IN.PACT DCB vs BMS in FP Lesions

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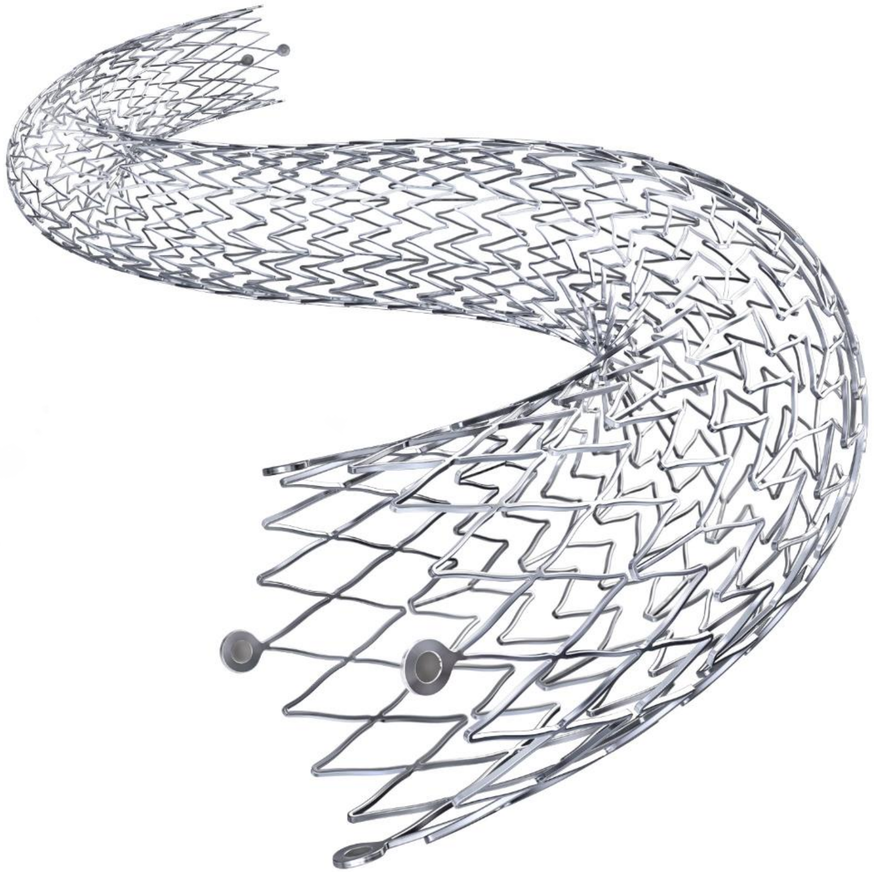
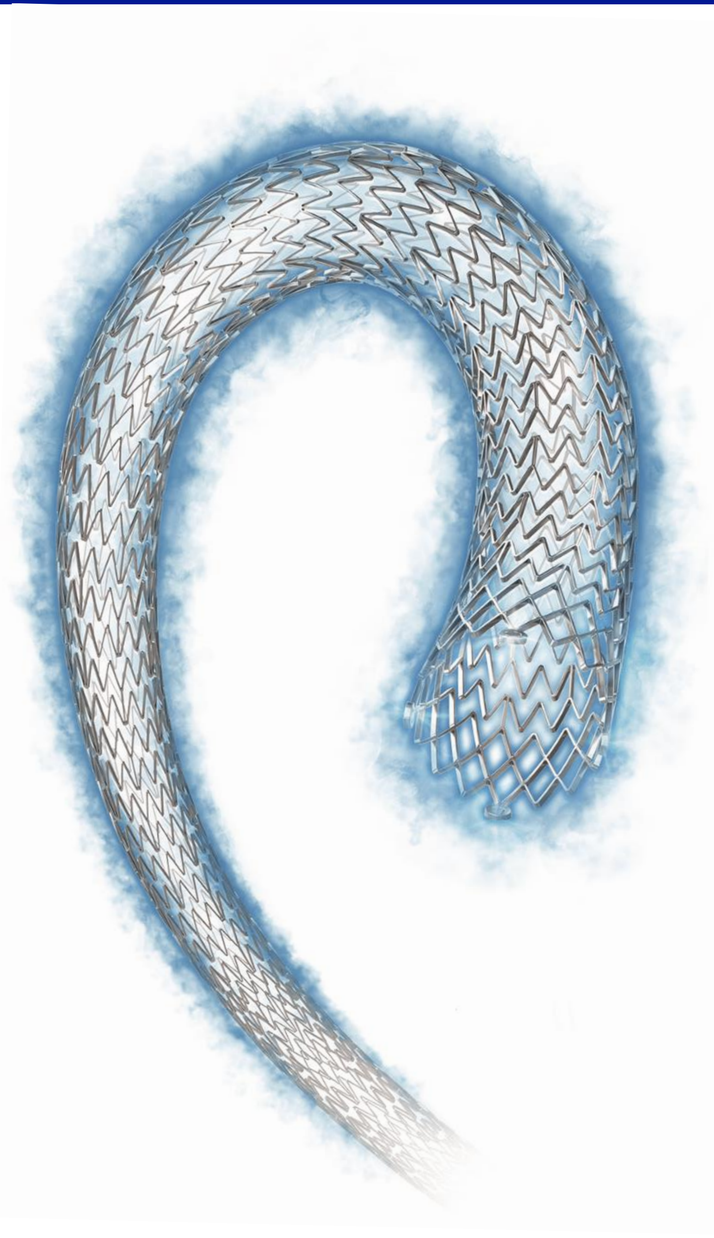
What would you choose?





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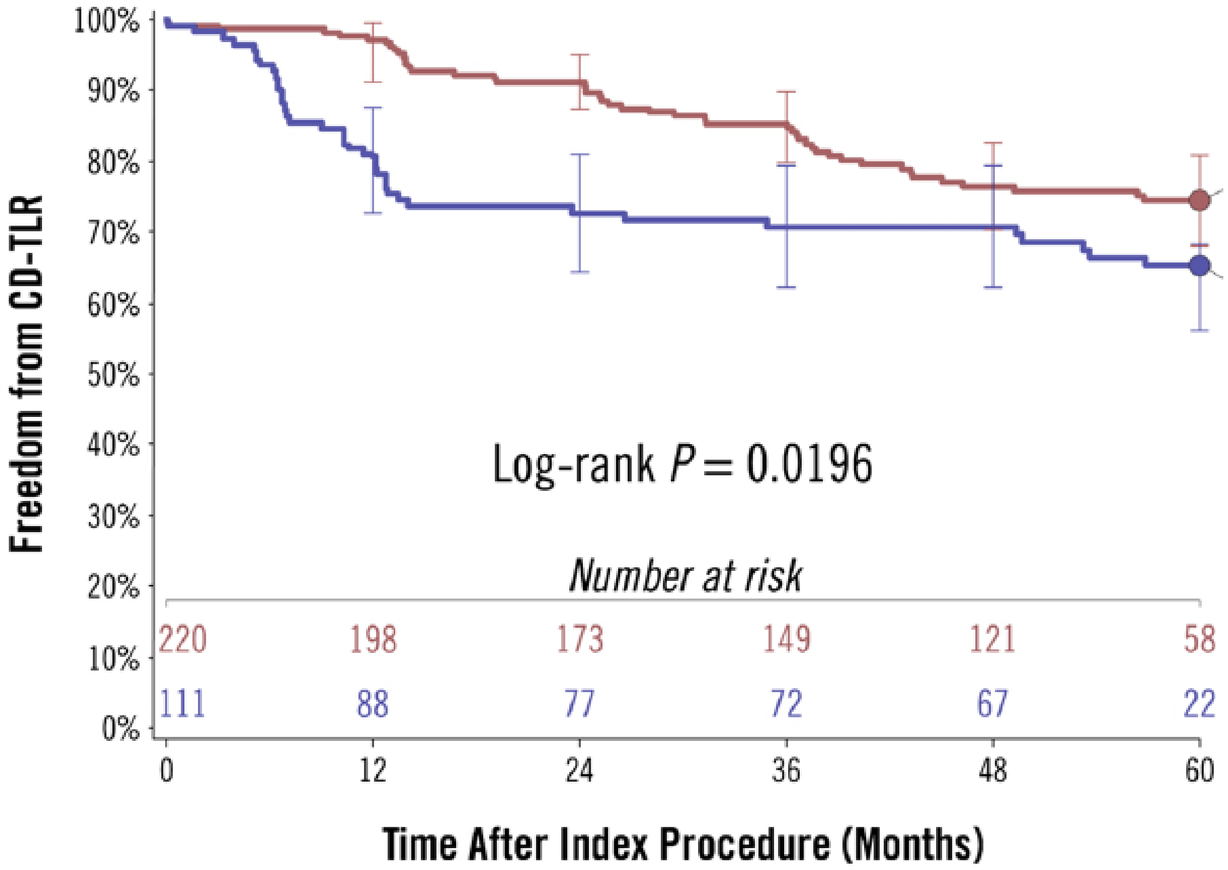
DCB vs. PTA in randomized trials

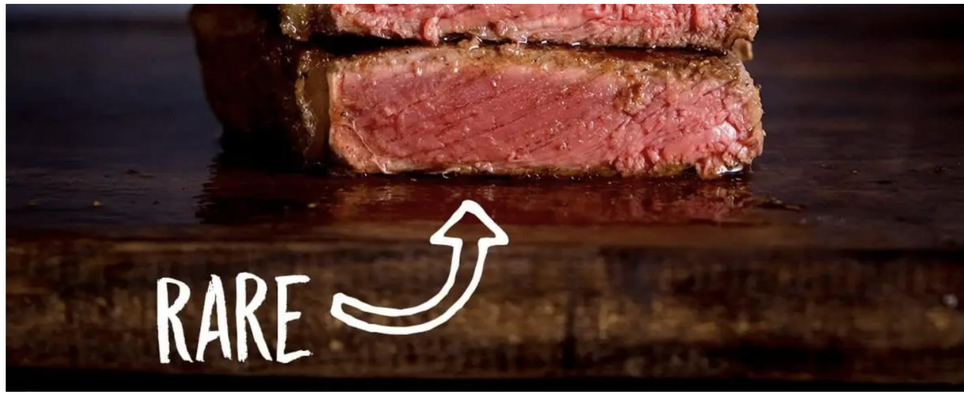


74.5% - IN.PACT™ Admiral™ drug-coated balloon (DCB)

