HERZZENTRUM LEIPZIG

Leipzig Heart Institute LHI

# SOLVE-TAVI

## A 2x2 Randomized Trial of Self-Expandable vs Balloon-Expandable Valves and General vs Local Anesthesia in Patients Undergoing Transcatheter Aortic Valve Implantation

## 1-year Results

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*On behalf of the SOLVE-TAVI Investigators*

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# Background I – Valve Strategy

- TAVR is developing as standard strategy for symptomatic patients with severe aortic stenosis at high to intermediate and now also low risk.
- TAVR device design led to relevant technical and clinical improvements (e.g. pacemaker rates, paravalvular leakage, vascular complications).
- There is limited evidence for direct valve comparisons (CHOICE, REPRISE III, SCOPE I, PORTICO IDE) in particular for latest generation valve designs.

# Background II – Anesthesia Strategy

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- In clinical routine TAVR is performed in ≈50% using general or local anesthesia with conscious sedation.
- Registry data suggest
  a) lower mortality
  b) lower morbidity
  c) shorter ICU and hospital stay
  d) shorter procedure times with local anesthesia.
- The impact of the anesthesia strategy on clinical outcomes during extended follow-up is unknown.

# SOLVE-TAVI – 2 x 2 Factorial Design

Symptomatic Aortic Stenosis with TAVR Indication

1:1

CoreValve Evolut R

Valve Strategy

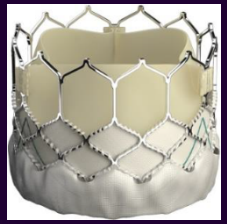
Edwards Sapien 3

1:1

Local Anesthesia

Anesthesia Strategy

General Anesthesia



# Baseline Characteristics – Valve Strategy

| Characteristic | Evolut R (n=219) | Sapien 3 (n=219) |
|---|---|---|
| Age (years); mean ±SD | 81.7 ± 5.3 | 81.5 ± 5.7 |
| Male sex; n/total (%) | 105/219 (47.9) | 109/219 (49.8) |
| Risk scores<br>STS score (%); mean ±SD | 7.7 ± 7.2 | 7.6 ± 7.4 |
| Log. EuroScore I (%), mean ±SD | 18.4 ± 12.1 | 18.3 ± 13.1 |
| EuroScore II (%), mean ±SD | 6.1 ± 5.5 | 5.4 ± 4.9 |
| Frailty; n/total (%) | 93/216 (43.1) | 80/217 (36.9) |
| Peripheral arterial disease; n/total (%) | 28/219 (12.8) | 27/219 (12.3) |
| Prior myocardial infarction; n/total (%)<br>Prior PCI; n/total (%)<br>Prior CABG; n/total (%)<br>Atrial fibrillation; n/total (%)<br>Pacemaker/ICD; n/total (%) | 19/219 (8.7)<br>84/219 (38.4)<br>26/219 (11.9)<br>103/219 (47.0)<br>24/218 (11.0) | 22/219 (10.1)<br>79/219 (36.1)<br>18/219 (8.2)<br>93/219 (42.5)<br>23/219 (10.5) |
| Prior stroke; n/total (%) | 25/219 (11.4) | 26/218 (11.9) |
| Renal insufficiency; n/total (%) | 177/216 (81.9) | 184/214 (86.0) |
| Pulmonary hypertension; n/total (%) | 106/216 (49.1) | 105/218 (48.2) |
| COPD; n/total (%) | 30/219 (13.7) | 29/217 (13.4) |
| Cardiovascular risk factors<br>Diabetes; n/total (%)<br>Arterial hypertension; n/total (%)<br>HLP; n/total (%)<br>Current smoking; n/total (%) | 79/218 (36.2)<br>193/219 (88.1)<br>118/218 (54.1)<br>8/218 (3.7) | 68/219 (31.1)<br>204/219 (93.2)<br>80/217 (36.9)<br>10/219 (4.6) |

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# 1-year Outcomes – Valve Strategy

| | Evolut R | Sapien 3 | p-value Gray's test | Cause specific HR (95% CI) |
|---|---|---|---|---|
| | n (%) | n (%) | | |
| Composite endpoint* | 87 (41.9) | 85 (40.4) | 0.76 | 0.95 (0.71-1.28) |
| All-cause mortality | 34 (17.6) | 33 (17.0) | 0.88 | 0.96 (0.60-1.55) |
| Cardiovascular mortality | 1 (0.5) | 4 (1.8) | 0.19 | 3.89 (0.44-34.67) |
| Stroke | 2 (1.0) | 14 (6.9) | 0.002 | 7.13 (1.62-31.32) |
| Moderate/severe PVL | 14 (7.0) | 9 (4.5) | 0.35 | 0.63 (0.27-1.45) |
| Permanent pacemaker implantation | 54 (24.7) | 44 (20.2) | 0.25 | 0.79 (0.53-1.16) |
| Time-related safety (VARC-2) | 45 (15.6) | 64 (20.8) | 0.10 | 1.36 (0.93-1.99) |

