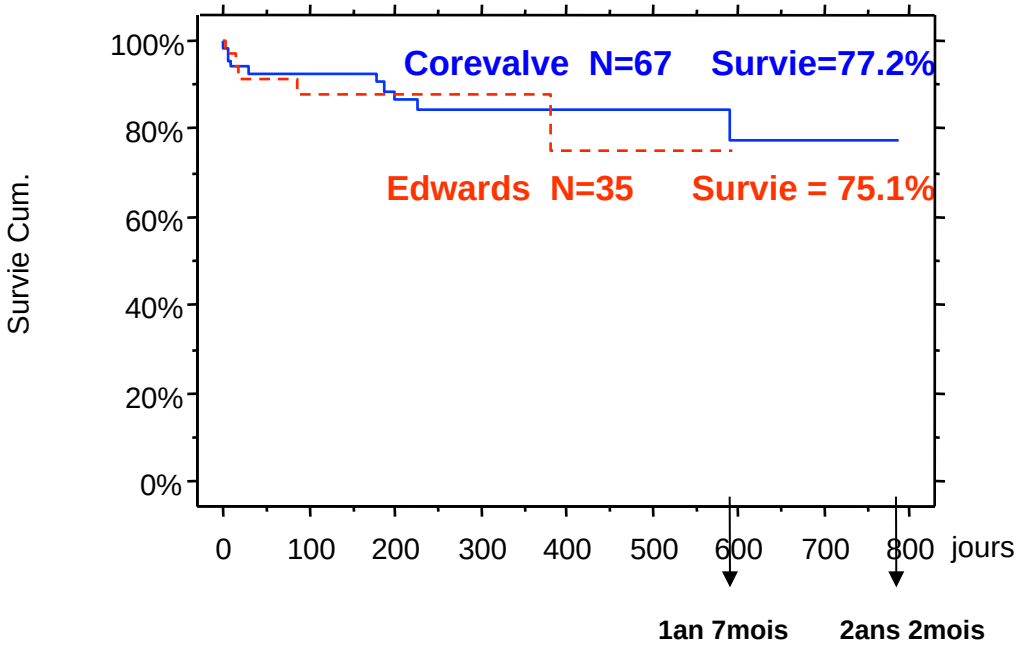
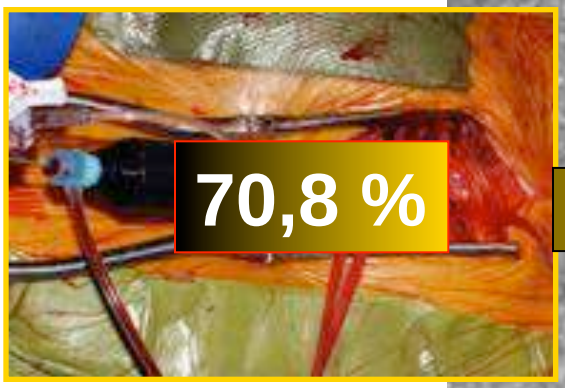
Que faire quand la voie fem. est impraticable ?



Hôpital Cardiothoracique

- LYON -

Que faire quand la voie fem. est impraticable ?



70,8 %

1) Sapiens

29,2 %

84,6 %

2) Corevalve

15,4 %

1) Sapiens Trans Apical (SOURCE European Registry)

" Wendler O, et al. ejcts.2010.11.018 "

Major Complications < 30 d

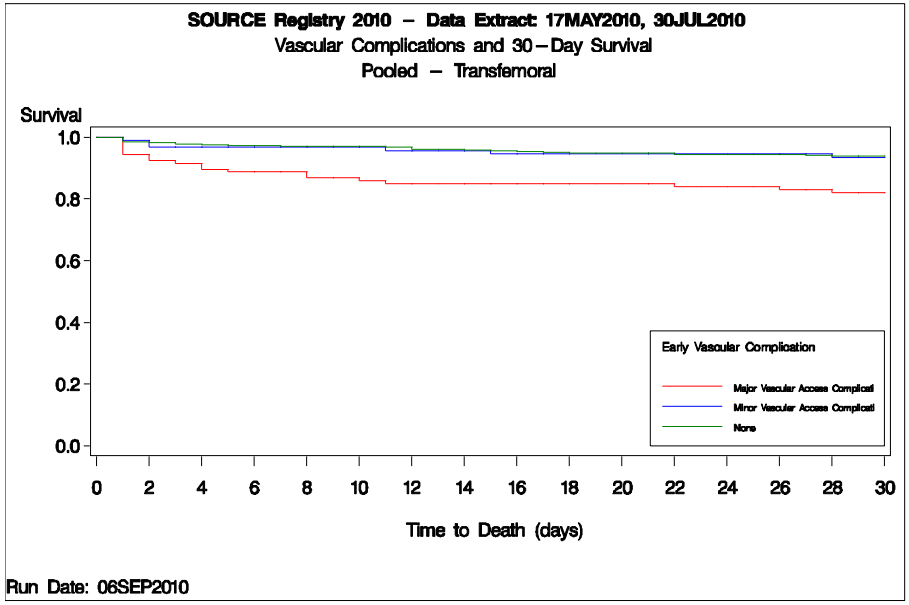
	TF (n=946)	TA/Other (n=1398)	Total (n=2344)
Death	71 (7.5%)	150 (10.7%)	221 (9.4%)
Stroke	27 (2.9%)	35 (2.5%)	62 (2.7%)
Renal Failure Requiring Dialysis	17 (1.8%)	89 (6.4%)	106 (4.5%)
Permanent Pacemaker	63 (6.7%)	99 (7.1%)	162 (6.9%)

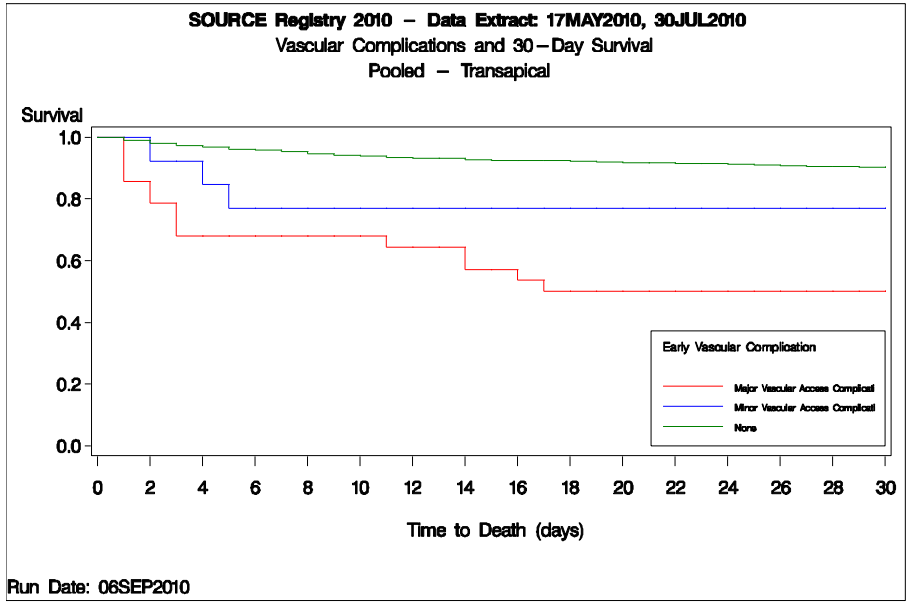
1) Sapiens Trans Apical (SOURCE European Registry)

" Wendler O, et al. ejcts.2010.11.018 "

Vascular/Access Complications and 30 Day Survival

	With No Vascular Complications	With Minor Vascular Complications	With Major Vascular Complications	P-value
Survival Transfemoral	93.8%	93.5%	82.2%	0.0023
Survival Transapical/Other	90.2%	76.9%	50.0%	<0.0001





