

# Minimalist TAVR with Edwards SAPIEN 3 Valve

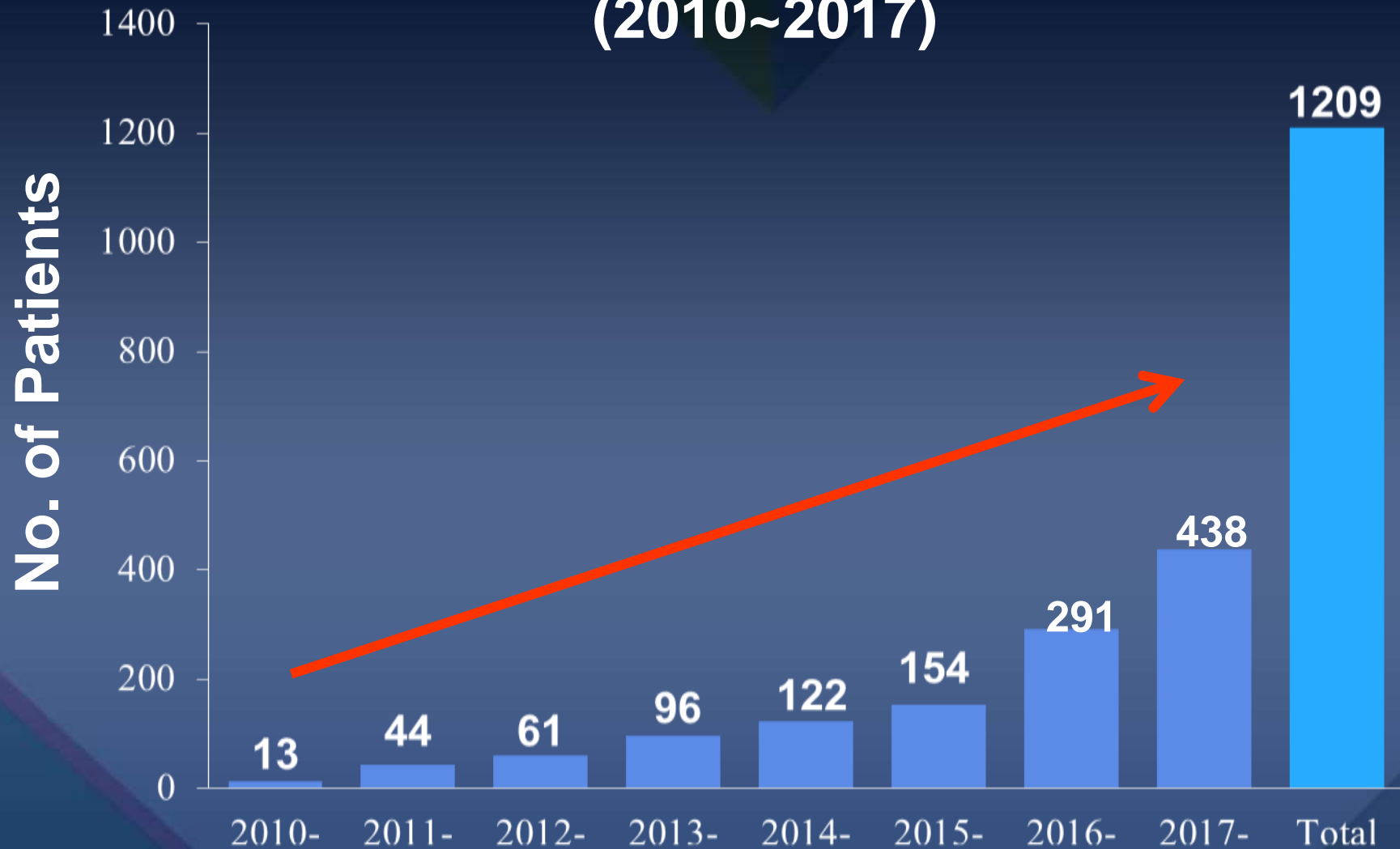
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Asan Medical Center

# Conflict of Interest Statement

- I received lecture fees from
  - Edwards Lifesciences
  - Medtronic, and
  - Boston Scientific

# TAVR in Korea (2010~2017)



# Baseline Characteristics (n=623)

	N=623
Age (Years)	<b>78.6±6.3</b>
Female	51.6 %
STS score	<b>7.83± 8.86</b>
DM	34.6 %
HTN	77.1 %
Stroke or TIA	15.3 %
PAOD	12.7 %
CKD on dialysis	6.4 %
Hospitalization period (Days)	<b>12.1±7.5</b>
TAVR to discharge (Days)	<b>7.8±6.2</b>

# Procedural Characteristics

	N=623
Approach	
Femoral	614 (97.8%)
Apical	11 (1.8%)
Subclavian	3 (0.5%)
Operation room	
<b>Hybrid room</b>	<b>358 (57.0%)</b>
<b>Cath room</b>	<b>270 (43.0%)</b>
Anesthesia duration (mins)	131.5±43.2
<b>General anesthesia</b>	<b>533 (84.9%)</b>
<b>Conscious sedation</b>	<b>95 (15.1%)</b>

