

# Quality of Life after TAVR

*What do we know?*

*Why should you care?*

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# Disclosures

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## Grant Support/Drugs

- Daiichi-Sankyo
- Janssen Pharmaceuticals
- Eli Lilly
- Astra-Zeneca

## Grant Support/Devices

- Edwards Lifesciences
- Medtronic
- Biomet
- Abbott Vascular
- Boston Scientific
- Covidien

## Consulting/Advisory Boards

- Medtronic
- Eli Lilly
- Astra-Zeneca

# QOL after TAVR- Why Should We Care?

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## *Inoperable Patients*

- PARTNER B demonstrated substantial and sustained survival benefit compared with standard care
- However, given the advanced age and multiple comorbidities present in the inoperable patients, improved QOL may be an even more important goal of therapy
- In the absence of improved QOL, it is questionable whether many inoperable patients would want to live longer

# QOL after TAVR- Why Should We Care?

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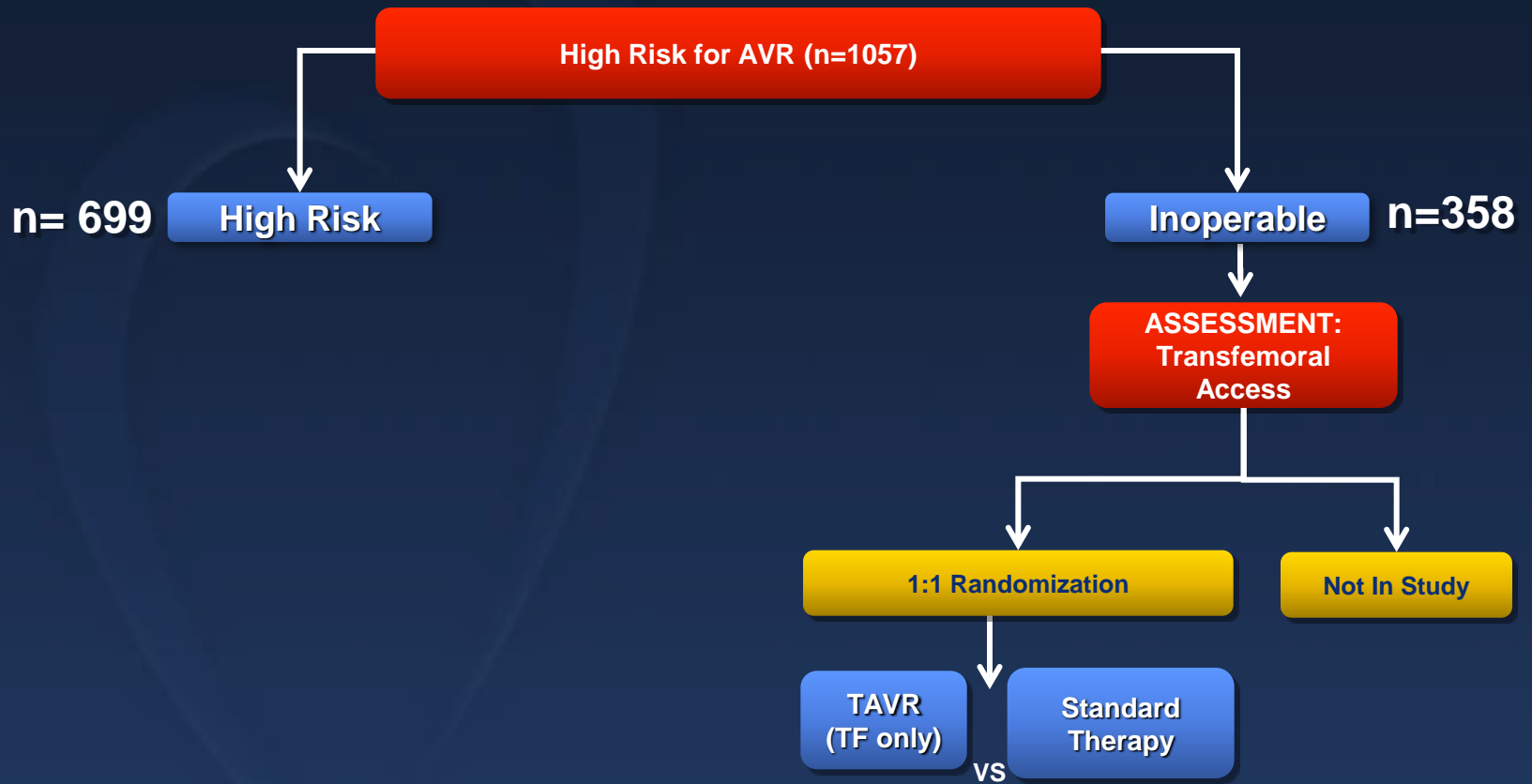
## **High-Risk Surgical Candidates (STS 10-15)**

