Tissue Valve for All Aortic Stenosis Patients: Safe and Well-proven option

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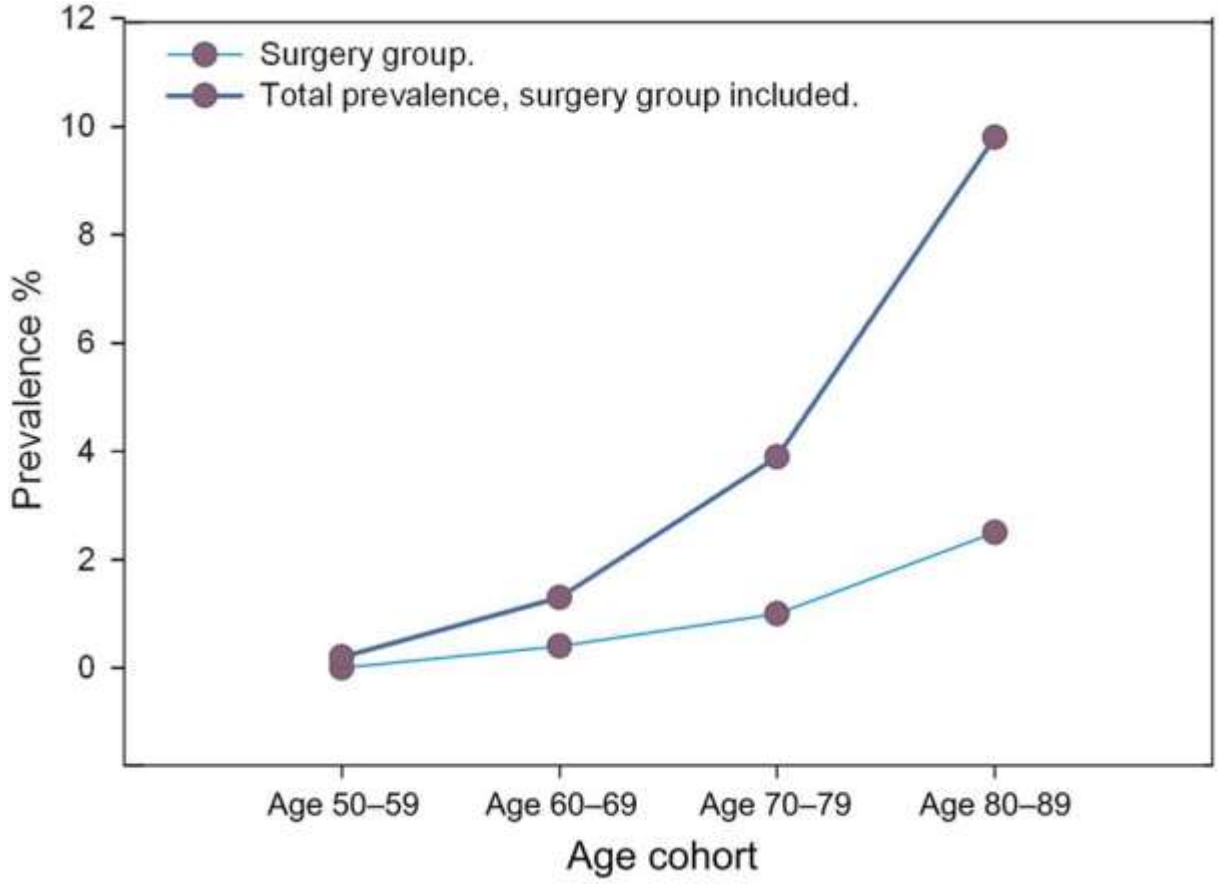
BACKGROUND

- 300,000 to 400,000 surgical valve replacements are performed annually world wide
- The majority is for aortic valve disease
- Severe symptomatic AS (age ≥ 75) is projected to more than double by 2050 in both the USA and Europe[1]



Coffey S, *et al. Heart* 2016;**102**:75–85. doi:10.1136/heartjnl-2014-307020

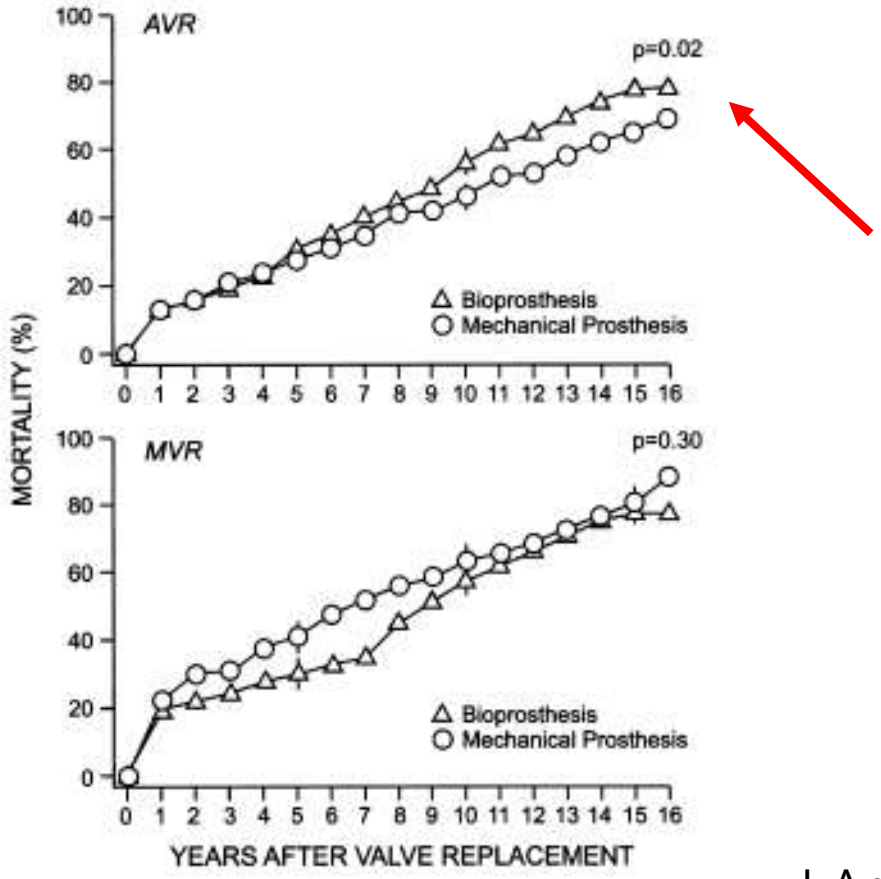
Published Guideline Recommendations

- No clear benefit between tissue and mechanical valves in patients between 50 to 70 years …. AHA ACC guidelines
- Between the ages 60 to 65 years … European guidelines
- These may be referred as the gray zone ages ”

Outcomes 15 Years After Valve Replacement With a Mechanical versus a Bioprosthetic valve:

Veterans Affairs Randomized Trial

Hammermeister K, Sethi Gk et al.



J Am Coll Cardiol 2000;36:1152-8

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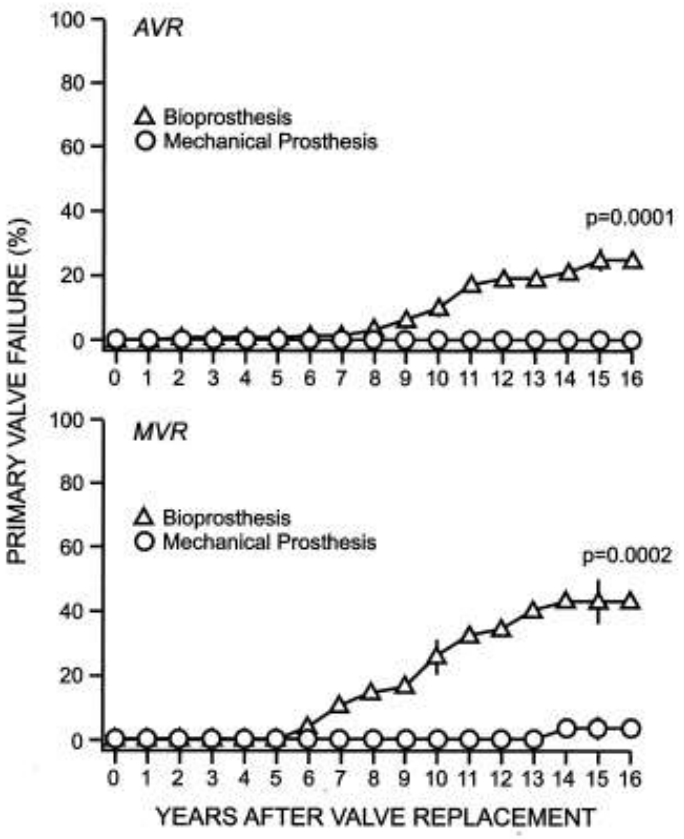

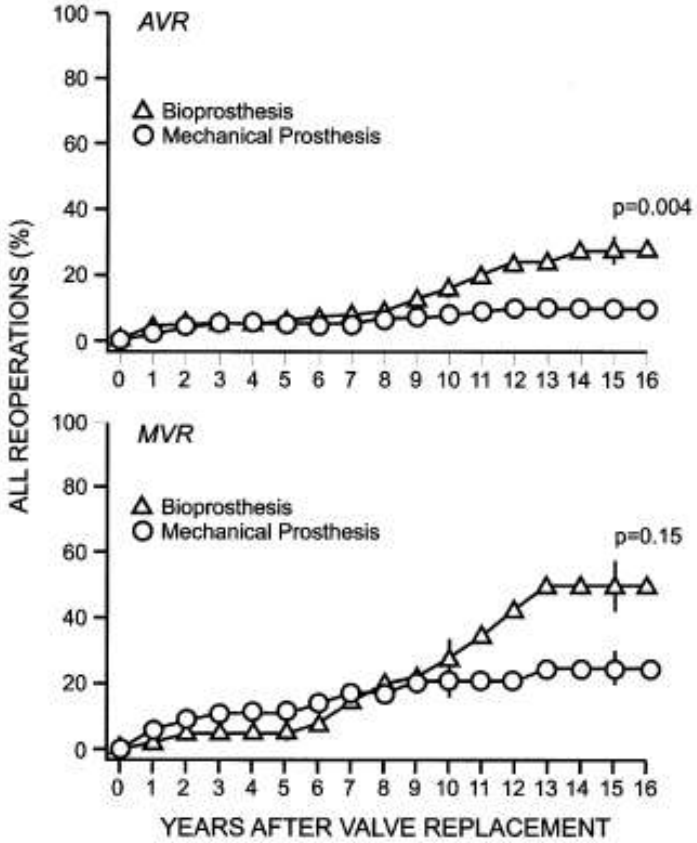

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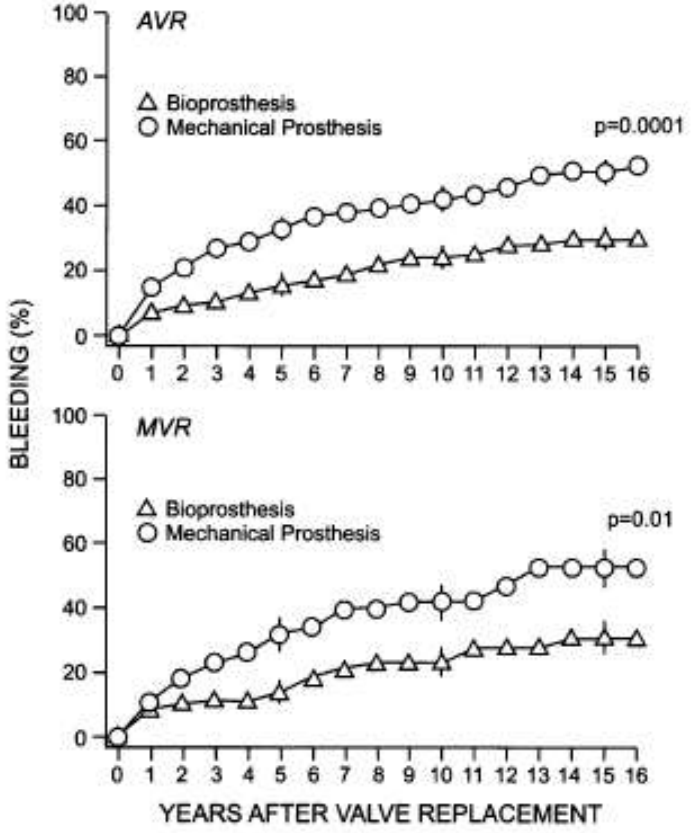
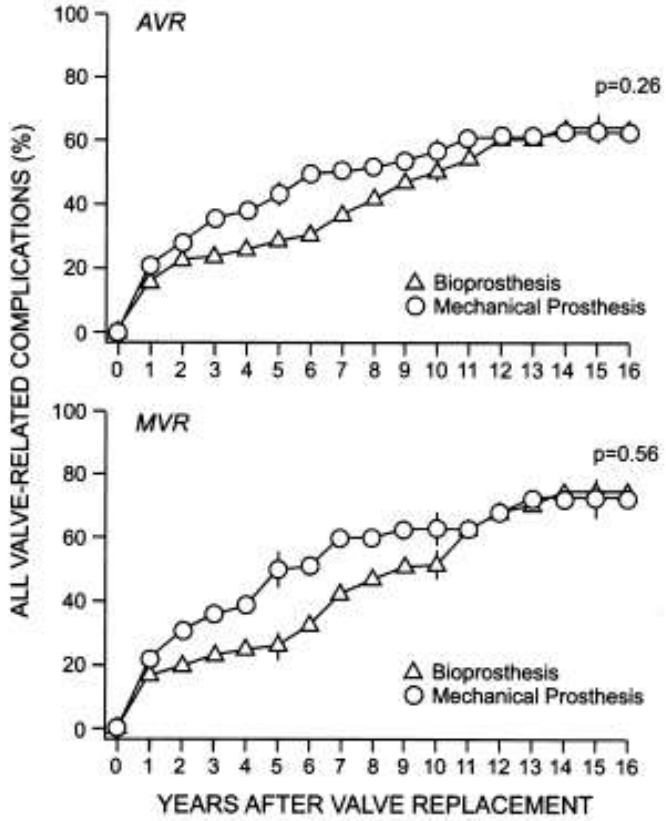
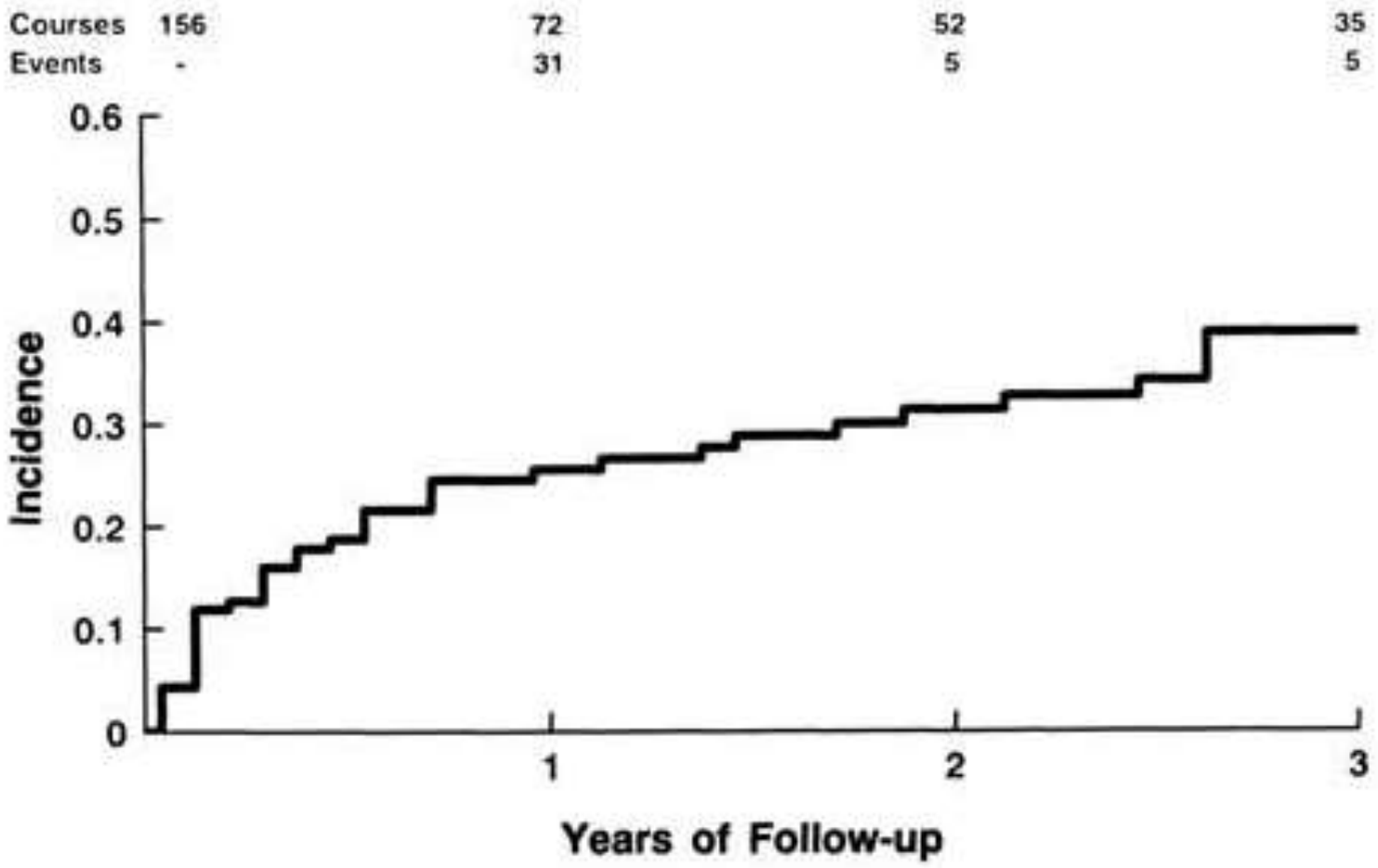




