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Clinical Outcomes of Repetition of Drug-Coated Balloon for Femoropopliteal Restenosis after Drug-Coated Balloon Treatment

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Disclosure

Speaker name:

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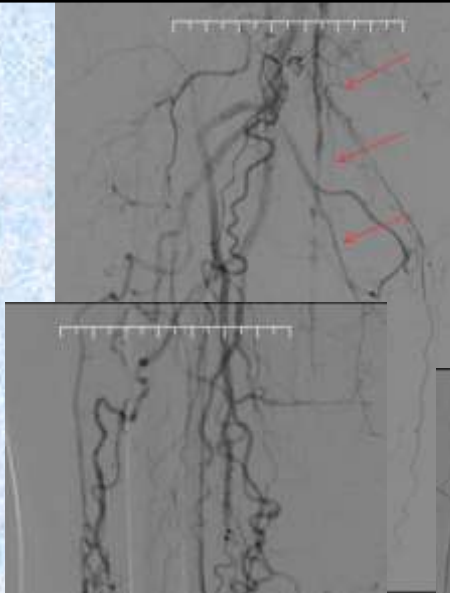
I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest

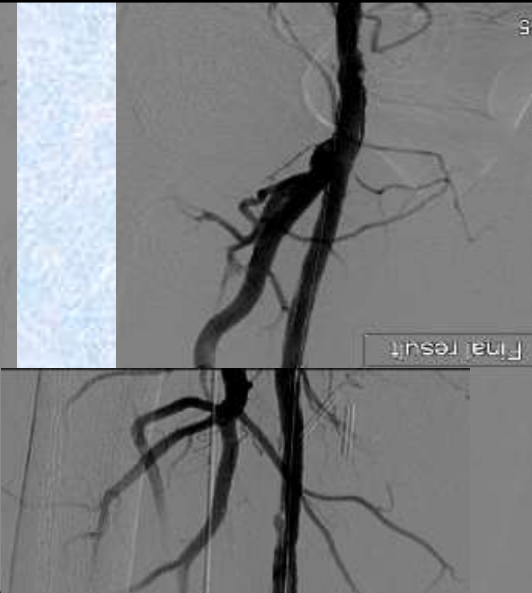
Background

- Previous report showed the 2-year results of DCB for complex FP lesions with a higher rate of late catch-up restenosis.
- Information regarding the optimal strategy for FP DCB restenosis is lacking.
- In this study, we evaluate the efficacy and outcome analysis of repetition of DCB for DCB restenosis during a 45-month follow-up.

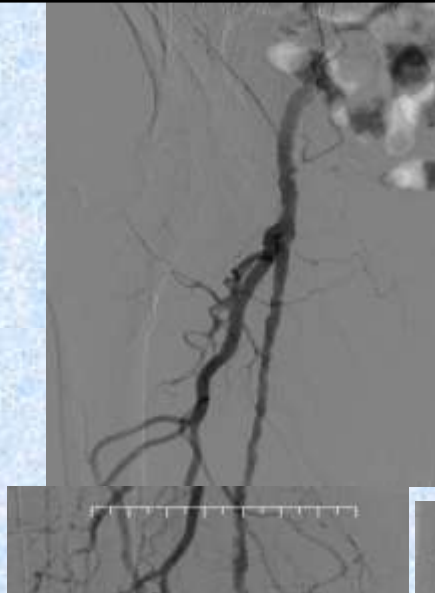


2014-8-21

Pre-PTA



post-PTA



2015-12-17

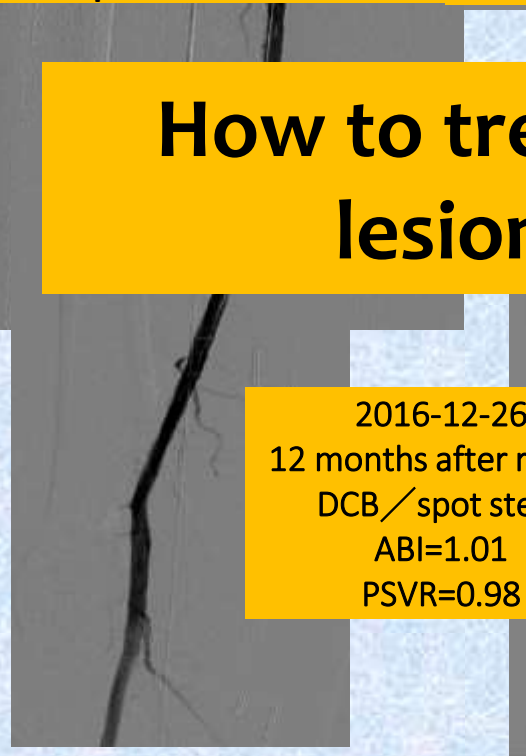
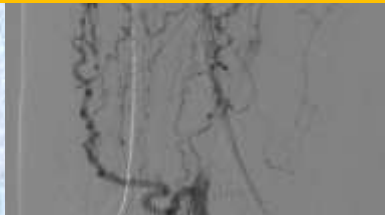
Pre-PTA



