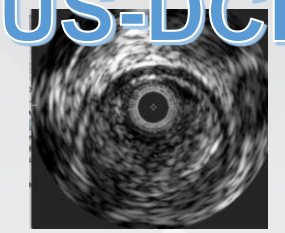
IVUS-DCB



Comparison of IVUS-guided vs. Angiography-guided Angioplasty for the Outcomes of DCB in the Treatment of Femoropopliteal Artery Disease

on behalf of IVUS-DCB Investigators

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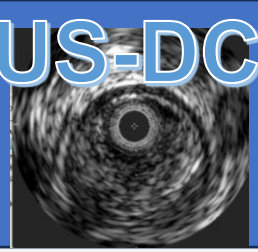
Disclosures

- This study was funded by Medtronic Inc. and Korea United Pharmaceutical, and supported by the Cardiovascular Research Center, Seoul, Korea.

- Drs. YG Ko and D Choi received research grants from Medtronic, Korea United Pharm, Cook Medical, Boston Scientific, Otsuka Korea, Dong-A ST, Samjin Pharm, and Cordis.

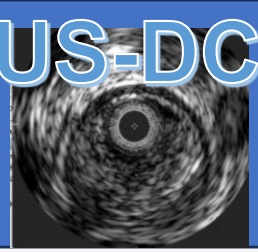
Background



- Drug-coated balloons (DCBs) have demonstrated favorable clinical outcomes in treating femoropopliteal artery disease.
- However, challenges such as vessel recoil, residual stenosis, and arterial dissection remain significant limitations of DCB treatment .
- Thus, improved vessel preparation and post-DCB optimization are needed to enhance endovascular treatment (EVT) outcomes.
- Intravascular ultrasound (IVUS) provides detailed information on vessel dimensions and plaque characteristics.
- However, there have been limited clinical data on the clinical benefit of IVUS in the EVT of femoropopliteal artery disease using DCBs.

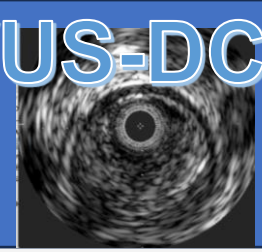
Zeller T, EuroIntervention 2022;18:e940.
Lee SJ, J Am Coll Cardiol Intv. 2023;16:1640.
Allan RB, J Am Coll Cardiol Intv. 2022;15(5):536

Study Purpose



To investigate the clinical advantages of IVUS-guided DCB angioplasty for femoropopliteal artery disease by comparing the outcomes of IVUS-guided versus angiography-guided DCB angioplasty.

Study Design

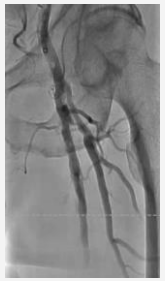


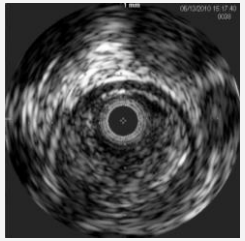
- *IIT*
- *Multicenter RCT*
- *To test superiority of IVUS guidance*

Patients with symptomatic femoropopliteal artery disease
- Rutherford category 2~5
- N = 237 from 7 centers in Korea

1:1 randomization

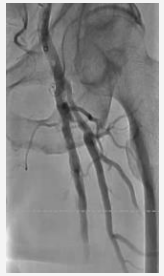
Stratified by the enrolling site and lesion length with a cutoff of 150 mm





IVUS Guidance (n=119)

Angiography Guidance (n=118)



cross-over (n=1)

cross-over (n=2)

Angioplasty using DCBs (IN.PACT, Medtronic)

Primary endpoint: Primary patency at 12 months

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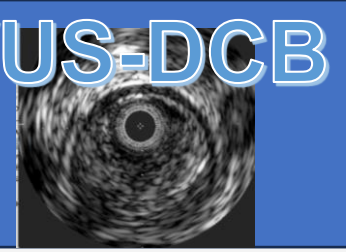
Institutions and Investigators



