

Six-Year Outcomes After Transcatheter vs Surgical Aortic Valve Replacement in Low-Risk Patients With Aortic Stenosis

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P (população)	Pacientes com estenose aórtica grave sintomática, valva tricúspide, baixo risco cirúrgico (STS < 3%), elegíveis tanto para TAVR quanto para cirurgia
I (intervenção)	Implante de prótese valvar aórtica transcateter (TAVR) com válvula autoexpansível supra-anular (plataforma Evolut).
C (comparação)	Cirurgia convencional de troca valvar aórtica (SAVR).
O (resultado/outcome)	Primário (análise de 6 anos): Composto de mortalidade por todas as causas ou AVC incapacitante. Secundários relevantes: Mortalidade total Mortalidade cardiovascular Reintervenção valvar Causas da reintervenção (estenose vs regurgitação)
T (tempo/tipo)	Ensaio clínico randomizado multicêntrico internacional Seguimento de 6 anos (com análise exploratória de dados disponíveis até 7 anos)

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Six-Year Outcomes After Transcatheter vs Surgical Aortic Valve Replacement in Low-Risk Patients With Aortic Stenosis

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ABSTRACT

BACKGROUND The Evolut Low Risk trial enrolled patients with severe aortic stenosis at low surgical risk. Annual follow-up is planned for 10 years, evaluating the composite of all-cause mortality or disabling stroke and key secondary endpoints.

OBJECTIVES Our prespecified objective was to report the 6-year clinical outcomes of transcatheter aortic valve replacement (TAVR) vs surgery from the Evolut Low Risk trial. Given an increase in reintervention rates at 6 years, we performed additional analyses in available 7-year data.

METHODS Low-risk patients with severe symptomatic aortic stenosis were randomized to TAVR or surgery from 2016-2019. Prespecified analyses at 6 years included annual follow-up of clinical outcomes reported as Kaplan-Meier estimates with log-rank test. Because the trial enrolled patients over several years, at the time of data lock, a majority of patients had completed 7-year follow-up. Given an increased reintervention rate at 6 years in the TAVR arm, we performed additional analysis of 7-year data available at the time of the database lock. Reintervention rates are reported as cumulative incidence.

RESULTS A total of 1,414 patients underwent an attempted implantation (730 TAVR, 684 surgery). At 6 years, the composite endpoint of all-cause mortality or disabling stroke was 23.3% for TAVR and 20.4% for surgery (difference: 2.8% [95% CI: -1.9% to 7.6%]; $P = 0.43$). All-cause mortality with vital status sweep at 6 years was 23.3% (95% CI: 20.6%-26.4%) for TAVR and 20.2% (95% CI: 17.4%-23.3%) for surgery ($P = 0.24$). The reintervention rate at 6 years was 5.5% for TAVR and 3.3% for surgery (sHR: 1.66 [95% CI: 0.96-2.86]; $P = 0.07$). Using available 7-year follow-up (555 TAVR and 480 surgery), the reintervention rate for TAVR was 9.8% and for surgery was 6.0% (sHR: 1.68 [95% CI: 1.10-2.58]; $P = 0.02$). In the TAVR and surgery groups, the rate of reintervention for regurgitation was 5.6% vs 1.6% (sHR: 3.39 [95% CI: 1.62-7.07]; $P < 0.001$) and the rate of reintervention for stenosis was 3.6% vs 3.5% (sHR: 1.14 [95% CI: 0.61-2.15]; $P = 0.70$).

