HERZZENTRUM LEIPZIG

Leipzig Heart Institute LHI

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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

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on behalf of the SOLVE-TAVI Investigators

Disclosure Statement of Financial Interest

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I, Holger Thiele DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

Background I

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- **TAVR is developing as standard strategy for symptomatic patients with severe aortic stenosis at high to intermediate 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) in particular for latest generation valve designs.**

Abdel-Wahab et al. JAMA 2014;311:1503-1514
Feldman et al. JAMA. 2018;319:27-37

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.
- There is a lack of adequately powered randomized trials.

Villablanca et al. Catheter Cardiovasc Interv. 2017;1–13

SOLVE-TAVI Program

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Symptomatic Aortic Stenosis with TAVR Indication

1:1

CoreValve Evolut R — **Valve Strategy** — **Edwards Sapien 3**

1:1

Local Anesthesia — **Anesthesia Strategy** — **General Anesthesia**

Hypotheses

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I) Self-expanding CoreValve Evolut R is equivalent to balloon-expandable Sapien 3 (Edwards) valve

II) Local anesthesia with conscious sedation is equivalent to general anesthesia

in symptomatic aortic stenosis patients undergoing transfemoral TAVR.

SOLVE-TAVI Trial

Investigator-initiated German multicenter trial; 1:1 randomization

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Study Flow Chart - Valve Strategy

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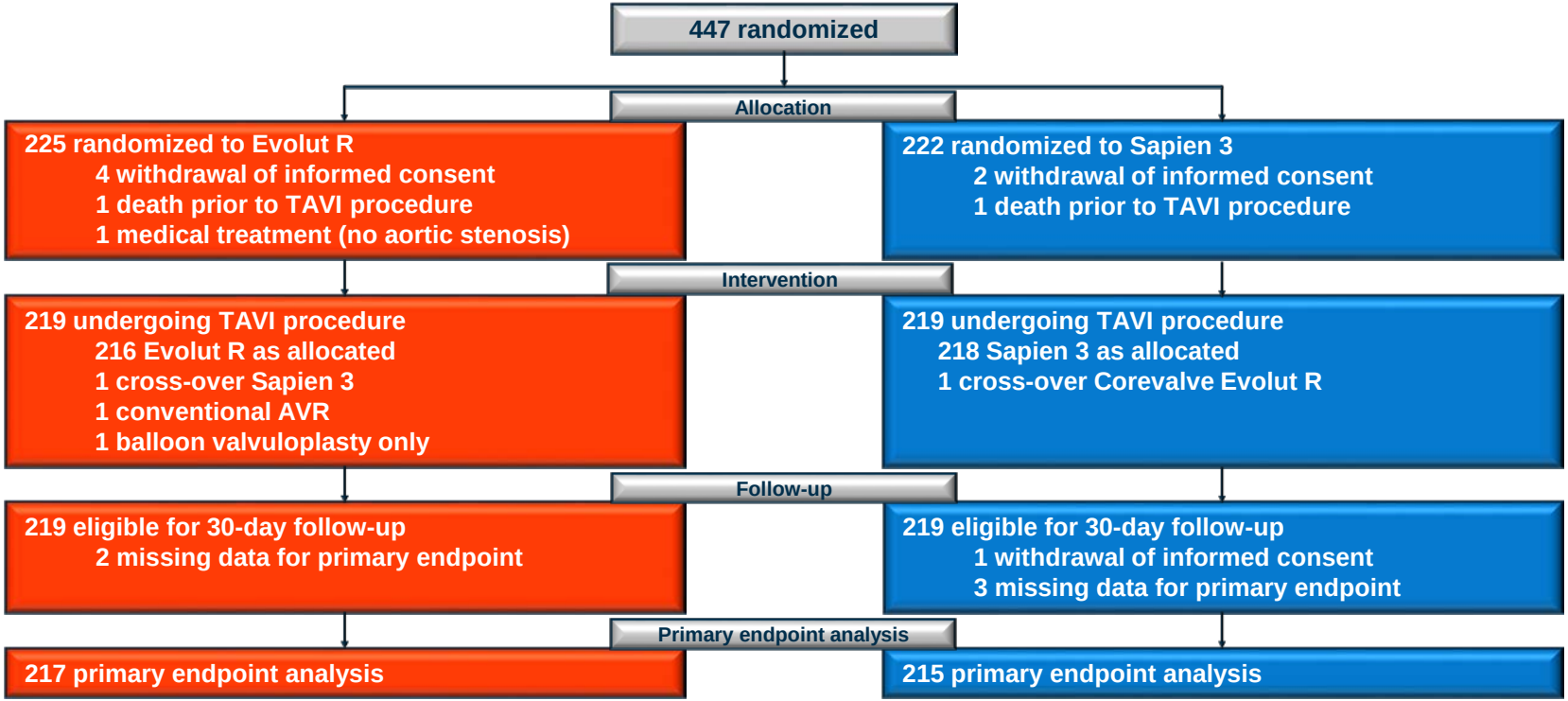

