

# **Advances in Surgical AVR: The Roles of Rapid Deployment Systems**

**Joon Bum Kim, MD, PhD**

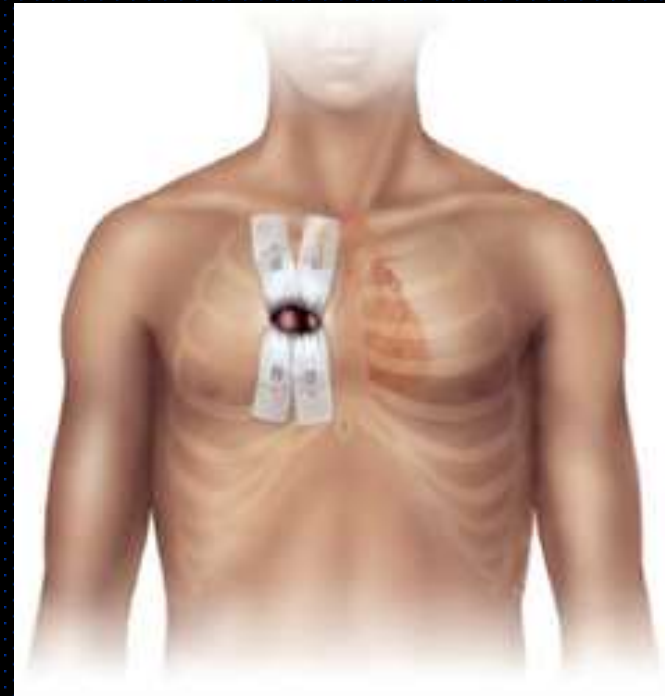
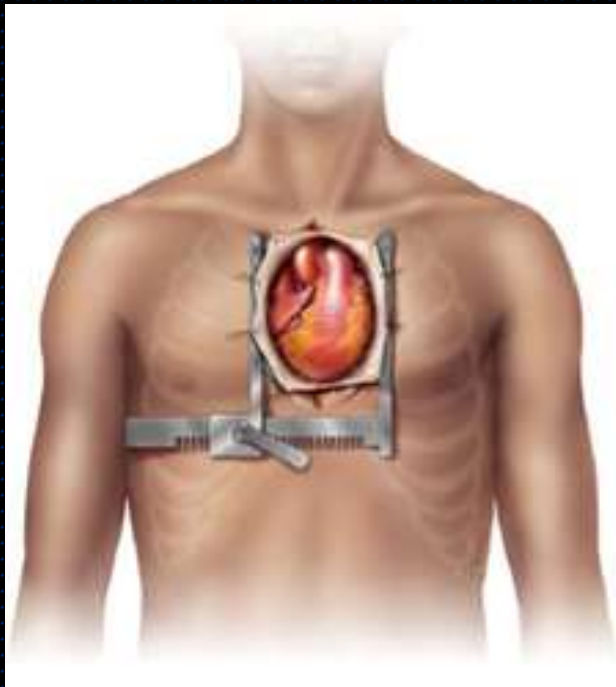
Dept. Thoracic and Cardiovascular Surgery  
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# Issue in AVR?

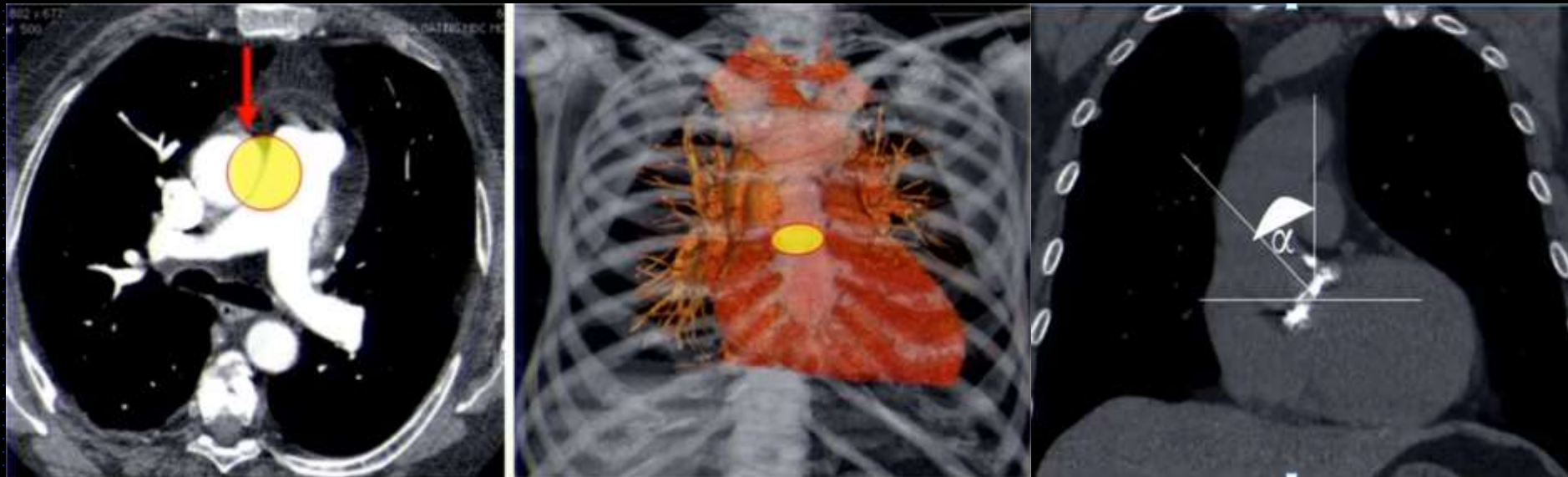
Conventional AVR via sternotomy

versus

AVR via MICS  $\pm$  Sutureless



# Selection Criteria? MICS AVR

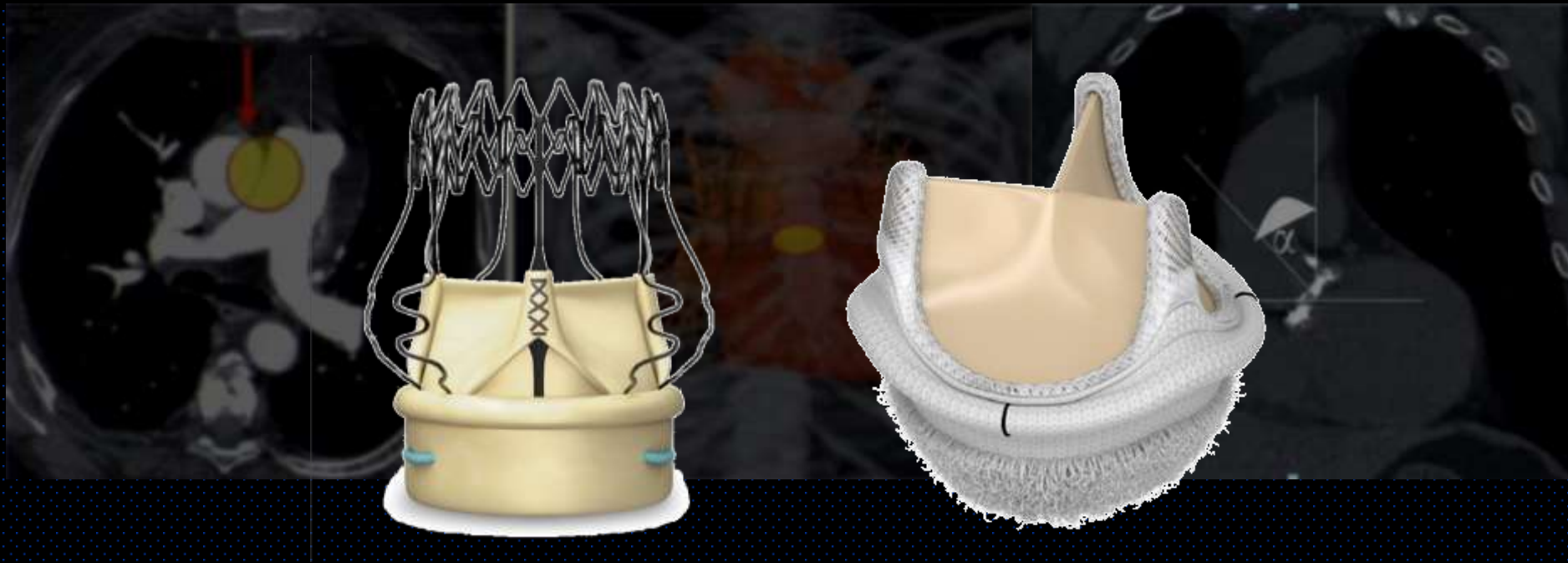


Rule 1. Aorta is rightward ( $>50\%$  aorta from right sternal)

Rule 2. The distance from ascending aorta to sternum  $< 10\text{cm}$

Rule 3. Angle  $\alpha \geq 45$  degrees

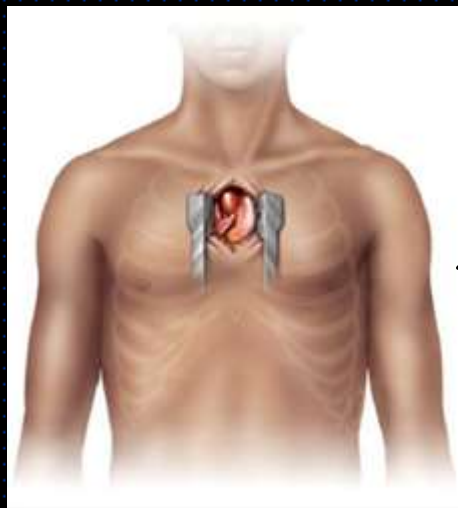
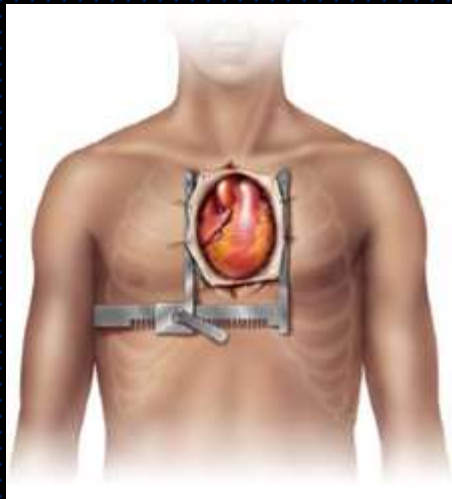
# Selection Criteria? MICS AVR



