Health Status Benefits of Transcatheter vs. Surgical Aortic Valve Replacement in Patients with Severe Aortic Stenosis at Intermediate Surgical Risk

Key Insights From The PARTNER 2 Trial

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TCT –AP 2017 | Seoul, Korea| April 2017

THE PARTNER II TRIAL

15 mins

Disclosure

The PARTNER 2 Trial was funded by a research grant from Edwards Lifesciences, Inc.

Background

- Improved quality of life (QOL) is a key goal of treatment for patients with severe AS and may be even more important than improved survival for many elderly patients
- Prior studies have shown that transcatheter aortic valve replacement (TAVR) results in substantial and durable QOL benefits in extreme risk/inoperable patients and an early QOL benefit compared with surgical aortic valve replacement (SAVR) in patients at high surgical risk
- However, the early QOL benefit of TAVR was confined to patients who were suitable for transfemoral access and was not seen in patients treated via the transapical approach

Background- 2

- In the PARTNER 2A trial, TAVR was found to be non-inferior to SAVR for the primary endpoint of 2-year death or disabling stroke among patients at intermediate surgical risk
- There were differences in procedure-related complications and valve performance at 1 year, however, with some endpoints favoring TAVR and others favoring surgical AVR
- The overall impact of these alternative treatments on health-related QOL from the patient's perspective has not yet been reported

Study Objectives

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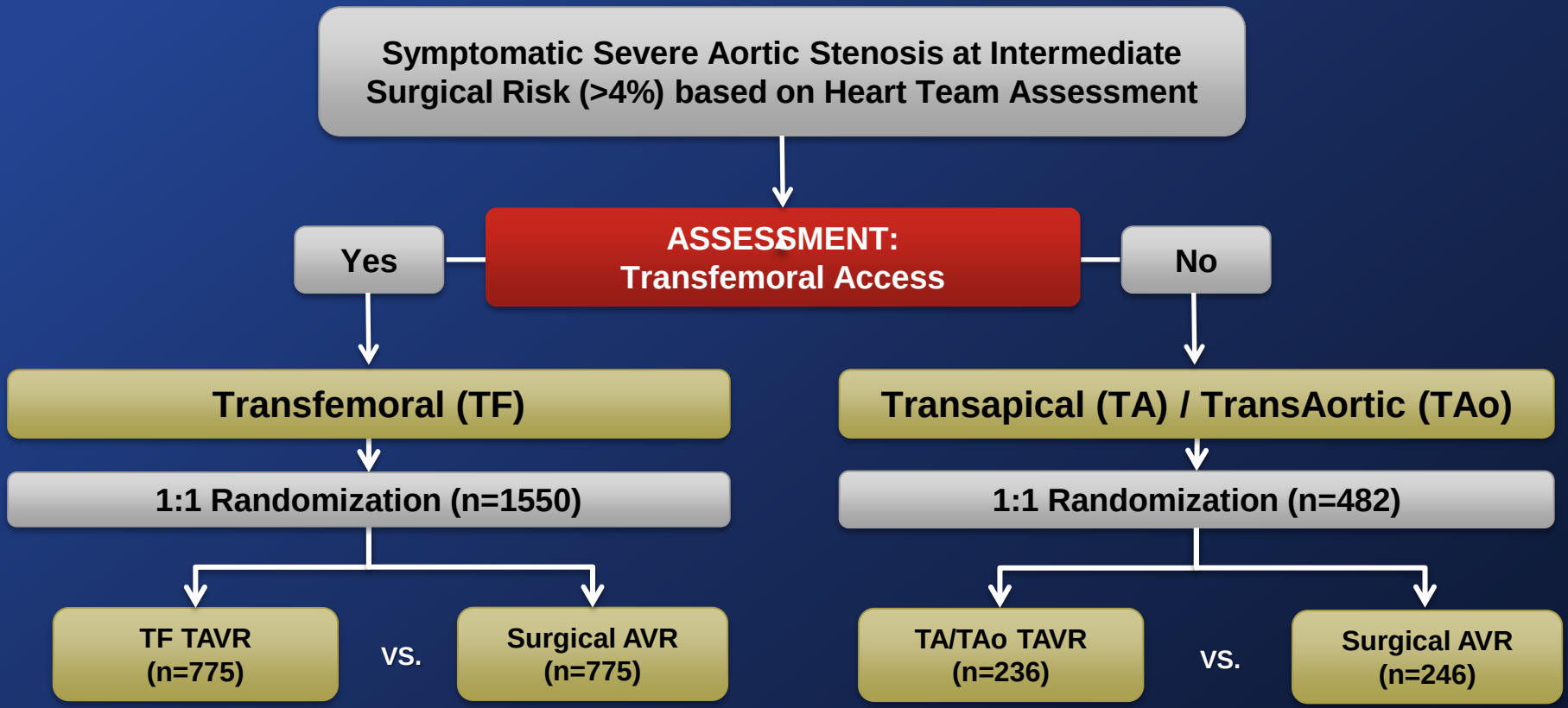
1. To compare health-related quality of life outcomes among patients with severe AS and intermediate surgical risk treated with either TAVR or SAVR
2. To determine whether the QOL benefits of TAVR vs. SAVR vary over time
3. To examine whether the QOL benefits of TAVR vs. SAVR in the intermediate risk population differ according to access site or other patient characteristics

The PARTNER 2A Trial
QOL Study Design



QOL assessed from all patients using validated questionnaires at baseline, 1 month, 1 year, and 2 years

Methods: Quality of Life

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Instrument	*Description/Role*
Kansas City Cardiomyopathy Questionnaire (KCCQ)	• **Heart Failure-specific QOL** • **Domains: Symptoms, Physical Limitations, Quality of Life, Social Limitations** • **Scores: 0-100 (higher = better)**

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SF-36	• **General physical and mental health** • **Scores standardized such that mean=50, standard deviation=10 (higher = better)**

Methods: Quality of Life

Instrument	*Description/Role*
Kansas City Cardiomyopathy Questionnaire (KCCQ)	• Heart Failure-specific QOL • Domains: Symptoms, Physical Limitations, Quality of Life, Social
SF-36	h an=50, etter)
EQ-5D (EuroQOL)	• Generic instrument for assessment of utilities and QALYs • Scores: 0-1 (0=death; 1=perfect health)

KCCQ: Clinically Important Change

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

Statistical Methods

- Study Population: All patients with baseline QOL data (n=1833, 90.2%)→ analyzed by ITT
- Primary QOL Endpoint = KCCQ Overall Summary Score
  - *All other QOL scales considered secondary endpoints*
- Scores between groups compared using analysis of covariance (ANCOVA), adjusting for baseline health status and access site
- Analytic plan specified that separate analyses would be performed for the transfemoral (TF) and transthoracic (TT) groups in case of a significant interaction between treatment effect and access site

Baseline Characteristics

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	TAVR (n = 950)	*AVR (n = 883)*
Age (yrs)	81 ± 7	81 ± 7
Male gender	54.4%	55.4%
STS risk score	5.8 ± 2.1	5.8 ± 1.8
Prior MI	18.1%	17.9%
Prior CABG	23.7%	25.6%
Prior Stroke	10.2%	10.2%
COPD (O_2 dependent)	11.2%	9.7%
Mean AVG (mmHg)	45 ± 13	45 ± 12