- Uncertain long-term survival benefit of TAVR compared with AVR and some complications may even be increased
  - *Stroke/TIA, vascular complications, paravalvular AI*
- Therefore, evidence of improved QOL in either the short or long-term is critical to demonstrating the value of TAVR

# PARTNER Study Design

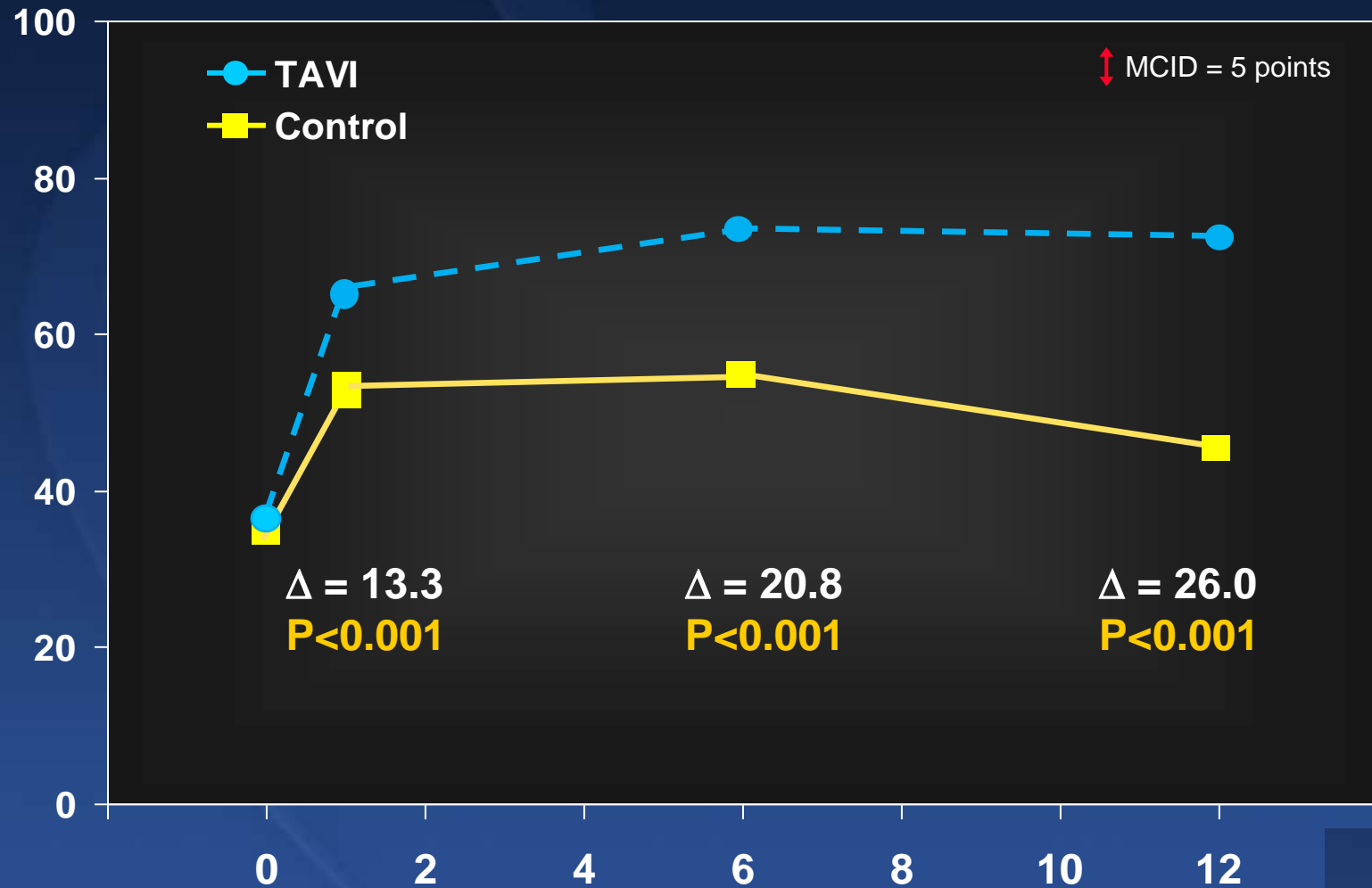


Symptomatic Severe Aortic Stenosis (3105 screened)



Primary Endpoint: All Cause Mortality over length of trial (Superiority)

