# AP VALVES & STRUCTURAL HEART 2022

## Introduction to ACURATE *neo2* valve system


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UKGM UNIVERSITÄTSKLINIKUM GIESSEN UND MARBURG

KERCKHOFF KLINIK

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# Disclosure

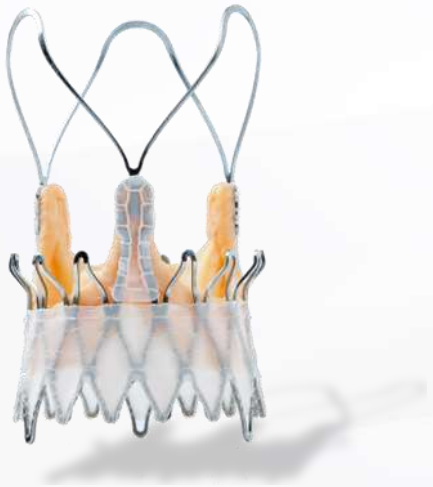
Proctor/speaker fees/advisory board

- Abbott
- Astra Zeneca
- Boston Scientific
- Daiichi
- Edwards Lifesciences
- Medtronic
- Meril Life Sciences
- Shockwave Medical

# ACURATE *neo2*™
# ACURATE Aortic Valve Platform

## 1st GENERATION

ACURATE TA (CE 2012)



ACURATE™

## 2nd GENERATION

ACURATE *neo* TF
(CE 2014) & TA (CE 2017)

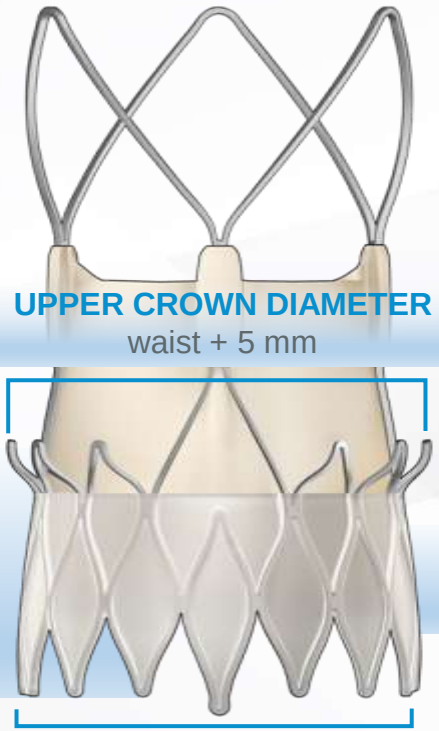
ACURATE *neo*™

## 3rd GENERATION

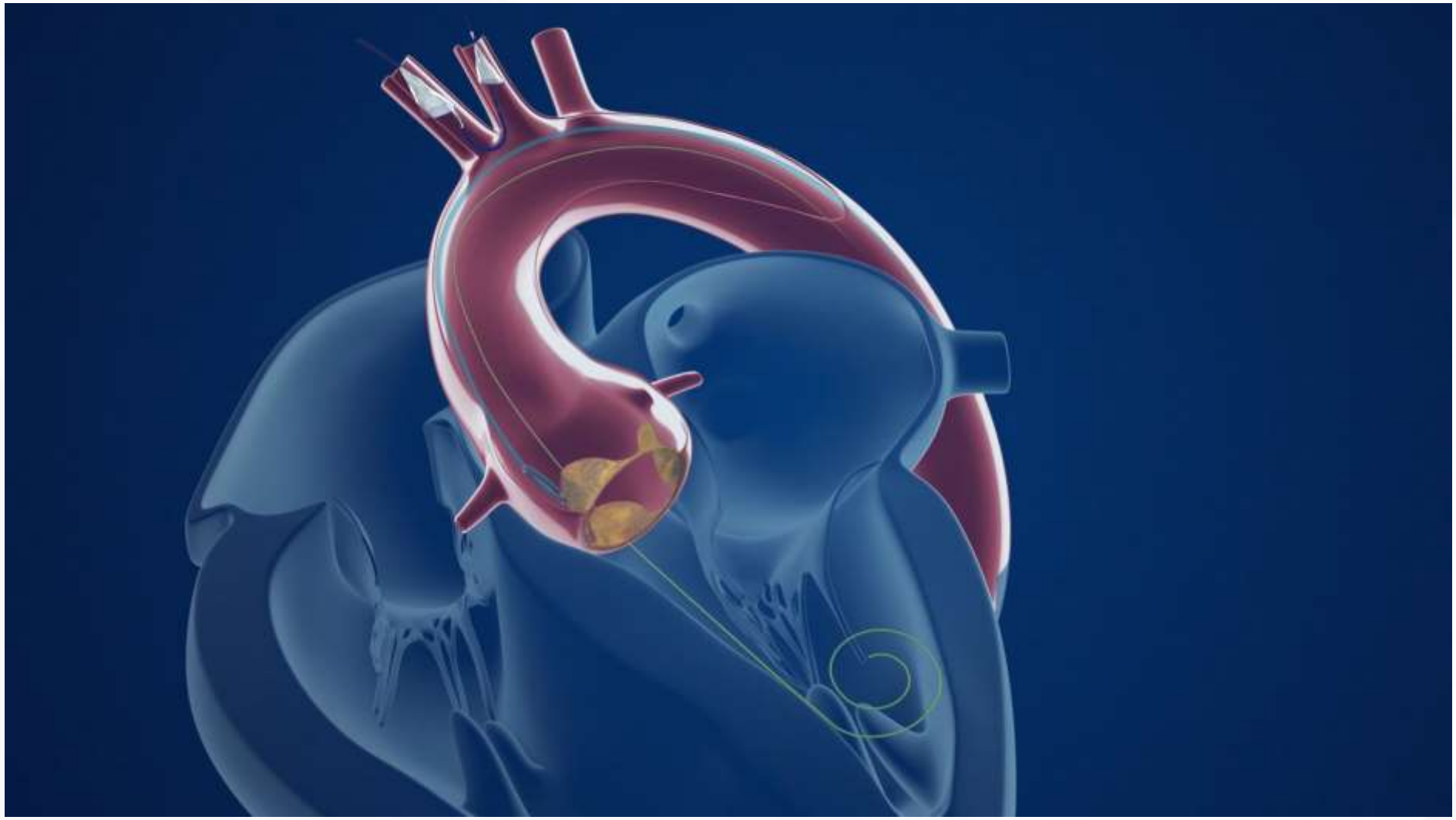
ACURATE *neo2* TF
(CE 2019)

ACURATE *neo2*™

# ACURATE *neo2*™ – Valve Measurements



# ACURATE *neo2*™ – Deployment



# Strengths and limitations of first-gen ACURATE

Ease of use

Horizontal aorta

Gentle procedure

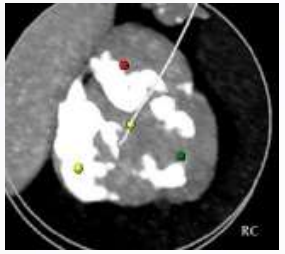
Low risk of coronary obstruction

Tortouos anatomies

Fast implant

Low gradients

Low pacemaker rate

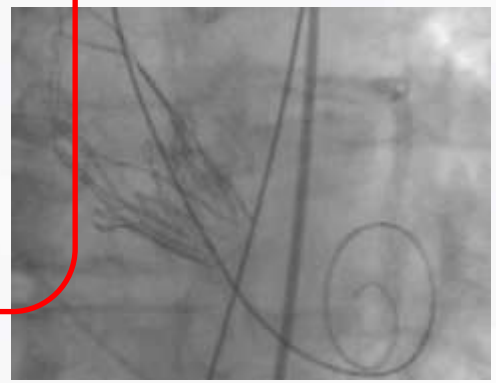


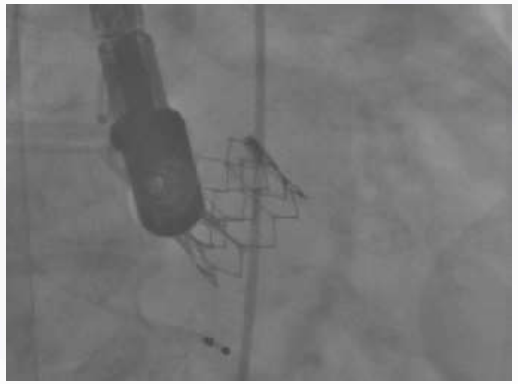
**Radial force**!

low → high

Incomplete expansion

PVL





Annular rupture

Coronary occlusion

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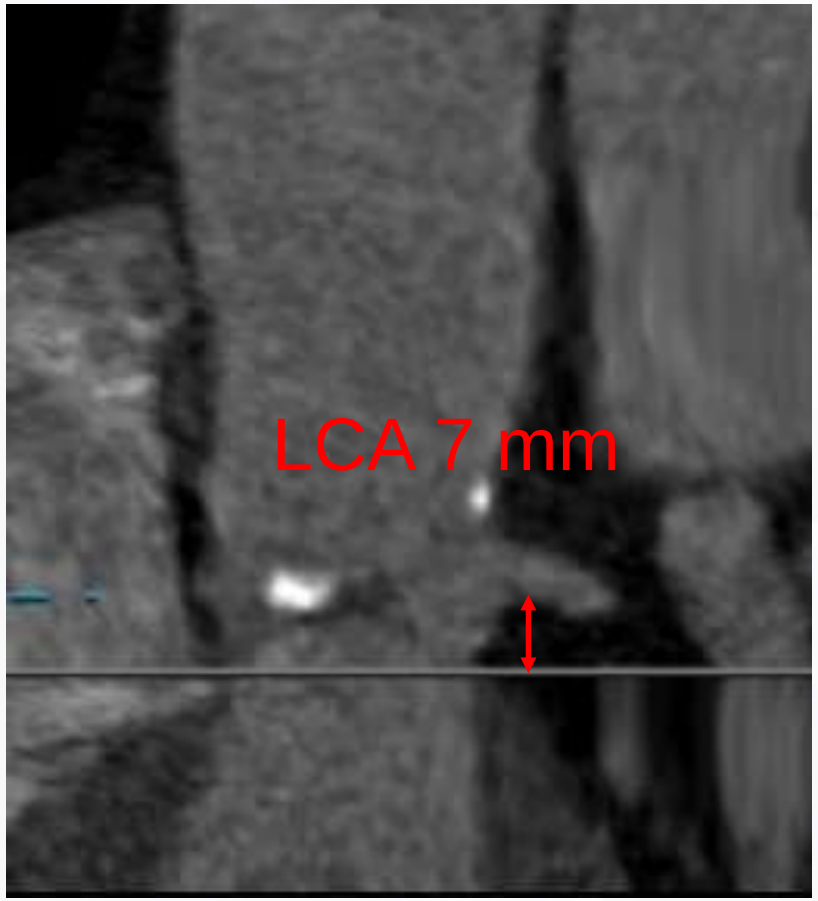
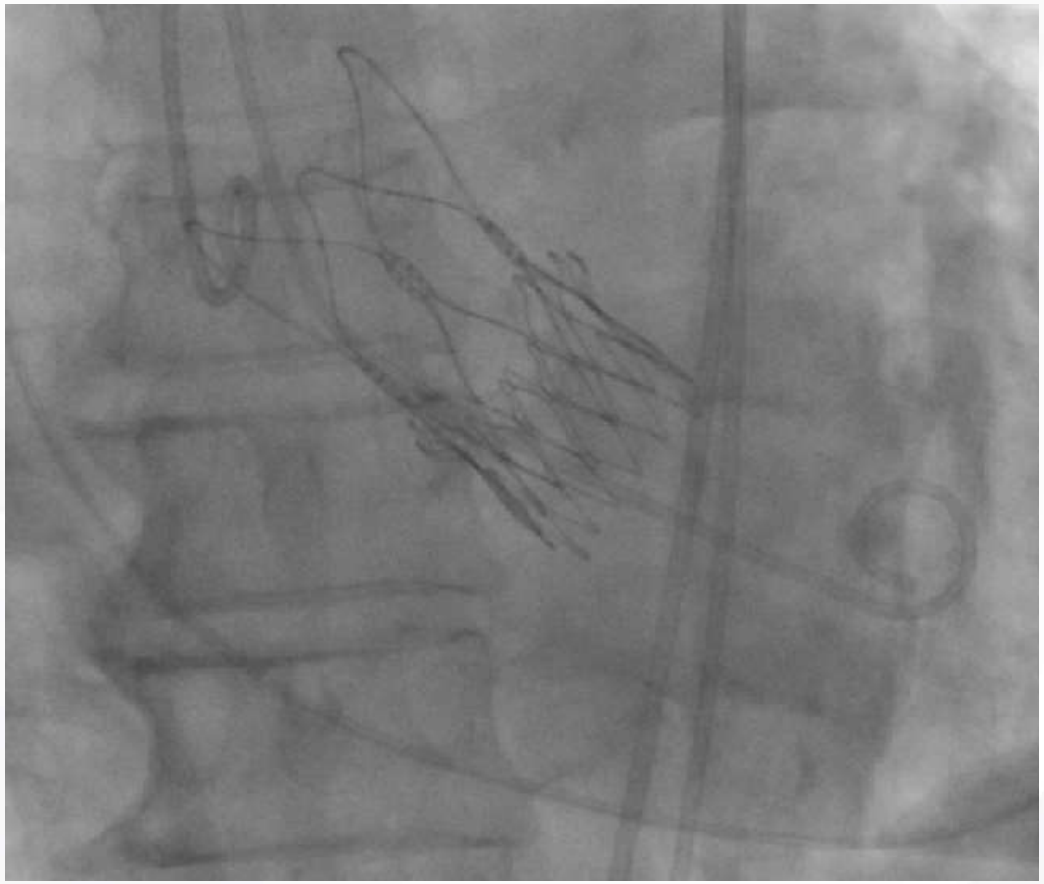
# Low risk of coronary obstruction

