Conoscere e Curare il Cuore 2019

SABATO 2 MARZO

CONFRONTO TRA LA CHIRURGIA VALVOLARE AORTICA TRADIZIONALE E L'APPROCCIO TRANSAPICALE

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IRCCS Istituto Scientifico San Raffaele, Milano

Contemporary Treatment of Heart Valve Disease

Availability of numerous therapeutic options

Expansion of the treated population

Personalized treatment

Aortic Valve Implantation

Multiple Therapeutic Options

Invasiveness

Conventional through midline sternotomy

Surgical through minimal incision

On pump, arrested heart sutureless valve replacement

Surgical apico-aortic valved conduit

Transaortic delivery

Transapical delivery

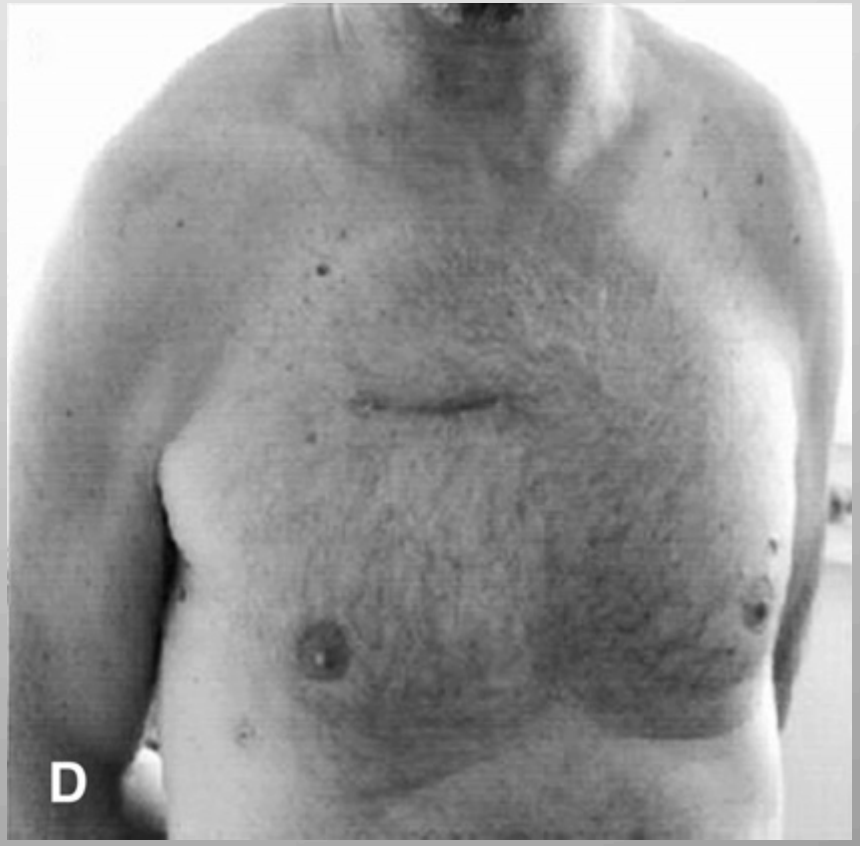
Transaxillary delivery

Transcarotid delivery

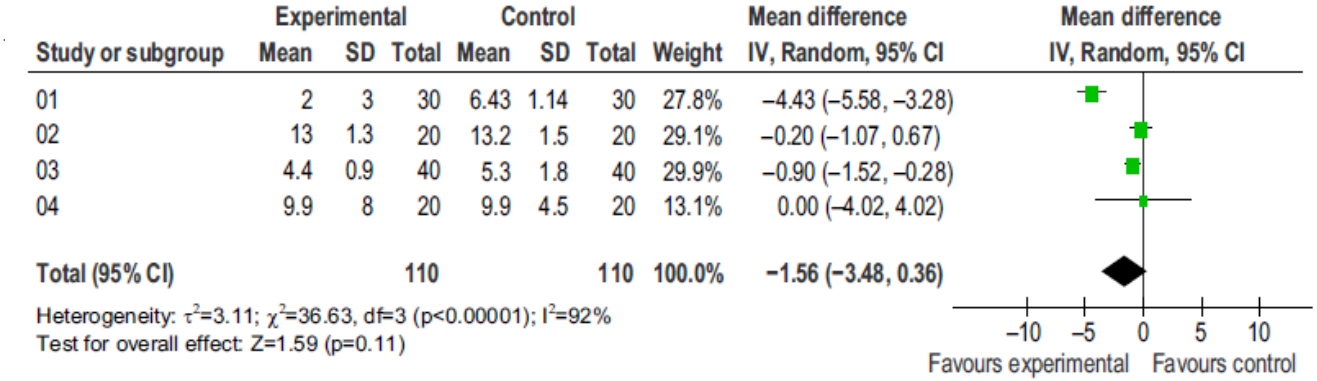
Transcaval delivery

Percutaneous transfemoral

TAVI


D

Mini-sternotomy for aortic valve replacement reduces the length of stay in the cardiac intensive care unit: meta-analysis of randomised controlled trials



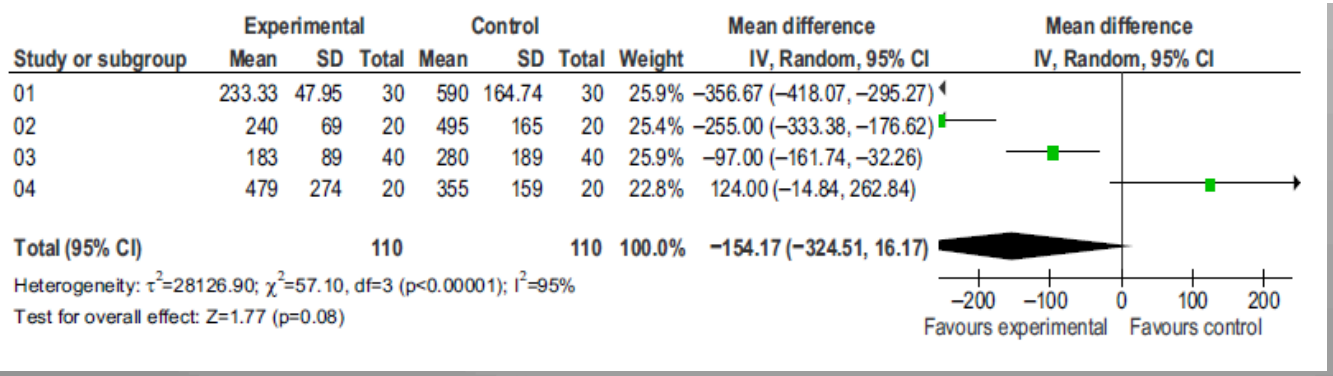
Study or subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean difference IV, Random, 95% CI
01	2	3	30	6.43	1.14	30	27.8%	−4.43 (−5.58, −3.28)
02	13	1.3	20	13.2	1.5	20	29.1%	−0.20 (−1.07, 0.67)
03	4.4	0.9	40	5.3	1.8	40	29.9%	−0.90 (−1.52, −0.28)
04	9.9	8	20	9.9	4.5	20	13.1%	0.00 (−4.02, 4.02)
Total (95% CI)			**110**			**110**	**100.0%**	**−1.56 (−3.48, 0.36)**

Heterogeneity: τ^2=3.11; χ^2=36.63, df=3 (p<0.00001); I^2=92%
Test for overall effect: Z=1.59 (p=0.11)

Mean difference IV, Random, 95% CI

−10 −5 0 5 10
Favours experimental Favours control

Figure 2 Duration of ventilation in hours.



Study or subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean difference IV, Random, 95% CI
01	233.33	47.95	30	590	164.74	30	25.9%	−356.67 (−418.07, −295.27)
02	240	69	20	495	165	20	25.4%	−255.00 (−333.38, −176.62)
03	183	89	40	280	189	40	25.9%	−97.00 (−161.74, −32.26)
04	479	274	20	355	159	20	22.8%	124.00 (−14.84, 262.84)
Total (95% CI)			**110**			**110**	**100.0%**	**−154.17 (−324.51, 16.17)**

Heterogeneity: τ^2=28126.90; χ^2=57.10, df=3 (p<0.00001); I^2=95%
Test for overall effect: Z=1.77 (p=0.08)

Mean difference IV, Random, 95% CI

−200 −100 0 100 200
Favours experimental Favours control

Figure 3 Postoperative bleeding in the first 24 h measured in millilitres.

BMJ Open 2011;**1**:e000266. doi:10.1136/bmjopen-2011-000266

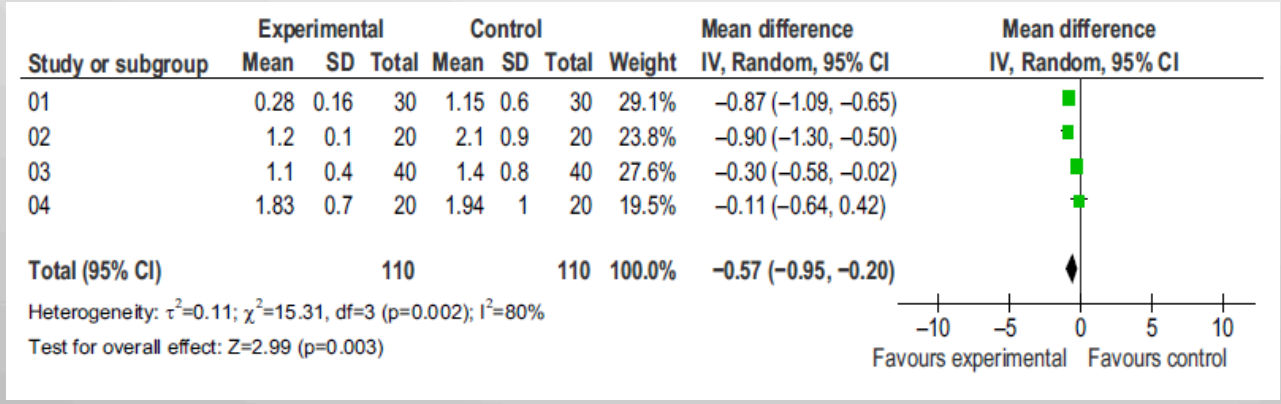


Figure 4 Length of intensive care unit stay in days.

