TAVI vs SAVR in the low-risk population:

A question of Follow-Up?

Time is up! We should finally have the right follow-up setting for the TAVI/SAVR issue.

Alessandro Parolari MD PhD
President, Italian Society for Cardiac Surgery
Professor of Cardiac Surgery – University of Milano
Chief, Universitary Cardiac Surgery,
Policlinico San Donato IRCCS
Chair, INTEGRITTY Board

No disclosures

Aortic Valve Replacement outcomes

Data from the best-performing bioprosthesis versus mechanical valves

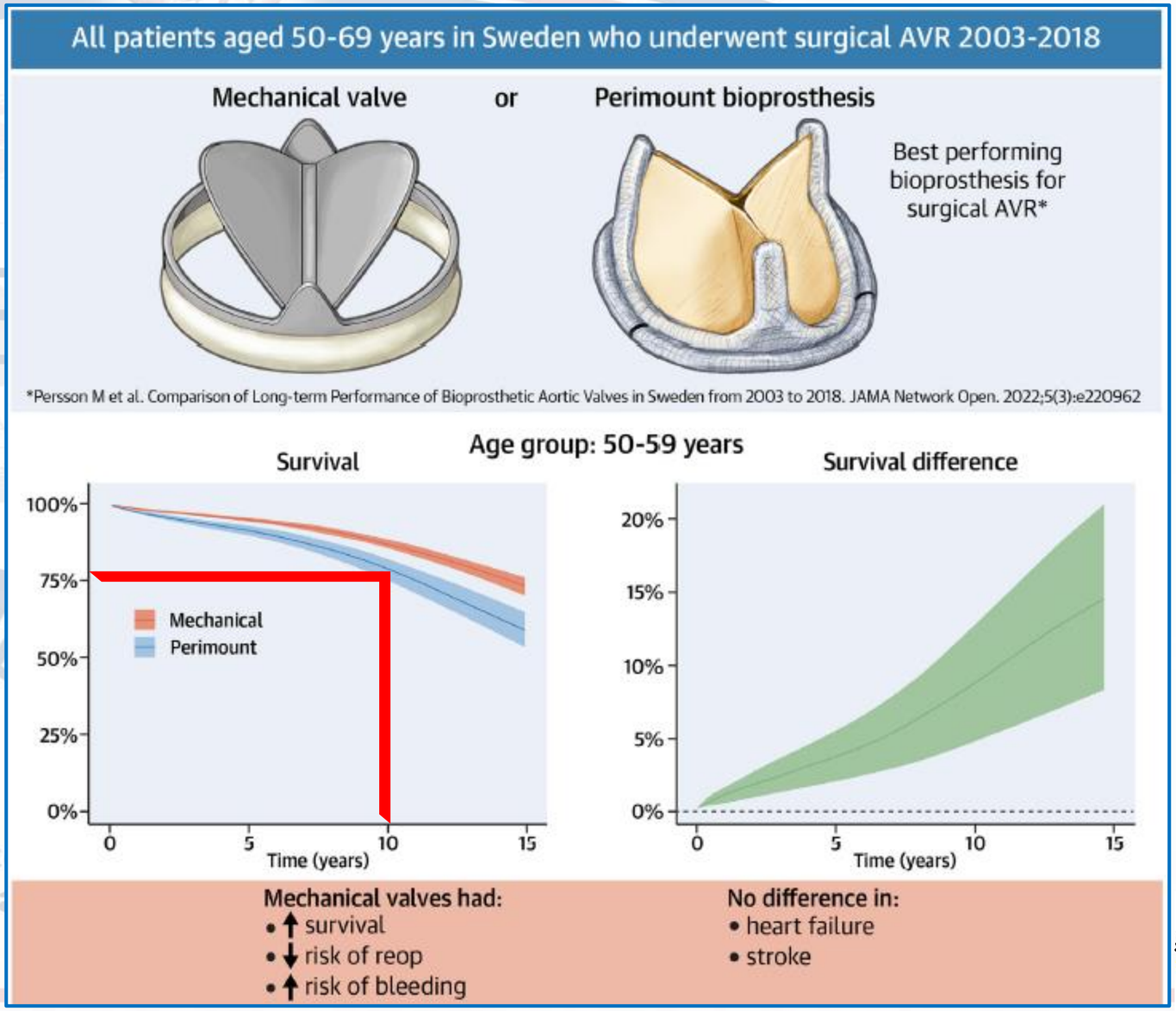
ORIGINAL RESEARCH

SURGERY

Aortic Valve Replacement With Mechanical Valves vs Perimount Bioprostheses in 50- to 69-Year-Old Patients

6907 patients enrolled:

- 3831 Perimount group
- 3076 mechanical group



Valve Durability

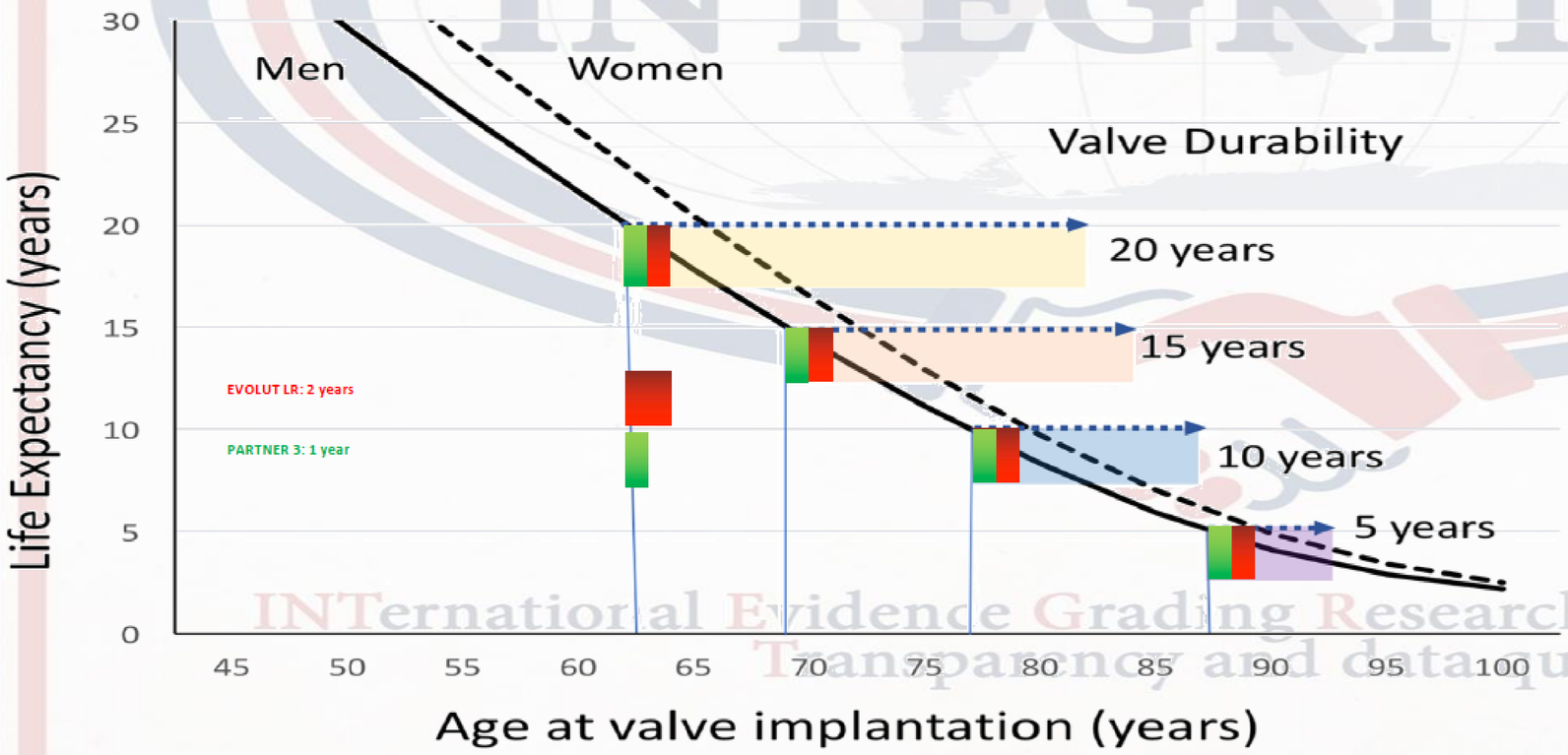
Life expectancy and durability should go hand-in-hand

Editorial > Heart. 2017 Nov;103(22):1756-1759. doi: 10.1136/heartjnl-2017-312348. Epub 2017 Sep 13.

Importance of the valve durability–life expectancy ratio in selection of a prosthetic aortic valve

Rodrigo Bagur [1 2 3], Philippe Pibarot [4], Catherine M Otto [5]

BIAS IN DESIGN: LONG-TERM OUTCOMES



Follow-up time needed

Age of the patients

Transcatheter aortic valve durability: a contemporary clinical review

Nicholas J. Montarello, Yannick Willemen, Gabriela Tirado-Conte, Alejandro Travieso, Gintautas Bieliauskas, Lars Sondergaard and Ole De Backer*

Transcatheter aortic bioprosthesis durability: data beyond 5 years

There is limited data pertaining to the long-term durability of TAVs predominantly due to their initial use in older and higher risk patients that often did not survive beyond 7 to 8 years (24).

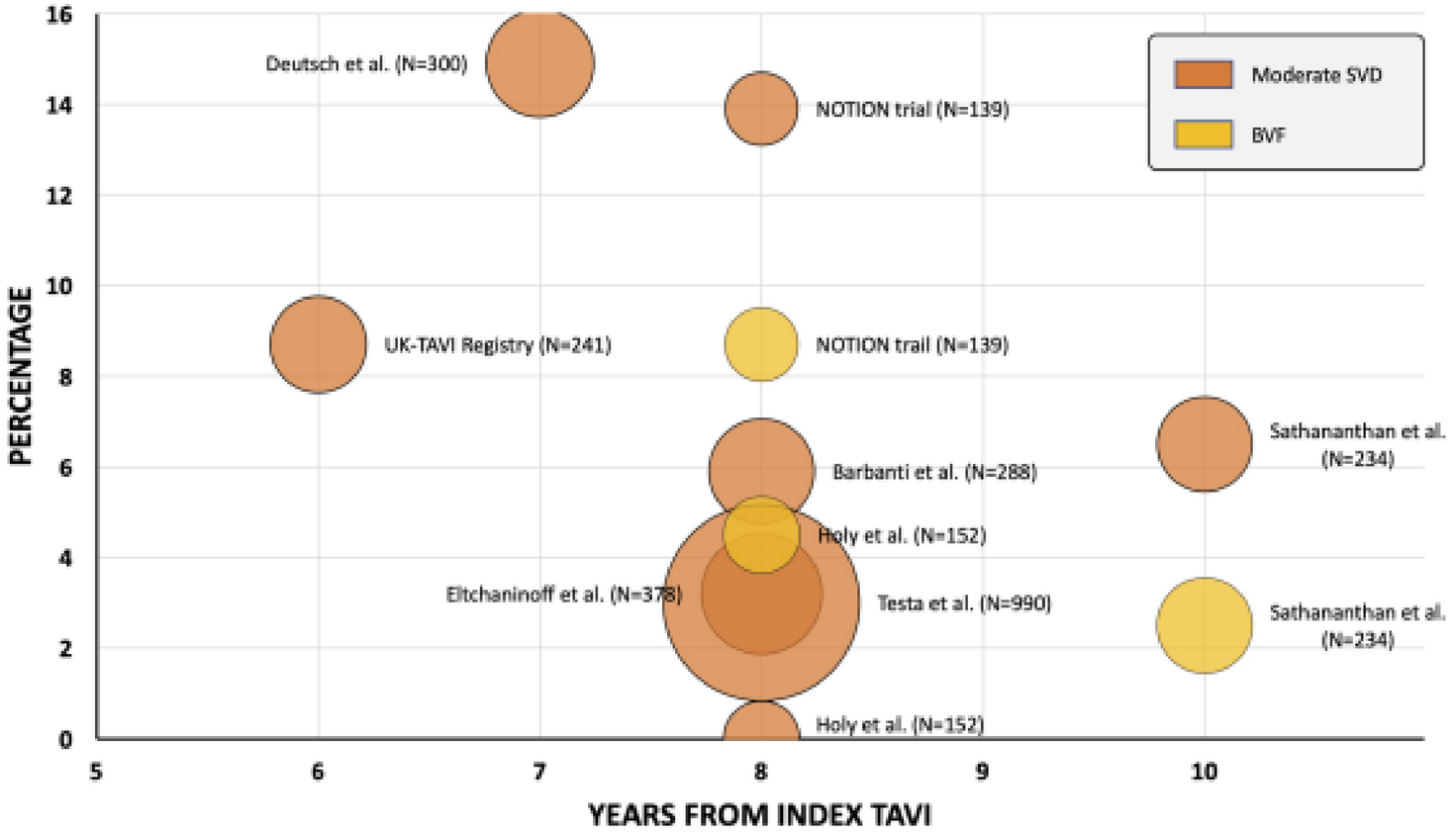


FIGURE 1
Transcatheter aortic valve freedom from moderate structural valve deterioration and bioprosthetic valve failure data—beyond 5 years. Orange = moderate structural valve deterioration; yellow = bioprosthetic valve failure. Bubble chart representative of study cohort size.TAV, transcatheter aortic valve; TAVI, transcatheter aortic valve replacement.

8 STUDIES CONSIDERED

TOTAL PTS STUDIED: 2718

AVERAGE PTS PER STUDY: 339,75

Data from Trials

NOTION 10 years

Patients aged 70 years or older with symptomatic severe AS were considered for inclusion.

