

**Up-to-date TAVR Data from AMC :**  
**TP-TAVR, ADAPT-TAVR, ASAN TAVR Registry**

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# Disclosure





- I, Do-Yoon Kang, DO NOT have a conflict of interest related to this presentation.

# TP-TAVR Registry

## Multi-National, Multi-Center, Multi-Ethnic Registry

Original research

### Inter-racial differences in patients undergoing transcatheter aortic valve implantation

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#### ABSTRACT

**Objective** Little information exists about inter-racial differences in patients with aortic stenosis (AS) undergoing transcatheter aortic valve implantation (TAVI). We investigated whether differences in baseline characteristics between Asian and non-Asian population may contribute to disparities in clinical outcomes after TAVI.

**Methods** We performed a registry-based, multinational cohort study of patients with severe AS who underwent TAVI at two centres in the USA and one centre in South Korea. The primary outcome was a composite of death, stroke or rehospitalisation at 1 year.

**Results** Of 1412 patients, 581 patients were Asian and 831 were non-Asian (87.5% white, 1.7% black, 6.1% Hispanic or 4.7% others). There were substantial differences in baseline characteristics between two racial groups. The primary composite outcome was significantly lower in the Asian group than in the non-Asian group (26.0% vs 35.0%; HR 0.73; 95% CI 0.59 to 0.89;  $p=0.003$ ). However, after adjustment of baseline covariates, the risk of primary composite outcome was not significantly different (HR 0.79; 95% CI 0.60 to 1.03;  $p=0.08$ ). The all-cause mortality at 1 year was significantly lower in the Asian group than the non-Asian group (7.4% vs 12.5%; HR 0.60; 95% CI 0.41 to 0.88;  $p=0.009$ ). After multivariable adjustment, the risk of all-cause mortality was also similar (HR 1.17; 95% CI 0.73 to 1.88;  $p=0.52$ ).

procedures is rapidly increasing worldwide and has currently surpassed the number of isolated surgical aortic valve replacements (SAVRs).<sup>10–11</sup>

Recent data suggest significant inter-racial and interethnic differences in the prevalence, management and outcomes among patients with severe AS.<sup>12–14</sup> In particular, given that the majority of TAVI trials have been conducted in Western population from the USA and Europe and the adoption of TAVI has been more delayed in Asia, further clinical investigations of TAVI are required in Asian population who have unique anatomical features (ie, lower body surface area, smaller aortic valve annulus sizes and smaller vascular access sites).<sup>15–17</sup> However, clinical studies specifically reporting potential inter-racial and international differences of TAVI patients are still lacking.<sup>18</sup> We therefore assessed differences in baseline demographic, clinical, anatomical and procedural characteristics according to different racial groups (Asian vs non-Asian), and evaluated how these differences were related to differences in clinical outcomes following TAVI using a multinational, multiracial transpacific transcatheter aortic valve replacement (TP-TAVR) registry. We also evaluated these baseline and outcome differences nationally (USA vs South Korea).

#### METHODS

##### Study population, database and procedures

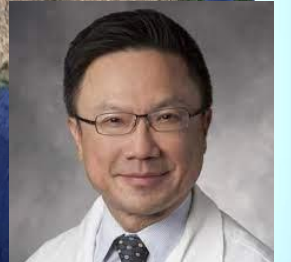
# TransPacific (TP) - TAVR Registry



Asan Medical Center  
Seoul, Korea  
Duk-Woo Park, MD

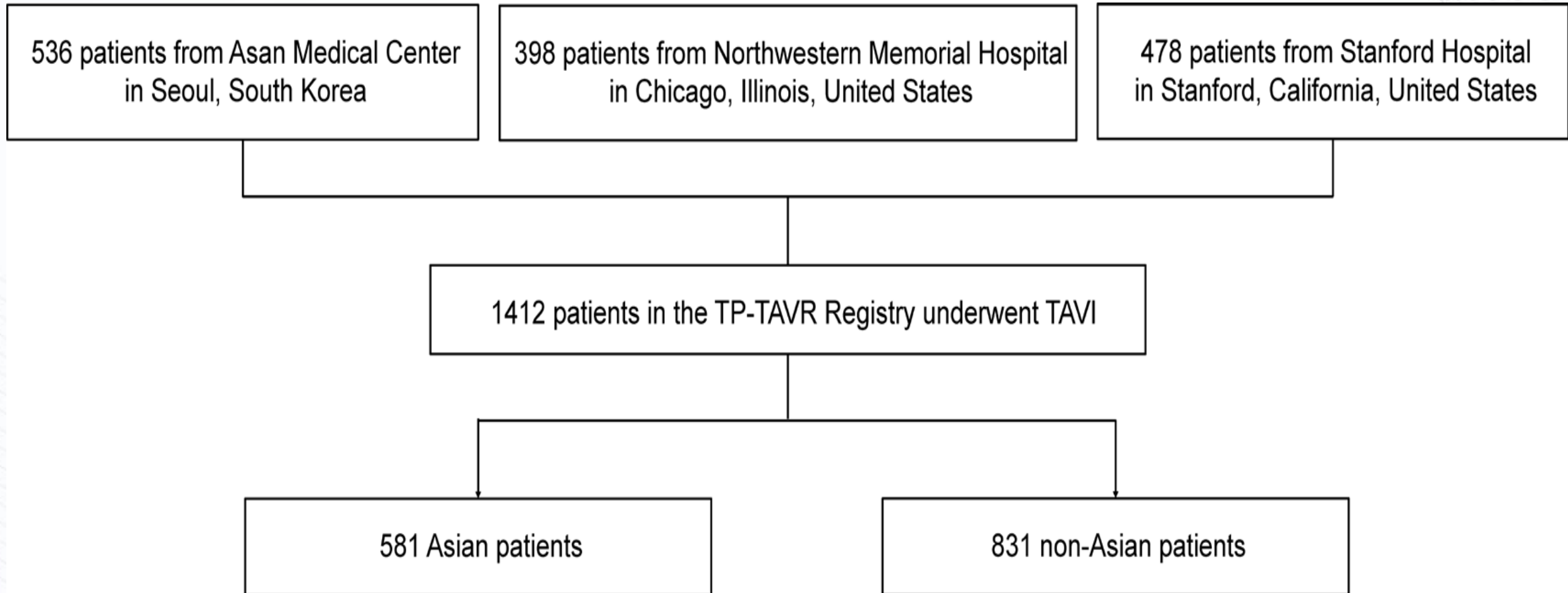


Northwestern  
Memorial Hospital,  
Chicago, IL, US  
James D. Flaherty, MD



Stanford University  
Stanford, CA, US  
Alan C. Yeung, MD

# TransPacific (TP) - TAVR Registry

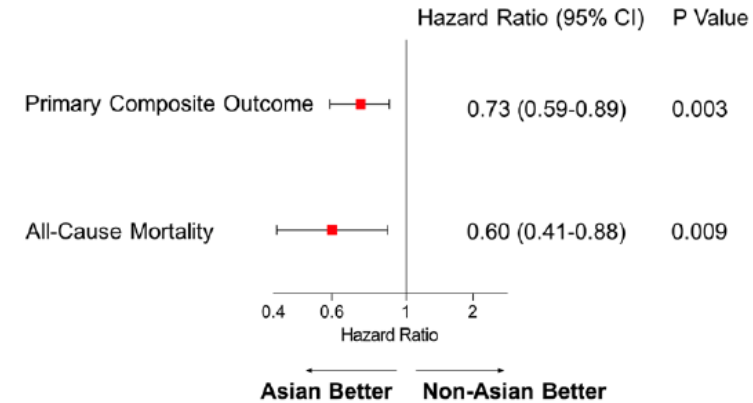


# Inter-racial Difference in TAVR Patients

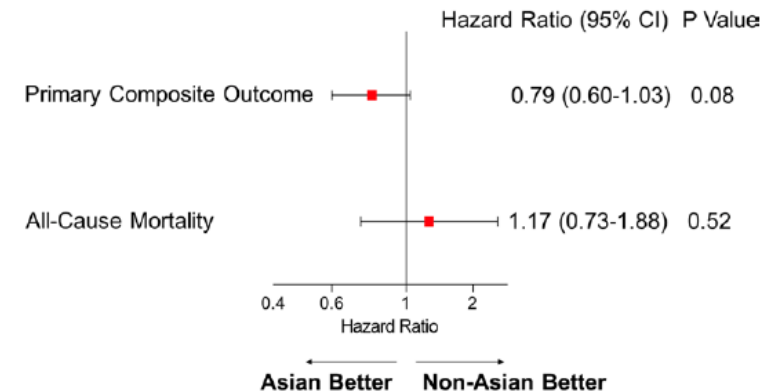
Characteristics	Asian	Non-Asian
Age	≈	
Gender	≈	
BMI		▲
STS score		▲
Diabetes		▲
Hypertension	≈	
Prior PCI	≈	
Prior CABG		▲
Atrial fibrillation		▲
ESRD on Dialysis	≈	
Aortic Valve Area		▲
Transaortic pressure gradient	▲	
Bicuspid AV	▲	
Aortic Annular area on CT		▲
LV Ejection fraction	≈	
Valve-in-valve TAVI		▲
Transfemoral approach	≈	
Valve type	≈	
Valve size		▲
In-hospital event		
Death or stroke	≈	
Bleeding complication	▲	
Vascular complications	▲	
New permanent pacemaker		▲
New-onset AF	≈	

## Clinical Outcomes at 1-year after TAVI

### Unadjusted Model



### Adjusted Model



# Racial Differences in the Incidence and Impact of Prosthesis-Patient Mismatch After Transcatheter Aortic Valve Replacement

