TAVR/SAVR u pacientů s nízkým rizikem:
LIMITACE TAVR

Aortální patologie – máme společný cíl

24. sympozium PS CHLOPENNÍ A VROZENÉ VADY V DOSPLĚLOSTI

Jan Vojáček

Kardiochirurgická klinika FN a LV v Hradci Králové

2022: a year of milestones

20th Anniversary of TAVI (FIM)

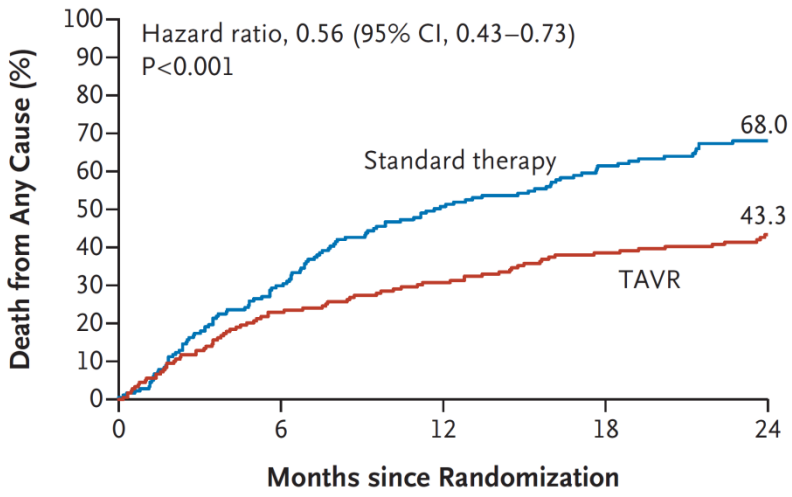
15th Anniversary of comnercial approval in Europe

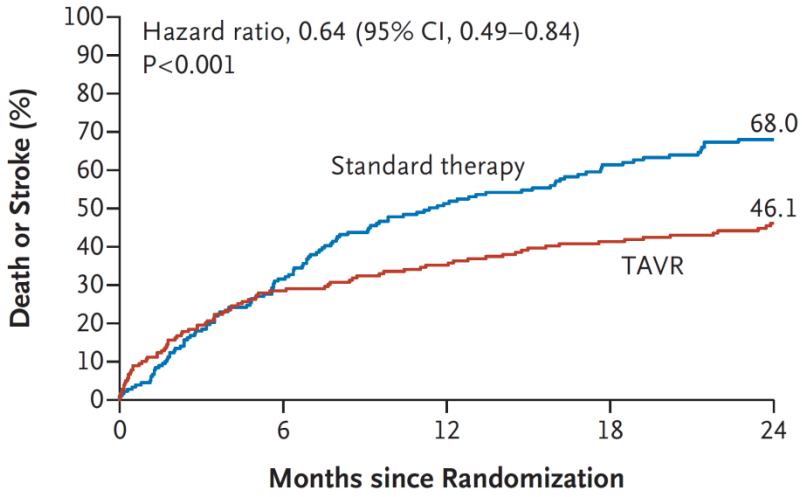
10th Anniversary of comnercial approval in the US

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Aortic-Valve Replacement for Inoperable Severe Aortic Stenosis



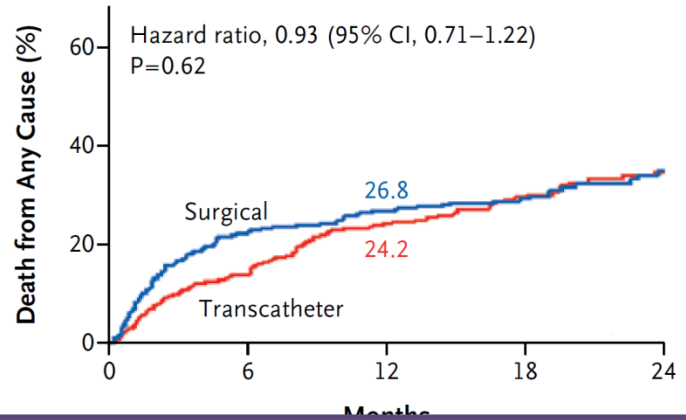


The NEW ENGLAND JOURNAL of MEDICINE

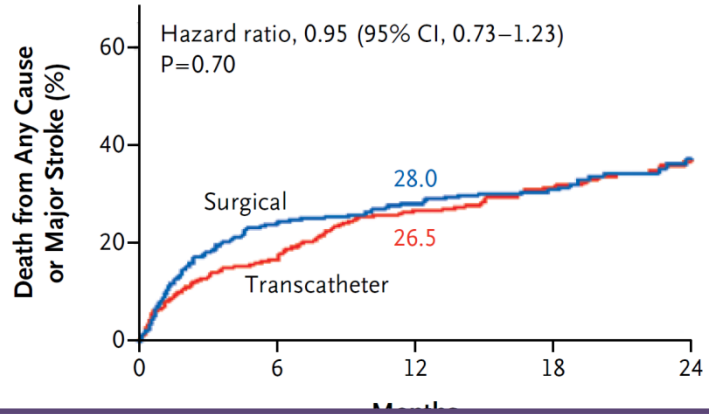
ESTABLISHED IN 1812 JUNE 9, 2011 VOL. 364 NO. 23

Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients

A Death from Any Cause, All Patients



D Death from Any Cause or Major Stroke



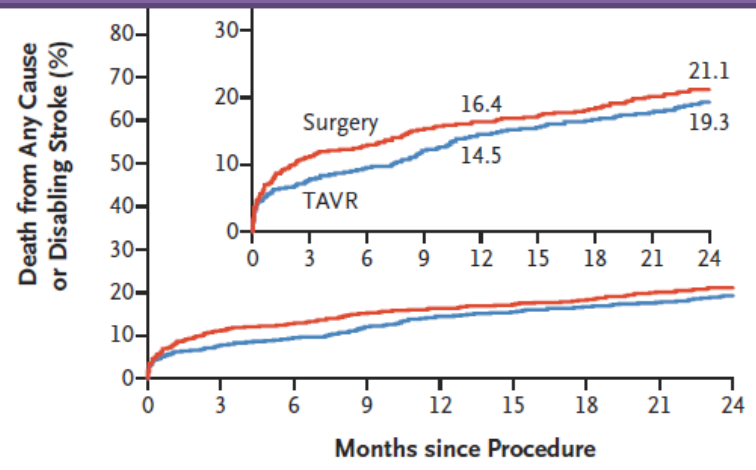
TAVI was NON – INFERIOR

The NEW ENGLAND JOURNAL of MEDICINE

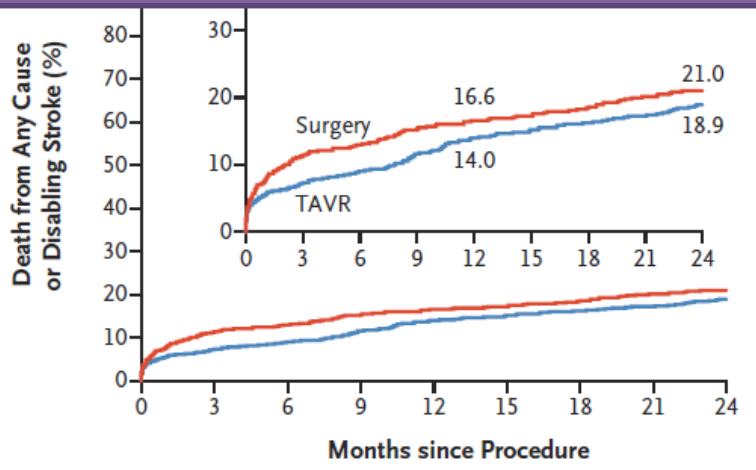
ESTABLISHED IN 1812 APRIL 28, 2016 VOL. 374 NO. 17

