

Lifetime Cost Effectiveness of Transcatheter Aortic Valve Replacement Compared with Standard Care Among Inoperable Patients with Severe Aortic Stenosis: Results from the PARTNER Trial (Cohort B)

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Disclosures

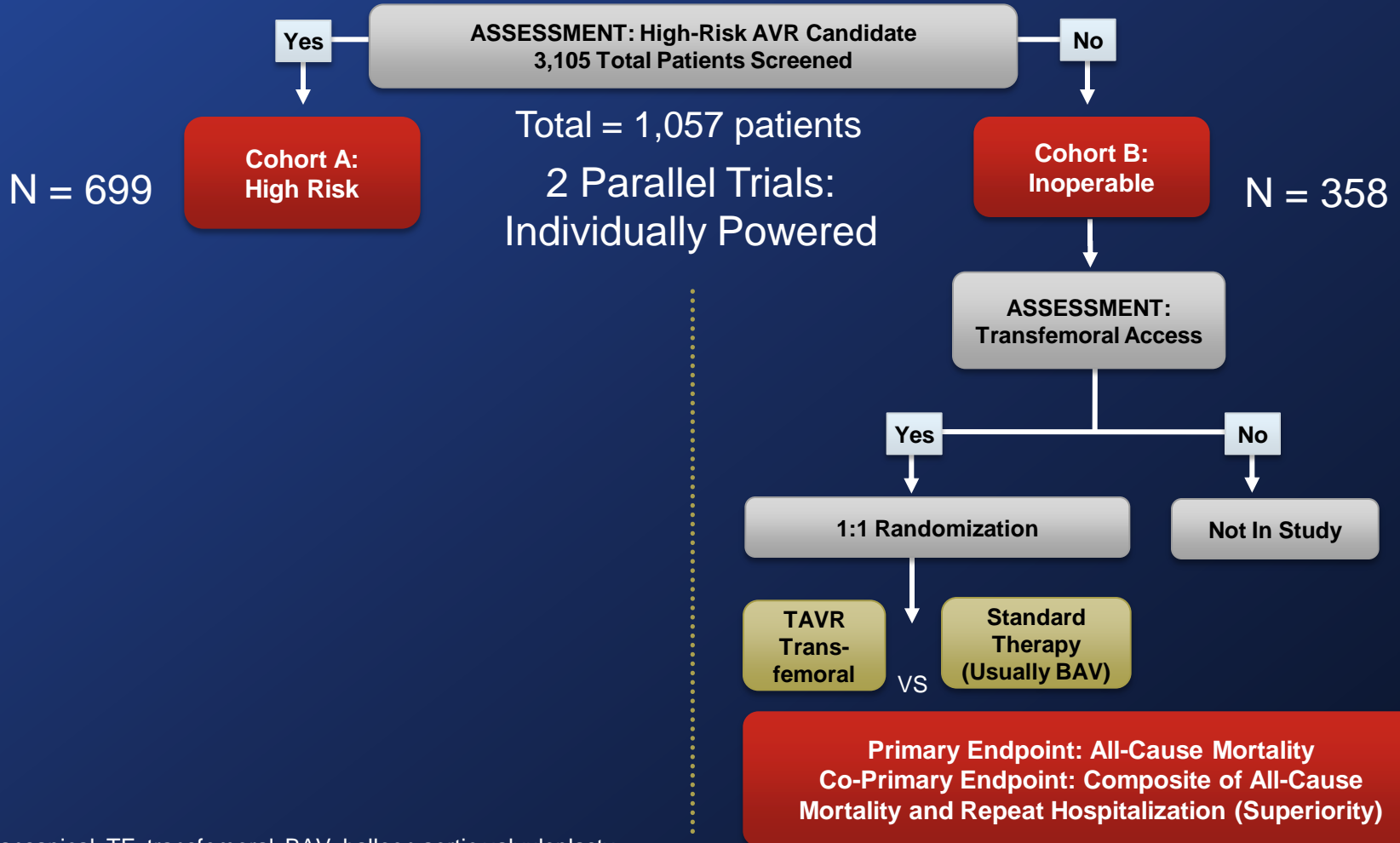
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PARTNER Trial: Cohort B



Symptomatic Severe Aortic Stenosis



TA, transapical; TF, transfemoral; BAV, balloon aortic valvuloplasty.