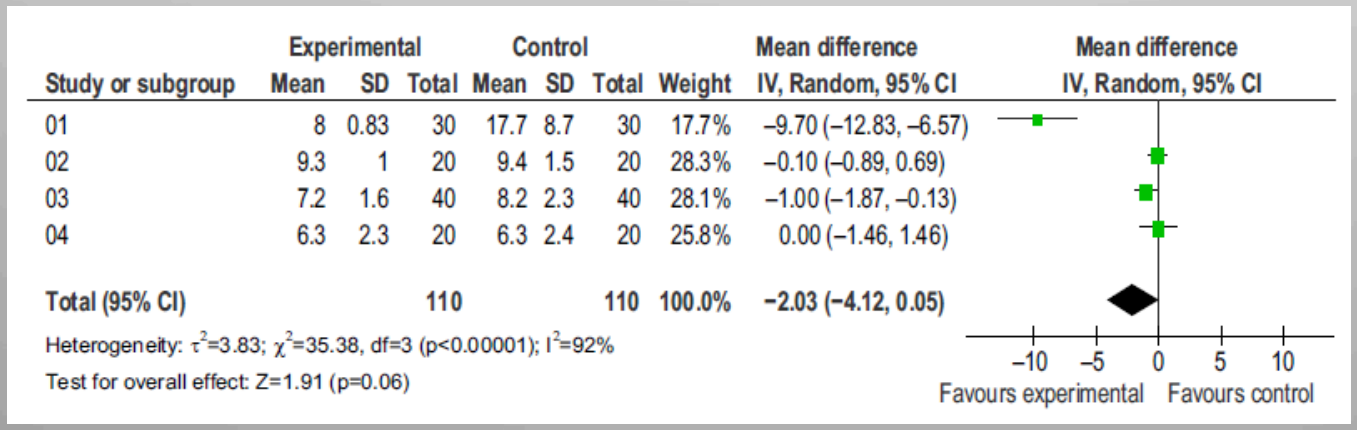


Figure 5 Length of hospital stay in days.

Sutureless aortic prosthesis

Sorin Perceval S

Edwards Intuity

Sutureless aortic valve replacement as an alternative treatment for patients belonging to the "gray zone" between transcatheter aortic valve implantation and conventional surgery: A propensity-matched, multicenter analysis

Augusto D'Onofrio, MD,[a] Antonio Messina, MD,[b] Roberto Lorusso, MD,[c] Ottavio R. Alfieri, MD,[d] Melissa Fusari, MD,[e] Paolo Rubino, MD,[f] Mauro Rinaldi, MD,[g] Roberto Di Bartolomeo, MD,[h] Mattia Glauber, MD,[i] Giovanni Troise, MD,[b] and Gino Gerosa, MD[a]

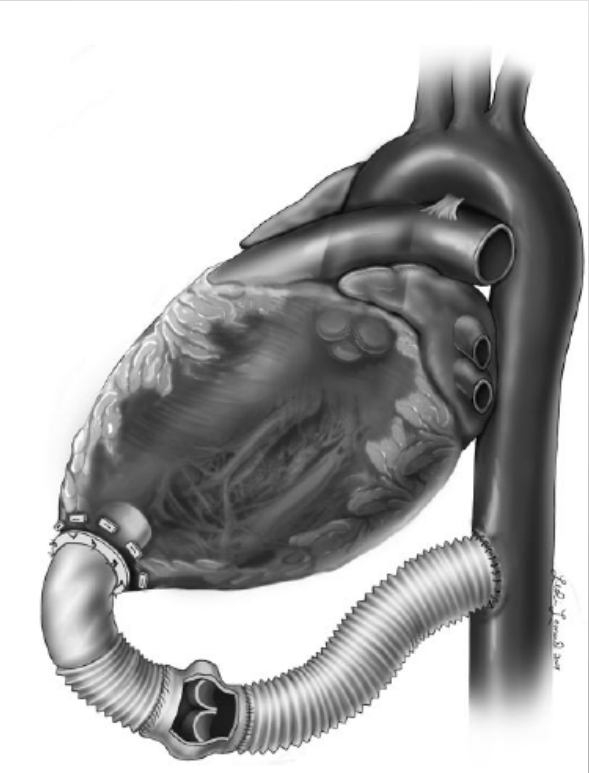
TABLE 3. Postoperative outcomes after TA-TAVI and SU-AVR

Variable	TA-TAVI (n = 38)	SU-AVR (n = 38)	*P* Value
Hospital mortality, n (%)	2 (5.3)	0 (0)	.49
ARF requiring CVVH, n (%)	1 (2.6)	2 (5.3)	1.00
AMI, n (%)	0 (0)	0 (0)	1.00
Stroke, n (%)	0 (0)	0 (0)	1.00
Bleeding (life-threatening/disabling, major), n (%)	2 (5.3)	1 (2.6)	1.00
PPM implantation, n (%)	2 (5.3)	2 (5.3)	1.00
Mean transaortic gradient, mm Hg	10.25 ± 5.03	10.95 ± 3.72	.59
AR at discharge (at least mild), n (%)	17 (44.7)	6 (15.8)	.001
LVEF at discharge, % (IR)	60 (55-60)	60 (54-65)	.75
New-onset atrial fibrillation, n (%)	7 (18.4)	16 (42.1)	.04
Orotracheal intubation time, hours (IR)	4 (0-5)	5.5 (4-8)	.21

Conclusions: This preliminary experience showed that, in patients at high risk for conventional surgery, SU-AVR is as safe and effective as TA-TAVI and that it is associated with a lower rate of postprocedural paravalvular leak. (J Thorac Cardiovasc Surg 2012;144:1010-8)

Aortic Valve Bypass Surgery : Midterm Clinical Outcomes in a High-Risk Aortic Stenosis Population

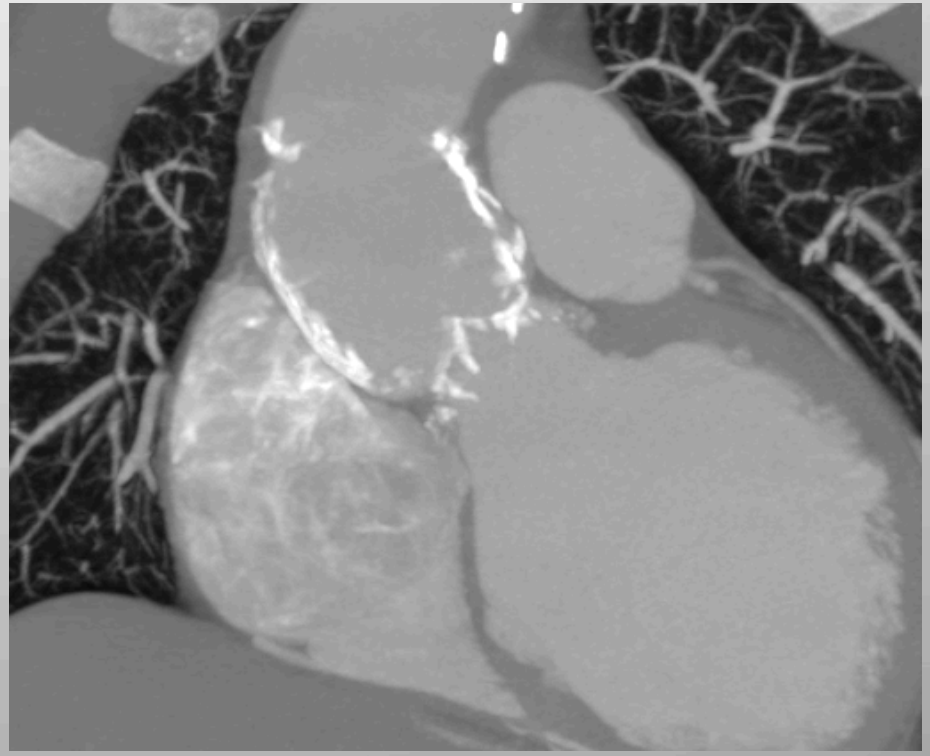
James S. Gammie, Leandra S. Krowsoski, James M. Brown, Patrick N. Odonkor, Cindi A. Young, Mary J. Santos, John S. Gottdiener and Bartley P. Griffith



31 high-risk pts
Operative mortality 13% (4/31 pts)

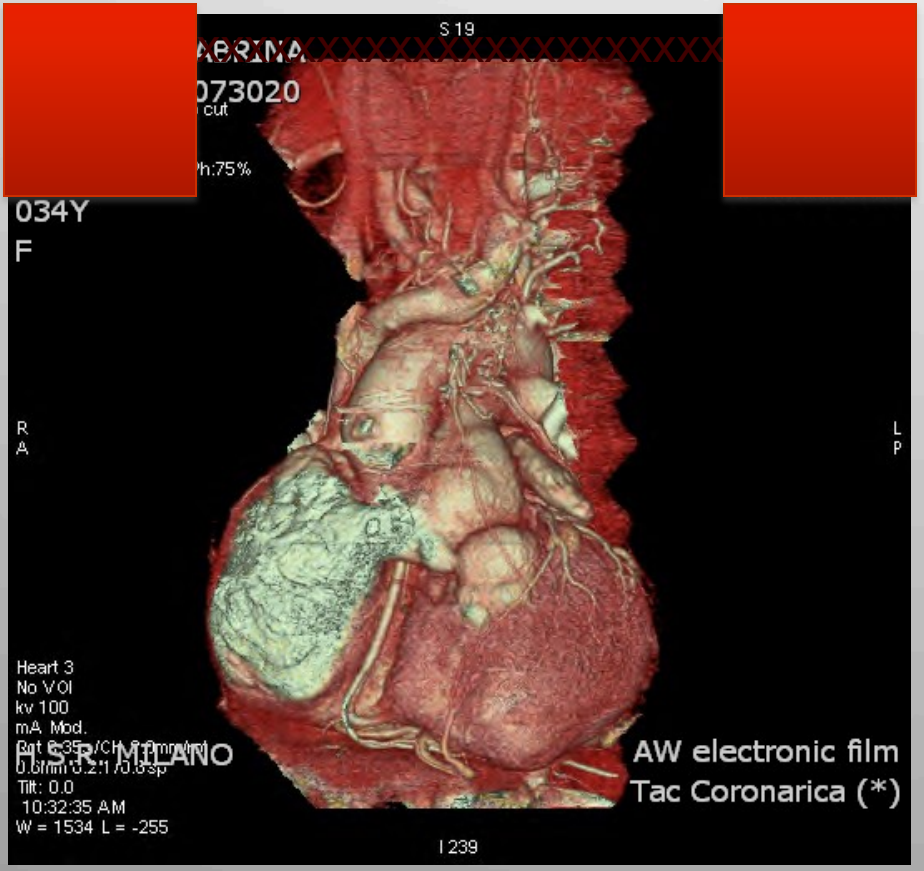
Conclusions—AVB surgery is an important therapeutic option for high-risk patients with symptomatic AS. Ventricular outflow is distributed in a predictable fashion between the conduit and the left ventricular outflow tract, and AVB surgery reliably relieves AS. Stroke and renal dysfunction were uncommon. (*Circulation*. 2008;118:1460-1466.)

