

TAVR for Aortic Stenosis in Patients who Cannot Undergo Surgery

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**Presenter Disclosure Information for
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NON-PAID Consultant:
Edwards Lifesciences, Medtronic

Consultant:
Symetis

Equity Relationship:
Claret, Sadra

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Transcatheter Aortic-Valve Implantation for Aortic Stenosis
in Patients Who Cannot Undergo Surgery

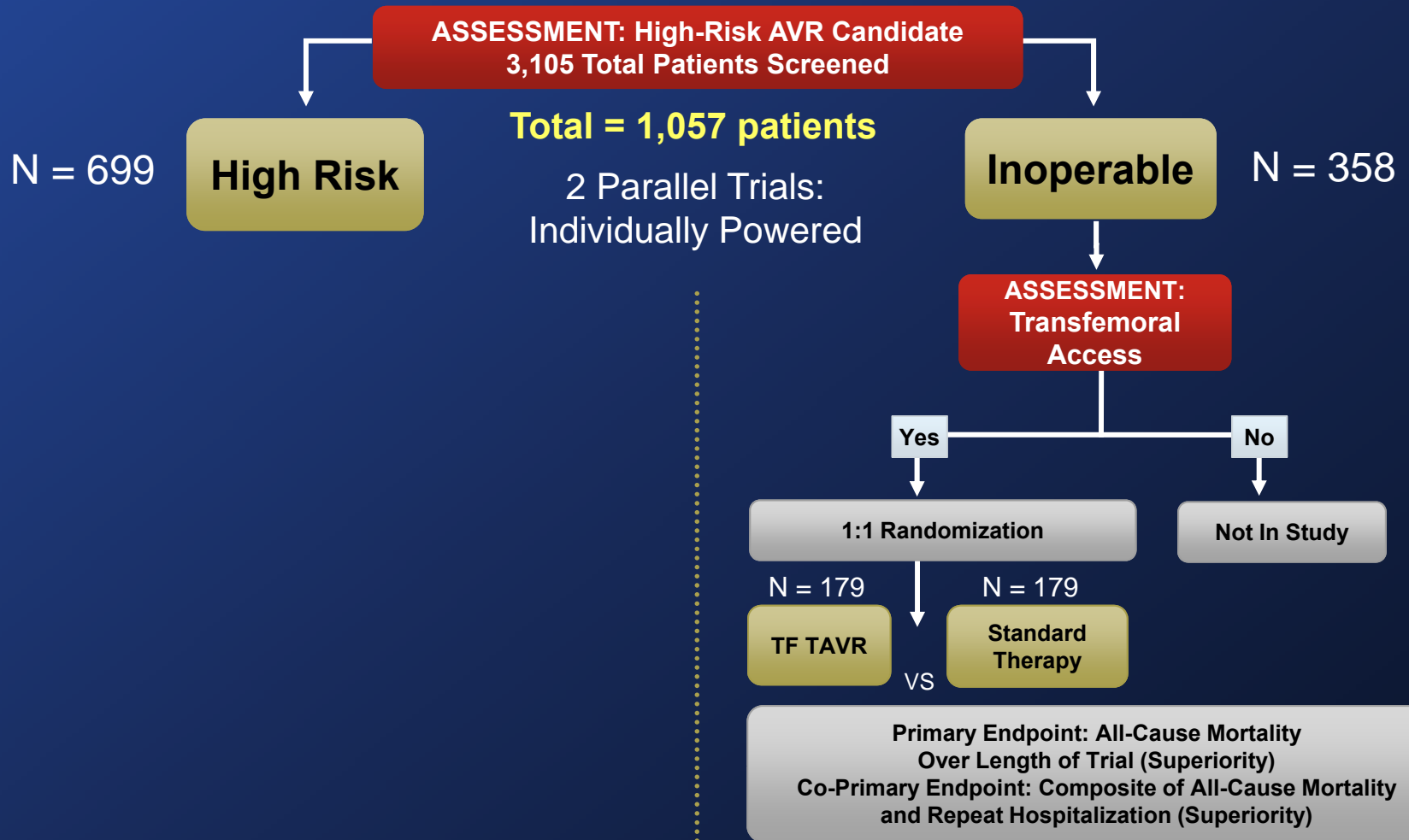
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Lars G. Svensson, M.D., Ph.D., E. Murat Tuzcu, M.D., John G. Webb, M.D., Gregory P. Fontana, M.D.,
Raj R. Makkar, M.D., David L. Brown, M.D., Peter C. Block, M.D., Robert A. Guyton, M.D.,
Augusto D. Pichard, M.D., Joseph E. Bavaria, M.D., Howard C. Herrmann, M.D., Pamela C. Douglas, M.D.,
John L. Petersen, M.D., Jodi J. Akin, M.S., William N. Anderson, Ph.D., Duolao Wang, Ph.D.,
and Stuart Pocock, Ph.D., for the PARTNER Trial Investigators*

*On behalf of the Executive Committee, the Investigator Sites,
and the courageous patients who participated in the PARTNER trial!*

PARTNER Study Design



Symptomatic Severe Aortic Stenosis

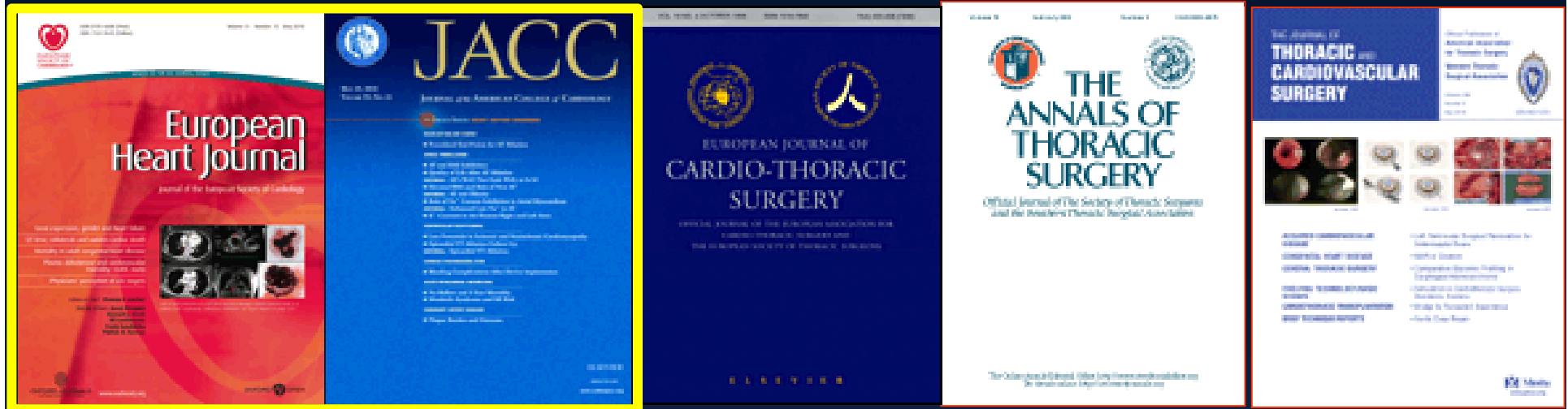


PARTNER Impact - 1



- PARTNER proved that we can rigorously conduct (even complex) RCTs in risk prone AS patients – a new evidence-based medicine standard for clinical research in valvular heart disease - ***we need more high quality data from both surgical AVR and TAVI studies in the future (no more excuses)!***

VARC MANUSCRIPT



CLINICAL RESEARCH

Valvular Medicine

Standardized Endpoint Definitions for Transcatheter Aortic Valve Implantation Clinical Trials

A Consensus Report From the Valve Academic Research Consortium

Martin B. Leon, Nicolo Piazza, Eugenia Nikolsky, Eugene H. Blackstone, Donald E. Cutlip, Arie Pieter Kappetein, Mitchell W. Krucoff, Michael Mack, Roxana Mehran, Craig Miller, Marie-angéle Morel, John Petersen, Jeffrey J. Popma, Johanna J. M. Takkenberg, Alec Vahanian, Gerrit-Anne van Es, Pascal Vranckx, John G. Webb, Stephan Windecker, Patrick W. Serruys

New York, New York

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- The multi-disciplinary culture (cardiac surgery + interventional cardiology) infused in every facet of PARTNER represents a necessary early step in a radical paradigm shift in patient care - ***optimal TAVI requires an integrated valve team approach and environment (shouldn't compromise)!***

