

Algorithm for Below the Knee Disease When Stenting is Not an Option

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Case 2

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BTK Case #2

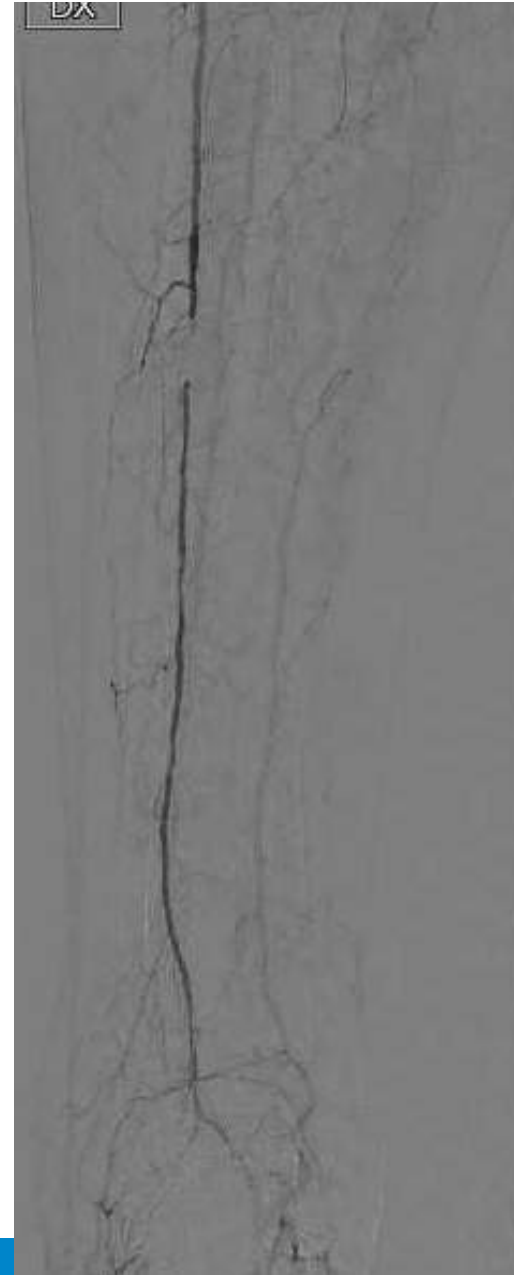
- 80+ year female
- Rutherford class 5
- Medical History
 - Type II diabetes mellitus
 - Hypertension
- Amputation 1st toe right foot, non-healing wound 1st MT
- PTA of anterior tibial artery 5 months earlier



