Cost-Effectiveness of Transcatheter Aortic Valve Replacement with a Self-Expanding Prosthesis Compared with Surgical Aortic Valve Replacement in High Risk Patients

Results from the CoreValve US High Risk Study

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Disclosure Statement of Financial Interest

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

Affiliation/Financial Relationship	Company
• Grant/Research Support	• Medtronic, Edwards Lifesciences
• Consulting Fees/Honoraria	• Medtronic
• Major Stock Shareholder/Equity	• None
• Royalty Income	• None
• Ownership/Founder	• None
• Intellectual Property Rights	• None
• Other Financial Benefit	• None

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Background

- Previous studies have shown that TAVR provides substantial clinical benefits at acceptable incremental costs for patients with symptomatic, severe aortic stenosis who are unsuitable for surgical AVR

- There is less consensus about the cost-effectiveness of TAVR relative to SAVR for high-risk surgical candidates

- Recently, the CoreValve US Pivotal High Risk Trial demonstrated improved 12-month survival with TAVR using a self-expanding prosthesis compared with SAVR in high-risk aortic stenosis patients

Objectives

- Quantify “in-trial” survival, quality of life, quality-adjusted survival, resource use and costs for both TAVR and SAVR through 12 months

- Characterize incremental cost-effectiveness of TAVR vs. SAVR over a lifetime horizon

Methods: Overview

Analytic Perspective

- US healthcare system (2013 US dollars)

Analysis Population

- All patients from As Treated trial population (N=747)
  - Crossovers within this population analyzed according to their randomized grouping (ITT principle)

General Approach

- In-trial (12-month) analysis with patient-level lifetime projections of life expectancy, quality-adjusted life expectancy, and costs
- Primary effectiveness measure = quality adjusted life-years (QALYs); secondary measure = life years (LYs)
- Future costs and benefits discounted at 3%/year

Methods

- Costs through 12 months were calculated using a combination of resource-based accounting and hospital billing data. Observed costs from the 6-12 month interval were used to project future costs
  - CoreValve estimated commercial price = $32,000
  - Cath lab overhead for IF-TAVR procedures; OR overhead for all other procedures
- EQ-5D utilities measured at baseline, 1, 6 and 12 months and used to estimate quality-adjust life expectancy

Methods: Survival Projections

- SAVR Group: Observed mortality (6-18 months) calibrated to age/gender matched mortality from US life tables. Life tables, with calibration factor, used to project patient-level survival beyond 12 months
- TAVR Group: Hazard ratio (TAVR vs. SAVR) for survival projections derived from 6-18 month landmark analysis of trial data
  - Observed hazard ratio = 0.94 (95% CI: 0.57 to 1.56)
  - For base case analysis, hazard ratio assumed = 1.0

Baseline Characteristics

Characteristic	TAVR N=390	SAVR N=357
Age, years	83.1 ± 7.1	83.2 ± 6.4
Men, %	53.1	52.4
STS Predicted Risk of Mortality, %	7.3 ± 3.0	7.5 ± 3.4
Logistic EuroSCORE, %	17.7 ± 13.1	18.6 ± 13.0
Prior MI	25.4	25.2
Prior coronary artery bypass surgery	29.5	31.1
Prior stroke	12.6	14.0
Home oxygen	12.9	11.5
Creatinine clearance <30 cc/min	12.0	11.7
Peripheral artery disease	41.1	41.7

