Mainstream of TAVR: Minimalist Approach

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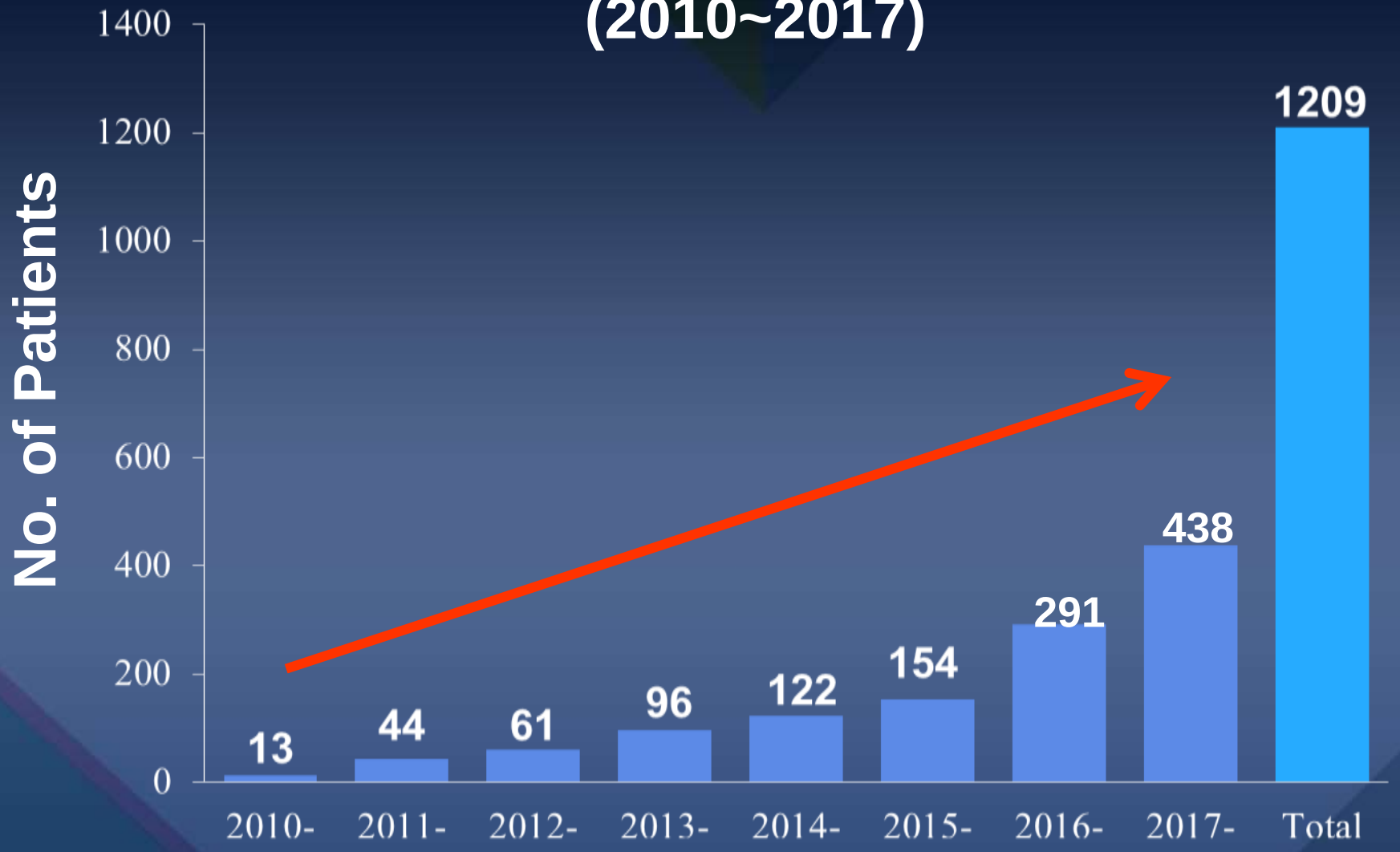
Conflict of Interest Statement

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
Consulting Fees/Honoraria	Edwards LifeSciences
Consulting Fees/Honoraria	Medtronic Inc
Consulting Fees/Honoraria	Boston Scientific

TAVR in Korea

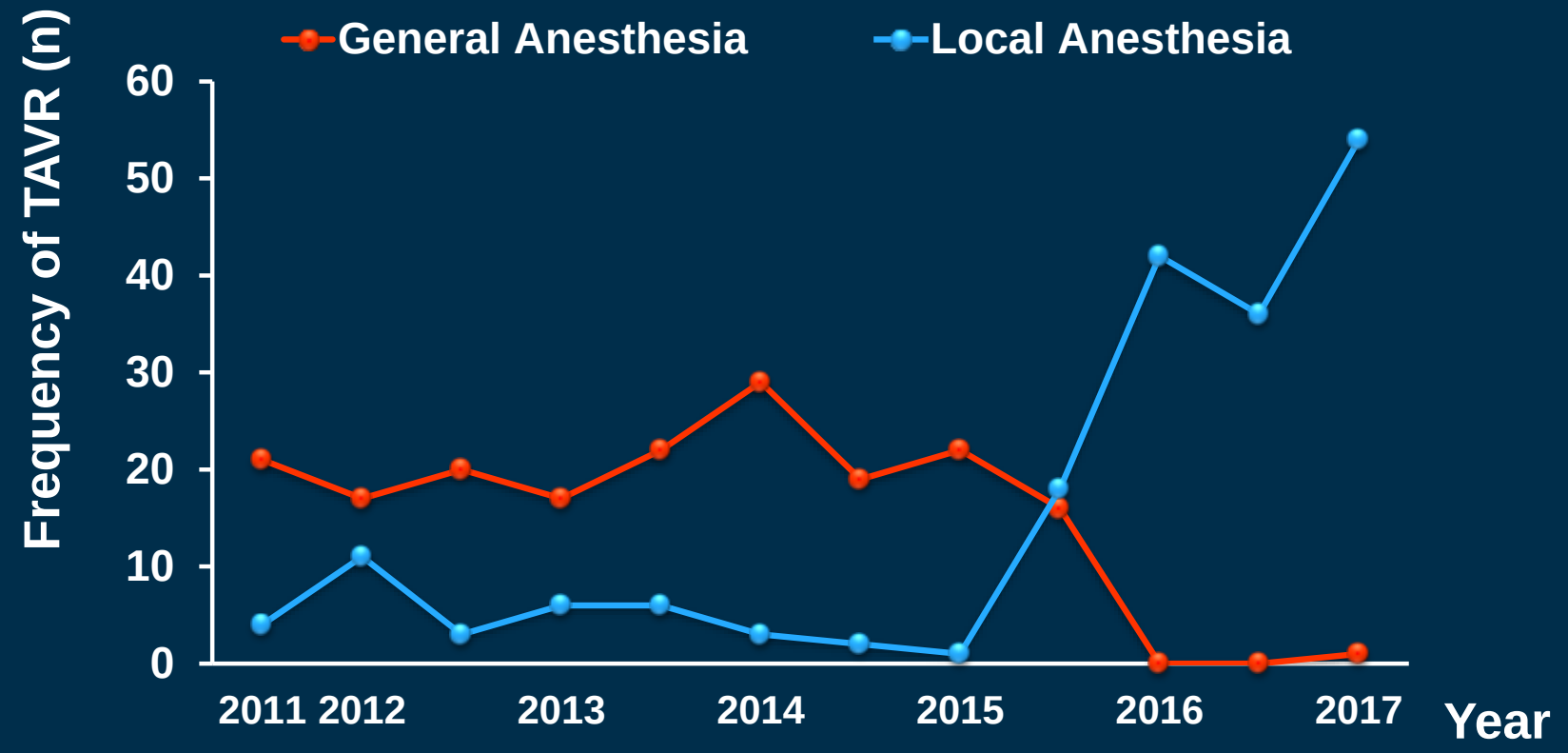
(2010~2017)