Images courtesy Jos van den Berg, MD

BTK Case #2

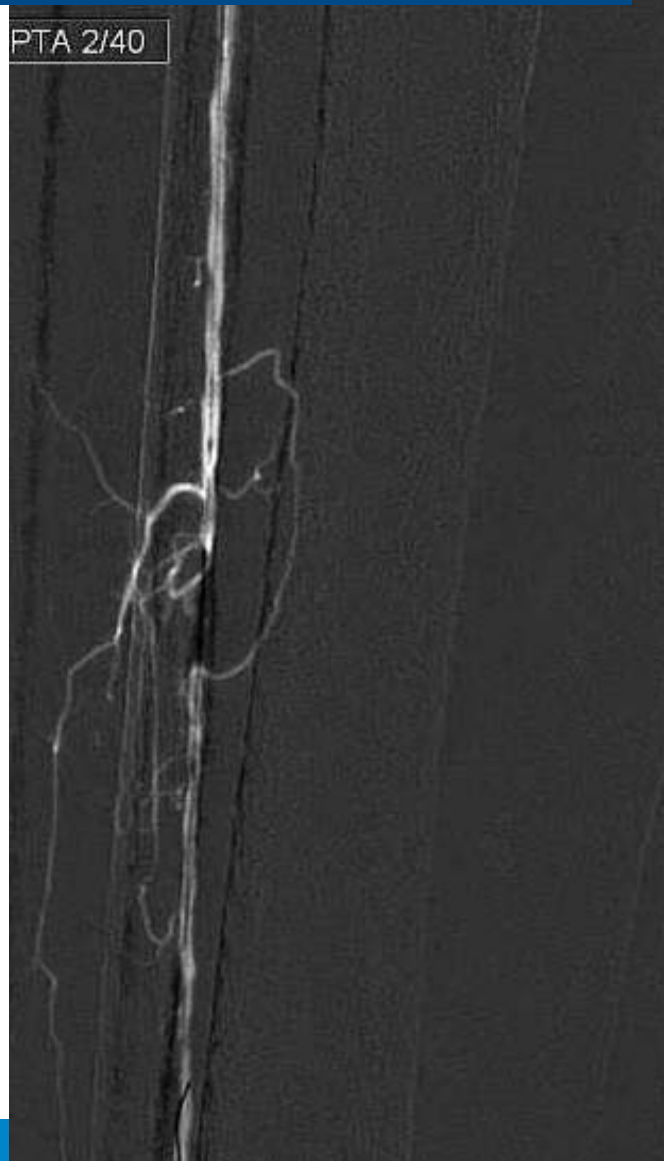
Baseline Angiogram 3 months earlier



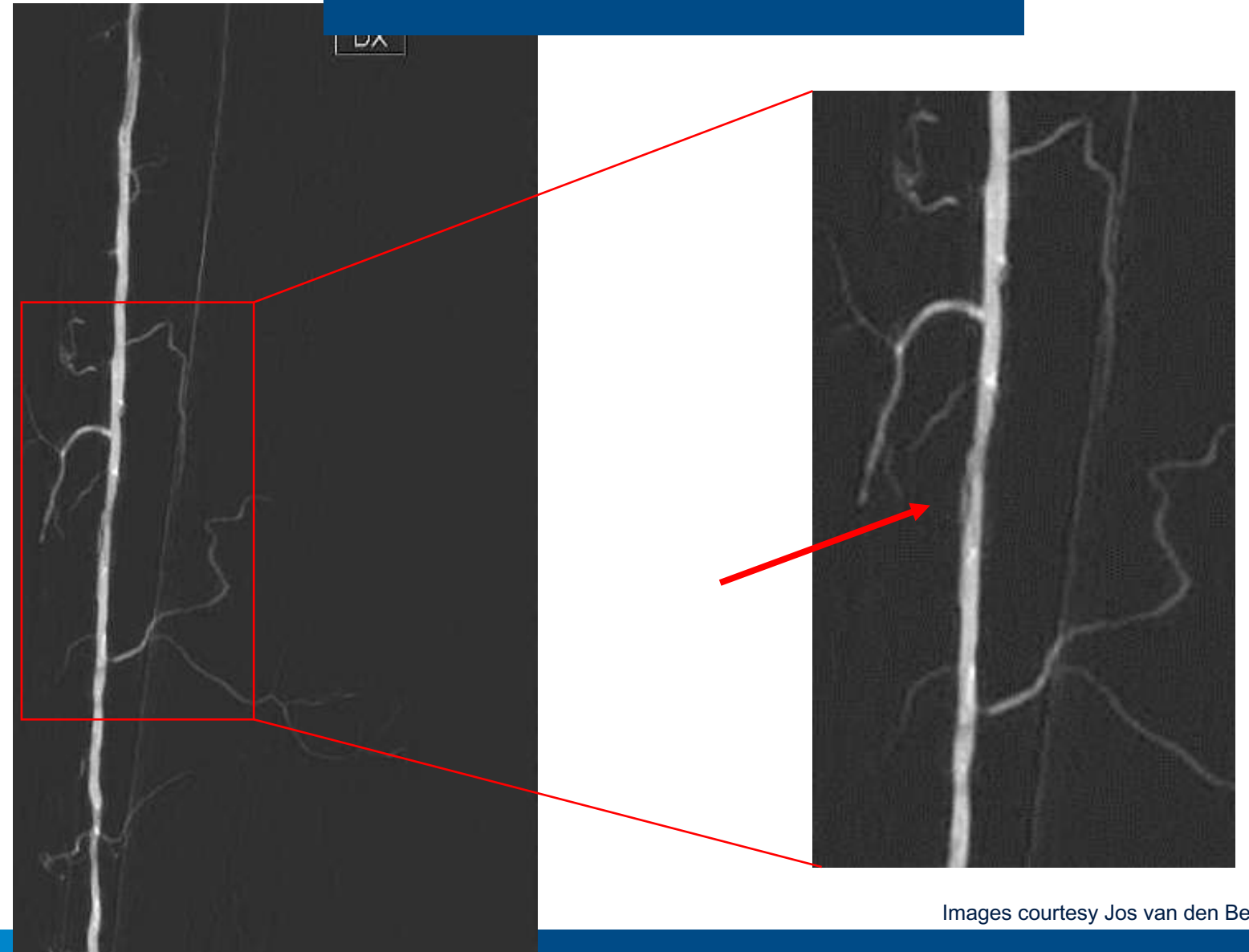
Images courtesy Jos van den Berg, MD

BTK Case #2

Procedure



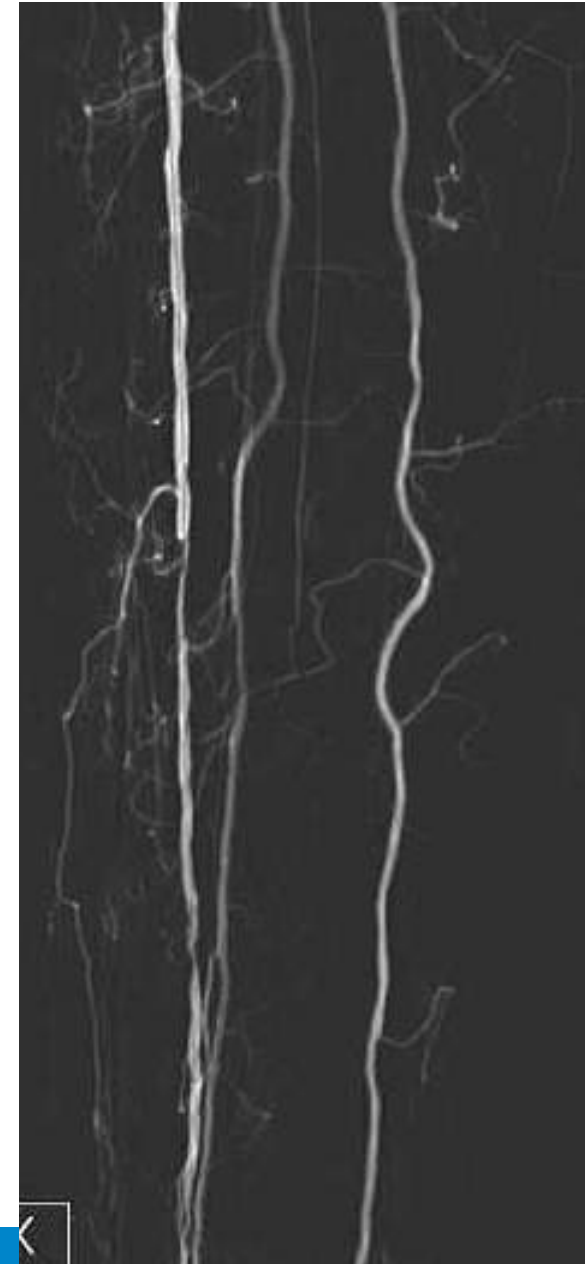
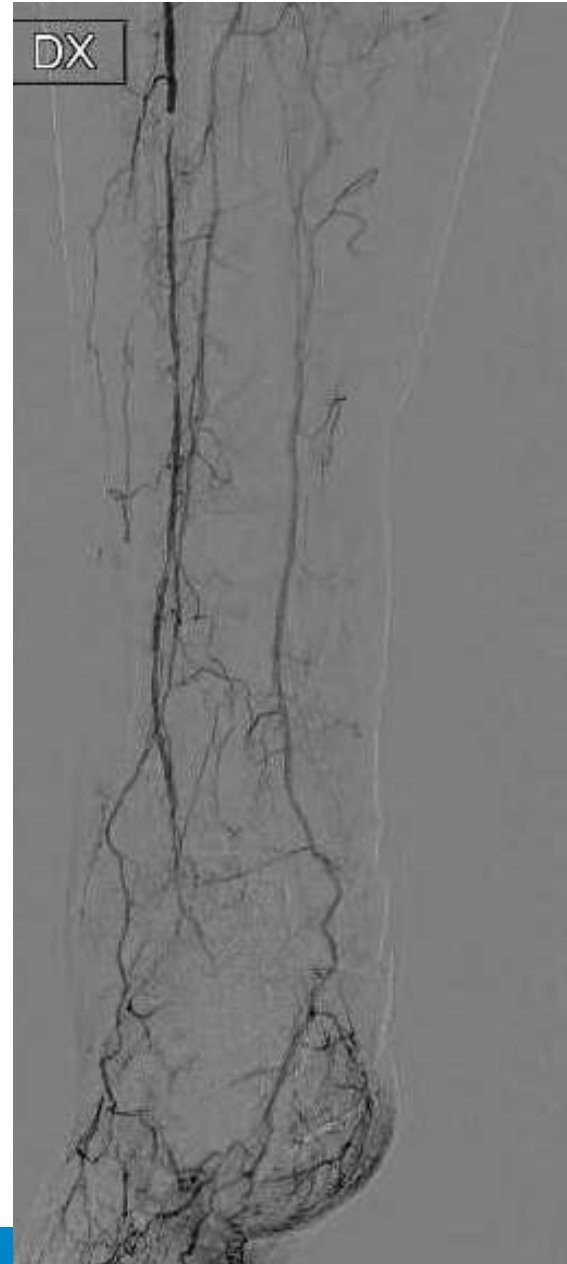
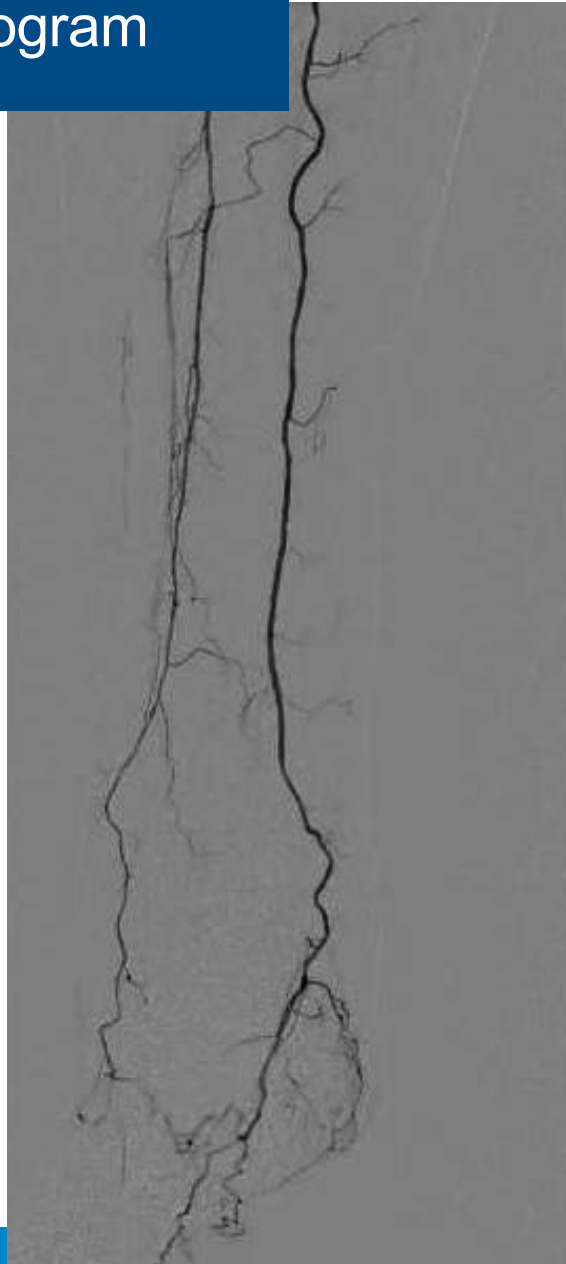
Final Result