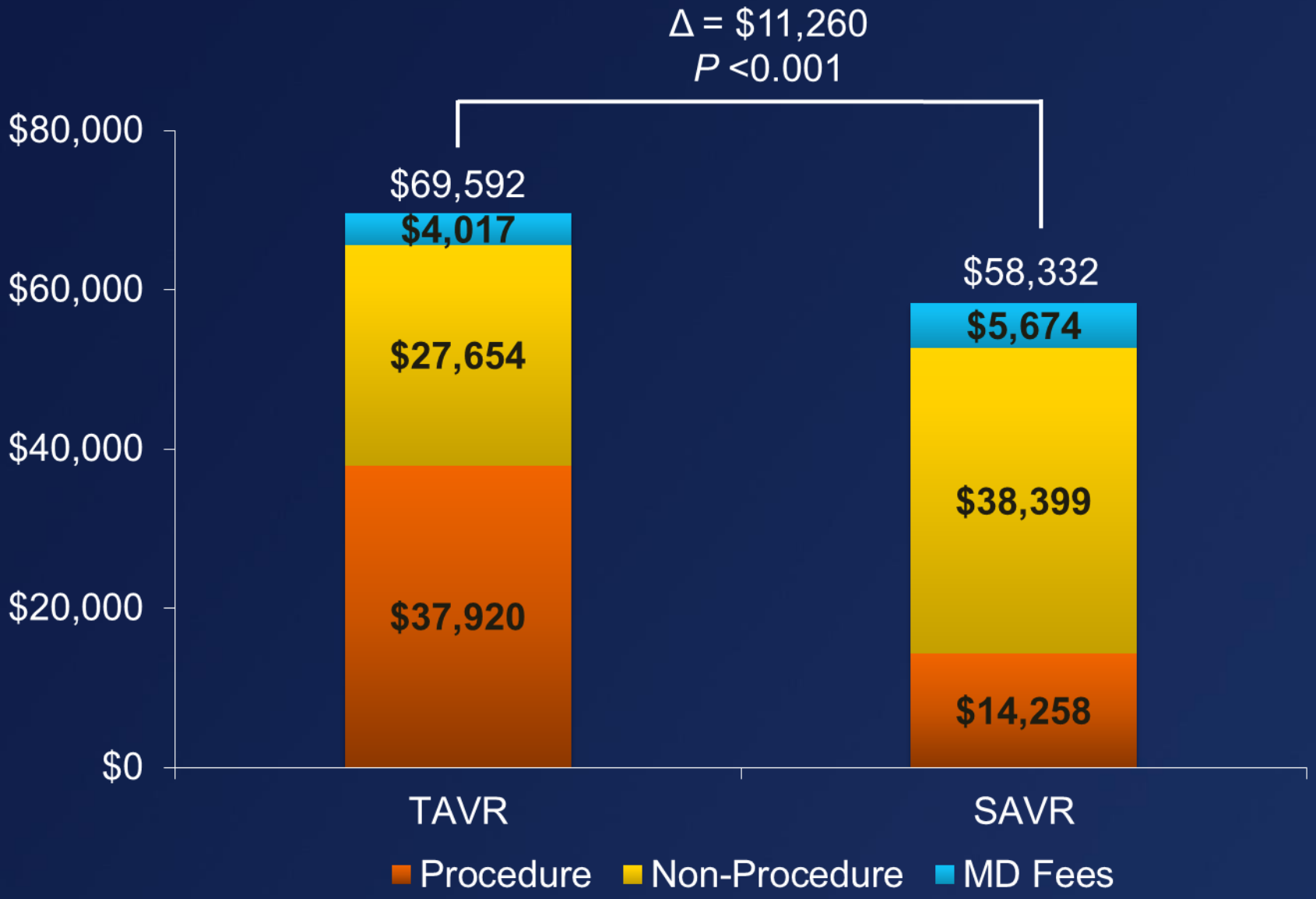
P=NS for all comparisons

Index Procedure/Admission Resource Use

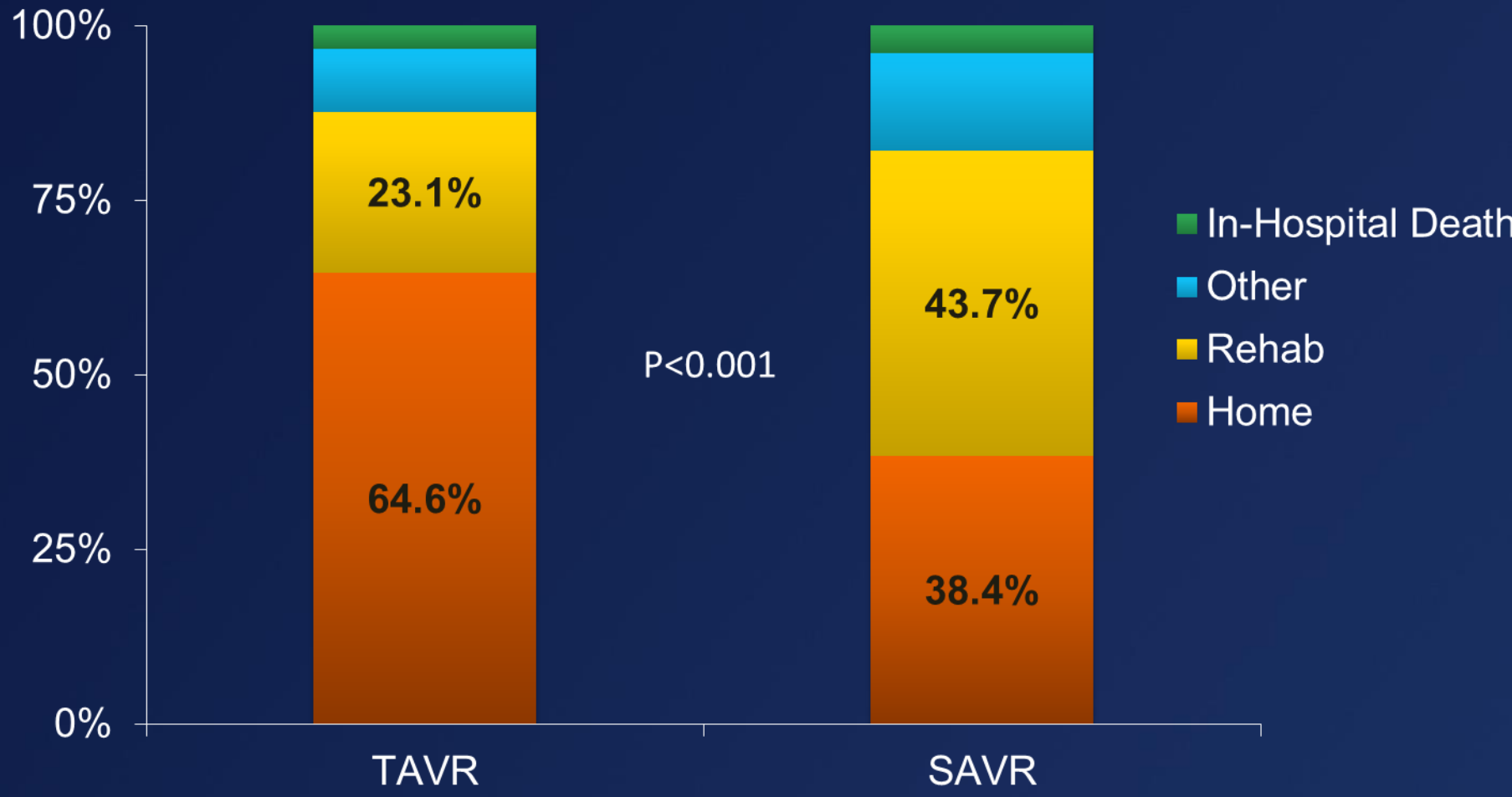
Resource Category	TAVR N=390	SAVR N=357	Difference (95% CI)	P Value
Procedure duration, min	61±35	221±85	-161 (-151 to -170)	<0.001
Room time, min	216±62	315±94	-99 (-87 to -110)	<0.001
Total hospital LOS*, days	8.1 (6)	12.5 (9)	-4.4 (-3.1 to -5.7)	<0.001
ICU	3.1 (2)	4.7 (3)	-1.6 (-0.9 to -2.3)	<0.001
Non-ICU	5.0 (4)	7.7 (5)	-2.8 (-1.8 to -3.8)	<0.001
Post procedure	6.7 (5)	11.5 (8)	-4.8 (-3.6 to -5.9)	<0.001
Total ventilator time, hr	14.2±64.1	36.2±84.3	-22.0 (-11.1 to -32.8)	<0.001

*LOS data are shown as mean (median)

