Minimalist TAVI: Achieving Great TAVI Efficiency and Optimal Patient Outcome

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Current Status of TAVR

Where We Are ?

TAVR in Low Risk, ACC 2019

1. **PARTNER III (Sapiens3)**
2. **Evolut Low Risk Trial**

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 is Better for Low-risk Patients

Metanalysis of RCTs (n=2,887)

All-Death

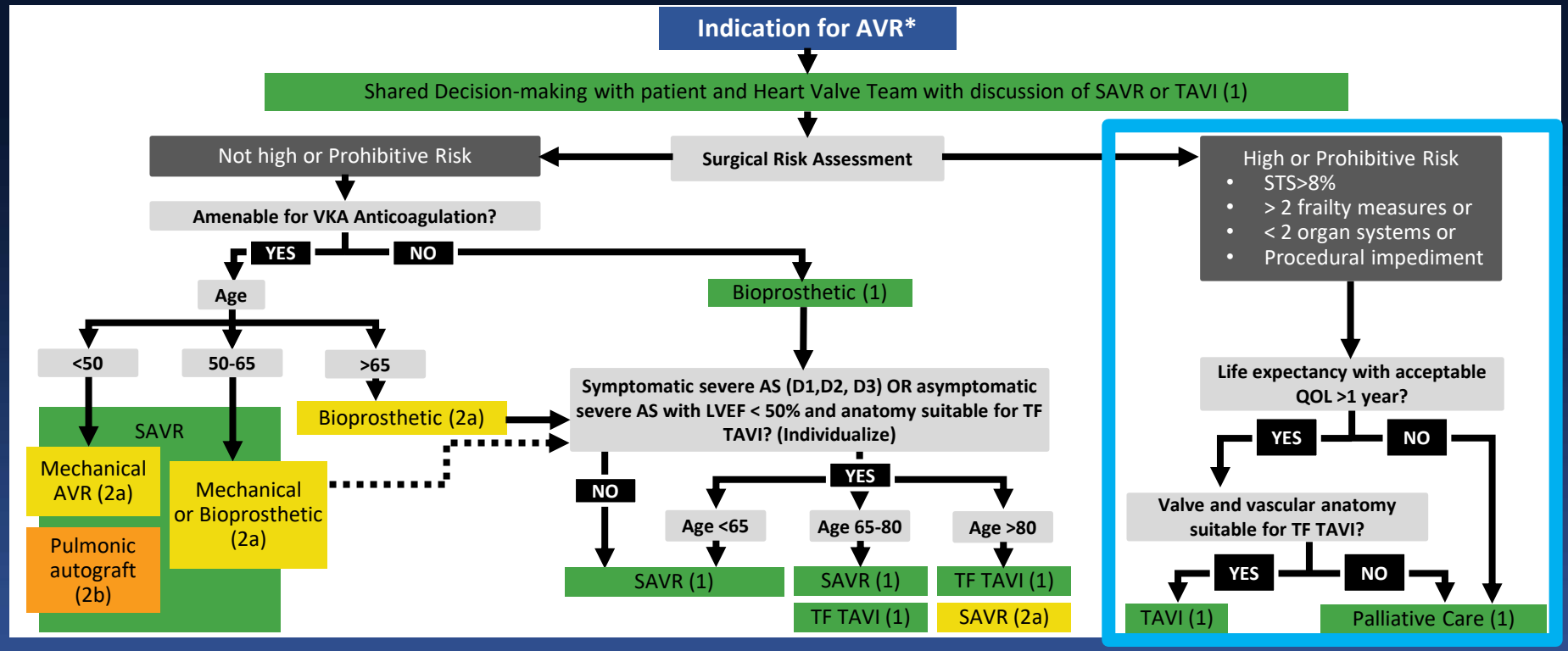
Cardiovascular Death

Kolte D et.al. JACC. 2019 Sep 24;74(12):1532-1540.

