



PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

ROMA

Centro Congressi
di Confindustria

**Auditorium
della Tecnica**

9^a Edizione

**30 Settembre
1 Ottobre
2022**



Prevenzione e gestione delle complicanze durante la TAVI

Luca Testa, MD, PhD

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Contract Professor of Cardiology, «Vita e Salute» Univ. San Raffaele Hospital, Milan



Main sources of complications

- Access site
- Stroke
- Coronary arteries
- Paravalvular leak
- Heart rhythm disturbances

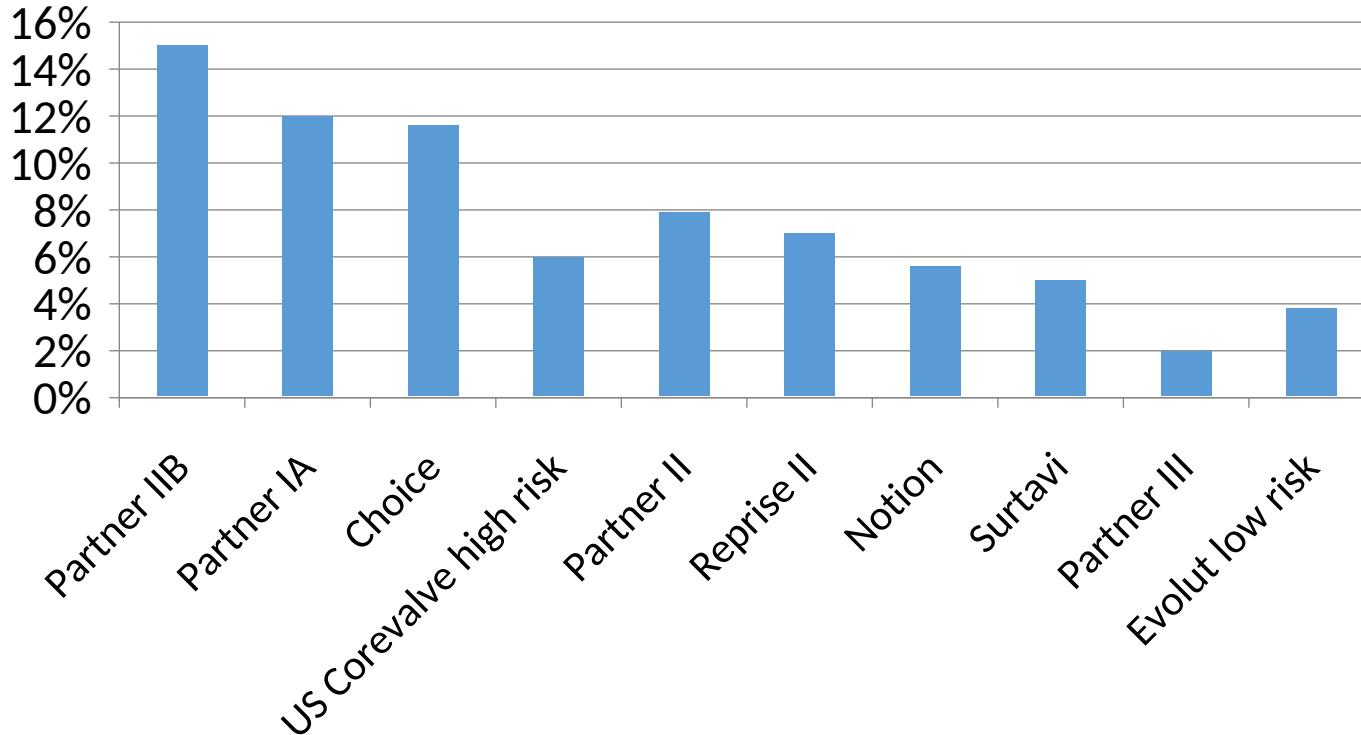


Main sources of complications

- **Access site** ☰ **Bleeding complication**
- **Stroke**
- **Coronary arteries**
- **Paravalvular leak**
- **Heart rhythm disturbances**



Vascular complications in TAVI trials through the reduction of the delivery sheaths





Vascular Complications

Prevention and treatment

- **Vascular imaging and patient selection**
- **Lower profile of delivery systems**
- **Technique of puncture**
- **Management of access closure**
- **Endovascular management of complications**
- **Site and operator experience**

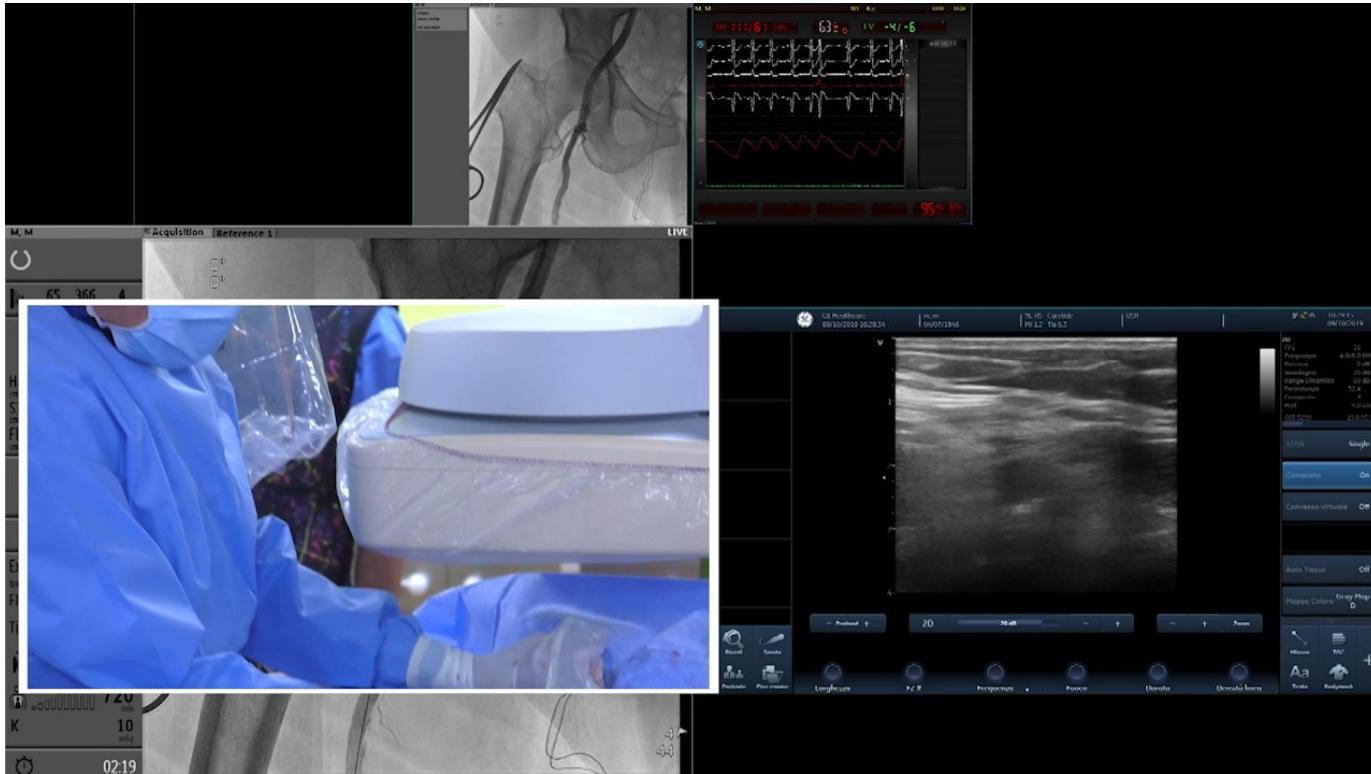


Right way?





Echo guided transfemoral approach





Circulation: Cardiovascular Interventions

AHA Journals Journal Information All Issues Subjects Features Resources & Education

Home > Circulation: Cardiovascular Interventions > Vol. 3, No. 4 > Safety and Efficacy of the Subclavian Approach for Transcatheter Aortic Valve Implantation With ...

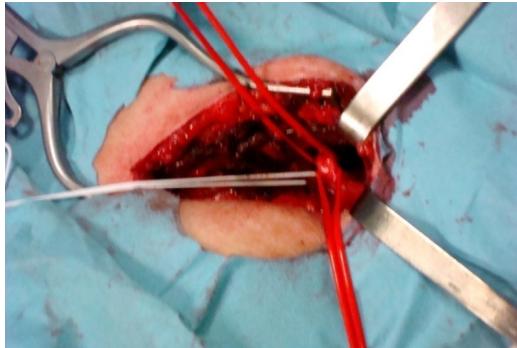
FREE ACCESS
RESEARCH ARTICLE

Safety and Efficacy of the Subclavian Approach for Transcatheter Aortic Valve Implantation With the CoreValve Revalving System

Anna Sonia Petronio, Marco De Carlo, Francesco Bedogni, Antonio Marzocchi, Silvio Klugmann, Francesco Maisano, Angelo Ramondo, Gian Paolo Ussia, Federica Ettori, Arnaldo Poli, Nedy Brambilla, Francesco Saia, Federico De Marco and Antonio Colombo

Originally published 6 Jul 2010 | https://doi.org/10.1161/CIRCINTERVENTIONS.109.930453 | Circulation: Cardiovascular Interventions, 2010;3:359–366

Other version(s) of this article ▾



Left Transsubclavian Approach

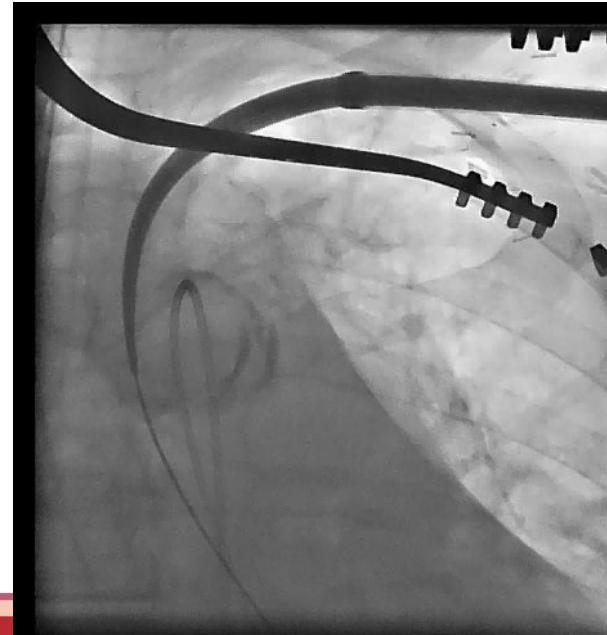


Table 3. Safety endpoints at 30-day follow-up according to VARC definitions.

	Left subclavian (n=60)	Right subclavian (n=10)	p
Overall death (%) (Cardiac death), (%)	4 (6.6) (4), (6.6)	0	NS
Stroke (%)	0	0	—
Myocardial infarction (%)	0	0	—
Cardiac tamponade (%)	2 (3.3)	0	NS
Life-threatening bleeding (%)	0	0	—
Acute renal failure (%)	2 (7.4)	0	NS
Major bleeding (%)	0	0	—
Minor bleeding (%)	0	0	—
Major vascular complications (%)	0	0	—
Minor vascular complications (%)	4 (6.6)	1 (10)	NS
PM implantation (%)	8 (13.3)	3 (30)	NS

Right subclavian approach as a feasible alternative for transcatheter aortic valve implantation with the CoreValve ReValving System

Luca Testa^{1*}, MD, PhD; Nedy Brambilla¹, MD; Maria Luisa Laudisa¹, MD; Marco De Carlo², MD; Stefania Lanotte¹, MD; Roberto Adriano Latini¹, MD; Samuele Pizzocri¹, MD; Matteo Casavecchia¹, MD; Mauro Luca Agnifili¹, MD; Cristina Giannini², MD; Uberto Bortolotti³, MD; Anna Sonia Petronio², MD; Francesco Bedogni¹, MD

1. Istituto Clinico S. Ambrogio, Dept of Interventional Cardiology, Milan, Italy; 2. Cardiothoracic and Vascular Dept, Azienda Ospedaliero-Universitaria Pisana, Pisa, Italy; 3. Cardiothoracic and Vascular Dept, Cardiac Surgery Division, Azienda Ospedaliera Universitaria Pisana, Pisa, Italy

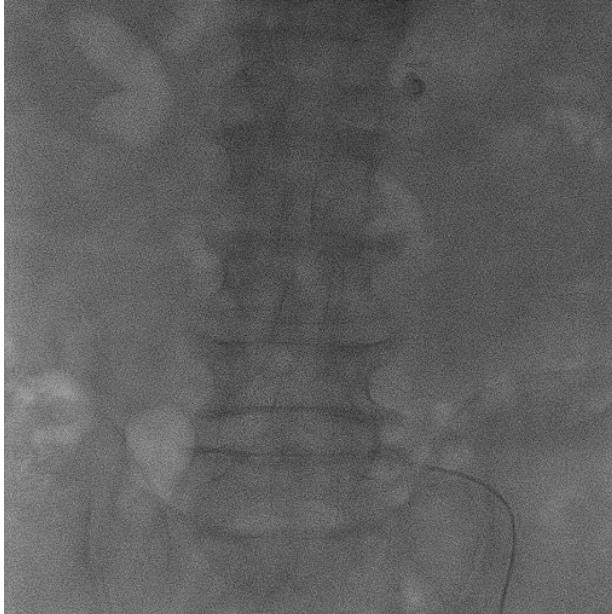
Table 4. Efficacy endpoint at 6-month follow-up according to VARC definitions (fatalities which occurred during the first month in the left subclavian group have not been included).