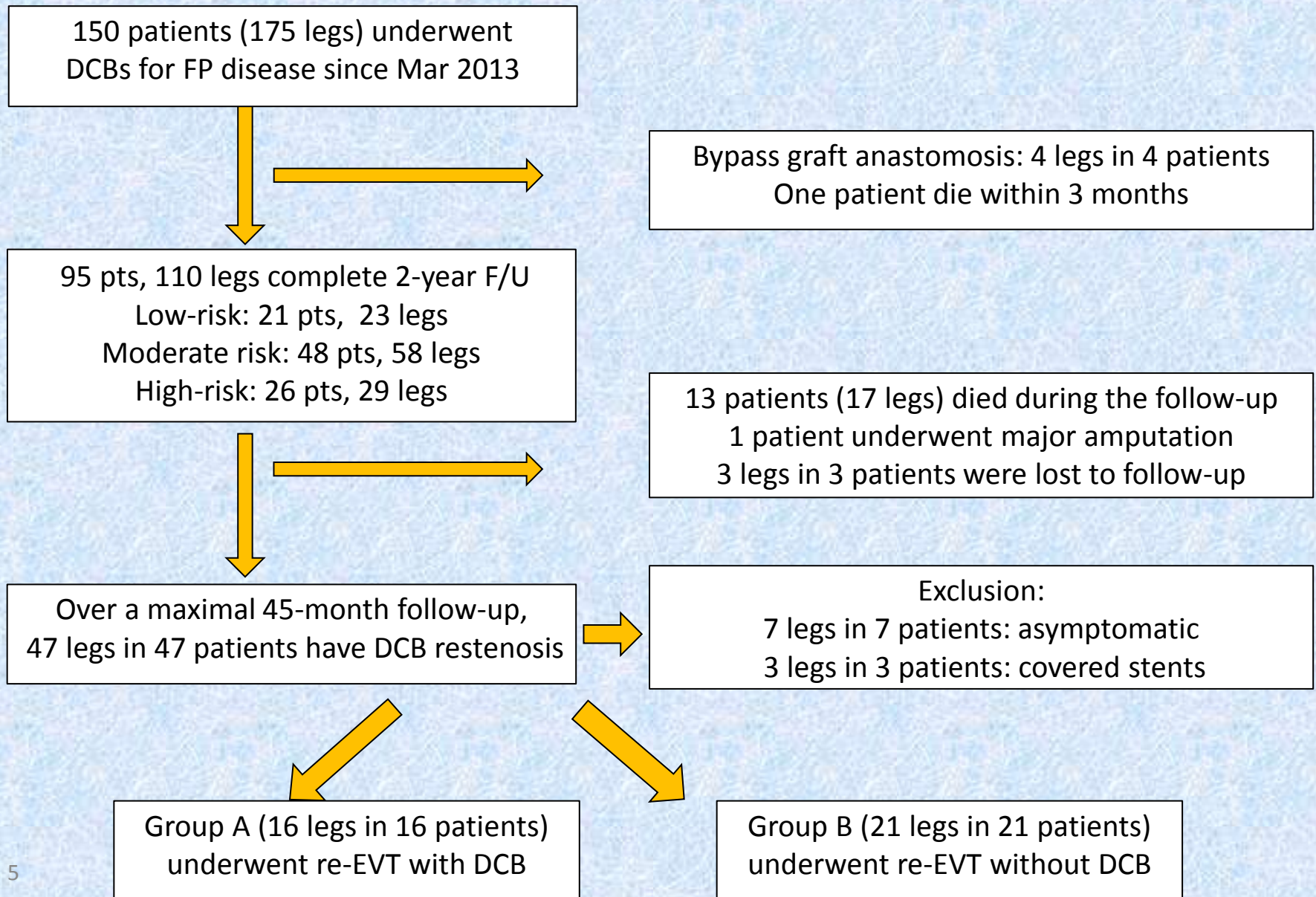
post-PTA

How to treat this lesion ?