P = NS for all comparisons

Baseline Characteristics- QOL

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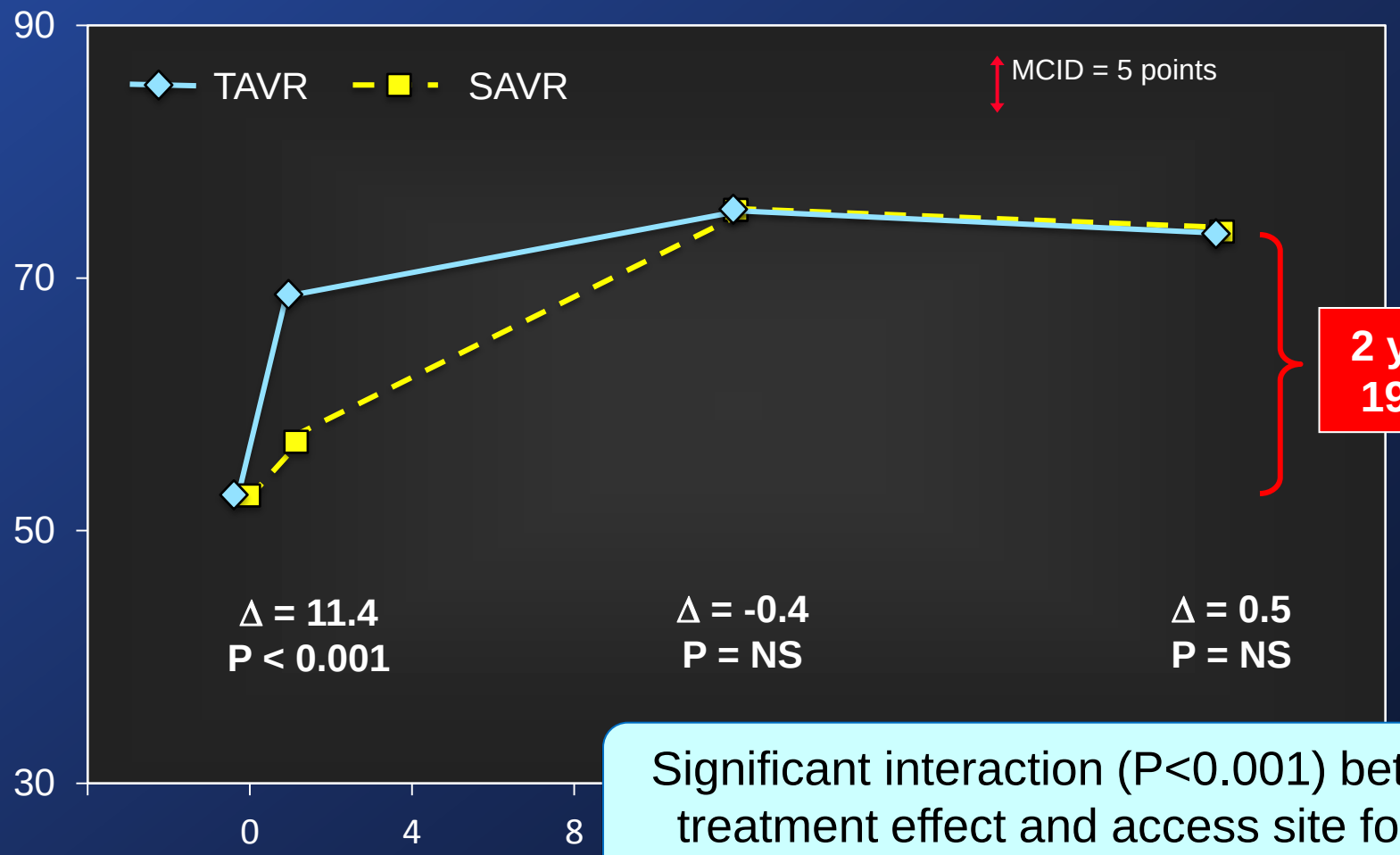
	TAVR (n = 950)	*AVR (n = 883)*
KCCQ Overall Summary	53.2 ± 21.8	52.9 ± 21.3
75-100 (~NYHA I)	18.4%	16.9%
60-74 (~NYHA II)	21.4%	22.9%
45-59 (~NYHA III)	23.5%	23.1%
0-45 (~NYHA IV)	36.7%	37.0%
SF-12 Physical	36.1 ± 8.9	35.9 ± 8.7
SF-12 Mental	48.7 ± 11.3	47.7 ± 11.7

