

Economic Consequences of Drug-coated Balloon Usage for AV Access Based on 12-Month Data from the IN.PACT AV Access Study

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On behalf of the economic analysis author group

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Faculty Disclosure

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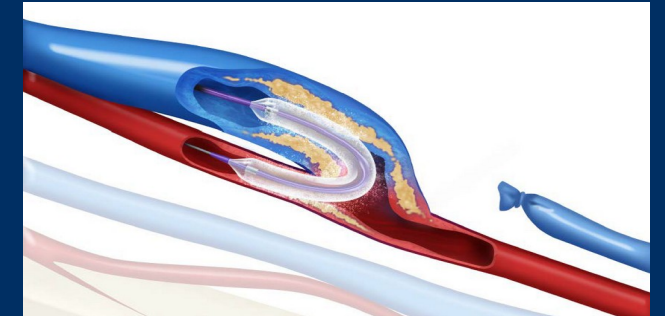
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- **Consulted for:** Medtronic, Boston Scientific, Penumbra
- **Held common stock in:** None
- **Research, clinical trial, or drug study funds received from:** Medtronic, Boston Scientific, Vesper, BlackSwan, Terumo, BD Bard, Penumbra, Inari, Ethicon

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IN.PACT AV DCB Economic Analysis

The recent IN.PACT AV Access Trial evaluated the safety and clinical benefit of the IN.PACT AV drug-coated balloon (DCB) compared to percutaneous transluminal angioplasty (PTA) for treatment of obstructive lesions of native AVFs



Objectives:

- Assess the economic implications of drug-coated balloon (DCB) versus standard balloon angioplasty (PTA) in the US healthcare system based on 12-month Data from the IN.PACT AV Access Trial



Methods and Materials

Analytic Approach 1 (Primary Analysis): Index and Reintervention Based Costs

- Decision-analytic Markov model to capture index costs and reinterventions
- Clinical inputs: Access circuit reintervention rates (12M, from IN.PACT AV Access Trial)
- Cost Inputs: US Medicare FY 2020 facility and physician fees per reintervention
- Analysis horizons:
 - 12M (trial-observed), and
 - 36M (projected from 12M data)

Approach 2 (Secondary Analysis): Comprehensive Vascular Access Costs

- Calculation based on cost data of n=2,704 Medicare patients with *maintained vs. not maintained primary patency* (Thamer et al., 2018*)
- Clinical inputs: Access circuit primary patency rates (12M, from IN.PACT AV Access Trial)
- Cost Inputs: Annualized vascular access costs per patient per year from Thamer et al, 2018
- Analysis horizon:
 - 30M (Thamer et al. study follow-up)

*Thamer M, Lee T, Wasse H et al, Medicare Costs Associated with AV Fistulas Among US Hemodialysis Patients. *Am J Kidney Dis.* 2018 Jul;72(1):10-18

Methods and Materials

Approach 1 (Primary Analysis): Reintervention Event Based Costs

Clinical Effectiveness (IN.PACT AV Access Trial)	IN.PACT AV DCB	Standard PTA	Difference (95% CI)	p-value
Mean number of interventions required to maintain access circuit patency (12M)	0.65	1.05	-0.4 [-0.6, -0.2]	<0.001

Cost Data – US	Cost	Source/Comment
PTA Procedure Cost	\$3,142	Weighted average CY 2020 payment (51% OBL, 26% hospital outpt., 19% ASC, 4% inpt.)
DCB Procedure Cost	\$3,142 (+ any additional DCB therapy cost)	Same as PTA, plus incremental DCB therapy cost (exploratory analysis in absence of established therapy cost)
Reintervention cost	\$3,475	Weighted average payments, assuming 85% PTA, 10% stent placement, 5% thrombectomies and surgical interventions as observed in trial

Other Inputs and Assumptions

- 1.23 DCBs per procedure
- Mortality HR of ESRD population: 6.75 (IN.PACT AV Access Trial relative to general US population mortality)
- Discount rate for health care costs: 3% p.a.



