Six-month Outcome of Distal Emboli due to Paclitaxel-Coated Balloon in Femoropopliteal Artery.
～Analysis with a Laser-doppler Flowmetry～

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Backgrounds

Several trials have already shown that paclitaxel drug-coated balloons (DCB) significantly reduce the rates of restenosis.
Some reports have shown distal embolism after DCBs *JACC Cardiovasc Imaging. Epub 2018 Dec 6 Med Devices (Auckl). 2019 Feb 12;12:53-64*
But no reports have analyzed the patency rate after DCB induced-distal embolism.

Methods

34 patients
- IN. PACT Admiral® :17 patients
- LUTONIX® :17 patients

Exclusion criteria

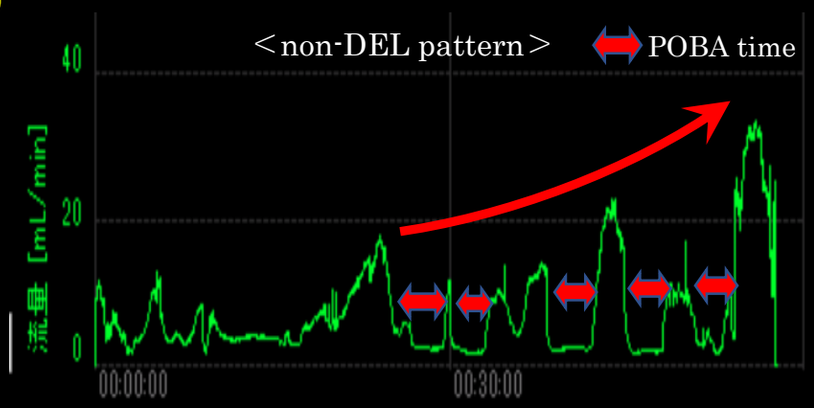
① Rutherford 5-6
② DCB off-label use in Japan

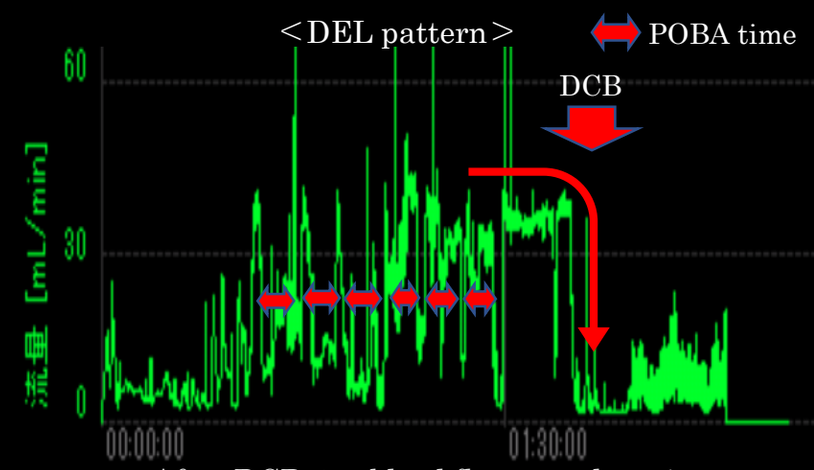
Distal emboli with laser-doppler flowmetry guidance (DEL)

Terminal points of blood flow

DEL was defined as the case that the blood flow of the first toe or the fifth toe dropped around the DCB treatment

Laser Doppler Typical Patterns





After DCB, toe blood flow was dropping suddenly or gradually.

Results

44%(n=15) of the cases had the DEL. IN. PACT Admiral (n=8) and LUTONIX(n=7) were used in the cases with DEL.

Patient Characteristics

	Overall(n=34)	DEL(n=15)	non-DEL(n=19)	p-Value
Age, y	73.4±1.44	75.2±2.3	72.0±1.7	0.21
Men	22(64.7%)	12(80%)	10(52.6%)	0.09
Hypertension	30(88.2%)	12(80%)	18(94.7%)	0.18
Diabetes	18(52.9%)	10(66.6%)	8(42.1%)	0.15
Dyslipidemia	26(76.4%)	11(73.3%)	15(78.9%)	0.7
BMI	22.6±0.6	22.6±0.85	22.7±0.86	0.76
Current smoker	10(33.3%)	5(38.4%)	5(29.4%)	0.94
Hemodialysis	5(14.7%)	2(13.3%)	3(15.7%)	0.84
Coronary artery disease	25(73.5%)	14(93.3%)	11(57.8%)	0.0136
Myocardia infarction	4(11.7%)	2(13.3%)	2(10.5%)	0.49
Cerebrovascular disease	8(23.5%)	2(13.3%)	6(31.5%)	0.2

	Overall(n=34)	DEL(n=15)	non-DEL(n=19)	p-Value
Rutherford classification				
Category 2/3	32(94.1%)	13(86.6%)	19(100%)	0.45
Category 4	2(5.88%)	2(13.3%)	0(0%)	0.06
Cilostazol	6(18.1%)	4(26.6%)	2(11.1%)	0.2
Dual antiplatelet therapy	22(66.6%)	11(73.3%)	11(61.1%)	0.45
DOAC	4(11.7%)	2(13.3%)	2(10.5%)	0.8
Warfarin	3(9.09%)	1(6.67%)	2(11.1%)	0.65
Statin	24(72.7%)	13(86.6%)	11(61.1%)	0.18
Ambulation difficulty	3(8.8%)	3(20%)	0(0%)	0.021

Logistics or Nonparametric statistics, p<0.05

Lesion Characteristics

	Overall(n=34)	DEL(n=15)	non-DEL(n=19)	p-Value
TASC C/D lesions	6(27.2%)	0(0%)	6(31%)	0.25
Lesion length, mm	109±13.3	105.3±20.6	112.3±17.9	0.76
RVD, mm	5.0±0.15	5.2±0.22	4.9±0.2	0.48
Occlusions	11(32.3%)	5(33.3%)	6(31.5%)	0.91
Calcification				
None	20(58.8%)	8(53.3%)	12(63.1%)	
Moderate	5(14.7%)	3(20%)	2(10.5%)	0.68
Severe	9(26.4%)	4(26.6%)	5(26.3%)	0.72
BK run off≦1	6(17.6%)	5(33.3%)	1(5.26%)	0.033
Cutting/scoring	22(64.7%)	10(66.6%)	12(63.1%)	0.83
Balloon size, mm	5.0±0.13	5.13±0.19	4.94±0.17	0.48
Total balloon length, mm	144±12.9	130±18.7	155.2±17.8	0.34
Dissection grade D after DCB	5(14.7%)	2(13.3%)	3(15.7%)	0.84
POP lesion	8(23.5%)	6(40%)	2(10.5%)	0.044

Re-treatment rate is 11.7%(n=4)
IN. PACT Admiral (n=2)
LUTONIX(n=2)

Risk of restenosis	Odds rate	Confidence interval	p-Value
Lazer flow	1.307	0.161-10.559	0.801
Severe calcification	12	1.15-135.05	0.028

✔RVD, Lesion Length, DCB diameter, All DCB length, HD, DM, Rutherford 4 and female are not significant.

Summary

44%(n=15) of the cases had the DEL.
IN. PACT Admiral (n=8) and LUTONIX(n=7) were used in the cases with DEL.
DEL appeared significantly in BK run off≦1, POP lesion and ambulation difficulty cases.
The patency rate of 6 months was not worse in DEL(n=15) group than NDE.