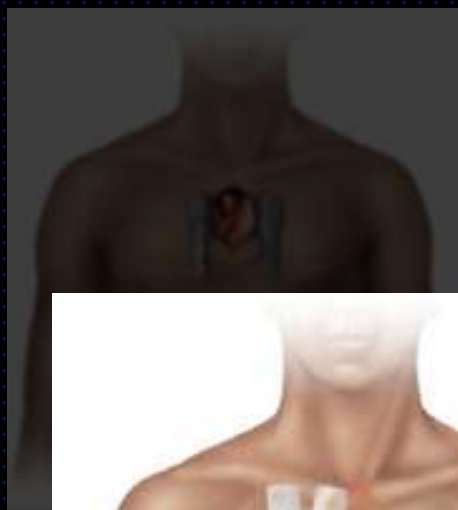
Rule 1. Aorta is rightward (>50% aorta from right sternal)

Rule 2. The distance from ascending aorta to sternum < 10cm

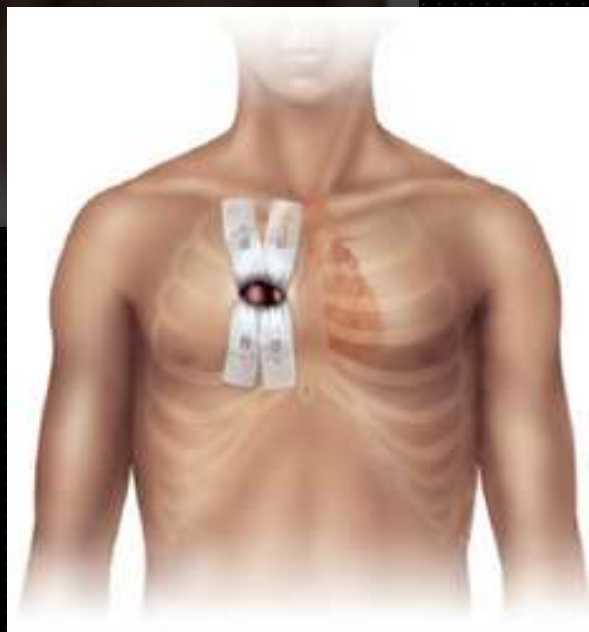
Rule 3. Angle  $\alpha \geq 45$  degrees



2015~

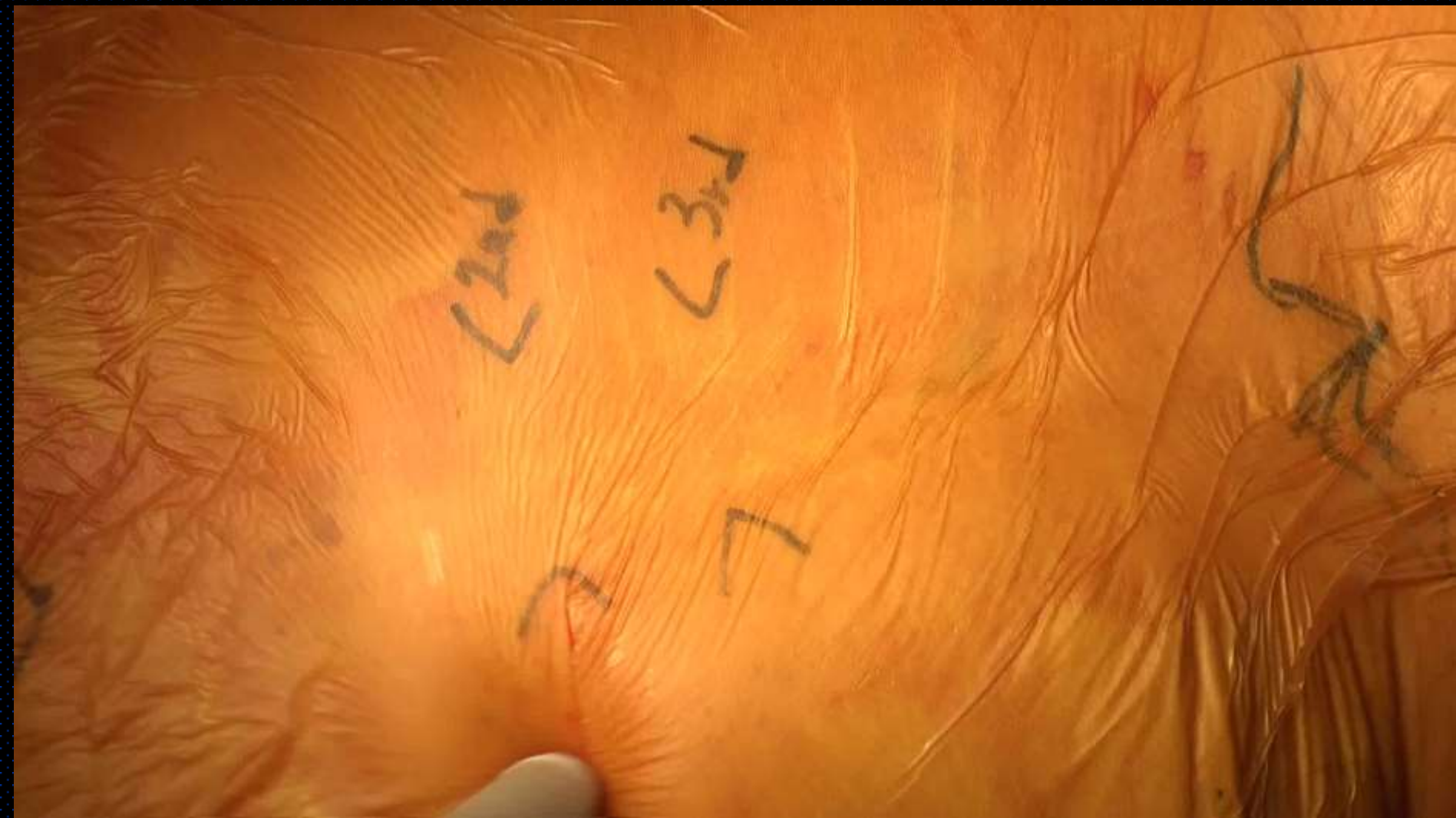


Nov 2017~





# Mini-Thoracotomy Intuity AVR



# Mini-Thoracotomy Intuity AVR

- ACC time: 46 min
- CPB time: 60 min
- **Skin-to-skin time: 1hr 40min**
- Transfer to general ward on POD#1
- Postop Echo (POD#4)
  - LVEF=62%
  - Mean PG=14mmHg
  - No leak
- Discharge on POD#5

