Title: EBC TWO Five Year Follow-Up: Two-Stent Vs One for Large Bifurcation Lesions
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Dr Sandeep Aranothayaraj

"So my name is Sandeep Arunothayaraj, I'm an interventional cardiologist, did my training in Australia and have come over to the UK to do some further structural work and research with David Hildick Smith in Brighton and looking to doa bit more in terms of CTO work with Colin next year as well.

What is the background of this study?

So getting a bit of a European experience before I head back home. EBC Two looked to address quite a common question that interventional cardiologists have, which is how to treat bifurcation disease. It's estimated about 20% of the lesions we treat are bifurcation lesions. And there have been various trials looking at how to best treat this, whether you use one stent in a provisional strategy or whether you use a two-stent technique upfront. And the previous trials, especially the early trials, really showed that two stents often did neutral or did worse with increased MI and increased mortality. And some of these trials included BBC One, BBK One and the Nordic Bifurcation study. Those trials were done with first-generation stents in patients with often small calibre side branches. And the question really was maybe they weren't functionally significant. And with modern stents in patients with larger side branches, perhaps a difference might be found. So that's what this study really tried to look at.

What was the study design, patient population and outcome measures?

So it was a randomized controlled trial, it was done through Europe, so six European countries and 20 different centers, 200 patients were randomized. In the end, for selection, patients needed to have side branches of at least 2.5 and at least5 mm or greater side branch disease length. Patients obviously had to have one, one one, a true non left main bifurcation disease. And the patients that ended up in the study were

overall quite a high risk for cardiac events. So the average age was in the low60s, there was a high prevalence of diabetes, high prevalence of previous ACS, previous PCI. So really, patients that we would consider at high risk for future events, the main findings really were at five years.

What were the key findings?

This was the follow-up results for five years. There was no difference in major adverse cardiovascular outcomes in the two groups between culotte routinely or a stepwise provisional strategy with T stenting of the side branch if needed. This result was not influenced by the length of side branch disease as well, whether that was less than or greater than 10mm.When we looked specifically at the bifurcation specific adverse cardiac events, and we composed a composite endpoint of procedural acute vessel closure, target lesion, myocardial infarction, target lesion, revascularization and cardiac mortality, there was also still no difference between the groups.

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

There was no prescription for entry into the trial, but realistically, just by the fact that hospitals decided to enrol in this trial, clearly the operators who were involved had a specific interest in bifurcations. What we would say is that the strategies that were tested are quite widespread through Europe and indeed worldwide and are very well prescribed especially in the EBC guidelines. So a very standard protocol was used, but granted by some operators that likely had more interest and more experience in this field.

Based on these findings which patients would benefit from provisional T-stent strategy?

I think the real message of this study was that you should start with a stepwise provisional strategy for all patients with Bifurcation disease. The incidence of side branch stenting in patients with true non left main bifurcation lesions with a provisional approach was only 16%. And this really means that you can avoid a second stent along

with all the additional procedural involvement that requires. So passing a second stent, repeat pot of that, repeat distal cell rewiring, and repeat kissing balloon inflation, all tasks that take more radiation, take more time, and potentially leave you open to more procedural complication. Those can all be avoided in nearly85% of patients, and the similar clinical outcomes can be achieved in five years. So we would suggest that we should start provisionally for all patients and then insert a second stent if it's needed at the time, and that there's no clinical evidence to suggest that there's worse outcomes with this approach. I think operators need to also keep in mind that bifurcation PCI is operator dependent. It’s not purely just a technique. So operators do need to do what they are comfortable with. And there are some rare situations where if there is a slight branch dissection or there's a particular concern about losing wire access, you may want to use a two-stent strategy from the start. But that's why we all have our experience and our training is to make those decisions.

What are the next steps?

I think it was good for us to know that a more simple, straightforward strategy had good outcomes. And this should be highlighted actually, that the incidence of bifurcation adverse cardiac events was lowered about six and a half percent in both groups at five years. This if the trial was to be repeated again today with modern drug eluting stents, modern medical therapy likely would be lower. So it suggests that good bifurcation PCI outcomes can be achieved with the techniques we've got. We’re always looking for ways to improve, and I think would imagine a lot of people would have thought that two stents might have been the way to do that, to reduce outcomes further. That’s shown to not be the case, but there are other alternatives coming up. And certainly, there's been a lot of growth in the field of drug eluting balloons as well. So it's likely that that might be a future direction for research looking at whether a drug eluting balloon in the side branch maybe beneficial to reduce cardiac events further.