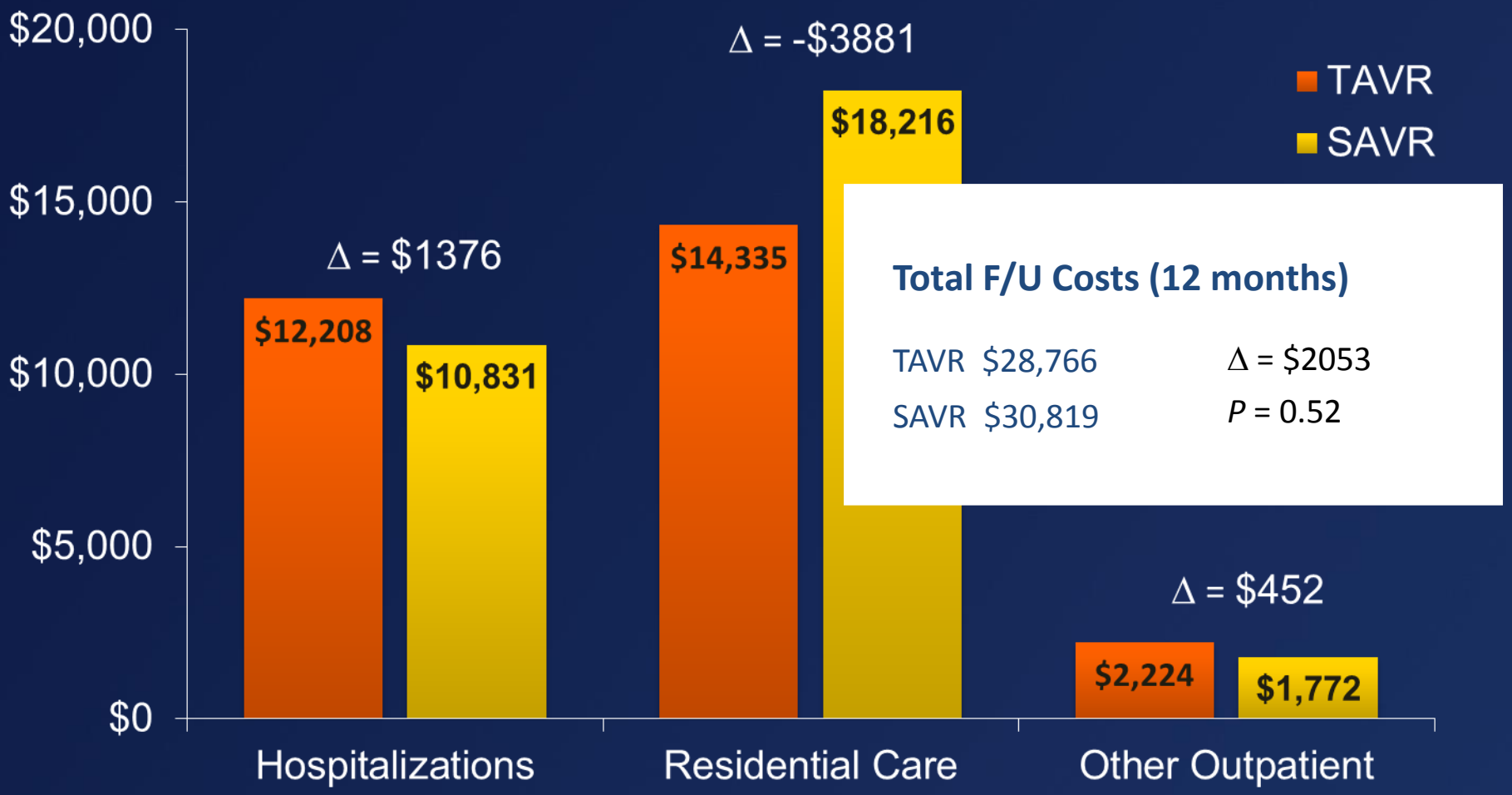
Index Admission: Costs



Discharge Destination



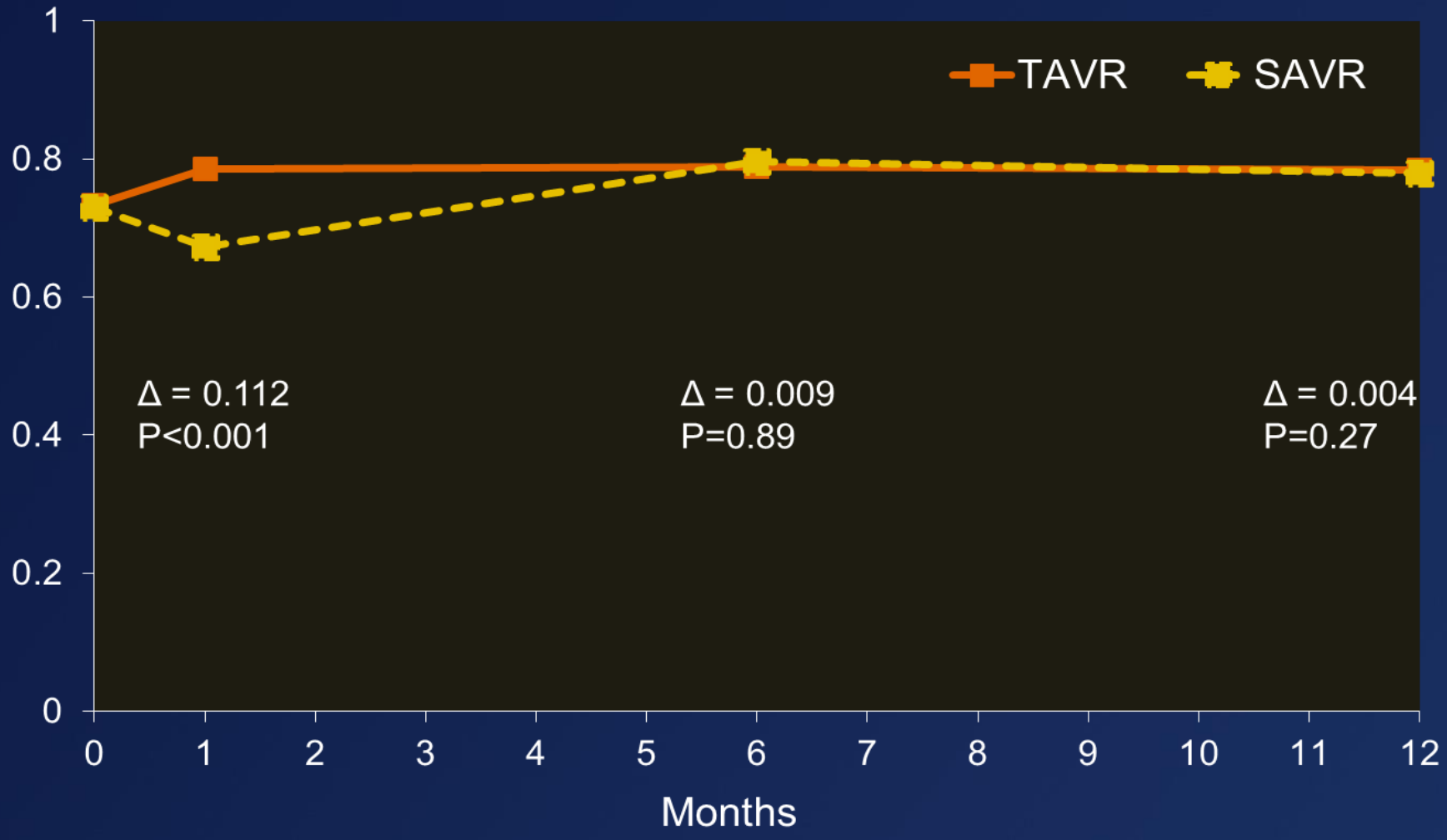