Literature:  
70-100 min

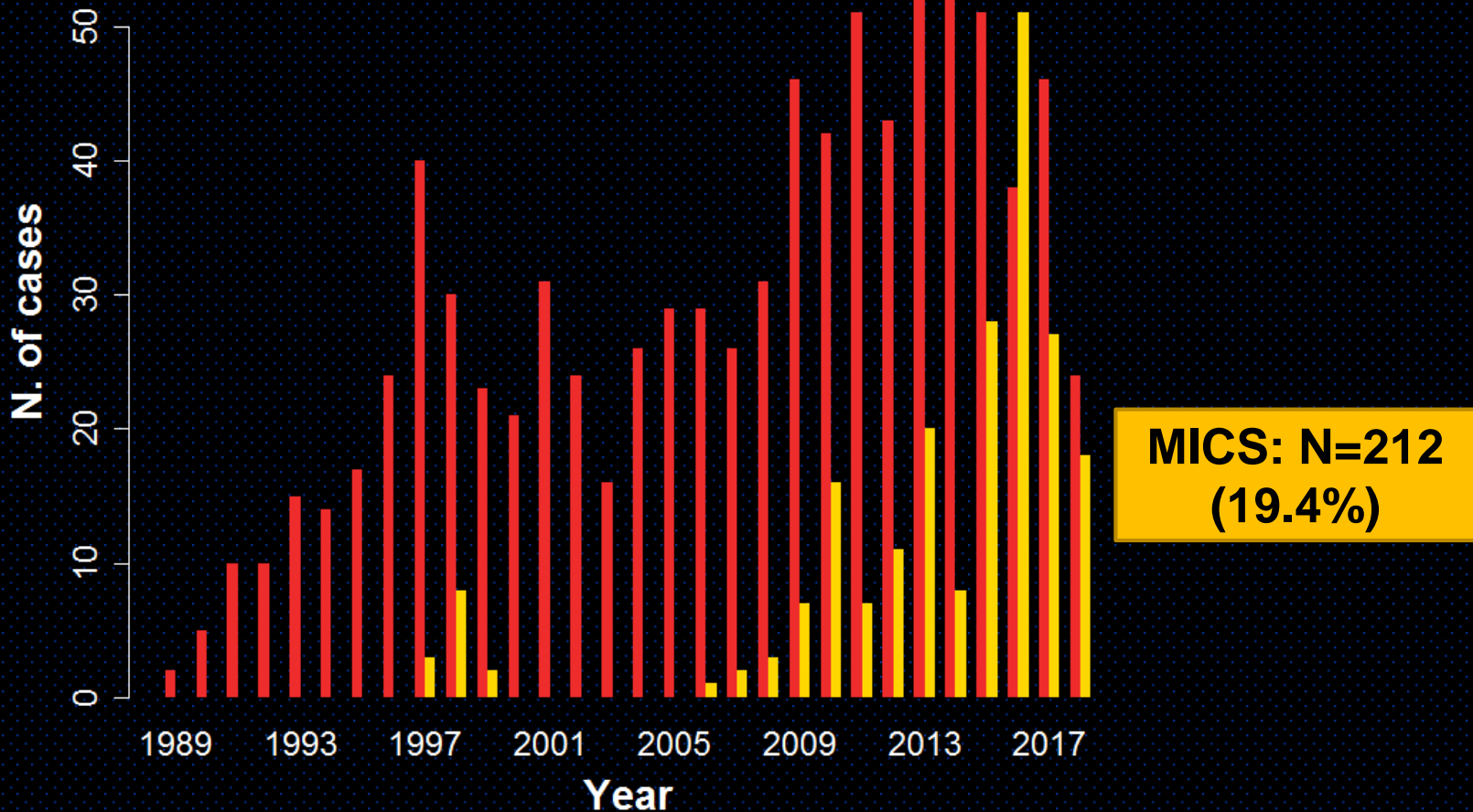


# Mini-Thoracotomy AVR

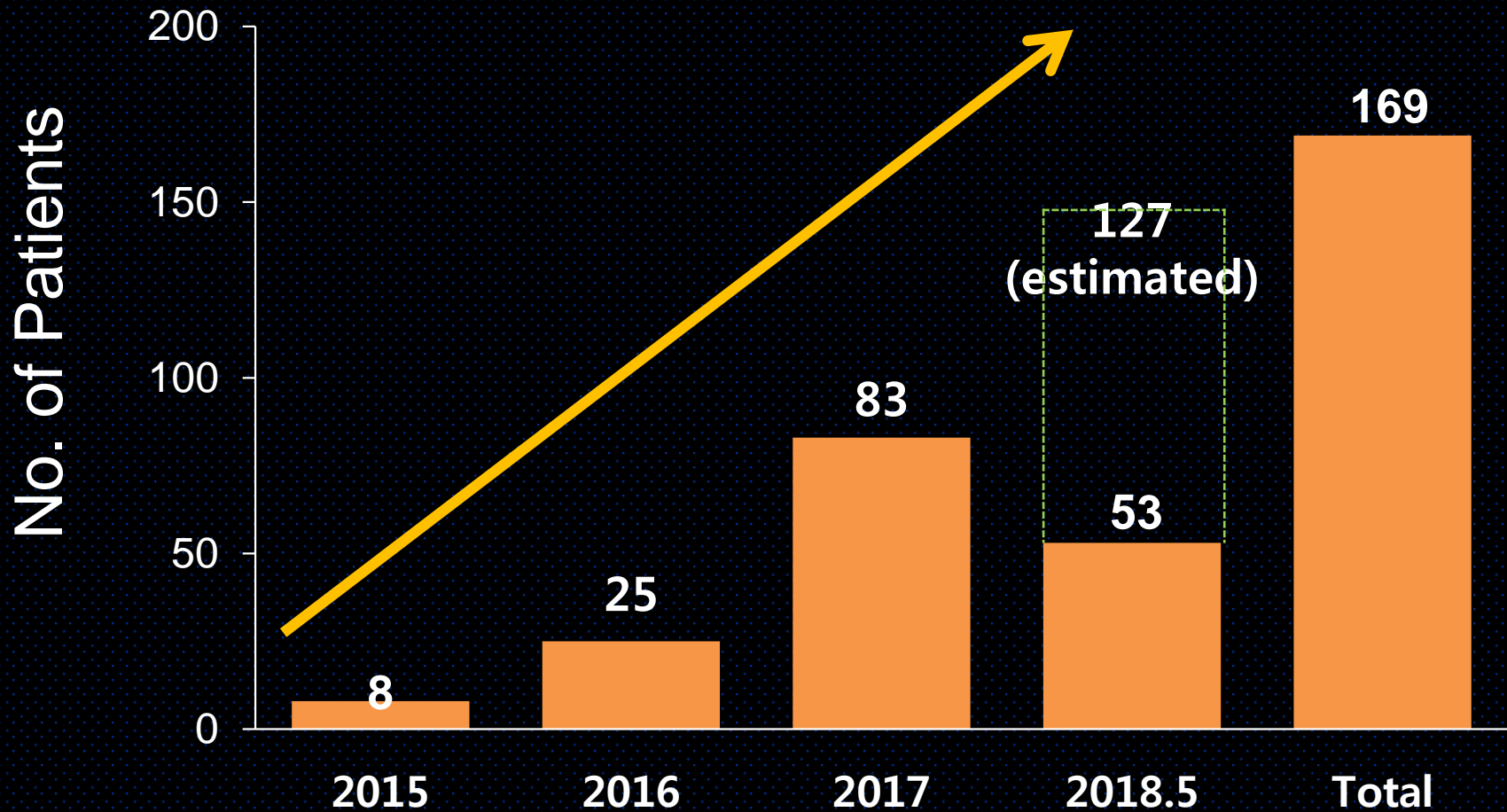
- ACC time: 42min (32-46 min)
- Skin-to-skin time: 2hr 59 min (100-221min)
- Extension of the use
  - AVR + Maze
  - AVR + TVP



# Minimally-Invasive vs. Conventional Isolated AVR (N=1092)

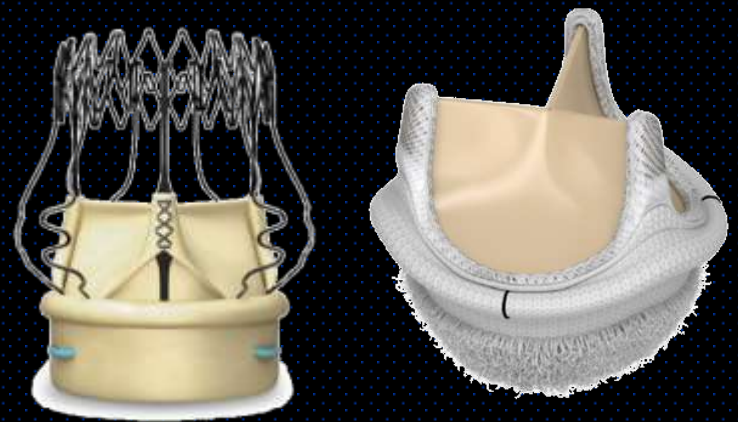


# Rapid Deployment AVR in AMC



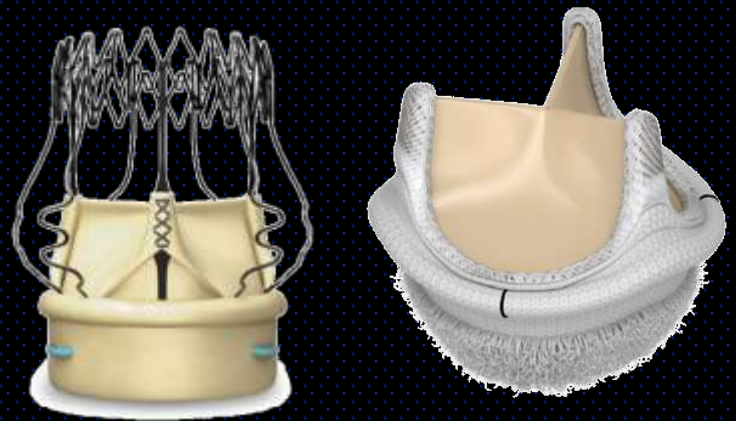
# Differences from TAVR

- Complete resection of the AV (less para-leak, etc.)
- No valve-crimping: superior longevity?
- Cheaper



# Differences from AVR

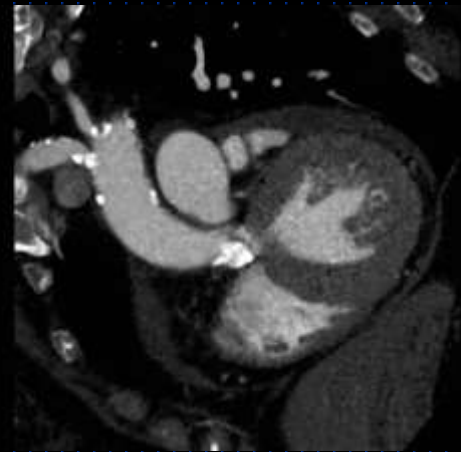
- Much easier
- Costly
- Safer?
- Superior hemodynamics?
- Higher risk of AV block?
- More para-valvular leak?





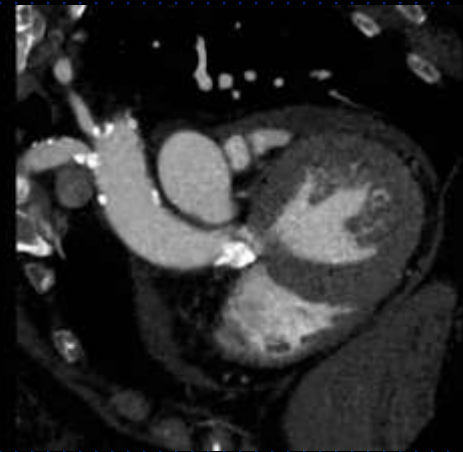
# Best Candidates for Sutureless AVR

- AVR + multi-CABG in high comorbidity
- AVR + other multiple procedures
- Extensive annular calcification
- Extensive root calcification



# Best Candidates for Sutureless AVR

- AVR + multi-CABG in high comorbidity
- AVR + other multiple procedures
- Extensive annular calcification
- Extensive root calcification
- **Mini-AVR**



# TRANSFORM (Multicenter Experience With Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement) US clinical trial: Performance of a rapid deployment aortic valve



Glenn R. Barnhart, MD,<sup>a</sup> Kevin D. Accola, MD,<sup>b</sup> Eugene A. Grossi, MD,<sup>c</sup> Y. Joseph Woo, MD,<sup>d</sup> Mubashir A. Mumtaz, MD,<sup>e</sup> Joseph F. Sabik, MD,<sup>f</sup> Frank N. Slachman, MD,<sup>g</sup> Himanshu J. Patel, MD,<sup>h</sup> Michael A. Borger, MD, PhD,<sup>i</sup> H. Edward Garrett, Jr, MD,<sup>j</sup> Evelio Rodriguez, MD,<sup>k</sup> Patrick M. McCarthy, MD,<sup>l</sup> William H. Ryan, MD,<sup>m</sup> Francis G. Duhay, MD, MBA,<sup>n</sup> Michael J. Mack, MD,<sup>m</sup> and W. Randolph Chitwood, Jr, MD,<sup>o</sup> on behalf of the TRANSFORM Trial Investigators

## ABSTRACT

**Background:** The TRANSFORM (Multicenter Experience With Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement) trial (NCT01700439) evaluated the performance of the INTUITY rapid deployment aortic valve replacement (RDAVR) system in patients with severe aortic stenosis.