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

TAVI was NON – INFERIOR



No. at Risk									
TAVR	1011	918	901	870	842	825	811	801	774
Surgery	1021	838	812	783	770	747	735	717	695



No. at Risk									
TAVR	994	917	900	870	842	825	811	801	774
Surgery	944	826	807	779	766	743	731	715	694

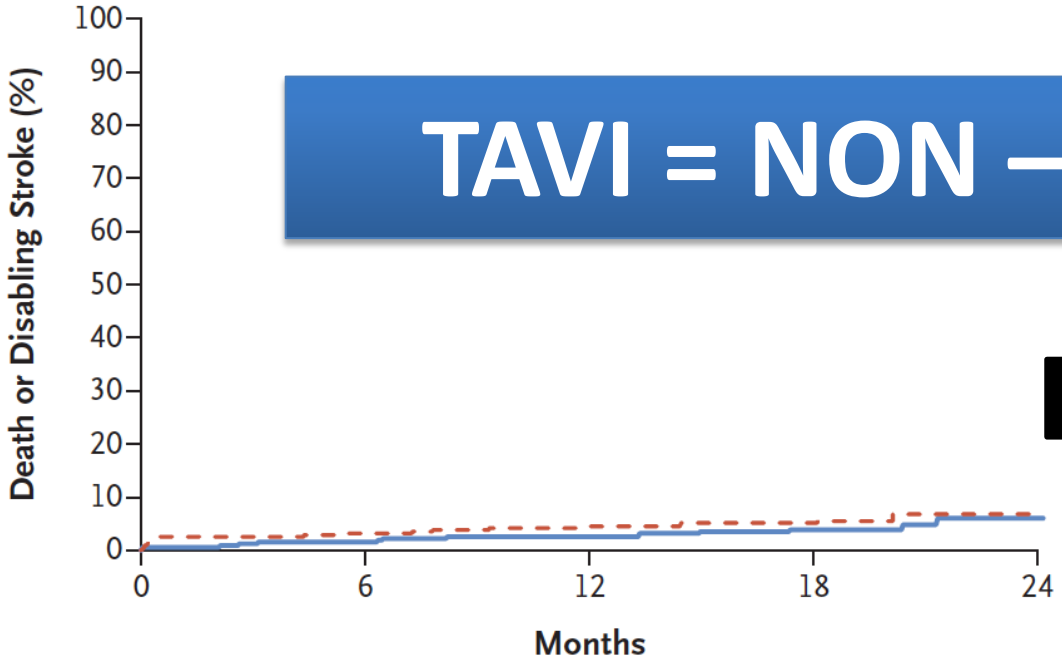
NEJM, March 2019

The NEW ENGLAND JOURNAL of MEDICINE

EVOLUT LOW RISK TRIAL

ORIGINAL ARTICLE

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



TAVI = NON – INFERIOR

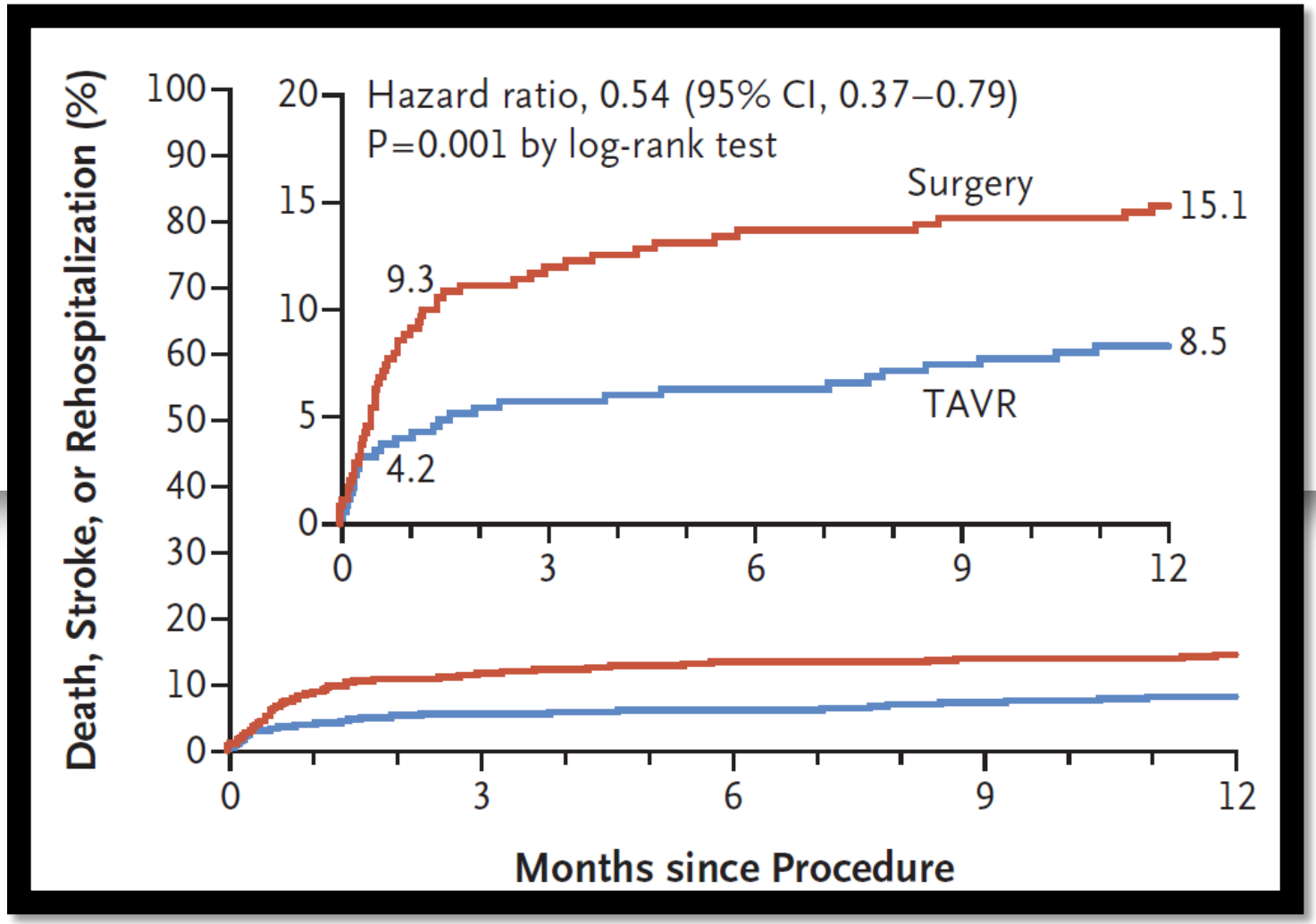
PM implantation: 17% versus 6%

The NEW ENGLAND JOURNAL of MEDICINE

NEJM, March 2019

PARTNER 3

ORIGINAL ARTICLE



FDA NEWS RELEASE

FDA expands indication for several transcatheter heart valves to patients at low risk for death or major complications associated with open-heart surgery

