

Cost-Effectiveness of Transcatheter vs. Surgical Aortic Valve Replacement in Intermediate Risk Patients

Results From The PARTNER 2A and Sapien 3 Intermediate Risk Trials

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TCT 2017 | Denver, CO | October 31, 2017



Disclosure



The PARTNER 2 and S3i trials (including the associated economic analyses) were funded by research grants from Edwards Lifesciences, Inc.

Background



- Previous studies have demonstrated that TAVR is cost-effective (but not cost saving) compared with medical therapy for patients with severe AS and extreme surgical risk and compared with SAVR for patients at high surgical risk
- Recently, based on the results of both the PARTNER 2A and SURTAVI trials, TAVR has been approved for intermediate risk patients as well
- Whether TAVR is cost-effective compared with SAVR for intermediate risk patients is currently unknown

P2A and S3i Study Designs



PARTNER 2A

Pts with severe AS and intermediate surgical risk (predicted mortality $\geq 4\%$)

Access Assessment

TF Access

Non-TF Access

Stratified Randomization

TAVR with Sapien XT valve
(N= 994)

SAVR
(N=944)

S3i

Pts with severe AS and intermediate surgical risk (predicted mortality $\geq 4\%$)

TAVR with SAPIEN 3 valve
(n=1077)

* Patient numbers are for as-treated cohorts

Economic Methods: Overview



Analytic Perspective

- US healthcare system (costs in 2016 US dollars)

Analysis Population

- P2A: As Treated population (XT- 994, SAVR- 944)
- S3i: Valve Implant population (S3- 1068, SAVR- 936)

General Approach

- In-trial (24 month) analysis based on observed data, followed by pt-level lifetime projections of survival, quality-adjusted life expectancy, and costs
- All future costs and benefits discounted at 3%/year

Methods: Costs



- Probabilistic matching used to link trial patients with Medicare claims data
- Index hospitalization costs calculated using a combination of resource-based accounting (for TAVR/SAVR procedures) and hospital billing data (from Medicare claims)
 - *Charges converted to costs based on hospital and cost-center specific cost to charge ratios*
 - *Valve costs based on current acquisition costs (TAVR- \$32,500; SAVR- \$5000)*
- All other costs (hospitalizations, MD services, outpatient testing, custodial care) based directly on Medicare payments derived from claims

Methods: Survival and QALYs



SAVR Group

- Observed mortality between 6 and 24 months compared with age/gender specific mortality from US life-tables
- Recalibrated life tables used to project patient-level survival beyond 24 months

TAVR Groups

- Hazard ratio (TAVR vs. SAVR) derived from 6-24 month landmark analysis of trial data
- Since observed HR (1.07, 95% CI 0.78 to 1.45) did not differ from unity, base case analysis assumed HR = 1.0

QALYs

- Utilities measured at baseline, 1, 6, 12, and 24 months using EQ-5D and used to calculate within-trial and lifetime QALYs

