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Device Choice for Femoropopliteal Therapy: Does This Predict Cost Effectiveness?

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Conflicts of Interest

- **Consultant**

- Abbott Vascular (non-compensated)
- AOPA
- Boston Scientific (non-compensated)
- Cardinal Health
- Cordis Corporation (non-compensated)
- Janacare, Inc
- Medtronic (non-compensated)
- Micell, Inc
- Novella (DSMB)
- Primacea
- Valiant
- Volcano

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- **Equity**

- Access Closure, Inc
- Embolitech
- I.C.Sciences, Inc
- Janacare, Inc
- MC10
- Northwind Medical, Inc.
- PQ Bypass, Inc
- Primacea
- Sano V, Inc.
- Vascular Therapies, Inc

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Background

- TLR is impacted by the initial choice of endovascular strategy
- The economic implications of procedure choice are affected by the initial procedure costs, the associated TLR risk, and the costs associated with repeat revascularization procedures
- The long-term clinical effectiveness of Supera has been demonstrated in the SUPERB clinical trial where freedom from TLR is sustained over a 3-year period
- Its economic impact compared to other endovascular strategies is not known

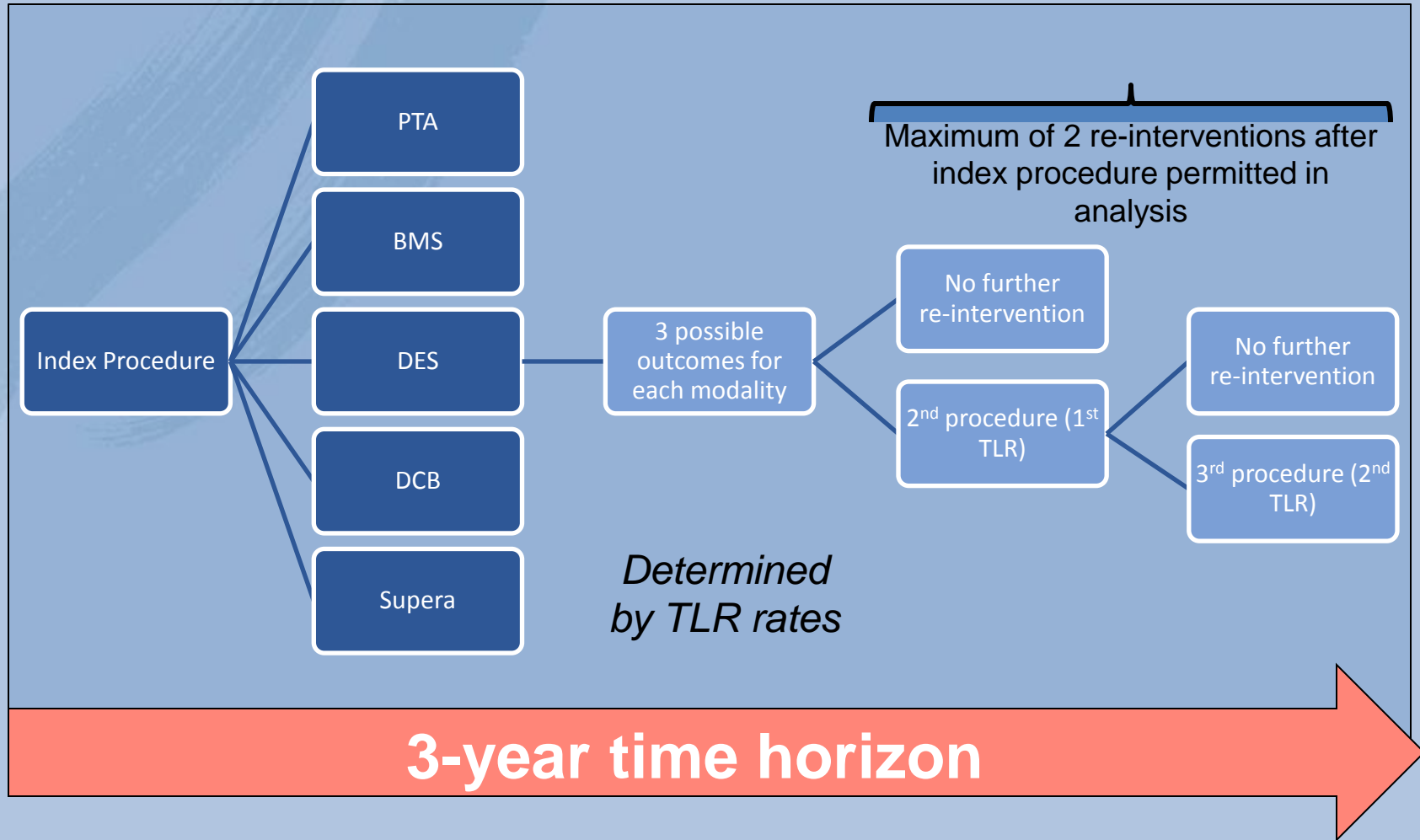
Objective

- To evaluate the 3-year economic impact of 5 different endovascular strategies for the treatment of femoropopliteal peripheral artery disease (PAD) from the perspectives of the United States (US) payer and provider

Methods

- 5 endovascular strategies included in the analysis:
 - Angioplasty (PTA)
 - Bare Metal Stent (BMS)
 - Drug Eluting Stent (DES)
 - Drug Coated Balloon (DCB)
 - Interwoven Nitinol Stent (Supera)
- Risk of TLR was used to estimate the expected number of re-interventions per patient for each strategy

Model Concept



TLR Rates