- Severance Hospital, Seoul, Korea

  Young-Guk Ko, Seung-Jun Lee, Chul-Min Ahn, Donghoon Choi

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  Tae-Hoon Kim, Ha-Wook Park

- Chungnam National University Hospital, Daejeon, Korea

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- Busan Veterans Hospital, Busan, Korea

  Su Hong Kim

- Yongin Severance Hospital, Yongin, Korea

  Eui Im

- Soonchunhyang University Cheonan Hospital, Cheonan, Korea

  Sang-Ho park

Severance Cardiovascular Hospital

Key Inclusion & Exclusion Criteria

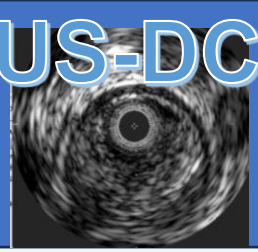
Inclusion criteria

- Age ≥19 years
- Symptomatic femoropopliteal artery disease (Rutherford 2~5)

Exclusion criteria

- Acute limb ischemia
- Age >85 years
- Life expectancy <1 year
- Previous bypass surgery or stenting in the target femoropopliteal artery
- Untreated inflow lesions

Primary & Secondary Endpoints

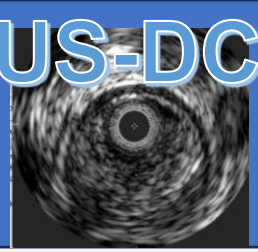


- **Primary endpoint:**
  - Primary patency defined as the absence of clinically-driven target lesion revascularization (CD-TLR) or binary restenosis on imaging studies (DUS, CT, angiography) at 12-month follow-up.

- **Secondary endpoints:**
  - Freedom from CD-TLR
  - Sustained clinical improvement (improved Sx ≥1 Rutherford category, no CD TLR)
  - Sustained hemodynamic improvement (improved ABI ≥ 0.15, no CD TLR)
  - Mortality
  - Major amputations
  - Major bleeding

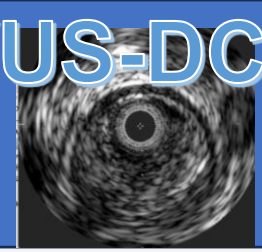
Eur Heart J. 2007;28:798

Procedures



- Randomization was performed after successful wire passage
- All lesions were routinely predilated except for cases treated with vessel prep using atherectomy.
- Pretreatment and post lesion optimization as well as the choice of device sizes were left to operators' discretion.
- IVUS was performed before and after the use of DCBs and the final treatment.
- No specific IVUS goals were recommended for the IVUS-guidance group.
- All lesions were treated with IN.PACT DCBs.
- DAPT was required for at least 90 days post procedure.
- All procedural and follow-up images were analyzed at central core labs by independent experts.

Baseline Clinical Characteristics

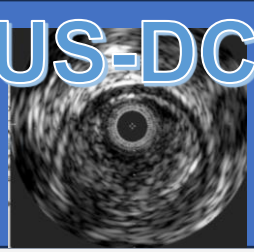


	IVUS Guidance (n=119)	Angiography Guidance (n=118)	P value
Age, years	69.0 ± 9.1	70.2 ± 8.6	0.31
Men	102 (85.7)	100 (84.7)	0.98
Body mass index, kg/m^2	23.8 ± 3.4	23.4 ± 3.1	0.32
Hypertension	94 (78.0)	99 (83.8)	0.44
Diabetes mellitus	71 (59.7)	79 (67.5)	0.26
Dyslipidemia	84 (70.6)	86 (72.9)	0.80
Chronic kidney disease	29 (24.4)	19 (16.1)	0.16
End-stage kidney disease on dialysis	14 (11.8)	8 (6.8)	0.27
Current smoker	37 (31.1)	41 (34.7)	0.76
CAD	45 (37.8)	31 (26.3)	0.08
Prior stroke	14 (11.8)	14 (11.9)	0.99
Prior peripheral revascularisation	18 (15.1)	18 (15.3)	0.99
Prior limb amputation	5 (4.2)	4 (3.4)	0.99
Clinical presentation			
Claudication	89 (74.8)	86 (72.9)	0.66
CLTI	39 (25.2)	32 (27.1)	
Pre-procedural ABI	0.64 ± 0.21	0.63 ± 0.21	0.74