Images courtesy Jos van den Berg, MD

BTK Case #2

Baseline Angiogram



Images courtesy Jos van den Berg, MD

BTK Case #2

Best practices for balloon crossing

1. Work from distal to proximal
2. In case of failure to cross perform pre-dilation with undersized standard angioplasty balloon (<2 mm in diameter)

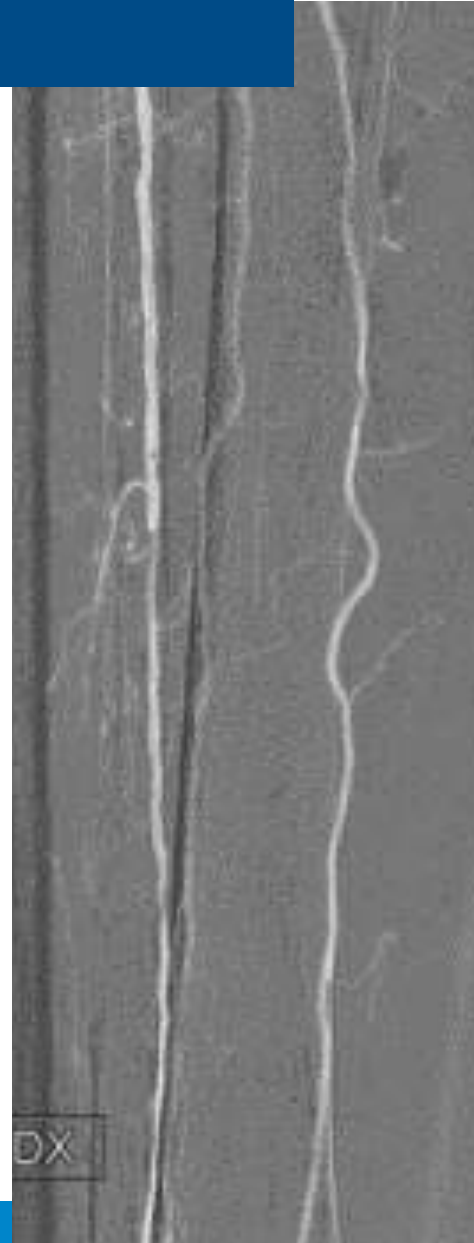
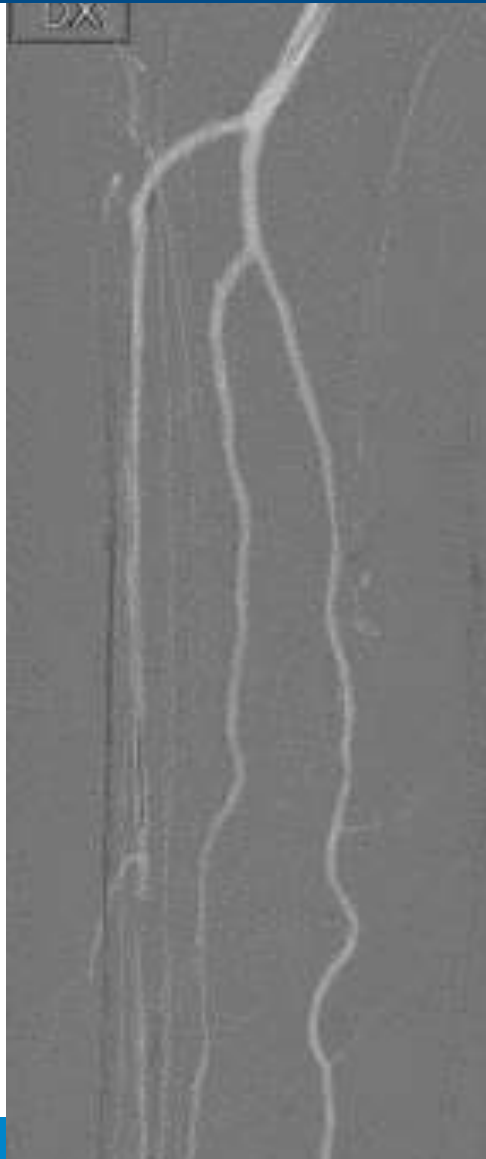
BTK Case #2

Best practices for balloon inflation: Recommended 2-minute total inflation time

1. Inflate the balloon slowly to half nominal. It should take 30 secs to get there
2. Once half nominal quickly inflate to full nominal
3. If lesion is not yielding take it up to full rated burst pressure
4. Hold full inflation for 90 secs