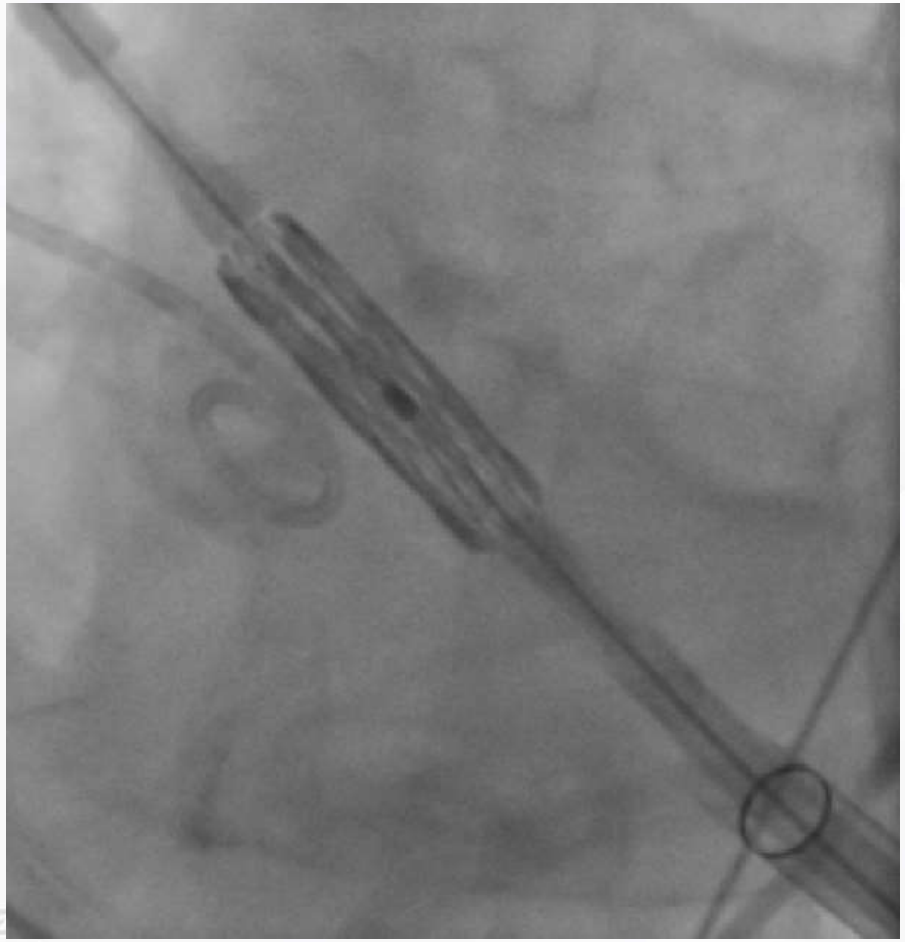
Case example: upper crown keeps leaflet away from coronary ostia.

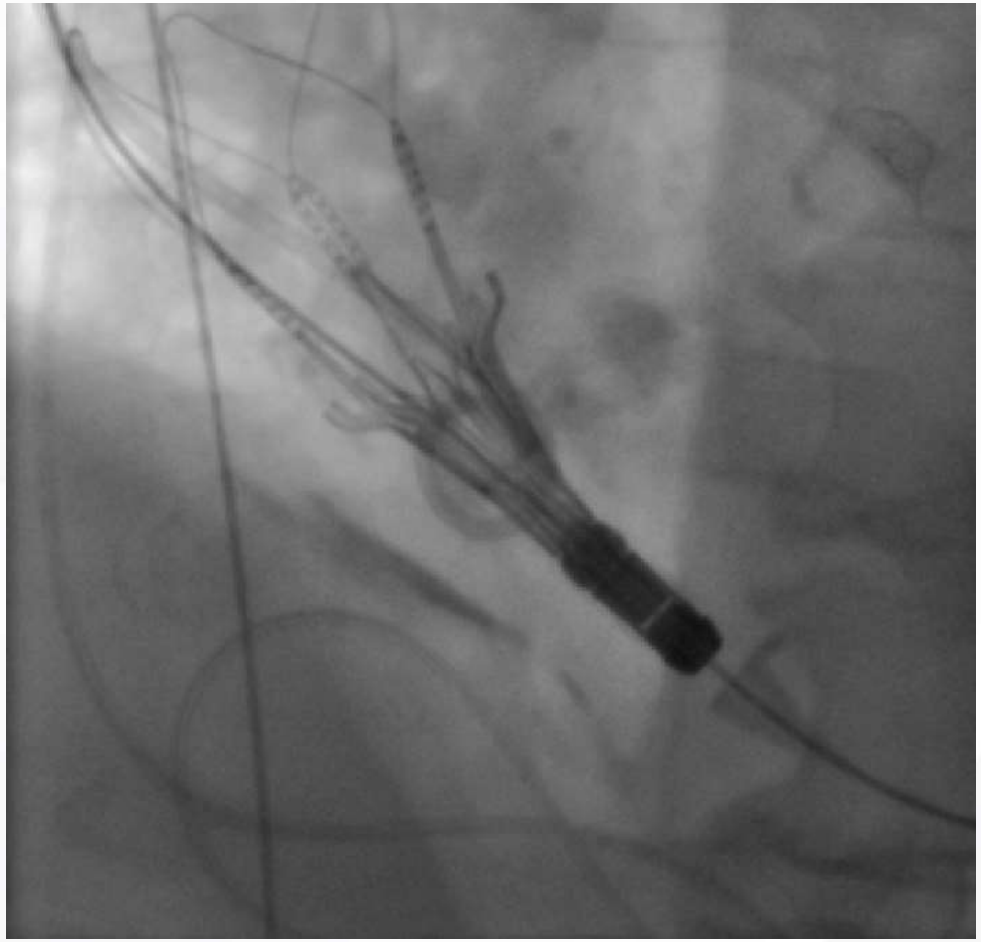


# Low risk of coronary obstruction

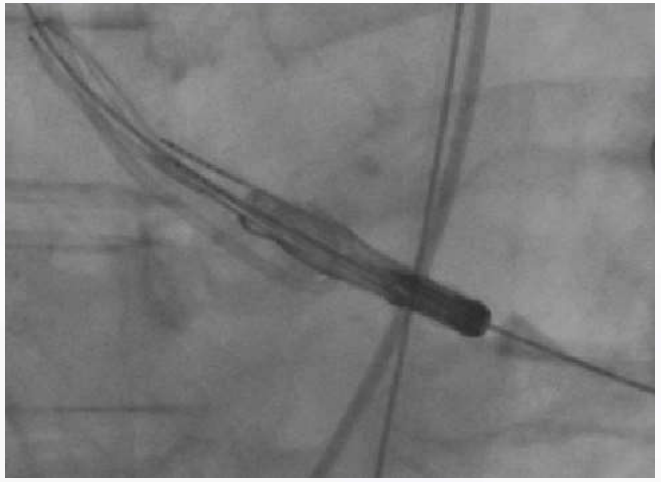
Impact of the upper crown!