J Am Coll Cardiol 2000;36:1152-8

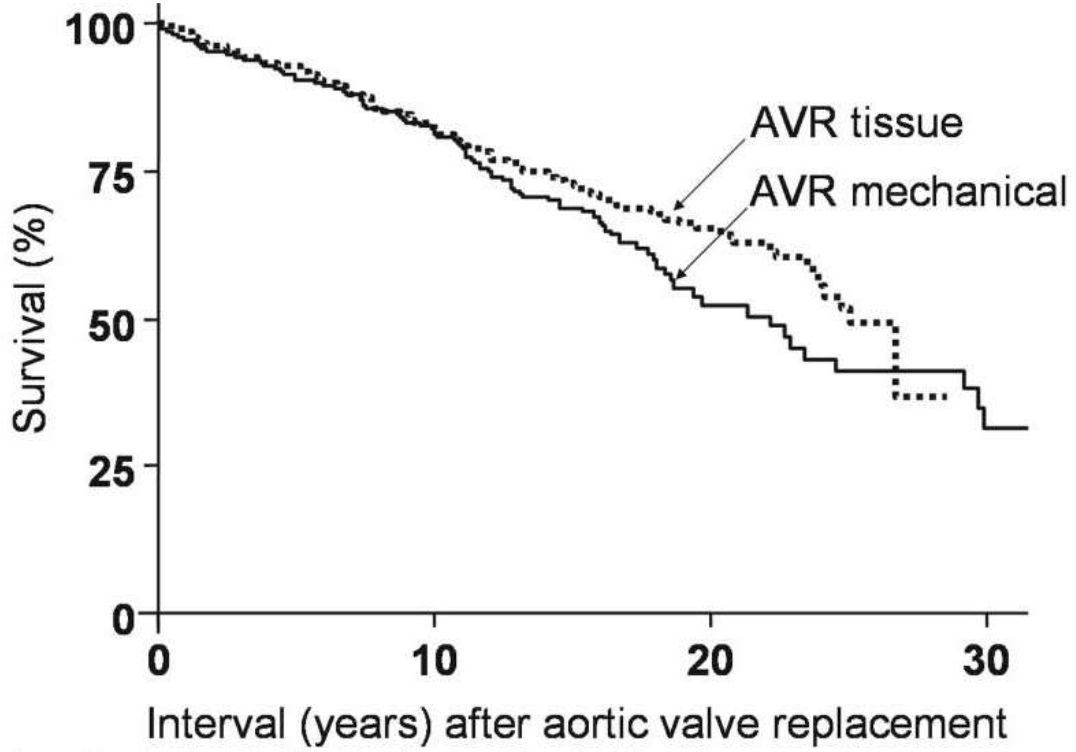
Warfarin Associated Bleeding Risk



Ann Int Med 1993;118:1152-8

Very Long-Term Survival differences between Tissue and Mechanical Heart Valves (<60)

No survival difference between patients implanted with a tissue versus mechanical aortic **valve** prosthesis implantation



Ruel M Circulation 2007;116 [suppl i]:I294-300

Very Long-Term Survival differences between Tissue and Mechanical Heart Valves (<60)

	HR	95% CI	P
Age at operation (per increasing year)	1.03	1.01, 1.04	0.008
Coronary artery disease	1.9	1.4, 2.6	0.002
Atrial fibrillation	1.5	1.01, 2.3	0.04
Year of surgery (per increasing year)	0.95	0.93, 0.97	<0.001
Nonsignificant covariates			
Female gender	0.8	0.6, 1.1	0.2
Preoperative NYHA class (per increasing class)	1.2	0.98, 1.3	0.1
LV dysfunction*	1.3	0.9, 1.7	0.1
Tissue prosthesis (vs mechanical)	0.95	0.7, 1.3	0.7
Contemporary† tissue prosthesis (vs contemporary mechanical)	1.2	0.7, 2.0	0.5

Ruel M Circulation 2007;116 [suppl i]:I294-300

Mechanical or Biologic Prostheses for Aortic-Valve and Mitral-Valve Replacement

Goldstone AB, Chiu P, Baiocchi M et al.

- AVR or MVR data from 142 nonfederal California hospitals
- Duration: Between Jan 1, 1996, and Dec 31,2013
- Evaluation to see the effect of prosthesis type

- Primary end points

  mortality, incidence of stroke, bleeding, and reoperation.

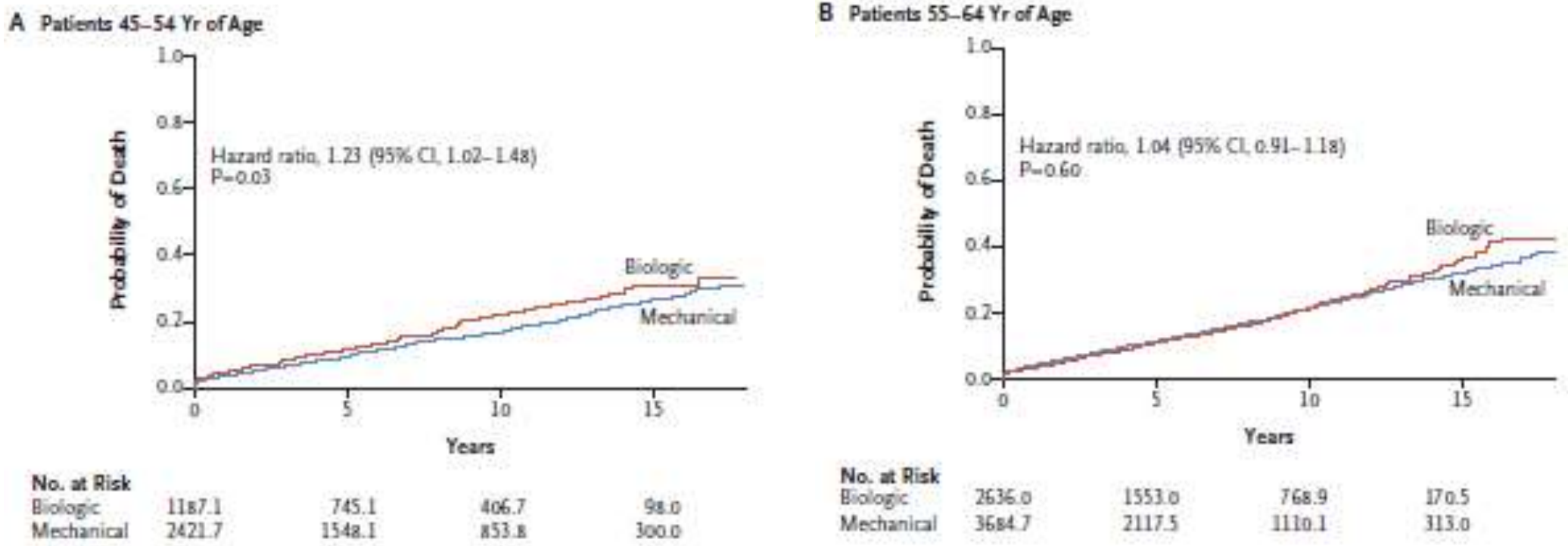
N Engl J Med 2017;377:1847-57

Mechanical or Biologic Prostheses for Aortic-Valve and Mitral-Valve Replacement

Goldstone AB, Chiu P, Baiocchi M et al.

