TAVR: Insights from QOL and Economic Evaluation

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26 slides

Disclosures

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- Astra-Zeneca - Merck

Grant Support/Devices

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

Consulting/Advisory Boards

- Medtronic - Astra-Zeneca
- Edwards Lifesciences

Why You Should Care

For inoperable patients….

- TAVR leads to substantial improvements in survival, with benefits sustained through 5 years
- Given the advanced age and burden of comorbidity in this population, improved QOL likely to be as important a therapeutic goal as increased survival

Key questions:

Can we afford to offer TAVR to all such patients?

Background- 2

For high-risk, but operable, patients ….

- No definitive difference in long-term survival with TAVR compared with surgical AVR
- Some complications actually increased (e.g., stroke, paravalvular AI)
- TAVR prosthesis much more costly ($30K vs. $5K)

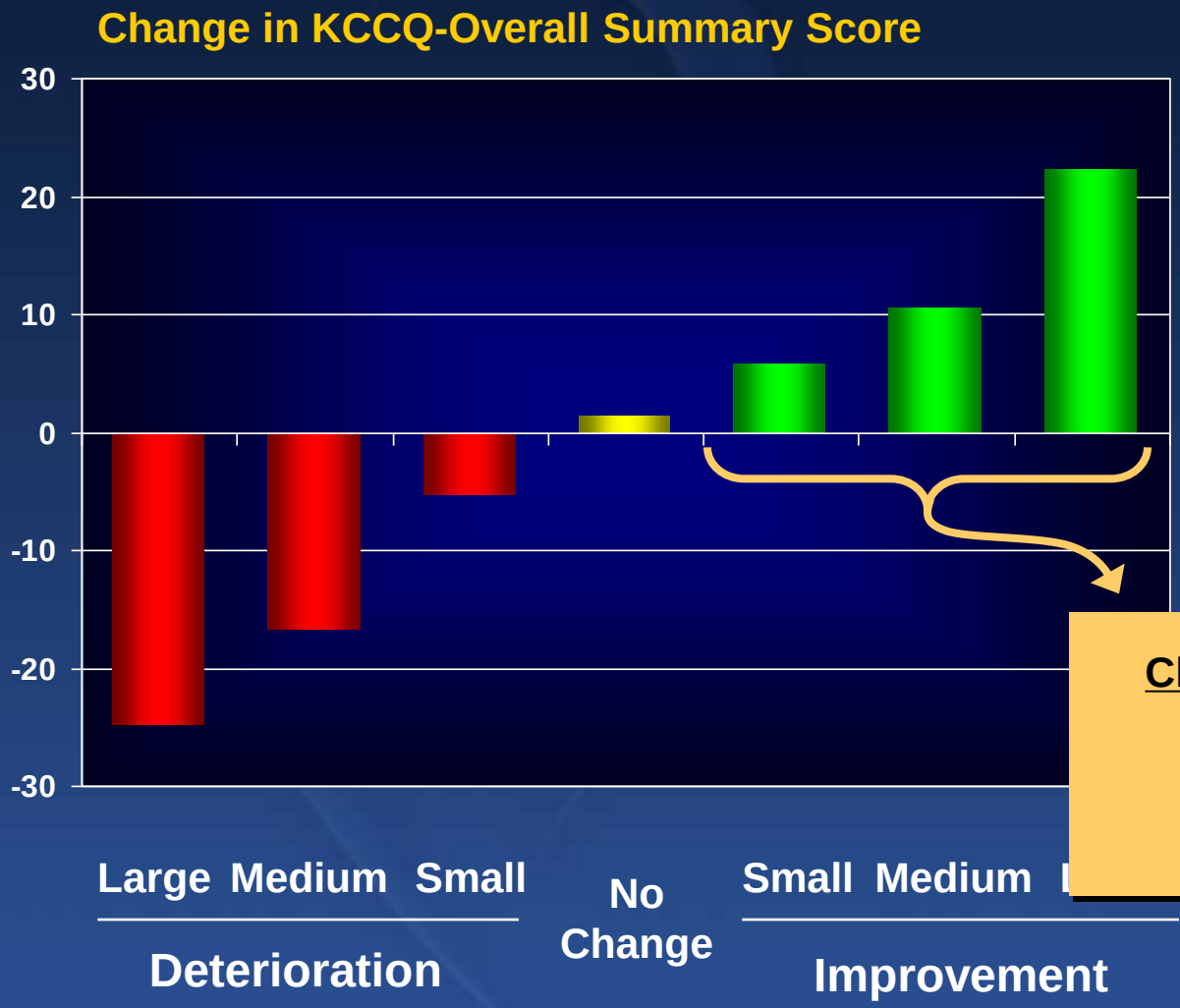
Key question:

Is there an economic or QOL benefit of TAVR that can justify the more costly procedure?

TAVR: QOL Insights

Quality of life improves substantially after TAVR, even among inoperable patients