Lesion Characteristics

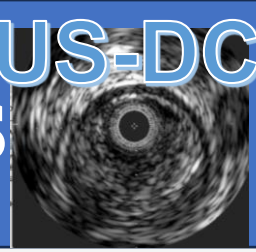
	IVUS Guidance (n=119)	Angiography Guidance (n=118)	P value
TASC II lesion type			
A/B	39 (32.8)	40 (33.9)	0.96
C/D	80 (67.2)	78 (66.1)	
Lesion length, mm	204.9 ± 103.1	214.5 ± 102.9	0.48
Reference vessel diameter, mm	5.0 ± 0.7	5.0 ± 0.7	0.79
Minimal lumen diameter, mm	0.36 ± 0.65	0.47 ± 0.68	0.20
Total occlusion	78 (66.7)	68 (58.1)	0.23
Severe calcification (PACCS grade 4)	38 (31.9)	30 (25.4)	0.34
Popliteal involvement	11 (9.2)	10 (8.5)	>0.99
Poor distal runoff (0 or 1 vessel)	30 (25.2)	36 (30.5)	0.44

Procedural Data



	IVUS Guidance (n=119)	Angiography Guidance (n=118)	P value
Subintimal approach	31 (26.5)	31 (26.5)	>0.99
Atherectomy	41 (35.0)	38 (32.5)	0.78
Pre-balloon diameter, mm	5.0 ± 0.9	4.5 ± 1.1	<0.001
Pre-balloon length, mm	122.3 ± 57.5	119.1 ± 62.8	0.69
Pre-balloon maximal pressure, mmHg	11.8 ± 3.6	8.9 ± 2.7	<0.001
Total number of DCBs	2.0 ± 0.8	2.0 ± 0.8	0.75
Maximal DCB diameter, mm	5.8 ± 0.7	5.8 ± 0.7	0.95
Mean DCB diameter, mm	5.4 ± 0.6	5.4 ± 0.6	0.92
Adjuvant post-dilatation	31 (26.1)	16 (13.6)	0.03
Maximal post-balloon pressure, mmHg	13.7 ± 2.9	9.6 ± 4.0	0.001
Bailout stenting	24 (20.5)	17 (14.5)	0.30
Post-procedural minimal lumen diameter, mm	3.90 ± 0.59	3.71 ± 0.73	0.03
Post-procedural diameter stenosis, %	21.5 ± 12.0	25.4 ± 13.3	0.02

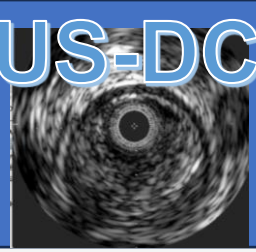
Immediate Procedural Outcomes



	IVUS Guidance (n=119)	Angiography Guidance (n=118)	P value
Technical success*	91 (76.5)	72 (61.0)	0.02
Procedural success†	88 (73.9)	71 (60.2)	0.03
Dissection type	70 (59.8)	68 (58.1)	0.67
A	8 (10.7)	15 (20.3)	
B	35 (46.7)	29 (39.2)	
C	20 (26.7)	18 (24.3)	
D	5 (6.7)	5 (6.8)	
E	2 (2.7)	1 (1.4)	
Distal embolisation	0	0	–
Target lesion perforation	1 (0.9)	1 (0.9)	>0.99
Access site complications	2 (1.7)	2 (1.7)	>0.99
Post-procedure ABI	0.99 ± 0.13	0.93 ± 0.15	0.001