2016-12-26
12 months after repeat
DCB / spot stent
ABI=1.01
PSVR=0.98

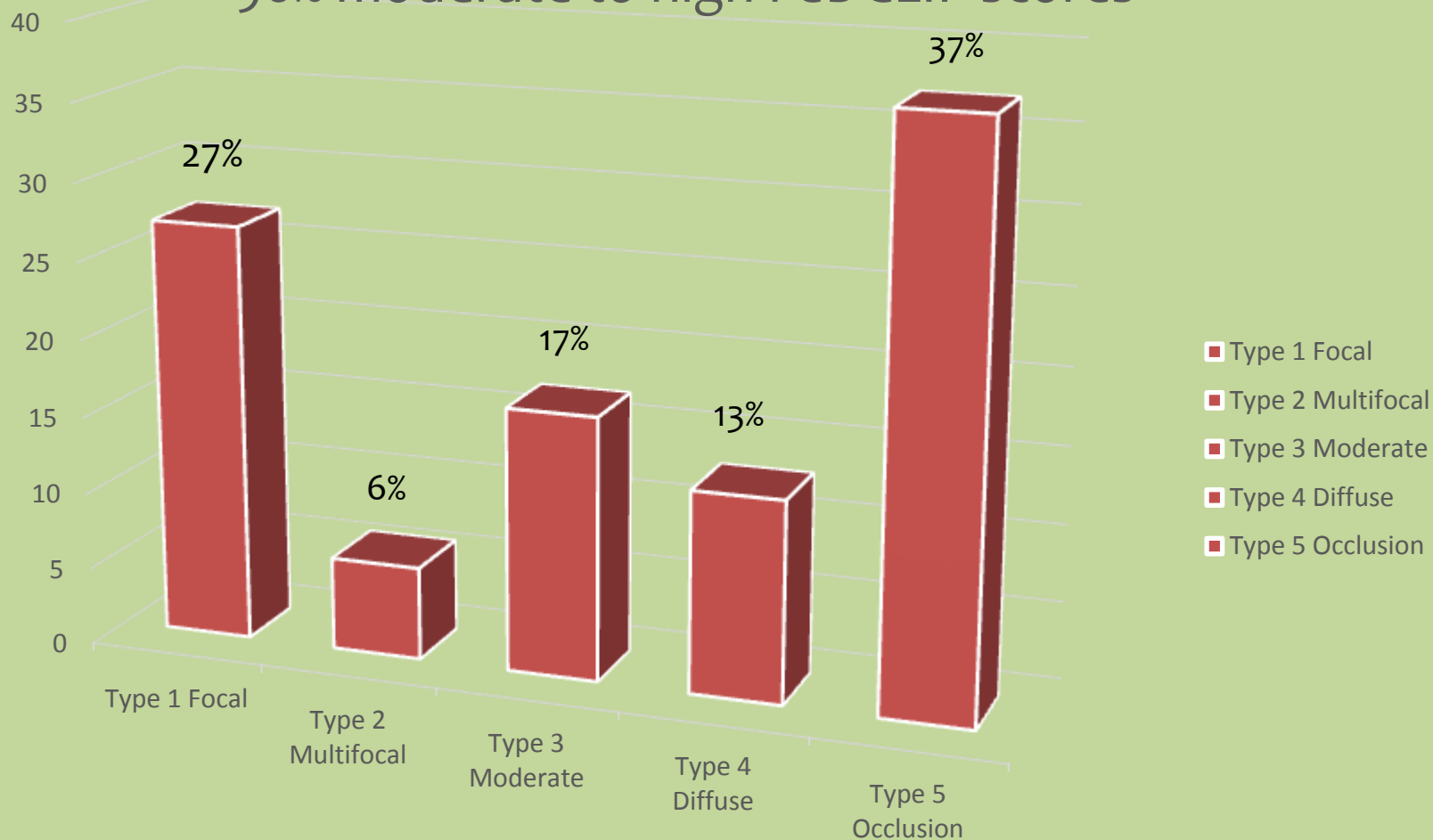


Flow chart of study participants



Restenosis Pattern after DCB Treatment

Restenosis pattern by index treated length
90% moderate to high FeDCLIP scores



Baseline Patient Characteristics

	Group A	Group B	p-Value
No. of patients	16	21	
Age (y)	70 ± 11	68± 11	0.569
Male gender	8 (50%)	9 (43%)	0.666
Diabetes mellitus	13 (81%)	19 (90%)	0.416
Hypertension	14 (88%)	20 (95%)	0.393
CAD	5 (31%)	12 (57%)	0.117
CVD	3 (19%)	4 (19%)	0.982
CKD	7 (44%)	9 (43%)	0.957
Dialysis	4 (22%)	12 (57%)	0.051
CHF	1 (17%)	4 (19%)	0.259
Smoking	8 (50%)	11 (52%)	0.886
Hyperlipidemia	9 (56%)	12 (57%)	0.957
BMI (Kg/m ²)	24.0±4.23	23.5±3.09	0.672
Hematocrit (mg/dL)	35.0±5.10	35.0±6.01	0.979
CRP (mg/dL)	1.36±2.48	1.48±2.92	0.897
HbA _{1c} (%)	7.8±1.4	7.6±1.5	0.741
LDL-C (mg/dL)	88±24	89±31	0.870