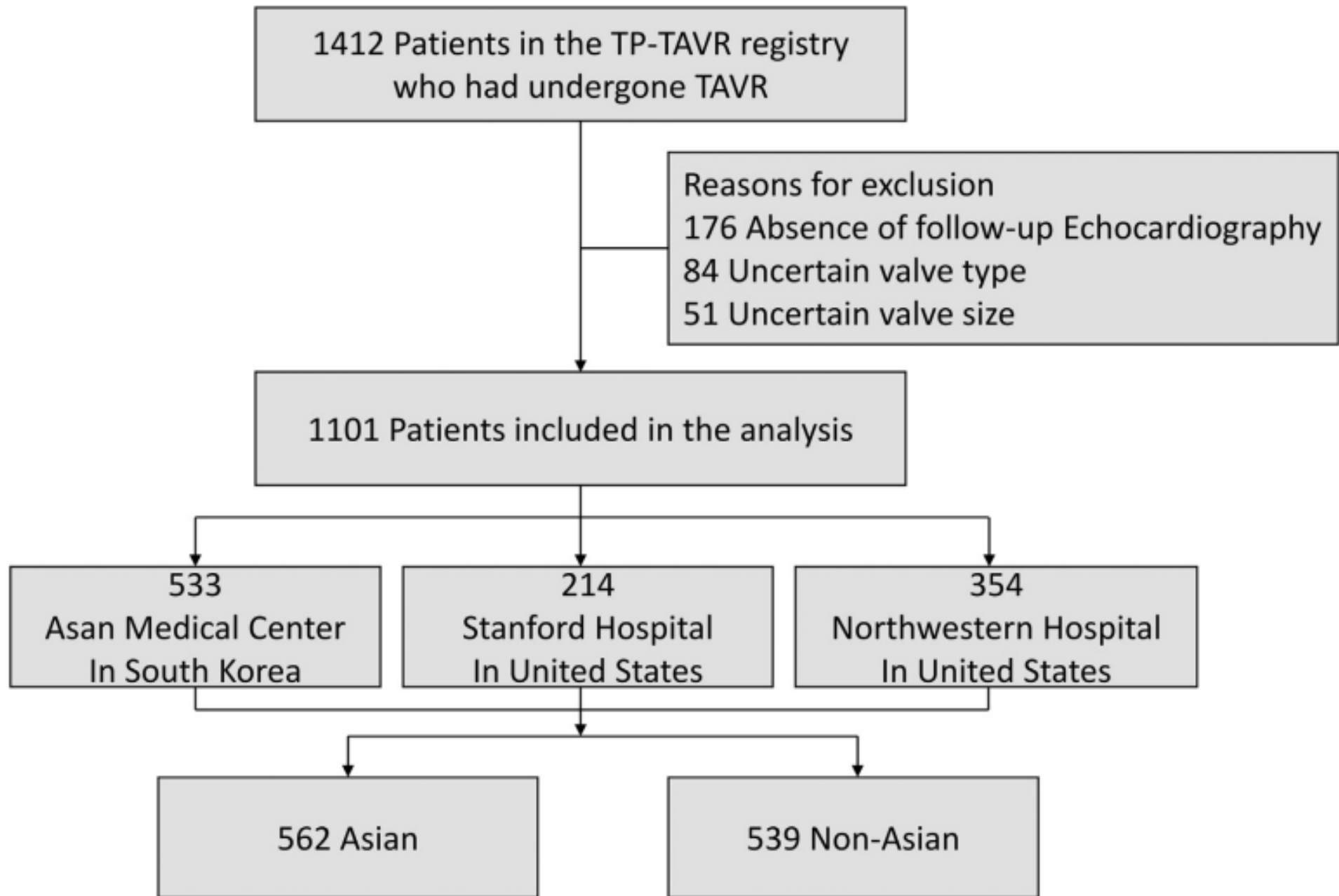


Hanbit Park, MD,<sup>a,\*</sup> Jung-Min Ahn, MD,<sup>a,\*</sup> Do-Yoon Kang, MD,<sup>a</sup> Juyong Brian Kim, MD,<sup>b</sup> Alan C. Yeung, MD,<sup>b</sup> Takeshi Nishi, MD,<sup>b</sup> William F. Fearon, MD,<sup>b</sup> Eric Page Cantey, MD,<sup>c</sup> James D. Flaherty, MD,<sup>c</sup> Charles J. Davidson, MD,<sup>c</sup> S. Christopher Malaisrie, MD,<sup>c</sup> Sehee Kim, PhD,<sup>d</sup> Sung-Cheol Yun, PhD,<sup>d</sup> Euihong Ko, MD,<sup>a</sup> Seung-Ah Lee, MD,<sup>a</sup> Dae-Hee Kim, MD,<sup>a</sup> Ho Jin Kim, MD,<sup>e</sup> Joon Bum Kim, MD,<sup>e</sup> Suk Jung Choo, MD,<sup>e</sup> Duk-Woo Park, MD,<sup>a</sup> Seung-Jung Park, MD<sup>a</sup>

## ABSTRACT

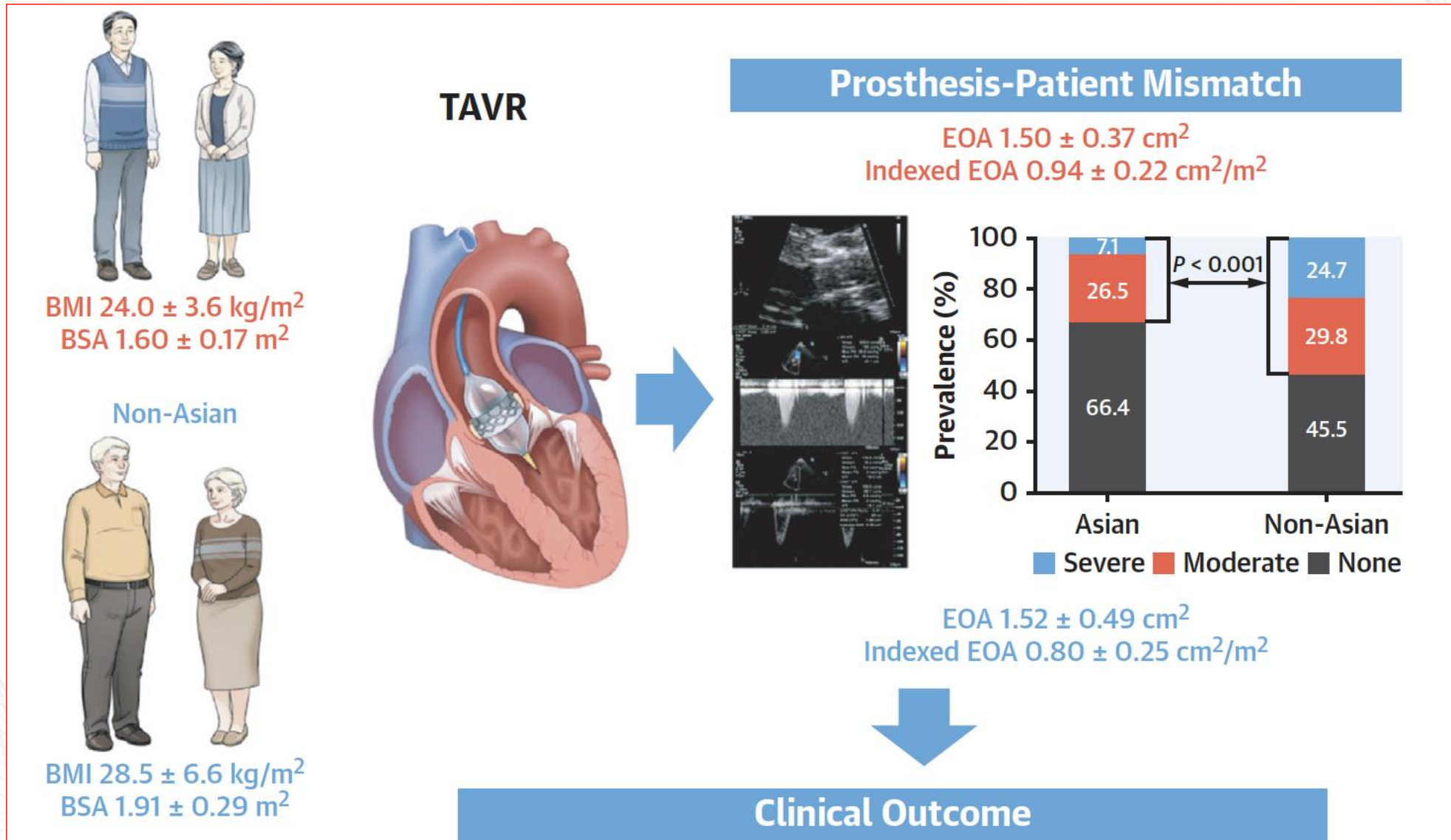
**OBJECTIVES** The aim of this study was to compare the incidence and prognostic significance of prosthesis-patient mismatch (PPM) after transcatheter aortic valve replacement (TAVR) according to racial groups.

**BACKGROUND** PPM after TAVR may be of more concern in Asian populations considering their relatively small annular and valve sizes compared with Western populations.

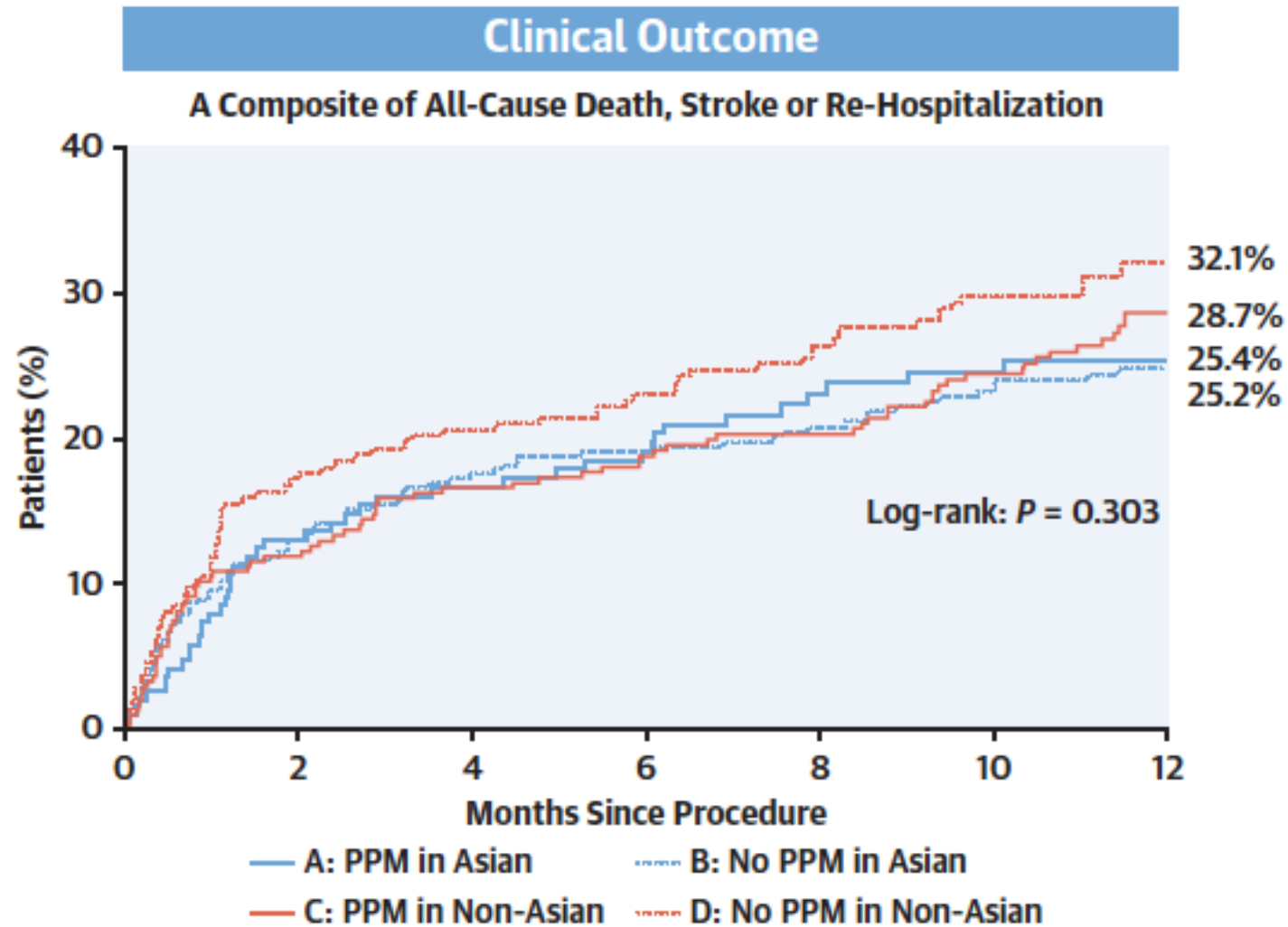




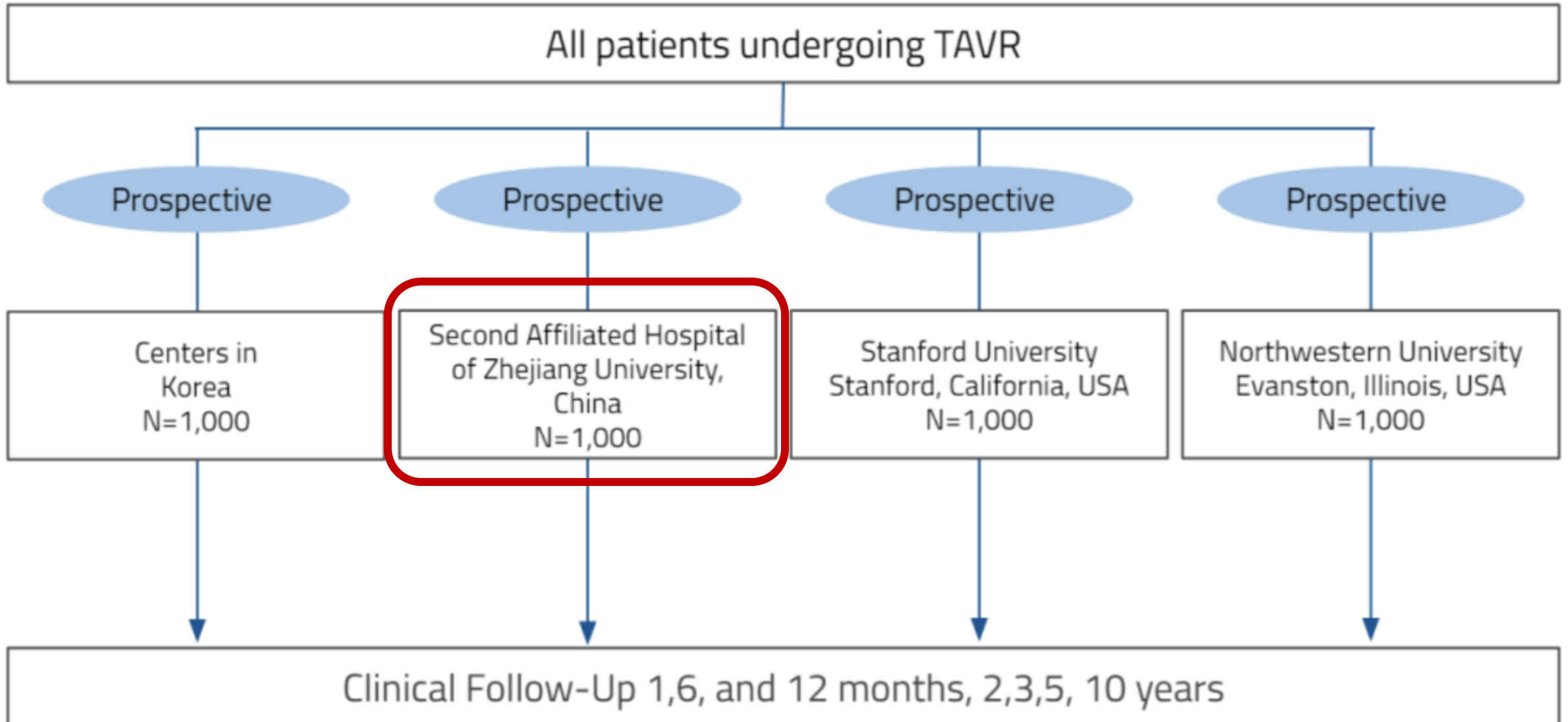
# Inter-Racial Disparity of PPM Incidence



