

TCT Asia-Pacific
Seoul, South Korea

Beyond the high-risk patient: can the indication for TAVR be expanded?

Eberhard Grube MD, FACC, FSCAI

Universitätsklinikum Bonn, Bonn, Germany
Hospital Alemão Oswaldo Cruz, São Paulo, Brazil
Stanford University, Palo Alto, California, USA

Disclosure of Financial Interest

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Physician Name

Company/Relationship

Eberhard Grube, MD

Medtronic, CoreValve: C, SB, AB, OF
Sadra Medical: E, C, SB, AB
Direct Flow: C, SB, AB
Mitralign: AB, SB, E
Symetis: AB
Boston Scientific: C, SB, AB
Biosensors: E, SB, C, AB
Cordis: AB
Abbott Vascular: AB
Capella: SB, C, AB
InSeal Medical: AB
Valtec: E, SB
Claret, SB

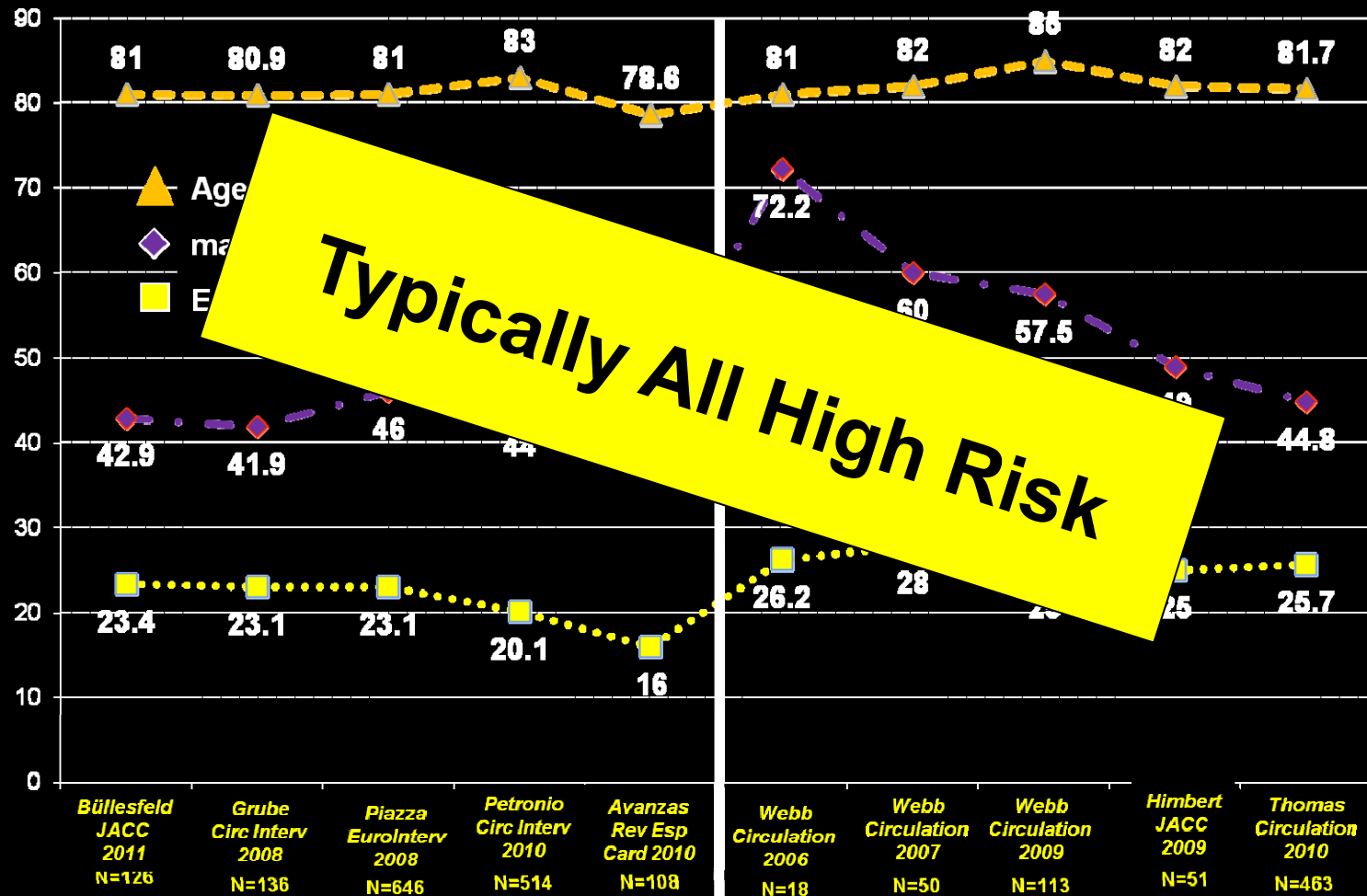
**Joint Task Force Positioning Paper:
"Transcatheter Valve Implantations for Patients with Aortic Stenosis"**

"The technique is feasible and provides hemodynamic and clinical improvements for up to 2 years"

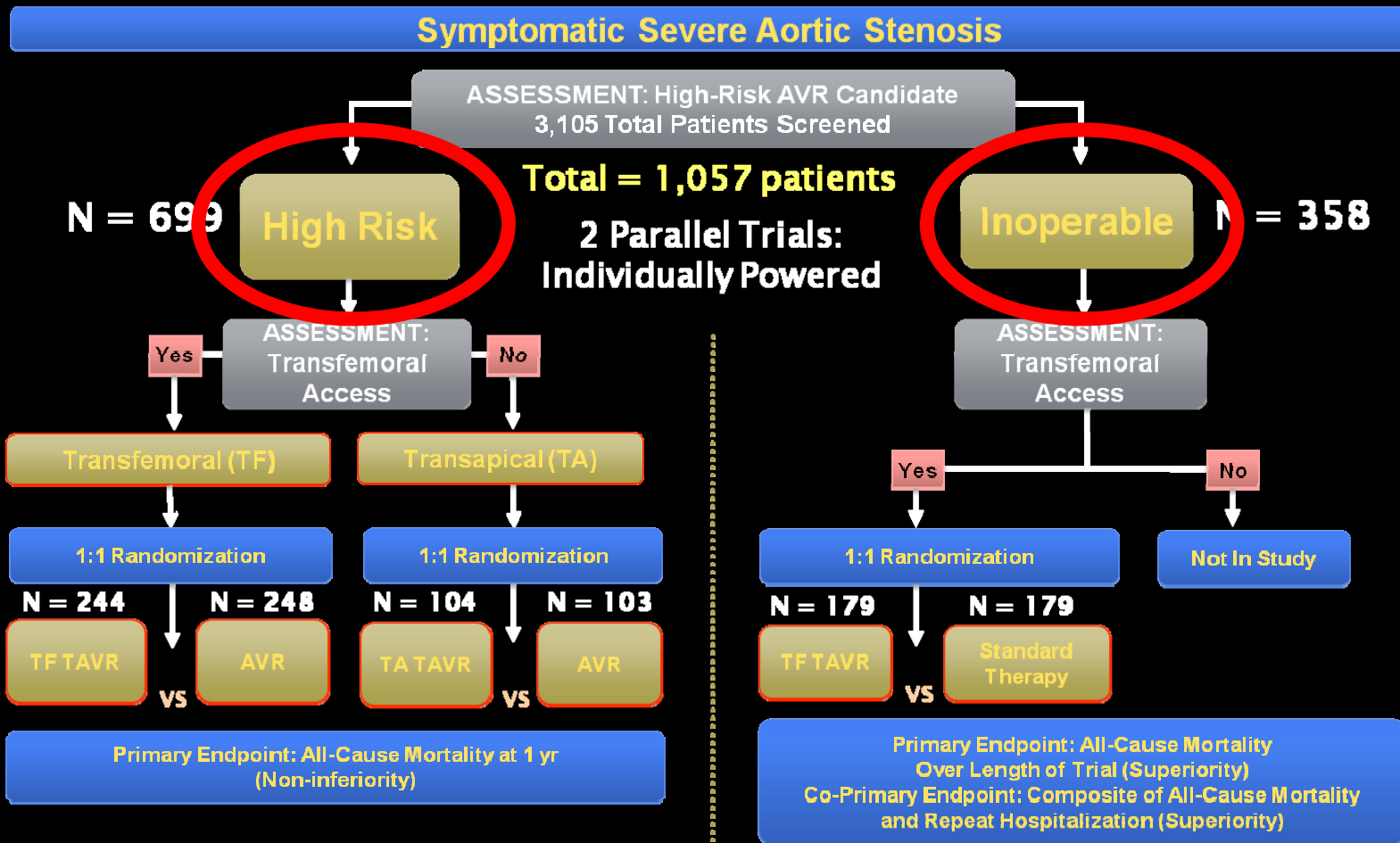
"This technique should be restricted to high-risk patients or those with contraindications for surgery"

