DukeHeart *On The Go*

A Randomized Trial to Confirm the Safety and Effectiveness of Chocolate Touch Paclitaxel Coated PTA Balloon Catheter in Above the Knee Lesions

Mehdi H. Shishehbor, DO, MPH, PhD on behalf of the Chocolate Touch Study Investigators

University Hospitals Harrington Heart and Vascular Institute,

Cleveland, OH

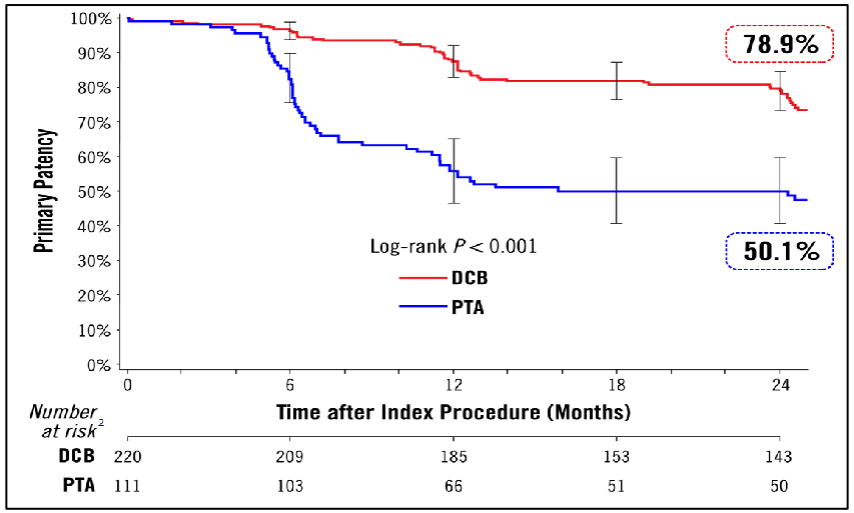
@shishem

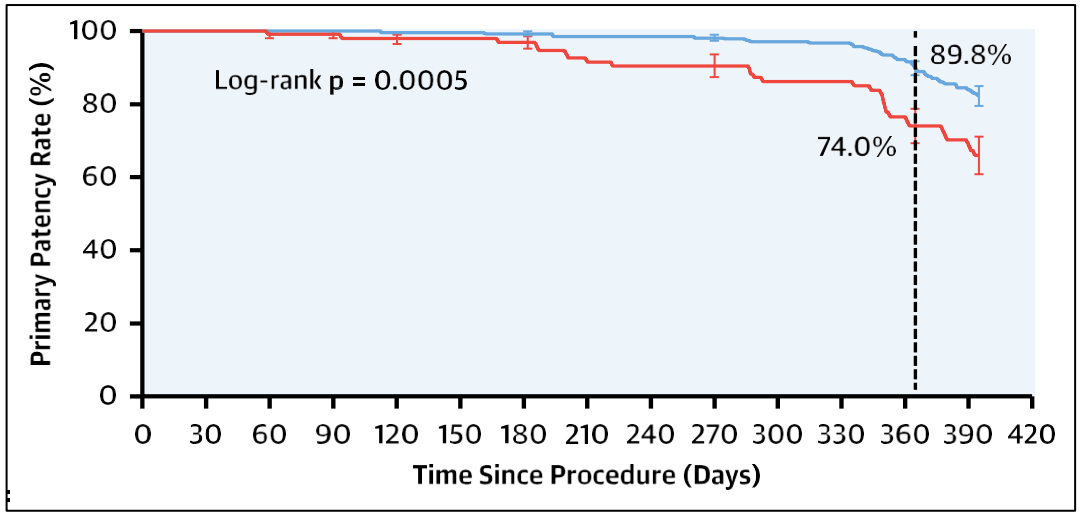
MedEd ON THE GO

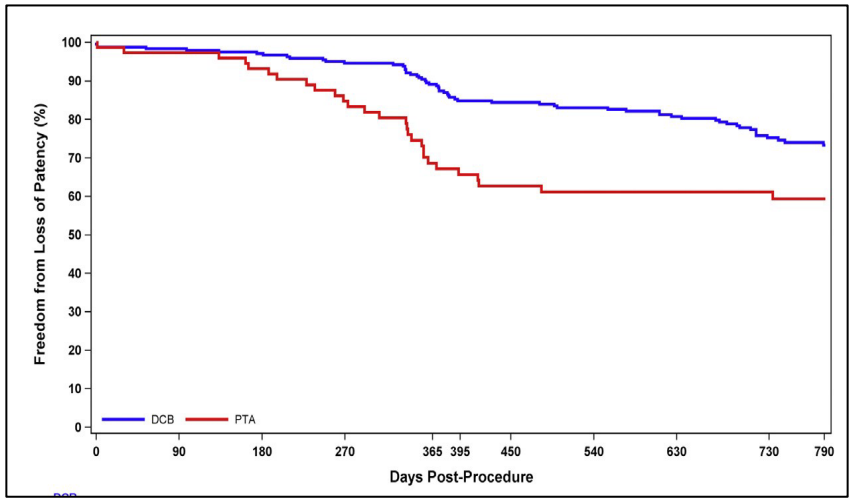
Disclosures

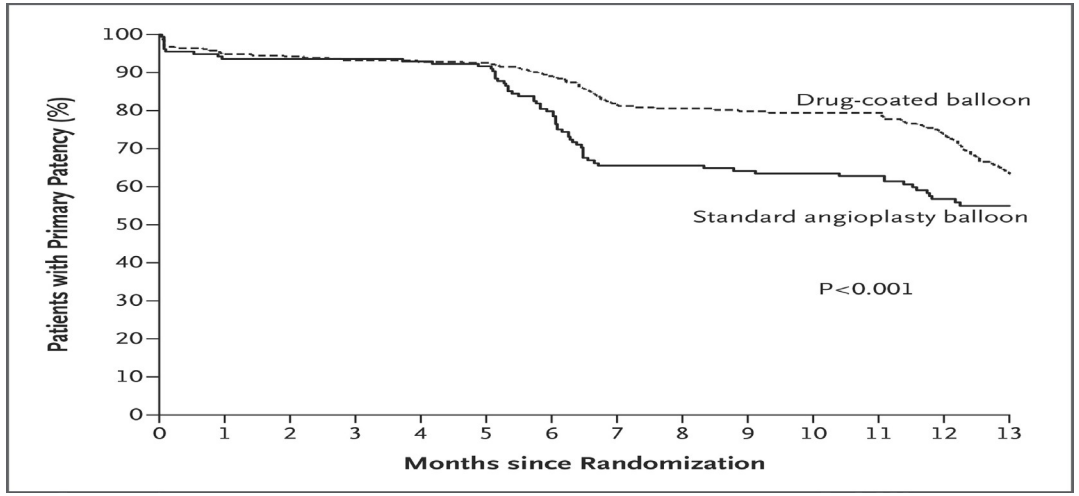
- Advisory board – Medtronic, Boston Scientific, Philips, Terumo, Abbott Vascular, ANT, Inquis Medical

