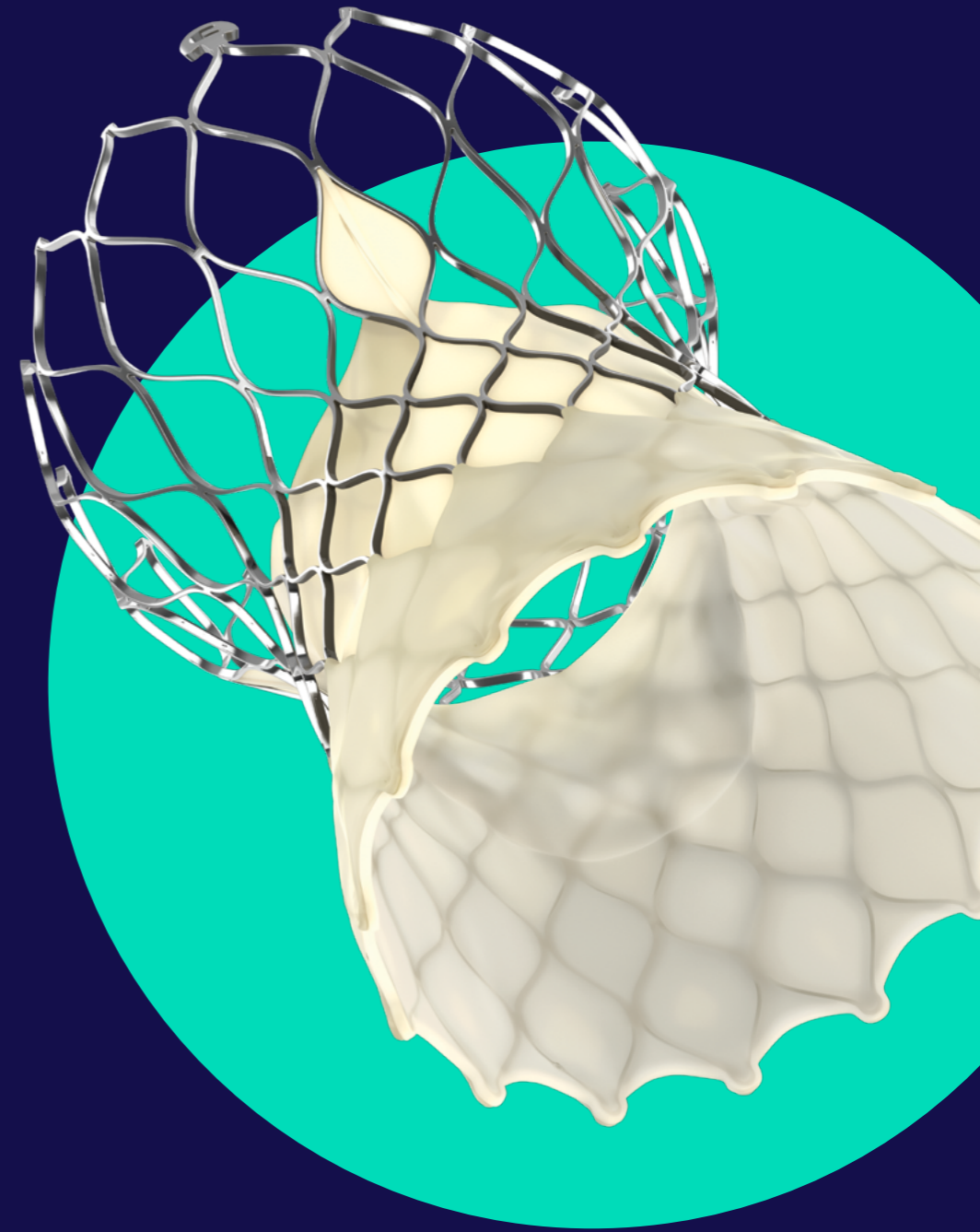


Medtronic

Designed  
to be  
durable.



People who know,  
think **Evolut™ First.**



Designed  
to be  
durable.

Valve  
design impacts  
durability.

Durability  
impacts  
mortality.



# Durability starts with design



## Built on a proven foundation

With its supra-annular, self-expanding valve frame, Evolut™ TAVI is built on the original CoreValve™ platform which has consistently shown strong EOAs and low gradients over time.

## How did we design for durability?

### More surface

Taller leaflet mounting allows for a greater distance between the commissure and the edge of the leaflet, distributing stress over a greater distance.

### More height

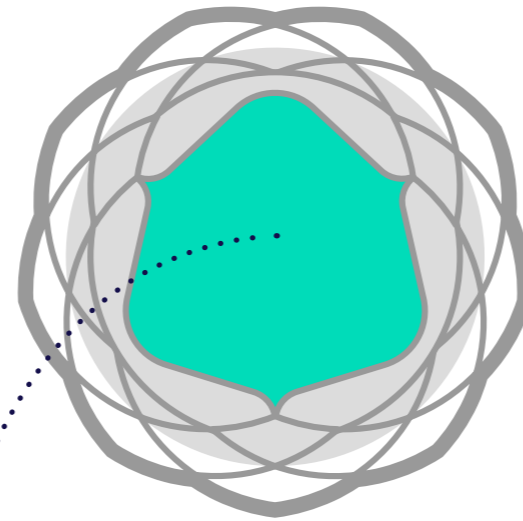
By decoupling the native annular plane where the sealing occurs, from the working portion of the prosthetic leaflets, you can facilitate circularity and maximize leaflet coaptation.

### More room

The tall valve keeps the working portion above and unconstrained by the native annulus, allowing for a large effective orifice area.



# Supra-annular design benefits



**Large EOAs** mean less restriction of blood through the valve.

Less restriction leads to low gradients (mean systolic gradient).

Large EOAs have been correlated to less patient-prosthesis mismatch (PPM).

Less PPM and low gradients after aortic valve replacement have been linked to:

- Better survival<sup>1,2</sup>
- Less heart failure rehospitalization<sup>2,3</sup>
- Better valve durability<sup>4,5</sup>

CoreValve™/Evolut™  
TAVI platform  
**Intermediate risk<sup>6</sup>**  
Average EOA at 5 years (cm<sup>2</sup>)

Devices used:  
83.8% CoreValve  
16.2% Evolut™ R

CoreValve/Evolut  
TAVI platform  
**Low risk<sup>7</sup>**  
Average EOA at 2 years (cm<sup>2</sup>)

Devices used:  
3.6% CoreValve  
74.1% Evolut R  
22.3% Evolut™ PRO

Consistently strong EOAs

<sup>1</sup> Playford D, et al. *J Am Soc Echocardiogr.* 2020;33:1077-1086.e1.

<sup>2</sup> Herrmann HC, et al. *J Am Coll Cardiol.* 2018;72:2701-2711.

<sup>3</sup> Anand V, et al. *Am J Cardiol.* 2020;125:941-947.

<sup>4</sup> O'Hair D. Presented at American College of Cardiology 70th Annual Scientific Session & Expo. May 2021.

<sup>5</sup> Søndergaard L, et al. *J Am Coll Cardiol.* 2019;73:546-553.

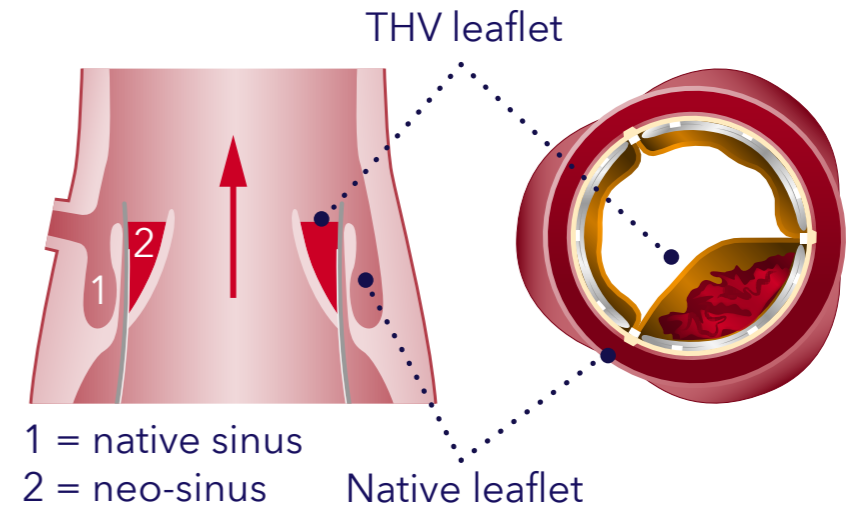
<sup>6</sup> Van Mieghem, et al. 5-Year Clinical and Echocardiographic Outcomes from the Randomized SURTAVI Trial. Presented at TCT 2021.

<sup>7</sup> Forrest JK, on behalf of the Evolut Low Risk Investigators. The Evolut Low Risk Trial Complete 2-year Follow-up. Presented at EuroPCR 2021.