Francesco Maisano², Neil Moat¹¹, Friedrich Mohr¹², Patrick Nataf¹, Luc Piérard¹³, José Luis Pomar¹⁴, Joachim Schofer¹⁵, Pilar Tornos¹⁶, Murat Tuzcu¹⁷, Ben van Hout¹⁸, Ludwig K. Von Segesser¹⁹, and Thomas Walther¹²

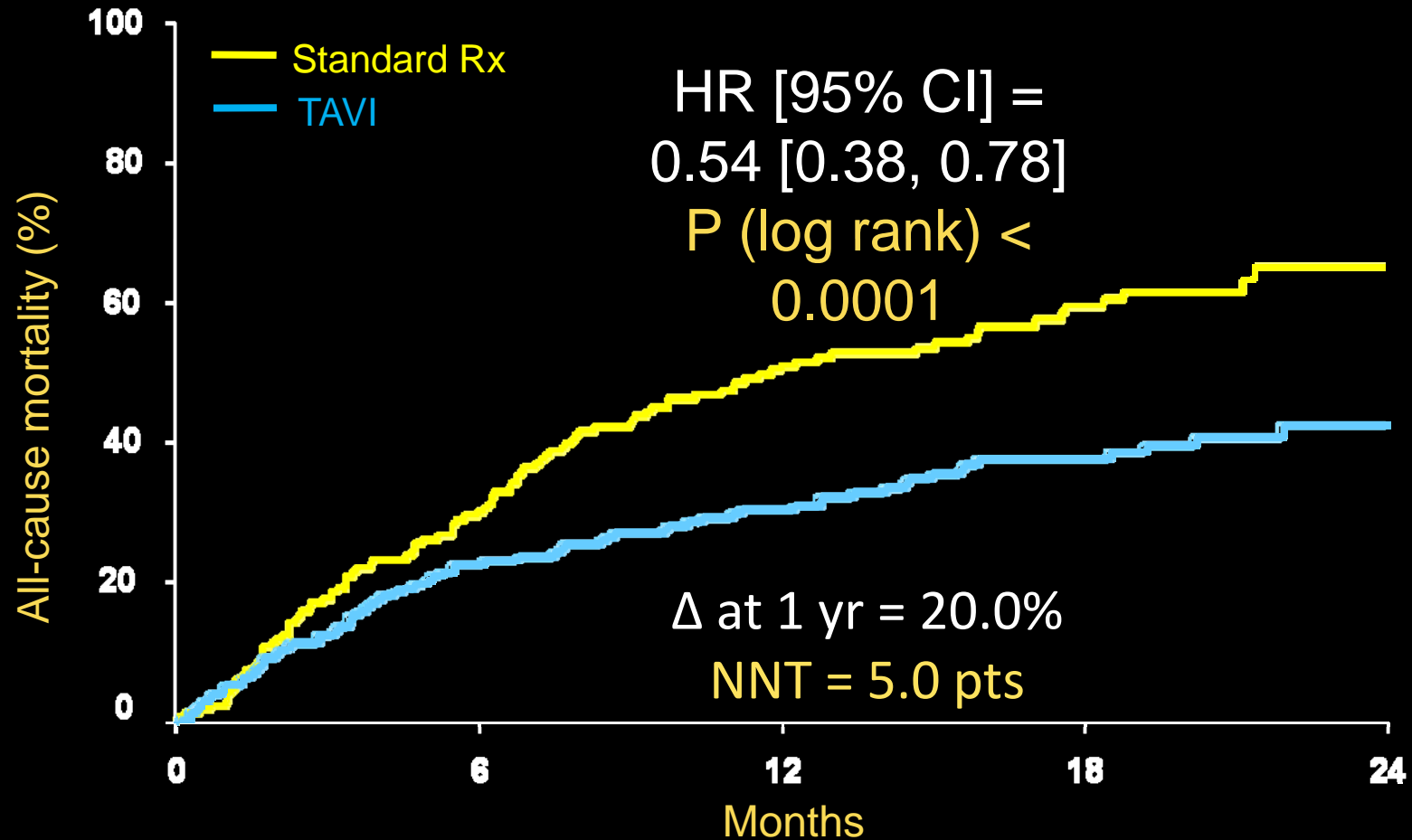
Baseline Characteristics in Previously Published TAVI Registries



