The Last 10 Year TAVR and Achievement of ASAN MEDICAL CENTER

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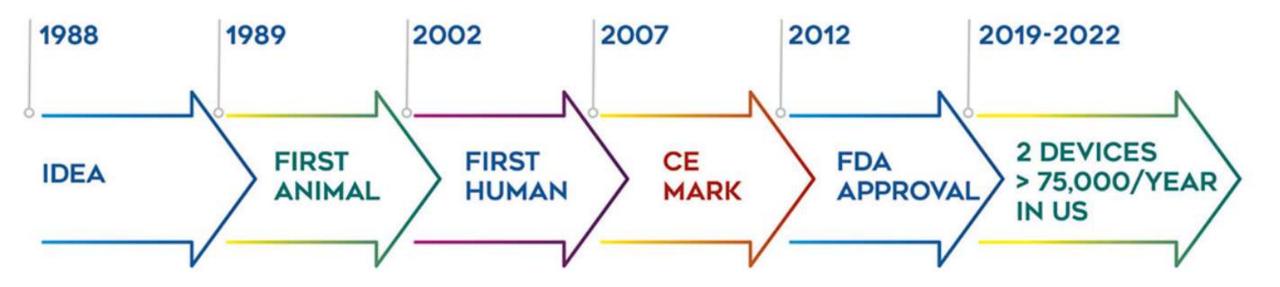
2002, First-In-Man TAVR



Alain Cribier



TIMELINE IN THE EVOLUTION OF TAVR



34 Years Since the Original Idea!



Current Status of TAVR Where We Are?





Current 2 Devices







SAPIEN 3

TAVR Trials

	STS Score	Age
Inoperable Population		
PARTNER IB Trial (2010)	11.6	83
High Risk Population (>8)		
PARTNER IA Trial (2011)	11.8	84
CoreValve US Pivotal Trial (2014)	7.4	83
Intermediate Risk Population (4-8)		
PARTNER II Trial (2016)	5.8	82
Low Risk Population (<4)		
NOTION Trial (2015)	3.0	79
PARTNER III (2019)	1.9	73
Evolut Low Risk Trial (2019)	1.9	74





TAVR Trials In Low Risk

Metanalysis of RCTs (n=2,887)

All Death

Cardio-Vascular Death



3	TAV	/R	SAN	/R		Risk Ratio	Risk Ratio		
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% CI		
SURTAVI (STS Below 3%)	2	131	4	123	8.8%	0.47 [0.09, 2.52]			
NOTION	6	145	10	135	25.6%	0.56 [0.21, 1.50]			
PARTNER 3	4	496	9	454	18.1%	0.41 [0.13, 1.31]			
Evolut Low Risk	12	725	18	678	47.5%	0.62 [0.30, 1.28]			
Total (95% CI)		1,497		1,390	100.0%	0.55 [0.33, 0.90]	•		
Total events	24		41						
Heterogeneity: Tau ² = 0.0	0; Chi ² =	0.41,	f = 3 (p	= 0.94); $I^2 = 0\%$	_			_
Test for overall effect: Z =	2.37 (p =	0.02)				0.02	8.1 1 Favors TAVR Favors	IO SAVR	50

TAVR is Better!

TAVR is Better!

TAVR @ 30 days, as compared with surgery, had a lower incidence of

- disabling stroke (0.5% vs. 1.7%),
- bleeding complications (2.4% vs. 7.5%),
- acute kidney injury (0.9% vs. 2.8%),
- atrial fibrillation (7.7% vs. 35.4%).



TAVR is Better!

TAVR @ 30 days, as compared with surgery, <u>had a higher incidence of</u>

- moderate or severe paravalvular aortic regurgitation (3.5% vs. 0.5%),
- pacemaker implantation (17.4% vs. 6.1%),



TAVR is Better!

TAVR @ 1 year, as compared with surgery <u>had</u>

- lower aortic-valve gradients (8.6 mmHg vs. 11.2 mmHg),
- larger effective orifice areas (2.3 cm² vs. 2.0 cm²).



