Health Related Quality of Life and U.S. Economic Outcomes of PCI with Drug-Eluting Stents vs. Bypass Surgery: *1-Year Results from the SYNTAX Trial*

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Disclosures

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Background

- Recently 1-year results from the SYNTAX trial have demonstrated that for patients with left main and/or 3-vessel disease, CABG results in lower rates of MACCE than PCI--driven by a significant reduction in the need for repeat revascularization
- Since there were no overall differences in irreversible endpoints, however, quality of life and economic factors should be important considerations in determining the optimal treatment for these highly prevalent conditions

Methods: Quality of Life

Instrument	Description/Role
Seattle Angina Questionnaire (SAQ)	• CAD-specific QOL • Domains: Angina Frequency, Physical Limitations, Disease Perception/QOL • Scores: 0-100 (higher = better)
SF-36	• General physical and mental health • Scores: 0-100 (higher = better)
EQ-5D (EuroQOL)	• Generic instrument for assessment of utilities and QALYs • Scores: 0-1 (0=death; 1=perfect health)

- Assessments performed by self-administered questionnaires at baseline, 1, 6, and 12 months

Costing Methods

Analytic Perspective

- US healthcare system

Patient Population

- All patients with complete 1 yr follow-up, regardless of country of origin

General approach

- Multiply counts of resources derived from trial population by price weights derived from a comparable US population

Costing Methods:
Revascularization Procedures/Hospitalizations

- Cath lab and CABG-related procedure costs based on measured resource utilization (procedure duration, balloons, stents, wires etc.) and current unit costs
  - *Drug-eluting stent cost =$2000/stent*
- Ancillary hospital costs based on event-based (rather than resource-based) regression models of SYNTAX-eligible U.S. patients using 2006 MedPAR data
  - *Avoids distortions due to marked differences in LOS across different health care systems*
  - *Events considered: Death, MI, stroke, re-operation, major bleeding, post-op infection, resp failure, arrhythmias, etc.*

Costing Methods (2)

Resource	Approach to Costing
Other hospitalizations	• DRG-specific Medicare reimbursement rates
Physician services	• Major procedures- Medicare fee schedule • Hospital care- DRG specific cost estimates
Rehabilitation services	• Medicare reimbursement rates
Outpatient care and testing	• Medicare fee schedule
Outpatient medications	• AWP for typical drug and dose

Economic Analysis Plan

Primary Endpoints

- Total 1-year medical care costs
- Incremental Cost-Effectiveness Ratio ($/QALY gained)

Secondary Endpoints

- Individual components of cost
- Disease-specific C/E ratio ($/repeat revascularization avoided, $/death, MI, or stroke avoided)

Prespecified Subgroups

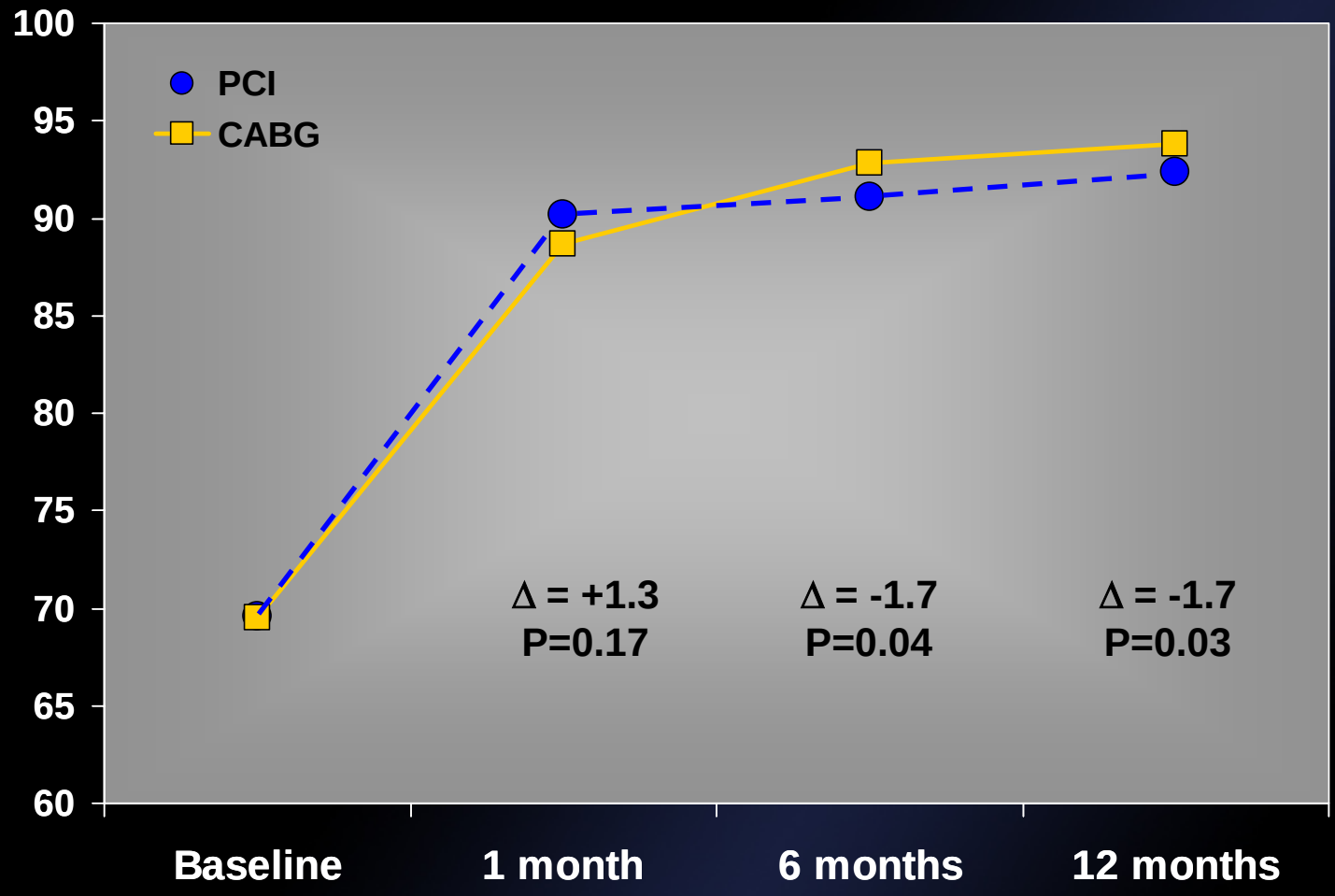
- Left main vs. 3-vessel disease
- SYNTAX score tertiles

