



# Cost-Effectiveness of PCI with Drug Eluting Stents vs. Bypass Surgery for Patients with Diabetes and Multivessel CAD:

## *Results from the FREEDOM Trial*

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# Disclosures

- FREEDOM was supported by U01 grants #01HL071988 and #01HL092989 from the National Heart Lung and Blood Institute

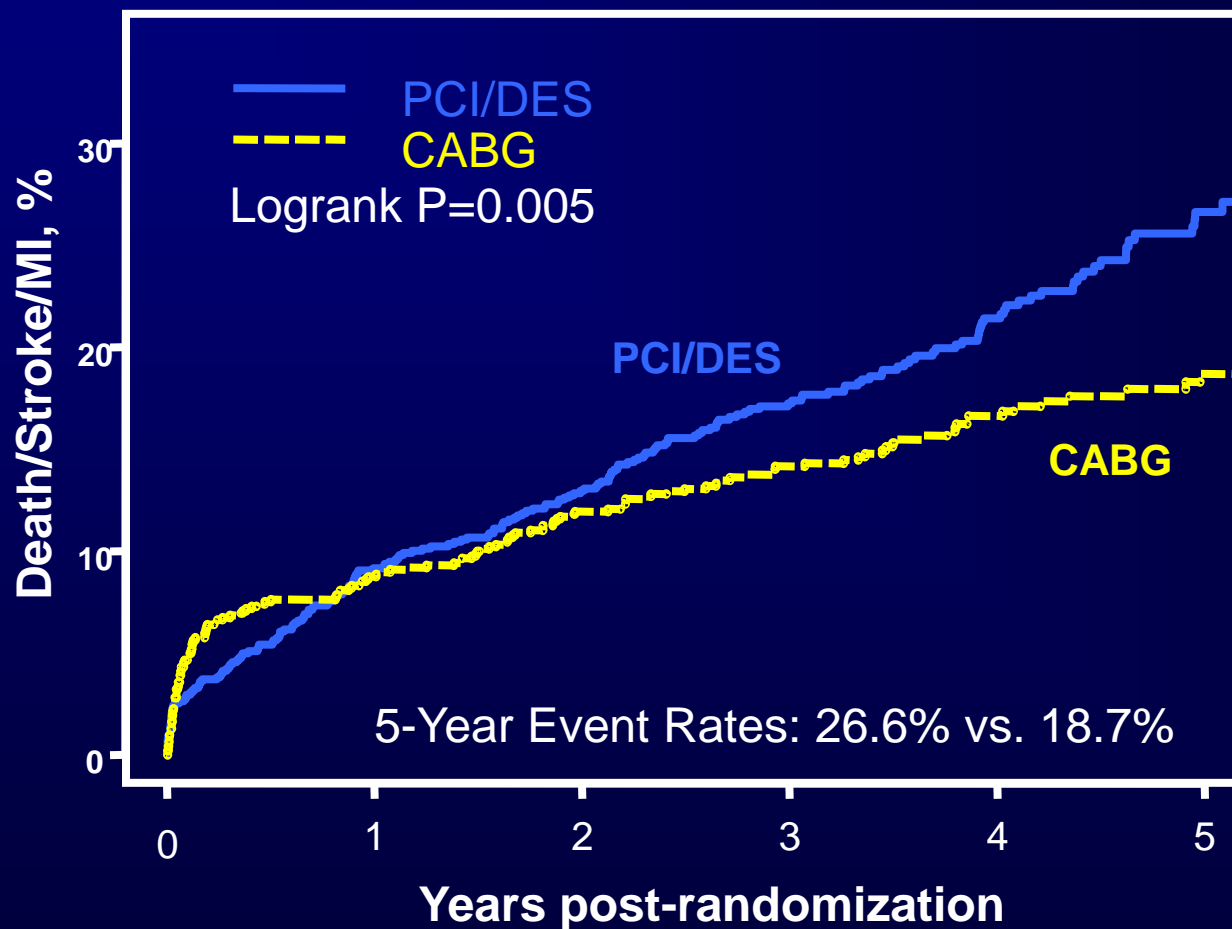
## Other support

- Drug eluting stents were provided by Cordis, Johnson and Johnson and Boston Scientific
- Abciximab and an unrestricted research grant were provided by Eli Lilly and Company
- Clopidogrel was provided by Sanofi Aventis and Bristol-Myers Squibb