US FDA Approved TAVR in 2019 for Low Risk Patients





Standard Performance of TAVR for High-Risk AS patients @ 30 days (VARC-2*)

All-cause mortality < 3%

Major (disabling) strokes < 2%

Major vascular complications < 5%

New permanent pacemakers < 10%

Mod-severe PVR < 5%





Recent New





SAPIEN 3

SAPIEN 3 Ultra

SAPIEN 3 Ultra

30 days (TVT registry, 2021)

n=1,324	S3U TAVI
All-cause mortality	0.9%
All-cause stroke	1.2%
Major vascular complication	1.1%
New permanent pacemaker	6.0%
Moderate or severe PVL	0.5%
Life-threatening bleeding	0.0%

Current TAVR Outcomes Are Good Enough!

Standard Performance (VARC-2*) for AS patients (@ 30 days)

All-cause mortality < 3%

Major (disabling) strokes < 2%

Major vascular complications < 5%

New permanent pacemakers < 10%

Mod-severe PVR < 5%

SAPIEN 3
Ultra

0.9%

1.2%

1.1%

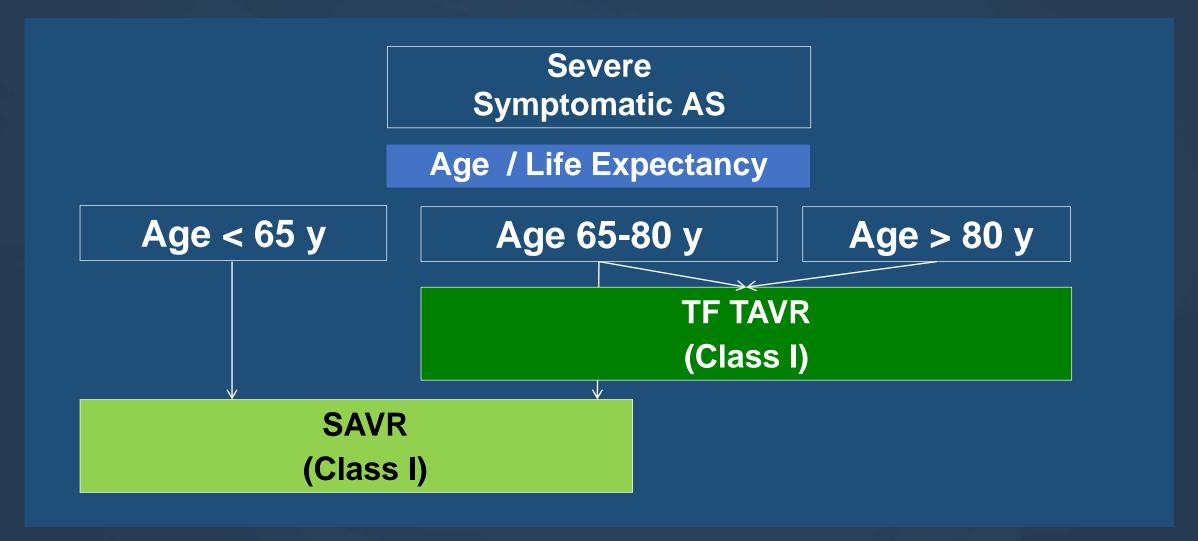
6.0%

0.5%





2020 AHA/ACC Guidelines



2021 ESC/EACTS Guidelines

Severe Symptomatic AS

Age / Life Expectancy

All other Patients, Age < 75 y

Age > 75 y

TAVI or SAVR (Unsuitable for TAVI)

TAVI (Class I)





2021 Conceptual Guidelines

Severe Symptomatic AS

Age / Life Expectancy

Whenever You Choose Tissue Valve

TAVR Is Choice!

SAVR for Only Unsuitable TAVR

First TAVR in AMC at 2010



TAVR Case Increased at AMC



TAVR in AMC What is the Difference?