**defined as residual stenosis of <30% without flow compromise; †defined as technical success without any acute complications*

Clinical Outcomes at 12 months

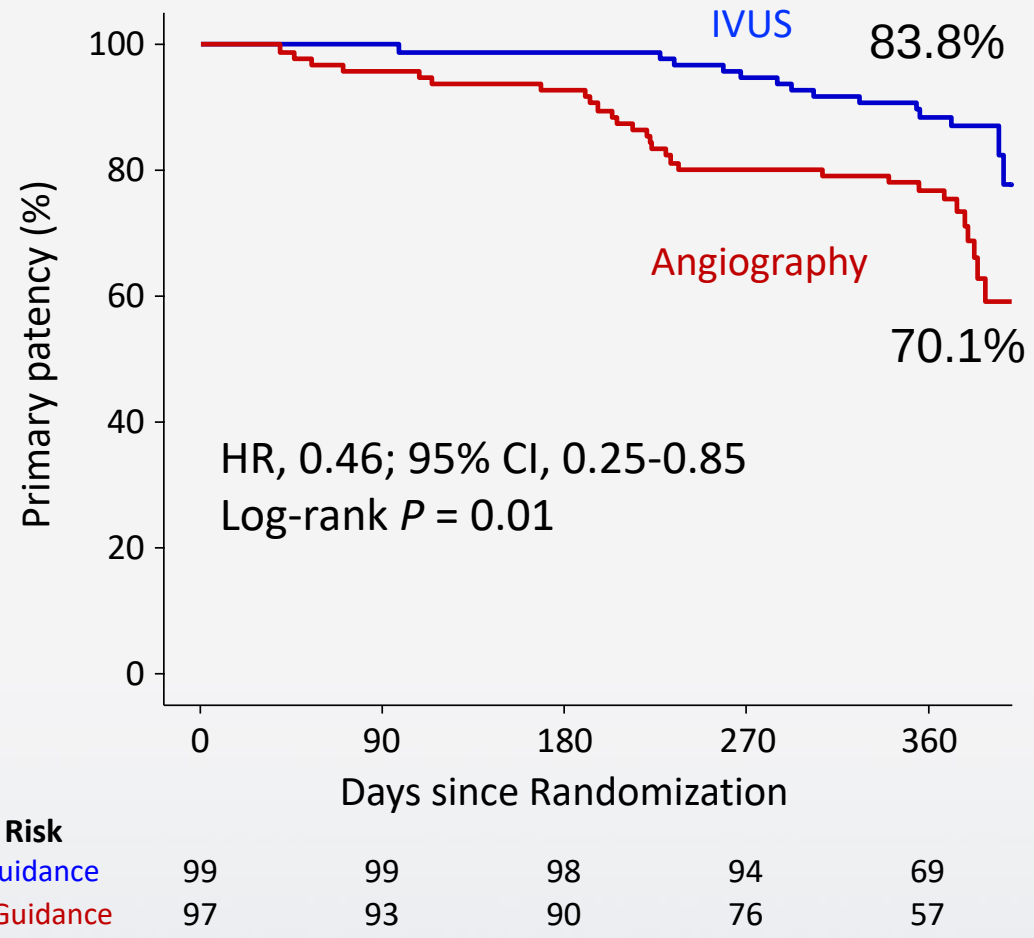


Outcomes	Event No. / Total. No (%)		Risk Difference[a] (95% CI)	Hazard Ratio[b] (95% CI)	P value
	IVUS (n=119)	Angiography (n=118)			
Primary endpoint					
Primary patency*	83.8 (83/99)	70.1 (68/97)	13.7 (2.1 – 25.4)	0.46 (0.25–0.85)	0.01
Secondary endpoints					
Freedom from CD TLR	92.4 (110/119)	83.0 (98/118)	9.4 (1.1 – 17.7)	0.41 (0.19-0.90)	0.03
Sustained clinical improvement	89.1 (106/119)	76.3 (90/118)	12.8 (3.3 – 22.3)	0.45 (0.23-0.86)	0.02
