Clinical Value "Stent-less" PCI

Study summaries SeQuent® Please / NEO Randomized controlled trials



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

Clinical value of drug-coated balloon angioplasty for de novo lesions in patients with coronary artery disease

Nishiyama N et al. Int. J. Cardiol. 2016; 222; 113-8

Key findings

In the DCB group was not a single case of TLR reported (0.0 %), in contrast to the DES group with a TLR rate of 6.1 % at 8-month follow-up. The authors conclude that "stentless" PCI could be useful with regards to the reduction of DAPT and a more safe discontinuation of DAPT than after DES implantation.

Description

Design: Randomized | Open-label | Prospective | Single

center

Indication: De novo

Primary endpoint: TLR @ 8-month follow-up

Secondary endpoint: LLL @ 8-month follow-up

Results

Patients: 60 consecutive patients were enrolled in this trial and randomized into the DCB or DES group. After lesion preparation with NSE Alpha, three patients in the DCB group had an unacceptable angiographic result and were moved into the DES group. Therefore, a total of 27 patients were in the DCB group, 33 patients in the DES group.

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

Primary endpoint:

	DCB n = 27	DES n = 33	p-value
TLR	0.0 %	6.1 %	0.193

Secondary endpoint:

	DCB n = 27	DES n = 33	p-value
LLL	0.25 ± 0.25 mm	0.37 ± 0.40 mm	0.11

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