Baseline QOL

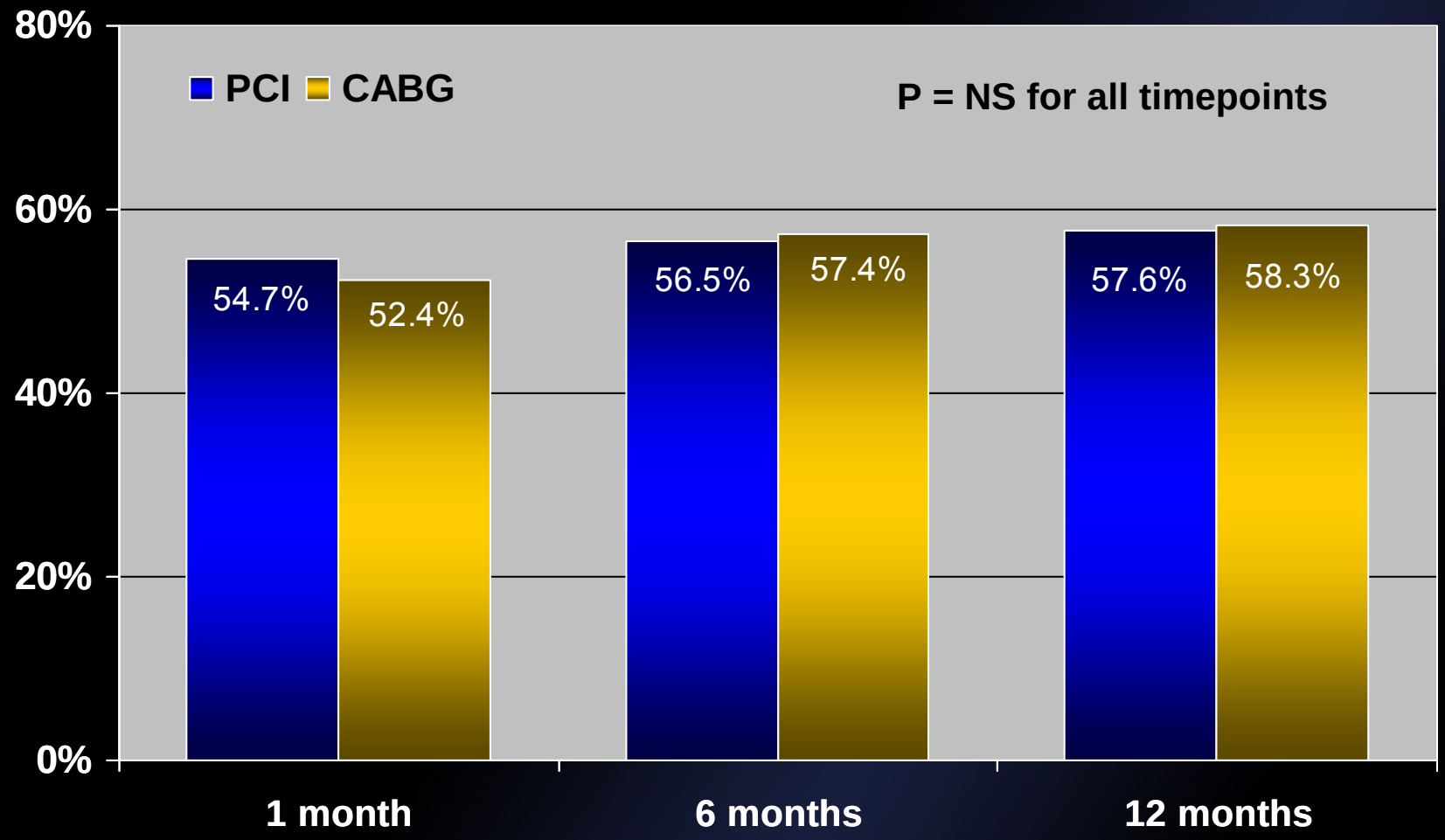
	PCI (n=837)	CABG (n=802)
SAQ Angina Frequency	70±26	69±27
Daily (0–30)	11.7%	11.6%
Weekly (40–60)	26.2%	27.9%
Monthly (70–90)	39.9%	38.4%
None (100)	22.2%	22.1%
SAQ QOL	46±23	45±23
SF-36 PCS	40±10	40±10
SF-36 MCS	45±12	45±12
EQ-5D Utility	0.75±0.19	0.74±0.19

