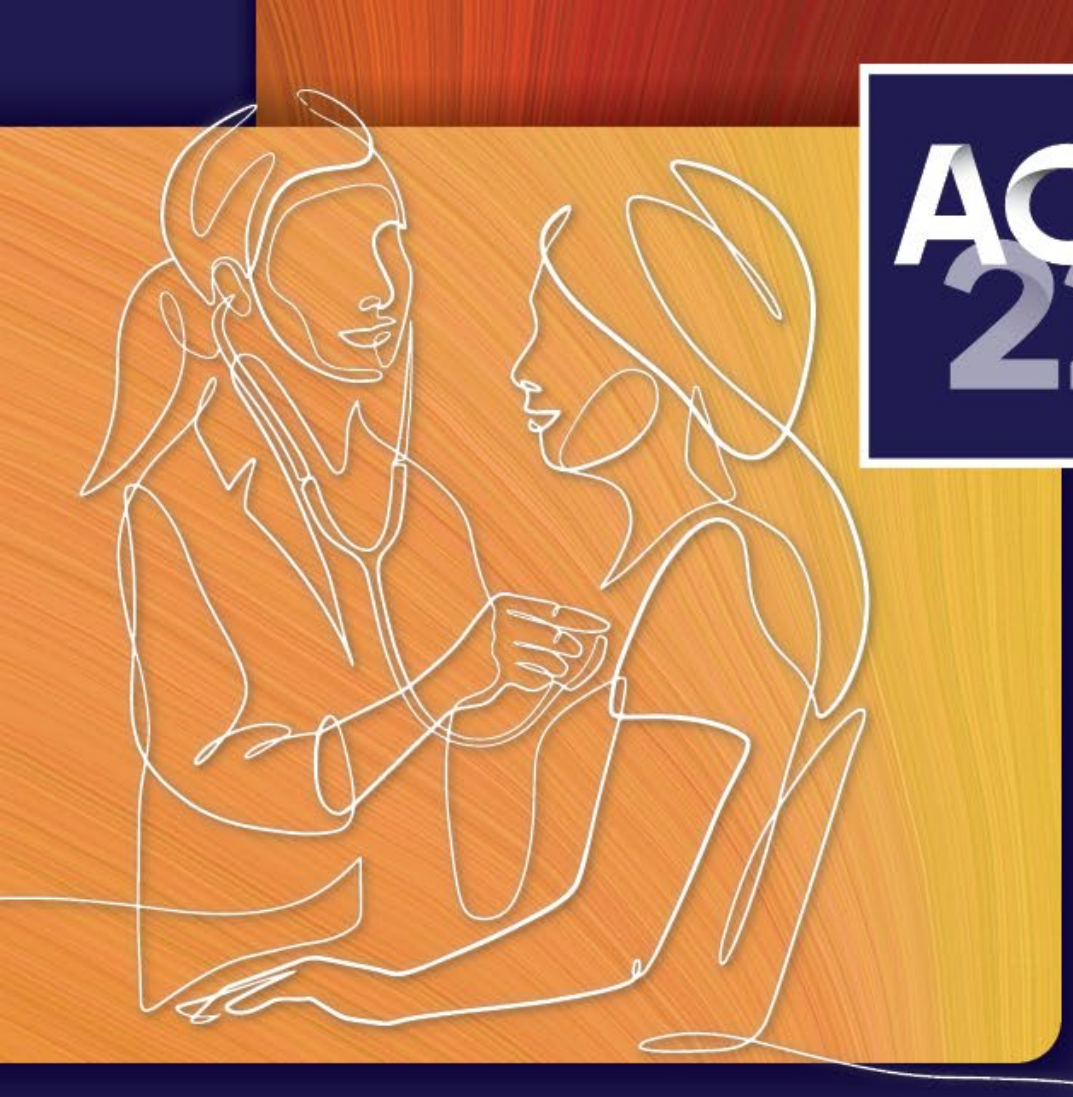

ACC 22

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

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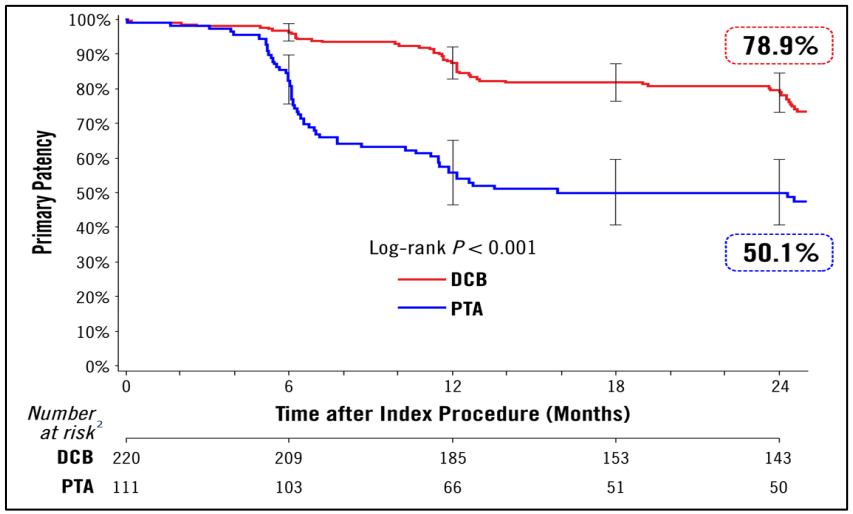
TRANSFORMING CARDIOVASCULAR CARE FOR YOU. FOR YOUR TEAM. FOR YOUR PATIENTS.

