# Smart TAVR Valve Selection in Asian Patients with Different Anatomy: What We Should Consider More

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# Disclosure

- ✓Receipt of honoraria or consultation fees: Medtronic, Abbott, Edwards Lifesciences

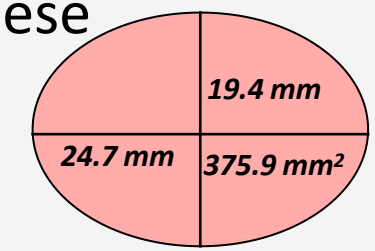
# Japanese TAVI Patients has small body size

**Initial 800 pts @Tokai Univ. Hosp.**

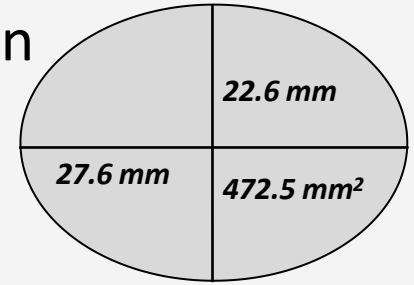
- ✓ Age 84yo (median)
- ✓ Female 62.7%
- ✓ STS 6.4 (median)
- ✓ BSA 1.46 (median)
- ✓ BW 50.8kg (median)
- ✓ NYHA 2.4
- ✓ Clinical Frailty Scale 3.5

# Current Japanese TAVI Patients has small body size

Japanese




European

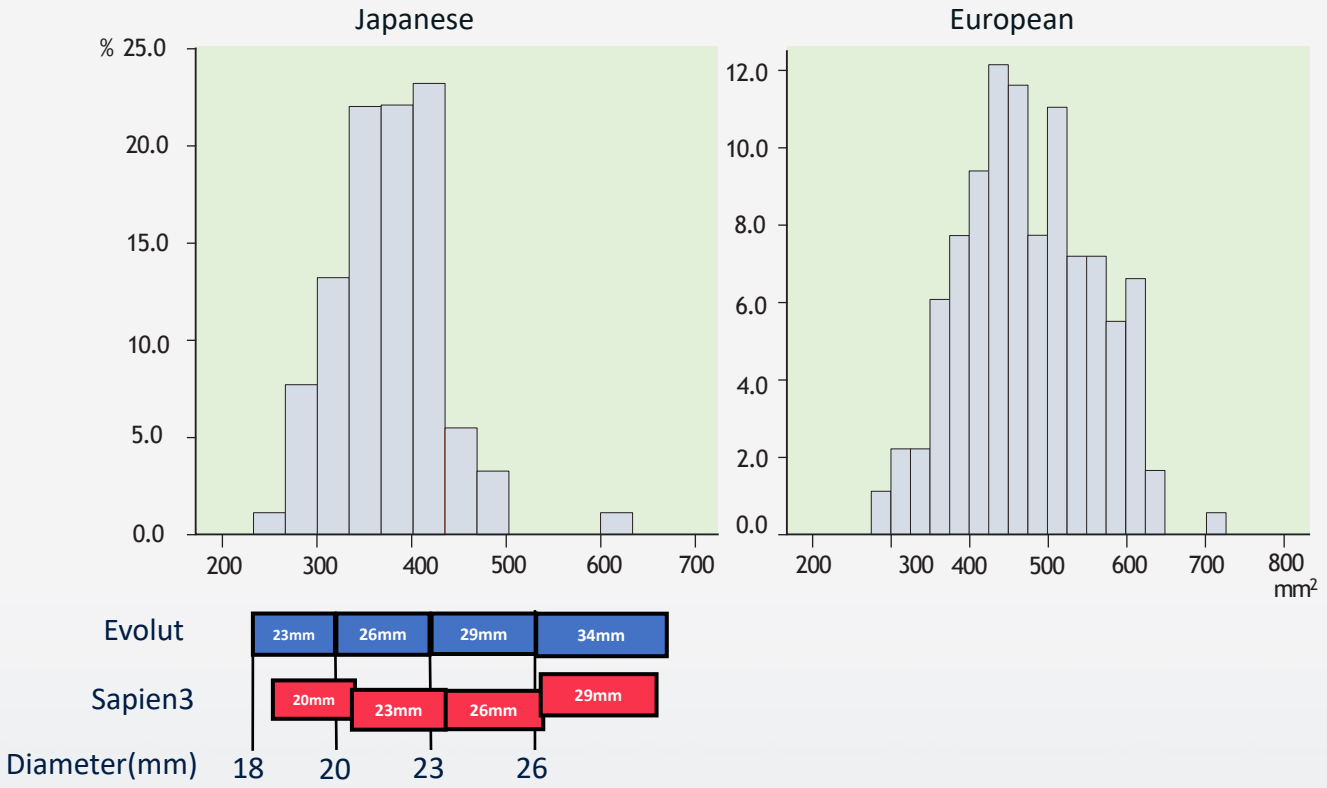



| | Japanese | European | p value |
|---|---|---|---|
| Patient number | 90 | 181 | |
| **sDiam, mm** | **19.4 ± 2.0** | **22.6 ± 2.3** | **<0.01** |
| **lDiam, mm** | **24.7 ± 1.9** | **27.6 ± 2.5** | **<0.01** |
| **Relation lDiam/sDiam** | **1.28 ± 0.10** | **1.24 ± 0.08** | **<0.01** |
| **Perimeter, mm** | **70.3 ± 5.0** | **80.4 ± 7.0** | **<0.01** |
| **CAAD (perimeter derived), mm** | **22.4 ± 1.6** | **25.6 ± 2.2** | **<0.01** |
| **Area, mm²** | **375.9 (333.8 - 410.7)** | **472.5 (415.3 – 536.6)** | **<0.01** |
| **CAAD (area derived), mm** | **21.8 ± 1.6** | **24.5 ± 2.2** | **<0.01** |