65.3% - Standard PTA

CD-TLR: clinically driven target lesion revascularization; PTA: Percutaneous transluminal angioplasty

DCB vs. BMS



Laird et al. Circ Cardiovasc Interv. 2019;12:e007702

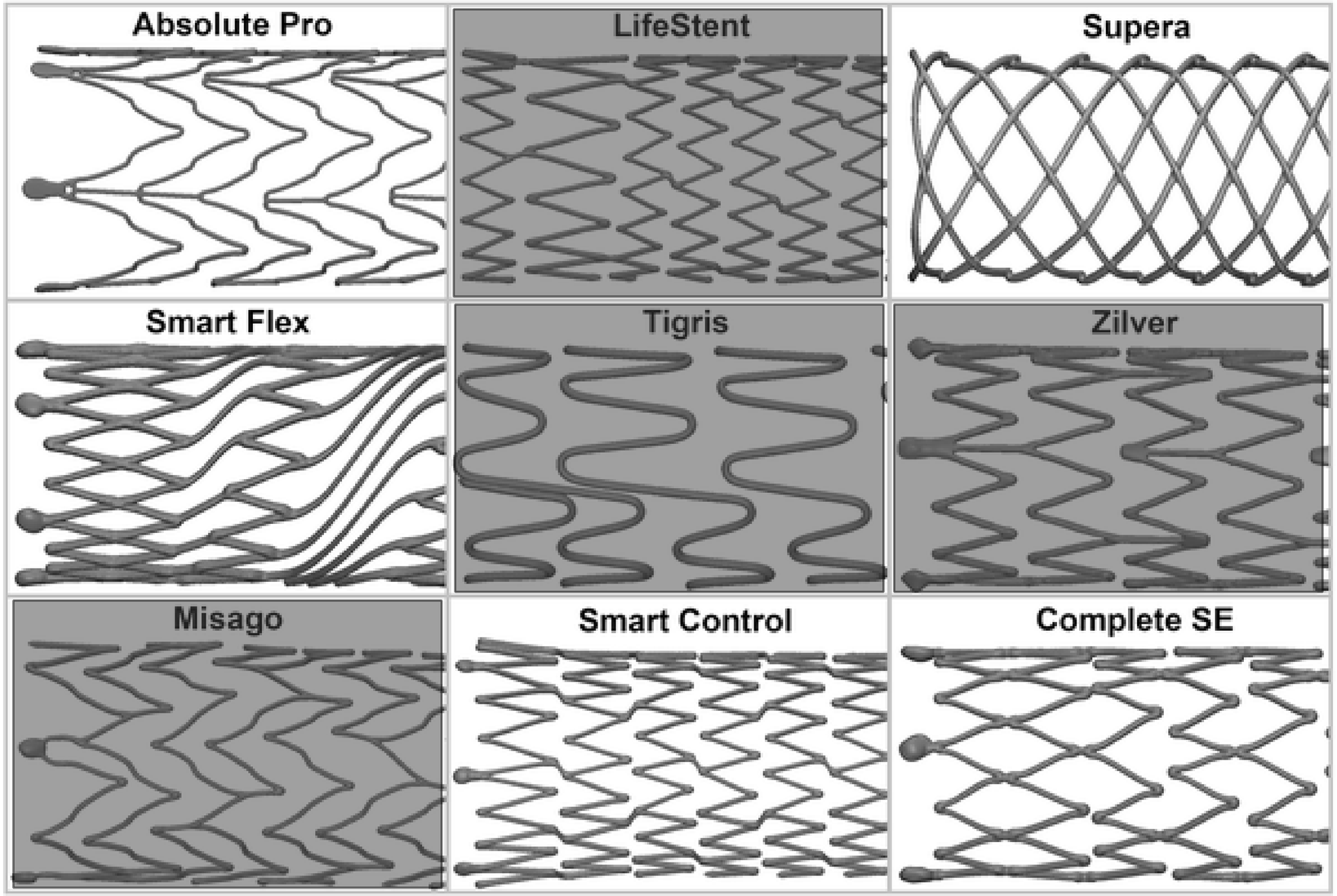
IN.PACT admiral DCB programs

			Lesion Length	Provisional Stenting	1-year Patency	1-year CD-TLR	2-years Patency	2-yeas CD-TLR	3-years Patency	3-years CD-TLR	4-years CD-TLR	5-years CD-TLR
Pivotal Studies		IN.PACT SFA Trial [1] (N=331, DCB 220 : PTA 110)	8.9 cm	7.3%	**87.5%**	2.4%	**79.0%**	9.1%	**69.5%**	15.2%	23.2%	**25.5%**
		IN.PACT Japan Trial [2] (N=100, DCB 68 : PTA 32)	9.2 cm	4.4%	**93.9%**	2.9%	**79.8%**	9.1%	**68.9%**	14.9%		
		IN.PACT China Trial [3] (N=143)	10.4 cm	4.2%	**90.9%**	2.9%						
IN.PACT Global Study		Clinical Cohort [4] (N=1406)	12.1 cm	25.3%	N/A	7.5%	N/A	16.9%	N/A	**23.5%**	**26.6%**	**30.6%**
	Pre-specified Cohorts	In-stent Restenosis [5] (N=131)	17.2 cm	14.5%	**88.7%**	7.3%						
		Long Lesion [6] (N=157)	26.4 cm	40.4%	**91.1%**	6.0%						
		CTO [7] (N=126)	22.8 cm	46.8%	**85.3%**	11.3%						
	Sub-Analysis	Complex Lesion [8] (N=227)	28.7 cm	N/A	**89.1%**	7.1%						
		Asian Subset [9] (N=114)	17.4 cm	19.3%	N/A	**3.8%**						
		CLI : RCC 4 & 5 [10] (N=156)	13.9 cm	23.4%	N/A	**14.1%**						
		Stented [11] (N=353)	15.37 cm	-	N/A	8.6%	N/A	19.6%				
		No-Stented [11] (N=1044)	10.97cm	-	N/A	7.2%	N/A	16.1%				

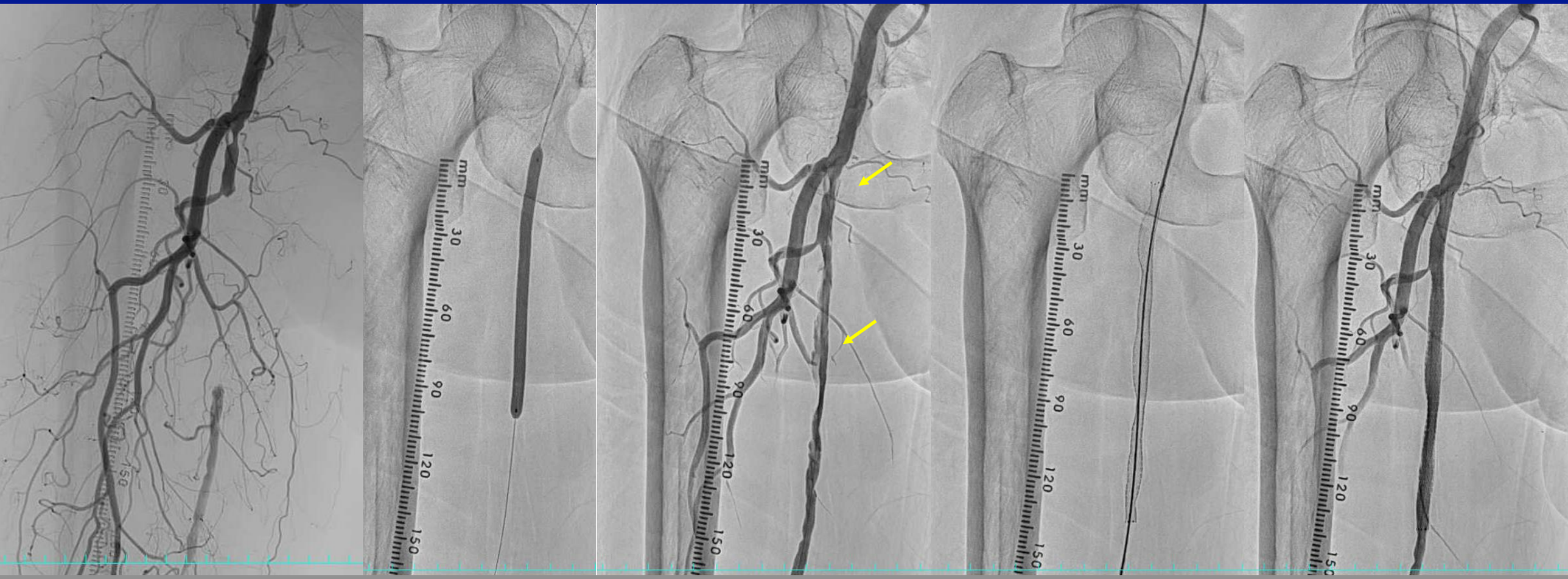
Patency values are KM estimates, Primary Patency is defined as the freedom from core laboratory-assessed restenosis (duplex ultrasound PSVR ≤2.4) or clinically-driven target lesion revascularization through 12 months (adjudicated by a Clinical Events Committee).

