HARVARD MEDICAL SCHOOL
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The Economic Value of Drug Eluting Balloons in Femoropopliteal Revascularization

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Conflicts of Interest

- **Consultant**
  - Abbott Vascular (non-compensated)
  - American Genomics, Inc
  - Astra Zeneca Pharmaceuticals, Inc
  - Biomet Biologics
  - Boston Scientific (non-compensated)
  - Cordis Corporation (non-compensated)
  - Covidien (non-compensated)
  - Ekos Corporation (DSMB)
  - Medtronic (non-compensated)
  - Micell, Inc
  - Primacea

- **Equity**
  - Access Closure, Inc
  - Embolitech, Inc
  - Hotspur, Inc
  - Icon Interventional, Inc
  - I.C.Sciences, Inc
  - Janacare, Inc
  - MC10
  - Northwind Medical, Inc.
  - PQ Bypass, Inc
  - Primacea
  - Sadra Medical
  - Sano V, Inc.
  - Vascular Therapies, Inc

- **Board Member**
  - VIVA Physicians (Not For Profit 501(c) 3 Organization)
    - www.vivapvd.com
  - CBSET

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Technology is Undoubtedly Improving Our Ability to Treat Patients with PAD….

SFA – Intermittent Claudication

- Reduce repeat revascularizations
- Improve quality of life and physi
  - Walking capacity
  - Positive ment

…ritical Limb Ischemia

- …mputations
- Improve wound healing
- Reduce repeat revascularizations
- Reduce hospital time
- Improve quality of life and physical function
  - Walking capacity

How Can We Pay For All Of This?

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Our Study: Health-Economic Analysis

Objective

Develop budget impact model to estimate 24-month costs to payers for four **SFA** index procedure modalities: PTA, BMS, DEB, DES

Methods

- Systematic Pubmed and EMBASE search for published trials and registries reporting TLR rates in femoral and/or popliteal artery disease
- Pooling of TLR rates, weighting by sample size
- Decision-analytic modeling to estimate total costs over 24-months;
- KEY ASSUMPTIONS:
  - 24-month period; constant TLR hazard rates assumed
  - Up to 1 revascularization post index procedure (modality distribution based on expert opinion)
  - Surgical bypass not considered as a revascularization technique; atherectomy only considered for TLR
  - Typical patient: 70 yo WM with PAD, Rutherford 3 Symptoms

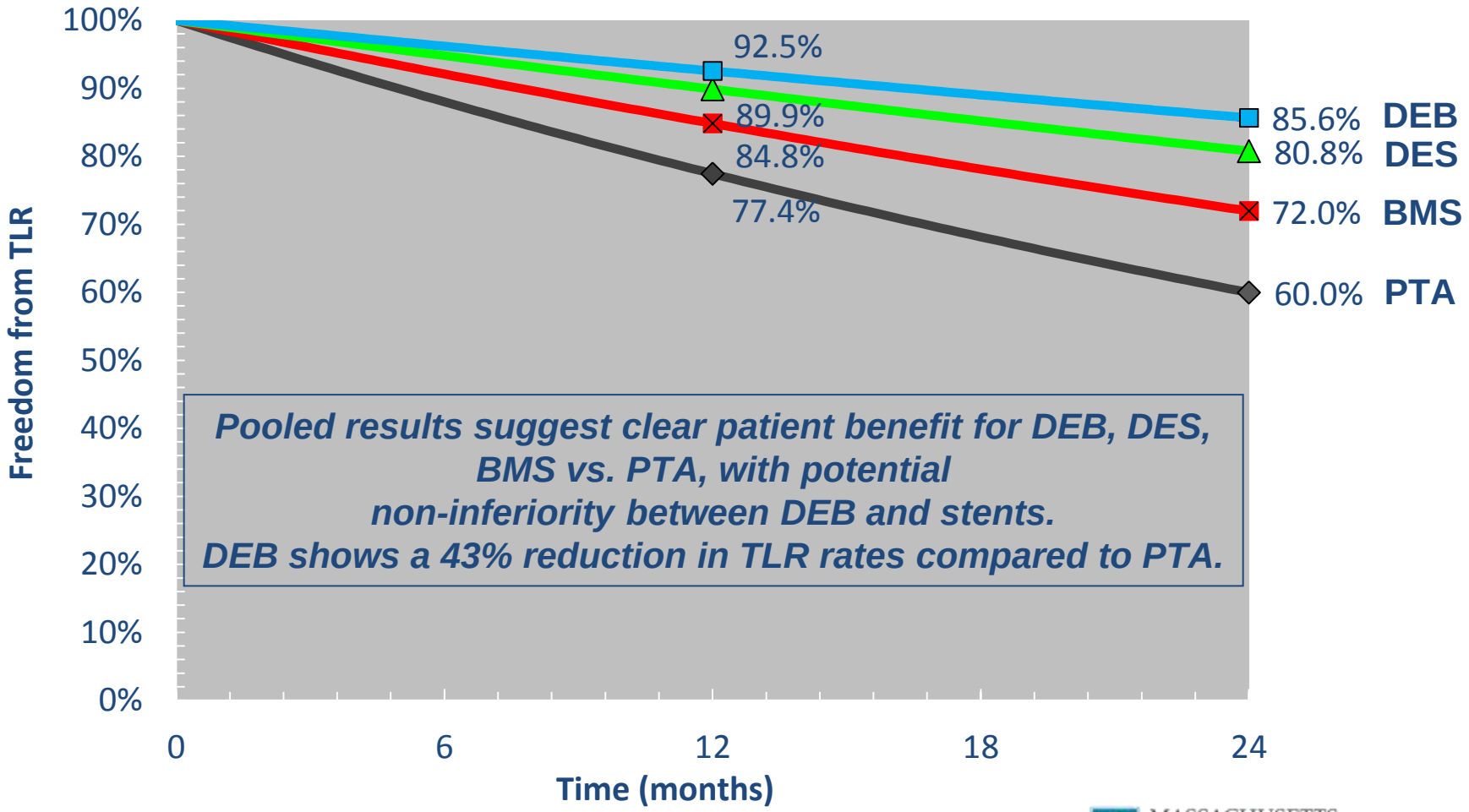
These Are The Clinical Trials We Identified in the Literature…