# Primary Endpoint: KCCQ Overall Summary



# KCCQ: Interpretation

## Change in KCCQ-Overall Summary Score

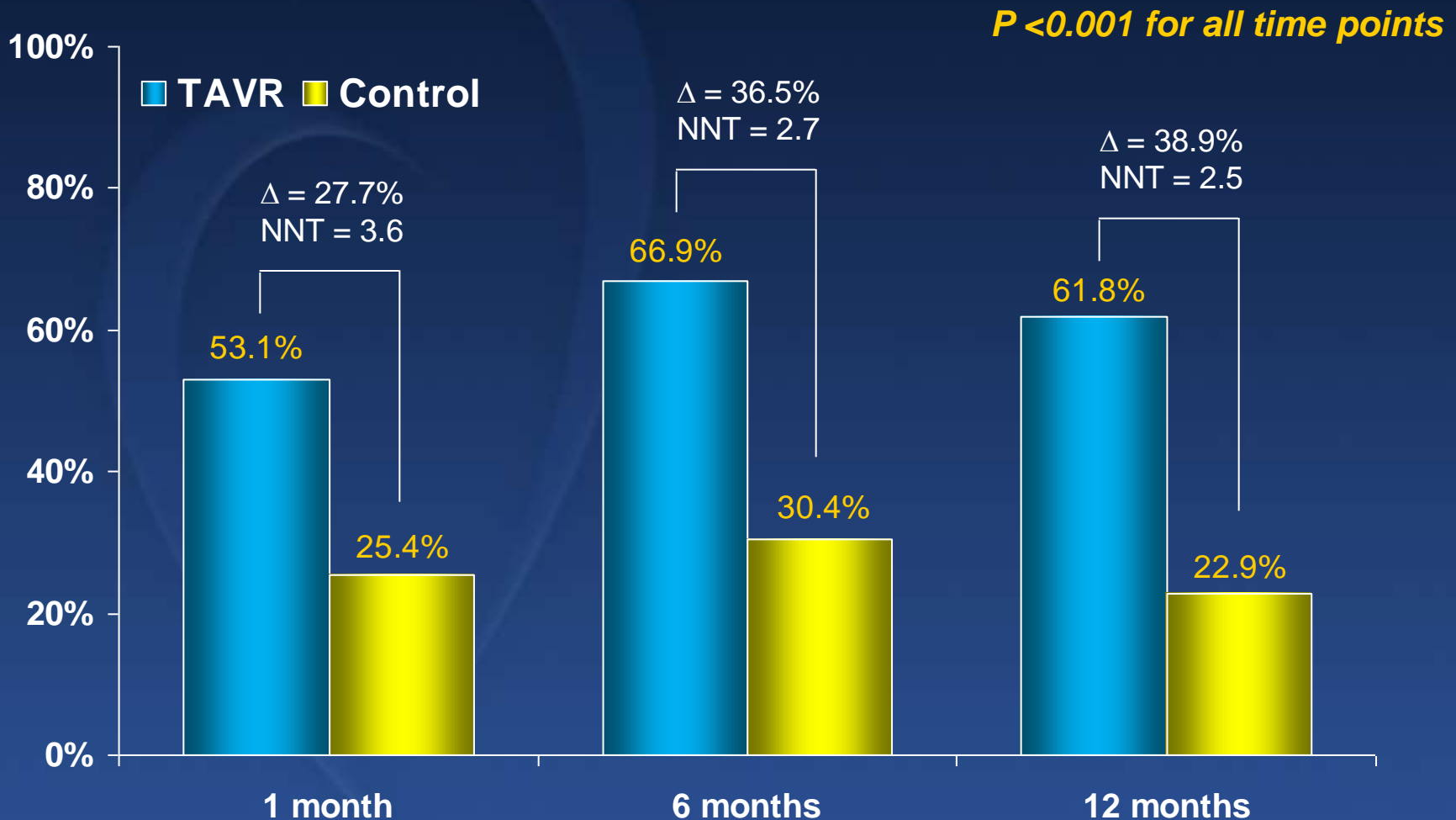


- 546 outpts with HF
- KCCQ assessed at baseline and 5 weeks
- Extent of deterioration or improvement assessed by physician based on sx and exam and correlated with KCCQ Overall

### Clinically Important Change

- Small = 5 points
- Moderate = 10 points
- Large = 20 points

# KCCQ-Summary: Substantial Improvement \*

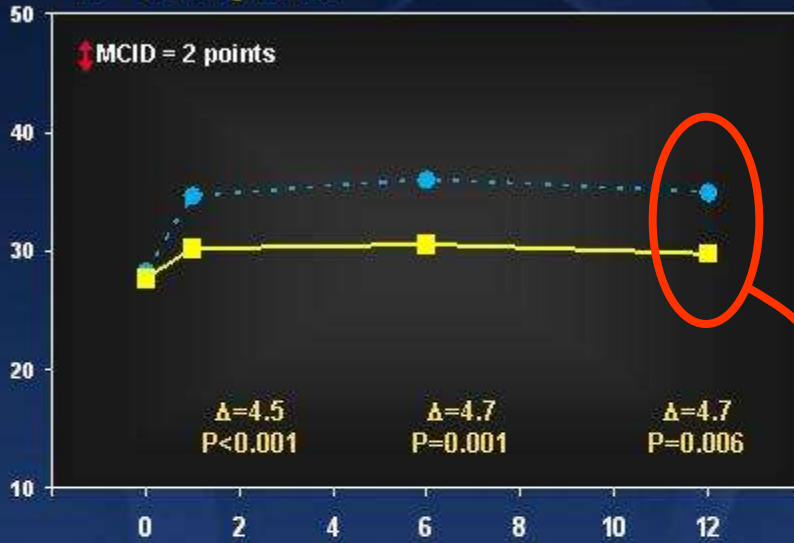


\* Improvement  $\geq$  20 points vs. baseline among patients with available QOL data