1-Medtronic Data on file. "The IN.PACT SFA Trial investigated the safety and efficacy of IN.PACT™ Admiral™ DCB versus PTA.: 1-year Outcomes: IN.PACT™ Admiral™ IFU M052624T001 Rev. 1F | 2-year Outcomes: Laird et al, JACC, VOL. 66, NO.21, 2015 | 3-year Outcomes: Schneider et al. CircCardiovasc Interv. 2018;11:e005891 | 4-year Outcomes: Schneider, P., VIVA 2017 | 5-year Outcomes: Laird, J., VIVA 2018
2-Medtronic data on file: 1-year Outcomes: Iida et al, JEVT, VOL .25 (1) 109-117 | 2-year outcomes-Iida,,O., LINC 2018 | 2-year outcomes-Iida,,O., LINC 2019
3-Medtronic data on file: 1-year Outcomes: Zhong Chen, VEITH 2017
4-Medtronic data on file: 1 year outcomes: Michael Jaff, DO, VIVA 2016 | 2-year Outcomes: IN.PACT Global Study Two-year outcomes Full Clinical Cohort. Zeller, T. VIVA 2017| | 3-year Outcomes: IN.PACT Global Study Three-year outcomes Full Clinical Cohort. TepeG.CIRSE 2018 | IN.PACT Global Study 4Y outcomes Full Clinical Cohort. Zeller, T. VIVA 2019
5-Medtronic data on file: M. Broadmann et a IJACC: Cardiovascular Interventions, Volume 10, Issue 20, October 2017
6-Medtronic data on file: D. Sheinert , EuroPCR 2015
7-Medtronic data on file: G. Tepe, LINC 2018
8-IN.PACT™ Admiral™ IFU M052624T001 Rev. 1G
9-Medtronic data on file: D.H. Choi, LINC 2017
10-Medtronic data on file: M. Reijnen, LINC 2018

Types of Nitinol BMS

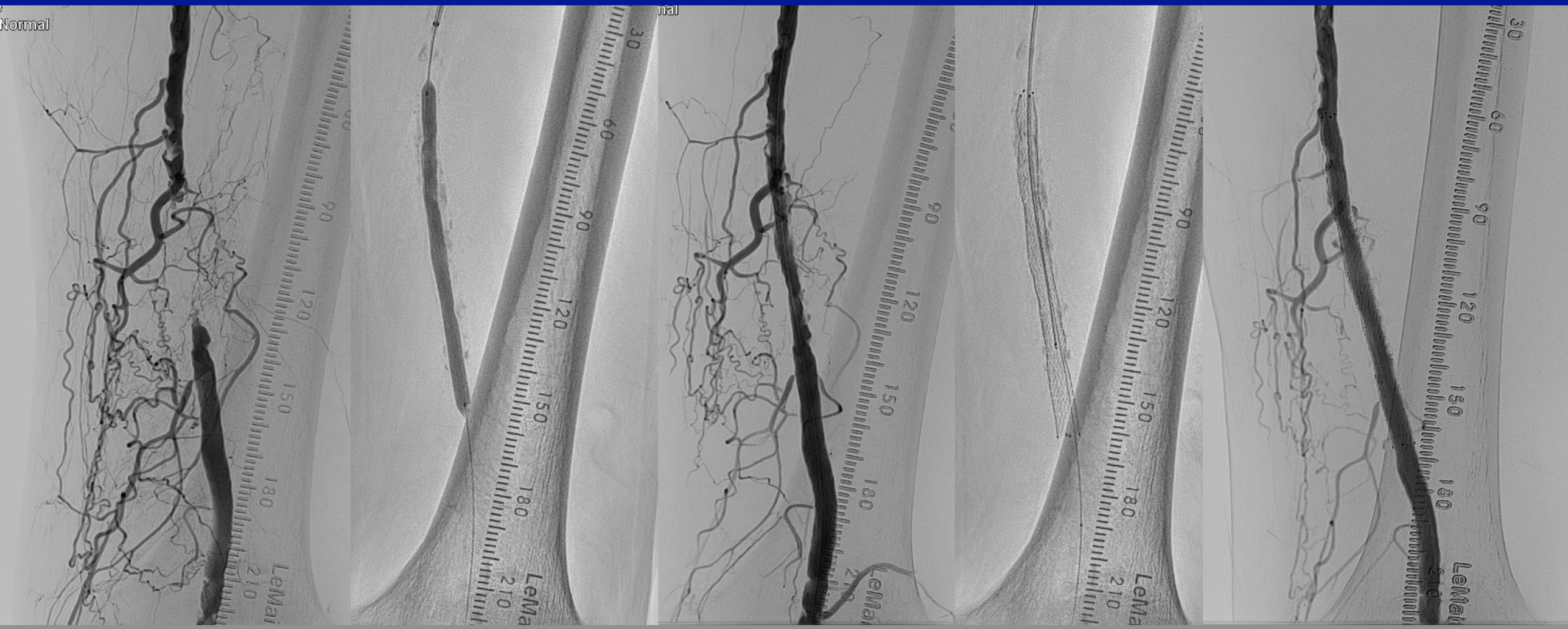


Good Points of Stent : Recoil, Dissection



Stent guarantee the Success

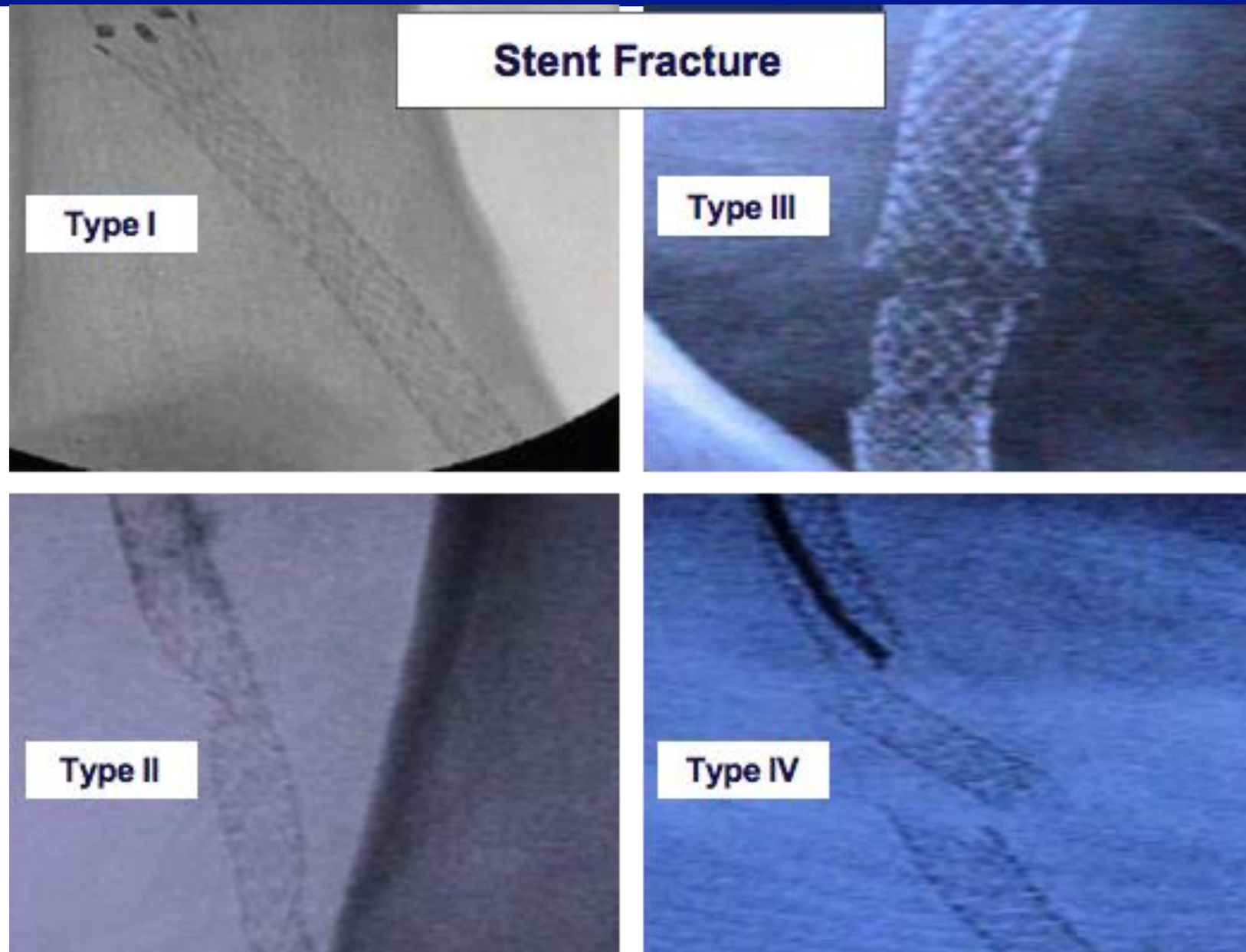
Traditional Tx. for FP lesions



Stenting after POBA is the Basic.