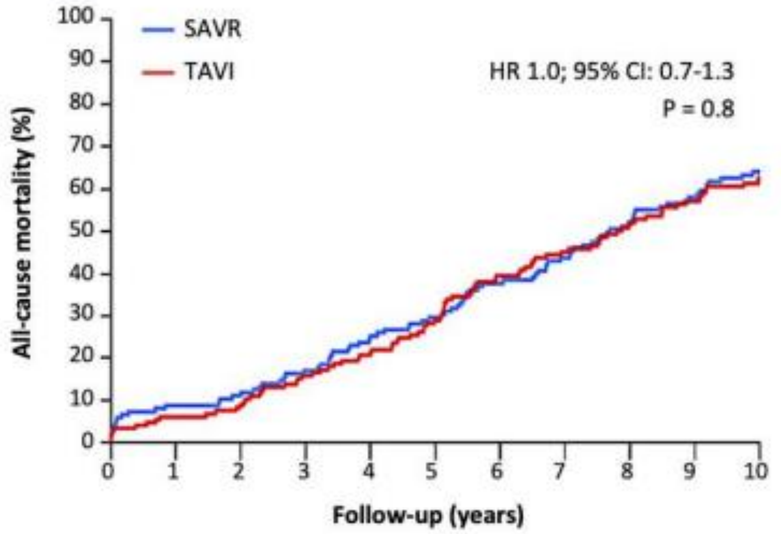
The trial randomized 280 patients to TAVI with the self-expanding bioprosthesis (n = 145) or SAVR with a bioprosthesis (n = 135)

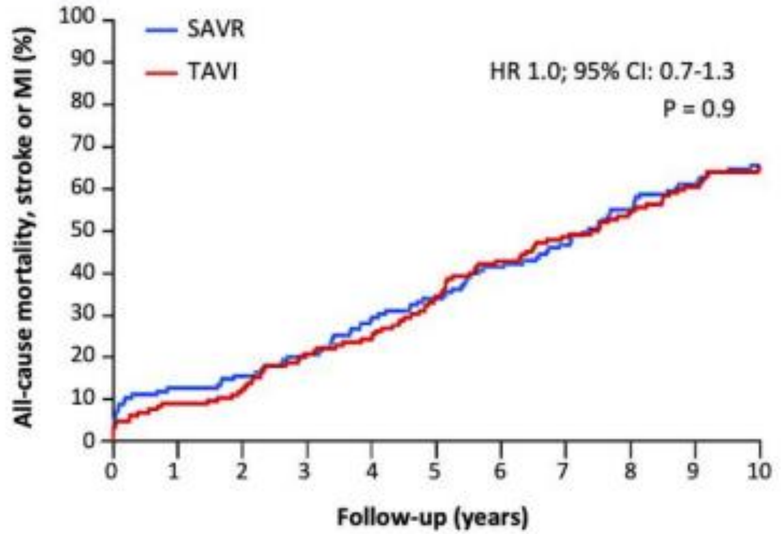
What does "lower risk" mean?

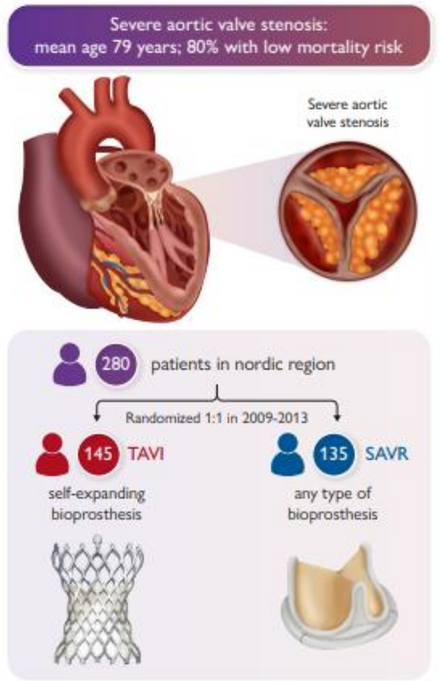
ESC European Society of Cardiology
European Heart Journal (2024) **45**, 1116–1124
https://doi.org/10.1093/eurheartj/ehae043
FASTTRACK CLINICAL RESEARCH
Interventional cardiology

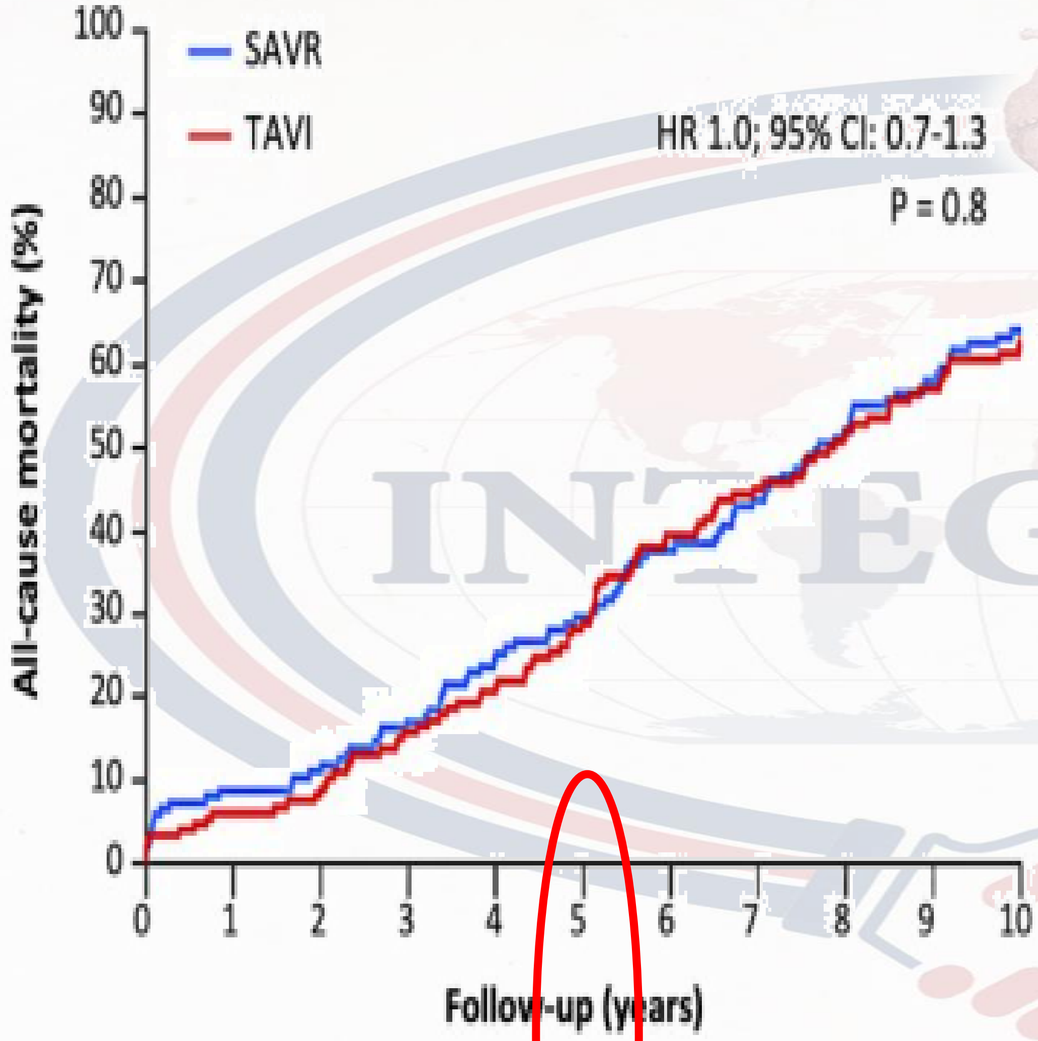
Transcatheter or surgical aortic valve implantation: 10-year outcomes of the NOTION trial

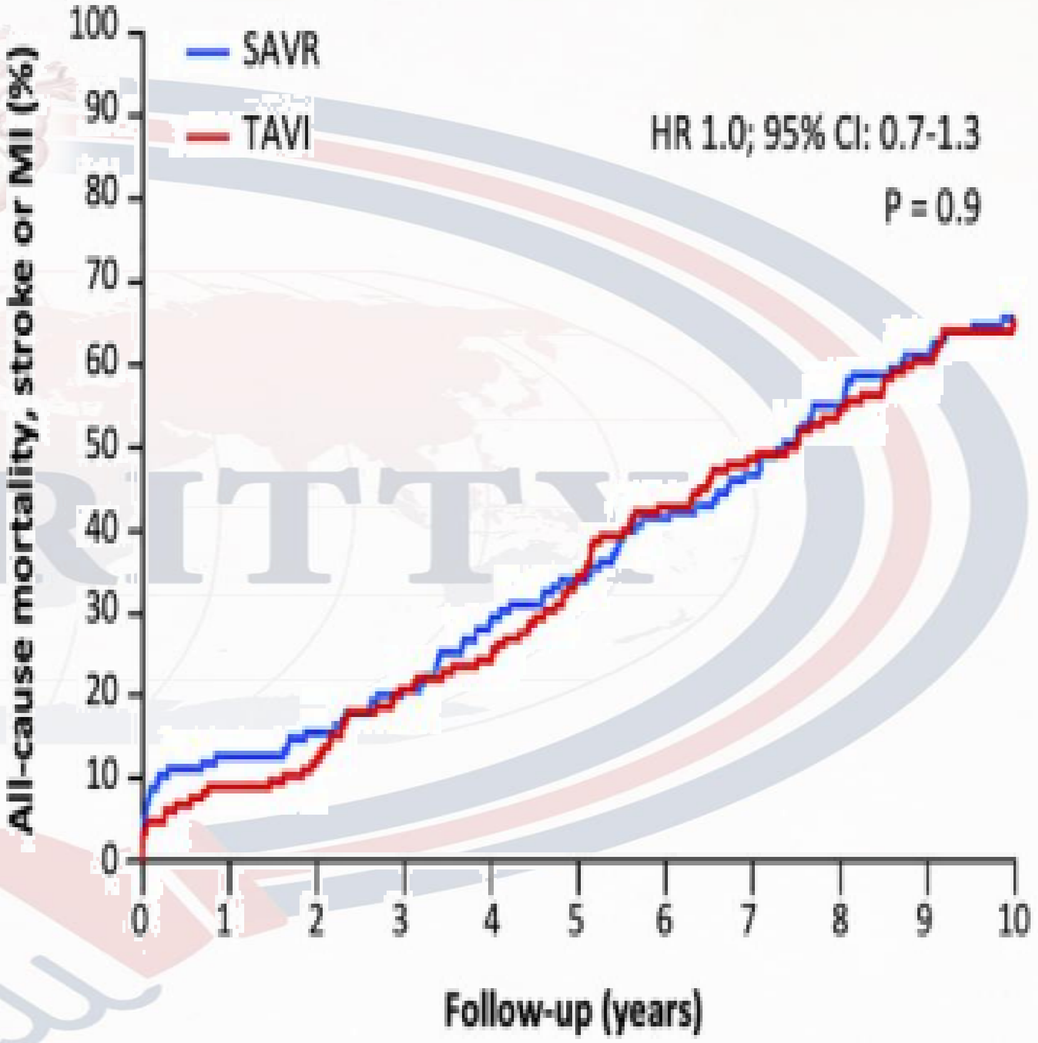
Hans Gustav Hørsted Thyregod [1]*†, Troels Højsgaard Jørgensen[2†], Nikolaj Ihlemann[3], Daniel Andreas Steinbrüchel[1‡], Henrik Nissen [4], Bo Juel Kjeldsen[5], Petur Petursson[6], Ole De Backer[2], Peter Skov Olsen[1], and Lars Søndergaard[2]











Patients at risk

TAVI	145	136	132	122	115	101	86	78	69	61	53
SAVR	135	123	120	112	102	95	83	75	64	56	48

Patients at risk

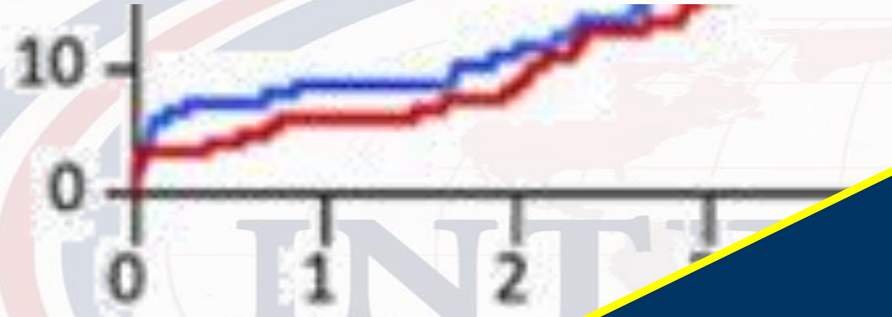
TAVI	145	133	128	116	110	93	81	73	65	56	49
SAVR	135	122	118	110	99	92	80	71	60	52	46

ESC European Society of Cardiology
European Heart Journal (2024) 45, 1116–1124
https://doi.org/10.1093/eurheartj/ehae043

FASTTRACK CLINICAL RESEARCH
Interventional cardiology

Transcatheter or sur… …tic valve implantation: 10-y… …es of the NOTION trial

Hans Gustav Hørst…
Nikolaj Ihlemann…
Bo Juel Kjelds…
and Lars S…
…Jørgensen[2†],
…k Nissen[4],
…er Skov Olsen[1],



Useless!!!