Trial	Year	Comparators/Arms (n)	Age	Lesion (cm)	TLR probabilities as reported (and calculated 6mo) PTA	DEB	BMS	DES
SIROCCO	2006	46 BMS / 47 DES	66	8.3			13% (3%)	6% (2%)
FAST	2007	121 PTA / BMS	67	4.5	18% (10%)		15% (8%)	
THUNDER	2008	54 PTA / 48 DEB	68	7.4	37%	4%		
FEM-PAC	2008	42 PTA / DEB	68	5.9	33%	7%		
ZILVER PTX SAS *,†	2011	DES: 787	68	6.4				17% (5%)
ZILVER PTX RCT *,†	2011	DES: 236	68	6.4				13% (4%)
ZILVER PTX (published)	2011	125 PTA / 62 DES	67	6.5	18% (2%)			10% (5%)
Shammas *et al.*	2011	48 PTA / atherect.	69	9.1	17% (9%)			
STRIDES	2011	104 DES	69	9.0				20% (11%)
PACIFIER *	2012	44 PTA / 47 DEB	71	6.8	28%	7% (3.6%)		
RESILIENT	2012	53 PTA / BMS	67	6.7	58% (14%)		25% (5%)	
Micari *et al.* registry	2012	105 DES	68	7.3		8% (4%)		

SIROCCO and STRIDES included in base case, excluded in scenario analysis

† only TLR for DES arm available – we combined TLR rates for randomized controlled trial and single arm study;
* Conference publication only

Clinical Model Results:
Freedom from TLR over 24 Months (pooled)