12-Month Follow-up Costs



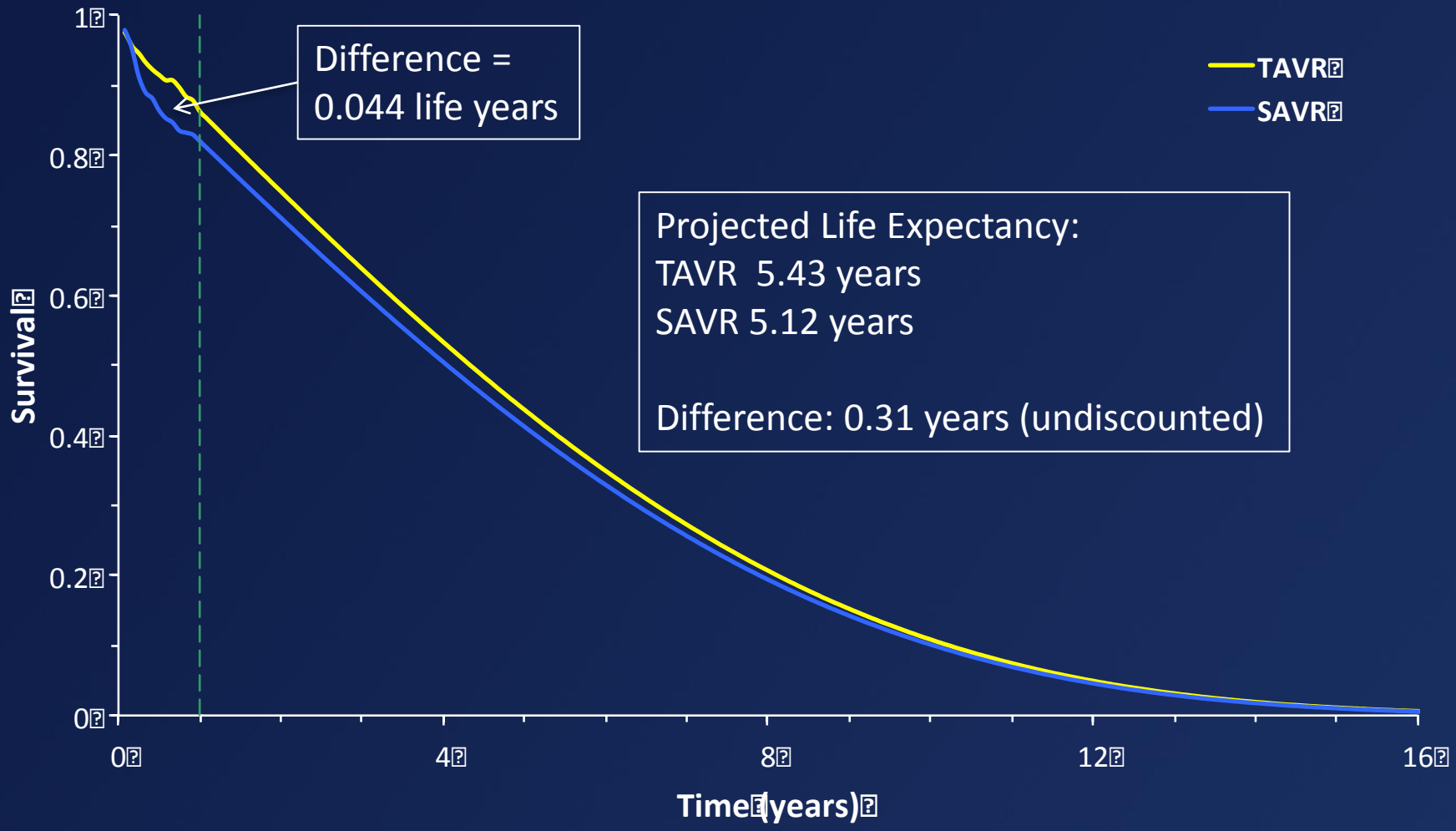
Total F/U Costs (12 months)

