AMI Feasibility Study

Study summaries SeQuent® Please / NEO
Randomized controlled trials

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AMI Feasibility Study

SeQuent® Please (NEO) vs. DES (SES) in de novo lesions

Drug-coated balloon versus drug-eluting stent in primary percutaneous coronary intervention: a feasibility study

Gobić D et al. Am. J. Med. Sci. 2017; 354(6): 553-60

Key findings

DCB angioplasty with SeQuent® Please and SeQuent® Please NEO is safe and feasible in patients with acute myocardial infarction with ST elevation.
The MACE rate was low in the DCB group with no events between the 1- and 6-month follow-up. The angiographic follow-up showed significantly smaller LLL in the DCB group than in the DES group. In the DCB group LLL was negative, meaning that patients experienced on average Late Lumen Gain.

Description

Design: Randomized | Open-label | Prospective | Single center

Indication: De novo

Main patient inclusion criterion: STEMI (< 12 h)

Endpoints:

- MACE @ 6-month follow-up. Components of MACE: Cardiac death, Re-infarction, TLR and Stent thrombosis
- LLL @ 6-month follow-up

DAPT: 12 months

Results

Patients: In total, 78 patients were enrolled in this trial. 37 patients were randomized into the DES group and 41 patients in the DCB group. Three patients in the DCB group required bailout stenting and were further excluded from the study.

Baseline characteristics: The two treatment groups were well balanced, there were no statistically significant differences between the groups.

Endpoints:

	DCB **n = 38**	**DES** **n = 37**	**p-value**
MACE @ 1-month follow-up	5.3 %	5.4 %	0.98
MACE @ 6-month follow-up (additional events after 1-month follow-up)	0 %	5.4 %	0.24
LLL	- 0.09 ± 0.09 mm	0.10 ± 0.19 mm	< 0.05

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