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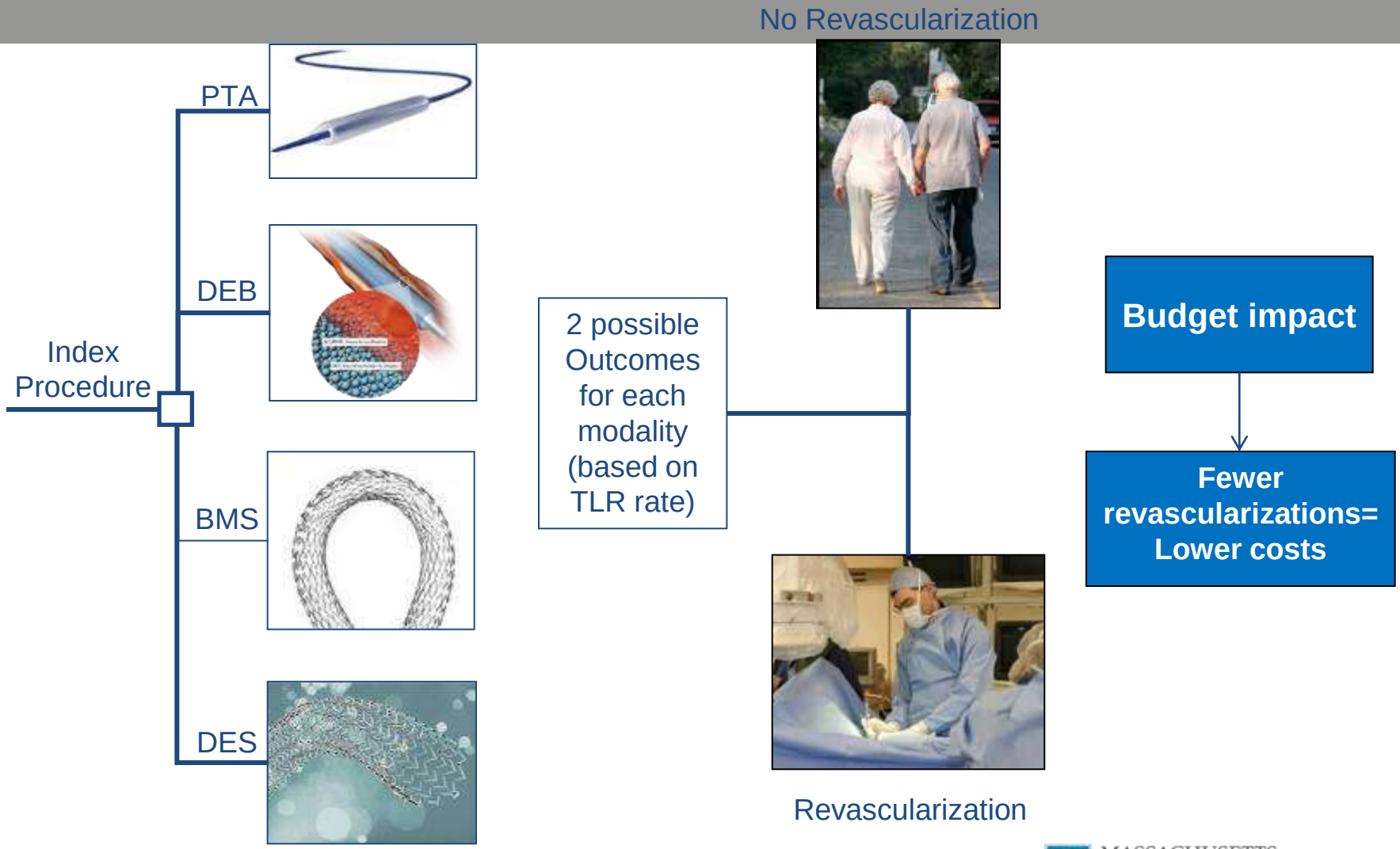
Structure of Decision-Analytic Model



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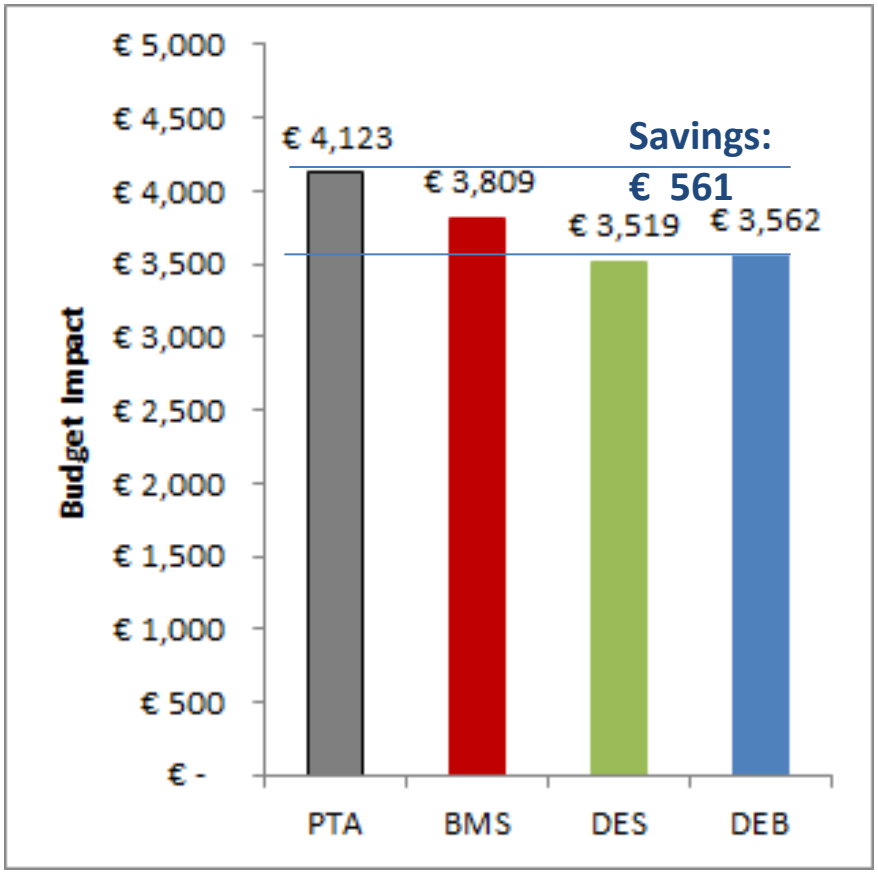
German Healthcare System Perspective

24-month Payer Cost by Index Procedure

Total G-DRG payments per patient over 24 months, index-procedure and possible revascularization



Based on 2013 German DRG schedule.