PARTNER Study Design

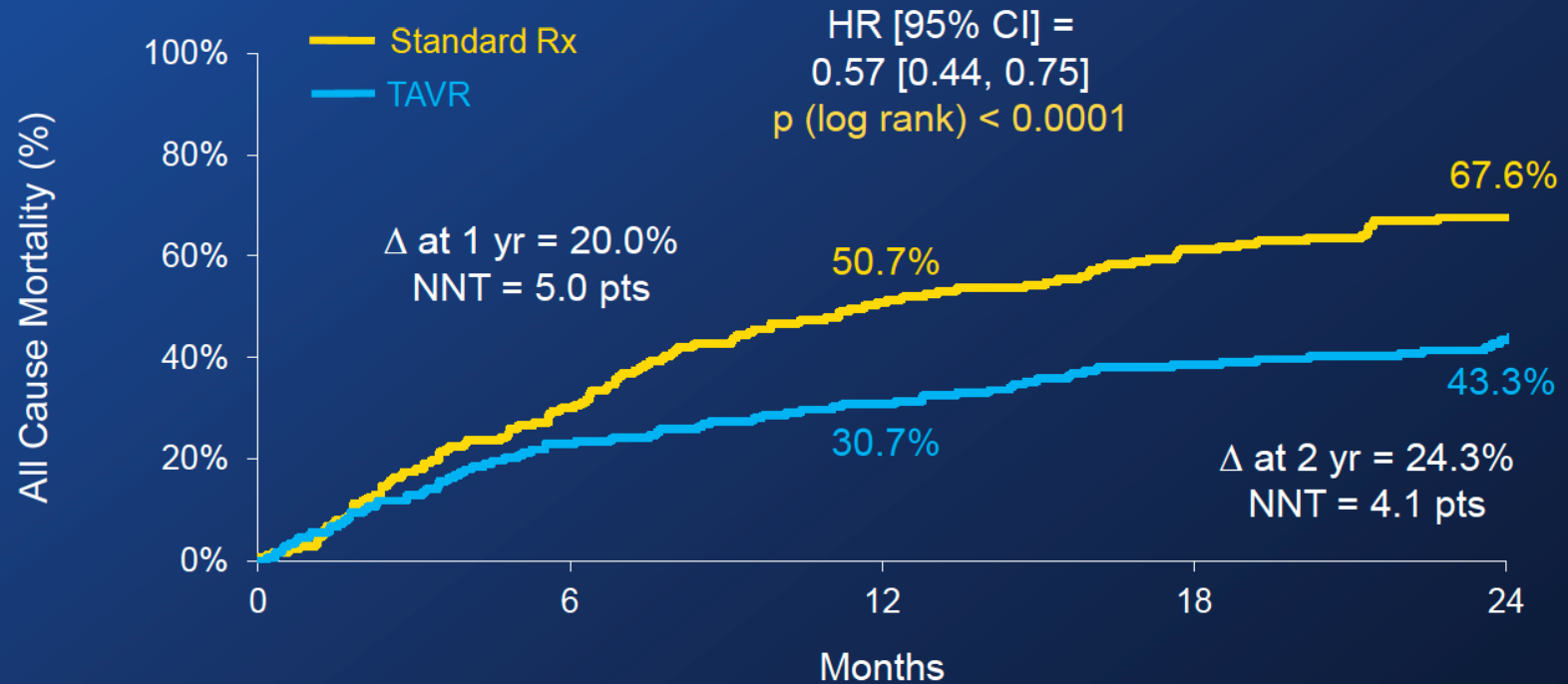


All Cause Mortality Cohort B



Numbers at Risk					
TAVI	179	138	122	67	26
Standard Rx	179	121	83	41	12

All Cause Mortality (ITT) Crossover Patients Followed



Numbers at Risk

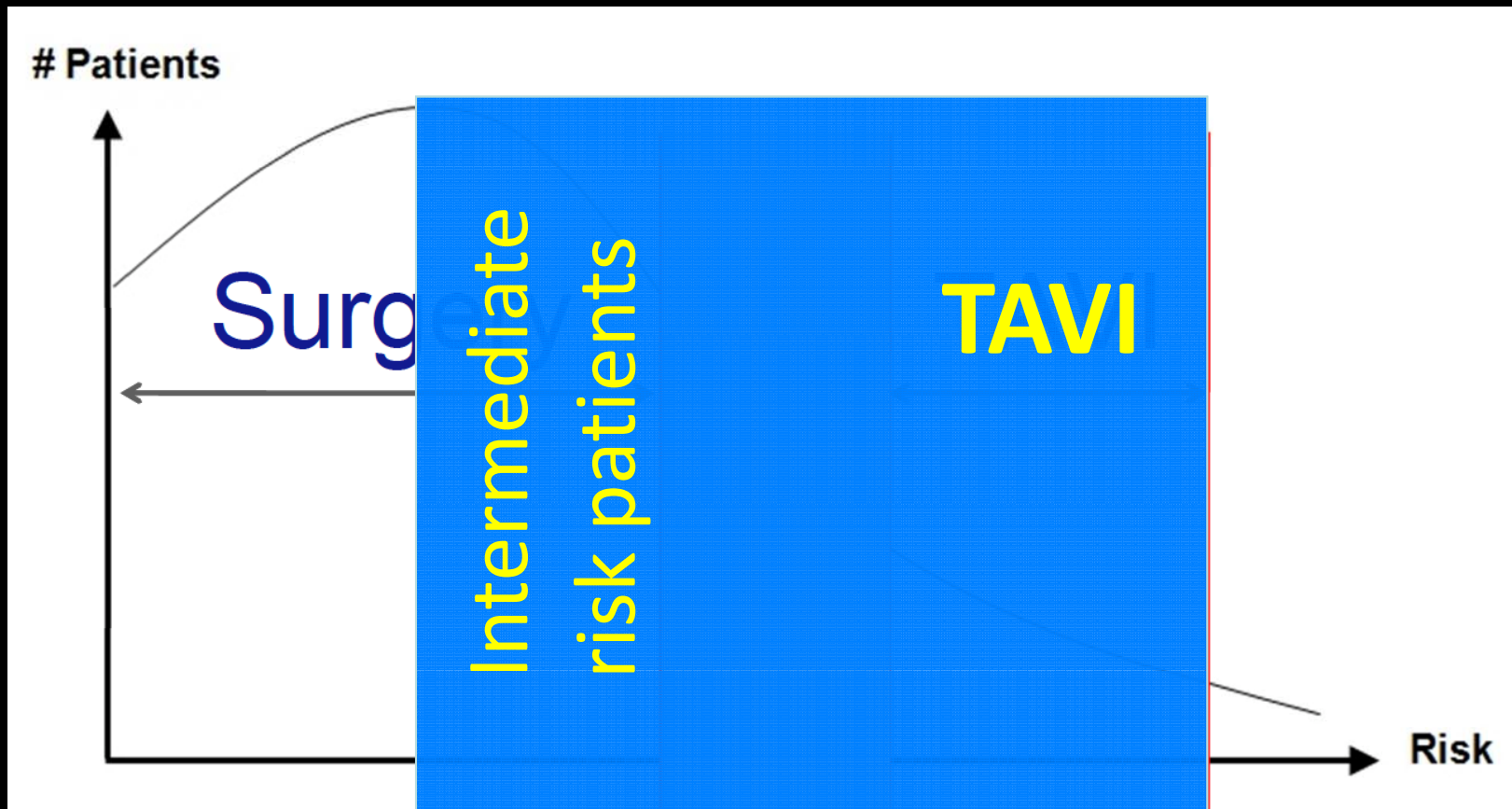
TAVR	179	138	124	110	83
Standard Rx	179	121	85	67	51