PARTNER 2A Randomized Trial

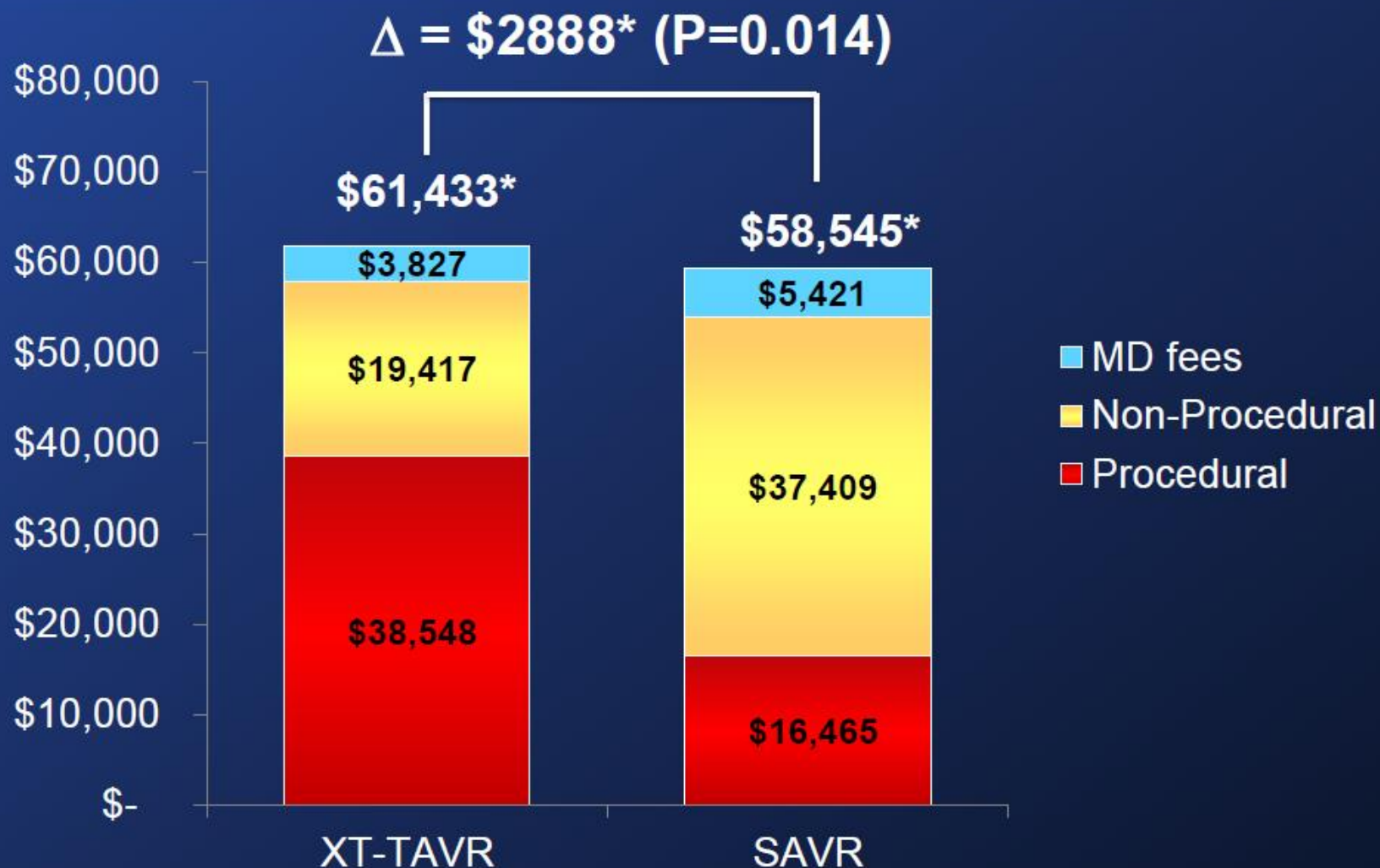
XT-TAVR vs. SAVR

Index Hospitalization: Resource Use

	<i>XT-TAVR</i> (<i>n</i> = 994)	<i>SAVR</i> (<i>n</i> = 944)	<i>P-Value</i>
Proc. duration, mins	102 ± 46 [94]	236 ± 83 [219]	<0.001
LOS, days	6.4 ± 5.5 [5]	10.9 ± 7.6 [8]	<0.001
ICU	2.4 ± 3.4 [1]	4.6 ± 6.1 [3]	<0.001
Non-ICU	4.0 ± 4.0 [3]	6.2 ± 4.7 [5]	<0.001
New PPM	7.2%	7.0%	NS