Mortality after AVR with Biological or Mechanical prosthesis

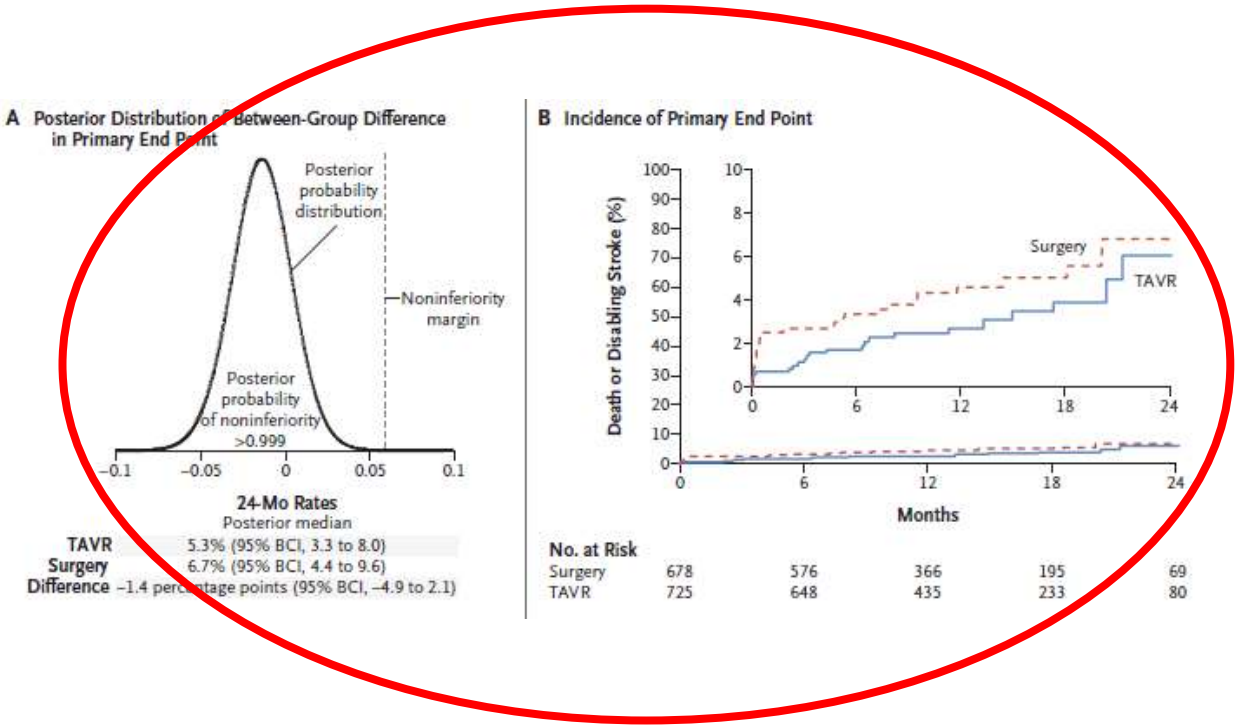
- Age bracket dependent differences-



N Engl J Med 2017;377:1847-57

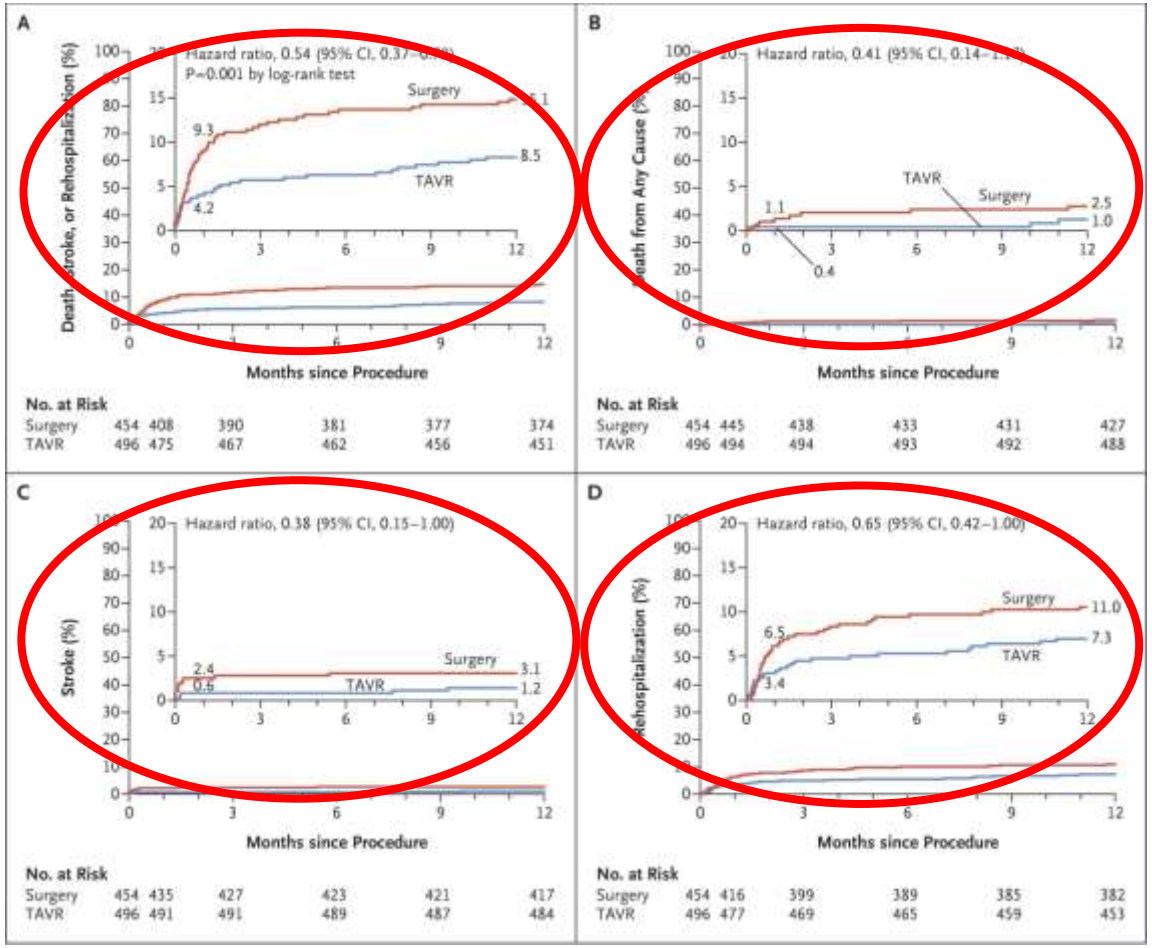
TAVR vs Surgery in Low Risk Patients

J.F Popma, M.G. Deeb, et al.



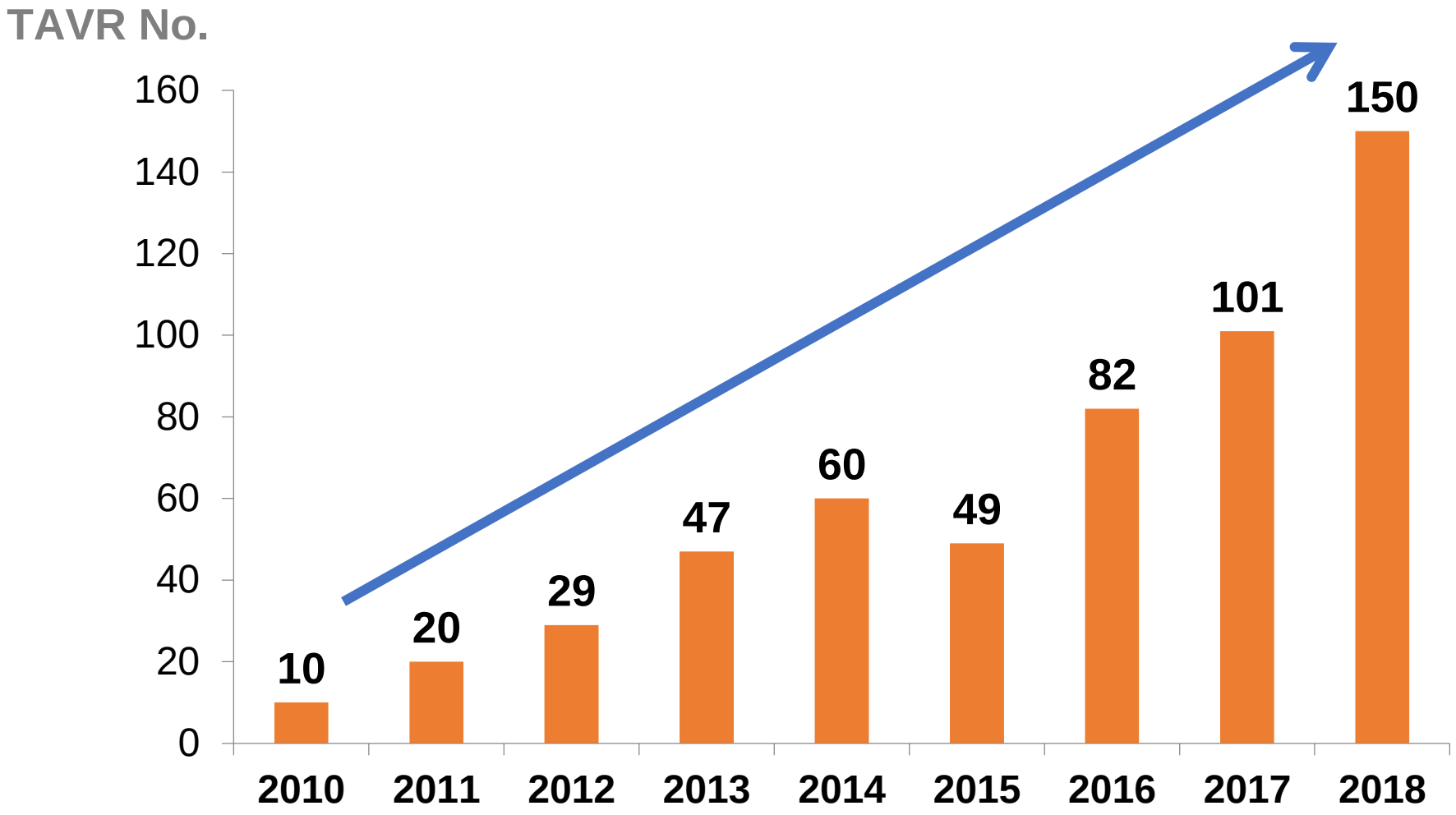
N Engl J Med 2019;380:1706-15

M.J Mack, M.B. Leon, et al.

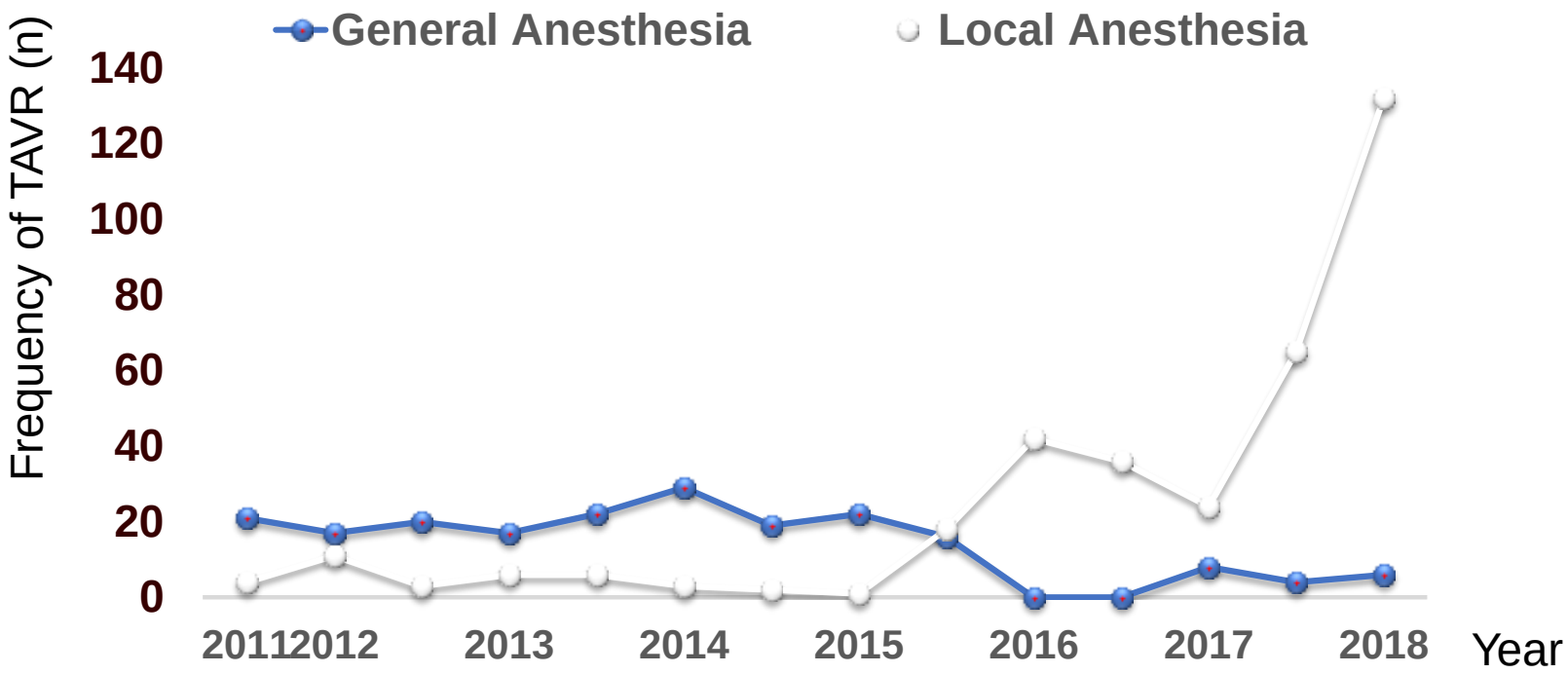


N Engl J Med 2019;380:1695-705

TAVR in Asan Medical Center



"Minimalist Approach"
TAVR in AMC

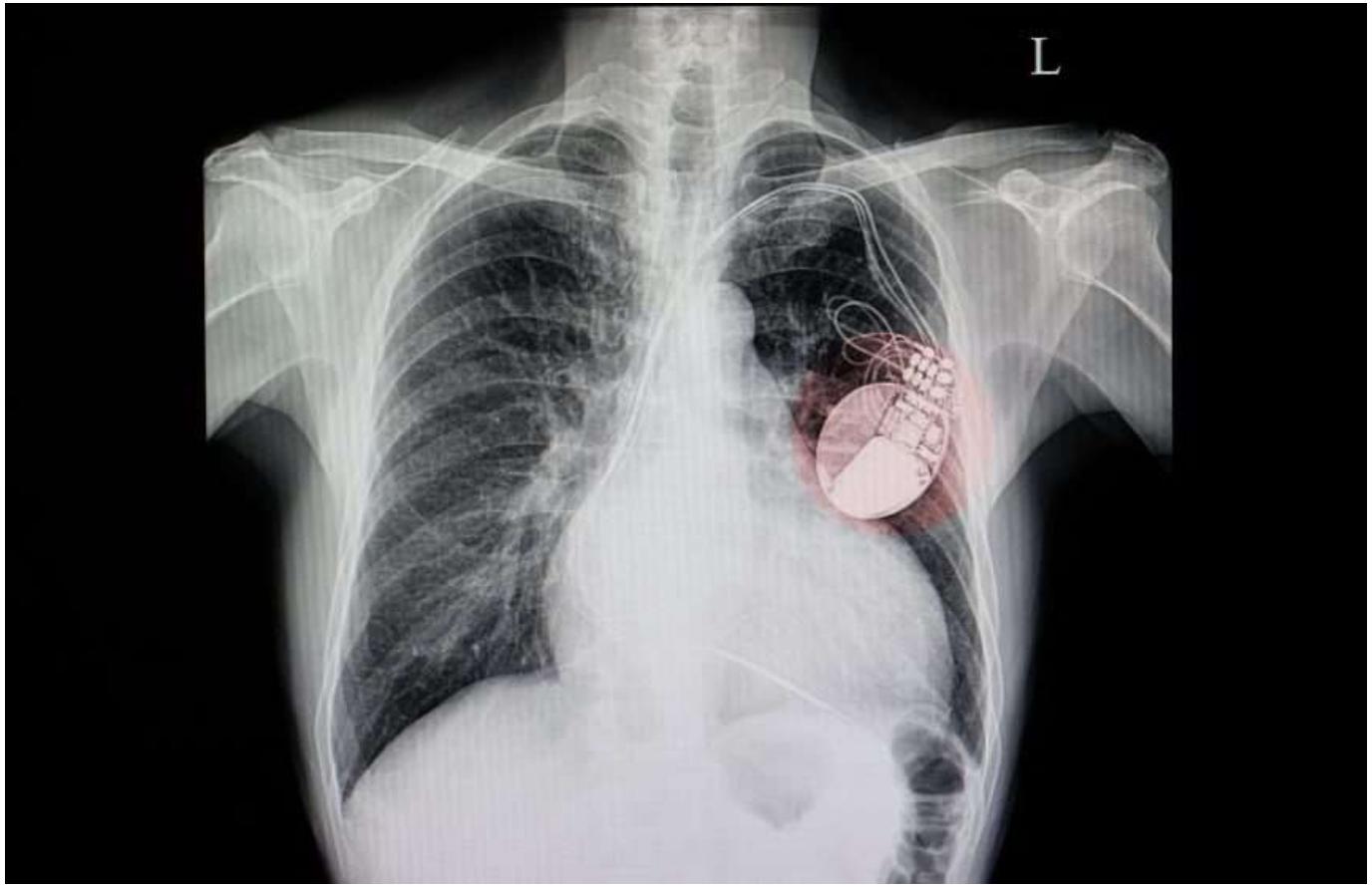


Outcomes of TAVR

Standard Performance (VARC-2) for High-Risk AS patients (@ 30 days)*		*Asian 2017*	***AMC 2018***	***AMC "MAC"***
All-cause mortality	< 3%	2.5%	2.2%	1.3%
Major (disabling) strokes	< 2%	2.2%	0.7%	0.9%
Major vascular complications	< 5%	5.0%	3.6%	3.1%
New permanent pacemakers	< 10%	9.5%	8.7%	8.2%
Mod-severe PVR	< 5%	9.8%	2.9%	4.4%

VARC Vascular Academic Research Consortium*

PPM after TAVR Increases Mortality and Readmission Risks



JAMA Network | Open.