Presented by Raj. R. Makkar at TCT 2011

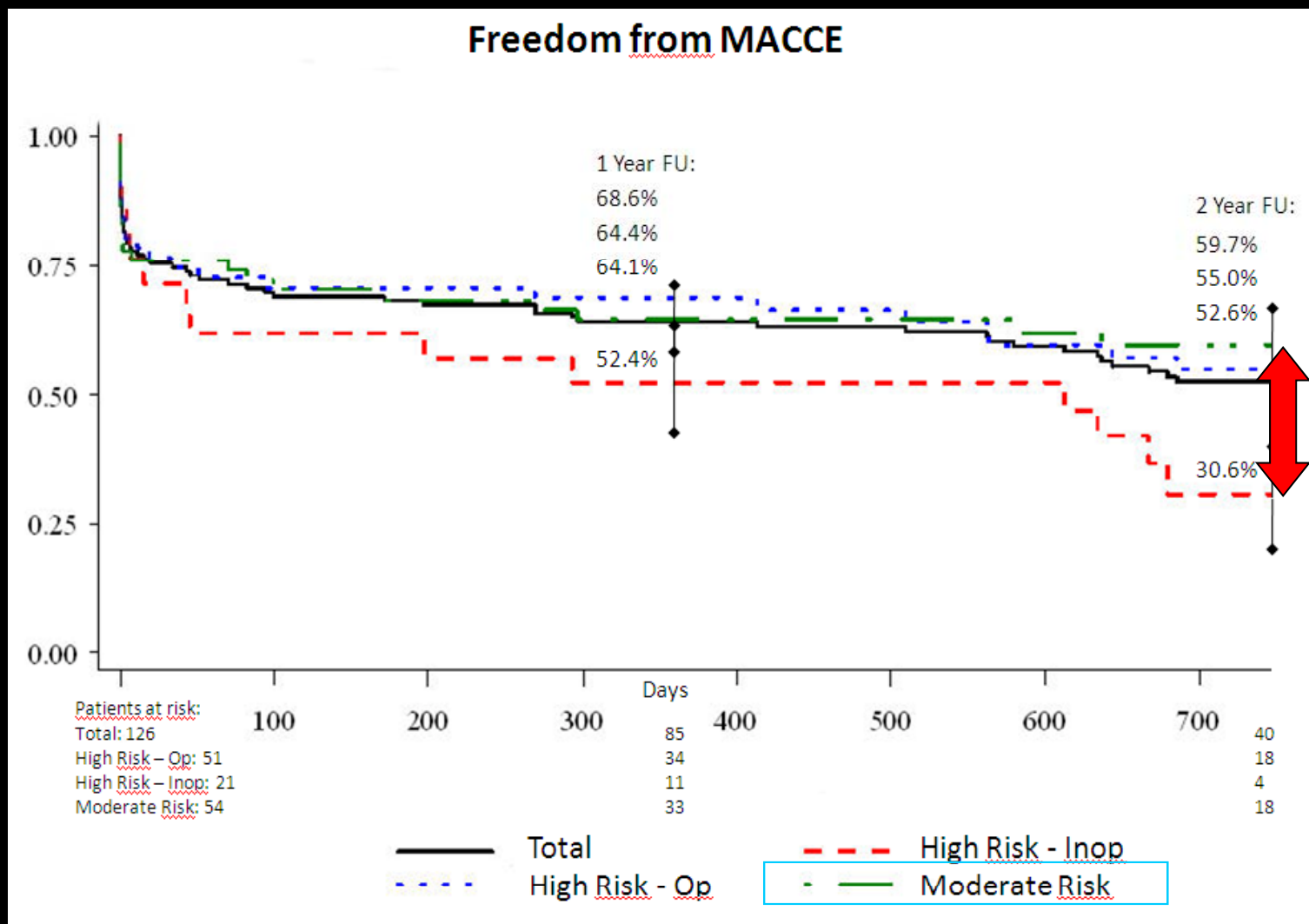
Lessons from PARTNER

- TAVI is already the standard-of-care for inoperable patients with severe AS (PARTNER B)
 - TAVI is an alternative to AVR (non-inferior) in selected *high-risk operable patients* (PARTNER A)
- Is TAVI also non-inferior to SAVR in patients with severe aortic stenosis at *intermediate* peri-operative risk?

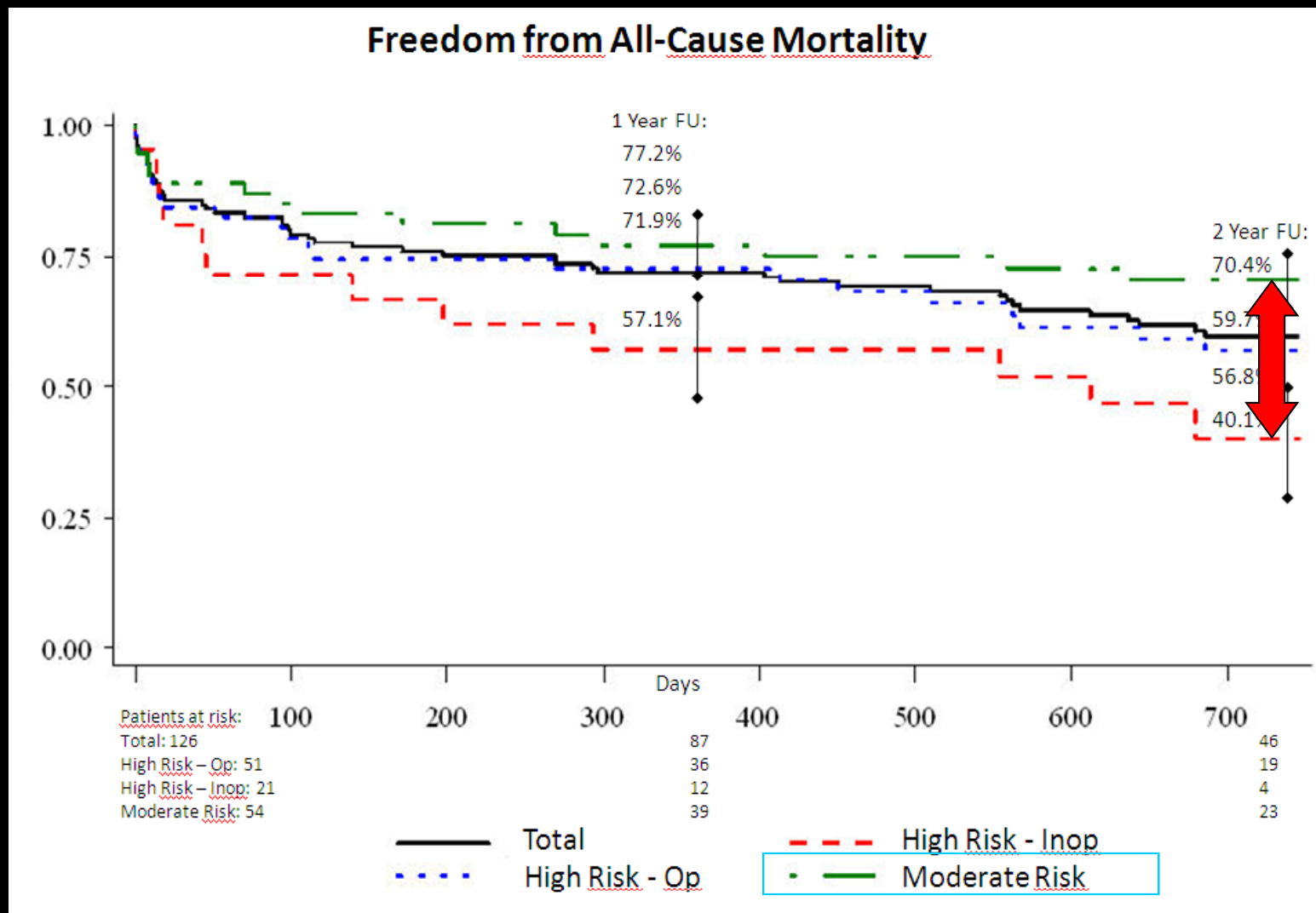
TAVI addresses an unmet clinical need in the treatment of aortic stenosis, but...



