosthetic Surgical Valves

JAMA. 2014;312(2):162-170

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Figure 2. Results of Multivariable Analyses for Correlates for 1-Year Mortality After Valve-in-Valve Implantation



Conclusion : 83% at 1 year, Small prosthesis and stenosis



CARDIOVASCULAR FLASHLIGHT

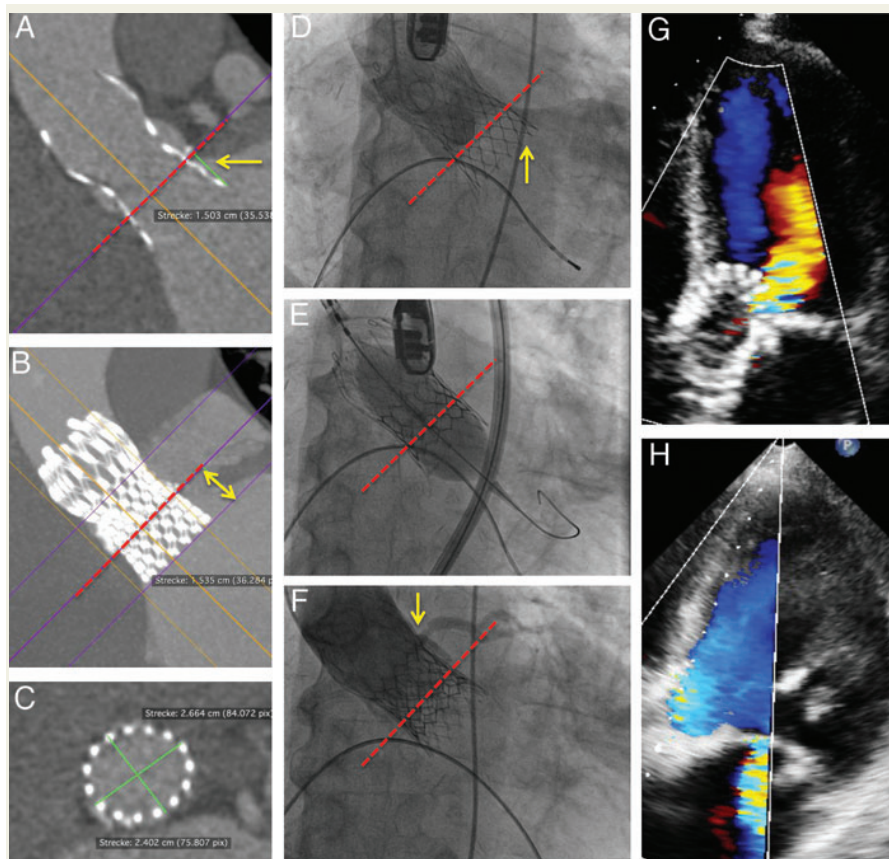
Eurheart j June 2014

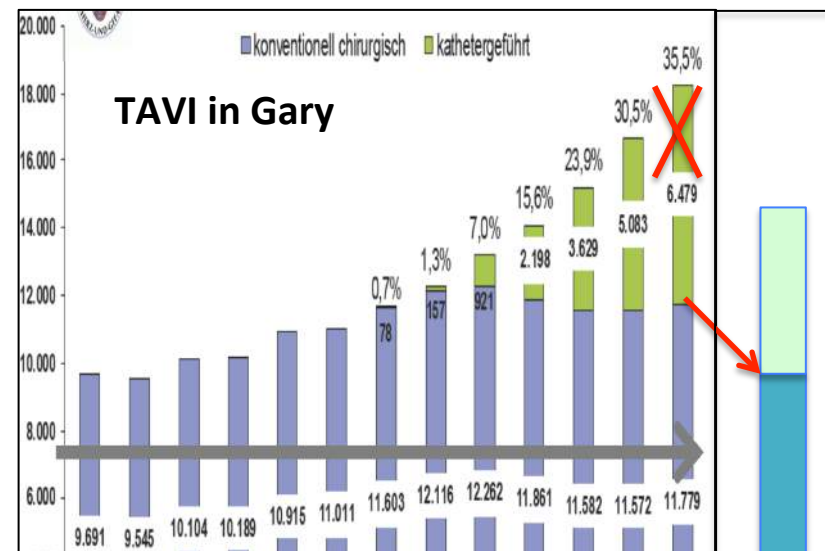
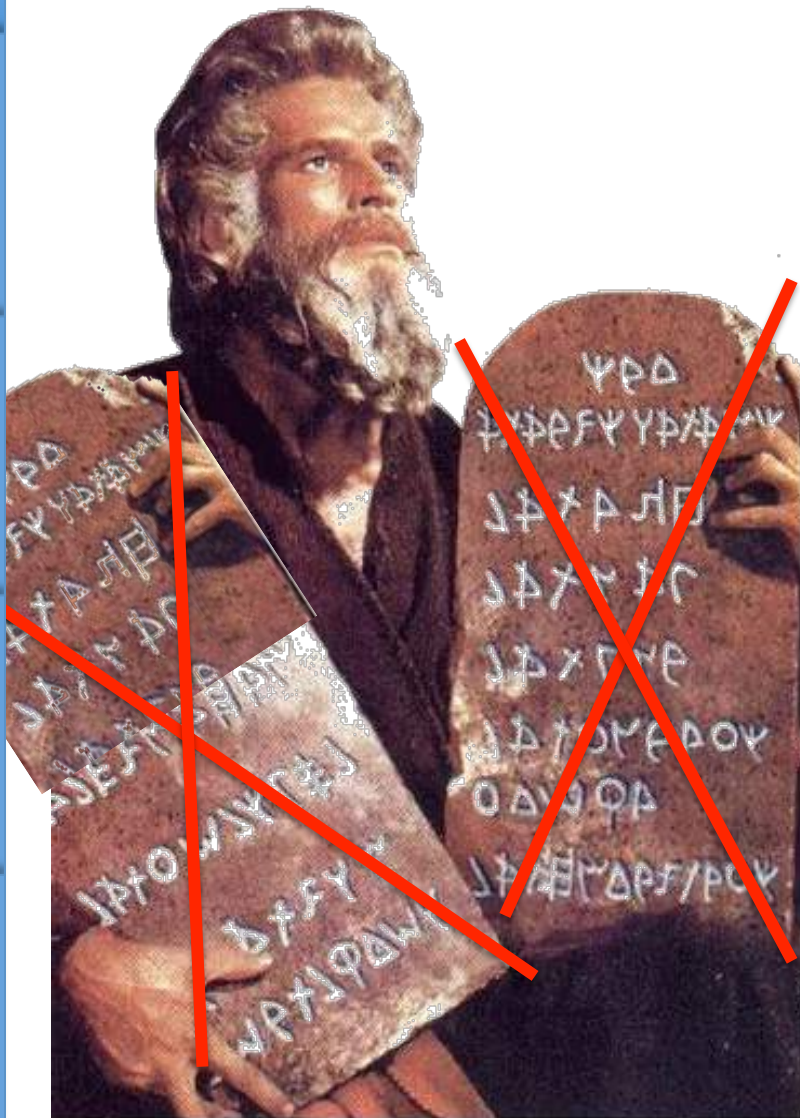
doi:10.1093/eurheartj/ehu266

Online publish-ahead-of-print 30 June 2014

Valve-in-valve transfemoral TAVR: Sapien 3 valve within a failed core valve bioprosthesis