KCCQ: Interpretation



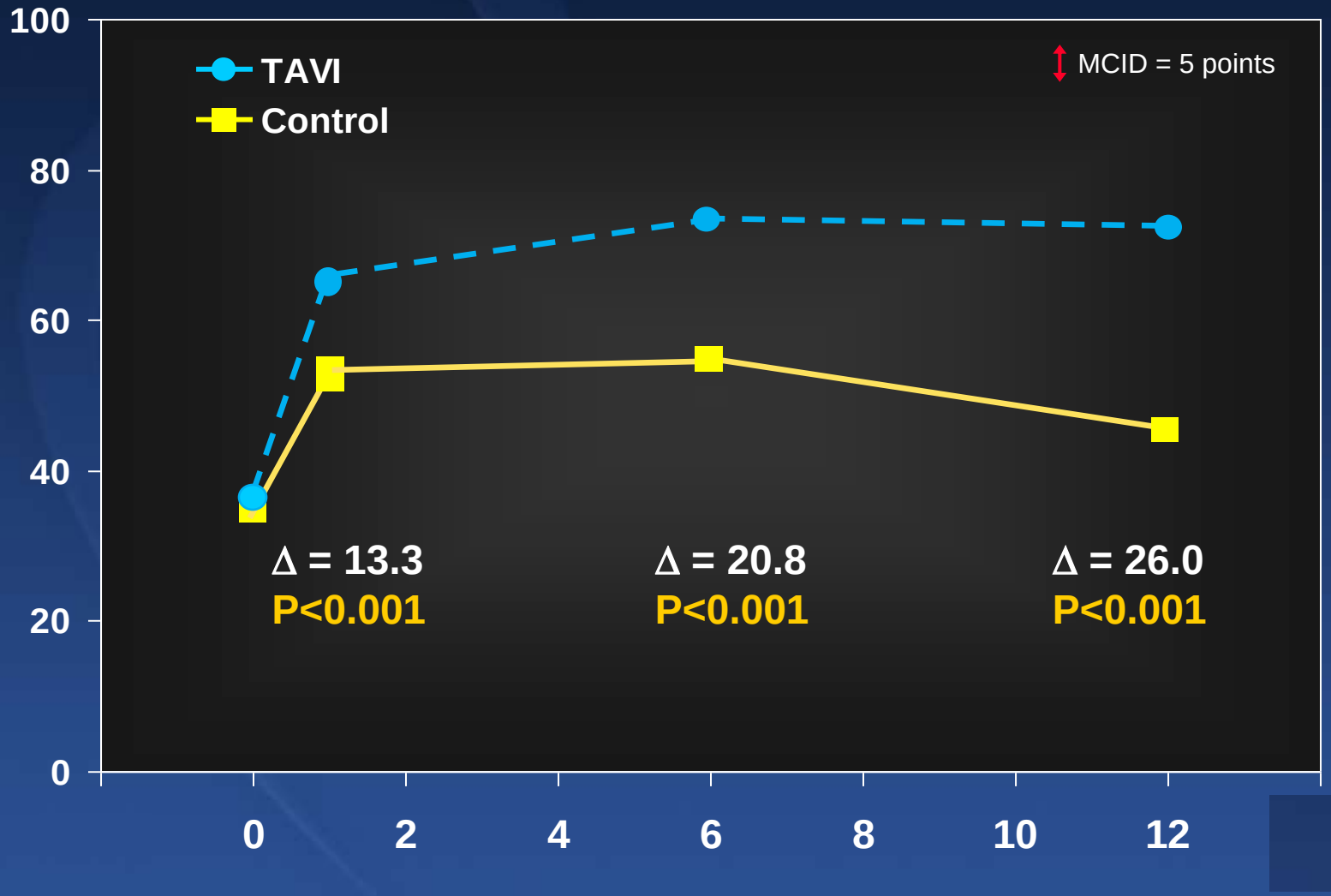
- 546 outpts with HF
- KCCQ assessed at baseline and 5 weeks
- Extent of deterioration or improvement assessed by physician based on sx and exam and correlated with KCCQ Overall