Executive Committee



Lars Svensson

Craig Miller Murat Tuzcu

Craig Smith

Jeff Moses

Marty Leon

John Webb

Michael Mack

Transcatheter AVR

Hybrid OR-Cath Lab



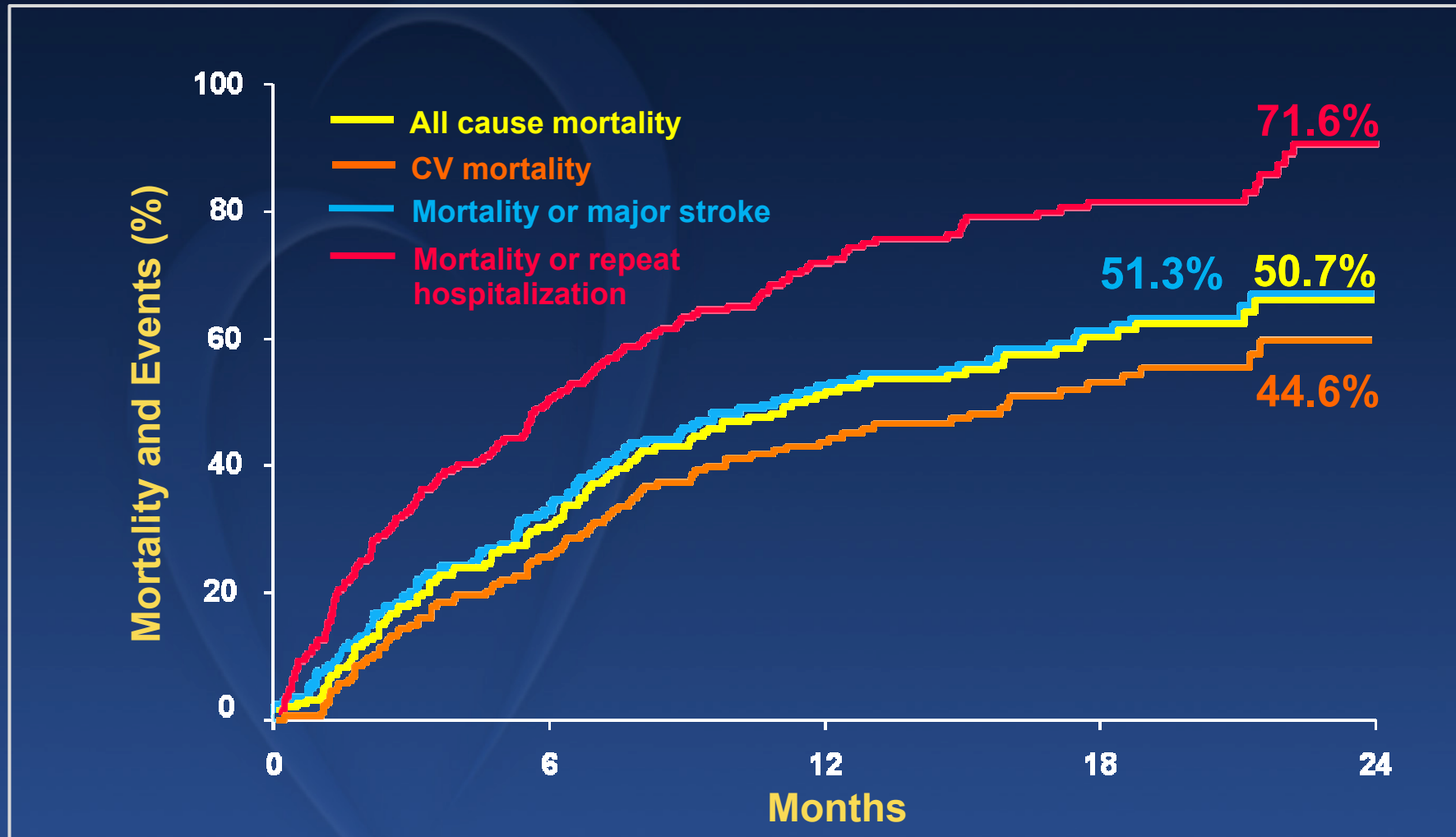
A unique collaborative experience!

PARTNER Impact - 2



- **Standard therapy (including BAV in ~ 80% of pts) did not alter the dismal natural history of patients with severe AS and cardiac symptoms**
 - **all-cause and cardiovascular mortality at 1 year was 50.7% and 44.6% respectively**

Standard Therapy Outcomes



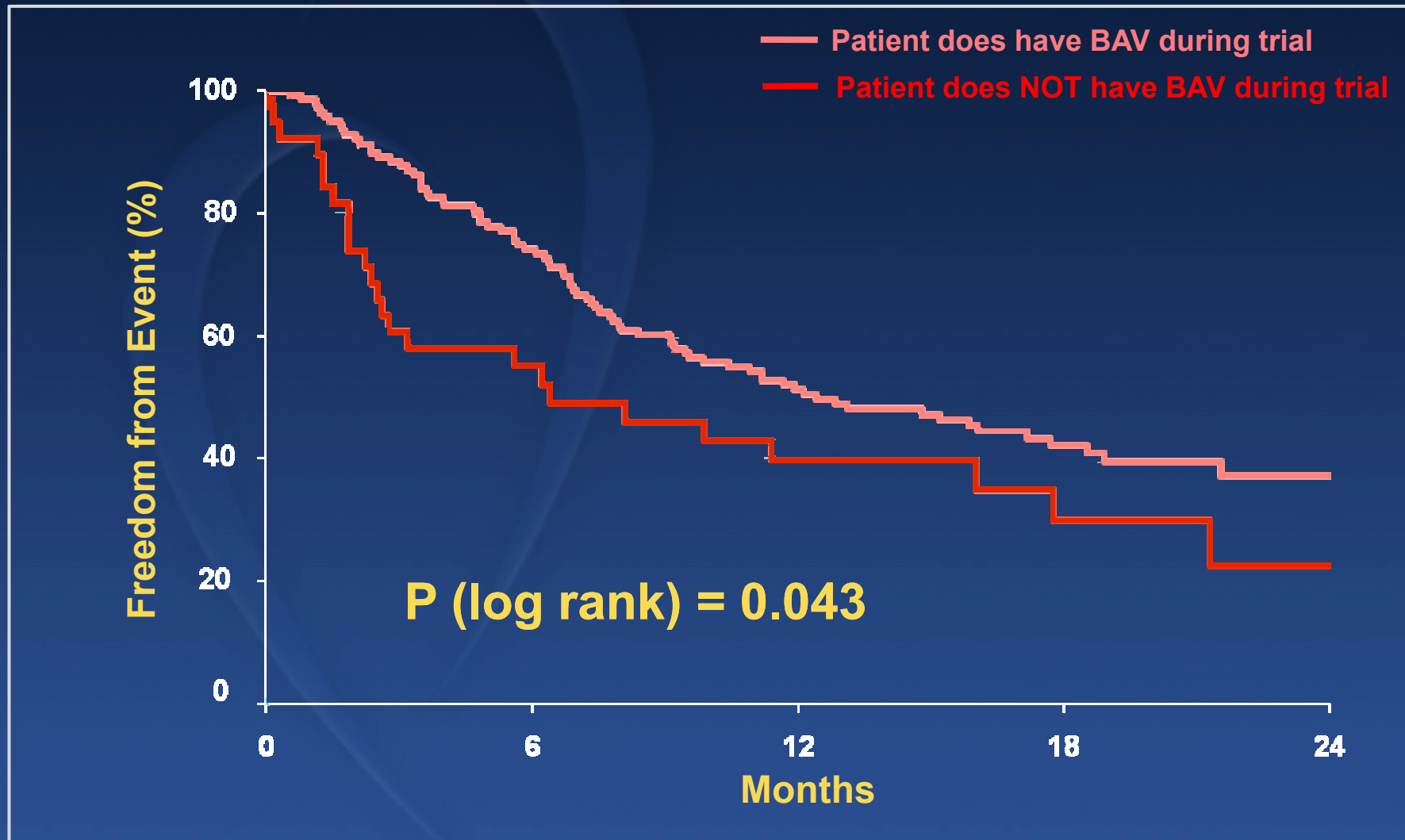
Standard Rx	179	121	83	41	12
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PARTNER Impact - 2



- **Standard therapy (including BAV in ~80% of pts) did not alter the dismal natural history of patients with severe AS and cardiac symptoms**
 - **all-cause and cardiovascular mortality at 1 year was 50.7% and 44.6% respectively**
- **BAV was a meaningful palliative therapy in these inoperable standard therapy patients**
 - **helped to refine optimal case selection**
 - **improved symptoms (usually transient)**
 - **reduced mortality (cw no BAV patients)**
 - **bridge to other therapies (improved overall condition may alter operable status)**