In patients with severe, inoperable aortic stenosis, “cohort B” of the PARTNER trial has demonstrated that, compared with standard care, TAVR led to:

- Improved 12-month survival (70% vs. 50%)
- Substantial and sustained improvement in symptoms, functional status, and quality of life
- Reduced hospitalization for aortic stenosis or its treatment: 22% vs. 44% at one year
 - A full accounting of the costs and cost-effectiveness of TAVR in this population has not yet been reported

Objectives



1. To compare the short and long-term costs of the TAVR strategy with those of standard care in patients with inoperable aortic stenosis
2. To project the long-term differences in overall and quality-adjusted life expectancy between these groups
3. To estimate the lifetime cost-effectiveness of TAVR compared with standard therapy based on the PARTNER trial results

Methods: Overview



Analytic Perspective

- US healthcare system. 2010 US dollars

Patient Population

- All intention to treat (N=358) subjects included

General approach

- In-trial (12-month) analysis based on observed survival, QOL, health care resource use, and hospital billing data
- Lifetime analysis based on projections of survival, quality-adjusted survival and costs beyond 12 months

Methods: Endpoints



Primary Endpoint

- Lifetime Incremental Cost-Effectiveness Ratio (\$/LYG)

Secondary Endpoint

- Lifetime incremental costs per quality-adjusted life year gained (\$/QALY)

Pre-specified Sensitivity Analyses

- Exclusion of non-cardiovascular costs
- Exclusion of all BAV procedure costs from control group
- Price of study device
- Removal of QOL improvement observed during follow-up

Methods: In-Trial Costs



- **TAVR procedure:** Measured resource utilization (procedure duration, supplies) multiplied by unit costs
 - SAPIEN Valve estimated commercial price = \$30,000
- **All other costs for index admission:** Itemized charges multiplied by department-specific cost-to-charge ratios
 - Where billing data unavailable, regression model ($R^2 = 0.84$) derived from subjects with bills used to impute costs
- **Follow-up hospitalizations:** Costs from billing data or MedPAR (when bills were unavailable)
- **Resource based costs:** Also included for rehabilitation days, SNF days, outpatient visits, ER visits, outpatient cardiac testing, and medications

Methods: Lifetime Analysis



- Parametric survival models fit to trial data used to extrapolate patient-level life expectancy beyond the observed follow-up period
- EQ-5D utilities measured at baseline, 1, 6 and 12 months and used to convert life-years to QALYs
- Calculated costs from the last 6 months for surviving patients used to project future costs beyond 12 months
- All future costs, life years, and QALYs discounted at 3% consistent with current guidelines

Baseline Characteristics



Characteristics	TAVI (N=179)	Control (N=179)
Age (yrs)	83 ± 9	83 ± 8
Female gender	54.2%	54.1%
STS Risk Score	11.2 ± 5.8	12.2 ± 6.1
STS > 15%	21.2%	24.7%
Prior MI	18.6%	26.4%
Prior CABG	37.4%	45.6%
Cerebrovascular Dz	27.4%	27.5%
COPD (O2 dependent)	21.2%	25.7%
Creatinine > 2.0 mg/dl	5.6%	9.6%
Frailty	18.1%	28.0%