Clinically Important Change

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

Am Heart J 2005; 150:707-15

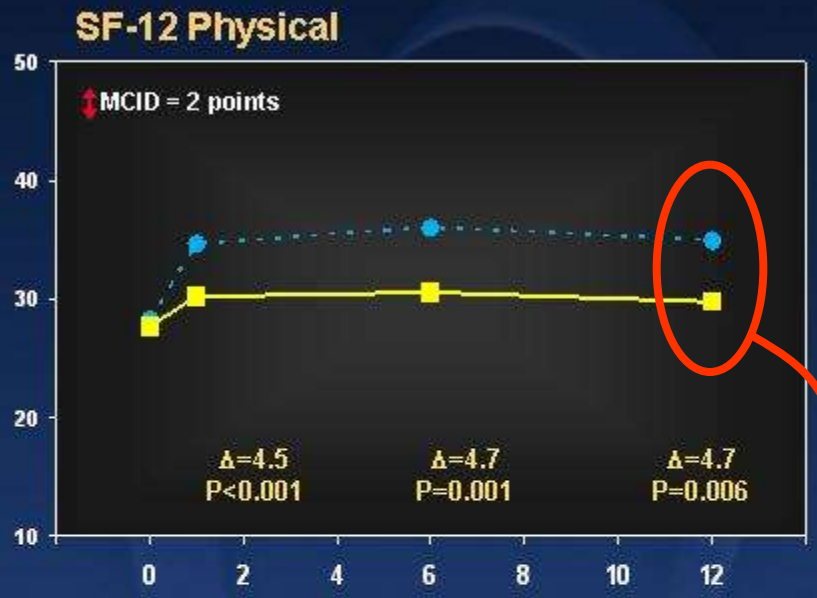
Primary Endpoint: KCCQ Overall Summary

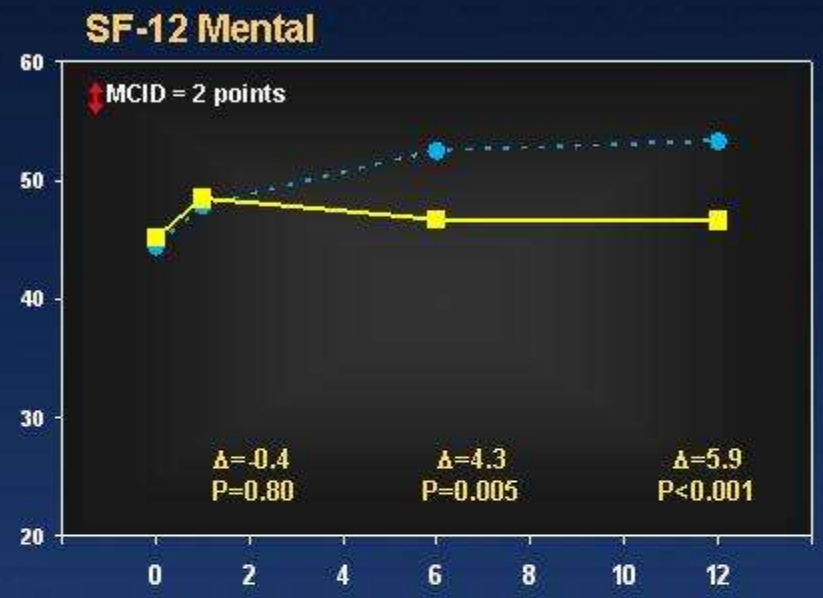


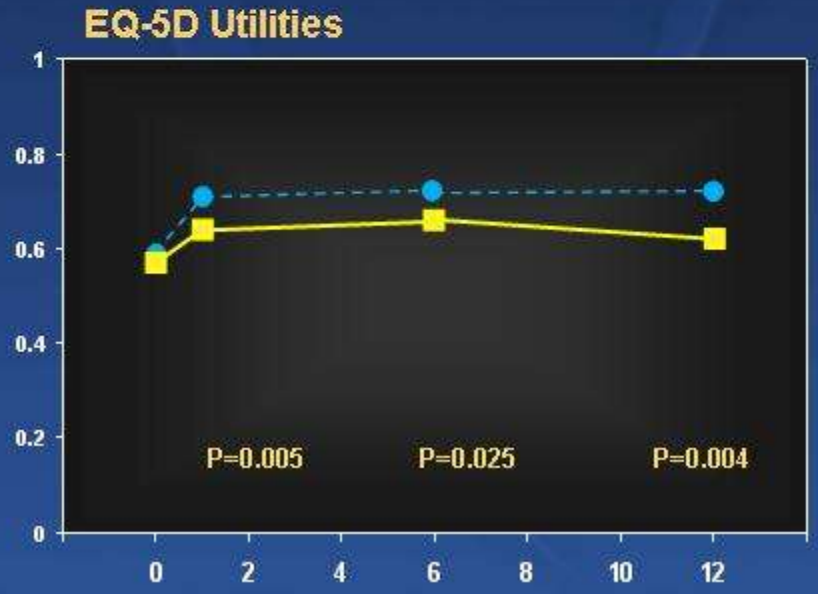
***MCID** = minimum clinically important difference*

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

Generic QOL and Utilities







5 point difference comparable to 10-year age difference

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

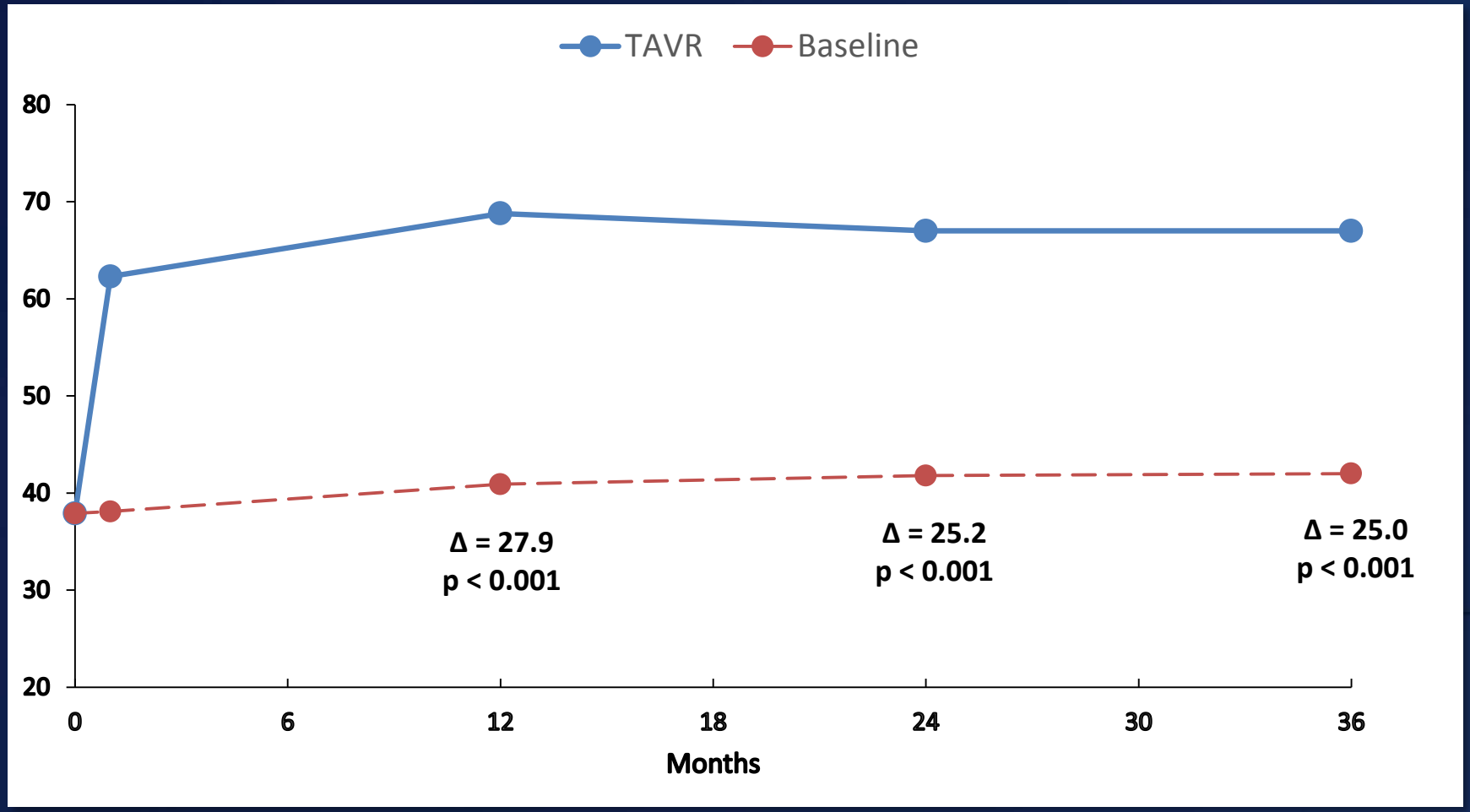
MCID = minimum clinically important difference