P=NS for all comparisons

Primary QOL Endpoint: SAQ-Angina Frequency

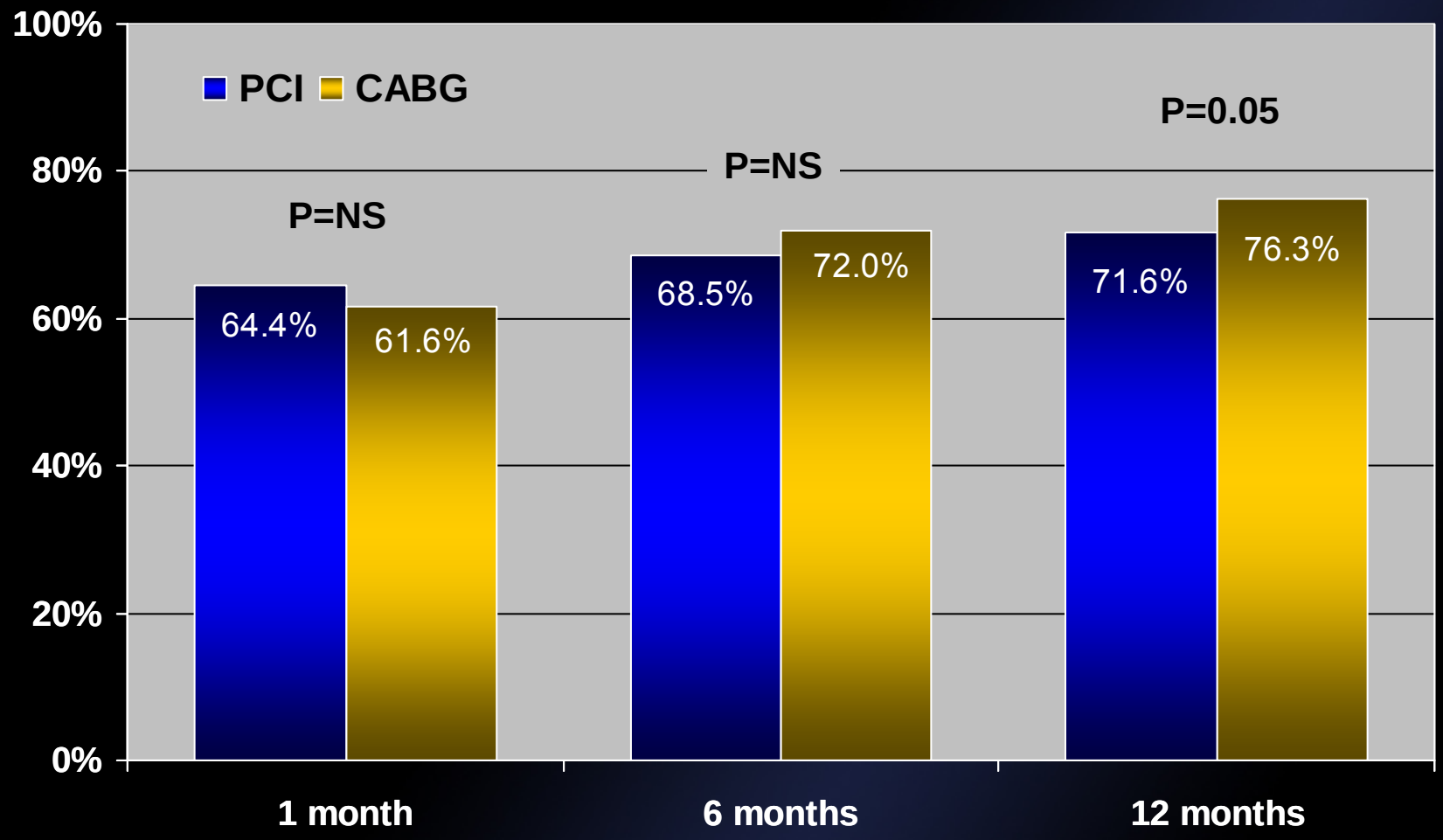


SAQ-AF: Substantial Improvement*



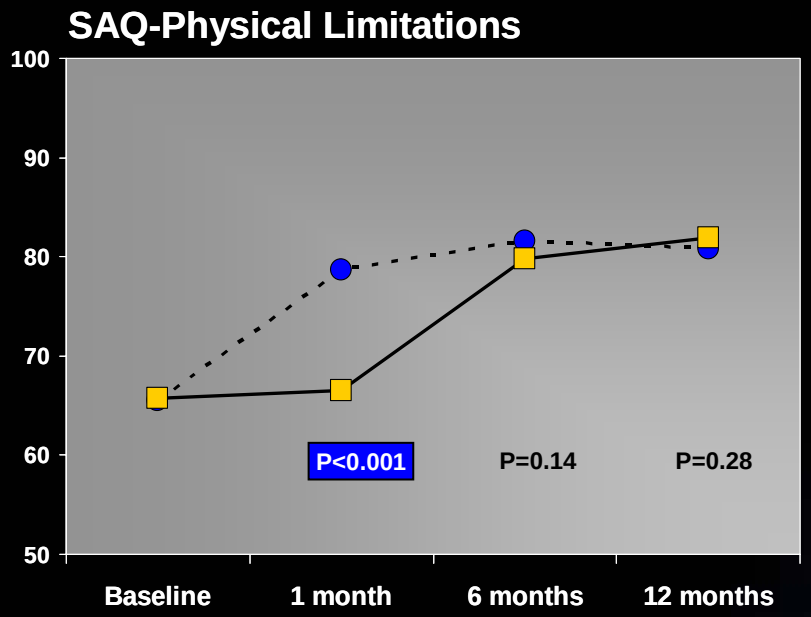
* Defined as improvement ≥ 20 points vs. baseline