For Immediate Release:

August 16, 2019

The U.S. Food and Drug Administration today approved an expanded indication for several transcatheter heart valves to include patients with severe aortic valve stenosis (a narrowing of the heart's aortic valve that restricts blood flow to aorta, the body's main artery) who are at low risk for death or major complications associated with open-heart surgery to replace the damaged valves. These transcatheter valves – Sapien 3, Sapien 3 Ultra, CoreValve Evolut R and CoreValve Evolut PRO – were previously indicated only for patients at intermediate or higher risk for death or major complications during open-heart surgery. In low risk patients, open-heart surgery has been the standard-of-care for aortic valve replacement. However, the procedure to insert a transcatheter heart valve is less invasive, and involves a smaller incision and shorter recovery time than open-heart surgery. The FDA is the first medical products regulatory body in the world to expand the indication for these devices to patients at low risk for death or major complications associated with open-heart surgery.

2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary

A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

Developed in collaboration with and endorsed by the American Association for Thoracic Surgery, American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions, Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons

Writing Committee Members*

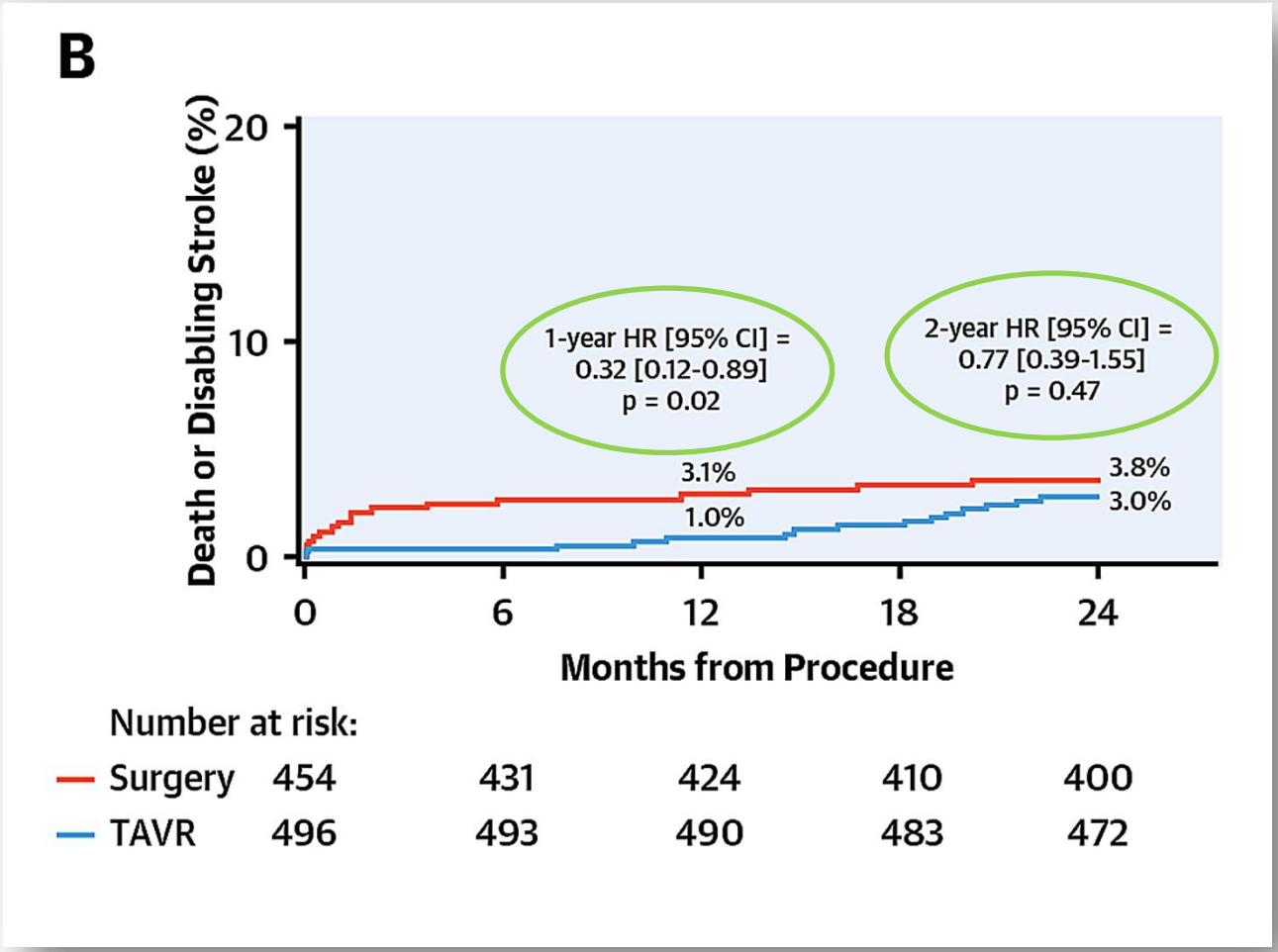
Catherine M. Otto, MD, FACC, FAHA, *Co-Chair*
Rick A. Nishimura, MD, MACC, FAHA, *Co-Chair*

Robert O. Bonow, MD, MS, MACC, FAHA
Blase A. Carabello, MD, FACC, FAHA
John P. Erwin III, MD, FACC, FAHA
Federico Gentile, MD, FACC
Hani Jneid, MD, FACC, FAHA
Eric V. Krieger, MD, FACC
Michael Mack, MD, MACC
Christopher McLeod, MBCHB, PhD, FAHA
Patrick T. O'Gara, MD, MACC, FAHA†
Vera H. Rigolin, MD, FACC, FAHA
Thoralf M. Sundt III, MD, FACC, FAHA
Annemarie Thompson, MD
Christopher Toly

*Writing committee members are required to recuse themselves from voting on sections to which their specific relationships with industry may apply; see Appendix 1 in the full guideline for detailed information.
†ACC/AHA Joint Committee on Clinical Practice Guidelines Liaison.