	Left subclavian (n=56)†	Right subclavian (n=10)	p
All-cause mortality (after 30 days) (%)	5 (8.9)	1 (10)	NS
Failure of current therapy for AS (%)	0	0	—
Prosthetic heart valve dysfunction* (%)	0	0	—

AS: aortic stenosis; † 56 patients were considered as a consequence of the fatalities within the first month (see text); * aortic valve area <1.2 cm² and mean aortic valve gradient ≥20 mmHg or peak velocity ≥3 m/s, or moderate or severe prosthetic valve regurgitation



Controlateral protection wire strategy

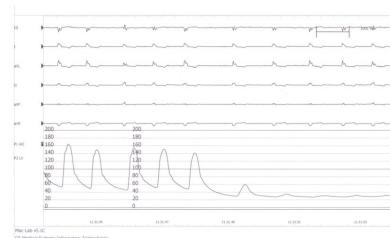
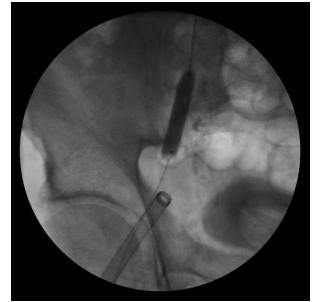
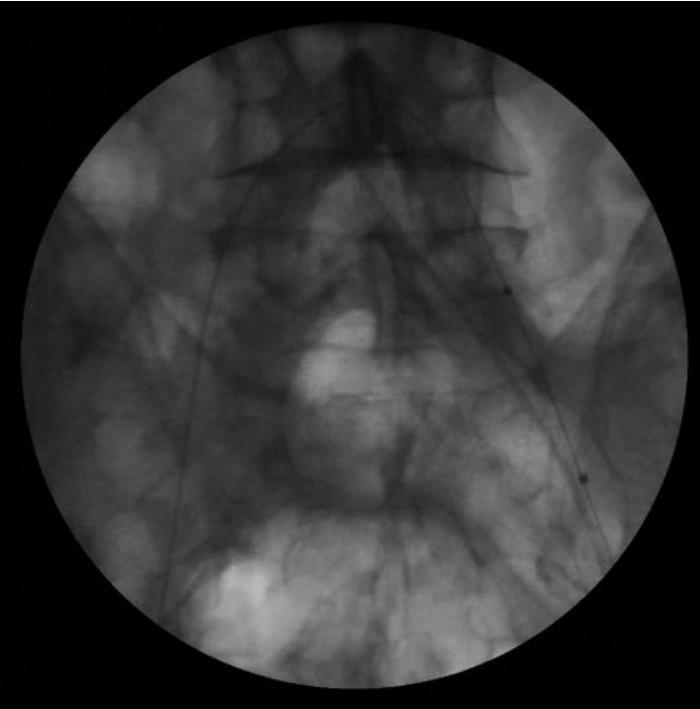
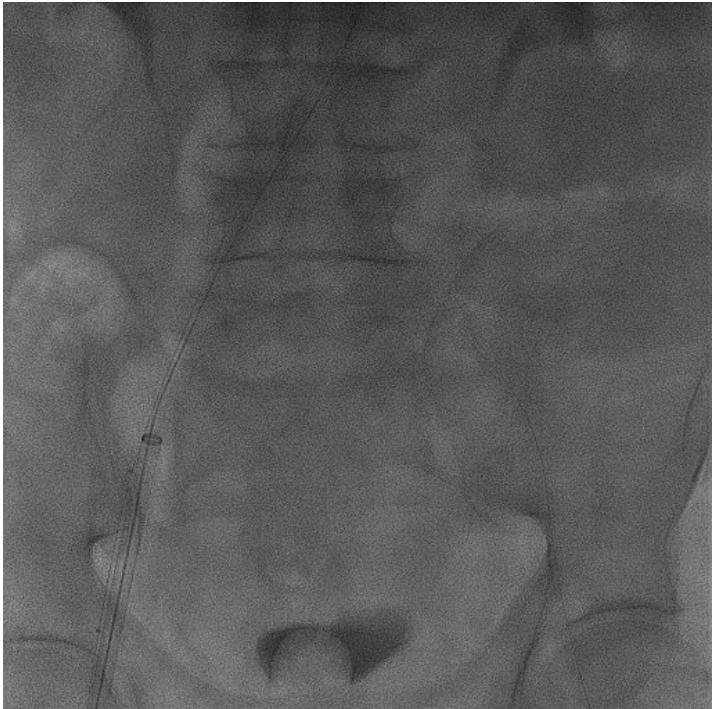


Crossover with IM / UF catheter



Advance 0.018" wire for protection

Cross-over balloon inflation



Final Angiogram



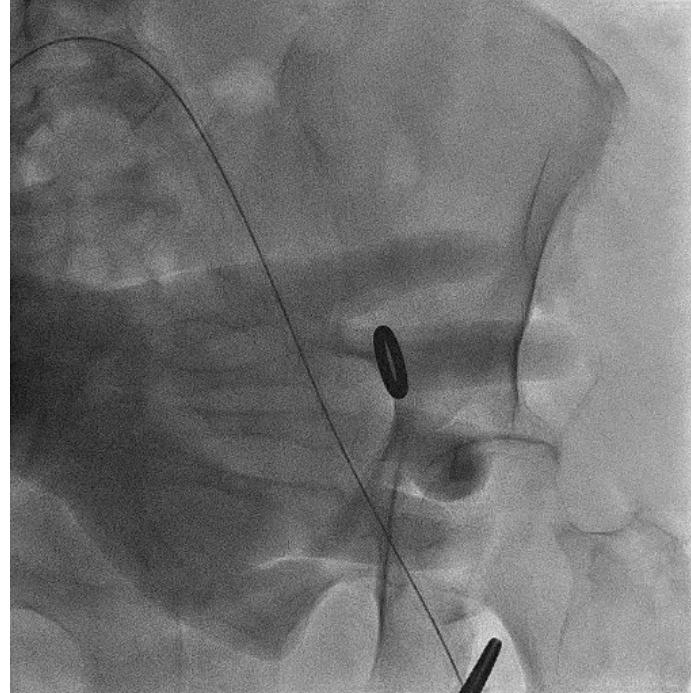


Contralateral protection wire strategy



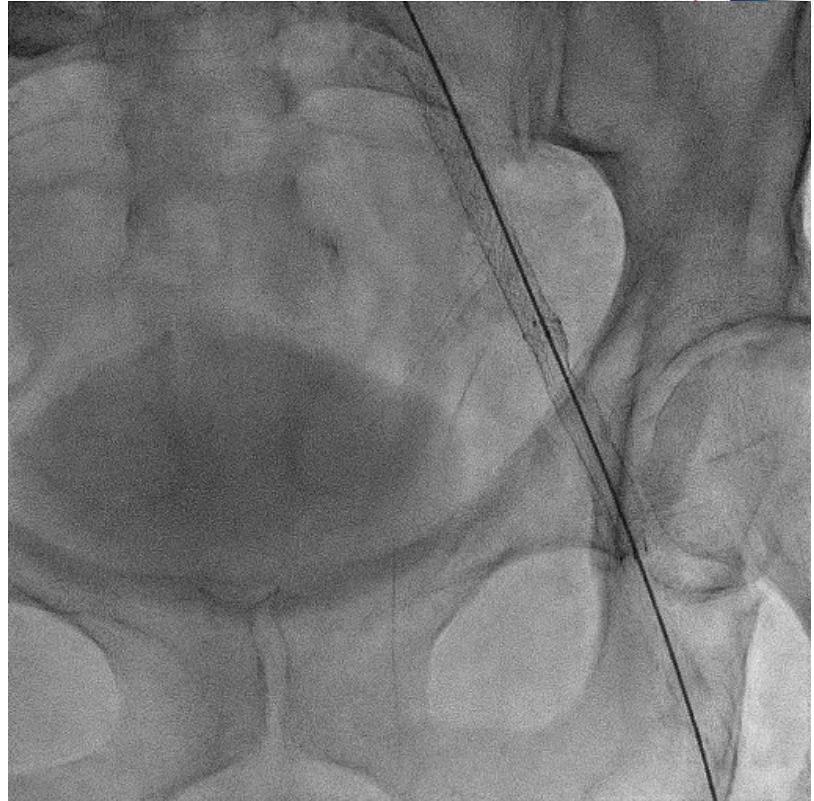


Dissection + Bleeding

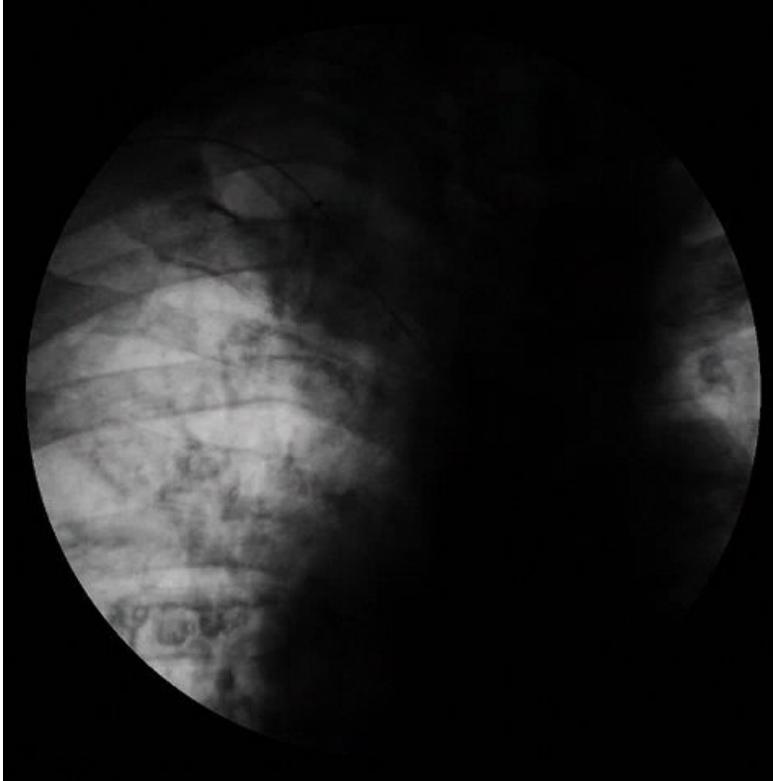




Final Result after covered stent in Femoral and self-expanding stent in iliac

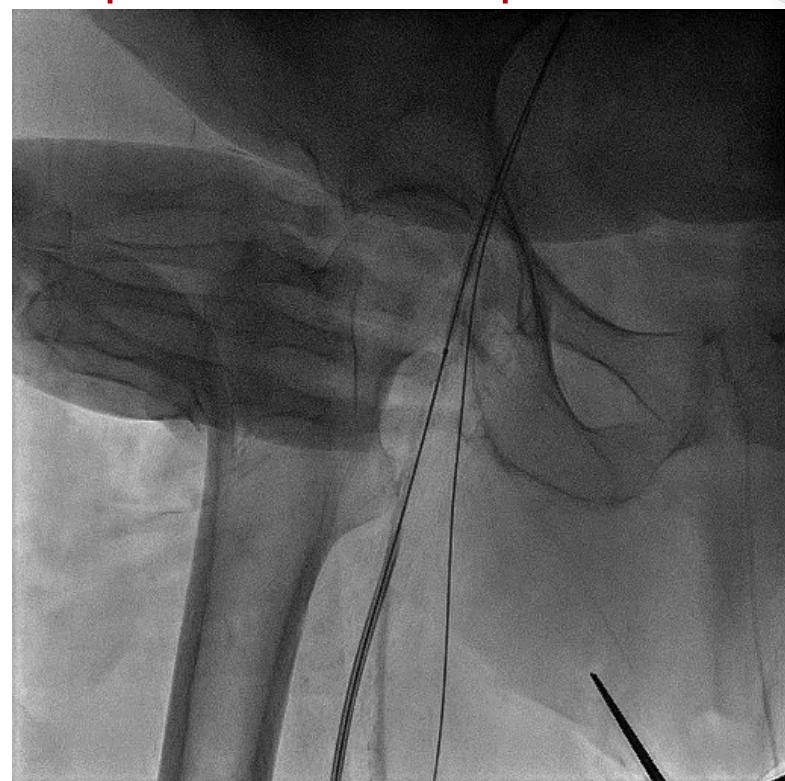


Radial protection



No covered stent with sheath long enough are available
for this approach!!