Current TAVR Status in Korea

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

"Minimalist Approach"
TAVR in AMC

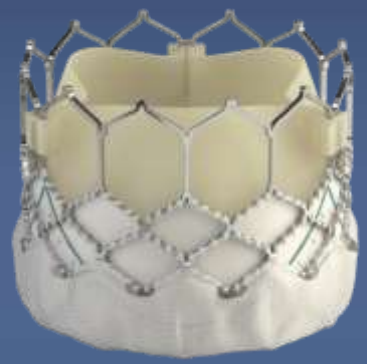


"Minimalist Approach"
TAVR in AMC

- Conscious Sedation, No General Anesthesia
- No TEE, but TTE
- No central venous catheter (i.e. jugular)
- No Foley
- <1 hour Procedure
- Early assessment of neurologic status
- Early recovery, shorter length of stay, discharge on Day #3
- Less Complications, Better Outcomes

What has allowed Minimalist TAVR evolution?

- Newer-generation TAVR systems (lower profile, more predictable deployment)



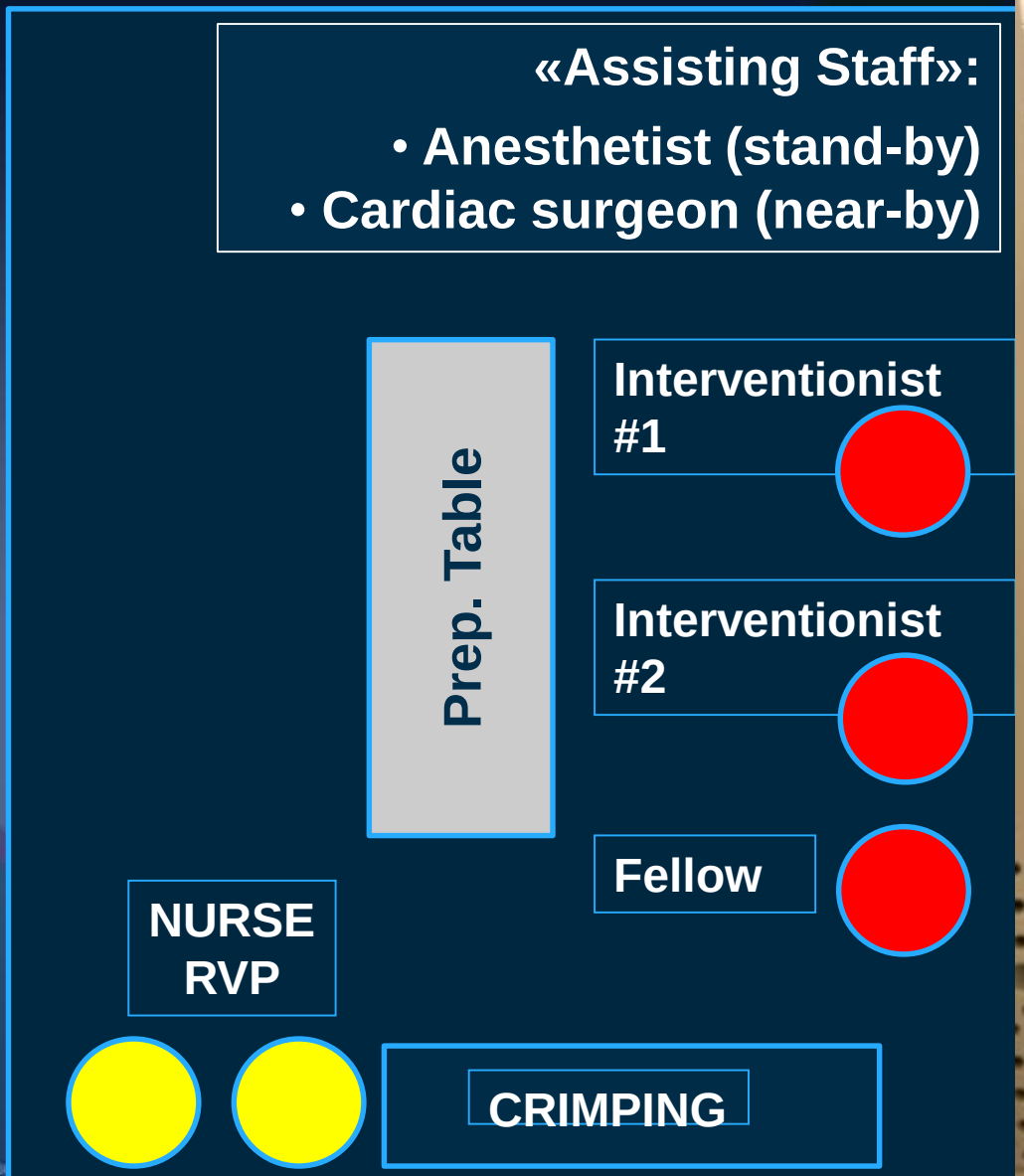
- Improved screening and patient selection
- Improved technique with lower complications
- Experienced operator expertise

Standard TAVR vs. Minimal TAVR

Minimal Approach: Cath Lab Setting

«Assisting Staff»:

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



"Minimalist Approach"
Post TAVR Care in AMC

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

Minimalist TAVR: Why? For What?