Albumin (mg/dL)	3.30±0.59	3.11±0.52	0.328

Baseline Lesion Characteristics

No. of affected limbs	16	21	P value
Target-limb ABI	0.55±0.17	0.59±0.30	0.650
Intermittent claudication	10 (62%)	10 (48%)	0.368
Rest pain	2 (13%)	2 (10%)	0.773
Non-healing ulcer	4 (25%)	8 (37%)	0.399
Gangrene	0 (0%)	1 (5%)	0.376
Combined BTK treatment	10 (63%)	15 (71%)	0.565
≤ 1 vessel BTK runoff	10 (63%)	16 (76%)	0.367
≥ 2 vessels BTK runoff	6 (37%)	5 (24%)	
Severe calcification	4 (25%)	8 (38%)	0.213
Occlusion	5 (31%)	11 (52%)	0.209

Baseline Lesion Characteristics

Location of treated lesions	43	53	P Value
Common femoral artery	1 (2.3%)	2 (3.7%)	0.685
Proximal SFA	10 (23.3%)	7 (13.2%)	0.200
Middle SFA	9 (20.9%)	8 (15.1%)	0.456
Distal SFA	13 (30.2%)	18 (34.0%)	0.698
Popliteal artery	10 (23.3%)	18 (34.0%)	0.251
FeDCLIP risk group	16	21	
Low-risk	7 (44%)	6 (29%)	0.338
Moderate-risk	5 (31%)	11 (52%)	0.199
High-risk	4 (25%)	4 (19%)	0.663