Patient…							
TAVI		101	86	78	69	61	53
SAVR	102	95	83	75	64	56	48

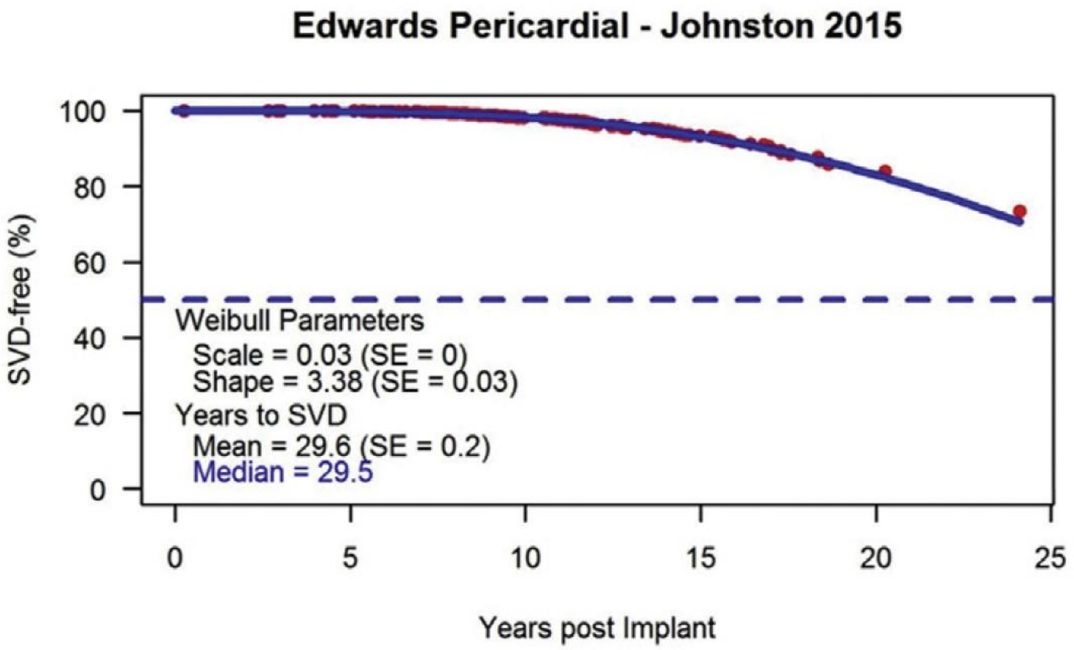
Valve Durability

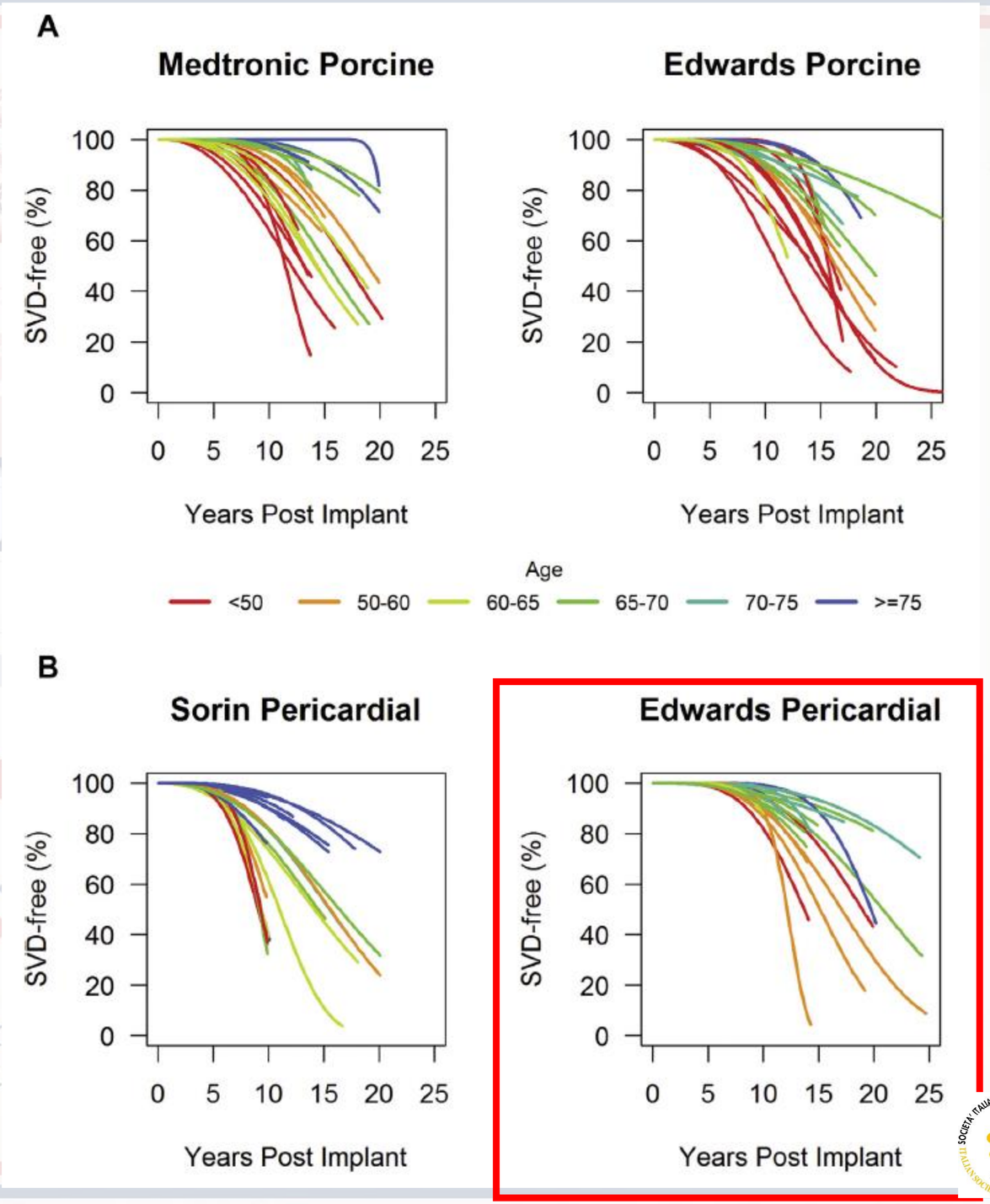
Choosing the right prosthesis matters

Review > Ann Thorac Surg. 2017 Sep;104(3):1080-1087. doi: 10.1016/j.athoracsur.2017.02.011. Epub 2017 May 9.

Bioprosthetic Aortic Valve Durability: A Meta-Regression of Published Studies

Mansen Wang [1], Anthony P Furnary [2], Hsin-Fang Li [3], Gary L Grunkemeier [3]





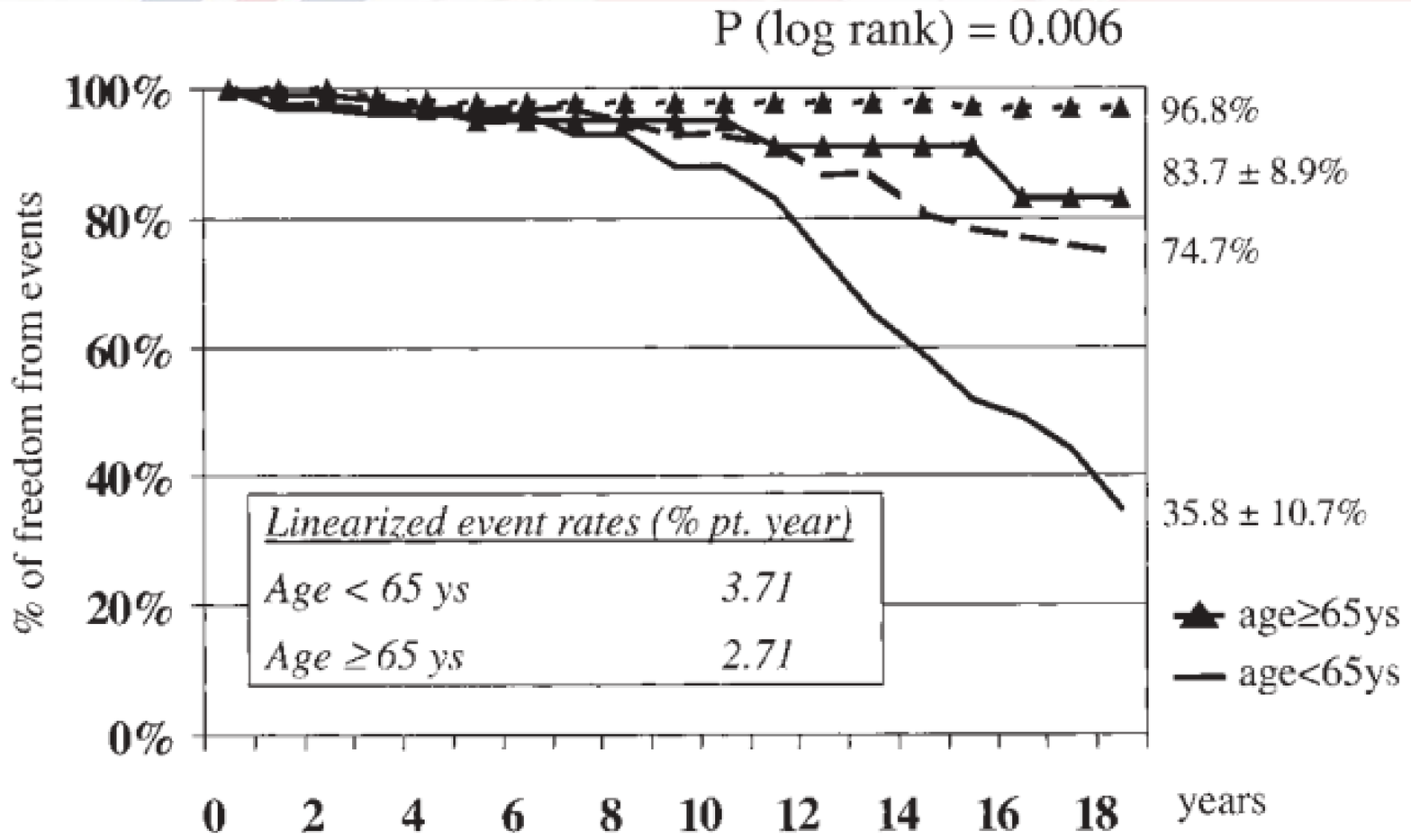
Valve Durability

The patients' age is a determinant factor

J Heart Valve Dis. 2004 May:13 Suppl 1:S49-51.

Long-term outcomes of the Carpentier-Edwards pericardial valve prosthesis in the aortic position: effect of patient age

Paolo Biglioli [1], Nicola Spampinato, Aldo Cannata, Antonino Musumeci, Alessandro Parolari, Cesare Gagliardi, Francesco Alamanni



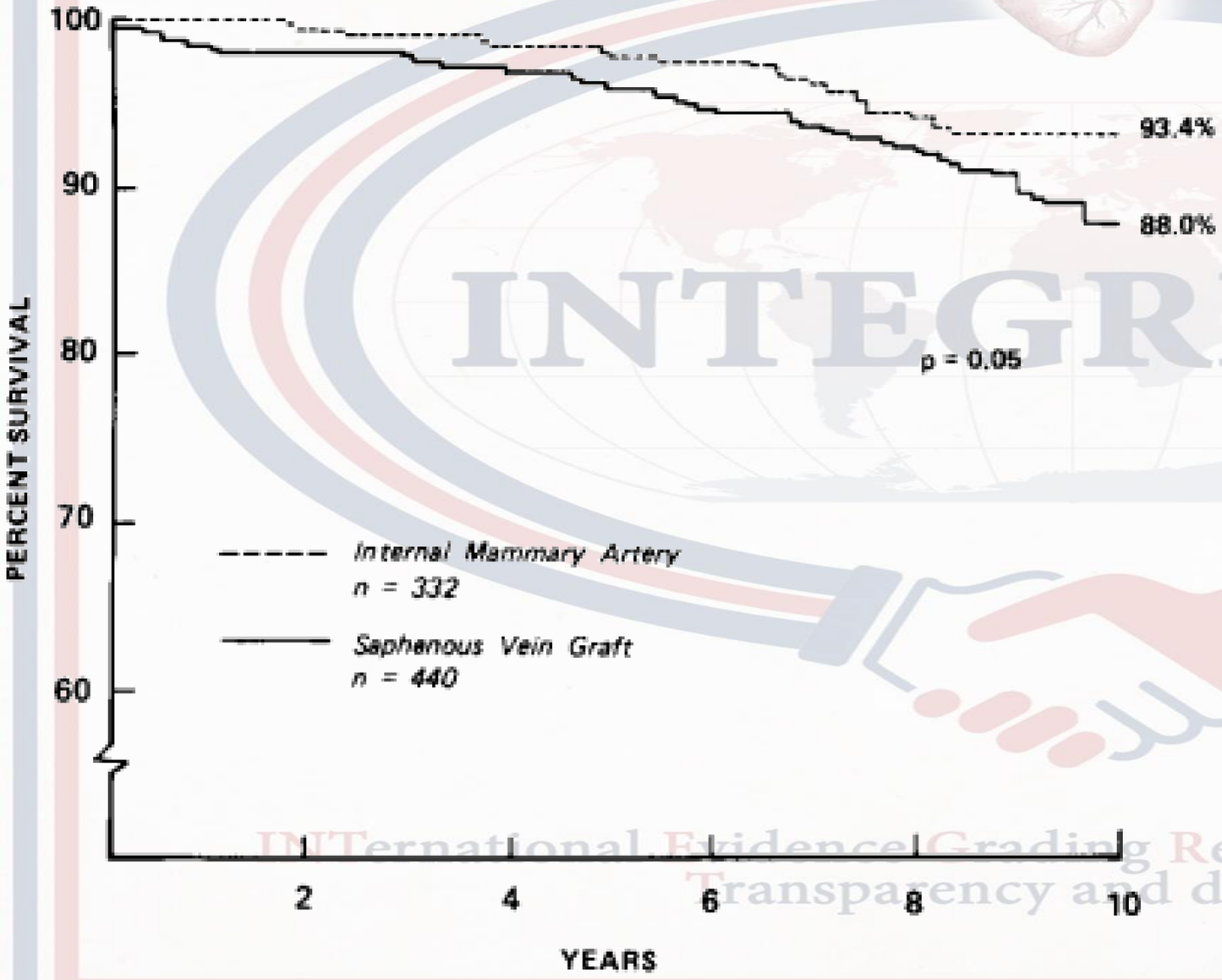
ALL THE OLD DATA IN THE GARBAGE?