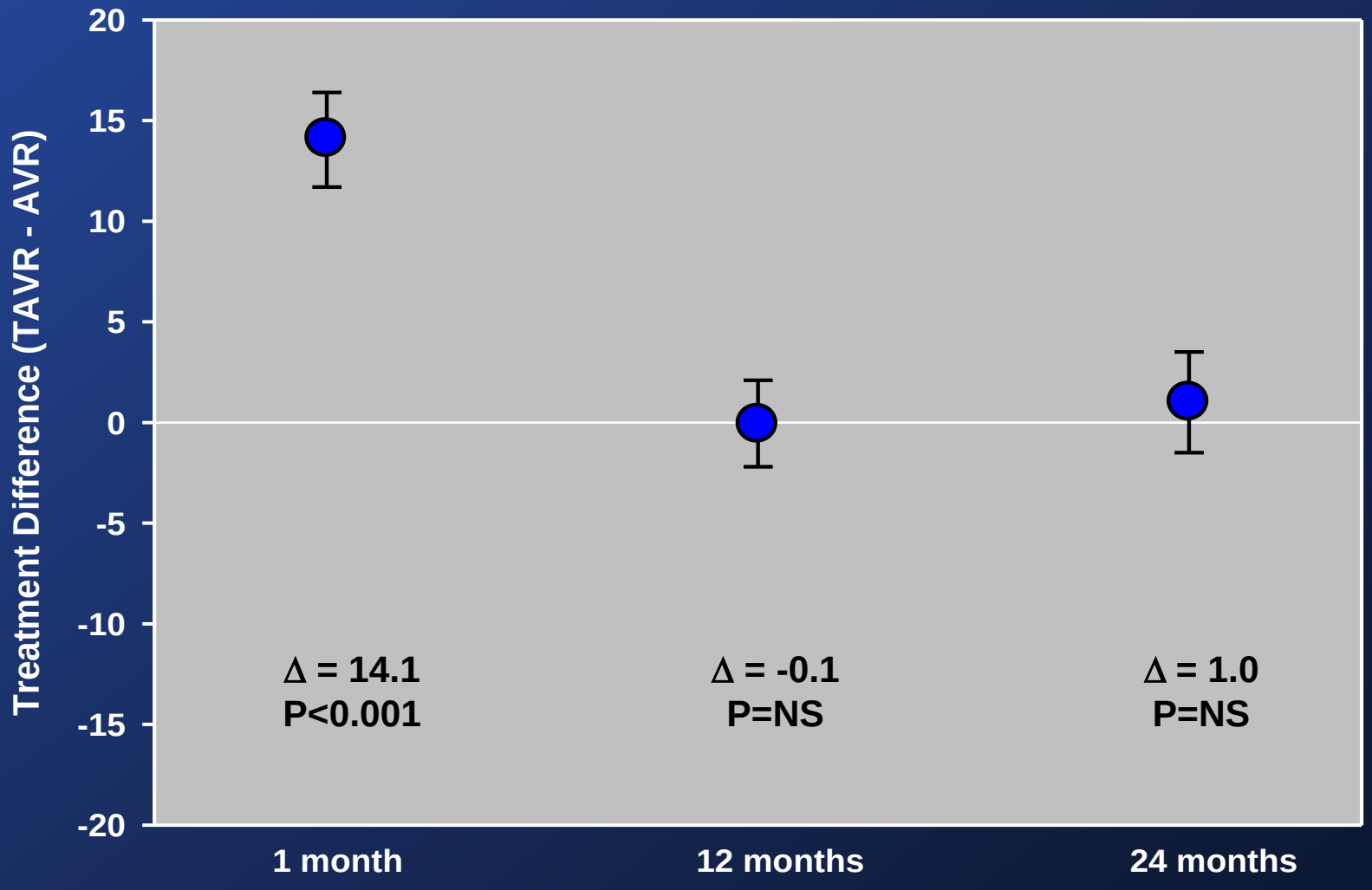
P = NS for all comparisons

Primary Endpoint
KCCQ Overall Summary



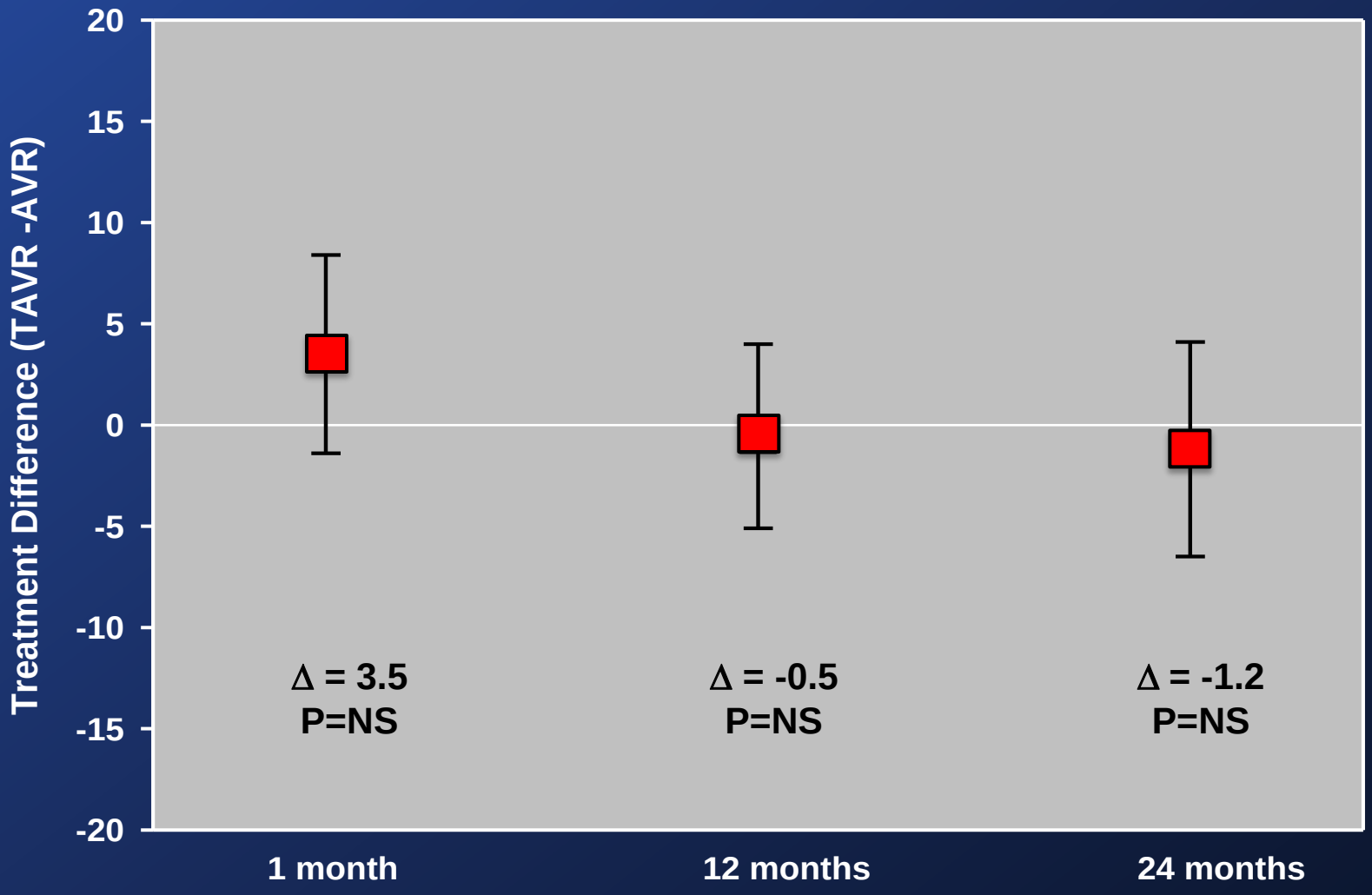
Significant interaction (P<0.001) between treatment effect and access site for the primary endpoint and multiple secondary endpoints

KCCQ Overall Summary (Primary Endpoint)
TF Subgroup



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

KCCQ Overall Summary (Primary Endpoint)
TT Subgroup



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

Generic QOL and Utilities
TF Subgroup

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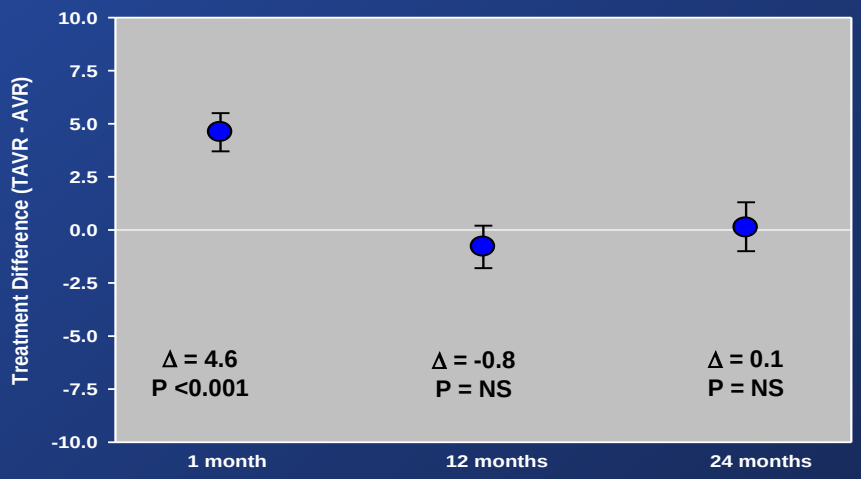
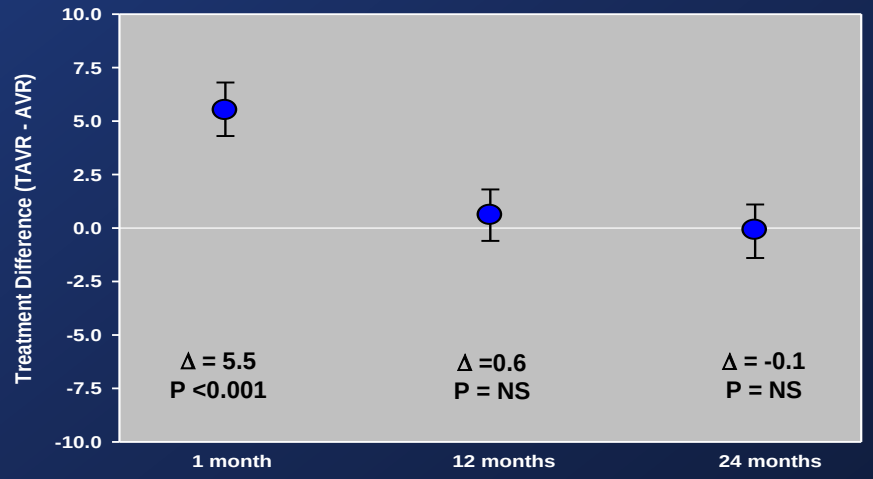
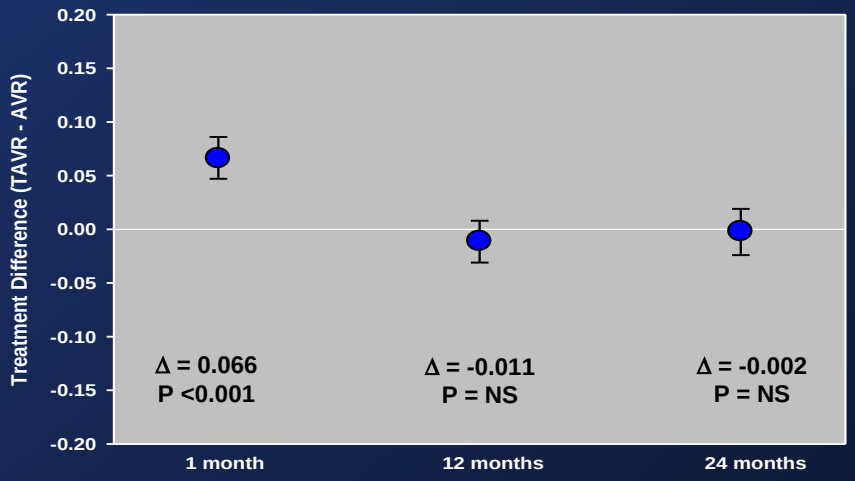
SF-36 Physical