# Standard TAVR

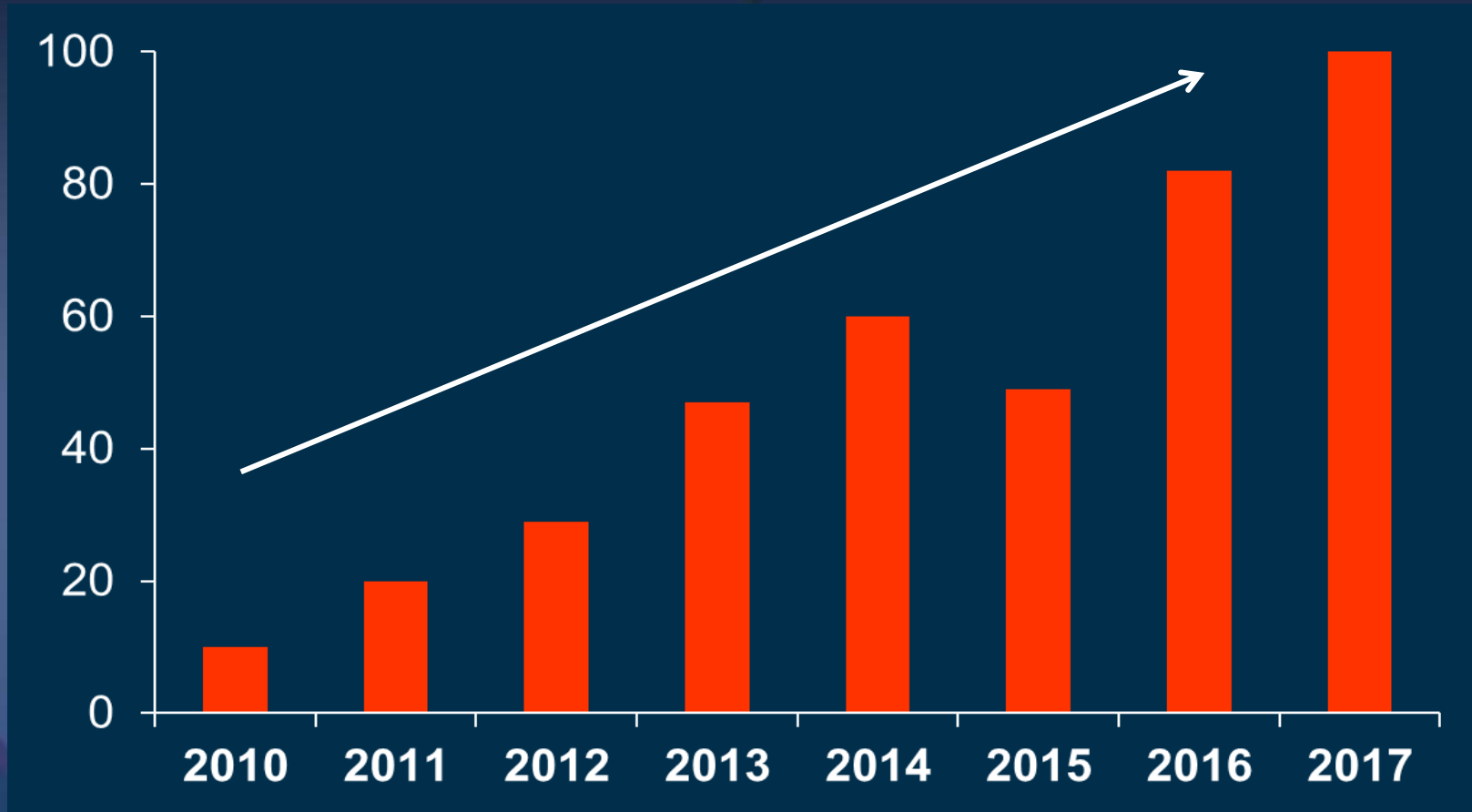
## *Defined by VARC*

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

		<i>Asian 2017</i>	<i>Korea 2017</i>
All-cause mortality	< 3%	2.5%	4.5%
Major (disabling) strokes	< 2%	2.2%	1.4%
Major vascular complications	< 5%	5.0%	? %
New permanent pacemakers	< 10%	9.5%	5.3%
Mod-severe PVR	< 5%	9.8%	5.4%

# *TAVR in AMC*

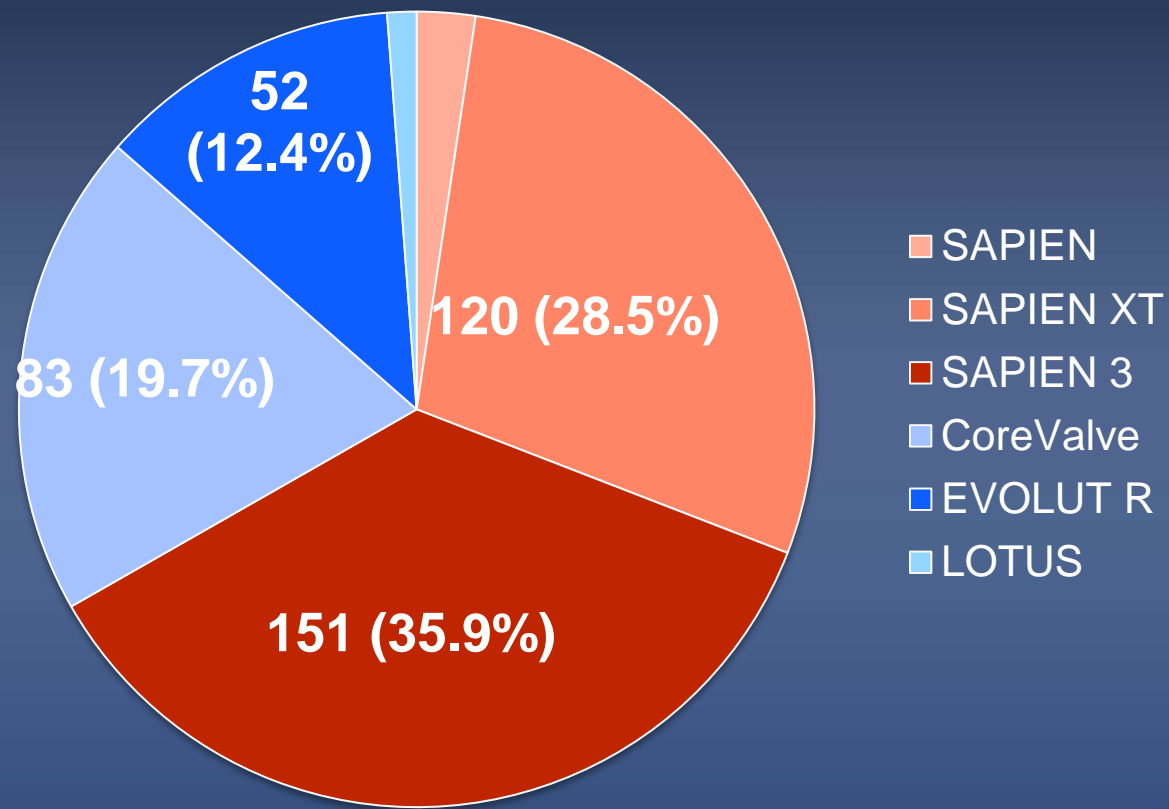
# TAVR in AMC (2010-2017, n=421)





# TAVR in AMC

## Device



# TAVR in AMC

1. Good Collaborative “Heart Team”,
2. Consistent, Meticulous CT Measurement,  
*“Own CT Algorithm for Device Selection”*
3. Simplification of the Procedure,  
*“Minimalist Approach”*

# Procedural Change in AMC : TAVR minimalist

- General anesthesia
- Intubation



## \*\*Simpler TAVR\*\*

- Procedure <60 min
- 1 night stay at CCU
- Discharge on Day #3

**TEE**



# Standard TAVR vs. Minimal TAVR



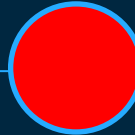
# Minimal Approach:

«Assisting Staff»:

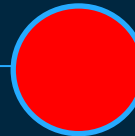
- Anesthetist (stand-by)
- Cardiac surgeon (near-by)