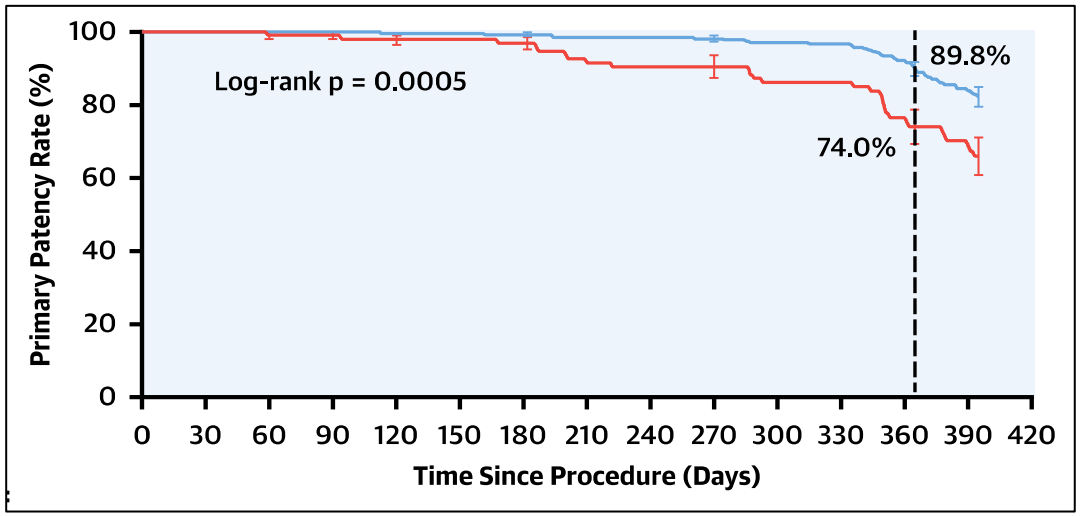
AMERICAN COLLEGE of CARDIOLOGY

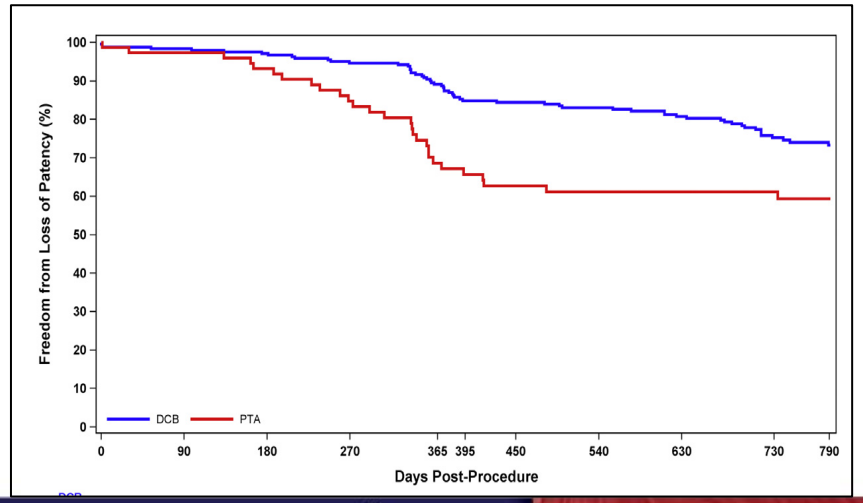
Disclosures

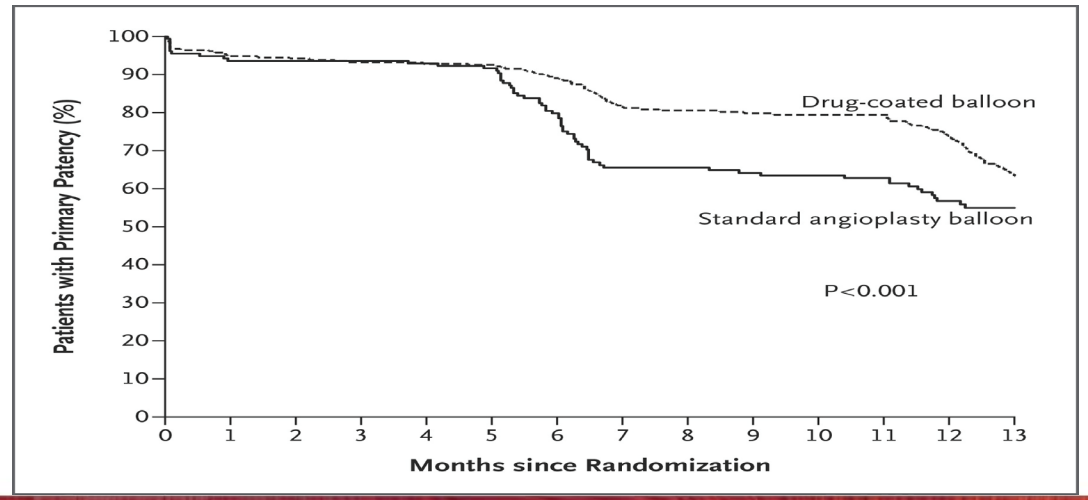
- Advisory board – Medtronic, Boston Scientific, Philips, Terumo, Abbott Vascular, ANT, Inquis Medical