Apico-aortic conduit: a revival for selected high risk patients



- 42-year-old patient with severe calcification of homograft in aortic position;
- 2° REDO operation

Apico-aortic conduit: a revival for selected high risk patients



- GUCH patient with severe aortic and subaortic obstruction
- Previous Fontan operation

Aortic Valve Implantation

Multiple Therapeutic Options

Invasiveness

Conventional through midline sternotomy

Surgical through minimal incision

On pump, arrested heart sutureless valve replacement

Surgical apico-aortic valved conduit

Transapical delivery

Transaortic delivery

Transaxillary delivery

Transcarotid delivery

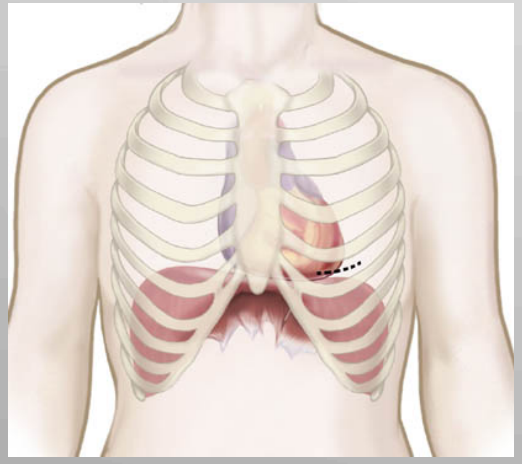
Transcaval delivery

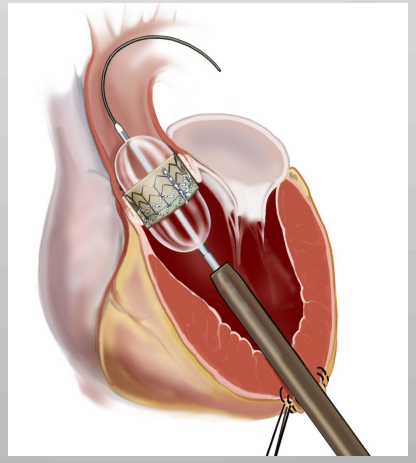
Percutaneous transfemoral

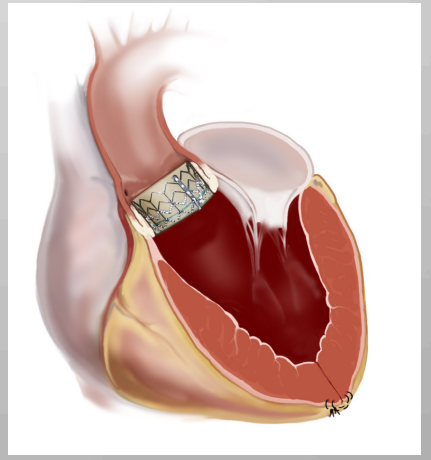
TAVI

Transcatheter Aortic Valve Implantation

TRANSAPICAL APPROACH

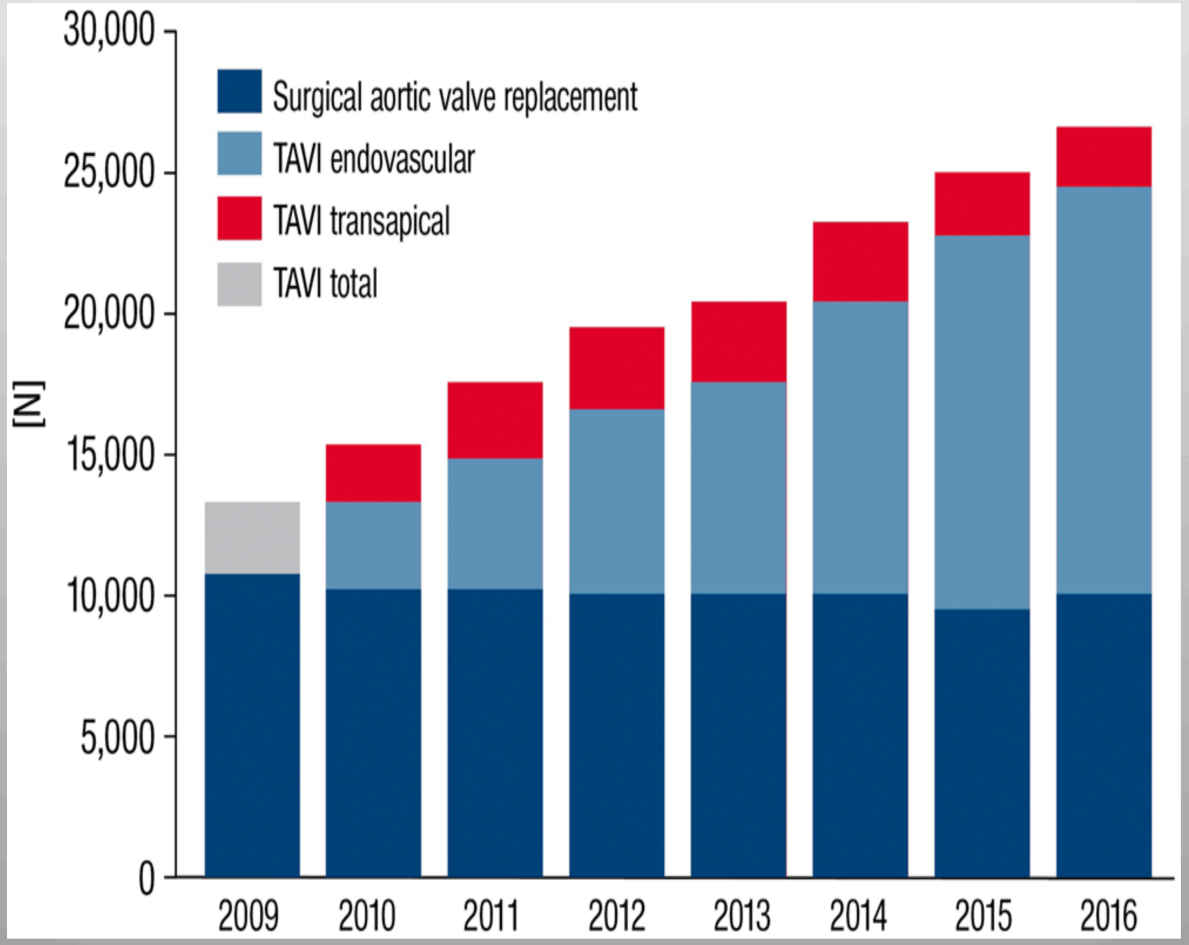




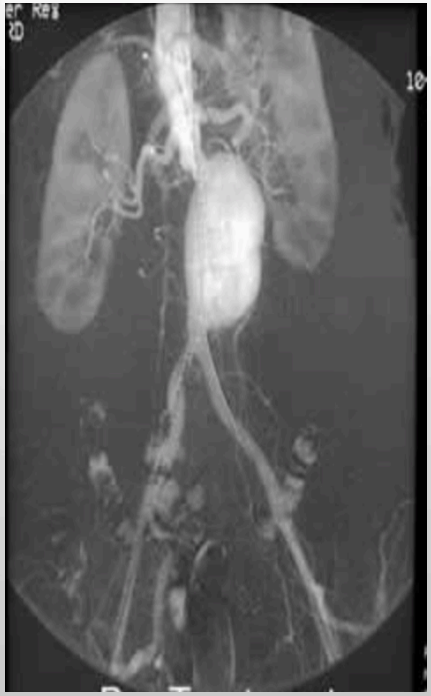


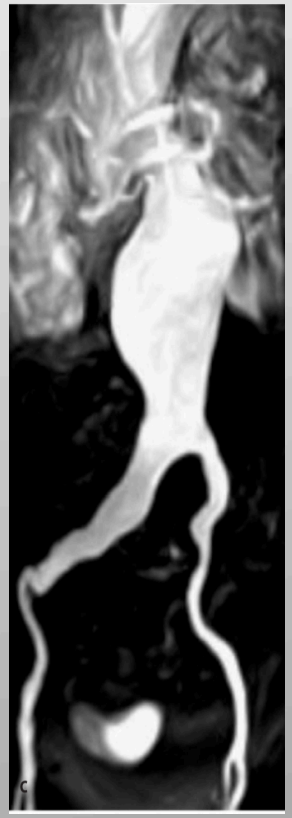
Development of TF+TA TAVI procedures vs SAVR since 2009

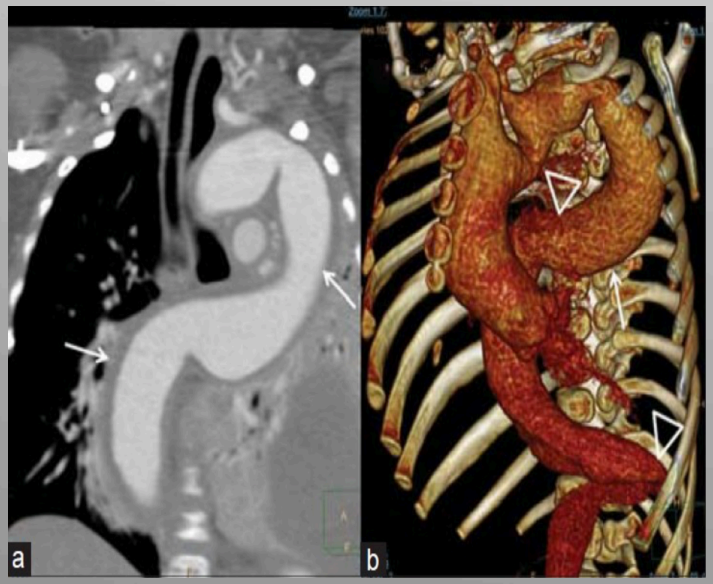
(from German Heart Report 2017)