Sustained hemodynamic improvement	82.4 (98/119)	66.9 (79/118)	15.4 (4.5 – 26.3)	0.52 (0.31-0.89)	0.02
Major amputation of target limb	0/119	0/118	–	–	–
All-cause death	6.7 (8/119)	7.6 (9/118)	−0.9 (−7.5 – 5.7)	1.21 (0.44–3.34)	0.72
Cardiovascular death	2.5 (3/119)	2.5 (3/118)	0.0 (−4.0 – 4.0)	1.45 (0.29–7.24)	0.65
Major bleeding	1.7 (2/119)	2.5 (3/118)	−0.9 (−4.5 – 2.8)	0.69 (0.11–4.18)	0.61

**Imaging follow-up rate at 12 months: 82.7%*

Primary patency at 12 months

ITT analysis



No. at Risk					
IVUS Guidance	99	99	98	94	69
Angio Guidance	97	93	90	76	57

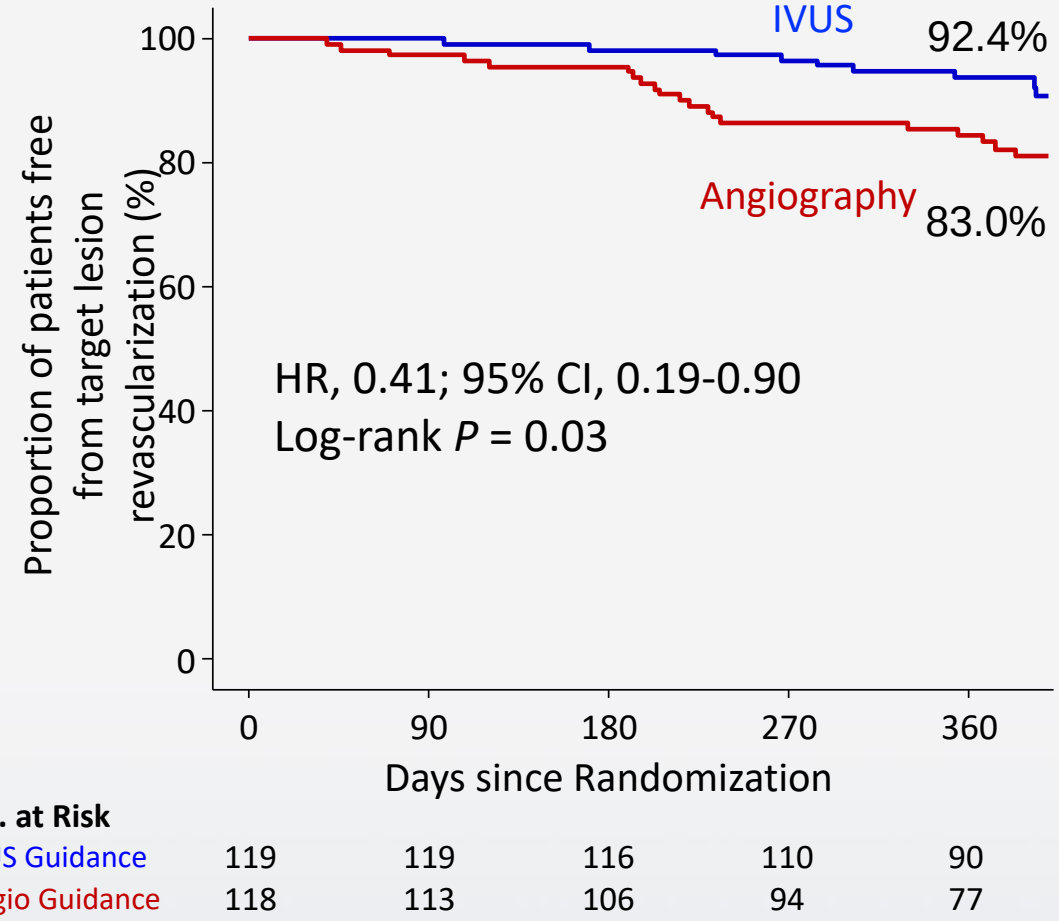
PP analysis

IVUS: 83.7% (82/98) vs.
Angiography: 70.8% (68/96)