BTK Case #2

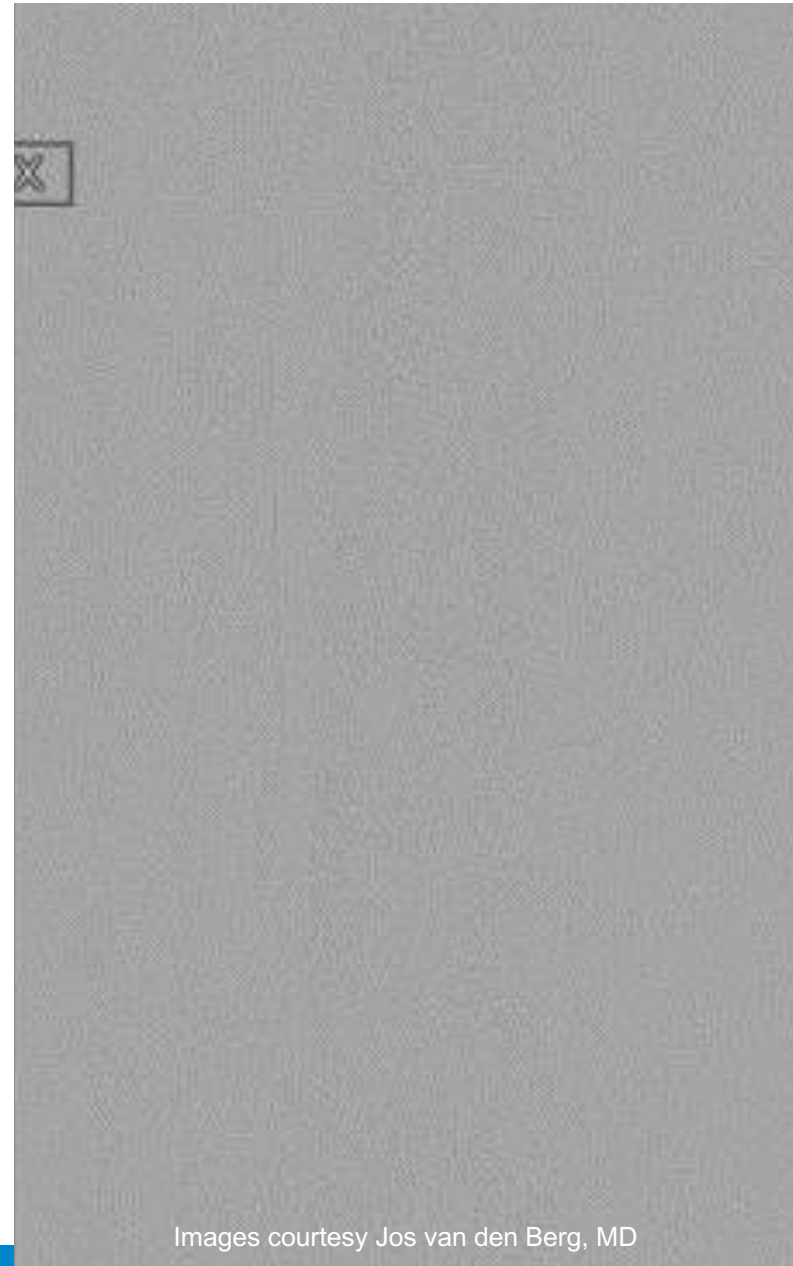
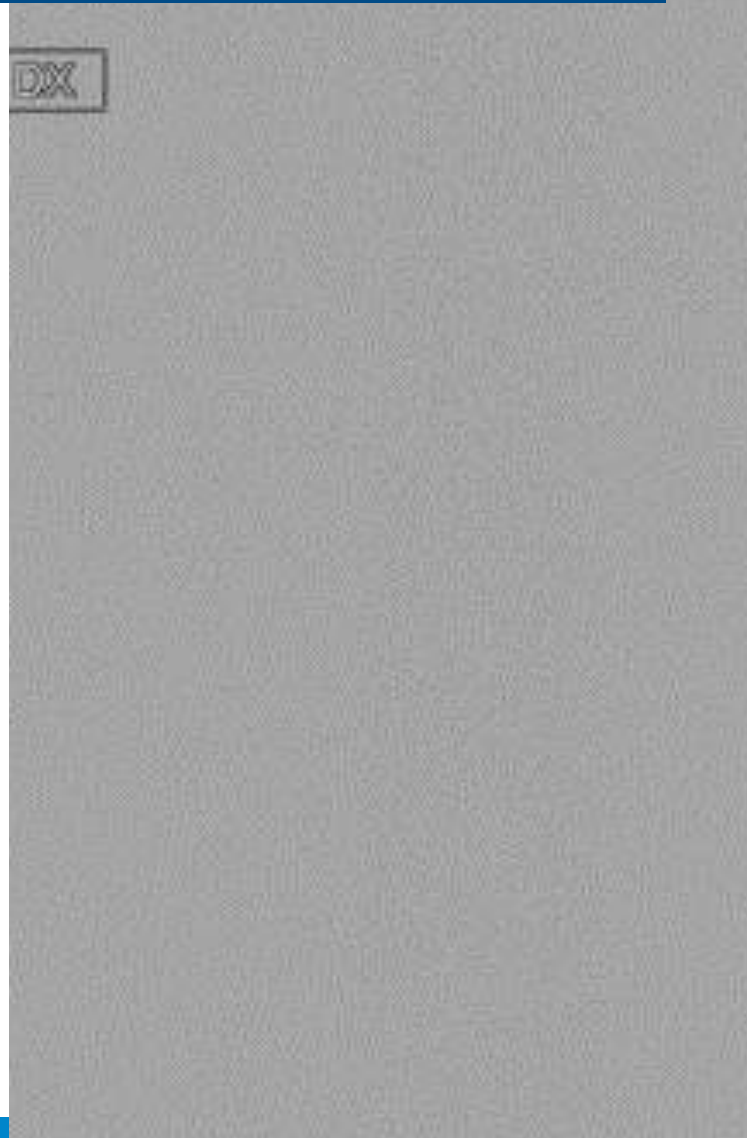
Procedure



Images courtesy Jos van den Berg, MD

BTK Case #2

Final Result



Images courtesy Jos van den Berg, MD



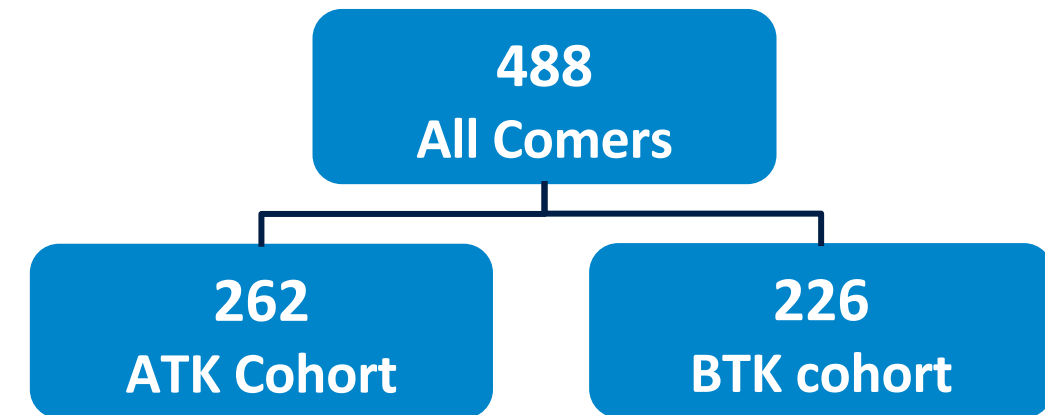
No dissection

CHOCOLATE BAR STUDY^{1,2}

Overview

Prospective, multicenter, real-world post market registry evaluating use of Chocolate balloon catheter in above and below the knee lesions