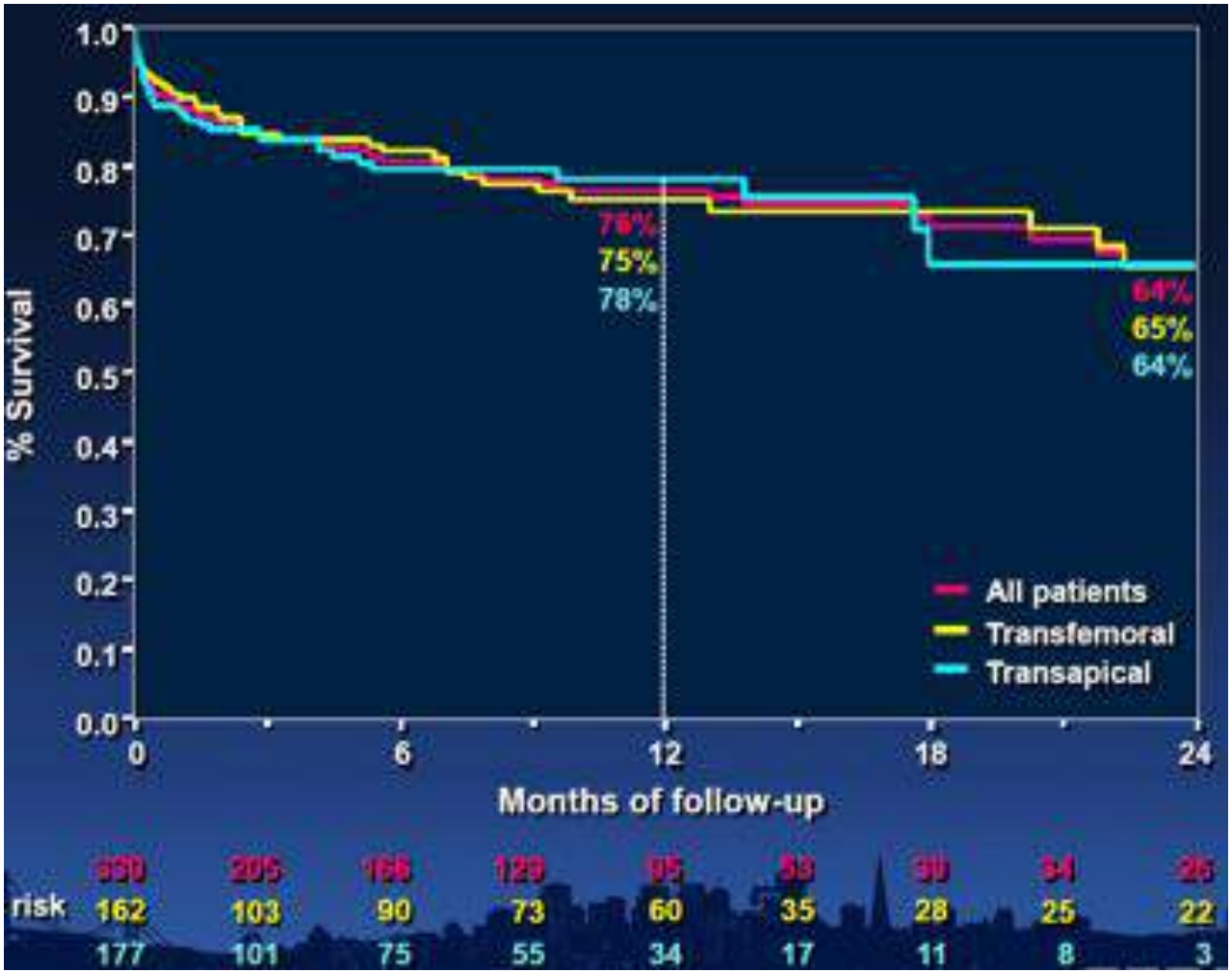
1) Sapiens Trans Apical (SOURCE European Registry)

" Wendler O, et al. ejcts.2010.11.018 "

	TF (n=946)	TA/Other (n=1398)	P-value
Age (yrs)	81.8 ± 6.6	80.6 ± 7.1	<0.0001
Female	56.1%	58.1%	0.4402
Pulmonary Disease	24.5%	26.1%	0.4115
Renal Dysfunction	24.8%	31.2%	0.0009
Logistic EuroSCORE	**24.0 ± 14.2**	**28.1 ± 22.0**	**<0.0001**
Peripheral Vascular Disease	10.3%	26.7%	<0.0001
Carotid Artery Stenosis (>50%)	%	15.3%	<0.0001
Incidence of CAD		56.1%	<0.0001
Porcelain Aorta	4.8	10.2%	<0.0001
Prior CABG	15.1%	5%	<0.0001
Mitral valve disease	21.4%		<0.0001
Log EuroSCORE >=20	55.7%	64	<0.0001
Log EuroSCORE >=30	27.2%	36.2%	<0.0001
Cardiovascular Conditions (none)	5.1%	2.7%	0.0035
Congestive Heart Failure	34.4%	28.2%	0.0016
Myocardial Infarction	12.5%	17.4%	0.0013

TA Patients are higher risk

1) Sapiens Trans Apical - *Canadian Registry " TCT 2009 "*



1) Edwards Transapical

"179 patients within 2 years"

- AHA - #6048 - Augusto D'Onofrio

Baseline clinical characteristics	n=179
Logistic EuroSCORE	22
Age (years)	81.4%
NYHA Class III/IV	82.1%
LVEF	55%
Previous PCI with stent implantation	25.7%
Preoperative mean gradient (mmHg)	50
Preoperative aortic valve area (cm2/m2)	0.55
23 mm valve	34.6%
26 mm valve	65.3%
Procedure success	100%

Severe intraoperative complications	13 (7.3%)
Emergency CPB/ECMO	8
Coronary involvement	3
RV or LV guidewire perforation	3
Fistula ascending aorta ➔ RV	1

	n=179
Padova	38
Venice-Mestre	17
Milan (Monzino)	81
Vicenza	43

1) Edwards Transapical

"179 patients within 2 years"

- AHA - #6048 - Augusto D'Onofrio

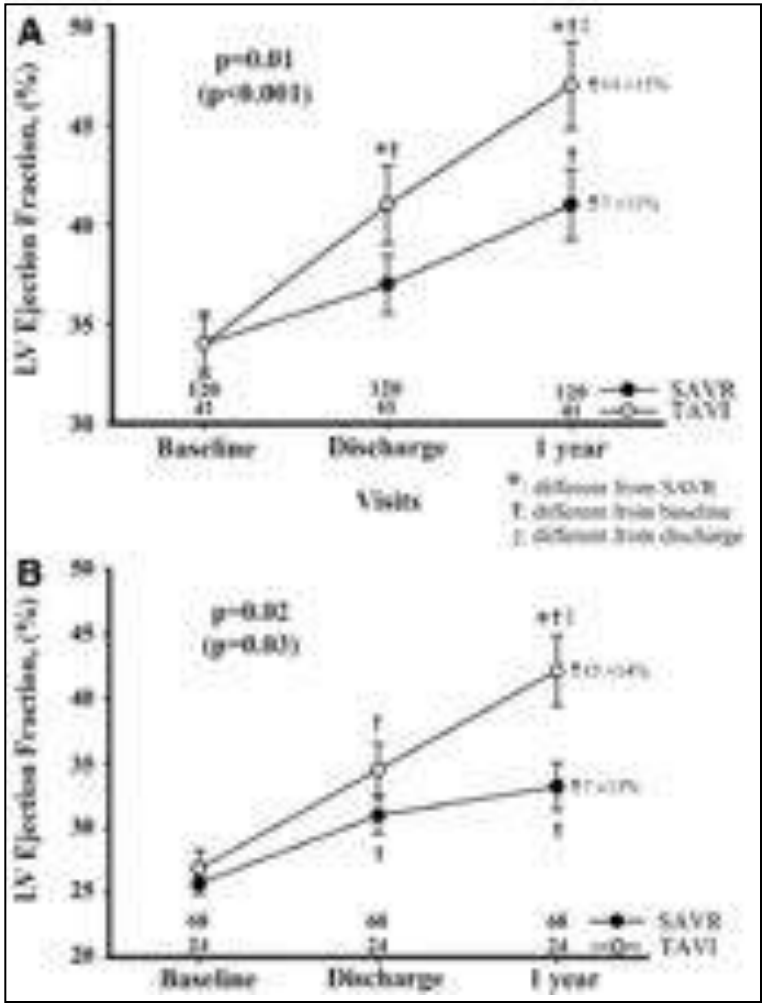
Early Results	n=179
Hospital mortality	3.9%
Median ICU stay (days)	2
Mild to moderate PV leak at discharge	8.4%
Permanent pacemaker implantation	5%
Permanent dialysis	7.8%

