IN.PACT SFA Health Economic Study

DCB Cost-Effectiveness at 2 Year Follow-up

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Disclosures

- David J Cohen– consulting income, research grants from Medtronic
- The INPACT-SFA II trial and the associated economic analysis were sponsored by Medtronic

Background

- Percutaneous transluminal angioplasty (PTA) of femoropopliteal disease achieves excellent initial success but is limited by high rates of restenosis
- Although bare metal and drug-eluting stents improve long-term patency, concerns remain about stent fracture and management of in-stent restenosis
- Recently, 2-year results of the IN.PACT SFA trial demonstrated that PTA using the IN.PACT Admiral drug-coated balloon (DCB) led to reduced rates of restenosis and clinically-driven target lesion revascularization compared with standard PTA
- The long-term cost-effectiveness of this approach is unknown

Methods

- Prospective economic analysis alongside the IN.PACT SFA II trial
- Analytic perspective = US healthcare system
- Co-Primary endpoints
  - Total PAD-related healthcare costs (target limb only)
  - Incremental cost-effectiveness of DCB vs. standard PTA assessed in terms of cost per quality-adjusted life-year (QALY) gained

Methods - Costs

- Costs for index procedure and subsequent target limb related care collected through 2 years of follow-up
  - *Resource-based accounting for revascularization procedures, medications, and outpatient vascular care*
  - *Other hospital costs based on hospital billing data → converted to costs using hospital and department-specific cost to charge ratios*
  - *Costs for treatment of PAD of the contralateral limb excluded*
- IN.PACT Admiral drug-coated balloons assigned a cost of $1,375 based on the current average acquisition cost in the United States

Methods - QALYs

- EQ-5D scores were collected prospectively at baseline, 1, 6, 12, and 24 month f/u
  - *Converted to utility weights using U.S. specific algorithm*
- QALYs calculated as time-weighted averages, assuming that transitions between health states occurred at the mid-point of each observation period

Methods – Accounting for Differential Mortality

- 2-year mortality was significantly higher in the DCB group (10.7% vs. 0%, p=0.005) of the IN.PACT SFA II trial (US phase)
- Detailed review of individual events suggests this difference is unlikely to be related to DCB treatment
- To avoid underestimation of both costs and QALYs for the DCB group, we used a decision-analytic Markov model to estimate 2-year event rates, costs, and QALYs under the assumption of no differential mortality between the DCB and PTA groups
  - *Model parameters with respect to event rates, relative risks, costs, and QALYs derived from the observed trial data*

Methods – Cost Effectiveness

- Costs and QALYs discounted at a rate of 3% per year consistent with current US guidelines
- Incremental cost-effectiveness ratios calculated in standard fashion:

$$\text{ICER} = \frac{\text{2-year cost}_{\text{DCB}} - \text{2 year cost}_{\text{PTA}}}{\text{2-year QALYs}_{\text{DCB}} - \text{2-year QALYs}_{\text{PTA}}}$$

- Uncertainty around estimates assessed using probabilistic sensitivity analysis (1000 replicates)

Baseline Patient Characteristics

	DCB (n=121)	PTA (n=60)	p-value
Age (years)	68.4 ± 8.8	68.2 ± 9.7	0.891
Male (%)	63.6%	63.3%	0.968
Diabetes (%)	47.9%	40.0%	0.313
Current smoking (%)	32.2%	30.0%	0.761
Rutherford class (%)			
II	41.3%	38.3%	
III	51.2%	56.7%	0.357
IV	7.4%	3.3%	
V	0.0%	1.7%	

Lesion Characteristics

	DCB (n=122*)	Standard PTA (n=61*)	p-value
Target lesion length (cm)	8.5 ± 4.9	9.3 ± 5.6	0.322
Total occlusion (%)	19.7%	16.4%	0.591
Ref. vessel diameter (mm)	4.8 ± 0.9	4.7 ± 0.8	0.486
Percent stenosis	79 ± 16	80 ± 13	0.541