HR 0.48 (0.26-0.88)
P = 0.02

Freedom from CD-TLR

ITT analysis



No. at Risk					
IVUS Guidance	119	119	116	110	90
Angio Guidance	118	113	106	94	77

PP analysis

IVUS: 92.4% (109/118) vs.
Angiography: 83.6% (97/116)

HR 0.43 (0.20-0.96)
P = 0.04

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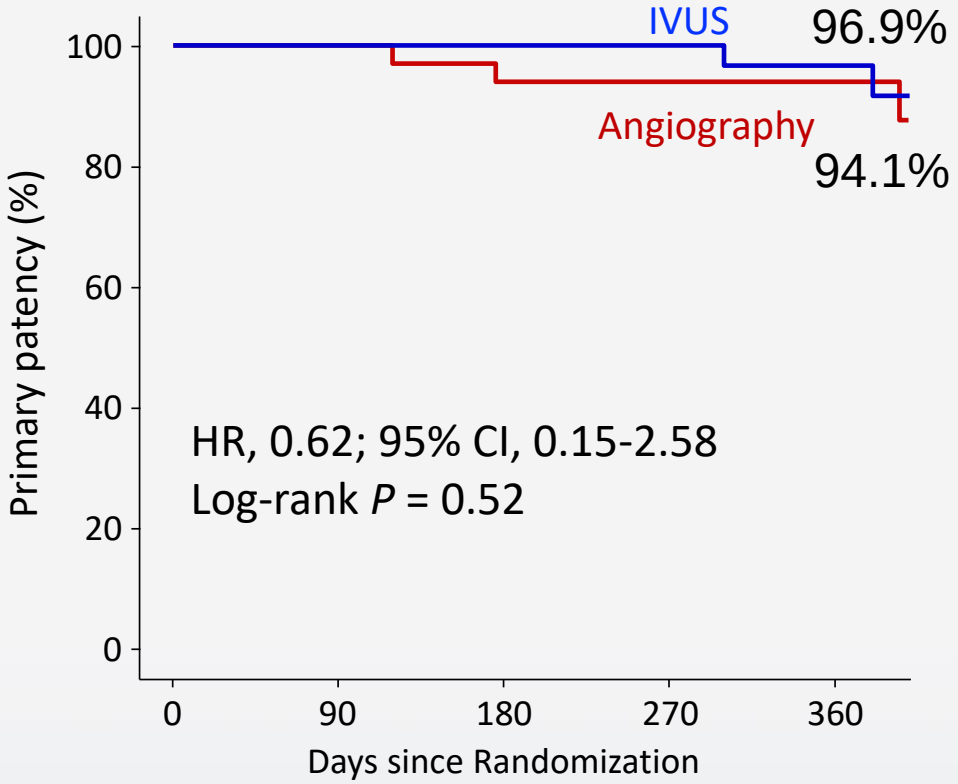
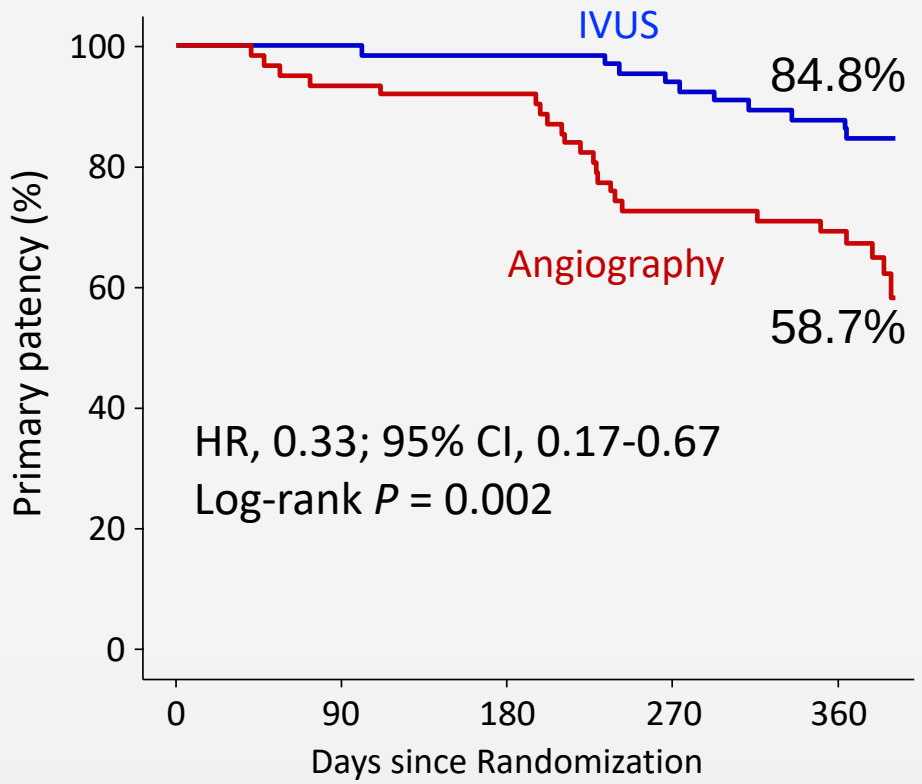
Primary Patency According to TASC II Lesion Types