- 1. Perfect "Heart Team" Collaboration
- 2. "Minimalist Approach" (MAC, >95%)
 Simplify the Procedure
- 3. "CT Algorithm for Device Selection"

 Pre-TAVR Meticulous CT Measurement





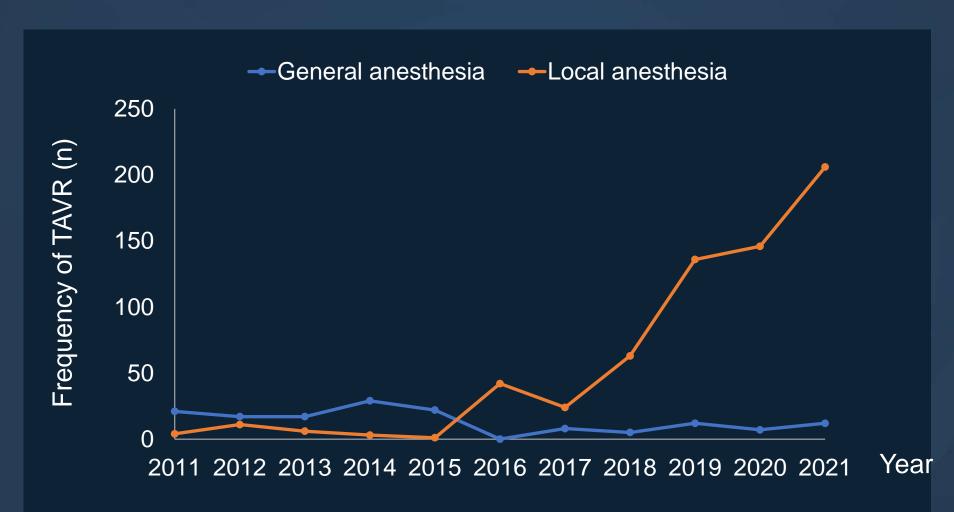
"Minimalist Approach" (MAC) TAVR in AMC

- No General Anesthesia,
- No TEE
- 30 min. Procedure
- One Day stay in CCU
- No Complications
- Discharge on Day #3
- Cardiac Rehabilitation Program





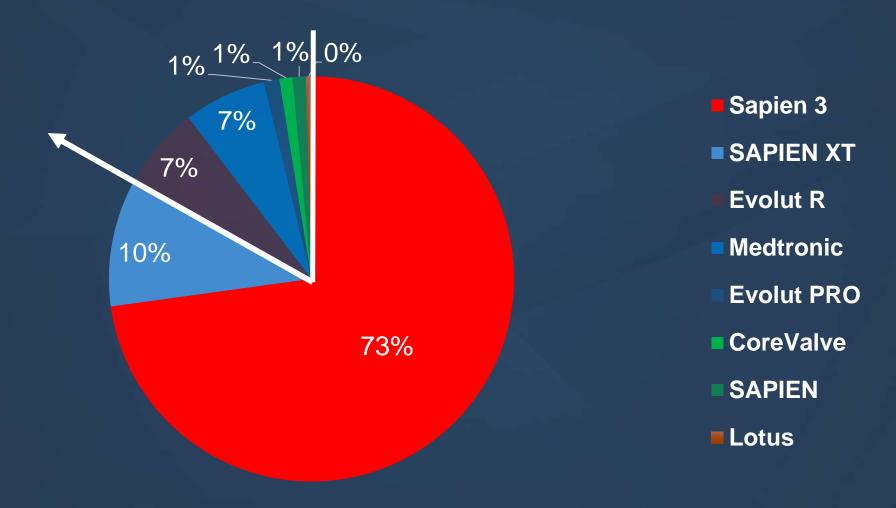
"Minimalist Approach" (MAC) TAVR in AMC







TAVR Devices in AMC



TAVR in AMC

	N = 1137
Age, years	80.18 ± 5.44
Male sex	536 (47.14%)
BMI, kg/m ²	25.67 ± 5.7
STS risk score (%)	4.06 ± 2.86
DM	397 (34.9%)
Hypertension	900 (79.1%)
Atrial fibrillation	139 (12.4%)
Coronary artery disease	274 (24.1%)
Previous MI	41 (3.6%)
Previous stroke	134 (11.7%)
Peripheral vascular disease	59 (5.1%)
Chronic Kidney Disease	44 (3.87%)
COPD	141 (12.4%)
LV Ejection fraction, %	58.87 ± 10.6