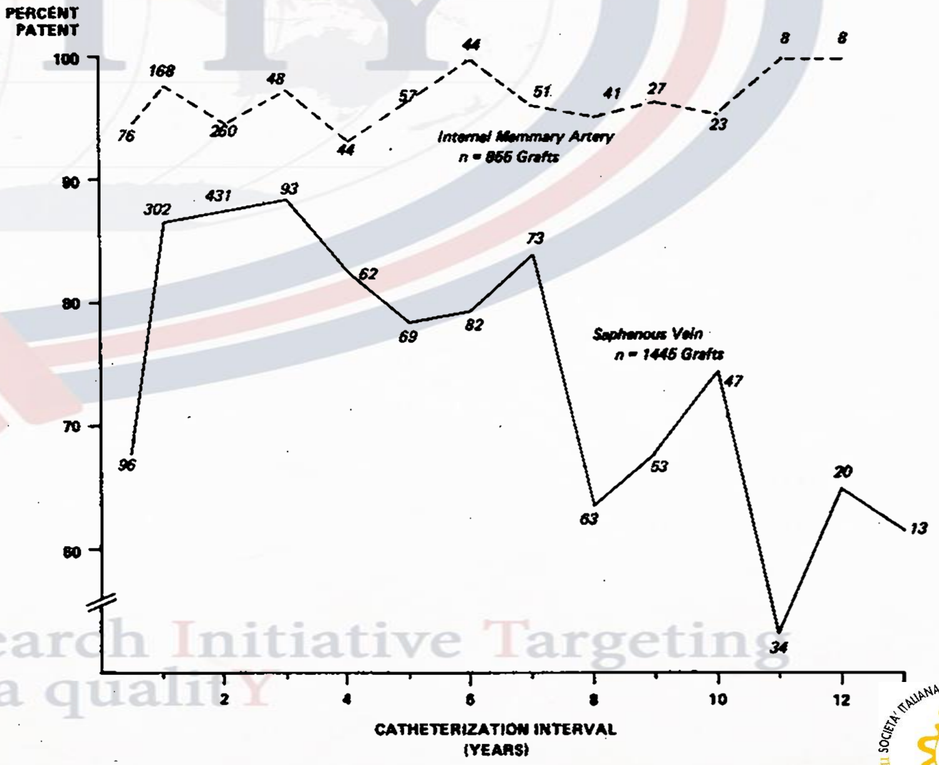
The New England
Journal of Medicine

Volume 314 JANUARY 2, 1986 Number 1

INFLUENCE OF THE INTERNAL-MAMMARY-ARTERY GRAFT ON 10-YEAR SURVIVAL AND OTHER CARDIAC EVENTS

FLOYD D. LOOP, M.D., BRUCE W. LYTLE, M.D., DELOS M. COSGROVE, M.D., ROBERT W. STEWART, M.D., MARLENE GOORMASTIC, M.P.H., GEORGE W. WILLIAMS, PH.D., LEONARD A.R. GOLDING, M.D., CARL C. GILL, M.D., PAUL C. TAYLOR, M.D., WILLIAM C. SHELDON, M.D., AND WILLIAM L. PROUDFIT, M.D.





Parachute use to prevent death and major trauma when jumping from aircraft: randomized controlled trial

Robert W Yeh,[1] Linda R Valsdottir,[1] Michael W Yeh,[2] Changyu Shen,[1] Daniel B Kramer,[1] Jordan B Strom,[1] Eric A Secemsky,[1] Joanne L Healy,[1] Robert M Domeier,[3] Dhruv S Kazi,[1] Brahmajee K Nallamothu[4] On behalf of the PARACHUTE Investigators

ABSTRACT

OBJECTIVE

To determine if using a parachute prevents death or major traumatic injury when jumping from an aircraft.

DESIGN

Randomized controlled trial.

SETTING

Private or commercial aircraft between September 2017 and August 2018.

PARTICIPANTS

92 aircraft passengers aged 18 and over were screened for participation. 23 agreed to be enrolled and were randomized.

INTERVENTION

Jumping from an aircraft (airplane or helicopter) with a parachute versus an empty backpack (unblinded).

MAIN OUTCOME MEASURES

Composite of death or major traumatic injury (defined by an Injury Severity Score over 15) upon impact with the ground measured immediately after landing.

RESULTS

Parachute use did not significantly reduce death or major injury (0% for parachute *v* 0% for control; P>0.9). This finding was consistent across multiple subgroups. Compared with individuals screened but not enrolled, participants included in the study were on aircraft at significantly lower altitude (mean of 0.6 m for participants *v* mean of 9146 m for non-participants; P<0.001) and lower velocity (mean of 0 km/h *v* mean of 800 km/h; P<0.001).

CONCLUSIONS

Parachute use did not reduce death or major traumatic injury when jumping from aircraft in the first randomized evaluation of this intervention. However, the trial was only able to enroll participants on small stationary aircraft on the ground, suggesting cautious extrapolation to high altitude jumps. When beliefs regarding the effectiveness of an intervention exist in the community, randomized trials might selectively enroll individuals with a lower perceived likelihood of benefit, thus diminishing the applicability of the results to clinical practice.

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the bmj | BMJ 2018;363:k5094 | doi: 10.1136/bmj.k5094

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Parachute use did not reduce death or major traumatic injury when jumping from aircraft in the first randomized evaluation of this intervention. However, the trial was only able to enroll participants on small stationary aircraft on the ground, suggesting cautious extrapolation to high altitude jumps.

Fig 2 | Representative study participant jumping from aircraft with an empty backpack. This individual did not incur death or major injury upon impact with the ground

ALL THE OLD DATA IN THE GARBAGE?

We only need relaible data on new devices !!!

The New England Journal of Medicine

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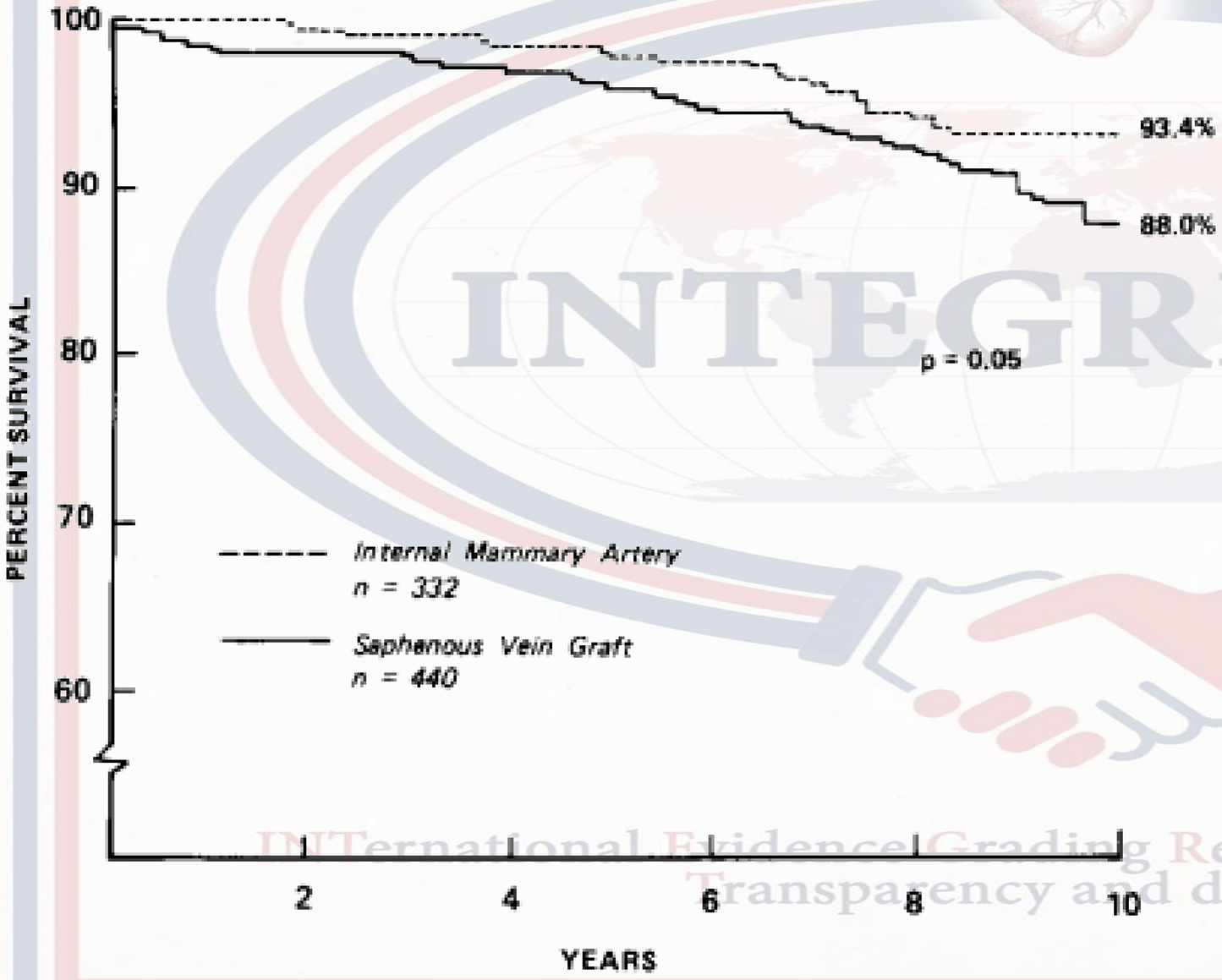
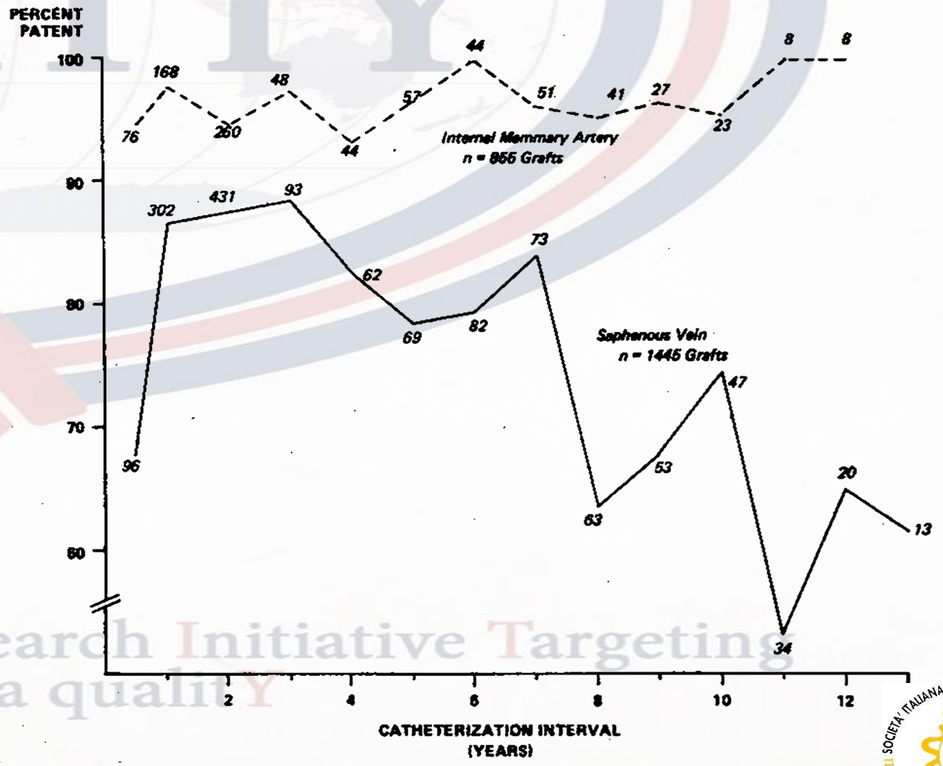
Volume 314 JANUARY 2, 1986 Number 1