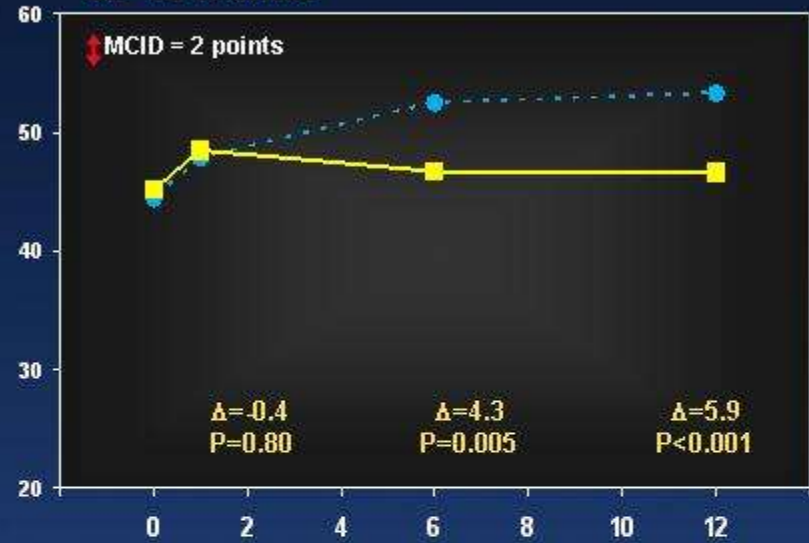


# Generic QOL and Utilities

### SF-12 Physical



### SF-12 Mental



### EQ-5D Utilities

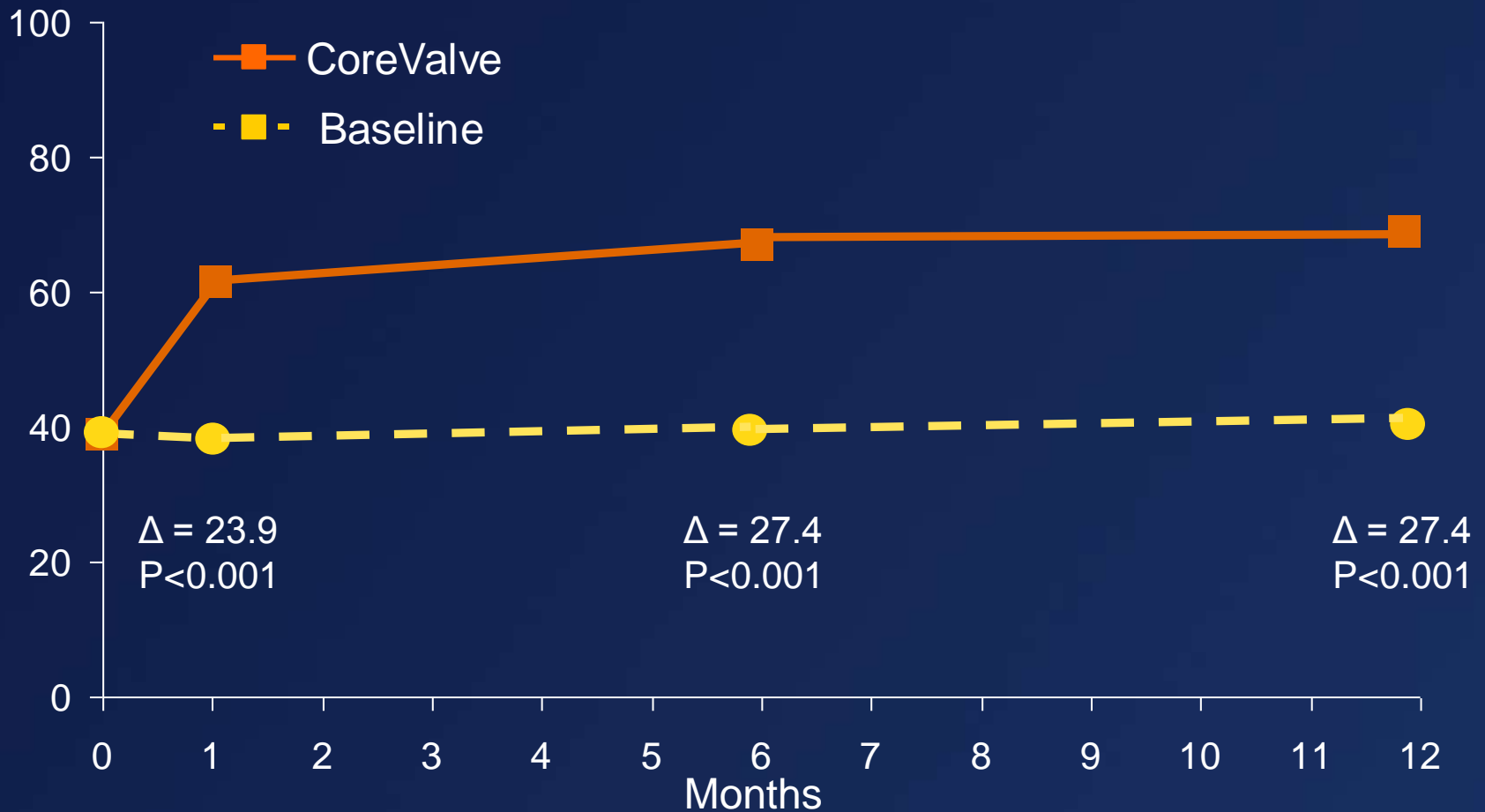


**5 point difference  
comparable to  
10-year age  
difference**

Reynolds MR, et al. *Circulation* 2011;124:1964-72

# Primary QOL Endpoint KCCQ Overall Summary

↑ MCID = 5 points



$\Delta = 23.9$   
 $P < 0.001$

$\Delta = 27.4$   
 $P < 0.001$

$\Delta = 27.4$   