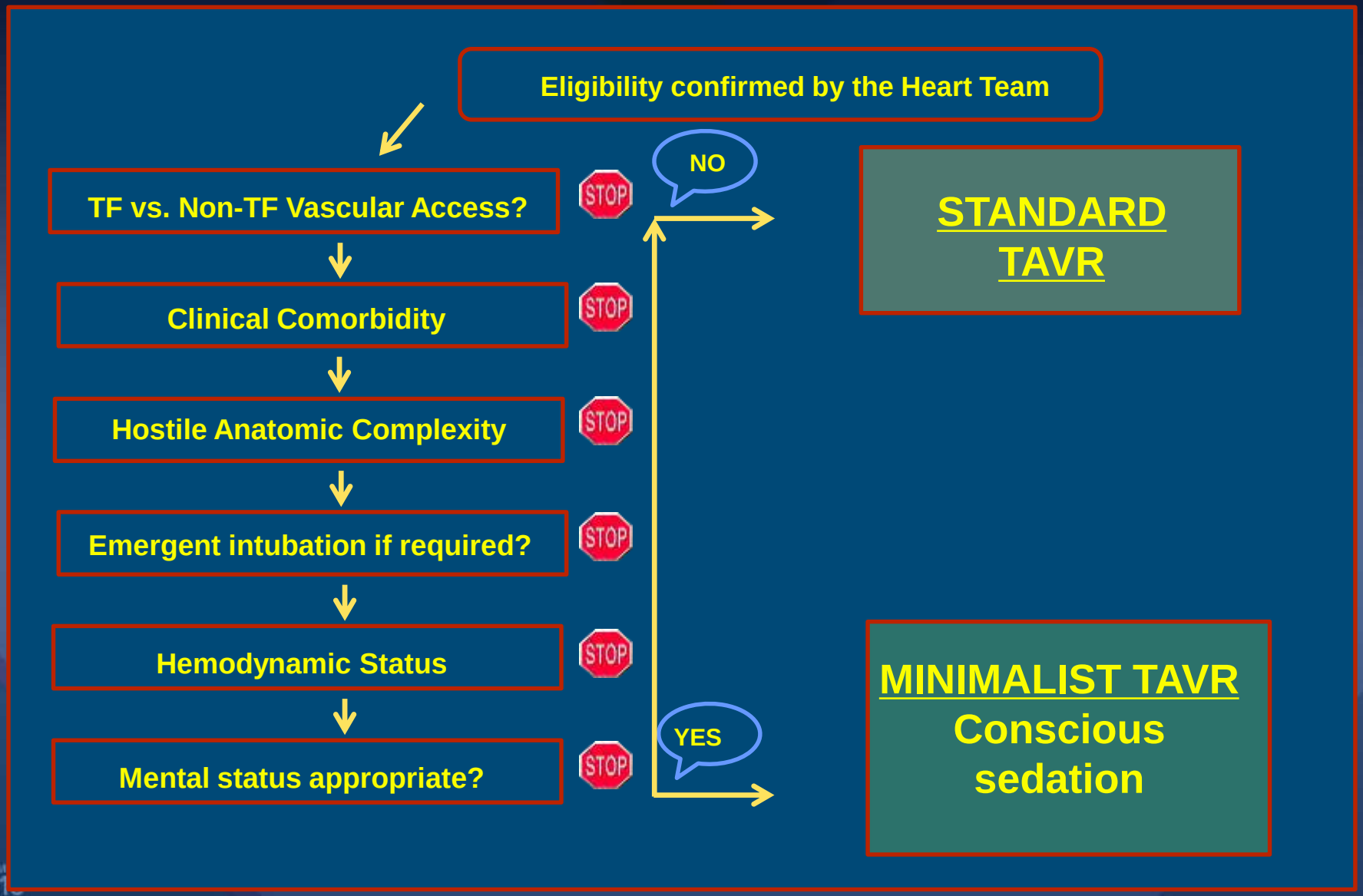
Patient Side

- Less invasive approach
- Least amount of morbidity
- Decreased pain
- Rapid return to normal activity
- Cognitive recovery
- Short hospitalization

Hospital Side

- Increased cost-effectiveness
- Less resource utilization
- Patient satisfaction
- Optimal hospital bed flow

Minimalist TAVR: Almost, but Selective



Minimalist TAVR

- **Goals**

Patient safety is paramount!

To maintain superior outcomes, short and long term

–this is not the pathway for every patient

(selective is more sense, extreme minimalism is dangerous)

- **Ensure procedural refinement first and foremost**
  - **Vast experience & comfort level of the Heart Team**
  - **Completely percutaneous approach – no cutdowns**
  - **Consistent positive clinical outcomes**

Standard vs. Minimalist 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^2	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

Standard vs. Minimalist TAVR in AMC
Procedural Characteristics

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

Standard vs. Minimalist 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%)	0.02
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%)	0.002
Major vascular complication	19 (4.7%)	17 (8.5%)	2 (1.0%)	<0.001
Length of hospital stay (days)	8.6±13.5	9.7±8.8	7.4±16.8	<0.001

Standard vs. Minimalist 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%)	0.01
Cardiac death	6 (1.5%)	5 (2.5%)	1 (0.5%)	0.10
Non-cardiac death	4 (1.0%)	4 (2.0%)	0	0.043
Stroke, all	13 (3.2%)	11 (5.5%)	2 (1.0%)	0.01
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%)	0.015
Bleeding	130 (32.3%)	86 (43.0%)	44 (21.7%)	<0.001
Life-threatening	30 (7.4%)	21 (10.5%)	9 (4.4%)	0.02
Major	117 (29.0%)	79 (39.5%)	38 (18.7%)	<0.001

Standard TAVR
Defined by VARC

Standard Performance (VARC-2) for High-Risk AS patients (@ 30 days)*		*Asian 2017*	*AMC 2018*	*AMC "MAC"*
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%