Mortality With and Without BAV



PARTNER Impact - 3

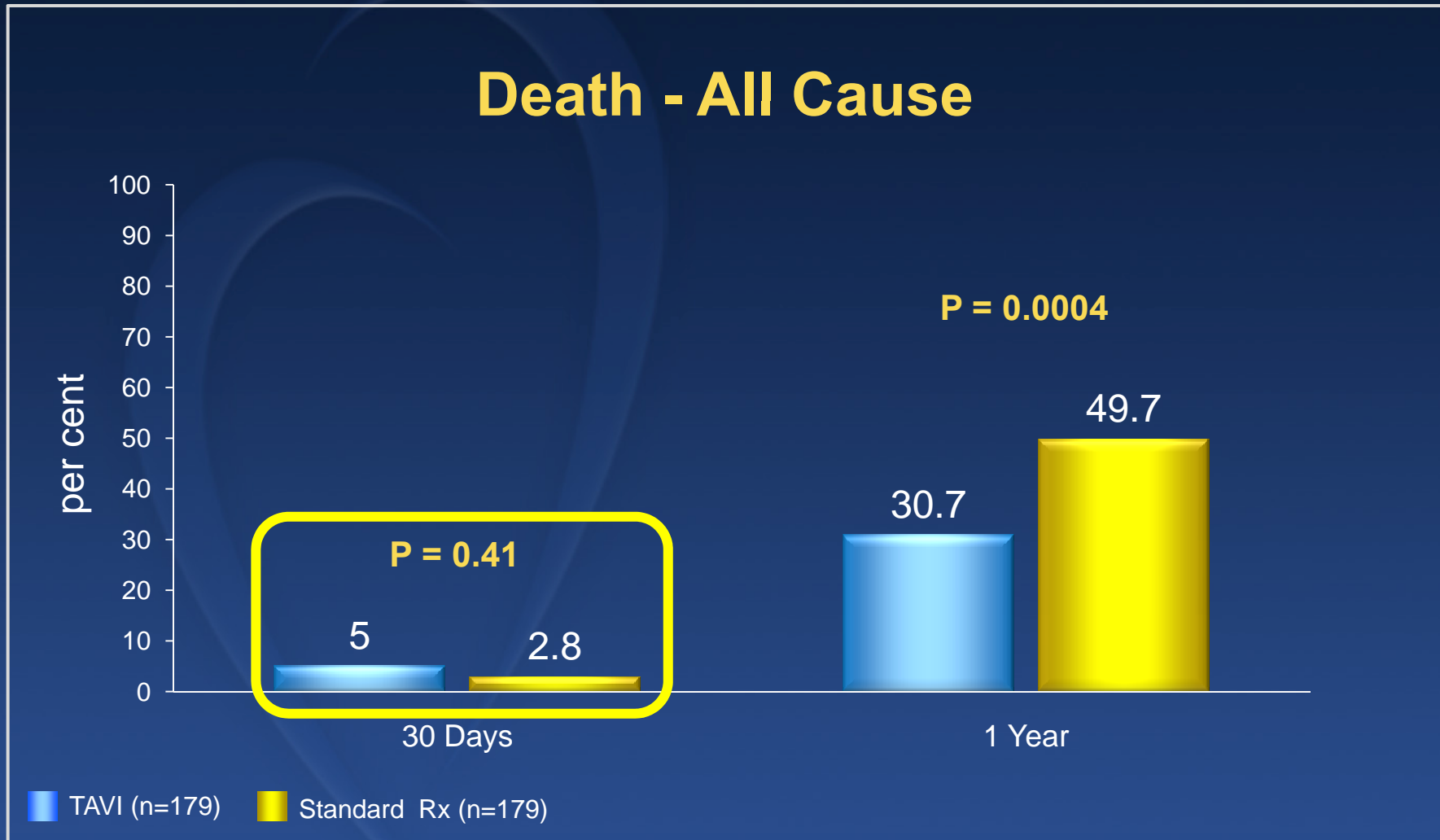


- PARTNER established a new standard for peri-procedural outcomes (5% mortality @ 30 days) after TAVI in high risk AS patients - *the case selection intensity and team training approach of PARTNER should become the future model (dare to predict results for the PARTNER high surgical risk cohort?)*

Clinical Outcomes at 30 Days and 1 Year



Death - All Cause

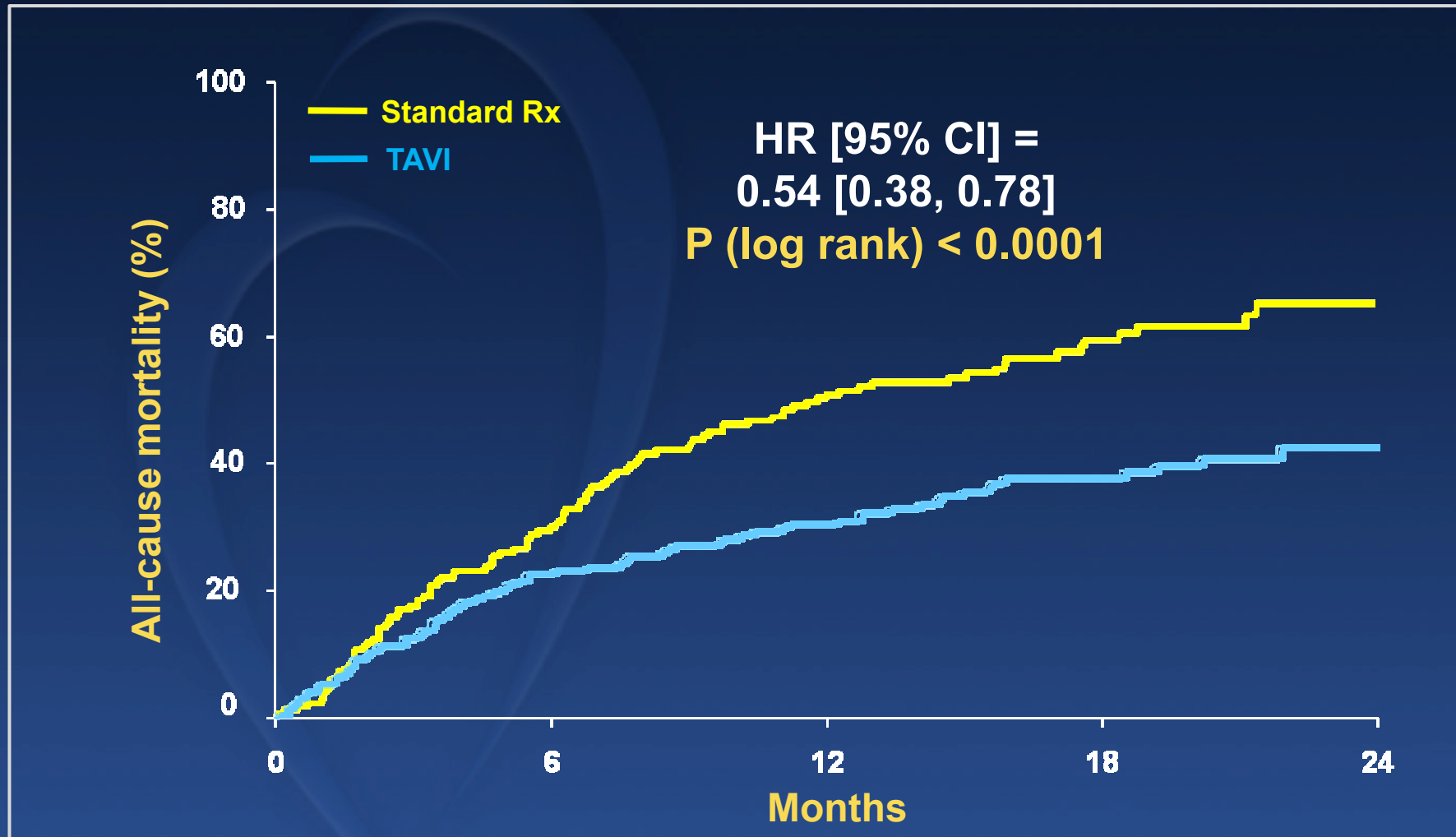


PARTNER Impact -3



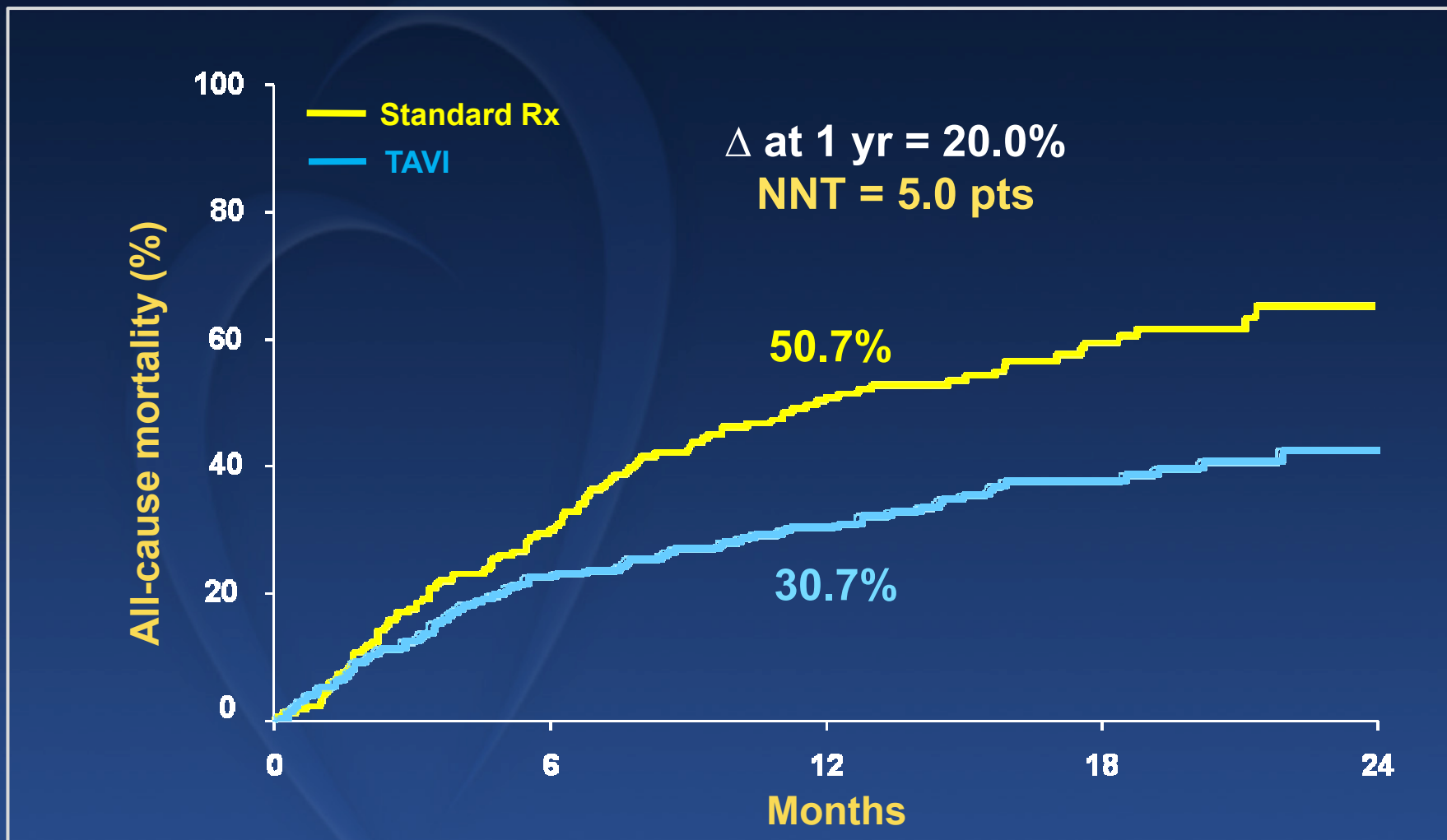
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- The mortality benefit of TAVI in PARTNER is of historic proportions (NNT = 5) - *TAVI is the new standard-of-care in inoperable AS patients!*