TAVR: QOL Insights

Quality of life benefits of TAVR are durable among surviving patients

CoreValve Extreme Risk: 3 Year QOL

KCCQ Overall Summary



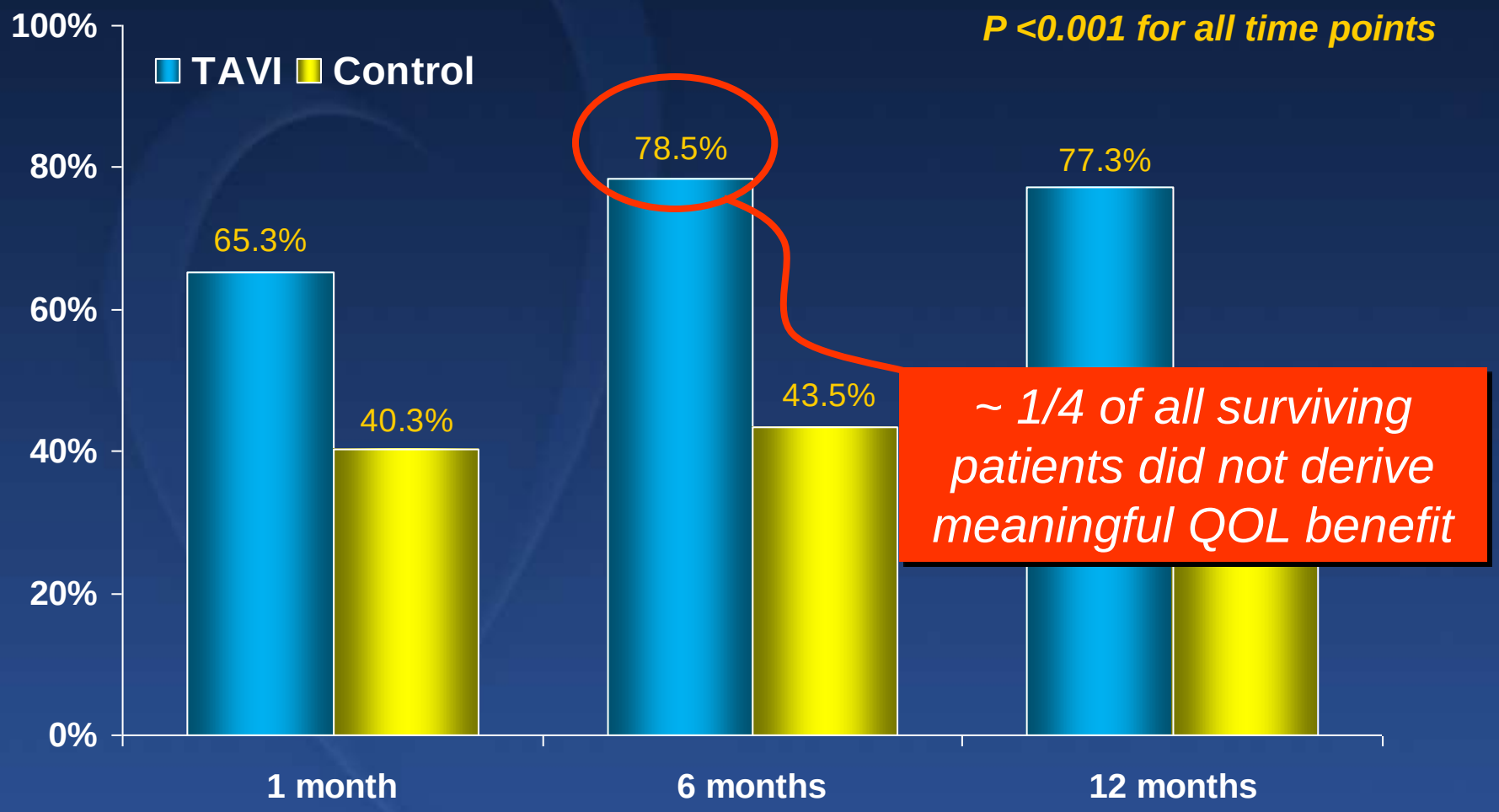
* Iliofemoral Access

Baron SJ, et al. ACC 2016

TAVR: Key QOL Insights

Although QOL improves substantially after TAVR, on an individual level there is still considerable heterogeneity of benefit