Drug Coated Balloons Are Superior to Balloon Angioplasty





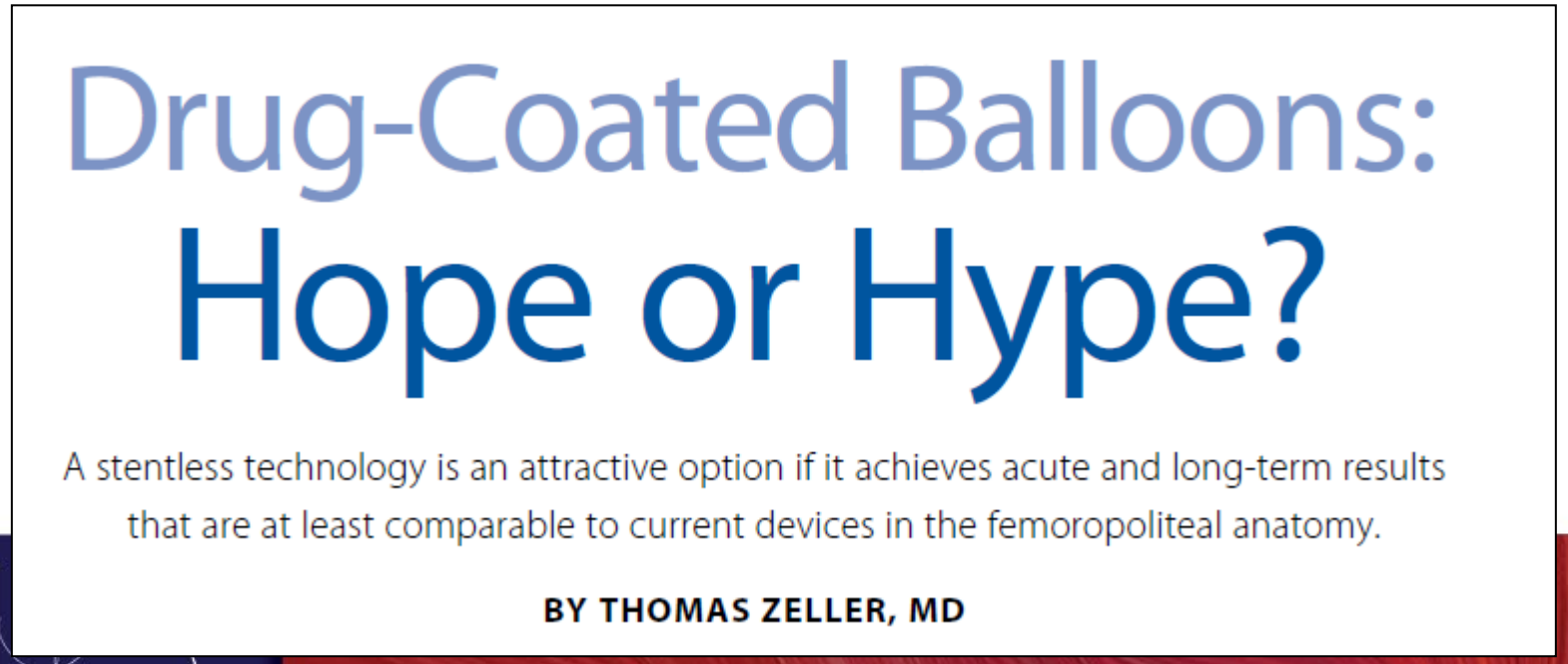




Krishnan et al. *Circulation*. 2017;136:1102-1113. Sachar et al. *JACC Cardiovasc Interv*. 2021;14:1123-1133. Rosenfield et al. *N Engl J Med*. 2015;373:145-53. Tepe et al. *Circulation*. 2015;131:495-502.

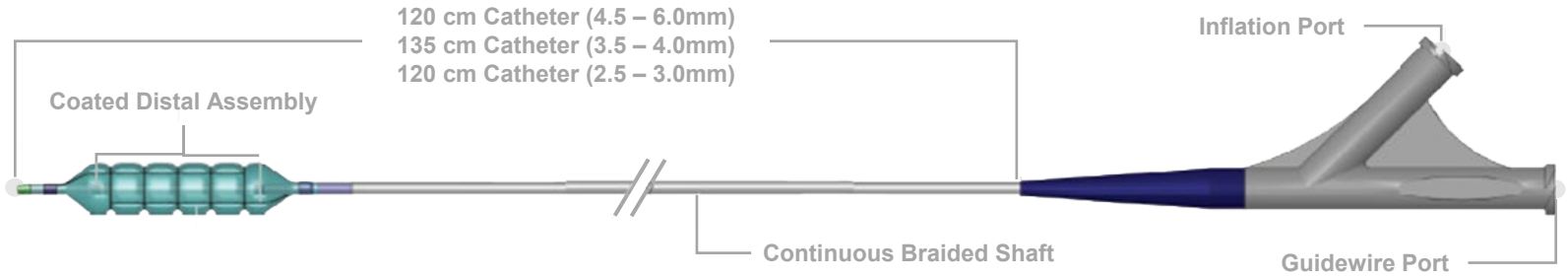
Current Limitations of Drug-Coated Balloons

