Title: ESC 22: 3 Trials That Will Change Your Practice With Interventionalist, Dr Mirvat Alasnag
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- Hello, everybody. My name is Mirvat Alasnag. I'm an Interventional Cardiologist practising in Jeddah, Saudi Arabia, and I'm here with Radcliffe Cardiology to present to you three of the most important trials in the interventional space that we're presented at the European Society of Cardiology Congress 2022.

REVIVED BCIS Trial

I'm going to start with one of the most interesting trials, which was the REVIVED BCIS trial, and caused quite a stir when it was presented during the Congress.
Now, this was a trial that enrolled 700 patients with impaired LV function, severely impaired LV function, defined by an ejection fraction of equal to or less than 35% with extensive coronary artery disease based on the BCIS jeopardy score. Viability was assessed in these patients and it needed to be demonstrated in four segments, and the majority of whom were detected by MRI, cardiac MRI.
There were several exclusion criteria, which are important. Patients who had an acute myocardial infarction within the last four weeks, decompensated heart failure, and sustained ventricular tachycardia were all exclusions and there was a one-to-one randomization to PCI with optimal medical therapy, or optimal medical therapy alone.
The mean age was 70, 88% were men, and the mean ejection fraction was 28%. The primary endpoint was a composite of all cause death and heart failure hospitalizations, and the secondary endpoints were ejection fraction improvement at 6 months and 12 months, as well as improvement in quality-of-life parameters.
So, the results were surprising that just over the 3 years of follow up of this trial, the primary composite endpoint of death and hospitalizations for heart failure occurred in 37.2% of the PCI arm, and 38% of the optimal medical therapy arm.
There was really no difference in the injection fraction. With regards to quality of life at 6 months and 12 months, there was a notable improvement in the PCI arm which was not sustained through 24 months. So overall, this was considered a neutral study.

RADIAL Trial

The next study was the RADIAL trial, which looked at individual patient level meta-analysis, and it was assessing the impact of transradial access versus transfemoral access on both major bleeding and mortality.
This was a pooled data from seven trials with over 21,000, actually 21,600 patients.
The mean age was 63.9%. Women were 31.9% of the cohort. 95% had an acute coronary syndrome, and 75.2% underwent percutaneous coronary revascularization.

The primary endpoint was all cause mortality at 30 days, and it occurred in 1.6% of the radial arm versus 2.1% of the femoral arm, and the co-primary outcome of major bleeding occurred in 1.5% of the radial arm, and 2.7% of the transfemoral arm. And when they looked at subgroups such as acute coronary syndrome PCI protocol as treated cohorts, all had a survival benefit with transradial access. And this was consistent in different subgroup analyses such as angina and women as well.
So, this was very favourable looking at contemporary data on transradial access and supports the current guidelines both European and American.

FRAME-AMI Study

So the final study that I wanted to discuss with you is the FRAME-AMI study. This was investigator initiated, open label trial that included 14 sites in Korea.
FRAME-AMI randomised patients with multi vessel disease who had an acute myocardial infarction and successful PCI of the infarct related artery to FFR guided complete revascularization, i.e. FFR guided revascularization of the non infarct related artery, and angina guided of the non infarct related artery. FFR significance was considered anything equal to or less than 0.8, and angio guided was anything more than 50%.
The PCI was done either in the index procedure, which was highly recommended, or at least index admission, but they did permit staged interventions. The primary endpoint was a composite of all cause death, myocardial infarction, repeat revascularization. So a total of 562 patients were included.
The mean average age was 63, 16% were women, and immediate complete revascularization was done in 60%, and it was achieved in 40% for staged intervention. The follow up was 3.5 years, and the composite endpoint of all cause death, MI, and repeat revascularization occurred in 7.4% of those who got FFR guidance, and 19.7% of those who got angio guidance only, and it was statistically significant. Looking at the individual components of the composite, when we look at death, it occurred in 2.1% of the FFR guided group, and 8.5% of the angio guided group. Again, statistically significant.
Myocardial infarction occurred in 2.5% of the FFR guided, and 8.9% in the angio guided alone. Again, this was statistically significant. And finally, unplanned revascularization occurred in 4.3% in the FFR guided, and 9.0% in those who were angio guided, but this was not statistically significant. So overall, FFR guidance was consistent for both STEMI and non-STEMI patients in terms of guiding complete revascularization. Will this prompt a change in the guidelines?
Perhaps too soon, particularly because it is focused on Korea and needs to be replicated elsewhere. So, thank you very much for staying tuned.

Other trials that I did not discuss in depth that are actually very interesting and were presented at ESC Congress looked at atherosclerosis detected by PET and predicting outcomes in terms of mortality and repeat cardiovascular events. And the second TRA studies that were presented looked at antithrombotic agent, direct antithrombotic agents, for

patients with acute myocardial infarctions or stroke on top of intensive antiplatelet therapies such as prasugrel and ticagrelor. Remember, these were safety trials designed for safety endpoints, and did not have the numbers, the adequate numbers, to power them to give us cardiovascular outcomes. Nevertheless, they laid the foundation to prepare phase three trials for these agents in these subgroups. So thank you, and hope to see you again in another episode.