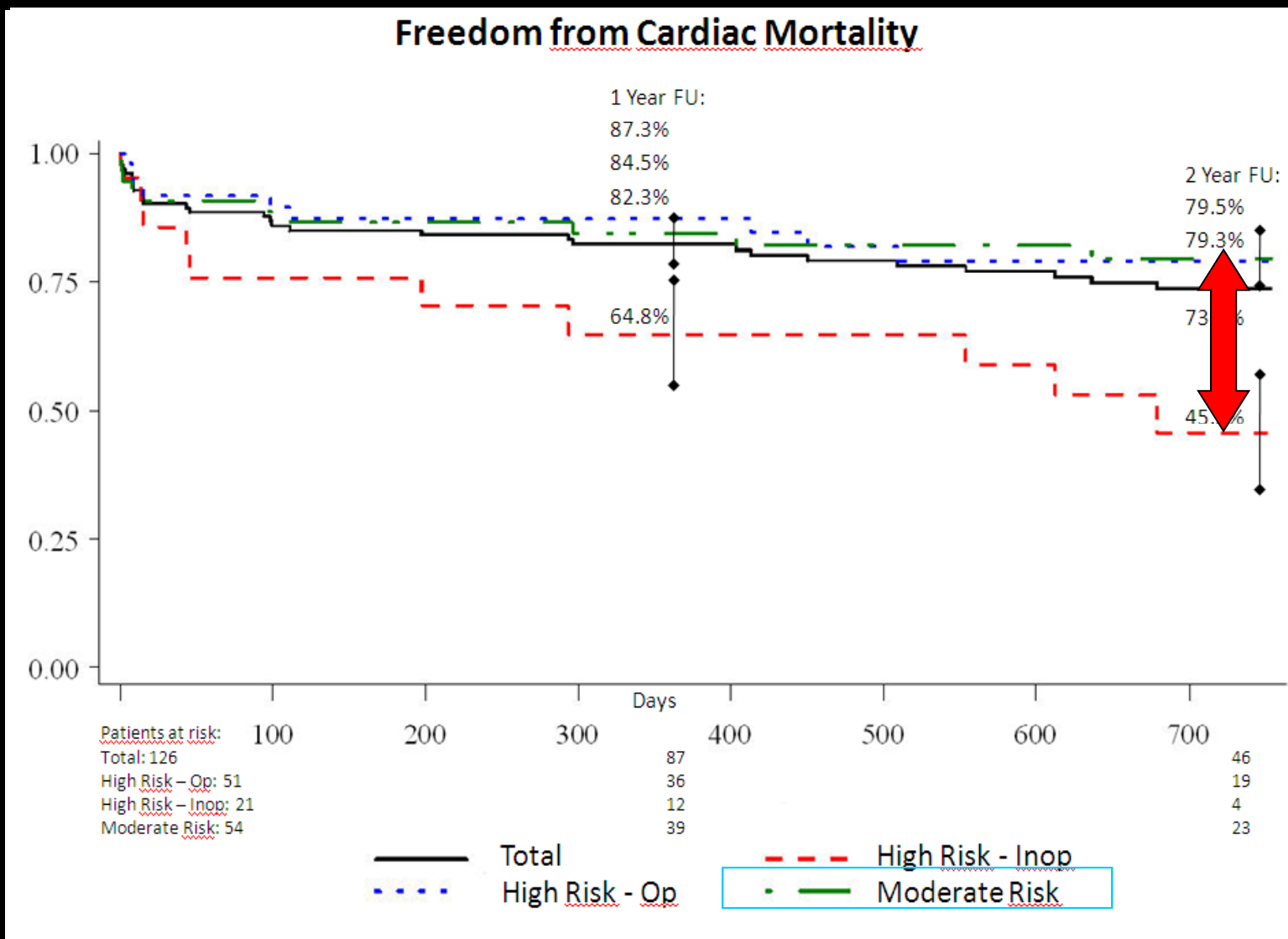
CoreValve 2 Year Clinical Follow up Stratified by Preprocedural Risk



CoreValve 2 Year Clinical Follow up Stratified by Preprocedural Risk



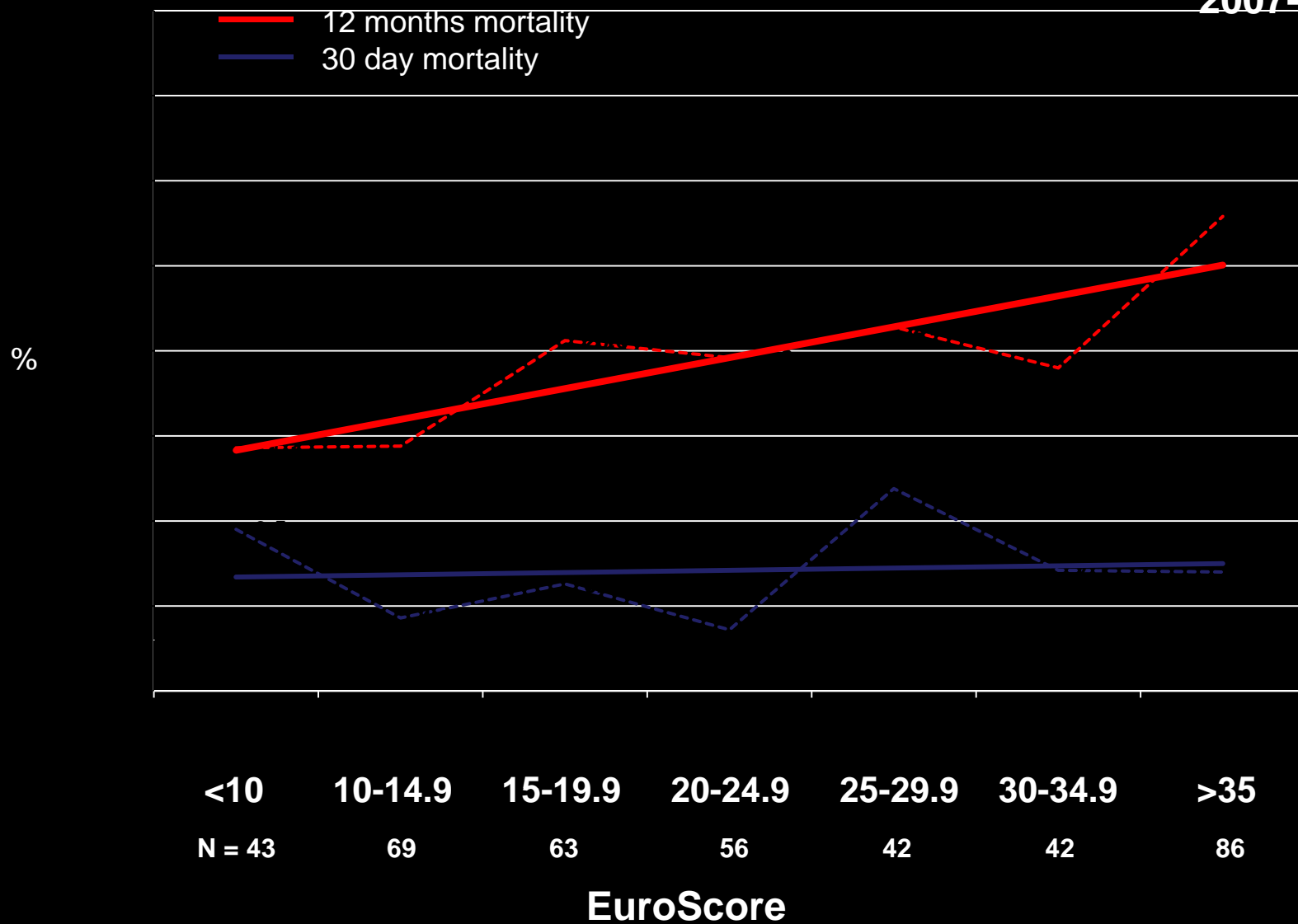
CoreValve 2 Year Clinical Follow up Stratified by Preprocedural Risk



Risk-Mortality Relation

Pooled Bern-Siegburg Experience

N=401
2007-2010



Improvement in TAVI outcomes in “lower” surgical risk patients: Can we go beyond the current borders?