# Inter-Racial Difference in PPM Impact



# 2<sup>ND</sup> Wave of TP-TAVR Registry in Ongoing



# ADAPT-TAVR Trial

Multi-National, Multi-Center,  
Open-Label Investigator-  
Initiated Randomized Trial

Presented at ACC 2022

## ORIGINAL RESEARCH ARTICLE

### Edoxaban Versus Dual Antiplatelet Therapy for Leaflet Thrombosis and Cerebral Thromboembolism After TAVR: The ADAPT-TAVR Randomized Clinical Trial

Duk-Woo Park<sup>1</sup>, MD; Jung-Min Ahn<sup>2</sup>, MD; Do-Yoon Kang, MD; Kyung Won Kim, MD; Hyun Jung Koo, MD; Dong Hyun Yang<sup>3</sup>, MD; Seung Chai Jung, MD; Byungjun Kim, MD; Yiu Tung Anthony Wong<sup>4</sup>, MD; Cheung Chi Simon Lam, MD; Wei-Hsian Yin, MD; Jeng Wei, MD; Yung-Tsai Lee, MD; Hsien-Li Kao<sup>5</sup>, MD; Mao-Shin Lin, MD; Tsung-Yu Ko, MD; Won-Jang Kim, MD; Se Hun Kang, MD; Sung-Cheol Yun, PhD; Seung-Ah Lee<sup>6</sup>, MD; Euihong Ko, MD; Hanbit Park, MD; Dae-Hee Kim<sup>7</sup>, MD; Joon-Won Kang, MD; Jae-Hong Lee<sup>8</sup>, MD; Seung-Jung Park<sup>9</sup>, MD; for the ADAPT-TAVR Investigators

**BACKGROUND:** It is unknown whether the direct oral anticoagulant edoxaban can reduce leaflet thrombosis and the accompanying cerebral thromboembolic risk after transcatheter aortic valve replacement. In addition, the causal relationship of subclinical leaflet thrombosis with cerebral thromboembolism and neurological or neurocognitive dysfunction remains unclear.

**METHODS:** We conducted a multicenter, open-label randomized trial comparing edoxaban with dual antiplatelet therapy (aspirin plus clopidogrel) in patients who had undergone successful transcatheter aortic valve replacement and did not have an indication for anticoagulation. The primary end point was an incidence of leaflet thrombosis on 4-dimensional computed tomography at 6 months. Key secondary end points were the number and volume of new cerebral lesions on brain magnetic resonance imaging and the serial changes of neurological and neurocognitive function between 6 months and immediately after transcatheter aortic valve replacement.

**RESULTS:** A total of 229 patients were included in the final intention-to-treat population. There was a trend toward a lower incidence of leaflet thrombosis in the edoxaban group compared with the dual antiplatelet therapy group (9.8% versus 18.4%; absolute difference, -8.5% [95% CI, -17.8% to 0.8%];  $P=0.076$ ). The percentage of patients with new cerebral lesions on brain magnetic resonance imaging (edoxaban versus dual antiplatelet therapy, 25.0% versus 20.2%; difference, 4.8%; 95% CI, -6.4% to 16.0%) and median total new lesion number and volume were not different between the 2 groups. In addition, the percentages of patients with worsening of neurological and neurocognitive function were not different between the groups. The incidence of any or major bleeding events was not different between the 2 groups. We found no significant association between the presence or extent of leaflet thrombosis with new cerebral lesions and a change of neurological or neurocognitive function.

# Study Design

## ADAPT-TAVR Trial:

**A**nticoagulant versus **D**ual **A**ntiplatelet Therapy for **P**reventing Leaflet **T**hrombosis  
After **T**ranscatheter **A**ortic **V**alve **R**eplacement

**220 patients without OAC indication after successful TAVR**

Stratified randomization by (1) device type and (2) participating site

**NOAC:**  
Edoxaban 60 mg or 30 mg once daily\*  
(N=110)

**DAPT:**  
ASA plus Clopidogrel  
(N=110)

### Mandatory evaluations:

- 4D, Cardiac CT at 6-Mo after TAVR
- Serial brain MRI and neurological/neurocognitive function tests at baseline and 6-Mo

\*30 mg once daily if moderate or severe renal impairment (creatinine clearance 15 – 50 mL/min), low body weight ≤60kg, or concomitant use of P-glycoprotein inhibitors (cyclosporin, dronedarone, erythromycin, ketoconazole).

# Enrollment: 5 centers, 3 countries



Asan Medical Center  
- DW Park, SJ Park  
CHA Bundang Medical Center  
- WJ Kim, SH Kang

Cheng Hsin General Hospital  
- WH Yin, J Wei, YT Lee  
National Taiwan University Hospital  
- HL Kao, MS Lin, TY Ko

Queen Mary Hospital  
- SCC Lam, AYT Wong

**Executive Committee:** DW Park (Trial PI), SJ Park, SCC Lam, WH Yin, HL Kao, WJ Kim

**Data Monitoring Committee:** MS Lee (Chairperson), BK Koo, YG Ko, YH Jeong, JH Kim

**Clinical Events Committee:** CH Lee (Chairperson), JH Lee, JH Kim

**Imaging (CT and MRI) Core Lab:** **Asan Image Metrics (Imaging Corelab)**, KW Kim (Chairperson), DH Yang (CT corelab), SC Jung (MRI corelab)

**Neurocognitive function and echo Core Lab:** JH Lee (Chair, Neurology Corelab), SA Lee (Chair, Echo. Corelab)

# Study Endpoints

## Primary endpoint

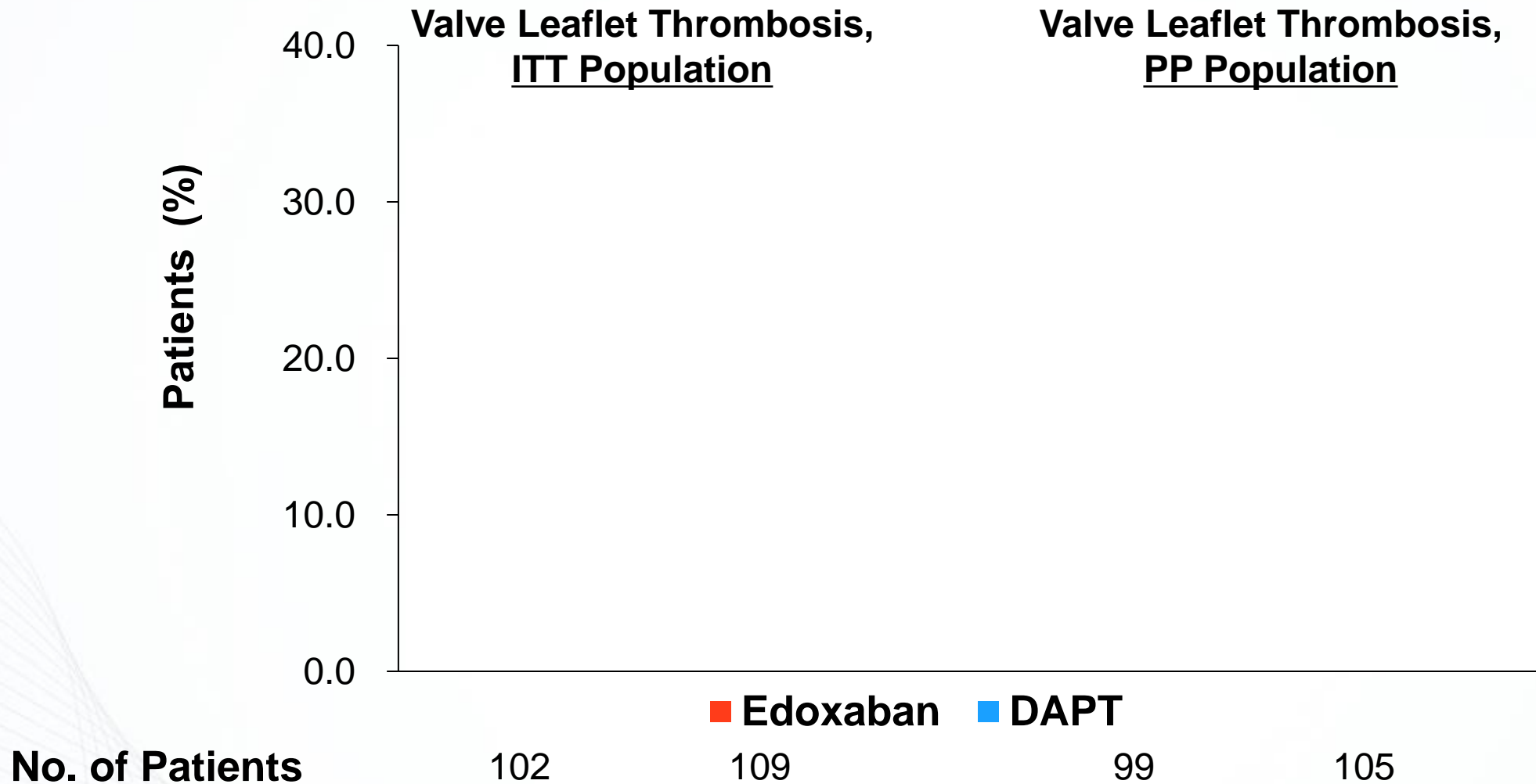
- Incidence of leaflet thrombosis on 4D, volume-rendered CT at 6 months

## Secondary endpoints

- Presence and number/volume of new cerebral lesions on brain MRI
- Serial change of neurological/neurocognitive assessment (NIHSS, mRS, and MoCA)
- Clinical safety and efficacy outcomes
- Serial echocardiographic parameters

NIHSS, National Institutes of Health Stroke Scale; mRS, modified Rankin Scale; MoCA, Montreal Cognitive Assessment