Watanabe et al, Asia intervention 2016

# Current Japanese TAVI Patients has small body size

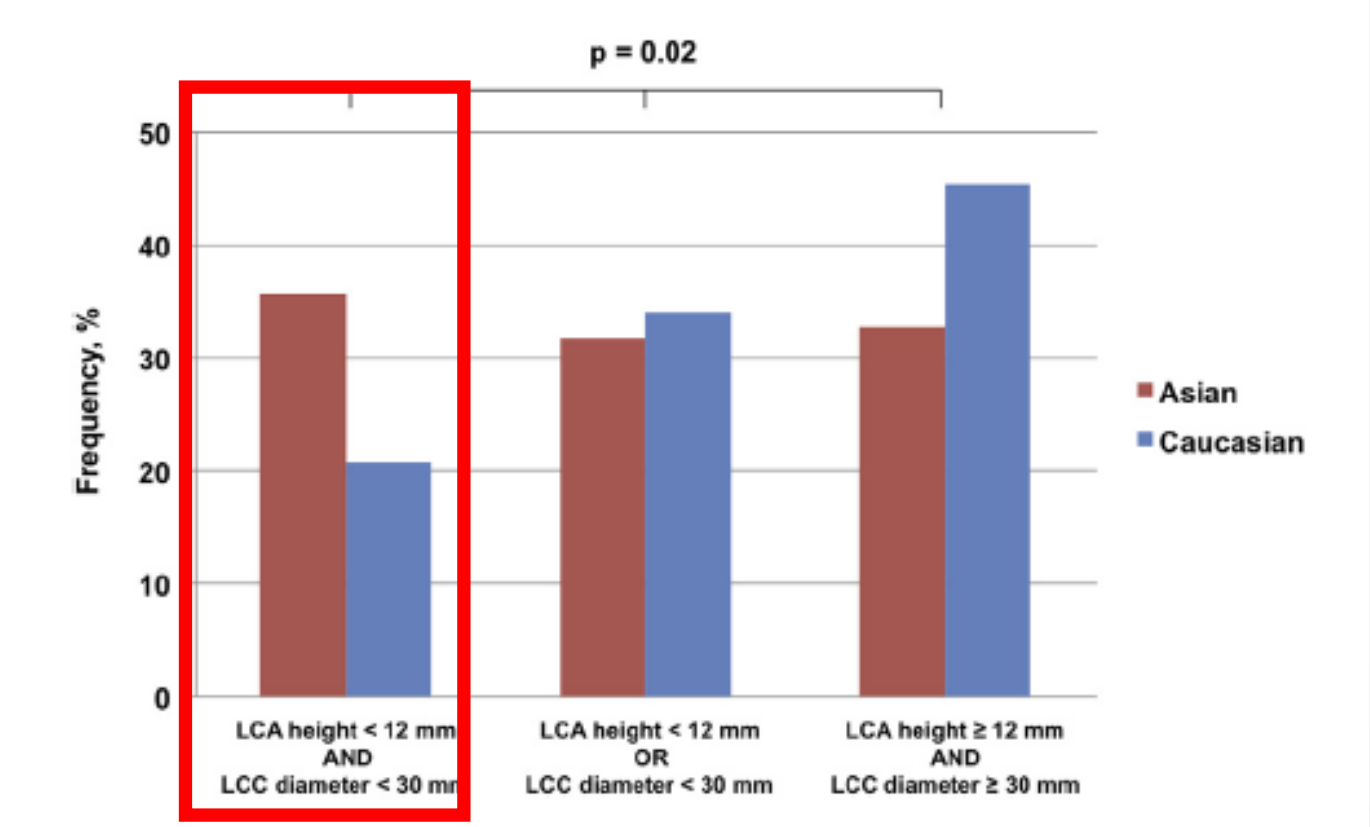
- 70% of TAVI patients in Japan have 18-23mm diameter (Area derived)




Watanabe et al, Asia intervention 2016

# Current Asian TAVI Patients has small body size

- Due to small SOV and low coronary height, Asian pts carry risk of coronary obstrucation




Yoon SH, Ohno Y et al, AJC 2015

# Potential risk of TAVI in small anatomy

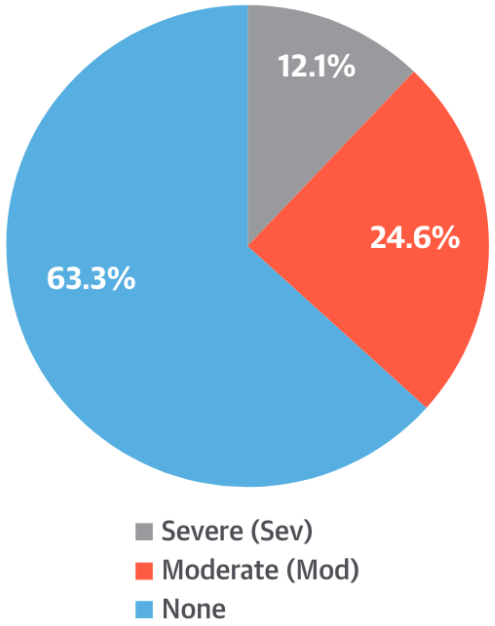
**140cm 40kg**

- ✓ PPM (Prosthesis Patient Mismatch)
- ✓ Coronary occlusion/ Sinus sequestration
- ✓ Vascular complication