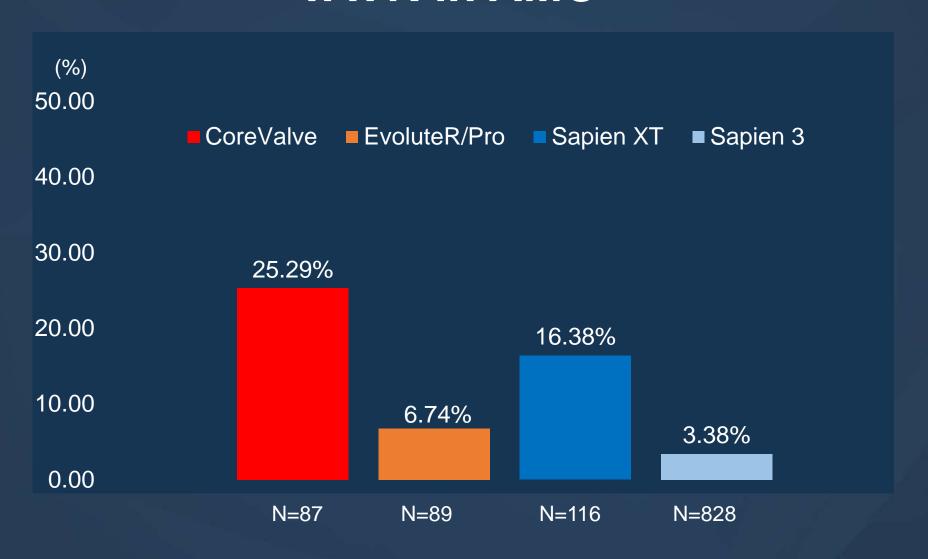
Procedural OutcomesTAVR in AMC

	Overall (N = 1137)
Procedural success	1101 (96.8%)
Conversion to surgery	14 (1.2%)
Coronary obstruction	3 (0.2%)
Implantation of two valves	20 (1.7%)
New permanent pacemaker	79 (6.9%)
PVL ≥ moderate	49 (4.3%)
Major vascular complication	61 (5.3%)
Length of hospital stay (days)	10.67±1.2





Incidence of PPM TAVR in AMC







30 Days Outcomes (Overall) TAVR in AMC

	Overall (N = 1137)
Death, all	20 (1.7%)
Cardiac death	13 (1.1%)
Non-cardiac death	7 (0.6%)
Stroke, all	42 (3.7%)
Disabling	12 (1.0%)
Non-disabling	30 (2.6%)
Death or disabling stroke	28 (2.4%)
Bleeding	406 (35.7%)
Life-threatening	48 (4.2%)
Major	154 (13.5%)





30 Days Outcomes (Recent 1 year Performance) TAVR in AMC

	Overall (N = 262)
Death, all	5 (1.9%)
Cardiac death	3 (1.1%)
Non-cardiac death	2 (0.7%)
Stroke, all	4 (1.5%)
Disabling	1 (0.3%)
Non-disabling	3 (1.1%)
Death or disabling stroke	10 (3.8%)
Bleeding, life-threatening	0 (0.0%)
Permanent pacemaker implantation	8 (3.0%)





1 year Outcomes TAVR in AMC

	Overall (N = 1137)
Death, all	79 (6.9%)
Cardiac death	23 (2.0%)
Non-cardiac death	56 (4.9%)
Stroke, all	60 (5.2%)
Disabling	15 (1.3%)
Non-disabling	45 (3.9%)
Death or disabling stroke	89 (7.8%)
Rehospitalization	75 (6.5%)
Infective endocarditis	17 (1.4%)

Outcomes of TAVR

Standard Performance (VARC-2*) for AS patients (@ 30 days)

All-cause mortality < 3%

Major (disabling) strokes < 2%

Major vascular complications < 5%

New permanent pacemakers < 10%

Mod-severe PVR < 5%

AMC AII

AMC 2021

1.7%

1.9%

1.0%

0.3%

5.3%

0.0%

6.9%

3.0%

4.3%

1.1%





"Minimalist Approach" (MAC) Improved Clinical Outcomes!