A first dedicated Heart Valve Unit. Eur Heart J. 2018;39(28):2612-2613. doi:10.1093/eurheartj/ehy341






a
b

Comparison between SAVR and TA TAVI

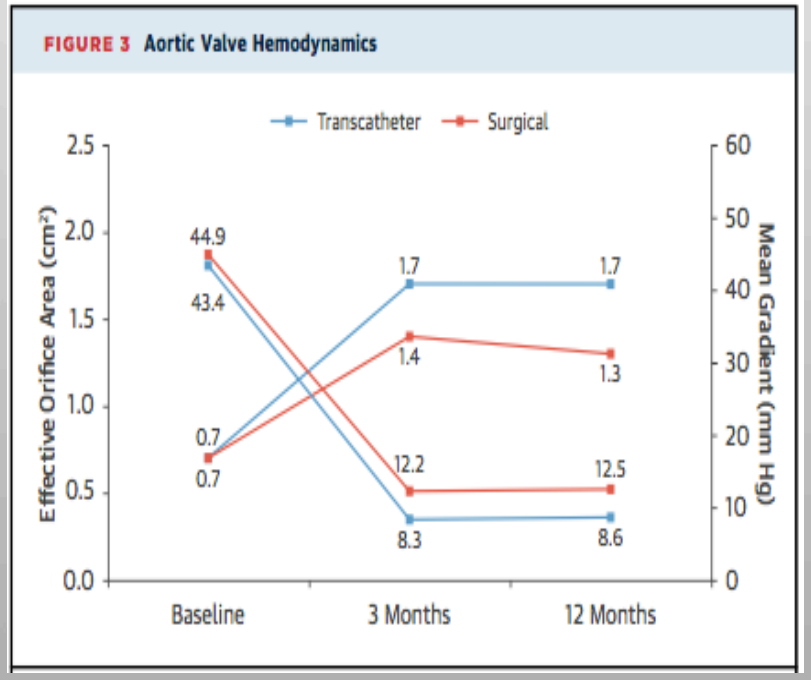
	SAVR	TA TAVI
Access	Surgical	Surgical
Anesthesia	General / Intubation	General / Intubation
Recovery time	Long	Intermediate
CPB	Yes	No
AoXclamp	Yes	No

Current Performance Benchmarks for TA TAVI *

- All-cause mortality ≤3%
- Major (disabling) strokes ≤2%
- New permanent pacemakers ≤15%
- Mod-severe para-valvular regurgitation ≤ 5%

* Not significantly different from TF TAVI

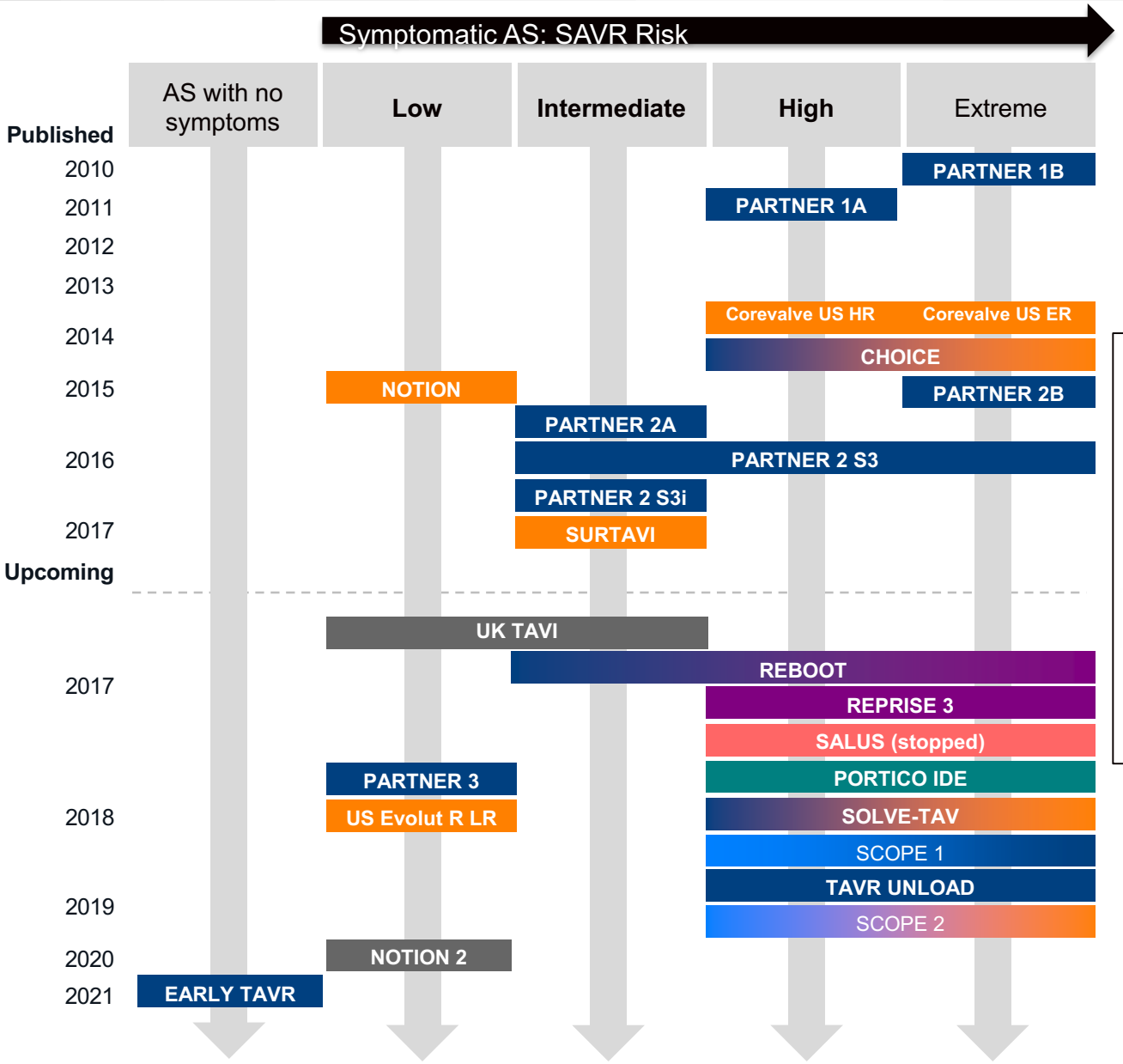
Hemodynamics



From all-comers NOTION RCT

Heart Team in action at the S. Raffaele

Pipeline of TAVI Trials across the spectrum of aortic stenosis



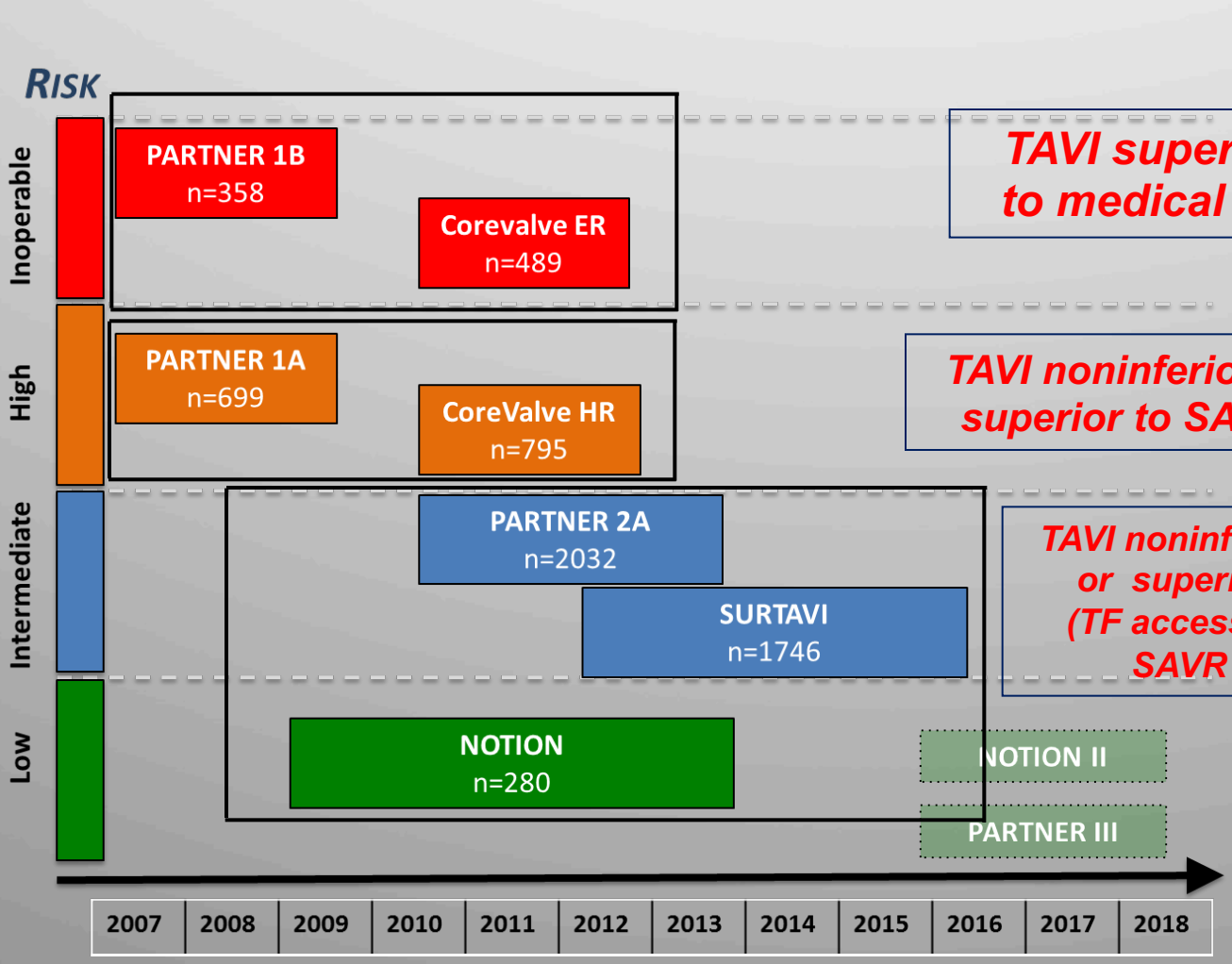
Investigational devices

- **Edwards** Sapien/Sapien XT/S3
- **Medtronic** CoreValve/Evolut R
- **Boston** Lotus
- **Direct Flow Medical** Direct Flow
- **Abbott Vascular** Portico
- **Symetis** Acurate Neo
- Any available TAVR system