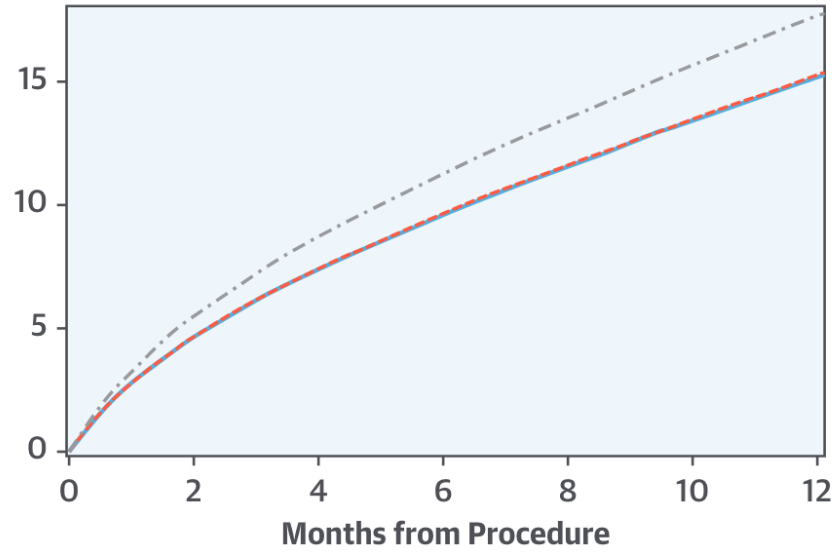
# PPM after TAVI

## From the STS/ACC TVT Registry (n= 62,125)

**Prosthesis-Patient Mismatch (PPM)**




**Mortality (%)**




PPM

Sev PPM (EOAi <0.65 cm²/m²) Mod PPM (EOAi 0.65-0.85 cm²/m²)

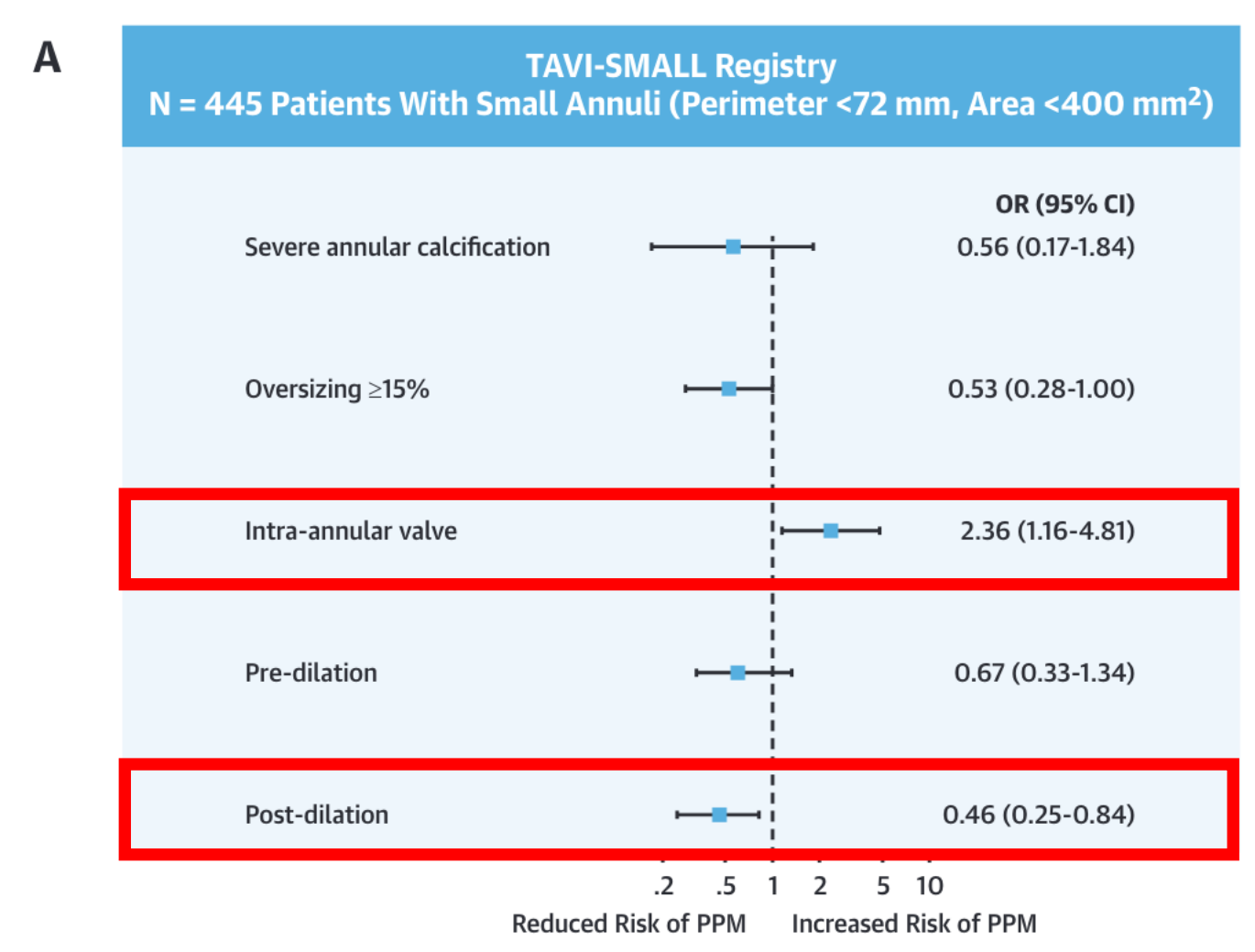
No PPM (EOAi >0.85 cm²/m²)