- Rates were obtained from US investigational device exemption (IDE) studies published in peer-reviewed journals for PTA, BMS, DES, and DCB procedures
- The SUPERB trial provided the risk of TLR with Supera*
- Only IDE studies were chosen to ensure high quality and consistent clinical trial methodology
- When reported follow-up was less than 3 years, probabilities were extrapolated to estimate the TLR risk assuming an exponential distribution

IDE trials included in the analysis: DURABILITY II, RESILIENT, COMPLETE SE, STROLL, ZILVER PTX, LEVANT II, IN.PACT SFA, SUPERB

**Manuscript submitted for publication*

Pooled 3-Year TLR Risk From IDE Trials

Strategy	Pooled 36 month TLR	Sources
PTA ¹	46.4%	RESILIENT, ZILVER PTX, LEVANT II, IN.PACT SFA
BMS ¹	29.2%	DURABILITY II, RESILIENT, COMPLETE SE, STROLL
DES ²	19.4%	ZILVER PTX
DCB ¹	24.6%	LEVANT II, IN.PACT SFA
Supera ³	6.0%	SUPERB

¹ Weighted average taken based on sample size and extrapolation carried out assuming exponential survival function.

² Extrapolation carried out assuming exponential survival function.

³ SUPERB nominal deployment

Kaplan-Meier point estimates for TLR rates

Data Sources: PTA: Laird 2012, Dake 2011, Rosenfield 2015, Laird 2015; BMS: Rocha-Singh 2015, Laird 2012, Laird 2014, Gray 2015; DES: Dake 2013; DCB: 2014-Rosenfield 2015, Laird 2015; Supera: Garcia SUPERB 3-Year VIVA 2014

Baseline Characteristics From Pooled Studies

Characteristic	PTA	BMS	DCB	DES	Supera
Patient characteristics					
Mean age (yrs)	67.9	68.0	67.7	67.9	68.7
Male sex	66%	65%	63%	66%	64%
Claudication (Rutherford 2–3)	92%	96%	93%	90%	95%
CLI (Rutherford 4–6)	7%	3%	7%	9%	5%
Diabetes	43%	44%	42%	50%	44%
Hypertension	86%	88%	90%	89%	94%
Hyperlipidemia	77%	84%	88%	76%	87%
History of smoking	83%	80%	79%	86%	80%
ABI pre-treatment	0.71	0.69	0.75	0.67	0.73
Lesion characteristics					
Lesion length (mm)	68	76	74	66	83
Percent diameter stenosis	79%	80%	81%	80%	78%
Severe calcification	20%	31%	9%	37%	45%