KCCQ-Summary: Significant Improvement *

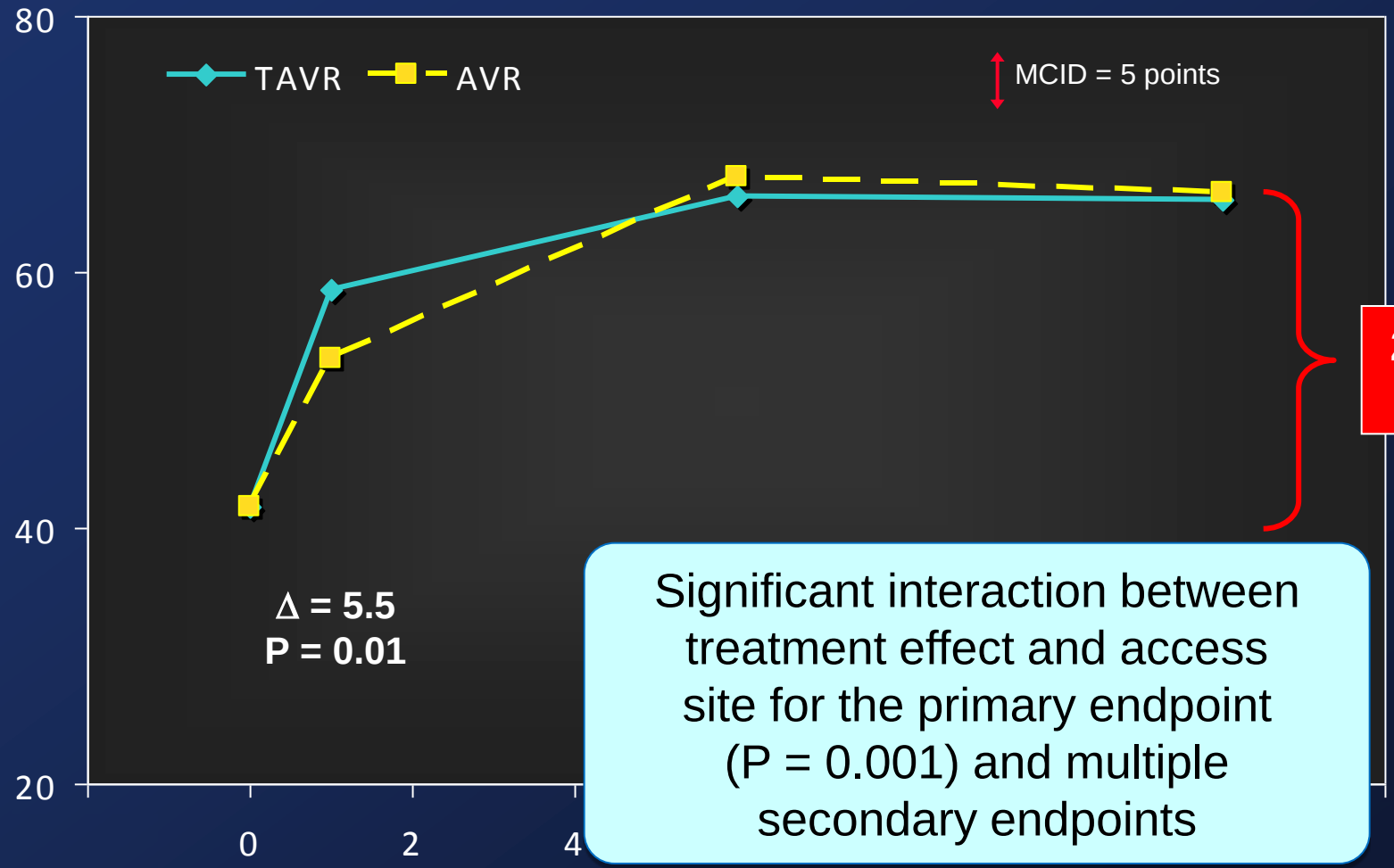


* Improvement ≥ 10 points vs. baseline among patients with available QOL data

TAVR: Key QOL Insights

"Less invasive" procedures don't always result in better quality of life

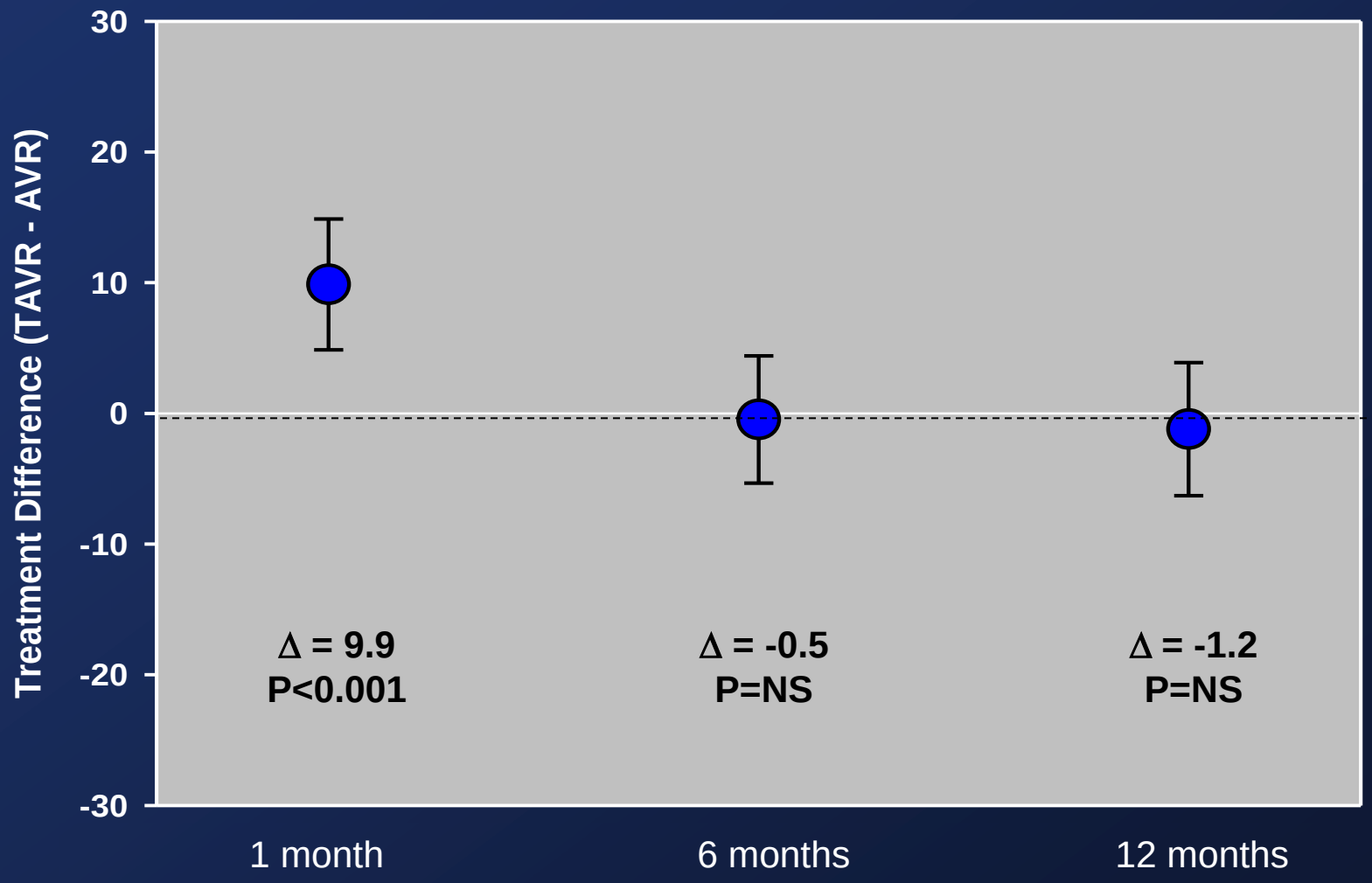
PARTNER A
KCCQ Overall Summary



Growth curve analysis; adjusted for baseline
MCID = minimum clinically important difference