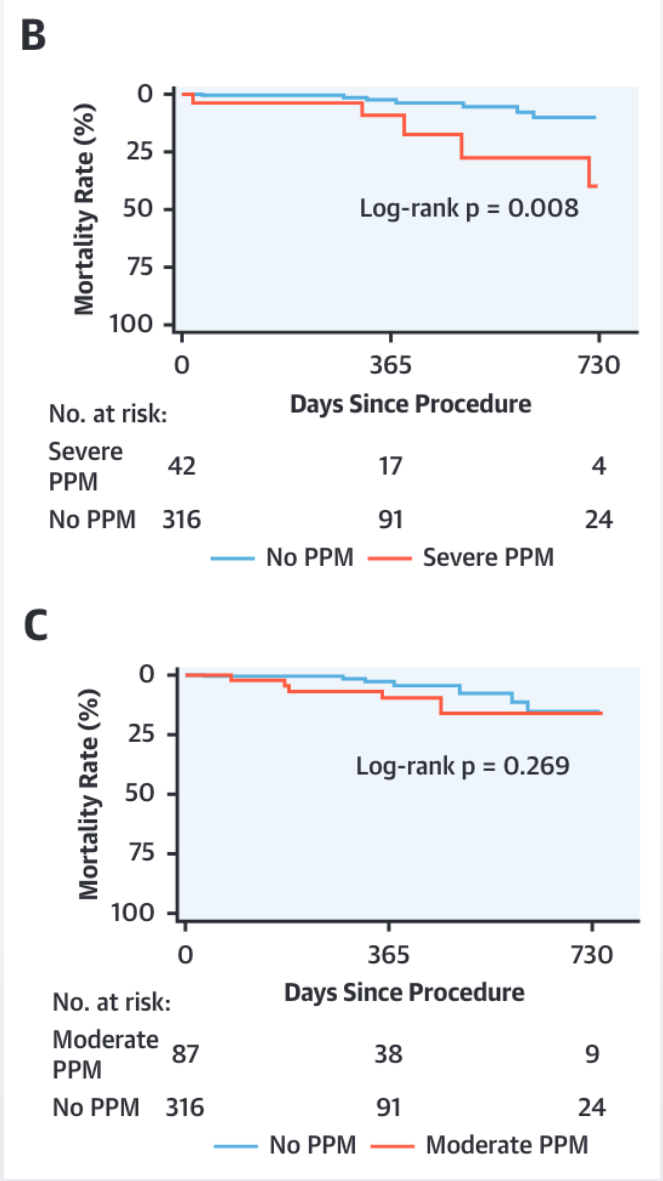
Number at Risk Adjusting for Baseline Covariates:

| | Day 0 | Month 4 | Month 8 | Month 12 |
|---|---|---|---|---|
| No PPM | 23,635 | 21,080 | 16,734 | 13,136 |
| Mod PPM | 8,983 | 7,995 | 6,277 | 4,831 |
| Sev PPM | 4,152 | 3,626 | 2,976 | 2,130 |

Herrmann, et al., J Am Coll Cardiol. 2018.

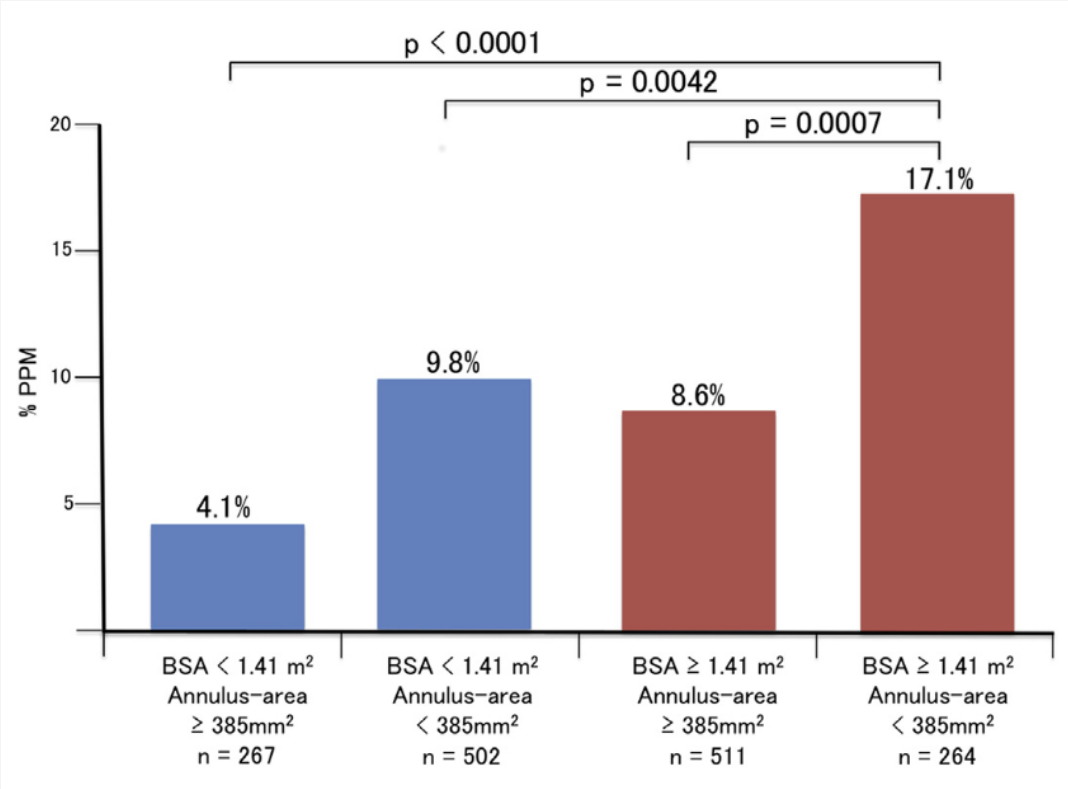
# PPM after TAVI




Leone PP, et al., J Am Coll Cardiol Intv. 2021.