Outcomes 2 Years After Transcatheter Aortic Valve Replacement in Patients at Low Surgical Risk

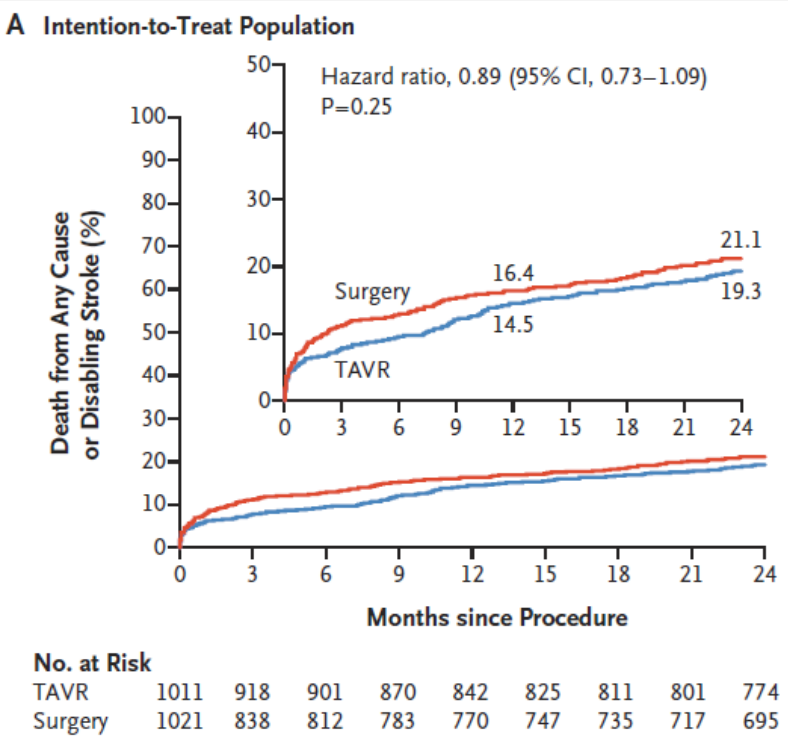
JACC 2021

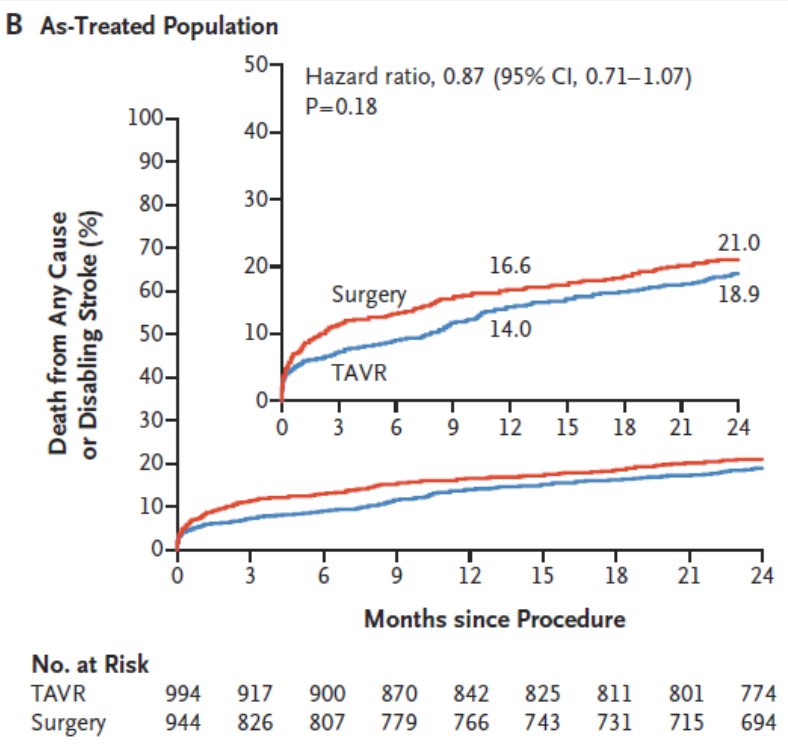


The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 APRIL 28, 2016 VOL. 374 NO. 17

Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients

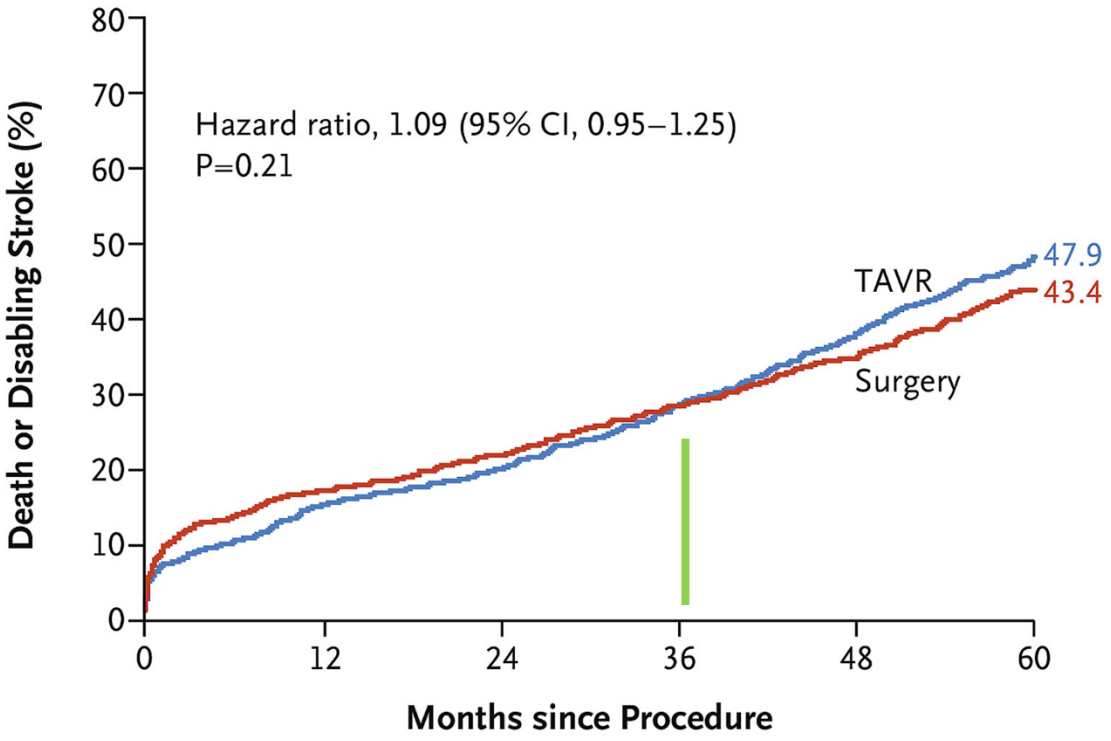




NEJM 2020

Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement

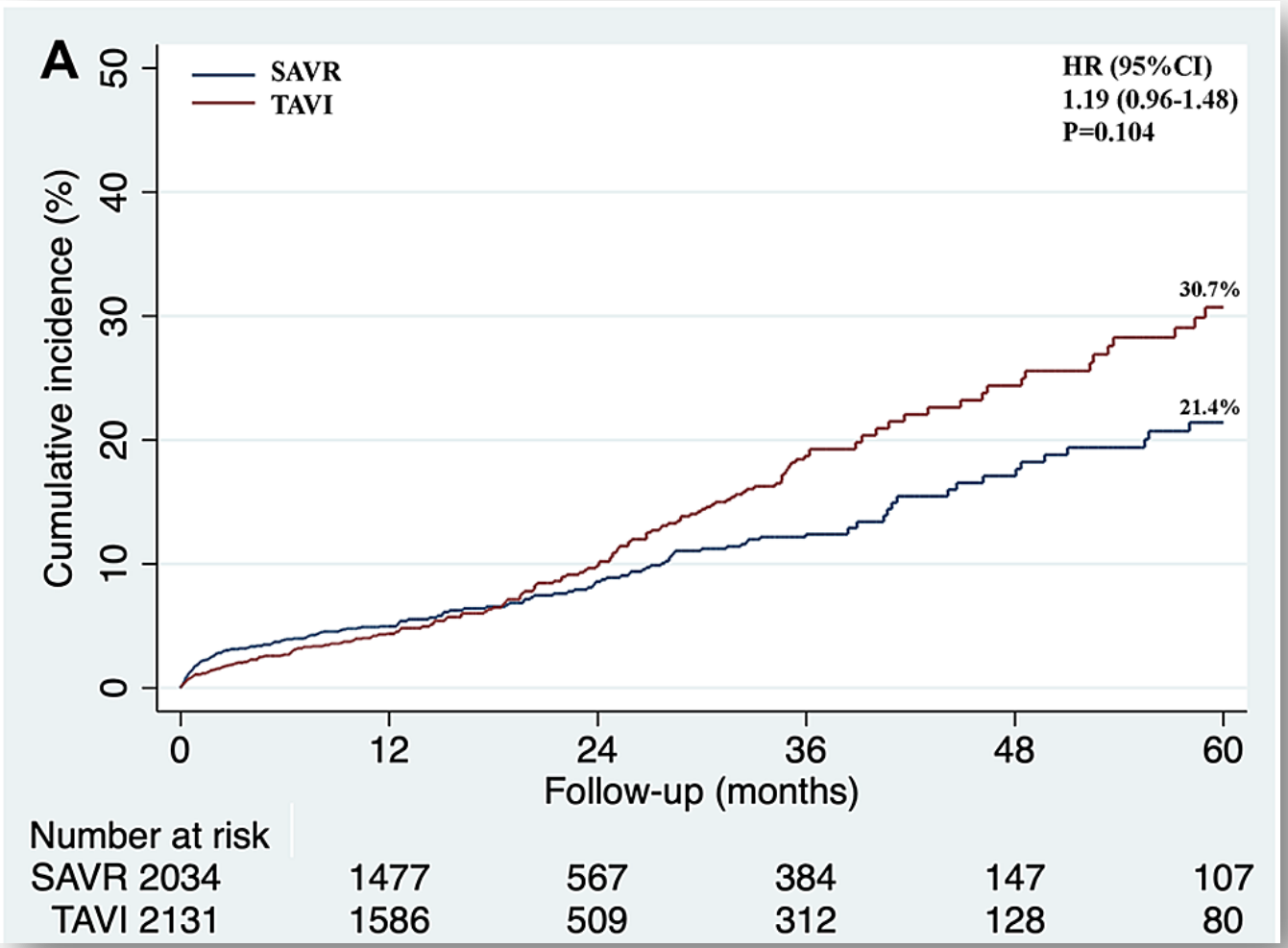
PARTNER 2



No. at Risk						
TAVR	1011	843	785	687	581	474
Surgery	1021	771	704	625	547	440

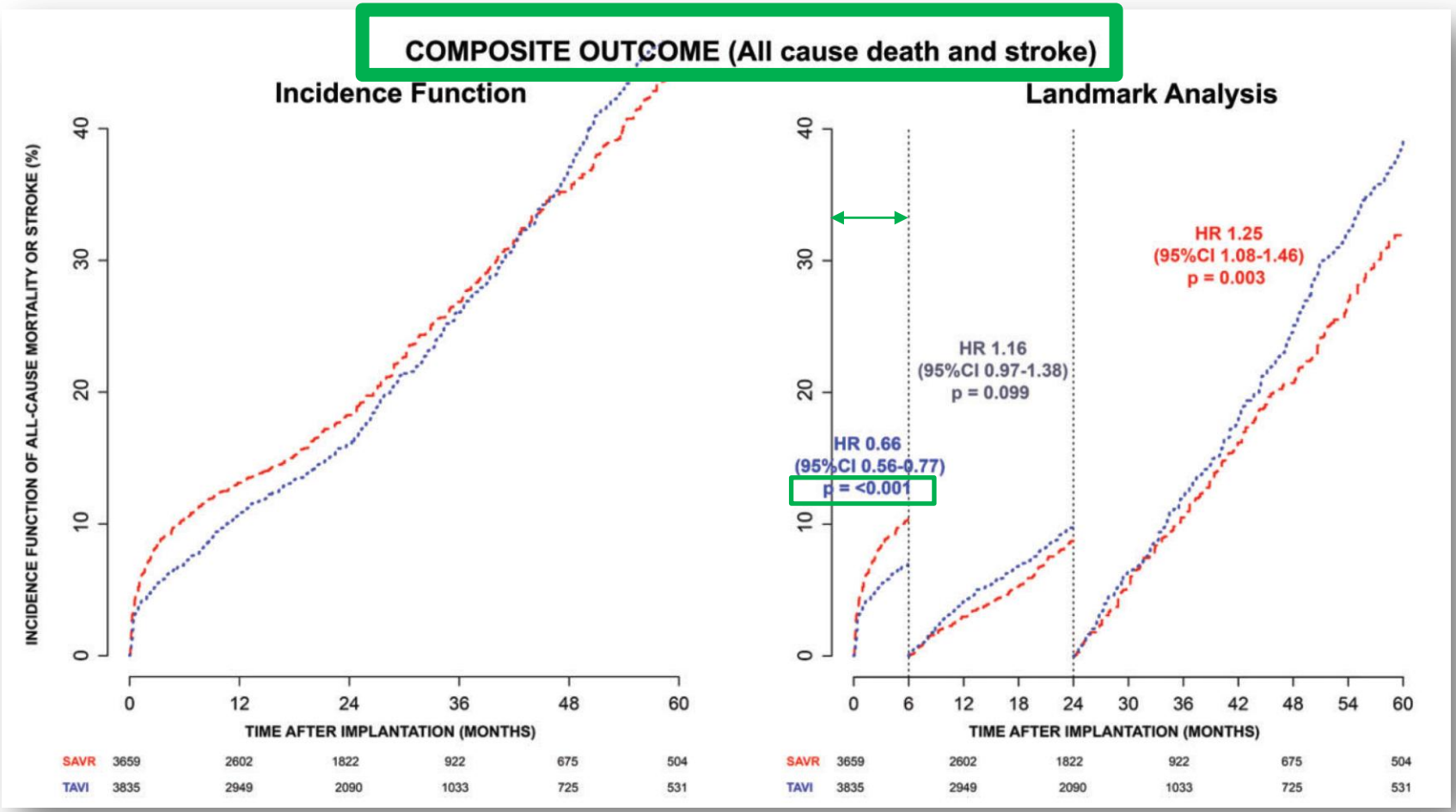
Mortality in low-risk patients with aortic stenosis undergoing transcatheter or surgical aortic valve replacement: a reconstructed individual patient data meta-analysis