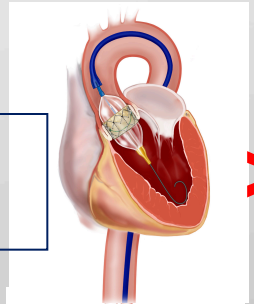
24 TAVI RCTs

Capodanno D, Leon MB. EuroIntervention 2016

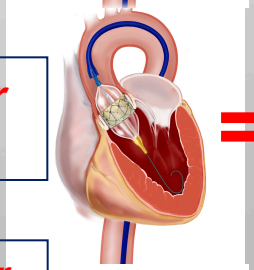
The Evolution of Clinical Evidence



TAVI superior to medical Rx



TAVI noninferior or superior to SAVR



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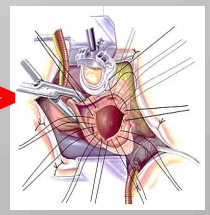
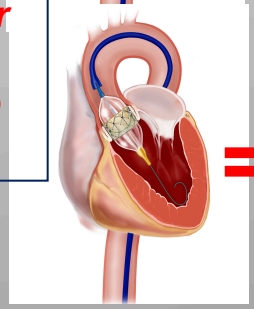


TAVI noninferior or superior (TF access) to SAVR



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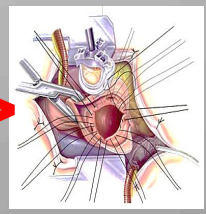
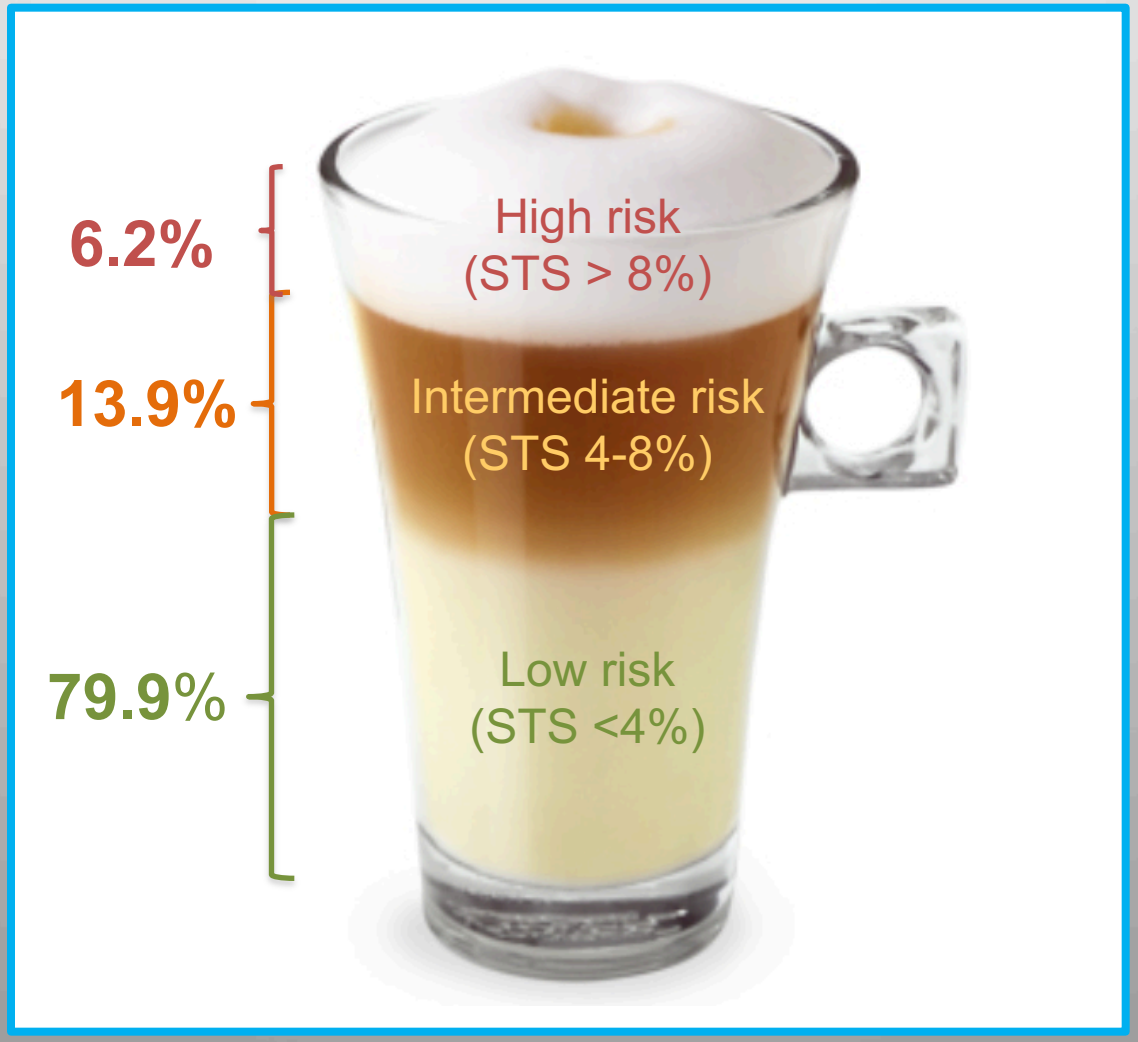


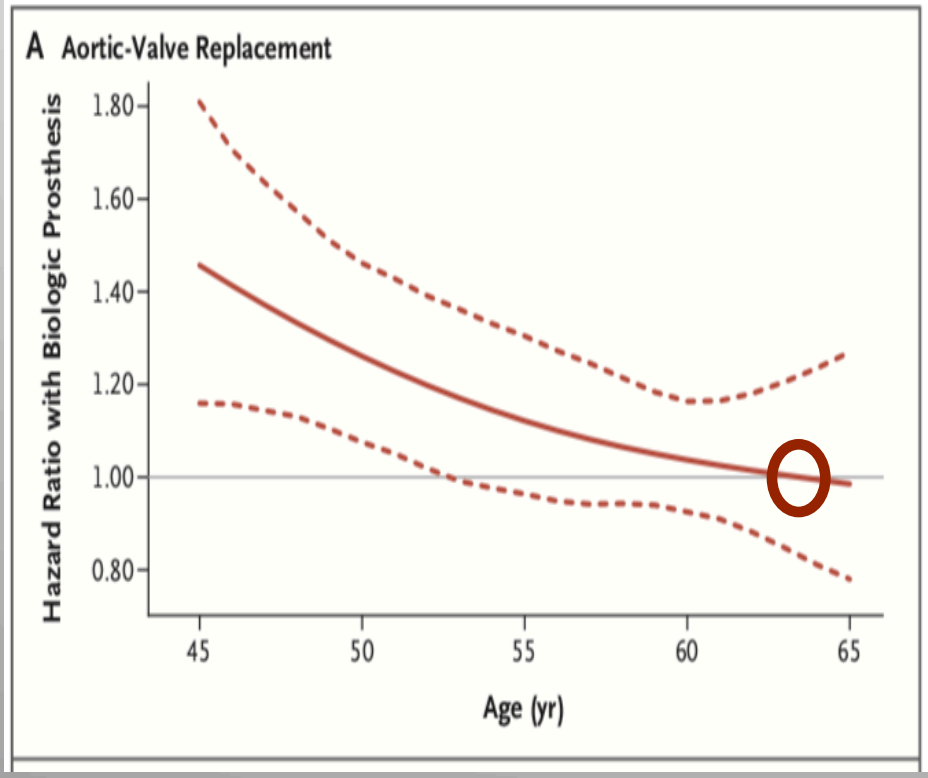
STS database 2002-2010

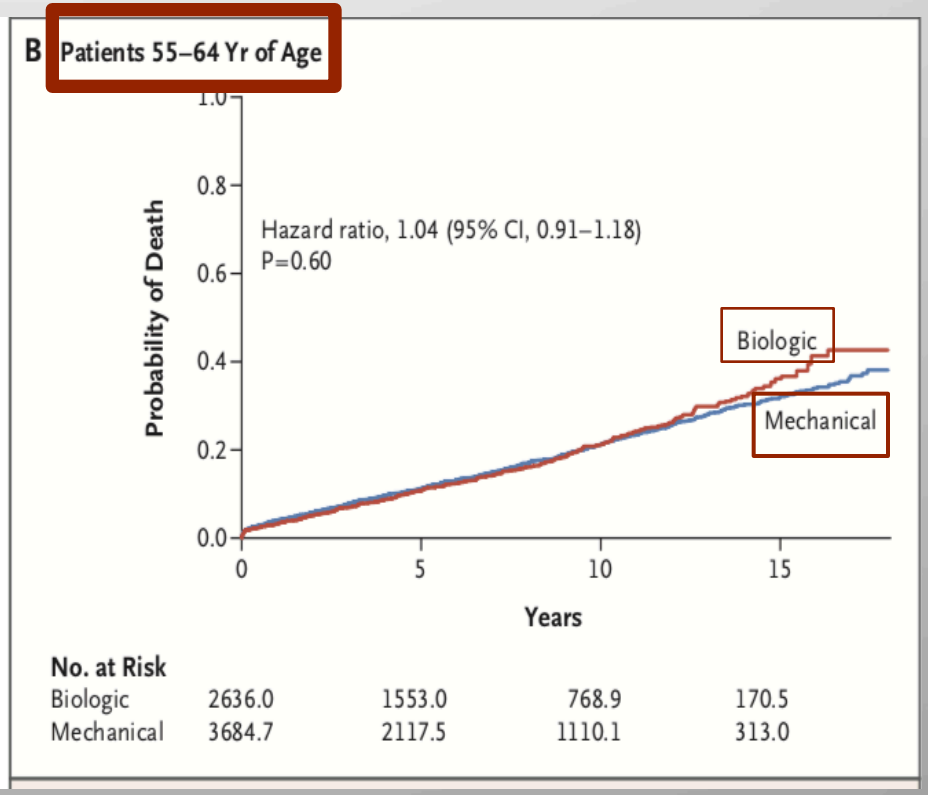
(141,905 pts)