Superficial Femoral protection



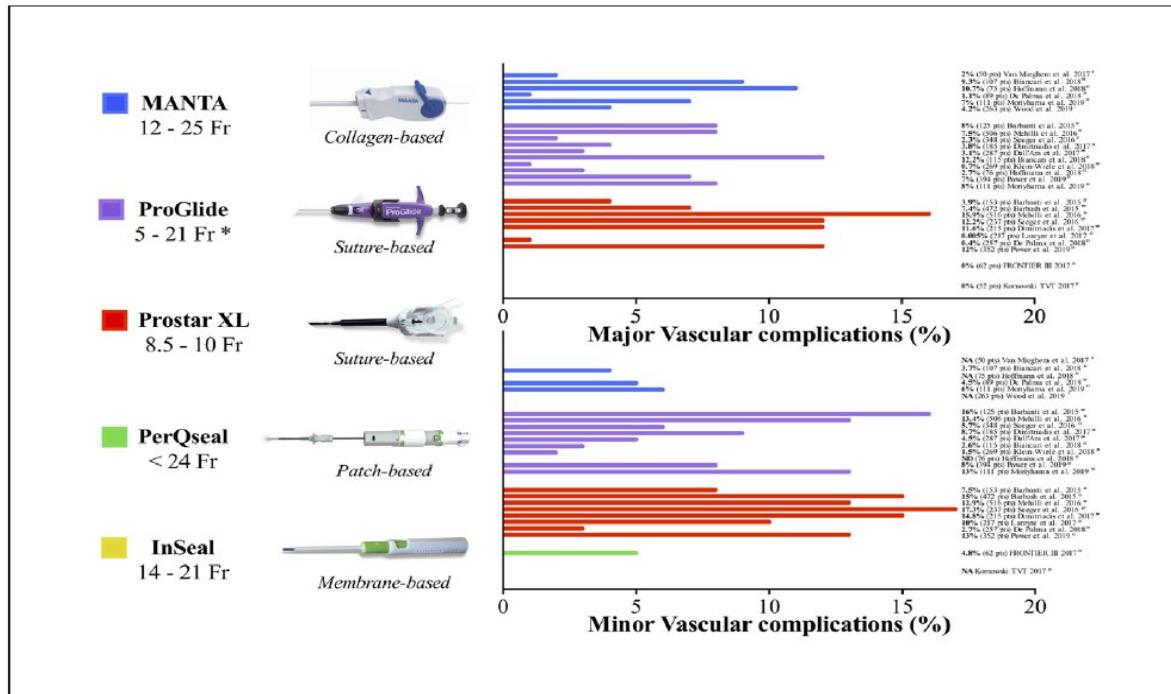


Consider the use cross-over wire protection because...

- In the PAD patients the vascular complications can further worsen the prognosis....
- In dramatic situations specially in PAD patients the cross-over to treat the acute vascular complication can be difficult to do...it's better to know before
- In big dissections to have a wire in true lumen can be helpful



Minor or Major Complications with different devices



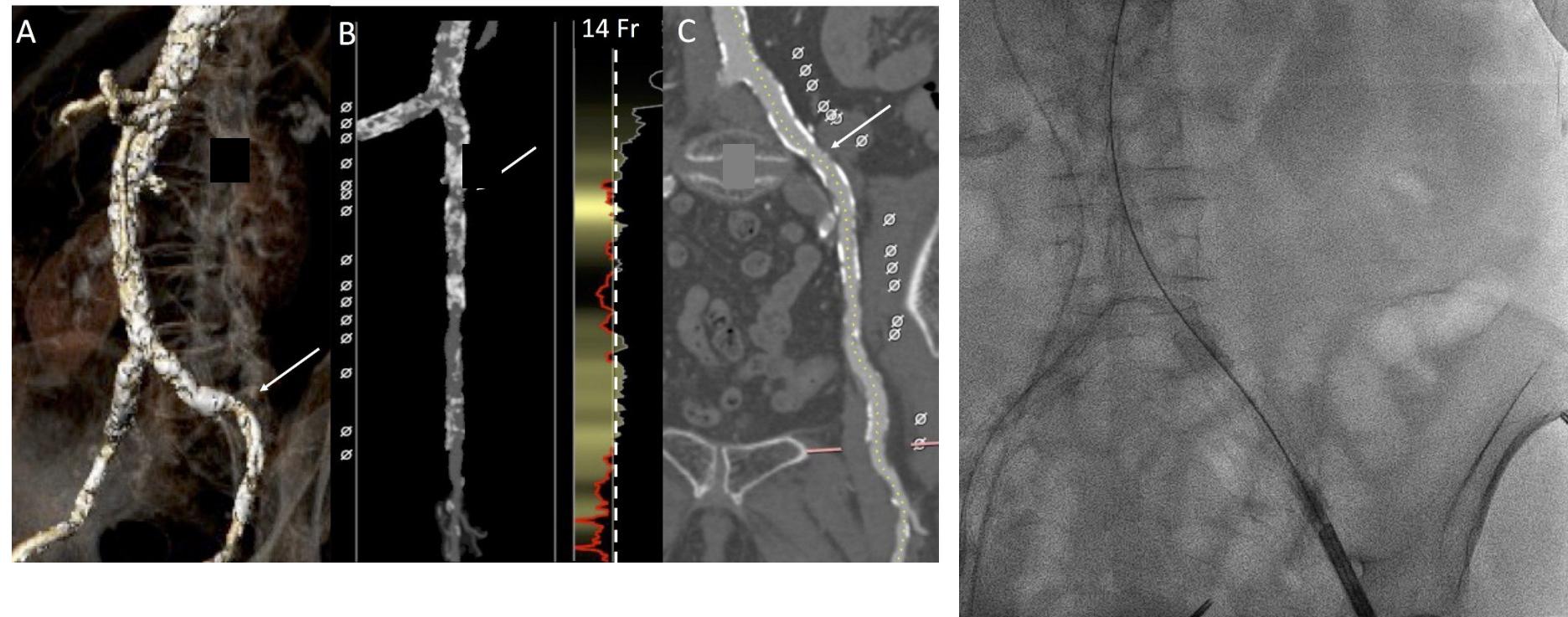
**Giuseppe Tarantini, MD,
PhD**
Circ Cardiovasc Interv. 2019;12:e008203.



How far can transfemoral TAVR go? ...



Physicians expertise in peripheral interventions

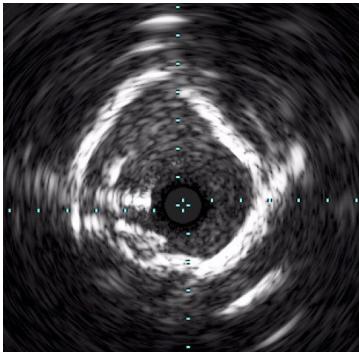


MLD of left proximal external iliac artery (5.1x8.0 mm, white arrows) was borderline with respect to the 14Fr-delivery system of a 26 mm Evolut-R valve

Lithoplasty of iliac artery with ShockWave balloon



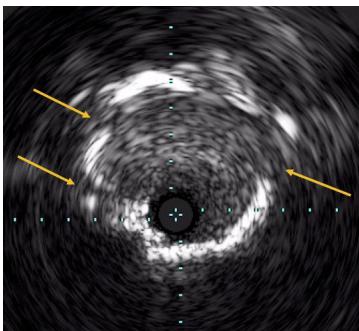
IVUS pre
at MLD



Near
circumferential
calcifications
MLA (21.7 mm^2)



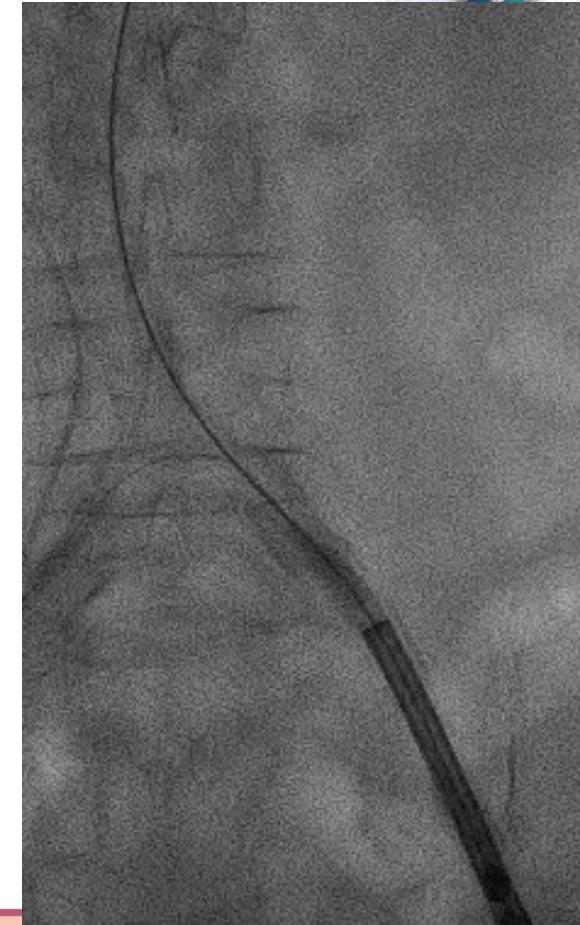
IVUS post
at MLD



Multiple calcium
fractures (yellow
arrows)
MLA (27.4 mm^2)

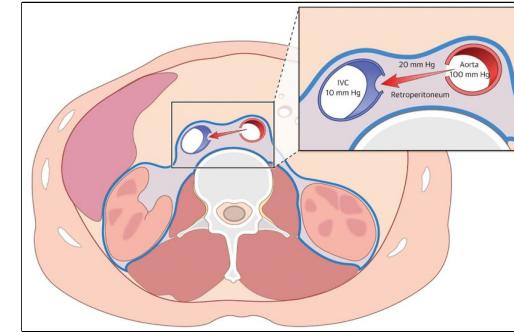
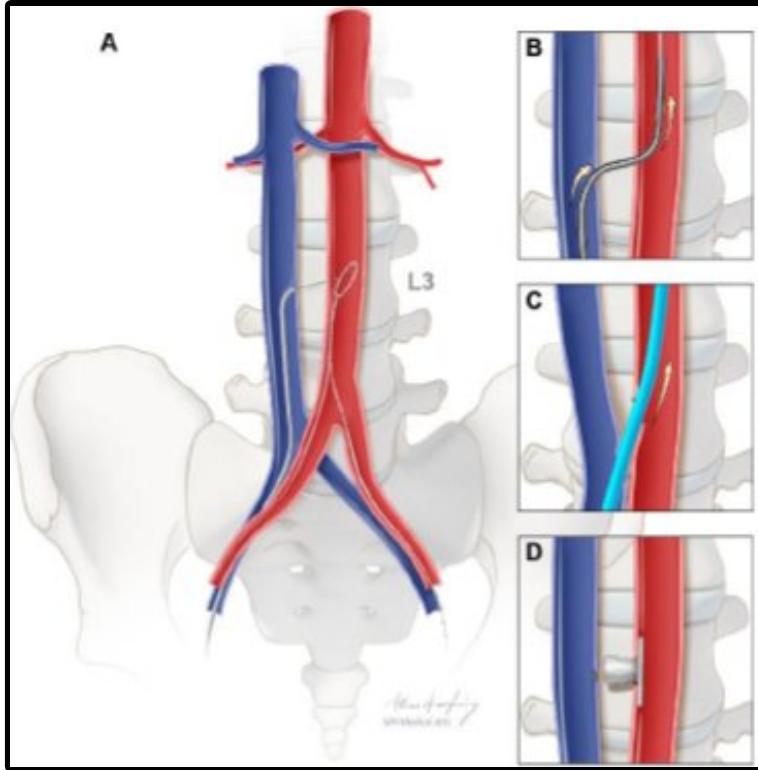


