

# Cost Effectiveness of Transcatheter Aortic Valve Replacement Compared With Surgical Aortic Valve Replacement in Patients With Severe Aortic Stenosis: Results from The PARTNER Trial (Cohort A)

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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

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity
- Royalty Income
- Ownership/Founder
- Intellectual Property Rights
- Other Financial Benefit

## Company

- Edwards Lifesciences
- Medtronic
- none
- none
- none
- none
- none

# Objectives



- Compare initial and 12-month costs of TAVR compared with surgical AVR in patients with high operative risk from cohort A of The PARTNER Trial
- Combine cost data with survival and QoL data to estimate the 12-month cost-effectiveness of TAVR compared with AVR
- Explore potential differences in costs and cost-effectiveness of TAVR vs. AVR for the transfemoral vs. the transapical populations

# Methods: Overview



## *Analytic Perspective*

- US healthcare system (2010 US dollars)

## *General Approach*

- In-trial (12-month) analysis based on observed survival, QOL, health care resource use, and hospital billing data
- As 12-month survival and QoL known to be equivalent between groups, no extrapolation of results beyond 12 months was performed
- Primary effectiveness measure = quality adjusted life-years (QALYs); secondary measure = life years (LYs)

# Analysis Populations



<b><i>Patient Group</i></b>	<b><i>Definition</i></b>	<b><i>Outcomes Reported</i></b>
Complete (N = 647)	TAVR or surgical AVR attempted, complete follow-up until death or 1 year	<i>Primary population for full CEA</i>
Treated (N = 657)	TAVR or surgical AVR procedure attempted; Includes patients who subsequently withdrew or were lost to follow-up (n = 10)	Secondary population for full CEA
Per-protocol (N = 647)	Excludes TAVR (n = 9) or surgical AVR (n = 1) cases abandoned based on TEE findings or failed vascular access	Procedural resource utilization and costs only

All subjects analyzed according to original treatment assignment

# Methods: Index Admission Costs



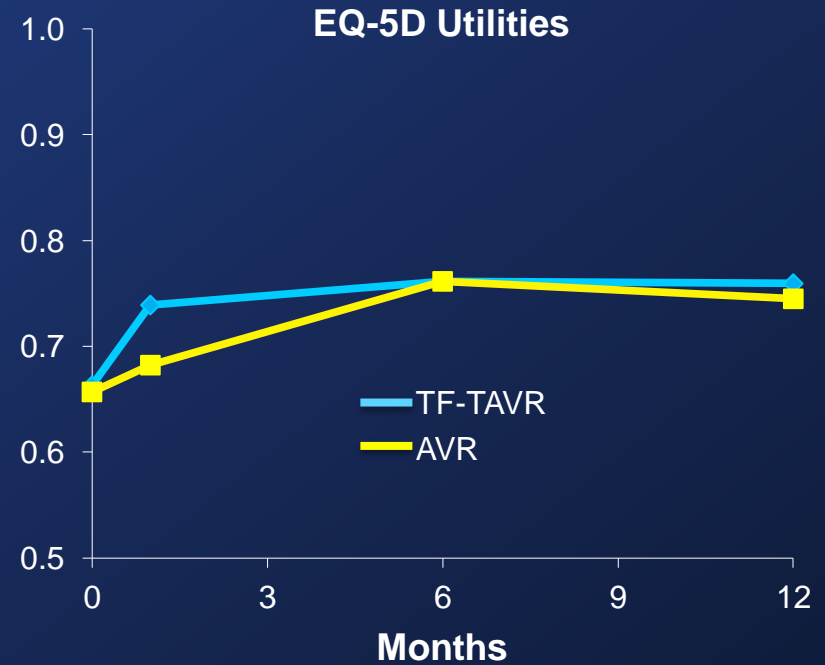
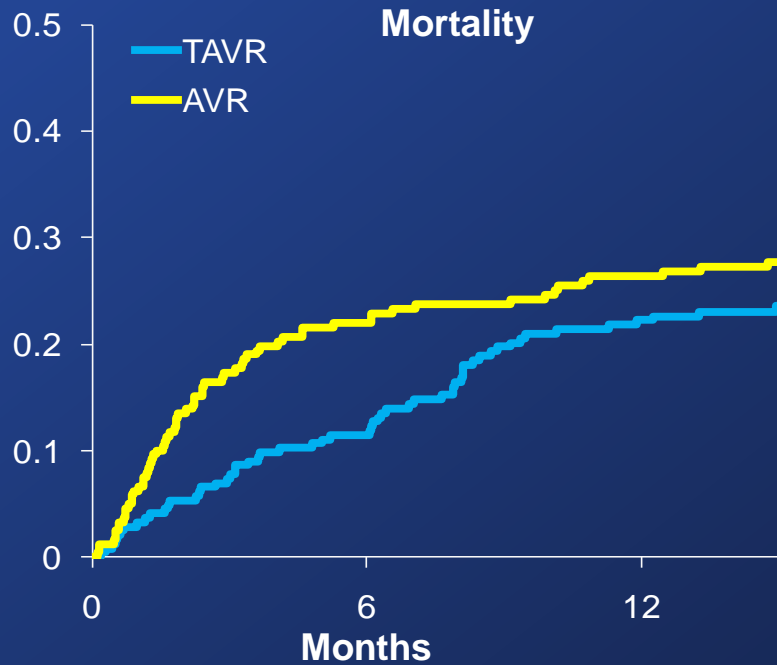
- *TAVR procedure*: Measured resource utilization (procedure duration, supplies) multiplied by unit costs
  - SAPIEN valve estimated commercial price = \$30,000
  - Cardiac OR overhead used for AVR and TA-TAVR cases; cath lab overhead used for all TF-TAVR cases
- *All other costs for index admission*: bills collected from consenting patients enrolled at participating US sites (541 of 699 ITT subjects)
  - Itemized charges multiplied by hospital and department-specific cost-to-charge ratios
  - Where billing data unavailable, regression models derived from subjects with bills used to impute costs separately for TAVR ( $R^2 = 0.83$ ) and AVR groups ( $R^2 = 0.78$ )