TAVR Won !!
in Low Risk at ACC 2019

US FDA Approved TAVR for Low Risk Patients

2020 ACC/AHA Guidelines for VHD



J Am Coll Cardiol 2020

Today,

- TAVR has become a routine procedure in many cath-labs around the world
- Conscious sedation or Local anesthesia
- Less than 1 hour
- Mortality < 1%

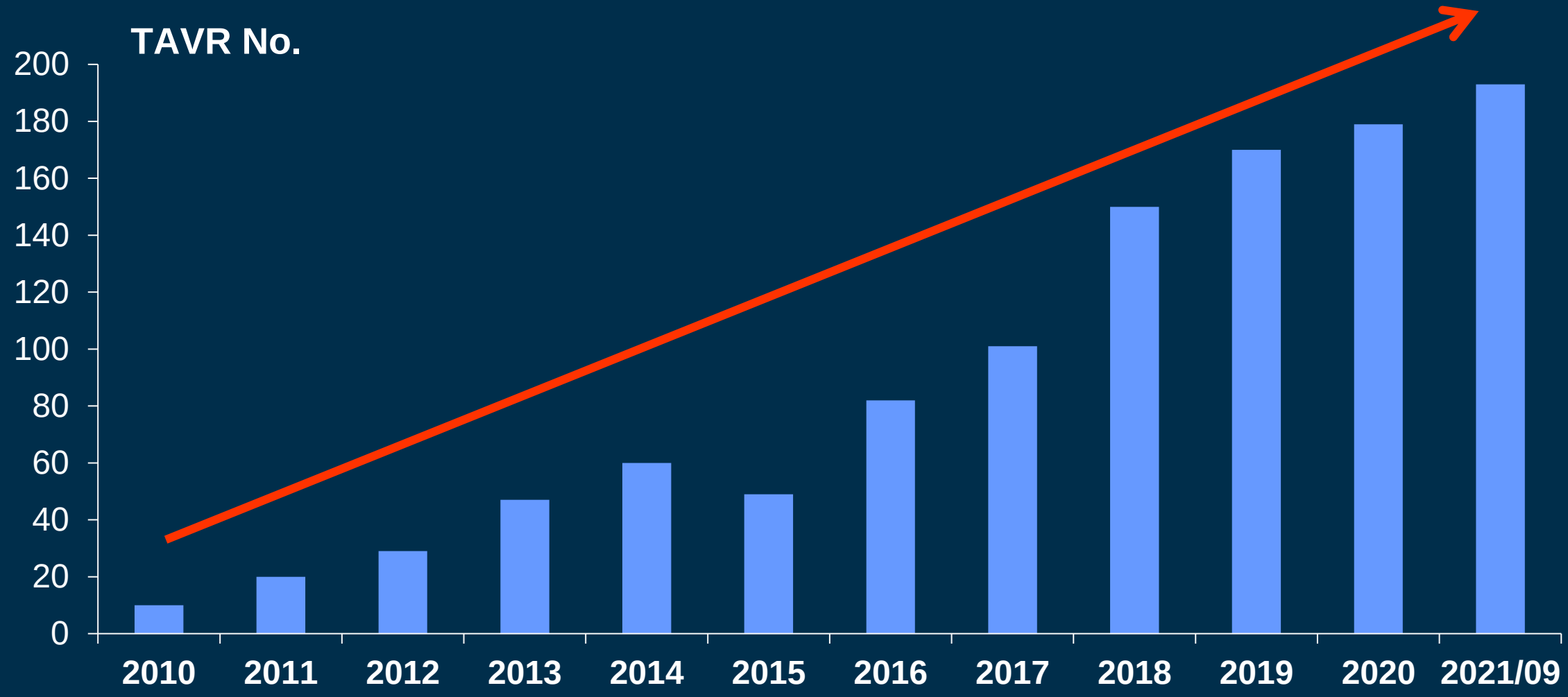
TAVR in AMC

What is the Difference ?