# 4D-CT Primary End Points

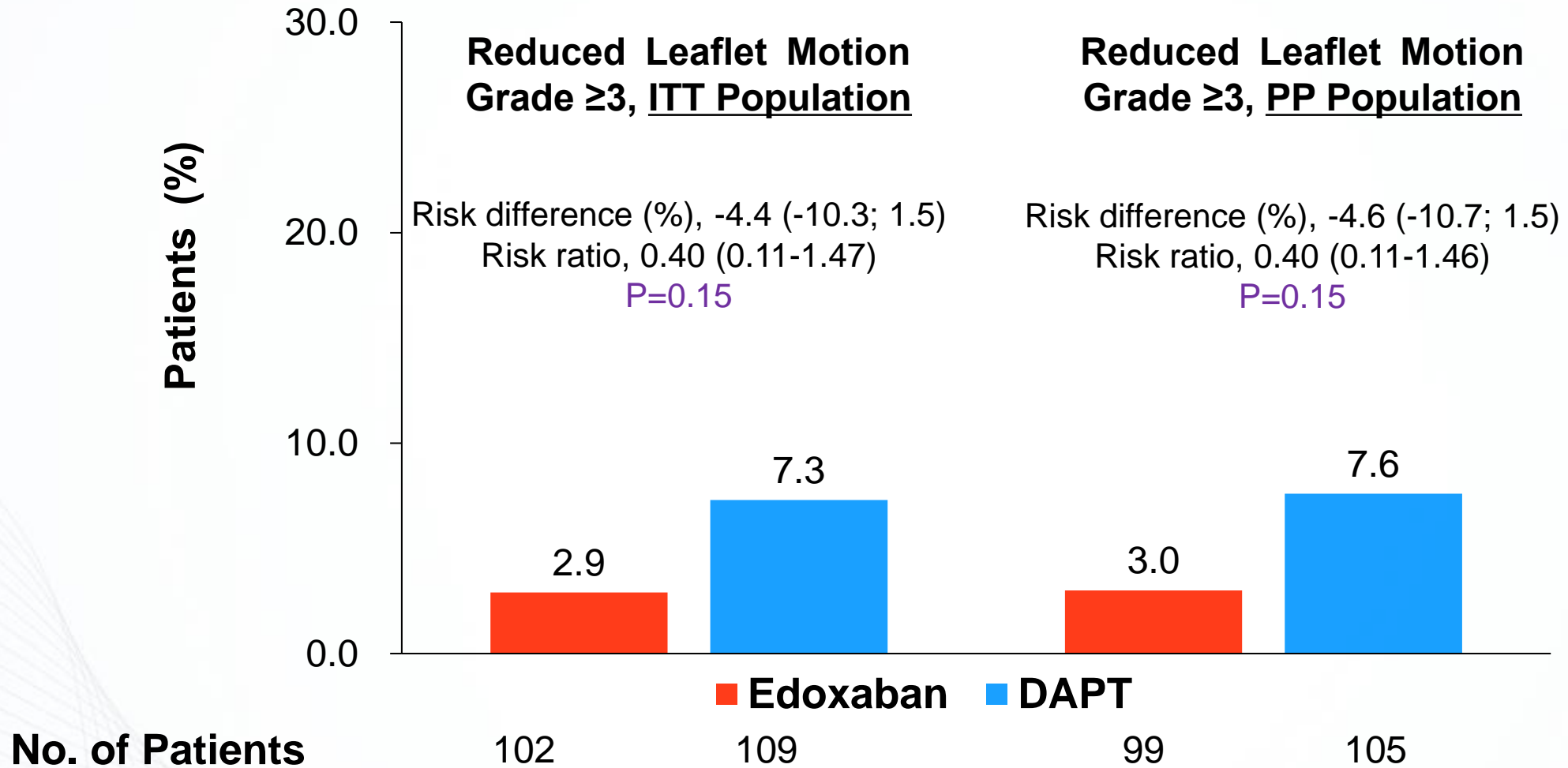


The degree of hypoattenuated leaflet thickening and the severity of reduced leaflet motion were classified according to the standard definition (Blanke P, et al. JACC Cardiovasc Imaging. 2019;12:1-24)

\*P values are derived from the chi-square test or Fisher's exact test as appropriate.



# 4D-CT Outcomes

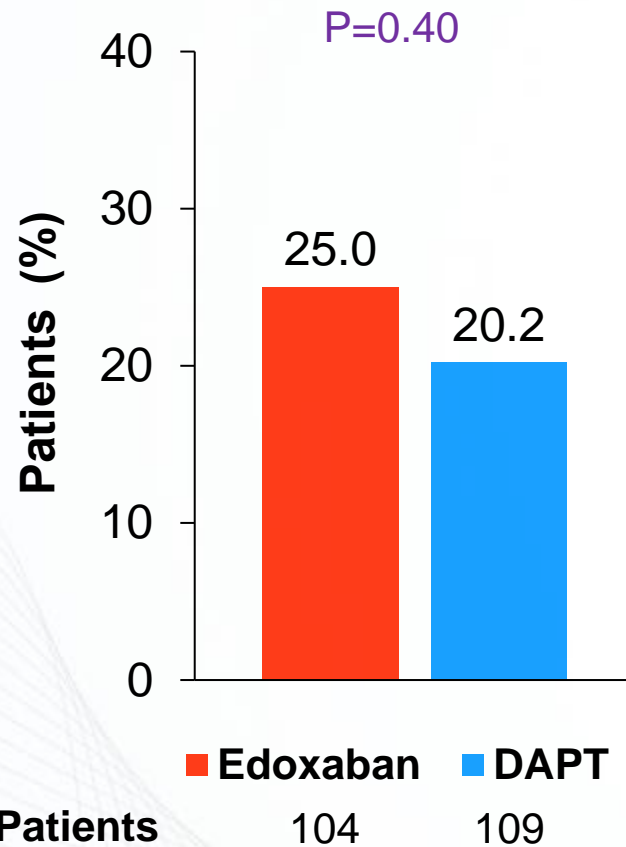


The degree of hypoattenuated leaflet thickening and the severity of reduced leaflet motion were classified according to the standard definition (Blanke P, et al. JACC Cardiovasc Imaging. 2019;12:1-24)

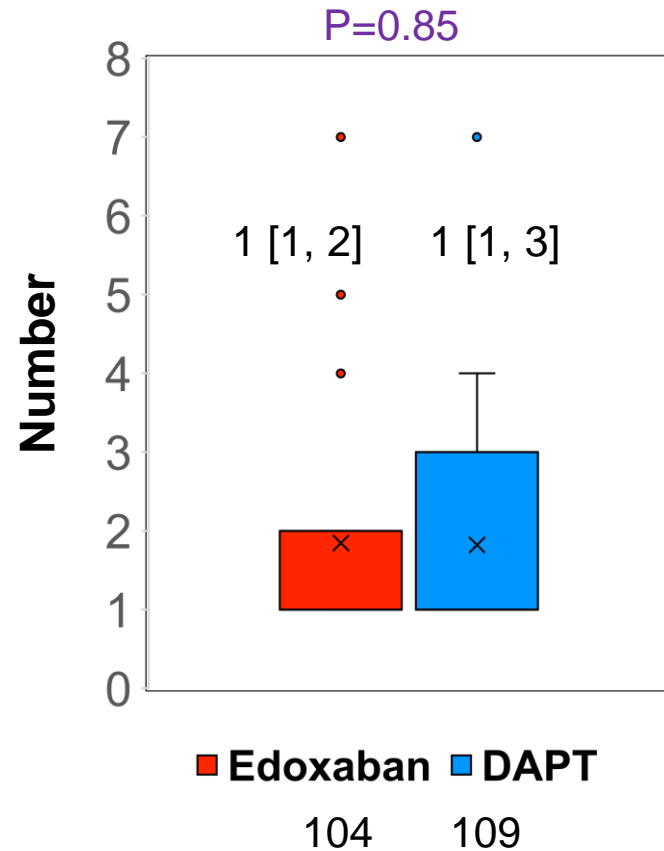
\*P values are derived from the chi-square test or Fisher's exact test as appropriate.

# MRI End Points, ITT Analysis

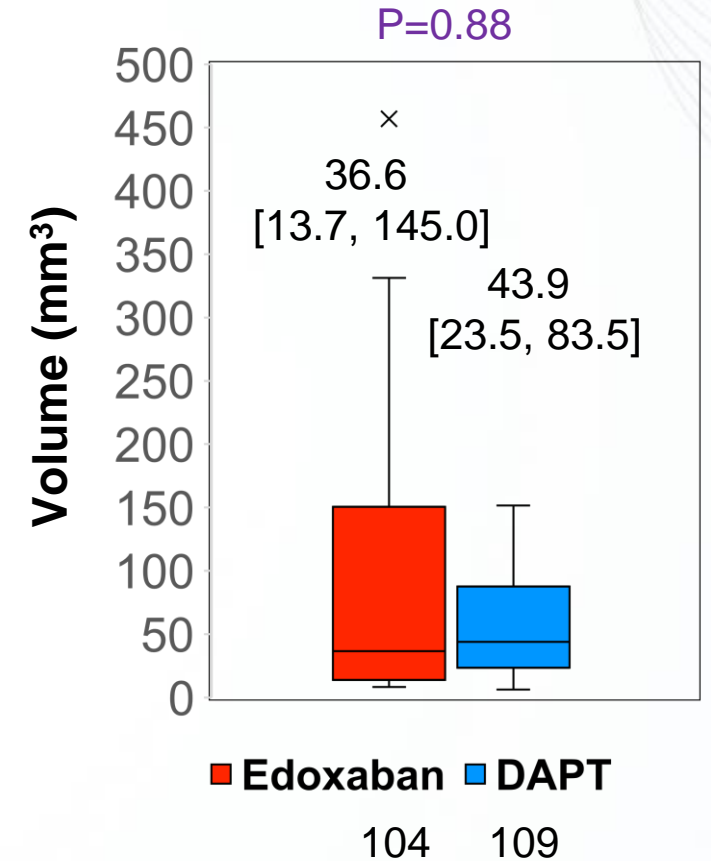
Presence of New Cerebral Lesions



Median Number of Total New Lesions

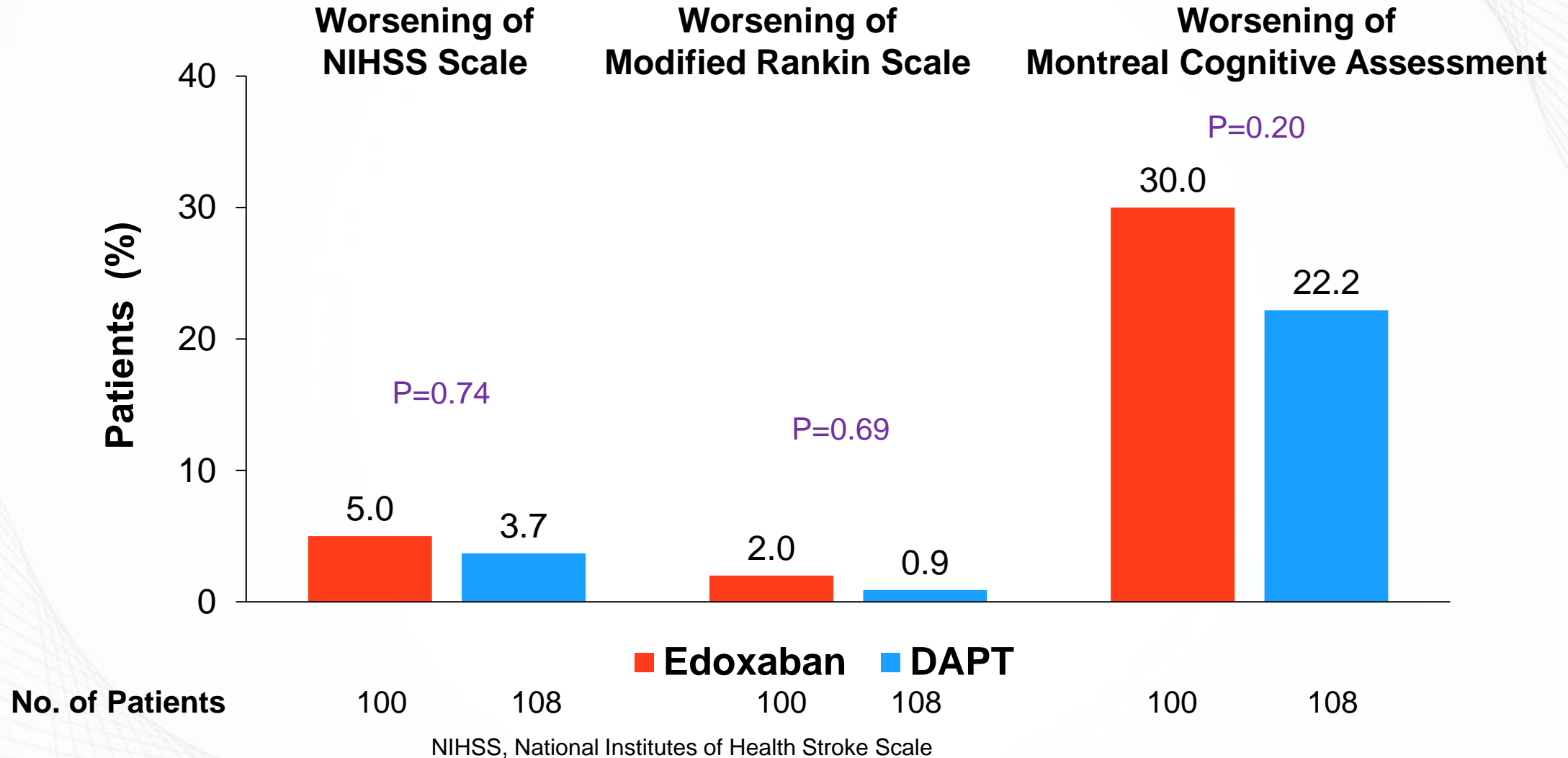


Median Volume of Total New Lesions (mm<sup>3</sup>)



P values are derived from the chi-square test or Fisher's exact test as appropriate.  
 Median differences calculated as independent samples Hodges-Lehmann median difference estimates.