Two cycles with a
 $6.5 \times 60 \text{ mm}$
lithoplasty balloon



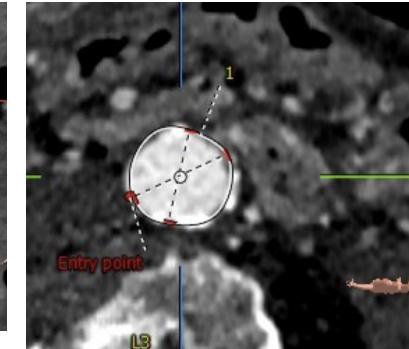
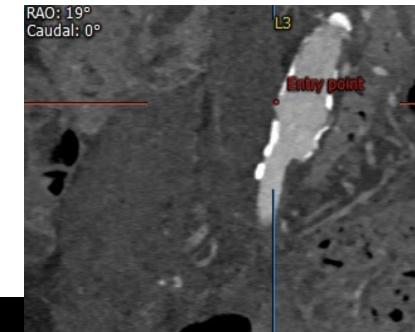
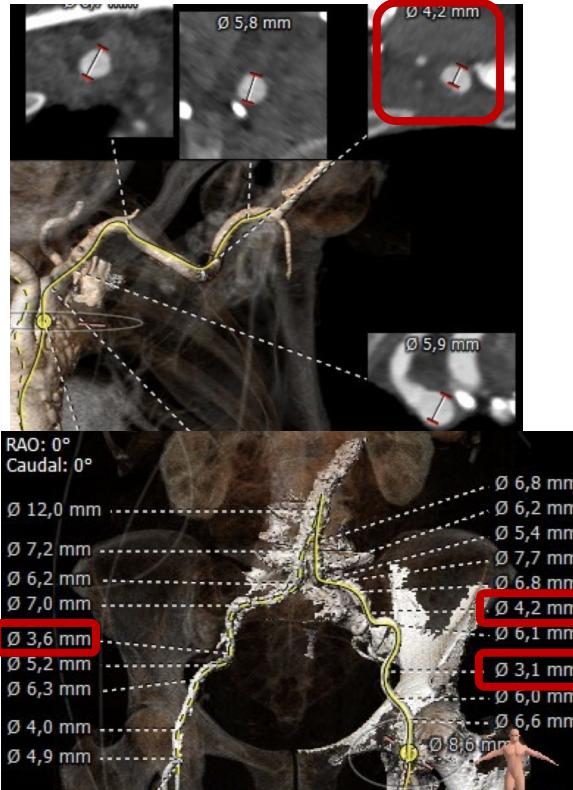


Trans-caval Access for TAVI



Key elements

- Calcium-free target
- Nothing interposed
- Retroperitoneal pressure higher than IVC pressure
- Bailout plan

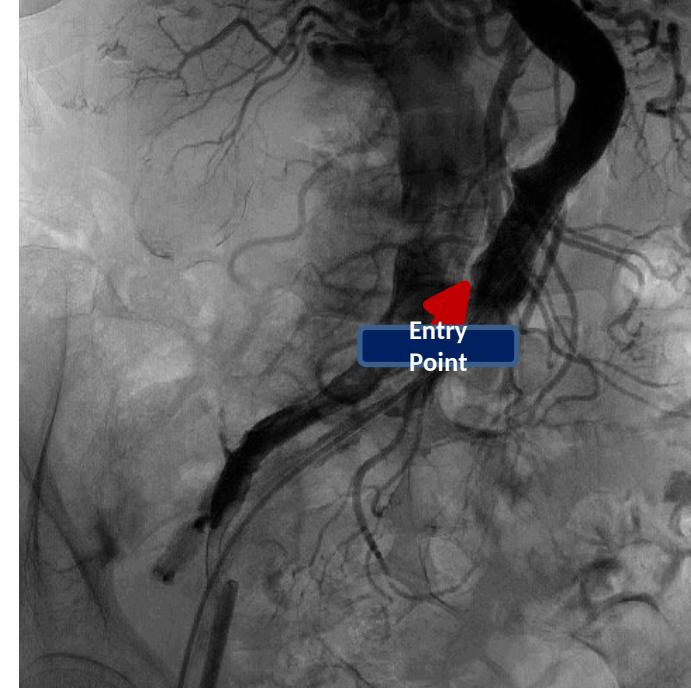


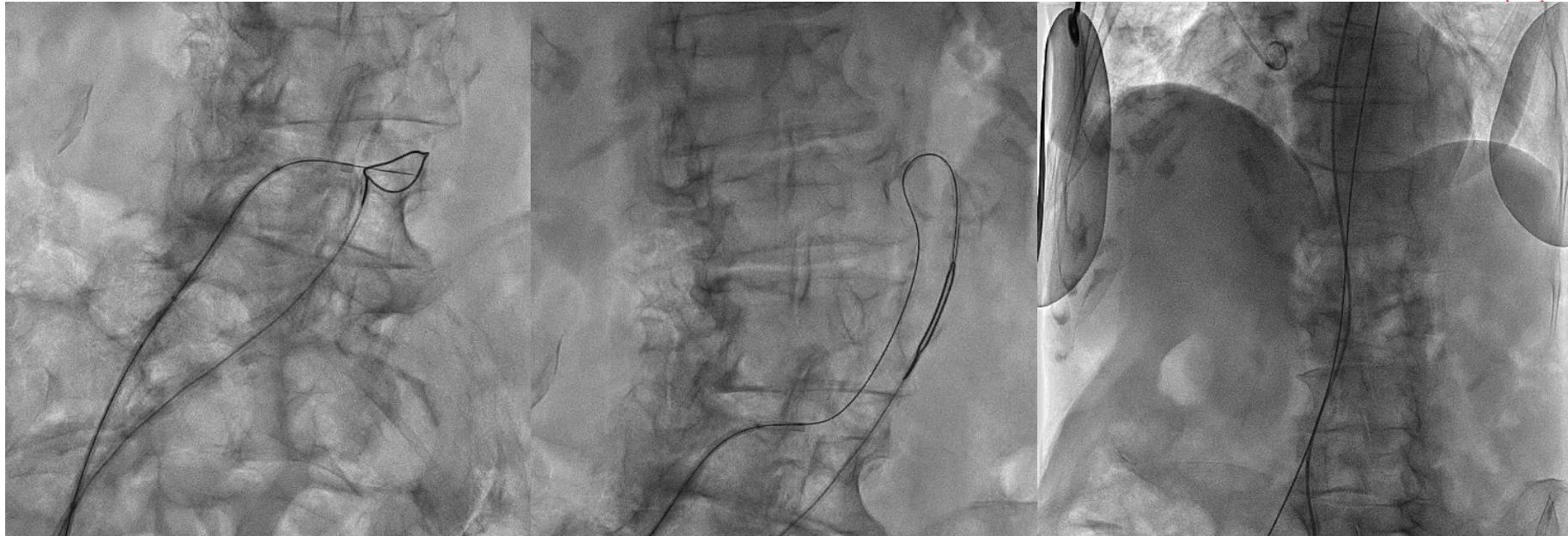
Key elements

- 1) Calcium-free target
- 2) Nothing interposed
- 3) Patent SMA/celiac
- 4) Away from renals and iliacs



Basal angiography





Wire Snaring

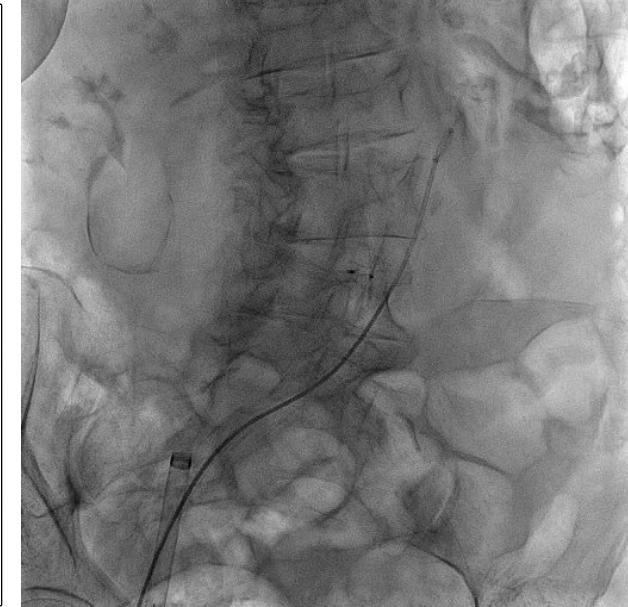
Extra-stiff wire advanced through
NaviCross
18 Fr sheath placement



10/8 Amplatz Duct Occluder



Balloon Fixation



Final results



Main sources of complications

- Access site
- **Stroke**
- Coronary arteries
- Paravalvular leak
- Heart rhythm disturbances

Stroke



The NEW ENGLAND JOURNAL of MEDICINE

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 insertion of an aortic-valve prosthesis was performed by Cribier et al.² Transcatheter aortic-valve

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 and colleagues report a 5.5% risk of stroke or transient ischemic attack within 30 days after



Incidence = 2.8 %

(adjusted HR 19.62)

95% CI 1.81-212.13, p=0.014)

Italian Registry 2007-2008
Ussia et al EHJ 2012

All Strokes at 1 year

The NEW ENGLAND JOURNAL of MEDICINE



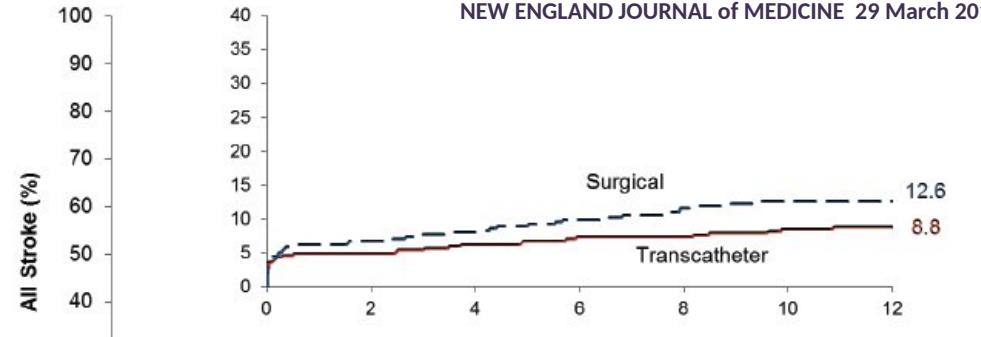
30 days stroke TAVR 4.9%
Surgery 6.2%

p 0.46

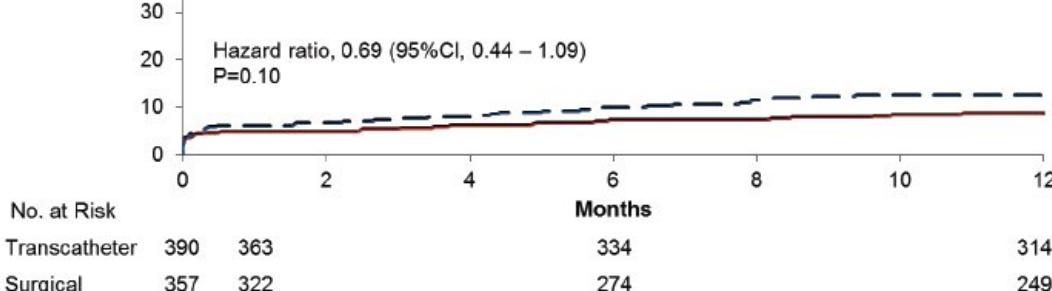
ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement
 with a Self-Expanding Prosthesis

NEW ENGLAND JOURNAL of MEDICINE 29 March 2014



Hazard ratio, 0.69 (95%CI, 0.44 – 1.09)
 P=0.10





Histopathology of Embolic Debris Captured During Transcatheter Aortic Valve Replacement Clinical Perspective

Nicolas M. Van Mieghem, Marguerite E.I. Schipper, Elena Ladich, Elham Faqiri, Robert van der Boon, Abas Randjgari, Carl Schultz, Adriaan Moelker, Robert-Jan van Geuns, Fumiyuki Otsuka, Patrick W. Serruys, Renu Virmani and Peter P. de Jaegere

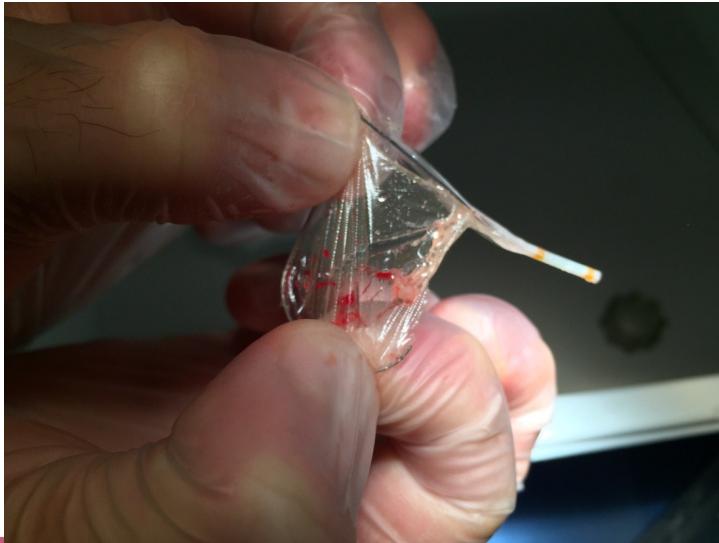
Circulation. 2013;127:2194-2201; originally published online May 7, 2013;

doi: 10.1161/CIRCULATIONAHA.112.001091

Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

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Predictors of Higher incidence of Neurological events or new MRI lesions