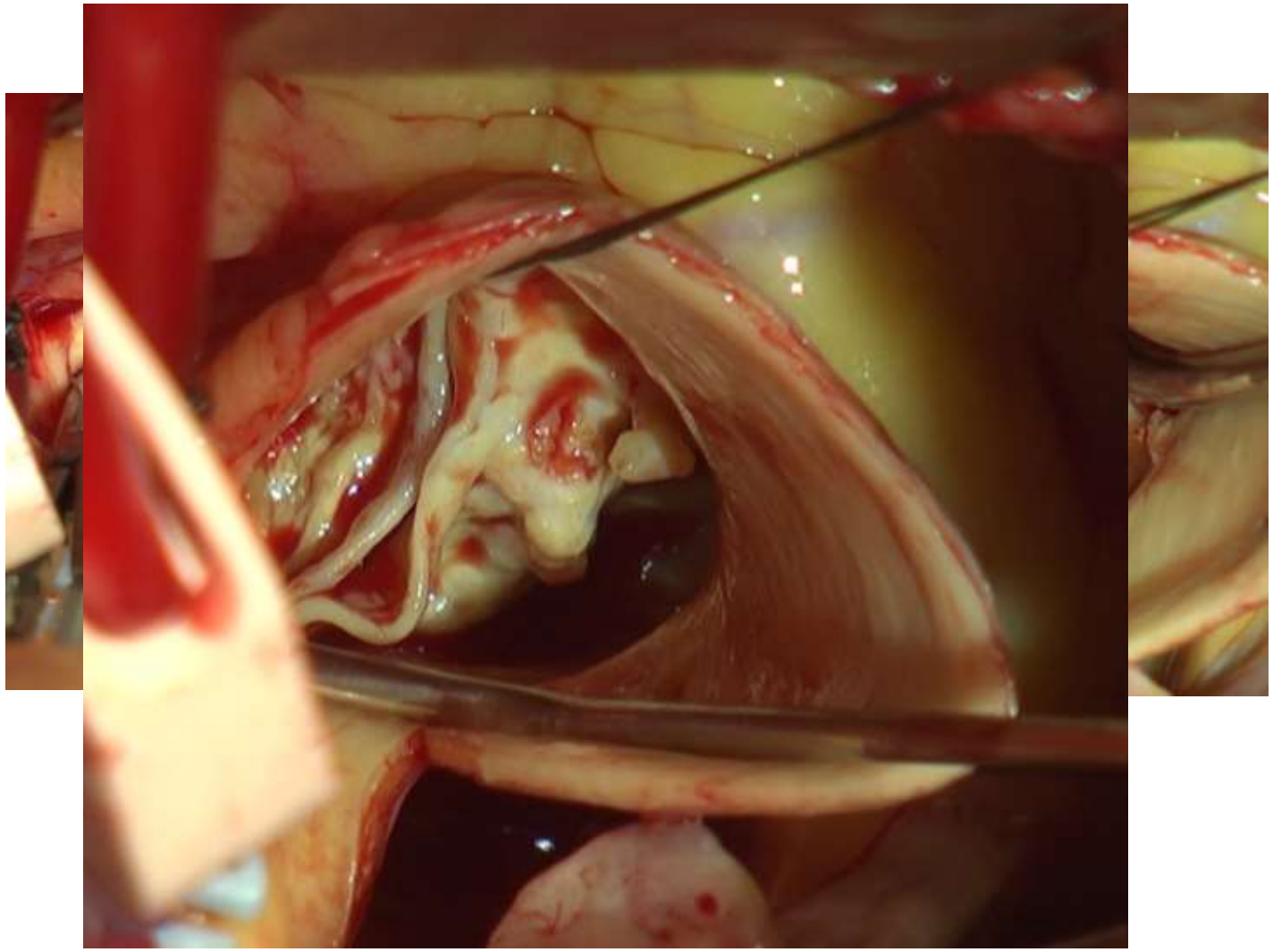
Original Investigation | Cardiology

Association of Clinical and Economic Outcomes With Permanent Pacemaker Implantation After Transcatheter Aortic Valve Replacement

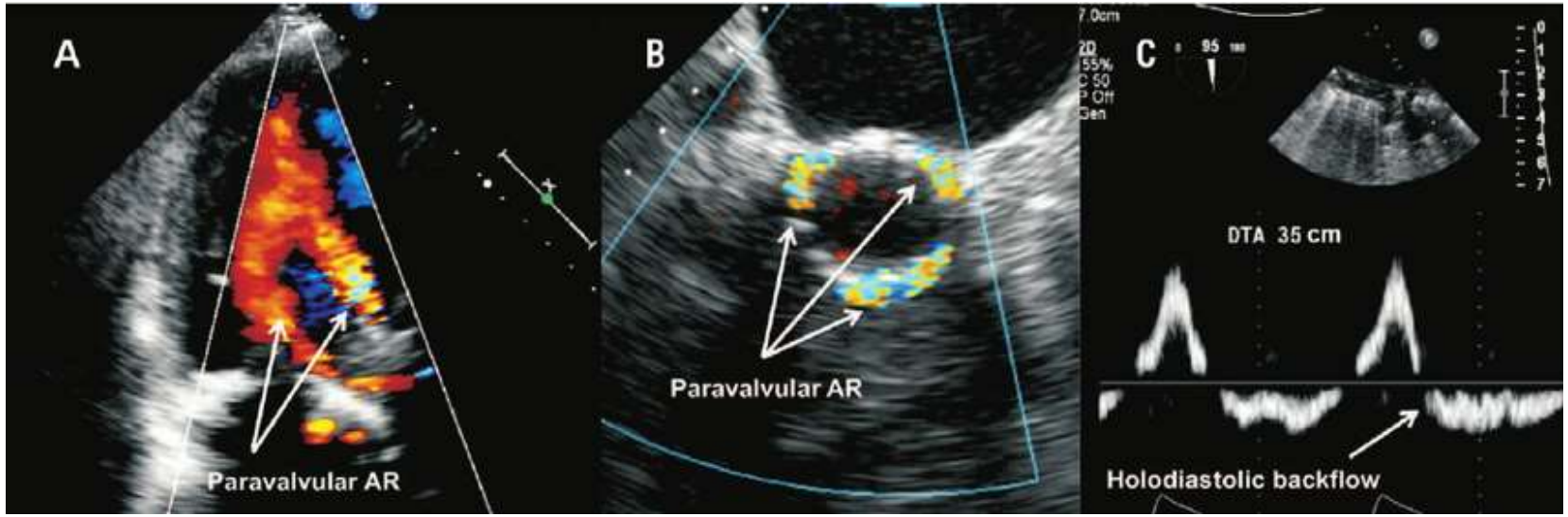
Talal Aljabbary, MD, MSc; Feng Qiu, MSc; Shannon Masih, MSc, MPH; Jiming Fang, PhD; Gabby Elbaz-Greener, MD, MHA; Peter C. Austin, PhD; Josep Rodés-Cabau, MD; Dennis T. Ko, MD, MSc; Sheldon Singh, MD; Harindra C. Wijeysundera, MD, PhD

"New permanent pacemaker implantation after Transcatheter aortic valve replacement was associated with significantly greater morbidity and mortality at longterm follow-up."

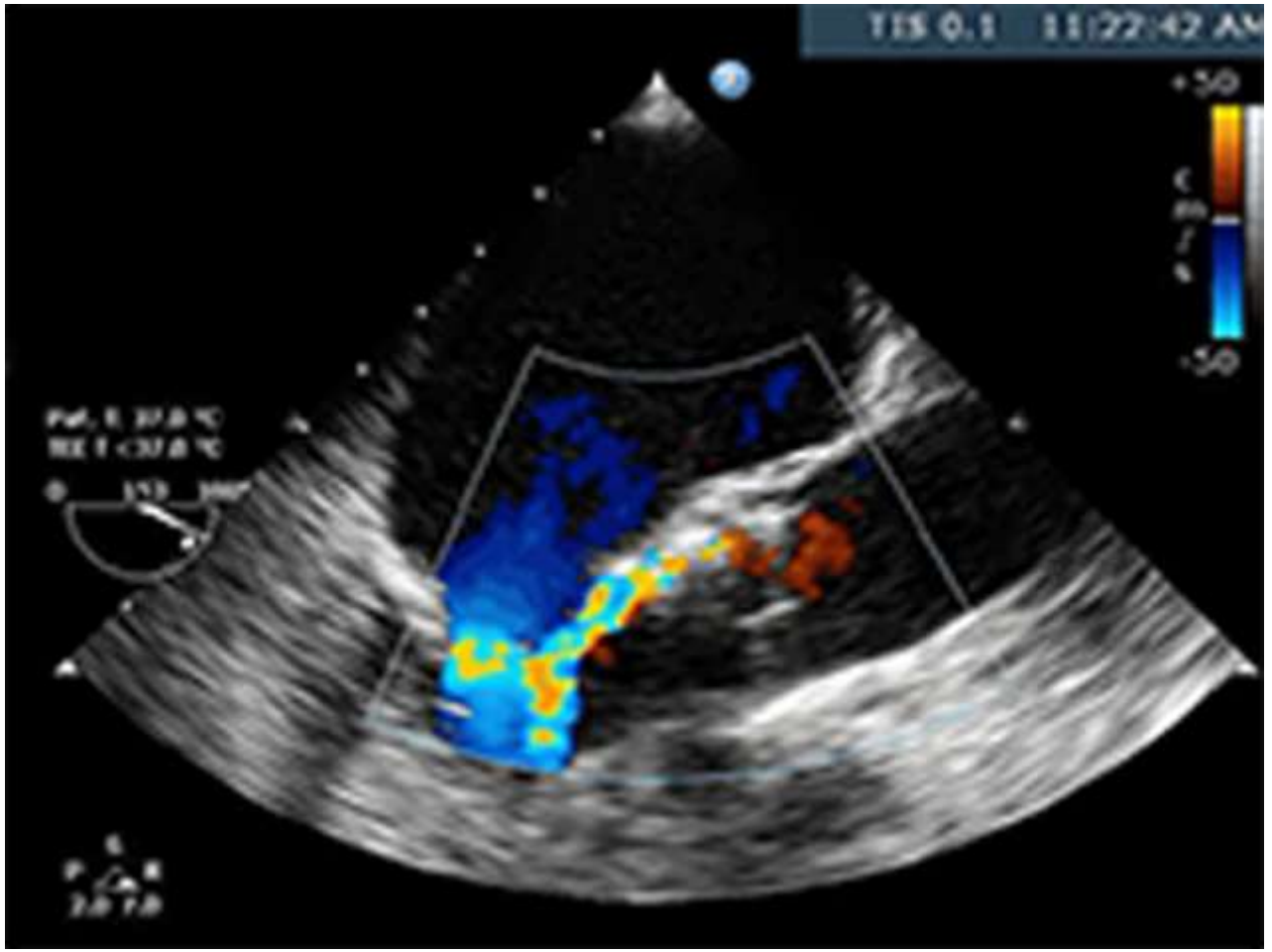
High Calcium Score and Subannular Calcification may cause PVL