**Methods:** TRANSFORM (n = 29), single-arm trial of the INTUITY rapid deployment aortic valve replacement (RDAVR) system in patients with severe aortic stenosis. Primary endpoint was 30-day mortality.

**Results:** Between 2012 and 2014, 29 patients were enrolled with a mean age of 73.5 ± 8.3 years. Full sternotomy was performed in 17 patients and minimally invasive surgical incisions in 12 patients. For RDAVR, mean cross-clamp and cardiopulmonary bypass times for FS were 49.3 ± 26.9 minutes and 69.2 ± 34.7 minutes, respectively, and for minimally invasive surgical 63.1 ± 25.4 minutes and 84.6 ± 33.5 minutes, respectively. These times were favorable compared with Society of Thoracic Surgeons database comparators for FS: 76.3 minutes and 104.2 minutes, respectively, and for minimally invasive surgical, 82.9 minutes and 111.4 minutes, respectively (P < .001). At 30 days, all-cause mortality was 0.8%; valve explant, 0.1%; thromboembolism, 3.5%; and major bleeding, 1.3%. In patients with isolated aortic valve replacement, the rate of permanent pacemaker implantation was 11.9%. At 1 year, mean effective orifice area was 1.7 cm<sup>2</sup>; mean gradient, 10.3 mm Hg; and moderate and severe paravalvular leak, 1.2% and 0.4%, respectively.



Prospective, non-randomized  
Multi-center: n=29  
N. of patients=839

## Perspective

Minimally invasive aortic valve replacement may confer patient benefits but is underused because of technical challenges and in part because of longer clamp times. Likewise, ischemia is also prolonged during complex concomitant aortic valve replacement cases. The TRANSFORM (Surgical Treatment of Aortic Stenosis With a Next Generation, Rapid Deployment Surgical Aortic Valve) trial demonstrated that the INTUITY valve eliminates the need for complete concentric annular suturing and provides an option for rapid surgical aortic deployment valve.

Barnhart et al

Acquired: Aortic Valve

## TRANSFORM (Multicenter Experience With Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement) US clinical trial: Performance of a rapid deployment aortic valve



- 30-day mortality: 0.8%
- Surgical bleeding: 1.3%
- Permanent pacemaker implantation: 11.9%

Glenn R. Barnhart, MD,<sup>a</sup> Kevin D. Accola, MD,<sup>b</sup> Eugene A. Grossi, MD,<sup>c</sup> Y. Joseph Woo, MD,<sup>d</sup> Michael J. Denzler, MD,<sup>e</sup> Joseph E. Saba, MD,<sup>f</sup> Frank N. Ozkan, MD,<sup>g</sup> Himanshu J. Patel, MD,<sup>h</sup> Michael J. Mack, MD,<sup>i</sup> Joseph J. Griffin, Jr, MD,<sup>j</sup> Eli Rodriguez, MD,<sup>k</sup> Patrick M. McCarthy, MD,<sup>l</sup> William H. Ryan, MD,<sup>m</sup> Francis G. Duhay, MD, MBA,<sup>n</sup> Michael J. Mack, MD,<sup>o</sup> and William J. Stetler, MD,<sup>p</sup> for the TRANSFORM Aortic Valve Study Group

### ABSTRACT

**Background:** The TRANSFORM (Multicenter Experience With Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement) trial (NCT01709430) evaluated the performance of the INTUITY rapid deployment aortic valve replacement (RDAVR) system in patients with severe aortic stenosis.

**Methods:** A FEASIBILITY was a prospective, randomized, controlled trial (n = 29) comparing the INTUITY RDAVR to a conventional bileaflet expandable frame attached to a Carpentier-Edwards PERIMOUNT Magna Ease aortic valve. Primary and effectiveness endpoints were evaluated at 1 year.

**Results:** Between 2012 and 2015, 839 patients underwent RDAVR. Mean age was  $73.5 \pm 8.3$  years. Full sternotomy (FS) was used in 59% and minimally invasive surgical approaches were used in 41%. For FS, mean operative time for RDAVR was  $49.3 \pm 26.9$  minutes and  $69.2 \pm 34.7$  minutes, respectively, and for minimally invasive surgical  $63.1 \pm 25.4$  minutes and  $81.6 \pm 33.0$  minutes, respectively. These times were significantly shorter (P < .001) than those of Transcatheter aortic valve replacement comparators for FS: 76.3 minutes and 104.2 minutes, respectively, and for minimally invasive surgical, 82.9 minutes and 111.4 minutes, respectively (P < .001). At 30 days, all-cause mortality was 0.8%; valve explant, 0.1%; thromboembolism, 3.5%; and major bleeding, 1.3%. In patients with isolated aortic valve replacement, the rate of permanent pacemaker implantation was 11.9%. At 1 year, mean effective orifice area was 1.7 cm<sup>2</sup>; mean gradient, 10.3 mm Hg; and moderate and severe paravalvular leak, 1.2% and 0.4%, respectively.



Deployed Intuity valve.

### Central Message

INTUITY eliminates complete concentric annular suturing providing an option for rapid surgical deployment and may facilitate smaller incision surgery.

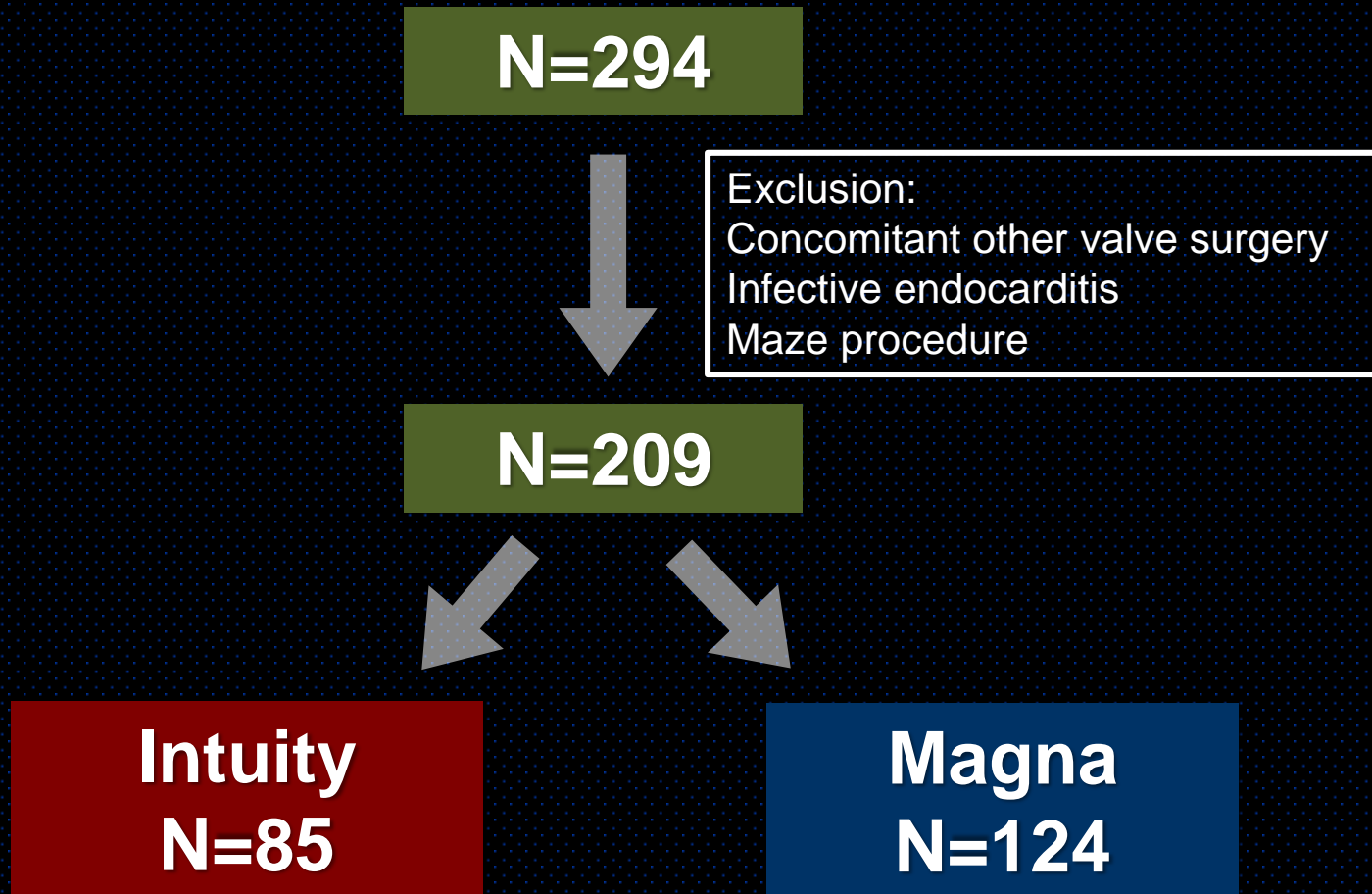
### Perspective

Minimally invasive aortic valve replacement may confer patient benefits but is undermined because of technical challenges and in part because of longer clamp times. Likewise, ischemia is also prolonged during complex concomitant aortic valve replacement cases. The TRANSFORM (Surgical Treatment of Aortic Stenosis With a Next Generation, Rapid Deployment Surgical Aortic Valve) trial demonstrated that the INTUITY valve eliminates the need for complete concentric annular suturing and provides an option for rapid surgical aortic deployment valve.