1st Endpt - All Cause Mortality



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

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PARTNER Impact -3

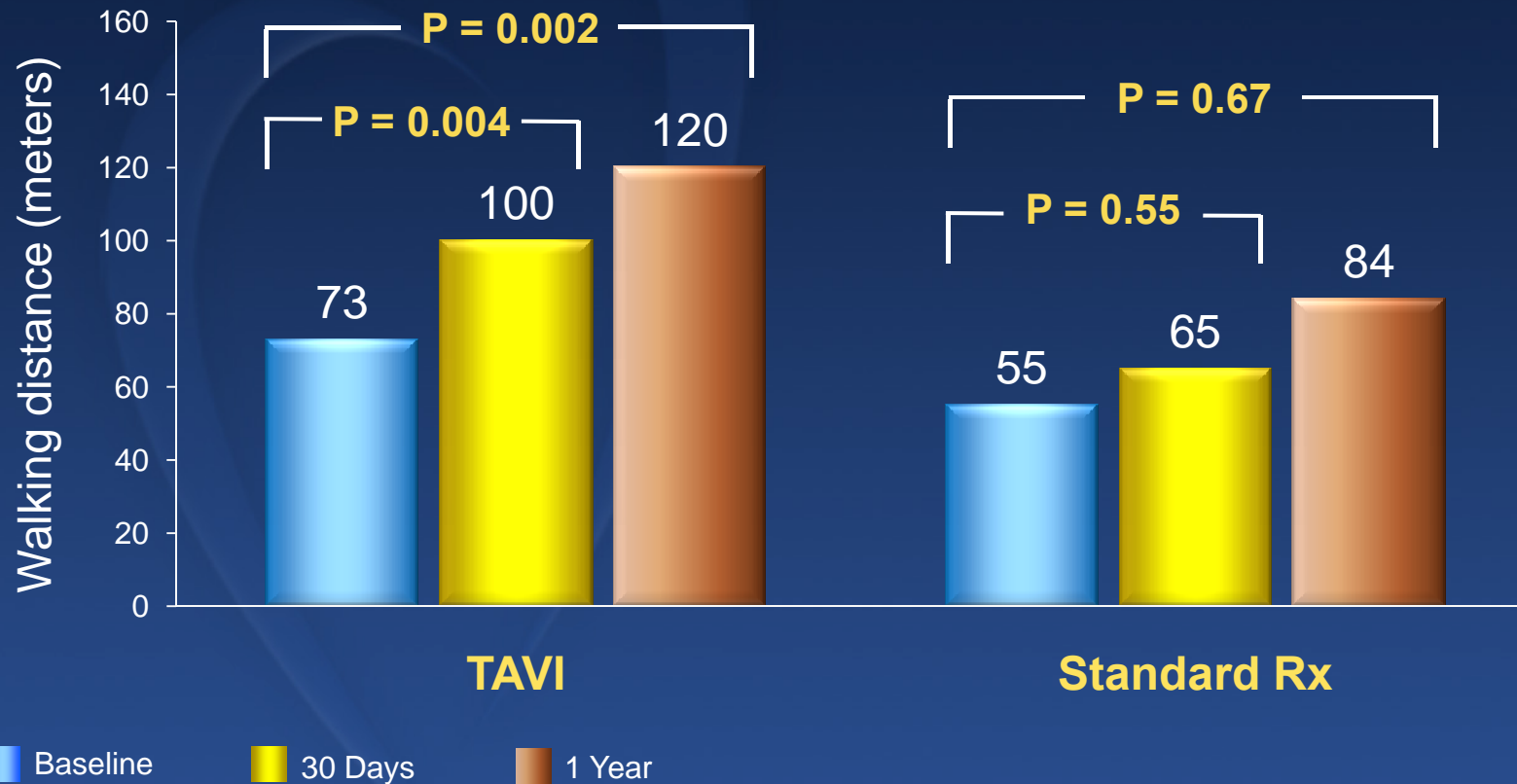


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- The mortality benefit of TAVI in PARTNER is of historic proportions (NNT = 5) - ***TAVI is the new standard-of-care in inoperable AS patients!***
- The QOL benefits of TAVI in PARTNER are equally impressive - ***the most fulfilling symptom-reducing interventional therapy ever (dwarfs PCI)!***