INFLUENCE OF THE INTERNAL-MAMMARY-ARTERY GRAFT ON 10-YEAR SURVIVAL AND OTHER CARDIAC EVENTS

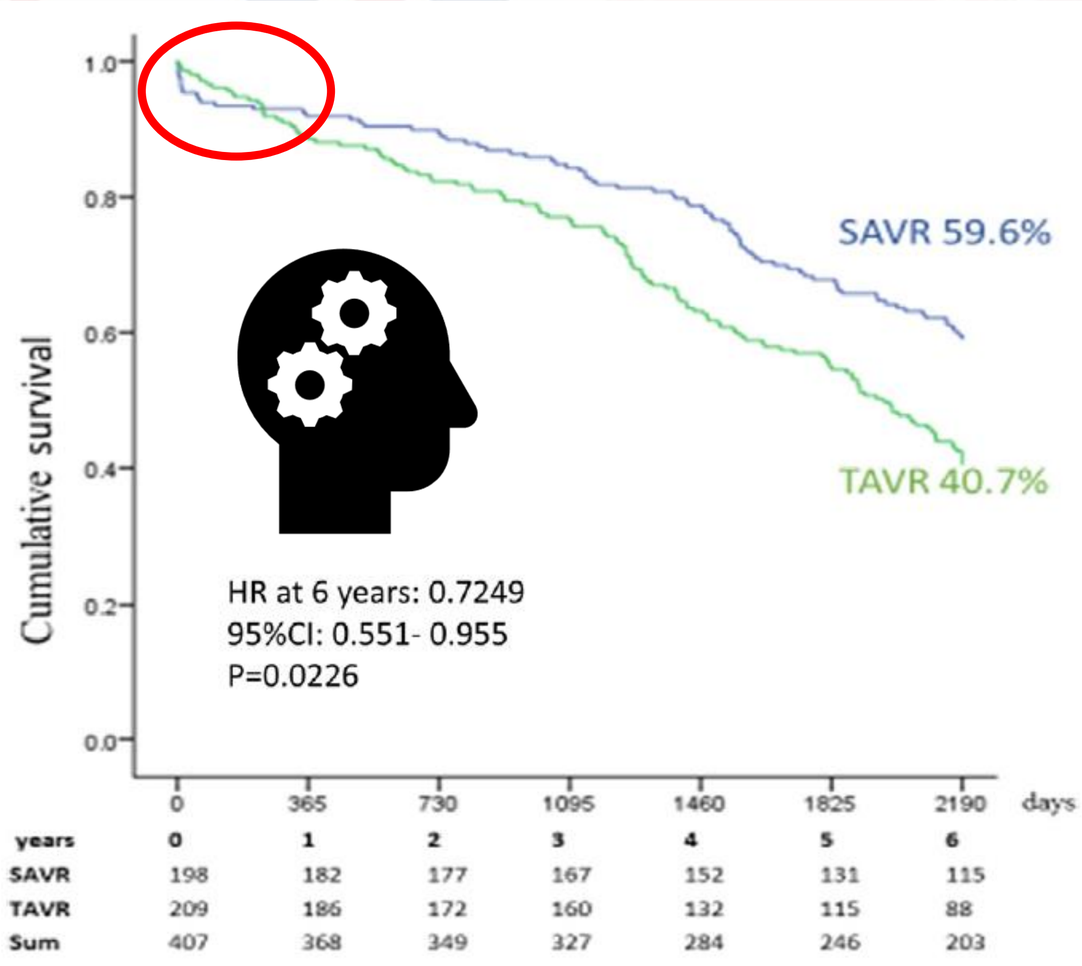
FLOYD D. LOOP, M.D., BRUCE W. LYTLE, M.D., DELOS M. COSGROVE, M.D., ROBERT W. STEWART, M.D., MARLENE GOORMASTIC, M.P.H., GEORGE W. WILLIAMS, PH.D., LEONARD A.R. GOLDING, M.D., CARL C. GILL, M.D., PAUL C. TAYLOR, M.D., WILLIAM C. SHELDON, M.D., AND WILLIAM L. PROUDFIT, M.D.





Are we playing the same match?

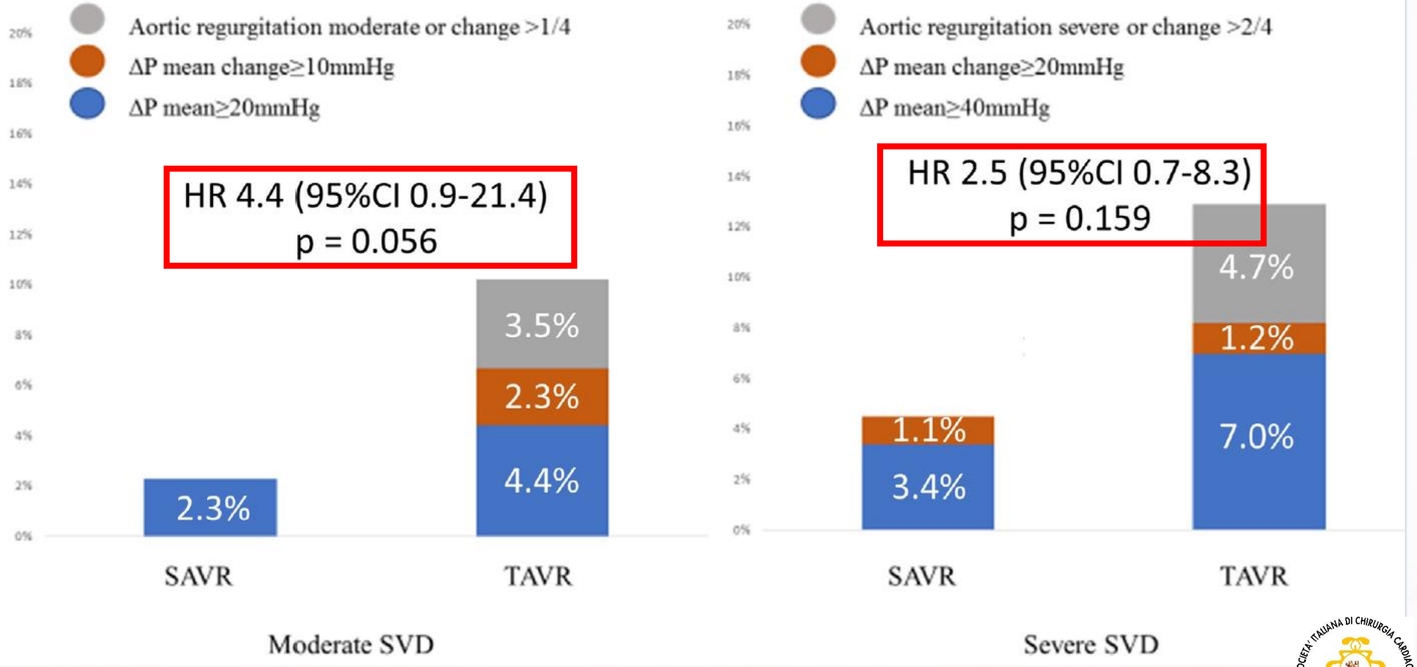
Long term outcomes from a PMS



Comparative Study > Am J Cardiol. 2020 Apr 15;125(8):1202-1208.
doi: 10.1016/j.amjcard.2020.01.015. Epub 2020 Jan 28.

Comparison of Valve Durability and Outcomes of Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement in Patients With Severe Symptomatic Aortic Stenosis and Less-Than-High-Risk for Surgery

Panagiotis Tzamalis [1], Sofia Alataki [2], Peter Bramlage [3], Claus Schmitt [2], Gerhard Schymik [2]

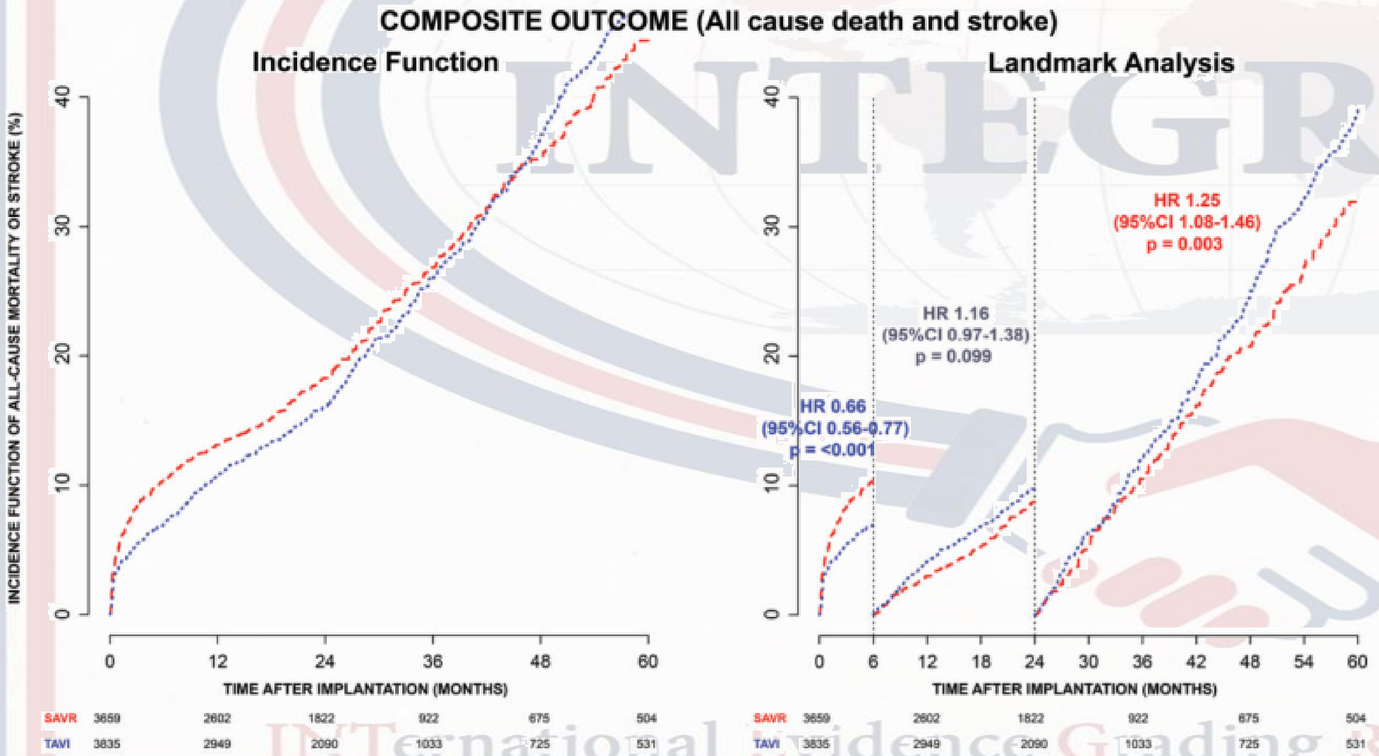


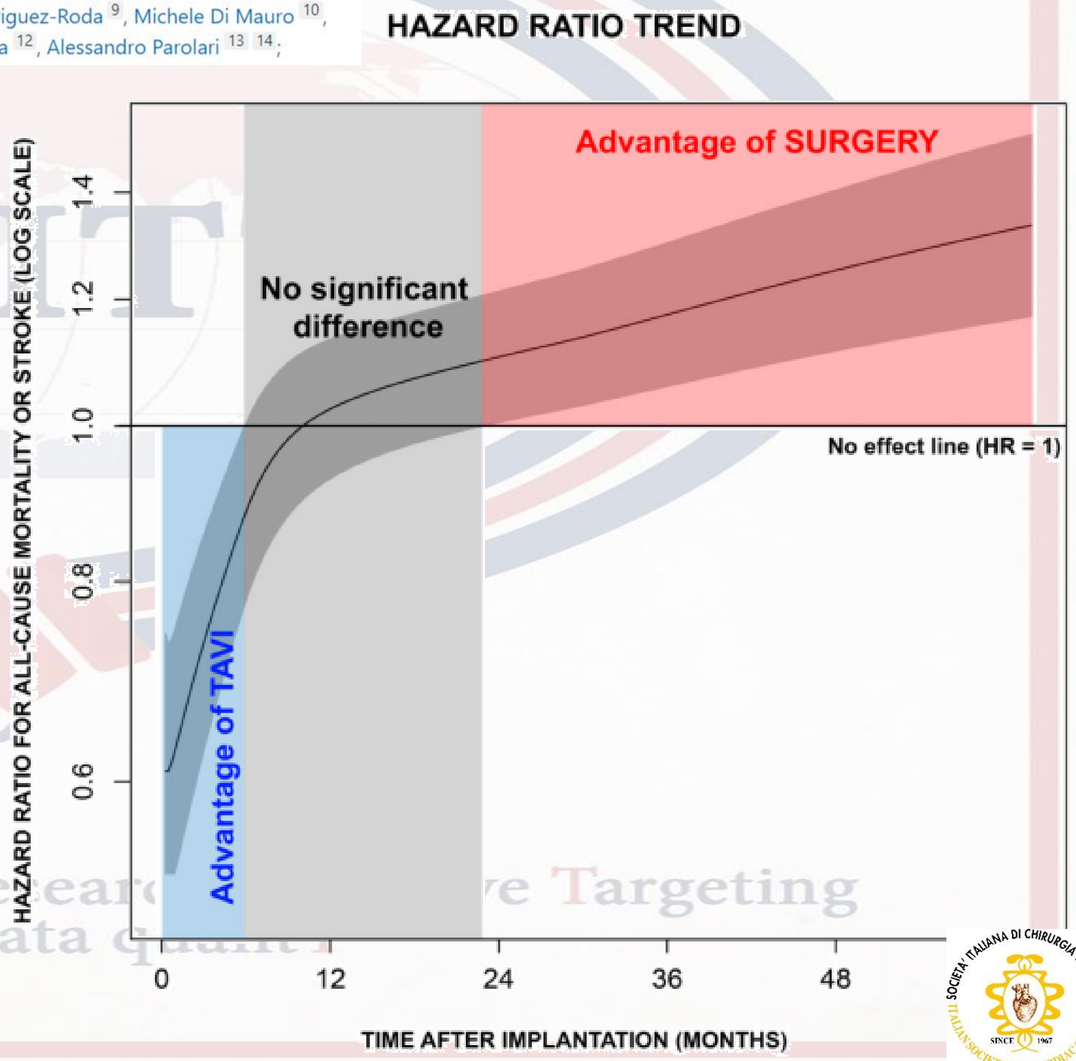
Data from INTEGRITTY

Meta-Analysis > Eur J Cardiothorac Surg. 2022 May 2;61(5):977-987. doi: 10.1093/ejcts/ezab516.