Courtesy of N. Piazza

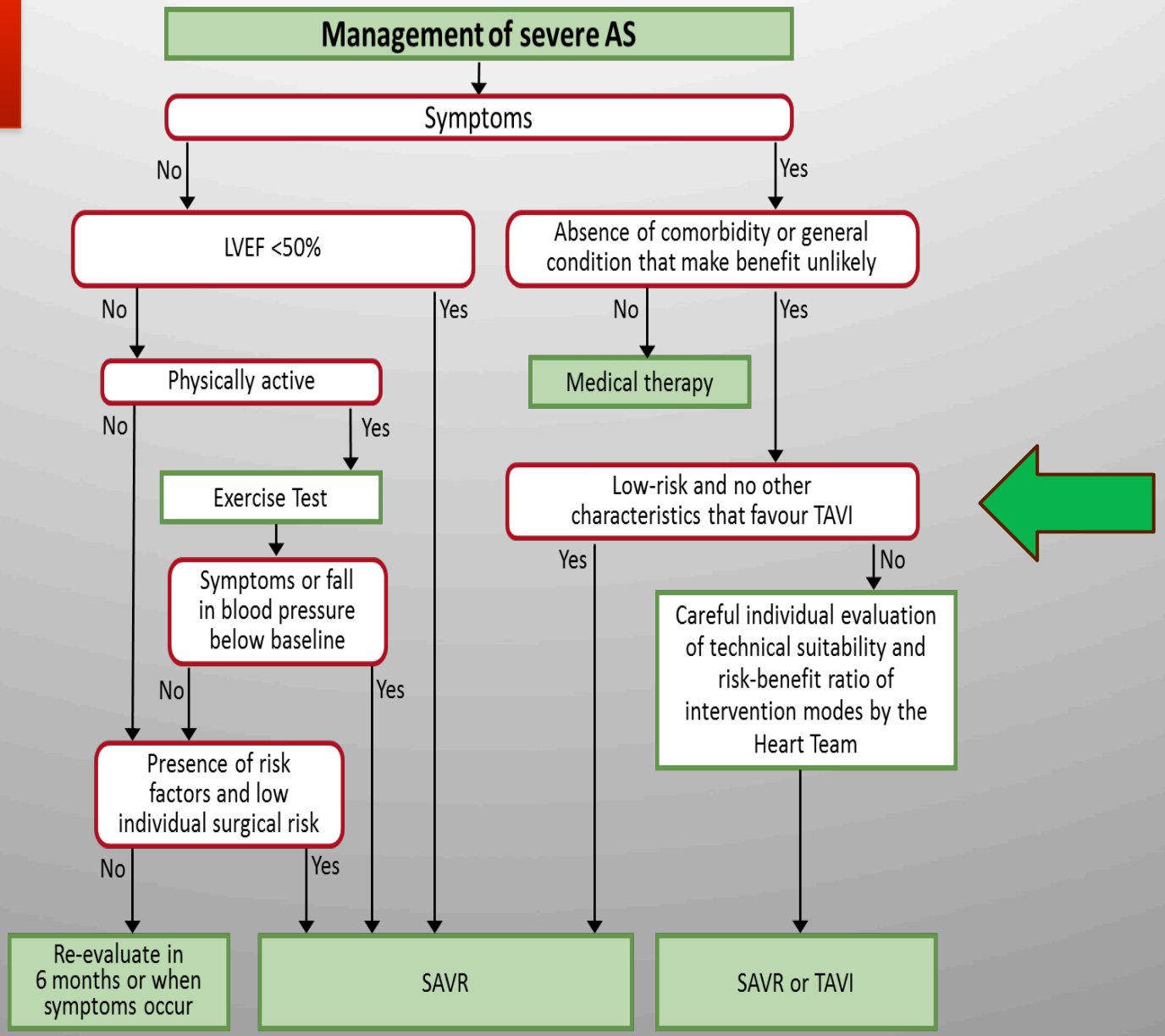
Biologic or Mechanical Aortic Valve Prostheses?





J Woo et al. ***N Engl J Med 2017;377:1847-57.***

ESC/EACTS Guidelines 2017



www.escardio.org/guidelines

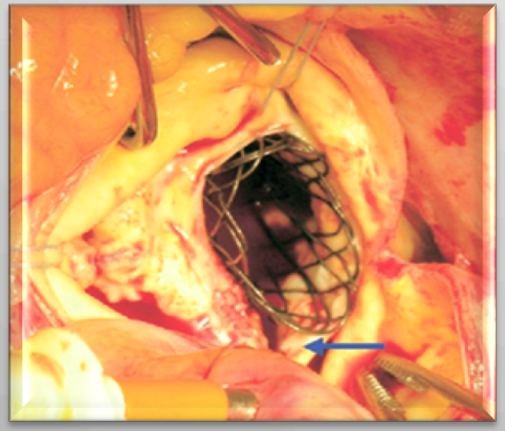
2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease
(European Heart Journal 2017 - doi:10.1093/eurheartj/ehx391)

Pro TAVI

Age > 75 y ; STS score >4%
Previous cardiac surgery
Frailty / Restricted mobility
Porcelaine aorta (or heavy calcifications)
Functioning grafts at risk with sternotomy
Chest deformities / scoliosis
Expected pt/prosthesis mismatch
Sequelae of chest radiations

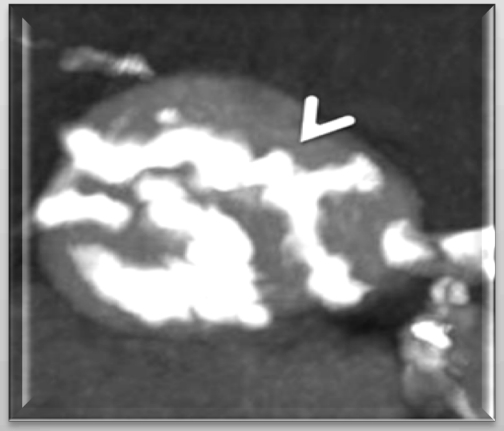
Challenges for TAVI

Elliptical Annulus



Impaired valve positioning and sealing
Ex: Bicuspid Valve

Asymmetrical and Heavy Calcification of Leaflets



Inadequate valve expansion and impaired valve hemodynamics

Associated Aortopathy

Increased risk of aortic complications
In younger patients persistent risk of evolution of aortic dilatation

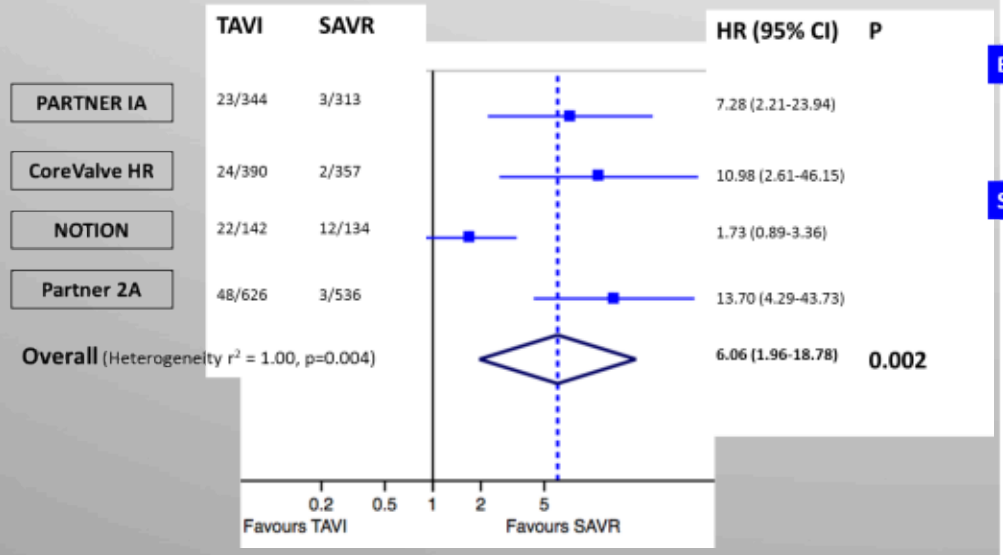
TAVI : Open Questions

- Permanent pacemaker & paravalvular leak rates
- Durability & leaflet thickening
- Brain damage