TAVR $28,766	Δ = $2053
SAVR $30,819	*P* = 0.52

In-Trial EQ-5D Scores

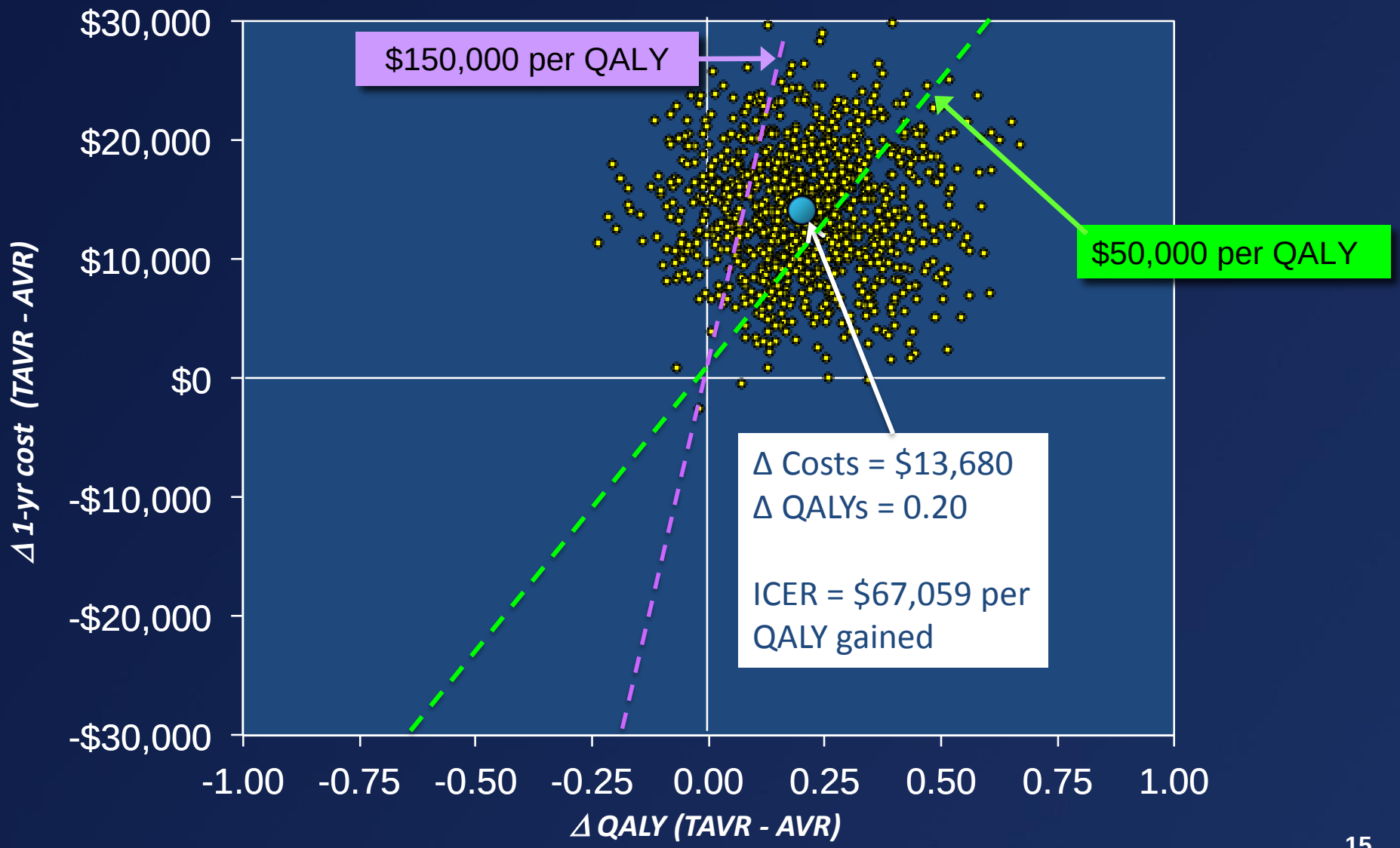


Projected Survival



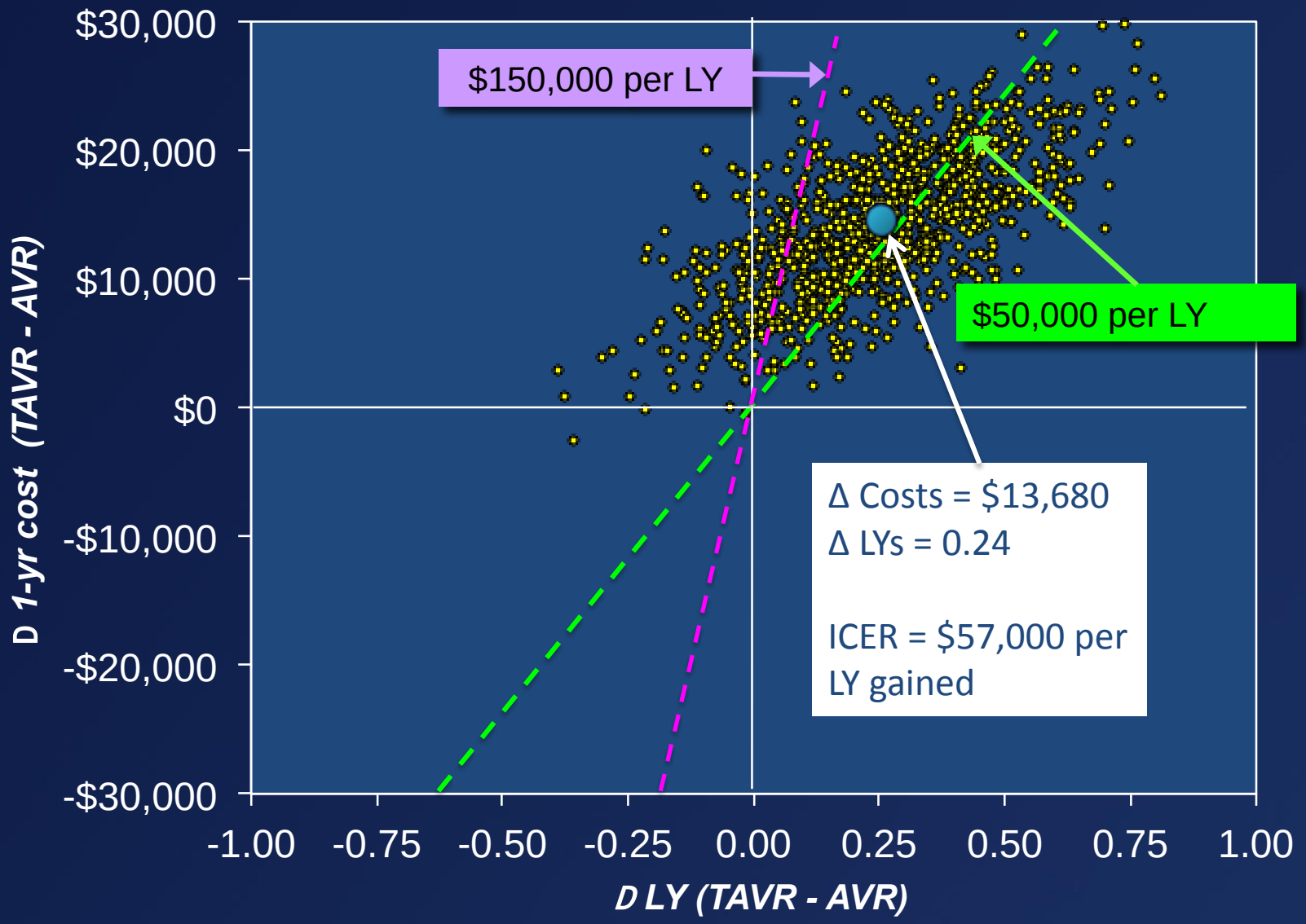
TAVR vs. SAVR

Cost per QALY gained, Lifetime



TAVR vs. SAVR

Cost per LY gained, Lifetime

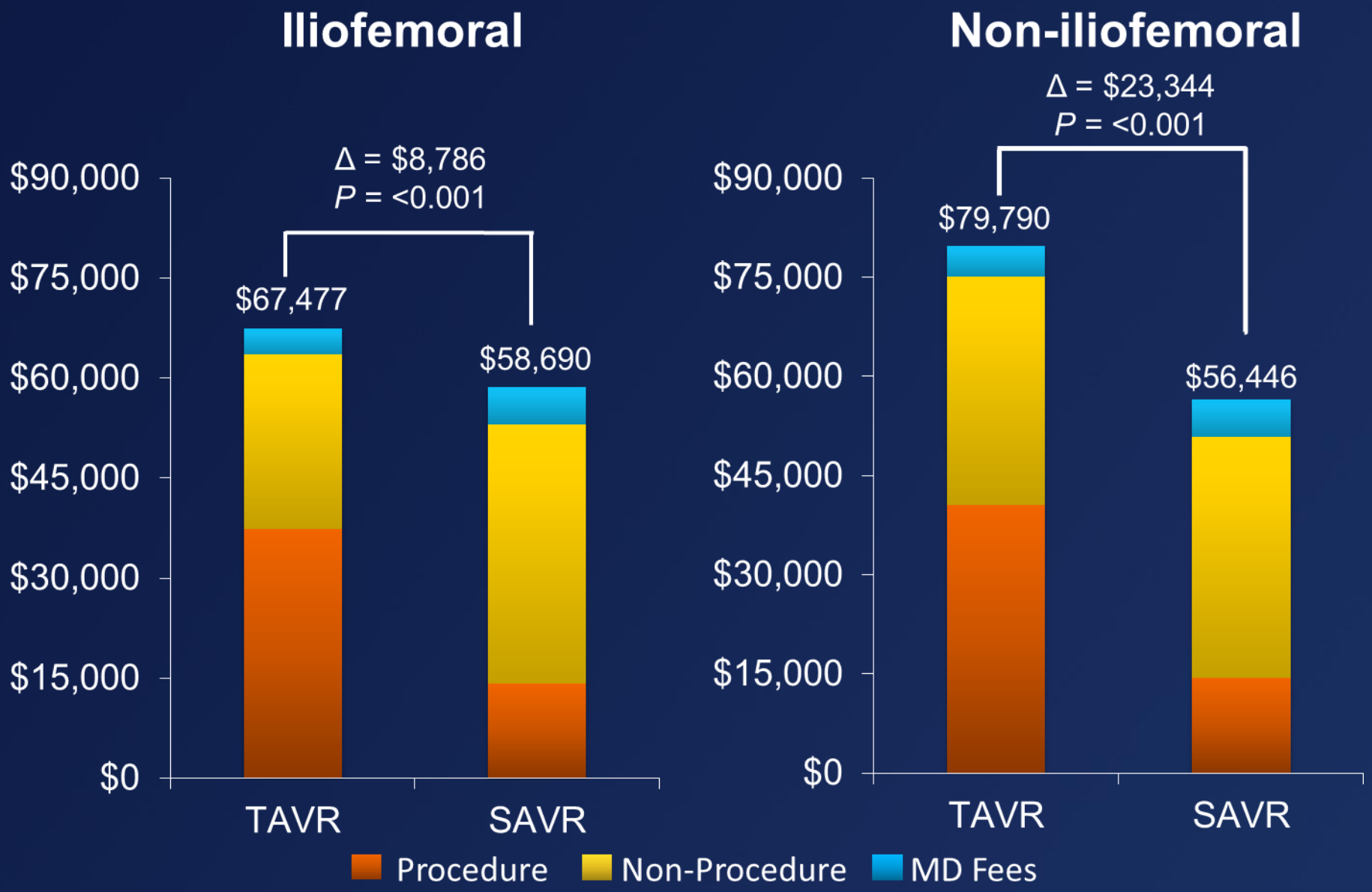


Index Procedure/Admission Resource Use Access Site

Resource Category	Iliofemoral			Non Iliofemoral		
	TAVR N=323	SAVR N=300	Difference	TAVR N=67	SAVR N=57	Difference
Procedure time, min	62±34	220±81	-158*	56±42	270±102	-172*
Room time, min	210±58	314±90	-104*	251±58	324±113	-73*
Total LOS, day	7.6 (6)	12.6 (9)	-5.0*	10.4 (8)	11.9 (10)	-1.4
Ventilator time, hr	11±41	37±88	-26.1*	31±124	33±63	-2.3
D/C to Rehab, %	20.4	44.3	-23.9*	35.8	40.4	-4.5