At discharge	23 mm	26 mm
mPG (mmHg)	13	10
EOA (cm2)	1.8	2.3
EOAi (cm2/m2)	1.1	1.4

Follow-up Results	n=179
Mean follow-up (months)	9.2 (ranging from 1-26)
2-year survival (Kaplan Meier)	88%
Structural valve deterioration	0%
Non-valve-related adverse events	0%

1) Trans apical / Fem

"Comparison TAVI and Surg"
Pibarot – Circulation 2010



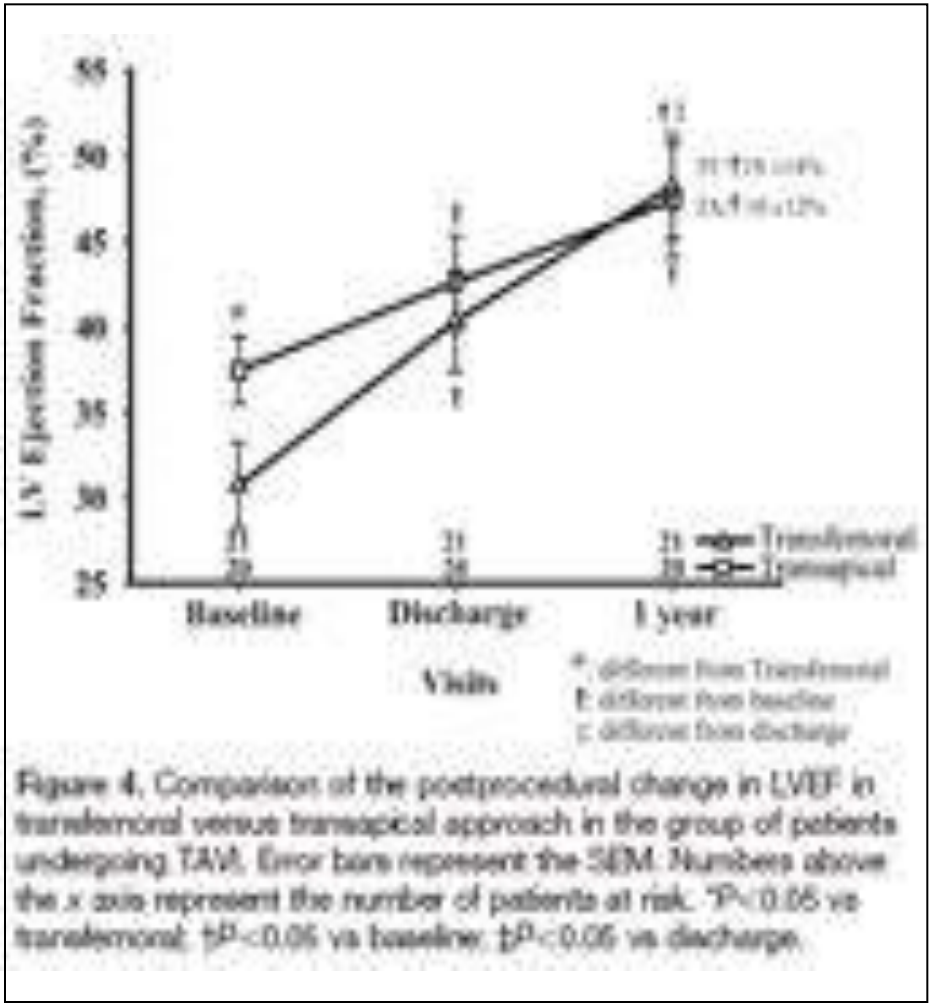


Figure 4. Comparison of the postprocedural change in LVEF in transfemoral versus transapical approach in the group of patients undergoing TAVI. Error bars represent the SEM. Numbers above the *x* axis represent the number of patients at risk. *P<0.05 vs transfemoral; †P<0.05 vs baseline; ‡P<0.05 vs discharge.

2) TAVI using the Axillary/Subclavian…

"Modine T et al. J Thor Cardiovasc Surg 2010"

17 patients :

13 AG / 4 AL
2 Dte / 15 G
2 MIG > 6,5 mm

-Lille 7

-Pitié 5

-Lyon 4

-Bordeaux 1

Age, y, mean ± SD	71 ± 11 y
Angina, n (%)	0
Heart failure, n (%)	26
NYHA III and IV failure class	40
Syncope, n (%)	13.3
Male gender, n (%)	46.2
Diabetes mellitus, n (%)	20
Coronary heart disease, n (%)	53.3
Porcelain aorta, n (%)	0
Prior bypass graft surgery, n (%)	26.6
Prior angioplasty, n (%)	20
Renal dysfunction,* n (%)	6.6
Logistic euroSCORE predicted mortality, mean ± SD, %	34 ± 11
Left ventricle ejection fraction % mean	52 ± 14

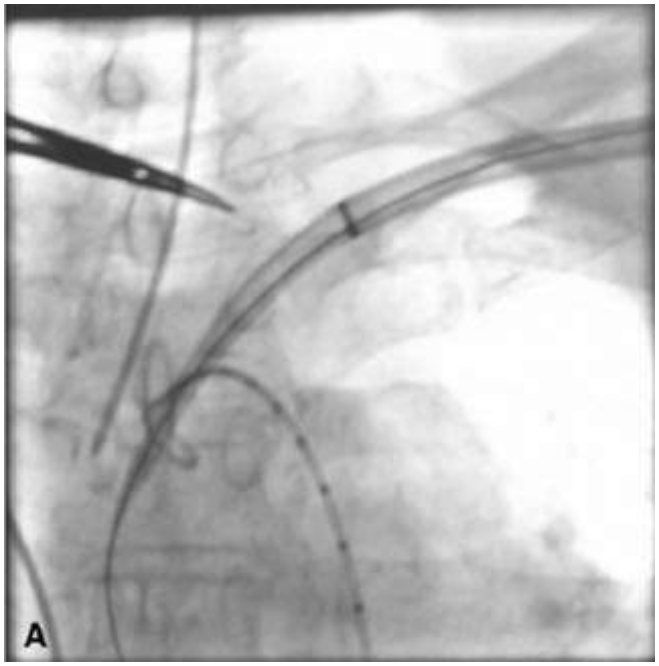
≠ 25 %

2) TAVI using the Axillary/Subclavian…

"Modine T et al. J Thor Cardiovasc Surg 2010"

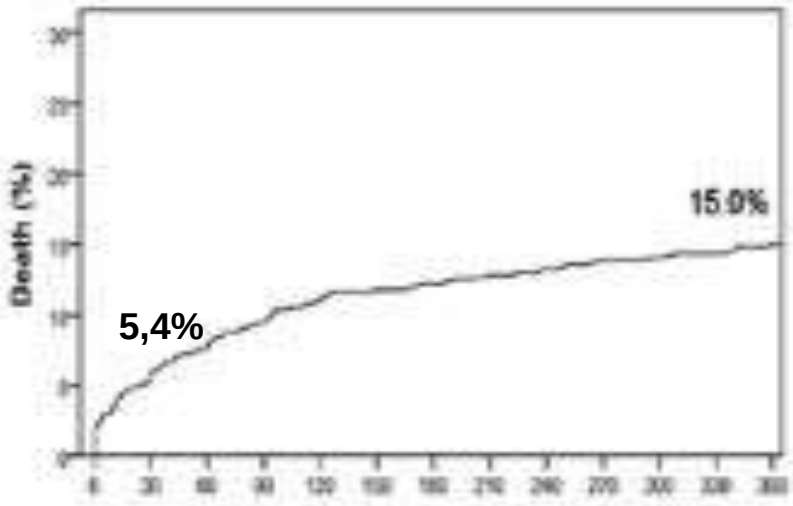
TABLE 3. Postprocedural outcome (follow-up of 30 days)