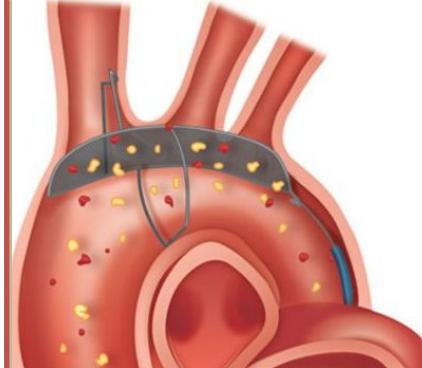


- Post dilatation
- Repeated repositioning
- Small calcified valves and peak gradient
- Previous stroke
- Age
- Atheromatous aortic arch
- Procedural Time
- Atrial fibrillation



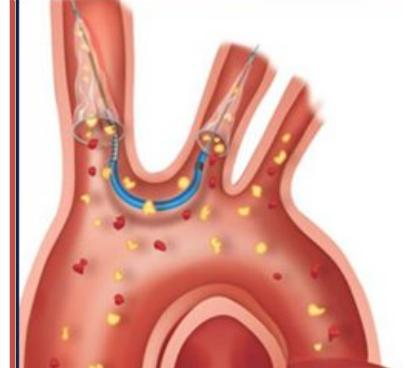
Most frequently used Cerebral Protection Devices

TriGuard Embolic Deflection Device (Keystone Heart)¹



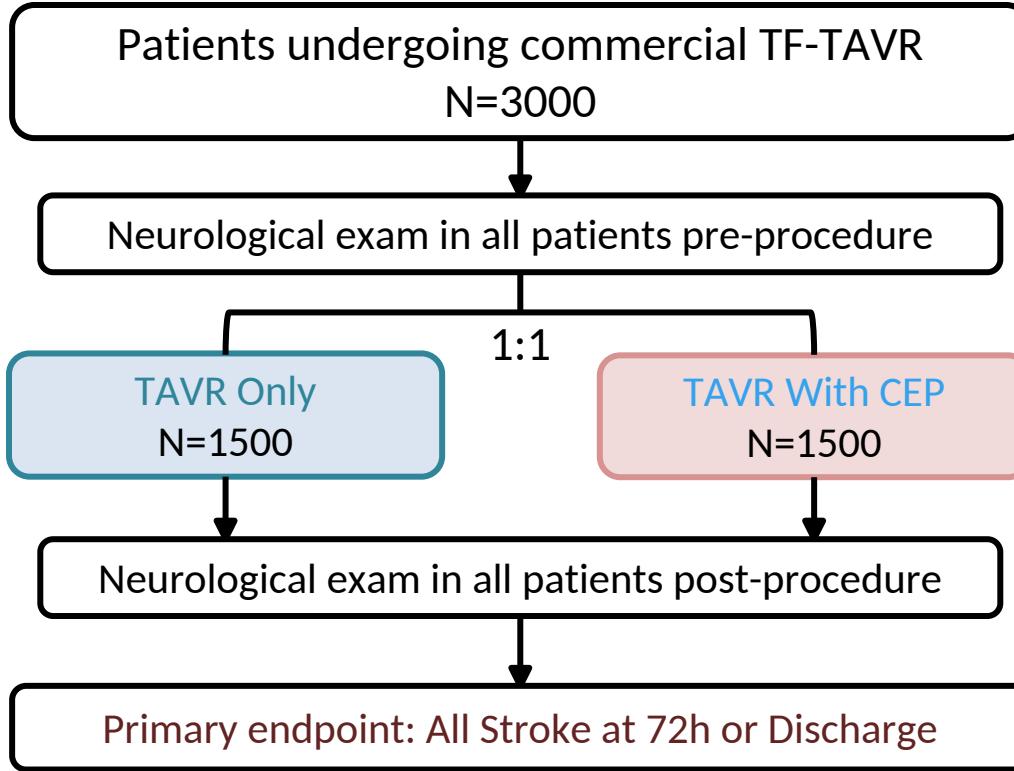
- ✓ Pore Size: 130 µm
- ✓ Delivery Sheath: 9F
- ✓ Access: Transfemoral
- ✓ Mechanism: Debris deflection

Sentinel Cerebral Protection System (Claret Medical)²



- ✓ Pore Size: 140 µm
- ✓ Delivery Sheath: 6F
- ✓ Access: Brachial or radial
- ✓ Mechanism: Debris capture and retrieval

PROTECTED TAVR Study Design



- Patients of all risk categories eligible
- Any commercially available TAVR device

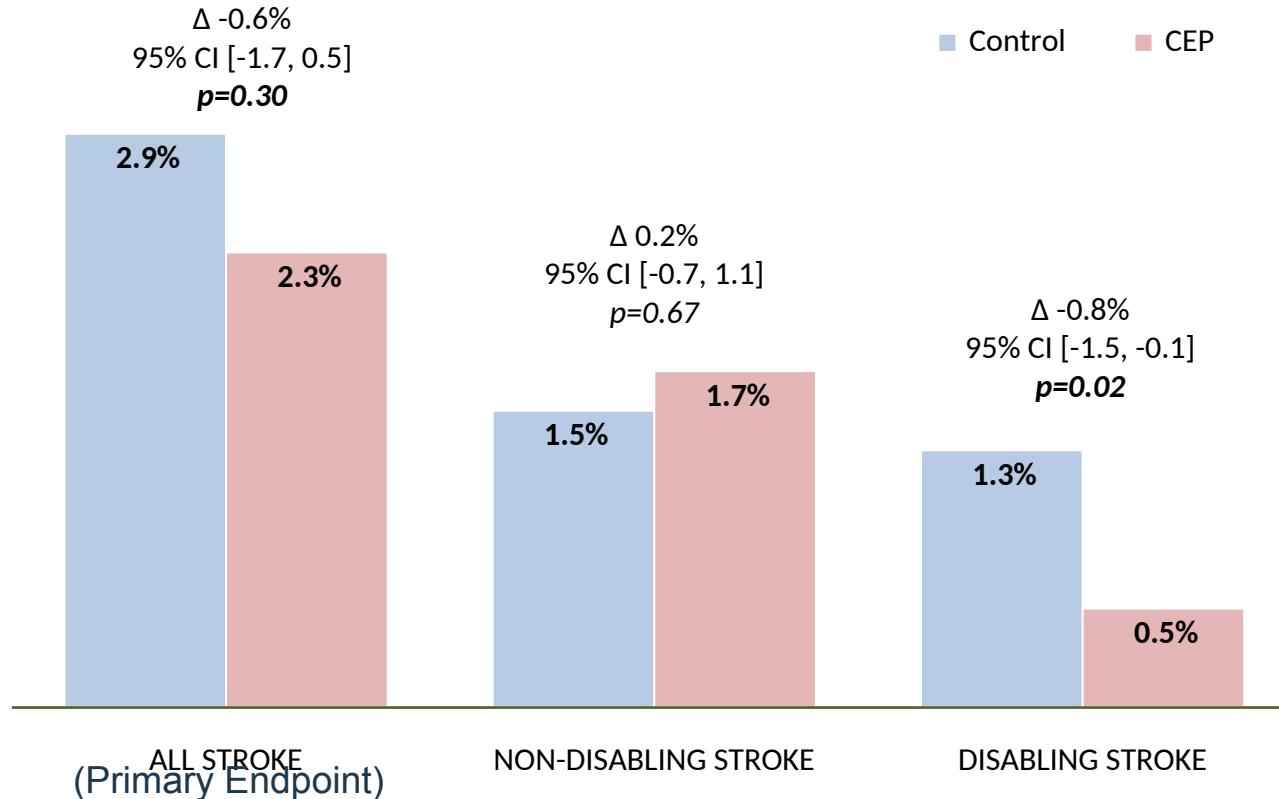
Neurological examination

- At baseline
- Discharge or 72 hours after TAVR (whichever comes first)
- Performed by a neurology professional
- mRS, NIHSS, MoCA, CAM-ICU

- Adaptive study design with interim analysis at 70% enrollment



Primary Endpoint: Stroke at 72h / Discharge





Conclusions (?)



Seatbelts
Are
For
Everyone



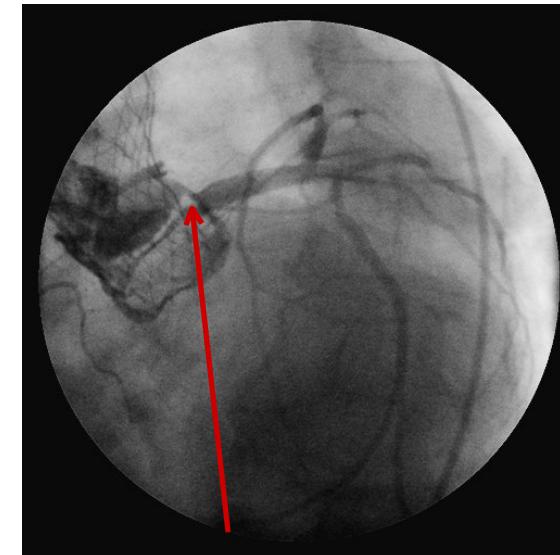
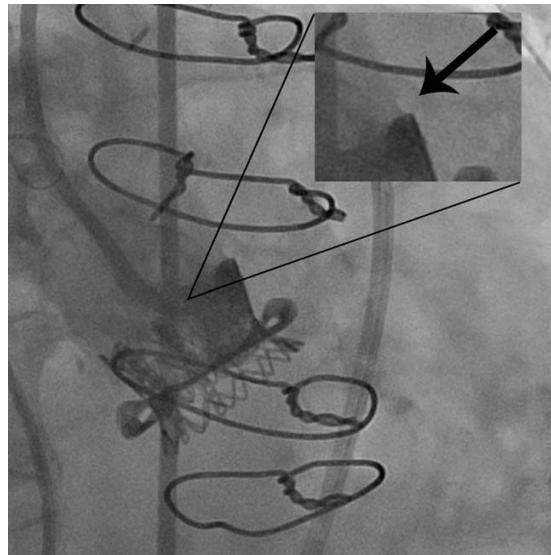
Main sources of complications

- Access site
- Stroke
- Coronary arteries
- Paravalvular leak
- Heart rhythm disturbances

Coronary Obstruction Following Transcatheter Aortic Valve-in-Valve Implantation For Failed Surgical Bioprostheses

Ronen Gurvitch,¹ MBBS, Anson Cheung,¹ MD, Francesco Bedogni,² MD,
and John G. Webb,^{1*} MD

Catheterization and Cardiovascular Interventions 77:439–444 (2011)





Coronary occlusions

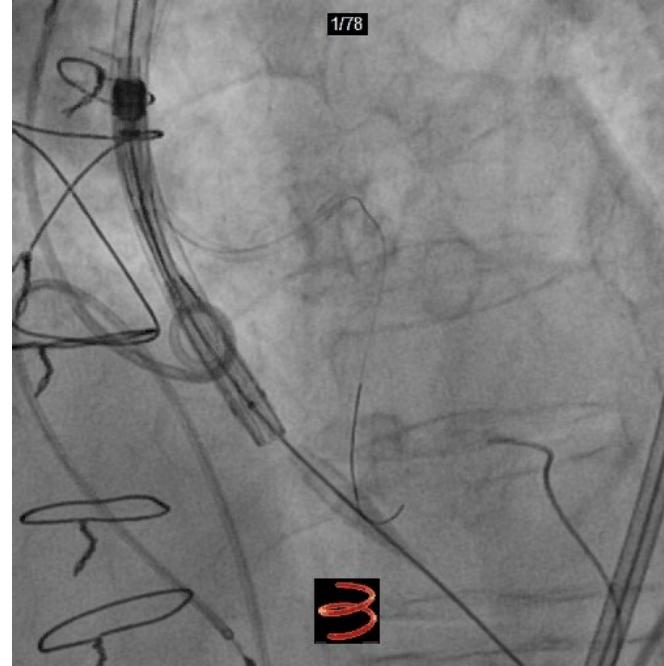
(old data, native anatomy)