- **488 patients enrolled**
- **34 sites**
- **Independent adjudication by independent core labs^{3,4}**



Inclusion Criteria

- Any ATK or BTK lesion with at least 1 vessel runoff successfully crossed with a guidewire
- Use of atherectomy/re-entry devices accepted

Exclusion Criteria

- Presence of a flow-limiting dissection at the target lesion prior to use of the Chocolate PTA balloon (secondary to the use of another device)
- Patients with Rutherford 6
- Chocolate PTA balloon not used in accordance with study protocol (2 min inflation to at least nominal pressure)

1. Data on file with Medtronic – CLR782: Final Study Report The Chocolate BAR by TriReme Medical, LLC
2. Mustapha J, et al. Chocolate BAR registry. CCI 2018;1-5
3. Vascore DUS Core Lab, Boston, MA, US
4. Yale University Core, New Haven, CT

Chocolate Bar Study

Patient and Lesion Characteristics¹⁻³

Patient Characteristics	ATK** N=262	BTK N=226
Age (yrs)	69.7 ± 10	71.5 ± 10.3
Male Gender	61.1% (160)	65.9% (149)
Diabetes	50.4%(132)	58.8% (133)
Hypertension	92.0%(241)	92.5% (209)
Hyperlipidemia	84.7%(222)	82.3%(186)
Current Smoker	29.4%(77)	11.9%(27)
CLI	32.1% (84)	55.7% (126)
RCC 5+	19.1% (50)	37.6% (85)
Lesion Characteristics [†]	N=265 lesions	N=245 lesions
Lesion Length (mm)	83.5 ± 59.8 (250)	66.0 ± 48.5 (207)
Total Occlusion	23.0% (60/261)	41.1% (99/241)
Calcification - Moderate	43.5% (111/255)	30.1% (69/229)
Calcification - Severe	20.0% (51/255)	2.2% (5/229)

Calcification: Readily apparent densities noted within the apparent vascular wall at the site of a stenosis.

- none/mild (=0)
- moderate (densities noted only during the cardiac cycle prior to contrast injection =1)
- severe (radiopacities noted without cardiac motion prior to contrast injection generally involving both sides of the arterial wall =2)

1. Data on file with Medtronic – CLR782: Final Study Report The Chocolate BAR by TriReme Medical, LLC
 2. Mustapha J, et al. Chocolate BAR registry. CCI 2018;1-5
 3. Mustapha JA Chocolate PTA presented TCT 2015
- ** many ATK patients had concurrent BTK disease
[†]Core lab reported

Chocolate Bar Study

Outcomes^{1,2}

Procedural Success	ATK** (n = 262)	BTK (n = 226)
Freedom from Flow Limiting Dissections* (Site Reported)	98.1%	99.1%
Freedom from Flow Limiting Dissections* (Adjudicated)	100%	100%
Achieved <30% Diameter Stenosis (Adjudicated)	85.1%	84.6%
Freedom from Bail-Out Stenting	98.4%	99.1%
Clinical Outcomes (Kaplan Meier)	ATK** (n = 262) 12 months	BTK (n = 226) 6 months
Freedom from Target Lesion Revascularization	78.5%	88.9%
Freedom from Major Unplanned Amputation	97.2%	96.7%
Freedom from All-Cause Mortality	93.3%	97.1%

*Flow Limiting Dissections defined as : Type E- Persistent luminal filling defect with delayed run-off of the contrast material in the distal lumen and Type F- Filling defect accompanied by total occlusion

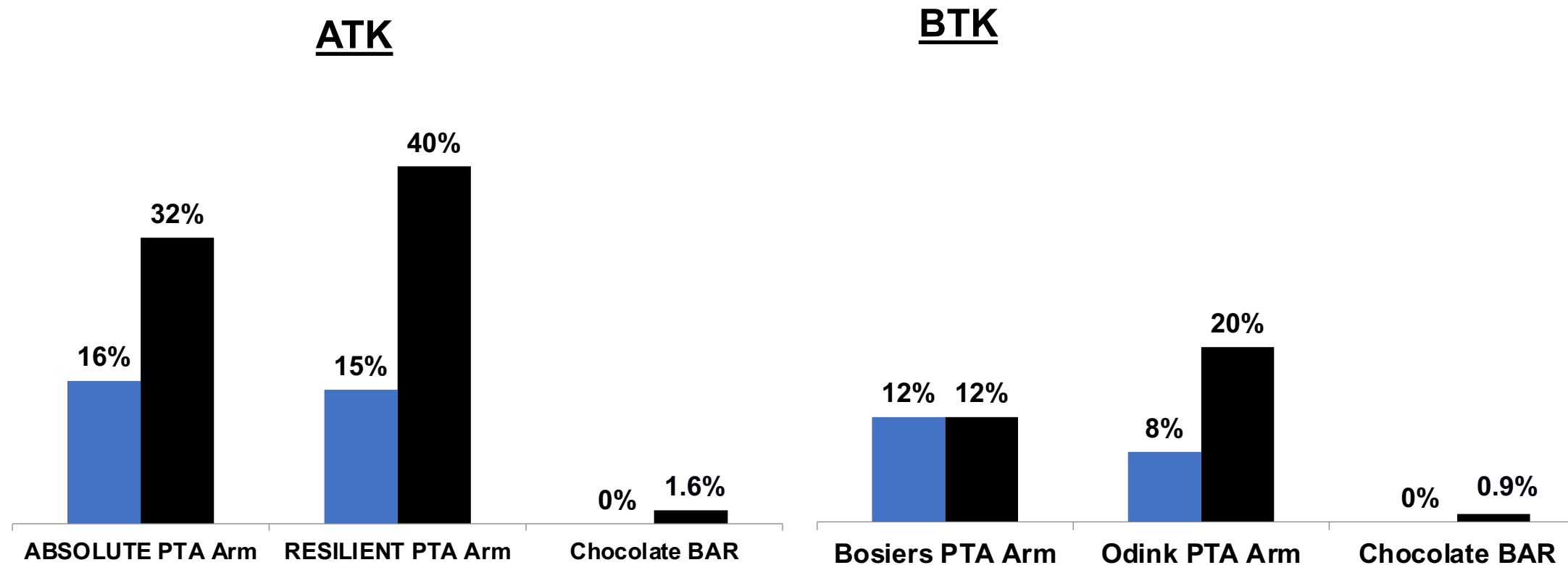
** many ATK patients had concurrent BTK disease

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2. Mustapha J, et al. Chocolate BAR registry. CCI 2018;1-5

Dissection Rate in Context

Standard and Specialty PTA

■ % flow-limiting dissections
 ■ % bail-out stents placed



- Schillinger M, et al. NEJM. 2006;354:1879-1888
- Laird JR, et al. J Endovasc Ther. 2012;19:1-9
- Data on file with Medtronic – CLR782: Final Study Report The Chocolate BAR by TriReme Medical, LLC
- Mustapha J, et al. Chocolate BAR registry. CCI 2018;1-5
- Boisers M, et al. J Vasc Surg 2012 55(2):390-398
- Odink H, et al. J Vasc Inter radio. Apr 2012: 23(4):461-467

Results are from different studies and results may vary in head-to-head study; for illustration purposes only.