* Number of lesions

Index Resource Use and Cost

	DCB n=121	Standard PTA n=60	p-value
Standard PTA balloons	1.3 ± 0.5	2.3 ± 0.7	<0.001
Drug-coated balloons	1.4 ± 0.6	0.0 ± 0.0	<0.001
Provisional stenting (%)	2.5%	13.3%	0.007
Stents	0.1 ± 0.3	0.2 ± 0.5	0.067
Costs			
Index procedure	$5953 ± 2434	$4604 ± 2331	<0.001
Index hospitalization	$8293 ± 3230	$7164 ± 3325	0.03

Δ Initial Cost = $1,129

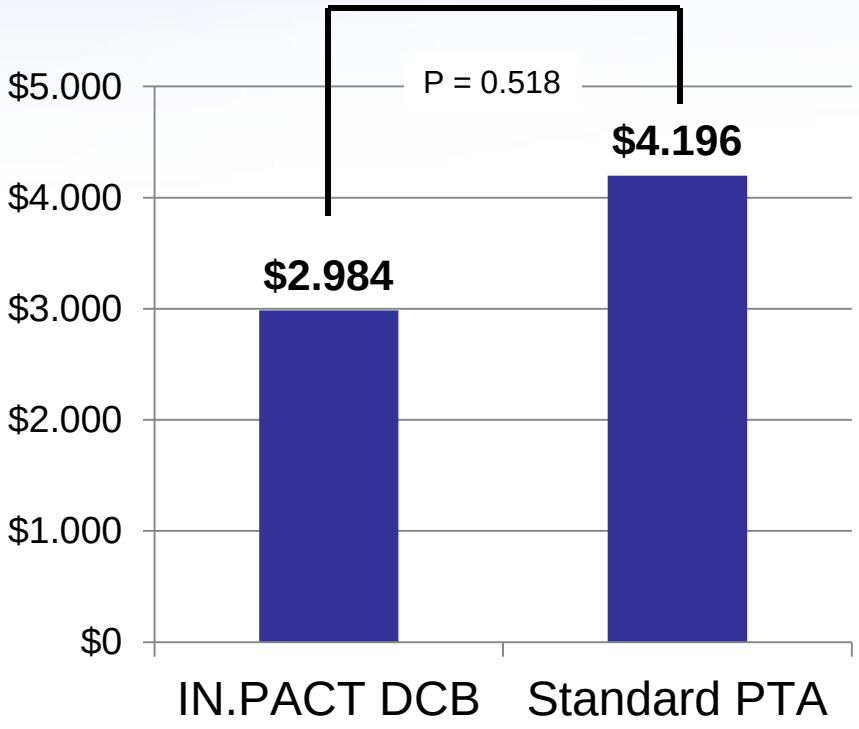
2-Year Outcomes (Unadjusted)

	DCB n=121	Standard PTA n=60	p-value*
Proportion of Patients			
Target Lesion Revasc.	5.8%	21.7%	0.001
Target Limb Revasc.	9.9%	30.0%	<0.001
Events per 100 patients			
Target Lesion Revasc.	12.4 ± 77.0	28.3 ± 61.3	0.002
Target Limb Revasc.	20.7 ± 99.9	41.7 ± 78.7	<0.001