SF-36 Mental



EQ-5D Utilities



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

Generic QOL and Utilities
TT Subgroup

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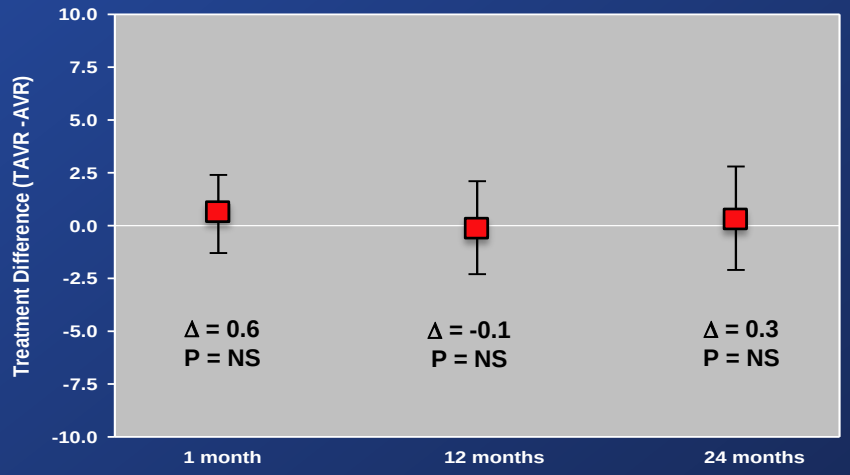
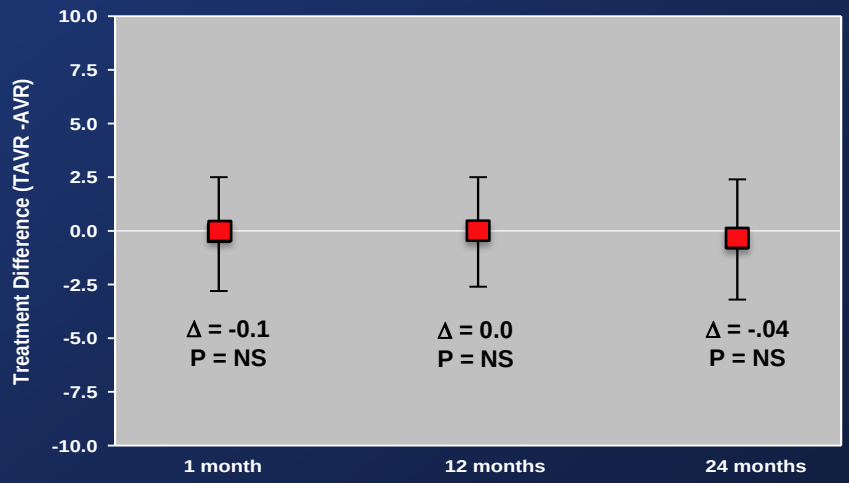
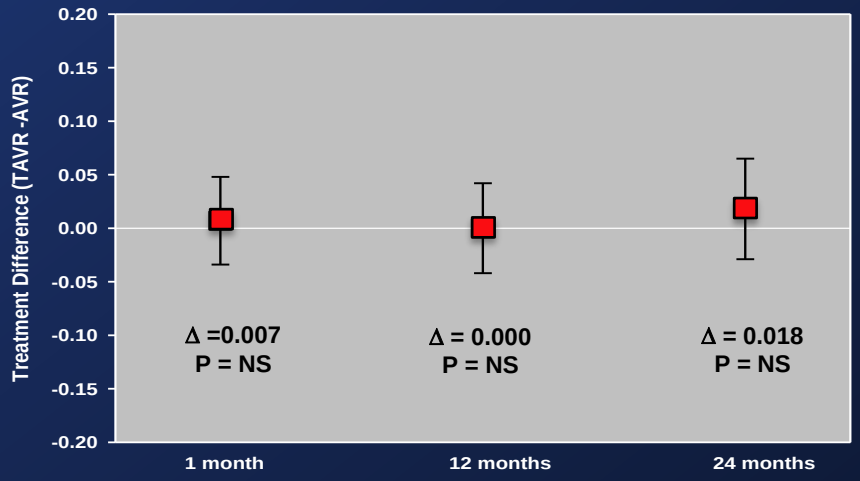
SF-36 Physical