# Neurological & Neurocognitive End Points, ITT Analysis



P values are derived from the chi-square test or Fisher's exact test as appropriate. Worsening is defined as  $\geq 1$  point increase in NIHSS,  $\geq 1$  point increase in modified Rankin scale, or  $\geq 1$  point decrease in Montreal Cognitive Assessment scores as compared to baseline.

# ASAN-TAVR : Single-Center Prospective Registry

## ORIGINAL RESEARCH

### Implication of Different ECG Left Ventricular Hypertrophy in Patients Undergoing Transcatheter Aortic Valve Replacement

Yujin Yang<sup>1</sup>, MD; Jung-Min Ahn<sup>1</sup>, MD; Do-Yoon Kang, MD; Euihong Ko, MD; Seonok Ki Tae Oh Kim<sup>1</sup>, MD; Ju Hyeon Kim<sup>1</sup>, MD; Junghoon Lee<sup>1</sup>, MD; Seung-Ah Lee<sup>1</sup>, MD; Dae-Hee Kim<sup>1</sup>, MD; Joon Bum Kim, MD; Suk Jung Choo, MD; Seung-Jung Park<sup>1</sup>, MD; Dae-Hee Kim, MD, PhD; Jin Kyung Oh, MD, PhD; Seung-Ah Lee, MD, PhD; Do-Yoon Kang, MD, PhD; Sahmin Lee, MD, PhD; Ho Jin Kim, MD; Jung-Min Ahn, MD, PhD; Joon Bum Kim, MD, PhD; Duk-Woo Park, MD, PhD; Jong-Min Song, MD, PhD; Suk Jung Choo, MD, PhD; Duk-Hyun Kang, MD, PhD; Jae-Kwan Song, MD, PhD; Seung-Jung Park, MD, PhD; Jang Hyun Choi, MD, and Dae-Hee Kim, MD, PhD, Seoul, Republic of Korea

**BACKGROUND:** Various ECG criteria for left ventricular hypertrophy (LVH) have been proposed, but the clinical outcomes in patients with severe aortic stenosis undergoing transcatheter aortic valve replacement investigated the prevalence of ECG LVH according to different criteria and its prognostic impact on transcatheter aortic valve replacement.

**METHODS AND RESULTS:** In this prospective observational cohort, we evaluated 700 patients who underwent aortic valve replacement between March 2010 and December 2019. Baseline preprocedural LVH criteria—Sokolow-Lyon, Romhilt-Estes, and Cornell voltage criteria. The primary outcome was cerebrovascular event (MACCE; composite of death, myocardial infarction, stroke, or rehospitalization); the key secondary outcome was all-cause and cardiovascular mortality. Among 596 eligible patients, LVH was determined as 56.3% by Sokolow-Lyon, 31.1% by Romhilt-Estes, and 48.1% by Cornell criteria. Patients with ECG LVH had more severe aortic stenosis hemodynamics and higher left ventricular hypertrophy. After multivariate adjustment, the presence of LVH by the Cornell criteria was significantly associated with (adjusted hazard ratio [HR], 0.68; 95% CI, 0.51–0.91;  $P=0.009$ ), all-cause mortality (adjusted HR, 0.0 [95% CI, 0.0–0.017]), and cardiovascular mortality (adjusted HR, 0.40; 95% CI, 0.20–0.79 [ $P=0.008$ ]). However, the Sokolow-Lyon and Romhilt-Estes criteria.

**CONCLUSIONS:** ECG LVH by Cornell criteria only was significantly associated with lower risks of MACCE and cardiovascular mortality.

**REGISTRATION:** URL: <https://www.clinicaltrials.gov>; Unique Identifier: NCT03298178.

**Key Words:** aortic valve stenosis ■ left ventricular hypertrophy ■ transcatheter aortic valve replacement

## STRAIN ECHOCARDIOGRAPHY IN AORTIC STENOSIS

### Incremental Prognostic Value of Left Ventricular Global Longitudinal Strain in Patients with Preserved Ejection Fraction Undergoing Transcatheter Aortic Valve Implantation

Sun-Hack Lee, MD, Jin Kyung Oh, MD, PhD, Seung-Ah Lee, MD, PhD, Do-Yoon Kang, MD, PhD, Sahmin Lee, MD, PhD, Ho Jin Kim, MD, Jung-Min Ahn, MD, PhD, Joon Bum Kim, MD, PhD, Duk-Woo Park, MD, PhD, Jong-Min Song, MD, PhD, Suk Jung Choo, MD, PhD, Duk-Hyun Kang, MD, PhD, Jae-Kwan Song, MD, PhD, Seung-Jung Park, MD, PhD, Jang Hyun Choi, MD, and Dae-Hee Kim, MD, PhD, Seoul, Republic of Korea

**Background:** Evaluation of left ventricular global longitudinal strain (LVGLS) has allowed better characterization than left ventricular ejection fraction (LVEF) of subtle differences in left ventricular performance. The aim of this study was to determine whether LVGLS has prognostic value in patients with severe aortic stenosis undergoing transcatheter aortic valve implantation (TAVI).

**Methods:** Among 412 consecutive patients who underwent TAVI, 344 patients (mean age, 78.9 ± 5.0 years; 161 men) with preserved LVEF (≥50%) at baseline were analyzed. Patients with low LVEF (<50%) were used as a comparison group in the survival analysis. The primary and secondary end points were all-cause death and a composite of cardiovascular death and heart failure hospitalization, respectively.

**Results:** The mean LVGLS and LVEF were  $-17.1 ± 2.7%$  and  $63 ± 5%$ , respectively. Impaired LVGLS defined as  $>-16%$ , which was the first LVGLS quartile (cutoff value,  $-16%$ ). The estimated actuarial survival rate was  $81.7 ± 4.2%$  in the normal LVGLS group and  $66.8 ± 7.5%$  in the impaired LVGLS group ( $P=0.05$ ). In the multivariate analysis, impaired LVGLS was an independent predictor of all-cause mortality (adjusted hazard ratio, 2.26; 95% CI, 1.11–4.60) and the composite outcome (adjusted hazard ratio 95% CI, 1.45–6.33). Moreover, the impaired LVGLS group had a poor prognosis, similar to the LVEF group (<50%). The addition of the absolute value of LVGLS to the clinical parameters and LVEF significantly improved the prediction of all-cause mortality.

**Conclusions:** In patients with severe aortic stenosis and preserved LVEF undergoing TAVI, subclinical dysfunction defined by impaired LVGLS is independently associated with poor clinical outcomes. LVEF measurement provides incremental prognostic value above the established clinical and echocardiographic parameters. (J Am Soc Echocardiogr 2022;35:947–55.)

**Keywords:** Global longitudinal strain, Outcomes, Transcatheter aortic valve implantation

## Prognostic Value of Baseline Sarcopenia on 1-year Mortality in Patients Undergoing Transcatheter Aortic Valve Implantation

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There is limited data regarding the association between sarcopenia and clinical outcomes in patients who underwent transcatheter aortic valve implantation (TAVI). From the prospective ASAN-TAVI registry, we evaluated a total of 522 patients with severe aortic stenosis who underwent TAVI between March 2010 and November 2018. Routine pre-TAVI computed tomography scan was used to calculate the skeletal muscle index (SMI), which was defined as skeletal muscle area at the L3 level divided by height squared; subject patients were classified into the gender-specific tertile groups of SMI. The patients' mean age was 79 years and 49% were men. Mean SMI values were  $41.3 ± 6.7$  cm<sup>2</sup>/m<sup>2</sup> in men and  $34.1 ± 6.5$  cm<sup>2</sup>/m<sup>2</sup> in women. The Kaplan–Meier estimates of all-cause mortality at 12 months were higher in the low-tertile group than in the mid- and high-tertile groups (15.5%, 7.1%, and 6.2%, respectively;  $p=0.036$ ). In multivariate analysis, low-tertile of SMI was an independent predictor of mortality (vs high-tertile of SMI, hazard ratio 2.69; 95% confidence interval, 1.18 to 6.12;  $p=0.019$ ). The all-cause mortality was substantially higher in the groups with high-surgical risk plus low SMI tertile. The risk assessment with addition of SMI on conventional STS-PROM score was significantly improved by statistical measures of model reclassification and discrimination. In patients who underwent TAVI, sarcopenia measured by SMI was significantly associated with an increased risk of 1-year mortality. The prognostic impact of SMI-measured sarcopenia was more prominent in patients with high surgical risks. © 2020 Elsevier Inc. All rights reserved. (Am J Cardiol 2021;139:79–86)

## Incidence, Predictors, and Prognostic Impact of Immediate Improvement in Left Ventricular Systolic Function After Transcatheter Aortic Valve Implantation

Yeong Jin Jeong, MD<sup>1</sup>, Jung-Min Ahn, MD<sup>1</sup>, Do-Yoon Kang, MD<sup>1</sup>, Hanbit Park, MD<sup>1</sup>, Euihong Ko, MD<sup>1</sup>, Ho Jin Kim, MD<sup>1</sup>, Joon Bum Kim, MD<sup>1</sup>, Suk Jung Choo, MD<sup>1</sup>, Seung-Ah Lee, MD<sup>1</sup>, Seung-Jung Park, MD<sup>1</sup>, Dae-Hee Kim, MD<sup>1</sup>, and Duk-Woo Park, MD<sup>1</sup>

Immediate improvement in left ventricular ejection fraction (LVEF) following transcatheter aortic valve implantation (TAVI) is common; however, data on the pattern and prognostic value of this improvement are limited. To evaluate the incidence, predictors, and clinical impact of immediate improvement in LVEF, we studied 694 consecutive patients who had undergone successful TAVI for severe aortic stenosis (AS) between March 2010 and December 2019. We defined immediate improvement of LVEF as an absolute increase of  $≥5%$  in LVEF at post-procedure echocardiogram. The primary outcome was major adverse cardiac or cerebrovascular event (MACCE), defined as a composite of death from cardiovascular cause, myocardial infarction, stroke, or rehospitalization from cardiovascular cause. Among them, 160 patients showed immediate improvement in LVEF. The independent predictors of immediate LVEF improvement were absence of hypertension and baseline significant aortic regurgitation, and greater baseline LV mass index. Immediate improvement in LVEF was significantly associated with a lower risk of MACCE (adjusted hazard ratio, 0.48; 95% confidence interval, 0.28–0.81;  $p=0.001$ ). In conclusion, approximately one-fourth of patients with severe AS who underwent TAVI showed immediate improvement in LVEF during index hospitalization. Immediate LVEF recovery was associated with a lower risk of MACCE during follow-up. © 2021 Elsevier Inc. All rights reserved. (Am J Cardiol 2021;152:99–105)

## Association of aortic valvular complex calcification burden with procedural and long-term clinical outcomes after transcatheter aortic valve replacement

Euihong Ko<sup>1</sup>, Do-Yoon Kang<sup>1</sup>, Jung-Min Ahn<sup>1</sup>, Tae Oh Kim<sup>1</sup>, Ju Hyeon Kim<sup>1</sup>, Junghoon Lee<sup>1</sup>, Seung-Ah Lee<sup>1</sup>, Dae-Hee Kim<sup>1</sup>, Ho Jin Kim<sup>2</sup>, Joon Bum Kim<sup>2</sup>, Suk Jung Choo<sup>2</sup>, Seung-Jung Park<sup>1</sup>, and Duk-Woo Park<sup>1</sup>\*

<sup>1</sup>Division of Cardiology, Department of Internal Medicine, Asan Medical Center, University of Ulsan College of Medicine, 88, Olympic-ro 43-gil, Songpa-gu, Seoul, Republic of Korea; and <sup>2</sup>Department of Thoracic and Cardiovascular Surgery, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Republic of Korea

**Aims** This study aimed to assess the impact of valvular/subvalvular calcium burden on procedural and long-term clinical outcomes in patients undergoing transcatheter aortic valve replacement (TAVR) for severe aortic stenosis

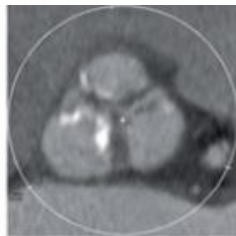
**Methods and results** In this prospective observational cohort study, we included patients with AS undergoing TAVR between 2010 and December 2019. Calcium burden at baseline was quantified using multidetector computed tomography and the patients were classified into tertile groups according to the amount of calcium. Procedural outcomes (PVL) or permanent pacemaker insertion (PPI) and 12-month clinical outcomes (death, stroke, or rehospitalization, and all-cause mortality) were assessed. A total of 676 patients (79.8 ± 5.4 years) were analyzed. The 30-day rates of moderate or severe PVL ( $P$ -for-trend = 0.03) and all-cause mortality were 0.002 and 0.002, respectively. The 12-month rate of composite outcomes was 34.2% in low-tertile, 23.9% in middle-tertile, and 25.8% in high-tertile groups ( $P=0.02$ ). After multivariate adjustment, the risk for primary composite outcomes at 12 months was significantly higher in the high-tertile group of calcium volume [reference = low-tertile; middle-tertile, (HR) 0.81; 95% confidence interval (CI) 0.54–1.22;  $P=0.31$ ; high-tertile, HR 0.93; 95% CI 0.56–1.57; similar pattern was observed for all-cause mortality.

