3rd TAVI Summit
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# One Year Outcomes in Real World Patients Treated with Transcatheter Aortic Valve Implantation

## The ADVANCE Study

on behalf of The ADVANCE investigators

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COREVALVE
ADVANCE STUDY

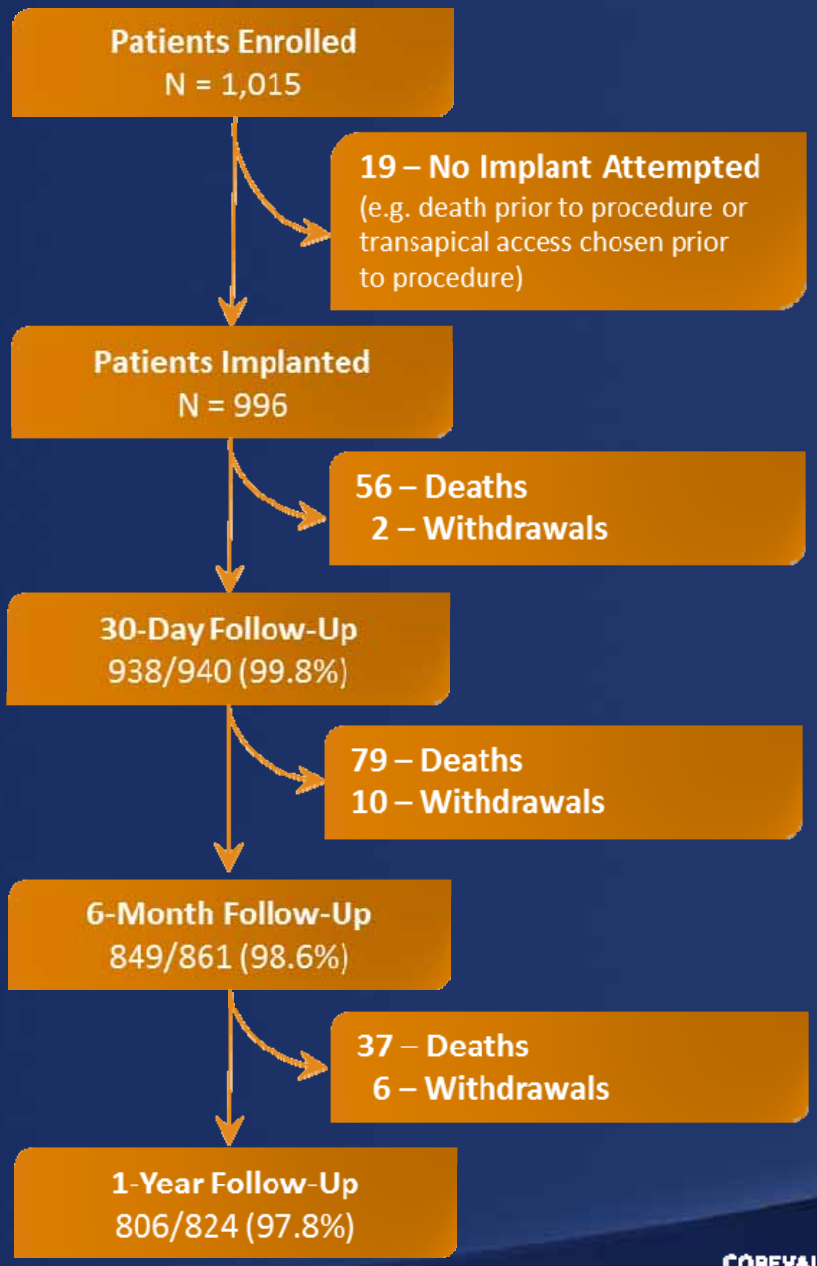
# Eberhard Grube MD

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

| Physician Name | Company/Relationship |
| --- | --- |
| **Eberhard Grube, MD** | Medtronic, CoreValve: C, SB, AB, OF<br>Sadra Medical: E, C, SB, AB<br>Direct Flow: C, SB, AB<br>Mitralign: AB, SB, E<br>Boston Scientific: C, SB, AB<br>Biosensors: E, SB, C, AB<br>Cordis: AB<br>Abbott Vascular: AB<br>Valtech: E, SB,<br>Claret: SB<br>Keystone Medical: SB |

# CoreValve ADVANCE | Methods

- 1,015 patients enrolled from March 2010 to July 2011
  - 5 year follow-up
- 44 centres - 12 countries in Western Europe, Asia and South America
- All centres had conducted at least 40 TAVI procedures prior to the study and had a Heart Team in place
- Clinical endpoints reported according to VARC
- As-treated analysis

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# CoreValve ADVANCE | Endpoints

- **Primary Endpoint- Major Adverse Cardiac & Cerebrovascular Events (MACCE) at 30-days post procedure**
  - MACCE defined as a composite of
    - All cause mortality
    - Myocardial Infarction (Q-wave and non-Q-wave)
    - Emergent Cardiac Surgery or Percutaneous Re-intervention
    - Stroke
- **Additional Clinical Endpoints (VARC)**
  - Cardiovascular Mortality
  - Bleeding
  - Vascular Complications
  - Acute Kidney Injury
  - New Pacemaker Implantation

# CoreValve ADVANCE | Study Oversight

- 100% of all Patients were monitored
- All Primary Endpoint events adjudicated by an Independent clinical events committee consisting of *TAVI-experienced* interventional cardiologists and cardiac surgeons using VARC I definitions
- All cerebrovascular events adjudicated by an independent neurologist
  - Adjudication of events utilized all available relevant source documents; including neuroimaging and systematic NIH Stroke Scale assessments
- Core laboratory for systematic review and assessment of EKGs and procedure angiograms
- Site reported echocardiographic data

# CoreValve ADVANCE | Baseline Characteristics

| Characteristics (N=1015) | % or mean ± SD | | % |
|---|---|---|---|
| Age (yrs) | 81.1 ± 6.4 | Prior MI | 16.4 |
| Male | 49.4 | Prior PCI | 31.5 |
| Logistic EuroSCORE (%) | 19.4 ± 12.3 | Permanent Pacemaker | 12.9 |
| NYHA III or IV | 79.6 | Prior CABG | 21.5 |
| Diabetes | 31.3 | Cerebrovascular Disease | 13.1 |
| CAD | 57.8 | COPD | 22.7 |
| PVD | 19.7 | Pulmonary Hypertension | 13.2 |
| Atrial Fibrillation | 33.2 | Renal Failure | 14.9 |
| LVEF (%) | 53.3 ± 13.7 | | |