Five-year outcomes in trials comparing transcatheter aortic valve implantation versus surgical aortic valve replacement: a pooled meta-analysis of reconstructed time-to-event data

Fabio Barili [1 2], Nicholas Freemantle [3], Francesco Musumeci [4], Barbara Martin [5], Amedeo Anselmi [6], Mauro Rinaldi [7], Sanjay Kaul [8], Jorge Rodriguez-Roda [9], Michele Di Mauro [10], Thierry Folliguet [11], Jean-Philippe Verhoye [6], Miguel Sousa-Uva [12], Alessandro Parolari [13 14];

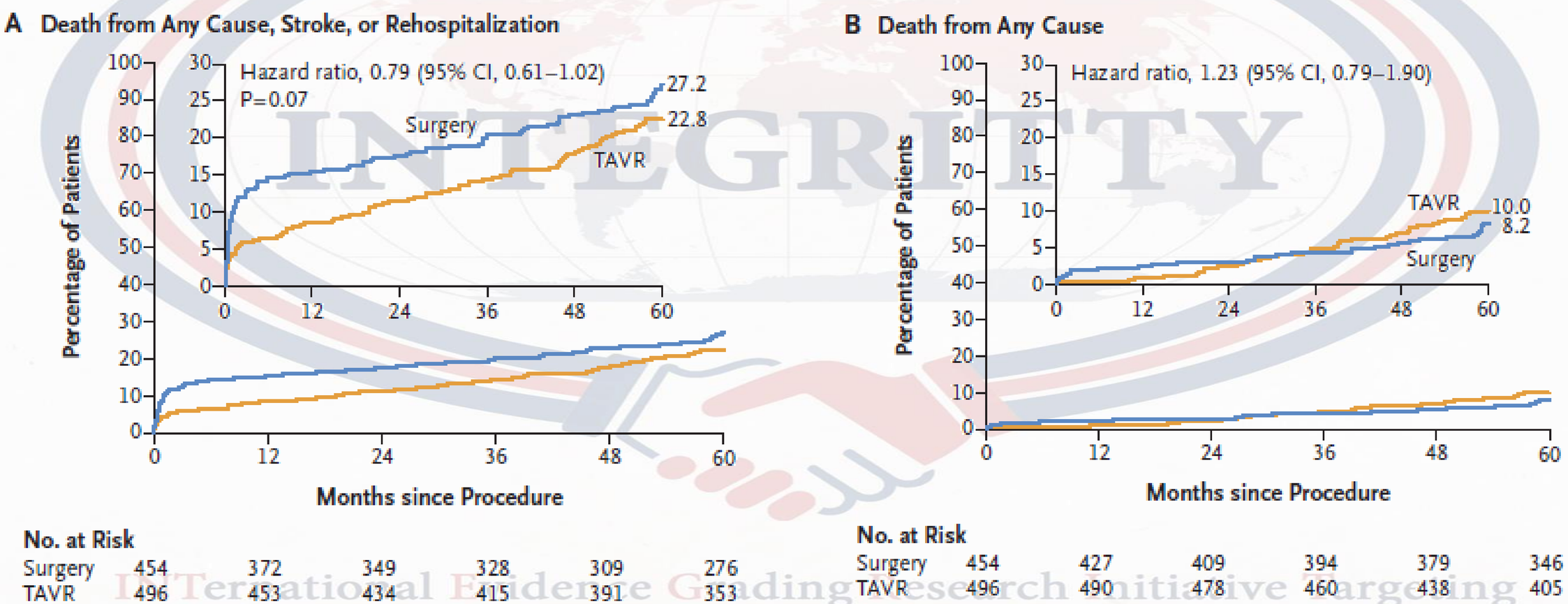




The trends are changing…

Randomized Controlled Trial > N Engl J Med. 2023 Nov 23;389(21):1949-1960.
doi: 10.1056/NEJMoa2307447. Epub 2023 Oct 24.

Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years



Time is of the essence

Landmark analysis in the PARTNER 3 cohort

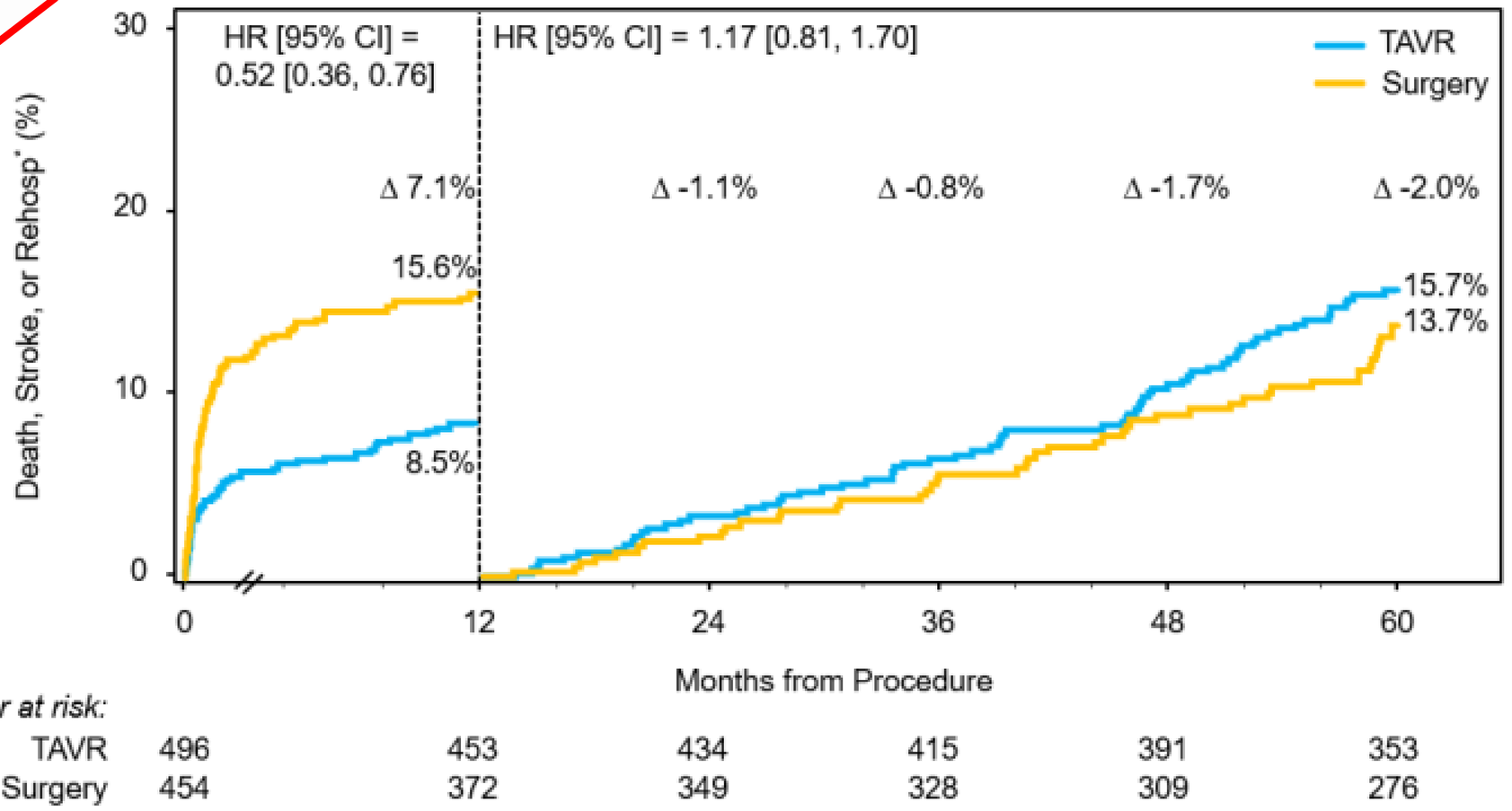
Randomized Controlled Trial > N Engl J Med. 2023 Nov 23;389(21):1949-1960.
doi: 10.1056/NEJMoa2307447. Epub 2023 Oct 24.

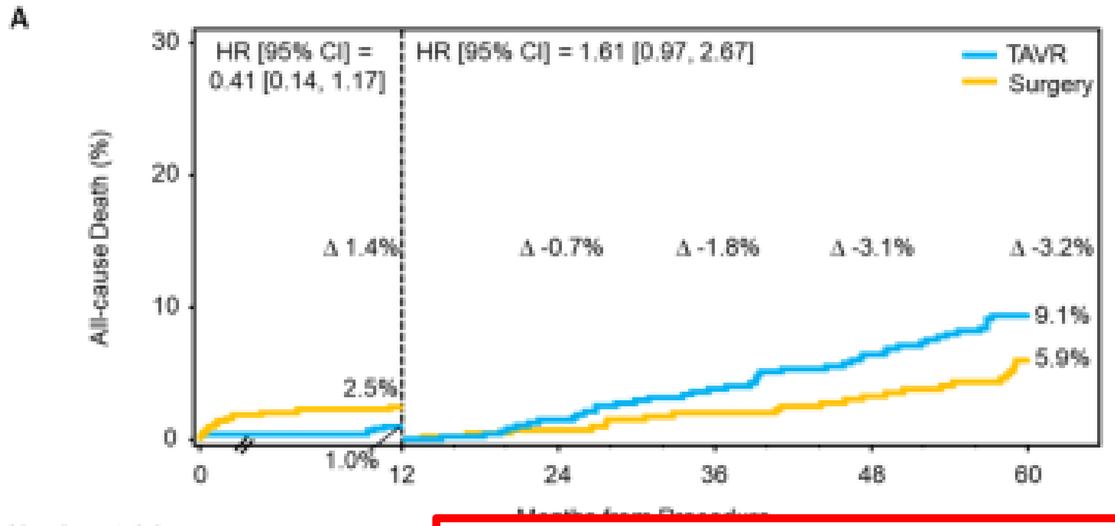
Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years

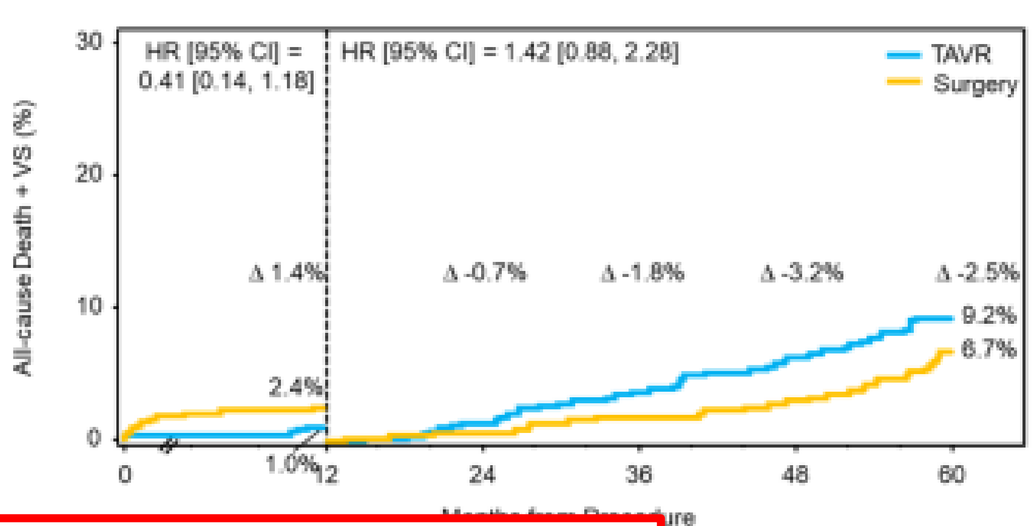
Supplementary Appendix

Supplement to: Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement in low-risk patients at five years. N Engl J Med 2023;389:1949-60. DOI: 10.1056/NEJMoa2307447

This appendix has been provided by the authors to give readers additional information about the work.







Number at risk:

TAVR	496	490			445	415
Surgery	454	427			404	378

Supplementary Appendix

Supplement to: Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement in low-risk patients at five years. N Engl J Med 2023;389:1949-60. DOI: 10.1056/NEJMoa2307447

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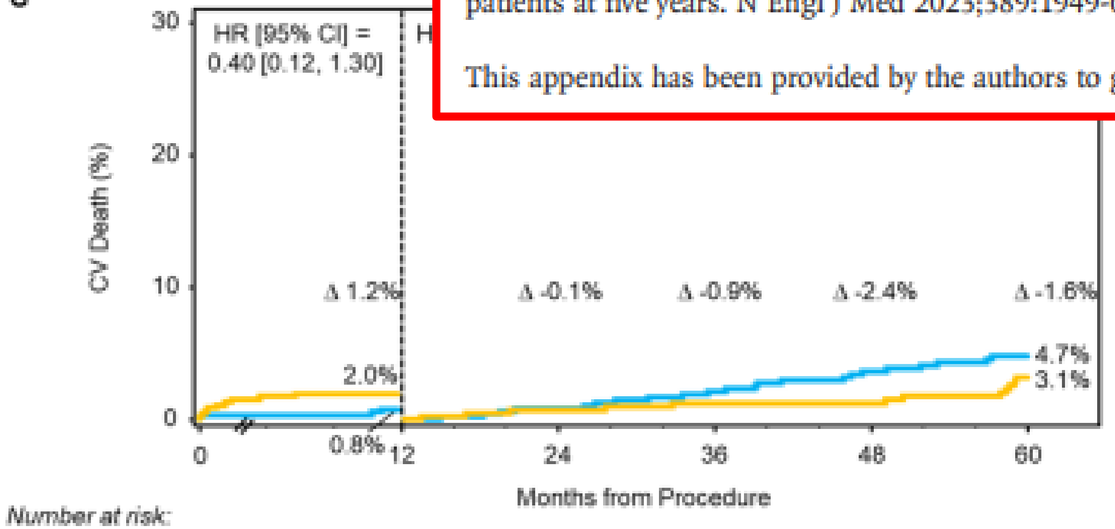
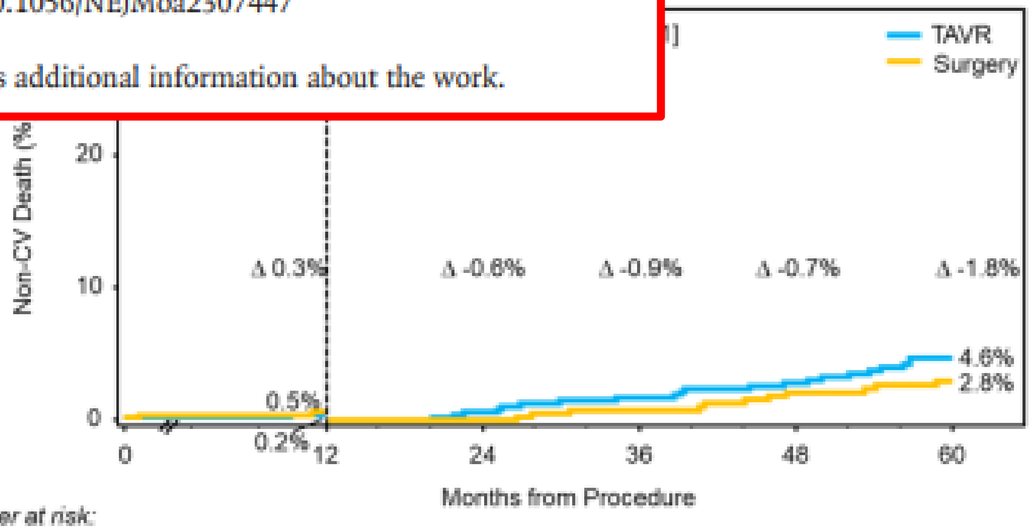