TAVR in AMC Baseline Characteristics

	Overall (N = 1137)	General Anesthesia (N = 276)	Conscious Sedation (MAC) (N = 861)	P value
Age	80.1 ± 5.4	79.7 ± 5.52	80.3 ± 5.41	0.11
Male sex	536 (47.1%)	141 (51.1%)	395 (45.8%)	0.15
BMI, kg/m²	25.6 ± 5.7	23.6 ± 3.36	26.36 ± 2.6	0.24
STS risk score, %	4.06 ± 2.86	4.51 ± 3.35	3.92 ± 2.67	0.008
DM	397 (34.9%)	94 (34.1%)	303 (35.2%)	0.78
HTN	900 (79.1%)	239 (86.6%)	661 (76.7%)	0.001
Atrial fibrillation	139 (12.4%)	35 (12.7%)	104 (12.5%)	0.87
CAD	274 (24.1%)	81 (29.3%)	193 (22.42%)	0.63
Previous MI	41 (3.6%)	16 (5.8%)	25 (2.9%)	0.04
Previous stroke	134 (11.7%)	29 (10.5%)	105 (12.2%)	0.51
PVD	59 (5.1%)	29 (10.5%)	30 (3.4%)	<0.001
Chronic Kidney Disease	44 (3.8%)	16 (5.8%)	28 (3.2%)	0.08
COPD	141 (12.4%)	43 (15.5%)	98 (11.3%)	0.08

TAVR in AMC Procedural Characteristics

	Overall (N = 1137)	General Anesthesia (N = 276)	Conscious Sedation(MAC) (N = 861)	P value
Aortic-valve area, cm ²	0.63 ± 0.15	0.62 ± 0.18	0.63 ± 0.14	0.52
AV Vmax, m/s	4.82 ± 0.79	4.85 ± 0.87	4.81 ± 0.77	0.44
Mean gradient, mmHg	57.1 ± 20.2	59.1 ± 22.6	56.5 ± 19.3	0.09
Bicuspid AV	114 (10.4%)	22 (8.0%)	92 (10.6%)	0.24
LV EF, %	58.8 ± 10.6	57.1 ± 12.1	59.4 ± 10.2	0.003
Device type				<0.001
Balloon-expandable	956 (84.1%)	169 (61.2%)	787 (91.4%)	
Self-expandable	181 (15.9%)	107 (38.7%)	74 (8.59%)	





TAVR in AMC Procedural Outcomes

	Overall (N = 1137)	General Anesthesia (N = 276)	Conscious Sedation(MAC) (N = 861)	P value
Procedural success	1101 (96.8%)	252 (91.3%)	849 (98.6%)	<0.001
Conversion to surgery	14 (1.2%)	7 (2.5%)	7 (0.8%)	0.053
Coronary obstruction	3 (0.2%)	0 (0.0%)	3 (0.3%)	0.75
New permanent pacemaker	79 (6.9%)	36 (13.0%)	43 (4.9%)	<0.001
PVL ≥ moderate	49 (4.3%)	18 (6.5%)	31 (3.6%)	0.056
Major vascular complication	61 (5.3%)	30 (10.8%)	31 (3.6%)	<0.001
Length of hospital stay (days)	10.6 ± 1.2	10.7 ± 2.3	10.6 ± 0.6	0.554