# CoreValve ADVANCE | Procedural Results

| Procedural Parameters | |
|---|---|
| **N=996** | % |
| Successful vascular access, delivery & deployment of device & successful retrieval of the delivery system | 97.5 |
| Correct position of the device in the proper anatomical location | 98.7 |
| Mean aortic valve gradient < 20 mmHg* | 96.2 |
| Aortic Regurgitation ≤ 2* | 97.9 |
| Only one valve implanted in the proper anatomical location | 96.0 |

| Major Complications, Valve Related | |
|---|---|
| **N=996** | % |
| Annulus Rupture | 0.0 |
| Valve Embolization | 0.2 |
| Conversion to open AVR | 0.1 |
| Coronary Compromised | 0.1 |

*measured by angiography

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# CoreValve ADVANCE | Primary Endpoint

| Endpoint | 1 Month | 1 Year |
|---|---|---|
| N=996 | %* | %* |
| MACCE | 8.0 | 21.2 |
| All-cause Mortality | 4.5 | 17.9 |
| Myocardial Infarction | 0.2 | 0.9 |
| Emergent Cardiac Surgery or Percutaneous Re-intervention | 1.3 | 1.6 |
| Stroke | 3.0 | 4.5 |
| Minor | 1.8 | 2.3 |
| Major | 1.2 | 2.2 |

*Kaplan-Meier Estimates

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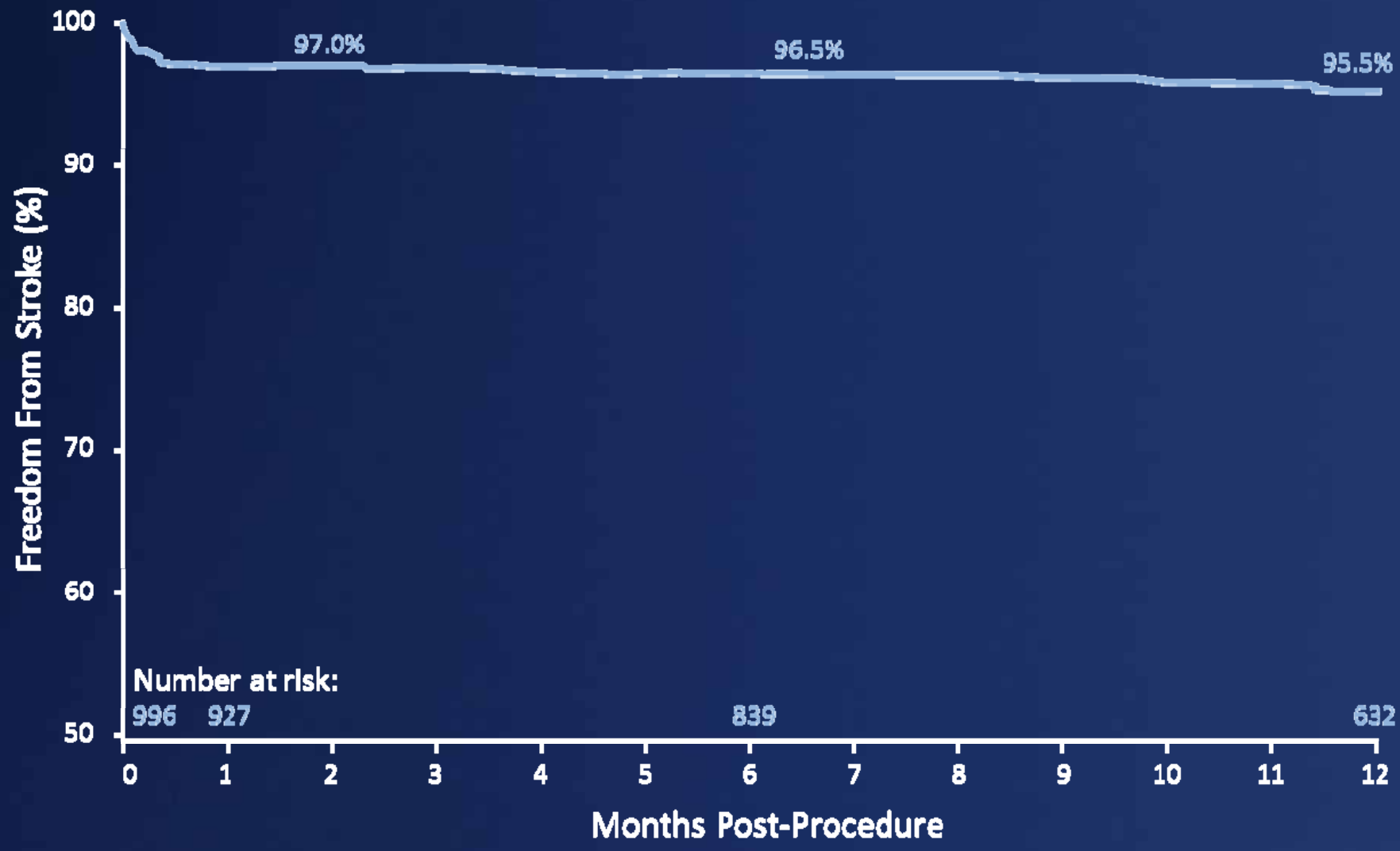
# CoreValve ADVANCE | 1-Year Stroke