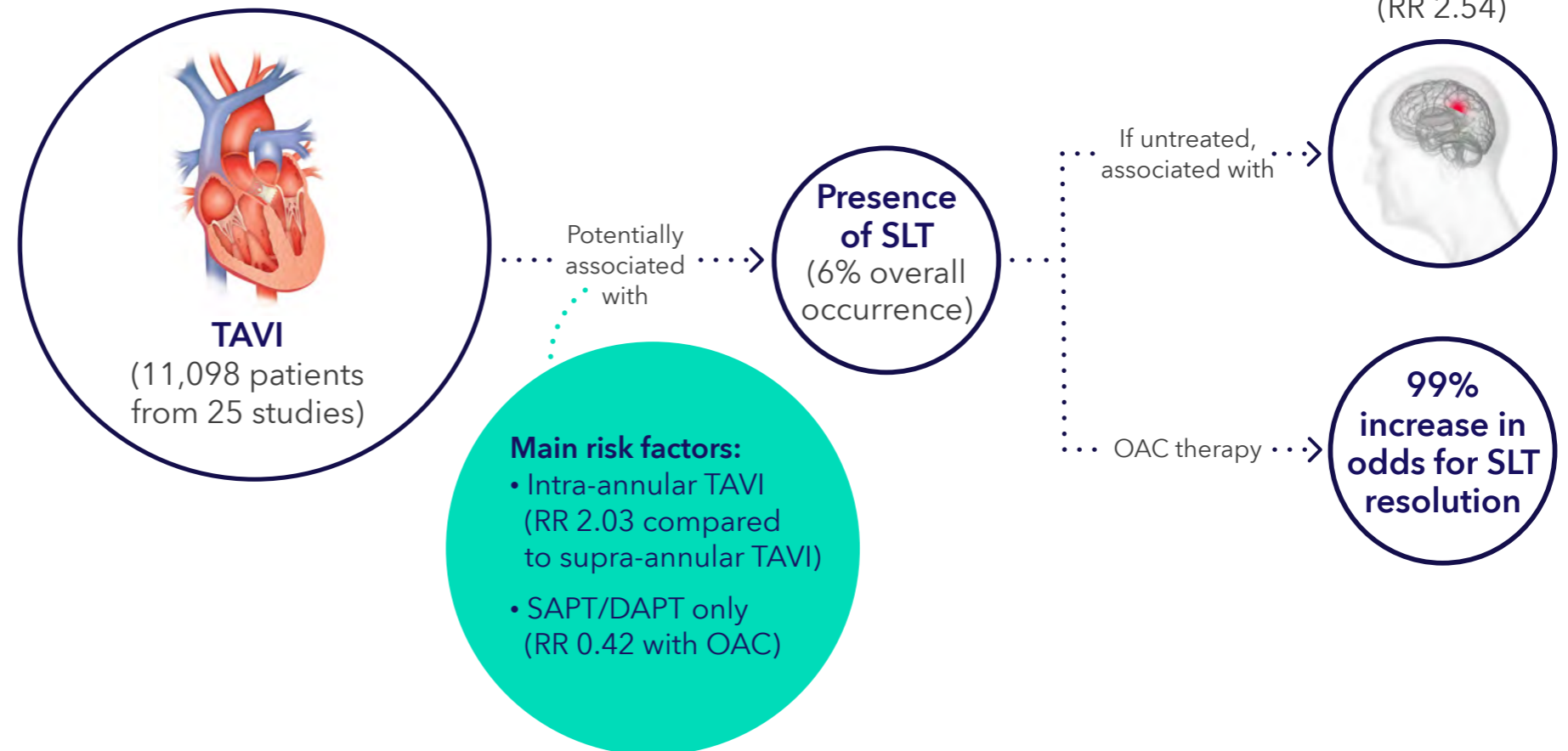
# Supra-annular design benefits

Design elements that produce blood flow stasis and extended blood residence time on the leaflets could increase the risk of thrombosis, resulting in sub-optimal clinical results.<sup>1</sup>



## Subclinical leaflet thrombosis after TAVI: risk factors, effect on outcome, and treatment options<sup>2</sup>

**RR:** Relative risk  
**SAPT:** Single antiplatelet therapy  
**DAPT:** Dual antiplatelet therapy  
**OAC:** Oral anticoagulation  
**SLT:** Subclinical leaflet thrombosis

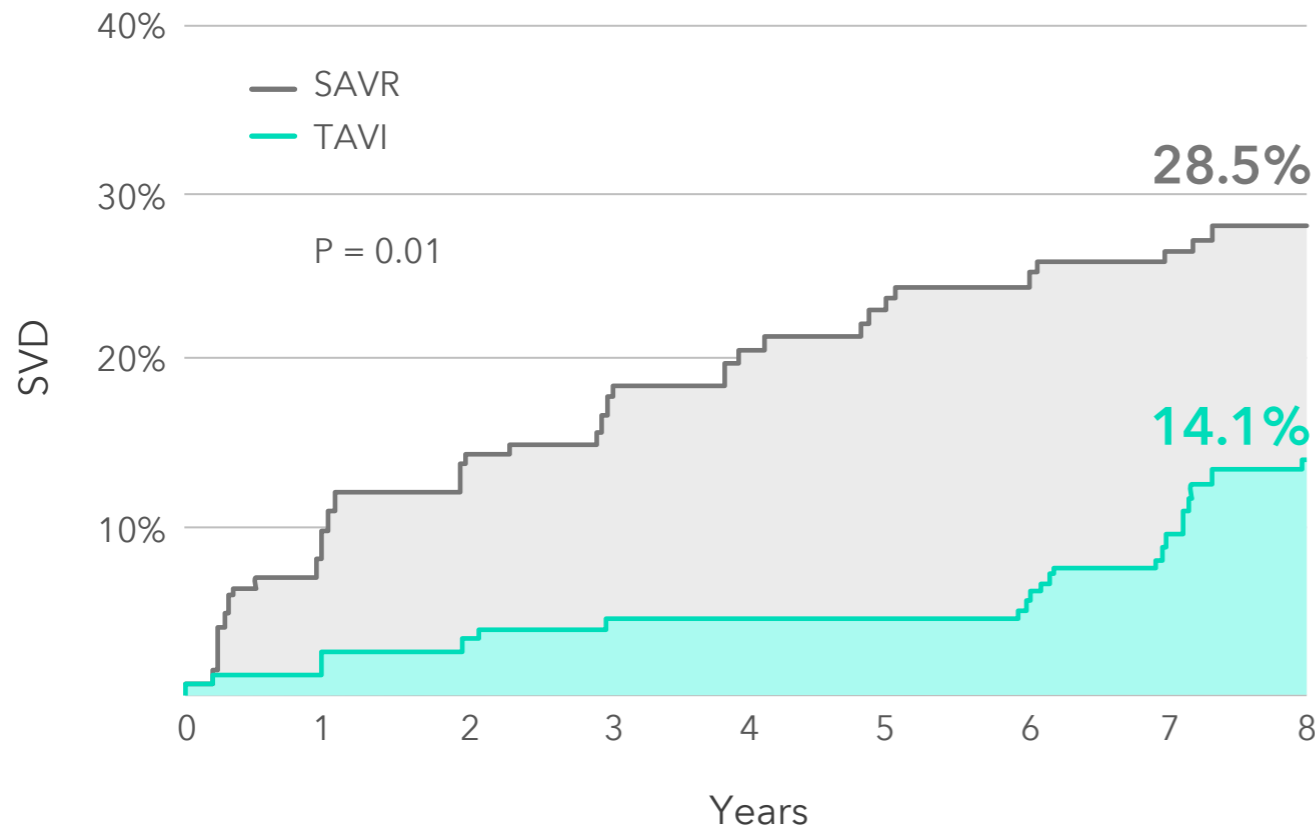


<sup>1</sup> Midha PA, et al. *Circulation*. 2017;136:1598-1609.  
<sup>2</sup> Bogyi M, et al. *JACC Cardiovasc Interv*. 2021;14:2643-2656.



## NOTION<sup>1</sup> 8 years

SVD out to 8 years<sup>1</sup>



SAVR	135	113	105	97	84	75	62	54	30
TAVI	139	130	126	115	107	94	80	68	44

The NOTION trial is a multicenter, randomized, head-to-head comparison of CoreValve TAVI versus SAVR followed out to 8 years in lower surgical risk patients  $\geq 70$  years of age who are eligible for surgery. TAVI had significantly less hemodynamic SVD out to 8 years.

The NOTION 8-year data demonstrates excellent SVD rates in a lower surgical risk patient population. Perhaps most importantly, the data provides a signal of durability for the CoreValve platform versus SAVR.

<sup>1</sup> Søndergaard L. Long-term follow-up of transcatheter and surgical bioprosthetic aortic valves in patients with severe aortic stenosis and lower surgical risk. Presented at PCR Valvese-Course. November 24, 2020.

The CoreValve™ platform was more durable than SAVR at eight years.

> SVD definition

Device used:  
100% CoreValve

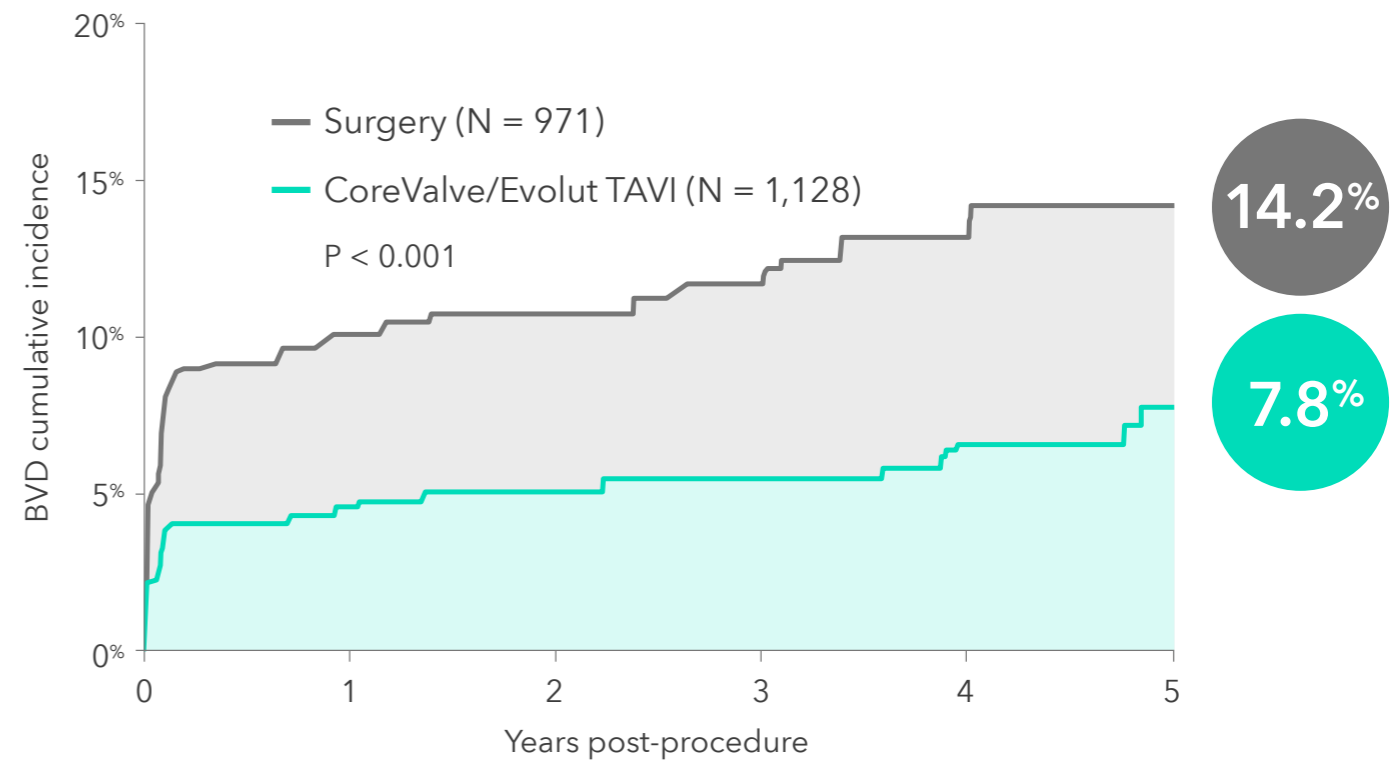


CoreValve™/Evolut™ TAVI is the first and only platform to demonstrate a durability and valve performance benefit over SAVR at five years in randomized clinical trials.<sup>†1</sup>

Devices used:  
88% CoreValve  
12% Evolut™ R

## Bioprosthetic valve dysfunction<sup>‡</sup> out to 5 years<sup>1</sup>

Significantly better valve performance<sup>‡</sup> versus SAVR at 5 years



<sup>†</sup>In pooled analysis of intermediate- and high-risk patients.