ICVTS 2020



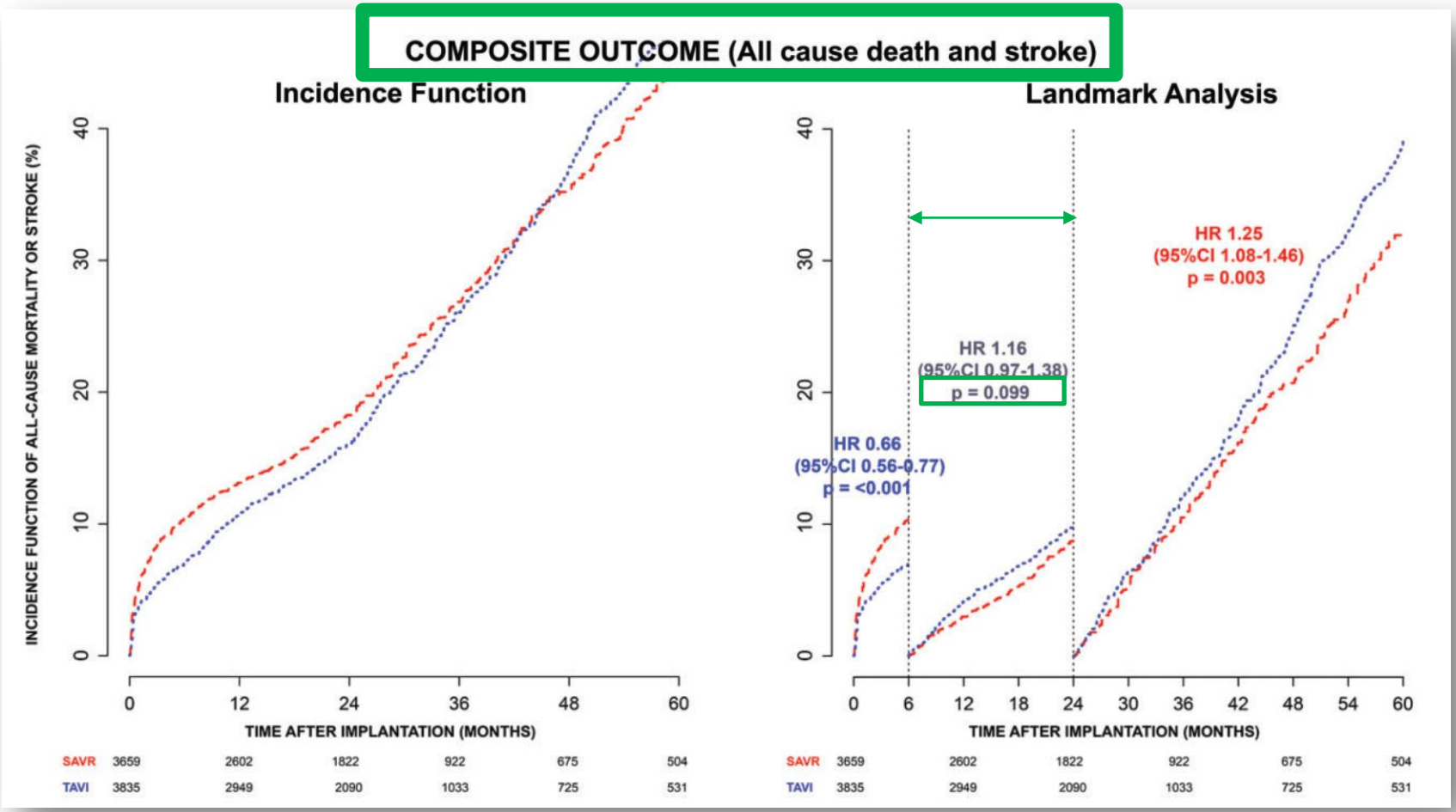
Five-year outcomes in trials comparing transcatheter aortic valve implantation versus surgical aortic valve replacement: a pooled meta-analysis of reconstructed time-to-event data

EJCTS 2022



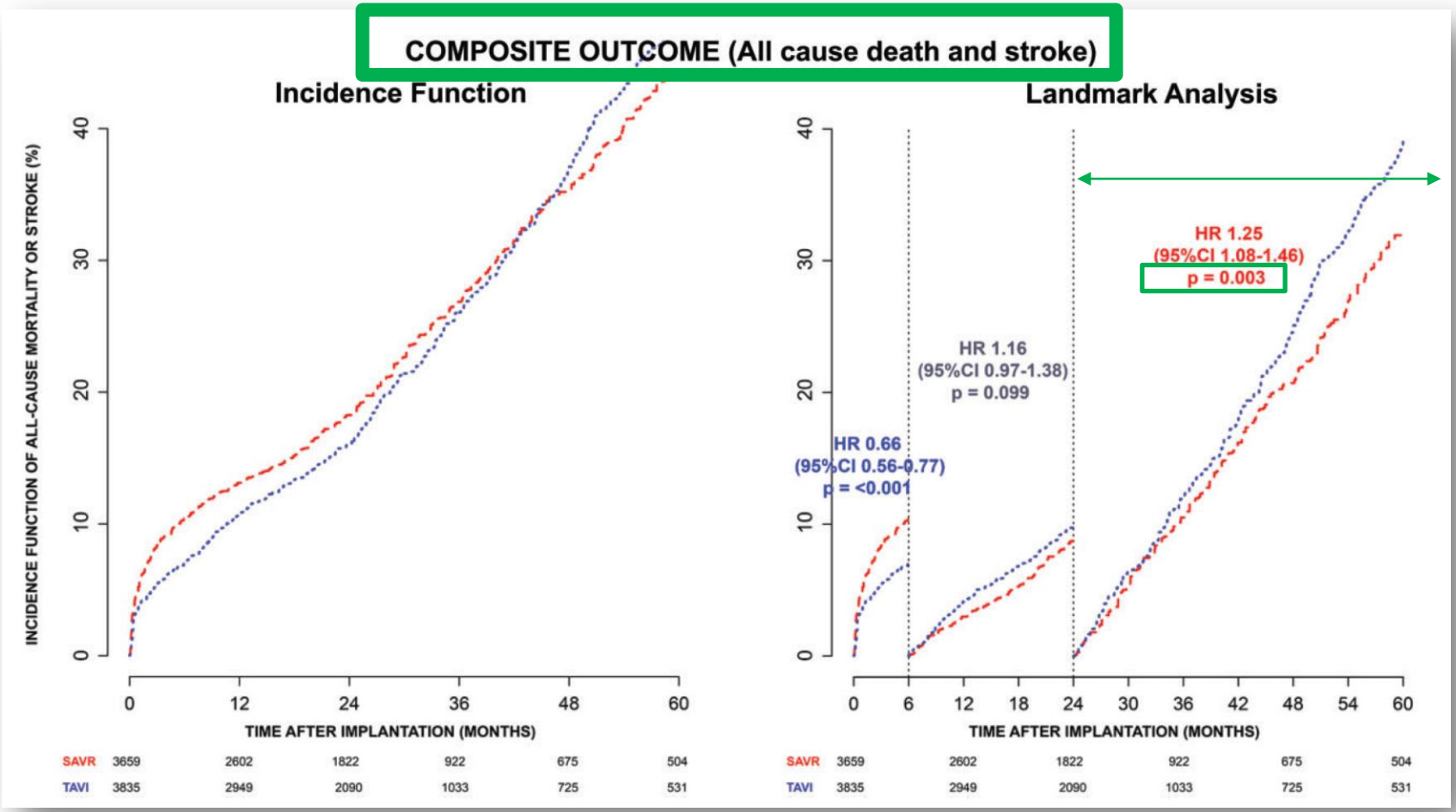
Five-year outcomes in trials comparing transcatheter aortic valve implantation versus surgical aortic valve replacement: a pooled meta-analysis of reconstructed time-to-event data