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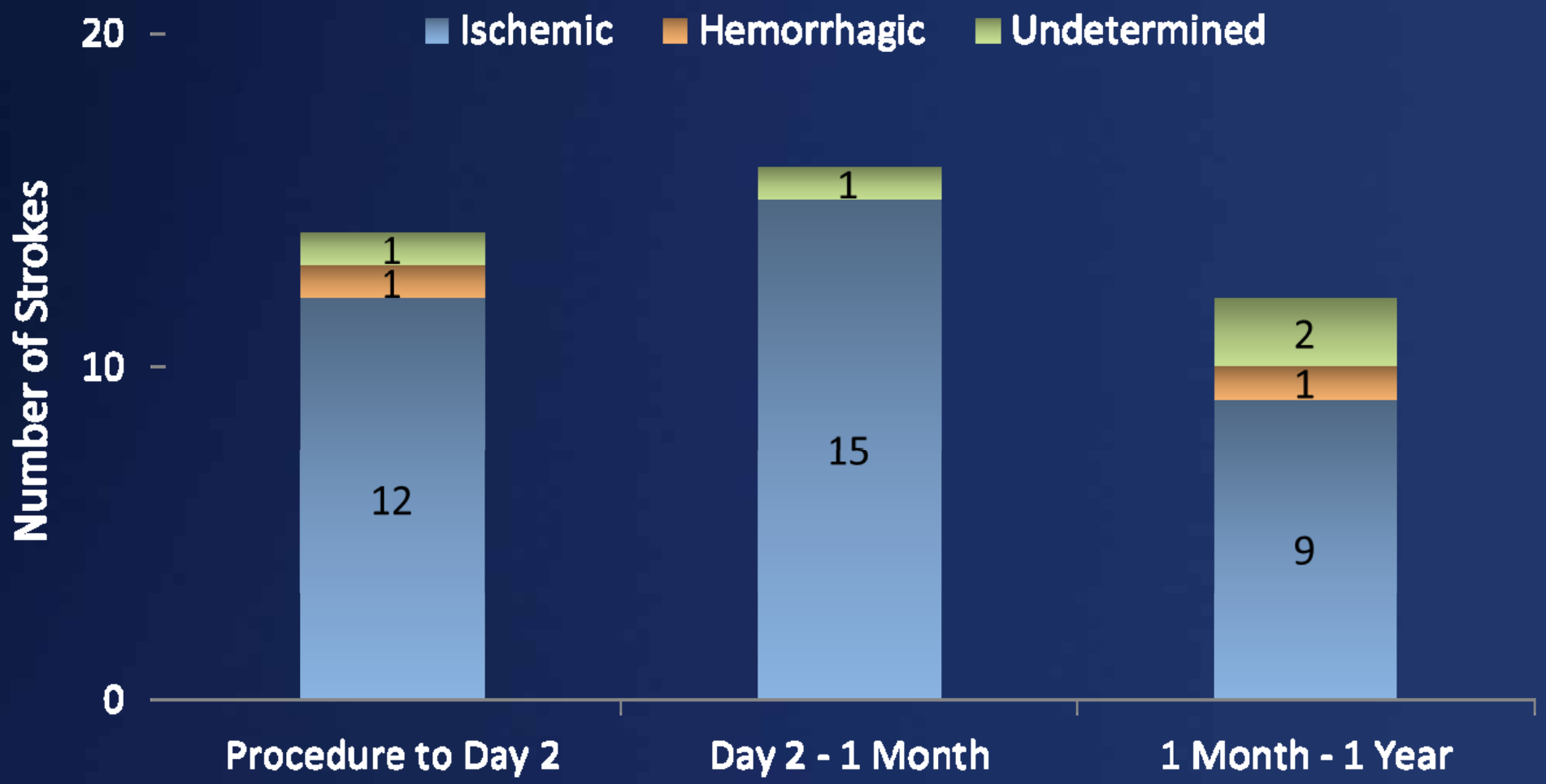
# CoreValve ADVANCE | Type and Timing of Stroke




996 patients implanted

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# CoreValve ADVANCE | Additional VARC I Endpoints

| Endpoint | 1 Month | 1 Year |
|---|---|---|
| N=996 | %* | %* |
| Cardiovascular Mortality | 3.4 | 11.7 |
| Bleeding | 29.0 | 32.0 |
| Life Threatening or Disabling Bleeding | 4.0 | 4.9 |
| Major Bleeding | 9.7 | 11.2 |
| Minor Bleeding | 17.4 | 19.3 |
| Vascular Complications | 20.7 | 21.9 |
| Major | 10.9 | 12.0 |
| Minor | 10.2 | 10.3 |
| Acute Kidney Injury—Stage III† | 0.4 | 0.6 |
| Pacemaker Implantation | 26.4 | 29.3 |

