Evolut™ Low Risk Trial

Primary Results From the Evolut Low Risk Trial

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Study Timeline and Valves Studied

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2016	2017	2018

First Patient Randomized
Mar. 28, 2016

*Last Patient Randomized
Nov. 27, 2018

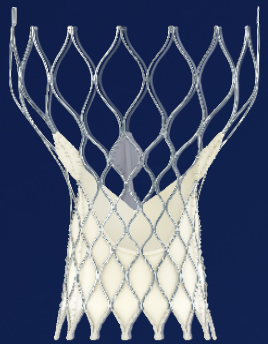
CoreValve 31 mm

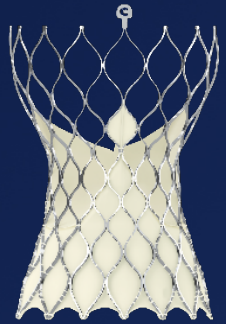
Evolut R: 23, 26, 29

Added Evolut R 34 mm

Evolut PRO: 23, 26, 29 mm

Primary Endpoint Assessment
Dec. 27, 2018





CoreValve 31 = 3.6%	Evolut R = 74.1%	Evolut PRO = 22.3%

Vascular access

- 99% transfemoral
- 0.6% subclavian
- 0.4% direct aortic

*For this analysis

Primary Endpoint

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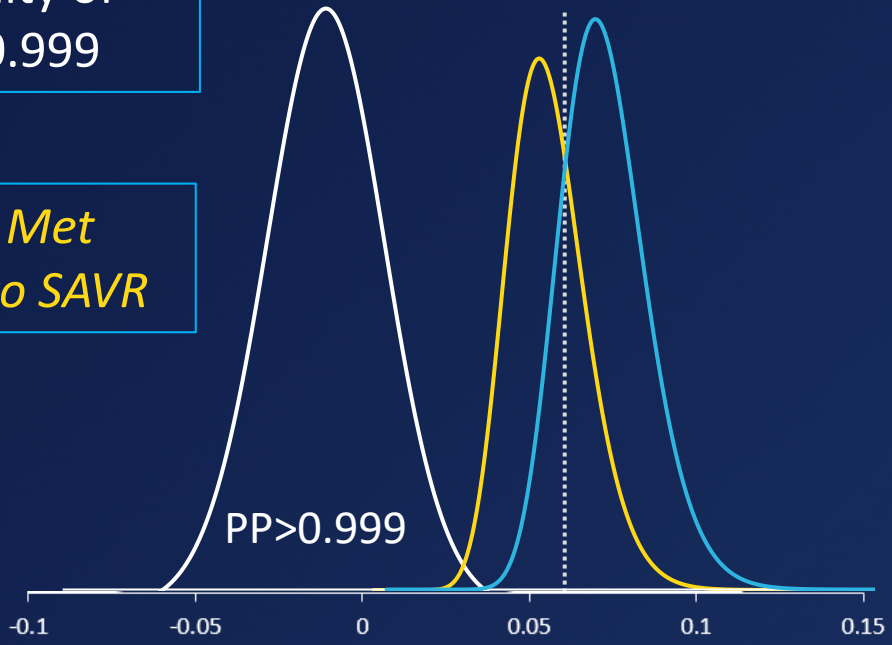
Posterior probability of noninferiority > 0.999

Primary Endpoint Met
TAVR is noninferior to SAVR



SAVR 6.7%

TAVR 5.3%

TAVR –SAVR difference = -1.4% (95% BCI; -4.9, 2.1)

Hierarchical Secondary Endpoints

All Noninferiority and Superiority Endpoints Met

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	TAVR	SAVR	Difference TAVR–SAVR	Posterior Probability
Noninferiority (margin)			(90% BCI)	
Mean gradient at 12 months (5 mmHg)	8.6 ± 3.7	11.2 ± 4.9	-2.6 (-3.1, -2.1)	> 0.999 ✓
Mean EOA at 12 months (0.1 cm^2)	2.3 ± 0.7	2.0 ± 0.6	0.3 (0.2, 0.4)	> 0.999 ✓
Mean NYHA class change (12 months –Baseline) (0.375)	0.9 ± 0.7	1.0 ± 0.7	-0.1 (-0.2, 0.0)	> 0.999 ✓
Mean KCCQ change (12 months –Baseline) (5)	22.2 ± 20.3	20.9 ± 21.0	1.3 (-1.2, 3.8)	> 0.999 ✓
Superiority			(95% BCI)	
Mean gradient at 12 months, mmHg	8.6 ± 3.7	11.2 ± 4.9	-2.6 (-3.2, -2.0)	> 0.999 ✓
Mean EOA at 12 months, cm^2	2.3 ± 0.7	2.0 ± 0.6	0.3 (0.2, 0.4)	> 0.999 ✓
Mean KCCQ change (30 Days–Baseline)	20.0 ± 21.1	9.1 ± 22.3	10.9 (8.6, 13.2)	> 0.999 ✓

Clinical Outcomes at 30 days

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Bayesian rates as %	TAVR (N=725)	SAVR (N=678)	(95% BCI for Difference)
30-Day composite safety end point*	5.3	10.7	(-8.3, -2.6)
All-cause mortality	0.5	1.3	(-1.9, 0.2)
Disabling stroke*	0.5	1.7	(-2.4, -0.2)
Life-threatening or disabling bleeding*	2.4	7.5	(-7.5, -2.9)
Acute kidney injury, stage 2-3*	0.9	2.8	(-3.4, -0.5)
Major vascular complication	3.8	3.2	(-1.4, 2.5)
Atrial fibrillation*	7.7	35.4	(-31.8, -23.6)
Permanent pacemaker implant*	17.4	6.1	(8.0, 14.7)
All-cause mortality or disabling stroke*	0.8	2.6	(-3.2, -0.5)
All stroke	3.4	3.4	(-1.9, 1.9)
Aortic valve reintervention	0.4	0.4	(-0.8, 0.7)

* Significantly favors TAVR; * significantly favors SAVR

BCI = Bayesian credible interval.

Summary

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- TAVR with self-expanding valves was noninferior to surgery in patients with severe aortic stenosis at low surgical risk.
- TAVR showed an better safety and recovery profile than surgery, with less death or disabling stroke, less disabling stroke, shorter length of stay and better QOL while SAVR had fewer pacemakers implanted and less residual AR at 30 days.
- At 1 year, both groups had excellent survival. TAVR showed fewer disabling strokes and heart failure rehospitalizations with superior hemodynamics manifest by lower gradients and larger EOAs.
- TAVR may be a preferred strategy to surgery in patients with severe aortic stenosis at low risk of surgical mortality.