# Methods: Follow-Up Costs



- *Follow-up hospitalizations:* Costs from billing data or when bills unavailable from average Medicare reimbursement for respective DRG (MedPAR)
- *Resource-based costs:* Also included for rehabilitation days, SNF days, outpatient visits, ER visits, and outpatient cardiac testing

# Life Years and QALYs: Transfemoral



	<b>TF-TAVR</b> (N = 239)	<b>AVR</b> (N = 217)	<b>TAVR-AVR</b>	<b>95% CI *</b>
<b>LYs</b>	<b>0.878</b>	<b>0.813</b>	<b>0.065</b>	<b>0.011 to 0.125</b>
<b>QALYs</b>	<b>0.659</b>	<b>0.591</b>	<b>0.068</b>	<b>0.017 to 0.123</b>

\*95 CIs from 1,000 bootstrap replications of trial data.

# Index Procedure/Admission

## Resource use (per-protocol population)



<b>Resource Category</b>	<b>TF-TAVR</b> (N = 234)	<b>AVR</b> (N= 221)	<b>Difference</b> (95% CI)*	<b>P-value</b>
Procedure duration (min)	244 ± 78	330 ± 102	-87 (-69 to -104)	<0.001
Total hospital LOS, days	10.2 (7)	16.4 (12)	-6.2 (-3.8 to -8.2)	<0.001
ICU	3.3 (2)	5.6 (3)	-2.3 (-0.9 to -3.3)	<0.001
Non-ICU	6.9 (4)	10.8 (8)	-4.0 (-2.2 to -5.5)	<0.001
Post procedure	7.4 (5)	13.5 (10)	-6.1 (-3.7 to -8.0)	<0.001
Major vasc. complication	13.2%	3.2%	10.1% (5.1 to 15.1)	<0.001
Major bleeding	9.4%	22.6%	-13.2% (-6.6 to -19.9)	<0.001

LOS data are shown as mean (median).