Change in baseline characteristics and impact on clinical outcomes

The Munich cohort

- 420 consecutive patients undergoing CoreValve or Edwards Sapien implantation
- Data analyzed according to temporal quartiles (enrolment period) (n=105)
- Primary endpoint: 30-day and 6-month all-cause mortality

Better TAVR Outcomes in Lower Risk Patients

Improvements in Transcatheter Aortic Valve Implantation Outcomes in Lower Surgical Risk Patients

A Glimpse Into the Future

Ruediger Lange, MD, PhD, Sabine Bleiziffer, MD, Domenico Mazzitelli, MD, Yacine Elhmidi, MD, Anke Opitz, MD, Marcus Krane, MD, Marcus-Andre Deutsch, MD, Hendrik Ruge, MD, Gernot Brockmann, MD, Bernhard Voss, MD, Christian Schreiber, MD, Peter Tassani, MD, PhD, Nicolo Piazza, MD, PhD

N=420 patients (105 per quartile)

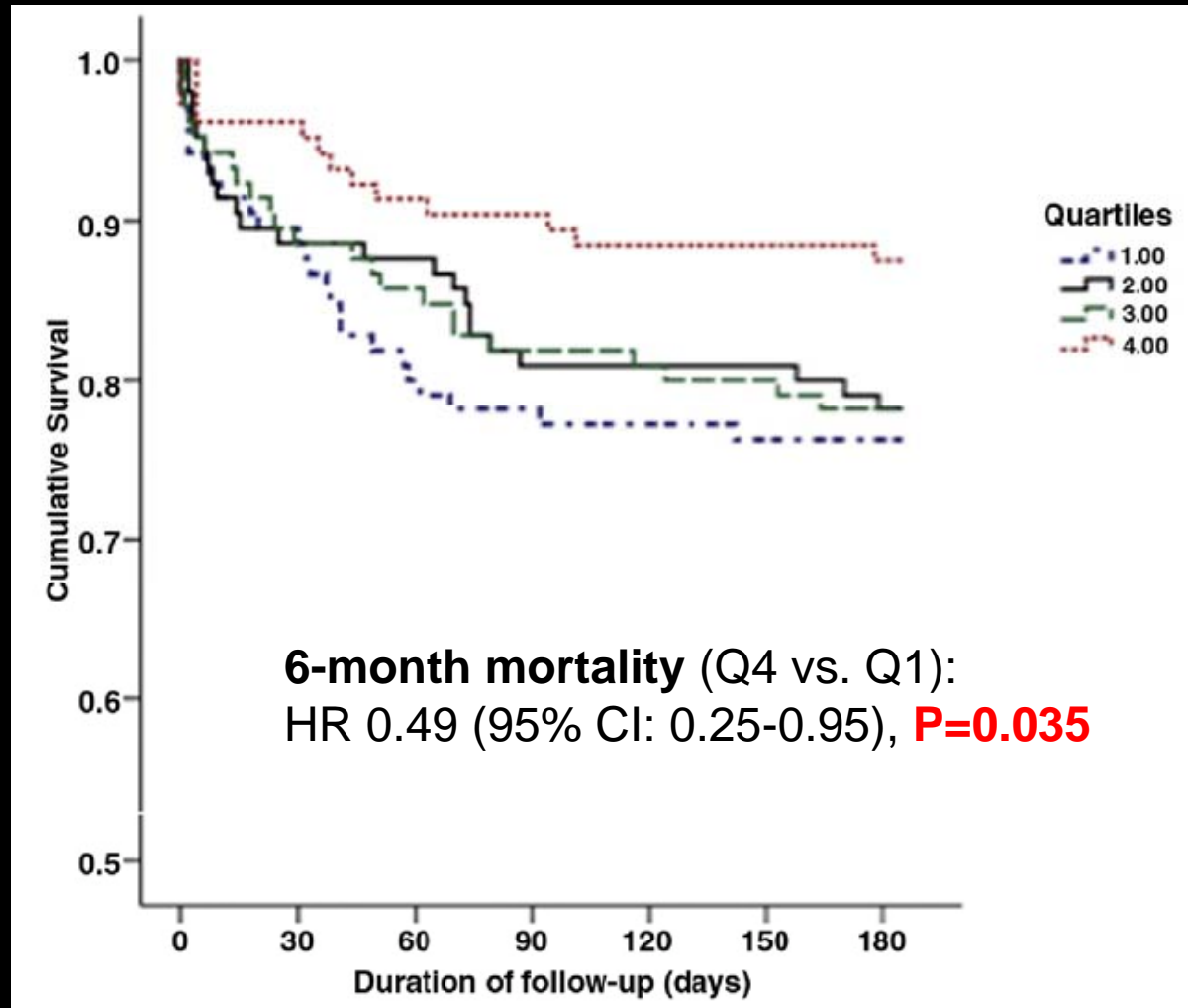
Munich, Germany

	Quartile 1	Quartile 4
Age, years	81.1 years	78.9 years
Logistic Euroscore, %	25.4%	17.8%
STS-PROM, %	7.13%	4.8%
Crude 30 day Mortality, %	11.4%	3.8%

Change in baseline characteristics

	Q1	Q2	Q3	Q4
Age (years)	81	81	80	78
Log. ES (%)	25	19	18	17
STS (%)	7	6	5	4

6-month unadjusted Cox proportional hazard's model



„Learning curve“

30-day mortality:

→ 4-fold reduction from 11.4% (quartile 1)
to 3.8% (quartile 4)

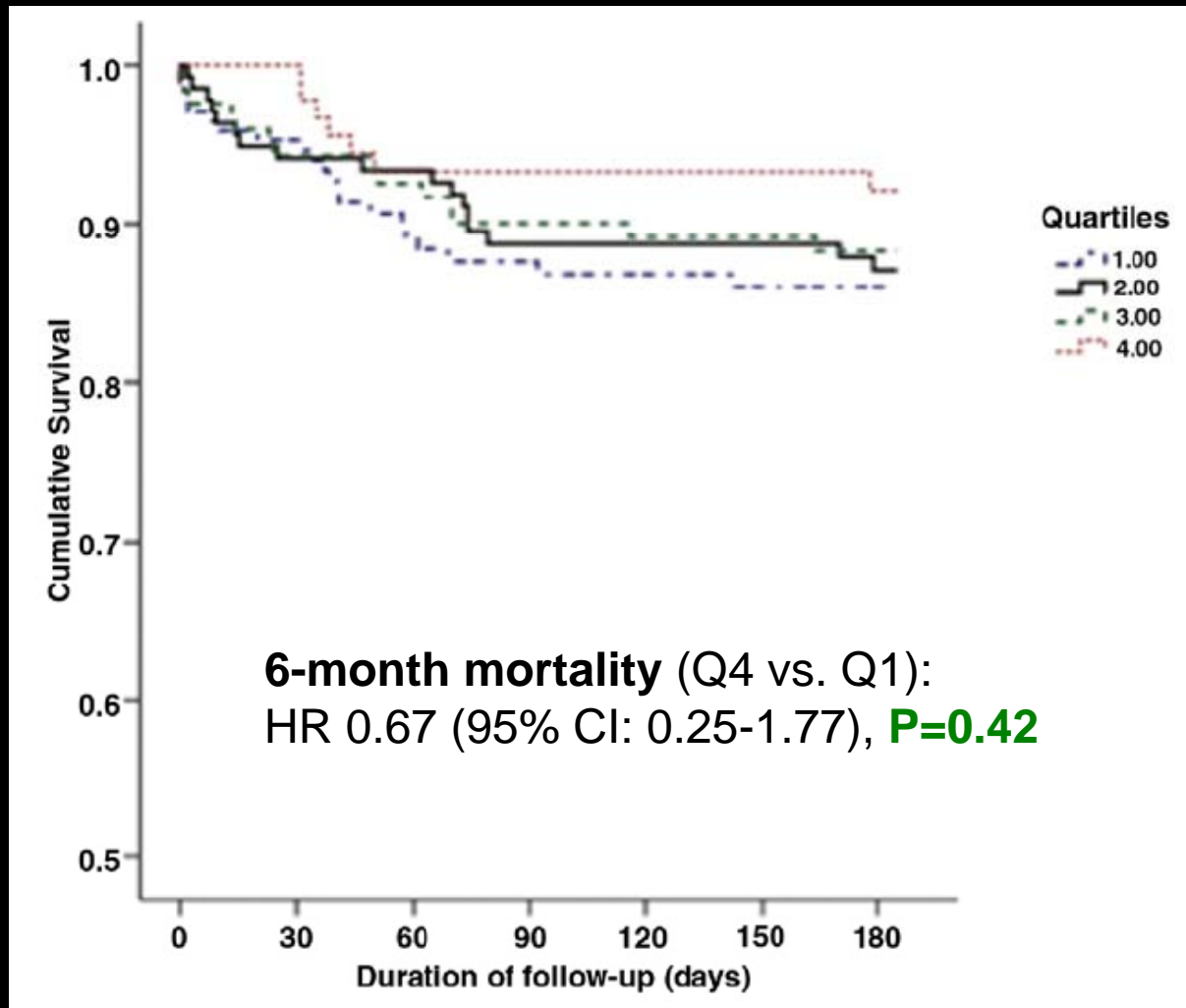
6-month mortality:

→ 2-fold reduction from 23.5% (quartile 1)
to 12.4% (quartile 4)

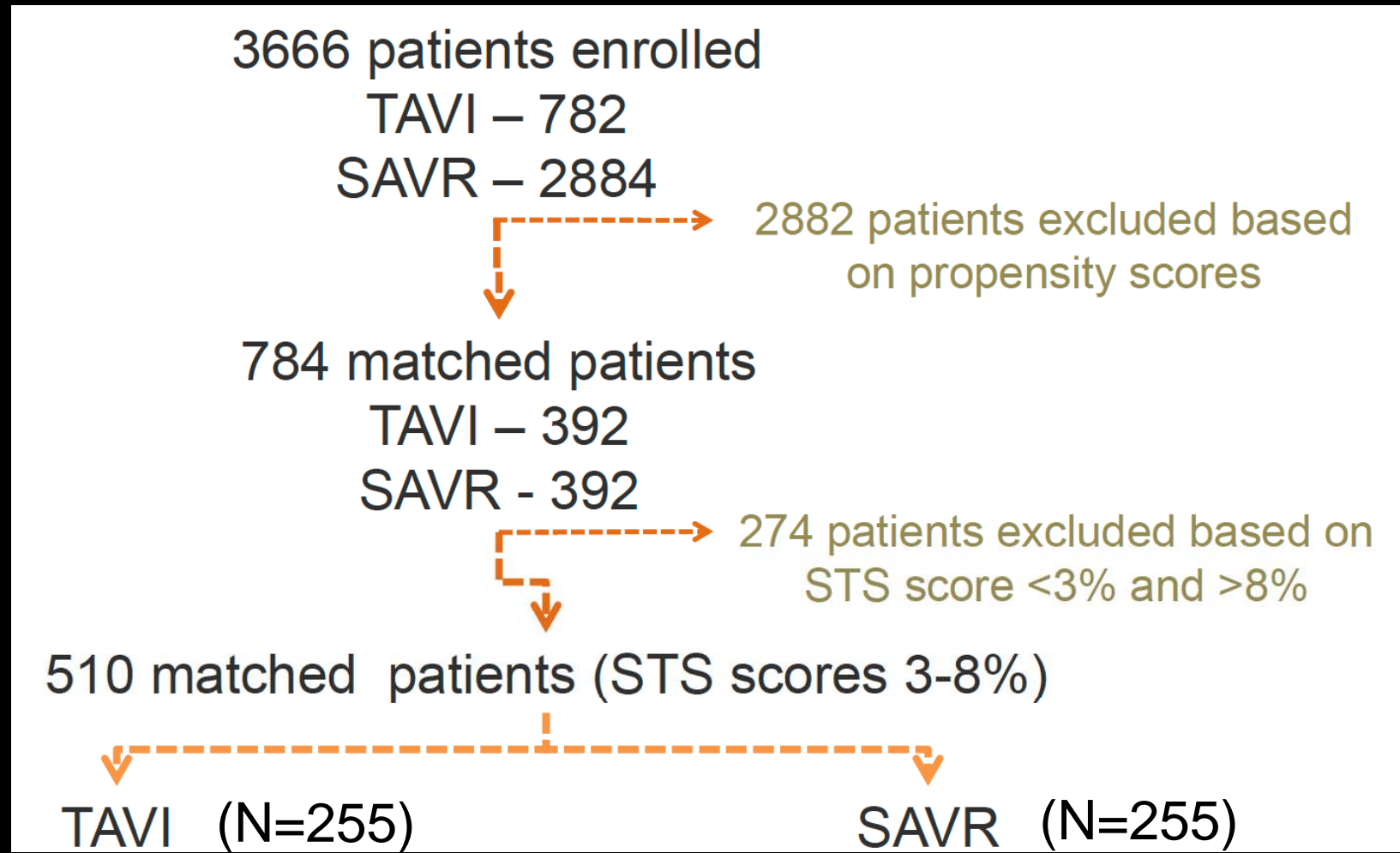
Major contributors to the improvements in outcomes