Anupama Shivaraju*, Ilka Ott, Adnan Kastrati, and Albert M. Kasel





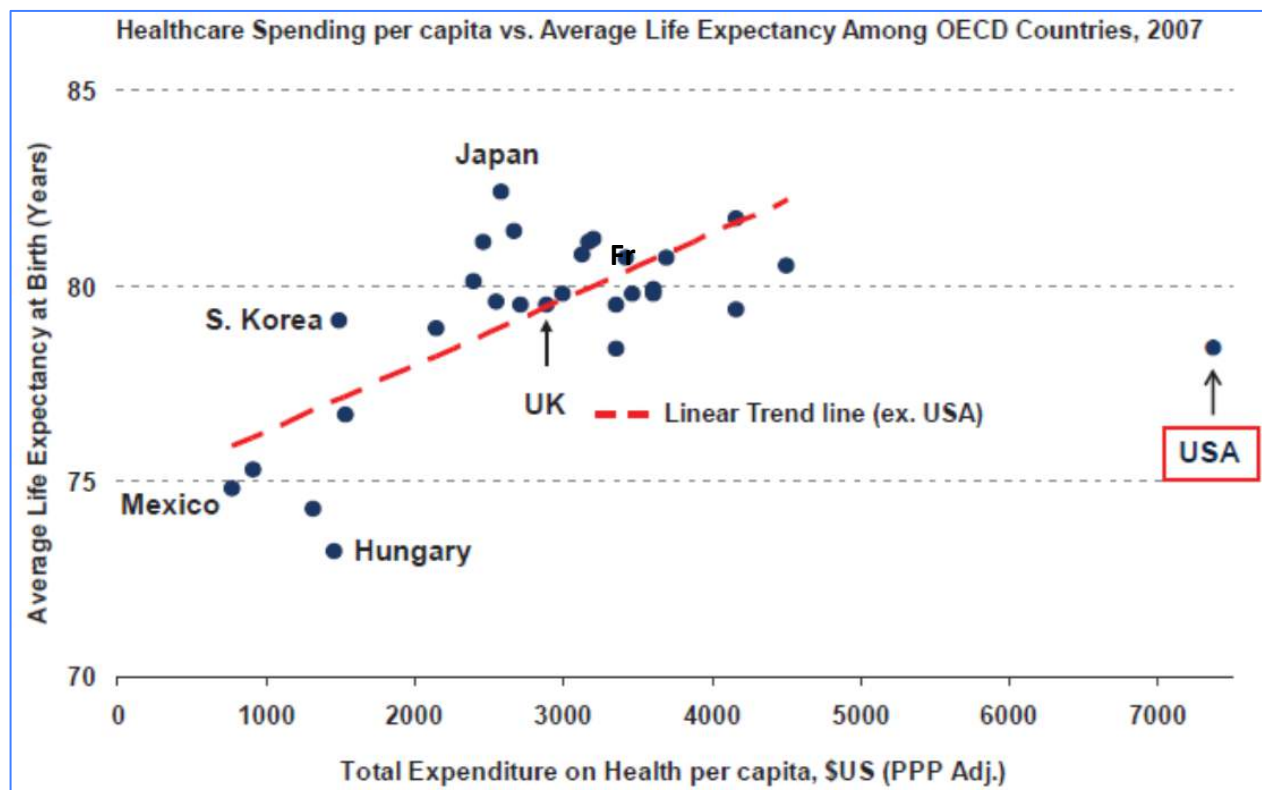
Conclusion :

- V in V → easier and better
- Specific design
- Rethink the valve techniques
 - Bigger valves

BMJ

Transcatheter aortic valve implantation (TAVI): risky and costly Published 31 July 2012

Many of the 40 000 transcatheter procedures so far carried out cannot be justified on medical or cost effectiveness grounds. **Hans Van Brabandt, Mattias Neyt, and Frank Hulstaert** examine why practice has gone beyond the evidence



