

PEPCAD Japan SVD

Study summaries SeQuent® Please / NEO
Randomized controlled trials

SeQuent[®] Please vs. POBA (SeQuent[®] NEO) in small vessel de novo lesions

A multicenter randomized comparison of paclitaxel-coated
balloon with plain balloon angioplasty in patients with small
vessel disease

Funatsu A et al. Clin. Res. Cardiol. 2017; 106(10): 824-32

Key findings

TVF was low for treatment of SVD with DCB. In addition,
LLL was observed significantly more frequent in the DCB
group in comparison to the POBA group.

Description

Design: Randomized | Open-label | Prospective |
Multicenter | Superiority (test for difference)

Indication: De novoMain patient inclusion criterion:
Reference vessel diameter ≤ 2.75 mm, ≥ 2 mm

Primary endpoint: TVF @ 6-month follow-up. Components
of TVF:

- Cardiac death: Death due to target vessel
- MI: Creatine phosphokinase (CPK) elevation C3 times the normal value in addition to continuous chest symptoms and electrocardiogram changes due to target vessel
- Composite events: Revascularization of target vessel (PCI or CABG)

Secondary endpoints:

- TLR @ 6-month follow-up: Ischemia-driven if the lesion revealed restenosis ($DS \geq 50$) associated with symptom or presence of ischemia, or if lesion diameter stenosis $> 70\%$ (by core laboratory QCA), even in the absence of clinical or functional ischemia
- LLL @ 6-month follow-up

DAPT: 6 months

Results

Patients: In total, 135 patients were enrolled and randomized into a DCB group and POBA group with a ratio of 2:1. Some patients were excluded from the trial due to unsuccessful treatment, consent withdrawal and protocol violation. Follow-up was performed in 88 patients from the DCB group and in 39 patients from the POBA group.

Baseline characteristics: The two treatment groups were well balanced. Apart from a higher proportion of diabetes

mellitus in the DCB group, there were no statistically significant differences between the two treatment groups.

Primary endpoints: TVF was low in the DCB group

	DCB n = 88	POBA n = 39	p-value
TVF	3.4 %	10.3 %	0.20
Cardiac death	0 %	0 %	-
MI	0 %	0 %	-
TLR	2.3 %	10.3 %	0.07

Secondary endpoints:

	DCB	POBA	p-value
Clinical follow-up			
No. of patients	88	39	-
TLR	2.3 %	10.3 %	0.07
Angiographic follow-up			
No. of lesions	103	43	-
LLL	0.01 ± 0.31 mm	0.32 ± 0.34 mm	< 0.01