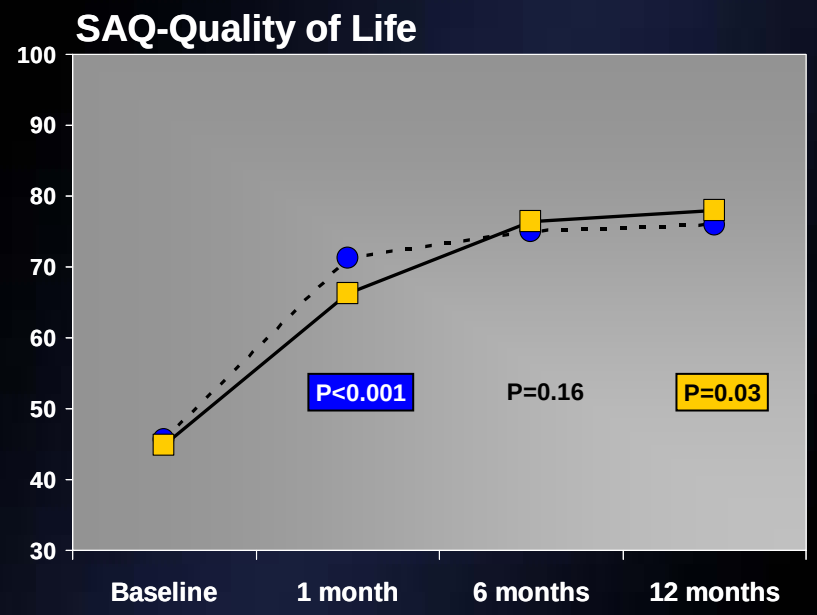
SAQ-AF: Angina-Free*

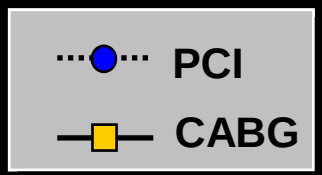


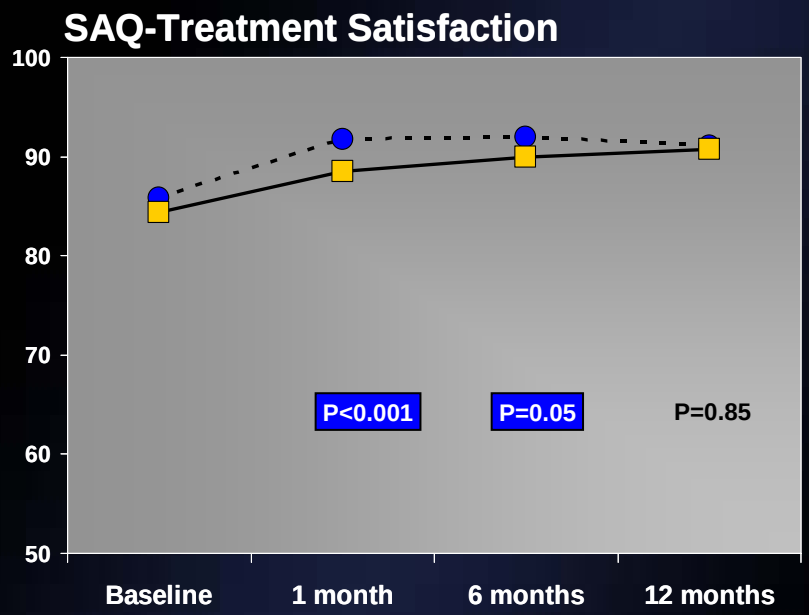
* Defined as SAQ-AF score = 100

SAQ Subscales

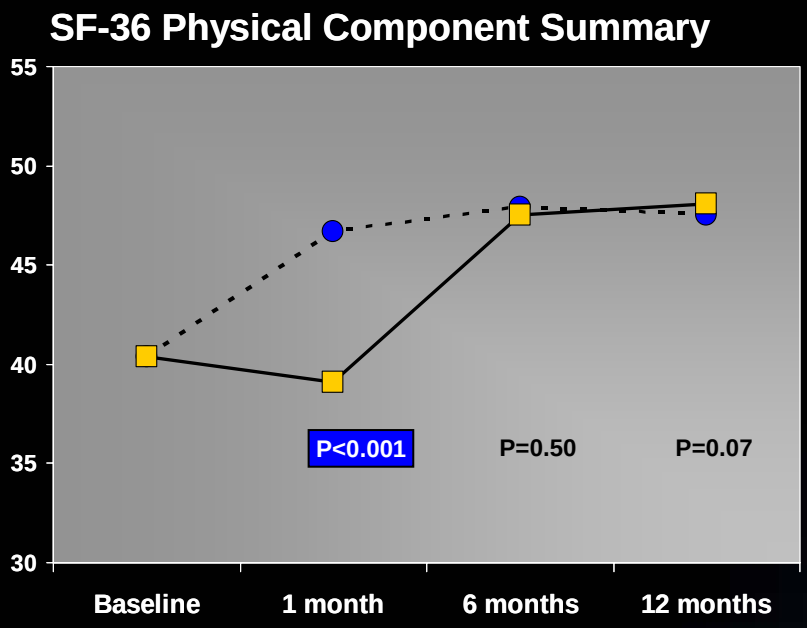


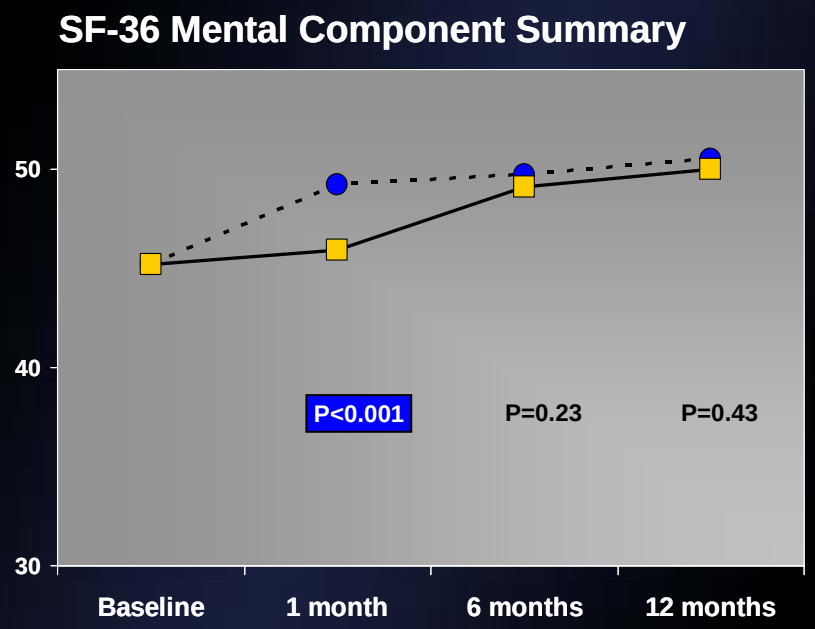


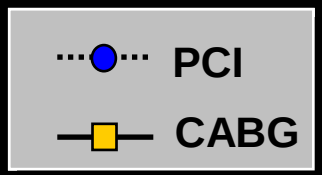


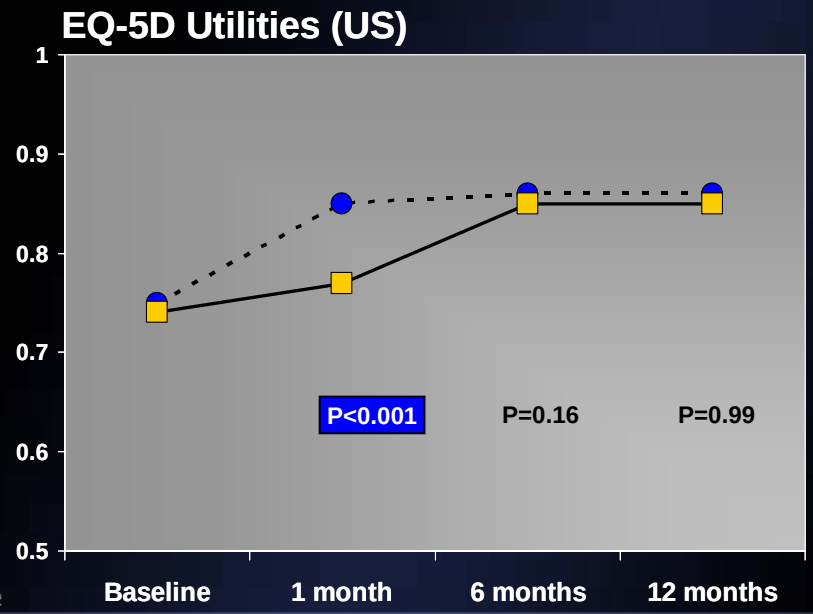