Baseline Characteristics – Valve Strategy

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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		
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 (%)	19/219 (8.7)	22/219 (10.1)
Prior PCI; n/total (%)	84/219 (38.4)	79/219 (36.1)
Prior CABG; n/total (%)	26/219 (11.9)	18/219 (8.2)
Atrial fibrillation; n/total (%)	103/219 (47.0)	93/219 (42.5)
Pacemaker/ICD; n/total (%)	24/218 (11.0)	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		
Diabetes; n/total (%)	79/218 (36.2)	68/219 (31.1)
Arterial hypertension; n/total (%)	193/219 (88.1)	204/219 (93.2)
HLP; n/total (%)	118/218 (54.1)	80/217 (36.9)
Current smoking; n/total (%)	8/218 (3.7)	10/219 (4.6)

Primary Endpoint – Valve Strategy

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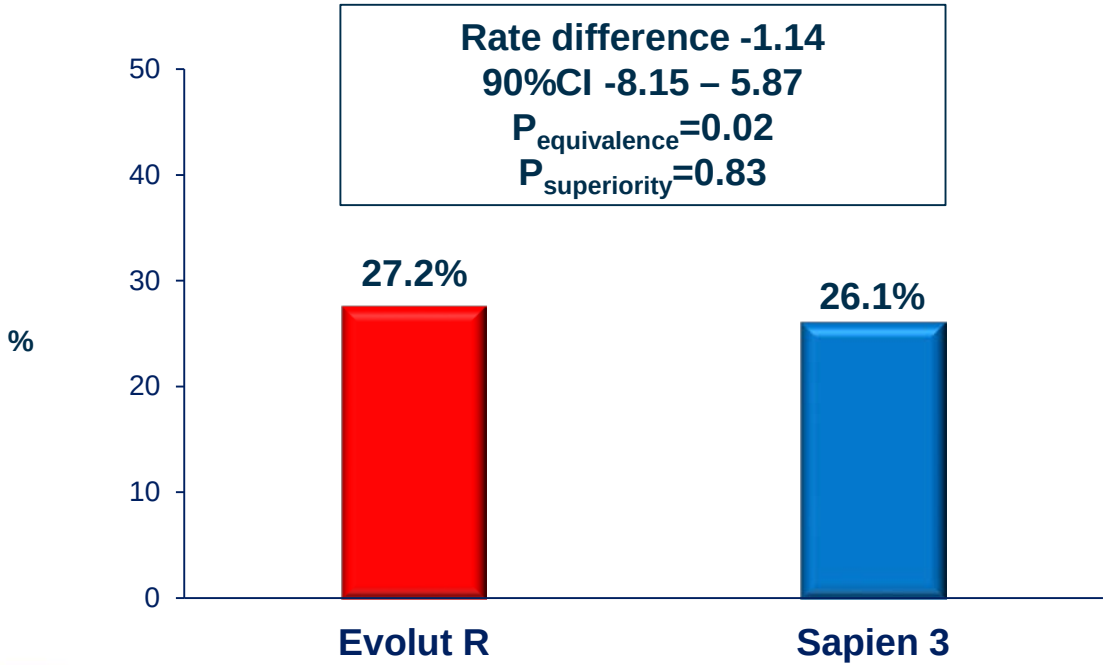
All-cause mortality, stroke, moderate or severe prosthetic valve regurgitation, permanent pacemaker implantation at 30 days