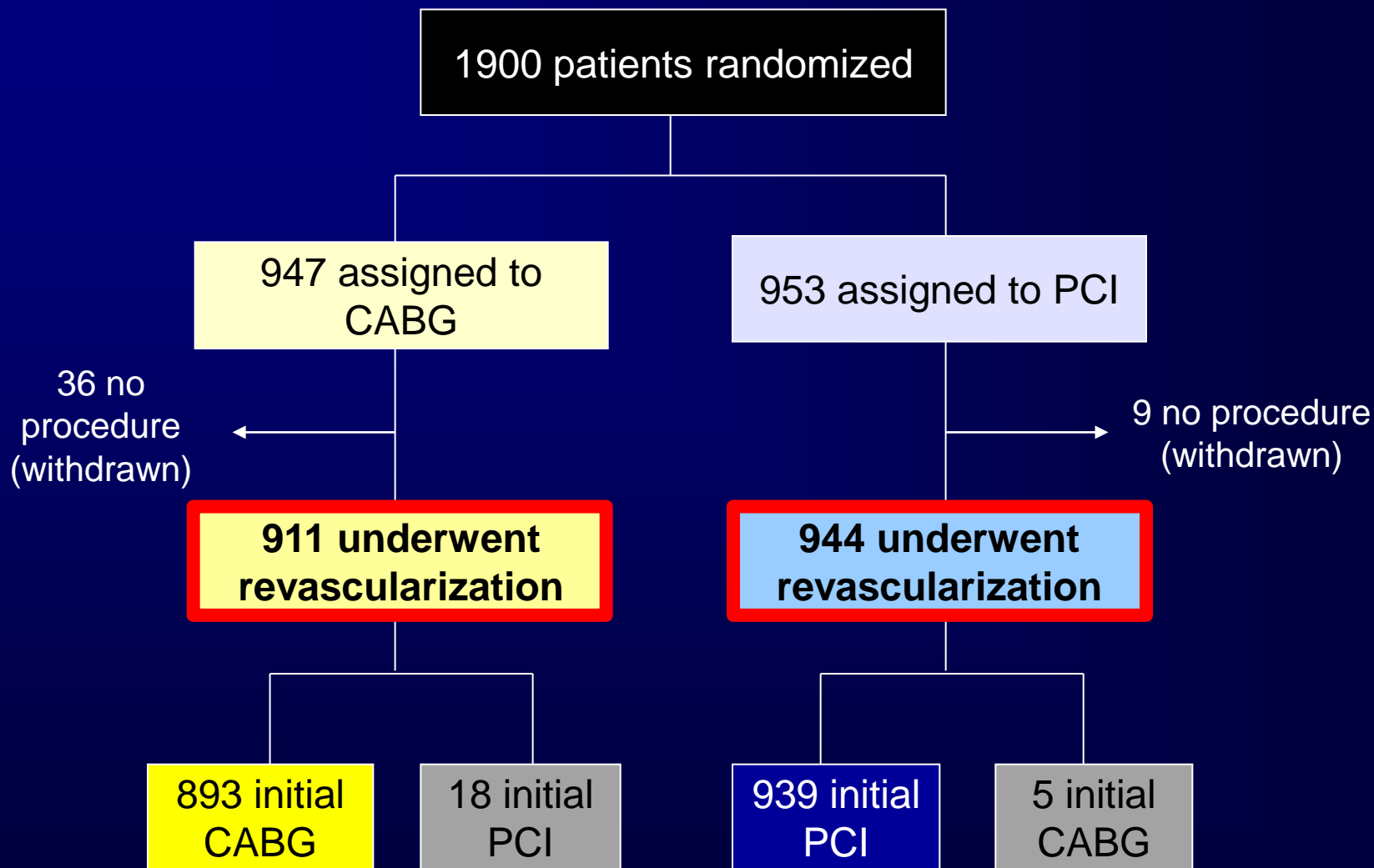
# Background

Time to Death/MI/Stroke





# Patient Flow



*Median follow-up duration: 47 months*



# Economic Study Analysis Plan

## Primary Endpoint:

- Incremental cost-effectiveness ratio expressed as cost per quality-adjusted life year (QALY) gained
  - » Costs and QALYs were discounted at 3% annually

## General Approach – 2 Stages:

- In-trial analysis based on observed survival, health state utility (EQ-5D), and costs derived from reported health care resource use during the trial period
- Lifetime analysis based on projections of survival, quality-adjusted survival and costs beyond the trial period



# Costing Methods

## PCI and CABG Procedures:

- Cath lab and CABG-related procedure costs based on measured resource utilization (procedure duration, balloons, stents, wires, etc.) and current unit costs  
*DES cost = \$1500/stent*
- Ancillary hospital costs based on regression models developed from 2010 MedPAR data for FREEDOM-eligible patients
  - *Clinical events and complications rather than LOS were used as key predictors to avoid distortions due to marked differences in LOS across different countries/health care systems*

**Additional costs:** CV and non-CV rehospitalizations, MD fees, outpatient CV care/testing and medications, cardiac rehabilitation and nursing home stays