- DES and DEB least costly index procedure strategies over 24 months
- Per patient savings:
  - € 561 for DEB vs. PTA index procedure
- Potential total savings/yr.:
  - For hypothetically assumed 25,000 cases per year treated with DEB instead of PTA in German healthcare system

~ € 14 M savings

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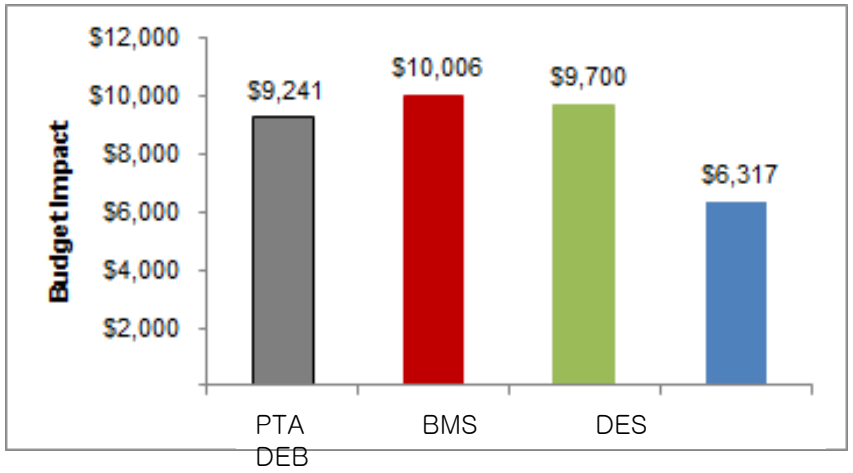
Results: U.S. Budget Impact, 100% Outpatient

Medicare Perspective

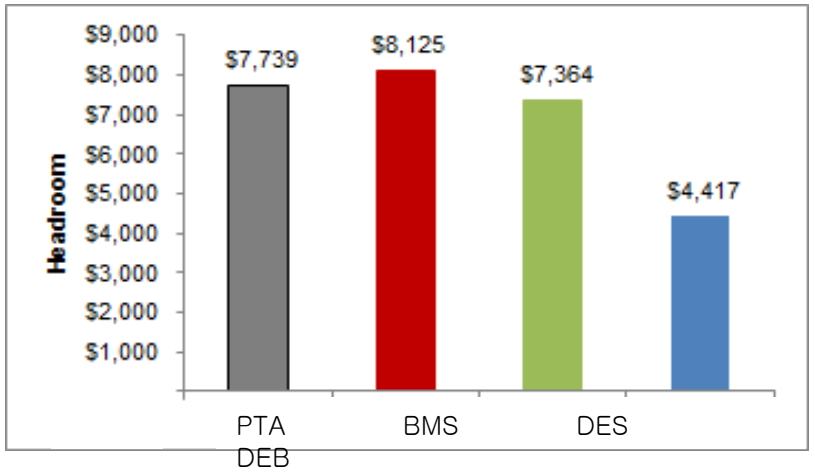
Total **charges*** for 24 months post index-procedure



Rank	Strategy	24-month total Cost	Incremental Costs (to lowest-cost strategy)
1	DEB	$ 6,317	
2	PTA	$ 9,241	$ 2,924
3	DES	$ 9,700	$ 3,383
4	BMS	$ 10,006	$ 3,689

Facility Provider Perspective

Total **headroom** (APC – device price) for 24 mths



Rank	Strategy	24-month total headroom	Incremental (to highest-profit strategy)
1	BMS	$ 8,125	
2	PTA	$ 7,739	($ 386)
3	DES	$ 7,364	($ 761)
4	DEB	$ 4,417	($ 3,708)

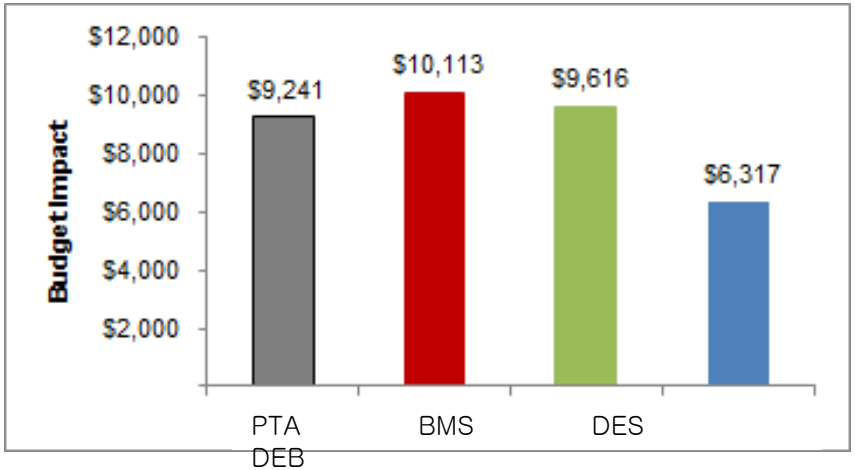
Assumption: DEB reimbursed at PTA rate; DES at BMS rate. * Charges= 2012 Medicare APC Schedule