<sup>‡</sup>Bioprosthetic Valve Dysfunction (BVD) was defined as<sup>2,3</sup>: SVD<sup>4</sup> (mean gradient  $\geq 10$  mm Hg increase from discharge/30 days AND  $\geq 20$  mm Hg at last echo or new onset/increase of  $\geq$  moderate intraprosthetic aortic regurgitation), NSVD (30-day severe PPM at 30-day/discharge<sup>2</sup> or severe PVR through 5 years), clinical valve thrombosis, and endocarditis.

<sup>1</sup> Yakubov S, et al. Five-Year Incidence of Bioprosthetic Valve Dysfunction in Patients Randomized to Surgery or TAVR: Insights From the CoreValve US Pivotal and SURTAVI Trials. Presented at CRT; February 2023.

<sup>2</sup> Adapted from VARC-3 Writing Committee, et al. *Eur Heart J*. 2021;42:1825-1857.

<sup>3</sup> Capodanno D, et al. *Eur Heart J*. 2017;38:3382-3390.

<sup>4</sup> Adapted from VARC-3 Writing Committee, et al. and Capodanno D, et al.



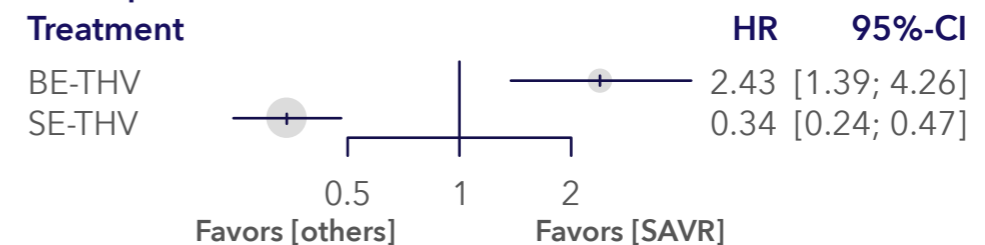
Valve durability for supra-annular, self-expandable TAV found to be statistically better at five years versus both SAVR and balloon-expandable TAV.

## Dr. Attizzani 5-year meta analysis<sup>1</sup>

Structural valve deterioration<sup>†</sup>

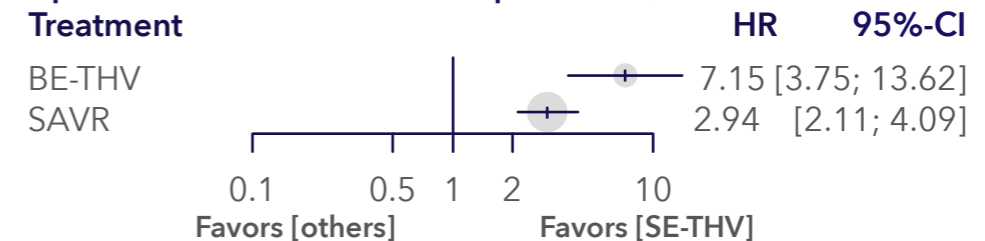
**Only SE performs better than SAVR**

Comparison: others versus SAVR (random effects model)



**SE performs better than SAVR and BE**

Comparison: others versus self-expandable (random effects model)



At five years, supra-annular, self-expandable (SE) valves demonstrated:

- Lowest risk of structural valve deterioration (SVD) compared with balloon-expandable (BE) valves and SAVR.
- Significantly stronger hemodynamics with larger EOAs and lower mean gradients versus BE valves.

### Study design

- Meta-analysis
- 10 randomized controlled trials
- 9,388 patients
- Follow-up 1 to 6 years
- Multiple devices<sup>‡</sup>

<sup>†</sup>Based on the longest available follow-up for each of the 10 studies used for this meta-analysis. SVD was defined by the respective authors of each paper.

<sup>‡</sup>CoreValve™, Evolut™ R, Evolut™ PRO, Sapien™\*, Sapien 3, Sapien XT, and ACURATE neo™\*.

<sup>1</sup> Ueyama H, et al. *Am J Cardiol.* 2021;158:104-111.





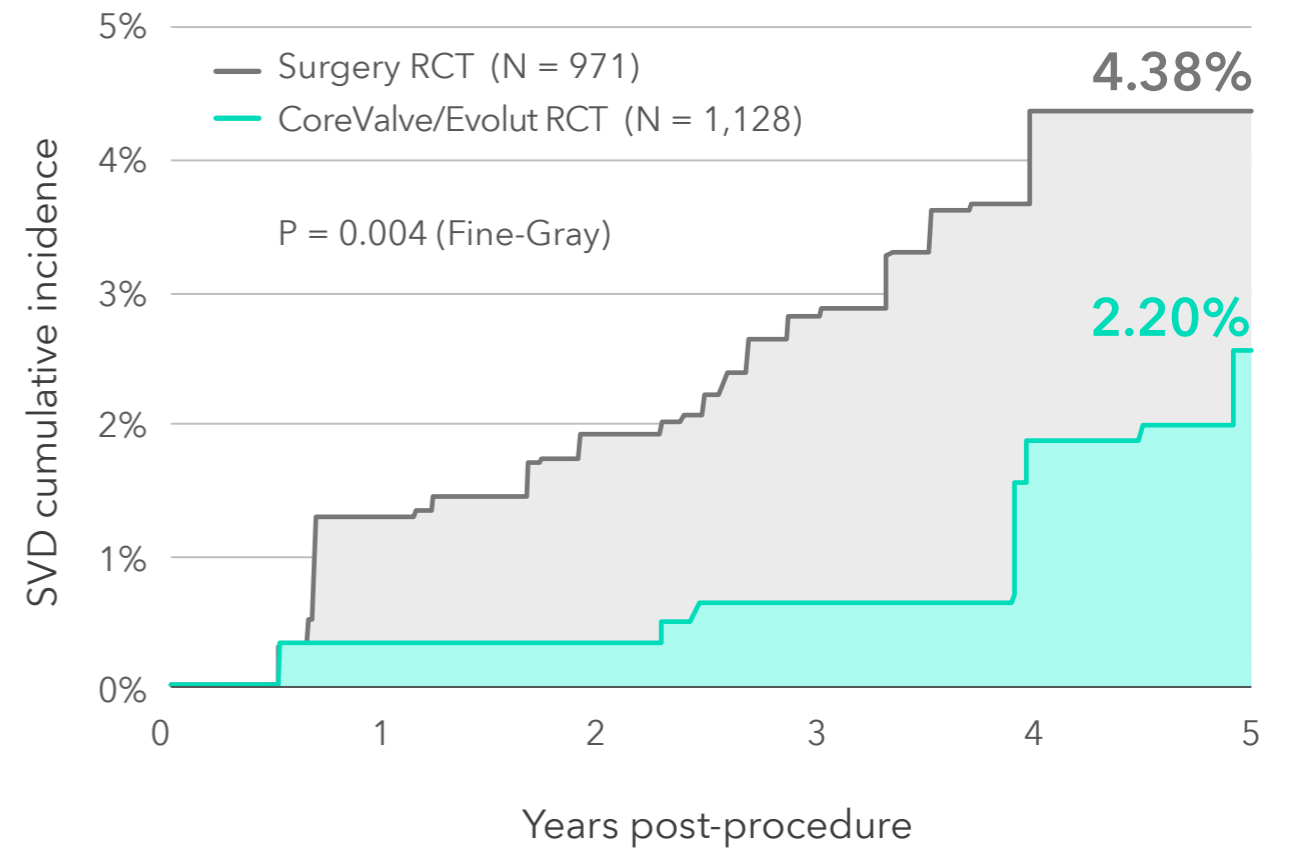
CoreValve™  
and Evolut™ are  
the first and only  
TAVI platforms  
to demonstrate  
a lower SVD  
than SAVR.

SVD definition >

Devices used:  
88.5% CoreValve  
11.5% Evolut™ R

## CoreValve and Evolut pooled analysis:

5-year SVD adjusted for competing risk of mortality<sup>1</sup>



<sup>1</sup> Reardon et al. 5-Year Incidence, Timing and Predictors of Structural Valve Deterioration of Transcatheter and Surgical Aortic Bioprostheses: Insights from the CoreValve US Pivotal and SURTAVI Trials. Presented at ACC 2022. Updated data on file.



Patients with SVD had a near **two-fold increased risk** for all-cause mortality ( $P < 0.001$ ) and hospitalization for AV disease or worsening heart failure ( $P = 0.01$ ) at five years.

## CoreValve™ and Evolut™ pooled analysis:

Worsened clinical outcomes in patients who develop SVD<sup>1</sup>

		HR (95% CI)	P value
<b>Pooled surgery RCT and all CoreValve/Evolut (N = 4,762)</b>			
All-cause mortality		2.03 (1.46, 2.82)	< 0.001
Cardiovascular mortality		1.86 (1.20, 2.90)	0.006
Aortic valve-related hospitalization		2.17 (1.23, 3.84)	0.008
Composite <sup>†</sup>		2.02 (1.42, 2.88)	< 0.001
<b>Surgery RCT (N = 971)</b>			
All-cause mortality		2.45 (1.40, 4.30)	0.002
Cardiovascular mortality		2.37 (1.10, 5.08)	0.003
Aortic valve-related hospitalization		2.20 (0.81, 5.98)	0.120
Composite <sup>†</sup>		2.73 (1.53, 4.88)	< 0.001
<b>All CoreValve/Evolut TAVI (N = 3,791)</b>			
All-cause mortality		2.34 (1.55, 3.53)	< 0.001
Cardiovascular mortality		2.17 (1.26, 3.76)	0.006
Aortic valve-related hospitalization		2.45 (1.22, 4.93)	0.010
Composite <sup>†</sup>		2.03 (1.29, 3.19)	0.002

0.10      1.00      10.00  
Lower risk with SVD ← → Higher risk with SVD

<sup>†</sup>All-cause mortality or aortic valve-related hospitalization.