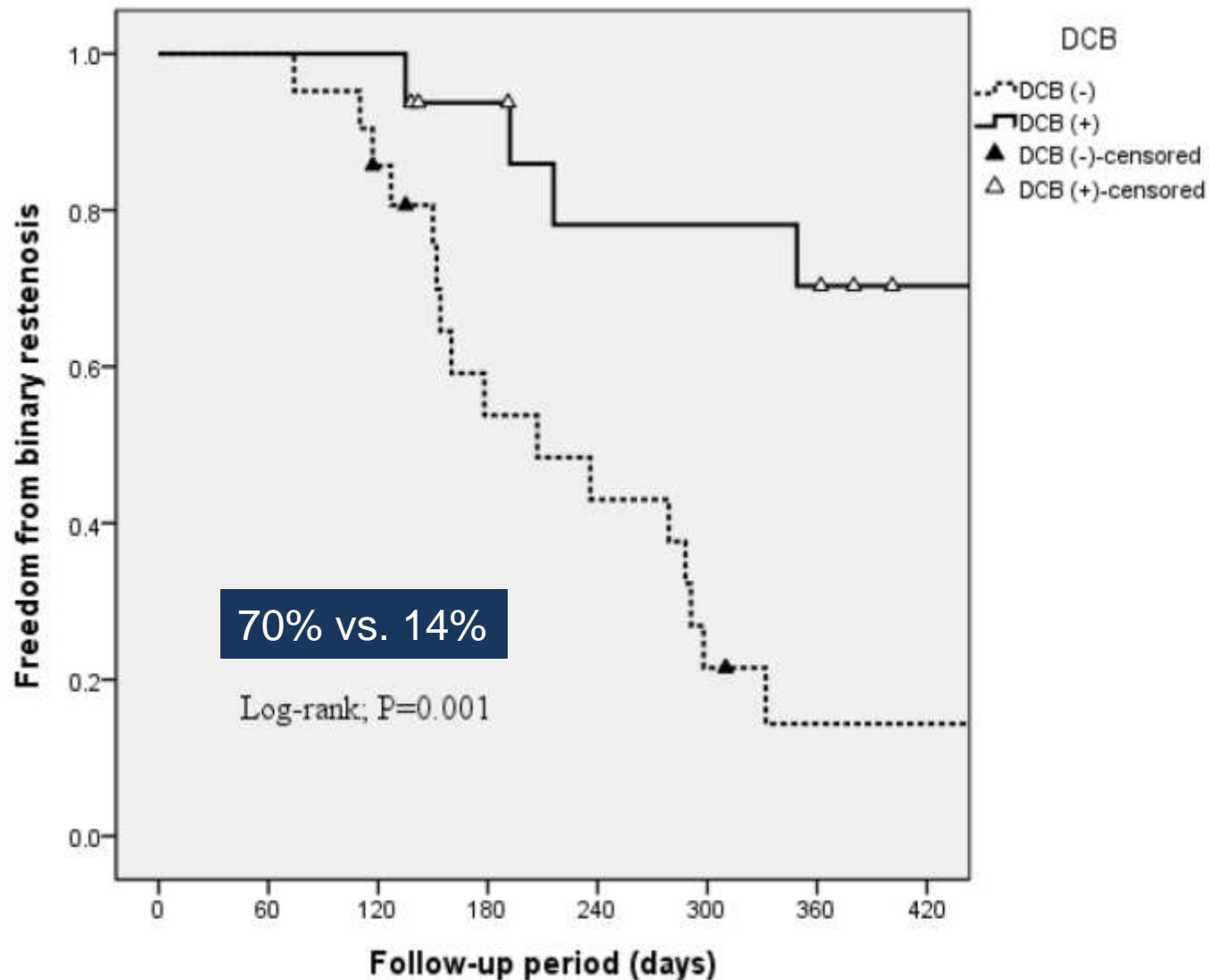
Procedural and Follow-up Outcomes

	Group A	Group B	p-Value
No of affected limbs	16	21	
Mean lesion length (mm)	200.8±113.1	195.2±134.6	0.894
LL <15 cm	7 (44%)	11 (52%)	0.603
LL ≥15 cm	9 (56%)	10 (48%)	0.843
Additional stenting	7 (44%)	11 (52%)	0.602
Additional stent length (mm)	160.0±84.9	170.9±89.9	0.801
Atherectomy	1 (6.3%)	1 (4.8%)	0.843
Use of IVUS	6 (38%)	9 (43%)	0.742
Treated lesions	43	53	
ISR lesions	19 (44%)	22 (42%)	0.792
Non-ISR lesions	24 (56%)	31 (58%)	

