**Title: TCT 24 - ECLIPSE: Orbital Atherectomy vs. Conventional Balloon Angioplasty in Calcified Coronary Arteries Prior to DES Implantation**

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**What are the current unmet needs in percutaneous coronary intervention, and why is the ECLIPSE trial important?**

I think most people that do coronary interventions these days know that there's a greater and greater incidence of severe coronary calcification when you do cases. Anybody in the lab will look at the films, and people are presenting more downstream. They're on statins and other therapies like that. And that's one of the reasons why calcification is such a key area for so many interventionalists. It makes your life miserable during the case. Also, late outcomes are not so great with calcium either. So we want new technologies and new ways of treating calcium that can help our patients.

**What was the study design and patient population?**

ECLIPSE is a randomized trial with 2,005 patients. So why did we randomize so many patients? Because we wanted to look at clinical outcomes when patients were treated with one strategy, which is orbital atherectomy, versus another, conventional balloon angioplasty. I'll mention, though, that in the space of randomized trials, there are very minimal trials with advanced calcium modification therapies that are randomized. There's some trials with rota. There's virtually nothing in a large scale with IVL. And this was a trial of orbital atherectomy. Basically, patients had to have the wire across the lesion, and then they were randomized to one versus the other.

Importantly, though, investigators needed to feel comfortable that patients could be treated with both approaches. So if you had extensive calcification, balloon uncrossable, the typical atherectomy case, those are not cases that were necessarily represented in the trial to a large extent. But nonetheless, we randomized those patients and looked at both OCT endpoints as well as clinical endpoints.

**What were the key findings?**

Well, we were surprised to show that, really, when you looked at the OCT images, there was no appreciable difference in minimal stent area at the site of max calcification between the two groups. But the areas were over 7 in both groups — so hard to improve on that outcome. And when we looked at target vessel failure, it was also similar in both groups, orbital atherectomy and conventional balloon angioplasty.

So some might say, well, does that mean that, you know, this doesn't work? No, and in fact, what the big finding for me when I looked at these data was that we looked at the rate of intravascular imaging, and it was 62% in the trial, which is, frankly, I think, for calcified lesions, still short of what it ought to be. But in clinical practice around the world, we don't see imaging used that frequently. But that might have changed things, because when we assess the effect of imaging, it did lower event rates in both groups.

**What are the take-home messages for clinical practice?**

You know, for me there's a few take-home messages. Number one, be attuned to calcium because it makes your case worse, longer, bad outcomes for patients. Number two, just because you see calcium on the angiogram doesn't mean that you need to use one therapy or another. You really need to image to understand that better. If the imaging catheter doesn't cross, atherectomy is a great tool for that and there's still a role for atherectomy. But if the imaging catheter crosses, despite what you may hear on podiums, and presentations and the like, don't just use a specific technology because of that. Try to look at studies like this and understand that a lot of cases can be done with conventional balloons, scoring balloons, cutting balloons, and other devices.

And I'll also point out that there are randomized trials being done right now comparing some of these devices: cutting balloon to IVL, OPM balloon to IVL. That should really help inform practice because we do need randomized evidence to make these treatment decisions.

**What further research is needed in this area?**

So those two studies I want to see the results of and you don't need to randomize 2,000 patients. I think the imaging endpoints are pretty reasonable. I think further elucidation of what the best algorithms would be, would be great. Calcium is an area of increasing development. So do we really just believe the pretty pictures that say that in eccentric calcification plaque can be modified, or do we actually study that and show that it's going to make a difference one way or the other?

I think the final thing is from a cost effectiveness standpoint, there is no harm to going in with an NC balloon, seeing if it dilates, seeing if you had fractures, and then going from there rather than pulling out a more expensive device.