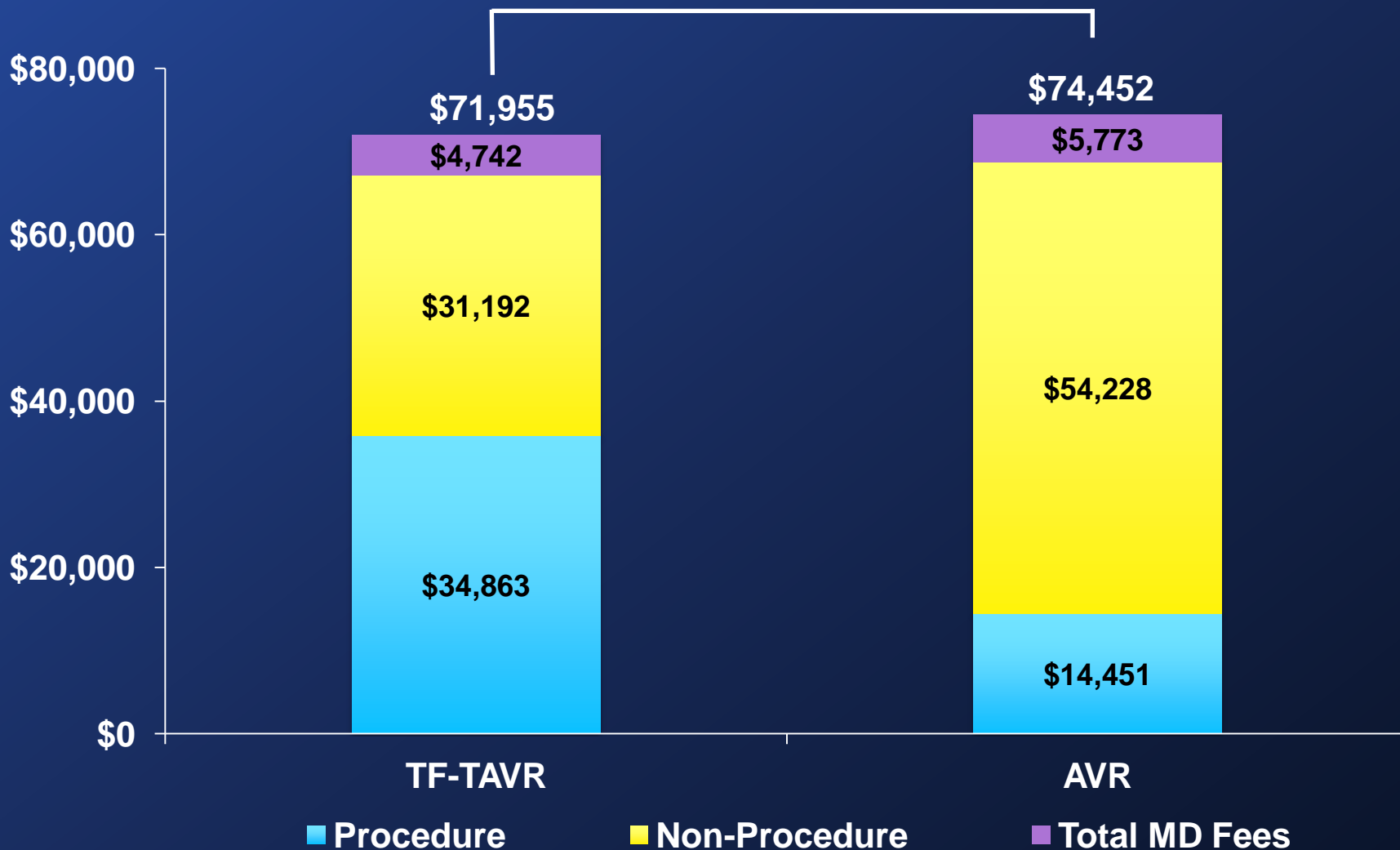
\*95% CIs from 1,000 bootstrap replications of study data.