Well Known Limitations of SFA stenting

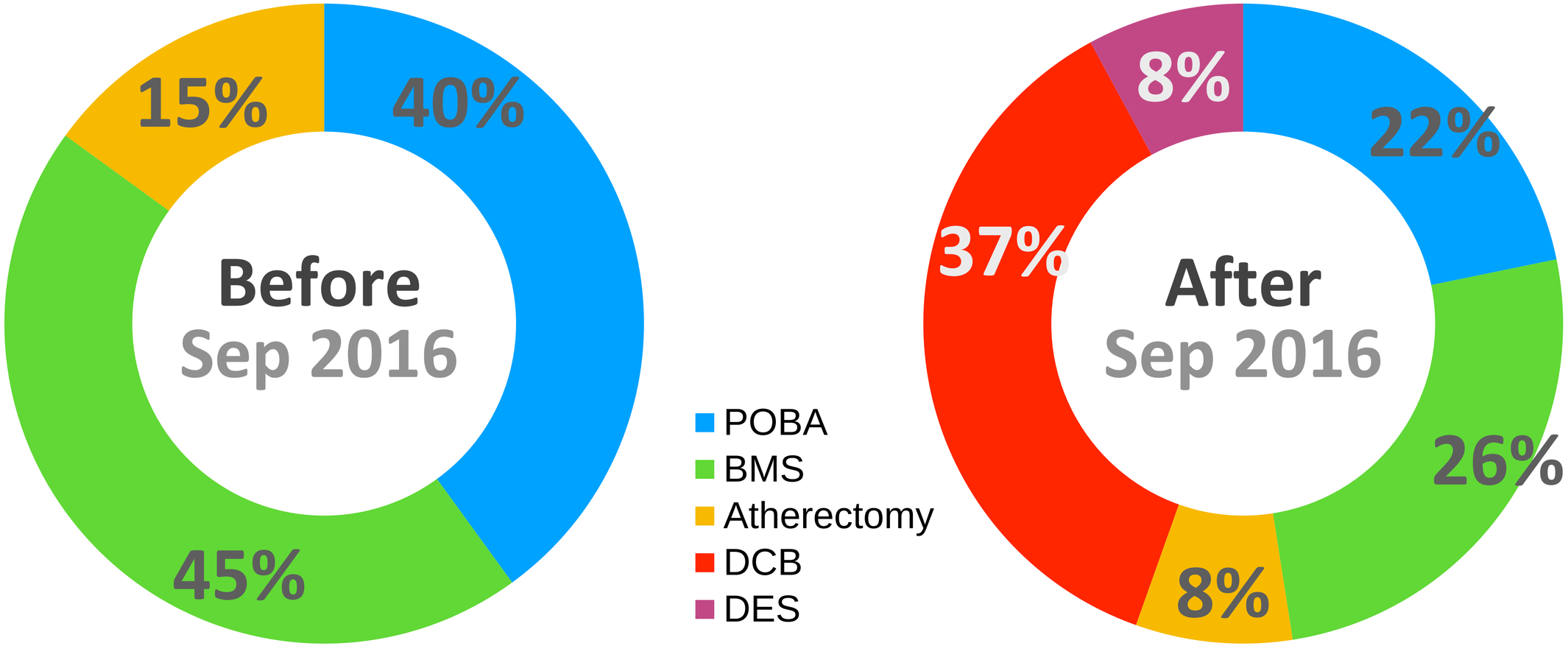
- Patency in Long Lesion?
- Stent Fracture
- Restenosis : Tosaka 3
- Thrombosis
- Cost-Effective?



1. Scheinert et al. J Am Coll Cardiol. 2005;45:312-5

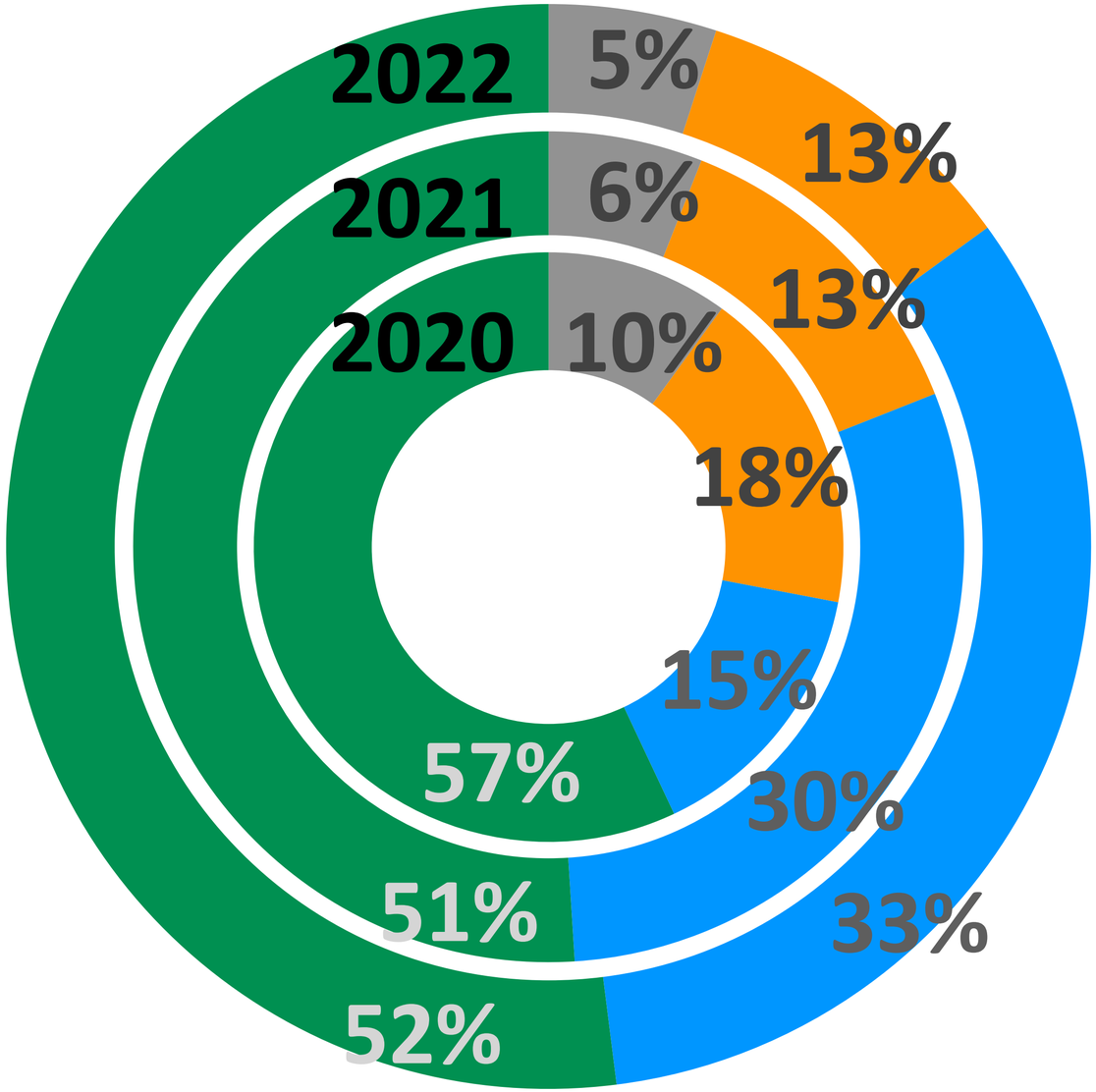
US trends in Peripheral Vascular Interventions

- Vascular Quality Initiative
- 2010-2107, All FP EVT, 74,842 EVTs
- Before vs. After 1st drug coated device entry into the database (Sep. 2016)



Mohapatra et al. J Vasc Surg. 2020;71:560-6
BMS: bare metal stent; DCB: drug-coated balloon; DES: drug-elutiong stent; POBA: plain old balloon angioplasty.

Market Share of DCBs in Korea



- other
- Lutonix
- Ranger
- INPACT

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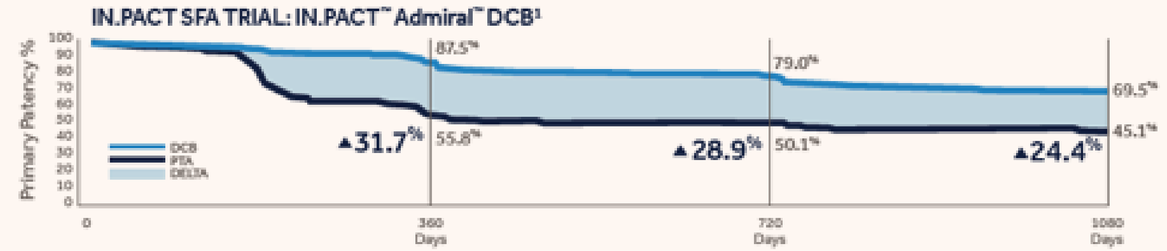
Why do they sell the most in Korea?

IN.PACT™
Medtronic



S*******
P*******

L***
B*****

R***
B**** S*********

Highest Patency
Unparalleled Effectiveness

Compared to PTA.

[1] Schneider PA, Laird J, Tepe G, et al. Treatment Effect of Drug-Coated Balloons Is Durable to 3 Years in the Femoropopliteal Arteries: Long-Term Results of the IN.PACT SFA Randomized Trial. *Circ Cardiovasc Interv*. January 2018;11(1):e005891.

[2] Mathews SJ. Stellarex in the Treatment of the SFA and Popliteal: Late-Breaking 3-Year Data. Presented at: NCVH 2019; New Orleans, LA.

[3] LEVANT 2 Trial. Presented at SVS 2015; Chicago, IL.

[4] Brodmann M. Data presented at LINC 2020; Leipzig, Germany.

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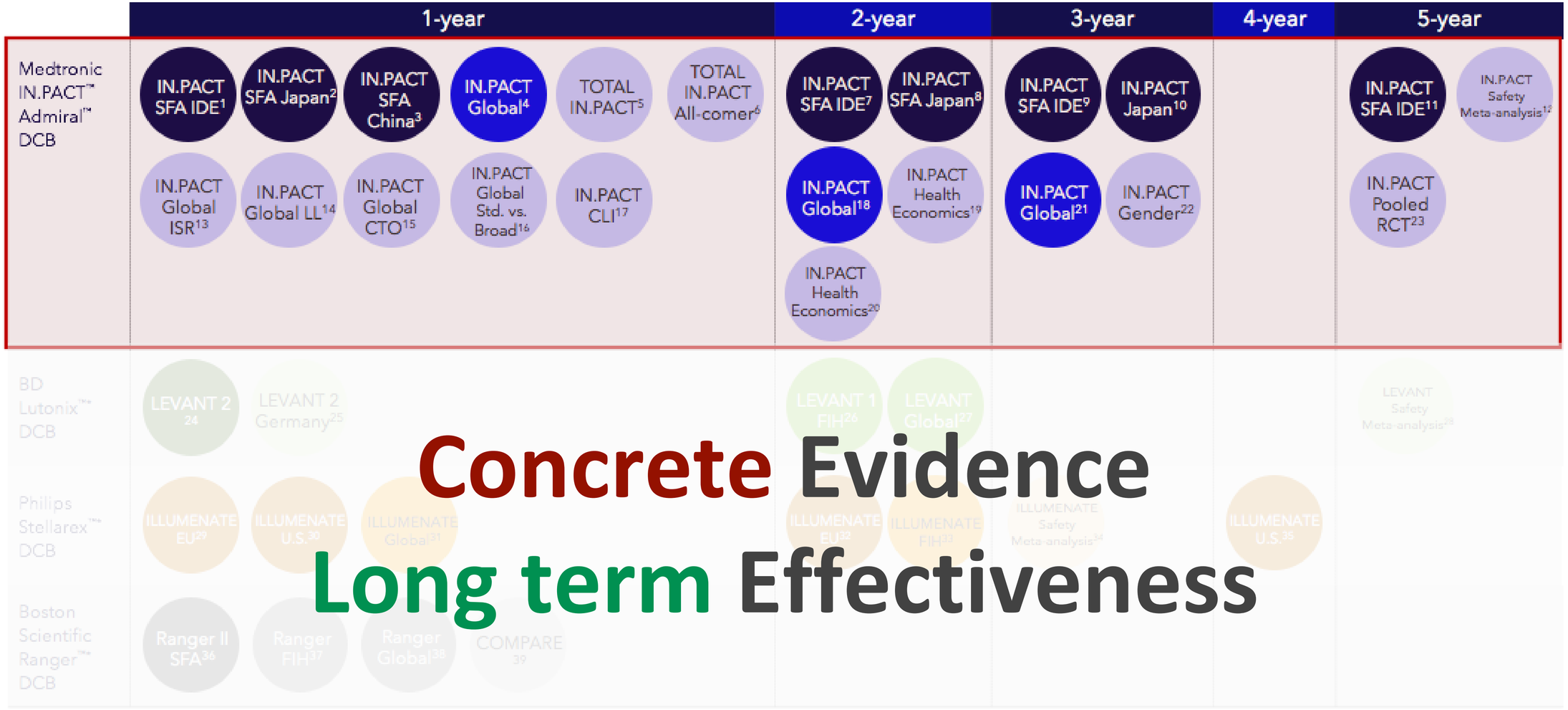
VHS Busan Hospital