LOS data are shown as mean (median); *P<0.05

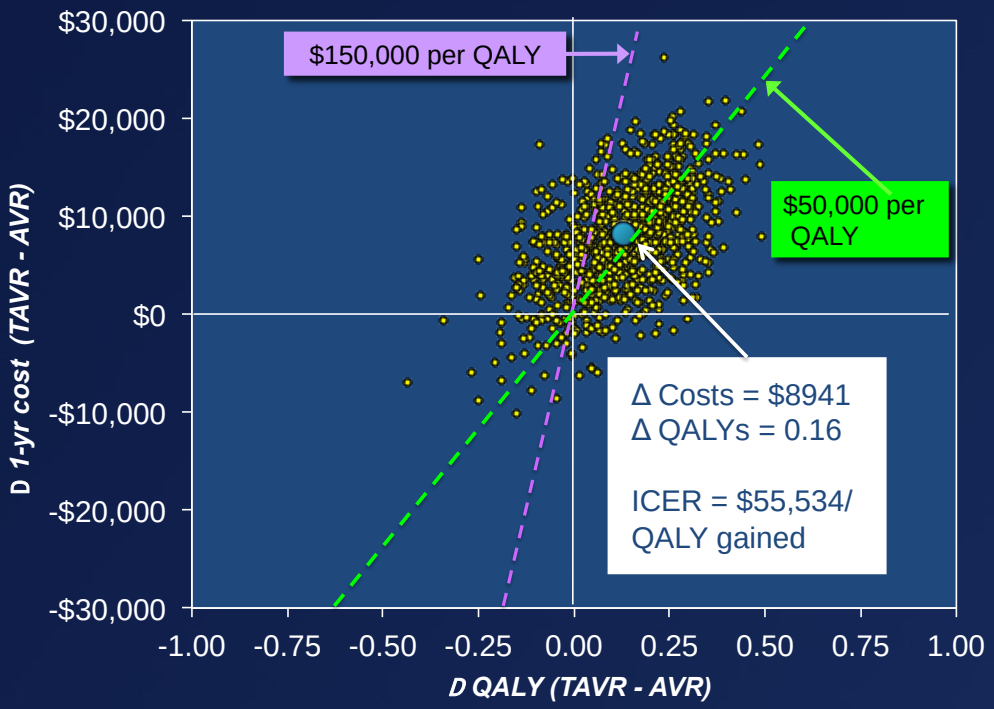
Index Costs – Access Site



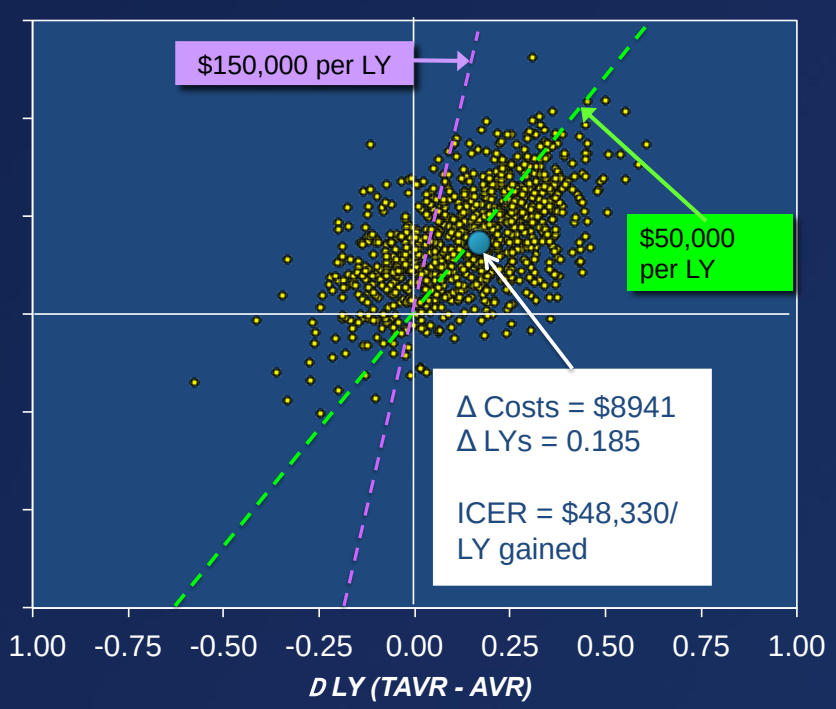
Iliofemoral Group

Lifetime Cost Effectiveness

Cost per QALY

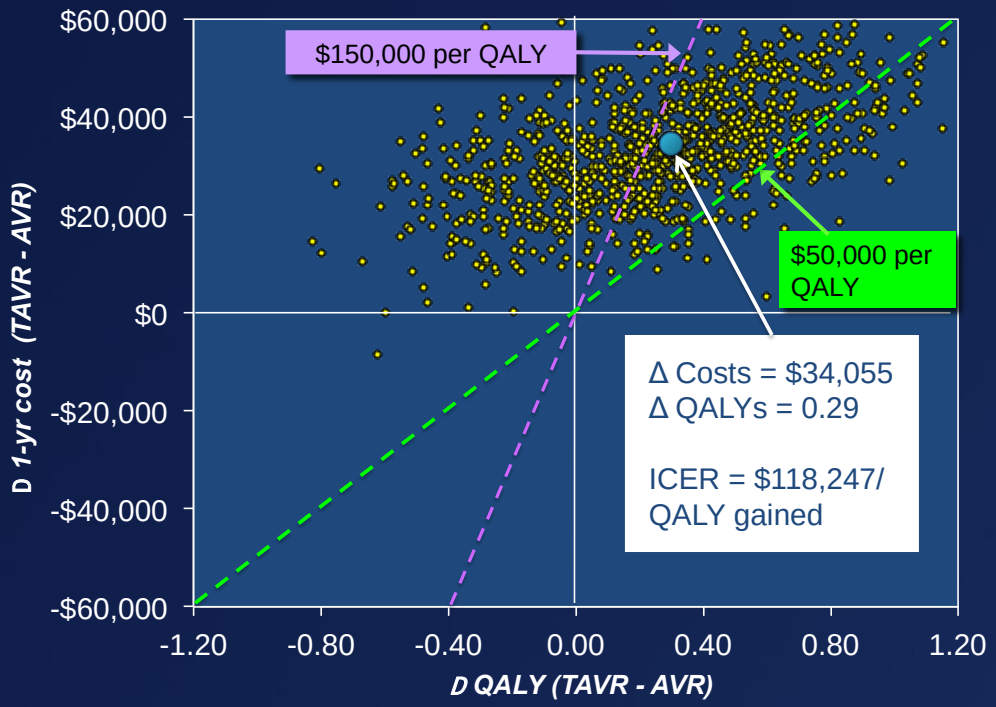


Cost per LY

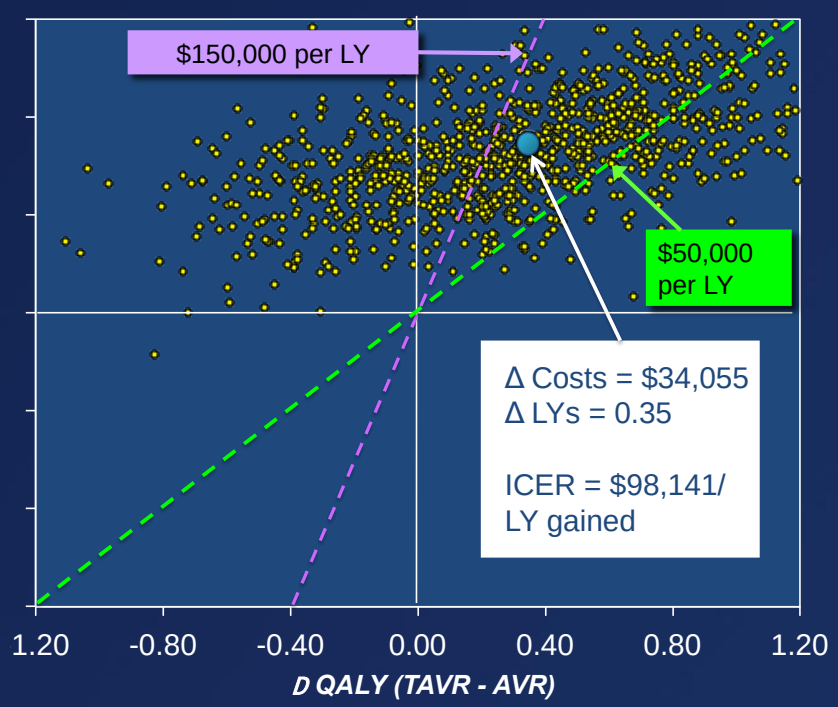


Non-iliofemoral Group
Lifetime Cost Effectiveness

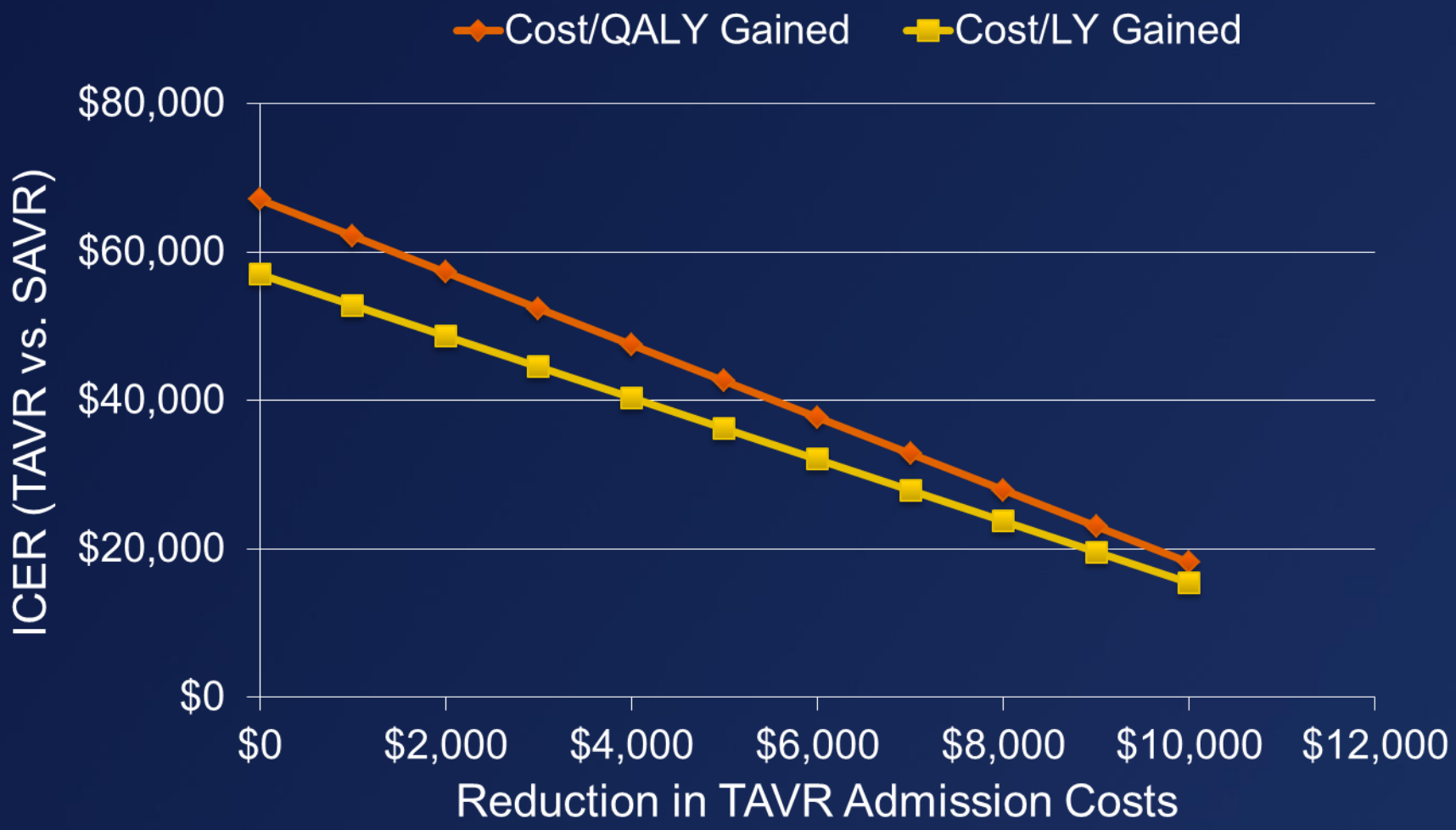
Cost per QALY



Cost per LY



Impact of Reducing TAVR Admission Costs



Summary of Findings

- In the CoreValve US Pivotal High Risk Trial, TAVR improved 1-month quality of life and 12-month survival relative to SAVR
- In projections, TAVR added ~0.24 life years and 0.20 QALYs per patient (with 3% discounting)
- Index admission costs were higher with TAVR by ~$11,000 per patient, and lifetime costs were projected to be higher by ~$13,700
- Projected lifetime ICERs were ~$67,000 per QALY gained and $57,000 per LY gained, and were slightly lower in the iliofemoral sub-group

Conclusions

- In this high risk population, TAVR provided meaningful clinical benefits relative to SAVR, with incremental costs considered acceptable from a US perspective