TASC II type A/B



No. at Risk					
IVUS Guidance	32	32	32	31	21
Angio Guidance	34	34	32	31	24

TASC II type C/D



No. at Risk					
IVUS Guidance	67	67	66	62	48
Angio Guidance	63	59	58	45	31

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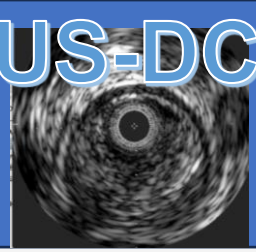
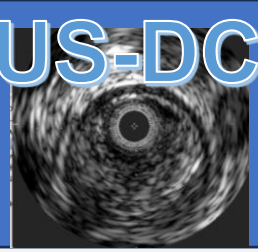
Predictors of Restenosis



	Univariate		Multivariate			
			Model 1		Model 2	
	HR (95% CI)	P-value	HR (95% CI)	P-value	HR (95% CI)	P-value
Lesion length ≥200 mm	2.96 (1.50-5.87)	0.002	2.36 (1.14-4.91)	0.02	2.15 (1.07-4.34)	0.03
Total occlusion	2.32 (1.12-4.84)	0.02	1.43 (0.62-3.29)	0.40	1.59 (0.69-3.70)	0.28
Subintimal recanalization	2.57 (1.42-4.64)	0.001	1.91 (1.02-3.60)	0.04	1.43 (0.73-2.80)	0.30
Use of IVUS	0.46 (0.25-0.85)	0.01	0.40 (0.21-0.75)	0.004	-	-
Post-procedural MLD (per 0.1 mm decrease)	1.14 (1.09-1.20)	<0.001	-	-	1.13 (1.07-1.18)	<0.001

Conclusions



- IVUS guidance significantly improved the outcomes of DCB angioplasty for FPA disease in terms of primary patency, freedom from CD TLR, and sustained clinical and hemodynamic improvement at 12 months.
- The benefit of IVUS guidance for primary patency after DCB treatment was more evident in complex FPA lesions.