Results: U.S. Budget Impact, 100% Outpatient

STRIDES and SIROCCO excluded

Medicare Perspective

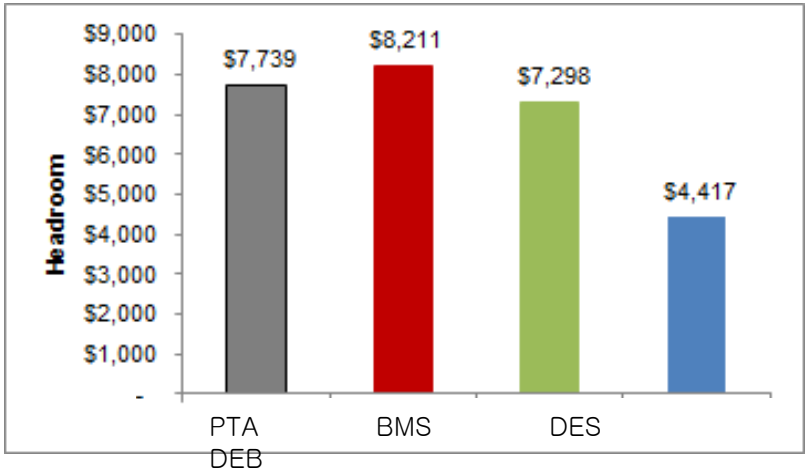
Total **charges*** for 24 months post index-procedure



Rank	Strategy	24-month total Cost	Incremental Costs (to lowest-cost strategy)
1	DEB	$ 6,317	
2	PTA	$ 9,241	$ 2,924
3	DES	$ 9,616	$ 3,299
4	BMS	$ 10,113	$ 3,797

Facility Provider Perspective

Total **headroom** (APC – device price) for 24 mths



Rank	Strategy	24-month total headroom	Incremental (to highest-profit strategy)
1	BMS	$ 8,211	
2	PTA	$ 7,739	($ 472)
3	DES	$ 7,298	($ 913)
4	DEB	$ 4,417	($ 3,793)

Numbers Needed to Treat (NNT) to Avoid 1 TLR Over 24 Months

DEB vs. PTA

- Freedom from TLR at 24 months: 85.6% for DEB vs. 60.0% for PTA
- Absolute difference : 25.6%
- **NNT : 4**

DEB vs. BMS

- Freedom from TLR at 24 months: 85.6% for DEB vs. 72.0% for BMS
- Absolute difference : 13.6%
- **NNT : ~7**

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Limitations

- Clinical Data
  - Comparative data still limited, especially RCTs
  - TLR rates vary highly between trials
  - For some trials, only 6-month TLR rates available
  - Study designs and populations vary

- Budget Impact Model
  - Constant TLR hazard rates assumed
  - Only includes up to one potential TLR post index procedure
  - Distribution of reintervention modalities based on expert opinion
  - Reintervention strategies assumed constant over time
  - Quality of life/ functional health status impact not considered

What's Missing?

IN.PACT SFA

Randomized Trial of IN.PACT Admiral DCB vs. PTA for the Treatment of Atherosclerotic Lesions in the SFA and/or PPA

1-year Primary Outcomes

Gunnar Tepe - RoMed Klinikum Rosenheim, Rosenheim (Germany)

Peter Schneider - Hawaii Permanente, Honolulu, HI (US)

John Laird - UC Davis Medical Center, Sacramento, CA (US)

