The COMPLETE Trial: Nonculprit Revascularization in STEMI

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Abstract

In October of 2019, the COMPLETE Trial [1] was published in New England Journal of Medicine by Mehta et al. This was a randomized control trial that included 4,041 patients, from 140 centers in 31 countries, who underwent primary percutaneous coronary intervention (PCI) for acute ST-elevation myocardial infarction (STEMI).

Patients were randomized within 72 hours of initial successful culprit-lesion PCI to:

- No further revascularization (n = 2025)
- Complete revascularization of significant nonculprit lesions (n = 2016)

Complete revascularization group was further stratified to timing of staged PCI:

- During the index hospitalization (n = 1353)
- Within 45 days of discharge (n = 663).

Guideline directed medical therapy in both arms included dual antiplatelet therapy (DAPT), high intensity statin therapy, angiotensin converting enzyme inhibitor or angiotensin receptor blocker, and beta blockers.

Inclusion criteria:

- Multivessel coronary disease (≥ 1 significant nonculprit lesions)
- Amenable to successful PCI
- Vessel diameter ≥ 2.5 mm (not stented during index PCI)

Angiographic significance definition:

- ≥ 70% stenosis on visual estimation
- 50 - 69% stenosis, with fractional flow reserve (FFR) ≤ 0.80

Exclusion criteria:

- Intention, before randomization, to revascularize a nonculprit lesion
- Planned surgical revascularization
- Previous coronary artery bypass grafting surgery (CABG)
- No cardiogenic shock patients were enrolled, though not an exclusion criterion

Co primary composite outcomes:

- Death from cardiovascular (CV) causes, new MI
- Death from CV causes, new MI, or ischemia-driven revascularization

Results

After about 4 years of follow-up:

- Both coprimary composite outcomes were significantly lower in the complete revascularization group (7.8%, 8.9%) compared with the culprit-lesion-only group (10.5%, 16.7%; P < 0.01)
- This difference was driven by a 32% lower incidence of new MI in the complete revascularization group
- The benefit was observed whether nonculprit-lesion PCI was performed during the index hospitalization or within 45 days after discharge
- Number needed to treat (NNT) to prevent one CV death or MI: 37

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- NNT to prevent one CV death, MI, or ischemia-driven revascularization: 13

There was no statistically significant difference in the safety outcomes that were examined, including major bleeding, stroke, stent thrombosis and contrast induced kidney injury.

Discussion

About 50% of patients who present with STEMI have multivessel coronary artery disease (CAD), which places them at higher risk of early and late mortality, along with recurrent MI. Recently, there has been much debate regarding complete revascularization of all angiographically significant arteries in this patient population. In the last five years, key trials have been published suggesting a positive outcome with complete revascularization. The PRAMI trial [2] examined the effect of performing preventive PCI on noninfarct coronary arteries with significant stenosis in STEMI patients with multivessel CAD; the trial was stopped earlier than intended after it was found to have a major benefit on outcomes. The CVLPRIT trial [3] and the Danami 3 Primulti Trial [4] also showed similar positive outcomes of revascularizing all arteries with angiographically significant stenoses, either visually or using FFR guidance. Although these studies were criticized for being underpowered, their impact along with other key clinical trials was immense. In 2015, a focused update was made to the ACC/AHA/SCAI STEMI guidelines [5], with regards to intervention on non-culprit lesions during primary PCI in STEMI patients. The previous Class III recommendation (harmful or no benefit) was modified to a Class IIB recommendation (may be considered).

Clinical Implications

The field of interventional cardiology has witnessed great advances ever since its inception greater than 40 years ago [6]. The development of newer and safer stents [7] was paralleled by the advancement of novel dual antiplatelet agents [8]. With the advent of such advanced interventional therapies, the enthusiasm mounted to perform simultaneous multivessel revascularization, a practice traditionally allocated to coronary artery bypass grafting [9].The findings from the COMPLETE clinical trial give further credence to the feasibility of such approach in the setting of STEMI in hemodynamically stable patients, and allow the completion of revascularization within 45 day of hospital discharge. Whether these findings, combined with comparable results from other recent trials, will lead to further more favorable reclassification of non-culprit-vessel PCI during STEMI recommendations by the guidelines remains to be seen [10].

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