<sup>1</sup> Reardon, et al. 5-Year Incidence, Timing and Predictors of Structural Valve Deterioration of Transcatheter and Surgical Aortic Bioprostheses: Insights from the CoreValve US Pivotal and SURTAVI Trials. Presented at ACC 2022. Updated data on file.

SVD definition


RCT and Non-RCT cohorts:  
97% CoreValve  
3% Evolut R



# Designed to be durable.



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## The hemodynamic performance of the supra-annular TAVI platform

**8-year data from the NOTION trial<sup>1</sup>**  
 In a recent update from the NOTION trial on patients at lower surgical risk over the age of 70, we continue to see statistically better hemodynamics versus surgery – as well as a promising signal of durability.

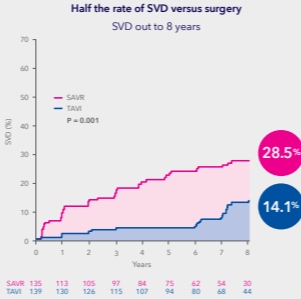
**Findings from 8-year follow-up of the NOTION trial<sup>1</sup>**

- CoreValve™ hemodynamics were statistically better versus surgery out to 8 years.
- CoreValve structural valve deterioration (SVD) was statistically better than surgery out to 8 years.

**Structural valve deterioration (SVD)<sup>2</sup>**

- Moderate or greater hemodynamic SVD
- Mean gradient ≥ 20 mm Hg or
- Mean gradient ≥ 10 mm Hg change from baseline or
- Moderate/severe intra-prosthetic aortic regurgitation (AR) (new or worsening from baseline)

**Half the rate of SVD versus surgery**  
 SVD out to 8 years



SAVR 135 113 105 97 84 75 62 54 30  
 TAVI 129 130 126 115 107 94 80 68 44

28.5%  
 14.1%

**Established failure rates**  
 NOTION suggested the CoreValve™ platform fails at half the rate of surgery in low-risk patients.

**Medtronic**

EVIDENCE UPDATE

## Valve durability

**Study design**

- Meta-analysis
- 10 randomized controlled trials
- 9,388 patients
- Follow-up 1 to 6 years
- Multiple devices<sup>2</sup>

**Key observations from the five-year meta-analysis:**  
 At five years, supra-annular, self-expandable (SE) valves demonstrated:

- Lowest risk of structural valve deterioration (SVD) compared with balloon-expandable (BE) valves and SAVR.
- Significantly stronger hemodynamics with larger EOAs and lower mean gradients versus BE valves.

Authors noted that additional studies including newer generations of valves are warranted to address known THV-specific risks, such as AR and reintervention.

Valve durability for supra-annular, self-expandable TAV found to be statistically better at five years versus both SAVR and balloon-expandable TAV

**Structural valve deterioration<sup>1</sup>**

**Only SE performs better than SAVR**  
 Comparison: others versus SAVR (random effects model)

Treatment	HR	95%-CI
BE-THV	2.43	[1.39; 4.26]
SE-THV	0.34	[0.24; 0.47]

**SE performs better than SAVR and BE**  
 Comparison: others versus self-expandable (random effects model)

Treatment	HR	95%-CI
BE-THV	7.15	[3.75; 13.62]
SAVR	2.94	[2.11; 4.09]

**Both SE and SAVR perform better than BE**  
 Comparison: others versus balloon-expandable (random effects model)

Treatment	HR	95%-CI
SAVR	0.41	[0.23; 0.72]
SE-THV	0.14	[0.07; 0.27]

SVD was less frequent in SE-THV compared with BE-THV and SAVR (HR 0.14, 95% CI 0.07 to 0.27; HR 0.34, 95% CI 0.24 to 0.47, respectively).

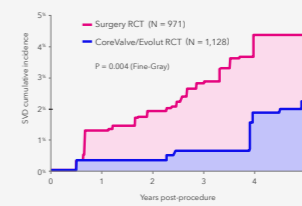
Based on the longest available follow-up for each of the 10 studies used for this meta-analysis. SVD was defined by the respective authors of each paper.  
<sup>1</sup>Structural valve deterioration (SVD) was defined as a moderate or greater increase in mean gradient ≥ 10 mm Hg over five years with a mean gradient ≥ 20 mm Hg at last follow-up OR new onset/progression of central AR of a moderate to severe intensity.  
<sup>2</sup>Sapien 3, Sapien XT, and ACURATE™ neo™.

**Established difference among platforms at five years**  
 Dr. Attizzani established that self-expandable valves demonstrated the lowest risk of SVD compared to balloon-expandable valves and SAVR.

**Medtronic**

## The best TAVI vs. SAVR durability data yet.

CoreValve™ and Evolut™ TAVI systems are the only platforms to demonstrate a durability benefit over SAVR at five years.<sup>1</sup>  
 Valve durability is important to you and your patients. It's important to us too.



4.38%  
 2.20%

**Medtronic TAVI platforms demonstrated significantly lower rates of structural valve deterioration (SVD)<sup>1</sup> vs. SAVR at five years.**

TAVI risks may include, but are not limited to, death, stroke, damage to the arteries, bleeding, and need for permanent pacemaker.  
<sup>1</sup>In pooled analysis of intermediate and high-risk patients. Devices used: CoreValve™ Evolut™ RCT (N = 1,128).  
<sup>2</sup>Structural valve deterioration (SVD) was defined as a moderate or greater increase in mean gradient ≥ 10 mm Hg over five years with a mean gradient ≥ 20 mm Hg at last follow-up OR new onset/progression of central AR of a moderate to severe intensity.

**Consequence of failure**  
 Dr. Reardon's pooled analysis shows the same statistical trend in durability of SEV over SAVR, as well as the consequence of developing SVD.

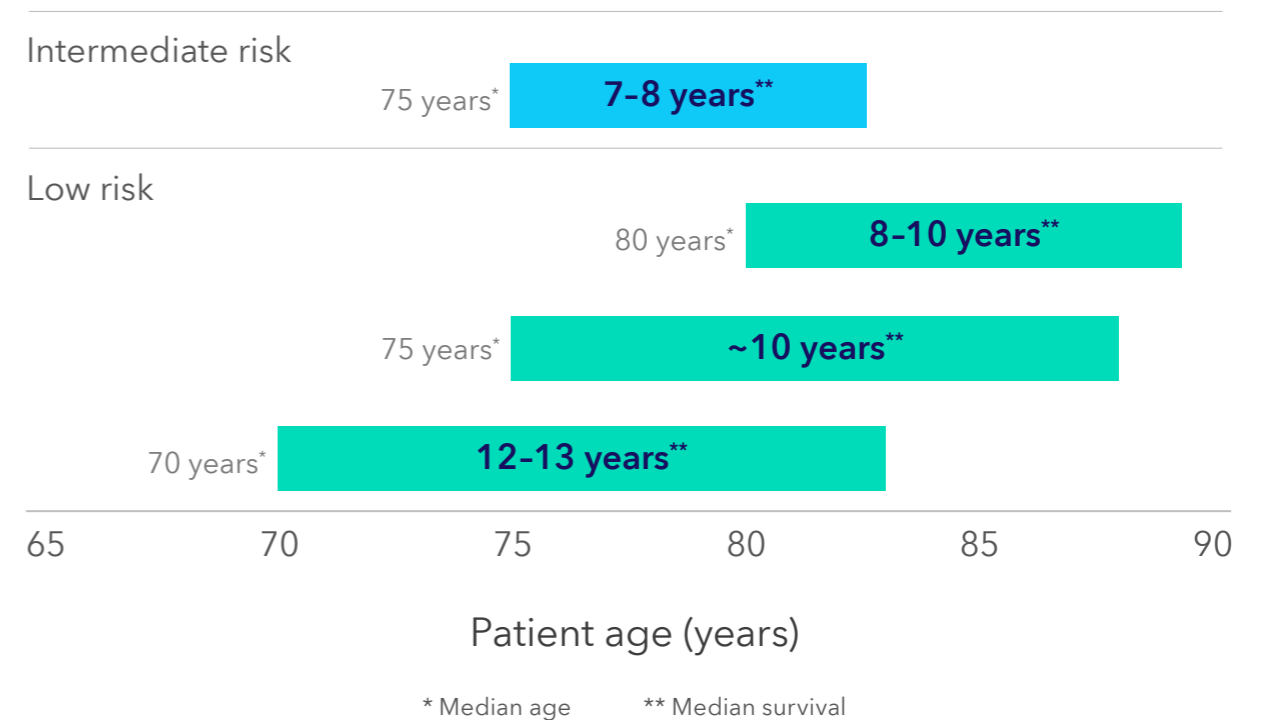


# Longevity after surgical aortic valve replacement.

Stratification by age and surgical risk groups

## For most TAVI patients, one valve is all they will need

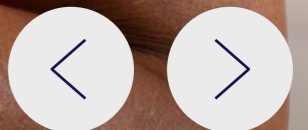
Lifetime management of patients undergoing AVR<sup>1</sup>



<sup>1</sup> Martinsson A, et al. *J Am Coll Cardiol.* 2021;78:2147-2157.