Generic QOL and Utilities







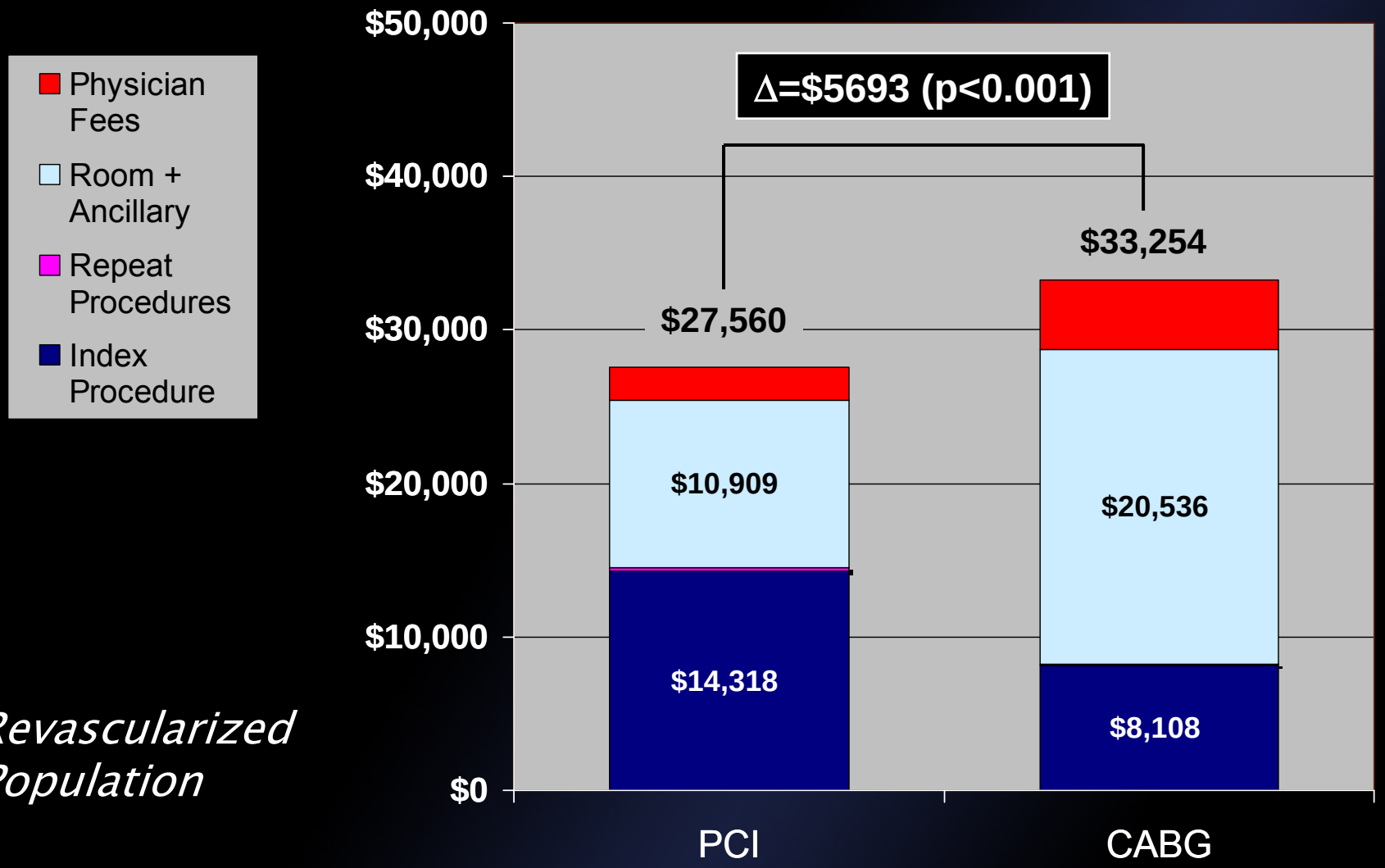


Index Procedure Resource Use*

	PCI	CABG
PCI procedures		
1	85.9%	
2	14.0%	
3	0.1%	
Procedure duration (mins)	101 ± 55	207 ± 65
Contrast volume (ml)	415 ± 208	NA
Drug-eluting stents	4.6 ± 2.3	NA
Balloons	3.8 ± 2.8	NA
Guidewires	3.5 ± 2.3	NA
Total Procedure Cost	$14,406 ± 6,887	$8,108 ± 1930

