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References

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Discussion
Presenter: Craig Jarrett

Unidentified Speaker 1. Dr Jarrett, thank you for that presentation. I’m going to ask David Taggart, who was the single largest enroller in the EXCEL trial, to comment.

Dr David Taggart (Oxford, England). The ultrasound [inaudible] is the second largest part of why we contributed 100 patients. But yes, we were substantial contributors seeing to the trial from cardiologists and surgeons in Oxford. Umberto Benedetto and I published 3-year outcomes where we demonstrated that there did seem to be inferior outcomes with off-pump surgery at 3 years compared with on-pump surgery. However, we also demonstrated, and it comes back to really what Mario Gaudino talked about earlier today, is the experience of surgeons doing off-pump surgery. In our 3-year analysis, what we noted was a significantly lower rate of revascularization with off-pump surgery to both the lateral wall and to the inferior wall. So, the question comes back again, and I think we’ve had a superb presentation just now.

Dr Craig Jarrett (Cleveland, Ohio).
Dr Rosemary Kelly (Minneapolis, Minn). The EXCEL trial has obviously undergone extensive analysis and reanalysis from many perspectives. What was great about the current presentation is that this really focuses on a uniquely surgical perspective of on-pump versus off-pump. I appreciate what the panel has discussed today is that revascularization is most successful when it’s complete. I think that was the consideration that we just discussed. That was one of my concerns for the authors of this presentation. The other question I would have as we look at this going forward because these are striking findings, what would the authors consider in left main disease to be the most appropriate patient to consider for on-pump going forward from what they have found through their studies? Conversely, what would you identify as the appropriate candidate for off-pump strategies given what you’ve now analyzed?

Dr Jarrett. To answer your first question, what is the best candidate for patients with left main disease for on-pump surgery? I think the devil is in the details, and it probably goes to the experience of the surgeon. We haven’t gotten to that point in the analysis as far as the experience of the surgeons. That is something we would like to finish if all that information is available. To some extent, it is. But I think that is probably the biggest factor. As far as patients who are good candidates for off-pump surgery, there were a fair number of patients in the EXCEL trials who had more right than just left main disease. Perhaps in patients with only left main disease we wouldn’t have to worry about the lateral walls, which is what I think everyone on this panel is most concerned with, but also taking into account the experience of the surgeon.

Dr Kelly. Was there any evidence in your analysis, looking at the expertise of the institutions—and as to Dr Taggart’s point, the high enrollers clearly had extensive off-pump experience. Was there any further analysis of the maybe lower enrollees who had any evidence of their expertise or lack of expertise in off-pump techniques?

Dr Jarrett. No. That is another factor we would like to consider. But given everyone’s comments today, experience, and not only of the surgeon but also of the center, are super important questions we need to answer to finish up that project.

Dr Kelly. Okay. Thank you for your presentation.

Dr Mario Gaudino (New York, NY). I want to raise a bit of caution about a propensity-matched study on such a small cohort of patients. The off-pump group is a small subgroup of the [inaudible] group. I think it’s probably less than 50% on the [inaudible] group and then on the on-pump group. And it’s even smaller when you propensity match. So, in those situations, the risk of type I and II errors is relatively high. If I look at the [inaudible] I have for your primary composite outcome, they are more or less parallel for on-pump and off-pump, but the fact that one reached statistical significance and the other doesn’t with less than 200 matching the patient, it can very well be the type II error. On the other hand, I don’t see a biological rationale why on-pump surgery should be better than PCI for stroke and off-pump should not. So, this is potentially a type I error. It’s a great presentation, great hypothesis-generating data, but we just need to be cautious in interpreting them because of the small sample size.