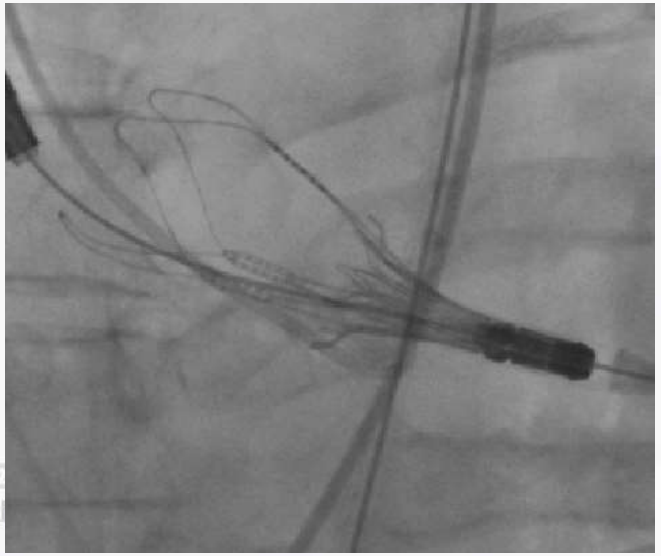


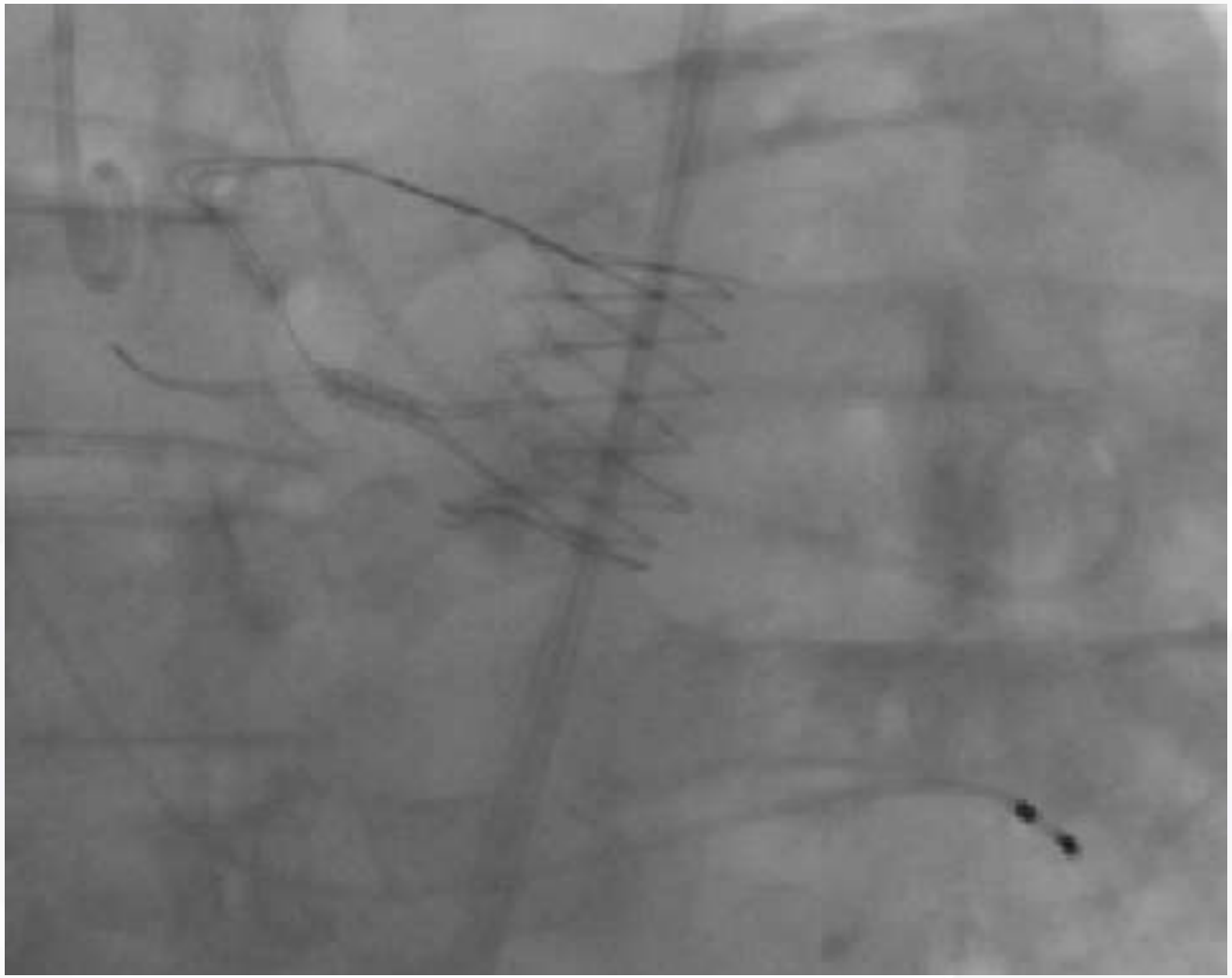


# Horizontal aorta

Self-alignment due to stabilization arches







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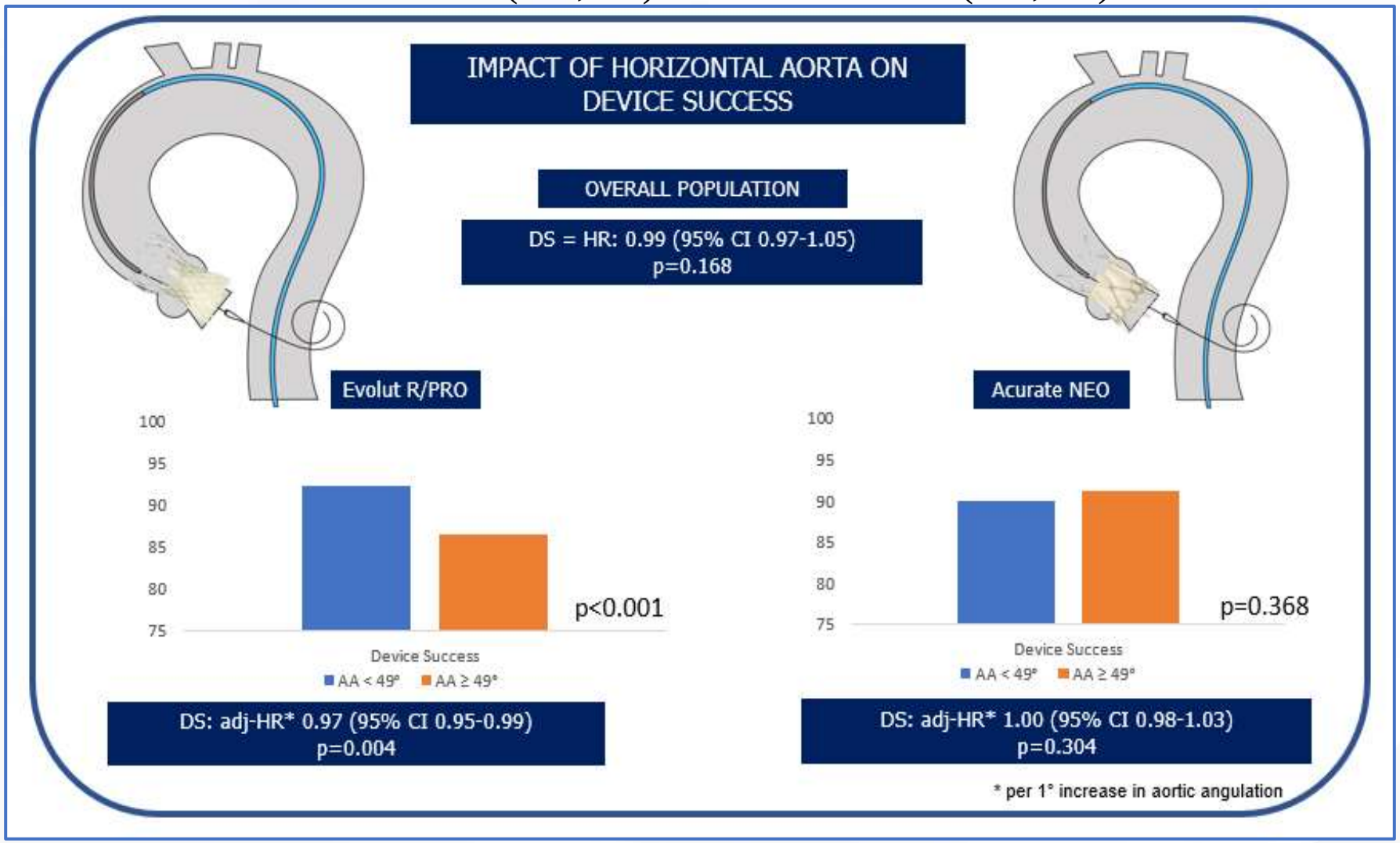
# HORSE International Registry

Evolut R/PRO (n=1,959) vs. ACURATE neo (n=1,903)

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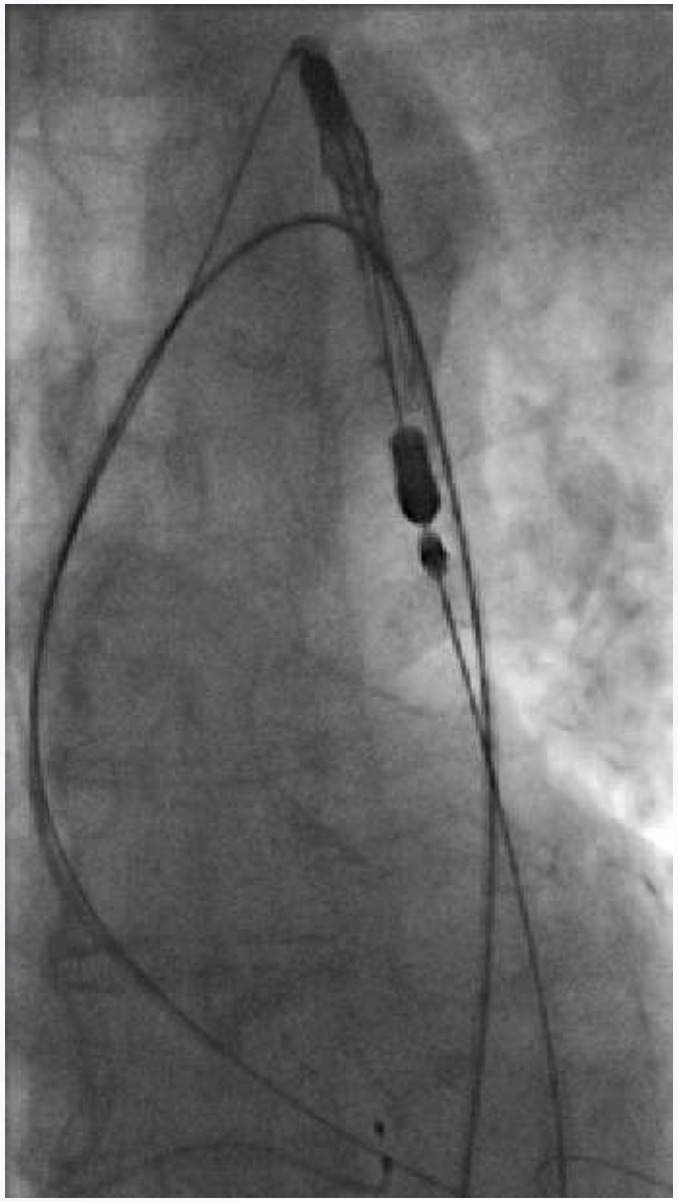
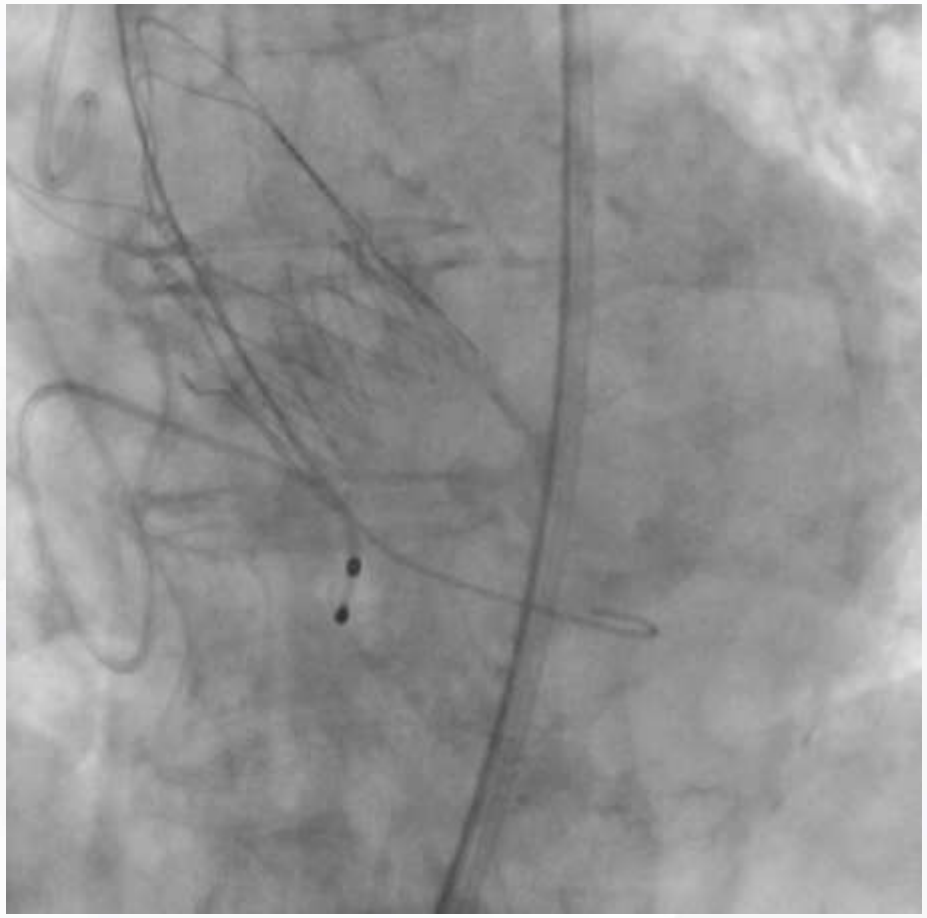
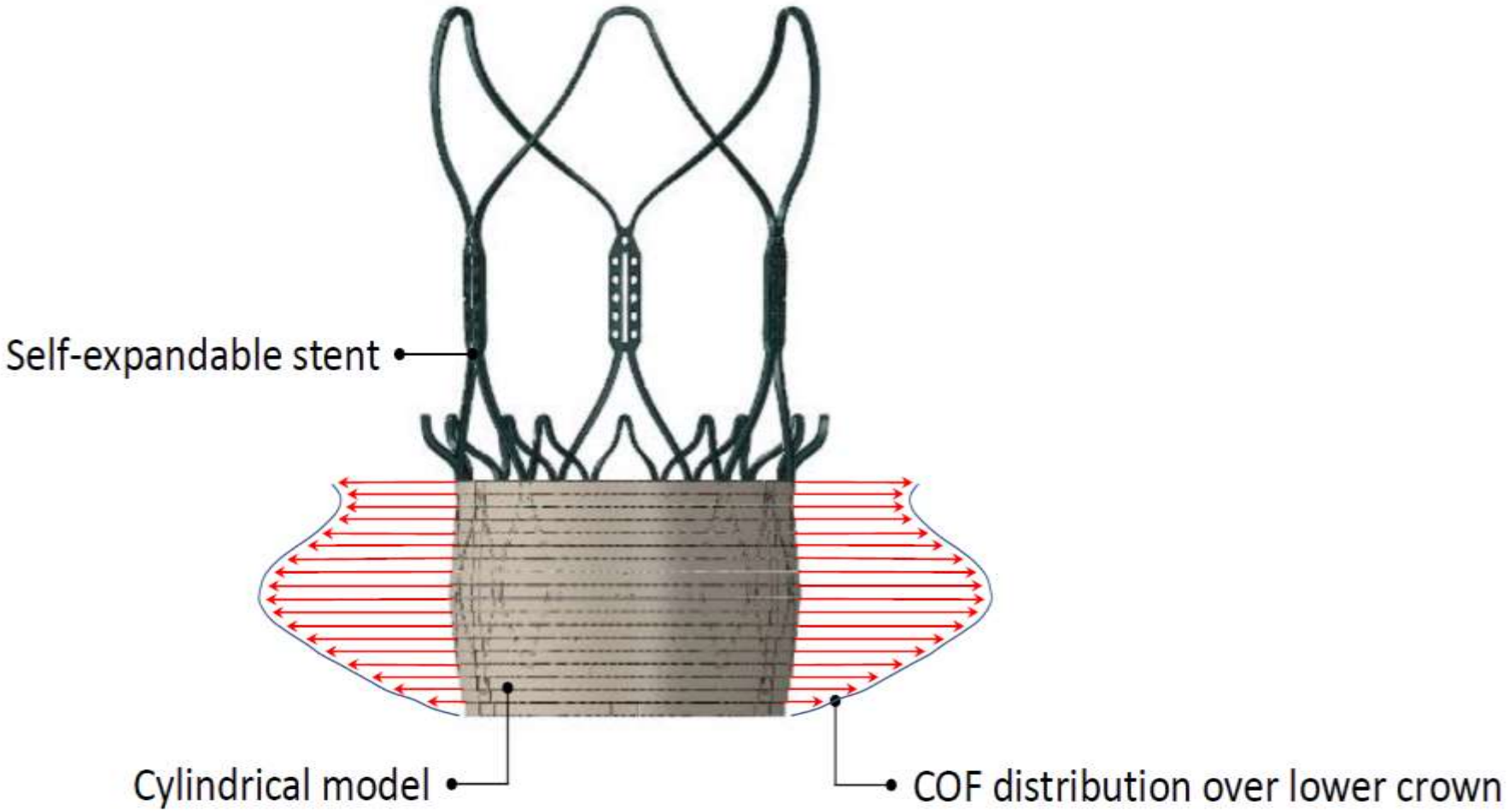
Gallo et al, Circulation CVI 2020