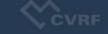




TAVR in AMC 30 Days Outcomes

	Overall (N = 1137)	General Anesthesia (N = 276)	Conscious Sedation(MAC) (N = 861)	P value
Death, all	20 (1.7%)	12 (4.3%)	8 (0.9%)	<0.001
Cardiac death	13 (1.1%)	8 (2.9%)	5 (0.5%)	0.005
Non-cardiac death	7 (0.6%)	4 (1.4%)	3 (0.3%)	0.11
Stroke, all	42 (3.7%)	15 (5.4%)	27 (3.14%)	0.11
Disabling	12 (1.0%)	4 (1.4%)	8 (0.9%)	0.69
Non-disabling	30 (2.6%)	11 (3.9%)	19 (2.2%)	0.16
Death or disabling stroke	28 (2.4%)	15 (5.4%)	13 (1.5%)	0.001
Bleeding	406 (35.7%)	136 (49.2%)	270 (31.3%)	<0.001
Life-threatening	48 (4.2%)	27 (9.7%)	21 (2.4%)	<0.001
Major	154 (13.5%)	71 (25.7%)	83 (9.6%)	<0.001





Outcomes of TAVR

Standard Performance (VARC-2*) for AS patients (@ 30 days)

All-cause mortality < 3%

Major (disabling) strokes < 2%

Major vascular complications < 5%

New permanent pacemakers < 10%

Mod-severe PVR < 5%

AMC All

1.7%

1.0%

5.3%

6.9%

4.3%

AMC "MAC"

0.9%

0.9%

3.6%

4.9%

3.6%





TAVR in AMC Sapien3 vs Evolut R



TAVR in AMC Baseline Characteristics

	Overall (N = 1137)	Balloon Expandable (N = 956)	Self Expandable (N = 181)	P value
Age	80.1 ± 5.4	80.1 ± 5.5	80.1 ± 4.9	0.91
Male sex	536 (47.1%)	457 (47.8%)	79 (43.6%)	0.34
BMI, kg/m ²	25.6 ± 5.7	26.0 ± 3.4	23.8 ± 3.4	0.28
STS risk score, %	4.06 ± 2.86	4.07 ± 2.93	4.04 ± 2.46	0.88
DM	397 (34.9%)	338 (35.3%)	59 (32.6%)	0.52
HTN	900 (79.1%)	755 (78.9%)	145 (80.1%)	0.80
Atrial fibrillation	139 (12.4%)	115 (12.0%)	24 (13.2%)	0.73
CAD	274 (24.1%)	231 (24.1%)	43 (23.7%)	0.98
Previous MI	41 (3.6%)	35 (3.6%)	6 (3.3%)	0.99
Previous stroke	134 (11.7%)	116 (12.1%)	18 (9.9%)	0.47
PVD	59 (5.1%)	48 (5.0%)	11 (5.0%)	0.68
Chronic Kidney Disease	44 (3.8%)	41 (4.2%)	3 (1.6%)	0.14
COPD	141 (12.4%)	110 (11.51%)	31 (17.1%)	0.048

TAVR in AMC Baseline Characteristics

	Overall (N = 1137)	Balloon Expandable (N = 956)	Self Expandable (N = 181)	P value
Age	80.1 ± 5.4	80.1 ± 5.5	80.1 ± 4.9	0.91
Male sex	536 (47.1%)	457 (47.8%)	79 (43.6%)	0.34
BMI, kg/m ²	25.6 ± 5.7	26.0 ± 3.4	23.8 ± 3.4	0.28
STS risk score, %	4.06 ± 2.86	4.07 ± 2.93	4.04 ± 2.46	0.88
DM	397 (34.9%)	338 (35.3%)	59 (32.6%)	0.52
HTN	900 (79.1%)	755 (78.9%)	145 (80.1%)	0.80
Atrial fibrillation	139 (12.4%)	115 (12.0%)	24 (13.2%)	0.73
CAD	274 (24.1%)	231 (24.1%)	43 (23.7%)	0.98
Previous MI	41 (3.6%)	35 (3.6%)	6 (3.3%)	0.99
Previous stroke	134 (11.7%)	116 (12.1%)	18 (9.9%)	0.47
PVD	59 (5.1%)	48 (5.0%)	11 (5.0%)	0.68
Chronic Kidney Disease	44 (3.8%)	41 (4.2%)	3 (1.6%)	0.14
COPD	141 (12.4%)	110 (11.51%)	31 (17.1%)	0.048