Why do they sell the most in Korea?



Concrete Evidence

Long term Effectiveness

Why do they sell the most in Korea?

Medtronic	IN.PACT	Aug 2015
BD	Lutonix	Oct 2018
BIOTRONIK excellence for life	Passeo-35 Lux	May 2018
B BRAUN SHARING EXPERTISE	Sequent Please	Aug 2018
Boston Scientific Advancing science for life™	Ranger	Feb 2019

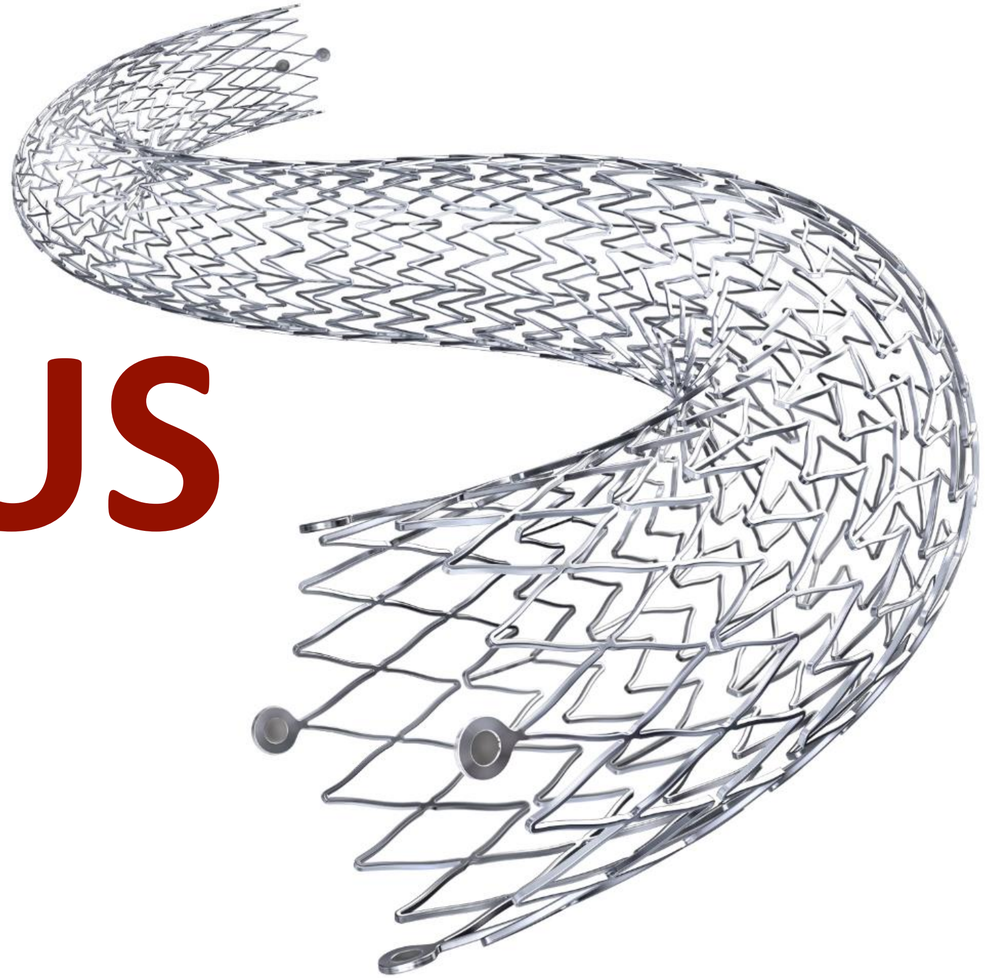
조강지처 糟糠之妻

Wife who has shared one's difficulties

보훈공단 부산보훈병원 VHS Busan Hospital

DCB vs. BMS in FP disease

VERSUS



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DCB vs. BMS in FP disease

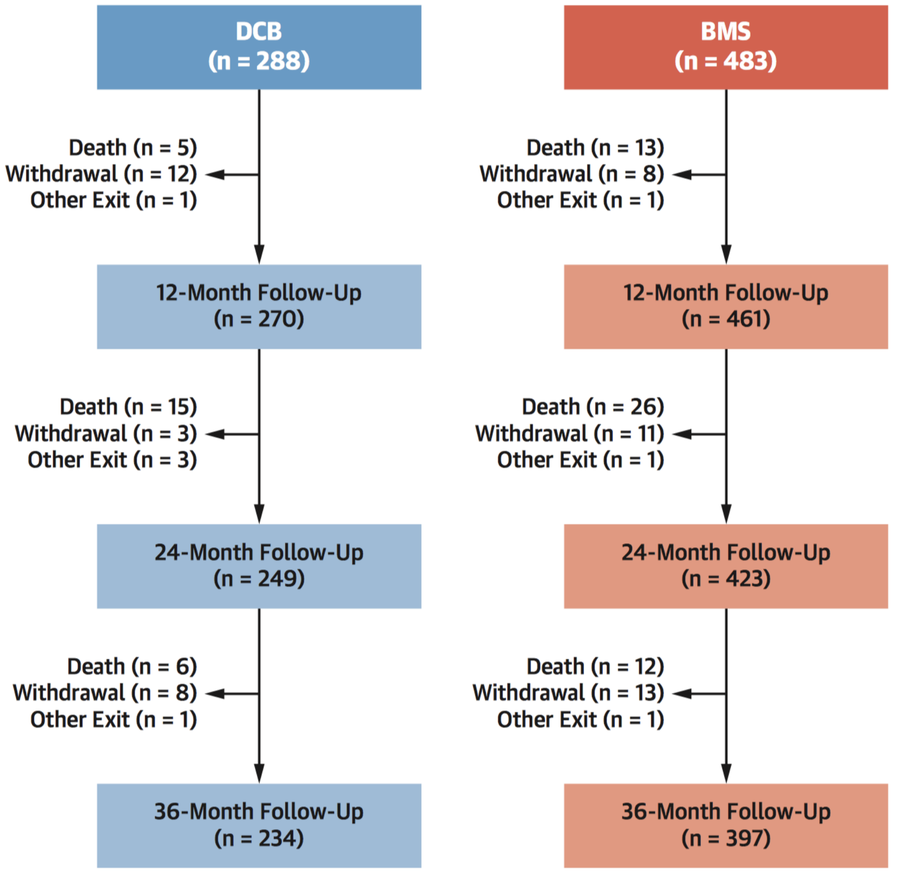
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 81, NO. 3, 2023

Comparison of Drug-Coated Balloons vs Bare-Metal Stents in Patients With Femoropopliteal Arterial Disease

Mehdi H. Shishehbor, DO, MPH, PhD,[a] Dierk Scheinert, MD,[b] Ashit Jain, MD,[c] Marianne Brodmann, MD,[d] Gunnar Tepe, MD,[e] Kenji Ando, MD,[f] Prakash Krishnan, MD,[g] Osamu Iida, MD,[h] John R. Laird, MD,[i] Peter A. Schneider, MD,[j] Krishna J. Rocha-Singh, MD,[k] Thomas Zeller, MD, PhD[l]

- Patient level pooled analysis
- 4 prospective multicenter pivotal trials
- Clinical outcomes to 36 Mos
- Primary patency to 12 Mos

FIGURE 1 Patients Included in the Analysis



A pooled analysis was conducted of patients treated with drug-coated balloons (DCB) from the IN.PACT SFA and IN.PACT SFA Japan studies and patients treated with bare-metal stents (BMS) in the Complete SE and DURABILITY II studies. Figure shows the follow-up compliance at 12 months, 24 months, and 36 months; n represents the number of patients eligible for evaluation at each time point.