# PPM after TAVI



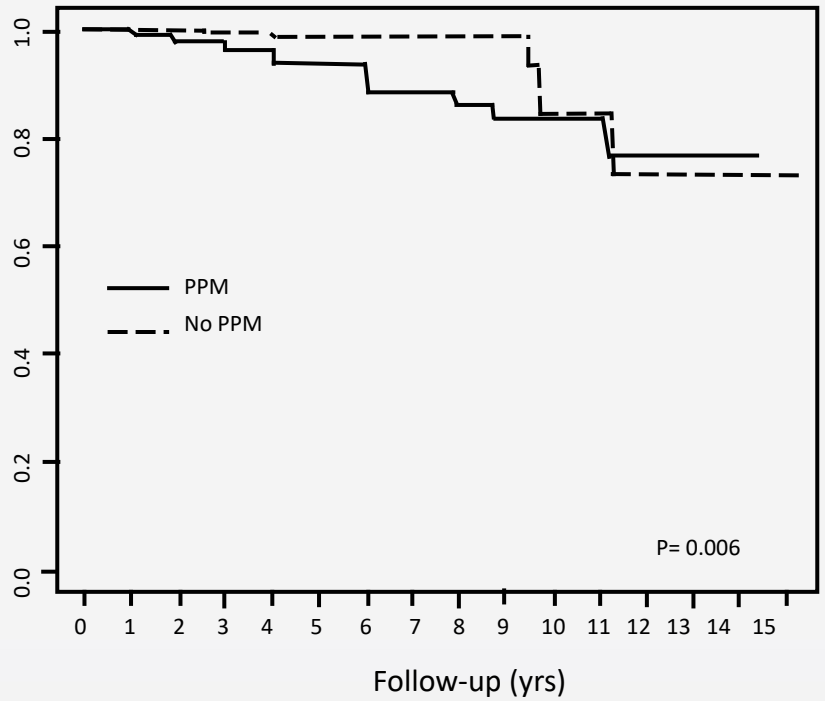

Incidence of PPM: 9.8%
Moderate PPM 8.9%
Severe PPM 0.7%

In both small and large BSA, small annulus was significantly associated with higher PPM.

Miyasaka et al. JACC cardiovasc Interv 2018

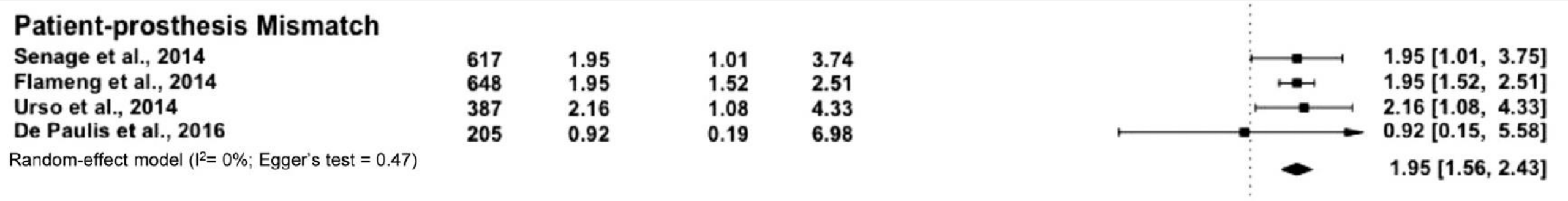
# Is PPM a potential risk for SVD?