Drug Coated Balloons Are Superior to Balloon Angioplasty





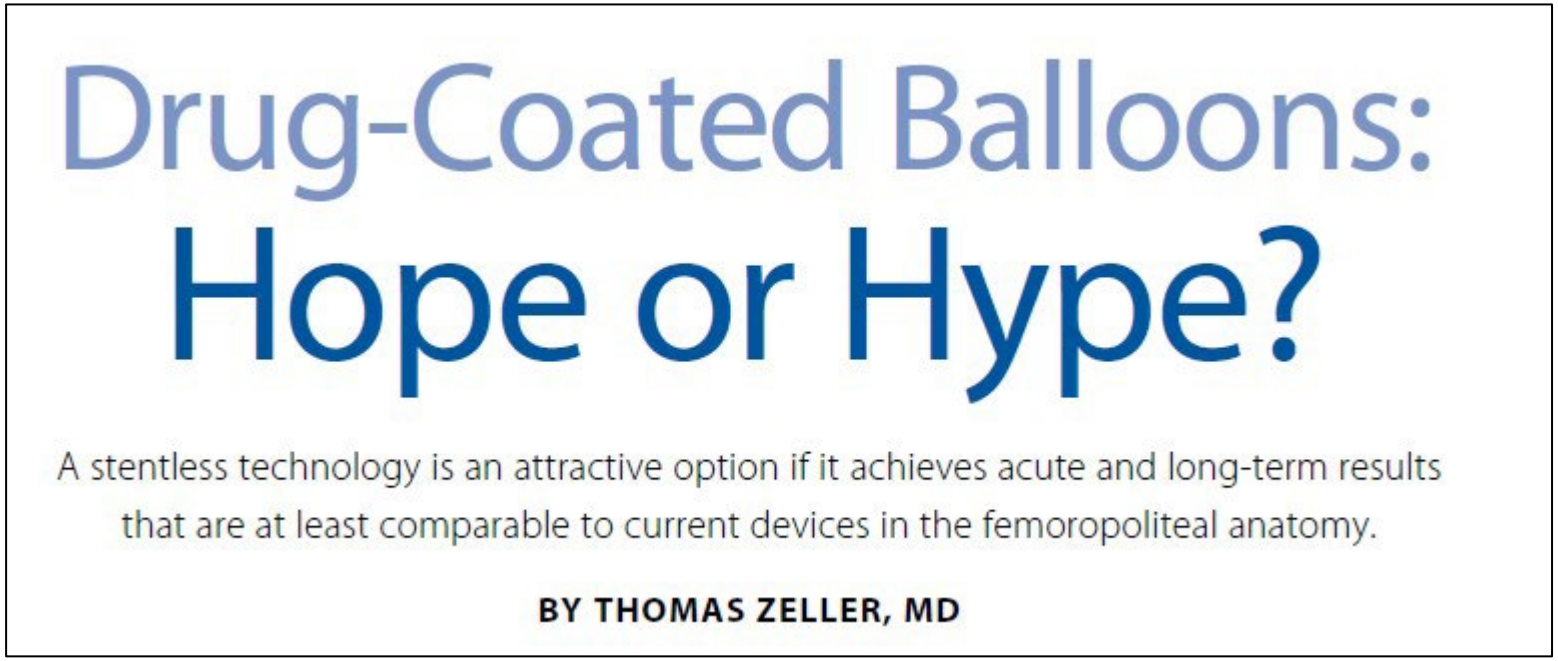




Krishnan et al. *Circulation.* 2017;136:1102-1113. Sachar et al. *JACC Cardiovasc Interv.* 2021;14:1123-1133. Rosenfield et al. *N Engl J Med.* 2015;373:145-53. Tepe et al. *Circulation.* 2015;131:495-502.

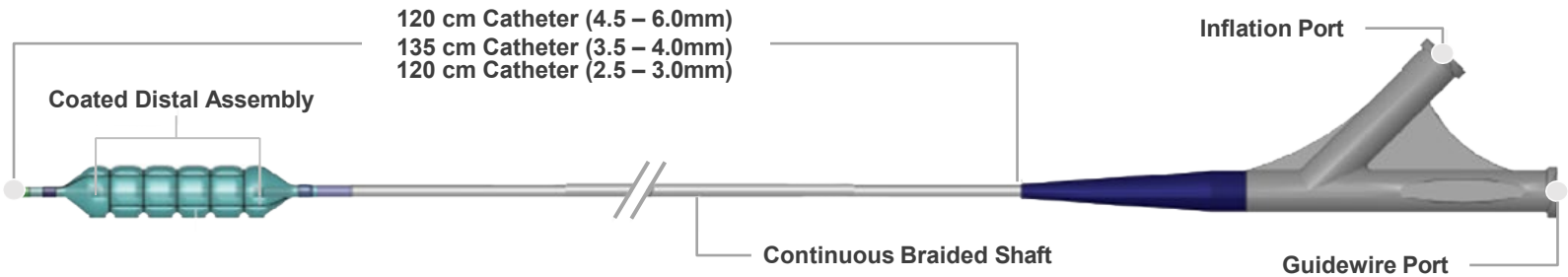
Current Limitations of Drug-Coated Balloons