 $P < 0.001$

Differences and p-values based on paired t-test compared with baseline

MCID = minimum clinically important difference

# CoreValve

## Extreme Risk vs. PARTNER B

### 12 month $\Delta$ vs. Baseline

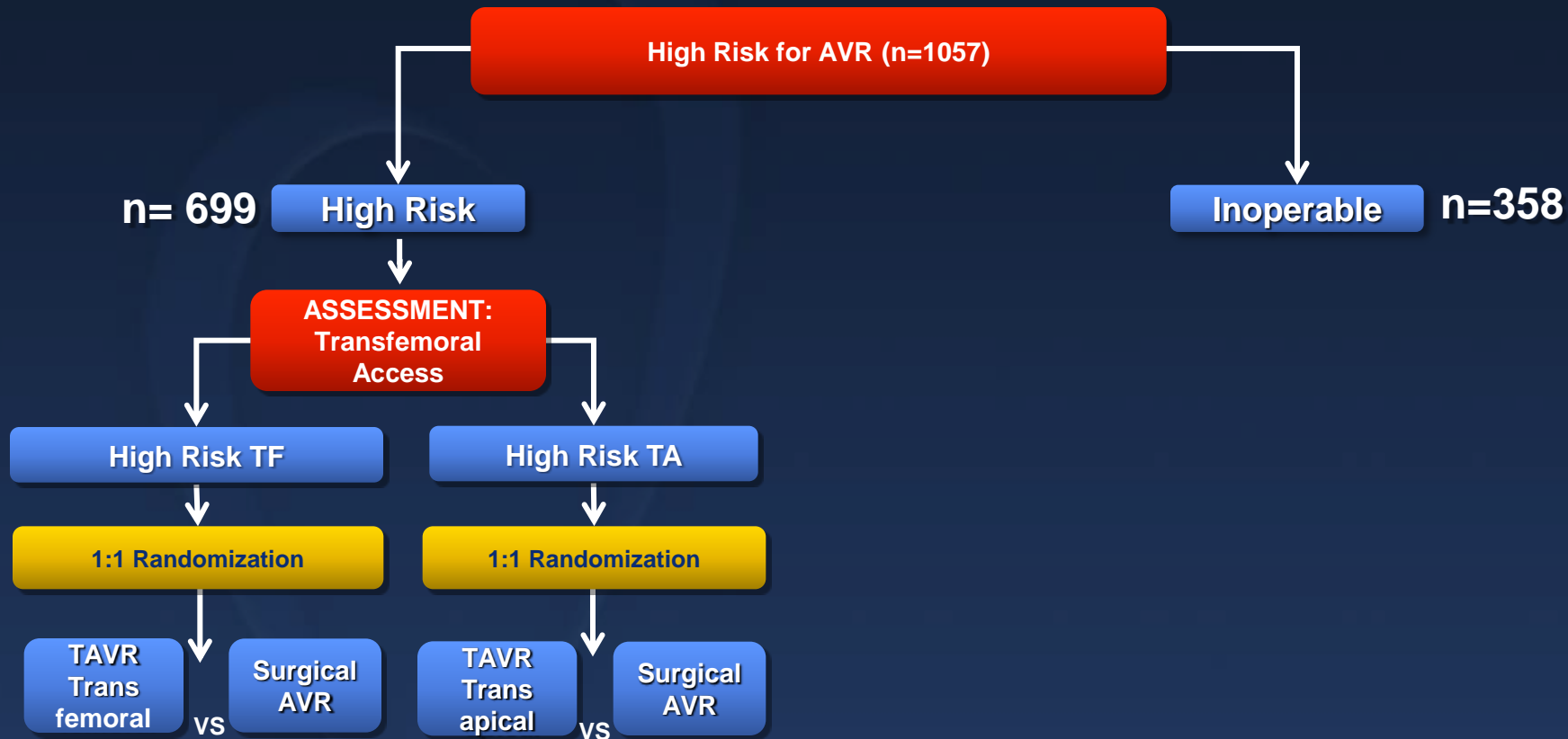
Scale	CoreValve Ext. Risk	PARTNER B
KCCQ Overall Summary	27.4	31.8
KCCQ Symptoms	22.8	26.2
KCCQ Physical Limitations	14.1	16.8
KCCQ QOL	36.3	41.2
SF-12 Physical	5.1	6.6
SF-12 Mental	5.1	7.0