# Tortouos anatomies





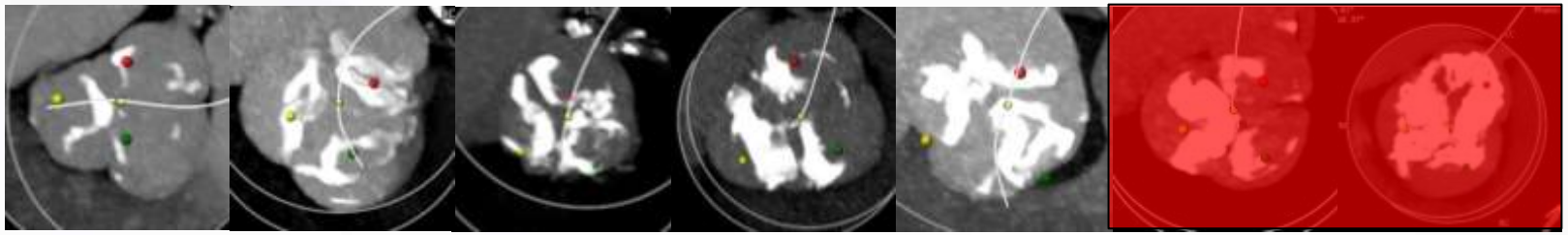
# Distribution of radial force




Courtesy of Stephane Delaloye

# Limitations & caveats of first gen ACURATE neo

Aortic valve calcification

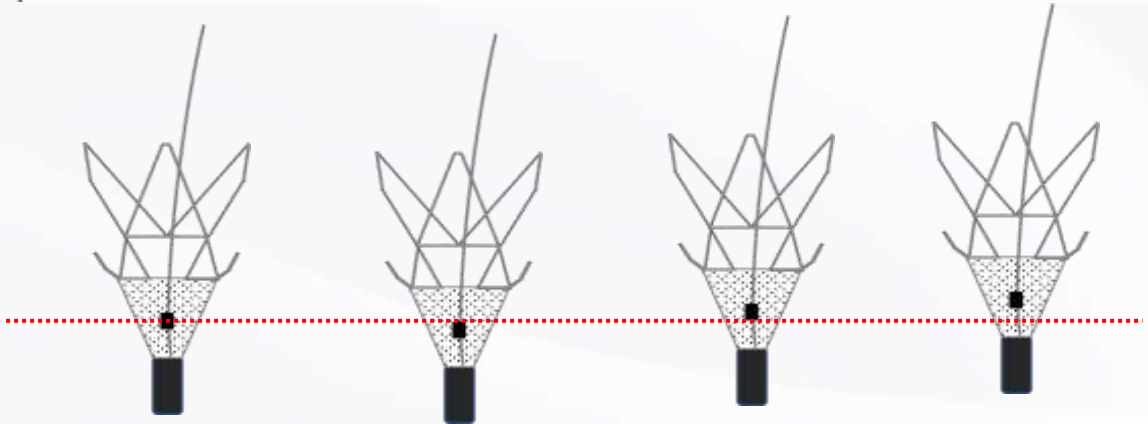


Annulus range

Appropriate Sizing

| ACURATE neo Size | Annular Range According to Official Sizing Recommendation (mm) | Perimeter-Derived Annulus in Diastole (mm) (Oversizing) | Perimeter-Derived Annulus in Systole (mm) (Oversizing) |
|---|---|---|---|
| Small | 21.0-23.0 | 20.0-22.0 (13.0%-4.4%) | 20.0-22.4 (13.0%-2.6%) |
| Medium | 23.0-25.0 | 22.1-23.9 (11.6%-4.4%) | 22.5-24.3 (10.0%-2.8%) |
| Large | 25.0-27.0 | 24.0-25.8 (11.1%-4.4%) | 24.4-26.3 (9.6%-2.6%) |

Correct positioning



Kim et al, JACC Cardiovasc Interv 2019

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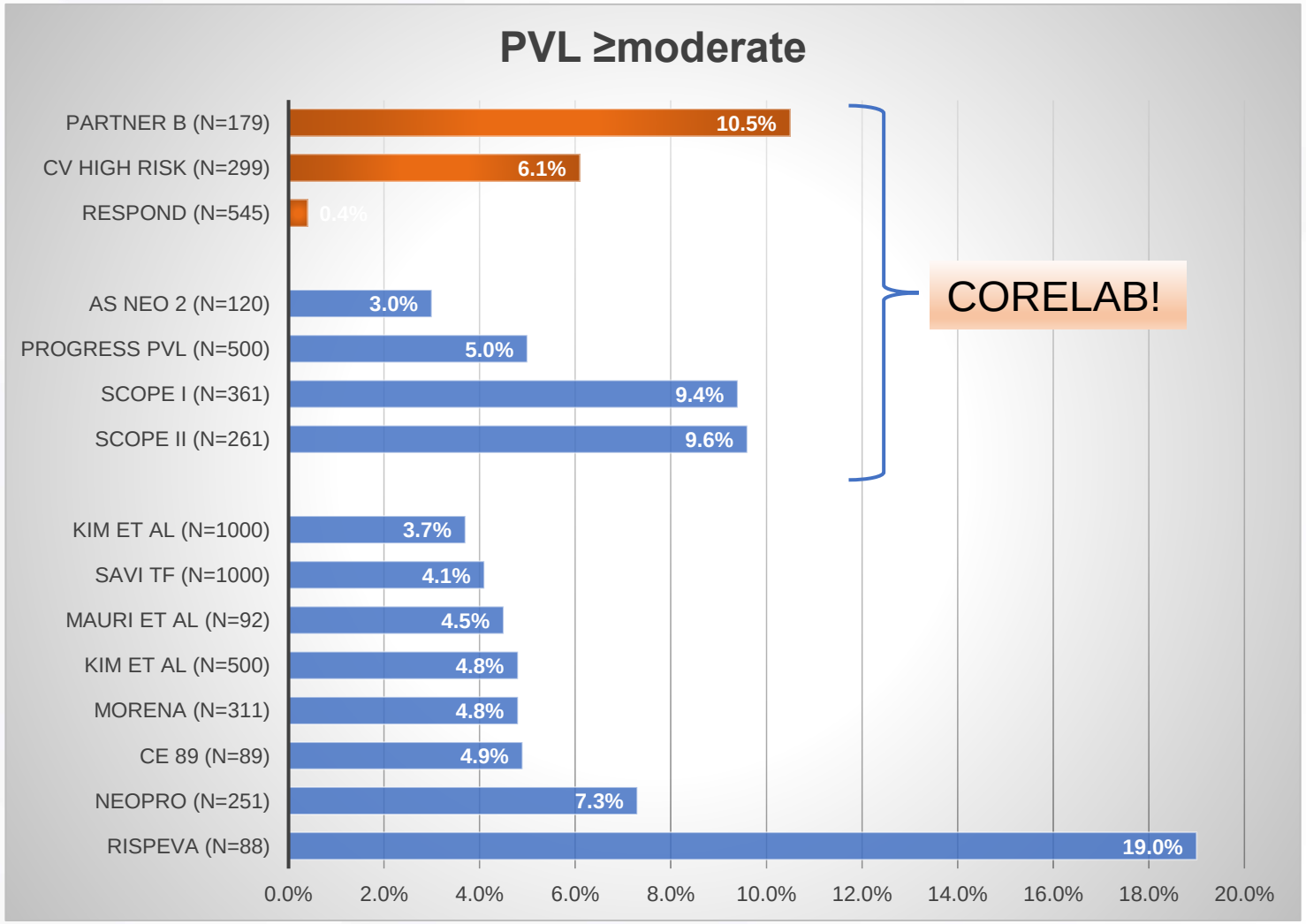
# ACURATE neo & PVL