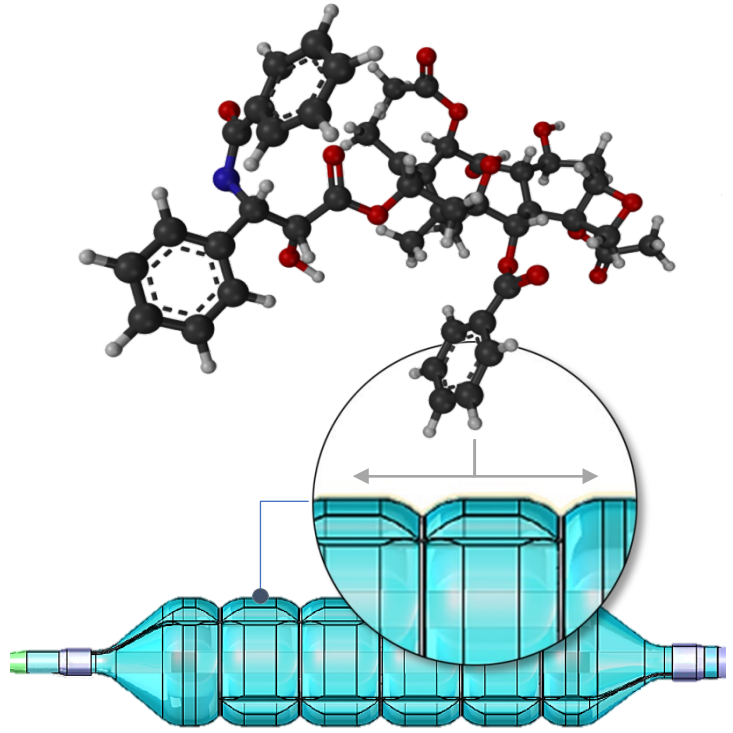
- Acute dissection and bailout stenting
- Significant recoil
- Minimal acute luminal gain
- Presence of Ca+



Purpose

- **Chocolate Touch DCB**
  - Pillow effect - nitinol constrained balloon designed to reduce vessel trauma and dissections
  - The distal assembly is coated with paclitaxel to inhibit neointimal formation