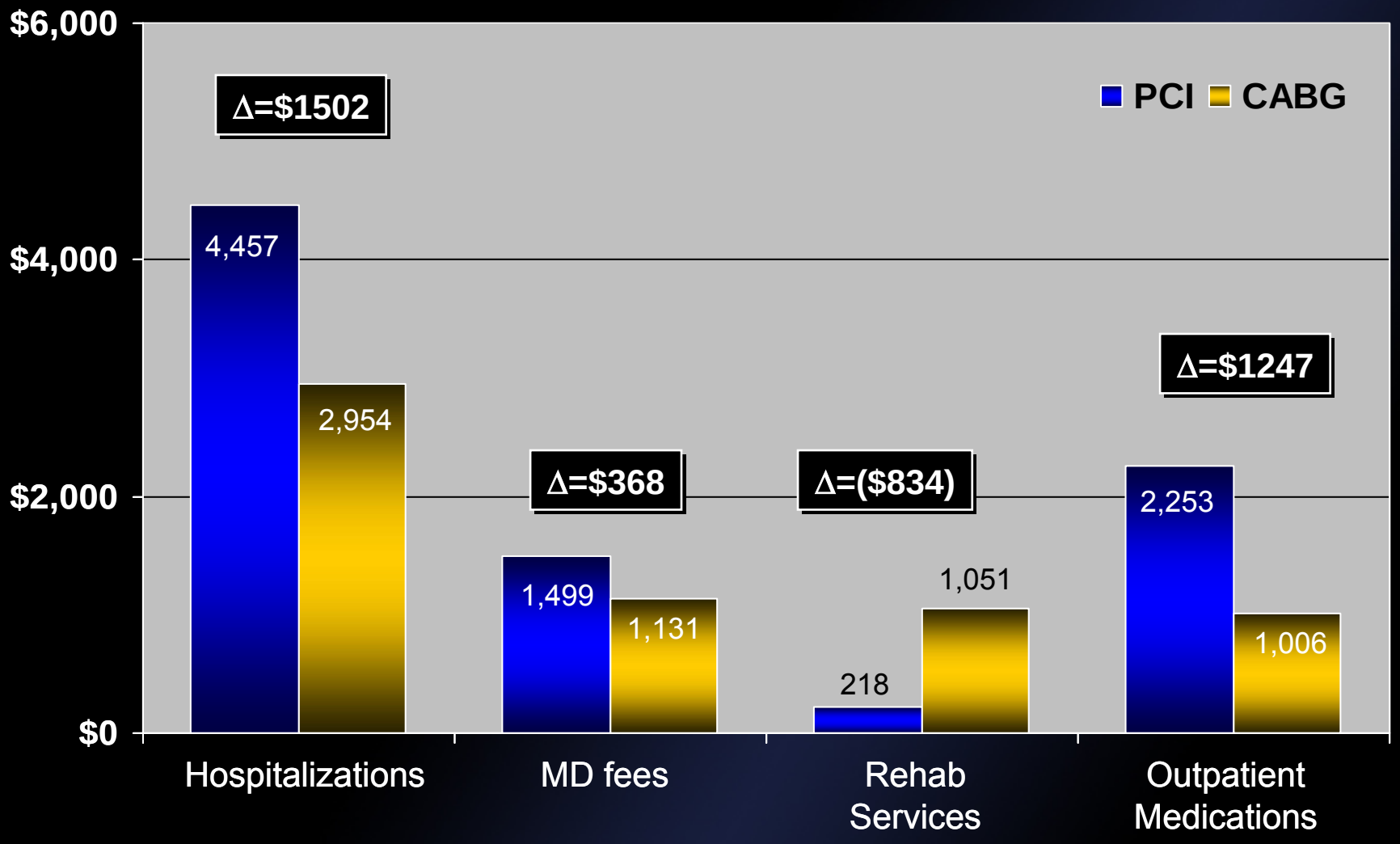
* Per protocol population (includes planned staged procedures)

