FFR-Guided DCB-Angioplasty

Study summaries SeQuent® Please / NEO
Not randomized controlled trials &
observational studies

B|BRAUN
SHARING EXPERTISE

FFR-Guided DCB-Angioplasty

SeQuent® Please and DES (ZES/EES/BMS) in de novo lesions

Fractional flow reserve-guided paclitaxel-coated balloon treatment for de novo coronary lesions

Shin E et al. Catheter. Cardiovasc. Interv. 2016; 88(2): 193-200

Key findings

FFR-guided DCB treatment with SeQuent® Please is safe and effective in de novo lesions. MLD was comparable in the DCB and DES group at 9-month follow-up, and LLL was significantly lower in the DCB group.

Description

Design: Open-label | Prospective | Single center

Indication: De novo

Main patient inclusion criterion: Reference vessel diameter ≤ 3.5 mm, ≥ 2.5 mm

Endpoints:

- LLL @ 9-month follow-up
- FFR @ 9-month follow-up
- MI @ 12-month follow-up

DAPT:

- DCB-only: 1.5 months
- BMS: ≥ 6 months
- DES: ≥ 12 months

Additional information: Method of treatment was determined through FFR measurements

- FFR ≥ 0.85: DCB angioplasty
- FFR < 0.85: Stent implantation

Results

Patients: 67 lesions were included in this trial due to successful lesion preparation and FFR. All patients with FFR ≥ 0.85 and some additional lesions with FFR ≤ 0.85 were treated with a DCB, in total 45 lesions (67.2 %). Lesions with FFR ≤ 0.85 were chosen for DCB angioplasty if measurements were close to the limit or patients were not able to receive long-term DAPT. The remaining 22 lesions (32.8 %) with FFR ≤ 0.85 were treated with a stent.

Baseline characteristics: The two treatment groups were well balanced, there were no statistically significant

differences between the groups.

Endpoints:

	DCB n = 45	DES n = 22	p-value
9-month follow-up			
LLL	0.05 ± 0.27 mm	0.40 ± 0.54 mm	0.022
FFR	0.85 ± 0.08	0.85 ± 0.05	0.973
12-month follow-up			
MI	0 patients	1 patient	-
TLR	0 patients	1 patient	-

[1] Cutlip D et al. Circulation 2007; 115: 2344-51.