- 1-yr mean EOA: 1.7cm<sup>2</sup>
- 1-yr mean PG: 10.3mmHg
- 1-yr moderate leak: 1.2%
- severe leak: 0.4%

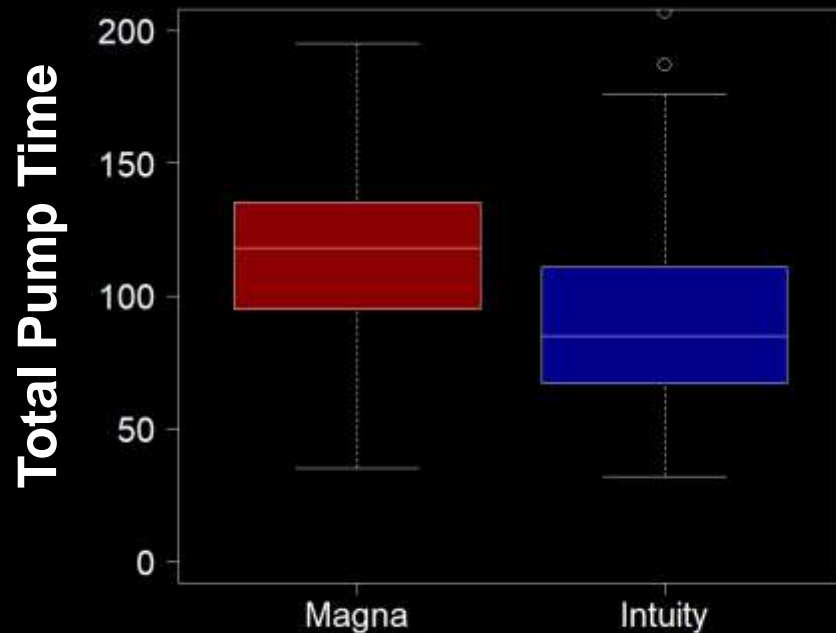
# Intuity vs. Magna

*Feb 2016 to Mar 2018, AVR (Intuity + Magna) in AMC and Sejong hospitals*

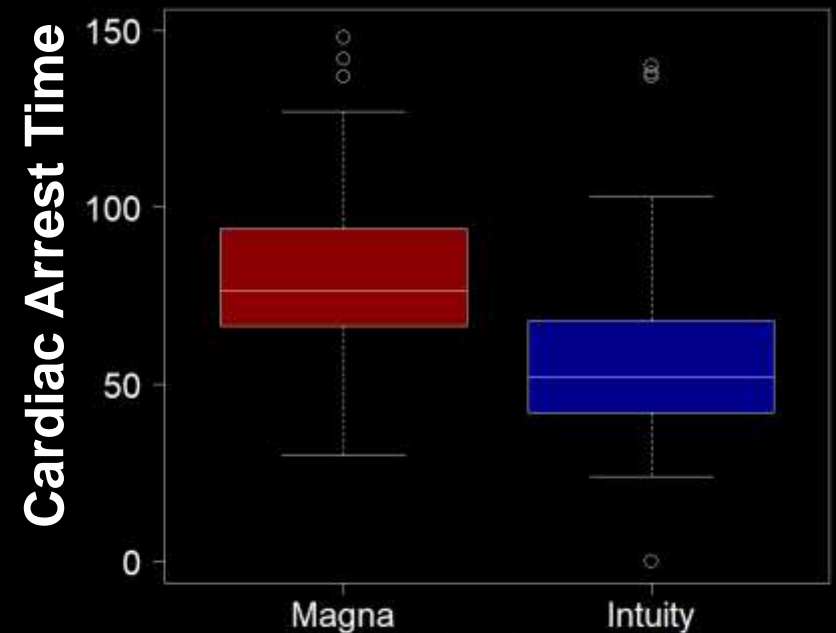


# Operative Profiles

	Intuity (n=85)	Magna (n=124)	P value
Total pump time, min	92.0 ± 38.8	116.6 ± 38.8	<0.001
Cardiac arrest time, min	56.5 ± 24.4	79.9 ± 23.1	<0.001



**Valve Types**



**Valve Types**



# Permanent Pacemaker Implantation

**Intuity**

**5.9% (N=5)**

\*. Underlying RBBB N=2

**Magna**

**2.4% (N=3)**

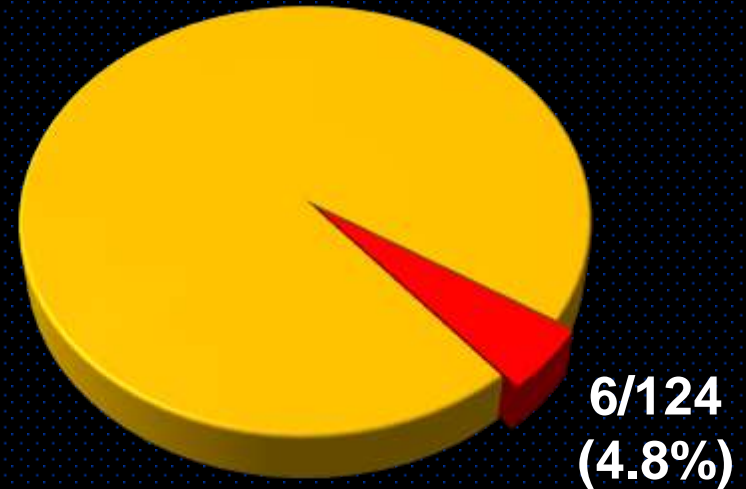
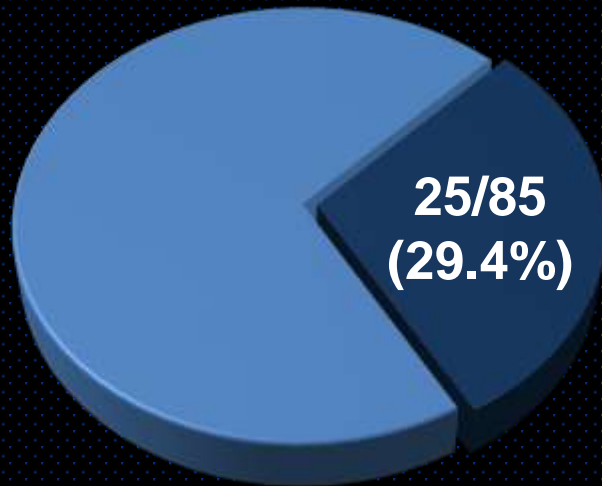
**P =0.36**

# New LBBB

Intuity

versus

Magna



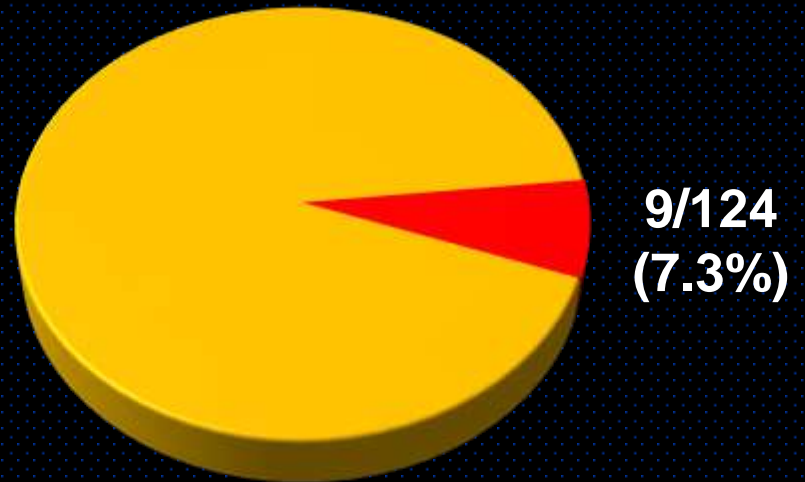
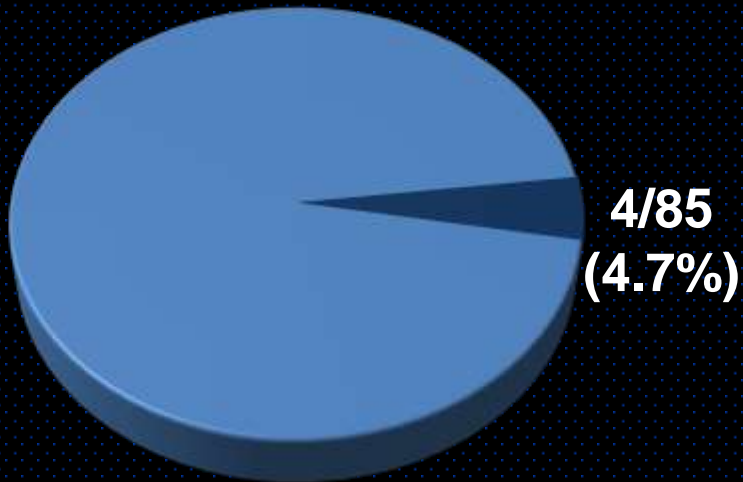
$P < 0.001$