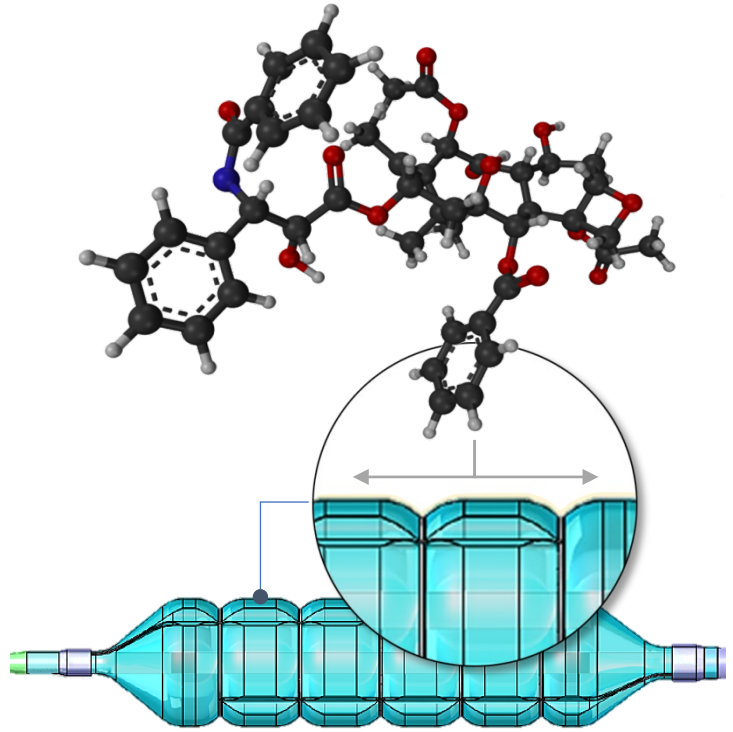
- Acute dissection and bailout stenting
- Significant recoil
- Minimal acute luminal gain
- Presence of Ca+



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

Open-label, randomized, non-inferiority trial
Patient with symptomatic SFA or popliteal arteries

34 sites (USA, Europe, New Zealand)
July 26, 2017, to May 26, 2020
1:1 Randomization