P=NS for all comparisons

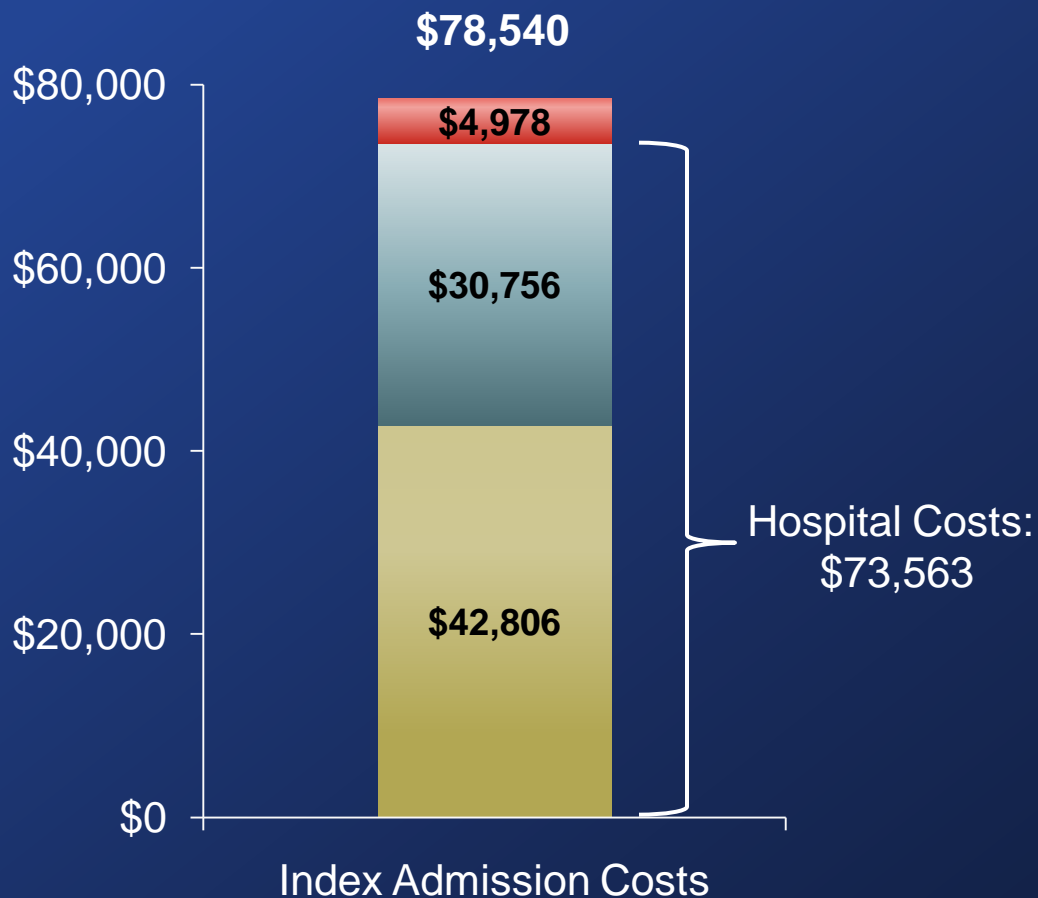
TAVR Procedural Resource Use



Resource Category	Mean \pm SD or Count (N=175)
Procedure Duration (min)	150 \pm 84
TAVR Devices	
1	164 (93.7%)
2	10 (5.7%)
3	1 (0.6%)
Valvuloplasty Balloons	1.3 \pm 0.6
Arterial Site Closure	
Surgical	146 (83%)
Closure Device	33 (19%)
Concomitant Procedure*	21 (12.0%)
Total Procedural Costs (excl MD fees)	\$42,806 \pm 15,206 (median = \$38,706)

*peripheral arterial surgery = 10, peripheral arterial stent/PTA = 6, CABG = 1, other = 4

TAVR Admission Costs



- Procedure
- Non-Procedure
- MD Fees

Mean (median) LOS (days)

ICU	4.0 (2.0)
Non-ICU	6.1 (5.0)
Total	10.1 (7.0)
Post-Procedure	8.6 (6.0)

(N=175)