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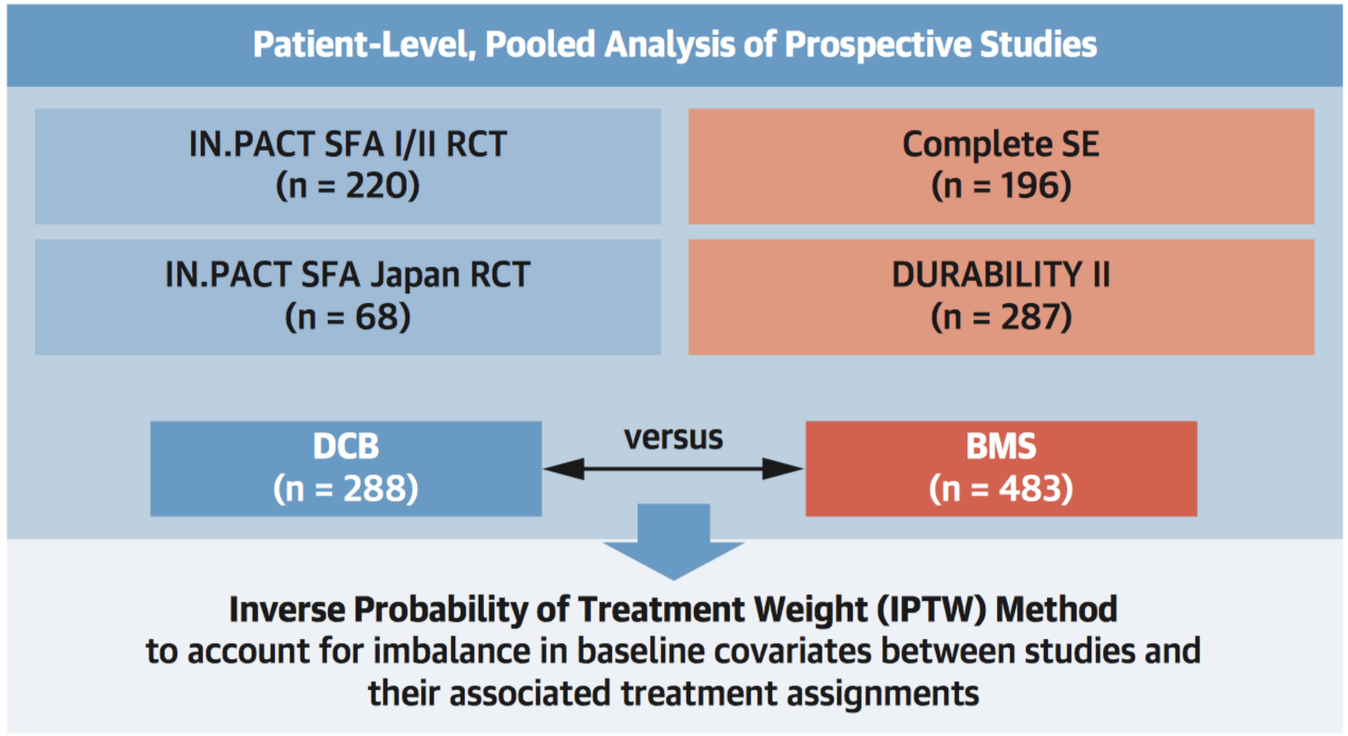
Shishehbor MH et al. J Am Coll Cardiol 2023;81:237-249

Study Design



12-Month Primary Patency and 36-Month Freedom From CD-TLR Statistically Significantly Better in DCB vs BMS

DCB	BMS
90.4% Primary Patency	**80.9%** Primary Patency
85.6% Freedom from CD-TLR	**73.7%** Freedom from CD-TLR

	36-Month Incidence	DCB	BMS	*P* Value
MAE lower in DCB group	MAE	25.3 (69)	38.8 (175)	<0.001
	All-Cause Death	9.5 (25)	13.0 (51)	0.23
No difference in mortality	Major Amputation	0.0 (0)	0.8 (4)	0.29
	Thrombosis	1.0 (5)	2.1 (10)	0.41

Values are % (number of patients with an event) or mean ± SD. Cumulative incidence based on Kaplan-Meier estimates with IPTW-adjusted log-rank *P* values.

1. Laird et al. Circ Cardiovasc Interv. 2019;12:e007702.
2. Soga et al. J Endovasc Ther. 2020;27:946-55.
3. Laird et al. J Endovasc Ther. 2014;21(2):202-212.
4. Rocha-Singh et al. Catheter Cardiovasc Interv. 2015;86:164-170.

BMS: bare metal stent; DCB: drug-coated balloon; PTA: percutaneous transluminal angioplasty

IPTW adjusted Demographics

TABLE 1 IPTW-Adjusted Baseline, Lesions, and Procedure Characteristics

	DCB (n = 288; 289 Lesions)	BMS (n = 483; 500 Lesions)	Difference [95% CI]	*P* Value[a]
Age, y	68.9 ± 9.6	68.5 ± 10.4	0.3 [−1.1 to 1.8]	0.64
Male	64.7	65.3	−0.6 [−7.5 to 6.4]	0.87
Hypertension	90.2	89.6	0.6 [−3.8 to 5.0]	0.78
Hyperlipidemia	82.4	83.1	−0.7 [−6.2 to 4.8]	0.81
Diabetes mellitus	39.7	43.3	−3.6 [−10.8 to 3.6]	0.33
Insulin dependent	7.7	5.8	1.9 [−1.9 to 5.6]	0.31
Coronary heart disease	48.7	50.6	−1.9 [−9.3 to 5.4]	0.61
Active smoker	33.5	34.0	−0.5 [−7.4 to 6.4]	0.90
Prior smoker	31.5	33.9	−2.5 [−9.3 to 4.4]	0.48
Renal insufficiency[b]	10.3	10.3	−0.0 [−4.5 to 4.4]	0.99
Previous peripheral revascularization	38.7	37.4	1.2 [−5.9 to 8.3]	0.73
Rutherford category				0.65
2	43.2	41.5	1.7 [−5.6 to 8.9]	
3	52.6	54.1	−1.5 [−8.8 to 5.8]	
4	4.2	3.8	0.4 [−2.5 to 3.3]	
5[c]	0.0	0.6	−0.6 [−1.3 to 0.1]	
ABI (mm Hg ratio)[d]	0.71 ± 0.22	0.73 ± 0.23	−0.02 [−0.05 to 0.02]	0.34
Target vessel				
SFA only	95.8	96.4	−0.5 [−3.4 to 2.3]	0.71
PPA only	2.5	3.6	−1.2 [−3.6 to 1.3]	0.38
SFA and PPA	1.7	0.0	1.7 [0.2 to 3.2]	0.004
Preprocedure[e]				
Calcification	69.4	71.5	−2.2 [−8.8 to 4.5]	0.52
RVD, mm	4.7 ± 0.8	4.8 ± 0.9	−0.0 [−0.1 to 0.1]	0.83
MLD, mm	0.9 ± 0.8	0.9 ± 0.8	−0.0 [−0.1 to 0.1]	0.95
Occluded lesion (100% stenosis)	34.7	33.7	1.0 [−5.9 to 7.9]	0.78
Diameter stenosis, %	82.5 ± 16.3	82.0 ± 16.0	0.4 [−1.9 to 2.8]	0.71
Lesion length, cm	8.1 ± 4.7	7.9 ± 4.5	0.2 [−0.5 to 0.9]	0.57
Postprocedure[e]				
MLD, mm	4.0 ± 0.8	4.0 ± 0.8	0.0 [−0.1 to 0.1]	0.98
Residual stenosis, %	20.0 ± 9.8	17.1 ± 9.9	2.9 [1.5 to 4.3]	<0.001
Acute gain, mm	3.1 ± 1.0	3.1 ± 1.0	0.0 [−0.1 to 0.2]	0.88