SAPIEN
CoreValve
Lotus

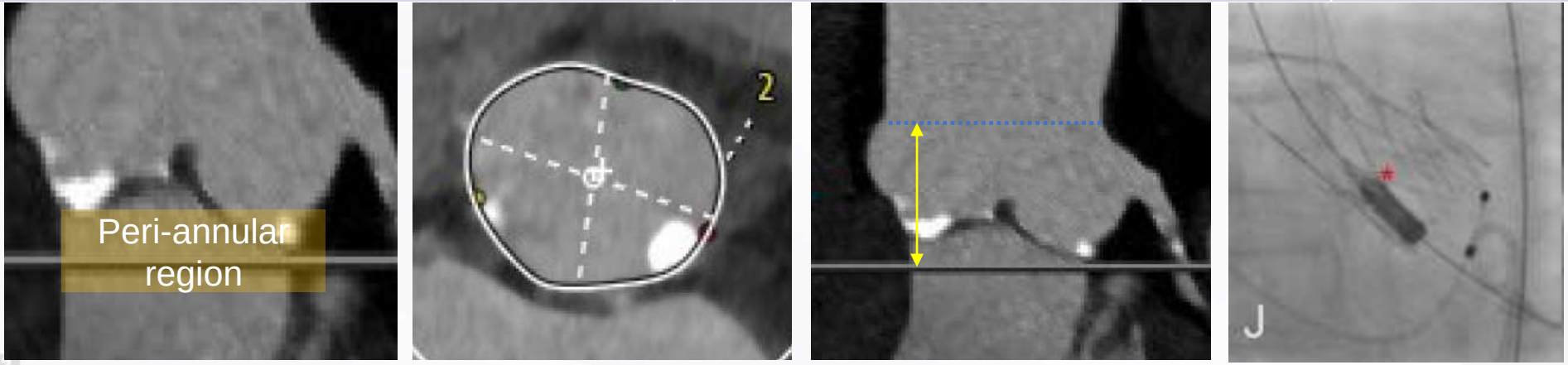
AS neo2

ACURATE
neo



# Predictors of paravalvular leakage

| | Odds ratio [95% CI] | p | Threshold |
|---|---|---|---|
| Calcium volume annulus, $mm^3$ | 1.006 [1.003-1.010] | <0.001 | 97 $mm^3$ |
| Annular plaque protrusion | 2.895 [1.212-6.913] | 0.017 | NA |
| Cover $index_{Perimeter}$ | 0.881 [0.781-0.994] | 0.04 | 4.4% |
| Sinotubular junction height, mm | 1.169 [1.022-1.337] | 0.04 | 21.5 mm |
| Aortic movement of the delivery system after deployment | 5.593 [1.299-24.071] | 0.02 | NA |




Kim et al, JACC Cardiovasc Interv 2019

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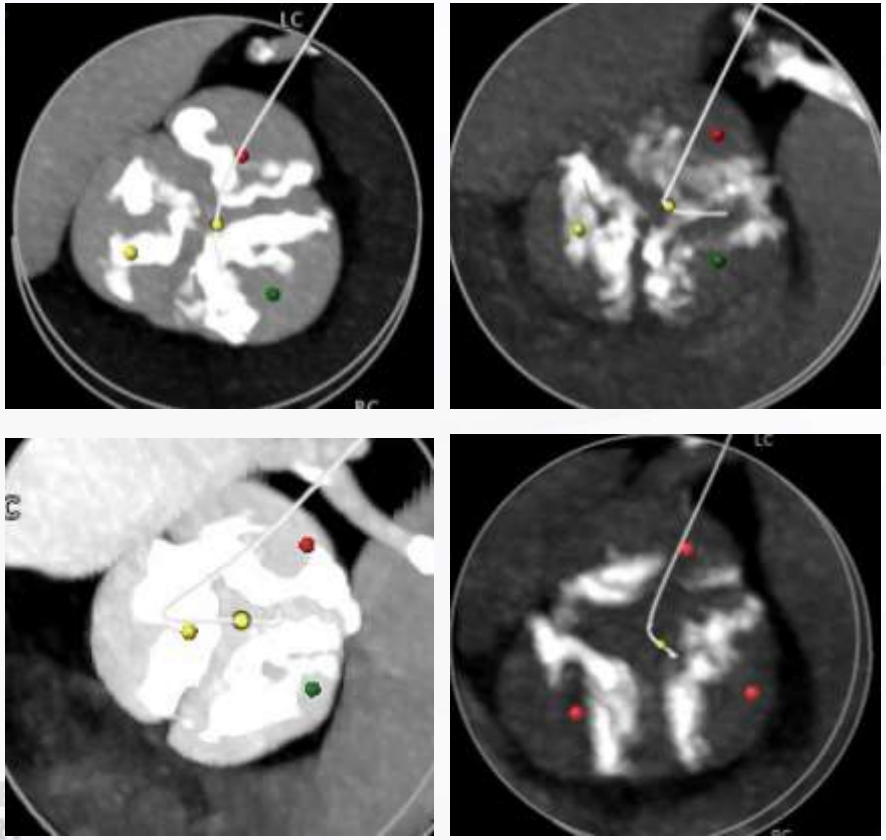
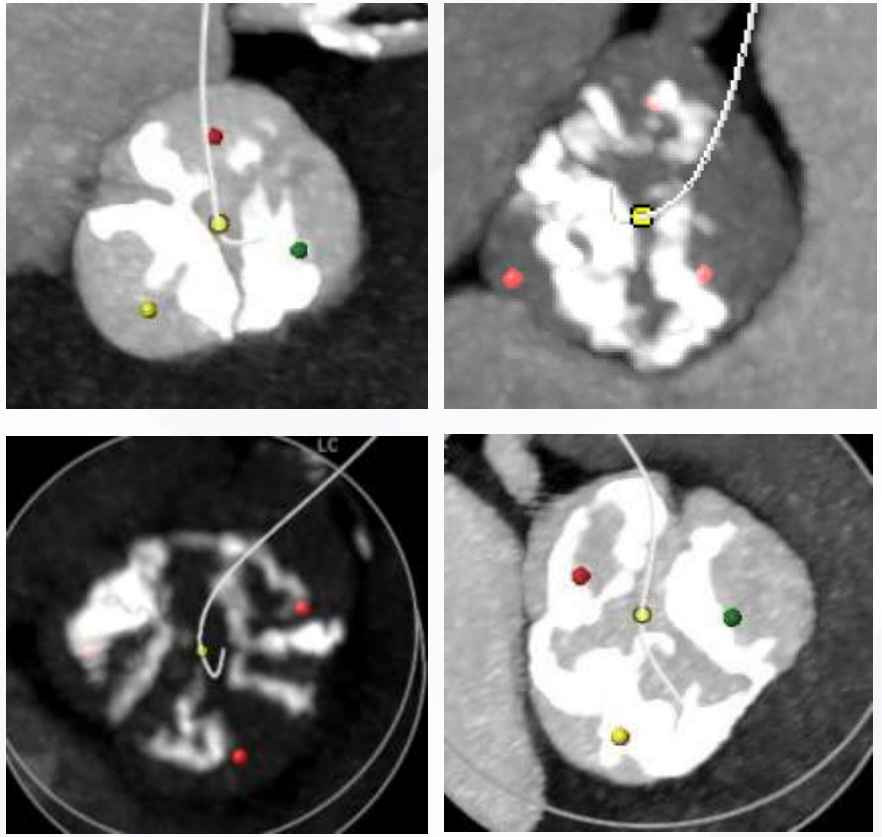
# Eccentric calcification: risk of PVL

Gallery of severely calcified aortic valves (Ca-score > 4500 AU)

PVL <moderate



PVL ≥moderate



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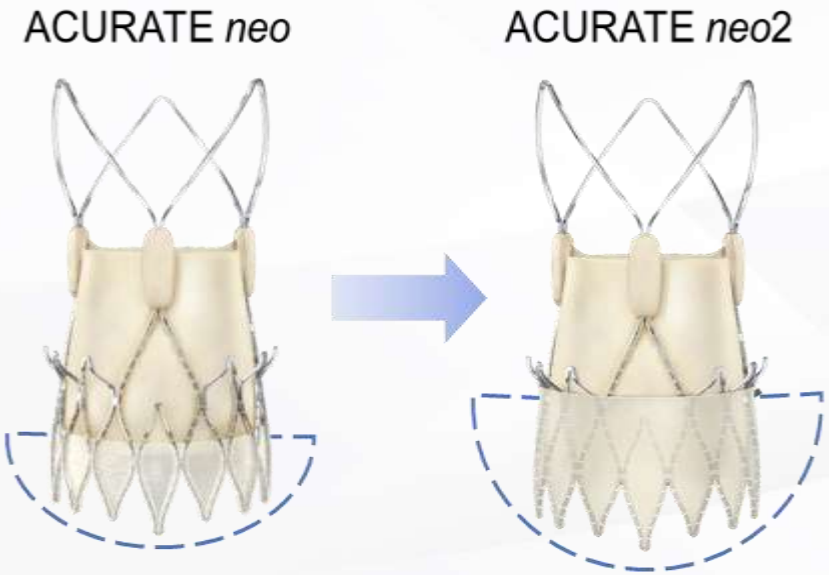
# Despite the limitations of the first gen ACURATE neo, with careful sizing and selection it was possible to achieve excellent outcomes!

| Variable | Quartile 1 (Case 1–250) | Quartile 2 (Case 251–500) | Quartile 3 (Case 501–750) | Quartile 4 (Case 751-1000) | p |
|---|---|---|---|---|---|
| Cover index (%) | 3.87 [1.86; 6.37] | 5.13 [3.04; 7.30] | 5.38 [3.39; 7.52] | 6.17 [4.20; 7.90] | <0.001 |
| Aortic valve calcium score (AU) | 2395 [1646; 3111] | 2049 [1494; 2872] | 1955 [1385; 2893] | 1989 [1280; 2726] | <0.001 |
| Compact peri-annular $Ca^{++}$ formation | 64 (25.6%) | 41 (16.4%) | 42 (16.8%) | 29 (11.6%) | 0.001 |
| Implantation depth at LCC (mm) | 5.0 [3.0; 6.0] | 6.0 [5.0; 7.0] | 6.0 [4.0; 6.0] | 5.0 [4.0; 6.0] | <0.001 |
| Device success (VARC-2) | 171 (85.5%) | 177 (88.5%) | 181 (90.5%) | 186 (93.0%) | 0.002 |
| ≥moderate PVL at discharge | 18/243 (7.4%) | 7/241 (2.9%) | 9/246 (3.7%) | 2/246 (0.8%) | 0.001 |
| Permanent pacemaker | 25 (10.0%) | 26 (10.4%) | 26 (10.4%) | 17 (6.8%) | 0.444 |



Kim et al, AJC 2020

# ACURATE neo => neo2




Preserved features:

- Self-expanding Nitinol frame
- Axial stabilization arches & open cells to facilitate coronary access
- Porcine pericardium leaflets
- Supra-annular anchoring; minimal protrusion into LVOT
- Porcine pericardium sealing skirt

Enhanced features:

- Radiopaque positioning markers for placement accuracy
- Augmented inner and outer skirt (60% larger) with active sealing capabilities