*Composite of all-cause mortality, stroke, moderate/severe PVL, and permanent pacemaker implantation

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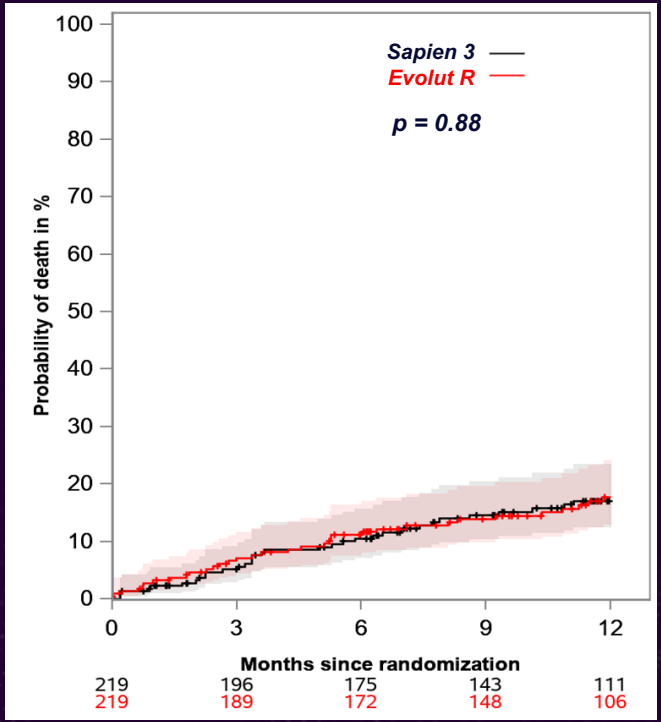
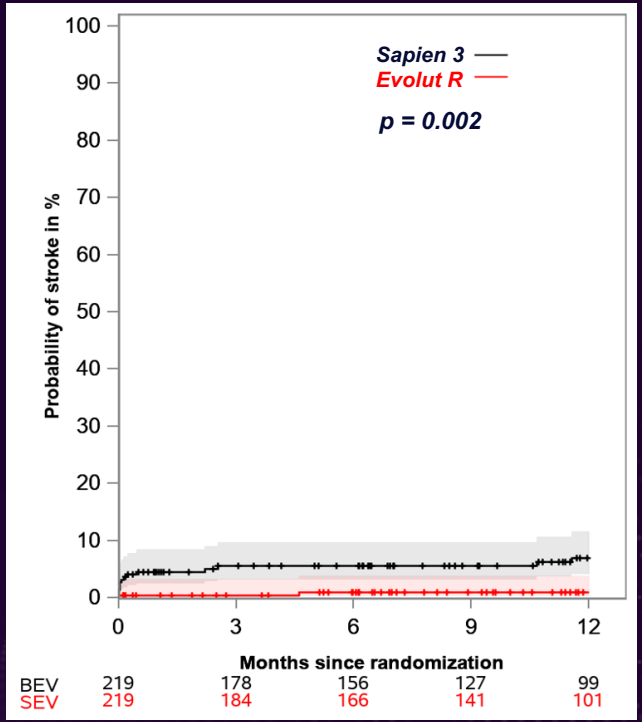
# 1-year Outcomes – Valve Strategy