Prep. Table

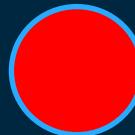
Interventionist  
#1



Interventionist  
#2



Fellow



NURSE  
RVP



CRIMPING



# ***“Minimalist Approach”***

## **TAVR in AMC**

**Conscious Sedation, No General Anesthesia**

**Requires High Operator/Team Experience**

**No TEE, but TTE**

**No central venous catheter**

**30 min. Procedure**

**Early assessment of neurologic status**

**Early recovery, shorter length of stay,**

**Discharge on Day #3**

**Less Complications, Better Outcomes**

# ***“Minimalist Approach”***

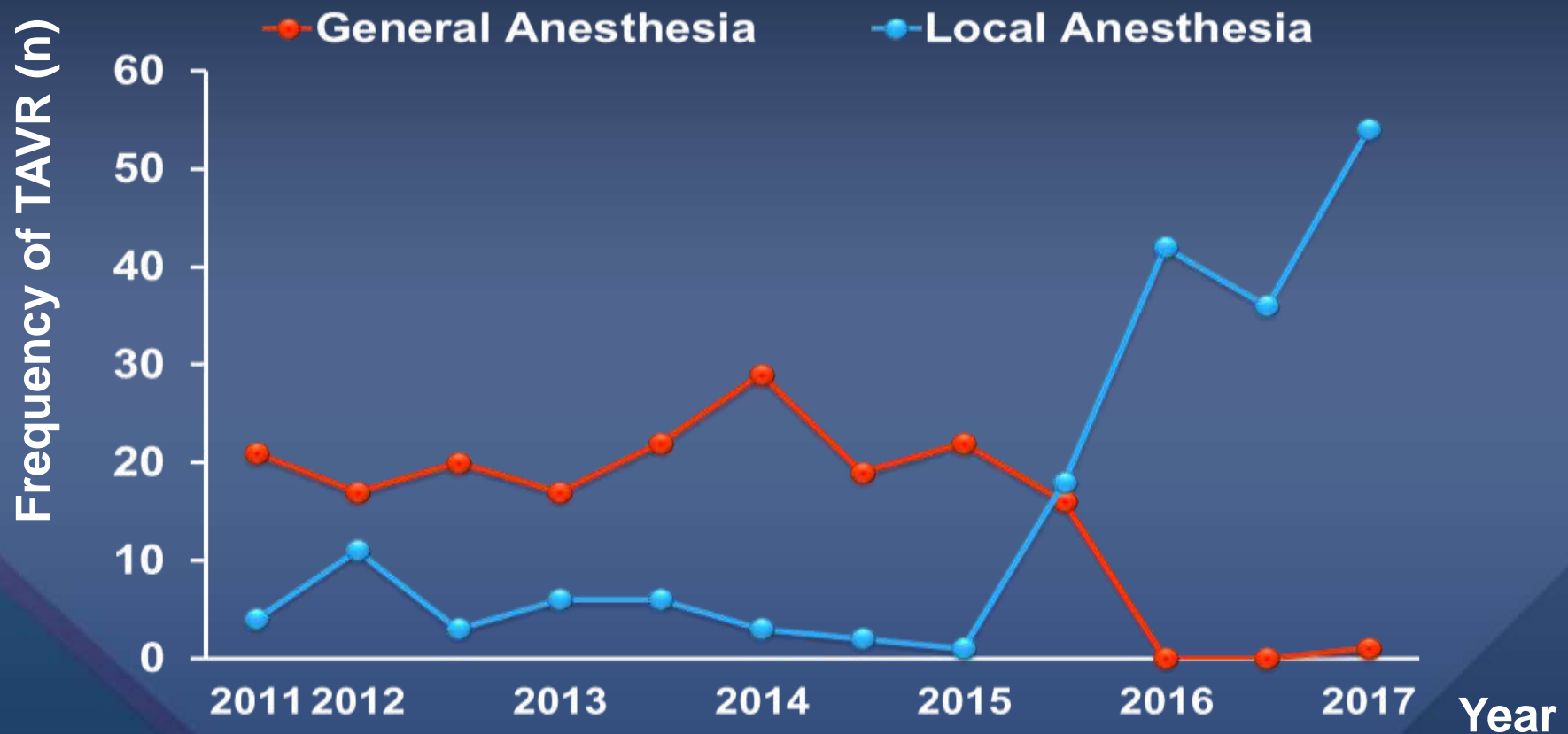
## **Post TAVR Care in AMC**

- Short stay (1 day) in ICU
- Optional temporary pacemaker
- Early mobilization
- Avoid polypharmacy
- Cardiac Rehabilitation Clinic



# *“Minimalist Approach”*

## TAVR in AMC





# TAVR in AMC

## Baseline Characteristics

	Overall (N = 403)	General Anesthesia (N = 200)	Conscious Sedation (N = 203)	P value
Age	78.8 ± 5.0	77.9 ± 5.3	79.7 ± 4.6	0.001
Male sex	189 (46.9%)	99 (49.5%)	90 (44.3%)	0.30
BMI, kg/m <sup>2</sup>	24.0 ± 3.3	24.1 ± 3.2	23.8 ± 3.4	0.41
STS risk score, %	4.1 ± 3.2	4.2 ± 3.8	4.0 ± 2.5	0.57
DM	128 (31.8%)	67 (33.5%)	61 (30.0%)	0.39
HTN	339 (84.1%)	168 (84.0%)	171 (84.2%)	0.94
Atrial fibrillation	57 (14.1%)	28 (14.0%)	29 (14.3%)	0.92
CAD	143 (35.5%)	78 (39.0%)	65 (32.0%)	0.11
Previous MI	19 (4.7%)	6 (3.0%)	13 (6.4%)	0.12
Previous stroke	39 (9.7%)	16 (8.0%)	23 (11.3%)	0.22
PVD	21 (5.2%)	13 (6.5%)	8 (3.9%)	0.31
CKD	114 (28.3%)	61 (30.5%)	53 (26.1%)	0.29
COPD	62 (15.4%)	36 (18.0%)	26 (12.5%)	0.11

# TAVR in AMC

## Procedural Characteristics

	Overall (N = 403)	General Anesthesia (N = 200)	Conscious Sedation (N = 203)	P value
<b>Aortic-valve area, cm<sup>2</sup></b>	0.60 ± 0.17	0.60 ± 0.17	0.60 ± 0.16	0.92
<b>AV Vmax, m/s</b>	5.0 ± 0.8	4.9 ± 0.8	5.0 ± 0.9	0.33
<b>Mean gradient, mmHg</b>	60.8 ± 22.9	59.7 ± 22.6	62.4 ± 23.4	0.29
<b>Bicuspid AV</b>	35 (8.7%)	20 (10.0%)	15 (7.4%)	0.37
<b>LV EF, %</b>	58.3 ± 11.1	58.8 ± 10.8	57.8 ± 11.4	0.45
<b>Device type</b>				<b>0.003</b>
<b>Balloon-expandable</b>	261 (64.8%)	115 (57.5%)	146 (71.9%)	
<b>Self-expandable</b>	142 (35.2%)	85 (42.5%)	57 (28.1%)	

# TAVR in AMC

## Procedural Outcomes

	Overall (N = 403)	General Anesthesia (N = 200)	Conscious Sedation (N = 203)	P value
Device success	393 (97.5%)	193 (96.5%)	200 (98.5%)	0.16
Conversion to surgery	6 (1.5%)	5 (2.5%)	1 (0.5%)	0.10
Coronary obstruction	1 (0.2%)	1 (0.5%)	0	0.50
Implantation of two valves	12 (3.0%)	10 (5.0%)	2 (1.0%)	<b>0.02</b>
New permanent pacemaker	34 (8.4%)	20 (10.0%)	14 (6.9%)	0.26
PVL ≥ moderate	25 (6.3%)	20 (10.2%)	5 (2.5%)	<b>0.002</b>
Major vascular complication	19 (4.7%)	17 (8.5%)	2 (1.0%)	<b>&lt;0.001</b>
Length of hospital stay (days)	8.6 ± 13.5	9.7 ± 8.8	7.4 ± 16.8	<b>&lt;0.001</b>