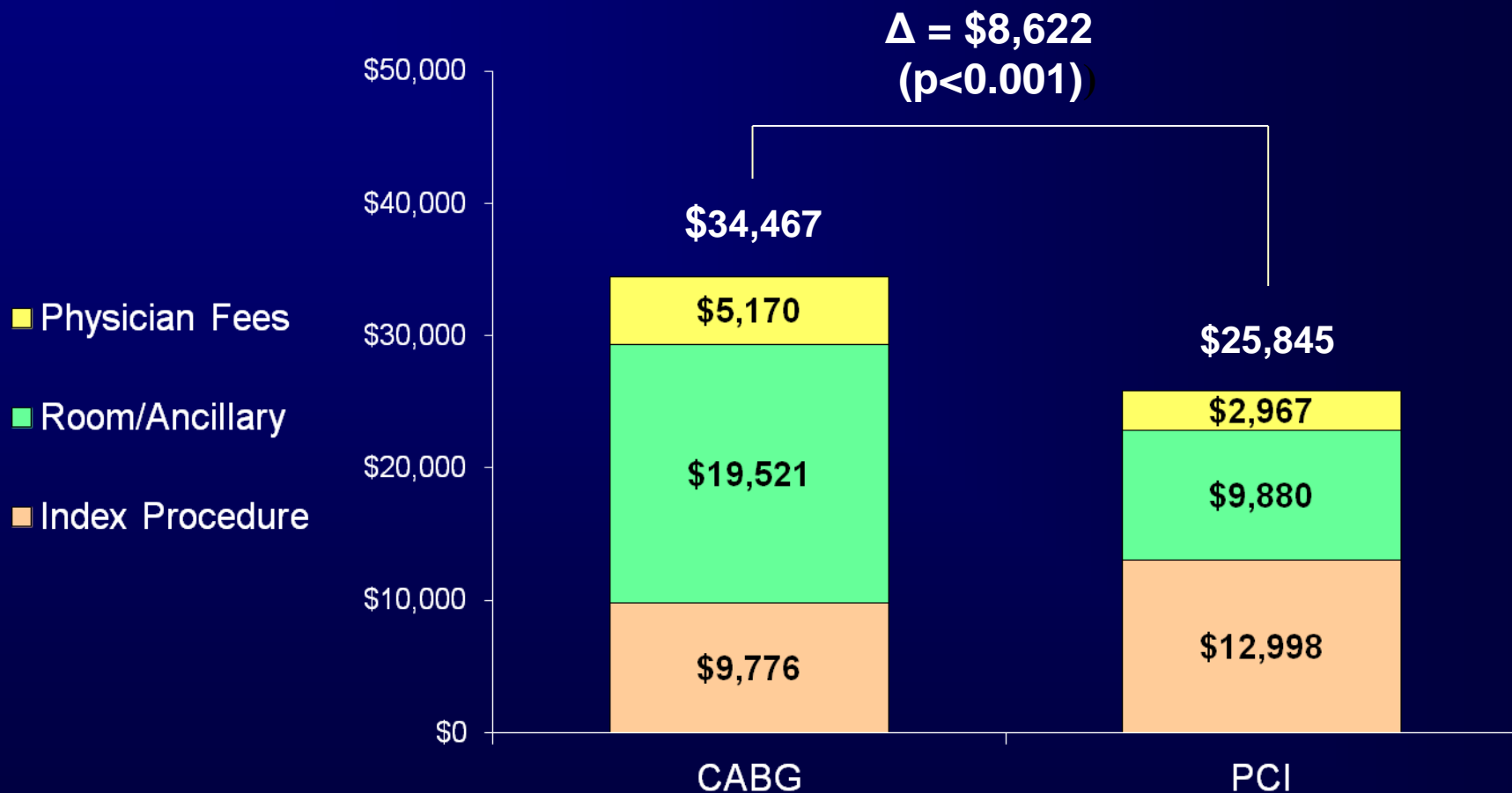
# Index Procedure Resource Use\*

	CABG	PCI
PCI procedures		
1		66.6%
2		30.9%
3-4		2.3%
Drug-eluting stents		4.1 ± 1.9
Paclitaxel-eluting		45.6%
Sirolimus-eluting		51.7%
Other drug-eluting stents		2.7%
Procedure duration (mins)	248 ± 78	107 ± 6.7
<b>Total Procedure Cost</b>	<b>\$9,739 ± \$2,453</b>	<b>\$13,014 ± \$5,173</b>

\* Per protocol population (includes planned staged procedures)