## *All-cause mortality*




## *Stroke*



# Echocardiographic Findings – Valve Strategy

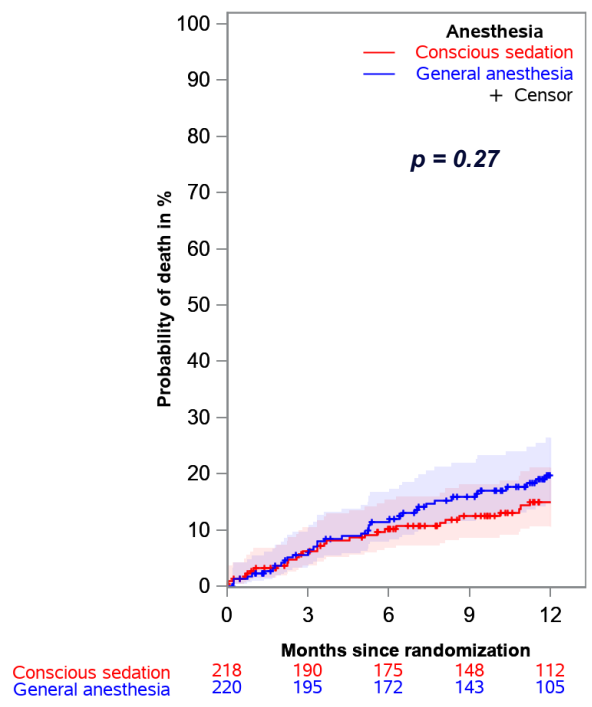
| | Evolut R | | Sapien 3 | | Difference | | p-value |
|---|---|---|---|---|---|---|---|
| | Median | IQR | Median | IQR | Median | 95%CI | |
| AVA, $cm^2$ | 1.9 | (1.6, 2.3) | 1.7 | (1.5, 2.0) | -0.2 | -0.3 to 0 | 0.063 |
| AVA index, $cm^2/m^2$ | 1.0 | (0.9, 1.2) | 1.1 | (0.8, 1.3) | 0 | -0.1 to 0.2 | 0.75 |
| Mean aortic valve gradient, mmHg | 6 | (4, 8) | 10 | (8, 12) | 4 | 3 to 5 | <0.001 |
| Max. aortic valve gradient, mmHg | 12 | (8, 16) | 19 | (13, 24) | 7 | 5 to 9 | <0.001 |

# 1-year Outcomes – Anesthesia Strategy

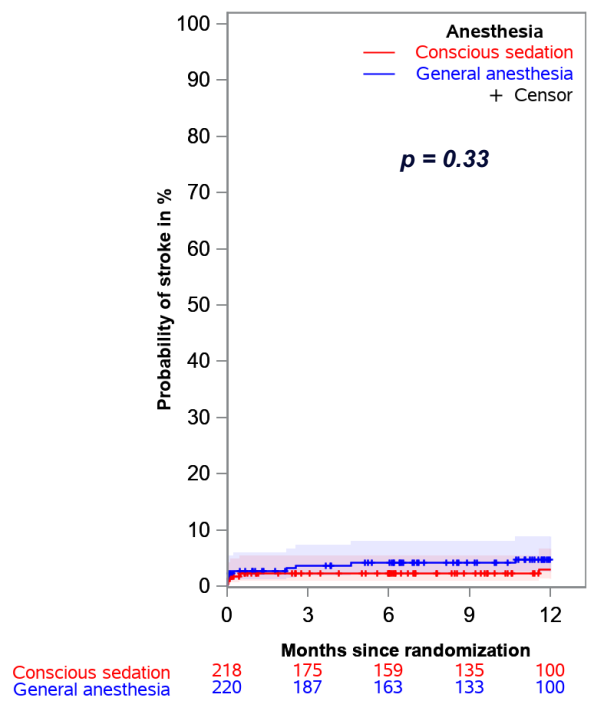
| Outcome | Local anesthesia | General anaesthesia | p-value Gray's test | Cause specific HR (95% CI) |
|---|---|---|---|---|
| | n (%) | n (%) | | |
| All-cause mortality | 29 (15.2) | 38 (19.4) | 0.27 | 1.31 (0.81 to 2.13) |
| Cardiovascular mortality | 2 (0.9) | 3 (1.4) | 0.68 | 1.46 (0.24 to 8.73) |
| Stroke | 6 (3.0) | 10 (4.9) | 0.33 | 1.64 (0.60 to 4.49) |
| Myocardial Infarction | 2 (1.0) | 1 (0.5) | 0.56 | 0.50 (0.05 to 5.45) |
| Infection requiring antibiotics (at 6 months) | 52 (17.7) | 56 (18.8) | 0.72 | 1.07 (0.73 to 1.55) |
| Acute kidney injury | 28 (12.2) | 27 (11.7) | 0.87 | 0.96 (0.57 to 1.63) |
| Time-related safety (VARC-2) | 54 (17.6) | 55 (18.8) | 0.72 | 1.07 (0.73 to 1.55) |