Death	2 patients **11%**
Thromboembolism	0%
Transient ischemic attack	1 patient
Myocardial infarction	0%
Aortic dissection	1 patient
Tamponade	0%
Conversion to surgery	0%
NYHA class I and II	100%
endocarditis	0%



2) Subclavian Clinical Experience
Italian results in 663 Corvalve *"Circulation 20011;123:299-308"*

	Overall Population (n=663)
Baseline characteristics	
Age, years±SD	81.0±7.3
Female gender, n (%)	371 (56.0)
Body mass index, Kg/m²±SD	25.7±5.0
Low weight†, n (%)	240 (36.2)
Logistic EuroSCORE, %±SD	23.0±13.7
Prior pacemaker, n (%)	42 (6.3)➔**17%**



Approach	
Trans-femoral, n (%)	599 (90.3)
Trans-subclavian, n (%)	64 (9.7)

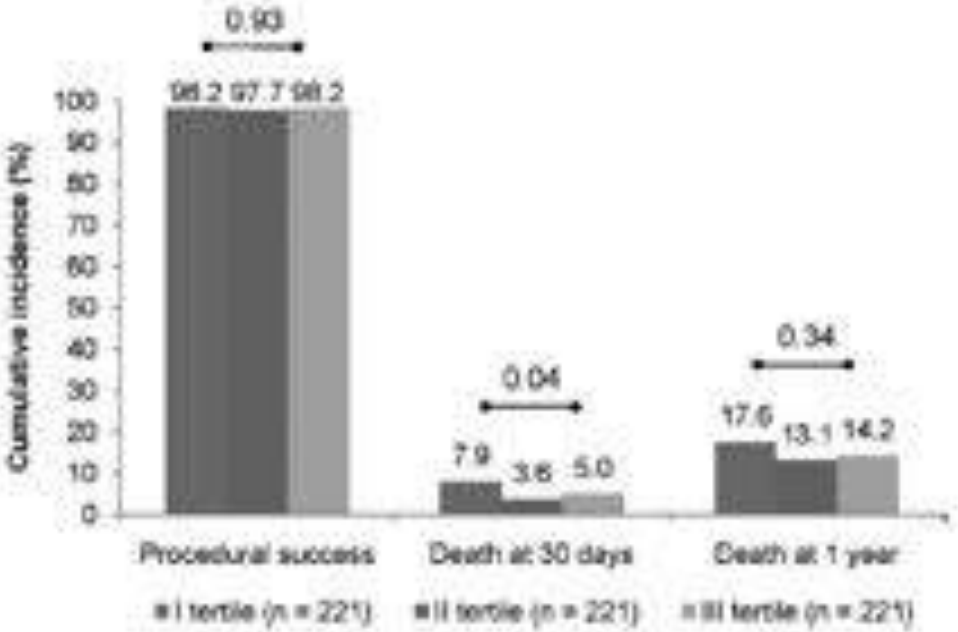
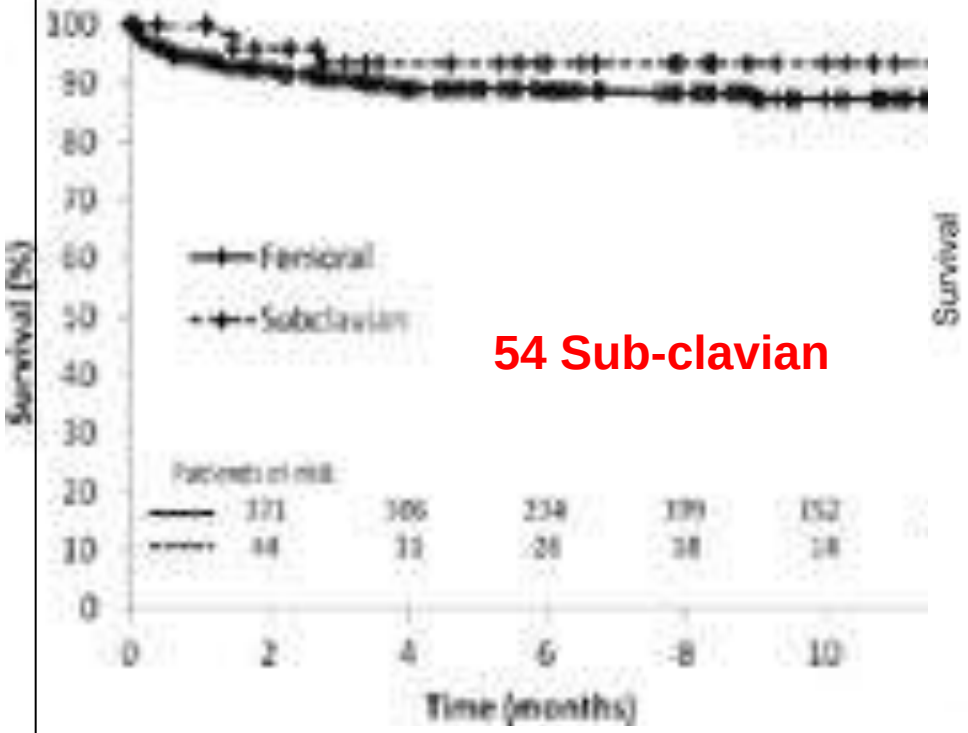


Figure 3. Learning curve across study periods.

2) Subclavian Clinical Experience
Italian results 514 Corvalve *"Circ Cardiovasc Interv 2010;3:359-66"*