	Total (n=202)	CoreValve (n=124)	Edwards SAPIEN (n=78)	P*
Procedural success†	188 (93.1)	120 (96.8)	68 (87.2)	0.009
Preimplantation valvuloplasty	56 (27.7)	20 (16.1)	36 (46.2)	<0.0001
Postimplantation valvuloplasty	25 (12.4)	21 (16.9)	4 (5.1)	0.01
Ostial coronary obstruction	7 (3.5)	4 (3.2)	3 (3.8)	1.0
Need for an emergent surgery	4 (2)	1 (0.8)	3 (3.8)	0.3

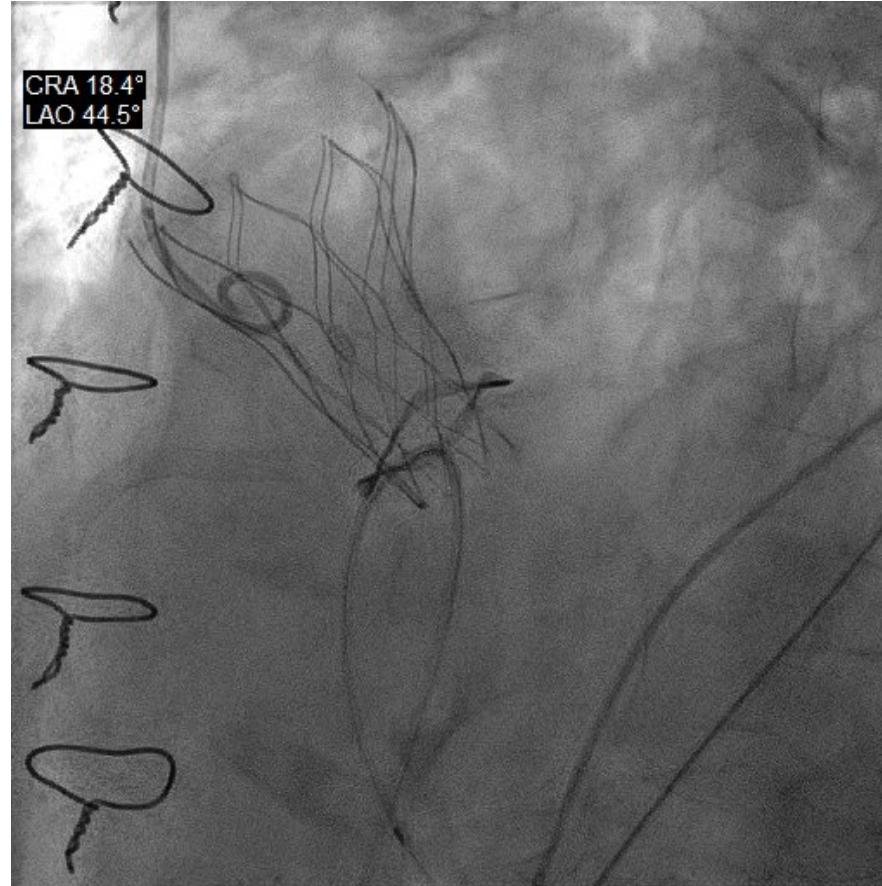
(*Circulation.* 2012;126:2335-2344.)

Left Main protection during very high risk Transcatheter Aortic Valve-in-Valve procedure. A Collaborative Registry

Luca Testa¹, Tarun Chakravarty², Azeem Latib³, Fausto Castriota⁴, Montone RA¹,
Alberto Cremonesi⁴, Antonio Colombo³, Raj Makkar², Francesco Bedogni¹

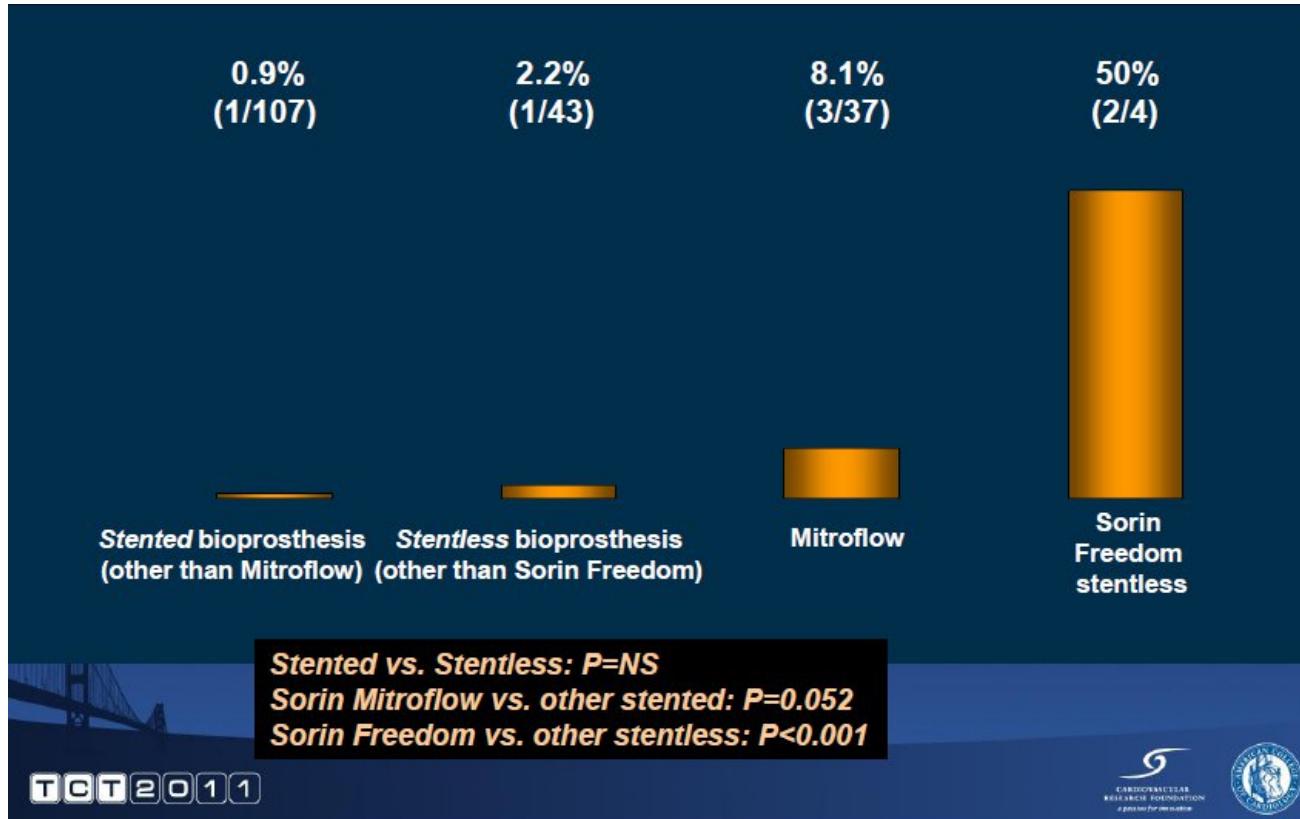


Controllo angio finale



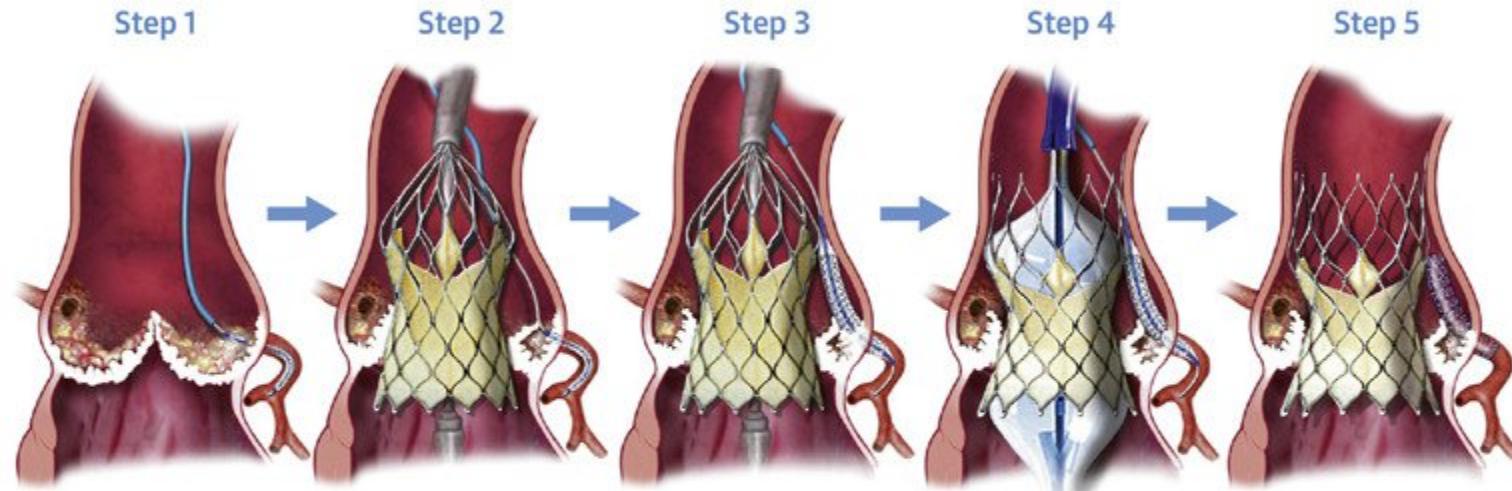


Ostial Coronary occlusion





CENTRAL ILLUSTRATION: Chimney Stenting Procedural Steps



Patient at risk.
Safety wire
and stent

Valve deployment
with safety wire
and stent

Chimney
stenting if
coronary
obstruction

Simultaneous
kissing
(only if post-
dilatation of
TAVR required)

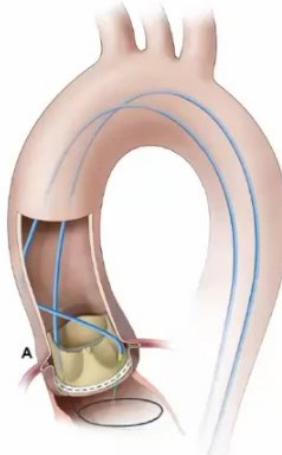
Final result

Mercanti, F. et al. J Am Coll Cardiol Intv. 2020;13(6):751-61.

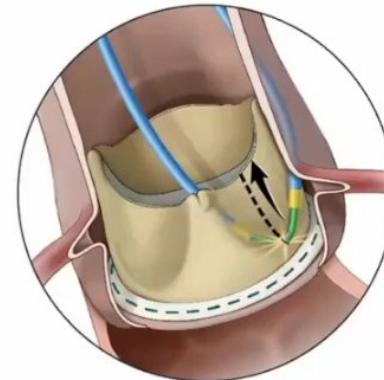


BASILICA - laceration of cusp

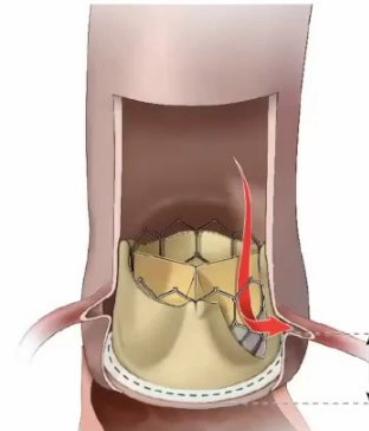
Leaflet wire transversal and snaring



Leaflet slicing



Preserved coronary flow





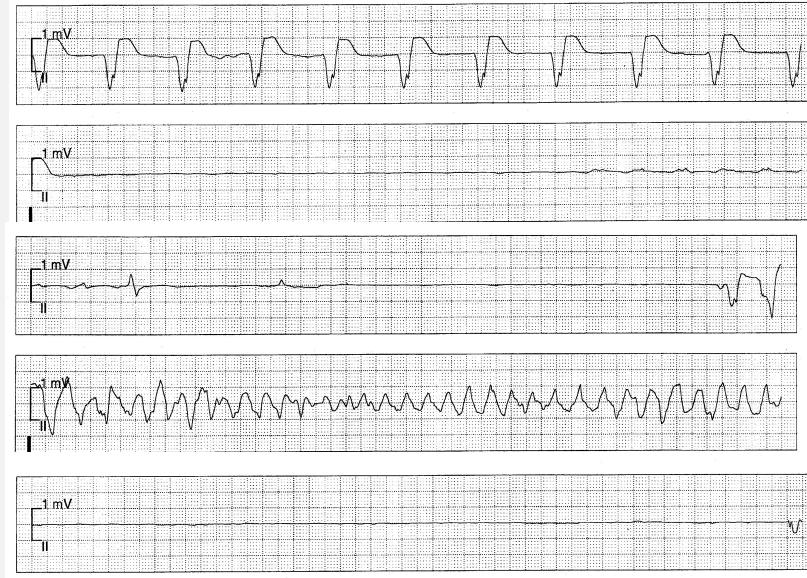
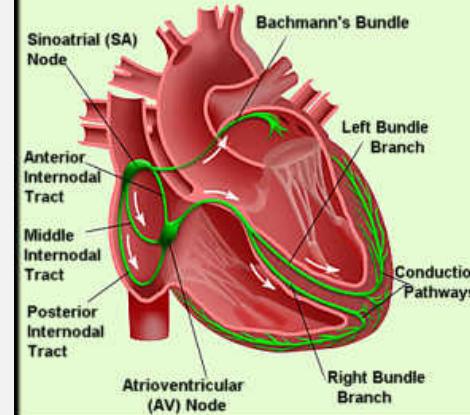
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Cardiac rhythm disturbances