VARC Vascular Academic Research Consortium*

Standard vs. Minimalist TAVR
Current Cumulative Evidence

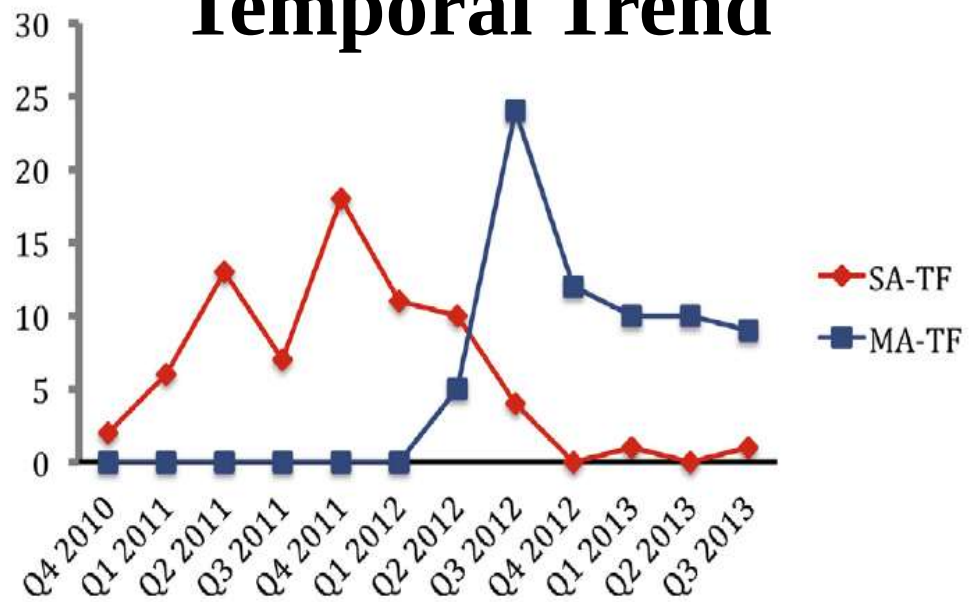
JACC: CARDIOVASCULAR INTERVENTIONS VOL. 7, NO. 8, 2014
AUGUST 2014:898–904

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

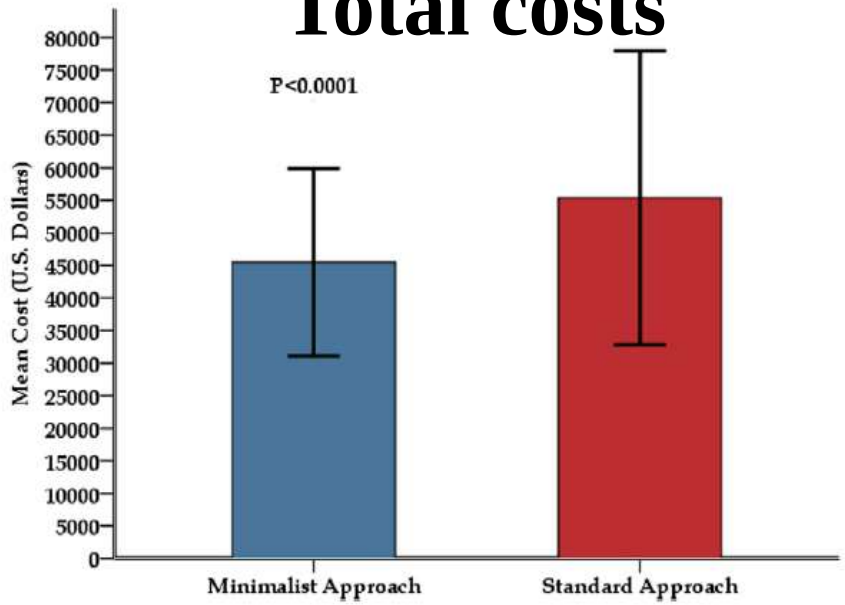
Outcomes and Cost Analysis

- A total of 142 patients: 70 MAC vs. 72 GA at **Emory University**, USA.

Temporal Trend



Total costs

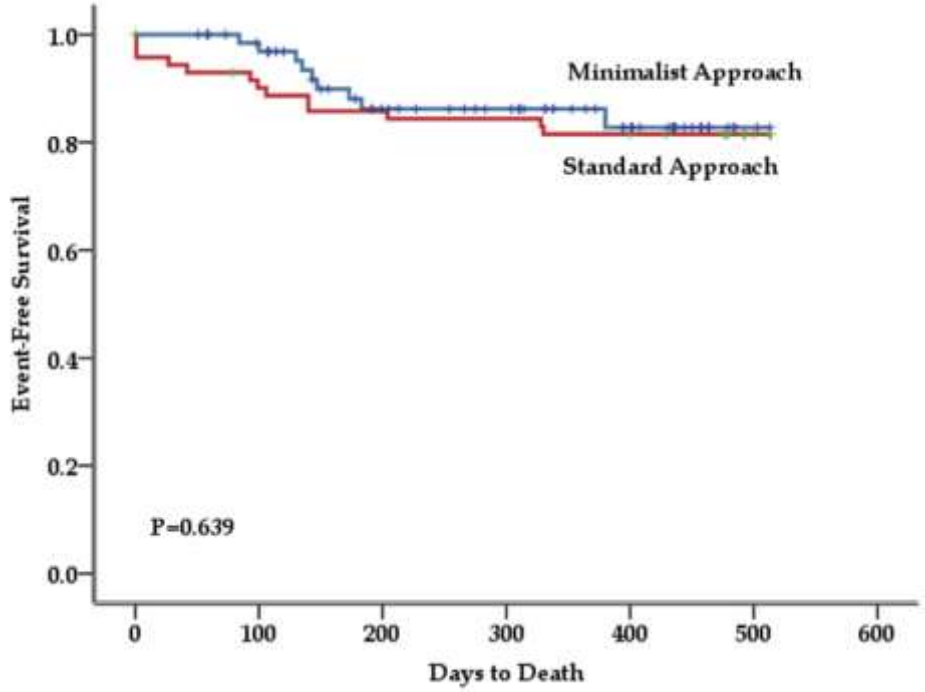


J Am Coll Cardiol Intv 2014;7:898–904.

Minimal vs. Standard Approach Outcomes

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



J Am Coll Cardiol Intv 2014;7:898–904.