Reynolds MR, et al. J Am Coll Cardiol *2012*

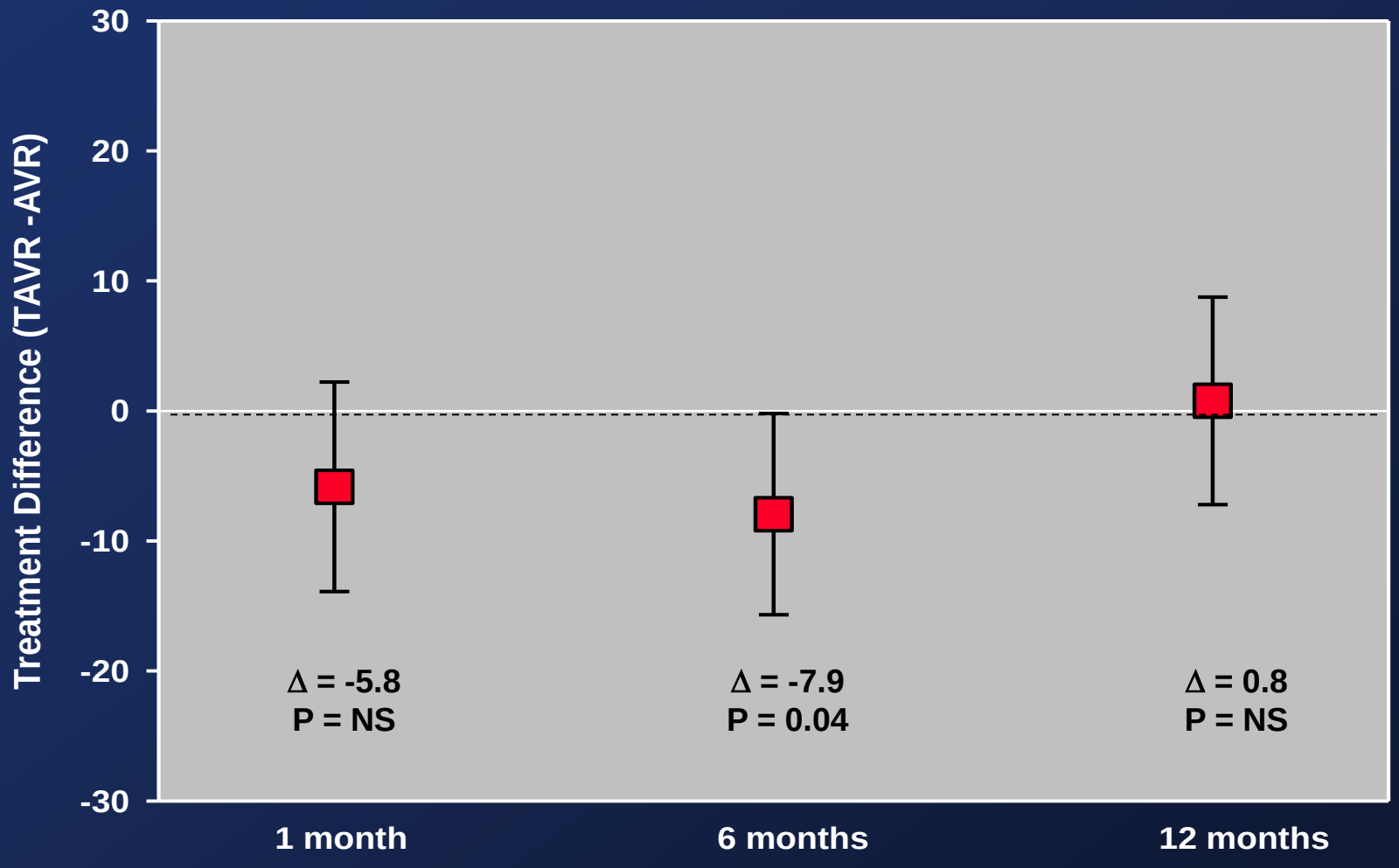
KCCQ Overall Summary
TF Subgroup



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

Reynolds MR, et al. J Am Coll Cardiol *2012*

KCCQ Overall Summary
TA Subgroup

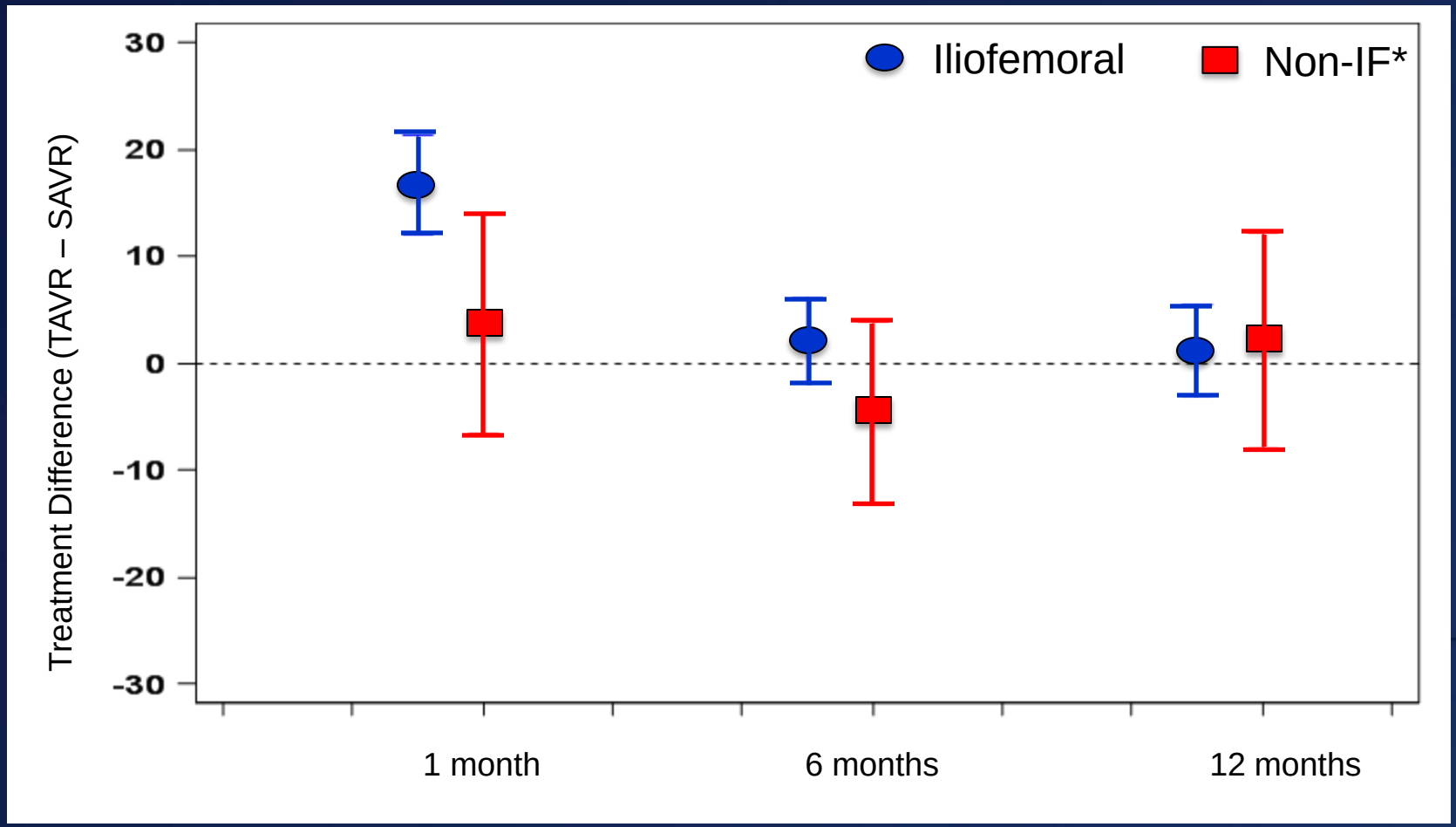


P-values are for mean treatment effect of TAVR vs. AVR

