# SVD
# Registry

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

# SeQuent® Please in small vessel de novo lesions

Prospective "real world" registry for the use of the "PCB only" strategy in small vessel de novo lesions

Zeymer U et al. Heart 2014; 100(4): 311-6

# Key findings

Treatment of SVD with SeQuent® Please had a very high procedural success rate. At 9-month clinical follow-up, TLR and MACE rates were low in real world patients. The authors conclude that DCBs might be an attractive alternative to DES for treating SVD.

# Description

**Design:** Open-label | Prospective | Multicenter

**Indication:** De novo

**Main patient inclusion criterion:** Reference vessel diameter ≤ 2.75 mm, ≥ 2.0 mm

**Primary endpoint:** TLR @ 9-month follow-up. Components of TLR:

- Re-PCI
- CABG

**Secondary endpoints:**

- Procedural success rate

- MACE @ 9-month follow-up. Components of MACE:
  Cardiac death: Death not clearly of extracardiac origin
  MI: ECG changes and/or cardiac enzyme elevations
  according to each institution's routine diagnostic algorithms
  TLR

- Definite lesion and vessel thrombosis @ 9-month follow-up:
  according to academic research consortium definition [1]

**DAPT:**
- 1, 3-6 or 12 months

# Results

**Patients:** 447 patients with 471 lesions were enrolled in this registry. 420 patients were treated with DCB-only (94 %) and 27 patients with DCB + BMS (6 %).

**Baseline characteristics:** The two treatment groups were well balanced. Of note are the high rate of diabetics (36.7 %) and the moderate ACS rate (23.5 %) in the overall patient population. The only statistically significant difference between the DCB-only and DCB + BMS group

were the incident of STEMI, with a higher percentage in the DCB + BMS group.

**Primary endpoint:** TLR rates at 9-month follow-up were low and comparable between both treatment groups.

|  | All patients n = 447 | DCB-only n = 420 | DCB + BMS n = 27 | p-value |
|---|---|---|---|---|
| TLR | 3.6 % | 3.6 % | 4.0 % | 0.922 |

**Secondary endpoint:** Procedural success was achieved in 99 % of cases. Remaining endpoints at 9-month follow-up:

|  | All patients n = 447 | DCB-only n = 420 | DCB + BMS n = 27 | p-value |
|---|---|---|---|---|
| MACE | 4.7 % | 4.7 % | 4.0 % | 0.866 |
| Cardiac death | 0.0 % | 0.0 % | 0.0 % | - |
| MI | 1.8 % | 1.9 % | 0.0 % | 0.481 |
| TLR | 3.6 % | 3.6 % | 4.0 % | 0.922 |
| Thrombosis | 0.8 % | 0.6 % | 4.2 % | 0.054 |

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