Six-Minute Walk Tests

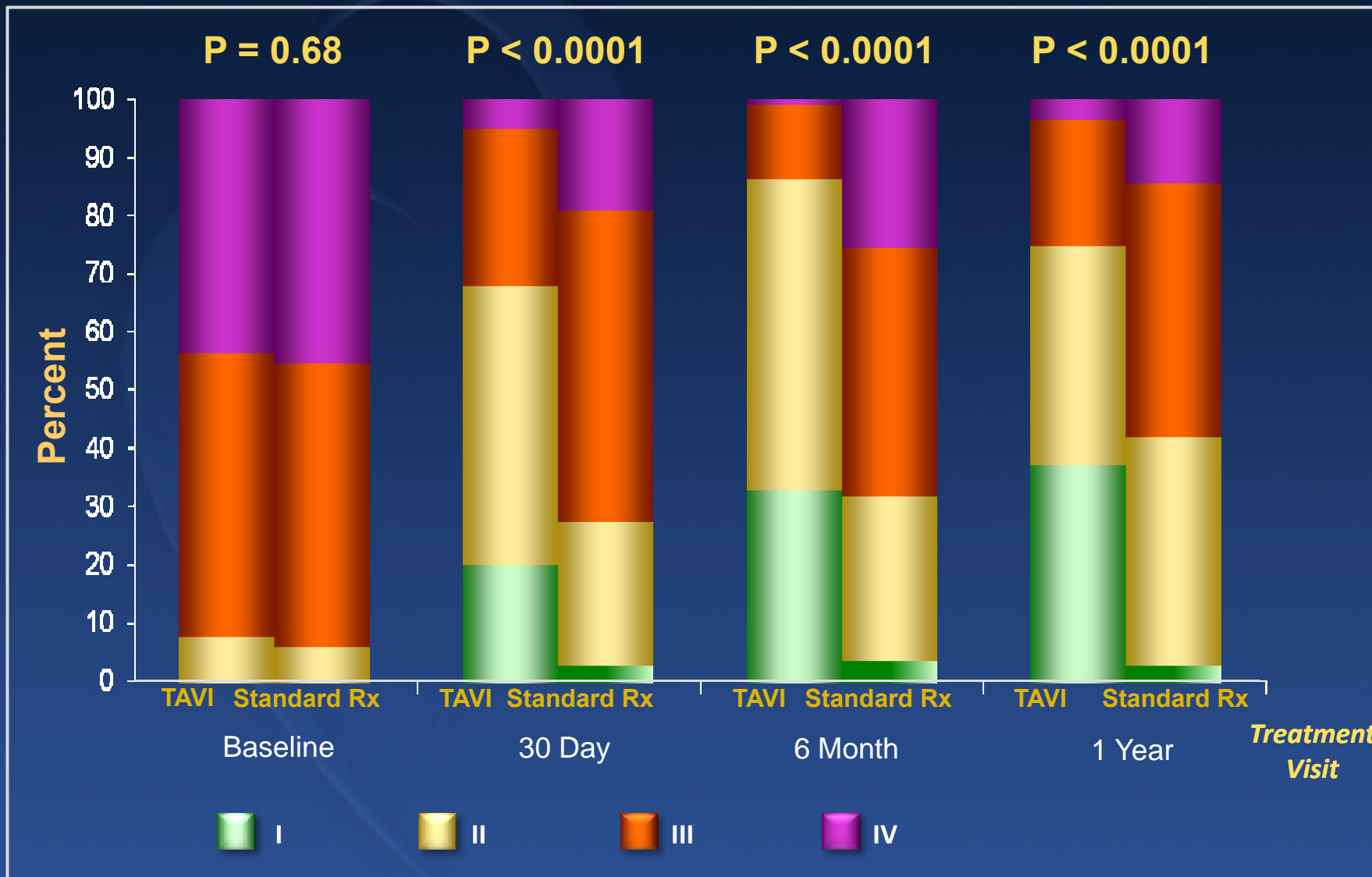


Walking Distance

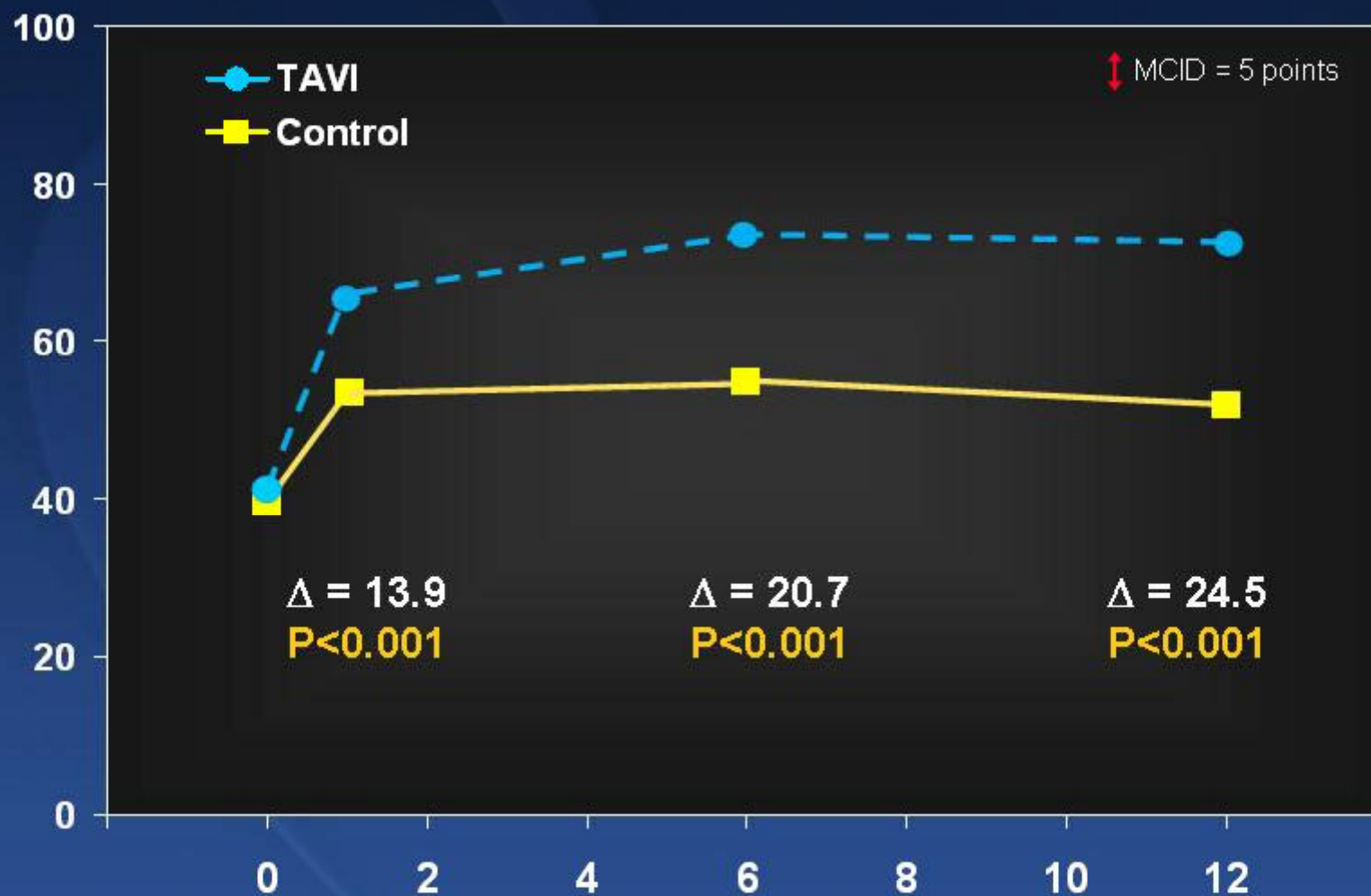


NYHA Class Over Time

Survivors



Primary Endpoint: KCCQ Overall Summary



MCID = minimum clinically important difference

PARTNER QOL Analyses



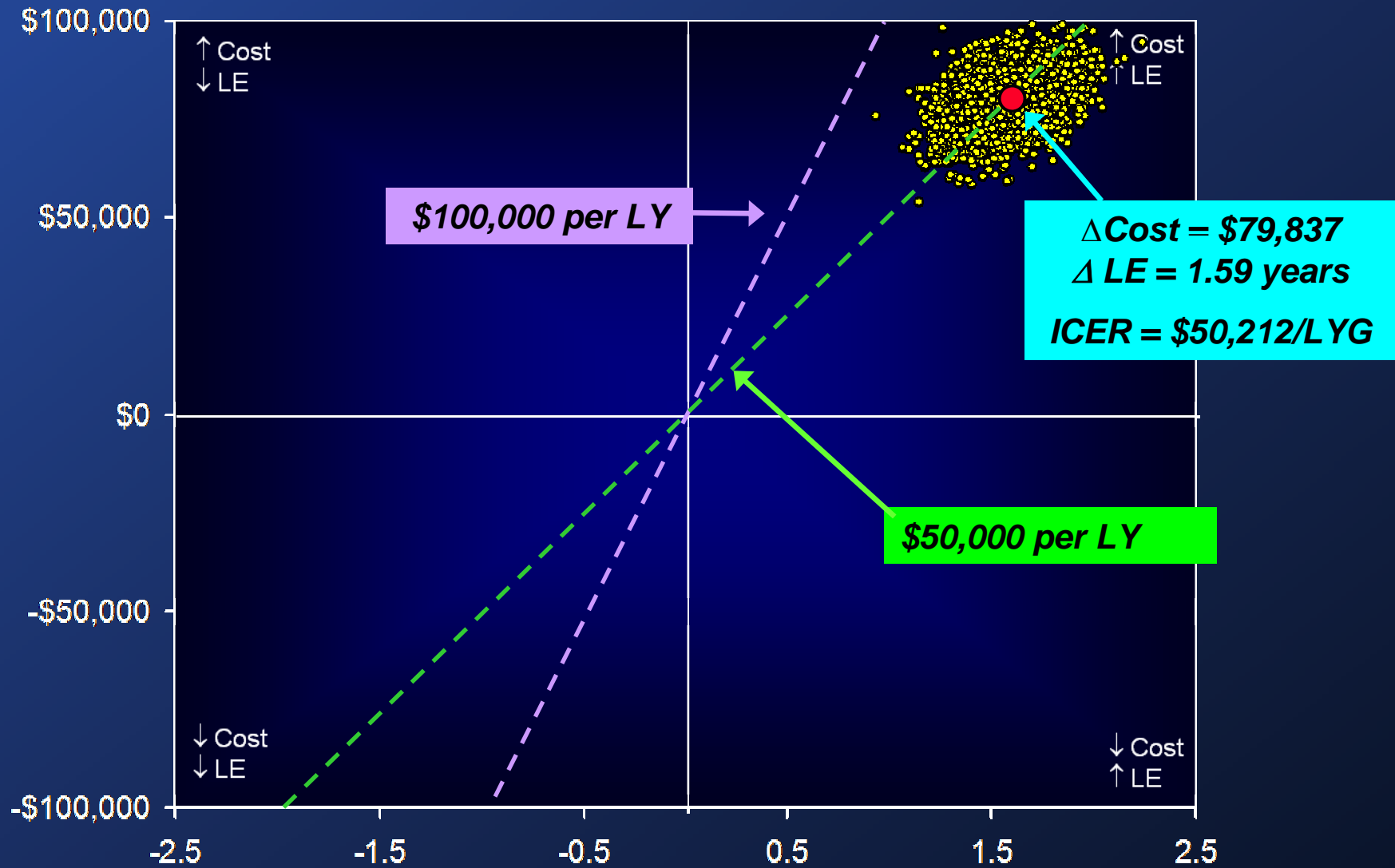
***TAVR not only
adds years to life,
but also,
adds life to years!***