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

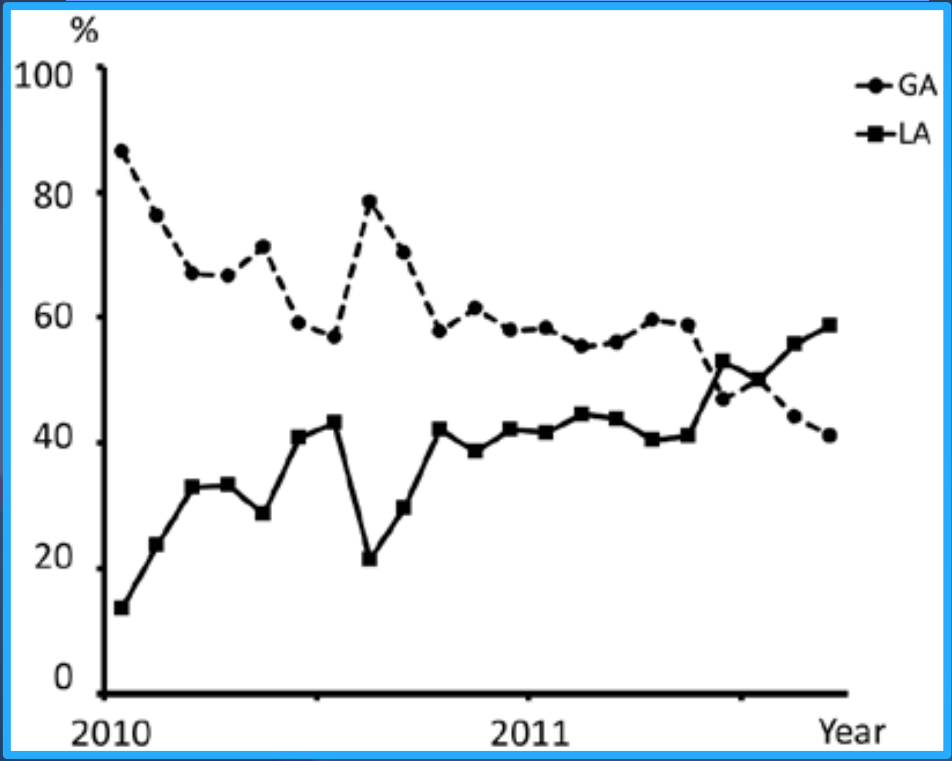
Atsushi Oguri, MD; Masanori Yamamoto, MD; Gauthier Mouillet, MD; Martine Gilard, MD; Marc Laskar, MD; Helene Eltchaninoff, MD; Jean Fajadet, MD; Bernard Iung, MD; Patrick Donzeau-Gouge, MD; Pascal Leprince, MD; Alain Leguerrier, MD; Alain Prat, MD; Michel Lievre, PhD; Karine Chevreul, MD; Jean-Luc Dubois-Rande, 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)

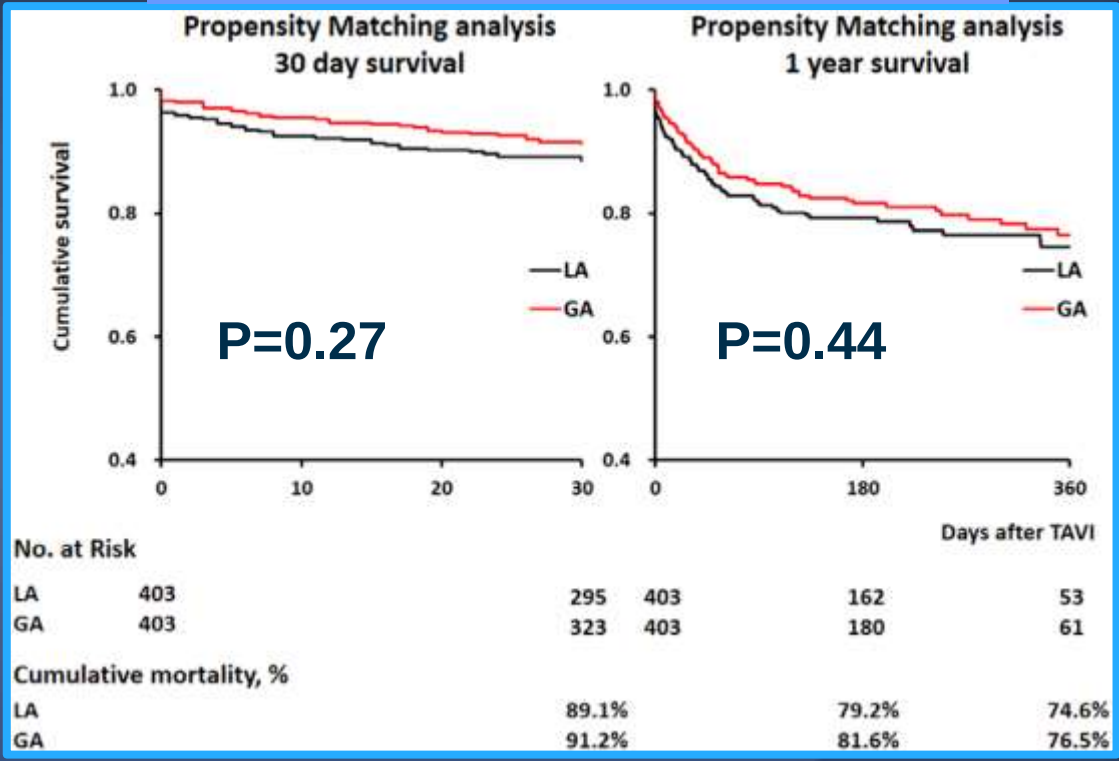
Circ Cardiovasc Interv. 2014;7:602-610

Change of TAVR Pattern and Outcome

Change of Anesthesia



Mortality of Propensity-Matched Cohort



Circ Cardiovasc Interv. 2014;7:602-610

International Journal of Cardiology 177 (2014) 448–454

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Local and general anaesthesia do not influence outcome of transfemoral aortic valve implantation

Gianni Dall'Ara [a,1], Helene Eltchaninoff [b,2], Neil Moat [a,2], Cécile Laroche [c,2], Javier Goicolea [d,2], Gian Paolo Ussia [e,2], Petr Kala [f,2], Peter Wenaweser [g,2], Marian Zembala [h,2], Georg Nickenig [i,2], Thomas Snow [j,2], Susanna Price [a,2], Eduardo Alegria Barrero [k,2], Rodrigo Estevez-Loureiro [l,2], Bernard Iung [m,2], José Luis Zamorano [n,2], Gerhard Schuler [o,2], Ottavio Alfieri [p,2], Bernard Prendergast [q,2], Peter Ludman [r,2], Stephan Windecker [g,2], Manel Sabate [s,2], Martine Gilard [t,2], Adam Witkowski [u,2], Haim Danenberg [v,2], Erwin Schroeder [w,2], Francesco Romeo [e,2], Carlos Macaya [x,2], Genevieve Derumeaux [y,2], Alessio Mattesini [a,2], Luigi Tavazzi [z,2], Carlo Di Mario [a,*,1], on behalf of the Transcatheter Valve Treatment Sentinel Registry (TCVT) Investigators of the EurObservational Research Programme (EORP) of the European Society of Cardiology

