DCB-only All-Comers Registry

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

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SHARING EXPERTISE

DCB-only All-Comers Registry

SeQuent® Please in de novo lesions, DES- and BMS-ISR

Prospective, large-scale multicenter trial for the use of drug-coated balloons in coronary lesions: The DCB-only All-Comers Registry

Rosenberg M et al. Catheter. Cardiovasc. Interv. 2019; 93(2): 181-8

Key findings

DCB-only angioplasty with SeQuent® Please in de novo lesions is associated with low MACE and TLR rates. The authors conclude that DCBs appear to be an attractive alternative for the interventional, stent-less treatment of suitable de novo coronary lesions.

Description

Design: Open-label | Prospective | Multicenter

Indication: De novo, ISR

Primary endpoint: TLR @ 9-month follow-up

Secondary endpoints: MACE @ 9-month follow-up.
Components of MACE:

- TLR
- Cardiac death: Death not clearly of extracardiac origin
- MI: Typical clinical symptoms, relevant ECG changes and/ or elevated troponin T or troponin I increases (3 × the upper limit of normal)
- Definite vessel thrombosis: According to Academic Research Consortium definition [1]

DAPT:

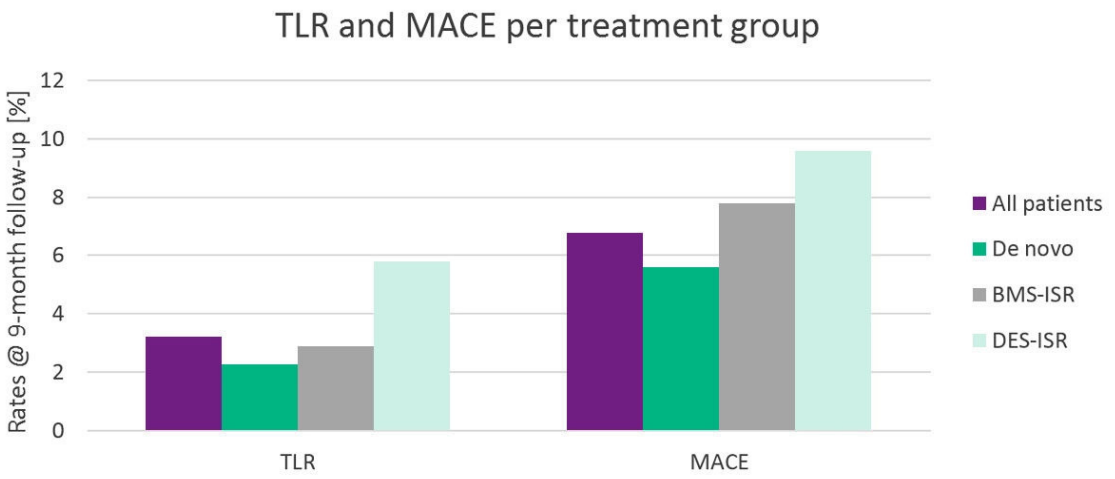
- DCB-only: 1 month
- DCB + stent: ≥ 6 months

Results

Patients: A total of 1,025 patients were enrolled. 686 of these patients (66.9 %) were treated in de novo lesions, 231 (22.6 %) in DES-ISR and 108 (10.5 %) in BMS-ISR.

Baseline characteristics: The different patient groups were well balanced. Statistically significant differences were observed with regards to the history of smoking and STEMI. The percentage of patients with a history of smoking was highest in the BMS-ISR group, while the percentage of STEMI was highest in the de novo group.

Primary endpoint: TLR rates at 9-month follow-up were low across all treatment groups, with a lower rate for the de novo group.



Secondary endpoints:

	All patients	De novo	BMS-ISR	DES-ISR	p-value
Patients with clinical follow-up	915 (89.3 %)	604 (88.0 %)	103 (95.4 %)	208 (90.0 %)	0.067
MACE	6.8 %	5.6 %	7.8 %	9.6 %	0.131
TLR	3.2 %	2.3 %	2.9 %	5.8 %	0.049
Cardiac death	1.3 %	1.0 %	1.9 %	1.9 %	0.499
MI	3.4 %	3.6 %	3.9 %	2.4 %	0.666
Definite vessel thrombosis	0.8 %	0.5 %	1.9 %	1.0 %	0.278

[1] Cutlip D et al. Circulation 2007 15: 2344-51.

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