# The Early neo2 registry

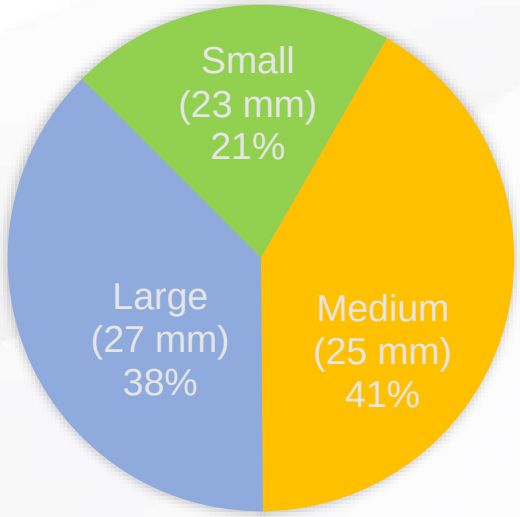
- Investigator-initiated European registry
- 554 consecutive Acurate neo2 cases from September 2020 to March 2021
- Database at Karolinska; Global PI Prof. Andreas Rück
- Imaging core-lab at CORRIB, Galway, Ireland

| Center | Site PI | n |
|---|---|---|
| Kerkhoff Klinik, Bad Nauheim | Won-Keun Kim | 142 |
| Karolinska, Stockholm | Chris Meduri | 86 |
| Herzzentrum Leipzig | Mohamed Abdel-Wahab | 77 |
| HDZ NRW, Bad Oeynhausen | Tanja Rudolph | 48 |
| Elisabeth-Krankenhaus, Essen | Alexander Wolf | 40 |
| Rigshospitalet, Copenhagen | Ole de Backer | 35 |
| Medizinische Universität Wien | Christian Hengstenberg | 31 |
| University Hospital Helsinki | Mika Laine | 28 |
| SUS, Lund | Henrik Bjursten | 25 |
| DHZ München | Costanza Pellegrini | 20 |
| Kantonsspital Luzern | Stefan Toggweiler | 15 |
| University Medical Center Groningen | Joanna Wykrzykowska | 7 |

Submitted data

# Baseline & procedural data

| | N=554 |
|---|---|
| Age | 82 |
| Female % | 66 |
| Atrial fibrillation % | 38 |
| Prior pacemaker % | 10 |
| EuroScore II | 4,5 |
| STS score | 3,7 |
| LVEF % | 56 |
| Aortic mean gradient | 43 |
| Bicuspid % | 3 |
| Valve-in-valve % | 2 |
| General anesthesia % | 0.2 |
| Femoral access % | 99.6 |
| Predilatation % | 87.0 |
| Postdilatation % | 36.0 |
| Anulus size mm (average) | 23.7 |

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# Procedural complications

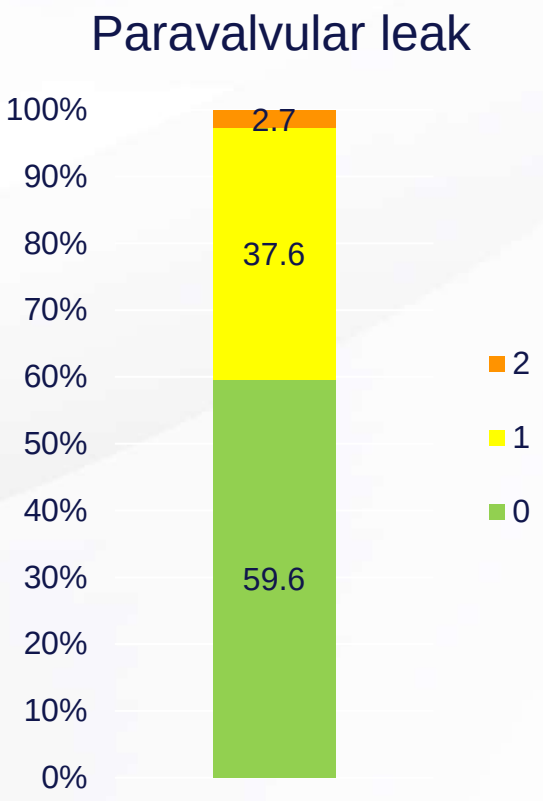
| Complications | N=554 |
|---|---|
| Second valve implanted % | 0.9 |
| Annular rupture % | 0 |
| Coronary obstruction % | 0 |
| Intraprocedural death % | 0.2 |
| Major vascular complication (in-hospital) % | 3.4 |
| Major or life-threatening bleeding (in-hospital) % | 4.8 |
| Acute kidney injury (AKIN grade 3) % | 0.2 |

Submitted data

# Primary outcomes

| Primary outcomes | |
|---|---|
| Paravalvular leak >mild % * | 2.7 |
| Postoperative mean gradient (mmHg) * | 8 |
| New pacemaker % | 6.0 |
| Mortality 30 days % | 1.3 |
| Stroke in-hospital % ** | 2.1 |

* 85% of patients had echo available to core-lab
** Major and minor stroke

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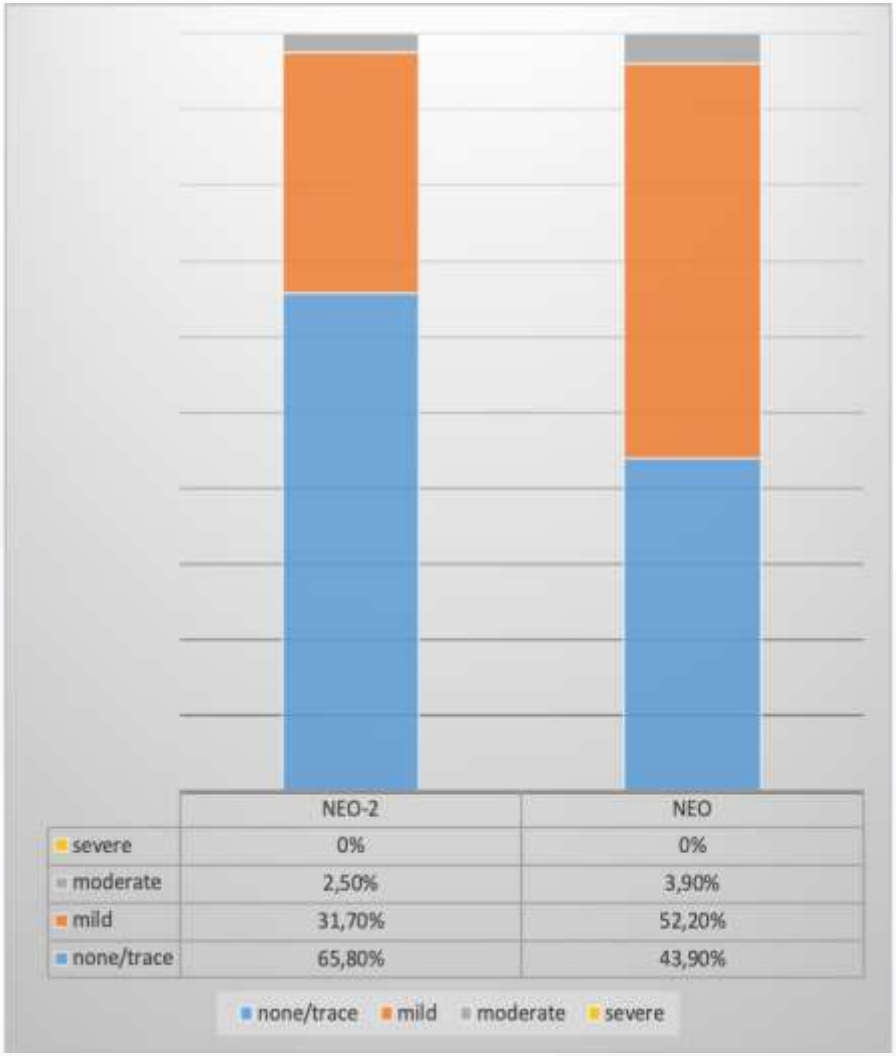
# Neo vs. Neo2

| Variable | NEO-2 (n=810) | NEO (n=2,055) | p |
|---|---|---|---|
| AVCS, AU | 2169 [1456; 3105] | 2184 [1408; 3071] | 0.734 |
| Eccentric AV calcification | 117 (14.5%) | 236 (11.5%) | 0.032 |
| LVOT calcification | 52 (6.4%) | 149 (7.3%) | 0.465 |
| Technical success (VARC-3) | 741 (91.5%) | 1836 (89.3%) | **0.098** |
| Device success (VARC-3) | 701 (86.5%) | 1704 (82.9%) | **0.018** |
| 30-day all-cause mortality | 10 (2.8%) | 9 (2.9%) | 1.000 |
| PVR ≥moderate | 20/805 (2.5%) | 81/2046 (4.0%) | 0.055 |
| Any relevant PVR | 22 (2.7%) | 92/2051 (4.5%) | **0.029** |
| Annular rupture | 0 | 0 | NA |
| Conversion to sternotomy | 3 (0.4%) | 21 (1.0%) | 0.110 |
| Device embolization | 10 (1.2%) | 33 (1.6%) | 0.609 |
| Major vascular complication | 56 (6.9%) | 179 (8.7%) | 0.130 |
| Type 2-4 bleeding | 120 (14.8%) | 406 (19.8%) | **0.002** |
| Any stroke | 29 (3.6%) | 56 (2.7%) | 0.223 |
| Acute kidney injury St. 2-4 | 27 (3.3%) | 91 (4.4%) | 0.210 |
| Pacemaker implantation | 70 (8.6%) | 191 (9.3%) | 0.614 |




Kim et al, JIC 2022

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# Neo vs. Neo2

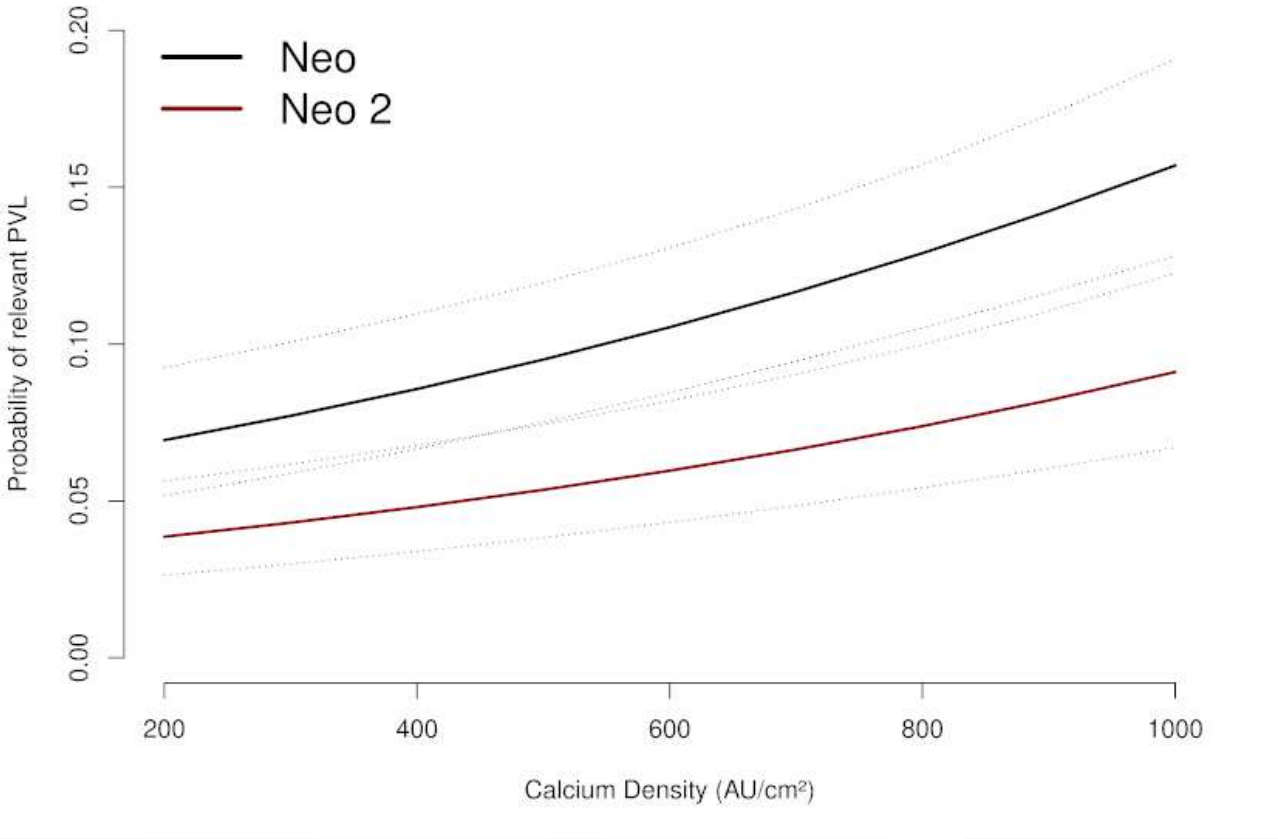
NEO

NEO-2

| 4.5% | Relevant PVR | 2.7% |
|---|---|---|

**Predictors of relevant PVR**

| | |
|---|---|
| Eccentric calcification (OR 4.19) | Eccentric calcification (OR 5.57) |
| Cover index (OR 0.91*) | Cover index (OR 0.76*) |
| STJ-Ann index (OR 1.03*) | STJ-Ann index (OR 1.04* ) |
| Ca density (OR 1.12†) | |