CONCLUSIONS The 6-year results from the Evolut Low Risk trial show no significant difference in the composite endpoint of all-cause mortality or disabling stroke. At 6 and 7 years, the TAVR arm had a higher reintervention rate compared with surgery, driven by an increased incidence of aortic regurgitation. (Medtronic Evolut Transcatheter Aortic Valve Replacement in Low Risk Patients; [NCT02701283](#)) (JACC. 2026;■■■) © 2026 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Contexto

TAVI expandiu rapidamente nas últimas décadas

Inicialmente indicado para:

- Pacientes inoperáveis
- Alto risco cirúrgico

Posteriormente:

- Risco intermediário
- Baixo risco

Apesar dos bons resultados iniciais:

- Durabilidade da prótese em baixo risco ainda é incerta

Seguimentos prévios mostraram:

- Equivalência até 5 anos

Necessidade de **dados mais longos**



Objetivos

- Avaliar **desfechos clínicos em 6 anos** após TAVI vs cirurgia em pacientes com **estenose aórtica grave sintomática de baixo risco**

Métodos – desenho do estudo

- Internacional, prospectivo, multicêntrico e randomizado
- 87 centros - Austrália, Canadá, França, Japão, Holanda, Nova Zelândia e Estados Unidos.
- Randomização **1:1**
- TAVI vs SAVR

Métodos – população

Critérios principais:

- Estenose aórtica grave sintomática, morfologia tricúspide
- Baixo risco cirúrgico (STS <3%)

Total:

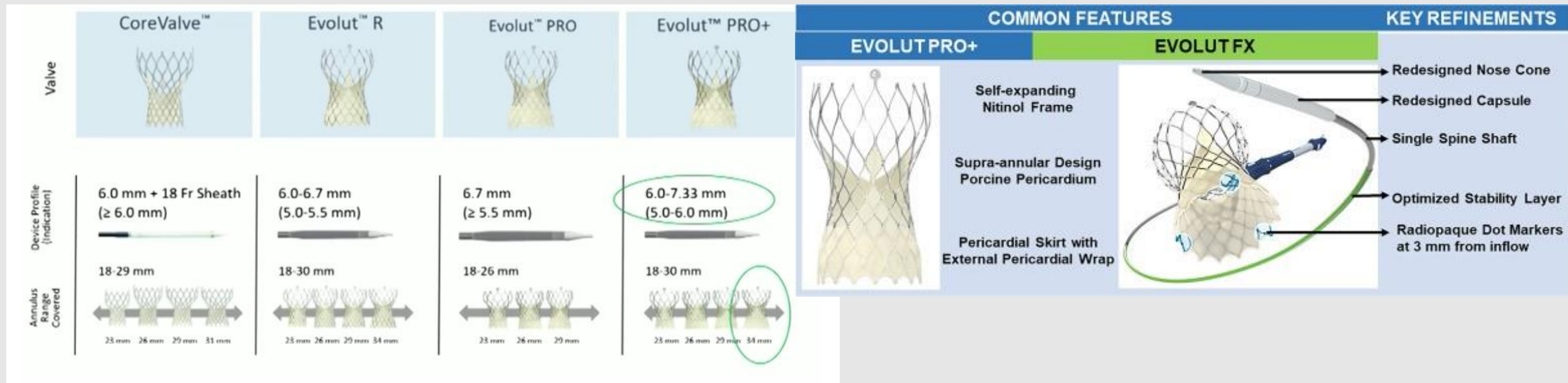
- 1414 pacientes

730 → TAVI

684 → SAVR

Métodos – intervenção

- TAVI com válvulas autoexpansíveis



Métodos – desfechos

Desfecho primário:

- Composto de mortalidade por todas as causas ou acidente vascular cerebral incapacitante

Desfechos secundários:

- Mortalidade
- AVC
- Reintervenção valvar

Resultados

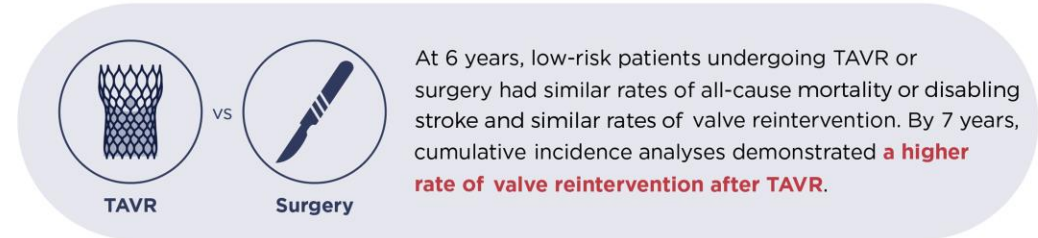
Desfecho primário:
Morte ou AVC incapacitante em 6 anos

TAVI
23.3%

SAVR
20.4%

$p = 0.43$

CENTRAL ILLUSTRATION: 6-Year Outcomes After Transcatheter vs Surgical Aortic Valve Replacement in Low-Risk Patients With Aortic Stenosis



The Evolut Low Risk trial is one of the largest and longest-running trials for TAVR in low-risk patients, and continued follow-up is critical for assessing and monitoring outcomes in this patient population.