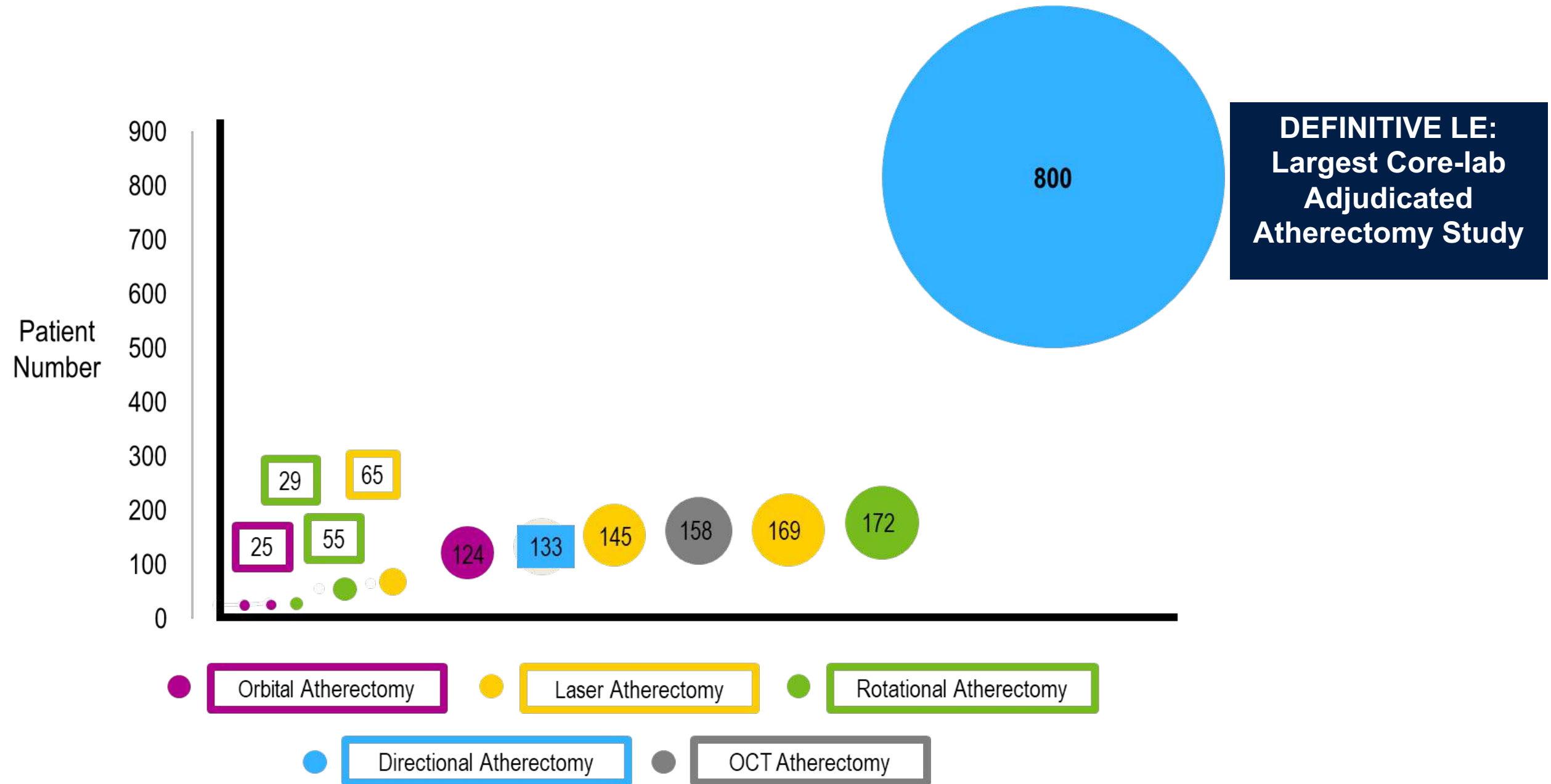
DEFINITIVE LE

Atherectomy Trials: 30-Day to 1-Year Outcomes

	Trial	Patient Number	Core Lab Adjudicated	Citation
Directional Atherectomy	DEFINITIVE LE	800	✓	McKinsey, J. F., et al. (2014). <i>JACC Cardiovasc Interv</i> 7(8): 923-933.
	DEFINITIVE Infrapopliteal subgroup	145	✓	Rastan, A., et al. (2015) <i>J Endovasc Ther</i> 22(6): 839-846.
	DEFINITIVE Popliteal subgroup	158	✓	Rastan, A., et al. (2017). <i>J Endovasc Ther</i> https://doi.org/10.1177/1526602817740133
	DEFINITIVE Ca++	133	✓	Roberts, D., et al. (2014). <i>Catheter Cardiovasc Interv</i> 84(2): 236-244.
	DEFINITIVE AR	121	✓	Zeller, T., et al. (2017). <i>Circ Cardiovasc Interv</i> 10(9):e004848.
Laser Atherectomy	LACI	145		Laird, J. R., et al. (2006). <i>J Endovasc Ther</i> 13(1): 1-11.
	CELLO	65	✓	Dave, R. M., et al. (2009). <i>J Endovasc Ther</i> 16(6): 665-675.
	EXCITE ISR	169	✓	Dippel, E. J., et al. (2015). <i>JACC Cardiovasc Interv</i> 8(1 Pt A): 92-101.
Rotational Atherectomy	Jetstream ISR	29	✓	Shammas, N. W., et al. (2016). <i>J Endovasc Ther</i> 23(2): 339-346.
	Jetstream IVUS	55	✓	Maehara, A., et al. (2015). <i>EuroIntervention</i> 11(1): 96-103.
	Pathway PVD	172	✓	Zeller, T., et al. (2009). <i>J Endovasc Ther</i> 16(6): 653-662.
Orbital Atherectomy	Compliance 360	25		Dattilo, R., et al. (2014). <i>J Invasive Cardiol</i> 26(8): 355-360.
	Calcium 360	25		Shammas, N. W., et al. (2012). <i>J Endovasc Ther</i> 19(4): 480-488.
	Oasis	124		Safian, R. D., et al. (2009). <i>Catheter Cardiovasc Interv</i> 73(3): 406-412.
OCT Atherectomy	VISION IDE	158	✓	Schwindt, A. G., et al. (2017). <i>J Endovasc Ther</i> : 24(3): 355-366.