Reynolds MR, et al. J Am Coll Cardiol *2012 (in press)*

CoreValve High Risk

Benefit of TAVR over SAVR by Access Site



* Non-IF = TAo or Subclavian

Arnold SV, et al. *J Am Coll Cardiol Intv* 2015;8:1207-17

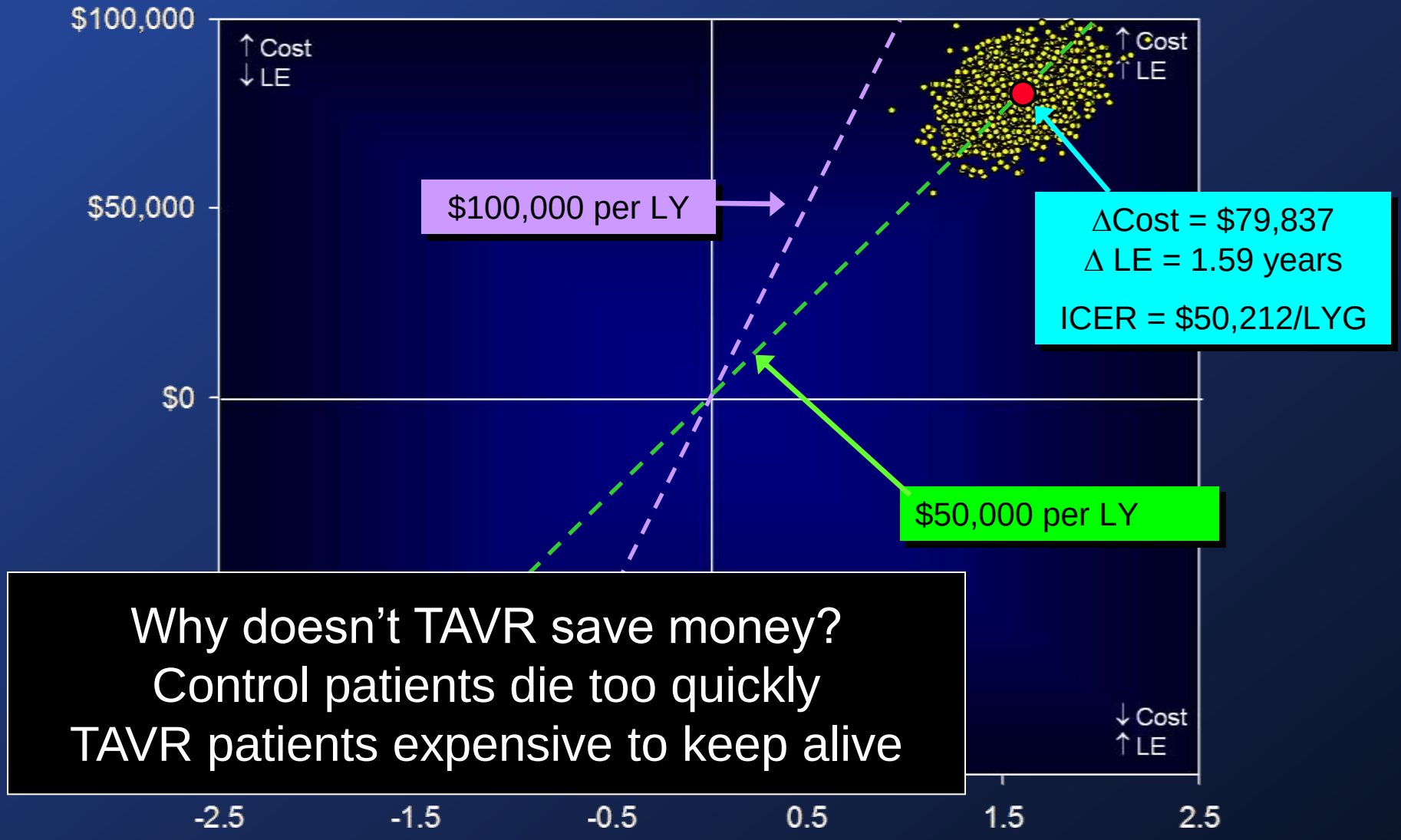
Differential QOL Outcomes with Femoral vs. Alternative Access: *Potential Mechanisms*

