



RESEARCH TOPIC MECM_3

Optimizing treatment strategies: reduced stent strategy versus conventional percutaneous coronary revascularization in patients with acute myocardial infarction.

Curriculum

MECM Clinical

Research Area

Cardio

Laboratory name

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Abstract

Introduction

Primary percutaneous coronary intervention (PCI) with drug-eluting stent implantation (DES) is the standard of treatment in patients presenting with ST segment elevation myocardial infarction (STEMI).(1) Second-generation DES as compared to bare metal stent have shown to reduce the rate of short-term target lesion revascularization and stent thrombosis as well as long-term patient-orientated composite events (all-cause death, any myocardial infarction, or any revascularization).(2) However, this approach is not without limitations, as stent-related complications occur with cardiac adverse events reported to be as high as 32.4% at 10-year follow-up.(3) Drug coated balloons (DCB) have been developed as a potential alternative treatment option to DES. DCBs are balloon catheters coated with an antiproliferative agents that are released into the vessel wall upon balloon inflation. The drug is absorbed by the vessel, inhibiting cell proliferation, and reducing neointimal hyperplasia.(4,5) The absence of a permanent metallic scaffold may help to preserve vessel vasomotion and potentially reduce the risk of long-term adverse events.(6) However, data regarding the role of DCBs in patients presenting with STEMI is lacking. During the last decade improvement in the management of patients presenting with STEMI has been achieved by the implementation of networks between hospitals and by iterations in secondary prevention medical therapy.(1) However, the revascularization of this population has remained unvaried for more than a decade and exclusively focused in the implantation of DES. Therefore, we have designed the Reduced stent strategy versus conventional percutaneous coronary revascularization in patients presenting with STEMI (the COPERNICAN trial).

Objectives and randomization

The COPERNICAN trial (ClinicalTrials.gov: NCT06353594) is a prospective, pragmatic, investigator-initiated randomized clinical trial aimed to compare a reduced stent strategy (DCB-based) with a conventional DES revascularization strategy in patients presenting with STEMI across Spain, Italy and France. Patients presenting with STEMI and with indication to undergo primary PCI will be screened for enrollment in the study. Exclusion criteria are:

cardiogenic shock, left ventricular ejection fraction <15%, left main disease, stent thrombosis, patients with prior bypass graft lesions requiring PCI, patients with chronic total occlusions. Randomization will be performed after successful culprit-lesion guidewire crossing and vessel flow restoration and will be stratified per center and presence of multivessel disease within the electronic case report forms.

Random allocation will be performed in a 1:1 fashion to one of the following strategies:

A) Study group: reduced stent strategy (DCB-based)

a. Prior to DCB use, meticulous lesion preparation will be required. Any device can be used for lesion preparation according to operator's preference with a distal reference balloon diameter/vessel diameter ratio of 1:1.

b. Culprit lesion revascularization with any paclitaxel-DCB will be performed after coronary predilation if residual stenosis $\leq 30\%$, lack of dissections >type B and TIMI 3 flow. A paclitaxel-DCB with ratio 1:1 between distal vessel size and balloon diameter is recommended.

c. If some of the following lesion characteristics are present after lesion preparation (residual stenosis >30%, dissections >type B and TIMI <3 flow) or a relevant dissection is present after DCB-PCI (Type C dissection or TIMI flow <3) a sirolimus-DES will be implanted following standard recommendations.

B) Control group: culprit-lesion revascularization with the implantation of any sirolimus-DES.

Patients presenting with multivessel coronary artery disease requiring a staged non-culprit lesion percutaneous coronary intervention (PCI) procedure will also be included. Staged procedures should be performed during index hospitalization or within 15 days after hospital discharge. The assessment of the need for revascularization through evaluation of ischemia/coronary physiology is encouraged. The revascularization strategy will be determined according to the culprit-lesion allocation group. Any paclitaxel DCB and any sirolimus-DES can be used in the study. Use of intracoronary imaging during procedure will be left to the discretion of the operator, as well as antithrombotic therapy, according to the current European guidelines on the management of patients presenting with STEMI.(1)

Study endpoints and follow up

Primary endpoint is target lesion failure (TLF), a composite of cardiac death, target-vessel myocardial infarction or ischemia-driven target lesion revascularization at 12-month follow-up. All endpoints will be defined according to Academy Research Consortium criteria except for myocardial infarction that will be defined according to the fourth universal definition. An independent Clinical Event Committee will review and adjudicate all events according to the study protocol.

Statistical analysis and sample size considerations

Assuming an event rate for TLF of 6% in the conventional (DES-based) revascularization arm, the inclusion of a total of 1,272 patients will provide 80% power to demonstrate non-inferiority with a margin of 3.6% assuming an attrition rate of 15%.

The primary objective is to determine if a reduced stent strategy will be noninferior to conventional revascularization in reducing the rate of TLF. If non-inferiority is shown after one year, superiority at three years after randomization will be tested. Secondary objective is to determine whether a reduced stent strategy will be superior to conventional DES-based revascularization. To control the overall type I error, prespecified hierarchical sequential

testing will be performed first on the primary outcome for noninferiority and finally on the primary outcome for superiority.

All primary analyses will be performed in the intention-to-treat population, which includes all randomized patients by their allocated strategy. Predefined subgroup analyses will include age, sex, renal insufficiency, diabetes mellitus, complex lesions, severe coronary calcification, presence of multivessel coronary artery disease, prior history of myocardial infarction, bleeding/ischemic risk, use of intracoronary-imaging, type of DCB or DES implanted, use of coronary physiology of non-culprit lesions

Main technical approaches

The applicant will need to have experience in clinical research and biostatistics.

Scientific references

1. Stefanini GG. et al. Management of myocardial revascularisation failure: an expert consensus document of the EAPCI. *EuroIntervention* 2020;16(11):e875–90. Doi: 10.4244/EIJ-D-20-00487
2. Sanz-Sánchez J, et al. Reduced stent strategy versus conventional percutaneous coronary revascularization in patients presenting with STEMI: design of the COPERNICAN trial. *Rev Esp Cardiol (Engl Ed)*. 2026 Feb;79(2):100-105. doi: 10.1016/j.rec.2025.05.005
3. Boden WE, et al. Myocardial Ischemic Syndromes: A New Nomenclature to Harmonize Evolving International Clinical Practice Guidelines. *Circulation*. 2024 Nov 12;150(20):1631-1637. doi: 10.1161/CIRCULATIONAHA.123.065656

Type of contract

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