PARTNER Impact -3

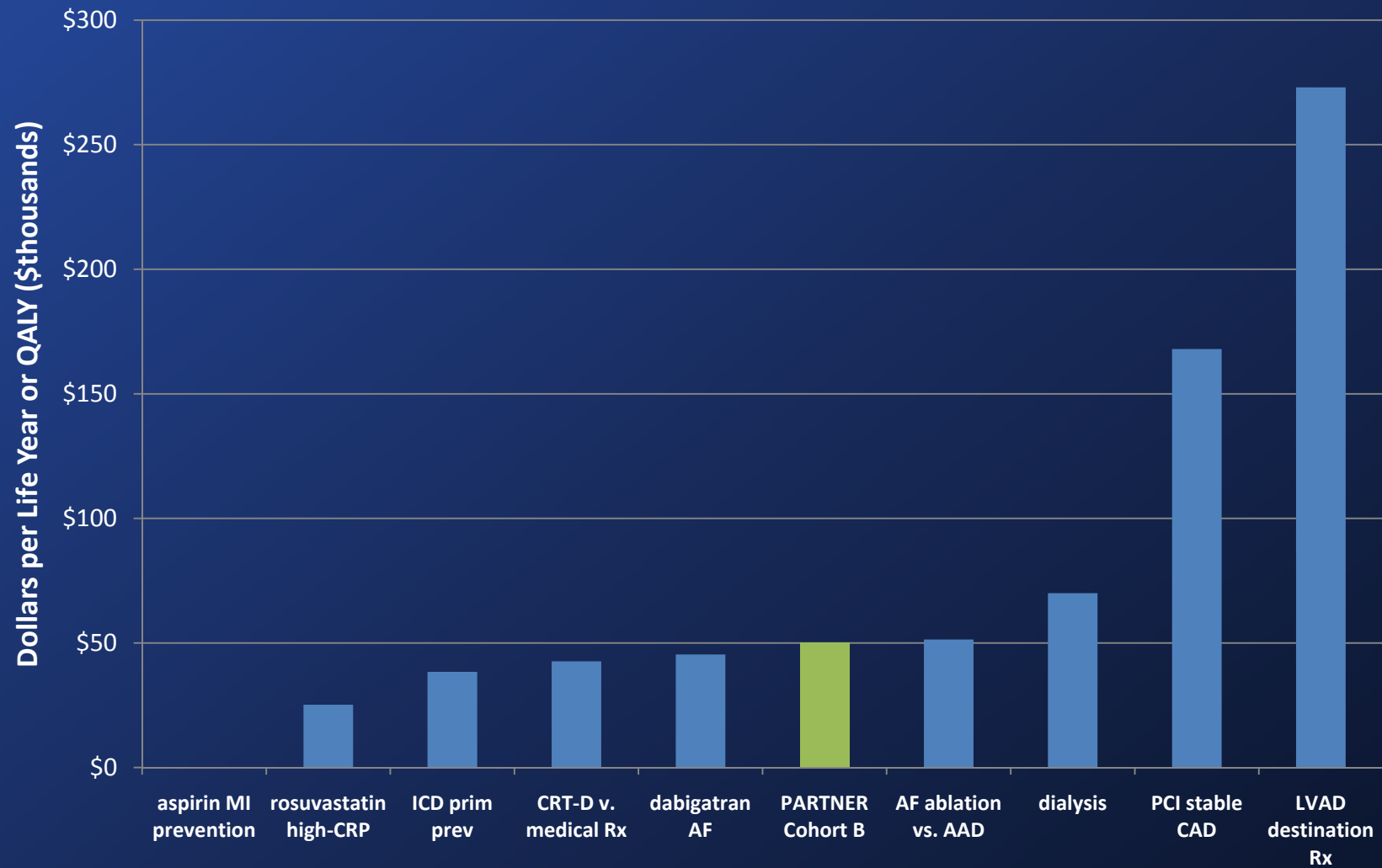


- TAVR is associated with increased procedural costs, but reduced outpatient expenses during the first year of FU - ***considering the increased survival the incremental cost-effectiveness ratio is favorable!***

Cost-Effectiveness of TAVR vs. Control Lifetime Results



Published Cost Effectiveness Estimates



PARTNER Impact - 4



- TAVI-related complications, esp. neurologic events, bear close scrutiny - *can future iterative enhancements (e.g. lower system profiles) reduce complications? ...await surgical control arm results (PARTNER high surgical risk cohort) for better perspective!*