ELECTRICAL SYSTEM OF THE HEART



Post-implant

EuroPCR: National Registries Outcomes

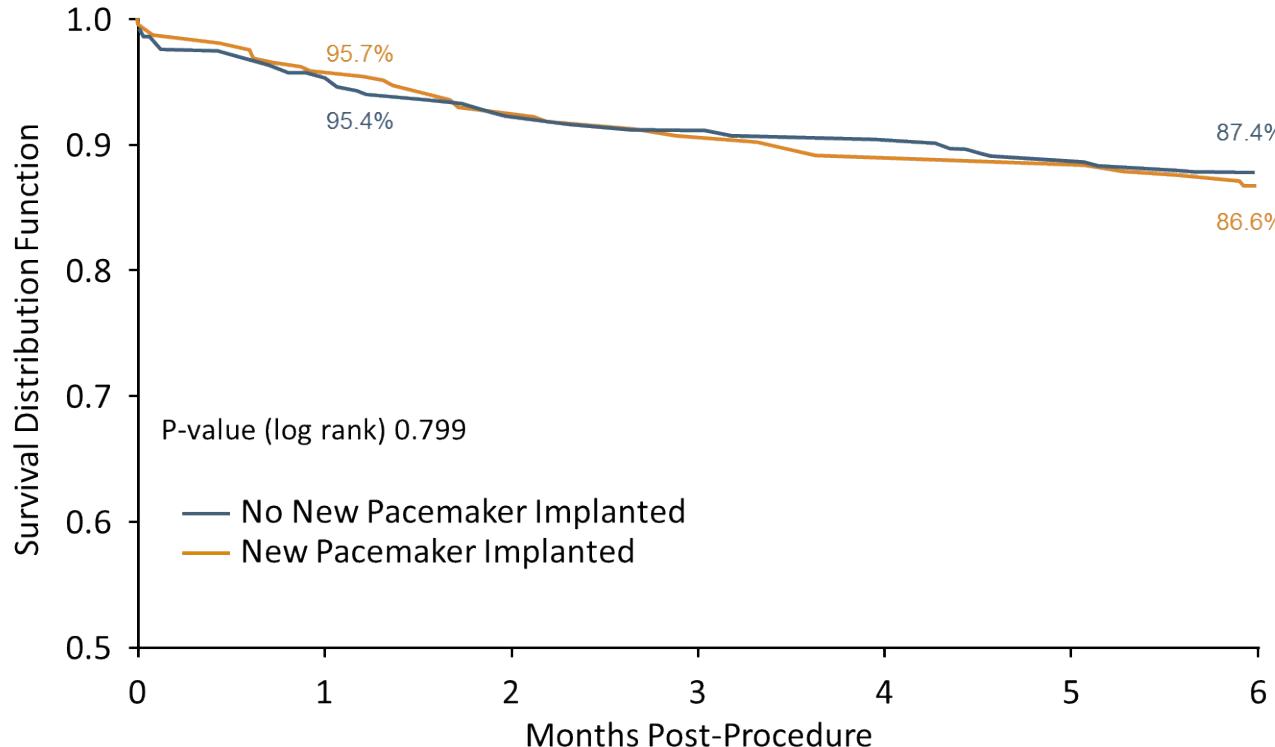


Registry	Pts	Device	Stroke	PPM
COR02-2006 ¹	72	Corevalve	7.1	25.4
Contemporary Registries				
Italian Registry ²	772	CoreValve	1.7	18.5
Belgian Registry ³	141	CoreValve	4	23.0
French Transfemoral ⁴	66	CoreValve	3.6	26.9
UK CoreValve Registry ⁵	417	CoreValve	NR	26.0
Total	1,396			
Source Registry (Cohort 1)	463	Edwards Appropriate PPM will likely be < 20%	4.0	8

¹Gerckens et al; ²Petronio et al; ³ Bosmans et al; ⁴ Eltchaninoff et al; ⁵ Ludman et al; ⁶ Thomas et al

ADVANCE | Pacemaker Implantation

No mortality differences between those patients receiving a new pacemaker and those without a new pacemaker out to 6-months





Conduction abnormalities

Need of new PPM after TAVI (Corevalve)

- Pre-existing LBBB 7/37 (19%)
- Pre-existing LAH 13/45 (28%)
- Pre-existing RBBB 14/31 (55%)



Procedural characteristics

	No new PPM n = 209	New PPM n= 66	p value
--	-----------------------	------------------	---------

Subclavian approach, %	37(18%)	19(29%)	0.053
Postdilatation,%	25(12%)	4(6%)	0.17
Valve in valve	11(5%)	4(6%)	0.78
Valve Position, mm	0.78±0.34	0.89±0.31	0.03
Large Valve size, %	72(34%)	33(50%)	0.01
prosthesis/annulus	1.21±0.8	1.23±1.2	0.13
prosthesis/LVOT	1.44±0.24	1.39±0.18	0.017



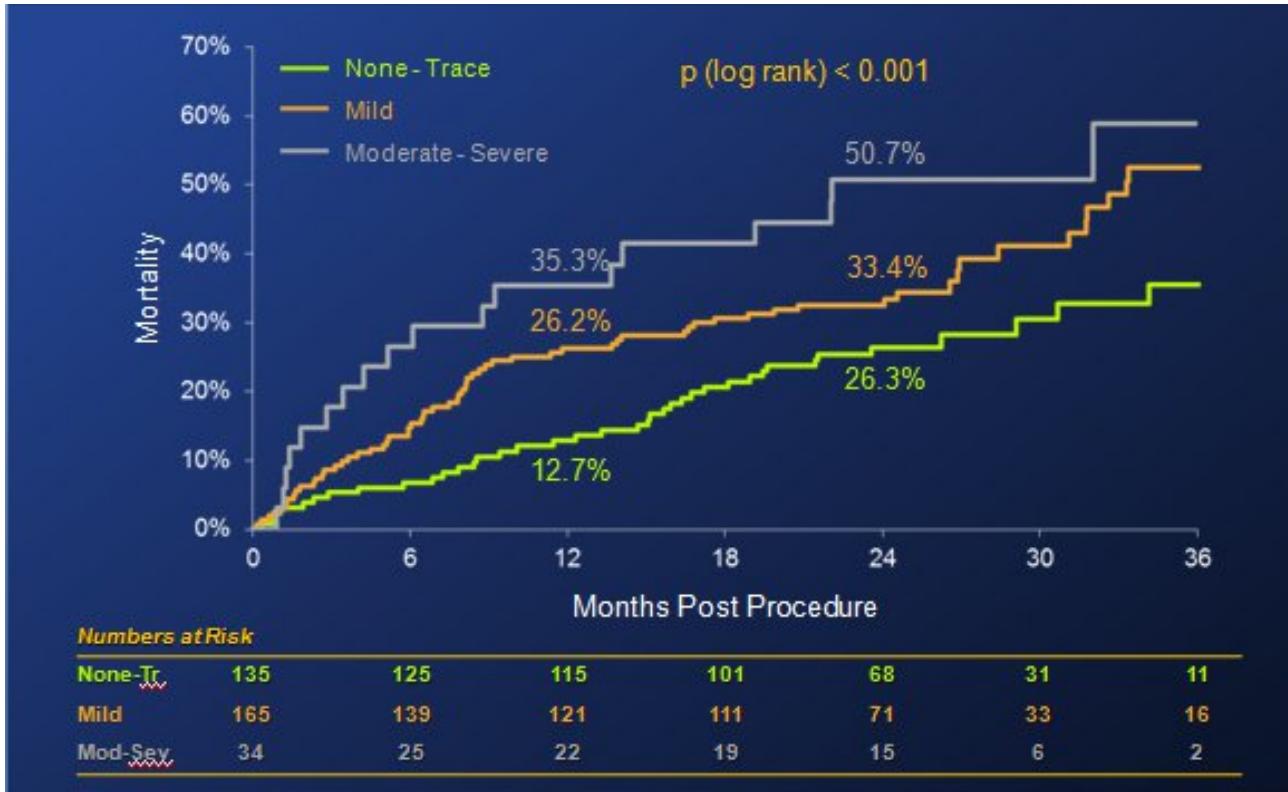
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- Heart rhythm disturbances
- Paravalvular leak

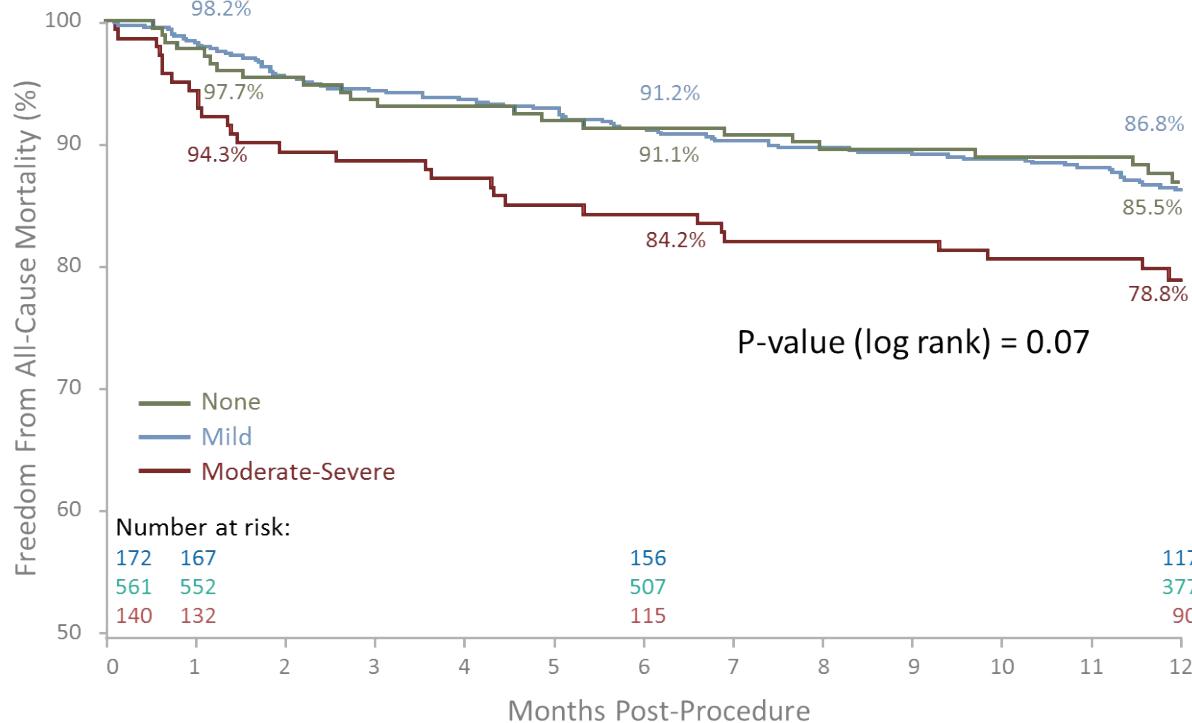


Total AR and Mortality

TAVR Patients (AT)



Survival by Aortic Regurgitation*



*At discharge



Meccanismi

1. Inadeguata espansione/apposizione della protesi
2. Non corretto posizionamento della protesi
3. Mis-match protesi/dimensione annulus