Endpoints – Valve Strategy

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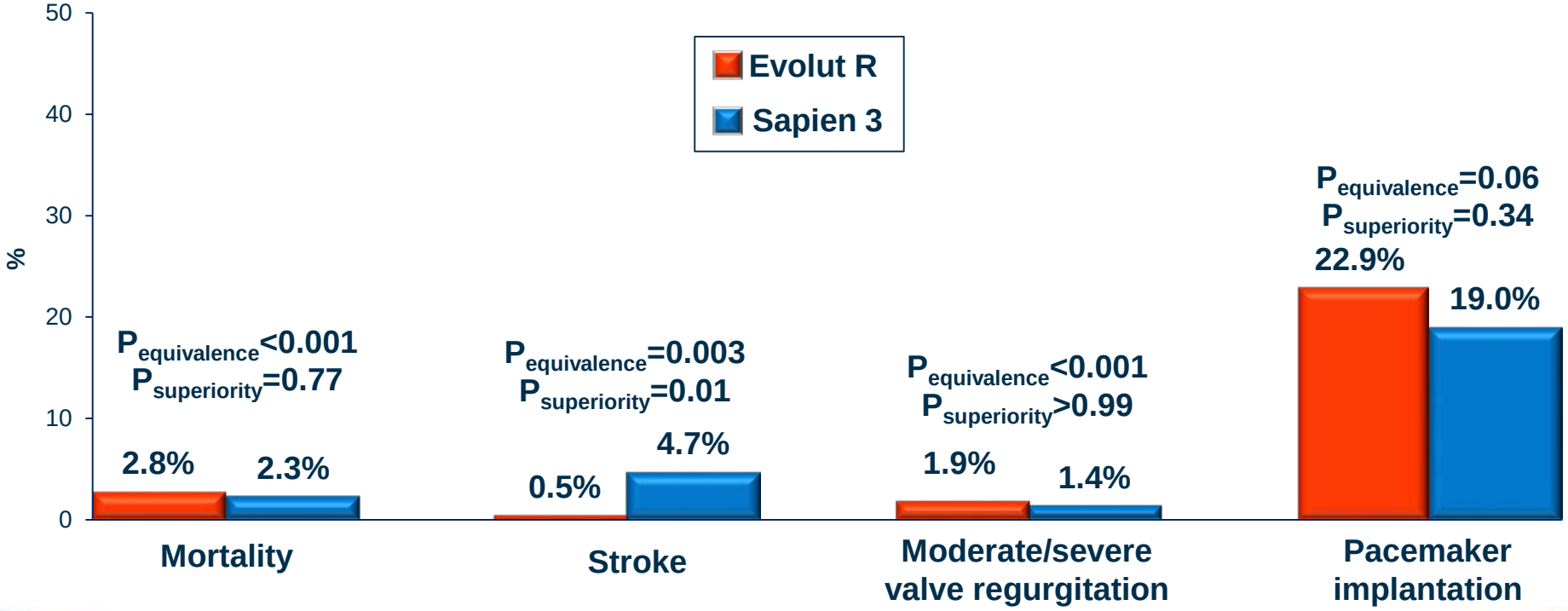
Individual components primary endpoint