Chocolate Balloon Distal Assembly

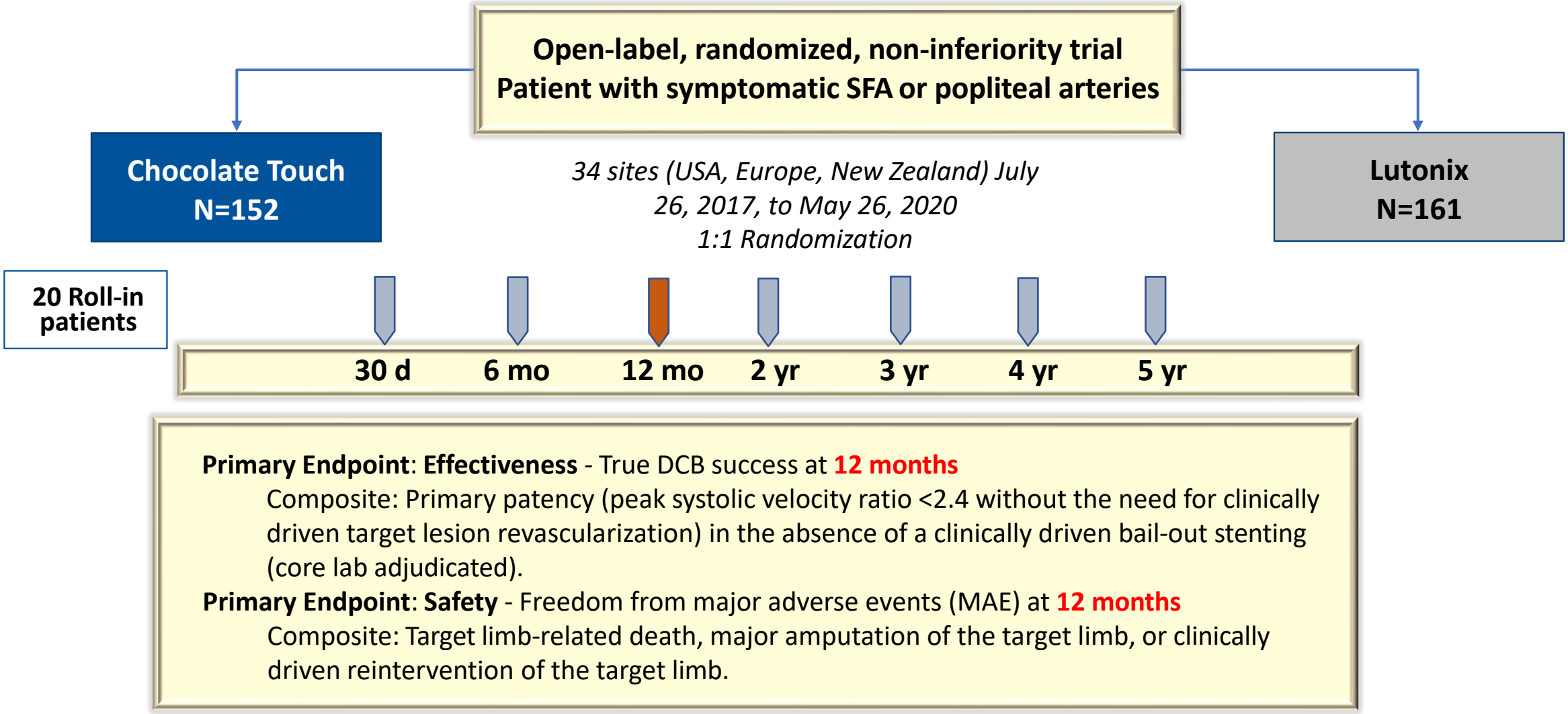
- **Surface area increased by 20%**

- We sought to compare the efficacy and safety of the **Chocolate Touch DCB** to the commercially approved **Lutonix DCB** in an international randomized clinical trial

Chocolate Touch versus Lutonix DCB

	Chocolate Touch DCB	Lutonix DCB
Balloon	Chocolate™	Moxy™
Drug	Paclitaxel	Paclitaxel
Dose	3 µg/mm^2	2 µg/mm^2
Excipient	Propyl gallate	Polysorbate, Sorbitol
Sizing	1.1:1	1:1

Chocolate Touch Study Design



Primary Endpoint: **Effectiveness** - True DCB success at **12 months**

Composite: Primary patency (peak systolic velocity ratio <2.4 without the need for clinically driven target lesion revascularization) in the absence of a clinically driven bail-out stenting (core lab adjudicated).

Primary Endpoint: **Safety** - Freedom from major adverse events (MAE) at **12 months**

Composite: Target limb-related death, major amputation of the target limb, or clinically driven reintervention of the target limb.