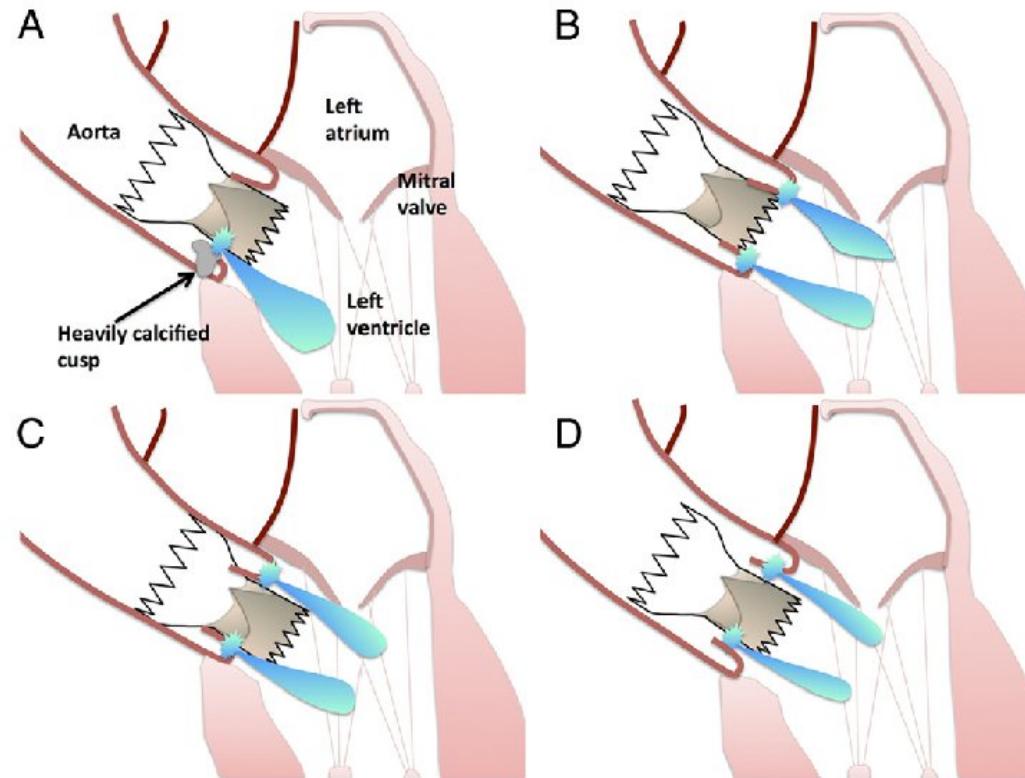
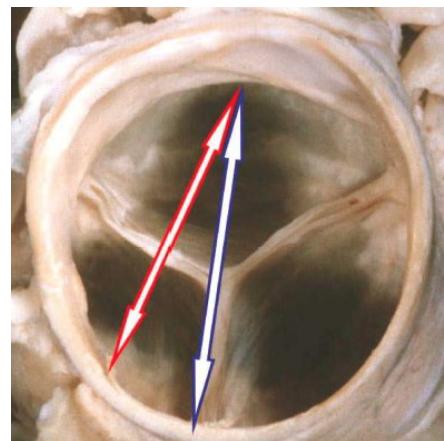
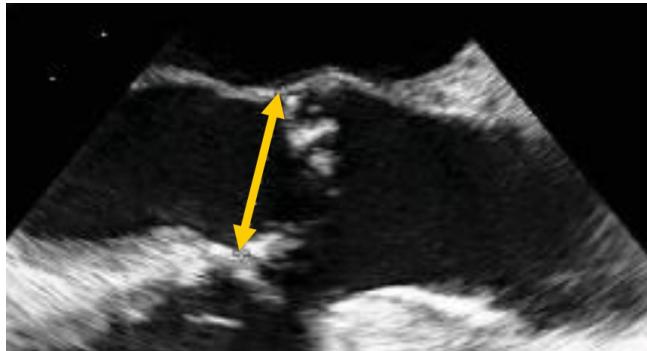
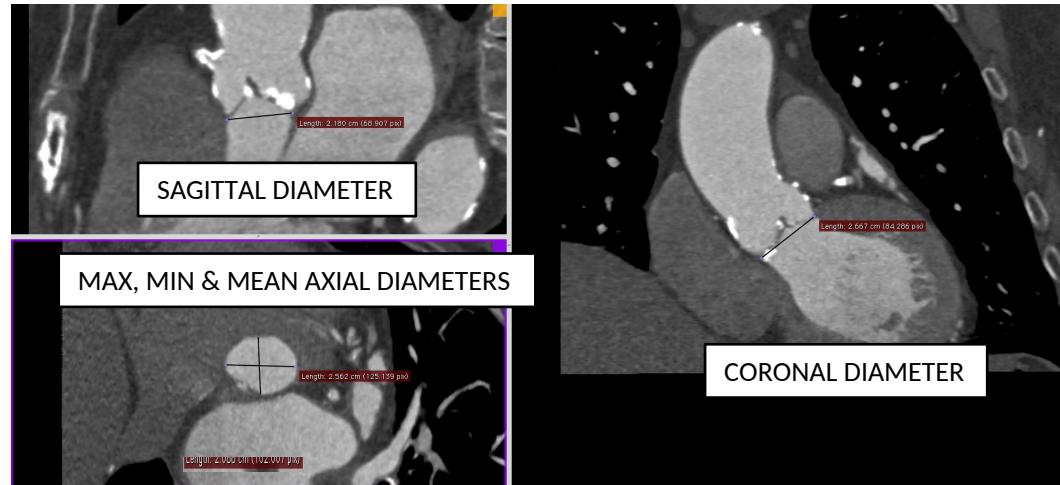


Figure 5 Mechanisms of Peri-Prosthetic Aortic Regurgitation After Transcatheter Aortic Valve Implantation

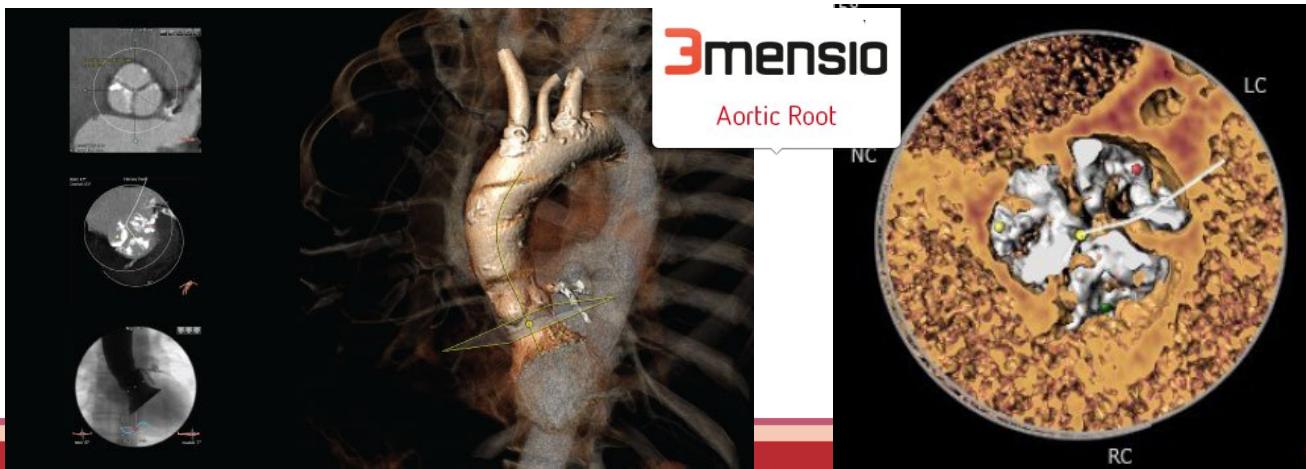
Paravalvular leaks with consecutive peri prosthetic aortic regurgitation result from under expansion of the prosthesis stent frame, which might be caused by calcifications of the annulus or the cusps of the native valve (A), valve malposition with too shallow (B) or too deep (C) implantation depth of the prosthesis, and/or annulus-prosthesis-size mismatch (D).

Sizing is crucial !





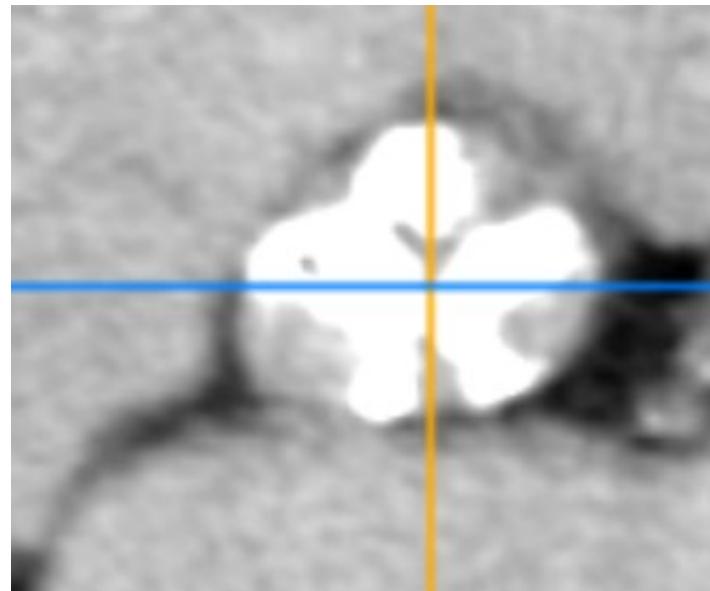
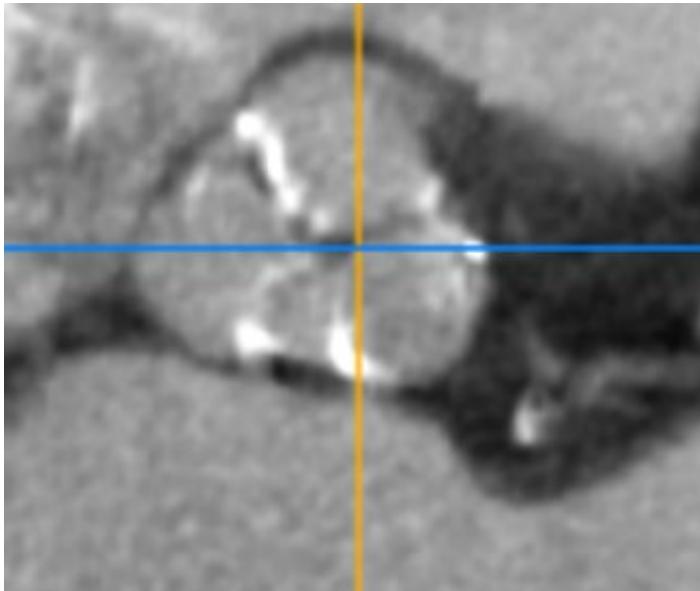
Virtual basal ring measurement: MDCT





Sizing is crucial but NOT everything !

Calcium burden

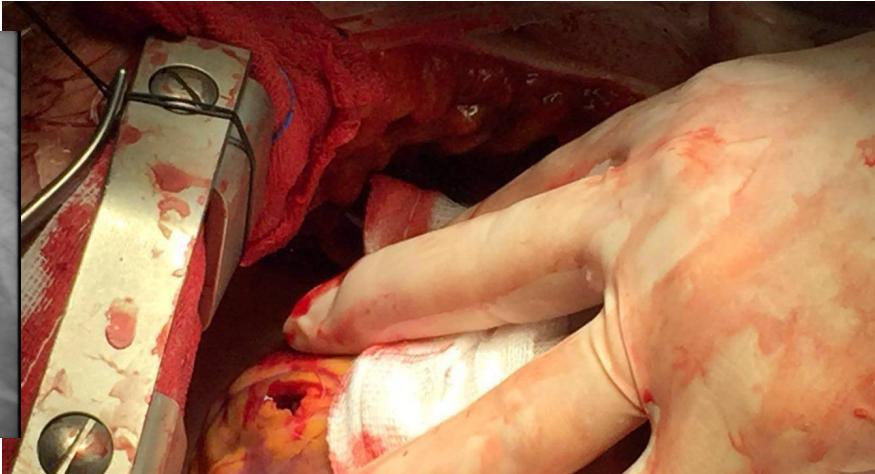
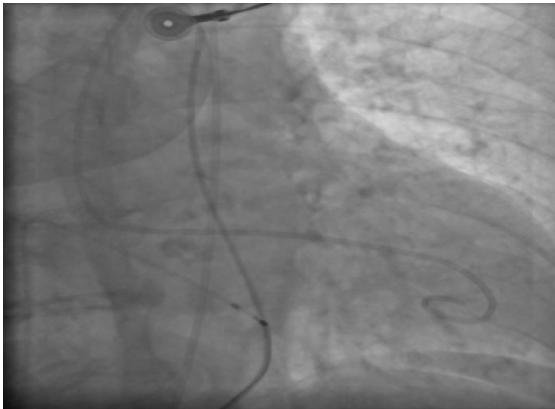




Main sources of complications

- Access site
- Stroke
- Coronary arteries
- Heart rhythm disturbances
- Paravalvular leak
- **RV/LV perforation**

RV or LV perforation





Key Elements

- RV perforation is essentially subsequent to RV pacing and usually self limiting
- Careful wire handling is required
- Careful THV positioning is required
- Pre-shaped wires are a good idea

PLACE

PLATFORM OF LABORATORIES FOR ADVANCES IN CARDIAC EXPERIENCE

ROMA

Centro Congressi
di Confindustria

**Auditorium
della Tecnica**

9^a Edizione

**30 Settembre
1 Ottobre
2022**



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