TAVR in AMC Procedural Characteristics

	Overall (N = 1137)	Balloon Expandable (N = 956)	Self Expandable (N = 181)	P value
Aortic-valve area, cm ²	0.63 ± 0.15	0.63 ± 0.15	0.60 ± 0.17	0.014
AV Vmax, m/s	4.82 ± 0.79	4.8 ± 0.8	4.9 ± 0.9	0.13
Mean gradient, mmHg	57.1 ± 20.2	56.4 ± 19.5	60.4 ± 23.1	0.03
Bicuspid AV	114 (10.4%)	93 (9.7%)	21 (11.6%)	0.52
LV EF, %	58.8 ± 10.6	59.0 ± 10.3	57.9 ± 11.7	0.23
Approach site				<0.001
Transfemoral	1106 (97.2%)	927 (96.9%)	179 (98.9%)	
Transapical	29 (2.5%)	29 (3.03%)	0 (0.0%)	
Transaortic	2 (0.1%)	0 (0.0%)	2 (1.1%)	





TAVR in AMC Procedural Outcomes

	Overall (N = 1137)	Balloon Expandable (N = 956)	Self Expandable (N = 181)	P value
Device success	1101 (96.8%)	933 (97.5%)	168 (92.8%)	0.002
Conversion to surgery	14 (1.2%)	11 (1.1%)	3 (1.6%)	0.95
Coronary obstruction	3 (0.2%)	3 (0.3%)	0 (0.0%)	1.00
New permanent pacemaker	79 (6.9%)	51 (5.3%)	28 (15.4%)	<0.001
PVL ≥ moderate	49 (4.3%)	36 (3.7%)	13 (7.1%)	0.06
Major vascular complication	61 (5.3%)	43 (4.5%)	18 (9.9%)	0.005
Length of hospital stay (days)	10.6 ± 1.2	10.6 ± 1.15	10.7 ± 1.6	0.28





TAVR in AMC 30 Days Outcomes

	Overall (N = 1137)	Balloon Expandable (N = 956)	Self Expandable (N = 181)	P value
Death, all	20 (1.7%)	16 (1.6%)	4 (2.2%)	0.84
Cardiac death	13 (1.1%)	9 (0.9%)	4 (2.2%)	0.27
Non-cardiac death	7 (0.6%)	7 (0.7%)	0 (0.0%)	0.52
Stroke, all	42 (3.7%)	32 (3.3%)	10 (5.5%)	0.22
Disabling	12 (1.0%)	8 (0.8%)	4 (2.2%)	0.20
Non-disabling	30 (2.6%)	24 (2.5%)	6 (3.3%)	0.71
Death or disabling stroke	28 (2.4%)	21 (2.2%)	7 (3.8%)	0.28
Bleeding	406 (35.7%)	331 (34.6%)	75 (41.4%)	0.09
Life-threatening	48 (4.2%)	33 (3.4%)	15 (8.2%)	0.006
Major	154 (13.5%)	111 (11.6%)	43 (23.7%)	<0.001





Outcomes of TAVR

Standard Performance (VARC-2*) for AS patients (@ 30 days)