# New RBBB

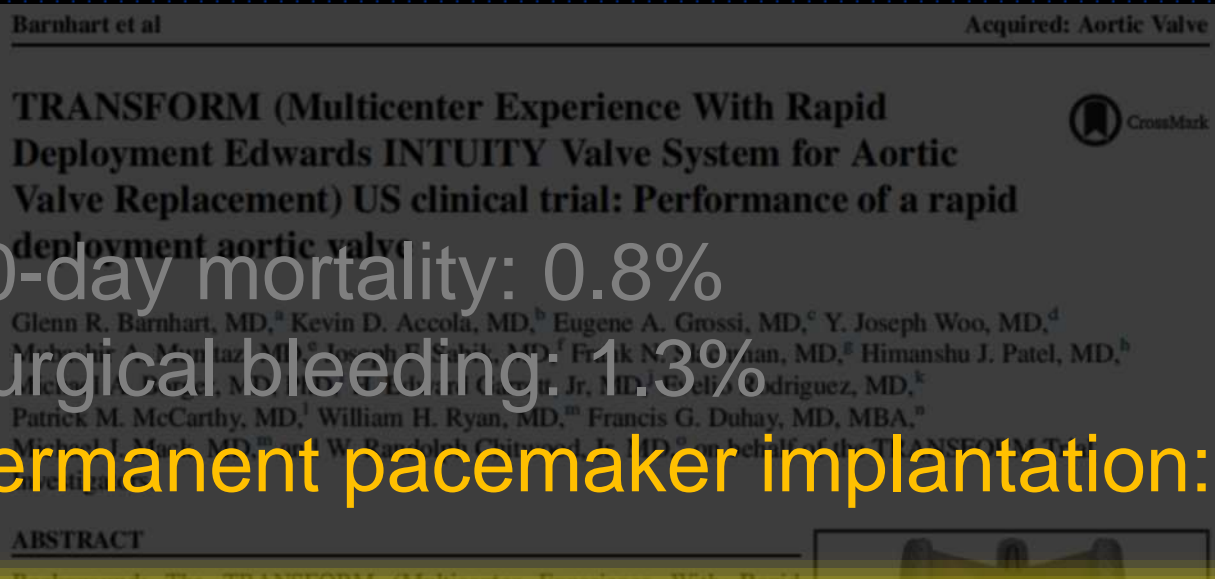
Intuity

versus

Magna



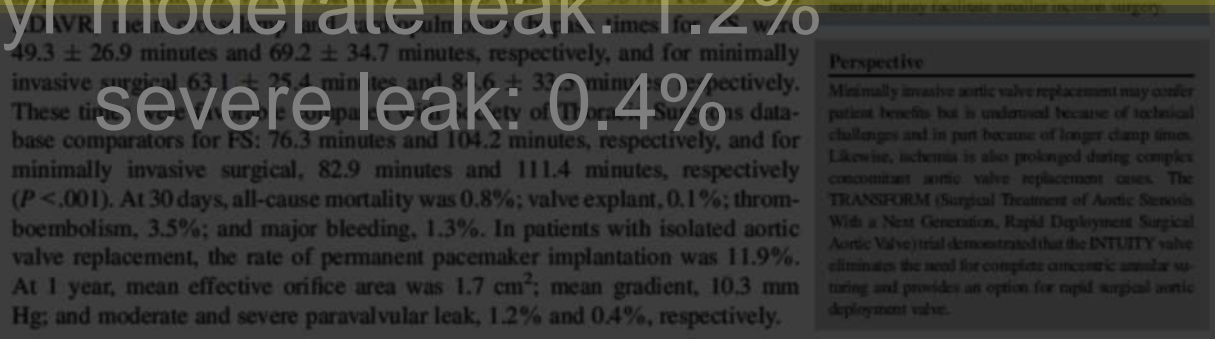
**P = 0.46**



- 30-day mortality: 0.8%
- Surgical bleeding: 1.3%
- **Permanent pacemaker implantation: 11.9%**

Of those patients having postoperative pacemaker implant, 73.3% had preexisting complete right bundle branch block and 19.65% had preexisting sinus bradycardia.

- 1-yr moderate leak: 1.2%
- **severe leak: 0.4%**



May not feasible in RBBB

Barnhart et al Acquired: Aortic Valve

# TRANSFORM (Multicenter Experience With Rapid Deployment Edwards INTUITY Valve System for Aortic Valve Replacement) US clinical trial: Performance of a rapid deployment aortic valve



Glenn R. Barnhart, MD,<sup>a</sup> Kevin D. Accola, MD,<sup>b</sup> Eugene A. Grossi, MD,<sup>c</sup> Y. Joseph Woo, MD,<sup>d</sup> Mubashir A. Mumtaz, MD,<sup>e</sup> Joseph F. Sabik, MD,<sup>f</sup> Frank N. Slachman, MD,<sup>g</sup> Himanshu J. Patel, MD,<sup>h</sup> Michael A. Borger, MD, PhD,<sup>i</sup> H. Edward Garrett, Jr, MD,<sup>j</sup> Evelio Rodriguez, MD,<sup>k</sup> Patrick M. McCarthy, MD,<sup>l</sup> William H. Ryan, MD,<sup>m</sup> Francis G. Duhay, MD, MBA,<sup>n</sup> Michael J. Mack, MD,<sup>o</sup> and W. Randolph Chitwood, Jr, MD,<sup>p</sup> on behalf of the TRANSFORM Trial Investigators

**Conventional AVR  
STS database**

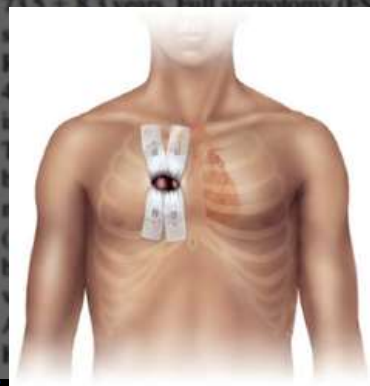
	Sternotomy (59%)	MICS (41%)	Sternotomy	MICS (<10%)
ACC time, min	49.3	63.1	76.3	82.9
CPB time, min	69.2	84.6	104.2	111.4

... 73.5 ± 8.3 cases. Full sternotomy (FS) was used in 59% and minimally invasive al success rate was 95%. For isolated diopulmonary bypass times for FS were 7 minutes, respectively, and for minimally t and 84.6 ± 33.5 minutes, respectively. d with Society of Thoracic Surge s and 104.2 minutes, respectively, and for minutes and 111.4 minutes, respectively ility was 0.8%; valve explant, 0.1%; throm- ng, 1.3%. In patients with isolated aortic nent pacemaker implantation was 11.9%. a was 1.7 cm<sup>2</sup>; mean gradient, 10.3 mm ular leak, 1.2% and 0.4%, respectively.

INTUITY eliminates complete concentric annular re- turing providing an option for rapid surgical deploy- ment and may facilitate smaller incision surgery.

Perspective

... INTUITY eliminates complete concentric annular re- turing providing an option for rapid surgical deploy- ment and may facilitate smaller incision surgery.



**dT ≈ 20~30 min**



# Intuity vs. Magna

Feb 2016 to Mar 2018, AVR (Intuity + Magna) in AMC and Sejong hospitals

## Operative Profiles

	N=294		
	Intuity (n=85)	Magna (n=124)	P value
Surgical approaches, n (%)			0.03
Full-sternotomy	36 (42.4)	82 (66.2)	
Upper-sternotomy	37 (43.5)	35 (28.2)	
Right anterior thoracotomy	12 (14.1)	7 (5.6)	
Concomitant procedures, n (%)			
CABG	12 (14.1)	15 (12.1)	0.83
Aorta procedures	7 (8.2)	13 (10.5)	0.76

Exclusion:  
Concomitant other valve surgery  
Infective endocarditis  
Maze procedure

intuity N=85

Magna N=124

N=209

Impact on survival?

# Rapid deployment or sutureless versus conventional bioprosthetic aortic valve replacement: A meta-analysis



Suk Ho Sohn, MD,<sup>a</sup> Myoung-jin Jang, PhD,<sup>b</sup> Ho Young Hwang, MD, PhD,<sup>a</sup> and Kyung Hwan Kim, MD, PhD<sup>a</sup>

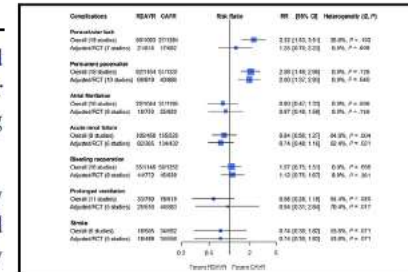
## ABSTRACT

**Objectives:** This meta-analysis was conducted to compare the early and follow-up outcomes of aortic valve replacement using rapid deployment or sutureless (RD) valves (RDAVR group) with aortic valve replacement using conventional bioprostheses (CAVR group).

**Methods:** A literature search of 5 online databases was conducted. The primary outcomes were postoperative complications and the secondary outcomes included the aortic cross-clamp (ACC) and cardiopulmonary bypass (CPB) times and early mortality and all-cause mortality during follow-up.

**Results:** Twenty-one articles (RDAVR group = 1297 patients; CAVR group = 1488 patients) were selected. The pooled analyses showed that the ACC and CPB times were significantly shorter in the RDAVR group than in the CAVR group (mean difference,  $-26.34$ ; 95% confidence interval [CI],  $-31.86$  to  $-20.82$  and mean difference,  $-25.33$ ; 95% CI,  $-30.79$  to  $-19.87$ , respectively). The pooled risk ratios (RRs) of any paravalvular leak and permanent pacemaker (PPM) insertion were significantly higher in the RDAVR group than in the CAVR group (RR, 2.32; 95% CI, 1.53-3.51 and RR, 2.08; 95% CI, 1.49-2.90, respectively). The pooled analysis showed that the risk of a paravalvular leak grade  $\geq 2$  in the RDAVR group did not significantly differ between the RDAVR and CAVR groups (RR, 2.05; 95% CI, 0.71-5.93). The risk of PPM insertion remained significant when only studies reporting adjusted outcomes were pooled. The risks of other postoperative complications, early mortality, and all-cause mortality during follow-up were not significantly different between the RDAVR and CAVR groups.

**Conclusions:** RDAVR is associated with significantly shorter ACC and CPB times than CAVR, although this difference did not translate into improved postoperative outcomes, early mortality, and all-cause mortality during follow-up. Care might be needed when implanting RD valves because they are associated with a higher incidence of PPM insertion, regardless of the RD valve type. (J Thorac Cardiovasc Surg 2018;155:2402-12)



Pooled estimates of postoperative complications between RDAVR and conventional AVR.

## Central Message

Rapid deployment or sutureless AVR is associated with shorter ACC and CPB times without differences in postoperative complications except for a higher occurrence of permanent pacemaker insertion.

## Perspective

This study showed that aortic valve replacement using rapid deployment or sutureless valves was associated with shorter aortic cross-clamp and cardiopulmonary bypass times but also a greater occurrence of permanent pacemaker insertion. Surgeons should carefully select valve types according to the benefit and disadvantage of rapid deployment or sutureless valves and conventional valves.

See Editorial Commentary page 2413.

See Editorial page 2400.



## Rapid deployment or sutureless versus conventional bioprosthetic aortic valve replacement: A meta-analysis

Check for updates

Suk Ho Sohn, MD,<sup>a</sup> Myoung-jin Jang, PhD,<sup>b</sup> Ho Young Hwang, MD, PhD,<sup>a</sup> and Kyung Hwan Kim, MD, PhD<sup>a</sup>

### ABSTRACT

**Objectives:** This meta-analysis was conducted to compare the early and follow-up outcomes of sutureless and conventional bioprosthetic aortic valve replacement.

**Methods:** We searched the PubMed, Embase, and Cochrane databases for studies comparing sutureless and conventional bioprosthetic aortic valve replacement.