SF-36 Mental

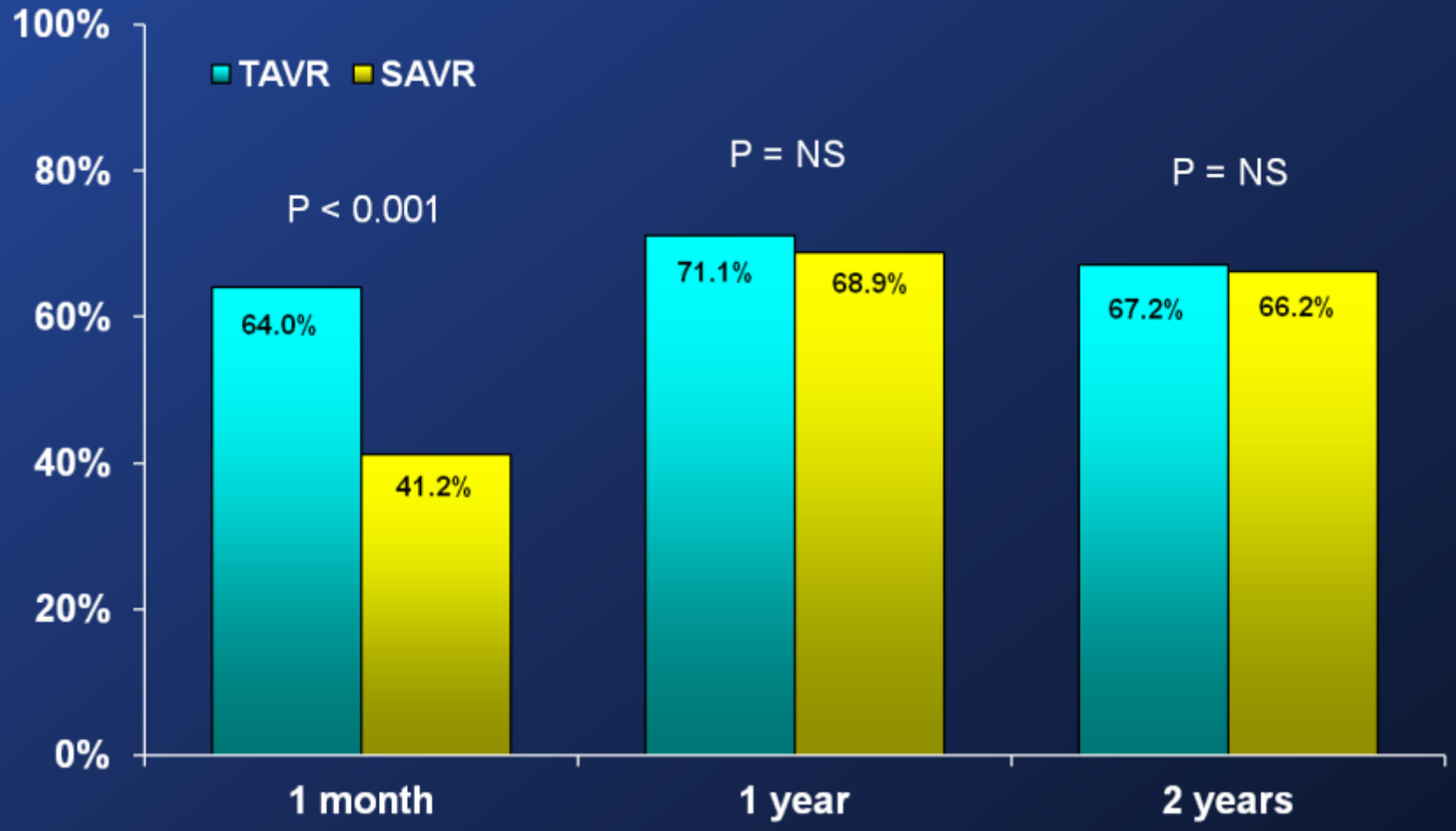


EQ-5D Utilities



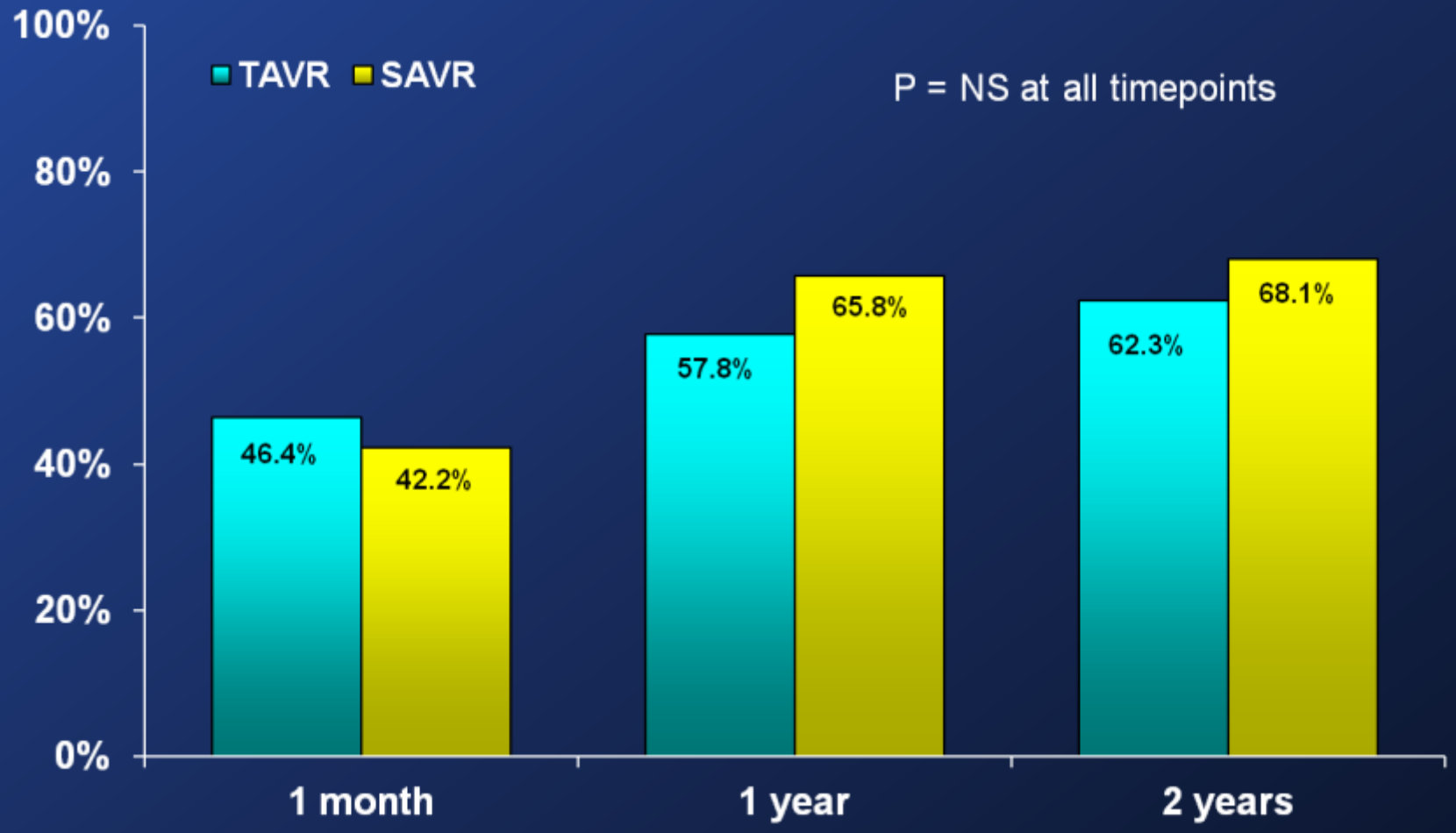
P-values are for mean treatment effect of TAVR vs. SAVR