TRIAL DESIGN & POPULATION

 **International, multicenter study**

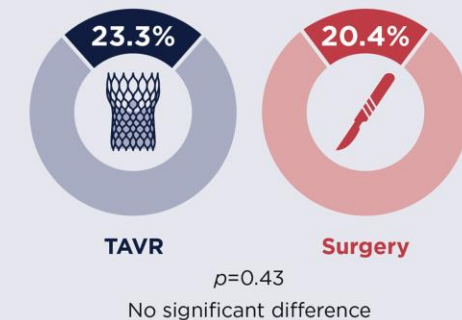
 **Randomized 1:1**
to TAVR or surgery

 **1,414 patients**
with severe trileaflet aortic stenosis at low surgical risk (surgical mortality risk below 3%)

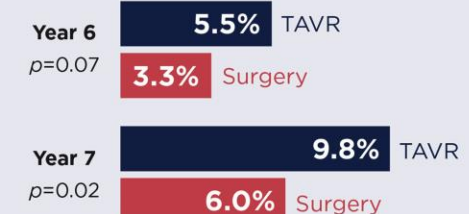
 **6-year analysis**
with additional 7-year reintervention assessment

RESULTS

Composite endpoint of all-cause mortality or disabling stroke through 6 years



Reintervention—cumulative incidence



Resultados

- Mortalidade por todas as causas

TAVI

23.3%

SAVR

20.2%

- Mortalidade cardiovascular

TAVI

11.1%

SAVR

11.0%

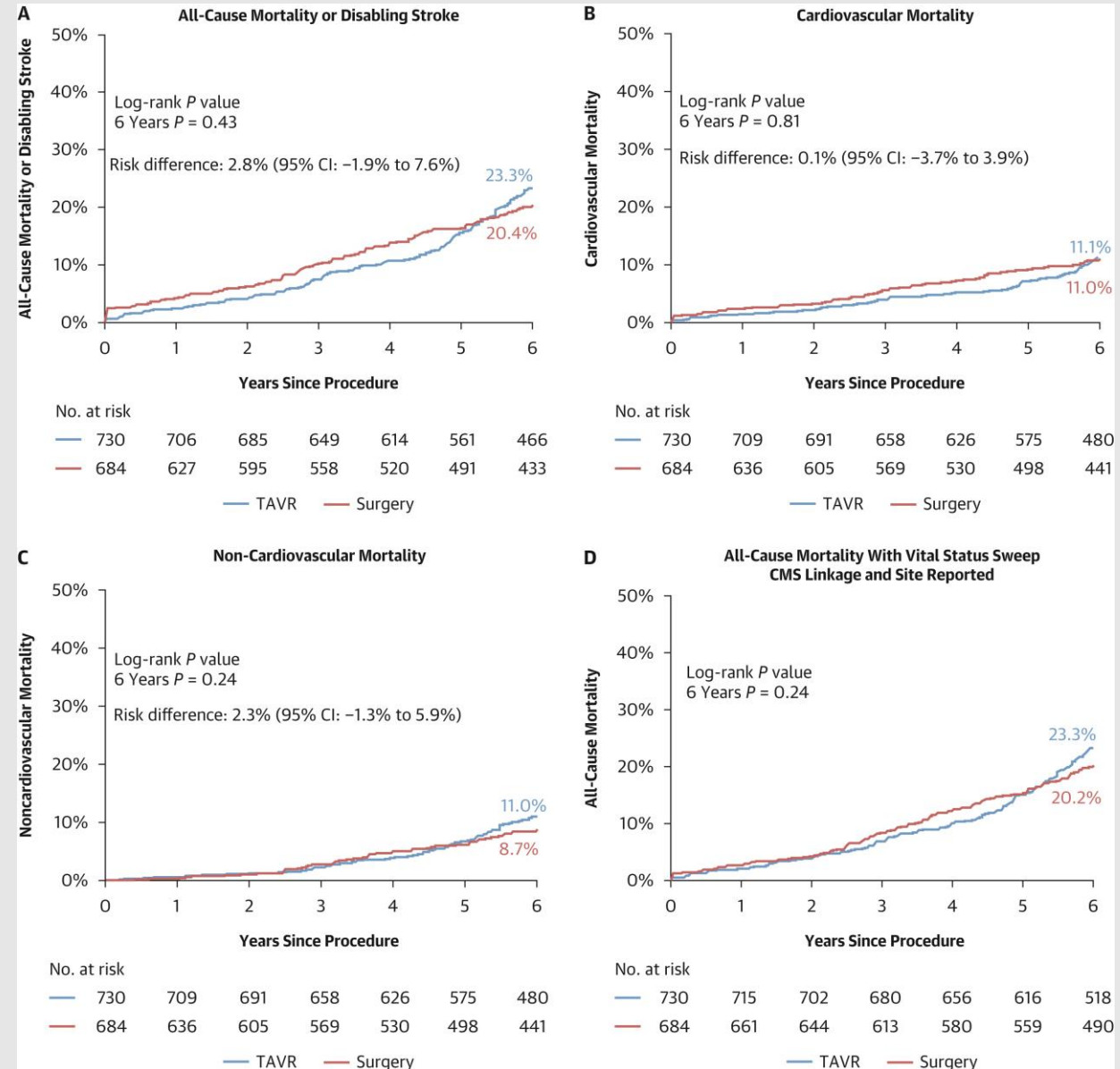


TABLE 1 6-Year Clinical Outcomes

	TAVR (n = 730)	Surgery (n = 684)	P Value (Log-Rank)
All-cause mortality or disabling stroke	159 (23.3)	127 (20.4)	0.43
All-cause mortality	142 (20.9)	115 (18.7)	0.54
Cardiovascular mortality	72 (11.1)	66 (11.0)	0.81
Noncardiovascular mortality	70 (11.0)	49 (8.7)	0.24
All-cause mortality with vital status sweep ^a	169 (23.3)	134 (20.2)	0.24
All stroke	73 (10.8)	59 (9.6)	0.51
Disabling stroke	29 (4.4)	28 (4.6)	0.75
Aortic valve hospitalization ^b	121 (18.9)	107 (18.2)	0.94
All-cause mortality, disabling stroke, or aortic valve hospitalization	241 (35.0)	197 (31.3)	0.48
Major vascular complication	32 (4.5)	28 (4.2)	0.82
Myocardial infarction	48 (7.5)	28 (4.8)	0.07
New permanent pacemaker implant ^{b,c}	198 (29.4)	79 (13.4)	<0.001
