

STEMI後の非責任病変におけるPCIで予後を改善

COMPLETE試験:STEMI後の完全血行再建は責任病変のみの血行再建よりも優れている

COMPLETE: Complete revascularization is superior to culprit-lesion only intervention following STEMI

ST上昇型心筋梗塞(STEMI)後患者において、完全血行再建は責任病変のみに対する経皮的冠動脈形成術(PCI)に比べ主要心血管イベントを減少させる。最初のコプライマリーエンドポイント(心血管死または心筋梗塞)は、完全血行再建術群の7.8%に発現したのに対し、責任病変のみの群では10.5%であった($p=0.004$)。2番目のコプライマリーエンドポイント(心血管死、心筋梗塞、または虚血に対する血行再建術施行)は、完全血行再建術群で8.9%であったのに対し、責任病変のみの群では16.7%であった($p<0.001$)。このCOMPLETE試験の結果はESC Congress 2019のHot Line Sessionで発表され、*New England Journal of Medicine*に掲載された。

Full Text

An international randomized trial has shown that complete revascularization reduces major cardiovascular events compared to culprit-lesion only percutaneous coronary intervention (PCI). Late breaking results of the COMPLETE trial are presented in a Hot Line Session at ESC Congress 2019 together with the World Congress of Cardiology and published in the *New England Journal of Medicine*.

Up to 50% of patients with ST-segment elevation myocardial infarction (STEMI) have multivessel coronary artery disease. In STEMI patients, opening the culprit artery with PCI reduces cardiovascular death or myocardial infarction. It is unclear whether additional PCI of non-culprit lesions also prevents these events.

"The question of whether to routinely revascularize non-culprit lesions or manage them conservatively with guideline-directed medical therapy alone is a common dilemma," said principal investigator Professor Shamir R. Mehta of the Population Health Research Institute, McMaster University, Hamilton, Canada.

Observational studies suggest a reduction in clinical events with staged, non-culprit lesion PCI, but are limited by selection bias and confounding. Prior randomized trials found declines in composite outcomes with non-culprit lesion PCI but were not powered to detect improvements in hard, irreversible clinical outcomes such as cardiovascular death or new myocardial infarction. While meta-analyses indicate a decline in cardiovascular death or myocardial infarction with non-culprit lesion PCI, there has been no single, large trial showing benefit on this clinically important outcome. The COMPLETE trial was designed to address this evidence gap.

A total of 4,041 patients with STEMI and multivessel coronary artery disease were enrolled from 140 centers in 31 countries. Patients were randomly allocated to complete revascularization with additional PCI of angiographically significant non-culprit lesions, or to no further revascularization. Randomization was stratified by the intended timing of non-culprit lesion PCI: either during or after the index hospitalization.

The first co-primary outcome was the composite of cardiovascular death or myocardial infarction; the second co-primary outcome also included ischemia-driven revascularization.

At a median follow-up of three years, the first co-primary outcome of cardiovascular death or myocardial infarction occurred in 158 patients (7.8%) in the complete revascularization group compared to 213 (10.5%) in the culprit-lesion only group (hazard ratio [HR] 0.74; 95% confidence interval [CI] 0.60–0.91; $p=0.004$).

The second co-primary outcome of cardiovascular death, myocardial infarction, or ischemia-driven revascularization occurred in 179 patients (8.9%) in the complete revascularization group compared to 399 (16.7%) in the culprit-lesion only group (HR 0.51; 95% CI 0.43–0.61; $p<0.001$).

There were no significant differences between groups in the occurrence of stroke ($p=0.27$) or major bleeding ($p=0.15$).

Regarding the timing of non-culprit lesion PCI, complete revascularization consistently reduced the first co-primary outcome in those stratified to receive non-culprit lesion PCI during the index hospitalization (HR 0.77; 95% CI 0.59–1.00) and after hospital discharge (HR 0.69; 95% CI 0.49–0.97; interaction $p=0.62$).

Prof Mehta said: "COMPLETE is the first randomized trial to show that complete revascularization reduces hard cardiovascular events compared to culprit-lesion only PCI in patients with STEMI and multivessel coronary artery disease. The benefits emerged over the long term and were observed regardless of whether non-culprit lesion PCI was performed early, during the initial hospitalization or shortly after hospital discharge. These findings are likely to have a large impact on clinical practice and prevent many thousands of recurrent heart attacks globally every year."

The Canadian Institutes of Health Research, AstraZeneca, and Boston Scientific funded the study. The authors received research grants AstraZeneca and Boston Scientific.

Conference News

[News 01]

大気汚染は血管形成術の施行率を上昇させる

[News 02]

糖尿病患者におけるチカグレロルの臨床的有用性

[News 03]

STEMI後の非責任病変におけるPCIで予後を改善

[News 04]

ダバグリフロジンは糖尿病だけでなく心不全も治療する

[News 05]

ACSにおいてプラスグレルはチカグレロルに勝る

[News 06]

駆出率の保たれた心不全は依然として治療が困難である

[News 07]

高感度トロポニンを用いた単回の検査でMIを除外する

[News 08]

16年経過してもPCIは未だ血栓溶解療法に勝る

[News 09]

β 遮断薬は腎機能障害を有する患者であっても死亡率を低下させる

[News 10]

PCIとCABGには10年後の死亡率に差はない

[News 11]

2年後の時点で経皮的僧帽弁修復術の有益性は認められなかった

[News 12]

コレステロールおよび血圧の穏やかな低下の効果

[News 13]

地域住民を対象とした塩分置換プログラムは血圧を低下させる

[News 14]

心不全における一次予防としてのICDは死亡リスクを低下させる

[News 15]

PCI後予防的ICDの長期の有益性

[News 16]

末梢動脈疾患に対してスタチンを開始するのに遅すぎることはない

[News 17]

心不全および脳卒中患者において白質病変は一般的である

[News 18]

うつ病は介護者の身体的健康と関連がある

[News 19]

MI後の内出血はがんを疑うきっかけとなる