KCCQ-Summary: Moderate or Substantial Improvement*: TF Subgroup



* Improvement ≥ 10 points vs. baseline among patients with available QOL data

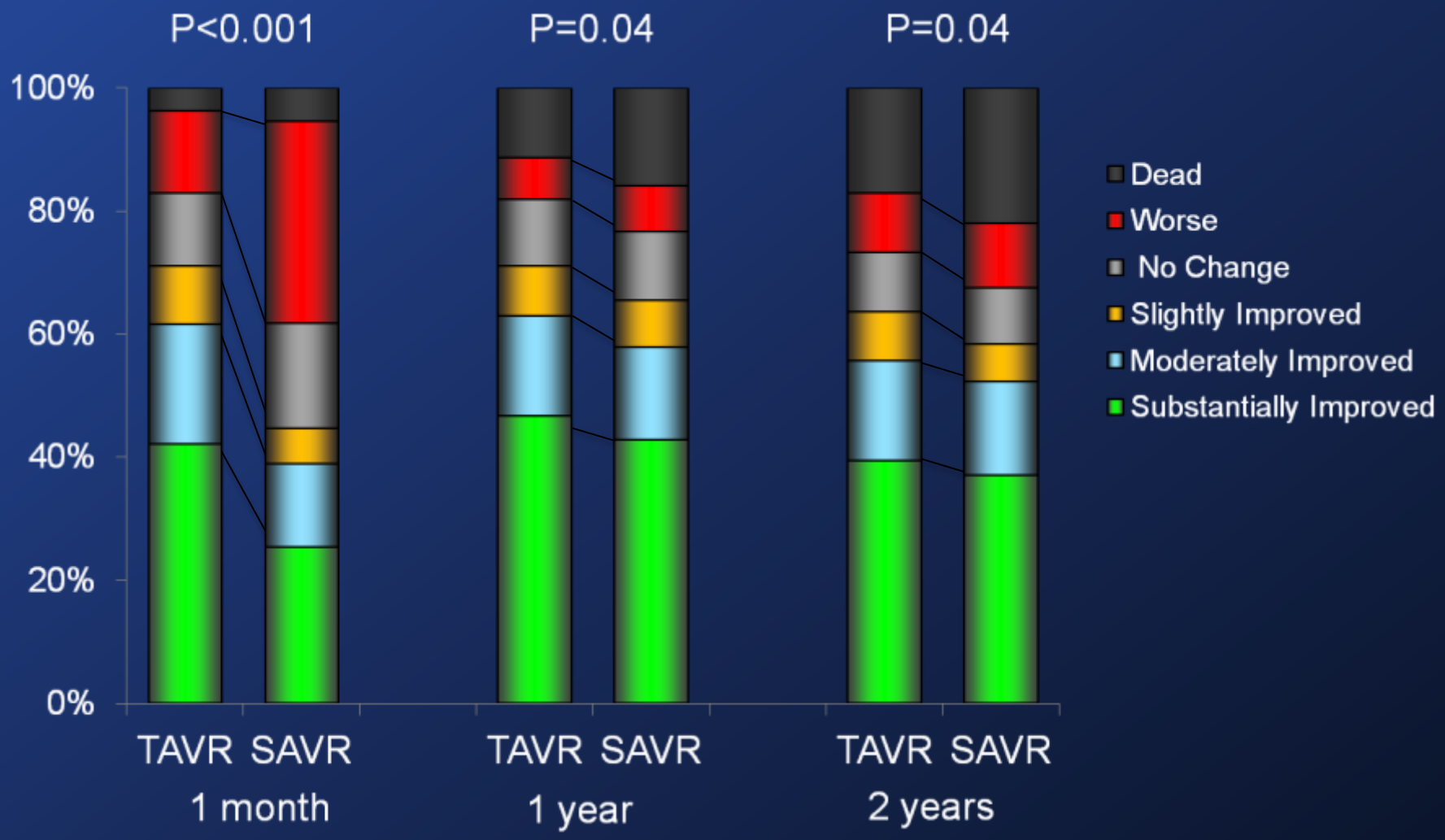
KCCQ-Summary: Moderate or Substantial Improvement*: TT Subgroup