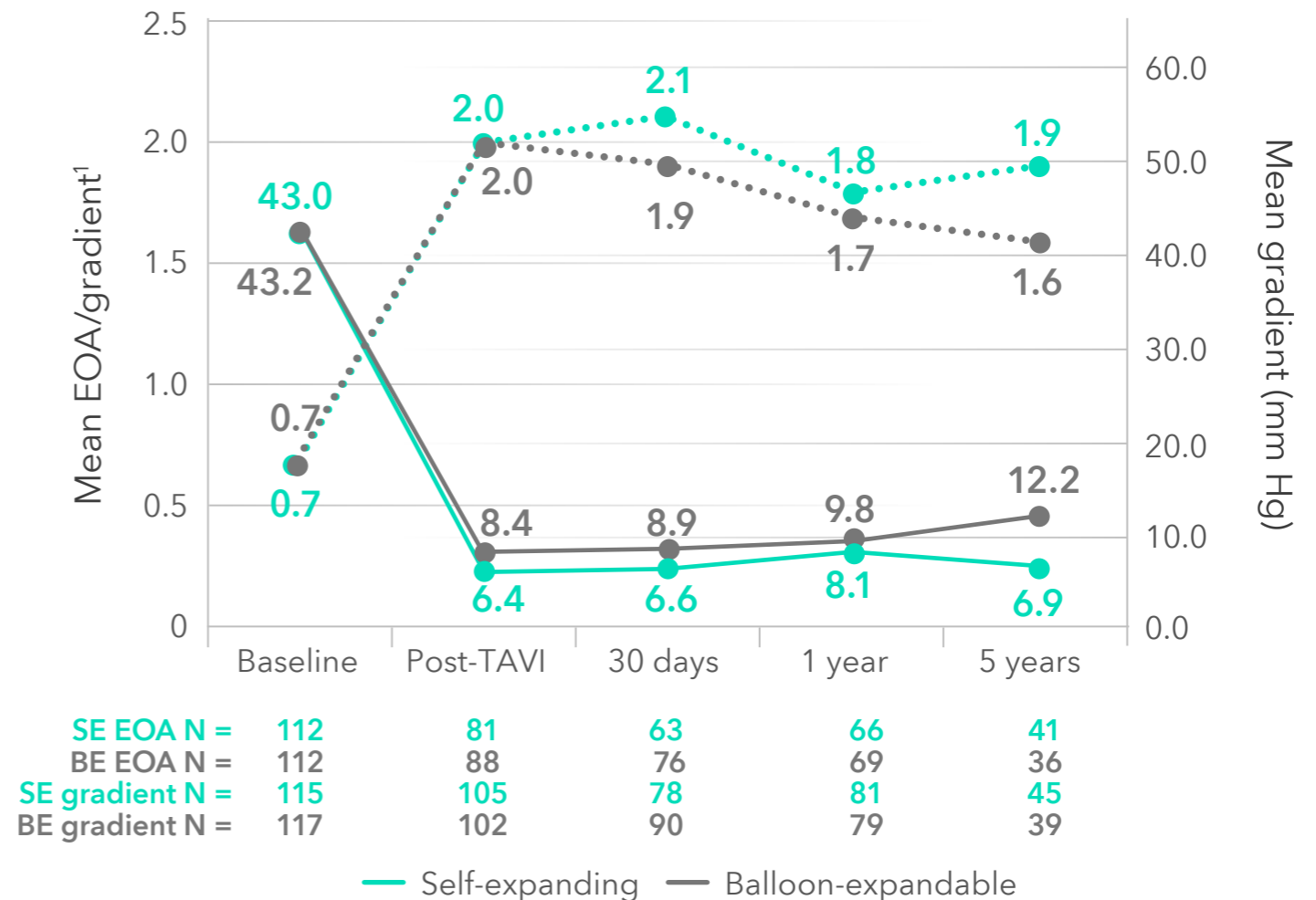
# Supporting data



CoreValve™  
TAV remained  
hemodynamically  
stable at  
five years.

## CHOICE<sup>1</sup> 5 years

Hemodynamics to 5 years<sup>1</sup>



### For EOAs:

Baseline: p = 0.71  
Post-TAVI: p = 0.86  
30 days: p = 0.13  
1 year: p = 0.34  
5 years: p = 0.02

### For gradients:

Baseline: p = 0.90  
Post-TAVI: p < 0.001  
30 days: p < 0.001  
1 year: p = 0.007  
5 years: p = 0.001

In this prospective, randomized study, CoreValve TAV remained hemodynamically stable at 5 years whereas the SAPIEN™ TAV had a 20% decline in EOA and a 40% increase in gradient.

CoreValve also had a statistically significant advantage in terms of freedom from SVD over SAPIEN (0.0% vs. 6.6%; p = 0.018).

SVD definition >

Device used:  
100% CoreValve

<sup>1</sup> Abdel-Wahab M, et al. Five-year outcomes after TAVI with balloon-expandable vs. self-expanding valves: Results from the CHOICE randomised clinical trial. Presented at EuroPCR 2019. Paris, France.



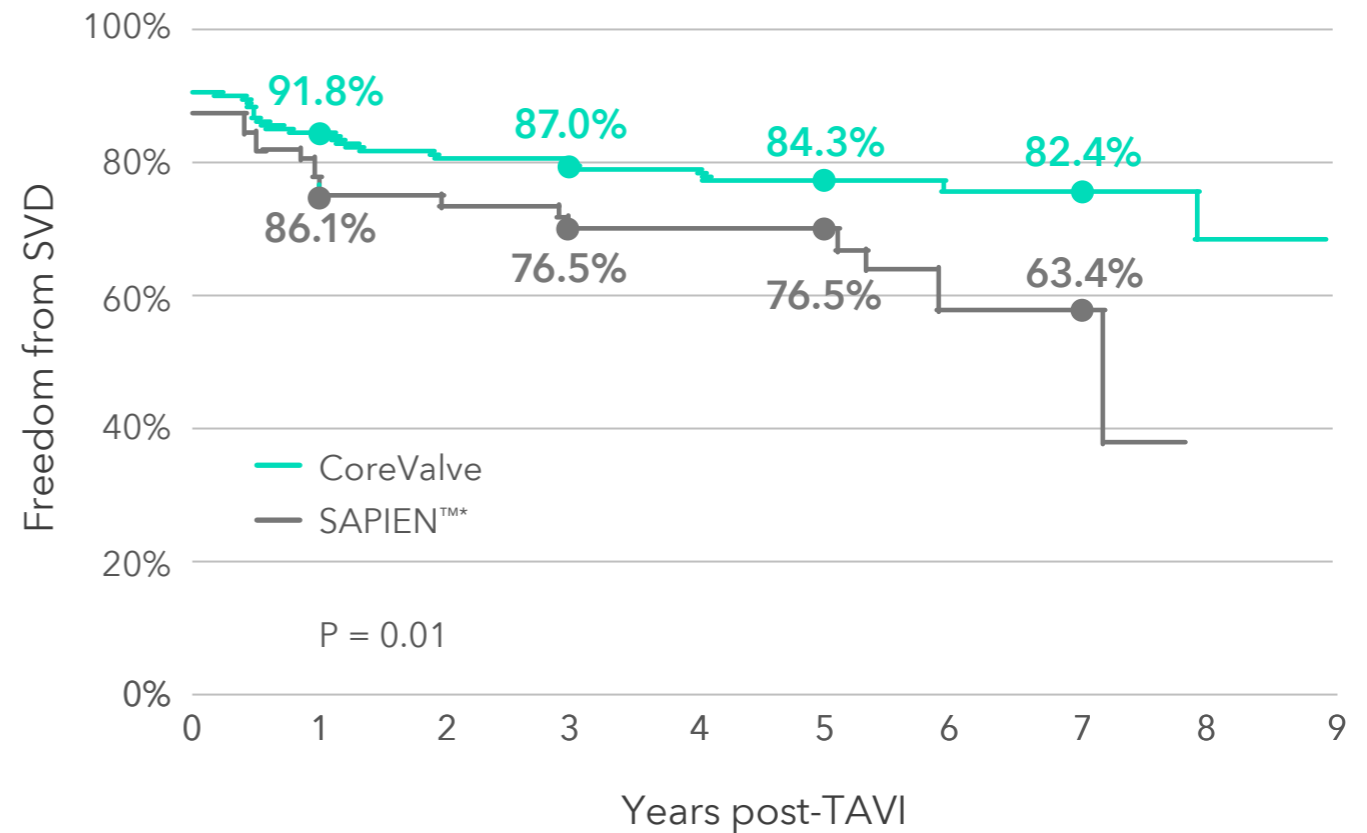
Freedom from SVD:

82.4%

for CoreValve™ TAV at seven years.

## DEUTSCH<sup>1</sup> 7 years

Freedom from SVD<sup>1</sup>



Patients at risk	214	147	121	106	93	75	44	24
	86	57	52	43	36	23	8	4

Retrospective analysis from a single-center registry

This chart clearly demonstrates significantly less SVD for CoreValve than SAPIEN out to 7 years. Freedom from SVD: 82.4% for CoreValve; 63.4% for SAPIEN.

When looking at freedom from SVD, at every time point (1, 3, 5, and 7 years), there was numerically less SVD with CoreValve than with SAPIEN.

<sup>1</sup> Deutsch MA, et al. *EuroIntervention*. 2018;14:41-49.