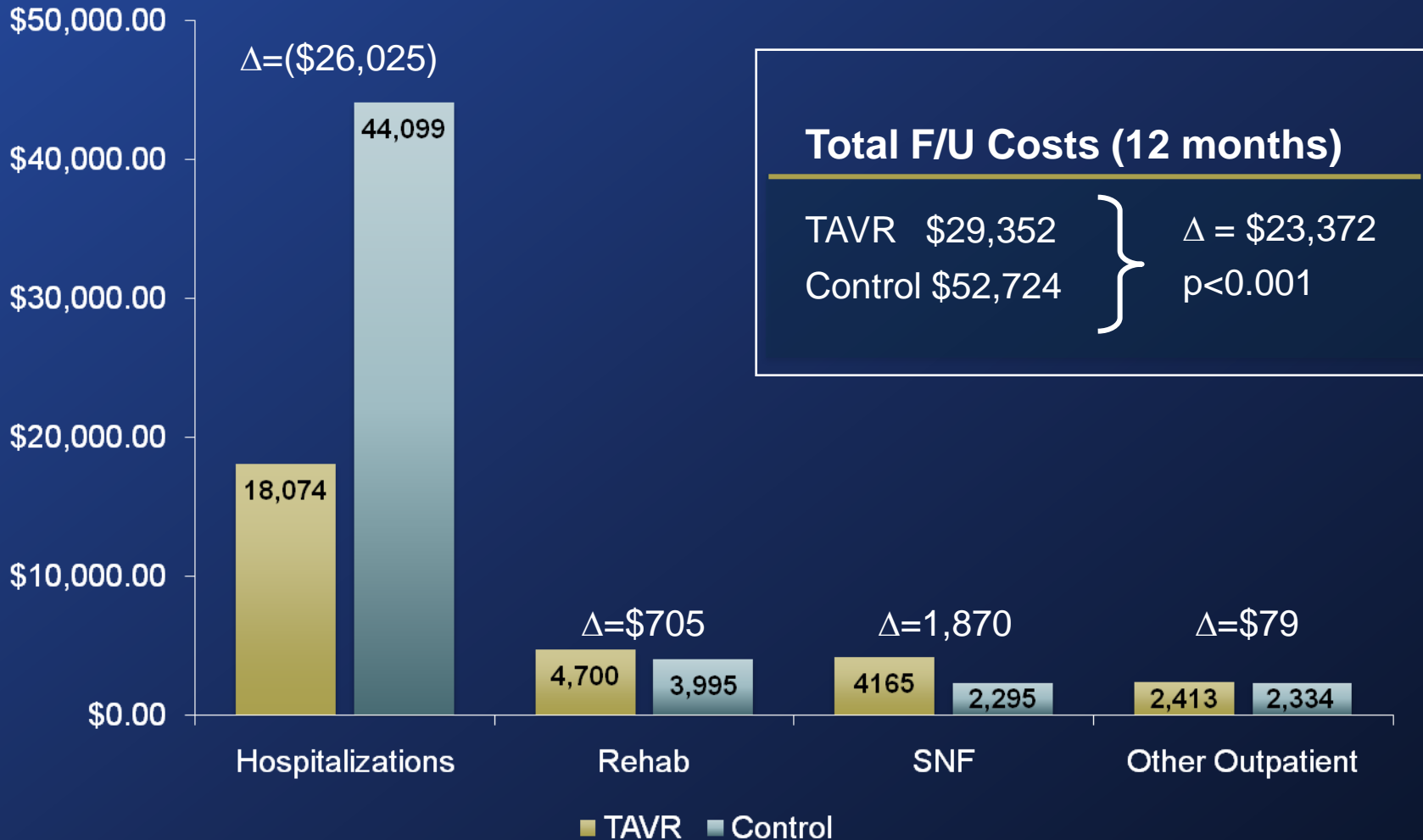
12-Month Follow-up Resource Utilization



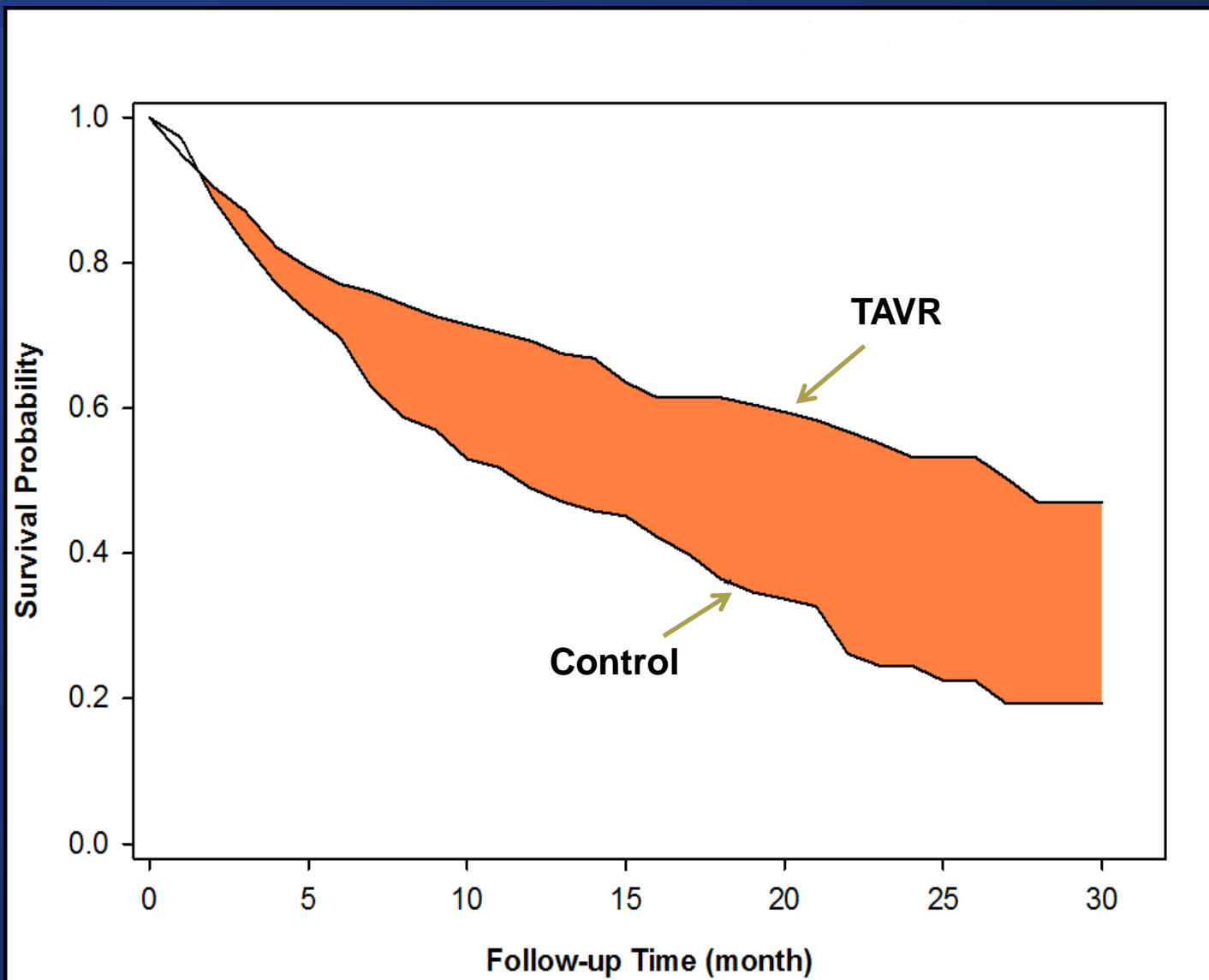
	TAVR Group* (N=179)	Control Group (N=179)	P-value
Hospitalizations	1.02	2.15	<0.001
Cardiovascular	0.50	1.70	<0.001
Non-cardiovascular	0.51	0.45	0.43
Rehab Days	4.6	3.9	0.75
SNF Days	14.5	8.0	0.21