Clinical Outcomes at 30 Days and 1 Year

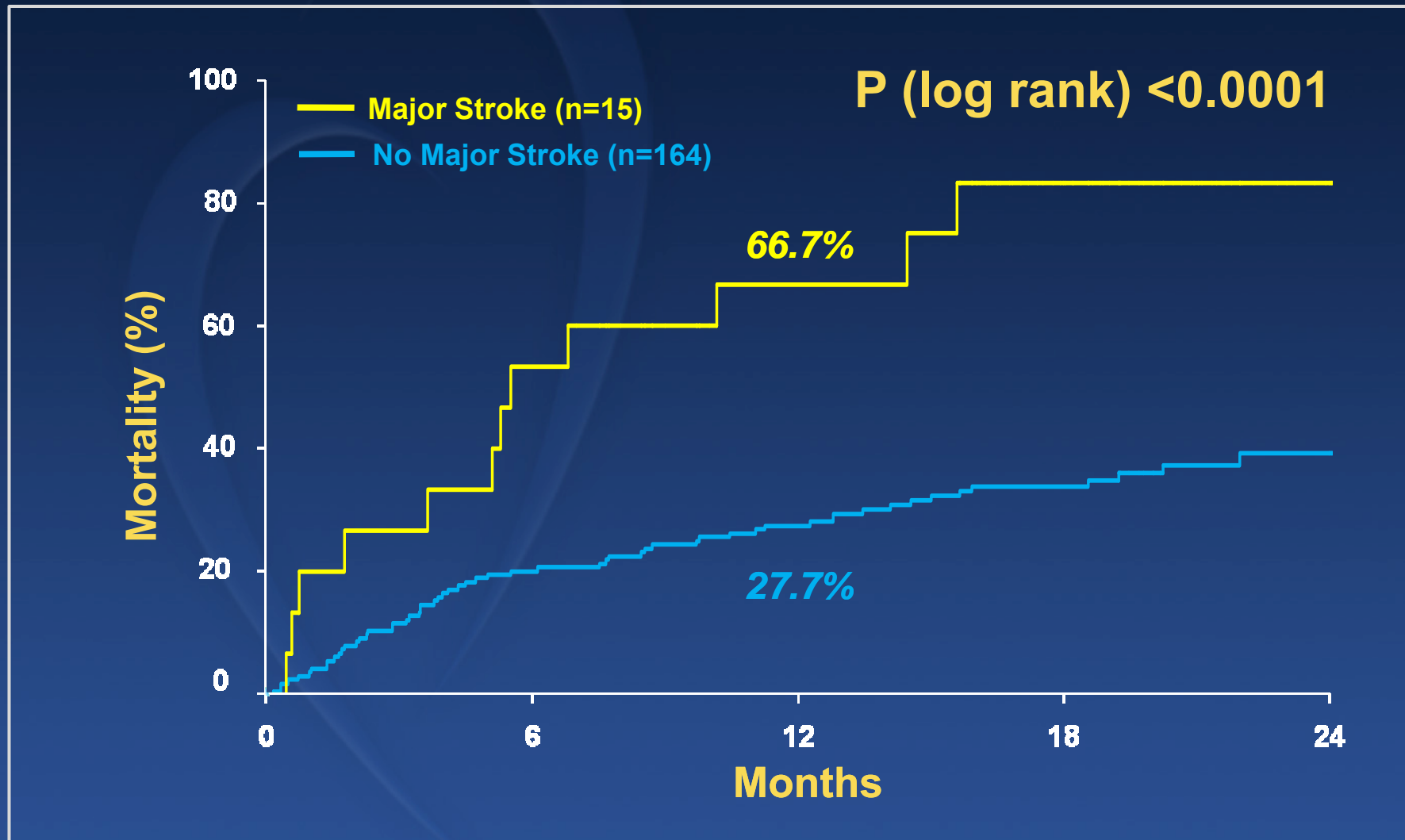


Major Stroke

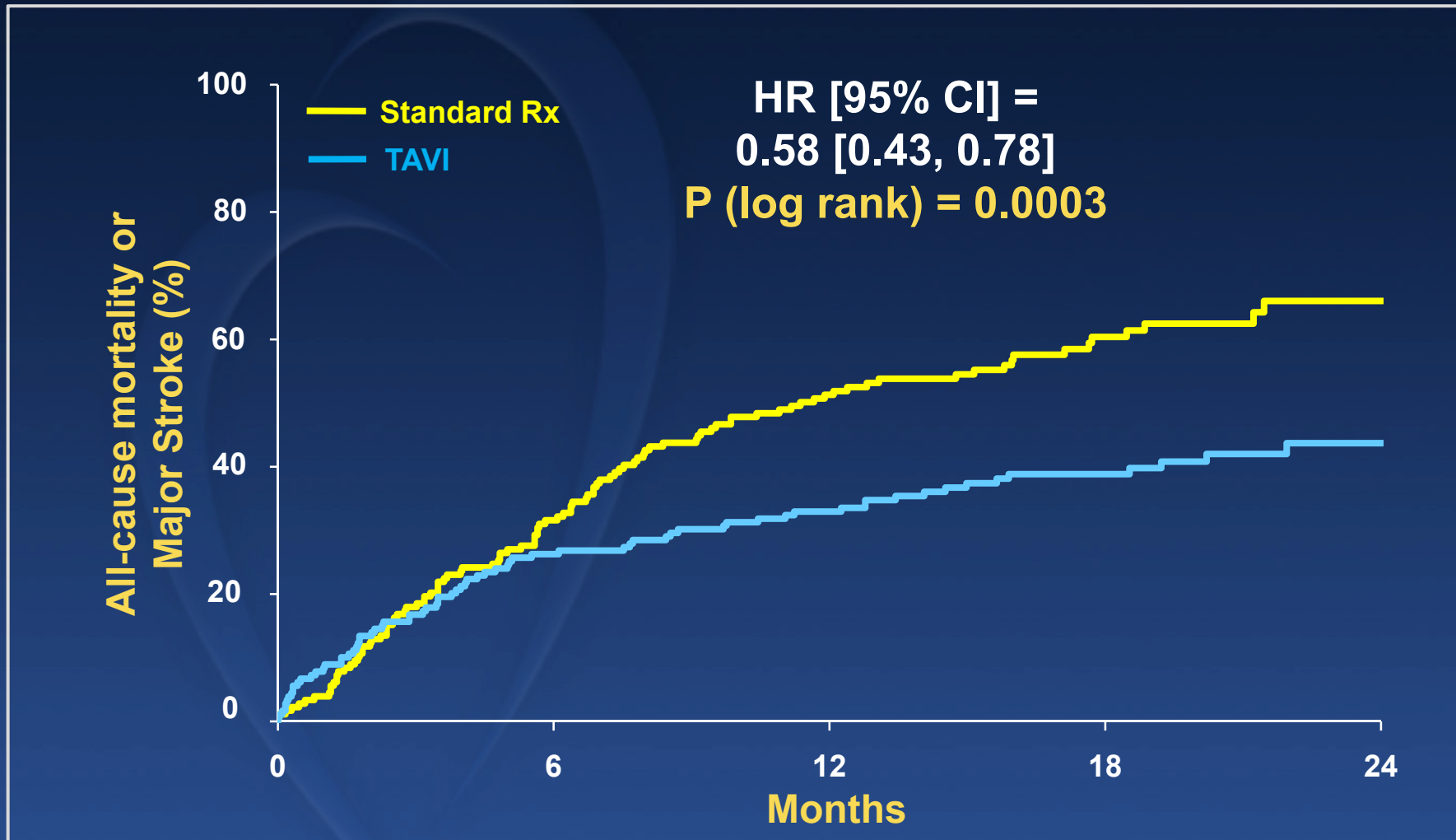
All Stroke or TIA



Mortality vs. Major Stroke TAVI patients



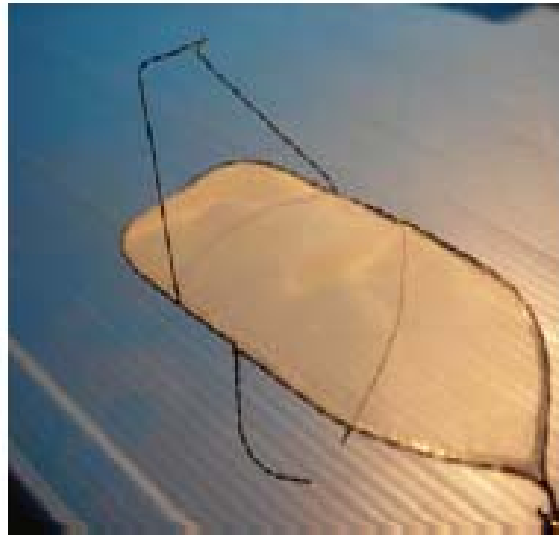
Mortality or Major Stroke



Numbers at Risk					
	0	6	12	18	24
TAVI	179	132	118	56	25
Standard Rx	179	118	83	41	12