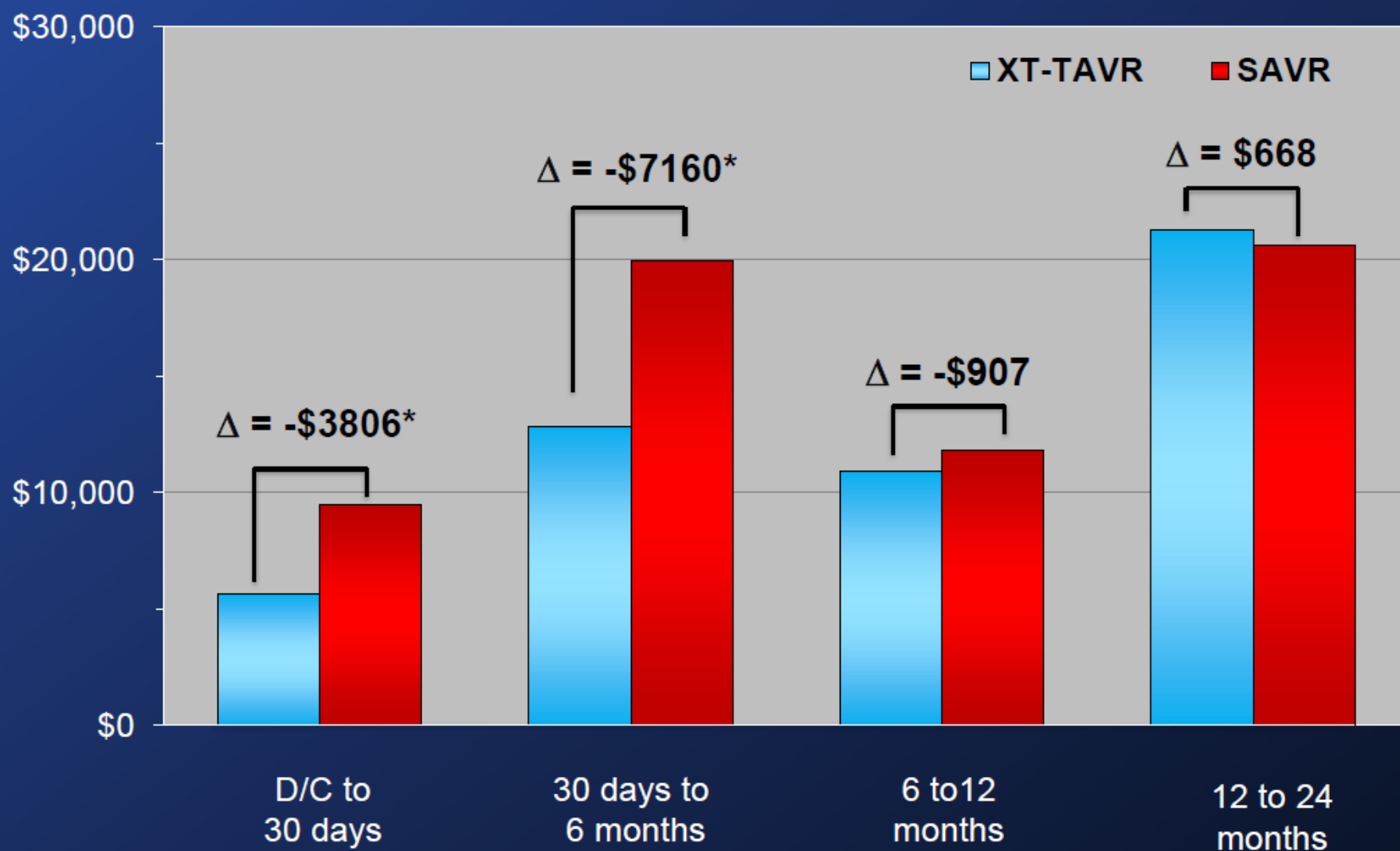
Values in brackets are medians

Index Hospital Costs



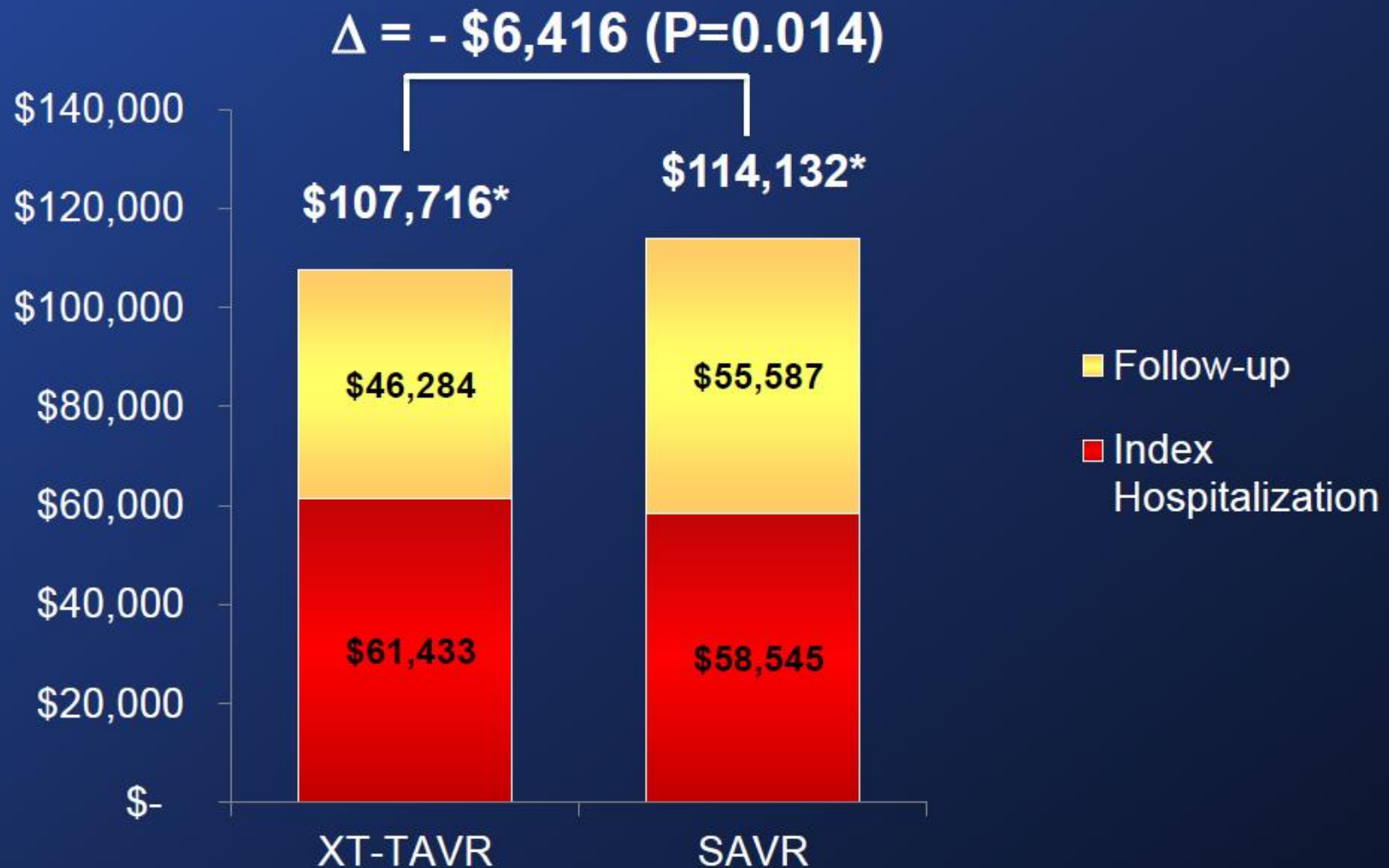
* Trimmed means

Follow-up Costs by Time Interval



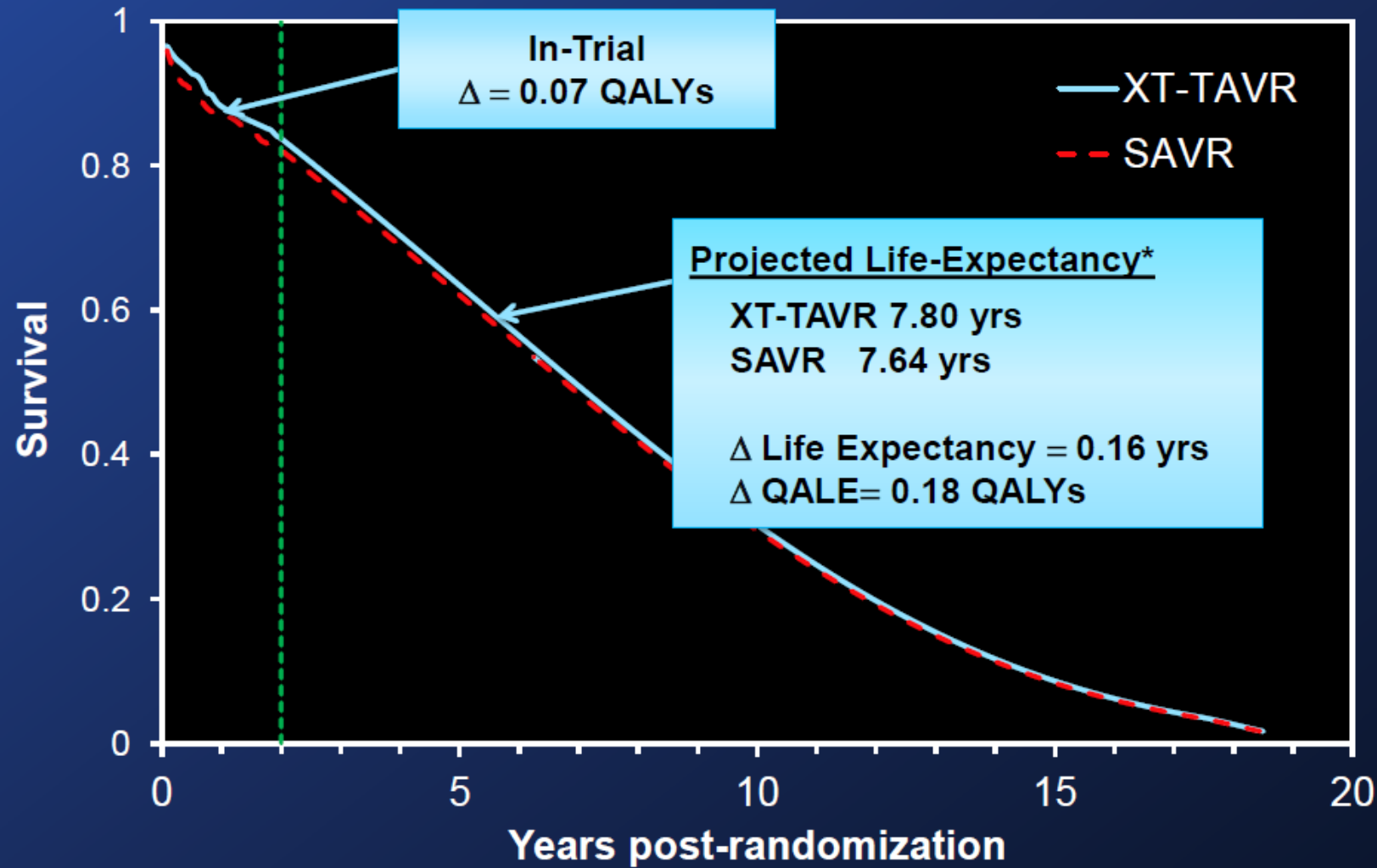
* $P < 0.05$

Total 2 Year Costs



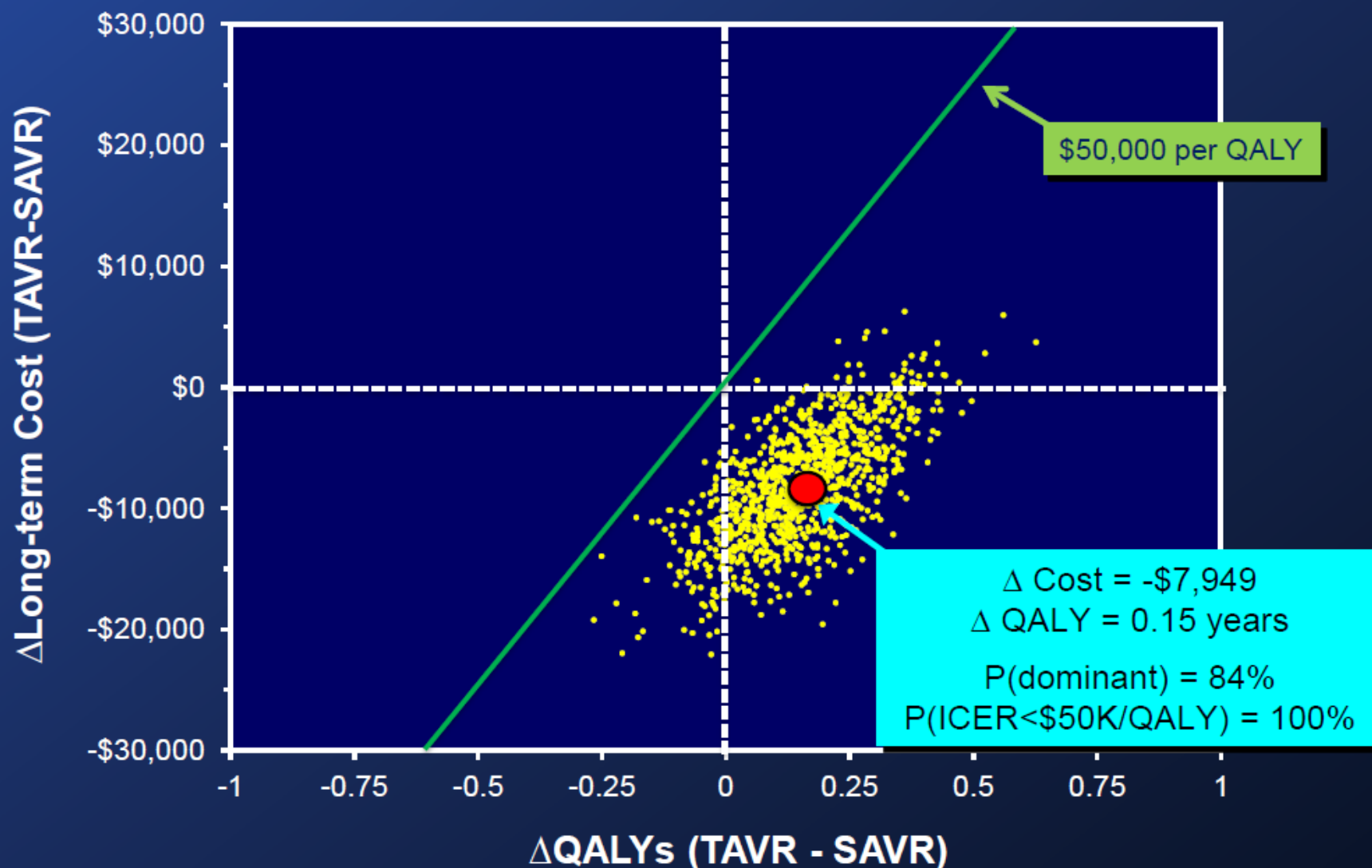
* Trimmed means

Projected Survival



* Undiscounted

XT-TAVR vs. SAVR: Cost-Effectiveness



* Costs and benefits discounted at 3%

Sapien-3 Intermediate Risk Trial

S3-TAVR vs. SAVR

S3i Economic Methods

Differences vs. P2A



Cost data

- Since S3i enrolled after P2A, complete Medicare claims only available through 1-year follow-up
- Year 2 costs estimated based on regression analysis