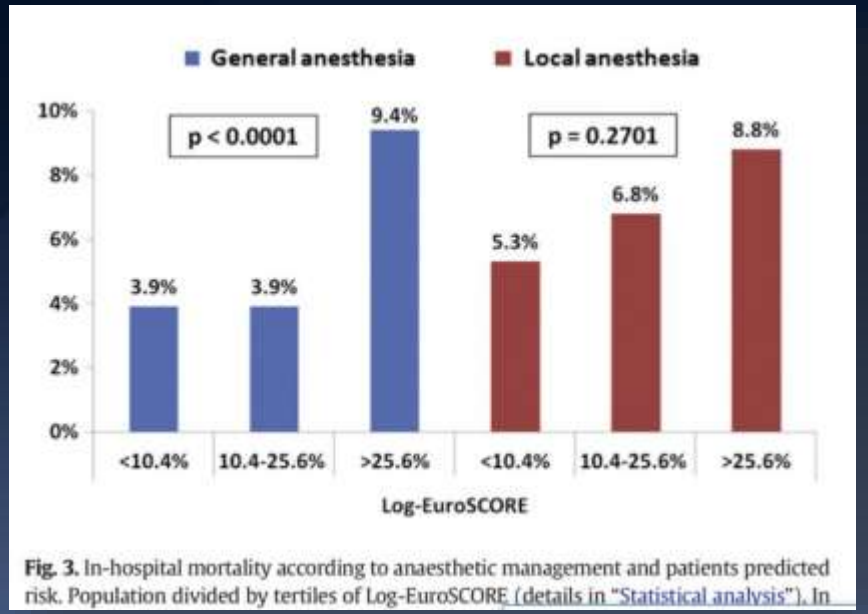


Fig. 3. In-hospital mortality according to anaesthetic management and patients predicted risk. Population divided by tertiles of Log-EuroSCORE (details in "Statistical analysis"). In

- **European Society of Cardiologist's Transcatheter Valve Treatment (TCVT) Registry**
  - 2807 patients, divided according to management strategy into the LA/ CS-group (1095 patients, 39%) and the GA-group (1712 patients, 61%)
  - Survival at 1 year, compared by Kaplan-Meier analysis, was similar between groups (log-rank: p=0.1505)
    - In-hospital mortality was higher in the low and intermediate risk groups for LA/CS but higher in the GA group for the highest risk group

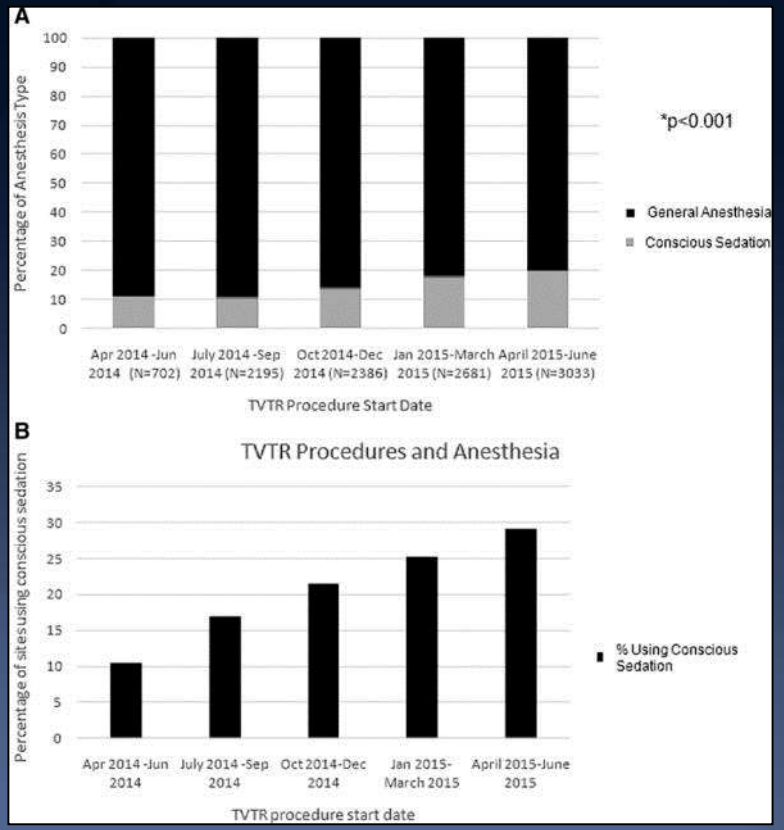
Int J Cardiol. 2014;177:448-454

Conscious Sedation Versus General Anesthesia for Transcatheter Aortic Valve Replacement

Insights from the National Cardiovascular Data Registry Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry

Editorial, see p 2141

Matthew C. Hyman, MD, PhD



Conscious sedation was used in 1737/10 997 (15.8%) cases with a significant trend of increasing usage over the time period studied

- When propensity-matched for factors known to predict early TAVR mortality (51 covariates), conscious sedation compared to GA was associated with
  - Lower procedural success (97.9% vs. 98.6%, *P*<0.001)
  - Reduced rate of mortality at the in-hospital (1.5% vs. 2.4%, *P*<0.001) and 30-day (2.3% vs. 4.0%, *P*<0.001) time points.
  - Reductions in procedural inotrope requirement, intensive care unit and hospital length of stay (6.0 vs. 6.5 days, *P*<0.001),
  - Combined 30-day death/ stroke rates (4.8% vs. 6.4%, *P*<0.001).