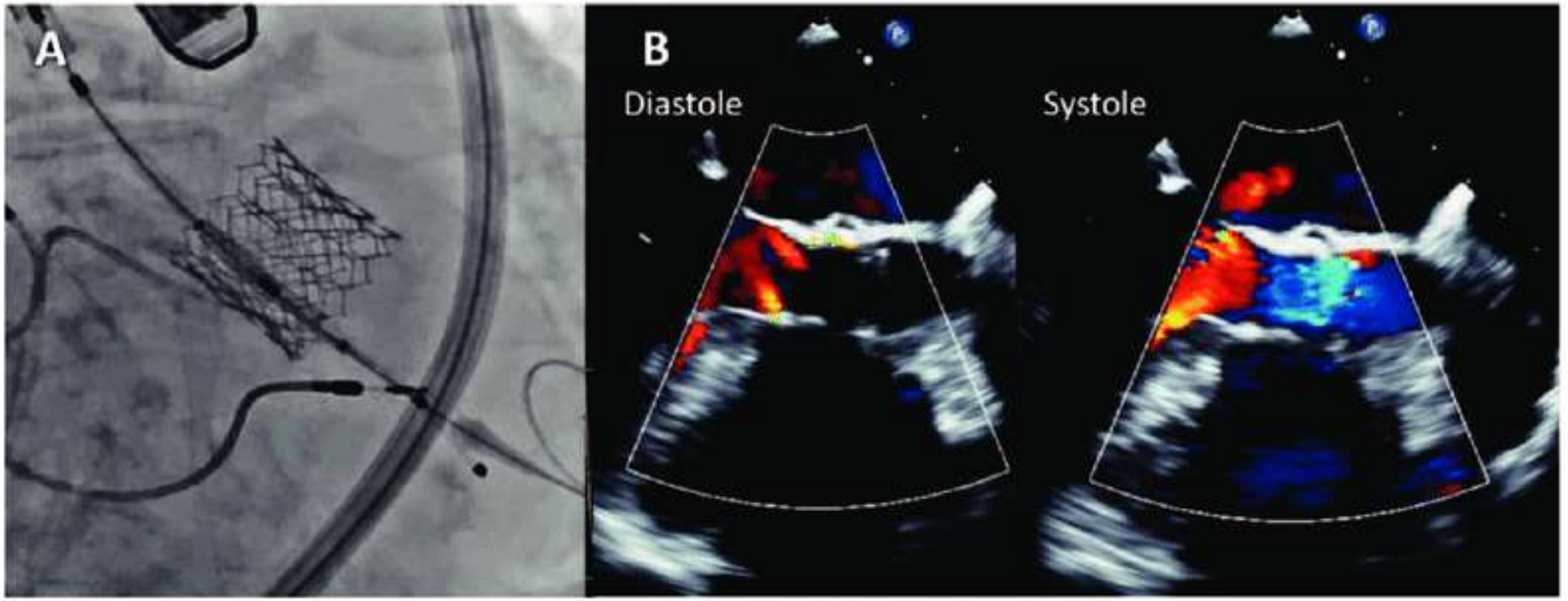
CoreValve 31mm



Paravalvular leak after Sapien 3 TAVR

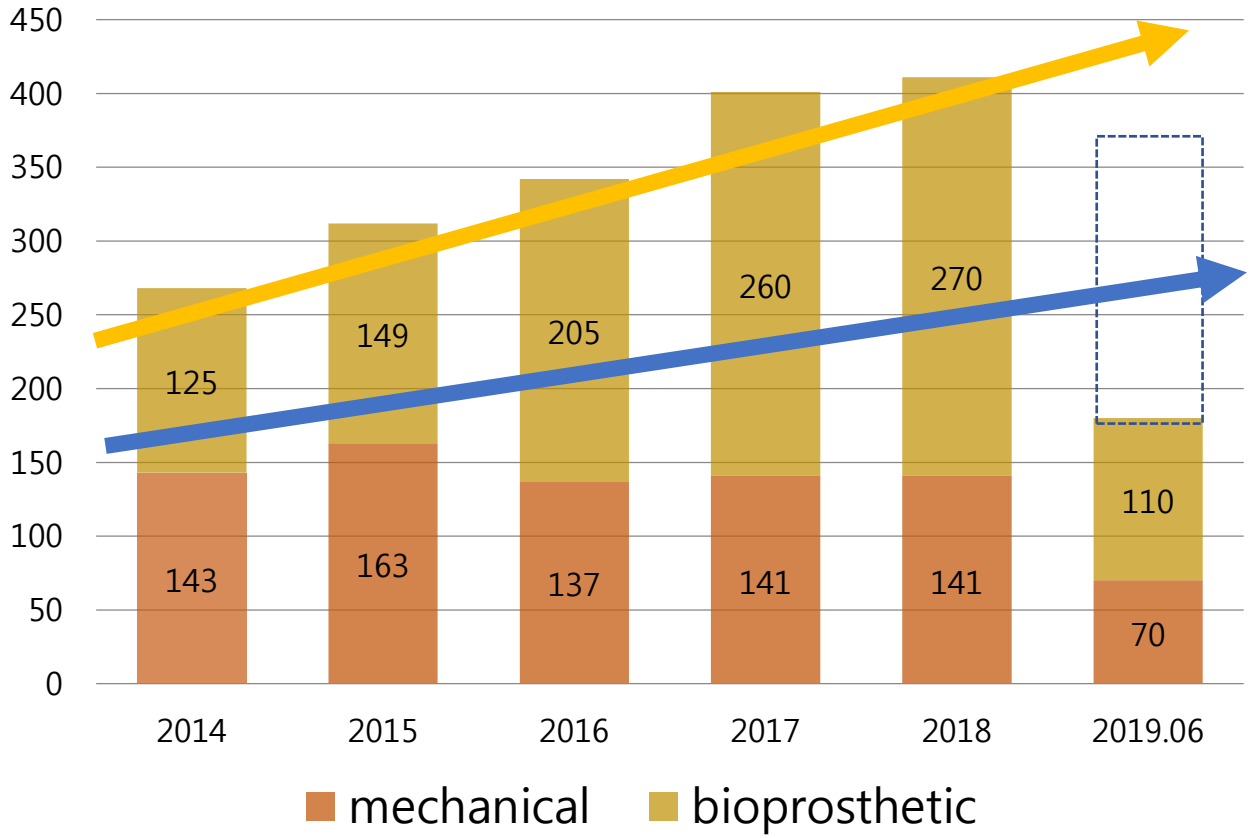


PVL after Sapien valve in valve

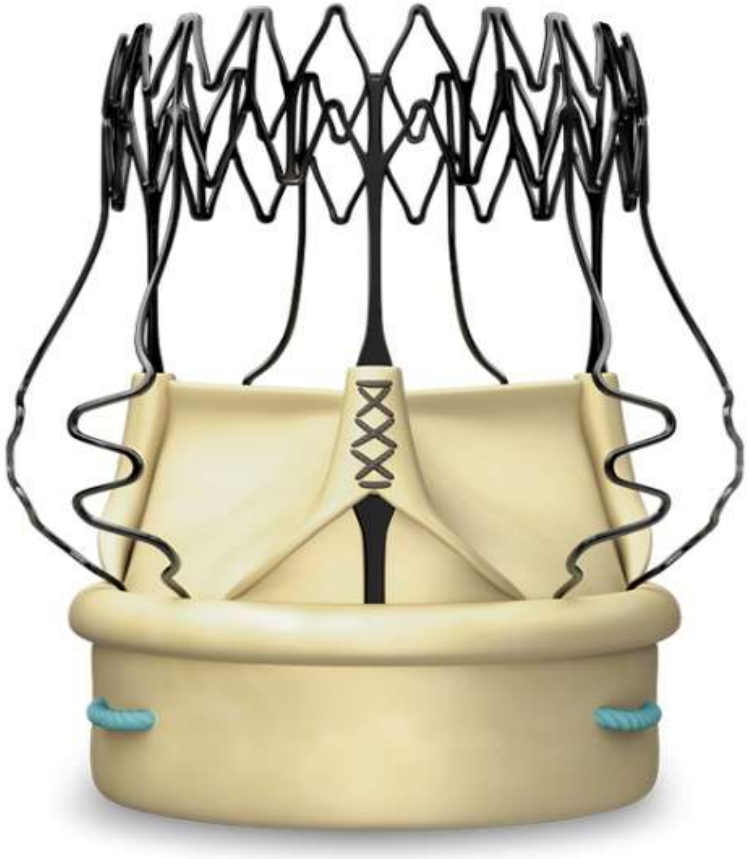


Asan Medical Center Experience

JAN 2014 to JUN 2019, AV Replacement in AMC



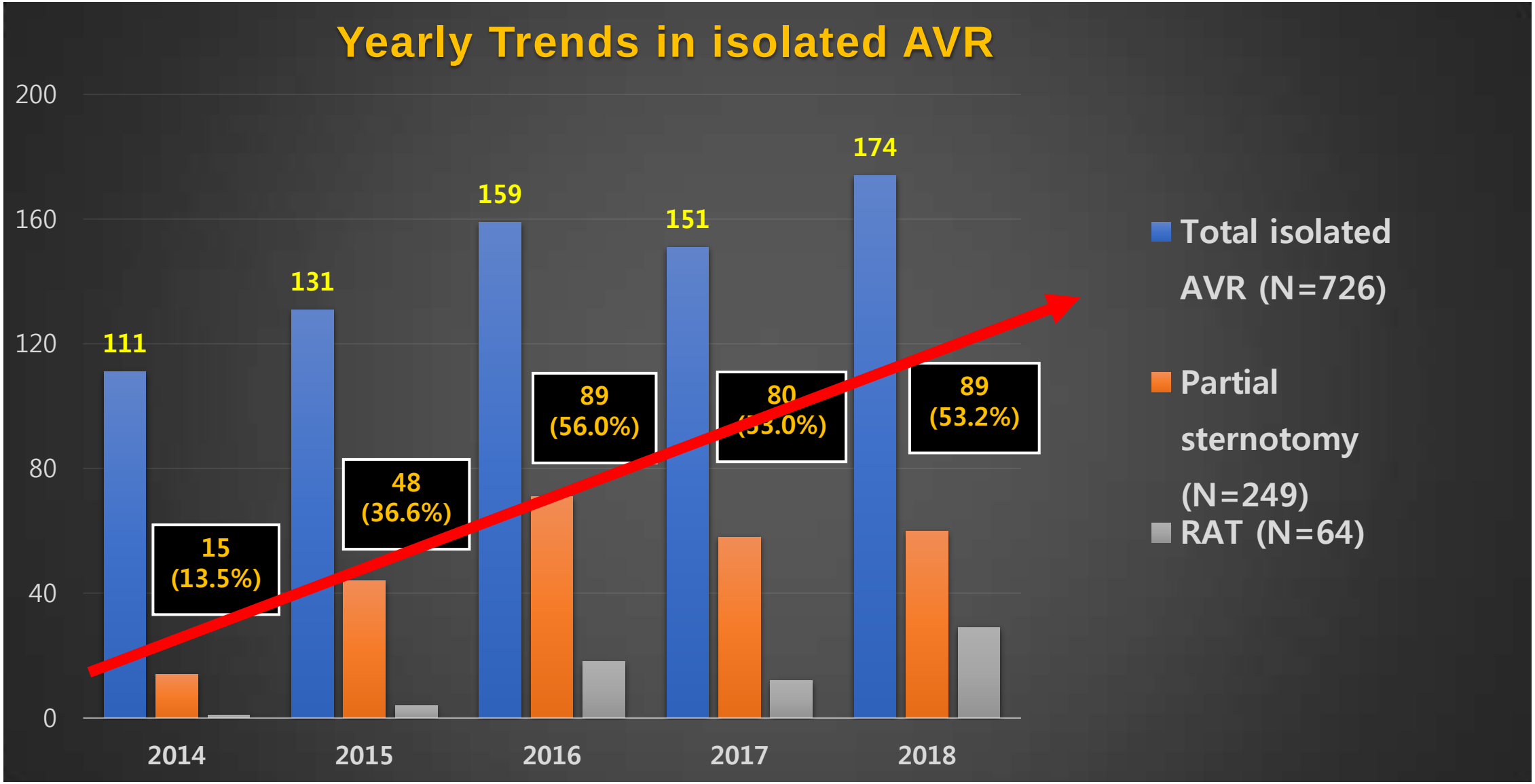
Right anterior thoracotomy AVR



Mini-Thoracotomy Perceival AVR

- Male 75 YO
- ACC time: 59 min
- CPB time: 96 min

- Postop Echo (POD#4)
  LVEF=63%
  Mean PG=10mmHg
  No leak
- Discharge on POD#6
- No pain


Yearly Trends in isolated AVR
200
160
120
80
40
0
111
15
(13.5%)
131
48
(36.6%)
159
89
(56.0%)
151
80
(53.0%)
174
89
(53.2%)
2014
2015
2016
2017
2018
Total isolated AVR (N=726)
Partial sternotomy (N=249)
RAT (N=64)

	Full-sternotomy (N=412)			Partial sternotomy (N=249)			RAT (N=64)		
	No. of patients	CPB (min)	ACC (min)	No. of patients	CPB (min)	ACC (min)	No. of patients	CPB (min)	ACC (min)
Total isolated AVR	412	98.9±31.2	64.9±22.8	249	92.1±42.0	61.4±29.1	64	97.7±32.2	64.1±26.3
Conventional AVR	391	99.6±31.5	65.8±23.0	184	98.4±45.5	66.9±31.0	30	110.6±30.1	79.8±24.8
Intuity	20	84.8±17.8	49.5±11.7	37	74.2±24.7	46.7±15.6	21	94±35.6	53.7±24.1
Perceval	1	65	36	28	74.6±17.0	44.1±10.6	13	73.7±7.7	47.2±9.0
Early Death	4 (0.9%)			0 (0%)			1 (1.6%)		

Closing remark

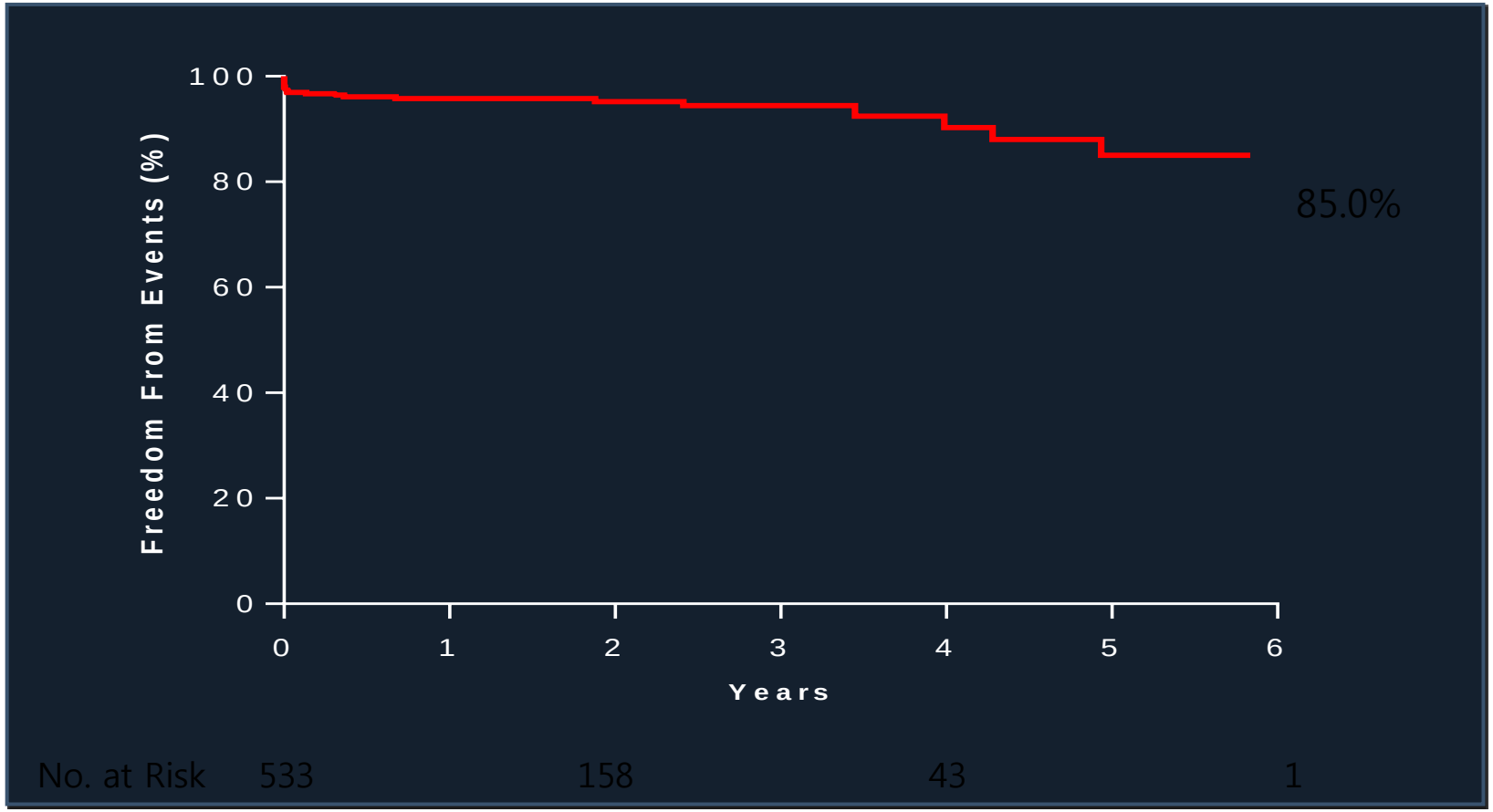
I would like to conclude by saying that advances in TAVR as well as SAVR, most notably minimally invasive procedures may be used in complementary manner to safely and effectively expand the use of tissue valves over a broader population to include most or all isolated aortic stenosis patients.


Thank you

TAVR in AMC

533 pts from 2010 (> 5 years FU)

Freedom from Re-operation or Re-intervention



Preliminary Data from AMC TAVR, 2018

The New York Times

Tens of Thousands of Heart Patients May Not Need Open-Heart Surgery

Replacement of the aortic valve with a minimally invasive procedure called TAVR proved effective in younger, healthier patients.

