radcliffe cardiology

Title: ACC.24: FFR or Culprit-Only PCI in STEMI
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Background and Study Design

Patients with acute myocardial infarction and multivessel disease, they are at increased risk of serious complications, and it's long been unclear what is the best strategy for the non-culprit lesions. So vessels narrowing in other parts of the heart. So the strategy to do what to do with those vessels, that's been unclear. So the study was performed as a multinational, RRCT hybrid, registry-based, randomized controlled clinical trial. In 32 hospitals in seven countries, and all the patients in Sweden were actually randomized directly in the registry. And some of the data was also collected from the registry to the database and in other countries. In the study, in Denmark, Serbia, Latvia, Finland, Australia, New Zealand, they were randomized through a separate web page and then all the data was merged into the full Revasc study database. The patients that were included were 91% STEMI and 9% very high-risk non-STEMI, and all had to have multivessel disease. So with at least one more non-culprit lesion, at least 2.5 millimeters in diameter, and with 50% to 99% stenosis grade, and then they were randomized in a one-to-one fashion to either FFR-guided PCI of all non-culprit lesions sometime during the index hospitalization, or to initial conservative management of all non-culprit lesions. And then they were followed for a median of 4.8 years until we had 304 primary outcome events.

Key Findings

Well, the key findings are the following: there was no difference between the study groups in the primary combined endpoint of all-cause mortality, new myocardial infarction, or unplanned revascularization, and the p-value was 0.53, hazard risk ratio

of 0.93. Also, the key secondary endpoint of death and MI did not differ between the study groups, and the key secondary endpoint of unplanned revascularization did not differ significantly between the study groups. However, there were numerically fewer events in that endpoint by the complete study strategy. And as a secondary endpoint, the combination of planned and unplanned revascularization was significantly reduced by a hazard ratio of 0.59 by the complete strategy we had. Furthermore, one secondary endpoint, the combination of cardiovascular death, MI or unplanned revasc, and that was actually not significant either, but numerically fewer by the complete strategy.

Study Results and Implications

So those are the main endpoints. Our study results must be put in perspective with other large recent trials like the COMPLETE trial and the FIRE trial, where they both showed a clear reduction in hard clinical endpoints like cardiovascular death or new MI. Our results were quite neutral in terms of hard endpoints, but we could avoid repeat revascularization. So I would say that our study results, they complemented previous studies and at least in our study, we did not see any clear effect on hard endpoints. I would say that this means that you sometimes, if there is a circumstance that makes a complete revascularization complicated, that perhaps you can wait and only treat the patients if they come back with angina. Because the good news is that most people actually are doing well regardless of the strategy we choose, at least in our study. And if they come back with angina, we can of course help them. So I would imagine that we would still aim for a complete revascularization, taking all the other studies together. But if there is a complication, or if there is some circumstance that makes it difficult, then you can wait.

Conclusion and Future Directions

Well, the key message is that a strategy of FFR-guided complete revascularizations in patients with STEMI and multivessel disease was not superior to a strategy of culprit lesion-only PCI in reducing the combination of all-cause mortality, myocardial infarction or unplanned revascularization at a median follow-up of 4.8 years. The COMPLETE 2 trial is an ongoing study which is led by Professor Shamir Mehrta in Canada. And it's

comparing. We're also taking part in that in Sweden and that's comparing complete revascularization as determined by visual estimation of stenosis grade in one arm to FFR-guided or physiology-guided complete revascularization in the other arm. And that will include over 5000 patients with both STEMI and non-STEMI in that study. There will also be in other studies as well an OCT substudy. So we can see also whether vulnerable plaques play a role here, if we should treat them, or with preventing stenting or nothing.