Hyman MC et al Circulation. 2017;136:2132–2140

Systemic Review and Meta-Analysis
Local and General Anesthesia

Open Access Research

BMJ Open

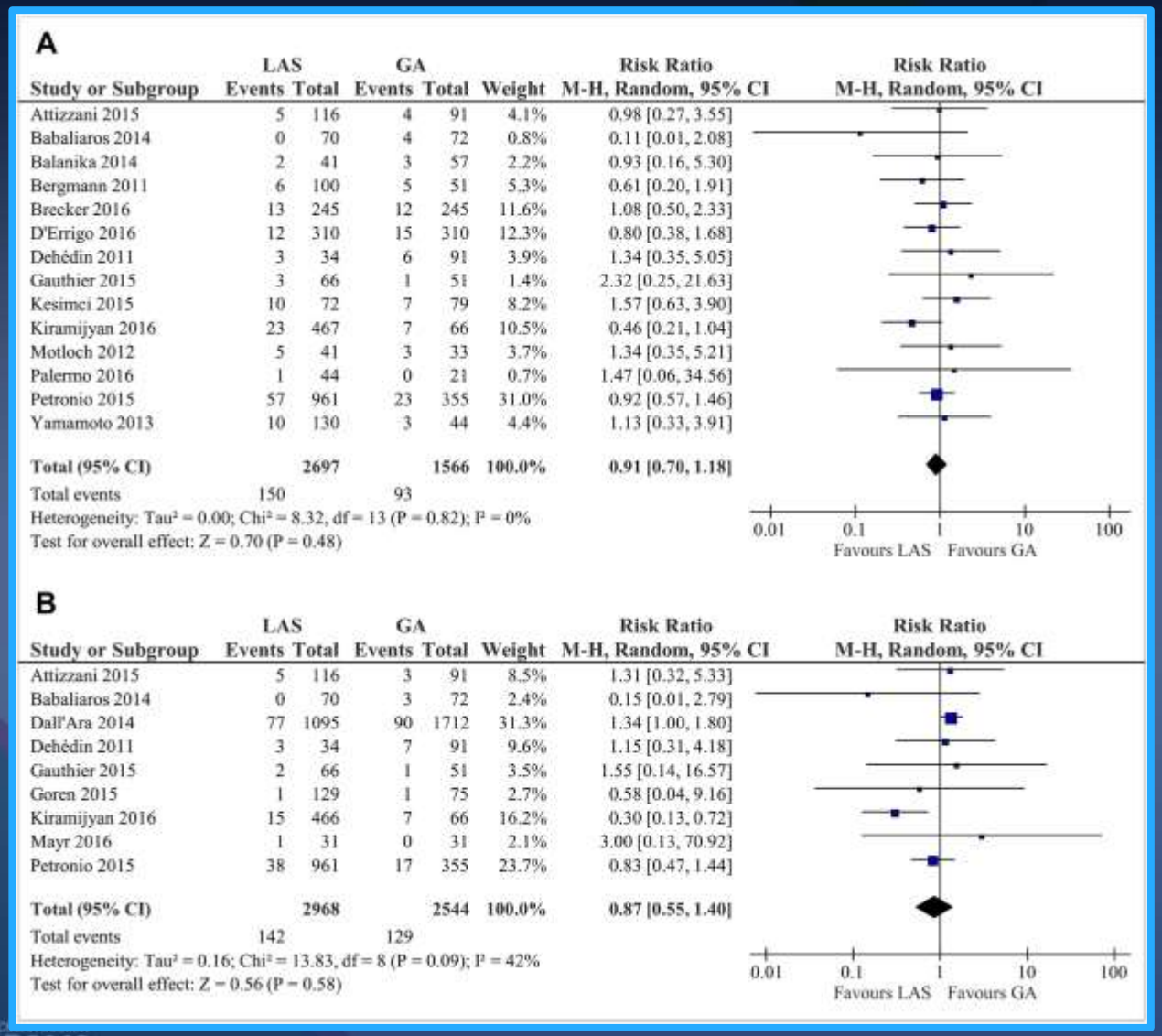
Is local anaesthesia a favourable approach for transcatheter aortic valve implantation? A systematic review and meta-analysis comparing local and general anaesthesia

Constanze Ehret,[1] Rolf Rossaint,[1] Ann Christina Foldenauer,[2] Christian Stoppe,[1] Ana Stevanovic,[1] Katharina Dohms,[1] Marc Hein,[1] Gereon Schälte[1]

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

Ehret C et al. BMJ Open. 2017;7(9):e016321.

Systemic Review and Meta-Analysis
Local and General Anesthesia



A

Study or Subgroup	LAS Events	LAS Total	GA Events	GA Total	Weight	Risk Ratio M-H, Random, 95% CI
Attizzani 2015	5	116	4	91	4.1%	0.98 [0.27, 3.55]
Babaliaros 2014	0	70	4	72	0.8%	0.11 [0.01, 2.08]
Balanika 2014	2	41	3	57	2.2%	0.93 [0.16, 5.30]
Bergmann 2011	6	100	5	51	5.3%	0.61 [0.20, 1.91]
Brecker 2016	13	245	12	245	11.6%	1.08 [0.50, 2.33]
D'Errigo 2016	12	310	15	310	12.3%	0.80 [0.38, 1.68]
Dehédin 2011	3	34	6	91	3.9%	1.34 [0.35, 5.05]
Gauthier 2015	3	66	1	51	1.4%	2.32 [0.25, 21.63]
Kesimci 2015	10	72	7	79	8.2%	1.57 [0.63, 3.90]
Kiramijyan 2016	23	467	7	66	10.5%	0.46 [0.21, 1.04]
Motloch 2012	5	41	3	33	3.7%	1.34 [0.35, 5.21]
Palermo 2016	1	44	0	21	0.7%	1.47 [0.06, 34.56]
Petronio 2015	57	961	23	355	31.0%	0.92 [0.57, 1.46]
Yamamoto 2013	10	130	3	44	4.4%	1.13 [0.33, 3.91]
Total (95% CI)		**2697**		**1566**	**100.0%**	**0.91 [0.70, 1.18]**
Total events	150		93			

Heterogeneity: Tau² = 0.00; Chi² = 8.32, df = 13 (P = 0.82); I² = 0%
Test for overall effect: Z = 0.70 (P = 0.48)