EJCTS 2022



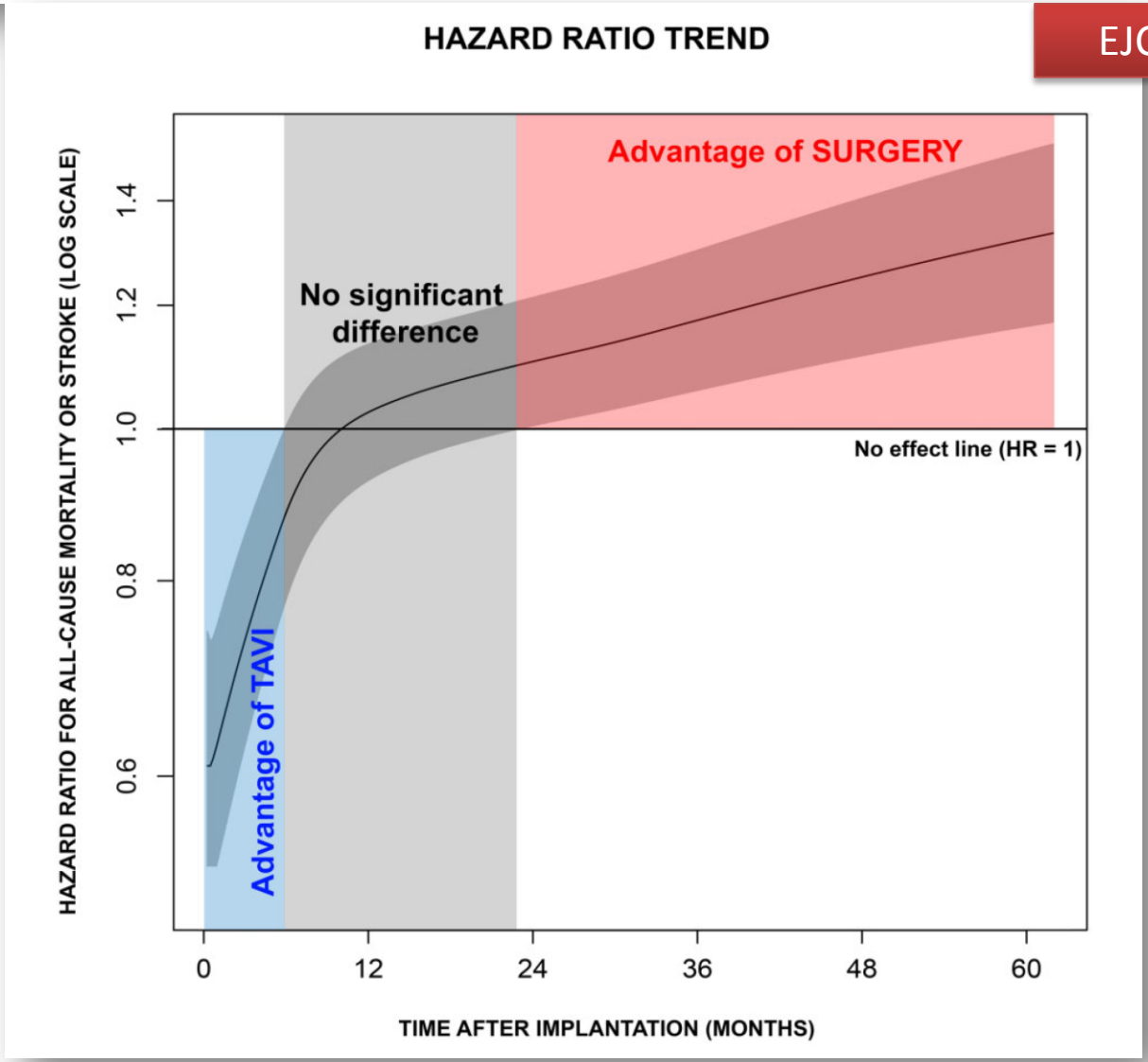
Five-year outcomes in trials comparing transcatheter aortic valve implantation versus surgical aortic valve replacement: a pooled meta-analysis of reconstructed time-to-event data