Chocolate Touch n=152

Lutonix n=161

20 Roll-in patients

30 d | **6 mo** | **12 mo** | **2 yr** | **3 yr** | **4 yr** | **5 yr**

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

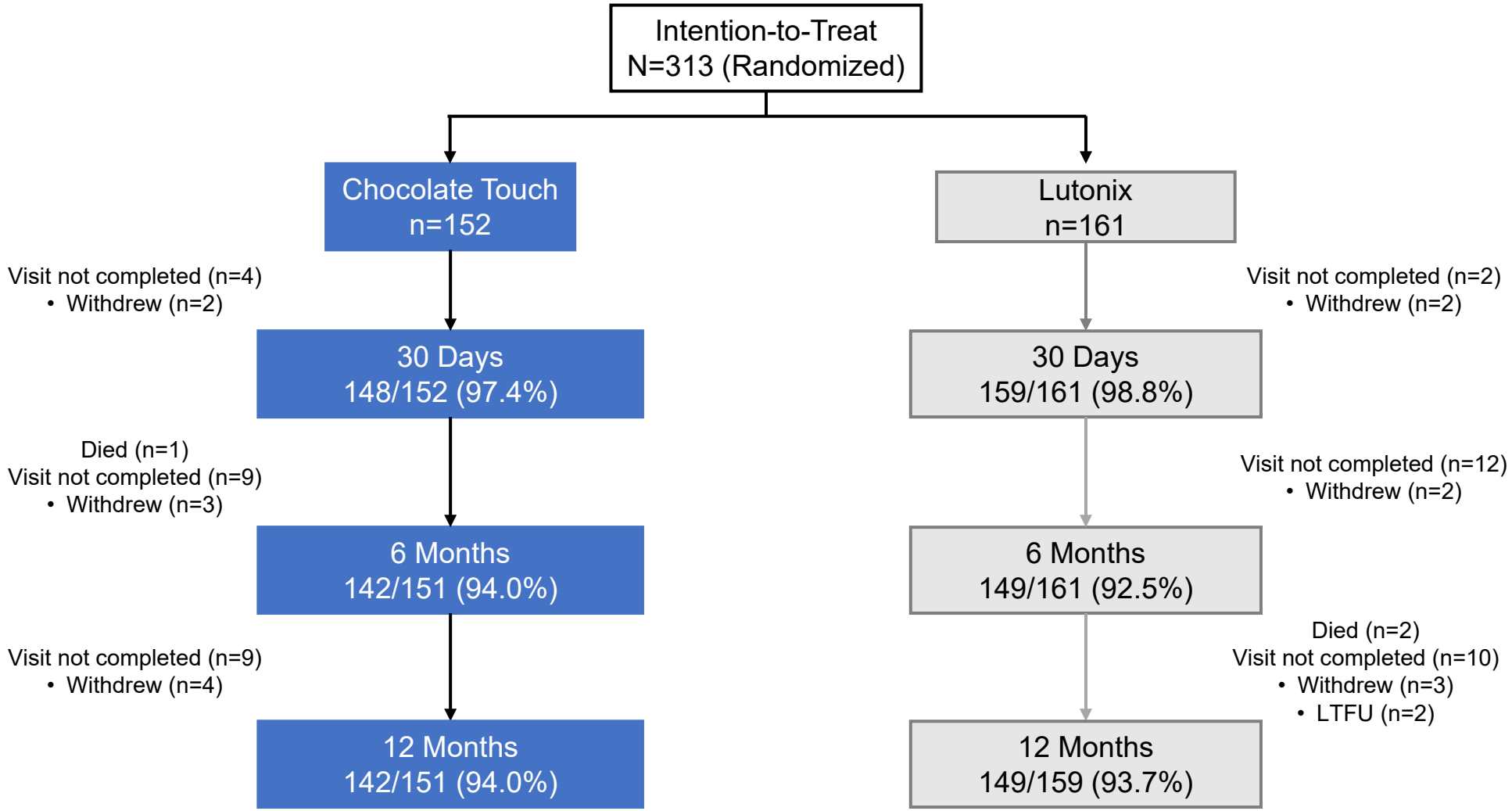
Primary Efficacy (DCB Success)	Primary Safety (Freedom from MAE)
Non-inferiority assumptions: 216 evaluable subjects would provide >90% power to declare non-inferiority • DCB success rate: 80% for Chocolate Touch and 70% for Lutonix • one-sided alpha=0.025 • 10% non-inferiority margin • 15% Loss to FU	**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



