BASKET-SMALL 2

Study summaries SeQuent® Please / NEO
Randomized controlled trials

B|BRAUN
SHARING EXPERTISE

BASKET-SMALL 2 (3-year data available – October 2020)

Basel Stent Kosten Effektivitäts Trial Drug Coated Balloons vs. Drug Eluting Stents in Small Vessel Interventions

Jeger R et al. The Lancet, August 2018.

Trial Registration Number: NCT01574534 on https://www.clinicaltrials.gov

Jeger R et al. The Lancet, October 2020. Same trial registration.

Key findings

Largest randomized clinical trial with primary clinical endpoint, testing the efficacy of SeQuent® Please NEO (DCB) vs. 2nd generation DES for the treatment of small vessel coronary artery disease.

DCB-only treatment with SeQuent® Please NEO achieves clinical results comparable to 2nd generation DES implantation in de novo lesions up to 3 mm in reference vessel diameter.

Description

Design: Investigator initiated | Randomized | Open-label | Prospective | Multicenter | Non-inferiority

Indication: Ischemic coronary artery disease (CAD) in native de novo lesions

Main inclusion criteria:

- Vessel diameter ≥ 2 mm to < 3 mm
- Native vessel
- Successful pre-dilation according to consensus recommendations for DCB-usage

Primary outcome:

- MACE @ 12 months (MACE includes: TVR, non-fatal MI, cardiac death)
- MACE @ 36 months (MACE includes: TVR, non-fatal MI, cardiac death)

Secondary outcomes:

- TVR, non-fatal MI, cardiac death, stent thrombosis, bleeding

Dual Antiplatelet Therapy (DAPT):

- 4 weeks of DAPT in stable patients treated with DCB or 6 months for DES. In patients with acute coronary syndrome (ACS) 12-month DAPT

Results

758 patients randomized after pre-dilation (86 % of 883 initially assessed patients)

- 382 assigned for DCB-treatment, 376 for DES-treatment
- Well-balanced demographic and procedural parameters between the treatment groups

Primary outcome: No statistical difference between groups

- **MACE @ 12 months** 7.3% in the DCB group vs. 7.5% in the DES group (p=0.92)
- The primary endpoint was met for non-inferiority at both time points (DCB not worse than DES)

Secondary outcome:

- **MACE @ 36 months** 15% in both groups (p=0.95)
- **@ 12 months DCB** vs. DES – cardiac death: 3.1 vs. 1.3 %, MI 1.6 vs. 3.5 % or TVR 3.4 vs. 4.5%
- **@ 36 months DCB** vs. DES – cardiac death: 5 vs. 4 %, MI 6 vs. 6 % or TVR 9 vs. 9%

Other endpoints:

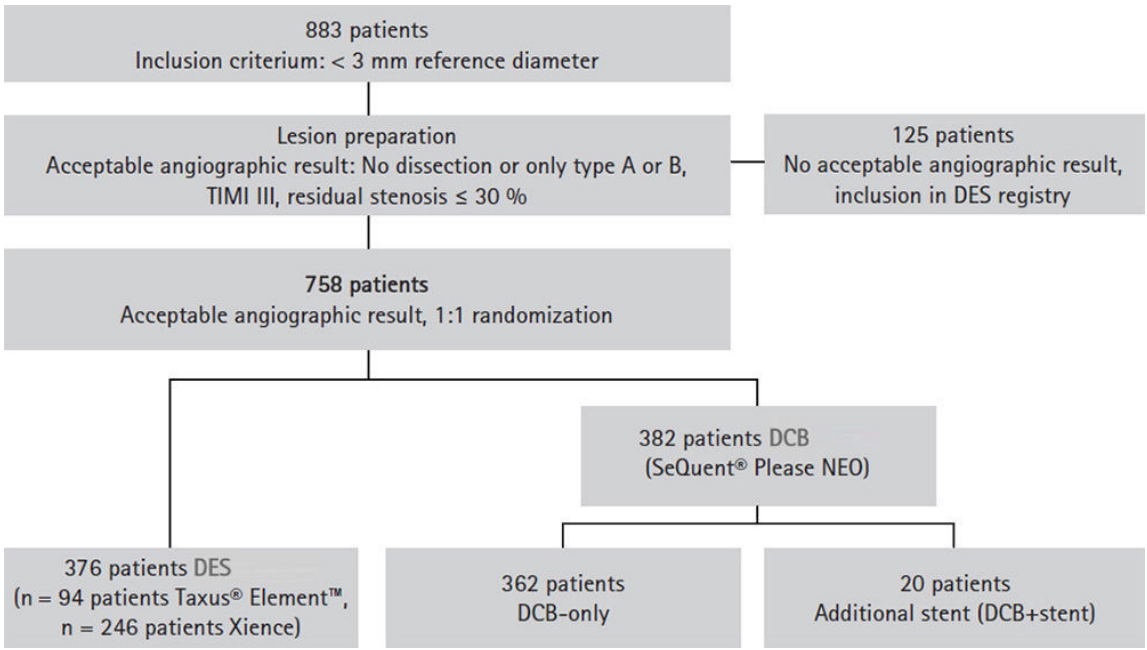
- **@ 12 months: Probable or definite thrombosis** were low and comparable between DCB and DES patients (0.79 vs. 1.60 %). Rates of major bleeding were low and similar in DCB and DES patients (1.1 vs. 2.4 %).