on behalf of the IN.PACT SFA Investigators

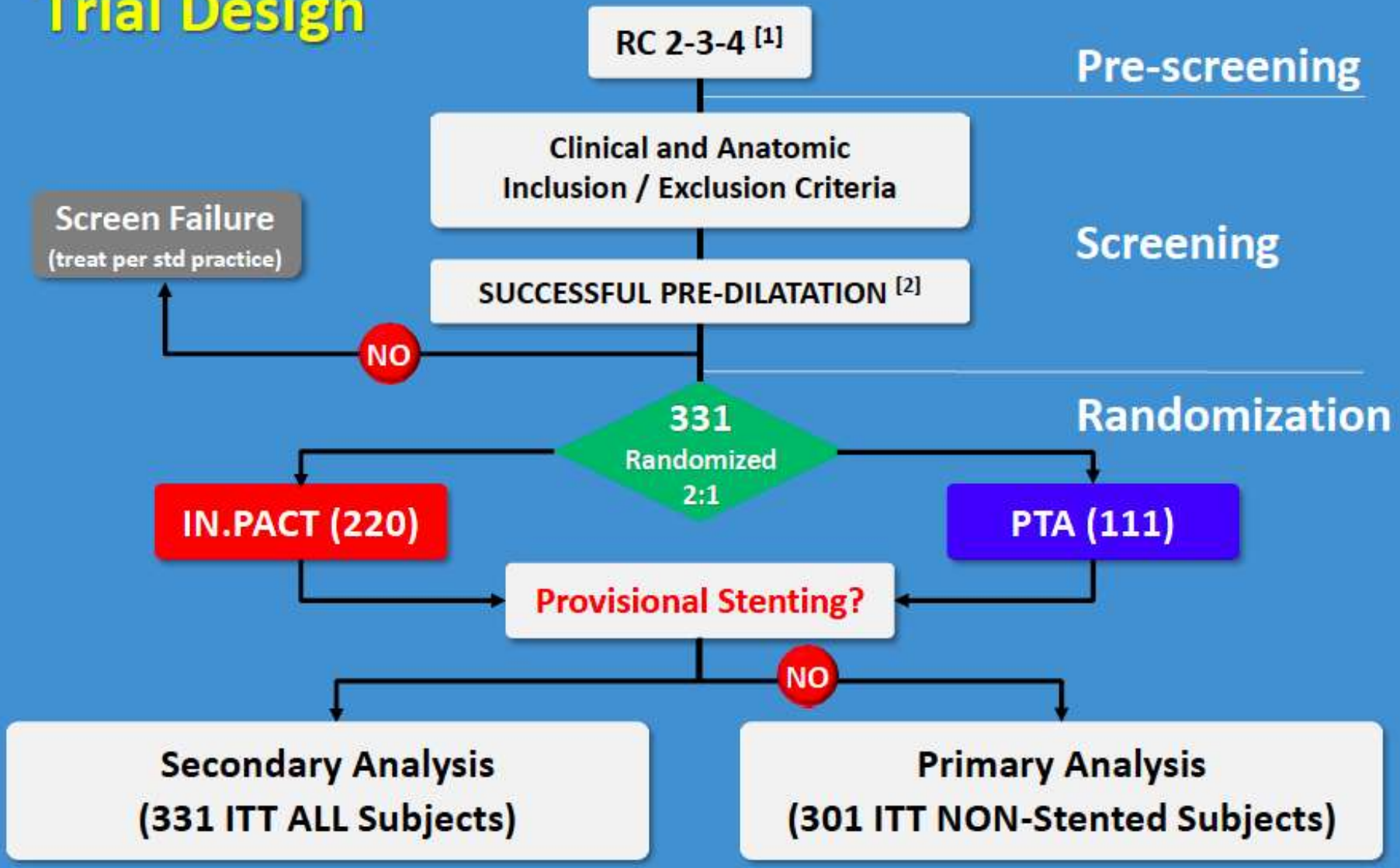
IN.PACT SFA Trial Overview

IN.PACT Admiral DCB vs. standard PTA
for the treatment of superficial femoral and proximal popliteal artery disease due to claudication and rest pain

- Prospective, multicenter EU and US, randomized (2:1), single blinded
- Independent and blinded Duplex Ultrasound Core Lab [1], Angiographic Core Lab [2], and Clinical Events Committee [3]
- Independent Data Safety Monitoring Board [3]
- External monitoring with 100% source data verification
- Subjects followed up to 5 years