TAVI 2011

Cerebral Embolic Protection



SMT



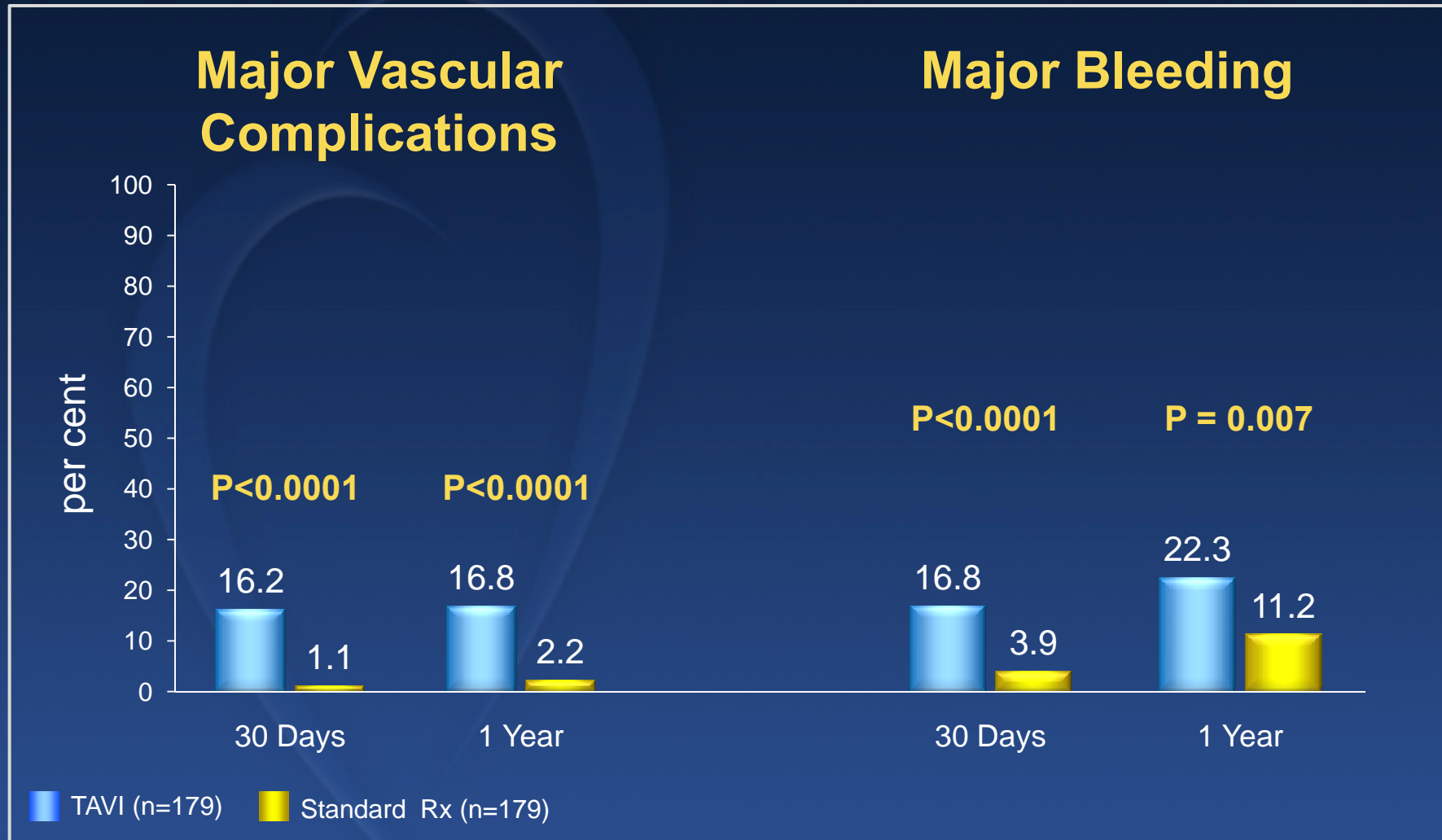
Embrella



Claret

Deflectors and Filters

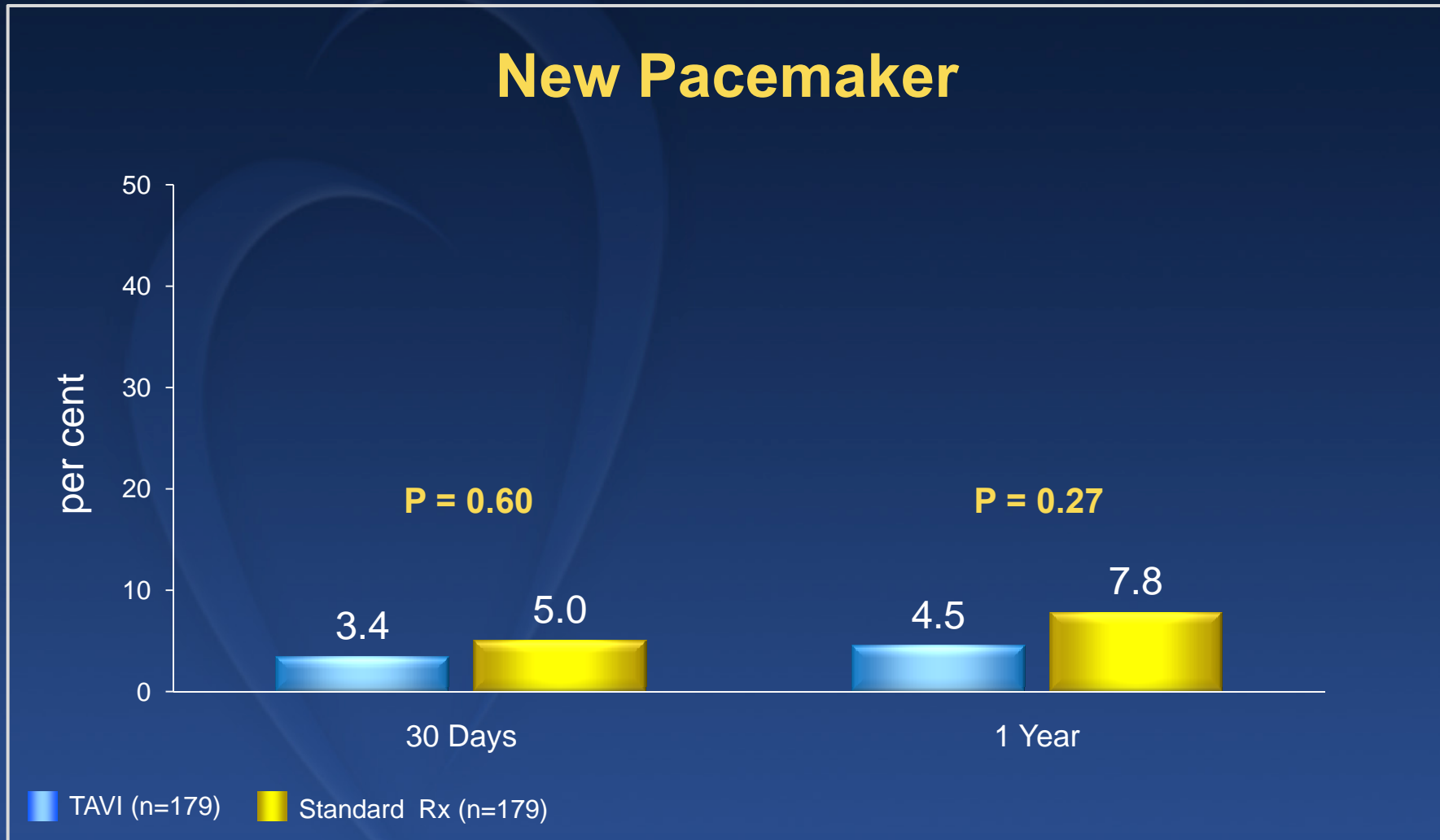
Clinical Outcomes at 30 Days and 1 Year



Clinical Outcomes at 30 Days and 1 Year



New Pacemaker

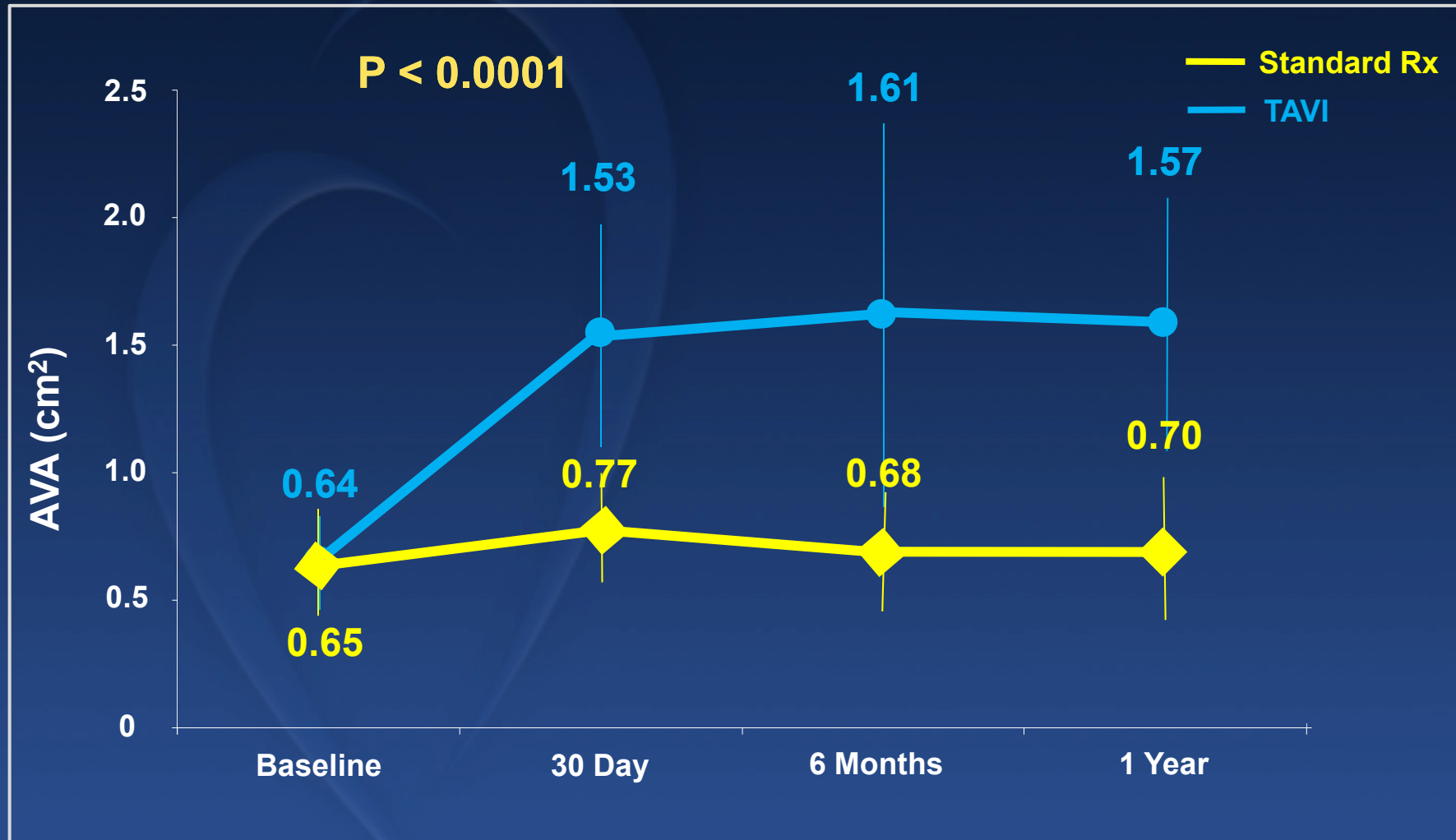


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- TAVI-related complications, esp. neurologic events, bear close scrutiny - *can future iterative enhancements (e.g. lower system profiles) reduce complications? ...await surgical control arm results (PARTNER high surgical risk cohort) for better perspective!*
- TAVI echo results (except para-valvular leak) are strikingly similar to surgical AVR.

Aortic Valve Areas Over Time

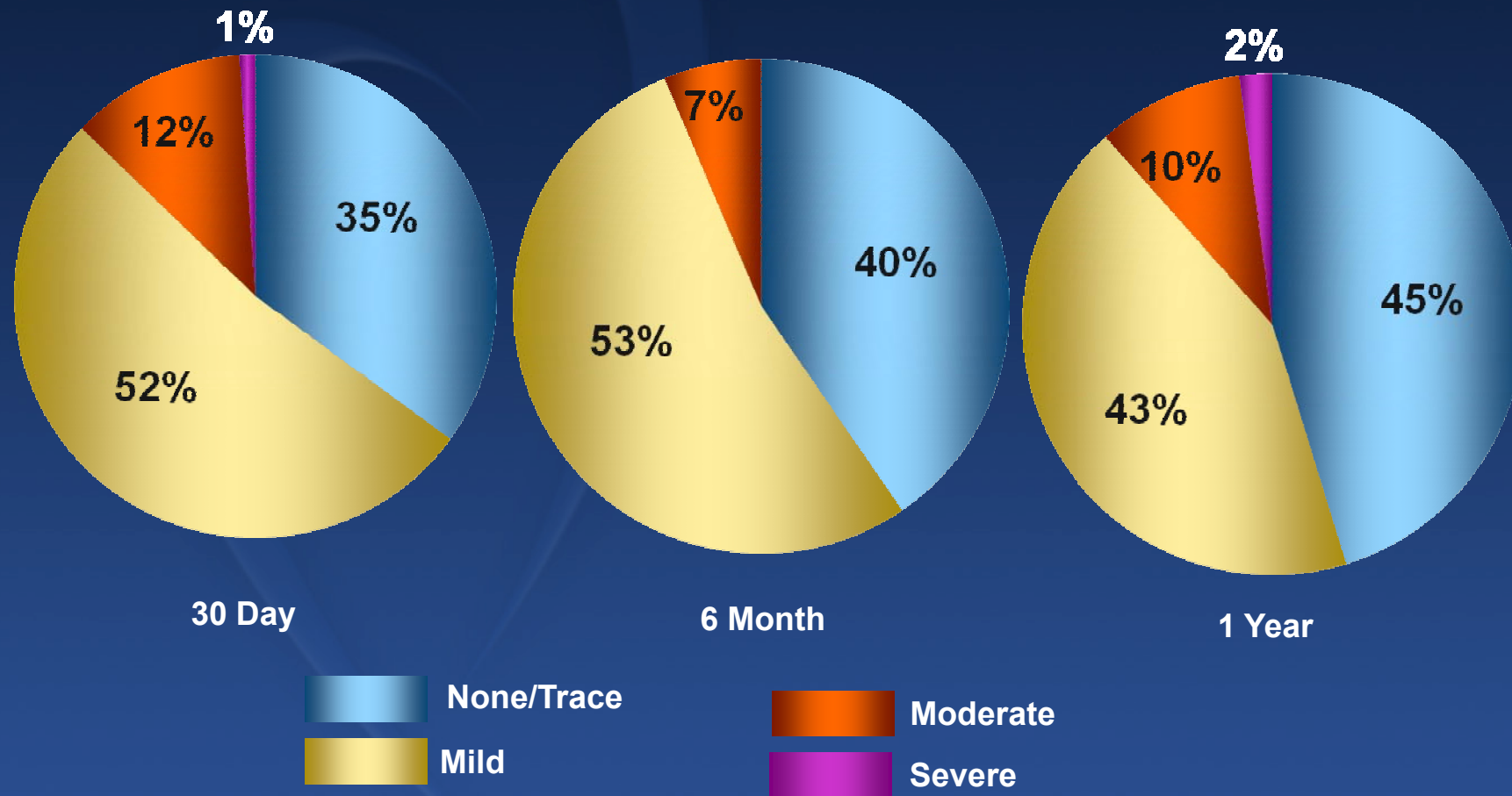


Error bars = ± 1 Std Dev

Paravalvular Regurgitation: TAVI



No changes over time



PARTNER Impact - 4



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- TAVI echo results (except para-valvular leak) are strikingly similar to surgical AVR.
- The overall unexpectedly favorable results from TAVI in PARTNER are a “game changer” - *TAVI incremental value clearly demonstrated and significant carryover momentum to more normal risk and other “new” patient cohort studies!*