# TAVR in AMC

## 30 Days Outcomes

	Overall (N = 403)	General Anesthesia (N = 200)	MAC (N = 203)	P value
Death, all	10 (2.5%)	9 (4.5%)	1 (0.5%)	<b>0.01</b>
Cardiac death	6 (1.5%)	5 (2.5%)	1 (0.5%)	0.10
Non-cardiac death	4 (1.0%)	4 (2.0%)	0	<b>0.043</b>
Stroke, all	13 (3.2%)	11 (5.5%)	2 (1.0%)	<b>0.01</b>
Disabling	6 (1.5%)	4 (2.0%)	2 (1.0%)	0.40
Non-disabling	7 (1.7%)	7 (3.5%)	0	0.07
Death or disabling stroke	15 (3.7%)	12 (6.0%)	3 (1.5%)	<b>0.015</b>
Bleeding	130 (32.3%)	86 (43.0%)	44 (21.7%)	<b>&lt;0.001</b>
Life-threatening	30 (7.4%)	21 (10.5%)	9 (4.4%)	<b>0.02</b>
Major	117 (29.0%)	79 (39.5%)	38 (18.7%)	<b>&lt;0.001</b>

# Standard TAVR

## *Defined by VARC*

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

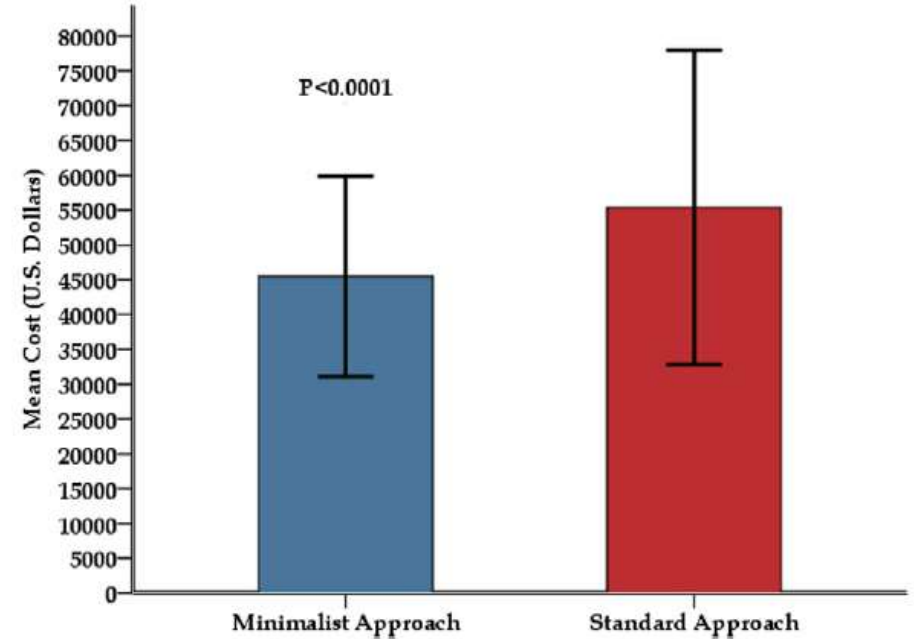
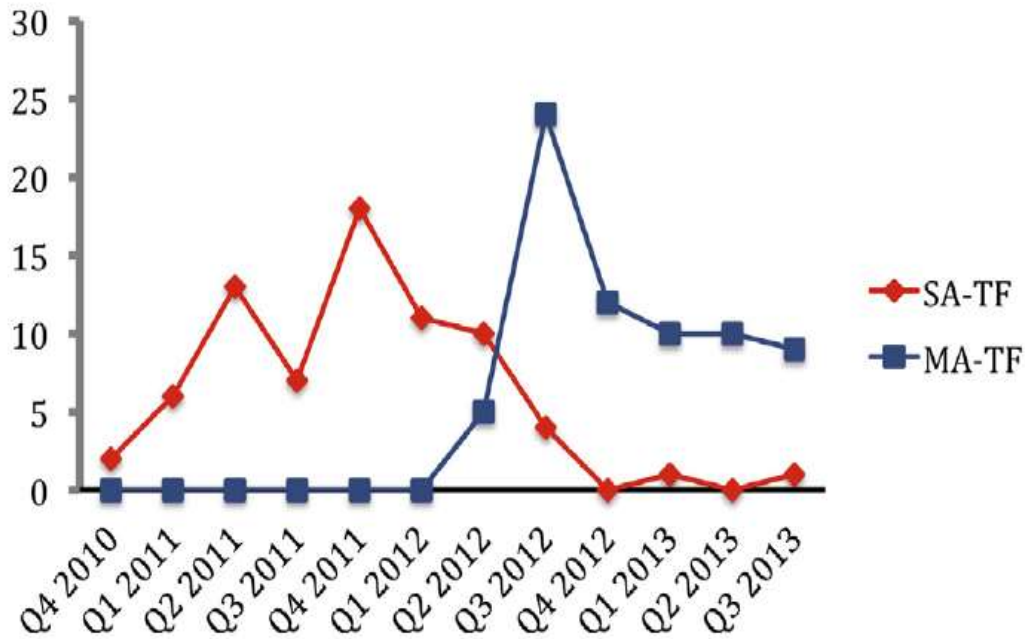
		<i>Asian 2017</i>	<i>AMC 2018</i>	<i>AMC “MAC”</i>
All-cause mortality	< 3%	2.5%	2.5%	0.5%
Major (disabling) strokes	< 2%	2.2%	3.2%	1.0%
Major vascular complications	< 5%	5.0%	4.7%	1.0%
New permanent pacemakers	< 10%	9.5%	8.4%	6.9%
Mod-severe PVR	< 5%	9.8%	6.3%	2.5%

# General Anesthesia vs. Local Anesthesia Current Cumulative Evidence

# Comparison of Transfemoral Transcatheter Aortic Valve Replacement Performed in the Catheterization Laboratory (Minimalist Approach) Versus Hybrid Operating Room (Standard Approach) Outcomes and Cost Analysis

- A total of 142 patients: 70 MA vs. 72 standard approach at Emory University, USA.