All-cause mortality < 3%

Major (disabling) strokes < 2%

Major vascular complications < 5%

New permanent pacemakers < 10%

Mod-severe PVR < 5%

AMC AII	AMC SAPIEN	AMC Core
1.7%	1.6%	2.2%
1.0%	0.8%	2.2%
5.3%	4.5%	9.9%
6.9%	5.3%	15.4%
4.3%	3.7%	7.1%





Remaining Issues of TAVR

Durability





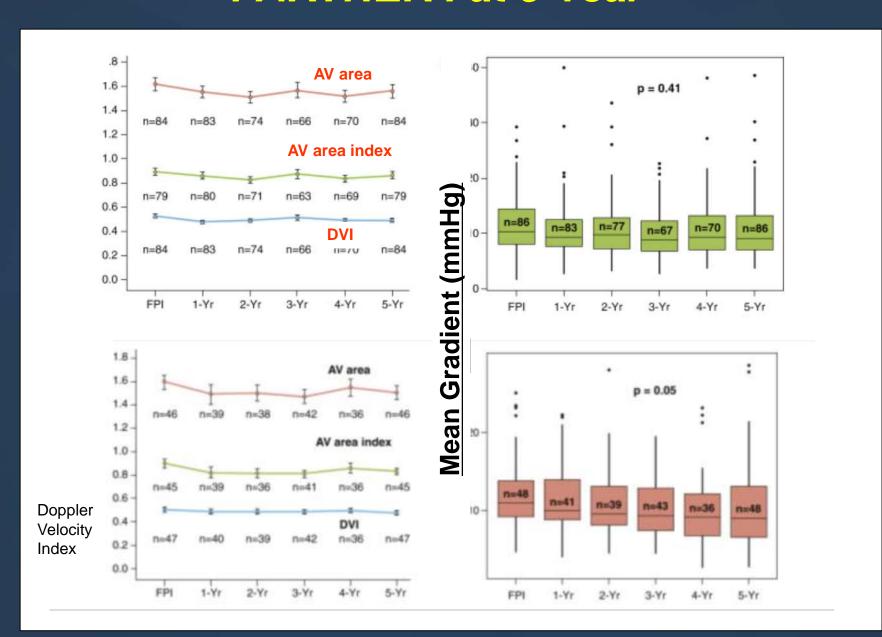
A Report From the PARTNER I Trial at 5 Year

Long-Term Valve Performance of TAVR and SAVR:

PARTNER I at 5 Year



SAVR

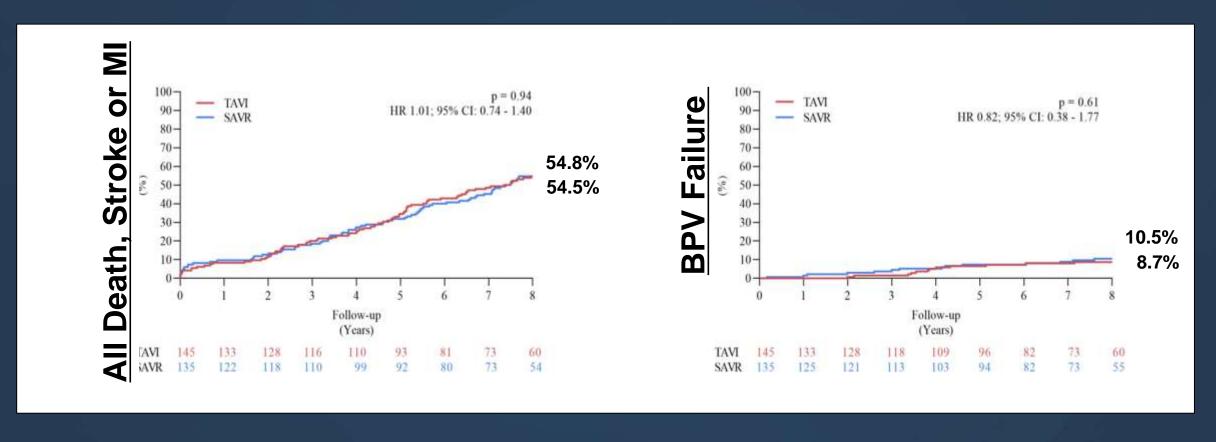


NOTION at 8 Year





Aortic Bioprosthetic Valve Failure 8 years after Transcatheter and Surgical Aortic Valve



At 5~8 Years After TAVR, TAVR Is Still Comparable with Surgery!



Remaining Issues Of TAVR, We need more data

- Bicuspid AV disease
- Bioprosthetic valve failure (aortic and mitral)
- Severe asymptomatic AS
- Low-flow, low-gradient AS
- Moderate AS + CHF
- High-risk AR
- Routine use of cerebral protection device ?





TAVR in AMC, 2022

Whenever you choose tissue valve, (at any age or at any cases) <u>TAVR has become the standard of treatment in patients with symptomatic severe aortic stenosis(>65y).</u>
SAVR would be considered only for patients who are not suitable for TAVR.