Statistical Design

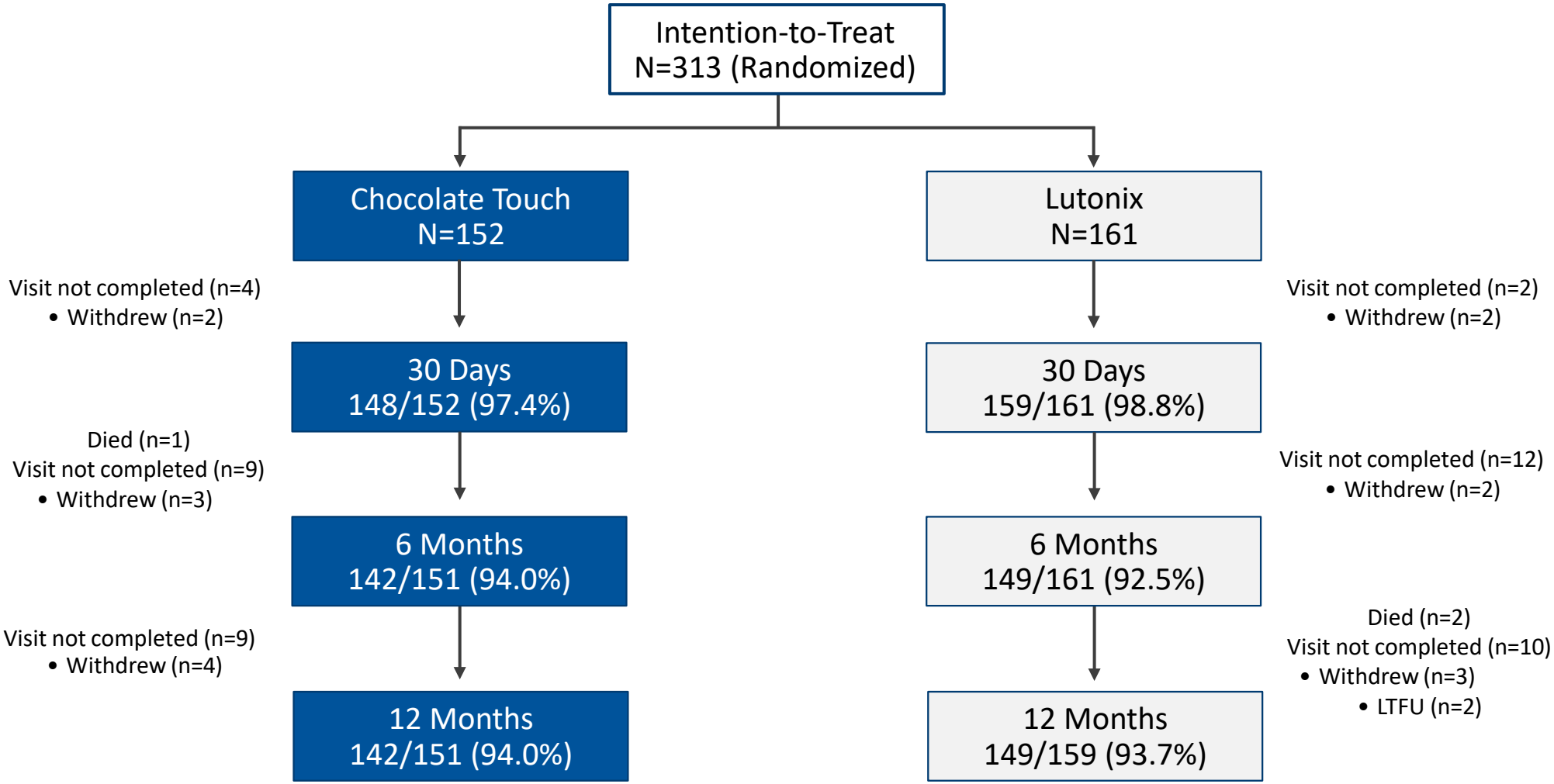
Primary Efficacy (DCB Success)	Primary Safety (Freedom from MAE)
Non-inferiority assumptions: 216 evaluable subjects would provide >90% power to declare non-inferiority • DCB success rate: 80% for Chocolate Touch and 70% for Lutonix • one-sided alpha=0.025 • 10% non-inferiority margin • 15% Loss to FU	**Non-inferiority** assumptions: 230 evaluable subjects would provide ~85% power to declare non-inferiority assuming • Freedom from MAE of 88% for Chocolate Touch and 84% in the Lutonix • one-sided alpha=0.025 • 10% non-inferiority margin
Sequential Superiority testing for Efficacy followed by Safety only if non-inferiority met for both primary endpoints tested at the two-sided alpha=0.05 level	
Trial Success required both primary efficacy and safety endpoints to meet non-inferiority	

This trial had an adaptive design with a prespecified interim analysis planned at 75% of enrolled patients with completed 12-month FU. Based on conditional power the trial allowed enrollment of a maximum population of 510 patients.