# Minimal vs. Standard Approach Trend Over Time and Total Costs

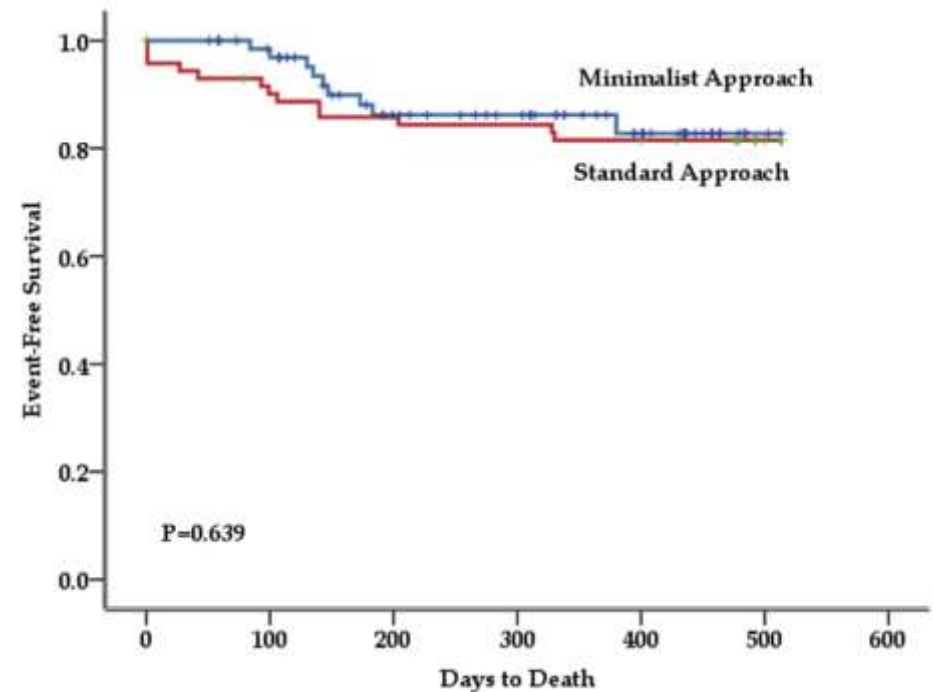




# Minimal vs. Standard Approach Outcome

**TABLE 3** Outcomes

Outcome	Minimalist Approach (n = 70)	Standard Approach (n = 72)	p Value
In-hospital mortality	0 (0)	3 (4.2)	0.24
Patients receiving ICU care	53 (75)	69 (100)	<0.001
Total ICU time, h*	22 (2-28)	28 (23-48)	<0.001
Length of stay, days*	4 (3-7)	6 (4-9)	0.01
Length of stay: procedure to discharge, days*	3 (2-4)	5 (3-6.5)	<0.001



# Structural Heart Disease

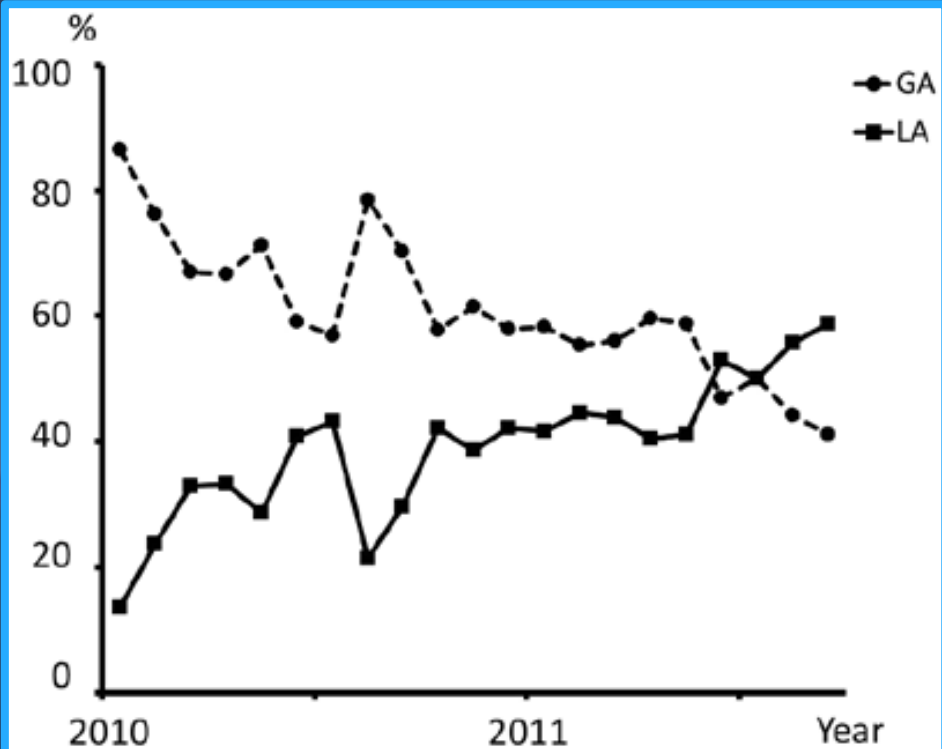
## Clinical Outcomes and Safety of Transfemoral Aortic Valve Implantation Under General Versus Local Anesthesia Subanalysis of the French Aortic National CoreValve and Edwards 2 Registry

Atsushi Oguri, MD; Masanori Yamamoto, MD; Gauthier Mouillet, MD; Martine Gilard, MD;  
Marc Laskar, MD; Helene Eltchaninoff, MD; Jean Fajadet, MD; Bernard Iung, MD;  
Patrick Donzeau-Gouge, MD; Pascal Leprince, MD; Alain Leguerrier, MD; Alain Prat, MD;  
Michel Lievre, PhD; Karine Chevreul, MD; Jean-Luc Dubois-Rande, MD;  
Romain Chopard, MD; Eric Van Belle, MD; Toshiaki Otsuka, MD; Emmanuel Teiger, MD;  
on behalf of FRANCE 2 Registry Investigators

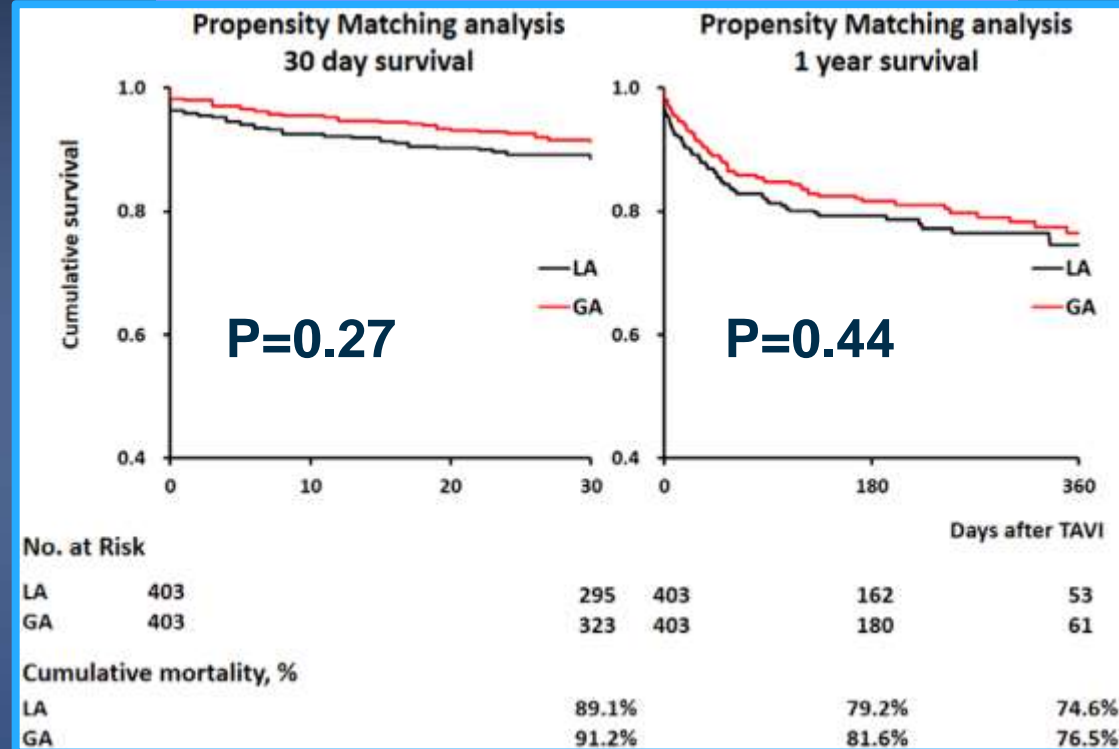
- 2326 TF-TAVR patients in the FRANCE 2 registry.
- All patients: GA (n=1377) and LA (n=949)
- Propensity-matched cohort (N=401)