# Index Hospitalization Costs



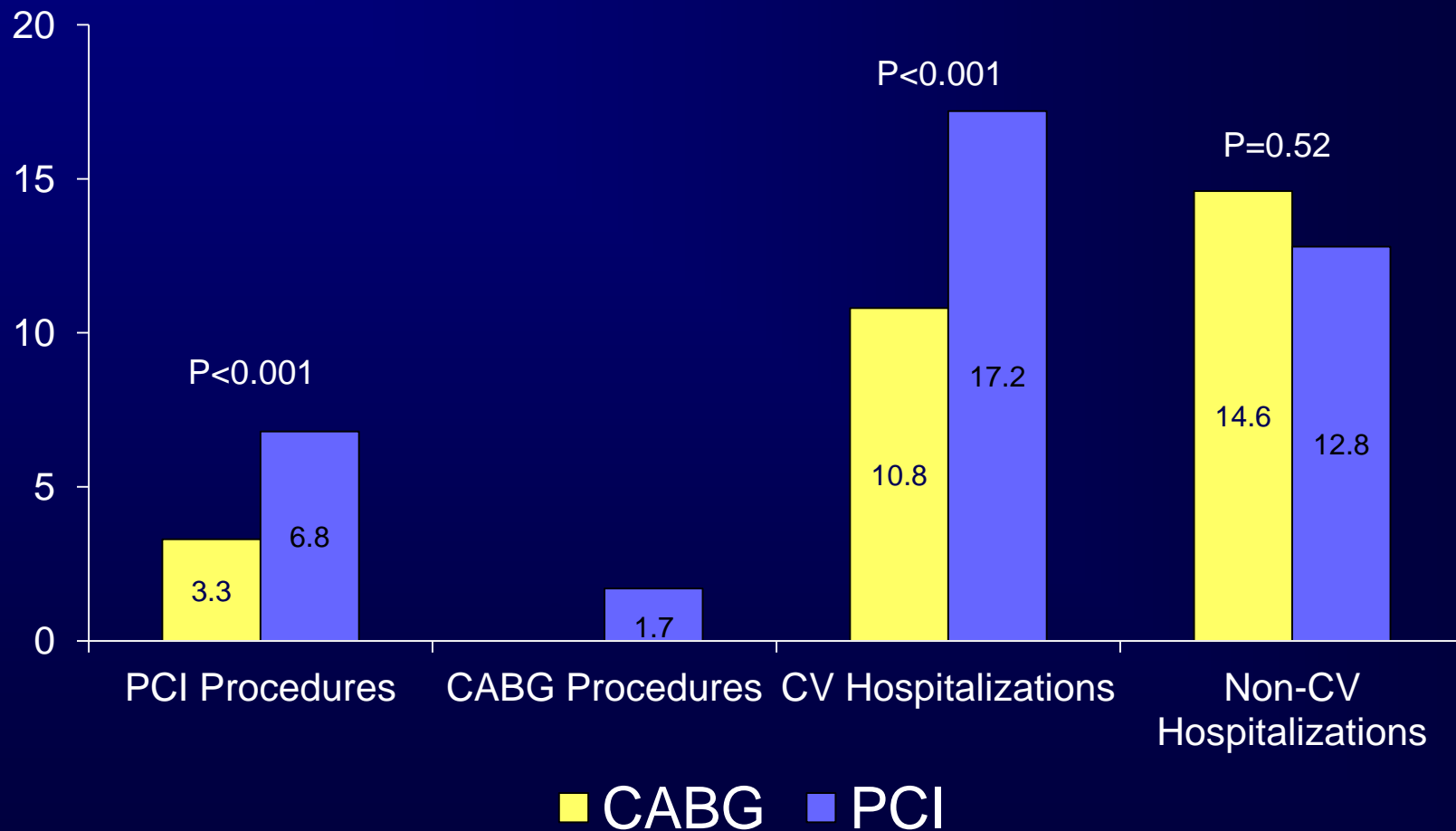
\* ITT population (includes planned staged procedures)