Trial Administration

Principal Investigators	**Mehdi Shishehbor, DO, MPH, PhD** **Thomas Zeller, MD, PhD**
Angiographic Core Lab **Clinical Events Committee** **Data Safety Monitoring Board**	**Yale Cardiovascular Research Group** Director: Alexandra J. Lansky, MD
Duplex Ultrasound Core Lab	**CoreLab Black Forest GmbH** Director: Ulrich Beschorner, MD

Study Flow and Follow-up



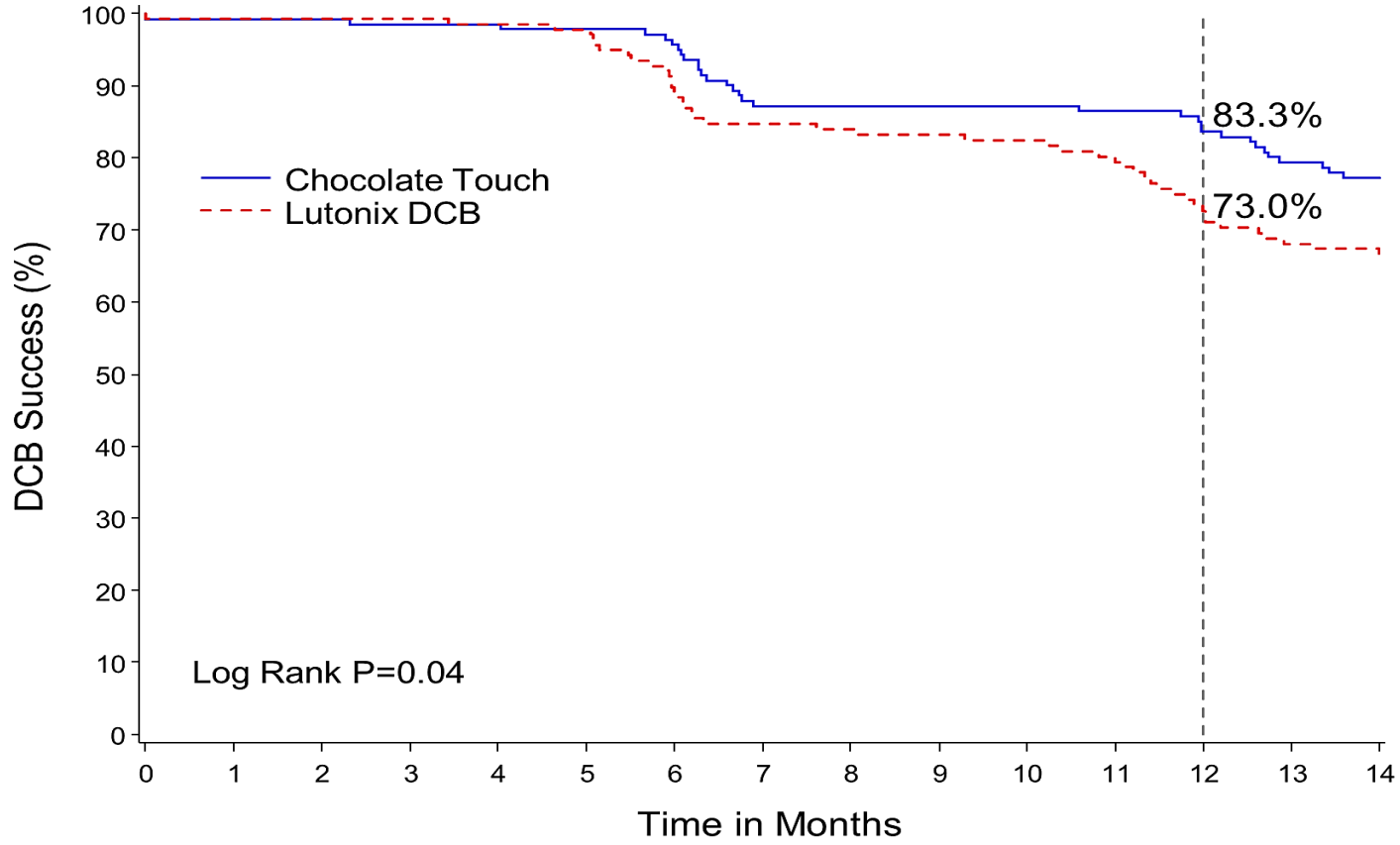
Baseline Characteristics

	Chocolate Touch	Lutonix DCB
Age	70.0±9.7	68.8±9.3
Male sex	57.2%	57.8%
Current smoker	33.6%	33.5%
Hypertension	90.1%	86.3%
Hyperlipidemia	86.2%	86.3%
Coronary artery disease	31.6%	46.6%
Chronic kidney disease	11.8%	8.1%
Diabetes mellitus	43.4%	32.9%
Rutherford category		
2	17.8%	14.4%
3	77.0%	80.0%
4	5.3%	5.6%
Ankle-brachial index	0.71±0.16	0.75±0.22

Angiographic and Procedural Characteristics

	Chocolate Touch	Lutonix DCB
Lesion Length, mm	78.5 ± 46.3	77.8 ± 47.7
Total occlusion, %	22.0	20.3
Severe Calcification, %	25.0	21.3
Atherectomy device use, %	12.5	11.2
Dissection requiring bailout stenting, %	0	0
Flow limiting dissection, %	0	0

Primary Efficacy Endpoint (Chocolate Touch 78.8% versus Lutonix DCB 67.7%) ($P_{non\text{-}inferiority}<0.0001$)