**Results:** In the sutureless group, the aortic cross-clamp time (ACC) was significantly shorter than in the conventional group (mean difference, -26.3 min; 95% CI, -33.1 to -19.5 min; P < 0.001). The risk of para-aortic leak was significantly higher in the sutureless group (RR, 1.25; 95% CI, 0.70-2.23). The risk of postoperative mortality was significantly lower in the sutureless group (RR, 0.78; 95% CI, 0.50-1.22). The mean pressure gradient was significantly lower in the sutureless group (mean difference, -1.19 mmHg; 95% CI, -2.47 to 0.10 mmHg; P < 0.001).

**Conclusion:** Sutureless bioprosthetic aortic valve replacement is associated with shorter ACC, lower risk of para-aortic leak, lower risk of postoperative mortality, and lower mean pressure gradient compared with conventional bioprosthetic aortic valve replacement.

**Meta-analysis: 21 papers**  
**Sutureless in 1297**  
**Conventional in 1488**

ACC time: -26.3 min (P<0.001)

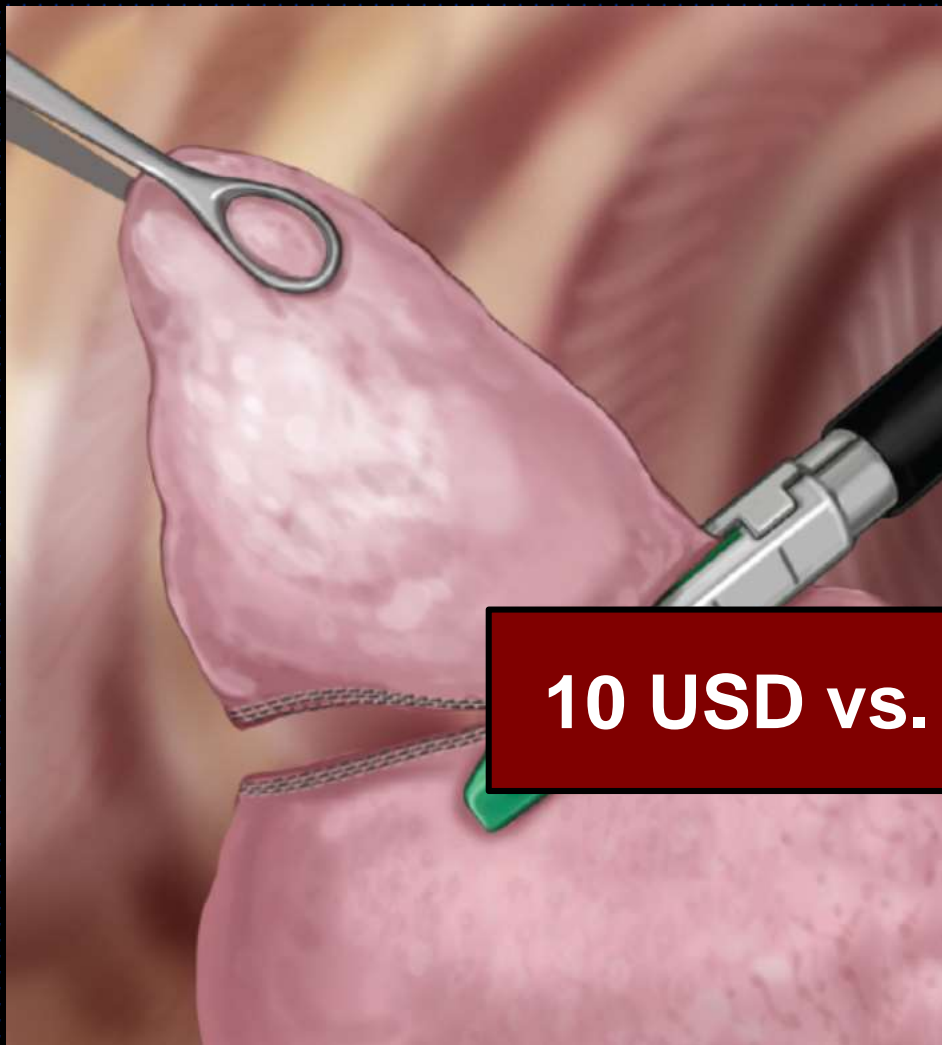
Para-leak: RR, 1.25 (95% CI, 0.70-2.23)

**PPM: RR, 2.00 (95% CI, 1.37-2.93)**

Mortality: RR, 0.78 (95% CI, 0.50-1.22)

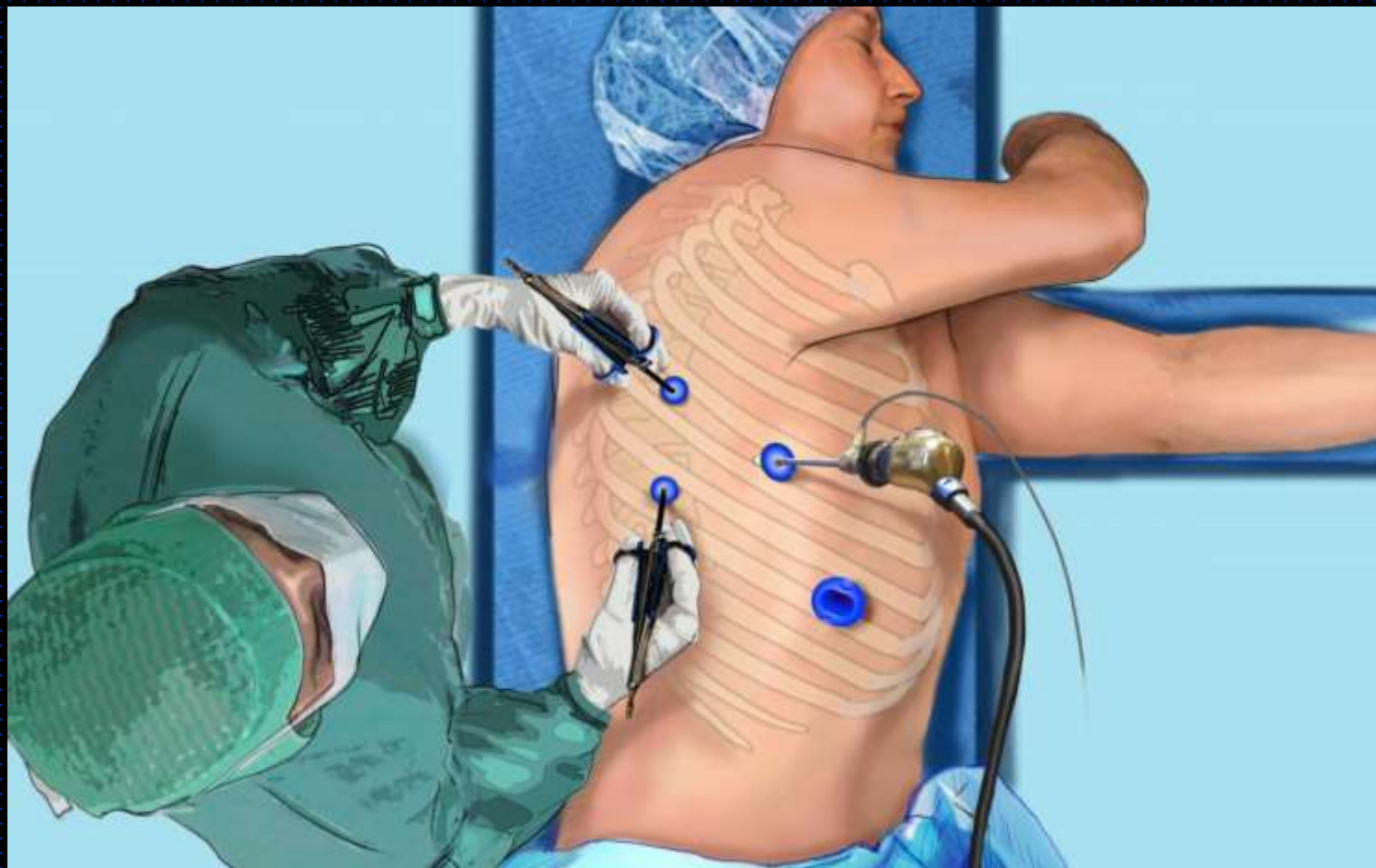
Mean pressure gradient: -1.19 (-2.47-0.10)