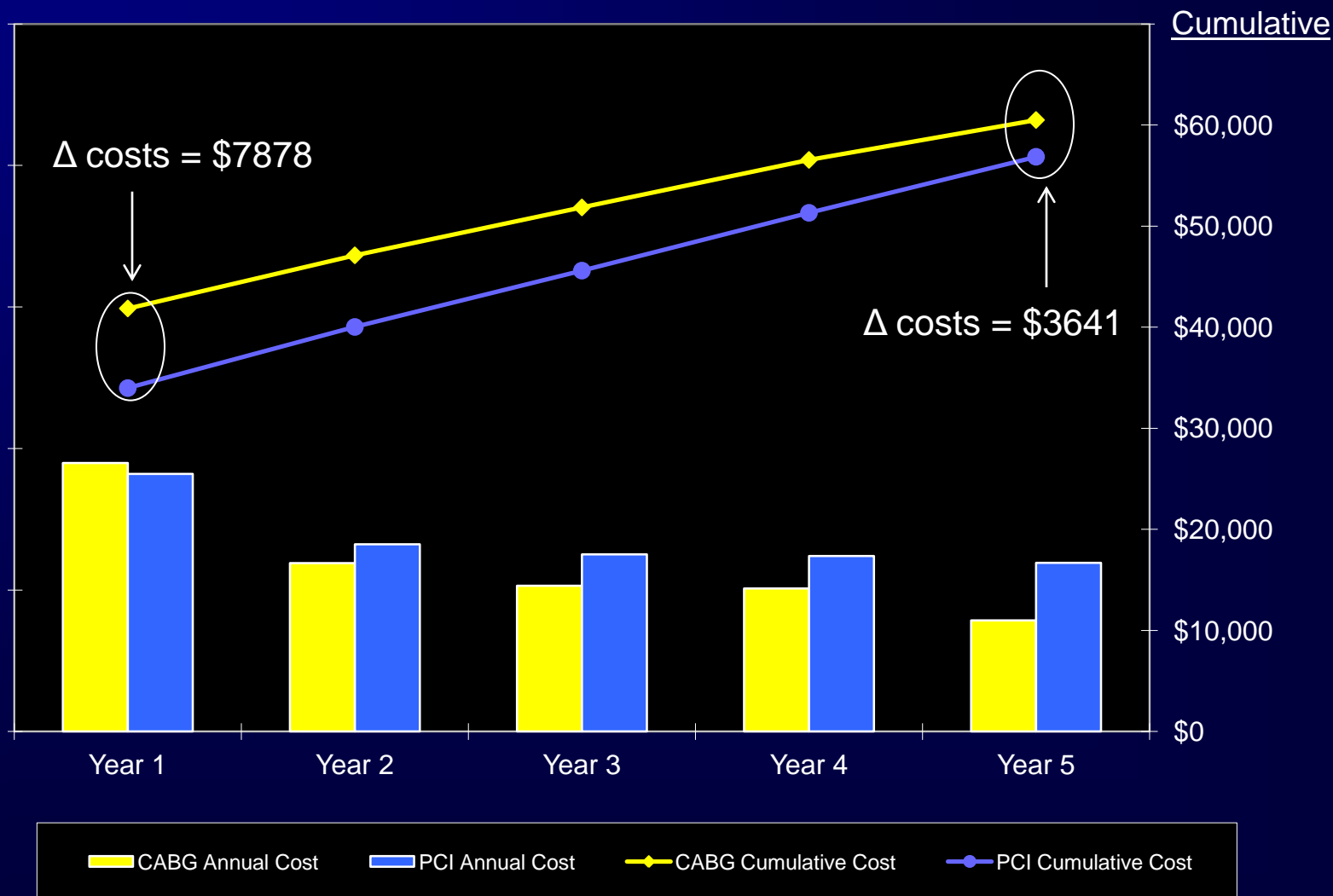
# 5-Year Follow-up Resource Utilization

*Rates per 100 person-years*





# Annual and Cumulative Costs: Years 1- 5





# Annual Differences in Life Years and QALYs

Time Since Randomization (Years)	$\Delta$ Life Years (CABG-PCI)	$\Delta$ QALYs (CABG-PCI)
1	-0.008	-0.033
2	-0.010	-0.034
3	-0.0006	-0.029
4	+0.015	-0.004
5	+0.053	+0.031



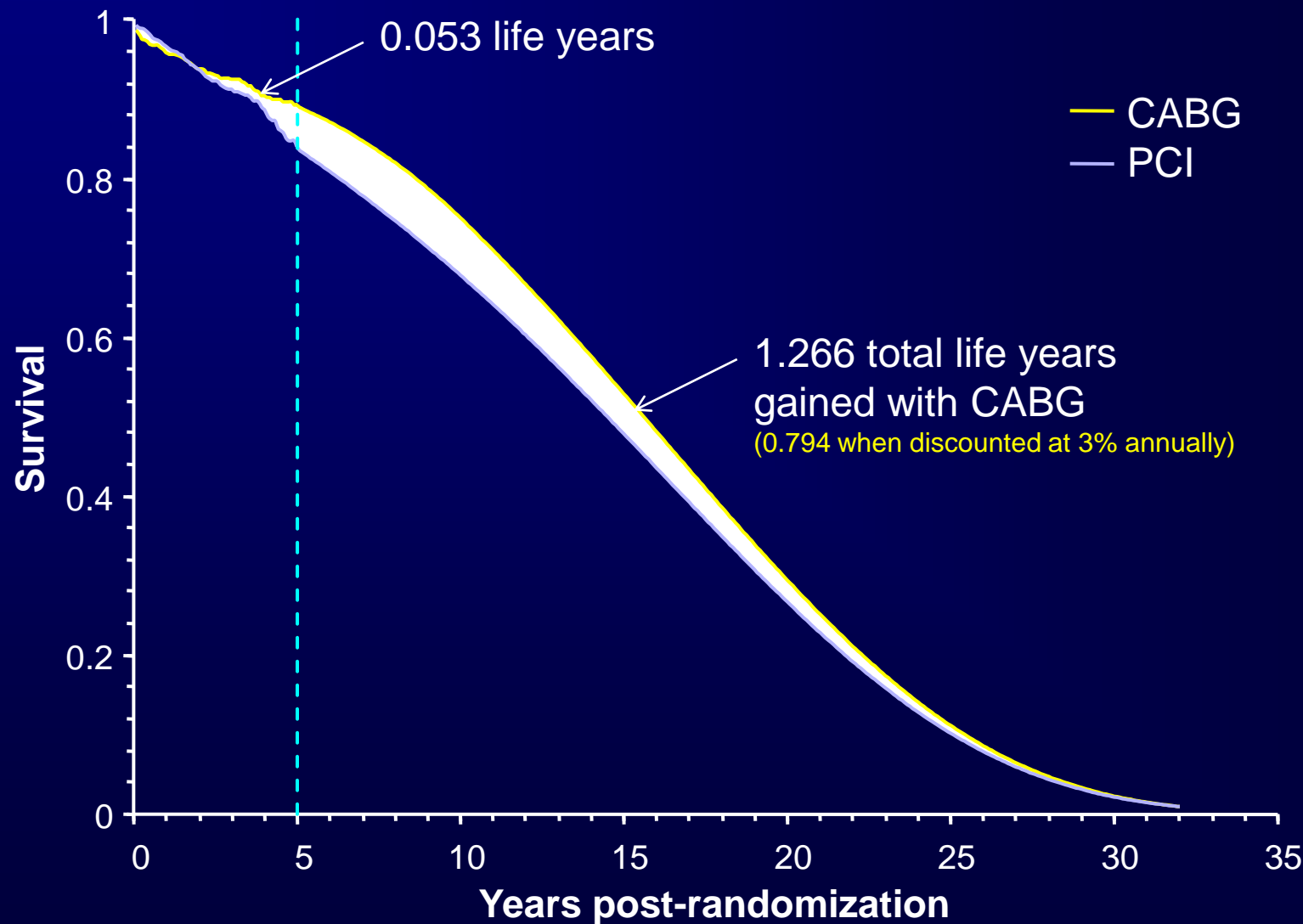
# Markov Model

*For the Projection of Post-Trial Life Years, QALYs and Costs*

- Monthly risk of death based on age, sex and race-matched data from US life tables calibrated to the observed 5 year mortality for the PCI population
  - *CABG effect based on a landmark analysis for years 2-5: mortality hazard ratio for CABG vs. PCI = 0.60*
- Base case: Gradual attenuation of CABG effect
  - *Mortality hazard ratio increases from 0.60 to 1 in a linear fashion between 5 and 10 years; no impact of CABG beyond 10 years*
- Long-term costs and utility weights obtained from regression models developed from trial data