Risk Ratio M-H, Random, 95% CI
0.01 0.1 1 10 100
Favours LAS Favours GA

B

Study or Subgroup	LAS Events	LAS Total	GA Events	GA Total	Weight	Risk Ratio M-H, Random, 95% CI
Attizzani 2015	5	116	3	91	8.5%	1.31 [0.32, 5.33]
Babaliaros 2014	0	70	3	72	2.4%	0.15 [0.01, 2.79]
Dall'Ara 2014	77	1095	90	1712	31.3%	1.34 [1.00, 1.80]
Dehédin 2011	3	34	7	91	9.6%	1.15 [0.31, 4.18]
Gauthier 2015	2	66	1	51	3.5%	1.55 [0.14, 16.57]
Goren 2015	1	129	1	75	2.7%	0.58 [0.04, 9.16]
Kiramijyan 2016	15	466	7	66	16.2%	0.30 [0.13, 0.72]
Mayr 2016	1	31	0	31	2.1%	3.00 [0.13, 70.92]
Petronio 2015	38	961	17	355	23.7%	0.83 [0.47, 1.44]
Total (95% CI)		**2968**		**2544**	**100.0%**	**0.87 [0.55, 1.40]**
Total events	142		129			

Heterogeneity: Tau² = 0.16; Chi² = 13.83, df = 8 (P = 0.09); I² = 42%
Test for overall effect: Z = 0.56 (P = 0.58)

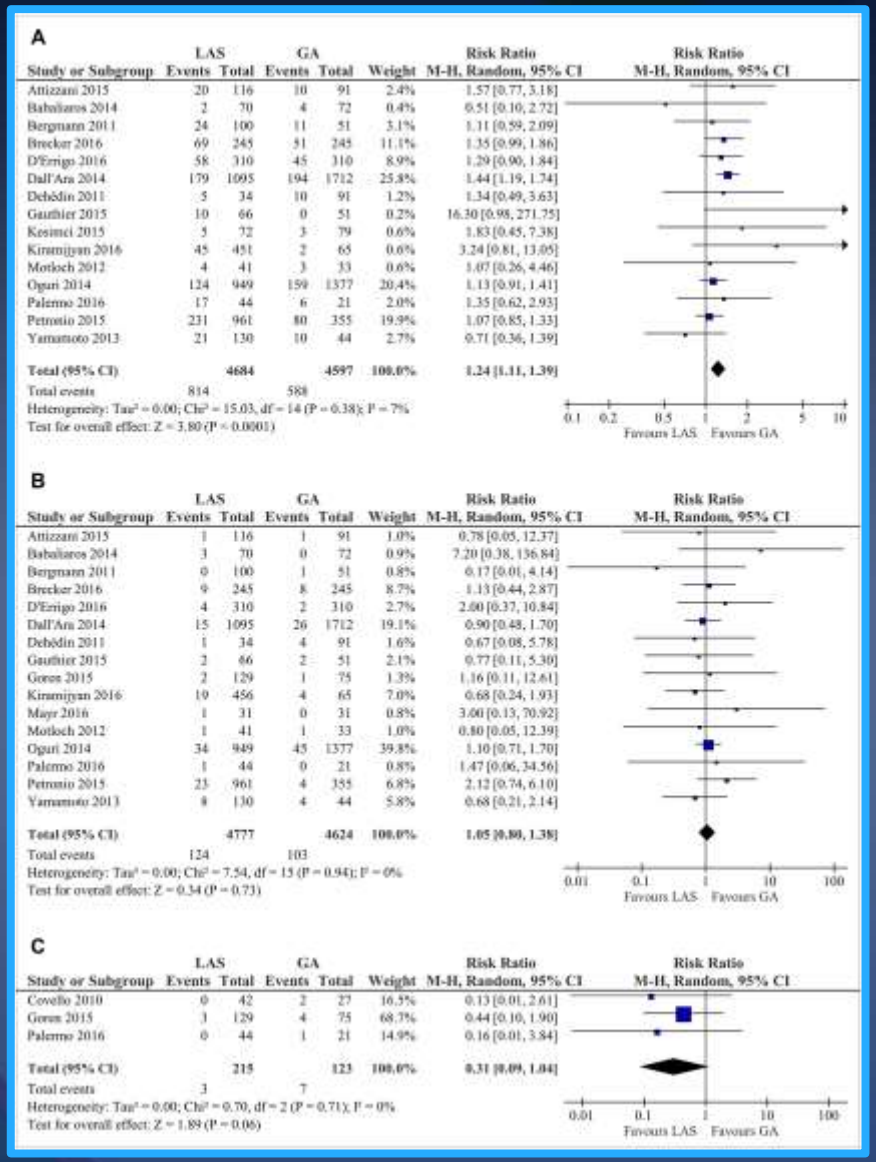
Risk Ratio M-H, Random, 95% CI
0.01 0.1 1 10 100
Favours LAS Favours GA

30-Days Mortality
"No Difference"

In-Hospital Mortality
"No Difference"

Ehret C et al. BMJ Open. 2017;7(9):e016321.

Systemic Review and Meta-Analysis
Local and General Anesthesia



New pacemaker insertion
"GA Is Better"

Stroke
"No Difference"

Pneumonia
"LAS Is Better"

Ehret C et al. BMJ Open. 2017;7(9):e016321.

Advantages of GA and TEE on TAVR Procedures

- Controlled, “emotionally peaceful” setting
- TEE imaging
  - Anticipate problems
  - **Identify immediate complications**
    - PVL assessment
    - Causes of hypotension
      - Annular rupture
      - Pericardial effusion
      - Coronary obstruction
      - Mitral regurgitation
      - RV dysfunction

A "Selective" Minimalist Strategy Makes More Sense
: Optimal Case Selection Based on High-Risk Anatomy and Clinical Characteristics

MAC vs. GA for TAVR

MAC Preferred

- High quality CTA demonstrates appropriate lower risk anatomy
- Significant RV/LV dysfunction
- Contraindications to TEE
- Poor respiratory function or high risk for intubation

GA Preferred

- High risk anatomy, grey zone sizing or lack of preoperative CTA
- Decompensated heart failure
- Impaired cognitive state with inability to cooperate

What Are Key Milestones Starting a Minimalist TAVR?

- Patient selection is critical.
- Sophisticated understanding of TAVR sizing (multi-modality imaging)
- Understanding of TAVR risks and their management
- Experienced heart team – experienced anesthesiologists and interventionists are KEY.
- Straightforward procedural approach and increased experience and expertise.

Summary: Minimalist TAVR

- An international trend toward minimalist TAVR.
  - appears as safe as conventional strategy
- Minimalist TAVR if done appropriately can provide clinical and economic benefits
- When an TAVR center decides to transition from GA to MAC;
  - Careful patient selection, meticulous procedural technique and dedicated post-procedural care are keys to success
  - As centers gain experience, there will be a trend toward more minimalist procedures
  - Acute procedural success and clinical outcomes should not be jeopardized.