# Change of TAVR Pattern and Outcome

## Change of Anesthesia



## Mortality of Propensity-Matched Cohort



# Systemic Review and Meta-Analysis Local and General Anesthesia

Open Access

Research

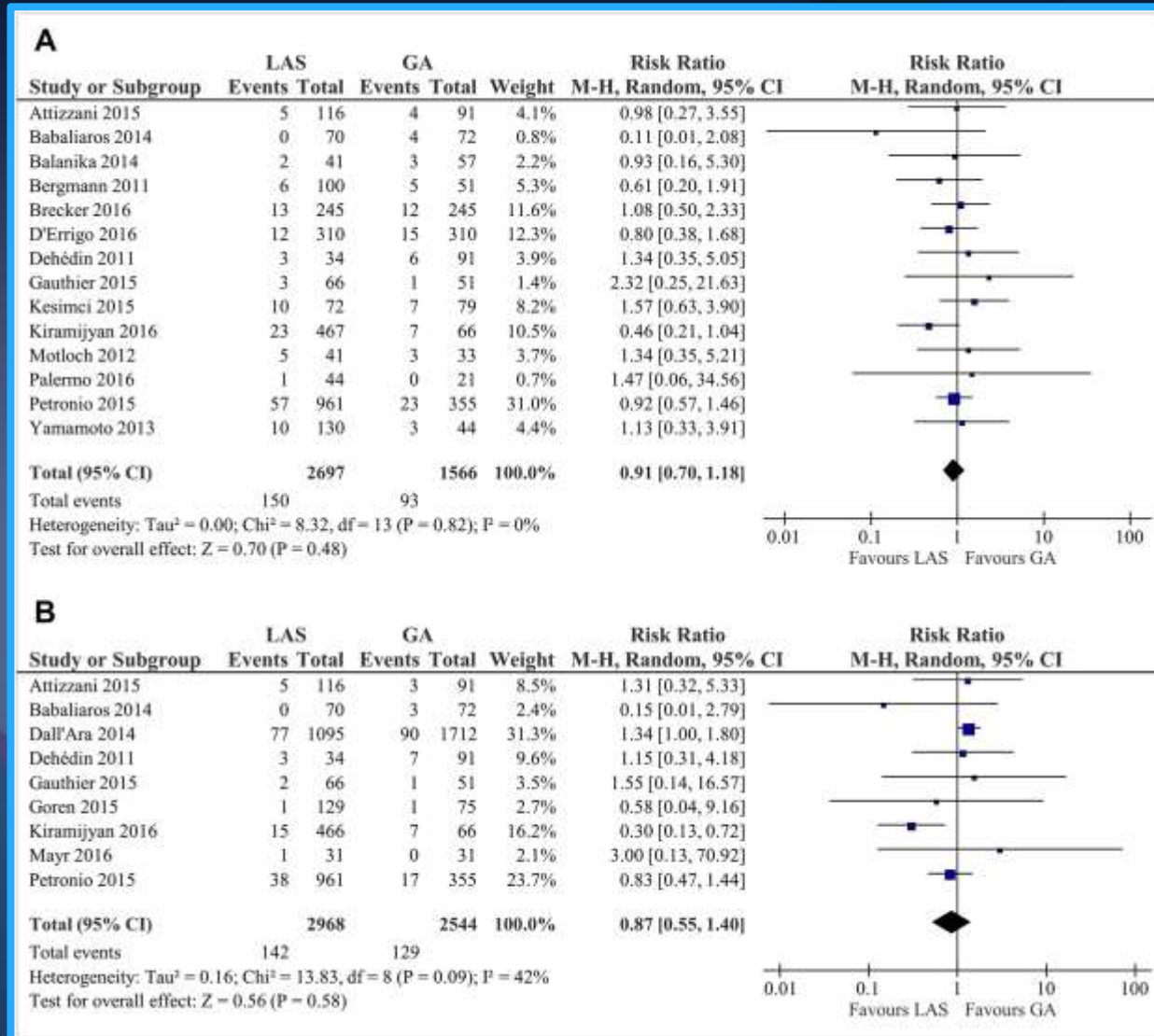
## BMJ Open Is local anaesthesia a favourable approach for transcatheter aortic valve implantation? A systematic review and meta-analysis comparing local and general anaesthesia

Constanze Ehret,<sup>1</sup> Rolf Rossaint,<sup>1</sup> Ann Christina Foldenauer,<sup>2</sup> Christian Stoppe,<sup>1</sup> Ana Stevanovic,<sup>1</sup> Katharina Dohms,<sup>1</sup> Marc Hein,<sup>1</sup> Gereon Schälte<sup>1</sup>

1 RCT and 19 observational studies were included in the review.



# Systemic Review and Meta-Analysis Local and General Anesthesia

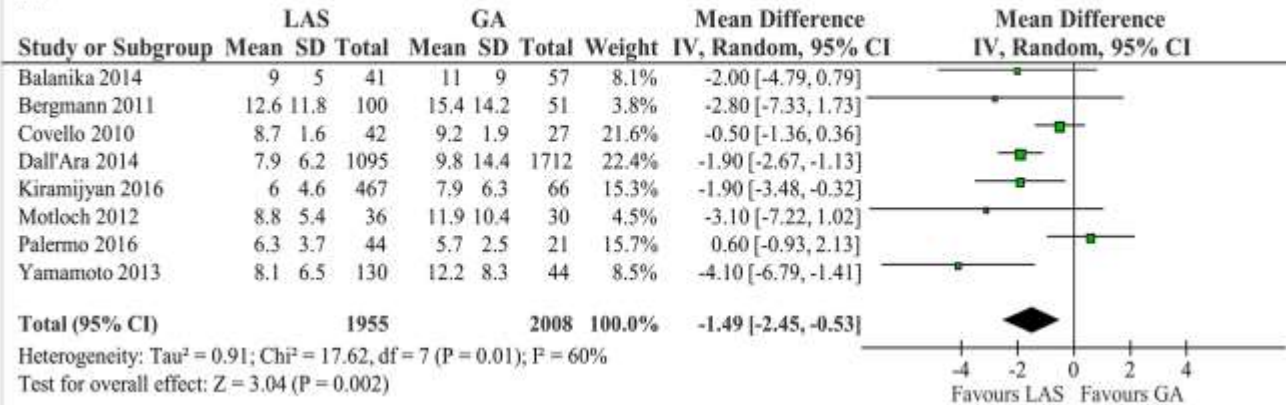


30-Days Mortality  
“No Difference”

In-Hospital Mortality  
“No Difference”