**Conclusion** The rates of PVL and PPI proportionally increased according to the levels of valvular/subvalvular calcium burden, while the adjusted risks for composite outcomes and mortality at 12 months were not significantly different.

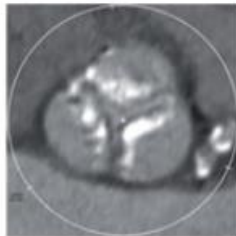
# Prognostic Value of Calcium in TAVR Patients

676 Patients undergoing TAVR

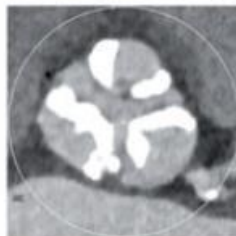
Primary Outcome : Composite of death, stroke, rehospitalization at 12-month



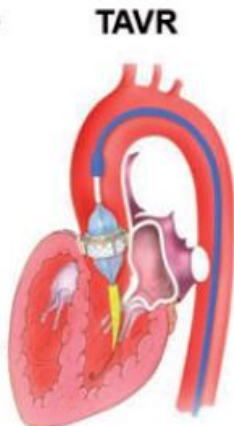
**Low-Tertile**  
Mean:  $104.6 \pm 52.4 \text{ mm}^3$   
Median:  $104.0 (64.5-149.5) \text{ mm}^3$



**Middle-Tertile**  
Mean:  $302.5 \pm 64.8 \text{ mm}^3$   
Median:  $301.5 (248.3-356.3) \text{ mm}^3$

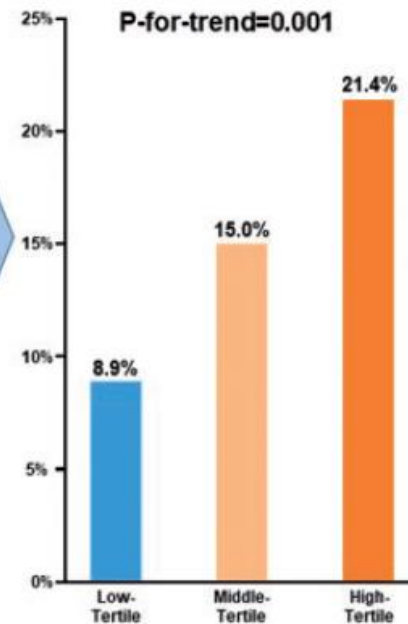


**High-Tertile**  
Mean:  $755.6 \pm 321.7 \text{ mm}^3$   
Median:  $660.0 (513.0-849.5) \text{ mm}^3$



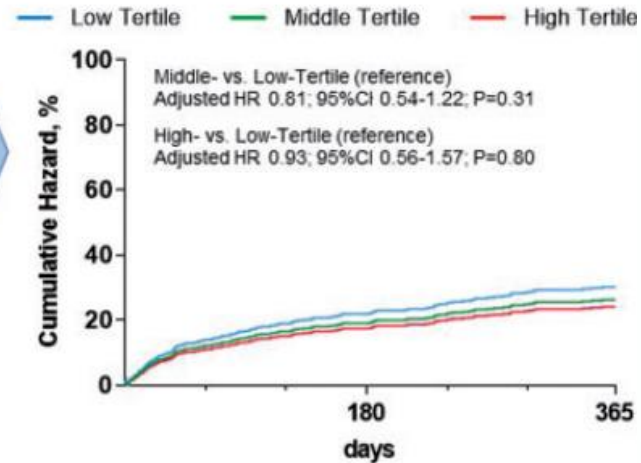
## 30-day Procedural Outcomes

Composite of Moderate or Severe PVL and New Permanent Pacemaker Insertion



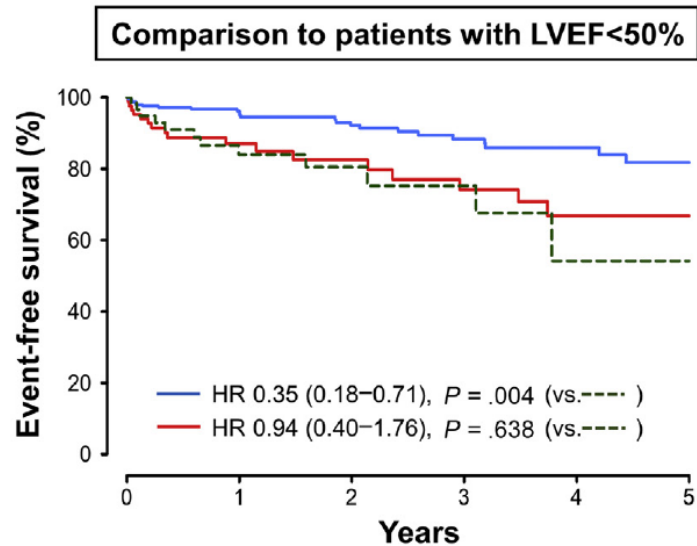
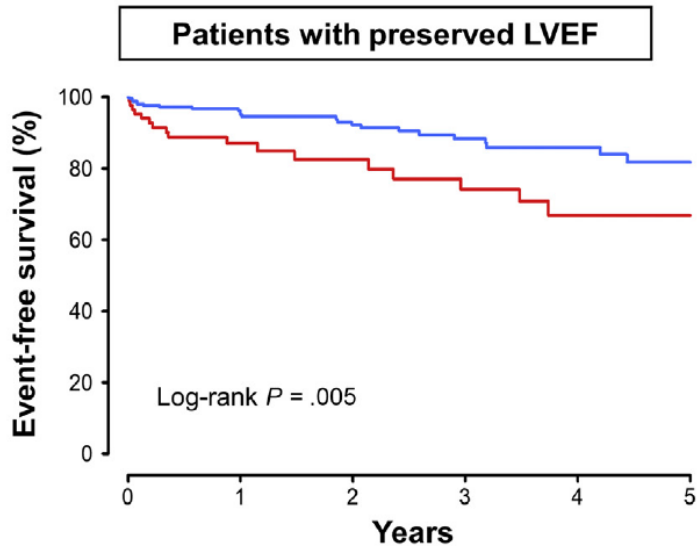
## Adjusted 1-Year Clinical Outcomes

Composite of death, stroke, or rehospitalization

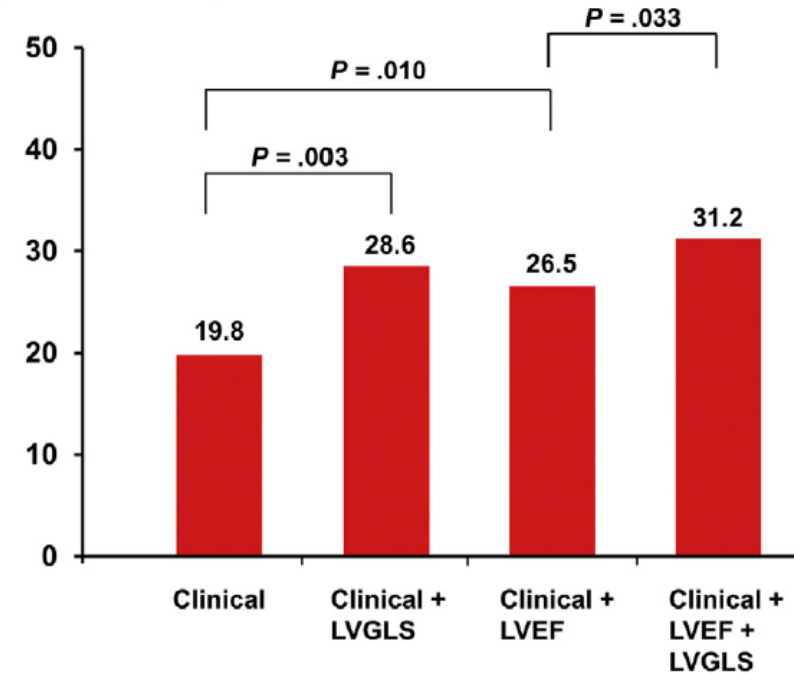


# Prognostic Value of LV GLS in TAVR Patients

344 Patients with Preserved EF undergoing TAVR  
 Primary Outcome : All-cause death



Chi-square for mortality



No. at risk

Normal LVGLS	258	174	116	75	46	26
Impaired LVGLS	86	47	32	26	16	8

No. at risk

Normal LVGLS, LVEF ≥ 50%	258	174	116	75	46	26
Impaired LVGLS, LVEF ≥ 50%	86	47	32	26	16	8
LVEF < 50%	60	34	20	10	4	3

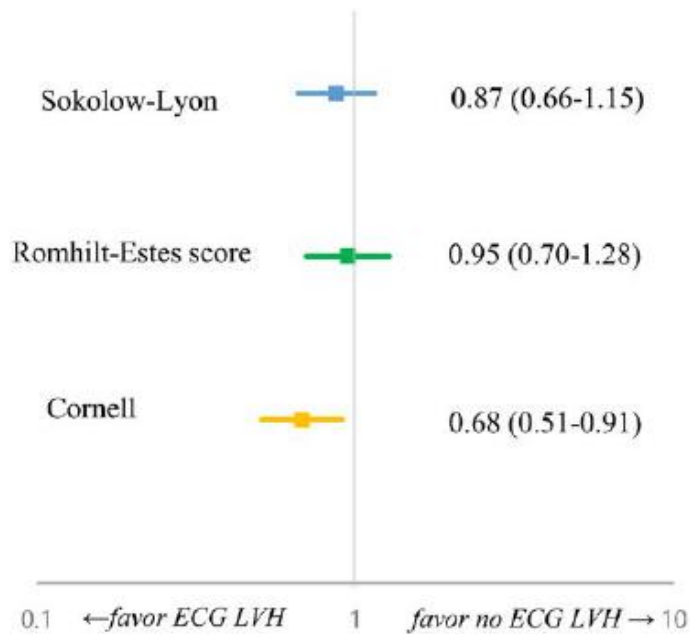
— Normal LVGLS, LVEF ≥ 50% — Impaired LVGLS, LVEF ≥ 50% - - - LVEF < 50%

# Impact of Different ECG LVH in TAVR Patients

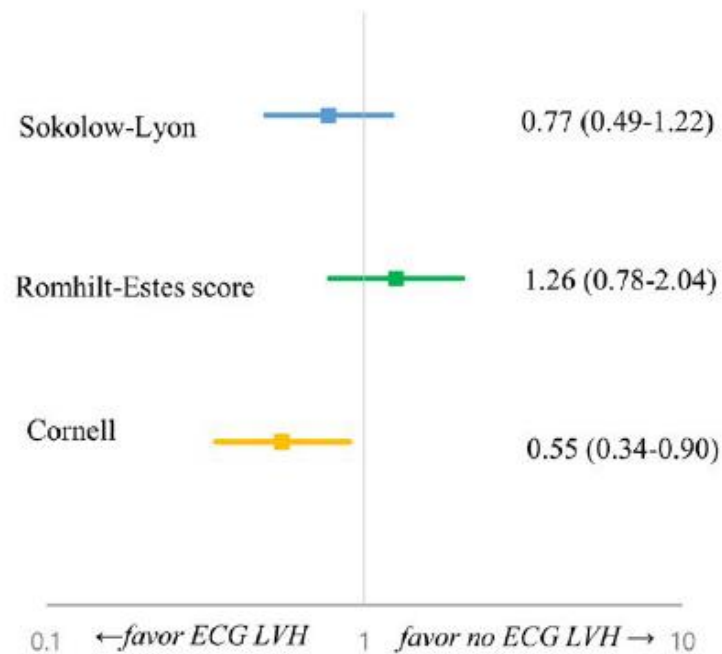
700 Patients underwent TAVR

Primary Outcome : Composite of death, MI, Stroke, or CV rehospitalization at 3 years