*Kaplan-Meier Estimates

†New AKI that occurred outside of the 72 hr post-TAVI window are included

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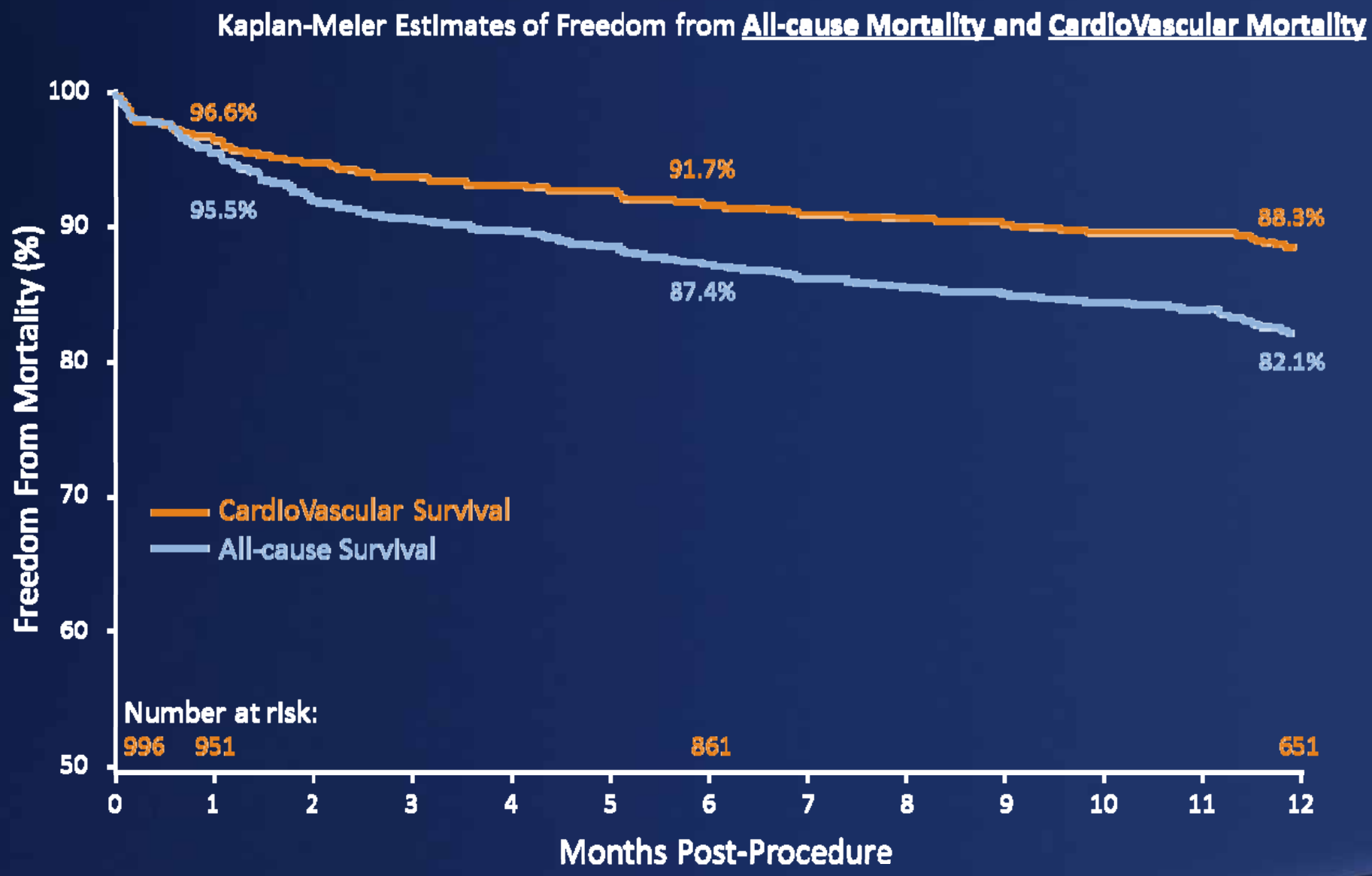
# CoreValve ADVANCE | 1-Year Survival

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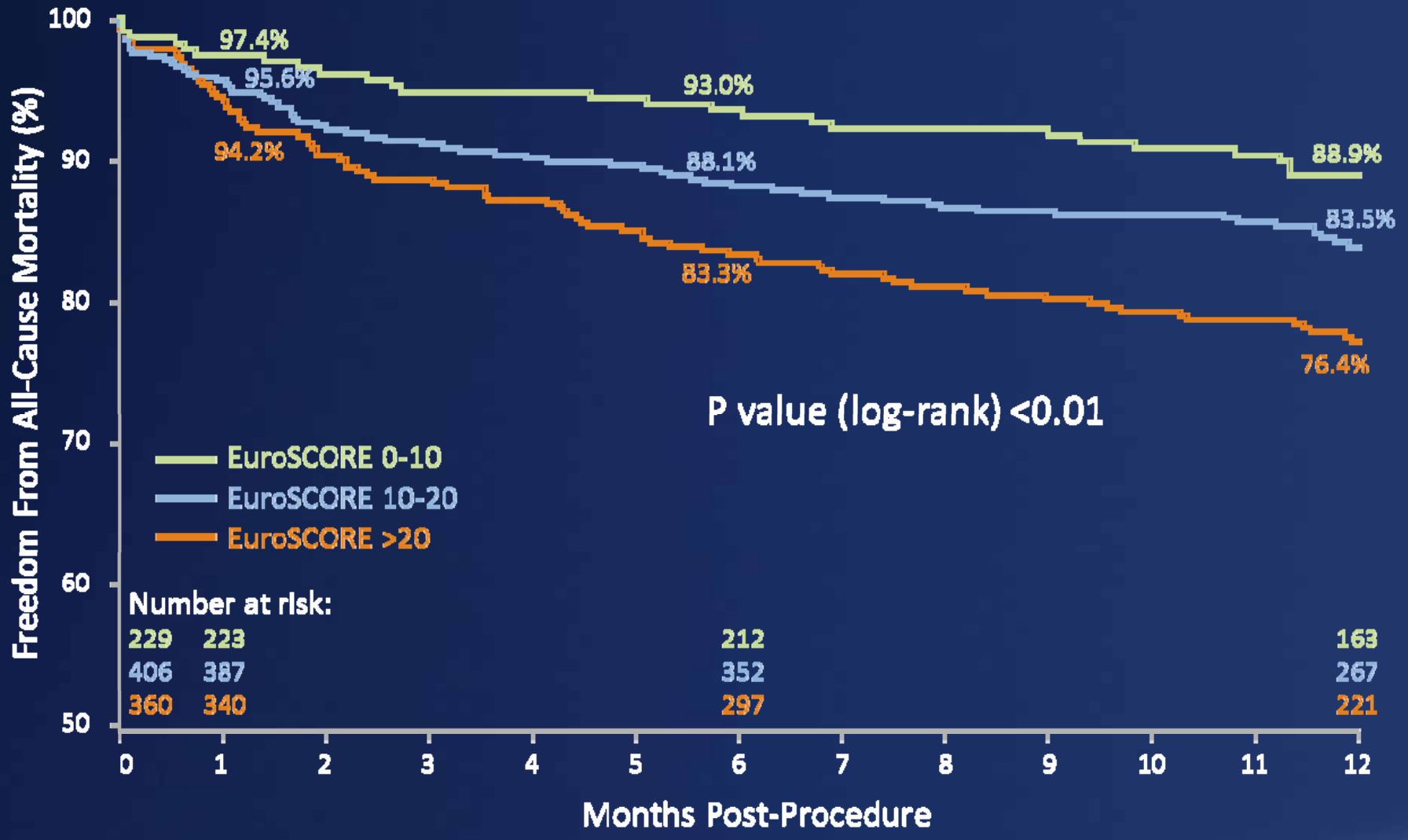
# CoreValve ADVANCE | Survival by EuroSCORE