PPM (Prosthesis-Patient Mismatch) related to SVD after SAVR



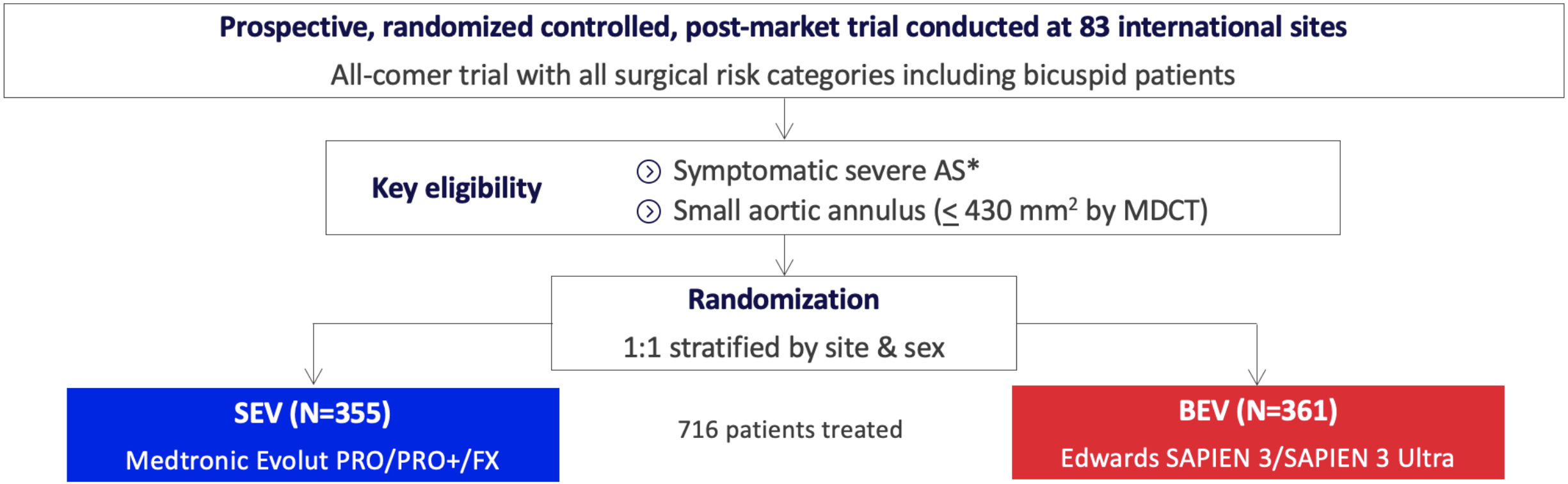

Flameng, et al., Circulation. 2010

# Is PPM a potential risk for SVD?




Ochi A et al. Hear, Lung and Circulation 2020

# Trial design




**Co-Primary Endpoints at 1 year with planned 5-year follow-up**

Co-Primary Endpoint 1: Composite of mortality, disabling stroke, or heart failure rehospitalization through 12 months
Co-Primary Endpoint 2: Bioprosthetic valve dysfunction through 12 months

*AVA ≤1.0 $cm^2$ (AVAi ≤0.6 $cm^2/m^2$) or mean gradient ≥40 mmHg or max velocity ≥4.0 m/s; 30-day predicted risk of surgical mortality <15% by heart team assessment.

# Statistical methods

## Co-primary endpoint #1

Clinical outcome composite through 12 months

- Mortality
- Disabling stroke
- Heart failure rehospitalization

- Powered for **noninferiority**, margin of 8%
- As-treated population (1st attempted device)
- K-M estimate with risk difference (90% CI) through 12 months
- 85% power with 700 patients

## Co-primary endpoint #2

Bioprosthetic valve dysfunction through 12 months

- Hemodynamic structural valve dysfunction:
  *Mean gradient ≥20 mmHg*
- Nonstructural valve dysfunction:
  *Severe PPM (VARC-3), ≥moderate total AR*
- Clinical valve thrombosis (VARC-2)
- Endocarditis (Duke criteria)
- Aortic valve reintervention

- Powered for **superiority**
- Implanted population (final valve received)
- K-M estimate with risk difference (95% CI) through 12 months
- >99% power with 700 patients

# Baseline characteristics

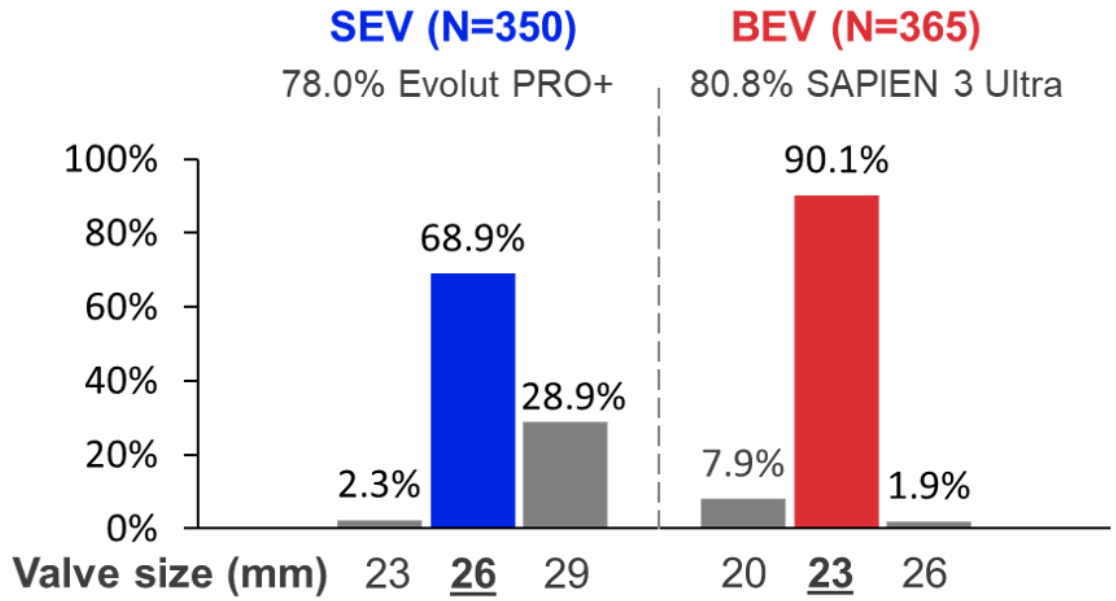
| Characteristic | SEV (N=355) | BEV (N=361) |
|---|---|---|
| **Age – yr** | **80.1 ± 6.3** | **80.3 ± 6.1** |
| **Female sex** | **87.9%** | **85.6%** |
| **STS-PROM score – %** | **3.3 ± 1.9** | **3.2 ± 1.7** |
| NYHA functional class III/IV | 43.4% | 39.9% |
| Diabetes | 29.3% | 34.1% |
| Hypertension | 82.5% | 86.7% |
| COPD or chronic lung disease | 18.0% | 17.6% |
| Cerebrovascular disease | 12.0% | 11.4% |
| Previous CABG | 3.4% | 5.0% |
| Previous PCI | 17.0% | 23.3% |
| Previous myocardial infarction | 5.4% | 8.0% |
| History of RBBB | 5.9% | 6.9% |
| Coronary artery disease | 35.2% | 41.0% |
| Pre-existing permanent pacemaker/ICD | 8.5% | 6.9% |
| Bicuspid aortic valve morphology | 3.9% | 4.2% |