\*For reference only; comparisons not statistically valid due to differences in patient population and rates of data collection

# PARTNER Study Design



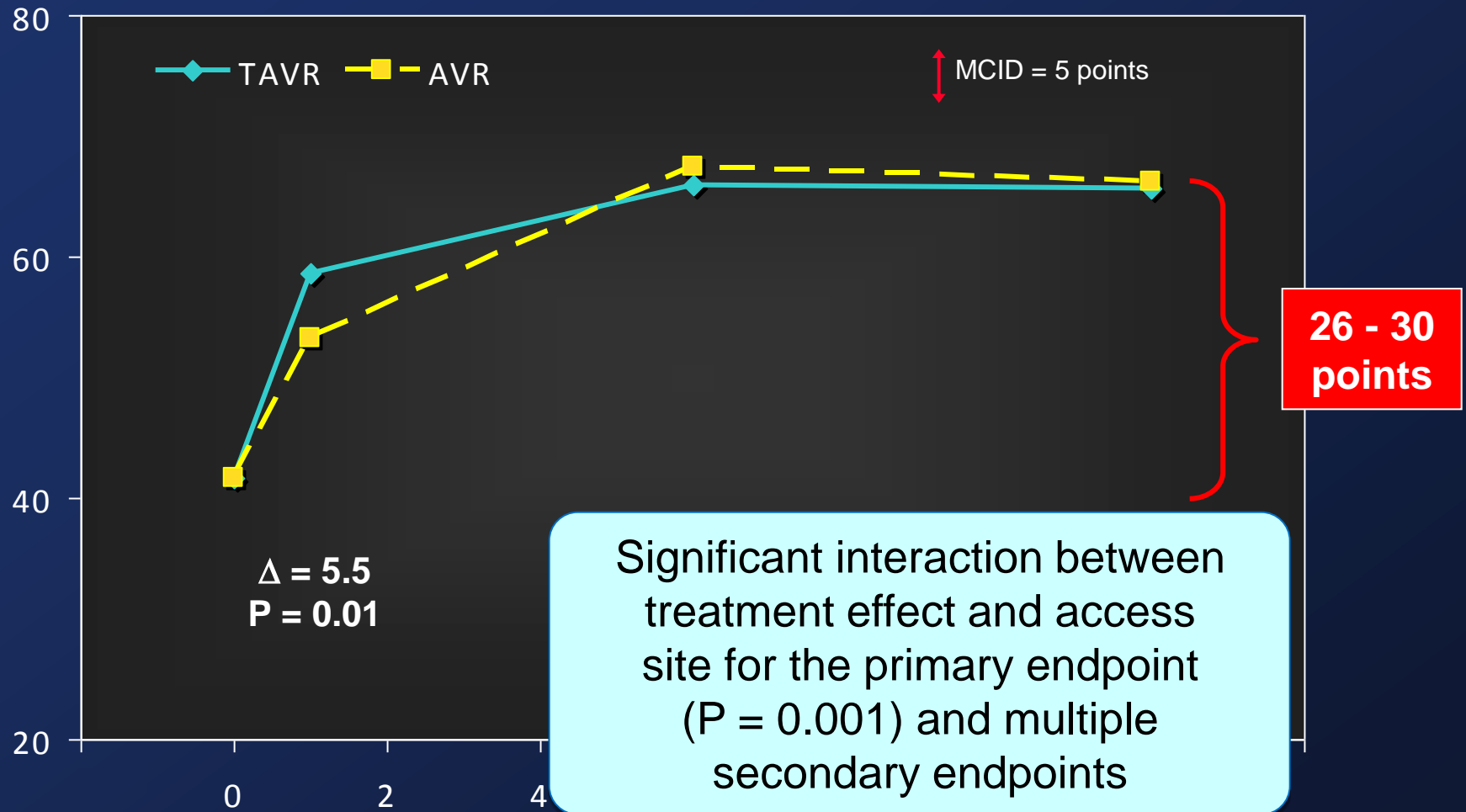
Symptomatic Severe Aortic Stenosis (3105 screened)