*Not including index TAVR admission

Results: 12-Month Follow-up Costs

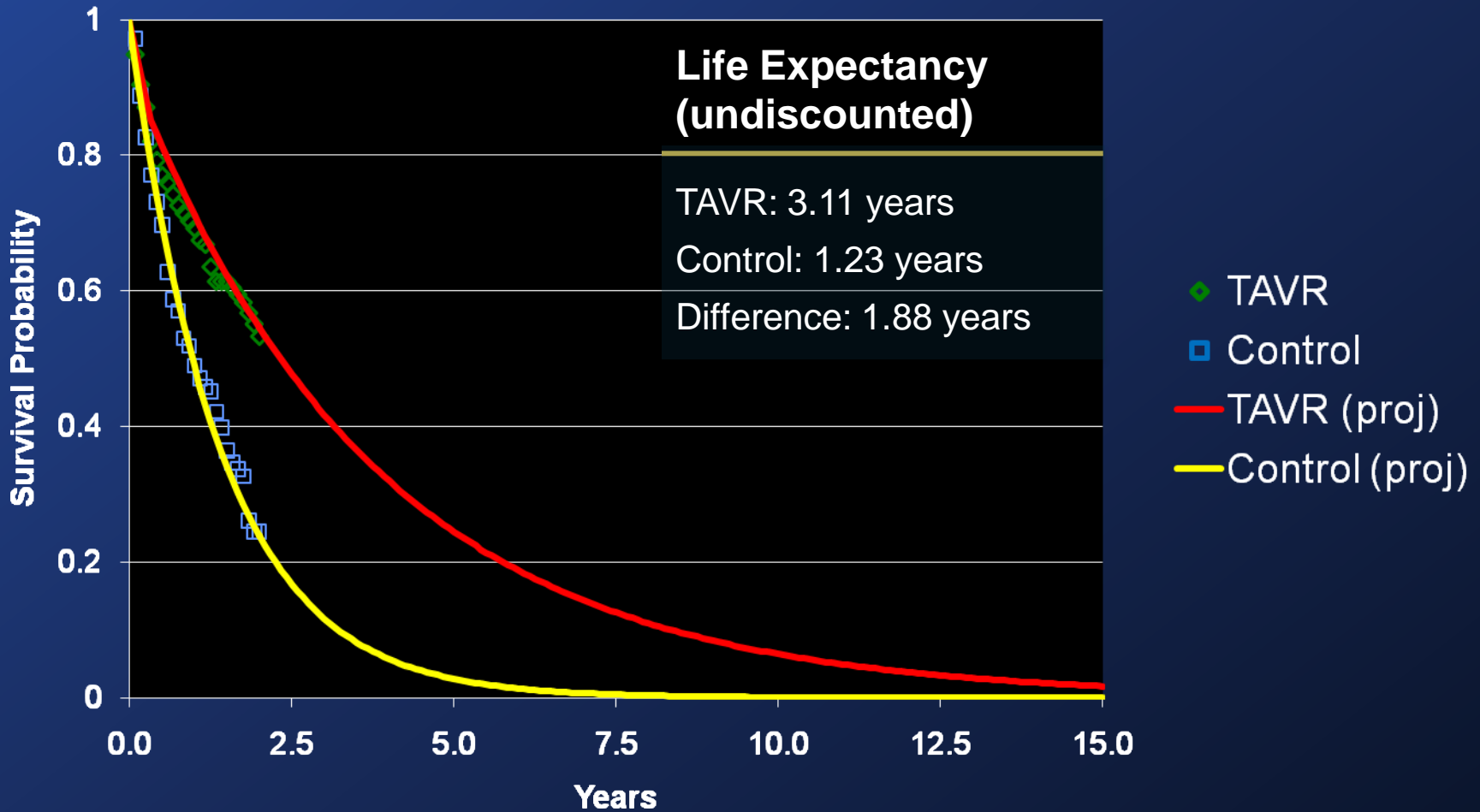


Results: Observed Survival

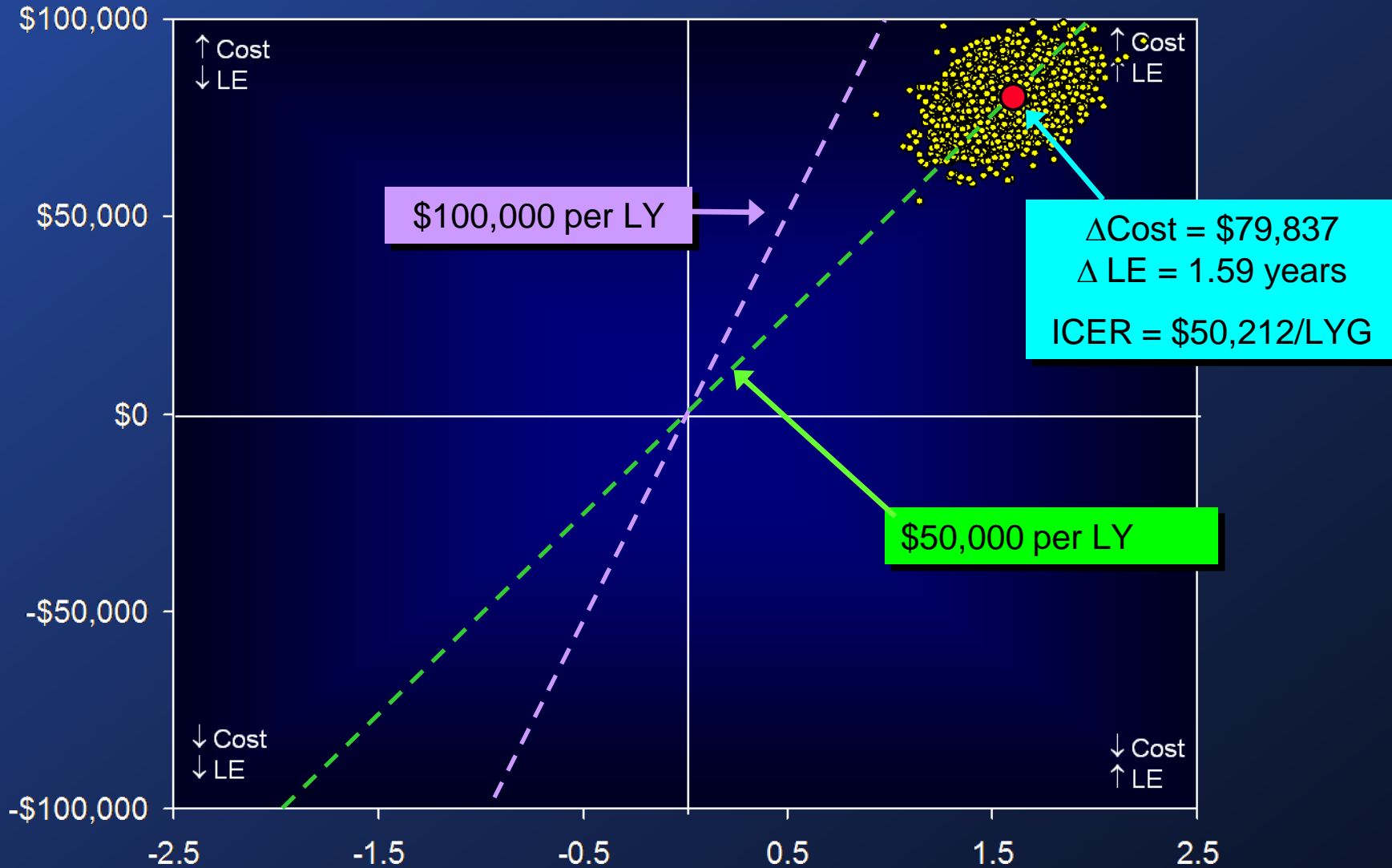


Difference in In-Trial Life Expectancy = 0.49 years

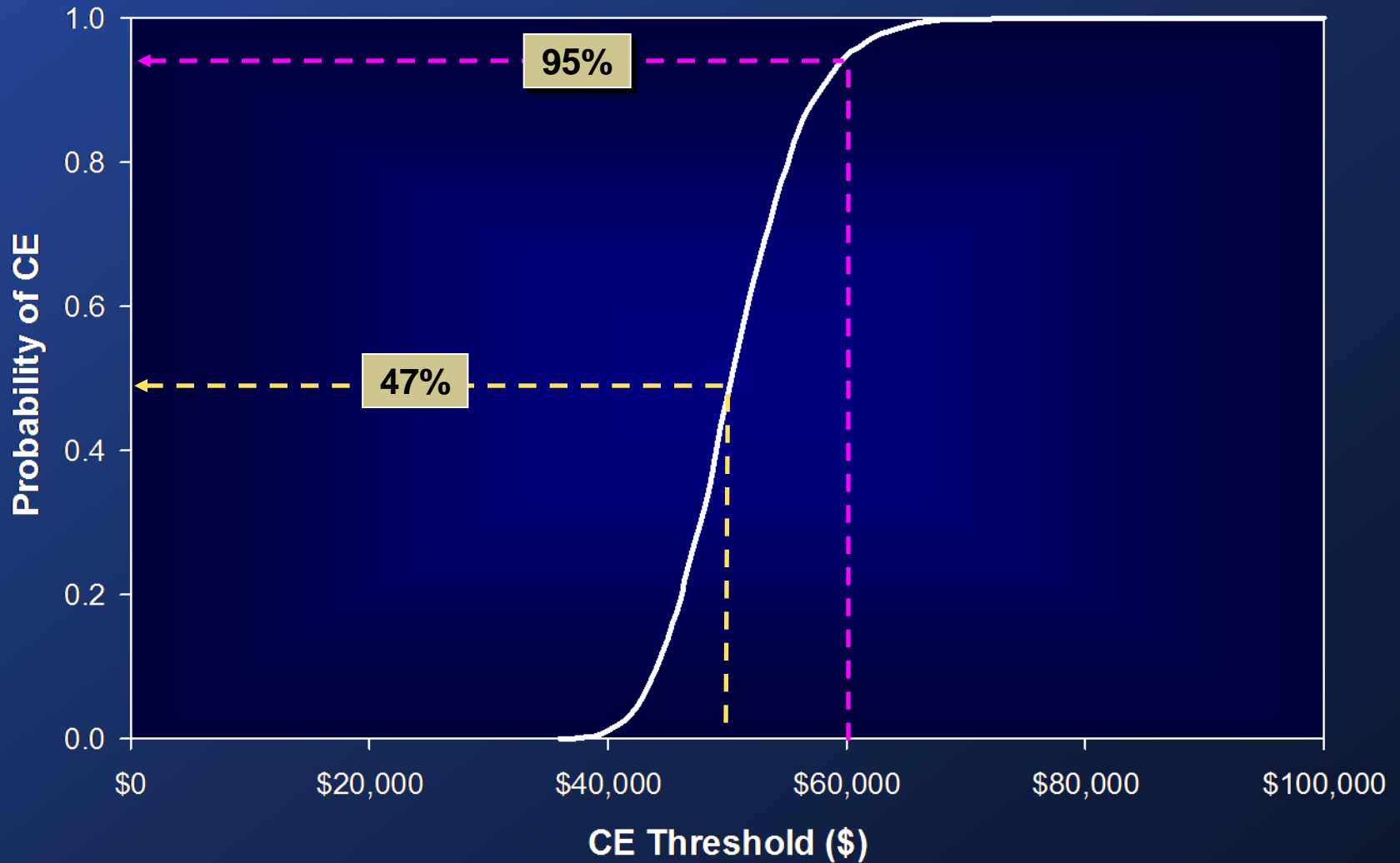
Results: Projected Survival



Cost-Effectiveness of TAVR vs. Control Lifetime Results



Cost-Effectiveness of TAVR vs. Control Lifetime Results



Secondary/Sensitivity Analyses



	Incremental Costs (TAVR – Control)	Incremental Life Years (TAVR – Control)	ICER (\$/LY)
Base Case	\$79,837	1.59	50,212
QALYs	\$79,837	1.29	61,889*
QALYs assuming no QOL improvement	\$79,837	0.96	83,163*
Exclude non-CV costs	\$53,837	1.59	33,860
Study device = \$20,000	\$69,390	1.59	43,642
Study device = \$40,000	\$90,284	1.59	56,782
Exclude BAV costs	\$82,623	1.59	51,964

* \$/QALY

Limitations



- Still early experience for TAVR device and procedure; care may become more efficient in future
- Care of control group patients in trial may have differed from care of similar pts in community practice
- Lifetime analysis, particularly cost projections beyond the trial period, associated with some uncertainty
- Uniquely old and high-risk patient population; results cannot be extrapolated to other groups

Summary of Findings



- TAVR was associated with index admission costs of ~\$78,500 (including estimated MD fees)
- Although observed follow-up costs were ~\$23,000/pt lower with TAVR vs. standard care (mainly due to reduced CV hospitalizations), overall costs remained substantially higher with TAVR at 1 year
- Based on observed data from PARTNER trial, we project that TAVR will result in an increased life expectancy of ~1.9 years and an iCER of \$50,200 per life-year gained
- Results were minimally impacted by major sensitivity analyses

Conclusions



For patients with severe aortic stenosis who are unsuitable for surgical AVR, TAVR significantly increases life expectancy at an incremental cost per life year gained well within accepted values for commonly used cardiovascular technologies

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Published Cost Effectiveness Estimates