Initial Hospitalization Costs



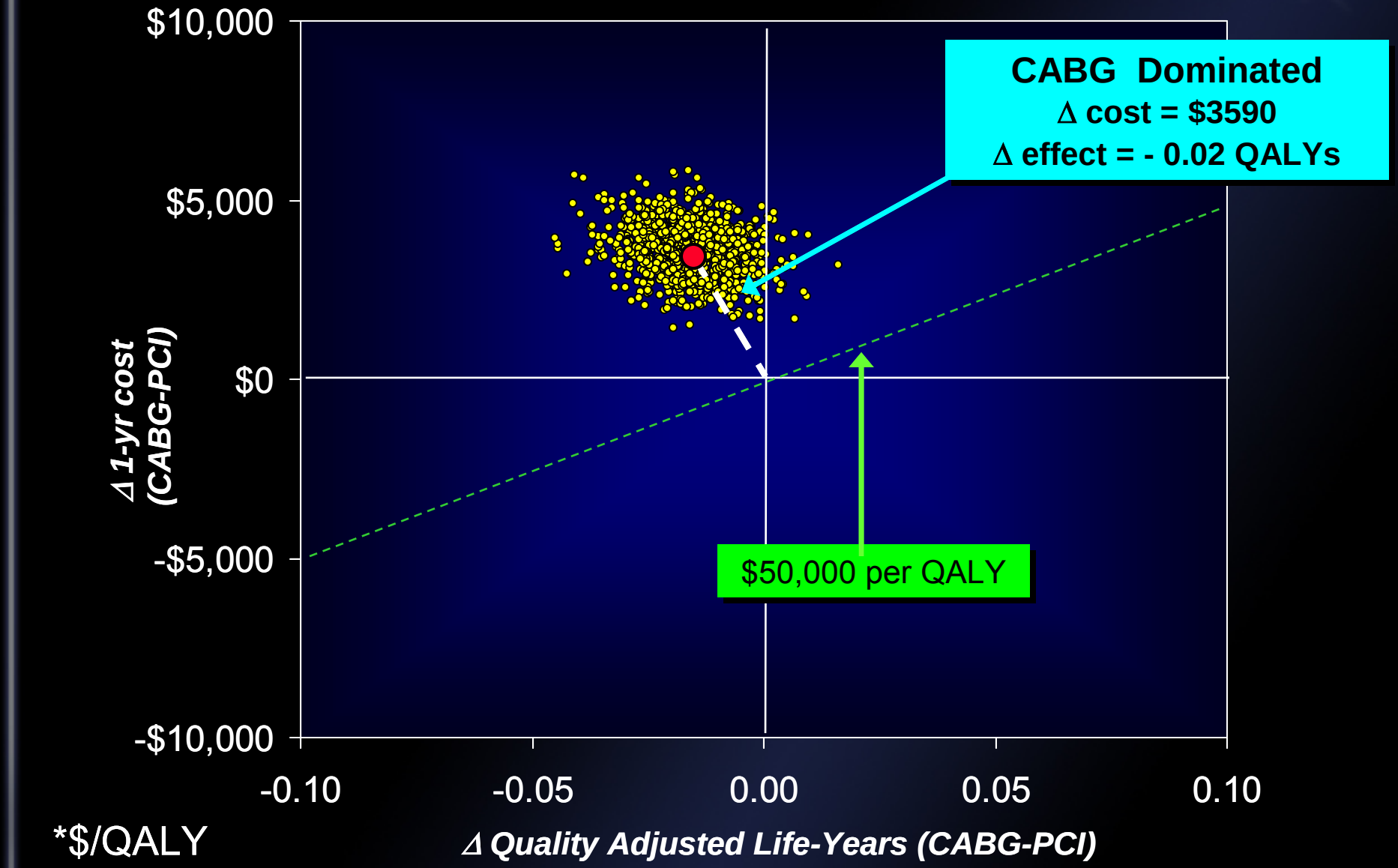
Revascularized Population

Follow-up Costs



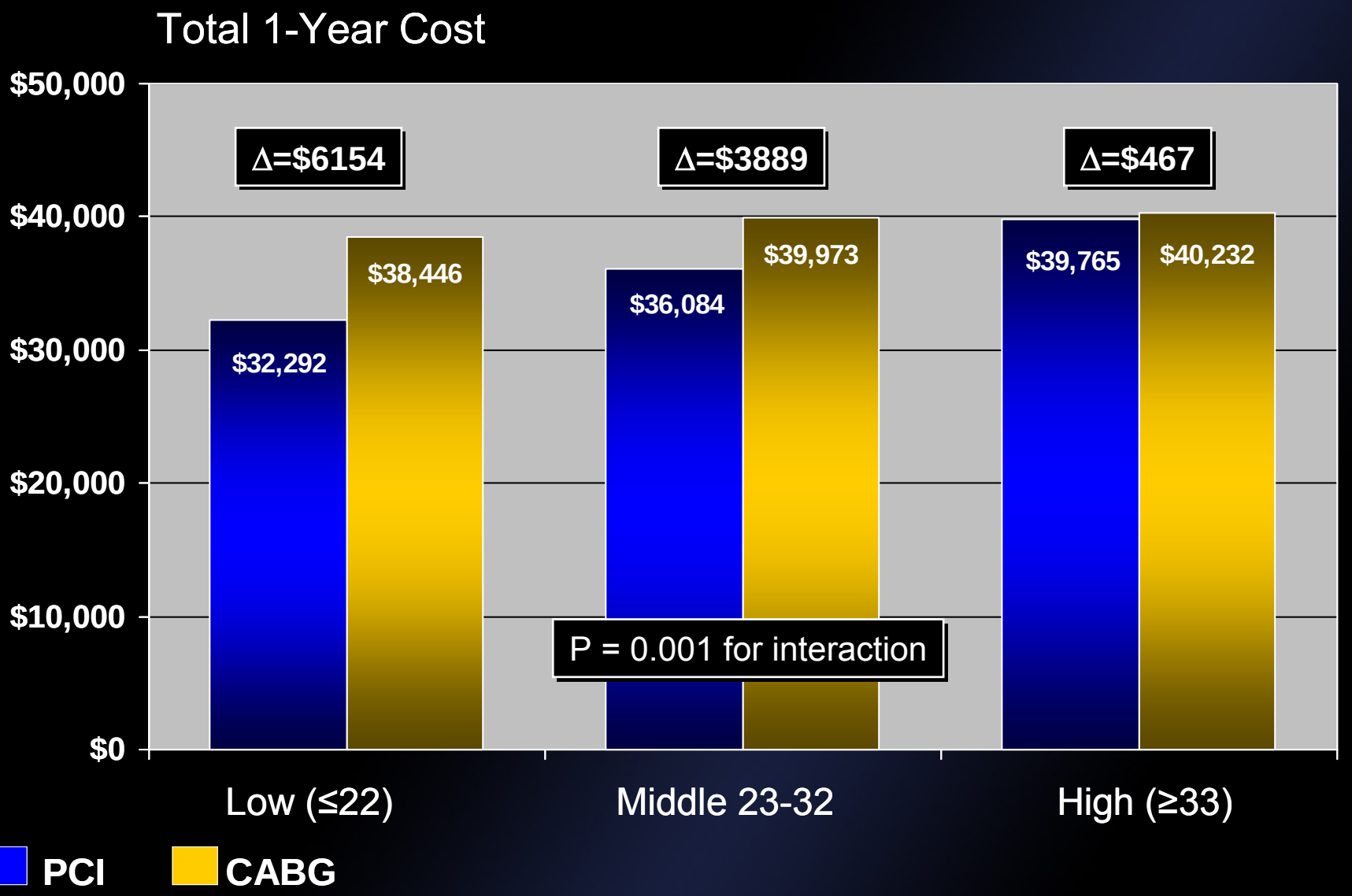
Total 1-Year Costs

Cost-Effectiveness of CABG vs. PCI*
Overall Population



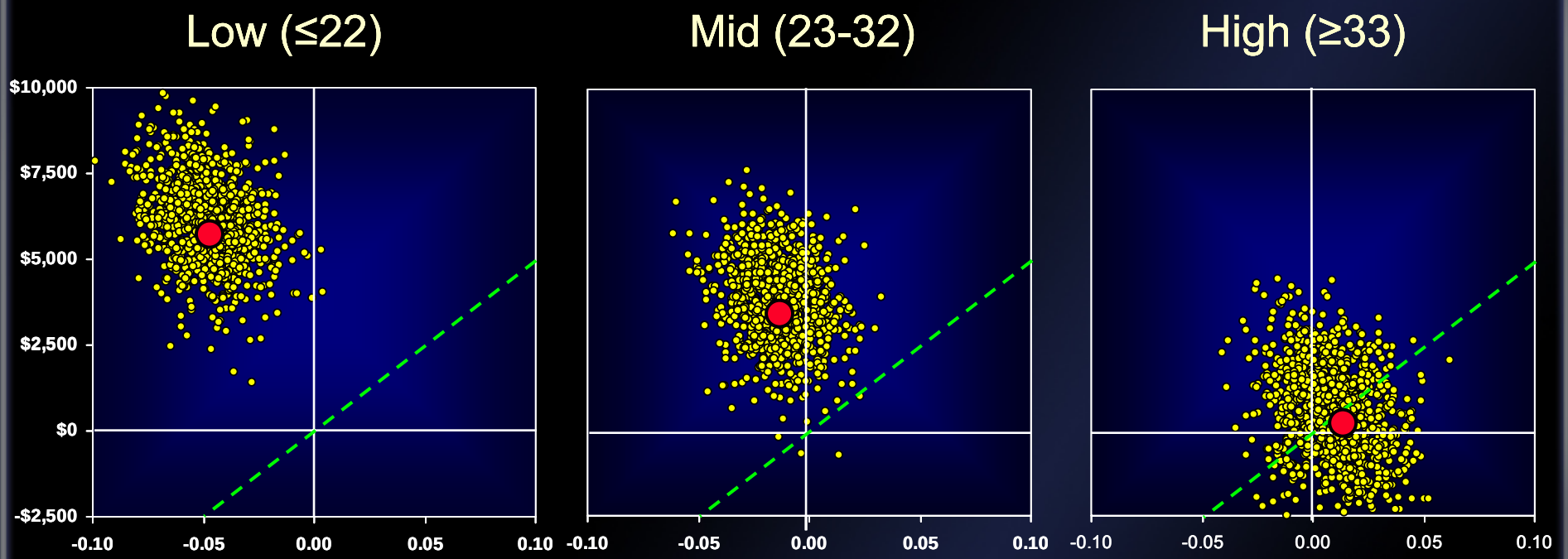
*$/QALY

Subgroup Analysis:
SYNTAX Score Tertiles



Cost-Effectiveness of CABG vs. PCI ($/QALY)

SYNTAX Score Tertiles



Δ Cost	$6154
Δ QALY	-0.047
ICER	Dominated

Pr <$50K/QALY = 0.0%

Δ Cost	$3889
Δ QALY	-0.013
ICER	Dominated

Pr <$50K/QALY = 0.3%

Δ Cost	$467
Δ QALY	+0.010
ICER	$43,000/QALY

Pr <$50K/QALY = 49%

Limitations

- Analysis performed from US perspective → results may differ in other healthcare systems because of differences in patterns of resource use and costs
  - DES cost: US- $2000 UK- $600 GER- $400
  - Hosp. day: US- $1500 UK- $500 GER- $200
- 1-year time horizon may be insufficient to fully capture differences in long-term survival and QOL
  - 5 yr economic and QOL analyses planned

Summary: QOL

- Among patients with left main and/or 3-vessel coronary disease, angina relief was slightly better with CABG than DES at 6 and 12 months. The magnitude of benefit was smaller than in previous CABG vs. PCI comparisons, however, and below the threshold that most patients would find clinically meaningful.
- All other QOL endpoints favored PCI at 1 month, although these differences were transient and largely resolved by 6 months.

Summary: Cost-Effectiveness

- Despite substantially higher procedural costs, initial treatment costs were ~$6000/pt higher with CABG than PCI—mainly due to differences in LOS, complications, and physician costs
- Follow-up costs were ~$2500/pt lower with CABG, driven largely by differences in the need for additional revascularization procedures and lower medication costs
- Although total 1-year costs remained significantly lower with PCI, the overall cost-effectiveness of PCI vs. CABG differed substantially according to pt characteristics- particularly angiographic complexity

Summary: Cost-Effectiveness (2)

SYNTAX Score	Net Cost of PCI	1-Yr Cost-Effectiveness
Low (0-22)	↓ 20%	PCI dominant
Med (23-32)	↓ 8%	PCI dominant
High (≥33)	Neutral	CABG economically attractive

- Longer-term follow-up is essential (and planned) to fully assess both QOL and cost-effectiveness for these challenging populations