Atrial fibrillation ^b	124 (18.1)	283 (42.3)	<0.001
Valve endocarditis	9 (1.4)	18 (3.2)	0.04
Valve thrombosis	9 (1.4)	4 (0.6)	0.23
Clinical ^d	2 (0.3)	1 (0.2)	0.61
Subclinical ^e	7 (1.2)	3 (0.5)	0.27

Values are n (%): clinical outcomes are presented as n (Kaplan-Meier %) for the attempted implant cohort as prespecified in the statistical analysis plan. Results do not account for the competing risk of death. ^aVital status sweep included Centers for Medicare and Medicaid Services linkage and site reported status. ^bNot adjudicated by clinical events committee. ^cPatients with pacemaker or implantable cardioverter-defibrillator at baseline are not included. ^dDefined as any thrombus not caused by infection attached to or near the trial valve that occludes part of the blood flow path, interferes with valve function, or is sufficiently large to warrant treatment and is associated with any of the following clinical sequelae: any ischemic stroke, any peripheral embolic event, ST-segment elevation or non-ST-segment elevation myocardial infarction, or hemodynamic impairment associated with a worsening heart failure. ^eDefined as thrombus without evident clinical sequelae causing a hemodynamic impediment meeting the following criteria: increase in aortic regurgitation resulting in a severity of moderate or severe, a postdischarge mean gradient of ≥ 20 mm Hg that increased by $>50\%$, or a decrease in the Doppler Velocity Index by $>50\%$.