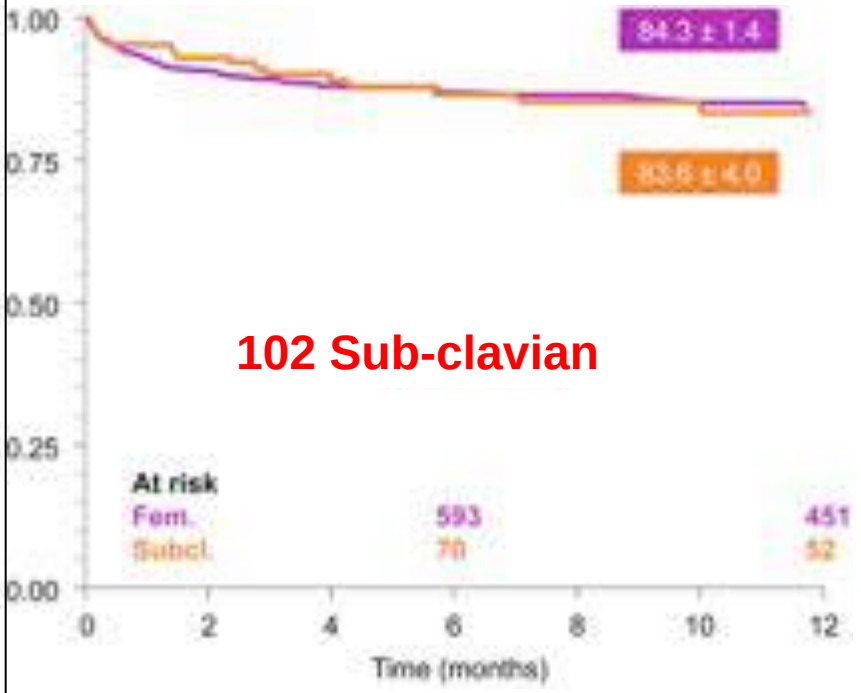
	Total (n=514)	Femoral (n=460)	Subclavian (n=54)	P
Age	83 (78–86)	83 (78–86)	83 (80–86)	0.24
Female sex, n (%)	288 (56.0)	270 (58.7)	18 (33.3)	0.0004*
Logistic EuroSCORE	20.1 (12.8–30.5)	19.4 (12.5–29.8)	25.3 (15.1–36.6)	0.03*
Carotid artery stenosis, n (%)	62 (12.1)	51 (11.1)	11 (20.4)	0.05
Peripheral artery disease, n (%)	99 (19.3)	69 (15.0)	30 (55.6)	<0.0001*
Coronary artery disease, n (%)	259 (50.4)	224 (48.7)	35 (64.8)	0.03*
Prior myocardial infarction, n (%)	113 (22.0)	95 (20.7)	18 (33.3)	0.03*
Prior percutaneous coronary intervention, n (%)	149 (29.0)	124 (27.0)	25 (46.3)	0.003*
Procedure duration, min	74 (50–120)	70 (50–101)	120 (90–127)	<0.0001*
Transfusion ≥3 packed cells units, n (%)	53 (10.3)	48 (10.4)	5 (9.3)	0.79
Transfusion ≥5 packed cells units, n (%)	16 (3.1)	15 (3.3)	1 (1.9)	0.72
In-hospital mortality, n (%)	20 (3.9)	20 (4.3)	0 (0)	0.15
In-hospital MI, n (%)	2 (0.4)	2 (0.4)	0 (0)	1.00
In-hospital stroke, n (%)	9 (1.8)	8 (1.7)	1 (1.9)	1.00
In-hospital reoperation, n (%)	1 (0.2)	1 (0.2)	0 (0)	1.00
In-hospital MACCEs, n (%)	31 (6.0)	30 (6.5)	1 (1.9)	0.23

2) Subclavian Clinical Experience
Italian results 514 Corvalve *"Circ Cardiovasc Interv 2010;3:359-66"*



54 Sub-clavian

"Circ Cardiovasc Interv 2010;3:359-66"

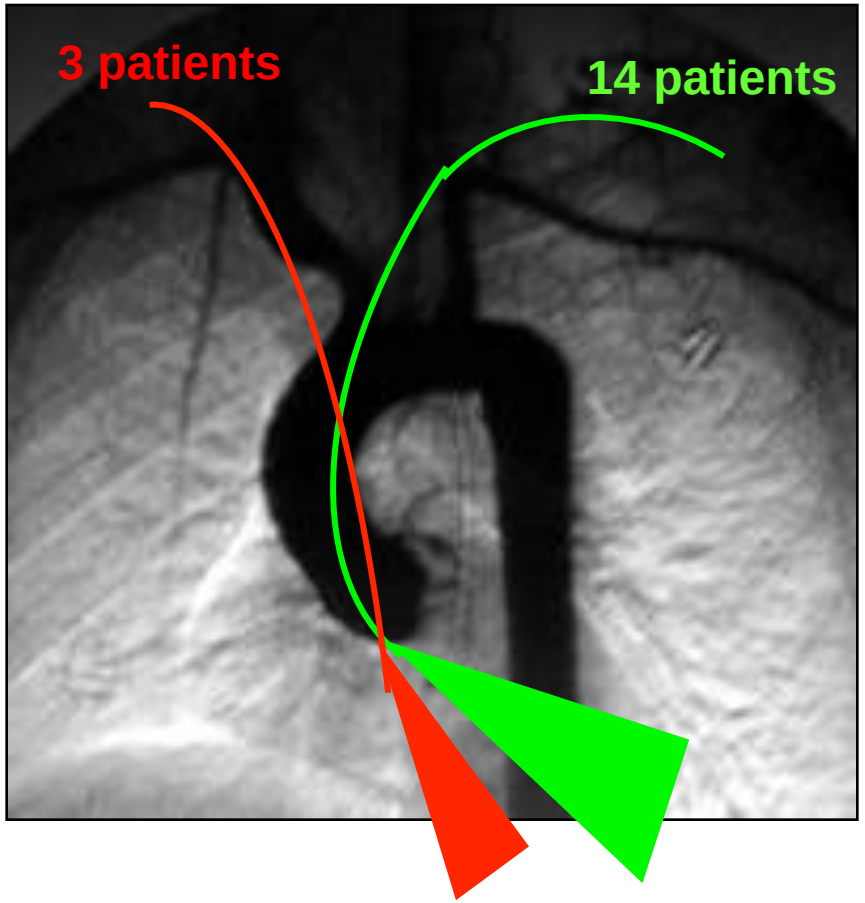


102 Sub-clavian

Presented at ESC 2010
Stockholm, Sweden

2) Sous-Clavière Lyon

- Lyon : 17 patients
  - *2 AL, 10 AG*
  - *2 échecs d'implantation (SC dte)*
    - *AVC ➔ DCD*
    - *DCD*
  - *1 Dissection SC*
  - *15 succès*
  - *Peu hémorragique*
    - *Témoin Jéhovah*
  - *Bon contrôle des gestes*

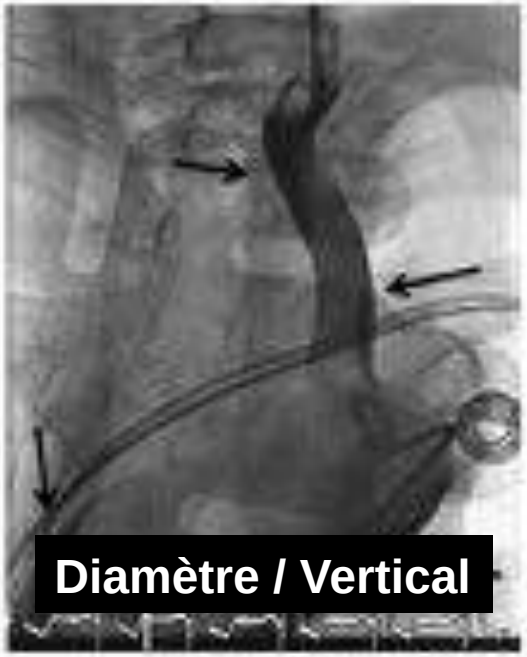


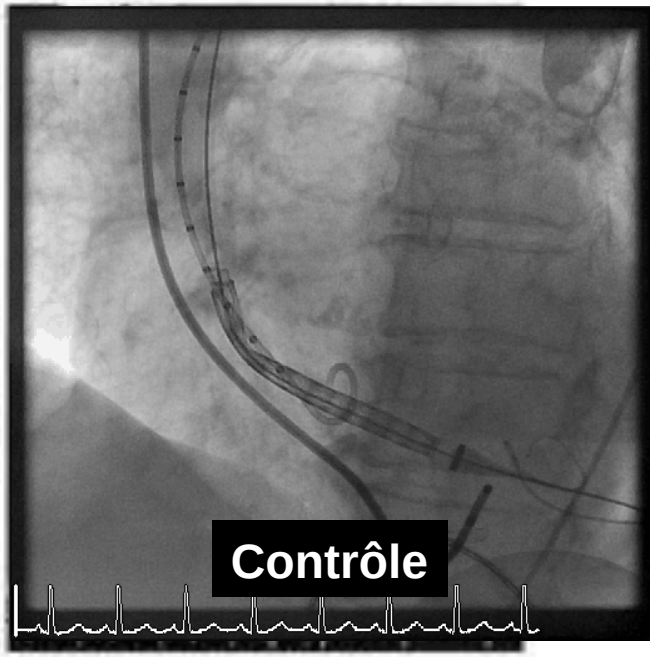
3) Trans Carotide *"8 pts à Lille, 2 pts à Mondor"*

Aortic valve implantation with the CoreValve ReValving System via left carotid artery access: First case report