Number at risk:

TAVR	496	490	478	460	438	404
Surgery	454	427	409	394	379	346



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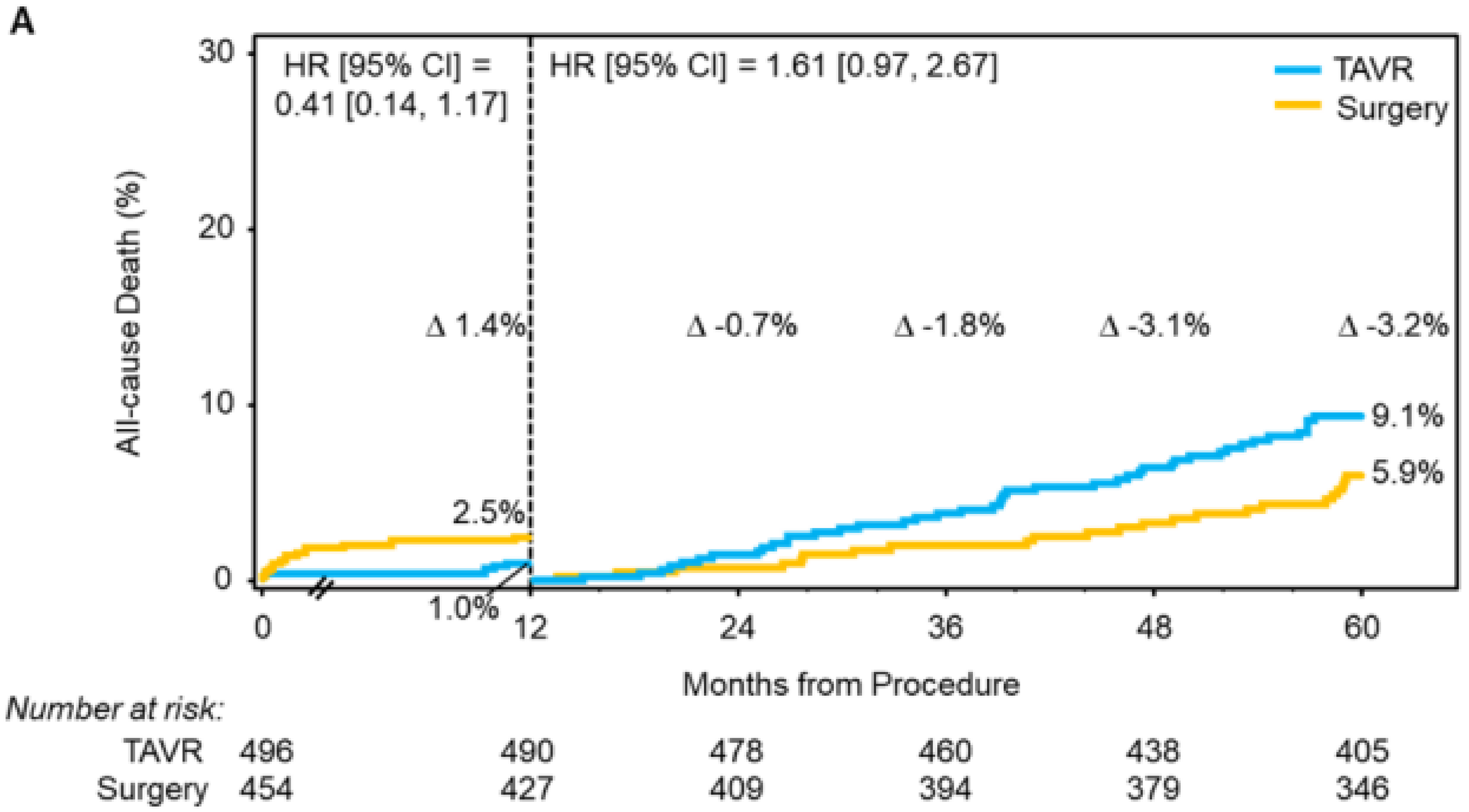

A
HR [95% CI] = 0.41 [0.14, 1.17]
HR [95% CI] = 1.61 [0.97, 2.67]
TAVR
Surgery
All-cause Death (%)
30
20
10
0
Δ 1.4%
Δ -0.7%
Δ -1.8%
Δ -3.1%
Δ -3.2%
9.1%
5.9%
2.5%
1.0%
0
12
24
36
48
60
Months from Procedure
Number at risk:
TAVR 496 490 478 460 438 405
Surgery 454 427 409 394 379 346

Data from Trials

Evolut Low Risk

Mean age was 74 years at time of enrollment: 5-10 year results should be expected…

The NEW ENGLAND JOURNAL of MEDICINE

SPECIALTIES TOPICS MULTIMEDIA CURRENT ISSUE LEARNING/CME AUTHOR CENTER PUBLICATIONS

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients

Authors: Jeffrey J. Popma, M.D., G. Michael Deeb, M.D., Steven J. Yakubov, M.D., Mubashir Mumtaz, M.D., Hemal Gada, M.D., Daniel O'Hair, M.D., Tanvir Bajwa, M.D., +24, for the Evolut Low Risk Trial Investigators* Author Info & Affiliations

Published March 16, 2019 | N Engl J Med 2019;380:1706-1715 | DOI: 10.1056/NEJMoa1816885

VOL. 380 NO. 18

Study Completion (Estimated)

2026-03

[…] primary end point, a composite of death or disabling stroke at 24 months […]

AND AFTER 2 YEARS???

Data from Trials

Some concerns…

JACC Journals › JACC › Archives › Vol. 82 No. 12

Previous

Concerns Regarding the Report of 3-Year Outcomes of the Evolut Low Risk Trial

FREE ACCESS

To The Editor

Fabio Barili, Amedeo Anselmi, William E. Boden, Miguel Sousa Uva, Alessandro Parolari, and on behalf of the International Evidence Grading Research Initiative Targeting Transparency and Quality (INTEGRITTY)

JACC. 2023 Sep, 82 (12) e101

NUMBER OF LOST AT FOLLOW-UP

!

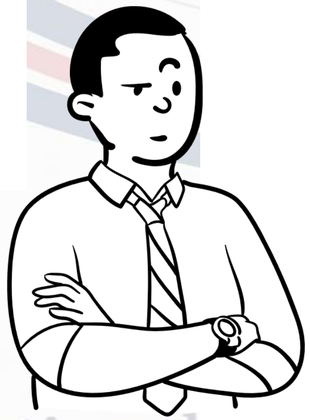
Data from Trials

Reluctancy in publishing long-term trial data

Letters

Research Letter

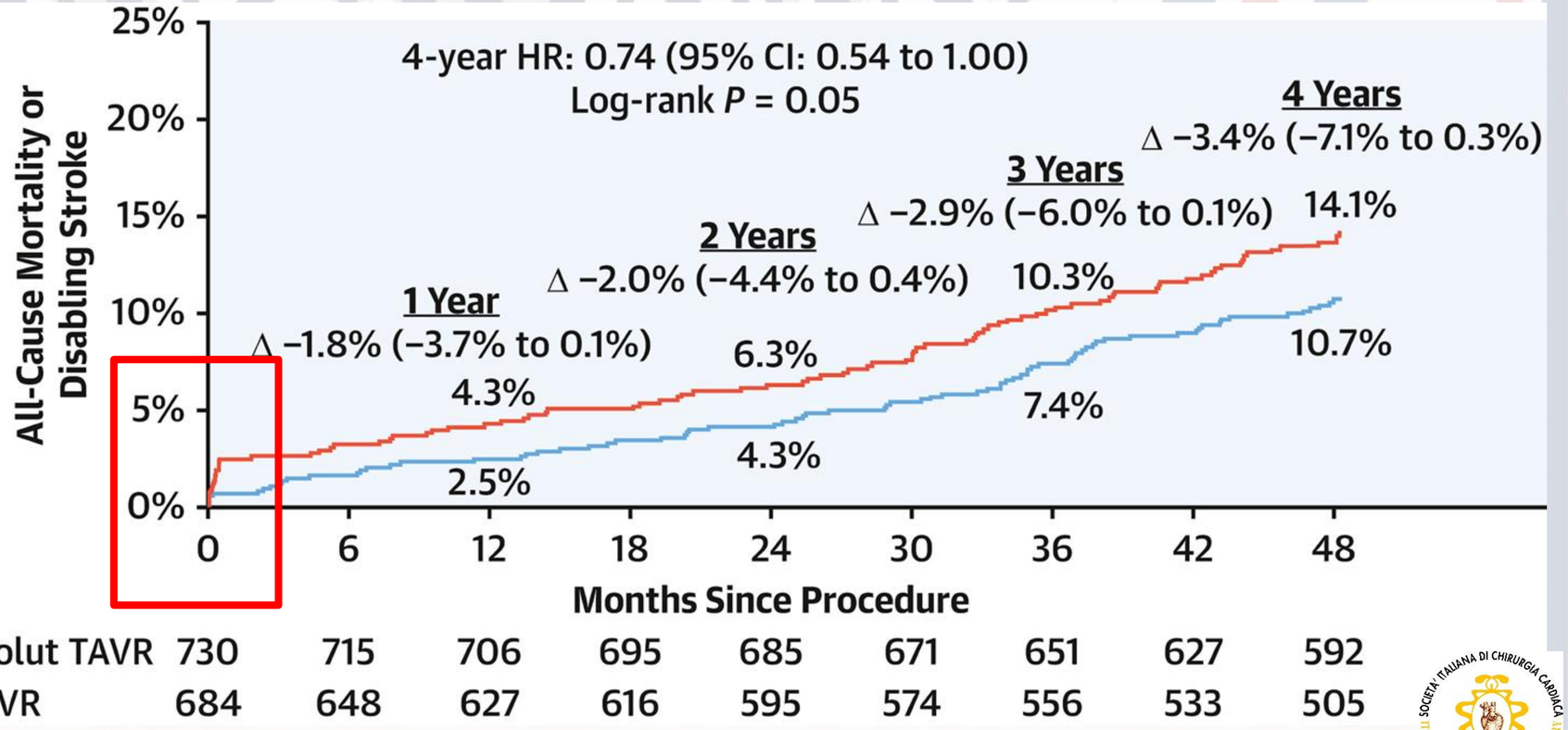
4-Year Ou
Aortic Ste
Trial



J Am Coll Cardiol. 2023 Nov 28;82(22):2163-2165. doi: 10.1016/j.jacc.2023.09.813.
Epub 2023 Oct 24.

4-Year Outcomes of Patients With Aortic Stenosis in the Evolut Low Risk Trial

John K Forrest [1], G Michael Deeb [2], Steven J Yakubov [3], Hemal Gada [4], Mubashir A Mumtaz [4], Basel Ramlawi [5], Tanvir Bajwa [6], Paul S Teirstein [7], Didier Tchétché [8], Jian Huang [9], Michael J Reardon [10]; Evolut Low Risk Trial Investigators



The latest data

Cardiac Surgery after Transcatheter Aortic Valve Replacement: *Trends and Outcomes*

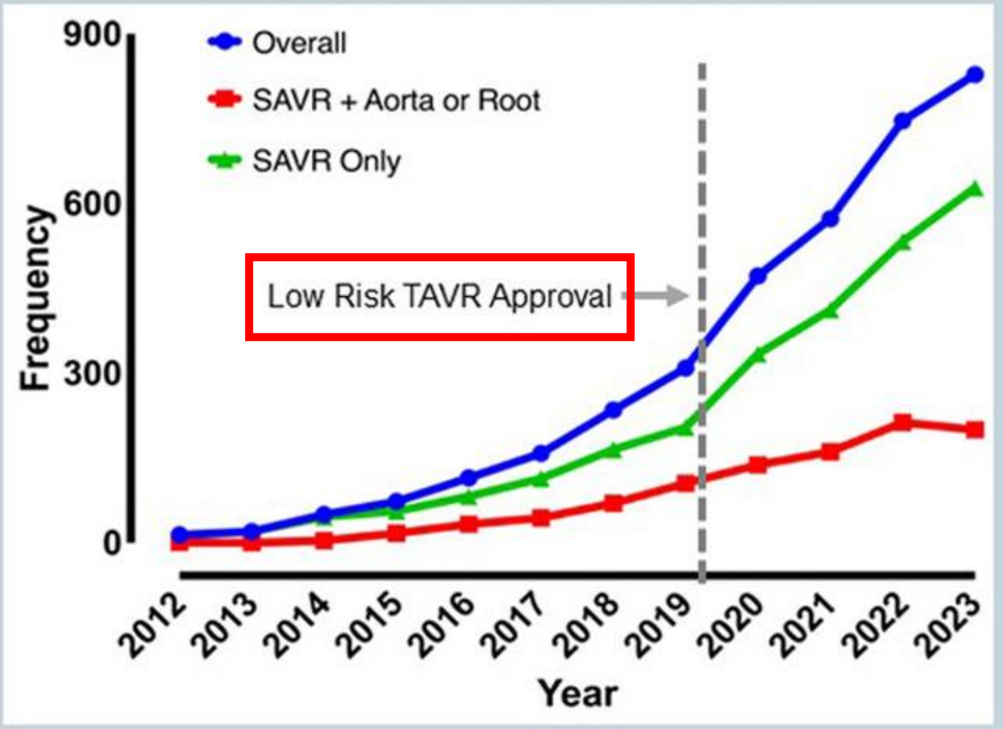
5,457 Operations after TAVR
2,972 (54.5%) SAVR
2,485 (45.5%) non-SAVR