Study Flow Chart - Anesthesia Strategy

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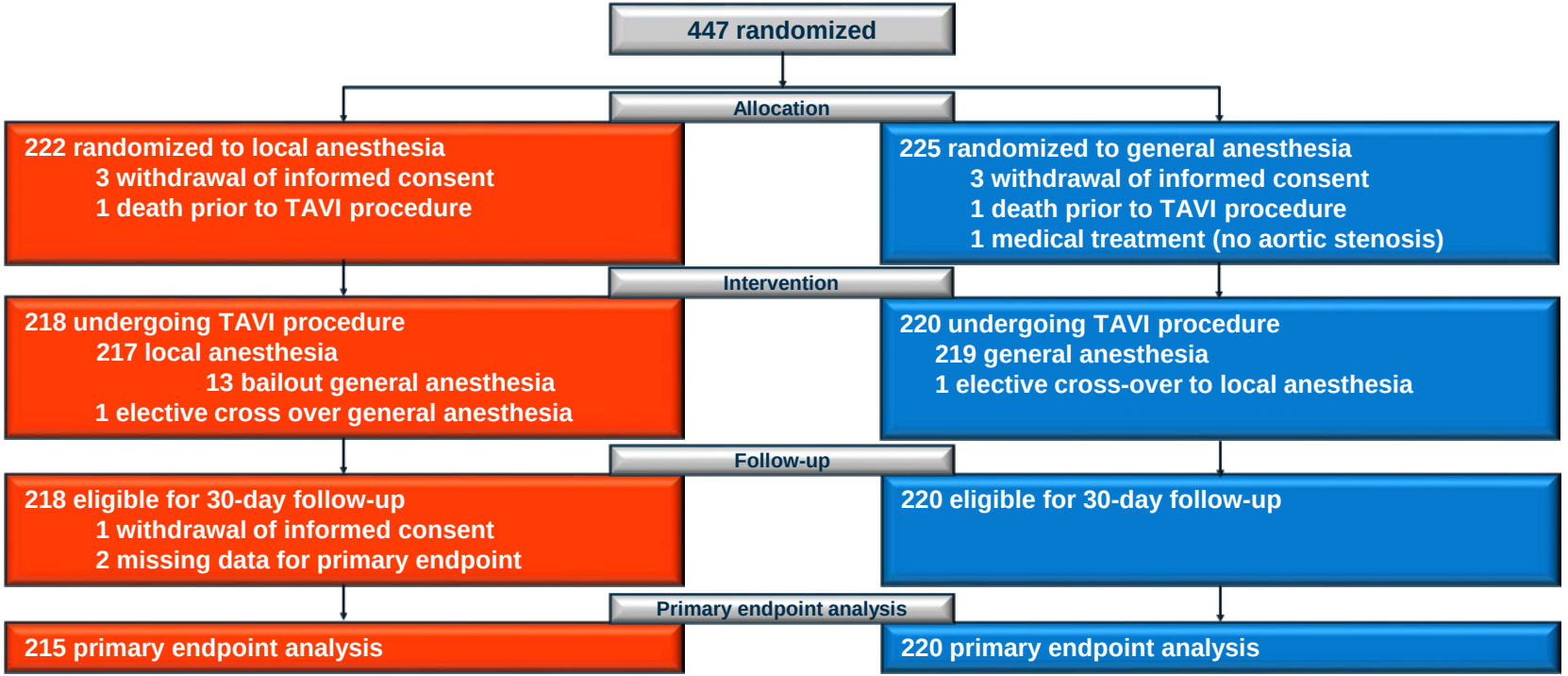