EJCTS 2022



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

EJCTS 2022



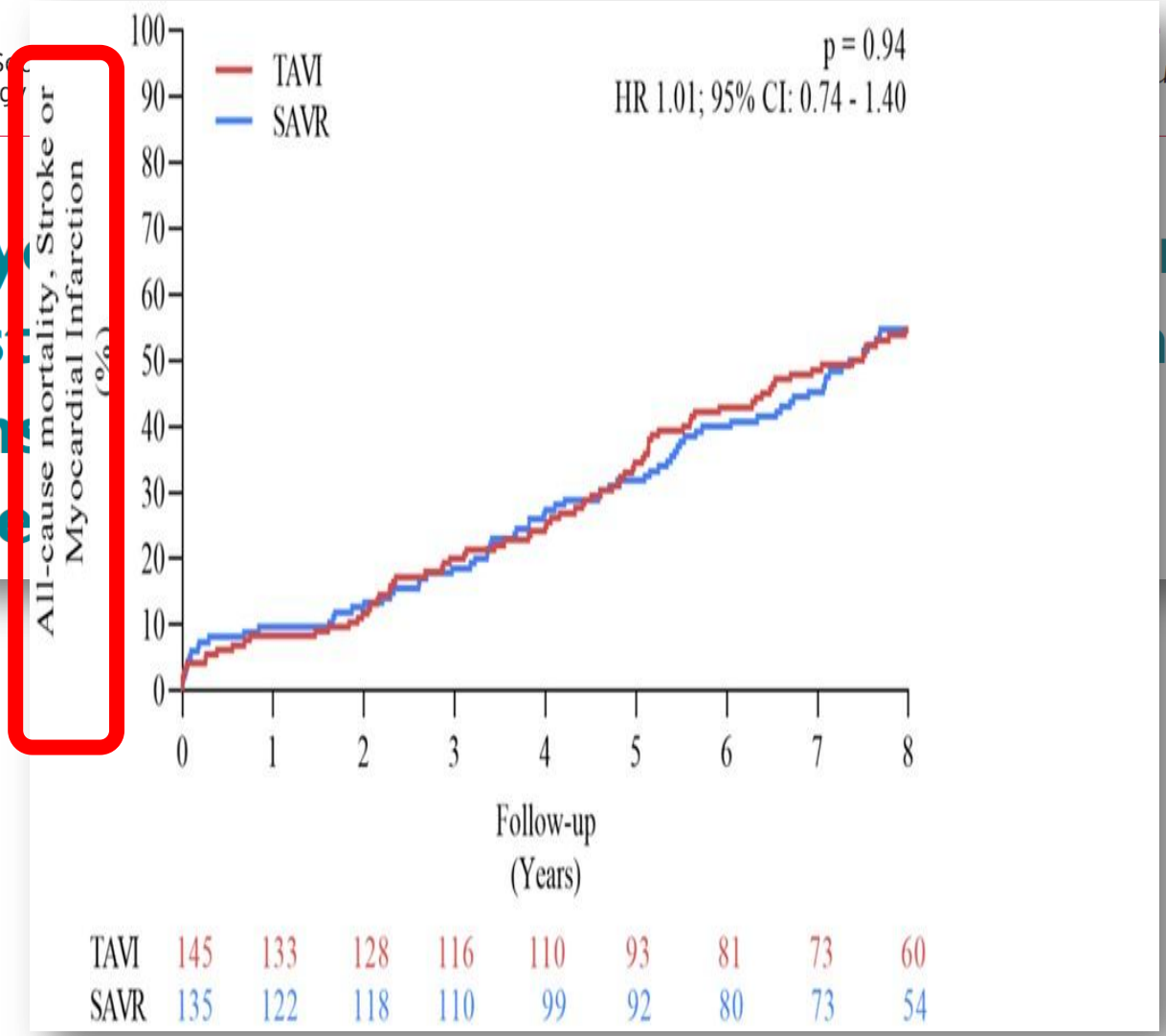
NOTION TRIAL

ESC
European S
of Cardiolog

RESEARCH
ular heart disease

Eight-y
valve s
to tran
replace

rtic
ized



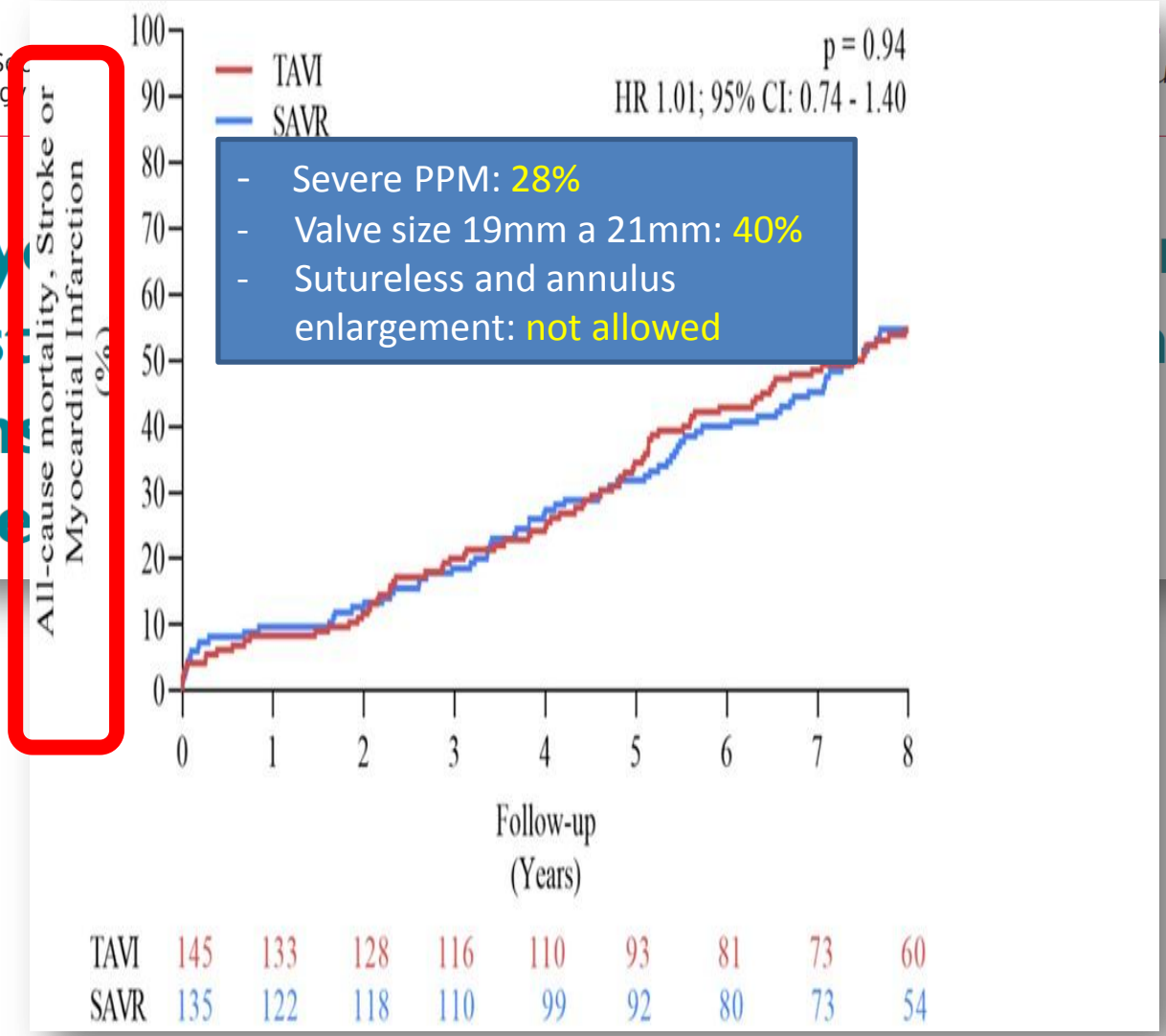
NOTION TRIAL

ESC
European S
of Cardiolog

RESEARCH
ular heart disease

Eight-y
valve s
to tran
replace

rtic
ized



CONCLUSIONS

- TAVI: an excellent options for high-risk and selected intermediate risk patients (HEART TEAM)

- **Limitations of TAVI**
  - Durability
  - Subclinical leaflet thrombosis
  - PVL AR
  - PM
  - Vascular complication
  - Annular rupture
  - BAV

- No TAVI: low-risk patients, normal life expectancy – limited long-term data supporting TAVI in low-risk patients

Postavení chirurgie aortální chlopně v éře TAVI:

Are we dinosaurs?☺

20. Symposium Pracovní skupiny Chlopenní a vrozené srdeční vady v dospělosti

Jan Vojáček
Kardiochirurgická klinika LF UK a FN HK
Komplexní kardiovaskulární centrum FN HK