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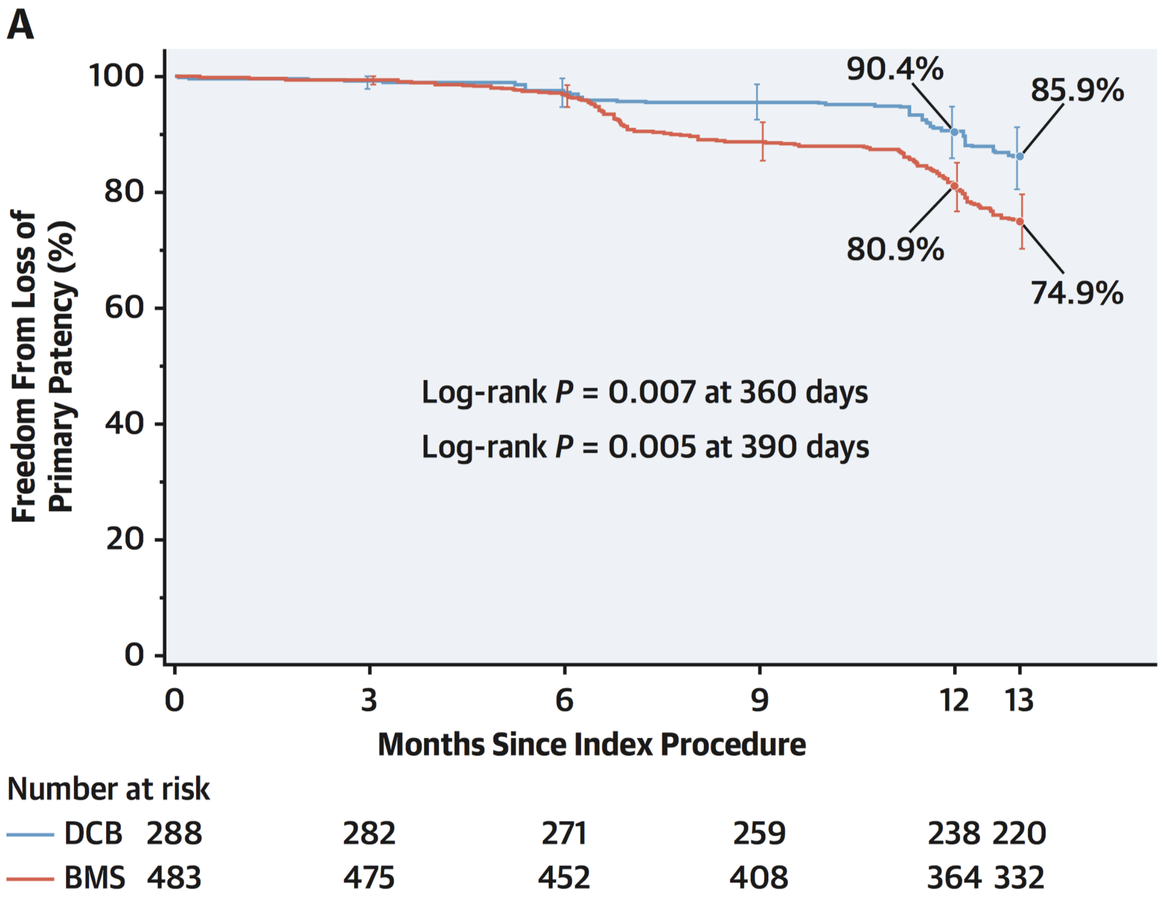
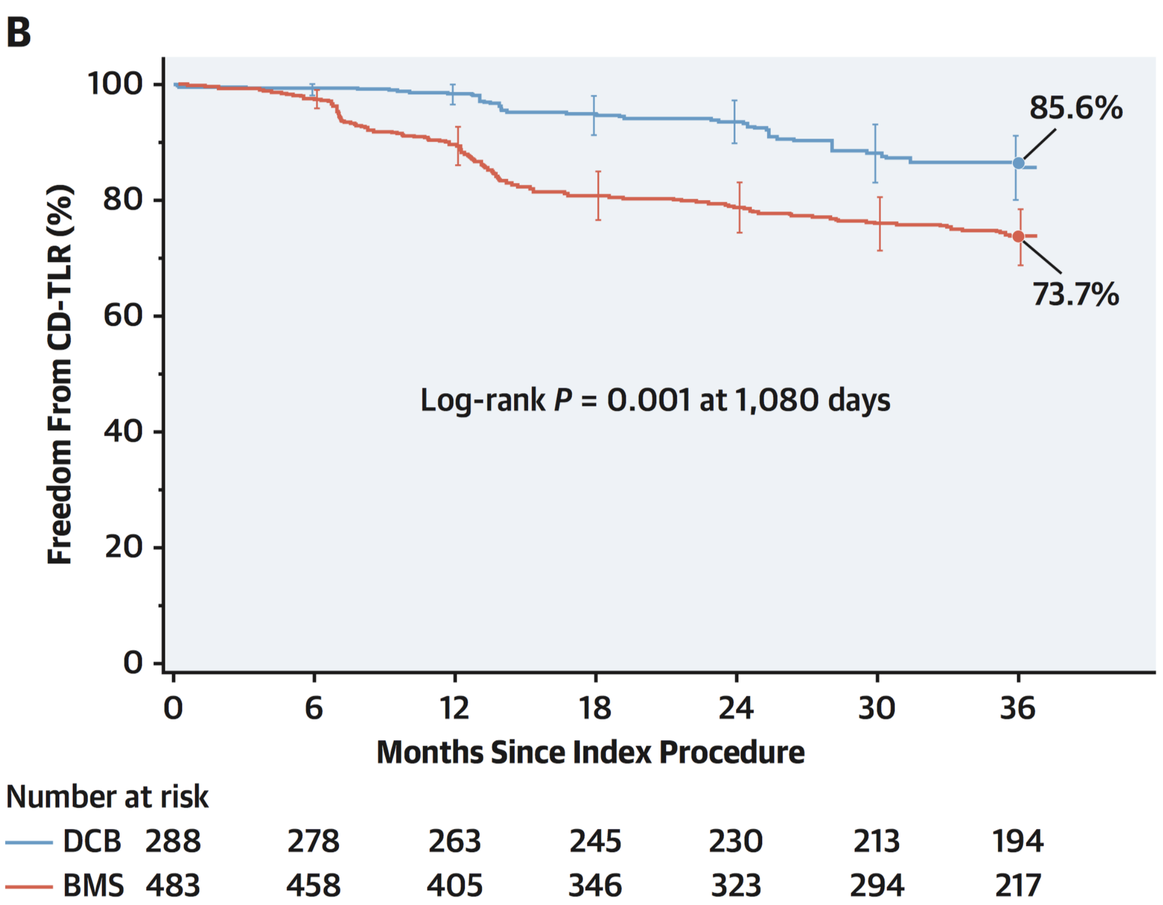
Results (1) : 12 Months





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Results (2) : 36 Months

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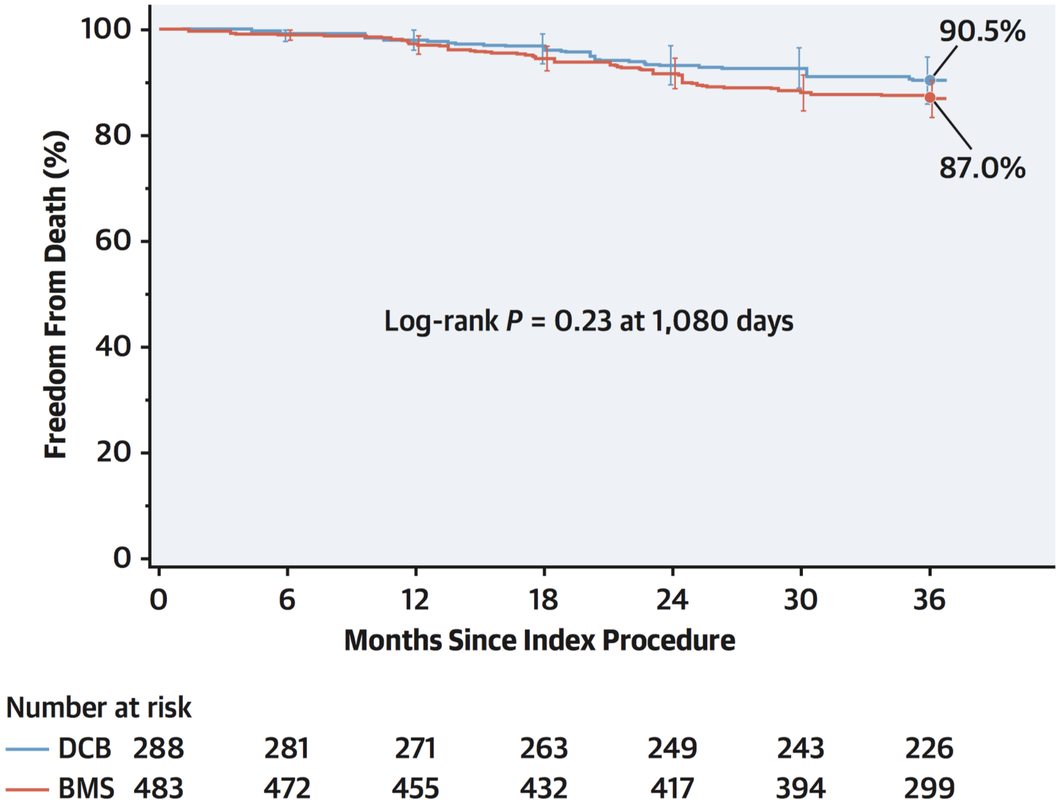

TABLE 2 Clinical Outcomes Through 3 Years

Kaplan-Meier Estimates of Cumulative Incidence	DCB (n = 288)	BMS (n = 483)	HR [95% CI] (DCB vs BMS)	*P* Value
MAE	25.3 (69)	38.8 (175)	0.57 [0.43 to 0.75]	<0.001
Death (all-cause)	9.5 (25)	13.0 (51)	0.72 [0.46 to 1.15]	0.23
CD-TVR	17.3 (48)	27.6 (126)	0.55 [0.39 to 0.77]	0.006
Major target limb amputation	0.0 (0)	0.8 (4)	–	0.29
Thrombosis	1.0 (5)	2.1 (10)	0.49 [0.13 to 1.82]	0.41
CD-TLR	14.4 (40)	26.3 (121)	0.47 [0.32 to 0.67]	0.001
Any TVR	17.4 (49)	27.7 (127)	0.55 [0.39 to 0.78]	0.006
Any TLR	14.7 (42)	26.4 (122)	0.48 [0.33 to 0.69]	0.001
	DCB (n = 288)	BMS (n = 483)	Difference [95% CI]	*P* Value
RMST to first CD-TLR[a]	1002.0 [976.9 to 1027.0]	908.0 [879.2 to 936.8]	94.0 [55.8 to 132.1]	<0.001

Values are % (n) unless otherwise indicated. Cumulative incidence based on Kaplan-Meier estimates, HR and its 95% CI, and log-rank *P* value are all adjusted with IPTW. [a]RMST [95% CI]. The restricted mean survival time difference and its 95% CI and *P* value are all adjusted with IPTW.

BMS = bare metal stent; CD = clinically driven; DCB = drug-coated balloon; IPTW = inverse probability of treatment weighting; MAE = major adverse event; RMST = restricted mean survival time; TLR = target lesion revascularization; TVR = target vessel revascularization.