* Improvement ≥ 10 points vs. baseline among patients with available QOL data

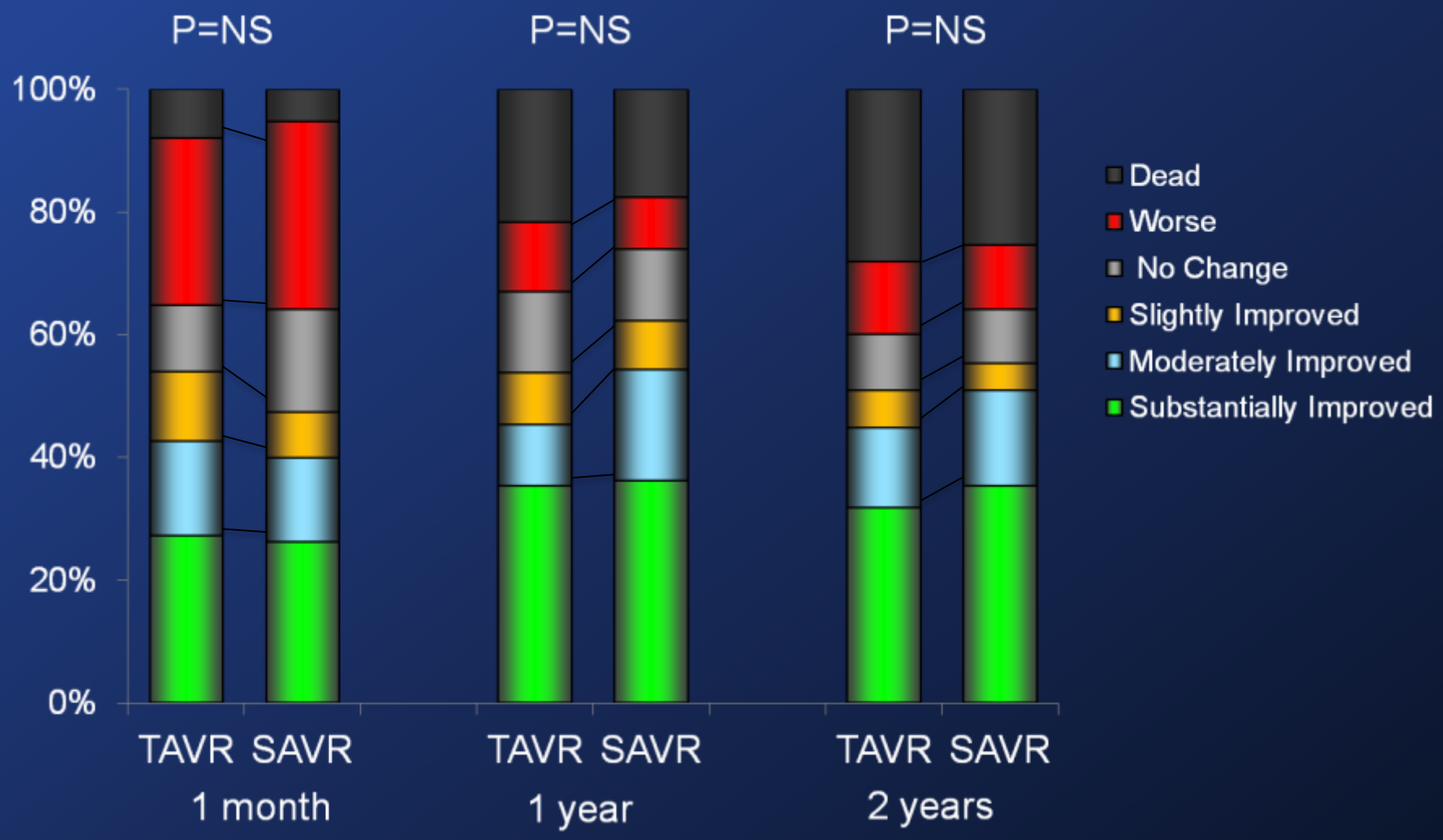
Overall Clinical Status

TF Cohort



*P-values from ordinal logistic regression

Overall Clinical Status
TT Cohort



*P-values from ordinal logistic regression

TT vs. TF: Indirect Comparison

KCCQ Summary Scale

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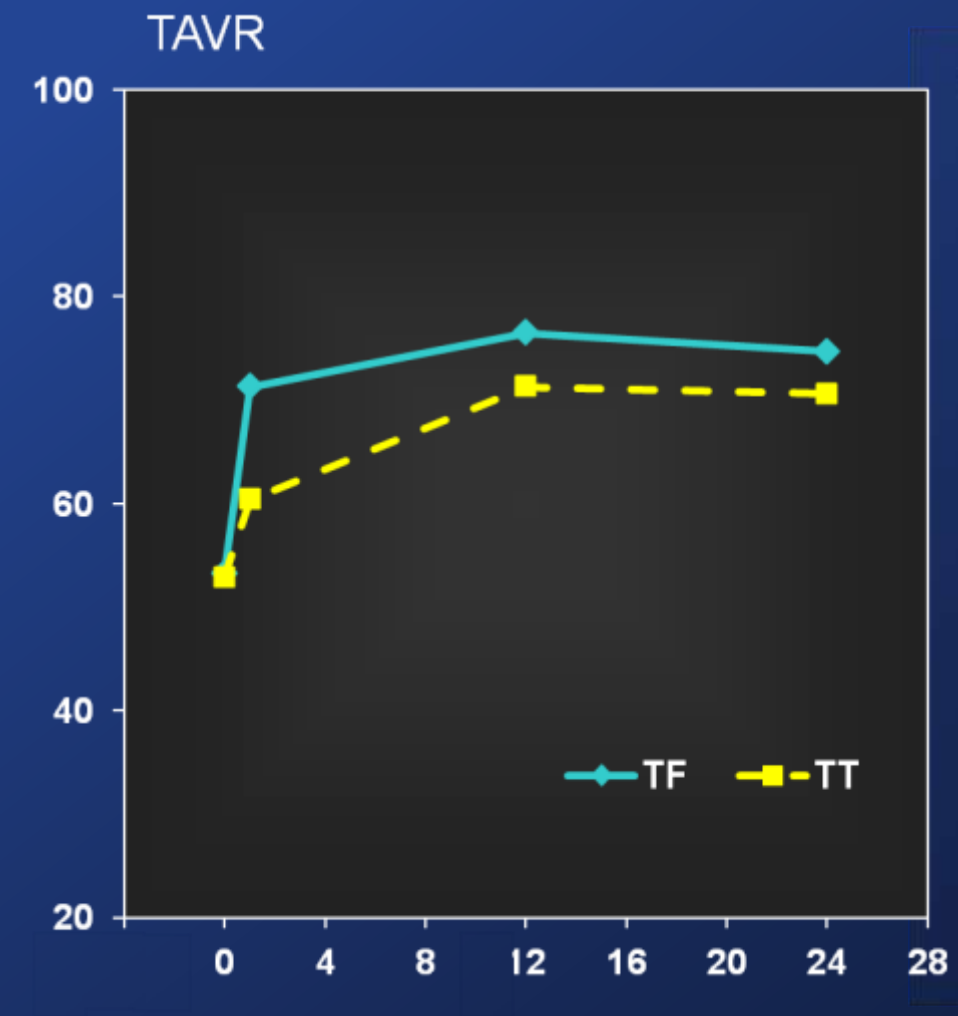