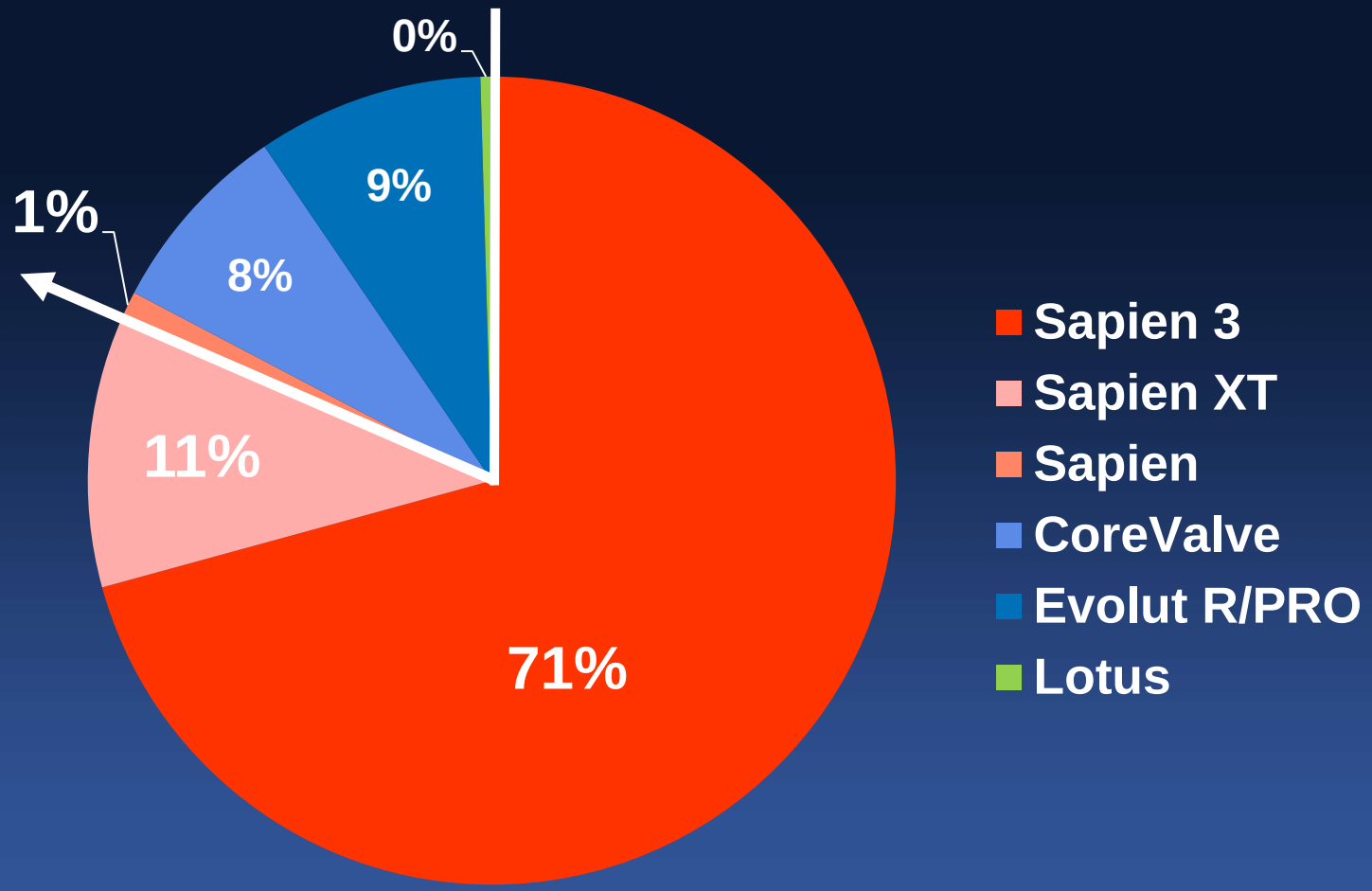
TAVR in AMC

N=1096, 2021/10

over 200 cases/yr



TAVR Devices in AMC



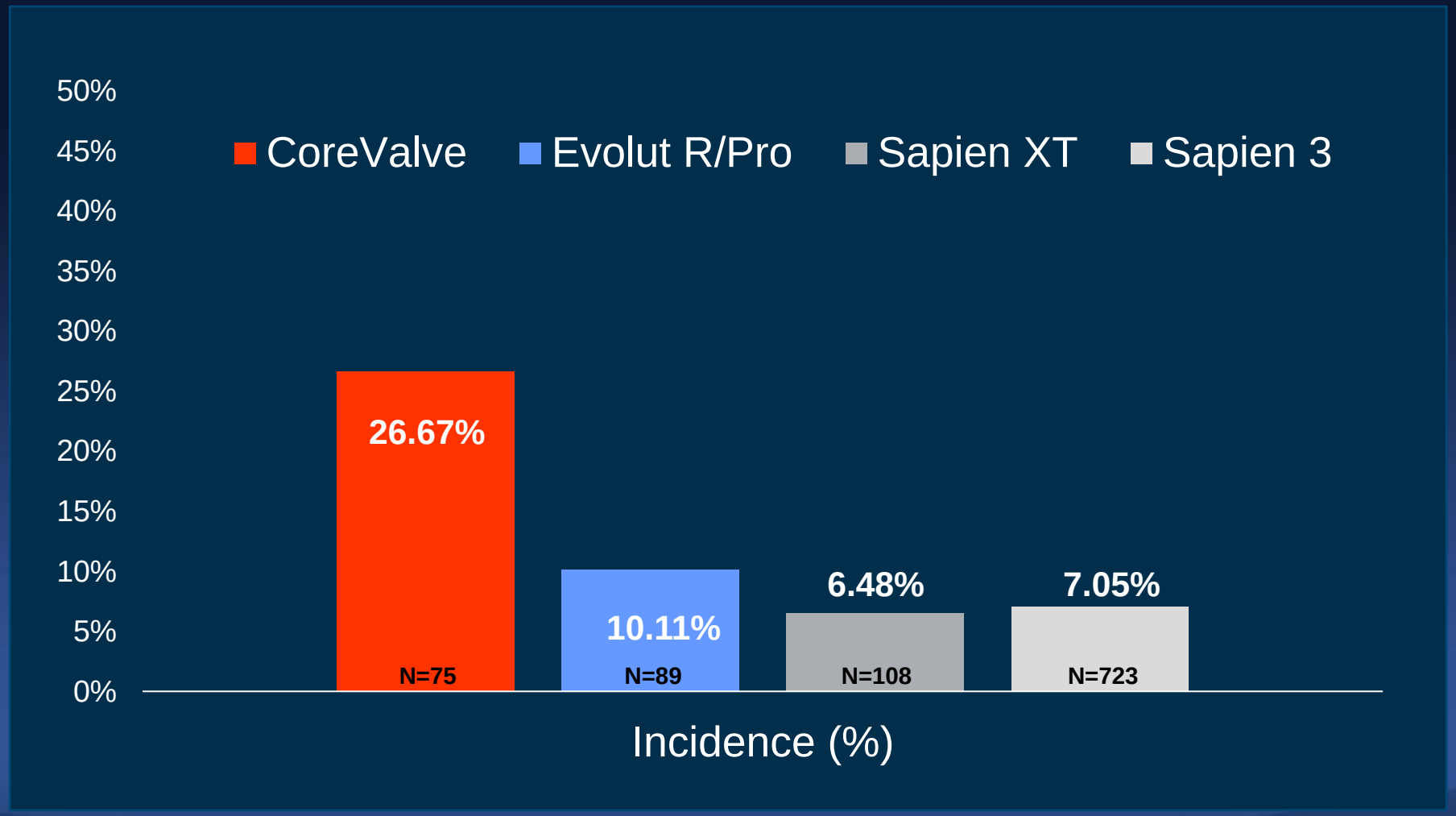
TAVR in AMC

	N = 1017
Age, years	80.30 ± 5.38
Male sex	487 (47.9%)
BMI, kg/m^2	25.95 ± 9.1
STS risk score (%)	4.05 ± 2.71
DM	341 (34.0%)
Hypertension	801 (79.9%)
Atrial fibrillation	126 (12.4%)
Coronary artery disease	401 (40.0%)
Previous MI	4 (4.0%)
Previous stroke	126 (12.6%)
Peripheral vascular disease	53 (5.3%)
ESRD	36 (37.5%)
COPD	130 (13.0%)
LV Ejection fraction, %	60.40 ± 11.5