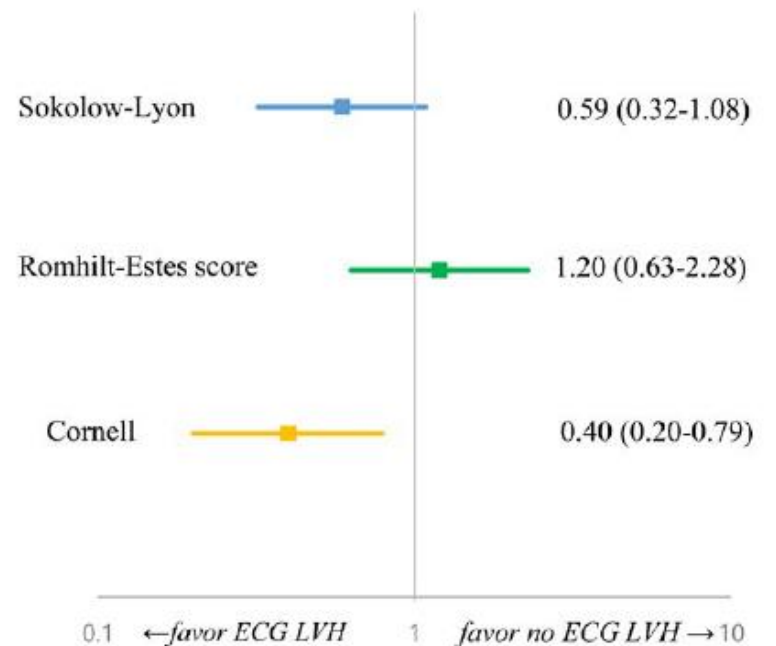
## Adjusted HR for MACCE



## Adjusted HR for all-cause death



## Adjusted HR for cardiovascular death

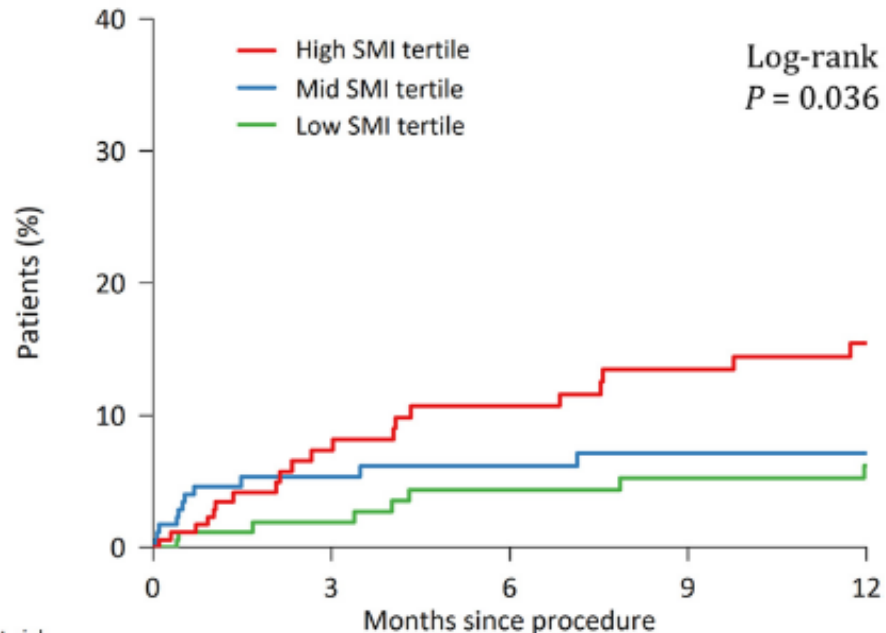


# Impact of Sarcopenia on 1-year Mortality after TAVR

522 Patients undergoing TAVR

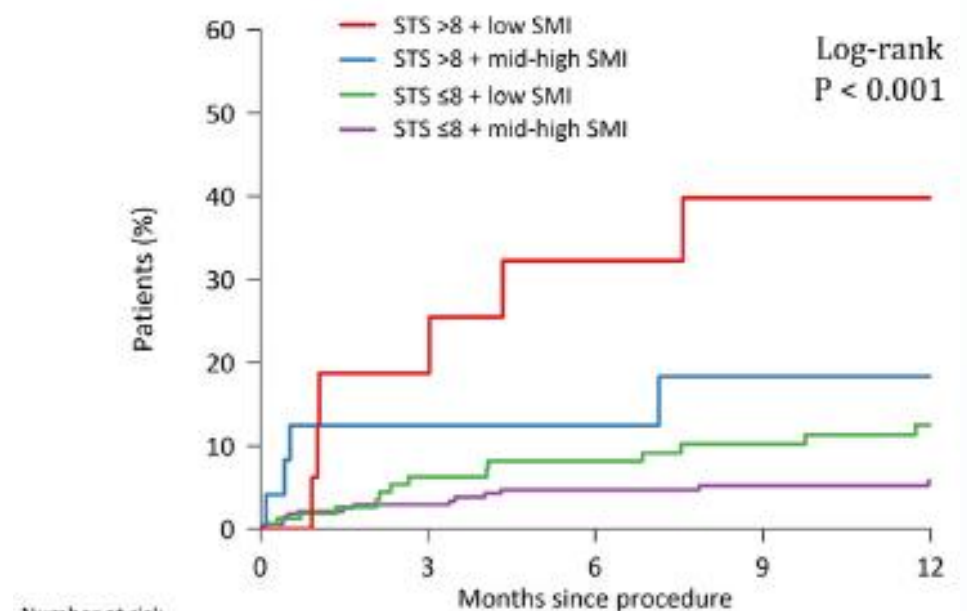
Skeletal muscle index (SMI) : skeletal muscle area at the L3 level divided by height<sup>2</sup>

All-cause mortality by SMI



Number at risk	0	3	6	9	12
High SMI tertile	174	114	103	90	83
Mid SMI tertile	174	119	102	95	87
Low SMI tertile	174	124	115	104	100

All-cause mortality by STS score and SMI

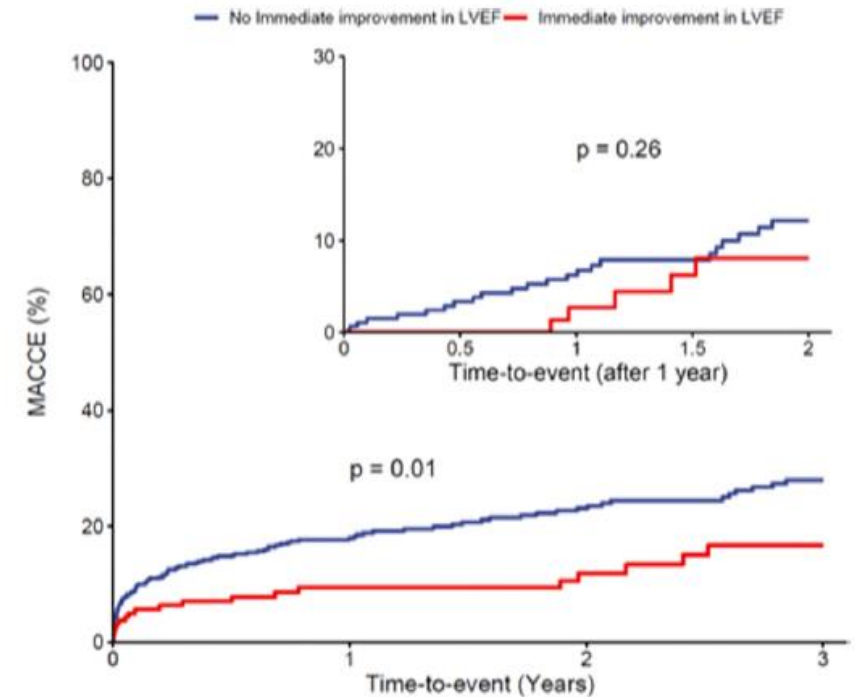
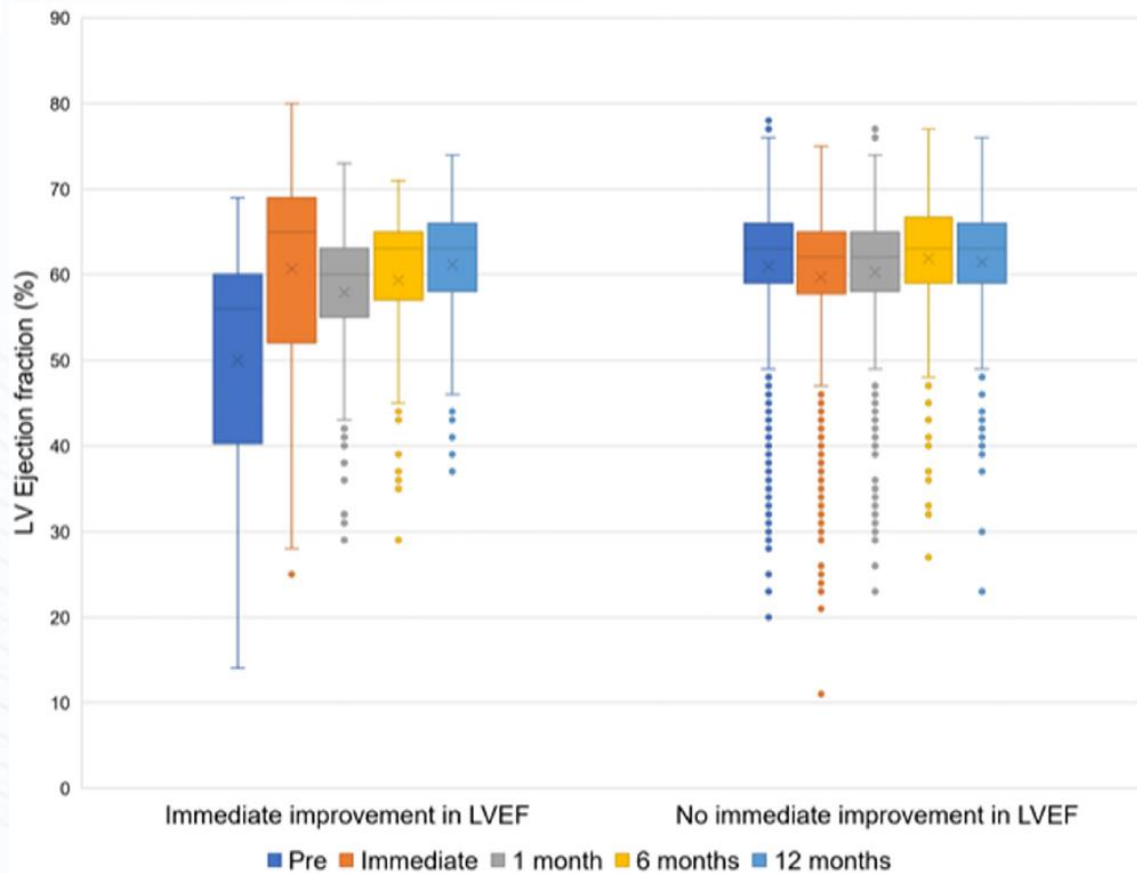


Number at risk	0	3	6	9	12
STS >8 + low SMI	16	12	10	8	8
STS >8 + mid-high SMI	24	16	15	14	14
STS <=8 + low SMI	158	102	93	82	75
STS <=8 + mid-high SMI	324	227	202	185	173



# Impact of Immediate Improvement of LVEF after TAVR

160 of 694 Patients showed  $\geq 5\%$  absolute increase of LV EF  
 Primary Outcome : Composite of CV death, MI, Stroke, or CV rehospitalization



		No. at risk			
		0	1	2	3
No II-LVEF	534	307	186	108	
II-LVEF	160	107	70	40	

# ASAN-AVR Registry

## Single-Center Registry of Surgical and Transcatheter AVR for severe AS

### ORIGINAL RESEARCH

## Comparison of Sutureless Bioprosthetic Valve With Surgical or TAVR for Severe Aortic Stenosis



Ho Jin Kim, MD,<sup>a,\*</sup> Do-Yoon Kang, MD,<sup>b,\*</sup> Hanbit Park, MD,<sup>b</sup> Jung-Min Ahn, MD,<sup>b</sup> Joon Bum Kim, MD,<sup>a</sup> Seon-Ok Kim, MSc,<sup>c</sup> You Jung Ok, MD,<sup>a</sup> Seung Hun Lee, MD,<sup>a</sup> Won Kyung Pyo, MD,<sup>a</sup> Euihong Ko, MD,<sup>b</sup> Seung-Ah Lee, MD,<sup>b</sup> Dae-Hee Kim, MD, PhD,<sup>b</sup> Seung-Jung Park, MD,<sup>b</sup> Duk-Woo Park, MD,<sup>b</sup> Suk Jung Choo, MD<sup>a</sup>