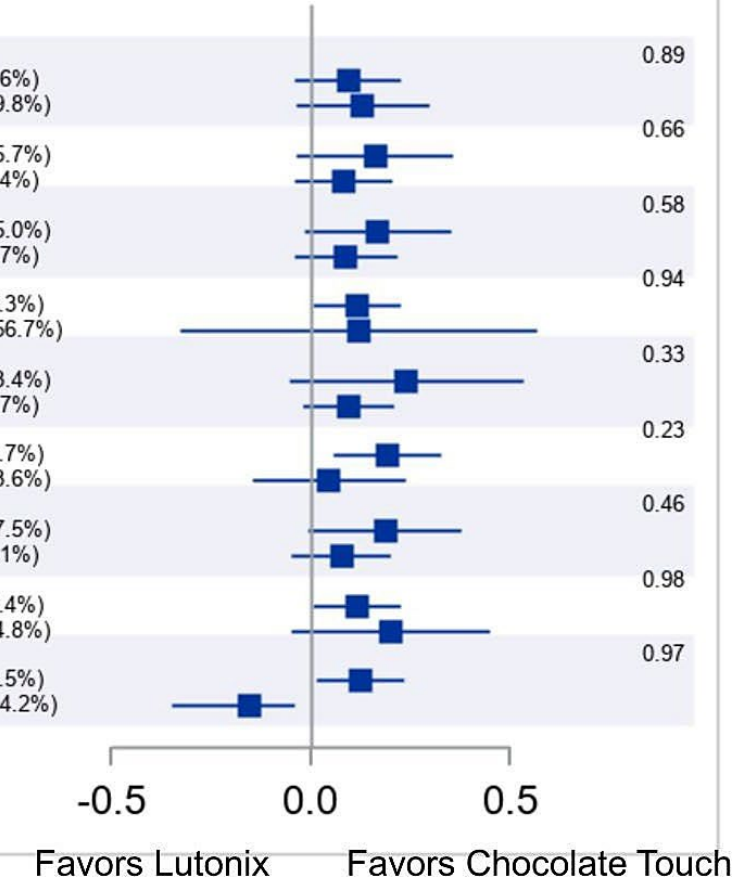


Number at risk						
Chocolate Touch	152	139	134	113	107
Lutonix DCB	161	138	123	94	88

Chocolate Touch DCB Showed Consistent Efficacy

Primary Effectiveness Endpoint of True DCB Success at 12 Months

Subgroup	Chocolate Touch	Lutonix	Difference (95% CI)	Interaction P-Value
Sex				0.89
Male	66/81 (81.5%)	52/72 (72.2%)	9.3% (-4.1%, 22.6%)	
Female	42/56 (75.0%)	36/58 (62.1%)	12.9% (-3.9%, 29.8%)	
Geography (US VS OUS)				0.66
US	31/42 (73.8%)	26/45 (57.8%)	16.0% (-3.6%, 35.7%)	
OUS	77/95 (81.1%)	62/85 (72.9%)	8.1% (-4.2%, 20.4%)	
Diabetes				0.58
Diabetes	44/57 (77.2%)	26/43 (60.5%)	16.7% (-1.5%, 35.0%)	
No Diabetes	64/80 (80.0%)	62/87 (71.3%)	8.7% (-4.2%, 21.7%)	
Baseline Rutherford				0.94
<=3	103/131 (78.6%)	82/122 (67.2%)	11.4% (0.5%, 22.3%)	
>3	5/6 (83.3%)	5/7 (71.4%)	11.9% (-32.9%, 56.7%)	
Predilatation				0.33
Atherectomy	15/17 (88.2%)	9/14 (64.3%)	23.9% (-5.5%, 53.4%)	
Standard Balloon Angioplasty	93/120 (77.5%)	79/116 (68.1%)	9.4% (-1.9%, 20.7%)	
Calcification				0.23
Minimal/None	68/84 (81.0%)	50/81 (61.7%)	19.2% (5.7%, 32.7%)	
Moderate/Severe	34/45 (75.6%)	27/38 (71.1%)	4.5% (-14.6%, 23.6%)	
Lesion Length				0.46
<=10	36/47 (76.6%)	25/43 (58.1%)	18.5% (-0.6%, 37.5%)	
>10	72/90 (80.0%)	63/87 (72.4%)	7.6% (-4.9%, 20.1%)	
Treatment Location				0.98
Hospital Based Procedure	103/132 (78.0%)	80/120 (66.7%)	11.4% (0.4%, 22.4%)	
Outpatient Based Lab	5/5 (100.0%)	8/10 (80.0%)	20.0% (-4.8%, 44.8%)	
Location				0.97
SFA	97/124 (78.2%)	81/123 (65.9%)	12.4% (1.3%, 23.5%)	
Popliteal	11/13 (84.6%)	7/7 (100.0%)	-15.4% (-35.0%, 4.2%)	