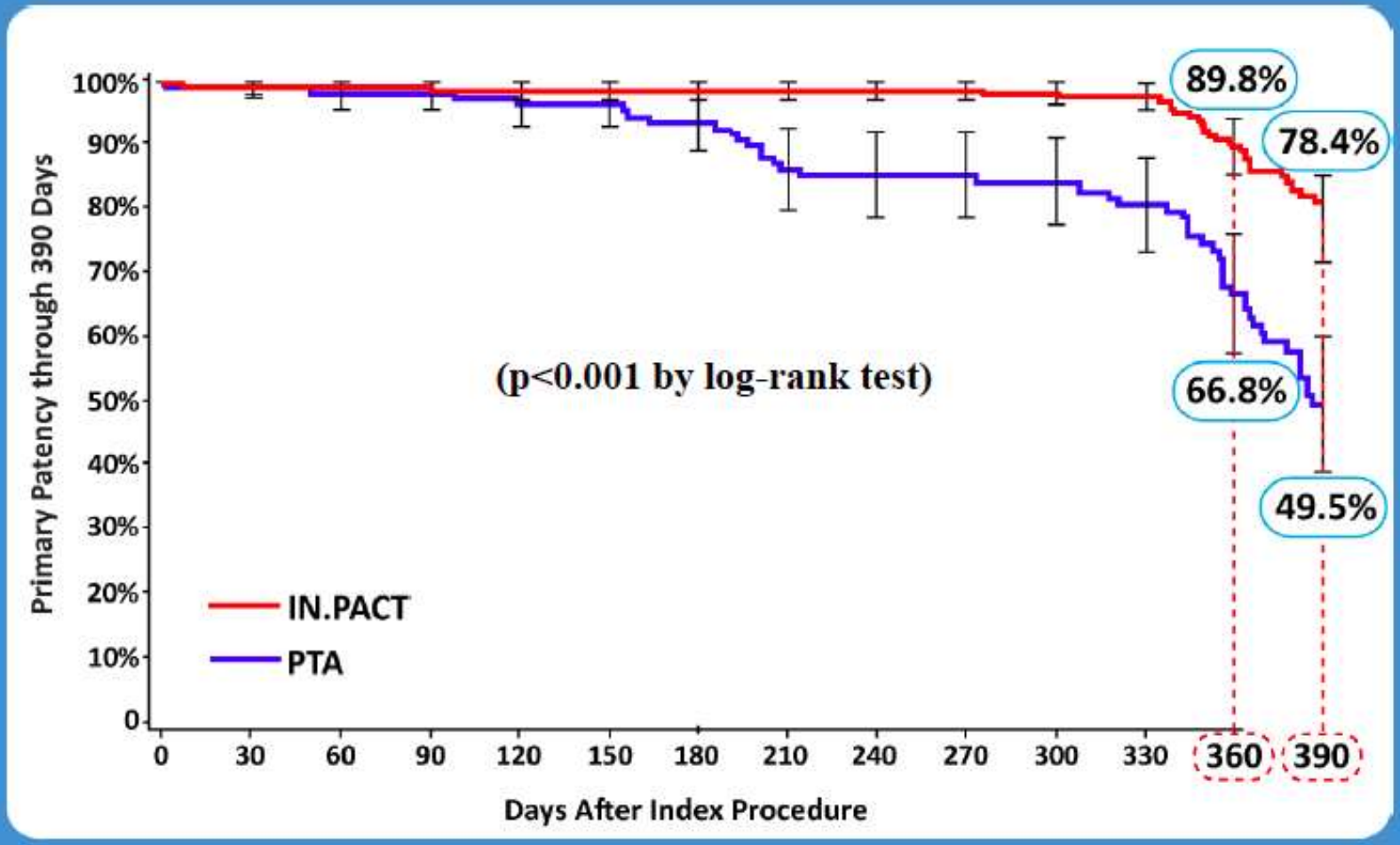
1. VasCore DUS Core Laboratory, Boston, MA, US
2. SynvaCor Angiographic Core Laboratory, Springfield, IL, US
3. Clinical Events Committee and Data Safety Monitoring services provided by HCRI, Boston, MA, US

Trial Design



1. With symptoms of claudication and/or rest pain and angiographic evidence of SFA/PPA stenosis
2. Pre-dilatation mandatory for all subjects in IN.PACT SFA II phase only