Methods and Materials

Approach 2 (Secondary Analysis): Comprehensive Vascular Access Costs

Clinical Effectiveness (IN.PACT AV Access Trial)	IN.PACT AV DCB	Standard PTA	Difference (95% CI)	p-value
Access circuit primary patency (12M)	53.8%	32.4%	21.4% [10.2%, 32.6%]	<0.001

Costs: Per-Patient Per-Year Vascular Access Related Costs Based on AVF Outcomes in Year 1 post AVF Creation*		
Medicare Cohort: Patients initiating HD with a mature AVF	Costs in Patients who Maintained Primary Patency	Costs in Patients who Experienced Loss of Primary Patency
Year 1	\$6,442 ± \$8,882	\$15,009 ± \$16,896
Year 2	\$4,279 ± \$11,378	\$7,403 ± \$14,179
Average Per-Patient-Per-Year Costs	\$5,560 ± \$8,368	\$11,761 ± \$15,871

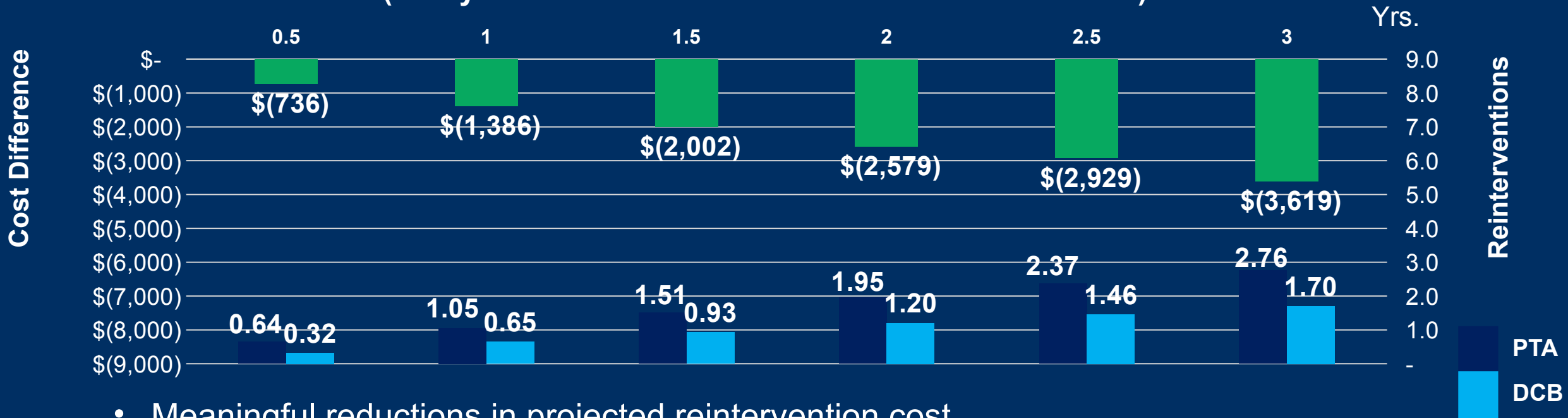
Adjusted to 2019 US\$

Resulting Total Per-Patient Costs at 2.5 Years	\$16,315	\$34,511
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Results: Primary Analysis

Reintervention Rates & Follow-up Cost Difference, IN.PACT AV DCB vs PTA, Years 1-3
(Analysis considers no add-on DCB reimbursement)