Procedural Outcomes
TAVR in AMC

	Overall (N = 1004)
Device success	995 (99.1%)
Conversion to surgery	14 (1.4%)
Coronary obstruction	3 (0.3%)
Implantation of two valves	19 (1.9%)
New permanent pacemaker	74 (7.4%)
PVL ≥ moderate	39 (3.9%)
Major vascular complication	35 (3.5%)
Length of hospital stay (days)	7.35±11.10

Incidence of PPM
TAVR in AMC



30 Days Outcomes
TAVR in AMC

	Overall (N = 1004)
Death, all	18 (1.8%)
Cardiac death	13 (1.3%)
Non-cardiac death	5 (0.5%)
Stroke, all	27 (2.7%)
Disabling	9 (0.9%)
Non-disabling	18 (1.8%)
Death or disabling stroke	27 (2.7%)
Bleeding	279 (27.9%)
Life-threatening	46 (4.6%)
Major	152 (15.1%)

30 Days Outcomes in 2020
TAVR in AMC

	Overall (N = 167)
Death, all	1 (0.6%)
Cardiac death	1 (0.6%)
Non-cardiac death	0 (0%)
Stroke, all	2 (1.2%)
Disabling	1 (0.6%)
Non-disabling	1 (0.6%)
Death or disabling stroke	2 (1.2%)
Bleeding, life-threatening	1 (0.6%)
Permanent pacemaker implantation	11 (6.6%)

1 Year Outcomes
TAVR in AMC

	Overall (N = 1004)
Death, all	75 (7.5%)
Cardiac death	24 (2.4%)
Non-cardiac death	51 (5.1%)
Stroke, all	44 (4.4%)
Disabling	16 (1.6%)
Non-disabling	28 (2.8%)
Death or disabling stroke	30 (3.0%)
Rehospitalization	227 (22.6%)
Infective endocarditis	17 (1.7%)

Outcomes of TAVR

Standard Performance (VARC-2*) for AS patients (@ 30 days)		***AMC All***	***AMC 2020***
All-cause mortality	< 3%	1.8%	0.6%
Major (disabling) strokes	< 2%	0.9%	0.6%
Major vascular complications	< 5%	3.5%	0.0%
New permanent pacemakers	< 10%	7.4%	6.6%
Mod-severe PVR	< 5%	3.9%	1.8%