Data presented as mean ± SD or %

# Valve and procedural data

## Valve size

| Aortic annulus size | SEV (N=355) | BEV (N=361) |
|---|---|---|
| Mean area ($mm^2$) | 380.9 ± 34.2 | 382.8 ± 33.9 |
| Mean perimeter (mm) | 70.3 ± 3.2 | 70.4 ± 3.2 |

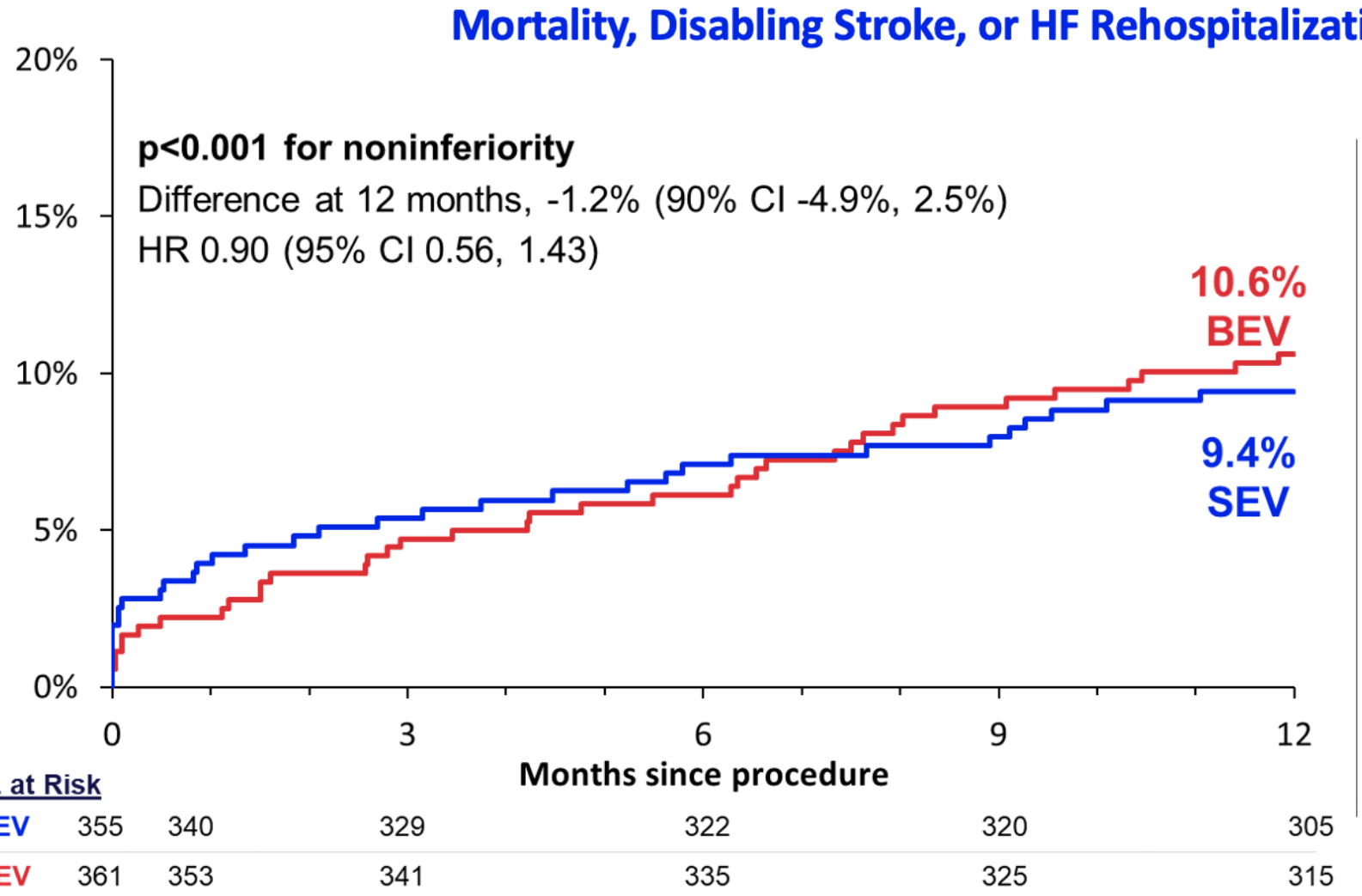



## Procedural characteristics and outcomes

| Characteristic | SEV (N=355) | BEV (N=361) | P Value[a] |
|---|---|---|---|
| Total time in the procedure room[b] (min) | 116 ± 44 | 106 ± 43 | 0.002 |
| Catheter (device) time in the body (min) | 18 ± 15 | 14 ± 12 | <0.001 |
| Contrast volume[c] (ml) | 121 ± 59 | 95 ± 43 | <0.001 |
| Valve embolization | 1.1% | 0.0% | 0.06 |
| Device success at 30 days (VARC-2)[d] | 85.2% | 59.2% | <0.001 |
| Device success at 30 days (VARC-3)[e] | 94.5% | 86.6% | <0.001 |

[a]Continuous variables compared using t-tests; categorical variables compared using chi-squared tests. Valve embolization compared using Fisher's Exact test. [b]Data available for 354 SEV and 361 BEV patients. [c]Data available for 347 SEV and 357 BEV patients. [d]Evaluated according to VARC-2 criteria in 291 SEV and 319 BEV patients. [e]Evaluated according to VARC-3 criteria in 327 SEV and 328 BEV patients.