Survival data/Life expectancy

- Identical to P2A analysis

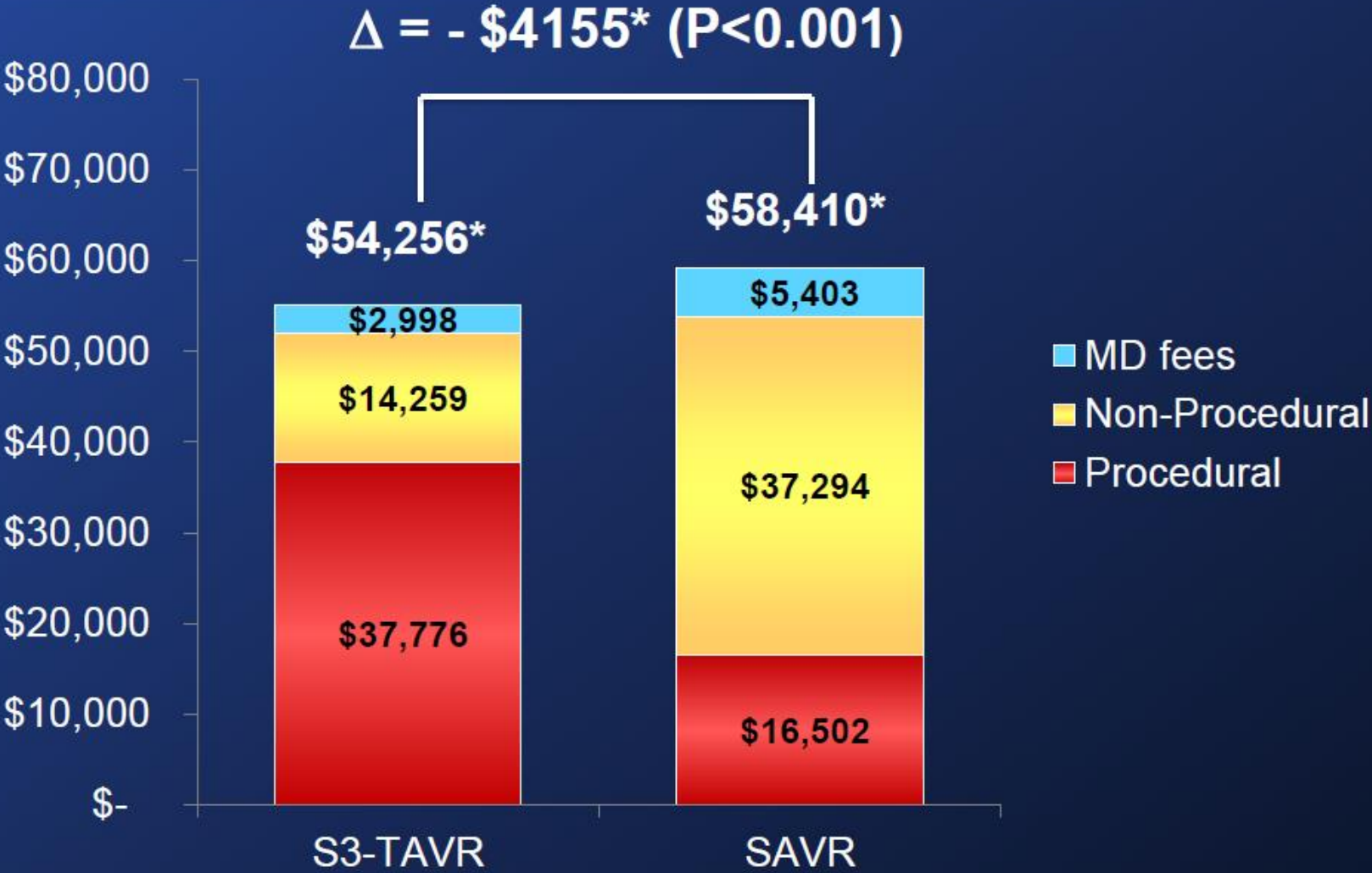
Statistical Approach

- All comparisons adjusted for imbalances in baseline characteristics using propensity score stratification (for clinical outcomes) or propensity bin bootstrapping (for costs)

Index Hospitalization: Resource Use

	<i>S3-TAVR</i>	<i>SAVR</i>	<i>P-Value</i>
Proc. duration, mins	84 ± 38	236 ± 83	<0.001
LOS, days	4.6 ± 5.7	10.9 ± 7.6	<0.001
ICU	1.8 ± 2.9	4.6 ± 6.1	<0.001
Non-ICU	2.7 ± 4.8	6.2 ± 4.7	<0.001
New PPM	8.4%	7.0%	NS