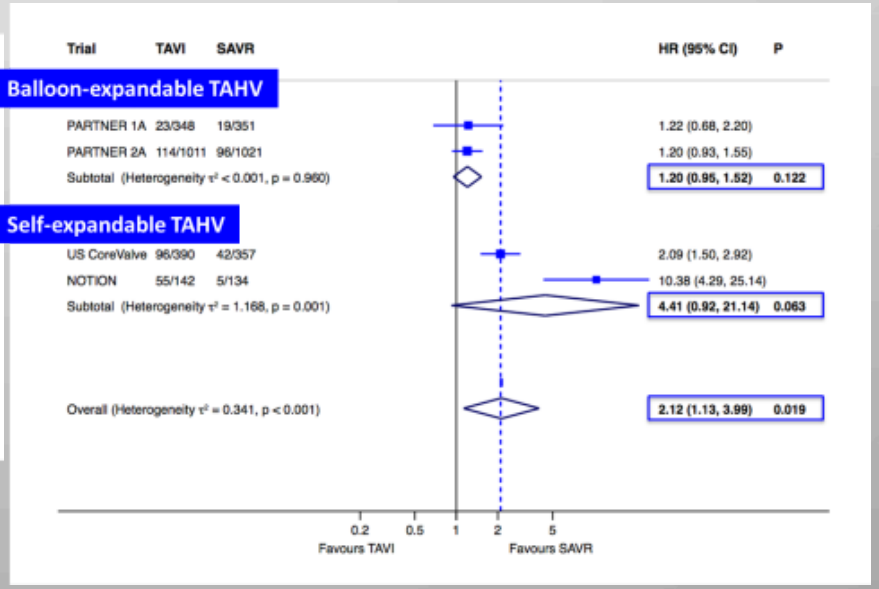
TAVI VS. SAVR: PARAVALVULAR REGURGITATION AND PPM

Siontis et al *Eur Heart J.* 2016 Dec 14;37(47):3503-3512

Paravalvular regurgitation



Permanent pacemaker implantation



5-Years Durability in Registries

5-Year Outcome After Transcatheter Aortic Valve Implantation

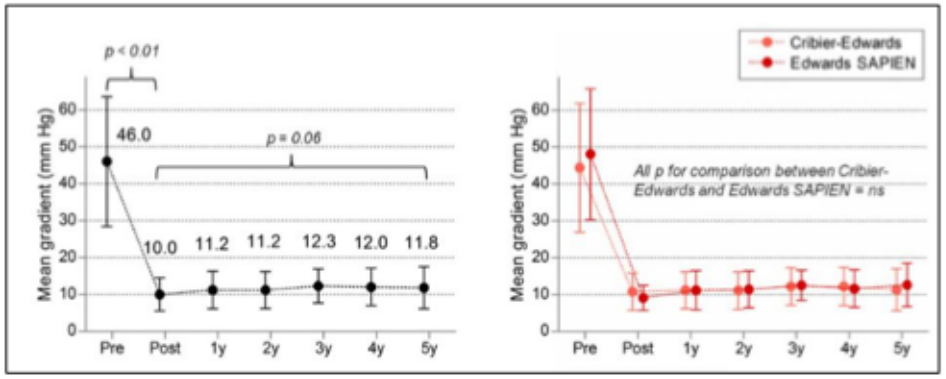
Stefan Toggweiler, MD, Karin H. Humphries, DSc, May Lee, MSc, Ronald K. Binder, MD, Robert R. Moss, MD, Melanie Freeman, MBBS, Jian Ye, MD, Anson Ch[illegible], David A. Wood, MD, John G. Webb, MD

Vancouver, British Columbia, Canada

Vancouver

JACC 2013;61:413-9

88 Pts
2005-2007



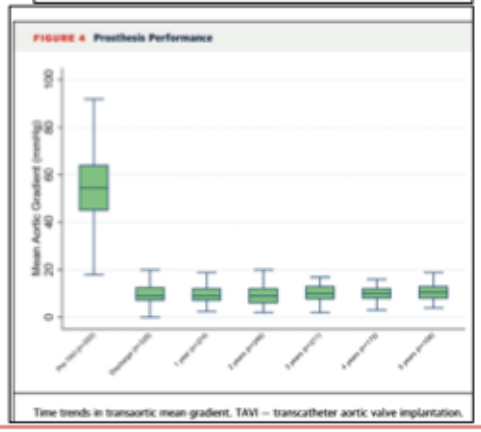
3 patients (3,4% of the total cohort) showed signs of SVD

5-Year Outcomes After Transcatheter Aortic Valve Implantation With CoreValve Prosthesis

The Italian registry

JACC Intv 2015;8:1084-91

353 Pts
2007-2009



5 definite SVD cases (1.4%) requiring Redo-TAVI in 2
+ 10 (2.8%) with mild stenosis (20-40 mm Hg)

Centre for
Heart Valve Innovation
St. Paul's Hospital, Vancouver

2016 euroPCR

First look at long-term durability of transcatheter heart valves:

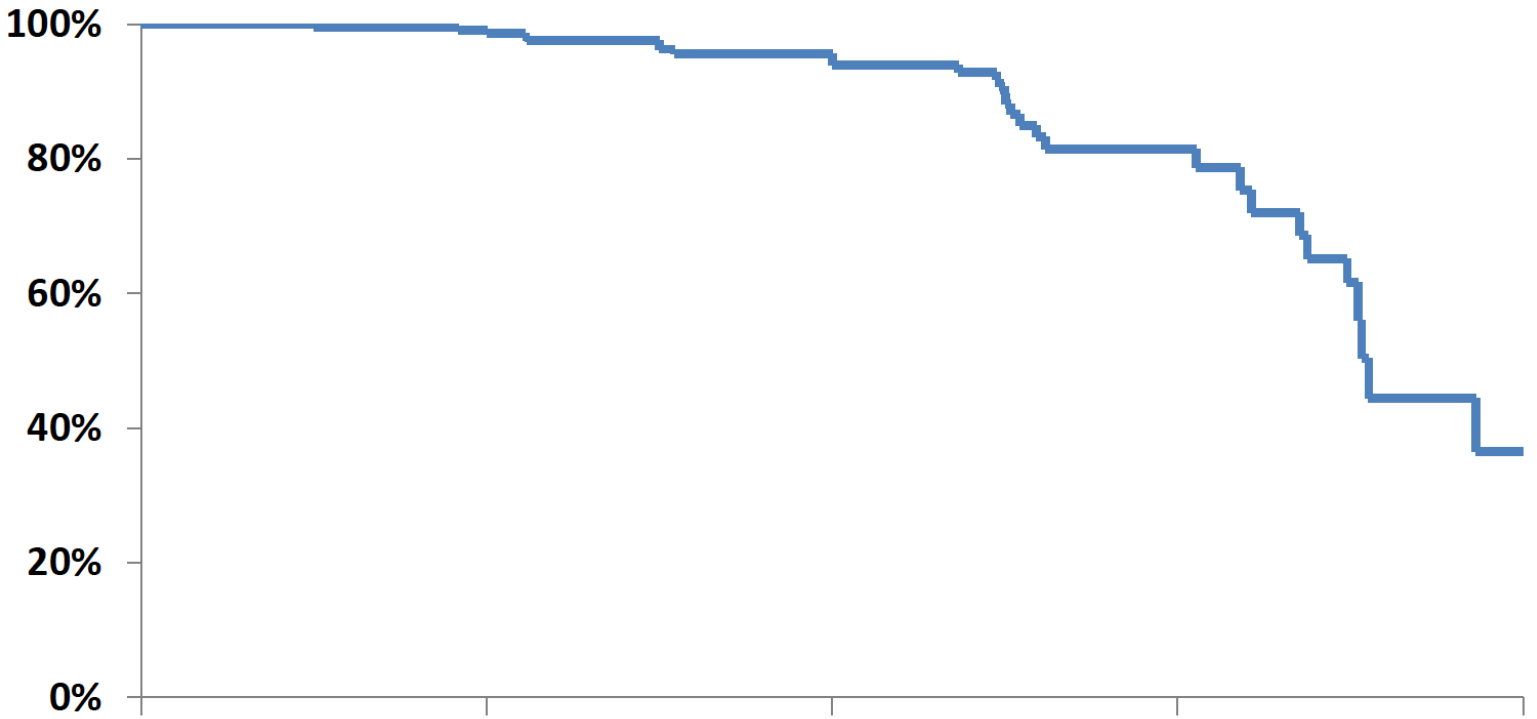
Assessment of valve function up to 10-years after implantation

Danny Dvir, St. Paul's Hospital, Vancouver, Canada.

On behalf of coauthors: Helene Eltchaninoff, Jian Ye, Arohumam Kan, Eric Durand, Anna Bizios, Anson Cheung, Mina Aziz, Matheus Simonato, Christophe Tron, Yaron Arbel, Robert Moss, Jonathon Leipsic, Hadas Ofek, Gidon Perlman, Marco Barbanti, Michael A. Seidman, Philippe Blanke, Robert Yao, Robert Boone, Sandra Lauck, Sam Lichtenstein, David Wood, Alain Cribier, John Webb

EAPCI · EUROPEAN SOCIETY OF CARDIOLOGY® · EACTS

Freedom from THV degeneration



# at risk	378	199	116	43	7

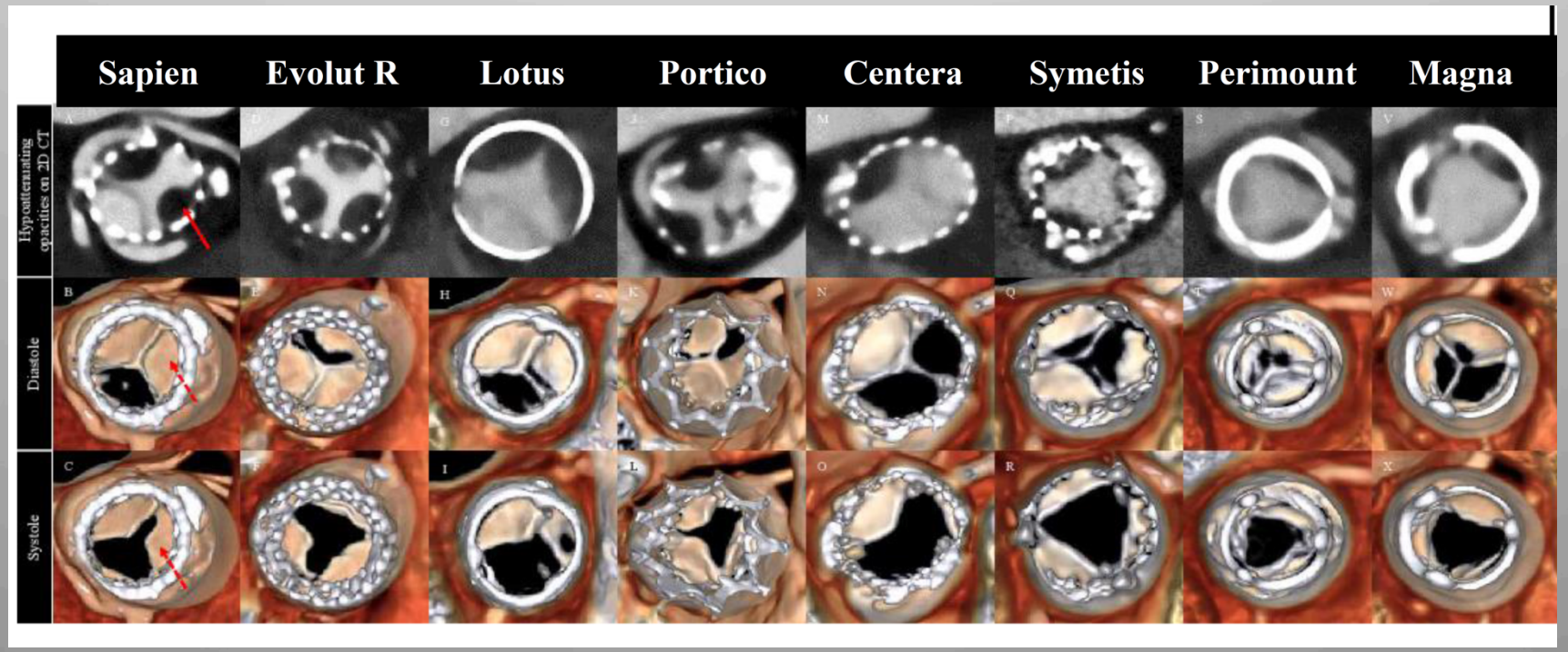
THV degeneration was defined as at least moderate regurgitation AND/OR mean gradient ≥ 20mmHg, which did not appear within 30 days of the procedure and is not related to endocarditis.

