



AMERICAN
COLLEGE of
CARDIOLOGY®

REC-CAGEFREE I

Rescue Stenting vs. Intended Stenting in Patients
With De Novo Coronary Artery Lesions

OBJECTIVE

Assess the noninferiority of drug-coated balloon (DCB) angioplasty with rescue stenting compared with intended stenting with second-generation thin-strut sirolimus-eluting stents (DES) in patients with de novo coronary artery lesions.

STUDY METHODS

TOTAL NO. OF PATIENTS: 2,272

(43 sites in China; median age 62 years; 30.7% Female)

INCLUSION CRITERIA:

De novo, non-complex coronary artery disease and an indication for PCI

STUDY DESIGN:

Randomized 1:1 to DCB with rescue stenting or intended stenting with DES

PRIMARY ENDPOINTS

AT 24 MONTHS, FEWER PATIENTS IN THE DCB GROUP VS. THE DES GROUP EXPERIENCED A DEVICE-ORIENTED COMPOSITE ENDPOINT (CARDIOVASCULAR DEATH, TARGET VESSEL MYOCARDIAL INFARCTION, AND CLINICALLY AND PHYSIOLOGICALLY INDICATED TARGET LESION REVASCULARIZATION):

DCB GROUP: 72 PATIENTS

DES GROUP: 38 PATIENTS

NONINFERIORITY WAS NOT MET.

CONCLUSION

DES should remain the preferred treatment for patients with de novo coronary artery lesions.

Gao C, He X, et al. Drug-Coated Balloon Angioplasty with Rescue Stenting Versus Intended Stenting for the Treatment of Patients with De Novo Coronary Artery Lesions (REC-CAGEFREE I): An Open-Label, Randomised, Non-Inferiority Trial. *The Lancet* 2024;Sept. 2:[https://doi.org/10.1016/S0140-6736\(24\)01594-0](https://doi.org/10.1016/S0140-6736(24)01594-0).