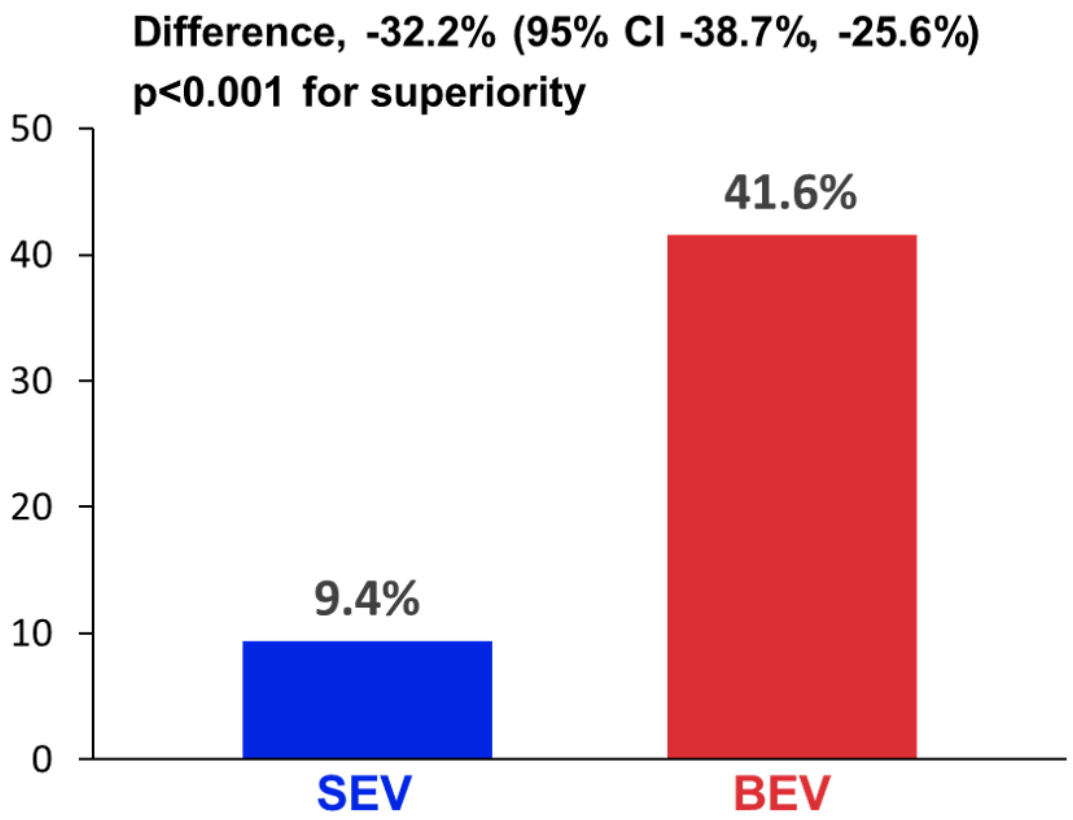
# Co-primary endpoint 1:
# Clinical outcome composite through 12 months powered for noninferiority




| 12 Months | SEV (N=355) | BEV (N=361) | HR (95% CI) |
|---|---|---|---|
| All-cause mortality | 5.1% | 5.9% | 0.88 (0.47, 1.65) |
| Disabling stroke | 3.1% | 2.6% | 1.26 (0.52, 3.03) |
| HF rehosp | 3.8% | 3.5% | 1.11 (0.51, 2.44) |

# Co-primary endpoint 2:
# BVD through 12 months powered for superiority

## Bioprosthetic Valve Dysfunction through 12 months




| | SEV (N=350) | BEV (N=365) | P Value |
|---|---|---|---|
| **BVD composite** | **9.4%** | **41.6%** | **<0.001** |
| HSVD | 3.2% | 32.2% | |
| NSVD | 5.9% | 18.2% | |
| Thrombosis (clinical) | 0.3% | 0.3% | |
| Endocarditis | 0.6% | 2.3% | |
| AV Reintervention | 0.9% | 0.6% | |

HSVD = Mean gradient ≥ 20 mmHg
NSVD = Severe PPM per VARC-3 or ≥moderate total AR

# Summary

**The SMART trial is the largest, most rigorous trial to date, to randomize patients to the 2 most widely used TAVR devices, and the largest TAVR trial to enroll mostly women.**

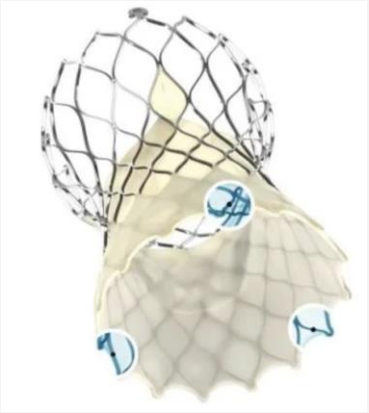
**The SMART trial met both primary and all 5 prespecified secondary endpoints.**

Compared with BEV, the supra-annular SEV demonstrated:

- Noninferior clinical outcomes at 1 year
- Superior valve performance at 1 year:
  - 32.2% lower incidence of BVD
  - 8 mmHg lower mean gradient
  - 0.5 $cm^2$ greater effective orifice area
  - 0.19 larger Doppler velocity index
  - 6.8% lower incidence of severe PPM
- Improvements in other secondary outcomes at 1 year:
  - Less total AR and better QOL per the KCCQ ordinal outcome

*Based on the large differences observed in valve performance, we expect that the SEV will demonstrate improved valve durability and outcomes during longer follow-up*

# Smart TAVR Valve Selection in Asian Patients



| | | | |
|---|---|---|---|
| Ease of Use/ Shorter proc. time | ++ | + | + |
| Valve Performance/ Durability | + | +++ | ++ |
| Coronary Access | ++ | + | + |
| Repeatability | ++ | + | + |
| Vessel access | + | ++ | +++ |

## Patient's Age and Anatomy Matter