1. Patient-related factors
2. Procedural- or operator-related factors
3. Device-related factors

6-month adjusted Cox proportional hazard's model

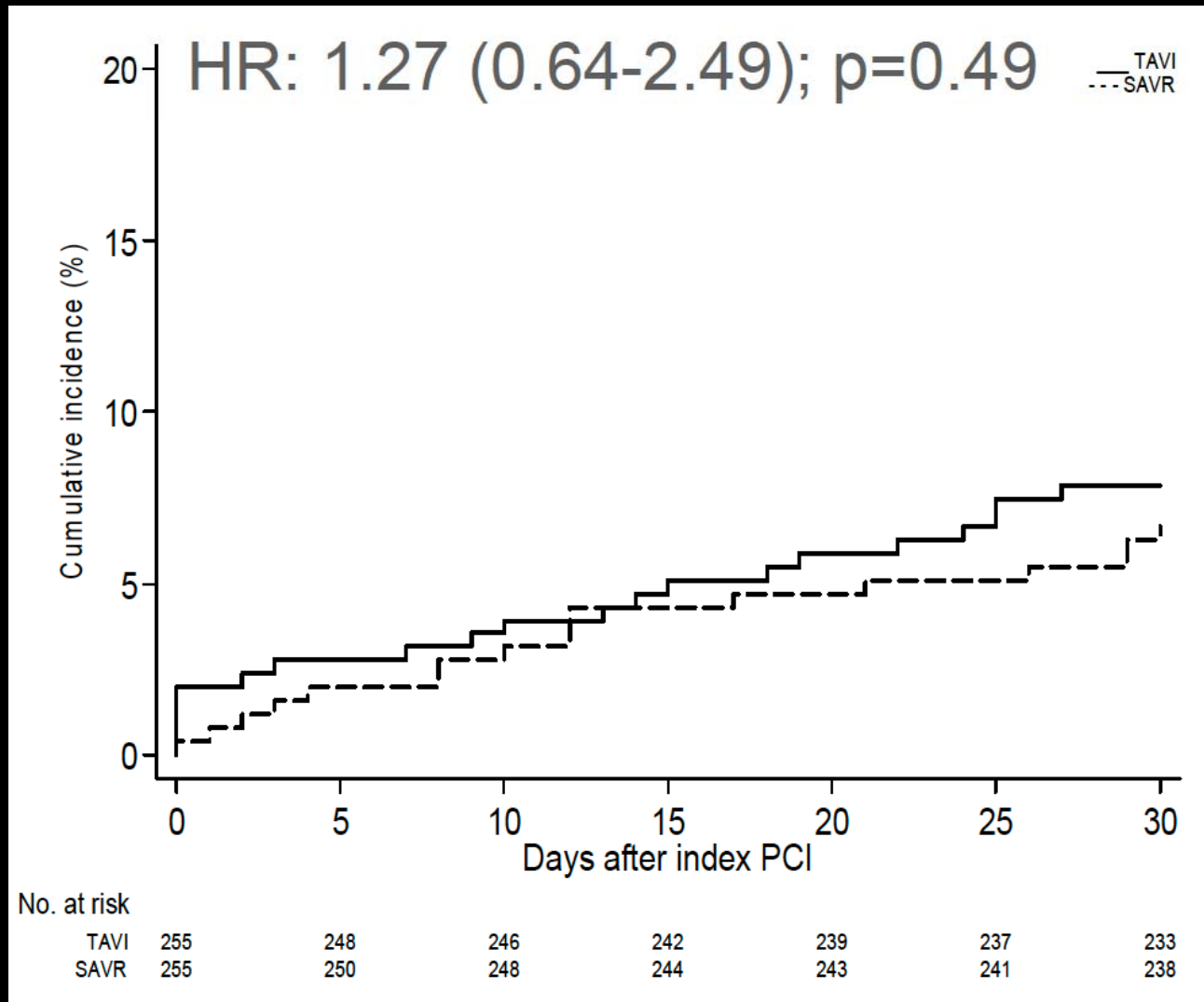


BERMUDA - BERn Munich rotterDAm



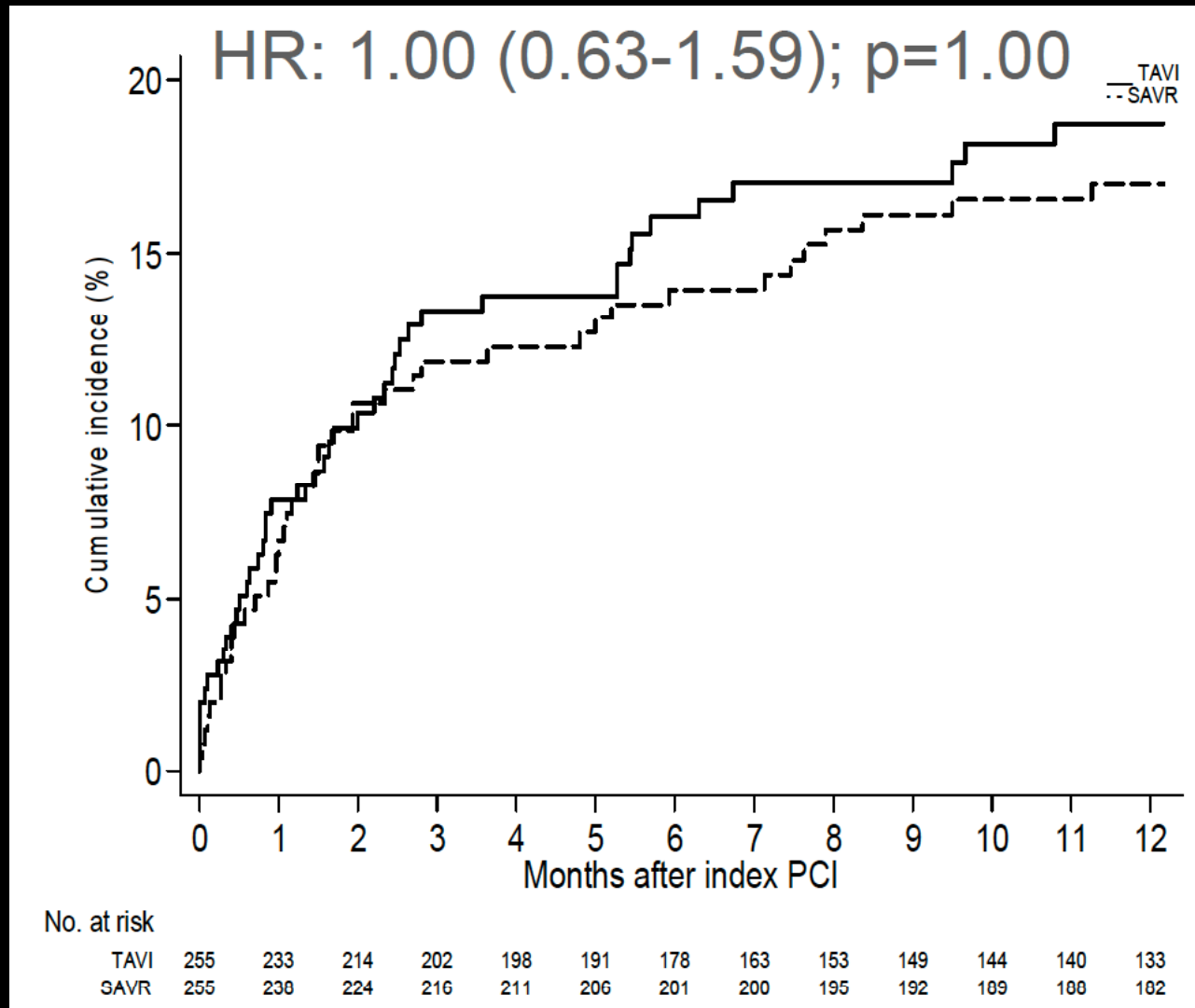
Courtesy Stephan Windecker

The BERMUDA study



Courtesy Stephan Windecker

The BERMUDA study



Courtesy Stephan Windecker

TAVI in Intermediate Risk Patients

Issues

- Complications
 - Access site
 - Stroke
 - Pacemaker
- Lack of proven long term durability
- Coronary access (MDT)
- Redo strategy

TAVI in Low Risk Patients

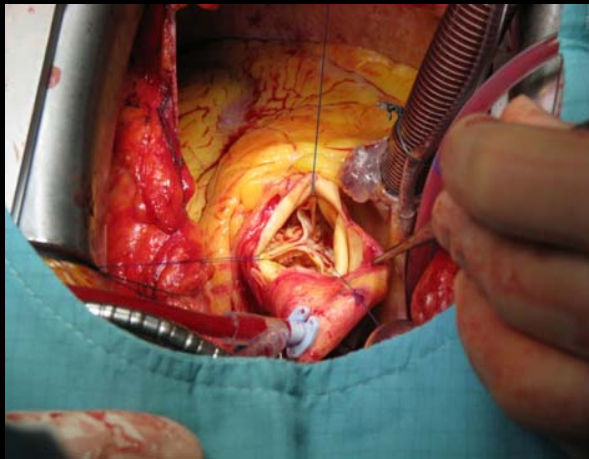
What is needed?

Randomized clinical studies

Comparison of TAVI vs SAVR in Lower Risk Patients

SURTAVI

RCT comparing
TAVI with SAVR
STS score 3/4–8%



PARTNER II

RCT comparing
TAVI with SAVR
STS score 4–8%



vs.