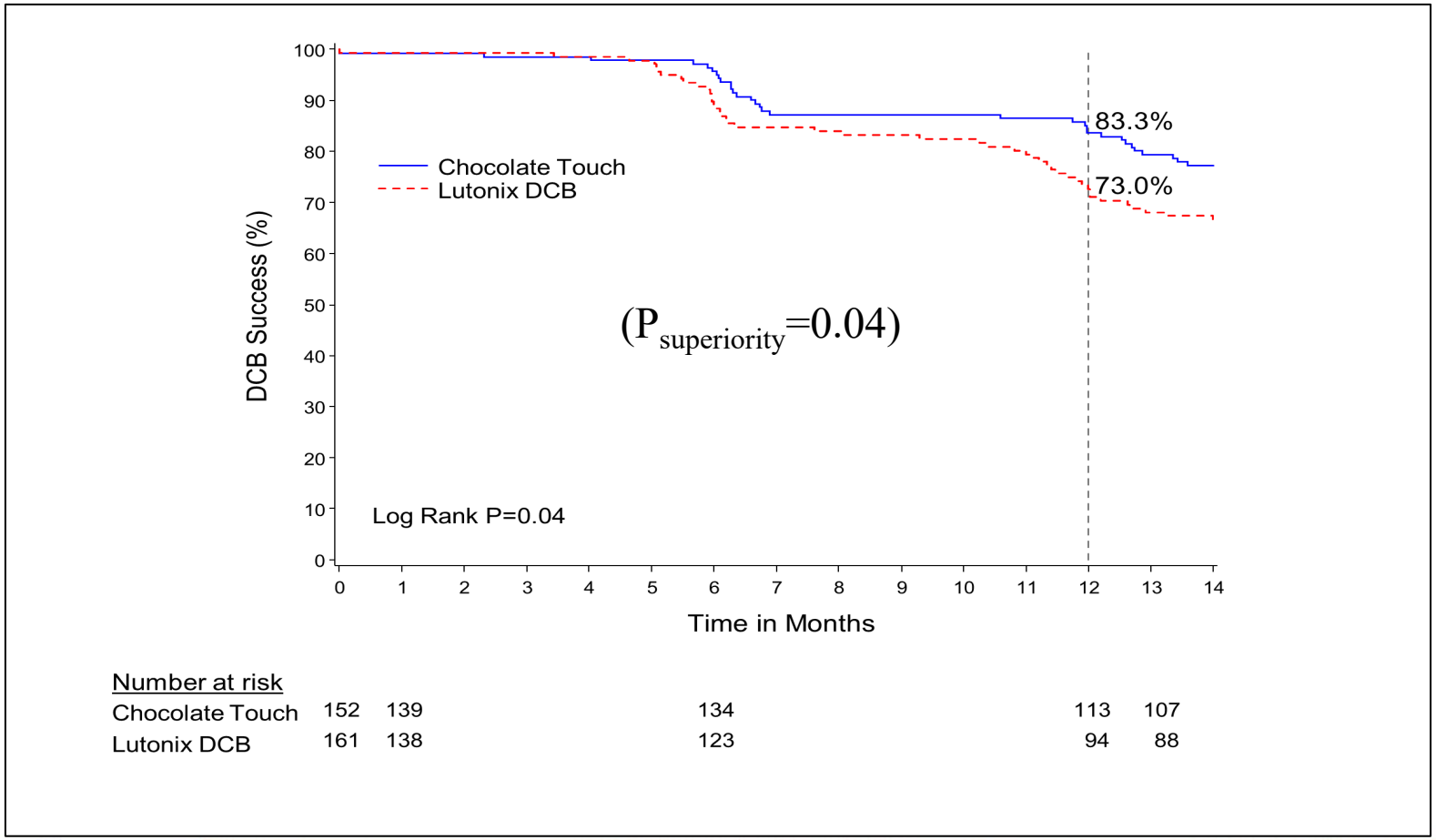
Baseline Characteristics

	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