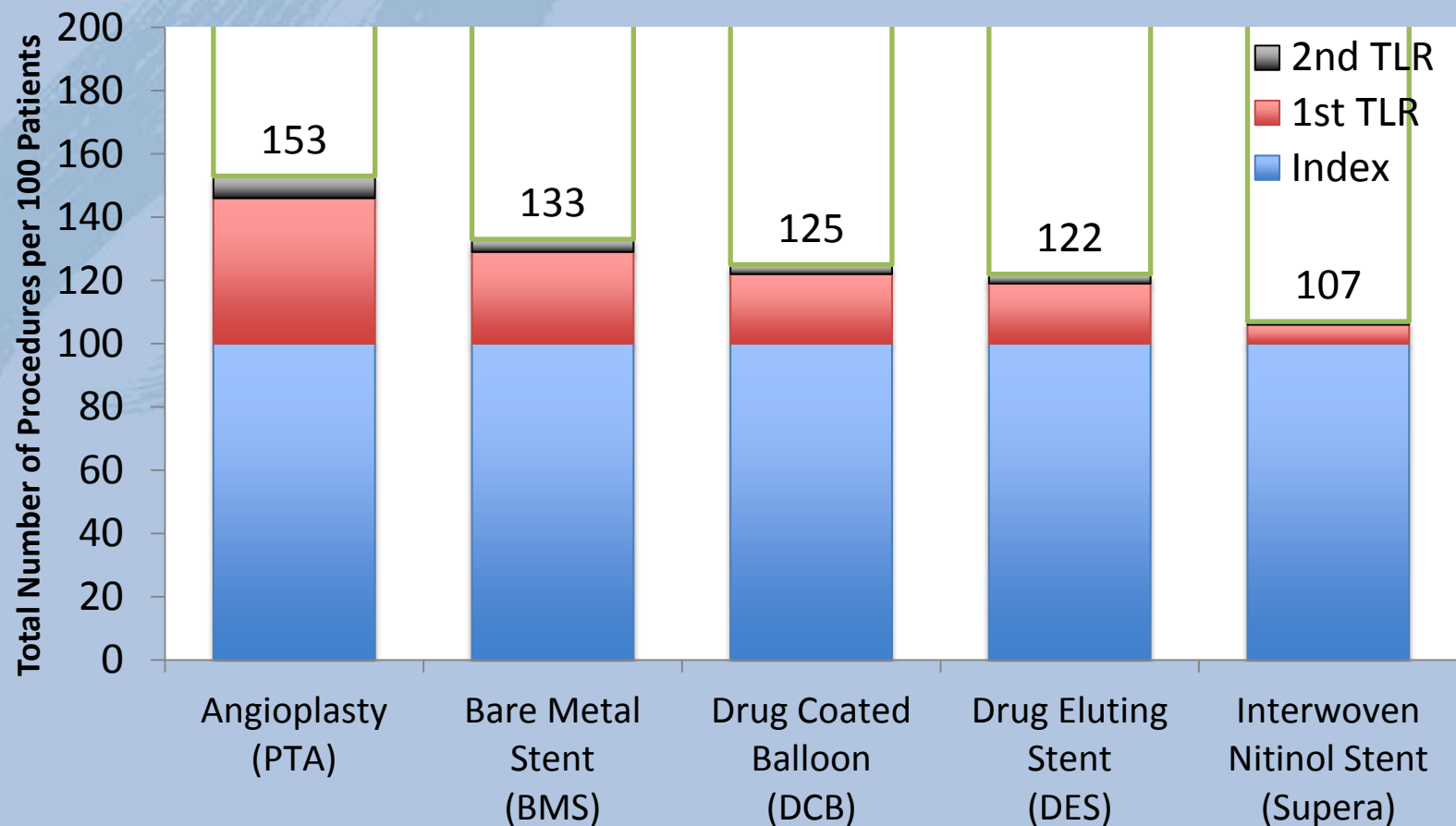
Methods – Costs

- Costs evaluated from the US payer and provider perspectives
- **US payer perspective:** Medicare facility and physician reimbursement
- **Provider perspective:** hospital **remaining payment**, defined as the facility reimbursement payment minus the cost of the device(s) used in the procedure

Input	Amount	Sources / Assumptions
Setting of care: hospital inpatient/outpatient	40%/60%	CMS, 2013 MEDPAR file
Number of devices used per procedure	1	Assumption
Incremental reimbursement for DCBs		
New technology add-on payment (NTAP, hospital inpatient setting)	\$1,036	CMS, full NTAP for all inpatient DCB procedures
Transitional pass-through payment (hospital outpatient setting)	\$1,403	CMS, payment covers full cost of DCB(s) for outpatient procedures

Device costs: PTA - \$187, BMS - \$1,293, DES - \$2,021, DCB - \$1,403, Atherectomy - \$2,859, ViaBahn - \$2,807 (Pietzsch 2014, 2013 dollars converted to 2015 dollars); Supera - \$1,500

Results: Total Number Of Procedures Per 100 Patients Over 3-Years



Number of revascularization procedures calculated using economic model

Risk of a second TLR is assumed to be the same as the risk of the first TLR for a given therapy

Results: Payer Perspective, Cost To Medicare Per Patient Over 3-Years

Treatment	Cost to Medicare Per Patient Over 3-Years
Bare Metal Stent (BMS)	\$16,158
Angioplasty (PTA)	\$15,166
Drug Eluting Stent (DES)	\$14,845
Drug Coated Balloon (DCB)	\$13,421
Interwoven Nitinol Stent (Supera)	\$13,036