# Index Admission Costs

## Transfemoral

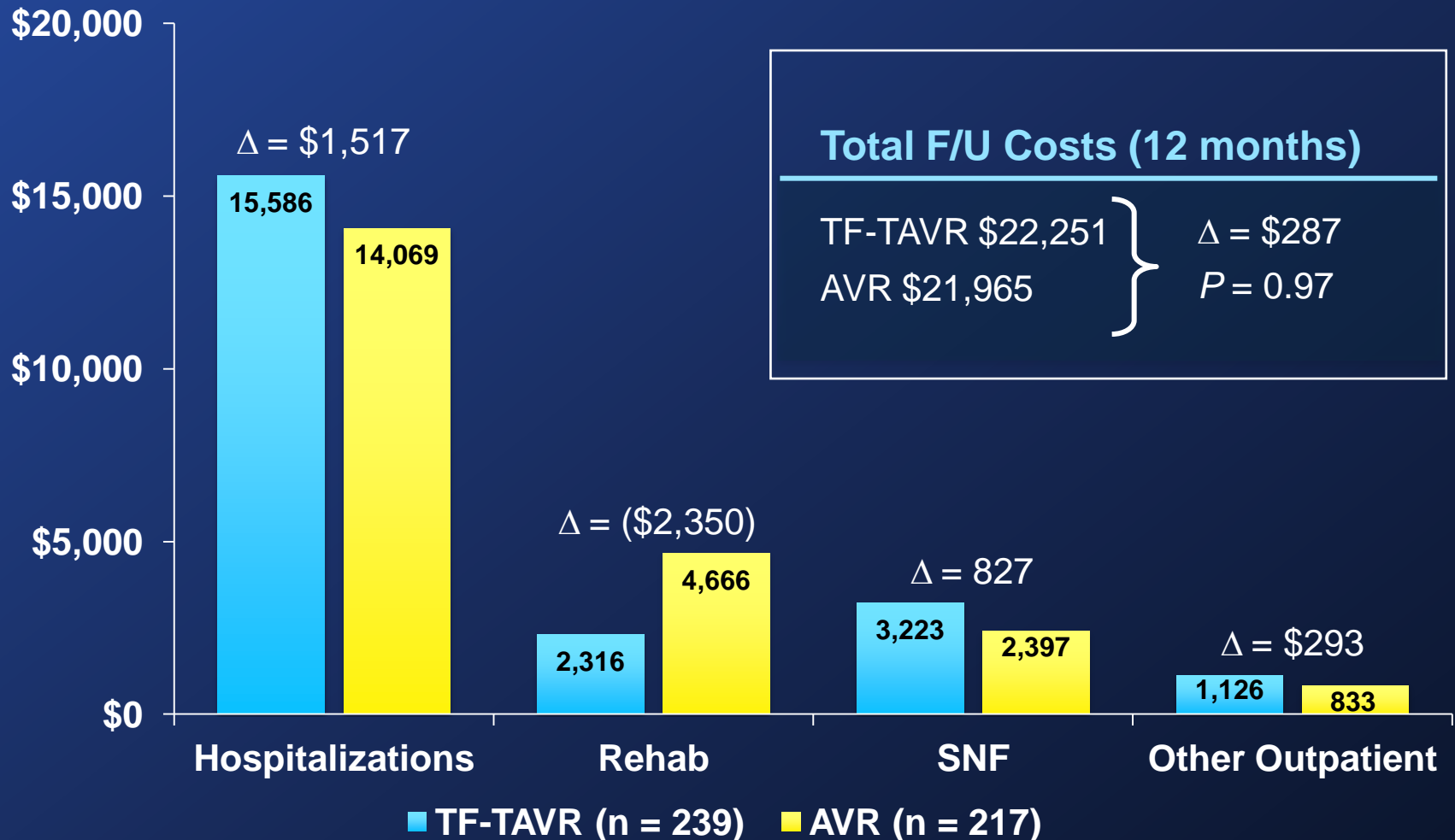


$\Delta = (\$2,496)$   
 $P = 0.53$



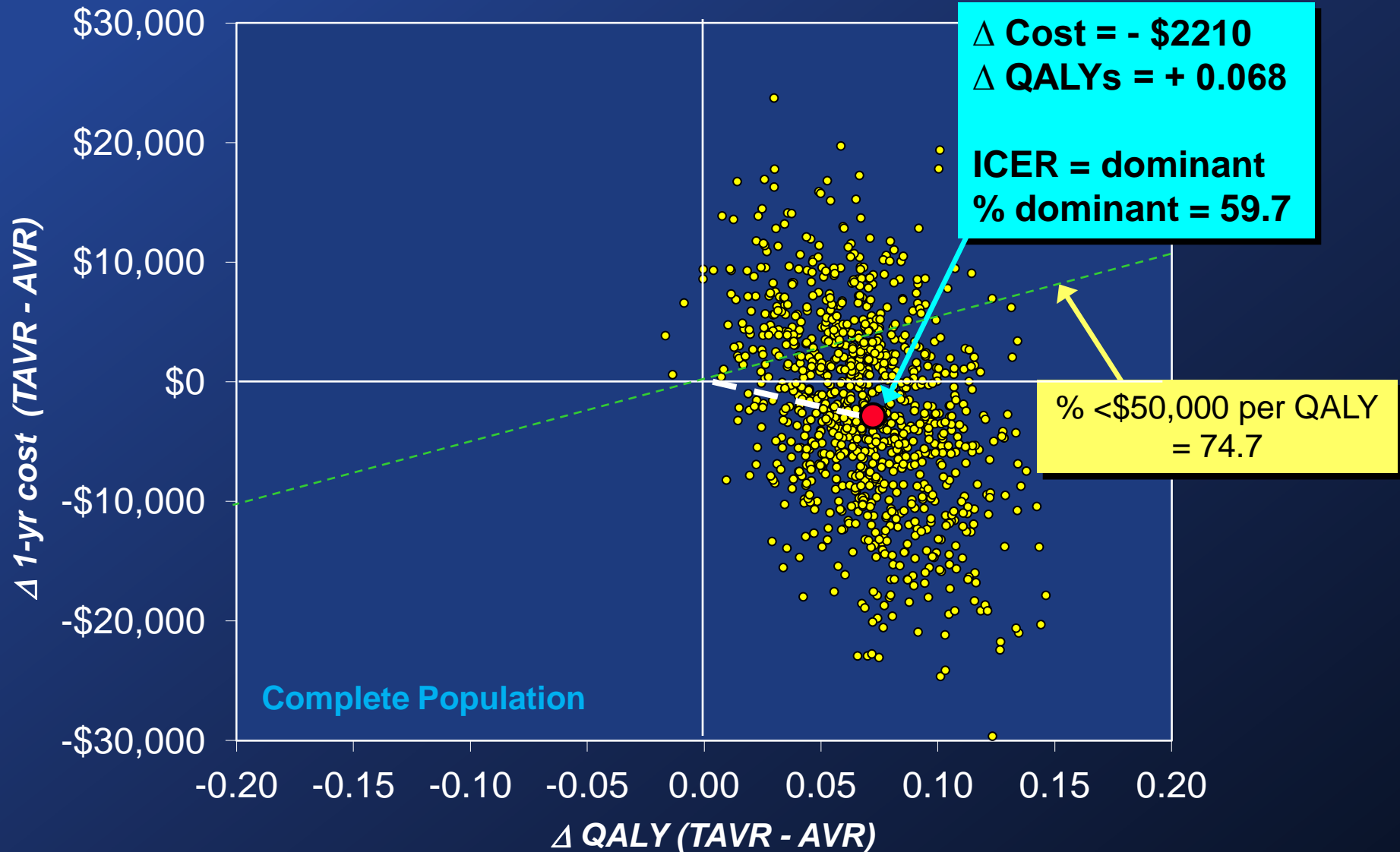
# 12-Month Follow-up Costs

## Transfemoral

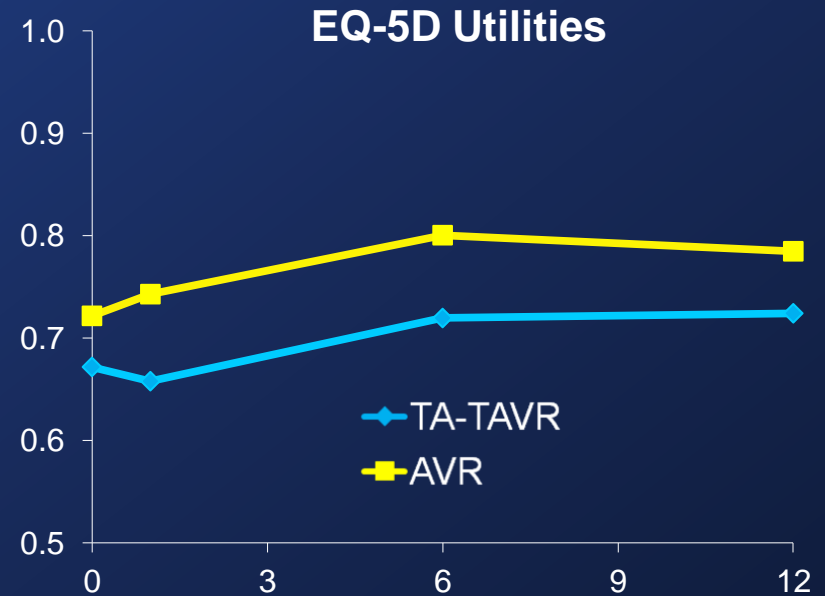
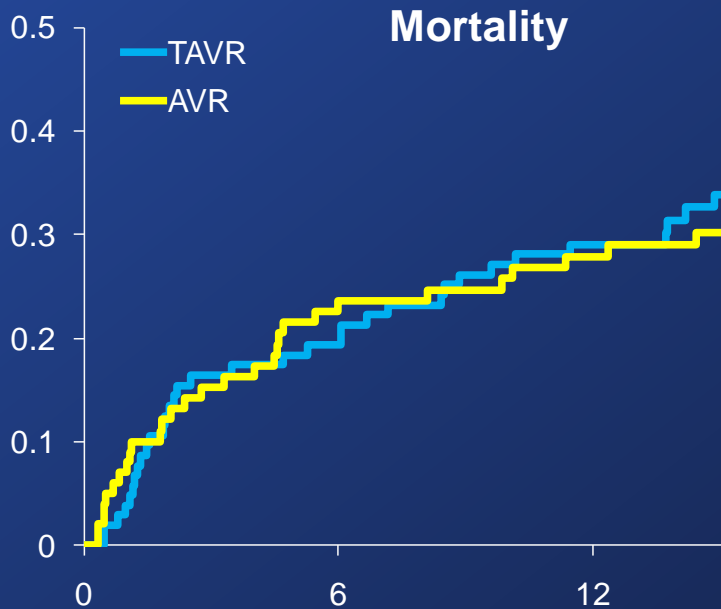


# TAVR vs. AVR: Transfemoral

## Cost per QALY gained



# Life Years and QALYs Transapical



	<b>TA-TAVR</b> (N = 101)	<b>AVR</b> (N = 90)	<b>TAVR-AVR</b>	<b>95% CI</b>
LYs	0.811	0.826	-0.015	-0.103 to 0.080
QALYs	0.570	0.641	-0.070	-0.151 to 0.012

\*95 CI's from 1000 bootstrap replications of trial data.