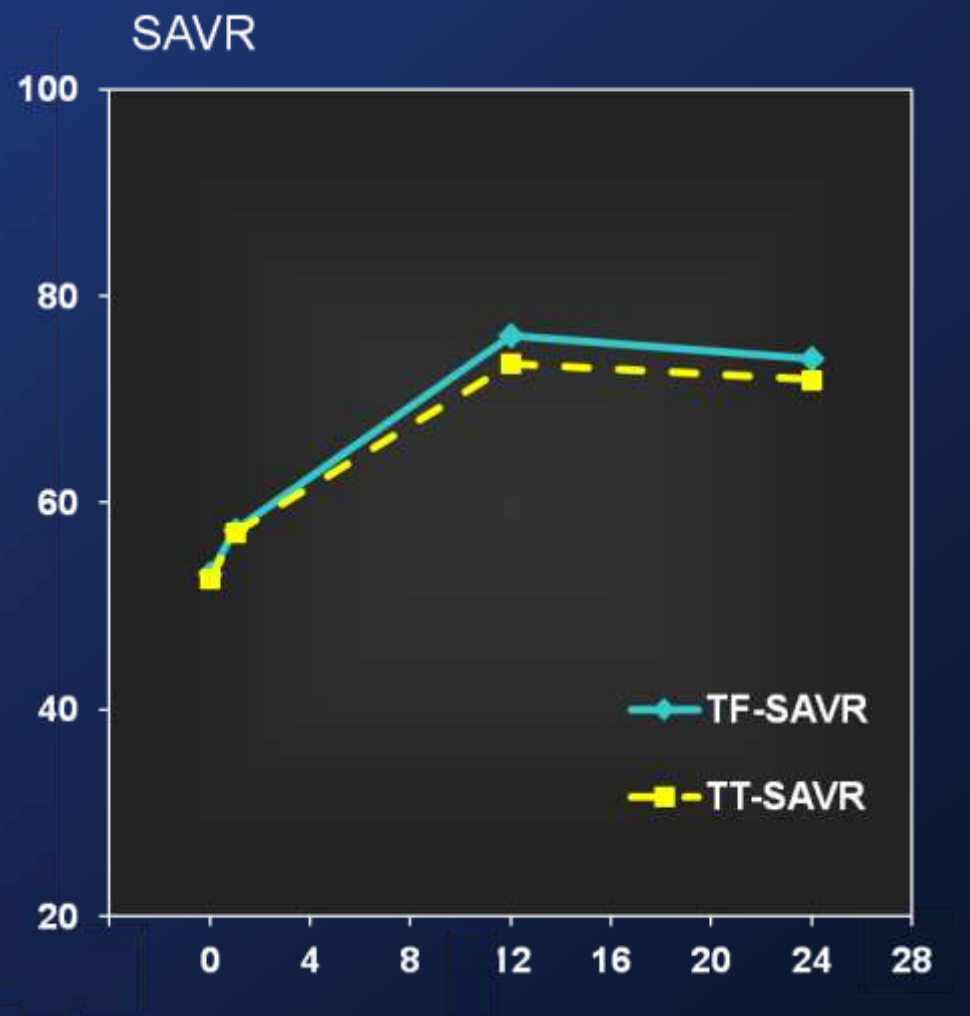

Non-randomized comparison

TAo vs. TA vs. TF
KCCQ Summary Scale

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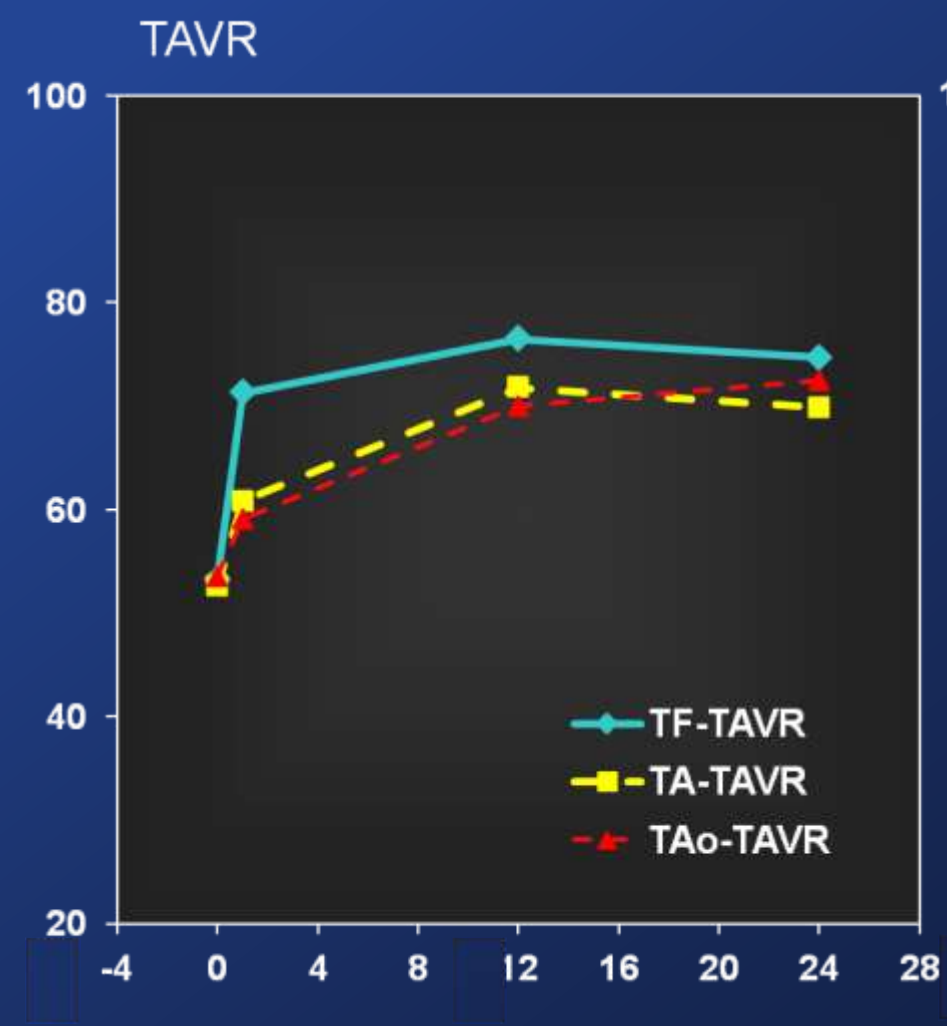

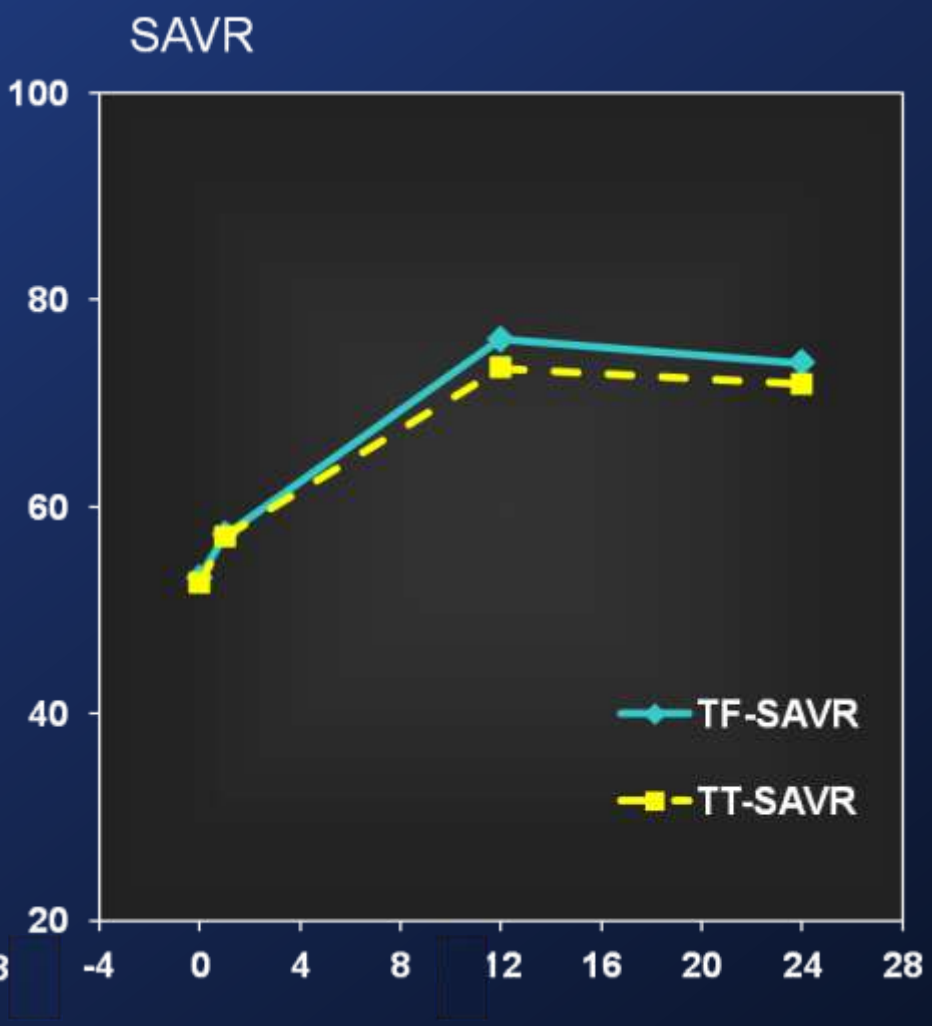

Non-randomized comparison

Summary-1

- Among patients with severe AS who were at intermediate risk for surgical valve replacement, both surgical and transcatheter AVR resulted in substantial improvement in disease-specific and generic HRQOL over 2 year follow-up
  - *KCCQ Summary Scale ~ 20 points (MCID = 5)*
  - *SF-36 Physical ~ 4 points (MCID = 2)*
  - *SF-36 Mental ~ 3 points (MCID = 2)*
- Although the extent of improvement at 2 years was similar with TAVR and SAVR, there were important differences in the rate and extent of recovery at the earlier time points

Summary-2

- For patients eligible for a TF approach, TAVR resulted in substantial QOL benefits compared with SAVR at 1 month with similar QOL at later time points
- For patients eligible only for a transthoracic approach (i.e., transapical or transaortic), there was no benefit of TAVR over SAVR at any time point
- When both mortality and the extent of quality of life improvement were evaluated together, TF-TAVR was superior to SAVR at all follow-up timepoints

Conclusions

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- Taken together with previous data, these findings demonstrate that for intermediate risk patients suitable for a TF approach, TAVR provides both early and late benefits compared with surgical AVR from the patient's perspective
- The lack of benefit among patients ineligible for the TF approach suggests that a TT approach may not be preferable to SAVR in such patients– at least in the short to intermediate term
- Further studies will be necessary to determine whether use of other alternative access sites (e.g., subclavian, carotid, transcaval) can overcome these limitations of the TT approach