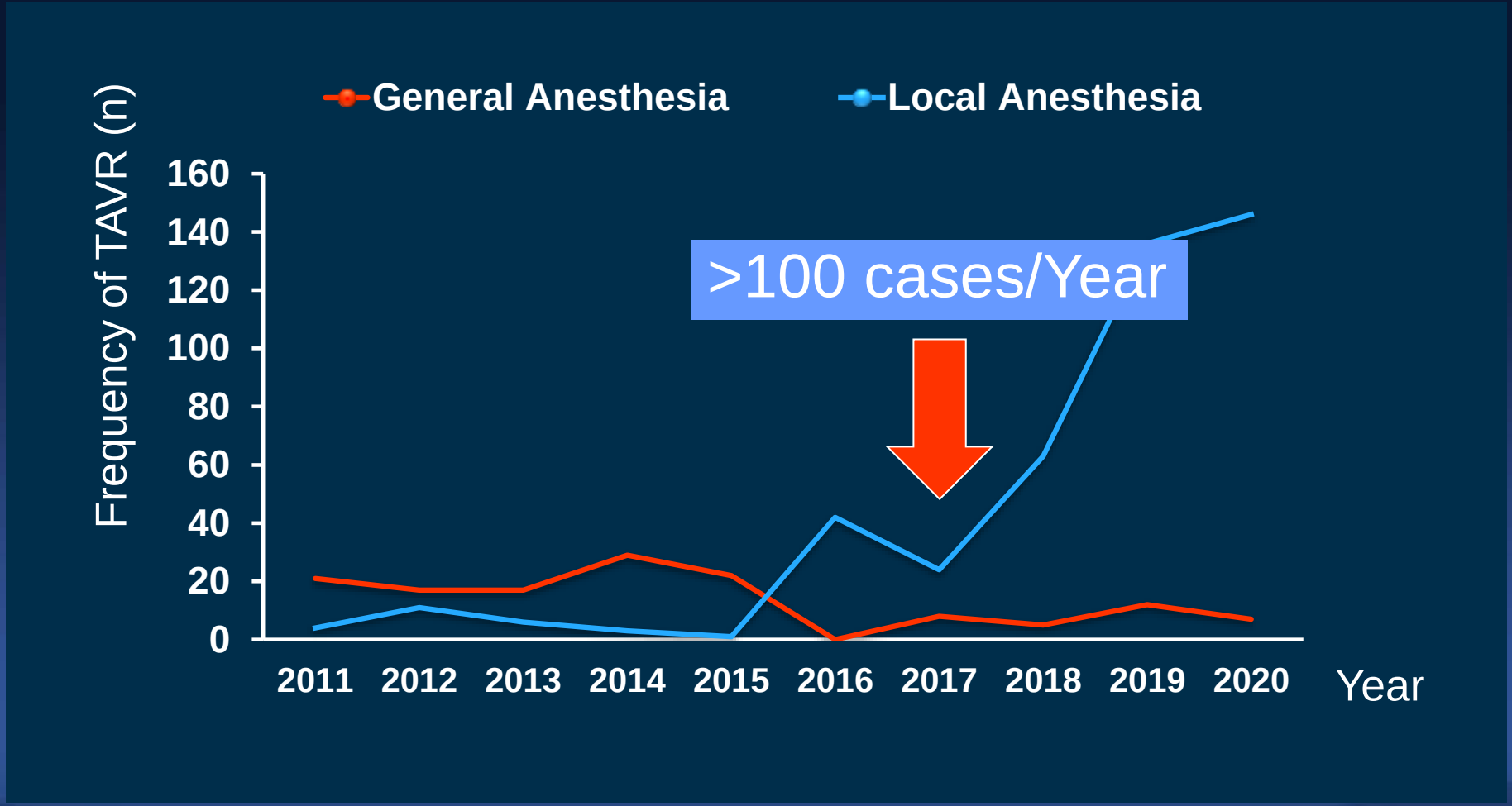
What is the Difference ?
TAVR in AMC

1. *"Heart Team" Perfect Collaboration*
2. *Contemporary "Minimalist Approach"(MAC)*
   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
- No Complications
- 30 min. Procedure
- No Urinary Catheter
- One Day stay in CCU
- Discharge on Day #3
- Cardiac Rehabilitation Program

"Minimalist Approach" (MAC)
TAVR in AMC



TAVR in AMC
Baseline Characteristics

	Overall (N = 1004)	General Anesthesia (N = 245)	Conscious Sedation (MAC) (N = 759)	P value
Age	80.3 ± 5.4	79.79 ± 5.53	80.44 ± 5.30	0.097
Male sex	480 (47.8%)	125 (51.0%)	355 (46.8%)	0.278
BMI, kg/m^2	26.0 ± 3.4	23.76 ± 3.40	26.66 ± 2.6	0.52
STS risk score, %	4.05 ± 2.71	4.32 ± 2.80	3.97 ± 2.67	0.08
DM	341 (34.0%)	81 (33.1%)	260 (34.3%)	0.20
HTN	801 (79.8%)	214 (87.3%)	587 (77.3%)	<0.001
Atrial fibrillation	126 (12.5%)	31 (12.7%)	95 (12.5%)	1.00
CAD	401 (39.9%)	73 (29.1%)	123 (27.4%)	0.63
Previous MI	40 (4.0%)	13 (5.3%)	27 (3.6%)	0.10
Previous stroke	126 (12.5%)	26 (10.6%)	100 (13.2%)	0.13
PVD	53 (5.3%)	27 (11.0%)	26 (3.4%)	<0.001
ESRD	96 (9.6%)	27 (11.0%)	69 (9.1%)	0.14
COPD	130 (12.9%)	39 (15.9%)	91 (12.0%)	0.06