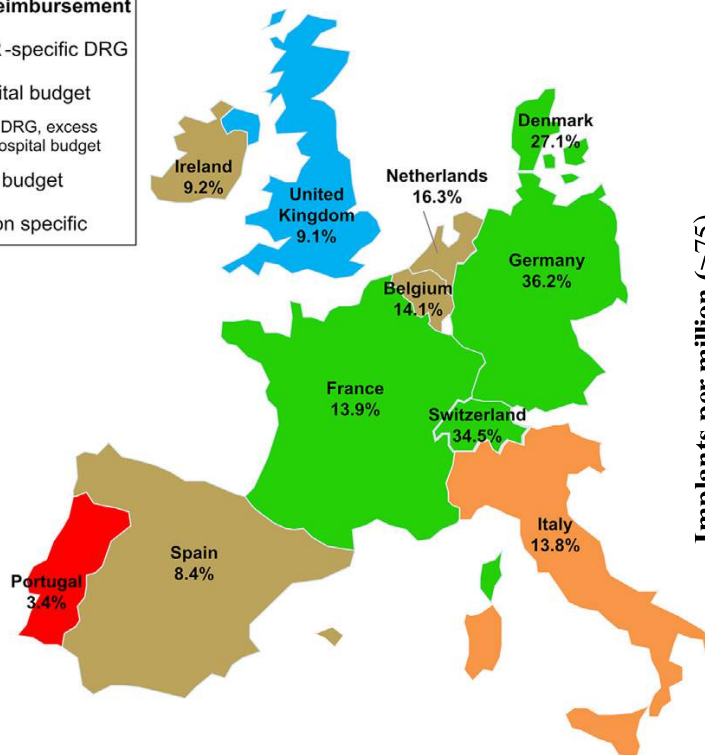
Transcatheter Aortic Valve Replacement in Europe

Adoption Trends and Factors Influencing Device Utilization

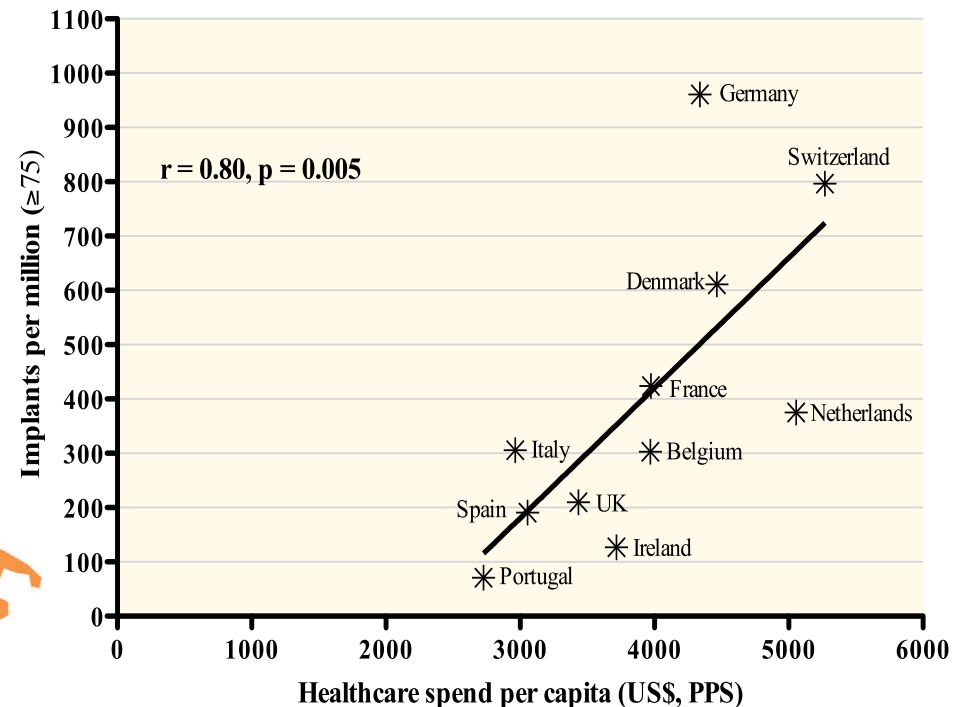
Montreal, Canada; Galway, Ireland; Rotterdam, the Netherlands; Bern and Basel, Switzerland; Massy, France; Milan, Italy; London and Belfast, United Kingdom; Copenhagen, Denmark; Wilrijk, Belgium; Lisbon, Portugal; Madrid, Spain; and Munich, Germany **JACC Vol. 62, No. 3, 2013**

TAVR Reimbursement

- TAVR -specific DRG
- Hospital budget
- SAVR DRG, excess from hospital budget
- Trust budget
- Region specific



Healthcare Spend per capita and Implants per Million



INTRO



Context

Technic

Results

Conclusion

INTRO

Material and Methods

Results

Discussion

Conclusion

Logo and images BACKUP