* Event counts compared by Wilcoxon test

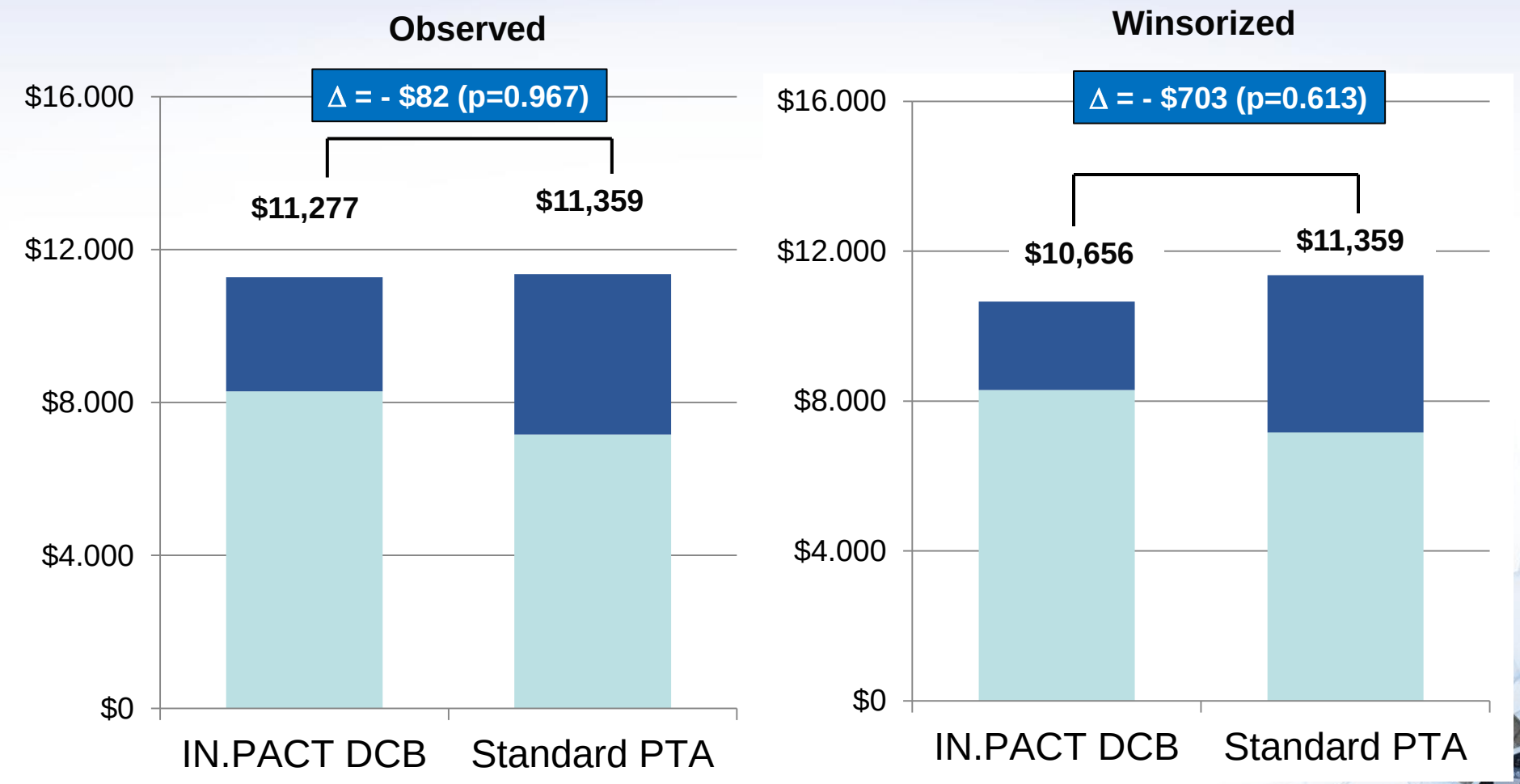
Follow-up Costs Through 2 Years

Δ Follow-up Cost = - $1,212/patient



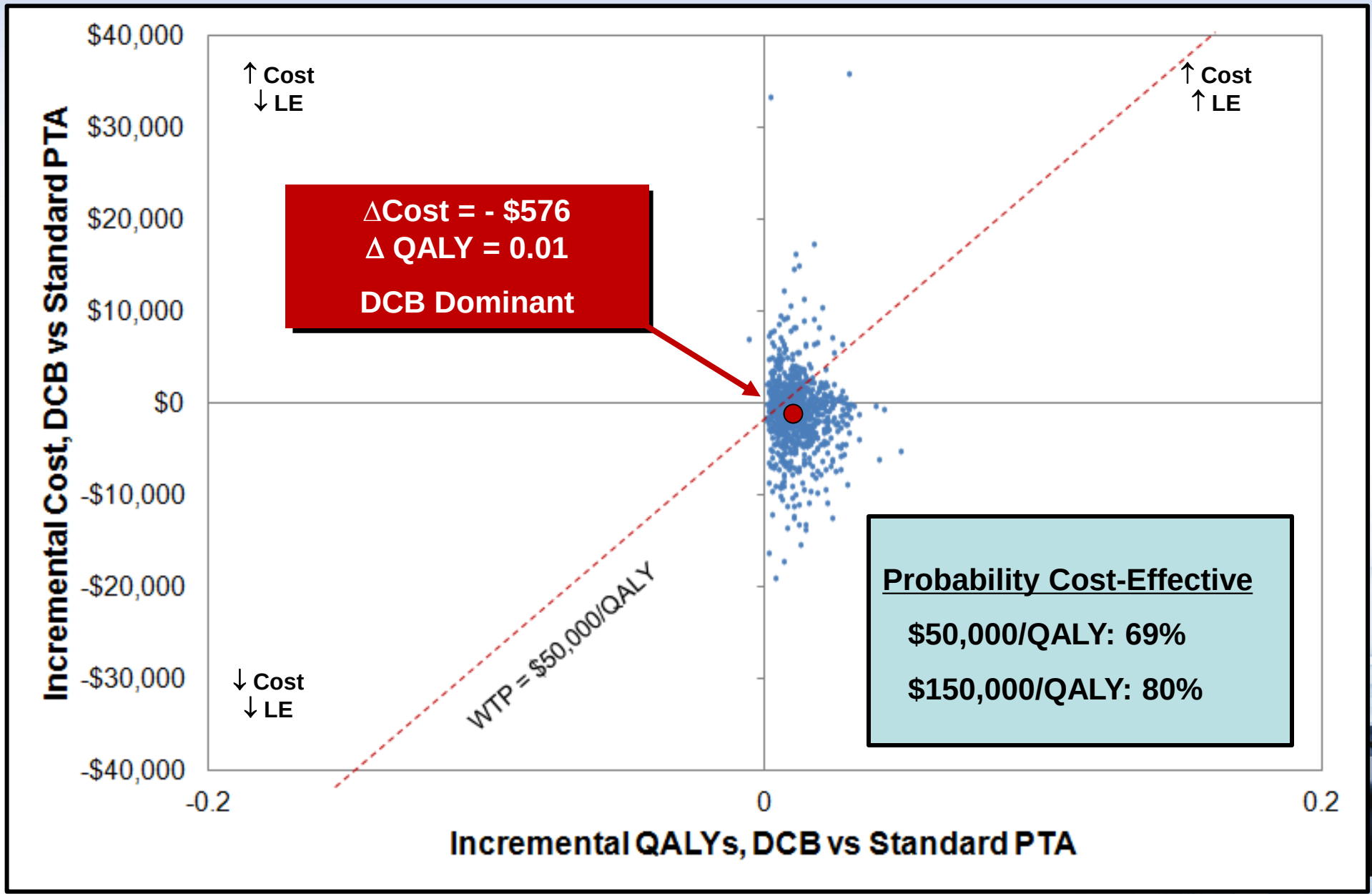
F/U Cost Components	DCB	PTA	p-value
Inpatient Physician Fees	$208	$368	0.31
Antiplatelet Medications	$605	$670	0.59
Hospitalization Costs	$2,171	$3,158	0.56

Total Costs Through 2 Years*



** Winsorized– costs for 1 extreme outlier reduced to next highest value*

Cost-Effectiveness: Modeled Results



Summary

- Index hospitalization costs were ~$1100/pt higher in patients treated with DCB, driven primarily by the cost of the DCB itself
- Over the 2-yr follow-up period, PAD related costs were ~$1200/pt less with DCB than standard PTA– driven mainly by fewer target limb revascularization procedures. As a result, total 2 year costs were similar for the 2 groups
- QOL was improved modestly with DCB as well, although there were no significant differences at the end of 2-year f/u
- Assuming that there is no difference in long-term mortality between DCB and standard PTA, formal cost-effectiveness analysis demonstrates that DCB is an economically dominant strategy and has a high probability of being economically attractive (ICER <$50,000/QALY) compared with standard PTA

Conclusions

- For patients similar to those enrolled in the IN.PACT SFA II trial, the IN.PACT Admiral DCB appears to be economically attractive (i.e., cost-effective) compared with standard PTA based on accepted U.S. standards