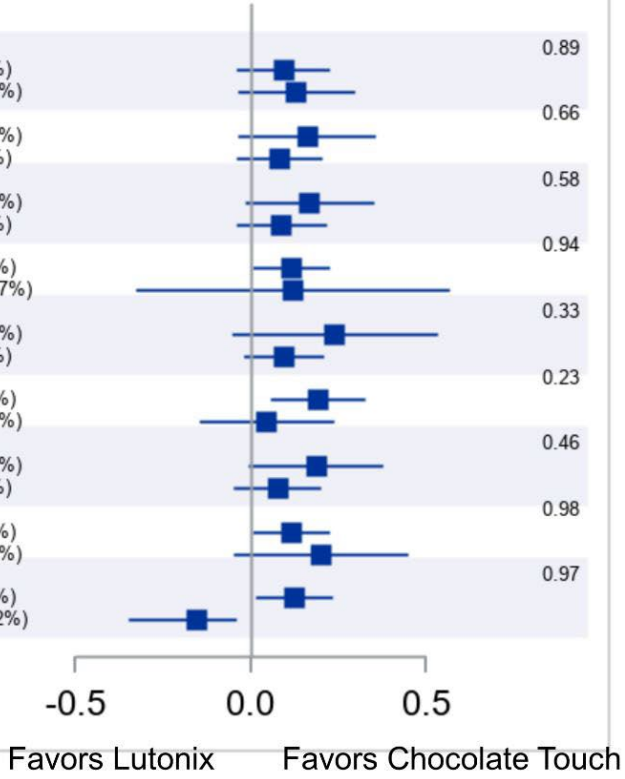
Primary Efficacy Endpoint (Chocolate Touch 78.8% versus Lutonix DCB 67.7%) ($P_{non\text{-}inferiority}<0.0001$)