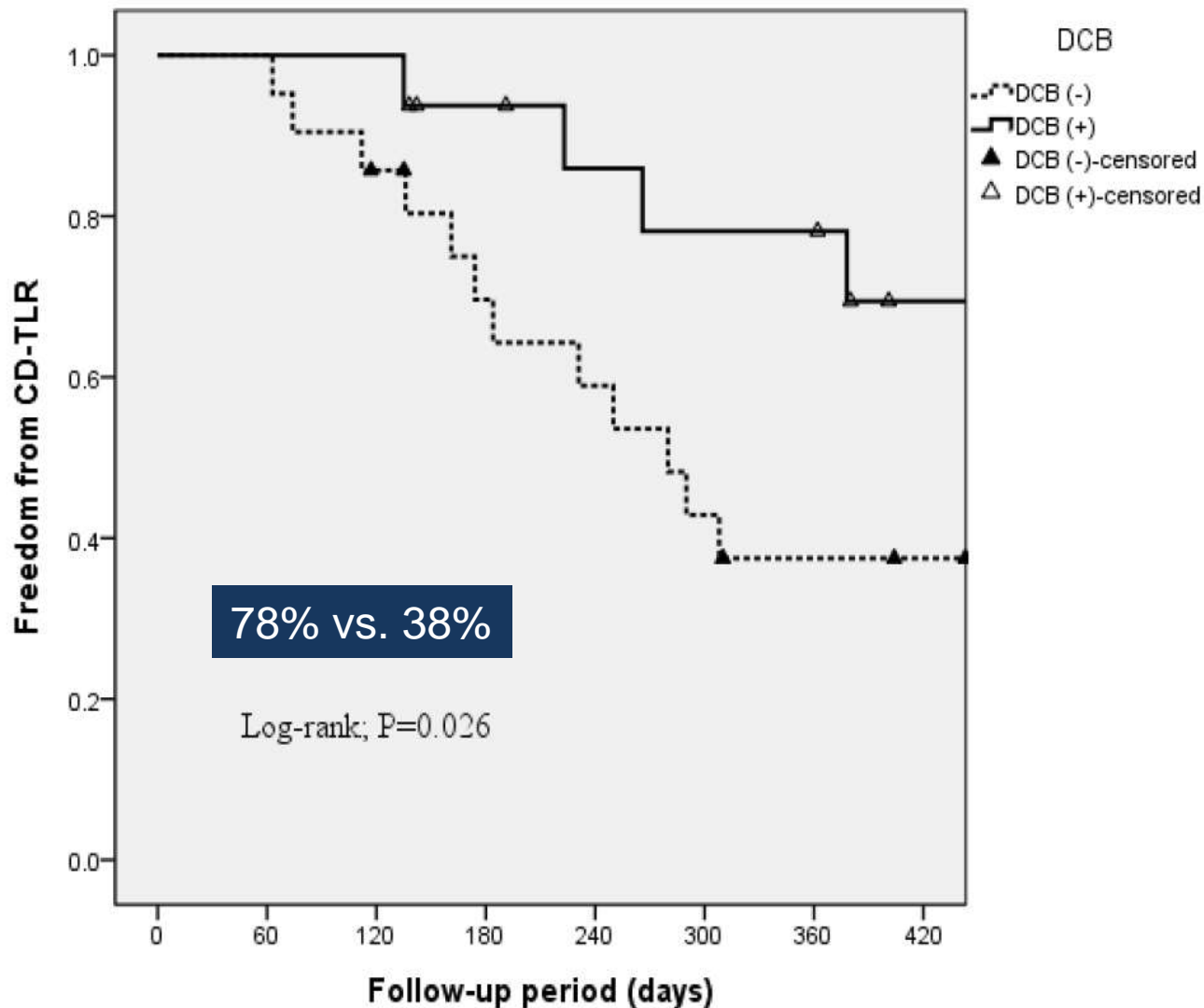
Procedural and Follow-up Outcomes

	Group A	Group B	p-Value
RVD at distal SFA (mm)	5.34±0.70	5.51±1.14	0.508
RVD at popliteal artery (mm)	4.59±0.71	4.79±0.95	0.545
Final balloon size (mm)	5.56±0.63	5.76±0.83	0.429
Final MLD at SFA (mm)	5.02±0.65	5.16±0.80	0.505
Final MLD at popliteal artery (mm)	4.22±0.64	4.35±0.62	0.603
Total follow-up period (days)	925±255	939±285	0.872
Time to re-EVT (days)	410±200	400±233	0.757
Follow-up time after re-EVT (days)	515±251	539±226	0.893
Death	0	0	
Planned minor amputation	2 (13%)	3 (14%)	0.875

KM analysis of freedom from Binary Restenosis



KM analysis of freedom from CD-TLR



Multivariate regression analysis

Factors	Binary restenosis	p	CD-TLR	p
	HR (95% CI)	value	HR (95% CI)	value
Age	0.96 (0.90–1.04)	0.311	0.97 (0.89–1.04)	0.384
Female	1.59 (0.54–4.73)	0.404	2.03 (0.63–6.57)	0.237
Diabetes mellitus	2.49 (0.33–18.8)	0.378	2.46 (0.31–19.2)	0.391
Dialysis	1.12 (0.18–7.03)	0.891	2.20 (0.30–16.2)	0.438
CLI	1.51 (0.31–7.40)	0.611	1.12 (0.21–6.02)	0.898
Hyperlipidemia	1.79 (0.47–6.80)	0.388	1.14 (0.26–5.08)	0.860
Vessel calcification	1.43 (0.23–9.06)	0.702	1.16 (0.16–8.53)	0.887
Occlusion	1.18 (0.34–4.11)	0.796	1.39 (0.37–5.29)	0.629
Lesion length	1.03 (0.98–1.08)	0.281	1.02 (0.97–1.08)	0.364
Level of CRP	1.32 (0.81–2.14)	0.268	1.63 (0.67–3.95)	0.280
Repetition of DCB	6.15 (1.60–23.6)	0.008*	5.37 (1.32–22.0)	0.019*



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Conclusion

For femoropopliteal DCB restenosis

- ▣ The same drug platform might be was feasible and efficient for those restenotic lesions.
- ▣ Repetition of DCB can potentially improve vessel patency and significantly reduces the need for reintervention as compared to conventional treatment.
- ▣ However, these observations require further confirmation in larger scale studies.



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