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Observational Study

Indian Heart J. 2025 Mar-Apr;77(2):105-109. doi: 10.1016/j.ihj.2025.03.003.

Epub 2025 Mar 3.

# Drug-coated balloon in patients with in-stent restenosis: A prospective observational study



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PMID: 40043905 PMCID: PMC12138078 DOI: 10.1016/j.ihj.2025.03.003



#### **Abstract**

**Aim:** The aim of this study was to compare the safety and efficacy of paclitaxel-coated balloons (PCB) and sirolimus-coated balloons (SCB) in patients with in-stent restenosis (ISR).

**Methods:** This prospective, observational, single-centre pilot study enrolled 85 patients diagnosed with drug-eluting stent ISR. For all the eligible patients, various clinical baseline characteristics were collected, and angiography was performed to evaluate the lesion characteristics. After assessment, patients were treated with either PCB or SCB based on our center's time-based approach. Intravascular ultrasound (IVUS) imagining was used to assess the pre- and post-procedural minimal stent area (MSA). All the patients were followed up and major adverse cardiovascular events were documented for patients in both the groups.

**Results:** Of total 85 patients with ISR, 32 underwent treatment with PCB and 53 with SCB. A significant difference was noted in the post procedural MSA in both the groups (p = 0.005) and the values were 7.01  $\pm$  1.11 mm<sup>2</sup> and 8.01  $\pm$  1.70 mm<sup>2</sup> for PCB and SCB group, respectively. At median follow-up of 3.8 years, no cardiac death was noted in PCB group and one death was reported in SCB group (p = 0.459). In PCB group, target lesion revascularization (TLR) was noted in one (12.5 %) patient, while in SCB group TLR was noted in four (16.5 %) patients (p = 0.920).

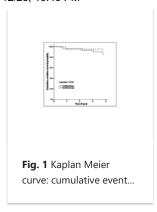
**Conclusion:** Both PCB and SCB are found to be effective and safe in treating in patients with drugeluting stents-ISR. Also, the use of DCB with imaging techniques like IVUS enhances treatment outcomes and optimizes patient care in ISR treatment.

**Keywords:** Coronary balloon angioplasty; Coronary restenosis; Death; Drug-eluting stents; Paclitaxel; Sirolimus.

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