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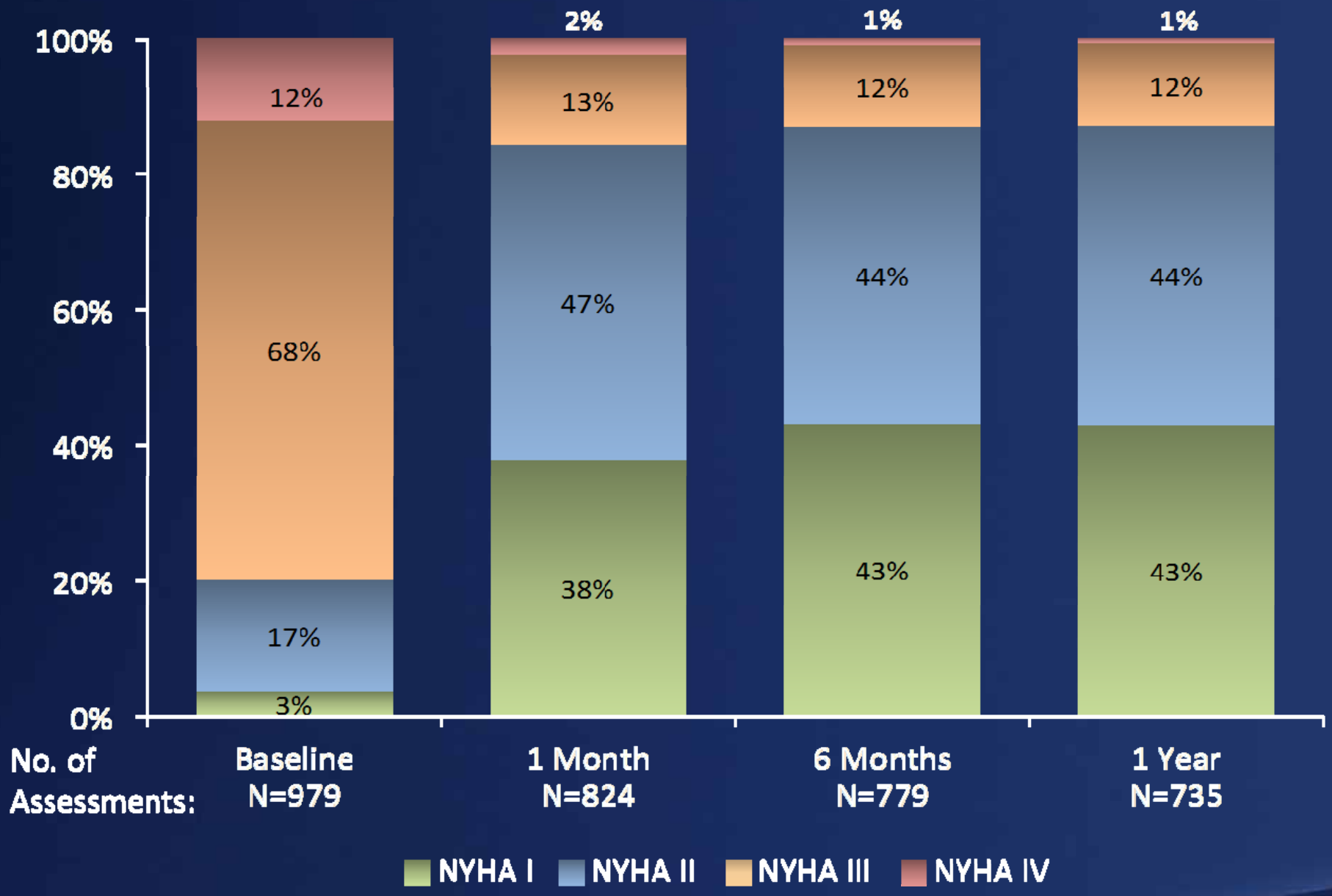
# CoreValve ADVANCE | NYHA Symptom Status

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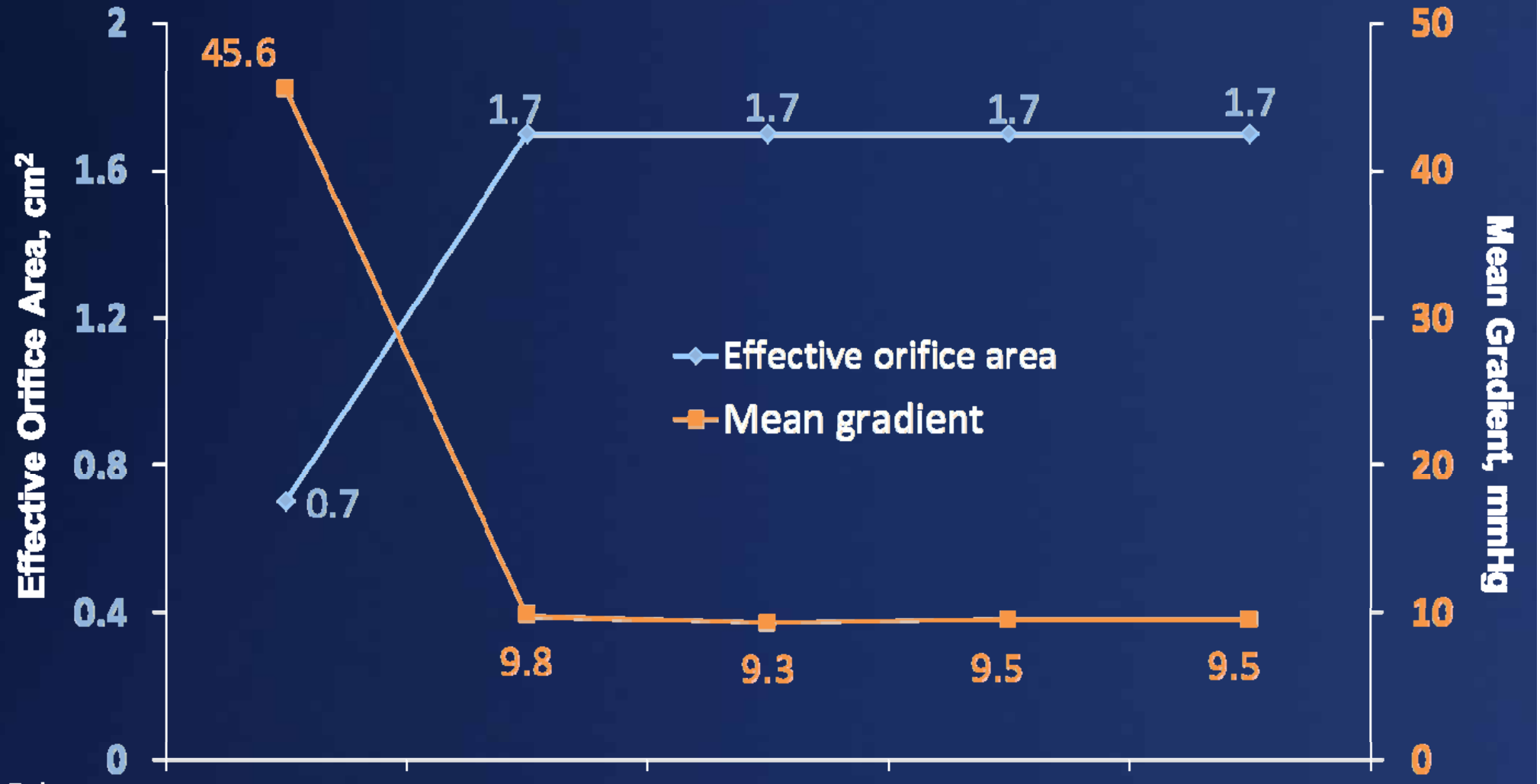
# CoreValve ADVANCE | Valve Performance