- **@ 36 months: Probable or definite thrombosis** (1% in DCB and 2% in DES, p=0.18). Rates of major bleeding (2% in DCB vs. 4% in DES, p=0.088) were numerically lower in the DCB group without statistical significance.

Conclusion

BASKET SMALL 2 is the largest randomized trial with primary clinical endpoint comparing DCB with 2nd generation DES in small vessel coronary artery disease – DCB is non-inferior to 2nd generation DES in the treatment of SVD.

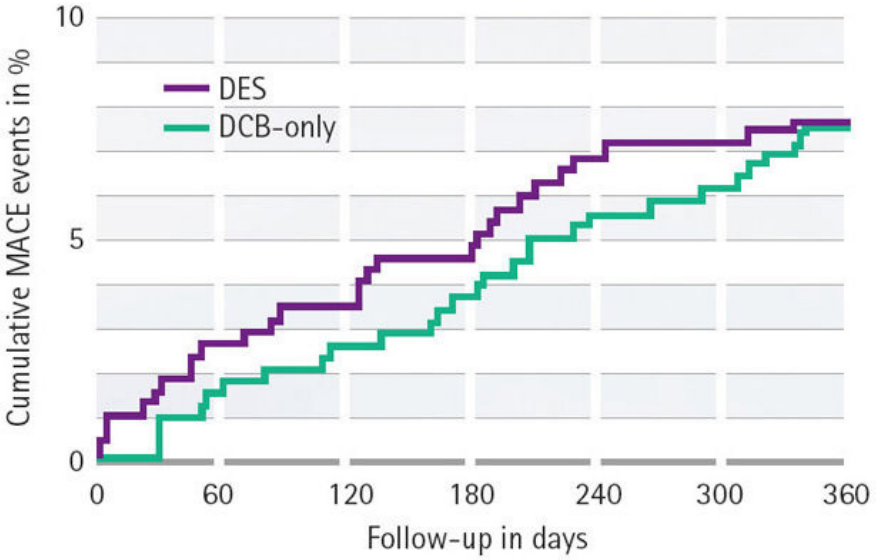
Study flowchart

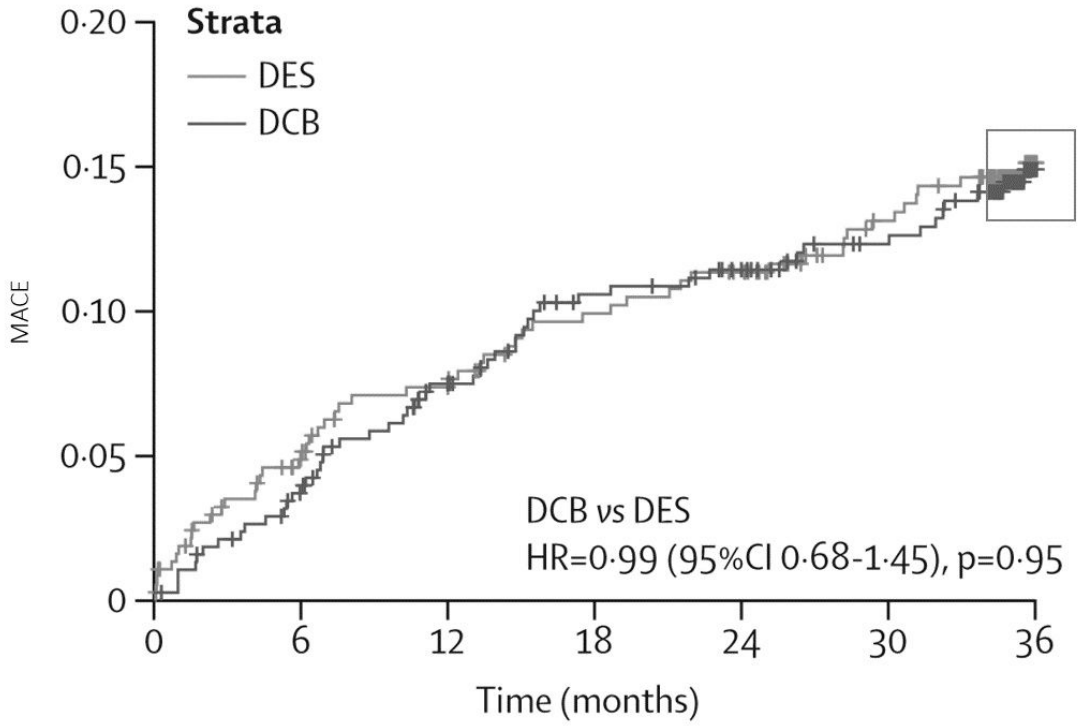


12-month follow-up:

	DCB n = 362	DES n = 376	p-value
TVR	3.4 %	4.5 %	0.44
MI	1.6 %	3.5 %	0.11
Cardiac death	3.1 %	1.3 %	0.11
MACE	7.3 %	7.5 %	0.92

36-month follow-up:





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