Thomas Modine, MD,[b] Gilles Lemesle, MD,[a] Richard Azzaoui, MD,[b] and Arnaud Sudre, MD,[a] Lille, France

The Journal of Thoracic and Cardiovascular Surgery • October 2010





4) Trans Ascending Aorta “Sapiens”

First successful trans-catheter aortic valve implantation through ascending aorta using Edwards SAPIEN THV system

Vinayak Bapat*, Martyn Thomas, Jane Hancock, Karen Wilson

Department of Cardiothoracic Surgery and Cardiology, Guy's and St. Thomas' Hospital, London, UK

Received 21 January 2010; received in revised form 15 March 2010; accepted 21 March 2010

Eur J Cardiothorac Surg (2010), doi:10.1016/j.ejcts.2010.03.044

4) Trans Ascending Aorta “Corevalve”

Direct aortic access through right minithoracotomy for implantation of self-expanding aortic bioprosthetic valves

Giuseppe Bruschi, MD,[a] Federico De Marco, MD,[a] Pasquale Fratto, MD,[a] Jacopo Oreglia, MD,[a] Paola Colombo, MD, PhD,[a] Roberto Paino, MD,[b] Silvio Klugmann, MD,[a] and Luigi Martinelli, MD,[a] Milan, Italy

The Journal of Thoracic and Cardiovascular Surgery • September 2010

Direct Aortic Access Routes

- Surgical access performed via minimally invasive thoracotomy (e.g. right anterior mini-thoracotomy) or sternotomy (e.g. upper partial mini-sternotomy)
- Mini-sternotomy versus mini-thoracotomy decision may be based on
  - Clinical preference (e.g. familiarization with approach)
  - Anatomy
    - Distance between vascular access site and basal plane
    - Aortic root angulation / coaxial alignment
    - Intended access site with respect to surrounding anatomical structures
  - Comorbidities (e.g. avoiding pleural space with COPD)
- Clinician to discuss risks pertaining to the intended access route with the patient

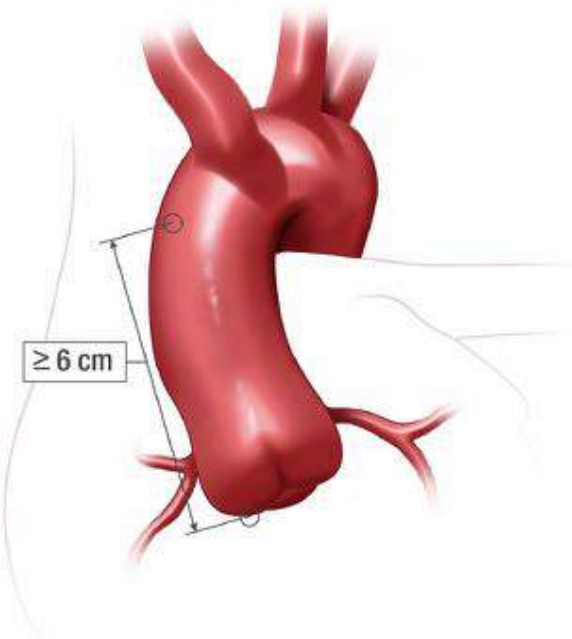
Mini-Sternotomy

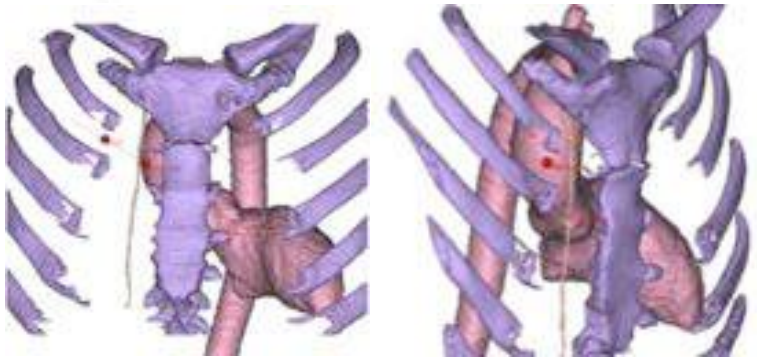
Mini-Thoracotomy

Patient Screening

Pre-operative CT mandatory to:

- Determine aortic access site meets ≥6 cm basal plane to aortic access site distance requirement
- Select delivery trajectory that optimizes coaxial alignment with native aortic valve
- Identify appropriate thoracic access location (e.g. 2nd intercostal space commonly used for thoracotomy)
- Confirm aortic access site can be digitally palpated through anatomical measurement
- Assess absence of calcification at aortic access site
- Identify critical vessels (e.g. right internal mammary artery [RIMA], patent RIMA graft) in delivery trajectory

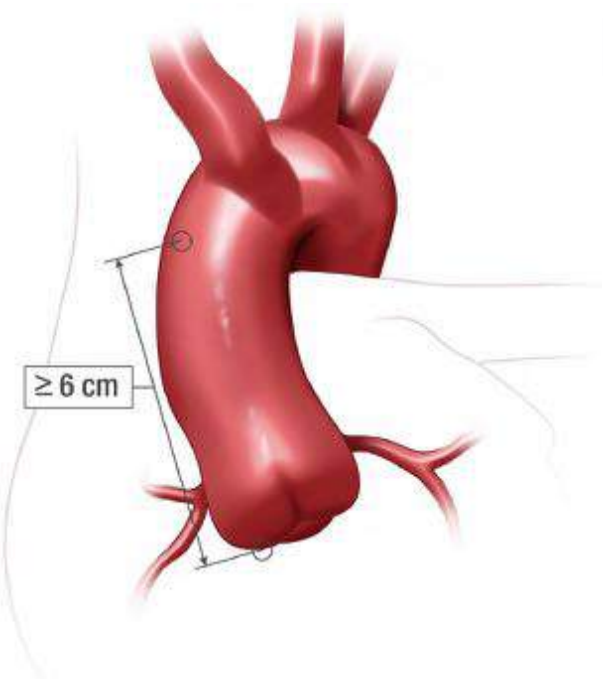




Patient Selection Criteria

Patient selection criteria unique for direct aortic approach:

- Aortic root angulation criteria (see table below)
- Basal plane to aortic access site distance ≥6 cm (see figure to right)
- Soft tissue depth allows for digital palpation of aortic access site
- Aortic access site free of calcification
- Access site and delivery trajectory free of RIMA or patent RIMA graft

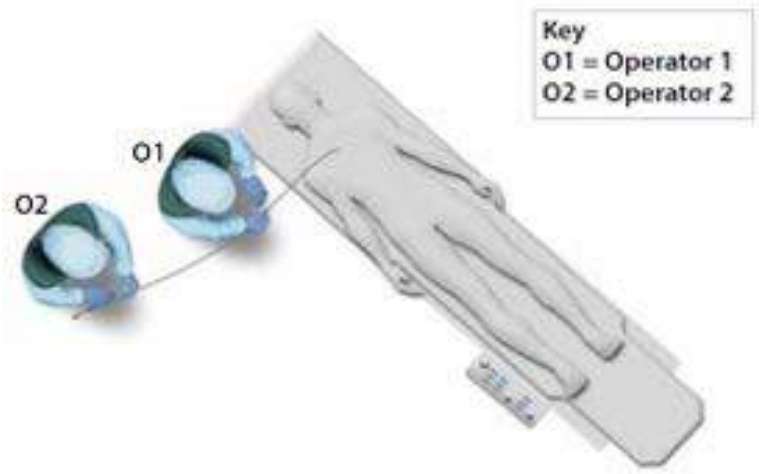


	Approach			
	Direct Aortic	Left Subclavian / Axillary	Right Subclavian / Axillary	Iliofemoral
Acceptable Aortic Root Angle*	Any angle	<70°	<30°	<70°

* Aortic root angle = angle between plane of aortic valve annulus and horizontal plane