March 16, 2019

To

or not to

Mini-Thoracotomy AVR

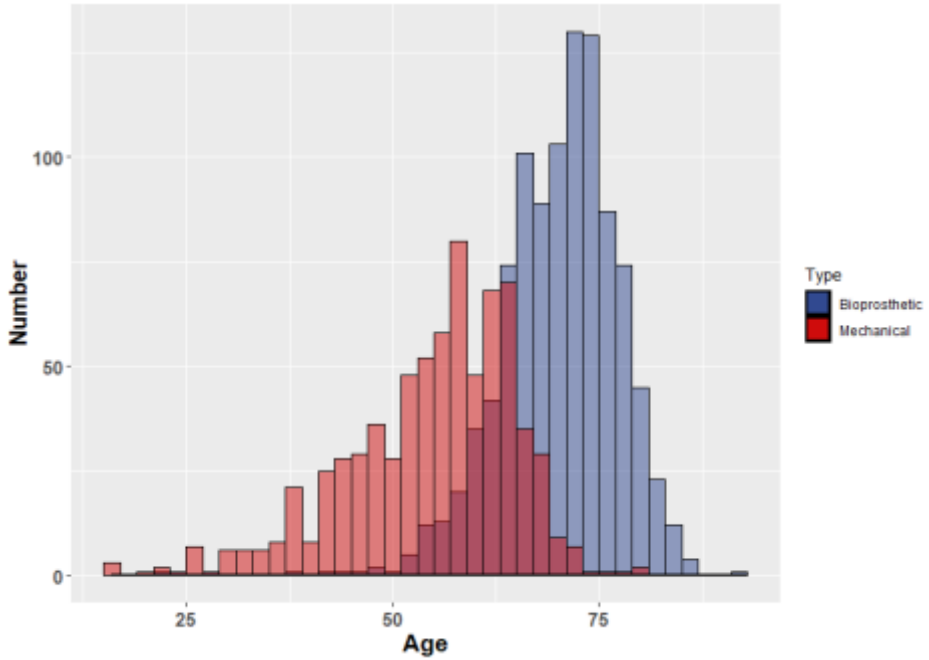
- ACC time: 42min (32-46 min)
- Skin-to-skin time: 2hr 59 min (100-221min)

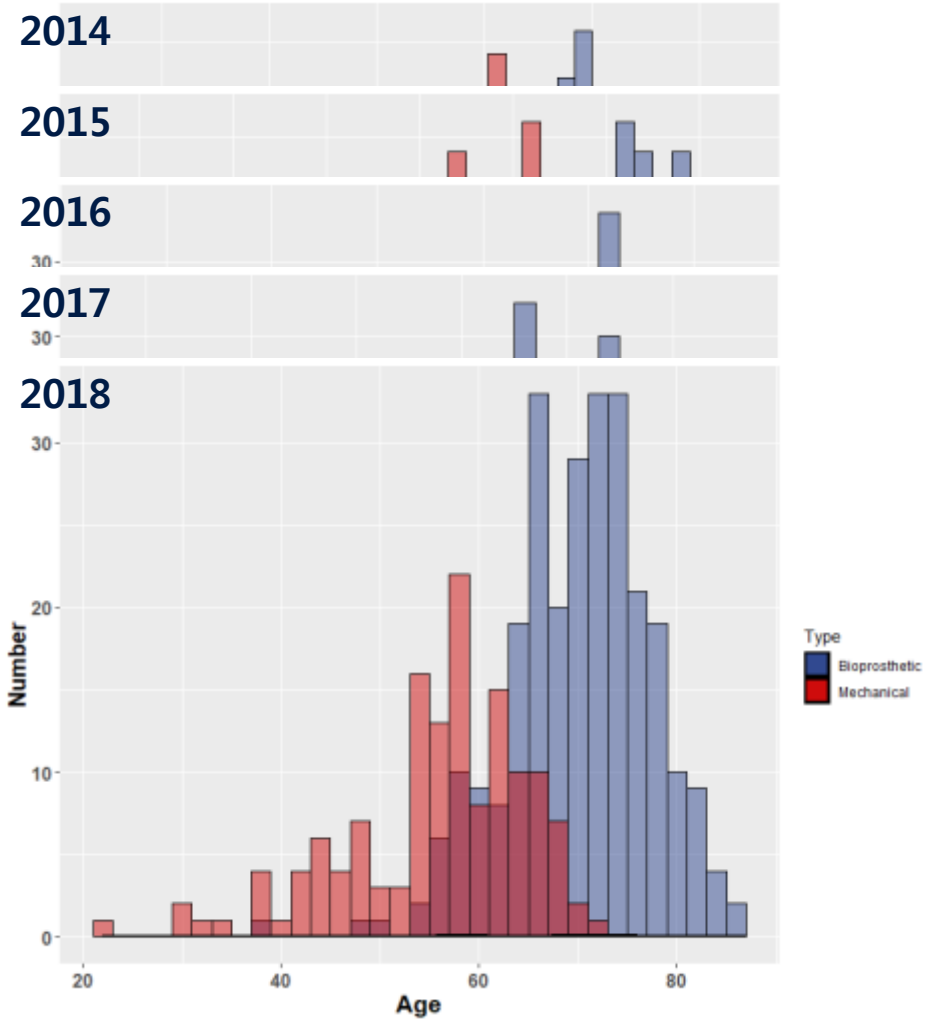
- Extension of the use

  AVR + Maze

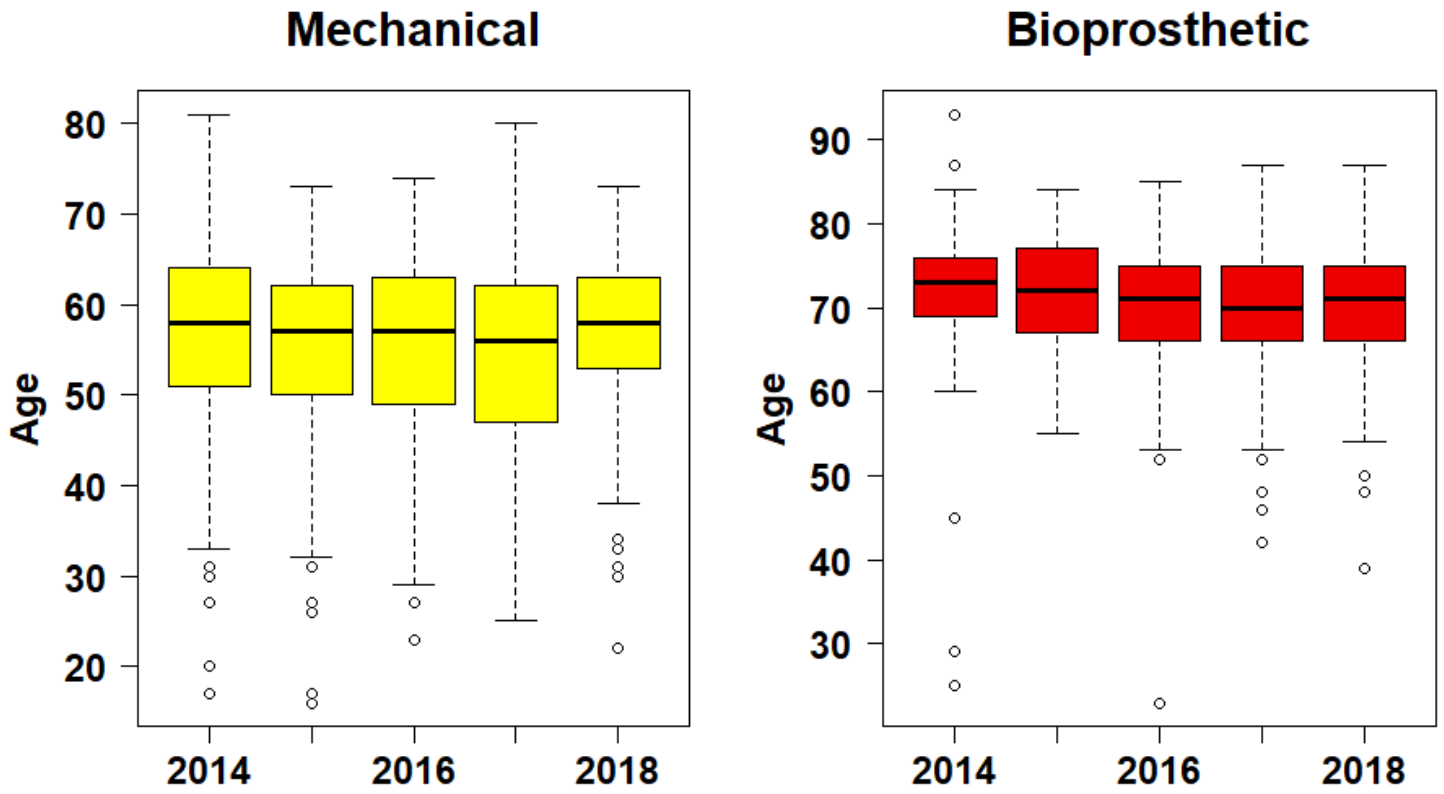
  AVR + TVP

Distribution of Age by Valve Types





Trends of Mean Age by Year according to Valve Type



Very Long-Term Survival differences between Tissue and Mechanical Heart Valves (<60)

Differences in Major Event Free Survival (AVR)

	Tissue	Mechanical	P value
20 yr. freedom from valve reoperation	11.4±3.5%	73.0±4.9%	0.001
Median time to reoperation	10.2	Beyond maximum follow up (ie, >35.0 yrs)	

Ruel M Circulation 2007;116 [suppl i]:I294-300

PARTNER 3 Trial

Mean STS score	; 1.9%	
Mean age	; 73	
Device type	; Sapien 3	
N	; 950	

		TAVR	Surgery
Primary combined end point (1 year)	;	8.5%	15.1%
Death and disabling stroke	;	1.0%	2.9%
LBBB	;	24%	8%
PPM implantation	;	similar	
Mild PVL	;	29%	2%

Low risk self expanding valve Trial

Mean STS score ; 1.9%

Mean age ; 74

Device type ; Core valve design

N ; 748

		TAVR	Surgery
Death and disabling stroke	;	2.9%	4.9%
New PPM implantation	;	17.4%	6.1%
Mod/ severe PVL	;	3.5%	0%

Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients

N Engl J Med 2019; 380:1706-1715

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BACKGROUND

Gen Thorac Cardiovasc Surg (2008) 56:215–221
DOI 10.1007/s11748-008-0234-y

ORIGINAL ARTICLE

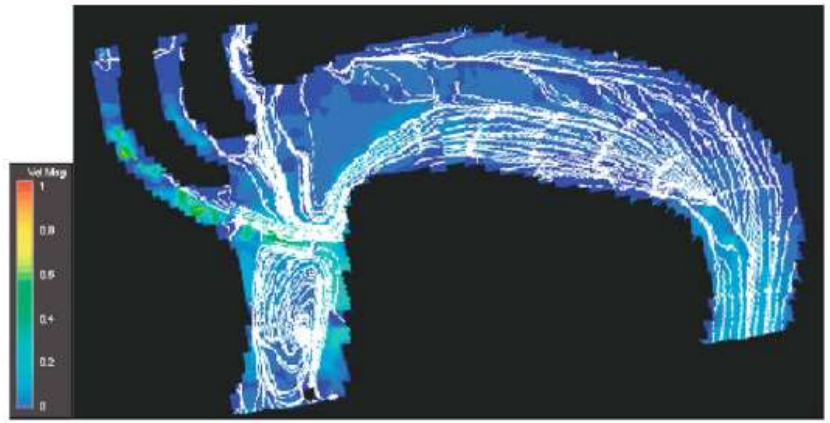
Hydrodynamic evaluation of axillary artery perfusion for normal and diseased aorta

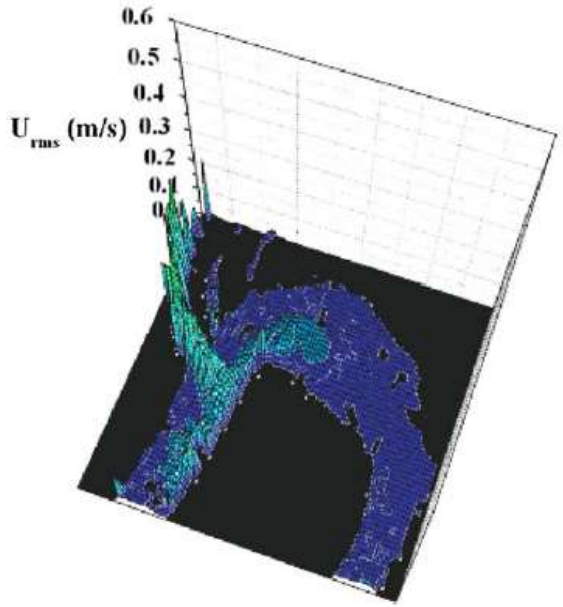
Masahito Minakawa, MD, PhD
Ikuo Fukuda, MD, PhD · Takao Inamura, DEng
Hideki Yanaoka, DEng · Kozo Fukui, MD, PhD
Kazuyuki Daitoku, MD, PhD
Yasuyuki Suzuki, MD, PhD
Hiroshi Hashimoto, MD, PhD

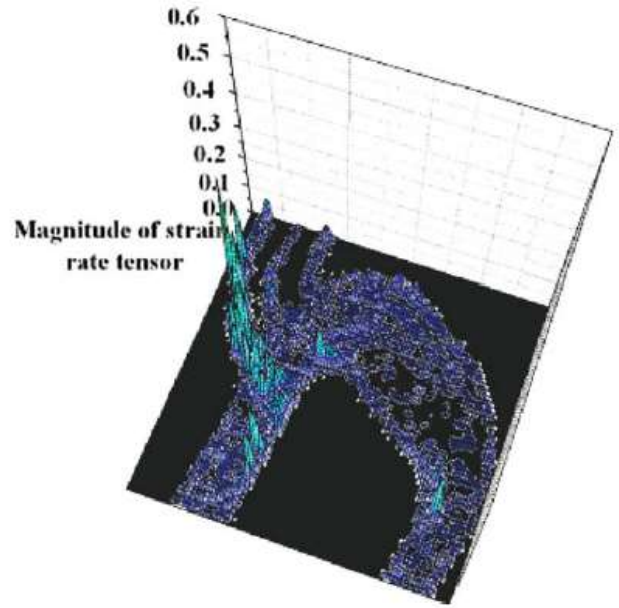
Received: 21 November 2007 / Accepted: 18 January 2008