Atherectomy Trials: 30-Day to 1-Year Outcomes

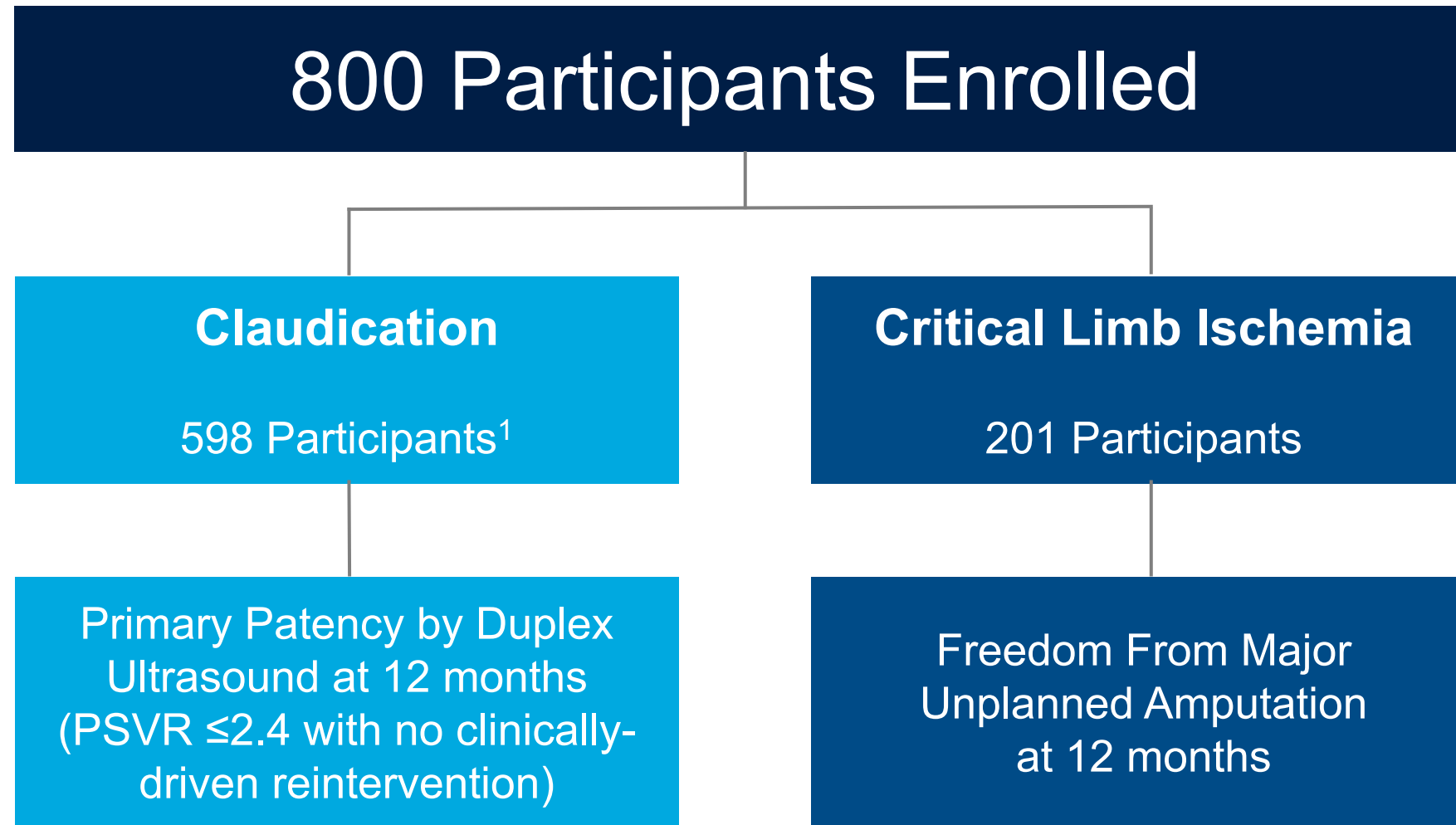
Trial Size



See References at end of presentation

DEFINITIVE LE Primary

Trial Overview



¹ One patient censored due to informed consent violation
McKinsey, J. F., et al. (2014). JACC Cardiovasc Interv 7(8): 923-933.

DEFINITIVE LE Primary Periprocedural Events

	Claudicant n = 598	CLI n = 201	P value	All Participants n = 799
Distal embolization	2.5%	7.5%	0.004	3.8%
Abrupt closure	0.7%	6.0%	<0.001	2.0%
Flow-limiting dissection*	2.2%	2.5%	0.786	2.3%
Perforation†	6.2%	2.5%	0.044	5.3%
Aneurysm	0.5%	0%	0.576	0.4%

Bailout stenting rate: 3.2%

*Flow-limiting dissection defined as ≥Grade D. Garcia LA, et al. J Endovasc Ther 2015;22:701-711

†Perforations from any source included DA, wire passage, adjunctive therapy

McKinsey, J. F., et al. (2014). JACC Cardiovasc Interv 7(8): 923-933.