KM estimate of THV degeneration included censoring of patients at their date of last known THV functioning well without evidence for degeneration per study definition.

Subclinical Leaflet Thrombosis in Bioprosthetic Valves

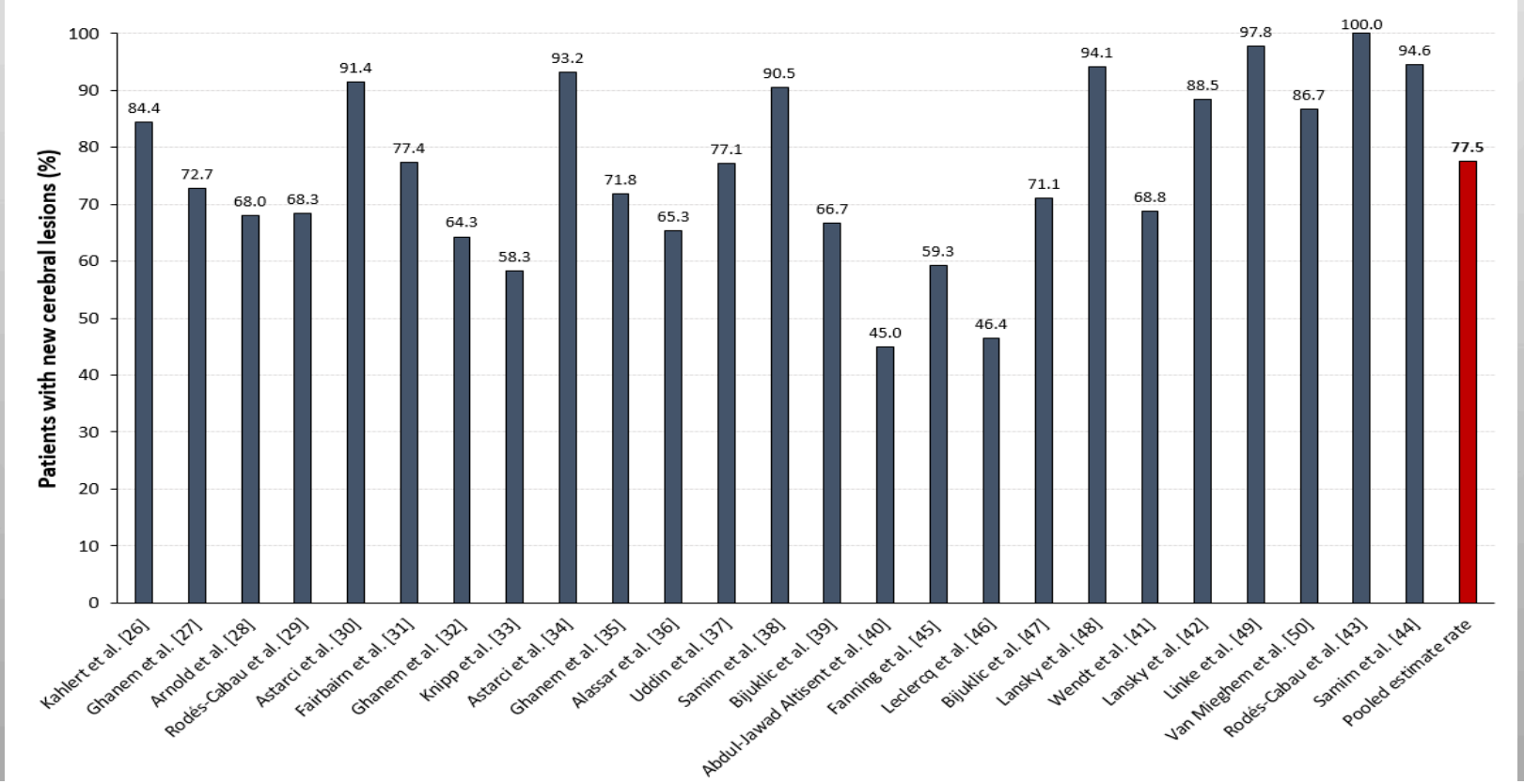
Chakravarty et al. Lancet 2017

- *890 patients with interpretable CT scans were included (RESOLVE registry, n=626; SAVOR Registry, n=264)*
- *Incidence: 12%: 4% after SAVR and 13% after TAVI (p<0.001)*



DW-MRI Lesions are frequent after TAVI

Pagnesi……Latib. IJC 2016 (221): 97-106



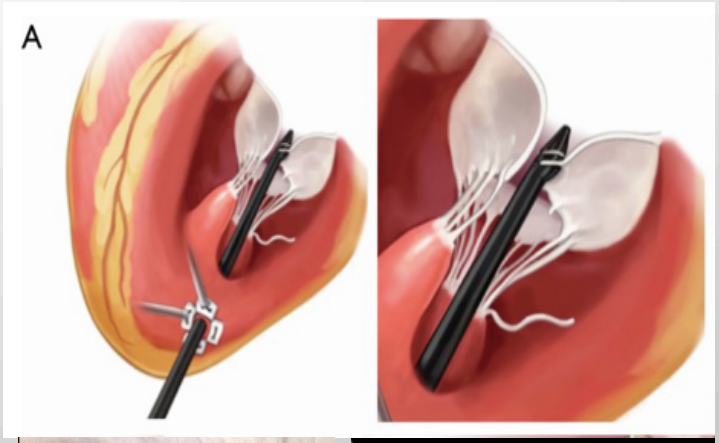
◆Cerebral emboli detected on DW MRI increase the risk of clinically overt stroke by 2-4 times and lead to cognitive dysfunction, depression, impaired mobility, dementia, and increased mortality.[1-2]

◆The greater the volume of DWI lesions seen on MRI the greater the long-term risk of cognitive dysfunction and long-term dementia.[1-2]

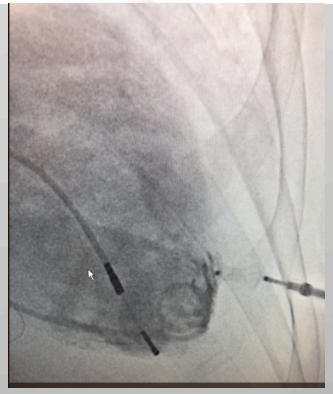
[1]Sacco RL, Stroke. 2013;44:00. [2]Vermeer SE, Lancet Neurol 2007;6:611.

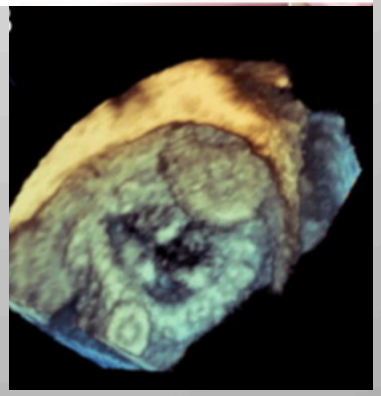
TA approach

1. Artificial chordae

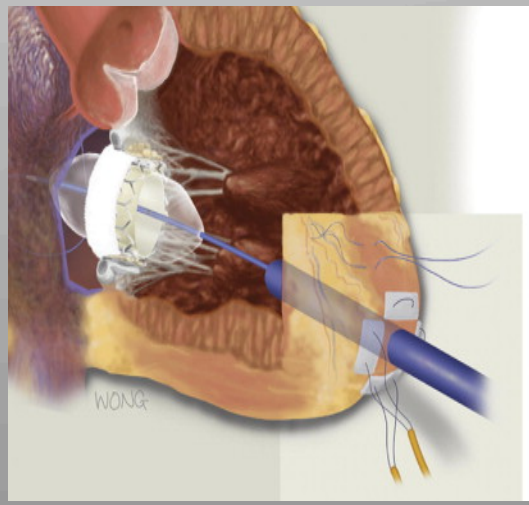


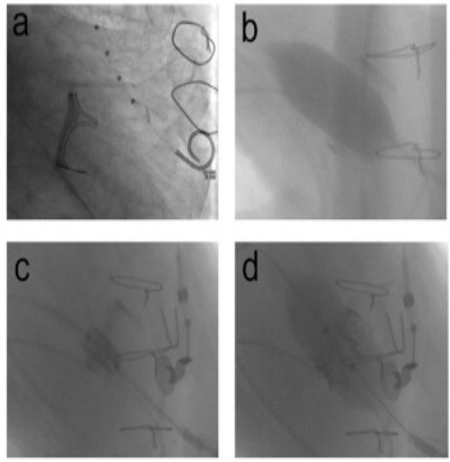
2. Paravalvular leaks





3. TMVR





Take-Home Message

SAVR and TA TAVI play a complementary role in the treatment of severe AS.

SAVR is carried out in low risk pts without other characteristics that favour TAVI.

TA TAVI is a good option for candidates to TAVI who cannot be treated with a TF approach

The decision between SAVR and TA TAVI has to be taken by heart team on the basis of scientific evidences and guidelines

The TA approach has other applications in the treatment of HVD and should be nowadays in the surgical armamentarium