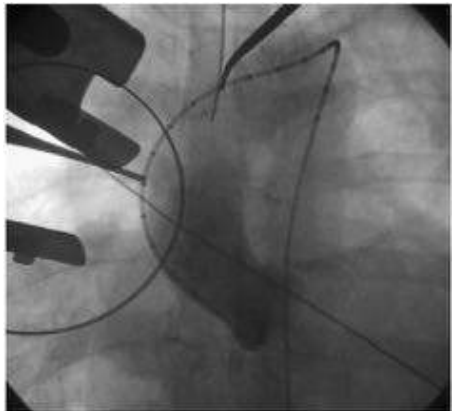
Room Setup

- Plan room setup upfront
- Recommend pre-procedure planning (and training, if necessary) to ensure both operators understand and are proficient at their roles (e.g. access site management, wire management, catheter operations) throughout procedure
- Operator 1 (O1) needs to be at access site to have control of access site and delivery catheter system. Meticulous access site management is critical to avoiding access site complications
- Operator 1 (O1) and Operator 2 (O2) must be in comfortable working positions with clear and close view of imaging screens
- Consider location of any additional equipment (e.g., additional table) to avoid/minimize C-arm interference
- Consider use of third operator on patient's left side to maintain dedicated control of introducer sheath throughout procedure



Aortic Access

1. Place graduated pigtail into noncoronary native aortic valve cusp and along greater curvature of ascending aorta
2. Perform minimally invasive surgical cut down (right internal mammary artery sparing if necessary). Use caution to avoid damage to any lung tissue present.
3. Perform aortography with radiographic instrument (e.g. forceps) pointing to aortic access site to confirm ≥6 cm basal plane to aortic access site distance is met
4. Manually palpate access site to confirm absence of calcification and suitability. Echocardiography may also be helpful tool for this assessment.
5. Place two (2) standard double purse-string sutures around access site using caution to avoid vessel dissection/tearing*. Consider suture type (e.g. pledgeted prolene) selection to minimize vessel trauma.
6. Gain arterial access via seldinger technique (or direct cannulation via scalpel puncture)
7. Follow standard CoreValve guidewire-catheter exchange sequence to place super stiff guidewire, prior to 18 Fr introducer insertion

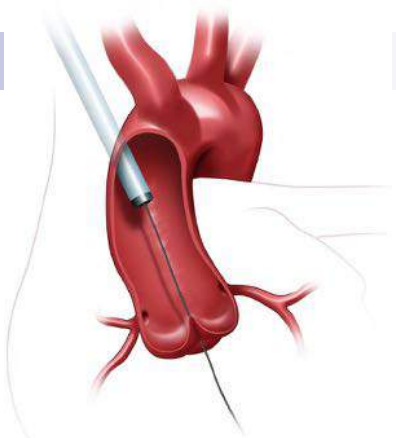


Bruschi G, et al. Direct Aortic Access Through Right Minithoracotomy for Implantation of Self-Expanding Aortic Bioprosthesis Valves . *The Journal of Thoracic and Cardiovascular Surgery.* 140 (3): 715-7 (2010).

* Ensure double purse-string sutures are managed appropriately in the event they are needed to regain hemostasis during the procedure.

Introducer Access & Positioning

- Use of an 18 Fr kink-resistant introducer is recommended
- Pre-shaping introducer may help optimize delivery trajectory to achieve coaxial alignment with native aortic valve
- Advance 18 Fr introducer under direct fluoroscopy over super stiff guidewire using extreme caution to avoid aortic or left ventricular perforation, coronary or septum injury, or other trauma that could lead to bleeding, dissection, or thromboembolism by monitoring introducer dilator tip position
- Position distal end of introducer approximately 2 cm into the aortic lumen
- Use extreme caution to maintain this recommended introducer position throughout procedure to avoid introducer popout from the aortic vessel (proximal movement) or interaction with the aortic root complex anatomy (distal movement)
- Operator 1 should always be aware of introducer position throughout procedure
- Introducer position management needs to control both axial and lateral displacement, and may be accomplished by:
  - Securing introducer in place with one suture looped around the introducer length via the flush port (axial securement) and a second suture wrapped around the distal introducer end (lateral securement), or
  - A dedicated hand or operator to manually hold introducer in place*
- Introducer movement will move delivery catheter system (once it is placed through introducer)



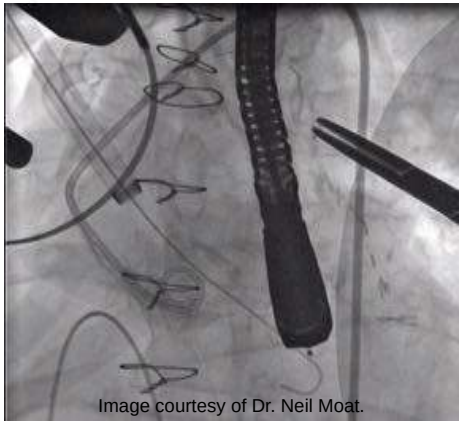
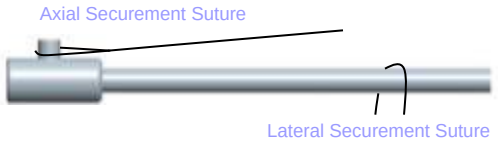


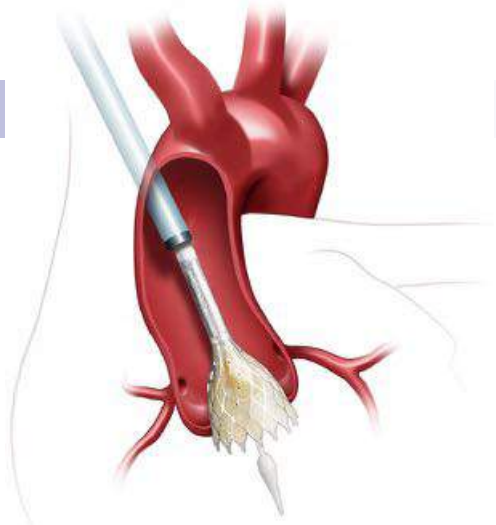
Image courtesy of Dr. Neil Moat.



* Caution: Due to close proximity of operators to fluoroscope, use caution to avoid unnecessary radiation exposure.

Deployment

- Direct aortic procedure provides direct delivery catheter system response (one-to-one movement between delivery catheter system and valve) due to the short and straight approach to the native aortic valve
- Target implant depth is 4-6 mm
- Start deployment at or 1 mm below target implant depth
- Consider fast pacing during deployment in patients with aortic regurgitation, hypertension, and/or large anatomies
- Slow release during first 1/3 deployment and reposition if necessary until annular engagement
- Understand foreshortening – potential contributor to minor (~2 mm) valve antegrade movement during first 1/3 deployment, and tension in catheter during remainder of deployment (~4 mm foreshortening during final 2/3 deployment)
- If present, release system tension just prior to final valve release from catheter by:
  - releasing pressure on guidewire*, and
  - slightly pushing on delivery catheter system to remove any tension placed on valve by catheter
- Ensure appropriate introducer position to allow sufficient clearance to deploy and release outflow end of frame



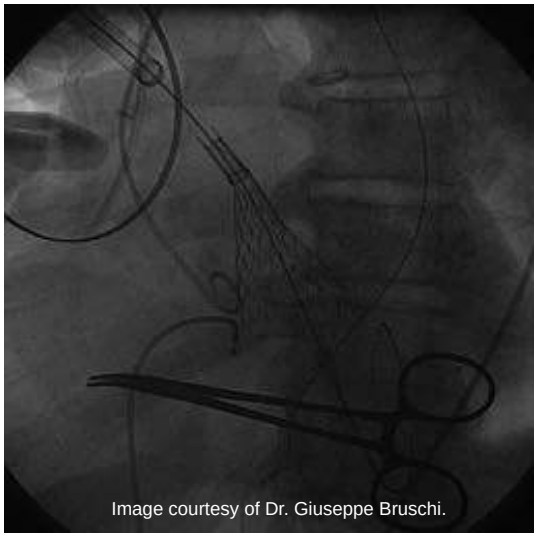
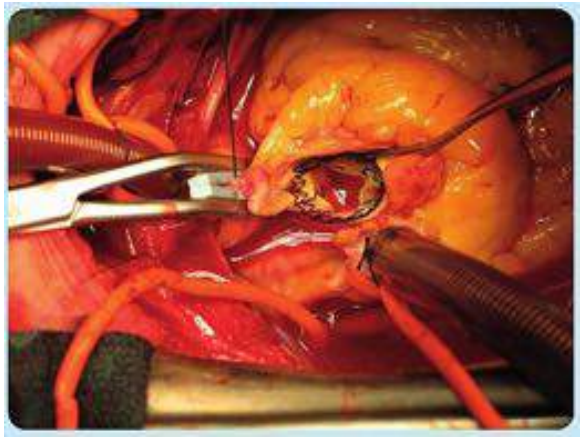