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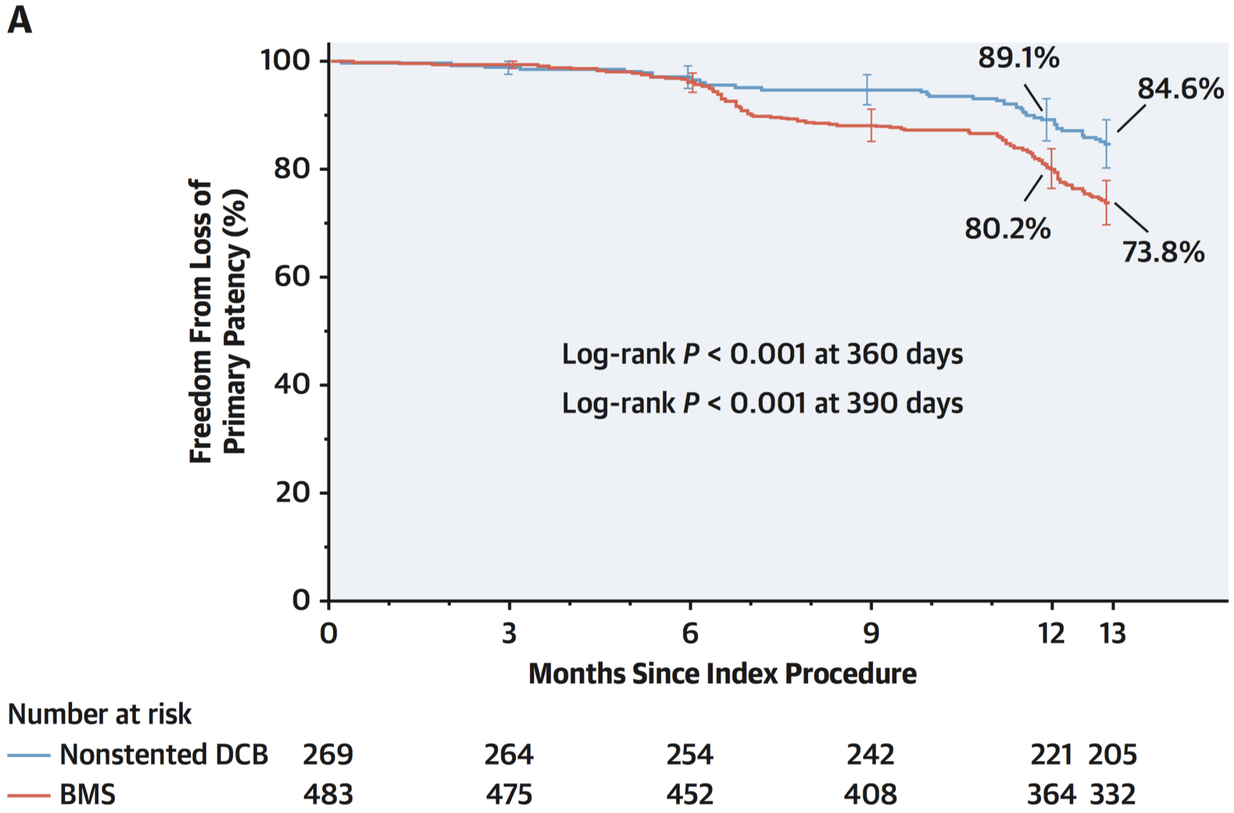
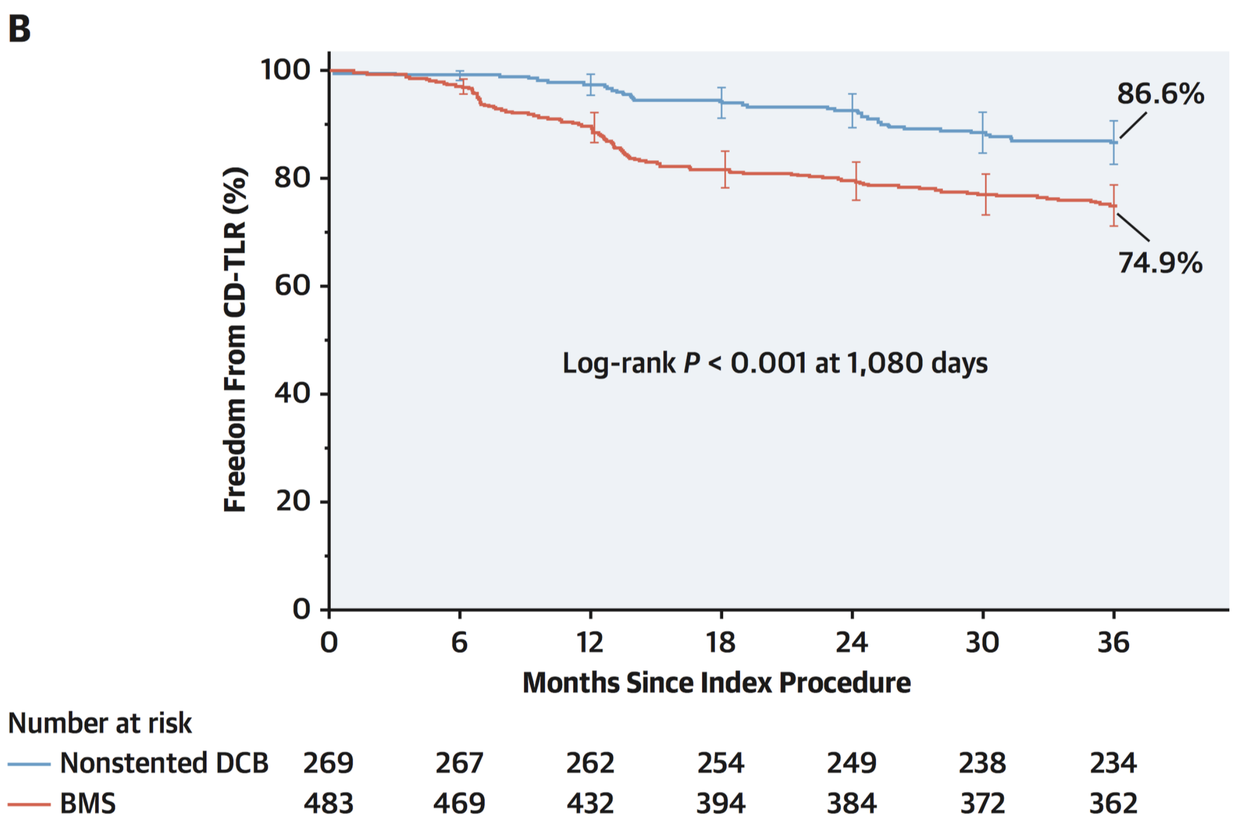
Results (3) : Outcomes removed Provisional stenting @ 36 Mos

- Provisional stenting rate in DCB arm : 6.6%
- Outcomes with removed provisional stenting





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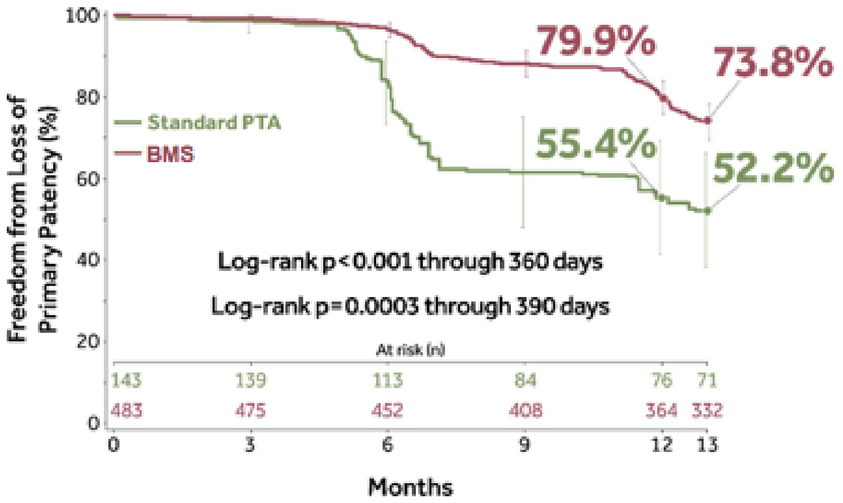
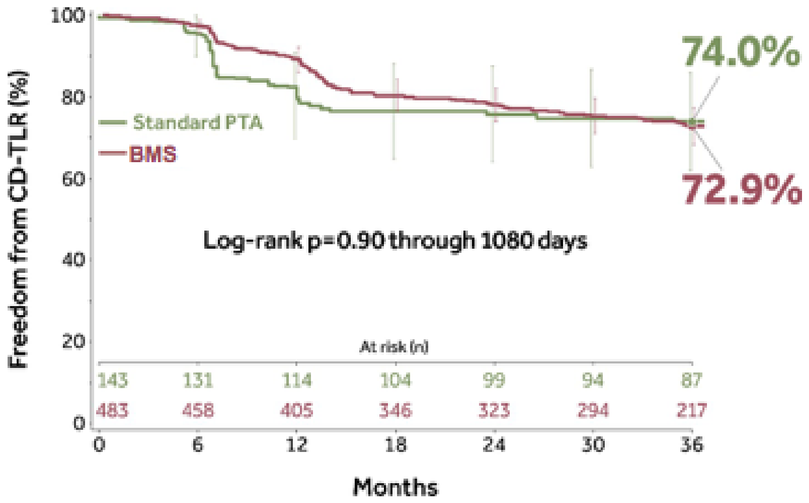
Going Back to : PTA vs. BMS

Primary Patency to 12 Months



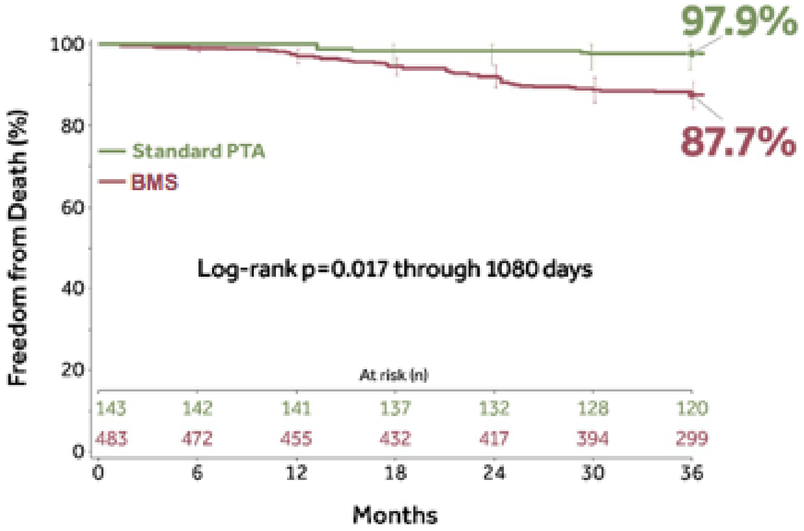
Statistically significant short-term primary patency benefit for BMS

Freedom from CD-TLR to 36 Months



No long-term difference in CD-TLR to 36 months

Freedom from All-cause Death to 36 Months



Mortality significantly higher in the BMS group versus PTA

BMS: bare metal stent; DCB: drug-coated balloon; CD-TLR: clinically driven target lesion revascularization; PTA: percutaneous transluminal angioplasty

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Wrap Up

- Patient level pooled analysis : DCB vs. BMS
- DCBs showed superior primary patency @ 12 mos & CD-TLR @ 36 mos vs. BMS
- No significant difference in all-cause mortality @ 36 mos
- Not all DCB in FP showed same results
- IN.PACT DCB > BMS = PTA in FP lesions

DCB showed some better results versus BMS in FP

Many thanks for your attention