

Clinical and angiographic results after scoring-balloon angioplasty and sirolimus-eluting balloon angioplasty for the treatment of diffuse, small vessel coronary artery disease (SCA-DEB Study)

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Background: The treatment of diffuse, small vessel coronary artery disease is challenging, with high rates of repeat revascularizations, without satisfactory treatment. We designed a prospective, single-center, single-arm study to evaluate the feasibility and safety of a new strategy for the treatment of diffuse, small vessel coronary artery disease using a systematic combination of Scoring-balloon Angioplasty and Sirolimus-eluting balloon Angioplasty (the SCA-DEB study).

Methods: We included patients with diffuse (lesion length ≥ 20 mm), small vessel (diameter 1.5–2.75 mm) coronary disease. Patients with STEMI, left-main stenosis, and a life expectancy of less than 12 months were excluded. The procedure strategy was scoring-balloon angioplasty (SBA) – WedgeNC, Brosmed, China, 1:1 diameter ratio with distal reference plus sirolimus-eluting balloon angioplasty (SEB) using Mozec balloon. If scoring balloon did not pass predilatation with 1.5 mm balloon and/or rotablation was allowed.

Results: From December 2022 until June 2024, 146 patients with 161 vessels were included.

The mean age was 67 ± 9 years, 73% males, 97% with dyslipidemia, 56% smokers, 45% diabetics, 40% with previous myocardial infarction, 86% with previous PCI, 10% previous CABG, 10% with peripheral artery disease, 18% with previous stroke or transient ischemic attack, 10% with COPD, 33% with eGFR < 60 ml/kg/min, with mean left ventricular ejection fraction $52 \pm 8\%$. The left anterior descending artery was the most frequently treated – 45%, followed by the circumflex artery – 32%. Rotablation was necessary in 3 cases. The mean reference vessel diameter was 2.1 ± 0.74 mm, MLD 0.71 ± 0.31 mm, %DS $67 \pm 14\%$. The mean lesion length was 35 ± 15 mm treated with scoring balloon with diameters and lengths – 2.21 ± 0.22 mm and 24 ± 5 mm; and Mozec balloons (length 33 ± 11 , diameter of 2.3 ± 0.24 mm).

Additional stent was implanted in 48 patients (33%). At 3 months angiographic follow up for the first 91 patients demonstrated the late lumen loss of 0.01 ± 0.20 mm and net lumen gain 0.93 ± 0.45 mm. The final %DS was $35 \pm 12\%$ and at follow-up $33 \pm 12\%$, $p = .19$. For a median clinical follow up of 13 [8–19] months, 4.8% (7/146) had TVR. The overall rate of MACE was 7.5% ($n = 11/146$).

Conclusions: A new strategy using combination of scoring balloon angioplasty followed by sirolimus-eluting Mozec balloon inflation for the treatment of diffuse coronary artery disease gives promising angiographic and clinical outcomes results.