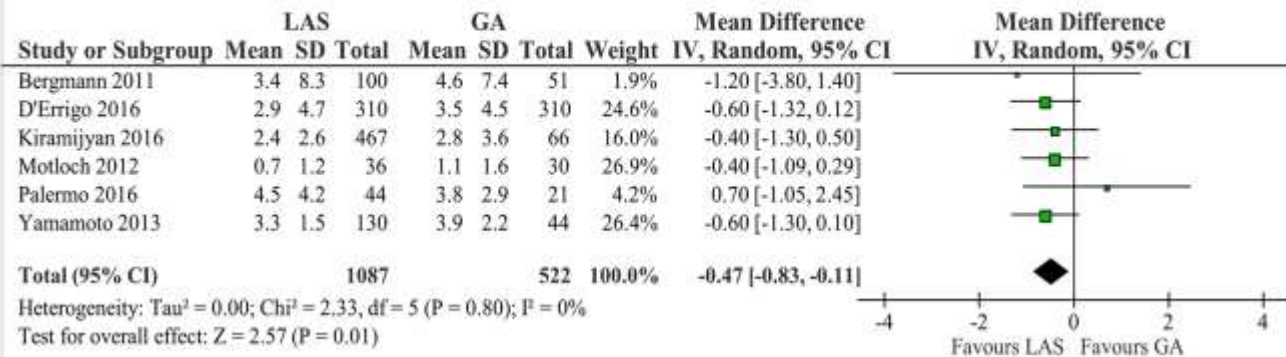
# Systemic Review and Meta-Analysis Local and General Anesthesia

**A**



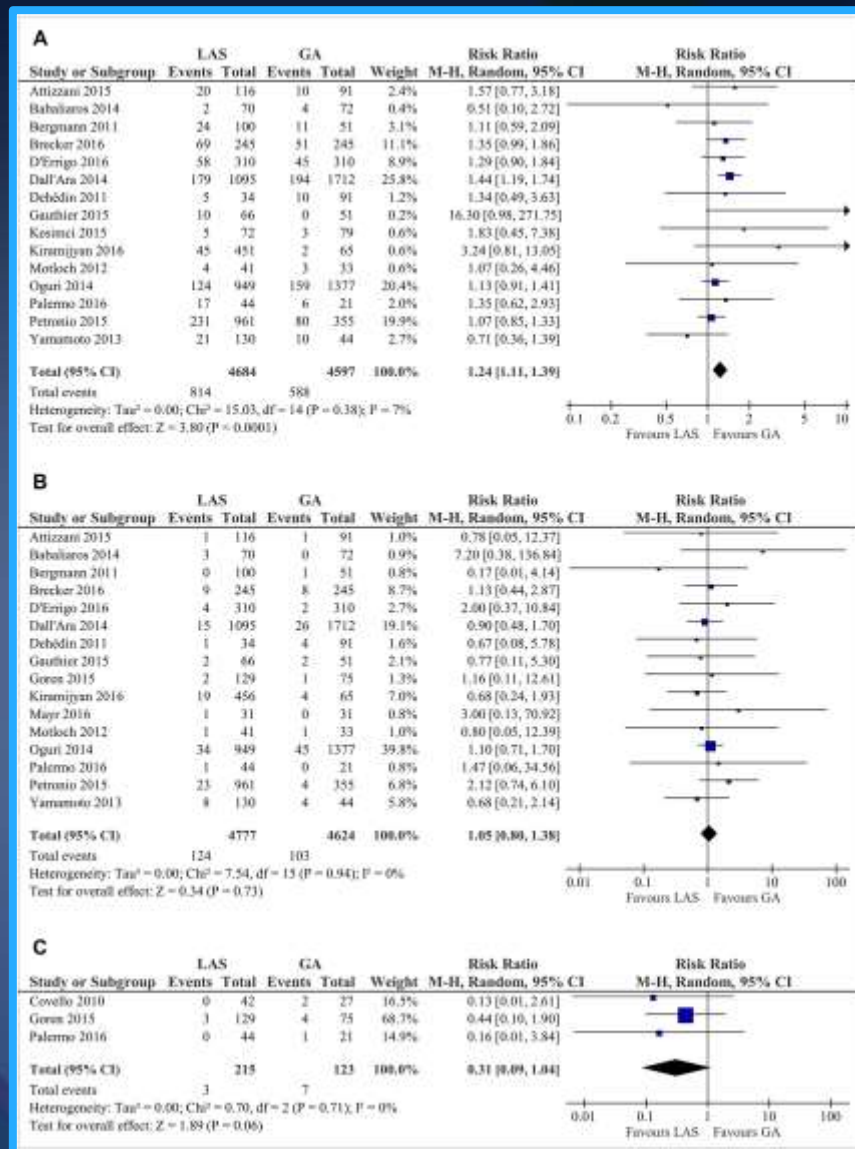
Length of hospital stay  
“LAS Is Better”

**B**



Length of ICU stay  
“LAS Is Better”

# Systemic Review and Meta-Analysis Local and General Anesthesia



New pacemaker insertion  
“GA Is Better”

Stroke  
“No Difference”

Pneumonia  
“LAS Is Better”