TAVR = transcatheter aortic valve replacement.

Resultados

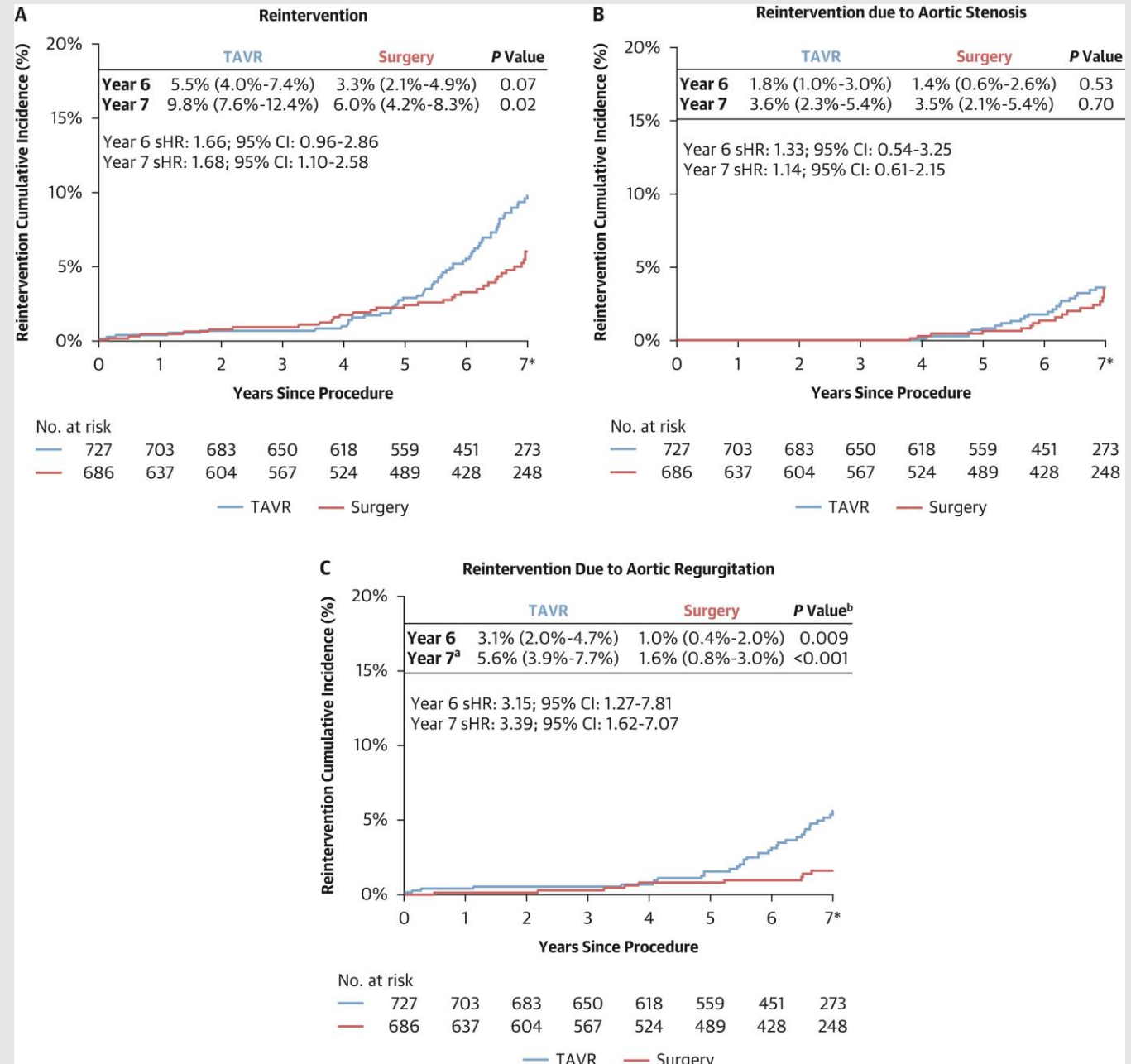
- Reintervenção valvar
6 anos

TAVI

5.5%

SAVR

3.3%



Resultados



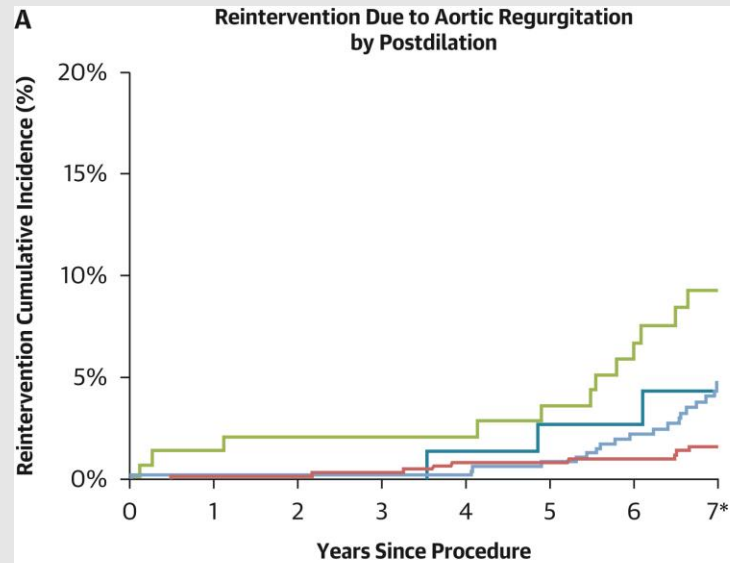
TABLE 2 Reintervention Estimates and Type Through 7 Years

	6 Years			7 Years ^a		
	TAVR	Surgery	HR or sHR (95% CI), P Value ^b	TAVR	Surgery	HR or sHR (95% CI), P Value ^b
Reintervention, rate						
Kaplan-Meier (prespecified)- attempted implant cohort ^c	730	684		730	684	
	38 (6.5) (4.6-9.0)	19 (3.6) (2.2-5.8)	1.76 (1.01-3.05), 0.04	61 (12.1) (8.9-16.2)	31 (7.1) (4.6-10.9)	1.77 (1.15-2.72), 0.009
Cumulative incidence with competing risk of death-implanted cohort ^c	727	686		727	686	
	37 (5.5) (4.0-7.4)	20 (3.3) (2.1-4.9)	1.66 (0.96-2.86), 0.07	60 (9.8) (7.6-12.4)	32 (6.0) (4.2-8.3)	1.68 (1.10-2.58), 0.02
Reintervention, type ^d						
Surgical	25/37 (67.6)	13/20 (65.0)		39/60 (65.0)	15/32 (46.9)	
Percutaneous	12/37 (32.4)	7/20 (35.0)		21/60 (35.0)	17/32 (53.1)	

Values are n, n (%) (95% CI), or n/N (%), unless otherwise indicated. Kaplan-Meier (KM) rates are presented as n (KM %) (95% CI) and reported in the attempted implant cohort. Cumulative incidence rates are presented as n (cumulative incidence %) (95% CI) and reported in the implanted cohort. Reintervention type is presented as n/N (simple proportion %). ^aFollow-up beyond 6 years is incomplete.

^bP value were calculated using log-rank test for KM estimates and Gray's test for cumulative incidence. ^cOne patient crossed treatment arms and had a reintervention. This patient was initially classified as attempted transcatheter aortic valve replacement (TAVR) implant but ultimately received a surgical valve and was included in the surgery implanted cohort. ^dOne patient who underwent both a surgical and percutaneous reintervention was classified based on the type of their first reintervention (transcatheter percutaneous).