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

TAVR: Key Economic Insights

The cost-effectiveness of TAVR is dependent on the patient population, alternative treatment options, and access site

Cost-Effectiveness of TAVR vs. Control
Lifetime Results



Why doesn't TAVR save money?
Control patients die too quickly
TAVR patients expensive to keep alive

Reynolds MR et al. Circulation 2012; 125:1102-9

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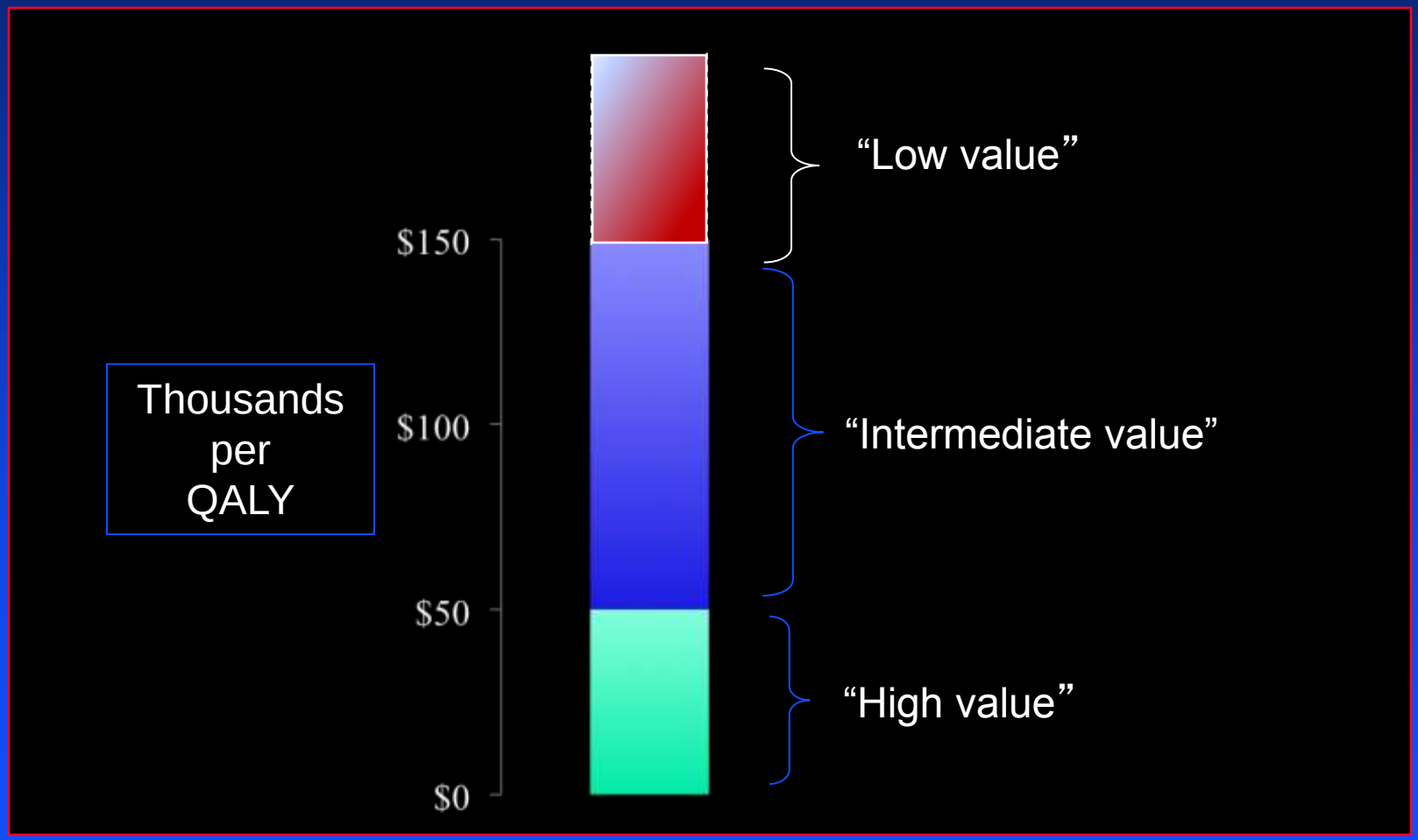
PERFORMANCE MEASURES

ACC/AHA Statement on Cost/Value Methodology in Clinical Practice Guidelines and Performance Measures

A Report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and Task Force on Practice Guidelines



Anderson JL et al. JACC doi: 10.1016/j.**jacc**.2014.03.016

Impact of Patient Population on Cost-Effectiveness of TAVR

Population	Δ Costs	Life Expectancy	ICER
Extreme Risk	↑↑↑	↑↑↑	Intermediate to High Value

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Very High Risk	Similar	Slight ↑	Dominant/ High Value

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Impact of Patient Population on Cost-Effectiveness of TAVR

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Very High Risk	Similar	Slight ↑	Dominant/ High Value
High Risk	↑↑	↑↑	Intermediate to High Value
Intermediate Risk	???	???	???

Final Thoughts

- For inoperable patients, cost-effectiveness of TAVR depends mainly on its ability to achieve substantial long-term survival and QOL benefits
  - *How can we prospectively identify patients who are unlikely to derive meaningful QOL and survival benefit from TAVR?*
- For operable patients, benefits of TAVR relate both to short-term improvement in QOL and reduced cost
  - *Improved cost-effectiveness will be driven by reductions in LOS, particularly for uncomplicated admissions (i.e., minimalist approach)*
  - *Eventually, reductions in valve pricing will also lead to substantial cost savings → essential to justify TAVR in lower risk populations*