**STRUCTURAL: FOCUS ON TAVR**

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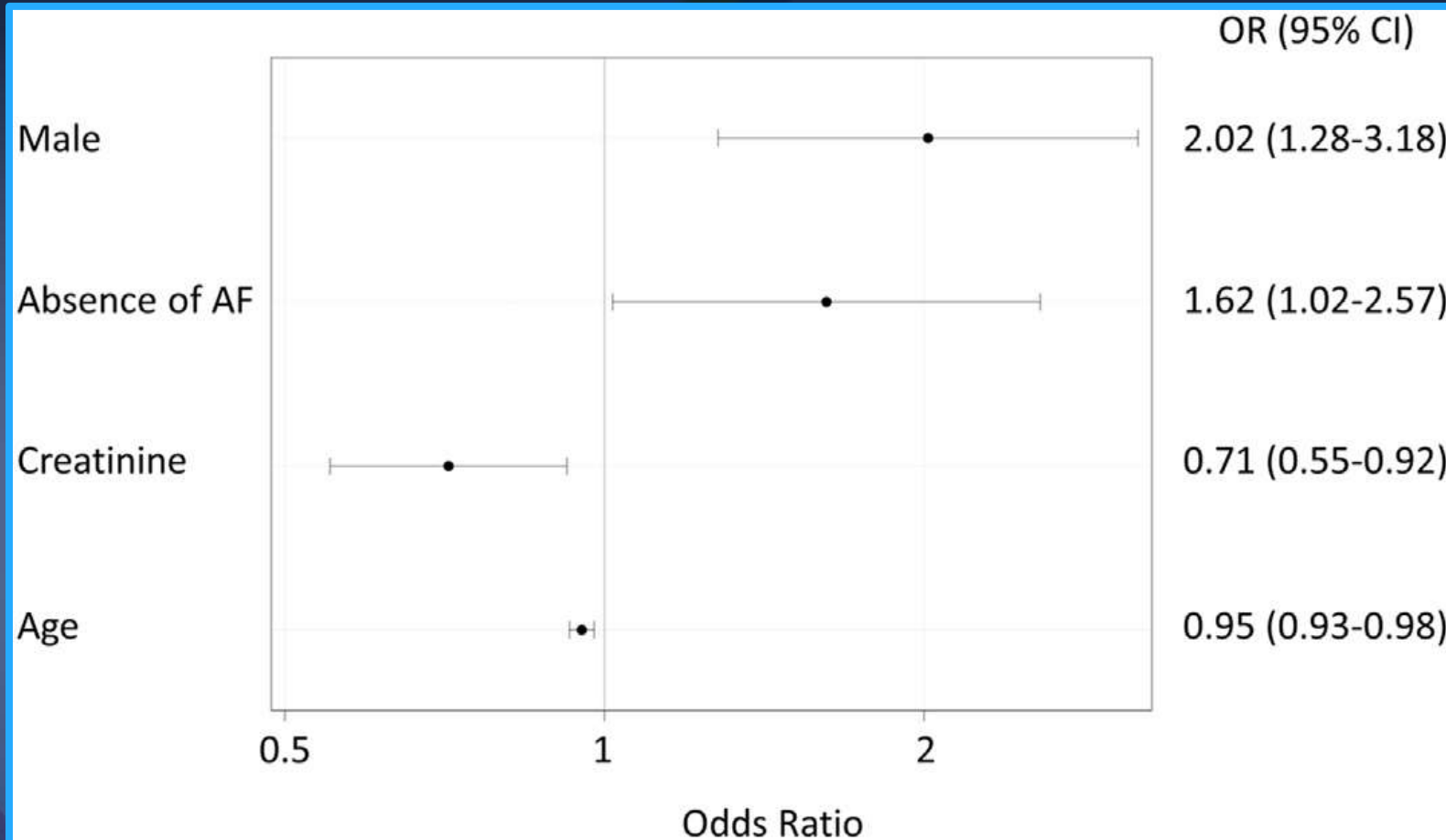
# Predictors and Clinical Outcomes of Next-Day Discharge After Minimalist Transfemoral Transcatheter Aortic Valve Replacement



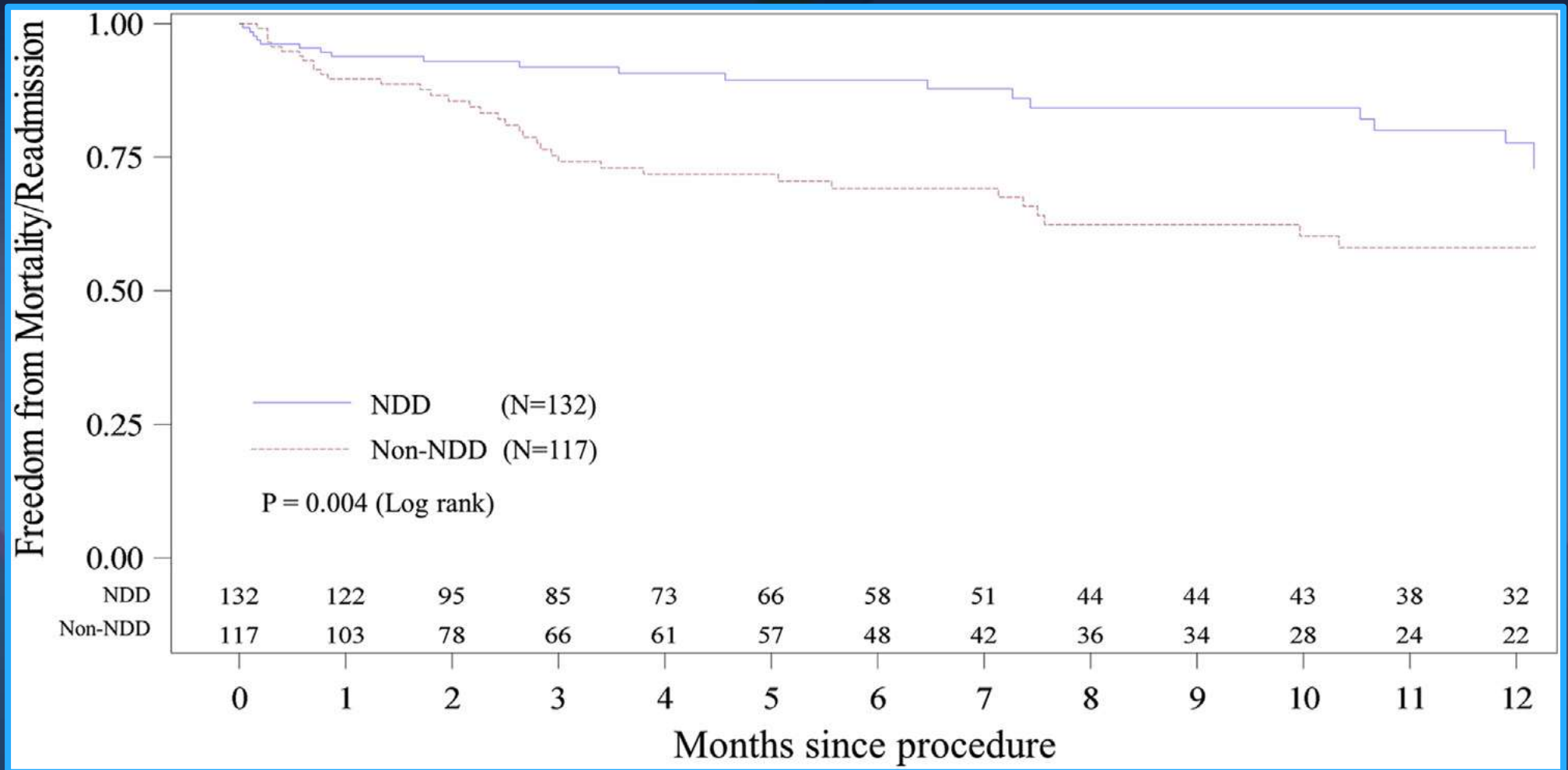
- TF-TAVR with minimalist approach using SXT/S3.
- Among 360 eligible patients, 150 cases with next-day discharge and 210 cases with non-next-day discharge.



# Predictors of Next-Day Discharge



# Kaplan-Meier Curves of the Composite Endpoint of Death and Readmission



# Key Milestones Starting a Minimalist TAVR

- Pre-procedural Planning - Focus on the use of MDCT.
- Understanding of the anatomy.
- Minimalist procedure setting - reducing procedure duration, hemodynamic instability.
- Rigorous step-wise procedural approach.

# Summary

- An international trend toward minimalist TAVR.
  - appears as safe as conventional strategy
  - rapid recovery, shorter length of stay, and dramatic reduction in cost are achievable.
- When an experienced TAVR center decides to transition from GA to MAC;
  - procedural expertise, collaborative heart-team approach and anesthesia care should be guaranteed.
  - acute procedural success and long-term outcomes should not be jeopardized.

# Minimalist TAVR

- No high risk clinical or anatomic features
- Minimalist Approach:
  - Conscious sedation
  - Transthoracic echo
  - No neck line or Swan
  - Groin access only
  - No Foley catheter
  - Avoid ICU admission



**“Expedited Recovery”**