| No. Echos | Baseline | Discharge | 1 Month | 6 Months | 1 Year |
|---|---|---|---|---|---|
| EOA: | 795 | 514 | 389 | 405 | 394 |
| Mean Gradient: | 885 | 807 | 610 | 601 | 575 |

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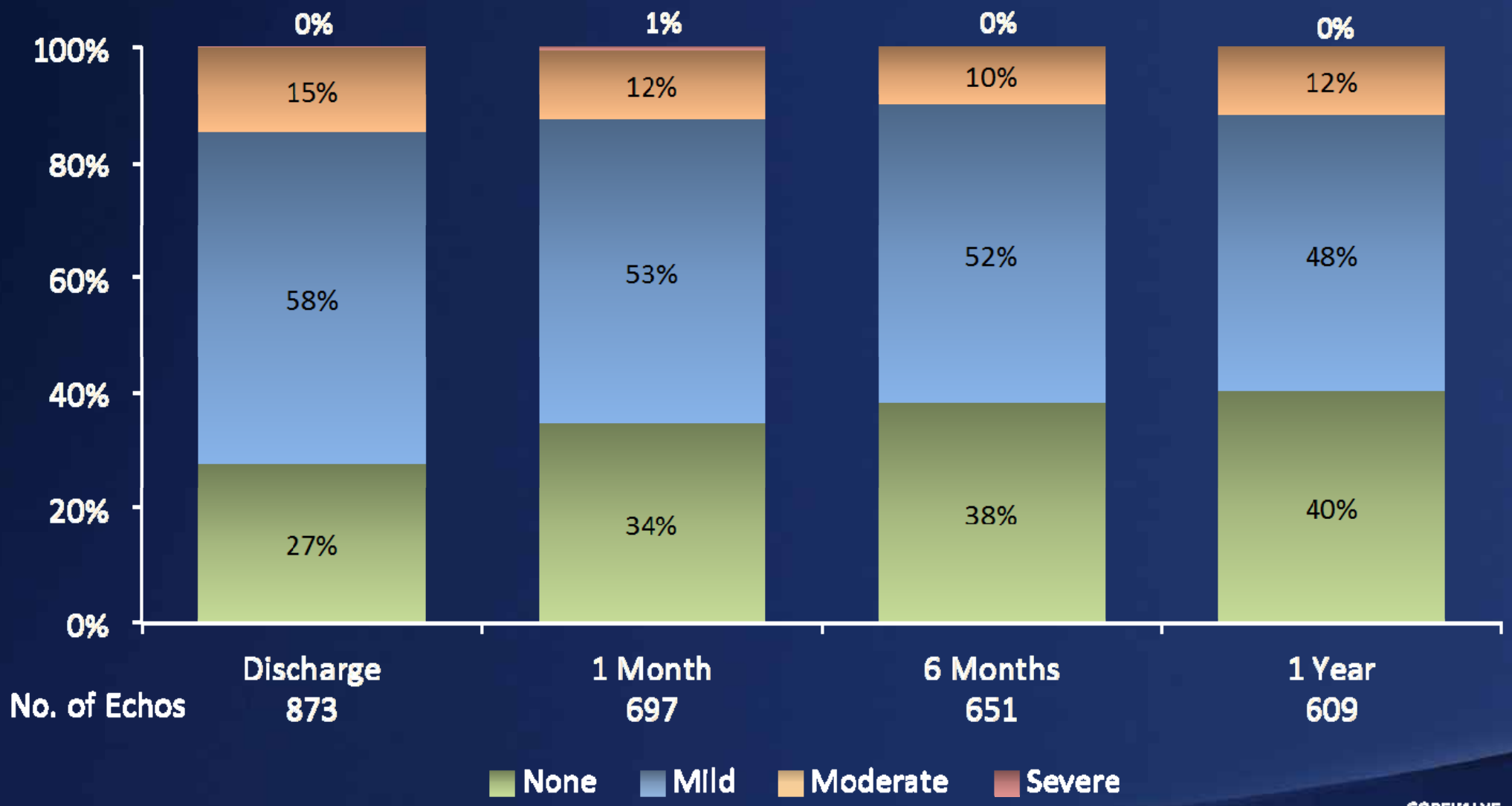
# CoreValve ADVANCE | Paravalvular Leak