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%)	



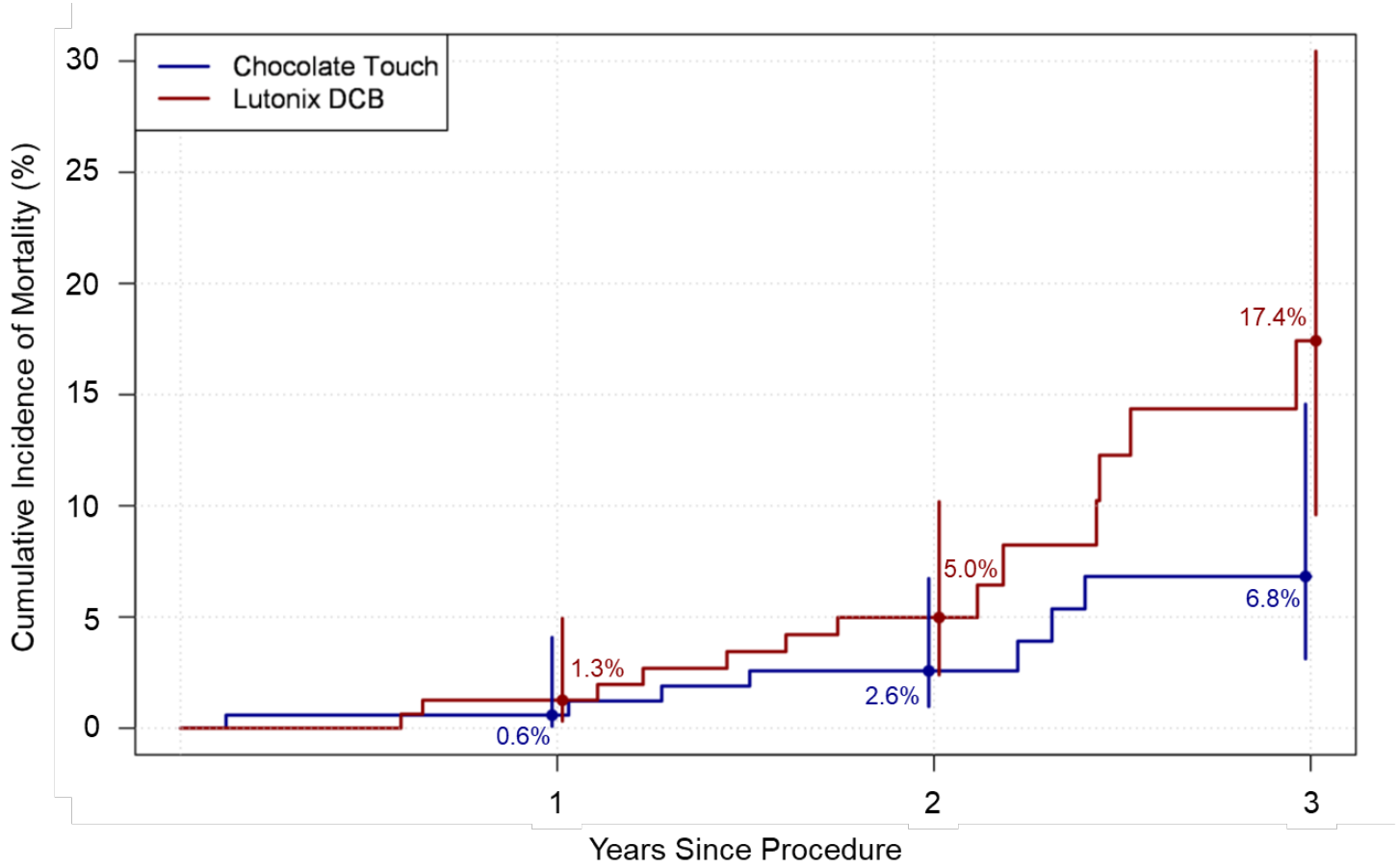
Interaction P-value from the fixed effects logistic regression model treatment by subgroup interaction term.

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

Thank You!