Experimental report for
***degenerative arch aneurysm* model**
Evaluation of flow patterns
during axillary artery perfusion

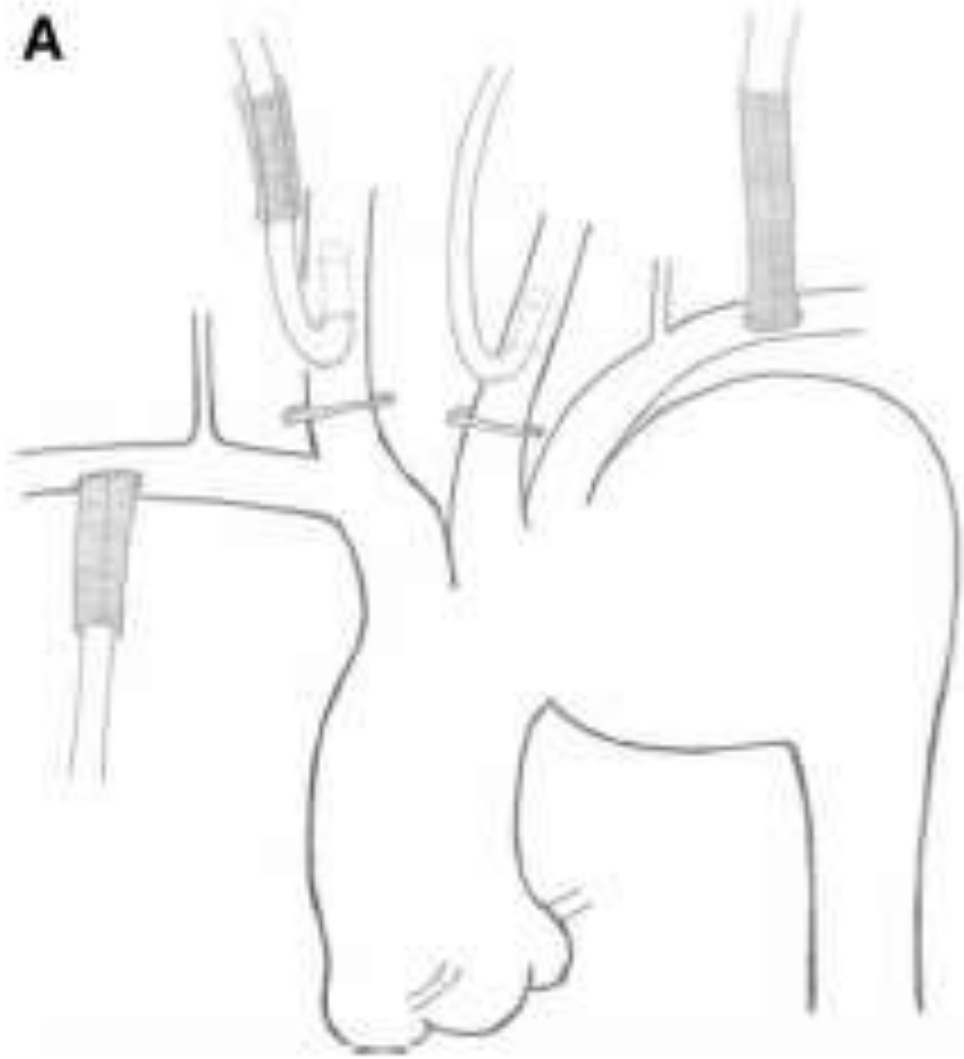
Mini-Thoracotomy Intuity AVR







Gen Thorac Cardiovasc Surg (2008) 56:215–221



Gen Thorac Cardiovasc Surg (2015) 63:533–535

Arch-vessel isolation technique

Total-arch repair for **degenerative arch aneurysm**
Specially aimed for addressing **Shaggy aorta**

- From Nov 2017
- By a single surgeon
- Selectively performed in ***18 patients***

(out of total *52 patients* who received total-arch repair)

Arch-vessel isolation technique

- **Concept**

  Separation of head vessels from aortic arch ***before*** CPB

- **Dual circulation system**

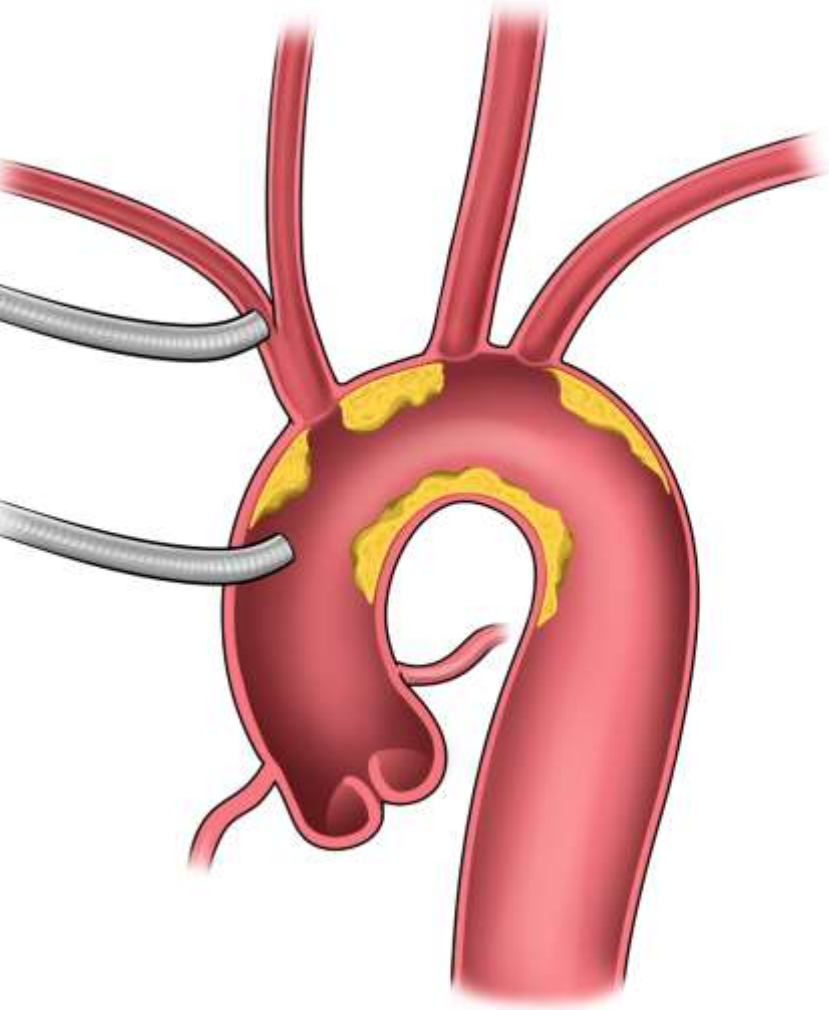
  Parallel circulation at cerebran circulation & Lower body

  2 arterial inflow catheters; ***Innominating artery (IA)*** &

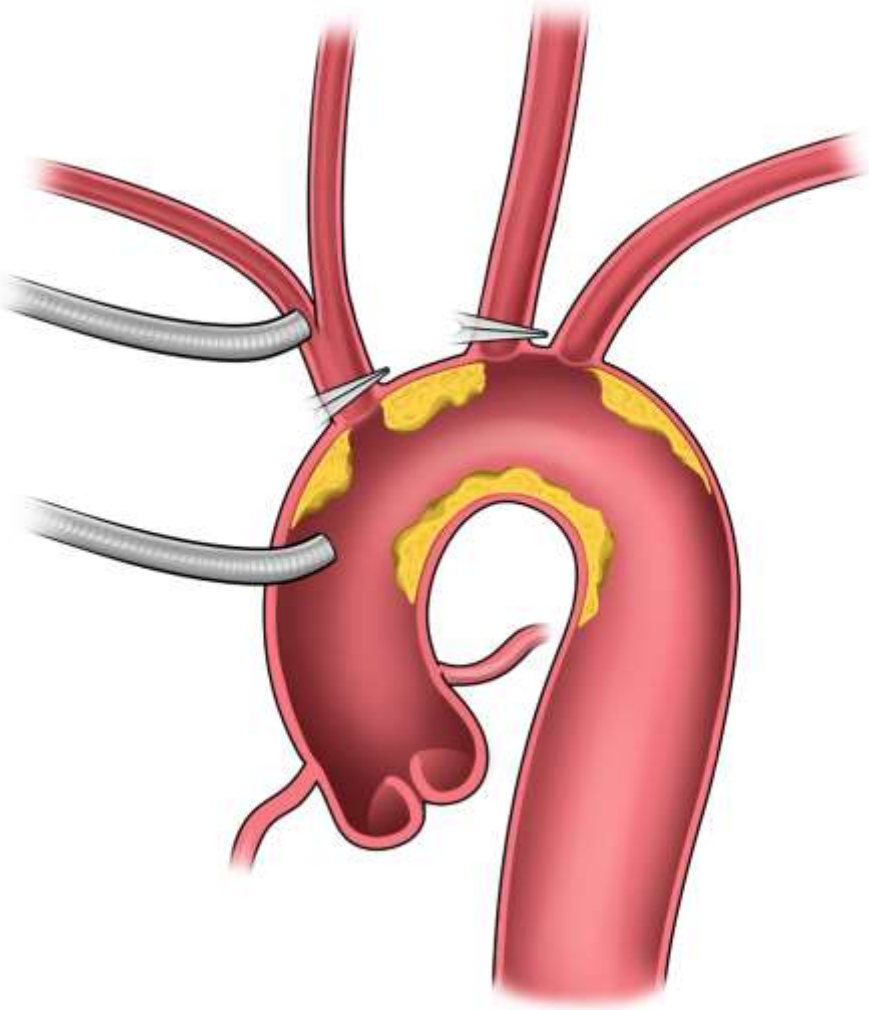
  Asc. Aorta

  IA & LCCA clamping before Pump-on

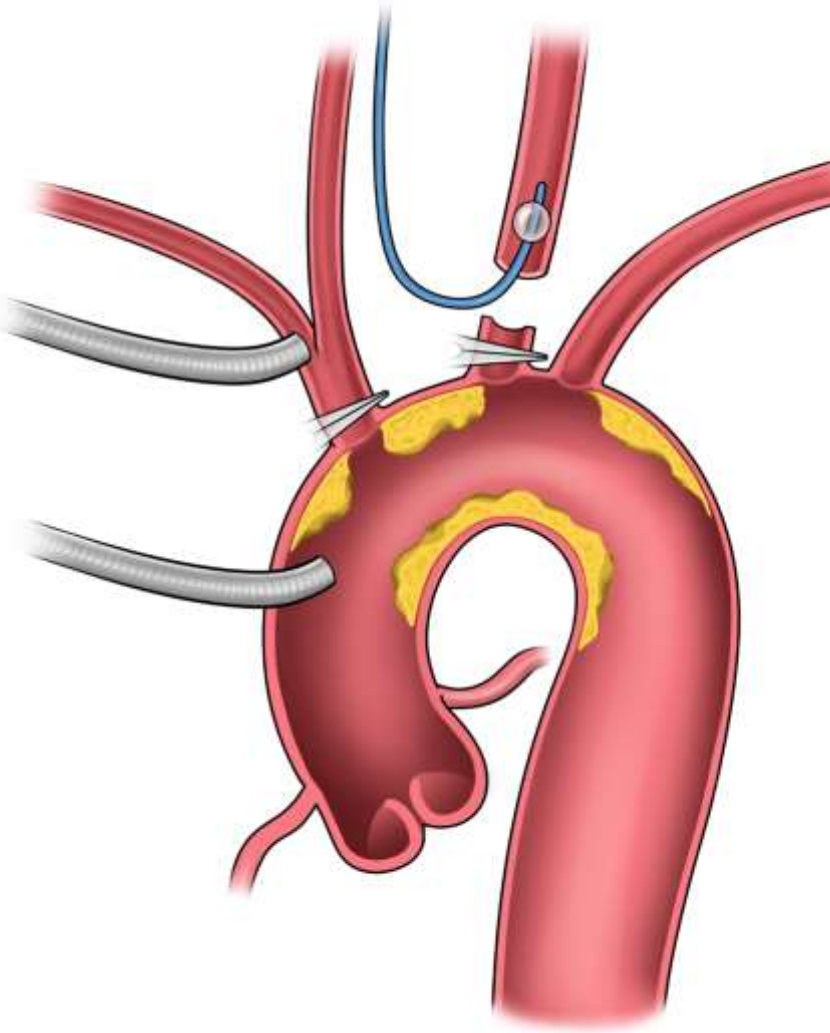
1. Dual inflow cannulation



2. IA & LCCA clamping before CPB on



3. Pump on & LCCA perfusion



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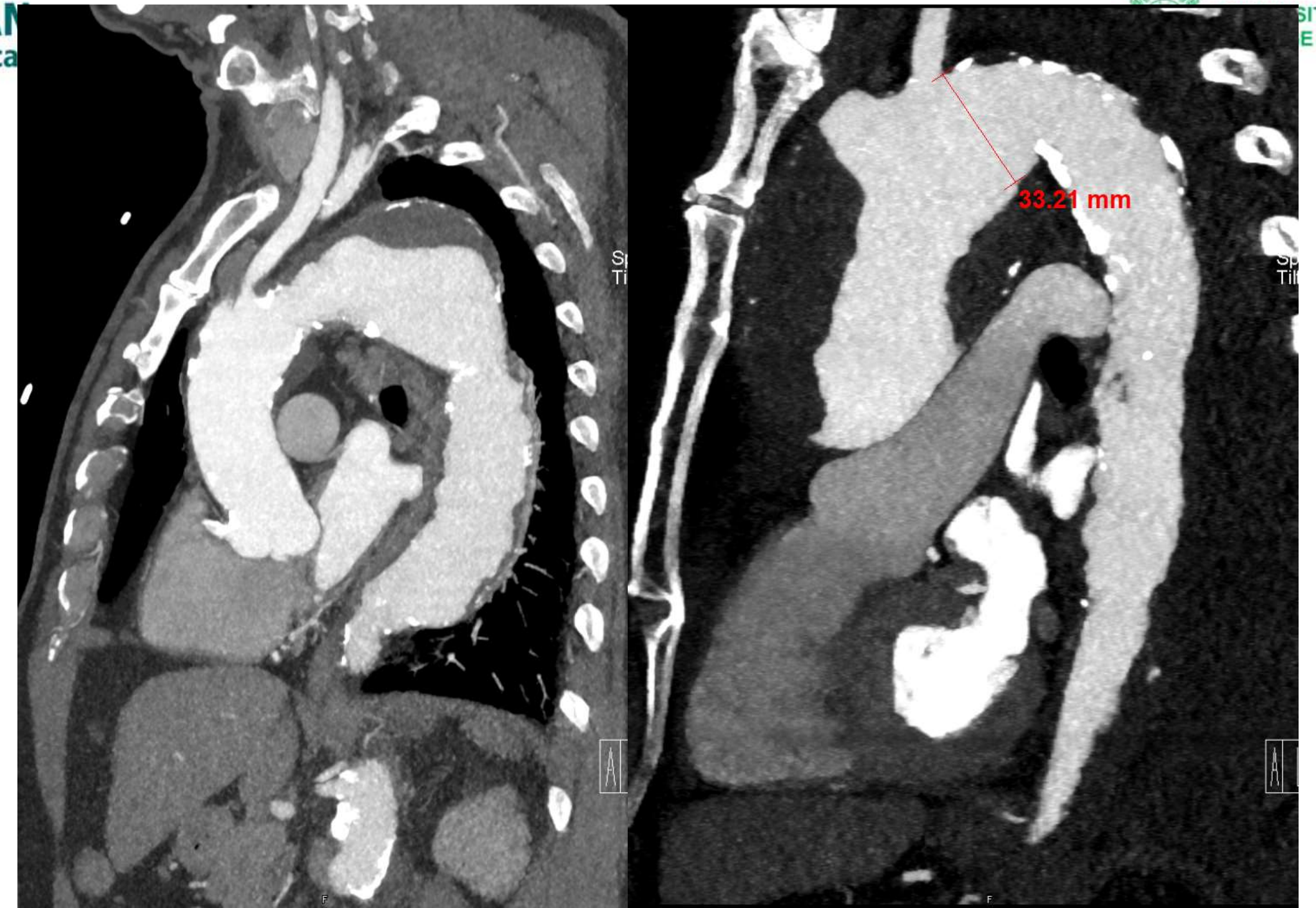
Baseline Profiles