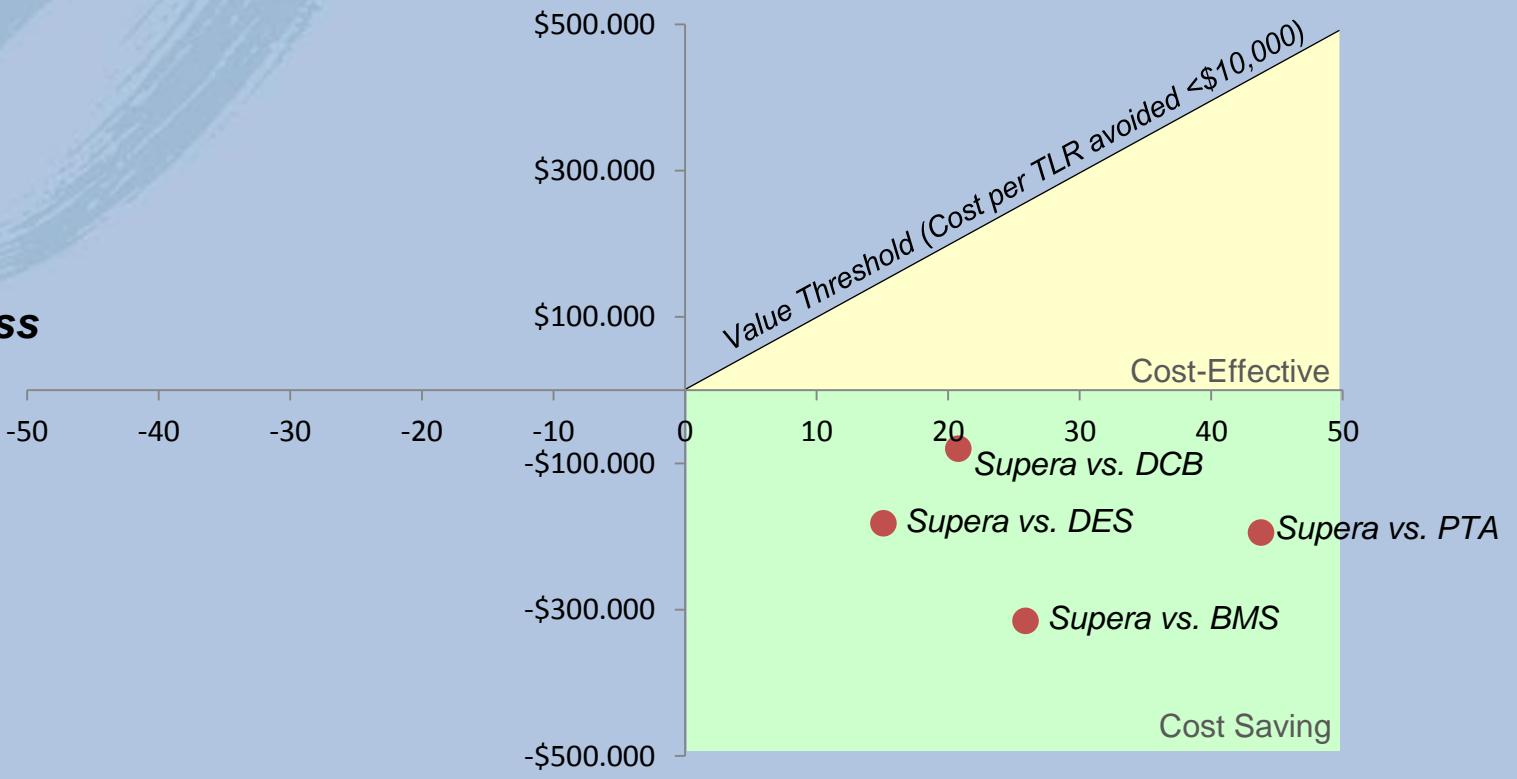
Analysis based on 2015 Medicare national average payment rates

Results: Supera Is Cost-Saving Compared To PTA, BMS, DES, And DCB

Supera Compared to:	PTA	BMS	DES	DCB
Number needed to treat to avoid one TLR with Supera	2	4	7	6

Δ Cost (per 100 patients)

Δ Effectiveness
Number of TLRs
Avoided per 100
patients



Results: Provider Perspective, Hospital Remaining Payment Over 3-Years

Treatment	Total Hospital Remaining Payment* <i>(per 100 patients over 3 years)</i>	Total Number of Procedures <i>(per 100 patients over 3 years)</i>	Average Hospital Remaining Payment* per Procedure <i>(over 3 years)</i>
Supera	\$1.06M	107	\$9,926
BMS	\$1.31M	133	\$9,885
DES	\$1.14M	122	\$9,375
PTA	\$1.31M	153	\$8,588
DCB	\$1.05M	125	\$8,442

** Remaining payment = facility reimbursement – device costs
Analysis based on 100 index procedures per treatment strategy*

Limitations

- TLR risk was based on statistical model using published TLR rates from IDE trials
 - TLR risk may not reflect real world patient outcomes
 - Heterogeneity between trials was not formally incorporated into pooling estimates, although the choice of using only IDE trials helped to mitigate this heterogeneity and sensitivity analysis was conducted to determine the impact of different TLR rates on economic outcomes.
- This model did not consider events such as death, amputation, and atherothrombotic complications (MI, stroke, bleeding), which may have cost implications and affect the subsequent risk of clinical events

Conclusions

In this 3-year economic analysis of various treatment modalities:

- From the patient perspective, Supera has the lowest risk of repeat procedures (TLR)
- From the payer perspective (Medicare), Supera is an economically attractive (i.e., cost-saving) strategy compared to PTA, BMS, DES, and DCB
- From the provider perspective, Supera results in the greatest remaining payment per procedure compared to PTA, BMS, DES, and DCB

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