## *Echo Assessment*

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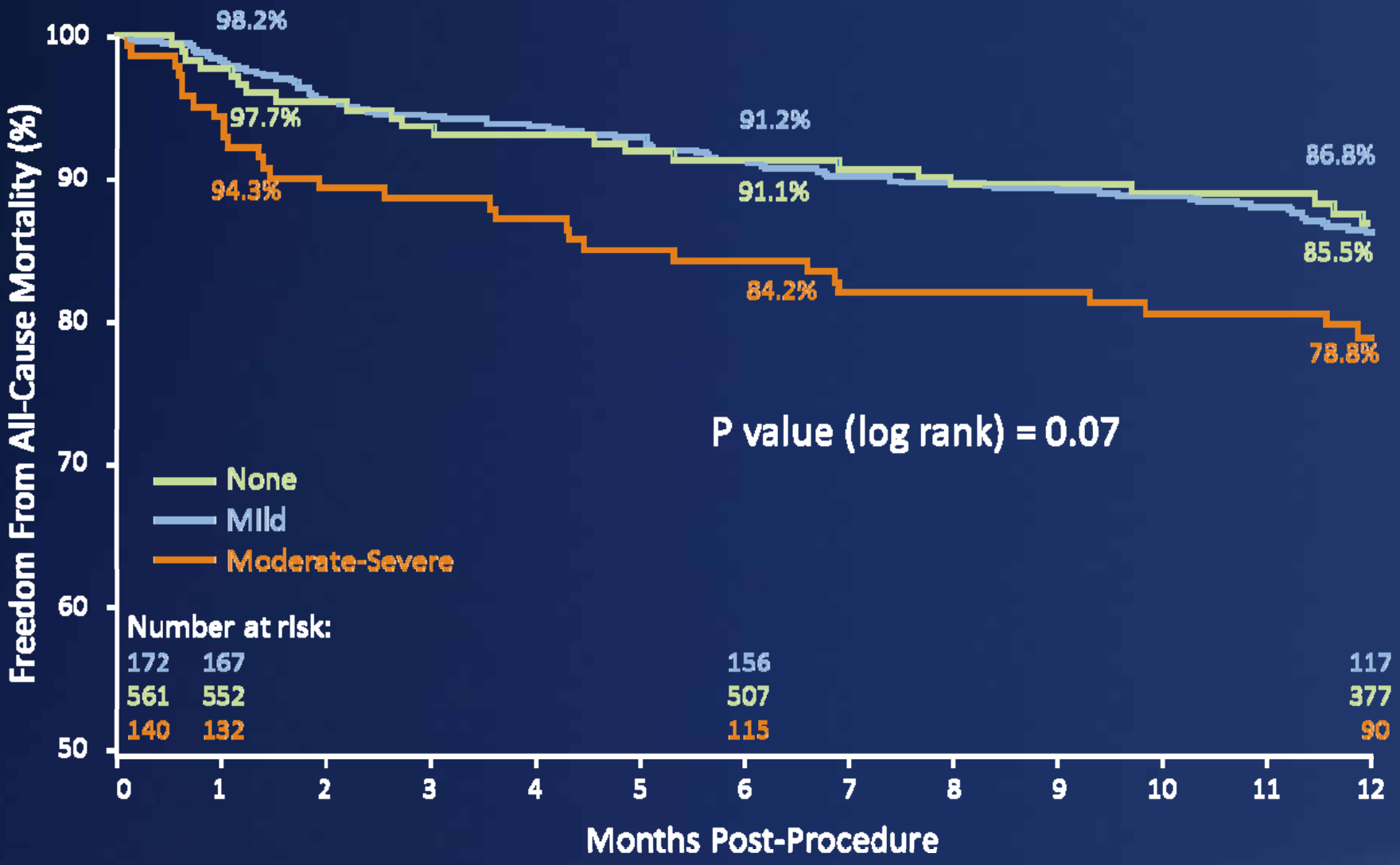
# CoreValve ADVANCE | Survival by AR*




*At discharge

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# CoreValve ADVANCE | Conduction Disturbance & Pacemaker Outcomes

| Core Lab Recorded Data | 1 Month | 1 Year |
|---|---|---|
| N=996 | % | % |
| New Pacemaker Implantation*† | 26.4 | 29.3 |
| AccuTrak Delivery System* | 24.4 | 27.7 |
| Pre-AccuTrak Delivery System* | 34.1 | 35.0 |
| New LBBB | 23.8 | 23.1 |
| New Atrial Fibrillation | 2.3 | 3.1 |

*Kaplan-Meier Estimates
†Prior pacemakers not excluded from the denominator

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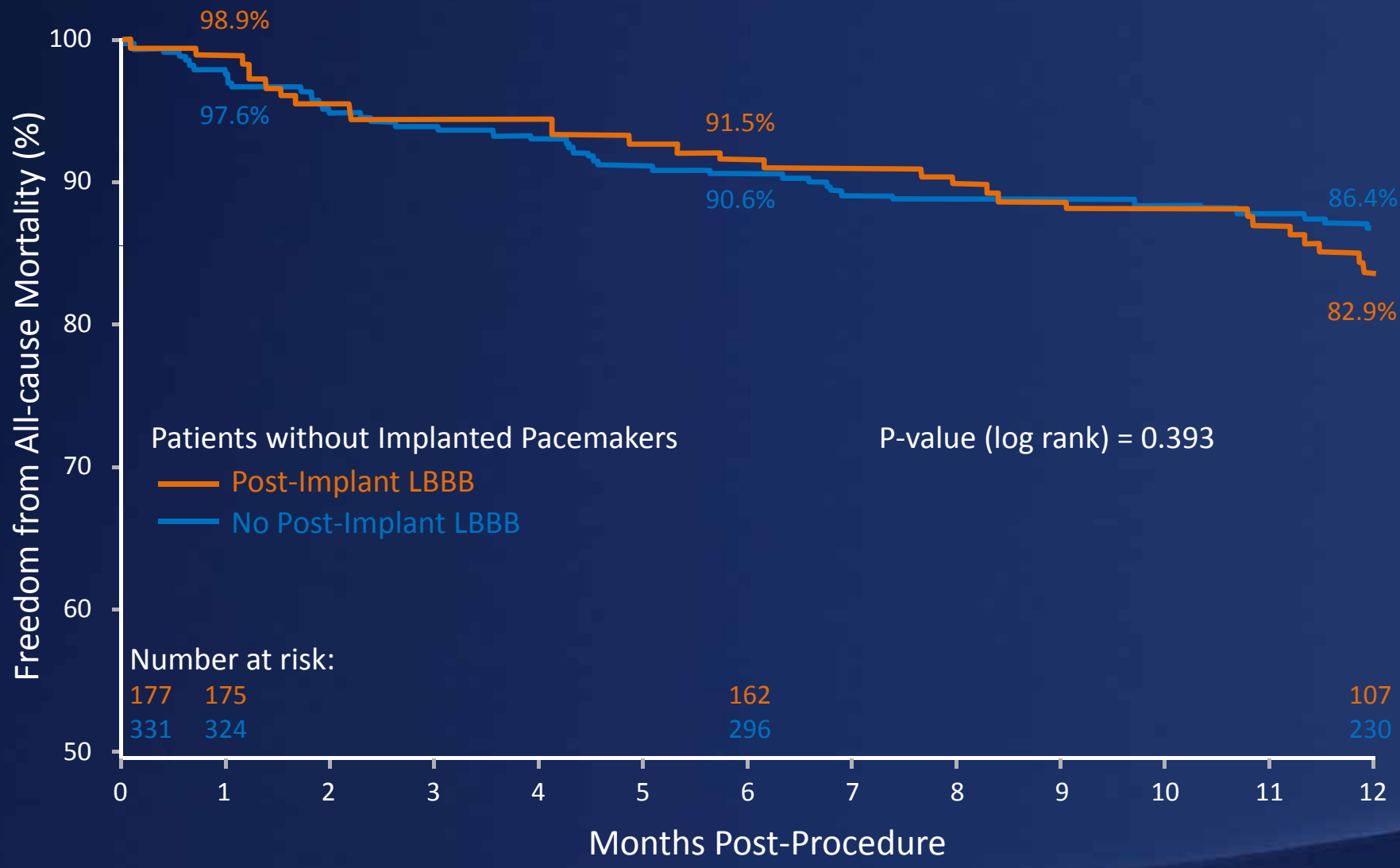
# CoreValve ADVANCE | Impact of LBBB on Survival