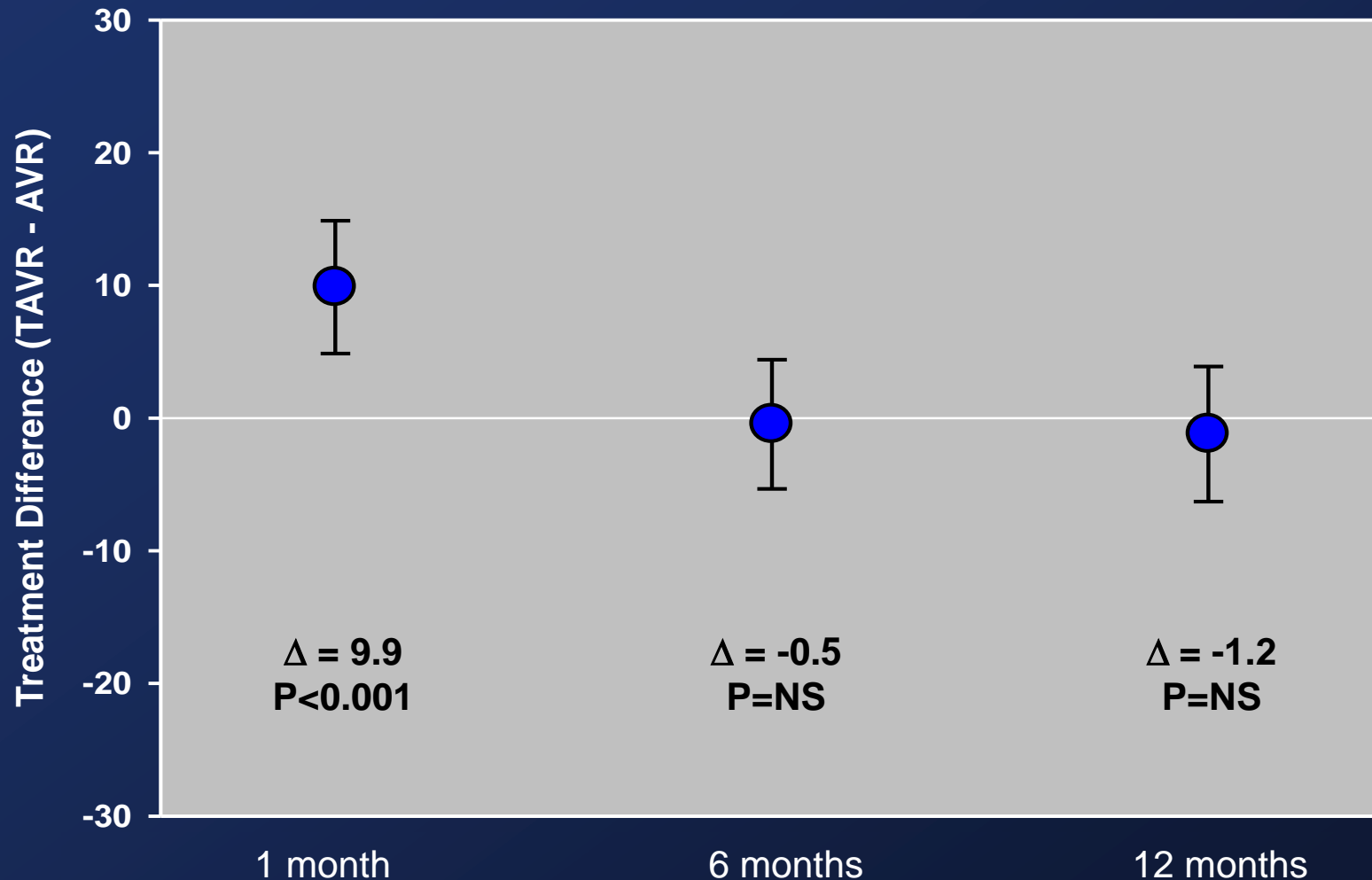
Primary Endpoint: All Cause Mortality (1 yr)  
(Non-inferiority)