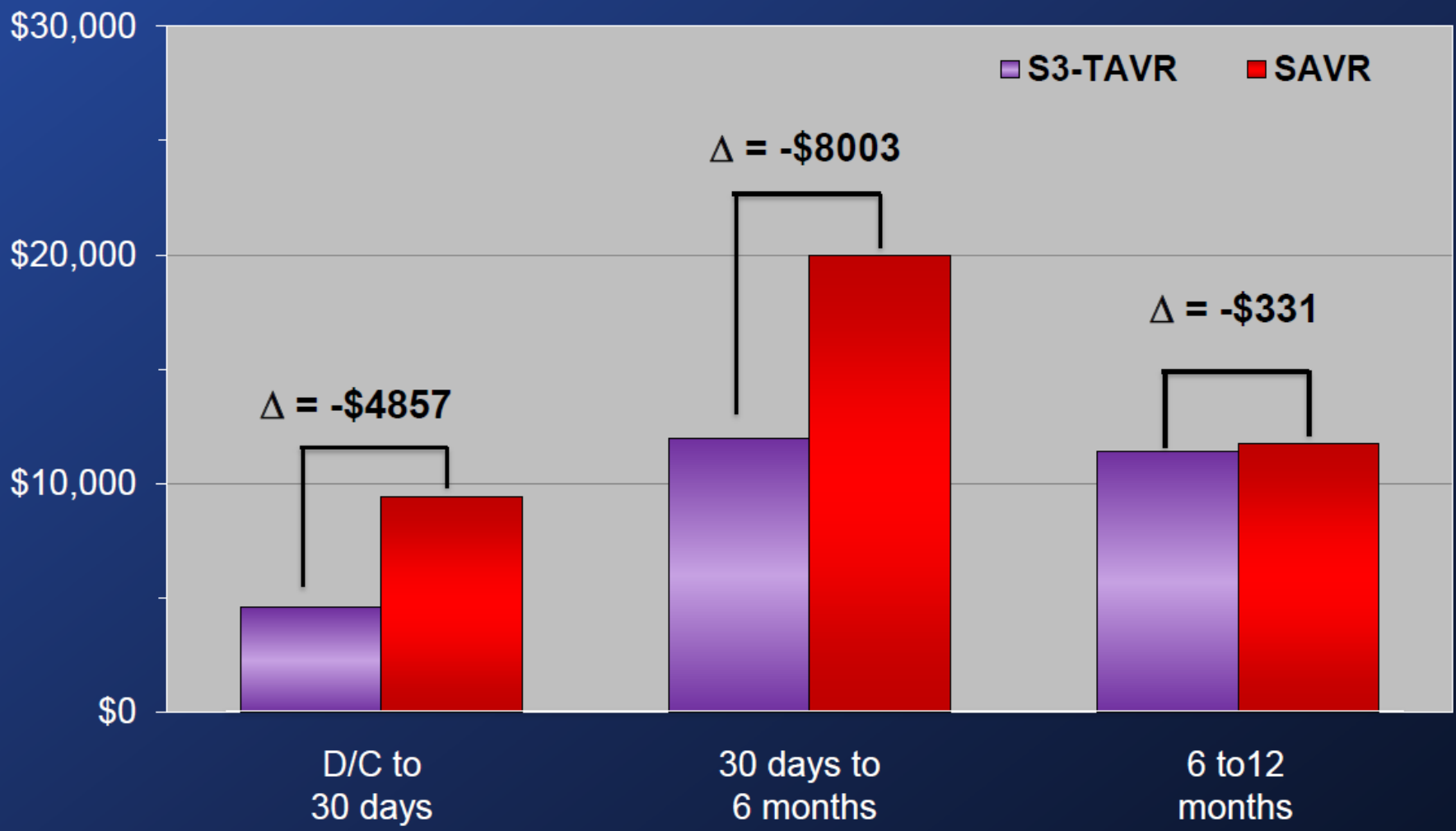
Index Hospital Costs



* Trimmed means

** All costs propensity-adjusted

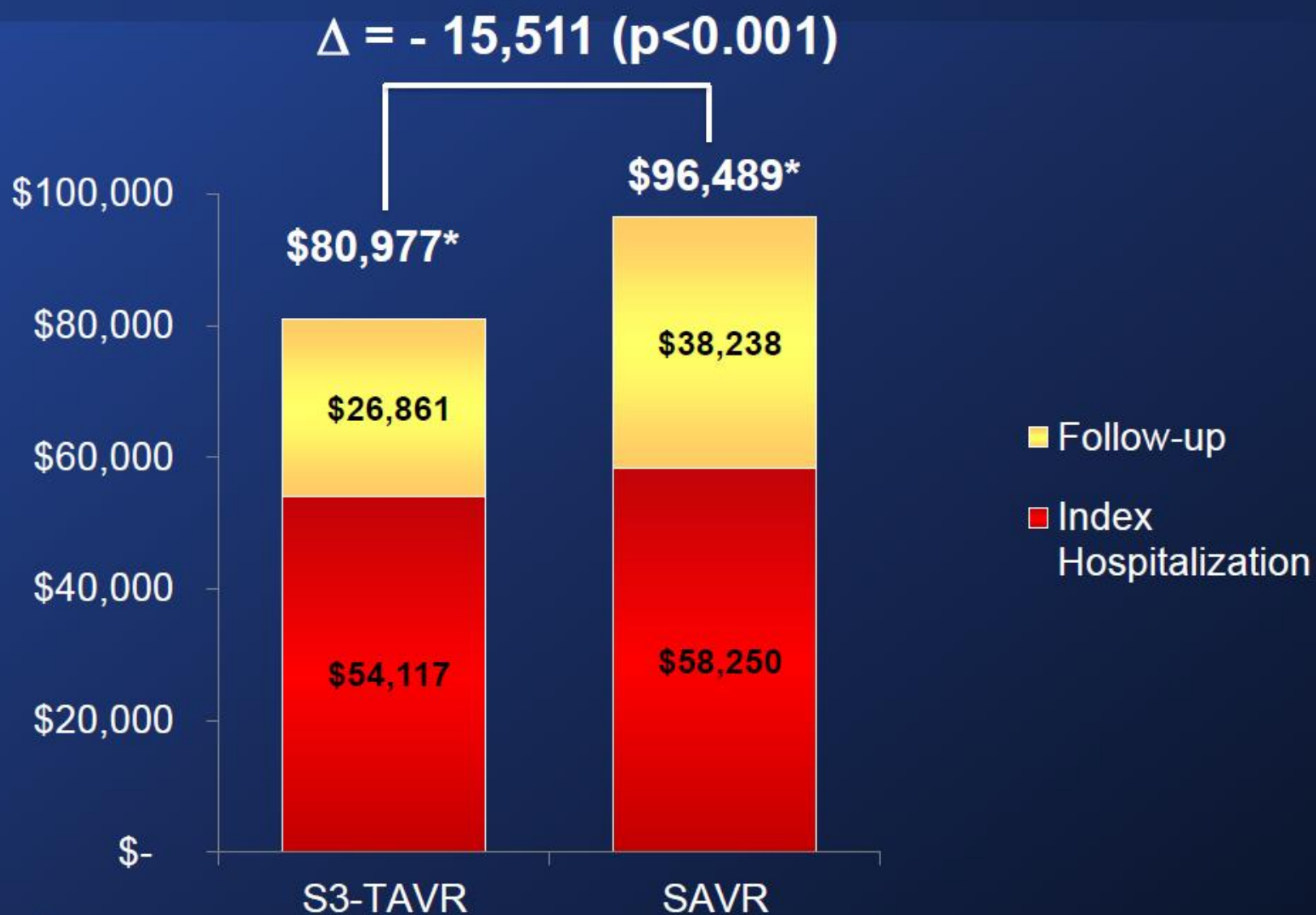
Follow-up Costs by Time Interval