Variables, n(%)	**N=18**
Age, yrs	**73.5±6.2**
Female, n (%)	6 (33.3)
Body mass index, kg/m^2	25.0±4.0
Diabetes mellitus, n (%)	5 (27.8)
Hypertension, n (%)	**18 (100)**
Smoking history, n (%)	8 (44.4)
Coronary artery disease, n (%)	4 (22.2)
Cerebrovascular accident, n (%)	3 (16.7)
Peripheral arterial occlusive disease, n (%)	2 (11.1)
Chronic lung disease, n(%)	3 (16.7)



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Operative Profiles

Variables, n(%)	N=18
CPB time, min	193.1 ± 29.3
ACC time, min	90.2 ± 20.1
Lower body ischemia time, min	24.2 ± 5.5
Body temperature, ℃	24.9 ± 0.9
Associated procedures, n (%)	
Off-pump CABG	4 (22.2)
AVR	1 (5.6)

Early Outcomes

Variables, n(%)	N=18
Operative outcomes	
Early mortality, n (%)	**1 (5.6)**
Bleeding, n (%)	1 (5.6)
Stroke, n (%)	**1 (5.6)**
New-dialysis, n (%)	4 (22.2)
LCOS, n (%)	0 (0)

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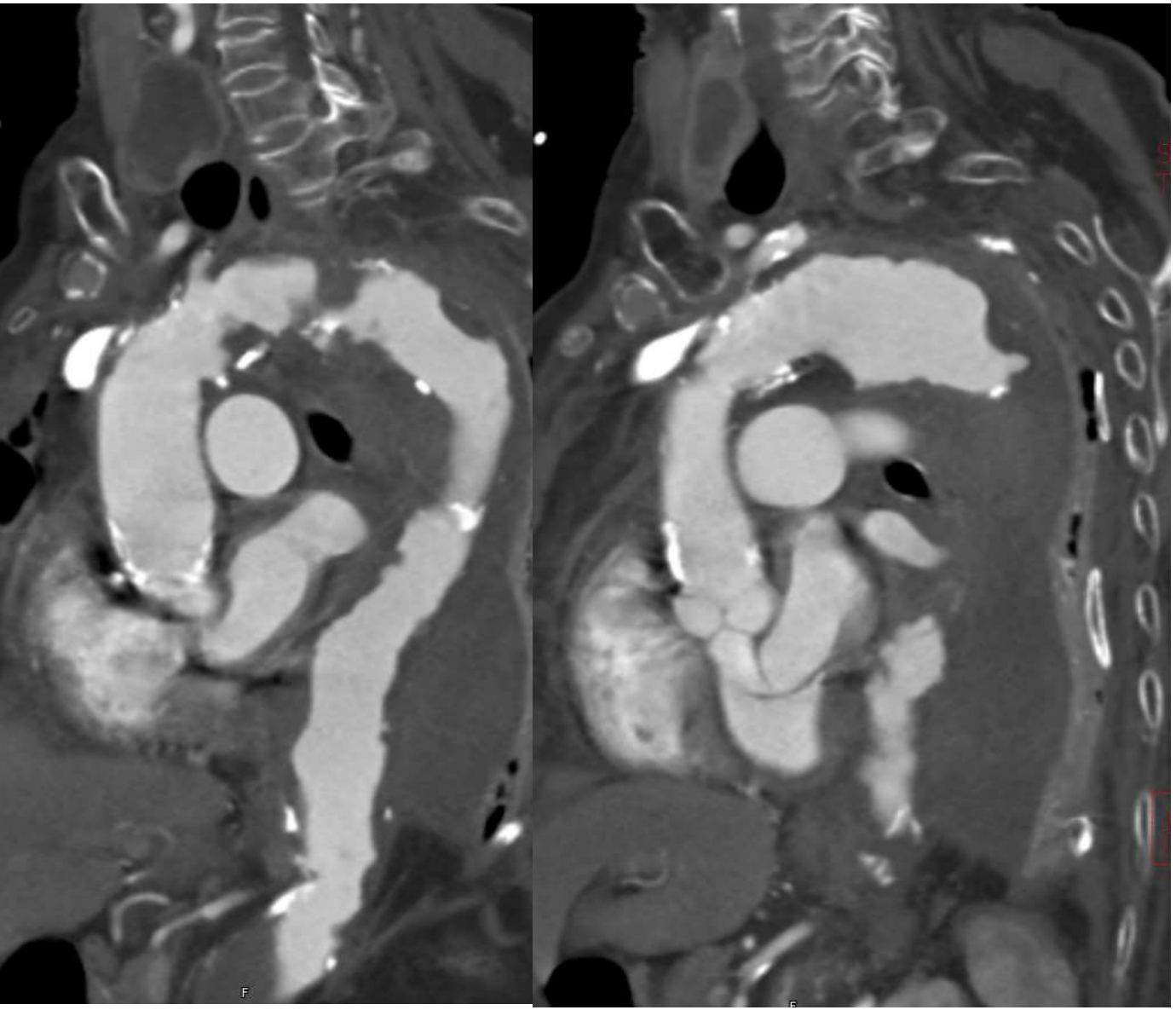
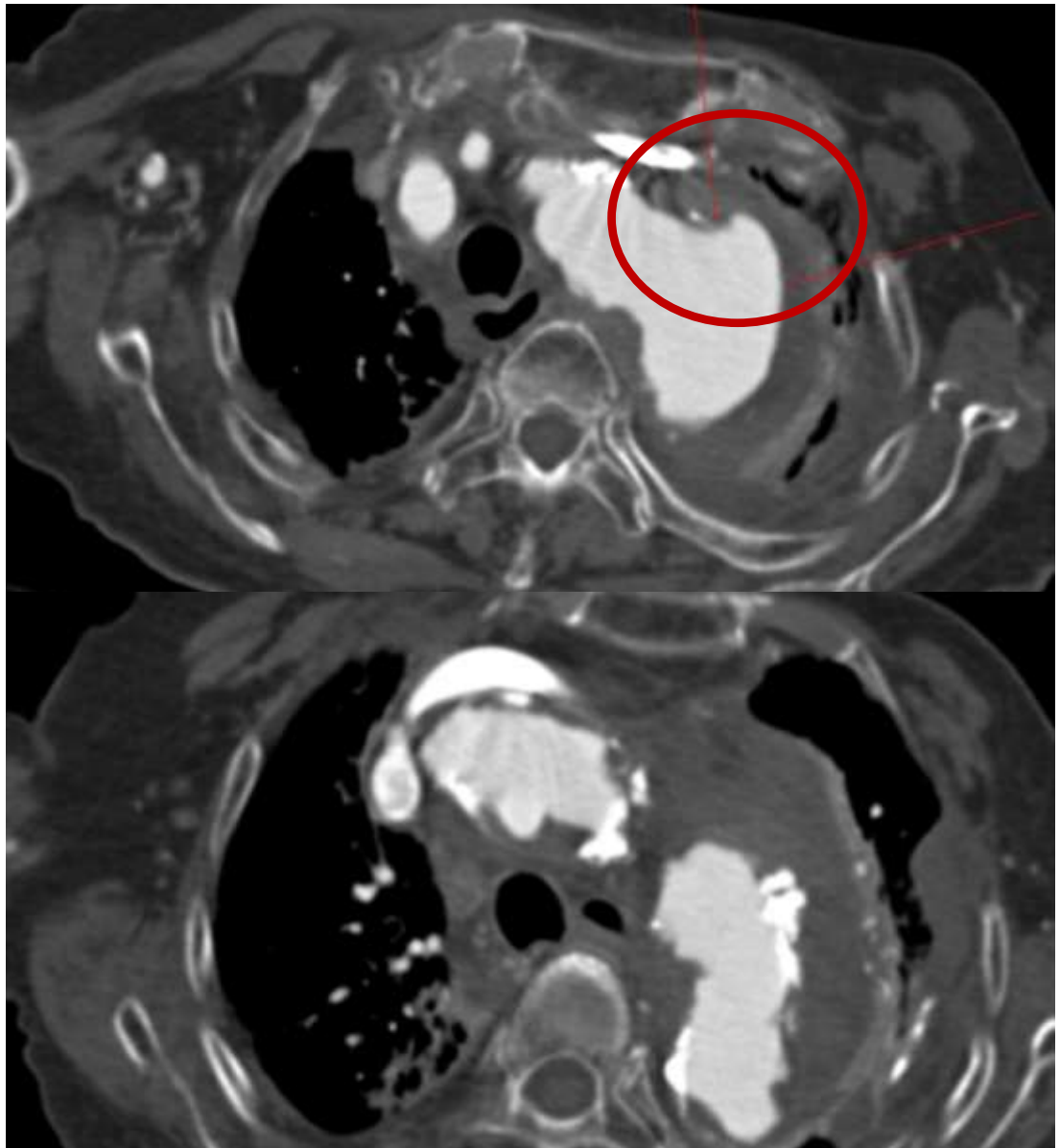
Case: 84/F

- ***Chest pain***, onset 3 days ago
- Aortic rupture 소견으로 타원 경유 ER visit
- DM/HTN, AAA
- 92/58mmHg, HR 71, 37kg/150cm
- Hb 6.6/CRP 10.81





- **Diagnosis**

  Degenerative arch aneurysm & contained rupture in distal arch

- **Emergency operation planned**

  Replacement of Total-arch and DTA

- **Operative findings**

  Distal arch & prox. DTA rupture a/w severe lung adhesion

  Shaggy aorta with heavy atherosclerosis

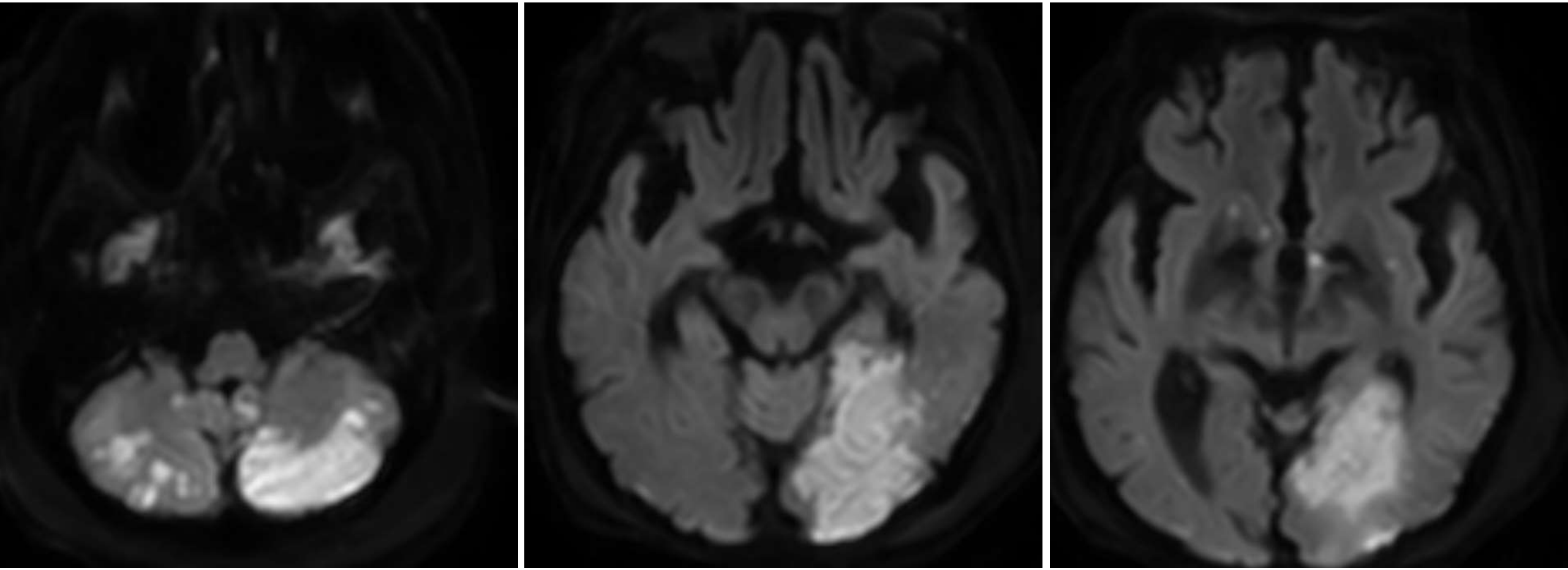
CPB time: 221min

ACC time: 114min

Lower body ischemic time: 31min

- **Mental recovery (-)**

  → **Brain MR at POD #2**



Rt. internal carotid artery

Rt. vertebral artery

Occluded
Lt. internal carotid artery

Enlarged
Lt. vertebral artery

CONCLUSIONS

- To prevent postoperative embolic stroke in patients with heavy atheroma in aorta
- **Arch-vessel isolation technique** can be performed ***safely***, ***efficiently*** and ***reproducibly.***
- Prevention of embolism through left vertebral artery should also be considered