Kim et al, JIC 2022

# NEO vs. NEO 2

## ITAL-neo Registry

From 1st September 2018 to 31st May 2021 consecutive patients with severe native aortic valve stenosis treated with ACURATE neo and ACURATE neo2 THVs in 13 Italian Centers

- Valve-in-valve
- Pure AR
- Different access from TF and TS

ACURATE neo
N=680
(98.9% TF-TAVI)

ACURATE neo2
N=220
(99.1% TF-TAVI)

1:1 Propensity score matching

ACURATE neo
N=205
(100% TF-TAVI)

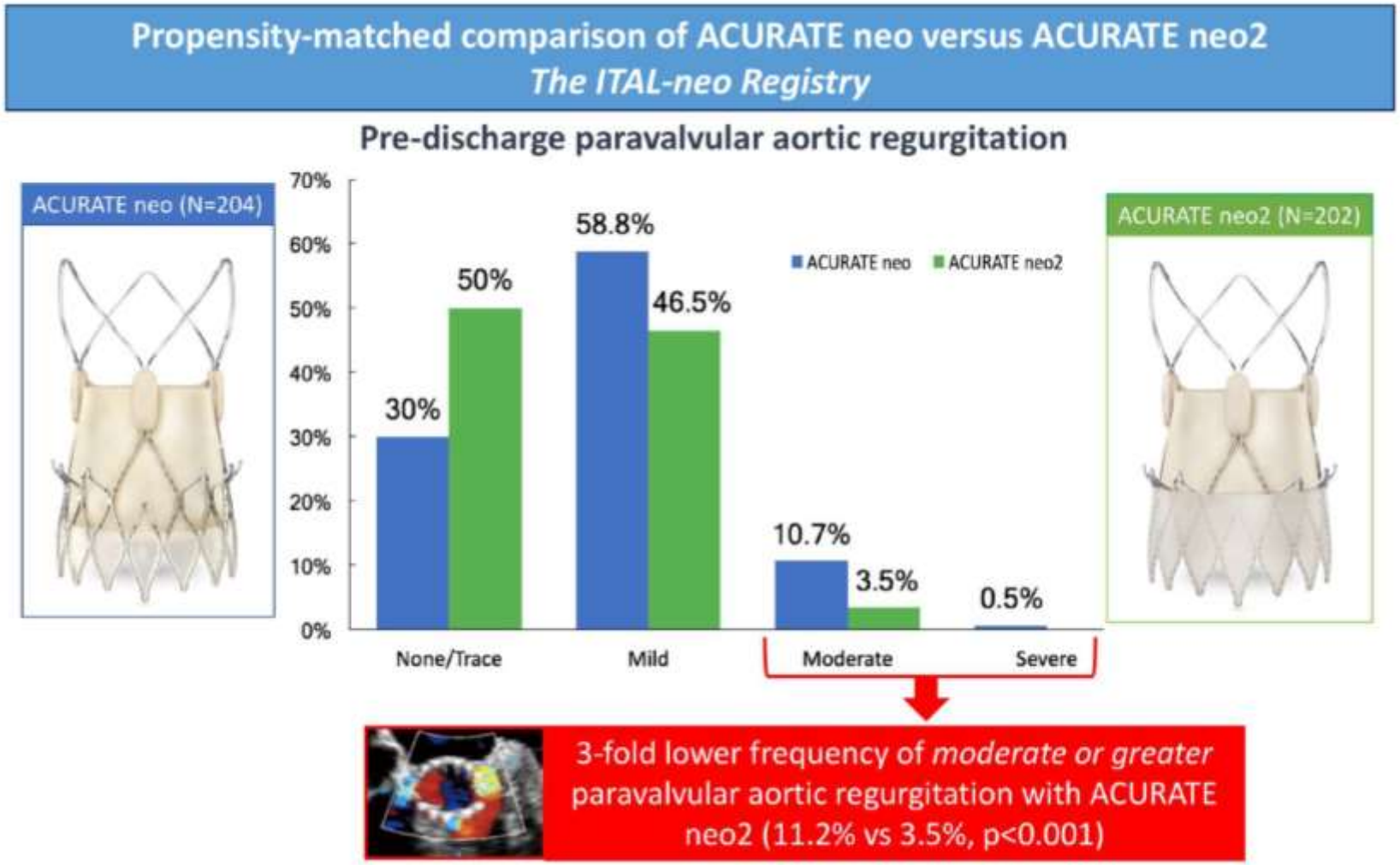
ACURATE neo2
N=205
(100% TF-TAVI)



Buono et al, JACC Interv 2022

# NEO vs. NEO 2

## ITAL-neo Registry

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# ACURATE *neo2 vs. SAPIEN 3 Ultra*
# Multicenter Registry

Kerckhoff Heart Center
German Heart Center Munich
Elisabeth Hospita Essen
UKGM University of Giessen

**03/2019 – 12/2021**
**n=1356**
transfemoral TAVI for severe native aortic valve stenosis

**Neo2**
n=608

**Ultra**
n=748

**1:1 nearest neighbour matching**

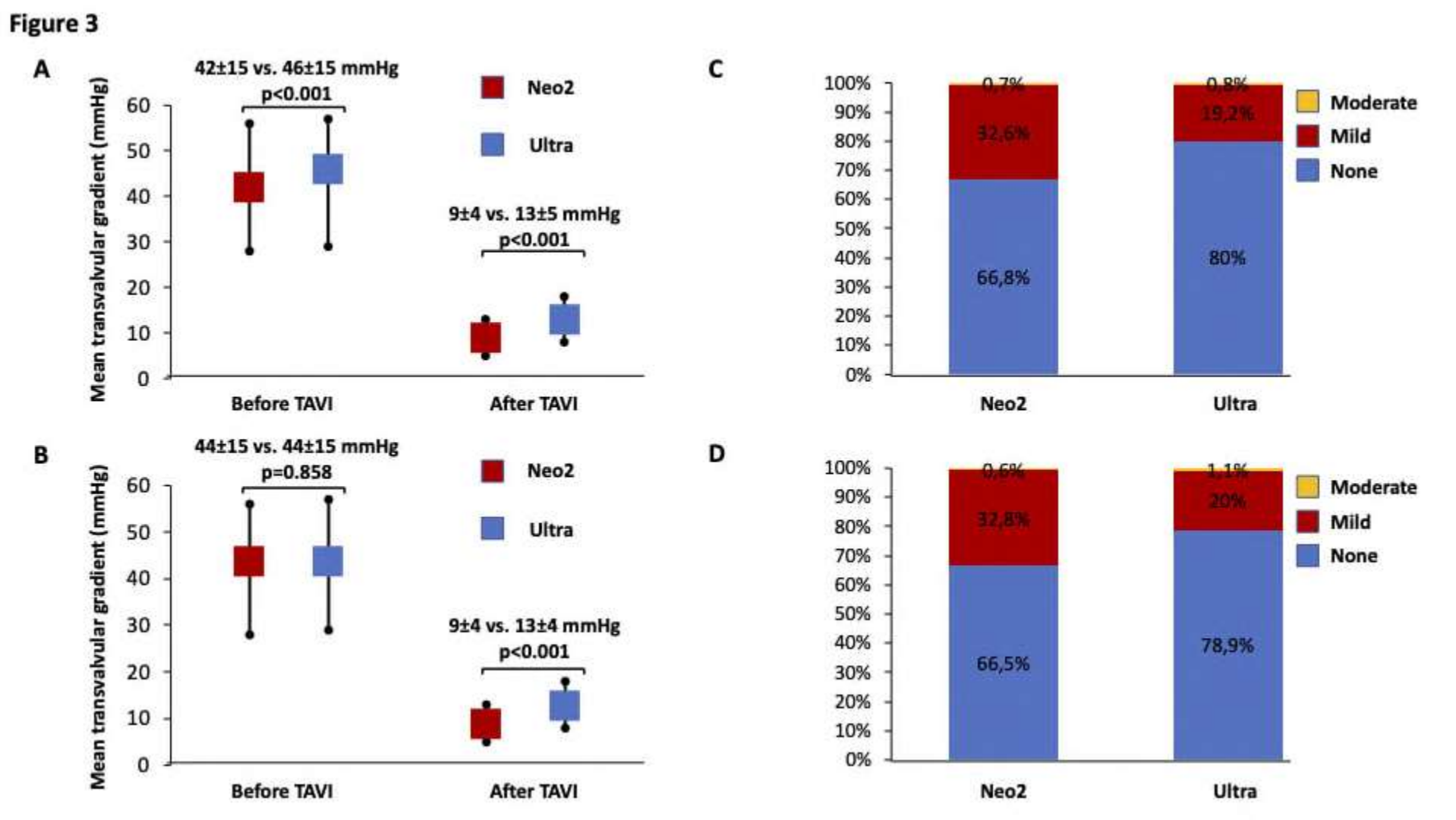
| | |
|---|---|
| Age | Mean transvalvular gradient |
| Female gender | iEOA |
| EuroScore I | Bicuspid aortic valve |
| NYHA III/IV | Severe calcification |
| Coronary artery disease | Asymmetric calcification |
| Previous PCI | Mean annulus diameter |
| LVEF < 35% | |

**Neo2**
n=472

**Ultra**
n=472

In revision at Eurointervention

# ACURATE *neo2 vs. SAPIEN 3 Ultra*
# Multicenter Registry




In revision at Eurointervention

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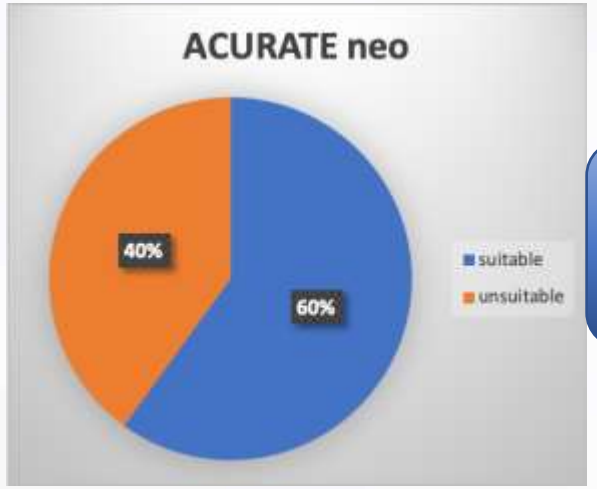
# ACURATE *neo2 vs. SAPIEN 3 Ultra*
# Multicenter Registry