# 1-year Outcomes – Anesthesia Strategy

## *All-cause mortality*

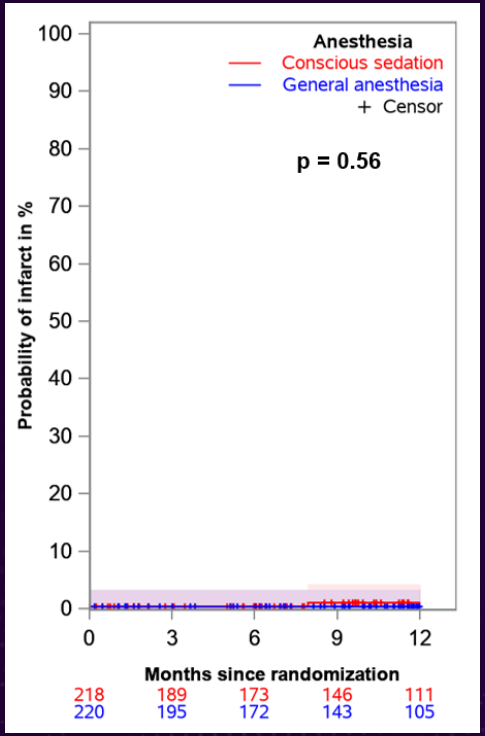



## *Stroke*

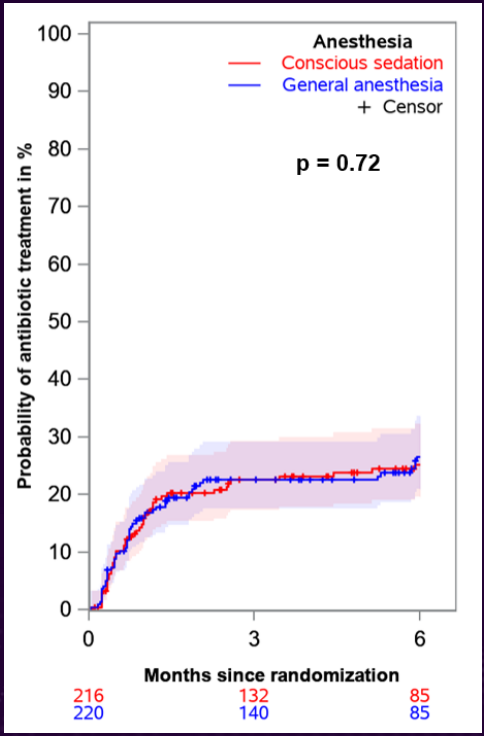


# 1-year Outcomes – Anesthesia Strategy

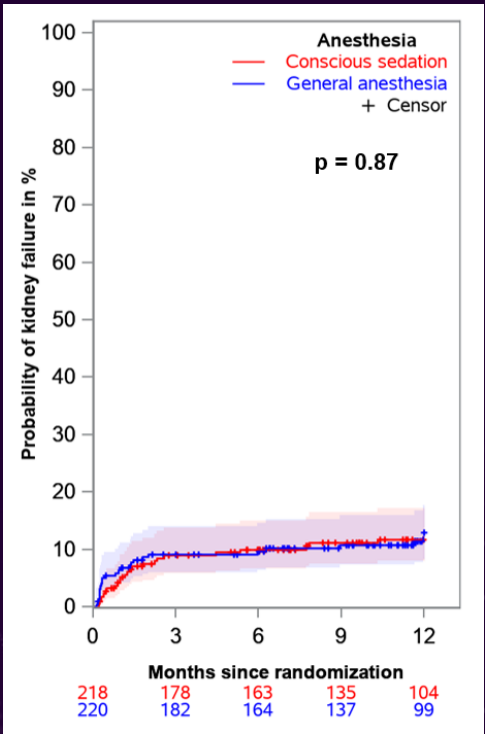
## *Myocardial infarction*




## *Infections*




## *Acute kidney failure*



# Summary and Conclusions I

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*In symptomatic patients with severe aortic stenosis undergoing transfemoral TAVR, newer generation SEV compared to BEV resulted in*

- *-similar rates of the composite endpoint of all-cause death, stroke, moderate/severe PVL, and permanent pacemaker implantation*
- *-higher stroke rates in BEV treated patients*
- *-similar time-related safety according to the VARC-2 criteria*
- *-lower aortic gradients in SEV*

# Summary and Conclusions II

SOLVE-TAVI

*LA with conscious sedation compared to GA resulted in*

*-similar rates of all-cause and cardiovascular death, stroke, myocardial infarction, infections, and acute kidney injury*

*-similar time-related safety according to the VARC-2 criteria*

*at 1-year follow-up.*

# Acknowledgement and Thank You
# SOLVE-TAVI Patients and Investigators


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