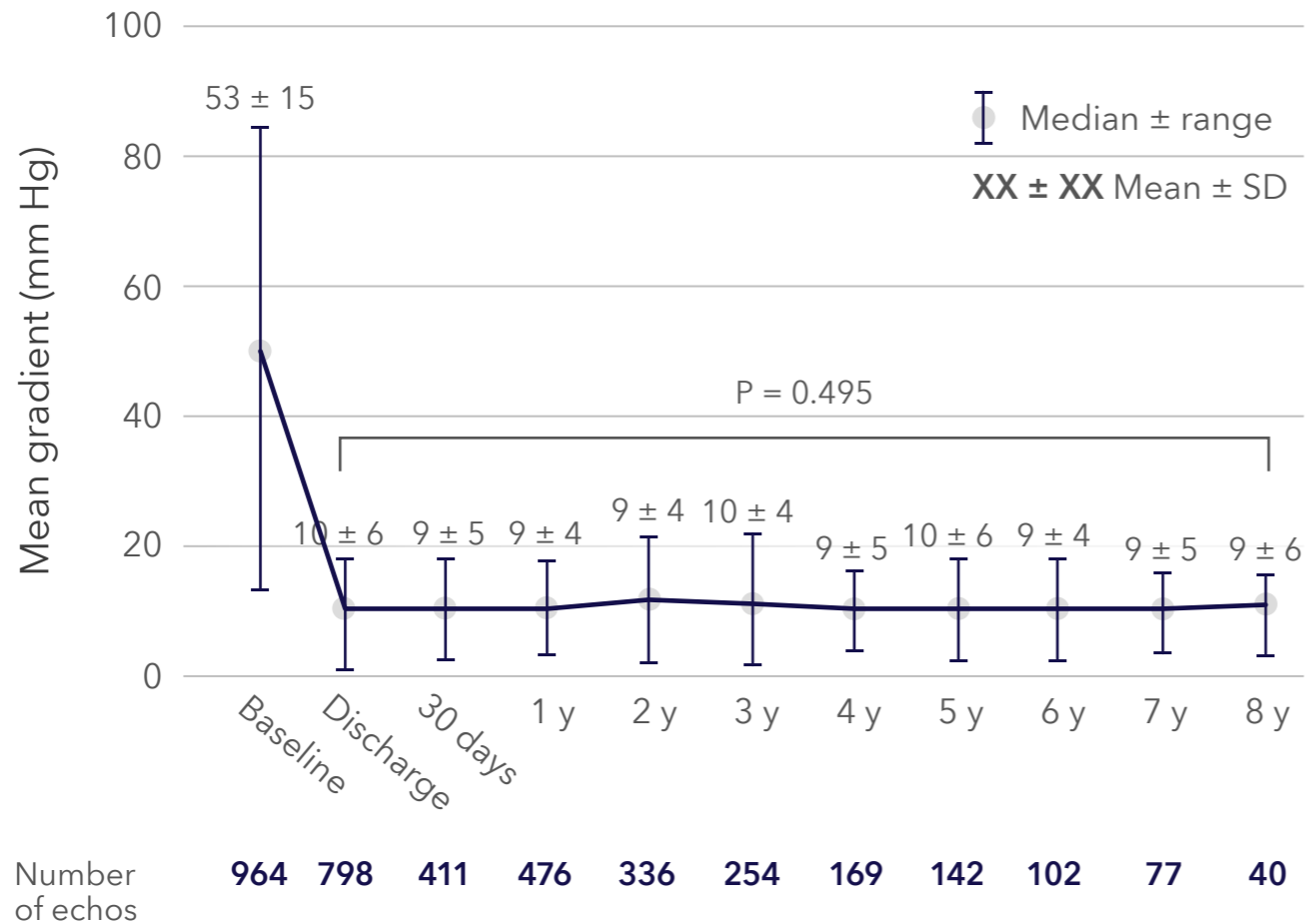
SVD definition >

Device used:  
100% CoreValve



## ITALIAN REGISTRY<sup>1</sup> 8 years

Mean gradient to 8 years<sup>1</sup>



Long-term data on the self-expanding, supra-annular CoreValve™ platform.

### Multicenter registry

Together with NOTION, this is the long-term data on the self-expanding, supra-annular CoreValve platform. Data demonstrates very low rates of moderate and severe hemodynamic SVD. The cumulative incidence of moderate and severe SVD at 8 years are 3.0% and 1.6%, respectively.

Additionally, the bioprosthetic valve failure (BVF) was also very low at 2.5% (includes any valve intervention, severe SVD, and any valve-related deaths), signaling durability for the CoreValve platform. The mean gradients remained low through 8 years.

> SVD definition

Device used:  
100% CoreValve

<sup>1</sup> Testa L, et al. Valve Performance and echocardiographic data throughout 8 years follow up after TAVR. Presented at EuroPCR 2019. Paris, France.





See the CoreValve™ Evolut™ R, the CoreValve™ Evolut™ PRO and the Evolut™ PRO+ device manuals for detailed information regarding the instructions for use, the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

For applicable products, consult instructions for use on manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser.

For best results, use Adobe Acrobat® Reader with the browser.

The commercial name of the Evolut™ R device is Medtronic CoreValve™ Evolut™ R System, the commercial name of the Evolut™ PRO device is Medtronic CoreValve™ Evolut™ PRO System, and the commercial name of the Evolut™ PRO+ device is Medtronic Evolut™ PRO+ System.

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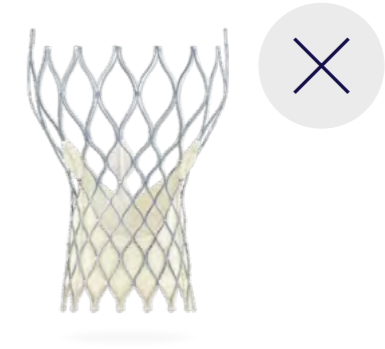
[medtronic.eu](https://www.medtronic.eu)



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# The hemodynamic performance of the supra-annular TAVI platform



## 8-year data from the NOTION trial<sup>1</sup>

In a recent update from the NOTION trial on patients at lower surgical risk over the age of 70, we continue to see statistically better hemodynamics versus surgery – as well as a promising signal of durability.

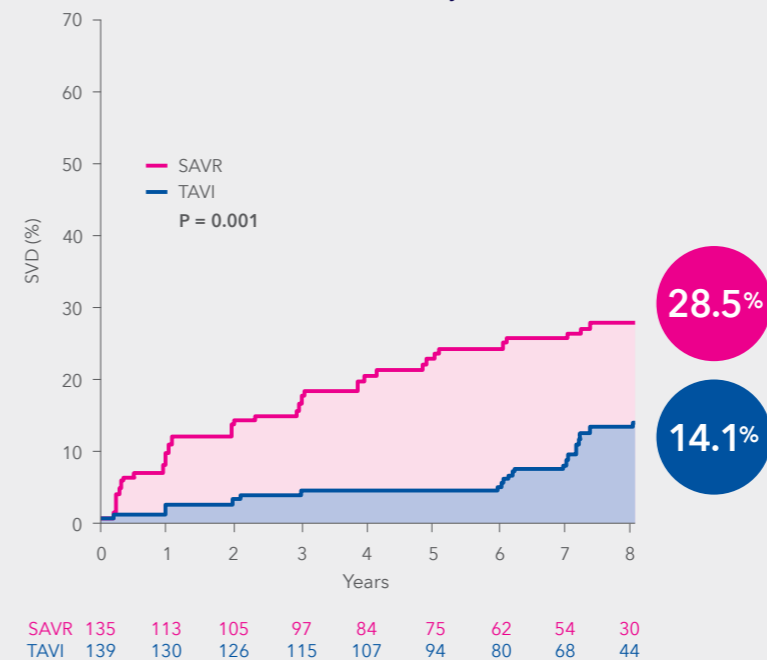
### Findings from 8-year follow-up of the NOTION trial<sup>1</sup>

- CoreValve™ hemodynamics were statistically better versus surgery out to 8 years.
- CoreValve structural valve deterioration (SVD) was statistically better than surgery out to 8 years.

### Structural valve deterioration (SVD)<sup>2</sup>

- Moderate or greater hemodynamic SVD
- Mean gradient  $\geq 20$  mm Hg or
- Mean gradient  $\geq 10$  mm Hg change from baseline or
- Moderate/severe intra-prosthetic aortic regurgitation (AR) (new or worsening from baseline)

### Half the rate of SVD versus surgery SVD out to 8 years



AVR data yet.

the only platforms  
AVR at five years.<sup>11</sup>  
our patients.

4.38%  
2.20%  
Medtronic TAVI platforms demonstrated significantly lower rates of structural valve deterioration (SVD)<sup>1</sup> vs. SAVR at five years.

f failure  
pooled analysis  
statistical trend  
EV over SAVR,  
consequence of

Designed to be durable.

Evolut™ first

# Medtronic

## EVIDENCE UPDATE

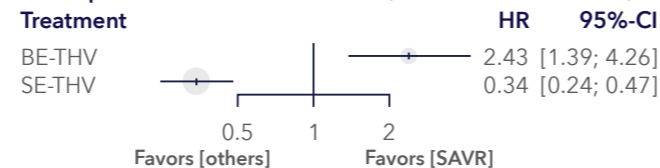
# Valve durability

Valve durability for supra-annular, self-expandable TAV found to be statistically better at five years versus both SAVR and balloon-expandable TAV

### Structural valve deterioration†

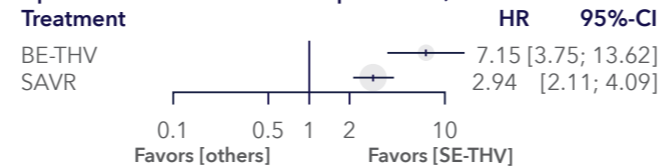
Only SE performs better than SAVR

Comparison: others versus SAVR (random effects model)



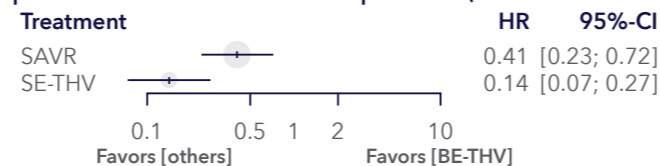
SE performs better than SAVR and BE

Comparison: others versus self-expandable (random effects model)



Both SE and SAVR perform better than BE

Comparison: others versus balloon-expandable (random effects model)



### Study design

- Meta-analysis
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- Significantly stronger hemodynamics with larger EOAs and lower mean gradients versus BE valves.

Authors noted that additional studies including newer generations of valves are warranted to address known THV-specific risks, such as AR and reintervention.

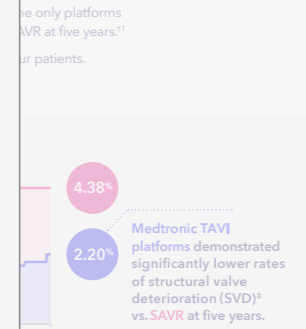
SVD was less frequent in SE-THV compared with BE-THV and SAVR (HR 0.14, 95% CI 0.07 to 0.27; HR 0.34, 95% CI 0.24 to 0.47, respectively).

†Based on the longest available follow-up for each of the 10 studies used for this meta-analysis. SVD was defined by the respective authors of each paper.  
‡CoreValve™, Evolut™ R, Evolut™ PRO, Sapien™, Sapien 3, Sapien XT, and ACURATE neo™.



3

AVR data yet.



f failure  
pooled analysis  
statistical trend  
EV over SAVR,  
consequence of



Designed to be durable.