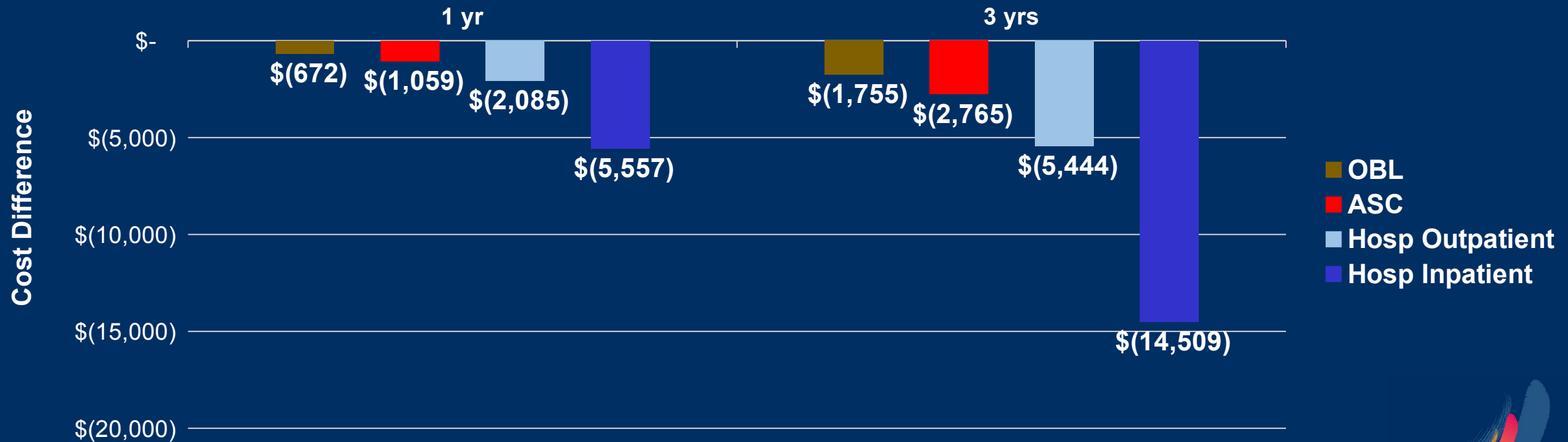


- Meaningful reductions in projected reintervention cost
- If DCB cost is \$1,800 or less, DCB strategy would break-even at 2 years horizon and achieve savings of ~\$1,400 at 3 years horizon



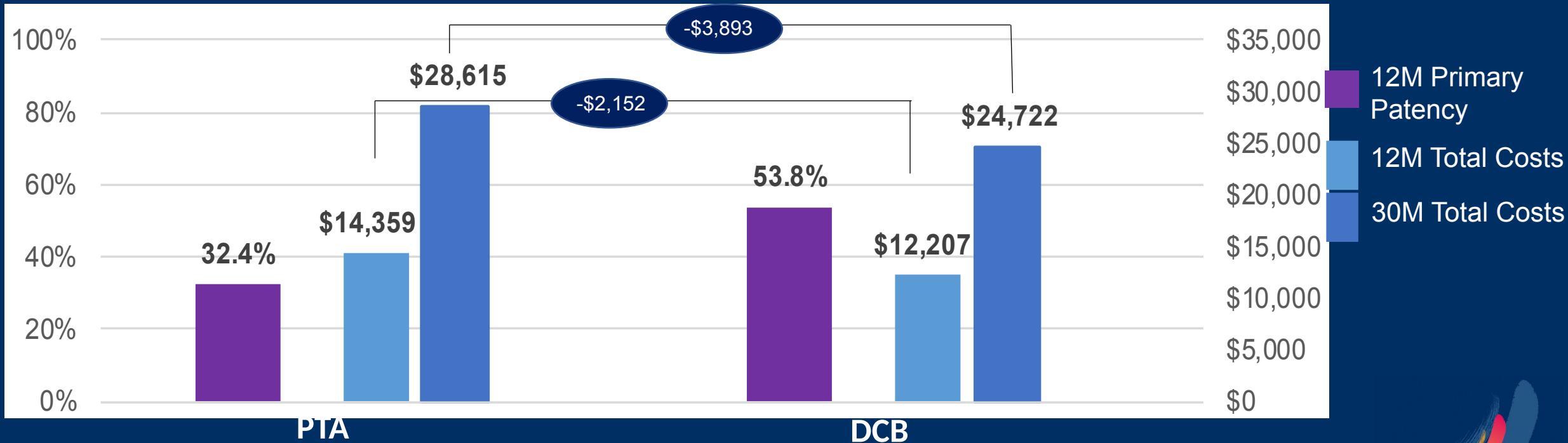
Results: Primary Analysis, by Site of Service

Follow-up Cost Difference for DCB vs. PTA at 1 and 3 years, by Site of Service



Results: Secondary Analysis

12M Primary Patency and Corresponding 12M and 30M Estimated Costs PTA vs. DCB



- Notable cost reductions at one and 2.5 years
- For DCB cost of \$1,800, cost-neutrality at 12M and savings >\$1,650 at 2.5 yrs.



Additional Results & Implications at Healthcare System level

- **Number needed to treat (NNT)** to avoid one reintervention: **2.48**
- Over a one-year horizon, **cost per reintervention avoided**:
 - **\$1,680** for assumed incremental DCB therapy cost of \$2,000
 - **\$3,050** for assumed incremental DCB therapy cost of \$2,500
- **Potential savings to Medicare** if 50% of current 233,000 annual procedures performed with DCB instead of PTA:
 - **\$160-250M** over one year
 - **>\$420M** over three years
- **If incremental DCB device reimbursement is implemented**, the improved clinical outcomes could be achieved at overall cost savings at 2.5 years as long as device reimbursement is <\$2,380*

*Using the more conservative calculation (Approach 1); based on Approach 2, amount would increase to \$3,165.



Conclusions

- Using two independent calculation approaches, treatment with the IN.PACT AV DCB can be expected to lead to **substantive per-patient and health system savings**
- Savings increase with longer analysis horizon, and vary by site of service
- Reductions in reinterventions can help reduce patient morbidity and improve quality of life
- *Findings are based on data from the IN.PACT AV ACCESS Trial and may not apply to other DCB devices*