* Trimmed means

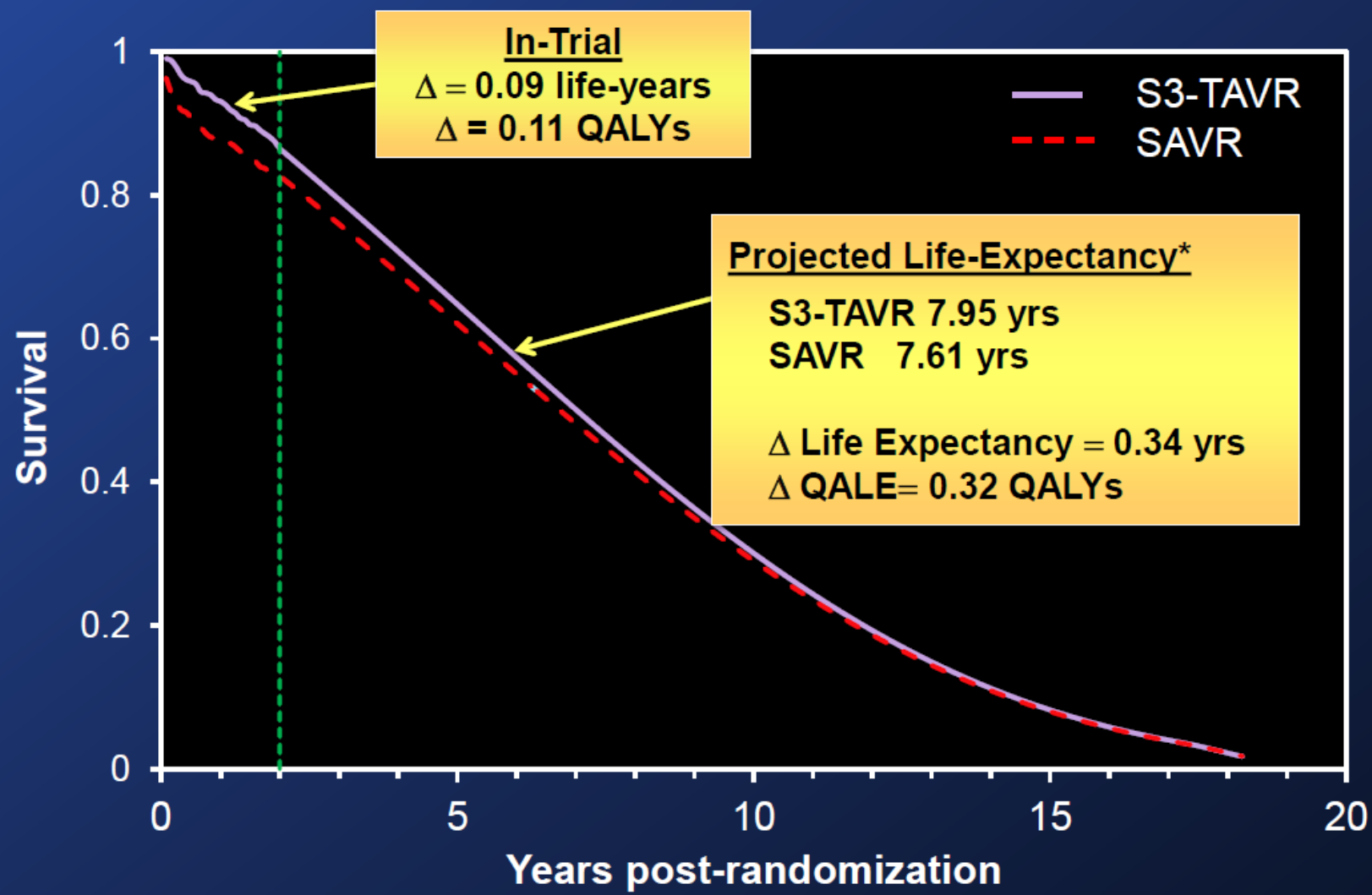
All costs propensity-adjusted

Total 1-Year Costs



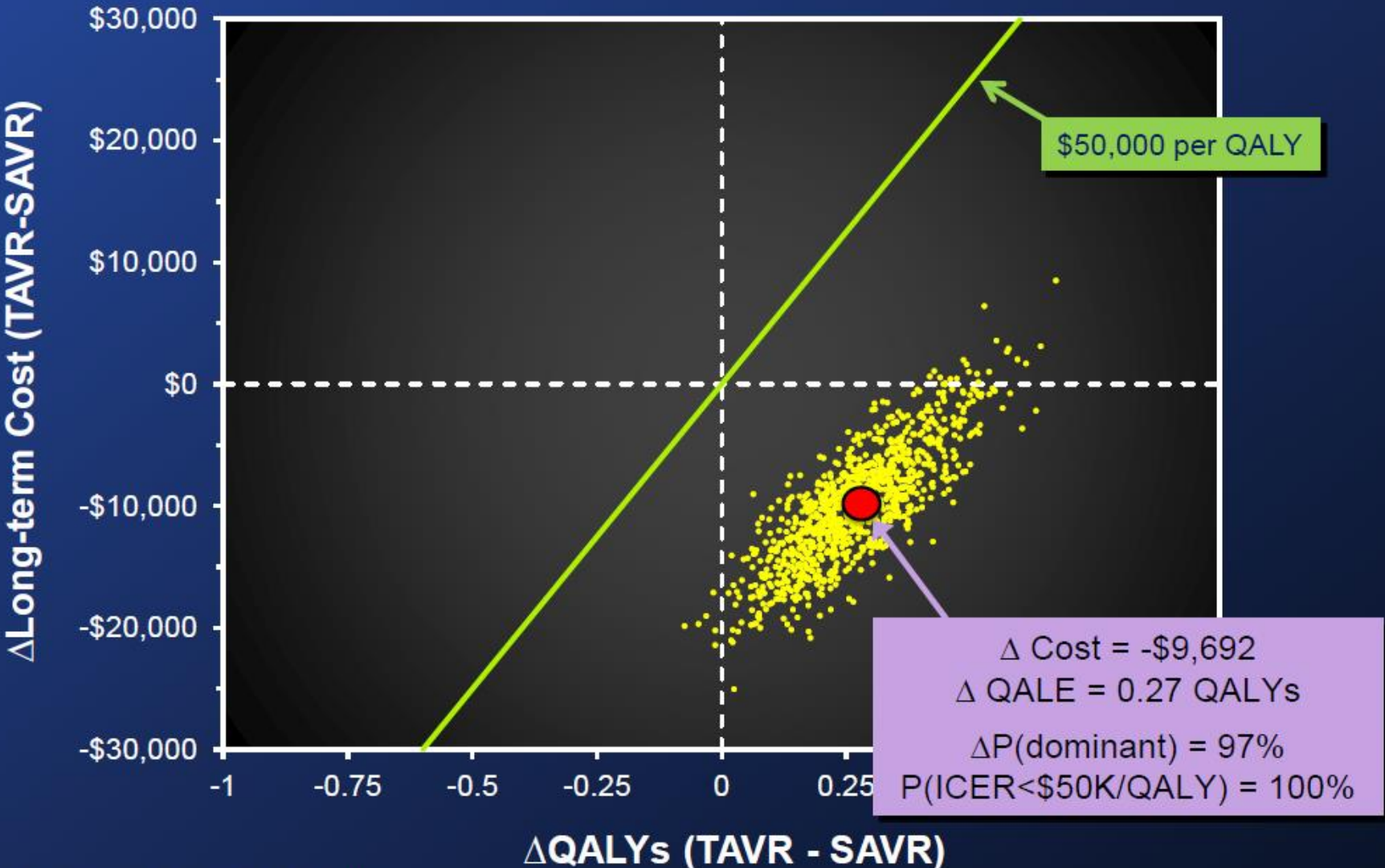
* Trimmed means

Projected Survival (Risk-Adjusted)