# Real Benefit of Stapling?



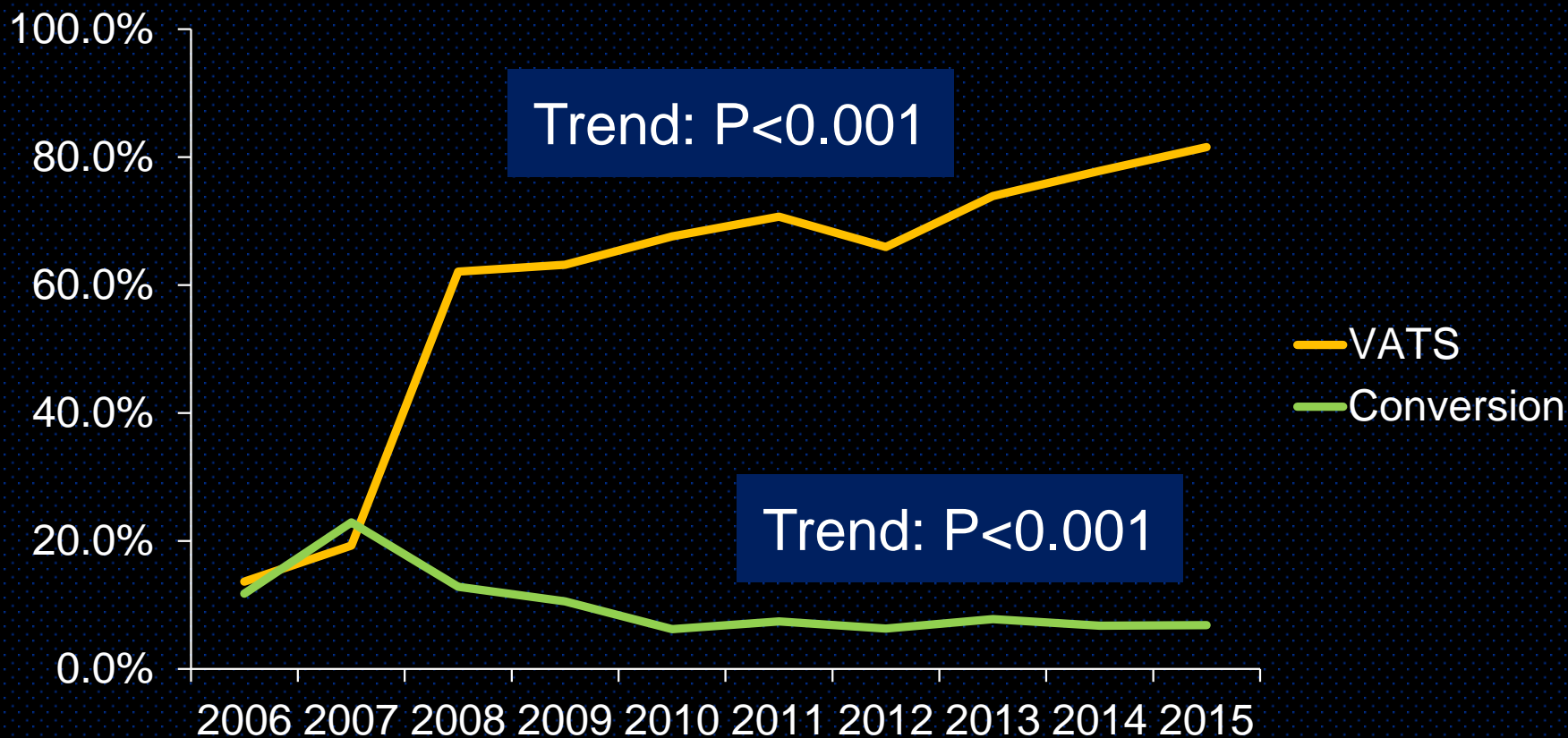
**10 USD vs. >>300 USD**

# Real Benefit of Stapling?



# Curative Lobectomy

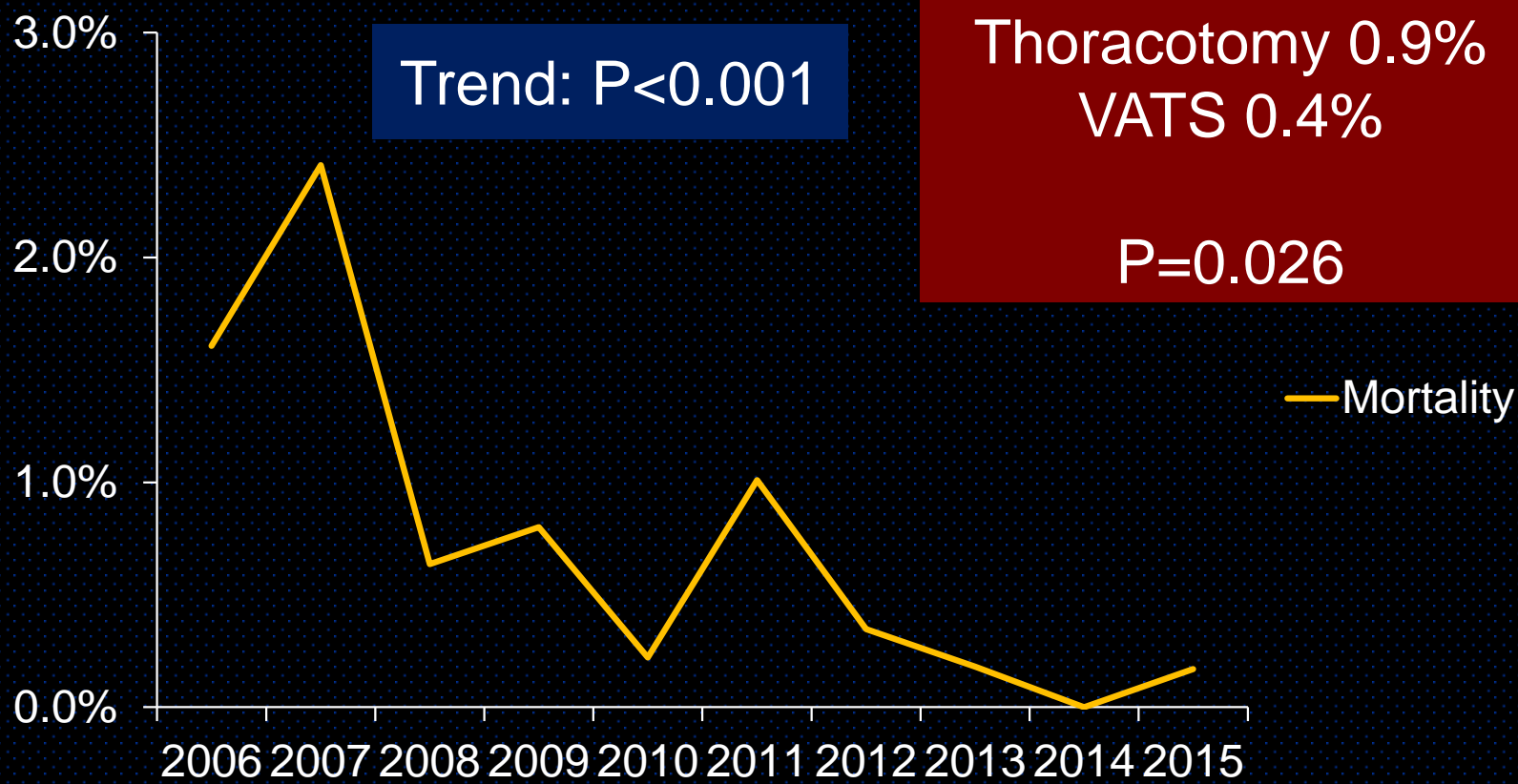
## Open vs. VATS 2006-2015 (N=4426)



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
VATS	13.7%	19.3%	62.1%	63.2%	67.6%	70.7%	66.0%	73.9%	77.9%	81.6%
Conversion	11.8%	22.9%	12.8%	10.5%	6.2%	7.4%	6.3%	7.8%	6.8%	6.8%

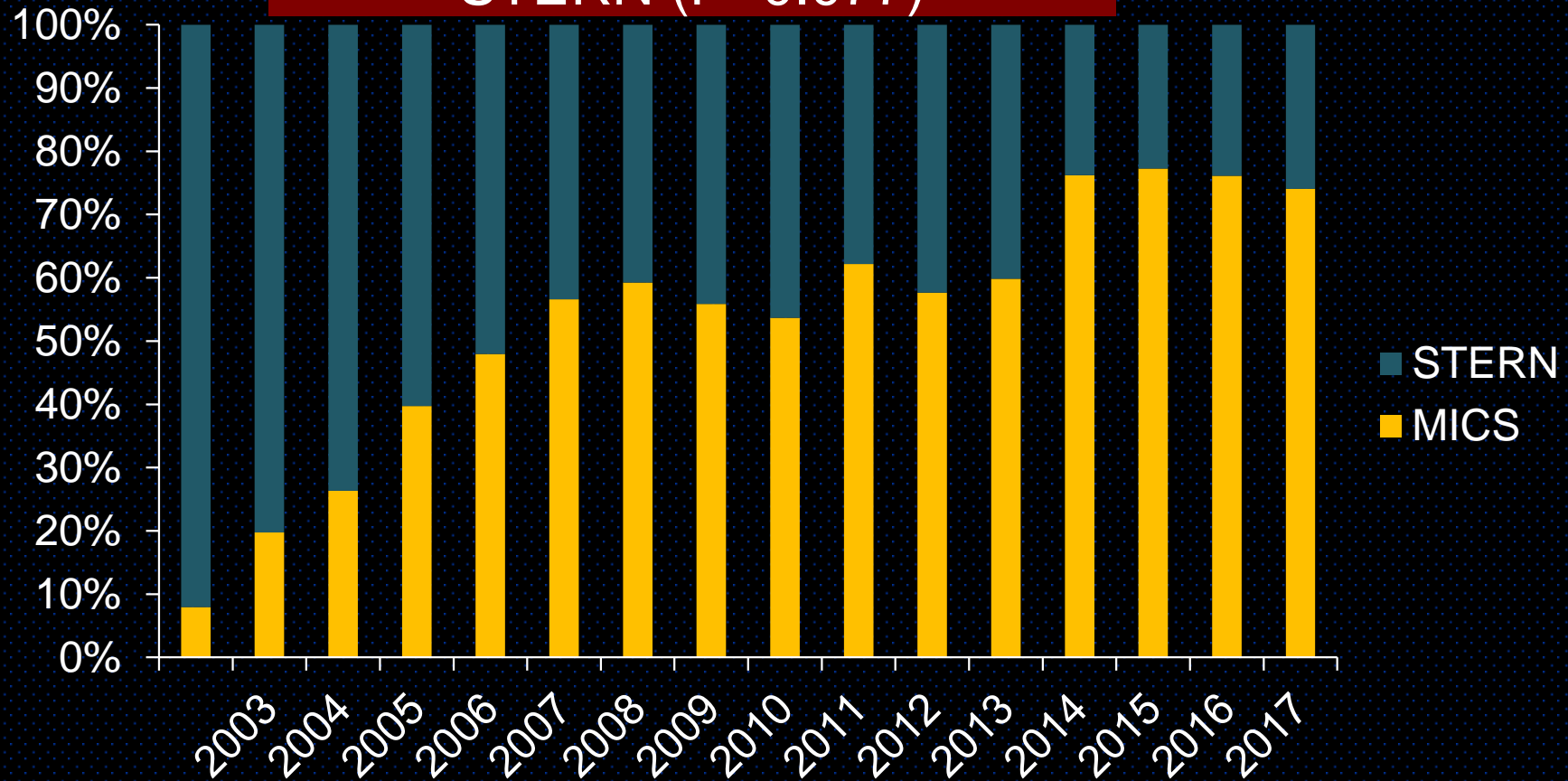


# Operative Mortality



# MV surgery (+/- Maze) : N=1824

Early mortality rate  
0.3% in MICS vs. 1.0% in  
STERN (P=0.077)



# Take Home Message

- Overt clinical benefits of rapid deployment system (RDS) in AVR: yet to be proven
- With high procedural efficiency, RDS are well married with MICS
  - : may contribute to improved outcomes
- This issue is await of results from larger datasets.



**Thank you**