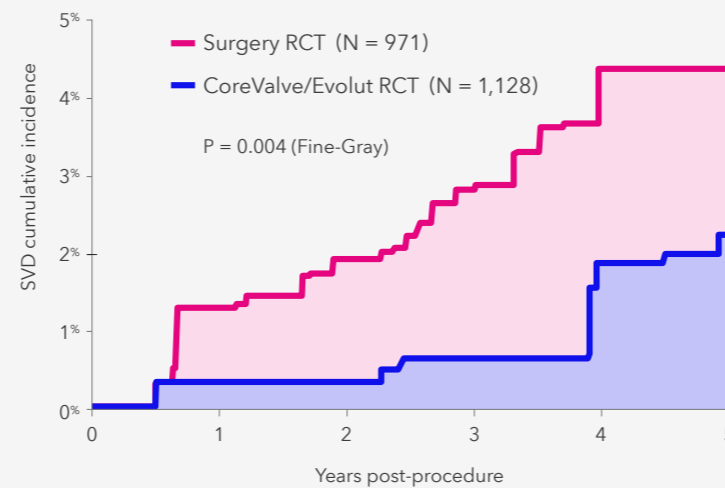
Evolut™ first

Medtronic

# The best TAVI vs. SAVR durability data yet.

CoreValve™ and Evolut™ TAVI systems are the only platforms to demonstrate a durability benefit over SAVR at five years.<sup>†1</sup>

Valve durability is important to you and your patients. It's important to us too.

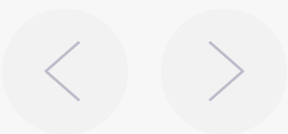


4.38%

2.20%

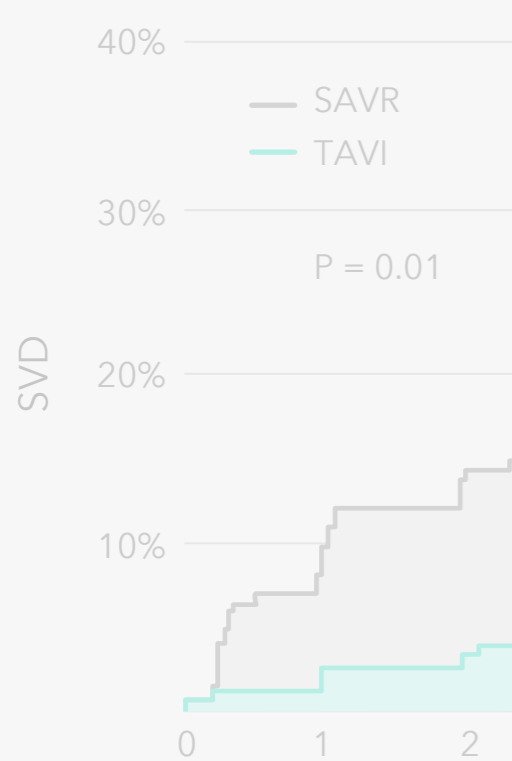
Medtronic TAVI platforms demonstrated significantly lower rates of structural valve deterioration (SVD)<sup>‡</sup> vs. SAVR at five years.

TAVR risks may include, but are not limited to, death, stroke, damage to the arteries, bleeding, and need for permanent pacemaker.  
<sup>†1</sup>In pooled analysis of intermediate and high-risk patients. Devices used: CoreValve 88%/Evolut R 12%.  
<sup>‡</sup>Structural valve deterioration (SVD) was defined as an increase in mean gradient  $\geq 10$  mm Hg over five years with a mean gradient  $\geq 20$  mm Hg at last echo OR new onset/increase of central AR of  $\geq$  moderate in severity.



## NOTION<sup>1</sup> 8 years

SVD out to 8 years<sup>1</sup>



### SVD definition<sup>1</sup>

- Moderate or greater hemodynamic SVD
- Mean gradient  $\geq 20$  mm Hg OR
- Mean gradient  $\geq 10$  mm Hg change from baseline OR
- Moderate/severe intra-prosthetic aortic regurgitation (AR) (new or worsening from baseline)

<sup>1</sup> Capodanno D, et al. *Eur Heart J.* 2017;38:3382-3390.

SAVR	135	113	105	97	84	75	62	54	30
TAVI	139	130	126	115	107	94	80	68	44

The NOTION trial is a multicenter, randomized, head-to-head comparison of CoreValve TAVI versus SAVR followed out to 8 years in lower surgical risk patients  $\geq 70$  years of age who are eligible for surgery. TAVI had significantly less hemodynamic SVD out to 8 years.

The NOTION 8-year data demonstrates excellent SVD rates in a lower surgical risk patient population. Perhaps most importantly, the data provides a signal of durability for the CoreValve platform versus SAVR.

<sup>1</sup> Søndergaard L. Long-term follow-up of transcatheter and surgical bioprosthetic aortic valves in patients with severe aortic stenosis and lower surgical risk. Presented at PCR Valvese-Course; November 24, 2020.

CoreValve™  
 arm was  
 durable  
 AVR at  
 years.

> SVD definition

Device used:  
 100% CoreValve



CoreValve<sup>™</sup>  
and Evolut<sup>™</sup>  
the first an  
TAVI platfo  
to demons  
a lower SV  
than SAVR.

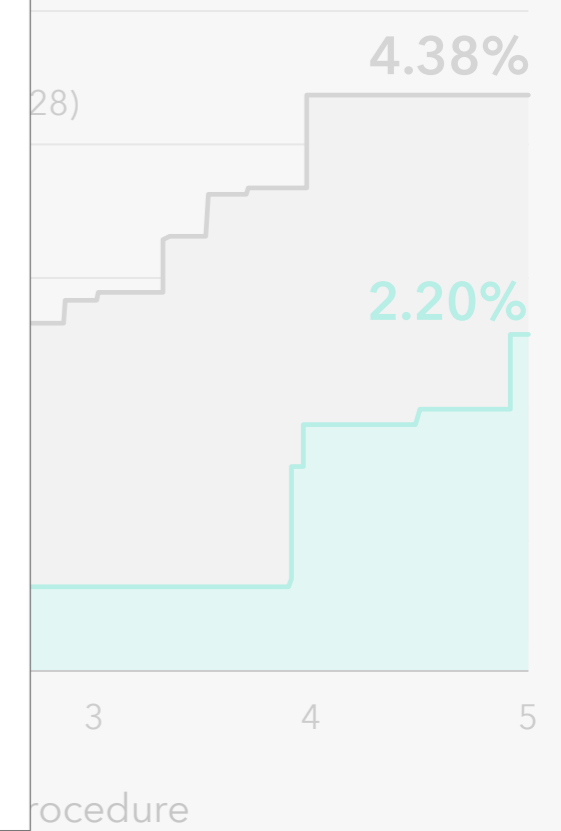
## CoreValve and Evolut pooled analysis:

5-year SVD adjusted for competing risk of mortality<sup>1</sup>

### SVD definition<sup>1</sup>

SVD was defined as  $\geq$  moderate hemodynamic valve deterioration (HVD): Increase in mean gradient  $\geq$  10 mm Hg from discharge/30-day echo to last available echo AND mean gradient  $\geq$  20 mm Hg at last available echo OR new onset/increase of intra-prosthetic aortic regurgitation (AR)  $\geq$  moderate.

<sup>1</sup> Adapted from VARC-3 Writing Committee, et al. *Eur Heart J.* 2021;42:1825-1857.



SVD definition >

Devices used:  
88.5% CoreValve  
11.5% Evolut R

<sup>1</sup> Reardon et al. 5-Year Incidence, Timing and Predictors of Structural Valve Deterioration of Transcatheter and Surgical Aortic Bioprostheses: Insights from the CoreValve US Pivotal and SURTAVI Trials. Presented at ACC 2022. Updated data on file.



## CoreValve™ and Evolut™ pooled analysis:

Worsened clinical outcomes in patients who develop SVD<sup>1</sup>

Patients with SVD had a near two-fold increased risk of mortality (P < 0.001), hospitalization for heart failure (P < 0.001) or worse heart failure (P < 0.001) at five years.

### SVD definition<sup>1</sup>

SVD was defined as  $\geq$  moderate hemodynamic valve deterioration (HVD): Increase in mean gradient  $\geq$  10 mm Hg from discharge/30-day echo to last available echo AND mean gradient  $\geq$  20 mm Hg at last available echo OR new onset/increase of intra-prosthetic aortic regurgitation (AR)  $\geq$  moderate.

<sup>1</sup> Adapted from VARC-3 Writing Committee, et al. *Eur Heart J.* 2021;42:1825-1857.



	HR (95% CI)	P value
2)	2.03 (1.46, 2.82)	< 0.001
	1.86 (1.20, 2.90)	0.006
	2.17 (1.23, 3.84)	0.008
	2.02 (1.42, 2.88)	< 0.001
	2.45 (1.40, 4.30)	0.002
	2.37 (1.10, 5.08)	0.003
	2.20 (0.81, 5.98)	0.120
	2.73 (1.53, 4.88)	< 0.001
	2.34 (1.55, 3.53)	< 0.001
	2.17 (1.26, 3.76)	0.006
	2.45 (1.22, 4.93)	0.010
	2.03 (1.29, 3.19)	0.002

0.10 1.00 10.00  
Lower risk with SVD ← → Higher risk with SVD

SVD definition >

RCT and Non-RCT cohorts:  
97% CoreValve  
3% Evolut R

<sup>†</sup>All-cause mortality or aortic valve-related hospitalization.

<sup>1</sup> Reardon, et al. 5-Year Incidence, Timing and Predictors of Structural Valve Deterioration of Transcatheter and Surgical Aortic Bioprostheses: Insights from the CoreValve US Pivotal and SURTAVI Trials. Presented at ACC 2022. Updated data on file.



CoreValve™ TAV remain hemodynamically stable at five years.