# Primary Endpoint

## KCCQ Overall Summary

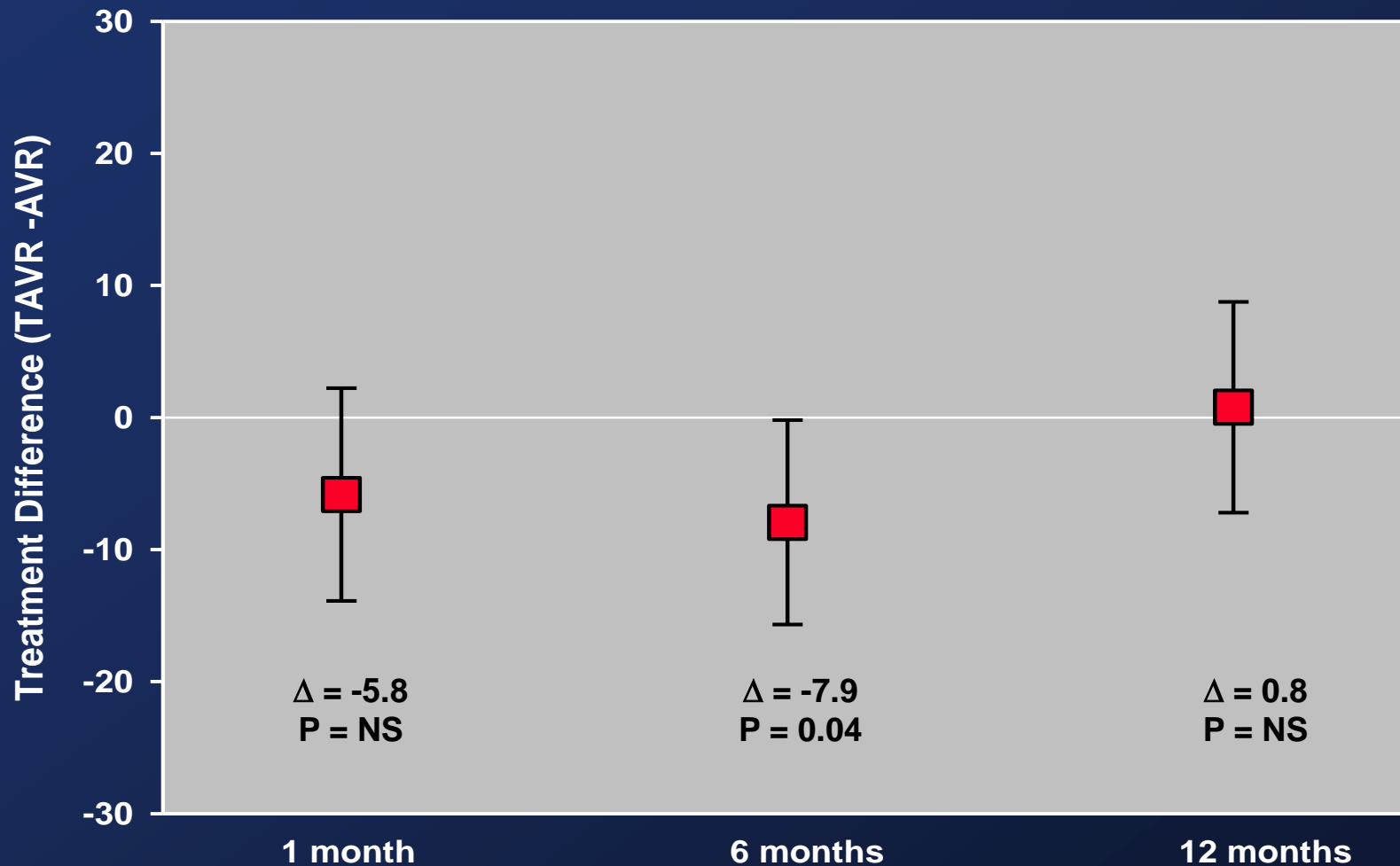


# KCCQ Overall Summary (Primary Endpoint) TF Subgroup



P-values are for mean treatment effect of TAVR vs. AVR

# KCCQ Overall Summary (Primary Endpoint) TA Subgroup



P-values are for mean treatment effect of TAVR vs. AVR

# Differential QOL Outcomes with TA vs. TF Approach: *Potential Mechanisms*

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- TA patients are different-- the best TAVR candidates were selected for a TF approach
- Less invasive isn't necessarily less painful
  - *Thoracic surgery experience suggests that median sternotomy is generally less painful than other forms of thoractomy*
- Inexperienced operators/Learning curve
  - *Improved results seen for other outcomes in TA cohort → QOL impact less clearcut*



# Summary

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- For inoperable patients, TAVR with both balloon-expandable and self-expanding prostheses provides substantial and sustained QOL improvement across a broad range of disease-specific and generic domains
  - *QOL benefit comparable to ~10 year reduction in age*
  - *? Can we prospectively identify patients who will not benefit*
- For high-risk surgical candidates, the impact of TAVR on QOL differs according to the access site
  - *TF approach: Substantial early QOL benefits compared with AVR with similar results at later timepoints*
  - *TA approach: No benefit of TAVR over AVR at any timepoint*

## Summary- 2

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- Further study will be necessary to determine whether the TA approach provides measurable benefits over surgical AVR with greater experience or whether alternative access sites (e.g., T-Ao, subclavian) may eventually be preferred