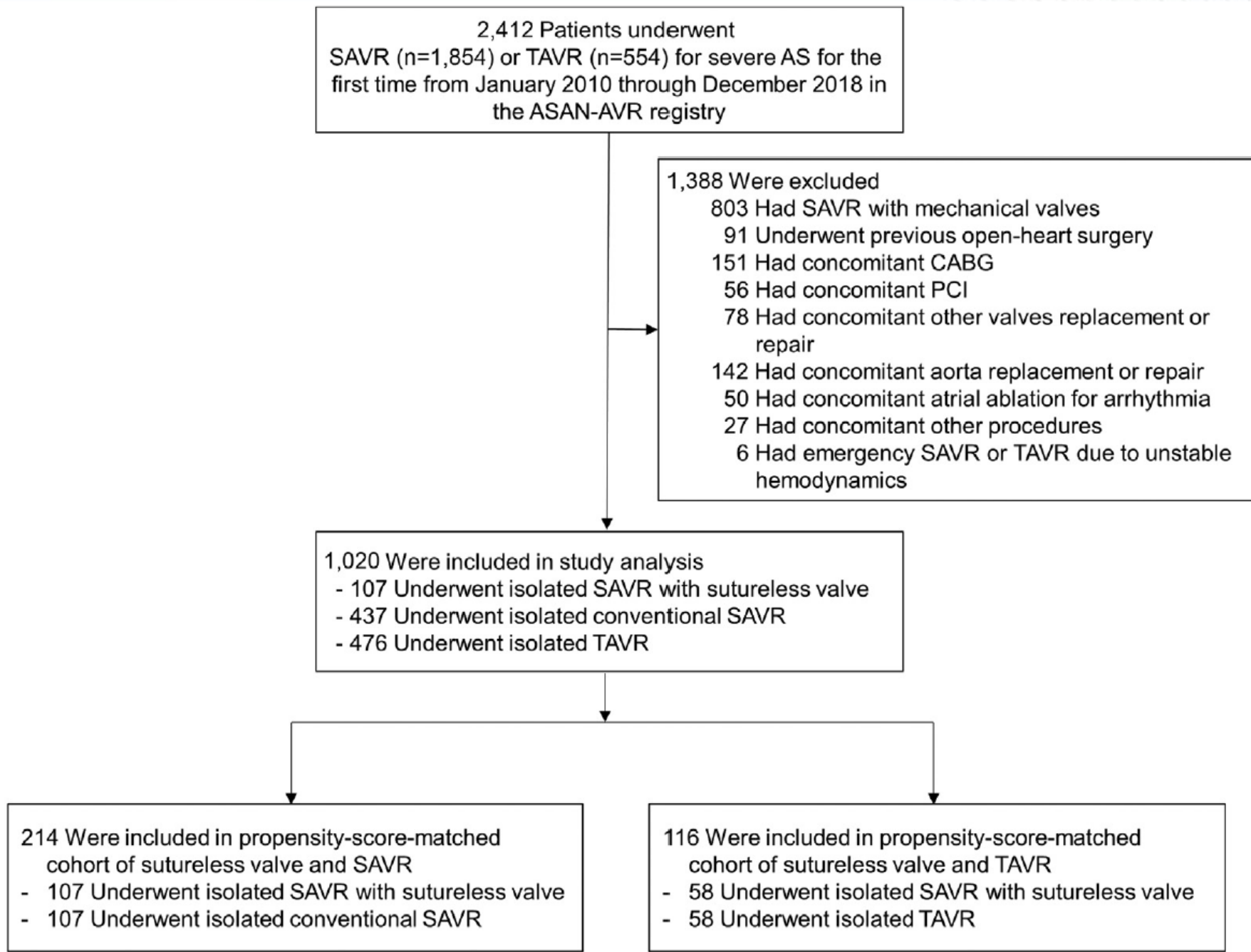
### ABSTRACT

**BACKGROUND** Clinical advantages of sutureless rapid-deployment (RD) aortic valve replacement (AVR) for severe aortic valve stenosis (AS) have not been elucidated compared with surgical (SAVR) or transcatheter (TAVR) aortic valve replacement.

**OBJECTIVES** This study sought to investigate comparative effectiveness and safety of RD-AVR compared with SAVR and TAVR in a prospective cohort of patients with severe AS.

**METHODS** The primary outcome was a composite of death, stroke, or rehospitalization at 12 months. Propensity score matching was used to assemble a cohort of patients with similar baseline characteristics.

**RESULTS** Among 1,020 eligible patients, 107 (10.5%) underwent RD-AVR, 437 (42.8%) underwent SAVR, and 476 (46.7%) underwent TAVR. In the matched cohorts of RD-AVR and SAVR (n = 107), the incidence of primary composite outcome at 12 months was similar between the 2 groups (8.0% vs 10.8%, respectively; hazard ratio [HR]: 0.74; 95% confidence interval [CI]: 0.30-1.84; P = 0.52). In the matched cohorts of RD and TAVR (n = 58), the incidence of primary composite outcome at 12 months did not statistically differ between the 2 groups (9.4% vs 16.2%, respectively; HR: 0.53; 95% CI: 0.18-1.57; P = 0.25).



## Sutureless/RD AVR



- Short operative time
- Easy application to MICS
- Resection of native calcified valve

## TAVR



- Less invasive approach
- Feasible in inoperable patients
- Leaving native calcified valve

## SAVR



- Traditional standard, invasive
- Low PVL and PPM rate
- Resection of native calcified valve

## Propensity-Matched Cohort

### Sutureless/RD vs. SAVR (Referent)

Primary composite outcome		HR: 0.74 (95% CI: 0.30-1.84)
Death or stroke		HR: 0.84 (95% CI: 0.26-2.74)
Rehospitalization		HR: 0.63 (95% CI: 0.15-2.63)

Sutureless/RD Better      SAVR Better

### Sutureless/RD vs. TAVR (Referent)

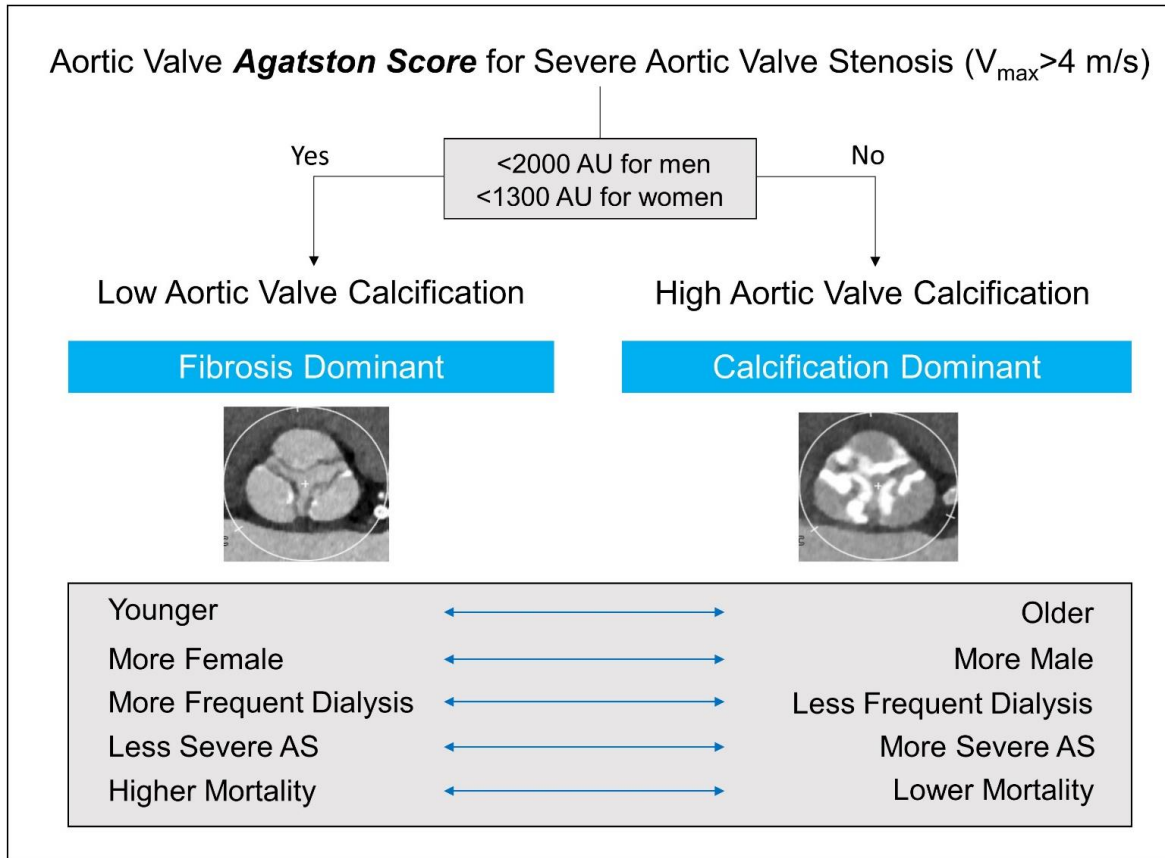
Primary composite outcome		HR: 0.53 (95% CI: 0.18-1.57)
Death or stroke		HR: 0.48 (95% CI: 0.12-1.89)
Rehospitalization		HR: 0.68 (95% CI: 0.11-4.02)

0.0 1.0 2.0 3.0 4.0 5.0

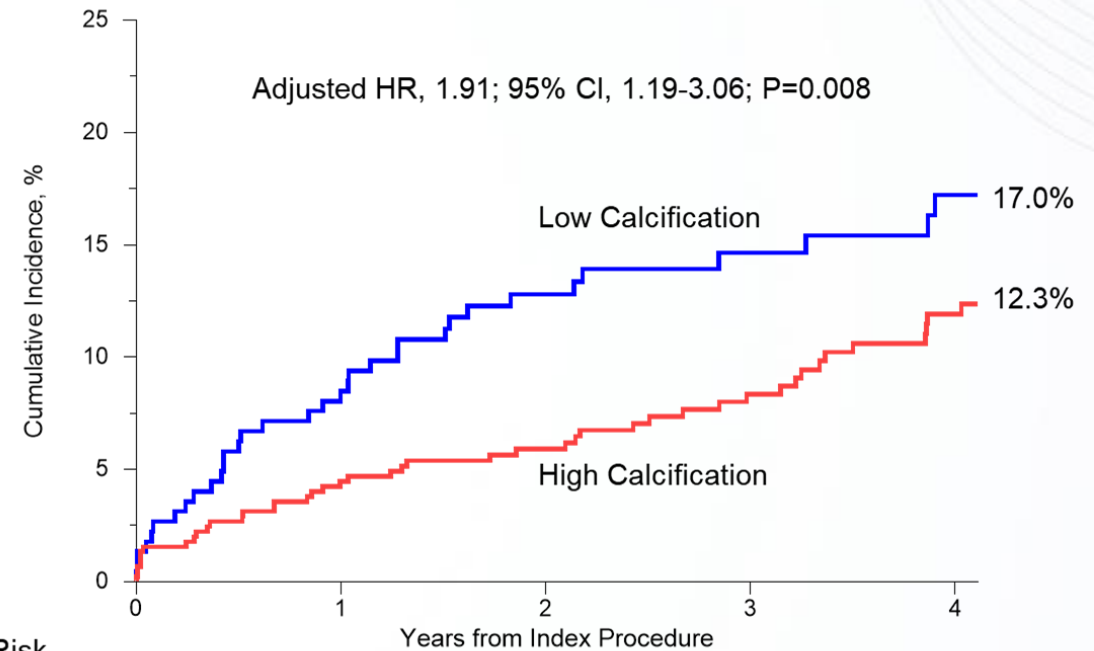
Sutureless/RD Better      TAVR Better

# Severe AS with Low Valve Calcification

242 of 1,002 patients underwent SAVR/TAVR had low valve calcification



Adjusted Survival Curve According to AV Calcification



Patients at Risk	0	1	2	3	4
Low Calcification	224	206	163	118	88
High Calcification	448	428	351	267	195