TAVR in AMC
Procedural Characteristics

	Overall (N = 1004)	General Anesthesia (N = 245)	Conscious Sedation(MAC) (N = 759)	P value
Aortic-valve area, cm²	0.61 ± 0.16	0.62 ± 0.19	0.63 ± 0.14	0.39
AV Vmax, m/s	4.9 ± 0.8	4.87 ± 0.87	4.80 ± 0.77	0.24
Mean gradient, mmHg	59.5 ± 21.6	59.5 ± 22.8	56.3 ± 20.9	0.17
Bicuspid AV	72 (10.3%)	20 (8.2%)	85 (11.2%)	0.22
LV EF, %	58.4 ± 11.0	57.1 ± 12.1	59.3 ± 10.2	0.01
Device type				<0.001
Balloon-expandable	831 (82.8%)	158 (64.5%)	673 (88.7%)	
Self-expandable	173 (17.2%)	87 (35.5%)	86 (11.3%)	

TAVR in AMC
Procedural Outcomes

	Overall (N = 1004)	General Anesthesia (N = 245)	Conscious Sedation(MAC) (N = 759)	P value
Device success	995 (99.1%)	237 (96.7%)	758 (99.9%)	<0.001
Conversion to surgery	14 (1.4%)	7 (2.9%)	7 (0.9%)	0.053
Coronary obstruction	3 (0.8%)	1 (0.4%)	7 (0.9%)	0.71
New permanent pacemaker	74 (7.4%)	26 (10.6%)	48 (6.3%)	0.04
PVL ≥ moderate	39 (3.9%)	23 (9.4%)	16 (2.1%)	<0.001
Major vascular complication	35 (3.5%)	21 (8.6%)	14 (1.8%)	<0.001
Length of hospital stay (days)	7.35 ± 11.1	10.2 ± 12.9	6.43 ± 10.3	<0.001

TAVR in AMC
30 Days Outcomes

	Overall (N = 1004)	General Anesthesia (N = 245)	Conscious Sedation(MAC) (N = 759)	P value
Death, all	18 (1.8%)	11 (4.5%)	7 (1.0%)	0.002
Cardiac death	13 (1.3%)	8 (3.3%)	5 (0.7%)	0.005
Non-cardiac death	5 (0.5%)	3 (1.2%)	2 (0.3%)	0.18
Stroke, all	29 (2.9%)	12 (4.9%)	17 (2.2%)	0.18
Disabling	9 (0.9%)	4 (1.6%)	5 (0.7%)	0.31
Non-disabling	20 (2.0%)	8 (3.3%)	12 (1.5%)	0.17
Death or disabling stroke	27 (2.7%)	15 (6.1%)	12 (1.7%)	<0.001
Bleeding	268 (26.8%)	95 (38.8%)	103 (13.6%)	<0.001
Life-threatening	46 (4.6%)	26 (10.6%)	20 (2.6%)	<0.001
Major	152 (15.1%)	69 (28.2%)	83 (10.9%)	<0.001

Outcomes of TAVR

Standard Performance (VARC-2*) for AS patients (@ 30 days)		***AMC All***	***AMC "MAC"***
All-cause mortality	< 3%	2.0%	1.0%
Major (disabling) strokes	< 2%	1.3%	0.7%
Major vascular complications	< 5%	3.5%	1.8%
New permanent pacemakers	< 10%	7.4%	6.3%
Mod-severe PVR	< 5%	3.9%	2.1%

In 2022, TAVR is a Routine Practice

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
30	31	1	2 Groundhog Day Visiting Clinic, EchoCG	3	4	5
6	7 CT & Screening	8 Heart Team Discussion Informed Consent		10 Cardiac Rehab	11 Discharge	12
13	14 Valentine's Day	15	TAVR		18	19
20	21 Presidents' Day	22	23	24	25	26
27	28	1	2	3	4	5

Low-Risk Subset for Same-day G/W Transfer

- Age under 80 years-Old
- Normal LV systolic function
- Tricuspid Valve
- No Frailty
- Lower Calcium Volume < 800
- No Conduction disturbance
  - Pacemaker independent & No A-H block on RA pacing
- No Vascular complication after TAVR

Minimalist TAVR

- Careful patient selection, dedicated procedural technique and post-procedural care are keys to success.
- Minimalist TAVR if done appropriately can provide clinical and economic benefits.