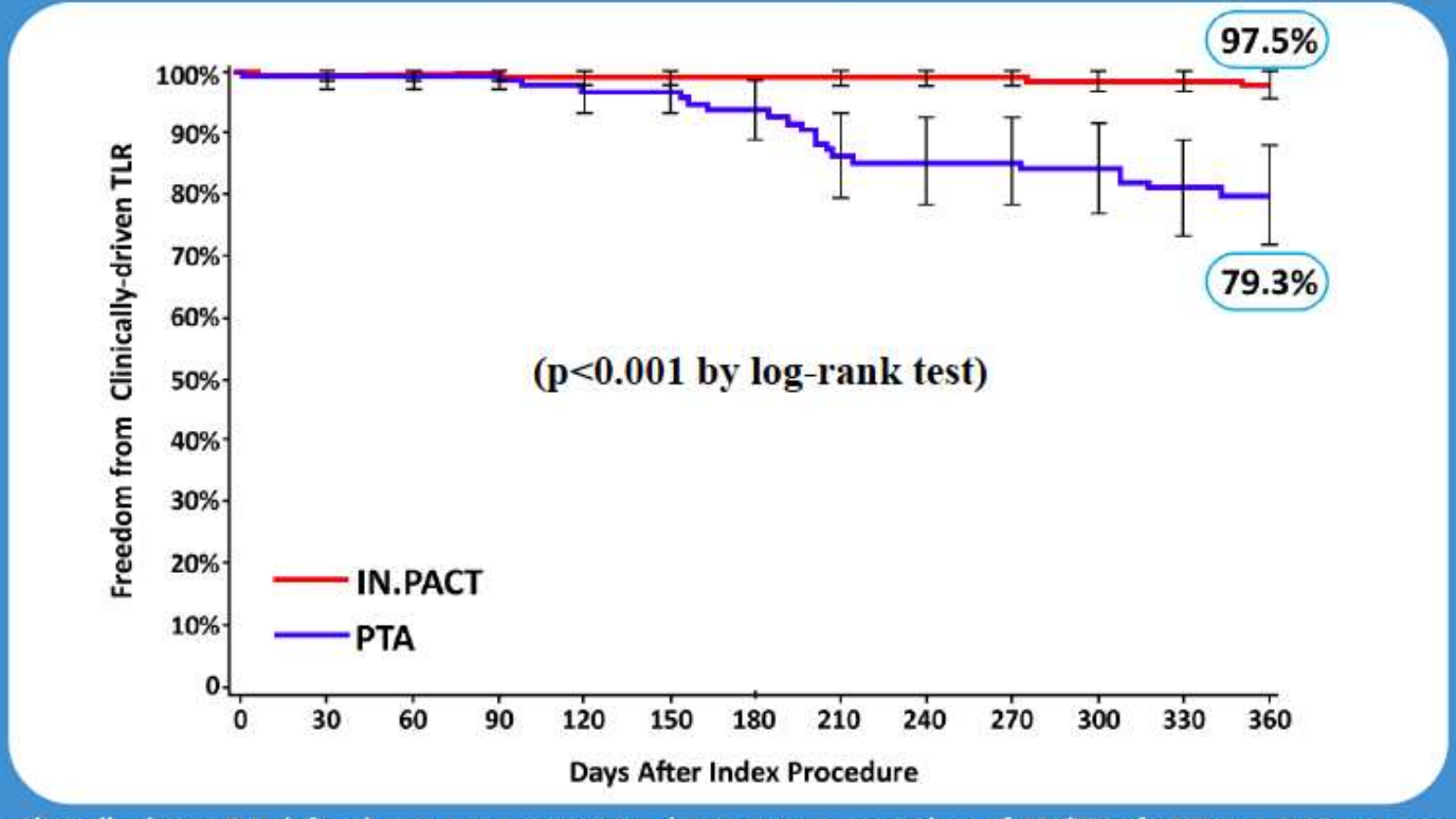
ALL ITT, 12-month Primary Patency [1]



1. Primary patency is defined as freedom from clinically-driven TLR and freedom from restenosis as determined by duplex ultrasound (DUS) Peak Systolic Velocity Ratio (PSVR) ≤ 2.4

ALL ITT, 12-month Clinically-driven TLR

	IN.PACT	PTA	*p*
Clinically-driven TLR [1]	2.4%	20.6%	*<0.001* [2]



1. Clinically-driven TLR defined as any re-intervention due to symptoms or drop of ABI/TBI of >20% or >0.15 compared to post-procedure ABI/TBI
2. Actual event rate by frequency ratio algorithm calculation

ALL ITT, Safety Outcomes

	IN.PACT	PTA	p
Primary Safety Composite [1]	**95.7% (198/207)**	**76.6% (82/107)**	***<0.001***
30-day Device- and Proc.-related Death	0.0% (0/218)	0.0% (0/111)	*>0.999*
12-month Clinically-driven TVR	4.3% (9/207)	23.4% (25/107)	*<0.001*
12-month Target Limb Major Amputation	0.0% (0/207)	0.0% (0/107)	*>0.999*
12-month Major Adverse Events [2]	**6.3% (13/207)**	**24.3% (26/107)**	***<0.001***
All-cause Death	1.9% (4/207)	0.0% (0/107)	*0.926*
Clinically-driven TVR	4.3% (9/207)	23.4% (25/107)	*<0.001*
Target Limb Major Amputation	0.0% (0/207)	0.0% (0/107)	*>0.999*
Thrombosis	1.4% (3/207)	3.7% (4/107)	*0.096*

1. Freedom from 30-day device and procedure-related death and target limb major amputation and clinically-driven TVR within 12 months
2. Composite of death, clinically-driven TVR, target limb major amputation, and thrombosis within 12 months

SFA Conclusions

- Pooling analysis suggests clear patient benefit for DEB, BMS, DES vs. PTA, with potential non-inferiority between BMS, DES, and DEB
- From the payer perspective, DEB is financially attractive in Germany and represents significant savings potential vs. PTA
- If reimbursed at current PTA rate in markets like the US, DEB will be financially attractive to payers, but access may be impacted because of financial constraints of providers
- DEB combines clinical benefits with economic value. Future reimbursement should consider the value proposition of DEB and balance it with provider incentives for adoption
- **Clinicians and providers must work to influence reimbursement rates to improve patient access to improved clinical results**

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