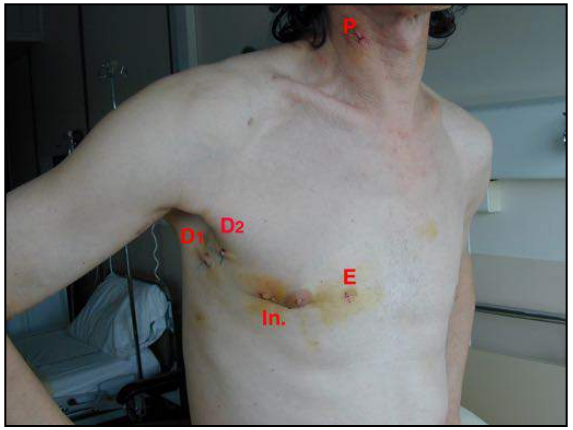
Image courtesy of Dr. Giuseppe Bruschi.

* Always ensure guidewire is located in an atraumatic position

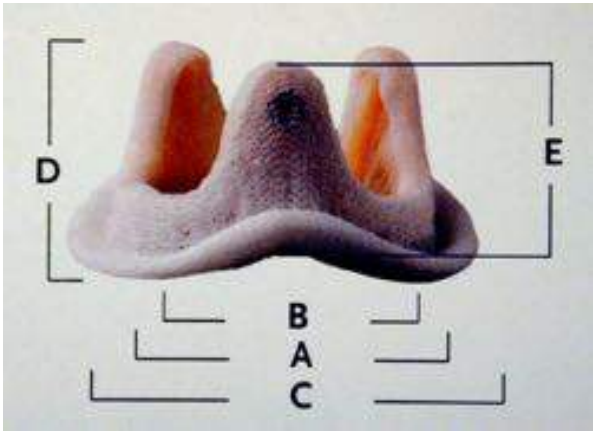
5) Surgery

Sternotomy ➔ **Mini-thoracotomie**





Stented ➔ **Stentless** ➔ **Suturless**



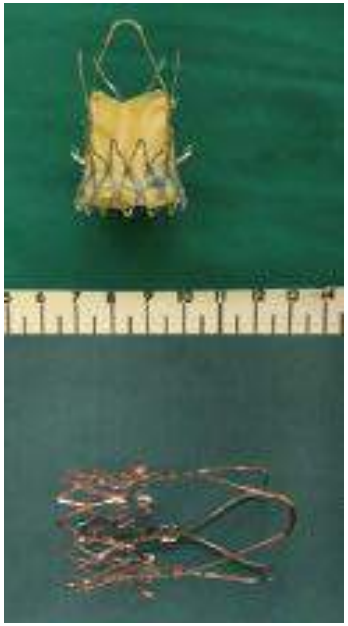
6) Trans VD ➔ VG ➔ Ao "Experimental Pig model"

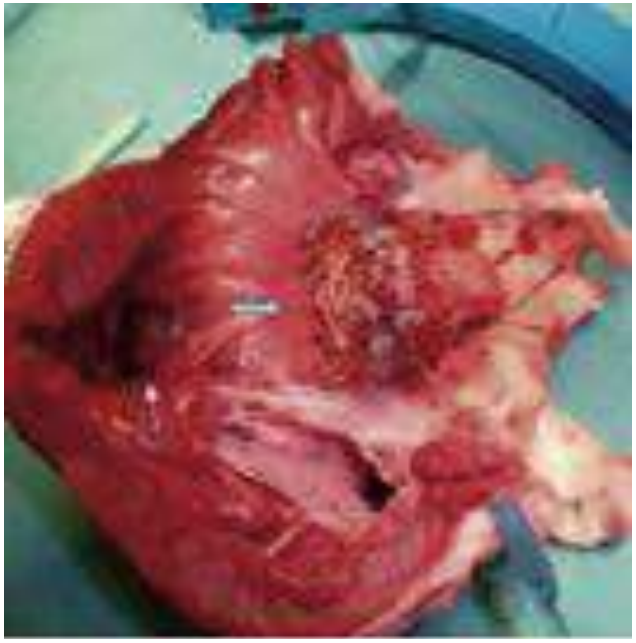
The transventricular–transseptal access to the aortic root: a new route for extrapleural trans-catheter aortic stent-valve implantation☆

Ligang Liu*, Piergiorgio Tozzi, Enrico Ferrari, Ludwig K. von Segesser

Department of Cardio-Vascular Surgery, University Hospital of Lausanne (CHUV), Rue du Bugnon 46, CH-1011 Lausanne, Switzerland

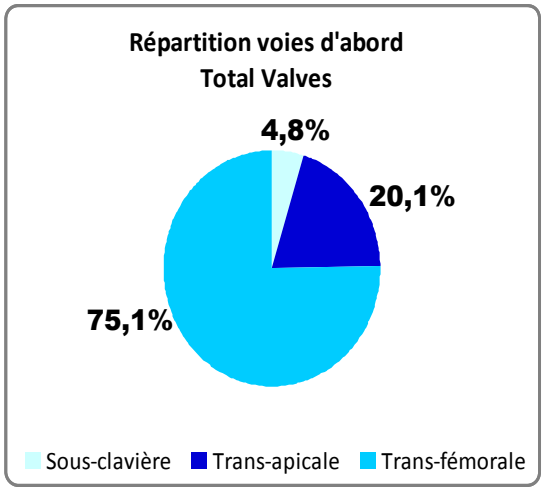
Eur J Cardiothorac Surg (2010),





Conclusion

Bio Proth.	Chir. (N)	Chir +	TAVI (N)	TAVI +
2010	14 030	1,7 %	1 500	128%
2009	13 793	7 %	657	87 %
2008	12 832	5 %	350	
2007	12 225	9 %	ξ	
2006	11 194		ξ	



Per Cutané

Fem.

Sternotomie CEC

Carpentier

Conclusion

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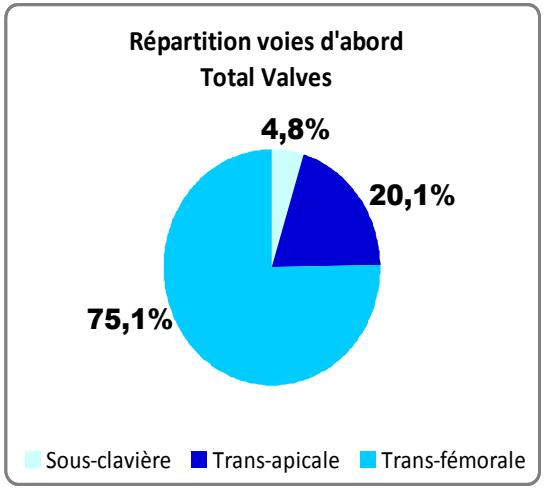

Per Cutané	**Abord ss cut.**	**Mini-Thoraco cœur battant**	**Minithoraco CEC**	**Sternotomie CEC**
Fem.	*Ss Clav*	*Apical*		
	Carotide	*Trans Ao Asc*	*Suturless*	*Carpentier*