Baseline Characteristics – Anesthesia Strategy

SOLVE-TAVI

Characteristic	Local Anesthesia (n=218)	General Anesthesia (n=220)
Age (years); mean ±SD	81.8 ± 5.3	81.4 ± 5.7
Male sex; n/total (%)	107/218 (49.1)	107/220 (48.6)
Risk scores		
STS score (%); mean ±SD	6.9 ± 6.2	8.3 ± 8.2
Log. EuroScore I (%), mean ±SD	17.8 ± 12.6	18.9 ± 12.5
EuroScore II (%), mean ±SD	5.5 ± 4.8	6.0 ± 5.6
Frailty; n/total (%)	91/214 (42.5)	82/219 (37.4)
Peripheral arterial disease; n/total (%)	29/218 (13.3)	26/220 (11.8)
Prior myocardial infarction; n/total (%)	24/218 (11.0)	17/220 (7.7)
Prior PCI; n/total (%)	92/218 (42.2)	71/220 (32.3)
Prior CABG; n/total (%)	22/218 (10.1)	22/220 (10.0)
Atrial fibrillation; n/total (%)	98/218 (45.0)	98/220 (44.6)
Pacemaker/ICD; n/total (%)	13/218 (6.0)	20/220 (9.1)
Prior stroke; n/total (%)	24/217 (11.1)	27/220 (12.3)
Renal insufficiency; n/total (%)	179/213 (84.0)	182/217 (83.9)
Pulmonary hypertension; n/total (%)	100/216 (46.3)	111/218 (50.9)
COPD; n/total (%)	27/216 (12.5)	32/220 (14.6)
Cardiovascular risk factors		
Diabetes; n/total (%)	70/218 (32.1)	77/219 (35.2)
Arterial hypertension; n/total (%)	199/218 (91.3)	198/220 (90.0)
HLP; n/total (%)	92/216 (42.6)	88/219 (40.2)
Current smoking; n/total (%)	9/218 (4.1)	9/219 (4.1)

Primary Endpoint – Anesthesia Strategy

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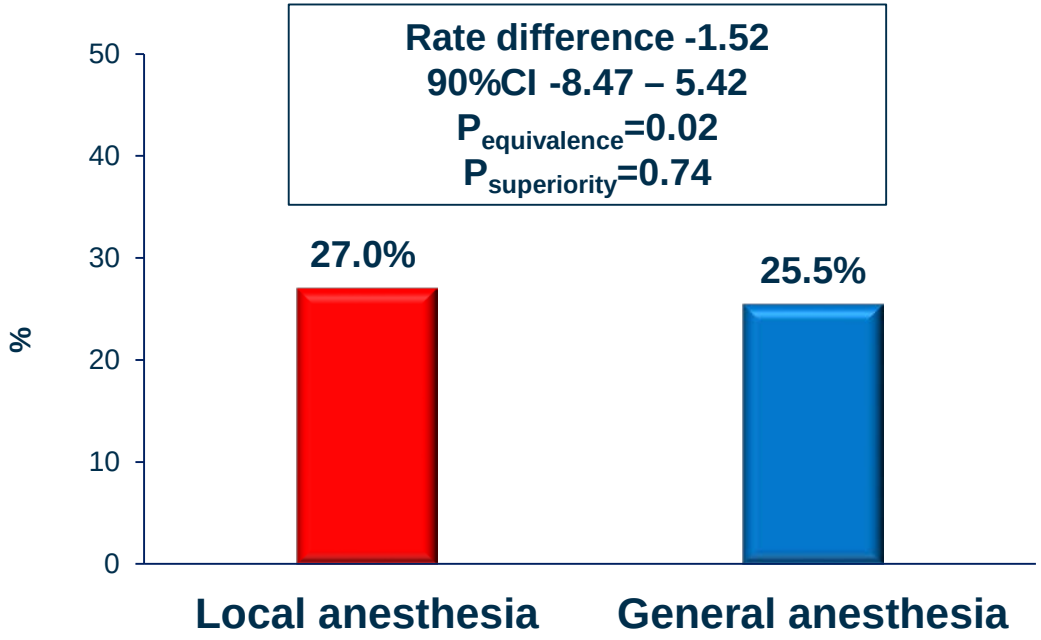
All-cause mortality, stroke, myocardial infarction, infection requiring antibiotic treatment, acute kidney injury at 30 days