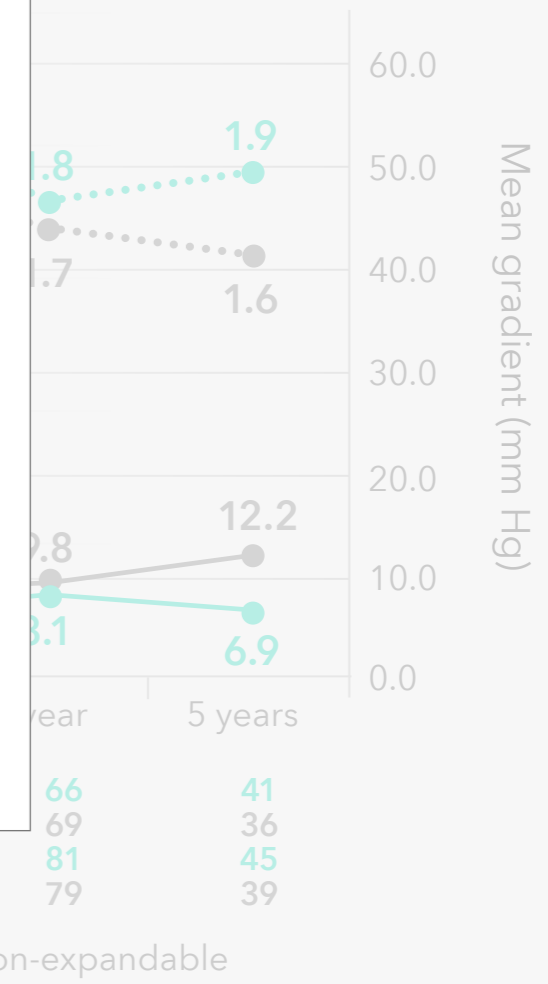
## CHOICE<sup>1</sup> 5 years

Hemodynamics to 5 years<sup>1</sup>

### SVD definition<sup>1</sup>

- Moderate or greater hemodynamic SVD
- Mean gradient  $\geq 20$  mm Hg OR
- Mean gradient  $\geq 10$  mm Hg change from baseline OR
- Moderate/severe intra-prosthetic aortic regurgitation (AR) (new or worsening from baseline)

<sup>1</sup> Capodanno D, et al. *Eur Heart J.* 2017;38:3382-3390.



	1 year	5 years
SE gradient N =	115	105
BE gradient N =	117	102

— Self-expanding — Balloon-expandable

SVD definition >

Device used:  
100% CoreValve

#### For EOAs:

Baseline: p = 0.71  
Post-TAVI: p = 0.86  
30 days: p = 0.13  
1 year: p = 0.34  
5 years: p = 0.02

#### For gradients:

Baseline: p = 0.90  
Post-TAVI: p < 0.001  
30 days: p < 0.001  
1 year: p = 0.007  
5 years: p = 0.001

In this prospective, randomized study, CoreValve TAV remained hemodynamically stable at 5 years whereas the SAPIEN™ TAV had a 20% decline in EOA and a 40% increase in gradient.

CoreValve also had a statistically significant advantage in terms of freedom from SVD over SAPIEN (0.0% vs. 6.6%; p = 0.018).

<sup>1</sup> Abdel-Wahab M, et al. Five-year outcomes after TAVI with balloon-expandable vs. self-expanding valves: Results from the CHOICE randomised clinical trial. Presented at EuroPCR 2019; Paris, France.





## DEUTSCH<sup>1</sup> 7 years

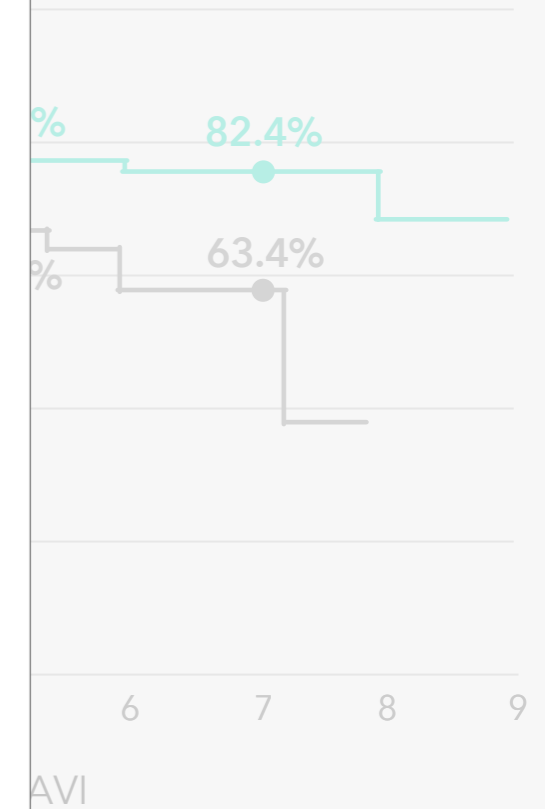
Freedom from SVD<sup>1</sup>

Freedom from  
**82.4%**  
for CoreValve™  
at seven years

### SVD definition<sup>1</sup>

- Moderate or greater hemodynamic SVD
- Mean gradient  $\geq 20$  mm Hg OR
- Mean gradient  $\geq 10$  mm Hg change from baseline OR
- Moderate/severe intra-prosthetic aortic regurgitation (AR) (new or worsening from baseline)

<sup>1</sup> Capodanno D, et al. *Eur Heart J.* 2017;38:3382-3390.



Patients at risk	214	147	121	106	93	75	44	24
	86	57	52	43	36	23	8	4

Retrospective analysis from a single-center registry

This chart clearly demonstrates significantly less SVD for CoreValve than SAPIEN out to 7 years. Freedom from SVD: 82.4% for CoreValve; 63.4% for SAPIEN.

When looking at freedom from SVD, at every time point (1, 3, 5, and 7 years), there was numerically less SVD with CoreValve than with SAPIEN.

<sup>1</sup> Deutsch MA, et al. *EuroIntervention.* 2018;14:41-49.

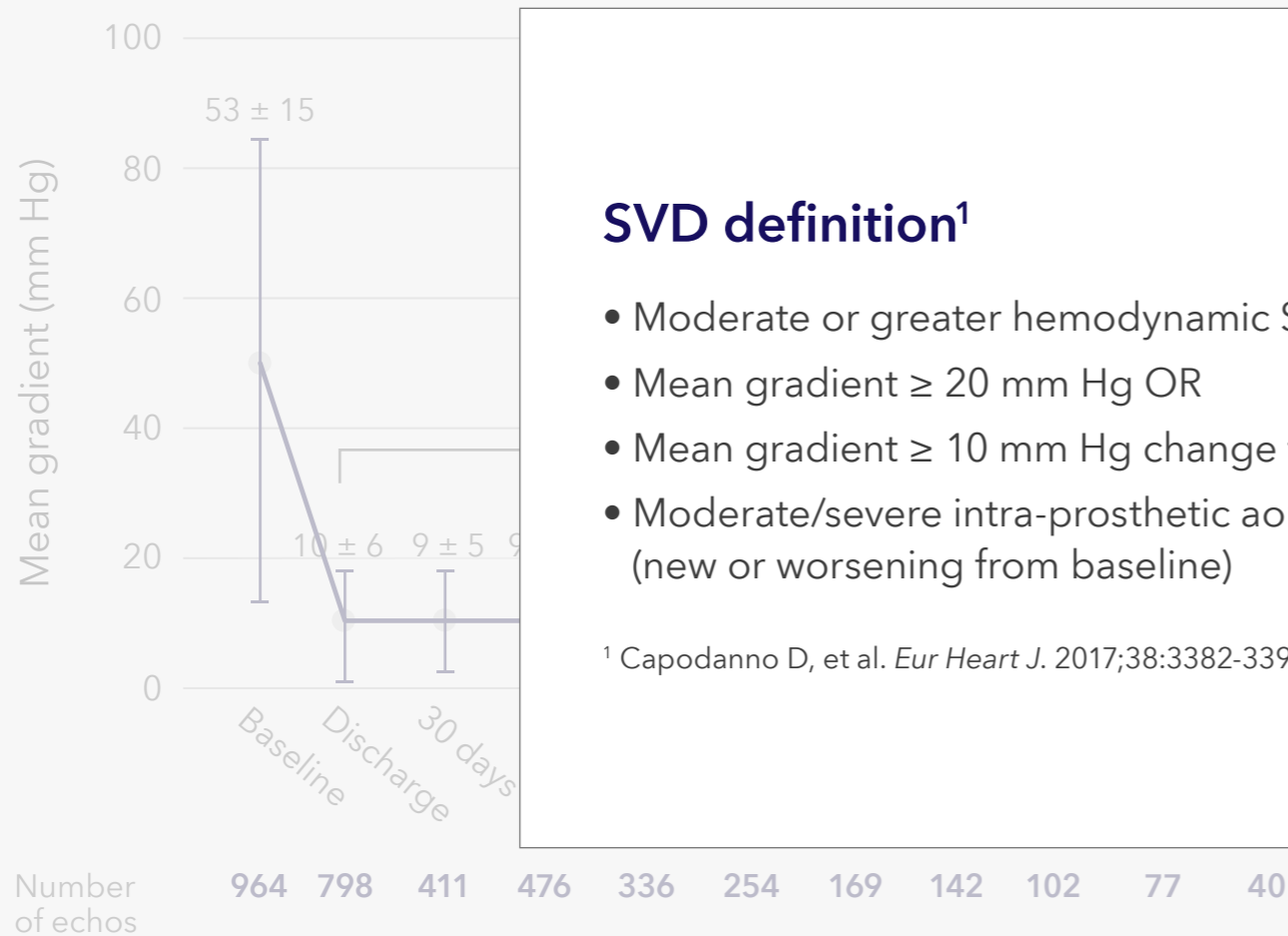
SVD definition >

Device used:  
100% CoreValve



## ITALIAN REGISTRY<sup>1</sup> 8 years

Mean gradient to 8 years<sup>1</sup>



### SVD definition<sup>1</sup>

- Moderate or greater hemodynamic SVD
- Mean gradient  $\geq 20$  mm Hg OR
- Mean gradient  $\geq 10$  mm Hg change from baseline OR
- Moderate/severe intra-prosthetic aortic regurgitation (AR) (new or worsening from baseline)

<sup>1</sup> Capodanno D, et al. *Eur Heart J.* 2017;38:3382-3390.

### Multicenter registry

Together with NOTION, this is the longest-term data on the self-expanding, supra-annular CoreValve platform. Data demonstrates very low rates of moderate and severe hemodynamic SVD. The cumulative incidence of moderate and severe SVD at 8 years are 3.0% and 1.6%, respectively.

Additionally, the bioprosthetic valve failure (BVF) was also very low at 2.5% (includes any valve intervention, severe SVD, and any valve-related deaths), signaling durability for the CoreValve platform. The mean gradients remained low through 8 years.

### > SVD definition

Device used:  
100% CoreValve

<sup>1</sup> Testa L, et al. Valve Performance and echocardiographic data throughout 8 years follow up after TAVR. Presented at EuroPCR 2019. Paris, France.