DEFINITIVE LE Primary

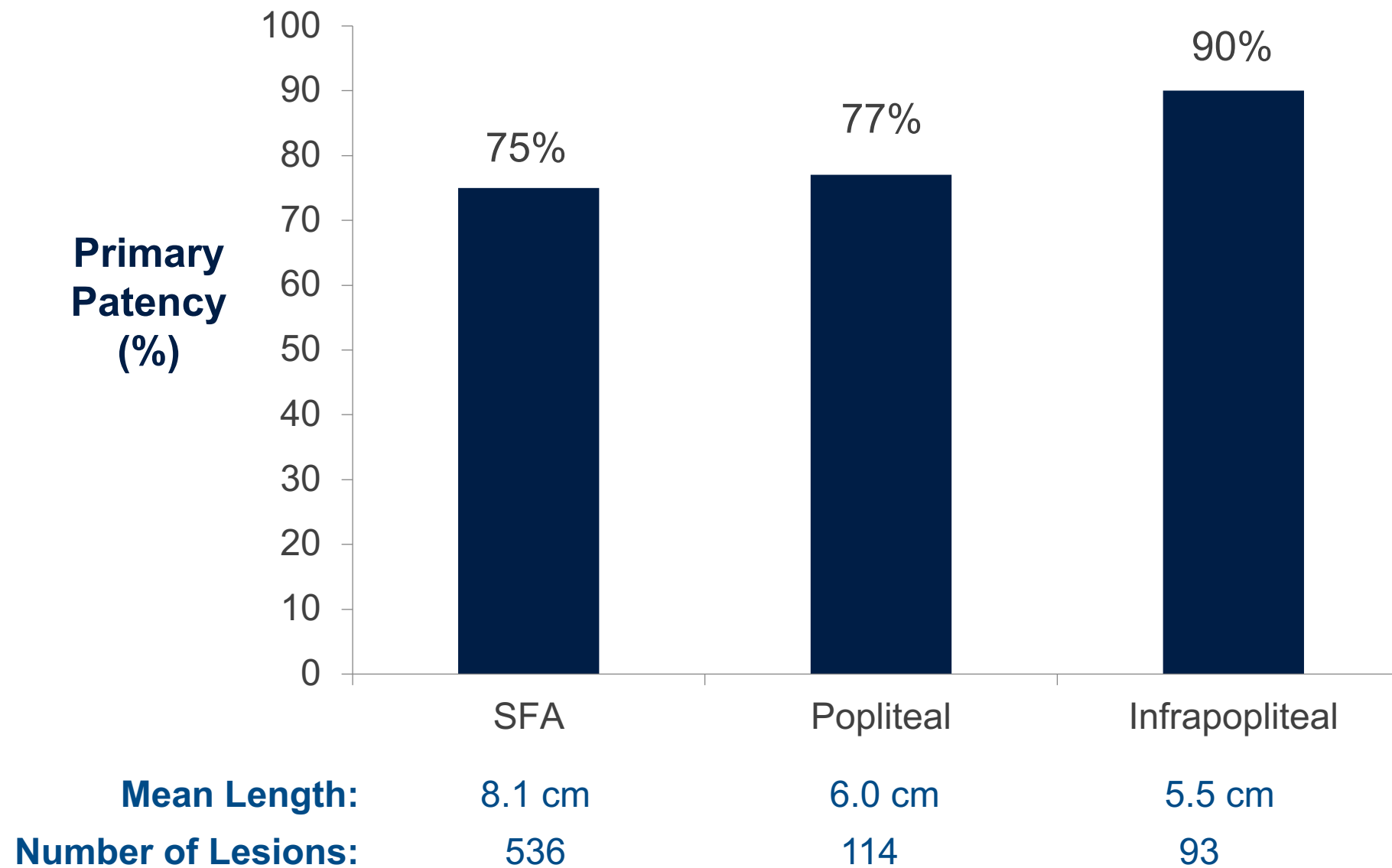
Patency: All Claudicants

	Lesion Number	Lesion Length (cm)	Primary Patency at 12 months
All Claudicants	743	7.5	78%

Primary patency by duplex ultrasound at 12 months (PSVR \leq 2.4 with no clinically-driven reintervention)

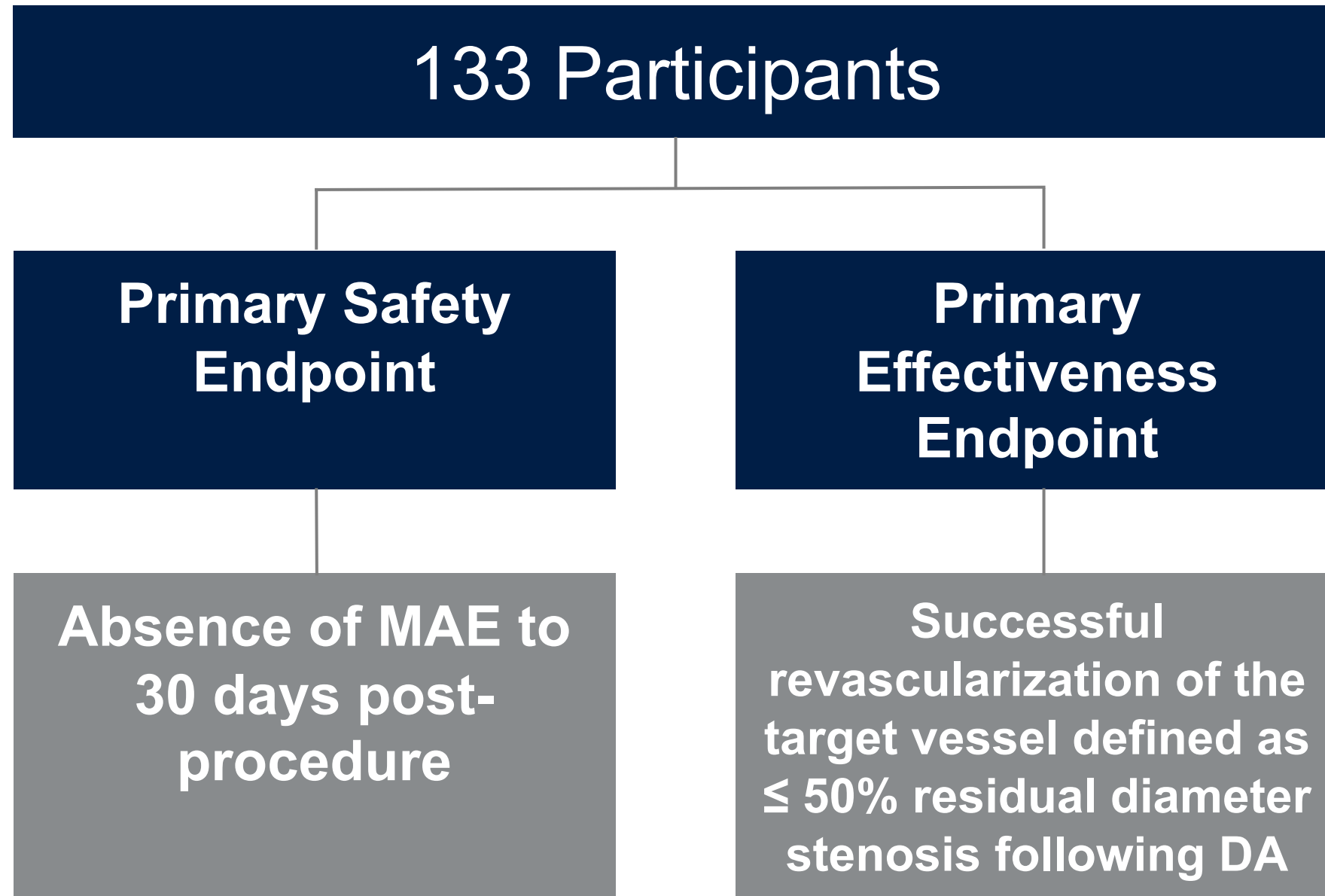
Primary Patency value determined by Kaplan-Meier analysis
McKinsey, J. F., et al. (2014). JACC Cardiovasc Interv 7(8): 923-933.

DEFINITIVE LE Primary Patency: All Claudicants



Primary patency by duplex ultrasound at 12 months (PSVR ≤ 2.4 with no clinically-driven reintervention); Patency value determined by Kaplan-Meier analysis
McKinsey, J. F., et al. (2014). JACC Cardiovasc Interv 7(8): 923-933.

DEFINITIVE Ca++ Trial Overview



Roberts, D., et al. (2014). Catheter Cardiovasc Interv **84**(2): 236-244.

DEFINITIVE Ca++

Site- and Core Lab-Adjudicated Procedural Outcomes

	Site-reported	Core Lab-reported
Primary Effectiveness¹	97.0%	92.0%
Primary Safety²		93.1%

1. Primary effectiveness: successful revascularization of the target vessel defined as $\leq 50\%$ residual diameter stenosis following directional atherectomy
2. Primary Safety defined as 30-day freedom from any serious adverse event leading to death, myocardial infarction, vessel dissection classified as \geq Type C, clinical perforation, pseudoaneurysm, thrombosis, distal embolization requiring surgical or medical intervention and/or the presence of symptoms, unplanned amputation or clinically-driven TVR

Roberts, D., et al. (2014). Catheter Cardiovasc Interv 84(2): 236-244.