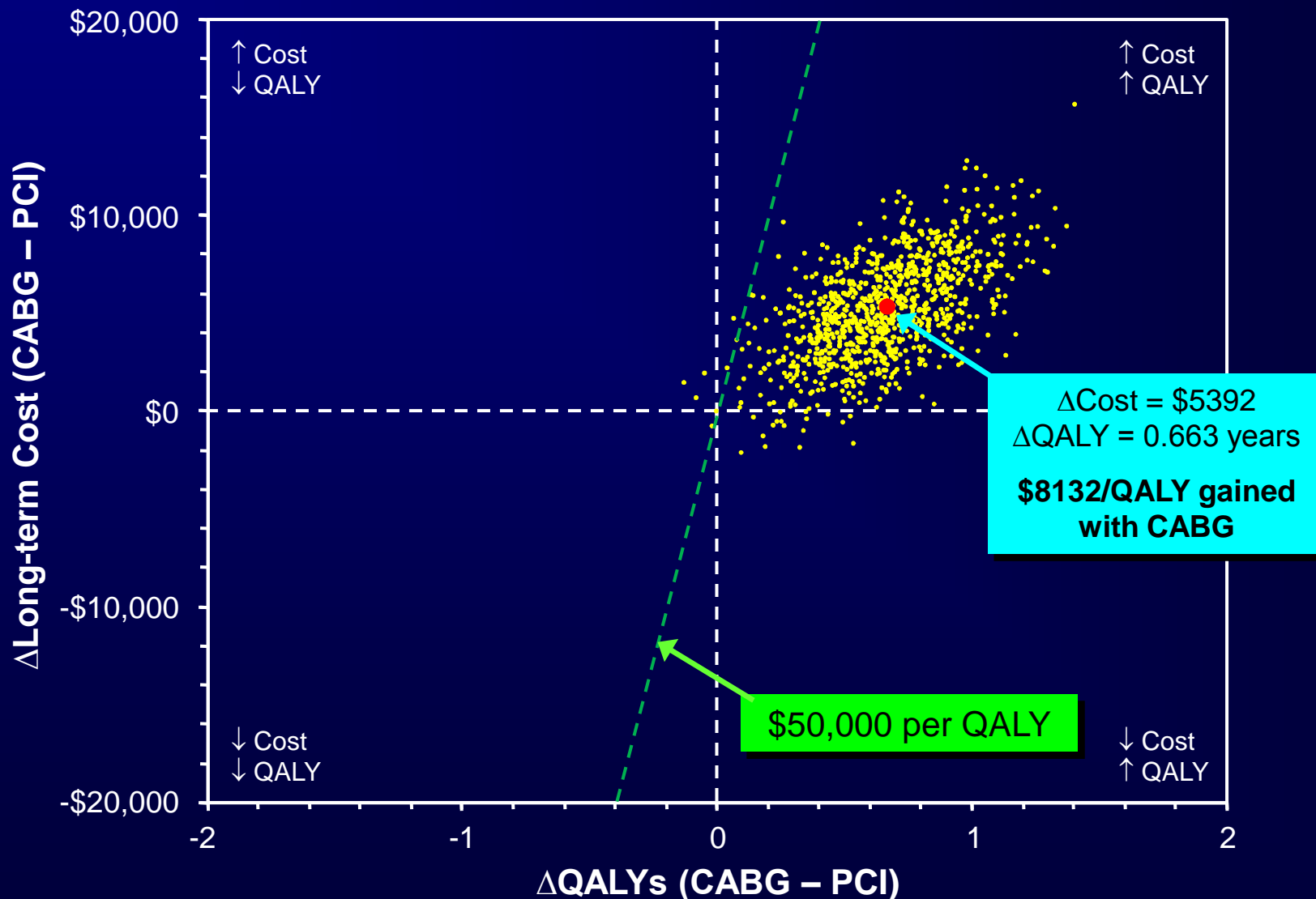


# In-Trial and Projected Survival





# Lifetime Cost-Effectiveness Results

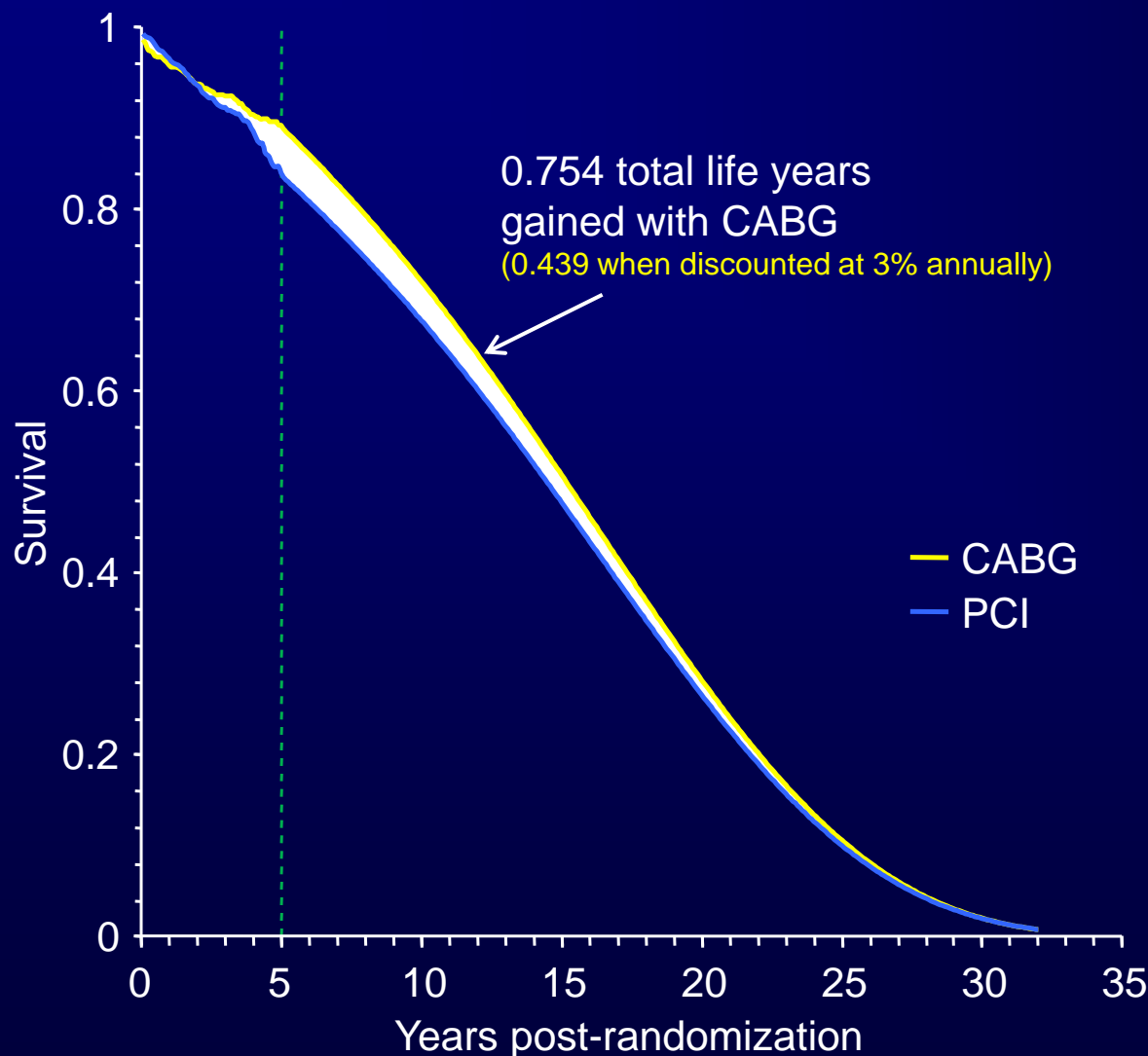


Costs and QALYs discounted 3% annually

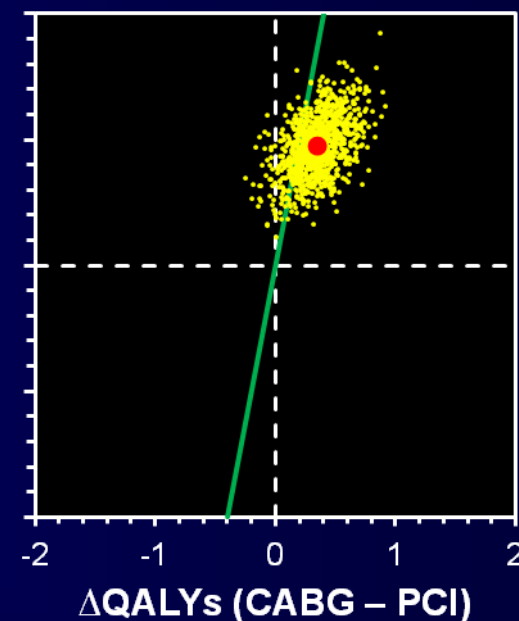


# Cost-Effectiveness of CABG vs. PCI

Sensitivity Analysis – No CABG Effect Beyond 5 Yrs



No CABG Effect  
Years 5 - 10



$\Delta$ Costs	\$9,485
$\Delta$ QALYs	0.351
ICER	\$27,022

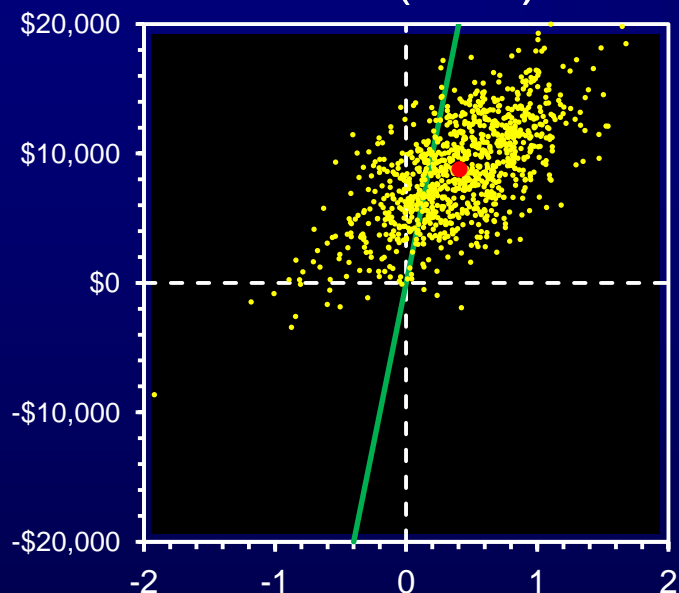
Pr < \$50K/QALY= 82.4%



# Cost-Effectiveness of CABG vs. PCI

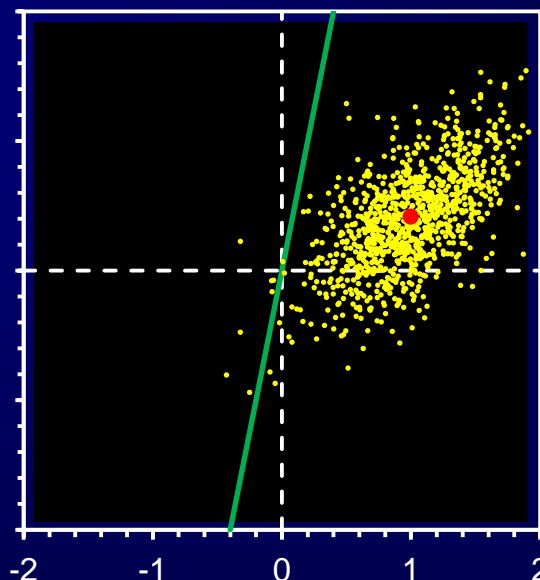
## SYNTAX Score Tertiles

Low (<23)



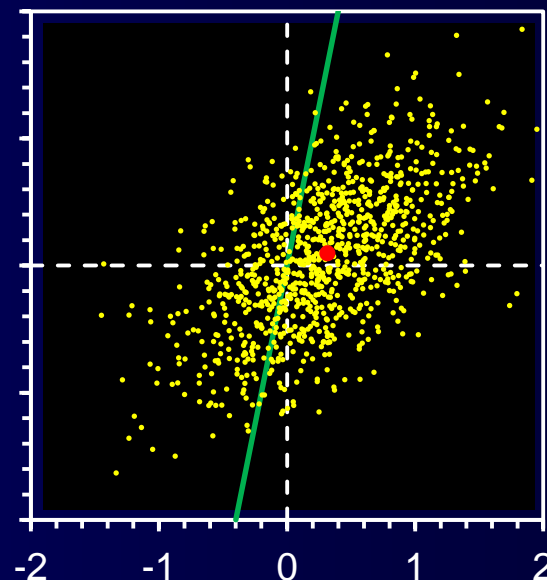
$\Delta$ Costs	\$8,784
$\Delta$ QALYs	0.407
ICER	\$21,582

Mid (23-32)



$\Delta$ Costs	\$4,160
$\Delta$ QALYs	0.997
ICER	\$4,172