There was no significant difference in survival between those patients with a new LBBB post-implant and those without.

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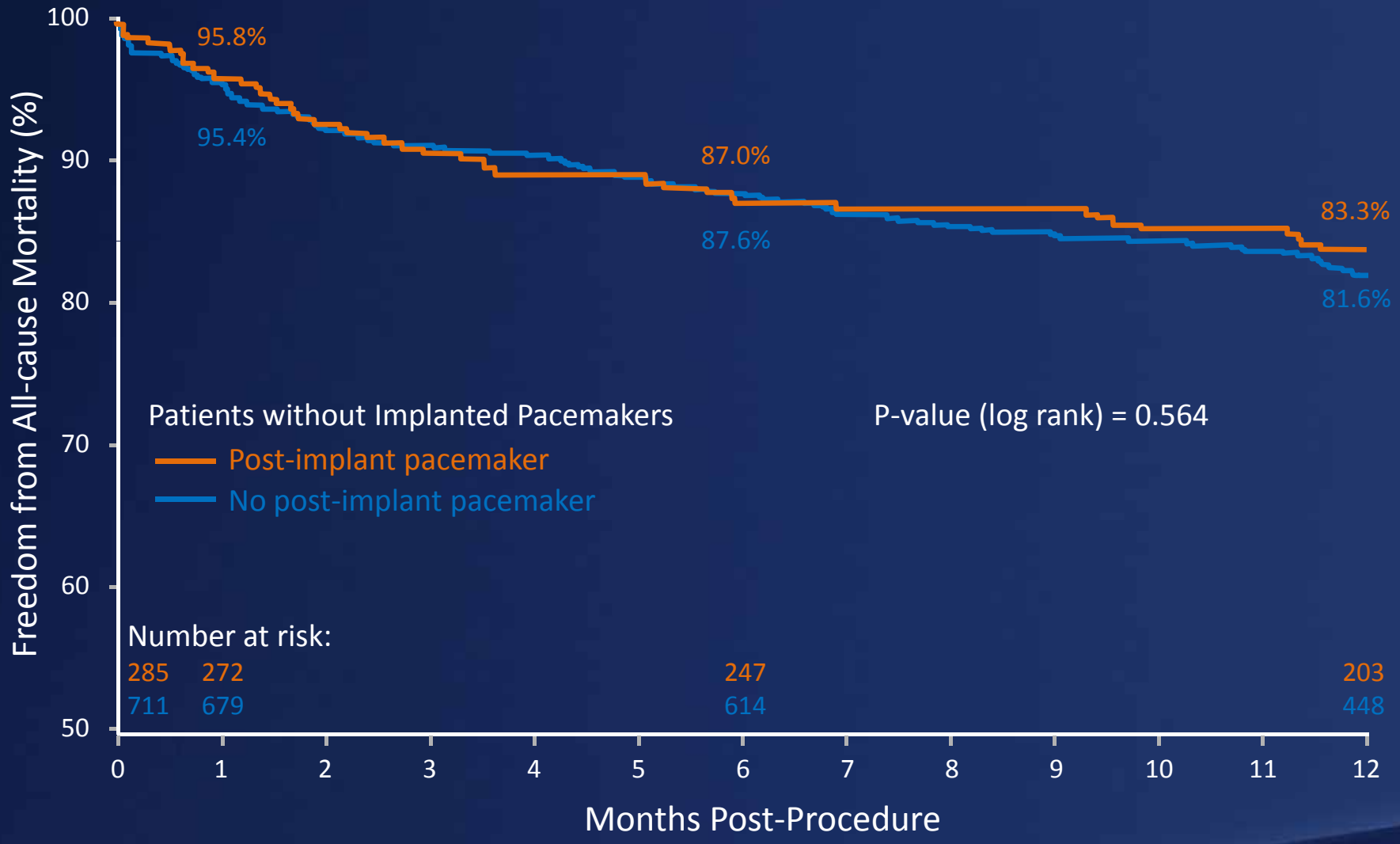
# Impact of Permanent Pacemaker Implant on Survival

There was no significant difference in survival between those patients with a post-implant pacemaker and those without.

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# CoreValve ADVANCE | Summary and Conclusions

- Medtronic CoreValve ADVANCE is one of the largest "real world" TAVI trials performed in multiple experienced centres.

- One year outcomes continue to demonstrate
  - low 1-year mortality
  - low stroke rates at 1-year
  - low rates of AR and PVL at 1-year
  - mild AR with the same low mortality rate as those patients with no AR
  - improved valve performance