- Results were slightly more favorable for patients eligible for iliofemoral access and slightly less favorable, though still acceptable, for patients not eligible for iliofemoral access. The latter group was small and their results are uncertain
- With modest reductions in the cost of index TAVR admissions, the value of TAVR compared with SAVR in this patient population would become high

CoreValve US Clinical Trials

Sensitivity/sub-Group Analyses, Cost per QALY Gained

	Effectiveness		Diff.	Lifetime Cost		Diff.	ICER
	TAVR	SAVR		TAVR	SAVR		
0% discount	4.23	3.97	0.26	$206,508	$191,103	$15,406	$59,483
5% discount	3.33	3.15	0.18	$178,834	$165,898	$12,936	$71,867
Men	3.34	3.38	-0.04	$177,313	$171,238	$6075	dominated
Women	3.92	3.53	0.39	$199,355	$179,482	$19,873	$50,311
HR = 0.94	3.74	3.43	0.28	$191,477	$174,583	$16,894	$54,851
No QOL Benefit	3.62	3.44	0.18	$188,263	$174,583	$13,680	$73,946
No Costs in Added Yrs	3.63	3.43	0.20	$98,358	$89,151	$9207	$45,132

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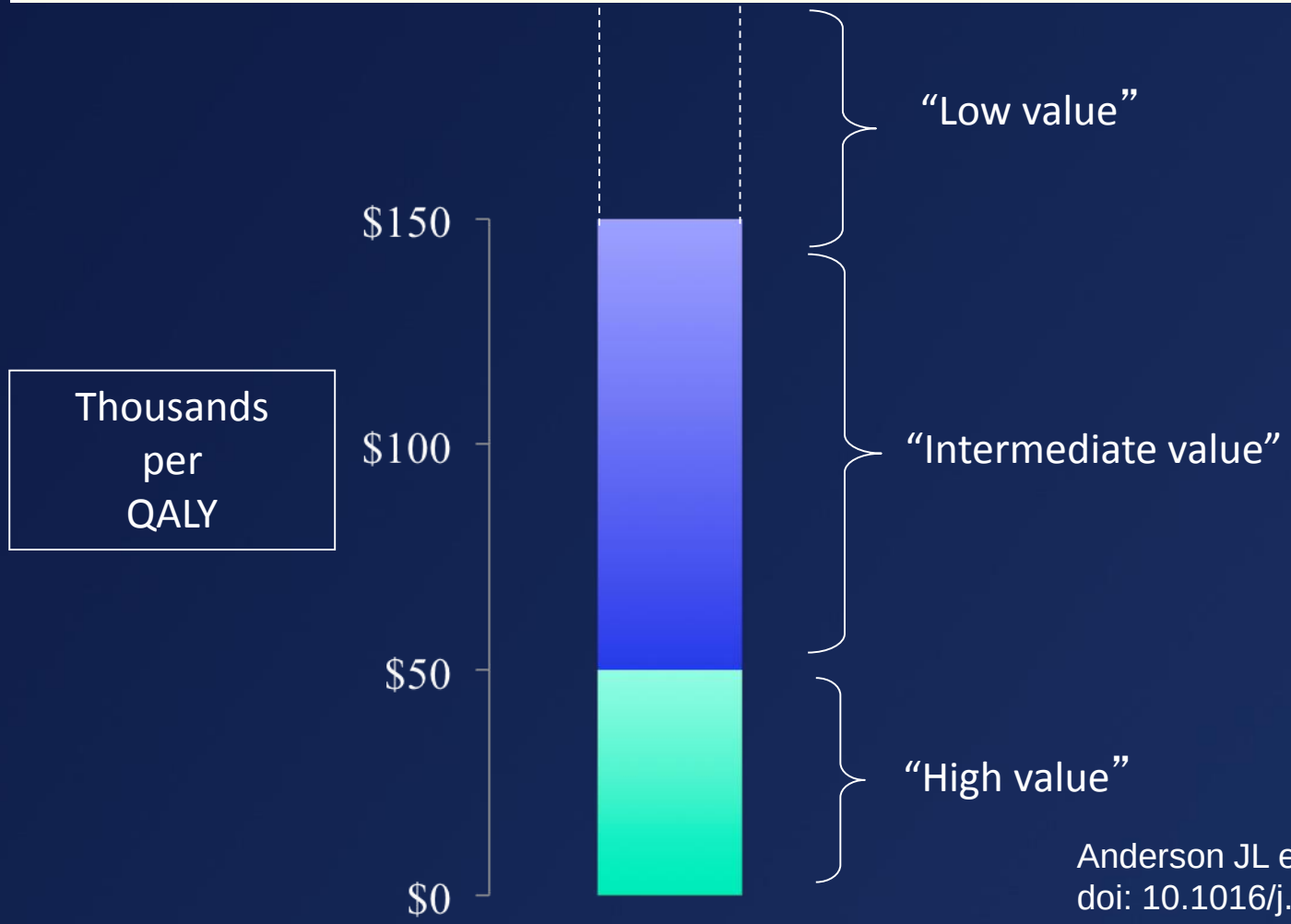
PERFORMANCE MEASURES

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 2014
doi: 10.1016/j.**jacc**.2014.03.016

Cost Effectiveness in Cardiovascular Medicine