Resultados

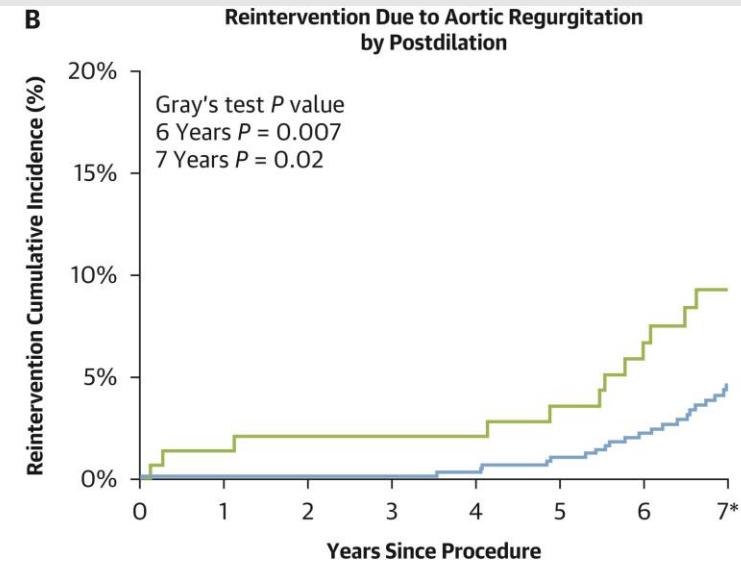


No. at risk

—	144	136	130	126	118	108	90	57
—	77	77	75	73	69	64	58	35
—	506	490	478	451	431	387	303	181
—	686	637	604	567	524	489	428	248

	Reintervention Cumulative Incidence	
	Year 6	Year 7*
— Off-Guid PD	6.7% (3.3%-11.8%) (9)	9.3% (5.0%-15.1%) (12)
— On-Guid PD	2.7% (0.5%-8.5%) (2)	4.3% (1.1%-11.1%) (3)
— No PD	2.2% (1.1%-3.8%) (10)	4.8% (2.9%-7.2%) (19)
— Surgery	1.0% (0.4%-2.0%) (6)	1.6% (0.8%-3.0%) (9)

Value represented as cumulative incidence % (95% CI) and (n).



No. at risk

—	144	136	130	126	118	108	90	57
—	583	567	553	524	500	451	361	216

	Reintervention Cumulative Incidence	
	Year 6	Year 7*
— Off-Guid PD	6.7% (3.3%-11.8%) (9)	9.3% (5.0%-15.1%) (12)
— All Other TAVR	2.2% (1.2%-3.8%) (12)	4.7% (3.0%-6.9%) (22)

Value represented as cumulative incidence % (95% CI) and (n).

Discussão

Principais achados:

- Desfechos clínicos semelhantes em 6 anos
- Mortalidade e AVC comparáveis
- Maior taxa de reintervenção no grupo TAVI
- Pós-dilatação

Limitações

- Seguimento **incompleto em 7 anos**
- **Ecocardiogramas não realizados no 6º ano**
- Desfechos além do endpoint primário pré-especificado
- **Análise observacional da pós-dilatação**
- Tipo de prótese cirúrgica não padronizado
- Impacto da **reintervenção em morbimortalidade ainda limitado**

Conclusão – Take-home messages

- TAVI e cirurgia apresentaram **desfechos clínicos semelhantes em 7 anos** em pacientes de **baixo risco cirúrgico**.
- Mortalidade, AVC incapacitante e reinternação ocorreram em taxas comparáveis entre as estratégias.
- TAVI manteve bom desempenho hemodinâmico valvar ao longo do seguimento.
- **Reintervenção valvar foi rara**, porém numericamente mais frequente após TAVI.
- Os resultados de 7 anos estendem os achados prévios do PARTNER 3, sustentando o uso de TAVI em pacientes selecionados de baixo risco.
- **Seguimento até 10 anos será fundamental** para avaliar definitivamente **durabilidade da prótese e impacto clínico tardio**.