Endpoints – Anesthesia Strategy

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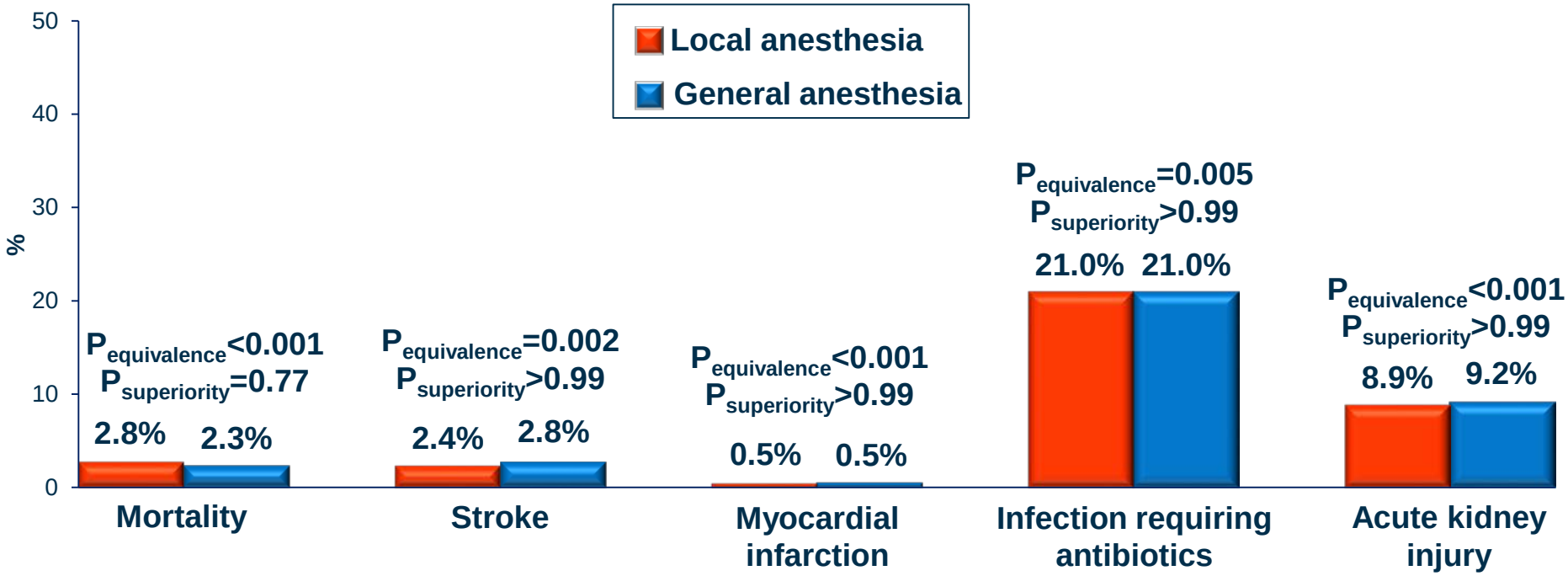
Individual components primary endpoint



Summary and Conclusions I

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- In patients with symptomatic aortic stenosis undergoing transfemoral TAVR the self-expanding Corevalve Evolut R valve is equivalent to the balloon-expandable Edwards Sapien 3 with respect to the composite of all-cause mortality, stroke, moderate or severe prosthetic valve regurgitation, and permanent pacemaker implantation at 30 days.

- The rate of relevant valve regurgitation was low whereas permanent pacemaker rates are still relatively high.

- There may be a higher stroke rate with the balloon-expandable valve.

Summary and Conclusions II

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- **Local anesthesia with conscious sedation is equivalent to general anesthesia with respect to the composite of all-cause mortality, stroke, myocardial infarction, infection requiring antibiotic treatment, and acute kidney injury.**

- **General anesthesia is associated with a higher rate of catecholamine use but does not affect procedure times, valve-related outcome, or clinical outcome.**

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SOLVE-TAVI Patients and Investigators

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