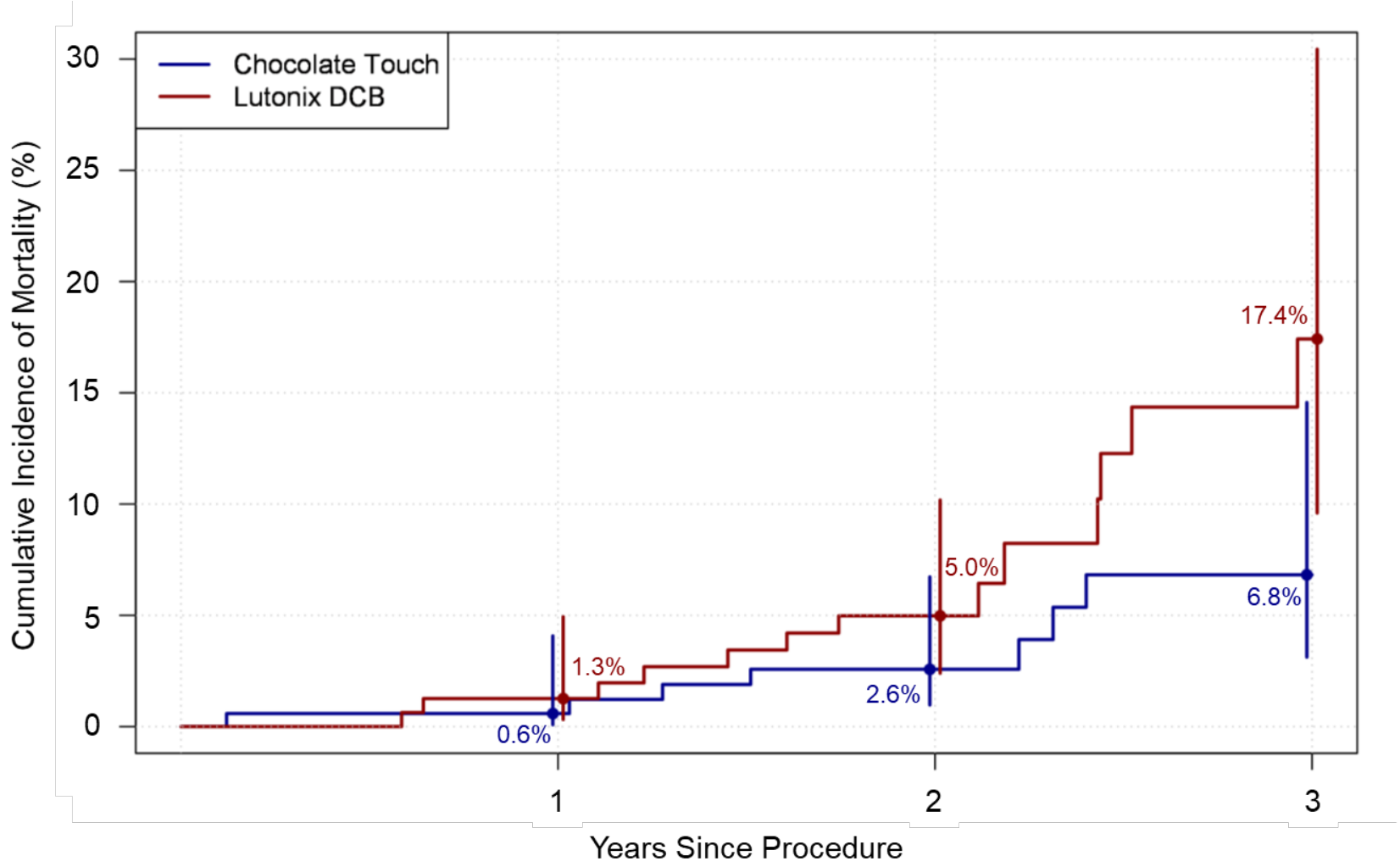
Interaction P-value from the fixed effects logistic regression model treatment by subgroup interaction term.

Chocolate Touch Met Its Primary Safety Endpoint

Event	Chocolate Touch	Lutonix DCB	Difference (95% CI)	Non-inferiority P-Value	Superiority P-value
Freedom from MAE	88.9%	84.6%	4.3% (-3.4%, 12.1%)	0.0001	0.2759
Target Limb-Related Death	0.7%	0.0%	0.7% (-0.7%, 2.1%)		
Major Target Limb Amputation	0.0%	0.0%	—		
Target Limb re-Intervention	10.5%	15.4%	-4.9% (-12.6%, 2.7%)		

Primary Safety endpoint met non-inferiority

Similar Mortality Was Observed in the As Treated Population



Number at Risk				
Chocolate Touch	171	159	119	44
Lutonix DCB	160	154	106	22

Conclusions

- The Chocolate Touch Study met its primary effectiveness endpoint of **True DCB Success** at 12 months:
  - Non-inferiority
  - Superior efficacy
- Chocolate Touch also met its non-inferiority endpoint for safety
- No difference in mortality, although the trial was not adequately powered for a mortality endpoint