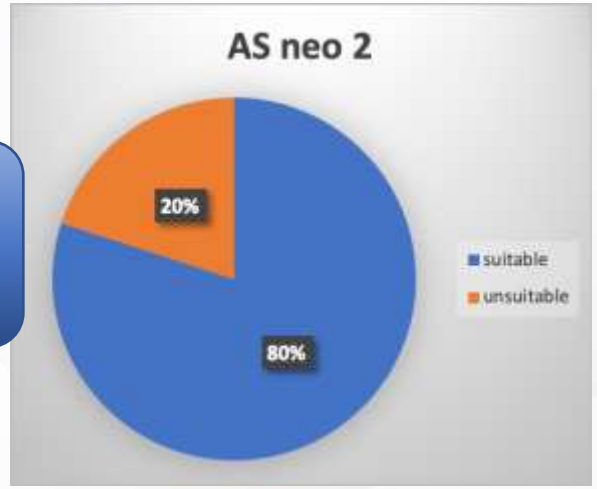
| | Neo2 (n=472) | Ultra (n=482) | p-value |
|---|---|---|---|
| **Severe AV calcification** | 114 (24.3) | 115 (24.4) | 0.954 |
| **Asymmetric calcification** | 120 (25.4) | 135 (28.6) | 0.305 |
| **Pre-dilatation** | 434 (91.9) | 148 (31.4) | <0.001 |
| **Post-dilatation** | 211 (44.7) | 69 (14.6) | <0.001 |
| **Technical success (VARC-3)** | 448 (94.9) | 450 (95.3) | 0.880 |
| **Device success (VARC-3)** | 434 (91.9) | 401 (85.0) | 0.001 |
| **Mean gradient ≥ 20mmHg** | 11 (2.4) | 36 (7.7) | <0.001 |
| **Severe PPM** | 10 (2.9) (n=342) | 25 (15.0) (n=167) | <0.001 |
| **Multiple valves** | 3 (0.6) | 1 (0.2) | 0.624 |
| **Conversion to surgery** | 1 (0.2) | 3 (0.6) | 0.624 |
| **All stroke** | 16 (3.4) | 11 (2.3) | 0.435 |
| **New permanent pacemaker*** | 33/415 (8.0) | 42/426 (9.9) | 0.332 |
| **Major vascular complication** | 29 (6.1) | 45 (9.5) | 0.069 |
| **Bleeding type 3 and 4** | 18 (3.8) | 17 (3.6) | 0.999 |
| **Coronary obstruction** | 1 (0.2) | 2 (0.4) | 0.999 |
| **AKIN 2/3/4** | 15 (3.2) | 15 (3.2) | 0.999 |
| **All-cause mortality** | 8 (1.7) | 11 (2.4) | 0.646 |

In revision at Eurointervention

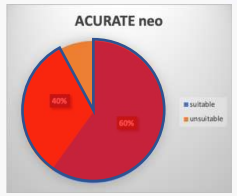
# Suitability of Neo vs Neo2



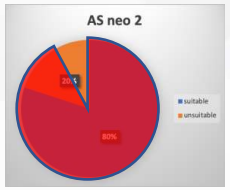

Limiting factors:
Calcification
Annulus size



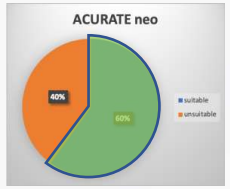

Limiting factors:
Extreme Calcification
(?)
Annulus size



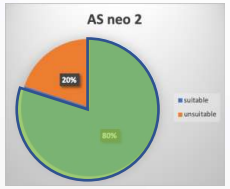

PVL ≥moderate
5 - 10%




PVL ≥moderate
2 - 5%



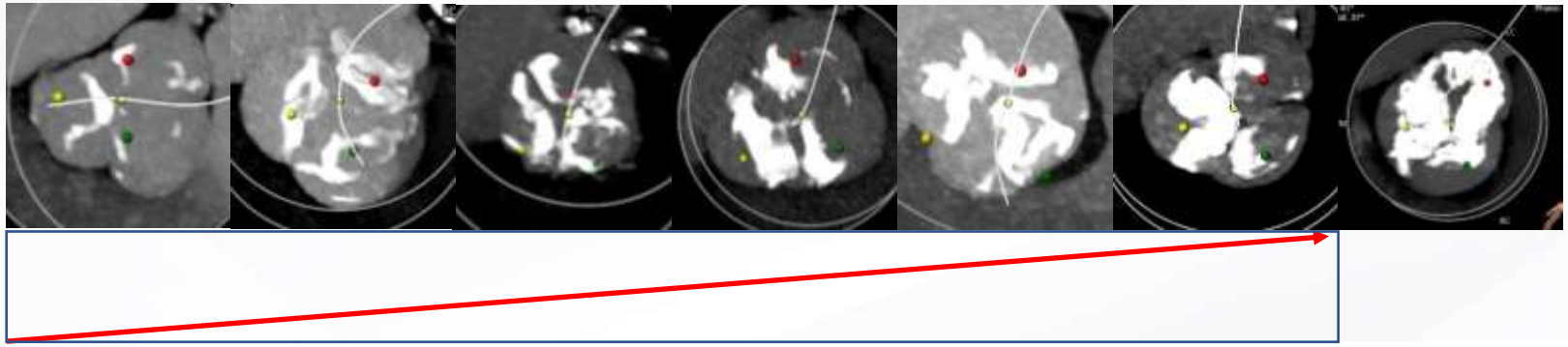

PVL ≥moderate
<1%



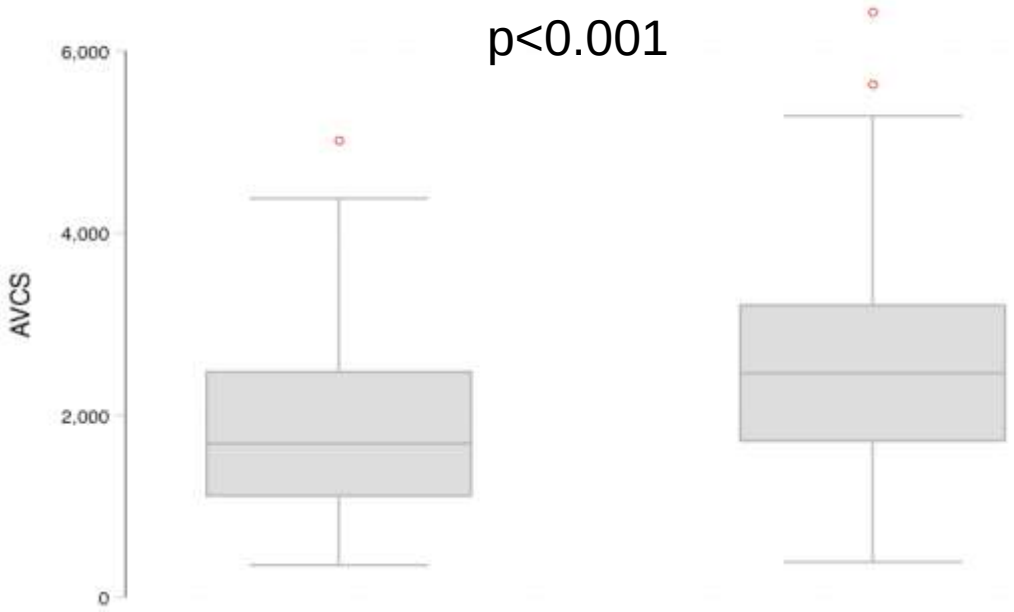

PVL ≥moderate
<1%

# ACURATE neo2 - Kerckhoff experience (n=256)

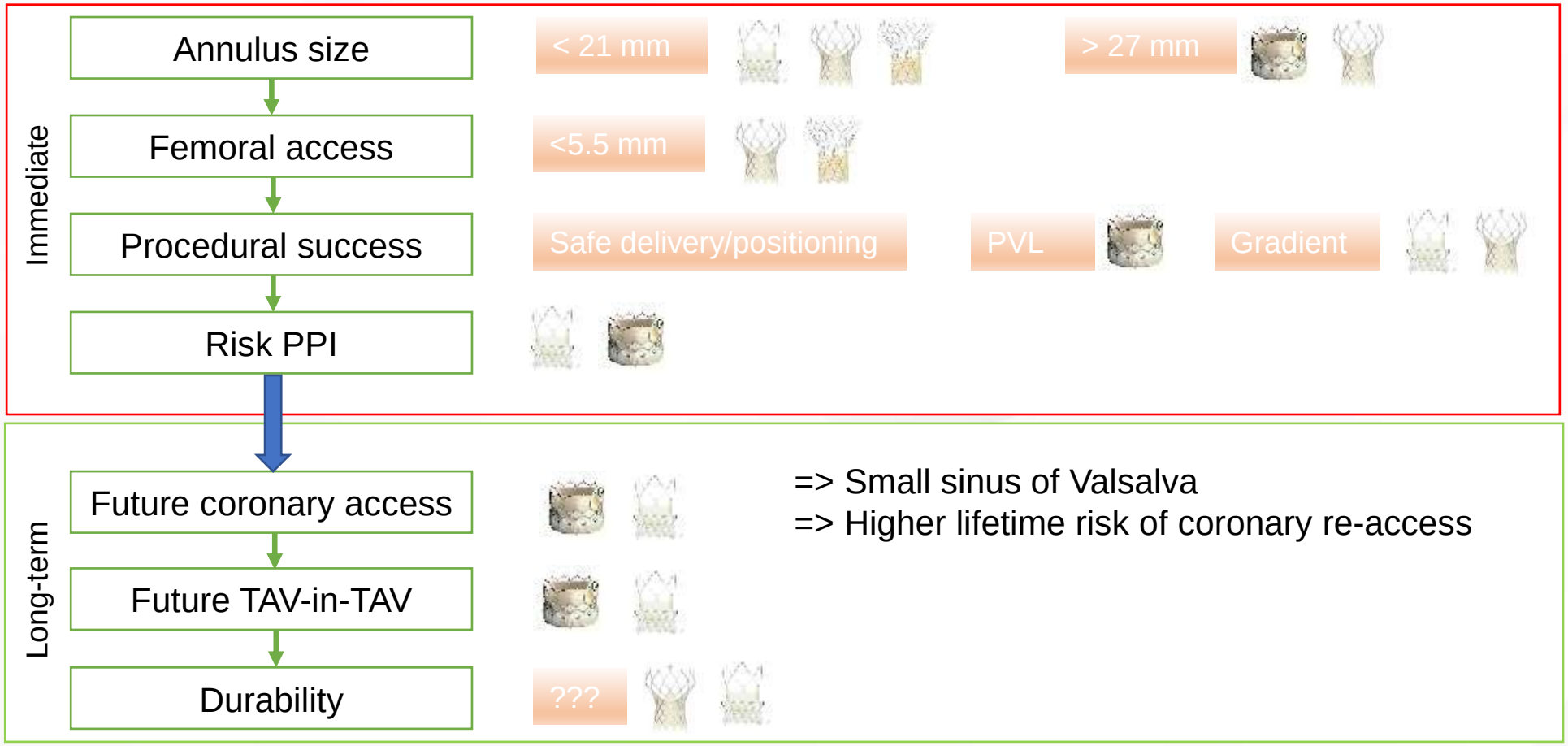
Increasing calcification



| | First half (n=128) | Second half (n=128) |
|---|---|---|
| Moderate paravalvular leakage | 2 (1.6%) | 1 (0.8%) |
| Device success (VARC-2) | 124 (96.9%) | 122 (95.3%) |



# TAVI valve selection for life time management



# Conclusion

- The ACURATE neo platform has several benefits including easy implantation, low risk of coronary obstruction, good coronary reaccess, commissural alignment, suitable for horizontal or tortuous aorta, favorable hemodynamics and low pacemaker rates.
- The ACURATE neo2 demonstrates markedly reduced PVL and maintains the benefits.