

Title: EuroPCR 23: EBC Main Three-Year Follow-Up
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Dr David Hildick-Smith

"Hi, I'm Dave Hildick-Smith. I'm a professor of cardiology in Brighton in the UK.

What is the importance of the EBC Main study?

I think it's an important study because a lot of left main stem intervention is now done and most of the disease, at least 80% of it, is bifurcation. And people are a little unclear exactly what the optimal strategy will be for treating the left main when it is a bifurcation. So, trying to clarify in general terms with a randomized study whether one approach is better than another ought really to help people to decide, okay, this is how the evidence suggests I should approach this, because at the moment there's loads of different ways that people will approach it. And it's not a very systematic kind of strategy.

What was the study design and patient population?

We took 450 odd patients, all had bifurcation left main stem disease, true bifurcation left main stem disease. So, both vessels diseased, they were randomly allocated one to one to either a stepwise provisional stent strategy, or, on the other hand, a systematic dual stent strategy. This ran through the European Bifurcation Club with CIRC as the CRO. It recruited for several years, six different countries, 25 or so sites. And what we're looking to get from the results is, is there a difference, death, MI, target lesion revascularization, et cetera, between the two groups and compare those results to results that have been obtained in other territories in the world.

How were operator experience and expertise accounted for in the trial?

We had in the protocol, actually, that people should be high volume operators, and that meant more than 150 PCI per year. It wasn't actively policed, as it were, but I think if you look at the sites that were involved, all of them were cardiothoracic centers where

high volume activity is done. And certainly, looking at the various names who undertook the procedures, I don't think there's much doubt it was done by people who are very familiar with, competent at and experienced at bifurcation left mainstream stem stenting.

What are the main findings?

So, at one year, we found that there wasn't any significant difference between the two groups, either Death, MI or target lesion revascularization. But at three years, there was then a difference. So, Death and MI were still the same between the two groups, but actually there was significantly more target lesion revascularization in the two-stent strategy than there was in the provisional approach. And interestingly, actually, the change between one year and three years was quite significant between the two groups. In the provisional strategy, there was only a 2% addition of target lesion vascularization, whereas in the dedicated two stent strategy, there was 5%. So statistically, that was quite significant, and it was actually nearly double the TLR in the more involved, more complex stenting procedure. So that contrasts with evidence that's come from other investigators. And that should be something which generates quite a lot of discussion, I think, over the coming months.

What are the take home messages?

For me, the take home message is quite clear, and it is that you shouldn't decide at the start of your procedure what the end of it is going to look like in terms of number of stents. So very frequently in live cases or other situations where you look at angiograms, people will say is, I would do a DK crush. Ah yes, I would do a culotte, I would do a thing. And what this study really shows is it's not necessary and indeed, it's not sensible to prejudge the issue and declare at the outset how it's going to finish. Because in the provisional arm, even though all the operators were happy for the patient to have been randomized to the two-stent arm, in the provisional arm, actually only one fifth of them ended up needing that second stent. So, you may think at the outset, oh, I'm going to do a two-stent procedure, but actually, in practice, four fifths of the time, you don't actually need it. So don't decide at the outset, just take it step by step and stop when you've got a good result.

What are the next steps?

Well, for this particular study, we will be looking to go out to five years. And I think it's important when you look at some of the longer-term stent studies that you do go out to five, ideally ten, but certainly five years to see if you do catch any of those signals, that actually the more metalwork you've implanted, the more there is a price to pay in the longer term for that. So, can you do better having a bit less metal work implanted? So that's a key area. And similarly, I think there's been a great deal of interest at this meeting in particular about drug coated balloons and bifurcations are an area which may well lend themselves to drug coated balloon therapy. So, we'll be looking at that as well."