* Undiscounted

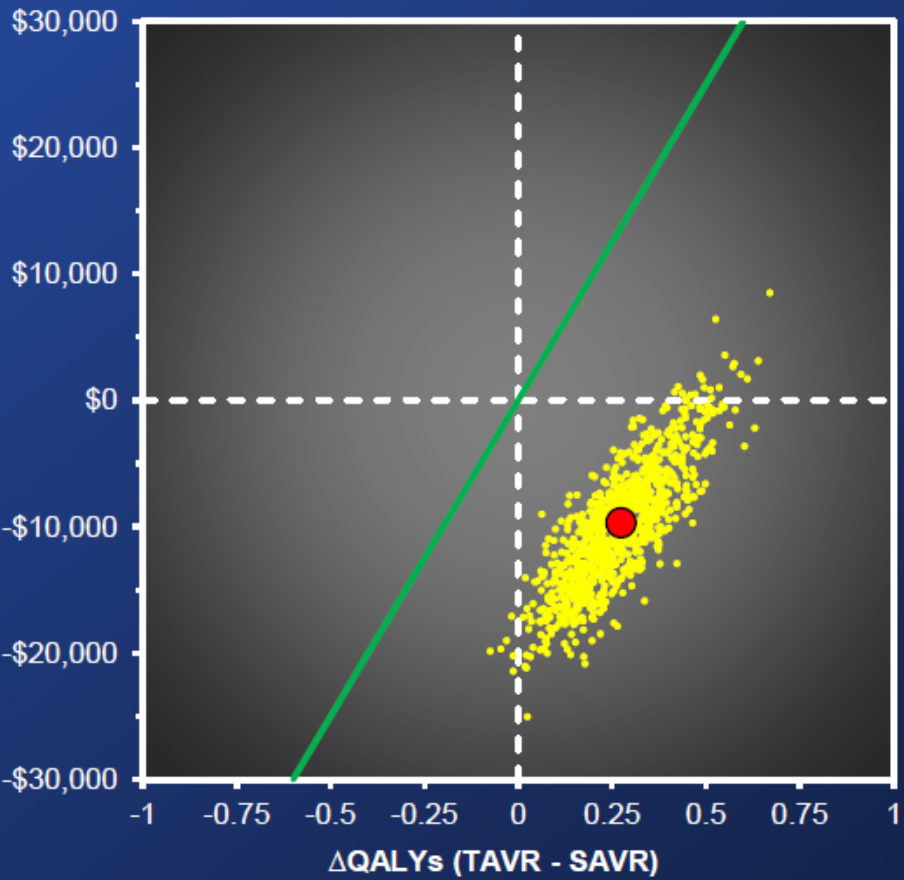
S3-TAVR vs. SAVR: Cost-Effectiveness



* Costs and benefits discounted at 3%

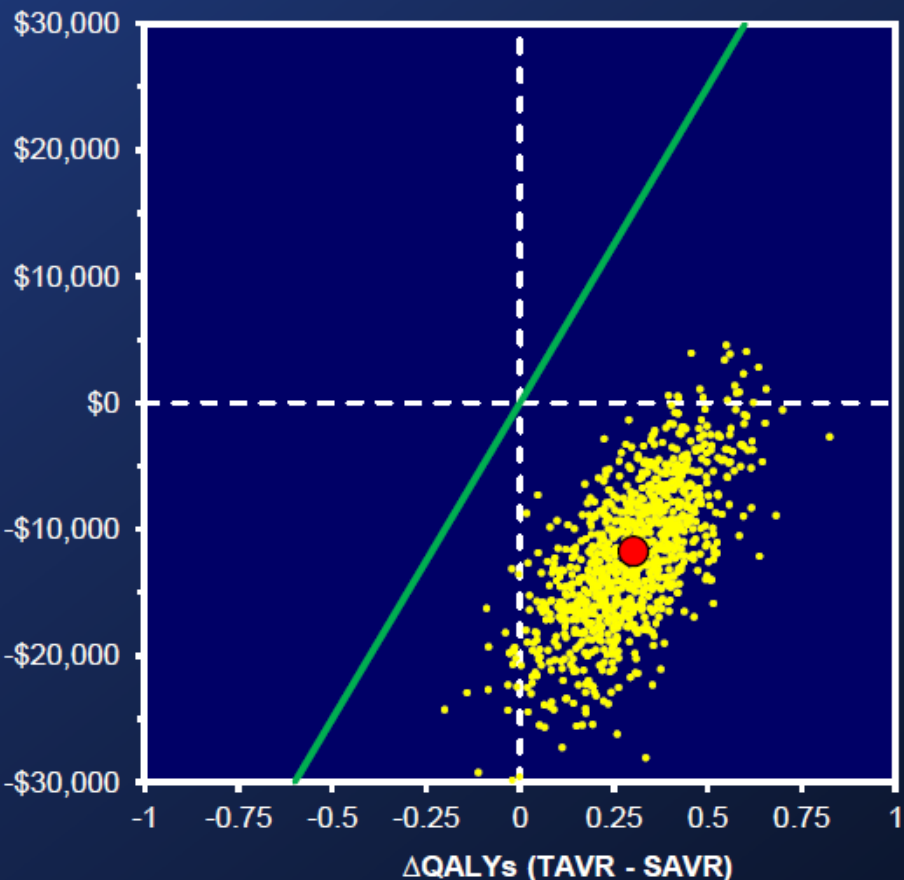
Are the S3 Results Real?

S3 (88% TF) vs. SAVR



ΔCost = -\$9,692
Δ QALY = 0.27 years

XT vs. SAVR (TF Subgroup)



ΔCost = -\$11,738
Δ QALY = 0.30 years

Summary



- Although procedural costs for TAVR remain substantially higher than for surgical AVR, for intermediate risk patients with severe AS, TAVR using the SAPIEN-XT valve led to substantial reductions in hospital LOS, resulting in initial treatment costs that were only slightly higher than for SAVR
- Over the ensuing 6-12 months, follow-up costs were substantially lower with XT-TAVR (by ~\$9,000/pt) such that total medical care costs were lower with TAVR than SAVR at 1 and 2-year follow-up

Summary- 2



- Over a lifetime horizon, XT-TAVR was projected to be an economically dominant strategy-- providing both greater quality-adjusted life expectancy and lower long-term costs than SAVR with a high degree of confidence
- Results using the SAPIEN-3 valve and more contemporary care patterns demonstrated outcomes that were even more favorable with TAVR (lifetime cost savings ~\$10,000/pt, significant gain in QALYs)

Conclusions



- For patients with severe AS and intermediate surgical risk similar to those enrolled in the PARTNER 2A and S3i trials, TAVR should be the preferred strategy based on both clinical and economic considerations

Thank You



MAHI Health Economics and Technology Assessment

- Suzanne J. Baron, MD, MSc
- John A. House, M.S.
- Kaijun Wang, Ph.D.
- Elizabeth A. Magnuson, Sc.D.

PARTNER Investigators and Publications Office

- Maria Alu, MS