# Index Procedure/Admission

## Resource use (per-protocol population)

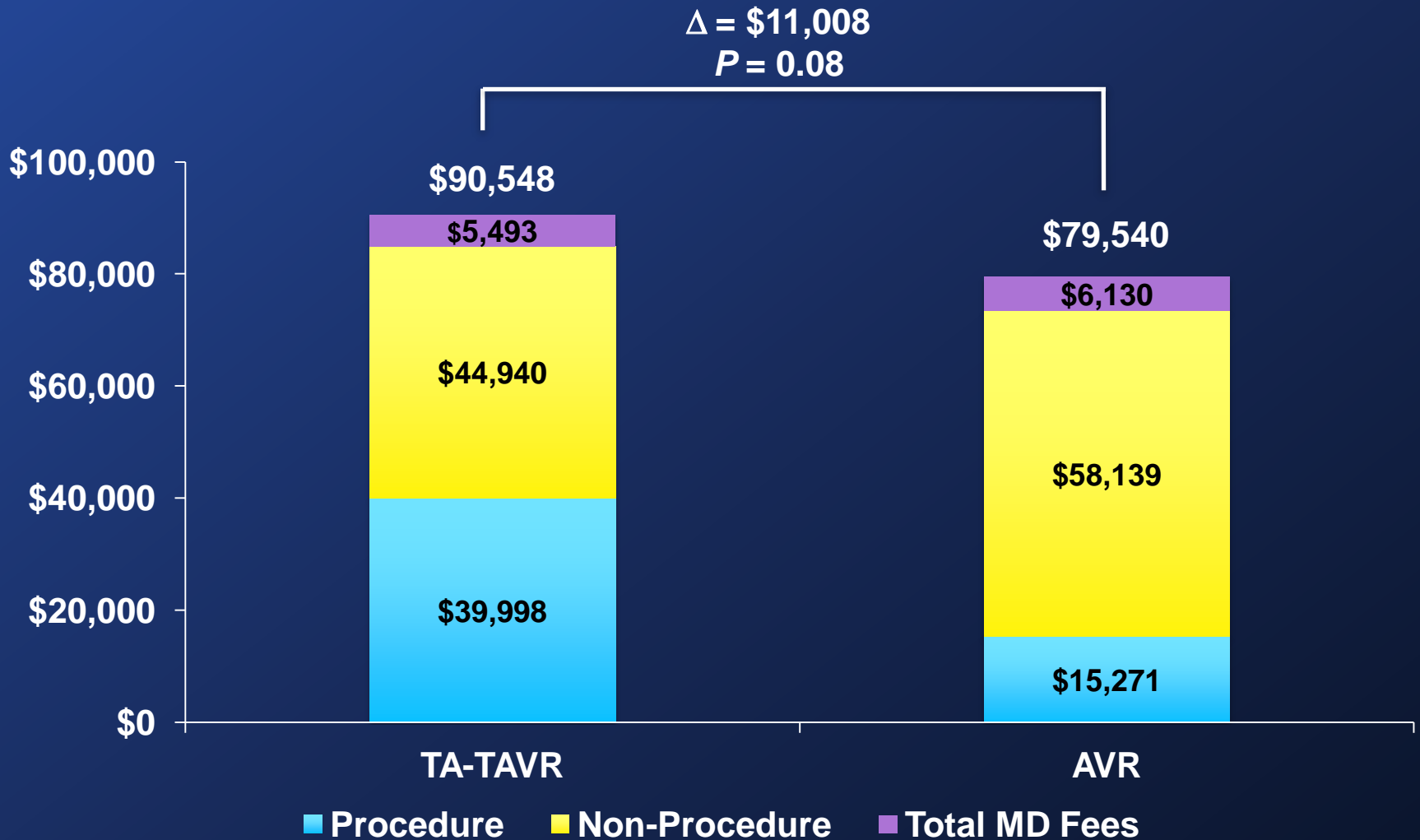


<b>Resource Category</b>	<b>TA-TAVR (N = 101)</b>	<b>AVR (N = 91)</b>	<b>Difference (95% CI)*</b>	<b>P-value</b>
Procedure duration, min	224 ± 76	354 ± 104	-130 (-104 to -155)	< 0.001
Total hospital LOS, days	14.7 (10)	16.1 (12)	-1.4 (1.7 to -4.7)	0.39
ICU	6.6 (3)	8.0 (4)	-1.4 (1.3 to -4.4)	0.33
Non-ICU	8.1 (6)	8.1 (7)	0.0 (1.9 to -1.8)	1.0
Post procedure	12.4 (9)	14.4 (9)	-2.0 (1.1 to -5.3)	0.22
Major vasc. complication	4.0%	4.4%	-0.4% (6.2 to -5.3)	1.0
Major bleeding	5.9%	20.9%	-14.9% (-5.5 to -24.3)	0.002

LOS data are shown as mean (median).