High (>32)



$\Delta$ Costs	\$973
$\Delta$ QALYs	0.315
ICER	\$3,088





# Subgroups

Subgroup	$\Delta$ Costs	$\Delta$ QALYs	ICER	Prob. < \$50,000
Male (n=1328)	\$3,059	0.778	\$3,932	99.8
Female (n=527)	\$9,249	0.510	\$18,135	77.3
Age <60 (n=624)	\$11,190	1.160	\$9,647	99.8
Age 60-69 (n=621)	-\$1,765	0.276	Dominant	80.5
Age $\geq$ 70 (n=610)	\$6,892	0.349	\$19,748	71.9
US (n=351)	\$4,701	1.120	\$4,197	98.1
Non-US (n=1504)	\$5,622	0.576	\$9,760	96.5



# Summary (1)

- CABG is associated with initial costs  $\approx$  \$9,000/patient higher than PCI
- Partially offset by lower costs associated with repeat revascularization and to a lesser extent cardiac meds
- At 5 years, CABG improved quality-adjusted life expectancy by  $\sim$  0.03 years while increasing total costs by  $\sim$  \$3,600/patient
- Over a lifetime horizon, CABG associated with 0.66 QALYs gained and  $\sim$  \$5,400/patient higher costs yielding an ICER of \$8,132/QALY gained



## Summary (2)

- Results were robust to a broad range of sensitivity analyses regarding the duration of the CABG effect on both survival and costs
- Results were also consistent across a wide range of subgroups



# Conclusions

- For patients with diabetes and multivessel CAD, CABG provides not only better long-term clinical outcomes than DES-PCI but these benefits are achieved at an overall cost that represents an attractive use of societal health care resources
- These findings provide additional support for existing guidelines that recommend CABG for diabetic patients with multivessel CAD