STS Adult Cardiac Surgery Database 2012 to 2023

Stroke 4.5%
Mortality 15.5%

Marked increase in TAVR Explant and SAVR since Low Risk TAVR Approval

SAVR AFTER TAVR



SAVR after TAVR is the fastest growing adult cardiac operation

THE ANNALS OF THORACIC SURGERY
Official Journal of The Society of Thoracic Surgeons and the Southern Thoracic Surgical Association

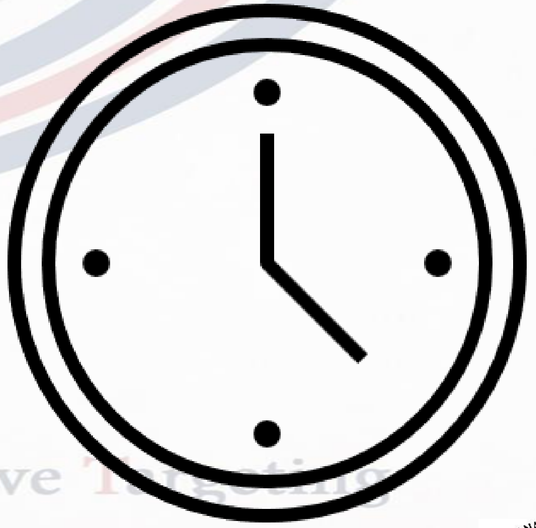
145% increase per year of cardiac surgery after TAVR

Bowdish ME et al, 2024

#VisualAbstract #AnnalsImages
@annalsthorsurg

Conclusions

- **Follow-up data should be adequately reported.**
- **Much longer follow-up data with an adequate number of patients reaching longer FUPs are eagerly expected.**
- **The literature so far seems to favor SAVR in younger patients**
  - The short-term benefit of TAVR is clear especially in the elderly and higher risk patients.
- **More transparency in the setting of sponsored studies is warranted, although practically not reasonable.**
- **New studies should address new prostheses.**
- **A rising issue will be cardiac surgery post-TAVI.**



The race has started, but how will it end?

INTernational Evidence Grading Research Initiative Targeting
Transparency and data qualitY

INTernational Evidence Grading Research Initiative Targeting
Transparency and data qualitY

In the world of CAD

Things seem different in the world of CABG vs PCI

Performance

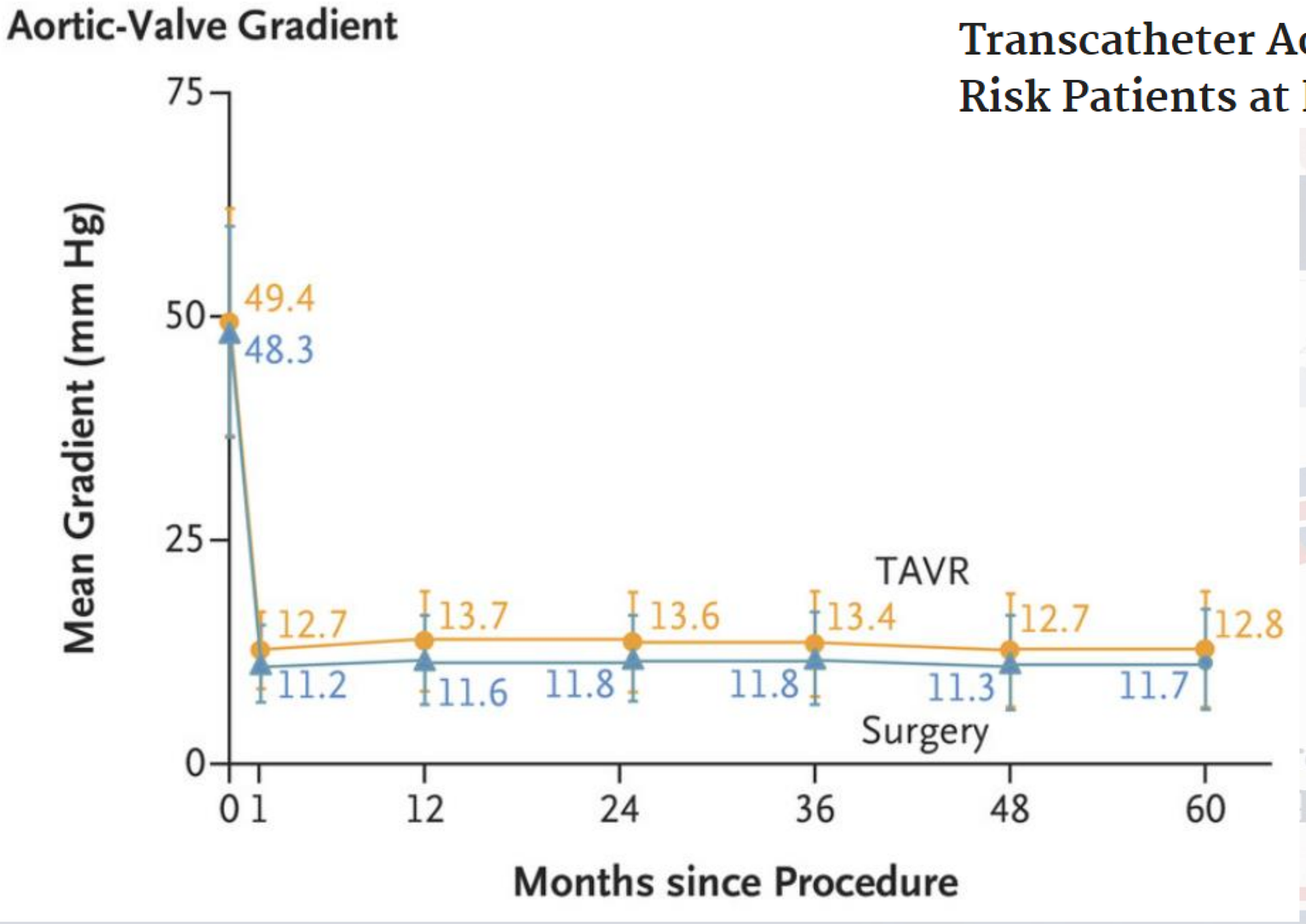
Not all valves are the same…

Performance comparison

Data from the PARTNER III Cohort

Randomized Controlled Trial > N Engl J Med. 2023 Nov 23;389(21):1949-1960.
doi: 10.1056/NEJMoa2307447. Epub 2023 Oct 24.

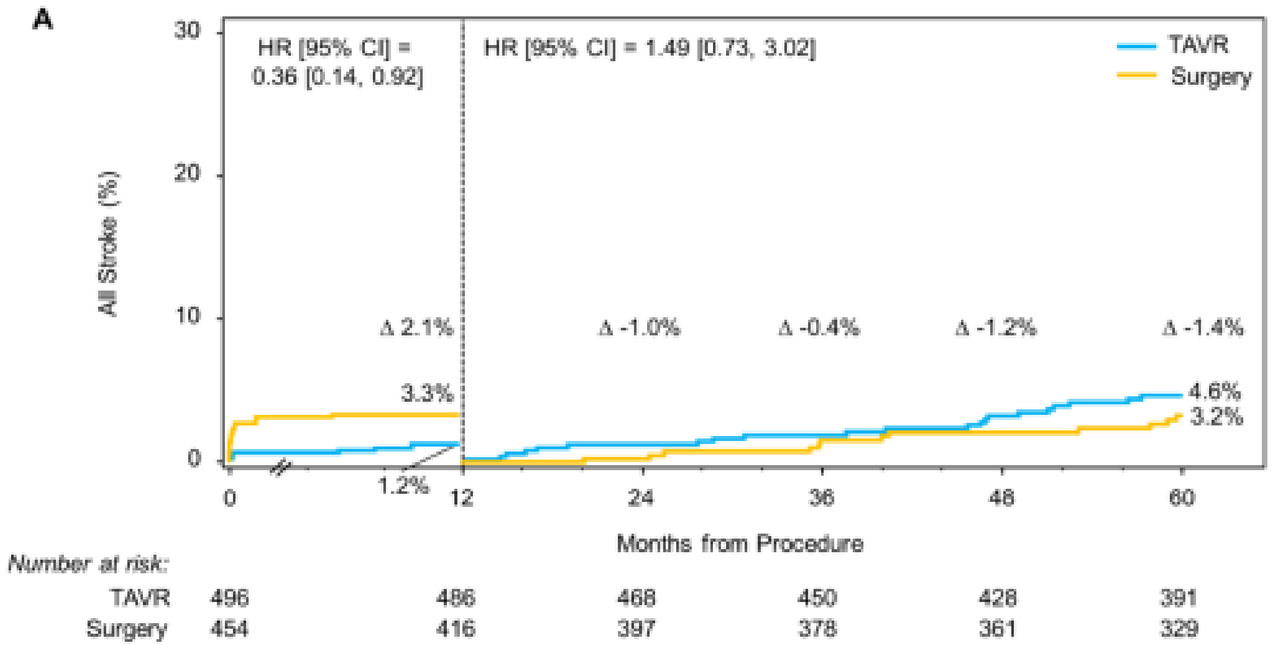
Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years

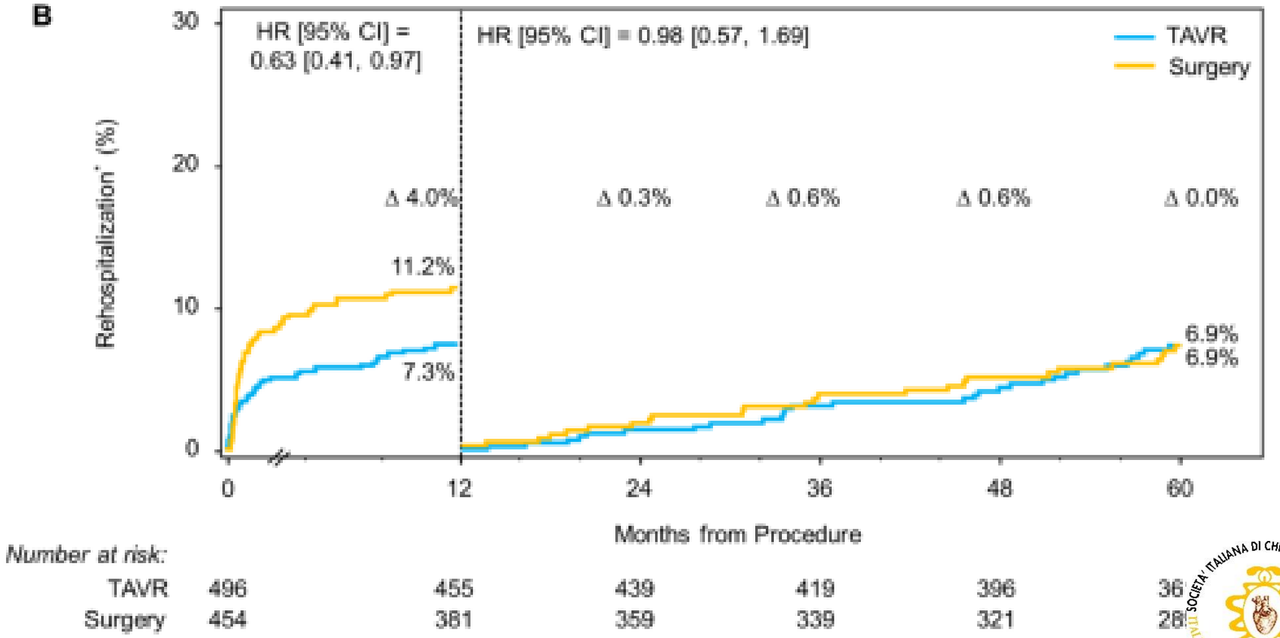


Supplementary Appendix

Supplement to: Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement in low-risk patients at five years. N Engl J Med 2023;389:1949-60. DOI: 10.1056/NEJMoa2307447

This appendix has been provided by the authors to give readers additional information about the work.





Data from RCT

Even RCTs designed to promote TAVI cannot compete…

Review > Methodist Debakey Cardiovasc J. 2023 May 16;19(3):15-25. doi: 10.14797/mdcvj.1201. eCollection 2023.

Transcatheter Aortic Valve Implantation: Long-Term Outcomes and Durability

Parth V Desai [1], Sachin S Goel [2], Neal S Kleiman [2], Michael J Reardon [2]

PARTNER 3*[17] (Mean STS 1.9%)	2021	N = 950 496 TAVI 454 SAVR	BE SAPIEN 3 (Edwards)	73	69	99% TAVI 93.8% SAVR	*At 2 years, TAVI vs SAVR: • All-cause death, stroke, or rehospitalization (11.5% vs 17.4%, ss) • Death or Disabling stroke (3% vs 3.8%, ns) • Rehospitalization (8.5% vs 12.5%, ss) • Valve thrombosis (VARC-2) (2.6% vs 0.7%, ss) • Mild PVR (26% vs 2.3%, ss)
Evolut Low risk trial**[18] (Mean STS 1.9%)	2023	N = 1414 730 TAVI 684 SAVR	SE CoreValve (3.6%) Evolut R (74.1%) Evolut PRO (22.3%) (Medtronic)	74	65	97.3% TAVI 92.3% SAVR	**At 3 years, TAVI vs SAVR: • All-cause death or disabling stroke (7.4% vs 10.4%, ns) • All-cause death (3.5% vs 4.4%, ns) • Disabling stroke (1.5% vs 2.7%, ns) • Mild PVR (21.3% vs 2.7%, ss) • New PPI (23.2% vs 9.1%, ss)