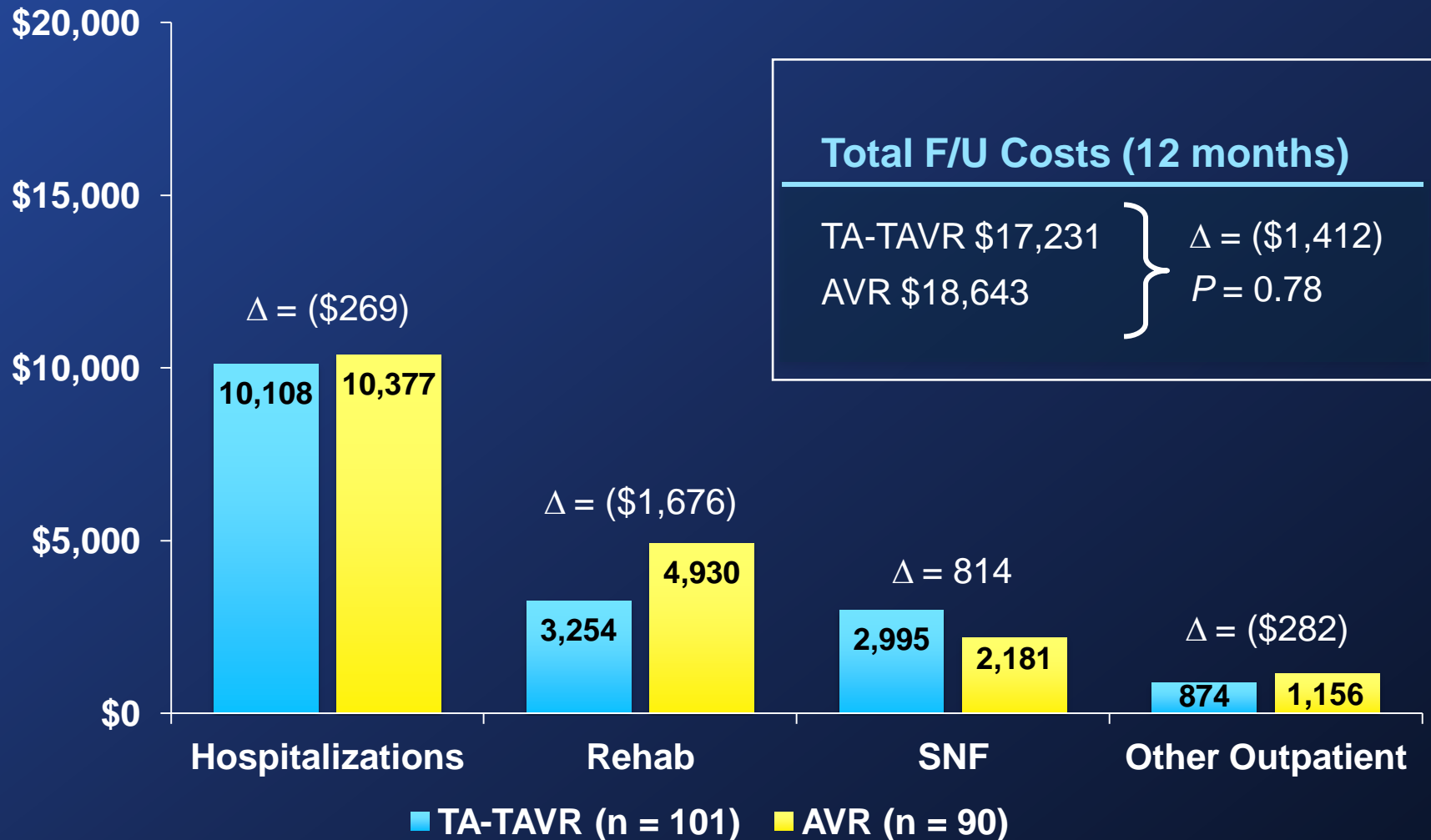
\*95% CI's from 1000 bootstrap replications of study data.

# Index Admission Costs Transapical



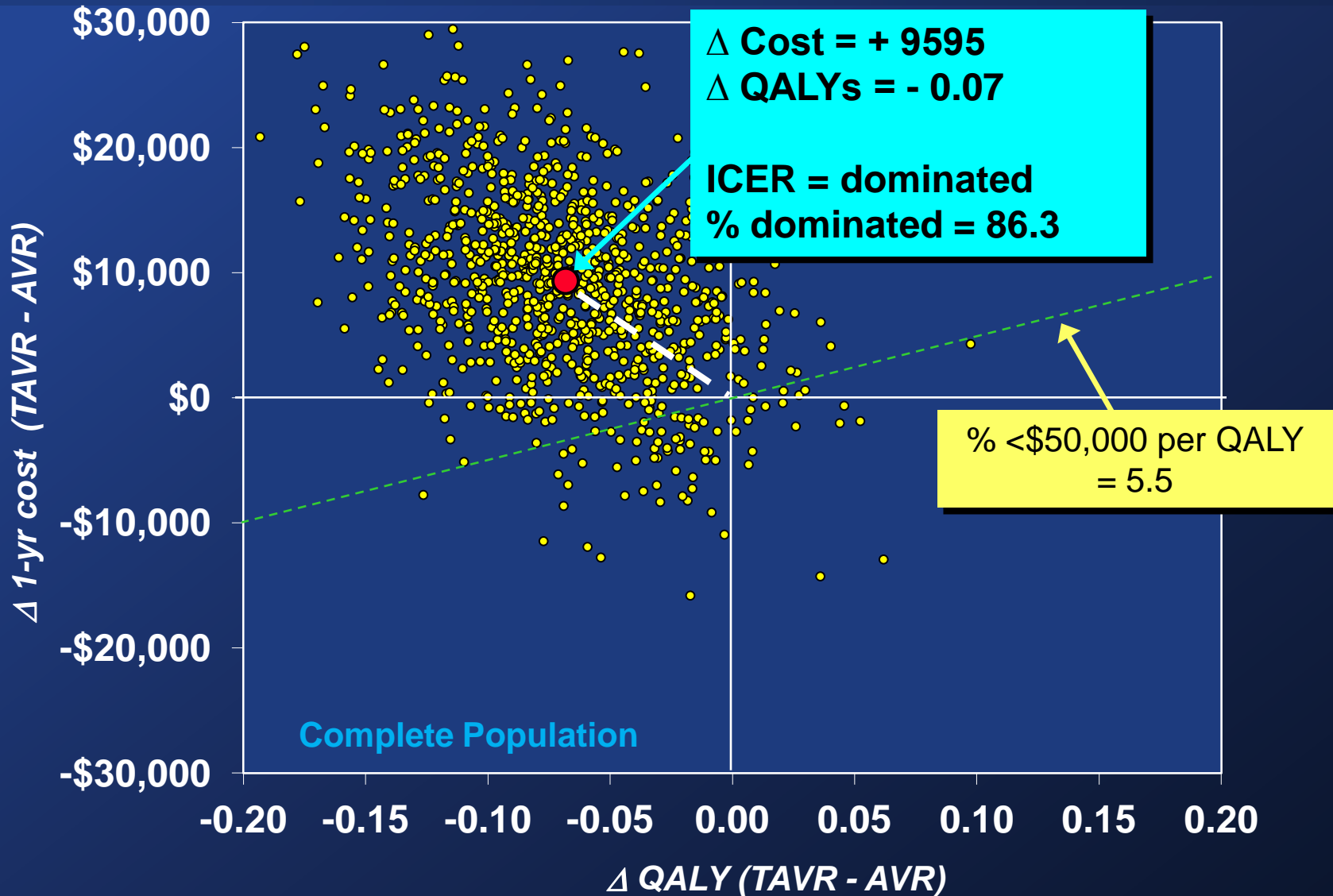
# 12-Month Follow-up Costs

## Transapical



# TAVR vs. AVR: Transapical

Cost per QALY gained



# Summary of Findings



- Among high risk AS patients eligible for the transfemoral approach, TAVR, compared with surgical AVR:
  - Provided small but significant gains in 12-month quality-adjusted life expectancy (0.06 – 0.07 QALYs)
  - Was associated with higher procedural costs but slightly lower index hospitalization and total 12 month costs
- Among patients only eligible for the transapical approach:
  - TAVR provided no increase (and possible decrease) in QALYs
  - TAVR increased procedural, index admission, and 12 month costs (by ~\$10,000/patient)

# Conclusions



- For patients with severe AS and high surgical risk, TAVR is an economically attractive and possibly dominant strategy compared with AVR, provided that patients are suitable for the transfemoral approach.
- Current results for TAVR via the transapical approach compared with surgical AVR are unattractive from a health economic perspective

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